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 DEHP-free; 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 CMR[1)] 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: 0.2 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

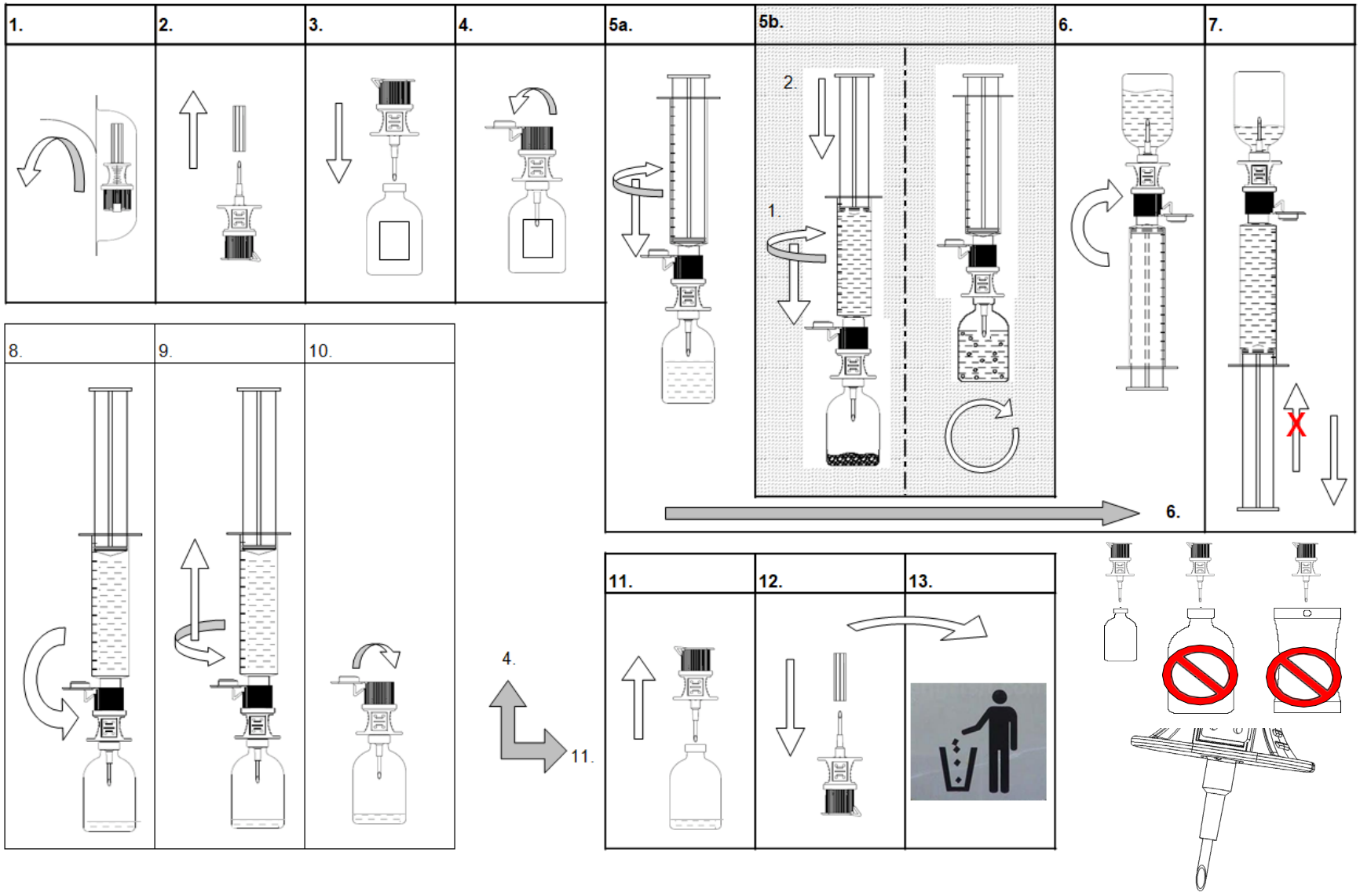
Manufacturer

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

Distributor

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

Instruction manual



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