INSTRUMENTS / AUTOMATED REPROCESSING

# THERMOSHIELD® FLEX



**ENZYMATIC CLEANER FOR CHEMOTHERMAL REPROCESSING OF ENDOSCOPES** 

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Excellent cleaning performance thanks to a unique combination of enzymes, surfactants and mild alkalinity

Perfect balance between **outstanding cleaning performance** and a very high level of material compatibility

Wide range of possible applications,

from flexible endoscopes to surgical instruments

Lower cleaning temperatures combined with excellent cleaning performance mean process cost savings

Powerful in every detail



**INSTRUMENTS / AUTOMATED REPROCESSING** 

### THERMOSHIELD® FLEX



### PRODUCT DESCRIPTION

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**THERMOSHIELD FLEX** is a mildly alkaline, powerful cleaning product, specially designed for automated reprocessing of flexible endoscopes and other thermolabile medical devices, such as anesthesia accessories.

The synergistic power of enzymes and surfactants removes any organic load, even in narrow lumens, while special surfactants successfully prevent reattachment. This excellent cleaning performance is verified in accordance with EN 15883-5. It covers a wide field of organic soiling and works just as effectively at low temperatures. The mild alkaline pH and gentle but efficient cleaning action of **THERMOSHIELD** 

**FLEX** make for excellent long-term protection of high-quality and sensitive medical devices.

**THERMOSHIELD FLEX** is ideal for use in combination with machine disinfectant THERMOSHIELD DESINFEKTANT and also manual cleaners PERFEKTAN ENZYME and PLURAZYME EXTRA, which were developed for pre-cleaning flexible endoscopes and thermolabile medical devices. The result is stable and energy-efficient reprocessing that contributes to patient safety and cost reduction. **THERMOSHIELD FLEX** can be used in washer-disinfectors from established manufacturers.

**THERMOSHIELD FLEX** is a mildly alkaline, powerful cleaning product, specially designed for automated reprocessing of flexible endoscopes and other thermolabile medical devices, such as anesthesia accessories. The synergistic power of enzymes and surfactants removes any organic load, even in narrow lumens, and successfully prevents reattachment. This excellent cleaning performance is verified in accordance with EN 15883-5 and works just as effectively at low temperatures. The mild alkaline pH and gentle cleaning complex give excellent long-term protection of medical devices. **THERMOSHIELD FLEX** is ideal for use in combination with machine disinfectant THERMOSHIELD DESINFEKTANT and also manual cleaners PERFEKTAN ENZYME and PLURAZYME EXTRA. The result is stable and energy-efficient reprocessing that contributes to patient safety and cost reduction.

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### **THERMOSHIELD® FIFX**



### APPLICATIONS AND NOTES

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### Range of application

Mildly alkaline machine cleaner based on enzymes and surfactants for the reprocessing of flexible endoscopes, thermolabile medical devices and surgical instruments.

#### Dosage

Reprocessing of flexible endoscopes and thermolabile medical devices:

3 - 5 ml/L (0.3 % - 0.5 %)

Surgical instruments and medical auxiliary instruments:

3 - 10 ml/L (0.3 % - 1 %)

Follow manufacturer's instructions for use with washing machines.

### **Application**

Place instruments into washer according to recommendations (e.g. hygiene plan). All surfaces and cavities to be disinfected must be wetted completely by the working solution.

- 1. Cleaning cylcle with THERMOSHIELD FLEX
- 2. Disinfection cycle with THERMOSHIELD DESINFEKTANT

The product is also suitable for the manual pre-cleaning of in the ultrasonic bath.

According to the EU Medical Device Regulation, users/patients are obligated to report any serious incident that has occurred in relation to the device to the manufacturer and the competent authority of the EU Member State in which the user/ patient is established.

### **Application notes**

Program setting: Do not meter under 35 °C. For the final rinse the use of de-ionised water is implicitly recommended.

Recommended cleaning temperature: 50 °C. Confirmed cleaning performance in the range of 35 - 55 °C.

When cleaning in an ultrasonic bath: Do not exceed the sonication time according to the manufacturer's instructions and temperatures of 40 °C.

Automated cleaning: Recommended reprocessing program for the chemothermal reprocessing in the washer-disinfector for endoscopes with the use of demineralized water from at least the intermediate rinsing:

- Pre-rinse with cold water
- Cleaning step: Cold water intake, then heat to 50 °C,
- Dosage of THERMOSHIELD FLEX at 35 °C.
- 5 min cleaning at 50 °C
- Intermediate rinsing, recommended: demineralized water
- Chemothermal disinfection: Dosage of THERMOSHIELD DESINFEKTANT (to 1 %) at ≥30 °C; disinfection in 5 min at 55 °C
- Final rinse with demineralized water

Manual precleaning in an ultrasonic bath: Fill with demineralized water, dose THERMOSHIELD FLEX to 0.3 - 2 % and set ultrasonic bath to a max. of 40 °C. Immerse instruments in the cleaning solution.

### Composition

< 5 % non-ionic surfactants, enzymes.

### Material compatibility

The use of THERMOSHIELD FLEX is not recommended for the following materials: aluminium, brass, copper. For further information on material compatibility see

### **Precautionary and hazard statements**

Contains Subtilisin. May produce an allergic reaction. Safety data sheet available on request. For professional use only by personnel with corresponding specialist knowledge according to national directives.

