INSTRUCTION FOR USE:
ADVAN EXTRA ORAL IMPLANT

PRODUCT DESCRIPTION AND INDICATIONS

The Extra extra-oral implant system consists of endosseous implants, made of Grade 4 c.p. Titanium, with special shape, size and surface characteristics, to be inserted into the bone through a surgical procedure. The Extra extra-oral implant system has a surface partially treated by sandblasting with medical-grade hydroxyapatite microparticles (OsseoGRIP treatment).
Extra extra-oral implants, after decontamination, are packed in a controlled environment and sterilized by β-beam (electron-beam).
Extra extra-oral implants are supplied sterile. Intact sterile packaging protects the implant and its sterility and ensures its durability, if stored correctly, until the indicated expiration date (see label).
Extra extra-oral implants can be implanted in bone, in different cranial districts. A successfully implanted screw will osseointegrated realizing complete stability between the bone and the titanium surface.
Refer to the surgical guidelines regarding implants and prosthetic components.

INTENDED USE

The Extra extra-oral implant system is intended to be surgically inserted into different cranial districts to retain or permanently support facial prostheses (ear, eye, and nasal platforms), better known as epithesis, which are faithful reproductions of missing facial structures in silicone made by trained technicians based on an impression taken directly on the patient.

CONTRAINDICATIONS

Extra extra-oral implants are contraindicated in cases of poor bone thickness and height and, more generally, where bone cannot provide implant stability. Lack of osseointegration and subsequent implant loss can occur when bone is insufficient, or of poor quality, and patient hygiene is inappropriate, or the clinical picture is compromised by local and/or systemic pathology. Carefully evaluate the placement of extra-oral implants in bone tissue that has previously undergone courses of radiation therapy. In addition, any mental disorders, tobacco, drug and alcohol abuse should be evaluated in patient selection. Implants are contraindicated if the patient has an allergy to titanium.

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

For safe and effective use of Extra extra-oral implants, adequate surgeon training is strongly recommended: the operating technique required is highly specialized and the implantation procedures are complex. Improper patient selection and/or misapplication of the implant technique could result in implant failure and perishing of the surrounding bone. 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.
The selection of patients for the fabrication of an epithesis anchored on Extra extra-oral implants must be particularly careful. Axial computed tomography (C.A.T.) scans provide valuable support in all complex cases.

SURGICAL PROCEDURE

Before proceeding with the surgery, following the preparation of the surgical field, the surgeon and anaplastologist define the location of the implant sites for the best aesthetic result.

1. When inserting implants to anchor ear prostheses, make a skin incision about 10 mm away from the implant site; expose the periosteum and incise it near each implant site.

