



COVEX™ Face Shield
and Respirator (Reusable)
PN FS99S, FS99R, FS99L
and Replacement Filters PN FS125

WARNING

The COVEX Face Shield and Respirator (the “COVEX Shield”) helps protect against certain particles. **Misuse may result in sickness or death.** For correct use, consult these Instructions for Use or call Augustine Surgical Inc. at 888-439-2767.

IMPORTANT

The COVEX Shield is designed to meet *all* FDA standards, not merely the Enforcement Policy for Face Mask and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency. <https://www.fda.gov/media/136449/download>
Before use, wearer should read and understand these Instructions for Use. Keep these instructions for reference.

Use For

Protecting the face and breathing zone.

Do Not Use

1. For protection against gases, vapors, asbestos, oil aerosols, for sandblasting, or paint spray operations.
2. In atmospheres containing less than 19.5% oxygen.
3. When concentrations of contaminants are immediately dangerous to life and health.

Biological Particles

The COVEX Shield may help reduce inhalation exposures to certain airborne biological particles, but cannot eliminate the risk of contracting infection, illness, or disease. See Technical Data below for details.

Use Instructions

1. Failure to follow all instructions and limitations on the use of the COVEX Shield and/or failure to wear the COVEX Shield during all times of exposure can reduce its effectiveness and **may result in sickness or death.**
2. Store your reusable COVEX Shield away from contaminated areas when not in use.
3. Prior to the initial use, and when returned from service after a period of non-use, the reusable COVEX Shield should be wiped thoroughly with a hospital disinfectant or soap and water.
4. Prior to use, the single-use COVEX high-efficiency filtration fabric (“Filter”) should be installed on the Mask. The Filter is affixed to a pre-filter. Ensure that the Filter is completely covering the inhalation holes in the Mask. See

Fig. 1A, 1B, and 1C for details. The Filter should be replaced daily or according to institutional protocols. Do not wash and reuse the Filter.

5. The COVEX Shield has an exhalation valve located below the Mask that seals when the user inhales and aides in moisture management from condensation. Ensure that the exhalation valve is not obstructed by pressure from the pre-filter.
6. When removed from the face, the COVEX Shield may hang from the wearer’s neck, shield facing out, against non-contaminated clothing.
7. The COVEX Shield may be wiped with any standard disinfectant solution or wipes, or washed with soap and water between exposures or as often as necessary.
8. Inspect the COVEX Shield, the Mask, and the Filter prior to each use to ensure no damage has occurred.
9. The inhalation holes are fitted with 2 or 4 grommets to maintain the hole diameter while donning the Mask.
10. Conduct a user seal check of the Mask before each use as specified in the Fitting Instructions. **If you cannot achieve a proper seal, do not use the COVEX Shield.**

Use Limitations

1. Do not use with beards or other facial hair or other conditions if they prevent a good seal between the face and the Mask.
2. The COVEX Shield can help protect against certain airborne contaminants. It will not prevent entry through other routes such as the skin, which would require additional personal protective equipment.
3. Do not wash the high-efficiency filtration fabric.
4. The exhalation valve does not filter air exiting the Mask. To filter exhaled air, fold the exhalation valve at a 90-degree angle and tuck under the pre-filter. Exhalations will pass through the filtration fabric.

Fitting Instructions

Must be followed each time COVEX Shield is worn.

1. Select the correct size for your face (Small, Regular or Large). The objective is to achieve an effective and comfortable seal around the nose and mouth.
2. Ensure that the Filter is secured around the Mask. To place the Filter, align the Filter so that it covers the inhalation holes on the Mask, then stretch the pre-filter around the remainder of the Mask (**Figs 1A, 1B, 1C**).
3. Take care to not obstruct the exhalation valve with excessive pressure from the Filter and pre-filter.
4. Place straps over the head and position the Mask over the nose and mouth. The bottom of the Mask should be positioned above the base of the chin (**Fig 2**).
5. Begin tightening straps with the cord stop. The longer strap should be positioned under the ear and behind the neck with the foam padding against the base of the nape. The shorter strap should be positioned around the crown of the head for added stability and fit (**Fig 3**).
6. Tighten the straps with the cord stops until the Mask has a good seal around the nose and mouth. The fit should snug enough to create a good seal. **Do not overtighten.**

7. If you are struggling to achieve an effective seal, try the following steps:
 - a. Readjust the strap location to accommodate your face and provide the best seal.
 - b. Make sure that the upper part of the mask crosses the bridge of your nose—not the tip of your nose.
 - c. Adjust tightness to conform to contours of your face.
 - d. If there is a gap near your nose, then add the Nose Space Filler foam by securing it to the mask with the attached tape. This piece can be trimmed with scissors if necessary (**Fig 5**).
8. Perform a User Seal Check prior to each use. To check the seal, exhale sharply while wearing the COVEX Shield. If air leaks around nose or the edges, readjust the position and the tightness. **If you CANNOT achieve a proper seal, DO NOT enter a contaminated area.**

build-up. Nevertheless, it is recommended to store the COVEX Shield in a ventilated area to allow residual moisture to dry.

