

NEW VIRUS BARRIER

Medical Face Masks

Strong

Soft

Breathable

The best **VIRUS**
barrier



Perfect balance between protection and comfort

With Sanitary Registry

SSMMS MASK WITH TURNS

Made in SSMMS fabric (Spunbond x 2 – Meltblown x 3 – Spunbond) **5 layered** 100% Polypropylene nonwoven fabric manufactured using 5 beams. This fabric offers amazing benefits like fine filtration of particles.



SSMMS ANATOMICAL MASK

Made in SSMMS fabric (Spunbond x 2 – Meltblown x 3 – Spunbond) **5 layered** 100% Polypropylene. With holes in the area of the ears, to provide better fit on the face.



BVT PLEATED MASK

Breathable viral barrier of last generation!

Coronavirus, HIV, Tuberculosis, avian influenza, H1N1, among others greater than 0.027 microns.



Breathable viral barrier (BVT)

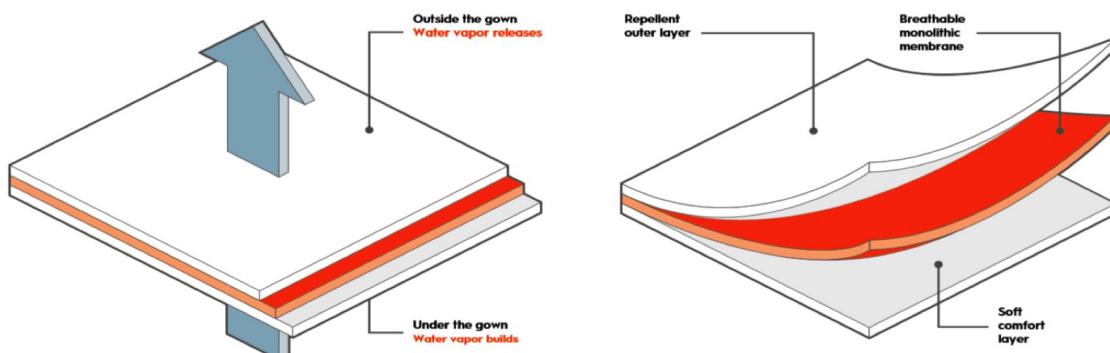
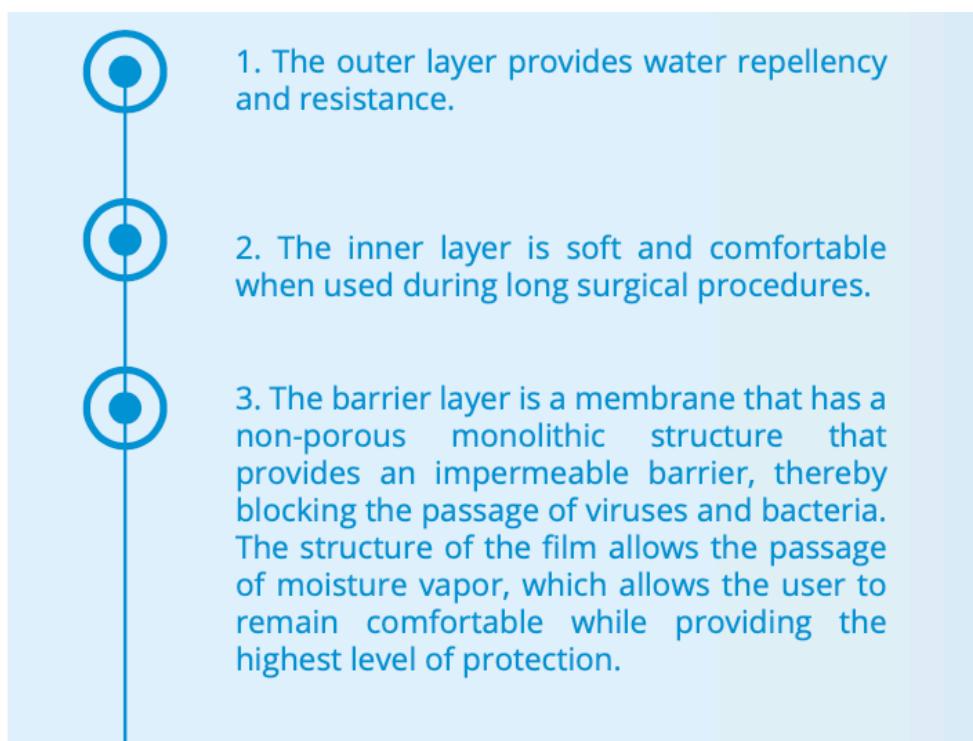
This innovative medical face mask is built for the most critical circumstances, keeping health professionals protected and comfortable.

