Manufacture life-saving medical masks at scale with the Mayku FormBox

Third edition - published 10th October 2020

Contents

Introduction

Mayku Mask

The Mayku Mask has been designed for use during the COVID-19 pandemic. It is a vacuum-formed reusable medical mask consisting of an impermeable semi-flexible body made from recyclable PETG, which can be tightly fitted to the user's face. A cap clips onto the body to secure a disk of filter material in place through which all inhaled and exhaled air flows when the mask is properly fitted, filtering particulate and biological matter. The mask is held onto the head with elastic straps attached to the cap, and can be adjusted. The plastic parts of the mask are intended to be reusable and are easy to sterilise, while the disks of filter material are single use and last for up to a day.

The method of manufacture outlined in this document offers the following advantages over other PPE solutions:

- The process can be decentralised and undertaken by manufacturing hubs globally, as and when required.
- The manufacturing equipment is low-cost.
- The manufacturing process does not require a high-level of expertise.
- The cost per item is low compared to similar quality products.
- The mask can be sterilised between uses and therefore has a longer life than paper or cloth surgical masks.
- The flexibility of the material allows for a good air-tight fit that passes stringent fit-testing procedures.

The respirator is an open source variation of the **Care-Mayku Mask**. The original project is a collaboration between Mayku, the Royal Academy of Engineering and the University of Leeds, with further support from various other organisations. The design is published by the University of Leeds and as such Mayku acts as a distributor of the manufacturing equipment, instructional materials and usage guidelines. The associated materials can be licenced for free and downloaded from the University of Leeds here.

The Care-Mayku Mask has been tested using specific filter material, **Separet 2402** and **Separet 1520**, produced by Freudenberg Filtration Technologies KG. It has been tested in accordance with the EN 1827:1999 + A1:2009 European Standard for particle filtering half masks with separable filters (identical to the tests mandated by the EN 149:2001 + A1:2009 European Standard for particle filtering half masks), in accordance with the EU 2020/403 recommendation for minimum test requirements appropriate for the specific circumstances of healthcare workers during the COVID-19 pandemic.

The results of these tests are detailed on the University of Leeds website and highlight the inherent benefits of the Care-Mayku Mask because of its good face fitting and reduced air leakage which is an issue with most conventional face coverings and cloth masks.

We recognise that the filter materials used in the Care-Mayku Mask tests may not be available in all locations. Given the inherent advantages of the mask design, we are therefore releasing the **Mayku Mask** detailed in this document. It can be used with a range of different filter materials which can be chosen to comply with local regulations or available suppliers. This Mayku Mask is therefore more suitable for low volume applications in global markets. Please note that if the mask is distributed with any filtration material other than those listed on University of Leeds website, all public health liability falls to the manufacturer of masks designed as-per the Mayku Mask specifications.

Manufacturing instructions and additional resources continue on the following pages.

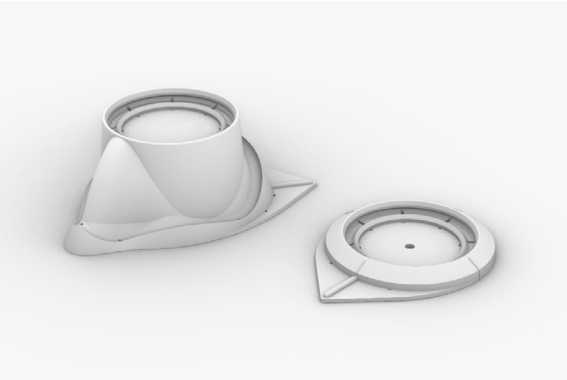
Mayku would like to thank the various organisations and individuals who have already developed open-source solutions to PPE using the FormBox. This design represents a combination of the best aspects of these as well as additional engineering and usability features developed by the CARE design team, led by the Royal Academy of Engineering.

For limited technical support related to the Formbox please contact hello@mayku.me

Preparing the vacuum-forming templates

1. Downloading the 3D files

1

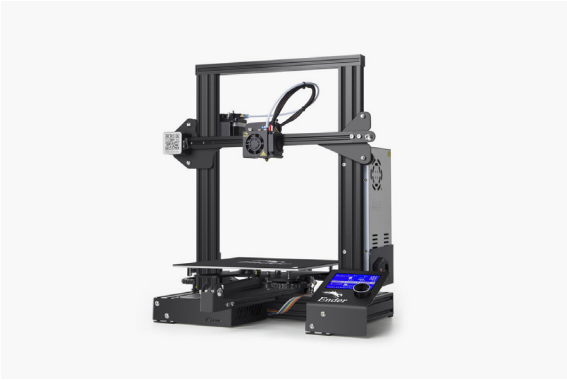


Click here to download all of the digital files that are necessary to manufacture the mask forming templates.

Ensure you choose the correct template sizes, either 0.5mm or 0.7mm depending on the thickness of PETg sheets that you will be using.

You will also need to choose the correct cap thickness depending on the filter material that you will be using. The thin cap is suitable for filter material < 0.6mm. The thick cap is suitable for filter material 0.6mm - 1.6mm uncompressed.

