PRODUCT INFORMATION **Berner Micro-Spike**



Spike with extra-long cannula for mini-vials

Scope of application and properties

- + Maximum protection: The withdrawal cannula Berner Micro-Spike was developed for use with CMR drugs such as cytostatics, virostatics, anabolics etc. and offer maximum protection in combination with easy handling.
- + Area of application: The withdrawal cannula Micro-Spike is used for non-drip multiple extraction from supply bottles (vials) and for injections.
- + Distinctive features of the Micro-Spike: Especially long cannula (stainless steel needle tubing in accordance with ISO 9626 suitable for medical devices); no particle filter (liquid filter); 0.1 μm air PTFE vent filter; Latex-, PVC- and DEHPfree; ergonomic design for optimum handling. Protective cap prevents contamination.
- + Before use: Inspect sterile blister packaging for any damage! Do not use if blister pack is damaged. We recommend disinfecting the blister pack using a sterilizing wipe before use. Single use product.
- + Application instructions: When injecting liquid do not hold the vial upside down, as it clogs the PTFE membrane and prevents pressure equalization.
- + Disposal: For use in connection with CMR¹ drugs: Waste requiring supervision (European waste code: 18 01 04 in as per 2000/532/EC); in case of heavy contamination, waste requiring special supervision (European waste code: 18 01 08* as per 2000/532/EC); separate collection and disposal!

¹⁾: Carcinogenic mutagenic reproductive toxic

Version

Order No.	126215	PU	50 pieces

- + No particle filter (liquid filter)
- + 0.1 m bacteria-free PTFE aeration and deaeration filter (aerosol filtration efficiency: 99.9999997%)
- + long stainless steel cannula (according to EN ISO 9626:1995), Ø 1.5 x 45 mm
- + Latex-, silicone oil-, PVC- and PHT/DEHP-free,
- + Housing: transparent MABS
- + Low dead volume: 0.115 ml
- + Integrated protective cap as contamination protection

CE marking & notified body

CE-marking in accordance with medical devices directive 93/42/EEC. Notified body "0482"; MEDCERT Certification and Notified Test Body for the Medicine GmbH, Pilatuspool 2, 20355 Hamburg

Quality management system

Our quality management system is tested and certified by the TÜV Product Service GmbH in accordance with DIN EN ISO 9001:2015. Regular audits and production site inspections guarantee the quality of our products.

Storage and transport conditions

Dark (protect against UV- and sun light), cool (+15 to +25°C), dry (relative humidity 30% - 60%)

Shelf life

5 years from the date of sterilisation

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Manufacturer

ROWEMED AG; Juri-Gagarin-Ring 4; D-19370 Parchim, Germany

Distributor

Berner International GmbH, Werner-von-Siemens-Str. 19, D-25337 Elmshorn, Germany

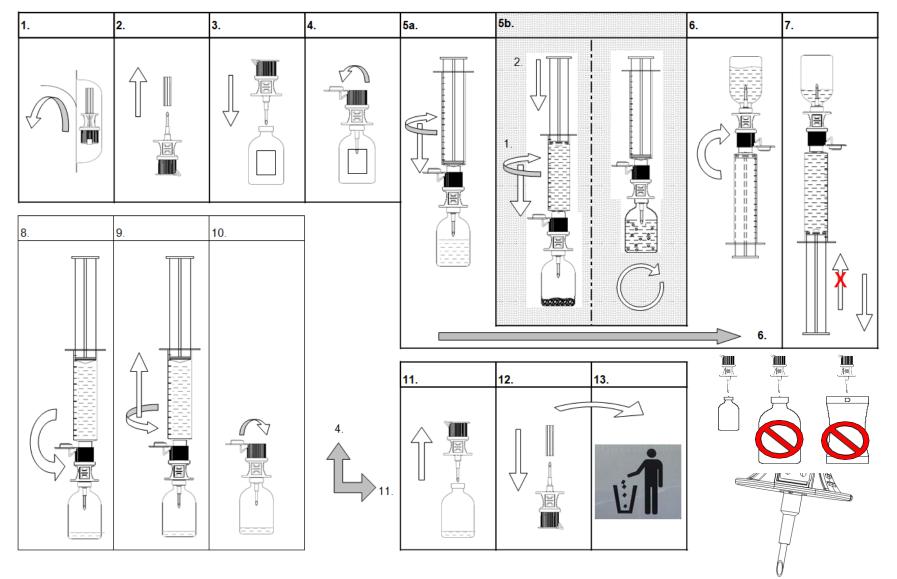
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Instruction manual



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