PRODUCT FEATURES

The I-RES Sagl zygomatic implants are made of grade 4 biocompatible titanium, have a self-tapping tapered body with triple threads at 55 ° on the whole body of the implant and 3 aggressive apical cuts that guarantee better primary stability and centering of the implant varying the direction during the insertion phase.

INSTRUCTIONS FOR USE

Often in edentulous subjects with marked maxillary atrophy, implant placement is only possible after having performed major reconstructive surgery.
I-RES Sagl zygomatic implants offer the dentist a valid alternative to additive surgery, as, by exploiting the bone available in the zygomatic region, they are anchored directly to it, avoiding additive procedures, reducing waiting times for making immediate loading possible, eliminating the considerable inconvenience due to the numerous interventions and, finally, rehabilitating the aesthetic and masticatory function in patients.

PRECAUTIONS

The I-RES Sagl zygomatic implant is delivered in sterile packages and the operator must pay close attention, during positioning into the oral cavity, that the implant does not come into contact with elements that can alter the surface so inhibiting the healing processes. Therefore, all handling must be done in an environment suitable for surgical activities.
The I-RES Sagl zygomatic implant foresees a series of surgical instruments dedicated to the implant line to be used for the atraumatic preparation of the implant site as well as instruments dessigned to remove the implant from the blister and position it into the oral cavity for its insertion. Each blister containing the implant is equipped with a closing screw, used to seal the internal part of the implant after its insertion into the mandibular or maxillary bone.
For the implant to be successful, compliance with the implant measures and procedures indicated, as well as close collaboration between the surgeon, prosthetist and dental technician is recommended.

THE COMPANY I-RES Sagl IS EXEMPT FROM ANY LIABILITY FROM NON-COMPLIANCE OF THE RECOMMENDATIONS HEREIN AND/OR OF THE WHOLE PACKAGE LEAFLET.

CONTRAINDICATIONS

Do not use the I-RES Sagl zygomatic implants:
- In patients who are unsuitable for oral surgical treatment;
- In patients who have a small amount of bone able to ensure primary stability of the implant in the first phase of insertion;
- In patients for whom it is not possible to insert implants with an optimal size, number and position so as not to guarantee safe support for the functional masticatory load;
- In patients who have poor oral hygiene, uncontrolled systemic pathologies, blood disorders and smokers;
- In patients allergic or hypersensitive to grade 4 and grade 5 titanium;
- Patients whose prostheses will be made up of single elements.

The conditions described above, in addition to the normal contraindications for general surgery, can negatively affect the partial or total integration of the implant.

WARNINGS

For the use of I-RES Sagl zygomatic implants, the dentist must be aware of general and specific surgical and prosthetic techniques following the indications of the surgical protocol and specific training courses. The incorrect choice of implant and surgical technique can jeopardize the success of the surgery, causing loss of the implant and surrounding bone. The error in evaluating the length of the implant and its drilling up against radiographs, can lead to permanent injury as well as damage to the nerves and blood vessels.
Any previously used implant or an implant that has come into contact with third party organic elements is not to be reused. The sterility of the system is guaranteed by the sealed package, by its proper storage in dry and controlled environments; packages that are not intact and which are damaged affect the use of the system. It is important to keep the batch number shown on the implant packaging and on the adhesive labels inside the package for the traceability of the product. For the same reason, it is practical for the dentist to keep the medical records of their patients for as long as possible, where they record the anamnesis, treatment plans, types of surgery and prosthetic rehabilitations performed and everything that can be useful for the medical history of the patient. The use of non-original I-RES Sagl equipment is not recommended and failure to comply with the instructions for use for the insertion of the i_RES Sagl zygomatic implant and the related prosthetic components is inadvisable, as it has been designed to obtain the best result.
I-RES Sagl zygomatic implants must be inserted with a maximum torque of 50 Ncm: exceeding this force could compromise the precision of the connection with the subsequent prosthetic part.

SIDE EFFECTS

The possible known side effects are identifiable in the partial or total lack of osseointegration, with consequent loss of the prosthetic function for which the implant system was designed, pain and transient paraesthesia, fracture due to excess load of the implant system, abutment, prosthesis. Possible nerve damage, sinusitis and fistula formation.

PRE-OPERATIVE PLANNING

The careful radiological study and clinical evaluation of patients who are candidates for implant-prosthetic therapy is of fundamental importance. Objective, instrumental, radiological examinations (a CT scan or CBCT analysis, cone beam ITC) and study of the models allow the dentist to be able to make the best diagnosis and consequent therapy – the patient must not present sinusitis symptoms, nor pathologies concerned with the loading of the bone and associated tissues, nor factors that could interfere with the healing process (smoking, poor oral hygiene, steroid therapy, uncontrolled diabetes, orofacial radiotherapy). The preparation of the patient for implant surgical therapy, as well as the preparation of the operating room, must have the same precautions and attention as for general surgery, the preparation of the implant site by means of dedicated drills with controlled rotations and submitted to cooling by means of physiological solution are indispensable conditions for implant therapy.

SURGICAL COMPLICATIONS

Implant surgeries may involve some complications which are usually temporary and localized to the area of the operation such as inflammatory states, paraesthesia, hematomas, injuries to nerves, vascular centres and the maxillary sinus membrane may also occur. Bone seizures have rarely occurred.

MATERIALS AND PACKAGING

I-RES Sagl zygomatic implants are produced in commercially pure grade 4 titanium - ASTM F67 - and are surface treated to improve osseointegration by sandblasting and subsequent double etching.
The decontamination is carried out by means of cold Argon plasma, the packaging takes place in a clean room and the final sterilization by means of gamma or beta rays.
The packaging of the implant and its cover screw must be opened in a sterile field during the phases of implant surgical therapy. If there is no MRI symbol on the package, it means that the device has not been tested for safety and compatibility in an MRI environment.
I-RES Sagl zygomatic implants are DISPOSABLE devices. Their reuse is undesirable from a medical, legal and ethical point of view. The use of non-validated sterilization procedures risks causing an infection to the patient and compromising the functional performance of the device. Failure to comply with this indication implies a use other than that envisaged by the Manufacturer and those who carry out reuse must assume responsibility for it.

STORAGE AND DISPOSAL

I-RES Sagl zygomatic implants must be stored in a cool and dry place, at room temperature, away from direct heat sources and in ways that do not lead to the breaking of the device.
Disposal takes place in accordance with local provisions relating to environmental pollution of the product.

SYMBOLS ON THE PACKAGING

MANUFACTURER
I-RES® SAGL Piazzale Roncaa 4
6850 Mendrisio [Switzerland]
info@ires.dental
www.ires.dental

CE Mark according to standard
MDD 93/42/EEC

EUROPEAN AUTHORIZED REPRESENTATIVE
IESS GROUP Srl
Via Madonna della Salute
33050 Pozzuolo del Friuli (UD)
info@iess.dental

Batch number

Use by

Sterilized by gamma or beta rays

Do not reuse

Do not restirilize

Follow the instructions given in the illustrative leaflet

Do not expose to direct sunlight

Do not expose to rain and keep in an environment free from damp

Do not use if the packaging is damaged

Non-steril