Medline International France SAS
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France

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DEVICE DESCRIPTION

1. Device Description & Features

1.1. A complete description of medical device, Primary Packaging and Secondary Packaging

Medline Surgical Drapes are intended to provide a barrier between the patient and the clinician as well as between the patient and the surgical environment. It is designed to isolate the surgical site from contamination (e.g. microorganisms, body fluids, particulate matter) on the patient's body. These drapes are intended to be used in sterile conditions.

This product is a single-use, disposable device.

The description of the packaging materials incorporated in the packaging are described in the table below:

Part name	Material Description
Primary packaging	Polyethylene film
Secondary packaging	Cardboard

1.2. Principles of operation or mode of action

Surgical procedure drapes are removed aseptically from the sterile packaging and unfolded on the patient. Where appropriate, specific polyethylene windows of surgical drapes can be incised to locate the surgical site.

1.3. Risk class and applicable classification rule for the medical device according to the Thai Regulations

Class 1 Rule 4

1.4. A description of the accessories, other medical devices and other products that are not medical devices, which are intended to be used in combination with the medical device

Not applicable

1.5. A description or complete list of the various configurations of the medical device to be registered

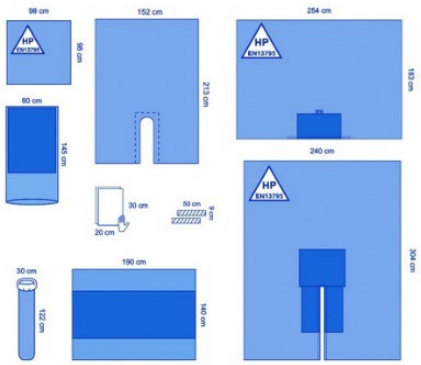
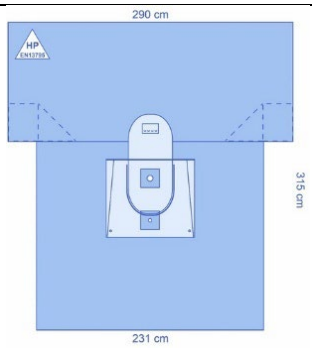
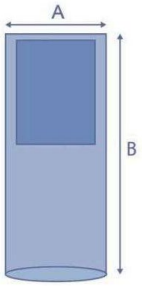
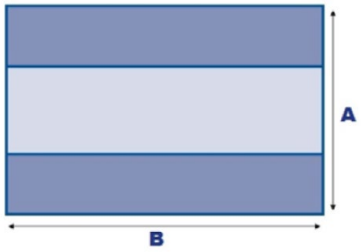
Identifier	Product Name
TB29630CE	OPS™ Ultimate Orthopaedic Split Pack, reinforced
DYJPEARDTB	OPS™ Ultimate Arthroscopy Sheet
8339CCE	Mayo Stand Cover
DYNJPE2314	Table Cover
ES29561CE	OPS™ Essential Cardiovascular Pack
TB29081CE	OPS™ Ultimate TUR Pack
TB29429CE	OPS™ Ultimate Hip Drape with Pouches

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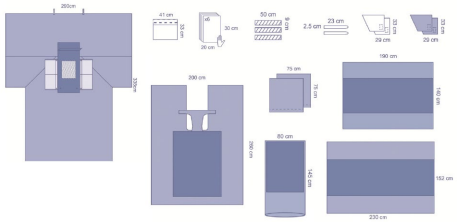
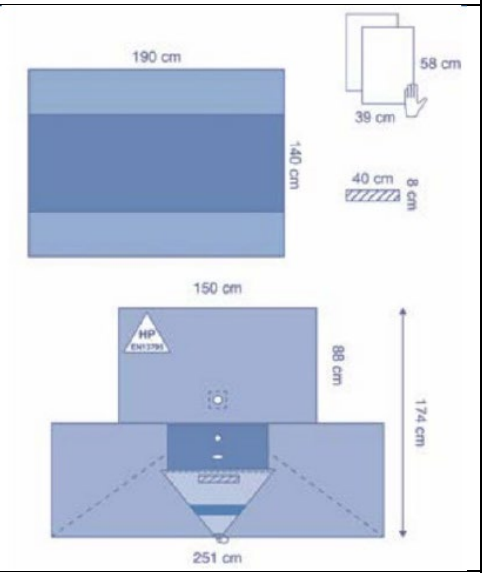
1.6. A complete description of the key functional elements (e.g. its parts or components), its formulation, its composition and its functionality.

