DELTA ABUTMENT SYSTEM

Instrucciones de uso

Introduction

This instructions show indications, contraindications, warnings and methods of use of the Delta Abutments system.

Warnings

Following warnings apply globally to the whole Delta Abutments System.
In case of doubt please contact the manufacturer.
The product is designed to be single-used. Do not reuse product.
Mechanical properties of a reused product may have been altered and the implant connection damaged.
Sinumetrics Systems can not guarantee the correct performance of a reused product.
Delta Abutments Systems clinical abutments must only be used by odontology professionals specialized in implantology and prosthetics.
If Delta Abutment systems is used by non specialised personnel , possible defects as well as new material reclaim will not be covered by guarantee.
Sinumetrics Systems recommends procedural use of dental product by the customer to guarantee the processes used are performed as intended. These processes include: Inspection of purchased material, surgical planification, cleansing, sterilisation, clinical case review, surgical procedure, systematic review plan and customer complaints among other.
For the correct use of Delta Abutment System it is recommended to use indicated instrumentation.

Intended use

Delta Abutment System's intended use is to successfully complete dental prostheses restoration processes in the clinical or laboratory environment.

Contraindications

Delta Abutment systems is not intended to be used on patients suffering from allergies or other harmful reactions to materials of the system. Please read carefully table 1 to identify the component meant to be used and the material it's made of. According to customer protocols, Sinumetrics Systems recommends compiling all the important information about the patient to avoid this potential negative effects.
Some patient's habits such as dental hygiene and smoking can affect negatively to abutment's system's intended use. It is recommended to inform the patient about the importance of healthy dental habits.

Compatibility with other products

Delta Abutment system is designed and tested so it's intended use is meant to be used with other products from other brands. Please check table 2 regarding compatibilities and make sure the product that has been planned to be used is suitable for the dental implants the patient is using.

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Information regarding cleaning and sterilisation

Cleaning

Cleaning is performed by Sinumetrics Systems. In case the customer needs to perform cleaning according his or her procedures, it is recommended to use neutral detergent, whether is manual or automated cleaning.

Sterilisation

Sinumetrics systems does not perform Sterilisation to Delta Abutment system. Sinumetrics recommends the following indications to sterilise the medical device (in accordance with standard EN ISO 17665-1:2006):

- To correctly sterilise the medical device, original packaging must be disposed and put on a double bag of sterilisation paper roll thermosealed at 175ºC. (This settings have been validated with AMCOR BOP MIXED ROLLS in paper 60gr/m2 and film PE-PP (12/40 µm) 53gr/m2) and a thermosealing machine Matachana 680 DE-V).
- To correctly sterilise medical devices, pre-vacuum autoclaving has to be performed at 121ºC during 30 minutes with a drying time of 15 minutes. (This settings have been validated in a Matachana M30-B autoclave machine)

This processes are validated by outsourced analysis laboratories. Other equivalent sterilization methods can be used as long as they are to be validated by the user according to EN ISO 17665-1:2006 and EN ISO 11607-1:2017.

Table.1 Information about componentes of Delta Abutment System

Product	**Códe(*)**	**Class according MDD CE 93/42**	**Material**
Scanbody	01RRRR	N/A	Aluminum
Analog	02RRRR	N/A	Stainless steel 304 L
Laboratory Screw	03RRRR	N/A	Stainless steel 304 L
Rotary Castable	04RRRR	N/A	POM
Anti-Rotary Castable	05RRRR	N/A	POM
Open tray transfer	06RRRR	IIa	Titanium g.V
Closed tray transfer	07RRRR	IIa	Titanium g.V
Implant cap	08RRRR	IIa	Titanium g.V
Clinical screw	09RRRR	IIb	Titanium g.V
Millable abutment	10RRRR	IIb	Titanium g.V
Temporary abutment	11RRRR	IIb	Titanium g.V
Healing Abutment	12RRRR	IIb	Titanium g.V
Multiunit abutment 1mm	13RRRR	IIb	Titanium g.V
Multiunit abutment 2mm	14RRRR	IIb	Titanium g.V
Multiunit abutment 3mm	15RRRR	IIb	Titanium g.V
Rotary Interface 0,5mm	16RRRR	IIb	Titanium g.V
Anti-Rotary Interface 0.5mm	17RRRR	IIb	Titanium g.V
Rotary Interface 1,5mm	18RRRR	IIb	Titanium g.V
Anti-Rotary Interface 1.5mm	19RRRR	IIb	Titanium g.V
Locator	20	IIa	Titanium g.V
Code expressedwith letter R refers to the compatible connection shown in table.2			

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Table.2 Compatibility references naming

