Instructions for Use, Cleaning and Sterilization of Surgical Instruments

Intended Use

Our instruments are reusable surgical instruments intended for surgical use by cutting, scratching, scraping, clamping, retracting, clipping or similar procedures, without connection to any active medical device and which can be reused after appropriate procedures have been carried out. They are intended for temporary use only, i.e. under normal conditions intended for uninterrupted use for a period of less than 60 minutes.

The medical person responsible provides the indication and the risk/benefit assessment of the use for the patient. The following general uses are intended:

- Scissors / Micro-spring scissors: Cutting tissues with standard or microsurgical precision
- Forceps / Micro-forceps: Grasping and holding tissue or objects
- Needle holders / Micro-needle holders: Holding suturing needles during closure
- Atraumatic vascular clamps: Reducing or stopping blood flow with minimal tissue damage
- Hooks: Grasping or holding tissue during surgery
- Retractors / Self-retaining retractors: Holding incisions or tissues open for exposure
- Rulers: Measuring surgical sites internally or externally
- Scalpel handles: A scalpel is a small and sharp bladed instrument used in surgery to make incisions or to cut tissues. Only the handle can be sterilized and reused with a fresh blade every time
- MICS clip appliers: Applying clips to ligate tubular structures in minimally invasive surgery
- MICS knot pushers: Assisting in knot reduction during minimally invasive procedures
- MICS rongeurs: Cutting or biting soft tissue in minimally invasive procedures
- Micro-surgery instruments: Standard instruments redesigned for higher precision

Intended Patient Population

The patient population includes a wide variety of subjects who require a general surgical procedure. All instruments are intended for adult use and pediatric use, as preferences of individual surgeons pertaining to the right instrument size may vary based on vessel size of the patient and other factors not dictated by patient age alone.

Qualification of users and selection of instruments

The products may only be used by appropriately trained and qualified personnel for the intended use. A healthcare professional is responsible for the selection of the instruments for certain applications, for adequate training and sufficient information for the operating room personnel as well as for the surgical use.

First Use and Handling

Please check the products for possible transport damage. After removing the protective caps (if present), all instruments must also be cleaned, disinfected and sterilized before first use. The instruments must not be overstressed by twisting or levering, as this could lead to damage. This devices requires no installation or assembly prior to use. Safe performance is ensured through correct handling by qualified hospital personnel and the operating surgeon in accordance with standard clinical practice.

Caution

The instruments may only be used for their intended purpose in the surgical specialties by qualified personal. The surgeon shall be responsible for the proper selection of the instruments for each application, for obtaining the appropriate training, knowledge and experience, and for their operative use. Cardio Surgical will not be held liable for immediate or consequential damages caused by inappropriate application and use or by inappropriate cleaning, sterilization and maintenance of the instruments.

Checking

The functionality of the instruments must be checked before and after each use. For safe use, the surface and functionality of the product in the areas of cutting edges, tips, keys, closings, locks and all moving parts with regard to corrosion, cracks, scratches, breakage, damaged surfaces, chipping, deformation, mobility/function and contamination. The areas of cutting edges, tips, closures, notches and locks on all moving parts must be checked with particular care. Worn, corroded, deformed, porous and otherwise damaged instruments must be sorted out immediately. After checking, remove damaged instruments immediately. Instruments that are still dirty must be cleaned and disinfected again.

Repair, Warranty, Safe Disposal

NEVER repair a medical device yourself!

If defective products can and should be repaired, they must first be cleaned, disinfected and sterilized in accordance with these instructions for use and sent to us together with our completed “Instruments Decontamination Declaration”.

You can request the Declaration at info@cardio-surgical.cloud or + 353 91 796 770.

If the products are repaired by companies and persons who have not been authorized by Cardio Surgical Ltd., our guarantee and warranty expire. Additionally, Cardio Surgical Ltd. assumes no liability for direct damage or consequential damage caused by improper use, handling or improper preparation, sterilization and maintenance. Faulty or no longer usable instruments must be disposed of in accordance with applicable national or local regulations for medical waste. Proper disposal helps prevent cross-contamination and ensures that unsterile products are not reused.

Reprocessing guidelines

The high-grade steels (rustproof, stainless) that are used for manufacturing surgical instruments create due to the chemical composition specific passive layers as protective surfaces. Those steels however are only to a certain extent resistant against attacks of chloride ions and aggressive waters!

Chloride ions mainly cause pitting, but can also cause stress corrosion cracking. The greatest danger is water in which considerable quantities of common salts (sodium chloride) are dissolved.

