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SURGICAL RADIATION ATTENUATION GLOVES

A CRITICAL TOOL IN FLUOROSCOPIC SAFETY

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Fluoroscopy & Associated Health Risks

Fluoroscopy is an imaging technique that provides real-time X-Ray moving images on a monitor, enabling operators and surgeons to visualize the positioning of devices during procedures.
In recent years, the use of fluoroscopic procedures has increased [1,2]. The radiation used in fluoroscopy passes through the patient undisturbed, creating a negative image. However, the remaining radiation can be absorbed by the patient's tissue or scattered after interaction with the patient's tissue atoms.
Although scattered radiation is less irradiated than the primary beam, it poses a risk for the operating surgeon and the assisting personnel placed in the vicinity of the patient. Research indicates that orthopedic surgeons [3,4], spine surgeons [1], and cardiac [5] surgeons face significantly higher risks due to the procedures applied. In particular, hands are exposed to the highest doses; X-ray induced dermatitis was identified as early as 1896.[6] Lifetime incidents of cancer incidents among orthopedic surgeons is about five times higher than among unexposed staff.[7] A recent study even found that 31.4% of the orthopedic surgeons sampled had radiation-induces skin injuries.[4]
While the threshold for avoiding health-effects from long-term intermittent exposure to low-dose fluoroscopy radiation is still unknown [3], recent research suggests that longer occupational periods and accumulated exposure time further increase health risks.[4]

Mitigating Radiation-Induced Risk: Radiation Attenuation Gloves

Radiation attenuation gloves offer a simple yet effective way to minimize radiation exposure to the hands.[8] These gloves reduce the risk by incorporating metallic shielding particles into the glove material, which can constitute up to 75% of the glove's composition. However, these particles usually negatively impact the glove's softness and other mechanical properties, posing a challenge for glove manufacturers.

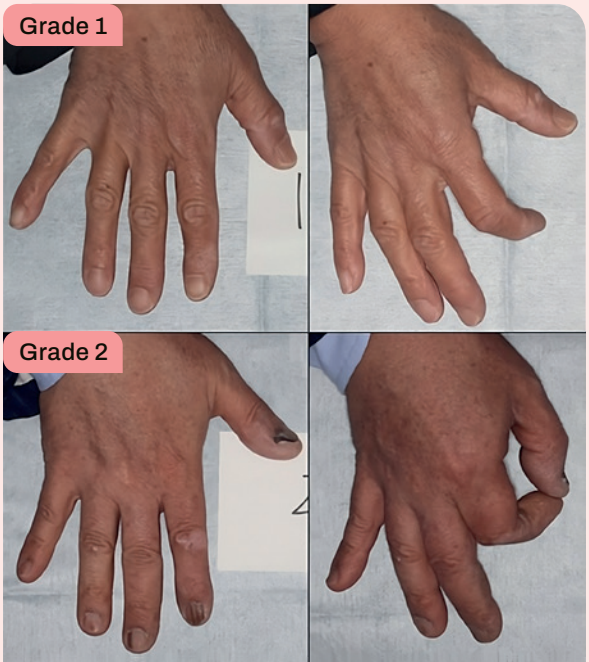
Toxic Protection? Lead – a dangerous and toxic matrial

In some cases, lead is used as the shielding material in these gloves. Lead is toxic and must be disposed of as hazardous waste. The acidity of sweat can cause the solubilization of lead ions from lead oxide allowing lead to be absorbed through the skin.[2]

Allergies from Residual Chemicals

Natural rubber latex gloves, especially those with powder, were once identified as a major cause of allergy development within the healthcare sector. After transitioning to powder-free and synthetic gloves since the turn of the millennium, Type I allergies decreased, but Type IV allergies, such as allergic contact dermatitis have noticeably increased.[9] Accelerators have long been identified as a major cause for this development.[10] In fact the accelerator 1,3-diphenylguanidine (DPG) has been found particularly allergenic.[11] Accelerators are used in the manufacturing of rubber and synthetic rubber products to speed up the vulcanization process and thus save energy.
Recent glove innovations focus on safer compositions of accelerators reducing their allergy potential and improved glove washing procedures to minimize chemical residues.

