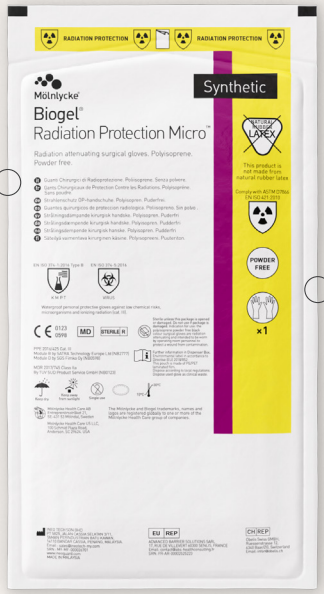
Biogel®
Radiation Protection Micro™

Radiation protection surgical glove

Biogel® Radiation Protection Micro™ surgical gloves are designed with a unique ultra-soft material composition, protecting surgeon hands from radiation exposure without compromising fit, comfort and dexterity.



Biogel® Radiation Protection Micro™ surgical gloves are formulated without latex, lead, or DPG and MBT chemical accelerators, promoting skin health and offering a safer option to professionals and the environment.

High Performance

Biogel® Radiation Protection Micro™ surgical gloves offer uncompromised radiation safety in compliance with ASTM D7866, ASTM 2547, EN 421 and EN 61331, combined with the fit, comfort and dexterity expected in FDA-cleared Class I surgical gloves.

Biogel quality

The glove is manufactured in a dedicated factory that do not use any natural rubber product or lead compound. The company employs 100% Malaysian workforce and strictly adhere to the highest ethical and social responsibility standards.

Recommended use

The Biogel® Radiation Protection Micro™ and Biogel® Radiation Protection™ surgical gloves are intended for use by healthcare providers during fluoroscopic guided procedures to protect a surgical wound from contamination, and has FDA 510(k) clearance as a Class I surgical glove.

The glove contains radiation-attenuating particles to offer some degree of protection to the hand from secondary or scatter radiation.

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Material information

- Synthetic polyisoprene
- Polymer coating
- Anatomical shape and smooth surface
- Powder-free
- Tungsten alloy

General information

Registering authority: These gloves have 510(k) clearance in the USA. They are a Class IIa product according to the Medical Device Regulation and Class I according to the FDA. In Europe the gloves are CE-marked (notified body BSI, number 2797) indicating compliance with Medical Device Regulation 2017/745. In the UK the gloves are UKCA marked (authorized body BSI 0086) indicating compliance with the provisions of the Medical Device Regulation 2002 (S1618) as subsequently amended by the EU Exit Regulations of 2019 (SI 791) and 2020 (SI 1478).
Storage: The glove must be stored in its original packaging at room temperature in a dry place away from 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). 5 pairs per collation case.
After use: Gloves are supplied as single use. The used gloves shall be disposed as clinical waste.
Shelf life: Three (3) years from date of manufacture.
Manufacturer: Made and packed in Malaysia by IneoTech Sdn Bhd.
Country of origin: Malaysia
E-mail address: biogel@molnlycke.com

Biogel® Radiation Protection Micro™ REF 520 – Product specifications and order information

Product number	Size	Length, mm	Lay flat palm width, mm	Pairs
52060	6	285	77 ± 5	5/Box
52065	6.5	285	83 ± 5	5/Box
52070	7	285	89 ± 5	5/Box
52075	7.5	285	95 ± 5	5/Box
52080	8	285	102 ± 6	5/Box
52085	8.5	285	108 ± 6	5/Box
52090	9	285	114 ± 6	5/Box

4 boxes per case

Average attenuation values*

X-ray tube voltage (kV)	EN 421 & EN 61331-1	ASTM F2547 & ASTM D7866
60	52%	41%
80	44%	34%
100	40%	28%
120	36%	24%

*Typical performance level, all gloves with ≤3% uncertainty

Typical thickness profile – single wall (min)

Cuff	9.8 mils	0.25 mm
Palm	9.8 mils	0.25 mm
Finger	9.8 mils	0.25 mm

Biogel Radiation Protection Micro are tested and manufactured to the following standards

Quality/Environment	ISO 13485
Product	ASTM D3577, EN 455-1, EN 455-2, EN 455-3, EN 455-4, EN 374-1, EN 374-2, EN 374-4, EN 374-5, EN 16523-1, EN ISO 14971, EN 61331-1, EN 388, EN ISO 21420, EN 421, ASTM D7866, ASTM F2547, ASTM D6124, ASTM D5151
Sterilization	ISO 11137-1, ISO 11137-2 , sterilized using irradiation, min 25 kGy (SAL 10^{-6})
Allergenicity	ISO 10993 (Part 5 and 10)
Labelling	EN ISO 15223-1
Packaging	EN ISO 11607-2

Physical glove properties	Standard requirement	Biogel Radiation Protection
Force at break (N)		
Initial	≥ 9	Meets requirement
Aged	≥ 9	Meets requirement
Tensile strength (MPa)		
Initial	≥ 17	Meets requirement
Aged	≥ 12	Meets requirement
Modulus Stress @500% elongation (MPa)		
Initial	7.0 max	Meets requirement
Aged	n/a	n/a
Elongation at break (%)		
Initial	≥ 650	Meets requirement
Aged	≥ 490	Meets requirement
Typical accelerator analysis (% w/w)		
Diphenylguanidine (DPG)	n/a	none
Mercaptobenzothiazole (MBT)	n/a	none
AQL freedom from holes (1000 ml water leak test)		
EN 455-1 / ASTM D5151	0.65	0.65
Grip (Measure of the surface grip)	n/a	1.5

Find out more at molnlycke.us

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