1 - Intended use and expected clinical benefits
The 'healing screw' device is made of Titanium Gr. 5 ASTM F136 and is intended, after being screwed to the implant, to guide healing and determine the adaptation of the neighbouring gingival tissues in order to be able to replace it with the definitive prosthesis after removal.

1.1 – Materials used
Patients are exposed to contact with the materials constituting the DM:

Titanio Gr. 5 ASTM F136

TABLE 1 Chemical Requirements

Element	Composition, %
Nitrogen, max	0.05
Carbon, max	0.08
Hydrogen, max	0.012[A]
Iron, max	0.25
Oxygen, max	0.13
Aluminum	5.5–6.50
Vanadium	3.5–4.5
Titanium[B]	balance

Its use is not recommended in patients with allergies or hypersensitivity to these materials

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
Healing screws must be cleaned and sterilised before use. After its intended use, the product can be disposed of after cleaning and sterilisation through conventional routes.

4 - Restrictions on Use
Use only for its intended purpose.
Healing screws may only be coupled with devices specified by ISOMED in its catalogue. Combination with different devices may cause failure.
The device is disposable, reuse may compromise the safety features of the device making it unsuitable for its intended use. ISOMED explicitly declares DM disposable and assumes no liability for any re-use by users.

5 - Mode of use
After implant surgery in order to prepare the mucosa to accommodate the abutment in an atraumatic manner, place the Healing Screw of a height appropriate to the thickness of the mucosa. The healing time is around 3 to 5 months. To make it easier to grip the screw, it is advisable to tilt the test tube on a towel, pull out the polyethylene container and grasp the screw; then hook it onto the hexagonal key.
Before use, the device must be subjected to a cleaning and sterilisation cycle.
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 - Patient information and traceability
Current regulations require the patient to be informed by the doctor about the risks related to the device and possible surgical complications, as well as the need for periodic check-ups and in case of unexpected situations. For the purposes of implant traceability, the package contains two labels with the device's identification data; one must be affixed to the patient's medical record and the second to the 'Personal Card'.

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

8 - 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.