 Amaryllis Healthcare Pvt.Ltd.	<b>Instructions for Use</b> <b>Sterile Disposable Surgical Kits</b>		
	<b>Doc No: AHPL KT</b>	<b>Rev. #: 02</b>	<b>Date: 29.01.2024</b>

**Product Name:**

Sterile Disposable Surgical Kits

**Product Description:**

The disposable surgical kits are ready to use combinations of surgical Drapes and Surgical Gowns. These kits are designed and utilized for specific surgical procedures. Each disposable surgical kit is for a single use and is efficient and economical. These surgical kits are sterilized by Ethylene Oxide. These are packed in a sterility maintenance package to ensure the shelf life of 3 years.

**Features:**

- Easy to use, safety and non-pollution can effectively prevent cross infection;
- The non-woven accessories in the kits have good leakage prevention ability;
- The disposable gowns and drapes have strong absorption ability, prevent-infection ability and permeability;
- These kits are easy to operate, and the drapes are easy to spread for single use;
- All the accessories are stacked according to the demand of the medical workers which is convenient for operation;
- Kits with a complete range of accessories ensure the operation safety and integrity.

**List of Disposable Surgical Kits:**

Product Code	Description	Product Code	Description
<b>AHCTBG10</b>	CVTS OT Pack - Adult	<b>AHGYAH10</b>	Abdominal Hysterectomy OT pack
<b>AHCTBG11</b>	Surgical Gown pack	<b>AHGYVH10</b>	Vaginal Hysterectomy OT pack
<b>AHCTBG13</b>	TROLLEY Pack	<b>AHGYIF10</b>	IVF OT Pack
<b>AHCTBG20</b>	CVTS OT Pack - Pediatric	<b>AHGYDC10</b>	D&C OT Pack
<b>AHCTBG30</b>	CVTS OT Pack - Infant	<b>AHSKS11</b>	Safety kit - Standard
<b>AHCTBG12</b>	CVTS Patient pack - Adult	<b>AHSKI12</b>	Safety kit - Intra
<b>AHCTBG22</b>	CVTS Patient pack - Pediatric	<b>AHSKU13</b>	Safety kit - Ultra
<b>AHCTBG32</b>	CVTS Patient pack - Infant	<b>AHSKA14</b>	Safety kit - Advanced
<b>AHCIAP10</b>	Angioplasty OT Pack	<b>AHSKR10</b>	Safety OT kit - Regular
<b>AHCIPP20</b>	Pacemaker OT Pack	<b>AHNENO10</b>	Neuro OT Pack
<b>AHCABG10</b>	CABG Adult Cardiac Pack	<b>AHNENO11</b>	Neuro Gown pack
<b>AHCABG12</b>	CABG - Patient Drape	<b>AHNENO12</b>	Neuro patient Pack

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Product Code	Description	Product Code	Description
AHCABG13	CABG - Trolley Drape	AHNENO13	Neuro Trolley pack
AHCABG20	Pediatric pack	AHNECR10	Craniotomy OT Pack
AHCIAG10	Angiography Kit	AHNECR11	Craniotomy Gown pack
AHORTH12	THR Patient pack	AHNECR12	Craniotomy patient pack
AHORTH10	THR OT Pack	AHURPC10	PCNL OT Pack
AHORTH11	THR Gown Pack	AHURTU10	TURP OT Pack
AHORTH13	THR Trolley Pack	AHSGKD10	Kidney Transplant Donor OT Pack
AHORTK10	TKR OT Pack	AHSGKD11	Surgeon Gown
AHORTK11	TKR Gown Pack	AHSGKD12	Patient Drape Kit
AHORTK12	TKR Patient Pack	AHSGKD13	Basin Stand Cover
AHORTK13	TKR Trolley Pack	AHSGKD14	Thomas Refractor Kit
AHORKA10	Knee Arthroscopy OT Pack	AHSGKD15	Trolley Drape Kit
AHORKA11	Knee Arthroscopy Gown Pack	AHSGKD16	Perfusion Kit
AHORKA12	Knee Arthroscopy Patient Pack	AHSGKR12	Patient Drape Kit
AHORKA13	Knee Arthroscopy Trolley Pack	AHSGKR13	Basin Stand Cover
AHORSA10	Shoulder Arthroscopy OT Pack	AHSGKR14	Thomas Refractor Kit
AHORSA11	Shoulder Arthroscopy Gown Pack	AHSGKR15	Trolley Drape Kit
AHORSA12	Shoulder Arthroscopy Patient Pack	AHGSGE10	General Surgery Minor OT Pack
AHORSA13	Shoulder Arthroscopy Trolley Pack	AHGSGE20	General Surgery Major OT Pack
AHORMJ10	Ortho Major OT Pack	AHGSLP10	Laparoscopy OT Pack
AHORMJ11	Ortho Major Gown Pack	AHGSLP11	Laparoscopy Pack
AHORMJ12	Ortho Major Patient Pack	AHGSPS11	Plastic Surgery (Major)
AHORMJ13	Ortho Major Trolley Pack	AHGSPS10	Plastic Surgery (Minor)
AHOPOK10	Ophthalmic Kit	AHGSUP10	Universal Pack
AHHYPG10	Patient Gown Kit	AHETEN10	ENT Pack
AHORMN10	Ortho Minor OT Pack	AHGSIU10	CU/CVP Line Kit
AHORMN11	Ortho Minor Gown Pack	AHSGLD10	Liver Transplant Donor OT Pack
AHORMN12	Ortho Minor Patient Pack	AHSGLD11	Surgeon Gown Kit
AHORMN13	Ortho Minor Trolley Pack	AHSGLD12	Patient Drape Kit
AHORLS10	Lamino Spinal OT Pack	AHSGLD13	Thomas Refractor Kit
AHORLS11	Lamino Spinal Gown Pack	AHSGLD14	Trolley Drape Kit
AHORLS12	Lamino Spinal Patient Pack	AHSGLR10	Liver Transplant Recipient OT Pack
AHORLS13	Lamino spinal Trolley pack	AHSGLR11	Surgeon Gown Kit
AHGYND10	Normal Delivery OT pack	AHSGLR12	Patient Drape Kit



