



## Endo Star Neu

### Instrument disinfection

#### EN - Instructions for use

Thank you for purchasing this product from Laboratorium Dr. Deppe GmbH.

If you have any questions about the contents of these instructions for use or the application of the product, please contact us. Your Laboratorium Dr. Deppe Team



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#### About these instructions for use

These instructions for use contain the necessary information for the correct use of Endo Star Neu (referred to below as the "product"). The instructions for use must be kept with the product and must be available to the user at all times. Anyone using the product must have read and understood the instructions for use in full, in particular the section on safety and the accompanying documents. Report all serious incidents (damage, injuries, infections, etc.) that occur in connection with the product to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

#### Accompanying documents

The following documents must be complied with in addition to the instructions for use: Labels on the product packaging, product data sheets, material safety data sheets, operating instructions, dosing tables, information on the shelf life of open containers. The documents can be downloaded from the Laboratorium Dr. Deppe GmbH website or requested by e-mail.

#### Explanation of symbols

These instructions for use and the labelling on the product use symbols to draw your attention to certain information and hazards.

Symbol	Description
	Manufacturer
	Use-by date
	Lot number
	Catalogue number, Dr. Deppe item number
	Consult instructions for use
	Medical device
	Unique Device Identifier
	The letters CE stand for European Conformity; this symbolises the compliance of the product with the applicable requirements that the European Community places on the manufacturer.
	Hazardous to the environment
	Corrosive
	Serious health hazard

#### Safety

The following section provides information on the safe use of the product. Read and follow all safety instructions and contact the manufacturer if anything is unclear.

#### Personal protective equipment\*

Eye protection: Safety glasses with side protection (EN 166)  
Skin and body protection: Long-sleeved work wear (DIN EN ISO 6530)  
Hand protection: Chemical-resistant protective gloves made of nitrile rubber (NBR) (EN ISO 374). Follow the glove manufacturer's instructions regarding penetration times, taking particular account of workplace conditions such as mechanical stress and duration of contact.  
Respiratory protection: Wear suitable respiratory protective equipment if ventilation is inadequate.

\*Section 8.2. Exposure controls / Safety data sheet

#### Safety information

##### The following safety instructions apply when handling the product

Use the product solely for its intended purpose. Not suitable for final disinfection of semi-critical instruments. This product may cause organ damage through prolonged or repeated exposure. The product causes severe skin burns and serious eye damage. Avoid breathing mist, vapour or aerosol. Effectiveness is only guaranteed with the specified mixing ratio and in compliance with the specified contact times and temperature limits. Very toxic to aquatic life, with long lasting effects. Avoid release into the environment. Ensure good ventilation of the workplace and, if necessary, provide local exhaust ventilation or general room ventilation. Do not inhale the product. Take all necessary protective measures to prevent or minimise the release of the product into the workplace. If the concentrate is accidentally released: Please follow the instructions in the "Safety Precautions" section. Do not combine with detergents or disinfectants containing aldehyde. Do not mix with detergents or disinfectants. Do not eat, drink or smoke when using this product. Protect the product from direct sunlight and keep it away from food, beverages, and animal feed. Do not wear contaminated protective clothing outside the workplace and wash separately before reuse. Limit the amount of product used to the minimum necessary and minimise the number of users exposed to the product. Not suitable for splashing or spraying. Remove product residues by rinsing (note TOC value).

#### Contains

Laurylpropylenediamine; N-(3-Aminopropyl)-N-dodecylpropane-1,3-diamine; Quaternary ammonium compound, C12-14 (even-numbered) alkylidimethyl, ethyl sulfate; reaction mass of 1-(3-((C12-18-(even-numbered))-alkyl-amino)propyl)guanidine acetate salt and 1-(C12-18-(even-numbered))-alkyl-1-(3-guanidinopropyl)guanidine acetate salt and 1-(C12-18-(even-numbered))-alkyl-tetrahydropyrimidine-2(1H)-imine acetate salt; polyhexamethylene biguanide hydrochloride (PHMB)

#### Safety measures

Take the following measures in the event of improper use or accidents with the product.

##### First-aid measures

General: Call a doctor immediately.  
After inhalation: Move the person to fresh air and ensure unobstructed breathing.  
After skin contact: Rinse skin with water/shower. Remove/Take off immediately all contaminated clothing. Call a doctor immediately. Acute and delayed symptoms: Chemical burns.  
After eye contact: Rinse carefully with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a doctor immediately. Acute and delayed symptoms: Serious eye damage.  
After ingestion: Rinse mouth. Do not induce vomiting. Call a doctor immediately. Acute and delayed symptoms: Chemical burns.

#### Firefighting measures

Comply with the following instructions and measures in the event of fire. Suitable extinguishing media: Water spray jet, dry extinguishing powder, foam, carbon dioxide.  
Unsuitable extinguishing media: Do not use a full jet of water to prevent the fire from scattering and spreading.

#### Special hazards arising from the substance or mixture

In the event of fire, toxic fumes may be released as hazardous decomposition products.

#### Advice for firefighters

Protection during firefighting: Do not attempt to work without suitable protective equipment. Wear a self-contained breathing apparatus and full protective clothing.  
Disposal of extinguishing media: Do not allow the extinguishing water to enter the sewage system or watercourses. The disposal of extinguishing water must be carried out in accordance with official regulations.

#### Accidental release measures

Comply with the following instructions and measures in the event of accidental release of the product.

