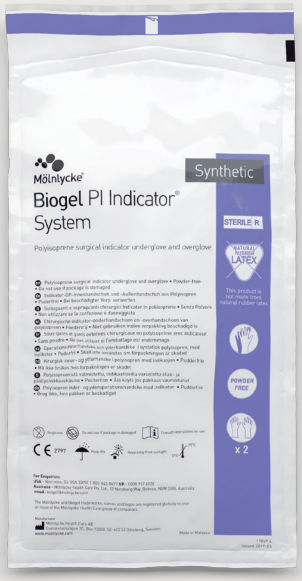
Biogel PI Indicator® System

Synthetic surgical underglove and overglove



Biogel PI Indicator® System consists of a blue synthetic surgical indicator underglove and a straw-coloured overglove, creating a Puncture Indication System proven to provide clear, fast and large coloured puncture indication[1]. It is a general purpose double-gloving system that offers excellent barrier protection as well as fit, feel and comfort[2].

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]
- Best-in-class perforation detection[5,6]
- Low endotoxin level (<20EU/pair) which may reduce the risk of post-operative complications[3,7]
- MD (Medical Device) certified as well as PPE (Personal Protective Equipment) Category III, certified to Type B chemical permeation testing

Material information

- Synthetic polyisoprene
- Biogel hydrogel polymer coating
- Curved finger and smooth surface
- Anti-slip, beaded cuff
- Powder-free

Recommended use

Biogel PI Indicator System is a general purpose puncture indication system, recommended for all surgical procedures where extra protection through double gloving is sought. It is also recommended to be used when latex allergies are a concern for the patient or clinician.

Biogel quality

Biogel gloves are designed to be comfortable with maintained tactile sensitivity when double gloving[2,8]. They are manufactured using rigorous quality checks, numerous washing cycles[3] and air-inflation testing of every single glove[4].

Ordering information REF 414

REF	Size	Pairs
41455	5½	2 x 25/Box
41460	6	2 x 25/Box
41465	6½	2 x 25/Box
41470	7	2 x 25/Box
41475	7½	2 x 25/Box
41480	8	2 x 25/Box
41485	8½	2 x 25/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.

Biogel PI Indicator® System REF 414 – Product specifications

Biogel overglove (straw)

REF	Size	Length, mm (Tolerance +20 mm; -10 mm)	Lay flat palm width, mm (±3 mm)
41455	5½	283	71
41460	6	285	77
41465	6½	285	85
41470	7	288	91
41475	7½	298	96
41480	8	299	103
41485	8½	301	109

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 underglove (blue)

REF	Size	Length, mm (Tolerance +20 mm; -10 mm)	Lay flat palm width, mm (±3 mm)
41455	6	285	77
41460	6½	285	85
41465	7	288	91
41470	7½	298	96
41475	8	299	103
41480	8½	301	109
41485	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 System 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

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.

Physical glove properties	Standard requirement	Typical value overglove	Typical value underglove
Force at break (N)			
Initial	≥ 9	19	18
Aged	≥ 9	15	16
Tensile strength (MPa)			
Initial	≥17	30	28
Aged	≥12	25	25
Modulus stress @500% elongation (MPa)			
Initial	7.0 max	2.0	2.0
Aged	n/a	2.0	2.0
Elongation at break (%)			
Initial	≥ 650	1100	1090
Aged	≥ 490	1070	1060
Typical accelerator analysis (% w/w)			
Dithiocarbamate (DTC)	n/a	<0.10	<0.10
Diphenyl thiourea (DPTU)	n/a	<0.03	<0.03
Diphenylguanidine (DPG)	n/a	<0.25	<0.25
Zinc mercaptobenzothiazole (ZMBT)	n/a	<0.10	<0.10
Thiurams	n/a	none	none
AQL freedom from holes (1000 ml water leak test)			
ASTM D3577	1.5	0.65**	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	<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	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: Two pairs per pack, in a high quality inner wrap, packed into a film pack (constructed of a laminate of polyester and low-density polyethylene). 2x25 pairs per collation case; 200 pairs per transit case.

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

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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.** Wigmore SJ & Rainey JB. Use of coloured undergloves to detect puncture. BJS 1994: 81:1480. **6.** Glove puncture detection systems. Mölnlycke Health Care, 2017. 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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