

# Latex Biogel Eclipse®



The Biogel Eclipse® is a sterile, latex surgical glove for extra tactile sensitivity. It is 30% softer than our standard surgical gloves for an improved fit, feel and comfort.



ACTUAL COLOUR REF 750

## Biogel® key features and benefits

- 9/10 surgeons prefer Biogel for fit, feel and comfort<sup>1</sup>
- Reduced chance of a hole with an industry-leading AQL\* result of 0.65<sup>1</sup>
- Every glove (100%) is air inflation tested and visually inspected for quality and safety<sup>1</sup>
- Non-pyrogenic, potentially reducing the risk of post-operative complications<sup>2</sup>

## Recommended use

Recommended for all surgical procedures, especially neurosurgery, plastics and cardiac.

## Material information

- Natural rubber latex
- Biogel hydrogel polymer coating
- Straight finger and textured surface
- Beaded, anti-slip 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 gloves<sup>3</sup>.

## Re-order REF 750

REF	Size	Pairs
75055	5½	50/Box
75060	6	50/Box
75065	6½	50/Box
75070	7	50/Box
75075	7½	50/Box
75080	8	50/Box
75085	8½	50/Box
75090	9	40/Box

4 boxes per case

## Product specifications Biogel Eclipse® REF 750

REF	Size	Length, mm (Tolerance ±15 mm)	Lay flat palm width, mm (±3 mm) 5.5 - (+2 -4)
75055	5.5	280	74
75060	6.0	280	79
75065	6.5	280	85
75070	7.0	285	90
75075	7.5	295	96
75080	8.0	295	101
75085	8.5	295	106
75090	9.0	302	114

Pairs per box: 50/40 for size 9

Typical thickness profile – single wall		
Cuff	6.5 mils	0.17 mm
Palm	8.9 mils	0.23 mm
Finger	9.6 mils	0.25 mm

Physical glove properties	Standard requirement	Biogel
<b>Force at break (N) (EN455)</b>		
Initial	≥9	14
Aged	≥9	13
<b>Typical accelerator analysis % w/w</b>		
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
<b>Typical extractable protein</b> (using Modified Lowry EN455/ ASTM D5712)	<50µg/g	<40µg/g
<b>AQL* freedom from holes</b> (1000 ml water leak test) Post packing and irradiation Process average typically	1.5	0.65 <0.20%
<b>Grip</b> (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

**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:** 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. 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 from polyolefin material which is recyclable). 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 & 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

**Date of issue:** May 2012.

References: 1. Why Choose Biogel. MKT004. 2009. Data on file. 2. Biogel Endotoxin Report. REPRHJV004. 2010. Data on file. 3. In Use Surgical Glove Failure Rate Comparison. Study G009-005. 2009. 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.molnlycke.com](http://www.molnlycke.com)

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