MECHANICAL IRRIGATION SET

The irrigation line is a medical device for the transfer of coolant (physiological solution at 4 - 5 °C) from the vial to the oral cavity of the patient. It is used with mechanical pumps in order to obtain the correct and measured flow of coolant solution for bringing the bur "up to temperature" during implant site preparation.

DEVICE CLASSIFICATION

CLASS IIA	CE NUMBER: 0123	STERILE	Code: 270606

CND: A03010105 (national classification of medical devices)

GMDN: Not applicable

TECHNICAL FEATURES

- Two-way perforator in PE/ABS/PP and 3 µm air filter;
- Roller for flow regulation;
- PVC tip to facilitate positioning on the cooling needle of the handpiece;
- Y connection for internal and external irrigation (accessory);
- Segment of medical grade silicone tube, suitable for connection to irrigation pumps;
- The product is free of latex and phthalate components (DEHP).
- The product is non pyrogenic.

Compatible with	Total Length	Length of silicone tube	Outer diameter of silicone tube	Pieces per pack
DE GIORGI: Intramatic 2, Intramatic Plus, Intrasurgery 2.0, Steril Intraplant/ FRIATEC AG: Implantology surgical/ TISSIDENTAL: Oral Max System	2.56 m	10 cm	6,5 mm	10

APPLICABLE STANDARDS

ISO 8536-4, ISO 8536-8, ISO 10993-1, ISO 10993-7

PACKAGING

Irrigation sets in protective wrapping, individually packaged in bags/blisters for peel-open sterilization marked with the sterilization batch and packed in cardboard containers.

Keep away from sunlight. Keep dry.

STERILIZATION

Sterilization is carried out with ethylene oxide; the sterilization process is regularly validated and kept under constant control by routine analysis; and the residue of the sterilizing gas is kept within the limits established by the current legislation. Sterilization is performed by a specialized laboratory.

EXPIRY

The validity of the sterile device is **59 months** from the date of sterilization (MONTH-YEAR).
The expiry date indicated refers to the device in its unopened and correctly stored package.

LABELLING

Device with removable adhesive labels to facilitate traceability.
Each blister comes with removable adhesive labels to help operators with traceability of the devices used during operations. The removable parts of the label can be detached from the pack and applied to the medical record or to any other document that, according to the procedures used, is used for traceability.
In addition, each individual pack is labelled with all the information required to identify the product:

- product description (contents list)
- trade name of the product
- product code number
- manufacturer's name
- method of sterilization
- expiry date
- sterile symbol
- single-use symbol
- production area
- CE marking and number of the notified body

- production batch number
- precautions

There is an adhesive label on the transport packaging bearing all the information required to identify the product as indicated above and the no. of pieces per pack

N	Component Description
1	Assembled 2-way suspended hole punch
2	Roller
3	Blue roller wheel
4	Silicone fitting
5	Tube / tube connection
6	Green tip