schülke

gigasept® powerSET3

The new standard in manual reprocessing using wipes

we protect lives worldwide

Good things come in threes:

gigasept® powerSET3

In a restaurant we would obviously expect the spoon we're given for our soup to be cleaned thoroughly. Patients are even more entitled to expect medical devices that are placed on or inserted into the body to have been reprocessed to a professional standard.

That's why we have come up with the gigasept® powerSET3 for manual reprocessing of non-lumened ultrasound probes or flexible endoscopes. The gigasept® powerSET3 is a handy solution you can rely on: practical, safe and both cost efficient and designed with the environment in mind.

The powerful trio of cleaning, disinfection and rinsing:

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

Detailed instructions for using the **gigasept® powerSET3** are available at **www.schuelke.com/gigaseptpowerset3/int**

Safety

The gigasept® powerSET3 is ready-to-use. In addition, the surface of the box has an antimicrobial coating (Lock 3) to protect against cross-contamination.

Efficacy

The gigasept® powerSET3 is effective within 5 minutes: bactericidal, yeasticidal, mycobactericidal, fungicidal, virucidal, sporicidal against *Clostridioides difficile (C. difficile)*.

Validation

Manual reprocessing with the gigasept® powerSET3 has been exemplarily validated on different medical devices in terms of cleaning and disinfection.

Sustainability

The gigasept® powerSET3 not only eliminates microbial load but also reduces waste. That's because it produces less plastic waste compared to three-component systems with individually packed wipes.

Economic viability

The gigasept® powerSET3 is an economical solution. The reprocessing saves personnel time and investment costs.

Do you have high expectations? We exceed them.

Are you looking for a solution that saves valuable time? Our gigasept® powerSET3 provides reliable efficacy, fast reprocessing cycles and secure documentation. And we'll go even further: **The gigasept® powerSET3 is easy-to-use, flexible and space-saving.**

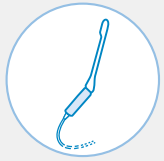
You can rely on the gigasept® powerSET3 when it comes to safety: For patients, you ensure a clean and disinfected medical device within a short time; users benefit from seamless documentation of the reprocessing cycle and safe handling during use.

Over the next few pages we'd like to show you how our solution keeps our word. We promise: Your curiosity will be rewarded!

gigasept® powerSET3 – for reprocessing of the following non-lumened medical devices*:

Transvaginal ultrasound probes (TVUS)

Transoesophageal echocardiography probes (TEE/TOE)



Transrectal ultrasound probes (TRUS)

Non-invasive ultrasound probes

Flexible endoscopes without channels (e.g. nasopharyngoscopes)

* Please follow the reprocessing recommendations of the medical device manufacturers. Not suitable for reprocessing of critical medical devices.

