



Ready-to-use wipes for manual reprocessing in three steps: cleaning, disinfection and rinsing.

gigasept® powerSET3

Our Plus:

- 100 % ready-to-use – no preparation or activation needed
- comprehensive efficacy (bactericidal, yeasticidal, mycobactericidal, fungicidal, virucidal, sporicidal against *C. difficile*) within 5 minutes
- flexible and space-saving packaging
- microbiological tests according to latest standards
- large wipe format (20 x 20 cm) and high-quality non-woven fabric quality for optimal cleaning and wetting
- antimicrobial cardboard coating as additional protection against cross-contamination

Application areas

The gigasept® powerSET3 is used for manual reprocessing of the following non-lumened medical devices: transvaginal and transrectal ultrasound probes, transoesophageal echocardiography (TEE/TOE) probes, non-invasive ultrasound probes and flexible endoscopes without channels (e.g. nasopharyngoscopes). The product consists of three components that are used in three successive steps and thus represent a complete reprocessing cycle:

- gigasept® powerSET3 cleaning wipe** for cleaning of the medical device
- gigasept® powerSET3 disinfection wipe** for high-level disinfection of the medical device
- gigasept® powerSET3 rinsing wipe** for rinsing of possible disinfectant residues on the medical device

Automated processes are generally preferred for reprocessing medical devices. If a wipe decontamination is to be used and the reprocessing recommendation of the respective medical device manufacturer permits this procedure, gigasept® powerSET3 can be applied. Not suitable for reprocessing of medical devices with lumen and critical medical devices.

Product Profile

Efficient cleaning:

Powerful surfactants of the gigasept® powerSET3 cleaning wipe remove in particular organic contaminations within a very short time. With their lipophilic part, the surfactant molecules envelope water-insoluble substances (e.g. greasy soiling) and form small aggregates (micelles), thus detaching contamination from surfaces and enabling efficient cleaning.

Powerful disinfection:

The gigasept® powerSET3 disinfection wipe is impregnated with a solution containing 0.06 % peracetic acid. Peracetic acid has an inactivating effect against a broad spectrum of bacteria, including mycobacteria and bacterial spores, as well as fungi, enveloped and non-enveloped viruses – already at low concentrations. It also provides very good material compatibility and is therefore suitable for use with medical devices made from various materials. Due to the lower consumption of raw materials and the low energy balance, peracetic acid is a resource-saving antimicrobial agent. Moreover, it exhibits very good biodegradability – the active ingredient peracetic acid decomposes into acetic acid and oxygen after application.

Instructions for use

All components are part of the reprocessing cycle. For proper reprocessing of medical devices, the following three steps are necessary: cleaning, disinfection, and rinsing.

Perform the reprocessing without interruptions and only by verifiably trained staff. In the event of interruptions, individual reprocessing steps are to be repeated, if applicable.

Upon opening the gigasept® powerSET3 cleaning wipes and gigasept® powerSET3 disinfection wipes for the first time, pay attention to hygiene when pulling the first wipe through.

Pre-cleaning should be performed according to standard operating procedures immediately after use. If applicable, remove the protective cover and ultrasound gel from the medical device with a disposable wipe before proceeding with gigasept® powerSET3.



gigasept® powerSET3

Thoroughly wipe medical devices until they are completely wetted and visible soiling or possible residues are removed. Pay particular attention to joints, edges and recesses.

The tubs of gigasept® powerSET3 cleaning wipes and gigasept® powerSET3 disinfection wipes should not be removed from the set. The packaging is optimised for ideal handling with tubs remaining in the packaging.

Please ensure that cross-contamination by contact of the medical device with unclean objects or surfaces is excluded during and after reprocessing.

Close the lid tightly after removing the gigasept® powerSET3 cleaning wipes or gigasept® powerSET3 disinfection wipes.

After reprocessing of the medical device, thoroughly clean and disinfect any transport containers, all hand contact surfaces (e.g. keyboard, ultrasound gel bottle, handle, etc.) and work surfaces.

Microbiological efficacy

Efficacy	Concentration	Contact time
bactericidal EN13727, EN14561, EN16615 in accordance with VAH - dirty conditions	ready-to-use	1 min.
yeastcidal EN 13624, EN 14562, EN 16615 in accordance with VAH - dirty conditions	ready-to-use	1 min.
mycobactericidal EN 14348, EN 14563, EN 16615 - dirty conditions	ready-to-use	5 min.
fungicidal EN 13624, EN 14562, EN 16615 - dirty conditions	ready-to-use	5 min.
virucidal EN 14476, EN 16777, EN 17111, EN 16615 (mod.) - dirty conditions	ready-to-use	5 min.
virucidal in accordance with DVV (German Registered Association for Combating Viral Diseases)/RKI Guideline	ready-to-use	5 min.
Polyoma SV40 EN 16615 (mod.) - dirty conditions	ready-to-use	1 min.
Polyoma SV40 in accordance with DVV (German Registered Association for Combating Viral Diseases)/RKI Guideline	ready-to-use	1 min.
sporicidal (C. difficile) EN 17126, EN 17846, in accordance with VAH - dirty conditions	ready-to-use	5 min.

Certificates

- VAH certificate
- IHO listed
- ÖGHMP certificate



gigasept® powerSET3 cleaning wipe
gigasept® powerSET3 rinsing wipe



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gigasept® powerSET3 disinfection wipe



Schülke & Mayr GmbH holds a Manufacturer's Authorisation according to sect 13 para 1 German Drug Law and Certificates of GMP Compliance for medicinal products.

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Product data

Composition:

gigasept® powerSET3 cleaning wipe:

100 g of solution contain: surfactants

gigasept® powerSET3 disinfection wipe:

100 g of solution contain the following active substance(s):
0.06 % peracetic acid. Other ingredients: hydrogen peroxide, acetic acid

gigasept® powerSET3 rinsing wipe:

100 g of solution contain: deionised water

Special advice

Read label, instructions for use and product information before use.

For professional use only. Please follow the reprocessing recommendations provided by the medical device manufacturers. Any serious incidents related to the product are to be reported to the manufacturer and competent authority.

Wear protective gloves. Do not use on aluminium.

Shelf life after opening: 3 months.

Information for order

Item	Delivery form	Item no.
gigasept® powerSET3 (30 applications)	5 / carton	on request

These products are not available in every country. For more information please contact our local subsidiary or distributor.

Environmental information

schülke manufactures products economically and with advanced, safe and environmentally friendly production processes while at the same time maintaining our high quality standards.

Expert opinion and information

Please visit our website for an overview of all available literature/reports on the product: www.schuelke.com

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