	<b>ST. MARYS RUBBERS PVT.LTD</b>	Doc No: SMR/IFU/SLEGPF
	<b>Instruction For Use- Sterile Latex Examination Gloves Powder Free</b>	Revision No: 03
		Date: 21.02.2024
		Page 1 of 5

### 1. Product Description

Sterile Latex Examination Gloves powder free (polymer coated) are manufactured from natural rubber latex and supplied in Small, Medium & Large sizes. Sterilized by Ethylene Oxide. Ambidextrous with straight fingers and beaded cuff. The gloves are made powder free by polymer coating process. Manufactured under hygienic condition. Conforms to ASTM D 3578, EN 455 and ISO 11193-1 standard. Products have shelf life of 5 years from the date of manufacturing. Gloves compounded primarily from natural rubber latex (Type-1)..Beaded and long cuff gloves. Refer to above image. Creamy white in colour. Free from dirt marks, oil stains, embedded foreign particles, coagulum etc. Textured at fingertip area. The cuff shall fit closely without being constructive and it shall not roll back or ruckle while in use. Nontoxic and non-irritant. Single Use Gloves dimensions comply EN 455 /ASTM D 3578 standards.

### 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. Device Variant List

#	Variant Name	Variant Description/Details
1.	Sterile Latex Examination Gloves – Powder Free (Polymer Coated)	Extra Small (XS), Small (S), Medium (M), Large (L), Extra Large (XL)

### 4. Guidance regarding choice of right size of gloves

- It's important to find the correct sizing to ensure the optimal levels of comfort and tactility.
- Glove size measures in mm, so a tape measure to find the right size gloves for the hands.
- To find out glove size, wrap a measuring tape around the widest part of hand (excluding thumb)
- Measure from the tip of the middle finger to the base of the hand
- Use the largest of these two measurements for the correct size glove (e.g.: If your hand measures 6.5 - 7, choose size 7.

### 5. Duration of Use

Duration of Use is Transient Use (<60 minutes). If the device is used continuously for more than 60 minutes, there is a chance for blood borne infection, post operative wound infection. User should change the gloves hourly once.

### 6. 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
- Defined pathogen barrier as protection from biological agents.
- Acts as a barrier protection for microorganisms

### 7. 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

### 8. Intended User

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

	<b>ST. MARYS RUBBERS PVT.LTD</b>	Doc No: SMR/IFU/SLEGPF
	<b>Instruction For Use- Sterile Latex Examination Gloves Powder Free</b>	Revision No: 03
		Date: 21.02.2024
		Page 2 of 5

### 9. Target Patient Population

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

### 10. 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
- Do not use if the pouch is torn or sterility is compromised
- Glove is not used in handling food and cytotoxic agents
- Double gloving is not recommended, double gloving is done for procedures with contact with large amounts of blood or body fluids, for some high-risk orthopaedic procedures

### 11. Condition not involving glove usage of direct and indirect patient exposure

Direct Patient Exposure: Taking blood pressure, temperature and pulse; performing Subcutaneous and Intramuscular injections; bathing and dressing the patient; transporting patient; caring for eyes and ears (without secretions); any vascular line manipulation in absence of blood leakage.

Indirect Patient Exposure: Using the telephone; writing in the patient chart; giving oral medications; distributing or collecting patient dietary trays; removing and replacing linen for patient bed; placing non-invasive ventilation equipment and oxygen cannula; moving patient furniture.

Contact Precaution: When indicated, use of medical gloves is recommended as part of contact precautions, to reduce the risk of pathogen dissemination to the patient's environment, to other patients and for the protection of healthcare workers.

Reference: [glove-use-information-leaflet.pdf \(who.int\)](#)

### 12. 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
- Adjust the gloves as needed
- Must check the date of manufacturing and expiry date before using.

### 13. Side Effects/Adverse Events

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


### 14. Residual Risks

- 1.Latex Allergy (Type-I Allergy, Anaphylaxis)
- 2.Infections, cross contamination, Allergic reaction, Inadequate barrier protection
- 3.Inflammation
- 4.Toxic to environment
- 5.Poor dexterity, Puncture or perforation to the gloves.

