

and tertiary structures of the proteins may be replaced and broken by the water at high temperatures. The water vapour has a heat transfer coefficient that is much higher than air; therefore, the moist materials conduct the heat much more quickly than dry materials due to the energy released during condensation.

1. GENERAL INSTRUCTIONS FOR USE

Please pay special attention to the instructions for use described below to ensure the proper use of the product. Not observing these instructions could harm the patient and give rise to one or all of the following complications:

- Aspiration / swallowing of the components.
- Damage to the implant, the abutment, the components or instruments.
- Loosening of the abutment or other components.
- Incorrect definitive restoration or defective functioning of the crown, bridge or other definitive prosthesis.
- Reduction of the patient's masticatory function.
- Failure of the implant.
- Removal of the implant.

In case of doubt, please contact the customer support department at **Smart Implant Solutions**, either by email at info@smartimplantsolutions.com or telephone at 943.322.812.

1. STORAGE AND HANDLING

Products manufactured by Smart Implant Solutions are supplied properly packaged and sealed but NOT sterilised. The product must not be removed from its original packaging or handled before use. Before fitting the restoration in the patient's mouth, the product must be cleaned, disinfected and sterilised. The procedure recommended by Smart Implant Solutions is specified in section 1.5.

2. WARNINGS AND CONTRAINDICATIONS

Note the signs on the product labelling. The reuse of a single use product (see label) can pose the risk of infection to the tissues, irritation or injuries in the implant or soft tissue.

3. RISKS ARISING DURING THE USE OF THE PRODUCT

All products must be safeguarded against accidental aspiration when they are being used intraorally; therefore, they must be used by qualified professionals.

4. PRECAUTION

Smart Implant Solutions products are intended to be used by qualified health professionals (dental prosthetists, dentists and odontologists). The professional must have the relevant knowledge and experience in the handling of the product in order to make use of it in a proper and safe way in accordance with these instructions for use. It is the responsibility of the professional to use the health products in accordance with these instructions for use, and to determine if it is appropriate for the patient's particular situation.

Smart Implant Solutions will not be responsible for the safety and effectiveness of its products when they are not handled by authorised persons.

5. STERILISATION METHODS

Smart Implant Solutions products are supplied in an UNSTERILISED condition. For cleaning and disinfection an automatic method must be used. It is not recommended to use manual baths alone (including the ultrasound bath) as its effectiveness is significantly lower.

Smart Implant Solutions recommends the following sterilisation process: use of a moist heat autoclave at a temperature of 134°C (273°F) for 5 minutes or at 121°C (249°F) for 15 minutes.

This process destroys spore forming organisms. Sterilisation is produced by means of a physical agent, the moist heat, which causes protein denaturation and coagulation.










Water is a very reactive chemical substance and many biological structures (DNA, RNA, proteins, etc.) are produced by reactions that eliminate water. Therefore, reverse reactions may damage the cell due to the production of toxic products. Moreover, the secondary

Pressure	Temperature (°C)			
	Complete discharge of the air	Discharge of 2/3 of the air	Discharge of 1/2 of the air	No air discharge
1/3	109	100	90	72
2/3	115	109	100	90
1	121	115	109	100
4/3	126	121	115	109
5/3	130	126	121	115
2	133	130	126	121

Influence of incomplete air discharge on the autoclave temperature

Note: use the products immediately after sterilisation. DO NOT store sterilised products.

6. LABEL SYMBOLS

Symbol	Description	Standard
	Manufacturing date	EN ISO 980:2005 ISO 15223:2005
	Manufacturer	EN ISO 980:2005
	Single use. Do not reuse.	EN ISO 980:2005 ISO 15223:2005
	Batch number	EN ISO 980:2005 ISO 15223:2005
	Note. See the instructions for use	EN ISO 980:2005 ISO 15223:2005
	Consult the instructions for use.	EN ISO 980:2005 ISO 15223:2005
	CE marking, which includes the number of the ON which grants the approval in the case of Class II products, in accordance with the European directive	EN ISO 980:2005 93/42/EEC
	Product reference	EN ISO 980:2005
	Non-sterile product	ISO 15233:2005

7. PRODUCT WARRANTY

The excellence of our product is the aim of the quality system implemented by **Smart Implant Solutions**, it is supported by ISO 9001, ISO 13485, Quality IQ certification, and CE marking. CE marking on a health product guarantees that it meets all the requirements established by the European directive and that the appropriate procedures have been used in the design, manufacture, marketing and distribution of the product. These methods result in products that are safe and suitable for their intended use. Moreover, this marking also authorises the marketing of the health product throughout Europe.

Annually, **Smart Implant Solutions** is subject to independent external audits which periodically verify compliance with the international standards for the product and system applicable to us.

2. INSTRUCTIONS FOR SPECIFIC USE

1. IMPRESSION COPINGS (TRANSFERS)

Manufactured in grade 5 titanium for the best preservation of the implant properties, they are used to transfer the exact position of the patient's implant to the laboratory.

