

## WARNINGS

To use the **SHAPEI, iMAX, VOLUTION, iMAXMUA, HANDY and SHAPEMINI** implant systems by I-RES SAGL, the dentist must know the general surgical and prosthetic techniques and the specific techniques for **SHAPEI, iMAX, VOLUTION, iMAXMUA, HANDY and SHAPEMINI**, following the indications of the surgical protocol and specific training courses. An incorrect choice of implant and surgical technique can be prejudicial to the success of the operation, causing the loss of the implant and of the surrounding bone. No implant must be used that has been used previously, or that has come in contact with the organic elements of third parties. The sterility of the implant is guaranteed by the sealed packaging and by correct storage in controlled dry environments; packages that are not intact or damaged are prejudicial to the use of the implant. For product traceability it is important to keep the batch number marked on the implant package and on the adhesive labels to be found in the same package.

For the same reason it is recommended that the dentist keep as long as possible his patients' medical files, in which he has a record of their medical history, treatment plans, types of operations and prosthetic rehabilitations performed and everything that can be useful for the patient's medical history. The use of non-original I-RES instruments is not advised, as is the failure to follow the indications for inserting the **SHAPEI, iMAX, VOLUTION, iMAXMUA, HANDY and SHAPEMINI** implant systems and the respective prosthetic components, because they have been designed to obtain the best result.

**SHAPEI, iMAX, VOLUTION, iMAXMUA, HANDY and SHAPEMINI** implant systems must be inserted with a maximum torque of 50 Nm, exceeding this force could be prejudicial to the precision of connection with the subsequent prosthetic part.

The **SHAPEI, iMAX, VOLUTION, iMAXMUA, HANDY and SHAPEMINI** implant systems include, in their range of implants, very small diameters made not only in pure titanium but also in titanium alloy (such as  $\varnothing$  3.3 mm,  $\varnothing$  3.7 mm in the connections internal hexagon and for  $\varnothing$  2.7 mm for **SHAPEMINI** mini-implants), which must be used as implants only in the front of the mouth and not in diastoric areas where there is great masticatory stress. Especially the mini implants, with a  $\varnothing$  2.7 mm, may be used only for the anchorage of the prosthesis. Furthermore, the implants with  $\varnothing$  3.7 mm must not be inserted individually on premolars and molars, but at most should be only linked with bars to distribute the loading force. **SHAPEMINI** mini-implants may be used only in the front part of the mouth for single tooth replacement and not in the rear part of the mouth where masticatory stress are higher, in this sites, they can only be used for dentures anchoring.

**THE COMPANY I-RES SAGL DISCLAIMS HERSELF FOR ANY LIABILITY DUE TO THE NON OBSERVANCE OF THE INDICATIONS REPORTED IN THIS INSTRUCTION LEAFLET.**

## COLLATERAL EFFECTS

The known possible collateral effects are the partial or total failure of osseointegration, with consequent loss of the prosthetic function for which the implant system is intended, pain and transient paresthesia, fracture due to excessive load on the implant system, post or prosthesis.

## PRE-OPERATIVE PLANNING

The careful study and assessment of patients who are candidates for implant-prosthetic therapy is of fundamental importance. Physical, instrumental, and radiological examinations and the study of models allow the dentist to make the best diagnosis and consequent therapy. The preparation of the patient for surgical implant therapy and the preparation of the operating room must be given the same care and attention as general surgery; the preparation of the implant site using dedicated drills with controlled revolutions, cooled with saline solution, these are all indispensable conditions for implant therapy.

## SURGICAL COMPLICATIONS

Implant surgery operations may lead to some complications that are usually temporary and restricted to the area of operation, such as inflammation, paresthesia, haematoma; there may also be injuries to nerves, to vascular complexes and the membrane of the maxillary sinus. Bone sequestration has rarely occurred.

## MATERIALS AND PACKAGING

The **SHAPEI, iMAX, VOLUTION, iMAXMUA, HANDY and SHAPEMINI** implant systems are produced in commercially pure grade 4 titanium - ASTM F67 - and in grade 5 titanium alloy (Q 3.3 and

$\varnothing$  3.7 in internal hexagon connections) - ASTM F136. **SHAPEI, iMAX, VOLUTION, iMAXMUA, HANDY and SHAPEMINI** implants are surface treated to improve osseointegration by means of sandblasting followed by double acid-etching. In the market are also available implants with different surface treatments depending on the intended use of the product, as well as implants with a final coating with hyaluronic acid for a better bone tissue healing. The only machined implants are suitable for the patient with periodontitis. The Hybrid implants (presenting a surface half machined and half superficially treated) are specified both for patients with periodontitis and for all those patients where greater care is necessary aimed at reducing or better treating peri-implantitis. Decontamination is performed with cold Argon plasma followed by packaging in a cleanroom, for the final sterilisation phase with gamma or beta rays. The pack containing the implant and the respective cover screw must be opened in a sterile environment in the phases of surgical implant therapy. I-RES SAGL implants are DISPOSABLE devices. Their reuse is not desirable from a medical, legal and ethical point of view. The use of not validated sterilization procedures can cause both the infection onset in the patient and impair the product performances. The failure compliance with these instructions implies a different use as provided by the manufacturer and those who make the reuse must take this action on their own responsibility.

## SYMBOLS ON THE PACKAGE

  
(EN) MANUFACTURER  
I-RES<sup>+</sup> SAGL, Piazzale Roncaia 4  
6850 Mendrisio [Switzerland]  
Info@ires.dental  
www.ires.dental



(EN) EUROPEAN  
AUTHORIZED REPRESENTATIVE  
IESS GROUP SRL Via Madonna della Salute 23  
33050 Pozzuolo del Friuli (UD) [Italy]



(EN) CE Mark according to standard  
MD93/42/EEC



(EN) Batch number



(EN) Use by



(EN) Sterilized by gamma or beta rays



(EN) Do not reuse



(EN) Do not restitilize



(EN) Follow the instructions  
given in the illustrative leaflet



(EN) Do not expose to direct sunlight



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



(EN) Do not use if the packaging is damaged