



Instructions for Use

Product name:	ISOL/8 Surgical Masks (FLUIDSAFE range)
	Models: FLUIDSAFE Surgical Mask FLUIDSAFE Anti-fog Surgical Mask FLUIDSAFE Surgical Mask with Visor FLUIDSAFE Surgical Mask with Child-friendly Pattern FLUIDSAFE Procedure Mask FLUIDSAFE Anti-fog Procedure Mask FLUIDSAFE Procedure Mask with Visor FLUIDSAFE Procedure Mask with Child-friendly Pattern
Product numbers:	IS8RM01S-04S (Surgical masks) IS8RM01P-04P (Procedure masks)
Product description:	Disposable theatre masks
Size(s):	17.5x9.5cm (One size fits all adults)
Fabric:	3-Ply Fabric: Outer: 35gsm Spunbond Polypropylene, Middle: 30gsm Meltblown Polypropylene, Inner: 18gsm extra soft ES silk-like fibre Aluminium nose bar Earloops – Spandex polyurethane coated in nylon thread Ties – Nonwoven polypropylene

Intended purpose:

The mask is intended to limit the transmission of infective agents between staff and patients during surgical procedures and in medical settings with similar requirements, reducing the emission of infective agents from the nose and mouth of an asymptomatic carrier or a patient with clinical symptoms. During surgical procedures the masks are used to limit the spread of particles or microorganisms into the sterile operating field.

Clinical Benefit to be Expected:

The mask minimizes a transfer of infectious agents between the healthcare professional and a patient, thus preventing the spread of infection.

Performance and Standards:

All the masks mentioned in this document meet the EN14683 Type IIR Standard. These masks are fluid resistant and are suitable for procedures where the wearer may be exposed to fluids or blood.

EN14683, Type IIR Parameters	
Bacterial filtration efficiency (BFE), (%)	≥98%
Differential pressure (Pa/cm ²)	<60
Splash resistance pressure (kPa)	≥16
Microbial cleanliness (cfu/g)	<30

Type IIR masks are not intended to protect the wearer from contagious infectious diseases. If encountering a patient with a potential or known infectious disease please choose a more suitable mask to protect the wearer in accordance with your organisation’s guidelines.

Selecting the right mask:

All the masks mentioned in this document are suitable for use during procedures where the wearer may be exposed to fluids or blood.

Masks with earloops are more suitable for everyday wear in the hospital, during patient encounters and during minor procedures.

Masks with ties are more suitable for sterile surgical procedures in the operating theatre or during prolonged use where ties would offer more comfort to the wearer.

Mask Model	When to use
FLUIDSAFE Standard Masks (IS8RM01S/IS8RM01P)	Standard Surgical Procedures where fluid exposure to the eyes or upper face is not expected.
FLUIDSAFE Anti-fog Masks (IS8RM02S/IS8RM02P)	For use by persons wearing glasses to prevent fogging. Standard Surgical Procedures where fluid

	exposure to the eyes or face is not expected.
FLUIDSAFE Anti-fog Masks with Visor (IS8RM03S/IS8RM03P)	Surgical Procedures where fluid or particle exposure to the face is expected. The visor helps protect the eyes and face from fluids and small particles. Suitable for use by persons wearing glasses to prevent fogging.
FLUIDSAFE Child-friendly Masks (IS8RM04S/IS8RM04P)	Standard Paediatric Surgical Procedures where fluid exposure to the eyes or upper face is not expected.

Please note that the above are recommendations on when to use the different products. Always consult your local guidelines and follow their guidance where applicable.

How to apply and use:

1. Surgical Masks (Tie-on):

- 1) Ensure hands are washed thoroughly.
- 2) Inspect the box to ensure that the correct mask and level of cover is chosen.
- 3) Ensure that the coloured side on the mask is facing outwards and that the metal band is at the top of the mask.
- 4) Place the mask over the nose, mouth and chin and bend the metal band to the shape of your nose so that it fits closely against the contours of your face and nose.
- 5) Tie the upper ties at the crown of your head.
- 6) Tie the lower ties around the back of your neck.
- 7) Adjust the mask so that it lies centrally on your face and covers your nose, mouth and chin.
- 8) Wear appropriate eye protection or use a FLUIDSAFE surgical mask with visor if there is a risk of fluid/blood/particle exposure to the eyes.
- 9) After use, dispose of the mask in the clinical waste bin and in accordance with your organisation's guidelines and wash hands thoroughly.

2. Procedure Masks (Earloops):

- 1) Ensure hands are washed thoroughly.
- 2) Inspect the box to ensure that the correct mask and level of cover is chosen.
- 3) Ensure that the ISOL/8 stamp on the mask is facing outwards and that the metal band is at the top of the mask.
- 4) Place the mask over the nose, mouth and chin and bend the metal band to the shape of your nose so that it fits closely against the contours of your face and nose.
- 5) Stretch the earloops so that they fit securely behind the back of your ears.
- 7) Adjust the mask so that it lies centrally on your face and covers your nose, mouth and chin.
- 8) Wear appropriate eye protection or use a FLUIDSAFE Surgical Mask with Visor if there is a risk of fluid/blood/particle exposure to the eyes.
- 9) After use, dispose of the mask in the clinical waste bin and in accordance with your organisation's guidelines and wash hands thoroughly.

It is recommended to change mask every 3 hours

Warnings & Contraindications:

- 1) Do not use this product if you are allergic to polypropylene, spandex, nylon or aluminium.
- 2) Stop using this product if you experience any breathing difficulties or shortness of breath while wearing. Extra caution must be exercised by persons with existing respiratory conditions such as Asthma or COPD.
- 3) Do not share masks with others, clean or attempt to reuse. Re-use of mask may result in an increased risk of contracting and spreading infections, including severe infections
- 4) Do not use this product after the expiry date has passed.
- 5) Do not use this product if the packaging is opened, wet or visibly damaged.
- 6) Do not expose products to flames, heat or high intensity light source.
- 7) This product is only to be used by trained medical personnel.
- 8) Keep packaging and products away from children.
- 9) Dispose of used masks as clinically contaminated waste and ensure you are following your organisation's guidelines for waste disposal.

Single-use only:

This device is a disposable single-use product. It is not to be cleaned, re-sterilised or reused under any circumstance. Re-use of masks may result in an increased risk of contracting and spreading infections, including severe infections.

Storage conditions:

Store in a dry, cool, ventilated environment away from flammable and corrosive materials.

Transport conditions:

During transport, avoid trauma to the carton, direct sunlight, rain, snow and other forms of precipitation.

Disposal Instructions:

Please dispose of masks as clinically contaminated waste and ensure you are following your organisation's guidelines for waste disposal.

Recycling Instructions:

Carton: 100% recyclable (cardboard)

Product Box: 100% recyclable (cardboard)

















Masks: Not to be recycled. Please dispose of as clinical waste in accordance with your organisation's guidelines.

Sterility:

Product is not sterile.

Any serious incidents that have occurred in relation to the device should be reported to the manufacturer (contact details are provided below) and the competent authority of the Member State in which the user is established.

Product labelling explanation:

	Product is a medical device (MDR)		Manufacturer information
	Consult instructions for use		Date of manufacture
	Product is for single-use only		Product use-by date
	Do not use if the package is damaged		CE Mark MDR (EU) 2017/745
	Keep dry and away from moisture		Product is non-sterile
	Catalogue/ product number		Handle package with care
	UDI (Unique Device Identifier) code		Keep away from sunlight
	LOT/Batch code		This side upwards



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