

Biogel® PI UltraTouch®

Synthetic surgical glove



Biogel® PI UltraTouch® is a straw-coloured synthetic surgical glove that offers excellent barrier protection as well as fit, feel and comfort¹. Biogel PI UltraTouch can be worn alone or in combination with any Biogel PI Indicator Underglove to create a Biogel Puncture Indication System with Best-in-Class puncture detection^{2,3}. It has been tested and cleared for use with chemotherapy agents.



Biogel key features and benefits:

- AQL* of 0.65, determined post packaging⁴
- Every glove (100%) is air-inflation tested for holes typically not detected in a visual inspection⁵
- Low endotoxin level (<20 EU/pair), which may reduce the risk of post-operative complications^{4,6}

Recommended use

Recommended for all surgical procedures or surgeries where latex allergies are a concern for the patients or clinicians. It can be used alone or as part of a Biogel Puncture Indication System with a Biogel PI Indicator® Underglove for improved protection.

Biogel quality

Biogel gloves are designed to be comfortable with maintained tactile sensitivity when double gloving^{1,7}. They are manufactured using rigorous quality checks, numerous washing cycles⁴ and air-inflation testing of every single glove⁵.

Material information

- Synthetic polyisoprene
- Biogel hydrogel polymer coating
- Straight finger and textured surface
- Beaded cuff
- Powder-free



Tested for use with chemotherapy agents

Please refer to separate permeation sheet for breakthrough times.

Ordering information REF 431

| REF | Size | Pairs |
|-------|------|--------|
| 43155 | 5½ | 50/Box |
| 43160 | 6 | 50/Box |
| 43165 | 6½ | 50/Box |
| 43170 | 7 | 50/Box |
| 43175 | 7½ | 50/Box |
| 43180 | 8 | 50/Box |
| 43185 | 8½ | 50/Box |
| 43190 | 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® PI UltraTouch® REF 431 – Product specifications

| REF | Size | Length, mm (Tolerance ±15 mm) | Lay flat palm width, mm (±3 mm) 5.5- (+2, -4) |
|-------|------|----------------------------------|--|
| 43155 | 5½ | 280 | 74 |
| 43160 | 6 | 280 | 79 |
| 43165 | 6½ | 280 | 85 |
| 43170 | 7 | 285 | 91 |
| 43175 | 7½ | 285 | 97 |
| 43180 | 8 | 295 | 104 |
| 43185 | 8½ | 295 | 108 |
| 43190 | 9 | 302 | 114 |

Typical thickness profile – single wall

| | | |
|--------|-----------|---------|
| Cuff | 7.9 mils | 0.20 mm |
| Palm | 10.6 mils | 0.27 mm |
| Finger | 11.2 mils | 0.29 mm |

Biogel PI UltraTouch 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 |
| 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 |

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. They are a Class IIa product according to the Medical Device 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.

References: 1. Collins J. J A Clinical Evaluation of Polyisoprene Biogel Orthopaedic Surgical Gloves. Design Validation DP36_/3.6.1, Mölnlycke Health Care 2011. 2. Wigmore SJ & Rainey JB. Use of coloured undergloves to detect puncture. BJS 1994; 81:1480. 3. Glove puncture detection systems. Mölnlycke Health Care, 2017. Data on file. 4. Summary of Technical Documents. Mölnlycke Health Care. Data on File. 5. Internal SOP. Automatic Glove Inspection by QMAX. Mölnlycke Health Care. Data on File. 6. Asplund Peiro S et al. Quantitative determination of endotoxins on surgical gloves. Journal of Hospital Infection 1990; 16:167-172. 7. 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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| Physical glove properties | Standard requirement | Biogel PI UltraTouch Typical value |
|---|----------------------|------------------------------------|
| Force at break (N) | | |
| Initial | ≥9 | 16 |
| Aged | ≥9 | 15 |
| Tensile strength (MPa) | | |
| Initial | ≥17 | 28 |
| Aged | ≥12 | 26 |
| Modulus Stress @500% elongation (MPa) | | |
| Initial | 7.0 max | 1.9 |
| Aged | n/a | 1.9 |
| Elongation at break (%) | | |
| Initial | ≥ 650 | 1110 |
| Aged | ≥ 490 | 1060 |
| Typical accelerator analysis (% w/w) | | |
| Dithiocarbamate (DTC) | n/a | <0.10 |
| Diphenyl thiourea (DPTU) | n/a | <0.03 |
| Diphenylguanidine (DPG) | n/a | <0.25 |
| Zinc mercaptobenzothiazole (ZMBT) | n/a | <0.10 |
| 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

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

