



DrDeppe



Instru Extra

Instrument disinfectant

EN - Instructions for use



Instru Extra

Concentrated liquid instrument disinfectant

- aldehyde- and phenol-free
- for reprocessing of medical instruments using immersion method

Thank you for your purchase from Laboratorium Dr. Deppe.

These instructions for use apply to the following product variants:

- Instru Extra

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

Your Laboratorium Dr. Deppe team



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About these instructions for use

These instructions for use contain the necessary information for correctly using **Instru Extra** (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
- Dosing charts
- 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
	Corrosive: causes severe skin burns and eye damage upon contact
	May cause damage to organs through prolonged or repeated exposure.
	Very toxic to aquatic life. Toxic to aquatic life with long lasting effects.





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 Extra	
	Chemically resistant protective gloves. Nitrile rubber. EN 374.
	Wear closed safety glasses. EN 166.
	Wear suitable protective clothing. EN ISO 13688. EN 13034.
	In case of insufficient ventilation, wear suitable respiratory equipment. EN 143. A-P2. Breathing apparatus with filter.

Safety instructions

The following safety instructions apply when handling the product:

- The product must only be used for its intended use.
- Not suitable for final disinfection of semi-critical instruments.
- The product may cause damage to organs through prolonged or repeated exposure.
- The product causes severe skin burns and eye damage.
- Do not breathe mist, vapours, spray.
- The effectiveness is only guaranteed in the specified mixing ratio and in compliance with the specified exposure times and temperature limits for the application.
- Very toxic to aquatic organisms, with long lasting effects. Avoid release into the environment.
- Ensure good ventilation of the workplace and provide local exhaust or general room ventilation if necessary.
- Take all necessary protective measures to prevent or minimise release of the product in the workplace.
- In case of accidental release of the concentrate: Please observe the notes „Safety measures“ on page 8.
- Do not combine with cleaners or disinfectants containing aldehyde.
- Do not eat, drink or smoke when using this product.
- Protect the product from direct sunlight and keep away from food, drink and animal feeding stuffs.
- Do not wear contaminated protective clothing outside the workplace and clean separately before reuse.
- 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 Extra**, take the following safety measures.

If swallowed:

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

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

- Rinse skin with water/shower. Take off immediately all contaminated clothing. Call a physician immediately.

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. Call a physician immediately.

Accidental release measures:

- Only qualified personnel in appropriate protective equipment may intervene.
- Ensure good ventilation of the work station and do not breathe mist, vapours, spray.
- Avoid contact with skin and eyes.
- Avoid sub-soil penetration. 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.
- Immediately inform the authorities if the product enters the sewage system or public waters.

Intended use

Instru Extra is intended for the reprocessing of medical instruments using the immersion method. Not suitable as final disinfectant for 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 latex, EPDM, PMMA (Plexiglas), limited suitability for copper and brass (risk of corrosion), as well as aluminium, PVC, polycarbonate and polysulphone. Changes may occur with prolonged exposure (contrary to intended use).

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

Product features

Instru Extra 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 Extra	Unit	Value
Alkyl dimethyl ammonium methyl sulfate	[g]	5,0
Polyhexamethylenebiguanide hydrochloride	[g]	1,0
Cocospolylenediamine guanidinium diacetate	[g]	1,8

Chemico physical properties

Colour	colourless, clear
State	liquid
pH-value	9,2 - 9,6
Density	0,988 - 1,00 g/ml

Listing

Instru Extra	
Listing	

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.
- Effectiveness is only guaranteed when the indicated mixing ratio is used, in compliance with the specified exposure times and temperature limits for the application.
- Keep the surface moistened with the working solution for the entire exposure time to ensure effectiveness.

The recommended exposure times and concentrations for Instru Extra are shown in the table below.

Instru Extra	Condition		Norm	Concentration/ Exposure time
	dirty	clean		
Bactericidal		X	EN 13727	3% 15 min.
			EN 14561	
Yeasticidal		X	EN 13624	
			EN 14562	
Tuberculocidal (M. terrae)		X	EN 14348	
			EN 14563	
Active against enveloped viruses (Vaccinia Stamm Elstree, BVDV)	10% FBS		DVV/RKI	
Application in ultrasonic bath				

Application

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

Correct dosing of Instru Extra

The product is available as a concentrate for preparing a working solution. The recommended application concentration is 3%. Prepare the working solution prior to use, taking into account the required concentration for the planned application.

1. Personal protective equipment: Wear chemical-resistant protective gloves, protective clothing, respiratory protection, and tight-fitting safety goggles (see page 6).
2. To protect high-quality instruments, mix the product with drinking-quality water to form a working solution (see table below).

Example of use: To prepare 10 litres of a 1% working solution, mix 9.9 litres of water with 100 ml Instru Extra.

Total amount of working solution	Concentration of working solution [%]								
	0,25	0,5	1,0	1,5	2,0	2,5	3,0	4,0	5,0
	Quantity of disinfectant concentrate [ml]								
1 litre	2,5	5	10	15	20	25	30	40	50
2 litres	5,0	10	20	30	40	50	60	80	100
3 litres	7,5	15	30	45	60	75	90	120	150
4 litres	10,0	20	40	60	80	100	120	160	200
5 litres	12,5	25	50	75	100	125	150	200	250
6 litres	15,0	30	60	90	120	150	180	240	300
7 litres	17,5	35	70	105	140	175	210	280	350
8 litres	20,0	40	80	120	160	200	240	320	400
9 litres	22,5	45	90	135	180	225	270	360	450
10 litres	25,0	50	100	150	200	250	300	400	500

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 Extra 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.

Using Instru Extra

Follow the steps below to disinfect instruments with the product:

1. Prepare the working solution according to the requirements for the planned application (see page 11 and 12).
2. Disinfect the instruments with the working solution using the immersion method.
3. Keep the instruments to be disinfected moist for the entire period of exposure (see page 11).
4. After disinfection, rinse with water that is at least of drinking quality and free of facultative microorganisms.
We recommend you use demineralised or distilled water unless the instrument's manufacturer specifies otherwise.

Storage and disposal

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

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 Extra

Dispose of the product in accordance with official regulations.

Also observe the information in the safety data sheet for the concentrate and the working solution.

Ordering details

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

Instru Extra

Item number	Container size
601477	6 x 2 litres
600041	2 x 5 litres



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