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TF04_IFU Frese
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1 - Intended use and expected clinical benefits

Milling cutter: The purpose of the drill is to allow the creation of the implant site and thus the placement of the implant inside the jawbone by means of a hole of appropriate diameter drilled by the device connected to an active medical device called a 'contra-angle'.

Drill extension: its purpose is to connect the drill to the micromotor whenever the presence of dental elements prevents the insertion of the drill into the bone, up to the desired depth.

Core cutters: Core drills allow bone harvesting for autogenous grafting or dental implant removal.

Bushings and cutter stop: The purpose of the bushing/bushing is to adapt cutters to larger diameter bushings. It is placed in the case of guided implantology on the 4.15 bushing burs so that they can also be used on 5.5 diameter burs.

The drill stop is intended to create interference with the bushing in the case of guided implantology 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 cutter and any extension should not be rotated at speeds exceeding 500-600 rpm and should not be used for more than 25 cycles. Ensure copious spraying with physiological fluid.

5 - Mode of use

Attach the sterilised drill to the micromotor, proceed to make the surgical alveolus by rotating it at approximately 500-600 rpm and ensuring copious irrigation of saline solution. To avoid damaging the bone, it is very important not to overheat it above 40°C. For this reason, the flow of saline must never be reduced or lacking and the bur must have a good sharpness. If necessary, pause intervals should be added to allow the bone and the drill to cool. The depth to be reached is indicated by the reference notches on the cutters. 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		