INSTRUCTION FOR USE:

ADVAN ZYGOMATIC IMPLANTS

PRODUCT DESCRIPTION AND INDICATIONS

Advan zygomatic implants are endosseous implants made of Titanium Alloy Ti6Al4V ELI (Grade 23) partially treated by sandblasting with medical-grade hydroxyapatite microparticles (OsseoGRIP treatment). Advan zygomatic implants feature a parallel walled implant body with a specific apex for zygomatic cortical bone and a straight implant neck with internal hexagonal connection for prosthetic rehabilitation. The implants, after decontamination, are packed in a controlled environment and sterilized by β-beam (electron-beam). The zygomatic implants are supplied sterile. Intact sterile packaging protects the implant and its sterility and ensures its durability, if properly stored, until the indicated expiration date (see label).

The ZYGOMA APEX zygomatic implant features a threaded apex of only 13.5 mm with a low surface roughness and the coronal portion of the implant machined untreated. This ensures that, should the implant emerge into the maxillary or nasal cavity, it incentivizes better soft tissue stability and healing and is easier to clean compared to an implant with an entirely threaded rough surface. The smooth surface also reduces the possible adhesion of periopathogenic agents. The ZYGOMA APEX zygomatic implant, indicated in cancer patients and with an extramaxillary approach, can also be used for conventional extramaxillary placement in the case of a defect-free atrophic maxilla. This surgical procedure provides good visualization of the osteotomy and simplifies easy placement of the implant head in the buccal area relative to the alveolar ridge. This prosthetic-driven implant position will place the implant head below the occlusal surface and relatively reduce the bulk of the buccolingual prosthesis, improving phonetic ability and facilitating plaque control.

Dedicated multi-unit abutments (MUA) with 45° and 60° angulation are available for prosthetic rehabilitation.

The Advan zygomatic implant system is indicated for oral endosseous placement in the maxillary upper arch to provide support for fixed or removable dentures and for functional and aesthetic rehabilitation in patients with partially or completely edentulous jaws. All implants are appropriate for immediate loading when good primary stability is achieved and there is an appropriate occlusal loading condition. These implants are not intended for single rehabilitation.

INTENDED USE

Zygomatic implants are long-term use medical devices, intended to be surgically placed in the upper jaw arch to treat partially or fully edentulous patients with severely resorbed or absent maxillae, providing support for the prosthetic components.

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.
- RELATED CONTRAINDICATIONS: 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: insufficient bone quantity and/or inadequate bone quality, local apical remnants.

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.

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.

WARNING/CAUTIONS

ADVAN zygomatic 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 overlay 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

The patient must have clinically symptom-free sinuses, no pathology in the associated bone and soft tissue, and must have completed all necessary dental treatment. Special attention should be given to patients who have local or systemic factors that could interfere with the bone or soft tissue healing or osseointegration process (e.g., smoking, poor oral hygiene, uncontrolled diabetes, orofacial radiotherapy, steroid therapy, infection in adjacent bone). Special care should be taken with patients receiving bisphosphonate therapy.

In general, zygomatic implant placement and prosthetic design should be adapted to the individual patient's condition. In cases of bruxism or unfavourable jaw ratios, a re-evaluation of the treatment option may be considered. Regarding paediatric patients, routine treatment is not recommended until the end of the jawbone growth phase has been adequately documented. Preoperative hard tissue or soft tissue deficits may produce a compromised aesthetic result or unfavourable implant angulation.

WARNING: Advan zygomatic implant treatments can be performed under local anaesthesia, by IV-sedation, or general anaesthesia.

SURGICAL PROCEDURE

The descriptions below are not sufficient for immediate use of Advan zygomatic implants.

Zygomatic implants should only be used by dentists, physicians, and surgeons trained regarding the use of the zygomatic implant system.

It is strongly recommended that both new and experienced users of zygomatic implants always undergo specific training before embarking on a new treatment methodology.

In the case of first-time use, discussion with an Advan opinion leader regarding zygomatic implants is recommended. Advan invites beginners in zygomatic implantology to the international training center for this purpose.

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:

To begin exposure of the lateral maxillary wall, the entire mucoperiosteal flap is reflected following a crestal incision with bilateral distal vertical release incisions over the areas of the maxillary tuberosity.

WARNING: it is imperative to be aware of vital structures including nerves, veins and arteries during surgical exposure of the lateral maxillary wall. Injury to vital anatomic structures can lead to complications including eye injury, extensive bleeding, and nerve dysfunction.

WARNING: it is essential to identify and protect the infraorbital nerve.

For direct visualization of the lateral maxillary wall and fronto-zygomatic notch area, a retractor is placed in the fronto-zygomatic notch with lateral retraction.

To assist in direct visualization of the drills during osteotomy preparation, a "window" is drilled through the lateral maxillary wall. Attempt to keep Schneider's membrane intact if possible. Begin the trajectory of the implant at the first-second bicuspid area on the maxillary crest, follow the posterior maxillary wall and end at the lateral cortex of the zygomatic bone slightly inferior to the fronto-zygomatic notch.

