INSTRUCTION FOR USE
ADVAN ZYGOMATIC IMPLANTS

DESCRIPTION

IMPLANTS:

Advan zygomatic implants are endosseous implants made from biocompatible Ti6Al4V ELI (grade 23) titanium alloy with Osseogrip surface. It is a parallel walled implant body with a specific apex for zygoma cortical bone and a straight abutment neck with a internal hexagonal connection for prosthodiontic rehabilitation. The implant has 3 different tread design for specific use due to the clinical condition of the patient:

- ZYGOMA APEX family line is designed with only 13,5 mm threaded apex with a low surface roughness and coronal machined surface, this ensures that where the implant emerges into the maxillary or nasal defect, it promotes improved soft tissue health and is easier to clean compared to an implant with roughened threads, the machined surface also reduce the adhesion of periopathogenic agents. This oncology implant also functions well for conventional extra-maxillary placement where this is required on a non-defect atrophic maxilla. This surgical procedure provides good visualization of the osteotomy and simplifies easy positioning of the implant head buccal to the crest of the ridge. This prosthetic-driven implant position will place the head of the implant beneath the proposed occlusal surface and comparatively reduce the bulk of the prosthesis buccolingually, improving speech and facilitating plaque control. This implant type is indicated in oncologic patients and extra-maxillary approach;
- ZYGOMA FULL family line is designed with all body threaded with a low surface roughness, this ensure the implant contacts bone at the alveolar crest, lateral sinus wall and zygomatic bone, so the expectation is subsequent osseointegration along the entire length of the implant. This type of implant is indicated in intra-sinus approach;
- ZYGOMA TWIN family line is designed with 13,5 mm threaded apex, a small portion of coronal thread with a low surface roughness and a central machined surface, this ensure the implant contacts bone in the coronal alveolar crest and apical zygomatic bone, most of the implant body is not touching the most concave part of the lateral sinus wall, so the expectation is subsequent osseointegration in zygomatic bone and in alveolar crest, to reduce the bending moment thanks the two osseointegrated point. This type of implant is indicated in alveolar-out extra sinus approach.

Dedicated 45° and 60° Multi Unit Abutments (MUA) are available for prosthodontics rehabilitation.

INTENDED USE

The ADVAN zygomatic implant is intended to be surgically placed to treat partially or fully eden-tulous patients with severely resorbed or absent maxillae for whom conventional implants are not an option as a means of fixing a permanent or removable dental or maxillofacial prosthesis.
The ADVAN zygomatic implant system is an implantable medical device intended for long-term use.

INDICATIONS

The ADVAN zygomatic implant system is indicated for oral endosseous placement in the upper jaw arch to provide support for fixed dental prostheses and for functional and aesthetic rehabilitation in patients with partially or fully edentulous maxillae. All implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading. These implants are not intended for single unit loading.

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, where adequate numbers of implants could not be placed to achieve full functional support for a prosthesis.

POTENTIAL COMPLICATIONS

Activities in which the body is exposed to severe physical strain should be avoided immediately after the insertion of zygomatic 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 zygomatic implants could be:

- TEMPORARY COMPLICATIONS: pain, swelling, phonetic difficulties, gingival inflammation.
- MORE PROLONGED COMPLICATIONS: chronic pain associated with the zygomatic implant, permanent paraesthesia, dysaesthesia, loss of maxillary alveolar bone, localized or systemic infections, oroantral or oronasal fistulas, irreversible damage to adjacent implant, jaw, bone or denture fractures, aesthetic problems, nerve injury, exfoliation, hyperplasia, formation of fat emboli, perforation of the maxillary sinus, perforation of the labial and lingual plates.

WARNING/CAUTIONS

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 zygomatic 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 re-use 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.

DIRECTIONS FOR USE

The following descriptions are not sufficient for immediate use of the Advan zygomatic implants.
Zygomatic implants should be used only by dentists, physicians, and surgeons trained to the use of the zygomatic implant system.
It is strongly recommended that clinicians, new as well as experienced implant users, always go through special training before undertaking a new treatment method.
Advan offers specific formation for clinicians of various levels of knowledge and experience. For more information please visit www.advanimplantology.com.
Working the first time with a Advan opinion leader for zygomatic implants is recommended. Advan invites beginners in zygomatic implantology at the international training center for this purpose.

PRINCIPLES OF TREATMENT PLANNING:

Careful clinical and radiological examination of the patient has to be performed prior to surgery to determine the psychological and physical status of the patient. It is highly recommended to perform a medical CT scan or a CBCT (cone beam CT) analysis prior to the final treatment decision.

SELECTION CRITERIA/INDICATIONS:

The patient must have clinically symptom-free sinuses, no pathology in associated bone and soft tissue and completed all necessary dental treatment.
Special attention has to be given to patients who have local or systemic factors that could interfere with the healing process of either bone or soft tissue or the osseointegration process (e.g., cigarette smoking, poor oral hygiene, uncontrolled diabetes, orofacial radiotherapy, steroid therapy, infections in the neighbouring bone). Special caution is advised in patients who receive bisphosphonate therapy.
In general, implant placement and prosthetic design must accommodate individual patient conditions. In case of bruxism or not favorable jaw relationships reappraisal of the treatment option may be considered.
With respect to pediatric patients, routine treatment is not recommended until the end of the jawbone growth phase has been properly documented.
Pre-operative hard tissue or soft tissue deficits may yield a compromised aesthetic result or not favorable implant angulation.
WARNING: Advan zygomatic implant treatments may be performed under local anaesthesia, IV-sedation or general anaesthesia.

