

## Warning

Read this document to the end. It is very important that you do so or you may have important doubts about what we want to communicate.

#### Disclaimer

The following information refers to a non-profit altruistic development within the framework of the fight against COVID19.

Keep in mind that the correct way to obtain these devices is to order them from approved manufacturers, therefore, as soon as you have the opportunity to receive these products from a manufacturer, you must use that channel.

Also note that there are patents on this type of device. It is known that manufacturing companies are donating plans and advice, however starting a production for profit, for example, it could be violating patent rights. There has been no study of intellectual property that could be affected by the use of the product in each of the territories. Get informed.

Files must be analyzed and validated before use. It is also necessary for a health authority to be responsible for the validation of the product resulting from the use of these contents. Do not use in a medical treatment a product not validated by a health professional and the proper health authorities.

In any case, our intention is to inspire and provide previous work to all those who can take these files and can take responsibility for putting in place a safe solution that saves lives. This necessarily involves verifying that the technical solution that we propose is viable, with the corresponding organizations in your country, and that the solution that you propose based on these elements that we make available to you, does not pose a health hazard.

We present the results of the tests carried out, and we make a series of recommendations that you must verify for yourself, and verify that under the conditions that you are going to implement this solution, the system works as you need it to work.

If you do not have the possibility of assuring 100% that the result of the device that you are going to manufacture from these plans is safe and effective, you should know that the responsibility for the damages that it may cause is solely yours, and that is why we ask that you put this solution in the hands of your local administration or government so that you receive expert assistance, and its implementation is 100% safe and verified by experts.

While the pandemic lasts and there is a need in your country that cannot be satisfied by the commercial offer of these devices, you have our permission to use, modify and distribute these files, including this document, always under your responsibility. If you modify the design, this document is no longer valid, and you do not have the right to use it, unless you modify it, therefore, you are responsible for everything that appears in that new version.

If you, despite having these files, cannot manufacture the helmet, contact us on the web <u>https://breathingbubble.com</u> to see if we can help you, or write to us at <u>hi@breathingbubble.com</u> indicating your contact details.

Understanding that in some cases it is this or nothing, I wish with all my heart that you can find a solution inspired by our work, and can save other people's lives.

A greeting and good luck,

J. de Donostia

## WARNING – IMPORTANT INFORMATION

- Manufacture this device so that it is a physical barrier to COVID19. Some materials are porous, and although they appear solid and waterproof, they are not. You must make sure that the material you use is watertight, or that you can treat it to make it watertight, otherwise the virus will infect the environment.
- Please note that the patient must wear earplugs to withstand the pressure inside the helmet. Try to use a plastic bubble as transparent as possible so that the patient can at least see, since they will hear very little.
- In this design, moorings are placed so that the helmet can be fixedly attached to the body, by means of straps that would be located under the armpits.
- Never use the helmet without a filter, or you'll spread the virus all over the room.



