Biogel® Skinsense®

Synthetic surgical glove

Biogel® Skinsense® is a synthetic surgical glove made from polychloroprene (non-natural rubber latex). It can be worn alone or in combination with the Biogel® Skinsense® Indicator® Underglove to create a Puncture Indicator System. It has been tested and cleared for use with chemotherapy agents.

Biogel® key features and benefits:

- Every glove (100%) is air-inflation tested for holes typically not detected in a visual inspection[1]
- AQL* of 0.65, determined post packaging[2]
- Low endotoxin level (<20 EU/pair), which may reduce the risk of post-operative complications[2,3]
- MD (Medical Device) certified as well as PPE (Personal Protective Equipment) Category III, certified to Type A chemical permeation testing

Material information

- Synthetic polychloroprene
- Biogel hydrogel polymer coating
- Curved finger and smooth surface
- Beaded cuff
- Powder-free

Recommended use

Recommended for all general surgeries, especially when latex allergies are a concern for patients or clinicians or when a longer chemical breakthrough time (BTT) is desired. We always recommend to double-glove with the Biogel Skinsense Indicator Underglove in the presence of chemicals, cytotoxic agents and bone cement.

Biogel quality

Biogel gloves are designed to be comfortable with maintained tactile sensitivity when double gloving[4,5]. They are manufactured using rigorous quality checks, numerous washing cycle[2] and air-inflation testing of every single glove[1].

Ordering information REF 509

REF	Size	Pairs
50955	5½	50/Box
50960	6	50/Box
50965	6½	50/Box
50970	7	50/Box
50975	7½	50/Box
50980	8	50/Box
50985	8½	50/Box
50990	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® Skinsense® REF 509 – Product specifications

REF	Size	Length, mm (Tolerance +20 mm; -10 mm)	Lay flat palm width, mm (±3 mm)
50955	5½	283	71
50960	6	285	77
50965	6½	285	85
50970	7	288	91
50975	7½	298	96
50980	8	299	103
50985	8½	301	109
50990	9	301	115

Typical thickness profile – single wall		
Cuff	6.7 mils	0.17 mm
Palm	7.5 mils	0.19 mm
Finger	8.3 mils	0.21 mm

Biogel Skinsense 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 Skinsense Typical value
Force at break (N)		
Initial	≥ 9	12
Aged	≥ 9	14
Tensile strength (MPa)		
Initial	≥ 17	21
Aged	≥ 12	28
Modulus stress @500% elongation (MPa)		
Initial	7.0 max	2.0
Aged	n/a	2.7
Elongation at break (%)		
Initial	≥ 650	1040
Aged	≥ 490	890
Typical accelerator analysis (% w/w)		
Dithiocarbamate (DTC)	n/a	Below detection limit
Diphenyl thiourea (DPTU)	n/a	<0.25
Diphenylguanidine (DPG)	n/a	<0.07
Zinc mercaptobenzothiazole (ZMBT)	n/a	none
Thiurams	n/a	none
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

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 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


Tested for use with chemotherapy agents

EN ISO 374-1:2016 Type A


K L M N P T

EN ISO 374-5:2016


VIRUS

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

References: **1.** Internal SOP. Automatic Glove Inspection by QMAX. Mölnlycke Health Care. Data on file. **2.** Summary of Technical Documents. 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.** Gottrup F, Müller K, Bergmark S, Nørregaard S. Powder-free, non sterile gloves assessed in a wound healing centre. Eur J Surg. 2001 Aug;167(8):625-7. **5.** 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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