HYGENIC

Latex Dental Dam

Instructions for Use

LATEX

Rx ONLY

COLTENE

Table of Contents

EN Instructions for Use 1
DE Gebrauchsanweisung 12
FR Mode d'emploi 22
ES Instrucciones de uso 32
BG Инструкции за употреба 42
CS Návod k použití 52
DA Brugsanvisning 62
EL Οδηγίες χρήση 72
ET Kasutusjuhend 82
HR Upute za upotrebu 92
HU Használati útmutató 102
IT Istruzioni per l'uso 112
LT Naudojimo instrukcijos 122
LV Lietošanas instrukcija 132
MT Istruzzjonijiet għall-Użu 142
NL Gebruiksaanwijzing 152
PL Instrukcja użycia 162
PT Instruções de utilização 172
RO Instrucțiuni de utilizare 182
SK Návod na použitie 192
SL Navodila za uporabo 202
SV Bruksanvisning 212
TR Kullanma Talimatları 222

Intended Use/ Indications for Use:
Dental Dam is intended to be used intraorally to isolate one or more teeth and create a barrier to the surrounding area during a dental procedure.

Contraindications:
Latex Dental Dam should not be used on patients with a latex allergy.

Intended Users:
- Dental Practitioners
- Dental Assistants

Patient Target Group(s):
Suitable for all patient groups.

Clinical Benefits:
The use of Dental Dam has the following clinical benefits:
- Increased visibility through tooth/teeth isolation
- Reduced risk of the patient aspirating or swallowing instruments, tooth debris, medicaments or irrigation solutions
- Creation of a dry operating field
- Protection of soft tissue from contact with instruments
- Infection control barrier

Characteristics:
- Available in different colors and thicknesses
- Two sizes: 5″ x 5″ or 6″ x 6″ (127 mm x 127 mm or 152 mm x 152 mm)
- The lighter colors have the advantage of naturally illuminating the operating field whereas the darker colors can help with visual contrast

Storage:
Store Dental Dam between 32° F – 80^0 F (0°C – 26°C).
Keep dry and keep away from heat.

Residual Risks, Warnings and Precautions:
Refer to the Warnings and Precautions section for disclosure of risk associated with the use of the Dental Dam in line with its Intended Use.

Instructions

CAUTION! This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.

Dental Dam is intended to be used with various other devices including clamps and frames. Refer to the instructions for use for the other devices being used.

The following general steps are provided as guidance and can be tailored to fit the specific case:

Step 1: Determine the Operating Field.

Step 2: Dental Dam Preparation.
- Determine hole positions
- Mark hole positions
- Punch holes

Step 3: Clamp/Retainer Selection

Step 4: Clamp/Retainer Application

Step 5: Dental Dam Placement

Parts List

Note: Not all Catalog Numbers are available in all regions

Catalog #	Description
390020	ROEKO Dental Dam, Latex, Thin, 36 pcs
390021	ROEKO Dental Dam, Latex, Medium, 36 pcs
390022	ROEKO Dental Dam, Latex, Heavy, 36 pcs
60013793	ROEKO Elasti-Dam, 152x152mm, Medium, Green, 36 pcs
60013794	ROEKO Elasti-Dam, 152x152mm, Heavy, Green, 36 pcs
60013870	Sample ROEKO Elasti-Dam, 152x 52mm, Medium, Green
60013795	ROEKO Elasti-Dam, 127x127mm, Medium, Blue, 36 pcs
60013796	ROEKO Elasti-Dam, 127x127mm, Heavy, Blue, 36 pcs
H00523	HYGENIC Dental Dam, Latex, Thin, Light, 5'' x 5'' (127x127mm), 52 pcs
H00524	HYGENIC Dental Dam, Latex, Medium, Light, 5'' x 5'' (127x127mm), 52 pcs
H00525	HYGENIC Dental Dam, Latex, Heavy, Light, 5'' x 5'' (127x127mm), 52 pcs
H00533	HYGENIC Dental Dam, Latex, Thin, Light, 6'' x 6'' (152 x152mm), 36 pcs
H00534	HYGENIC Dental Dam, Latex, Medium, Light, 6'' x 6'' (152x152mm), 36 pcs
H00535	HYGENIC Dental Dam, Latex, Heavy, Light, 6'' x 6'' (152x152mm), 36 pcs
H00536	HYGENIC Dental Dam, Latex, Extra Heavy, Light, 6'' x 6'' (152x152mm), 36 pcs
H00538	HYGENIC Dental Dam, Latex, Thin, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00539	HYGENIC Dental Dam, Latex, Medium, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00540	HYGENIC Dental Dam, Latex, Heavy, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00541	HYGENIC Dental Dam, Latex, Extra Heavy, Dark, 6'' x 6'' (152x152mm), 36 pcs

Catalog #	Description
H02141	HYGENIC Dental Dam, Latex, Thin, Green, 5'' x 5'' (127x127mm), 52 pcs
H02142	HYGENIC Dental Dam, Latex, Medium, Green, 5'' x 5'' (127x127mm), 52 pcs
H02143	HYGENIC Dental Dam, Latex, Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H02144	HYGENIC Dental Dam Latex, Extra Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H02146	HYGENIC Dental Dam, Latex, Thin, Green, 6'' x 6'' (152x152mm), 36 pcs
H02147	HYGENIC Dental Dam, Latex, Medium, Green, 6'' x 6'' (152x152mm), 36 pcs
H02148	HYGENIC Dental Dam, Latex, Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H02149	HYGENIC Dental Dam, Latex, Extra Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H02778	HYGENIC FIESTA Winged Complete Kit, 1 pc
H02779	HYGENIC FIESTA Winged Standard Kit W/O Punch & Forceps, 1 pc
H02790	HYGENIC FIESTA Wingless Complete Kit, 1 pc
H02900	HYGENIC Simple Dam Kit - W/ Elasti-Dam, 1 pc
H03529	HYGENIC Dental Dam, Latex, Medium, Blue, 5'' x 5'' (127x127mm), 52 pcs
H03530	HYGENIC Dental Dam, Latex, Medium, Blue, 6'' x 6'' (152x152mm), 36 pcs
H04237	HYGENIC Dental Dam, Latex, Convenience Pack, Medium, Light, 5'' x 5'' (127x127mm), 364 pcs
H04241	HYGENIC Dental Dam, Latex, Convenience Pack, Medium, Green, 5'' x 5'' (127x127mm), 364 pcs
H04243	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Light, 6'' x 6'' (152x152mm), 360 pcs
H04245	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Dark, 6'' x 6'' (152x152mm), 360 pcs

Catalog #	Description
H04247	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Green, 6'' x 6'' (152x152mm), 360 pcs
H04639	HYGENIC FIESTA Dental Dam, Thin, 6'' x 6'' (152x152mm), 36 pcs
H04640	HYGENIC FIESTA Dental Dam, Thin, 5'' x 5'' (127x127mm), 52 pcs
H04641	HYGENIC FIESTA Dental Dam, Medium, 5'' x 5'' (127x127mm), 52 pcs
H04642	HYGENIC FIESTA Dental Dam, Medium, 6'' x 6'' (152x152mm), 36 pcs
H04643	HYGENIC FIESTA Dental Dam, Heavy, 5'' x 5'' (127x127mm), 52 pcs
H04644	HYGENIC FIESTA Dental Dam, Heavy, 6'' x 6'' (152x152mm), 36 pcs
H07315	HYGENIC Dental Dam, Latex, Heavy, Blue, 6'' x 6'' (152x152mm), 36 pcs
H07316	HYGENIC FIESTA Dental Dam, Latex, Convenience Pack, Medium, 5'' x 5'' (127x127mm), 364 pcs
H07317	HYGENIC FIESTA Dental Dam, Latex, Convenience Pack, Medium, 6'' x 6'' (152x152mm), 360 pcs
H11624	HYGENIC Elasti-Dam, Medium, Green, 5'' x 5'' (127x127mm), 52 pcs
H11625	HYGENIC Elasti-Dam, Medium, Green, 6'' x 6'' (152x152mm), 36 pcs
H11626	HYGENIC Elasti-Dam, Medium, Blue, 5'' x 5'' (127x127mm), 52 pcs
H11627	HYGENIC Elasti-Dam, Medium, Blue, 6'' x 6'' (152x152mm), 36 pcs
H11675	HYGENIC Elasti-Dam, Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H11676	HYGENIC Elasti-Dam, Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H11677	HYGENIC Elasti-Dam, Heavy, Blue, 5'' x 5'' (127x127mm), 52 pcs
H11678	HYGENIC Elasti-Dam, Heavy, Blue, 6'' x 6'' (152x152mm), 36 pcs

Catalog #	Description
H11690	HYGENIC Elasti-Dam Trial Pack, Medium, Green, 6'' x 6'' (152X152mm)

Warnings and Precautions

Warnings	Statement
 **WARNING!**	Failure to properly follow the directions in this IFU may result in patient injury or compromise the integrity of the dental dam. Use the product only in accordance with its intended use, see Intended Use.
	Do not reuse Dental Dam. Dental Dam is intended to be used only once. Reuse of Dental Dam intraorally is a biological hazard and can result in cross contamination.
	Dental Dam should be inspected prior to use. Discard torn or brittle Dental Dam. Use of Dental Dam that has lost its performance characteristics can result in loss of functionality and compromise the integrity of the procedure.

Precautions	Statement
 CAUTION	This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.
	Do not expose Dental Dam to high temperatures. Store Dental Dam away from heat sources.
	Dental Dam has a specified shelf life. Do not use the device after the Use-by Date because the device functionality and performance characteristics may be compromised.
	Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare practitioner
	Do not store near non-latex products.

Additional Information

Note: Dispose of device in accordance with local, regional, national, and/or international regulations. Devices used intraorally should be treated as a biohazard and disposed of properly per local regulations.

Note: Upon request, a hardcopy of the IFU will be supplied free of charge.

For users located in the EU: Any serious incident that has occurred in relation to the use of the device should be reported to Coltène/Whaledent, Inc. and the competent authority of the member state in which the user and/or patient is established.

Symbol Glossary

Symbol	Title and description of symbol
	Caution
 www.coltene.com	Consult electronic instructions for use - Indicates the need for the user to consult the instructions for use
MD	Medical Device – Indicates the item is a medical device
Rx ONLY	Sale Restricted: The purchase of the device is restricted to licensed healthcare practitioners only.
	Use-by Date - Indicates the date after which the medical device is not to be used
REF	Catalog Number - Indicates the manufacturer's catalogue number so that the medical device can be identified
	Do not re-use - Indicates a medical device that is intended for use on a single patient during a single procedure
CE	CE mark
	Importer - Indicates the entity importing the medical device into the locale
	Manufacturer - Indicates the medical device manufacturer

Symbol	Title and description of symbol
	Batch code - Indicates the manufacturer's batch code so that the batch or lot can be identified
	Authorized representative in the European Community - Indicates the authorized representative in the European Community
	Contains natural rubber latex - Indicates the presence of dry natural rubber latex as a material of construction within the medical device.

Storage

Store Dental Dam between 32° F – 80° F (0°C – 26°C).
Keep dry and keep away from heat.

Symbol	Title and description of symbol
	Keep dry - Indicates a medical device that needs to be protected from moisture
	Keep away from heat - Indicates a medical device that needs protection from heat
	Temperature Limit - Indicates the temperature limits to which the medical device can be safely exposed. The upper and lower limits of temperature shall be indicated adjacent to the upper and lower horizontal lines.

HYGENIC

Latex Dental Dam

Gebrauchsanweisung

LATEX

Rx ONLY

COLTENE

Verwendungszweck/Indikationen:
Dental Dam ist zur intraoralen Trockenlegung eines oder mehrerer Zähne und zur Schaffung einer Barriere gegenüber der Umgebung während eines zahnmedizinischen Eingriffs indiziert.

Kontraindikationen:
Latex Dental Dam darf nicht bei Patienten mit Latexallergie verwendet werden.

Vorgesehene Anwender:
• Zahnärzte
• Zahnmedizinische Fachangestellte

Patientenzielgruppe(n):
Geeignet für alle Patientengruppen.

Klinischer Nutzen:
Die Verwendung von Dental Dam hat den folgenden klinischen Nutzen:
• Erhöhte Sichtbarkeit durch Trockenlegung des Zahns/der Zähne
• Geringeres Risiko, dass der Patient Instrumente, Zahnreste, Medikamente oder Spüllösungen aspiriert oder verschluckt
• Herstellung eines trockenen Behandlungsfelds
• Schutz des Weichgewebes vor Instrumentenkontakt
• Barriere zur Infektionskontrolle

Eigenschaften:
• Erhältlich in verschiedenen Farben und Stärken
• Zwei Größen: 127 mm x 127 mm (5″ x 5″) oder 152 mm x 152 mm (6″ x 6″)
• Die helleren Farben haben die Eigenschaft, das Operationsgebiet natürlich zu beleuchten, während die dunkleren Farben für einen sichtbaren Kontrast sorgen.

Lagerung:
Dental Dam zwischen 0 °C und 26 °C (32 °F und 80 °F) lagern.
Trocken aufbewahren und vor Hitze schützen.

Restrisiken, Warnhinweise und Vorsichtsmaßnahmen:
Dem Abschnitt „Warnhinweise und Vorsichtsmaßnahmen“ sind Angaben zu den Risiken zu entnehmen, die mit der Verwendung von Dental Dam entsprechend seinem Verwendungszweck verbunden sind.

Anweisungen

VORSICHT! Dieses Produkt enthält Naturkautschuklatex, das allergische Reaktionen hervorrufen kann.

Dental Dam ist für die Verwendung mit verschiedenen anderen Produkten einschließlich Klammern und Rahmen vorgesehen.

Siehe Gebrauchsanweisungen der anderen verwendeten Produkte.

Die folgenden allgemeinen Schritte stellen einen Leitfaden dar und können dem Einzelfall entsprechend ausgelegt werden:

Schritt 1: Bestimmung des Operationsgebiets.

Schritt 2: Vorbereitung von Dental Dam.
- Lochpositionen bestimmen
- Lochpositionen markieren
- Löcher ausstanzen

Schritt 3: Auswahl der Klammer/des Retainers

Schritt 4: Anlegen der Klammer/des Retainers

Schritt 5: Platzierung von Dental Dam

Teileliste

Hinweis: Nicht alle Katalognummern sind in allen Regionen verfügbar

Katalognr.	Beschreibung
390020	ROEKO Dental Dam, Latex, Thin, 36 pcs
390021	ROEKO Dental Dam, Latex, Medium, 36 pcs
390022	ROEKO Dental Dam, Latex, Heavy, 36 pcs
60013793	ROEKO Elasti-Dam, 152x152mm, Medium, Green, 36 pcs
60013794	ROEKO Elasti-Dam, 152x152mm, Heavy, Green, 36 pcs
60013870	Sample ROEKO Elasti-Dam, 152x 52mm, Medium, Green
60013795	ROEKO Elasti-Dam, 127x127mm, Medium, Blue, 36 pcs
60013796	ROEKO Elasti-Dam, 127x127mm, Heavy, Blue, 36 pcs
H00523	HYGENIC Dental Dam, Latex, Thin, Light, 5'' x 5'' (127x127mm), 52 pcs
H00524	HYGENIC Dental Dam, Latex, Medium, Light, 5'' x 5'' (127x127mm), 52 pcs
H00525	HYGENIC Dental Dam, Latex, Heavy, Light, 5'' x 5'' (127x127mm), 52 pcs
H00533	HYGENIC Dental Dam, Latex, Thin, Light, 6'' x 6'' (152 x152mm), 36 pcs
H00534	HYGENIC Dental Dam, Latex, Medium, Light, 6'' x 6'' (152x152mm), 36 pcs
H00535	HYGENIC Dental Dam, Latex, Heavy, Light, 6'' x 6'' (152x152mm), 36 pcs
H00536	HYGENIC Dental Dam, Latex, Extra Heavy, Light, 6'' x 6'' (152x152mm), 36 pcs
H00538	HYGENIC Dental Dam, Latex, Thin, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00539	HYGENIC Dental Dam, Latex, Medium, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00540	HYGENIC Dental Dam, Latex, Heavy, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00541	HYGENIC Dental Dam, Latex, Extra Heavy, Dark, 6'' x 6'' (152x152mm), 36 pcs

Katalognr.	Beschreibung
H02141	HYGENIC Dental Dam, Latex, Thin, Green, 5'' x 5'' (127x127mm), 52 pcs
H02142	HYGENIC Dental Dam, Latex, Medium, Green, 5'' x 5'' (127x127mm), 52 pcs
H02143	HYGENIC Dental Dam, Latex, Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H02144	HYGENIC Dental Dam Latex, Extra Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H02146	HYGENIC Dental Dam, Latex, Thin, Green, 6'' x 6'' (152x152mm), 36 pcs
H02147	HYGENIC Dental Dam, Latex, Medium, Green, 6'' x 6'' (152x152mm), 36 pcs
H02148	HYGENIC Dental Dam, Latex, Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H02149	HYGENIC Dental Dam, Latex, Extra Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H02778	HYGENIC FIESTA Winged Complete Kit, 1 pc
H02779	HYGENIC FIESTA Winged Standard Kit W/O Punch & Forceps, 1 pc
H02790	HYGENIC FIESTA Wingless Complete Kit, 1 pc
H02900	HYGENIC Simple Dam Kit - W/ Elasti-Dam, 1 pc
H03529	HYGENIC Dental Dam, Latex, Medium, Blue, 5'' x 5'' (127x127mm), 52 pcs
H03530	HYGENIC Dental Dam, Latex, Medium, Blue, 6'' x 6'' (152x152mm), 36 pcs
H04237	HYGENIC Dental Dam, Latex, Convenience Pack, Medium, Light, 5'' x 5'' (127x127mm), 364 pcs
H04241	HYGENIC Dental Dam, Latex, Convenience Pack, Medium, Green, 5'' x 5'' (127x127mm), 364 pcs
H04243	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Light, 6'' x 6'' (152x152mm), 360 pcs
H04245	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Dark, 6'' x 6'' (152x152mm), 360 pcs

Katalognr.	Beschreibung
H04247	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Green, 6'' x 6'' (152x152mm), 360 pcs
H04639	HYGENIC FIESTA Dental Dam, Thin, 6'' x 6'' (152x152mm), 36 pcs
H04640	HYGENIC FIESTA Dental Dam, Thin, 5'' x 5'' (127x127mm), 52 pcs
H04641	HYGENIC FIESTA Dental Dam, Medium, 5'' x 5'' (127x127mm), 52 pcs
H04642	HYGENIC FIESTA Dental Dam, Medium, 6'' x 6'' (152x152mm), 36 pcs
H04643	HYGENIC FIESTA Dental Dam, Heavy, 5'' x 5'' (127x127mm), 52 pcs
H04644	HYGENIC FIESTA Dental Dam, Heavy, 6'' x 6'' (152x152mm), 36 pcs
H07315	HYGENIC Dental Dam, Latex, Heavy, Blue, 6'' x 6'' (152x152mm), 36 pcs
H07316	HYGENIC FIESTA Dental Dam, Latex, Convenience Pack, Medium, 5'' x 5'' (127x127mm), 364 pcs
H07317	HYGENIC FIESTA Dental Dam, Latex, Convenience Pack, Medium, 6'' x 6'' (152x152mm), 360 pcs
H11624	HYGENIC Elasti-Dam, Medium, Green, 5'' x 5'' (127x127mm), 52 pcs
H11625	HYGENIC Elasti-Dam, Medium, Green, 6'' x 6'' (152x152mm), 36 pcs
H11626	HYGENIC Elasti-Dam, Medium, Blue, 5'' x 5'' (127x127mm), 52 pcs
H11627	HYGENIC Elasti-Dam, Medium, Blue, 6'' x 6'' (152x152mm), 36 pcs
H11675	HYGENIC Elasti-Dam, Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H11676	HYGENIC Elasti-Dam, Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H11677	HYGENIC Elasti-Dam, Heavy, Blue, 5'' x 5'' (127x127mm), 52 pcs
H11678	HYGENIC Elasti-Dam, Heavy, Blue, 6'' x 6'' (152x152mm), 36 pcs

Katalognr.	Beschreibung
H11690	HYGENIC Elasti-Dam Trial Pack, Medium, Green, 6'' x 6'' (152X152mm)

Warnhinweise und Vorsichtsmaßnahmen

Warnhinweise	Aussage
 **WARNUNG!**	Die Nichtbefolgung dieser Gebrauchsanweisung kann zur Verletzung des Patienten führen oder die Integrität des Dental Dam beeinträchtigen. Das Produkt nur entsprechend seinem Verwendungszweck verwenden, siehe Verwendungszweck.
	Dental Dam nicht wiederverwenden. Dental Dam ist zum Einmalgebrauch bestimmt. Die Wiederverwendung von Dental Dam stellt eine biologische Gefahr dar und kann zu einer Kreuzkontamination führen.
	Dental Dam sollte vor dem Gebrauch überprüft werden. Gerissenen oder spröden Dental Dam entsorgen. Die Verwendung von Dental Dam, der seine Leistungseigenschaften verloren hat, kann zu einem Verlust der Funktionalität führen und die Integrität des Eingriffs beeinträchtigen.

Vorsichtsmaßnahmen	Aussage
 VORSICHT	Dieses Produkt enthält Naturkautschuklatex, das allergische Reaktionen hervorrufen kann.
	Dental Dam keinen hohen Temperaturen aussetzen. Dental Dam von Wärmequellen entfernt lagern.
	Dental Dam hat eine bestimmte Haltbarkeit. Das Produkt nicht nach Ablauf des Verfallsdatums verwenden, da die Funktionalität und die Leistungseigenschaften des Produkts beeinträchtigt sein können.
	Vorsicht: Laut Bundesgesetz (der USA) darf dieses Produkt nur an zugelassenes medizinisches Fachpersonal oder auf dessen Anordnung verkauft werden.
	Nicht in der Nähe von latexfreien Produkten lagern.

Zusätzliche Informationen

Hinweis: In Übereinstimmung mit den jeweiligen lokalen, regionalen, nationalen und/oder internationalen Vorschriften entsorgen. Intraoral angewendete Produkte sind als Biogefährdung zu behandeln und entsprechend den lokalen Vorschriften zu entsorgen.

Hinweis: Auf Anfrage wird kostenlos eine Papierversion dieser Gebrauchsanweisung zur Verfügung gestellt.

Für Anwender in der EU: Alle schweren Vorfälle, die sich im Zusammenhang mit diesem Produkt ereignet haben, sollten Coltène/Whaledent, Inc. und der zuständigen Behörde des Mitgliedstaates, in dem der Anwender niedergelassen ist und/oder der Patient seinen Wohnsitz hat, gemeldet werden.

Symbolglossar

Symbol	Symbolbezeichnung und -beschreibung
	Vorsicht
 www.coltene.com	Elektronische Gebrauchsanweisung beachten – weist darauf hin, dass der Anwender die Gebrauchsanweisung beachten muss
	Medizinprodukt – gibt an, dass der Artikel ein Medizinprodukt ist
	Eingeschränkter Verkauf: Der Kauf des Produkts ist medizinischen Fachkräften vorbehalten.
	Verfallsdatum – gibt das Datum an, nach dem das Medizinprodukt nicht mehr verwendet werden darf
	Katalognummer – gibt die Katalognummer des Herstellers an, damit das Medizinprodukt identifiziert werden kann
	Nicht wiederverwenden – weist auf ein Medizinprodukt hin, das für die Verwendung an einem einzelnen Patienten während eines einzelnen Verfahrens bestimmt ist
	CE-Kennzeichnung
	Importeur – gibt das Unternehmen an, das das Medizinprodukt in das Land importiert
	Hersteller – gibt den Hersteller des Medizinprodukts an

Symbol	Symbolbezeichnung und -beschreibung
	Chargenbezeichnung – gibt die Chargenbezeichnung des Herstellers an, damit die Charge oder das Los identifiziert werden kann
	EU-Bevollmächtigter – gibt den Bevollmächtigten in der Europäischen Gemeinschaft an
	Enthält Naturkautschuklatex – weist auf das Vorhandensein von trockenem Naturkautschuklatex als Werkstoff innerhalb des Medizinprodukts hin.

Lagerung

Dental Dam zwischen 0 °C und 26 °C (32 °F und 80 °F) lagern.
Trocken aufbewahren und vor Hitze schützen.

Symbol	Symbolbezeichnung und -beschreibung
	Trocken aufbewahren – weist auf ein Medizinprodukt hin, das vor Feuchtigkeit geschützt werden muss
	Vor Hitze schützen – weist auf ein Medizinprodukt hin, das vor Hitze geschützt werden muss
	Temperaturbegrenzung – gibt die Temperaturen an, denen das Medizinprodukt sicher ausgesetzt werden kann. Die Temperaturober- und -untergrenzen werden jeweils neben der oberen bzw. unteren horizontalen Linie angegeben.

HYGENIC

Latex Dental Dam

Mode d’emploi

LATEX

Rx ONLY

COLTENE

Utilisation prévue / Indications :
Dental Dam est conçu pour un usage intraoral et indiqué pour l'isolation d'une ou de plusieurs dents et la création d'une barrière avec la zone environnante pendant des soins dentaires.

Contre-indications :
Dental Dam en latex ne doit pas être utilisé sur les patients avec une allergie au latex.

Utilisateurs ciblés :
• Praticiens dentaires
• Assistants dentaires

Groupe(s) de patients ciblés :
Conviennent à tous les groupes de patients.

Bénéfices cliniques :
L'utilisation de Dental Dam a les bénéfices cliniques suivants :
• Visibilité accrue via l'isolation de la dent/des dents
• Réduction du risque que le patient n'aspire ou n'avale les instruments, les débris dentaires, les médicaments ou les solutions d'irrigation
• Création d'un champ opératoire sec
• Protection du tissu mou contre tout contact avec les instruments
• Barrière contre les infections

Description :
• Existe en différentes couleurs et épaisseurs
• Deux tailles : 127 mm x 127 mm ou 152 mm x 152 mm
• Les couleurs claires ont l'avantage d'illuminer naturellement le champ opératoire pendant que les couleurs foncées favorisent le contraste visuel.

Conservation :
Conserver Dental Dam à une température comprise entre 0 et 26 °C.
Tenir au sec et à l'écart de toute source de chaleur.

Risques résiduels, avertissements et précautions :
Se reporter à la rubrique Avertissements et précautions pour connaître les risques associés à l'utilisation de Dental Dam conformément à l'usage prévu.

Instructions

ATTENTION ! Ce produit contient du latex de caoutchouc naturel qui peut provoquer des réactions allergiques.

Dental Dam est conçu pour être utilisé avec divers autres dispositifs, notamment des pinces et des cadres.

Se reporter au mode d'emploi des autres dispositifs utilisés.

Les étapes générales suivantes sont données à titre indicatif et peuvent être adaptées à un cas spécifique :

Étape 1 : détermination du champ opératoire.

Étape 2 : préparation de Dental Dam.
- Détermination de l'emplacement des trous
- Marquer l'emplacement des trous
- Percer les trous

Étape 3 : choix des crampons/attaches

Étape 4 : application des crampons/attaches

Étape 5 : placement de Dental Dam

Liste des produits

Remarque : certaines références de catalogue peuvent ne pas être disponibles dans toutes les régions

Réf. catalogue	Description
390020	ROEKO Dental Dam, Latex, Thin, 36 pcs
390021	ROEKO Dental Dam, Latex, Medium, 36 pcs
390022	ROEKO Dental Dam, Latex, Heavy, 36 pcs
60013793	ROEKO Elasti-Dam, 152x152mm, Medium, Green, 36 pcs
60013794	ROEKO Elasti-Dam, 152x152mm, Heavy, Green, 36 pcs
60013870	Sample ROEKO Elasti-Dam, 152x 52mm, Medium, Green
60013795	ROEKO Elasti-Dam, 127x127mm, Medium, Blue, 36 pcs
60013796	ROEKO Elasti-Dam, 127x127mm, Heavy, Blue, 36 pcs
H00523	HYGENIC Dental Dam, Latex, Thin, Light, 5'' x 5'' (127x127mm), 52 pcs
H00524	HYGENIC Dental Dam, Latex, Medium, Light, 5'' x 5'' (127x127mm), 52 pcs
H00525	HYGENIC Dental Dam, Latex, Heavy, Light, 5'' x 5'' (127x127mm), 52 pcs
H00533	HYGENIC Dental Dam, Latex, Thin, Light, 6'' x 6'' (152 x152mm), 36 pcs
H00534	HYGENIC Dental Dam, Latex, Medium, Light, 6'' x 6'' (152x152mm), 36 pcs
H00535	HYGENIC Dental Dam, Latex, Heavy, Light, 6'' x 6'' (152x152mm), 36 pcs
H00536	HYGENIC Dental Dam, Latex, Extra Heavy, Light, 6'' x 6'' (152x152mm), 36 pcs
H00538	HYGENIC Dental Dam, Latex, Thin, Dark, 6'' x 6'' (152x152mm), 36 pcs

Réf. catalogue	Description
H00539	HYGENIC Dental Dam, Latex, Medium, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00540	HYGENIC Dental Dam, Latex, Heavy, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00541	HYGENIC Dental Dam, Latex, Extra Heavy, Dark, 6'' x 6'' (152x152mm), 36 pcs
H02141	HYGENIC Dental Dam, Latex, Thin, Green, 5'' x 5'' (127x127mm), 52 pcs
H02142	HYGENIC Dental Dam, Latex, Medium, Green, 5'' x 5'' (127x127mm), 52 pcs
H02143	HYGENIC Dental Dam, Latex, Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H02144	HYGENIC Dental Dam Latex, Extra Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H02146	HYGENIC Dental Dam, Latex, Thin, Green, 6'' x 6'' (152x152mm), 36 pcs
H02147	HYGENIC Dental Dam, Latex, Medium, Green, 6'' x 6'' (152x152mm), 36 pcs
H02148	HYGENIC Dental Dam, Latex, Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H02149	HYGENIC Dental Dam, Latex, Extra Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H02778	HYGENIC FIESTA Winged Complete Kit, 1 pc
H02779	HYGENIC FIESTA Winged Standard Kit W/O Punch & Forceps, 1 pc
H02790	HYGENIC FIESTA Wingless Complete Kit, 1 pc
H02900	HYGENIC Simple Dam Kit - W/ Elasti-Dam, 1 pc
H03529	HYGENIC Dental Dam, Latex, Medium, Blue, 5'' x 5'' (127x127mm), 52 pcs
H03530	HYGENIC Dental Dam, Latex, Medium, Blue, 6'' x 6'' (152x152mm), 36 pcs
H04237	HYGENIC Dental Dam, Latex, Convenience Pack, Medium, Light, 5'' x 5'' (127x127mm), 364 pcs

Réf. catalogue	Description
H04241	HYGENIC Dental Dam, Latex, Convenience Pack, Medium, Green, 5'' x 5'' (127x127mm), 364 pcs
H04243	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Light, 6'' x 6'' (152x152mm), 360 pcs
H04245	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Dark, 6'' x 6'' (152x152mm), 360 pcs
H04247	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Green, 6'' x 6'' (152x152mm), 360 pcs
H04639	HYGENIC FIESTA Dental Dam, Thin, 6'' x 6'' (152x152mm), 36 pcs
H04640	HYGENIC FIESTA Dental Dam, Thin, 5'' x 5'' (127x127mm), 52 pcs
H04641	HYGENIC FIESTA Dental Dam, Medium, 5'' x 5'' (127x127mm), 52 pcs
H04642	HYGENIC FIESTA Dental Dam, Medium, 6'' x 6'' (152x152mm), 36 pcs
H04643	HYGENIC FIESTA Dental Dam, Heavy, 5'' x 5'' (127x127mm), 52 pcs
H04644	HYGENIC FIESTA Dental Dam, Heavy, 6'' x 6'' (152x152mm), 36 pcs
H07315	HYGENIC Dental Dam, Latex, Heavy, Blue, 6'' x 6'' (152x152mm), 36 pcs
H07316	HYGENIC FIESTA Dental Dam, Latex, Convenience Pack, Medium, 5'' x 5'' (127x127mm), 364 pcs
H07317	HYGENIC FIESTA Dental Dam, Latex, Convenience Pack, Medium, 6'' x 6'' (152x152mm), 360 pcs
H11624	HYGENIC Elasti-Dam, Medium, Green, 5'' x 5'' (127x127mm), 52 pcs
H11625	HYGENIC Elasti-Dam, Medium, Green, 6'' x 6'' (152x152mm), 36 pcs
H11626	HYGENIC Elasti-Dam, Medium, Blue, 5'' x 5'' (127x127mm), 52 pcs

Réf. catalogue	Description
H11627	HYGENIC Elasti-Dam, Medium, Blue, 6'' x 6'' (152x152mm), 36 pcs
H11675	HYGENIC Elasti-Dam, Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H11676	HYGENIC Elasti-Dam, Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H11677	HYGENIC Elasti-Dam, Heavy, Blue, 5'' x 5'' (127x127mm), 52 pcs
H11678	HYGENIC Elasti-Dam, Heavy, Blue, 6'' x 6'' (152x152mm), 36 pcs
H11690	HYGENIC Elasti-Dam Trial Pack, Medium, Green, 6'' x 6'' (152X152mm)

Avertissements et précautions

Avertissements	Mention
 **AVERTISSEMENT**	Le non-respect strict des instructions contenues dans ce mode d'emploi est susceptible d'occasionner la blessure du patient ou de compromettre l'intégrité de Dental Dam. Utiliser le produit conformément à son utilisation prévue - voir paragraphe Utilisation prévue.
	Ne pas réutiliser Dental Dam. Dental Dam est conçu pour être utilisé une seule fois. La réutilisation intra-orale de Dental Dam comporte un danger biologique et peut entraîner une contamination croisée.
	Il convient d'inspecter Dental Dam avant utilisation. Jeter Dental Dam s'il est déchiré ou poreux. L'utilisation d'une digue Dental Dam ayant perdu ses caractéristiques peut occasionner une perte de fonctionnalité et compromettre l'intégrité de la procédure.

Précautions	Mention
 ATTENTION	Ce produit contient du latex de caoutchouc naturel qui peut provoquer des réactions allergiques.
	Ne pas exposer Dental Dam à des températures élevées. Stocker Dental Dam à l'écart des sources de chaleur.
	Dental Dam a une durée de vie limitée. Ne pas utiliser le dispositif après la date limite d'utilisation car ses fonctionnalités et ses performances pourraient être compromises.
	Attention : la loi fédérale (États-Unis d'Amérique) limite la vente de ce dispositif par un professionnel de santé agréé ou sur sa prescription
	Ne pas ranger à proximité de produits sans latex.

Informations complémentaires

Remarque : éliminer le dispositif conformément aux réglementations locales, régionales, nationales et/ou internationales. Les dispositifs utilisés en intra-oral doivent être traités comme un danger biologique et éliminés correctement conformément aux réglementations locales.

Remarque : un exemplaire papier du mode d'emploi sera expédié gratuitement, sur demande.

Pour les utilisateurs au sein de l'UE : tout incident grave survenant en lien avec l'utilisation du dispositif doit être signalé à Coltène/Whaledent, Inc. et aux autorités compétentes de l'État membre où l'utilisateur et/ou le patient sont installés.

Signification des symboles

Symbole	Intitulé et description du symbole
	Attention
 www.coltene.com	Consulter le mode d'emploi électronique - Indique la nécessité pour l'utilisateur de consulter le mode d'emploi
	Dispositif médical – Indique que l'article est un dispositif médical
	Vente limitée : l'achat du dispositif est strictement limité aux professionnels de la santé autorisés.
	À utiliser avant - Indique la date après laquelle le dispositif médical ne doit pas être utilisé
	Référence catalogue - Indique la référence au catalogue du fabricant permettant d'identifier le dispositif médical
	Ne pas réutiliser - Indique que le dispositif médical est destiné à un usage sur un seul patient au cours d'une seule procédure
	Marque CE
	Importateur - Indique l'entreprise qui importe le dispositif médical au niveau local
	Fabricant - Indique l'entreprise qui fabrique le dispositif médical

Symbole	Intitulé et description du symbole
LOT	Numéro de lot - Indique le numéro de lot du fabricant permettant d'identifier le lot
EC REP	Représentant autorisé au sein de la Communauté européenne - Indique le représentant autorisé au sein de la Communauté européenne
LATEX	Contient du latex de caoutchouc naturel - Indique la présence de latex de caoutchouc naturel sec dans le dispositif médical.

Conservation

Conserver Dental Dam à une température comprise entre 0 et 26 °C.
Tenir au sec et à l'écart de toute source de chaleur.

Symbole	Intitulé et description du symbole
	Tenir au sec - Indique que le dispositif médical doit être protégé contre l'humidité
	Tenir à l'écart de toute source de chaleur - Indique que le dispositif médical doit être protégé contre la chaleur
	Limite de température - Indique les limites de température à laquelle le dispositif médical peut être exposé sans danger. Les limites supérieure et inférieure doivent être indiquées à côté des lignes horizontales supérieure et inférieure.

HYGENIC

Latex Dental Dam

Instrucciones de uso

LATEX

Rx ONLY

COLTENE

Uso previsto/indicaciones para el uso:
El Dental Dam está previsto para su uso intrabucal para aislar una o varias piezas dentales y crear una barrera frente al entorno durante el procedimiento dental.

Contraindicaciones:
El Latex Dental Dam no se debe usar en pacientes con alergia al látex.

Usuarios previstos:
• Dentistas
• Auxiliares dentales

Grupo(s) objetivo de pacientes:
Indicado para todos los grupos de pacientes.

