



Instructions for Use

Product name:	Non-Woven Sterile Surgical Gowns
Product numbers:	IS8E01 - IS8E14 IS8P01 - IS8P14 IS8S01 - IS8S06
Product description:	Long-sleeved sterile surgical gown with knitted cuffs & surgical ties, available in a range of sizes. The product complies with EN 13795-1:2019.
Size(s):	M, L, XL, XL-long, XXL, XXL-long, XXXL
Fabric:	SMMS 48g/m ² (Elemental) Spunlace 68g/m ² (Plush) Tri-layer SFS 60g/m ² (Supreme) Polyethylene (Poly-Reinforced Gowns)

Selecting the right gown:

The gown packaging will specify either EN13795 Standard Performance or High Performance. The gowns are also colour coded as below:

For ease of selection, our gowns come colour-coded depending on the level of protection they provide.

Standard-Performance gowns (non-reinforced) have a white collar and white passcard and High-Performance gowns (poly-reinforced, impervious) have a purple collar and passcard.



Please choose the appropriate gown for the procedure at hand. Suggested procedures below:

Gown Type	Performance according to EN13795-1:2019	Suggested procedures
Standard Gowns (Elemental and Plush standard)	Standard-Performance	Procedures with low to moderate fluid exposure
Poly-reinforced Gowns (Elemental and Plush poly-reinforced)	High-Performance	Procedures with moderate to high fluid exposure
Impervious Gowns (Supreme)	High-Performance	Procedures with very high fluid exposure

Intended Use

Intended for use by medical personnel to protect both the wearer and the patient from the transfer of microorganisms, fluids and blood. The gown is appropriate for use during surgical and non-surgical procedures which require the maintenance of a sterile field and sterile operating environment. The gown acts as a sterile barrier between the patient, medical instruments, operating field and the wearer.

Sterility

ISOL/8 Healthcare Surgical Gowns are sterilized by ethylene oxide.

Patient Population

Medical personnel/ healthcare professionals.

Contraindications

Allergic reaction to the materials used in gowns.

Warnings and Cautions

- 1) Do not use this product if you are allergic to polypropylene, polyethylene, cotton or polyester materials.
- 2) The product is single use. Do not re-use or re-sterilise the product. Re-use or re-sterilisation can affect the sterility of the product and put the patient at major risk of infection or death.
- 3) Do not use this product after the expiry date has passed
- 4) Do not use this product if the sterile packaging is opened or visibly damaged
- 5) Do not expose the gown to flames, heat or high intensity light source.
- 6) This product is only to be used by trained medical personnel.
- 7) Keep packaging and products away from children.

Directions for Use

- 1) Before using the product, please check to ensure there is no damage to the carton or packaging. If the product or the packaging is damaged or wet, please dispose appropriately.
- 2) Ensure you have selected a gown with appropriate protection for the procedure ahead of you.
- 3) Carefully read the labelling on the front of the packaging paying careful attention to the harmonised symbols, expiry date and any warnings. If the expiry date has passed, please dispose of the gown appropriately.
- 4) Open the packaging and remove the wrapped sterile gown pack and place on a clean surface.
- 5) Open the 4 corners of the sterile wrap making sure to touch the corners only in order to create the square sterile field. Do not touch the inside of the sterile wrap or the gown/towels.
- 6) Open your sterile glove packaging and empty the contents onto the sterile field without touching the gloves.
- 7) Scrub your hands and forearms up to the elbow as per the guidance of your institution to ensure your skin is sterile up to the elbow.
- 8) Dry your hands up to the elbow using the 2 scrim towels provided in the gown pack. Ensure that the towel does not touch any unwashed area of your skin. Do not retrace over any areas. After using the towels dispose of them without touching the bin.
- 9) Pick up the gown by slotting your hands into the arm folds, hold it with outstretched arms in front of you at shoulder level and allow the gown to unfold downwards without touching the floor or any other surface.
- 10) Slide your arms inside the sleeves, ensuring you do not touch the outside of the gown.

- 11) At this point your assistant should pull the gown over your shoulders by grasping the inside of the gown and close the collar using the hook and loop closure without touching any of the outside surface of the gown.
- 12) Your assistant should then use a bow to tie the inner ties at the rear of the gown.
- 13) Don your sterile gloves using the appropriate sterile technique and ensure that they cover the gown cuffs and the cuff seam.
- 14) Hold the sterile passcard at the point closest to you, pull out the left outer tie and hold it with your left hand. Using your right hand, pass the passcard to your assistant who should grip it as directed on the card and hold it at full length (being careful not to touch the gown or tie). Slowly turn 180-270 degrees in an anti-clockwise direction until the tie has wrapped around you. At this point, the assistant should grasp the card tightly and you can pull the tie out of the passcard. Tie the outer ties on your left side using a tight bow.
- 15) Your assistant should dispose of the passcard in the bin.
- 16) During any point in this process or during the use of the gown, if anything non-sterile touches either the sterile field, towels or the outside of the gown, immediately dispose of the gown, take a new gown pack and repeat this procedure to ensure sterility is maintained.
- 17) After use, please dispose of the gown as clinical waste as per the guidelines of your organisation or in accordance with your country's relevant regulations.

Shelf Life

Three years from the date of manufacture.

Handling and Storage Conditions

Store in a dry, cool, ventilated environment away from flammable and corrosive materials. Protect from direct sunlight and moisture.

Transport conditions

During transport, avoid damage to the outer packaging, direct sunlight and rain, snow and other forms of precipitation.

Disposal Instructions:

Please dispose of surgical gowns as clinically contaminated waste as per your organisation's guidelines for waste disposal.

Recycling Instructions:

Carton: 100% recyclable (cardboard)

Product Package: Non-recyclable

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

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.

Symbols of the Packaging

	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
	Sterilized using Ethylene Oxide		



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