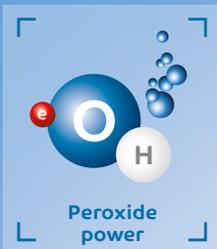


# schülke -+

Focus on endoscopy:  
Your safety is our priority.

With schülke's hygiene plan you're way ahead on safety.



we protect lives  
worldwide

# Prevention beats infection!

schülke's extensive product range delivers the highest level of hygiene.

The constant structural changes occurring in the healthcare market are forcing hospitals and medical practices to optimize their quality assurance and cost effectiveness. Alongside today's increasing economic challenges, the infection prevention plays a critical role. Preventing infection is much easier and less expensive than fighting against it.

schülke offers flexible solutions in the form of a product range tailored for use in many different areas. Our range makes it possible to meet the varied challenges of everyday life in a clinical environments with optimal prevention.

In the context of quality assurance, preventing infection is and remains the overall goal in all healthcare establishments.



# The schülke endoscopy concept.

We are more than just process chemicals.

Modern endoscopy now enables the use of gentle, invasive and non-invasive examination and operating techniques. It is indispensable today for diagnostics and therapy in all medical disciplines.

The endoscope's complex design and sensitive materials require professional and extremely careful reprocessing in order to minimise the known high risk of infection as much as possible.

The schülke endoscopy concept has been developed for this purpose from both the economic and the ecological standpoint. As with all other services and activities provided by our company, we are committed to sustainability for a safe future. We also focus on resource efficiency, environmental protection and social responsibility in product development.



## Always the right product for endoscopy.

- manual cleaning (e.g. gigazyme®)
- manual disinfection (e.g. gigasept® pearls)
- automated cleaning (e.g. thermostept® EndoCleaner)
- automated disinfection (e.g. thermostept®\*\* PAA or ED)

### Safe reprocessing according to currently valid standards and requirements e.g.:

- Preparation of endoscopes in accordance with the "German association for sterile goods supply" guidelines
- DIN EN ISO 15883
- KRINKO/BfArM recommendation: Hygiene requirements for the preparation of flexible endoscopes and auxiliary endoscopic instruments

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# Only really thorough cleaning ...

In the reprocessing of medical equipment, cleaning and disinfection are going hand in hand. This is the only way to achieve the best results. In this process, new high performing substances are crucial; they are not only highly effective but also gentle to materials and environmentally friendly.

## Enzymes and surfactants – a good combination:



Enzymes are proteins of biological origin which act as catalysts to break down particular organic materials, and as such they do not attack any materials making them suitable for cleaning many different surfaces. They are easy to rinse off and they can be drained away into the normal sewage system as they do not harm the environment. In general they are user friendly.

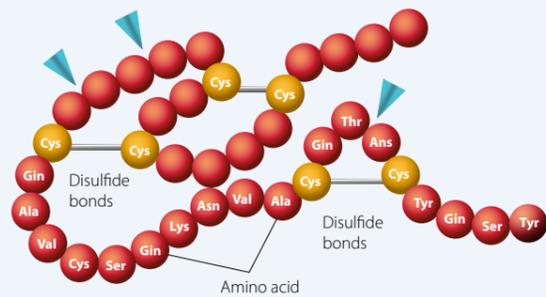
In the reprocessing of flexible endoscopes, proteases play a particularly important role; they are able to split protein-based impurities into smaller molecules.

Surfactants reduce the water surface tension and allow adequate wetting of the surfaces to be cleaned. Surfactants adapt to constituents that are insoluble in water (e.g. fats, proteins, starch) and form small spherical micelles. The soiling is lifted up from the surface as water solubilized matter ready to be removed with the cleaning solution during the rinsing phase.

