

# Synthetic Biogel® Skinsense®



The Biogel® Skinsense® sterile, synthetic surgical glove material has a longer chemical breakthrough time than other Biogel® gloves in the presence of common surgical chemicals and cytotoxic agents than other surgical gloves.



ACTUAL COLOUR REF 314

## Biogel® key features and benefits

- Longer chemical breakthrough time<sup>1</sup>
- Reduced chance of a hole with an industry-leading AQL\* result of 0.65<sup>2</sup>
- Every glove (100%) is air inflation tested and visually inspected for quality and safety<sup>2</sup>
- Non-pyrogenic, potentially reducing the risk of post-operative complications<sup>3</sup>

## Recommended use

Recommended for surgeries where a longer chemical breakthrough time is desired or where latex allergies are a concern for the patients or clinicians. Double gloving with the Biogel® Skinsense® Indicator® Underglove is recommended. For surgical procedures involving bone cement please see reverse for breakthrough times.

## Material information

- Synthetic polychloroprene
- Biogel hydrogel polymer coating
- Micro-roughened surface
- Beaded cuff
- Powder-free
- Non-pyrogenic

## Biogel quality

Biogel has an industry leading freedom from holes AQL\* of 0.65. The industry standard requirement for AQL\* is 1.5. The lower the number, the fewer the holes and the higher the quality of glove. Biogel is proven to have the lowest glove failure rate among major competitors. Non-Biogel gloves are at least 3.5 times as likely to fail than Biogel gloves<sup>4</sup>.

## Re-order REF 314

REF	Size	Pairs
31455	5 ½	50/Box
31460	6	50/Box
31465	6 ½	50/Box
31470	7	50/Box
31475	7 ½	50/Box
31480	8	50/Box
31485	8 ½	50/Box
31490	9	40/Box

4 boxes per case

## Product specifications Biogel® Skinsense® REF 314

REF	Size	Length, mm (Tolerance +20 mm; -10 mm)	Lay flat palm width, mm (±3 mm)
31455	5,5	283	71
31460	6.0	285	77
31465	6.5	285	85
31470	7.0	288	91
31475	7.5	298	96
31480	8.0	299	103
31485	8.5	301	109
31490	9.0	301	115

Pairs per box: 50/40 for size 9

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

Permeation breakthrough time		
Methylmethacrylate (bone cement)	3 minutes	CAS No. 80-62-6

## General information

**Pyrogenicity:** Each batch of Biogel gloves is tested to have a low endotoxin level (<20 EU/pair).

**Product standards:** Biogel gloves are tested and manufactured to the following standards:

- **Quality/Environmental:** ISO 9001, ISO 13485, ISO 14001
- **Product:** ASTM D3577, EN455-1, EN455-2, EN455-3, EN455-4, EN388, EN420, EN374, EN374-2, EN374-3
- **Sterilisation:** Gamma irradiation
- **Viral penetration:** Bacteriophage test, ASTM F1671
- **Allergenicity/Pyrogenicity:** ISO 10993, (PART 5 and 10)

**Registering authority:** In Europe the gloves are CE marked (notified body BSi, number 0086) indicating compliance with Council Directive 93/42/EEC, section 3.2. In US the gloves are FDA registered. Biogel Surgical gloves are a Class IIa Product.

**References:** 1. REPR0618. Permeation and Degradation. 2010. Data on file. 2. Why Choose Biogel. MKT004. 2009. Data on file. 3. Biogel Endotoxin Report, Non-Pyrogenic Surgical Gloves. REPRHJV004. 2010. Data on file. 4. In Use Surgical Glove Failure Rate Comparison. Study G009-005. 2009. Data on file.

\*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.

If a surgical glove should come into contact with a fast permeating agent such as bone cement, please remove and replace the glove as soon as possible.

(Breakthrough time, BTT): BTT is the time between the application of the test chemical into the test cell to when the permeation rate  $1.0 \mu\text{g} \cdot \text{cm}^{-2} \cdot \text{min}^{-1}$  (EN374).

## Find out more at [www.molnlycke.com](http://www.molnlycke.com)

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Physical glove properties	Standard requirement	Biogel
<b>Force at break (N) (EN455)</b>		
Initial	≥9	12
Aged	≥9	14
<b>Typical accelerator analysis % w/w</b>		below detection limit
Dithiocarbamate (DTC)	n/a	
Diphenyl thiourea (DPTU)	n/a	<0.25
Diphenyl guanidine (DPG)	n/a	<0.07
Zinc mercaptobenzothiazole (ZMBT)	n/a	none
Thiurams	n/a	none
<b>AQL* freedom from holes</b> (1000ml water leak test) Post packing and irradiation Process average typically	1.5	0.65  <0.20%
<b>Grip</b> (Measure of the surface grip. Scale of 1-5, the higher the value, the greater the level of drag)	n/a	1.5

**Storage:** Store in a cool, dry place 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 & outer wrap dispose of as clinical waste. Paper inner wrap, collation case & 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.

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