

INSTRUMENT PREPARATION

Effective endoscope disinfection and care



Safely reprocess endoscopes
with solutions from Dr. Schumacher

IMPRINT

Publisher

Dr. Schumacher GmbH
Am Roggenfeld 3
34323 Malsfeld
Germany
T +49 5664 9496-0
P +49 5664 8444
info@schumacher-online.com
www.schumacher-online.com

Picture credits

Dr. Schumacher GmbH
iStock - YakobchukOlena
Unsplash - National Cancer Institute
Shutterstock - AndriyShevchuk
Shutterstock - Doro Guzenda
iStock - kot63
Shutterstock - Alex_Traksel

LISTINGS

IHO

ÖGHMP

RKI A

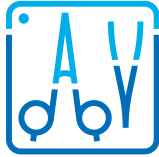
RKI A/B

RKI/DVV

VAH

IHO –Industrieverband Hygiene und Oberflächenschutz für industrielle und institutionelle Anwendung e.V. Disinfectant list (www.desinfektionsmittelliste.de). **ÖGHMP** - Product listed in the disinfectant list of the Austrian Society for Hygiene, Microbiology and Preventive Medicine (www.oeghmp.at). **RKI A** - Product listed in the disinfectant list of the Robert Koch Institute according to § 18 IfSG, effective range A. **RKI A/B** - Product listed in the disinfectant list of the Robert Koch Institute according to § 18 IfSG, effective range AB. **RKI/DVV** - Virucidal effective product according to the guideline of the German Association for the Control of Viral Diseases (DVV) and the Robert Koch Institute (RKI). **VAH** - Product listed in the disinfection medium list of the Association for Applied Hygiene e.V. (www.vah-online.de).

Introduction

Focus on **quality**

For years, the medical community has continued to develop less invasive diagnostics and treatment. Endoscopies play a large role in this trend by reducing the risk of complications and costs that come with surgery.

As precise and minimal as endoscope procedures are, they do come with their own set of risks. One potential danger is post-endoscopic infection. These infections are caused by contaminated material or inadequately reprocessed endoscopes and are entirely preventable through proper disinfection measures.

As one of the leading developers and manufacturers of quality products for instrument reprocessing, Dr. Schumacher has the right solution for both the manual and automated reprocessing of endoscopes and other medical instruments.

Our goal is to minimize preventable infections and thus protect patients' health!

Our solutions for Manual and automated reprocessing



PLURAZYME® EXTRA

Multi-enzymatic cleaner for reprocessing surgical instruments and endoscopes

Page **22**

NEU



MANUSHIELD CLEANER

Liquid cleaner for instruments and endoscopes

Page **22**



PERFEKTAN® ENZYME

Multi-enzymatic disinfecting cleaner for the reprocessing of instruments and endoscopes

Page **23**



PERFEKTAN® ACTIVE

Powder concentrate for instrument disinfection

Page **23**



DESCOTON EXTRA

Disinfectant for instruments and endoscopes

Page **24**



THERMOSHIELD® DESINFEKTANT

Disinfectant for the chemothermal reprocessing of endoscopes

Page **24**

NEW



THERMOSHIELD® FLEX

Enzymatic cleaner for chemothermal reprocessing of endoscopes

Page **25**



ECO WIPES

Reusable wipe dispenser system for filling with disinfectants

Page **26**



ONE SYSTEM BASIC

Single-use wipe dispenser for filling with disinfectants¹

Page **26**

Contents

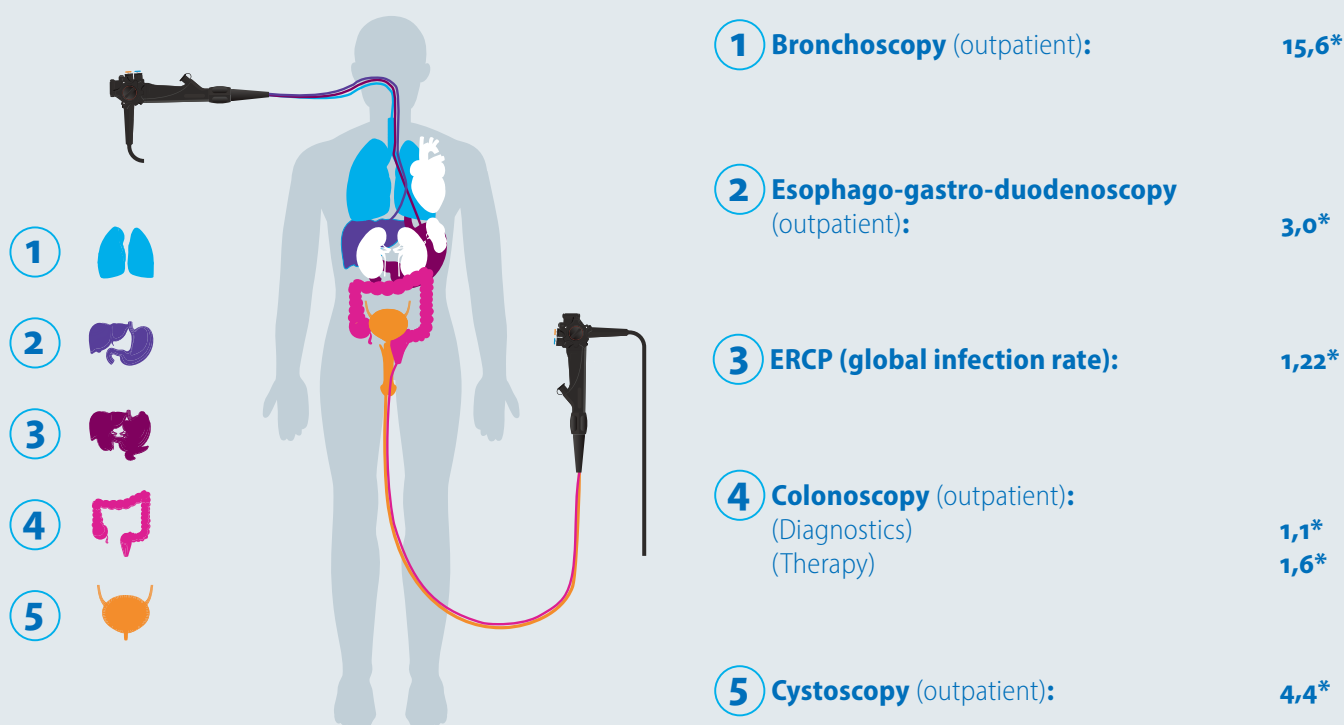
Product overview	4
Infections	6
Hotspots	9
The reprocessing cycle	10
Manual pre-cleaning	13
Cleaning	14
Effectiveness	16
Contingency Plan	17
Best Practice	18
Quality	19
Endoscope reprocessing	20
Manual cleaning	22
Machine processing	24
Surfaces	26
Sources	27

Infection risks associated with different procedures

Since the 1970s, individual studies have documented infections resulting from endoscopic procedures. Beginning in 2010, the rates of numerous infections, particularly those of multi-resistant pathogens, have been published. The risk of a nosocomial infection depends on various factors and differs according to the type of procedure. For example, flexible bronchoscopy

and endoscopic retrograde cholangiopancreatography (ERCP) is associated with higher risks and generally, therapeutic endoscopy carries a higher risk of infection than diagnostic procedures. Recent studies also show that we tend to underestimate the infection risks of outpatient procedures.