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<b>AHGYCS10</b>	LSCS OT Pack	<b>AHSGLR13</b>	Basin Stand Cover
<b>AHGYHS10</b>	Hysteroscopy OT pack	<b>AHSGLR14</b>	Thomas Refractor Kit
<b>AHSGKR10</b>	Kidney Transplant Recipient OT Pack	<b>AHSGLR15</b>	Trolley Drape Kit
<b>AHSGKR11</b>	Surgeon Gown Pack		

#### Intended use:

The sterile disposable surgical kits are intended to minimize the risk of germ transfer in medical procedures between healthcare professionals and patients. The disposable surgical kits are single use only.

#### Product Type:

Spun Bond, SMS, Spunlace, Spunlamination, and Spunlace 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:

Disposable Surgical Kits

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
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 disposable surgical kits are used as a protective covering for medical professionals, patients, and equipment to isolate a surgical site from transfer of micro-organisms, particulates, fluids and for general cover. This minimizes the potential for contamination during the surgery/medical procedures and also post-operative recovery.

**Contraindication:**

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

**Instruction for use:**

Peel opens the pouch to remove the product.

Use the Kit with Gowns, Patient Drapes and Trolley Drapes to either cover the Doctor, patient (or) trolley to obtain sterile field using sterile technique.

Contents are sterile unless package is opened or damaged.

- Kits can be used as one-piece, (or) as multiple layers. Gowns, Patient Drapes and Trolley Drapes are made of SMS fabric (or) Absorbent fabric (or) Laminated fabric to provide protective field.
- Gowns are intended to be used to cover the Doctor, Patient Drapes are intended to be placed over the patient (or) Trolley Drapes are intended to cover the 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 doctor (or) patient (or) trolley and surgical site from microbial penetration.
- Drapes are to be used from trained medical professional using sterile draping technique.


**Warnings:**

1. Device is 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 kits for any other indications rather than manufacturer claimed as a protective covering for medical professionals, patients, and equipment to isolate a surgical site from transfer of micro-organisms, particulates, fluids and for general cover.
6. Do not use
  - i) Incorrect type or size
  - ii) Defected product
  - iii) Damaged product

**Precautions:**

1. Carefully read all instructions for use and product labeling.
2. The disposable surgical kits 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:**

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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:**

a) Sterile Disposable Surgical Drapes

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


b) Disposable Surgical Gown

1. Less bacterial transmission in the laboratory
2. Lower rates of contamination in the operating room
3. Prevent or reduce exposure of blood borne 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:**

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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:**





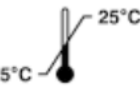

On completion of the procedure, dispose-off the device as per institutional and local regulatory guidelines for bio-hazardous medical waste disposal.
















**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. Lint Free
2. Antistatic property
3. Absorbency
4. Repellence
5. Fluid resistance
6. Fluid control

**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 ethyleneoxide
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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### 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