

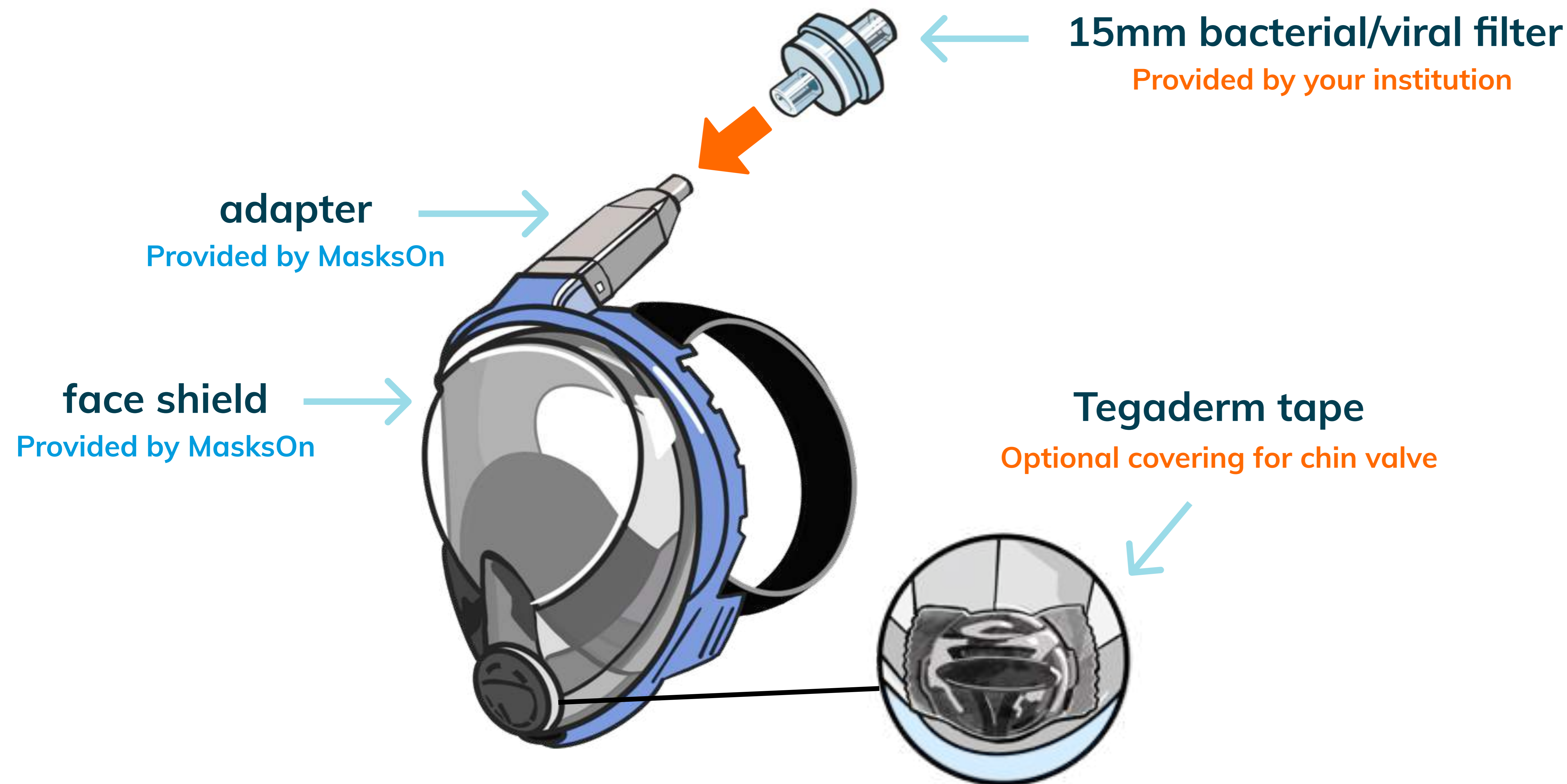


MasksOn Reusable Face Shield

For more information, visit MasksOn.org

Face shield for medical purposes
NOT FDA CLEARED OR APPROVED

Face Shield Overview



Preparation & Safety

⚠ Use clean gloves when touching face shield

- Follow your institution's standard protocols for personal protective equipment (PPE).
- Users must be clean shaven and cannot wear glasses** in order to ensure a proper seal around the face.
- Wear the face shield in a non-clinical setting** for 15 minutes to adjust to the feel.
- If you feel lightheaded or dizzy, or if the face shield is not sealing, **move to a safe area and remove the face shield.**
- The face shield is the last PPE that should be removed.** Use new PPE while sanitizing the face shield.

