

Instructions for use

EXXOCUT MICRODEBRIDEMENT CANNULA

Technical Name: Cannula
Trade Name: Exxocut Microdebridement Cannula
Content: 1 unit

ANVISA Registration No. 80743230026

UI Rev. 2.0

Indication of Use / Purpose

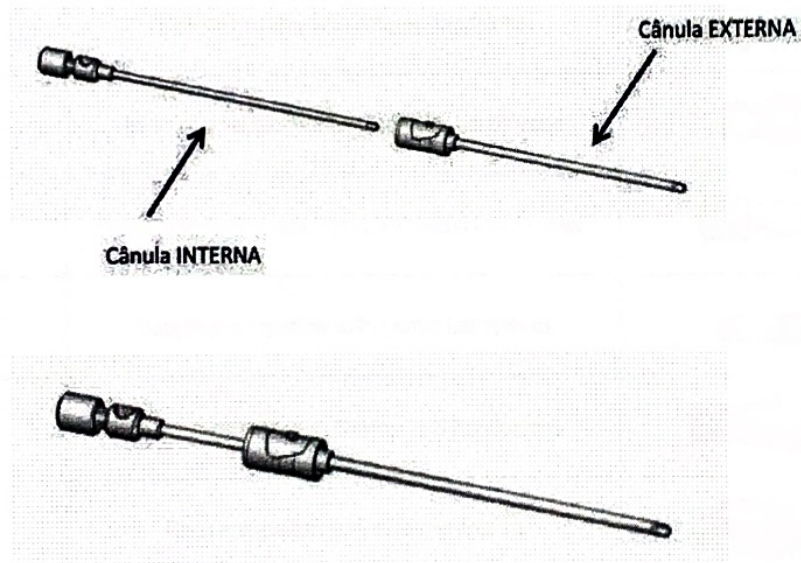
The cannulas are made for use with equipment known as a shaver, used in arthroscopies performed by doctors trained in this type of intervention. They are used to cut, pierce, scrape and remove tissue and bone from the knee, shoulder, elbow, wrist, ankle, hip and smaller joints by means of controlled abrasion.

Composition

- Direct Contact
Tubes: AISI 304 stainless steel (ASTM F899)
- No Direct Contact
Rear coupling: Aluminum and ABS (Acrylonitrile Butadiene Styrene) rear bushing and PTFE (Polytetrafluoroethylene/Teflon) lubricant
















Commercial models

All models have the same intended use/purpose, safety features, performance and warnings and have the same morphology/structure, composition and materials - see Fig. 1.








All the models maintain the basic morphology, varying some parameters to suit the needs of the procedures, without, however, modifying the basic structure of the product. The parameters that vary are: type of cut, coupling (rear coupling) and diameter.

Comparison table: Breakdown of Coupling Types

Models with Code Ending In	Description	Illustrative Image
LV	Hitch compatible with Linatec handpieces	
RZ	Hitch compatible with Razek handpieces	
ST	Hitch compatible with Stryker handpieces	
SZ	Hitch compatible with Storz handpieces	
XX	Hitch compatible with Exxomed handpieces	
FS	Hitch compatible with FMS handpieces	
AX	Hitch compatible with Arthrex handpieces	
EP	Hitch compatible with Dyonics EP1 handpieces	
PS	Hitch compatible with Dyonics PS4800 handpieces	
TA	Coupling compatible with Taimin handpieces	
TP	Hitch compatible with Stryker TPS handpieces	
WF	Hitch compatible with Wolf handpieces	
AT	Hitch compatible with Artrotek handpieces	
X1	Hitch compatible with Exxomed X1 handpieces	
X2	Hitch compatible with Exxomed X2 handpieces	



Comparison table: Detailing the Types of Cut

Models with code starting with	Description	Illustrative Image
FR	Full Radius The edges of the distal opening of the inner and outer cannula are smooth for preferential use when removing soft/cartilaginous tissues	
RS	Resector The edge of the distal opening of the outer cannula is smooth and the inner cannula has a jagged edge to increase efficiency (aggressive removal) of soft/cartilaginous tissues	
IN	Incisor The edges of the distal opening of the inner and outer cannulae are notched to increase efficiency when removing larger soft/cartilaginous tissues	
OB	Oval Burr Edge of the distal opening of the outer cannula in the shape of a sheath and inner cannula in the shape of an oval drill for greater efficiency in microdebridement.	
RB	Round Burr Sheath-shaped distal opening edge of the outer cannula and round drill-shaped inner cannula for greater efficiency in removing small bone tissue.	

Comparison table: Diameters

Outer Diameter (mm)	Internal Diameter (mm)
2.7	1.4
3.0	2.0
3.5	2.0
4.2	2.4
4.5	2.4
4.8	2.9
5.0	2.9
5.5	2.9

Forms of Presentation and Traceability

The product will be marketed in primary (internal) packaging consisting of a PET polymer blister sealed with surgical paper and labeling, containing 01 product. The primary (internal) packaging will be individually wrapped in secondary (external) packaging made of printed cardboard and external labeling.









The packaging mentioned is properly sealed and labeled. The Instruction for Use is available on the Nexxmed website, in accordance with IN 04:2012.

The labels display the following information:

- Technical Name;
- Product code and description;
- ANVISA registration number;
- Date of manufacture;
- Validity;

- Manufacturing batch;
- E-mail address for accessing the Instructions for Use;
- Full identification of the manufacturer, including contact details;
- Identification of the Technical Manager;
- Symbology.

