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Anthogyr SAS 2 237, Av. André Lasquin 74700 Sallanches - France Phone : +33(0)4 50 58 02 37 Fax : +33(0)4 50 93 78 60 ifu.anthogyr.com Email : sales@anthogyr.com Edition : 2018-11 REF. 0630PLA_NOT_US

Medical device complying with European Directive 93/42/EEC.

Attention: The accompanying instructions must be consulted; Danger.

See the precautions for use.

🖌 🛛 Do not reuse

Not sterile

Sterilization by autoclave without packaging, at the specified temperature

temperatur

REF Catalogue reference

LOT Batch number

Do not use if the package is damaged

Store in a dry place with humidity between 30% and 70%

🕅 Store away from light

Manufacturer

Manufacturing date

R Federal (U.S.) law restricts this device to sale by or on the order of an authorised dentist.

АИ49

Complies with norms and standards in Russia

GTIN : Global Trade Item Number

LOCATOR® Attachment System,

Includes

Specific LOCATOR[®] Attachments, restorative parts, dental laboratory components, and instruments.

Important: This document contains the most current Instructions for Use.

Please read and retain.

Description

Universal hinge, resilient attachment for endosseous implants Axiom[®] REG or Axiom[®] PX.

Indications

The LOCATOR[®] Implant Attachment System is designed for use with overdentures or partial dentures, retained in whole or in part, by Axiom[®] REG or Axiom[®] PX implants in the mandible or maxilla.

Contraindications

Not appropriate where a totally rigid connection is required. Use of a single implant with divergence of greater than 20 degrees from vertical is not recommended.

Caution

Federal (USA) law restricts this device to sale by or on the order of a licensed dentist.

Warnings, precautions & directions for use

The LOCATOR[®] Attachment Systems have not been evaluated for safety and compatibility in the MR environment. The LOCA-TOR[®] Attachment Systems have not been tested for heating or migration in the MR environment.

Single-use devices

The LOCATOR[®] Attachment Systems are single-use devices. Single-use devices must not be reused, not resterilized (risk of contamination and risk of alteration of functional surfaces)

If re-used, Anthogyr cannot guarantee the functionality or the safety of the product. Anthogyr accepts no responsibility for components re-sterilized by the user.

Sterilization

All components and instruments are supplied NON-STERILE.

To clean and sterilise Anthogyr components, please refer to the sterilisation manual (AXIOMR-PX_NOT_US).

The nylon males may be sterilized/ disinfected using a liquid chemical sterilant. In order to ensure that the nylon males are sterilized/disinfected (all microorganisms including Clostridium sporogenes and Bacillus subtilis spores are eliminated), the nylon males must be soaked for a minimum of 3 hours in the liquid sterilant at room temperature.

Prosthetic procedures and technique manual

Using a calibrated torque wrench, tighten the Locator Abutment to 25 N.cm

Warning: Use of higher torque values than recommended above could cause a fracture of the LOCATOR® Abutment and/or implant.

The Technique Manuals for the LOCATOR® Attachment System, are available from the manufacturer or your distributor. These are also available online at <u>www.zestdent.com</u>

The instructions are not sufficient by themselves for risk-free implantation of Axiom[®] REG and Axiom[®] PX' implants. You absolutely must follow the instructions of the surgical manual "Axiom[®] REG and Axiom[®] PX user guide". This document is delivered with each surgical kit. It is available at <u>ifu.anthogyr.com</u> or by simply requesting it from Anthogyr at the contacts above.

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