

Ultra Gloves Beadless, Non-Sterile Powdered

DEVICE INTENDED USE:

The surgical gloves are intended to act as a protective barrier between the patient and health care worker during invasive surgeries and to facilitate general hand hygiene.

DEVICE CATALOGUE NO. AND AVAILABLE SIZES:

Catalogue no.	Sizes.
ULTLPNBL	5.5,6.0,6.5,7.0,7.5,8.0,8.5,9.0

BASIC UDI:

8905159SRGLPWCB

DEVICE DESCRIPTION:

Ultra Gloves Beadless – Non- Sterile (Powdered Gloves)

Ultra Gloves anatomically shaped medical gloves with the thumb positioned towards the palmer surface of the index finger rather than lying flat and intended for surgery.

INTENDED USER:

This is used by surgeons, operation theatre staff and healthcare professional.

TARGET PATIENT POPULATION:

Used for all patient population except in patients with known allergy to natural latex rubber.

DEVICE SHELF LIFE:

5 years from the date of manufacture printed on the Product Label

STORAGE INSTRUCTION:

It is recommended to store the gloves in dry place, in the temperature of 5°C to 40°C and to protect them against direct sunlight.

METHOD OF STERILIZATION:

Supplied non-sterile, shall be sterilized using ethylene oxide gas as per below validated parameters before using.

Ethylene Oxide gas sterilization parameters:

Ethylene Oxide gas concentration	Humidity	Temperature	Exposure period
575 gm/m ³ ± 12.50 gm/m ³	≥ 30 %	49 ± 5°C	420 minutes

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INDICATIONS:

Intended to be worn on the hands during medical surgical procedures to provide barrier against potentially infectious fluids and other contaminants.

WARNINGS AND PRECAUTIONS:

1. Do not use after the expiry date printed on the label.
2. Do not use if the Package is opened or damaged. Use of product whose package is opened, or damage may cause inflammation.
3. After donning remove powder by wiping gloves thoroughly with a sterile wet sponge, sterile wet towel or other effective method.
4. The supplied gloves are non-sterile and shall be sterilized before using with ethylene oxide gas as per validated parameters provided.
5. Do not Re Use - The reuse of the gloves may cause severe complications such as cross contamination, dermatitis, loss of physical properties, Blood-Borne Infection, Post-operative wound infection, allergic reaction and poor barrier protection.
6. Latex gloves are made of Natural rubber latex, which may cause allergic reactions including Latex Allergy – Anaphylactic if the user is allergic to latex.
7. Gloves may contain excess powder residues which may cause respiratory tract and pulmonary disease.
8. Single Use Packaging label and Sales Packaging Label.
9. Device should not be stored in direct sunlight
10. Device disposable should be done as per local regulatory. Failing to do so may lead to toxic to environment.

CONTRA INDICATIONS:

1. Gloves contain Powder content, persons who are sensitive to powder may develop allergy towards the powder content
2. Latex gloves are made of Natural rubber latex, which may cause allergic reactions including Latex Allergy – Anaphylactic if the user is allergic to latex.
3. Gloves contain Natural Latex; persons who are sensitive to Latex should consult a physician before using

DIRECTION FOR USE:

- 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.

A) How to Don Gloves:

- Rubbing the hand with alcohol or wash with water
- Dry hands before donning the gloves.

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- Take out gloves from single unit packaging.
- Gloves need to be donned carefully; do not apply excessive force to pull the gloves when donning.
- Keep the fingernails short and change gloves frequently to avoid tearing issue.

B) How to Remove Gloves:

- The gloves should be discarded with an appropriate waste disposal container after use according to local disposal regulations

DURATION OF USE:

Duration of Use is short term use (< 24 hours)













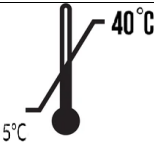




MEDICAL BENEFITS:

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

SIDE EFFECTS:

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

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SYMBOLS USED IN DEVICE SINGLE UNIT PACKAGING AND SALES PACKAGING					
	Manufacturer		Date of Manufacture		Keep away from Sunlight
	Authorized Representative in the European Community/ Authorized representative European Union		Use by Date/ Expiry Date		Keep Dry
	Contains presence of Natural Rubber Latex		Batch Code		Use only once
	No: of gloves in the package		Do not use if package is damaged and consult instructions for use		Caution
	Storage Temperature		Medical Device		Unique Device Identifier
	Non sterile symbol		CE Mark Symbol with notified body number		

• In case of any adverse event noted, contact manufacturer (MRK Healthcare Pvt Ltd) or authorized representative and competent authority of the member state where user/ patient is established without any delay or within 24 hrs.

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Authorized EU REP

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Revision History

Rev. No.	Date	Reason for Revision
A	20/04/2022	Initial Release
B	09/08/2022	Sterile & Nonsterile segregated as per TR comments
C	10/09/2022	Warning & precaution updated with residual risk as per TR comments
D	30/09/2022	Sterilization parameters added based on TR comments
E	25/10/2022	Sterilization instruction included word shall by replacing the word suggested as per TR comments