

Instruction of use

Reusable surgical instruments
Self retaining retractors



16-XXX-XX - 16-XXX-XX



AS Medizintechnik GmbH
Sattlerstraße 15
78532 Tuttlingen
Germany

Tel: +49/74 61/966 32-6
Fax: +49/74 61/966 32-88
www.AS-Medizintechnik.de
info@AS-Medizintechnik.de



IMPORTANT INFORMATION - PLEASE READ BEFORE USE

1 Products:

16-274-10
16-274-14
16-275-18
16-276-00
16-277-18
16-277-20
16-277-25
16-278-18
16-279-00
16-280-01
16-280-02
16-280-05

2 Intended use:

A Retractor is a surgical instrument by which a surgeon can either actively separate the edges of a surgical incision or wound, or can hold back underlying organs and tissues, so that body parts under the incision may be accessed.

3 Warnings:



- All types of Retractors are sold non-sterile.
- All types of Retractors must be cleaned, disinfected and sterilized before and after each use.
- Do not use strong alkaline or acidic cleaning solutions

4 Limitations on Reprocessing:

- Frequent re-treating (like ultrasonic, mechanical washing, sterilization) has minimal effect on the instruments.
- Carefully inspect devices between uses to verify proper function.
- End of product life is usually determined by wear or damage in surgical use.
- Evidence of damage and wear on a device may include but is not limited to corrosion (i.e. rust, pitting), discoloration, excessive scratches, flaking, wear and cracks. Improperly functioning devices, devices with unrecognizable markings, missing or removed (buffed off) part numbers, damaged and excessively worn devices should not be used.
- Do not use damaged instruments. They are to be disposed of according to hospital procedure.

Instructions:

5 Point of use:

- Remove excess soil with disposable cloth / paper wipe.
- All instruments should be flushed with high pressure water.

6 Containment and transportation:

It is recommended to transport contaminated instruments in a closed clean box / container.

It is recommended that the device is reprocessed not later than 2 hours after usage.

7 Preparation for decontamination:

- Wear personal protective equipment (gloves, water repellent protective skirt, face protection mask or protective glasses, see also instructions of the manufacturer for the detergent and the disinfectant).

8 Pre-cleaning

- **Equipment:** Personal protective equipment (as listed above), cold tap water ($20 \pm 2^\circ \text{C}$) of at least drinking water quality (in accordance with RKI guideline), high pressure water pistol

1. Flush the devices with attention to the critical and hard-to-reach areas at least 1 minute with a high-pressure water pistol.

9 Cleaning: Manually

- Prior to manual cleaning and subsequent manual disinfection: Do Pre-cleaning (see pre-cleaning above).
 - **Equipment:** Detergent: multistage enzymatic cleaner (e.g. Sekusept® MultiEnzyme of ECOLAB (www.ecolab.com), soft brush (e.g. Interlock # 09098) detergent tank, tap water ($20 \pm 2^\circ \text{C}$) of at least drinking water quality (in accordance with RKI guideline), a sterile 20-ml syringe (e.g. B. Braun # 4606205V)
1. The cleaner is prepared in accordance to the manufacturer's instructions (e.g. Sekusept® MultiEnzyme 2% solution).
 2. Soak the device into cleaning solution.
 3. Exposure time in accordance to the manufacturer's instructions (at least 15 minutes for Sekusept® MultiEnzyme 2% solution).
 4. During exposure time while device is soaked brush the hinge and all hard-to-reach areas and accessible areas of the device to remove all visible dirt with a soft brush. Pay attention to the critical and hard-to-reach areas where it is not possible to assess the cleaning efficacy for the devices by means of visual inspection.

Instruction of use

Reusable surgical instruments
Self retaining retractors



REF

16-XXX-XX - 16-XXX-XX



AS Medizintechnik GmbH
Sattlerstraße 15
78532 Tuttlingen
Germany

Tel: +49/7461/966 32-6
Fax: +49/7461/966 32-88
www.AS-Medizintechnik.de
info@AS-Medizintechnik.de



- Fill a 20-ml syringe with detergent solution and flush the hinge and all hard-to-reach areas and accessible areas of the device. Repeat step this step 5 x. Pay attention to the critical and hard-to-reach areas where it is not possible to assess the cleaning efficacy for the devices by means of visual inspection.
- Remove the device from the detergent.
- Rinse the device for 1 minute under running tap water all surfaces must be in contact with the tap water for at least 10 seconds.
- Check on cleanliness, if dirt is visible, repeat the above steps.

