

Calcium Line for Prismaflex – CA 250

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REF 113763

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Made in Germany

INSTRUCTION FOR USE

Calcium Line for Prismaflex – CA 250

INTENDED USE

The Calcium Line for Prismaflex is a medical device to be used only with the PrisMax Control Unit (in countries where PrisMax is cleared or registered) or with the Prismaflex Control Unit software version 5.0 or later for performing the "Citrate-calcium via internal syringe pump" anticoagulation method. Carefully read the Control unit Operator's Manual and on-line screen instructions. All treatments administered via the Calcium Line for Prismaflex must be prescribed by a physician.

CONTRAINDICATIONS AND ADVERSE REACTIONS

There are no known contraindications or adverse reactions to the use of the Calcium Line for Prismaflex if used as indicated in the intended use section above.

CAUTIONS AND WARNINGS

-  30°C
5°C The lines must be stored in a dry place, between 5°C (41°F) and 30°C (86°F).
-  Do not store in direct sunlight.
-  Expiration date of the product is shown on the packaging.
-  Do not use an individual unit if package is damaged.
- In order to reduce the risk of disease transmission, the use of protective clothing (gloves, glasses, masks, etc.) by nurses, doctors, and other medical staff is recommended when handling the Calcium Line for Prismaflex.
- Before using the Calcium Line for Prismaflex check that all caps are in place.
- The Calcium Line for Prismaflex must be used as soon as the packaging and the protective caps have been removed.
- Before starting, and also during the treatment using Calcium Line for Prismaflex, ensure that the all connections are secure.
- The minimum temperature for use is 20°C (68°F).
- The Calcium Line for Prismaflex is sterile and non-pyrogenic. Use an aseptic technique when installing the line and throughout the treatment.
- Make sure the Calcium Line for Prismaflex and the patient's vascular access are not kinked.
- Verify safe operation of the system comprising the Prismaflex or PrisMax control unit (in countries where PrisMax is cleared or registered), any accessories, and the Calcium Line for Prismaflex during set up.
- The safe connection of the Calcium Line for Prismaflex shall be performed by skilled personnel only or under the supervision of the medical officer in charge.
- Watch carefully for leaks during priming and use.
- All connections must be checked carefully throughout the treatment to prevent any misconnection, leakage or disconnection issues that could result in potential patient injuries such as blood loss, air embolism or fluid imbalance.
- During the treatment, it should be regularly checked that the line is not kinked or obstructed in order to prevent any risk of electrolytic imbalance for the patient.
- Use only drugs compatible with PVC.
-  The Calcium Line for Prismaflex is intended for single use only. Discard it after use, following local laws and regulations for potentially contaminated equipment.
- The Calcium Line for Prismaflex must not be reused in order to avoid bacteriological contamination and possible performance decrease.
- Sterility and performance of this device is guaranteed by the manufacturer only if it is intact and prepared as recommended for single use only.

OTHER SYMBOLS USED ON THE PRODUCT LABELING

	Consult Instructions For Use
	Date of Manufacture
LOT	Batch code
STERILE R	The Calcium Line for Prismaflex is sterilized by irradiation
	Do not resterilize
	Non pyrogenic fluid path

	Manufacturer
REF	Catalogue number
	The product doesn't contain latex or its derivatives
	Fragile, handle with care
	Keep dry

INSTRUCTIONS FOR USE AND RECOMMENDATIONS

 Use the Calcium Line for Prismaflex by following the detailed on-line instructions provided by the Prismaflex Control Unit or the PrisMax Control Unit (in countries where PrisMax is cleared or registered). Additional information is available in the control unit Operator's Manual.

- Unpack and remove the protective caps.
- Follow online-instruction on the Control Unit screen for the following steps:
 - Connection of the line to the syringe,
 - Automatic priming of the line by the Control Unit system,
 - Connection of the line to the patient.
- Remove eventual air bubbles before use.

 Please refer to the Control Unit Operator's Manual for more information on the "Citrate-calcium via internal syringe pump" anticoagulation method and calcium line infusion.

SPECIFICATIONS

- Line: The Calcium Line for Prismaflex is compliant with the applicable parts of the DIN EN ISO 8536 standard.

Pump line ISO 8536-9-SPL-P

- Length: **2500 mm**
- Inner diameter: **0.59 mm**
- Storage volume at 40°C (104°F): 0.7 mL

- Luer-lock connectors: Both male Luer and female Luer-lock connectors comply with the following standards: EN 20594-1 and EN 1707.

- Check valve is compliant with the applicable parts of the DIN EN ISO 8536 standard.

- Slide clamp**
- "Calcium" tags**

The materials in direct or indirect contact with blood are: Acrylonitrile Butadiene Styrene (ABS), high and low density polyethylene (HDPE, LDPE), plasticized Polyvinylchloride (PVC), acrylic-based multipolymer, silicone.

WARRANTY AND LIMITATION OF LIABILITY

- The manufacturer, Medizintechnik Promedt GmbH, warrants that the lines have been manufactured in accordance with their specifications and in compliance with DIN EN ISO 13485, and other regulatory requirements.
- Medizintechnik Promedt GmbH Quality system is working in accordance with DIN EN ISO 13485 as it is assessed by the Notified Body MEDCERT.
- The manufacturer shall not be held responsible for failure to use the lines with the dialysis machines they have been specifically designed for.
- The manufacturer shall not be liable for any misuse, improper handling, non compliance with warnings and instructions, damage arising from events after the manufacturer's release of the lines, failure or omission to inspect the lines before use in order to insure that they are in proper condition, or any warranty

given by independent distributors or dealers.

- The manufacturer is Medizintechnik Promedt GmbH, Kleiner Moorweg 4, 25436 Tornesch, Germany.

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DRAWING OF THE LINE