Please do not use any chlorous or fluorine-containing disinfectants as the instruments may corrode. Further, chemical disinfection is not suitable for aluminium instruments/containers.

When choosing cleaning agents and disinfectants, please make sure that the following components are not included:

- Acids (<pH 5) / oxidizing acids
- Alkalis (> pH 11)
- Organic solvents
- Gasoline or ammonia
- Halogens, halogenated hydrocarbons, sodium chloride (in higher concentrations)
- Oxidizing agents / peroxides / hypochlorite

All instruments may only be exposed to temperatures not higher than 141 °C (286 °F)! Any liability is excluded in the event of a breach!

In addition to the endeavours undertaken by the manufacturer with regards to the selection of the proper materials and its careful processing, the user must ensure continuous and proper care of the surgical instruments as well as proper preparation, cleaning and sterilization.

General principles of preparation

The instruments are delivered non-sterile and must be cleaned, disinfected and sterilized before use.

The instruments may only be prepared by people who have the necessary specialist knowledge and training and who can assess the risks involved with the corresponding effects.

Effective cleaning and disinfection are an essential prerequisite for effective sterilization.

As part of your responsibility for the sterility of the instruments, please note that only adequately device and product-specific validated procedures for cleaning/disinfection and sterilization are to be used, the devices used (disinfector, sterilizer) are to be regularly maintained and checked and the validated parameters are to be observed with every cycle.

For certain instruments, the additional aspects listed under “Special Notes” must be observed.

If guidelines as out lined in this instruction for use are followed correctly, the surgical instruments can be reprocessed for a minimum of 300 cycles. Further information can be obtained by contacting Cardio Surgical Ltd

Please also observe the legal regulations applicable in your country as well as the hygiene regulations of the medical practice or the hospital. This applies in particular to the different requirements regarding effective prion inactivation.

Compatibility with Endoscopically used devices

There are no special requirements for using reusable surgical instruments with Endoscopically used devices as there is no energy emitted from the devices.

Pre-Cleaning

The instruments must be disinfected and cleaned immediately after use. Contamination on the instrument must not get dry or encrusted, as this could cause difficulties in cleaning and disinfection.

The following points are to be observed:

1. Solutions (e.g. Neodisher MediClean forte) used for the mechanical cleaning must be prepared strictly following the instructions given by the manufacturer.

2. Remove blood and all contamination under running tap water (<40° C) with a soft brush until no residues are visible. Never use metal brushes or metal sponges for cleaning. If possible, move all movable parts of the instruments.

- For the cleaning of cannulas and dead-end holes a suitable brush must be used so any area can be reached.
- Clean channels/cavities during manual/pre-cleaning with a water-pressure gun until visual clean
- Clean and detach instruments with hinges and box-locks in open as well as in closed position with a water pressure gun
- Pay special attention to the cleaning of slots, gaps, ratchets etc. with a water pressure gun

Ultrasonic treatment:

For ultrasonic treatment instruments should be placed in open condition on proper perforated trays or in wire baskets. Please ensure to avoid any “wave shadows” or covering surfaces caused by wire baskets or perforated trays or by large or bulky instruments.

Ultrasonic bath for 10 min with 0.5% Neodisher MediClean forte at <40°C should be carried out at a frequency of at least 35 kHz. Follow strictly the instructions given by the manufacturers regarding concentration.

If the temperature is above 113°F (45°C), the proteins may coagulate.

A too dirty solution in the ultrasonic basin decreases the cleaning effect. Therefore, the solution should be renewed at intervals according to the instructions given by the manufacturer.

After ultrasonic treatment all instruments must be rinsed for 15 sec. with deionized water (<40°C) and checked for loose parts (e.g. screws etc.). For rinsing fully demineralised or distilled water must be used to avoid water spots.

Machine Cleaning and disinfection

Below the cleaning program for the Miele washer-disinfector (PG 8535):

1. 1 min pre-cleaning with tap water (<40°C)
2. 10 min cleaning with 0.5% Neodisher MediClean forte at 55°C
3. 2 min cleaning with deionized water (<40°C)
4. ≥5 min thermal disinfection at 93°C
5. 30 min drying at 110°C (machine parameters)

1. Machine cleaning and disinfection is always a preferable method compared to manual cleaning since machine procedures can be standardized.

2. Follow the operation and loading instruction provided by the manufacturer or the washing machine. Use only the detergents and cleaning agents recommended by the manufacturer for the specific purpose.

