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On the basis of the tests carried out on the materials analysed to date, we believe we can provide the general indications summarised on the following pages, regarding the most promising production materials and methods.

GENERAL DESCRIPTION of the typical "SURGICAL" type masks

SURGICAL masks typically consist of the overlapping of 3 layers of nonwoven fabric with different functions:

1) OUTER LAYER (WORLD SIDE):
   Non-woven fabric produced with SPUNBOND technology with hydrophobic treatment (optional); this layer has the function of conferring mechanical resistance and hydrophobic properties to the mask (optional).
2) INTERMEDIATE LAYER (FILTER LAYER):
   Nonwoven fabric produced with MELTBLOWN technology and consisting of microfibers with a diameter of 1-3 micron; this layer performs the filtering function.
3) INNER LAYER (FACE SIDE):
   Non-woven fabric produced with SPUNBOND technology; this layer protects the face by preventing the skin from coming into direct contact with the intermediate filtering layer.

It is possible to make masks with different layers but containing at least 3 layers with the abovementioned characteristics, provided that the functionality requirements are met.

BROAD GUIDELINES

The tests carried out in our laboratories have shown that, in order to meet the requirements on the **particle filtering effectiveness (PFE)** and **breathability** of the mask, the laminate of which the mask itself is made must have an adequate **meltblown content** (generally **more than 20g/sqm**) in a single layer or in the sum of several layers.

Materials and layers for surgical masks

The tests carried out on the materials received at our laboratories have confirmed that the most suitable material for the realisation of the 3 layers of the mask is nonwoven fabric in polypropylene or (as a second option) in polyester.

It was also pointed out that the following materials were **NOT** found to be functionally suitable:

- non-hydrophobic/water repellent materials
- materials without a dense weave, free of visible gaps even under traction
- materials that lack sufficient breathability
- also in the case of non-woven fabrics, materials that are made with fibres with a diameter greater than 3 microns.

The scarce availability on the Italian market of nonwoven fabric produced with meltblown technology (to be used for the filter layer of the mask) has led to consider the use of **several layers of a laminated nonwoven fabric called SMS** with a reduced meltblown layer between two layers of spunbond.

The **overlapping of 2 or more layers** of such laminate (depending on the amount of meltblown present in a single SMS, which is typically between 7-10 gr/sqm) has made it possible to reach a meltblown content suitable to ensure sufficient filtering capacity (>20gr/sqm).

In addition, it has been observed that the outer spunbond layers present in the SMS laminate can perform the functions of the outer and inner mask layers (see above), thereby making it possible **to construct the mask layer from the simple overlapping of 2 or more SMS layers**.

MATERIALS

As at today, the **nonwoven fabrics** produced with **meltblown** technology and coupled **nonwoven fabrics** of the SMS type which, to our knowledge, are **produced and available in Italy** are, among others, those listed below.

The designation used in the table is the following:

"M": indicates the single layer of PP **M**-eltblown nonwoven fabric;

"S": indicates the single layer of PP **S**-punbond nonwoven fabric;

"SMS": indicates the **S**-punbond/**M**-eltblown/**S**-punbond combination obtained by overlapping in sequence the three individual layers of spunbond, meltblown and spunbond.

PRODUCT	Mass per square meter (gr/sqm)	Mass of Meltblown present (gr/sqm)	MANUFACTURER
SMS	35	7	ATEX
SMS	40	8	Fitesa
SMS SMS SMS	90	10	Plastik textile (Radici group)
SMS	70	30	Ahlstrom-munksjo
Meltblown	25	25	Farè
SMS	40	7	Union Industries
TNT	30	0	Qualsiasi
Meltblown T4	50	50	UFI Filters
Meltblown T6	60	60	UFI Filters
SMS-A	120	45	UFI Filters

STRATIFICATIONS

The tests carried out in our laboratories by suitably combining the abovementioned materials have shown the following possible configurations, recommended to the packers. The performance obtained for the masks, in terms of filtering capacity and breathability, using these configurations are the following:

