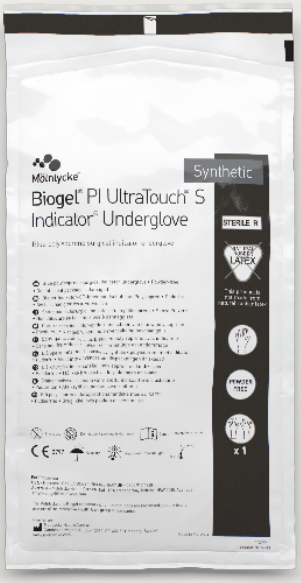
Biogel® PI UltraTouch® S Indicator® Underglove

Synthetic surgical indicator underglove



Biogel® PI UltraTouch® S Indicator® Underglove is a skin-friendly, blue surgical underglove that reduces the risk of dermatitis[1]. It is made from synthetic polyisoprene excluding chemical accelerators known to cause contact dermatitis, such as Thiazoles, Thiurams, Carbamates, Thioureas and Diphenylguanidine[2]. It is also manufactured without CPC (Cetylpyridinium Chloride). It can be used with the Biogel PI UltraTouch S overglove to create a coloured Puncture Indication System, proven to provide the fastest and largest puncture indication available[3].

Key features and benefits:

- Manufactured without chemical accelerators known to cause contact dermatitis[2*]
- Reduced risk of Type IV allergic contact dermatitis[1]
- Best-in-Class puncture detection[4,5]
- Reduced risk of a hole with an industry-leading AQL** of 0.65, determined post packaging[6]
- Every glove (100%) is air-inflation tested for holes typically not detected in a visual inspection[7]
- Low endotoxin level (<20 EU/pair), which may reduce the risk of post-operative complications[6,8]

Material information

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

Recommended use

Recommended to be used as an underglove for all surgical procedures where extra protection through double gloving is sought. We particularly recommend to wear this glove 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[9].

Ordering information REF 459

REF	Size	Pairs
45955	5½	50/Box
45960	6	50/Box
45965	6½	50/Box
45970	7	50/Box
45975	7½	50/Box
45980	8	50/Box
45985	8½	50/Box
45990	9	40/Box

4 boxes per case

*Thiazoles, Thiurams, Carbamates, 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® Underglove REF 459 – Product specifications

REF	Size	Length, mm (Tolerance +20 mm; -10 mm)	Lay flat palm width, mm (±3 mm)
45955	5½	283	71
45960	6	285	77
45965	6½	285	85
45970	7	288	91
45975	7½	298	96
45980	8	299	103
45985	8½	301	109
45990	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 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, 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	Biogel PI UltraTouch S Indicator Underglove Typical value
Force at break (N)		
Initial	≥ 9	18
Aged	≥ 9	16
Tensile strength (MPa)		
Initial	≥ 17	22
Aged	≥ 12	21
Modulus Stress @500% elongation (MPa)		
Initial	7.0 max	2.1
Aged	n/a	2.0
Elongation at break (%)		
Initial	≥ 650	990
Aged	≥ 490	1001
Typical accelerator analysis (% w/w)		
Dithiocarbamate (DTC)	n/a	none
Diphenylthiourea (DPTU)	n/a	none
Diphenylguanidine (DPG)	n/a	none
Zinc mercaptobenzothiazole (ZMBT)	n/a	none
Thiurams	n/a	none
AQL freedom from holes (1000 ml water leak test)	1.5	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 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) and have 510(k) clearance in the USA. They are a Class IIa product according to the medical device directive, Class I according to the FDA, 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: 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

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References: 1. Negative Skin Sensitization Test Using The Modified Draize-95 Test on 200 Subjects. 2019. Mölnlycke Health Care. Data on File. 2. Final Design Verification Report. Mölnlycke Health Care. Data on File. 3. Evaluation of Indication Performance of Biogel Synthetic Double Gloving Combinations versus Competitors' Double Gloving Combinations. 2019. Data on file. 4. Wigmore SJ & Rainey JB. Use of coloured undergloves to detect puncture. BJS 1994: 81:1480. 5. MHC Report, Glove puncture detection systems, GMCS-2017-098. Data on file. 6. Summary of Technical Documents. Mölnlycke Health Care. Data on File. 7. Internal SOP. Automatic Glove Inspection by QMAX. Mölnlycke Health Care. Data on File. 8. Asplund Peiro S et al. Quantitative determination of endotoxins on surgical gloves. Journal of Hospital Infection 1990; 16:167-172. 9. 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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