Biogel® Neoderm®

Synthetic surgical glove

Biogel® Neoderm® is a synthetic surgical glove made of polychloroprene. It is manufactured without chemical accelerators known to cause contact dermatitis, such as Thiazoles, Thiurams, Carbamates, Thioureas and Diphenylguanidine[1].

Biogel® key features and benefits:

- AQL* of 0.65, determined post packaging[2]
- Every glove (100%) is air-inflation tested for holes typically not detected in a visual inspection[3]
- Low endotoxin level (<20 EU/pair), which may reduce the risk of post-operative complications[2,4]

Material information

- Synthetic polychloroprene
- Manufactured without chemical accelerators
- Biogel hydrogel polymer coating
- Curved finger and smooth surface
- Beaded cuff
- Powder-free

Recommended use

Recommended for all surgical procedures or surgeries where latex allergies and/or chemical sensitivities are a concern for patients or clinicians.

Biogel quality

Biogel gloves are designed to be comfortable with maintained tactile sensitivity when double gloving[5]. They are manufactured using rigorous quality checks, numerous washing cycles[2] and air-inflation testing of every single glove[3].

Ordering information REF 429

REF	Size	Pairs
42955	5½	50/Box
42960	6	50/Box
42965	6½	50/Box
42970	7	50/Box
42975	7½	50/Box
42980	8	50/Box
42985	8½	50/Box
42990	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.

Biogel® Neoderm® REF 429 – Product specifications

REF	Size	Length, mm (Tolerance +20 mm; -10 mm)	Lay flat palm width, mm (±3 mm)
42955	5½	283	71
42960	6	285	77
42965	6½	285	85
42970	7	288	91
42975	7½	298	96
42980	8	299	103
42985	8½	301	109
42990	9	301	115

Typical thickness profile – single wall		
Cuff	6.3 mils	0.16 mm
Palm	7.7 mils	0.20 mm
Finger	8.7 mils	0.22 mm

Biogel Neoderm 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
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 Neoderm Typical value
Force at break (N)		
Initial	≥ 9	12
Aged	≥ 9	13
Tensile strength (MPa)		
Initial	≥ 17	23
Aged	≥ 12	25
Modulus Stress @500% elongation (MPa)		
Initial	7.0 max	2.7
Aged	n/a	3.0
Elongation at break (%)		
Initial	≥ 650	960
Aged	≥ 490	900
Typical accelerator analysis (% w/w)		
Dithiocarbamate (DTC)	n/a	none
Diphenyl thiourea (DPTU)	n/a	none
Diphenylguanidine (DPG)	n/a	none
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. 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 dispose 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: Threes (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. Safer Neotech Design Verification Report. Mölnlycke Health Care. Data on File. 2. Summary of Technical Documents. Mölnlycke Health Care. Data on File. 3. Internal SOP. Automatic Glove Inspection by QMAX. Mölnlycke Health Care. Data on File. 4. Asplund Peiro S et al. Quantitative determination of endotoxins on surgical gloves. Journal of Hospital Infection 1990; 16:167-172. 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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