STERIS
Instrument Management Services

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Washing, Decontamination & Sterilising instructions – INS001 issue 004

Intended Use
Manual, non-powered instruments intended for surgical use.

Product characteristics
General surgical use, multiple patient multiple use, reusable instruments are supplied in non-sterile conditions. The sterility of any instrument prior to use is the responsibility of the Customer.

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Devices to be used by licensed medical professionals trained in their use, including appropriate selection of instrument size for the application.

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Device proper functionality, including cleaning and sterilisation verification, shall be verified prior to each use.
Device lifetime is determined by device proper functionality and careful care during use. End of lifetime is determined by wear and damage caused by use. Improperly functioning, damaged or worn general surgical use reusable instruments should be removed from service and not used. Devices can be damaged due to inappropriate selection for use, cleaning, decontamination and/or sterilization.

Contraindications
General surgical use reusable instruments shall not be used with the heart, central circulatory system, and central nervous system. Any use of the instrument that is not corresponding with the intended use.

⚠
Physical removal of gross debris and bioburden, through soaking and wiping of instrumentation with water should be initiated immediately after the procedure, at the point of use. Where practical, keep instruments moist prior to processing. Do not use metal or wire brushes, abrasive detergents, or isopropyl alcohol on instruments.

Washing, Decontamination & Sterilizing instructions
Use only those cleaning agents that have been tested according to national public health regulations and local medical practice. The Decontamination Process is dependent on effective cleaning and washing of instruments by staff appropriately trained to your local procedures for the process. Severe soiling should be removed by submerging the instruments in the detergent solution and, using brushes and rigid nylon bristles to brush the items clean while holding them below the surface until no soil can be detected visually. Attention should be paid to any areas where debris may enter. Staff carrying out decontamination and washing process should operate according to local policy and procedures.

Following pre-cleaning, the instrument should be washed in a washer-disinfector meeting the requirements of the ISO 15883 series, using a neutral, neutral enzymatic or alkaline detergent (pH 7-10), and incorporating a thermal disinfection cycle (minimum 90°C for 1 minute) using high purity RO water for the rinse. Pivoted instruments should be presented open for the washer, disinfection process. If an appropriate machine is not available, a manual process can also be used. However, the low effectiveness and reproducibility shall be considered. Furthermore, the manual cleaning and disinfection process must be assured under the responsibility of the user (additional product and process-specific standardization).

The surgical instruments must be sterilized prior to use using high temperature steam. Effective cleaning and disinfection are prerequisites for effective sterilization. The instrument must be sterilized using validated equipment meeting the requirements of the ISO 17665 series and processed in accordance with national standards and guidelines. The standard parameters of 134-137°C for 3 – 3 ½ minutes are appropriate. A vacuum assisted air removal phase prior to steam admission for sterilisation is recommended.

Packaging materials used should conform to EN ISO 11607 or the relevant parts of EN 868-7.

The parameters above have been validated as appropriate and are effective for the instruments provided with these instructions.

The majority of surgical instruments are one-piece items; however, some are made up of several components. These must be disassembled into their constituent parts to be washed, cleaned and decontaminated effectively.

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For further information, related to the use of these instruments, please contact your STERIS Instrument Management Services Limited representative.

Return of instruments
Before returning any instrument to STERIS Instrument Management Services Limited, please ensure that washing and sterilizing has been carried out in accordance with national standards and guidelines. All used and returned instruments must reference washing and sterilization cycles onto the decontamination certificate.

Damaged Instruments
If any instruments have been damaged or are found to be below your standard of expectation, please supply details so that we may investigate and rectify and situation.

Serious Incidents
Serious incidents that have occurred in relation to this medical device should be reported to STERIS Instrument Management Services Limited representative and competent authority in the country where the incident occurred.

Disposal after use
The device itself does not require special disposal instructions. The device should be cleaned and disinfected to remove any possibility of infection. When disposing of or recycling a device, and its packaging, please follow all national regulations and standards.

Repair Service
For any repair service inquiries, please contact your STERIS Instrument Management Services representative.

Glossary
Please refer to the table below for definitions of the symbols used within the labelling.

Symbol	Meaning
	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Indicates the date when the medical device was manufactured.
	Indicates the medical device manufacturer.
	Indicates the authorized representative in the European Community.
	Indicates the medical device CE marking.
	Indicates a medical device that has not been subjected to a sterilization process.
	Indicates a medical device that needs protection from light sources.
	Indicates a medical device that needs to be protected from moisture.
	Indicates the need for the user to consult the instructions for use.
	Indicates the need for the user to consult the instructions for use for important cautionary information.
	Indicates a Medical Device.
	Indicates Unique Device Identifier.