##### Personal safety precautions

For non-emergency personnel: Ventilate the contaminated area. Avoid contact with eyes and skin and do not inhale dust, smoke, gas, mist, vapour or aerosol. For emergency responders: Do not attempt to work without suitable protective equipment.

##### Environmental precautions

If the product enters the sewage system or public waters, the authorities must be notified. Avoid penetration into the subsoil. Prevent the product from entering the sewage system and public waters.

##### Methods and material for containment and cleaning up

For containment: Collect spillage.  
Cleaning procedure: Soak up the spilled liquid using mechanical methods (wiping up, sweeping up) with absorbent material. Take substances or residual quantities in solid form to an authorised facility.  
Disposal: Disposal must be carried out in accordance with official regulations.

#### Intended purpose

The product is a disinfectant concentrate for the reprocessing of medical instruments using the immersion method. It is not suitable for the final disinfection of semi-critical instruments.

##### Requirements for the user

The product is intended exclusively for use by trained medical personnel and cleaning specialists from the healthcare sector.

##### Requirements for the usage environment

The product is intended for use within the following temperature ranges. Outside the temperature limits there are no data on efficacy. Recommended ambient temperature for use (min. - max.): 20 - 25°C.

##### Material compatibility

Not suitable for latex, EPDM, PMMA (Plexiglas), and limited use for copper and brass (risk of corrosion), as well as aluminium, PVC, polycarbonate, and polysulfone. Changes may occur with prolonged exposure (contrary to intended use). Before using the product, check its material compatibility with the instrument materials; the manufacturer's instructions must be followed.

#### Product properties

The product is used as a disinfectant to eliminate microorganisms on medical instruments and ultimately helps to prevent infections.

##### Composition/Active substance

The following information refers to 100 g of the product:  
Alkyldimethylethyl ammonium ethyl sulfate: 5.0 g  
Polyhexamethylene biguanide hydrochloride: 1.0 g  
Cocospropylenguanidinium diacetate: 1.8 g

##### Chemical and physical properties

Colour: colourless-clear  
State: fluid  
pH-value: 9.2 - 9.6  
Density: 0.988 - 1 g/ml

#### Contact Times

The efficacy of the product depends on the combination of concentration and contact time of the product on the instrument. The instruments to be disinfected are placed in the instrument holder, and cavities must be thoroughly rinsed. Contaminants such as blood, saliva, or similar substances can impact the effectiveness of the disinfectant. Only disinfect instruments that have been adequately pre-cleaned and rinsed. Effectiveness is guaranteed with the specified mixing ratio and in compliance with the specified contact times and temperature limits. To ensure safe and reliable results, keep the instruments moistened with working solution for the entire contact time.

Efficacy: bactericidal (EN 13727; EN 14561; VAH 15)/ yeasticidal (EN 13624; EN 14562; VAH 15) clean condition 3% 15 min.; tuberculocidal (M. terrae/ EN 14348; EN 14563) clean condition 3% 15 min.; limited spectrum of virucidal activity (Vaccinia strain Elstree; BVDV/DVV-RK1) 10% FBS 3% 15 min.; limited spectrum of virucidal activity (Modified Vaccinia Ankara/ EN 14476) clean condition 1% 15 min.; instrument disinfection in an ultrasonic bath (VAH 15) dirty condition 3% 5 min.

#### Use

##### Dosing the product correctly

The product is supplied as a concentrate for the preparation of a ready-to-use solution. Before use, the working solution is prepared taking into account the required concentration for the planned application. Mix the product with water of drinking quality to form a working solution.

Application example: To prepare 1 litre of a 1% working solution, mix 990 ml of water with 10 ml of concentrate.

#### Using the product

Follow the instructions below for using the product and contact the manufacturer if you have any questions or concerns. Follow the hygiene requirements for the reprocessing of medical devices. Follow the instructions for preparation, cleaning and disinfection, rinsing and drying, and storage as stated in the instructions for use from the manufacturer of the instrument or device. Do not combine products containing amines with aldehyde-based products. Clean and rinse all instruments, accessories, trays, processing equipment, and application aids thoroughly when using the product for the first time or when changing products.

##### Immersion Method

After cleaning, immerse the instruments. All surfaces and cavities must be covered or filled. Please follow the application concentration and contact times. Remove instruments, rinse thoroughly with water (drinking water quality), and dry. The TOC values must be observed (TOC <12.6 mg/L).

##### Ultrasound Application

Similar to the immersion method. Adhere to the exposure times specified for ultrasound application.

##### Product change

The product is not compatible with disinfectants containing aldehyde. The product is not permitted to be mixed with cleaning agents or other disinfectants. On first use and when changing products, thoroughly clean and rinse the instruments and accessories, trays, reprocessing equipment, and application aids. The in-use solution is resistant to protein and can potentially be reused multiple times. In case of cloudiness or visible changes (e.g. cloudiness, flocculation, discolouration), replacing the working solution is recommended.

#### Storage and Disposal

##### Requirements for the storage environment

Store the product in a well-ventilated place in a sealed condition and protect it from unauthorised access.

##### Shelf Life

Do not use the product after the expiry date indicated on the packaging and dispose of it properly. The product has a shelf life of 12 months after opening.

##### Disposal

Disposal must be carried out in accordance with the applicable national and local regulations. The instructions in the safety data sheet for the concentrate must also be complied with.