Sterile Surgical Radiation protection Gloves (X-Ray Protective Gloves) are used to prevent contamination of the patient during invasive procedures and to protect the hand from exposure to potentially infectious materials. In addition Sterile Surgical Radiation protection Gloves (X-Ray Protective Gloves) are also used for protection against scattered radiation during radiological and interventional procedures. These are used by Radiology professionals, surgeons and technicians.

Sterile Surgical Radiation protection Gloves (X-Ray Protective Gloves) are available in variable thicknesses from 0.020 mm to 0.035mm providing X-Ray attenuation (protection percentage) from 20% to 60%.

There are 4 types of Sterile Surgical Radiation protection Gloves (X-Ray Protective Gloves) are produced in various sizes.

1. X ray protective Gloves – Prime
2. X ray protective Gloves – Sheer
3. Latex free X ray protective Gloves – Prime
4. Latex free X ray protective Gloves – Sheer

Device Description	Protection Level at 60 KV	Device Reference	
X ray protective Gloves – SHEER	Up to 40%	NRPG 20	SRPG 20
X ray protective Gloves – PRIME	Up to 60%	NRPG 35	SRPG 35

Measurements to assess their attenuation efficiency have been carried out from 60KV to 120kV with a copper filtration of 0.25 mm. The test method includes comparison with standard step wedge of known lead equivalence, tested as per EN 61331-1:2014.

Where relevant we also comply with EN 420:2003 requirements which deals with General requirements and test methods for protective Gloves

- On the accompanying documents, and on design and materials used;
- Standard sizes, Particular design features
- Marking and standardized forms of statements of compliance with this standard.

Warnings:

1. The function of this Glove is to provide protection from secondary radiations and not from the direct x-ray beam. Gloves should be worn only during the time of x-ray exposure. We have not come across allergies to users due to the gloves, but the user may seek medical advice, if necessary.
2. The Gloves when made of natural Latex may cause allergic reaction to users who are sensitive to proteins from natural rubber. These gloves may contain less 50 micrograms or less of water extractable proteins per glove.
3. Though the Gloves is in compliance with the requirements of EN 388:2016 Protective gloves for Mechanical risks, the Glove should not be used for any other application other than the intended use as specified by the manufacturer.

Storage:

1. Store in a cool and dry place away from Ozone and UV Light.
2. Never fold device or hang over edges.
3. Product should be stored in the original Packaging provided.
4. Keep away from direct sunlight and heat.
5. Room temperature and Humidity at the storage place should be maintained within the range of values usual for living and working areas.
6. Please do not use the product if the packing is open or damaged.

Cleaning, Examination and disinfection:

Not Applicable as this is a sterile product.

List of main constituents of Gloves:

Elements providing X-Ray Protection properties:

Bismuth Tri Oxide in various combinations

Binding Material used for compounding X –Ray protection elements

Natural Latex or Synthetic Latex

Instructions for recycling, safe destruction and disposal:

Due to the high content of metallic content in the product, any waste material should be disposed of in registered landfill sites in accordance with the local authority regulations. The material should not be disposed of by incineration and use of self-contained breathing apparatus is recommended if the product is ignited by an internal fire.

Warning against problems likely to be encountered during use:

If the X ray Protective Glove is not worn properly or not torn at the time of donning there is a likelihood of exposure to X ray radiation resulting into insufficient protection and injury. The user has to choose an adapted size of PPE/ Medical Device. The corresponding details of sizes are as given in the Table below. Please ensure that it is worn properly.

Table 2 — Sizes of hands

Hand size[a]	Hand circumference mm	Hand length mm
6	152	160
7	178	171
8	203	182
9	229	192
10	254	204
11	279	215

[a] This code is a conventional designation of hand size corresponding to the hand circumference expressed in inches.

Warning against significant penalties of using the equipment:

1. The function of this Glove is to provide protection from secondary radiations and not from the direct x-ray beam. Gloves should be worn only during the time of x-ray exposure. We have not come across allergies to users due to the gloves, but the user may seek medical advice, if necessary.
2. The Gloves when made of natural Latex may cause allergic reaction to users who are sensitive to proteins from natural rubber. These gloves may contain less 50 micrograms or less of water extractable proteins per glove

3. These gloves are not intended to be used as protective gloves for mechanical risks. The gloves are manufactured in compliance with EN 388:2016 to improve the performance when used for its intended use of radiation protection.

