

Amendment to general Stille instructions for care 950-100-14ML10

Valid for Stille standard instruments, article groups 101-119

Caution

- New instruments must be cleaned, inspected and sterilized prior to first use.
- The instruments may only be used for their intended purpose by qualified personnel. The surgeon shall be responsible for the proper selection of instrument for each application and for its operative use.
- Instruments in need of repair or service must be returned to a Stille authorized repair facility. Incorrect repair will void the warranty.
- Carefully examine the instruments before each use. Extra important to control is the sharp edge of cutting instruments and jaws and joints of grasping instruments. Check for blunt tip, fractures, loose play, corrosion etc.

Preparation for cleaning and disinfecting

- Any surgical residues should be removed as soon as possible after use, preferably
 directly in the OR. Contaminations on the instruments must not get dry or encrusted,
 as this could cause difficulties in cleaning and disinfection, and in the end lead to
 corrosion.
- Never immerse stainless steel instruments in a saline solution as this leads to pitting and stress corrosion.
- So called "dry disposal" is preferred rather than "wet disposal". If using wet disposal, immerse the instruments in a solution without protein-fixing effect. Aldehyde containing disinfectants are not suitable.
- Always follow the manufacturer's instructions regarding concentration and exposure time.

Manual Cleaning

- For manual cleaning, active non-protein-fixing cleaners can be used.
- Always follow the manufacturer's instructions regarding concentration, temperature and exposure time.
- Cleaning/disinfectant solutions should be freshly prepared on at least a daily basis.
- Powdery products must be completely dissolved in water before immersing the instruments.
- Rinse instruments carefully using demineralised water.
- After rinsing, instruments must be dried immediately.

Machine Cleaning and Disinfection

- Follow standard ISO 15883 and national guidelines only validated machine cleaning and disinfection should be used.
- Use a neutral or alkaline cleaning solution with a pH value between 8-10.5 in correct dosage according to manufacturer's instructions. Any cleaning process containing Hydrogen peroxide is not recommended for instruments with black-chrome coating (e.g. micro instruments), as the surface coating may become affected. The function of the instrument itself is not affected. STILLE SuperCut scissors manufactured from

2012 and STILLE Diamond SuperCut scissors withstand Hydrogen peroxide relatively well.

- If wet disposal has been used, low-foam cleaner and disinfectant must be used or the instruments must first be properly rinsed.
- High chloride concentration in the water can cause spot corrosion. The risk for this can be reduced by using alkaline cleaning agents or demineralised water.
- Adding an acidic neutralizer facilitates the removal of alkaline detergent residues.
- The instruments should be removed from the machine immediately after finished program to prevent residual moisture from causing corrosion.

Ultrasonic Treatment

- Ultrasonic treatment is suitable for cleaning stainless steel instruments to dissolve encrustations. A suitable temperature on the detergent is between 40-45°C. Add a suitable cleaning agent for better effect. Follow the manufacturer's instructions regarding concentration, temperature and exposure time.
- Use only suitable trays that do not create wave shadows.
- Be careful to protect sharp instrument tips.
- The solution should be renewed at intervals as instructed by the manufacturer.
- 3 minutes at a frequency of at least 35 kHz should be sufficient.
- Ultrasonic treatment is not suitable for any coated instruments.
- After ultrasonic treatment, the instruments must be carefully rinsed with demineralised water.

Instrument care & Maintenance

- Instruments to be sterilized must be macroscopically clean.
- Only use brushes intended for surgical instruments. Never use steel wool for removing stains.
- Control instruments carefully for corrosion, cracks, function etc.
- After each use, Stille instruments should be lubricated where metal parts are moving towards each other, such as joints, inside part of scissor blades and around joint screws.

Sterilization

- The preferred sterilization method is steam sterilization with fractioned vacuum, according to ISO 17665. Recommended temperature 134°C.
- The sterilization steam used must be free from foreign substances such as corrosive particles or dirt to avoid subsequent corrosion or deposits. The tolerances specified in EN 285 relating to water quality must not be exceeded.
- Carefully follow the instructions given by the manufacturer of the autoclave.
- Stille instruments should not be sterilized by hot air sterilization as the high temperature may affect the instruments' hardening.
- Hydrogen peroxide sterilization is not recommended for instruments with blackchrome coating (e.g. micro instruments), as the surface coating may become affected. The function of the instrument itself is not affected. STILLE SuperCut scissors manufactured from 2012 and STILLE Diamond SuperCut scissors withstand Hydrogen peroxide relatively well.

Storage

- The instruments should be stored in dry and dust-free conditions.
- Never store the instruments near chemicals.