

## INSTRUCTIONS FOR USE





12001-02, 12001-03, 12001-04: Gloves, cotton insert

12407, 12408: Sensi-Gloves

12410: Slitted Mittens

12419, 12422, 12425: Superflex



- 1) INDICATIONS FOR USE: Personal Protective Equipment (PPE) is designed to protect the wearer against exposure to medical X-ray radiation. Instruction for Use: Product is designed to be placed on the user by a trained medical professional. Always follow internal procedures regarding this device. Should you have any questions regarding proper use, consult a radiation physicist or radiologist prior to use.
- 2) CLEANING AND DISINFECTION: Refer to the CDC guidelines for disinfecting of environmental surfaces (https://www.cdc.gov/infectioncontrol/guidelines/index.html).

We recommend spot cleaning the surface of the PPE as needed. To spot clean the surface:

- Use a soft bristle brush and a water-diluted mild soap solution (NEVER use bleach, hard chemicals or
- Isopropyl alcohol may be used for disinfecting purposes or to treat stubborn stains.
- Wipe the area gently with water and hang to FLAT to dry. (NEVER machine launder, dry clean or autoclave)
- The following wipes may be used according to their product directions for use: Clorox Hydrogen Peroxide Cleaner Disinfectant Wipes, Sani-Cloth AF3 wipes (Grey Top)
- 3) STORAGE, HANDLING & DISPOSAL INSTRUCTIONS:  $\, \mathbb{I} \,$ Do not fold or crease gloves. Always store flat or on a PPE glove rack when not in use. Gloves should be disposed of according to applicable local government laws.



4) INSPECTION: I

Gloves/Mittens should be checked fluoroscopically at regular intervals (at least once a year) as standard practice. Even a slight crack in the lead core material can render the glove/mitten damaged, which can expose the user to radiation. Replacement should be considered every 18-24 months, depending on the amount of usage and general wear and tear.

- 5) LIMITATIONS: LIMITATIONS: PPE is not intended for nuclear or gamma use. Products contains a sewn-in permanent label stating the product's protection level, material lot number, and the original date of manufacture. Do not remove the label.
- 6) WARNINGS: Follow all internal procedures regarding the use of these devices. If questions arise regarding proper use, consult radiation physicist or radiologist prior to use. Improper use of this device may expose person to unwanted levels of X-radiation. PPE containing lead are environmentally hazardous. PPE is to be disposed of according to local laws.
- 7) Performance: **ENTER CHART HERE**
- 8) Regulatory Information:

Made in USA. Wolf X-Ray PPE are manufactured to meet EU 2016/425 regulations; EC-Type examination conducted by Notified Body 0598, SGS. Fimko Oy, P.O. Box 30 (Särkiniementie 3), 00211 Helsinki, Finland. Wolf X-Ray PPE is tested and manufactured to meet IEC 61331-1:2014 and IEC 61331-3:2014 standards. Pictograms meet ISO 15223-1:2016 standard. Wolf X-Ray is an ISO 13485:2016 certified company. To view a Wolf X-Ray EU Declaration of Conformity please visit <a href="https://www.wolfxray.com">www.wolfxray.com</a>

Pictograms:

Manufacturer Manufactu	Lot number	Instructions for use	Stock number REF	Indicates a device that can be damaged if not handled correctly
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