

Decontaminated by



Sustainability Solutions

Instructions for Use

Decontamination Compatible N95 and N95-equivalent Respirators

Decontaminated Device for Single Patient Use

Explanation of Symbols



Consult Instructions For Use



Product Number



Lot Number



Date of Decontamination



Non Sterile



Decontaminated Device for Single Patient Use



This respirator contains no components made from natural rubber latex

PRODUCT NOTICE

- The SSS VHP N95 Respirator Decontamination System has neither been cleared or approved for the decontamination of compatible N95 respirators for multiple-user reuse by HCP to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates;
- The SSS VHP N95 Respirator Decontamination System has been authorized by FDA under an EUA;
- The SSS VHP N95 Respirator Decontamination System is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical or medical devices during the COVID-19 outbreak, under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

WARNING

This respirator helps protect against certain particulate contaminants but does not eliminate exposure to or the risk of contracting disease or infection. Improper usage may result in illness or death.

IMPORTANT: Before use wearer must read and understand these *User Instructions*. Keep these *User Instructions* for reference.

Description:

The compatible N95 and N95-equivalent Respirator is designed to help provide respiratory protection for the wearer. This respirator is tested for particle filtration efficiency against particulate aerosols free of oil. It is fluid resistant and has been tested for bacterial filtration efficiency (BFE). It is disposable and can fit a wide range of face sizes.

Intended Use:

To help reduce the exposure to certain airborne particles, including those generated by electrocautery, laser surgery, and other powered medical instruments.

Contraindications:

Not recommended for industrial use. 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 (i.e. anesthetic gases such as isoflurane or vapors from sterilant such as glutaraldehyde). **This respirator was not designed to be used by children.**

Use Instructions:

1. 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. Follow all applicable local regulations. This respirator is designed for occupational/professional use by adults who are properly trained in its use and limitations.
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, staples, nose foam, nose clip and facepiece material. The respirator should be disposed of immediately if it is soiled, or damaged or missing parts.
3. Leave the contaminated area immediately and contact your supervisor if dizziness, irritation or other distress occurs.
4. Respirator may be used until damaged, breathing becomes difficult or contaminated with blood or body fluids. Discard after every use when used for surgical procedures. Follow national, state, local, and facility infection control guidance and policies.

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

1. Cup the respirator in your hand with the nose piece at fingertips, allowing the head straps to hang freely below hand (Fig. 1).
2. Position the respirator under your chin with the nose piece up (Fig.2).
3. While holding the respirator in place, pull the top strap over your head so it rests high on the back of your head (Fig.3).
4. While continuing to hold the respirator firmly in place, pull the bottom strap over your head and position it around your neck, below your ears. Untwist the straps. Position the respirator low on your nose (Fig.4).
5. Using both hands, mold the nose piece to the shape of your nose by pushing inward while moving your fingertips down both sides of the nose piece (Fig.5). **Note: Always use two hands when molding nose piece. Pinching with one hand may result in improper fit and less effective respirator performance.**

6. To perform the user seal check, place both hands completely over the respirator, being careful not to disturb the position, and exhale sharply. If air leaks around your nose, adjust the nosepiece as described in step 5. If air leaks at respirator edges, adjust the straps back along the sides of your head. Perform seal check again if an adjustment is made. If you cannot achieve a proper fit, see your supervisor. Do not enter area requiring respirator use (Fig.6).

Removal Instruction:



1. Without touching the respirator facepiece, slowly lift the bottom strap from around your neck up and over your head (Fig. 1).
2. Then lift off the top strap (Fig. 2).
3. Store or discard according to your facility's infection control policy (Fig. 3). Dispose of used product in accordance with applicable regulations.

Storage Conditions:

Before use, store respirators in the original packaging, away from contaminated areas, dust, sunlight, extreme temperatures, excessive moisture and damaging chemicals.

Decontamination:

The N95 and N95-equivalent respirators are decontaminated using Vaporized Hydrogen Peroxide (VHP).