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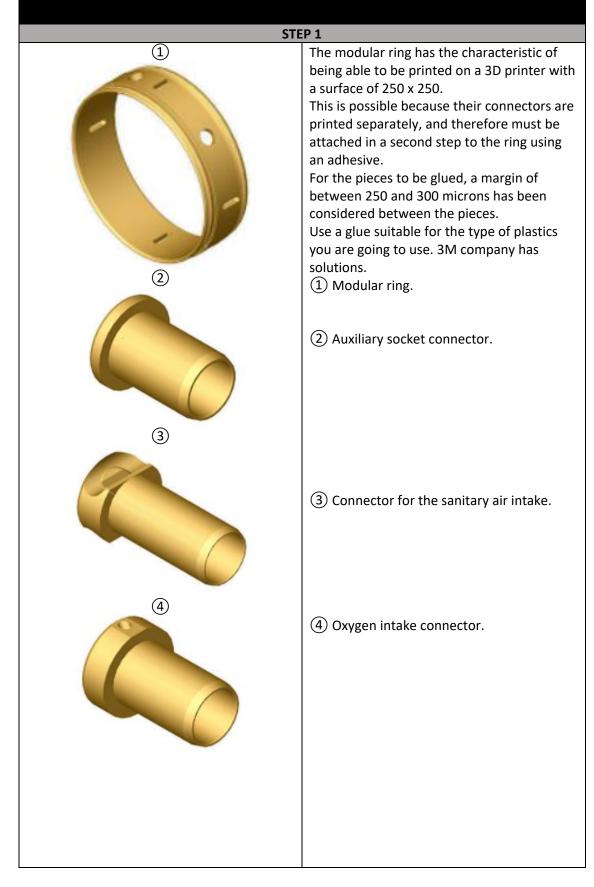
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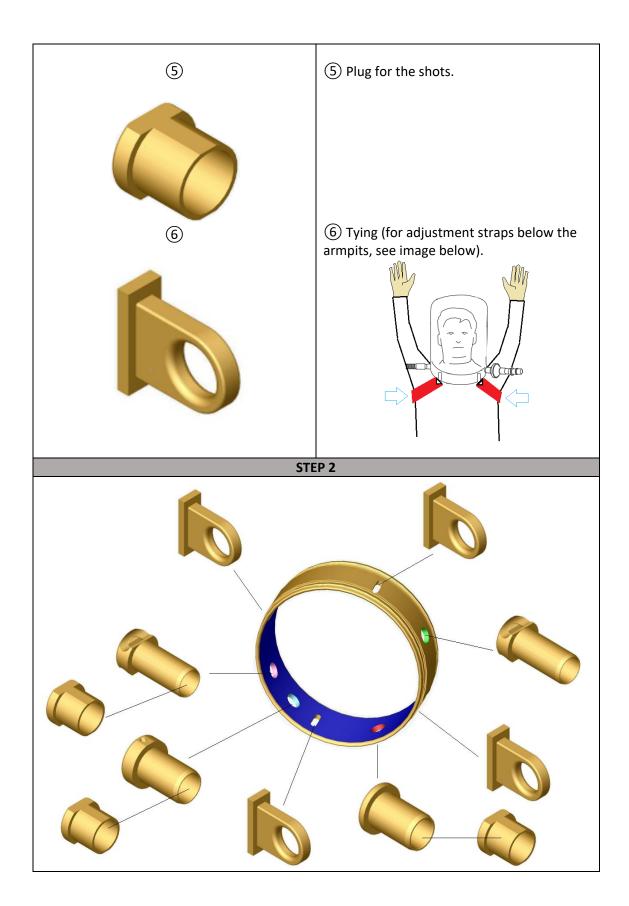
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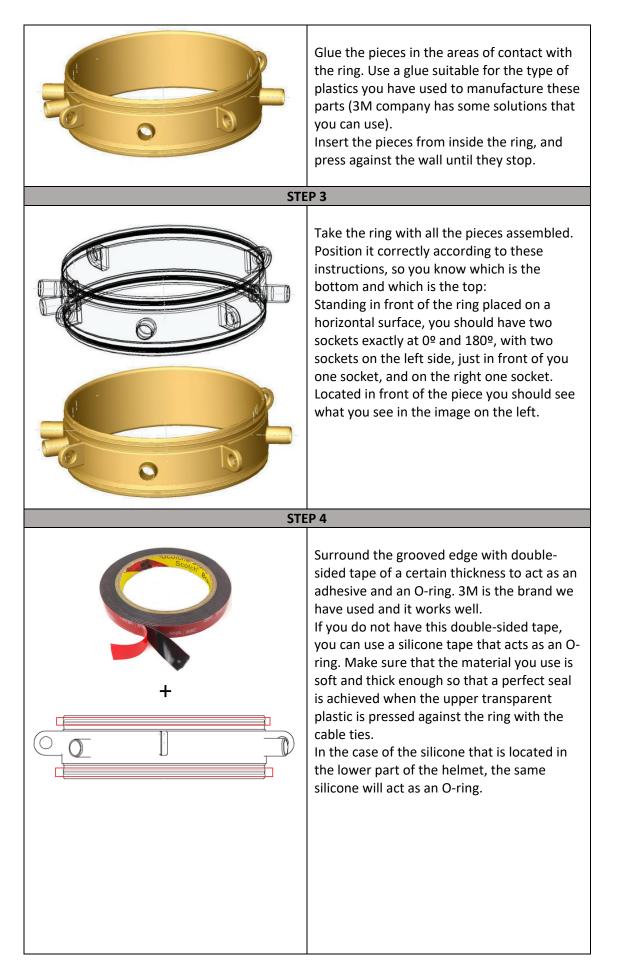