Occupational ionizing radiation-induced skin injury among orthopedic surgeons:



SYNTEGRA X:
THE ADVANCED SOLUTION

A glove, designed with a unique material composition offering enhanced flexibility, excellent tactile sensitivity, prolonged wearing comfort, and reduced hand fatigue. It is ideal for reducing hand exposure to harmful scattered ionizing rays during fluoroscopic procedures.

X–cellent Wearing Comfort

Our synthetic polyisoprene radiation attenuation glove provides sublime wearing comfort compared to other radiation attenuation gloves. Its textured finger micro-surface enhances flexibility and comfort for instrument handling.

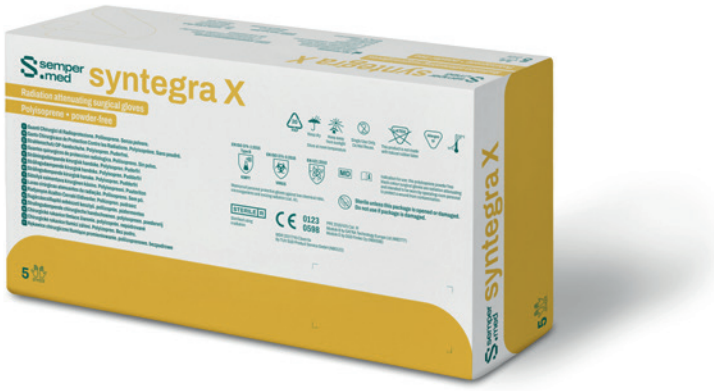
X–tra Safe

The proprietary tungsten composition of syntegra X is 75% denser than lead, offering superior attenuation ability than leaded gloves at equivalent thickness. Additionally, the glove is latex- and lead-free.

X–ccelerator Optimized

Formulated without DPG and MBT, which has recently been classified as a cancer-causing agent in California Prop-65. Syntegra X undergoes an extensive washing process to reduce residues of other manufacturing related chemicals.

Syntegra X represents a significant advancement in radiation attenuation glove technology, prioritizing both safety and comfort for healthcare professionals. Radiation attenuating surgical gloves to reduce the exposure from harmful scattered ionizing rays on the operator´s hand during fluoroscopic procedures. These gloves are not to be used in or next to primary X-Ray beam.



Technical data

Color	dark grey
Size / Overall length as per EN 455-2	min. 285 mm
Wall thickness measured in single layer in the palm area	Model 1 – min. 0.24mm Model 2 – min. 0.32mm
Barrier performance	AQL 0.65
Material	Soft synthetic polyisoprene containing lead-free radiation attenuating tungsten alloy. Formulated without DPG and without MBT.
Glove shape	fully anatomical with curved fingers and rolled rim
Force at break as per EN 455-2	≥ 9.0 N
Shelf life in original packaging if stored according to product specification	3 years
Sterilization	radiation STERILE R
Labeling & conformity to standards	EN455-1:2020, EN455-2:2024, EN455-3:2023, EN455-4:2009; EN 61331-1:2014; EN ISO 10993-5:2009; EN ISO 10993-10:2021; EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 15223-1:2021, EN ISO 11607-2 :2020, EN ISO 11137-1 :2015, EN ISO 11137-2 :2015, EN388:2016+A1:2018, EN ISO 21420:2020, EN421:2010 and EN374-1:2016, EN16523-1:2015+A1:2018, EN374-2:2014, EN374-4:2013 and EN374-5:2016
Purpose	**Single-use medical device class IIa** according to EU MDR 2017/745 **Single-use protective glove – PPE category III** protection against low chemical risks, microorganisms and ionizing radiation PPE Regulation EU 2016/425 Cat. III

Packaging

1 pair with folded cuffs in folded bag protected against microbiological contamination.
5 pairs per dispenser box: 60 x 157 x 290mm
4 boxes per transport carton: 135 x 293 x 330mm

Article numbers

	Model 1	Model 2
size 5½	3000016262	3000016270
size 6	3000016263	3000016271
size 6½	3000016264	3000016268
size 7	3000016265	3000016272
size 7½	3000016266	3000016274
size 8	3000016267	3000016275
size 8½	3000016268	3000016276
size 9	3000016269	3000016277

