INSTRUCTION FOR USE
DENTAL IMPLANTS

DESCRIPTION

The Advan dental implants are bone-implantable screws presenting peculiar geometry and surface properties that permit the achievement of primary stability and successive osseointegration. The implants are made of Commercially Pure grade 4 Titanium or Titanium Alloy Ti6Al4V ELI (grade 23), and present a surface obtained by (partly) sandblasting with HA particles (OsseoGRIP) and/or by coating with Titanium plasma spray (TiPS).
The implants, after decontamination, are packaged in a controlled environment and sterilized by β-rays. Dental implants are supplied sterile. If appropriately stored, the intact sterile packaging protects the implant and its sterility to the specified expiration date (see label).

INDICATIONS

Dental implants are intended for surgical placement into the alveolar bone, where they will be thereafter osseointegrated; they are used for the anchoring of the dental prosthetics. For further details and information about the use of dental implants and other components of Advan implant system, see the reference documentation available at the respective national distributors or sales representatives and on the website www.advanimplantology.com.

CONTRAINDICATIONS

- ABSOLUTE CONTRAINDICATIONS: severe uncontrolled systemic diseases, metabolic bone disorders, uncontrolled haemorrhagic diseases, uncooperative/unmotivated patient, drug or alcohol abuse, psychosis, prolonged treatment-resistant functional disorders, xerostomia, reduced immunity, diseases with periodic use of steroids, allergy to implant materials (titanium in particular), uncontrollable endocrine diseases.
- RELATIVE CONTRAINDICATIONS: previously irradiated bone, diabetes mellitus, medical anticoagulation/haemorrhagic diathesis, bruxism, parafunctional habits, unfavorable bone anatomy, tobacco abuse, uncontrolled periodontitis, temporomandibular joint disease, pathological jaw disease and oral mucosal abnormalities amenable to treatment, pregnancy, inadequate oral hygiene.
- LOCAL CONTRAINDICATIONS: inadequate bone quantity and/or inadequate bone quality, local residual roots.

POTENTIAL COMPLICATIONS

Activities in which the body is exposed to severe physical strain should be avoided immediately after the insertion of dental implants. It is recommended that the physician, or other authorized personnel, informs the patient regarding the precautions and potential complications, as below reported, which may occur as a consequence of the surgical procedure for implanting the components. It is also recommended to invite the patient to promptly contact the physician in case of any loss of performance of the implant or of the prosthetic components. Possible complications after the insertion of dental implants can be:

- TEMPORARY COMPLAINTS: pain, swelling, phonetic difficulties, gingival inflammation.
- MORE PROLONGED COMPLAINTS: chronic pain associated with the dental implant, permanent paraesthesia, dysaesthesia, loss of maxillary/mandibular alveolar bone, localized or systemic infections, oroantral or oronasal fistulas, unfavorable effect on adjacent teeth, irreversible damage to adjacent teeth, implant, jaw, bone or denture fractures, aesthetic problems, nerve injury, exfoliation, hyperplasia.

WARNINGS / CAUTIONS

The dental implant is part of an overall concept and must be used only with the original components and surgical instruments, following the instructions and recommendations of the relevant surgical manual. The use of non original components, or produced by third parties can severely affect the implant function. The implant must not be used after the printed expiry date (see label). The implants must be stored in the original packaging in a dry room, protected from direct sunlight and at room temperature. Advan does not accept any responsibility for resterilized implants, independent of whom has carried out resterilization or by which method. A previously used or non-sterile implant should not be implanted under any circumstance. Product reuse would expose patients to high risks, such as cross infection, lack of osseointegration and implant functional failure. If the original packaging is damaged, the contents will not be accepted and replaced by Advan.

PRINCIPLES OF TREATMENT PLANNING

The surgical phase of the implant-supported restoration must be preceded by comprehensive patient evaluation, preoperative diagnosis, and treatment planning. Inadequate treatment planning can cause implant loss. Use of the appropriate X-ray template is essential for proper treatment planning.