Drilling procedure: the ratio of the handpiece used is 20:1 at a maximum speed of 2000 rpm. Drill under constant and copious irrigation with sterile saline (NaCl) or precooled Ringer's solution (5 °C).

WARNING: the drill guide can be used during osteotomy preparation to prevent contact of the drill with adjacent soft tissues. If the drill shaft is not protected, injury to the tongue, lips and/or other soft tissues may occur.

Depth measurement system: the drill guide can be used during osteotomy preparation to prevent contact of the drill with adjacent soft tissues. If the drill shaft is not protected, injury to the tongue, lips and/or other soft tissues may occur.

WARNING: Avoid lateral pressure on drills during implant site preparation. Lateral pressure can cause fracture of the drill.

WARNING: verify that the drills lock into the handpiece before beginning any drilling operation. A loose handpiece can accidentally injure the patient or members of the surgical team.

WARNING: verify that all interconnecting instruments lock properly before intraoral use to prevent accidental swallowing or aspiration.

Drilling sequence: the initial osteotomy is performed using the Advan round drill and the Advan twist drill 2.9-mm, followed by the Advan twist drill 3.5-mm and the Advan twist drill 4.2-mm.

WARNING: ensure the angle is correct and avoid oscillation of the drill, as this may inadvertently widen the preparation site.

WARNING: If the sinus membrane cannot be kept intact during osteotomy preparation, carefully irrigate debris during implant insertion. Any mucosal debris at the bone site may prevent osseointegration of the implant.

Use Advan depth indicators to determine the length of the Advan zygomatic implant to be placed. Copious irrigation of the sinus prior to implant placement is recommended.

Plan the implant placement as posteriorly as possible, with the implant head as close to the alveolar crest as possible (typically in the 2nd premolar region). Anchorage of the implant will be achieved by entering the base of the zygomatic bone (the posterior-lateral portion of the sinus floor), which engages through the lateral cortical of the zygoma below the fronto-zygomatic notch. Depending on the patient's anatomy, the implant body can be placed inside or outside the maxillary sinus.

NOTE: Adjustment to this implant placement may need to be considered because of anatomic variations in the maxilla and sinus.

IMPLANT PLACEMENT:

Implant placement with drilling tools: the implant may be inserted using an implant driver and drills with an insertion torque of 20 Ncm. Increase the insertion torque to a maximum of 50 Ncm for full implant placement. Once an insertion torque of 40 to 50 Ncm is achieved, the manual Advan driver can be used. Disengage the implant driver with the handpiece. Now connect the Advan manual driver to the implant driver's torque wrench adapter and insert it into the implant. Rotate the Advan driver clockwise until the desired depth and head position is achieved. Confirm through the "window" relative to the lateral maxillary wall the correct implant insertion angle by continuing through the sinus until the apex of the implant engages the zygomatic bone.

Manual tightening: disengage the implant driver with the handpiece. Now attach the Advan out-of-occlusion driver to the implant connection, rotate the Advan out-of-occlusion driver clockwise until the desired depth and head position is achieved.

WARNING: when using the Advan off-occlusion driver the application of excessive torque may distort or damage the implant connection.

Perform copious irrigation of the apical portion of the implant (the subperiosteal portion of the zygomatic bone) before removing the retractor from the fronto-zygomatic notch.

Premaxillary implants are placed following the conventional protocol for implant placement. For immediate loading, implants should be able to achieve a final torque between 35 and 45 Ncm. For the two-stage protocol, relocate the prosthesis to the implants.

WARNING: Advan zygomatic implants can be tilted up to 45° from the occlusal plane. When used at angles between 30° and 45°, the following applies: the inclined implant must be parallelized; a minimum of 4 implants must be used when supporting a fixed prosthesis in a complete edentulous arch. After implant placement, the surgeon's assessment regarding bone quality and primary stability will determine when implants can be loaded. Lack of adequate quantity and/or quality of remaining bone, infection, and generalized pathology can be potential causes of osseointegration failure either immediately after surgery or after osseointegration has been initially achieved.

Bending moment: the forces that cause bending moment are known to be the most unfavorable, as they can potentially compromise the long-term stability of an implant-supported prosthesis. In order to reduce bending moment, force distribution should be optimized by cross-arch stabilisation, minimising distal cantilevers, having a balanced occlusion as well as decreased cuspal inclination of the prosthetic teeth.

WARNING: use only Advan zygomatic abutments; dedicated 45° and 60° MUA abutments are available for this implant.

For more information on surgical procedures, see the Advan zygomatic implant surgical guidelines.

STORAGE

Advan zygomatic implants should not be used after the expiration date (see label). Advan zygomatic 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 Advan zygomatic implants 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 Advan zygomatic implants 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
LOT	Batch code
REF	Catalogue number
STERILE R	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
N	Multi packaging (the number reported in the symbol refers to the number of units in the packaging)
MD	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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