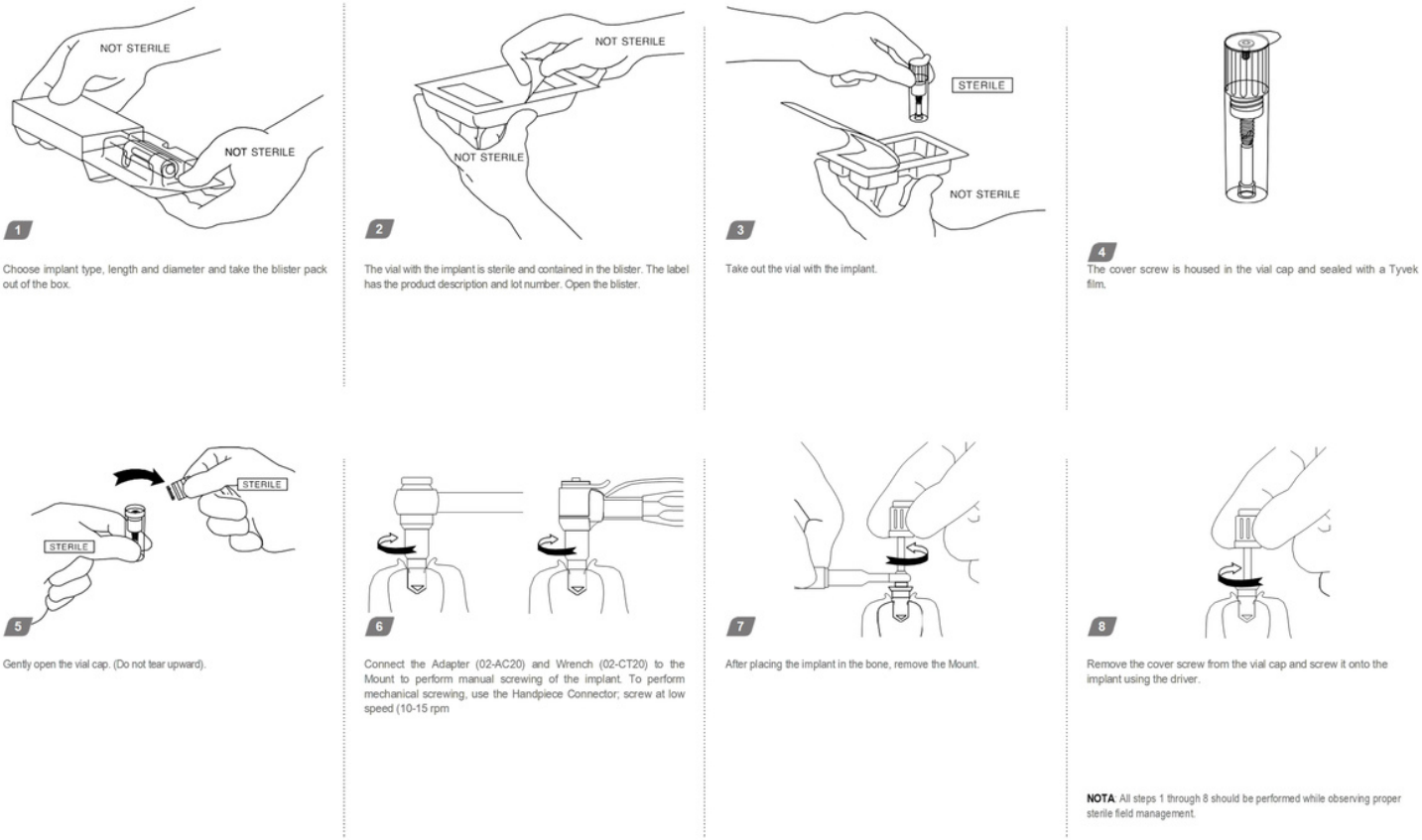
2. Drill an initial hole using the round drill (07- FP11; 07-FP12 depending on the length of the implant to be placed). The hole is drilled along the entire length of the implant site. Do not exceed 600 rpm.
Warning: Inaccurate control of the hole depth could result in perforation of the sigmoid sinus wall and exposure of the dura mater.

3. Prepare the implant site using the drill of appropriate length and profile for the type and length of implant to be placed (07FEP01; 07FEP02; 07-FE01; 07-FE02). Do not exceed 300 rpm. Cool the implant site thoroughly with sterile refrigerated saline solution.

4. In the case of particularly dense bone, implant site preparation can be finalized by using the tap (02-MC37). Do not exceed 10-20 rpm.
Note: Use this instrument with copious external irrigation of refrigerated saline solution, only for the cortical portion of bone.

5. Insert the implant using the handpiece connection (07-MA10) and finalize positioning using the wrench adapter (02-AC20) and torque wrench (02-CT20).

Note: In the case of an auricular prosthesis, two implants are normally sufficient to achieve satisfactory retention; however, in some cases the placement of three implants may be necessary to ensure satisfactory retention and proper bar construction. In the case of orbital prostheses, if the orbital is thin, the use of a flangeless implant is recommended.



STORAGE
Extra extra-oral implant should not be used after the expiration date (see label). Extra extra-oral 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 Extra extra-oral 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 Extra extra-oral 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
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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