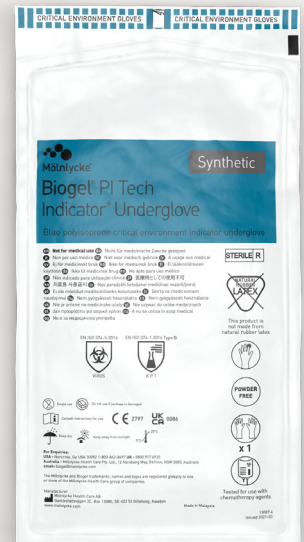


Biogel® PI Tech Indicator® Underglove

Sterile synthetic critical environment underglove



Biogel® PI Tech Indicator® Underglove is a blue, synthetic critical environment underglove made from polyisoprene. It offers excellent barrier protection as well as fit, feel and comfort¹. It can be worn alone or in combination with a Biogel® PI Tech overglove for improved protection of the goods handled as well of the operator. It has been tested and cleared for use with chemotherapy agents.



Biogel key features and benefits:

- AQL* of 0.65, determined post packaging²
- Every glove (100%) is air-inflation tested for holes typically not detected in a visual inspection³
- Low endotoxin level (<20 EU/pair)²
- PPE Category III, certified to Type B chemical permeation testing
- Total Liquid Particle Count ($\geq 0.5\mu\text{m}$): ≤ 2500 counts/cm² ⁴
- Suitable for use in aseptic and Class 100 (ISO 5) / EU GMP Grade A environments

Recommended use

The Biogel PI Tech Indicator Underglove is recommended to be used in any critical environment or controlled environment when a high quality sterile glove is required for protection from cross contamination, preferably in combination with a Biogel PI Tech overglove.

Biogel quality

Biogel gloves are designed to be comfortable with maintained tactile sensitivity when double gloving^{1,5}. They are manufactured using rigorous quality checks, numerous washing cycles² and air-inflation testing of every single glove³.

*AQL = Acceptable Quality Level refers to the maximum number of defective products that could be considered acceptable during the random sampling of an inspection, in this case freedom from holes in gloves. The lower the number, the fewer the holes and the higher the glove quality.

Material information

- Synthetic polyisoprene
- Curved finger and smooth surface
- Beaded cuff
- Powder-free
- Biogel hydrogel polymer coating

Ordering information REF 44416

REF	Size	Pairs
4441655	5½	25x2/polybag
4441660	6	25x2/polybag
4441665	6½	25x2/polybag
4441670	7	25x2/polybag
4441675	7½	25x2/polybag
4441680	8	25x2/polybag
4441685	8½	25x2/polybag
4441690	9	20x2/polybag

4 polybags per case

Biogel® PI Tech Indicator® Underglove



Biogel® PI Tech Indicator® Underglove REF 44416 – Product specifications

REF	Size	Length, mm (Tolerance +20 mm; -10 mm)	Lay flat palm width, mm (±3 mm)
4441655	5½	283	71
4441660	6	285	77
4441665	6½	285	85
4441670	7	288	91
4441675	7½	298	96
4441680	8	299	103
4441685	8½	301	109
4441690	9	301	115

Typical thickness profile – single wall		
Cuff	8.3 mils	0.21 mm
Palm	10.5 mils	0.26 mm
Finger	11.3 mils	0.28 mm

Biogel PI Tech Indicator Underglove are tested and manufactured to the following standards	
PPE Regulation	(EU) 2016/425 Category III
Particle count	IEST-RP-CC005.4: Total Liquid Particle Count (≥0.5µm): ≤ 2500 counts/cm ²
Quality/Environment	ISO 13485, ISO 14001
Product	EN 455-1, EN 455-2, EN 455-3, EN 455-4, ASTM D3577, ISO 10282, EN ISO 374-1, EN 374-2, EN 374-4, EN 16523-1, EN ISO 374-5
Sterilisation	ISO 11137, Gamma Irradiation, SAL 10 ⁻⁶ (at ≥ 25 kGy dose)
Viral penetration	Bacteriophage Test, ISO 16604, ASTM F1671
Allergenicity	ISO 10993 (Part 5 and 10)
Pyrogenicity	ASTM D7102
Labelling/ Packaging	EN 556-1, EN ISO 15223-1, EN ISO 21420

