

 Amaryllis Healthcare Pvt. Ltd.	Instructions for Use Sterile Disposable Surgical Drapes		
	Doc No: AHPL DR	Rev. #: 02	Date: 29.01.2024

Product Name:

Sterile Disposable Surgical Drapes

Product Description:

During surgical procedures, the risk of pathogen transmission increases if the barrier materials become wet. Consequently, the multiple- or single-use materials of the drapes and gowns used in a surgical procedure should prevent the penetration of liquids. Disposable Surgical Drapes isolate the surgical site from the rest of the body and other possible sources of contamination.

Our disposable surgical drapes are blue in color and made of single use nonwoven material. Nonwoven stands for hi-tech infection prevention. The sterile disposable drapes 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.

The disposable surgical drapes are effective towards barrier protection, ignition resistance, and durable. The disposable surgical drapes are sterilized by Ethylene Oxide. These are packed in a sterility maintenance package to ensure the shelf life of 3 years.

Features:

- Fire-resistant or Non-flammable
- Good absorbency on one side and repellence on the other side
- Helps reduce glare from operating room lights
- No or less post-operative swelling of wound
- Negligible post-operative fever
- Lesser incidence of post-operative infections
- Lesser morbidity and faster recovery of patient

List of Drapes:

Group-1 – Drapes for Patient and Healthcare Personnel

a) Drapes used for **GYNECOLOGY & OBSTETRICS** Surgery

Product codes	Description
IPCS10	Caesarean Drape
IPMM10	Maternity Drape
IPND10	Normal Delivery Drape
IPND10W	Hysteroscopy Drape

b) Drapes used for **ANGIOGRAPHY** surgery

Product codes	Description
IPAG10	Angiography drape
IPFR10	Femoral Radial Drape



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IPFR11	Femoral Drape
IPRS10	Radial Drape

c) Drapes used for **EENT** Surgery

Product codes	Description
IPBA21W	Patient Head Drape
IPED10	Eye Drape Ophthalmic Drape

d) Drapes used for **Orthopedic** Surgery

Product codes	Description
IPBK10	Bilateral Knee O Drape Premium
IPBL10	Boot leggings
IPCL10	Cling Drape
IPSA10	Shoulder Arthroscopy Drape
IPHO10P	Hip O Drape
IPHU10	Hip U Drape
IPIS10P	Impervious Split Drape Premium
IPSU10	Split U Drape
IPKA10	Knee Arthroscopy Drape
IPKO10	Knee O Drape
IPLD15	Wing Sheet
IPLS10	Lamino spinal Drape

e) Drapes used for **GENERAL** Surgery and **MULTIPURPOSE** procedures

Product codes	Description
IPAD10	Abdominal Drape with 12cm Fenestration
IPAD11	Abdominal Drape
IPAD12	Abdominal Drape
IPLY10	Laparoscopy Drape
IPBS26W	Patient Bed Drape
IPDX10P	Drape X-Large Premium
IPPR10	Perineal Drape
IPGU10	General U Drape
IPHD10	Hole Drape
IPHD11	Hole Drape -Medium with Adhesive
IPHD12	Hole Drape -Large with Adhesive
IPHD15	Hole Drape -Small with ABS
IPTS10	Triangle Sheet
IPHF10P	Half Drape Premium
IPSD10	Small Drape
IPSD10W	Surgery Drape Sheet Medium
IPHL10	Drape-Leggings
IPLD10	Large Drape with Adhesive



