

DELTA ABUTMENT SYSTEM

Instructions for use

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.



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 175°C. (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 121°C 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.

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. If 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. Responsibility 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 the 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.

09-29-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.

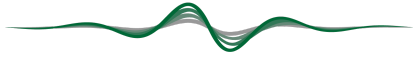
12-Healing Abutment-Intended use and indications for use

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 indicated 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.

16-17-18-19-26-38-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.

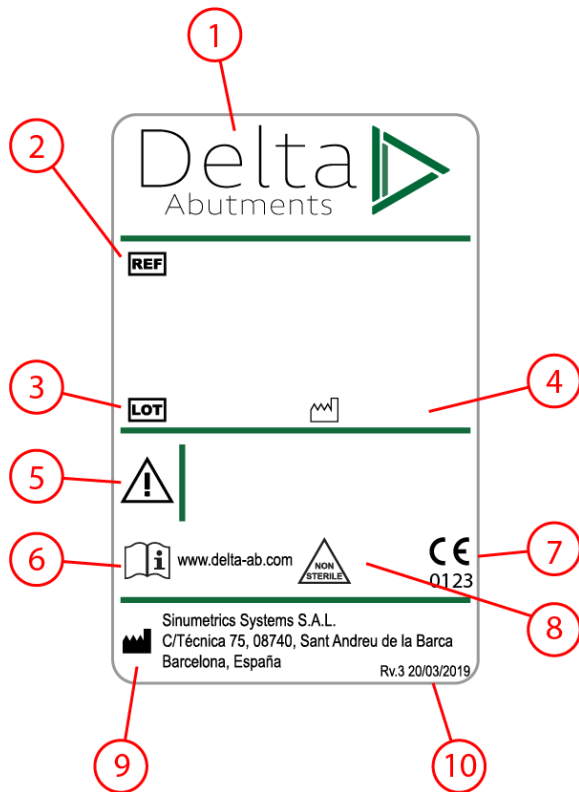
Locator has an M2.0 class thread. The recommended maximum torque for this screw is indicated in table.3.

31-Scanbody-Intended use and indications for use

Intended use of scanbodies is to scan patient's mouth in order to determine dental implant position. Scanbodies are linked to digital files associated to it's scanning system. 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 position, connection does not fit accordingly, scanning information may be wrong.



Label indications



1. Product brand
2. Reference of the product
3. LOT number
4. Manufacturing date
5. Warnings
6. Online site for instructions for use
7. CE marking and Notified body code (0123, TÜV-SÜD)
8. Symbol indications (non reusable, non sterile. etc.)
9. Manufacturer and it's address. (Sinumetrics Systems S.A.L. C/Técnica 75, 08740, Sant Andreu de la Barca, Barcelona, Spain.)
10. Date of the last revision of the label



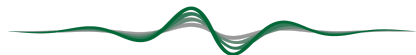
Information Tables

Product	Código(*)	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	Ila	Titanium g.V
Closed tray transfer	07RRRR	Ila	Titanium g.V
Implant cap	08RRRR	Ila	Titanium g.V
Clinical screw	09RRRR 29RRRR	IIb	Titanium g.V
Millable abutment	10RRRR	IIb	Titanium g.V
Temporary abutment	11RRRR 22RRRR	IIb	Titanium g.V
Healing Abutment	12RRRR	IIb	Titanium g.V
Multiunit abutment	13RRRR 14RRRR 15RRRR	IIb	Titanium g.V
Rotary Interface 0,5mm	16RRRR 17RRRR 18RRRR 19RRRR 26RRRR 38RRRR	IIb	Titanium g.V
Locator	20RRRR	Ila	Titanium g.V
Scanbody Intraoral	31RRRR	Ila	Titanium g.V

Code expressed with letter R refers to the compatible connection shown in table.2

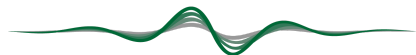
0111	compatible with 3i Certain 3.4
0112	compatible with 3i Certain 4.1
0113	compatible with 3i Certain 5.0
0121	compatible with 3i Externa 3.4
0122	compatible with 3i Externa 4.1
0123	compatible with 3i Externa 5.0
0211	compatible with Adin Interna 3.5
0311	compatible with Astra Tech Yellow
0312	compatible with Astra Tech Aqua
0313	compatible with Astra Tech Lilac
0321	compatible with Astra Evo 3.6
0322	compatible with Astra Evo 4.2
0323	compatible with Astra Evo 4.8
0324	compatible with Astra Evo 3.0
0331	compatible with Astra Evo Multiunit





