

	ST. MARYS RUBBERS PVT.LTD	Doc No: SMR/IFU/SLEGPF
	Instruction For Use- Sterile Latex Examination Gloves Powder Free (polymer coated)	Revision No: 00
		Date: 07.04.2022
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1. Product Description

The Sterile Latex Examination Gloves Powder Free are manufactured from natural rubber latex (Type-I) and supplied in various sizes from Ex- small, Small, Medium, Large and Ex-Large. It is Sterilized by Ethylene Oxide. Glove is free from dirt marks, oil stains, embedded foreign particles, coagulum etc. Glove is ambidextrous. The glove is creamy white in colour. Gloves is coated with unique blend of polymer to provide excellent donning capability. The cuff shall fit closely without being constrictive and it shall not roll back or ruckle while in use. Product is having a shelf life of 5 years from the date of manufacturing. It is sterilized by validated process cycle and sterility assurance level (SAL) is 10^{-6} . It passes viral penetration test as per ASTM F 1671. Glove is Nontoxic and non-irritant. Glove is biologically compatible as per ISO 10993-Part-5,7 & 10 and it is manufactured in a hygienic environment to achieve low bio burden level prior to sterilization.

2. Intended Use

Manufactured from natural rubber latex. Gloves intended for use in the medical field to protect patient and user from cross-contamination, conducting medical examinations, diagnostic and therapeutic procedures and for handling contaminated medical materials. The gloves are designed for transient use and are intended to be used in conjunction with invasive procedures. The gloves are made powder free by polymer coating process.

3. Duration of Use

Duration of Use is Transient Use (<60 minutes)

4. Medical Indication

- Protection of the wearer from contamination with blood, Secretions and excretions and the associated risk of contamination with pathogens capable of reproduction.
- Prevention of pathogen release from the hand into sterile work area during aseptic duties
- Protection from chemicals
- Defined pathogen barrier as protection from biological agents.

5. Contraindication

- Latex gloves are made of Natural rubber latex, which may cause allergic reactions including Latex Allergy – Anaphylactic if the user is allergic to latex.
- Gloves contain Natural Latex; persons who are sensitive to Latex should consult a physician before using

6. Intended User

Doctors, nurses, caregivers, dentists and other healthcare Professionals can use the Examination gloves

7. Target Patient Population

It can be used in all patient population except in patients with known allergy to natural latex rubber.

8. Precaution and Warnings

- This product contains natural rubber latex which may cause allergic reaction such as latex allergy, including anaphylactic responses in some individuals
- Store in a cool, dry place and away from direct sunlight
- Do not Re-sterilize – Re-sterilization can cause product damage / Contamination
- Do not Re Use - Reuse can cause infection, allergic reaction and poor barrier protection.
- For transient use only
- Dispose after use as per hospital policies or country's regulatory norms

9. Direction for Use

- Select the appropriate size gloves for the hands
- Take out the wallet from the pouch by peeling it off at the site of direction for open
- Put hand through the glove opening

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- Adjust the gloves as needed
- Must check the date of manufacturing and expiry date before using.

10. Side Effects/Adverse Events

Itching, rashes, inflammation, pain, latex allergy, skin redness, ulcerated skin, peeling skin, hypersensitivity type-I reaction

11. Residual Risks

Latex Allergy (Type-I Allergy, Anaphylaxis), Infections, Inflammation and Toxic to environment

12. Clinical Benefits

NRL or Natural Rubber Latex Gloves:

- Are competent barrier to protect against infections for both healthcare professionals and the patients.
- Are easy to put on comfortable to wear and provide adequate, durable protection.
- Have less after-use defects.
- Has significant greater satisfaction with regard to factors such as quality, safety and durability.
- Have good barrier integrity.
- Have good fit and comfort
- Have high tear propagation strength
- Have high tensile strength

13. Disposal Instruction

Dispose after use as per hospital policies or country's regulatory norms.

14. How Gloves are Supplied

Gloves are supplied as a pair

15. Symbols used on Label

	Do not re-use		Consult Instructions for Use		Do not Re-sterilize
	Sterilized by ethylene oxide		Contains or presence of latex rubber		Size
	Expiry Date		CE Mark		Lot/Batch No
	Do not use if package is opened or damaged		Authorized representative in the European Community (Emergo Europe)		Manufacturer (St.Marys Rubbers Pvt Ltd)
	Date of Manufacture		Unique Device Identification		Sterile Barrier System
	Keep away from sun light		Keep Dry		Temperature limit
	Medical Device				