Instructions for Use

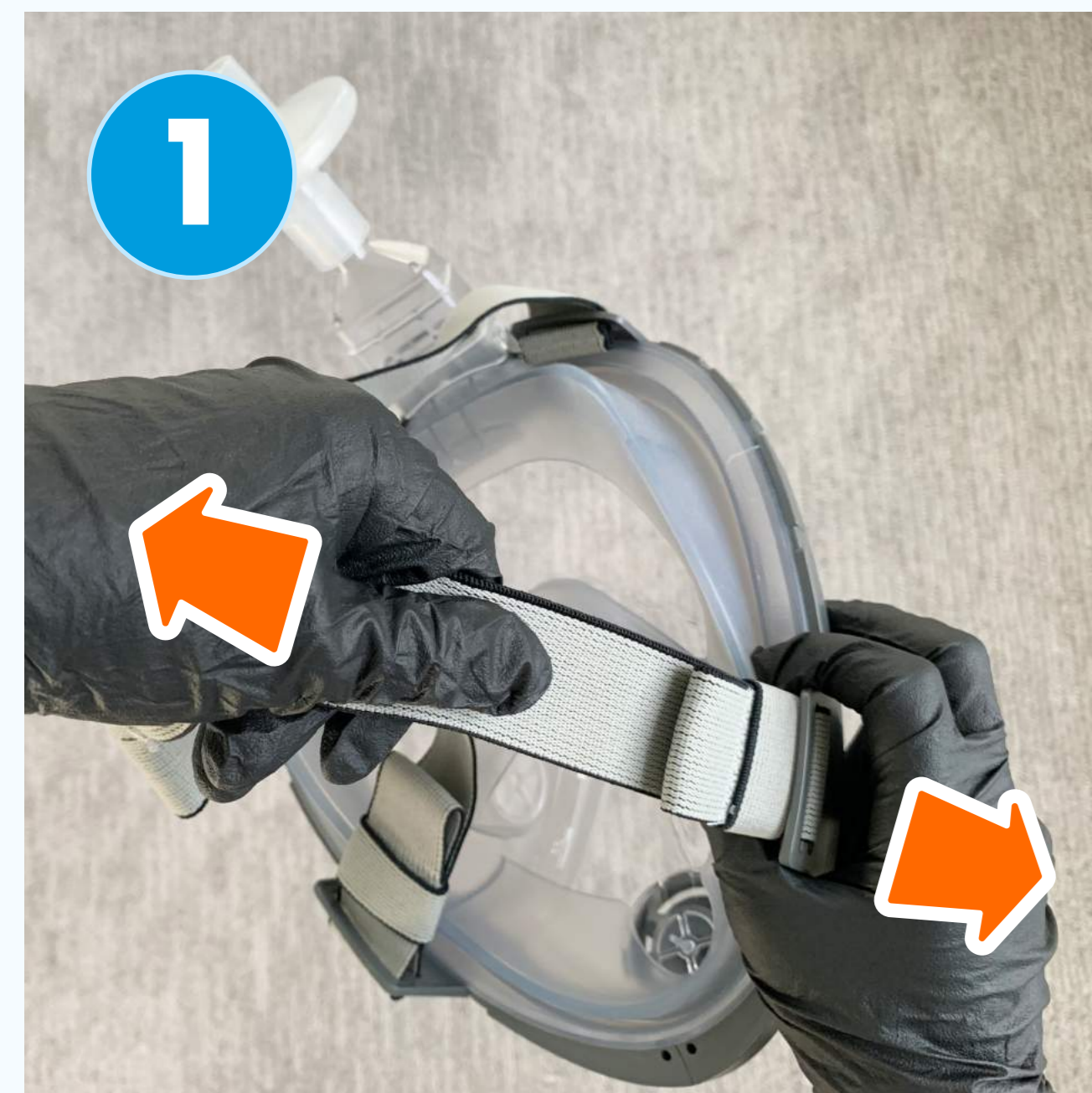
- Check MasksOn.org for updated instructions before each use.
- Attach a 15mm bacterial/viral filter to the adapter. Only one end of the filter will fit; push it down until it can't go any farther. **The filter must be supplied by your institution** (a list of compatible filters is available at MasksOn.org).
- Follow safe donning and doffing instructions (page 2). Before each use, inspect the face shield, adapter, and filter for cracks or signs of wear and perform the suction test.
- Sanitize using bleach solution (page 3). Sanitization wipes may be used between patients.
- OPTIONAL:** The chin valve is sealed; however, this area can be difficult to clean. Apply optional Tegaderm (or equivalent dressing) over the valve for easier sanitization.



