

INSTRUCTIONS FOR IRES ROTARY INSTRUMENTS (DRILLS - COUNTERSINKS - TAPS) FOR THE PREPARATION OF THE SITE THAT HAS TO RECEIVE IRES® SHAPE1® IMPLANTS

Product description:

Dental drills, produced by I-RES Sagl, must be used as tools to perforate the bone. The diameters to be used, the lengths and the drilling sequence (number of drills to be used) are the sole choice and decision of the dentist, depending on the surgical protocol that must be followed. The maximum recommended speed is 800 rpm with saline solution applied directly on the drill to assist cooling.

a) The sole purpose of the initial precision drill is to incise the cortical bone in a very precise point where it will later be drilled.

b) The helical drills have laser markings for reference which identify the depth to be reached. Of course, in the use of this type of drill the manual skill and experience of the dental surgeon are extremely important, especially for stopping at the chosen depth.

c) Countersinks are used when it is necessary to widen the initial part of the hole made to adapt the shape that of the neck of the implant to be inserted. The maximum recommended speed is 300 rpm with saline solution applied directly on the drill to assist cooling.

d) Bone taps: in particularly dense bone (type I), before insertion it is advisable to use a bone tap with the same profile as the implant to be inserted. The bone tap has a greater cutting power than the implant, allowing the site to be prepared with reduced trauma. The maximum recommended speed is 30 rpm with saline solution applied directly on the bone tap to

assist cooling.

Materials used:

All I-RES Sagl drills are made of medical grade steel and undergo hardening heat treatment. The maximum recommended number of uses of the devices is 40 times.

Warnings and general precautions:

- It is fundamental to respect the surgical protocol that establishes the diameters, lengths and the sequence of use. The operator is fully responsible for any uses other than those indicated.
- Check that the drills to be used are in good condition, already cleaned and sterilized.
- Check that the drills are in good condition and have not been used more than 40 times.
- Before using them, check that the hand-piece holds the drills perfectly secure and that they rotate in the correct direction.
- Ensure that there is adequate irrigation.
- The application of leverage during drilling could cause breakage of the drill, the hand-piece, or the bone walls on which you are working.

During drilling always exert alternating pressure, using the intermittent drilling technique.

- Always check that the laser marking that indicates diameter and length is clearly visible.
- Any eccentricity or lack of straightness in the drill could result in an oversized hole.

- Wear eye protection, to protect against particles that may be ejected.

CLEANING / STERILIZATION / STORAGE:

The medical devices are supplied NON-STERILE.

Before use, all rotary devices must be cleaned, disinfected and sterilized.

Failure to follow these indications may lead to the onset of infections and complications for the implant and, more generally, for the patient.

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 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 re-sterilize in new bags before using them again. The storage 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.

More detailed information on the use of the medical device can be found in the Surgical Protocol. If you do not have a copy, request one from your distributor or directly from the manufacturer.

Symbols on the package:

-  MANUFACTURER
I-RES® SAGL
Piazzale Roncaa, 4
6850 Mendrisio [Switzerland]
info@ires.dental
www.ires.dental
-  European Authorized Representative
IESS GROUP SRL Via Madonna della
Salute 23 - 33050 Pozzuolo del Friuli (UD)
[Italy]
-  CE Mark according to standard
MDD93/42/EEC
-  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
-  Not sterile