INSTRUCTION FOR USE FOR LATEX SURGICAL GLOVES (POWDER FREE)

Product Name : Latex Surgical Gloves (Powder Free)

Brand Name : Ultra Surgical Gloves

Manufacturer's Name : Ultra for Medical Products (ULTRAMED) Co. (U.M.I.C) S.A.E

Manufacturer's Address : Part No. (304:310) & part no. (312) – Industrial Area, Arab El Awamer – Abnoub - Assiut – Egypt.

Description of the Device:

- The Latex Surgical Gloves (Powder-Free) are sterile, single-use, disposable medical gloves manufactured from natural rubber latex (Type-1). They are supplied in a creamy white to pale yellow in color and are intended to provide a sterile protective barrier between healthcare professionals and patients during surgical and other invasive procedures. They protect from infection, cross-contamination through contact with blood, body fluids, tissues, and other potentially infectious materials while maintaining the tactile sensitivity, dexterity, and precision required for surgical practice.
- Powder free gloves coated with unique blend of polymer to provide excellent donning capability.
- The gloves are anatomically shaped (hand-specific), with separate left- and right-hand designs.
- The thumb is positioned toward the palmar surface of the index finger to follow the natural anatomical resting position of the hand, providing an ergonomic fit that improves comfort, minimizes wrinkling, reduces finger fatigue, and enhances manual performance during surgical procedures.
- The surgical gloves feature a micro-roughened textured finish on the palm and inner finger areas, providing a secure grip on surgical instruments while preserving tactile sensitivity.
- A beaded cuff facilitates donning, improves cuff strength, and helps prevent cuff roll-down during use.
- These powder free surgical gloves do not bear powder to facilitate donning, reducing the potential risks associated with glove powder, such as powder-related contamination and irritation.
- The gloves are available in sizes 6.5, 7.0, 7.5, 8.0, and 8.5 to ensure an appropriate fit for different users.
- The latex surgical gloves provide excellent elasticity, durability, and tactile properties, natural rubber latex (NRL) gloves have been most widely used.
- Each pair of gloves is individually packaged in a sterile peel pouch.
- A box of 50 pairs "each pair in a single unit".
- Gloves are supplied as pair in each unit of packing.
- The product is sterilized using EO (Ethylene Oxide).
- This product is for single use.
- The device is supplied sterile and intended for single use only. It is intended for transient use (continuous use of less than 60 minutes).
- The physical properties, dimension and tensile strength of the material are as per EN 455 (1-4), ISO 10282.

Description of the packaging:

Product	Quantity per PE Bag	Quantity per Outer Carton	Carton Dimensions
Latex Surgical Gloves (Powder Free)	50 units	400 units	54*27.5*44

Material Used:

- Natural rubber Latex

Intended purpose:

The Latex Surgical Gloves (Powder-Free) are sterile, single-use medical devices intended to be worn by surgeons and other healthcare professionals during surgical and other invasive procedures to provide a protective barrier between the patient and the user, thereby protect from cross-contamination and exposure to blood, body fluids, and other potentially infectious materials. It also facilitates general hand hygiene.

Variants:

Ref Code	Item
9013/PF-6.5	Ultra Surgical Gloves Powder Free Size 6.5
9013/PF-7	Ultra Surgical Gloves Powder Free Size 7
9013/PF-7.5	Ultra Surgical Gloves Powder Free Size 7.5
9013/PF-8	Ultra Surgical Gloves Powder Free Size 8
9013/PF-8.5	Ultra Surgical Gloves Powder Free Size 8.5

Clinical Indications:

- The product is worn on the hands during surgical and other invasive medical procedures, including vaginal delivery and vascular access procedures, to provide a sterile protective barrier and help prevent cross-contamination between the healthcare professional and the patient.
- Prevention of pathogen release from the hand into the surgical Site during surgery.
- Defined pathogen barrier as protection from biological agents.
- Act as a barrier protection for microorganisms.

Contraindications:

- Do not use if the patient or user has a known hypersensitivity or allergy to natural rubber latex due to the risk of allergic reactions, including anaphylaxis.

