

Current Stryker Flyte Personal Protection System User,

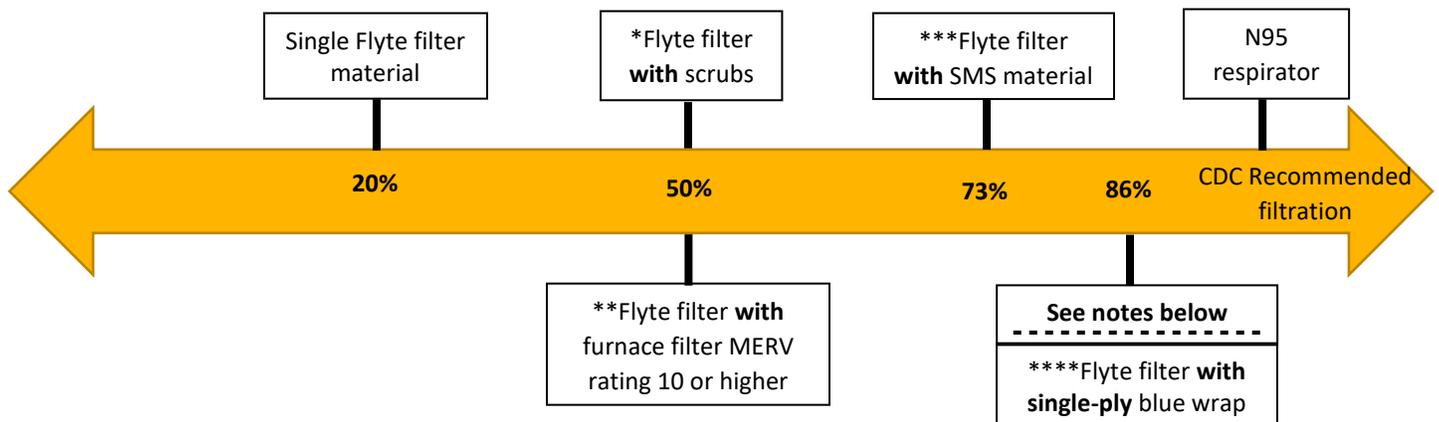
The Stryker Steri-Shield Flyte Toga/Hood is a component of the Stryker Personal Protection System and is intended to protect the patient, healthcare personnel and operating room personnel against contamination, exposure of infectious bodily fluids, and the transfer of microorganism and particulate material.

**The Flyte PPE products are not cleared as respiratory protective products. CDC guidance for respiratory protection directs the use of an N95 or higher rated mask for staff performing Aerosol Generating Procedures.** In the context of PPE, respiratory devices are devices that protect the wearer from inhalation of a hazardous atmosphere at a prescribed level. Stryker PPE products do not provide this level of respiratory protection. The hoods and togas are intended to provide resistance to blood-borne pathogens and non-aerosolized viral penetration whereas the N95 Respirator provide respiratory protection. N95 respirators can be used under any Stryker hood or toga.

Per FDA regulation, Stryker cannot promote the use of a modified helmet for air filtration as changes to the system, without FDA approval, is considered off-label use. However, due to the COVID-19 pandemic and decreasing availability of PPE, Stryker has received videos and pictures of HCP's taking action on their own. HCP's are adding filtration media to the Flyte System in creative ways. In response to these DIY actions, Stryker will highlight two aspects to consider. This will help decisions on any DIY modification be more informed and aware of the consequences.