Rate of post-endoscopic infections^{2,3}



* per 1000 procedures within 7 days. Wang P, Xu T, Ngamruengphong S, et al. Gut 2018;67:1626-1636

** Ellrichmann M, Eickhoff A. Gastroenterologie 2022;17:15-21

1,2,3 – see references p. 27

Infectious microorganisms in endoscopy

Post-endoscopic infections are caused by a variety of pathogens. Most infections are endogenous, or caused by the spread of the body's own microorganisms to other areas.

Exogenous infections are less common and are caused by transmission through contaminated material or inadequately reprocessed endoscopes.

Transmission routes and microorganisms^{1,2}



Endogenous infections

Germ from the patient's local flora enters the endoscopy area.

- **Normal flora or colonizing germs**

Escherichia coli
Klebsiella species
Enterobacter species
Enterococci

- **Infectious flora or chronic carrier status**

Salmonella
Helicobacter pylori
Mycobacterium tuberculosis
Clostridioides difficile
HBV, HCV, HIV



Exogenous infections

Microorganisms are carried into the endoscopy area by contaminated disposables or endoscopes.

- **Irrigation solution**

Pseudomonas
Atypical mycobacterium

- **Devices**

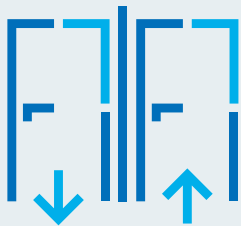
Enterobacteria
Citrobacter
Pseudomonas



Know the hotspots, avoid mistakes

Almost 90% of post-endoscopic exogenous infections can be prevented by strictly adhering to the evidence-based recommendations of specialist societies. As a result, the risk of nosocomial infection is officially considered "fully manageable".

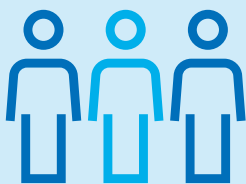
The spread of germs can occur at various points in the endoscope unit in various ways. It is therefore important to monitor compliance with regulatory recommendations at the hotspots.



Hotspot: rooms & equipment

To follow:

- "One-way street" principle
- Sufficient space and work surfaces
- Sufficient number of treatment sinks (at least two)
- Preferred two-room solutions (clean/unclean)



Hotspot: staff

To follow:

- Reprocessing only with a certificate of competence and expertise
- Additional internal and external training
- No other competing tasks
- Minimize time pressure
- Observe hand hygiene



Hotspot: preparation cycle

To follow:

- Standardized and validated reprocessing according to manufacturer specifications and guidelines
- Good organization e.g. immediate preparation, detailed pictorial SOP
- Ensure that specialist personnel are familiar with the devices
- Provide the right equipment (e.g. channel-specific brushes)
- Update instructions for new accessories
- Microbiological checks of all ducts and valves

The reprocessing cycle

Step by step safe processing

The requirements for hygienic reprocessing of medical devices must take into account both the type of application and the nature of the product. For this purpose, medical devices, such as Endoscopes, are classified into certain risk groups. The classification determines the type and scope of the reprocessing process.

Classification of endoscopes

Based on the recommendations of KRINKO and BfArM, endoscopes are evaluated and classified as follows¹:

A Semi-critical:

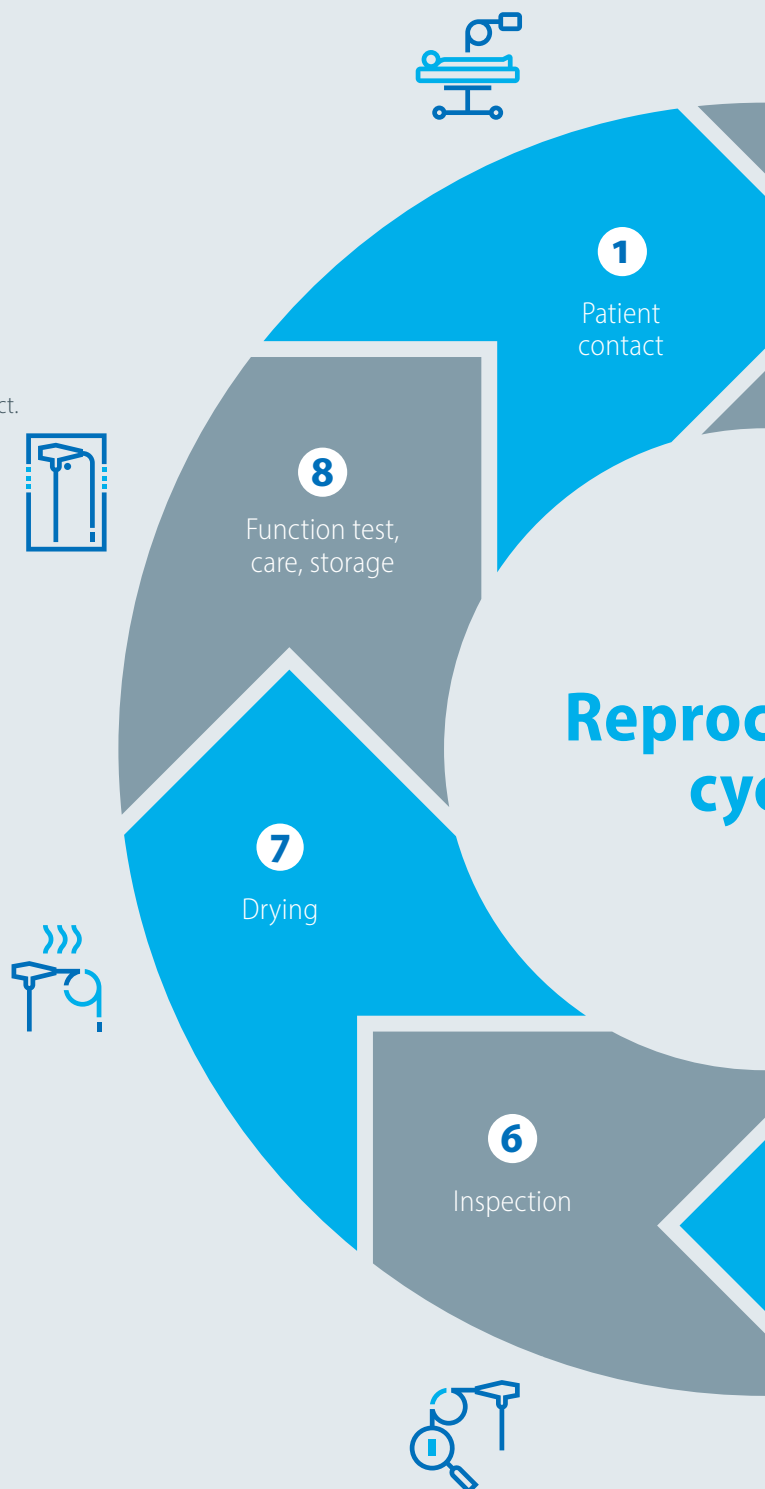
Contact with mucous membrane or abnormally altered skin

