

INSTRUCTIONS FOR USE

Single Use Shaver Blade

1. DESCRIPTION

Entellus Medical offers several types of Shaver Blades. The blade types include straight and curved blades with double serrated cutting edges of different diameters. 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.

2. INTENDED USE

The Shaver Blades are designed for shaping bone and for the resection of soft and hard tissues as part of surgical procedures in the field 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 a Shaver Blade if its packaging is breached or damaged because there is no more protection against the risk of cross-contamination.
- Single use only. Do not resterilize or reuse Shaver Blades. Due to the complex design of the Shaver Blades, this product can't be decontaminated with reliability. Decontamination processes could also destroy the product's joint and plastic material. The result would be a contamination risk for the patient in addition to the heating and seizing risk to the Shaver Blade.
- Do not use after the use by date indicated on the packaging.
- Shaver Blades are supplied as a single piece so avoid removing the internal part as these components could become damaged and prevent the blade from functioning correctly.
- Always inspect Shaver Blades before and after use to ensure they are not damaged. If a blade is damaged, replace it before starting any surgical procedure.
- 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 as it may cause cuts or wounds.
- 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 is designed solely for medical treatment. Any use not in conformance with intended use is unauthorized and may prove dangerous.

5. ASSEMBLY INSTRUCTIONS

⚠ **Important note: Never insert a tool on a rotating device.**

5.1 Shaver Blade attachment (fig. 1)

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 starting position in **fig. 1**. If the blade is not correctly in place and the joint is still visible, remove it and start insertion again.
- Pull on the blade slightly to ensure that it is correctly attached.

5.2 Shaver Blade withdrawal (fig. 2)

- Pull the clamping band to the rear of the blade and remove the blade, **fig. 2**. 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.

- Dispose blade after use in accordance with local legislation governing the disposal of contaminated waste.

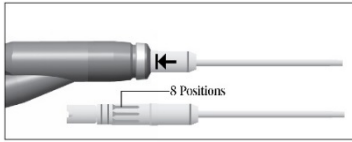


Fig. 1

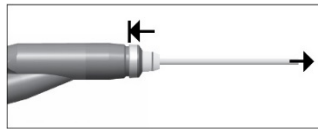


Fig. 2

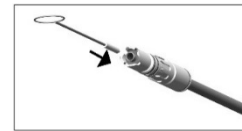


Fig. 3

6. CLEANING, MAINTENANCE, AND STORAGE

⚠ Disposable Shaver Blades are intended for single-use only. Do not resterilize or autoclave them.

Surgical Blades are supplied in sterile packaging and, to avoid any risk of cross-contamination, are not intended for repeat usage.

⚠ Do not use a Shaver Blade if its packaging is open or damaged because there is no more protection against the risk of cross-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 and use the small brush supplied with the blade **fig. 3**. (Avoid separating the internal part from the external part of the Shaver Blade).

Environmental conditions

	Work	Transport	Storage
Temperature	+10°C (+50°F) to +40°C (+104°F)	-25°C (-13°F) to +60°C (+140°F)	+10°C to +30°C (+50°F to +86°F)
Relative humidity (including condensation):	30% to 80%	10% to 90%	25% to 75%
Atmospheric pressure:	700 hPa to 1060 hPa	500 hPa to 1060 hPa	500 hPa to 1060 hPa

7. TROUBLESHOOTING

Use the table below to solve any problem encountered. If the problem is insoluble, 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.

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 authorised 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

REF Reorder Number	LOT Lot Number	Materials to be recycled	Consult Instructions for use	CAUTION! Refer to the accompanying documents
Quantity	Do Not Reuse	STERILE EO Sterilization with Ethylene Oxide Gas	Rx Only Prescription Use Only	Use By

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