

INSTRUCTIONS FOR USE

Reusable Shaver Blade

1. DESCRIPTION

Entellus Medical offers several types of Reusable Shaver Blades. Reusable Shaver Blades are made of stainless steel and may be used for up to 20 procedures. The Shaver Blade package contents include one Shaver Blade, one cleaning brush and one IFU.



⚠ Shaver Blades are intended solely and exclusively to be used along with the Entellus Medical Shaver System Handpiece.

⚠ These operating instructions apply only to Shaver Blades Reusable, recognizable by their stainless steel casing, and not Shaver Blades Single Use with white plastic casing.

2. INTENDED USE

The Shaver Blades are designed for shaping bone and the resection of soft and hard tissues as part of surgical procedures in the areas of otorhinolaryngology.

3. CONTRAINDICATIONS

None known

4. WARNINGS AND PRECAUTIONS

The technical specifications, illustrations and dimensions contained in these instructions are given only as a reference. The manufacturer reserves the right to bring technical improvements to this device without modifying the present instructions.

- Do not use breached or damaged packages, since the sterility and functionality of the Shaver Blades may be compromised.
- Do not use after the use by date indicated on the packaging.
- When handling Shaver Blades, be sure to hold inner blade and outer blade by their proximal side.
- Always inspect Shaver Blades before and after use to ensure that they are not damaged. If a blade is damaged, replace it before starting any new surgical intervention.
- Avoid all contact between Shaver Blades and metal objects. Metal objects can cause the blades to break and could leave fragments in the wound that may prove difficult to extricate.
- Test each Shaver Blade at the desired speed before use. If the device vibrates or functions in an abnormal manner, ensure the blade is installed properly and/or replace the blade. Never use a blade which is not operating correctly.
- Exercise extreme caution when applying the moveable outermost cutting edge of the device, and only do so on appropriate anatomical reference points.
- Always ensure that the tip of the blade is properly irrigated and the suction system is enabled every time the device is operating. This will aid in sufficient blade cooling, prevention of foreign material build-up in the surgical area and abnormal wear of the cutting surfaces.

The device should be used by trained and competent medical personnel, in particular in compliance with legal provisions in force regarding occupational safety, health and accident prevention measures, and the present instructions for use. According to these measures, the user has the following obligations:

- Only use devices in perfect working condition. In the event of irregular operation, excessive vibrations, abnormal overheating or other signs suggesting mal-functioning of the device, the work must be suspended immediately. In this case, contact Entellus Medical
- Make sure that the device is used only for the purpose for which it is intended, protect yourself, patients and third parties from all danger and avoid contamination by the product.

The device and its accessories are designed solely for medical treatment. Any use not in conformance with the intended use is unauthorized and may prove dangerous.

Universal precautions must be complied with by personnel working with contaminated or potentially contaminated medical instruments. Pointed and sharp instruments should be handled with great caution.

5. ASSEMBLY INSTRUCTIONS

Shaver Blades are supplied in sterile packaging and are ready to use.

⚠ Important note: Never insert a tool on a rotating instrument.

5.1 Shaver Blade assembly

After cleaning, maintenance, sterilization and storage, and before any surgical intervention, insert the inner blade into the outer blade.

5.2 Shaver Blade attachment

Choose one of the 8 angular positions necessary for the cutting zone relative to the Handpiece. To do so:

- Gently insert the blade into the Handpiece up to the thrust stop; the clamping band should retract and then return to the position. If the blade is not correctly in place and joint is still visible, remove it and start insertion again.
- Pull the blade slightly to ensure that it is correctly attached.

⚠ Do not use a Shaver Blade if its packaging is open or damaged due to risk of contamination.

During surgical interventions, if the blade clogs, immerse its tip in sterile water and set the suction level to maximum. If the obstruction persists, withdraw the blade from the Handpiece unit and use the small brush supplied with the blade.

5.3 Shaver Blade withdrawal

- Pull the clamping band to the rear of the blade and remove the blade. Note: The blade consists of two separate parts. If the internal part remains retained in the Handpiece, pull on this component axially to withdraw it.
- After the operation, perform cleaning, maintenance and sterilization of the blade in accordance with the instructions below.

6. CLEANING, MAINTENANCE, STERILIZATION AND STORAGE

Reusable Shaver blades are supplied in sterile packaging and are ready to use.