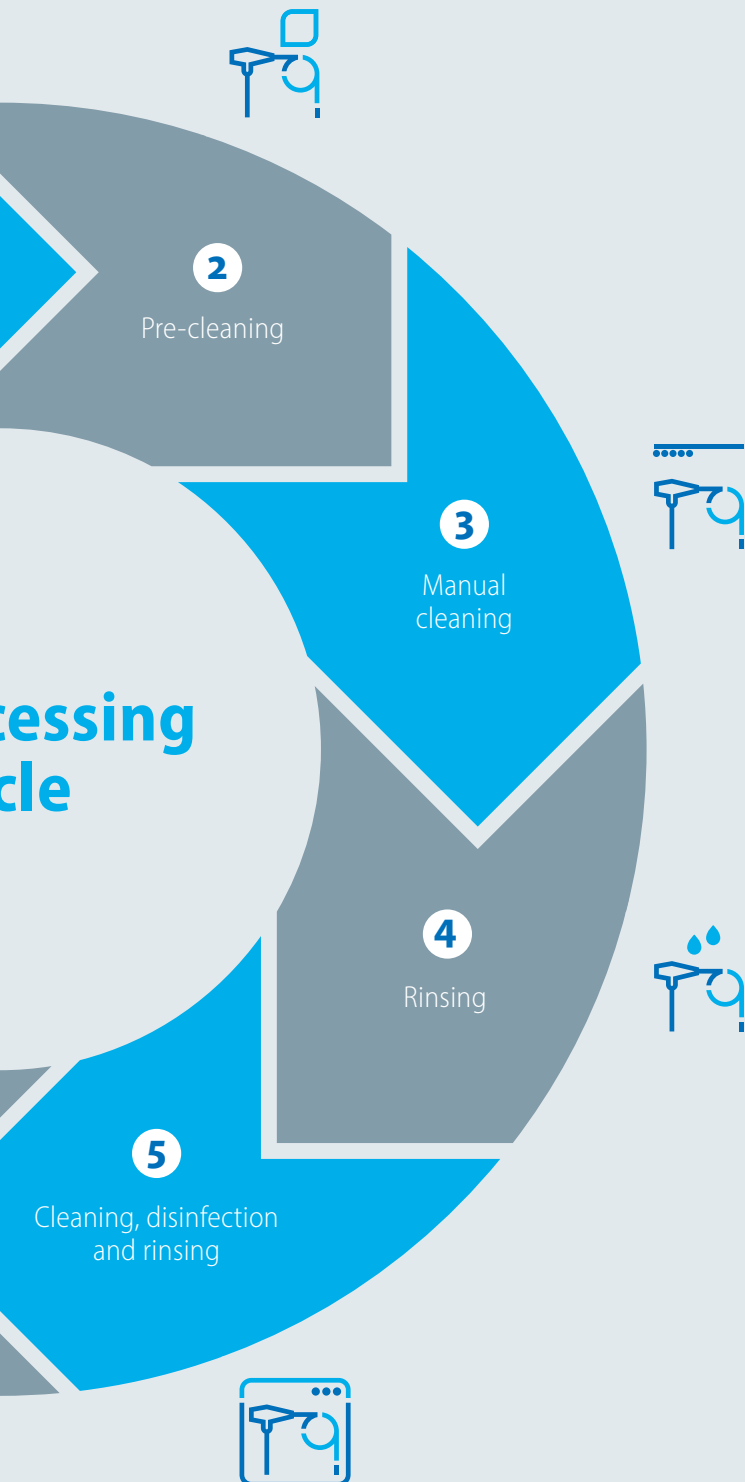
B with increased requirements:

Having a complex structure, lumina (cavities), or rough surfaces that are difficult to clean. The efficiency of cleaning cannot be directly assessed by inspection either.

Proper reprocessing

Reprocessing must begin with pre-cleaning at the light source (immediately after use). After the leak test, manual cleaning with repeated brushing of all channels must be carried out in the reprocessing room. The subsequent intermediate rinsing is followed by disinfection, either manually in an immersion bath or in a washer-disinfector. Even if automated reprocessing is preferred, a plan for manual reprocessing should be in place as a fallback.





2 Pre-cleaning

Immediately after the examination:

- Wipe the outer sheath of the endoscope and flush the channels
- Leak test (preferably wet)

3 Manual cleaning

- Repeated brush cleaning of the endoscope channels

4 Rinsing

- Careful flushing of all channels

5a Automated cleaning, disinfection and rinsing in the washer-disinfector

- Correct connection of the endoscope
- Post-drying if necessary

5b Manual cleaning, disinfection and rinsing if mechanical processes are not available.

- Use standardized procedure (SOP)
- Thorough final rinse (no process chemical residues)
- Drying

6 Inspection

- Disinfect hands
- Magnifying glass (factor 10, illuminated)

7 Drying

- Complete drying not necessary when used immediately for the next examination
- Complete drying required at end of day and for storage

8 Storage

- Dry, properly hung, well ventilated
- No valves and water protection cap
- No foam protector at the distal end





Manual pre-cleaning

At the heart of reprocessing

On its own, cleaning isn't everything, but it is critical for proper disinfection. The aim is the complete removal of organic and inorganic soiling – a prerequisite for successful disinfection. This is because organic contamination in the cavities of the appliances promotes biofilm formation, which makes the microorganisms inaccessible for disinfection measures.

Completely remove contamination

Studies on infections and outbreaks show that inadequate cleaning of endoscopes in particular can lead to contamination and eventual infection.

Challenge: Protein residues, like blood and other body fluids, can dry and subsequently become fixed by disinfectants.

Biofilm formation: When microorganisms remain in the endoscope channels after cleaning or rinsing, there is a risk of biofilm formation. Microorganisms embedded in biofilms are up to 100 times more resistant to chemicals than those not embedded¹. Once a biofilm has established itself, it can no longer be removed. The affected passage or tube must be replaced. Biofilms are particularly problematic because they can only be detected with microbiological tests.

Remove soiling by hand

Manual brushing and careful rinsing are the most important aspects of cleaning. The following should be noted:

- Each appliance type and the area of application requires its own type of brush
- Disposable brushes are an advantage. Worn brushes can scratch materials.
- Always brush in one direction, usually towards the distal end.
- No impurities should be visible in the pre-cleaning tank.

Preparation tips

2 x

Recently, there has been an increase in outbreaks caused by contaminated duodenoscopes. Studies show that after two cycles of manual cleaning/high-level disinfection, the values of the duodenoscope elevator channel were similar to those of sterile water².



^{1,2,3} – see sources p. 27

30 min

The time between the end of the procedure and biofilm formation is short. To prevent the growth of germs, European guidelines recommend allowing a maximum of 30 minutes between the procedure and cleaning and rinsing³.



1 x

The cleaning solution should be changed in accordance with local guidelines and regulations and at latest when soiling is visible³.