### Advantages:

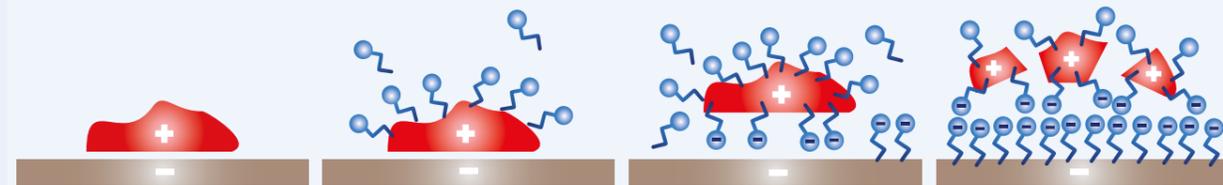
- effective removal of soiling
- organic impurities are split and dissolved
- works at low temperatures too
- good cleaning within areas that are hard to reach
- especially kind to materials – helps to retain value

-  Protein (contamination)
-  Proteolytic enzyme



Enzymes accelerate biochemical reactions. The enzyme protease splits proteins into their individual components (peptides, amino acids) and reduces contamination risk.

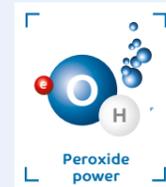
Surfactants – building blocks of a micelle  
  
 Lipophilic portion    Hydrophilic portion



Surfactants consist of a hydrophobic ('water-repellent') and a hydrophilic (having an affinity for water) molecular part. They surround materials insoluble in water (e.g. contaminants containing fats) and form small, spherical aggregates which are known as micelles. In this way, contaminants are detached from surfaces and held in suspension and efficient cleaning is made possible.

# ... makes optimal disinfection possible.

## Disinfection with peroxide power



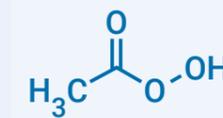
Ongoing research and development activities are focusing on working with active substances best fitting the specific needs of endoscopy decontamination. Oxidising actives such as hydrogen peroxide or peracetic acid are the most prominent components; schülke has succeeded in harnessing their microbiocidal potential whilst ensuring material compatibility making them ideal for the reprocessing of flexible endoscopes. We call this peroxide power, as these substances display a targeted shift of the pH value which, in turn changes them from being classical acetic peracetic acids. An additional advantage of these peroxide compounds is their broad spectrum of activity.

They are effective against bacteria, enveloped and non-enveloped viruses and bacterial spores including *C.difficile*.

These formulations have proven to be very environmentally friendly with regards to low resource consumption and excellent biodegradability; the active peracetic acid disintegrates after use into acetic acid and oxygen.

### Advantages:

- effective even at low concentrations and temperatures
- easily biodegradable: disintegrates into acetic acid and oxygen after use
- broad spectrum of activity
- targeted shift in pH ensures optimal compatibility



Material: In PAA products the active agent degrades into acetic acid and oxygen making it biodegradable.

## Top products for reprocessing endoscopes

	<b>gigasept® pearls</b>	<b>Manual cleaning &amp; disinfection</b>	Effective solution for manual cleaning and high level disinfection. Rapid effect, including: non-enveloped viruses and spores.	 
	<b>thermosept® EndoCleaner</b>	<b>Automated cleaning</b>	High performance cleaner with optimized material compatibility for use in automated cleaning.	
	<b>thermosept® PAA base + additive</b>	<b>Automated disinfection**</b>	Very effective material-friendly two-component system for rapid high level disinfection at low temperatures.	