Ventajas clínicas:
El uso del Dental Dam tiene las siguientes ventajas clínicas:
• Visibilidad aumentada a través del aislamiento del diente/los dientes
• Menor riesgo de que el paciente aspire o se trague instrumentos, restos de dientes, medicamentos o soluciones irrigadoras
• Creación de un área de trabajo seca
• Protección del tejido blando frente al contacto con los instrumentos
• Barrera para el control de las infecciones

Características:
• Disponible en diferentes colores y grosores
• Dos tamaños: 127 mm x 127 mm o 152 mm x 152 mm (5″ x 5″ o 6″ x 6″)
• Los colores más claros tienen la ventaja de que iluminan de manera natural el campo operatorio, mientras que los oscuros ayudan a crear contraste visual

Almacenaje:
Guarde el Dental Dam entre 0 °C – 26 °C (32 °F – 80 ^{0}F).
Mantener seco y alejado del calor.

Riesgos residuales, advertencias y precauciones:
Consulte los riesgos asociados al uso del Dental Dam cuando se usa de la manera prevista en el apartado «Advertencias y precauciones».

Instrucciones

¡PRECAUCIÓN! Este producto contiene látex de goma natural que puede causar reacciones alérgicas.

El Dental Dam está previsto para su uso con otros dispositivos, como clamps y marcos.
Consulte las instrucciones de uso de los dispositivos que esté usando.

Los siguientes pasos generales sirven de orientación y se pueden adaptar al caso específico:

Paso 1: Determinar el campo operatorio.

Paso 2: Preparación del Dental Dam.
- Determinar las posiciones de los orificios
- Marcar las posiciones de los orificios
- Perforar los orificios

Paso 3: Selección del clamp/retenedor

Paso 4: Colocación del clamp/retenedor

Paso 5: Colocación del Dental Dam

Lista de componentes

Nota: No todos los números de catálogo están disponibles en todas las regiones

N.º de catálogo	Descripción
390020	ROEKO Dental Dam, Latex, Thin, 36 pcs
390021	ROEKO Dental Dam, Latex, Medium, 36 pcs
390022	ROEKO Dental Dam, Latex, Heavy, 36 pcs
60013793	ROEKO Elasti-Dam, 152x152mm, Medium, Green, 36 pcs
60013794	ROEKO Elasti-Dam, 152x152mm, Heavy, Green, 36 pcs
60013870	Sample ROEKO Elasti-Dam, 152x 52mm, Medium, Green
60013795	ROEKO Elasti-Dam, 127x127mm, Medium, Blue, 36 pcs
60013796	ROEKO Elasti-Dam, 127x127mm, Heavy, Blue, 36 pcs
H00523	HYGENIC Dental Dam, Latex, Thin, Light, 5'' x 5'' (127x127mm), 52 pcs
H00524	HYGENIC Dental Dam, Latex, Medium, Light, 5'' x 5'' (127x127mm), 52 pcs
H00525	HYGENIC Dental Dam, Latex, Heavy, Light, 5'' x 5'' (127x127mm), 52 pcs
H00533	HYGENIC Dental Dam, Latex, Thin, Light, 6'' x 6'' (152 x152mm), 36 pcs
H00534	HYGENIC Dental Dam, Latex, Medium, Light, 6'' x 6'' (152x152mm), 36 pcs
H00535	HYGENIC Dental Dam, Latex, Heavy, Light, 6'' x 6'' (152x152mm), 36 pcs
H00536	HYGENIC Dental Dam, Latex, Extra Heavy, Light, 6'' x 6'' (152x152mm), 36 pcs
H00538	HYGENIC Dental Dam, Latex, Thin, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00539	HYGENIC Dental Dam, Latex, Medium, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00540	HYGENIC Dental Dam, Latex, Heavy, Dark, 6'' x 6'' (152x152mm), 36 pcs

N.º de catálogo	Descripción
H00541	HYGENIC Dental Dam, Latex, Extra Heavy, Dark, 6" x 6" (152x152mm), 36 pcs
H02141	HYGENIC Dental Dam, Latex, Thin, Green, 5" x 5" (127x127mm), 52 pcs
H02142	HYGENIC Dental Dam, Latex, Medium, Green, 5" x 5" (127x127mm), 52 pcs
H02143	HYGENIC Dental Dam, Latex, Heavy, Green, 5" x 5" (127x127mm), 52 pcs
H02144	HYGENIC Dental Dam Latex, Extra Heavy, Green, 5" x 5" (127x127mm), 52 pcs
H02146	HYGENIC Dental Dam, Latex, Thin, Green, 6" x 6" (152x152mm), 36 pcs
H02147	HYGENIC Dental Dam, Latex, Medium, Green, 6" x 6" (152x152mm), 36 pcs
H02148	HYGENIC Dental Dam, Latex, Heavy, Green, 6" x 6" (152x152mm), 36 pcs
H02149	HYGENIC Dental Dam, Latex, Extra Heavy, Green, 6" x 6" (152x152mm), 36 pcs
H02778	HYGENIC FIESTA Winged Complete Kit, 1 pc
H02779	HYGENIC FIESTA Winged Standard Kit W/O Punch & Forceps, 1 pc
H02790	HYGENIC FIESTA Wingless Complete Kit, 1 pc
H02900	HYGENIC Simple Dam Kit - W/ Elasti-Dam, 1 pc
H03529	HYGENIC Dental Dam, Latex, Medium, Blue, 5" x 5" (127x127mm), 52 pcs
H03530	HYGENIC Dental Dam, Latex, Medium, Blue, 6" x 6" (152x152mm), 36 pcs
H04237	HYGENIC Dental Dam, Latex, Convenience Pack, Medium, Light, 5" x 5" (127x127mm), 364 pcs
H04241	HYGENIC Dental Dam, Latex, Convenience Pack, Medium, Green, 5" x 5" (127x127mm), 364 pcs
H04243	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Light, 6" x 6" (152x152mm), 360 pcs

N.º de catálogo	Descripción
H04245	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Dark, 6'' x 6'' (152x152mm), 360 pcs
H04247	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Green, 6'' x 6'' (152x152mm), 360 pcs
H04639	HYGENIC FIESTA Dental Dam, Thin, 6'' x 6'' (152x152mm), 36 pcs
H04640	HYGENIC FIESTA Dental Dam, Thin, 5'' x 5'' (127x127mm), 52 pcs
H04641	HYGENIC FIESTA Dental Dam, Medium, 5'' x 5'' (127x127mm), 52 pcs
H04642	HYGENIC FIESTA Dental Dam, Medium, 6'' x 6'' (152x152mm), 36 pcs
H04643	HYGENIC FIESTA Dental Dam, Heavy, 5'' x 5'' (127x127mm), 52 pcs
H04644	HYGENIC FIESTA Dental Dam, Heavy, 6'' x 6'' (152x152mm), 36 pcs
H07315	HYGENIC Dental Dam, Latex, Heavy, Blue, 6'' x 6'' (152x152mm), 36 pcs
H07316	HYGENIC FIESTA Dental Dam, Latex, Convenience Pack, Medium, 5'' x 5'' (127x127mm), 364 pcs
H07317	HYGENIC FIESTA Dental Dam, Latex, Convenience Pack, Medium, 6'' x 6'' (152x152mm), 360 pcs
H11624	HYGENIC Elasti-Dam, Medium, Green, 5'' x 5'' (127x127mm), 52 pcs
H11625	HYGENIC Elasti-Dam, Medium, Green, 6'' x 6'' (152x152mm), 36 pcs
H11626	HYGENIC Elasti-Dam, Medium, Blue, 5'' x 5'' (127x127mm), 52 pcs
H11627	HYGENIC Elasti-Dam, Medium, Blue, 6'' x 6'' (152x152mm), 36 pcs
H11675	HYGENIC Elasti-Dam, Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H11676	HYGENIC Elasti-Dam, Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs

N.º de catálogo	Descripción
H11677	HYGENIC Elasti-Dam, Heavy, Blue, 5'' x 5'' (127x127mm), 52 pcs
H11678	HYGENIC Elasti-Dam, Heavy, Blue, 6'' x 6'' (152x152mm), 36 pcs
H11690	HYGENIC Elasti-Dam Trial Pack, Medium, Green, 6'' x 6'' (152X152mm)

Advertencias y precauciones

Advertencias	Declaración
 **¡ADVERTENCIA!**	Si no se siguen adecuadamente las indicaciones de estas instrucciones de uso, el paciente puede resultar lesionado o la integridad del dental dam puede verse comprometida. Use el producto exclusivamente conforme a su uso previsto, véase Uso previsto.
	No reutilice el Dental Dam. El Dental Dam está previsto para un solo uso. La reutilización intrabucal del Dental Dam supone un riesgo biológico y puede provocar una contaminación cruzada.
	Inspeccione el Dental Dam antes de su uso. Deseche el Dental Dam si está rasgado o quebradizo. El uso de un Dental Dam que ha perdido sus propiedades puede suponer la pérdida de la funcionalidad y comprometer la integridad del procedimiento.

Precauciones	Declaración
 PRECAUCION	Este producto contiene látex de goma natural que puede causar reacciones alérgicas.
	No exponga el Dental Dam a temperaturas altas. Guarde el Dental Dam lejos de fuentes de calor.
	El Dental Dam tiene una vida útil específica. No utilice el producto después de la fecha de caducidad, porque su funcionalidad y su rendimiento pueden estar comprometidos.
	Atención: La ley federal de los EE. UU. limita la venta de este dispositivo a profesionales sanitarios autorizados o bajo prescripción facultativa de estos.
	No se debe guardar cerca de productos sin látex.

Información adicional

Nota: Deseche el producto siguiendo las normativas locales, regionales, nacionales y/o internacionales. Los productos que se usan intraoralmente se deben tratar como un riesgo biológico y se tienen que desechar siguiendo las normas locales.

Nota: Se suministrará una copia gratuita impresa de las instrucciones de uso bajo previa solicitud.

Para los usuarios establecidos en la UE: Cualquier incidente grave que se produzca en relación con el uso del producto se debe notificar a Coltène/Whaledent, Inc. y a las autoridades competentes del Estado miembro donde esté establecido el usuario o el paciente.

Glosario de símbolos

Símbolo	Nombre y descripción del símbolo
	Precaución
 www.coltene.com	Consulte las instrucciones de uso electrónicas - Indica que es necesario que el usuario consulte las instrucciones de uso
	Producto sanitario - Indica que el artículo es un producto sanitario
	Venta restringida - La compra de este dispositivo está restringida en exclusiva a profesionales sanitarios autorizados.
	Fecha de caducidad - Indica la fecha después de la que ya no se debe usar el producto sanitario
	Número de catálogo - Indica el número de catálogo del fabricante para que el producto sanitario se pueda identificar
	No reutilizar - Indica un producto sanitario que está previsto para el uso en el mismo paciente durante un único procedimiento
	Marca CE
	Importador - Indica la empresa que importa el producto sanitario en el mercado local
	Fabricante - Indica el fabricante del producto sanitario

Símbolo	Nombre y descripción del símbolo
LOT	Código de lote - Indica el código de lote del fabricante para que el lote se pueda identificar
EC REP	Representante autorizado en la Comunidad Europea - Indica el representante autorizado en la Comunidad Europea
LATEX	Contiene látex de goma natural - Indica la presencia de látex de goma natural seco como material de construcción dentro del producto sanitario.

Almacenaje

Guarde el Dental Dam entre 0 °C – 26 °C (32 °F – 80 ^{0}F).
Mantener seco y alejado del calor.

Símbolo	Nombre y descripción del símbolo
	Manténgase seco - Indica que el producto sanitario se debe proteger de la humedad.
	Protéjase de las fuentes de calor - Indica que el producto sanitario se debe proteger del calor.
	Límite de temperatura - Indica los límites de temperatura a los que el producto sanitario se puede exponer con seguridad. Los límites superior e inferior de temperatura deben aparecer indicados junto a las líneas horizontales superior e inferior.

HYGENIC

Latex Dental Dam

Инструкции за употреба

LATEX

Rx ONLY

COLTENE

Предназначение/Показания за употреба
Dental Dam е предназначен за интраорална употреба с цел изолация на един или няколко зъба и създаване на бариера спрямо заобикалящата зона по време на дентална процедура.

Противопоказания:
Latex Dental Dam не трябва да се използва при пациенти с алергия към латекс.

Целеви потребители:
• Стоматолози
• Дентални асистенти

Целеви групи пациенти
Подходящи за всички групи пациенти.

Клинични ползи:
Употребата на Dental Dam има следните клинични ползи:
• Подобрена видимост чрез изолация на зъба/зъбите
• Намален риск от аспирация или поглъщане на инструменти, частици от зъби, медикаменти или иригационни разтвори от пациента
• Създаване на сухо операционно поле
• Защита на меката тъкан от контакт с инструменти
• Бариера за контрол на инфекции

Характеристики:
• Налични са различни цветове и дебелини
• Два размера: 127 mm x 127 mm или 152 mm x 152 mm (5″ x 5″ или 6″ x 6″)
• По-светлите цветове имат предимството, че осветяват операционното поле по естествен начин, а по-тъмните цветове предоставят визуален контраст

Съхранение:
Съхранявайте Dental Dam при температура между 0 °C – 26 °C (32° F – 80° F).

Да се пази сухо и далеч от топлина.

Остатъчни рискове, предупреждения и предпазни мерки:
Направете справка в раздела с предупреждения и предпазни мерки относно рисковете, свързани с употребата на Dental Dam по предназначение.

Инструкции

ВНИМАНИЕ! Този продукт съдържа естествен каучуков латекс, който може да причини алергични реакции.

Dental Dam е предназначен за употреба с различни други изделия, включително клампи и рамки.

Направете справка в инструкциите за употреба относно другите изделия, които се използват.

Следните общи стъпки служат като насока и могат да се адаптират според специфичния случай:

Стъпка 1: Определяне на операционното поле.

Стъпка 2: Подготовка на Dental Dam.
• Определяне на позициите на дупките
• Маркиране на позициите на дупките
• Пробиване на дупките

Стъпка 3: Избор на клампа/ретайнер

Стъпка 4: Прилагане на клампа/ретайнер

Стъпка 5: Поставяне на Dental Dam

Списък на частите

Забележка: Не всички каталожни номера са налични във всички региони

Каталожен №	Описание
390020	ROEKO Dental Dam, Latex, Thin, 36 pcs
390021	ROEKO Dental Dam, Latex, Medium, 36 pcs
390022	ROEKO Dental Dam, Latex, Heavy, 36 pcs
60013793	ROEKO Elasti-Dam, 152x152mm, Medium, Green, 36 pcs
60013794	ROEKO Elasti-Dam, 152x152mm, Heavy, Green, 36 pcs
60013870	Sample ROEKO Elasti-Dam, 152x 52mm, Medium, Green
60013795	ROEKO Elasti-Dam, 127x127mm, Medium, Blue, 36 pcs
60013796	ROEKO Elasti-Dam, 127x127mm, Heavy, Blue, 36 pcs
H00523	HYGENIC Dental Dam, Latex, Thin, Light, 5'' x 5'' (127x127mm), 52 pcs
H00524	HYGENIC Dental Dam, Latex, Medium, Light, 5'' x 5'' (127x127mm), 52 pcs
H00525	HYGENIC Dental Dam, Latex, Heavy, Light, 5'' x 5'' (127x127mm), 52 pcs
H00533	HYGENIC Dental Dam, Latex, Thin, Light, 6'' x 6'' (152 x152mm), 36 pcs
H00534	HYGENIC Dental Dam, Latex, Medium, Light, 6'' x 6'' (152x152mm), 36 pcs
H00535	HYGENIC Dental Dam, Latex, Heavy, Light, 6'' x 6'' (152x152mm), 36 pcs
H00536	HYGENIC Dental Dam, Latex, Extra Heavy, Light, 6'' x 6'' (152x152mm), 36 pcs
H00538	HYGENIC Dental Dam, Latex, Thin, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00539	HYGENIC Dental Dam, Latex, Medium, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00540	HYGENIC Dental Dam, Latex, Heavy, Dark, 6'' x 6'' (152x152mm), 36 pcs

Каталожен №	Описание
H00541	HYGENIC Dental Dam, Latex, Extra Heavy, Dark, 6'' x 6'' (152x152mm), 36 pcs
H02141	HYGENIC Dental Dam, Latex, Thin, Green, 5'' x 5'' (127x127mm), 52 pcs
H02142	HYGENIC Dental Dam, Latex, Medium, Green, 5'' x 5'' (127x127mm), 52 pcs
H02143	HYGENIC Dental Dam, Latex, Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H02144	HYGENIC Dental Dam Latex, Extra Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H02146	HYGENIC Dental Dam, Latex, Thin, Green, 6'' x 6'' (152x152mm), 36 pcs
H02147	HYGENIC Dental Dam, Latex, Medium, Green, 6'' x 6'' (152x152mm), 36 pcs
H02148	HYGENIC Dental Dam, Latex, Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H02149	HYGENIC Dental Dam, Latex, Extra Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H02778	HYGENIC FIESTA Winged Complete Kit, 1 pc
H02779	HYGENIC FIESTA Winged Standard Kit W/O Punch & Forceps, 1 pc
H02790	HYGENIC FIESTA Wingless Complete Kit, 1 pc
H02900	HYGENIC Simple Dam Kit - W/ Elasti-Dam, 1 pc
H03529	HYGENIC Dental Dam, Latex, Medium, Blue, 5'' x 5'' (127x127mm), 52 pcs
H03530	HYGENIC Dental Dam, Latex, Medium, Blue, 6'' x 6'' (152x152mm), 36 pcs
H04237	HYGENIC Dental Dam, Latex, Convenience Pack, Medium, Light, 5'' x 5'' (127x127mm), 364 pcs
H04241	HYGENIC Dental Dam, Latex, Convenience Pack, Medium, Green, 5'' x 5'' (127x127mm), 364 pcs
H04243	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Light, 6'' x 6'' (152x152mm), 360 pcs

Каталожен №	Описание
H04245	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Dark, 6'' x 6'' (152x152mm), 360 pcs
H04247	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Green, 6'' x 6'' (152x152mm), 360 pcs
H04639	HYGENIC FIESTA Dental Dam, Thin, 6'' x 6'' (152x152mm), 36 pcs
H04640	HYGENIC FIESTA Dental Dam, Thin, 5'' x 5'' (127x127mm), 52 pcs
H04641	HYGENIC FIESTA Dental Dam, Medium, 5'' x 5'' (127x127mm), 52 pcs
H04642	HYGENIC FIESTA Dental Dam, Medium, 6'' x 6'' (152x152mm), 36 pcs
H04643	HYGENIC FIESTA Dental Dam, Heavy, 5'' x 5'' (127x127mm), 52 pcs
H04644	HYGENIC FIESTA Dental Dam, Heavy, 6'' x 6'' (152x152mm), 36 pcs
H07315	HYGENIC Dental Dam, Latex, Heavy, Blue, 6'' x 6'' (152x152mm), 36 pcs
H07316	HYGENIC FIESTA Dental Dam, Latex, Convenience Pack, Medium, 5'' x 5'' (127x127mm), 364 pcs
H07317	HYGENIC FIESTA Dental Dam, Latex, Convenience Pack, Medium, 6'' x 6'' (152x152mm), 360 pcs
H11624	HYGENIC Elasti-Dam, Medium, Green, 5'' x 5'' (127x127mm), 52 pcs
H11625	HYGENIC Elasti-Dam, Medium, Green, 6'' x 6'' (152x152mm), 36 pcs
H11626	HYGENIC Elasti-Dam, Medium, Blue, 5'' x 5'' (127x127mm), 52 pcs
H11627	HYGENIC Elasti-Dam, Medium, Blue, 6'' x 6'' (152x152mm), 36 pcs
H11675	HYGENIC Elasti-Dam, Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H11676	HYGENIC Elasti-Dam, Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs

Каталожен №	Описание
H11677	HYGENIC Elasti-Dam, Heavy, Blue, 5'' x 5'' (127x127mm), 52 pcs
H11678	HYGENIC Elasti-Dam, Heavy, Blue, 6'' x 6'' (152x152mm), 36 pcs
H11690	HYGENIC Elasti-Dam Trial Pack, Medium, Green, 6'' x 6'' (152X152mm)

Предупреждения и предпазни мерки

Предупреждения	Пояснение
 **ПРЕДУПРЕЖДЕНИЕ!**	Неспазване на указанията в настоящите инструкции за употреба може да доведе до нараняване на пациента или нарушаване на целостта на Dental Dam. Използвайте продукта само в съответствие с неговото предназначение, вж. Предназначение.
	Не използвайте повторно Dental Dam. Dental Dam е предназначен само за еднократна употреба. Повторна интраорална употреба на Dental Dam представлява биологична опасност и може да доведе до кръстосано замърсяване.
	Dental Dam трябва да се провери преди употреба. Изхвърлете разкъсан или напукан Dental Dam. Употребата на Dental Dam с нарушени работни характеристики може да доведе до загуба на функционалността и да наруши целостта на процедурата.

Предпазни мерки	Пояснение
 **ВНИМАНИЕ**	Този продукт съдържа естествен каучуков латекс, който може да причини алергични реакции.
	Не излагайте Dental Dam на високи температури. Съхранявайте Dental Dam далеч от източници на топлина.
	Dental Dam има определен срок на годност. Не използвайте изделието след изтичане на срока на годност, тъй като функционалността и работните характеристики на изделието може да са нарушени.
	Внимание: Федералните закони на САЩ ограничават продажбата на това изделие само от или по поръчка на лицензиран медицински специалист
	Не съхранявайте в близост до нелатексови продукти.

Допълнителна информация

Забележка: Изхвърлете изделието в съответствие с местните, регионалните, националните и/или международните разпоредби. Използвани интраорално изделия трябва да се третират като биологична опасност и да се изхвърлят правилно съгласно местните разпоредби.

Забележка: По заявка инструкциите за употреба могат да се доставят безплатно на хартиен носител.

За потребители, намиращи се в ЕС: Всички сериозни инциденти, възникнали във връзка с употребата на изделието, трябва да се докладват на Coltène/Whaledent, Inc. и компетентния орган в държавата членка, в която пребивават потребителят и/или пациентът.

Пояснение на символите

Символ	Заглавие и описание на символа
	Внимание
 www.coltene.com	Направете справка в инструкциите за употреба на уеб сайта: индикира, че потребителят трябва да се консултира с инструкциите за употреба
MD	Медицинско изделие: индикира, че артикулът представлява медицинско изделие
Rx ONLY	Ограничена продажба: закупуването на изделието е ограничено само до лицензирани медицински специалисти.
	Срок на годност: индикира датата, след която медицинското изделие повече не трябва да се използва
REF	Каталожен номер: индикира каталожния номер на производителя с цел идентифициране на медицинското изделие
	Не използвайте повторно: индикира медицинско изделие, което е предназначено за употреба само веднъж и за един пациент
CE	Маркировка „CE“
	Вносител: индикира вносителя на медицинското изделие на място
	Производител: индикира производителя на медицинското изделие

Символ	Заглавие и описание на символа
LOT	Код на партидата: индикира кода на партидата на производителя с цел идентифициране на партидата
EC REP	Упълномощен представител в Европейската общност: индикира упълномощения представител в Европейската общност
LATEX	Съдържа естествен каучуков латекс: индикира наличието на сух естествен каучуков латекс като съставен материал на медицинското изделие.

Съхранение

Съхранявайте Dental Dam при температура между 0 °C – 26 °C (32° F – 80° F).
Да се пази сухо и далеч от топлина.

Символ	Заглавие и описание на символа
	Да се пази сухо: индикира медицинско изделие, което трябва да се предпази от влага
	Да се пази от топлина: индикира медицинско изделие, което трябва да се предпази от топлина
	Температурно ограничение: индикира границите на температурата, на която може да се излага безопасно медицинското изделие. Горната и долната граница на температурата трябва да се индикират в близост до горната и долната хоризонтална линия.

HYGENIC

Latex Dental Dam

Návod k použití

LATEX

Rx ONLY

COLTENE

Určené použití / indikace k použití:
Dental Dam je určen k intraorálnímu použití k izolaci jednoho nebo více zubů a vytvoření bariéry vůči okolí během stomatologického zákroku.

Kontraindikace:
Latexový kofferdam Dental Dam by se neměl používat u pacientů s alergií na latex.

Zamýšlení uživatelé:
• Zubní lékaři
• Dentální asistenti

Cílová skupina (skupiny) pacientů:
Vhodné pro všechny věkové skupiny.

Klinické přínosy:
Používání kofferdamu Dental Dam má následující klinické výhody:
• Lepší viditelnost díky izolaci zubu/zubů
• Snížení rizika, že pacient vdechne nebo spolkne nástroje, zbytky zubů, léky nebo irigační roztoky
• Vytvoření suchého operačního pole
• Ochrana měkkých tkání před kontaktem s nástroji
• Bariéra pro zvládání infekce

Charakteristické vlastnosti:
• Dodává se v různých barvách a tloušťkách.
• Dvě velikosti: 127 mm × 127 mm nebo 152 mm × 152 mm (5″ × 5″ nebo 6″ × 6″)
• Světlejší barvy mají tu výhodu, že přirozeně osvětlují operační pole, zatímco tmavší barvy mohou zvyšovat vizuální kontrast.

Skladování:
Dental Dam uchovávejte při teplotě 0 až 26 °C (32 až 80 °F).
Uchovávejte v suchu a mimo zdroje tepla.

Zbytková rizika, varování a bezpečnostní upozornění
Informace o rizicích spojených s používáním kofferdamu Dental Dam v souladu s jeho určeným použitím najdete v části Varování a bezpečnostní upozornění.

Pokyny

UPOZORNĚNÍ! Tento výrobek obsahuje přírodní kaučuk, který může způsobovat alergické reakce.

Dental Dam je určen k používání s různými dalšími zdravotnickými prostředky, např. svorkami nebo rámečky.

Přečtěte si také návod k použití k dalším zdravotnickým prostředkům, které budete používat.

Následující obecné kroky slouží jako vodítko a lze je přizpůsobit konkrétnímu případu:

Krok 1: Určení operačního pole

Krok 2: Příprava kofferdamu Dental Dam
- Určení polohy otvorů
- Označení polohy otvorů
- Proděravění otvorů

Krok 3: Výběr spony/přidržovače

Krok 4: Nasazení spony/přidržovače

Krok 5: Umístění kofferdamu Dental Dam

Seznam dílů

Poznámka: Ne všechna katalogová čísla jsou dostupná ve všech regionech.

Katalogové č.	Popis
390020	ROEKO Dental Dam, Latex, Thin, 36 pcs
390021	ROEKO Dental Dam, Latex, Medium, 36 pcs
390022	ROEKO Dental Dam, Latex, Heavy, 36 pcs
60013793	ROEKO Elasti-Dam, 152x152mm, Medium, Green, 36 pcs
60013794	ROEKO Elasti-Dam, 152x152mm, Heavy, Green, 36 pcs
60013870	Sample ROEKO Elasti-Dam, 152x 52mm, Medium, Green
60013795	ROEKO Elasti-Dam, 127x127mm, Medium, Blue, 36 pcs
60013796	ROEKO Elasti-Dam, 127x127mm, Heavy, Blue, 36 pcs
H00523	HYGENIC Dental Dam, Latex, Thin, Light, 5'' x 5'' (127x127mm), 52 pcs
H00524	HYGENIC Dental Dam, Latex, Medium, Light, 5'' x 5'' (127x127mm), 52 pcs
H00525	HYGENIC Dental Dam, Latex, Heavy, Light, 5'' x 5'' (127x127mm), 52 pcs
H00533	HYGENIC Dental Dam, Latex, Thin, Light, 6'' x 6'' (152 x152mm), 36 pcs
H00534	HYGENIC Dental Dam, Latex, Medium, Light, 6'' x 6'' (152x152mm), 36 pcs
H00535	HYGENIC Dental Dam, Latex, Heavy, Light, 6'' x 6'' (152x152mm), 36 pcs
H00536	HYGENIC Dental Dam, Latex, Extra Heavy, Light, 6'' x 6'' (152x152mm), 36 pcs
H00538	HYGENIC Dental Dam, Latex, Thin, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00539	HYGENIC Dental Dam, Latex, Medium, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00540	HYGENIC Dental Dam, Latex, Heavy, Dark, 6'' x 6'' (152x152mm), 36 pcs

Katalogové č.	Popis
H00541	HYGENIC Dental Dam, Latex, Extra Heavy, Dark, 6" x 6" (152x152mm), 36 pcs
H02141	HYGENIC Dental Dam, Latex, Thin, Green, 5" x 5" (127x127mm), 52 pcs
H02142	HYGENIC Dental Dam, Latex, Medium, Green, 5" x 5" (127x127mm), 52 pcs
H02143	HYGENIC Dental Dam, Latex, Heavy, Green, 5" x 5" (127x127mm), 52 pcs
H02144	HYGENIC Dental Dam Latex, Extra Heavy, Green, 5" x 5" (127x127mm), 52 pcs
H02146	HYGENIC Dental Dam, Latex, Thin, Green, 6" x 6" (152x152mm), 36 pcs
H02147	HYGENIC Dental Dam, Latex, Medium, Green, 6" x 6" (152x152mm), 36 pcs
H02148	HYGENIC Dental Dam, Latex, Heavy, Green, 6" x 6" (152x152mm), 36 pcs
H02149	HYGENIC Dental Dam, Latex, Extra Heavy, Green, 6" x 6" (152x152mm), 36 pcs
H02778	HYGENIC FIESTA Winged Complete Kit, 1 pc
H02779	HYGENIC FIESTA Winged Standard Kit W/O Punch & Forceps, 1 pc
H02790	HYGENIC FIESTA Wingless Complete Kit, 1 pc
H02900	HYGENIC Simple Dam Kit - W/ Elasti-Dam, 1 pc
H03529	HYGENIC Dental Dam, Latex, Medium, Blue, 5" x 5" (127x127mm), 52 pcs
H03530	HYGENIC Dental Dam, Latex, Medium, Blue, 6" x 6" (152x152mm), 36 pcs
H04237	HYGENIC Dental Dam, Latex, Convenience Pack, Medium, Light, 5" x 5" (127x127mm), 364 pcs
H04241	HYGENIC Dental Dam, Latex, Convenience Pack, Medium, Green, 5" x 5" (127x127mm), 364 pcs
H04243	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Light, 6" x 6" (152x152mm), 360 pcs

Katalogové č.	Popis
H04245	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Dark, 6'' x 6'' (152x152mm), 360 pcs
H04247	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Green, 6'' x 6'' (152x152mm), 360 pcs
H04639	HYGENIC FIESTA Dental Dam, Thin, 6'' x 6'' (152x152mm), 36 pcs
H04640	HYGENIC FIESTA Dental Dam, Thin, 5'' x 5'' (127x127mm), 52 pcs
H04641	HYGENIC FIESTA Dental Dam, Medium, 5'' x 5'' (127x127mm), 52 pcs
H04642	HYGENIC FIESTA Dental Dam, Medium, 6'' x 6'' (152x152mm), 36 pcs
H04643	HYGENIC FIESTA Dental Dam, Heavy, 5'' x 5'' (127x127mm), 52 pcs
H04644	HYGENIC FIESTA Dental Dam, Heavy, 6'' x 6'' (152x152mm), 36 pcs
H07315	HYGENIC Dental Dam, Latex, Heavy, Blue, 6'' x 6'' (152x152mm), 36 pcs
H07316	HYGENIC FIESTA Dental Dam, Latex, Convenience Pack, Medium, 5'' x 5'' (127x127mm), 364 pcs
H07317	HYGENIC FIESTA Dental Dam, Latex, Convenience Pack, Medium, 6'' x 6'' (152x152mm), 360 pcs
H11624	HYGENIC Elasti-Dam, Medium, Green, 5'' x 5'' (127x127mm), 52 pcs
H11625	HYGENIC Elasti-Dam, Medium, Green, 6'' x 6'' (152x152mm), 36 pcs
H11626	HYGENIC Elasti-Dam, Medium, Blue, 5'' x 5'' (127x127mm), 52 pcs
H11627	HYGENIC Elasti-Dam, Medium, Blue, 6'' x 6'' (152x152mm), 36 pcs
H11675	HYGENIC Elasti-Dam, Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H11676	HYGENIC Elasti-Dam, Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs

Katalogové č.	Popis
H11677	HYGENIC Elasti-Dam, Heavy, Blue, 5'' x 5'' (127x127mm), 52 pcs
H11678	HYGENIC Elasti-Dam, Heavy, Blue, 6'' x 6'' (152x152mm), 36 pcs
H11690	HYGENIC Elasti-Dam Trial Pack, Medium, Green, 6'' x 6'' (152X152mm)

Varování a bezpečnostní upozornění

Varování	Instrukce
 **VAROVÁNÍ!**	Nedodržení pokynů uvedených v tomto návodu k použití může mít za následek poranění pacienta nebo narušení kofferdamu Dental Dam. Zdravotnický prostředek používejte pouze v souladu s jeho určeným použitím, viz Určené použití.
	Dental Dam nepoužívejte opakovaně. Dental Dam je určen k jednorázovému použití. Opakované použití kofferdamu Dental Dam v ústech představuje biologické riziko a může vést ke křížové kontaminaci.
	Dental Dam je třeba před použitím zkontrolovat. Poškozený nebo křehký Dental Dam vyhoďte. Pokud Dental Dam ztratí své funkční vlastnosti, hrozí, že nebude fungovat a může dojít i k porušení integrity zákroku.

Bezpečnostní upozornění	Instrukce
 UPOZORNĚNI	Tento výrobek obsahuje přírodní kaučuk, který může způsobovat alergické reakce.
	Chraňte Dental Dam před vysokými teplotami. Uchovávejte Dental Dam mimo zdroje tepla.
	Dental Dam má stanovenou dobu použitelnosti. Zdravotnický prostředek nepoužívejte po uplynutí data použitelnosti, protože může dojít k narušení funkčnosti a funkčních vlastností zdravotnického prostředku.
	Upozornění: Federální zákony USA omezují prodej tohoto zdravotnického prostředku pouze licencovaným zubním lékařům nebo na základě jejich objednávky.
	Neskladujte v blízkosti nelatexových výrobků.

Další informace

Pozn.: Zdravotnický prostředek likvidujte v souladu s místními, regionálními, národními a/nebo mezinárodními předpisy. Se zdravotnickými prostředky použitými intraorálně je třeba zacházet jako s nebezpečným biologickým materiálem a řádně je likvidovat podle místních předpisů.

Pozn.: Na vyžádání vám bude bezplatně poskytnuta tištěná verze návodu k použití.

Pro uživatele v EU: Případné závažné nežádoucí příhody, k nimž dojde v souvislosti s tímto zdravotnickým prostředkem, hlaste společnosti Coltène/Whaledent, Inc. a příslušnému orgánu členského státu, ve kterém má uživatel a/nebo pacient bydliště či sídlo.

Slovníček symbolů

Symbol	Název a popis symbolu
	Upozornění
 www.coltene.com	Čtěte elektronický návod k použití: Označuje, že je nutné, aby se uživatel seznámil s návodem k použití.
	Zdravotnický prostředek: Označuje, že se jedná o zdravotnický prostředek.
	Omezení prodeje: Tento zdravotnický prostředek smějí kupovat pouze zdravotničtí pracovníci.
	Datum použitelnosti: Označuje datum, po kterém se zdravotnický prostředek nemá používat.
	Katalogové číslo: Označuje katalogové číslo výrobku podle výrobce kvůli možnosti identifikace zdravotnického prostředku.
	Nepoužívat opakovaně: Označuje zdravotnický prostředek, který je určen pro jedno použití nebo pro použití jedním pacientem při jednom zákroku.
	Značka CE
	Dovozce: Označuje dovozce zdravotnického prostředku.
	Výrobce: Označuje výrobce zdravotnického prostředku.

Symbol	Název a popis symbolu
LOT	Kód dávky: Označuje kód dávky výrobce pro možnost identifikace dávky nebo šarže.
EC REP	Zplnomocněný zástupce v Evropském společenství: Označuje zplnomocněného zástupce v Evropském společenství.
LATEX	Obsah nebo přítomnost latexu z přírodního kaučuku: Označuje přítomnost kaučuku nebo suchého latexu z přírodního kaučuku jako konstrukčního materiálu zdravotnického prostředku.

Skladování

Dental Dam uchovávejte při teplotě 0 až 26 °C (32 až 80 °F).
Uchovávejte v suchu a mimo zdroje tepla.

Symbol	Název a popis symbolu
	Uchovávejte v suchu: Označuje, že zdravotnický prostředek musí být chráněn před vlhkostí.
	Chraňte před teplem: Označuje, že zdravotnický prostředek musí být chráněn před teplem.
	Omezení teploty: Označuje meze teplot, kterým může být zdravotnický prostředek bezpečně vystaven. Horní a dolní meze teploty musejí být uvedeny v blízkosti horní a dolní vodorovné čáry.

HYGENIC

Latex Dental Dam

Brugsanvisning

LATEX

Rx ONLY

COLTENE

Tilsigtet brug/Indikationer for brug:
Dental Dam er beregnet til intraoral anvendelse med henblik på at tørlægge en eller flere tænder og skabe en barriere mod det tilstødende område i forbindelse med tandbehandling.

Kontraindikationer:
Latex Dental Dam må ikke bruges på patienter, der er allergiske over for latex.

Tilsigtede brugere:
• Tandlæger
• Klinikassistenter

Patientmålgruppe(r):
Egnet til alle patientgrupper.

Kliniske fordele:
Anvendelsen af Dental Dam har følgende kliniske fordele:
• Bedre synlighed for tand/de tænder, der er blevet tørlagt
• Nedsat risiko for, at patienten indånder eller sluger instrumentdele, tandrester, medikamenter eller skylleopløsninger
• Skaber et tørt arbejdsfelt
• Beskytter det bløde væv mod kontakt med instrumenterne
• Infektionskontrolbarriere

Egenskaber:
• Fås i forskellige farver og tykkelser
• To størrelser: 127 mm x 127 mm eller 152 mm x 152 mm (5″ x 5″ or 6″ x 6″)
• Fordelen ved de lysere farver er, at de oplyser operationsfeltet på naturlig vis, hvorimod de mørkere farver giver en naturlig kontrast.

