



### 11. MAINTENANCE

Complications linked to implant prostheses are documented in the related literature. These complications can lead to a lack of osseointegration and a failure of the implant. A correct up-keep on the part of the patient, with a regular attention to dental hygiene at home, combined with periodic check-ups and visits to a professional hygienist lengthen the useful life of the device. Complications such as, for example, loosening of the screws securing the prosthesis to the implant, or bone re-absorption causing loss of mucosa support for removable prostheses, can easily be detected by regular control visits. Should it be necessary to tighten the abutment or the prosthetic screws, these operations must be carried out by the doctor using the appropriate devices that are able to verify the tightening torque. Devices must be calibrated on a regular basis. Should the patient become aware that any of the conditions above have occurred, they should contact their doctor as soon as possible so that the prosthesis can be restored to its proper functional condition. Any delay in requesting medical intervention could, in the first instance, lead to the fastening screw or the prosthesis fracturing and, in the second instance, to loss of the implant, affecting the rehabilitation result achieved. Doctors must therefore prepare patients for these circumstances. Complications can be biological (integration loss) or mechanical (component fracture due to excessive load). If no complications occur, the duration of the devices and of the prosthesis as a whole depends on the mechanical resistance of the device with respect to the accumulated fatigue.

Sweden & Martina has subjected Premium TG implants to the required fatigue resistance tests at 5,000,000 cycles, and the implants passed the test.

Fatigue tests are carried out in compliance with the specific normative and the results assessed by performing calculations on the finished elements.

### 12. EXPIRY DATE

Implants must not be used after the expiry date indicated.

### 13. LEGAL REFERENCES

The design and production of Premium TG implant fixtures are carried out in conformity with the directives and most up-to-date harmonised normatives regarding the materials used, production processes, sterilisation, information provided and packaging.

### 14. WASTE DISPOSAL PROCEDURES

Fixture implants, if removed from the oral cavity as a result of a biological or mechanical failure, must be treated as organic waste for their disposal, according to the laws that apply locally.

On the other hand, if the implants are sent to Sweden & Martina with a request for execution of a Surf Test, the protocol given on the website [www.sweden-martina.com](http://www.sweden-martina.com) must be followed.

### 15. LIABILITY FOR DEFECTIVE PRODUCTS AND TERMS OF WARRANTY

Excellent patient care and attention to their needs are necessary conditions for the success of the implant. It is therefore necessary to select the patient carefully, inform them of the inherent risks and of the duties associated with the treatment, encouraging them to co-operate with the dentist to achieve a good outcome from the treatment. The patient must therefore maintain a good level of oral hygiene - confirmed by means of regular check-ups and control visits - that must be guaranteed and documented, along with the pre- and post-surgical directions and prescriptions.

The instructions provided by Sweden & Martina are available at the moment of treatment and have been accepted by the Dental Practice. These instructions must be observed and applied during all the care phases: from the patient medical history stage to the post-surgery check-ups.

The Warranty covers exclusively defects that are established to be attributed production-related and on submission of the piece identified by item and batch code, within validity period of the Warranty. The Warranty Conditions are available on the [www.sweden-martina.com](http://www.sweden-martina.com) website.

### 16. DATE AND VALIDITY OF INSTRUCTIONS FOR USE

These Instructions for Use have validity and effect from the month of July 2021.

picture 01



picture 02



picture 03



picture 04

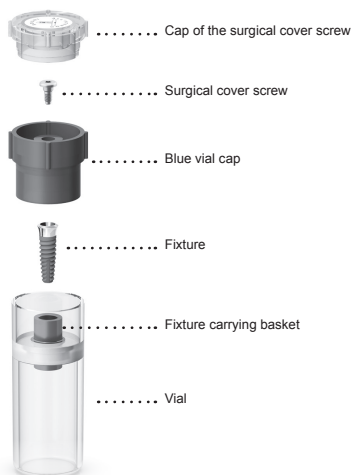


Table 01

Device	Packaging	Regulation (EU) 2017/745	Classification Rule	Risk Class
Implant fixtures for dental use, belonging to the Premium TG implantological system	Sterile, single-use packages. Fixtures come complete with cover screw	Implantable devices intended for long term use (over 30 days)	8	Iib
Cover screws	Sold either complete with appropriate fittings or individually (single-use, sterile package)	Implantable devices intended for long term use (over 30 days)	8	Iib

Table 02

ø 3.30 TG	ø 3.80 TG	ø 4.25 TG	ø 5.00 TG
Light blue	Green	Blue	Magenta

### EXPLANATION OF SYMBOLS

	Caution! See instruction for use	✓
	Batch number	✓
	Code	✓
	Manufacturer	✓
	Country of manufacture	✓
	UDI code, Unique Device Identification	✓
	Medical Device	✓
	Consult instruction for use <a href="http://www.sweden-martina.com">www.sweden-martina.com</a>	✓
	CE marking Where applicable: The identification number of the Notified Body shall follow this symbol.	✓
	American federal law restricts this device to sale by or by order of a professional practitioner	✓
	Do not resterilize	✓
	Disposable product, do not reuse	✓
	Do not use if the packaging is damaged	✓
	Sterilized with ionizing radiation	✓
	Single sterile barrier system with protective packaging inside	✓
	Expiry date after which the product must not be used	✓

  
**sweden & martina**

Sweden & Martina S.p.A.  
Via Veneto, 10 - 35020 Due Carrare (Padova) - Italy  
Tel. +39.049.9124300 - Fax + 39.049.9124290  
e-mail: [info@sweden-martina.com](mailto:info@sweden-martina.com)  
[www.sweden-martina.com](http://www.sweden-martina.com)