Biogel PI Pro-Fit®

Synthetic surgical glove

Biogel PI Pro-Fit® is a straw-coloured synthetic surgical glove. It is made on a biomechanically optimised former with special thumb position to fit wider hands to reduce strain and ease hand and thumb fatigue during demanding surgeries[1]. The Biogel PI Pro-Fit has a longer cuff for added protection and improved glove-gown interface.

Biogel® key features and benefits:

- AQL* of 0.65, determined post packaging[2]
- Every glove (100%) is air-inflation tested for holes typically not detected in a visual inspection[3]
- Low endotoxin level (<20 EU/pair), which may reduce the risk of post-operative complications[2,4]

Material information

- Synthetic polyisoprene
- Biogel hydrogel polymer coating
- Curved finger and smooth surface
- Extra-long, beaded cuff
- Powder-free

Recommended use

Recommended for demanding, long-lasting surgeries particularly when natural rubber latex allergy is a concern for patients or clinicians. Biogel PI Pro-Fit can be worn alone or in combination with Biogel PI OrthoPro for improved protection while double-gloving.

Biogel quality

Biogel gloves are designed to be comfortable with maintained tactile sensitivity when double gloving[1,5]. They are manufactured using rigorous quality checks, numerous washing cycles[2] and air-inflation testing of every single glove[3].

Ordering information REF 479

REF	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

*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. The lower the number, the fewer the holes and the higher the glove quality.

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Biogel PI Pro-Fit® REF 479 – Product specifications

REF	Size	Length, mm (Tolerance +20 mm; -10 mm)	Lay flat palm width, mm (±3 mm)
47960	6	295	77
47965	6½	295	85
47970	7	298	91
47975	7½	308	96
47980	8	309	103
47985	8½	311	109
47990	9	311	115

Typical thickness profile – single wall		
Cuff	8.5 mils	0.22 mm
Palm	10.4 mils	0.26 mm
Finger	10.6 mils	0.27 mm

Biogel PI Pro-Fit are tested and manufactured to the following standards	
Quality/Environment	ISO 13485, ISO 14001
Product	ASTM D3577, ISO 10282, EN 455-1, EN 455-2, EN 455-3, EN 455-4
Sterilisation	ISO 11137, sterilised using irradiation, SAL 10^{-6}
Viral penetration	Bacteriophage Test, ISO 16604, ASTM F1671
Allergenicity	ISO 10993 (Part 5 and 10)
Pyrogenicity	ASTM D7102
Labelling	EN 1041, EN 556-1, EN ISO 15223-1
Packaging	EN ISO 11607

Physical glove properties	Standard requirement	Biogel PI Pro-Fit Typical value
Force at break (N)		
Initial	≥ 9	17
Aged	≥ 9	16
Tensile strength (MPa)		
Initial	≥ 17	26
Aged	≥ 12	24
Modulus Stress @500% elongation (MPa)		
Initial	7.0 max	1.7
Aged	n/a	2.0
Elongation at break (%)		
Initial	≥ 650	1060
Aged	≥ 490	1020
Typical accelerator analysis (% w/w)		
Dithiocarbamate (DTC)	n/a	<0.10
Diphenyl thiourea (DPTU)	n/a	<0.03
Diphenylguanidine (DPG)	n/a	<0.25
Zinc mercaptobenzothiazole (ZMBT)	n/a	<0.10
Thiurams	n/a	none
AQL freedom from holes (1000 ml water leak test)		
ASTM D3577	1.5	0.65**
EN 455-1	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	1.5

**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 Medical Device Regulation 2017/745. These gloves have 510(k) clearance in the USA. They are a Class IIa product according to the Medical Device Regulation and Class I according to the FDA.

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 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 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. Collins J. An Open label Evaluation of the Biogel PI ProFit Surgical Glove. CIR_BioGel_PI_ProFit_Design Validation DP35_ /3.6.1. Mölnlycke Health Care 2012. 2. Summary of Technical Documents. Mölnlycke Health Care. Data on file. 3. Internal SOP. Automatic Glove Inspection by QMAX. Mölnlycke Health Care. Data on File. 4. Asplund Peiro S et al. Quantitative determination of endotoxins on surgical gloves. Journal of Hospital Infection 1990;16:167-172. 5. Fry D E et al. Influence of double-gloving on manual dexterity and tactile sensation of surgeons. J Am Coll Surg. 2010; 210(3):325-30.

Find out more at www.molnlycke.com

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