INSTRUCTION FOR USE
EXTRA-ORAL IMPLANT

DESCRIPTION

The extra-oral implant system Extra includes bone-implantable screws, manufactured with Titanium c.p. Grade 4 according to peculiar geometry and surface properties and they are designed to be surgically implanted into different region of cranial bone. A successfully positioned implant achieves osteointegration resulting in firm stability between bone and Titanium surface.

CONTRAINDICATIONS

The implants should not be placed in cases where the bone thickness is poor and, in general, where the bone does not guarantee implant anchorage. Lack of osteointegration and implant failure may occur in cases where there is insufficient available bone, poor bone quality, when patient shows poor hygiene, or in presence of poor medical conditions due to local or systemic pathologies. Carefully consider the placement of extra-oral implants in bone previously received radiotherapy. Moreover, in patient selection, psychotic diseases, tobacco, alcohol or drug abuse must be evaluated. The implants are contrindicated when patient shows allergy to Titanium.

WARNINGS

For safe and effective use of the implants, it is strongly recommended that specialized training is achieved by the surgeon: the proper surgical techniques to place extra-oral implants are complex and high specialised. Improper patient selection and/or technique can result in implant failure and loss of surrounding bone. The use of original surgical instruments, organised in the dedicated box and properly sterilized is recommended. To achieve a good implant stability it is mandatory an accurate preparation of the implant site with adequate surgical instruments. The product must not be re-sterilized and re-used. In case of re-use of the product or of any of its accessories patients would be exposed to high risks, such as cross infection or device functional failure. It is mandatory to stick the product labelling on patient's clinical documentation. Do not use the device if packaging has been previously opened or damaged.

PRECAUTIONS

Selection of prospective implant candidates must be particularly accurate. CT scans and tomograms may be a valid support in all complex cases.

ADVERSE EFFECTS

Loss of implant stability (failure of osteointegration) is a possible adverse effect both during healing period and during its functionalization (with possible loss of epithesis). Bone deficiency or poor quality, infections, improper surgery, poor hygiene or cooperation, and generalized pathologies (e.g. diabetes) are potential causes for loss of stability.

SURGICAL PROCEDURE

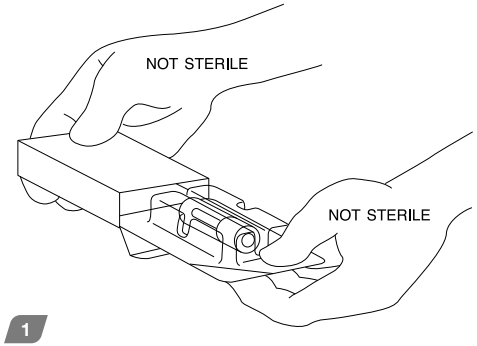
Before proceeding with intervention, after the preparation of the surgical field, the surgeon and the anaplastologist define the position of the implant sites, to obtain the best aesthetic result.

1. When implants are positioned to anchor ear prosthesis, make an incision 10 mm away from the implant site; expose the periosteum and incise it near each implant site.
2. Drill a initial hole using the round bur (07-FP11; 07-FP12 according to the length of the planned implant). The hole is for the entire length of the implant site. Do not exceed 600 rpm. A not accurate control of depth of the site may cause perforation of the wall of the sigmoid sinus and exposure of the dura mater.
3. Prepare the implant site with the appropriate bur, according to the type and length of the planned implant (07FEP01; 07FEP02; 07-FE01; 07-FE02). Do not exceed 300 rpm. Cool the site with chilled and sterile physiological saline solution.
4. In case of very dense bone, the implant site preparation may be finalized through the use of tap (02-MC37). Do not exceed 10-20 rpm. **WARNING**: use this instrument with chilled and sterile physiological saline solution, only for the cortical portion of the implant site.
5. Insert the implant with the contra-angle connector (07-MA10) and finalize the positioning with the ratchet adapter (02-AC20) and the torque wrench (02-CT20).

WARNING: in case of prosthetic ear, two implants are usually sufficient to obtain satisfactory retention; but in some cases it may be necessary to place three implants to ensure a satisfactory retention and a correct construction of the bar. In case of orbital prosthesis, if the orbit is thin, it is advisable to use an implant without flange.