The latest generation of Breathable Viral Barrier surgical fabric takes advantage of decades of experience in the manufacture of products for surgical protection.

The fabric is made up of a LAMINATED TRI-LAYER built to be waterproof, breathable and comfortable.

But above all, it be an infallible BARRIER against viruses and bacteria of all kinds.

The Breathable Viral Barrier fabric is strong, soft, highly breathable and provides excellent barrier properties against viruses that cause infectious diseases such as HIV / AIDS (Human Immunodeficiency Virus), H1N1 and Avian Influenza.



AAMI PB 70 AAMI – Association for the Advancement of Medical Instrumentation.

Anticipated Risk of Exposure			Examples of procedure with anticipated exposure risks	ANSI/AAMI PB 70 Barrier performance	Test	Result
Fluid amount	Fluid spray or splash	Pressure on gown or drape				
Minimal	Minimal	Minimal	- Simple excisional biopsies - Excision of 'lumps and bumps' - Ophthalmological procedures - Simple ear, nose and throat (ENT) procedures	Level 1 (least protective)	AATCC 42 Water impact (WI)	≤ 4.5 g
Low	Low	Low	- Tonsilectomies and adenoidectomies - Endoscopic gastrointestinal procedures - Simple orthopedic procedures with tourniquets - Open hernia repair - Minimally invasive surgery - Interventional radiology or catheter lab procedures	Level 2	AATCC 42, WI AATCC 127 Hydro Head (HH)	≤ 1.0 g ≥ 20 cm
Moderate	Moderate	Moderate	- Mastectomies - Arthroscopic orthopedic procedures - Endoscopic urological procedures (e.g. transurethral prostate resections) - Open gastrointestinal and genito-urinary procedures	Level 3	AATCC 42, WI AATCC 127, HH	≤ 1.0 g ≥ 50 cm
High	High	High	- Any procedure in which the surgeon's hands and arms are in a body cavity - Orthopedic procedures without a tourniquet - Open cardiovascular or thoracic procedures - Trauma procedures - Caesarean sections	Level 4 BVB (most protective)	ASTM F1671, Gowns ASTM F1670 Drapes	Pass Pass

. Comfort. Thanks to breathability • Strong, light and with little noise.

. Reliability. Meets the highest international standards • Without FC (Fluorine Chemical)

The Protection and Comfort found in BVT protective masks meet the highest standards of regulatory performance. It is designed to pass the criteria of AAMI PB 70 Level 4 and high-performance critical area gowns in accordance with the European Standard for surgical curtains, gowns and clean air suits EN13795.

ASTM F1671 * is the standard test method for the resistance of materials used in protective clothing to blood-borne penetration using Phi-X174 bacteriophage penetration as a test system. The test system has been designed to measure the penetration of a microbe substitute for hepatitis (B and C) and human immunodeficiency virus (HIV).

The bacteriophage substitute Phi-X174, used in the test method, is similar to HCV in size and shape, but also serves as a substitute for HBV and HIV. Inferences from other pathogens should be evaluated on a case-by-case basis.

Source: Annual Standard Book ASTM, vol. 11.03. October 2002.

International industry standards are used to test and measure the performance of the barrier for blood fluids and pathogens for materials used in protective clothing. This fabric exceeds these strict standards that provide the necessary waterproof protection in the surgical environment.