Opbevaring:
Opbevar Dental Dam mellem 0 °C – 26 °C (32 °F – 80 °F).
Opbevares tørt og holdes væk fra varme.

Restrisici, advarsler og forholdsregler:
Se advarsler og forholdsregler med henblik på afdækning af risici forbundet med brugen af Dental Dam til dens tilsigtede brug.

Anvisninger

FORSIGTIG! Dette produkt indeholder naturligt gummilatex, som kan forårsage allergiske reaktioner.

Dental Dam er beregnet til at blive brugt med flere andre anordninger, herunder klemmer og stel. Se brugsanvisningen til de andre anordninger, der anvendes.

Følgende generelle trin er beregnet som en vejledning og kan tilpasses til den individuelle patient:

Trin 1: Fastlæg operationsfeltet.

Trin 2: Klargøring af Dental Dam.
• Fastslå hulpositionerne
• Marker hulpositionerne
• Udstans huller

Trin 3: Valg af klemme/bøjle

Trin 4: Påsætning af klemme/bøjle

Trin 5: Placering af Dental Dam

Stykliste

Bemærk: Alle katalognumre er ikke tilgængelige i alle regioner

Katalognr.	Beskrivelse
390020	ROEKO Dental Dam, Latex, Thin, 36 pcs
390021	ROEKO Dental Dam, Latex, Medium, 36 pcs
390022	ROEKO Dental Dam, Latex, Heavy, 36 pcs
60013793	ROEKO Elasti-Dam, 152x152mm, Medium, Green, 36 pcs
60013794	ROEKO Elasti-Dam, 152x152mm, Heavy, Green, 36 pcs
60013870	Sample ROEKO Elasti-Dam, 152x 52mm, Medium, Green
60013795	ROEKO Elasti-Dam, 127x127mm, Medium, Blue, 36 pcs
60013796	ROEKO Elasti-Dam, 127x127mm, Heavy, Blue, 36 pcs
H00523	HYGENIC Dental Dam, Latex, Thin, Light, 5'' x 5'' (127x127mm), 52 pcs
H00524	HYGENIC Dental Dam, Latex, Medium, Light, 5'' x 5'' (127x127mm), 52 pcs
H00525	HYGENIC Dental Dam, Latex, Heavy, Light, 5'' x 5'' (127x127mm), 52 pcs
H00533	HYGENIC Dental Dam, Latex, Thin, Light, 6'' x 6'' (152 x152mm), 36 pcs
H00534	HYGENIC Dental Dam, Latex, Medium, Light, 6'' x 6'' (152x152mm), 36 pcs
H00535	HYGENIC Dental Dam, Latex, Heavy, Light, 6'' x 6'' (152x152mm), 36 pcs
H00536	HYGENIC Dental Dam, Latex, Extra Heavy, Light, 6'' x 6'' (152x152mm), 36 pcs
H00538	HYGENIC Dental Dam, Latex, Thin, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00539	HYGENIC Dental Dam, Latex, Medium, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00540	HYGENIC Dental Dam, Latex, Heavy, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00541	HYGENIC Dental Dam, Latex, Extra Heavy, Dark, 6'' x 6'' (152x152mm), 36 pcs

Katalognr.	Beskrivelse
H02141	HYGENIC Dental Dam, Latex, Thin, Green, 5'' x 5'' (127x127mm), 52 pcs
H02142	HYGENIC Dental Dam, Latex, Medium, Green, 5'' x 5'' (127x127mm), 52 pcs
H02143	HYGENIC Dental Dam, Latex, Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H02144	HYGENIC Dental Dam Latex, Extra Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H02146	HYGENIC Dental Dam, Latex, Thin, Green, 6'' x 6'' (152x152mm), 36 pcs
H02147	HYGENIC Dental Dam, Latex, Medium, Green, 6'' x 6'' (152x152mm), 36 pcs
H02148	HYGENIC Dental Dam, Latex, Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H02149	HYGENIC Dental Dam, Latex, Extra Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H02778	HYGENIC FIESTA Winged Complete Kit, 1 pc
H02779	HYGENIC FIESTA Winged Standard Kit W/O Punch & Forceps, 1 pc
H02790	HYGENIC FIESTA Wingless Complete Kit, 1 pc
H02900	HYGENIC Simple Dam Kit - W/ Elasti-Dam, 1 pc
H03529	HYGENIC Dental Dam, Latex, Medium, Blue, 5'' x 5'' (127x127mm), 52 pcs
H03530	HYGENIC Dental Dam, Latex, Medium, Blue, 6'' x 6'' (152x152mm), 36 pcs
H04237	HYGENIC Dental Dam, Latex, Convenience Pack, Medium, Light, 5'' x 5'' (127x127mm), 364 pcs
H04241	HYGENIC Dental Dam, Latex, Convenience Pack, Medium, Green, 5'' x 5'' (127x127mm), 364 pcs
H04243	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Light, 6'' x 6'' (152x152mm), 360 pcs
H04245	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Dark, 6'' x 6'' (152x152mm), 360 pcs

Katalognr.	Beskrivelse
H04247	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Green, 6'' x 6'' (152x152mm), 360 pcs
H04639	HYGENIC FIESTA Dental Dam, Thin, 6'' x 6'' (152x152mm), 36 pcs
H04640	HYGENIC FIESTA Dental Dam, Thin, 5'' x 5'' (127x127mm), 52 pcs
H04641	HYGENIC FIESTA Dental Dam, Medium, 5'' x 5'' (127x127mm), 52 pcs
H04642	HYGENIC FIESTA Dental Dam, Medium, 6'' x 6'' (152x152mm), 36 pcs
H04643	HYGENIC FIESTA Dental Dam, Heavy, 5'' x 5'' (127x127mm), 52 pcs
H04644	HYGENIC FIESTA Dental Dam, Heavy, 6'' x 6'' (152x152mm), 36 pcs
H07315	HYGENIC Dental Dam, Latex, Heavy, Blue, 6'' x 6'' (152x152mm), 36 pcs
H07316	HYGENIC FIESTA Dental Dam, Latex, Convenience Pack, Medium, 5'' x 5'' (127x127mm), 364 pcs
H07317	HYGENIC FIESTA Dental Dam, Latex, Convenience Pack, Medium, 6'' x 6'' (152x152mm), 360 pcs
H11624	HYGENIC Elasti-Dam, Medium, Green, 5'' x 5'' (127x127mm), 52 pcs
H11625	HYGENIC Elasti-Dam, Medium, Green, 6'' x 6'' (152x152mm), 36 pcs
H11626	HYGENIC Elasti-Dam, Medium, Blue, 5'' x 5'' (127x127mm), 52 pcs
H11627	HYGENIC Elasti-Dam, Medium, Blue, 6'' x 6'' (152x152mm), 36 pcs
H11675	HYGENIC Elasti-Dam, Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H11676	HYGENIC Elasti-Dam, Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H11677	HYGENIC Elasti-Dam, Heavy, Blue, 5'' x 5'' (127x127mm), 52 pcs
H11678	HYGENIC Elasti-Dam, Heavy, Blue, 6'' x 6'' (152x152mm), 36 pcs

Katalognr.	Beskrivelse
H11690	HYGENIC Elasti-Dam Trial Pack, Medium, Green, 6'' x 6'' (152X152mm)

Advarsler og forholdsregler

Advarsler	Sikkerhedssætning
 **ADVARSEL!**	Manglende overholdelse af anvisningerne i denne brug-sanvisning kan resultere i patientskade eller kompromittere integriteten af den anvendte dental dam. Brug kun produktet i overensstemmelse med dets tilsigtede anvendelse, se Tilsigtet brug.
	Dental Dam må ikke genbruges. Dental Dam er kun beregnet til engangsbrug. Genbrug af en Dental Dam intraoralt udgør en biologisk risiko og kan resultere i krydskontaminering.
	Dental Dam bør efterses grundigt inden brug. I tilfælde af brud eller skørhed skal Dental Dam bortskaffes. Brug af en Dental Dam, hvis egenskaber er forringet, kan medføre tab af funktion-alitet og kompromittere indgrebets integritet.

Forholdsregler	Sikkerhedssætning
 **FORSIGTIG**	Dette produkt indeholder naturligt gummilatex, som kan forårsage allergiske reaktioner.
	Dental Dam må ikke udsættes for høje temperaturer. Dental Dam skal opbevares væk fra varme.
	Dental Dam har en specificeret holdbarhed. Enheden må ikke anvendes efter sidste anvendelsesdato, da enhedens funktionalitet og egenskaber kan blive kompromitteret.
	Forsigtig: Ifølge amerikansk lov må dette produkt kun sælges af eller på recept fra en tandlæge
	Må ikke opbevares i nærheden af latexfri produkter.

Yderligere oplysninger

Bemærk: Apparatet bortskaffes i henhold til lokale, regionale, nationale og/eller internationale bestemmelser. Instrumenter, der anvendes intraoralt, skal behandles som en biologisk risiko og bortskaffes korrekt i henhold til lokale bestemmelser.

Bemærk: På anmodning udleveres en gratis papirkopi af brugsanvisningen.

For brugere i EU: Enhver alvorlig hændelse, der er indtruffet i forbindelse med brugen af udstyret, skal indberettes til Coltène/Whaledent, Inc. og den kompetente myndighed i den medlemsstat, hvor brugeren og/eller patienten er bosiddende.

Symboloversigt

Symbol	Titel og symbolforklaring
	Forsigtig
 www.coltene.com	Se brugsanvisningen i elektronisk format – betyder at brugeren henvises til brugsanvisningen
	Medicinsk udstyr – angiver, at enheden er medicinsk udstyr
	Salg begrænset: Køb af enheden er begrænset til autoriserede sundhedsfaglige personer.
	Sidste anvendelsesdato – angiver den dato, hvorefter det medicinske udstyr ikke må bruges
	Katalognummer – angiver producentens katalognummer, så det medicinske udstyr kan identificeres
	Må ikke genbruges – angiver, at den medicinske enhed er beregnet til brug på en enkelt patient til et enkelt indgreb
	CE-mærke
	Importør – angiver den enhed, der importerer det medicinske udstyr til lokaliteten
	Producent – angiver producenten af det medicinske udstyr

Symbol	Titel og symbolforklaring
	Batchkode – angiver producentens batchkode, så batchen eller partiet kan identificeres
	Autoriseret repræsentant i Det Europæiske Fællesskab – angiver den bemyndigede repræsentant i Det Europæiske Fællesskab
	Indeholder naturgummilatex – angiver, at tør naturgummilatex er til stede og indgår som fremstillingsmateriale i det medicinske udstyr.

Opbevaring

Opbevar Dental Dam mellem 0 °C – 26 °C (32 °F – 80 °F).
Opbevares tørt og holdes væk fra varme.

Symbol	Titel og symbolforklaring
	Holdes tørt – angiver medicinsk udstyr, der skal beskyttes mod fugt
	Opbevares væk fra varme – angiver medicinsk udstyr, der skal beskyttes mod varme
	Temperaturgrænse – angiver de temperaturgrænser, som det medicinske udstyr sikkert kan udsættes for. De øvre og nedre temperaturgrænser skal angives ved siden af de øvre og nedre vandrette linjer.

HYGENIC

Latex Dental Dam

Οδηγίες χρήση

LATEX

Rx ONLY

COLTENE

Προοριζόμενη χρήση / Ενδείξεις χρήσης:
Το Dental Dam προορίζεται να χρησιμοποιείται ενδοστοματικά για την απομόνωση ενός ή περισσότερων δοντιών και τη δημιουργία φραγμού στη γύρω περιοχή κατά τη διάρκεια μιας οδοντιατρικής διαδικασίας.

Αντενδείξεις:
Το Latex Dental Dam δεν πρέπει να χρησιμοποιείται σε ασθενείς με αλλεργία στο λάτεξ.

Προοριζόμενοι χρήστες:
• Οδοντίατροι
• Βοηθοί οδοντιάτρων

Ομάδα(ες)-στόχος ασθενών:
Κατάλληλο για όλες τις ομάδες ασθενών.

Κλινικά οφέλη:
Η χρήση του Dental Dam έχει τα ακόλουθα κλινικά οφέλη:
• Αυξημένη ορατότητα μέσω απομόνωσης του δοντιού/των δοντιών
• Μειωμένος κίνδυνος εισρόφησης ή κατάποσης εργαλείων, συγκριμάτων δοντιών, φαρμάκων ή διαλυμάτων διακλυσμού από τον ασθενή
• Δημιουργία στεγνού εγχειρητικού πεδίου
• Προστασία των μαλακών ιστών από την επαφή με τα εργαλεία
• Φραγμός ελέγχου λοιμώξεων

Χαρακτηριστικά:
• Διατίθεται σε διάφορα χρώματα και πάχη
• Δύο μεγέθη: 127 mm x 127 mm ή 152 mm x 152 mm (5″ x 5″ ή 6″ x 6″)
• Τα ανοιχτότερα χρώματα έχουν το πλεονέκτημα ότι φωτίζουν με φυσικό τρόπο το εγχειρητικό πεδίο, ενώ τα πιο σκούρα χρώματα μπορούν να βοηθήσουν στην οπτική αντίθεση

Αποθήκευση:
Φυλάσσετε το Dental Dam σε θερμοκρασία μεταξύ 0°C – 26°C (32°F – 80°F).

Διατηρείτε στεγνό και μακριά από θερμότητα.

Υπολειμματικοί κίνδυνοι, προειδοποιήσεις και προφυλάξεις:
Ανατρέξτε στην ενότητα "Προειδοποιήσεις και προφυλάξεις" για τη γνωστοποίηση των κινδύνων που σχετίζονται με τη χρήση του Dental Dam σύμφωνα με την προοριζόμενη χρήση του.

Οδηγίες

ΠΡΟΣΟΧΗ! Αυτό το προϊόν περιέχει φυσικό ελαστικό λάτεξ που μπορεί να προκαλέσει αλλεργικές αντιδράσεις.

Το Dental Dam προορίζεται για χρήση με διάφορα άλλα προϊόντα, όπως αρπάγες και πλαίσια. Ανατρέξτε στις οδηγίες χρήσης για τα άλλα προϊόντα που χρησιμοποιούνται.

Τα ακόλουθα γενικά βήματα παρέχονται ως καθοδήγηση και μπορούν να προσαρμοστούν στην εκάστοτε περίπτωση:

Βήμα 1: Καθορισμός του εγχειρητικού πεδίου.

Βήμα 2: Προετοιμασία του Dental Dam.
- Καθορισμός των θέσεων οπών
- Σημείωση των θέσεων οπών
- Τρύπημα των οπών

Βήμα 3: Επιλογή αρπάγης/συγκρατητήρα

Βήμα 4: Εφαρμογή αρπάγης/συγκρατ

Βήμα 5: Τοποθέτηση του Dental Dam

Κατάλογος μερών

Σημείωση: Δεν είναι διαθέσιμοι όλοι οι αριθμοί καταλόγου σε όλες τις περιοχές

Αρ. καταλόγου	Περιγραφή
390020	ROEKO Dental Dam, Latex, Thin, 36 pcs
390021	ROEKO Dental Dam, Latex, Medium, 36 pcs
390022	ROEKO Dental Dam, Latex, Heavy, 36 pcs
60013793	ROEKO Elasti-Dam, 152x152mm, Medium, Green, 36 pcs
60013794	ROEKO Elasti-Dam, 152x152mm, Heavy, Green, 36 pcs
60013870	Sample ROEKO Elasti-Dam, 152x 52mm, Medium, Green
60013795	ROEKO Elasti-Dam, 127x127mm, Medium, Blue, 36 pcs
60013796	ROEKO Elasti-Dam, 127x127mm, Heavy, Blue, 36 pcs
H00523	HYGENIC Dental Dam, Latex, Thin, Light, 5'' x 5'' (127x127mm), 52 pcs
H00524	HYGENIC Dental Dam, Latex, Medium, Light, 5'' x 5'' (127x127mm), 52 pcs
H00525	HYGENIC Dental Dam, Latex, Heavy, Light, 5'' x 5'' (127x127mm), 52 pcs
H00533	HYGENIC Dental Dam, Latex, Thin, Light, 6'' x 6'' (152 x152mm), 36 pcs
H00534	HYGENIC Dental Dam, Latex, Medium, Light, 6'' x 6'' (152x152mm), 36 pcs
H00535	HYGENIC Dental Dam, Latex, Heavy, Light, 6'' x 6'' (152x152mm), 36 pcs
H00536	HYGENIC Dental Dam, Latex, Extra Heavy, Light, 6'' x 6'' (152x152mm), 36 pcs
H00538	HYGENIC Dental Dam, Latex, Thin, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00539	HYGENIC Dental Dam, Latex, Medium, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00540	HYGENIC Dental Dam, Latex, Heavy, Dark, 6'' x 6'' (152x152mm), 36 pcs

Αρ. καταλόγου	Περιγραφή
H00541	HYGENIC Dental Dam, Latex, Extra Heavy, Dark, 6" x 6" (152x152mm), 36 pcs
H02141	HYGENIC Dental Dam, Latex, Thin, Green, 5" x 5" (127x127mm), 52 pcs
H02142	HYGENIC Dental Dam, Latex, Medium, Green, 5" x 5" (127x127mm), 52 pcs
H02143	HYGENIC Dental Dam, Latex, Heavy, Green, 5" x 5" (127x127mm), 52 pcs
H02144	HYGENIC Dental Dam Latex, Extra Heavy, Green, 5" x 5" (127x127mm), 52 pcs
H02146	HYGENIC Dental Dam, Latex, Thin, Green, 6" x 6" (152x152mm), 36 pcs
H02147	HYGENIC Dental Dam, Latex, Medium, Green, 6" x 6" (152x152mm), 36 pcs
H02148	HYGENIC Dental Dam, Latex, Heavy, Green, 6" x 6" (152x152mm), 36 pcs
H02149	HYGENIC Dental Dam, Latex, Extra Heavy, Green, 6" x 6" (152x152mm), 36 pcs
H02778	HYGENIC FIESTA Winged Complete Kit, 1 pc
H02779	HYGENIC FIESTA Winged Standard Kit W/O Punch & Forceps, 1 pc
H02790	HYGENIC FIESTA Wingless Complete Kit, 1 pc
H02900	HYGENIC Simple Dam Kit - W/ Elasti-Dam, 1 pc
H03529	HYGENIC Dental Dam, Latex, Medium, Blue, 5" x 5" (127x127mm), 52 pcs
H03530	HYGENIC Dental Dam, Latex, Medium, Blue, 6" x 6" (152x152mm), 36 pcs
H04237	HYGENIC Dental Dam, Latex, Convenience Pack, Medium, Light, 5" x 5" (127x127mm), 364 pcs
H04241	HYGENIC Dental Dam, Latex, Convenience Pack, Medium, Green, 5" x 5" (127x127mm), 364 pcs
H04243	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Light, 6" x 6" (152x152mm), 360 pcs

Αρ. καταλόγου	Περιγραφή
H04245	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Dark, 6'' x 6'' (152x152mm), 360 pcs
H04247	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Green, 6'' x 6'' (152x152mm), 360 pcs
H04639	HYGENIC FIESTA Dental Dam, Thin, 6'' x 6'' (152x152mm), 36 pcs
H04640	HYGENIC FIESTA Dental Dam, Thin, 5'' x 5'' (127x127mm), 52 pcs
H04641	HYGENIC FIESTA Dental Dam, Medium, 5'' x 5'' (127x127mm), 52 pcs
H04642	HYGENIC FIESTA Dental Dam, Medium, 6'' x 6'' (152x152mm), 36 pcs
H04643	HYGENIC FIESTA Dental Dam, Heavy, 5'' x 5'' (127x127mm), 52 pcs
H04644	HYGENIC FIESTA Dental Dam, Heavy, 6'' x 6'' (152x152mm), 36 pcs
H07315	HYGENIC Dental Dam, Latex, Heavy, Blue, 6'' x 6'' (152x152mm), 36 pcs
H07316	HYGENIC FIESTA Dental Dam, Latex, Convenience Pack, Medium, 5'' x 5'' (127x127mm), 364 pcs
H07317	HYGENIC FIESTA Dental Dam, Latex, Convenience Pack, Medium, 6'' x 6'' (152x152mm), 360 pcs
H11624	HYGENIC Elasti-Dam, Medium, Green, 5'' x 5'' (127x127mm), 52 pcs
H11625	HYGENIC Elasti-Dam, Medium, Green, 6'' x 6'' (152x152mm), 36 pcs
H11626	HYGENIC Elasti-Dam, Medium, Blue, 5'' x 5'' (127x127mm), 52 pcs
H11627	HYGENIC Elasti-Dam, Medium, Blue, 6'' x 6'' (152x152mm), 36 pcs
H11675	HYGENIC Elasti-Dam, Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H11676	HYGENIC Elasti-Dam, Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs

Αρ. καταλόγου	Περιγραφή
H11677	HYGENIC Elasti-Dam, Heavy, Blue, 5'' x 5'' (127x127mm), 52 pcs
H11678	HYGENIC Elasti-Dam, Heavy, Blue, 6'' x 6'' (152x152mm), 36 pcs
H11690	HYGENIC Elasti-Dam Trial Pack, Medium, Green, 6'' x 6'' (152X152mm)

Προειδοποιήσεις και προφυλάξεις

Προειδοποιήσεις	Δήλωση
 **ΠΡΟΕΙΔΟΠΟΙΗΣΗ!**	Η μη σωστή τήρηση των οδηγιών σε αυτές τις οδηγίες χρήσης μπορεί να έχει ως αποτέλεσμα τον τραυματισμό του ασθενούς ή τη διακύβευση της ακεραιότητας του Dental Dam. Χρησιμοποιείτε το προϊόν μόνο σύμφωνα με την προοριζόμενη χρήση του, βλ. Προοριζόμενη χρήση.
	Μην επαναχρησιμοποιείτε το Dental Dam. Το Dental Dam προορίζεται να χρησιμοποιηθεί μόνο μία φορά. Η επαναχρησιμοποίηση του Dental Dam ενδοστοματικά αποτελεί βιολογικό κίνδυνο και μπορεί να οδηγήσει σε διασταυρούμενη μόλυνση.
	Το Dental Dam πρέπει να επιθεωρείται πριν από τη χρήση. Απορρίψτε ένα σχισμένο ή εύθραυστο Dental Dam. Η χρήση Dental Dam που έχει χάσει τα χαρακτηριστικά απόδοσής του μπορεί να οδηγήσει σε απώλεια λειτουργικότητας και διακύβευση της ακεραιότητας της διαδικασίας.

Προφυλάξεις	Δήλωση
 ΠΡΟΣΟΧΗ	Αυτό το προϊόν περιέχει φυσικό ελαστικό λάτεξ που μπορεί να προκαλέσει αλλεργικές αντιδράσεις.
	Μην εκθέτετε το Dental Dam σε υψηλές θερμοκρασίες. Φυλάσσετε το Dental Dam μακριά από πηγές θερμότητας.
	Το Dental Dam έχει καθορισμένη διάρκεια ζωής. Μη χρησιμοποιείτε το προϊόν μετά την ημερομηνία λήξης, διότι ενδέχεται να έχουν επηρεαστεί η λειτουργικότητα και τα χαρακτηριστικά απόδοσης του προϊόντος.
	Προσοχή: Η ομοσπονδιακή νομοθεσία (Η.Π.Α.) περιορίζει την πώληση αυτής της συσκευής σε αδειούχο επαγγελματία υγείας
	Μην αποθηκεύετε κοντά σε προϊόντα χωρίς λάτεξ.

Πρόσθετες πληροφορίες

Σημείωση: Απορρίψτε το προϊόν σύμφωνα με τους τοπικούς, περιφερειακούς, εθνικούς ή/και διεθνείς κανονισμούς. Τα προϊόντα που χρησιμοποιούνται ενδοστοματικά πρέπει να αντιμετωπίζονται ως βιολογικός κίνδυνος και να απορρίπτονται σωστά σύμφωνα με τους τοπικούς κανονισμούς.

Σημείωση: Κατόπιν αιτήματος, θα παρέχεται δωρεάν έντυπο αντίγραφο των οδηγιών χρήσης.

Για χρήστες που είναι εγκατεστημένοι στην ΕΕ: Οποιοδήποτε σοβαρό περιστατικό συμβεί σε σχέση με τη χρήση του προϊόντος πρέπει να αναφερθεί στην Coltène/Whaledent, Inc. και στην αρμόδια αρχή του κράτους-μέλους στο οποίο έχει την έδρα του ο χρήστης ή/και ο ασθενής.

Γλωσσάριο συμβόλων

Σύμβολο	Τίτλος και περιγραφή του συμβόλου
	Προσοχή
 www.coltene.com	Συμβουλευτείτε τις ηλεκτρονικές οδηγίες χρήσης – Υποδεικνύει ότι ο χρήστης πρέπει να συμβουλευτεί τις οδηγίες χρήσης
	Ιατροτεχνολογικό προϊόν – Υποδεικνύει ότι το προϊόν είναι ιατροτεχνολογικό προϊόν
	Περιορισμένη πώληση: Η αγορά του προϊόντος περιορίζεται σε αδειούχους επαγγελματίες υγείας μόνο.
	Ημερομηνία λήξης – Υποδεικνύει την ημερομηνία μετά την οποία το ιατροτεχνολογικό προϊόν δεν πρέπει να χρησιμοποιηθεί
	Αριθμός καταλόγου – Υποδεικνύει τον αριθμό καταλόγου του κατασκευαστή, ώστε να μπορεί να αναγνωριστεί το ιατροτεχνολογικό προϊόν
	Μην επαναχρησιμοποιείτε – Υποδεικνύει ένα ιατροτεχνολογικό προϊόν που προορίζεται για χρήση σε έναν μόνο ασθενή κατά τη διάρκεια μίας μόνο διαδικασίας
	Σήμανση CE
	Εισαγωγέας – Υποδεικνύει την οντότητα που εισάγει το ιατροτεχνολογικό προϊόν στην τοποθεσία

Σύμβολο	Τίτλος και περιγραφή του συμβόλου
	Κατασκευαστής – Υποδεικνύει τον κατασκευαστή του ιατροτεχνολογικού προϊόντος
	Κωδικός παρτίδας – Υποδεικνύει τον κωδικό παρτίδας του κατασκευαστή, ώστε να μπορεί να αναγνωριστεί η παρτίδα
	Εξουσιοδοτημένος αντιπρόσωπος στην Ευρωπαϊκή Κοινότητα – Υποδεικνύει τον εξουσιοδοτημένο αντιπρόσωπο στην Ευρωπαϊκή Κοινότητα
	Περιέχει φυσικό ελαστικό λάτεξ – Υποδεικνύει την παρουσία ξηρού φυσικού ελαστικού λάτεξ ως υλικό κατασκευής εντός του ιατροτεχνολογικού προϊόντος.

Αποθήκευση

Φυλάσσετε το Dental Dam σε θερμοκρασία μεταξύ 0°C – 26°C (32°F – 80°F).
Διατηρείτε στεγνό και μακριά από θερμότητα.

Σύμβολο	Τίτλος και περιγραφή του συμβόλου
	Διατηρείτε στεγνό – Υποδεικνύει ένα ιατροτεχνολογικό προϊόν που πρέπει να προστατεύεται από την υγρασία
	Διατηρείτε μακριά από θερμότητα – Υποδεικνύει ένα ιατροτεχνολογικό προϊόν που χρειάζεται προστασία από τη θερμότητα
	Όριο θερμοκρασίας – Υποδεικνύει τα όρια θερμοκρασίας στην οποία το ιατροτεχνολογικό προϊόν μπορεί να εκτεθεί με ασφάλεια. Το άνω και το κάτω όριο θερμοκρασίας πρέπει να υποδεικνύονται δίπλα στην άνω και την κάτω οριζόντια γραμμή.

HYGENIC

Latex Dental Dam

Kasutusjuhend

LATEX

Rx ONLY

COLTENE

Kasutusotstarve / näidustused kasutamiseks
Dental Dam on ette nähtud suusiseseks kasutuseks, et hambaraviprotseduuri ajal isoleerida üks või mitu hammast ja luua ümbritseva ala eraldamiseks barjäär.

Vastunäidustused
Lateksist Dental Dam ei sobi lateksiallergiaga patsientidele.

Kasutajad
• Hambaravispetsialistid
• Hambaravispetsialistide assistendid

Patsientide sihtrühm(ad)
Sobib kõigile patsiendirühmadele.

Kliiniline kasu
Kofferdami Dental Dam kasutusel on järgmine kliiniline kasu.
• Nähtavuse parendamine läbi hambaisolatsiooni
• Väiksem oht, et patsient hingab sisse või neelab alla instrumente, hambarãbu, medikamente või loputuslahust
• Kuiva tööala tekitamine
• Pehmete kudede kaitsmine instrumentidega kokkupuute eest
• Infektsioonitõke

Omadused
• Saadaval eri värvitoonid ja jämedused
• Kaks suurust: 127 mm × 127 mm või 152 mm × 152 mm (5″ × 5″ või 6″ × 6″)
• Heledamate värvide eeliseks on tööala loomulik valgustamine ning tumedad värvid aitavad luua visuaalse kontrasti

Hoiustamine
Hoidke Dental Dam temperatuuril 0...26 °C (32...80 °F).
Hoida kuivas ja eemal kuumusallikatest.

Jääkriskid, hoiatused ja ettevaatusabinõud
Kofferdami Dental Dam kasutusotstarbele vastaval kasutamisel esinevate riskide kirjelduse leiate jaotisest „Hoiatused ja ettevaatusabinõud".

Juhised

ETTEVAATUST! See toode sisaldab looduslikku kummilateksit, mis võib põhjustada allergilisi reaktsioone.

Dental Dam on ette nähtud kasutamiseks koos mitmesuguste muude seadmetega, sealhulgas klambrite ja raamidega.

Lugege muude kasutatavate seadmete kasutusjuhendit.
Järgmised üldtoimingud on esitatud suunistena ja neid võib kohandada vastavalt kindlale kasutusjuhule.

1. toiming: määrake kindlaks tööala.

2. toiming: valmistage Dental Dam ette.
• Määrake aukude asukohad.
• Märkige aukude asukohad.
• Tehke augud.

3. toiming: klambri/fiksaatori valimine

4. toiming: klambri/fiksaatori rakendamine

5. toiming: kofferdami Dental Dam paigutamine

Osade loend

Märkus. Kõik kataloginumbrid ei pruugi olla saadaval igas piirkonnas

Kataloogi-number	Kirjeldus
390020	ROEKO Dental Dam, Latex, Thin, 36 pcs
390021	ROEKO Dental Dam, Latex, Medium, 36 pcs
390022	ROEKO Dental Dam, Latex, Heavy, 36 pcs
60013793	ROEKO Elasti-Dam, 152x152mm, Medium, Green, 36 pcs
60013794	ROEKO Elasti-Dam, 152x152mm, Heavy, Green, 36 pcs
60013870	Sample ROEKO Elasti-Dam, 152x 52mm, Medium, Green
60013795	ROEKO Elasti-Dam, 127x127mm, Medium, Blue, 36 pcs
60013796	ROEKO Elasti-Dam, 127x127mm, Heavy, Blue, 36 pcs
H00523	HYGENIC Dental Dam, Latex, Thin, Light, 5'' x 5'' (127x127mm), 52 pcs
H00524	HYGENIC Dental Dam, Latex, Medium, Light, 5'' x 5'' (127x127mm), 52 pcs
H00525	HYGENIC Dental Dam, Latex, Heavy, Light, 5'' x 5'' (127x127mm), 52 pcs
H00533	HYGENIC Dental Dam, Latex, Thin, Light, 6'' x 6'' (152 x152mm), 36 pcs
H00534	HYGENIC Dental Dam, Latex, Medium, Light, 6'' x 6'' (152x152mm), 36 pcs
H00535	HYGENIC Dental Dam, Latex, Heavy, Light, 6'' x 6'' (152x152mm), 36 pcs
H00536	HYGENIC Dental Dam, Latex, Extra Heavy, Light, 6'' x 6'' (152x152mm), 36 pcs
H00538	HYGENIC Dental Dam, Latex, Thin, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00539	HYGENIC Dental Dam, Latex, Medium, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00540	HYGENIC Dental Dam, Latex, Heavy, Dark, 6'' x 6'' (152x152mm), 36 pcs

Kataloogi-number	Kirjeldus
H00541	HYGENIC Dental Dam, Latex, Extra Heavy, Dark, 6" x 6" (152x152mm), 36 pcs
H02141	HYGENIC Dental Dam, Latex, Thin, Green, 5" x 5" (127x127mm), 52 pcs
H02142	HYGENIC Dental Dam, Latex, Medium, Green, 5" x 5" (127x127mm), 52 pcs
H02143	HYGENIC Dental Dam, Latex, Heavy, Green, 5" x 5" (127x127mm), 52 pcs
H02144	HYGENIC Dental Dam Latex, Extra Heavy, Green, 5" x 5" (127x127mm), 52 pcs
H02146	HYGENIC Dental Dam, Latex, Thin, Green, 6" x 6" (152x152mm), 36 pcs
H02147	HYGENIC Dental Dam, Latex, Medium, Green, 6" x 6" (152x152mm), 36 pcs
H02148	HYGENIC Dental Dam, Latex, Heavy, Green, 6" x 6" (152x152mm), 36 pcs
H02149	HYGENIC Dental Dam, Latex, Extra Heavy, Green, 6" x 6" (152x152mm), 36 pcs
H02778	HYGENIC FIESTA Winged Complete Kit, 1 pc
H02779	HYGENIC FIESTA Winged Standard Kit W/O Punch & Forceps, 1 pc
H02790	HYGENIC FIESTA Wingless Complete Kit, 1 pc
H02900	HYGENIC Simple Dam Kit - W/ Elasti-Dam, 1 pc
H03529	HYGENIC Dental Dam, Latex, Medium, Blue, 5" x 5" (127x127mm), 52 pcs
H03530	HYGENIC Dental Dam, Latex, Medium, Blue, 6" x 6" (152x152mm), 36 pcs
H04237	HYGENIC Dental Dam, Latex, Convenience Pack, Medium, Light, 5" x 5" (127x127mm), 364 pcs
H04241	HYGENIC Dental Dam, Latex, Convenience Pack, Medium, Green, 5" x 5" (127x127mm), 364 pcs
H04243	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Light, 6" x 6" (152x152mm), 360 pcs

Kataloogi-number	Kirjeldus
H04245	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Dark, 6'' x 6'' (152x152mm), 360 pcs
H04247	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Green, 6'' x 6'' (152x152mm), 360 pcs
H04639	HYGENIC FIESTA Dental Dam, Thin, 6'' x 6'' (152x152mm), 36 pcs
H04640	HYGENIC FIESTA Dental Dam, Thin, 5'' x 5'' (127x127mm), 52 pcs
H04641	HYGENIC FIESTA Dental Dam, Medium, 5'' x 5'' (127x127mm), 52 pcs
H04642	HYGENIC FIESTA Dental Dam, Medium, 6'' x 6'' (152x152mm), 36 pcs
H04643	HYGENIC FIESTA Dental Dam, Heavy, 5'' x 5'' (127x127mm), 52 pcs
H04644	HYGENIC FIESTA Dental Dam, Heavy, 6'' x 6'' (152x152mm), 36 pcs
H07315	HYGENIC Dental Dam, Latex, Heavy, Blue, 6'' x 6'' (152x152mm), 36 pcs
H07316	HYGENIC FIESTA Dental Dam, Latex, Convenience Pack, Medium, 5'' x 5'' (127x127mm), 364 pcs
H07317	HYGENIC FIESTA Dental Dam, Latex, Convenience Pack, Medium, 6'' x 6'' (152x152mm), 360 pcs
H11624	HYGENIC Elasti-Dam, Medium, Green, 5'' x 5'' (127x127mm), 52 pcs
H11625	HYGENIC Elasti-Dam, Medium, Green, 6'' x 6'' (152x152mm), 36 pcs
H11626	HYGENIC Elasti-Dam, Medium, Blue, 5'' x 5'' (127x127mm), 52 pcs
H11627	HYGENIC Elasti-Dam, Medium, Blue, 6'' x 6'' (152x152mm), 36 pcs
H11675	HYGENIC Elasti-Dam, Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H11676	HYGENIC Elasti-Dam, Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs

Kataloogi-number	Kirjeldus
H11677	HYGENIC Elasti-Dam, Heavy, Blue, 5'' x 5'' (127x127mm), 52 pcs
H11678	HYGENIC Elasti-Dam, Heavy, Blue, 6'' x 6'' (152x152mm), 36 pcs
H11690	HYGENIC Elasti-Dam Trial Pack, Medium, Green, 6'' x 6'' (152X152mm)

Hoiatused ja ettevaatusabinõud

Hoiatused	Avaldus
 **HOIATUS!**	Käesolevas kasutusjuhendis toodud suuniste eiramine või mittekorrektne järgimine võib põhjustada patsiendi kehavigastuse või ohustada kofferdami Dental Dam terviklust. Kasutage toodet üksnes vastavalt selle kasutusotstarbele, vt jaotist Kasutusotstarve.
	Kofferdami Dental Dam ei tohi korduskasutada. Dental Dam on ette nähtud ainult ühekordseks kasutamiseks. Kofferdami Dental Dam suusisene korduskasutamine on bioloogiline oht ja võib põhjustada ristsaastumist.
	Enne kasutamist vaadake Dental Dam üle. Rebenenud või murenenud Dental Dam visake ära. Toimeomadused kaotanud kofferdami Dental Dam kasutamine võib halvendada selle funktsionaalsust ja ohustada protseduuri terviklust.

