

Synthetic ● Biogel PI Pro-Fit®



A synthetic, powder-free, sterile, polyisoprene, surgical glove with the fit, feel and comfort of natural latex. This sterile surgical glove is produced on a biomechanically optimized former to reduce hand and thumb fatigue during surgery.



ACTUAL COLOR

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 is air inflation tested for quality¹
- Improved efficiency as less gloves are wasted²

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 an overglove with Biogel® PI OrthoPro®.

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 the actual process average for Biogel is <math><0.20\%</math>. The lower the number, the fewer the holes and the higher the quality of glove. A study showed that non-Biogel gloves are at least 3.5 times as likely to have an in-use failure vs Biogel gloves².

Material information:

- Synthetic polyisoprene
- Biogel hydrogel polymer coating
- Micro-roughened surface
- Beaded cuff
- Powder-free

Re-order #479

#	Size	Pairs
47960	6	50/Box
47965	6½	50/Box
47970	7	50/Box
47975	7½	50/Box
47980	8	50/Box
47985	8½	50/Box
47990	9	40/Box

4 boxes per case

Product specifications Biogel® Sterile Surgical Gloves; #479

#	Size	Length, mm (Tolerance +20 mm; 10 mm)	Lay flat palm width, mm (±3 mm)
47960	6.0	295	77
47965	6.5	295	85
47970	7.0	298	91
47975	7.5	308	96
47980	8.0	309	103
47985	8.5	311	109
47990	9.0	311	115

Pairs per box: 50/40 for size 9

Typical thickness profile single wall		
Cuff	8.5 mils	0.26 mm
Palm	10.4 mils	0.27 mm
Finger	10.6 mils	0.27 mm

Physical glove properties	Standard requirement	Biogel
Force at break (N)		
Initial	≥9	17
Aged	≥9	18
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	1.5

General information

Allergenicity: Biogel gloves are produced to have low levels of water extractable protein and have been shown to have a low potential for inducing allergic contact dermatitis or 'Type IV allergy'.

Pyrogenicity: Each batch of Biogel gloves is certified to be either non-pyrogenic or to have a low endotoxin level (5 \pm) EU/glove).

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

Registering authority: In Europe the gloves are CE marked (notified body BSI, number 0086) indicating compliance with Council Directive 93/42/EEC, Annex VII and Annex V, section 3.2. 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 6.0-8.5; 40 pairs for size 9.0; 200 pairs per transit case for sizes 6.0-8.5; 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: Five (5) 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. Why Choose Biogel. MKT004. 2009. Data on file. 2. 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.com

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