

GENTL Mask Material Selection Guide V1.1

Introduction

About this document

This document is meant to be a reference for proper material selection for the GENTL Mask. This can be utilized by the manufacturer of the mask. The open source GENTL Mask design is a response to a crisis and is an improvised solution. We've posted the open-source design and parts list [here](#) and will update the design as we receive feedback and complete further testing. See legal disclaimer at the bottom of this page. This information sheet is meant to be a reference for proper material selection and ideal requirements for the GENTL Mask, as well as to share candidate materials the team has evaluated. This can be utilized by the manufacturer of the mask, or an entity performing verification and validation testing.

Overview of materials

As an improvised solution without FDA review it is up to the end-user to be able to make an informed judgement as to whether to adopt this mask. It is critical to use the best materials available and that the recipient of the mask is informed and aware of the materials used, and what functional benefits and standards have and have not been verified through testing. For further information on FDA guidance on surgical masks during COVID-19 public health crisis, please visit <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-face-masks-and-respirators-during-coronavirus-disease-covid-19-public-health>.

The five materials required to fulfill orders of the GENTL Mask are:

Outer Barrier Layer



Inner Filter Layer



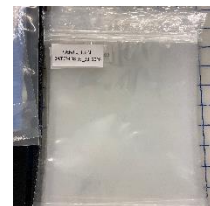
Nosepiece



Strap



Packaging



EPAM Continuum is not looking for financial gains from this design. We are putting this into the public domain as an Open Source design with the desire to connect local manufacturers with local hospitals in need around the world in an effort to reduce the negative impact of Covid-19 and help to protect our healthcare professionals.

EPAM Continuum is offering the GENTL Mask design idea as an Open Source offering to the community during this public health emergency. These statements and the GENTL Mask are not intended to diagnose, treat, cure or prevent any specific diseases. The statements made with respect to the GENTL Mask have not been evaluated by the U.S. Food and Drug Administration or any other regulatory authority. The GENTL Mask has not been tested, nor has it been put through any necessary regulatory design review as may typically associated with medical design and development. Individuals or organizations that manufacture masks utilizing the design and specifications are responsible for any federal or state regulatory requirements that apply to the manufacture or distribution of masks intended for medical use. Individuals and organizations are free to use, copy, modify and share this design and specifications, including for commercial manufacture, without payment of any fees or charges, but may not assert ownership in the design and specifications or "GENTL Mask" mark, ownership of which belongs to EPAM Continuum. EXCEPT WHERE SPECIFICALLY PROHIBITED BY LAW, NO WARRANTIES OF ANY KIND ARE OFFERED FOR THE MASK DESIGN AND SPECIFICATIONS, INCLUDING WARRANTIES OF NON-INFRINGEMENT AND FITNESS FOR A PARTICULAR PURPOSE.

Requirements and Testing

Requirements and applicable tests are based on the relevant standards for face masks, surgical masks, and N95 respirators. GENTL masks may be produced for a variety of healthcare settings, with many medical institutions having different requirements, as well as for non-healthcare settings. These requirements are relevant for showing how the mask may compare to standards used for PPE produced in the standard way. Materials selection may affect the performance of the mask against the relevant requirements.

Please see the *Summary of Testing – GENTL 3 Layer* document for requirements and testing details.

Considerations for Material Selection

Considerations for all materials

In addition to meeting the clinical requirements for the mask as a whole, when selecting alternate materials for use in the mask it is important that you consider whether the materials are:

- Readily available in quantities required
- Pre-certified for any of the desired requirements
- Robust enough to handle daily use in a clinical setting
- Able to withstand manufacturing methods (heat seal)
- Not hazardous or uncomfortable to the wearer
- In form factors that minimize time and effort required to prepare the material (e.g., roll stock of filter material vs. harvesting from an off the shelf furnace filter)

Considerations for outer barrier layer

OUTER BARRIER	
PURPOSE	<p>Sits against the skin, provides resistance to fluid ingress. Material is important to maintaining breathability and user comfort.</p> <p>The outer barrier also serves an important role in the construction method, allowing the layers to be heat-sealed together.</p>
RECOMMENDED MATERIAL	<p>Spunbond Meltblown Spunbond (commonly known as SMS) is a tri-laminate non-woven fabric. It is made up of a top layer of spunbond polypropylene, a middle layer of meltblown polypropylene, and a bottom layer of spunbond polypropylene.</p> <p>An ideal material, used in EPAM Continuum-produced prototypes to-date, is SMS sterile surgical drape (Medline DYNJP2413). SMS surgical drape offers several key advantages over non-medical SMS: familiarity to HCPs, medical institutions, and regulatory agencies; efficacy as a liquid barrier; and breathability. This material is approximately 0.25mm (.01”) in thickness.</p> <p><i>Note: There are many types of surgical drape, some of which are not SMS and may contain paper fibers, or that include additional layers of laminate which would hinder the breathability. Confirm that any surgical drape you source is 100% SMS Polypropylene.</i></p>
MATERIAL AMOUNTS	<p>Each small size mask requires two squares of material 10.5” x 8.5”, each large mask requires two squares of material 12” x 10”</p>
SUGGESTED REQUIREMENTS	
Synthetic (heat-sealable)	<p>Material should be made of synthetic fibers that will melt when heat is applied to allow construction via heat sealer.</p>