2

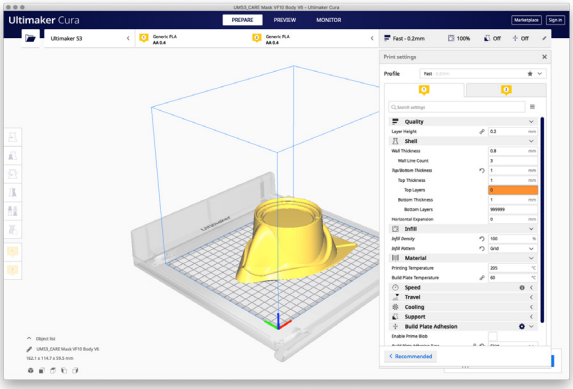


We have prepared ready-to-use gCode for Ender 3 Printers. For all other printers please download the STL files and print them using settings in the next section.

Preparing the vacuum-forming templates

2. 3D Printing the templates

1



Open the STL files in the slicer software of your choice, we recommend Slic3r or Cura.

2

Use the manufacturer recommended filament settings for the filament that you're using. (Nozzle and filament temperature, retraction settings) we recommend standard PLA to print with, and strongly advise against PETg filament.

3

It is very important that you use the following settings exactly, or the print is likely to fail. The templates are purposefully hollow and have complex internal geometry.

Template print settings

Layer height	0.2mm
Perimeters	3
Solid Top Layers	3
Solid Bottom Layers	3
Ensure vertical shell thickness	Yes
Avoid crossing perimeters	Yes
Detect bridging perimeters	Yes
Infill density	100%
Fill pattern	Rectilinear
Top fill pattern	Concentric
Skirt	Off
Raft	Off
Support material	Off

4

Export the gCode and proceed to print the parts on your printer, we recommend printing one item at a time.

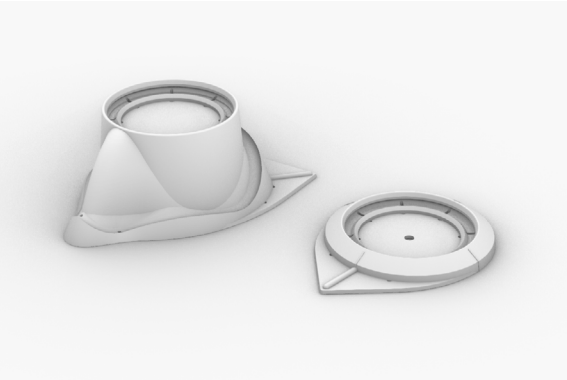
5

In order to speed up the manufacture of the masks we recommend that you print two sets of templates, however you can begin preparation and manufacturing with one set.

Preparing the vacuum-forming templates

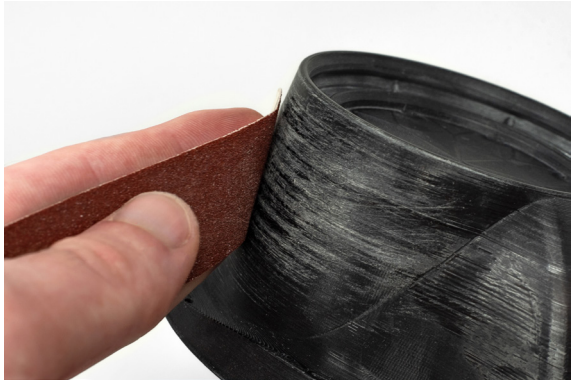
3. Quality assurance

1



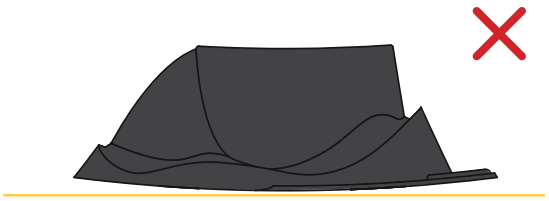
Check that the 3D print matches the STL files you downloaded earlier, if there are any obvious defects the part should be printed again.

2



Check the outside of the prints for any lumps or ridges. These should be carefully sanded down with a fine grit sandpaper until smooth.

3



Check for any warping in the print, it should sit flat on a table without any severe bowing or gaps.

4

Check that there are no unintended holes in the perimeter of the print.

5

Carefully remove any stringing or unintended bridging on the inside of the body and cap templates.

Preparing the vacuum-forming templates

4. Filling the templates with plaster

1

You will notice that the body and cap templates are hollow on the inside. This is so that you can fill them with plaster: this creates a very strong template that is much better at resisting the heat from the vacuum-former.

2

Do not form the templates before filling them with plaster. They are likely to deform and you will need to reprint them.

3

Turn the Body template upside down.

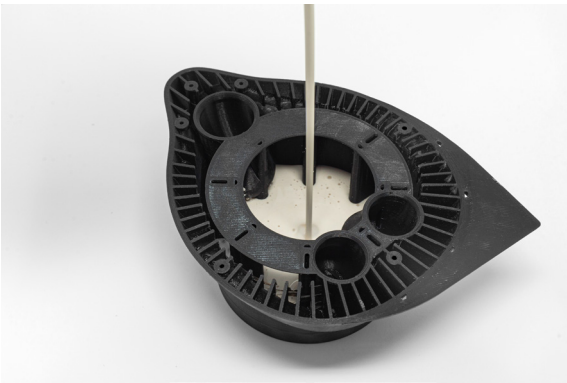
4

Mix up 500 grams of plaster by following the manufacturer instructions of the plaster you have sourced. (If you are using Mayku Pour, mix 5 large scoops of plaster powder with 5 small scoops of water)

5

Stir thoroughly to ensure that there are no lumps in the mixture.

