Non-latex
Biogel® PI UltraTouch®

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

ACTUAL COLOUR REF 431

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 0.65[1]
- Every glove (100%) is air inflation tested and visually inspected for quality and safety[1]

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.

Material information

- Synthetic polyisoprene
- Biogel hydrogel polymer coating
- Straight finger and textured surface
- Beaded
- Powder-free
- Non-pyrogenic

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 gloves[2].

Re-order REF 431

REF	Size	Pairs
43155	5½	50/Box
43160	6	50/Box
43165	6½	50/Box
43170	7	50/Box
43175	7½	50/Box
43180	8	50/Box
43185	8½	50/Box
43190	9	40/Box

4 boxes per case

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Product specifications Biogel® PI UltraTouch® 431

REF	Size	Length, mm (Tolerance ±15 mm)	Lay flat palm width, mm (±3 mm) 5.5 - (+2 -4)
43155	5.5	280	73
43160	6.0	280	79
43165	6.5	280	85
43170	7.0	285	91
43175	7.5	285	97
43180	8.0	295	104
43185	8.5	295	108
43190	9.0	302	114

Pairs per box: 50/40 for size 9

Typical thickness profile – single wall	
Cuff	0.20 mm
Palm	0.27 mm
Finger	0.29 mm

Physical glove properties	Standard requirement	Biogel
Force at break (N) (EN455)		
Initial	≥9	16
Aged	≥9	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)	1.5	0.65
Post packing and irradiation Process average typically		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

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.

Storage: 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.

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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.

*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.

Find out more at www.molnlycke.co.uk

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