



Strategic Business Holdings, Inc.

...Quality Products, Superior Customer Service, & Support

IFU for GENERAL SURGICAL INSTRUMENTS

GENERAL INFORMATION

Field of application

All reusable surgical instruments, which






- consist of only one piece
- may contain simple joints or simple movable parts
- may be composed of several exchangeable parts

Basics

These instructions cannot replace training, carefulness and the user's knowledge of the state-of-the-art-technology. We therefore assume that the respective legal rules, standards and recommendations (e.g. those of "RKI" or also of "AKI") are known (see "Standards/References").

ATTENTION: READ THESE INSTRUCTIONS VERY CAREFULLY BEFORE YOU PREPARE AND USE THE PRODUCT FOR THE FIRST TIME.

Labelling

-  Item or order number
-  Batch number
-  Inscription for non-sterile products
-  Caution, note the accompanying documents
-  European approval symbol

Intended use

All reusable surgical instruments supplied by SBH may only be used for the purpose of which they are designed, by adequately qualified personnel 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.

Restrictions

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 reutilization! We recommend destroying the instruments. If you reprocess and reutilize the instrument nevertheless, even according to the RKI2-guidelines, you bear all responsibility. Instruments containing aluminum get damaged by alkaline cleaners >pH 7!

Warning

The instruments are generally delivered unsterile. After having received the products, please check their identity, completeness, intactness and functioning before you reprocess them. It is indispensable to inspect the instruments prior to use for breakage, deformation, damage and proper functioning. In particular, you have to check parts such as cutting edges as well as all movable parts. Instruments that are fully worn, corroded, deformed, porous or otherwise destroyed have to be rejected.

Combination with other products/instruments

If instruments are reassembled after having been disassembled, the individual parts must not be replaced by parts of other manufacturers, even if a part is exchangeable because of the product's specific function (e.g. different inserts).

Material durability

Cleaning supplies and disinfectants must not contain the following components:

- organic, mineral and oxidizing acids,
- powerful leaches (> pH 12,5, mild alkaline cleaner are recommended)
- halogenated hydrocarbons, chlorine, iodine organic solvents(alcohol, acetone, etc.)
- ammoniac

The products are thermoresistant but they must not be exposed to temperatures higher than 141° C (286° F).

Disposal; return consignment

SBH only accepts returns if the products are declared as "hygienically inoffensive" (i.e. they passed the whole reprocessing) and if they are marked as "non decontaminated" (pink reparation note), and if they are safely packed. After a successful disinfection the defect or out-of-date instruments are to be disposed of professionally or returned to a recycling system.

Warranty

Security advice:

The user is responsible for the appropriate cleaning, disinfection and sterilization of the instruments. National rules, including restrictions, have to be observed as well.

SBH excludes any warranty claims and assumes no liability for damages or subsequent damages resulting from:

- use for purposes other than intended
- inappropriate use, employment, or handling
- inappropriate treatment and sterilization
- inappropriate maintenance and reparations
- nonobservance of these instruction guidelines

Reparations may only be made by companies or persons authorized by SBH. In case of nonobservance any warranty will be excluded.

Combination with other products/instruments

If instruments are reassembled after having been disassembled, the individual parts must not be replaced by parts of other manufacturers, even if a part is exchangeable because of the product's specific function (e.g. different inserts). We recommend ordering equipment (e.g. cleaning and care products) at SBH, too.

Materials

The raw materials used are stainless steels according to DIN EN ISO 7153-1, titanium alloys in accordance with DIN ISO 5832-3 or aluminum alloys in accordance with DIN EN 573-3. Synthetics are approved for medical products, and biocompatibility is verified.

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INSTRUCTION FOR REPROCESSING

General basics for hygiene and reprocessing

Brand-new instruments and repaired instruments have to be reprocessed before their first employmen just as used instruments. The transport protective package, protection caps, etc. cannot be sterilized. Only approved agents (RKI, DGHM/VHA, FDA, etc.) may be used, alkaline as well as enzymatic cleaning supplies are applicable.

ATTENTION: DO NOT USE ALKALINE CLEANERS > PH 7 FOR ALUMINIUM INSTRUMENTS!

- water quality according to DIN EN 285 annex B
- sterilizers according to DIN EN 285 or DIN EN 13060
- cleaning and disinfection machines according to DIN EN ISO 15883 part 1 and 2
- only processes specifically and sufficiently validated for devices and products may be used for cleaning/disinfection/sterilization
- the manufacturer's instructions and recommendations have to be observed
- furthermore, national legal and hygienic regulations, in particular for the different specifications suitable for inactivation of prions, have to be observed

Containment and Transport

Used instruments must be stored and transported to the decontamination area for reprocessing in closed or covered containers to prevent unnecessary contamination risk or damages.

