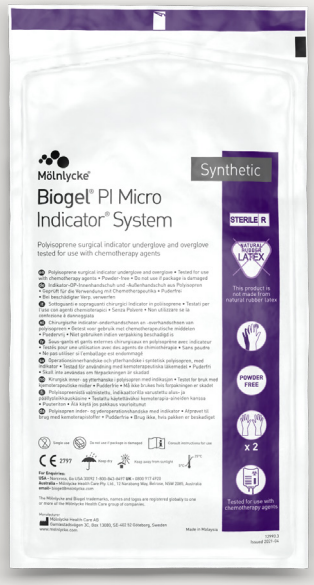
Biogel® PI Micro Indicator® System

Synthetic surgical underglove and overglove



Biogel® PI Micro Indicator® System consists of a blue, polyisporene surgical indicator underglove and a straw-coloured overglove, creating a Puncture Indicator System proven to provide clear, fast and large coloured puncture indication[1]. It is made 20% thinner than our regular synthetic gloving system for best possible tactile sensitivity[2], 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[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 (<20 EU/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
- Curved finger and smooth surface
- Anti-slip, beaded cuff
- Powder-free

Recommended use

Recommended for all surgical procedures where extra tactile sensitivity is sought even when double gloving. This Indicator system is also recommended to be used when latex allergy is a concern for patients or clinicians.

Biogel quality

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

Ordering information REF 483

REF	Size	Pairs
48355	5½	2 x 25/Box
48360	6	2 x 25/Box
48365	6½	2 x 25/Box
48370	7	2 x 25/Box
48375	7½	2 x 25/Box
48380	8	2 x 25/Box
48385	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.

Mölnlycke®

Biogel® PI Micro Indicator® System REF 483 – Product specifications

Biogel overglove (straw)

REF	Size	Length, mm (Tolerance +20 mm; -10 mm)	Lay flat palm width, mm (±3 mm)
48355	5½	283	71
48360	6	285	77
48365	6½	285	85
48370	7	288	91
48375	7½	298	96
48380	8	299	103
48385	8½	301	109

Typical thickness profile – single wall		
Cuff	6.3 mils	0.16 mm
Palm	7.7 mils	0.20 mm
Finger	8.3 mils	0.21 mm

Biogel underglove (blue)

REF	Size	Length, mm (Tolerance +20 mm; -10 mm)	Lay flat palm width, mm (±3 mm)
48355	6	285	77
48360	6½	285	85
48365	7	288	91
48370	7½	298	96
48375	8	299	103
48380	8½	301	109
48385	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 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

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	15	14
Aged	≥ 9	12	12
Tensile strength (MPa)			
Initial	≥17	29	24
Aged	≥12	23	25
Modulus stress @500% elongation (MPa)			
Initial	7.0 max	1.8	1.8
Aged	n/a	1.7	1.6
Elongation at break (%)			
Initial	≥ 650	1110	1150
Aged	≥ 490	1120	1170
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	<0.50	<0.40
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	1.5	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 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

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. A Clinical Investigation to Evaluate the Biogel PI Micro Surgical Glove. Mölnlycke Health Care, 2014. Data on file. **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.

Find out more at www.molnlycke.com

Mölnlycke®