Device Limitations:

- Do not use the gloves in direct contact with a naked flame.
- Do not use the gloves for protection against ionizing radiation nor for use in containment enclosures.
- Do not use the gloves for more than 60 minutes, in order to reduce the risk of strain/fatigue on hands and loss of barrier protection.
- Do not use for protection against sharp instruments or puncture hazards beyond its normal mechanical resistance. Needle sticks and cuts can penetrate the glove.
- Do not use as electrical insulation or protection against electrical hazards.
- Do not use as thermal protection against extreme heat or cold.

Patient Target Group:

- No specific requirements or restrictions on use for patient population or user group.
- It is used for male and female patients (all ages).
- It is used for all patient population except in patients with known allergy to natural latex rubber.

Application site in the body:

- The Latex Surgical Glove is an invasive device which penetrates inside the body through the surface of the body, including through mucous membranes of body orifices with the aid or in the context of a surgical operation; and a device which produces penetration other than through a body orifice.

Replacement Frequency:

- Replace the device immediately if contamination, damage, or loss of integrity is suspected.

- Do not use the latex surgical gloves powder free for more than 60 minutes.

Intended User:

- To be used by an expert qualified medical professional, Skilled or Trained Personnel **(In-Charge).**

Clinical benefits:

1. **Reduced Allergy Risks:** Powder-free surgical gloves eliminate the risk of powder-related allergic reactions, which can occur in both patients and healthcare providers. Powder-free gloves are often recommended for individuals with latex allergies or sensitivities to glove powders.
2. **Decreased Risk of Contamination:** The powder used in powdered gloves can create a risk of contamination, particularly in sterile environments. Powder-free gloves help reduce the potential for powder particles to become airborne and contaminate the sterile field or wound site, ensuring a cleaner and more controlled environment.
3. **Maintenance of the Sterile Field:** Helps preserve a clean surgical environment by preventing the introduction of glove powder.
4. **Advances in Comfort and Fit:** powder-free gloves are designed to offer comfort and dexterity to the user. It provides a snug fit and excellent tactile sensitivity.
5. **Regulatory compliance:** Powder-free meets the current medical standard; powdered medical gloves are banned in major markets.
6. **Reduced airborne allergen spread:** Prevents powder from carrying latex proteins into the air, lowering respiratory exposure and sensitization risk.
7. **Reduced Skin Irritation:** Eliminates glove powder, reducing skin dryness and irritation during prolonged use.

Use Environment:

- The device is intended for use in healthcare facilities, including Hospital, Emergency Departments, Intensive Care Units (ICUs), Operating Rooms, outpatient surgical clinics and other healthcare facilities where sterile surgical procedures are performed.

Life time of device:

- The Latex surgical gloves (powder free) is used for maximum 60 minutes.

Sterility status and Method of sterilization:

- The Latex surgical gloves (powder free) is supplied in sterile state and sterilized using ethylene oxide.

Information on medical device intended to be used with other devices:

The latex surgical gloves (powder free) are not intended to be used with any other devices.

Performance Characteristics:

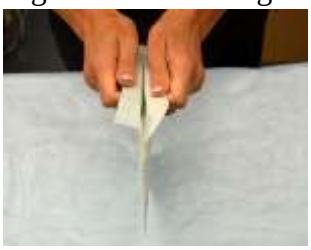
- ❖ Natural Rubber Latex Surgical Gloves (Type-1) [2 pieces (left & right hands)]
- ❖ Anatomically shaped medical gloves with the thumb positioned towards the palmar surface of the Index finger rather than lying flat.
- ❖ Micro rough surface in inner palm and in inner part of finger area which provides good grip at wrist and in curved fingers.
- ❖ The product has a beaded cuff for proper donning. The cuff shall fit closely without being constrictive and it shall not roll back or ruckle while in use.
- ❖ Powder free as it helps reducing risks of contamination and allergy related to latex or powder.
- ❖ Powder free gloves coated with unique blend of polymer to provide excellent donning capability.
- ❖ The product is available with different sizes to be more suitable for different intended users.
- ❖ Are easy to put on comfortable to wear and provide adequate, durable protection.

- ❖ Have good barrier integrity to protect against infections for both healthcare professionals and the patients.
- ❖ Have less after-use defects.
- ❖ Have significant greater satisfaction with regard to factors such as quality, safety and durability.
- ❖ Have high tear propagation strength.
- ❖ Have low perforation rate and lower viral leakage rates.
- ❖ Have high tensile strength.
- ❖ Have good fit and comfort.