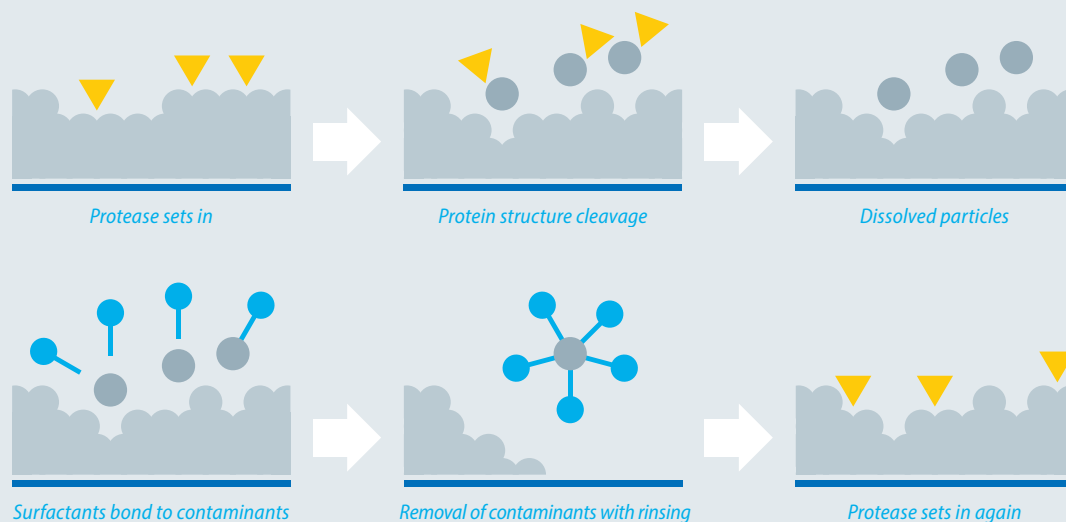


Expertly solved

Reprocessing chemicals for cleaning

Manual cleaning of endoscopes is the most important reprocessing step. Cleaners must reliably remove soiling without damaging the sensitive endoscope materials. When cleaning is the focus, products based surfactants and enzymes do a great job. A multi-enzymatic cleaner like PLURAZYME EXTRA, with its non-ionic surfactants and a 3-fold complex of different enzymes, dissolves a wide range of organic and non-organic soiling. With a pH-neutral value, this cleaner also protects materials and ensures that endoscopes and accessories retain their value.

INTERACTION OF ENZYMES AND SURFACTANTS



The powerful protease break down proteins into smaller, more easily removable components, actively support the cleaning process. The surfactants envelop dirt particles at the surface level, including protein residues, making it easier to rinse

away contaminants with water and allowing greater access to the surface of the instruments for effective disinfection. The instruments are thoroughly cleaned through the interactions of the enzymes and surfactants.

Legal status of reprocessing chemicals

Chemicals used to reprocess endoscopes must be developed, tested and manufactured in accordance with the European Medical Device Directive (MDR). They are subject to different classifications:

Class I medical devices

These include cleaners, neutralizing agents, rinsing and care products.

Class II b medical devices

These include cleaners with antimicrobial efficacy for manual disinfecting pre-cleaning and disinfectants for manual or automated final disinfection. Manufacturers of reprocessing chemicals must provide evidence of the advertised properties, such as cleaning performance, disinfecting efficacy or material compatibility, to the regulatory authorities. The application instructions must be described in detail, in particular the dosage, temperature and exposure times.

Expertly protected

Disinfecting pre-cleaning

Reprocessing after endoscope procedures also poses risks to staff. It is often unknown whether patients carry infectious diseases. The regulations on biological and hazardous substances are important components of health protection. In addition to wearing the correct personal protective equipment, using a disinfecting cleaner for pre-cleaning can increase hygiene safety for personnel.



PERFEKTAN® ENZYME

Multi-enzymatic disinfectant cleaner for reprocessing instruments and endoscopes

On the safe side

Enzymes as active cleaning substances can further improve the properties of QAV-based cleaners. PERFECTAN ENZYME has a multi-enzyme complex of four enzymes combined with selected surfactants. The formula provides excellent cleaning results on stubborn organic soiling.

Cleaner with antimicrobial effect

Specific requirements are placed on cleaners for endoscope reprocessing with antimicrobial effect^{1,2}:

- Ingredients must not result in protein-fixing. For example, organic soiling such as proteins and blood coagulate under the influence of aldehydes.
- Protecting personnel requires at least proven bactericidal, levurocidal and limited virucidal efficacy (including protection against hepatitis B, C and HIV).
- Cleaning agents must be compatible with the active ingredients of the chemicals for final disinfection. Otherwise, problems from unwanted chemical interactions may arise during reprocessing.
- Dr. Schumacher offers a comprehensive range for all stages of reprocessing.

Extensive safety



Effectiveness of disinfection processes

In order to keep the risk of infection as low as possible, comprehensive efficacy requirements apply to chemical and chemo-thermal reprocessing. The essential requirements for reprocessing are regulated in the national and international recommendations and guidelines of KRINKO/BfArM and ESGENA as well as EN 15883-4 and EN 14885.

Disinfectants must have the following efficacies¹:

- Bactericidal
- Yeastcidal; effective against yeasts/Candida (*C. albicans*)
- Tuberculocidal; effective against *Mycobacterium* / *M. terrae*
- Virucidal; effective against enveloped and non-enveloped viruses

In some cases, additional efficacies may be required:

- Fungicidal; effective against molds
- Mycobactericidal; effective against *M. terrae* and *M. avium*
- Sporicidal

The KRINKO/BfArM recommendation deviates here and generally requires sporicidal efficacy.

Sporicidal disinfection

In general, all patients can carry *C. difficile* pathogens. The *C. diff* strain Ribotype 027 is considered to be particularly dangerous and can lead to severe illness and increased risk of mortality. PERFECTAN ACTIVE inactivates *C. diff* and also *C. diff* Rb027 in 5 minutes at 1.5 % concentration and in 15 minutes at 1 % concentration - with both low and high soiling.

THERMOSHIELD FLEX and THERMOSHIELD DESINFECTANT also offer sporicidal efficacy when used with the chemo-thermal treatment programs.²



Manual Disinfection Contingency Plan



Manual disinfection as a contingency plan

Manual reprocessing of endoscopes comes with more risks of contamination and human error than chemo-thermal reprocessing. This is why using a manual immersion bath method should be seen as a contingency plan in case the washer disinfectors fail or are otherwise unavailable. Professional associations have developed guidelines to increase the safety of manual reprocessing.

The following specifications must be observed to ensure successful disinfection and safety:

- Identify the required spectrum of efficacy
- Observe manufacturer's instructions
- Observe personnel protection
- Prepare fresh disinfectant solution
- Use dosing devices

Guidelines for manual reprocessing

To ensure that the success of manual disinfection is documented, professional societies* have developed guidelines for the validation of manual cleaning and manual chemical disinfection of medical devices¹. The guidelines provide information on the regulatory background, help with the creation of work instructions and their validation, and offers detailed checklists on all aspects of manual reprocessing: from the structural and technical requirements to testing as part of the validation process. If the disinfection step is not followed by chemo-thermal sterilization, guidelines recommend using products based on aldehydes or peracetic acid



PERFEKTAN® ACTIVE

Powder concentrate for instrument disinfection

Active reprocessing with maximum effectiveness

The peracetic acid in PERFEKTAN ACTIVE**, a completely soluble powder, is activated when combined with water and creates a mildly alkaline solution. The working solution offers comprehensive efficacy, including sporicidal. It is convenient to use and has excellent material compatibility.