REF	compatible with	REF	compatible with
0111	compatible with 3i® Certain® 3.4	0911	compatible with Nobel® Active® NP
0112	compatible with 3i® Certain® 4.1	0912	compatible with Nobel® Active® RP
0113	compatible with 3i® Certain® 5.0	0921	compatible with Nobel® Brånemark® NP
0121	compatible with 3i® External 3.4	0922	compatible with Nobel® Brånemark® RP
0122	compatible with 3i® External 4.1	0923	compatible with Nobel® Brånemark® WP
0123	compatible with 3i® External 5.0	0931	compatible with Nobel® Multiunit RP
0211	compatible with Adin® Internal 3.5	0932	compatible with Nobel® Multiunit® WP
0311	compatible with Astra Tech® Yellow	0941	compatible with Nobel® Replace® NP
0312	compatible with Astra Tech® Aqua	0942	compatible with Nobel® Replace® RP
0313	compatible with Astra Tech® Lilac	0943	compatible with Nobel® Replace® WP
0321	compatible with Astra® Evo 3.6	0944	compatible with Nobel® Replace® 6.0
0322	compatible with Astra® Evo 4.2	1011	compatible with Straumann® Bone Level NC
0323	compatible with Astra® Evo 4.8	1012	compatible with Straumann® Bone Level RC
0331	compatible with Astra® Evo Multiunit	1021	compatible with Straumann® Tissue Level RN
0411	compatible with Avinent® External 3.5	1022	compatible with Straumann® Tissue Level WN
0412	compatible with Avinent® External 4.0	1031	compatible with Straumann® Pilar Tissue Level RN
0421	compatible with Avinent® Internal 3.5	1032	compatible with Straumann® Pilar Tissue Level WN
0422	compatible with Avinent® Internal 4.0	1041	compatible with Straumann® Pilar Bone level
0511	compatible with Bego® Internal 3.75	1111	compatible with Sweden Martina® External 3.3
0512	compatible with Bego® Internal 4.5	1112	compatible with Sweden Martina® External 4.1
0611	compatible with BioHorizons® Internal 3.0	1113	compatible with Sweden Martina® External 5.0
0612	compatible with BioHorizons® Internal 3.5	1121	compatible with Sweden Martina® Kohno® 3.3
0613	compatible with BioHorizons® Internal 4.5	1122	compatible with Sweden Martina® Kohno® 3.8
0614	compatible with BioHorizons® Internal 5.7	1123	compatible with Sweden Martina® Kohno® 4.25
0621	compatible with BioHorizons® External 3.5	1124	compatible with Sweden Martina® Kohno® 5.0
0622	compatible with BioHorizons® External 4.0	1211	compatible with Zimmer® TSV® Green
0623	compatible with BioHorizons® External 5.0	1212	compatible with Zimmer® TSV® Purple
0624	compatible with BioHorizons External 6.0	1213	compatible with Zimmer® TSV® Yellow
0713	compatible with BTI® External 5.5	1311	compatible with Dentsply® Xive® 3.4
0711	compatible with BTI® External 3.5	1312	compatible with Dentsply® Xive® 3.8
0712	compatible with BTI® External 4.1	1313	compatible with Dentsply® Xive® 4.5
0721	compatible with BTI® Internal 3.5	2611	Compatible with Ziacom® External NP
0722	compatible with BTI® Internal 4.0	2612	Compatible with Ziacom® External RP
0723	compatible with BTI® Internal 5.5	2613	Compatible with Ziacom® External WP
0811	compatible with Mis® Internal NARROW	2621	Compatible with Ziacom® Internal RP
0812	compatible with Mis® Internal 3.75	2622	Compatible with Ziacom® Internal WP
0813	compatible with Mis® Internal 4.5	2631	Compatible with Ziacom® Zinic® NP
0814	compatible with Mis® Internal 5.7	2632	Compatible with Ziacom® Zinic® RP
		2633	Compatible with Ziacom® Zinic® WP

Please check the reference you plan to use exists before ordering. Check online catalog or contact Sinumetrics Systems. Not all cross references exist for all components.

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Products

01-Scanbody-Intended use and indications for use

Intended use of scanbodies is laboratory work model scans to determine dental implant position. Scanbodies are linked to digital files associated to it's scanning system. Scanbodies are not intended to be used with the patient. They can only be used with laboratory dental model. Scanbodies must be connected to the analogs of the work model and scan them.It is necessary to check scanbodies correct fitting for accurate scanning. It is highly recommended to check scanbodies wear out. If, due to wear, connection does not fit accordingly, scanning information may be wrong.

02-Analog-Intended use and indications for use

Intended use of analogs is laboratory model creation with the exact position of the analogs where implants should be in mouth. Analog can be reused, however the customer must check no damage has altered the connection. I this is so this can lead to wrong measurements and incorrect prostheses adjustments.

03-Laboratory Screw-Intended use and indications for use

Intended use of the lab screw is the manipulation of the dental prosthesis with ease in the laboratory dental model. The use of this screw is specifically intended to work with restorations which use acrylic resin in prosthesis manufacturing.

04-05-Castable-Intended use and indications for use

Intended use of castable is the manufacturing of prostheses using casting through lost wax technique. Castable replicates connection and has retentions for wax to adhere properly. Casting is a manual process in which several variables intervene. Responsability for castable use is on the customer.