Ettevaatusabinõude	Avaldus
 ETTEVAATUST	See toode sisaldab looduslikku kummilateksit, mis võib põhjustada allergilisi reaktsioone.
	Vältige kofferdami Dental Dam kokkupuudet kõrgete temperatuuridega. Hoidke Dental Dam kuumusallikatest eemal.
	Kofferdamil Dental Dam on kindel kasutusiga. Ärge kasutage seadet pärast „Kõlblik kuni“ kuupäeva möödumist, kuna seadme toimivuse ja mõju näitajad ei pruugi olla enam endised.
	Ettevaatust. Föderaalseadustega (USA) kehtestatud piirangute tõttu tohib selle toote müümine toimuda ainult litsentsiga tervishoiutöötaja poolt või tema korraldusel.
	Mitte hoiustada mittelatekstoodete läheduses.

Lisateave

Märkus. Kõrvaldage seade kasutuselt kooskõlas kohalike, riiklike ja/või rahvusvaheliste eeskirjadega. Suusiseselt kasutatud seadmeid tuleb kohelda kui bioohtlikke jäätmeid ja need tuleb kõrvaldada kasutuselt kooskõlas asjakohaste kohalike eeskirjadega.

Märkus. Vastava taotluse korral tarnitakse kasutajale tasuta kasutusjuhendi füüsiline eksemplar.

Euroopa Liidus asuvatele kasutajatele. Kõigist selle seadme kasutamisega seoses toimuvatest tõsistest intsidentidest tuleb teatada ettevõttele Coltène/Whaledent, Inc. ning kasutaja ja/või patsiendi asukohaks oleva liikmesriigi pädevale ametkonnale.

Sümbolite selgitus

Sümbol	Sümboli nimetus ja kirjeldus
	Ettevaatust
 www.coltene.com	Vaadake elektroonilist kasutusjuhendit - näitab, et kasutajal tuleb lugeda kasutusjuhendit
MD	Meditsiiniseade – näitab, et toode on meditsiiniseade
Rx ONLY	Müügipiirang: seadet tohivad osta üksnes litsentsiga tervishoiutöötajad.
	Kõlblik kuni - näitab kuupäeva, mille möödumisel ei tohi meditsiiniseadet enam kasutada
REF	Kataloginumber - näitab tootja kataloginumbrit, mille järgi saab meditsiiniseadme tuvastada
	Mitte korduvkasutada - näitab, et see meditsiiniseade on mõeldud kasutamiseks ühel patsiendil ühe protseduuri käigus
CE	CE-märk
	Importija - näitab, kes on meditsiiniseadme kohalikule turule importija
	Tootja - näitab, kes on meditsiiniseadme tootja

Sümbol	Sümboli nimetus ja kirjeldus
LOT	Partii kood - näitab tootja partii koodi, mille järgi saab tuvastada tootmispartii
EC REP	Volitatud esindaja Euroopa Ühenduses - näitab, kes on volitatud esindaja Euroopa Ühenduses
LATEX	Sisaldab looduslikku kummilateksit - näitab, et meditsiiniseadme valmistamiseks kasutatud materjalide hulgas on kuiv looduslik kummilateks.

Hoiustamine

Hoidke Dental Dam temperatuuril 0...26 °C (32...80 °F).
Hoida kuivas ja eemal kuumusallikatest.

Sümbol	Sümboli nimetus ja kirjeldus
	Hoida kuivas - näitab, et meditsiiniseadet tuleb kaitsta niiskuse eest
	Hoida kuumusallikate eest - näitab, et meditsiiniseadet tuleb kaitsta kuuma eest
	Temperatuuripiirang - näitab temperatuurivahemikku, milles viibimine on meditsiiniseadmele ohutu. Temperatuuri ülem- ja alampiir on toodud vastavalt ülemise ja alumise horisontaaljoone juures.

HYGENIC

Latex Dental Dam

Upute za upotrebu

LATEX

Rx ONLY

COLTENE

Predviđena upotreba/Indikacije za upotrebu:
Plahtica Dental Dam namijenjena je za intraoralnu primjenu u svrhu izolacije jednog ili više zubi i stvaranja barijere prema okolnom području tijekom stomatološkog postupka.

Kontraindikacije:
Plahtica Latex Dental Dam se ne smije primijeniti na pacijentima s alergijom na lateks.

Predviđeni korisnici:
• stomatolozi u ordinacijama
• stomatološki tehničari

Ciljne skupine pacijenata:
Prikladno za sve skupine pacijenata.

Kliničke koristi:
Plahtica Dental Dam upotrebljava se za postizanje sljedećih kliničkih koristi:
• povećane vidljivosti kroz izolaciju zuba/zubi
• smanjenja rizika da pacijent udahne ili proguta instrumente, ostatke zuba, lijekove ili otopine za ispiranje
• stvaranja suhog operacijskog polja
• zaštite mekog tkiva od dodira s instrumentima
• barijere za kontrolu infekcije

Svojstva:
• Dostupna u različitim bojama i debljinama
• Dvije veličine: 127 mm x 127 mm ili 152 mm x 152 mm
• Svjetlije boje imaju prednost da prirodno osvjetljavaju radno polje dok tamnije boje mogu poboljšati vizualni kontrast

Skladištenje:
Skladištite Dental Dam na temperaturi 0°C – 26°C.
Čuvajte na suhom mjestu i podalje od izvora topline.

Preostali rizici, upozorenja i mjere opreza:
Pogledajte odjeljak Upozorenja i mjere opreza u kojem su navedeni rizici povezani s upotrebom plahtice Dental Dam u skladu s njenom namjenom.

Upute

OPREZ! Ovaj proizvod sadrži lateks prirodne gume koji može prouzročiti alergijske reakcije.

Dental Dam nije namijenjen za korištenje s drugim proizvodima uključujući stezaljke i okvire.

Za korištenje drugih proizvoda pogledajte njihove upute za upotrebu.

Sljedeći koraci navedeni su kao općenite smjernice i mogu se prilagoditi specifičnostima pojedinog slučaja:

1. korak: Određivanje radnog polja.

2. korak: Priprema plahtice Dental Dam.
• odredite pozicije otvora
• označite pozicije otvora
• izbušite otvore

3. korak: Odabir stezaljki/kvačica.

4. korak: Stavljanje stezaljki/kvačica.

5. korak: Postavljanje plahtice Dental Dam.

Popis dijelova

Napomena: Nisu svi kataloški brojevi dostupni u svim regijama.

Kataloški br.	Opis
390020	ROEKO Dental Dam, Latex, Thin, 36 pcs
390021	ROEKO Dental Dam, Latex, Medium, 36 pcs
390022	ROEKO Dental Dam, Latex, Heavy, 36 pcs
60013793	ROEKO Elasti-Dam, 152x152mm, Medium, Green, 36 pcs
60013794	ROEKO Elasti-Dam, 152x152mm, Heavy, Green, 36 pcs
60013870	Sample ROEKO Elasti-Dam, 152x 52mm, Medium, Green
60013795	ROEKO Elasti-Dam, 127x127mm, Medium, Blue, 36 pcs
60013796	ROEKO Elasti-Dam, 127x127mm, Heavy, Blue, 36 pcs
H00523	HYGENIC Dental Dam, Latex, Thin, Light, 5'' x 5'' (127x127mm), 52 pcs
H00524	HYGENIC Dental Dam, Latex, Medium, Light, 5'' x 5'' (127x127mm), 52 pcs
H00525	HYGENIC Dental Dam, Latex, Heavy, Light, 5'' x 5'' (127x127mm), 52 pcs
H00533	HYGENIC Dental Dam, Latex, Thin, Light, 6'' x 6'' (152 x152mm), 36 pcs
H00534	HYGENIC Dental Dam, Latex, Medium, Light, 6'' x 6'' (152x152mm), 36 pcs
H00535	HYGENIC Dental Dam, Latex, Heavy, Light, 6'' x 6'' (152x152mm), 36 pcs
H00536	HYGENIC Dental Dam, Latex, Extra Heavy, Light, 6'' x 6'' (152x152mm), 36 pcs
H00538	HYGENIC Dental Dam, Latex, Thin, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00539	HYGENIC Dental Dam, Latex, Medium, Dark, 6'' x 6'' (152x152mm), 36 pcs

Kataloški br.	Opis
H00540	HYGENIC Dental Dam, Latex, Heavy, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00541	HYGENIC Dental Dam, Latex, Extra Heavy, Dark, 6'' x 6'' (152x152mm), 36 pcs
H02141	HYGENIC Dental Dam, Latex, Thin, Green, 5'' x 5'' (127x127mm), 52 pcs
H02142	HYGENIC Dental Dam, Latex, Medium, Green, 5'' x 5'' (127x127mm), 52 pcs
H02143	HYGENIC Dental Dam, Latex, Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H02144	HYGENIC Dental Dam Latex, Extra Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H02146	HYGENIC Dental Dam, Latex, Thin, Green, 6'' x 6'' (152x152mm), 36 pcs
H02147	HYGENIC Dental Dam, Latex, Medium, Green, 6'' x 6'' (152x152mm), 36 pcs
H02148	HYGENIC Dental Dam, Latex, Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H02149	HYGENIC Dental Dam, Latex, Extra Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H02778	HYGENIC FIESTA Winged Complete Kit, 1 pc
H02779	HYGENIC FIESTA Winged Standard Kit W/O Punch & Forceps, 1 pc
H02790	HYGENIC FIESTA Wingless Complete Kit, 1 pc
H02900	HYGENIC Simple Dam Kit - W/ Elasti-Dam, 1 pc
H03529	HYGENIC Dental Dam, Latex, Medium, Blue, 5'' x 5'' (127x127mm), 52 pcs
H03530	HYGENIC Dental Dam, Latex, Medium, Blue, 6'' x 6'' (152x152mm), 36 pcs
H04237	HYGENIC Dental Dam, Latex, Convenience Pack, Medium, Light, 5'' x 5'' (127x127mm), 364 pcs
H04241	HYGENIC Dental Dam, Latex, Convenience Pack, Medium, Green, 5'' x 5'' (127x127mm), 364 pcs

Kataloški br.	Opis
H04243	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Light, 6'' x 6'' (152x152mm), 360 pcs
H04245	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Dark, 6'' x 6'' (152x152mm), 360 pcs
H04247	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Green, 6'' x 6'' (152x152mm), 360 pcs
H04639	HYGENIC FIESTA Dental Dam, Thin, 6'' x 6'' (152x152mm), 36 pcs
H04640	HYGENIC FIESTA Dental Dam, Thin, 5'' x 5'' (127x127mm), 52 pcs
H04641	HYGENIC FIESTA Dental Dam, Medium, 5'' x 5'' (127x127mm), 52 pcs
H04642	HYGENIC FIESTA Dental Dam, Medium, 6'' x 6'' (152x152mm), 36 pcs
H04643	HYGENIC FIESTA Dental Dam, Heavy, 5'' x 5'' (127x127mm), 52 pcs
H04644	HYGENIC FIESTA Dental Dam, Heavy, 6'' x 6'' (152x152mm), 36 pcs
H07315	HYGENIC Dental Dam, Latex, Heavy, Blue, 6'' x 6'' (152x152mm), 36 pcs
H07316	HYGENIC FIESTA Dental Dam, Latex, Convenience Pack, Medium, 5'' x 5'' (127x127mm), 364 pcs
H07317	HYGENIC FIESTA Dental Dam, Latex, Convenience Pack, Medium, 6'' x 6'' (152x152mm), 360 pcs
H11624	HYGENIC Elasti-Dam, Medium, Green, 5'' x 5'' (127x127mm), 52 pcs
H11625	HYGENIC Elasti-Dam, Medium, Green, 6'' x 6'' (152x152mm), 36 pcs
H11626	HYGENIC Elasti-Dam, Medium, Blue, 5'' x 5'' (127x127mm), 52 pcs
H11627	HYGENIC Elasti-Dam, Medium, Blue, 6'' x 6'' (152x152mm), 36 pcs

Kataloški br.	Opis
H11675	HYGENIC Elasti-Dam, Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H11676	HYGENIC Elasti-Dam, Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H11677	HYGENIC Elasti-Dam, Heavy, Blue, 5'' x 5'' (127x127mm), 52 pcs
H11678	HYGENIC Elasti-Dam, Heavy, Blue, 6'' x 6'' (152x152mm), 36 pcs
H11690	HYGENIC Elasti-Dam Trial Pack, Medium, Green, 6'' x 6'' (152X152mm)

Upozorenja i mjere opreza

Upozorenja	Izjava
 **UPOZORENJE!**	Nepridržavanje točnih naputaka iz ovih uputa za upotrebu može rezultirati ozljedom pacijenta ili narušiti cjelovitost plahtice Dental Dam. Upotrebljavajte proizvod samo sukladno s njegovom predviđenom upotrebom, vidjeti Predviđena upotreba.
	Nemojte ponovno upotrebljavati plahticu Dental Dam. Plahtica Dental Dam namijenjena je samo za jednokratnu upotrebu. Ponovna upotreba plahtice Dental Dam intraoralno predstavlja biološku opasnost i za posljedicu može imati križnu kontaminaciju.
	Plahticu Dental Dam treba pregledati prije upotrebe. Bacite pokidanu ili krutu plahticu Dental Dam. Upotreba plahtice Dental Dam, koja je izgubila svoja svojstva, može rezultirati gubitkom funkcionalnosti i ugroziti cijeli postupak.

Mjere opreza	Izjava
 OPREZ	Ovaj proizvod sadrži lateks prirodne gume koji može prouzročiti alergijske reakcije.
	Nemojte izlagati plahticu Dental Dam visokim temperaturama. Skladištite plahticu Dental Dam podalje od izvora topline.
	Plahtica Dental Dam ima određeni rok trajanja. Nemojte upotrebljavati proizvod nakon isteka roka upotrebe jer funkcionalnost proizvoda i svojstva učinkovitosti mogu biti umanjeni.
	Oprez: federalni zakon (u SAD-u) ograničava prodaju ovog uređaja od strane ili po nalogu licenciranog zdravstvenog radnika.
	Nemojte skladištiti u blizini proizvoda koji ne sadrže lateks.

Dodatne informacije

Napomena: zbrinite proizvod sukladno s lokalnim, regionalnim, državnim i/ili međunarodnim odredbama. S proizvodima koji se upotrebljavaju intraoralno treba postupati kao s biološki opasnim tvarima i oni se moraju propisno zbrinuti sukladno s lokalnim odredbama.

Napomena: na zahtjev će besplatno biti dostavljena tvrda kopija ovih uputa za upotrebu.

Za korisnike koji se nalaze u EU: svaki ozbiljan incident koji se javi vezano uz primjenu ovog proizvoda trebate prijaviti tvrtki Coltène/Whaledent, Inc. i nadležnom tijelu u državi članici u kojoj korisnik i/ili pacijent imaju prebivalište.

Pojmovnik simbola

Simbol	Naslov i opis simbola
	Oprez
 www.coltene.com	Pogledajte elektroničke upute za upotrebu – označava potrebu da korisnik pogleda upute za upotrebu
	Medicinski proizvod – označava da je taj predmet medicinski proizvod
	Ograničena prodaja: kupnja ovog uređaja je ograničena samo na licencirane zdravstvene radnike.
	Rok upotrebe – označava datum nakon kojeg se ovaj medicinski proizvod ne smije upotrebljavati
	Kataloški broj – označava proizvođačev kataloški broj s pomoću kojeg se medicinski proizvod može identificirati
	Nemojte ponovno upotrebljavati – označava medicinski proizvod koji je predviđen samo za upotrebu na jednom pacijentu tijekom jednog postupka
	Oznaka CE
	Uvoznik – označava entitet koji uvozi medicinski proizvod na lokalno tržište
	Proizvođač – označava proizvođača medicinskog proizvoda

Simbol	Naslov i opis simbola
	Broj serije – označava proizvođačev broj serije radi identifikacije serije ili lota
	Ovlašteni zastupnik u Europskoj zajednici – označava ovlaštenog zastupnika u Europskoj zajednici
	Sadrži prirodni gumeni lateks – označava prisutnost suhog prirodnog gumenog lateksa kao konstrukcijskog materijala u medicinskom proizvodu.

Skladištenje

Skladištite Dental Dam na temperaturi 0°C – 26°C.
Čuvajte na suhom mjestu i podalje od izvora topline.

Simbol	Naslov i opis simbola
	Držite na suhom mjestu – označava da je medicinski proizvod potrebno zaštititi od vlage
	Držite podalje od topline – označava da je medicinski proizvod potrebno zaštititi od topline
	Ograničenje temperature – označava ograničenja temperature kojoj se ovaj medicinski proizvod sigurno može izložiti. Gornje i donje ograničenje temperature trebaju se nalaziti u blizini gornje i donje vodoravne crte.

HYGENIC

Latex Dental Dam

Használati útmutató

LATEX

Rx ONLY

COLTENE

Rendeltetésszerű használat/Alkalmazási javallatok:
A Dental Dam intraorális használatra szolgál, egy vagy több fog izolálására és gát létrehozására a környező területtel szemben egy fogászati eljárás során.

Ellenjavallatok:
A latexből készült Dental Dam latexallergiában szenvedő pácienseknél nem használható.

Rendeltetés szerinti felhasználók:
• Fogorvosok
• Fogászati asszisztensek

Betegcélcsoport(ok):
Minden betegcsoport számára alkalmas.

Klinikai előnyök:
A Dental Dam használata az alábbi klinikai előnyökkel jár:
• Jobb láthatóság a fog/fogak izolálásával
• A műszerek, a fogtörmelék, a gyógyszerek, illetve az irrigáló oldatok beszívásának vagy lenyelésének csökkent kockázata
• Száraz operációs terület létrehozása
• A lágyszövet védelme a műszerekkel való érintkezéstől
• Fertőzésmegelőzési gát

Jellemzők:
• Különböző színekben és vastagságokban kapható
• Két méret: 127 mm x 127 mm vagy 152 mm x 152 mm
• A világosabb színek előnye, hogy természetes módon megvilágítják az operációs területet, míg a sötétebb színek a vizuális kontrasztot segíthetik

Tárolás:
A Dental Dam terméket 0 °C és 26 °C közötti hőmérsékleten tárolja.
Tartsa szárazon és hőhatástól távol.

Fennmaradó kockázatok, figyelmeztetések és óvintézkedések:
A Dental Dam termék rendeltetésszerű használatával összefüggő kockázatok megismeréséhez olvassa el a Figyelmeztetések és óvintézkedések című részt.

Utasítások

FIGYELEM! Ez a termék természetes gumilatexet tartalmaz, amely allergiás reakciókat okozhat.

A Dental Dam termék különféle egyéb eszközökkel, például szorítókapcsokkal és vázakkal együtt történő használatra szolgál.

Lásd az egyéb használt eszközök használati utasítását.

Az alábbi általános lépések útmutatásként szolgálnak, és testre szabhatók az adott esetnek megfelelően:

1. lépés: Az operációs terület meghatározása

2. lépés: A Dental Dam preparálása
• Határozza meg a lyukak elhelyezkedését
• Jelölje meg a lyukak elhelyezkedését
• Hozza létre a lyukakat

3. lépés: A szorítókapcsok/rögzítőelemek kiválasztása

4. lépés: A szorítókapcsok/rögzítőelemek felhelyezése

5. lépés: A Dental Dam elhelyezése

Terméklista

Megjegyzés: Nem minden katalógusszám áll rendelkezésre minden régióban

Kataló-gusszám	Leírás
390020	ROEKO Dental Dam, Latex, Thin, 36 pcs
390021	ROEKO Dental Dam, Latex, Medium, 36 pcs
390022	ROEKO Dental Dam, Latex, Heavy, 36 pcs
60013793	ROEKO Elasti-Dam, 152x152mm, Medium, Green, 36 pcs
60013794	ROEKO Elasti-Dam, 152x152mm, Heavy, Green, 36 pcs
60013870	Sample ROEKO Elasti-Dam, 152x 52mm, Medium, Green
60013795	ROEKO Elasti-Dam, 127x127mm, Medium, Blue, 36 pcs
60013796	ROEKO Elasti-Dam, 127x127mm, Heavy, Blue, 36 pcs
H00523	HYGENIC Dental Dam, Latex, Thin, Light, 5'' x 5'' (127x127mm), 52 pcs
H00524	HYGENIC Dental Dam, Latex, Medium, Light, 5'' x 5'' (127x127mm), 52 pcs
H00525	HYGENIC Dental Dam, Latex, Heavy, Light, 5'' x 5'' (127x127mm), 52 pcs
H00533	HYGENIC Dental Dam, Latex, Thin, Light, 6'' x 6'' (152 x152mm), 36 pcs
H00534	HYGENIC Dental Dam, Latex, Medium, Light, 6'' x 6'' (152x152mm), 36 pcs
H00535	HYGENIC Dental Dam, Latex, Heavy, Light, 6'' x 6'' (152x152mm), 36 pcs
H00536	HYGENIC Dental Dam, Latex, Extra Heavy, Light, 6'' x 6'' (152x152mm), 36 pcs
H00538	HYGENIC Dental Dam, Latex, Thin, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00539	HYGENIC Dental Dam, Latex, Medium, Dark, 6'' x 6'' (152x152mm), 36 pcs

Kataló-gusszám	Leírás
H00540	HYGENIC Dental Dam, Latex, Heavy, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00541	HYGENIC Dental Dam, Latex, Extra Heavy, Dark, 6'' x 6'' (152x152mm), 36 pcs
H02141	HYGENIC Dental Dam, Latex, Thin, Green, 5'' x 5'' (127x127mm), 52 pcs
H02142	HYGENIC Dental Dam, Latex, Medium, Green, 5'' x 5'' (127x127mm), 52 pcs
H02143	HYGENIC Dental Dam, Latex, Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H02144	HYGENIC Dental Dam Latex, Extra Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H02146	HYGENIC Dental Dam, Latex, Thin, Green, 6'' x 6'' (152x152mm), 36 pcs
H02147	HYGENIC Dental Dam, Latex, Medium, Green, 6'' x 6'' (152x152mm), 36 pcs
H02148	HYGENIC Dental Dam, Latex, Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H02149	HYGENIC Dental Dam, Latex, Extra Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H02778	HYGENIC FIESTA Winged Complete Kit, 1 pc
H02779	HYGENIC FIESTA Winged Standard Kit W/O Punch & Forceps, 1 pc
H02790	HYGENIC FIESTA Wingless Complete Kit, 1 pc
H02900	HYGENIC Simple Dam Kit - W/ Elasti-Dam, 1 pc
H03529	HYGENIC Dental Dam, Latex, Medium, Blue, 5'' x 5'' (127x127mm), 52 pcs
H03530	HYGENIC Dental Dam, Latex, Medium, Blue, 6'' x 6'' (152x152mm), 36 pcs
H04237	HYGENIC Dental Dam, Latex, Convenience Pack, Medium, Light, 5'' x 5'' (127x127mm), 364 pcs
H04241	HYGENIC Dental Dam, Latex, Convenience Pack, Medium, Green, 5'' x 5'' (127x127mm), 364 pcs

Kataló-gusszám	Leírás
H04243	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Light, 6'' x 6'' (152x152mm), 360 pcs
H04245	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Dark, 6'' x 6'' (152x152mm), 360 pcs
H04247	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Green, 6'' x 6'' (152x152mm), 360 pcs
H04639	HYGENIC FIESTA Dental Dam, Thin, 6'' x 6'' (152x152mm), 36 pcs
H04640	HYGENIC FIESTA Dental Dam, Thin, 5'' x 5'' (127x127mm), 52 pcs
H04641	HYGENIC FIESTA Dental Dam, Medium, 5'' x 5'' (127x127mm), 52 pcs
H04642	HYGENIC FIESTA Dental Dam, Medium, 6'' x 6'' (152x152mm), 36 pcs
H04643	HYGENIC FIESTA Dental Dam, Heavy, 5'' x 5'' (127x127mm), 52 pcs
H04644	HYGENIC FIESTA Dental Dam, Heavy, 6'' x 6'' (152x152mm), 36 pcs
H07315	HYGENIC Dental Dam, Latex, Heavy, Blue, 6'' x 6'' (152x152mm), 36 pcs
H07316	HYGENIC FIESTA Dental Dam, Latex, Convenience Pack, Medium, 5'' x 5'' (127x127mm), 364 pcs
H07317	HYGENIC FIESTA Dental Dam, Latex, Convenience Pack, Medium, 6'' x 6'' (152x152mm), 360 pcs
H11624	HYGENIC Elasti-Dam, Medium, Green, 5'' x 5'' (127x127mm), 52 pcs
H11625	HYGENIC Elasti-Dam, Medium, Green, 6'' x 6'' (152x152mm), 36 pcs
H11626	HYGENIC Elasti-Dam, Medium, Blue, 5'' x 5'' (127x127mm), 52 pcs
H11627	HYGENIC Elasti-Dam, Medium, Blue, 6'' x 6'' (152x152mm), 36 pcs

Kataló-gusszám	Leírás
H11675	HYGENIC Elasti-Dam, Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H11676	HYGENIC Elasti-Dam, Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H11677	HYGENIC Elasti-Dam, Heavy, Blue, 5'' x 5'' (127x127mm), 52 pcs
H11678	HYGENIC Elasti-Dam, Heavy, Blue, 6'' x 6'' (152x152mm), 36 pcs
H11690	HYGENIC Elasti-Dam Trial Pack, Medium, Green, 6'' x 6'' (152X152mm)

Figyelmeztetések és óvintézkedések

Figyelmeztetések	Kijelentés
 **VIGYÁZAT!**	A jelen használati útmutatóban szereplő utasítások megfelelő követésének elmulasztása a páciens sérülését okozhatja, vagy veszélyeztetheti a dental dam termék integritását. A terméket kizárólag a rendeltetésének megfelelően használja – lásd a Rendeltetésszerű használat c. részt.
	Ne használja fel újra a Dental Dam terméket. A Dental Dam terméket kizárólag egyszeri használatra tervezték. A Dental Dam intraorális újrafelhasználása biológiai veszélyt jelent, és keresztszennyeződést eredményezhet.
	Használat előtt a Dental Dam terméket meg kell vizsgálni. A szakadt vagy morzsolódó Dental Dam terméket dobja ki. Az olyan Dental Dam termék használata, amely elvesztette a teljesítményjellemzőit, a funkcionalitás elvesztését eredményezheti, és veszélyeztetheti az eljárás integritását.

Óvintézkedések	Kijelentés
 **FIGYELEM**	Ez a termék természetes gumilatexet tartalmaz, amely allergiás reakciókat okozhat.
	Ne tegye ki a Dental Dam terméket magas hőmérsékletnek. A Dental Dam terméket hőforrásoktól távol tárolja.
	A Dental Dam meghatározott eltarthatósági idővel rendelkezik. Ne használja az eszközt a lejárati idő után, mert az eszköz funkcionalitása és teljesítményjellemzői romolhattak.
	Figyelem: a szövetségi törvény (Amerikai Egyesült Államok) értelmében ez az eszköz csak egészségügyi szakember által vagy annak rendelvényére értékesíthető
	Ne tárolja latexmentes termékek mellett.

Kiegészítő információk

Megjegyzés: Az eszközt a helyi, regionális, országos és/vagy nemzetközi előírásoknak megfelelően ártalmatlanítsa. Az intraorálisan használt eszközöket biológiai veszélyként kell kezelni, és megfelelő módon, a helyi előírások szerint kell ártalmatlanítani.

Megjegyzés: Kérésre ingyenesen rendelkezésre bocsátjuk a használati útmutató egy nyomtatott példányát.

Az EU-ban élő felhasználók számára: Minden, az eszköz használatával kapcsolatban bekövetkezett súlyos eseményt jelenteni kell a Coltène/Whaledent, Inc. vállalatnak, valamint a felhasználó és/vagy a beteg letelepedési helye szerinti tagállam illetékes hatóságának.

Szimbólumjegyzék

Szimbólum	A szimbólum neve és leírása
	Figyelem
 www.coltene.com	Olvassa el az elektronikus használati útmutatót – Azt jelzi, hogy a felhasználónak el kell olvasnia a használati útmutatót
MD	Orvostechnikai eszköz – Azt jelzi, hogy a termék orvostechnikai eszköz
Rx ONLY	Korlátozott értékesítés: Az eszköz megvásárlásának joga kizárólag az engedéllyel rendelkező egészségügyi szakemberekre korlátozódik.
	Lejárati idő – Azt az időpontot jelöli, amely után az orvostechnikai eszköz nem használható
REF	Katalógusszám – A gyártói katalógusszámot jelzi, hogy az orvostechnikai eszköz azonosítható legyen
	Ne használja fel újra – Olyan orvostechnikai eszközt jelöl, amely egyetlen betegnél egyetlen eljárás során történő használatra szolgál
CE	CE-jelölés
	Importőr – Az orvostechnikai eszközt az adott területre importáló szervezetet jelöli
	Gyártó – Az orvostechnikai eszköz gyártóját jelöli

Szimbólum	A szimbólum neve és leírása
LOT	Gyártási tételkód – A gyártó gyártási tételkódját jelöli a tétel azonosításához
EC REP	Meghatalmazott képviselő az Európai Közösségben – A meghatalmazott képviselőt jelöli az Európai Közösségben
LATEX	Természetes gumilatexet tartalmaz – A száraz természetes gumilatex szerkezeti anyagként való jelenlétét jelzi az orvostechnikai eszközben.

Tárolás

A Dental Dam terméket 0 °C és 26 °C közötti hőmérsékleten tárolja.
Tartsa szárazon és hőhatástól távol.

Szimbólum	A szimbólum neve és leírása
	Szárazon tartandó – Olyan orvostechnikai eszközt jelöl, amelyet védeni kell a nedvességtől
	Hőhatástól távol tartandó – Olyan orvostechnikai eszközt jelöl, amelyet védeni kell a hőhatástól
	Hőmérsékleti határ - Azokat a hőmérsékleti határértékeket jelzi, amelyeknek az orvostechnikai eszköz biztonságosan kitehető. Az alsó és felső hőmérsékleti határértékeket fel kell tüntetni az alsó és a felső vízszintes vonalak mellett.

HYGENIC

Latex Dental Dam

Istruzioni per l'uso

LATEX

Rx ONLY

COLTENE

Uso previsto/indicazioni d'uso:
La Dental Dam è destinata all'uso intraorale per isolare uno o più denti e creare una barriera verso l'area circostante durante una procedura odontoiatrica.

Controindicazioni:
La Dental Dam in lattice non deve essere utilizzata nei pazienti con allergia al lattice.

Utilizzatori previsti:
• Odontoiatri
• Assistenti dentali

Gruppo o gruppi target di pazienti:
Indicati per tutti i gruppi di pazienti.

Vantaggi clinici:
L'uso della Dental Dam ha i seguenti benefici clinici:
• Aumento della visibilità mediante isolamento del o dei denti
• Riduzione del rischio di aspirazione o deglutizione di parti di strumenti, frammenti di denti, farmaci o soluzioni di irrigazione da parte del paziente
• Creazione di un campo operatorio asciutto
• Protezione del tessuto molle dal contatto con gli strumenti
• Barriera di controllo delle infezioni

Caratteristiche:
• Disponibile in diversi colori e spessori
• Due misure: 127 mm x 127 mm o 152 mm x 152 mm
• I colori più chiari hanno il vantaggio di illuminare in modo naturale il campo operatorio mentre i colori più scuri possono contribuire ad aumentare il contrasto

Conservazione:
Conservare la Dental Dam ad una temperatura compresa tra 0°C e 26°C.
Conservare in luogo asciutto e al riparo dal calore.

Rischi residui, avvertenze e precauzioni:
Consultare la sezione Avvertenze e precauzioni per conoscere i rischi associati all'uso della Dental Dam in conformità con l'Uso previsto.

Istruzioni

ATTENZIONE! Questo prodotto contiene lattice di gomma naturale che può causare reazioni allergiche.

La Dental Dam è destinata ad essere utilizzata con svariati dispositivi, tra cui uncini e telai.

Consultare le istruzioni per l'uso degli altri dispositivi utilizzati.

Le seguenti fasi generali vengono fornite a titolo indicativo e possono essere personalizzate per adattarsi al caso specifico:

Fase 1: Definizione del campo operatorio.

Fase 2: Preparazione della Dental Dam.
- Definizione della posizione dei fori
- Contrassegno della posizione dei fori
- Esecuzione dei fori

Fase 3: Scelta degli uncini/dei fermi

Fase 4: Applicazione degli uncini/dei fermi

Fase 5: Posizionamento della Dental Dam

Elenco dei componenti

Nota: Non tutti i Numeri di catalogo sono disponibili in tutte le regioni

N. catalogo	Descrizione
390020	ROEKO Dental Dam, Latex, Thin, 36 pcs
390021	ROEKO Dental Dam, Latex, Medium, 36 pcs
390022	ROEKO Dental Dam, Latex, Heavy, 36 pcs
60013793	ROEKO Elasti-Dam, 152x152mm, Medium, Green, 36 pcs
60013794	ROEKO Elasti-Dam, 152x152mm, Heavy, Green, 36 pcs
60013870	Sample ROEKO Elasti-Dam, 152x 52mm, Medium, Green
60013795	ROEKO Elasti-Dam, 127x127mm, Medium, Blue, 36 pcs
60013796	ROEKO Elasti-Dam, 127x127mm, Heavy, Blue, 36 pcs
H00523	HYGENIC Dental Dam, Latex, Thin, Light, 5'' x 5'' (127x127mm), 52 pcs
H00524	HYGENIC Dental Dam, Latex, Medium, Light, 5'' x 5'' (127x127mm), 52 pcs
H00525	HYGENIC Dental Dam, Latex, Heavy, Light, 5'' x 5'' (127x127mm), 52 pcs
H00533	HYGENIC Dental Dam, Latex, Thin, Light, 6'' x 6'' (152 x152mm), 36 pcs
H00534	HYGENIC Dental Dam, Latex, Medium, Light, 6'' x 6'' (152x152mm), 36 pcs
H00535	HYGENIC Dental Dam, Latex, Heavy, Light, 6'' x 6'' (152x152mm), 36 pcs
H00536	HYGENIC Dental Dam, Latex, Extra Heavy, Light, 6'' x 6'' (152x152mm), 36 pcs
H00538	HYGENIC Dental Dam, Latex, Thin, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00539	HYGENIC Dental Dam, Latex, Medium, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00540	HYGENIC Dental Dam, Latex, Heavy, Dark, 6'' x 6'' (152x152mm), 36 pcs

N. catalogo	Descrizione
H00541	HYGENIC Dental Dam, Latex, Extra Heavy, Dark, 6'' x 6'' (152x152mm), 36 pcs
H02141	HYGENIC Dental Dam, Latex, Thin, Green, 5'' x 5'' (127x127mm), 52 pcs
H02142	HYGENIC Dental Dam, Latex, Medium, Green, 5'' x 5'' (127x127mm), 52 pcs
H02143	HYGENIC Dental Dam, Latex, Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H02144	HYGENIC Dental Dam Latex, Extra Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H02146	HYGENIC Dental Dam, Latex, Thin, Green, 6'' x 6'' (152x152mm), 36 pcs
H02147	HYGENIC Dental Dam, Latex, Medium, Green, 6'' x 6'' (152x152mm), 36 pcs
H02148	HYGENIC Dental Dam, Latex, Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H02149	HYGENIC Dental Dam, Latex, Extra Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H02778	HYGENIC FIESTA Winged Complete Kit, 1 pc
H02779	HYGENIC FIESTA Winged Standard Kit W/O Punch & Forceps, 1 pc
H02790	HYGENIC FIESTA Wingless Complete Kit, 1 pc
H02900	HYGENIC Simple Dam Kit - W/ Elasti-Dam, 1 pc
H03529	HYGENIC Dental Dam, Latex, Medium, Blue, 5'' x 5'' (127x127mm), 52 pcs
H03530	HYGENIC Dental Dam, Latex, Medium, Blue, 6'' x 6'' (152x152mm), 36 pcs
H04237	HYGENIC Dental Dam, Latex, Convenience Pack, Medium, Light, 5'' x 5'' (127x127mm), 364 pcs
H04241	HYGENIC Dental Dam, Latex, Convenience Pack, Medium, Green, 5'' x 5'' (127x127mm), 364 pcs
H04243	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Light, 6'' x 6'' (152x152mm), 360 pcs

N. catalogo	Descrizione
H04245	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Dark, 6'' x 6'' (152x152mm), 360 pcs
H04247	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Green, 6'' x 6'' (152x152mm), 360 pcs
H04639	HYGENIC FIESTA Dental Dam, Thin, 6'' x 6'' (152x152mm), 36 pcs
H04640	HYGENIC FIESTA Dental Dam, Thin, 5'' x 5'' (127x127mm), 52 pcs
H04641	HYGENIC FIESTA Dental Dam, Medium, 5'' x 5'' (127x127mm), 52 pcs
H04642	HYGENIC FIESTA Dental Dam, Medium, 6'' x 6'' (152x152mm), 36 pcs
H04643	HYGENIC FIESTA Dental Dam, Heavy, 5'' x 5'' (127x127mm), 52 pcs
H04644	HYGENIC FIESTA Dental Dam, Heavy, 6'' x 6'' (152x152mm), 36 pcs
H07315	HYGENIC Dental Dam, Latex, Heavy, Blue, 6'' x 6'' (152x152mm), 36 pcs
H07316	HYGENIC FIESTA Dental Dam, Latex, Convenience Pack, Medium, 5'' x 5'' (127x127mm), 364 pcs
H07317	HYGENIC FIESTA Dental Dam, Latex, Convenience Pack, Medium, 6'' x 6'' (152x152mm), 360 pcs
H11624	HYGENIC Elasti-Dam, Medium, Green, 5'' x 5'' (127x127mm), 52 pcs
H11625	HYGENIC Elasti-Dam, Medium, Green, 6'' x 6'' (152x152mm), 36 pcs
H11626	HYGENIC Elasti-Dam, Medium, Blue, 5'' x 5'' (127x127mm), 52 pcs
H11627	HYGENIC Elasti-Dam, Medium, Blue, 6'' x 6'' (152x152mm), 36 pcs
H11675	HYGENIC Elasti-Dam, Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H11676	HYGENIC Elasti-Dam, Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H11677	HYGENIC Elasti-Dam, Heavy, Blue, 5'' x 5'' (127x127mm), 52 pcs

N. catalogo	Descrizione
H11678	HYGENIC Elasti-Dam, Heavy, Blue, 6'' x 6'' (152x152mm), 36 pcs
H11690	HYGENIC Elasti-Dam Trial Pack, Medium, Green, 6'' x 6'' (152X152mm)

Avvertenze e precauzioni

Avvertenze	Dichiarazione
 **AVVERTENZA!**	Il mancato rispetto di quanto indicato in queste istruzioni per l'uso potrebbe causare lesioni al paziente o compromettere l'integrità della Dental Dam. Utilizzare il prodotto esclusivamente in conformità con l'uso previsto; vedere Uso previsto.
	Non riutilizzare la Dental Dam. La Dental Dam è esclusivamente monouso. Il riutilizzo intraorale della Dental Dam rappresenta un rischio biologico e può causare contaminazione crociata.
	Ispezionare la Dental Dam prima dell'uso. Scartare la Dental Dam se strappata o consumata. L'uso di una Dental Dam che ha perso le proprie caratteristiche prestazionali può comportare la perdita di funzionalità e compromettere l'integrità della procedura.

