

# Non-Latex Biogel® PI

Powder-free synthetic Polyisoprene surgical gloves with Biogel® coating



## Benefits

- Unique Biogel coating on the inner surface
  - Makes gloves easy to don even with damp hands
  - Soothes the skin to help prevent moisture loss<sup>1</sup>
- Beaded cuff for added security
- Every glove is air inflation tested and visually inspected for quality and user confidence
- Industry leading AQL freedom from holes of 0.65
- Powder-free to eliminate starch powder-related complications
- Low dermatitis potential - this product demonstrated reduced potential for sensitizing users to chemical additives
- Non-pyrogenic

## Features

- Curved finger design
- Micro-roughened surface
- Straw colored

## Material Information

- Synthetic polyisoprene
- Biogel polymer coating

A sterile, powder-free, non-latex polyisoprene glove that reduces the possibility of glove-related latex protein sensitization because it is made from a synthetic elastomer.

The gloves provide levels of fit, feel and comfort comparable to natural rubber latex because synthetic polyisoprene shares a similar molecular structure to natural rubber latex.

Recommended for use in all general surgeries or surgeries where latex allergies are a concern for patients or clinicians.



ACTUAL  
COLOR

## RE-ORDER # 408

| #     | SIZE | PAIRS  | #     | SIZE | PAIRS  |
|-------|------|--------|-------|------|--------|
| 40855 | 5 ½  | 50/Box | 40875 | 7 ½  | 50/Box |
| 40860 | 6    | 50/Box | 40880 | 8    | 50/Box |
| 40865 | 6 ½  | 50/Box | 40885 | 8 ½  | 50/Box |
| 40870 | 7    | 50/Box | 40890 | 9    | 40/Box |

4 BOXES PER CASE

## Essential Information

Responsible company: Mölnlycke Health Care AB, Gamlestadsvägen 3C, SE-402 52 Gothenburg, Sweden

For Inquiries: USA: Norcross GA USA 30092 1-800-843-8497

E-mail address: biogel@molnlycke.com

Website address: www.molnlycke.com

Manufacturer: Made and packed in Malaysia by Regent Hospital Products. Regent Hospital Products is a member of the Mölnlycke Health Care Group.

<sup>1</sup> Source: Testing conducted at PRAC and overseen by a board-certified dermatologist, 2004. Report 04-007

**PRODUCT SPECIFICATIONS**

| SIZE | MIN LENGTH (mm) | AVERAGE PALM WIDTH (mm) |
|------|-----------------|-------------------------|
| 5 ½  | 283 (+20/-10)   | 71 (±3)                 |
| 6    | 285 (+20/-10)   | 77 (±3)                 |
| 6 ½  | 285 (+20/-10)   | 85 (±3)                 |
| 7    | 288 (+20/-10)   | 91 (±3)                 |
| 7 ½  | 298 (+20/-10)   | 96 (±3)                 |
| 8    | 299 (+20/-10)   | 103 (±3)                |
| 8 ½  | 301 (+20/-10)   | 109 (±3)                |
| 9    | 301 (+20/-10)   | 115 (±3)                |

**TYPICAL THICKNESS PROFILE SINGLE WALL**

|        |           |          |
|--------|-----------|----------|
| Cuff   | 9.3 mils  | 0.235 mm |
| Palm   | 11.6 mils | 0.295 mm |
| Finger | 12.2 mils | 0.310 mm |

**PHYSICAL GLOVE PROPERTIES**

|  |         | STANDARD REQUIREMENT | BIOGEL         |
|--|---------|----------------------|----------------|
| <b>Force at Break (N):</b>   | Initial | ≥9                   | Typically 21   |
|  | Aged    | ≥6                   | Typically 19   |
| <b>Typical Accelerator Analysis % w/w:</b>   |         |                      |                |
| Dithiocarbamate (DTC)  |         | n/a                  | <0.10          |
| Diphenyl thiourea (DPTU)   |         | n/a                  | <0.03          |
| Diphenyl guanidine (DPG)   |         | n/a                  | <0.25          |
| Zinc mercaptobenzothiazole (ZMBT)  |         | n/a                  | <0.05          |
| <b>AQL Freedom from Holes</b> (1000ml water leak test. Post packing and irradiation) - Process Average Typically |         | 1.5                  | 0.65<br><0.20% |

**General Information**

**Contraindications:** Do not use this product if you have a known allergy to chemical additives.

**Pyrogenicity:** Each batch of Biogel gloves is certified to be either non-pyrogenic or to have a low endotoxin level (<0.5 EU/ml).

**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  
**Sterilization-** Gamma irradiation (25 kGy (2.5 Mrad)), EN552, EN556  
**Viral Penetration-** Bacteriophage test, ASTM F1671  
**Allergenicity / Pyrogenicity-** ISO 10993, (PART 5 and 10) / US Pharmacopoeia USP: (151 & 85)

**Distributed by:** Mölnlycke Health Care, LLC, 5550 Peachtree Parkway, Suite 500, Norcross, GA 30092, USA.

**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 for clinical waste. Paper Inner Wrap, Collation Case & Transit Case can be recycled as paper or disposed of as for clinical waste.

**Country of Origin:** Malaysia

**Date of issue:** October 2010

For further information on any of the above, please contact your local dealer or Mölnlycke Health Care representative directly.

