

Biogel® PI Tech

Sterile synthetic critical environment glove



Biogel® PI Tech is a synthetic critical environment glove 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 Indicator® Underglove 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
- PPE Category III, certified to Type B chemical permeation testing
- Low endotoxin level (<20 EU/pair)²
- Total Liquid Particle Count ($\geq 0.5\mu\text{m}$): ≤ 2500 counts/cm²⁴
- Suitable for use in aseptic and Class 100 (ISO 5) / EU GMP Grade A environments

Material information

- Synthetic polyisoprene
- Curved finger and smooth surface
- Anti-slip, beaded cuff
- Powder-free

Recommended use

The Biogel PI Tech 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 the Biogel PI Tech Indicator Underglove.

Biogel quality

Biogel gloves are designed to be comfortable with maintained tactile sensitivity even 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.

Ordering information REF 44409

REF	Size	Pairs
4440955	5½	25 x2 /polybag
4440960	6	25 x2 /polybag
4440965	6½	25 x2 /polybag
4440970	7	25 x2 /polybag
4440975	7½	25 x2 /polybag
4440980	8	25 x2 /polybag
4440985	8½	25 x2 /polybag
4440990	9	20 x2 /polybag

4 polybags per case

Biogel® PI Tech REF 44409 – Product specifications

REF	Size	Length, mm (Tolerance ±15mm)	Lay flat palm width mm (+ 3 mm) 5.5- (+2, -4)
4440955	5½	283	71
4440960	6	285	77
4440965	6½	285	85
4440970	7	288	91
4440975	7½	298	96
4440980	8	299	103
4440985	8½	301	109
4440990	9	301	115

Typical thickness profile – single wall

Cuff	7.9 mils	0.20 mm
Palm	9.8 mils	0.25 mm
Finger	10.6 mils	0.27 mm

Biogel PI Tech 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 Typical value
Force at break (N)		
Initial	≥ 9	19
Aged	≥ 9	15
Tensile strength (MPa)		
Initial	≥ 17	30
Aged	≥ 12	25
Modulus stress @500% elongation (MPa)		
Initial	7.0 max	2.0
Aged	n/a	2.0
Elongation at break (%)		
Initial	≥ 650	1100
Aged	≥ 490	1070
Typical accelerator analysis (% w/w)		
Dithiocarbamate (DTC)	n/a	<0.10
Diphenyl thiourea (DPTU)	n/a	<0.03
Diphenyl guanidine (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	1.5

**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-011880-01 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

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