3. Hinged and box-lock instruments must be loaded and cleaned in open condition. Place instruments into the machine in a way that allows the water to flow out of cannulations and dead-end holes.

4. Take instruments apart as much as possible for cleaning,

5. Machine cleaning and disinfection is only suitable for instruments with long or thin cannulations if the hot disinfection solution can actually flow through them.

6. When removing instruments from the washing machine, pay special attention to the proper cleaning of slots, gaps, ratchets, box-locks, cannulations and dead-end holes. Check for any visible remaining contamination. If necessary clean manually and/ or repeat cycle.

STERILIZATION

Steam - Sterilization:

It is very important to avoid that the steam could be polluted by impurity, such as rust or other contaminants – they must be excluded. This may avoid corrosion or pollution (development of covering) of the surgical instruments. Steam for sterilization purposes must comply with DIN 58946, section 7. The manufacturer‘s instructions for steam sterilization must be observed

Steam sterilization / Autoclaving

The below parameters have been validated to achieve a Sterility Assurance Level (SAL) of 10^{-5}

Recommended sterilization method: Steam sterilization with fractionated vacuum

	Europe	**USA**
Temperature	134°C	132°C
Holding time	5 min	4 min
Drying time	20 min	20 min

When using autoclaves for sterilization of surgical instruments, it has to be strictly ensured that the steam used is absolutely free of foreign substances such as corrosive particles or dirt to avoid subsequent corrosion or dirt (scum) deposit. Please observe strictly the instructions for use given by the manufacturers of autoclaves.

Special Instructions

For the following products/product groups, the following aspects must also be observed:

- Instruments with a joint (e.g. clamps, scissors, needle holder, etc.)
    - Open and close the instrument several times during pre-cleaning and disinfection.
    - Open and close the instrument several times before cleaning and insert it in the half-open position during machine

cleaning and disinfection.

- If necessary, oil the joint (and not other product surfaces) with as little oil as possible.

- Instruments with channels/cavities (e.g. mini-invasive instruments)
  - During machine cleaning and disinfection, if necessary, use a suitable rinsing adapter to connect directly to the rinsing connection of the cleaning and disinfection unit.
  - Through the cleaning port of the instrument, rinse 3 x 10ml of Heparin or Saline (with a syringe).
  - If the patency is impaired, do not use the instrument again.

Maintenance

Put the disassembled instruments back together.

Instrument oils should only be used if explicitly stated (see “Special information”). If use is nevertheless desired, care should be taken to ensure that only instrument oils (white oil) are used which, taking into account the maximum sterilization temperature used, are approved for steam sterilization and have tested biocompatibility. Only moving parts may be oiled; complete oiling of the instruments and in particular oiling of plastic components should not be carried out.

Storage

Instruments should be stored in a clean, dry, moisture free area. Instruments should be stored individually in their shipping carton or in a protective tray with partitions. Protect Tips, edges etc. with tubing, protection caps, gauze or fabric. Make sure that no chemicals are close to or in the storage area.

Contradictions, Warnings or Residual Risks

There have been not Contradictions, Warnings or Residual Risks identified with the medical devices as part of the conformity assessment. These are kept under constant review and this Information for use document will be updated where there are new elements identified.

Reporting of Incidents

Please report any intraoperative, serious incidents (death or serious deterioration in the patient's state of health) that is causally related to a malfunction of one of our instruments, immediately and with anonymized patient data, with precise details of the sender to info@cardio-surgical.com or (091) 796 770. The competent authority is Health Products Regulatory Authority (HPRA) https://www.hpra.ie

List of Countries where the medical devices will be marketed

Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and Sweden as well as Iceland, Liechtenstein, Norway, United Kingdom and Switzerland.

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CE marking according to Regulation (EU) 2017/745

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Document Approval

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Revision History

Revision	Effective Date *(Same as approval date)*	Change Details
00	21-apr-2021	First Issue
01	Jul-03-2025	Update to contact details Updated parameters and added mention to disinfectant
02	Aug-27-2025	Aligned with reprocessing validation
03	Oct-14-2025 | 11:16 AM BST	Updated intended use and instrument list to align with Technical File First Use paragraph renamed and expanded NB number added to CE Mark symbol Reporting to regulatory authorities paragraph expanded Substituted MDD reference with MDR Repair, warranty, safe disposal paragraph renamed and updated with safe disposal according to national guidelines Added reference to minimum cycles Added contradictions, warnings, residual risk section Updated special instructions section with heparin flushing