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:

To begin exposure of the lateral maxillary wall, a full thickness mucoperiosteal flap is reflected following a crestal incision with bilateral distal vertical releasing incisions over the tuberosity areas.
Warning: It is imperative to be aware of vital structures including nerves, veins and arteries during the surgical exposure of the lateral maxillary wall. Injuries to vital anatomic structures can lead to complications including injury to the eye as well as extensive bleeding and nerve-related dysfunction.
Caution: It is essential to identify and protect the infraorbital nerve.
For direct visualization of the lateral maxillary wall as well as the 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 the preparation of the osteotomy, a “window” is made through the lateral maxillary wall. Attempt to keep the Schneiderian 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 speed of max. 2000 rpm. Drill under constant and profuse irrigation by sterile saline at room temperature.
Caution: The Drill guide may be used during the preparation of the osteotomy to avoid contact of the rotating drill with the adjacent soft tissues. Injury to the tongue, corner of the lips and or other soft tissues may occur if the drill shaft is unprotected.
Depth measurement system: The parallel drills have a true depth measurement system. All drills and components are marked to prepare the site to the correct depth and obtain a secure and predictable position.
Caution: Avoid lateral pressure on drills during implant-site preparation. Lateral pressure may cause drill fracture.
Caution: Verify that drills lock in the handpiece before starting any drilling. A loose drill may accidentally harm the patient or members of the surgical team.
Caution: Verify that all interconnecting instruments lock properly before intraoral use to prevent accidental swallowing or aspiration.
Drilling Sequence: The initial osteotomy is made using the

Advan Round Bur and the Advan Twist Drill 2.9 mm, followed by the Advan Twist Drill 3.5 mm and Advan Twist Drill 4.2 mm.
Caution: Ensure correct angulation and avoid drill wobble, as this can inadvertently widen the preparation site.
Caution: If the sinus membrane cannot be kept intact during osteotomy preparation, carefully irrigate away debris when inserting the implant. Any mucosal remnants in the bone site may prevent osseointegration of the implant.
Use the Advan depth indicators to determine the length of the Advan zygomatic implant to be placed. Copious irrigation of the sinus is recommended prior to implant placement.
Plan to insert the implant 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 zygoma bone (the posterior-lateral portion of the maxillary sinus roof), engaging through the lateral cortex of the zygoma below the fronto-zygomatic notch. Depending on the anatomy of the patient, the implant body may be positioned inside or outside the maxillary sinus.
Note: Adjustment to this implant placement may be considered due to anatomical variations in the maxilla as well as the maxillary sinus

IMPLANT PLACEMENT.

Insert implant with drilling unit: The implant may be inserted using an implant driver and the drilling unit at 20 Ncm insertion torque. Increasing the insertion torque up to maximum 50 Ncm may be used for the complete seating of the implant. Once an insertion torque of 40 to 50 Ncm is reached, the Advan Handle may be used. Disengage the implant driver with Handpiece. Now connect the Advan Handle to the Implant Driver Wrench Adapter and insert into the implant. Rotate the Advan Handle clockwise until the desired depth and head position are achieved.
Confirm through the “window” of the lateral maxillary wall the correct insertion angle of the implant while continuing through the sinus until the implant apex engages in the zygomatic bone.

TIGHTEN MANUALLY:

Disengage the implant driver with Handpiece. Now connect the Advan Handle to the Implant Driver Wrench Adapter and insert into the implant. Rotate the Advan Handle clockwise until the desired depth and head position are achieved.
Caution: When using the Advan Handle, applying excessive torque can distort or fracture the implant connection.
Perform copious irrigation of the apical portion of the implant (the subperiosteal portion of the zygomatic bone) prior to the removal of the retractor from the fronto-zygomatic notch.
The premaxillary implants are placed following the conventional protocol for placement of implants.
For Immediate Function, the implants should be able to withstand a final torque between 35–45 Ncm. For two-stage protocol relieve the denture over the implants.
Caution: Advan zygomatic implants may be tilted up to 45° relative to the occlusal plane. When used with angulations between 30° and 45°, the following applies: the tilted implant must be splinted; a minimum of 4 implants must be used when supporting a fixed prosthesis in a full edentulous arch. After the implant installation, the surgeon’s evaluation of bone quality and primary stability will determine when implants may be loaded. Lack of adequate quantity and/or quality of remaining bone, infection and generalised diseases may be potential causes for failure of osseointegration both immediately after surgery, or after osseointegration is initially achieved.
Bending moment: forces that cause bending moment are known to be the most unfavourable, as they can potentially jeopardise the long-term stability of an implant-supported restoration. In order to decrease bending moment, the distribution of forces should be optimised by cross-arch stabilisation, minimising distal cantilevers, having a balanced occlusion as well as decreased cuspal inclination of the prosthetic teeth.
Caution: Use only Advan zygomatic abutment, there are dedicated MUA 45° and 60° available for this implant.
For additional information on surgical procedures please consult the Advan zygomatic implant surgical guidelines (request latest version from a Advan representative)

GENERAL HANDLING, CARE AND MAINTENANCE OF THE SURGICAL INSTRUMENTS

WARNING: the clinical success of the surgical procedure of inserting a zygomatic implant requires the use of instruments in perfect condition.
Care and maintenance of instruments are crucial for a successful treatment. Sterilised instruments not only safeguard your patients and staff against infection and cross-infection but are also essential for the outcome of the total treatment.
Because of the small size of components, care must be taken that they are not swallowed or aspirated by the patient. It is recommended to use a rubber dam in order to prevent inhalation of loose parts.
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 on the Tyvek surface there are three detachable 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 wha-

tsoever 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
LOT	Batch code
REF	Catalogue number

Symbol	Description
STERILE R	Sterilized using irradiation
	Do not resterilize
NON STERILE	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

Symbol	Description
	Distributor
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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