\*\* view page 17

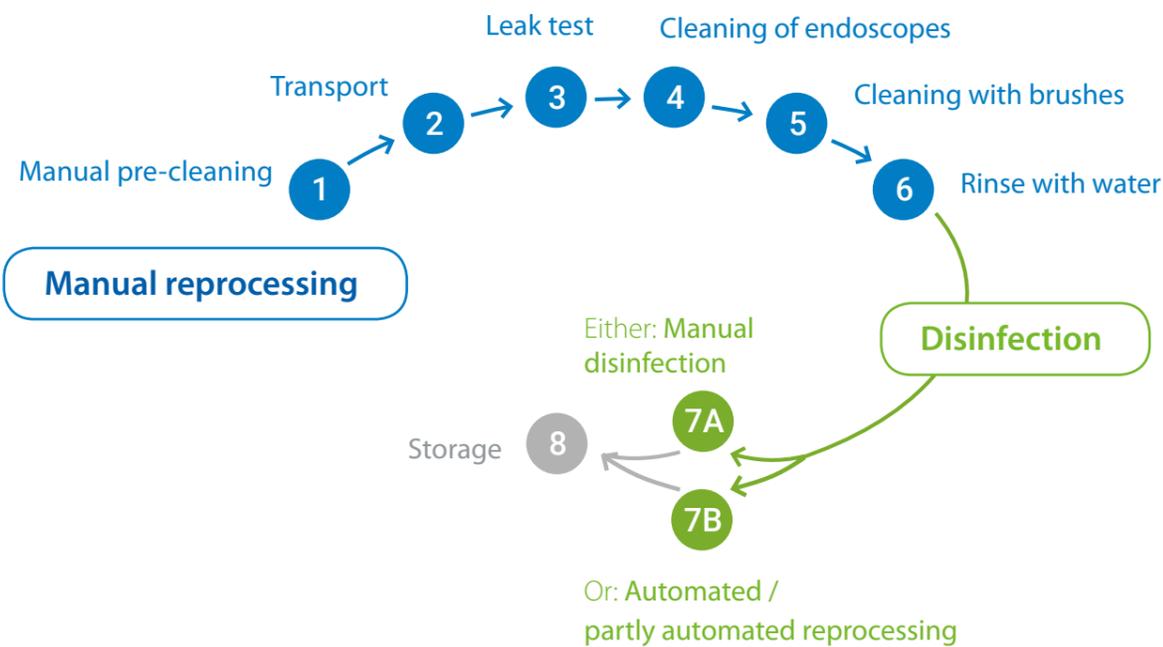
## Correct reprocessing from the very beginning!

### Pre-cleaning, transportation and leak test.

Cleaning of the endoscope begins immediately after an examination to prevent organic material from drying on and fixing to the endoscope, and to ensure the functionality of the channels.

The leak test is a vital part of the reprocessing of every endoscope to ensure that it is undamaged and therefore watertight. The test must be carried out in accordance with the manufacturer's instructions.

➔ Minimise risk of infection with eight reprocessing steps.



### 1 Manual pre-cleaning at the examination area



- When the endoscope is removed from the body, wipe off external contamination with a damp disposable or fleece cloth.
- Immerse the distal end of the endoscope in the disinfection/cleaning solution.
- By operating the extraction valve, suck disinfection/cleaning solution. Cleaning solution from the container through the instrumentation and extraction channel until clear solution can be seen in the extraction tube.
- Open the air/water valve to flush the air and water channel.
- With video endoscopes, fit a water cap to protect electrical contacts.

Recommended products: e.g. gigazyme® X-tra, gigazyme®

### 2 Transport to the reprocessing area



- To avoid contamination of the environment, move the endoscope and its accessories to the reprocessing area in a closed transport container. Always clean and disinfect the transport container.

Recommended products: e.g. mikrozyd® universal wipes, terralin® protect

### 3 Leak test



- Remove all channel valves and distal cap if necessary and place in the cleaning solution.
- Connect the plug of the leak tester to the vent connection on the endoscope supply plug.
- Place hand pump in a protective film sleeve to protect it against contamination.
- Pressurise the endoscope in the dry state. The distal end should expand slightly. Take note of the maximum permissible pressure specified by the manufacturer.
- Then check the contaminated endoscope for leaks under pressure and while bending the distal end in all directions in a cleaning bowl of adequate size. Air bubbles will rise if there are any defects.
- If there are no defects or leaks, pre-clean the endoscope manually.

# Manual cleaning.

## Endoscope cleaning, brush cleaning and rinsing.

Manual cleaning of the endoscope and brushing of all accessible channels must be carried out even when the endoscope is subsequently reprocessed automatically.

All cleaning steps, in particular brushing the channels, must be carried out below the surface of the liquid in order to avoid contamination of the environment and personnel by splashing.

**Recommendations require, as a basic principle, that the items being reprocessed be thoroughly rinsed after any manual pre-treatment and before further automatic reprocessing to prevent the pre-treatment solution from being carried over into the subsequent reprocessing stages.**

In order to avoid any undesired chemical interactions use only chemicals that have proven to be compatible to each other. This avoids any irreversible damage to the scope and the cleaning and disinfecting unit.

