

Layfield Medical Products
Particulate Respirator 1970EU
Medical + Particulate Mask with Ear Loops

USER INSTRUCTION

Important: Before use, the wearer must read and understand these User Instructions. Keep these User Instructions for reference.

Cautions and limitations

- The respirator helps protect against certain particulate contaminants but does not eliminate exposure to or the risk of contracting any disease or infection.
- Do not use in atmospheres containing less than 19.5% oxygen.
- Do not use in atmospheres immediately dangerous to life or health.
- Do not exceed maximum use concentrations established by regulatory standards.
- Failure to properly use and maintain this product could result in injury or death.
- All approved respirators shall be selected, fitted, used and maintained in accordance with OSHA, CSA and other applicable regulations.
- Never substitute, modify, add or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.
- This device does not contain materials made of latex.
- This respirator is designed for adults who can fully understand the User Instructions.
- It is not designed to be used by children or patients.

Product Description

Layfield Particulate Respirator is a single-use medical device designed to help provide respiratory protection for the wearer who used as directed in health care environments. This respirator is qualified as FFP2 (≥ 94% filter performance) It can fit a wide range of face sizes. This product contains no components made from natural rubber latex.

Intended Use

As a particulate respirator, this product is intended to help reduce wearer exposure to certain airborne particles, including small particle aerosols and large droplets. It is also designed to protect the patients and other individuals in the vicinity from the wearer's respiratory emissions.

Contraindications

This respirator is designed for adults who can fully understand the User Instructions. It is not designed to be used by children. Not for use with beards or other facial hair or conditions that prevent a good seal between the face and the sealing edge of the respirator. Does not protect against gases or vapors. Check local regulations and requirements to be certain that this respirator is appropriate for your workplace.

Use Instructions

1. Select and use respirator in accordance with all applicable laws, regulations, standards and professional guidance.
2. Follow all instructions and limitations on the use of this respirator and continue to wear this respirator during all times of exposure. Failure to follow all instructions may reduce the effectiveness of the respirator and result in sickness or death.
3. Before use of this respirator, the wearer must be fit tested in accordance with the Fitting and Use Instructions and any local regulations or guidelines specified for the proper use of this respirator.
4. Use the respirator only in adequately ventilated areas containing sufficient oxygen to support life. It does not supply oxygen.
5. Inspect the respirator before each use to ensure it is in good working condition. Examine all the respirator parts for signs of damage including the two straps, the nose clamp, and the cover body. The respirator should be disposed of immediately upon observation of damaged or missing parts.
6. Leave the contaminated area and contact your supervisor if dizziness, irritation, or other distress occurs.
7. Discard the respirator and replace with a new one if it is damaged, excessively clogged, or contaminated with blood or body fluids or breathing becomes difficult while using it. Discard after every use when used for surgical procedures. Follow national, provincial, state, local and facility infection control guidance and policies.
8. Dispose of used product in accordance with applicable regulations.

Fitting Instruction



1. Wash your hands. Pull the ear loops to open the mask.
2. Flatten the nose bridge wire and gently curve to form a nose shape.
3. Place respirator under chin and position on face.
4. Pull the strap over your ears. Position the mask so it is comfortable.
5. Use fingertips to shape the nose wire to the bridge of your nose. Start at the top and move downwards. It is very important to press the nose piece firmly to the bridge to form a good seal. Pinching the nose piece using one hand may result in improper fit and less effective respirator performance (Use two hands).
6. Your mask should have a good fit at the chin and cheeks. Make sure hair, facial hair, jewelry and clothing are not between your face and the respirator as they will interfere with fit.
7. Perform a Wearer Seal Check. Without disturbing the position, cover the respirator with both hands. Exhale sharply. If air leaks around the edges of the respirator, adjust position of straps and ensure the respirator edges fit tightly against the face. If necessary, readjust nose piece and straps to form a good seal. If you CANNOT achieve a proper seal, DO NOT enter the contaminated area. See your supervisor.
8. Use the adjustment clip to achieve a better seal or to reduce pressure on the ears.
9. If no leaks are detected, you are ready to work. Please continue to monitor the fit of your mask and obey all other instructions.

Removal Instruction



1. Do not touch the respirator face.
2. Slowly lift any one of the ear loops. Then lift the other remaining ear loop.
3. Discard according to your facility's infection control policy and applicable regulations.
4. Wash your hands with soap and water or perform hand hygiene as recommended.

Use Limitations

1. The respirator provides protection against certain particles. It does not eliminate the risk of any infection or contracting any disease.
2. Do not use when concentrations of contaminants are immediately dangerous to life and health, are unknown, or when concentrations exceed the allowed exposure limit or the limit according to any applicable standards or regulations, whichever is lower.
3. The respirator can protect you from particulate entry through the nose and mouth. It cannot prevent entry through other ways such as skin and eyes which should be protected by other personal protective equipment(s).
4. This respirator is designed for adults who can fully understand the User Instructions. It is not designed to be used by children or patients.
5. Persons having problem(s) with the respiratory system should consult a physician before use.

Warnings

1. The wearer must conduct a fit check in accordance with Fitting and Use Instructions and any applicable regulations prior to use.
2. This respirator shall not be used for more than one shift of up to 12 hours. Do not alter, wash, reuse or misuse respirator in any way.
3. When the respirator is contaminated or damaged, or breathing becomes difficult, replace it with a new one.
4. It is possible that the requirements for leakage effectiveness may not be achieved in for users with beards, facial hair or other similar features.
5. Do not use the respirator or enter or stay in a contaminated area under the following circumstance:
 - a) Atmosphere contains less than 19.5% oxygen.
 - b) If you smell or taste contaminant.
 - c) For protection against gases or vapors.
 - d) Contaminants or their concentrations are unknown or immediately dangerous to life or health.
 - e) For sandblasting, paint-spray operations and asbestos.
 - f) In explosive atmospheres.

Storage and Transportation

- Product should be stored in clean, dry conditions within the temperature range: -10°C to +40°C with a maximum relative humidity of <85%.
- When storing or transporting this product, use original packaging provided.
- Keep away from fire.

Period of Use

- Shelf life: 3 years from the manufacturing date.
- Subject to the Storage Conditions specified above, the respirator may be used until the expiry date printed on the packaging.
- One-time use only.

Disposal

Dispose of respirator according to your facility or institution or employer policy, and local regulations.

Product Details

- Item No. MLL-1970EU
- EN-149-2001 Qualified

PRODUCT COMPOSITION

COMPONENT	MATERIAL
Inner Layer	Non-woven fabric (100% polypropylene)
Filter Layer 1	Melt-blown, non-woven fabric (100% polypropylene)
Filter Layer 2	Melt-blown, non-woven fabric (100% polypropylene)
Outer Layer	Non-woven fabric (100% polypropylene)
Nose Strip	Polyethylene and Galvanized Iron Wire
Ear Loops	30% Elastane, 70% polyester
Adjustment Clip	100% Polypropylene



More information

For more information about this product, please contact the manufacturer using any of the following methods:

- Website: LayfieldMedical.com
- Phone: 1-888-434-1230
- Mail: 11120 Silversmith Place, Richmond, BC V7A5E4 CANADA



Layfield Medical Products
 A division of Layfield Canada Ltd in partnership with Maple Leaf Laboratories Ltd.

MDEL (Medical Device Establishment License).
 Company ID# 157719 157722
 License# 13512