Precauzioni	Dichiarazione
 **ATTENZIONE**	Questo prodotto contiene lattice di gomma naturale che può causare reazioni allergiche.
	Non esporre la Dental Dam a temperature elevate. Conservare la Dental Dam lontana da fonti di calore.
	La Dental Dam ha un periodo di validità specifico. Non usare il dispositivo dopo la data di scadenza poiché le funzioni e le caratteristiche prestazionali potrebbero essere compromesse.
	Attenzione: le leggi federali (USA) limitano la vendita di questo dispositivo ai medici abilitati o su loro prescrizione
	Non conservare in prossimità di prodotti senza lattice.

Informazioni aggiuntive

Nota: smaltire il dispositivo in conformità con le norme locali, regionali, nazionali e/o internazionali. I dispositivi destinati all'uso intraorale devono essere considerati a rischio biologico e smaltiti correttamente in conformità con le norme locali.

Nota: su richiesta sarà fornita gratuitamente una copia cartacea delle istruzioni per l'uso.

Per utilizzatori con sede nell'UE: qualsiasi grave incidente verificatosi in relazione all'uso del dispositivo deve essere segnalato a Coltène/Whaledent, Inc. e all'autorità competente dello Stato membro in cui l'utilizzatore e/o il paziente risiedono.

Glossario dei simboli

Simbolo	Titolo e descrizione del simbolo
	Attenzione
 www.coltene.com	Consultare le istruzioni per l'uso in formato elettronico - Indica la necessità per l'utilizzatore di consultare le istruzioni per l'uso
MD	Dispositivo medico – Indica che l'articolo è un dispositivo medico
Rx ONLY	Vendita limitata: l'acquisto del dispositivo è limitato esclusivamente a medici abilitati.
	Data di scadenza - Indica la data dopo la quale non si deve utilizzare il dispositivo medico
REF	Numero catalogo - Indica il numero di catalogo del fabbricante che consente di identificare il dispositivo medico
	Non riutilizzare - Indica un dispositivo medico destinato ad essere utilizzato su un solo paziente durante una singola procedura
CE	Marchio CE
	Importatore - Indica l'entità che ha importato il dispositivo medico nel paese d'utilizzo
	Fabbricante - Indica il fabbricante del dispositivo medico

Simbolo	Titolo e descrizione del simbolo
LOT	Codice lotto - Indica il codice di lotto del fabbricante che consente di identificare il lotto
EC REP	Rappresentante autorizzato nella Comunità Europea - Indica il rappresentante autorizzato nella Comunità Europea
LATEX	Contiene lattice di gomma naturale - Indica la presenza di lattice di gomma essiccato come materiale strutturale all'interno del dispositivo medico.

Conservazione

Conservare la Dental Dam ad una temperatura compresa tra 0°C e 26°C.
Conservare in luogo asciutto e al riparo dal calore.

Simbolo	Titolo e descrizione del simbolo
	Conservare in luogo asciutto - Indica un dispositivo medico che deve essere protetto dall'umidità
	Conservare al riparo dal calore - Indica un dispositivo medico che deve essere protetto dal calore
	Limite di temperatura - Indica i limiti di temperatura a cui il dispositivo medico può essere esposto in sicurezza. I limiti superiore e inferiore di temperatura devono essere indicati accanto alle linee orizzontali superiore e inferiore.

HYGENIC

Latex Dental Dam

Naudojimo instrukcijos

LATEX

Rx ONLY

COLTENE

Paskirtis / naudojimo nurodymai
„Dental Dam“ naudojamas norint intraoraliai izoliuoti vieną ar daugiau dantų ir sukurti aplinkinės srities barjerą odontologinės procedūros metu.

Kontraindikacijos
Iš latekso pagamintas „Dental Dam“ neskirtas naudoti pacientams, kurie yra alergiški lateksui.

Numatyti naudotojai
• Odontologai
• Odontologų padėjėjai

Pacientų tikslinė grupė (-s)
Tinkama visoms pacientų grupėms.

Klinikinė nauda
„Dental Dam“ naudojamas siekiant šios klinikinės naudos:
• didesnio matomumo izoliavus dantį (-is);
• mažesnio pavojaus, kad pacientas įkvėps arba nuris instrumentus, dantų nuolaužas, medikamentus arba drėkinimo tirpalus;
• sausos darbo srities sukūrimo;
• minkštųjų audinių apsaugos nuo kontakto su instrumentais;
• infekcijų kontrolės barjero.

Charakteristikos
• Prieinamas įvairių spalvų ir storių
• Dviejų dydžių: 127 mm x 127 mm arba 152 mm x 152 mm (5 col. x 5 col. arba 6 col. x 6 col.)
• Šviesesnės spalvos natūraliai apšviečia darbo sritį, o tamsesnės spalvos gali padėti vizualiai sukurti kontrastą

Saugojimas
Laikyti „Dental Dam“ nuo 0 iki 26 °C (32–80 °F).
Laikyti sausai ir saugoti nuo kaščio.

Liekamasis pavojus, įspėjimai ir perspėjimai
Norėdami susipažinti su pavojais, susijusiais su „Dental Dam“ naudojimu pa

Instrukcijos

PERSPĖJIMAS! Šiame gaminyje yra natūralios gumos latekso, kuris gali sukelti alergines reakcijas.

„Dental Dam“ skirtas naudoti su įvairiais kitais prietaisais, įskaitant spaustukus ir rėmus.

Žr. kitų naudojamų prietaisų naudojimo instrukcijas.

Toliau aprašyti bendrieji veiksmai yra pateikti kaip pavyzdys ir gali būti pritaikyti konkrečiam atvejui.

1 veiksmas: darbo srities nustatymas.

2 veiksmas: „Dental Dam“ paruošimas.
• Skylių padėčių nustatymas
• Skylių padėčių žymėjimas
• Skylių pradūrimas

3 veiksmas: spaustuko / laikiklio pasirinkimas

4 veiksmas: spaustuko / laikiklio uždėjimas

5 veiksmas: „Dental Dam“ įdėjimas

Dalių sąrašas

Pastaba: tam tikri katalogo numeriai galimi ne visuose regionuose

Katalogo Nr.	Aprašas
390020	ROEKO Dental Dam, Latex, Thin, 36 pcs
390021	ROEKO Dental Dam, Latex, Medium, 36 pcs
390022	ROEKO Dental Dam, Latex, Heavy, 36 pcs
60013793	ROEKO Elasti-Dam, 152x152mm, Medium, Green, 36 pcs
60013794	ROEKO Elasti-Dam, 152x152mm, Heavy, Green, 36 pcs
60013870	Sample ROEKO Elasti-Dam, 152x 52mm, Medium, Green
60013795	ROEKO Elasti-Dam, 127x127mm, Medium, Blue, 36 pcs
60013796	ROEKO Elasti-Dam, 127x127mm, Heavy, Blue, 36 pcs
H00523	HYGENIC Dental Dam, Latex, Thin, Light, 5'' x 5'' (127x127mm), 52 pcs
H00524	HYGENIC Dental Dam, Latex, Medium, Light, 5'' x 5'' (127x127mm), 52 pcs
H00525	HYGENIC Dental Dam, Latex, Heavy, Light, 5'' x 5'' (127x127mm), 52 pcs
H00533	HYGENIC Dental Dam, Latex, Thin, Light, 6'' x 6'' (152 x152mm), 36 pcs
H00534	HYGENIC Dental Dam, Latex, Medium, Light, 6'' x 6'' (152x152mm), 36 pcs
H00535	HYGENIC Dental Dam, Latex, Heavy, Light, 6'' x 6'' (152x152mm), 36 pcs
H00536	HYGENIC Dental Dam, Latex, Extra Heavy, Light, 6'' x 6'' (152x152mm), 36 pcs
H00538	HYGENIC Dental Dam, Latex, Thin, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00539	HYGENIC Dental Dam, Latex, Medium, Dark, 6'' x 6'' (152x152mm), 36 pcs

Katalogo Nr.	Aprašas
H00540	HYGENIC Dental Dam, Latex, Heavy, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00541	HYGENIC Dental Dam, Latex, Extra Heavy, Dark, 6'' x 6'' (152x152mm), 36 pcs
H02141	HYGENIC Dental Dam, Latex, Thin, Green, 5'' x 5'' (127x127mm), 52 pcs
H02142	HYGENIC Dental Dam, Latex, Medium, Green, 5'' x 5'' (127x127mm), 52 pcs
H02143	HYGENIC Dental Dam, Latex, Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H02144	HYGENIC Dental Dam Latex, Extra Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H02146	HYGENIC Dental Dam, Latex, Thin, Green, 6'' x 6'' (152x152mm), 36 pcs
H02147	HYGENIC Dental Dam, Latex, Medium, Green, 6'' x 6'' (152x152mm), 36 pcs
H02148	HYGENIC Dental Dam, Latex, Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H02149	HYGENIC Dental Dam, Latex, Extra Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H02778	HYGENIC FIESTA Winged Complete Kit, 1 pc
H02779	HYGENIC FIESTA Winged Standard Kit W/O Punch & Forceps, 1 pc
H02790	HYGENIC FIESTA Wingless Complete Kit, 1 pc
H02900	HYGENIC Simple Dam Kit - W/ Elasti-Dam, 1 pc
H03529	HYGENIC Dental Dam, Latex, Medium, Blue, 5'' x 5'' (127x127mm), 52 pcs
H03530	HYGENIC Dental Dam, Latex, Medium, Blue, 6'' x 6'' (152x152mm), 36 pcs
H04237	HYGENIC Dental Dam, Latex, Convenience Pack, Medium, Light, 5'' x 5'' (127x127mm), 364 pcs
H04241	HYGENIC Dental Dam, Latex, Convenience Pack, Medium, Green, 5'' x 5'' (127x127mm), 364 pcs

Katalogo Nr.	Aprašas
H04243	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Light, 6'' x 6'' (152x152mm), 360 pcs
H04245	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Dark, 6'' x 6'' (152x152mm), 360 pcs
H04247	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Green, 6'' x 6'' (152x152mm), 360 pcs
H04639	HYGENIC FIESTA Dental Dam, Thin, 6'' x 6'' (152x152mm), 36 pcs
H04640	HYGENIC FIESTA Dental Dam, Thin, 5'' x 5'' (127x127mm), 52 pcs
H04641	HYGENIC FIESTA Dental Dam, Medium, 5'' x 5'' (127x127mm), 52 pcs
H04642	HYGENIC FIESTA Dental Dam, Medium, 6'' x 6'' (152x152mm), 36 pcs
H04643	HYGENIC FIESTA Dental Dam, Heavy, 5'' x 5'' (127x127mm), 52 pcs
H04644	HYGENIC FIESTA Dental Dam, Heavy, 6'' x 6'' (152x152mm), 36 pcs
H07315	HYGENIC Dental Dam, Latex, Heavy, Blue, 6'' x 6'' (152x152mm), 36 pcs
H07316	HYGENIC FIESTA Dental Dam, Latex, Convenience Pack, Medium, 5'' x 5'' (127x127mm), 364 pcs
H07317	HYGENIC FIESTA Dental Dam, Latex, Convenience Pack, Medium, 6'' x 6'' (152x152mm), 360 pcs
H11624	HYGENIC Elasti-Dam, Medium, Green, 5'' x 5'' (127x127mm), 52 pcs
H11625	HYGENIC Elasti-Dam, Medium, Green, 6'' x 6'' (152x152mm), 36 pcs
H11626	HYGENIC Elasti-Dam, Medium, Blue, 5'' x 5'' (127x127mm), 52 pcs
H11627	HYGENIC Elasti-Dam, Medium, Blue, 6'' x 6'' (152x152mm), 36 pcs

Katalogo Nr.	Aprašas
H11675	HYGENIC Elasti-Dam, Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H11676	HYGENIC Elasti-Dam, Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H11677	HYGENIC Elasti-Dam, Heavy, Blue, 5'' x 5'' (127x127mm), 52 pcs
H11678	HYGENIC Elasti-Dam, Heavy, Blue, 6'' x 6'' (152x152mm), 36 pcs
H11690	HYGENIC Elasti-Dam Trial Pack, Medium, Green, 6'' x 6'' (152X152mm)

Įspėjimai ir perspėjimai

Įspėjimai	Teiginys
 **ĮSPĖJIMAS!**	Tinkamai nesilaikant šių naudojimo instrukcijų nurodymų, galima sužeisti pacientą ar pakenkti „Dental Dam“ vientisumui. Gaminį naudokite tik pagal paskirtį, žr. skyrių „Paskirtis“.
	Pakartotinai nenaudokite „Dental Dam“. „Dental Dam“ skirtas naudoti tik kartą. Pakartotinai naudojant „Dental Dam“ kyla biologinis pavojus dėl kryžminio užteršimo.
	Prieš naudojimą „Dental Dam“ reikia patikrinti. Išmeskite „Dental Dam“, jei jis sulaužytas ar trapus. Naudojant našumo charakteristiką praradusius „Dental Dam“ galima pakenkti funkcionalumui ir procedūros vientisumui.

Perspėjimai	Teiginys
 **PERSPĖJIMAS**	Šiame gaminyje yra natūralios gumos latekso, kuris gali sukelti alergines reakcijas.
	Nelaikykite „Dental Dam“ aukštoje temperatūroje. Laikykite „Dental Dam“ atokiau nuo kaščio šaltinių.
	„Dental Dam“ galiojimo laikas nurodytas. Nenaudokite priemonės praėjus „Naudoti iki“ datai, nes priemonės funkcijos ir našumo charakteristikos gali būti nebetinkamos.
	Atsargiai: pagal federalinę (JAV) teisę šia priemone prekiauti galima tik licencijuotiems sveikatos priežiūros specialistams arba jų nurodymu.
	Nelaikykite netoli nelateksinių gaminių.

Papildoma informacija

Pastaba: priemonę šalinkite laikydamiesi vietinių, regiono, nacionalinių ir (arba) tarptautinių taisyklių. Burnoje naudojamos priemonės turėtų būti laikomos pavojingomis biologiškai ir šalinamos tinkamai pagal vietines taisykles.

Pastaba: pateikus prašymą, spausdintinė naudojimo instrukcijų kopija gali būti pateikiama nemokamai.

ES esantiems naudotojams: apie bet kokį rimtą incidentą, susijusį su priemonės naudojimu, būtina pranešti „Coltène/Whaledent, Inc.“ ir kompetentingai valstybės narės institucijai, kurioje įsikūręs naudotojas ir (arba) pacientas.

Simbolių žodynas

Simbolis	Titolo e descrizione del simbolo
	Perspėjimas
 www.coltene.com	Peržiūrėkite elektronikos naudojimo instrukcijas – nurodo, kad naudotojas turėtų peržiūrėti naudojimo instrukcijas
	Medicinos priemonė – nurodo, kad elementas yra medicinos priemonė
	Riboto pardavimo: priemonę gali įsigyti tik licencijuoti sveikatos priežiūros specialistai.
	„Naudoti iki“ data – nurodo datą, kuriai praėjus medicinos priemonė nebeturėtų būti naudojama
	Katalogo numeris – nurodo gamintojo katalogo numerį, pagal kurį galima identifikuoti medicinos priemonę
	Nenaudoti pakartotinai – nurodo medicinos priemonę, kuri skirta naudoti vienam pacientui vienai procedūrai
	CE ženklas
	Importuotojas – nurodo įmonę, importuojančią medicinos priemonę į lokalę
	Gamintojas – nurodo medicinos priemonės gamintoją

Simbolis	Titolo e descrizione del simbolo
LOT	Partijos numeris – nurodo gamintojo partijos kodą, kad būtų galima identifikuoti partiją ar siuntą
EC REP	Įgaliotasis Europos bendruomenės atstovas – nurodo įgaliotąjį Europos bendruomenės atstovą
LATEX	Yra natūralaus gumos latekso – nurodo, kad sudėtyje yra sauso natūralaus gumos latekso, naudoto kaip medicinos priemonės konstrukcinė medžiaga.

Saugojimas

Laikyti „Dental Dam“ nuo 0 iki 26 °C (32–80 °F).
Laikyti sausai ir saugoti nuo kaščio.

Simbolis	Simbolio pavadinimas ir aprašas
	Laikyti sausai – nurodo medicinos priemonę, kurią reikia saugoti nuo drėgmės
	Saugoti nuo karščio – nurodo medicinos priemonę, kurią reikia saugoti nuo karščio
	Temperatūros apribojimas – nurodo temperatūros apribojimus, kurių nesiekiant medicinos priemonę galima saugiai laikyti. Viršutinę ir apatinę temperatūros ribas reikia nurodyti greta viršutinės ir apatinės horizontalios linijos.

HYGENIC

Latex Dental Dam

Lietošanas instrukcija

LATEX

Rx ONLY

COLTENE

Paredzētais lietojums/Lietošanas norādījumi
Dental Dam ir paredzēts izmantot mutes dobumā, lai izolētu vienu vai vairākus zobus un izveidotu barjeru apkārtējai zonai zobārstniecības procedūras laikā.

Kontrindikācijas.
Lateksa Dental Dam nedrīkst izmantot pacientiem ar alerģiju pret lateksu.

Paredzētie lietotāji.
• Zobārsti
• Zobārstu asistenti

Pacientu mērķa grupa(-as).
Piemērots visām pacientu grupām.

Klīniskās priekšrocības.
Dental Dam lietošanai ir šādas klīniskās priekšrocības:
• Uzlabota redzamība zoba/zobu izolācijas dēļ
• Samazināts instrumentu, zoba sārņu, medikamentu vai skalošanas šķīdumu norīšanas vai nokļūšanas elpceļos risks pacientam
• Sausa operācijas lauka izveide
• Mīksto audu aizsargāšana pret saskari ar instrumentiem
• Infekcijas kontroles barjera

Raksturīgās iezīmes.
• Pieejams dažādās krāsās un ar dažādu biezumu
• Divi izmēri: 5″ x 5″ vai 6″ x 6″ (127 mm x 127 mm vai 152 mm x 152 mm)
• Gaišākās krāsas var dabiski izgaismot operācijas lauku, savukārt tumšākās krāsas var palīdzēt nodrošināt vizuālu kontrastu

Uzglabāšana.
Uzglabājiet izstrādājumus Dental Dam temperatūras diapazonā 32° F–80^0 F (0 °C–26 °C). Turiet sausumā un sargājiet no karstuma iedarbības.

Atlikušie riski, brīdinājumi un piesardzības pasākumi.
Skatiet sadaļu Brīdinājumi un piesardzības pasākumi, lai saņemtu informāciju par risku, kas saistīts ar Dental Dam lietošanu

Norādījumi

UZMANĪBU! Šis izstrādājums satur dabisko kaučuka lateksu, kas var izraisīt alerģiskas reakcijas.

Dental Dam ir paredzēts izmantot ar dažādām citām ierīcēm, tostarp spailēm un rāmjiem.

Skatiet pārējo izmantoto ierīču lietošanas instrukcijas.

Tālāk norādītās vispārīgās darbības ir sniegtas kā vadlīnijas un tās var pielāgot specifiskam gadījumam:

1. darbība. Darbības lauka noteikšana.

2. darbība. Dental Dam sagatavošana.
• Nosakiet atveru pozīcijas
• Atzīmējiet atveru pozīcijas
• Izduriet atveres

3. darbība. Spaiļu/statīva izvēle

4. darbība. Spaiļu/statīva lietošana

5. darbība. Dental Dam novietošana

Daļu saraksts

Piezīme. Ne visi kataloga numuri ir pieejami visos reģionos

Kataloga Nr.	Apraksts
390020	ROEKO Dental Dam, Latex, Thin, 36 pcs
390021	ROEKO Dental Dam, Latex, Medium, 36 pcs
390022	ROEKO Dental Dam, Latex, Heavy, 36 pcs
60013793	ROEKO Elasti-Dam, 152x152mm, Medium, Green, 36 pcs
60013794	ROEKO Elasti-Dam, 152x152mm, Heavy, Green, 36 pcs
60013870	Sample ROEKO Elasti-Dam, 152x 52mm, Medium, Green
60013795	ROEKO Elasti-Dam, 127x127mm, Medium, Blue, 36 pcs
60013796	ROEKO Elasti-Dam, 127x127mm, Heavy, Blue, 36 pcs
H00523	HYGENIC Dental Dam, Latex, Thin, Light, 5'' x 5'' (127x127mm), 52 pcs
H00524	HYGENIC Dental Dam, Latex, Medium, Light, 5'' x 5'' (127x127mm), 52 pcs
H00525	HYGENIC Dental Dam, Latex, Heavy, Light, 5'' x 5'' (127x127mm), 52 pcs
H00533	HYGENIC Dental Dam, Latex, Thin, Light, 6'' x 6'' (152 x152mm), 36 pcs
H00534	HYGENIC Dental Dam, Latex, Medium, Light, 6'' x 6'' (152x152mm), 36 pcs
H00535	HYGENIC Dental Dam, Latex, Heavy, Light, 6'' x 6'' (152x152mm), 36 pcs
H00536	HYGENIC Dental Dam, Latex, Extra Heavy, Light, 6'' x 6'' (152x152mm), 36 pcs
H00538	HYGENIC Dental Dam, Latex, Thin, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00539	HYGENIC Dental Dam, Latex, Medium, Dark, 6'' x 6'' (152x152mm), 36 pcs

Kataloga Nr.	Apraksts
H00540	HYGENIC Dental Dam, Latex, Heavy, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00541	HYGENIC Dental Dam, Latex, Extra Heavy, Dark, 6'' x 6'' (152x152mm), 36 pcs
H02141	HYGENIC Dental Dam, Latex, Thin, Green, 5'' x 5'' (127x127mm), 52 pcs
H02142	HYGENIC Dental Dam, Latex, Medium, Green, 5'' x 5'' (127x127mm), 52 pcs
H02143	HYGENIC Dental Dam, Latex, Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H02144	HYGENIC Dental Dam Latex, Extra Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H02146	HYGENIC Dental Dam, Latex, Thin, Green, 6'' x 6'' (152x152mm), 36 pcs
H02147	HYGENIC Dental Dam, Latex, Medium, Green, 6'' x 6'' (152x152mm), 36 pcs
H02148	HYGENIC Dental Dam, Latex, Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H02149	HYGENIC Dental Dam, Latex, Extra Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H02778	HYGENIC FIESTA Winged Complete Kit, 1 pc
H02779	HYGENIC FIESTA Winged Standard Kit W/O Punch & Forceps, 1 pc
H02790	HYGENIC FIESTA Wingless Complete Kit, 1 pc
H02900	HYGENIC Simple Dam Kit - W/ Elasti-Dam, 1 pc
H03529	HYGENIC Dental Dam, Latex, Medium, Blue, 5'' x 5'' (127x127mm), 52 pcs
H03530	HYGENIC Dental Dam, Latex, Medium, Blue, 6'' x 6'' (152x152mm), 36 pcs
H04237	HYGENIC Dental Dam, Latex, Convenience Pack, Medium, Light, 5'' x 5'' (127x127mm), 364 pcs
H04241	HYGENIC Dental Dam, Latex, Convenience Pack, Medium, Green, 5'' x 5'' (127x127mm), 364 pcs

Kataloga Nr.	Apraksts
H04243	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Light, 6'' x 6'' (152x152mm), 360 pcs
H04245	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Dark, 6'' x 6'' (152x152mm), 360 pcs
H04247	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Green, 6'' x 6'' (152x152mm), 360 pcs
H04639	HYGENIC FIESTA Dental Dam, Thin, 6'' x 6'' (152x152mm), 36 pcs
H04640	HYGENIC FIESTA Dental Dam, Thin, 5'' x 5'' (127x127mm), 52 pcs
H04641	HYGENIC FIESTA Dental Dam, Medium, 5'' x 5'' (127x127mm), 52 pcs
H04642	HYGENIC FIESTA Dental Dam, Medium, 6'' x 6'' (152x152mm), 36 pcs
H04643	HYGENIC FIESTA Dental Dam, Heavy, 5'' x 5'' (127x127mm), 52 pcs
H04644	HYGENIC FIESTA Dental Dam, Heavy, 6'' x 6'' (152x152mm), 36 pcs
H07315	HYGENIC Dental Dam, Latex, Heavy, Blue, 6'' x 6'' (152x152mm), 36 pcs
H07316	HYGENIC FIESTA Dental Dam, Latex, Convenience Pack, Medium, 5'' x 5'' (127x127mm), 364 pcs
H07317	HYGENIC FIESTA Dental Dam, Latex, Convenience Pack, Medium, 6'' x 6'' (152x152mm), 360 pcs
H11624	HYGENIC Elasti-Dam, Medium, Green, 5'' x 5'' (127x127mm), 52 pcs
H11625	HYGENIC Elasti-Dam, Medium, Green, 6'' x 6'' (152x152mm), 36 pcs
H11626	HYGENIC Elasti-Dam, Medium, Blue, 5'' x 5'' (127x127mm), 52 pcs
H11627	HYGENIC Elasti-Dam, Medium, Blue, 6'' x 6'' (152x152mm), 36 pcs

Kataloga Nr.	Apraksts
H11675	HYGENIC Elasti-Dam, Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H11676	HYGENIC Elasti-Dam, Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H11677	HYGENIC Elasti-Dam, Heavy, Blue, 5'' x 5'' (127x127mm), 52 pcs
H11678	HYGENIC Elasti-Dam, Heavy, Blue, 6'' x 6'' (152x152mm), 36 pcs
H11690	HYGENIC Elasti-Dam Trial Pack, Medium, Green, 6'' x 6'' (152X152mm)

Brīdinājumi un piesardzības pasākumi

Brīdinājumi	Skaidrojums
 **BRĪDINĀJUMS!**	Precīzi neievērojot lietošanas instrukcijas norādījumus, var rasties pacienta traumas un var tikt apdraudēta Dental Dam integritāte. Lietojiet šo izstrādājumu tikai saskaņā ar tā paredzēto lietojumu; skat. Paredzētais lietojums.
	Nelietojiet atkārtoti izstrādājumu Dental Dam. Dental Dam ir paredzēts izmantot tikai vienreiz. Dental Dam atkārtota lietošana mutes dobumā ir bioloģiski bīstama darbība, un var rasties šķērspiesārņojums.
	Dental Dam pirms lietošanas jāpārbauda. Izmetiet saplēstus vai trauslus Dental Dam. Lietojot Dental Dam, kam zaudēti veiktspējas raksturlielumi, iespējams zaudēt funkcionalitāti un ietekmēt procedūras integritāti.

Piesardzības pasākumi	Skaidrojums
 UZMANĪBU	Šis izstrādājums satur dabisko kaučuka lateksu, kas var izraisīt alerģiskas reakcijas.
	Nepakļaujiet Dental Dam augstas temperatūras iedarbībai. Neglabājiet Dental Dam siltuma avotu tuvumā.
	Dental Dam ir norādīts glabāšanas laiks. Nelietojiet ierīci pēc lietošanas derīguma termiņa beigām, jo var būt ietekmēta ierīces funkcionalitāte un veiktspējas raksturlielumi.
	Uzmanību! Saskaņā ar ASV Federālo likumu šo ierīci atļauts pārdot tikai licencētiem veselības aprūpes speciālistiem vai pēc to pasūtījuma.
	Neuzglabāt tādu izstrādājumu tuvumā, kas nesatur lateksu.

Papildinformācija

Piezīme. Iznīciniet ierīci atbilstoši vietējiem, reģiona, valsts un/vai starptautiskiem noteikumiem. Ierīces, kas tiek izmantotas mutes dobumā, jāuzskata par bioloģisku apdraudējumu un jāiznīcina atbilstoši vietējiem noteikumiem.

Piezīme. Pēc pieprasījuma tiek nodrošināts lietošanas instrukciju drukāts eksemplārs bez maksas.

Lietotājiem ES: Par visiem nopietniem incidentiem, kas radušies saistībā ar ierīces lietošanu, jāziņo uzņēmumam Coltène/Whaledent, Inc. un kompetentajai valsts iestādei lietotāja un/vai pacienta mītnes dalībvalstī.

Simbolu vārdnīca

Simbols	Simbola nosaukums un apraksts
	Uzmanību!
 www.coltene.com	Skatiet elektroniskās lietošanas instrukcijas: norāda, ka lietotājam jāmeklē informācija lietošanas instrukcijās.
	Medicīniska ierīce: norāda, ka vienums ir medicīniska ierīce.
	Tirdzniecība ierobežota: ierīci drīkst iegādāties tikai licencēti veselības aprūpes profesionāļi.
	Lietošanas derīguma termiņš: norāda datuma, pēc kura medicīnisko ierīci vairs nedrīkst lietot.
	Kataloga numurs: norāda ražotāja kataloga numuru, lai varētu identificēt medicīnisko ierīci.
	Nelietot atkārtoti: norāda, ka medicīniskā ierīce paredzēta lietošanai vienam pacientam vienas procedūras laikā.
	CE marķējums
	Importētājs: norāda juridisko personu, kas importē medicīnisko ierīci attiecīgajā lokalizācijā.
	Ražotājs: norāda medicīniskās ierīces ražotāju.

Simbols	Simbola nosaukums un apraksts
LOT	Partijas kods: norāda ražotāja partijas kodu, lai varētu identificēt partiju vai sēriju.
EC REP	Pilnvarotais pārstāvis Eiropas Kopienā: norāda pilnvaroto pārstāvi Eiropas Kopienā.
LATEX	Satur dabiskā kaučuka lateksu: norāda, ka medicīniskās ierīces konstrukcijā kā materiāls izmantots sauss dabiskā kaučuka latekss.

Uzglabāšana

Uzglabājiet izstrādājumus Dental Dam temperatūras diapazonā 32° F–80^0 F (0 °C–26 °C). Turiet sausumā un sargājiet no karstuma iedarbības.

Simbols	Simbola nosaukums un apraksts
	Turiet sausumā: norāda, ka medicīniskā ierīce jāsargā no mitruma iedarbības.
	Sargājiet no karstuma iedarbības: norāda, ka medicīniskā ierīce jāsargā no karstuma iedarbības.
	Temperatūras ierobežojums: norāda temperatūras ierobežojumus, kam var droši pakļaut medicīnisko ierīci. Temperatūras augšējais un apakšējais ierobežojums tiek norādīts blakus augšējai un apakšējai horizontālajai līnijai.

HYGENIC

Latex Dental Dam

Istruzzjonijiet għall-Użu

LATEX

Rx ONLY

COLTENE

Użu Intenzjonat/ Indikazzjonijiet għall-Użu:
Dental Dam huwa maħsub biex jintuża ġol-ħalq biex jiżola sinna waħda jew aktar u joħloq barriera fiż-żona tal-madwar waqt proċedura dentali.

Kontraindikazzjonijiet:
Il-Latex Dental Dam m'għandux jintuża f'pazjenti li jbatu minn allerġija għal-lattiċi.

Utenti Intenzjonati:
• Dentisti
• Assistenti Dentali

Grupp(i) ta' Pazjenti fil-Mira:
Adattati għal kull grupp ta' pazjenti.

Benefiċċji Kliniċi:
L-użu tad-Dental Dam għandu l-benefiċċji kliniċi li ġejjin:
• Aktar viżibilità permezz tal-iżolament tas-sinna/snien
• Tnaqqis fir-riskju li pazjent jaspira jew jibla' l-istrumenti, il-frak tas-snien, il-mediċini jew is-soluzzjonijiet tal-irrigazzjoni
• Ħolqien ta' żona niexfa fejn issir il-proċedura
• Protezzjoni tat-tessut artab milli jiġi f'kuntatt mal-istrumenti
• Barriera li sservi ta' kontroll għall-infezzjonijiet

Karatteristiċi:
• Disponibbli f'kuluri u ħxuna differenti
• Żewġ qisien: 5" x 5" jew 6" x 6" (127 mm x 127 mm jew 152 mm x 152 mm)
• Il-kuluri aktar ċari għandhom il-vantaġġ li jdawlu ż-żona fejn issir il-proċedura b'mod naturali filwaqt li l-kuluri aktar skuri jistgħu jgħinu għaliex jipprovdu kuntrast viżiv

Ħażna:
Aħżen id-Dental Dam f'temperatura ta' bejn 32°F – 80^{0}F (0°C – 26°C).
Żommu xott u żommu 'l bogħod mis-sħana.

Riskji Residwi, Twissijiet u Prekawzjonijiet:
Irreferi għas-sezzjoni tat-Twissijiet u l-Prekawzjonijiet biex taqra dwar

Istruzzjonijiet

ATTENZJONI! Dan il-Prodott Fih Latex tal-Gomma Naturali Li Jista' Jikkawża Reazzjonijiet Allerġiċi.

Id-Dental Dam huwa maħsub biex jintuża ma' diversi strumenti oħra inklużi klampi u oqfsa.

Irreferi għall-istruzzjonijiet dwar l-użu tal-istrumenti l-oħra li qed jintużaw.

Il-passi ġenerali li ġejjin huma pprovduti bħala gwida u jistgħu jitfasslu b'mod individwali skont il-każ speċifiku:

Pass numru 1: Iddetermina ż-Żona fejn se ssir il-Proċedura.