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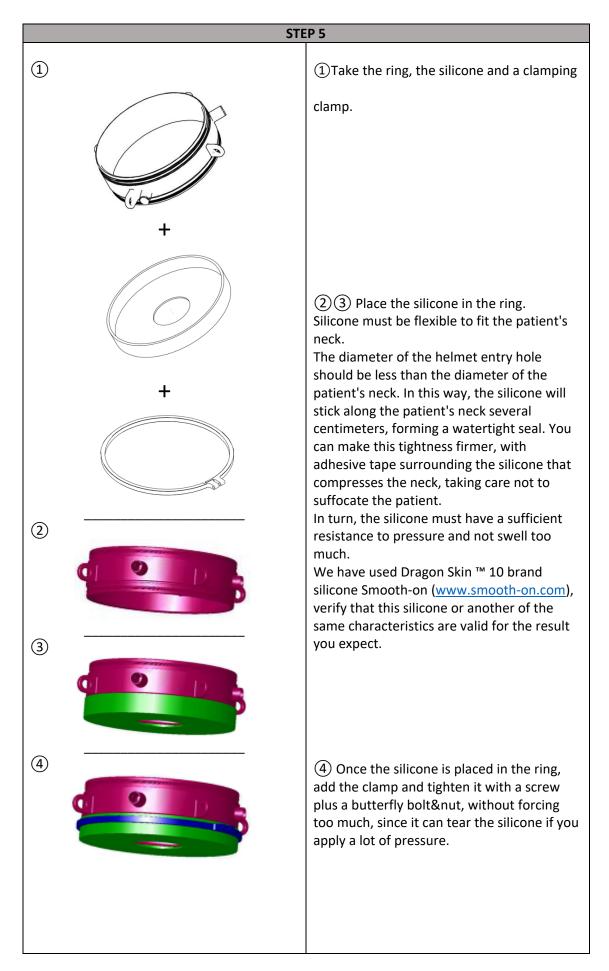
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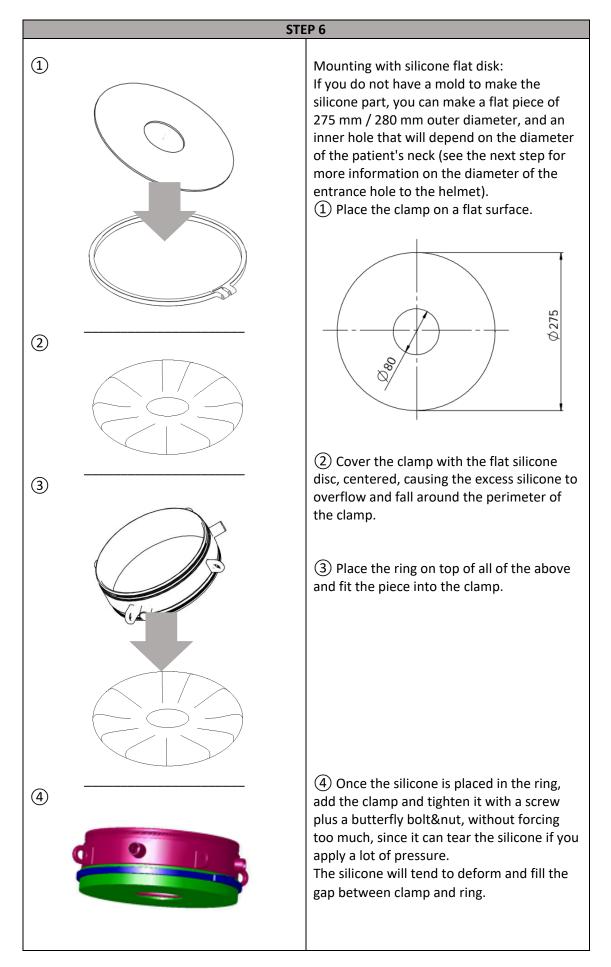
## Assembly instructions for the helmet with modular ring

