iRES
complete solutions
for oral surgery

PROSTHETIC COMPONENTS

INSTRUCTIONS FOR USE OF CLASS I PROSTHETIC COMPONENTS AND SURGICAL INSTRUMENTS

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 techni- cian 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 characteristic

Transfer
The transfer in gr. 5 titanium is the tool that allows to transfer, from the mouth to a replica model, the information useful for the prosthetic connection and the construction of the respective prosthesis. There are different types of transfers and they are all made up of two parts (a screw and a repositioner). After being inserted into the implant and firmly screwed to it by means of the screw, the transfer is ready to be detected in its position in the oral cavity by means of an impression.

Analog
The analogue is made of gr. 5 titanium and has the function to reproduce the internal characteristics of the implant and must be firmly fixed to the transfer. Once joined, the model can be poured.

Castable abutments
The compatible castable abutments are the most economical and practical prosthetic solution in the implantology field, consisting of a base in castable material such as POM that allow the dental technician to model an implant abutment in wax or resin starting from a pre-built castable base. These abutments will then be completed in their missing anatomical parts by the dental technician and subsequently the entire abutment will be invested and cast in metal alloys. The abutment that will come out of the casting machine will be a replica of the castable base and the modeled portion.

Steel surgical instruments in steel
Ratchet connectors, handpiece connectors, manual screwdrivers, prosthetic screwdrivers, etc., in stainless steel, provide the user with surgical instruments for performing proper dental surgery.

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 and surgical instruments to be used for the case is the specific responsibility of the dentist and of the dental technician, depending on their re- quirements.

Materials and packaging:

All I-RES prosthetic components and surgical instruments 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 purpose of traceability.
Whether it has been processed or not, before inserting the I-RES prosthetic component in the oral cavity it is of undamental 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 processes must also be performed before intraoral use, i.e. before each use for any test phases and in any case before final restorationloading. Repetition of the processes 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 detergentsonly. 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 distilled 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 sterilization bags. Only open the bags immediately prior to use. In normal conditions, sterilization bags maintain 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 resterilizes 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 fromdirect sunlight, water and heat sources.

ATTENTION:

Some components, such as transfer and surgical instruments, are devices that can be reused after. prior follow the respective indications reported in CLEANING/ STERILIZATION/STORAGE.

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.ires.dental or in the IRES catalogue supplied by the Manufacturer.

SIMBOLS ON THE PACKAGE

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

EC REP CE MARK

European Authorized Representative
IESS GROUP Srl
Via Madonna della Salute
33050 Pozzuolo del Friuli (UD)
info@iess.dental

LOT Batch number

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