0341	compatible with Astra Pilar 20°
0342	compatible with Astra Pilar 45°
0411	compatible with Avinent Externa 3.5
0412	compatible with Avinent Externa 4.0
0421	compatible with Avinent Interna 3.5
0422	compatible with Avinent Interna 4.0
0511	compatible with Bego Interna 3.75
0512	compatible with Bego Interna 4.5
0611	compatible with BioHorizons Interna 3.0
0612	compatible with BioHorizons Interna 3.5
0613	compatible with BioHorizons Interna 4.5
0614	compatible with BioHorizons Interna 5.7
0621	compatible with BioHorizons Externa 3.5
0622	compatible with BioHorizons Externa 4.0
0623	compatible with BioHorizons Externa 5.0
0624	compatible with BioHorizons Externa 6.0
0711	compatible with BTI Externa 3.5
0712	compatible with BTI Externa 4.1
0713	compatible with BTI Externa 5.5
0721	compatible with BTI Interna 3.5
0722	compatible with BTI Interna 4.0
0723	compatible with BTI Interna 5.5
0731	compatible with BTI Unit 4.0
0732	compatible with BTI Unit 5.5
0811	compatible with Mis Interna NARROW
0812	compatible with Mis Interna 3.75
0813	compatible with Mis Interna 4.5
0814	compatible with Mis Interna 5.7
0821	compatible with Mis Multiunit
0822	compatible with Mis Multiunit Angulado
0911	compatible with Nobel Active NP
0912	compatible with Nobel Active RP
0921	compatible with Nobel Branemark NP
0922	compatible with Nobel Branemark RP
0923	compatible with Nobel Branemark WP
0931	compatible with Nobel Multiunit RP
0932	compatible with Nobel Multiunit WP
0941	compatible with Nobel Replace NP
0942	compatible with Nobel Replace RP
0943	compatible with Nobel Replace WP
0944	compatible with Nobel Replace 6.0
1011	compatible with Straumann Bone Level NC
1012	compatible with Straumann Bone Level RC
1021	compatible with Straumann Tissue Level RN
1022	compatible with Straumann Tissue Level WN





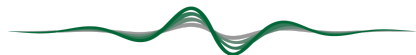
1031	compatible with Straumann Pilar Tissue Level RN
1032	compatible with Straumann Pilar Tissue Level WN
1041	compatible with Straumann Pilar Bone level
1111	compatible with Sweden Martina Externa 3.3
1112	compatible with Sweden Martina Externa 4.1
1113	compatible with Sweden Martina Externa 5.0
1121	compatible with Sweden Martina Kohno 3.3
1122	compatible with Sweden Martina Kohno 3.8
1123	compatible with Sweden Martina Kohno 4.25
1124	compatible with Sweden Martina Kohno 5.0
1211	compatible with Zimmer TSV Green
1212	compatible with Zimmer TSV Purple
1213	compatible with Zimmer TSV Yellow
1311	compatible with Dentsply Xive 3.4
1312	compatible with Dentsply Xive 3.8
1313	compatible with Dentsply Xive 4.5
1321	compatible with Dentsply Xive TG 4.8
1511	compatible with Camlog Interna 3.8
1612	compatible with Eckermann Interna 4.3
1711	compatible with Galimplant Interna
1721	compatible with Galimplant Pilar Recto Rotatorio
1722	compatible with Galimplant Pilar Recto Antirrotatorio
1731	compatible with Galimplant Externa 4.0
1732	compatible with Galimplant Externa 5.0
1811	compatible with Implant Direct Legacy 3.0
1911	compatible with Klockner Essential 4.5
1912	compatible with Klockner Essential 6.0
1921	compatible with Klockner Octa 4.5
1922	compatible with Klockner Octa 6.0
1931	compatible with Klockner SK2 3.3
1932	compatible with Klockner SK2 4.2
1933	compatible with Klockner SK2 5.5
1941	compatible with Klockner Vega MV
1942	compatible with Klockner Vega NV
1943	compatible with Klockner Vega RV
1951	compatible with Klockner SH
2011	compatible with Megagen Anyridge 3.3
2012	compatible with Megagen Anyridge 3.75
2021	compatible with Megagen Octa 3.8
2022	compatible with Megagen Octa 4.8
2111	compatible with Neodent CM Interna
2121	compatible with Neodent GM Interna 4.8
2131	compatible with Neodent CM Pilar 3.5
2132	compatible with Neodent CM Pilar AR
2133	compatible with Neodent CM Pilar RO





