FABRICANT/ MANUFACTURER

INOMED Technology SA
La Praye 5
CH-2608 Courtelary
Switzerland

Tel. +41 (0)32 372 13 80
Fax. +41 (0)32 372 13 84

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NON STERILE

NOT-STERIL

GENERAL NOTICE

English

Medical Devices

Description

The medical devices developed and manufactured by Inomed Technology are designed and intended for surgical operations. These medical devices belong to class I of manual devices or to the class IIa of invasive devices driven by an energy source (Directive 93/42/CEE).
The medical devices will be handled, conditioned and used only by professionals from the health industry, by hospital staff, or by people suited, trained, recognized and authorized to practice surgical operations on patients or to handle such devices.

Materials

Inomed Technology's medical devices consist of following materials:
- Stainless steels
- Titanium
- Polymerized materials without latex and/or animal/organic matter

These materials are subject to homologations for medical uses in accordance with their characteristics of use.

Utilization

Before any clinical use, the hospital staff must assimilate all aspects of surgical operations as well as the limits of the medical device. They also will take into account the specific notices of the medical device, such as the instruction for use & cleaning. The hospital staff will also take care to receive an adequate training from his implant distributor before to use the medical device.

Warning

Some instruments may present arises/edges or include sharp parts as wicks, borers, taps, drills. The hospital staff will take care to handle such instruments with precaution in order not to be wounded, not to notch the surgical gloves and not to wound the patient. He will also have to take account of the infection risk in case of injury.
Do consult an expert in infections control in order to develop and check the suitable safety procedures for all direct contact levels with instruments being able to generate infections.

Cleaning and decontamination

Withdrawal of the rough contamination from the medical device.
The subsequent process decontamination efficiency depends on the preliminary withdrawal of all important stains, because this effectiveness could be compromised by dried or coagulated protein. Major stains, even in the cavities, must be withdrawn with water by integrating a mechanical process such a brush with rigid nylon silks. Do avoid to splash and/or to produce aerosols by holding the instruments under the water surface in a sink where water runs and is evacuated continuously. Do not hold instruments under the tap because that will produce splashes. The operative staff must carry protective gears, including gloves, glasses and protection masks.

Cleaning and disinfection

It is recommended to decontaminate the instruments in a disassembled mode (if possible) with the mean of an automatic washing-disinfection apparatus using a thermal disinfection system. It is recommended to use a continuous or ultrasonic tunnel process type. Typical initial cleaning temperature is equal or lower than 35 °C (95 °F). During the disinfecting rinsing step with warm water, the instruments surface temperature must reach at least 71 °C (160 °F) during at least 3 minutes, 80 °C (176 °F) during at least 1 minute or 90 °C (194 °F) during 1 second. Detergents and compatible rinsing products can be used according to the recommendations of the washing-disinfection apparatus manufacturer. These detergents and/or compatible rinsing products must be pH neutral or close to. Excessively acid or alkaline solutions could corrode or damage some devices.
After this step, the devices will be reassembled together and place inside washing basket or a sterilization tray.

Instrument maintenance and handling

Surgical instruments and instruments trays are likely to be damaged for many reasons, as for example a prolonged use, a misuse, an abrupt or unsuited handling. We should avoid compromising their exceptional performances. In order to reduce possible damage and the lesion risks, the following is recommended :
- Inspect all medical devices in order to detect any damage sign at the reception of those and after each use & cleaning
- Clean again all instruments that are not fully cleaned
- Remove all instruments that require repair and return them to the distributor
- Use instrument only at its envisaged ends

General Cleaning

General cleaning
Clean the instruments before the first sterilization and immediately after use. Don't leave blood or remains drying on the instruments. In the event of delayed cleaning, place the instruments within a closed container with detergent or adapted enzymatic solution in order to delay drying. Wash all instruments, whether or not they have been used, most particularly if they accidentally came into contact with blood or physiological salt solution.

