


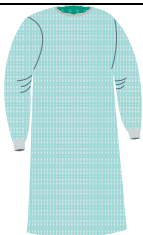




TECHNICAL DATASHEET FOR EASY SURGICAL GOWN SERIES

Product Group	Ref.No for Sterile Gown	Ref. No for Nonsterile Gown	Product Name	Carton Dimensions (W x D x H – mm)	Sterile Units per Carton	Nonsterile Units per Carton	Product Drawing
Standard Surgical Gowns	SG-001-1	NG-001-1	Standard Surgical Gown, S	600 x 400 x 500 mm	80 pcs	80 pcs	
	SG-001-2	NG-001-2	Standard Surgical Gown, M	600 x 400 x 500 mm	80 pcs	80 pcs	
	SG-001-3	NG-001-3	Standard Surgical Gown, L	600 x 400 x 500 mm	75 pcs	80 pcs	
	SG-001-4	NG-001-4	Standard Surgical Gown, XL	600 x 400 x 500 mm	65 pcs	80 pcs	
	SG-001-5	NG-001-5	Standard Surgical Gown, XXL	600 x 400 x 500 mm	65 pcs	80 pcs	
	SG-001-6	NG-001-6	Standard Surgical Gown, XXXL	600 x 400 x 500 mm	60 pcs	80 pcs	
Reinforced Surgical Gowns	SG-002-1	NG-002-1	Reinforced Surgical Gown, S	600 x 400 x 500 mm	80 pcs	80 pcs	
	SG-002-2	NG-002-2	Reinforced Surgical Gown, M	600 x 400 x 500 mm	80 pcs	80 pcs	
	SG-002-3	NG-002-3	Reinforced Surgical Gown, L	600 x 400 x 500 mm	75 pcs	80 pcs	
	SG-002-4	NG-002-4	Reinforced Surgical Gown, XL	600 x 400 x 500 mm	65 pcs	80 pcs	
	SG-002-5	NG-002-5	Reinforced Surgical Gown, XXL	600 x 400 x 500 mm	65 pcs	80 pcs	
	SG-002-6	NG-002-6	Reinforced Surgical Gown, XXXL	600 x 400 x 500 mm	60 pcs	80 pcs	
Full Reinforced Surgical Gown	SG-003-1	NG-003-1	Full Reinforced Surgical Gown, S	600 x 400 x 500 mm	80 pcs	80 pcs	
	SG-003-2	NG-003-2	Full Reinforced Surgical Gown, M	600 x 400 x 500 mm	80 pcs	80 pcs	
	SG-003-3	NG-003-3	Full Reinforced Surgical Gown, L	600 x 400 x 500 mm	75 pcs	80 pcs	
	SG-003-4	NG-003-4	Full Reinforced Surgical Gown, XL	600 x 400 x 500 mm	65 pcs	80 pcs	
	SG-003-5	NG-003-5	Full Reinforced Surgical Gown, XXL	600 x 400 x 500 mm	65 pcs	80 pcs	
	SG-003-6	NG-003-6	Full Reinforced Surgical Gown, XXXL	600 x 400 x 500 mm	60 pcs	80 pcs	
Extra Reinforced Surgical Gown	SG-004	NG-004	Extra Reinforced Surgical Gown	600 x 400 x 500 mm	80 pcs	80 pcs	
Patient Gown	_	NG-005-1	Patient Gown without cuff, 30 gr/m ²	600 x 400 x 500 mm	_	80 pcs	
	_	NG-005-2	Patient Gown without cuff, 35 gr/m ²	600 x 400 x 500 mm	_	80 pcs	
	_	NG-005-3	Patient Gown without cuff, 40 gr/m ²	600 x 400 x 500 mm	_	80 pcs	
	_	NG-006-2	Patient Gown with cuff, 35 gr/m ²	600 x 400 x 500 mm	_	80 pcs	
	_	NG-006-3	Patient Gown with cuff, 40 gr/m ²	600 x 400 x 500 mm	_	80 pcs	
Standard L Gown	SG-006-1	NG-006-1	Standard L Gown	600 x 400 x 500 mm	_	80 pcs	

Usage

EASY Surgical Gowns are used to reduce risk of infection and create a layer of protection for both for surgeons and patients. Reinforced, Full Reinforced and Extra Reinforced, Surgical Gowns have reinforced with an extra layer.