### 4 Cleaning of endoscopes



- Clean/disinfect external surfaces of the endoscope with a disposable lint-free cloth paying particular attention to air/water nozzles and the surface of the distal end.
- Combined cleaning and disinfection of all channel valves, biopsy valves, distal flaps and mouthpieces with special soft, short synthetic brushes and also in the ultrasonic bath if required.
- Connect all channels using a cleaning adapter, flush with cleaning agent/disinfectant and remove the adapter.  
**Recommended products: e.g. gigazyme® X-tra and gigazyme®, gigasept® pearls, mucadont® zymaktiv**

### 5 Cleaning with brushes



- To remove invisible contamination in the channels and to check continuity, mechanically brush all accessible endoscope channels; carry out this work below the surface of the liquid.
- Brush cleaning can also be carried out in a cleaning agent solution or combined cleaning agent and disinfectant solution if required. Combined solutions provide protection against contamination of the working environment.
- Use only brushes which have been approved by the manufacturer.  
**Recommended products: e.g. gigazyme® X-tra and gigazyme®, gigasept® pearls, mucadont® zymaktiv**

### 6 Rinse with water



- Remove endoscope and accessories from the cleaning solution and place in a bowl with clean tap water. Replace water after every rinsing operation.
- Rinse channels several times with a water jet gun (alternatively with hand pump and syringe).
- Blow channels free with compressed air in order to remove residual liquid from the endoscope.

# Disinfect thoroughly for safety!

## Manual or automatic disinfection and storage.

**Safe endoscope reprocessing requires manual or automated processes that are validated and reproducible. This includes the correct use of disinfectants.**

It is recommended to change a solution as soon as visible soiling or turbid clouds are appearing. If this is required by the manufacturer's instructions or if the solution becomes optically impure (cloudy). Details about the lifetime of the disinfectant solution are given in the relevant product information.

After changing, the bath must be thoroughly cleaned and disinfected mechanically. The name of the disinfectant, the date the solution was prepared up, maximum period of use, concentration and reaction time must be written on the disinfection bath or recorded in the disinfection handbook.

In the case of exclusively manual reprocessing, current recommendations require that the cleaning stages (with cleaning agent or combined disinfectant product) and the final disinfection (with virucidal disinfectant) occur separately from each other.

### 7A Either: Manual disinfection in the instrument bath



- Place the cleaned endoscope and its accessories in the bath with the disinfectant solution so that all parts of the instruments are adequately covered.
- Rinse all channel systems using an adapter and large syringe; fill channels with disinfectant solution so that there are no bubbles. Remove adapter below the surface of the liquid and leave in the solution. The lid must be closed.
- After the reaction time, carefully rinse channels and outer jacket with microbiologically pure water.
- Then carefully blow channels dry using compressed air; dry off outer jacket with a clean disposable cloth.  
**Recommended products: e.g. gigasept® pearls, gigasept® PAA conc., gigasept® FF (new)**

### 7B Or: Automated validated process in the cleaning and disinfecting unit



- Place endoscope in the machine basket in accordance with the manufacturer's instructions and fit adapter to all channels.
- Connect leak tester to endoscope.
- Place small parts basket in machine basket.
- Start unit with validated program.  
**Recommended products: thermostepto® EndoCleaner, thermostepto® PAA\*\*, thermostepto® ED**

### 8 Store endoscopes properly

- Disinfected endoscopes must be kept suspended from special holders, without valves, dry and protected against dust in a closed and regularly disinfected endoscope cabinet.
- The endoscope must be clearly marked as having been reprocessed.



### ! Application check and microbiological check

#### Application check before every examination

Inspect and correctly reprocess endoscope in accordance with the instructions, including functional check, e.g. check for damage, flex bends in order to check bend rubbers.

#### Microbiological endoscope check

According to KRINKO/BfArM RKI, microbiological checks of the disinfected endoscope, the lens rinsing system and the cleaning and disinfecting unit must be carried out every 3 – 6 months.

# The right products for manual reprocessing.



Safe and efficient – manual reprocessing.



