



Non-Latex Biogel®

PI Indicator® Underglove

Blue synthetic Polyisoprene surgical underglove with Biogel® coating

Can be used alone or as part of a Puncture Indication System

Sterile, powder-free, non-latex polyisoprene gloves that reduce the possibility of glove-related latex protein sensitization because they are made from a synthetic elastomer.

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

The underglove is blue in color and can be worn alone or as part of the Puncture Indication System, as the smooth surface is specifically engineered for unparalleled ease of double-donning.

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

Benefits

- Helps prevent glove punctures from going unnoticed
- Blue underglove worn under any Biogel powder-free surgical glove creates the Puncture Indication System
- Blue color spot alerts wearer of punctures in outer latex glove, if a perforation occurs in the presence of fluid
- Unique Biogel coating on the inner surface
 - Makes gloves easy to don even with damp hands
 - Soothes the skin to help prevent moisture loss¹
- 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
- Smooth surface for ease of double donning
- Blue colored

Material Information

- Synthetic polyisoprene
- Biogel polymer coating
- Non-leachable blue pigment



ACTUAL COLOR

RE-ORDER # 416

#	SIZE	PAIRS	#	SIZE	PAIRS
41655	5 ½	50/Box	41675	7 ½	50/Box
41660	6	50/Box	41680	8	50/Box
41665	6 ½	50/Box	41685	8 ½	50/Box
41670	7	50/Box	41690	9	40/Box

4 BOXES PER CASE

Essential Information

Responsible company: Mölnlycke Health Care AB, Gamlestadvägen 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.

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

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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	8.3 mils	0.210 mm
Palm	10.4 mils	0.265 mm
Finger	11.0 mils	0.280 mm

PHYSICAL GLOVE PROPERTIES

	STANDARD REQUIREMENT	BIOGEL
Force at Break (N): Initial Aged	≥9 ≥6	Typically 18 Typically 16
Typical Accelerator Analysis % w/w: Dithiocarbamate (DTC) Diphenyl thiourea (DPTU) Diphenyl guanidine (DPG) Zinc mercaptobenzothiazole (ZMBT)	n/a n/a n/a n/a	<0.10 <0.03 <0.25 <0.05
AQL Freedom from Holes (1000ml water leak test. Post packing and irradiation) - Process Average Typically	1.5	0.65 <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.

