# Latex





Thinner for extra tactile sensitivity, the Biogel Eclipse Indicator Underglove, sterile, latex surgical gloves are 30% softer than the standard surgical gloves, for improved fit, feel and comfort. The underglove is coloured green so that it can be worn together with the Biogel Eclipse Overglove to create a coloured puncture indication system, and is proven to provide the clearest, fastest and largest coloured puncture indication available.



# 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 REF 732

### Recommended use

Recommended to be used as an underglove for all surgical procedures where glove puncture is likely, especially trauma, cardiac, transplant, orthopaedic and gastrointestinal. It can be used alone or as part of the Biogel Puncture Indication System with the Biogel Eclipse as an overglove.

### 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

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

### Re-order REF 732

REF	Size	Pairs	
73255	5 1/2	50/Box	
73260	6	50/Box	
73265	6 1/2	50/Box	
73270	7	50/Box	
73275	7 1/2	50/Box	
73280	8	50/Box	
73285	8 1/2	50/Box	
73290	9	40/Box	

4 boxes per case



# Product specifications Biogel Eclipse Indicator Underglove REF 732

REF	Size	Length, mm (Tolerance +20 mm; -10 mm)	Lay flat palm width, mm (±3 mm)
73255	5.5	283	71
73260	6.0	285	77
73265	6.5	285	85
73270	7.0	288	91
73275	7.5	298	96
73280	8.0	299	103
73285	8.5	301	109
73290	9.0	301	115

Pairs per box: 50/40 for size 9

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		

Physical glove properties	Standard requirement	Biogel
Force at break (N) (EN455) Initial Aged	≥9 ≥9	15 12
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
<b>Typical extractable protein</b> (using Modified Lowry EN455/ASTM D5712)	<50µg/g	<40µg/g
AQL* freedom from holes [1000 ml water leak test] Post packing and irradiation Process average typically	1.5	0.65
		\0.2070
Grip (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 9.5-8.5; 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:** info@molnlycke.com.au

Date of issue: May 2012.

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.

# Find out more at www.molnlycke.com.au

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<sup>\*</sup>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.