Image source with friendly support from Fujifilm Germany

## schülke's range of products to meet your needs

Manual reprocessing		Application	Listings	Efficacies										
Manual pre-cleaning	Manual cleaning & disinfection	Cleaning Disinfection	VAH - listing IHO virucidal list tested according to Euro norms	bactericidal	tuberculocidal	mycobactericidal	levurocidal	fungicidal	limited virucidal enveloped viruses	virucidal	Clostridium difficile	sporocidal	in an ultrasonic bath	
gigazyme®		•											•	
mucadont® zymaktiv		•											•	
gigazyme® X-tra		•	•	•	•			•	•				•	
gigasept® AF forte		•	•	•	•	•	•	•	•				•	
gigasept® pearls		•	•	•	•	•	•	•	•	•	•	•	•	
gigasept® PAA concentrate		•	•	•	•	•	•	•	•	•	•	•	•	
gigasept® FF (new)		•	•	•	•	•	•	•	•	•	•	•	•	

### Manual pre-cleaning



**gigazyme®**  
Enzymatic cleaner for flexible endoscopes and surgical instruments.



#### Our plus

- mix of enzymes and surfactants for enhanced cleaning performance
- very good material compatibility
- suitable for use in ultrasonic baths
- economic dosage
- pleasant fragrance
- compatible manual pre-cleaning with automated disinfectant components thermosept® ED and thermosept® PAA

#### Pack size

Carton with 5 x 2 l-bottles  
5 l-canister

## Manual pre-cleaning



### mucadont® zymaktiv

High-performance enzymatic cleaner for manual reprocessing.



#### Our plus

- the unique formulation releases and removes even the most persistent contaminants such as blood, proteins and biofilms
- approved for instruments supplied by RICHARD WOLF, KARL STORZ and PENTAX
- fresh fragrance

#### Pack size

5 l-canister

## Manual cleaning and disinfection



BAC

### gigazyme® X-tra

Multi-enzyme high-performance detergent with disinfecting effect for the manual cleaning of endoscopes and surgical instruments\*



#### Our plus

- effective against bacteria and enveloped viruses\* (incl. HIV, HBV, HCV)
- excellent cleaning performance
- disinfectant properties reduce risk of cross contamination for decontamination staff
- use in ultrasonic baths
- very good material compatibility
- compatible manual pre-cleaning with automated disinfectant components thermosept® ED and thermosept® PAA



#### Pack size

Carton with 5 x 2 l-bottles

5 l-canister



BAC

TB

### gigasept® AF forte

Disinfection and cleaning of rigid and flexible endoscopes, anaesthesia accessories and surgical instruments.\*

#### Our plus

- complies with current standard methods and European norms
- effective against bacteria, mycobacteria, enveloped viruses\* (incl. HIV, HBV, HCV)
- aldehyde-free
- standing time of clean and not contaminated solution up to 7 days
- enhanced formulation ensures short contact times with heavy organic load
- suitable for use in ultrasonic baths
- pleasant fragrance



#### Pack size

Carton with 5 x 2 l-bottles

5 l-canister

\* Not for final disinfection of semicritical and critical medical devices.

## Manual cleaning and final virucidal disinfection



BAC

TB

VIRU

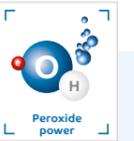
CIDAL

SPORI

CIDAL

### gigasept® pearls

Active oxygen-based instrument disinfectant for manual cleaning and disinfection with a multi-enzyme formula.



#### Our plus

- effective against bacteria incl. TB, yeasts, viruses and spores (incl. *C. difficile*)
- outstanding cleaning performance multi-enzyme formula (protease, lipase and amylase) in combination with a neutral pH-value (non-protein-fixing) and powerful surfactants
- excellent material compatibility including sensitive materials such as flexible endoscopes
- innovative pearl structure offers enhanced user safety (reduces the risk of inhalation exposure)
- innovative packaging system for safe and easy removal
- pleasant fragrance
- compatible manual pre-cleaning with automated disinfectant components thermosept® ED and thermosept® PAA



#### Pack size

Carton with 6 kg-bucket

Carton with 4 x 1.5 kg-buckets

## Manual final virucidal disinfection



BAC

TB

VIRU

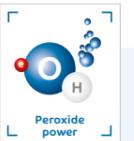
CIDAL

SPORI

CIDAL

### gigasept® PAA concentrate

High level disinfectant for manual reprocessing of endoscopes and surgical instruments.