ID	CONFIGURATION	PFE (%) [1] Tolerance ± 5%	ΔP (Pa/cm^2) [2] Tolerance ± 5%	BFE (%) [3] Tolerance ± 10%
16	UFI SMS-A	75	34	
9	Ahlstrom-munksjo SMS 70 gr/mq + Ahlstrom-munksjo SMS 70 gr/mq	82	50	95
18	Union Industries 40 gr/mq + UFI T4 + Union Industries 40 gr/mq	82	64	
19	Union Industries 40 gr/mq + UFI T4 + TNT 30 gr/mq	78	52	
22	Fitesa 40 gr/mq + UFI T4 + TNT 30 gr/mq	76	54	
23	Fitesa 40 gr/mq + UFI T6 + TNT 30 gr/mq	76	55	

20	Union Industries 40 gr/mq + UFI T6 + TNT 30 gr/mq	73	51	
17	Union Industries 40 gr/mq + Farè 25 gr/mq + Union Industries 40 gr/mq	70	55	
21	Fitesa 40 gr/mq + Farè 25 + Fitesa 40 gr/mq	68	58	
13	Fitesa SMS 40 gr/mq + Fitesa SMS 40 gr/mq + Fitesa 40 gr/mq	64	63	
15	Union Industries 40 gr/mq + Union Industries 40 gr/mq + Union Industries 40 gr/mq	61	53	99
8	Ahlstrom-munksjo SMS 70 gr/mq	59	29	
3	Atex SMS 35 gr/mq + Atex SMS 35 gr/mq + Atex SMS 35 gr/mq	58	37	98
6	Atex SMS 35 gr/mq + Atex SMS 35 gr/mq	52	30	98
12	Fitesa SMS 40 gr/mq + Fitesa SMS 40 gr/mq	52	44	
7	SMSSMSSMS 90 gr/mq + SMSSMSSMS 90 gr/mq + SMSSMSSMS 90 gr/mq	49	33	
14	Union Industries 40 gr/mq + Union Industries 40 gr/mq	46	36	

1 Particulate Filtration Efficiency (PFE). It assesses the filtering capacity of the material. It is derived from the measurement of particulate matter (aerosols) upstream and downstream of the sample.
Class A materials: PFE ≥ 65%.
Class B materials: PFE ≥ 50%

2 Pressure drop per unit area (as expressed in EN14683:2019).
It assesses breathability. It is obtained by measuring the difference in pressure through the sample.
Class A materials: $\Delta P \leq 40$ Pa/cm^2
Class B materials: $\Delta P \leq 60$ Pa/cm^2

3 Bacterial Filtration Efficiency (PFE). It assesses the filtering capacity of the material with respect to bacteria. It is derived from the measurement of bacterial CFU upstream and downstream of the sample.
Class A materials:: BFE ≥ 90%
Class B materials: BFE ≥ 70%

Mask manufacturers must also provide the results of the following tests at the time of application to the ISS:
• biocompatibility (responsibility of the material supplier)
• bioburden (a first reference: info@abich.it)

For materials certified for surgical masks, the regulations prescribe a pressure drop < 40 Pa/cm2 or < 60 Pa/cm2 depending on the class. The filtration efficiency (PFE) of the certified surgical masks is in the 50 - 70% range.

Manufacturers of masks who select one of the configurations presented are **not** required to submit the masks produced to the Politecnico di Milano. They shall request, directly from the companies supplying the material used, a copy of the results of the tests carried out on the material itself by the Politecnico di Milano.

Please note that the ISS shall express a favorable opinion on the production and marketing of the product if, among other requirements, the company guarantees that the production is implemented and managed according to a Quality Management System. The same guarantee must be provided by the manufacturer of the raw material with special attention to the constancy of the characteristics of the product supplied.

Typical production cycle of a generic "SURGICAL" type mask

GENERAL DESCRIPTION

SURGICAL masks typically consist of the overlapping of at least 3 layers of nonwoven fabric with different functionalities (see above). The layering must, overall, have an adequate meltblown content (generally greater than 20 g/sqm) in a single layer or in the sum of several layers. The use of coupled nonwoven fabrics of the SMS type is possible.

Where it is necessary to use a multilayer consisting of several layers, these can be joined with bonding points, provided the adhesive is approved for food or biomedical use. Conversely, other joining methods (e.g. needling, basting or any other method involving perforation of the fabric) are not acceptable.
Sewing along the perimeter is of course allowed.