Transport

Gowns are transported in a carton boxes. Basic warnings and information is printed on cartons with manufacturer information and contact details. CE marking and name of set can be seen on carton boxes.

Packing

All components are packed in operational order so that efficiency is ensured.

Depending on the preference 3 options are available for sterile and nonsterile gowns:

- Pouch Pack: Sterile Gowns are packed in a pouch with size depending on the selection of dimension and type of folding requested. Pouch has necessary peeling opening available.
- Blister Pack: Sterile Gowns are packed inside a blister pack. Blister pack has a peeling side marked.
- PE Bag : Nonsterile gowns are packeg in PE bags.

In these packing methods, packages show the information below:

- Product series name & product name
- Set type (dimensions and type of drape)
- Set contents with quantities
- Manufacturing date
- Date of expiry
- Lot number
- Reference number
- Method of sterilization (if gown is sterile)
- Warnings (don't use if package is damaged, don't reuse, don't re-sterile etc.)
- Manufacturer contact & company information
- CE mark

Sterility

Sterile Surgical Gowns are sterilized with EO sterilizer in house. Sterilization is documented and monitored through necessary forms, biological indicators, chemical indicators and data loggers.

It is possible to have Nonsterile products upon request with same variety of selections from sizes and materials available.

Shelf Life

Product has been tested for stability. Test reports show that Sterile Surgical Gowns have a shelf life of 3 years and Nonsterile Surgical Gowns have a shelf life of 5 years.

Quality Certification & Compliance

All process across SUBMED is run in compliance with EN ISO 13485:2016.

Independent third party laboratories tested **EASY GOWN** series for packing sealing strength is in compliance with EN ISO 868-5, stability according to ASTM F 1980 and package leak tests according to ASTM F 1929. Thermoforming line is validated for temperature and pressure settings according to EN ISO 17025.

Sterilization process has been validated according to EN ISO 11135-1, for sterilization by Ethylene Oxide. Sterilizer is also validated by IQ and OQ tests.

Our manufacturing plant and clean room is in compliance and been tested for EN ISO 11605, EN ISO 14644-1, EN ISO 14644-2, EN ISO 14698-1 and EN ISO 14698-2 tests for bio contamination levels in order to assure relevant safety levels in all products.

EASY GOWN series are tested for bio-burden according to EN ISO 11737-1. To achieve highest quality EO residue is also tested according to EN ISO 10993-7.

EASY GOWN series are manufactured in compliance with EN 13795. According to EN 13795, **EASY GOWN** series comply with EN ISO 22610, EN ISO 11737-1, EN ISO 22612, EN ISO 9073-10, EN 20811, EN 13938 and EN 29073-3.

Sterile Surgical Gowns are CE Class IS and Nonsterile Surgical Gowns are Class I nonsterile products.

Content

Sterile Surgical Gowns		Nonsterile Surgical Gowns	
Qty.	Description	Qty.	Description
1	Surgical Gown	1	Surgical Gown
1	Hand Towel	-	-

Materials of Selection

1. **Standard, Reinforced and Full Reinforced Surgical Gowns** are made of from below listed materials :

Standard Surgical Gowns	Reinforced Surgical Gowns	Full Reinforced Surgical Gowns
<ul style="list-style-type: none"> • SMS Fabric (100 % Polypropylene, 3 layers, 43 gr/m²) 	<ul style="list-style-type: none"> • SMS Fabric (100 % Polypropylene, 3 layers, 43 gr/m²) • Fluid Resistance (Polyethylene / Spunbond, 1 layer, 28 gr/m²) 	<ul style="list-style-type: none"> • SMS Fabric (100 % Polypropylene, 3 layers, 43 gr/m²) • Fluid Resistance (Polyethylene / Spunbond, 1 layer, 28 gr/m²)

Standard, Reinforced and Full Reinforced Surgical Gowns have velcro on backside of neck section. Standard, Reinforced and Full Reinforced Surgical Gowns are folded back and have elastic cotton cuffs on sleeves.

Chest and sleeves of Reinforced and Full Reinforced Surgical Gowns are reinforced with a second layer for additional protection.

