Biogel® M

Natural rubber latex surgical glove with extra grip

Industry leading AQL* of 0.40, determined post packaging[1]

Low endotoxin level (<20 EU/pair) which may reduce the risk of post-operative complications[1,3]

Every glove (100%) is air-inflation tested for holes typically not detected in a visual inspection[2]

Excellent barrier protection

Biogel® M is a general purpose surgical glove made from natural rubber latex. It offers excellent barrier protection[4,5] as well as fit, feel and comfort[6]. Biogel M is designed with extra grip for enhanced surface control. It can be worn alone or in combination with a Biogel® Indicator® Underglove to create a Puncture Indicator System proven to provide Best-in-Class perforation detection[7,8].

Biogel quality

Biogel gloves are designed to be comfortable with maintained tactile sensitivity when double gloving[6,9]. They are manufactured using rigorous quality checks, numerous washing cycles[1] and air-inflation testing of every single glove[2].

Recommended use

This is a general purpose glove suitable for a variety of surgical procedures particularly when extra grip is needed and when latex allergy is not a concern for patients or clinicians. We recommend it to be worn with a Biogel Indicator Underglove for improved protection[10] and excellent tactile sensitivity while double-gloving[6,9].

* 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.

Mölnlycke®

Material information

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

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. In the UK the gloves are UKCA marked (authorized body BSI 0086) indicating compliance with the provisions of the Medical Device Regulation 2002 (S1618) as subsequently amended by the EU Exit Regulations of 2019 (SI 791) and 2020 (SI 1478). These gloves have 510(k) clearance in the USA. They are a Class IIa product according to the Medical Device Regulation and Class I according to the FDA.

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
E-mail address: biogel@molnlycke.com

Biogel® M REF 305 – Product specifications and order information

Product number	Size	Length, mm (Tolerance ±15mm)	Lay flat palm width, mm (±3mm) 5.5 (+2,-4)	Pairs
30555	5½	280	74	50/Box
30560	6	280	79	50/Box
30565	6½	280	85	50/Box
30570	7	285	90	50/Box
30575	7.5	285	96	50/Box
30580	8	295	101	50/Box
30585	8.5	295	106	50/Box
30590	9	302	114	40/Box

4 boxes per case

Typical thickness profile – single wall

Cuff	8.1 mils	0.21 mm
Palm	10.0 mils	0.26 mm
Finger	11.0 mils	0.28 mm

Biogel M are tested and manufactured to the following standards

Quality/Environment	ISO 13485, ISO 14001
Product	ASTM D3577, EN 455-1, EN 455-2, EN 455-3, EN 455-4, ISO 10282
Sterilization	ISO 11137, sterilized 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 M Typical value
Force at break (N)		
Initial	≥ 9	19
Aged	≥ 9	18
Tensile strength (MPa)		
Initial	≥ 24	30
Aged	≥ 18	29
Modulus Stress @500% elongation (MPa)		
Initial	5.5 max	3.0
Aged	n/a	2.8
Elongation at break (%)		
Initial	≥ 750	910
Aged	≥ 560	930
Typical accelerator analysis (% w/w)		
Dithiocarbamate (DTC)	n/a	<0.02
Diphenyl thiourea (DPTU)	n/a	none
Diphenylguanidine (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	0.40*
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	2.0

*post packaging

References:
1. Summary of Technical Documents. Mölnlycke Health Care. Data on file. **2.** Internal SOP. Automatic Glove Inspection by QMAX. Mölnlycke Health Care. Data on File. **3.** Asplund Peiro S et al. Quantitative determination of endotoxins on surgical gloves. Journal of Hospital Infection 1990; 16:167-172. **4.** Aldlyami, Ehab; Kulkarni, Ashwin; et al. Latex-free gloves Safer for Whom?; The Journal of Arthroplasty; 2010; Vol. 25 No. 1 pp. 27-30. **5.** 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. **6.** 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. **7.** Wigmore SJ & Rainey JB. Use of coloured undergloves to detect puncture. BJS 1994; 81:1480. **8.** Glove puncture detection systems. Mölnlycke Health Care, 2017. Data on file. **9.** 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. **10.** Tanner J, et al. Double gloving to reduce surgical cross-infection. Cochrane Database Syst Rev. 2006; 19;(3):CD003087.

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