*DGKH - German Society for Hospital Hygiene

DGSV - German Society for Sterile Supply

AKI - Instrument Reprocessing Working Group in cooperation with the VAH - Association for Applied Hygiene

**Only for professional use by personnel with appropriate expertise in accordance with national guidelines.

Increase Compliance

Best Practices



Mechanical preparation

Automated reprocessing is the gold standard in endoscope reprocessing because chemo-thermal cleaning and disinfection in washer-disinfectors not only simplify the processes, but also ensure a reproducible, standardized procedure with complete documentation. In most countries, the cleaning and disinfection processes must be validated in accordance with local regulatory authorities.³

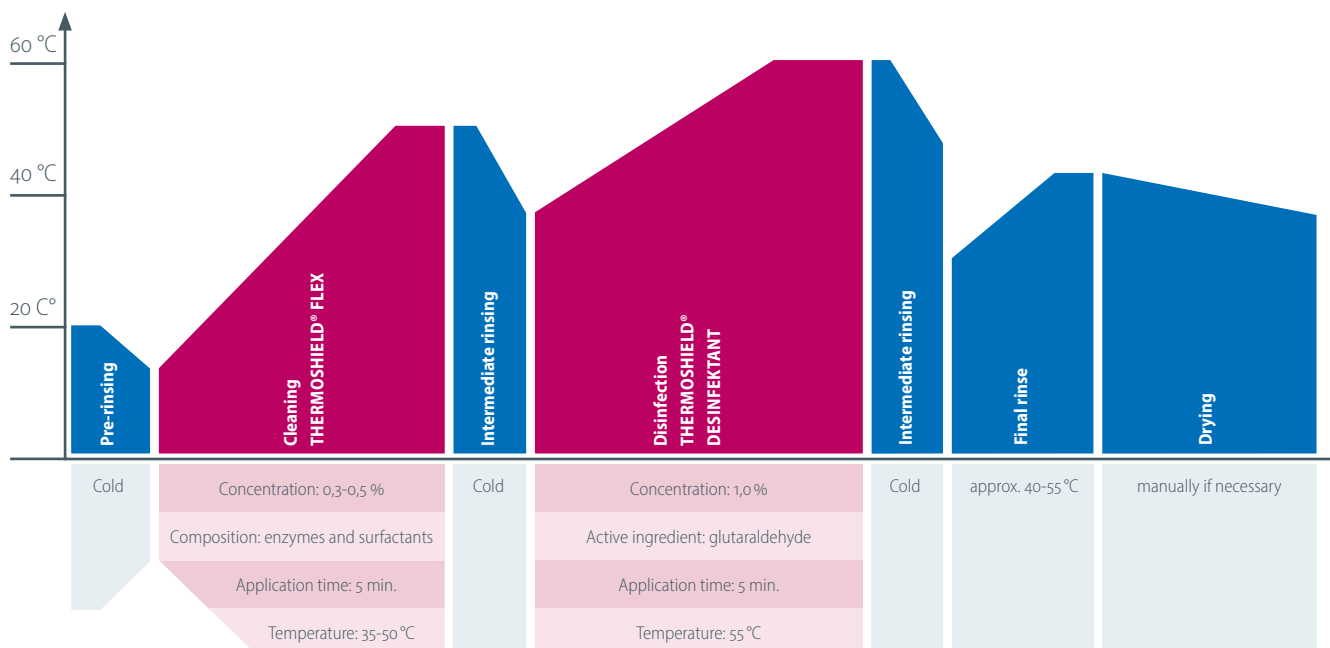
The following specifications must be observed to ensure successful disinfection and safety:

- Select required spectrum of efficacy
- Observe manufacturer's instructions
- Observe personnel protection

Best practice for Washer Disinfectors for Endoscopes (WD-E) with THERMOSHIELD FLEX and THERMOSHIELD DESINFECTANT

THERMOSHIELD® FLEX* and THERMOSHIELD® DESINFECTANT* offer comprehensive efficacy in the WD-E reprocessing in accordance with national and international recommendations and guidelines of KRINKO/BfArM and ESGENA as well as the European standards EN 15883-4 and EN 14885 including sporidical efficacy. The low aldehyde content minimizes unpleasant odors.

EXAMPLE PROGRAM: WD-E



*Only for professional use by personnel with appropriate expertise in accordance with national guidelines.

1,2,3 – see sources p. 27

Quality assurance



Microbiological controls

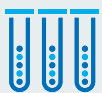
In order to minimize the risk of infectious agents being transmitted during the endoscope procedure, the entire process, including the washer-disinfector, must undergo regular microbiological checks. A microbiological check for each endoscope is required at least once a year. The guidelines of the Gastroenterology and Endoscopy Nurses and Associates (ESGENA) together with the European Society of Gastrointestinal Endoscopy (ESGE)¹ and the recommendations of the German Society for Hospital Hygiene (DGKH) in collaboration with other specialist societies contain specific procedural instructions.²

Microbiological testing of endoscopes is carried out in two steps:

1. Swab samples for qualitative detection of microorganisms

2. Liquid samples for quantitative detection of specific microorganisms

Procedure according to DGKH²



Sampling

Procedure: 2 people, aseptic conditions (PPE, hand disinfection).
Sequence: First swab sample, then liquid sample

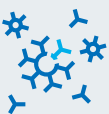


Processing

1. Reading after 24 hours, $36 \pm 1^\circ\text{C}$.
2. Reading after 44 ± 4 hours, $36 \pm 1^\circ\text{C}$

Smear sample: smear on blood agar plates and Enrichment in BHI-Bullion

Liquid sample: filtration and incubation on blood agar plate; Plating on selective culture medium.



Evaluation

Swab samples: One result per swab evaluated.
Bacterial growth on selective culture media = positive result per species.

Liquid sample: Counting of germs.
Result CFU/ml of filtered sample



Findings

Permissible colony count = < 20 CFU per channel.
The following germs must not be detectable:
Escherichia coli, other enterobacteria, enterococci, Pseudomonas aeruginosa and other pseudomonads, non-fermenting bacteria, nosocomial pathogens such as Staphylococcus aureus, mycobacteria and Legionella, greening streptococci*



Interpretation

Microbial growth indicates sources of error, e.g. fecal bacteria indicate inadequate cleaning; pseudomonads and other non-fermenting bacteria indicate inadequate quality of the final rinse water. Skin and environmental microorganisms indicate inadequate storage and/or insufficient hand hygiene.

* for endoscopes used for examination in areas of the upper gastrointestinal tract or respiratory tract that are not microbially colonized (according to risk analysis).

1,2 – see sources p. 27

Security for each steps

Products for endoscope reprocessing

From initial cleaning at the light source to final disinfection: Dr. Schumacher products for cleaning and disinfecting endoscopes offer safe and user-friendly solutions for every step of the process. All products comply with national and international standards and recommendations to ensure maximum patient and staff protection

