

PREV





Isolator protective sleeves for cytostatics
and biological agents



Areas of application and properties

- **Maximum protection for working with isolators:** Type-tested and certificated as complex PPE¹⁾ category III; chemical protective equipment type PB [4], partial protection impermeable to liquids in coated sleeve area; elasticated cuffs at both ends; cone-shaped for optimum comfort fit; the material is latex-free, lint-free and particle-free; sterile version.
- **Area of application:** Protective sleeve covers for working with an isolator glove box (e.g. BERNER cytostatic isolator **BFS**[®] I-[MaxPro]). The protective sleeves are worn inside the isolator over the standard isolator protective sleeves. Their purpose is to protect these isolator sleeve covers from CMR medical drugs²⁾.
- **Protective barrier:** Impermeable to liquids. It can be assumed that, in accordance with EN 14126:2003, there will be a high barrier function of the coated materials against bacteria and viruses.
- **Protective properties:** Protection against all CMR drugs or chemicals cannot be guaranteed! In case of exposure to biological agents or chemicals, which do not correspond to the degree of imperviousness of the protective clothing, the isolator sleeve covers may be contaminated.
- **Directions for use:** Always wear with the coated side on the outside (Logo visible) and the seam pointing downwards. Keep away from flames and heat sources.
- **Change interval:** Daily, i.e. use up to a maximum of 8 h³⁾; in case of obvious contamination change immediately! Single use!
- **Before use:** Check for any damage! Do not use damaged sleeve covers!
- **Disposal:** Waste requiring supervision (waste code: 18 01 04 in accordance with 2000/532/EC); in case of heavy contamination, waste requiring special supervision⁵⁾ (waste code: 18 01 08^{*6)} or 18 01 03⁷⁾* in accordance with 2000/532/EC; collect and dispose of waste separately!

¹⁾: Personal protective equipment. ²⁾: Carcinogenic mutagenic reprotoxic.

³⁾: Dependent on the utilized chemicals/CMR-medical drugs or biological agents.

⁴⁾: Any waste marked with an asterisk (*) is considered as hazardous waste as listed in Article § 41 of the KrW-AbfG (German waste law).

⁵⁾: Cytotoxic and cytostatic medication.

⁶⁾: Waste, whose collection and disposal is subject to special requirements in view of prevention of infection.

Types

Size	Universal	
Dimensions	Length: ca. 80 cm Diameter: 28 cm or 12 cm	
Elasticated cuffs, Sleeve cover white		
Item No. (15 Pairs/PU)	Sterile	6451



Material





Material	Spun polypropylene fleece
Material properties	Latexfree
Material weight	65 g/m ²
Water-resistant coating	Micro-porous polyethylene
Total weight of sleeves (pair)	68 g

Protection against mechanical hazards

Mechanical properties tested in accordance with EN 14325:2004.