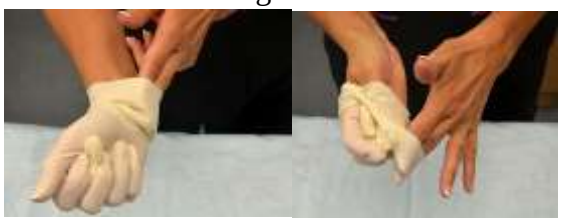
Risks Associated with reuse

- Re-use of the device may create a potential risk to the patient, including contamination and/or impairment of the device function.

Instruction for Use:

Surgical Gloves Action	Rational
Applying a Surgical Gloves	
Select the appropriate size Gloves for the hand	- To allow comfortable hand movement with reduced friction and perspiration. - To provide optimal comfort and tactile sensitivity.
Remove all jewelry from the hands and wrists.	To prevent glove damage and minimize the risk of contamination.
Perform hand hygiene using an alcohol-based hand rub or by washing with soap and water. Dry the hands thoroughly before donning the gloves.	To reduce the risk of infection, prevent contamination, and facilitate glove donning.
Inspect the sterile glove package for integrity, dryness, and expiry date before opening.	To ensure the gloves remain sterile and are suitable for use.
Take out the Gloves from the peel pouch without contaminating the sterile contents by peeling it off at the site of direction for open.	To maintain sterility while preparing the gloves for donning. 
Take out the inner wrap. Open the inner wrapper so that you can see both gloves.	To maintain sterility while preparing the gloves for donning.
Place the opened inner wrapper on a clean, dry surface. Identify the right and left gloves and begin with the dominant hand.	To maintain a sterile field and facilitate correct glove application.

	 
Before use, inspect the gloves for visible defects such as tears, pinholes, or other physical damage.	- To ensure the integrity of the gloves and maintain an effective sterile barrier.
Don the gloves carefully without applying excessive force. Keep fingernails short to minimize the risk of tearing. Replace the gloves if they become damaged, torn, or contaminated.	To maintain glove integrity and reduce the risk of contamination.
Pick up your dominant hand glove using the hand you don't use to write by touching the inside cuff of the glove. Do not touch the outside of the glove.	To maintain the sterility of the glove's outer surface.  
Insert gloved hand into the cuff of the remaining glove. Pull remaining glove on non-dominant hand and insert fingers. Adjust gloves if necessary.	To maintain sterility while achieving a secure and comfortable fit and prevent any potential contamination.  
Once the gloves are donned, keep the gloved hands in front of the body, above waist level and below shoulder level, and avoid contact with clothing or other non-sterile surfaces.	To maintain glove sterility throughout the procedure. 

Inspect the gloves for tears, punctures, or other damage before and during use. Replace the gloves immediately if damage is detected.	To ensure an effective sterile barrier is maintained throughout the procedure.
Removal of the Surgical Gloves after using	
To remove the first glove, grasp the outside of the glove near the cuff without touching the skin, and peel it away from the hand, turning it inside out. Hold the removed glove in the still-gloved hand.	Doing this, prevents the contamination of the hand when removing glove. 
Slide the fingers of the ungloved hand under the cuff of the remaining glove. Peel it off from the inside, turning it inside out over the first glove. Discard both gloves appropriately.	To avoid contaminating the bare hand and ensure safe glove removal. 
Perform hand hygiene immediately after removing the gloves.	To remove any microorganisms that may have contaminated the hands during glove removal. 

Warnings:

- ❖ For Single use.
- ❖ Discard after single use, Reusing can be associated with Cross infection, Device Malfunction and Reactions to endotoxins as sterilization will not inactivate toxins produced by the breakdown of Gram-negative bacteria even if the bacteria themselves are killed.
- ❖ DO NOT re-sterilize and /or reuse the device, as this can compromise the device performance (functionality) and may cause inadequacy, deterioration of the device technical factors, rendering the device non-functional and unfit for intended use and also this may increase the risk of cross contamination due to several aspects including inappropriate reprocessing.
- ❖ Re-use of single use device creates a potential risk for patient or user. It may lead to contamination and / or impairment of functional capability. 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.

