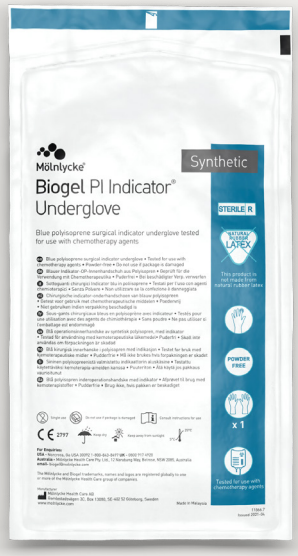
Biogel PI Indicator® Underglove

Synthetic surgical indicator underglove



Biogel PI Indicator® Underglove is a blue, synthetic polyisoprene surgical underglove. It is designed to be worn in combination with any Biogel PI overglove to create a Puncture Indicator System providing clear, fast and large coloured puncture indication[1]. It offers excellent barrier protection as well as fit, feel and comfort[2]. It has been tested and cleared for use with chemotherapy agents.

Biogel® key features and benefits:

- AQL* of 0.65, determined post packaging[3]
- Every glove (100%) is air inflation tested for holes typically not detected in a visual inspection[4]
- Low endotoxin level (<20 EU/pair) which may reduce the risk of post-operative complications[3,5]
- MD (Medical Device) certified as well as PPE (Personal Protective Equipment) Category III, certified to Type B chemical permeation testing

Material information

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

Recommended use

This is a general purpose indicator underglove suitable for a variety of surgical procedures particularly when natural rubber latex allergy is a concern for patient or clinicians. We recommended it to be worn with a Biogel PI overglove for improved protection[6] and excellent tactile sensitivity while double-gloving[2].

Biogel quality

Biogel gloves are designed to be comfortable with maintained tactile sensitivity when double gloving[2,7]. They are manufactured using rigorous quality checks, numerous washing cycles[3] and air-inflation testing of every single glove[4].

Ordering information REF 416

REF	Size	Pairs
41655	5½	50/Box
41660	6	50/Box
41665	6½	50/Box
41670	7	50/Box
41675	7½	50/Box
41680	8	50/Box
41685	8½	50/Box
41690	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 Indicator® Underglove REF 416 – Product specifications

REF	Size	Length, mm (Tolerance +20 mm; -10 mm)	Lay flat palm width, mm (±3 mm)
41655	5½	283	71
41660	6	285	77
41665	6½	285	85
41670	7	288	91
41675	7½	298	96
41680	8	299	103
41685	8½	301	109
41690	9	301	115

Typical thickness profile – single wall		
Cuff	8.3 mils	0.21 mm
Palm	10.4 mils	0.26 mm
Finger	11.0 mils	0.28 mm

Biogel PI Indicator Underglove is tested and manufactured to the following standards	
Quality/Environment	ISO 13485, ISO 14001
Product (MDD)	EN 455-1, EN 455-2, EN 455-3, EN 455-4, EN ISO 374-1, EN ISO 374-2, EN ISO 374-4, EN 16523-1, EN ISO 374-5, ASTM D3577, ISO 10282
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 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) 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 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

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

References: 1. Summary of Indication Performance of Biogel Indicator Systems versus Competitors' Double Gloving Combinations. Mölnlycke Health Care, 2020. Data on file. **2.** Collins J. J. A Clinical Evaluation of Polyisoprene Biogel Orthopaedic Surgical Gloves. Design Validation DP36_/3.6.1, Mölnlycke Health Care 2011. **3.** Summary of Technical Documents. Mölnlycke Health Care. Data on file. **4.** Internal SOP. Automatic Glove Inspection by QMAX. Mölnlycke Health Care. Data on File. **5.** Asplund Peiro S et al. Quantitative determination of endotoxins on surgical gloves. Journal of Hospital Infection 1990; 16:167-172. **6.** Tanner J, et al. Double gloving to reduce surgical cross-infection. Cochrane Database Syst Rev. 2006; 19;(3):CD003087. **7.** 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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