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RETAIN THESE INSTRUCTIONS FOR USE FOR THE WHOLE LIFE CYCLE OF THE PRODUCT AND PASS THEM ON TO ANY SUBSEQUENT HOLDER OR USER OF THE PRODUCT.

Producer: KLARO, spol. s r.o., Ke Hřišti 187, Velké Chvalovice, 289 11 Pečky, Czech Republic / www.klaro.cz

<u>Product:</u>	<u>Basic UDI-DI</u>	<u>Variant</u>	<u>Cat. no.</u>
Stainless steel infusion bottle holder	85942088381NXXDQ	Stainless steel infusion bottle holder	00081N
		Stainless steel infusion bottle holder for attaching to a trapeze bar of a bed.	00081NH
Stainless steel double infusion bottle holder	85942088381NDXBU	Stainless steel double infusion bottle holder	00081ND
		Stainless steel double infusion bottle holder for attaching to a trapeze bar of a bed.	00081NDH
Stainless steel infusion bag holder for attaching to a trapeze bar of a bed.	85942088381NSXD9	Stainless steel infusion bag holder for attaching to a trapeze bar of a bed.	00081NSH

00081N



00081NH



00081ND



00081NDH



00081NSH



The design of the holders does not allow any marks to be placed on the device. The type of variant (catalogue number) can be determined using the search engine on the KLARO website.

Classification/risk class of the medical device: class I (rule 1)

Indication, description of the medical device:

The infusion holders are intended for professional use in healthcare facilities for intravenous administration of medication by infusion therapy to patients indicated for this treatment. We offer the following variants for the use of infusion bottles (single holder for insertion of one infusion bottle, double holder for insertion of two infusion bottles) and for the use of infusion bags.

Variants 00081N, 00081ND are designed for hanging on the infusion stand.

Variants 00081NH, 00081NDH, 00081NSH are designed to be hung on the trapeze bar of a bed.




TOTAL LOAD CAPACITY of the variants 00081N, 00081NH, 00081NSH - max. 2 kg

TOTAL LOAD CAPACITY of the variants 00081ND, 00081NDH - max. 4 kg with a max. load of 2 kg on each half of the holder

Sterilisation, period of use, storage conditions, warranty period

The product is supplied in a non-sterile state and is not intended for sterilisation in a medical facility.

The product is intended for repeated use. The life cycle of the product is limited only by mechanical wear and tear or damage. For this reason, the period of use is set at 10 years from the first use; for use beyond this period, a service inspection is required.

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Storage conditions are not set.
These products are covered by a warranty period of 2 years.

Cleaning and disinfection

Wash the products with highly diluted solutions of standard disinfectants or with water and standard detergent. None of these agents shall contain abrasives.



Never use disinfectants or other substances containing chlorine or its derivatives - this applies to all parts of the product.

Wipe the surface of the product only with a damp, non-abrasive cloth or sponge. You can damage the surface of the product by mechanical stress, such as scraping and wiping with increased pressure applied by objects with sharp edges or abrasive surfaces.

Warnings, safety instructions

Use the product only in accordance with the information given in this instruction manual, particularly with the information on the purpose of use and warnings.

Do not use any damaged products.

Disinfect and clean the device regularly and as needed to prevent the initiation of the growth of pathogenic microorganisms.

Any modifications of the product are not recommended and any consequences will not be covered by the support service or product warranties.

After placing the holder on the stand / trapeze bar, make sure that the holder is hung properly and secured against falling.

For bottle holders: **After placing the infusion bottle in the bottle holder, make sure the bottle is positioned correctly and secured against falling.**

For the bag holder: **After hanging the infusion bag on the hook of the holder, make sure the bag is hung correctly and secured against falling.**

Do not exceed the set maximum load capacity of the holder - this could lead to damage to the product.