Process reliability in the hectic daily routine

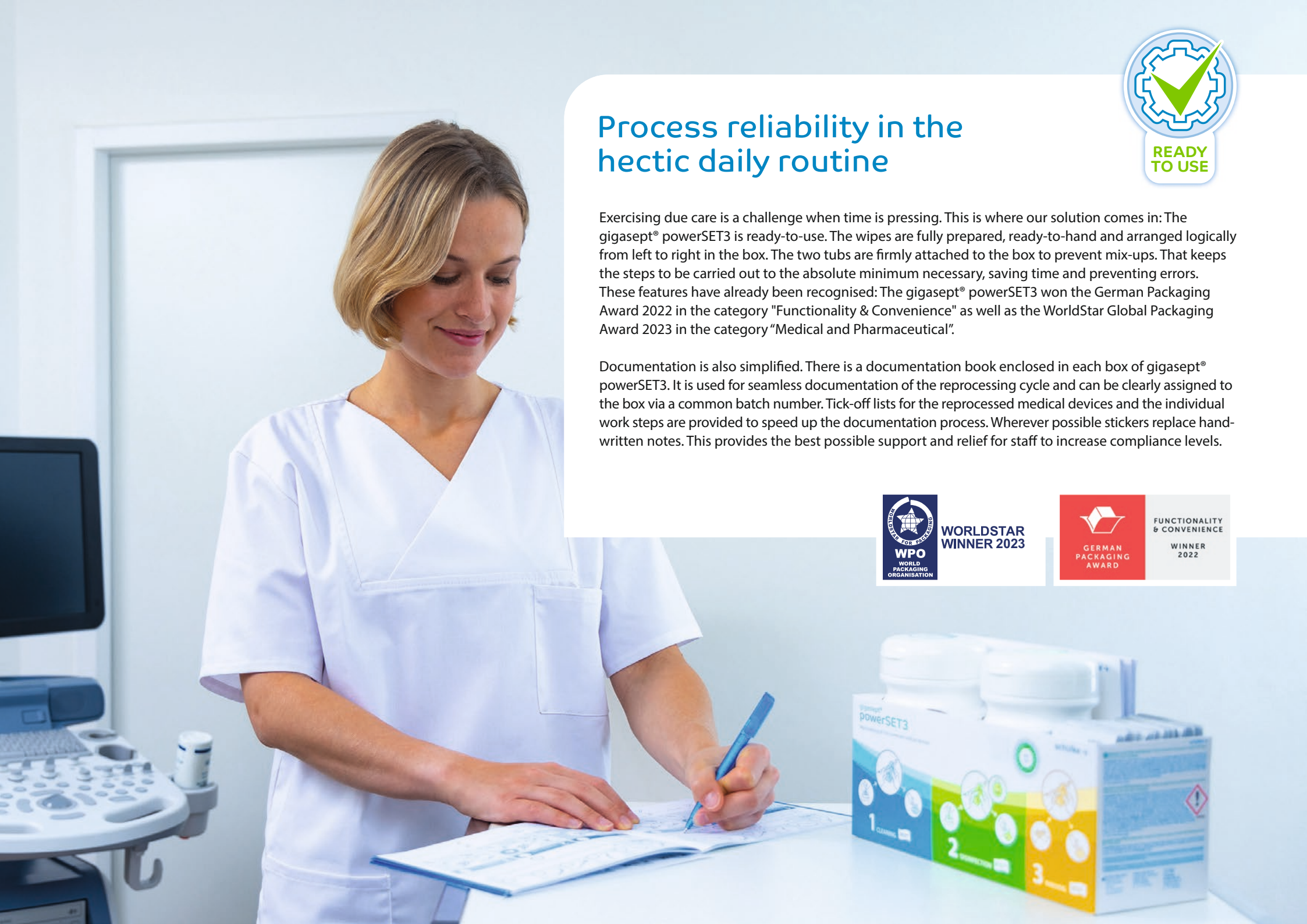
READY TO USE

Exercising due care is a challenge when time is pressing. This is where our solution comes in: The gigasept® powerSET3 is ready-to-use. The wipes are fully prepared, ready-to-hand and arranged logically from left to right in the box. The two tubs are firmly attached to the box to prevent mix-ups. That keeps the steps to be carried out to the absolute minimum necessary, saving time and preventing errors. These features have already been recognised: The gigasept® powerSET3 won the German Packaging Award 2022 in the category "Functionality & Convenience" as well as the WorldStar Global Packaging Award 2023 in the category “Medical and Pharmaceutical”.

Documentation is also simplified. There is a documentation book enclosed in each box of gigasept® powerSET3. It is used for seamless documentation of the reprocessing cycle and can be clearly assigned to the box via a common batch number. Tick-off lists for the reprocessed medical devices and the individual work steps are provided to speed up the documentation process. Wherever possible stickers replace hand-written notes. This provides the best possible support and relief for staff to increase compliance levels.

WPO WORLD PACKAGING ORGANISATION
WORLDSTAR WINNER 2023

GERMAN PACKAGING AWARD
FUNCTIONALITY & CONVENIENCE
WINNER 2022



Optimum formulas are used for cleaning, disinfection and rinsing

1. Cleaning wipe:
Special surfactant formula for reliable cleaning of residues after removal of any protective covers

2. Disinfection wipe:
Antimicrobial solution based on peracetic acid for high-level disinfection

3. Rinsing wipe:
Deionised water for safe removal of possible disinfectant residues

High-quality non-woven fabric (lint-free quality) is used for the cleaning and disinfection wipes. Using this material ensures optimal cleaning and even wetting of the medical device surfaces.

Automated reprocessing vs manual reprocessing using wipes

Complete automated reprocessing of medical devices is optimal due to the higher level of standardisation and reproducibility and is given precedence under current recommendations.* However, many probes on the market cannot be completely inserted into a machine or fully immersed. Manual reprocessing with wipes is therefore a method that is often used in practice and has established itself as standard for many users.

Sometimes, though, manual reprocessing using wipes is criticised on the basis that it cannot be validated. But our studies on the wipe-based reprocessing of different medical devices with hard-to-reach areas and large surfaces have shown the opposite: The entire process can be reliably reproduced and validated using the gigasept® powerSET3.** You can learn more about the validation process on the next page.

Proper reprocessing of the probe is also necessary when using protective covers, e.g. for transvaginal ultrasound probes.*

* Recommendation from the Commission on Hospital Hygiene and Infection Protection (KRINKO) at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) on the "Hygiene requirements for the reprocessing of medical devices"; Bundesgesundheitsblatt 2012, 55: 1244–1310.
** Reprocessing must be validated according to the individual conditions on site.

Successful validation under conditions close to actual practice

They present particular challenges for manual reprocessing using wipes: Endocavitary probes vary in shape and size, contain non-immersible elements (e.g. handles, connectors) as well as areas that are difficult to clean and disinfect, such as grooves or recesses. In collaboration with an accredited testing laboratory, we successfully conducted a hygienic-microbiological assessment on four different ultrasound probes (two each for transvaginal and transrectal probes). In doing so, we paid attention to conditions close to actual practice. For example, probes with typical signs of use and realistic test suspensions were selected. In addition, each test was repeated three times and carried out by different people to ensure the reproducibility of the results, also taking into account the individual execution of different people.