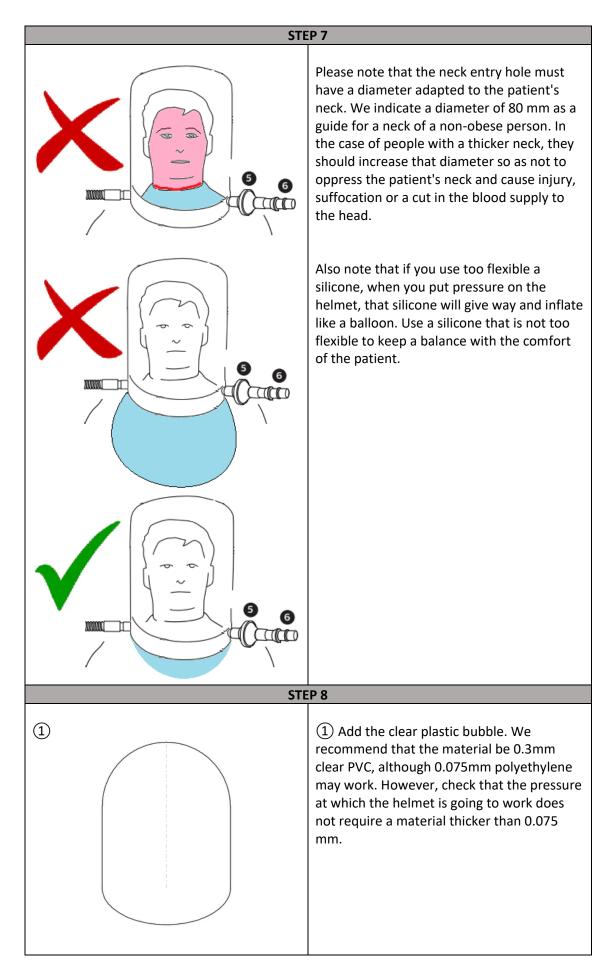


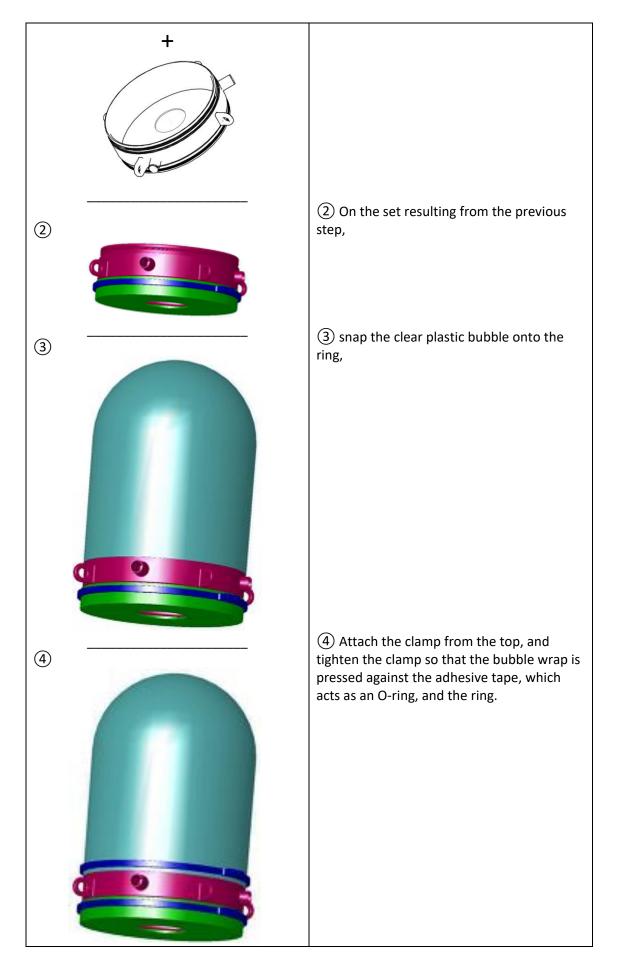




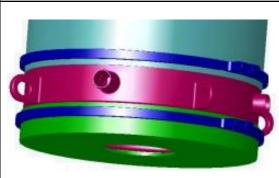




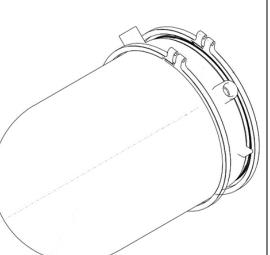




#### **STEP 9**







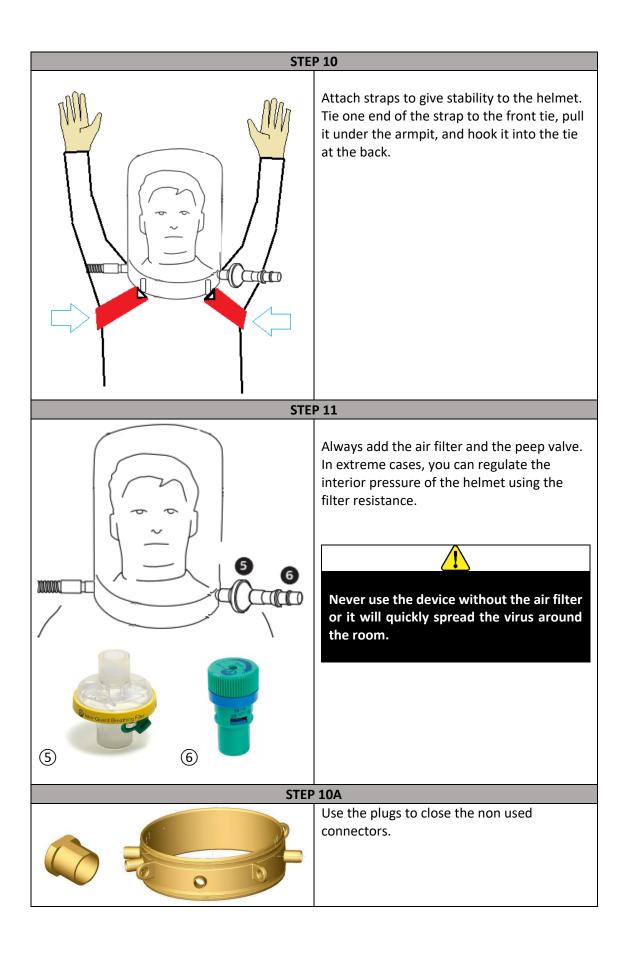
Place and tighten the clamps with screws, with a nut or butterfly bolt&nut, so that the clamps cover the entire grooved perimeter, and press the transparent plastic bubble and the silicone against the grooved area of the ring, so that there are no gaps for air to escape.

Make sure that part of the clear plastic and part of the silicone are beyond the clamping clamp, extending further along the surface of the outer face of the ring, as if they were to meet halfway.

If you do not have the clamps that we have designed, you can replace them with normal clamps. In this case, you should pay special attention to the area of the clamp head, since this area will not conform to the surface of the ring. At this point, add silicone or another similar material that acts as a filler, and that due to its flexibility fits perfectly in the hole.

