

Nitrile Surgical gloves- Powder free

Instruction for Use

Doc No: PGPL/IFU/NSG PF

Rev No: 01

Date: 29.08.2022

Instruction for Use

1. Device Name

Nitrile Surgical gloves- Powder free

2. Model/Variant and Brand Name

Model/Variant Name	Brand Name
Regular Cuff	Protac

3. Device Description:

The Nitrile Surgical gloves- Powder free are made of synthetic nitrile rubber latex. The Nitrile Examination Gloves – Powder Free 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 Nitrile Examination Gloves – Powder Free are more precise sizing with better precision and complies as per the standards ASTM D 6319-19 and EN 455. The Nitrile Examination Gloves – Powder Free are sterilized by Ethylene Oxide or Gamma Irradiation as per the customer requirement.

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- 280

5. Unique Device Identification (UDI)

Basic UDI-DI - 89060124503002N

6. Device Intended Use

Nitrile Surgical Gloves Powder free 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

7. Duration of Use

Duration of Use is Transient use (< 60 minutes).

8. Device Intended User

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

9. Target Patient Population

Gloves are used for all patient population except in patients with known allergy to Synthetic Latex.

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 using.
- Adjust the gloves as needed.

11. Precautions & Warnings:

- 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.

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- 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.
- Gloves contain synthetic nitrile rubber latex persons who are sensitive to synthetic nitrile rubber 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

- Gloves are made of synthetic nitrile rubber latex, which might cause allergic reactions if the user is allergic to synthetic nitrile rubber latex.

14. Side Effects/Adverse Events

Surgical site infection, Inflammation, Allergy, Pain, Rashes, Itching, Peeling of skin, Skin redness, ulcerated skin

15. Residual Risks

- Infection

16. Clinical Benefits

- Nitrile medical gloves has effective barrier protection qualities
- Nitrile medical gloves have lowest failure rate against stress
- Nitrile medical gloves have good elastic and resistance properties
- Nitrile medical gloves has good strength
- Nitrile medical gloves are Hypo-allergenic
- Nitrile medical gloves have low resistance to friction making it easy to don and doff
- Nitrile medical gloves are chemically resistant
- Nitrile medical gloves have high level of sensitivity
- Nitrile medical gloves have good fit and comfort

17. Method of Sterilization

The method of Sterilization is Ethylene Oxide / Gamma Irradiation.

18. Disposal instructions:

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

19. How Gloves are Supplied:

- The Colour of the gloves Creamy White.
- Gloves are supplied as a 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.

Primus Gloves Private Limited

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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 Free	 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 11, 19 and 21 and added section 22 as per TR1 comments	29.08.2022