Better threat barrier / Excellent breathability

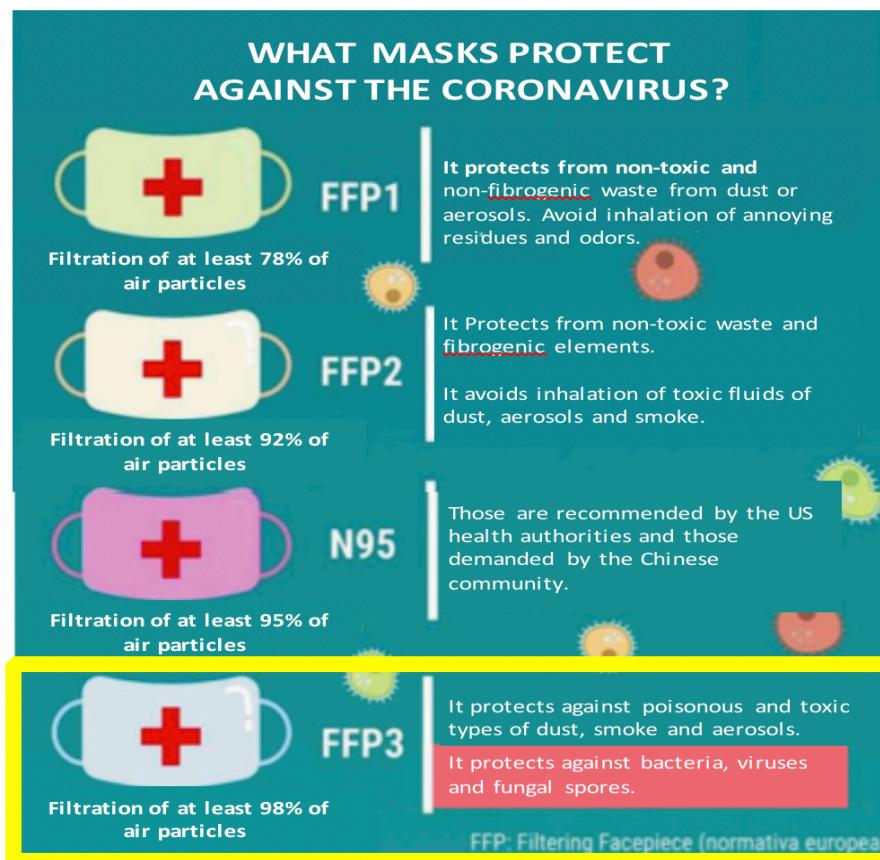
Compared to pleated three-layer masks, the monolithic film provides a significantly better barrier to all fluids in the operating room, including bacteria and viruses.

Pleated three-layer masks

The breathability in the structure of the three layers is formed by adding an intermediate layer made of short fibers, which under tension form micro holes to allow the passage of air. Due to its nature, it could have potential changes in its barrier performance under tension.

BVT Medical Face Mask

Breathability is inherent in the membrane, which allows the passage of water vapor. The membranes will not change the barrier performance, even under stressful conditions. It is a complete barrier against fluids and viruses as small as 0.027 microns. (CORONAVIRUS 0.030 microns) which **exceeds the FFP3.ical environment.**



BVB mouth covers exceeds the FFP3 protection factor

Viral Penetration ASTM Method F 1671 Final Report

Test Article: Set# 1: Grade WL26403, Run# T31513, Lot# 361800174703
 Purchase Order: [REDACTED]
 Study Number: [REDACTED]
 Study Received Date: 20 Jan 2016
 Test Procedure(s): Standard Test Protocol (STP) Number: STP0062 Rev 14

Summary: This test method was performed to evaluate the barrier performance of protective materials which are intended to protect against blood borne pathogen hazards. Test articles were conditioned for a minimum of 24 hours at $21 \pm 5^\circ\text{C}$ and 30-80% relative humidity (RH), and then tested for viral penetration using a $\Phi\text{X}174$ bacteriophage suspension. At the conclusion of the test, the observed side of the test article was rinsed with a sterile medium and assayed for the presence of $\Phi\text{X}174$ bacteriophage. The viral penetration method complies with ASTM F1671; sampling was at the discretion of the sponsor. All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Number of Test Articles Tested: 8
 Number of Test Articles Passed: 8
 Test Article Side Tested: Darker Side (Labeled Side)
 Test Article Preparation: Cut from the Material at Random
 Test Article Sealed: Paraffin Wax
 Exposure Procedure: A (No retaining screen)
 Compatibility Ratio: 1.0 per sponsor
 Environmental Plate Results: Acceptable

Results:

Test Article Number	Pre-Challenge Concentration (PFU/mL)	Post-Challenge Concentration (PFU/mL)	Assay Titer (PFU/mL)	Visual Penetration	Test Result
1-8	2.5×10^8	3.0×10^8	<1 ^a	None Seen	Pass
Negative Control	2.5×10^8	3.0×10^8	<1 ^a	None Seen	Acceptable
Positive Control	2.5×10^8	3.0×10^8	1.5×10^2	Yes	Acceptable

^a A value of <1 plaque forming unit (PFU)/mL is reported for assay plates showing no plaques.


 Study Director for Jennifer Jorgenson, B.S.



02 Feb 2016

Study Completion Date



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INC.