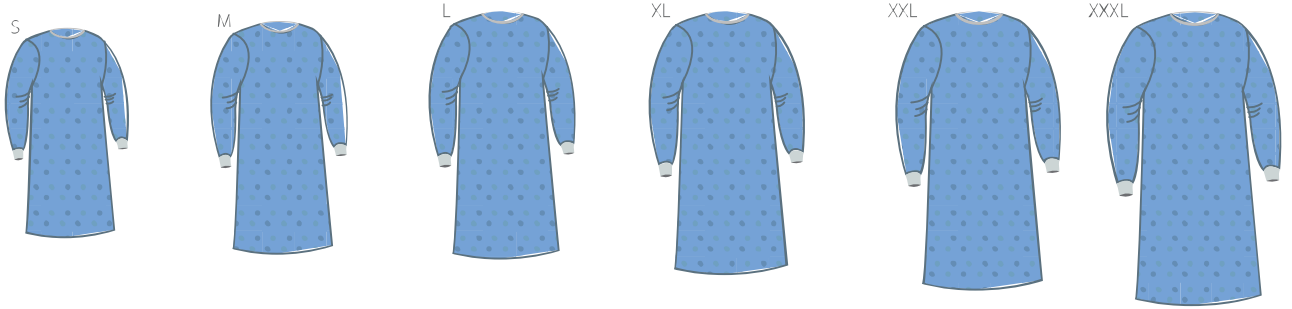
Hand towels in packages can be made of from one of the below listed selections for gown:

- Cellulose - PE (65 gr/m²)

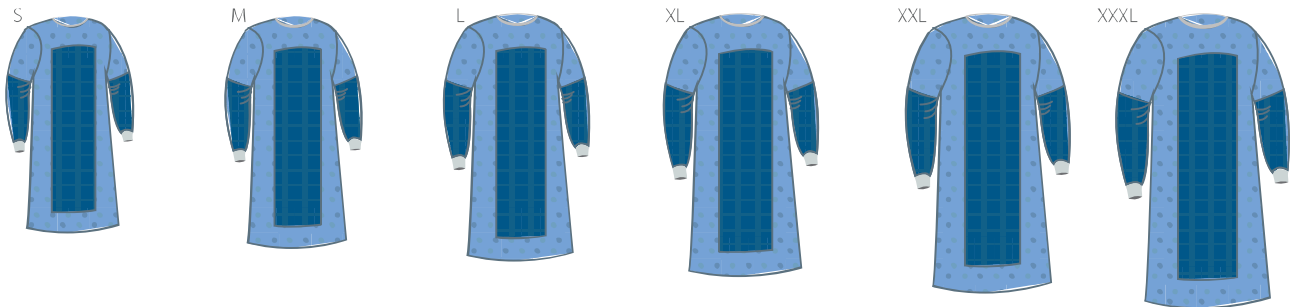
Hand towels in packages can be sized from one of the below listed selections for towel:

- 20 x 40 cm. (Standard)
- 40 x 40 cm.
- No towel!

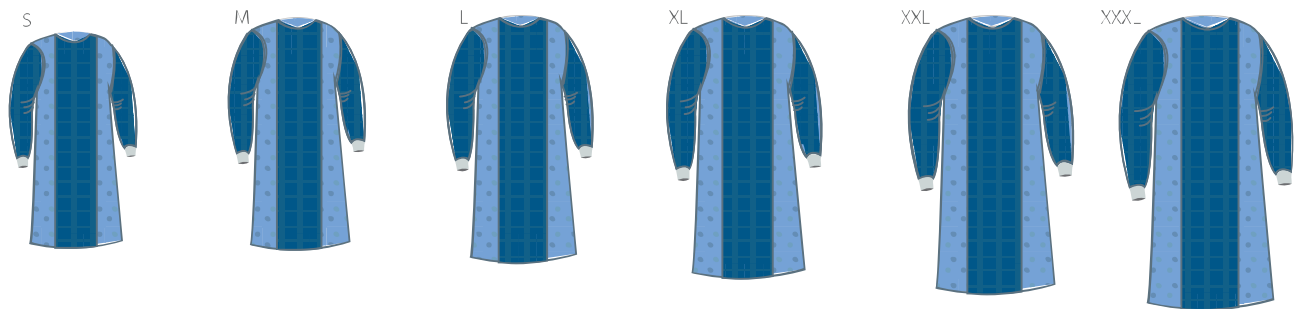
Standart Surgical Gown



Reinforced Surgical Gown



Full Reinforced Surgical Gown



Standard, Reinforced and Full Reinforced Surgical Gowns are available in S (117,5 cm. ±5%), M (125 cm. ±5%), L (132,5 cm. ±5%), XL (140 cm. ±5%) , XXL (150 cm. ±5%) and XXXL (155 cm. ±5%) sizes.

