



Instru Star rfu

Instrument disinfectant

EN - Instructions for use



Instru Star rfu

Ready-to-use liquid disinfectant solution

- aldehyde-free
- for reprocessing medical instruments using the immersion method, e.g. drills or rotating instruments

Thank you for your purchase from Laboratorium Dr. Deppe.

These instructions for use apply to the following product variants:

- Instru Star rfu

Please contact us if you have any questions about these instructions or how to use the product.

Your Laboratorium Dr. Deppe team



Laboratorium Dr. Deppe GmbH

Hooghe Weg 35

47906 Kempen

Germany

+49 (0) 2152 5565-0

E-Mail: info@drdeppe.de

Internet: www.drdeppe.de



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About these instructions for use

These instructions for use contain the necessary information for correctly using **Instru Star rfu** (hereinafter referred to as the „product“).

The instructions for use must be kept in the immediate vicinity of the product and must be available to the user at all times.

All persons using the product must have fully read and understood the instructions for use, in particular the chapter on safety, and the other applicable documents.

Report all serious incidents (damage, injuries, infections, etc.) that have occurred in connection with the product immediately to the manufacturer (see page 2), as well as to the competent authority of your country; in Germany, this is the BfArM (visit <https://www.bfarm.de> for contact information).

Other applicable documents

In addition to the instructions for use, the following documents must be observed:

- Labels on the packaging of the product
- Product data sheets
- Safety data sheets
- Operating instructions
- Information on the shelf lives of opened containers

The documents can be accessed on the website of Laboratorium Dr. Deppe GmbH or requested by e-mail.



Internet:
(www.drdeppe.de)














E-Mail:
(info@drdeppe.de)

Explanation of symbols

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

Ensure the symbols remain legible for the entire service life of the product and replace them immediately if they become worn.

Symbol	Description
	The letters CE stand for European conformity; they indicate that the product conforms to the applicable requirements that European Community imposes on manufacturers.
	DrDeppe pictogram for instrument disinfection. It is a marketing element without a legal background.
	Product manufacturer
	Maximum shelf life
	Production lot number / batch number
	Item number
	Follow the instructions for use
	Medical device
	Unique Device Identifier
	Caution: Causes serious eye irritation
	Acute and chronic aquatic 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 (see page 2).

Personal protective equipment

Personal protective equipment must be checked for integrity each time before use and replaced immediately in the event of damage or wear.

The following personal protective equipment must be worn when handling the product:

Instru Star rfu	
	Not required for normal conditions of use. Handling large quantities of product: In case of repeated or prolonged contact wear gloves. Nitrile rubber. EN 374.
	Not required for normal conditions of use. Safety goggles recommended during refilling. EN 166.
	Wear suitable protective clothing. EN ISO 13688. EN 13034.
	No respiratory protection needed under normal use conditions. In case of insufficient ventilation, wear suitable respiratory equipment. Short term exposure. Breathing apparatus with filter. A-P2. EN 143.

Safety instructions

The following safety instructions apply when handling the product:

- The product must only be used for its intended use.
- It is not suitable for the final disinfection of semi-critical instruments.
- The product may cause skin and eye irritation. Avoid contact with eyes or skin.
- Effectiveness is only guaranteed when the indicated mixing ratio is used, in compliance with the specified exposure times and temperature limits for the application.
- Very toxic to aquatic organisms with long-term effects. Avoid release into the environment.
- Ensure good ventilation of the workplace and, if necessary, provide local extraction or general room ventilation.
- Take all necessary protective measures to prevent or minimise the release of the product in the workplace.
- Should the ready-to-use solution be released accidentally: Please observe the instructions “Safety measures” on page 8.
- Do not combine with aldehyde-based cleaners or disinfectants.
- Do not eat, drink or smoke when the product is being used.
- Protect the product from direct sunlight and keep it away from food, drink and animal feeding stuffs.
- Do not wear contaminated protective clothes outside the workplace. Wash them separately before wearing them again.
- Keep the amount of product used to the minimum required, and minimise the number of users exposed to the product.
- Not suitable for squirting or spraying.

Safety measures

When using **Instru Star rfu**, take the following safety measures.

If swallowed:

- Rinse mouth. Do not induce vomiting. Call a doctor immediately.

In case of contact with the skin (or hair):

- Wash skin with plenty of water. Take off contaminated clothing.
If skin irritation occurs: Get medical advice/attention.

If inhaled:

- Remove person to fresh air and keep comfortable for breathing.

In case of eye contact:

- Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

Accidental release measures:

- Only qualified staff in suitable protective equipment may intervene.
- Ventilate the contaminated area.
- Avoid sub-soil penetration and prevent entry to sewers and public waters.
- Take up liquid spill into absorbent material. Take up mechanically (sweeping, shovelling) and collect in suitable container for disposal.
- Notify the authorities immediately if the product enters the sewage system or public waters.

