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MANUAL DISINFECTION & REPROCESSING

PROTECT

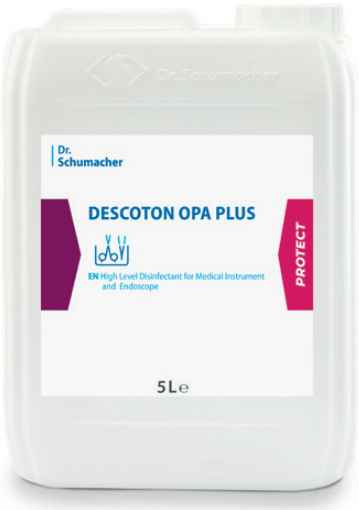
DESCOTON OPA PLUS

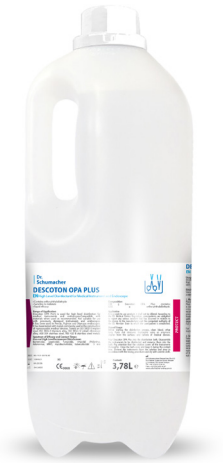
High Level Disinfectant for Medical Instrument and Endoscope

Contans ortho-phthalaldehyde

Senstve to materals

Rapid efficacy





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PRODUCT DESCRIPTION

When used in accordance with the user manual of Descoton OPA Plus, it provides high level disinfection for heat-sensitive reusable semicritical medical devices, especially of which sterilization is not possible. Descoton OPA Plus is suitable for disinfection of all kinds of heat-resistant and heatabile materials and is compatible with all kinds of materials. It is suitable for use both in disinfection baths processing manually and in semi-automatic endoscopic machines. It has anti-corrosive effect as it contains anticorrosion agents.

RANGE OF APPLICATION

Descoton OPA Plus is used for high level disinfection for medical instruments and endoscopes. Descoton OPA Plus is designed to be used in instrument disinfection baths manually for disinfection of endoscopes and anesthetic materials including medical and surgical instruments, MIC surgical instruments. However, it can also be used in semi-automatic endoscope washing machines if used in accordance with the instructions of device manufacturers.

APPLICATION

It is a ready to use product, it shall not be diuted.

In accordance with the EU Medical Device Regulation (MDR), users and patients are obliged to report any serious incident associated with the device to the manufacturer and to the competent authority of the EU Member State in which the user or patient is located.

Manuel Usage:

Before starting the disinfection process, clean blood, other body uid and lubricants throroughly using an enzymatic cleaner from the surfaces and lumens of medical devices. Pour Descoton OPA Plus into the disinfection bath. Disassemble the instruments to be disinfected and immerse them into the bath. Pay attention that the solution covers all the instruments-thoroughly. Close the bath cover and keep it during the contact time. Remove the instruments from the solution and rinse in accordance with the rinsing procedures and dry with a sterile cloth.

Usage in Semi-Automatic Endoscope Washers:

It should be used in semi-automatic endoscope washers that can be adjusted to at least 25°C in accordance with the instructions of device manufacturer's.

Rinsing Procedure

1. Manual Rinsing:

Rinse the device taken out from the Descoton OPA Plus Solution thoroughly by immersing it in plenty of water (eg 8 liters). If drinking water is not recommended, use sterile water. See article 3 or 4 below. If the device manufacturer does not recommend a longer period, immerse the device in water for a minimum of 1 minute. If no other type of rinsing is recommended by the device manufacturer, manually squeeze plenty of water (at least 100 ml) into all lumens. Remove the device from the water and pour the rinse water. Always use fresh water for every rinse. Do not reuse water for rinsing or any other purpose. Repeat this process TWO (2) more times; so rinse the device THREE (3) TIMES with plenty of water and clean it from the residues of Descoton OPA Plus. Residues can cause serious side eects. IN ORDER TO COMPLETE THE RINSING PROCESS, DO THREE (3) SEPARATE RINSE AND USE A LOT OF WATER. For additional rinsing information, check the label of the reusable medical device manufacturer.

2. Semi-Automatic Rinsing:

Choose a rinsing cycle in a semi-automatic endoscope washer of which use has been approved with this product. Make sure that the semi-automatic rinsing cycle selected can rinse the medical device thoroughly including all lumens with plenty of water, according to the recommendations of reusable device manufacturer's. If the device manufacturer does not recommend a longer period, make sure that each rinse takes a minimum of 1 minute. Do not use rinse water again for rinsing or any other purpose.For additional rinsing information, check the label of the reusable medical device manufacturer.