The head of the screws manufactured by **Smart Implant Solutions** have two tightening systems: grooves that allow direct manual tightening and tightening with screwdrivers.

For it to function correctly, ensure that the connection seat to the implant is clean. Any traces of dirt may affect the fitting of the prosthesis.

2. ANALOGUES (REPLICAS)

Manufactured in AISI-303 stainless steel, it is a prosthetic attachment, the head of which replicates the implant system connection.

The **Smart Implant Solutions** analogues are designed with effective circular and self-locking retentive anchors that embedded in the plaster enable an exceptional fixing.

3. HEALING ABUTMENTS (CAPS)

Manufactured in grade 5 titanium, they are fitted over the implant in order to protect it during its osseointegration phase.

There are available in different heights for each implant system. The **Smart Implant Solutions** abutments have a safety cut-out for use with a medical spatula for extreme locations.

4. CASTABLE ABUTMENTS

The **Smart Implant Solutions** castable abutments are produced by machining and not injection. This allows us to ensure a perfect casting with high dimensional stability.

They are available in rotating format for bridges or rehabilitations and not rotating for unit restorations.

Designed on multiple connections for all implant systems (internal and external).

5. SCREWS

Manufactured in grade 5 titanium, they are designed to fix any prosthetic element to the implant.

Smart Implant Solutions screws are notable for their high mechanical hardness and strength. They are machined in compliance with EC regulations.

It is recommended not to use screws from the prosthetic laboratory for clinical use.

It is important to use the correct size spanner for screwing and unscrewing. In case of doubt, check that the next largest spanner does not enter the housing.

The torques recommended by **Smart Implant Solutions** for definitive prosthesis, if the product label does not state otherwise, are as follows:

Size	Torque
M2.5	> 30 N*cm
M2	≤ 25 N*cm
M1.8	≤ 25 N*cm
M1.6	≤ 20 N*cm
M1.4	≤ 15 N*cm

List of sizes with tightening torque (for information purposes).

6. MILLABLE TITANIUM ABUTMENTS

Manufactured in grade 5 titanium to ensure maximum compatibility and durability. There are two types of abutments: straight and angled.

In order to verify the coupling, **Smart Implant Solutions** recommends taking an x-ray once screwed in at the height of the joint with the implant, and with the axis perpendicular to this joint.

7. INTERFACES

The interfaces are designed for carrying out digital or contact scans. They have a milled part that assists the replacement during the cementing of the zirconia structure. Its size and design ensures a stable joint which reinforces the zirconia structure in the areas of greatest force thus assuring the lifespan of the prosthesis.

Manufactured in grade 5 titanium to ensure maximum compatibility and durability.

In order to verify the coupling, **Smart Implant Solutions** recommends taking an x-ray once screwed in at the height of the joint with the implant, and with the axis perpendicular to this joint.

Relyx Unicem (3M) or similar is recommended for cementing.

8. CONVERTER ABUTMENTS (TRANSEPIHELIAL)

Manufactured in grade 5 titanium, they raise the height level and convert the connections in order to meet the needs of special clinical cases.

Available in multiple connections and in straight versions from 1 to 5 mm and angled at 17° and 30°.

9. TEMPORARY ABUTMENTS

Abutments for temporary use. Manufactured in PEEK medical plastic (suitable for replacing the titanium in the mouth to improve the aesthetic) or in grade 5 titanium.

10. SiScator PROCESSING AND MALE PACK

The SiScator processing and male packs are single use items. In case of reuse, **Smart Implant Solutions** cannot guarantee the functionality or the safety of the product, nor assume any responsibility for the reused items.

These products can be sterilised with a liquid chemical sterilising agent. To ensure sterilisation, they should be soaked in the liquid sterilising agent for a minimum of 3 hours at ambient temperature.

11. TOOLS

Smart Implant Solutions tools are characterised by the high quality of their material. Manufactured in stainless steel with heat treatment to ensure the right rigidity and durability. They ensure excellent torque tightening results and an exceptional resistance to wear.

They are sold in kits (both for the clinic and laboratory) and spares for replacement of the various tips are guaranteed.

Ensure that the tip is well fitted and secured to the screwdriver handle before placing it in the patient's mouth. To do so, insert the tip in the handle hole, rotate it and exert a light pressure until it is fully secure. Ensure that the end of the tip is fully engaged before applying any force or rotation to the surface that is to be turned.

12. IMPLANT AND SCREW EXTRACTOR

Insert the extractor straight and aligned with the implant and turn in an anticlockwise direction to position it.

Couple the spanner or ratchet to the extractor and turn to the left in an anticlockwise direction, applying pressure to the spanner or ratchet.

When the extractor is anchored to the implant thread, this will gradually unscrew.



In case of doubt, contact the Smart Implant Solutions customer support department.
(info@smartimplantsolutions.com – +34 943.322.812).

Smart Implant Solutions S.L.
Parque Científico y Tecnológico de Gipuzkoa
Po. Mikeletegi, 56. 20009 San Sebastián (Spain)

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