

INSTRUMENTS / AUTOMATED REPROCESSING

THERMOSHIELD® XTREME



MILDLY ALKALINE ENZYMATIC CLEANING AGENT FOR AUTOMATED PROCESSING

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High cleaning capacity

Intelligent combination of surfactants

Visible shine and preservation of value of instruments



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THERMOSHIELD® XTREME



PRODUCT DESCRIPTION

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THERMOSHIELD XTREME is an enzymatic, mild alkaline cleaner for automatic processing of medical and surgical instruments in washer disinfectors. A special complementary combination of surfactants with a highly active enzyme complex ensures optimal cleaning. The synergistic mechanism of action of the ingredients efficiently removes organic contamination such as proteins, blood, residual tissue and fatty residues. **THERMOSHIELD XTREME** can be used without additional neutralizers or rinse aids when demineralized water is used. At the same time, **THERMOSHIELD XTREME** is gentle to materials* and even

sensitive materials, such as anodized aluminum, can be reprocessed. The recommended working concentrations correspond to a pH of more than 10. Even in the case of particularly stubborn organic soiling (such as on bone punches), reliable results can be achieved with **THERMOSHIELD XTREME** through manual pre-cleaning in the ultrasonic bath combined with automated reprocessing. In the case of encrusted HF surgery instruments, we recommend pre-cleaning with PERFECTAN DUO EFFECT and subsequent automated reprocessing with **THERMOSHIELD XTREME**.

APPLICATIONS AND NOTES

Range of application

THERMOSHIELD XTREME is a cleaner for the reprocessing of medical and surgical instruments in washer-disinfectors. This includes dental instruments, robotics instruments, and medical accessories such as OR shoes. The product is also suitable for the manual pre-cleaning of dental/medical and surgical instruments in the ultrasonic bath (e.g. 1 % up to 40 °C).

Dosage

Depending on contamination and application: 3 - 10 ml/L – Contact time: 10 min at 55 °C

Application

THERMOSHIELD XTREME should not be combined with products which contain quaternary ammonium compounds (QACs).

Do not overload the machine to ensure that all parts of the instruments are cleaned. If necessary, disassemble instruments according to the manufacturer's instructions and open hinged instruments. THERMOSHIELD XTREME must not be combined with other products during the cleaning stage. When demineralized water is used, neutralizers and rinse aids can be omitted; however, if they are needed, they should not be added until after the cleaning step.

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

Automated cleaning: Recommended reprocessing program for the thermal reprocessing in the washer-disinfector 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 55 °C,
- Dosage of THERMOSHIELD XTREME at 45 °C. In the case of washer-disinfectors with tempered water intake of 40 - 45 °C, it is recommended that it be added directly in the incoming water.
- 10 min cleaning at 55 °C
- Intermediate rinsing
- Thermal disinfection
- Final rinse

Manual precleaning in an ultrasonic bath:

Fill with demineralized water, dose THERMOSHIELD XTREME to 0.5 – 2 % and set ultrasonic bath to a max. of 40 °C. Immerse instruments in the cleaning solution.

Notes on automated cleaning:

For the use of demineralized water: The use of demineralized water has the advantage that, in the case of THERMOSHIELD XTREME, neutralizers and rinse aids can subsequently be omitted. If it is necessary to use neutralizers and rinse aids, we recommend THERMOSHIELD C and THERMOSHIELD SHINE. Demineralized water is recommended for at least the rinse stages after cleaning. This prevents spots on the washed items and the materials are optimally protected. Demineralized water is always recommended for processing aluminium or anodised aluminium. Do not dispense the neutraliser or rinse aid until the rinse stages following the cleaning.

Indication for validation, respectively cleaning performance test for THERMOSHIELD XTREME:

An increased water level is required for the cleaning stage. The cleaner dosage can not be added at temperatures lower than 40°C. A pressure drop of more than 20 % after dosing is possible, this does not affect the cleaning performance and

*Compared to common medical device materials, such as stainless steel

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is more than compensated for by the product's innovative tenside combination. If using the modified OPA-Method as a cleaning performance check an additional negative control is necessary. Some ingredients of the cleaner can lead to false-positive results. When using the Biuret/BCA-Method there is no impact.

Composition

5 - 15 % non-ionic surfactants, < 5 % anionic surfactants. Enzymes.

Material compatibility

THERMOSHIELD XTREME is not compatible with copper, brass and polyvinyl chloride (PVC) and is compatible only to a limited extent with polyethylene (PE) and polyethylene terephthalate (PET). In the case of aluminum and anodized aluminum, the long-term use of THERMOSHIELD XTREME can lead to changes to the surface.

Precautionary and hazard statements

Causes severe skin burns and eye damage. May cause respiratory irritation. Do not breathe vapour. Wear protective gloves/protective clothing/eye protection/face protection. IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor. Dispose of contents/container to approved disposal company or local collection.

For professional use only by personnel with corresponding specialist knowledge according to national directives.

Read label before use.

PURCHASING INFORMATION

Product	Single unit	Delivery unit	Content	REF
THERMOSHIELD XTREME	Flat canister	3	5 L	00-170-050
	Canister	1	10 L	00-170-100

National information may differ. For further information, please contact our subsidiary or your local dealer.

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 environment management system according to EMAS and is a member of IHO, VCI, BAH, DGVS and of the DGKH.