- ❖ Contamination and / or limited functionality of the device may lead to injury, illness of the patient.
- ❖ Do not use if the package is opened, damaged, or compromised, as sterility cannot be guaranteed and use may increase the risk of contamination or infection.
- ❖ Do not use if the glove is visibly torn or damaged.
- ❖ Do not use the device after the expiry date.
- ❖ The device should be used only by trained healthcare professionals familiar with the clinical application and operation of the device.
- ❖ Destroy the device & its accessories after single use as bio-medical waste as per applicable laws.
- ❖ Storage up to 30º C ± 2°C, avoid excessive heat, protect from direct sunlight and moisture.
- ❖ Ultramed will not assume any responsibility in case of any incidental or consequential damages resulting from reuse of the product.
- ❖ Products containing natural rubber latex may cause allergic reactions. Some gloves might contain ingredients which are known to be a possible cause of allergies in sensitized persons, who may develop irritant and/or allergic contact reactions. If allergic reactions should occur, obtain medical advice immediately.
- ❖ Gloves that are discolored or stiff may also indicate excessive use or degradation from chemicals. Dispose of gloves when they show any sign of deterioration.

Precautions:

- ❖ Carefully read all instructions prior to use. Observe all warnings & precautions noted throughout these instructions.
- ❖ Failure to do so may result in complications. This device is Sterile & Ready for Use. Sterility is guaranteed - if pack is undamaged.
- ❖ Before usage, inspect the gloves for any defects or imperfections such as holes, pinholes and tears. If the gloves are ripped or punctured during use, dispose of them immediately. If in doubt, do not use the gloves, get a new pair.
- ❖ Contaminated gloves should be cleaned or washed before removal.
- ❖ Ensure the body fluids, blood, chemicals and other infectious materials cannot enter via the cuff.
- ❖ The gloves should not come in contact with a naked flame.
- ❖ Gloves shall not be used for protection against ionizing radiation nor for use in containment enclosures.
- ❖ The gloves should be worn on dry hands only.
- ❖ Remove any jewelry or sharp objects from hands & finger before wearing gloves; Healthcare professional should not have sharp fingernail.
- ❖ Conduct procedure under strict surgical protocol and ensure complete asepsis.
- ❖ Use the product immediately after opening the individual blister packing.
- ❖ Do not use if the sterile package is opened, damaged, or compromised, as sterility cannot be assured, there may be a risk of infection and the device may not perform as intended.
- ❖ Storage up to 30º C ± 2°C, avoid excessive heat, protect from direct sunlight and moisture.
- ❖ Destroy the device & its accessories after single use as bio-medical waste as per applicable laws.
- ❖ Check the integrity and functionality of the surgical gloves before use.
- ❖ This device is powder free; as marked.
- ❖ Do not Re-sterilize. Do not Re-use. Single use only.
- ❖ Do not use the device after the Expiry Date.
- ❖ Care must be taken when selecting the correct glove size to reduce the risk of strain/fatigue on hands during use
- ❖ Promptly and safely dispose of any gloves that have touched a potentially contaminated surface in accordance with relevant local regulations pertaining to safe disposal of clinical waste.

- ❖ The gloves contain natural rubber latex. If any allergic reaction occurs during use, discontinue use immediately and seek medical attention.
- ❖ When wearing gloves change or remove gloves in the following situations: During patient care if moving from a contaminated body site to another body site (including a mucous membrane, non-intact skin or a medical device with in the same patient or the environment).
- ❖ Use of petroleum-based hand lotions or creams may adversely affect the integrity of latex gloves and some alcohol-based hand-rubs may interact with residual powder on health-care worker's hands.
- ❖ Gloves need to be donned carefully; do not apply excessive force to pull the gloves when donning
- ❖ Glove is not used in handling food and cytotoxic agents.
- ❖ The glove is not intended to provide protection against all chemical substances. Resistance to chemicals varies depending on the type, concentration, and duration of exposure.
- ❖ Double gloving is done for procedures with contact with large amounts of blood or body fluids, and for some high-risk orthopedic procedures.

