B BRAUN
SHARING EXPERTISE

HIGH-LEVEL
INSTRUMENT
DISINFECTANT

Stabimed® ultra

Advanced granulated formulation with outstanding fast virucidal & sporicidal activity of 2 % / 10 minutes.

Stabimed® ultra

THE SOLUTION FOR MANUAL REPROCESSES

- Aldehyde-, QAC- & phenol-free
- High material compatibility thanks to neutral pH
- Extremely effective active agent based on peracetic acid
- Excellent cleaning performance
- Dust-free pearl-granulation
- Suitable for invasive & non-invasive instruments, especially for flexible endoscopes
- Approved and listed by Karl Storz Endoskope
- Bactericidal & Fungicidal
- Mycobactericidal
- Virucidal
- Sporicidal

THE CHALLENGE: REPROCESSING OF FLEXIBLE ENDOSCOPES

Within the last years reprocessing of flexible endoscopes has become more and more standardized worldwide. Nearly all guidelines focus on cleaning using enzymatic cleaners and brushes followed by validated machine reprocessing (automated cleaning and disinfection) in a washer-disinfector for flexible endoscopes. All process steps should be documented and traceable.

If washer-disinfectors for flexible endoscopes are not available, manual reprocessing is performed using a high-level disinfectant to guarantee patient safety. In the past, 2.4 % glutaraldehyde solution has been the global standard for this indication. Due to its volatile and sanitizing properties cost-intensive precautions had to be arranged, e.g. special ventilation systems or monitoring of staff, to fulfill maximum exposure limits and occupational exposure standards.
For years, users have required an odour-free alternative to glutaraldehyde which should be rapidly effective, safe, non-volatile and non-sensitizing.

INDICATION

Stabimed® ultra is an aldehyde-free product and is suitable for the manual cleaning and disinfection of thermostable as well as thermolabile medical devices. Especially designed for the terminal disinfection of flexible endoscopes. Furthermore Stabimed® ultra is appropriate for the manual treatment of medical devices before automated reprocessing. Its broad activity spectrum comply the latest CEN test criteria (Centre for European Norms).

Stabimed® ultra differentiates itself from glutaraldehyde-containing products as it is not protein fixing. The active ingredient has comparable cleaning properties to phenols and is biodegradable in accordance with OECD (Organisation for Economic Cooperation and Development).

A sophisticated corrosion-inhibition system allied to a nearly neutral pH allows reprocessing of stainless steel rigid endoscopes and other medical equipment through brief immersion in Stabimed® ultra solution.
The most common dilution is 1.5 – 2.0 % with an exposure time of 10 – 15 minutes. Thanks to the included measuring device with every delivery of an 800 g bottle and 4 kg bucket dosing is very easy. The pearl-granulation of Stabimed ultra ensures a dust-free application. Stabimed ultra is suitable for use in ultrasonic baths.
Dilute the granulate in lukewarm water of at least drinking water quality to the required working concentration (desired concentration see table of antimicrobial efficacy). Mix the solution gently several times over an activation time of 10 minutes. Small amounts of unsolved granulate do not effect the activity and represent an effective activation-depot for the working solution.

ACTIVE INGREDIENT

Stabimed® ultra contains peracetic acid 0.16 % in situ (diluted at 10 g/l in water).

PHYSICO-CHEMICAL DATA

	Concentrate	Ready-to-use solution
Concentration	100 %	1.5 – 2.0 %
Appearance	white powder	clear, light blue
Density (20 °C)	powder 0.8 g / ml	ca. 1 g / cm^3
pH-value	n.a.	7 – 8
Odour	neutral	characteristic

ANTIMICROBIAL EFFICACY

Microorganism	Test Norms	Concentration
Cleaning and disinfection of thermostable and thermolabile instruments for bacteria, mycobacteria, yeasts, viruses and spores	~~DGHM/~~VAH ~~2001~~ EN 13727, EN 13624 EN 14348, EN 14561 EN 14562, EN 14563 EN 14476, EN 13704	~~2.0~~ %/10 min 1.5 %/15 min
Fungi *(A. brasiliensis)*	~~DGHM/~~VAH ~~2001~~ EN 14562	2.0 %/15 min

* According to VAH-Statement ~~4/2007~~

TERMINAL DISINFECTION OF THERMOLABILE INSTRUMENTS E.G. FLEXIBLE ENDOSCOPES

- Wear gloves and protective clothing, follow the reprocessing recommendations of the endoscope manufacturer
- Pre-cleaning in the examination room: immediately after the examination (with an enzymatic cleaner e.g. Helizyme)
- Manual cleaning in the reprocessing room: clean the channels and other parts of the endoscope with special cleaning brushes (with an enzymatic cleaner e.g. Helizyme)
- Rinsing: Rinse with water
- Terminal manual disinfection: with Stabimed® ultra (e.g. 2 %, 10 min.)
- Rinsing: Thoroughly rinse with water, use fully demineralized sterile water for the final rinse
- Allow to dry completely (low temperature sterilization: if available and required)

It is not recommended to alternate between manual and automatic reprocessing, especially when different disinfectants have to be used. This is due to potential unknown chemical interactions.