Manual Cleaning



PLURAZYME® EXTRA

Multi-enzymatic cleaner for reprocessing surgical instruments and endoscopes



MANUSHIELD® CLEANER

Liquid cleaner for instruments and endoscopes

Mechanical preparation



THERMOSHIELD® DESINFECTANT

Disinfectant for chemo-thermal endoscope reprocessing



THERMOSHIELD® FLEX

Cleaner for chemo-thermal endoscope reprocessing

Manual disinfection



PERFEKTAN® ACTIVE

Powder concentrate for instrument disinfection



DESCOTON EXTRA

Disinfectant for instruments and endoscopes

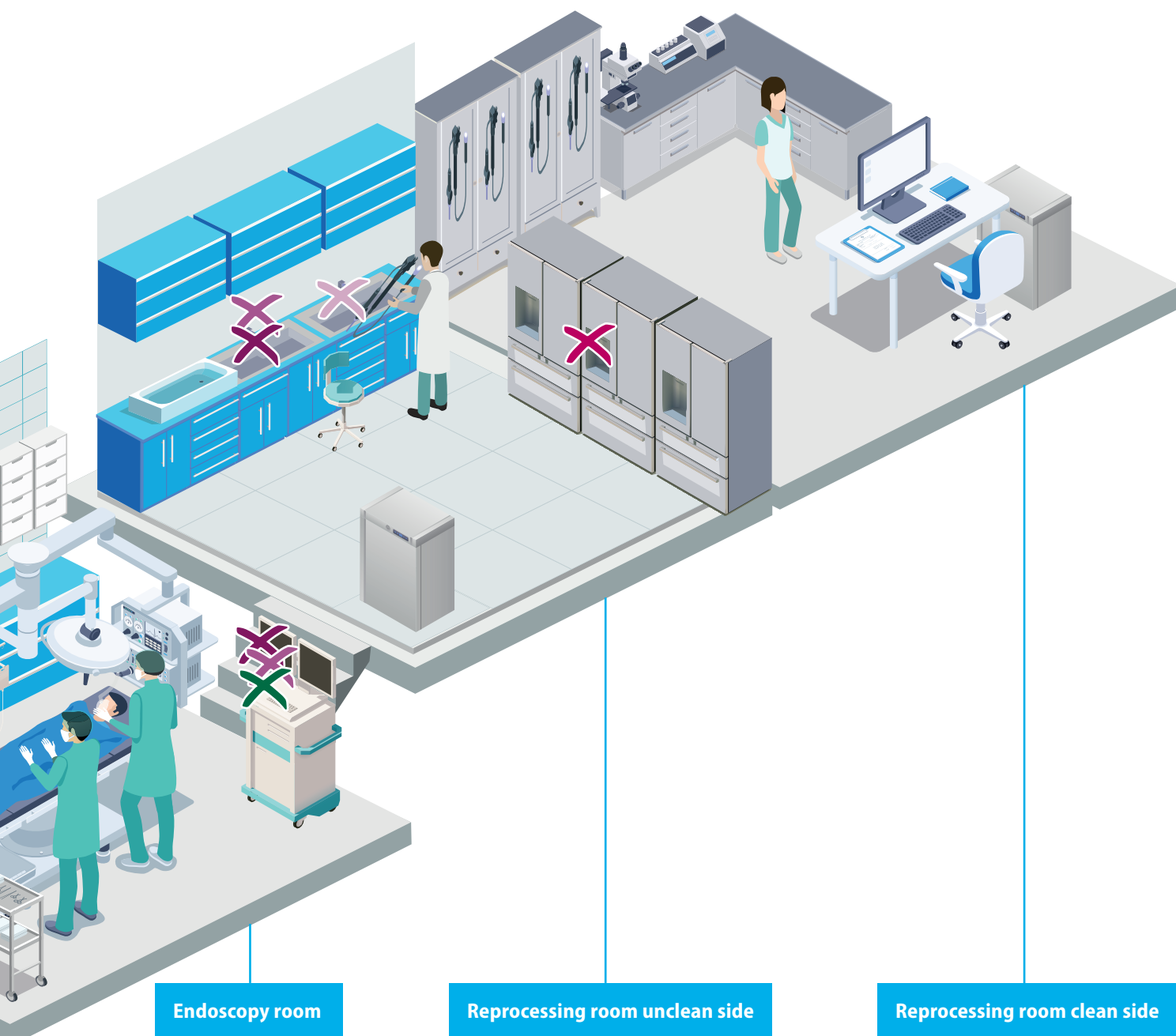
Manual disinfecting cleaner



PERFEKTAN® ENZYME

Multi-enzymatic disinfectant cleaner for instruments and endoscopes





✗ Non-woven wipe dispenser systems



ECO WIPES
Reusable non-woven wipe
dispenser system



ONE SYSTEM BASIC
Disposable non-woven wipe dispenser
system for filling with disinfectant



PLURAZYME EXTRA

Multi-enzymatic cleaner for reprocessing surgical instruments and endoscopes

- **Innovative, 3-enzyme formula with a pleasant scent**
- **Preservation of instruments through neutral pH and coordinated cleaning complex**
- **Non-fixing – ideal for pre-cleaning**

PLURAZYME EXTRA is the ideal cleaning concentrate for the manual reprocessing of a variety of medical devices. The high material compatibility enables the cleaning of surgical instruments, rigid and also flexible endoscopes. The mild fragrance ensures a pleasant user-experience, whether in an immersion or ultrasound bath. The active formula of 3 enzymes and ionic surfactants effectively penetrates a wide range of organic contaminants: from coagulated blood to mucus to fat – without fixation. The high level of compatibility with other cleaners and disinfectants ensures that PLURAZYME EXTRA can be easily and flexibly integrated into your processes.

Application and dosage recommendation for cleaning

Depending on the degree of pollution	0,4 – 2 % (4 ml/L – 20 ml/L) max. 40 °C mind. 5 min
Recommendation for ultrasonic baths	0,25 % (2,5 ml/L) max. 40 °C mind. 5 min

Composition – 100 g solution contain

5 – 15 % non-ionic surfactants

Enzymes

preservative 1,2-benzisothiazol-3(2H)-one,
didecylmethyl poly(oxyethyl)ammonium propionate

Contains perfumes: Limonene

Single Unit	Unit	Content	REF
Dosierflasche	10	1 L	00-138-010-01E
Kanister	3	5 L	00-138-050-02E

NEU



MANUSHIELD® CLEANER

Liquid detergent cleaner for instruments and endoscopes

- **pH-neutral and gentle to materials**
- **Good cleaning strength and easy to integrate**
- **Perfume-free**

MANUSHIELD CLEANER is a pH neutral cleaner concentrate for the cleaning of flexible and rigid endoscopes as well as other surgical, dental and medical instruments. The perfume-free formulation is surfactant-based, extremely efficient, and can be used in ultrasonic baths and in combination with all water hardness levels. In addition, MANUSHIELD CLEANER is compatible with the following Dr. Schumacher disinfectants: PERFEKTAN ENZYME, PERFEKTAN NEU, PERFEKTAN ENDO, PERFEKTAN TB, PERFEKTAN ACTIVE, and DESCOTON EXTRA. This makes it easy to integrate MANUSHIELD CLEANER into reprocessing procedures.

Application and dosage recommendation for cleaning

Cleaning of endoscopes as well as medical and surgical instruments	1 % (10 ml/L) Depending on the degree of pollution: 0,25 % (2,5 ml/L) – 5 % (50 ml/L)
--	---

Composition – 100 g solution contain

5 – 15 % non-ionic surfactants

Single Unit	Unit	Content	REF
bottle	6	2 L	00-104-020-02E
canister	3	5 L	00-104-050-01E

PREVENT**PROTECT**

VAH

IHO

PERFEKTAN® ENZYME

Multi-enzymatic disinfecting cleaner for the reprocessing of instruments and endoscopes

- High material compatibility with neutral pH
- For effective non-fixing enzymatic pre-cleaning
- Disinfectant effect with pleasant scent
- 4 enzyme formulation with QACs

PERFEKTAN ENZYME is the ideal disinfectant cleaner for the manual reprocessing of thermostable and thermolabile medical devices. Through its high-performance multi-enzyme complex made of four enzymes and selected surfactants, PERFEKTAN ENZYME yields an excellent cleaning result, removing organic contamination without protein fixation. The fresh scent creates a pleasant user experience and QACs disinfect, adding an advantage in terms of occupational safety. This formula is aldehyde and amine-free. The neutral pH ensures good material compatibility and value retention of medical devices. PERFEKTAN ENZYME is also suitable for use in an ultrasonic bath. In addition, PERFEKTAN ENZYME can be used for the reprocessing of flexible endoscopes and is fully compatible with THERMOSHIELD NR and THERMOSHIELD DESINFECTANT