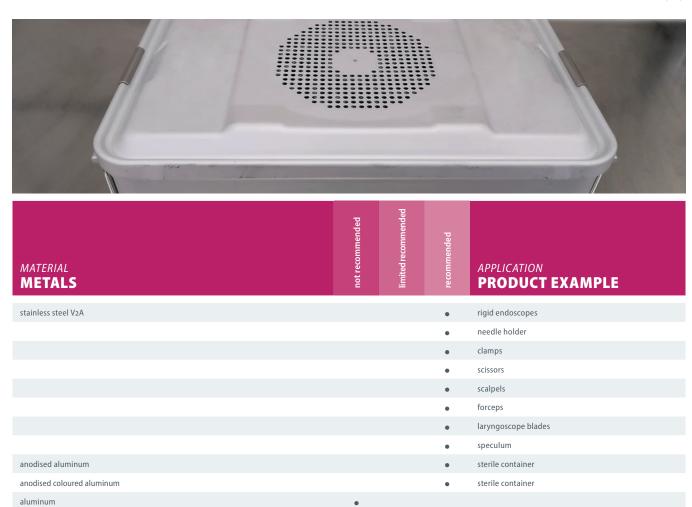
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## THERMOSHIELD® FLEX



### **MATERIAL COMPATIBILITY**

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# THERMOSHIELD® FLEX



### **MATERIAL COMPATIBILITY**

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MATERIAL PLASTICS: THERMOPLASTICS  PC (polycarbonate e.g. Makrolon)  • housing of hollow fiber dialyzers • inhalers • cardiotomy reservoirs  PC/ABS (polycarbonate/acrylonitrile-butadiene-styrene blends)  ABS (acrylonitrile-butadiene-styrene copolymer)  PE-HD (polyethylene-high density)  PA (polyamide)  PP (polypropylene)  • test implants, caddies for surgical instruments  PMMA (polymethylmethacrylate)		A short			
<ul> <li>inhalers</li> <li>cardiotomy reservoirs</li> <li>PC/ABS (polycarbonate/acrylonitrile-butadiene-styrene blends)</li> <li>ultrasound probes</li> <li>ABS (acrylonitrile-butadiene-styrene copolymer)</li> <li>tracheal tubes</li> <li>instrument baths</li> <li>PA (polyamide)</li> <li>tubing</li> <li>test implants, caddies for surgical instruments</li> </ul>		not recommended	limited recommended	recommended	
PC/ABS (polycarbonate/acrylonitrile-butadiene-styrene blends)  ABS (acrylonitrile-butadiene-styrene copolymer)  PE-HD (polyethylene-high density)  PA (polyamide)  PP (polypropylene)  • cardiotomy reservoirs  • ultrasound probes  tracheal tubes  • instrument baths  • tubing  PP (polypropylene)	PC (polycarbonate e.g. Makrolon)			•	housing of hollow fiber dialyzers
PC/ABS (polycarbonate/acrylonitrile-butadiene-styrene blends)  ABS (acrylonitrile-butadiene-styrene copolymer)  PE-HD (polyethylene-high density)  PA (polyamide)  PP (polypropylene)  ultrasound probes  tracheal tubes  instrument baths  tubing  PP (polypropylene)				•	inhalers
ABS (acrylonitrile-butadiene-styrene copolymer)  PE-HD (polyethylene-high density)  PA (polyamide)  PP (polypropylene)  tracheal tubes  instrument baths  tubing  PP (polypropylene)  test implants, caddies for surgical instruments				•	cardiotomy reservoirs
PE-HD (polyethylene-high density)  PA (polyamide)  PP (polypropylene)  instrument baths  tubing  test implants, caddies for surgical instruments	PC/ABS (polycarbonate/acrylonitrile-butadiene-styrene blends)			•	ultrasound probes
PA (polyamide)  PP (polypropylene)  tubing  test implants, caddies for surgical instruments	ABS (acrylonitrile-butadiene-styrene copolymer)			•	tracheal tubes
PP (polypropylene) • test implants, caddies for surgical instruments	PE-HD (polyethylene-high density)			•	instrument baths
	PA (polyamide)			•	tubing
PMMA (polymethylmethacrylate)  • acrylic glass	PP (polypropylene)			•	test implants, caddies for surgical instruments
	PMMA (polymethylmethacrylate)			•	acrylic glass

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### **MATERIAL COMPATIBILITY**

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MATERIAL PLASTICS: ELASTOMERS	not recommended	limited recommended	recommended	APPLICATION PRODUCT EXAMPLE
CR (chloroprene rubber)			•	sealing
EPDM (ethylene-propylene-diene (monomer) rubber)			•	flexible endoscopes
PUR (polyurethane)			•	tubing
Silicone			•	respiratory masks

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### **PURCHASING INFORMATION**

Product	Single Unit	Delivery Unit	Content	REF
THERMOSHIELD FLEX	Flat canister	3	5 L	00-183-050

The availability of the products and container sizes depend on a completed national registration.



### **CERTIFICATIONS**













Dr. Schumacher is certified according to DIN EN 13485, DIN EN ISO 9001, DIN EN ISO 14001, BS OHSAS 18001, has a validated enviroment management system according to EMAS and is a member of IHO, VCI, BAH, DGSV and of the DGKH.