Performance as per EN 388:2016:

Protection against Mechanical hazard is represented by a pictogram followed by 4 numbers representing the performance levels of the glove against each hazards. The pictogram is available on the peel pouch as well as on the box label as below

1 1 1 1

Four types of hazards as per EN 388:2016 are

a) Resistance to Abrasion
b) Blade cut Resistance
c) Tear Resistance
d) Puncture Resistance

As per EN 388:2016, the performance levels are as follows

TEST	PERFORMANCE LEVEL RATING					
	0	1	2	3	4	5
a. Abrasion resistance (cycles)	<100	100	500	2,000	8,000	
b. Blade cut resistance (factor)	<1.2	1.2	2.5	5.0	10.0	20.0
c. Tear resistance (newton)	<10	10	25	50	75	
d. Puncture resistance (newton)	<20	20	60	100	150	

The performance rating of Radiation Protection Gloves (X-ray Protective Gloves) are as follows

Resistance to Abrasion	-1
Blade cut Resistance	-1
Tear Resistance	-1
Puncture Resistance	-1

Test results of these gloves in compliance with EN 388:2016 are available with the manufacturer and same can be availed upon request of the user.

Special Warnings / Notes with respect to EN 388:2016:

1. The function of Radiation protection Glove (X-Ray protective Glove) is to provide protection from secondary radiations and not from the direct x-ray beam. Gloves should be worn only during the time of x-ray exposure. These Gloves should not be used for any other application other than the intended use as specified by the manufacturer by misunderstanding that these gloves are against mechanical hazards.
2. Though the performance levels of these gloves are meeting the minimum requirements of EN 388:2016, these gloves alone should not be used for applications other than the intended use.
3. Tear Resistance provides information on the mechanical resistance of the glove, but is not indicative of protection against specific risk. While higher value is normally considered as better, a low value is sometimes required based on the specific applications.
4. Gloves meeting the requirements for resistance to puncture may not be suitable for protection against sharply pointed objects such as hypodermic needles.
5. The gloves not to be worn when there is a risk of entanglement by moving parts of a machine.

Guideline for selection of a Glove to use:

Table 2 — Sizes of hands

Hand size[a]	Hand circumference mm	Hand length mm
6	152	160
7	178	171
8	203	182
9	229	192
10	254	204
11	279	215

[a] This code is a conventional designation of hand size corresponding to the hand circumference expressed in inches.

Dimensions of Radiation Protection Gloves (x ray Protective Gloves):

Dimensions		
Size	Glove Length, in mm	Palm Width, in mm
6.0	280	78 (+/- 2)
6.5	290	83 (+/- 3)
7.0	290	89 (+/- 3)

7.5	290	95 (+/- 3)
8.0	290	101 (+/- 3)
8.5	290	107 (+/- 3)
9.0	290	114 (+/- 4)

Size Printing on the Gloves:

L 6.5 = Size 6.5 for Left hand

R 6.5 = Size 6.5 for Right hand

Location of the CE marking on the product:

Marking is done on Product packaging (Box Label) and Pouch Label

Information concerning applicable rules to users:

PPE /MDD products are placed in European market are subject to the regulation (EU) 2016/425 and 93/42/EEC. They are subject to essential requirements to Safety, Health and Environment and to EC Type Examination procedure as and when applicable. As regards to the selection and use of a PPE, we remind that it has to be done in accordance with regulation (EU) 2016/425 but essential requirements of 93/42/EEC Annex-V also need to be met with.

Notified body responsible for EC type examination:

Notified Body (SGS Fimko Oy)

SGS Fimko Oy,
Takomotie 8, FI-00380 Helsinki, Finland.

Identifying Number: 0598

Notified Body (SGS BELGIUM NV)

SGS BELGIUM NV,
SGS House, Noorderlaan 87 - 2030 Antwerpen.

Identifying Number: 1639

Name and address of European Authorized Representative (EAR):

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