#### Our plus

- effective against bacteria, mycobacteria, yeasts, viruses and spores (incl. *C. difficile*)
- short contact time
- very easy handling, no dosing aid required
- excellent material compatibility due to targeted adjustment of the pH-value and added protection against corrosion
- ready to use immediately upon preparation of solution



#### Pack size

Carton with 12 x (2 x 100 ml)-bottles



BAC

TB

VIRU

CIDAL

SPORI

CIDAL

### gigasept® FF (new)

For high level manual disinfection of surgical instruments and sensitive medical instruments.

#### Our plus

- complies with current standard methods and European norms
- effective against bacteria, mycobacteria, yeasts, viruses and spores (incl. *C. difficile*)
- outstanding material compatibility
- ideal for thermolabile and thermostable endoscopes
- tested under high organic load, therefore suitable for treatment of heavily contaminated instruments
- the uncontaminated working solution has a standing time of up to 7 days
- formaldehyde-free



#### Pack size

Carton with 5 x 2 l-bottles

5 l-canister

## Special aspects of endoscope reprocessing.

Flexible endoscopes are thermosensitive medical devices; and as such they cannot be subjected to the normal cleaning, disinfection and sterilisation processes. According to the international Spaulding Classification flexible endoscopes are classified semi-critical class B<sup>1</sup>.

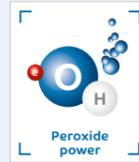
At a European level, virucidal action as specified by DIN EN ISO 14476 is required<sup>2</sup>.

However for some applications in particular colonoscopic endoscopy, there is a critical requirement to remove bacterial spores such as *Clostridium difficile* and *Bacillus subtilis*.

When dealing with highly resistant bacteria forming spores, disinfectants based on peroxide have advantages which previously did not exist: they are effective at both at low concentration (1-2%) and they are fast acting (>5 min.).

We recommend our peroxide based products gigasept® pearls, gigasept® PAA conc. and thermostept® PAA.

Please follow the guidelines and instructions from your local authorities.



High performance in the automated reprocessing of instruments.



<sup>1</sup> Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten [Hygiene requirements in the reprocessing of medical devices.] Recommendations of KRINKO (RKI) and BfArM. Bundesgesundheitsbl 2012 • 55:1244–1310  
<sup>2</sup> DIN EN 14476: Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of virucidal activity in the medical area – Test method and requirements (Phase 2, Step 1); German version EN 14476: 2013

Image source with friendly support from Fujifilm Germany

# The right products for automated reprocessing.

## schülke's range of products to meet your needs

Automated reprocessing		Application		Efficacies				
		Cleaning	Disinfection	bactericidal	Helicobacter pylori	fungicidal	virucidal	sporicidal
Cleaning	thermosept® EndoCleaner	•						
	thermosept® ER	•						
Disinfection	thermosept® ED		•	•	•	•	•*	•**
	thermosept® PAA		•	•	•	•	•*	•***

\* virucidal action in accordance with DIN EN 14476 and Guideline of DVV and RKI on testing chemical disinfectants for effectiveness against viruses in human medicine. Version dated 1 December 2014. Bundesgesundheitsbl 2015 • 58:493–504  
 \*\* proven effectiveness against bacterial spores in standard reprocessing (cleaning and disinfection).  
 \*\*\* tested in accordance with EN 14347 and prEN 17126:2017, fulfils the requirements of DIN EN ISO 15883-4 for sporicidal effectiveness

## Automated reprocessing – cleaning



Cleaner

**thermosept® EndoCleaner**  
Mildly alkaline cleaner for the automated chemo-thermal reprocessing of flexible endoscopes.



**Our plus**

- outstanding cleaning performance through a combination of enzymes and surfactants
- optimized material compatibility
- highly economical due to low application concentration
- minimises the build up of residues in the machines
- outstanding cleaning ability proven by Hygiene Institute of Mag. Dr. Miorini, Graz

**Pack size**

5 l-canister  
 thermosept® EndoCleaner can be used in all AER of all main producers, like Belimed, BHT, Olympus, Steelco, Steris and Wassenburg. thermosept® EndoCleaner is compatible with the disinfectant components thermosept® ED and thermosept® PAA within an automated chemo-thermal process.



