

# **HYGENIC Dental Dam Clamp Forceps**

Instructions for Use

**Rx ONLY**

 **COLTENE**

# Clamp Forceps

## Intended Use/ Indications for Use:

Dental Dam Clamp Forceps are intended to be used for the insertion and removal of Dental Dam Clamps.

## Contraindications:

There are no known contraindications.

## Intended Users:

- Dental Practitioners
- Dental Assistants

## Patient Target Group(s)

Clamp Forceps are suitable for all patient groups.

## Clinical Benefits:

The Clamp Forceps are used in combination with Dental Dam clamps and thus 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
- Can be used with both Winged and Wingless Clamps
- 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 forceps prior to use according to the instructions below.

**CAUTION!** Inspect forceps prior to use. Discard distorted, worn or cracked forceps.

### Instructions:

1. Engage the clamp by placing the tips of the forceps into the holes in the clamp.
2. To reduce use error, ensure the forceps have properly engaged the clamp prior to placing the clamp.
3. Spread forceps open so that slight tension is applied to the clamp. Overextension could cause distortion and premature wear.
4. Place the clamp according to the manufacturer's instructions for use.
5. Remove forceps from clamp.
6. Rinse and clean immediately following the procedure. Refer to Cleaning and Sterilization Instructions below.

### 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. Ultrasonic cleaning solutions should be changed at least daily and more often if the solution in the tank becomes visibly dirty.

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 forceps.

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 Clamp Forceps according to the parameters below:

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

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

### Staining

Stains on Instruments - 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
H01262	HYGENIC Clamp Forceps, 1 pc



## Other HYGENIC Dental Dam Products





The Clamp Forceps are intended to be used with HYGENIC Dental Dam Clamps.

Dental Dam Forceps are manufactured with a comfortable grip and allow the user to safely and accurately position dental dam clamps. They are light-weight and produced in a matte finish to reduce eye fatigue and glare from operatory lighting arrangements.











Dental Dam clamps focus are manufactured from high quality stainless steel for greater durability. They are available in gloss and matte finish and the Fiesta® clamps are color coded for ease-of-use.

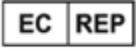
## Warnings & Precautions

Warnings	Statement
 <b>WARNING!</b>	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> .
 <b>WARNING!</b>	Clean and sterilize forceps prior to use.

Precautions	Statement
 <b>CAUTION</b>	To reduce use error, ensure the forceps have properly engaged the clamp prior to placing the clamp.
 <b>CAUTION</b>	Inspect forceps prior to use. Discard distorted, worn or cracked forceps.
 <b>CAUTION</b>	Do not use Chemical Disinfection or Cold Sterilization methods as these methods can cause premature failure of the forceps.
 <b>CAUTION</b>	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
 <a href="http://www.coltene.com">www.coltene.com</a>	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.

**Note:** 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.

# HYGENIC Dental Dam Clamp Forceps



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