DISINFECTION OF THERMOSTABLE INSTRUMENTS

- Wear gloves and protective clothing, pay attention to the reprocessing recommendations of the instrument manufacturer.
- Disinfection of pre-cleaned instruments: Place the instruments after the pre-cleaning in the Stabimed® ultra solution (2 % – 10 min.), making sure they are completely immersed.
- When disinfection is complete, rinse the instruments thoroughly under running tap-water, perform a final rinse with fully demineralized water, and allow to dry completely or use a lint-free towel for drying. Use a lubricant if indicated, inspect, perform a function check and pack the instruments e.g. in a closed container for steam sterilization.
- If more details are requested please see: www.a-k-i.org

STABILITY OF THE READY-TO-USE WORKING SOLUTION

For the disinfection of previously cleaned instruments, Stabimed® ultra solutions are usable for 24 hours after preparation or until the working solution is visibly contaminated. In general, disinfectants based on peroxide compounds are susceptible to organic load. Therefore and to be in line with good infection control practice, the working solution should be discarded immediately at the end of the working day.

SAFE USE AND LABELLING OF DANGEROUS GOODS

See material safety data sheet (MSDS).

Do not store at temperature ≥ 25 °C for a prolonged period.
Do not use the product after the expiry date.

Stabimed® ultra

APPROVED AND LISTED BY KARL STORZ

MATERIAL COMPATIBILITY

Stabimed® ultra can be used for invasive and non-invasive instruments and was developed especially for the terminal disinfection of heat sensitive instruments like flexible endoscopes. Stabimed® ultra is approved and listed by Karl Storz Endoskope.

QUALITY AND ENVIRONMENTAL INFORMATION

B. Braun is certified according to

- DIN EN ISO 9001 quality management system;
- DIN EN ISO 13485 to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services.;
- DIN EN ISO 14001 environmental management system and
- DIN EN ISO 50001 Energy management system
- OHSAS 18001 Occupational health and safety management systems
- For the production site Sempach a GMP certificate (pharmaceutical production) is also available.

BEHAVIOUR IN WASTE WATER

Do not discharge powder.
If ready-to-use solutions are discharged correctly into adapted biological sewage treatment plants, interference with the degradation activity of activated sludge is unlikely.
Do not discharge powder or ready-to-use solutions into ground water or the aquatic environment.

PACKAGING INFORMATION

Stabimed® ultra is supplied in a 800 g powder bottle with a lid both made of polyethylene (PE) and a sealing made of a mixture of polyethylene (PE) and Polyethylenterephthalate (PET).
The measuring cap is made of polypropylene (PP). The 4 kg bucket with lid and measuring cup are made of polypropylene (PP). All are labelled accordingly. The packaging is made of cardboard. The labels are made of PE. As a result, sorting is possible for optimum recycling. Packaging materials of B. Braun contain no PVC, and they can be recycled.

ACCESSORIES

Product Size	Size	REF
Instrument tray: volume 2 litres (325 x 176 x 150 mm) with transparent lid	1	390 8259
Instrument tray: volume 10 litres (530 x 325 x 150 mm) with transparent lid	1	390 8267

BIODEGRADABILITY

Active ingredients and surfactants of Stabimed® ultra are biodegradable according to OECD methods.

CERTIFICATION

Stabimed® ultra is registered in accordance with the requirements of the Medical Device Directive 93/42/EEC as a Medical Device and is labelled CE-0123.

COMMERCIAL PACKAGING/SHELF LIFE

Product Size	Shelf life	Size	REF
Stabimed® ultra 800 g powder bottle	2 years	2 pcs	19767
Stabimed® ultra 800 g powder bottle	2 years	6 pcs	19812
Stabimed® ultra 4 kg bucket	2 years	1 pc	19813

This international brochure contains information which is targeted to a wide range of audiences and could contain product details or information otherwise not accessible or valid in your country.

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