WEAR INSTRUCTIONS

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Donning: Put on Face Shield



1. Loosen the straps completely.

Move hair (such as bangs) out of the way before donning the face shield.



2. Using one hand to hold the face shield, pull the straps over the top of your head with your other hand. Avoid smudging the visor.



3. Check the seal for hair and adjust so it fits completely around your face.



4. Maintain a firm grip on the face shield and tighten the straps until it fits snugly.

User Suction Test

⚠ Suction test must be performed before each use

5. Cover the end of the filter.



6. Breathe in. **You should feel a tight vacuum on your face.** If you hear a sucking sound, check that hair is out of the way and retighten the straps.



⚠ If you are still unable to achieve suction, do not use the face shield



7. Put on an external cap over hair and straps to avoid contamination.

Doffing: Remove Face Shield

⚠ Avoid unprotected contact with the exterior of the face shield



1. Loosen the straps.



2. Place your thumb under one of the straps.



3. Slide your thumb all the way to the back of your head. Use your thumb to push the straps up and over the top of your head, moving the face shield away from your face.



4. The face shield should end up pointing away from you. Once the face shield is removed, follow sanitization instructions (page 3).

SANITIZATION INSTRUCTIONS

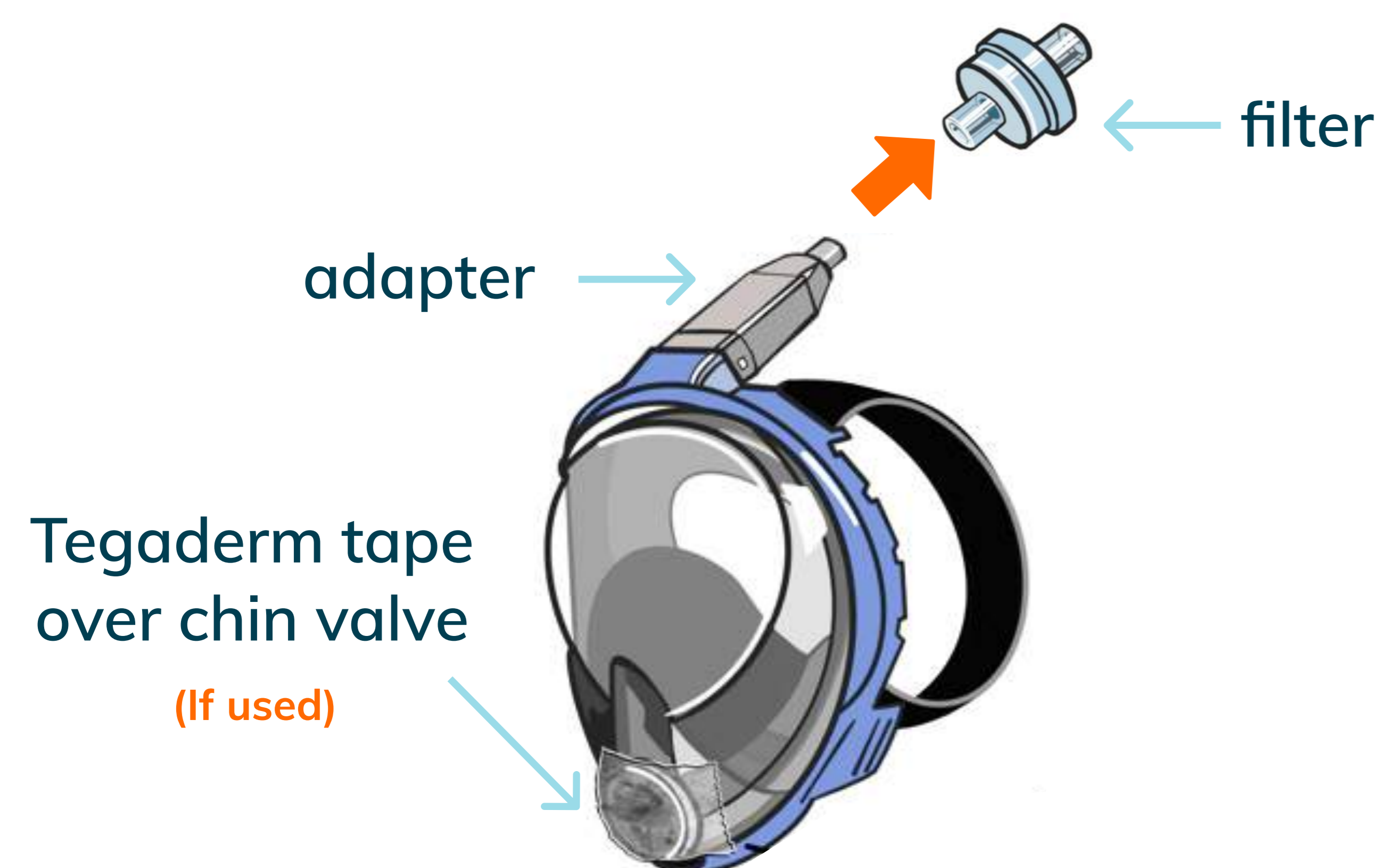
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Materials