6



Pour the plaster carefully into the template in the middle of the shell. The mix will work its way up into every gap.

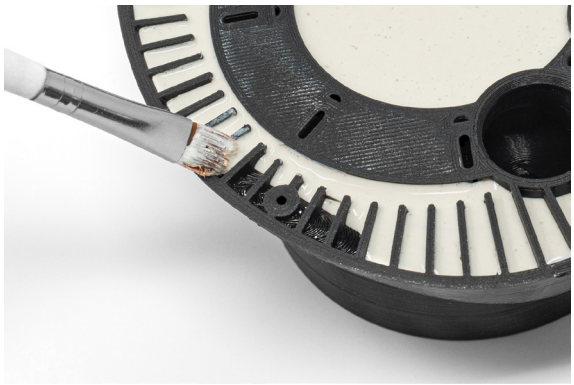
Preparing the vacuum-forming templates

4. Filling the templates with plaster

7

Be very careful not to get plaster inside of the small air holes, if you do, don't panic, they can be cleared out later on.

8

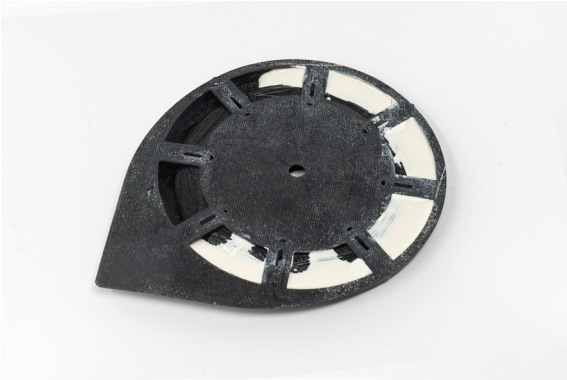


Tap the template to make sure that there are no air bubbles in the plaster, you may need to carefully work the plaster into areas around the perimeter with a small paint brush.

9

Fill to just below the bottom of the template.

10



Repeat the process with the cap. Add small amounts of plaster in each void segment and tap to gradually fill the template.

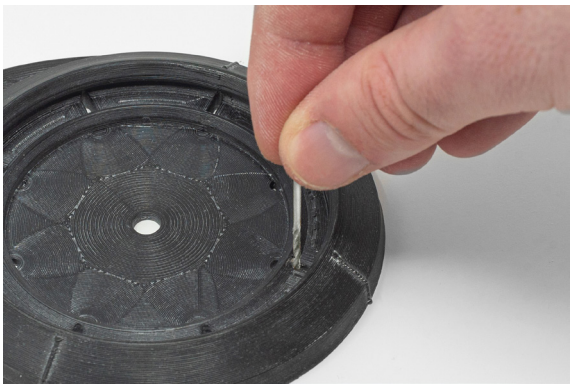
11

Allow to cure for at least 2 hours, preferably overnight, on a flat and level surface.

12

Level off any excess plaster on the underside with a knife.

13



If there are any blockages in the air holes, you can clear them with a 1.5mm - 2.0mm drill-bit or a sewing needle.

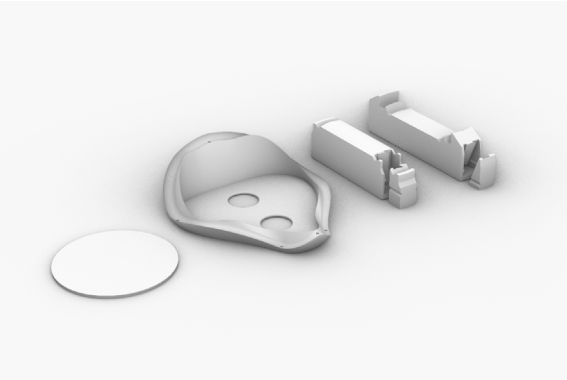
14

Check the template is free from any plaster on the outside. You can wipe it clean with a damp cloth.

Preparing the cutting tools

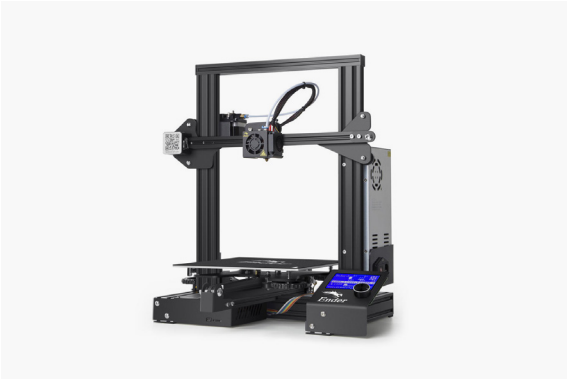
1. Downloading the 3D files

1



Click here to download all of the digital files that are necessary to manufacture the cutting tools.