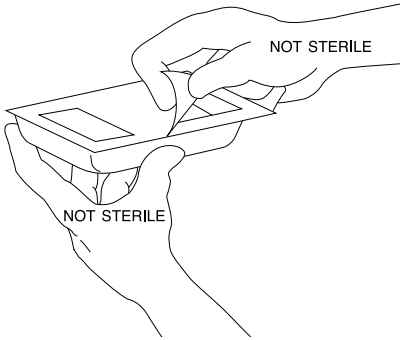
SURGICAL COMPLICATIONS

The implant surgical procedure has side effects as post-surgery inflammation. More serious complications are in general associated with improper surgical operations (penetration of the cranial bone and exposure of the dura mater, bone necrosis, etc.).



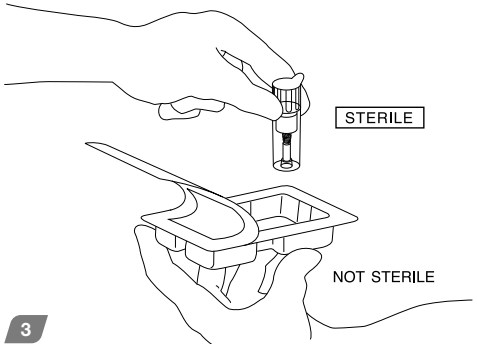
1

Choose the implant type, length and diameter and take the blister out of the cardboard box.



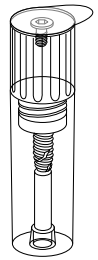
2

The vial containing the implant is sterile and lodged in the blister. The product description and the lot number are indicated on the label. Open the blister.



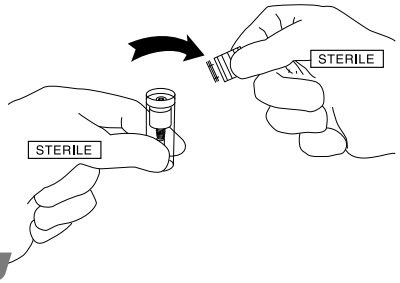
3

Take out the vial with the implant.



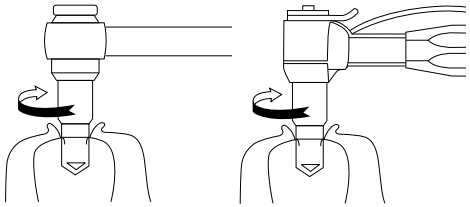
4

Surgical cover screw is placed in the vial cap and sealed with a Tyvek film.



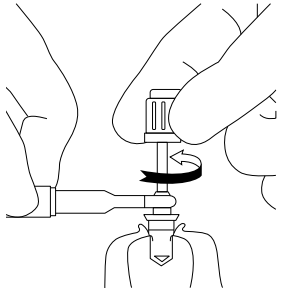
5

Gently open the vial cap (do not pull up with force).



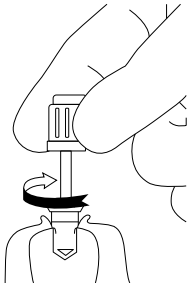
6

Connect the Ratchet Adaptor (02-AC20) and the Ratchet to the Mount (02-CT20) to perform manual implant screwing. To perform screwing with handpiece use Handpiece adaptor (07-MA10). Screw at slow speed (10-15 Rpm).



7

After placing the implant remove the Mount with the Open-end Wrench (01-CH10) and the Driver (02-EG20).



8

Withdraw the cover screw from vial cap and screw it onto the implant with the Driver (02-EG20).

WARNING: all steps from 1 to 8 must be performed following proper sterile field management.

GENERAL HANDLING, CARE AND MAINTENANCE OF THE SURGICAL INSTRUMENTS:

WARNING: the clinical success of the surgical procedure of inserting a extra-oral 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.

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

Symbol	Description
	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
	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)

Symbol	Description
MD	Medical device
	Single sterile barrier system with protective packaging inside
	Single sterile barrier system with protective packaging outside
	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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