- 1) Any modification to a Flyte helmet system can affect the performance of the system. Specifically, in terms of a filtration enhancement media being placed over the fan, this can decrease the amount of fresh air being pulled into the system. This can result in a build up of CO<sub>2</sub> under the disposable. In the FDA-cleared system, Stryker tests to and adheres to OSHA requirements for permissible CO<sub>2</sub> exposure limits. If an HCP opts to modify their Flyte helmet with any material, Stryker encourages them to be sensitive to the way they feel during use. Any modification to the system could have unintended consequences for the users, specifically increased CO<sub>2</sub> levels. Increased levels of CO<sub>2</sub> can lead to headaches, fatigue, eye and throat irritation and, in severe cases, seizures or loss of consciousness. Therefore, users are encouraged to be aware of the way they feel while wearing a DIY-modified helmet. Users can take periodic breaks and remove the system to balance their breathing.
- 2) In order to help HCPs understand the filtration efficiency of these materials, Stryker conducted development tests. The materials were tested at a challenge flow rate of 85 L/min using NaCl per NIOSH filtration efficacy testing for N95 respirators. The flow rate for Flyte PPE products exceeds 85

L/min, and therefore, filtration efficiencies based on this challenge flow rate may vary. For clarity, readers should be aware that the 95 in N95 indicates that the respirator prevents at least 95% of particles from passing through. Hence, a scaled was created from 0 to 95.”



\*Scrub material tested was new and had a material make-up of 35% cotton, 65% polyester. Depending on the condition of the material, results will vary.

\*\*Utilizing a furnace filter with MERV 10 or higher. Higher MERV rating could offer higher filtration efficiency.

\*\*\* SMS material is on the back of Flyte togas and the enclosure material of togas.

\*\*\*\*Single-ply blue wrap with a Flyte disposable offers a high level for enhanced filtration. However, blue wrap is not recommended for lengthy use as this material does not meet the required breathability and can lead to a build-up of CO<sub>2</sub>. HCP's who chose to use blue wrap should only wear the system for intermittent periods of time and be keenly aware of how they feel during use. Users can separate double-ply for a single-ply blue wrap. **NOTE:** Double-ply blue wrap with a Flyte disposable offers a higher level of filtration than single ply. However, the breathability of double-ply blue wrap is even lower. If double-ply blue wrap is implemented, users should limit the time used and be even more aware of how they feel during use.

# Flyte helmet

## Enhanced filtration assembly instructions



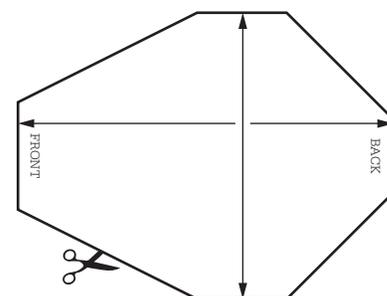
**To begin** obtain these materials

-  Filter material media
-  Scissors
-  Double-sided mounting tape (3/4 - 1 inch)

# 1

### Print and cut out paper template.

Print template on 8.5 X 11 inch sheet at 100%. Measure dimensions after print to ensure correct sizing. Trace template onto filter material, cut out, and set aside.



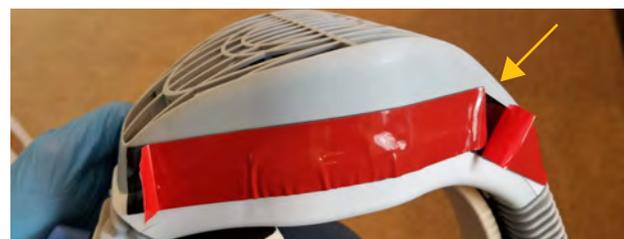
# 2

**Start at the front**, on one side of the helmet. Place a strip of mounting tape using the gap between the lighter plastic and the darker plastic as a guide. Fold over part of the liner as shown.



# 3

**Partially overlap another strip of tape** onto the existing strip and continue following the gap. Repeat steps 2 and 3 on opposite side of helmet.



# 4

**Place tape on front and back portion**, overlap on both strips of existing tape.



# 5

**Remove all tape liner.**



6

**Locate the front of the material** indicated on the pattern. Place the front of the filter material on the helmet as shown, press down to adhere material to the tape.



7

**Pull the material taut** and adhere the back portion of the material to the back of the helmet.



8

**Grab the middle section of one of the sides**, pull taut, and adhere to the tape.



9

**Fold both sides of the filter material as shown**, make sure to press the material firmly to the tape. Confirm the material is securely adhered to the tape.