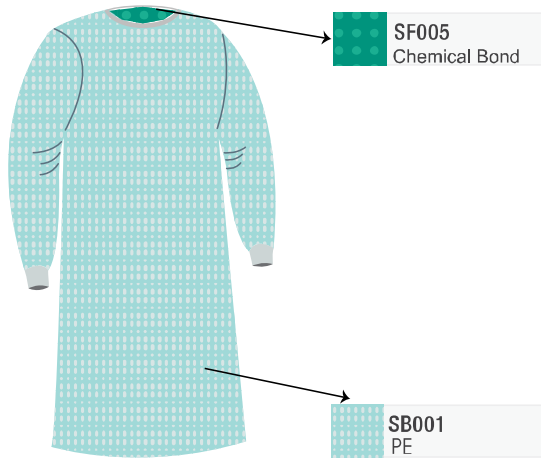
2. Extra Reinforced Surgical Gowns are made of from below listed materials :

TYPE A : PE/SPUNBOND	TYPE B : PE/CHEMICAL BOND
<ul style="list-style-type: none"> • Biflex Fabric (%100 PE / Spunbond) Outer side PE, Inner side Spunbond, 2 layers 54 gr/m ²	<ul style="list-style-type: none"> • Biflex Fabric (%100 PE / Chemical Bond) Outer side PE, Inner side Chemical Bond, 2 layers 54 gr/m ²

Extra Reinforced Surgical Gowns have velcro on backside of neck section. Extra Reinforced Surgical Gowns are folded back and have elastic cotton cuffs on sleeves.

All parts of Extra Reinforced Surgical Gowns are reinforced with a second layer for additional protection. Extra Reinforced Surgical Gowns are available in standard size (130 cm. ±5%).

Extra Reinforced Surgical Gown



3. Patient Surgical Gowns are made of from below listed materials :

Patient Gowns Without Cuff	Patient Gowns Without Cuff	Patient Gowns Without Cuff
<ul style="list-style-type: none"> • Spunbond (100 % Polypropylene, Hydrophobic Spunbond 30 gr/m²) 	<ul style="list-style-type: none"> • Spunbond (100 % Polypropylene, Hydrophobic Spunbond 35 gr/m²) 	<ul style="list-style-type: none"> • Spunbond (100 % Polypropylene, Hydrophobic Spunbond 40 gr/m²)

Patient Gown Without Cuff



30 gr/m²
Ref. No : NG-005-1



35 gr/m²
Ref. No : NG-005-2



40 gr/m²
Ref. No : NG-005-3

	SF010 %100 PP / Hydrophilic Spunbond 30 gr/m ²
	SF010-1 %100 PP / Hydrophilic Spunbond 35 gr/m ²
	SF010-2 %100 PP / Hydrophilic Spunbond 40 gr/m ²

Patient Gowns without cuff have velcro on backside of neck section. Patient Gowns are available in standard size (120 cm. ±5%).

Patient Gown With Cuff



35 gr/m²
Ref. No : NG-006-2



40 gr/m²
Ref. No : NG-006-3

SF010-1
%100 PP / Hydrophilic Spunbond
35 gr/m²

SF010-2
%100 PP / Hydrophilic Spunbond
40 gr/m²

4. Standart L Gowns are made of from below listed materials :

Standart L Gowns
<ul style="list-style-type: none"> • Spunbond (100 % Polypropylene, Hydrophobic Spunbond 30 gr/m²)

Standard L Gowns have velcro on backside of neck section. Standard L Gowns with cuff have standard size (120 cm. ±5%). Patient Gowns with cuff are folded back and have elastic cotton cuffs on sleeves.



50 gr/m²
Ref. No : NG-006-1

SF011
%100 PP / Hydrophobic Spunbond
50 gr

Storage

Store the product under normal conditions for healthcare material, in a cool and dry place protected from light. The use of medical grade paper and film guarantees its sterility for the duration of its shelf life under normal transport and storage conditions.

Comments

The product must be used by specialised personnel only. Check the package's integrity before use. Do not use if the package is open or damaged.