Face mask, reusable, polypropylene based

Country of origin | United States of America
Primary function | Prevention
Category | Personal protective equipment

Commercial information

List price (USD): $4.50[1]
Development Stage: The masks are currently sold at cost to select health facilities in the United States. It is not openly distributed. Protocols and manufacturing methods are intended to be distributed as widely as possible so that the device can be reproduced.[2]
Brand: Recyclablu[3]
Model: BluMask[3].

Health problem addressed

During the COVID-19 pandemic, there has been a lack of PPE in healthcare settings across the globe due to supply chain shortages. Additionally, 7,000 tons of medical waste is produced daily in the US alone. This solution attempts to find a viable and safe alternative to produce face masks from recycled waste material that will not only protect the health of communities but also protect the health of the planet.[1]

Product description

The technology is recycled surgical sterilization wraps repurposed into face masks. The repurposed material is currently used and produced globally for sterilization of surgical instruments. The material is 2-ply polypropylene with a tested filtration efficiency of 87%. It is trilaminated nonwoven fabric treated with electrostatic charge similar to N95 masks.[1]

Product details

Consumables: Surgical steel wire[1]
Lifetime: 0-2 years[1]
Facility Requirements: Clean water supply, sterilization[1]

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1 Reported by manufacturer on 25 January 2021
2 Reported by manufacturer on 24 December 2020
3 Reported by manufacturer on 4 November 2020

WHO ASSESSMENT

WHO specification comparison

At the time of report creation, WHO technical specifications are not available to compare against for this type of technology.

Regulatory assessment

Pre-market assessment	Proceed with caution
Post-market assessment	Proceed with caution
Quality system assessment	Proceed with caution

Significant work is needed on developing robust pre-market regulatory, post-market regulatory, and quality system plans to ensure this prototype will be able to be successfully brought to market. BluMask should develop their medical device support documentation and data. BluMask should share their collection protocol and manufacturing process with WHO to enable both groups to facilitate this distribution process to most effectively help LIMCs and facilities.

Technology evidence assessment

Domains	Evidence assessment: Risk/benefit ratio	Evidence assessment: Impact	Innovation
Medical	⚠	→	
Safety	✕	✕	
Economy	✕	✕	
Organizational	⚠	⚠	
Legal	✕	✕	
Social	→	→	
Ethical	→	→	
Green environment	⚠	⚠	⚡

The technology is under development. Based on current evidence, the level of filtration and protection is unclear. The cleaning and reuse process is uncertain.

Summary

Transferability	→	Technology readiness level	6
Evidence (according to GRADE)	⚠	Technology evidence assessment	Not recommended

Health technology and engineering management

Domains	Appropriateness	Domains	Appropriateness
Durability	✕	Ease of maintenance	✕
Ease of Use	→	Infrastructure requirements	→
Positive impact on clinical outcomes	⚠	Local access to sales support	N/A
Affordability	⚠	Local access to technical support	N/A
Engineering resources minimization	→	Local access to training	N/A
Cultural and social acceptability	→	Local access to spare parts	N/A
Environmental conditions	→	Local production	→
Aesthetics	→	Locations of use within target setting	⚠
Ease of cleaning	✕		

Target setting: Public and home settings

This product uses sterile surgical fabric that is formed and cut into face masks. The vendor claims that its performance is similar to N95 masks, however, the evidence that was reviewed does not provide clear indications to support this claim. There is a need to collect such fabrics and reformat their shape into face masks in localities with shortages of PPE. However, no evidence was provided to support safe individual use due to lack of insufficient identification of material in the tests.