10 Disinfection: Manually

- Equipment:** Disinfectant on peroxide basis (e.g. Sekusept® aktiv of ECOLAB (www.ecolab.com), disinfectant tank, tap water (20±2°C) of at least drinking water quality (in accordance with RKI guideline), ultrasonic bath (35 kHz), a sterile 20-ml syringe (e.g. B. Braun # 4606205V)
- The disinfectant is prepared in accordance to the manufacturer's instructions (e.g. Sekusept® aktiv 2% solution).
 - Soak the device completely into the disinfectant solution within the ultrasonic bath.
 - Exposure time in accordance to the manufacturer's instructions (at least 10 minutes for Sekuspet® aktiv 2%).
 - During exposure time fill a 20-ml syringe with disinfectant and flush the hinge and all hard-to-reach and accessible areas of the device 5 x. Pay attention to the critical and hard-to-reach areas where it is not possible to assess the cleaning efficacy for the devices by means of visual inspection.
 - After 5 minutes exposure time start ultrasonic for additional 5 minutes.
 - Turn off ultrasonic.
 - Remove the device from the disinfectant bath.
 - Rinse the device under running tap water for at least 1 minute.
 - Repeat the rinsing step with deionized water.
 - Wipe the device with single use, fluff free wipe or towel or dry by an air gun with compressed air.

11 Cleaning and disinfection: Automated

- If visible soil remains in gaps, holes, joining surfaces, threads and other hard to reach areas: Start with Precleaning (see pre-cleaning above) and continue with manual cleaning.
 - Equipment:** Washer disinfector in accordance with DIN EN ISO 15883-1+2 with thermal program (temperature 90-93°C), mildly alkaline cleaner detergent (e.g. Sekumatic® MultiClean 200 ml), air gun connected to compressed air of medical grade (in accordance with European Pharmacopeia).
- Bring all parts of the devices in a suitable tray on a load carrier module in the washer disinfector so that all internal and external surfaces are cleaned and disinfected.
 - After closing the door start the thermal program, the program parameters are shown in the table below.
 - At the end of the program remove the device.
 - Check if the device is completely dry, if necessary dry with single use, fluff free wipe or towel or dry by an air gun with compressed air.

Program Step	Water	Dosage	Time	Temperature
Pre-Rinse	Cold		5 minutes	
Dosage cleaner		According to manufacturer's instructions		According to manufacturer's instructions
Cleaning	Deionized water		10 minutes	55° C
Rinse	Deionized water		2 minutes	
Disinfection	Deionized water		A ₀ value >3000 ¹	(e.g. 5 minutes, 90° C)
Drying			15 minutes	Up to 120° C

¹ Public authorities may adopt other implementing provisions (parameters for disinfection performance) within their field of responsibility

12 Maintenance, Inspection and Testing:

Equipment: Silicone-free steam sterilizable lubricant allowed for use on medical products according to the manufacturer

- Inspect all components of the device under normal lightning for the removal of soil. Repeat manual cleaning (including pre-cleaning) and automated cleaning and disinfection if components are not visible clean.
- Check the device for completeness, damage and functionality.
- Check the device with long slender features for distortion.
- Check for smooth movement of hinge without excessive "play". Locking (ratchet) mechanisms should be checked for action.
- Do not use damaged instruments.
- Lubricate the instrument hinge of the device using silicone-free steam sterilization lubricant.

13 Packaging:

Packaging in sterile barrier system in accordance with DIN EN ISO 11607 or DIN 58953.

Instruction of use

Reusable surgical instruments
Self retaining retractors



REF

16-XXX-XX - 16-XXX-XX



AS Medizintechnik GmbH
Sattlerstraße 15
78532 Tuttlingen
Germany

Tel: +49/74 61/966 32-6
Fax: +49/74 61/966 32-88
www.AS-Medizintechnik.de
info@AS-Medizintechnik.de



14 Sterilization:

Equipment: Sterilizer according to DIN EN 13060 and/or DIN EN 285.

- Pre-vacuum process, 134°C, and sterilization time at least 3 minutes (longer holding times and temperatures (<141° C) are possible).
- Sterilization of the device in the disassembled status.

1. Place the package device in the sterilizer chamber.
2. Start the program.
3. At the end of the program remove the device and let it cool down.
4. Check that the seal of the package is closed and the package is dry.

15 Storage:

Storage and shelf life as established by the processor.

- Instruments should be stored in dry, clean and humidity-free environment without direct solar irradiation.
- Do not store them in places where chemicals may emit corrosive fumes or where fluctuating temperature of humidity may cause vapors to condense on the instruments.

16 Additional Information:

Only validated processes may be used for the processing of medical devices.

17 Symbols used on labelling:



Manufacturer



Catalogue Number



Lot Number



See instruction for use



Non-Sterile – Sterilize prior to use



Consult instructions for use



Keep away from rain



Keep away from sunlight



Product complies with requirements of directive 93/42/EEC for Class IIa

AS MEDIZINTECHNIK GMBH DOES NOT ACCEPT RESPONSIBILITY IF THIS CUSTOMER INFORMATION HAS BEEN VIOLATED PROVABLY.