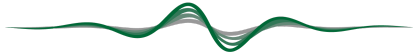
2141	compatible with Neodent GM Pilar Micro
2142	compatible with Neodent GM Pilar Mini
2151	compatible with Neodent Externa 3.3
2152	compatible with Neodent Externa 4.3
2153	compatible with Neodent Externa 5.1
2211	compatible with OXY Multiunit 5.0
2311	compatible with Phibo Aurea Evo 3.5
2312	compatible with Phibo Aurea Evo 4.3
2313	compatible with Phibo Aurea Evo 5.4
2321	compatible with Phibo TSA S3
2322	compatible with Phibo TSA S4
2323	compatible with Phibo TSA S5
2331	compatible with Phibo TSH S2
2332	compatible with Phibo TSH S3/S4
2333	compatible with Phibo TSH S5
2341	compatible with Phibo ConHex 4.75
2411	compatible with Samo Interna 4.2
2511	compatible with Anthogyr Axiom BL 2.8
2512	compatible with Anthogyr Axiom BL
2521	compatible with Anthogyr Axiom TL
2531	compatible with Anthogyr Axiom MultiLevel
2611	compatible with Ziacom Interna 4.0
2612	compatible with Ziacom Interna 5.0
2621	compatible with Ziacom Externa 3.3
2622	compatible with Ziacom Externa 4.0
2623	compatible with Ziacom Externa 5.0
2631	compatible with Ziacom Zinic NP
2632	compatible with Ziacom Zinic RP
2633	compatible with Ziacom Zinic WP
2711	compatible with JD Evolution S
2712	compatible with JD Evolution
2713	compatible with JD Evolution Plus+
2721	compatible with JD Icon UltraS
2811	compatible with Microdent Genius 3.0
2812	compatible with Microdent Genius 3.5
2813	compatible with Microdent Genius 4.0
2814	compatible with Microdent Genius 4.5
2815	compatible with Microdent Genius 5.0
2821	compatible with Microdent System 3.5
2822	compatible with Microdent System 4.2
2823	compatible with Microdent System 5.1
2824	compatible with Microdent System 5.6
2831	compatible with Microdent Universal 3.5
2832	compatible with Microdent Universal 4.1
2833	compatible with Microdent Universal 5.1





2834	compatible with Microdent Universal 5.6
2841	compatible with Microdent Trylogic 3.8
2842	compatible with Microdent Trylogic 4.3
2843	compatible with Microdent Trylogic 5.1
2844	compatible with Microdent Trylogic 5.5
2851	compatible with Microdent EK 3.5
2852	compatible with Microdent EK 4.5
2853	compatible with Microdent EK 5.7
2911	compatible with GMI Frontier RP
2912	compatible with GMI Frontier WP
2921	compatible with GMI Phoenix Estrecha
2922	compatible with GMI Phoenix Estándar
2923	compatible with GMI Phoenix Ancha
2924	compatible with GMI Phoenix Extra-Ancha
2931	compatible with GMI Avantgard RP
2932	compatible with GMI Avantgard WP
2941	compatible with GMI Monolith
3011	compatible with TBR Infinity 3.5
3012	compatible with TBR Infinity 4.0
3013	compatible with TBR Infinity 5.0
3021	compatible with TBR Infinity Z1 3.5
3022	compatible with TBR Infinity Z1 4.0
3023	compatible with TBR Infinity Z1 5.0
3111	compatible with Paltop Internal Hex Narrow
3112	compatible with Paltop Internal Hex Standard
3113	compatible with Paltop Internal Hex Wide
3121	compatible with Paltop Conical
3211	compatible with Radhex Interna IS
3212	compatible with Radhex Interna IM
3221	compatible with Radhex Externa ES
3222	compatible with Radhex Externa EM
3311	compatible with Intralock Gold&Blue Gs
3312	compatible with Intralock Gold&Blue Gw
3321	compatible with Intralock InDex Estrecho
3322	compatible with Intralock InDex Estándar
3323	compatible with Intralock InDex Ancha
3331	compatible with Intralock IntraHex 3.5
3332	compatible with Intralock IntraHex 4.5
3341	compatible with Intralock UniHex
3351	compatible with Intralock Flatone 3.5
3352	compatible with Intralock Flatone 5.0
3411	compatible with Alpha Bio IH 3.75/4.2/5.0
3421	compatible with Alpha Bio CHC Nice
3422	compatible with Alpha Bio CHC Ice
3511	compatible with Mozo Grau Inhex Mini





3512	compatible with Mozo Grau Inhex STD
3521	compatible with Mozo Grau Osseus Mini
3522	compatible with Mozo Grau Osseus STD
3621	compatible with Dentium Supeprline/Implantum
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.	

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	30
M2.5	40