The symbolism on product labeling complies with the ABNT NBR ISO 15223-1 standard:

Symbol	Description
	Sterilized by ethylene oxide
	Do not reuse / Single Use Product.
	See Instructions for Use.
	Attention! Consult Instructions for Use before use.
	Fragile, handle with care.
	Keep dry.
	Keep away from sunlight.
	Temperature limits.

How to use the product

The product consists of an inner cannula and an outer cannula, positioned coaxially. Each cannula has a coupling on the back which is an adapter for connection to a handpiece of the shaver-type equipment of the specialist doctor's choice. The external cannula does not move. The inner cannula has a rotating movement. The rotating movement of the inner cannula in relation to the outer cannula promotes the desired cutting action when it comes into contact with the tissue. The cannulas have a front opening, with a smooth, jagged or other geometric edge, allowing different types of cutting and suction of the tissue (through the hollow internal part of the cannulas).



Sterilization method

This product is supplied **STERILE** by ETO — Ethylene Oxide .

Storage and transportation conditions

For storage, a dry, well-ventilated place is recommended, with no exposure to light, humidity or contaminants.

It is recommended to store the product at temperatures between 5°C and 40°C.

Products must not be stored directly on the floor. We therefore recommend using shelves with a minimum height of 20 cm. It is also recommended not to lean them against walls.

The product must be kept in its original packaging until it is used, and the packaging must be opened for surgical use.

The product must be transported properly, avoiding falls and friction that could damage the packaging and the surface of the part.

For information on date of manufacture and batch number: see label.

Handling conditions

The product is supplied sterilized in sealed packaging. The packaging should only be opened at the time of use in a surgical environment and handled with gloves, avoiding contact with other materials. If the packaging is broken or tampered with, do not use the product and dispose of it in accordance with hospital regulations. The product is for single use only and should not be reused. It should be discarded after use.

Precautions

- Opening the packaging for surgical use and handling the product should only be done by personnel qualified to carry out this procedure, so as not to damage the material or cause cross-infection;
- **STERILE PRODUCT.** Do not use the product if its packaging has been tampered with;
- **SINGLE USE PRODUCT - DO NOT REUSE;**
- Handle with care;
- Do not allow the product to come into contact with other instruments during use.
- Avoid using for more than 1 minute at a time to prevent overheating.
- Use at the speeds and direction indicated or at the lowest speed possible to obtain the desired effect, reducing the possibility of failures
- Do not touch the movement area of the cannulas with other instruments or parts of the body. If this occurs, it could result in breakage, fracture or damage to the blade or equipment and harm to the user.
- Date of manufacture, expiry date and batch number: see label;
- The products have been developed for use following the above precautions, so any other uses are considered contraindicated or without a scientific basis to support their use.

Warnings

Any surgical procedure poses risks to the patient, such as bleeding, infections, allergic reactions to medication, among others.

Some risks may arise in connection with the product and should be warned against, such as:

- Before using the product, the user/medical professional should carefully read the Instructions for Use, which will help them to use it correctly and safely, as well as protecting them from possible risks. Carefully read the Instructions for Use and Operation of the equipment chosen for compatibility.
- This product should only be used by medical specialists with knowledge and training in the surgical procedures in question, and the general and specific warnings relating to them apply to the use of this product.
- This document is not a medical manual and does not replace training in general medicine, surgery or the techniques involved, but is limited to providing information on the product only.
- The choice making, handling, use and results of the product are the sole responsibility of the surgeon. It is the surgeon's responsibility to familiarize themselves with the appropriate techniques and decide on the safety of using this product in the specific surgical context and the selection and use of the appropriate models and parameters for the desired effect.
- Do not use the product if it is bent, crooked, has marks of mechanical stress or any visible alteration other than what is expected for an intact product
- Test before using on the patient. In the event of excessive vibration, do not use the product.
- Use only with watering of the area of use and suction to properly cool the blade and avoid jamming due to the accumulation of extracted material inside the blade.
- Excessive side loading does not improve cutting and can cause the product to wear out and even jam during use.
- Do not use the product as a lever or for other mechanical purposes.
- In the event of excessive vibration or sound and/or locking during use, stop the procedure immediately and replace the product. Continued use of the locked product may leave metal residue in the cavity.
- The end result depends not only on the product, but on a number of factors under the operator's control - configuration parameters, the type of fabric and its conditions, the desired effect and the specific conditions encountered during the procedure, speed, distance from the fabric, application time. The training and experience of the professional carrying out the intervention has a decisive influence on the final result.

SINGLE USE PRODUCT - REPROCESSING PROHIBITED

Contraindications

The use of the product is contraindicated in:

- Any other type of procedure that does not comply with the Indication for Use, as this may impair its progress and cause damage.

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Product disposal

The commercial models that make up the ENT Multiangle Microdebridement Cannula Family should be discarded after use. It is recommended that the product be de-characterized before disposal, for which purpose the parts can be cut, bent or filed.

According to ANVISA Resolution RE n. 2605, of 11/08/06, devices classified as single-use are prohibited from being reprocessed.

The methods and procedures for disposing of the medical product used must ensure that it is completely uncharacterized, preventing any possibility of its reuse. Disposal of the medical product is the sole responsibility of the hospital, as are the disposal methods and procedures used. However, Nexxmed recommends that such products be mechanically deformed. They must then be clearly and visibly marked as unfit for use.

The products must be disposed of in appropriate places to avoid contaminating the environment and other people. It is recommended to adopt local legal regulations for the disposal of potentially contaminating products.

Manufactured and Distributed by:

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