MAVIG

MAVIG´s sterile gloves with X-ray radiation shielding now offer an optimized protection for medical staff.

A combination of traditionally contradicting properties has been achieved with the development of these gloves: Great shielding, great elasticity, great sensitivity.

Important information to the legal regulatories in between the EU:

Sterile gloves for protection against X-rays are used as personal protective equipment, while classified as a medical device. Thus, the CE-conformity to both relevant European Directives 89/686/EEC (PPE) and 93/42/EEC (MDD) are mandatory for these products.

With MAVIG HS100 you are on the safe side:

Our gloves are certified correctly and CE-compliant to the EU directives mentioned before.

HS 100

Effi cient protection for hands against scattered radiation

To drastically lower the radiation dose equivalent for medical personal is a must, and not just to the permissible levels of the effective dose!

The idea of optimizing radiation protection demands that every possible measure has to be taken in order to minimize the amount of radiation exposure.

MAVIG offers with HS100 - X-ray-absorbing, sterile gloves - an efficient way for the reduction of scattered radiation exposure.

Remarkable is the achieved protection factor of 2 when the gloves are applied in the range of scatter radiation (X-ray tube voltage 60 – 80 kV).

The > 50% reduction effectively aids to minimize health risks.

Excellent product characteristics and the optimized fit easily provide a better protection.

- **Powder-free**
- **Low-protein natural rubber**
- **Lead free**
- **Non-toxic**
- **Sterile**
- **Excellent gripping ability**
- **High elasticity**
- **Great touch sensitivity**
- **Extreme tear-resistant**
- **Available in multiple sizes**

Characteristics

The product is classified as a powder-free sterile glove, which features the additional benefit of X-ray protection properties on top of its core material characteristics of impermeability and protection against chemicals and microorganisms.

Great elasticity in combination with an excellent anatomical fit allows for optimal working conditions, bringing it in the same category of high quality surgical gloves, while additionally offering efficient protection against secondary X-ray radiation (scattered radiation).
The product convinces with its high touch-sensitivity and dexterity. The micro-textured surface provides a secure grip, even in moist conditions. The soft, stretchable material with its anatomical form prevents fatigue and provides optimal ergonomic features.

The gloves are easy to put on and are especially tear-resistant due to their elasticity and rolled edge.

The product is intended for the shielding against secondary radiation and provides efficient protection.

The application in the range of the primary radiation can be counterproductive, if an automated dosage regulator is activated. The automated dosage regulator must be deactivated, if the intended use of the gloves are in the area of the primary radiation.

This sterile product is intended for single use.

Material

Lead free, metal oxides achieve the great shielding effect of our gloves.

The unique quality of the MAVIG gloves HS100 are enabled by the usage of elastic natural rubber.

Via the manufacturing process it is ensured that the protein content is kept at a minimum level. Water-soluble, allergenic proteins are extracted from the latex so that we are able to refer to our product as low-protein latex gloves.

Measured Values
Reduction of the skin dosage from scattered radiation
Lead Equivalent
Reduction of Primary Radiation

Sales unit

Sales units are made up of convenient dispenser boxes, each containing 5 pairs of gloves of the same size. Each pair is securely stored in a sterile peelpack with an additional inlay, assuring that the gloves use can be applied in a sterile condition.

Sizes and Article Codes

Size 6,5	HS10065	Size 8,0	HS10080
Size 7,0	HS10070	Size 8,5	HS10085
Size 7,5	HS10075	Size 9,0	HS10090

Sterile X-Ray Protective Gloves

	Average
X-ray tube voltage 60 kV	63 %
X-ray tube voltage 80 kV	53 %
X-ray tube voltage 100 kV	46 %
Pb 0.03 – 0.04 mm	
X-ray tube voltage 80 kV	20–25 %

The reduction parameters have been determined in the broad beam, according to IEC 61331-1 (EN 61331-1:2002).
The values of the skin dose reduction refer to a nominal material thickness of 0.30 mm.

In which texts of the applicable law are X-ray protection gloves mentioned?

DIN 6815
(Regulations for the control of radiation protection of medical X-ray equipment up to 300 kV). This regulation recommends the usage of surgical gloves with radiation protective properties as part of protective clothing for medical staff participating in Angio/DSA, cardiac catheter examinations, and intrasurgical X-ray examinations.

SV-RL
(Guideline for technical control of X-ray equipment and license required sources of scattered radiation – guideline for authorized expert inspections according to Xray regulation).
The guideline states in inspections for mobile C-bows, C-bows suspended from ceiling columns in operation rooms, as well as for combined radiography and radioscopic X-ray equipment, including for therapy purposes that surgical gloves with radiation shielding properties are a part of appropriate personal protection equipment.

RöV
(Regulation for the protection against harm caused by X-rays / X-ray regulation). RöV installs in its radiation protection principles that each radiation exposure should be kept at a minimum, even if it is below the allowed levels.

