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INSTRUCTIONS FOR USE- AISER Implant System

Description

Aiser dental implants, abutments and accessories such as scan bodies, transfers and analogs are made of Grade 5 ELI (TI6AI4V) Titanium according to the ASTM F136. Drills are made in Surgical Steel AISI 316.
Each implant is packaged in a aseptic blister and a vial. The primary container is in a transparent polystirene (EPS) bottle, a pressure cap and a medical (LDPE) insert; inside, a titanium mounter (cricket holder) supports the device. The implant collection is carried out using a cricket driver insert. The cover screw is housed in the LDPE insert. The vial is placed in a secondary package which act as sterile barrier: a PET thermally sealed blister.
The Blisters will be further packaged in a carton box.
The carton box, the blister, and the vial all bear labels containing the following informations: identification code, description, lot, expiry date, UDI, CE number and related symbols. On the blister and carton box Label further informations such as QR codes with UDI and IFU, are available. The dental implants are supplied in a sterile package. Sterilization is performed by Gamma irradiation (25 kGy).
AISER dental implants meet the essential requirements of directive 93/42/EEC following changes/additions, pertaining to medical devices. Abutments and other accessories are packaged in pet sleeves that bear labels with all due informations as above. Abutments and accessories are sold non-sterile.

Use of the products

AISER dental implants, abutments and implant accessories are designed to be used in functional and aesthetic rehabilitation of edentulism, both maxillary and mandibular. The use of the Implant System is intended for the treatment of both total or partial edentulism. The duration of the treatment varies,and it depends on various factors, on of those factor is the proper maintenance by the patient, which must be fully informed about the needed hygienic and behavioural standards. Also it is expected that the physician will periodically inspect the implants and prosthetics applied and that the due maintenance is performed.
Themys, Tytan, Ceos implants should be considered as an integral part of a complete implant system, which also includes AISER Conical Link System abutments and all AISER Accessories needed for implant placement, impression and prosthetic placement.
AISER Implants are equipped with an internal hexagon conical connection, and are designed to be paired with AISER Conical Link System abutments.
Conical Link System abutments come in a Universal Prosthetic platform, so any AISER abutment fit any AISER implant, regardless of diameter, implant line or lenght. Prosthetics are available in various transmucosal heights and size, to be chosen by the clinician based on the charachterics of the anatomical site to be rehabilitated. Themys implants are single coil implants developed for any bone phenotypes, particularly suitable in poor bone quality sites such as D3, D4.
Tytan Implants are dual coil implants developed for any bone sites particularly suitable for hard bone such as D1, D2.
Ceos Implant is developed for Zygomatic procedures, and oral implantology procedures with poor quality sites, such as D3, D4.
For additional information please refer to AISER Surgical protocol and AISER Prosthetic protocol, available on the website www.aiserimplants.com/en/protocols/
Caution is due when applying smaller sized implants as the duration of the restoration might be shorter than with bigger sized implants, the patient should be duly informed.

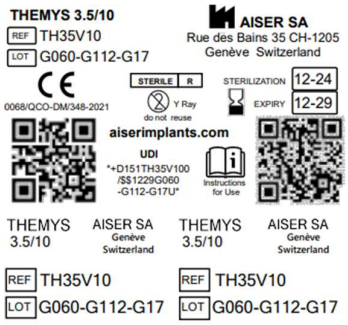
Applications

The implants must be selected according to the patient's condition and the surgical technique.
Specifically, the surgical technique is explained in AISER Surgical protocol, and the posthetic techniques and parameters in AISER Prosthetic protocol. A high degree of accuracy is required at all times in the preparation of the implant site, by respecting the sequence of the various steps in the surgical protocol. The heat trauma caused by friction of the drills must be kept to a minimum by using sharp cutters, in the right sequence, the appropriate number of rounds per minutes and irrigation with sterile solution and suitable healing times. Further informations can be found on AISER Surgical and Prosthetic protocols, available on the website www.aiserimplants.com/en/protocols/

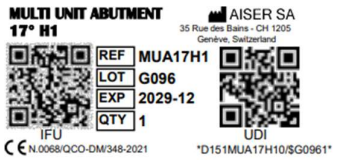
Labelling

AISER Labelling process follows law requirements, thermal printers using preformed labels are being used. Standard Operation Procedure "Label Control" defines the steps and procedures the operators must follow to attain label conformity.
The labels appear as follow:

Implants



Abutments and accessories



Batch Numbers are assigned as per following template XNNN-YNNN-ZNNN on all implants XNNN on abutments and accessories.

