CE 0459

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Dental implants: Axiom® REG; Axiom® 2.8 ; Axiom® PX ; Anthofit® HE ®

CE 0459 Class IIb medical device, complying with European Directive 93/42/EEC.

Attention: The accompanying instructions must be consulted; Danger.

Do not reuse

Do not re-sterilise.

STERILE R Sterilised by irradiation.

Use-by date.

REF Catalogue reference.

LOT Batch number.

Do not use if the package is damaged.

Manufacturer.

Manufacturing date.

See the precautions for use.

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

Complies with norms and standards in Russia.

GTIN Global Trade Item Number

The following instructions are not sufficient by themselves for risk-free implementation of Anthogyr implant systems. You absolutely must follow the instructions of the surgical manual corresponding to the type of implant inserted.
These documents are available on ifu.anthogyr.com or on simple request from Anthogyr to the contact details above .

Description

Implants of the Axiom® REG/PX/2.8 product lines are in Ti-6Al-4V ELI medical-grade titanium alloy.
Axiom® 2.8 implants are aimed for single replacement in cases presenting a restricted mesiodistal space. Cover plugs, healing plugs and temporary abutments for Axiom® 2.8 implants are in PEEK.
Implants of the Anthofit® HE product lines are in Ti60 medical-grade titanium.

Expected use

Anthogyr implants are intended for the replacement of missing tooth roots, and they provide for stabilisation of removable dentures or the fixation of single-unit or multiple-unit implant restorations (except Axiom® 2.8).

Indications

Implants can be placed with immediate function in appropriate clinical situations (good primary stability and appropriate occlusal loading).
Axiom® PX implants are designed to achieve good primary stability in low density bone. Axiom® PX implants are suitable for immediate or early implant placement using a conventional loading protocol (≥ 2 months after implantation).
Axiom® 2.8 : Intended only for single replacement of mandibular incisors and maxillary lateral incisors.

Contraindications

A general physical exam should be done before the surgical phase.
→ Absolute : serious diseases (tumours, heart disease, etc.), metabolism disorders, uncompensated haematologic diseases, drug addition, alcoholism or smoking, psychosis, functional disorders, xerostomia, immune deficiency, leukocyte disorder, local or systemic treatments (steroid, anticoagulant, chemotherapy or radiation therapy, etc.).
→ Relative : bruxism, occlusal stress, parafunction, unfavourable bone anatomy, pregnancy, growth not finished, insufficient oral hygiene, lack of motivation or cooperation, irradiated bone, uncontrolled periodontal disease, oral infections or inflammations.
→ Local : Insufficient volume and/or quality of bone, local radicular residues.

Axiom® PX : The implant is contraindicated in bone-type D1*, except in the context of the protocol described in the Axiom® Multi Level® additional surgical user guide available at ifu.anthogyr.com (search code: PXTA34L). This protocol is not available in all countries.

Anthofit® HE : The 3.5-Ø implant is contraindicated in the posterior area.

Warning / Caution

Be sure to use only original Anthogyr parts with the corresponding connection for an Anthogyr implant restoration: risk of injury, damage and dysfunction of the implant, risk of damage of the components or the accessory.
Dimensions and type of implant : see the label. A sufficient quantity of implants should be placed to provide support and to adequately distribute the loads. The diameter of each implant should be appropriate for the mechanical load to be supported:
Axiom® REG and Axiom® PX: The 3.4-Ø implant is not recommended in the molar area.
The angular orientation of the implant (except for the Axiom® 2.8 implant) predefines the final orientation of the anti-rotational prosthetic components.
Cutting instruments should be replaced as soon as they are perceived to be losing efficacy, in all cases after no more than 20 uses (10 for Anthofit® HE instruments).

Protocol

Appropriate training and qualification as well as good knowledge of surgical techniques for Anthogyr products are necessary. Anthogyr offers specific training sessions.

