metpak

Gebrauchsanweisung
Druckinfusionsgerät

Instructions
Pressure infusion instrument

Mode d'emploi
Appareil de perfusion à pression

Instrucciones para el uso
Equipo de infusión a presión

Инструкция по эксплуатации
Прибор для вливания под давлением

Istruzioni
Strumento per infusione a pressione

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CE

Riester

English

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1. Introduction

1.1 Important Information Prior to Use

You have purchased a high-quality Riester product, which has been manufactured in compliance with Regulation (EU) 2017/745 and is always subject to the strictest quality controls. Read these instructions for use (IFU) carefully before using the device and keep them in a safe place. If you have any questions, we are available at any time, and our contact information is provided at the end of this IFU. The address of our sales and distribution partners can be obtained upon request. Please note all instruments described in these instructions for use should only be used by clinically trained personnel. The safe functioning of this device is only guaranteed when Riester original parts and accessories are used.

1.2 Safety symbols

Symbol	Note on symbol
	Meaning of the symbol on the outer packaging/scale: Caution: follow the instructions for use!
	Meaning of the symbol on the outer packaging: Cuffs contain natural rubber latex
	Medical device
	**Caution!** The „Caution" symbol indicates a possible dangerous situation that can lead to mild or moderate injuries. The symbol may also indicate unsafe practices.
	Date of manufacture YYYY-MM-DD / (Year-Month-Day)
	Manufacturer
	Manufacturer's serial number
	Temperature requirements for transport and storage
	Relative humidity for transport and storage
CE	CE-Mark

1.3 Packaging symbols

Symbol	Note on symbol
	Fragile. The package should be handled with care.
	Keep the package from getting wet.
	This way up. The symbol indicates the correct positioning for transporting the package.
	Keep away from sunlight
	„Green Dot" (country-specific)

1.4 Purpose
The metpak by RIESTER was made for pressure infusion of solutions and blood in plastic bags.

1.4.1 Indications
The primary area of use for pneumatic pressure infusion is in emergency situations where rapid and massive volume substitution is required; for this purpose, the infusion bag can be compressed with a pressure infusion cuff. With compression pressures of up to 300 mm Hg, infusion rates can be roughly regulated.
The arrangement of device components for pneumatic pressure infusion is similar to that of gravity infusion.
The necessary application pressure however is not provided by the hydrostatic pressure difference alone, but by additional compression of the contained infusate by means of a special pressure cuff. The infusate cuff must be designed with flexibility for this purpose, and in contrast to gravity infusion, must never be vented during operation.

The infusion rate is determined by the height of the pressure and the flow rate of the IV cannula.

1.4.2 Contraindications
Any other use or use that goes beyond the above mentioned use is not in accordance with the intended use. The manufacturer is not liable for any damage that may result from such use. The risk is borne solely by the user.

1.4.3 Intended patient population
Pressure infusion devices are intended for patients ranging from pediatric to geriatric patients.

1.4.4 Intended operator/user
The pressure infusion devices are for outpatient and inpatient care and are used by doctors in hospitals, medical institutions, clinics, and doctor's offices.

1.4.5 Required skills/operator training
The user must be a licensed physician, nurse, or similar licensed clinician.
All functions, ports and connections are clearly explained in the user manual.
The user must adhere precisely to the specifications of the user manual.

1.4.6 Environmental conditions
The device is intended for use in a controlled environment.
The device must not be exposed to any adverse/harsh environmental conditions.

1.5 Warnings / Caution


Regulate the amount of infusion via the clamp on your infusion set. Follow the manufacturer's instructions exactly.


Never exceed the maximum pressure of 300 mm Hg indicated on the manometer.


Do not connect the metpak to other pressure-generating devices.


The cuff cover must not be ironed!


Never expose the cuff to intense sunlight!


Avoid touching the cuff cover, the bulb, the pad or the tubes with pointed objects!


When using 70% isopropyl alcohol, ensure that the room is well ventilated!
Do not use in the vicinity of fire-triggering devices or fire.