- Two 2-gallon or larger buckets
One for soap solution, one for 10% bleach solution
- 15cc / 0.5 oz liquid dishwashing soap
- 160cc / 5 oz bleach (5.25% sodium hypochlorite)
To create a 10% bleach solution
- Scrubbing tool (e.g. brush)
- Metal tongs or similar grasping tool
- PPE (gloves, gowns, face splash shield)

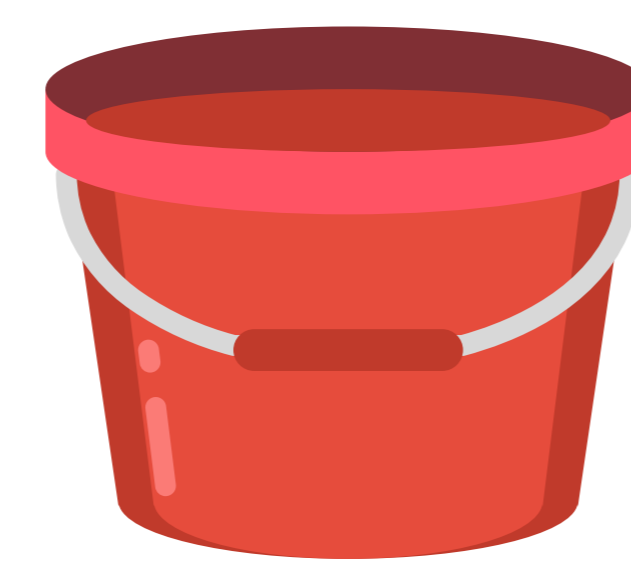
Remove Filter and Tape

1. Perform hand hygiene and don new PPE.
2. **Remove the filter and Tegaderm (if used).** If Tegaderm was not used, pay close attention to chin valve when cleaning.
3. Decide whether to reuse or replace the filter based on your institution's protocols.



Prepare Soap Solution

4. Combine **15cc / 0.5 oz of liquid dishwashing soap** and one gallon of warm water in the first bucket. The soap solution removes debris and organic material before sanitization in bleach.



