

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 contraindicated 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

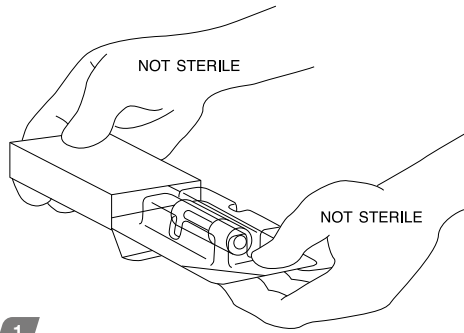
of tap (02-MC37). Do not exceed 10-20 rpm.
WARNING: use this instrument with chilled and sterile physiological saline solution, only for the cortical portion of the implant site.

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).

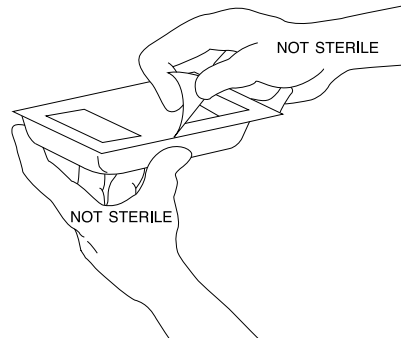
WARNING: in case of prosthetic ear, two implants are usually sufficient to obtain satisfactory retention; but in some cases it may be necessary to place three implants to ensure a satisfactory retention and a correct construction of the bar. In case of orbital prosthesis, if the orbit is thin, it is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

SURGICAL COMPLICATIONS

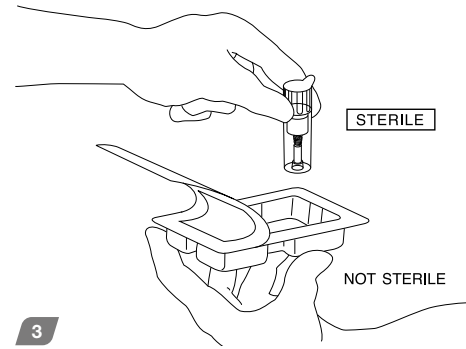
The implant surgical procedure has side effects as post-surgery inflammation. More serious complications are in general associated with improper surgical operations (penetration of the cranial bone and exposure of the dura mater, bone necrosis, etc.).



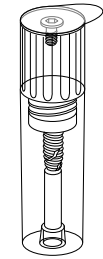
1
Choose the implant type, length and diameter and take the blister out of the cardboard box.



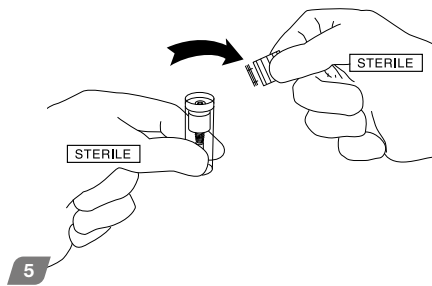
2
The vial containing the implant is sterile and lodged in the blister. The product description and the lot number are indicated on the label. Open the blister.



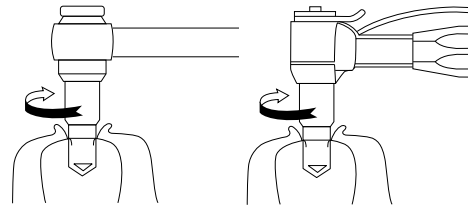
3
Take out the vial with the implant.



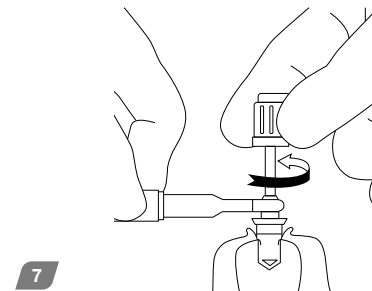
4
Surgical cover screw is placed in the vial cap and sealed with a Tyvek film.



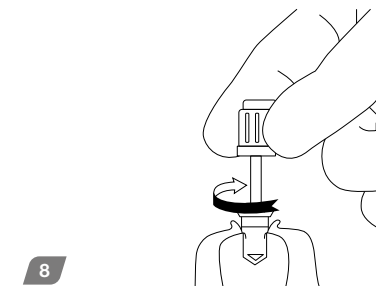
5
Gently open the vial cap (do not pull up with force).



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.

Symbols glossary

Symbol	Description
	Sterilize using irradiation.
	Serial number
	Consult instructions for use.
	Do not use if the package is damaged and consult instructions for use.
	Non-sterile
	Not locking prosthetic component
	Octagon locking prosthetic component
	Hexagon locking prosthetic component
	Keep away from sunlight.
	Keep dry

Symbol	Description
	Medical device
	Manufacturer
	Batch code
	Catalogue number
	Do not re-use
	Use-by date
	Advan products covered by the CE Mark fulfill the requirements of the Directive 93/42/CEE. With notified Body number.
	Advan products covered by the CE Mark fulfill the requirements of the Directive 93/42/CEE.
	Multi packaging (the number reported in the symbol refers to the number of units in the packaging).



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