

Biogel Eclipse®

Natural rubber latex surgical glove



Biogel Eclipse® is a general purpose natural rubber latex surgical glove. It is noticeably softer than our regular natural rubber latex gloves. It can be worn alone or in combination with a Biogel Indicator Underglove to create a Puncture Indicator System proven to provide clear, fast and large coloured puncture indication¹. Biogel Eclipse offers excellent barrier protection^{2,3} as well as fit, feel and comfort⁴. It has been tested and cleared for use with chemotherapy agents.



Biogel® key features and benefits:

- AQL* of 0.65, determined post packaging⁵.
- Every glove (100%) is air inflation tested for holes typically not detected in a visual inspection⁶.
- Low endotoxin level (<20 EU/pair) which may reduce the risk of post-operative complications^{5,7}.

Recommended use

This is a general purpose glove suitable for a variety of surgical procedures when latex allergy is not a concern for patient or clinicians. We recommend it to be worn with a Biogel Indicator Underglove for improved protection and excellent tactile sensitivity while double-gloving^{4,8}.

Biogel quality

Biogel gloves are designed to be comfortable with maintained tactile sensitivity when double gloving^{4,8}. They are manufactured using rigorous quality checks, numerous washing cycles⁵ and air-inflation testing of every single glove⁶.

Material information

- Natural rubber latex
- Biogel hydrogel polymer coating
- Straight finger and textured surface
- Beaded cuff
- Powder-free



Tested for use with chemotherapy agents

Please refer to separate permeation sheet for breakthrough times.

Ordering information 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

*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. The lower the number, the fewer the holes and the higher the glove quality.

Biogel Eclipse® REF 750 – Product specifications

REF	Size	Length, mm (Tolerance ±15 mm)	Lay flat palm width, mm (±3 mm) 5.5 - (+2 -4)
75055	5½	280	74
75060	6	280	79
75065	6½	280	85
75070	7	285	90
75075	7½	285	96
75080	8	295	101
75085	8½	295	106
75090	9	302	114

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

Biogel Eclipse are tested and manufactured to the following standards	
Quality/Environment	ISO 13485, ISO 14001
Product	EN 455-1, EN 455-2, EN 455-3, EN 455-4 ASTM D3577, ISO 10282
Sterilisation	IISO 11137, sterilised using irradiation, SAL 10 ⁻⁶
Viral penetration	Bacteriophage Test, ISO 16604, ASTM F1671
Allergenicity	ISO 10993 (Part 5 and 10)
Pyrogenicity	ASTM D7102
Labelling	EN 1041, EN 556-1, EN ISO 15223-1
Packaging	EN ISO 11607

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.

Pyrogenicity: Each batch of Biogel gloves is tested to have a low endotoxin level (<20 EU/pair).

Registering authority: In Europe the gloves are CE-marked (notified body BSI, number 2797) indicating compliance with Medical Device Regulation 2017/745. They are a Class IIa product according to the Medical Device Regulation.

Storage: Store in a dry place at a temperature of 5-25°C, away from sources of heat or direct sunlight.

Physical glove properties	Standard requirement	Biogel Eclipse Typical value
Force at break (N)		
Initial	≥ 9	14
Aged	≥ 9	13
Tensile strength (MPa)		
Initial	≥ 24	28
Aged	≥ 18	25
Modulus Stress @500% elongation (MPa)		
Initial	5.5 max	2.3
Aged	n/a	1.8
Elongation at break (%)		
Initial	≥ 750	910
Aged	≥ 560	940
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 (µg/g) (using Modified Lowry EN 455-3/ ASTM D5712)		
	<50	<50
AQL freedom from holes (1000 ml water leak test)		
ASTM D3577	1.5	0.65**
EN 455-1	0.65	
Process average (%) (Total water leak holes detected over total water leak test conducted for a year)		
	n/a	<0.20
Grip (Measure of the surface grip. Scale of 1-5, the higher the value, the greater the level of drag)		
	n/a	1.0

**post packaging

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). 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 and outer wrap may be disposed of as clinical waste. Paper inner wrap, collation case and 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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References: 1. Summary of Indication Performance of Biogel Indicator Systems versus Competitors' Double Gloving Combinations. Mölnlycke Health Care, 2020. Data on file. 2. Aldiyami, Ehab; Kulkarni, Ashwin; et al. Latex-free gloves Safer for Whom?; The Journal of Arthroplasty; 2010; Vol. 25 No. 1 pp. 27-30. 3. Naver, Lars P.S.; Gottrup, Finn; Incidence of glove perforations in gastrointestinal surgery and the protective effect of double gloves: A prospective, Randomized controlled study; Eur J. Surg 2000; Vol 166 pp. 293-295. 4. Carter S, Choong S, Marino A, Selu D. Can surgical gloves be made thinner without increasing their liability to puncture? Ann R Coll Surg Engl. 1996 May;78(3 [Pt 1]):186-7. 5. Summary of Technical Documents. Mölnlycke Health Care. Data on file. 6. Internal SOP. Automatic Glove Inspection by QMAX. Mölnlycke Health Care. Data on File. 7. Asplund Peiro S et al. Quantitative determination of endotoxins on surgical gloves. Journal of Hospital Infection 1990; 16:167-172. 8. Fry D E et al. Influence of double-gloving on manual dexterity and tactile sensation of surgeons. J Am Coll Surg. 2010; 210(3):325-30.

Find out more at www.molnlycke.com

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