Intended use

Instru Star rfu is intended for the reprocessing of medical instruments using the immersion method. The product is not suitable for final disinfection of semi-critical and critical instruments.

User requirements

This product is exclusively intended for use by trained healthcare professionals and cleaning professionals in the healthcare sector.

All persons using the product must have read and understood the entire instructions for use, in particular the chapter on safety, before use.

Storage environment requirements

The product is suitable for use in all areas where medical instruments are prepared using the immersion method.

The product is intended for use within the following temperature ranges. No effectiveness data is available for use outside these temperature limits.

Description	Unit	Value
Recommended ambient temperature for use (min. - max)	[°C]	20 - 25

Material compatibility

Not suitable for aluminium (slight discolouration) and polycarbonate (deformation) and not suitable for copper and brass (slight risk of corrosion) in case of longer exposure times/frequent reprocessing.

Before using the product, check the material compatibility with the instrument materials; observe the manufacturer's specifications.

Product features

Instru Star rfu serves as a disinfectant for the elimination of microorganisms on medical instruments, thereby ultimately helping to prevent infections during medical procedures.

Composition

The following information applies to each 100 g of the product.

Instru Star rfu	Unit	Value
Cocosporylene diammonium borate	[g]	1,125

Chemico physical properties

Colour	colourless, clear
State	liquid
pH-value	8 - 9,5
Density	0,9936 - 1,0036 g/ml

Recommended exposure times

The effectiveness of the product depends on the combination of the concentration and the length of an instrument's exposure to the product. The instruments to be disinfected should be immersed in the solution and hollow spaces must be thoroughly flushed.

Influencing factors:

- Contaminants such as blood, saliva, etc. may influence the disinfectant's effectiveness.
- Only disinfect instruments once they are sufficiently pre-cleaned and rinsed.
- Keep the instruments moistened with the working solution for the entire exposure time to ensure effectiveness.

The product is applied undiluted. The recommended exposure times for Instru Star rfu are given in the table below.

Instru Star rfu	Condition		Norm	Exposure time (min.)
	dirty	clean		
Bactericidal	X		DGHM	15
Yeasticidal				
Mycobactericidal				
Tuberculocidal				
Active against enveloped viruses (Vaccinia/BVDV)	X		DVV/RKI	5

Application

This chapter describes how to use the product safely and effectively.

Correct dosing of Instru Star rfu

The product is available as a ready-to-use solution.

Follow the steps below to disinfect instruments with the product:

1. Disinfect the instruments with the working solution in the insertion procedure. Keep the instruments to be disinfected moist during the entire exposure time (see page 11).
2. After disinfection, rinse with water of at least drinking water quality and free of facultative germs. It is recommended to use demineralised water or aqua dest, unless otherwise specified by the instrument manufacturer.

Instructions for use

Please observe the following instructions on how to use the product and contact the manufacturer if you have any questions or are unclear.

- Observe the hygiene requirements for the reprocessing of medical devices (in Germany: RKI, KRINKO, MPBetreibV).
- Observe the instructions for preparation, cleaning and disinfection, rinsing and drying as well as storage provided by the manufacturers of the instruments and devices.
- Instru Star rfu contains amines. Do not combine it with aldehydic products.
- Thoroughly clean and rinse all instruments, accessories, tubs, processing devices and application aids when using the product for the first time or when switching over products.

Storage and disposal

This chapter describes how to properly store and dispose of Instru Star rfu.

Storage environment requirements

Store the product closed, and in a cool, well-ventilated place, and protect it from unauthorised access. Observe the following temperature limits for storage.

Description	Unit	Value
Temperature limits for short-term storage (min. - max.)	[°C]	0 - 40 ¹⁾
Ambient temperature for long-term storage according to shelf life (min. - max.)	[°C]	15 - 20

¹⁾ Short-term storage (max. 24 hrs) up to a max. of 40°C has no impact on the product effectiveness.

Shelf life

Do not use the product after the expiry date indicated on the packaging. Dispose of it properly.

The product can be stored for 12 months after opening if the container is closed.

Disposing of Instru Star rfu

Dispose of the product in accordance with official regulations.

Also observe the information in the safety data sheet.



Ordering details

For orders from Laboratorium Dr. Deppe, use the item numbers given below.

Instru Star rfu

Item number	Container size
601490	6 x 2 L
600091	2 x 5 L
600071	10 L



DrDeppe

Laboratorium Dr. Deppe GmbH

Hooghe Weg 35

47906 Kempen

Deutschland

+49 (0) 2152 5565-0

E-Mail: info@drdeppe.de

Internet: www.drdeppe.de

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