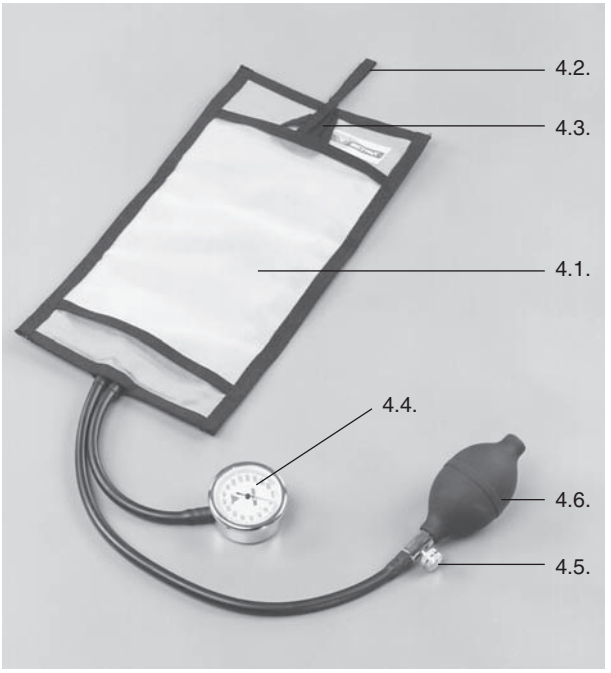

Never place the metpak pressure infusion device in liquids!


Pressure infusion devices
The metpak device is not approved for machine reprocessing and sterilization.
This will lead to irreparable damage!


All serious incidents occurring in connection with the product must be reported to the manufacturer and the competent authority of the Member State in which thethe user and/or the patient is a resident.

2. First use
2.1 Scope of delivery
Art.no. 5270 metpak for 500 ml - User manual
Art.no. 5275 metpak for 1000 ml - User manual
Art.no. 5270-536 metpak for 3000 ml - User manual
Art.no. 5270-537 metpak for 5000 ml - User manual

2.2 Device function



4.1. Cuff cover with mesh insert
4.2. Rear hanging loop
4.3. Front hanging loop
4.4. Manometer
4.5. Air release valve
4.6. Bulb

3. Operation and function
3.1 Symbol identification
mm Hg Millimetres of mercury - Unit of measurement for specifying the static pressure

3.2 Startup
Make sure you have acquired the correct metpak model and size for the infusion bags with blood or solutions you areusing (see 2.1)
Check the connection of the bulb (4.6.) with air release valve (4.5.)
(blower) to the tube.
Close the air release valve (4.5.)
Lift the mesh insert on the cuff cover.
Slide the infusion bag, with the bag opening
downwards, under the mesh insert until the
front hanging loop can be threaded through the opening on the bag.
Pull the rear hanging loop through the front hanging loop and hang the complete unit on the IV pole.
Generate the desired pressure by inflating the bulb (4.6.). You can read the values on the pressure scale on the manometer (4.4.).

3.3 Replacing the pad
Remove the bulb (4.6.) with the release valve (4.5.) from the tube.
Remove the pressure gauge from the tube.
Open the Velcro fastener on the back of the cuff cover (4.1.) by pulling on the loop
Remove the pad from the cuff cover.
Insert the new pad. Close the Velcro fastener and attach the manometer to the short tube, and the ball with air release valve to the long tube. For ease of use, moisten the tube connections with water beforehand.

4. Care instructions
4.1 General information
The cleaning and disinfection of medical devices serves to protect the patient, user, and third parties, and to maintain the integrity of the devices. Due to the product design and materials used, no defined limit of max. feasible re-processing cycles can be set. The lifespan of medical devices is determined by their safe use and careful handling. Before being returned for repair, defective products must have gone through the reprocessing procedure.

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For all reusable devices, if there are signs of material deterioration, the device should not be used and must be disposed of in accordance with the procedure described under disposal/warranty.
To avoid possible cross-contamination, devices must be cleaned and disinfected regularly.
The outside of the devices can be cleaned with a damp cloth (moistened with alcohol if necessary) until visual cleanliness is achieved. Use disinfectants (e.g. Bacillol AF by the company Bode Chemie GmbH / time 30s) only as per the manufacturer's specifications. Only disinfectants with proven effectiveness according to national guidelines should be used. After disinfection, please wipe the device with a damp cloth to remove any disinfectant residue.
Please make sure that the cloth is moistened, NOT wet, so no moisture penetrates the openings of the devices.
Make sure the glass cover is only cleaned with a dry and clean cloth.