Technical Data

NIOSH testing has not been completed.

The high-efficiency filtration fabric, however, has at least the following characteristics, depending on the precise version of the fabric used.

Filtration Performance

NaCl Penetration at 32 LPM	< 0.10%	<i>Tested in accordance to TS18130 NaCl 0.1 micron particle size</i>
NaCl Efficiency at 32 LPM	> 99.90%	
Pressure Drop at 32 LPM	< 2.3 mm H ₂ O	
BFE Efficiency*	> 99.99990%	<i>Tested in accordance to Spec MIL-M-36954C By Nelson Labs</i>
VFE Efficiency†	> 99.99975%	
<ul style="list-style-type: none"> • Material Specifications are in accordance with ASTM Standards for Evaluating Non-Woven Textiles • These specifications were not confirmed in the COVEX Shield application • *Bacterial Filtration Efficiency • †Viral Filtration Efficiency 		

For more technical information about the filter, please contact Augustine Surgical.

The COVEX Shield is designed to help provide protection to the face and breathing zone. Augustine Surgical makes no claims about the specific performance characteristics of the technology.

The COVEX Shield contains no components made from natural rubber latex.


The COVEX Shield is a product of Augustine Surgical, Inc., which also manufactures these medical devices:



Please give us your feedback at [CovexShield.com/feedback](https://www.covexshield.com/feedback)

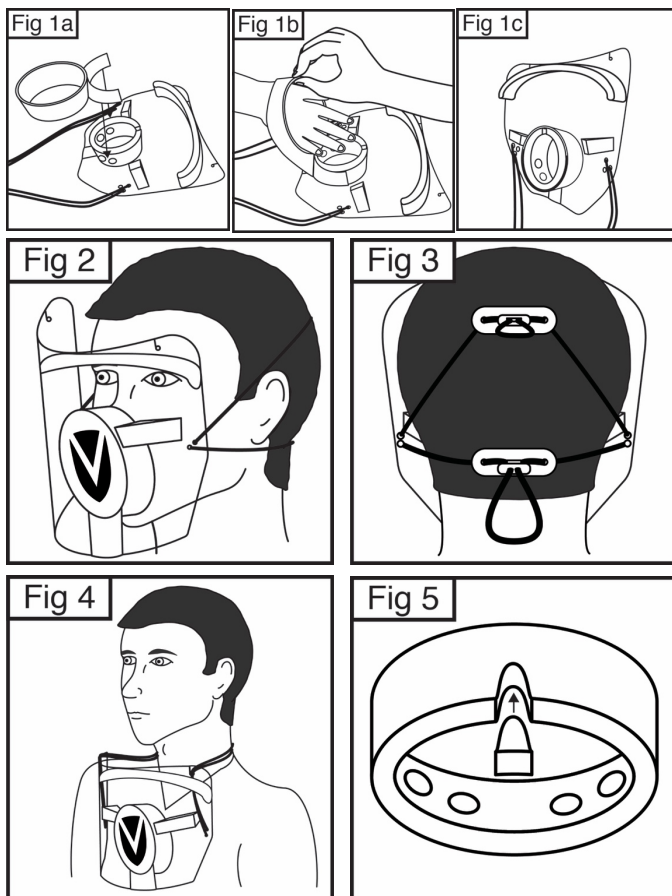
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FOR MORE INFORMATION, contact:

Website: [covexshield.com](https://www.covexshield.com)
 Augustine Surgical Inc
 6581 City West Parkway
 Eden Prairie, MN 55344
 PH: 952-465-3500 (888-439-2767)

**PATENTS
PENDING**

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Removal Instructions

Loosen the straps and lay the COVEX Shield against non-contaminated fabric on the chest with the exterior of the Shield facing out. The strap can be captured in the cord retainer holes on the upper side of the Shield to help the Shield lay flat against the chest (**Fig 4**).

Storage Instructions

Store the COVEX Shield away from contaminated areas when not in use. The exhalation valve reduces moisture