For example, use flat head clamps type HellermannTyton to improve the fit of the clamp head.

Do not overtighten the clamp or it will tear the silicone. When the silicone is firm and cannot be easily removed by pulling it, it is time to stop tightening the clamp.



## Assembly instructions for the helmet with compact ring



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## STEP 1A

Take a ring.

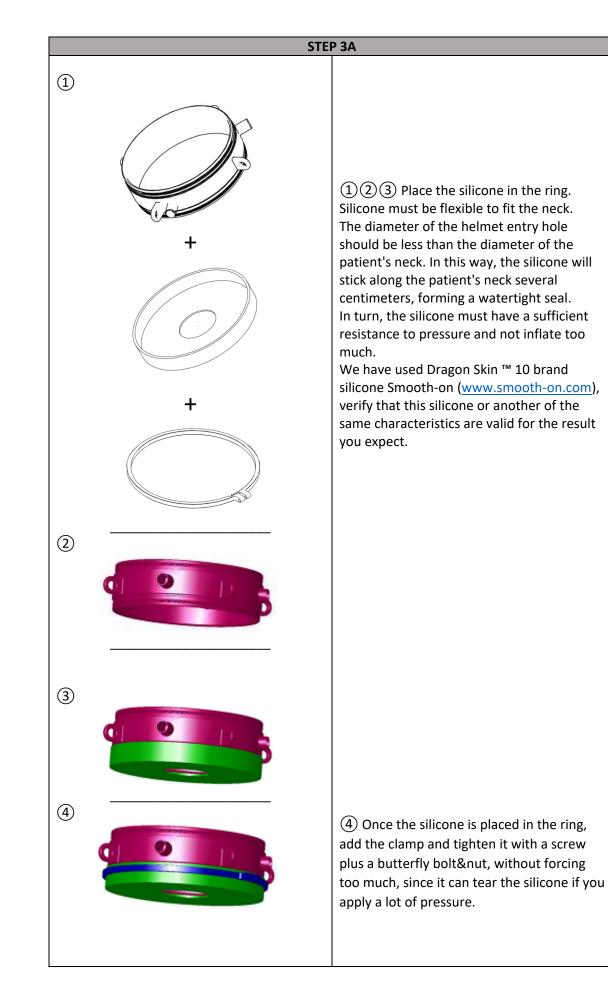
Position it correctly according to these instructions, so you know which is the bottom and which is the top: Standing in front of the ring placed on a horizontal surface, you should have two sockets exactly at 0° and 180°, with two sockets on the left side, just in front of you one socket, and on the right one socket. Located in front of the piece you should see what you see in the image on the left.

