

Latex Surgical Gloves- Powdered

Instruction for Use

Doc No: PGPL/IFU/LSG PD

Rev No: 02

Date: 01.03.2023

Instruction for Use

1. Device Name

Latex Surgical gloves- Powdered

2. Model/Variant and Brand Name

Model/Variant Name	Brand Name
Regular Cuff	Protac, Healthcare Plus, Novicare, Protex, Krivicare, Maxens
Long Cuff/Gynaecological	Protac ,Surgilac, HM Healthcare

3. Device Description:

The Latex Surgical Gloves – Powdered are made of natural rubber latex. The Latex Surgical Gloves – Powdered are sterile and disposable medical gloves. These are intended to use by healthcare professionals during medical procedures to help prevent cross-contamination between caregivers and patients. The Latex Surgical Gloves – Powdered are more precise sizing with better precision and complies as per the standards ASTM D3577-19 and EN 455. The Latex Surgical Gloves – Powdered are sterilized by Ethylene Oxide or Gamma Irradiation as per the customer requirement. These gloves can be used in gynaecological surgeries or procedures.

4. Device Sizes

#	Variant Name	Variant Details
1.	Regular cuff	Size- 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0 Length- 290 mm
2.	Long Cuff /Gynaecological	Size- 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0 Length- 350- 500 mm

5. Unique Device Identification (UDI)

Basic UDI-DI -89060124501002C

6. Device Intended Use

Latex Surgical Gloves Powdered is a Disposable Device Intended for medical purpose that is worn by operating/procedure room personnel to protect surgical wound/Personnel and to protect the personnel performing the Operation/Procedure from contamination. These gloves can be used in gynaecological surgeries or procedures.

7. Duration of Use

Duration of Use is Transient use (<60 minutes). If it exceeds, there is a high chance for glove perforation which may cause surgical site infections. User should change the gloves hourly once.

8. Device Intended User

Healthcare Surgeons, Operation Theatre Personnel and Healthcare providers for the patients at high risk of infections.

9. Target Patient Population

These sterile latex gloves are used for all patient population except in patients with known allergy to natural latex rubber.

10. Operating Instructions:

- Select the appropriate size Gloves for the hand.
- Take out the Gloves from the pouch by peeling it off at the site of direction for open.
- Wear the gloves as left to the Left hand & Right to the Right Hand as denoted on the pouch.
- Must check the date of manufacturing and expiry date before use.
- Adjust the gloves as needed.

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11. Precautions & Warnings:

- Gloves are powdered with absorbable Dusting powder. After donning gloves, powder may be removed by wiping gloves with sterile wet sponge or other effective method.
- The product should be protected from light sources, in particular direct sunlight or intense artificial light having high ultra-violet content.
- Do not Re-sterilize – The excess ETO residue which stays after re-sterilization may be toxic to the users and patients and Gamma re-sterilization can leads to loss of glove property.
- Do not Re Use - The reuse of the gloves may cause severe complications such as cross contamination, dermatitis, loss of physical properties, infection, allergic reaction and poor barrier protection.
- Do not use if the pouch is torn or sterility is compromised.
- Gloves contain Natural Latex; persons who are sensitive to Latex should consult a physician before using

12. Medical Indications

- 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 the surgical Site during surgery.
- Defined pathogen barrier as protection from biological agents.

13. Contraindications

- Sterile Latex Surgical Gloves Powdered contain Powder content, persons who are sensitive to powder may develop allergy towards the powder content
- Latex gloves are made of Natural rubber latex, which may cause allergic reactions including Latex Allergy – Anaphylactic if the user is allergic to latex.

14. Side Effects/Adverse Events

Latex Allergy, Surgical site infection, Inflammation, Allergy, Pain, Rashes, Itching, Peeling of skin, Hypersensitivity type-I reaction, Skin redness, Ulcerated skin

15. Residual Risks

Infection, Respiratory Diseases (Powder Caution), Anaphylaxis (Latex Allergy)

16. Clinical Benefits

- Gloves are competent barrier to protect against infections for both healthcare professionals and the patients.
- Gloves provide lower rates of perforation and lower viral leakage rates.
- Gloves are easy to put on comfortable to wear and provide adequate, durable protection.
- Gloves have good barrier integrity.
- Gloves have less after-use defects.
- Gloves has significant greater satisfaction with regard to factors such as quality, safety and durability.
- Gloves have high tear propagation strength
- Gloves have low perforation rate
- Gloves have high tensile strength
- Gloves have good fit and comfort

17. Method of Sterilization

The method of Sterilization is Ethylene Oxide or Gamma Radiation

18. Disposal instructions:

- Gloves after usage remove gently & carefully.
- Discard as per the Statutory & regulations laws.

Primus Gloves Private Limited

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19. How Supplied:

- The Colour of the gloves Creamy White.
- Gloves are supplied as pair in each unit of packing.
- IFU is shared per gloves package

20. Storage Conditions:

Prolonged storage of gloves should be in between 10 - 25°C.

21. Explanation of symbols used on label

 Do not Re-sterilize	 Do not use if package is Damaged	 Instructions for Use	 Expiry Date	 Sterilized using Ethylene Oxide	 Sterilized using Gamma Irradiation	 Do not Reuse
 Latex	 Material should be protected from oxidation	 Keep Away From Sunlight	 Size	 Lot Number	 Date of Manufacture	 Keep Dry
 Storage Condition	 CE Logo	 Unique Device Identification	 One pair	 Sterile Barrier System	 Medical Device	

Manufacturer



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22. Manufacturer License Number and GTIN Number

Manufacturer License Number: No.9/01/1998:IL:CSEZ/2676
GTIN No: 890601245

23. Revision History

Revision No	Changes Incorporated	Effective Date
00	Initial Release	07.04.2022
01	Updated section 7, 11, 19 and 21 and added section 22 as per TR1 comments	29.08.2022
02	Updated section 11	01.03.2023