

PLIWA Roto-Pren

Ready to use drill disinfection solution

VAH certificate of efficacy

Product description

PLIWA Roto-Pren is a ready to use drill disinfection solution. It contains potassium hydroxide, alcohols and amines as well as corrosion inhibitors for material protection. The extensive spectrum of efficacy and the very good material compatibility offer a safety level for the applicant during the reprocessing and application of rotating precision instruments. PLIWA Roto-Pren is free of aldehydes and phenols.

Area of application

PLIWA Roto-Pren is applied for the manual disinfection of rotating invasive medical devices (e.g. drills, mills, diamond grinders and other precision instruments) in an immersion bath.

Suitable for

- Stainless steel drills
- Diamond drills
- Mills
- Diamond grinders

Not suitable for aluminium parts, elastic polishers, ceramic grinding instruments and root canal instruments.

Do not use for squirting or spraying. Do not use for disinfection of skin and hands.

Special advice

Report serious incidents related to this product to the manufacturer and the respective authority.

Do not mix the product with other chemicals. Prior to the first application of the product or after the application of another product the containers have to be cleaned and rinsed thoroughly.

Rinse the instruments with demineralized water if they are supposed to be sterilized.

Application only by qualified personnel.

Do not pour disinfection solution that has been removed back into the original container.

Application

Put on protective clothing, protective gloves and safety glasses prior to disinfection! Do not allow debris to dry on the instruments.

Disinfection procedure:

- 1) Pour undiluted drill disinfection solution into the drill bath. Immerse instruments. Instruments must be completely covered by the solution.
- 2) After 5 minutes of contact time: Remove instruments from the drill bath and rinse them thoroughly with water (at least drinking water quality, approx. 20 °C) and dry them.
- 3) In case of persistent debris: Brush off debris under running water, repeat the disinfection procedure with 5 min contact time in fresh drill disinfection solution.
- 4) Afterwards, check instruments for cleanliness and integrity.

Comply with the instrument manufacturer's recommendations for reprocessing as well as with national guidelines for processing of medical devices.

Shelf life and expiry

Shelf life: Renew daily and in case of visible contamination.

The expiry date of the product is indicated on the label. Do not use the product after the expiry date.

Material compatibility

| | |
|----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Metals | Stainless steel |
| Plastics | PE, PSU, PVC |
| Rubber | silicone, EPDM, natural rubber |
| Ceramic | Porcelain |
| Advice: | Upon compliance to the intended use and the indicated contact time, no material damage is to be expected with the above mentioned materials. Avoid contact with aluminium and linoleum. Test material compatibility for polycarbonate, polyacrylate, brass and copper before use. |



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PLIWA Roto-Pren

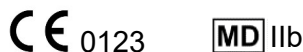
Ready to use drill disinfection solution

Spectrum of efficacy

| Efficacy under dirty conditions (undiluted, at room temperature) | Standard | Contact time |
|-----------------------------------------------------------------------------------------------------|----------------------|--------------|
| Bacteria | | |
| <i>S. aureus</i> , <i>E. hirae</i> , <i>P. aeruginosa</i> | EN 13727 | 1 min |
| | EN 14561 | 1 min |
| <i>S. aureus</i> , <i>E. hirae</i> , <i>E. coli</i> , <i>P. mirabilis</i> , <i>P. aeruginosa</i> | Standard methods VAH | 5 min |
| Yeasts | | |
| <i>C. albicans</i> | EN 13624 | 1 min |
| | EN 14562 | 1 min |
| <i>C. albicans</i> | Standard methods VAH | 5 min |
| Fungi | | |
| <i>A. brasiliensis</i> | Standard methods VAH | 5 min |
| Mykobacteria/TB | | |
| <i>M. terrae</i> , <i>M. avium</i> | EN 14348 | 2 min |
| | EN 14563 | 5 min |
| <i>M. terrae</i> , <i>M. avium</i> | Standard methods VAH | 5 min |
| Viruses | | |
| MVA modified Vacciniavirus Ankara | EN 14476 | 1 min |
| Polyomavirus SV40 | | 5 min |
| Poliovirus | | |
| Adenovirus | | |
| MNV Murine Norovirus | | |

Certificates

Listed on the VAH (German Association of Applied Hygiene) list of disinfectants in the section instrument disinfection („Instrumentendesinfektion“).



Storage advice

Store between 5 and 25 °C. Keep the container tightly closed in a well-ventilated place. Store product in an upright position. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Protect from sunlight. Keep only in original container. See safety datasheet for further advice.

Physico-chemical data

Appearance: clear, colourless liquid
pH-value: > 13
density (20 °C): 1,010 – 1,030 g/cm³

Product composition

100 g ready to use solution contain:

15.00 g Isopropanol, 2.97 g potassium hydroxide, 2.10 g N,N-Bis(3-aminopropyl)-dodecylamine (>90%), 1.25 g sodium nitrite, 1.12 g borax decahydrate

Labelling according to Regulation (EC) No 1272/2008 (CLP)

For information on labelling according to Regulation (EC) No 1272/2008 (CLP) see safety datasheet and label.

Expert opinions and additional information

The efficacy of the PLIWA Roto-Pren has been assessed by independent laboratories.

For further details concerning expert opinions, informations on products and answers to specific questions contact us by e-mail (info@pliwa.de) or telephone (0049 5661 73170).

PLIWA Hygiene GmbH has a manufacturer's authorisation as per §13 German medicines act as well as a GMP- and an EN ISO 13485 certificate.

Information for order (articles with German label)

| Single package | REF |
|----------------------------|-----------|
| 1 Liter cylinder bottle | 10-0051-1 |
| 2 Liter bottle with handle | 10-0052 |
| 5 Liter canister | 10-0053 |
| 10 Liter canister | 10-0054 |

Application aids for canisters

| | |
|--------------|-------|
| Dosing pump | 50006 |
| Drainage tap | 50009 |

