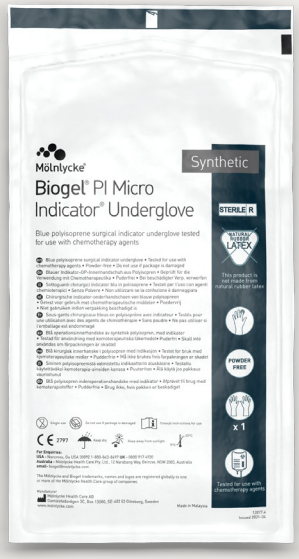
Biogel® PI Micro Indicator® Underglove

Synthetic surgical indicator underglove



Biogel® PI Micro Indicator® Underglove is a blue, synthetic surgical underglove made of polyisoprene. It can to be used with any Biogel® PI overglove to create a Biogel Puncture Indicator System proven to provide Best-in-Class puncture detection[1,2]. This underglove is 20% thinner than the regular Biogel PI Indicator® Underglove, for improved tactile sensitivity[3] even when double gloving. It has been tested and cleared for use with chemotherapy agents.

Biogel key features and benefits:

- AQL* of 0.65, determined post packaging[4]
- Every glove (100%) is air-inflation tested for holes typically not detected in a visual inspection[5]
- Clear, fast and large colour puncture indication[6]
- Low endotoxin level (<20 EU/pair) which may reduce the risk of post-operative complicaitons[4,7]
- MD (Medical Device) certified as well as PPE (Personal Protective Equipment) Category III, certified to Type B chemical permeation testing

Material information

- Synthetic polyisoprene
- Curved finger and smooth surface
- Beaded cuff
- Powder-free

Recommended use

Recommended for all surgical procedures, particularly surgeries where latex allergy is a concern for patient or clinician. We recommend it to be used as an underglove in combination with any Biogel PI overglove for improved tactile sensitivity even when double-gloving.

Biogel quality

Biogel gloves are designed to be comfortable with maintained tactile sensitivity when double gloving[4,8]. They are manufactured using rigorous quality checks, numerous washing cycles[4] and air-inflation testing of every single glove[5].

Ordering information REF 489

REF	Size	Pairs
48955	5½	50/Box
48960	6	50/Box
48965	6½	50/Box
48970	7	50/Box
48975	7½	50/Box
48980	8	50/Box
48985	8½	50/Box
48990	9	40/Box

4 boxes per case

*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.

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Biogel® PI Micro Indicator® Underglove REF 489 – Product specifications

REF	Size	Length, mm (Tolerance +20 mm; -10 mm)	Lay flat palm width, mm (±3 mm)
48955	5½	283	71
48960	6	285	77
48965	6½	285	85
48970	7	288	91
48975	7½	298	96
48980	8	299	103
48985	8½	301	109
48990	9	301	115

Typical thickness profile – single wall		
Cuff	6.3 mils	0.16 mm
Palm	7.5 mils	0.19 mm
Finger	8.3 mils	0.21 mm

Biogel PI Micro Indicator Underglove are tested and manufactured to the following standards	
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 ISO 374-2, EN ISO 374-4, EN 16523-1, EN ISO 374-5
Sterilisation	ISO 11137, sterilised using irradiation, SAL 10^{-6}
Viral penetration	Bacteriophage Test, ISO 16604, ASTM F1671
Allergenicity	ISO 10993 (Part 5 and 10)
Pyrogenicity	ASTM D7102
Labelling	EN 1041, EN 556-1, EN ISO 15223-1, EN ISO 21420
Packaging	EN ISO 11607

Physical glove properties	Standard requirement	Biogel PI Micro Indicator Underglove Typical value
Force at break (N)		
Initial	≥ 9	14
Aged	≥ 9	12
Tensile strength (MPa)		
Initial	≥17	24
Aged	≥12	25
Modulus stress @500% elongation (MPa)		
Initial	7.0 max	1.8
Aged	n/a	1.6
Elongation at break (%)		
Initial	≥ 650	1150
Aged	≥ 490	1170
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	<0.40
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) indicating compliance with Medical Device Regulation 2017/745 and also in conformity with PPE Regulation (EU) 2016/425. In the UK the gloves are UKCA marked (authorised body BSI 0086) indicating compliance with PPE Regulation (EU) 2016/425 as brought into UK Law and amended. In the USA the gloves have 510(k) clearance. They are a Class IIa product according to the Medical Device Regulation, Class III according to PPE Regulation, and Class I according to the FDA.

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 inner wrap, packed into a film pack (constructed of a laminate of polyester and low-density polyethylene). 50 pairs per collation case for sizes 5.5 – 8.5; 40 pairs for size 9.0; 200 pairs per transit case for sizes 5.5 – 8.5; 160 pairs for size 9.0.

Disposal: Gloves and outer wrap may be disposed of as clinical waste. Paper inner wrap, collation case and transit case may 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

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

References: 1. Wigmore SJ & Rainey JB. Use of coloured undergloves to detect puncture. BJS 1994: 81:1480. 2. Glove puncture detection systems. Mölnlycke Health Care, 2017. Data on file. 3. Collins J. A Clinical Investigation to Evaluate the Biogel PI Micro Surgical Glove. Mölnlycke Health Care, 2014. Data on file. 4. Summary of Technical Documents. Mölnlycke Health Care. Data on File. 5. Internal SOP. Automatic Glove Inspection by QMAX. Mölnlycke Health Care. Data on File. 6. Summary of Indication Performance of Biogel Indicator Systems versus Competitors' Double Gloving Combinations. Mölnlycke Health Care, 2020. Data on file. 7. Asplund Peiro S et al. Quantitative determination of endotoxins on surgical gloves. Journal of Hospital Infection 1990;16: 167-172. 8. 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.

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