



dba **INDIANA FACE MASK**

**Surgical N95 Respirator
SA105**

User Instructions

This respirator has been approved as a NIOSH N95 filtering facepiece respirator, for use in healthcare settings, as a Surgical N95 Respirator conforming to recognized standards for biocompatibility, flammability, and fluid resistance.

 **WARNING**

This respirator helps protect against certain particulate contaminants but does not eliminate exposure to or the risk of contracting any disease or infection. **Misuse may result in sickness or death.** For proper use, see supervisor, or *User Instructions*, or call Indiana Face Mask (219)866-2270

IMPORTANT:

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

Description:

FSSC LLC DBA Indiana Face Mask is designed to help provide respiratory protection for the wearer. This respirator has a filter efficiency level of at least 95% against particulate aerosols free of oil†. It is fluid resistant. ‡ It is disposable and can be used in surgery. It can fit a wide range of face sizes.



This product contains no components made from natural rubber latex.

This respirator has been approved as a NIOSH N95 filtering facepiece respirator, for use in healthcare settings, as a Surgical N95 Respirator conforming to recognized standards for biocompatibility, flammability, and fluid resistance.

Intended Use:

The SA105 is intended for use by operating room personnel and other health care workers to protect both patients and health care workers from transfer of microorganisms, blood and body fluids and airborne particulate materials. It also protects against particles such as those from grinding, sanding, sweeping, sawing, bagging, or processing minerals, coal, iron ore, flour, metal, wood, pollen, and certain other substances. Liquid or non-oil based particles from sprays that do not also emit oil aerosols or vapors. Follow all applicable local regulations.

Do Not Use For:

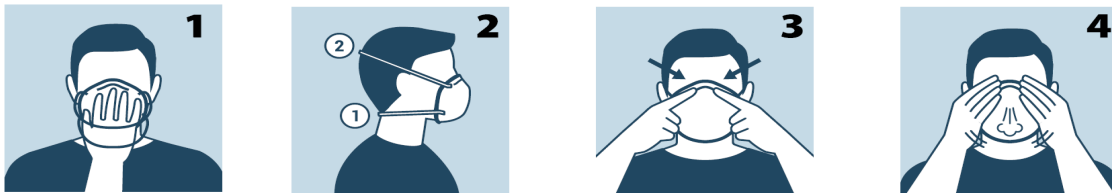
Do not use for gases and vapors, oil aerosols, asbestos, or sandblasting; particulate concentrations that exceed either 10 times the occupational exposure limit or applicable government regulations, whichever is lower. This respirator does not supply oxygen. In the U.S., do not use when OSHA substance specific standards, such as those for, arsenic, cadmium, lead in the construction industry, or 4,4'-methylene dianiline (MDA).

‡ Meets ASTM Fluid Resistant Challenge F1862 (160 mmHg).

Instructions for Use:

1. In the U.S., before occupational use of this respirator, a written respiratory protection program must be implemented meeting all requirements of U.S. OSHA 29 CFR 1910.134 such as medical evaluation, training and fit testing. These user instructions are not a substitute for a written respirator training program which meets the aforementioned requirements. Select and use respirator in accordance with all applicable regulations, standards, and professional guidance. Fit testing must be performed while the test subject is wearing any applicable safety equipment that may be worn during actual respirator use which could interfere with respirator fit, such as hair bonnets and eyewear. This respirator is designed for occupational/ professional use by adults who are properly trained in its use and limitations. OSHA accepted fit test protocols are recommended for fit testing this respirator. Each time a respirator is worn, a fit assessment should be made by the user.
2. Inspect respirator before each use to ensure that it is in good operating condition. Examine all the respirator parts for signs of damage including the two headbands, welds, nose piece, and facepiece material. Ensure there are no holes in the breathing zone and no damage has occurred. The respirator should be disposed of immediately upon observation of damage or missing parts.
3. Leave the contaminated area immediately and contact your supervisor if dizziness, irritation or other distress occurs.
4. This is a single use respirator. It may be used until it becomes difficult to breathe through, damaged, or is thought to be contaminated in any way. **Discard after every use when used for surgical procedures.**
5. 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. **This respirator was not designed to be used by children.**

Fitting Instructions: Must be followed each time respirator is worn.



1. Open individually wrapped SA105 respirator, and check for any visual defects, such as nose foam separating from respirator. Allow at least 30 seconds for the foam to return to its normal form.
2. Cup the respirator in your hand, with the nosepiece at your fingertips, allowing the headbands to hang freely below your hand.
3. Position the respirator under your chin with the nosepiece up. Pull the top strap over your head resting it high at the top back of your head. Pull the bottom strap over your head and position it around

the neck below the ears. Make certain hair, facial hair, jewelry and clothing are not between your face and the respirator as they will interfere with fit.

4. Place your fingertips from both hands at the top of the metal nosepiece. Using two hands, mold the nose area to the shape of your nose by pushing inward while moving your fingertips down both sides of the nosepiece. Pinching the nosepiece using one hand may result in improper fit and less effective respirator performance (Use two hands).

5. Perform a User Seal Check. To check the respirator-to-face seal, place both hands completely over the respirator and exhale. Be careful not to disturb the position of the respirator. If air leaks around nose, readjust the nosepiece as described in step 3. If air leaks around the respirator edges, adjust position of straps and make certain respirator edges fit snugly against the face. **If you CANNOT achieve a proper seal, DO NOT enter any contaminated areas. See your supervisor.**

Removal Instructions:

Without touching the respirator, slowly lift the bottom strap from around your neck up and over your head. Then lift off the top strap. Store or discard according to your facility's infection control policy. Dispose of used product in accordance with applicable regulations.

Storage Conditions and Shelf Life:

Before use, store respirators in the original packaging, away from contaminated areas, dust, sunlight, extreme temperatures, excessive moisture and damaging chemicals. When stored in original packaging between temperatures from -4°F (-20°C) to +86°F (+30°C) and not exceeding 80% RH, the product may be used until the date specified on packaging located next to the "Use by Date" symbol.



Use by Date



Manufacturer



Date of Manufacture



Manufacturer's Lot Number relevant to the device bearing the symbol

NIOSH Approved N95 Respirator:

At least 95% filtration efficiency against solid and liquid aerosols that do not contain oil.