SELECTION CRITERIA/INDICATIONS

Analysis of local and systemic contraindications, normal wound healing capacity, effective oral hygiene/healthy remaining teeth, full growth of maxilla and mandible, good general medical condition, adequate supply of healthy jaw bone.
Local examination: anatomy of the alveolar ridge, intermaxillary relationships, deep bite, quality and thickness of the mucosa, study models and bite registration on the articulator, radiographic and CT findings.
It is suggested to use bone screws with a diameter of less than 3.5 mm only for:

- single tooth replacement of the lateral incisors in the maxilla
- single tooth replacement of the lateral and central incisors in the mandible
- partially dentate jaws: with implant-borne, fixed constructions: combine with bone screws with diameter greater than 3.5 mm and splint the superstructure.

The implants should be surrounded by at least 1.0 mm of residual bone following implantation. If the thickness of the bone wall is less than 1.0 mm or the bone lamella is non-existent, a bone augmentation procedure is indicated.

WARNING: in case of intraoral use, a prevention of aspiration risks must be guaranteed.

DIRECTIONS FOR USE

The following descriptions are not sufficient for immediate use of the Advan dental implants.
Dental implants should be used only by dentists, physicians, and surgeons trained to the use of the dental implant system. If these conditions are not met, it is recommended to contact an adequately experienced surgeon, in order to acquire the necessary expertise in the management of dental implants or to follow a Advan approved course of dental implant surgery.

STERILE PACKAGING:

WARNING: when taking the implant out of its sterile packaging, appropriate aseptic technique should be followed.
WARNING: the sterile packaging must be opened only immediately before the operation. Prior to implant insertion, check that the sterile packaging is undamaged. If the sterile packaging is damaged, the implant sterility can be affected. It is advisable to have a corresponding replacement product available before starting the operation.
The implant package includes an outer cardboard box and a blister pack containing the vial with the implant. The box must be opened by the non-sterile operator breaking the seal and then he has to remove the sterile blister and finally remove the heat-sealed Tyvek lid. Then the sterile operator can remove the sterile vial containing the implant or drop it onto the sterile field. To withdraw the implant from the sterile vial the sterile operator should gently remove the cap (do not unscrew and do not pull roughly upwards).

SURGICAL TECHNIQUE:

the conservative treatment of soft and hard tissues is an essential condition for successful implant healing. Carefully prepare the implant site. Thermal trauma prevents healing of a dental implant. Hence temperature increase must be minimized with the following measures:

- using twist drills at a small number of revolutions per minute, with particular attention to the final drilling operations.
- Using sharp drills and burs (do not use more than 10 times on hard bone, not more than 50 times on medium/soft bone).
- Adopting intermittent drilling technique.
- Abundant cooling of drills and burs with chilled (5°C/41°F) sterile saline (NaCl) or Ringer solution.

Using drills in ascending order of diameter; more gradual diameter progression is recommended on hard bone.
Primary stability after insertion of the implant is an essential precondition for successful osteointegration. Please note that the twist drills have an apical overlength, i.e. the depth of preparation of the implant site does not correspond to the insertion depth of the implant. This shall be considered when selecting the implant length (ref. X-ray template). For more information, please refer to the surgical manual.

INSERTION OF AN IMPLANT AFTER PREPARATION OF THE IMPLANT SITE

WARNING: do not use excessive torque when screwing in the implant (max 50 Ncm). In case of mechanically assisted insertion, the speed should not exceed 15 rpm. Set the torque control at the appropriate value in relation to the bone quality. In case of manual insertion, always use the torque wrench.

TREATMENT OF SOFT TISSUES AND WOUND CLOSURE:

Advan implants are suitable for both bi-phasic and mono-phasic techniques. Before the wound healing, the appropriate cover screw or healing abutment is selected and screwed onto the implant. The wound edges are closely approximated with atraumatic suture material, avoiding excessive tightening. One suture is placed on either side of the cover screw or healing abutment so that the wound ed- ges are approximated without tension. Please read the surgical manual before using healing caps and closure screws.

