PRODUCT INFORMATION
Berner Ultraspike II
Spikes for the safe extraction of cytostatics drugs

Scope of application and properties

+ **Maximum protection:**
   The withdrawal cannulae **Berner UltraSpike II** was developed for use with CMR-drugs e.g. cytostatics, virostatics, monoclonal antibodies, etc. and offers maximum protection whilst being easy to handle.

+ **Application area:**
   The withdrawal cannulae are used for multiple extraction and injection from and into vials. Through the side opening of the liquid channel the bottles can be emptied completely, leaving virtually no residual volume. Suitable for use with viscous liquids and monoclonal antibodies, as both types are available without a particle filter - easily recognizable by the green protective cap.

+ **Before use:**
   Check sterile blister pack 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 prevents pressure equalization! Disinfect Halkey-Roberts-valve with Isopropanol (testet) before each use.

+ **Disposal:**
   For use in connection with CMR[1] 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

Version

Berner UltraSpike II

Order No.	126217	PU	50 pieces

+ Plastic spike
+ Luer-Lock-connection with integrated special valve (Halkey-Roberts)
+ Virtually complete emptying of the vial
+ Without liquid filter – therefore suitable for monoclonal antibodies and viscous liquids
+ 0.1 μm PTFE – ventilation filter for protection against aerosols
+ Latex-, PVC- and DEHP-free
+ Casing: transparent MABS[2] – resistant against cytostatics with alcohol content e.g. Paclitaxel
+ Insulin-resistant
+ Suitable for use with CMR drugs (e.g. cytostatics)
+ Low dead volume: 0,053 ml
+ This spike was specially developed for vials with a cap diameter of 20mm.

   [2]: Methyl Methacrylate Acrylonitrile Butadiene Styrene

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Product information Ultraspike II 126217.docx

Valid from: 18 September 2024

berner

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

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