Cleaner

**thermosept® ER**  
Enzyme cleaner concentrate for the chemo-thermal reprocessing of flexible endoscopes.

**Our plus**

- pH-neutral
- very good material compatibility
- excellent in combination with thermosept® ED

**Pack size**

5 l-canister

## Automated reprocessing – disinfection



Disinfection

**thermosept® ED**  
Highly effective disinfection component for the chemo-thermal reprocessing of flexible endoscopes.

**Our plus**

- broad spectrum of efficacy (bactericidal, mycobactericidal, levurocidal, virucidal, sporicidal)
- excellent material compatibility
- proven compatibility with schülke cleaners thermosept® ER and thermosept® EndoCleaner

**Pack size**

5 l-canister



Disinfection

**thermosept® PAA**  
High level disinfectant system based on peracetic acid for chemo-thermal reprocessing of flexible endoscopes.

**Our plus**

- broad spectrum of efficacy (bactericidal, mycobactericidal, levurocidal, virucidal, sporicidal incl. *C. diff.*)
- special peracetic acid based formulation
- very short contact time: 5 min. at low temperatures
- good material compatibility due to 2-component system
- proven compatibility with schülke cleaner thermosept® EndoCleaner

**Pack size**

thermosept® PAA base  
Carton with 2 x 5 l-canisters  
New: 200 l-barrel  
 thermosept® PAA additive  
Carton with 2 x 5 l-canisters  
New: 200 l-barrel

**NEW! For large reprocessing units:**  
 thermosept® PAA in large containers for use in combination with our automated central dosing/pumping system has been specially designed for peracetic acid.



Disinfection

**Suitable for Olympus ETD\*\***



**Pack size**

thermosept® PAA base (adapter)  
1 x 5 l-canister (flat canister shape – suitable for Olympus ETD\*\*\*)  
 thermosept® PAA additive (adapter)  
1 x 5 l-canister (flat canister shape – suitable for Olympus ETD\*\*\*)

\*\* Olympus ETD machines: For the use of thermosept® PAA base in Olympus miniETD 2 PAA, Olympus ETD 3 PAA, Olympus ETD 4 PAA, a replacement of the disinfectant canister connection is necessary. For this, a schülke adapter must be connected to the media hose and a recess in the media drawer of the ETD machine has to be made to professionally lay the hoses assemblies – see illustration. The corresponding work can be performed by customer order e.g. through technical staff of Schülke & Mayr GmbH. For detailed information, please contact your local sales representative.

## Advantages of powdered products based on Peroxidepower.

### Safety and efficiency!

#### Safety:

The innovative pearl structure ensures optimal user safety during the manual reprocessing of endoscopes without comprising on efficacy. The handling of this dust free formulation removes the risk of exposure to inhalation and splashes during preparation whilst also making the product safer for storage and transport by reducing the risk of spills and leakages.

#### Efficiency:

Outstanding performance is delivered through a combination of enzymes and surfactants for optimal cleaning, Peroxidepower ensures high level disinfection with a broad spectrum microbial effectiveness and a neutral pH for excellent material compatibility. This product is the ideal choice for sensitive materials and medical devices such as flexible endoscopes.



gigasept® pearls, the efficient solution for increased user safety

## gigasept® pearls notes of application.

### Instructions for use: safe and easy

#### Advice on manual reprocessing:

- maximum cleaning temperature in ultrasonic bath 40 °C
- disassemble and open articulated instruments to ensure a proper cleansing
- rinse thoroughly after manual cleaning and disinfection step
- **in case of any questions please contact your local sales service**

### Little helpers for extra safety in everyday endoscopy.



As practical support and to make your work easier we offer a range of chemical-resistant reprocessing baths, dilution tables and manual aids for measuring quantities. For clients working on a large scale we also supply automatic decentralised devices for providing chemicals and centralised concentrate conveyor equipment.



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