All efforts to minimise injury to host tissues should be agreed to, making sure in particular to avoid heat and surgical trauma and to eliminate all contaminants and any source of infection.
The surgical technique for placement of Anthogyr implants should be carried out only in combination with the Anthogyr instruments and components specific to the implant product line to be placed.

Small components should be fastened firmly to avoid inhalation or swallowing during intra-oral use.
Each time an instrument is changed, verify good hold in the contra-angle or the wrench by applying mild traction.

Each site should be prepared using a progressive sequence of drilling diameters.
Make sure never to exceed the depth of the planned drilling : depth stops on each rotational instrument or use of drills with a stop or a contra-angle with a stop system.

- Axiom® REG :

Tightening speed : 25 rpm.
Maximum recommended tightening torque : 80 N.cm.
Tapping recommended in type D1 bone*.

- Axiom® PX :

Tightening speed : 15 rpm.
Maximum recommended tightening torque :80 N.cm.
Do not tap, except in D1* type bone cases where the Axiom® Multi Level® additional surgery kit instruments are used in accordance with the protocol described in the manual available at ifu.anthogyr.com (search code: PXTA34L).

- Axiom® 2.8 :

Tightening speed: 20-25 rpm.
Maximum recommended tightening torque : 65 N.cm.

- Anthofit® HE :

Tightening speed : 25-50 rpm.
Maximum recommended tightening torque : 80 N.cm.

Implant tightening torque that is too high may cause implant damage, a fracture or bone necrosis. Unscrew and then re-screw the implant to limit the insertion torque if it becomes too high. Placement of cover screw / healing screw / protective cap for MU/OPAC/OPSC abutments. Moderate manual tightening (<10N.cm) with the OPCS100 surgical wrench. Placement of cover/healing plugs (Axiom® 2.8) with the OPCF100 wrench by applying moderate manual pressure with the OPCF100 wrench.

Use the detachable identification labels on the packaging to put the information in the patient's medical record and ensure the traceability of the implanted products.
Make sure that the implant is sufficiently stable before placing the prosthetic components.

**according to the C.Misch classification. [Misch CE, Judy KW (1987), Classification of partially edentulous arches for implant dentistry. Int J Oral Implants 4 (2): 7-13].*

Side-effects

Allergy or hypersensitivity to the chemical components of the materials used, oedema, haematoma, gingivitis, difficulty speaking, permanent paresthesia, dysesthesia, crestal bone loss, localised or systemic infection, aesthetic problems, postoperative pain.

Complications

Break of a component, loosening or loss of a component (in all cases, the removed implant cannot be reused), bone fracture, local nerve injury (transitory or permanent), hyperplasia, exfoliation, etc.

Patient information

The patient should be informed by the surgeon of the potential adverse effects and complications.
The patient should agree to regular medical follow-up and should see his/her doctor in the event of an unexpected change in the performance of the dental implant.
The patient's attention should be drawn to the necessity of regular oral hygiene.

Packaging and sterility

Anthogyr implants are delivered STERILE, and they are packaged in a blister pack and sterilised using gamma radiation.
The sterility of Anthogyr implants is guaranteed only if the following conditions are all present:
- package integrity
- expiry date not exceeded
- product stored in a clean, dry and cool place

Comply with the various sterility zones during unpacking: only the items inside the blister pack + seal are sterile.
The sterilisation status indicator turns red during the Anthogyr sterilisation process. It does not guarantee product sterility in itself. It should not be confused with the colour coding of the implant diameter.

Warnings

⚠ Implant surgery is a complex dental procedure. Incorrect techniques may result in implant failure and/or loss of the supporting bone.
You must plan for a safety space sufficient for anatomic obstacles particularly by taking into account the drilling allowances and the implant apical position in bone.
Single-use devices: do not reuse or re-sterilise. Risk of contamination and risk of deterioration of functional surfaces.
The facility performing the insertion is responsible for handling waste resulting from the procedure (packaging, extracted implant, etc.) as medical waste.
Anthogyr disclaims responsibility in the event of clinical failure related to not following the surgical protocol.

Anthogyr thanks you for your trust and is available to provide you with any additional information.