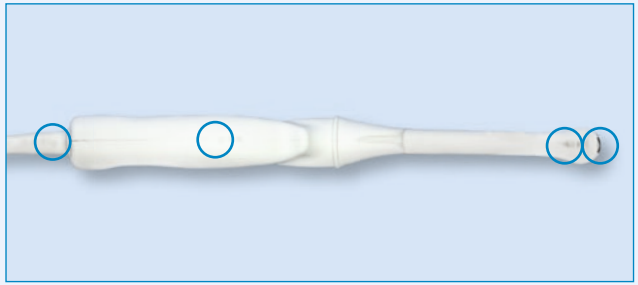
To demonstrate that medical devices with particularly large surfaces and a long, flexible insertion part can also be reliably reprocessed with the gigasept® powerSET3, a second study was conducted for TEE probes with the same study design.

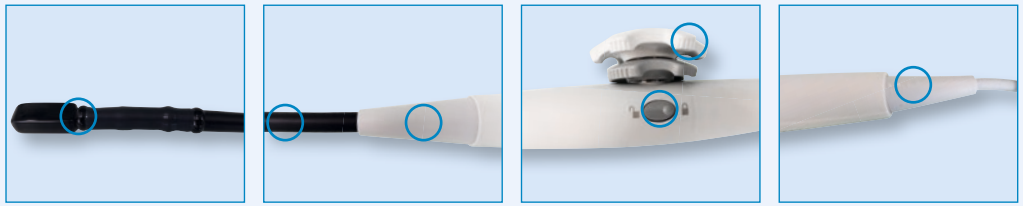
Validation of cleaning

- Contamination of the test fields with defined amounts of test suspension (ultrasound gel with components of blood and mucous membrane)
- Application of gigasept® powerSET3 cleaning wipe
- Proof of successful cleaning by determining the residual protein content and total organic carbon (TOC)

Validation of disinfection

- Contamination of the test fields with defined amounts of test suspension (ultrasound gel with components of blood and mucous membrane) with test organisms relevant to the respective application area
- Application of gigasept® powerSET3 disinfection wipe after prior cleaning with gigasept® powerSET3 cleaning wipe
- Proof of successful disinfection by microbiological determination of microbial count reduction





The validation of cleaning and disinfection was conducted at the particularly critical points of the probes, which are considered difficult to reprocess.

Above: Transvaginal probe with test fields on the transducer, recess, handpiece and transition to the cable

Below: TEE probe with test fields on the transducer, tube, controls and transitions to the tube and cable

Comprehensive efficacy within short period

The antimicrobial efficacy of the gigasept® powerSET3 disinfection wipe has been proven by all required testing according to the current version of EN 14885 and thus corresponds to the state of the art.

Efficacy	Test method	Contact time
Bactericidal	EN 13727 / EN 14561 / EN 16615 VAH	1 min.
Yeasticidal	EN 13624 / EN 14562 / EN 16615 VAH	1 min.
Mycobactericidal	EN 14348 / EN 14563 / EN 16615	5 min.
Fungicidal	EN 13624 / EN 14562 / EN 16615	5 min.
Virucidal	EN 14476 / EN 16777 / EN 17111 EN 16615 (mod.) / DVV/RKI	5 min.
Polyoma SV40	EN 16615 (mod.) / DVV/RKI	1 min.
Sporicidal *(C. difficile)*	EN 17126 / EN 17846 / VAH	5 min.

Your benefits using the gigasept® powerSET3

With the gigasept® powerSET3, manual reprocessing using wipes is possible within just a few minutes as all components are 100 % ready-to-use and ensure a simple reprocessing cycle.

Tested under conditions close to actual practice:

- Validated cleaning
- Validated disinfection

Rely on schülke for tried and tested quality:

- Resource-conserving formulations and packaging
- User-friendly handling due to functional packaging
- Comprehensive microbiological testing according to latest standards
- Bactericidal, yeasticidal, mycobactericidal, fungicidal, virucidal and sporicidal *(C. difficile)* within 5 minutes
- Broad material compatibility for use on different materials
- Large wipe format and high-quality non-woven fabric for optimal cleaning and wetting

Why you can expect more from us:

For more than 130 years, we have stood for pioneering spirit, innovation and quality. As an internationally operating and successful company, we are one of the market leaders in the areas of infection prevention and hygiene solutions. With the gigasept® powerSET3, we offer our customers a simple, safe and efficient way for manual reprocessing of non-lumened probes and endoscopes.

We look forward to hearing from you!
Would you like to find out more about the new standard in manual reprocessing using wipes? Our application department will be delighted to advise you.

Write to us or give us a call:
info@schuelke.com **+49 40 52100-666**

Item no.: 70003677

Carton with 5x gigasept® powerSET3 for 30 applications each

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