

HYGENIC Dental Dam Punch

Instructions for Use

Rx ONLY

 **COLTENE**

Dental Dam Punch

Intended Use/ Indications for Use:

The Dental Dam Punch is intended to create a hole of a specific size in a Dental Dam to allow a tooth to pass through.

Contraindications:

There are no known contraindications.

Intended Users:

- Dental Practitioners
- Dental Assistants

Patient Target Group(s)

The Dental Dam Punch is not used on or by patients.

Clinical Benefits:

The Dental Dam Punch is used in combination with Dental Dam to achieve 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:

- Stainless Steel Construction

- Ainsworth Style Punch Disc has 5 holes of graduating size to accommodate all teeth
- Autoclavable

Residual Risks, Warnings and Precautions:

Refer to the Warnings and Precautions section for disclosure of risk associated with the use of the device in line with its Intended Use.

Instructions

WARNING! Clean and sterilize the punch prior to use according to the instructions below.

CAUTION! Inspect the punch prior to use. The punch pin must be sharp and clean so the Dental Dam will not nick or tear. Discard distorted, worn or cracked punches.

Note: To avoid premature wear, use the Dental Dam Punch only with HYGENIC Dental Dam.

Instructions:

Determine Hole positions:

The appropriate positions for the holes can be determined using a HYGENIC Dental Dam Template.

Marking Hole Positions:

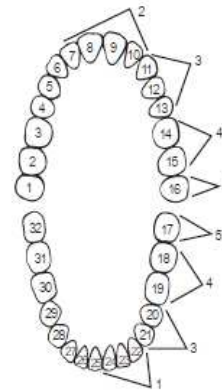
If using a template, place the Dental Dam on top of the template and mark the holes using a felt-tip pen.

Punching Holes:

Proper punching includes proper alignment of the punch table with the pin, alignment of the pin with the hole mark on the dam, and punching; then, pulling the dam up over the point of the punch.

1. Using the punch disc, select the appropriate hole size (1-5) for the tooth to be included in your isolation (See Diagram).
2. Align the pin with the hole marks on the dam, puncture the dam material while pulling the dam up and over the point of the punch.
3. Repeat for any remaining holes.

4. Remove any remaining rubber from holes in the punch disc with a sharp instrument.
5. Rinse and clean immediately following the procedure. Refer to Cleaning and Sterilization Instructions below.



Note: An improperly cut hole will result in a nick or tag which may cause the dam to rip while it is being placed. Refer the figure below. Consistent nicks or tags may be indicative of a dull punch. A dull punch should be replaced to reduce the risk of a rip in the Dental Dam.



Cleaning and Sterilization Instructions:

Presoak/ Rinsing

Rinse and clean immediately following the procedure. The device should be rinsed under warm running water to remove most blood, fluids and tissue from the instrument. If the device cannot be cleaned immediately, soak instruments in a neutral pH cleaning solution like BioSonic® UC30 or UC32.

Ultrasonic Cleaning (preferred)

Follow the ultrasonic cleaner manufacturer's instructions for use. Rinse and remove excess material according to the Presoak/ Rinsing instructions prior to ultrasonic cleaning. Use a pH neutral, general purpose cleaning solution such as, but not limited to BioSonic UC30 or UC32. All instruments should be completely submerged in the cleaner bath. Hinged instruments should be cleaned in the open position. For cleaning times, follow the instructions listed on the cleaning solution's label.

Following Ultrasonic Cleaning, rinse cleaning agents from instruments. Inspect to see that all debris has been removed from instrument. Repeat if necessary. Allow instrument to dry.

Manual Cleaning

Always wear appropriate Personal Protective Equipment (PPE) while handling used dental equipment. Use a stiff nylon cleaning brush to carefully scrub the instrument. Use of a stainless-steel wire brush or steel wool will damage the instrument. Use a pH neutral cleaning solution such as, but not limited to BioSonic UC30 or UC32.

Following manual cleaning, rinse cleaning agents from instruments. Inspect to see that all debris has been removed from instrument. Repeat if necessary. Allow instrument to dry.

Sterilization

CAUTION! Do not use Chemical Disinfection or Cold Sterilization methods as these methods can cause premature failure of the punch.

Ensure blood, dried bodily fluids and tissues are removed from the device prior to sterilization. Follow autoclave manufacturer's instructions for use and ensure that maximum load is not exceeded.

Lubricate hinged instruments with a non-silicone water soluble lubricant. Disposable sterilization pouches are recommended. Sterilize the punch according to the parameters below:

Gravity Autoclave	15 minutes at 132°C / 270°F
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CAUTION! Do not heat punches above 177°C/350°F.

Allow instrument to dry. Make sure instruments are dry before storing.

Staining

From time to time, instruments discolor during the cleaning process. Often this is misinterpreted as rust. Black stains are indicative that the pH of the cleaning solution was too low (acidic). Brown stains are indicative that the pH of the cleaning solution was too high (basic). Proper rinsing and drying of the instruments prior to autoclaving should reduce the risk of instrument staining. Dissimilar metals

should be cleaned and autoclaved separately as cleaning or autoclaving together can cause galvanic staining where the two instruments were touching.


Parts List


Catalog #	Description
H01261	HYGENIC Dental Dam Punch (Ainsworth-Styled, Stainless Steel), 1 pc

Other HYGENIC Dental Dam Products











The Dental Dam Punch is intended to be used with HYGENIC Dental Dam. When using Flexi Dam® Non-Latex Dental Dam, it is advisable to punch one-hole size smaller than recommended for latex dam.


Warnings & 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 <i>Intended Use</i> .
	Clean and sterilize the punch prior to use.

Precautions	Statement
 CAUTION	Inspect the punch pin prior to use. The punch must be sharp and clean so the Dental Dam will not nick or tear. Discard distorted, worn or cracked punches.
	Do not use Chemical Disinfection or Cold Sterilization methods as these methods can cause premature failure of the punch.
	Caution: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare practitioner.

Symbols 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
	Medical Device – Indicates the item is a medical device
	Sale Restricted: The purchase of the device is restricted to licensed healthcare practitioners only.
	Catalog Number - Indicates the manufacturer's catalogue number so that the medical device can be identified
	CE mark
	Importer - Indicates the entity importing the medical device into the locale
	Manufacturer - Indicates the medical device manufacturer
	Date of Manufacture - Indicates the date when the medical device was manufactured.
	Batch code - Indicates the manufacturer's batch code so that the batch or lot can be identified

Symbol	Title and Description of Symbol
	Authorized representative in the European Community - Indicates the authorized representative in the European Community

Storage

No additional storage requirements.

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.

Note: Refer to www.coltene.com for the latest revision of the Instructions for Use.

HYGENIC Dental Dam Punch



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Made in USA

Creation Date: 05/05/2021
P/N: 20005551A

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