Radiation Protection Regulation recognizes the principle of optimization as particularly important for applied radiation protection. The ALARA-guideline confirms the principle of exposure minimization. When dealing with ionizing radiation, the exposure should be kept as low as appropriate measures permit.

IEC (DIN) 61331-3
(Radiation protection in the field of medical X-ray diagnostics)
One chapter has its focus on radiation protective gloves, which are recommended to be worn by the operator during radiological examinations or interventional applications for as long as the hands are located in the primary beam or in an area of intensive scattered radiation.
Further comments can be found in the report of the Bavarian State Office for Work Protection, Industrial Medicine, and Safety Engineering (Lfas).

Have studies documented that gloves reduce the equivalent dose of medical staff exposed at the place of work?

A report from the Bavarian State Office for Work Protection, Industrial Medicine, and Safety Engineering (Lfas) describes that conventional X-ray protection gloves described in DIN 61331-3 with a Pb-value of 0.25 mm or more find only very limited application due to their stiffness, making them only adequate for holding uncooperative patients.

Due to their lack of practicality, these protective gloves are not used for most radiological applications.

Furthermore, the dose estimations of the study show that especially in the fields of surgical orthopedy and interventional applications, the RöV safety values are frequently exceeded.

If the gloves are being judged on their practical usage, then shielding values must be obtained which justify their usage.

One must also note that a minimum protection factor of 2 is required. This means a reduction of the dose by >50% must be achieved so that the X-Ray protective gloves can be classified as personal protective equipment.

Sound standing research also exists for the protection provided with the usage of beta emitters ***(Klinikum Augsburg, H. Wengenmair, J. Kopp, J. Sciuk).***
For example, the dose received on the skin's surface can be reduced by 70 – 80% in the case of nuclides of middle betaenergy (representative RE-186), and by more than 30% in the case of nuclides with very high beta energy (representative RE-186).

Therefore, the usage of surgical gloves with radiation protective properties can be regarded as appropriate to achieve dose reductions, particularly in the case of nuclides with middle beta energy, where other radiation shielding methods are difficult to apply.

Another research study dedicated to radiation protection of the hands during spine-surgery was published in the renowned ***Journal of Neurosurgery Spine (J. Kiwit, M. Synowitz).***
Modern neuro-surgical treatments such as vertebroplasty and kyphoplasty are carried out with the aid of X-rays.
They create a significantly longer period of time exposed to radiation than conventional surgery.

The surgeons easily reach the safe levels permitted by law as their hands are continuously exposed to the radiation while reconstructing the spine and injecting bone cement into the collapsed vertebra.

The result of the study was that the radiation exposure can be reduced to a quarter of the dose simply by protecting the surgeon's hands using appropriate gloves with radiation protection.

The above quoted research only represents a small selection, but due to the importance of protecting the hands, and due to the attention this subject deserves, we are optimistic that many more studies will be additionally carried out in the near future.

WORLDWIDE MAVIG OFFICES

REPRESENTATION

MAVIG GmbH
Headquarters

PO Box 82 03 62
81803 Munich
Germany

Stahlgruberring 5
81829 Munich
Germany

Phone: +49 (0) 89 420 96 0
Fax: +49 (0) 89 420 96 200
e-Mail: info@mavig.com

Nordic & Baltic Countries
MAVIG Nordic

Stockholm
Sweden

Phone: +46 (0) 722 25 25 68
e-Mail: larsson@mavig.com

Benelux, GB, Ireland
MAVIG B.V.

Dunne Bierkade 28
2512 BD Den Haag
Netherlands

Phone: +31 (0) 70 345 99 85
Mobile: +31 (0) 61 595 43 48
e-Mail: simmonds@mavig.nl

France
MAVIG France SARL

66, Ave. des Champs Elysées
F-75008 Paris
France

Phone: +33 (0)1 30 59 46 23
Fax: +33 (0)1 30 59 46 23
e-Mail: info@mavig.fr

China
MAVIG Healthcare Beijing Co., Ltd.

Tower 1, Block C - Room No. 2607
Wangjing SOHO
Futong East Street No. 1
Wangjng Area, Chaoyang District
Beijing 100102, China

Phone: +86 - 10 - 46 79 62 88
Fax: +86 - 10 - 46 79 62 88
Mobile: +86 - 13 70 122 85 86
e-Mail: zhang@mavig.com

USA & Canada
Ti-Ba Enterprises, Inc.

25 Hytec Circle
Rochester, NY 14606
USA

Phone: +1 (1) 585 247 1212
Fax: +1 (1) 585 247 1395
(international)
1 800 836 8422
(in the USA)
e-Mail: mavig@ti-ba.com

Middle East & Northern Africa
Mena Medical Development

Ashrafieh – Adlieh Square – Alfaras St.
- Alboustany Building, 5th floor
Beirut
Liban

Phone: +961 14 23 499
Fax: +961 14 26 499
e-Mail: mavig@mena-md.com

www.mavig.com

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