Attenuation properties

	X-ray tube voltage (kV)	Model 1	Model 2
Average % attenuation values EN 61331-1:2014	60	52%	61%
	80	44%	54%
	100	40%	49%
	120	36%	45%
Average % attenuation values ASTM F 2547-18 (2023) & ASTM F 7866-23	60	41%	50%
	80	34%	42%
	100	28%	36%
	120	24%	31%

Sampling according to EN 421, average on 4 locations and 2 gloves
Model complies with min. attenuation requirements defined in ASTM7866-23

REFERENCES

1 Hijikata Y, Kamitani T, Yamamoto Y, Itaya T, Kogame T, Funao H, Miyagi M, Morimoto T, Kanno H, Suzuki A, Kotani Y, Ishii K. Association of occupational direct radiation exposure to the hands with longitudinal melanonychia and hand eczema in spine surgeons: a survey by the society for minimally invasive spinal treatment (MIST). Eur Spine J. 2021 Dec;30(12):3702-3708. doi: 10.1007/s00586-021-06973-3. Epub 2021 Aug 24. PMID: 34427761.

2 Thibault T, Gurung M, Leuvrey C, Boos A, Ronot P, El Masoudi I, Hoerner P, Bellemin-Laponnaz S. Lead-containing radiation-attenuating sterile gloves in simulated use: Lead transfer to sweat as an unknown risk to users. Radiography (Lond). 2024 Jan;30(1):159-162. doi: 10.1016/j.radi.2023.10.013. Epub 2023 Nov 29. PMID: 38035427.

3 Hoffler CE, Ilyas AM. Fluoroscopic radiation exposure: are we protecting ourselves adequately? J Bone Joint Surg Am. 2015 May 6;97(9):721-5. doi: 10.2106/JBJS.N.00839. PMID: 25948518.

4 Asari T, Rokunohe D, Sasaki E, Kaneko T, Kumagai G, Wada K, Tanaka S, Sawamura D, Ishibashi Y. Occupational ionizing radiation-induced skin injury among orthopedic surgeons: A clinical survey. J Orthop Sci. 2022 Jan;27(1):266-271. doi: 10.1016/j.jos.2020.11.008. Epub 2020 Dec 19. PMID: 33349545.

5 Andreassi MG, Piccaluga E, Guagliumi G, Del Greco M, Gaita F, Picano E. Occupational Health Risks in Cardiac Catheterization Laboratory Workers. Circ Cardiovasc Interv. 2016 Apr;9(4):e003273. doi: 10.1161/CIRCINTERVENTIONS.115.003273. PMID: 27072525.

6 Grubbé, Emil Herman. X-ray treatment; its origin, birth and early history. Bruce Publishing Company, 1949.

7 Mastrangelo G, Fedeli U, Fadda E, Giovanazzi A, Scoizzato L, Saia B. Increased cancer risk among surgeons in an orthopaedic hospital. Occup Med (Lond). 2005 Sep;55(6):498-500. doi: 10.1093/occmed/kqi048. PMID: 16140840

8 Singer G. Radiation exposure to the hands from mini C-arm fluoroscopy. J Hand Surg Am. 2005 Jul;30(4):795-7. doi: 10.1016/j.jhsa.2005.01.007. PMID: 16039374.

9 Dejonckheere, G., Herman, A. & Baeck, M. (2019). Allergic contact dermatitis caused by synthetic rubber gloves in healthcare workers: Sensitization to 1,3- diphenylguanidine is common. Contact Dermatitis, 81(3), 167–173. https://doi.org/10.1111/cod.13269

10 Cao LY, Taylor JS, Sood A, Murray D, Siegel PD. Allergic Contact Dermatitis to Synthetic Rubber Gloves: Changing Trends in Patch Test Reactions to Accelerators. Arch Dermatol. 2010;146(9):1001–1007. doi:10.1001/archdermatol.2010.219

11 Crépy, M. (2016). Rubber: new allergens and preventive measures. European Journal Of Dermatology, 26(6), 523–530. https://doi.org/10.1684/ejd.2016.2839

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