MASK GEOMETRY AND SIZE

The shape of the SURGICAL mask must be such as to cover the mouth and nose and must ensure a minimum of "structure" (also conferred by the presence of a pleating) to avoid excessive adhesion to the face during inhalation.
The typical mask has a rectangular shape and has pleats on the short side as shown in the following images. The pleats must be oriented downwards to avoid the accumulation of dust or droplets in the folds of the pleats.
The mask is then equipped with laces and a nosepiece (optional).
There may be an edging made by applying a strip of additional material to the edges of the mask, which facilitates sewing and helps to give structure.

A B

Fig. 1: Examples of surgical mask

REQUIRED MATERIALS

STRATIFICATION: as defined above;
LACES: elastic gros-grain or non-elastic cotton gros-grain;
NOSEPIECE: metal or plastic (optional);
EDGING: optional. Polypropylene (if heat-sealed edging).

PRODUCTION AND PACKAGING CYCLE OF THE MASK

The production cycle of the masks can be divided into 6 stages:

Step 1 - Cutting of the layers

Step 2 - Overlapping of the layers
Step 3 - Pleating and edging
Step 4 - Lace application
Stage 5 - Bagging (optional)
Stage 6 - Sterilisation (optional)

Step 1 - Cutting of the layers: the cutting of the layers can be carried out with all the cutting and contouring technologies normally used in the textile and advanced technical materials industry: laser cutting plotter, hydro cutting, die-cutting, guillotine shears, scissors

Step 2 - Overlapping of the layers: the overlapping can be done manually or automatically.
Beware that excessive calendering pressure can compromise breathability.

Step 3 – Pleating and edging: by heat-sealing, ultrasonic welding or stitching

Step 4 – Lace application: by heat-sealing, ultrasonic welding or stitching

Step 5 – Bagging

Step 6 – Sterilisation (optional): gamma rays, UV rays, ethylene oxide, autoclave

Step 1, step 2 and step 3 are typically closely interlinked: textile laboratories can be equipped with industrial equipment capable of superimposing many layers of material, cutting them, folding them (pleating) and edging them at the same time.

EXAMPLE (FOR GUIDANCE ONLY)

CENTRAL BODY:
A 180mmx90mm (+-5) mask can be obtained starting from a 180mmx180mm (+-5mm) square plan laminate on which to make the folds according to the following scheme:

Sequence of folds from the top edge:

1) positive fold at 35mm,
2) negative fold at 48mm,
3) positive fold at 80mm,
4) negative fold at 97mm,
5) positive fold at 126mm;
6) negative fold at 142mm.

LACES:
The laces can be of 2 types:

Type 1: 2 elastic bands each of appropriate length attached to the 2 ends of the short side of the mask (see Fig. 1a).

Type 2: 4 laces in cotton or similar fabric of appropriate length attached to the 4 ends of the mask (see Fig. 1a) (NOT elastic). The laces can be placed either parallel to the short sides (as in the picture) or parallel to the long sides.

NOSEPIECE:

The mask can be fitted with a nosepiece or underwire fixed to the centre of the upper edge of the mask itself; material: metal with plastic coating; typical dimensions: 100mm long, 3mm wide.

OTHER EXAMPLES OF SUITABLE PACKAGING METHODS

The Coronavirus crisis unit of the Lombardy Region (coronavirusrl@regione.lombardia.it), based on dimensional criteria of face adaptability, ergonomics, fit and removability, has currently also approved the following solutions:

1. The mask may be obtained from a laminate with plant dimensions of 230 mm x 140 mm (±5). The masks are surrounded on all sides with elastic bands, and finally the straps are applied to the sides.


2. The mask is composed of a filtering side (green) with plant dimensions 300 mm x 130 mm (±5) and an equal non-filtering layer (white) useful for anchoring on the face. On the side there is a tear-off mechanism useful for removing the mask from the face.


The Politecnico di Milano does not certify masks, but evaluates, without any prescriptive purpose, their final configuration, in order to verify that the packaging methods have not altered the functionality of the material.