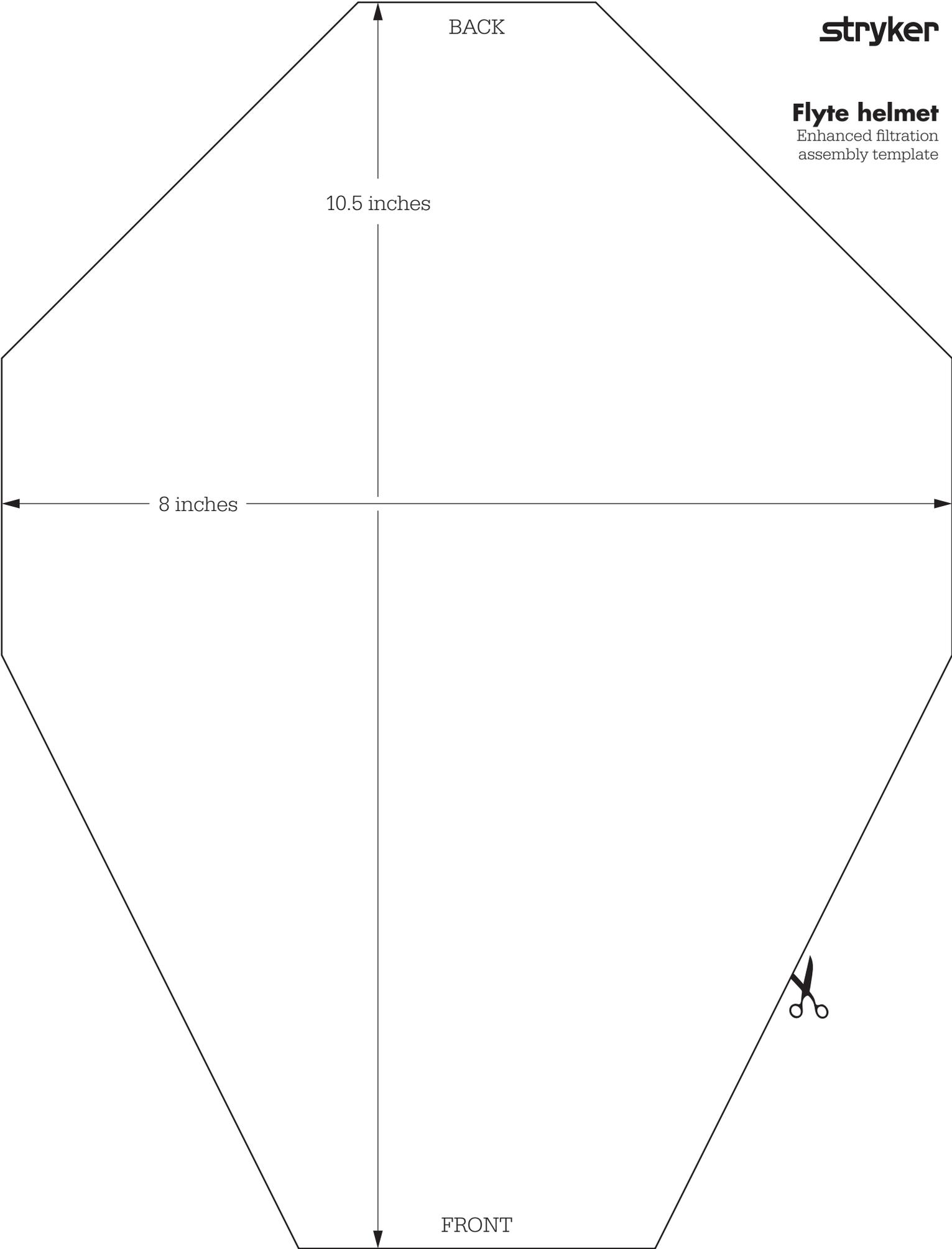
10

**After use, remove filter material, and discard.** Replace tape when adhesive properties have diminished, or filter material no longer adheres.

**stryker**

**Flyte helmet**

Enhanced filtration  
assembly template



BACK

10.5 inches

8 inches

FRONT