

 Amaryllis Healthcare Pvt. Ltd.	Instructions for Use Disposable Surgical Gown		
	Doc No: AHPL GW	Rev. #: 02	Date: 29.01.2024

Product Name:

Disposable Surgical Gown

Product Description:

The Disposable Surgical Gown are personal protective garments used in health care settings. The sterile Surgical disposable gowns are made with a protective fluid-resistant 3-layer SMS fabric and are recommended where there is the potential for low to moderate exposure to fluids or chemicals. The Surgical disposable gowns are composed of nonwoven fabrics and polyethylene films in weight range of 30–45 g/m². The Surgical disposable gowns are adopted to prevent the release of pollutant particles into the air which is a probable source of contamination to the patient.

Our Surgical disposable gowns are blue in color and made of single use nonwoven material. Nonwoven stands for hi-tech infection prevention. The sterile Surgical disposable gowns are made with a protective fluid-resistant medical grade, 3-layer Spunbond–Meltblown–Spunbond (SMS) fabric and are recommended where there is the potential for low to moderate exposure to fluids or chemicals. The medical grade SMS fabric is a non-woven material. Consists of two outer layers of SMS and a middle layer of polypropylene.

- Outer layers: Cloth-like, yet tough and abrasion-resistant spun bound polypropylene.
- Inner layer: Intricate web of microfibers filter out many water-based liquids and dry particles.

Our medical grade SMS fabric/non-woven material is strong, light and comfortable. The Surgical disposable gowns are effective towards barrier protection, ignition resistance, and durable. The Surgical disposable gowns are sterilized by Ethylene Oxide. These are packed in a sterility maintenance package to ensure the shelf life of 3 years.

List of Disposable Gowns:

Product Code	Description	Variants
IPRG30	Reinforced Gown	Size : (S/ M/ L / XL / XXL/ XXXL)
IPSG30	Surgeon Gown	Size : (S/ M/ L / XL / XXL/ XXXL)
IPSG30W	Surgeon Gown (Level 4)	Size : (S/ M/ L / XL / XXL/ XXXL)
IPPG10	Patient Gown	Size : (S/ M/ L / XL / XXL/ XXXL)
IPSR30	Scrub Suit Set	Size : (S/ M/ L / XL / XXL/ XXXL)
IPSR40	Scrub Suit Pant	Size : (S/ M/ L / XL / XXL/ XXXL)



Amaryllis Healthcare Pvt. Ltd.

Instructions for Use

Disposable Surgical Gown

Doc No: AHPL GW

Rev. #: 02

Date: 29.01.2024

Page 2 of 5

IPSR36	Scrub Suit Shirt	Size : (S/ M/ L / XL / XXL/ XXXL)
IPBG30	BVB GOWN	Size : (S/ M/ L / XL / XXL/ XXXL)
IPIG30	Isolation Gown	Size : (S/ M/ L / XL / XXL/ XXXL)
IPFG30	Cover all full Gown	Size : (S/ M/ L / XL / XXL/ XXXL)
IPCG30	Cathlab Gown	Size : (S/ M/ L / XL / XXL/ XXXL)

Intended use:

The surgical disposable gown is a personal protective garment intended to be worn by health care personnel during surgical/medical procedures, it provides total barrier to viral, fluid and particulate matter from the transfer of microorganisms, body fluids, and particulate matter. Also, surgical disposable gowns protect the wearer from the spread of infection or illness if the wearer comes in contact with potentially infectious liquid and solid material. The surgical disposable gowns are single use and disposable.

Product Type:

Spun Bond, SMS, Spun Lace, Spun Lamination, and Spun Lace Lamination fabric.

Latex Free:

Yes

Packing Material:

Polymer Impregnated Medical grade paper and film in medical clean room as per international standard.

Shelf life:

3 years


Performance specification:

Surgical Disposable Gowns

Performance Test Requirements	Biocompatibility, Sterility, Stability, Bio-burden Physical parameter Bursting Strength, Tensile Strength, Liquid Absorption, Liquid Resistance, Linting
-------------------------------	---

Quality Specification:

Manufacturing QMS	ISO 13485 : 2016
CABG Adult Cardiac Pack	BS-EN-13795-2011,+A1-2013.
MDR Requirement	Regulation (Eu) 2017/745 Of The European Parliament And of The Council of 5 April 2017
CE Classification	Class Is
Storage	Keep away from direct sunlight or fluorescent light. Store at a cool and dry place

 Amaryllis Healthcare Pvt. Ltd.	Instructions for Use Disposable Surgical Gown		
	Doc No: AHPL GW	Rev. #: 02	Date: 29.01.2024

Intended User:

Surgeons and Health Care Personnel's during surgical/medical procedures

Target Patient Population:

Adults, Children's & Infants

Indication:

Disposable Surgical Gowns are used as a protective cover for doctor, patient and to isolate a surgical site from transfer of micro-organisms, particulates and fluids. This minimizes the potential for contamination during the surgery & Pre or Post Operative recovery.

