INSTRUCTIONS FOR USE:
ADVAN DENTAL IMPLANTS

PRODUCT DESCRIPTION AND INDICATIONS

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 or totally) 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 (electron-beam). 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).
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.
Refer to the surgical guidelines for implants and prosthetic components.

INTENDED USE

The Advan dental implant system is intended to be surgically placed, either immediately after extraction or following healing, in the inferior or superior jawbone to reach the osseointegration and to provide support for the prosthetic components.
The Advan dental implant system is a medical device intended for long-term use.

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, unfavourable bone anatomy, tobacco abuse, uncontrolled periodontitis, temporo-mandibular 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

Potential complications include all the activities in which the body is exposed to severe physical strain that 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. The risks and complications with implants include but are not limited to:
Potential side effects and temporary symptoms: pain, swelling, phonetic difficulties, gingival inflammation.
More persistent symptoms: (1) chronic pain associated with implant and its prothesis, (2) swallowing, (3) permanent paraesthesia, (4) dysesthesia, (5) localized or systemic infection, (6) oroantral or oronasal fistulas, (7) jaw, bone oral denture fracture, (8) aesthetic problem, (9) nerve injury, (10) exfoliation, and (11) hyperplasia.

WARNINGS/CAUTIONS

Advan dental implants are 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.
It is very important to be aware and avoid damage to vital structures such as nerves, veins and arteries. Injuries to vital anatomical structures may cause serious complications like injury to the eye, nerve damage and excessive bleeding. It is essential to protect the infraorbital nerve. Failing to identify actual measurements relative to the radiographic data could lead to complications.
The use of the original surgical instrumentation organized in the appropriate kit and properly sterilized is recommended. To obtain good stability from an implant, careful preparation of the implant site with the appropriate surgical instruments is essential. The product should not be resterilized and reused. Advan assumes no responsibility for resterilized implants, regardless of who performed the resterilization or the method used. A previously used or non-sterilized implant should not be implanted under any circumstances. Reuse of the product would expose patients to high risks, such as cross-infection, failure to osseointegrated, and functional failure of the implant. In order to comply with applicable regulations, the physician is required to affix the product identification label found inside the box to the patient's medical record. Do not use the device if the packaging has been previously opened or damaged. 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 overlays is essential for proper treatment planning. A careful clinical and radiological examination of the patient should be performed before surgery to determine the patient's psychological and physical state. A medical CT scan or Cone beam CT (CBCT) analysis is strongly recommended before the final treatment decision is made.

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;
- support implant for larger diameter implants joined together by the superstructure.

After insertion, 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.

SURGICAL PROCEDURE

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 WITH IMPLANTS:

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.

Warning: Make sure the burs lock into the handpiece before starting any milling operation. A loose handpiece can accidentally injure the patient or members of the surgical team.
Warning: Make sure all interconnecting instruments lock properly before intraoral use to prevent accidental ingestion or aspiration.
Warning: Ensure proper angulation and avoid oscillation of the drill, as this may inadvertently widen the preparation site.
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 overlays). 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 dental 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 edges are approximated without tension. Please read the surgical manual before using healing caps and closure screws.

IMMEDIATE IMPLANT RESTORATION:

Unless contraindicated, all dental implants are indicated for immediate restoration of missing single teeth as well as in the edentulous or partially edentulous mandible. Good primary stability and adequate temporary occlusal loading are preconditions. For multiple edentulous rehabilitations, implants can be rigidly connected. In the case of overdentures, at least 4 implants with a diameter of not less than 3.5 mm should be connected together.

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:

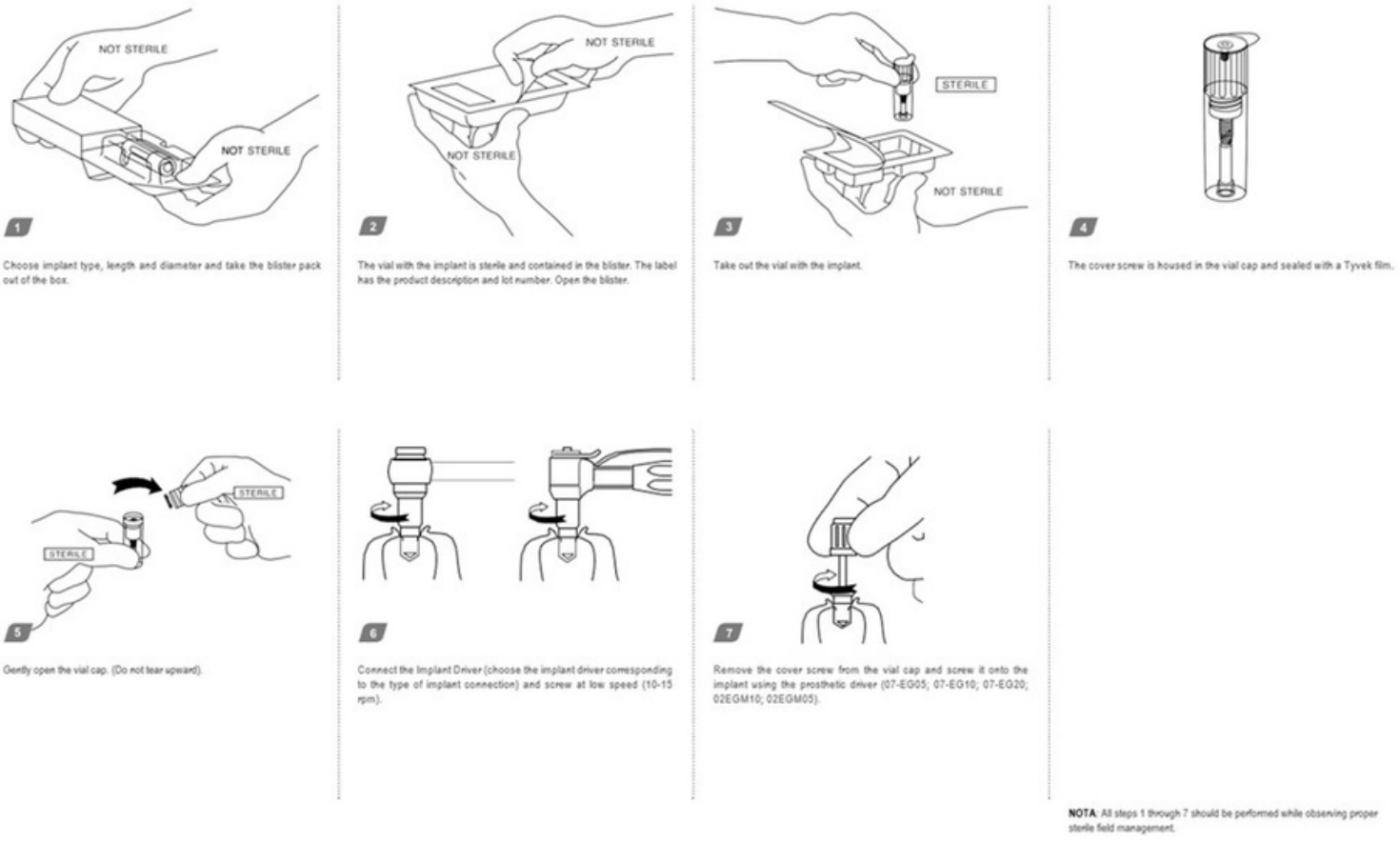
- in case of good bone quality and adequate bone availability.

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.



STORAGE
Advan dental implant should not be used after the expiration date (see label). Dental implants should be stored in the original packaging in a dry environment, out of direct sunlight and at room temperature.

GENERAL HANDLING, CARE AND MAINTENANCE OF THE SURGICAL INSTRUMENTS
Warning: The clinical success of the surgical procedure of dental implant placement requires the use of instruments in perfect condition.
Care and maintenance of instruments are critical to successful treatment. Sterilized instruments not only protect patients and staff from infection and cross-infection, but are also essential to the total treatment outcome.
Due to the small size of the components, care should be taken to ensure that the components are not swallowed or aspirated by the patient. A rubber dam is recommended to prevent inhalation of loose parts.
Please read the instructions on technical sheet for surgical kit use and maintenance.

DOCUMENTATION AND TRACEABILITY
Advan recommends complete clinical, radiological, photographic and statistical documentation. Each dental 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 also be found on the blister label. Inside the box on the Tyvek surface are three detachable labels intended to be placed on the patient's record. If not directly inside the box, contact Advan, national distributors, or sales agents to obtain the patient's implant passport.

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

DISPOSAL
Disposal must be handled in an environmentally sustainable manner, in accordance with local regulations. Hazardous waste from contaminated devices or sharps must be disposed of in appropriate containers that meet specific technical requirements.

NOTES
Physician who use the Advan product are required to have adequate technical knowledge and training, in order to ensure its safe use. The Advan product must be used in accordance with the manufacturer's instructions for use. The physician is responsible for using the device in accordance with these instructions for use and for determining the suitability of the device for the patient's individual situation. The Advan product is part of a complete program and should be used only in conjunction with its original components and instruments distributed directly by Advan and all national Advan dealers. Use of third-party products not distributed by Advan voids any warranty or other obligation, implied or express, of Advan.

VALIDITY
These operating instructions supersede all previous versions.

AVAILABILITY
Some Advan Implant System items may not be available in all countries.

SYMBOLS
The following table describes the symbols that can be identified on the packaging and on the device label. Refer to the packaging label for symbols applicable to the product.

Symbols glossary

Symbol	Description
	Manufacturer
	Date of manufacture
	Use-by date
	Batch code
	Catalogue number
	Sterilized using irradiation

Symbol	Description
	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
	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

Symbol	Description
UDI	Unique device identifier
R	Not locking prosthetic component
NR	Octagon locking prosthetic component
NR	Hexagon locking prosthetic component
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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