The I-RES implant-prosthetic system is intended for use in the oral cavity and is provided with useful components to enable the dentist and the dental technician to prosthetically complete the operation begun by the dentist by inserting the implant in the patient. The I-RES implant-prosthetic system completes the line of I-RES dental implants and the respective I-RES instruments.

Product characteristics

Straight, angled and millable abutment. They are made of grade 5 titanium; they have different shapes depend- ing on the characteristics they have to satisfy, they are used mostly for prosthetic rehabilitations of bridges or crowns. The choice of the device that must be con- nected to the analog in the first phase is dictated by the clinical and processing decisions, which are at the discretion of the dentist and the dental technician.

Plastic abutment. Plastic abutment may be divided into two families, one for using directly in the oral cavity, ap- propriately modified and connected to the post to support temporary prostheses, one for the transfor- mation of plastic abutment into metal abutment by the dental technician, with processing characteristics that are at the discretion of the dentist and the dental technician.

Gold Bases. These are components made of gold alloy and allow the creation of customized abutment using overcasting techniques.

Ball abutments. Ball abutments are made of grade 5 titanium and, once fixed to the implants, they are able to act as an anchorage by means of special attachments to the patient's mobile prosthesis.

Healing screws. The healing screw is a device used by the dentist to keep the oral mucosa pervious in the vi- cinity of the implant previously inserted. Once the soft tissues have healed, this will allow the dentist to per- form the subsequent manoeuvres for prosthetization. The healing screws are made of grade 5 titanium.

Transfer. The transfer in grade 5 titanium is the instru- ment that allows the transfer from the mouth to a model of the information needed for the prosthetic connec- tion and for making the respective prosthesis. There are two types of transfer: "closed tray and open tray", and they are all composed of two parts (a screw and a repositioner). After being inserted in the implant and secured to it with the screw, the transfer is ready to take the impression in the mouth.

Analog. The analog made of grade 5 titanium has the function of reproducing the internal characteristics of the implant and it must be securely fixed to the transfer. Once joined, the model can be cast.

Contraindications:

Do not use I-RES products on patients who have allergies to the materials of which the component is made. The use of I-RES components in patients who have metabolic and periodontal diseases or poor oral hygiene may be prejudicial to the success of the

work, as may prosthetic constructions not in line with international standards. The lack of periodic controls, which the patient must undergo with his dentist after prosthetisation, may compromise the life of the im- plant-prosthetic system.

Warnings:

I-RES prosthetic components are reserved for use by personnel with knowledge of the subject. I-RES points out that alterations to the implant/post connections may be prejudicial to the success of the work, as may the failure to use original components. When using prosthetic components it is important to follow the instructions given by the dentist and the dental technician. When using prosthetic components in the oral cavity it is important to respect the final tightening value which must be between 20 and 30 Ncm, as better specified in the catalogue.

Collateral effects

Today there are no known collateral effects in the use of I-RES components that can endanger the patient's health.

Prosthetic planning:

The choice of the I-RES components to be used for the case is the specific responsibility of the dentist and of the dental technician, depending on their requirements.

Materials and packaging:

All I-RES prosthetic components are packed in such a way as to be immediately identifiable, once removed from their pack; it is important for the operator to pay great attention in identifying them to avoid changes of position during work. It is useful to make note of the material batch used on the patient's file, for the pur- pose of traceability. Whether it has been processed or not, before inserting the I-RES prosthetic component in the oral cavity it is of fundamental importance that it be washed and sterilized. Some I-RES components are single-use, so intended for only one patient.

Cleaning | sterilization | storage:

Caution !!! All prosthetic components for dental implants are sold NON-STERILE.

Before use, all prosthetic components must be cleaned, disinfected and sterilized. These process- es must also be performed before intraoral use, i.e. before each use for any test phases and in any case before final restoration loading. Repetition of the pro- cesses described in this paragraph does not alter the characteristics of these devices. Failure to follow these indications may lead to the onset of infections and complications for the implant and, more generally, for the patient. Important: care must be taken during the subsequent phases in preserving the zone of the connection with the implant (hexagon/octagon/threading).

a. Cleaning:

In case of automatic cleaning: use an ultrasound bath with a suitable detergent solution. Use neutral detergents only. Follow the manufacturer's instructions concerning concentrations and washing times. Use demineralised water to prevent the formation of stains and marks.

When cleaning manually: use a suitable neutral detergent and follow the manufacturer's user instructions. Brush the products with a soft-bristled brush (non-metal bristles) under running water. Use the brush to apply the detergent to all surfaces. Rinse with dis- tilled water. After rinsing, dry the devices thoroughly and place them inside suitable sterilization bags.

b. Sterilization:

Place in a vacuum autoclave and sterilize as follows: Temperature = 121 – 124°C, with autoclave cycle of at least 20 minutes and drying cycle of 15 minutes.

c. Storage:

After sterilization, the product must remain in the ster- ilization bags. Only open the bags immediately prior to use. In normal conditions, sterilization bags main- tain the sterility of the contents, unless the wrapping is damaged. Therefore, do not use components if the bags in which they were kept are damaged, and rest- erilizes in new bags before using them again. The stor- age time of products sterilized inside the bags should not exceed that recommended by the manufacturer of the bags.

The product must be stored in a cool dry place, away from direct sunlight, water and heat sources.

ATTENTION:

Some components such as transfers and healing screws are devices that can be reused after.

CLEANING/STERILIZATION/STORAGE (follow the re- spective indications).

DO NOT REUSE a device classified as SINGLE-USE. Although it cannot be seen, it could be mechanically deformed or have been contaminated.

Disposal procedures:

If removed from the oral cavity due to biological or mechanical failure, the prosthetic components must be disposed of as biological waste according to local regulations. More detailed information on the use of the medical device can be found in the specific Surgical Protocol available on the site www.i-res-group.com or in the IRES Shape1 catalogue supplied by the Manufacturer.

Symbols on the package:

	MANUFACTURER I-RES® SAGL Riva Caccia, 1/D 6900 Lugano [Switzerland] info@ires.dental www.ires.dental
CE 0426	CE Mark according to standard MDD93/42/EEC
LOT	Batch number
	use before the expiry date
	Do not reuse
	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 STERILE	not sterile