Pass numru 2: Preparazzjoni għad-Dental Dam.
• Iddetermina l-pożizzjonijiet tat-toqob
• Immarka l-pożizzjonijiet tat-toqob
• Taqqab it-toqob

Pass numru 3: Għażla tal-Klamp/Tagħmir taż-Żamma

Pass numru 4: Applikazzjoni tal-Klamp/Tagħ

Pass numru 5: Tqegħid tad-Dental Dam

Lista tal-Parts

Nota: Mhux in-Numri tal-Katalgu kollha huma disponibbli fir-reġjuni kollha

Katalgu #	Deskrizzjoni
390020	ROEKO Dental Dam, Latex, Thin, 36 pcs
390021	ROEKO Dental Dam, Latex, Medium, 36 pcs
390022	ROEKO Dental Dam, Latex, Heavy, 36 pcs
60013793	ROEKO Elasti-Dam, 152x152mm, Medium, Green, 36 pcs
60013794	ROEKO Elasti-Dam, 152x152mm, Heavy, Green, 36 pcs
60013870	Sample ROEKO Elasti-Dam, 152x 52mm, Medium, Green
60013795	ROEKO Elasti-Dam, 127x127mm, Medium, Blue, 36 pcs
60013796	ROEKO Elasti-Dam, 127x127mm, Heavy, Blue, 36 pcs
H00523	HYGENIC Dental Dam, Latex, Thin, Light, 5'' x 5'' (127x127mm), 52 pcs
H00524	HYGENIC Dental Dam, Latex, Medium, Light, 5'' x 5'' (127x127mm), 52 pcs
H00525	HYGENIC Dental Dam, Latex, Heavy, Light, 5'' x 5'' (127x127mm), 52 pcs
H00533	HYGENIC Dental Dam, Latex, Thin, Light, 6'' x 6'' (152 x152mm), 36 pcs
H00534	HYGENIC Dental Dam, Latex, Medium, Light, 6'' x 6'' (152x152mm), 36 pcs
H00535	HYGENIC Dental Dam, Latex, Heavy, Light, 6'' x 6'' (152x152mm), 36 pcs
H00536	HYGENIC Dental Dam, Latex, Extra Heavy, Light, 6'' x 6'' (152x152mm), 36 pcs
H00538	HYGENIC Dental Dam, Latex, Thin, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00539	HYGENIC Dental Dam, Latex, Medium, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00540	HYGENIC Dental Dam, Latex, Heavy, Dark, 6'' x 6'' (152x152mm), 36 pcs

Katalgu #	Deskrizzjoni
H00541	HYGENIC Dental Dam, Latex, Extra Heavy, Dark, 6" x 6" (152x152mm), 36 pcs
H02141	HYGENIC Dental Dam, Latex, Thin, Green, 5" x 5" (127x127mm), 52 pcs
H02142	HYGENIC Dental Dam, Latex, Medium, Green, 5" x 5" (127x127mm), 52 pcs
H02143	HYGENIC Dental Dam, Latex, Heavy, Green, 5" x 5" (127x127mm), 52 pcs
H02144	HYGENIC Dental Dam Latex, Extra Heavy, Green, 5" x 5" (127x127mm), 52 pcs
H02146	HYGENIC Dental Dam, Latex, Thin, Green, 6" x 6" (152x152mm), 36 pcs
H02147	HYGENIC Dental Dam, Latex, Medium, Green, 6" x 6" (152x152mm), 36 pcs
H02148	HYGENIC Dental Dam, Latex, Heavy, Green, 6" x 6" (152x152mm), 36 pcs
H02149	HYGENIC Dental Dam, Latex, Extra Heavy, Green, 6" x 6" (152x152mm), 36 pcs
H02778	HYGENIC FIESTA Winged Complete Kit, 1 pc
H02779	HYGENIC FIESTA Winged Standard Kit W/O Punch & Forceps, 1 pc
H02790	HYGENIC FIESTA Wingless Complete Kit, 1 pc
H02900	HYGENIC Simple Dam Kit - W/ Elasti-Dam, 1 pc
H03529	HYGENIC Dental Dam, Latex, Medium, Blue, 5" x 5" (127x127mm), 52 pcs
H03530	HYGENIC Dental Dam, Latex, Medium, Blue, 6" x 6" (152x152mm), 36 pcs
H04237	HYGENIC Dental Dam, Latex, Convenience Pack, Medium, Light, 5" x 5" (127x127mm), 364 pcs
H04241	HYGENIC Dental Dam, Latex, Convenience Pack, Medium, Green, 5" x 5" (127x127mm), 364 pcs
H04243	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Light, 6" x 6" (152x152mm), 360 pcs

Katalgu #	Deskrizzjoni
H04245	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Dark, 6'' x 6'' (152x152mm), 360 pcs
H04247	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Green, 6'' x 6'' (152x152mm), 360 pcs
H04639	HYGENIC FIESTA Dental Dam, Thin, 6'' x 6'' (152x152mm), 36 pcs
H04640	HYGENIC FIESTA Dental Dam, Thin, 5'' x 5'' (127x127mm), 52 pcs
H04641	HYGENIC FIESTA Dental Dam, Medium, 5'' x 5'' (127x127mm), 52 pcs
H04642	HYGENIC FIESTA Dental Dam, Medium, 6'' x 6'' (152x152mm), 36 pcs
H04643	HYGENIC FIESTA Dental Dam, Heavy, 5'' x 5'' (127x127mm), 52 pcs
H04644	HYGENIC FIESTA Dental Dam, Heavy, 6'' x 6'' (152x152mm), 36 pcs
H07315	HYGENIC Dental Dam, Latex, Heavy, Blue, 6'' x 6'' (152x152mm), 36 pcs
H07316	HYGENIC FIESTA Dental Dam, Latex, Convenience Pack, Medium, 5'' x 5'' (127x127mm), 364 pcs
H07317	HYGENIC FIESTA Dental Dam, Latex, Convenience Pack, Medium, 6'' x 6'' (152x152mm), 360 pcs
H11624	HYGENIC Elasti-Dam, Medium, Green, 5'' x 5'' (127x127mm), 52 pcs
H11625	HYGENIC Elasti-Dam, Medium, Green, 6'' x 6'' (152x152mm), 36 pcs
H11626	HYGENIC Elasti-Dam, Medium, Blue, 5'' x 5'' (127x127mm), 52 pcs
H11627	HYGENIC Elasti-Dam, Medium, Blue, 6'' x 6'' (152x152mm), 36 pcs
H11675	HYGENIC Elasti-Dam, Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H11676	HYGENIC Elasti-Dam, Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H11677	HYGENIC Elasti-Dam, Heavy, Blue, 5'' x 5'' (127x127mm), 52 pcs

Katalgu #	Deskrizzjoni
H11678	HYGENIC Elasti-Dam, Heavy, Blue, 6'' x 6'' (152x152mm), 36 pcs
H11690	HYGENIC Elasti-Dam Trial Pack, Medium, Green, 6'' x 6'' (152X152mm)

Twissijiet u Prekawzjonijiet

Twissijiet	Dikjarazzjoni
 **TWISSIJA!**	Jekk ma ssegwix id-direzzjonijiet f'dan l-IFU kif suppost, dan jista' jirriżulta f'korriment għall-pazjent jew jikkompromettі l-integrità tad-dental dam. Uża l-prodott skont l-użu maħsub tiegħu biss, ara l-Użu Maħsub.
	Terġax tuża d-Dental Dam. Id-Dental Dam huwa maħsub biex jintuża darba biss. L-użu mill-ġdid tad-Dental Dam fil-ħalq huwa ta' periklu bijoloġiku u jista' jirriżulta f'kontaminazzjoni inkroċjata.
	Id-Dental Dam għandu jiġi spezzjonat qabel l-użu. Armi d-Dental Dam imqatta' jew li jkun qed jitfarrak. L-użu tad-Dental Dam li jkun tilef il-karatteristiċi tal-prestazzjoni tiegħu jista' jirriżulta f'telf ta' funzjonalità u jikkompromettі l-integrità tal-proċedura.

Prekawzjonijiet	Dikjarazzjoni
 **ATTENZJONI**	Dan il-Prodott Fih Latex tal-Gomma Naturali Li Jista' Jikkawża Reazzjonijiet Allerġiċi.
	Tesponix d-Dental Dam għal temperaturi għoljin. Aħżen id-Dental Dam 'il bogħod mis-sorsi tas-sħana.
	Id-Dental Dam jibqa' tajjeb għal żmien speċifiku. Tużax l-apparat wara d-Data tal-Iskadenza minħabba li l-funzjonalità u l-karatteristiċi tal-prestazzjoni tal-apparat jistgħu jiġu kompromessi.
	Attenzjoni: Il-liġi Federali (tal-Istati Uniti tal-Amerka) tirrestriġi dan l-apparat għal bejgħ minn, jew fuq l-ordni ta', professjonist tal-kura tas-saħħa liċenzjat
	Taħżinx viċin prodotti li mhumiex magħmulin mil-latex.

Informazzjoni Addizzjonali

Nota: Armi l-apparat skont ir-regolamenti lokali, reġjonali, nazzjonali u/jew internazzjonali. L-apparat użat ġewwa l-ħalq għandu jiġi ttrattat bħala periklu bijoloġiku u jintrema kif suppost skont ir-regolamenti lokali.

Nota: Fuq talba ta' dak li jkun, tista' tiġi pprovduta kopja stampata tal-IFU mingħajr ħlas.

Għal utenti li jinsabu fl-UE: Kwalunkwe inċident serju li seħħ b'rabta mal-użu tal-apparat għandu jiġi rrappurtat lil Coltène/Whaledent, Inc. u lill-awtorità kompetenti tal-istat membru li fih huwa stabbilit l-utent u/jew il-pazjent.

Glossarju tas-Simboli

Simbolu	Titlu u Deskrizzjoni tas-Simbolu
	Attenzjoni
 www.coltene.com	Ikkonsulta l-istruzzjonijiet elettroniċi għall-użu - Jindika l-ħtieġa li l-utent jikkonsulta l-istruzzjonijiet għall-użu
	Apparat Mediku – Jindika li l-oġġett huwa apparat mediku
	Il-Bejgħ Ristrett: Ix-xiri tal-apparat hu ristrett għall-professjonisti tal-kura tas-saħħa liċenzjati biss.
	Data tal-Iskadenza - Tindika d-data li warajha dan l-apparat mediku m'għandux jintuża
	Numru tal-Katalgu - Jindika n-numru tal-katalgu tal-manifattur sabiex l-apparat mediku jkun jista' jiġi identifikat
	Terġax tużah - Tindika apparat mediku li hu maħsub biex jintuża fuq pazjent wieħed waqt proċedura waħda
	Marka CE
	Importatur - Jindika l-entità li timporta l-apparat mediku lokalment
	Manifattur - Jindika l-manifattur tal-apparat mediku

Simbolu	Titlu u Deskrizzjoni tas-Simbolu
	Kodiċi tal-lott - Jindika l-kodiċi tal-lott tal-manifattur sabiex il-lott ikun jista' jiġi identifikat
	Rappreżentant awtorizzat fil-Komunità Ewropea - Jindika r-rappreżentant awtorizzat fil-Komunità Ewropea
	Fih latex tal-gomma naturali - Jindika l-preżenza ta' latex tal-gomma naturali niexfa bħala materjal ta' kostruzzjoni fl-apparat mediku.

Ħażna

Aħżen id-Dental Dam f'temperatura ta' bejn 32°F – 80^{0}F (0°C – 26°C).
Żommu xott u żommu 'l bogħod mis-sħana.

Simbolu	Titlu u Deskrizzjoni tas-Simbolu
	Żommu xott - Jindika apparat mediku li jeħtieġ li jiġi protett mill-umdità
	Żommu 'l bogħod mis-sħana - Jindika apparat mediku li jeħtieġ protezzjoni mis-sħana
	Limitu tat-Temperatura - Jindika l-limiti tat-temperatura li l-apparat mediku jista' jkun espost għalihom b'mod sikur. Il-limiti ta' fuq u ta' isfel tat-temperatura għandhom jiġu indikati ħdejn il-linji orizzontali ta' fuq u ta' isfel.

HYGENIC

Latex Dental Dam

Gebruiksaanwijzing

LATEX

Rx ONLY

COLTENE

Beoogd gebruik/gebruiksindicaties:
Dental Dam is bedoeld voor intraoraal gebruik voor de isolatie van een of meer gebitselementen en om een barrière te creëren ten opzichte van de omgeving tijdens een tandheelkundige procedure.

Contra-indicaties:
Latex Dental Dam mag niet worden gebruikt bij patiënten die allergisch zijn voor latex.

Beoogde gebruikers:
• Tandartsen
• Tandartsassistenten

Patiëntendoelgroep(en):
Geschikt voor alle groepen patiënten.

Klinische voordelen:
Het gebruik van Dental Dam heeft de volgende klinische voordelen:
• Betere zichtbaarheid door het isoleren van een of meerdere gebitselementen
• Verminderd risico voor de patiënt op aspireren of inslikken van instrumenten, resten van gebitselementen, geneesmiddelen of irrigatieoplossingen
• Creëren van een droog werkgebied
• Bescherming van de weke delen tegen contact met instrumenten
• Barrière ter bestrijding van infecties

Kenmerken:
• Beschikbaar in verschillende kleuren en diktes
• Twee maten: 127 mm x 127 mm of 152 mm x 152 mm
• Het voordeel van de lichtere kleuren is de natuurlijke verlichting van het operatiegebied, terwijl de donkere kleuren voor meer visueel contrast zorgen

Bewaren en opslaan:
Bewaar Dental Dam bij een temperatuur tussen 0 °C en 26 °C.

Droog bewaren en uit de buurt houden van warmtebronnen.

Restrisico's, waarschuwingen en voorzorgsmaatregelen:
Raadpleeg het gedeelte 'Waarschuwingen en voorzorgsmaatregelen' voor de mogelijke risico's van het gebruik van Dental Dam volgens het beoogde gebruik.

Instructies

LET OP! Dit product bevat natuurrubber latex, wat allergische reacties kan veroorzaken.

Dental Dam is bestemd voor gebruik met diverse andere hulpmiddelen waaronder klemmen en beugels.

Raadpleeg de gebruiksaanwijzing van de andere gebruikte hulpmiddelen.

De volgende algemene stappen dienen als richtlijn en kunnen aan de specifieke situatie worden aangepast:

Stap 1: Bepalen van het operatiegebied.

Step 2: Voorbereiden van Dental Dam.
- Bepaal de positie van de gaten
- Markeer de posities van de gaten
- Maak de gaten

Stap 3: Selecteren van klemmen/retainers

Stap 4: Bevestigen van klemmen/retainers

Stap 5: Plaatsen van Dental Dam

Lijst van onderdelen

Opmerking: niet alle catalogusnummers zijn verkrijgbaar in alle regio's

Catalogus-nummer	Omschrijving
390020	ROEKO Dental Dam, Latex, Thin, 36 pcs
390021	ROEKO Dental Dam, Latex, Medium, 36 pcs
390022	ROEKO Dental Dam, Latex, Heavy, 36 pcs
60013793	ROEKO Elasti-Dam, 152x152mm, Medium, Green, 36 pcs
60013794	ROEKO Elasti-Dam, 152x152mm, Heavy, Green, 36 pcs
60013870	Sample ROEKO Elasti-Dam, 152x 52mm, Medium, Green
60013795	ROEKO Elasti-Dam, 127x127mm, Medium, Blue, 36 pcs
60013796	ROEKO Elasti-Dam, 127x127mm, Heavy, Blue, 36 pcs
H00523	HYGENIC Dental Dam, Latex, Thin, Light, 5'' x 5'' (127x127mm), 52 pcs
H00524	HYGENIC Dental Dam, Latex, Medium, Light, 5'' x 5'' (127x127mm), 52 pcs
H00525	HYGENIC Dental Dam, Latex, Heavy, Light, 5'' x 5'' (127x127mm), 52 pcs
H00533	HYGENIC Dental Dam, Latex, Thin, Light, 6'' x 6'' (152 x152mm), 36 pcs
H00534	HYGENIC Dental Dam, Latex, Medium, Light, 6'' x 6'' (152x152mm), 36 pcs
H00535	HYGENIC Dental Dam, Latex, Heavy, Light, 6'' x 6'' (152x152mm), 36 pcs
H00536	HYGENIC Dental Dam, Latex, Extra Heavy, Light, 6'' x 6'' (152x152mm), 36 pcs
H00538	HYGENIC Dental Dam, Latex, Thin, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00539	HYGENIC Dental Dam, Latex, Medium, Dark, 6'' x 6'' (152x152mm), 36 pcs

Catalogus-nummer	Omschrijving
H00540	HYGENIC Dental Dam, Latex, Heavy, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00541	HYGENIC Dental Dam, Latex, Extra Heavy, Dark, 6'' x 6'' (152x152mm), 36 pcs
H02141	HYGENIC Dental Dam, Latex, Thin, Green, 5'' x 5'' (127x127mm), 52 pcs
H02142	HYGENIC Dental Dam, Latex, Medium, Green, 5'' x 5'' (127x127mm), 52 pcs
H02143	HYGENIC Dental Dam, Latex, Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H02144	HYGENIC Dental Dam Latex, Extra Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H02146	HYGENIC Dental Dam, Latex, Thin, Green, 6'' x 6'' (152x152mm), 36 pcs
H02147	HYGENIC Dental Dam, Latex, Medium, Green, 6'' x 6'' (152x152mm), 36 pcs
H02148	HYGENIC Dental Dam, Latex, Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H02149	HYGENIC Dental Dam, Latex, Extra Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H02778	HYGENIC FIESTA Winged Complete Kit, 1 pc
H02779	HYGENIC FIESTA Winged Standard Kit W/O Punch & Forceps, 1 pc
H02790	HYGENIC FIESTA Wingless Complete Kit, 1 pc
H02900	HYGENIC Simple Dam Kit - W/ Elasti-Dam, 1 pc
H03529	HYGENIC Dental Dam, Latex, Medium, Blue, 5'' x 5'' (127x127mm), 52 pcs
H03530	HYGENIC Dental Dam, Latex, Medium, Blue, 6'' x 6'' (152x152mm), 36 pcs
H04237	HYGENIC Dental Dam, Latex, Convenience Pack, Medium, Light, 5'' x 5'' (127x127mm), 364 pcs
H04241	HYGENIC Dental Dam, Latex, Convenience Pack, Medium, Green, 5'' x 5'' (127x127mm), 364 pcs

Catalogus-nummer	Omschrijving
H04243	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Light, 6'' x 6'' (152x152mm), 360 pcs
H04245	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Dark, 6'' x 6'' (152x152mm), 360 pcs
H04247	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Green, 6'' x 6'' (152x152mm), 360 pcs
H04639	HYGENIC FIESTA Dental Dam, Thin, 6'' x 6'' (152x152mm), 36 pcs
H04640	HYGENIC FIESTA Dental Dam, Thin, 5'' x 5'' (127x127mm), 52 pcs
H04641	HYGENIC FIESTA Dental Dam, Medium, 5'' x 5'' (127x127mm), 52 pcs
H04642	HYGENIC FIESTA Dental Dam, Medium, 6'' x 6'' (152x152mm), 36 pcs
H04643	HYGENIC FIESTA Dental Dam, Heavy, 5'' x 5'' (127x127mm), 52 pcs
H04644	HYGENIC FIESTA Dental Dam, Heavy, 6'' x 6'' (152x152mm), 36 pcs
H07315	HYGENIC Dental Dam, Latex, Heavy, Blue, 6'' x 6'' (152x152mm), 36 pcs
H07316	HYGENIC FIESTA Dental Dam, Latex, Convenience Pack, Medium, 5'' x 5'' (127x127mm), 364 pcs
H07317	HYGENIC FIESTA Dental Dam, Latex, Convenience Pack, Medium, 6'' x 6'' (152x152mm), 360 pcs
H11624	HYGENIC Elasti-Dam, Medium, Green, 5'' x 5'' (127x127mm), 52 pcs
H11625	HYGENIC Elasti-Dam, Medium, Green, 6'' x 6'' (152x152mm), 36 pcs
H11626	HYGENIC Elasti-Dam, Medium, Blue, 5'' x 5'' (127x127mm), 52 pcs
H11627	HYGENIC Elasti-Dam, Medium, Blue, 6'' x 6'' (152x152mm), 36 pcs

Catalogus-nummer	Omschrijving
H11675	HYGENIC Elasti-Dam, Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H11676	HYGENIC Elasti-Dam, Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H11677	HYGENIC Elasti-Dam, Heavy, Blue, 5'' x 5'' (127x127mm), 52 pcs
H11678	HYGENIC Elasti-Dam, Heavy, Blue, 6'' x 6'' (152x152mm), 36 pcs
H11690	HYGENIC Elasti-Dam Trial Pack, Medium, Green, 6'' x 6'' (152X152mm)

Waarschuwingen en voorzorgsmaatregelen

Waarschuwingen	Veiligheidsaanbeveling
 **WAARSCHUWING!**	Het niet opvolgen van de instructies in deze gebruiksaanwijzing kan leiden tot letsel bij de patiënt of kan de integriteit van Dental Dam beperken. Gebruik het product alleen overeenkomstig het beoogde gebruik, zie Beoogd gebruik.
	Dental Dam mag niet opnieuw worden gebruikt. Dental Dam is uitsluitend bedoeld voor eenmalig gebruik. Intraoraal hergebruik van Dental Dam vormt een biologisch gevaar en kan tot kruis-besmetting leiden.
	Dental Dam moet vóór gebruik worden gecontroleerd. Gooi Dental Dam weg als deze versleten of bros is. Het gebruik van Dental Dam die prestatiekenmerken heeft verloren, kan leiden tot een minder goede werking en kan de integriteit van de procedure aantasten.

Voorzorgsmaatregelen	Veiligheidsaanbeveling
 LET OP	Dit product bevat natuurrubber latex, wat allergische reacties kan veroorzaken.
	Stel Dental Dam niet bloot aan hoge temperaturen. Bewaar Dental Dam niet in de buurt van warmtebronnen.
	Dental Dam heeft een bepaalde uiterste gebruiksdatum. Gebruik het hulpmiddel niet na de uiterste gebruiksdatum, aangezien dit de werking van het hulpmiddel en de prestatiekenmerken kan beïnvloeden.
	Let op: Volgens de federale wetgeving van de VS mag dit medische hulpmiddel alleen worden verkocht door of in opdracht van een gediplomeerde zorgverlener
	Niet bewaren in de buurt van producten die niet van latex zijn.

Aanvullende informatie

Opmerking: Voer het hulpmiddel af in overeenstemming met de plaatselijke, regionale, nationale en/of internationale voorschriften. Behandel hulpmiddelen die intraoraal worden gebruikt als biologisch gevaarlijk materiaal en voer ze af volgens de geldende plaatselijke voorschriften.

Opmerking: Indien gewenst kan gratis een papieren versie van de gebruiksaanwijzing ter beschikking worden gesteld.

Voor gebruikers in de EU: Stel Coltène/Whaledent, Inc. en de bevoegde instanties van de lidstaat waarin de gebruiker en/of patiënt is gevestigd op de hoogte van elk ernstig voorval dat zich voordoet met betrekking tot het hulpmiddel.

Verklaring van de symbolen

Symbool	Titel en omschrijving van het symbool
	Let op
 www.coltene.com	Raadpleeg de elektronische gebruiksaanwijzing – Geeft aan dat de gebruiker de gebruiksaanwijzing moet raadplegen
MD	Medisch hulpmiddel – Geeft aan dat het om een medisch hulpmiddel gaat
Rx ONLY	Verkoopbeperking – De aanschaf van het medische hulpmiddel is alleen toegestaan voor personen die werkzaam zijn in de gezondheidszorg.
	Uiterste gebruiksdatum – Geeft aan na welke datum het medische hulpmiddel niet meer mag worden gebruikt
REF	Artikelnummer – Geeft aan welk artikelnummer het medische hulpmiddel heeft in de catalogus van de fabrikant, zodat het terug te vinden is
	Niet hergebruiken - Geeft aan dat een medisch hulpmiddel is bedoeld voor eenmalig gebruik, of voor gebruik bij één patiënt gedurende één ingreep
CE	CE-markering
	Importeur – Geeft aan welke rechtspersoon het medische hulpmiddel importeert

Symbool	Titel en omschrijving van het symbool
	Fabrikant – Geeft aan wie het medische hulpmiddel produceert
	Batchcode – Geeft de batchcode van de fabrikant aan, zodat de batch of partij terug te vinden is
	Gevolmachtigde in de Europese Unie – Geeft aan wie de gevolmachtigde in de Europese Unie is
	Bevat natuurlijk rubber - Geeft de aanwezigheid van droog natuurrubber aan als constructiemateriaal in het medische hulpmiddel.

Bewaren en opslaan:

Bewaar Dental Dam bij een temperatuur tussen 0 °C en 26 °C.
Droog bewaren en uit de buurt houden van warmtebronnen.

Symbool	Titel en omschrijving van het symbool
	Droog bewaren – Geeft aan dat een medisch hulpmiddel moet worden beschermd tegen vocht
	Niet blootstellen aan warmte – Geeft aan dat een medisch hulpmiddel moet worden beschermd tegen warmte
	Temperatuurbeperking – Geeft de temperatuurbeperkingen aan waaraan het medische hulpmiddel veilig kan worden blootgesteld. De bovenste en onderste temperatuurgrens moeten naast de bovenste en onderste horizontale lijn worden vermeld.

HYGENIC

Latex Dental Dam

Instrukcja użycia

LATEX

Rx ONLY

COLTENE

Przeznaczenie/wskazania do stosowania:
Koferdam Dental Dam jest przeznaczony do stosowania w jamie ustnej w celu wyizolowania jednego lub większej liczby zębów i utworzenia bariery względem okolicznego obszaru podczas zabiegu stomatologicznego.

Przeciwwskazania:
Lateksowego koferdamu Dental Dam nie należy używać u pacjentów z alergią na lateks.

Docelowi użytkownicy:
• Lekarze dentyści
• Asystenci stomatologiczni

Grupy docelowe pacjentów:
Można stosować we wszystkich grupach pacjentów.

Korzyści kliniczne:
Stosowanie koferdamu Dental Dam wiąże się z następującymi korzyściami klinicznymi:
• Większa widoczność dzięki zaizolowaniu zęba/zębów
• Mniejsze ryzyko aspiracji lub połknięcia przez pacjenta narzędzi, fragmentów zębów, leków lub roztworów płuczących
• Wytworzenie suchego pola roboczego
• Ochrona tkanek miękkich przed stycznością z narzędziami
• Kontrola zakażeń

Charakterystyka:
• Dostępne są różne kolory i grubości.
• Dwa rozmiary: 127 mm × 127 mm lub 152 mm × 152 mm.
• Zaletą jaśniejszych kolorów jest naturalne rozświetlenie pola zabiegowego, natomiast ciemniejsze kolory mogą poprawić kontrast wizualny.

Przechowywanie:
Przechowywać koferdam Dental Dam w temperaturze 0°C–26°C.

Przechowywać w suchym miejscu z dala od źródeł ciepła.

Ryzyko resztkowe, ostrzeżenia i środki ostrożności:
Informacje na temat ryzyka związanego z użytkowaniem koferdamu Dental Dam zgodnie z jego przeznaczeniem można znaleźć w punkcie Ostrzeżenia i środki ostrożności.

Instrukcja

OSTRZEŻENIE! Produkt zawiera lateks kauczuku naturalnego, który może wywołać reakcje alergiczne.

Koferdam Dental Dam jest przeznaczony do stosowania z różnymi wyrobami, w tym z klamrami i ramkami.

Należy zapoznać się z instrukcją użycia tych wyrobów.

Przedstawione poniżej etapy pracy mają charakter ogólnych wytycznych. Można je odpowiednio dostosować do konkretnego przypadku.

Etap 1: Ustalenie pola zabiegowego

Etap 2: Przygotowanie koferdamu Dental Dam
- Ustalenie położenia otworów
- Zaznaczenie położenia otworów
- Wykonanie otworów za pomocą przebijaka

Etap 3: Dobór klamry

Etap 4: Założenie klamry

Etap 5: Założenie koferdamu Dental Dam

Lista części

Uwaga: Nie wszystkie numery katalogowe są dostępne w każdym regionie.

Nr katalogowy	Opis
390020	ROEKO Dental Dam, Latex, Thin, 36 pcs
390021	ROEKO Dental Dam, Latex, Medium, 36 pcs
390022	ROEKO Dental Dam, Latex, Heavy, 36 pcs
60013793	ROEKO Elasti-Dam, 152x152mm, Medium, Green, 36 pcs
60013794	ROEKO Elasti-Dam, 152x152mm, Heavy, Green, 36 pcs
60013870	Sample ROEKO Elasti-Dam, 152x 52mm, Medium, Green
60013795	ROEKO Elasti-Dam, 127x127mm, Medium, Blue, 36 pcs
60013796	ROEKO Elasti-Dam, 127x127mm, Heavy, Blue, 36 pcs
H00523	HYGENIC Dental Dam, Latex, Thin, Light, 5'' x 5'' (127x127mm), 52 pcs
H00524	HYGENIC Dental Dam, Latex, Medium, Light, 5'' x 5'' (127x127mm), 52 pcs
H00525	HYGENIC Dental Dam, Latex, Heavy, Light, 5'' x 5'' (127x127mm), 52 pcs
H00533	HYGENIC Dental Dam, Latex, Thin, Light, 6'' x 6'' (152 x152mm), 36 pcs
H00534	HYGENIC Dental Dam, Latex, Medium, Light, 6'' x 6'' (152x152mm), 36 pcs
H00535	HYGENIC Dental Dam, Latex, Heavy, Light, 6'' x 6'' (152x152mm), 36 pcs
H00536	HYGENIC Dental Dam, Latex, Extra Heavy, Light, 6'' x 6'' (152x152mm), 36 pcs
H00538	HYGENIC Dental Dam, Latex, Thin, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00539	HYGENIC Dental Dam, Latex, Medium, Dark, 6'' x 6'' (152x152mm), 36 pcs

Nr katalo-gowy	Opis
H00540	HYGENIC Dental Dam, Latex, Heavy, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00541	HYGENIC Dental Dam, Latex, Extra Heavy, Dark, 6'' x 6'' (152x152mm), 36 pcs
H02141	HYGENIC Dental Dam, Latex, Thin, Green, 5'' x 5'' (127x127mm), 52 pcs
H02142	HYGENIC Dental Dam, Latex, Medium, Green, 5'' x 5'' (127x127mm), 52 pcs
H02143	HYGENIC Dental Dam, Latex, Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H02144	HYGENIC Dental Dam Latex, Extra Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H02146	HYGENIC Dental Dam, Latex, Thin, Green, 6'' x 6'' (152x152mm), 36 pcs
H02147	HYGENIC Dental Dam, Latex, Medium, Green, 6'' x 6'' (152x152mm), 36 pcs
H02148	HYGENIC Dental Dam, Latex, Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H02149	HYGENIC Dental Dam, Latex, Extra Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H02778	HYGENIC FIESTA Winged Complete Kit, 1 pc
H02779	HYGENIC FIESTA Winged Standard Kit W/O Punch & Forceps, 1 pc
H02790	HYGENIC FIESTA Wingless Complete Kit, 1 pc
H02900	HYGENIC Simple Dam Kit - W/ Elasti-Dam, 1 pc
H03529	HYGENIC Dental Dam, Latex, Medium, Blue, 5'' x 5'' (127x127mm), 52 pcs
H03530	HYGENIC Dental Dam, Latex, Medium, Blue, 6'' x 6'' (152x152mm), 36 pcs
H04237	HYGENIC Dental Dam, Latex, Convenience Pack, Medium, Light, 5'' x 5'' (127x127mm), 364 pcs
H04241	HYGENIC Dental Dam, Latex, Convenience Pack, Medium, Green, 5'' x 5'' (127x127mm), 364 pcs

Nr katalo-gowy	Opis
H04243	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Light, 6'' x 6'' (152x152mm), 360 pcs
H04245	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Dark, 6'' x 6'' (152x152mm), 360 pcs
H04247	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Green, 6'' x 6'' (152x152mm), 360 pcs
H04639	HYGENIC FIESTA Dental Dam, Thin, 6'' x 6'' (152x152mm), 36 pcs
H04640	HYGENIC FIESTA Dental Dam, Thin, 5'' x 5'' (127x127mm), 52 pcs
H04641	HYGENIC FIESTA Dental Dam, Medium, 5'' x 5'' (127x127mm), 52 pcs
H04642	HYGENIC FIESTA Dental Dam, Medium, 6'' x 6'' (152x152mm), 36 pcs
H04643	HYGENIC FIESTA Dental Dam, Heavy, 5'' x 5'' (127x127mm), 52 pcs
H04644	HYGENIC FIESTA Dental Dam, Heavy, 6'' x 6'' (152x152mm), 36 pcs
H07315	HYGENIC Dental Dam, Latex, Heavy, Blue, 6'' x 6'' (152x152mm), 36 pcs
H07316	HYGENIC FIESTA Dental Dam, Latex, Convenience Pack, Medium, 5'' x 5'' (127x127mm), 364 pcs
H07317	HYGENIC FIESTA Dental Dam, Latex, Convenience Pack, Medium, 6'' x 6'' (152x152mm), 360 pcs
H11624	HYGENIC Elasti-Dam, Medium, Green, 5'' x 5'' (127x127mm), 52 pcs
H11625	HYGENIC Elasti-Dam, Medium, Green, 6'' x 6'' (152x152mm), 36 pcs
H11626	HYGENIC Elasti-Dam, Medium, Blue, 5'' x 5'' (127x127mm), 52 pcs
H11627	HYGENIC Elasti-Dam, Medium, Blue, 6'' x 6'' (152x152mm), 36 pcs

Nr katalo-gowy	Opis
H11675	HYGENIC Elasti-Dam, Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H11676	HYGENIC Elasti-Dam, Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H11677	HYGENIC Elasti-Dam, Heavy, Blue, 5'' x 5'' (127x127mm), 52 pcs
H11678	HYGENIC Elasti-Dam, Heavy, Blue, 6'' x 6'' (152x152mm), 36 pcs
H11690	HYGENIC Elasti-Dam Trial Pack, Medium, Green, 6'' x 6'' (152X152mm)

Ostrzeżenia i środki ostrożności

Ostrzeżenia	Treść
 **ZAGROŻENIE!**	Nieprzestrzeganie wskazówek w niniejszej instrukcji użycia może prowadzić do obrażeń ciała u pacjenta lub mieć niekorzystny wpływ na integralność koferdamu Dental Dam. Produkt należy stosować wyłącznie zgodnie z jego przeznaczeniem — patrz Przeznaczenie.
	Nie używać ponownie koferdamu Dental Dam. Koferdam Dental Dam jest przeznaczony wyłącznie do jednorazowego użytku. Ponowne użycie koferdamu Dental Dam w jamie ustnej stwarza zagrożenie biologiczne i może prowadzić do zakażenia krzyżowego.
	Przed użyciem należy skontrolować koferdam Dental Dam. Jeśli koferdam Dental Dam jest rozdarty lub kruszy się, należy go wyrzucić. Stosowanie koferdamu Dental Dam, który utracił swoje parametry wydajności, może prowadzić do utraty funkcjonalności i niekorzystnie wpływać na integralność podczas zabiegu.

Środki ostrożności	Treść
 **OSTRZEŻENIE**	Produkt zawiera lateks kauczuku naturalnego, który może wywołać reakcje alergiczne.
	Nie wystawiać koferdamu Dental Dam na działanie wysokich temperatur. Przechowywać koferdam Dental Dam z dala od źródeł ciepła.
	Koferdam Dental Dam ma określony termin ważności. Nie należy używać wyrobu po upływie terminu ważności, ponieważ może to spowodować pogorszenie jego działania i parametrów wydajności wyrobu.
	Ostrzeżenie: Prawo federalne (USA) zezwala na sprzedaż tego produktu tylko lekarzom lub na ich zamówienie.
	Nie przechowywać w pobliżu produktów niezawierających lateksu.

Dodatkowe informacje

Uwaga: Wyrób należy usuwać zgodnie z przepisami lokalnymi, regionalnymi, krajowymi i/lub międzynarodowymi. Wyroby stosowane w jamie ustnej należy traktować jako zagrożenie biologiczne i utylizować zgodnie z lokalnymi przepisami.

Uwaga: Na życzenie wydruk instrukcji użycia zostanie dostarczony bezpłatnie.

Dotyczy użytkowników w UE: Każde poważne zdarzenie, które wystąpiło w związku z użyciem wyrobu, należy zgłaszać firmie Coltène/Whaledent, Inc. i właściwemu organowi państwa członkowskiego, w którym znajduje się siedziba użytkownika i/lub miejsce zamieszkania pacjenta.

Słownik symboli

Symbol	Nazwa i opis symbolu
	Ostrzeżenie
 www.coltene.com	Zapoznać się z elektroniczną instrukcją użycia — wskazuje konieczność zapoznania się przez użytkownika z instrukcją użycia.
	Wyrób medyczny — wskazuje, że produkt jest wyrobem medycznym.
	Ograniczenie sprzedaży — zakup wyrobu jest zastrzeżony wyłącznie dla lekarzy.
	Termin ważności — wskazuje datę, po której nie należy używać wyrobu medycznego.
	Numer katalogowy — wskazuje numer katalogowy producenta, umożliwiający identyfikację wyrobu medycznego.
	Nie używać ponownie — wskazuje wyrób medyczny, który jest przeznaczony do zastosowania u jednego pacjenta podczas jednego zabiegu.
	Znak CE
	Importer — wskazuje podmiot importujący wyrób medyczny do danej lokalizacji.
	Producent — wskazuje producenta wyrobu medycznego.

Symbol	Nazwa i opis symbolu
LOT	Kod partii — wskazuje kod partii producenta, umożliwiający identyfikację partii lub serii.
EC REP	Autoryzowany przedstawiciel we Wspólnocie Europejskiej — wskazuje autoryzowanego przedstawiciela we Wspólnocie Europejskiej.
LATEX	Zawiera lateks kauczuku naturalnego — Wskazuje obecność suchego lateksu kauczuku naturalnego jako materiału konstrukcyjnego w wyrobie medycznym.

Przechowywanie

Przechowywać koferdam Dental Dam w temperaturze 0°C–26°C.
Przechowywać w suchym miejscu z dala od źródeł ciepła.

Symbol	Nazwa i opis symbolu
	Przechowywać w suchym miejscu — wskazuje wyrób medyczny, który należy chronić przed wilgocią.
	Chronić przed wysoką temperaturą — wskazuje wyrób medyczny, który należy chronić przed wysoką temperaturą.
	Zakres temperatur — wskazuje zakresy temperatur, na których działanie wyrób medyczny może być bezpiecznie wystawiony. Górna i dolna granica temperatura jest wskazywana przy górnej i dolnej linii poziomej.

HYGENIC

Latex Dental Dam

Instruções de utilização

LATEX

Rx ONLY

COLTENE

Utilização prevista/Indicações de utilização:
Dental Dam destina-se a ser usado intraoralmente para isolar um ou mais dentes e criar uma barreira na área circundante durante um procedimento dentário.

Contraindicações:
Latex Dental Dam não deve ser usado em pacientes com alergia ao látex.

Utilizadores previstos:
• Profissionais dentários
• Assistentes dentários

Grupo(s)-alvo de pacientes:
Indicadas para todos os grupos de pacientes.

Vantagens clínicas:
A utilização de Dental Dam tem as seguintes vantagens clínicas:
• Maior visibilidade através do dente/isolamento dos dentes
• Risco reduzido de o paciente aspirar ou deglutir instrumentos, resíduos de dentes, medicamentos ou soluções de irrigação
• Criação de um campo operatório seco
• Proteção do tecido mole do contacto com os instrumentos
• Barreira de controlo contra infeções

Características:
• Disponível em várias cores e espessuras
• Dois tamanhos: 5″ x 5″ ou 6″ x 6″ (127 mm x 127 mm ou 152 mm x 152 mm)
• As cores mais claras têm a vantagem de iluminar naturalmente o campo operatório, ao passo que as cores mais escuras podem ajudar a obter um contraste visual

Armazenamento:
Guardar o Dental Dam entre 0 °C – 26 °C (32 °F – 80 °F).
Guardar em local seco e ao abrigo do calor.

Riscos residuais, avisos e precauções:
Consultar a secção Avisos e precauções para conhecer o risco associado à utilização do Dental Dam de acordo com a respetiva utilização prevista.

Instruções

CUIDADO! Este produto contém látex de borracha natural passível de causar reações alérgicas.

Dental Dam destina-se a ser usado com diversos dispositivos incluindo grampos e quadros.

Consultar as instruções de utilização dos outros dispositivos em uso.

