Biogel® Surgeons

Natural rubber latex surgical glove

Tested for use with chemotherapy agents

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

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

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

Excellent barrier protection

Biogel® Surgeons is a durable general purpose glove that offers excellent barrier protection[4,5] as well as fit, feel and comfort[6]. You can use it alone or in combination with a Biogel® Indicator® Underglove to create a Puncture Indication System with Best-in-Class puncture detection[7,8]. It has been tested and cleared for use with chemotherapy agents**.

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

Recommended for all general surgical procedures where latex allergy is not a concern.

* 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.

** Please refer to separate permeation sheet for breakthrough times.

Mölnlycke®

Material information

- Natural rubber latex
- Biogel hydrogel polymer coating
- Curved finger and smooth 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 from 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 may 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® Surgeons REF 304 – Product specifications and order information

Product number	Size	Length, mm (Tolerance +20 mm; -10 mm)	Lay flat palm width, mm (±3 mm)	Pairs
30455	5½	283	71	50/Box
30460	6	285	77	50/Box
30465	6½	285	85	50/Box
30470	7	288	91	50/Box
30475	7.5	298	96	50/Box
30480	8	299	103	50/Box
30485	8.5	301	109	50/Box
30490	9	301	115	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	10.6 mils	0.27 mm

Biogel Surgeons 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
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 Surgeons Typical value
Force at break (N)		
Initial	≥ 9	19
Aged	≥ 9	17
Tensile strength (MPa)		
Initial	≥ 24	30
Aged	≥ 18	28
Modulus Stress @500% elongation (MPa)		
Initial	5.5 max	3.3
Aged	n/a	3.0
Elongation at break (%)		
Initial	≥ 750	890
Aged	≥ 560	900
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	1.0

*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.

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