2



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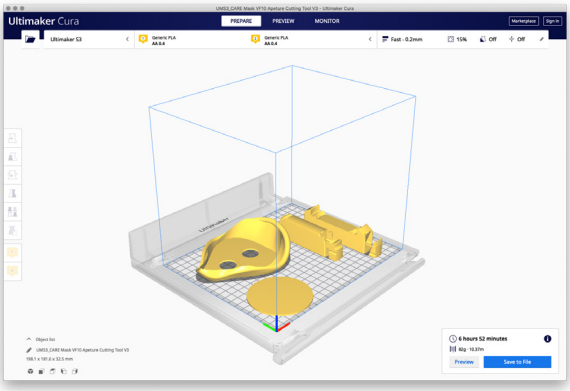
Preparing the cutting tools

2. 3D Printing the tools

1

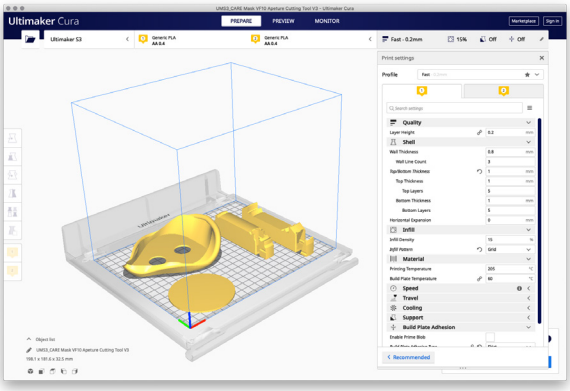


Open the STL files in the slicer software of your choice, we recommend Slic3r or Cura.

2

Use the manufacturer recommended filament settings for the filament that you're using. (Nozzle and filament temperature, retraction settings) we recommend standard PLA to print with.

3



These tools are easier to print than the templates, but we still recommend the following settings for a successful print. The settings here are not the same as the template settings.

Cutting tools print settings

Layer height	0.2mm
Perimeters	2
Solid Top Layers	3
Solid Bottom Layers	3
Ensure vertical shell thickness	Yes
Avoid crossing perimeters	Yes
Detect bridging perimeters	Yes
Infill density	15%
Fill pattern	Rectilinear
Top fill pattern	Rectilinear
Skirt	Off
Raft	Off
Support material	Off

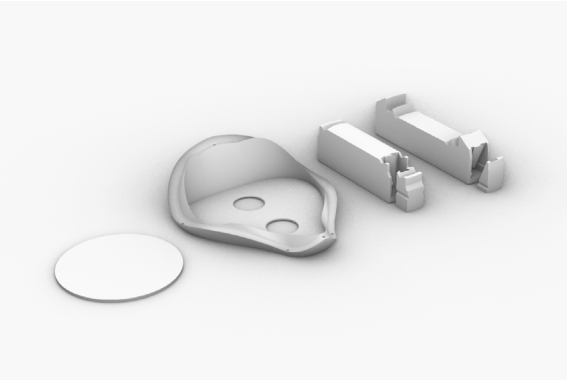
4

Export the gCode and proceed to print the parts on your printer, we recommend printing one item at a time.

Preparing the cutting tools

3. Quality assurance

1

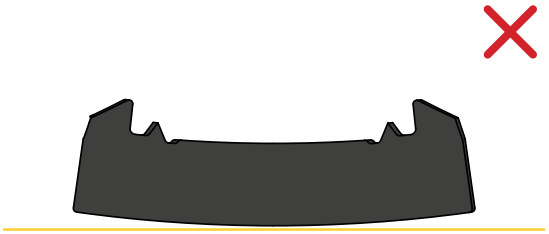


Check that the 3D print matches the STL files you downloaded earlier, if there are any obvious defects the part should be printed again.

2

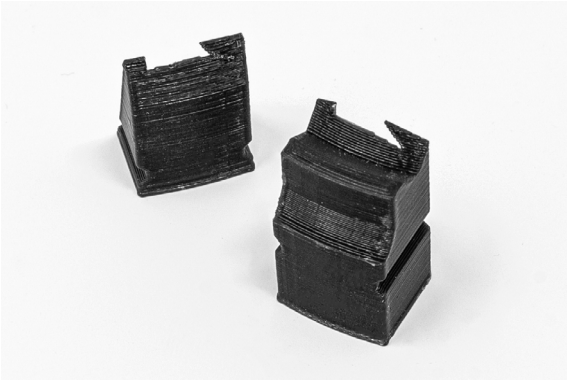
Check the outside of the prints for any lumps or ridges. These should be carefully sanded down with a fine grit sandpaper until smooth. Pay close attention to the small parts of the rectangular cutting tools.

3



Check for any warping in the print, it should sit flat on a table without any severe bowing or gaps.

4



Check that the narrow top edges of the small parts are clean and well-defined.

Preparing the cutting tools

4. Assembling the tools

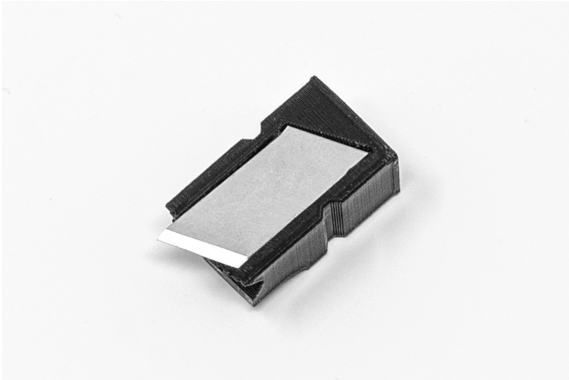
1

The cutting tools require the use of a standard craft knife / box cutter blade. They come pre-scored. Snap off one of the blade segments using a pair of pliers.

