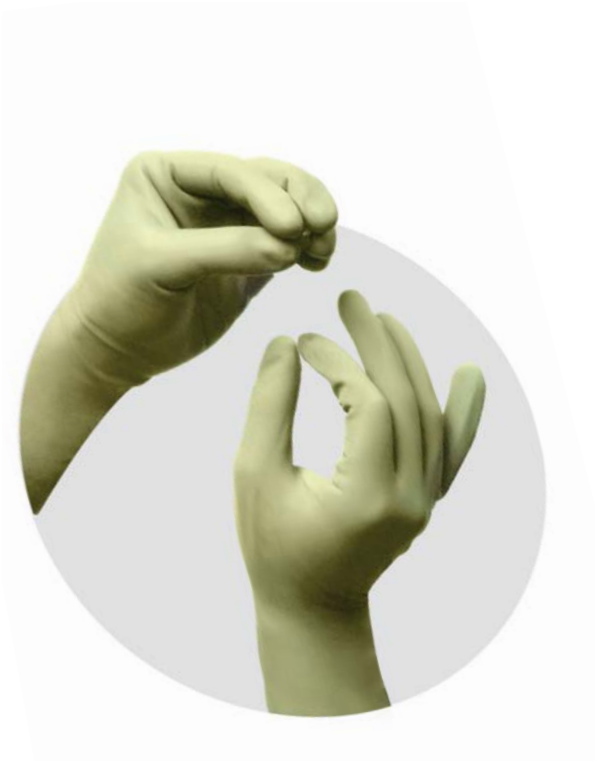
Reina Imaging
A UniRay Product

RADIATION PROTECTION GLOVES



HAND PROTECTION

Surgical Radiation Protection Gloves are specially designed sterile surgical gloves with x-ray radiation protective properties. These gloves protect the hands from scatter and secondary radiation during various surgical procedures.

FEATURES

- LEAD FREE
- POWDER FREE
- STERILE
- DISPOSABLE
- BEADED CUFF
- TEXTURED FINGER FOR PERFECT GRIP
- SUPERIOR TACTILE SENSITIVITY
- ANATOMIC SHAPE AND ERGONOMIC DESIGN
- SOFT, FLEXIBLE AND ELASTIC
- MADE IN TWO THICKNESSES
- HIGHEST PROTECTION IN EACH SEGMENT
- AVAILABLE IN SIZE FROM 6.0 TO 9.0

APPLICATIONS

- CARDIOLOGY
- INTERVENTIONAL RADIOLOGY
- RADIOLOGY
- FLUOROSCOPY
- PAIN MANAGEMENT
- UROLOGY
- ENDOSCOPY
- ORTHOPAEDICS
- EP/ CATH LABS
- NEUROLOGY

TECHNICAL SPECIFICATIONS

PHYSICAL DIMENSIONS - Typical Information

PARAMETER	MEASUREMENT						
Size	**6.0**	**6.5**	**7.0**	**7.5**	**8.0**	**8.5**	**9.0**
Palm Width (in mm)	79+/3	83+/-3	87+/-4	92+/-5	102+/-5	108+/-6	114+/-6
Minimum Length (in mm)	280	280	280	285	285	290	290

Thickness in mm	PRIME	SHEER
Finger	0.35	0.25
Palm	0.32	0.22
Cuff	0.32	0.22

RADIATION ATTENUATION – Tested as per EN 61331-1:2014

	LATEX GLOVES		LATEX FREE GLOVES	
DIRECT BEAM ENERGY LEVEL	**PRIME**	**SHEER**	**PRIME**	**SHEER**
60kV	69.6%	46.8%	63.1%	44.9%
80kV	60.9%	39.2%	54.4%	37.5%
100kV	53.8%	33.5%	47.4%	32.0%
120kV	48.2%	29.0%	42.0%	27.6%
L E, mm Pb 60 to 120kV	0.047	0.024	0.039	0.024