Preparation for cleaning/disinfection

- residues caused by the usage have to be removed immediately
- do not use metal brushes or steel wool
- do not put the instruments into common salt solution
- appropriate handling and deposition
- wet disposal: waiting time max. 1 hour until treatment
- dry disposal: waiting time max. 3 hours until treatment

ATTENTION: CLEANING AND DISINFECTION OF INSTRUMENTS IN CLEANING DEVICES SHOULD BE PREFERRED OVER MANUAL CLEANING, WHEREVER POSSIBLE, AS AUTOMATED PROCEDURES CAN BE STANDARDIZED!

Manual cleaning and disinfection

- mechanical cleaning/disinfection is always preferred
- only in case of non-availability and in exceptional cases, manual cleaning is permitted. If so, additional product- and process-specific validation in the responsibility of the user is necessary
- do not use metal brushes or steel wool
- narrow lumen instruments and parts have to be cleaned very carefully
- appropriate handling and deposition

Manual cleaning by ultrasonic cleaning

- maximal temperature: 50° C (122° F)
- frequency: 35 - 45 kHz
- time of cleaning: 4 - 5 minutes
- put in instruments with open joints
- all lumen must be filled with cleaning liquid, it must be free of air bubbles, and these instruments have to be arranged according to the sound

Mechanical cleaning - thermal disinfection

- mechanical cleaning / thermal disinfection are always preferred
- open all instruments which can be opened and then put them into a tray on the trolley and start the cleaning process
- MIC instruments: detach the instruments as far as possible prior to putting them on the MIC-trolley's inserts, instruments that cannot be inserted should be opened and put into a tray on the MIC-trolleys
- pre-rinse with cold water
- classic steel titanic instrument cleaning: alkaline up to pH 12,5, cleaning time 5 min. at 70 - 90° C (158 - 194° F) e.g. with AClean AlkaClean+
- titan and endoscopic instrument cleaning: mild alkaline/enzymatically cleaning up to pH 10,5, cleaning time 10 min. at not more than 55° C (131° F) e.g. with AClean CombiBasic/CombiZyme+
- rinsing with deionized/demineralized water (in case of using the AClean products a neutralization is not necessary)
- thermo-disinfection with consideration of the AO value (time duration/temperature) according to the product's classification on the basis of the RKI-guidelines

ATTENTION: PLEASE PAY ALSO ATTENTION TO THE CLEANING INSTRUCTIONS REFERRED TO BY THE MANUFACTURER OF YOUR CLEANING DETERGENTS!

Control and maintenance

- instruments have to be cooled down to room temperature
- reassemble the instruments for functional testing
- maintain joints, threads and sliding surface with oil spray after cleaning/disinfection but before the functional tests, use other care products (paraffin/white oil basic and free of silicone) only if they are approved of for steam pressure sterilization and biocompatibility has been checked
- sort out damaged instruments see "Disposal; return consignment"

Packaging

- packages according to DIN EN 868 can be used
- chose the package so that the instruments fit in well
- use a sterilization indicator for the package and note the dates of sterilization and expiry

Sterilization

- steam pressure sterilization
- other sterilization methods and the flash sterilization method are not authorized
- fractionated 3 pre-vacuum phase method with pressure of at least 60 milli-bar (with sufficient drying time of the product of not less than 15 minutes)
- Maximum temperature of sterilization: 138° C (280° F); plus tolerance corresponding to DIN EN ISO 17665-1 (or DIN EN 554)
- Time of sterilization (exposure time at the temperature of sterilization) at least 20 minutes at 121° C (250° F) or 4 minutes at 132 - 134° C (270 - 273° F)
- Steam-sterilizer corresponding to DIN EN 13060 or DIN EN 285
- Validated according to DIN EN ISO 17665-1 (or DIN EN 554)

Storing

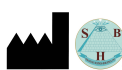
- dry, dustproof, without action of force from outside, without temperature variation and not within spitting distance to aggressive media
- expedient in trays, containers, cupboards

Confirmation – notices

The above instructions for treatment were validated as appropriate for the preparation of medical products for reuse. The user is responsible for the sterilization process being made with the equipment, materials and staff in the sterilization facilities and for the desired results being achieved. If the delivered instruments are split, the user has to make sure that there is an instruction in every department/field of application.

Standard/References:

- AKI-guide (AKI: Arbeitskreis Instrumenten-Aufbereitung)
- RKI-suggestion: "hygiene requirements at medicine products treatment (RKI: Robert-Koch-Institut)
- DIN EN 285 large steam sterilizer
- DIN EN 13060 small steam sterilizer
- DIN EN ISO 15883-1-3 cleaners – disinfectors
- DIN EN 868 packing materials
- DIN EN ISO 17664 Sterilization – Manufacturer's Information
- DIN EN ISO 17665-1 (or DIN EN 554)



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