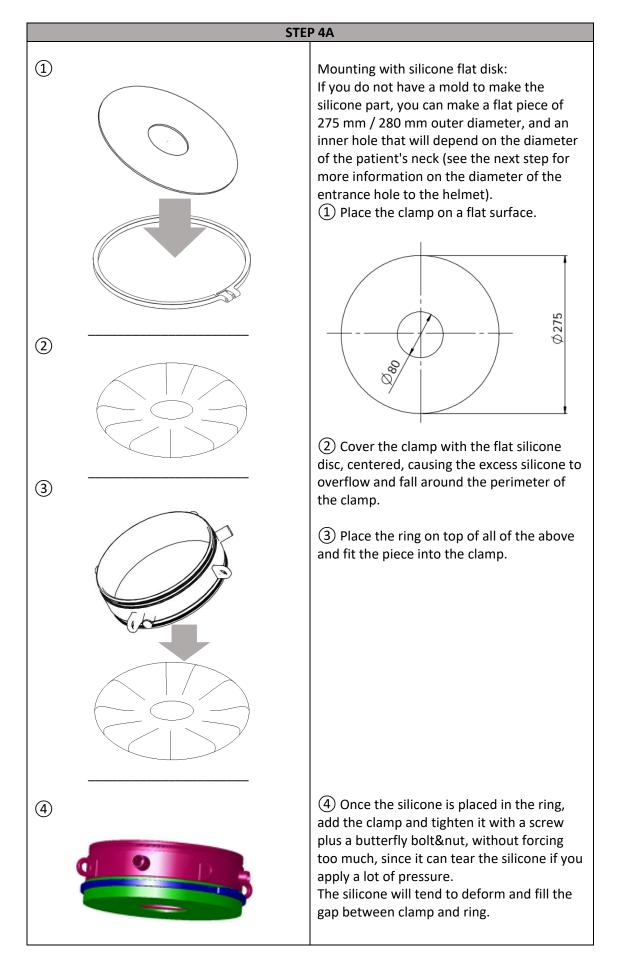
**STEP 2A** 

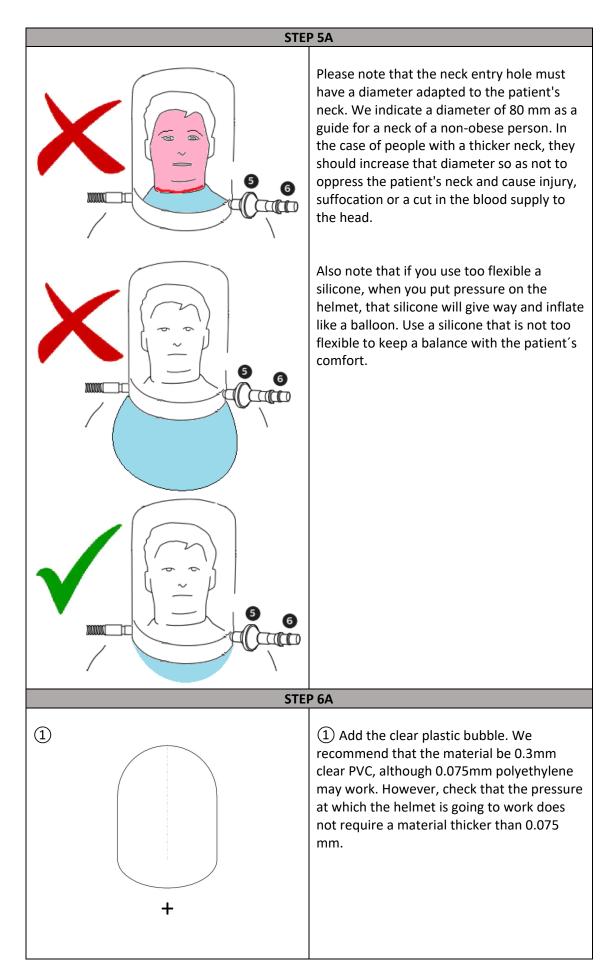
Surround the grooved edge with doublesided tape of a certain thickness to act as an adhesive and an O-ring. 3M is the brand we have used and it works well.