Potential Complications / Risks:

1) **Loss of barrier integrity over time:** Perforation, tearing, or puncture of the glove during use may compromise the sterile barrier, increasing the risk of cross-contamination, exposure to blood and body fluids, and surgical site infection.
2) **Irritant contact dermatitis:** The most common adverse reaction associated with latex gloves, caused by prolonged glove use. Clinical manifestations include erythema, dryness, cracking, scaling, vesicle formation, peeling, ulceration, and localized pain or inflammation.
3) **Allergic contact dermatitis (Type IV hypersensitivity)**
4) **Latex hypersensitivity (Type I immediate allergic reaction):** Natural rubber latex may cause allergic reactions ranging from localized itching, erythema, urticaria (hives), and angioedema to allergic rhinitis, conjunctivitis, rhinorrhea (runny nose), bronchospasm, and, in rare cases, life-threatening anaphylaxis.
5) **Microbial transmission:** resulting from barrier failure or improper glove use, increasing the risk of healthcare-associated infections.
6) **Reduced tactile sensitivity or manual dexterity**
7) **Pressure-related skin injury:** Prolonged use of tight-fitting gloves may cause localized discomfort, pain, pressure marks, erythema, numbness, impaired circulation, and, in severe cases, superficial skin injury.

General Instructions:

- To be used by an expert qualified medical professional. Use maximal sterile barrier precautions during administration. Dispose the device after use as bio-medical waste as per applicable laws.

Conditions of Handling, Preservation and Storage:

- Not more than 5 cartoons on each other.
- Nice Ventilated place.
- Out of Sunlight.
- Storage at room temperature up to 30℃ ± 2℃.
- Humidity: Up to RH 65% (± 5)

Safe Disposal of single-use medical devices:

- ❖ adopt adequate precautions for the elimination and disposal of the device and comply with the provisions of the laws in force on biologically hazardous waste.
- ❖ Single-use devices must be segregated from other reusable devices and, should not be returned to a Decontamination facility for reprocessing. Once discarded (used or unused) medical devices are

considered to be special waste and should be managed as healthcare (clinical) waste. All medical devices that are to be disposed of, must in accordance with Health and Safety, Carriage of Dangerous Goods and Waste Regulations.

- Discarded devices should be placed in UN-type approved waste containers suitable for clinical waste (UN 3291); these should be rigid and puncture-proof. In general devices other than sharps should not be placed in sharps boxes as sharps waste is treated and disposed of in a different manner. Guidance on the type and color of the container should be sought from the Board Waste Management Officer. rigid water-tight containers are used for waste requiring incineration in a suitably permitted or licensed facility.

Method of sterilization

- Sterilized Using Ethylene Oxide

Shelf life

- 5 years (from the date of manufacturing)

Basic UDI: 622300425SUG90133E

Reporting of incident to Manufacturer & Competent Authority:

- For providing feedback on this product write to shady@ultramedumic.com
- In case of any serious incident occurred, please report it to the Ultra for medical products (Ultramed) Co (U.M.I.C) S.A.E and/or its Authorized Representative and to your national authority. The contacts of national competent authorities (Vigilance Contact Points) and further information can be found on the following European Commission website: https://ec.europa.eu/growth/sectors/medical-devices/contacts_en

Details of symbols used in labels:

Symbol	Meaning
EU REP Obelis SA 53 Bd. Général Wahis B-1030 Brussels,Belgium Phone : 32.2.732.59.54 Fax : 32.2..732.60.03 E-mail: mail@obelis.net www.obelis.net	EU REP
CE 2803	CE Mark with notified body number 2803
STERILE EO	Sterilized by Ethylene Oxide
	For Single Use Only
LOT	Lot No.
	Date of Manufacturing
	Use by / Expiry date
REF	Catalogue No.
	Non- Pyrogenic
MD	Medical Device
UDI	Unique device Identifier

Symbol	Meaning
	Don't use if package is not intact
	Manufacturer’s address
	This product contains Latex
	One Pair
	Read Instructions for Use
	Not to be re-sterilized
	storage at room temperature up to 30 ℃ ± 2℃
	Cautions
	Protect from rain / Keep Dry
	Protect from sunlight / Keep away from Sunlight
	Symbol for „This way Up“
	Symbol for „handle with Care“
	Recycle
	Don’t put more than 5 cartons upon each other

ISSUE/REV DATE: 01 -09- 2013 / 20.07.2024

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Assuit Office: 23, July Str. **Tel:** 088/2364111 – 2364222 & **Fax:** 088/2334964 & **Mob. :** 0123988202
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