2

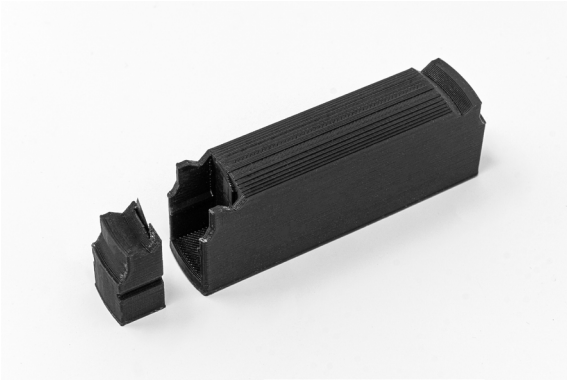
The snap should be clean and straight along the score line, clean up any debris outside of the score line with a file if necessary. Of course, be careful when handling the blades.

3



Place the blade into the holder. Made sure the sharp edge is poking out.

4



Slot the blade holder into the main part of the cutter.

5

Push it in tightly and make sure the holder is flush with the main part of the cutter.

6

Secure the blade holder in place using tape. Wrap it around the whole body twice. You can use standard clear sellotape, washi tape, duct tape or electrical tape.

7

Repeat this process with the second cutter.

8

If the blade becomes dull during manufacture, simply remove the tape, pull out the blade holder and replace the blade.

9

The larger trimming template does not require any preparation.

10

The filter cutting disk does not require any preparation.

FormBox setup

1. Receipt of FormBox and consumables

1

Wash your hands with soap and hot water for a minimum of 20 seconds before commencing work.

2

Wear disposable gloves if available and avoid touching your face with the gloves whilst handling the package.

3

If there is no PPE available, leave the package for 3 days prior to opening.

4

Wash your hands after unpacking or replace gloves.

5

You will need a corded vacuum cleaner to use the FormBox, please ensure you have one before beginning the FormBox setup process.

FormBox setup

2. Setup of the FormBox

1

Ensure you have space (one meter square table or bench with approx. one meter space around each side to enable easy access during forming) on a flat surface that will allow you to set up the FormBox at a convenient working height.

2

Go to www.mayku.me to watch the video on how to setup your FormBox.

3

The manual will also thoroughly guide you through the setup process, please read it carefully.

Mask Manufacture

1. Daily protocols

! The following procedure should be performed at least once per day.

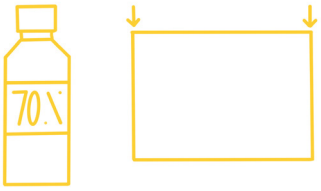
1

Check employees for Covid-19 symptoms and take their temperature before starting work. If anyone is showing signs of illness, do not allow work to commence.

2

Wash your hands with soap and hot water for a minimum of 20 seconds before operating the FormBox.

3



Wipe down equipment with 70% isopropyl alcohol, start from the top or furthest away point.

4

Make a cleaning solution by mixing 100ml of undiluted household bleach and 5litres of water. Follow the safety advice outlined on the products used.

5

Use the chlorine-based solution to mop or brush the floor and area around the FormBox and assembly stations.

6

The manufacturing area must be locked if unattended to prevent cross-contamination.

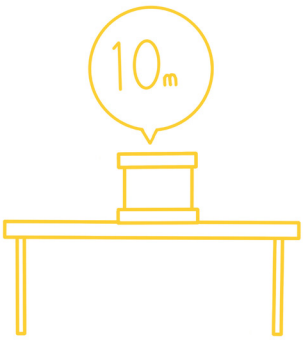
Mask Manufacture

2. Forming the templates

1

Turn on the FormBox and begin heating the machine.

2



Wait 10 minutes for the FormBox to get to full heat.

3

Use a large brush to dust talc onto the templates, make sure there is no excess blocking any of the air holes in the template.

4

Place a Mayku Cast Sheet (PETg 0.5mm) into the FormBox and begin to heat the sheet.

5

Place the cap template onto the FormBox vacuum plate, push the alignment fin into the top-right corner.

6

Place the body template onto the FormBox vacuum plate, push the alignment fin into the bottom-left corner.

7

When you see the plastic sheet droop approximately 1 inch, lower the trays over the templates.

8

Allow the form to cool for 10 seconds and then lift it out of the FormBox.

9

Allow the form to cool for a further 30 seconds on a flat surface.

10

If you have two sets of templates you can form the second set while the first set cools to speed up manufacture.

11

Pop out the cap template by applying pressure from above, and then pulling the alignment fin. Be careful not to crease the plastic form.

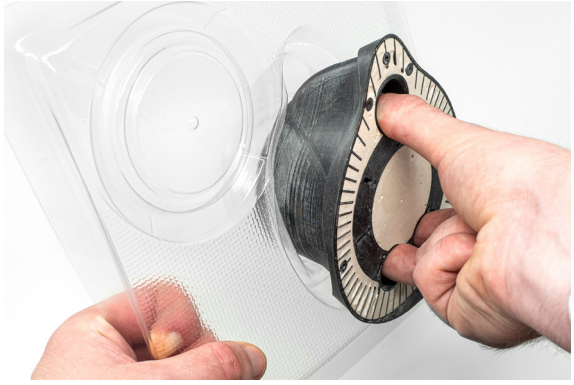
12

Turn the form upside-down. Hold the form on the left edge with one hand.