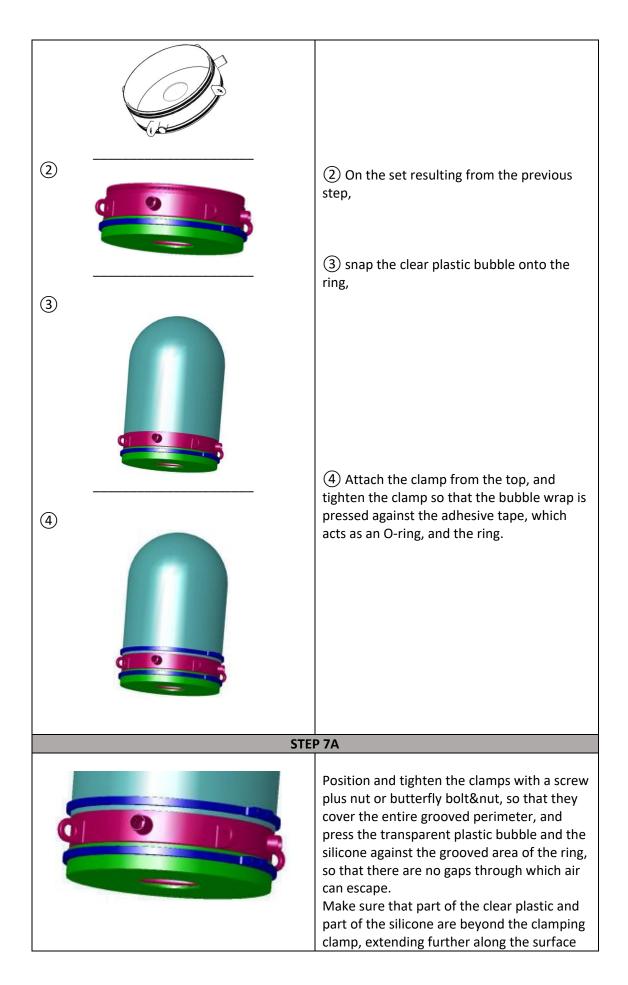
If you do not have this double-sided tape, you can use a silicone tape that acts as an oring. Make sure that the material you are using is soft and thick enough so that a perfect seal is achieved when the upper transparent plastic is pressed against the ring with the cable ties.

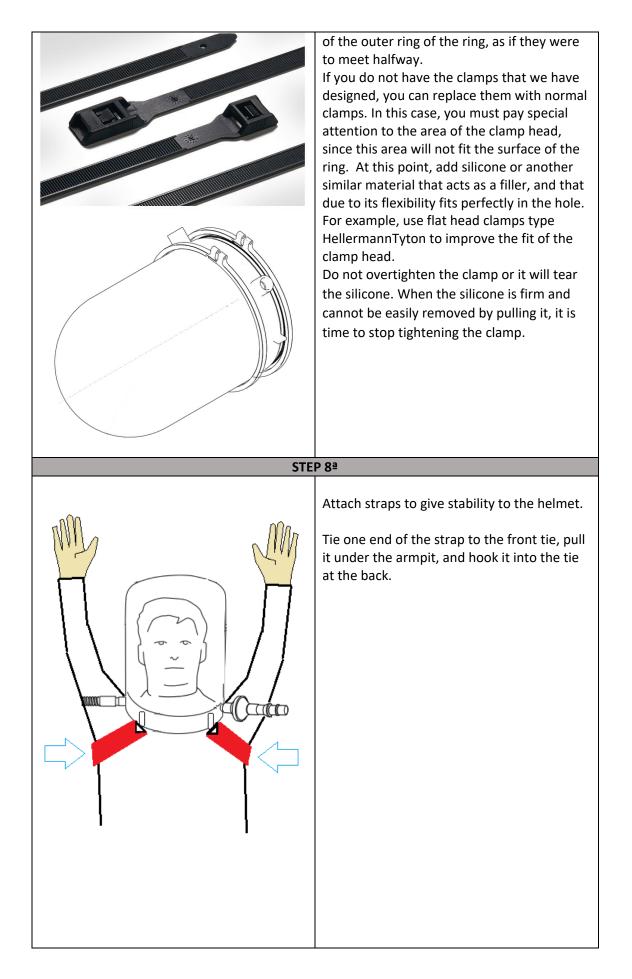
In the case of the silicone that is located in the lower part of the helmet, the same silicone will act as an O-ring.