### 15. Clinical Benefits

NRL or Natural Rubber Latex Gloves:

1. NRL gloves are competent barrier to protect against infections for both healthcare professionals and the patients.

 <b>ST. MARYS RUBBERS PVT. LTD.</b>	<b>ST. MARYS RUBBERS PVT.LTD</b>	Doc No: SMR/IFU/SLEGPF
	<b>Instruction For Use-</b> <b>Sterile Latex Examination Gloves Powder Free</b>	Revision No: 03
		Date: 21.02.2024
		Page 3 of 5

2. NRL gloves provide lower rates of perforation and lower viral leakage rates.
3. NRL gloves are easy to put on comfortable to wear and provide adequate, durable protection.
4. NRL gloves have good barrier integrity.
5. NRL gloves have less after-use defects.
6. NRL Gloves has significant greater satisfaction with regard to factors such as quality, safety and durability.
7. NRL gloves have high tear propagation strength
8. NRL gloves have lower perforation rate
9. NRL gloves have high tensile strength
10. NRL gloves have good fit and comfort

#### 16. Disposal Instruction

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




















#### 17. How Gloves are Supplied

Gloves are supplied as a pair

#### 18. Storage condition

Storage of gloves should be in between 5°C - 30°C.

#### 19. 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 Prinsessegracht 20, 2514 AP The Hague, The Netherlands)		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				


#### 20. Revision History

Revision No	Changes Incorporated	Effective Date
-------------	----------------------	----------------



**Instruction For Use-  
Sterile Latex Examination Gloves Powder Free**

00	Initial Release	07.04.2022
01	<ol style="list-style-type: none"> <li>1. Added section 3 (Medical Device Qualification) and section 4 (Medical Device Classification)</li> <li>2. Updated section 11 (Duration of Use)</li> <li>3. Added section 9 (Device Variant List)</li> <li>4. Added section 6, 7 and 8 (Physical and chemical Description including length, width specifications; Powder content&amp; specification)</li> <li>5. Added PPER - personal protective equipment regulation classification &amp; compliance in section 5.</li> <li>6. Protection against chemical and microorganism is updated in section 12</li> <li>7. Storage temperature is updated in section 24</li> <li>8. Guidance regarding choice of right size of gloves is updated in section 10.</li> <li>9. Details of protein and powder specification is updated in section 8.</li> <li>10. Use of this gloves in Contact precaution; handling cytotoxic agents, food etc updated in section 16</li> <li>11. Conditions not involving glove usage of direct and indirect patient exposure is updated in section 17</li> <li>12. Use when the sterility is compromised or the package is torn is updated in section 16</li> <li>13. Reference for details/ steps to be taken if the surgical procedures take more than one hour is provided in section 11</li> <li>14. Double Glove use addressed in section 16.</li> <li>15. Contact precaution is updated in section 17.</li> <li>16. Product description updated as per technical file in section 1</li> </ol>	23.06.2023
02	Updated residual risks in section 14	22.09.2023
03	<ol style="list-style-type: none"> <li>1. Inches is changed to mm in section 4</li> <li>2. Act as a barrier for chemical is removed from section 6</li> <li>3. Medical Device Qualification, Medical Device Classification, Physical and chemical Description including length, width specifications; Powder content&amp; specification, personal protective equipment regulation classification &amp; compliance, reference for details/ steps to be taken if the surgical procedures take more than one hour is removed.</li> <li>4. Updated Residual Risks in section 14 and Medical benefits in section 15</li> <li>5. Updated Unique Device Identification symbol in section 19</li> </ol>	21.02.2024

	<b>ST. MARYS RUBBERS PVT.LTD</b>	Doc No: SMR/IFU/SLEGPF
	<b>Instruction For Use- Sterile Latex Examination Gloves Powder Free</b>	Revision No: 03
		Date: 21.02.2024
		Page 5 of 5