Ultrasonic cleaning
Ultrasonic cleaning can be used with warm water according to the temperature recommended by the manufacturer (32-60 ºC or 90-140 ºF in a general way). Do follow the manufacturer recommendations by using the correct formulation of the cleaning solution specific for the ultrasounds washers. Don't forget that the patterns load, the instruments boxes, the water temperature and other external factors can modify the equipment effectiveness.

The equipment washing/decontamination
The equipment washing/decontamination will ensure the washing and the decontamination of the instruments. The complete withdrawal of slits dirt and serrations depends on the instrument manufacture, on the exposure time, on the provided pressure solution and on the pH of the detergent solution, and thus eventually

requiring a preliminary brushing. Get familiarized with the equipment manufacturer's instructions of use and operation. Don't forget that the loading, the detergent, the external water temperature and other factors can modify the equipment effectiveness.

Sterilization

The hospital staff is responsible to ensure the sterilization efficiency and to keep sterile the packaging and material. The sterilization trays do not provide a sterile barrier and must be used with a sterilization packaging in order to keep the instruments sterile.

STERILITY

The users should carry out in order to check that the essential conditions of sterilization are reached and that the specific configuration of the container content is acceptable for the sterilization procedure. The standard norm ANSI/AAMI ST33 ("Guidelines for the Selection and Uses off Reusable Rigid Container Systems for Ethylene Oxide Sterilization and Steam Sterilization in Health Care Facilities") explains the selection and use of the multi-use rigid sterilization containers systems. Provided directives are addressed for cleaning and decontamination processes, for the preparation / loading / unloading of the sterilizer, associating the container type with the requested methods for adapted sterilization cycle, quality assurance, sterile storage, aseptic transport and use.

WARNING AND PRECAUTIONS

Unless otherwise specified, the instruments sets are not sterile and must be entirely cleaned and sterilized before use. The medical instruments and devices are not sterile when leaving Inomed Technology's factory.
Instruments should not be subjected to an accelerated sterilization process in autoclave with instruments inside the. The accelerated instruments sterilization in an autoclave should be avoided. Sterilization trays not wrapped cannot maintain sterility.

STORAGE AND SHELF LIFE

Instrument trays which were treated and wrapped to maintain sterility must be stored in order to avoid high temperature, extreme moisture and/or other contaminations. Be careful when handling wrapped trays in order not to damage the sterile barrier. Based on the sterile packaging type used and those manufacturer recommendations, hospital staff must establish how long wrapped trays can last. Whether or not woven or not woven materials, trays or containers are used as packaging solution, the user must keep in mind that sterility maintenance depends on the event and that the probability of contaminating event increases with time and handling.

Inomed Technology instruments can be sterilized in autoclave with vapor and sterilized many time, unless otherwise specified on the label.
Surgical instruments can be autoclaved with complete cycle. Instruments used in surgical environment must be carefully cleaned before being put in autoclaves. It is recommended to follow the ANSI/AAMI ST46 standards ("Steam Sterilization and Sterility Insurance in Health Care Facilities ").

AUTOCLAVE WITH GRAVITY STEAM FLOW

Recommended exposure time	Recommended Temperature	Recommended drying time
15 minutes	121 °C = 250 °F	8 minutes
10 minutes	126 °C = 259 °F	8 minutes
3 minutes	134 °C = 273 °F	8 minutes

As Inomed Technology is not aware of the handling procedures, of the cleaning methods of and the contamination levels of each hospital, Inomed Technology does not take any responsibility for products sterilization in hospital even if the above general directives are followed.

WASHING AND STERILISATION AGENTS

The cleaning, washing and sterilisation agents have to be in accordance with Inomed Technology's above recommendations. No solvents should enter in contact with Inomed Technology's trays. In particular, nitro dilutive, acetone, dissolvent and toluene should not be used with the Inomed's trays.
In addition, no kind of tickets / labels in paper or in plastic should be glued on the trays.