Fluid resistance	Material should be fluid resistant (when in full stack prevent a spray of fluid from fully penetrating the mask)
Breathability	Material should be sufficiently breathable such that 2 layers of it (plus any filter material being used) will still allow breathability of the overall mask.
Material safety	Material should not contain latex or involve any solvents that are not safe to breathe. Any potential materials risk should be clearly stated in the labeling.
Additional considerations	<ul style="list-style-type: none"> • Familiarity to HCPs, hospitals, and regulatory institutions • Lacking crevices or high texture to prevent liquid entrapment • Able to resist soilage • A similar thickness to surgical drape to allow heat-sealing • Good tear and puncture resistance with high tensile strength in all directions

Considerations for filtering layer

FILTERING LAYER	
PURPOSE	A filter may be important for masks in some settings. The filter serves to prevent particulate from reaching the wearer. Additionally, when combined with the outer material is provides a component of the overall fluid resistance.
RECOMMENDED MATERIAL	<p>Filter material should ideally come on a roll for ease of use and a better unit cost, though can be harvested from commercially available HVAC filters. It is critically important that the filter does not contain material that would be harmful to breathe, such as glass fibers.</p> <p>A recommended material is a MERV13 filter or equivalent, or better. An example material would be Honeywell Model #91001.013030.</p> <p>Filters with a higher filtering efficiency (such as MERV 14+ and HEPA) may be more effective at filtering, but should be tested for breathability in the mask construction.</p>
MATERIAL AMOUNTS	Each small size mask requires one square of material 10.5" x 8.5", each large mask requires one square of material 12" x 10"
SUGGESTED REQUIREMENTS	
Breathability	Material should be sufficiently breathable such that, when encased in outer layers, will still allow breathability of the overall mask.
Filtration level	<p>Material should be rated to filter a minimum of:</p> <p>75% of particles between 0.3-1 micron</p> <p>90% of particles 1 micron and above</p> <p>(while still providing sufficient breathability).</p>
Heat Sealable	Materials should be polymer based, this is commonly a combination of polypropylene and polyethylene. The specified filter is approximately 2mm thick, thicker materials may present a challenge heat sealing.
Material safety	Material shall not contain any glass fibers or other additives that would be unsafe to breathe.
Additional considerations	<ul style="list-style-type: none"> • Ideally sold in roll form for ease of use and reduced unit cost

Considerations for strap

STRAP	
PURPOSE	The strap allows for ease of donning and doffing, as well as maintaining a snug and secure fit during prolonged use. The strap is also a factor in user comfort.
RECOMMENDED MATERIAL	<p>Ideal strap material is latex-free flat elastic (between 0.125" and 0.5" in width) with approximately 80% stretch. Other percentage of stretch can be used, but straps may need to be shortened or lengthened to accommodate a range of head sizes.</p> <p>Latex-free flat elastic may be difficult to source right now. Elastic containing latex may be accepted by some hospitals or medical centers during the PPE shortage; presence of latex must be disclosed to the medical institution. EPAM Continuum has used braided elastic containing latex (McMaster-Carr 88225K61) for initial prototypes.</p> <p>In response to elastic shortages other masks have used non-elastic flat ties. The GENTL Mask has not been tested with flat ties. Flat Ties should be tested before delivery to ensure they provide adequate fit, security, and comfort for the end user.</p>
MATERIAL AMOUNTS	26" length per mask (for continuous double-strap knotted in the back)
SUGGESTED REQUIREMENTS	
Elasticity	Approximately 80% stretch is recommended. Other percentage of stretch may be used, or non-elastic strap, but length may need to be adjusted.
Strap width	Strap should be flat to minimize slipping/rolling and between 0.125" and 0.5" in width to fit through holes on the mask.
Material safety	Material shall not contain latex, or shall clearly state the presence of latex in accompanying documentation (some hospitals may not accept materials containing latex).
Additional considerations	<ul style="list-style-type: none"> • Easy for user to don and doff mask (Take on and off without contamination) • Able to knot securely for prolonged use • Does not fray when cut

Considerations for nosepiece

NOSEPIECE	
PURPOSE	The nosepiece enables the mask to conform to a variety of facial topographies around the bridge of the nose. The nosepiece must be moldable by the individual end-user upon donning the mask. The nosepiece is instrumental to user comfort as well as efficacy of the seal and overall fit.
RECOMMENDED MATERIAL	<p>The nosepiece should be a ductile metal (able to be deformed without losing toughness; pliable rather than brittle).</p> <p>Based on EPAM Continuum prototyping, a recommended material is 3003-H14 Aluminum sheet (McMaster-Carr 8973K304) cut into strips. A variety of suitable replacements can be found online.</p>
MATERIAL AMOUNTS	4.25" x 0.25" strip used per mask (approximately 140 strips from a 6"x24" sheet)

SUGGESTED REQUIREMENTS	
Ductile	H14 temper or lower, such as H12 or O, is preferred for ideal ductility
Easily cut into strips	Largely equipment based, any material should be able to be cut into discrete strips
Easily formed by the user	The aluminum strip should be easily formed to the contour of their nose/face and remain in position.
Corrosion resistant	Material may be exposed to chemicals, moisture, or elevated temperatures.
Additional considerations	<ul style="list-style-type: none"> • Rounded edges are ideal to avoid sharp corners

Considerations for packaging

PACKAGING	
PURPOSE	The packaging protects the mask for transit and delivery to the intended end user.
RECOMMENDED MATERIAL	Resealable plastic bags approximately 6" x 9" for individual masks. Masks may also be packaged together in a larger bag.
MATERIAL AMOUNTS	1 bag per mask or 1 larger bag to hold several masks
SUGGESTED REQUIREMENTS	
Sealable	Bag should seal to protect the mask.
Additional considerations	<ul style="list-style-type: none"> • Consider applying a label or identifier to the bag to indicate the contents and when it was made.