iRES® IMPLANT SYSTEM (Shape1®, iMAX®, Volution®, iMAXMUA®, ShapeMini®)

package leaflet

Product characteristics:

The SHAPE1, IMAX, VOLUTION, iMAXMUA and SHAPEM- INI implant systems, by I-RES Sagl, offers the dentist a wide choice of titanium implant configurations that differ in diameter, height and possibility of surgical po- sitioning A) submerged/bone level, B) transmucosal/ tissue level, and various prosthetic components for the different rehabilitation procedures.

Indications for use:

The SHAPE1, IMAX, VOLUTION, iMAXMUA and SHAPEMINI implant systems are indicated for surgical treatment in the upper or lower jaw for the partial or to- tal replacement of teeth in patients who have lost part or all of their teeth.
The implant to be used must be chosen by the medical personnel based on the medical history and on the subsequent surgical and prosthetic plan required for each individual patient. The onepiece implants iMAXMUA, having the same geometric shape of iMAX dental implants, ensure an excellent retention of the prosthe- sis, thanks to the ability to accommodate the retained screw designed for MUA components with a pitch of 1,72 mm instead of 1,4 mm as in the classic MUA.
The implants are delivered in sterile packs and the op- erator must pay great attention when positioning it in the oral cavity, so that the implant does not come in contact with elements that could alter the surface, hin- dering the healing processes, so all manoeuvres must be performed in an environment suitable for surgical activities.
The SHAPE1, IMAX, VOLUTION and iMAXMUA implant system has a series of dedicated surgical instruments for its implant lines, useful for the non-traumatic preparation of the site that is to receive the implant, and instruments designed for extracting the implant from the blister and transporting it to the mouth for in- sertion. Each blister containing the implant is provided with a closing screw, useful for sealing the internal part of the implant after it has been inserted in the mandib- ular or maxillary bone.
SHAPEMINI implants fix the dentures but can also be used for the replacement of a single tooth.

Contraindications:

Do not use SHAPE1, IMAX, VOLUTION, iMAXMUA and SHAPEMINI implant systems in patients who have a scarce amount of bone suitable to guarantee the pri- mary stability of the implant in the first phase of inser- tion, in patients with poor oral hygiene, smokers, with uncontrolled systemic pathologies and blood disor- ders. In addition to the normal contraindications for general surgery, the conditions described above can have a negative influence on the partial or total inte- gration of the implant.

Warnings:

To use the SHAPE1, IMAX, VOLUTION, iMAXMUA and SHAPEMINI implant systems by I-RES Sagl, the dentist must know the general surgical and prosthetic tech-

niques and the specific techniques for SHAPE1, IMAX, VOLUTION, iMAXMUA and SHAPEMINI, following the indications of the surgical protocol and specific train- ing courses. An incorrect choice of implant and surgi- cal 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 dam- aged 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, treat- ment plans, types of operations and prosthetic reha- bilitations performed and everything that can be useful for the patient's medical history. The use of non-orig- inal I-RES instruments is not advised, as is the failure to follow the indications for inserting the SHAPE1, IMAX, VOLUTION, iMAXMUA and SHAPEMINI implant systems and the respective prosthetic components, because they have been designed to obtain the best result.

SHAPE1, IMAX, VOLUTION, iMAXMUA and SHAPEMI- NI implant systems must be inserted with a maximum torque of 50 Ncm, exceeding this force could be prej- udicial to the precision of connection with the subse- quent prosthetic part.

The SHAPE1, IMAX, VOLUTION, iMAXMUA and SHAPEMINI implant system includes, in its range, some implants with very small diameters (such as Ø 3.3 and Ø 2,7 mm for mini-implants) which must be used as im- plants only in the front of the mouth and not in diatoric areas where there is great masticatory stress.

Especially the mini implants, with a Ø 2.7 mm, may be used only for the anchorage of the prosthesis. Furthermore, the implants with Ø 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 den- tures 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 funda- mental importance. Physical, instrumental, and radio- logical 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 compli- cations 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 SHAPE1, IMAX, VOLUTION, iMAXMUA and SHAPEMINI implant system is made of commercially pure grade 4 titanium (ASTM F67) and grade 5 titanium alloy (ASTM F136).
SHAPE1, IMAX, VOLUTION, iMAXMUA and SHAPEMINI implants are surface treated to improve osseointe- gration 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 stimulation is necessary to facilitate a rapid osseointegration aimed to reduce the real and possible insurgence of the periimplantitis.
Decontamination is performed with cold Argon plasma followed by packaging in a cleanroom, for the final sterilization 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.
Ires' Sagl implants are DISPOSABLE devices. Their re- use is not desirable from a medical, legal and ethical point of view. The use of not validated sterilization pro- cedures can cause both the infection onset in the pa- tient 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 re- sponsibility.

Symbols on the package:

	MANUFACTURER I-RES® SAGL Riva Caccia, 1/D 6900 Lugano [Switzerland] info@ires.dental www.ires.dental
	CE Mark according to standard MDD93/42/EEC
	Batch number
	use before the expiry date
	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