Spectrum of efficacy and contact time**PREVENT PRESERVE PROTECT**

Application recommendation for disinfecting cleaning of flexible endoscopes and for disinfection of surgical instruments

3 % - 5 min

1 % - 15 min

Composition – 100 g solution contain

17,5 g N,N-didecyl-N-methyl-poly(oxyethyl)ammoniumpropionate

0,5 g N,N-Didecyl-N,N-dimethylammoniumcarbonate

Contains perfumes: Limonene, Linalool, Geraniol

Single Unit	Unit	Content	REF
dispenser bottle	12	1 L	00-128-010E
bottle	6	2 L	00-128-020E
canister	3	5 L	00-128-050E



RKI/DVV

VAH

IHO

ÖGHMP

PERFEKTAN® ACTIVE

Powder concentrate for instrument disinfection

- Very good material compatibility
- Rapid disinfection due to oxidative effect
- Completely soluble

PERFEKTAN ACTIVE is a highly effective powder concentrate for manual disinfection of medical instruments. This product is a powder, which dissolves fast and completely in water, for a reliable and safe application. Based on peracetic acid, which is generated in the mildly alkaline solution, PERFEKTAN ACTIVE achieves a maximum spectrum of efficacy with excellent material compatibility, even with sensitive materials like silicone. The oxidative effect of PERFEKTAN ACTIVE provides efficient disinfection through peracetic acid, which breaks down completely into water, acetic acid and oxygen.

Spectrum of efficacy and contact time**PREVENT PRESERVE PROTECT**

Application recommendation for final disinfection for semi-critical medical devices including rigid and flexible endoscopes

2 % - 60 min

3 % - 30 min

Composition

Active ingredient: Peracetic acid (in-situ) > 850 ppm (1 % dilution)

Single Unit	Unit	Content	REF
sachet	100	40 g	00-155-0004E
bucket (incl. measuring spoon)	6	1 kg	00-155-010E

Manual cleaning

PROTECT



VAH

IHO

DESCOTON EXTRA

Disinfectant for instruments and endoscopes

- Virucidal according to harmonized EN norm
- Formaldehyde-free concentrate
- Suitable for final disinfection

DESCOTON EXTRA is a fast acting, virucidal, liquid concentrate for disinfecting endoscopes and surgical instruments. The formaldehyde-free product formulation is characterised by economical concentrations, broad effectiveness (incl. virucidal and TB efficacy) and good material compatibility. DESCOTON EXTRA is ideal for virucidal final disinfection of flexible and rigid endoscopes as well as medical instruments.

Spectrum of Efficacy and Contact times

PREVENT PRESERVE PROTECT

Recommendation for use for
bactericidal, yeasticidal,
tuberculocidal, mycobactericidal
(M. avium, M. terrae), virucidal
Final disinfection

3 % - 60 min

Composition – 100 g solution contain

12 g Glutaraldehyd

Single Unit	Unit	Content	REF
dosage bottle	10	1 L	00-150-010
canister	3	5 L	00-150-050

Automated reprocessing

PROTECT



THERMOSHIELD® DESINFECTANT

Disinfectant for the chemothermal reprocessing of endoscopes

- Low aldehyde content for a pleasant user experience
- Virtually odour free
- Material-friendly – ideal for flexible endoscopes

THERMOSHIELD DESINFECTANT is a material-friendly and user-friendly preparation for chemothermal disinfection of flexible endoscopes at 55–60°C. In combination with the neutral cleaner THERMOSHIELD FLEX, it offers an optimal solution for gentle cleaning and disinfection in endoscope washers. The preceding manual endoscope preparation can ideally be carried out with MANUSHIELD CLEANER or PLURAZYME EXTRA. THERMOSHIELD DESINFECTANT is particularly material friendly due to its glutaraldehyde-based composition. Since the content of glutaraldehyde is so low in THERMOSHIELD DESINFECTANT, the odour during use is considerably lower than many comparable preparations

Spectrum of Efficacy and Contact times

PREVENT PRESERVE PROTECT

Application recommendation for
thermochemical disinfection of
flexible endoscopes and all kinds
of surgical instruments (55 – 60°C)

1 % – 5 min

Composition – 100 g solution contain

10 g Glutaral

Single Unit	Unit	Content	REF
Flachkanister	3	5 L	00-134-050-01E
Drumtainer	1	200 L	00-134-FD200E

NEU

THERMOSHIELD® FLEX

Enzymatic cleaner for chemothermal reprocessing of endoscopes

- **Powerful, modern cleaner for flexible endoscopes**
- **Gentle cleaning action removes organic soiling through use of enzymes and surfactants**
- **Excellent compatibility, especially for sensitive materials**

THERMOSHIELD FLEX is a mildly alkaline, high-performance cleaning product specially designed for the automated reprocessing of flexible endoscopes and other thermolabile medical devices, such as anesthesia accessories. The synergistic power of enzymes and surfactants dissolves all organic contaminations, even in narrow lumens, and a special selection of surfactants successfully prevent re-adhesion. This excellent cleaning performance is verified according to EN 15883-5 and covers a wide range of organic soiling and works just as effectively at low temperatures. Due to the mildly alkaline pH and the gentle but efficient. THERMOSHIELD FLEX

ensures very good material protection with long-term value retention of sensitive, high-end medical devices. THERMOSHIELD FLEX is ideally matched to the automated disinfectant THERMOSHIELD DESINFECTANT and also to the manual cleaners PERFEKTAN ENZYME and PLURAZYME EXTRA, which were developed for the pre-cleaning of flexible endoscopes and thermolabile medical devices. The result is a stable and energy-efficient reprocessing process that contributes to patient safety and cost reduction with no risk of unwanted chemical interactions. THERMOSHIELD FLEX can be used in washer-disinfectors from all major manufacturers.



Application and dosing recommendation for cleaning

Reprocessing of flexible endoscopes and thermolabile medical devices: depending on soiling

3 – 5 ml/L (0,3 – 0,5 %)

Surgical instruments and additional medical instruments¹

3 – 10 ml/L (0,3 – 1 %)

Composition – 100 g solution contain

< 5 % non-ionic surfactants

Enzyme

Single Unit	Unit	Content	REF
Flachkanister	3	5 L	00-183-050
Drumtainer	1	200 L	00-183-FD200



ONE SYSTEM BASIC

Single-use wipe dispenser for filling with disinfectants¹

- Compact flexi-packaging with high stability for easy handling and fill-level control
- DESOTEX non-woven wipes
- Ready for use in 15 minutes¹ up to 60 days¹ standing time

ONE SYSTEM BASIC is an innovative single-use wipe dispenser system. In combination with suitable disinfectants, it can be used for reliable hygienic reprocessing of medical devices and medical equipment as well as all types of surface. ONE SYSTEM BASIC is easy to use and saves time. The closed system comes with 120 DESOTEX XL wipes and is ready to use after just a 15-minute waiting time after filling with your choice of disinfectant. Together with selected and tested Dr. Schumacher products, ONE SYSTEM BASIC may be used for up to 60 days¹ depending on the disinfectant selected. ONE SYSTEM BASIC is designed for single use to avoid risk of contamination during reprocessing and increase compliance. When the wipes run out, simply flatten and compact the packaging for easy disposal. This system is ideal for use in areas with elevated infection risk as well as routine disinfection applications.

