

Synthetic

● Biogel® PI Micro Indicator® Underglove



The Biogel® PI Micro Indicator® Underglove is a blue, sterile, powder-free, synthetic surgical glove that can be worn alone or with any Biogel® overglove to create a colored puncture indication system. The Biogel® Puncture Indication® System™ provides a clear, fast and large colored puncture indication.¹ Typically 20% thinner than Biogel® PI Indicator® Underglove, the Biogel PI Micro Indicator Underglove is designed for improved tactile sensitivity.



ACTUAL COLOR

Biogel® key features and benefits:

- Clear, fast and large colored puncture indication¹
- Industry-leading freedom from holes AQL* result of 0.65²
- Every glove is 100% air inflation tested and visually inspected for quality²

Recommended use

Recommended to be used as an underglove for all surgical procedures or surgeries where latex allergies are a concern for patients or clinicians. It can be worn alone or with any Biogel overglove to create a Biogel Puncture Indication System and a thinner double-gloving system.

Biogel® quality

An industry leading AQL* of 0.65 is achieved through air inflation inspection of every single surgical glove. The industry standard requirement for AQL* is 1.5, whereas our actual process average is < 0.20%. The lower the number, the fewer the holes and the higher the quality of glove. A study showed that competitive surgical gloves were at least 3.5 times as likely to fail in-use compared to Biogel gloves.³

Material information:

- Synthetic polyisoprene
- Smooth surface for ease of double-donning
- Beaded cuff
- Powder-free
- Low endotoxin level <0.5 EU/mL

Re-order #489

REF	Size	Pairs
48955	5.5	50/Box
48960	6.0	50/Box
48965	6.5	50/Box
48970	7.0	50/Box
48975	7.5	50/Box
48980	8.0	50/Box
48985	8.5	50/Box
48990	9.0	40/Box

4 boxes per case

Product Specifications: Biogel® PI Micro Indicator® Underglove #489

#	Size	Length, mm (Tolerance +20 mm; -10 mm)	Lay flat palm width, mm (±3 mm)
48955	5.5	283	71
48960	6.0	285	77
48965	6.5	285	85
48970	7.0	288	91
48975	7.5	298	96
48980	8.0	299	103
48985	8.5	301	109
48990	9.0	301	115

Pairs per box: 50/40 for size 9

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

Physical glove properties	Standard requirement	Biogel®
Force at break (N)		
Initial	≥9	12.0
Aged	≥9	10.0
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	<0.40
Thiurams	n/a	none
AQL* freedom from holes, post packing (1000 ml water leak test) 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 (<0.5 EU/mL).

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
- **Sterilization:** Gamma irradiation
- **Viral penetration:** Bacteriophage test, ASTM F1671
- **Allergenicity/pyrogenicity:** ISO 10993 (PART 5 and 10)
/US Pharmacopeia USP: (151 & 85)

Registering authority: Biogel® PI Micro Indicator® Underglove has 510(k) clearance in the USA. In Europe the gloves are CE marked (notified body BSi, number 0086) indicating compliance with Council Directive 93/42/EEC. Biogel surgical gloves are a class IIa product in the EU.

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 and outer wrap 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

Date of issue: October 2015

References: 1. MHC Study REPR0355. 2. MHC Data on file. 3. MHC Study #G09-005.

*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.us

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