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Via Mezzavia, 122
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TF04_IFU Mucotomo
Rev. 02
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1 - Intended use and expected clinical benefits

The Handpiece Mucotome is used for circular gingival incisions of a predetermined diameter. DMs are configured in AISI 630 steel.

The device does not contain or incorporate:

- a medicinal product including a derivative of human blood or plasma
- human tissues or cells, or derivatives thereof, or
- tissues or cells of animal origin, or derivatives thereof, covered by Regulation (EU) No. 722/2012

2 - Warnings

Since DM is used in the application of implant procedures for functional and aesthetic rehabilitation resulting from the loss or congenital absence of one or more teeth, it should only be used by dentists with specialist training. Any serious incidents occurring in connection with devices covered by the Instructions for Use must be reported to ISOMED as well as to the competent authority of the Member State in which the patient and/or user reside.

3 - Precautions

DMs must be cleaned and sterilised before use. Make sure not to exceed the number of revolutions and number of reuses as indicated in the usage restrictions. If in doubt about the cutting capacity, replace the cutter.

4 - Restrictions on Use

Use only for its intended purpose.

The Mucotome must not be rotated at speeds exceeding 100 rpm and must not be used for more than 25 cycles.

5 - Mode of use

Attach the sterilised mucotome to the micromotor: proceed with the mucotomy by slowly incising (rotation at about 100 rpm) until the bone ridge is reached. The mucotome can also be used manually. Before use, the device must be subjected to a cleaning and sterilisation cycle, check the correct connection to the micromotor and ensure that the DM is on axis.

Cleaning: can be conducted by soaking for 5 minutes in multi-enzymatic detergent followed by manual disinfection for about 2 minutes with an absorbent cloth soaked in alcohol-based disinfectant (70% alcohol).

Sterilization: Steam autoclave; 134° cycle for 4', 2 bar.

Further procedures other than those defined must be validated.

6 - Storage Precautions

Store in a dry place and do not expose to direct sources of heat or sunlight.

7 - Disposal

In the case of DM disposal needs, one can proceed by referring to local laws concerning special medical waste at risk of contamination. The DM must be cleaned and sterilised before disposal.

 0426	 DM Code	 Manufacturer	 Lot number	 UDI code
 Date of manufacture	 www.isomed.it	 Medical Device		