

**ISOMED Srl**

Sede Legale: Via Mezzavia, 122
35020 Due Carrare (PD)
Sede Operativa: Via Mezzavia, 122
35020 Due Carrare (PD)

TF04_IFU Screwdrivers

Rev. 02

Data: 07-01-2026

1 - Intended use and expected clinical benefits

These are devices which, via connection to the micromotor, allow the screwing of ISOMED implant line components

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 the device is damaged, replace it.

4 - Restrictions on Use

Use only for its intended purpose.

The screwdriver must not be rotated at speeds exceeding 30 rpm. Check for wear and tear and absence of damage before each use.

5 - Mode of use

Attach the sterilised screwdriver to the micromotor. Rotation for the screwing phases must be at a speed of approximately 30 rpm. 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		