Biogel Eclipse® Indicator® Underglove

Natural rubber latex indicator underglove

Biogel Eclipse® Indicator® Underglove is a green natural rubber latex surgical indicator underglove. It is meant to be worn as an underglove in combination with a Biogel Eclipse® overglove to create a Puncture Indicator System providing clear, fast and large coloured puncture indication[1]. It is noticeably softer than our regular natural rubber latex gloves offering excellent barrier protection[2,3] as well as fit, feel and comfort[4]. It has been tested and cleared for use with chemotherapy agents.

Biogel® key features and benefits:

- AQL* of 0.65, determined post packaging[5]
- Every glove (100%) is air inflation tested for holes typically not detected in a visual inspection[6]
- Low endotoxin level (<20 EU/pair) which may reduce the risk of post-operative complications[5,7]

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.

Recommended use

This is a general purpose underglove suitable for a variety of surgical procedures when latex allergy is not a concern for patients or clinicians. We recommended it to be worn in combination with a Biogel overglove for improved protection and excellent tactile sensitivity while double-gloving[2-4].

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 cycles[5] and air-inflation testing of every single glove[6].

Ordering information REF 609

REF	Size	Pairs
60955	5½	50/Box
60960	6	50/Box
60965	6½	50/Box
60970	7	50/Box
60975	7½	50/Box
60980	8	50/Box
60985	8½	50/Box
60990	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.

Product specifications Biogel Eclipse® Indicator® Underglove REF 609

REF	Size	Length, mm (Tolerance ±15 mm)	Lay flat palm width, mm (±3 mm) 5.5 - (+2, -4)
60955	5½	280	74
60960	6	280	79
60965	6½	280	85
60970	7	285	90
60975	7½	285	96
60980	8	295	101
60985	8½	295	106
60990	9	302	114

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

Biogel Eclipse Indicator Underglove 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

Physical glove properties	Standard requirement	Biogel Eclipse Indicator Underglove Typical value
Force at break (N)		
Initial	≥ 9	14
Aged	≥ 9	12
Tensile strength (MPa)		
Initial	≥ 24	27
Aged	≥ 18	24
Modulus Stress @500% elongation (MPa)		
Initial	5.5 max	2.3
Aged	n/a	1.8
Elongation at break (%)		
Initial	≥ 750	910
Aged	≥ 560	950
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

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: 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. Aldlyami, 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. 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.

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