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IPMD10	Medium Drape with Adhesive
IPLD10W	Large drape
IPUS10	Underneath Sheet with Abs

f) Drapes used for **NEURO** Surgery

Product codes	Description
IPCR10	Craniotomy Drape

g) Drapes used for **CARDIOVASCULAR** Surgery

Product codes	Description
IPCT10	CVTS Drape-Adult
IPCT11	CVTS Drape-Pediatric
IPCT12	CVTS Drape-Infant
IPGD10	Groin drape

h) Drapes used for **UROLOGIC** Procedures

Product codes	Description
IPPC10	PCNL Drape
IPTU10	TURP Drape
IPUP15	Under Buttock Drape

i) Drapes used for **PACEMAKER** implantation surgery

Product codes	Description
IPPM10	Pacemaker Drape

j) Drapes used for **PERI-GYNEC** Procedures

Product codes	Description
IPPR10	Perineal Drape

Group-2 – Equipment Drapes

Product Codes	Description
IPBA21	Basin Stand Sheet
IPBA22	Basin Stand Cover
IPCC10	C-Arm Cover Drape
IPCC20	
IPEC20	Camera Cover
IPEC21	Camera Cover Mini
IPLD16	Plain Big Sheet
IPLT20	Main Trolley Sheet with Abs
IPLT20W	Trolley Sheet with Abs
IPMT20W	Large Trolley Sheet With ABS
IPMT20	Medium Trolley Sheet with Abs
IPLT21	Trolley Sheet
IPMT22	



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IPLT25P	Back Table Cover Premium
IPMC20 IPMC21	Mayo Trolley Cover
IPMC20P	Mayo Trolley Cover With ABS
IPMI20	Microscope Drape
IPMT21	Trolley sheet-Medium
IPOP10	Drape OP Tape
IPPS23 IPPS24	OT Table Sheet - Small OT Table sheet – Large
IPSI10 IPSI11	Side Drape
IPSI15	Utility Drape Big size
IPSS10	Screen Sheet

Intended use:

The sterile Surgical Disposable drapes are an active barrier against bacterial contamination of the surgical field and prevention of surgical site infections (SSI).

The sterile disposable surgical drapes are used:

- In the surgical field around the incision site to cover the patient and to absorb body fluids.
- In the operation theatre to protect the patient, clinicians, and equipment. To wrap sterile surgical instruments and to cover equipment in the surgical suite.
- The surgical drapes are single use. .

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:

Drapes

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

Manufacturing QMS	ISO 13485 : 2016
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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

Intended User:

Patient undergoing Surgery

Target Patient Population:

Adults, Children's & Infants

Indication:

The sterile Disposable Surgical drapes are used as a protective patient covering, to isolate a surgical site from transfer of micro-organisms, particulates and fluids. These drapes minimizes the potential for contamination during the surgery.

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 drape to either cover the patient (or) trolley to obtain sterile field using sterile technique. Contents are sterile unless package is opened or damaged.

- Drapes can be used as one-piece, (or) as multiple layers. Drapes are made of SMS fabric (or) Absorbent fabric (or) Laminated fabric to provide protective field.
- Drapes are intended to be placed over the patient (or) trolley prior to surgery and are designed to provide barrier property (or) absorbent property (or) laminated property during surgical procedures and stop fluid strike-through to protect the surgical site and patient (or) health care provider from microbial penetration.
- Drapes are to be used from trained medical professional using sterile draping 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 drapes for any other indications rather than manufacturer claimed as a protective patient covering, to isolate a surgical site from transfer of micro-organisms, particulates and fluids.
6. Do not use
 - i) Incorrect type of drape
 - ii) Defected Product
 - iii) Damaged product

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Precautions:

1. Carefully read all instructions for use and product labeling.
2. The drapes 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. Reducing the risk of surgical site infection
2. Provide increased protection against strikethrough of liquids
3. Minimize microbial contamination of the surgical site
4. Absorption capacity
5. No adverse patient outcomes
6. Greatest degree of comfort
7. Provides highest level of barrier protection
8. Levels of pooled oxygen beneath the drapes can be as high as 65%
9. Easy to use, flexible and can adjust to suit most surgical procedures Antistatic property
10. Fluid resistance

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.

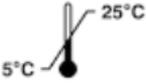
NOTE: Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is

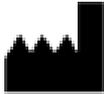
established.

Performance Characteristics:

1. Comfort
2. Fluid Control
3. Flexibility
4. Lint Free
5. Stretchability
6. Antistatic Property
7. Absorbency
8. Repellence
9. Fluid Resistance

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

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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 as per TR1 non-clinical comments of Gowns	29.01.2024