Single Unit	Unit	Content	Size	REF
ONE SYSTEM BASIC	4	120 Blatt	17,5 x 36 cm	00-915-OSEB120-01

¹ Compared to other common surface disinfectants with a standing time of 28 days and a pre-soak time of 30 minutes, the tested, VAH-listed surface disinfectants achieve OPTISAL PLUS, BIGUANID FLÄCHE NR, CLEANISEPT and OPTISAL N from Dr. Schumacher offer a pre-soaking time of just 15 minutes and an extended service life of 42 days for the filled system.

² Tested with all obligatory EN 16615 test germs (bactericidal/levurocidal)

³ according to the communication of the Disinfectant Commission of the VAH under the influence of the "4+4 Working Group".



ECO WIPES

Dispenser bucket

- Reusable wipes dispenser system for use with ECO WIPES in combination with suitable surface disinfectants
- Each refill comes with an ULTRASOL OXY Sachet for dispenser reprocessing

ECO WIPES is a reusable wipes dispenser system for cleaning and disinfection. The ECO WIPES system consists of a reusable wipe dispenser and corresponding non-woven rolls for refilling. It may be used for the cleaning and disinfection of medical devices, medical equipment and surfaces of all kinds. ECO WIPES can be used in combination with both ready-to-use, rapid disinfectants as well as disinfectant concentrates, making it a flexible solution for your varying hygiene needs. Each refill comes with an ULTRASOL OXY SACHET to ensure proper, manual reprocessing before reusing the dispenser.

Single Unit	Unit	Content	Size	REF
dispenser bucket	1	empty	-	00-915-SE001
dispenser bucket	6	empty	-	00-915-SE002
wall holder	1	-	-	00-902-EIM

ECO WIPES				
pack	3	100 Tücher	30 x 32 cm	00-915-REW10003-01
pack	6	100 Tücher	30 x 32 cm	00-915-REW10006-01
pack	3	50 Tücher	30 x 32 cm	00-915-REW5003-01

SOURCES

Focus on quality

1. Ellrichmann M, Eickhoff A. Single-use products in endoscopy-from consumables to single-use scopes. *Gastroenterologie* 2022;17(1):15-21

Infection risks according to the type of intervention

1. Kovaleva J, Peters FTM, van der Mei HC et al. Transmission of infection by flexible gastrointestinal endoscopy and bronchoscopy. *Clin Microbiol Rev* 2013 Apr;26(2):231-54
2. Wang P et al. Rates of infection after colonoscopy and esophagogastroduodenoscopy in ambulatory surgery centers in the USA. *Gut* 2018 Sep;67(9):1626-1636
3. Ellrichmann M, Eickhoff A. Single-use products in endoscopy-from consumables to single-use scopes. *Gastroenterologie* 2022;17(1):15-21.

Infectious microorganisms in endoscopy

1. Ellrichmann M, Eickhoff A. Single-use products in endoscopy-from consumables to single-use scopes. *Gastroenterologie* 2022;17(1):15-21
2. Swiss Society for Sterile Supply (ed.), Petignat C et al. Infection transmission risk during endoscopy.

Step by step safe processing

Recommendation of the Commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM). Hygiene requirements for the reprocessing of medical devices. *Federal Health Gazette* 2012 - 55:1244-1310

Manual pre-cleaning

1. Beilenhoff U. What time window is recommended for reprocessing? Can endoscopes be left longer or even overnight? How should infectious patients be treated? *Endo-Praxis* 2018; 34(03): 116-120
2. Sethi S et al. Adenosine triphosphate bioluminescence for bacteriologic surveillance and reprocessing strategies for minimizing risk of infection transmission by duodenoscopes. *Gastrointestinal Endoscopy* 2017; 85 (6): 1180-1187
3. Reprocessing of flexible endoscopes and endoscopic accessories used in gastrointestinal endoscopy: Position statement of the European Society of Gastrointestinal Endoscopy (ESGE) and European Society of Gastroenterology Nurses and Associates (ESGENA) - Update 2018. *Endoscopy* 2018; 50: 1205-1234.

Expertly protected

1. Schmidt V, Beilenhoff U, Jones A, Krüger S. Leitlinie zur Validierung maschineller Reinigungs-Desinfektionsprozesse zur Aufbereitung thermolabiler Endoskope. *Zentralsterilisation Suppl.* 3/2011
2. Reprocessing of flexible endoscopes and endoscopic accessories used in gastrointestinal endoscopy: Position statement of the European Society of Gastrointestinal Endoscopy (ESGE) and European Society of Gastroenterology Nurses and Associates (ESGENA) –

Extensive safety

1. Schmidt V, Beilenhoff U, Jones A, Krüger S. Guideline for the validation of automated cleaning-disinfection processes for the reprocessing of thermolabile endoscopes. *Central Sterilization Suppl.* 3/2011
2. HygGen Germany. Test report Thermoshield NR, Thermoshield disinfectant according to the guideline of the Robert Koch Institute "Hygiene requirements for the reprocessing of medical devices". Washer-disinfectors - Part 5: Test soils and methods for verification of cleaning efficacy (ISO / TS 15883-5: 2005), SOP 16-008. Schwerin 2019

Manual Disinfection - Contingency Plan

Guideline for the validation of manual cleaning and manual chemical disinfection of medical devices. 2013. prepared by DGKH - German Society for Hospital Hygiene DGSV - German Society for Sterile Supply AKI - Instrument Reprocessing Working Group in cooperation with the VAH - Association for Applied Hygiene

Increase Compliance - Best Practices

1. Ordinance on the Installation, Operation and Use of Medical Devices (Medical Device Operator Ordinance MPBetreibV) in the version published on August 21, 2002 (*Federal Law Gazette I* p. 3396), which was last amended by Article 7 of the Ordinance of April 21, 2021 (*Federal Law Gazette I* p. 833)
2. Recommendation of the Commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM). Hygiene requirements for the reprocessing of medical devices. *Federal Health Gazette* 2012 - 55:1244-1310
3. Schmidt V, Beilenhoff U, Jones A, Krüger S. Guideline for the validation of automated cleaning-disinfection processes for the reprocessing of thermolabile endoscopes. *Central Sterilization Suppl.* 3/2011

Quality assurance

1. Beilenhoff U, Neumann CS, Rey JF, Biering H, Blum R, Schmidt V and the ESGE Guidelines Committee. ESGE-ESGENA guideline for quality assurance in reprocessing: Microbiological surveillance testing in endoscopy. *Endoscopy* 2007;39: 175-181
2. German Society for Hospital Hygiene (DGKH). Communications of the Board of Directors. Hygienic-microbiological examination of flexible endoscopes after reprocessing. *Hyg Med* 2010, 35 (3): 75-79.



Visit us online!

CURRENT INFORMATION
AND THE WHOLE WORLD OF
DR. SCHUMACHER PRODUCTS
CAN ALSO BE FOUND
ON OUR WEBSITE.

www.schumacher-online.com



Contact

Dr. Schumacher GmbH
Am Roggenfeld 3
34323 Malsfeld
Germany
T +49 5664 9496-0
P +49 5664 8444
info@schumacher-online.com
www.schumacher-online.com

