USER MANUAL

Devices

Surgical Scissors, Needle Holders, Forceps, Forceps/thump, Nasal Rasps, Retractors, Osteotomes, Mallets, Morselizers, Joseph Saws, Curettes, Nasal Speculas, Elevators, Hooks, Measuring, Dissectors, Markers, Knives, Bone Cutting Forceps, Suction Tubes, Cannulas/Lipo Suction, Laminectomy Ronguers Punches, Laryngoscope, Flat Nose Pliers/Wire Cutting Pliers T.C. Inserted, Vaginal Specula, Uterine Dilators, Hollow Wares, (Non Sterile, Stainless steel) supplied by company comprising fixed assemblies and simple hinged assemblies made of stainless steel.

Product Specification

The product is made by hand or partly mechanically from high-grade stainless steel for the production of medical instruments according to ISO and ASTM standards.

Recommended Decontamination & Sterilization Procedure

As with the decontamination procedure, personnel should follow accepted guidelines for hand wash- ing, the sue of protective attire, etc. as recommended by A.A.M.I. Standards and Recommended Practice., "Safe Handling and Biological Decontamination of Medical Devices in Health Care Facilities and in Non-Clinical Settings", ANSI/AAMI ST35:2003.

A. Manual Decontamination. Is a process consisting of two steps:

I.Thorough Cleaning.
II. Sterilization / disinfection.

Pre-cleaning

To remove gross debris from the surgical instruments using a lap sponge and sterile water during the procedure to prevent drying out of the blood and bodily fluids over the instruments.

Manual cleaning

To minimize the risk to personnel undertaking manual cleaning, splashing and the creation of spray must be avoided at all times. Staff carrying out manual cleaning should wear PPE at all times. **Devices should be:**

1) Cleaned using a non-linting cloth, impregnated with the appropriate detergent solution, followed by a clean, damp, non-linting cloth; and then.
2) Dried using another clean, non-linting cloth. Alcohol-impregnated wipes may be used following a manual cleaning process. **Detergents:** Detergents used must be specifically designed to clean surgical instruments: washing-up liquid should not be used. Use of an enzymatic detergent to facilitate the cleaning of surgical instruments.

Disinfection

Long stone's powder / paper coated instruments are not autoclavable but they can be cleaned/disin- fected with disinfectants like Endo Star (high level instruments disinfectant) or

with any other better disinfectant/sterilizing solution. 20ml Endo Star in 1 liter tap water (2% dilution) require 30 minutes immersion and 30ml Endo Star in 1 liter tap water (3% dilution) require 15 minutes immersion.

Instruments with powder coating color can also be sterilized in simple mineral water up to temperature 110°C for about 5 - 10 minutes.

Point of use handling

All reusable surgical instruments supplied by **ADS 29 INSTRUMENTS** may only be used for the purpose of which they are designed, by adequately qualified personal only. The proper surgical technique for the use of the instrument is the responsibility of the surgeon. Moreover, the surgeon is responsible for an appropriate training and sufficient information for the operating theatre staff as well as for an adequate expertise with the handling of the instruments.

Limitations

Frequent reprocessing has little impact on the lifetime, which is generally determined by wear and damage incurred during the intended surgical use, or by misuse. After the instrument's utilization on patients with Creutzfeldt- Jacob disease (CJD) or its variations we refuse all responsibility for reutili- zation! We recommend destroying the instruments. If you reprocess and reutilize the instrument nev- ertheless, even according to the RKI2- guidelines, you bear all responsibility. Instruments containing aluminum get damaged by alkaline cleaner > pH7!

Storage & maintenance

The storage area should be appropriately designed to prevent damage to packs and to allow for the strict rotation of stocks. Shelving should be easily cleaned and allow the free movement of air around the stored product.
Products must be stored above floor level away from direct sunlight and water in a secure, dry and cool environment.

Containment & transportation

To minimise this risk, the instruments must be placed in closed, secure containers and transported to the decontamination area as soon as possible following use.
Transport containers must protect both the product during transit and the handler from inadvertent contamination and therefore must be:

- Leak-proof
- Easy to clean
- Rigid, to contain instruments, preventing them becoming a sharps hazard to anyone handling the goods and to protect them against accidental damage
- Capable of being closed securely
- Lockable, where appropriate, to prevent tampering
- Clearly labelled to identify the user and the contents
- Robust enough to prevent instruments being damaged in transit.

Inspection and testing

Before being used, the sterile product should be checked to ensure that:

- The packaging is intact;
- The sterilization indicator confirms the pack has been subjected to an appropriate sterilization process; and the product is still within the expiry date.

Warning

Don't use the rusty instrument. Sterilize before use. Wash the hands with anti-bacterial soap or use approved hand sanitizer before use. Must only be used by the Surgeon or person authorized by the Surgeon.

Precautions

Instruments must be handled by the trained personnel only. Only Surgeons or personnel authorized by the Surgeons must be allowed to use the instruments.

Don’t sterilize the instruments having the solution with Chloride ions. Sterilization solution must have the pH near to 6.0 - 7.0. For professional use only - disinfect before use.

RISK ASSESSMENT: EN 14971:2001
Estimation of Risk: The Risk related to rusting and breakage is minimal, as devices are tested for both the risks before shipping to the customer. A Boil tests are performed on 100% of lot to assess the effectiveness of the Passivation Process and resistance against oxidation / rust. Functional and hardness test are performed to test the strength and durability of the instruments.

Acceptability of risk

These Associated Risk are very low and therefore can be accepted without further Analysis or change in manufacturing.

Conclusion

This Medical Devices classified as class-I as per Medical Device Regulation (MDR) 2017/745. It is ob- vious that the risk to both the patient and the user are minimal if the instrument is used for its intended purpose by the qualified personnel. However, the sterilization and decontamination of the instruments must be performed before every use.