13

Place your other hand into the finger holes on the bottom of the body template.

14



Use your thumb to pull the body template out of the form.

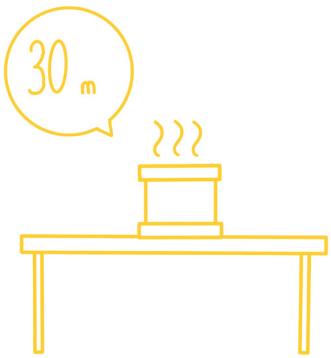
15

Place the formed plastic to one side in a neat pile.

16

Dust the templates with talc again and repeat the process.

17



Allow the FormBox to cool down for 30 mins every 2 hours to ensure the machine doesn't overheat.

Mask Manufacture

3. Forming quality assurance

! Ensure that the forms are of a good quality using the following checklist before cutting them out.

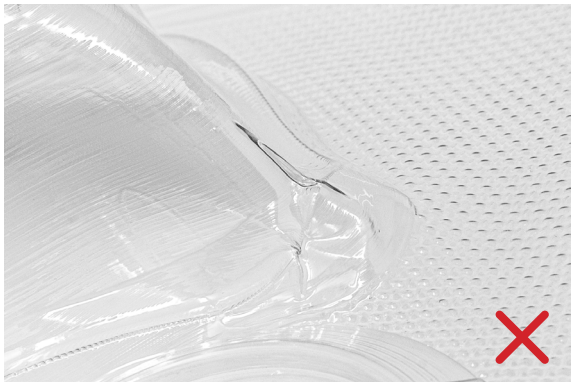
1

The plastic sheet should have been pulled into every part of the templates, especially the perimeter of the body template and the snap-fit clip area, as highlighted in this illustration.

2

The plastic sheet should not have "webbed" in the area between the body and cap templates, if you are noticing this happening, you are probably overheating the sheet in the FormBox.

3



Any form that folds or creases should be rejected if it alters the shape of the mask, especially around the perimeter of the body. Be careful when pulling the templates out of the form, to reduce the risk of creasing and folding.

Mask Manufacture

4. Cutting out the parts

1

We will be using a set of specially designed cutting tools that make cutting out the masks easier. You can find the instructions of how to print and assemble these tools in the previous **Preparing the cutting tools** section.

2

Start by using the aperture cutter to remove the filter hole on the body. The cutter rests on the filter rim and locates itself on the top-side of the form. Press downwards firmly but do not crease the mask.

3

Turn the plastic anti-clockwise while keeping the cutter held still. Rotate a full circle. The cutter will neatly cut out a large hole.

4

Repeat this process on the cap aperture.

5

Carefully cut between the body and the cap forms with a pair of scissors to separate them. Be careful not to cut into the shapes where they meet in the middle.

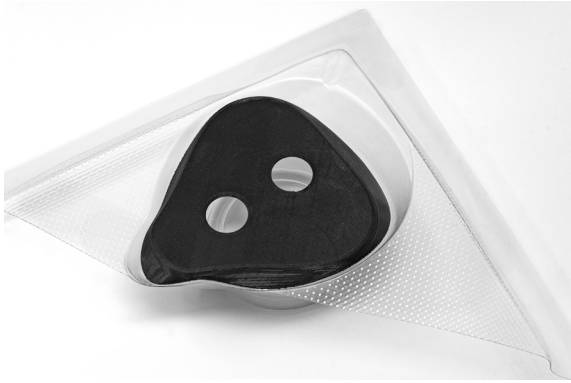
6

Flip over the cap and locate the cap cutting tool into the rim of the cap on the underside.

7

As you did before, hold the cutter still while rotating the form a full circle anti-clockwise. The cutter should neatly separate the cap from the excess plastic.

8



Flip over the body and place the body cutter template into the form. It should sit firmly inside, resting on the internal lip.

9

The template provides an edge to use as a guide when running a scalpel blade around the perimeter of the body. Carefully cut all the way around.

10

You may find it easier to use a pair of scissors to cut out the perimeter of the body. If using this method, cut around roughly first to separate the body and then carefully again along the cut line.

11

If there are any rough edges on any of the cuts, carefully sand these down with a fine sandpaper until smooth.

! Ensure that the parts are of a good quality using the following checklist before assembling them.

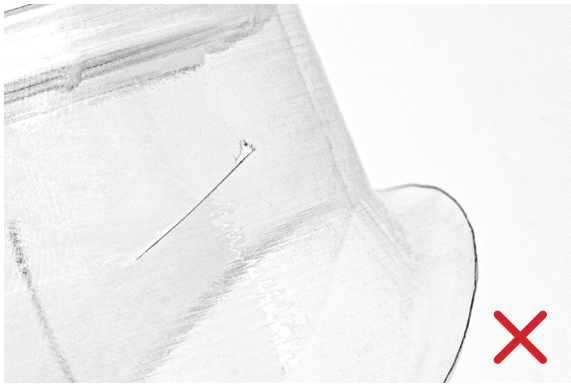
1

Check that all of the cut edges have a clean, smooth and consistent finish along the edge, if there are any sharp edges or corners go back and trim them with a pair of scissors.

