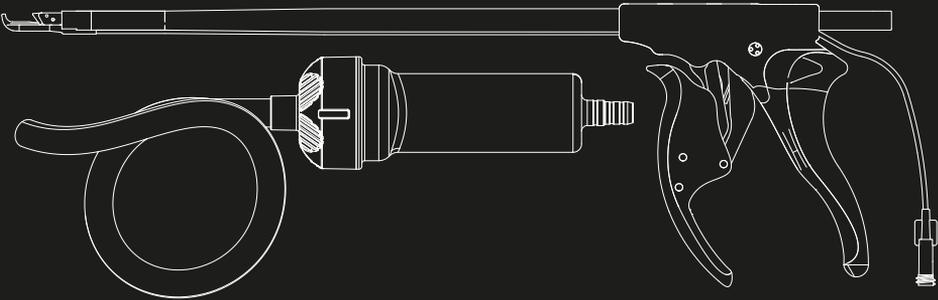


Rebellion





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Products

These instructions for use apply to the product REBELLION and the BONE AND TISSUE TRAP. The REBELLION is available in the following variants:

Length	Size
200 mm	2, 3, 4 mm
250 mm	2, 3, 4 mm

The BONE AND TISSUE TRAP is available in one size with a filling volume of 160 ml.

Important notes



Read these operating instructions carefully before use and keep them easily accessible for the user or operator.



Read the warnings marked with this symbol carefully. Improper use of the products may result in serious injury to the patient, users or third parties.



Scope

The REBELLION and the BONE AND TISSUE TRAP may only be used by trained and qualified personnel. The REBELLION is recommended to always being used according to the expertise of the surgeon and the individual patients' anatomy. The products are intended exclusively for the following use.

Intended Use

REBELLION: The REBELLION is intended for cutting and removing bone, vertebral bodies and tissue in orthopedic, neurosurgery and spine surgery involving the skull or spinal column.

BONE AND TISSUE TRAP: Cut material is collected with the BONE AND TISSUE TRAP.

Complications and unwanted side effects

Injury of tissue and/or nerves are typical complications for spinal procedures. These complications can occur when using the instruments not according the instruction for use.

Compatible devices and procedures supplies

The following devices are compatible with the REBELLION and BONE AND TISSUE TRAP:

- Universal fluid collection canisters and suction collection systems.
- Universal suction tubing

Warnings



Only cut when you have a clear view. Make sure that there are no nerves, vessels and/or other tissues in the cutting edge that should not be cut. It is recommended to use a surgical microscope for this purpose.



The REBELLION must only be used with suction. The BONE AND TISSUE TRAP can be used if required.



If the tube of the REBELLION is clogged with bone or tissue during the punching process, the tip of the REBELLION must be held in rinsing solution (NaCl 0.9%). Flushing the pipe may remove the blockage.



If the blockage cannot be removed, a new REBELLION must be used.

The decision whether the punched material that was collected in the Morpheus Bone and Tissue Trap should or could be processed or used is in the sole responsibility of the surgeon. In case the surgeon decides to process or use the collected material, he has to follow the IFU of the instruments he would like to use.



Safety instructions



The products are intended for single use only. Do not re-use the devices.



The expiry date must be checked before use. If the expiration date has passed, the product must be disposed.

Sterility



Sterilized with ethylene oxide.

The products must be kept in their original packaging. The products may only be removed from their packaging before use.



Do not re-sterilize the product.



Do not use the product if the primary packaging (pouch) is damaged.

Storage Conditions



Products to be stored protective from direct sunlight.



The products must be stored in a dry place.

The products must be stored at room temperature (max. 25°C / 77°F)

Disposal

Send the packaging for recycling. Dispose of contaminated parts in accordance with national regulations.

Explanation of Symbols



Manufacturer



Production lot number, batch



Item number



Follow the instruction for use



Warning



Latex free



Do not re-use



Can be used until



Sterilized with ethylene oxide



Do not re-sterilize



Do not use if packaging is damaged



Protect from sunlight



Store in a dry place



Caution: Federal law restricts this device to sale by or on the order of a physician



Conform to the Medical Device Directive 93/42/EEC

Notified Body number of ENTE CERTIFICAZIONE MACCHINE SRL; Via Ca' Bella, 243/A - loc. Castello di Serravalle 40053 Valsamoggia (BO) Country: Italy



Assembling Instruction

1. Select appropriate size and length of the REBELLION before use.
2. Unpack the REBELLION and place it on the operating table.
3. If required, the BONE AND TISSUE TRAP can be used. Move the hose of the BONE AND TISSUE TRAP over the distal end of the REBELLION approx. 2cm / 1 inch (see Fig.1). Connect a tube (inner diameter 7 to 8 mm or 9/32 to 5/16 inch) from a suction unit onto the distal end of the BONE AND TISSUE TRAP (see Fig.2).
4. If the BONE AND TISSUE TRAP is not used connect a tube (inner diameter 7 to 8 mm or 9/32 to 5/16 inch) from a suction unit directly onto the distal end of the REBELLION approx. 2cm / 1 inch (see Fig.1).
5. Turn the suction pump on and adjust the suction flow between -600 mmHg to -700 mmHg (approx. -0,8 bar) / -11 psi to 14 psi. The suction performance must be between 45 and 50 l/min.
6. Perform surgery

Application notes Bone and Tissue Trap

The punched material is collected in the BONE AND TISSUE TRAP.

To open the BONE AND TISSUE TRAP, turn the cap counterclockwise (see Fig.3).

The collected material can be taken out from the BONE AND TISSUE TRAP (see Fig.4). The decision whether the punched material that was collected in the Morpheus BONE AND TISSUE TRAP should or could be processed or used is in the sole responsibility of the surgeon. In case the surgeon decides to process or use the collected material, he has to follow the IFU of the instruments he would like to use.

Figures

Fig.1



Fig.2



Fig.3



Fig.4

