

Latex ● Biogel® Optifit® Orthopaedic



A thick, sterile, latex surgical glove, the Biogel® Optifit® Orthopaedic is 10% thicker than the Biogel® Surgeons for durability and added protection during more rigorous and/or longer procedures. With a specially treated slip-resistant surface for extra grip and control, Optifit gloves have an anatomically engineered gauntlet fit to minimise cuff roll-down and maintain glove position regardless of gown material.



Biogel® key features and benefits

- 9/10 surgeons prefer Biogel for fit, feel and comfort¹
- Reduced chance of a hole with an industry-leading AQL* result of 0.65¹
- Every glove (100%) is air inflation tested and visually inspected for quality and safety¹
- Improved efficiency as less gloves are wasted²
- Non-pyrogenic, potentially reducing the risk of post-operative complications³

ACTUAL COLOUR REF 310

Recommended use

Recommended for all orthopaedic surgeries or procedures where extra durability is important.

Material information

- Natural rubber latex
- Biogel hydrogel polymer coating
- Micro-roughened surface
- Beaded cuff
- 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 gloves².

Re-order REF 310

REF	Size	Pairs
31060	6	40/Box
31065	6 ½	40/Box
31070	7	40/Box
31075	7 ½	40/Box
31080	8	40/Box
31085	8 ½	40/Box
31090	9	40/Box

4 boxes per case

Product specifications Biogel® Optifit® Orthopaedic REF 310

REF	Size	Length, mm (Tolerance +20 mm; -10 mm)	Lay flat palm width, mm (±3 mm)
31060	6.0	285	77
31065	6.5	285	85
31070	7.0	288	91
31075	7.5	298	96
31080	8.0	299	103
31085	8.5	301	109
31090	9.0	301	115

Pairs per box: 40

Typical thickness profile – single wall		
Cuff	8.7 mils	0.22 mm
Palm	10.8 mils	0.28 mm
Finger	11.8 mils	0.30 mm

Physical glove properties	Standard requirement	Biogel
Force at break (N) (EN455)		
Initial	≥9	21
Aged	≥9	19
Typical accelerator analysis % w/w		
Dithiocarbamate (DTC)	n/a	<0.05
Diphenyl thiourea (DPTU)	n/a	none
Diphenyl guanidine (DPG)	n/a	none
Zinc mercaptobenzothiazole (ZMBT)	n/a	none
Thiurams	n/a	none
Typical extractable protein (using Modified Lowry EN455/ ASTM D5712)	<50µg/g	<50µg/g
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	3.0

General information

Contra-indications: This product contains natural rubber latex which may cause allergic reactions including anaphylactic responses.

Allergenicity: Biogel gloves are produced to have low levels of aqueous 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 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, section 3.2. In US the gloves are FDA registered. 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). 40 pairs per collation case for sizes 6–9; 160 pairs per transit case for sizes 6–9.

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@mölnlycke.com

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. 3. Biogel Endotoxin Report, Non-Pyrogenic Surgical Gloves. REPRHJV004. 2010. 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.mölnlycke.com

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