4.2 Cleaning and disinfection
After removing the pad, the cuff cover canbe machine washed periodically but should not exceed 60 °C, (140° F) which could adversely affect the cover's life-span. After hand washing, smooth the cuff with the hand.

⚠

The cuff cover must not be ironed!
Never expose the cuff to intense sunlight!
Avoid touching the cuff cover, bulb, pad or the tubes with pointed objects!

⚠

When using 70% isopropyl alcohol, ensure that the room is well ventilated!
Do not use in the vicinity of fire-triggering devices or fire.

⚠

Never place the metpak in liquids!

⚠

The article is not approved for machine reprocessing and sterilization. This will lead to irreparable damage!

5. Technical specifications

Operating conditions:	10°C to 40°C / 50°F to 104°F with a relative humidity of 85% (non-condensing)
Storage conditions:	-20°C to 70°C / -4°F to 158°F with a relative humidity of 85% (non-condensing)
Pressure cuff:	Available for plastic bags 500 ml, 1000 ml, 3000 ml and 5000 ml
Manometer:	Chrome-plated manometer with easy-to-read Ø 49 mm
Aluminium scale:	display area 0 - 300 mm Hg in steps of 2 mm Hg

No zero point fixation
Specially hardened copper-beryllium membrane

Pressure build-up:	Via the bulb
Pressure drop:	Via the adjustable air release valve

6. Spare parts and accessories

Art.no. 11235	Pad for 500 ml
Art.no. 11236	Pad for 1000 ml
Art.no. 11235-536	Pad for 3000 ml
Art.no. 11235-537	Pad for 5000 ml
Art.no. 11237	Cuff cover for 500 ml models
Art.no. 11238	Cuff cover for 1000 ml models
Art.no. 11237-536	Cuff cover for 3000 ml models
Art.no. 11237-537	Cuff cover for 5000 ml models
Art.no. 11239	Cuff cover with pad for 500 ml models
Art.no. 11240	Cuff cover with pad for 1000 ml models
Art.no. 11239-536	Cuff cover with pad for 3000 ml models
Art.no. 11239-537	Cuff cover with pad for 5000 ml models
Art.no. 11241	Manometer
Art.no. 11242	Bulb
Art.no. 10363	Air release valve

7. Maintenance / accuracy check / calibration

The metpak and its accessories require no special maintenance. To check accuracy please remove the tube from the manometer and hold the manometer in vertical position. If the pointer stops on the zero indicator of the scale, the device is accurate / in calibration. If the pointer is outside of the zero position, you should return the device to Riester or to an authorized RIESTER dealer in your area. We are happy to provide contact information of authorized Riester dealers upon request.

8. Disposal

⚠ **Caution!**

The used medical device must be disposed of in accordance with the medical practices in place, or local regulations for disposal of infectious biological medical waste.

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Batteries and electrical/electronic equipment must bedisposed of in accordance with local regulations, not together with domestic waste.

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If you have any questions about the disposal of products, please contact the manufacturer or a manufacturer representative.

9. Warranty

This product was manufactured to the highest quality standards and subjected to a thorough final inspection before leaving our factory.
We are pleased to issue a warranty of **2 years from the date of purchase** on all defects traceable to material or manufacturing defects. A warranty claim is excluded from cases of improper handling or use.
All defective parts will be replaced or repaired free of charge within the warranty period. This excludes wear parts.
A warranty claim can only be made if the product is accompanied by this warranty card, which is filled out in full and stamped by the dealer.
Please note that warranty claims must be made within the warranty period.
We are of course happy to charge for checks or repairs after the expiry of the warranty period. We also offer free, no-obligation quotes.
In case of warranty coverage or repair, we ask you to return the RIESTER product with the completed warranty card to the following address:

Rudolf Riester GmbH
Dept. Repairs RR
Bruckstr. 31
D-72417 Jungingen
Germany

Serial number or batch number,
date, stamp and signature of the specialist dealer

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