

Biogel Eclipse® Reveal® System

Natural rubber latex surgical
underglove and overglove



Biogel Eclipse® Reveal® System consists of a green natural rubber latex indicator underglove and a straw-coloured overglove, creating a Puncture Indicator System proven to provide clear, fast and large coloured puncture indication¹. It is noticeably softer than our regular natural rubber latex gloves and offers excellent barrier protection^{2,3} as well as fit, feel and comfort⁴.



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
- Best-in-Class puncture detection^{7,8}
- Low endotoxin level (<20 EU/pair) which may reduce the risk of post-operative complications^{5,9}

Material information

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

Recommended use

This is a general purpose Puncture Indication System recommended for all surgical procedures when latex allergy is not a concern for patients or clinicians. We recommend you to use this indicator system for improved protection and excellent tactile sensitivity²⁻⁴ while double-gloving.

Biogel quality

Biogel gloves are designed to be comfortable with maintained tactile sensitivity when double gloving^{4,10}. They are manufactured using rigorous quality checks, numerous washing cycles⁵ and air-inflation testing of every single glove⁶.

Ordering information REF 608

REF	Size	Pairs
60855	5½	2x25/Box
60860	6	2x25/Box
60865	6½	2x25/Box
60870	7	2x25/Box
60875	7½	2x25/Box
60880	8	2x25/Box
60885	8½	2x25/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.

Product specifications Biogel Eclipse® Reveal® System REF 608

Biogel overglove (straw)

REF	Size	Length, mm (Tolerance ±15 mm)	Lay flat palm width, mm (±3mm) 5.5 - (+2, -4)
60855	5½	280	74
60860	6	280	79
60865	6½	280	85
60870	7	285	90
60875	7½	285	96
60880	8	295	101
60885	8½	295	106

Typical thickness profile – single wall

Cuff	6.5mils	0.17 mm
Palm	8.9mils	0.23 mm
Finger	9.6mils	0.25 mm

Biogel underglove (green)

REF	Size	Length, mm (Tolerance ±15 mm)	Lay flat palm width, mm (±3 mm) 5.5 (+2,-4 mm)
60855	6	280	79
60860	6½	280	85
60865	7	285	90
60870	7½	285	96
60875	8	295	101
60880	8½	295	106
60885	9	302	114

Typical thickness profile – single wall

Cuff	6.5mils	0.17 mm
Palm	8.9mils	0.23 mm
Finger	9.6mils	0.25 mm

Biogel Eclipse Reveal System 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	ISO 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

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, Sellu 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. Wigmore SJ & Rainey JB. Use of coloured undergloves to detect puncture. BJS 1994; 81: 1480. 8. MHC Report, Glove puncture detection systems, GMCS-2017-098. Data on file. 9. Asplund Peiro S et al. Quantitative determination of endotoxins on surgical gloves. Journal of Hospital Infection 1990; 16:167-172. 10. 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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Physical glove properties	Standard requirement	Typical value overglove	Typical value underglove
Force at break (N)			
Initial	≥ 9	14	14
Aged	≥ 9	13	12
Tensile strength (MPa)			
Initial	≥ 24	28	27
Aged	≥ 18	25	24
Modulus Stress @500% elongation (MPa)			
Initial	5.5 max	2.3	2.3
Aged	n/a	1.8	1.8
Elongation at break (%)			
Initial	≥ 750	910	910
Aged	≥ 560	940	950
Typical accelerator analysis (% w/w)			
Dithiocarbamate (DTC)	n/a	<0.05	<0.05
Diphenyl thiourea (DPTU)	n/a	none	none
Diphenylguanidine (DPG)	n/a	none	none
Zinc mercaptobenzothiazole (ZMBT)	n/a	none	none
Thiurams	n/a	none	none
Typical extractable protein (µg/g) (using Modified Lowry EN 455-3/ ASTM D5712)			
	< 50	< 50	< 50
AQL freedom from holes (1000 ml water leak test)			
ASTM D3577	1.5	0.65**	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	<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	1.0

**post packaging

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.

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). 2x25 pairs per collation case; 200 pairs per transit case.

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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