RELEASE PARAMETERS (Certificate of analysis)*

PROPERTY	U/M	LATEX	LATEX FREE
Protein Level (type tested)	µg/g	≤ 50 micrograms /gram	NA
Residual Powder (type tested)	mg/glove	≤ 2mg	≤ 2mg
Pin Holes (1000ml water leak test)	PASS / FAIL	100%	100%
Tensile Strength	Mpa	14 Mpa	10 Mpa
Ultimate Elongation	%	730	600

** Periodic Testing*

GENERAL CHARACTERISTICS

Donning lubrication	Powder-free, Polymer coated
Product Compliance*	ASTM D3577, ASTM D6124, ASTM D5712, ASTM D412, EN 61331-1:2014 EN 420:2003, EN 455-3:2006, EN 374-3:2006, EN 388:2016, EN 421:2010
Manufacturing Compliance	ISO 13485:2016 Quality Management System Regulation (EU) 2016/425 for PPE 93/42/EEC for MDD
Biocompatibility compliance	As per ASTM F 719/ ASTM F 720, ISO 10993
Shelf Life	3 years as per ASTM 7160-05
Sterility	Gamma sterilized with dosage level of minimum 25 kGy with sterility assurance level (SAL) of 1/1,000,000 and compliance under EN 11137 and EN 11737
Storage Conditions	Store in a cool and dry place between 20° C and 40° C Keep away from direct sunlight, moisture, electrical equipment and ozone

** As applicable to product*

CAUTION

This glove is not intended for use in the direct or primary x-ray beam. The purpose of this radiation protective glove is to protect the hands from scattered secondary radiation exposure originating from the x-ray beam during various surgical procedures.

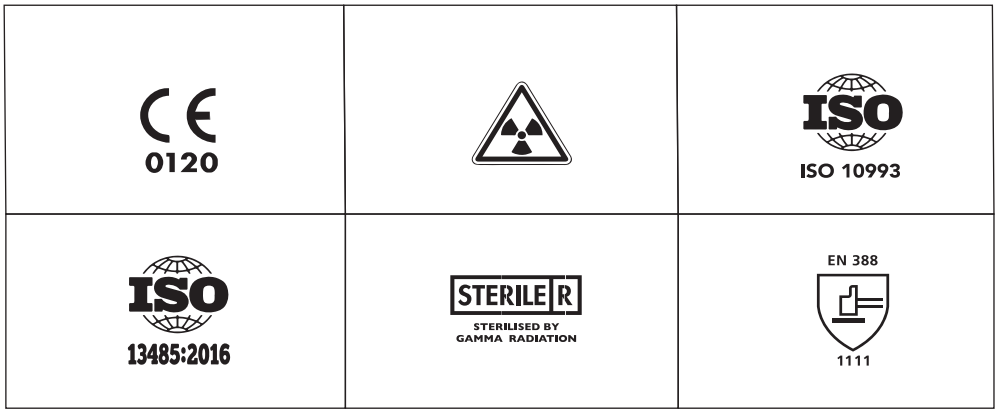
For Latex Gloves: Product contains natural rubber latex. May cause reactions in people who are allergic to natural rubber. This product should be stored in carton during transportation. This latex glove contains 50 micrograms or less of total water extractable protein per gram, according to Modified Lowry test.

PRODUCT CONFORMANCE

Tested in compliance with EN 420:2003, EN 374:2003, EN388:2016, EN 980:2008, EN ISO 10993:1:2009, ISO 13485:2016, ISO 11137-1:2015, ISO 11137-3:2006, ISO 11737-1:2018, EN 421:2010, EN 61331-1:2014
This device is manufactured in complaince to European Directive Medical Devices 93/42/EEC as amended by Directive 2007/47/EC and Regulation (EU) 2016/425

QUALITY ASSURANCE

US FDA Quality System Regulation (QSR)
ISO13485 Quality Management System



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