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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 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 in folded bag protected against microbiological contamination with folded cuffs.
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	Not available. Coming soon.	SXR650HD
size 6		SXR650HD
size 6½		SXR650HD
size 7		SXR700HD
size 7½		SXR750HD
size 8		SXR800HD
size 8½		SXR850HD
size 9		SXR900HD

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

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*Please note the Sempermed Chemical Resistance list is available on https://gotgloves.com/gloves-chemical-resistance-chart/
IMPORTANT NOTE: The latest product information is available at www.gotgloves.com under the «Products» tab. Failure to observe this information, in particular with regard to (chemical) resistance, frequency of use and tolerability of the gloves, can result in personal injury and/or material damage. **HARPS is not liable for incorrect use of the gloves nor will HARPS be liable for improper storage and handling. In case of damage or unusual signs of wear and tear, gloves shall not be used.** In case of any doubt, expert advice should be sought before use. The information and classification is up to date as of the date of publication. Technical details are average values from production and may vary in individual cases. This disclaimer is subject to mistakes, printing errors and amendments.

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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 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-induced 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 material

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

Syntegra X is 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 ionizing radiation during fluoroscopic procedures.

X–cellent Wearing Comfort

Our synthetic polyisoprene attenuation glove provides sublime 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 radiation attenuation that is superior to leaded gloves at equivalent thickness

X–ccelerator Optimized

Formulated without DPG and MBT, which has recently been classified as a cancer-causing agent in California Prop-65. Syntegra X underwent 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 reduce the exposure from harmful scattered ionizing radiation on the operator´s hands during fluoroscopic procedures. These gloves are not to be used in or next to primary X-Ray beam.

syntegra X IFU