2-gallon bucket



15cc / 0.5 oz dishwashing soap



1 gallon warm water

Prepare Bleach Solution

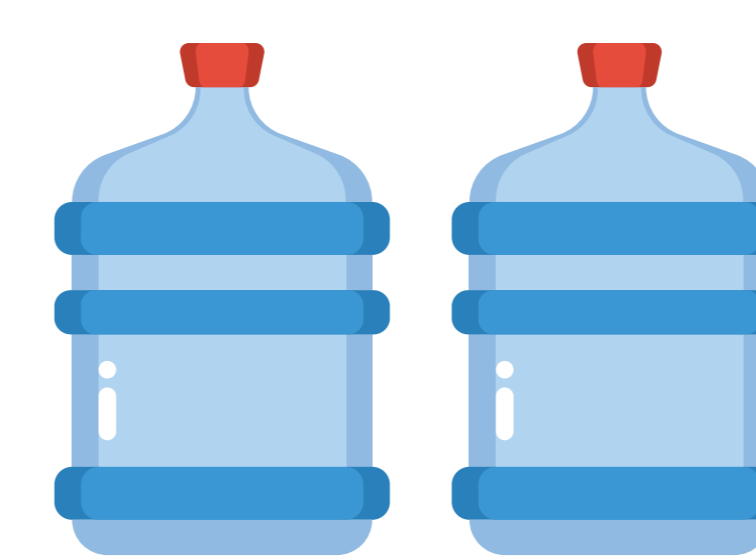
5. Combine **160cc / 5 oz bleach (5.25% sodium hypochlorite)** and two gallons of warm water in the second bucket to create a 10% bleach solution.



2-gallon bucket



160 cc / 5 oz bleach



2 gallons warm water

Clean in Soap Solution

6. After the filter has been removed (adapter stays connected), **fully submerge the face shield in the soap solution and scrub with a cleaning tool.**
7. Remove the face shield and rinse in running water to remove the soap solution before putting in the bleach solution.

Sanitize in 10% Bleach Solution

⚠ Avoid bare skin contact with bleach solution

8. Using metal tongs or similar tool, **fully submerge the face shield in the bleach solution** and turn face down. Gently agitate to dislodge air bubbles and so the bleach reaches all surfaces.



9. Keep the face shield submerged in the bleach solution for **2 minutes**.
10. Remove the face shield and rinse it under running water. Rinse all flaps and edges, especially near the chin if Tegaderm was not used. Stretch the straps while rinsing.
11. Dry the face shield using paper towels or air dry (hang the mask upside down to drain).
12. The face shield must be completely dry before attaching a filter or new Tegaderm.



MasksOn is a nonprofit initiative dedicated to providing 1,000,000 protected-clinician-days during the 2020 COVID-19 Pandemic. We are mobilizing top talent in medicine, technology and academia to generate immediate, low-cost and high-quality protective gear for healthcare workers at the front line of the COVID-19 Pandemic. The team is building durable, reusable, and sanitizable medical personal protective equipment (PPE). We source readily available full-face snorkel equipment, rapidly manufacture adaptors, and distribute assembled face shields. Healthcare professionals can combine the face shields with facility-provided bacterial/viral filters to provide care for the sickest patients in Intensive Care Units and Emergency Rooms.

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- This device has been authorized by FDA under an Emergency Use Authorization (EUA) for use by a healthcare provider (HCP) as personal protective equipment (PPE). This device is only authorized for the duration of the declaration that circumstances justifying the authorization of emergency use under Section 564(b)(1) of the Act, 21 USC 360bbb-3(b)(1) unless the authorization is terminated or revoked.
- This device is NOT manufactured in compliance with 21 CFR Part 820, ISO 13485, or similar Quality Management System regulations.
- The MasksOn Reusable Face Shield:
 - **should ONLY be used when FDA-cleared face shields are unavailable;**
 - makes no claims of antimicrobial or antiviral protection;
 - makes no claims of infection prevention or reduction;
 - makes no claims regarding flammability.

Clinician FAQ

What should I do if I lose these instructions?

These instructions are available at MasksOn.org. Check MasksOn.org before each use for updated information on safe use and sanitization.

Which filters can I use with this face mask?

Check with your institution about available 15mm bacterial/viral filters. Visit MasksOn.org for a list of compatible filters.

What testing has this face mask undergone? Is it safe to use?

This device may be effective at preventing exposure to certain particulates during face shield shortages by providing minimal or low-barrier protection to the wearer during COVID-19. Visit MasksOn.org for current information about safety and testing.

What do I do if the suction test fails?

First, check that nothing is obstructing the seal (hair, facial hair, glasses, etc.) and retighten the straps. Make sure you have the right size for your face. Then, check for signs of damage. If it continues to fail, do not use.

What do I do if I feel dizzy or claustrophobic?

If for any reason you do not feel well, go to a safe area and remove the face shield.

Additional questions, comments, or feedback?

Contact us at questions@maskson.org.