3. Rinsing with Sterile Water:

Due to microorganisms in the drinking water system are not normally pathogenic in patients with a healthy immune system, they can create a high risk of infection in AIDS patients or in people with a compromised immune system. For this reason, the following devices should be rinsed with sterile water, using sterile conditions during rinsing and use:

* Devices intended for use in normally sterile areas of the body.
* Devices designed for use in patients with known immnunodeficiency or potentially immunocompromised patients (eg high-risk patient population) based on institutional procedures.
* Bronoscopes whenever possible.

4. Rinsing With Drinking Water:

For all other devices, rinsing with sterile water is recommended whenever possible. Otherwise, rinsing can also be done with drinking water.Water treatment systems such as softeners or deionizers can add microorganisms to the microbial content of the treated water at the point of use, exceeding the microbial content of the drinking water. In order to obtain the required water quality, it is recommended that the cons-tant maintenance of the water treatment system(s) should not be disrupted. The use of a bacteria-retaining (0.2 micron) filter system can also eliminate or greatly reducethe amount of aquatic bacteria that arise from the drinking water source. However, to prevent biofilm formation or colonization in the filter, make contact with the UV system or filter manufacturer for instructions on regular replacement of the filter and preventive maintenance instructions.A device which is not fully dried will create an ideal environment for the rapid colonization of bacteria. Since the bacteria living in drin- king water show high resistance to drying, rapid drying will prevent possible colonizati- on, but will not completely purify the device from bacteria. A final rinse can be made using 70% isopropyl alcohol solution to speed up the drying process and reduce the number of organisms caused by rinsing with drinking water.

According to the EU Medical Device Regulation, users/patients are obligated to report any serious incident that has occurred in relation to the device to the manufacturer and the competent authority of the EU Member State in which the user/patient is established.

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COMPOSITION

100 g Descoton OPA Plus; 0,55 g ortho-phthalaldehyde

MATERIAL COMPATIBILITY

Compatible with materials when used as recommended. Not suitable for use with previously damaged instruments and endoscopes.It has been used in Pentax, Fujinon and Olympus endoscopes. It has been tested with metals commonly used in the construction of reprocessablemedical devices. Tested on ISO 5832-1 implant steel, ISO 5832-3 titanium alloy, ISO 5832-12 cobalt chromium alloy, AISI 304 stainless steel, AISI 420 B stainless steel metals.

STORAGE CONDITION

15–30°C in the original bottle should be stored in a well-ventilated middle.

REGISTRATION

Complies with 2017/745 Medical Device Regulation.

CAUTIONS

Contains ortho-phthalaldehyde. May produce an allergic reaction. Read label before use. Dispose of contents/container to in accordance with local regulation. Before the use of active substances containing ortho-phthalaldehyde, cleaning of the instruments should be done well; due to the nature of the raw material, dyeing is observed on the instruments that are not cleaned well due to the protein load. The solution must be neutralized with Glycine before disposal. (At least 30 g of glycine should be used for 5 L product) For professional use only by personnel with corresponding specialist knowledge according to national directives.

MANUFACTURER

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SPECTRUM ACTIVITY AND CONTACT TIME

SPECTRUM OF ACTIVITY AND CONTACT TIMES			1 min	5 min	15 min	30 min	3 h
Bacteri							
Bactericidal	EN 13727	clean conditions		•			
	EN 14561			•			
Mycobactericidal (M. avium ve M. terrae)	EN 14348	clean conditions			•		
	EN 14563	clean conditions		•			
Tuberculocidal (M. terrae)	EN 14348	clean conditions		•			
	EN 14563	clean conditions		•			
Yeast and Fungus							
Yeasticidal (C. albicans)	EN 13624	clean conditions		•			
	EN 14562	clean conditions		•			
Fungucidal (C. albicans, A. brasiliensis)	EN 13624	clean conditions		•			
	EN 14562	clean conditions		•			
Viruces							
Virucidal (Poliovirus, Adenovirus, MNV)	EN 14476	clean and dirty conditions		•			
Spor							
Sporcidal (B. subtilis)	EN 17126	clean conditions					•

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SYMBOLS AND EXPLANATIONS (EN ISO 15223-1:2021)

Symbol	Description
CE 0068	CE Symbol and Notified Body Number
REF	Catalog Number
LOT	Lot Number
	Expiration date
	Production Date
	Keep dry
	Keep away from sunlight
	Do not use if package is damaged and consult instructions for use
MD	Medical Device
	Caution
15°C 59°F 30°C 86°F	Temperature Limit (15 ° C- 35 °C)
	QR Code (3,78 L)
	QR Code (5 L)
UDI	Unique device identifier
	Manufacturer
	Consult instructions for use or consult electronic instructions for use

PURCHASE INFORMATION

Product	Single	Unit	Content	REF
DESCOTON OPA PLUS	Bottle	3	5 L	00-151-050E31
	Bottle	6	3,78 L	00-151-037E31

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