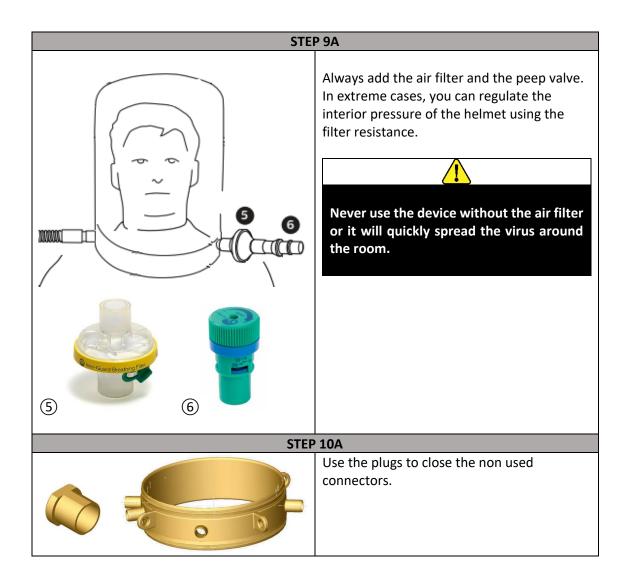










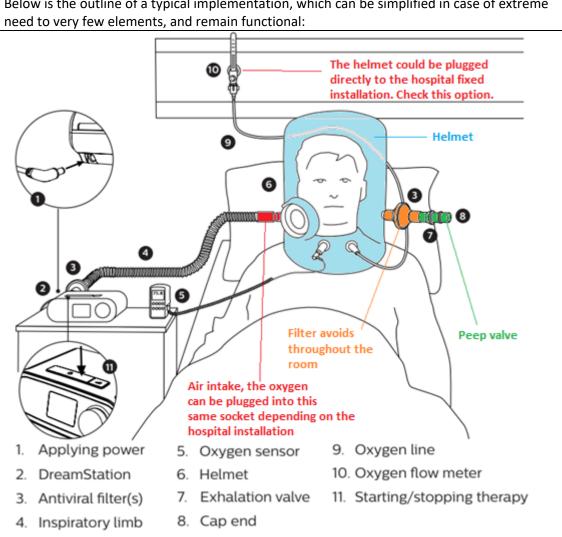


### Proposal

Our solution is inspired by a diving helmet and its different air intakes and outlets that keep the diver ventilated.

There are solutions on the market similar to the one presented in this document, and which are used in hospitals on a regular basis.





Below is the outline of a typical implementation, which can be simplified in case of extreme

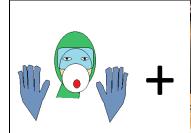
# WARNING – VERY IMPORTANT

- This device creates a pressurized space, and therefore has a pressurized air outlet. You should always put a filter in the air outlet, or the virus will spread throughout the room.
- If you put a suitable filter and guarantee the tightness of the entire device, the propagation stops.
- In the intubation and de-intubation operations, you must take into account that there is a high risk of contagion, due to the existence of aerosols. Use a protective screen or protect yourself with PPE.
- The materials in which the parts are manufactured cannot be porous, they must be watertight, otherwise the virus will infect the environment.

• Take into account that this device must have a constant flux of air and pressure, or the patient could suffer asphyxia, and if the patient is unconscious, can cause death. So asure that there is always supply of air/oxigen and pressure.



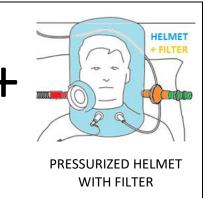
# Never use without filter or it will pollute the entire room.



INDIVIDUAL PROTECTION EQUIPMENT



METHACRYLATE SCREEN



## Advantages

- 1. Treatment with O2 intake to avoid collapse and ICU admission for patients who have difficulty breathing, but who can still do it themselves without the need for an invasive system.
- 2. Physical barrier that prevents the spread of the patient's COVID19-infected breath to the environment, which prevents infection by healthcare personnel.
- 3. Prepared to be connected directly to the sanitary air and oxygen intakes of the fixed hospital installation, or other available ventilating devices.

### Our testing

A low quality prototype has been tested in the laboratory at an air inlet flow rate 4 times higher than necessary, and at a pressure 50% higher than necessary.

You can see the video at the following link:

https://youtu.be/kuKx7GKkE-A



Photos and videos of the high quality Polyamide 12 ring:

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