Os passos gerais que se seguem servem de orientação e podem ser personalizados:

1.º passo: determinação do campo operatório.

2.º passo: preparação do Dental Dam.
• Determinação das posições dos furos
• Marcação das posições dos furos
• Abertura dos furos

3.º passo: seleção do grampo/retentor

4.º passo: aplicação do grampo/retentor

5.º passo: colocação do Dental Dam

Lista de peças

Nota: nem todas das referências estão disponíveis em todas as regiões

Referência	Descrição
390020	ROEKO Dental Dam, Latex, Thin, 36 pcs
390021	ROEKO Dental Dam, Latex, Medium, 36 pcs
390022	ROEKO Dental Dam, Latex, Heavy, 36 pcs
60013793	ROEKO Elasti-Dam, 152x152mm, Medium, Green, 36 pcs
60013794	ROEKO Elasti-Dam, 152x152mm, Heavy, Green, 36 pcs
60013870	Sample ROEKO Elasti-Dam, 152x 52mm, Medium, Green
60013795	ROEKO Elasti-Dam, 127x127mm, Medium, Blue, 36 pcs
60013796	ROEKO Elasti-Dam, 127x127mm, Heavy, Blue, 36 pcs
H00523	HYGENIC Dental Dam, Latex, Thin, Light, 5'' x 5'' (127x127mm), 52 pcs
H00524	HYGENIC Dental Dam, Latex, Medium, Light, 5'' x 5'' (127x127mm), 52 pcs
H00525	HYGENIC Dental Dam, Latex, Heavy, Light, 5'' x 5'' (127x127mm), 52 pcs
H00533	HYGENIC Dental Dam, Latex, Thin, Light, 6'' x 6'' (152 x152mm), 36 pcs
H00534	HYGENIC Dental Dam, Latex, Medium, Light, 6'' x 6'' (152x152mm), 36 pcs
H00535	HYGENIC Dental Dam, Latex, Heavy, Light, 6'' x 6'' (152x152mm), 36 pcs
H00536	HYGENIC Dental Dam, Latex, Extra Heavy, Light, 6'' x 6'' (152x152mm), 36 pcs
H00538	HYGENIC Dental Dam, Latex, Thin, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00539	HYGENIC Dental Dam, Latex, Medium, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00540	HYGENIC Dental Dam, Latex, Heavy, Dark, 6'' x 6'' (152x152mm), 36 pcs

Referência	Descrição
H00541	HYGENIC Dental Dam, Latex, Extra Heavy, Dark, 6'' x 6'' (152x152mm), 36 pcs
H02141	HYGENIC Dental Dam, Latex, Thin, Green, 5'' x 5'' (127x127mm), 52 pcs
H02142	HYGENIC Dental Dam, Latex, Medium, Green, 5'' x 5'' (127x127mm), 52 pcs
H02143	HYGENIC Dental Dam, Latex, Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H02144	HYGENIC Dental Dam Latex, Extra Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H02146	HYGENIC Dental Dam, Latex, Thin, Green, 6'' x 6'' (152x152mm), 36 pcs
H02147	HYGENIC Dental Dam, Latex, Medium, Green, 6'' x 6'' (152x152mm), 36 pcs
H02148	HYGENIC Dental Dam, Latex, Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H02149	HYGENIC Dental Dam, Latex, Extra Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H02778	HYGENIC FIESTA Winged Complete Kit, 1 pc
H02779	HYGENIC FIESTA Winged Standard Kit W/O Punch & Forceps, 1 pc
H02790	HYGENIC FIESTA Wingless Complete Kit, 1 pc
H02900	HYGENIC Simple Dam Kit - W/ Elasti-Dam, 1 pc
H03529	HYGENIC Dental Dam, Latex, Medium, Blue, 5'' x 5'' (127x127mm), 52 pcs
H03530	HYGENIC Dental Dam, Latex, Medium, Blue, 6'' x 6'' (152x152mm), 36 pcs
H04237	HYGENIC Dental Dam, Latex, Convenience Pack, Medium, Light, 5'' x 5'' (127x127mm), 364 pcs
H04241	HYGENIC Dental Dam, Latex, Convenience Pack, Medium, Green, 5'' x 5'' (127x127mm), 364 pcs
H04243	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Light, 6'' x 6'' (152x152mm), 360 pcs

Referência	Descrição
H04245	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Dark, 6'' x 6'' (152x152mm), 360 pcs
H04247	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Green, 6'' x 6'' (152x152mm), 360 pcs
H04639	HYGENIC FIESTA Dental Dam, Thin, 6'' x 6'' (152x152mm), 36 pcs
H04640	HYGENIC FIESTA Dental Dam, Thin, 5'' x 5'' (127x127mm), 52 pcs
H04641	HYGENIC FIESTA Dental Dam, Medium, 5'' x 5'' (127x127mm), 52 pcs
H04642	HYGENIC FIESTA Dental Dam, Medium, 6'' x 6'' (152x152mm), 36 pcs
H04643	HYGENIC FIESTA Dental Dam, Heavy, 5'' x 5'' (127x127mm), 52 pcs
H04644	HYGENIC FIESTA Dental Dam, Heavy, 6'' x 6'' (152x152mm), 36 pcs
H07315	HYGENIC Dental Dam, Latex, Heavy, Blue, 6'' x 6'' (152x152mm), 36 pcs
H07316	HYGENIC FIESTA Dental Dam, Latex, Convenience Pack, Medium, 5'' x 5'' (127x127mm), 364 pcs
H07317	HYGENIC FIESTA Dental Dam, Latex, Convenience Pack, Medium, 6'' x 6'' (152x152mm), 360 pcs
H11624	HYGENIC Elasti-Dam, Medium, Green, 5'' x 5'' (127x127mm), 52 pcs
H11625	HYGENIC Elasti-Dam, Medium, Green, 6'' x 6'' (152x152mm), 36 pcs
H11626	HYGENIC Elasti-Dam, Medium, Blue, 5'' x 5'' (127x127mm), 52 pcs
H11627	HYGENIC Elasti-Dam, Medium, Blue, 6'' x 6'' (152x152mm), 36 pcs
H11675	HYGENIC Elasti-Dam, Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H11676	HYGENIC Elasti-Dam, Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H11677	HYGENIC Elasti-Dam, Heavy, Blue, 5'' x 5'' (127x127mm), 52 pcs

Referência	Descrição
H11678	HYGENIC Elasti-Dam, Heavy, Blue, 6'' x 6'' (152x152mm), 36 pcs
H11690	HYGENIC Elasti-Dam Trial Pack, Medium, Green, 6'' x 6'' (152X152mm)

Avisos e precauções

Avisos	Advertência
 **AVISO!**	O incumprimento das instruções constantes destas instruções de utilização pode resultar em lesão do paciente ou comprometer a integridade do dental dam. Usar o produto apenas de acordo com a utilização prevista, ver Utilização prevista.
	Não reutilizar o Dental Dam. O Dental Dam destina-se a ser usado apenas uma vez. A reutilização do Dental Dam intraoralmente é um perigo biológico e pode resultar em contaminação cruzada.
	O Dental Dam deve ser inspecionado antes da utilização. Descartar o Dental Dam se estiver rasgado ou quebradiço. A utilização de um Dental Dam que tenha perdido as suas características de desempenho pode resultar em perda de funcionalidade e comprometer a integridade do procedimento.

Precauções	Advertência
 **CUIDADO**	Este produto contém látex de borracha natural passível de causar reações alérgicas.
	Não expor o Dental Dam a temperaturas elevadas. Guardar o Dental Dam ao abrigo de fontes de calor.
	Dental Dam tem uma vida útil especificada. Não usar o dispositivo depois de expirado o prazo de validade, dado que isso pode comprometer a sua funcionalidade e as suas características de desempenho.
	Cuidado: nos termos da lei federal (EUA), este produto só pode ser vendido diretamente por um profissional de saúde licenciado ou por ordem deste.
	Não guardar perto de produtos sem látex.

Outras informações

Nota: eliminar o dispositivo de acordo com os regulamentos locais, regionais, nacionais e/ou internacionais. Os dispositivos usados intraoralmente devem ser tratados como perigo biológico e devidamente eliminados de acordo com os regulamentos locais.

Nota: será fornecida gratuitamente uma cópia em papel das instruções de utilização mediante pedido.

Para os utilizadores localizados na UE: qualquer incidente grave ocorrido que esteja relacionado com a utilização do dispositivo deve ser comunicado à Coltène/Whaledent, Inc. e às autoridades competentes do Estado-Membro em que o utilizador e/ou o paciente se encontra estabelecido.

Glossário de símbolos

Símbolo	Título e descrição do símbolo
	Cuidado
 www.coltene.com	Consultar as instruções de utilização eletrónicas – Indica que o utilizador tem de consultar as instruções de utilização
	Dispositivo médico – Indica que o produto é um dispositivo médico
	Venda limitada: a aquisição do dispositivo é limitada a profissionais de saúde licenciados.
	Prazo de validade – Indica a data depois da qual o dispositivo médico não deve ser usado
	Referência – Indica a referência do fabricante para permitir a identificação do dispositivo médico
	Não reutilizar – Indica um dispositivo médico que se destina a utilização num único paciente durante um único procedimento
	Marcação CE
	Importador – Indica a entidade que importa o dispositivo médico para o local
	Fabricante – Indica o fabricante do dispositivo médico

Símbolo	Título e descrição do símbolo
LOT	Código do lote – Indica o código do lote do fabricante para permitir a sua identificação
EC REP	Representante autorizado na Comunidade Europeia – Indica o representante autorizado na Comunidade Europeia
LATEX	Contém látex de borracha natural – Indica a presença de látex de borracha natural seco como material de construção do dispositivo médico.

Armazenamento

Guardar o Dental Dam entre 0 °C – 26 °C (32 °F – 80 °F).
Guardar em local seco e ao abrigo do calor.

Símbolo	Título e descrição do símbolo
	Guardar em local seco – Indica um dispositivo médico que tem de ser protegido da humidade
	Guardar ao abrigo do calor – Indica um dispositivo médico que tem de ser protegido do calor
	Limite de temperatura – Indica os limites de temperatura dentro dos quais o dispositivo médico pode ficar exposto em segurança. Os limites superior e inferior de temperatura devem ser indicados junto às linhas horizontais superior e inferior.

HYGENIC

Latex Dental Dam

Instrucțiuni de utilizare

LATEX

Rx ONLY

COLTENE

Domeniu de utilizare/Indicații de utilizare:
Dental Dam se utilizează intraoral pentru a izola unul sau mai mulți dinți, cu scopul de a crea o barieră față de zona înconjurătoare în timpul unei proceduri dentare.

Contraindicații:
Latex Dental Dam nu este destinată utilizării la pacienți cu alergie la latex.

Utilizatori vizați:
• Medici stomatologi
• Asistenți de medicină dentară

Grup(uri) țintă de pacienți:
Adecvate pentru toate categoriile de pacienți.

Beneficii clinice:
Utilizarea Dental Dam oferă următoarele beneficii clinice:
• Creșterea vizibilității prin izolarea dintelui/dinților
• Reducerea riscului ca pacientul să aspire sau să înghită instrumente, reziduuri dentare, medicamente sau soluții de irigare
• Crearea unui câmp chirurgical uscat
• Protecția țesutului moale împotriva contactului cu instrumentele
• Barieră de control al infecției

Caracteristici:
• Disponibilă în diverse culori și grosimi
• Două mărimi: 5″ x 5″ sau 6″ x 6″ (127 mm x 127 mm sau 152 mm x 152 mm)
• Culorile mai deschise au avantajul de a ilumina natural câmpul operator, în timp ce culorile mai închise pot ajuta la crearea unui contrast vizual

Depozitare:
Depozitați Dental Dam la temperaturi între 32° F și 80° F (0°C – 26°C).
A se păstra la loc uscat și ferit de căldură.

Riscuri reziduale, avertizări și precauții:
Consultați secțiunea Avertizări și precauții pentru specificația referitoare la riscul asociat cu utilizarea Dental Dam în conformitate cu domeniul de utilizare.

Instrucțiuni

ATENȚIE! Acest produs conține latex din cauciuc natural, care poate provoca reacții alergice.

Dental Dam este destinată utilizării împreună cu diverse alte dispozitive, ce includ cleme și cadre.

Consultați Instrucțiunile de utilizare ale celorlalte dispozitive utilizate.

Următorii pași generali au rol orientativ și pot fi adaptați pentru fiecare caz individual:

Pasul 1: Stabiliți câmpul operator.

Pasul 2: Pregătirea Dental Dam.
• Stabiliți pozițiile orificiilor
• Marcați pozițiile orificiilor
• Efectuați perforațiile

Pasul 3: Selectarea clemei/opritorului

Pasul 4: Aplicarea clemei/opritorului

Pasul 5: Fixarea Dental Dam

Lista pieselor

Notă: Unele numere de catalog nu sunt disponibile în anumite regiuni

Nr. de catalog	Descriere
390020	ROEKO Dental Dam, Latex, Thin, 36 pcs
390021	ROEKO Dental Dam, Latex, Medium, 36 pcs
390022	ROEKO Dental Dam, Latex, Heavy, 36 pcs
60013793	ROEKO Elasti-Dam, 152x152mm, Medium, Green, 36 pcs
60013794	ROEKO Elasti-Dam, 152x152mm, Heavy, Green, 36 pcs
60013870	Sample ROEKO Elasti-Dam, 152x 52mm, Medium, Green
60013795	ROEKO Elasti-Dam, 127x127mm, Medium, Blue, 36 pcs
60013796	ROEKO Elasti-Dam, 127x127mm, Heavy, Blue, 36 pcs
H00523	HYGENIC Dental Dam, Latex, Thin, Light, 5'' x 5'' (127x127mm), 52 pcs
H00524	HYGENIC Dental Dam, Latex, Medium, Light, 5'' x 5'' (127x127mm), 52 pcs
H00525	HYGENIC Dental Dam, Latex, Heavy, Light, 5'' x 5'' (127x127mm), 52 pcs
H00533	HYGENIC Dental Dam, Latex, Thin, Light, 6'' x 6'' (152 x152mm), 36 pcs
H00534	HYGENIC Dental Dam, Latex, Medium, Light, 6'' x 6'' (152x152mm), 36 pcs
H00535	HYGENIC Dental Dam, Latex, Heavy, Light, 6'' x 6'' (152x152mm), 36 pcs
H00536	HYGENIC Dental Dam, Latex, Extra Heavy, Light, 6'' x 6'' (152x152mm), 36 pcs
H00538	HYGENIC Dental Dam, Latex, Thin, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00539	HYGENIC Dental Dam, Latex, Medium, Dark, 6'' x 6'' (152x152mm), 36 pcs

Nr. de catalog	Descriere
H00540	HYGENIC Dental Dam, Latex, Heavy, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00541	HYGENIC Dental Dam, Latex, Extra Heavy, Dark, 6'' x 6'' (152x152mm), 36 pcs
H02141	HYGENIC Dental Dam, Latex, Thin, Green, 5'' x 5'' (127x127mm), 52 pcs
H02142	HYGENIC Dental Dam, Latex, Medium, Green, 5'' x 5'' (127x127mm), 52 pcs
H02143	HYGENIC Dental Dam, Latex, Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H02144	HYGENIC Dental Dam Latex, Extra Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H02146	HYGENIC Dental Dam, Latex, Thin, Green, 6'' x 6'' (152x152mm), 36 pcs
H02147	HYGENIC Dental Dam, Latex, Medium, Green, 6'' x 6'' (152x152mm), 36 pcs
H02148	HYGENIC Dental Dam, Latex, Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H02149	HYGENIC Dental Dam, Latex, Extra Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H02778	HYGENIC FIESTA Winged Complete Kit, 1 pc
H02779	HYGENIC FIESTA Winged Standard Kit W/O Punch & Forceps, 1 pc
H02790	HYGENIC FIESTA Wingless Complete Kit, 1 pc
H02900	HYGENIC Simple Dam Kit - W/ Elasti-Dam, 1 pc
H03529	HYGENIC Dental Dam, Latex, Medium, Blue, 5'' x 5'' (127x127mm), 52 pcs
H03530	HYGENIC Dental Dam, Latex, Medium, Blue, 6'' x 6'' (152x152mm), 36 pcs
H04237	HYGENIC Dental Dam, Latex, Convenience Pack, Medium, Light, 5'' x 5'' (127x127mm), 364 pcs
H04241	HYGENIC Dental Dam, Latex, Convenience Pack, Medium, Green, 5'' x 5'' (127x127mm), 364 pcs

Nr. de catalog	Descriere
H04243	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Light, 6'' x 6'' (152x152mm), 360 pcs
H04245	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Dark, 6'' x 6'' (152x152mm), 360 pcs
H04247	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Green, 6'' x 6'' (152x152mm), 360 pcs
H04639	HYGENIC FIESTA Dental Dam, Thin, 6'' x 6'' (152x152mm), 36 pcs
H04640	HYGENIC FIESTA Dental Dam, Thin, 5'' x 5'' (127x127mm), 52 pcs
H04641	HYGENIC FIESTA Dental Dam, Medium, 5'' x 5'' (127x127mm), 52 pcs
H04642	HYGENIC FIESTA Dental Dam, Medium, 6'' x 6'' (152x152mm), 36 pcs
H04643	HYGENIC FIESTA Dental Dam, Heavy, 5'' x 5'' (127x127mm), 52 pcs
H04644	HYGENIC FIESTA Dental Dam, Heavy, 6'' x 6'' (152x152mm), 36 pcs
H07315	HYGENIC Dental Dam, Latex, Heavy, Blue, 6'' x 6'' (152x152mm), 36 pcs
H07316	HYGENIC FIESTA Dental Dam, Latex, Convenience Pack, Medium, 5'' x 5'' (127x127mm), 364 pcs
H07317	HYGENIC FIESTA Dental Dam, Latex, Convenience Pack, Medium, 6'' x 6'' (152x152mm), 360 pcs
H11624	HYGENIC Elasti-Dam, Medium, Green, 5'' x 5'' (127x127mm), 52 pcs
H11625	HYGENIC Elasti-Dam, Medium, Green, 6'' x 6'' (152x152mm), 36 pcs
H11626	HYGENIC Elasti-Dam, Medium, Blue, 5'' x 5'' (127x127mm), 52 pcs
H11627	HYGENIC Elasti-Dam, Medium, Blue, 6'' x 6'' (152x152mm), 36 pcs

Nr. de catalog	Descriere
H11675	HYGENIC Elasti-Dam, Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H11676	HYGENIC Elasti-Dam, Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H11677	HYGENIC Elasti-Dam, Heavy, Blue, 5'' x 5'' (127x127mm), 52 pcs
H11678	HYGENIC Elasti-Dam, Heavy, Blue, 6'' x 6'' (152x152mm), 36 pcs
H11690	HYGENIC Elasti-Dam Trial Pack, Medium, Green, 6'' x 6'' (152X152mm)

Avertizări și precauții

Avertizări	Frază
 **AVERTISMENT!**	Nerespectarea exactă a indicațiilor din aceste instrucțiuni de utilizare poate provoca vătămarea pacientului sau compromiterea integrității dental dam. Utilizați produsul numai în conformitate cu domeniul de utilizare; consultați Domeniu de utilizare.
	Nu reutilizați Dental Dam. Dental Dam este destinată unei singure utilizări. Reutilizarea intraorală a Dental Dam reprezintă un pericol biologic și poate duce la contaminare încrucișată.
	Dental Dam trebuie inspectată înainte de utilizare. Aruncați Dental Dam dacă este ruptă sau friabilă. Utilizarea unei Dental Dam care și-a pierdut caracteristicile de performanță poate duce la scăderea funcționalității și poate compromite integritatea procedurii.

Precauții	Frază
 ATENȚIE	Acest produs conține latex din cauciuc natural, care poate provoca reacții alergice.
	Nu expuneți Dental Dam la temperaturi ridicate. Depozitați Dental Dam la distanță de sursele de căldură.
	Dental Dam are un termen de valabilitate specificat. Nu utilizați dispozitivul după data expirării, deoarece funcționalitatea dispozitivului și caracteristicile de performanță pot fi compromise.
	Atenție: Legea federală (SUA) limitează acest dispozitiv la vânzarea de un specialist autorizat în asistență medicală sau la comanda acestuia.
	A nu se depozita în apropierea produselor fără latex.

Informații suplimentare

Notă: Eliminați dispozitivul în conformitate cu reglementările locale, regionale, naționale și/sau internaționale. Dispozitivele utilizate intraoral trebuie tratate ca pericol biologic și eliminate corespunzător, conform reglementărilor locale.

Notă: La cerere, puteți obține în mod gratuit IDU pe suport de hârtie.

Pentru utilizatorii aflați în UE: Raportați orice incident grav apărut în legătură cu utilizarea acestui produs către Coltène/Whaledent, Inc. și către autoritatea competentă din Statul Membru în care se află utilizatorul și/sau pacientul.

Glosar de simboluri

Simbol	Titlul și descrierea simbolului
	Atenție
 www.coltene.com	Consultați instrucțiunile electronice de utilizare – Indică necesitatea ca utilizatorul să consulte instrucțiunile de utilizare
	Dispozitiv medical – Indică faptul că articolul este un dispozitiv medical
	Restricție de vânzare: acest produs poate fi achiziționat doar de specialiști autorizați în asistență medicală.
	Data expirării – Indică data după care dispozitivul medical nu mai poate fi utilizat
	Număr de catalog – Indică numărul de catalog al producătorului, astfel încât dispozitivul medical să poată fi identificat
	A nu se reutiliza – Indică un dispozitiv medical destinat utilizării la un singur pacient, pentru o singură procedură
	Marcaj CE
	Importator – Indică importatorul dispozitivului medical în țara respectivă
	Producător – Indică producătorul dispozitivului medical

Simbol	Titlul și descrierea simbolului
LOT	Cod de serie – Indică codul de serie al producătorului, pentru a putea identifica seria sau lotul
EC REP	Reprezentant autorizat în Comunitatea Europeană – Indică reprezentantul autorizat în Comunitatea Europeană
LATEX	Conține latex din cauciuc natural – Indică prezența latexului din cauciuc natural ca materie primă în dispozitivul medical.

Depozitare

Depozitați Dental Dam la temperaturi între 32° F și 80° F (0°C – 26°C).
A se păstra la loc uscat și ferit de căldură.

Simbol	Titlul și descrierea simbolului
	A se păstra la loc uscat – Indică faptul că un dispozitiv medical trebuie protejat împotriva umezelii
	A se feri de căldură – Indică faptul că un dispozitiv medical trebuie protejat împotriva căldurii
	Limită de temperatură – Indică limitele de temperatură la care dispozitivul medical poate fi expus în siguranță. Limitele de temperatură superioare și inferioare vor fi indicate lângă liniile orizontale de sus și de jos.

HYGENIC

Latex Dental Dam

Návod na použitie

LATEX

Rx ONLY

COLTENE

Určené použitie/Indikácie na použitie:
Dentálna priehradka Dental Dam je určená na použitie v ústnej dutine na izolovanie jedného alebo viacerých zubov a vytvorenie bariéry voči okolitému prostrediu v priebehu dentálneho zákroku.

Kontraindikácie:
Latexová dentálna priehradka Dental Dam sa nemá používať u pacientov s alergiou na latex.

Určení používatelia:
• Stomatológovia
• Dentálni asistenti

Cieľová skupina pacientov:
Vhodné pre všetky skupiny pacientov.

Klinické účinky:
Používanie dentálnej priehradky Dental Dam má tieto klinické účinky:
• zvýšená viditeľnosť pomocou izolácie zuba/zubov;
• znížené riziko vdýchnutia alebo prehltnutia nástrojov, úlomkov zuba, liekov alebo vyplachovacích roztokov pacientom;
• vytvorenie suchého poľa na zákrok;
• ochrana mäkkých tkanív pred kontaktom s nástrojmi;
• bariéra na regulovanie infekcie.

Charakteristiky:
• k dispozícii v rôznych farbách a hrúbkach;
• dve veľkosti: 127 mm x 127 mm alebo 152 mm x 152 mm;
• svetlejšie farby majú výhodu, že prirodzene osvetľujú miesto zákroku, zatiaľ čo tmavšie farby môžu pomôcť s vizuálnym kontrastom.

Skladovanie:
Dentálnu priehradku Dental Dam skladujte pri teplote od 0 °C do 26 °C.

Uchovávajte v suchu a mimo tepla.

Zostatkové riziká, varovania a preventívne opatrenia:
Čo sa týka vyhlásenia o rizikách spojených s používaním dentálnej priehradky Dental Dam v súlade s jej určeným použitím, pozrite si časť Varovania a preventívne opatrenia.

Pokyny

UPOZORNENIE! Tento produkt obsahuje prírodný kaučukový latex, ktorý môže vyvolať alergické reakcie.

Dentálna priehradka Dental Dam je určená na používanie s rôznymi ďalšími pomôckami vrátane svoriek a rámov.

Pozrite si návod na použitie ostatných používaných pomôcok.

Tieto všeobecné kroky slúžia ako návod a môžu sa prispôsobiť konkrétnemu prípadu:

Krok 1: Určite miesto zákroku.

Krok 2: Pripravte dentálnu priehradku Dental Dam:
• určite polohu diery,
• vyznačte polohu diery,
• prerazte dieru.

Krok 3: Vyberte svorku/zarážku.

Krok 4: Zaveďte svorku/zarážku.

Krok 5: Umiestnite dentálnu priehradku Dental Dam.

Zoznam dielov

Poznámka: Nie všetky katalógové čísla musia byť k dispozícii vo všetkých oblastiach.

Katalógové č.	Opis
390020	ROEKO Dental Dam, Latex, Thin, 36 pcs
390021	ROEKO Dental Dam, Latex, Medium, 36 pcs
390022	ROEKO Dental Dam, Latex, Heavy, 36 pcs
60013793	ROEKO Elasti-Dam, 152x152mm, Medium, Green, 36 pcs
60013794	ROEKO Elasti-Dam, 152x152mm, Heavy, Green, 36 pcs
60013870	Sample ROEKO Elasti-Dam, 152x 52mm, Medium, Green
60013795	ROEKO Elasti-Dam, 127x127mm, Medium, Blue, 36 pcs
60013796	ROEKO Elasti-Dam, 127x127mm, Heavy, Blue, 36 pcs
H00523	HYGENIC Dental Dam, Latex, Thin, Light, 5'' x 5'' (127x127mm), 52 pcs
H00524	HYGENIC Dental Dam, Latex, Medium, Light, 5'' x 5'' (127x127mm), 52 pcs
H00525	HYGENIC Dental Dam, Latex, Heavy, Light, 5'' x 5'' (127x127mm), 52 pcs
H00533	HYGENIC Dental Dam, Latex, Thin, Light, 6'' x 6'' (152 x152mm), 36 pcs
H00534	HYGENIC Dental Dam, Latex, Medium, Light, 6'' x 6'' (152x152mm), 36 pcs
H00535	HYGENIC Dental Dam, Latex, Heavy, Light, 6'' x 6'' (152x152mm), 36 pcs
H00536	HYGENIC Dental Dam, Latex, Extra Heavy, Light, 6'' x 6'' (152x152mm), 36 pcs
H00538	HYGENIC Dental Dam, Latex, Thin, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00539	HYGENIC Dental Dam, Latex, Medium, Dark, 6'' x 6'' (152x152mm), 36 pcs

Katalógové č.	Opis
H00540	HYGENIC Dental Dam, Latex, Heavy, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00541	HYGENIC Dental Dam, Latex, Extra Heavy, Dark, 6'' x 6'' (152x152mm), 36 pcs
H02141	HYGENIC Dental Dam, Latex, Thin, Green, 5'' x 5'' (127x127mm), 52 pcs
H02142	HYGENIC Dental Dam, Latex, Medium, Green, 5'' x 5'' (127x127mm), 52 pcs
H02143	HYGENIC Dental Dam, Latex, Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H02144	HYGENIC Dental Dam Latex, Extra Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H02146	HYGENIC Dental Dam, Latex, Thin, Green, 6'' x 6'' (152x152mm), 36 pcs
H02147	HYGENIC Dental Dam, Latex, Medium, Green, 6'' x 6'' (152x152mm), 36 pcs
H02148	HYGENIC Dental Dam, Latex, Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H02149	HYGENIC Dental Dam, Latex, Extra Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H02778	HYGENIC FIESTA Winged Complete Kit, 1 pc
H02779	HYGENIC FIESTA Winged Standard Kit W/O Punch & Forceps, 1 pc
H02790	HYGENIC FIESTA Wingless Complete Kit, 1 pc
H02900	HYGENIC Simple Dam Kit - W/ Elasti-Dam, 1 pc
H03529	HYGENIC Dental Dam, Latex, Medium, Blue, 5'' x 5'' (127x127mm), 52 pcs
H03530	HYGENIC Dental Dam, Latex, Medium, Blue, 6'' x 6'' (152x152mm), 36 pcs
H04237	HYGENIC Dental Dam, Latex, Convenience Pack, Medium, Light, 5'' x 5'' (127x127mm), 364 pcs
H04241	HYGENIC Dental Dam, Latex, Convenience Pack, Medium, Green, 5'' x 5'' (127x127mm), 364 pcs

Katalógové č.	Opis
H04243	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Light, 6'' x 6'' (152x152mm), 360 pcs
H04245	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Dark, 6'' x 6'' (152x152mm), 360 pcs
H04247	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Green, 6'' x 6'' (152x152mm), 360 pcs
H04639	HYGENIC FIESTA Dental Dam, Thin, 6'' x 6'' (152x152mm), 36 pcs
H04640	HYGENIC FIESTA Dental Dam, Thin, 5'' x 5'' (127x127mm), 52 pcs
H04641	HYGENIC FIESTA Dental Dam, Medium, 5'' x 5'' (127x127mm), 52 pcs
H04642	HYGENIC FIESTA Dental Dam, Medium, 6'' x 6'' (152x152mm), 36 pcs
H04643	HYGENIC FIESTA Dental Dam, Heavy, 5'' x 5'' (127x127mm), 52 pcs
H04644	HYGENIC FIESTA Dental Dam, Heavy, 6'' x 6'' (152x152mm), 36 pcs
H07315	HYGENIC Dental Dam, Latex, Heavy, Blue, 6'' x 6'' (152x152mm), 36 pcs
H07316	HYGENIC FIESTA Dental Dam, Latex, Convenience Pack, Medium, 5'' x 5'' (127x127mm), 364 pcs
H07317	HYGENIC FIESTA Dental Dam, Latex, Convenience Pack, Medium, 6'' x 6'' (152x152mm), 360 pcs
H11624	HYGENIC Elasti-Dam, Medium, Green, 5'' x 5'' (127x127mm), 52 pcs
H11625	HYGENIC Elasti-Dam, Medium, Green, 6'' x 6'' (152x152mm), 36 pcs
H11626	HYGENIC Elasti-Dam, Medium, Blue, 5'' x 5'' (127x127mm), 52 pcs
H11627	HYGENIC Elasti-Dam, Medium, Blue, 6'' x 6'' (152x152mm), 36 pcs

Katalógové č.	Opis
H11675	HYGENIC Elasti-Dam, Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H11676	HYGENIC Elasti-Dam, Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H11677	HYGENIC Elasti-Dam, Heavy, Blue, 5'' x 5'' (127x127mm), 52 pcs
H11678	HYGENIC Elasti-Dam, Heavy, Blue, 6'' x 6'' (152x152mm), 36 pcs
H11690	HYGENIC Elasti-Dam Trial Pack, Medium, Green, 6'' x 6'' (152X152mm)

Varovania a preventívne opatrenia

Varovania	Vyhlásenie
 **VAROVANIE!**	Nedodržanie náležitých pokynov uvedených v tomto návode na použitie môže viesť k zraneniu pacienta alebo ohroziť integritu dentálnej priehradky Dental Dam. Produkt používajte iba v súlade s jeho určeným použitím, pozri časť Určené použitie.
	Dentálnu priehradku Dental Dam opakovane nepoužívajte. Dentálna priehradka Dental Dam je určená len na jedno použitie. Opakované použitie dentálnej priehradky Dental Dam v ústnej dutine predstavuje biologické riziko a môže zapríčiniť krížovú kontamináciu.
	Dentálna priehradka Dental Dam sa má pred použitím skontrolovať. Dentálnu priehradku Dental Dam, ktorá je roztrhnutá alebo rozstrapkaná, vyhoďte. Používanie dentálnych priehradok Dental Dam, ktoré stratili svoje výkonové vlastnosti, môže viesť k strate ich funkčnosti a ohroziť integritu zákroku.

Preventívne opatrenia	Vyhlásenie
 **UPOZORNENIE**	Tento produkt obsahuje prírodný kaučukový latex, ktorý môže vyvolať alergické reakcie.
	Dentálnu priehradku Dental Dam nevystavujte vysokým teplotám. Dentálnu priehradku Dental Dam uchovávajte mimo zdrojov tepla.
	Dentálna priehradka Dental Dam má stanovenú životnosť. Pomôcku nepoužívajte po dátume spotreby, pretože sa môže zhoršiť jej funkčnosť a výkonové vlastnosti.
	Upozornenie: Federálne zákony (USA) obmedzujú predaj alebo objednávku tejto pomôcky len zdravotníckym pracovníkom s licenciou.
	Neskladujte v blízkosti nelatexových produktov.

Dodatočné informácie

Poznámka: Pomôcku likvidujte v súlade s miestnymi, regionálnymi, vnútroštátnymi a/alebo medzinárodnými nariadeniami. S pomôckami používanými v ústnej dutine by sa malo nakladať ako s biologicky nebezpečnými a mali by sa likvidovať podľa miestnych nariadení.

Poznámka: na požiadanie sa poskytne bezplatná kópia návodu na použitie v tlačenej verzii.

Pre používateľov z EÚ: všetky závažné incidenty, ktoré sa objavili v súvislosti s používaním pomôcky by sa mali nahlásiť spoločnosti Coltène/Whaledent, Inc. a príslušnému orgánu členského štátu, v ktorom má používateľ a/alebo pacient sídlo.

Slovník symbolov

Symbol	Názov a opis symbolu
	Upozornenie
 www.coltene.com	Pozrite si elektronický návod na použitie – Uvádza, že je potrebné, aby si používateľ pozrel návod na použitie
	Zdravotnícka pomôcka – Uvádza, že položka je zdravotnícka pomôcka
	Predaj je obmedzený: obstaranie pomôcky sa obmedzuje len na zdravotníckych pracovníkov s osvedčením.
	Dátum spotreby – Uvádza dátum, po ktorom sa nemá zdravotnícka pomôcka používať
	Katalógové číslo – Uvádza katalógové číslo výrobcu, aby bolo možné zdravotnícku pomôcku identifikovať
	Nepoužívajte opakovane – Označuje zdravotnícku pomôcku, ktorá je určená na použitie u jedného pacienta počas jedného zákroku
	Značka CE
	Dovozca – Označuje subjekt, ktorý zdravotnícku pomôcku dováža na miesto
	Výrobca – Uvádza výrobcu zdravotníckej pomôcky

Symbol	Názov a opis symbolu
LOT	Číslo dávky – Uvádza číslo dávky výrobcu, aby bolo možné identifikovať dávku alebo šaržu
EC REP	Oprávnený zástupca v Európskom spoločenstve – Uvádza oprávneného zástupcu v Európskom spoločenstve
LATEX	Obsahuje prírodnú latexovú gumu – Označuje prítomnosť prírodnej latexovej gumy ako konštrukčného materiálu zdravotníckej pomôcky

Skladovanie

Dentálnu priehradku Dental Dam skladujte pri teplote od 0 °C do 26 °C.
Uchovávajte v suchu a mimo tepla.

Symbol	Názov a opis symbolu
	Uchovávajte v suchu – Označuje zdravotnícku pomôcku, ktorú je potrebné chrániť pred vlhkosťou
	Uchovávajte mimo tepla – Označuje zdravotnícku pomôcku, ktorú je potrebné chrániť pred teplom
	Teplotný limit – Označuje teplotné limity, ktorým môže byť zdravotnícka pomôcka bezpečne vystavená Vrchné a spodné limity teploty by mali byť uvedené vedľa vrchnej a spodnej horizontálnej línie.

HYGENIC

Latex Dental Dam

Navodila za uporabo

LATEX

Rx ONLY

COLTENE

Predvidena uporaba/indikacije za uporabo:
Dental Dam je namenjen za interoralno uporabo z namenom izolacije enega ali več zob ter oblikovanje ovire za okoliško območje med dentalnim postopkom.

Kontraindikacije:
Izdelka Dental Dam iz lateksa ne uporabljajte pri pacientih z alergijo na lateks.

Predvideni uporabniki:
• Zobozdravniki
• Zobozdravstveni asistenti

Cijna/-e skupina/-e pacientov:
Primerno za vse skupine pacientov.

Klinične koristi:
Uporaba Dental Dam ima naslednje klinične koristi:
• Boljša vidljivost z izolacijo zoba/zob
• Manjše tveganje, da bi pacient vdihnil ali pogoltnil pripomočke, ostanke zoba, zdravila ali raztopine za omočitev
• Oblikovanje suhega operacijskega polja
• Zaščita mehkega tkiva pred stikom s pripomočki
• Bariera za nadzor okužb

Lastnosti:
• Na voljo v različnih barvah in debelinah
• Dve velikosti: 5″ x 5″ ali 6″ x 6″ (127 mm x 127 mm ali 152 mm x 152 mm)
• Prednost svetlejših barv je, da naravno osvetlijo operativno polje, medtem ko temnejše barve lahko pomagajo ustvariti vizualni kontrast.

Shranjevanje:
Izdelek Dental Dam shranjujte pri temperaturi med 32 °F in 80 ^{0}F (od 0 °C do 26 °C).
Izdelek hranite na suhem in stran od virov vročine.