Requirements	Performance class															
Abrasion resistance (1-6) acc. EN 530	2															
Puncture resistance (1-5) acc. EN 863	2															
Seam resistance (1-5) acc. ISO 13935-2	3															
Flex cracking (1-6) acc. ISO 7854	4															
Trapezoidal tear strength (1-5) acc. ISO 9073-4	2															
 Protection from chemical hazards																
<p>Penetration tested to DIN EN 6530:2005. The resistance classes were determined for the following chemicals:</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Chemicals</th> <th style="text-align: center;">Penetration</th> <th style="text-align: center;">Resistance</th> </tr> </thead> <tbody> <tr> <td>Sulphuric acid 30%</td> <td style="text-align: center;">Class 3</td> <td style="text-align: center;">Class 3</td> </tr> <tr> <td>Caustic soda 10%</td> <td style="text-align: center;">Class 3</td> <td style="text-align: center;">Class 3</td> </tr> <tr> <td>Butan-1-ol, undiluted</td> <td style="text-align: center;">Class 3</td> <td style="text-align: center;">Class 2</td> </tr> <tr> <td>p-Xylol, undiluted</td> <td style="text-align: center;">Class 3</td> <td style="text-align: center;">Class 3</td> </tr> </tbody> </table>		Chemicals	Penetration	Resistance	Sulphuric acid 30%	Class 3	Class 3	Caustic soda 10%	Class 3	Class 3	Butan-1-ol, undiluted	Class 3	Class 2	p-Xylol, undiluted	Class 3	Class 3
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<p>Permeation¹⁾ tested to DIN EN 6529:2001. Performance classes were determined for the following cytostatics:</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tbody> <tr> <td style="width: 70%;">5-Fluorouracil, 10 mg/ml</td> <td style="text-align: center;">Class 4</td> </tr> <tr> <td>Cyclophosphamide, 20 mg/ml</td> <td style="text-align: center;">Class 2</td> </tr> <tr> <td>Doxorubicin, 5 mg/ml</td> <td style="text-align: center;">Class 4</td> </tr> <tr> <td>Methotrexate, 25 mg/ml</td> <td style="text-align: center;">Class 4</td> </tr> <tr> <td>Paclitaxel, 6 mg/ml</td> <td style="text-align: center;">Class 4</td> </tr> </tbody> </table>		5-Fluorouracil, 10 mg/ml	Class 4	Cyclophosphamide, 20 mg/ml	Class 2	Doxorubicin, 5 mg/ml	Class 4	Methotrexate, 25 mg/ml	Class 4	Paclitaxel, 6 mg/ml	Class 4					
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<p>¹⁾: Movement of a chemical through a material on a molecular level. The performance class does not reflect the actual duration of protection at the workplace!</p>																
 Sterilisation																
Procedure	Fumigation with ethylene oxide															
Care instructions																
Single use item: Do not wash, do not iron, do not tumble dry, do not dry clean.																
 CE-Mark																
<p>CE-Mark in accordance with the PPE-directive 89/686/EEC for complex PPE of the category III. Type test performed was based on</p> <ul style="list-style-type: none"> ▪ DIN EN 14605:2005 + A1:2009 ▪ DIN EN 340:2004 <p>Documented by the EC-type test certificate No. PS 12050048 Quality assurance (EC-quality assurance system with monitoring): Control measures (generally once a year) in accordance with Art. 11B, 89/686/EEC by the intermediary notified body, Expert Committee for PPE (0299).</p>																

Notified body „0299“	
Test and Certification body of the Expert Committee for PPE in DGUV Test, Zwengenberger Strasse 68, D-42781 Haan, Germany	
	Quality management system
Our quality management system is tested and certified by TÜV Management Service GmbH (a certification body accredited by the German Accreditation Council,) in accordance with DIN EN ISO 9001:2008. Regular audits and production site inspections guarantee the quality of our products.	
	Storage and transport conditions
<ul style="list-style-type: none"> ▪ Dark (protect from direct UV light and sunlight) ▪ Cool (+5 to +40°C) ▪ Dry ▪ No contact with pointed and/or sharp objects 	
	Shelf life
<ul style="list-style-type: none"> ▪ Sterile version: 4 years from the date of sterilisation 	
	Protection against infectious agents
Additional testing for penetration¹⁾ in accordance to EN 14126:2003:	
Resistance to wet bacterial penetration in accordance with EN ISO 22610:2006	Performance Class: 6 of 6
Resistance to penetration of bloodborne pathogens using the virus Phi-X174 in accordance to ISO 16603:2004	Performance Class: 6 of 6
Resistance to bloodborne pathogens using the virus Phi-X174 in accordance to ISO 16604:2004	Performance Class: 3 of 3
Resistance to dry bacterial penetration in accordance with ISO 22612:2005	Performance Class: 6 of 6
¹⁾ : Breakthrough of solid, liquid or gaseous material through microscopic holes (seams, faults). The performance class of the tests do not necessarily represent the actual protective duration at the workplace!	