

Latex Biogel® Indicator® Underglove

Powder-free green surgical underglove with Biogel® coating Can be used alone or as part of a Puncture Indication System

Sterile, powder-free natural rubber latex glove that is green 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 all types of surgery where glove puncture is likely, especially trauma, cardiac, transplant, orthopaedic and gastrointestinal.

Benefits

- · Helps prevent glove punctures from going unnoticed
- Green underglove worn under any Biogel® surgical glove creates the Puncture Indication System
- Green 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
- Powder-free to minimize the risk of allergic reactions to aerosolized natural rubber latex proteins
- Typically contains 50 μg/g or less of water-extractable proteins²
- Low dermatitis potential this product demonstrated reduced potential for sensitizing users to chemical additives
- · Non-pyrogenic

Features

- · Curved finger design
- · Smooth surface engineered for easy double-donning
- · Green colored

Material Information

- · Natural rubber latex
- Biogel polymer coating
- · Non-leachable green pigment

RE-ORDER # 312 SIZE



ACTUAL

COLOR

31255	5 1/2	50/Box
	0 / 2	
31260	6	50/Box
31265	6 ½	50/Box
31270	7	50/Box

4 BOXES PER CASE

#	S IZE	PAIRS
31275	7 ½	50/Box
31280	8	50/Box
31285	8 1/2	50/Box
31290	9	40/Box

Essential Information

Responsible company: Mölnlycke Health Care AB, Gamlestadsvägen 3C,

PAIRS

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.

Source: Testing conducted at PRAC and overseen by a board-certified dermatologist, 2004. Report 04-007 ²Using Modified Lowry (EN455) / ASTM D5712

Biogel® Indicator® Underglove

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 1/2	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	6.9 mils	0.175 mm	
Palm	8.1 mils	0.205 mm	
Finger	8.5 mils	0.215 mm	

PHYSICAL GLOVE PROPERTIES

		STANDARD REQUIREMENT	BIOGEL
	nitial Aged	≥12 ≥9	Typically 14 Typically 12
Typical Accelerator Analys Dithiocarbamate (DTC)	sis % w/w:	n/a	<0.01
Typical Extractable Protein (using Modified Lowry EN455 / ASTM D5712)		<50µg/g	<20µg/g
AQL Freedom from Holes (1000ml water leak test. Post packing and irradiation) - Process Average Typically		1.5	0.65 <0.20%

General Information

Contraindications: This product contains natural rubber latex which may cause allergic reactions including anaphylactic responses

Do not use this product if you have a known allergy to natural rubber protein or chemical additives.

Allergenicity: Biogel gloves are produced to have low levels of water extractable protein and have been shown to have a low

potential for inducing allergic contact dermatitis or 'Type IV allergy'.

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 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.



