SALVIN® Dental Specialties SALVIN® Regenerative

Everything For Your Implant Practice But The Implants

Instructions For Use

Products:
Reusable instruments in dentistry, which are:
one piece
contain simple hinges or simple moveable parts
in certain cases consist of several replaceable parts

Intended Use:

Instruments may only be used for their intended purpose in specialist medical fields by properly trained, qualified personnel. The attending doctor or operator is responsible for selection of the instrumentation for specific applications and operative use, appropriate training and information and adequate experience for handling of the instrumentation.

Warnings

Aluminum-containing instruments are damaged by alkaline (pH>7) detergents and solutions.

When cleaning easily accessible or difficult to access hinges, screws, or rivets, a separate precleaning must be carried out, see pre-cleaning.

Incorrect handling and care of the instruments as well as misuse or modifications to the instruments can contribute to damage or failure of the instrument, which could result in serious injury to patients or even death. On receipt, check the instrument for possible transport damage and perfect function.

Small instruments must be secured by the user to ensure that swallowing or separation is excluded, i.e. by using a rubber dam or attaching suture material.

Instruments are non-sterile on delivery and must be cleaned and sterilized by the operator before use.

Treat all instruments with the necessary care. Every instrument should be checked visually before each use. Check in particular for cracks, fractures, deformation, stiffness - also especially in areas like blades, tips, closures, locks, notches and all moveable parts. If the instrument has been disassembled, ensure perfect functioning and all screws and parts are securely fitted after assembly.

There is the possibility of a higher risk of infection if the products are used on patients suspected of having a prion disease (i.e. Creutzfeldt-Jakob disease). In such a case it is at the discretion of the doctor either to dispose of the product or reprocess it in accordance with the national regulations.

Restriction of reprocessing:

Due to the product design and the used materials, no defined limit of maximal realizable cycles for the treatment can be settled. The durability of the medical devices will be defined by its function and a gentle handling.

Defective products have to pass through the whole process of reconditioning before their return.

Manual Cleaning:
Do not use fixing agents or hot water (>104 F), as this results in residues becoming fixed and can affect the success of the subsequent cleaning operation.
Immediately after use, immerse all instruments for 5 minutes in a disinfection solution according to the manufacturer's instructions.
Use the lowest recommended concentration and lowest recommended temperature (an excessive concentration may cause corrosion).
While soaked scrub the device thoroughly and follow the disinfection solution manufacturer's instructions.
Allow drying for at least 10 minutes. Make sure that the product is completely dry.
Observe the device to assure that no discoloration or corrosion signs or other visual contamination appeared.
Move forward to the steam sterilization process.

Automated Cleaning:
Clean the instruments with a soft brush under cold water until no residue can be seen.
If the instruments have cavities, boreholes or convolutions, flush it with pressure for at least 10 seconds with a water pistol.
Put the instruments in an ultrasonic bath with the manufacturer's recommended enzymatic cleaner and run it for the manufacturer's recommended time.
Remove the instruments and rinse them with cold
Move forward to the steam sterilization process.

Steam Sterilization Instructions:
Follow the Autoclave manufacturer's instruction to sterilize the products.
Do not exceed the maximal load allowed by the manufacturer.
Use an Autoclave that is cleared by the US FDA (U.S. users) and CE-Marked (EU users).
Pack the instrument in a sterile pouch, or package according to ISO 11607.
Recommended:
Cycle Type: 3 pre-vacuum phases
Pressure: at least 60 millibar
Temperature: 135 C / 275 F
Exposure Time: 10 minutes
Drying Time: 30 minutes

Control and Functional Check:
Visual inspection and functional test (cleanliness, damage, joint instruments smooth, no excessive play, locking mechanisms, no notches on the cutting edges). Check disassembled instruments for cleanliness, assemble and then perform functional test. Worn, corroded, deformed, porous or otherwise damaged instruments or instrument components must be sorted out or replaced. If necessary, repetition of the reprocessing until the instrument is cleaned optically.

Storage:
After sterilization, keep the devices in sterilization packaging in a dry and clean environment.