Biogel® Surgeons

Natural rubber latex surgical glove

Biogel® Surgeons is a durable general purpose glove that offers excellent barrier protection[1,2] as well as fit, feel and comfort[3]. 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[4,5]. It has been tested and cleared for use with chemotherapy agents.

Biogel® key features and benefits:

- AQL* result of 0.65, determined post packaging[6]
- Every glove (100%) is air-inflation tested for holes typically not detected in a visual inspection[7]
- Low endotoxin level (<20 EU/pair) which may reduce the risk of post-operative complications[6,8]
- MD (Medical Device) certified as well as PPE (Personal Protective Equipment) Category III, certified to Type C chemical permeation testing

Material information

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

Recommended use

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

Biogel quality

Biogel gloves are designed to be comfortable with maintained tactile sensitivity when double gloving[3,9]. They are manufactured using rigorous quality checks, numerous washing cycles[6] and air-inflation testing of every single glove[7].

Ordering information REF 961

REF	Size	Pairs
96155	5½	50/Box
96160	6	50/Box
96165	6½	50/Box
96170	7	50/Box
96175	7½	50/Box
96180	8	50/Box
96185	8½	50/Box
96190	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.

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Biogel® Surgeons REF 961 – Product specifications

REF	Size	Length, mm (Tolerance ±15mm)	Lay flat palm width, mm (±3 mm) 5.5-(+2,-4)
96155	5½	280	74
96160	6	280	79
96165	6½	280	85
96170	7	285	90
96175	7½	285	96
96180	8	295	101
96185	8½	295	106
96190	9	302	114

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 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 , EN ISO 374-1, EN ISO 374-2, EN ISO 374-4, EN 16523-1, EN ISO 374-5
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, EN ISO 21420
Packaging	EN ISO 11607

Physical glove properties	Standard requirement	Biogel Surgeons Typical value
Force at break (N)		
Initial	≥9	17
Aged	≥ 9	16
Tensile strength (MPa)		
Initial	≥ 24	28
Aged	≥ 18	26
Modulus stress @500% elongation (MPa)		
Initial	5.5 max	3.0
Aged	n/a	2.6
Elongation at break (%)		
Initial	≥ 750	910
Aged	≥ 560	960
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	0.65**
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	1.5

**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 and also in conformity with PPE Regulation (EU) 2016/425. In the UK the gloves are UKCA marked (authorised body BSI 0086) indicating compliance with PPE Regulation (EU) 2016/425 as brought into UK Law and amended. They are a Class IIa product according to the Medical Device Regulation and Class III according to PPE 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 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


Tested for use with chemotherapy agents

Please refer to separate permeation sheet and instructions for use for breakthrough time for chemicals and chemotherapy agents.

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