IMMEDIATE IMPLANT RESTORATION:

All Advan implants, unless contraindicated, are indicated for immediate restoration of single tooth gaps and in the edentulous or partially dentate jaw. Good primary stability and appropriate occlusal loading are a precondition. Multiple tooth applications may be rigidly splinted. In the case of edentulous indications, at least 4 implants must be rigidly splinted. Immediate restoration or loading on a single implant in the following indications has not been studied and is not recommended:

- Terminal molar in the mandible and/or maxilla
- Cantilevering of a single implant

DELAYED IMPLANT RESTORATION – DURATION OF HEALING

4-6 weeks:

- in case of good bone quality and adequate bone availability

12 weeks:

- in case of cancellous bone
- in case of implants smaller than 3.5 mm diameter.

There is no difference in healing between the mandible and the maxilla.
In situations where the implant surface is not completely in contact with the bone or bone augmentation measures are necessary, planning should allow for an adequate healing phase. Before starting the prosthetic restoration, a radiographic assessment is recommended 4-8 week after healing.

GENERAL HANDLING, CARE AND MAINTENANCE OF THE SURGICAL INSTRUMENTS

WARNING: the clinical success of the surgical procedure of inserting a dental implant requires the use of instruments in perfect condition.
Please read the instructions on technical sheet for surgical kit use and maintenance.

DOCUMENTATION AND TRACEABILITY

Advan recommends full clinical, radiological, photographic and statistical documentation. Each implant can be traced using the reference and lot number. The adhesive label on the outer box contains all the appropriate data. The same information can be found on the blister label and on the vial. Inside the box there are two stickers, intended to be placed onto the patient documentation. Contact Advan, national distributors or sales reps in order to have the patient implant passport.

DISCLAIMER OF LIABILITY

This product is part of an overall concept and may only be used in conjunction with the associated original products (according to Advan's instructions and recommendation).
Non-recommended use of products made by third parties in conjunction with Advan products will void any warranty or other obligation, express or implied, of Advan. The user of Advan products has the duty to determine whether or not any product is suitable for the particular patient and circumstances.
Advan disclaims any liability, express or implied, and shall have no responsibility for any direct, indirect, punitive or other damages, arising out of or in connection with any errors in professional judgment or practice in the use of Advan products. The user is also obliged to study the latest developments in regard to this Advan product and its applications regularly. In cases where clarifications are needed, the user should contact a representative of Advan. Since the utilisation of this product is under the control of the user, it is his/her responsibility. Advan does not assume any liability whatsoever for damage arising thereof. Please, note that some products detailed in this Instruction for Use may not be regulatory cleared, released or licensed for sale in all markets.

FURTHER INFORMATIONS

For more information on the use of Advan products, contact Advan customer service.

DISPOSAL

Disposal must be managed in an environmentally sustainable way, in compliance with local regulations. Hazardous waste from contaminated devices or sharp objects must be disposed off in suitable containers that meet specific technical requirements.

SYMBOLS

The following table describes the symbols that can be found on the packaging label. Consult the packaging label for the symbols applicable to the product.

Symbols glossary

Symbol	Description
	Manufacturer
	Date of manufacture
	Use-by date
	Batch code
	Catalogue number
	Sterilized using irradiation
	Do not resterilize
	Non-sterile
	Do not use if package is damaged and consult instructions for use
	Keep away from sunlight
	Keep dry
	Do not re-use

Symbol	Description
	Consult instructions for use or consult electronic instructions for use
	Caution
	Multi packaging (the number reported in the symbol refers to the number of units in the packaging)
	Medical device
	Single sterile barrier system with protective packaging inside
	Single sterile barrier system with protective packaging outside
	Distributor
	Unique device identifier
	Not locking prosthetic component
	Octagon locking prosthetic component
	Hexagon locking prosthetic component

Symbol	Description
CE 0123	Advan products covered by the CE mark fulfill the requirements of the Directive 93/42/CEE concerning medical devices and falls within Classes IIa, IIb
CE	Advan products covered by the CE mark without the identification number fulfill the requirements of the EU Regulation 2017/745 (MDR) concerning medical devices and falls within Class I

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