2

If there are any tears in the plastic the part should be rejected, this could cause a failure under operation.

3



If there are any holes or slices in the plastic anywhere other than the cut edges then the part should be rejected.

Mask Manufacture

6. Assembly of the mask

1

Make a cleaning solution by mixing 100ml of undiluted household bleach and 5litres of water. Follow the safety advice outlined on the products used.

2

Disinfect all of the plastic parts by washing them thoroughly with the cleaning solution.

3

Allow all of the parts to dry.

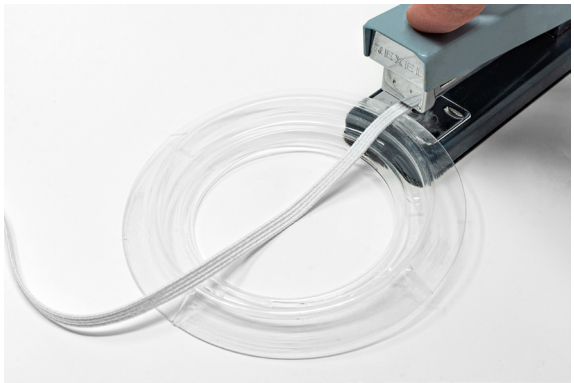
4

Cut 5mm wide standard elastic into 32cm lengths. Two lengths are required per mask.

5

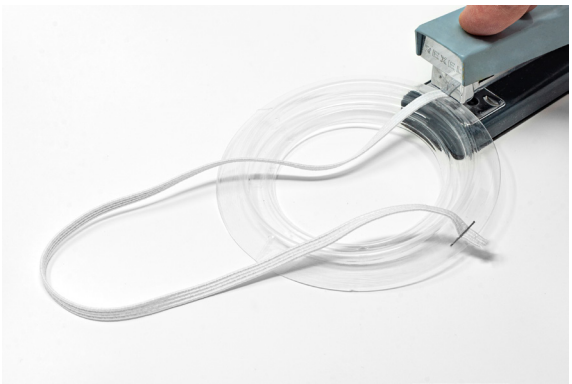
Position the elastic on one of the four markers around the perimeter of the cap, laying elastic with the long-end facing inwards.

6



Staple downwards. Ensure the staple is as far away from the edge as possible.

7



Loop the strap around and staple the other end in the same way, as illustrated.

8

Repeat this process on the opposite end of the cap.

9

Prepare the filter material in accordance with the Filter material specification.

10

Lay one filter material disk into the body, over the filter aperture.

11

Firmly snap the cap into place onto the body securing the filter tightly. The straps should loop above and below not side-to-side.

12

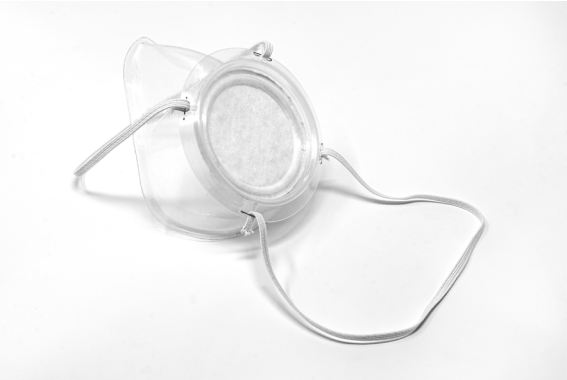
If the cap does not snap securely into the body the part may not be formed correctly, check the shape is correct and if not, the part should be rejected. Only one of the two parts may be faulty, you might not need to reject both parts.

Mask Manufacture

7. Packaging and delivering the masks

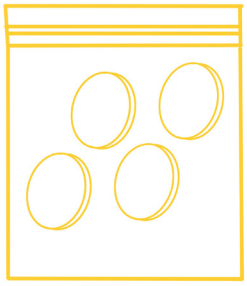
! Each finished mask needs to be packaged in a sealed plastic bag with the following items.

1



One complete mask with filter material, filter cap and elastic straps fitted.

2

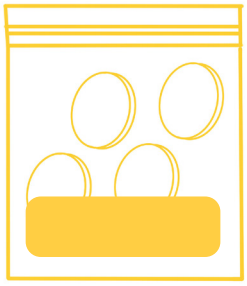


Additional filter material - minimum of one pack of replacement filters to be supplied with each mask.

3

One copy of the **Mayku Care - Guide for Users** protocol for every mask and one **Mayku Care - Guide for Hospitals** protocol per box of masks supplied. These can be downlaoded from **the University of Leeds website**

4

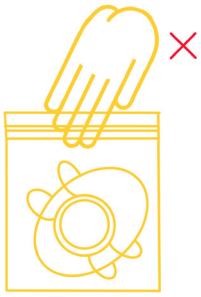


A label on the sealed plastic bag with the manufacturer details, date of manufacture and date of packing.

5

Once packaged and sealed the product must remain sealed for 3 days prior to dispatch. This is to remove the potential for cross contamination from manufacture to user.

