Synthetic Biogel® PI OrthoPro®

Sterile, powder-free, synthetic polyisoprene orthopedic surgical gloves. Thicker for increased protection.

Biogel® PI OrthoPro® reduces the possibility of glove-related latex protein sensitization because it is made from a synthetic elastomer. The new glove provides fit, feel and comfort comparable to natural rubber latex.

- Made from a biomechanically optimized glove mold designed to reduce hand and thumb fatigue during surgery.
- A specialized manufacturing process enables grip and control of surgical instruments.
- Longer cuff for added protection and improved glove-gown interface.
- Brown in color to potentially reduce glare.

Biogel® PI OrthoPro® is typically 13% thicker than Biogel® PI to provide durability and extra protection during more rigorous and/or longer procedures.

Recommended for all orthopedic surgeries, where robust barrier protection is necessary or surgeries where latex allergies are a concern for patients or clinicians.

Material information

- Biogel polymer coating
- Micro-roughened surface
- Brown pigment

ACTUAL COLOR

Re-order # 476

REF	Size	Pairs
47660	6	40/Box
47665	6 ½	40/Box
47670	7	40/Box
47675	7 ½	40/Box
47680	8	40/Box
47685	8 ½	40/Box
47690	9	40/Box

4 boxes per case

Superior quality with Biogel

- Unique Biogel coating on the inner surface
  - Makes gloves easy to don even with damp hands
  - Soothes the skin to help prevent moisture loss[2]
- Beaded cuff for added security
- Every glove is air inflation tested and visually inspected for quality and safety
- Industry leading AQL freedom from holes of 0.65
- Powder-free to eliminate starch powder related complications

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Biogel Sterile Surgical Gloves; #476

PRODUCT SPECIFICATIONS

REF	Size	Length, mm (Tolerance + 20 mm; -10 mm)	Lay Flat Palm With, mm (± 3 mm)
47660	6.0	295	77
47665	6.5	295	85
47670	7.0	298	91
47675	7.5	308	96
47680	8.0	309	103
47685	8.5	311	109
47690	9.0	311	115

4 boxes per case

Typical thickness profile – single wall		
Cuff	9.8 mils	0.255 mm
Palm	12.2 mils	0.315 mm
Finger	13.8 mils	0.350 mm

Physical glove properties	Standard requirement	Biogel
Force at break (N)		
Initial	≥9	Typically 22
Aged	≥9	Typically 17
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
AQL freedom from holes (1000ml water leak test)		
Post packing and irradiation	1.5	0.65
Process average typically		<0.2%

General information

Pyrogenicity: each batch of Biogel gloves is certified to be either non-pyrogenic or 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 (20 Kgy (2.0 Mrad)), EN556, ISO 11137
- **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 by 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). 40 pairs per collation case for sizes 6.0 – 9.0; 160 pairs per transit case for sizes 6.0 – 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: biogel@molnlycke.com.

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References 1. Cochrane Review 2006. 2. Source: Testing conducted at PRAC and overseen by a board-certified dermatologist, 2004. Report 04-007. 3. Using Modified Lowry (EN455) / ASTM D5712.

Find out more at www.molnlycke.com

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