Contraindication:

Do not use if the package is open or damage. Do not Re-sterile the product.

Instruction for use:

Peel opens the pouch to remove the product.


Use the gowns to either cover Surgeon to obtain barrier protection during surgery, outpatient procedures / Bed side procedures, and Patient Gown used for general cover during post op recovery period and stay at hospital. These gowns need to be gowned with appropriate sterile gowning technique.

Gowns are made of SMS fabric (or) Absorbent fabric (or) laminated fabric to provide protective cover.

- Surgeon Gowns are to be used by trained medical professional using appropriate gowning technique.
- Patient Gown is to be gowned by caregiver (or) patients accordingly with appropriate gowning technique

Warnings:

1. Device are for single use only.
2. Re-use may result in clinical complications.
3. If the sterile package is damaged or possibly opened, do not use.
4. Product should not be re-sterilized.
5. Do not use these gowns for any other indications rather than manufacturer claimed as a protective cover for doctor, patient and to isolate a surgical site from transfer of micro-organisms, particulates and fluids.
6. Do not use
 - i) Incorrect type or size
 - ii) Defected product
 - iii) Damaged product

 Amaryllis Healthcare Pvt. Ltd.	Instructions for Use Disposable Surgical Gown		
	Doc No: AHPL GW	Rev. #: 02	Date: 29.01.2024

Precautions:

1. Carefully read all instructions for use and product labeling.
2. The Surgical disposable gowns shall only be applied for its intended use and in accordance with these instructions.
3. Observe all cautions and warnings throughout these instructions. Failure to do so may result in complications.

Caution:

All medical staff is responsible for using the appropriate technique and deciding on the indication for use of this device based on own experience, training and medical judgment. The doctor must be trained in the proper use of the device.

Potential Complications:

Possible adverse effects of the device are documented. Use of this device should be based upon consideration of risk-benefit factors as they apply to your patient. Informed consent should be obtained to maximize patient compliance. Follow up procedures.

Clinical Benefit:

1. Less bacterial transmission in the laboratory
2. Lower rates of contamination in the operating room
3. Prevent or reduce exposure of bloodborne pathogens to HCWs
4. No Complaints of fluid leakage through gowns
5. Prevent transmission of micro-organisms from non-sterile to sterile areas.
6. Protection against the hepatitis (B and C) and HIV
7. Good moisture vapour permeability.
8. Reduced risk of nosocomial infection.
9. Protect the body against thermal strain
10. Reduced surgical site infection
11. Comfortable to wear and easy to operate
12. Antistatic property

Residual Risks:

1. Surgical Site Infection
2. Infectious Diseases
3. Infection due to contamination.

Sterility:

This device is sterilized by ethylene oxide. Do not re-sterilize, and do not reuse. Do not use it if the package is opened or damaged. Discard opened, unused Device.

Device Disposal:





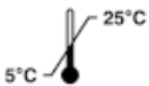
On completion of the procedure, dispose-off the device as per institutional and local regulatory guidelines for bio-hazardous medical waste disposal.














NOTE: Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.




Performance Characteristics:

1. Fit
2. Comfort
3. Lint free
4. Stretchability
5. Barrier protection
6. Fluid resistance
7. Absorption
8. Durability
9. Antistatic Property

EXPLANATION OF SYMBOLS USED ON LABEL:

Sl. No	Symbols	Description
1.		For single use only
2.		Caution
3.		Keep away from Sunlight
4.		Keep dry
5.		Temperature Limit

6.		Storage Humidity Range
7.		Expiration Date
8.		Lot number
9.		REF Number
10.		Manufactured address
11.		Date of Manufacture
12.		Sterilized using ethylene oxide
13.		Do not use if package is damaged
14.		European Conformity
15.		European Authorized Representative
16.		Do not re sterilize
17.		Consult Instructions for Use
18.		Medical Device

19.		Unique Device Identifier
20.		Single sterile barrier system
21.		Country of Manufacture



Amstermed BV,
 Saturnusstraat 46-62, Unit 032,
 2132 HB Hoofddorp, The Netherlands,



Amaryllis Healthcare Pvt. Ltd.,
 Plot No:112, Bommasandra Jigani Link Road Area,
 Bandenallasandra Village, Jigani Hobli, Anekal Taluk,
 Bangalore-560105

Revision History

Revision No	Changes Incorporated	Effective Date
00	Initial Release	17.06.2019
01	Updated as per MDR requirements	03.10.2023
02	Added performance characteristics, removed latex free symbol from label section and added country of manufacturer in label section	29.01.2024