XNNN = CNC mechanical procedure unique batch number.
YNNN = Surface treatment procedure unique batch number
ZNNN = Sterilization procedure unique batch number

As shown in the following example: F047-G039-H12

F047 = CNC mechanical procedure unique batch number.
G039 = Surface treatment procedure unique batch number
H12 = Sterilization procedure unique batch number

Contraindications

Insufficient amount of bone or gum tissues or insufficient or inadequate bone quality. Allergy to titanium or its alloy. Contraindications based on patient general health and conditions are the same as per dental and general surgeries, and the precautions to observe are the same. Here a non exhaustive list of contraindications: reduced blood clotting (anticoagulants to antiplatelet therapies or, hereditary or acquired coagulation disorders), infection and inflammation of the mouth and surrounding areas such as periodontitis and gingivitis (acute and chronic infections of the affected area, or infection inflammation of the soft tissues, bone infections, osteomyelitis), severe metabolic diseases, decompensated or inadequately treated diabetes, calcium metabolism disorder, treatment with steroids and other drugs that interfere in bone metabolism, therapy with immune-suppressants, chemotherapy and radiotherapy, active endocrinological diseases, bone diseases, anatomical proximity or interference with nerve routes, insufficient gingival soft tissue for recoating, incorrect occlusion and/or TMJ articulation, limited interocclusal space, pain syndromes, poor oral hygiene, poor patient motivation to treatment. Relative contraindications apply to bruxism, allergic patients, patients with addiction to alcohol, drugs, nicotine.

Warning

AISER dental implants may only be used by trained professionals such as: dentists, maxillo-facial surgeons, medical doctors, if properly trained in the use of implants and, particularly, in the use of AISER Implants. Failure to observe the surgical protocol could determine the implant failure.
AISER Themys, AISER Tytan, AISER Ceos and related Abutments and accessories are considered an integral part of a complete implant system. AISER recommends the use of original accessories, tools, and abutments. AISER deny any responsibilities in case of usage of non original components.
Dental implants must be stored in their original packaging, in a dry place, away from heat sources, and at room temperature until the time of placement.
Dental implants should not be used after the expiration date written on the package.
Do not reuse implants and abutments. Reuse accessories, such as drills, scan bodies, scredrivers and transfers, only if properly sterilized. Do not use if the package is opened or damaged. Do not use after expiration date. Don't remove the labels from packaging. Modifying the product packaging could compromise the functionality of the device, and for implants, their sterility.
Implants are sold in sterile and single use packaging, the reuse of products creates a potential risk of infection in the patient, or in the operators who use the device.
The manufacturer is not liable in case of sterilization performed by third parties on any AISER accessory, and reccomend not to reuse Implants and Abutments. Reprocessing may compromise the structural integrity of the products or cause it to malfunction. The collection of the implant from its packaging during procedures must be performed using appropriate tools, as described in AISER Surgical protocol available on the website www.aiserimplants.com/en/protocols/
During collection procedure, the operator must be aware of the risk of contamination of the medical device, hence performing the task with appropriate care.
Contamination of the Implant could result in implant loss and infection in the patient.
AISER provides labels with the critical features regarding the devices. In the implant packaging adhesive labels bearing critical informations about the implant must be placed on the patient's medical record. AISER recommand to keep tracks of critical informations also on abutments and accessories used during the procedure.
To obtain the replacement of the goods, if quality does not match the standards of the manufacturer, if the order is wrong or if packaging is visibly damaged, it is necessary to warn the manufacturer or the official representative for your country, by email within 10 days of receipt of goods; the return of the product must be in its original packaging, filling a regular transport document and the filed request of substitution received by the manufacturer or official representatives.
The device removed from the oral cavity in case of treatment failure must be disposed in biohazard waste. Always refer to your local regulations.

Precautions

For a correct surgical planning an accurate diagnosis and screening must be performed. AISER suggest the following steps: screening, panoramic radiographs and CT scan of the site to be treated.

Secondary Effects

Titanium and surgical steel used in drills are generally condidered safe when properly used. Despite the high success rate of Titanium implants, there is a risk of failure which is usually linked to an incorrect surgical technique or disregard for contraindications.

Supply

AISER Themys implant: 1 sterile dental implant with cover screw.
AISER Tytan implant: 1 sterile dental implant with cover screw.
AISER Conical Link System Abutments: nr.1 abutment with fastening screw
Accessories: drills, screwdrivers and surgical accessories according to the chosen kit; impression components with its fastening screw.

Additional Information

For any additional information please consult www.aiserimplants.com in the protocol section, or write an email to geneve@aiser.org.

 - Manufacturer

 - Caution

 - Keep away from sources of heat

 - Use by year/month

CE 0068

 - Store in dry place

 - See instruction

REF - Catalogue reference

LOT - Batch number

 - Do not use if container is damaged

 - Disposable

STERILE R - Sterilized using irradiation

 - Do not resterilize