CE 0459

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Edition : 2016-03
REF. 0630PLA_NOT_EN

CE 0459 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

135°C Sterilisation by autoclave without packaging, at the specified temperature

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

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

PG AM49 Complies with norms and standards in Russia

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 LOCATOR® 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

NON STERILE All components and instruments are supplied *NON-STERILE.* Titanium abutments and instruments may be sterilized by Autoclave or Dry Heat sterilization using the following parameters:

1. Autoclave sterilize using 121° C (250 ° F), (15-20 psig at sea level), for 20 minutes minimum.

2. Dry Heat sterilize using 170° C (338° F) for 2 hours minimum.

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 Ncm

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 www.zestanchors.com

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 www.anthogyr.com or by simply requesting it from Anthogyr at the contacts above.