Caution




Stainless steel is the generic name used for all types of steel that are not subject to corrosion, or that are resistant to oxidation. There is a so-called passive layer on the surface that is being renewed constantly and prevents corrosion. In essence, **corrosion is a phenomenon that occurs because of partial or total damage to the passive layer.**

The main general causes that cause corrosion of stainless steel materials are:

- **The level of chlorine** - corrosion may occur at concentrations higher than 2 mg/l depending on the period of time the stainless steel material is exposed to the elevated concentration.
- **The concentration of dissolved salt** - dissolved salt, deposited on the surface of the stainless steel, prevents oxygen access and creation of a passive layer and its regeneration. Electrolysis of table salt causes irreversible damage to all stainless steel materials.
- **Change in pH** - the correct pH is 7.2 - 7.6. Any change, especially lowering the pH, causes water corrosivity and corrosion of stainless steel materials.
- **Combination of chlorine effects and ambient humidity** - the most common situation is a combination of both factors, i.e. condensation and chlorine effects.
- **Combining or contact of different materials** - formation of an electrical cell and subsequent galvanic corrosion may occur

The stainless steel (AISI304) used is resistant to water, water vapour, air humidity, edible acids and weak organic and inorganic acids. It resists weathering outside coastal areas or outside environments with higher concentration of corrosive chemicals.

Surface treatment of stainless steel parts:

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Do not use abrasive cleaners - these may damage the surface of the product mechanically.

Never use steel wool for cleaning (it may contaminate the surface with iron particles).



Never use disinfectants or other substances containing chlorine or its derivatives - this applies to all parts of the product (not just stainless-steel parts).

If stainless steel comes into contact with acids (especially in strong concentrations), the surface must be washed immediately with plenty of warm water and wiped dry.

All cleaning agents must be used in accordance with the producer's instructions. If cleaning agents are used incorrectly (e.g. at high temperature or in high concentrations) they can cause discoloration or corrosion of the surface of stainless steel of any quality.

Do not leave any items subject to corrosion (e.g. containers and tools made of uncoated carbon steel) lying on the surface. These items may corrode when in prolonged contact with the wet surface and leave hard-to-remove stains on the stainless steel or cause permanent damage to the stainless steel material.

Do not leave food or materials with an adhesive effect (e.g. fruit juices, table salt, salt water, vinegar) on surfaces for extended periods of time - these may inhibit the formation of a passive layer and cause irreversible discoloration or corrosion of the stainless steel surface.

Avoid dirt deposition on the surface - it may contain small particles of metal and rust released from other materials and may cause surface corrosion.

Resistant stains and discoloration can be removed with gentle cleaning solutions (e.g. dishwashing products) - then rinse thoroughly with clean water and wipe dry.

Traces of oil and grease can be removed with organic solvents (e.g. acetone, alcohol) - then wash thoroughly with soap and water, rinse with clean water and wipe dry.

Incipient rust and other corrosion products can be removed with oxalic acid. Prepare the cleaning solution according to the producer's instructions, apply with a cloth, leave for 15 to 20 minutes and then rinse with water. As a subsequent step dish washing liquid can be used until completely clean. Caution - deterioration of sanded or polished surfaces may occur. Then rinse thoroughly with clean water. Precautions for cleaning using acids, prescribed by the producer of the product must be followed.

Safe disposal

When disposing of the product, follow the local applicable regulations and hand over the non-functioning product to an authorised person (specialized company) for environmentally-friendly disposal, preferably for recycling or further use. The authorised person will ensure that the product is disassembled into different types of recyclable or recoverable waste. The waste produced is not considered to be hazardous waste. In the event of contamination of the product with chemicals or mixtures, follow the instructions for disposal provided by the producer of these substances.

Note to users:

Report any serious adverse event occurring in connection with the use of these products to the producer without delay, write to (e-mail): klaro@klaro.cz.

Explanation of symbols



CE mark - marking of conformity of the product according to Article 20 of Regulation 2017/745/EU on Medical Devices (MDR)



The mark "Caution" - Alerts the user to the need to consult the Instructions for use for important warnings such as cautions and precautions for use that for various reasons cannot be placed directly on the medical device.



Medical device