- Clean, lubricate and sterilize the Shaver Blade before each further use.
- After each use, perform maintenance of the Shaver surgical blade as soon as possible (**within a maximum period of two hours**) to facilitate cleaning.

⚠ Do not place stainless steel instruments in physiological salt water solutions (NaCl solution), because prolonged contact may cause corrosion

6.1 Pre-cleaning

This operation is important to facilitate the subsequent cleaning stage (it prevents debris from drying and sticking to the Shaver Blades).

Brush / swab / cleaning gun

To avoid damaging the device, brushes should be clean, non-aggressive, preferably nylon, with flexible hairs or soft bristles. Use a cleaning gun with the appropriate nozzles for the device ducts as necessary.

⚠ Perform pre-cleaning and cleaning processes as soon as possible after completion of the surgical procedure and pre-cleaning must be followed by manual cleaning.

- Gently extract the internal part from the external part of the Shaver Blade.
- Rinse each part from both sides, inside and out with cold tap water (max. temperature 35°C / 95°F minimum duration of 20 seconds per part). Ensure water can flow through lumens. If obstructed, use a wire or brush to clear obstruction.
- Clean the inside of both parts with a nylon brush matching the whole diameter for at least 10 seconds.
- Brush the cutting part until visibly clean for each blade with a flexible hair brush (make sure not to damage device).
- Again, rinse each blade from the hub side inside and out with cold water (max. temperature 35°C / 95°F minimum duration of 5 seconds).
- Dry both the internal and external parts by swabbing with a non-woven towelette.
- Perform manual or automatic cleaning steps below.

6.2 Cleaning

Agents required for cleaning:

Detergents

Enzymatic detergent recommended for cleaning surgical instruments. For example a detergent containing proteolytic enzymes.

Detergents should be used in the concentration, temperature and duration recommended by the detergent manufacturer.

⚠ Do not use detergents that are corrosive or contain chlorine, acetone or bleach (aldehydic products, alcohols).

Manual cleaning

- Soak both parts in a fresh detergent solution at least 30 minutes and maximum 1 hour, not to exceed detergent manufacturers' recommendation for maximum duration (the detergent solution should be replaced for each use).
- With a flexible hair brush, brush the exterior surfaces of each blade for at least 15 seconds each.
- Push the spring mounted washer at the back of the internal blade 3 times to ensure it moves freely.
- Brush the washer with a flexible hair brush for at least 10 seconds.
- Brush the cutting part and the inner surfaces of each blade with a flexible hair brush for at least 10 seconds.
- Clean the inside of both parts with a nylon brush matching the whole diameter for at least 10 seconds. Rub with rotation movements all along the part making sure not to scratch or damage the interior of the part and the seals.
- Remove from the bath and rinse the parts inside and out with sterile water for at least 10 seconds.
- Dry the outside of the parts by swabbing with a non-woven sterile towelette. Dry the inside by blowing air into the canal.

6.3 Inspection, Lubrication and Testing

Carefully inspect each part to make sure that all visible contamination has been eliminated. Check in particular that the channels are clear. If contamination is present, repeat the cleaning process.

- Do not use an oxidized or damaged Shaver Blades.

- After each cleaning, and before each sterilization, lubricate the Shaver Blades with medical oil or grease; lubricate the inside, once on the back of the head and once on the O-ring seal.
- Check that the reference number and the lot number of each part are identical.
- Gently insert the internal blade into the external blade, subjecting it to slight rotary movements. Ensure the internal blade moves freely in the external blade. Properly operating blades have no noticeable scraping or friction.
- The cutting part of the tool should be intact with no broken teeth or impacts on the sharp part and no visible wear.
- The Shaver Blade should not be bent or damaged.
- Ensure the presence and integrity of all seals.

⚠ Do not use a Shaver Blade in poor condition as this may result in serious patient injury.

6.4 Sterilization

⚠ Sterilize the internal blade and the external blade non-assembled.

Packing for sterilization:

Separate instrument packing:

FDA approved sterilization wraps/pouches must be used. Wrap the instrument immediately in an individual packing, such as Halyard Health H300 or equivalent paper/plastic pouch or sterilization wrap, for steam sterilization.

Or

Packing of instruments in stiff boxes and trays with defined, pre-configured lids and apertures.

Bien Air sterilization tray or equivalent sterilization tray/container must be used.

