

# Latex

## ● Biogel Eclipse® Indicator® System



Conveniently packaged together, the sterile Biogel Eclipse Indicator System consists of a green, latex surgical glove combined with the Biogel Eclipse Overglove that, when worn together, create a coloured puncture indication system. The Biogel Eclipse Indicator System is 30% softer than the standard surgical gloves, providing additional comfort and dexterity. It has the clearest, fastest and largest coloured puncture indication available<sup>1</sup>.



### Biogel® key features and benefits

- 9 out of 10 surgeons prefer Biogel for fit, feel and comfort<sup>2</sup>
- Reduced chance of a hole with an industry-leading AQL\* result of 0.65<sup>2</sup>
- Every glove (100%) is air inflation tested and visually inspected for quality and safety<sup>2</sup>
- Clearer, faster and larger coloured puncture indication<sup>1</sup>

ACTUAL COLOUR STRAW REF 607

### Recommended use

Recommended for all surgical procedures, especially where extra tactile sensitivity is required e.g. neurosurgery, plastics and cardiac, and where glove puncture is likely, especially trauma, cardiac, transplant orthopaedic and gastrointestinal.

### 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>.

### Material information (overglove and underglove)

- Natural rubber latex
- Biogel hydrogel polymer coating
- Micro-roughened surface
- Beaded cuff
- Powder-free
- Non-pyrogenic

### Re-order REF 607

REF	Size	Pairs
60755	5½	2x25/Box
60760	6	2x25/Box
60765	6½	2x25/Box
60770	7	2x25/Box
60775	7½	2x25/Box
60780	8	2x25/Box
60785	8½	2x25/Box

4 boxes per case

# Product specifications Biogel Eclipse Indicator System REF 607

## Biogel straw (overglove)

REF	Size	Length, mm (Tolerance +20 mm; -10 mm)	Lay flat palm width, mm (±3 mm)
60755	5.5	283	71
60760	6.0	285	77
60765	6.5	285	85
60770	7.0	288	91
60775	7.5	298	96
60780	8.0	299	103
60785	8.5	301	109

Pairs per box: 2x25/Box

Typical thickness profile – single wall		
Cuff	6.7 mils	0.17 mm
Palm	8.5 mils	0.22 mm
Finger	9.4 mils	0.24 mm

## Biogel green (underglove)

REF	Size	Length, mm (Tolerance +20 mm; -10 mm)	Lay flat palm width, mm (±3 mm)
60755	6.0	285	77
60860	6.5	285	85
60765	7.0	285	91
60770	7.5	298	96
60775	8.0	299	103
60780	8.5	301	109
60785	9.0	301	115

Pairs per box: 2x25/Box

Typical thickness profile – single wall		
Cuff	6.7 mils	0.17 mm
Palm	8.5 mils	0.22 mm
Finger	9.4 mils	0.24 mm

## General information

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

**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, section 3.2. In US the gloves are FDA registered. Biogel surgical gloves are a Class IIa Product.

References: 1. REPR0704 / REPR0556 Measurement of Indication performance vs. Competitor. 2010. Data on file. 2. Why Choose Biogel. MKT004. 2009. 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.au](http://www.molnlycke.com.au)

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Physical glove properties	Standard requirement	Biogel straw (over)	Biogel green (under)
<b>Force at break (N) (EN455)</b>			
Initial	≥9	14	15
Aged	≥9	13	12
<b>Typical accelerator analysis % w/w</b>			
Dithiocarbamate (DTC)	n/a	<0.05	<0.05
Diphenyl thiourea (DPTU)	n/a	none	none
Diphenyl guanidine (DPG)	n/a	none	none
Zinc mercaptobenzothiazole (ZMBT)	n/a	none	none
Thiurams	n/a	none	none
<b>Typical extractable protein</b> (using Modified Lowry EN455/ASTM D5712)	<50µg/g	<40µg/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	0.65
<b>Grip</b> (Measure of the surface grip. Scale of 1-5, the higher the value, the greater the level of drag)	n/a	2.0	1.0

**Storage:** Store in a cool, dry place away from sources of heat or direct sunlight.

**Packaging:** Two pairs per pack, in a high quality inner wrap, packed into a film pack (constructed of a laminate of polyester and low-density polyethylene). 25x2 pairs per collation case; 100x2 pairs per transit case.

**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.

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