Synthetic Biogel® PI UltraTouch®



The Biogel PI UltraTouch sterile, synthetic surgical glove has the same great fit, feel and comfort as natural rubber latex. The Biogel coating makes the gloves easy to don, even with damp hands.



Biogel key features and benefits

- Same fit, feel and comfort as natural rubber latex
- Reduced chance of a hole with an industry-leading AQL* result of 0.651
- Every glove (100%) is air inflation tested and visually inspected for quality and safety¹

ACTUAL COLOUR REF 409

Recommended use

Recommended for all surgical procedures or surgeries where latex allergies are a concern for the patients or clinicians. It can be used alone or as part of the Biogel Puncture Indication System with the Biogel PI Indicator® Underglove.

Biogel quality

Biogel has an industry leading freedom from holes AQL* of 0.65. 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. Non-Biogel gloves are at least 3.5 times as likely to fail than Biogel gloves².

Material information

- Synthetic polyisoprene
- Biogel hydrogel polymer coating
- Micro-roughened surface
- Beaded, anti-slip cuff
- Powder-free
- Non-pyrogenic

Re-order REF 409

REF	Size	Pairs
40955	51/2	50/Box
40960	6	50/Box
40965	6 1/2	50/Box
40970	7	50/Box
40975	7 1/2	50/Box
40980	8	50/Box
40985	8 1/2	50/Box
40990	9	40/Box

4 boxes per case



Product specifications Biogel PI UltraTouch 409

REF	Size	Length, mm (Tolerance +20 mm; -10 mm)	Lay flat palm width, mm (±3 mm)
40955	5.5	283	71
40960	6.0	285	77
40965	6.5	285	85
40970	7.0	288	91
40975	7.5	298	96
40980	8.0	299	103
40985	8.5	301	109
40990	9.0	301	115

Pairs per	box:	50/	40	for	size	9
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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	

Physical glove properties	Standard requirement	Biogel
Force at break (N) (EN455) Initial Aged	≥9 ≥9	19 15
Typical accelerator analysis % w/w Dithiocarbamate (DTC)	n/a	<0.10
Diphenyl thiourea (DPTU)	n/a	<0.03
Diphenyl guanidine (DPG)	n/a	<0.25
Zinc mercaptobenzothiazole (ZMBT)	n/a	<0.05
Thiurams	n/a	none
AQL* freedom from holes (1000 ml water leak test) Post packing and irradiation Process average typically	1.5	0.65 <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

General information

Pyrogenicity: Each batch of Biogel gloves is tested to have a low endotoxin level (<20 EU/pair).

Product standards: Biogel gloves are tested and manufactured to the following standards:

- Quality/Environmental: ISO 9001, ISO 13485, ISO 14001
- Product: ASTM D3577, EN455-1, EN455-2, EN455-3, EN455-4
- Sterilisation: Gamma irradiation
- Viral Penetration: Bacteriophage test, ASTM F1671
- Allergenicity/Pyrogenicity: ISO 10993 (PART 5 and 10)

Registering authority: In Europe the gloves are CE marked (notified body BSi, number 0086) indicating compliance with Council Directive 93/42/EEC. In US the gloves are FDA registered. Biogel Surgical gloves are a Class IIa Product.

 $\textbf{Storage:} \ \text{Store in a cool, dry place away from sources of heat or direct sunlight.}$

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 & outer wrap dispose of as clinical waste. Paper inner wrap, collation case & 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: info@molnlycke.com.au

Date of issue: May 2012.

References: 1. Why Choose Biogel. MKT004. 2009. Data on file. 2. In Use Surgical Glove Failure Rate Comparison. Study G009-005. 2009. Data on file.

Find out more at www.molnlycke.com.au

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^{*}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.