Preostala tveganja, opozorila in previdnostni ukrepi:
Glejte razdelek z opozorili in previdnostnimi ukrepi za seznam tveganj, povezanih z uporabo izdelka Dental Dam v skladu s predvideno uporabo.

Navodila

POZOR! Ta izdelek vsebuje lateks iz naravnega kavčuka, ki lahko povzroči alergijske reakcije.

Dental Dam je namenjen za uporabo skupaj s številnimi drugimi pripomočki, vključno s sponkami in okvirji.

Glejte navodila za uporabo drugih pripomočkov, ki jih uporabljate.

Naslednji splošni koraki so navedeni kot smernice in jih je mogoče prilagoditi po meri, da ustrezajo specifičnemu primeru.

1. korak: Določite operativno polje.

2. korak: Pripravite Dental Dam.
• Določite položaje lukenj.
• Označite položaje lukenj.
• Naredite luknje.

3. korak: Izberite sponko/retainer.

4. korak: Namestite sponko/retainer.

5. korak: Namestite Dental Dam.

Seznam delov

Opomba: Vse kataloške številke niso na voljo v vseh regijah.

Kataloška št.	Opis
390020	ROEKO Dental Dam, Latex, Thin, 36 pcs
390021	ROEKO Dental Dam, Latex, Medium, 36 pcs
390022	ROEKO Dental Dam, Latex, Heavy, 36 pcs
60013793	ROEKO Elasti-Dam, 152x152mm, Medium, Green, 36 pcs
60013794	ROEKO Elasti-Dam, 152x152mm, Heavy, Green, 36 pcs
60013870	Sample ROEKO Elasti-Dam, 152x 52mm, Medium, Green
60013795	ROEKO Elasti-Dam, 127x127mm, Medium, Blue, 36 pcs
60013796	ROEKO Elasti-Dam, 127x127mm, Heavy, Blue, 36 pcs
H00523	HYGENIC Dental Dam, Latex, Thin, Light, 5'' x 5'' (127x127mm), 52 pcs
H00524	HYGENIC Dental Dam, Latex, Medium, Light, 5'' x 5'' (127x127mm), 52 pcs
H00525	HYGENIC Dental Dam, Latex, Heavy, Light, 5'' x 5'' (127x127mm), 52 pcs
H00533	HYGENIC Dental Dam, Latex, Thin, Light, 6'' x 6'' (152 x152mm), 36 pcs
H00534	HYGENIC Dental Dam, Latex, Medium, Light, 6'' x 6'' (152x152mm), 36 pcs
H00535	HYGENIC Dental Dam, Latex, Heavy, Light, 6'' x 6'' (152x152mm), 36 pcs
H00536	HYGENIC Dental Dam, Latex, Extra Heavy, Light, 6'' x 6'' (152x152mm), 36 pcs
H00538	HYGENIC Dental Dam, Latex, Thin, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00539	HYGENIC Dental Dam, Latex, Medium, Dark, 6'' x 6'' (152x152mm), 36 pcs

Kataloška št.	Opis
H00540	HYGENIC Dental Dam, Latex, Heavy, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00541	HYGENIC Dental Dam, Latex, Extra Heavy, Dark, 6'' x 6'' (152x152mm), 36 pcs
H02141	HYGENIC Dental Dam, Latex, Thin, Green, 5'' x 5'' (127x127mm), 52 pcs
H02142	HYGENIC Dental Dam, Latex, Medium, Green, 5'' x 5'' (127x127mm), 52 pcs
H02143	HYGENIC Dental Dam, Latex, Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H02144	HYGENIC Dental Dam Latex, Extra Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H02146	HYGENIC Dental Dam, Latex, Thin, Green, 6'' x 6'' (152x152mm), 36 pcs
H02147	HYGENIC Dental Dam, Latex, Medium, Green, 6'' x 6'' (152x152mm), 36 pcs
H02148	HYGENIC Dental Dam, Latex, Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H02149	HYGENIC Dental Dam, Latex, Extra Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H02778	HYGENIC FIESTA Winged Complete Kit, 1 pc
H02779	HYGENIC FIESTA Winged Standard Kit W/O Punch & Forceps, 1 pc
H02790	HYGENIC FIESTA Wingless Complete Kit, 1 pc
H02900	HYGENIC Simple Dam Kit - W/ Elasti-Dam, 1 pc
H03529	HYGENIC Dental Dam, Latex, Medium, Blue, 5'' x 5'' (127x127mm), 52 pcs
H03530	HYGENIC Dental Dam, Latex, Medium, Blue, 6'' x 6'' (152x152mm), 36 pcs
H04237	HYGENIC Dental Dam, Latex, Convenience Pack, Medium, Light, 5'' x 5'' (127x127mm), 364 pcs
H04241	HYGENIC Dental Dam, Latex, Convenience Pack, Medium, Green, 5'' x 5'' (127x127mm), 364 pcs

Kataloška št.	Opis
H04243	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Light, 6'' x 6'' (152x152mm), 360 pcs
H04245	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Dark, 6'' x 6'' (152x152mm), 360 pcs
H04247	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Green, 6'' x 6'' (152x152mm), 360 pcs
H04639	HYGENIC FIESTA Dental Dam, Thin, 6'' x 6'' (152x152mm), 36 pcs
H04640	HYGENIC FIESTA Dental Dam, Thin, 5'' x 5'' (127x127mm), 52 pcs
H04641	HYGENIC FIESTA Dental Dam, Medium, 5'' x 5'' (127x127mm), 52 pcs
H04642	HYGENIC FIESTA Dental Dam, Medium, 6'' x 6'' (152x152mm), 36 pcs
H04643	HYGENIC FIESTA Dental Dam, Heavy, 5'' x 5'' (127x127mm), 52 pcs
H04644	HYGENIC FIESTA Dental Dam, Heavy, 6'' x 6'' (152x152mm), 36 pcs
H07315	HYGENIC Dental Dam, Latex, Heavy, Blue, 6'' x 6'' (152x152mm), 36 pcs
H07316	HYGENIC FIESTA Dental Dam, Latex, Convenience Pack, Medium, 5'' x 5'' (127x127mm), 364 pcs
H07317	HYGENIC FIESTA Dental Dam, Latex, Convenience Pack, Medium, 6'' x 6'' (152x152mm), 360 pcs
H11624	HYGENIC Elasti-Dam, Medium, Green, 5'' x 5'' (127x127mm), 52 pcs
H11625	HYGENIC Elasti-Dam, Medium, Green, 6'' x 6'' (152x152mm), 36 pcs
H11626	HYGENIC Elasti-Dam, Medium, Blue, 5'' x 5'' (127x127mm), 52 pcs
H11627	HYGENIC Elasti-Dam, Medium, Blue, 6'' x 6'' (152x152mm), 36 pcs

Kataloška št.	Opis
H11675	HYGENIC Elasti-Dam, Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H11676	HYGENIC Elasti-Dam, Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H11677	HYGENIC Elasti-Dam, Heavy, Blue, 5'' x 5'' (127x127mm), 52 pcs
H11678	HYGENIC Elasti-Dam, Heavy, Blue, 6'' x 6'' (152x152mm), 36 pcs
H11690	HYGENIC Elasti-Dam Trial Pack, Medium, Green, 6'' x 6'' (152X152mm)

Opozorila in previdnostni ukrepi

Opozorila	Izjava
 **OPOZORILO!**	Neupoštevanje navodil v teh navodilih za uporabo lahko povzroči poškodbe pacienta ali ogrozi celovitost pripomočka Dental Dam. Izdelek uporabljajte samo v skladu s predvideno uporabo, glejte razdelek Predvidena uporaba.
	Pripomočka Dental Dam ne uporabljajte ponovno. Dental Dam je namenjen samo za enkratno uporabo. Ponovna interoralna uporaba pripomočka Dental Dam predstavlja biološko nevarnost in lahko povzroči navzkrižno kontaminacijo.
	Dental Dam pred uporabo preglejte. Izrabljen ali lomljiv Dental Dam zavrzite. Uporaba izdelka Dental Dam, ki je izgubil prvotne lastnosti, lahko povzroči izgubo funkcionalnosti ter ogrozi integriteto postopka.

Previdnostni ukrepi	Izjava
 **POZOR**	Pripomočka Dental Dam to ne izpostavljajte visokim temperaturam. Dental Dam hranite stran od virov toplote.
	Dental Dam ima omejen rok uporabe. Pripomočka ne uporabljajte po preteku roka uporabe, saj sta lahko njegova funkcionalnost in zmogljivost okrnjeni.
	Pozor: Zvezna zakonodaja (ZDA) omejuje prodajo tega pripomočka le stomatologom z licenco oziroma po njihovem naročilu.
	Ne hranite v bližini izdelkov brez lateksa.
	Neskladujte v blízkosti nelatexových produktov.

Dodatne informacije

Opomba: Pripomoček odstranite v skladu z lokalnimi, regionalnimi, nacionalnimi in/ali mednarodnimi predpisi. S pripomočki, ki se uporabljajo intraoralno, je treba ravnati kot z biološko nevarnimi pripomočki in jih je treba odstraniti v skladu z lokalnimi predpisi.

Opomba: Na zahtevo se brezplačno dostavi navodila za uporabo v papirni obliki.

Za uporabnike v EU: O kakršnem koli resnem incidentu, povezanem z uporabo pripomočka, je treba poročati družbi Coltène/Whaledent, Inc. in pristojnemu organu v državi članici, v kateri prebiva uporabnik in/ali pacient.

Glosar simbolov

Simbol	Ime in opis simbola
	Pozor
 www.coltene.com	Glejte elektronska navodila za uporabo – označuje, da mora uporabnik prebrati navodila za uporabo
MD	Medicinski pripomoček – pomeni, da je izdelek medicinski pripomoček
Rx ONLY	Omejena prodaja: pripomoček lahko kupijo samo stomatologi z licenco.
	Rok uporabe – označuje datum, po katerem se medicinskega pripomočka ne sme več uporabljati
REF	Kataloška številka – označuje kataloško številko proizvajalca, s pomočjo katere se lahko medicinski pripomoček identificira
	Ne uporabljajte ponovno – označuje medicinski pripomoček, predviden za uporabo pri enem pacientu med enim postopkom
CE	Oznaka CE
	Uvoznik – označuje subjekt, ki uvaža medicinski pripomoček na lokalni trg
	Proizvajalec – označuje proizvajalca medicinskega pripomočka

Simbol	Ime in opis simbola
LOT	Koda serije – označuje kodo serije proizvajalca, ki omogoča identifikacijo serije ali lota
EC REP	Pooblaščeni predstavnik v Evropski skupnosti – označuje pooblaščenega predstavnika v Evropski skupnosti
LATEX	Vsebuje lateks iz naravnega kavčuka – označuje prisotnost lateksa iz suhega naravnega kavčuka kot konstrukcijskega materiala v medicinskem pripomočku.

Shranjevanje

Izdelek Dental Dam shranjujte pri temperaturi med 32 °F in 80 ^{0}F (od 0 °C do 26 °C).
Izdelek hranite na suhem in stran od virov vročine.

Simbol	Ime in opis simbola
	Hraniti na suhem – označuje medicinski pripomoček, ki ga je treba zaščititi pred vlago
	Hraniti ločeno od vročine – označuje medicinski pripomoček, ki ga je treba zaščititi pred vročino
	Omejitev temperature – označuje omejitve temperature, ki ji je lahko medicinski pripomoček varno izpostavljen Zgornja in spodnja omejitev temperature morata biti navedeni poleg zgornje in spodnje vodoravne črte.

HYGENIC

Latex Dental Dam

Bruksanvisning

LATEX

Rx ONLY

COLTENE

Avsedd användning/användningsområde:
Dental Dam är avsedd att användas intraoralt för att isolera en eller flera tänder och skapa en barriär mot omgivningen under behandlingen.

K**ontraindikationer:**
Dental Dam med latex ska ej användas på patienter som är allergiska mot latex.

Avsedd användare:
• Legitimerade tandläkare och tandhygienister
• Tandsköterskor

Patientgrupp(er):
Lämplig för alla patientgrupper.

Kliniska fördelar:
Att använda Dental Dam ger följande kliniska fördelar:
• Ökad överskådlighet genom isolering av tanden/tänderna
• Minskad risk för att patienten ska aspirera eller svälja instrument, tandrester, läkemedel eller sköljvätskor
• Skapar ett torrt arbetsområde
• Mjukvävnaden skyddas från kontakt med instrument
• Barriär för infektionsskydd

Egenskaper:
• Finns i olika färger och tjocklekar
• Två storlekar: 127 mm x 127 mm eller 152 mm x 152 mm (5″ x 5″ eller 6″ x 6″)
• De ljusare färgerna ger fördelar genom att lysa upp operationsområdet på ett naturligt sätt medan de mörkare färgerna kan förbättra den visuella kontrasten

Förvaring:
Förvara Dental Dam mellan 0–26 °C (32–80 °F).
Förvaras torrt och åtskilt från värme.

Kvarstående risker, varningar och försiktighetsåtgärder:
Se avsnittet Varningar och försiktighetsåtgärder för riskbedömning vid användning av Dental Dam enligt Avsedd användning.

Bruksanvisning

FÖRSIKTIGHET! Denna produkt innehåller naturgummilatex, vilket kan orsaka allergiska reaktioner.

Dental Dam är avsett att användas tillsammans med flera andra produkter inklusive klamrar och kofferdamhållare.

Se bruksanvisningarna för övriga produkter som används.

Följande allmänna metod ges som vägledning och kan anpassas till det specifika fallet:

Steg 1: Fastställ operationsområdet.

Steg 2: Förbered Dental Dam.
• Bestäm hålens placering
• Markera hålens placering
• Gör hål med håltången

Steg 3: Välj klammer/förankring

Steg 4: Sätt fast klammern/förankringen

Steg 5: Placera Dental Dam

Stycklista

Obs: Alla katalognummer är inte tillgängliga i alla regioner

Katalognr	Beskrivning
390020	ROEKO Dental Dam, Latex, Thin, 36 pcs
390021	ROEKO Dental Dam, Latex, Medium, 36 pcs
390022	ROEKO Dental Dam, Latex, Heavy, 36 pcs
60013793	ROEKO Elasti-Dam, 152x152mm, Medium, Green, 36 pcs
60013794	ROEKO Elasti-Dam, 152x152mm, Heavy, Green, 36 pcs
60013870	Sample ROEKO Elasti-Dam, 152x 52mm, Medium, Green
60013795	ROEKO Elasti-Dam, 127x127mm, Medium, Blue, 36 pcs
60013796	ROEKO Elasti-Dam, 127x127mm, Heavy, Blue, 36 pcs
H00523	HYGENIC Dental Dam, Latex, Thin, Light, 5'' x 5'' (127x127mm), 52 pcs
H00524	HYGENIC Dental Dam, Latex, Medium, Light, 5'' x 5'' (127x127mm), 52 pcs
H00525	HYGENIC Dental Dam, Latex, Heavy, Light, 5'' x 5'' (127x127mm), 52 pcs
H00533	HYGENIC Dental Dam, Latex, Thin, Light, 6'' x 6'' (152 x152mm), 36 pcs
H00534	HYGENIC Dental Dam, Latex, Medium, Light, 6'' x 6'' (152x152mm), 36 pcs
H00535	HYGENIC Dental Dam, Latex, Heavy, Light, 6'' x 6'' (152x152mm), 36 pcs
H00536	HYGENIC Dental Dam, Latex, Extra Heavy, Light, 6'' x 6'' (152x152mm), 36 pcs
H00538	HYGENIC Dental Dam, Latex, Thin, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00539	HYGENIC Dental Dam, Latex, Medium, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00540	HYGENIC Dental Dam, Latex, Heavy, Dark, 6'' x 6'' (152x152mm), 36 pcs

Katalognr	Beskrivning
H00541	HYGENIC Dental Dam, Latex, Extra Heavy, Dark, 6'' x 6'' (152x152mm), 36 pcs
H02141	HYGENIC Dental Dam, Latex, Thin, Green, 5'' x 5'' (127x127mm), 52 pcs
H02142	HYGENIC Dental Dam, Latex, Medium, Green, 5'' x 5'' (127x127mm), 52 pcs
H02143	HYGENIC Dental Dam, Latex, Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H02144	HYGENIC Dental Dam Latex, Extra Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H02146	HYGENIC Dental Dam, Latex, Thin, Green, 6'' x 6'' (152x152mm), 36 pcs
H02147	HYGENIC Dental Dam, Latex, Medium, Green, 6'' x 6'' (152x152mm), 36 pcs
H02148	HYGENIC Dental Dam, Latex, Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H02149	HYGENIC Dental Dam, Latex, Extra Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H02778	HYGENIC FIESTA Winged Complete Kit, 1 pc
H02779	HYGENIC FIESTA Winged Standard Kit W/O Punch & Forceps, 1 pc
H02790	HYGENIC FIESTA Wingless Complete Kit, 1 pc
H02900	HYGENIC Simple Dam Kit - W/ Elasti-Dam, 1 pc
H03529	HYGENIC Dental Dam, Latex, Medium, Blue, 5'' x 5'' (127x127mm), 52 pcs
H03530	HYGENIC Dental Dam, Latex, Medium, Blue, 6'' x 6'' (152x152mm), 36 pcs
H04237	HYGENIC Dental Dam, Latex, Convenience Pack, Medium, Light, 5'' x 5'' (127x127mm), 364 pcs
H04241	HYGENIC Dental Dam, Latex, Convenience Pack, Medium, Green, 5'' x 5'' (127x127mm), 364 pcs
H04243	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Light, 6'' x 6'' (152x152mm), 360 pcs

Katalognr	Beskrivning
H04245	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Dark, 6'' x 6'' (152x152mm), 360 pcs
H04247	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Green, 6'' x 6'' (152x152mm), 360 pcs
H04639	HYGENIC FIESTA Dental Dam, Thin, 6'' x 6'' (152x152mm), 36 pcs
H04640	HYGENIC FIESTA Dental Dam, Thin, 5'' x 5'' (127x127mm), 52 pcs
H04641	HYGENIC FIESTA Dental Dam, Medium, 5'' x 5'' (127x127mm), 52 pcs
H04642	HYGENIC FIESTA Dental Dam, Medium, 6'' x 6'' (152x152mm), 36 pcs
H04643	HYGENIC FIESTA Dental Dam, Heavy, 5'' x 5'' (127x127mm), 52 pcs
H04644	HYGENIC FIESTA Dental Dam, Heavy, 6'' x 6'' (152x152mm), 36 pcs
H07315	HYGENIC Dental Dam, Latex, Heavy, Blue, 6'' x 6'' (152x152mm), 36 pcs
H07316	HYGENIC FIESTA Dental Dam, Latex, Convenience Pack, Medium, 5'' x 5'' (127x127mm), 364 pcs
H07317	HYGENIC FIESTA Dental Dam, Latex, Convenience Pack, Medium, 6'' x 6'' (152x152mm), 360 pcs
H11624	HYGENIC Elasti-Dam, Medium, Green, 5'' x 5'' (127x127mm), 52 pcs
H11625	HYGENIC Elasti-Dam, Medium, Green, 6'' x 6'' (152x152mm), 36 pcs
H11626	HYGENIC Elasti-Dam, Medium, Blue, 5'' x 5'' (127x127mm), 52 pcs
H11627	HYGENIC Elasti-Dam, Medium, Blue, 6'' x 6'' (152x152mm), 36 pcs
H11675	HYGENIC Elasti-Dam, Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H11676	HYGENIC Elasti-Dam, Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H11677	HYGENIC Elasti-Dam, Heavy, Blue, 5'' x 5'' (127x127mm), 52 pcs

Katalognr	Beskrivning
H11678	HYGENIC Elasti-Dam, Heavy, Blue, 6'' x 6'' (152x152mm), 36 pcs
H11690	HYGENIC Elasti-Dam Trial Pack, Medium, Green, 6'' x 6'' (152X152mm)

Varningar & försiktighetsåtgärder

Varningar	Uttalande
 **VARNING!**	Om instruktionerna i denna bruksanvisning inte följs korrekt kan det leda till att patienten skadas eller till defekter i Dental Dam. Använd endast produkten enligt avsedd användning, se Avsedd användning.
	Återanvänd inte Dental Dam. Dental Dam är endast avsedd för engångsbruk. Återanvändning av Dental Dam intraoralt utgör en biologisk risk och kan orsaka korskontamination.
	Dental Dam ska inspekteras före användning. Kassera trasiga eller spröda Dental Dam. Användning av Dental Dam som förlorat sina egenskaper kan ge försämrad funktion och omöjliggöra aseptiskt arbete.

Försiktighetsåtgärder	Uttalande
 FORSIKTIGHET	Denna produkt innehåller naturgummilatex, vilket kan orsaka allergiska reaktioner.
	Utsätt inte Dental Dam för höga temperaturer. Förvara Dental Dam avskilt från värmekällor.
	Dental Dam har en specifik hållbarhetstid. Använd inte produkten efter sista användningsdatum eftersom produktens funktion och prestanda inte kan garanteras.
	Varning: Amerikansk federal lagstiftning begränsar försäljningen av den här produkten till eller på beställning av legitimerad tandläkare.
	Förvara inte produkten nära latexfria produkter.

Övrig information

Anmärkning: Hantera avfall enligt lokal, nationell och/eller internationell lagstiftning. Produkter som använts intraoralt ska behandlas som riskavfall och kasseras korrekt enligt lokal lagstiftning.

Anmärkning: Vi tillhandahåller gratis en inbunden kopia av bruksanvisningen på förfrågan.

För användare inom EU: Rapportera alla allvarliga händelser som ägt rum vid användning av denna produkt till Coltène/Whaledent, Inc. och till behörig myndighet i det medlemsland där användaren och/eller patienten är etablerad.

Symbolförklaring

Symbol	Titel och beskrivning av symbol
	Försiktighet
 www.coltene.com	Läs den elektroniska bruksanvisningen – anger att användaren måste läsa bruksanvisningen
	Medicinteknisk produkt – anger att varan är en medicinteknisk produkt
	Begränsad försäljning: inköp av denna produkt är begränsad till legitimerad hälso- och sjukvårdspersonal.
	Sista användningsdatum – anger datumet efter vilket den medicintekniska produkten inte ska användas
	Katalognummer – anger tillverkarens katalognummer så att den medicintekniska produkten kan identifieras
	Får inte återanvändas – anger en medicinteknisk produkt ämnad för bruk för en enda patient vid ett enda behandlingstillfälle
	CE-märkning
	Importör – anger företaget som importerar den medicintekniska produkten till det lokala området
	Tillverkare – anger tillverkaren av den medicintekniska produkten

Symbol	Titel och beskrivning av symbol
	Satsnummer – anger tillverkarens satsnummer så att satsen kan identifieras
	Auktoriserad representant inom EU – anger den auktoriserade representanten inom Europeiska Unionen
	Innehåller latex – anger att torrt naturlatex ingår som material i den medicintekniska produkten.

Förvaring

Förvara Dental Dam mellan 0–26 °C (32–80 °F).
Förvaras torrt och åtskilt från värme.

Symbol	Titel och beskrivning av symbol
	Förvaras torrt – anger en medicinteknisk produkt som ska skyddas mot fukt
	Skyddas mot hög värme – anger en medicinteknisk produkt som ska skyddas mot hög värme
	Temperaturgränser – anger inom vilka temperaturgränser den medicintekniska produkten säkert kan exponeras. De övre och undre temperaturgränserna ska anges bredvid de övre och undre horisontella linjerna.

HYGENIC

Latex Dental Dam

Kullanma Talimatları

LATEX

Rx ONLY

COLTENE

Kullanım Amacı / Endikasyonlar:
Dental Dam, bir dental prosedür sırasında bir veya daha fazla dişi izole etmek ve çevredeki alana karşı bir bariyer oluşturmak için intraoral olarak kullanılmak üzere tasarlanmıştır.

Kontrendikasyonlar:
Lateks Dental Dam, lateks alerjisi olan hastalar üzerinde kullanılmamalıdır.

Amaçlanan Kullanıcılar:
• Diş Hekimleri
• Diş Hekimi Asistanları

Hedef Hasta Grupları:
Tüm hasta grupları için uygundur.

Klinik Faydalar:
Dental Dam kullanımı aşağıdaki klinik faydaları sağlar:
• Dişin/dişlerin izolasyonu sayesinde artan görünürlük
• Hastanın aletleri, diş debrisini, ilaçları veya irrigasyon çözeltilerini aspire etme veya yutma riskinin azalması
• Kuru bir çalışma alanının oluşturulması
• Yumuşak dokunun aletlerle temasa karşı korunması
• Enfeksiyon kontrolü bariyeri

Karakteristikler:
• Farklı renklerde ve kalınlıklarda mevcuttur
• İki farklı ebatta sunulur: 127 mm x 127 mm veya 152 mm x 152 mm
• Açık renkler operasyon alanını doğal olarak aydınlatma avantajını sunarken, koyu renkler görsel bir kontrast oluşturmaya yardımcı olabilir

Saklama:
Dental Dam 0°C – 26°C arası sıcaklıklarda saklanmalıdır.
Kuru halde ve ısıdan uzak bir yerde tutun.

Kalıntı Riskler, Uyarılar ve Önlemler:
Dental Dam'ın Kullanım Amacına uygun kullanılmasıyla ilgili risklerin açıklaması için Uyarılar ve Önlemler bölümüne başvurun.

Talimatlar

DİKKAT! Bu ürün, alerjik reaksiyonlara yol açabilecek doğal kauçuk lateks içerir.

Dental Dam, klempler ve çerçeveler dahil olmak üzere diğer çeşitli araçlarla birlikte kullanılmak için tasarlanmıştır.

Kullanılan diğer cihazlar için kendi kullanma talimatlarına başvurun.

Aşağıdaki genel adımlar yol göstermek amacıyla verilmiştir ve özel duruma göre uyarlanabilir:

Adım 1: Operasyon Alanını belirleyin.

Adım 2: Dental Dam'ı hazırlayın.
• Delik pozisyonlarını belirleyin
• Delik pozisyonlarını işaretleyin
• Delikleri açın

Adım 3: Klempi/Sabitleyiciyi seçin

Adım 4: Klempi/Sabitleyiciyi uygulayın

Adım 5: Dental Dam'ı yerleştirin

Parça Listesi

Not: Tüm Katalog Numaraları tüm bölgelerde mevcut değildir

Katalog no.	Açıklama
390020	ROEKO Dental Dam, Latex, Thin, 36 pcs
390021	ROEKO Dental Dam, Latex, Medium, 36 pcs
390022	ROEKO Dental Dam, Latex, Heavy, 36 pcs
60013793	ROEKO Elasti-Dam, 152x152mm, Medium, Green, 36 pcs
60013794	ROEKO Elasti-Dam, 152x152mm, Heavy, Green, 36 pcs
60013870	Sample ROEKO Elasti-Dam, 152x 52mm, Medium, Green
60013795	ROEKO Elasti-Dam, 127x127mm, Medium, Blue, 36 pcs
60013796	ROEKO Elasti-Dam, 127x127mm, Heavy, Blue, 36 pcs
H00523	HYGENIC Dental Dam, Latex, Thin, Light, 5'' x 5'' (127x127mm), 52 pcs
H00524	HYGENIC Dental Dam, Latex, Medium, Light, 5'' x 5'' (127x127mm), 52 pcs
H00525	HYGENIC Dental Dam, Latex, Heavy, Light, 5'' x 5'' (127x127mm), 52 pcs
H00533	HYGENIC Dental Dam, Latex, Thin, Light, 6'' x 6'' (152 x152mm), 36 pcs
H00534	HYGENIC Dental Dam, Latex, Medium, Light, 6'' x 6'' (152x152mm), 36 pcs
H00535	HYGENIC Dental Dam, Latex, Heavy, Light, 6'' x 6'' (152x152mm), 36 pcs
H00536	HYGENIC Dental Dam, Latex, Extra Heavy, Light, 6'' x 6'' (152x152mm), 36 pcs
H00538	HYGENIC Dental Dam, Latex, Thin, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00539	HYGENIC Dental Dam, Latex, Medium, Dark, 6'' x 6'' (152x152mm), 36 pcs
H00540	HYGENIC Dental Dam, Latex, Heavy, Dark, 6'' x 6'' (152x152mm), 36 pcs

Katalog no.	Açıklama
H00541	HYGENIC Dental Dam, Latex, Extra Heavy, Dark, 6'' x 6'' (152x152mm), 36 pcs
H02141	HYGENIC Dental Dam, Latex, Thin, Green, 5'' x 5'' (127x127mm), 52 pcs
H02142	HYGENIC Dental Dam, Latex, Medium, Green, 5'' x 5'' (127x127mm), 52 pcs
H02143	HYGENIC Dental Dam, Latex, Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H02144	HYGENIC Dental Dam Latex, Extra Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H02146	HYGENIC Dental Dam, Latex, Thin, Green, 6'' x 6'' (152x152mm), 36 pcs
H02147	HYGENIC Dental Dam, Latex, Medium, Green, 6'' x 6'' (152x152mm), 36 pcs
H02148	HYGENIC Dental Dam, Latex, Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H02149	HYGENIC Dental Dam, Latex, Extra Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H02778	HYGENIC FIESTA Winged Complete Kit, 1 pc
H02779	HYGENIC FIESTA Winged Standard Kit W/O Punch & Forceps, 1 pc
H02790	HYGENIC FIESTA Wingless Complete Kit, 1 pc
H02900	HYGENIC Simple Dam Kit - W/ Elasti-Dam, 1 pc
H03529	HYGENIC Dental Dam, Latex, Medium, Blue, 5'' x 5'' (127x127mm), 52 pcs
H03530	HYGENIC Dental Dam, Latex, Medium, Blue, 6'' x 6'' (152x152mm), 36 pcs
H04237	HYGENIC Dental Dam, Latex, Convenience Pack, Medium, Light, 5'' x 5'' (127x127mm), 364 pcs
H04241	HYGENIC Dental Dam, Latex, Convenience Pack, Medium, Green, 5'' x 5'' (127x127mm), 364 pcs
H04243	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Light, 6'' x 6'' (152x152mm), 360 pcs

Katalog no.	Açıklama
H04245	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Dark, 6'' x 6'' (152x152mm), 360 pcs
H04247	HYGENIC Dental Dam Latex, Convenience Pack, Medium, Green, 6'' x 6'' (152x152mm), 360 pcs
H04639	HYGENIC FIESTA Dental Dam, Thin, 6'' x 6'' (152x152mm), 36 pcs
H04640	HYGENIC FIESTA Dental Dam, Thin, 5'' x 5'' (127x127mm), 52 pcs
H04641	HYGENIC FIESTA Dental Dam, Medium, 5'' x 5'' (127x127mm), 52 pcs
H04642	HYGENIC FIESTA Dental Dam, Medium, 6'' x 6'' (152x152mm), 36 pcs
H04643	HYGENIC FIESTA Dental Dam, Heavy, 5'' x 5'' (127x127mm), 52 pcs
H04644	HYGENIC FIESTA Dental Dam, Heavy, 6'' x 6'' (152x152mm), 36 pcs
H07315	HYGENIC Dental Dam, Latex, Heavy, Blue, 6'' x 6'' (152x152mm), 36 pcs
H07316	HYGENIC FIESTA Dental Dam, Latex, Convenience Pack, Medium, 5'' x 5'' (127x127mm), 364 pcs
H07317	HYGENIC FIESTA Dental Dam, Latex, Convenience Pack, Medium, 6'' x 6'' (152x152mm), 360 pcs
H11624	HYGENIC Elasti-Dam, Medium, Green, 5'' x 5'' (127x127mm), 52 pcs
H11625	HYGENIC Elasti-Dam, Medium, Green, 6'' x 6'' (152x152mm), 36 pcs
H11626	HYGENIC Elasti-Dam, Medium, Blue, 5'' x 5'' (127x127mm), 52 pcs
H11627	HYGENIC Elasti-Dam, Medium, Blue, 6'' x 6'' (152x152mm), 36 pcs
H11675	HYGENIC Elasti-Dam, Heavy, Green, 5'' x 5'' (127x127mm), 52 pcs
H11676	HYGENIC Elasti-Dam, Heavy, Green, 6'' x 6'' (152x152mm), 36 pcs
H11677	HYGENIC Elasti-Dam, Heavy, Blue, 5'' x 5'' (127x127mm), 52 pcs

Katalog no.	Açıklama
H11678	HYGENIC Elasti-Dam, Heavy, Blue, 6'' x 6'' (152x152mm), 36 pcs
H11690	HYGENIC Elasti-Dam Trial Pack, Medium, Green, 6'' x 6'' (152X152mm)

Uyarılar ve Önlemler

Uyarılar	Beyan
 **UYARI!**	Bu Kullanma Talimatlarındaki talimatlara gerektiği gibi uyulmaması, hastanın yaralanmasına veya dental dam bütünlüğünün tehlikeye girmesine neden olabilir. Ürünü sadece kullanım amacı doğrultusunda kullanın, bkz. Kullanım Amacı.
	Dental Dam'ı tekrar kullanmayın. Dental Dam sadece tek seferlik kullanım için tasarlanmıştır. Dental Dam'ın ağız içinde tekrar kullanılması biyolojik bir tehlikedir ve çapraz kontaminasyona neden olabilir.
	Dental Dam kullanımdan önce gözden geçirilmelidir. Yırtık veya kırılganlaşmış Dental Dam'ları atın. Performans özelliklerini kaybetmiş bir Dental Dam'ın kullanılması, işlevsellik kaybına yol açabilir ve prosedürün bütünlüğünü tehlikeye atabilir.

Önlemler	Beyan
 DİKKAT	Bu ürün, alerjik reaksiyonlara yol açabilecek doğal kauçuk lateks içerir.
	Dental Dam yüksek sıcaklıklara maruz bırakılmamalıdır. Dental Dam ısı kaynaklarından uzak bir yerde saklanmalıdır.
	Dental Dam belirli bir raf ömrüne sahiptir. Son Kullanma Tarihi geçmiş olan cihazları kullanmayın; aksi takdirde cihazın işlevselliği ve performans özellikleri tehlikeye girebilir.
	Dikkat: ABD federal kanunlarına göre, bu cihaz yalnızca lisanslı bir sağlık çalışanı tarafından veya lisanslı bir sağlık çalışanının siparişi üzerine satılabilir
	Latekssiz ürünlerin yakınında saklamayın.

Ek Bilgiler

Not: Cihazı yerel, bölgesel, ulusal ve/veya uluslararası düzenlemelere uygun olarak atın. İntraoral kullanılan cihazlar biyolojik tehlike olarak ele alınmalı ve yerel yönetmeliklere göre uygun şekilde atılmalıdır.

Not: Talep üzerine, Kullanma Talimatlarının basılı bir kopyası ücretsiz olarak sağlanacaktır.

AB'de yerleşik kullanıcılar için: Cihazın kullanımıyla ilgili olarak meydana gelen her türlü ciddi olay, Coltène/Whaledent Inc. şirketine ve kullanıcının ve/veya hastanın yerleşik olduğu üye devletin yetkili makamına bildirilmelidir.

Simgeler Sözlüğü

Simge	Simgenin Başlığı ve Tanımı
	Dikkat
 www.coltene.com	Elektronik kullanma talimatlarına başvurun - Kullanıcının kullanma talimatlarına başvurması gerektiğini belirtir
	Tıbbi Cihaz – Ürünün bir tıbbi cihaz olduğunu belirtir
	Satış Kısıtlaması: Cihazın satın alımı sadece lisanslı sağlık uzmanları ile kısıtlıdır.
	Son Kullanma Tarihi - Tıbbi cihazın hangi tarihten sonra kullanılmaması gerektiğini belirtir
	Katalog Numarası - Tıbbi cihazın tanımlanabilmesi için üreticinin katalog numarasını belirtir
	Tekrar kullanmayın - Tek hasta üzerinde, tek bir işlem için kullanılmak üzere tasarlanmış bir tıbbi cihazı belirtir
	CE işareti
	İthalatçı - Tıbbi cihazı yerel pazara ithal etmiş olan kuruluşu belirtir
	Üretici - Tıbbi cihazın üretici firmasını belirtir

Simge	Simgenin Başlığı ve Tanımı
	Parti kodu - Parti veya lotun tanımlanabilmesi için üreticinin parti kodunu belirtir
	Avrupa Topluluğu yetkili temsilcisi - Avrupa Topluluğu'ndaki yetkili temsilciyi belirtir
	Doğal kauçuk lateks içerir - Tıbbi ürünün içinde bir yapı malzemesi olarak kuru doğal kauçuk lateks bulunduğunu belirtir.

Saklama

Dental Dam 0°C – 26°C arası sıcaklıklarda saklanmalıdır.
Kuru halde ve ısıdan uzak bir yerde tutun.

Simge	Simgenin Başlığı ve Tanımı
	Kuru tutun - Nemden korunması gereken bir tıbbi cihazı belirtir
	Isıdan uzak tutun - Isıya karşı korunması gereken bir tıbbi cihazı belirtir
	Sıcaklık Sınırı - Tıbbi cihazın güvenli bir şekilde maruz kalabileceği sıcaklık sınırlarını belirtir. Sıcaklık üst ve alt sınırları, üst ve alt yatay çizgilere bitişik olarak gösterilecektir.

CE MD

Coltène/Whaledent, Inc.
235 Ascot Parkway
Cuyahoga Falls, OH 44223 / USA
Tel: USA & Canada 1 800 221 3046
+1 330 916 8800
Fax: +1 330 645 8704
info.us@coltene.com

Coltène/Whaledent GmbH + Co. KG EC REP
Raiffeisenstrasse 30
89129 Langenau / Germany
Tel. +49 (0)7345 805 0
Fax +49 (0)7345 805 201
info.de@coltene.com

Made in USA
P/N 20005544A
Date of issue: 06/01/2021

COLTENE