

Rely+On® PeraSafe®

LANXESS

High Level Disinfectant for use with Medical Devices
For use on invasive and non-invasive medical devices.

Applications and instructions for use

These instructions for use (IFU) should be read in conjunction with the product label and SDS.

Rely+On® PeraSafe® is for use on rigid and flexible endoscopes, catheters, transducers and other thermolabile instruments and equipment. For a list of manufacturer approvals, contact your local representative.

The intended purpose of Rely+On® PeraSafe® is to be used as a rapid action disinfectant for invasive and non-invasive medical devices in all settings where such medical devices are typically used, for example hospitals. Rely+On® PeraSafe® is not intended to be used in AERs.

Rely+On® PeraSafe® is designed for and intended for use by healthcare professionals working in a healthcare setting such as a hospital. It is assumed that the users of Rely+On® PeraSafe® have the appropriate levels of education and training within healthcare to ensure the safe use of Rely+On® PeraSafe®. Rely+On® PeraSafe® is not intended for use by lay persons

Not to be used on materials constructed of copper, brass, mild steel, natural rubber, nitrile rubber, natural dental bristle brushes or EPDM rubber.

Always wear suitable eye protection when handling powder and in-use solutions of Rely+On® PeraSafe®. Where contact with dusts of the powder are foreseen, ensure adequate ventilation and/or respiratory protection (e.g. surgical mask).

Rely+On® PeraSafe® solutions can be used for up to 20 immersions or 12 hours, whichever is Instruments should be thoroughly pre-cleaned with a medical grade pH-neutral detergent to remove all visible soiling, followed by a thorough rinse with water to remove all

detergent prior to disinfection with Rely+On® PeraSafe®. Ensure all surfaces of the equipment are in contact with the solution.

Heavily soiled instruments may give faster degradation of the peracetic acid level present, this may result in a reduction of the maximum number of immersions.

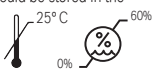
Composition: c. 0.25% w/v at 16.2 g/litre peracetic acid generated in-situ from tetraacetythylenediamine (TAED) and sodium percarbonate; surfactants; corrosion inhibitor; excipients.

Rely+On® PeraSafe® should be stored in the sealed original container, preferably at temperatures not exceeding 25°C and a 60% relative humidity. Storage for short periods at temperatures not exceeding 30 C and 65% relative humidity will not affect product performance.

Prepare only at the labelled concentration of ~16.2 g/litre. Do NOT make up over-strength solutions which are subsequently diluted

An overcap is provided as a tool only to aid in transferring powder from the container. It is not intended for use as a measuring device.

Notice to the user and/or patient: Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.



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Preparation and use of activated Rely+On® PeraSafe® solution for instrument disinfection

The performance and safety of Rely+On® PeraSafe® has been validated under the conditions of use described within this document. Always follow the instructions to ensure correct operation of the product.

Rely+On® PeraSafe® is effective against bacteria, bacterial spores, mycobacteria, viruses and yeasts, with a contact time of 10 minutes.

Preparation and use of Rely+On® PeraSafe® solution (1.62% w/v)


1. Weigh using an appropriate balance 16.2 g of Rely+On® PeraSafe® powder per 1 litre of lukewarm water (30-35°C). Do not prepare solutions of less than 1 Litre.
2. Activation takes 15 minutes. Stir periodically throughout this activation period. Solution becomes colourless after around 30 minutes. A small amount of undissolved material is expected.
3. Rely+On® PeraSafe® solutions should be used and stored at room temperature (20 ± 5°C). However, Rely+On® PeraSafe® can be used immediately after activation as the solution cools to room temperature.
4. Rely+On® PeraSafe® solution may be used in a static bath. Immerse instruments for exactly 10 minutes, after which they must be thoroughly rinsed in sterile water, being sure to remove all traces of the Rely+On® PeraSafe® solution, then dried.

It is recommended that Rely+On® PeraSafe® solutions are not prepared more than one hour prior to usage. Used Rely+On® PeraSafe® solution may be discarded, without special precautions, in the normal liquid waste disposal system in accordance with local authority regulations.

Organism	Standard
Yeast	EN 13624, EN 14562
Bacteria / Mycobacteria	EN 13727, EN 14348, EN 14561, EN 14563
Virus	EN 14476, EN 17111
Spores	EN 17126

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