Physical glove properties	Standard requirement	Biogel PI Tech Indicator Underglove Typical value
Force at break (N)		
Initial	≥ 9	18
Aged	≥ 9	16
Tensile strength (MPa)		
Initial	≥ 17	28
Aged	≥ 12	25
Modulus stress @500% elongation (MPa)		
Initial	7.0 max	2.0
Aged	n/a	2.0
Elongation at break (%)		
Initial	≥ 650	1090
Aged	≥ 490	1060
Typical accelerator analysis (% w/w)		
Dithiocarbamate (DTC)	n/a	<0.10
Diphenyl thiourea (DPTU)	n/a	<0.03
Diphenylguanidine (DPG)	n/a	<0.25
Zinc mercaptobenzothiazole (ZMBT)	n/a	<0.10
Thiurams	n/a	none
AQL freedom from holes (1000 ml water leak test)		
ASTM D3577	1.5	0.65**
EN 455-1	0.65	
Process average (%) (Total water leak holes detected over total water leak test conducted for a year)		
	n/a	<0.20
Grip (Measure of the surface grip. Scale of 1–5, the higher the value, the greater the level of drag)		
	n/a	1.0

**post packaging

General information

Pyrogenicity: Each batch of Biogel gloves is tested to have a low endotoxin level (<20 EU/pair).

Registering authority: In Europe the gloves are CE-marked (notified body BSI, number 2797) and UKCA marked in the UK (authorised body BSI 0086) indicating compliance with PPE Regulation (EU) 2016/425.

Storage: Store in a dry place at a temperature of 5–25°C, away from sources of heat or direct sunlight.

Packaging: One pair per pack, in a high quality polyethylene inner wrap, packed into a film pack (constructed of a laminate of polyester and low-density polyethylene). 25 pairs per inner LDPE polybags for sizes 5.5 – 8.5; 20 pairs for size 9.0; 2 inner LDPE polybags are packed in an outer LDPE polybag. Four outer polybags per transit case, total of 200 pairs for sizes 5.5 – 8.5; 160 pairs for size 9.0.

References: 1. Collins J. A Clinical Evaluation of Polyisoprene Biogel Orthopaedic Surgical Gloves. Mölnlycke Health Care, 2011. Data on file. 2. Summary of Technical Documents. Mölnlycke Health Care. Data on File. 3. SOP. Automatic Glove Inspection by QMAX. Mölnlycke Health Care. Data on File. 4. Liquid particle count test report AR-21-SV-011883-01 Eurofins, 2021. 5. Fry D E et al. Influence of double-gloving on manual dexterity and tactile sensation of surgeons. J Am Coll Surg. 2010; 210(3):325-30.

Disposal: Gloves, outer wrap, inner wrap and polybags may be disposed of as clinical waste. Transit case can be recycled as paper or disposed of as clinical waste.

Shelf life: Three (3) years from date of manufacture.

Manufacturer: Made and packed in Malaysia by Mölnlycke Health Care Sdn Bhd.

Country of origin: Malaysia

E-mail address: biogel@molnlycke.com



Tested for use with chemotherapy agents

EN ISO 374-1:2016 Type B



K P T

EN ISO 374-5:2016



VIRUS

Please refer to separate permeation sheet and instructions for use for breakthrough time for chemicals and chemotherapy agents.

Find out more at www.molnlycke.com

Mölnlycke Health Care AB, Gamlestadsvägen 3C, 402 52 Göteborg, Sweden. Phone + 46 31 722 30 00. The Mölnlycke, Biogel and Indicator trademarks, names and logos are registered globally to one or more of the Mölnlycke Health Care group of companies. ©2022 Mölnlycke Health Care AB. All rights reserved. HQIM003433


Mölnlycke®