

CE 0459

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CE 0459

Medical device compliant with European Directive 93/42/CEE



Warning: you must read the accompanying instructions; Danger



Do not reuse



Non-sterile



Sterilise without packaging in an autoclave at the indicated temperature.



Catalogue reference



Lot code



Do not use if the packaging is damaged



Manufacturer



Date of manufacture



United States Federal law restricts this device to sale by or on the order of authorised dentists.



Complies with Russian standards and regulations.



Tightening torque

Description

The FlexiBase® mentioned in the table below are used for personalised prosthetic restorations on Axiom® TL, Axiom® BL implants and Multi-Unit abutments.

The permanent prosthetic screw is delivered with FlexiBase®.

For the Axiom® BL range, FlexiBase® components are removable.

Indications

Single-unit and multiple-unit screw-retained restorations on Axiom® TL, Axiom® BL implants and Multi-Unit abutments.

Contraindications

Allergy to Titanium Ti6Al4V-ELI.

The FlexiBase® on Multi-Unit abutments must not be used if there is an axis gap wider than 40° between 2 abutment analogues, as inserting the prosthesis may turn out to be impossible.

Warnings and precautions

Only clinicians trained in dental implants should install these components.

Single-use devices: do not reuse or re-sterilise. Risk of contamination and risk of deterioration of functional surfaces.

Prosthetic components must be attached to prevent their accidental inhalation or swallowing during intraoral use.



FlexiBase® must not be altered (neither on the gingival nor on the crown area); risk of mechanical weakening.

Only the sanding of the crown portion is tolerated with corundum (Al2O3) with 50 µm to 125 µm granulometry and under a pressure of 2 to 4 bars.

The screws OPTS160, MU140, TS160 and TS160P must only be used to secure the prosthetic restoration on the implant in the mouth.

Failing to follow the procedures described in these instructions may lead to one or more of the following complications :

- Damage to the implant, prosthetic part, or other components
- Loosening of the prosthetic part or other components
- Improper final restoration
- Malfunction of the patient's chewing
- Implant rejection.

Cleaning and sterilisation



Please refer to the recommendations of the manufacturers of restoration materials (superstructure and adhesive) on the compatibility with means of sterilisation.

All components and instruments are supplied **NON-STERILE**. They must be cleaned and sterilised according to the cleaning and sterilisation manual available on the website ifu.anthogyr.com (search code: OPFLEX413, for example) or upon request from Anthogyr at the address above.

Instructions for Use

→ Manufacturing the superstructure:

- by CAD-CAM machining: the related CAD library can be downloaded from the www.anthogyr.com website



Please refer to the recommendations of the manufacturers of restoration materials on the minimum thickness of the superstructure in the event of zirconia manufacturing.

- by moulded technique: use of the associated castable cap (see table below).

→ Before applying the adhesive, screw the FlexiBase® on the analogue with the short laboratory screw (Ref. OPTS161 for Axiom® BL, Ref. TS163 for Axiom® TL, Ref. MU141-4 for Multi-Unit) or long (Ref. OPTS162 for Axiom® BL, Ref. TS162 for Axiom® TL, Ref. MUT101 and Ref. MUT102 for Multi-Unit).

→ Glue the superstructure on the FlexiBase®.



Please refer to the recommendations of the manufacturers of adhesive materials on the gluing protocol.

For gluing a ZIRCONIA supra-structure, Anthogyr recommends the following adhesives: PANAVIA TM (F2.0 / V5 / Cement Plus) from KURARAY DENTAL or MULTILINK AUTOMIX from IVOCAR VIVADENT.

→ Clean and sterilise the prosthetic restoration and the permanent prosthetic screw.

→ Screw the prosthetic restoration on the implant / abutment using its own permanent prosthetic screw using an INCCD or TORQ CONTROL® torque wrench. The FlexiBase® must be tightened to the recommended torques indicated in the table below.

→ Close the access channel with filling material after protecting the screw head.

Safety and responsibility

Correct use and manipulation of this product are carried out outside our control, and they are the user's responsibility.

Anthogyr shall not be held responsible for clinical failure due to not following the protocol explained above.

Patient information

Patients must accept regular medical follow-up and should consult their doctor in case of an unexpected change in the performance of the prosthetic reconstitution. Patients must be informed of the need to ensure regular oral hygiene.

Anthogyr thanks you for your trust and will be happy to supply you with additional information.

		FlexiBase® Reference	Visual	Permanent prosthetic screw (supplied with FlexiBase®)	Associated castable cap
AXIOM® BL	SINGLE-UNIT	OPFLEX413		 <i>OPTS160</i> Tightening torque : 25 N.cm	OPFLEXC403
		OPFLEX423			
		OPFLEX433			
		OPFLEX513			
		OPFLEX523			OPFLEXC503
		OPFLEX533			
	MULTIPLE-UNIT	MUNFLEX		 <i>MU140</i> Tightening torque : 15 N.cm	MUNFLEXC
		MUFLEX			MUFLEXC
AXIOM® TL	SINGLE-UNIT	TFLEX-N		 <i>TS160</i> Tightening torque : 25 N.cm	TFLEXC-N
		TFLEX-R			TFLEXC-R
	MULTIPLE-UNIT	TFLEX-N-P		 <i>TS160P</i> Tightening torque : 25 N.cm	TFLEXC-N-P
		TFLEX-R-P			TFLEXC-R-P