6



The mask must not come into direct contact with any person prior to being opened by the end user. If any sealed bags are compromised, they must be re-bagged and quarantined for 3 days as per the original packaging protocol.

PETg Sheet Specification

Mayku Mask

The masks detailed in this document are manufactured using Mayku Cast Sheets. We recommend you use these sheets as they are guaranteed to work with the FormBox and should deliver consistent results. We are aware that manufacturing the Mayku Masks at scale may require a greater volume of sheets than your local supplier can provide, or you may have sourced a more cost-effective solution that takes advantage of local suppliers. When using a third-party supplier of PETg the following specifications are critical to ensure that the masks perform as specified.

PETg sheet specification

Material	PETg [Polyethylene terephthalate Glycol Modified]
Thickness	0.5mm or 0.7mm
Sheet size	235mm x 235mm unrolled sheet
Colour	Any colour [transparent or white is recommended]
Grade	Virgin grade or a minority recycled content that does not include post consumer waste
Certifications	RohS & REACH required, FDA or medical grade prefered

Filter material specification

Mayku Mask

! The correct filter material is critical to the medical function of the masks. Please follow carefully.

The correct filter material is critical to the medical function of the masks. Please follow carefully.

The recommended filter material for the **Care-Mayku Mask** is **Separet 2402** and **Separet 1520**. It is a needlefelt material with polypropylene and polyacrylonitrile fibres. Although other filter materials are more widely available, Separet 2402 is very breathable and therefore more suitable for the limited filter surface area in this mask. This material allows comfortable wear over extended periods of time.

Please contact Freudenberg Filtration Technologies KG to enquire about purchasing the material in bulk sheets. **www.freudenberg-filter.com**

Although other filter materials can be used with the Mayku Mask, the only filters that have been medically tested are Separet 2402 and 1520. The results of these tests are published on the University of Leeds website. If approval by the appropriate medical certification body in your country is required, you may be required to provide test data for the specific filter material that you have selected. Please note that The University of Leeds, the publishers of the Care-Mayku Mask, are not liable for the safety and efficiency of filter materials chosen by third party manufacturers.

The breathability of the filter material is important for the **Mayku Mask** as the surface area of the active filter is comparatively small compared to other respirators. We therefore advise that a filter material is chosen which has both a high filtration efficiency and is as breathable as possible. Manufacturers of the Mayku Mask should assess the breathability with users once they have selected a filter material. If there is any discomfort or undue effort required for breathing over an extended period of time, an alternative filter material should be chosen.

The following table gives a summary of the filtration efficiencies of different commonly available materials that are equivalent to or better than a surgical or N95 mask. Many other specially produced filtration materials are available globally and should be chosen according to a specified filtration efficiency which is greater than or equal to a surgical mask. This data is provided as a reference point only. Mayku is not liable for the safety and efficiency of filter materials chosen by third party manufacturers, when used in conjunction with the Mayku Mask. Care should be taken to fully test the product before distribution.

Filtration efficiency of alternative materials used in face masks [1]

Material	Filter efficiency (%)
Surgical Mask	76 ± 22
N95	85 ± 15
Cotton quilt	96 ± 2
Cotton (600 TPI), 1 layer	79 ± 23
Cotton (600 TPI), 2 layers	82 ± 19
Chiffon, 2 layers	83 ± 9
Natual silk, 4 layers	86 ± 5
Cotton + chiffon	97 ± 2
Cotton + silk	94 ± 2
Cotton + flannel	95 ± 2

[1] Aerosol Filtration Efficiency of Common Fabrics Used in Respiratory Cloth Masks, Abhiteja Konda, Abhinav Prakash, Gregory A. Moss, Michael Schmoldt, Gregory D. Grant, and Supratik Guha, ACS Nano 2020, 14, 5, 6339–6347

Filter material specification

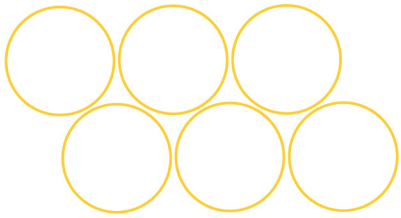
Mayku Mask

! The correct filter material is critical to the medical function of the masks. Please follow carefully.

1

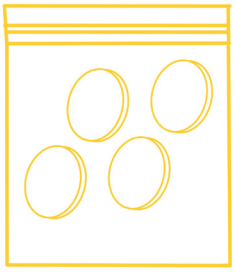
We have provided a circular template to help you cut out the filter material. You can download the 3D file and print it using the same settings at the rest of the cutting tools, shown earlier here.

2



Cut the filter material to 74mm diameter circular pieces, tessellating the circles to reduce waste.

3

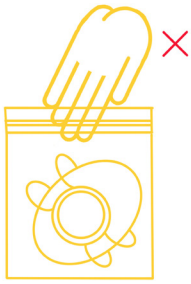


Package filters into plastic bags of either 15, 30 or 60 filters. These can be sold as 1, 2 or 4 weeks supply respectively.

4

Once packaged and sealed the product must remain sealed for 3 days prior to dispatch. This is to remove the potential for cross contamination from manufacturer to user.

5



The filter material must not come into direct contact with any person prior to being opened by the end user. If any sealed bags are compromised, they must be re-bagged and quarantined for 3 days as per the original packaging protocol.