

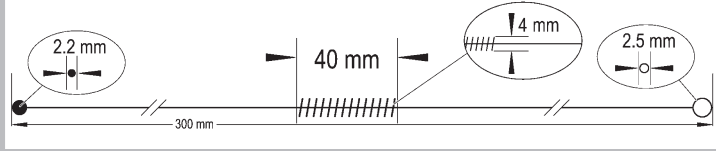


Instructions for Use

English

Ref. No. 200.62, 200.65

Fistula Brush



The Fistula Brush is an instrument for probing, cleaning and the removal of dead tissue or cellular debris from anorectal fistulas.



These instructions for use are to be read carefully. The user must be fully familiar with the function and the handling of the device.

DESCRIPTION OF THE COMPONENTS

The Fistula Brush consists of:

- Semi-flexible wire with a brush section in the middle (see dimensions in drawing above) equipped with a loop on one and an olive-shaped probe on the other end.

INDICATION

Proctological instrument for probing, cleaning and debridement of anorectal fistulas.

CONTRAINDICATIONS

The instrument is not suitable for use outside the anal region.

The instrument should not be used if mechanical manipulation of an anorectal fistula is contraindicated.



The Fistula Brush is intended for single use only. The materials used for the product do not withstand reprocessing and resterilisation. The components of the product are designed for single-patient use and do not withstand multiple use.

Reprocessing and reuse of disposable instruments may harm the patient (inadequate function, insufficient sterility, contamination, corrosion or other impairment).

Before use, please verify that packaging is undamaged and check date of expiry. Sterility of the product cannot be guaranteed if packaging is damaged or the date of expiry is exceeded.

WARNING NOTE/PRECAUTIONS

Use instrument with great care to avoid widening of the fistula tract and abrasion of too much vital tissue respectively.

- Please keep the instrument out of direct sunlight and away from other UV sources.
- Please do not keep the instrument close to chemicals, disinfectant or radiation sources.
- Please do not put any objects on the instruments and/or packaging of the instrument.
- Please understand that improper storage will render void all warranties.

COMPLICATIONS

The Fistula Brush may cause tissue injuries if used incorrectly.

These include in particular:

- Enforced pushing against resistance may give rise to a new fistula tract (Via falsa)
- Excessive pressure when cleaning may cause abrasion of vital tissue and subsequent dilatation of the fistula tract.
- Bleeding and haematoma
- Improper use may cause parts of the brush to break off.
- Mechanical tissue manipulation may cause or aggravate infection.

Please take all necessary precautions before using the instrument!

HANDLING & APPLICATION

- Carefully insert the Fistula Brush into the fistula opening
 - either by means of the olive-shaped probe.
 - or, in case of seton drainage, by attaching the seton to the loop of the brush and pulling the instrument into the fistula tract with the seton.
- Pull the Fistula Brush until the brush section is situated inside the fistula tract.
- Carefully clean/debride the fistula tract by alternating movements of the brush.
- Rinse the debrided fistula tract, e.g. with saline solution.

The Fistula Brush is disposed of after use.



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SYMBOLS USED ON LABELLING



0124 CE-mark and identification number of Notified Body



See instructions for use



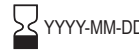
Batch number



Reference number



YYYY-MM-DD Date of manufacture: year-month-day



YYYY-MM-DD Use until: year-month-day



EO (ethylene oxide) sterilised



Do not reuse



Do not resterilise



Do not use if package is damaged

Not made with natural rubber latex

Latex free