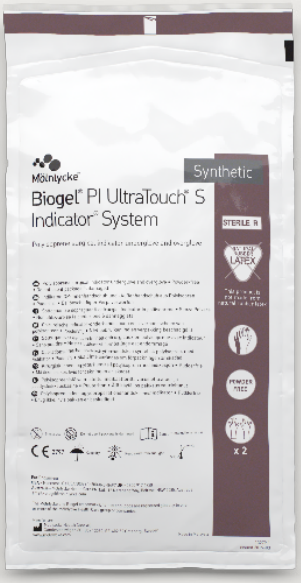
Biogel® PI UltraTouch® S Indicator® System

Synthetic surgical underglove and overglove



Biogel® PI UltraTouch® S Indicator® System consists of a blue underglove and a straw coloured overglove made from synthetic polyisoprene excluding chemical accelerators known to cause contact dermatitis, such as Thiazoles, Thiurams, Carbamates, Thioureas and Diphenylguanidine[1]. It is also manufactured without CPC (Cetylpyridinium Chloride). When worn together the two gloves create a coloured Puncture Indication System, proven to provide Best-in-Class perforation detection[2,3].

Key features and benefits:

- Manufactured without chemical accelerators known to cause contact dermatitis[1*]
- Reduced chance of a hole with an industry-leading 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]
- Low endotoxin level (<20 EU/pair), which may reduce the risk of post-operative complications[4,6]
- Clear, fast and large puncture indication[7]

Material information

- Synthetic polyisoprene
- Manufactured without accelerators* and CPC
- Biogel hydrogel polymer coating
- Curved finger and smooth surface
- Anti-slip, beaded cuff
- Powder-free

Recommended use

Recommended for all surgical procedures where extra protection through double gloving is sought. We particularly recommend to wear these gloves when allergic contact dermatitis is a concern for the clinician or when the risk of latex allergy for the patient or clinician needs to be considered.

Biogel quality

Biogel has an industry-leading freedom from holes AQL of 0.65, determined post-packaging. The industry standard requirement for AQL is 1.5. The lower the number, the fewer the holes and the higher the quality of glove. Biogel is proven to have the lowest glove failure rate among major competitors. A study showed that non-Biogel gloves are at least 3.5 times as likely to fail compared to Biogel gloves[8].

Ordering information REF 453

REF	Size	Pairs
45355	5½	2 x 25/Box
45360	6	2 x 25/Box
45365	6½	2 x 25/Box
45370	7	2 x 25/Box
45375	7½	2 x 25/Box
45380	8	2 x 25/Box
45385	8½	2 x 25/Box

4 boxes per case

*Thiazoles, Thiurams, Carbamate, Thioureas and Diphenylguanidine
**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.

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Biogel® PI UltraTouch® S Indicator® System REF 453 – Product specifications

Biogel overglove (straw)

REF	Size	Length, mm (Tolerance +20 mm; -10 mm)	Lay flat palm width, mm (±3 mm)
45355	5½	283	71
45360	6	285	77
45365	6½	285	85
45370	7	288	91
45375	7½	298	96
45380	8	299	103
48385	8½	301	109

Typical thickness profile – single wall		
Cuff	8.5 mils	0.22 mm
Palm	10.2 mils	0.26 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)
45355	6	285	77
45360	6½	285	85
45365	7	288	91
45370	7½	298	96
45375	8	299	103
45380	8½	301	109
45385	9	301	115

Typical thickness profile – single wall		
Cuff	8.3 mils	0.21 mm
Palm	10.2 mils	0.26 mm
Finger	10.4 mils	0.26 mm

Biogel PI UltraTouch S 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, EN 374-1, EN374-2, EN 374-4, EN 16523-1, EN 374-5, ASTM D3577, ISO 10282
Sterilisation	ISO 11137, Gamma Irradiation, SAL 10^{-6}
Viral penetration	Bacteriophage Test, ISO 16604
Allergenicity	ISO 10993 (Part 5 and 10)
Pyrogenicity	ASTM D7102
Labelling	EN 1041, EN 556-1, EN 15223-1, EN 420
Packaging	EN ISO 11607

Physical glove properties	Standard requirement	Typical value overglove	Typical value underglove
Force at break (N)			
Initial	≥ 9	19	18
Aged	≥ 9	18	16
Tensile strength (MPa)			
Initial	≥17	25	22
Aged	≥12	23	21
Modulus Stress @500% elongation (MPa)			
Initial	7.0 max	2.0	2.1
Aged	n/a	2.0	2.0
Elongation at break (%)			
Initial	≥ 650	1019	990
Aged	≥ 490	1023	1001
Typical accelerator analysis (% w/w)			
Dithiocarbamate (DTC)	n/a	none	none
Diphenylthiourea (DPTU)	n/a	none	none
Diphenylguanidine (DPG)	n/a	none	none
Zinc mercaptobenzothiazole (ZMBT)	n/a	none	none
Thiurams	n/a	none	none
AQL freedom from holes, (1000 ml water leak test)	1.5	0.65***	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 Council Directive 93/42/EEC, section 3.2. These gloves are in conformity with PPE Regulation (EU) 2016/425 and 93/42/EEC (Medical Devices). They are a Class IIa product according to the medical device directive and Class III according to PPE Regulation

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. Final Design Verification Report. Mölnlycke Health Care. Data on File. 2. Wigmore SJ & Rainey JB. Use of coloured undergloves to detect puncture. BJS 1994: 81:1480. 3. MHC Report, Glove puncture detection systems, GMCS-2017-098. 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. Asplund Peiro S et al. Quantitative determination of endotoxins on surgical gloves. Journal of Hospital Infection 1990; 16:167-172. 7. Evaluation of Indication Performance of Biogel Synthetic Double Gloving Combinations versus Competitors' Double Gloving Combinations. Data on file. 8. In Use Surgical Glove Failure Rate Comparison. Study G009-005. Mölnlycke Health Care 2009. Data on file.

Permeation data available on request

The actual duration of protection provided in the workplace may vary considerably from these performance levels due to other factors influencing the performance, such as temperature, abrasion and degradation.

Find out more at www.molnlycke.com

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