06-Open tray transfer-Intended use and indications for use

Intended use of open tray transfer is correct transference of the position of the implants from patient's mouth to a work model.Open tray transfer is indicated to be used in the open tray measuring procedure.

07-Closed tray transfer-Intended use and indications for use

Intended use of closed tray transfer is the correct transference of he position of the implants from patient's mouth to a work model. Closed tray transfer is indicated to be used in the closed tray measuring procedure.

08-Implant cap-Intended use and indications for use

Intended use of implant cap is to isolate the connection of the implant from possible damage or contamination during surgical procedure. It is indicated for rehabilitations that use immediate load or measuring techniques and other procedures that may be performed during implant positioning surgery.

09-Clinical screw-Intended use and indications for use

The intended use of clinical screw is fixing abutment and prosthesis to the implant. It is recommended to screw the product at the recommended maximum torque indicated in table.3. It is recommended to apply recommended torque and 10 minutes later apply that torque again.

10-Millable abutment-Intended use and indications for use

The intended use of the millable abutment is to create an artificial custom hand-made stump.
It is indicated to perform this procedure as far as possible from the patient. The scrap metal may be harmful to the patient.

11-Temporary abutment-Intended use and indications for use

The intended use of the temporal abutment is to support provisional restorations made in acrylic resin. To manufacture this restorations the abutment can be milled to desired shape. It is indicated to perform this procedure as far as possible from the patient. The scrap metal may be harmful to the patient.

12-Healing Abutment-Intended use and indications for use

The intended use of the healing abutment is to protect the connection of the implant during implant stability phases of primary and secondary stability. Additionally it's rounded shape is meant for the gingiva to recover safely. The recommended maximum torque is indicated in table.3. It is recommended to apply recommended torque and 10 minutes later apply that torque again.

13-14-15-Multiunit abutment-Intended use and indications for use

Intended use of the Multiunit abutment is to be used as a base for fixed screw restorations.
The recommended maximum torque is indicated in table.3. It is recommended to apply recommended torque and 10 minutes later apply that torque again.
Product labeling indicates screw metrics, it's maximum torque recommended for its screw is idicated in table.3.
Additionally, the abutment final restorations has to be screwed with screw REF:090931 which has an M1.4 class thread. The recommended maximum torque for this screw is indicated in table.3.

16-17-18-19-Interface-Intended use and indications for use

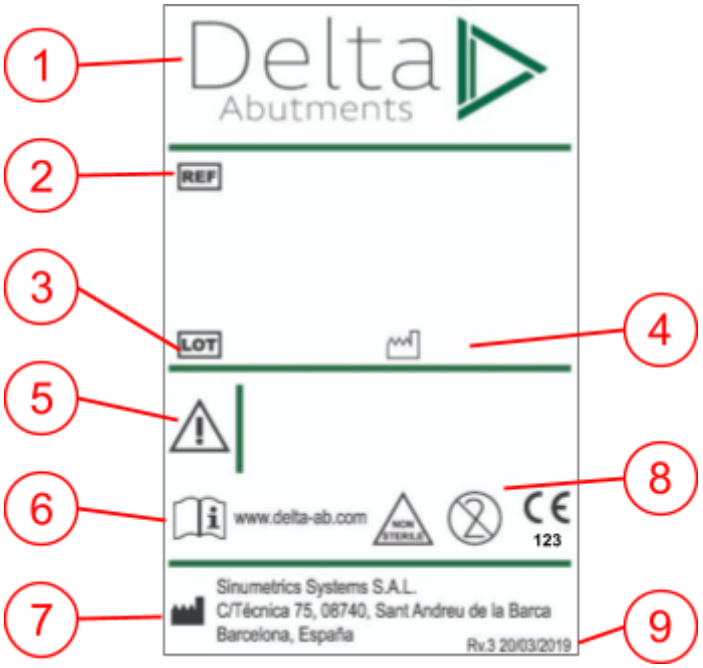
Intended use of the interface is to create an intermediate connection for cemented based restorations. The client must plan the use for these interfaces taking into account which implants are in patient's mouth and which type of restoration must be crafted, whether it is single or multiple.

20-Locator-Intended use and indications for use

Intended use for locator is anchoring of implant supported bars with removable provisional prosthetics.
Locator has an M2.0 class thread. The recommended maximum torque for this screw is indicated in table.3.

Table.3 Maximum torque according to M class thread.	
M class	**Torque [N·cm]**
M1.4	15
M1.6	20
M1.8	25
M2.0	35
M2.5	40

Label indications



Where:

1. Product brand
2. Reference of the packed product
3. Number of production lot
4. Production date
5. Indications for use
6. Online site for instructions for use
7. Manufacturer and it's address, that is Sinumetrics Systems S.A.L. C/Tecnica 75, 08740, Sant Andreu de la Barca, Barcelona, Spain.
8. Symbols according to Iso
   a. Not reusable
   b. Non sterile
   c. CE marking and Notified body code (that is 0123, TÜV-SÜD)
9. Date of the last revision of the label