⚠ Do not exceed a temperature of 138°C (280°F).

Sterilization by steam / moist heat must be used. To provide a sterility assurance level (SAL) of 10^{-6} , the following sterilization parameters must be used in a Pre-Vac cycle type B.

Temperature	134°C
Pressure	2.2 bar
Time	3 min
Drying	Minimum 30 Min ¹

¹ Refer to sterilizer manufacturer recommendations for drying times per load configuration.

The instructions of the sterilizer manufacturer concerning operation and the load configuration must be complied with explicitly.

The Shaver Blades must be allowed to cool to ambient conditions, without forced cooling, before being re-used.

6.5 Storage

Entellus Medical strongly advises storing only sterilized devices so as to reduce the risks of corrosion.

Ambient conditions of storage after sterilization

- Store the equipment in a clean, dry place at ambient temperature (+10°C to +30°C (50°F - 86°F), 25% to 75% humidity).
- Do not expose the equipment to direct sunlight.
- Do not expose the equipment to permanent X-ray irradiation.
- Do not store the equipment in places that could be reached by liquid splashes.
- Do not store the equipment in the following ambient conditions:
 - Dust
 - Saline or sulphurous atmosphere
- Do not store the equipment in a location where there is a risk of release of flammable gases.

Shelf life of sterilized instruments

The shelf life of stored sterilized instruments depends on the type of packaging used and the storage conditions.

Environmental conditions

	Work	Transport
Temperature	+10°C (+50°F) to +40°C (+104°F)	-25°C (-13°F) to +60°C (+140°F)
Relative humidity (including condensation):	30% to 80%	10% to 90%
Atmospheric pressure:	700 hPa to 1060 hPa	500 hPa to 1060 hPa

7. TROUBLESHOOTING

Use the table below to solve any problem encountered. If the problem is insolvable, stop using the product and contact Entellus Medical.

Problem	Solution
The blade appears to be damaged or defective	Remove and replace the blade.
The blade is not inserted correctly and is not in its final position	Remove the blade and reinsert this one. Check that nothing obstructs the insertion of the blade.
The blade is obstructed	Immerse the tip in sterile water and set suction to maximum. Remove the blade from Handpiece and use the small brush supplied with this unit. Change the blade.
The blade is blocked, i.e. is unable to rotate	Change the blade.










The irrigation fluid fails to arrive	Check that the tube is not pinched. Increase the flow rate. Check that the seals on the blade are fitted.
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8. GENERAL TERMS OF GUARANTEE

Entellus Medical endeavours to provide its customers with products and devices of impeccable quality, which it guarantees within the limits of the present general terms and the particular agreements signed, against any operating fault, material or manufacturing defect. The guarantee period is 12 months from the date of the invoice or 'Use by' date, whichever comes first. In general, the guarantee does not exempt the customer from the obligation of obtaining information from Entellus Medical in case of doubt and in particular when the product is used in conditions not explicitly provided for originally.

In the event of claims, the manufacturer or its authorized representative shall perform product repair or replacement free of charge, after analyzing the justification for the claim. All other claims of whatsoever kind, and in particular claims for damages, are excluded. Entellus Medical shall not be held responsible for damage or injury and the consequences thereof, resulting in particular from: excessive wear; inappropriate use; failure to comply with operating instructions, assembly instructions or maintenance instructions; exceptional environmental, chemical, electrical or electrolytic influences; or faulty connections. In any case the guarantee becomes null and void in the event of inappropriate servicing, use of non-recommended parts, accessories or consumables, or modifications to the product carried out by third parties not authorized by Entellus Medical. In case of dispute as to whether or not the defect exists, it shall be incumbent on the customer to prove the existence of the defect. Guarantee claims shall be taken into consideration only upon presentation, with the product, of a copy of the invoice or delivery slip on which should appear clearly the date of purchase the product reference and lot.

SYMBOLS USED

 Reorder Number	 Lot Number	 Sterilization with Ethylene Oxide Gas	 Use By	 Quantity
 Consult Instructions for use	 Prescription Use Only	 CAUTION! Refer to the accompanying documents	 Materials to be recycled	

Manufactured for:

Entellus Medical
3600 Holly Lane North, Suite 40
Plymouth, MN 55447
+ 1 866-620-7615 (f) + 1 866-620-7616
www.entellusmedical.com