

PRODUCT INFORMATION

Berner UltraSpike / SK / SKoF

Chemospikes with Luer-Lock and special valve



Scope of application and properties

- + **Maximum protection:** The withdrawal cannula **Berner UltraSafe** were 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 **Berner UltraSpike** is used for the non-drip multiple extraction from supply bottles (vials) and for injections. Special version **Berner UltraSpike SKoF** without particle filter for viscous substances and monoclonal antibodies - identifiable by the green cap.
- + **Distinctive features of the UltraSpike:** - Special Luer-lock-system with a valve for working efficiently and safely
- Increased contamination protection with the integrated, self-sealing valve; 5 µm liquid filter /particle filter **Berner UltraSpike SKoF** without particle filter); 0.1 µm air vent filter; latex-, PVC- and DEHP-free; ergonomic design for optimal handling.
- + **Before use:** Inspect the sterile blister packaging for any damage! Do not use, if the 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. The Halkey-Roberts-Valve must be disinfected before every syringe connection.
- + **Disposal:** For use in connection with CMR¹⁾ drugs: Waste requiring supervision (European waste code: 18 01 04 in accordance with 2000/532/EC), in case of heavy contamination waste requiring special supervision (European waste code: 18 01 08* in accordance with 2000/532/EC); separate collection and disposal!

¹⁾: Carcinogenic mutagenic reproductive toxic

Versions

Berner UltraSpike

Order No. 126211

PU

50 pieces

- + Plastic spike
- + Luer-lock connection with integrated special valve
- + Fits standard - Luer-lock syringes (prevents unintentional disconnection) and standard - Luer-syringes
- + 5 µm PET – liquid filter (particle filter) – size: 1.29 cm²
- + 0.1 µm PTFE – air vent filter – size: 0.36 cm²
- + Latex-, PVC- and DEHP-free
- + Casing: transparent MABS²⁾
- + Suitable for use with CMR-drugs (e.g. cytostatics), low dead volume 0,075 ml

²⁾: Methyl Methacrylate Acrylonitrile Butadiene Styrene

Berner UltraSpike SK

Order No. 126212

PU

50 pieces

- + Metal cannula (Stainless steel needle tubing in accordance with ISO 9626 suitable for medical devices)
- + Luer-lock connection with integrated special valve
- + Fits standard - Luer-lock syringes (prevents unintentional disconnection) and standard – Luer syringes
- + 5 µm PET – liquid filter (particle filter) – size: 1.29 cm²
- + 0.1 µm PTFE – air vent filter – size: 0.36 cm²
- + Latex-, PVC- and DEHP-free
- + Casing: transparent MABS²⁾
- + Suitable for use with CMR drugs (e.g. cytostatics), low dead volume 0,044 ml
- +

Berner UltraSpike SKoF

Order No. 126213

PU

50 pieces

- + Metal cannula (Stainless steel needle tubing in accordance with ISO 9626 suitable for medical devices)
- + Luer-lock connection with integrated special valve
- + Fits standard - Luer-lock syringes (prevents unintentional disconnection) and standard - Luer syringes
- + 0.1 µm PTFE – air vent filter – size: 0.36 cm²
- + Latex-, PVC- and DEHP-free
- + Casing: transparent MABS²⁾
- + Suitable for use with CMR drugs (e.g. cytostatics)
- + Special version without particle filter for viscous substances & monoclonal antibodies - identifiable by the green cap
- + low dead volume 0,059 ml

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-Siemens-Str. 19, D-25337 Elmshorn, Germany