Identifier	Description	Pack Description	Product Image
TB29630CE	OPS Ultimate Orthopaedic Split Pack, reinforced	Back table cover 140x190 cm contains: Tri-laminate head drape 254x183cm Tri-laminate split drape 240x304cm Tri-laminate utility drape 98x98cm Impervious stockinette 30x122cm 2 Adhesive tapes 9x50cm 2 Absorbent towels 30x20cm Plastic split sheet 152x213cm Mayo stand cover 80x145cm	
DYJPEARDTB	OPS Ultimate Arthroscopy Sheet	A sterile wrap, 112x112 cm, contains: - 1 tri-laminate arthroscopy drape 231/290x315 cm, 6 cm diameter elastic fenestration, fluid collection pouch with exit ports, cord holding tab, armboard covers	
8339CCE	Mayo Stand Cover, 80cm x 142cm	80cm x 142cm	
DYNJPE2314	Table Cover, 152cm x 229cm	152cm x 229cm	

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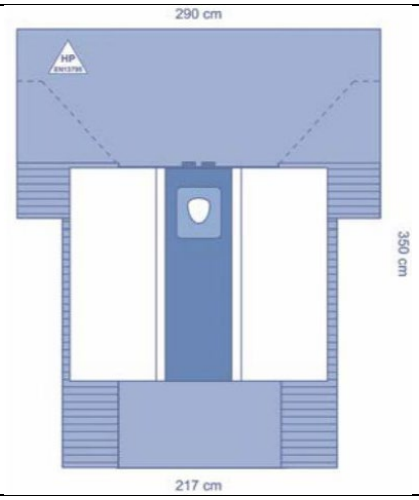
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ES29561CE	OPS Essential Cardiovascular Pack	A SMS wrap 120x120 cm contains: - 1 back table cover, 152x230 cm, 50µm containing : - 1 mayo stand cover, heavy duty, 80x145 cm, 100x75 cm reinforcement - 6 absorbent towels, 30x20 cm unfolded - 1 back table cover, 140x190 cm, 50 µm, folded - 1 clear plastic instrument pouch, 33x41 cm, adhesive - 2 hook and loop tube holders 2.5x23 cm - 3 adhesive tapes, 9x50 cm - 2 bi-laminate bootees, 29x33cm, with adhesive - 2 PE bootees, 29x33cm, with adhesive - 2 bi-laminate adhesive drapeS 75x75 cm - 1 bi-laminate peri-groin drape 200x260 cm, 20x102 cm adhesive split, perineal drape, 105x141 cm reinforcement - 1 bi-laminate cardiac T drape 200/290x338cm, 32x40 cm fenestration with full incise film, 51x115 cm reinforcement, 2 instrument pouches, armboard covers	
TB29081CE	OPS Ultimate TUR Pack	A sterile wrap 86x86 cm contains: - 1 back table cover, 140x190 cm, 50 µm containing*: - 1 tri-laminate TUR drape 150/251x174 cm, 6 cm diameter supra pubic adhesive fenestration, 6 cm diameter lower fenestration, 38x76 cm blue PE reinforcement, fluid collection pouch with filter and exit port* - 1 clear adhesive tape, 8x40 cm orbent towel, 58x39 cm unfolded	
TB29429CE	OPS Ultimate Hip Drape with Pouches	A sterile wrap 86x86 cm contains: - 1 tri-laminate hip drape 217/290x350 cm, 53x170 cm reinforcement, 17x21 cm elastic fenestration, 81x170 cm hip pouch x 2, armboard covers, 2 cord holding tabs	

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1.7. An explanation of any novel features (if any)

NA

2. Intended Use

A Surgical drape is designed to isolate a surgical site from contamination (e.g., microorganisms, body fluids, particulate matter) on the patient's body.

3. Indications

A Surgical drape is designed to isolate a surgical site from contamination (e.g., microorganisms, body fluids, particulate matter) on the patient's body.

4. Instructions for use

1. Before opening the pack, visually inspect the packaging. Ensure that the packaging is intact, frere from tears, punctures, or any signs of damage.
2. Open the packaging carefully – use caution when opening to avoid damaging the contents or packaging.
3. Remove the drapes aseptically and unfold on the patient.
4. When removing the surgical drapes after surgery, gently lift the drape from the patient and discard accordingly.

5. Storage condition

General warehouse conditions. Keep away from sunlight and keep dry.

6. Shelf life

5 years.

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7. Contraindications

Not applicable

8. Warnings

a. The packaging is sterile when unopened and undamaged. Do not use the product if it is damaged or contaminated before use.
b. Do not expose the product to a flame or high intensity heat sources.

9. Precautions

a. The packaging is sterile when unopened and undamaged. Do not use the product if it is damaged or contaminated before use.
b. Do not expose the product to a flame or high intensity heat sources.

10. Potential adverse effects

Not applicable

11. Alternative therapy

Not applicable

12. Materials

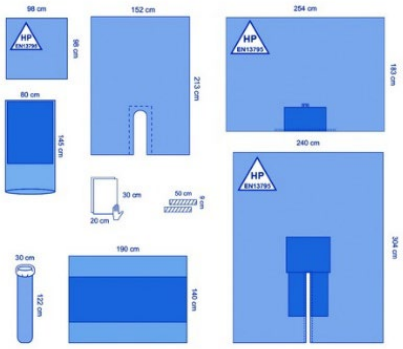
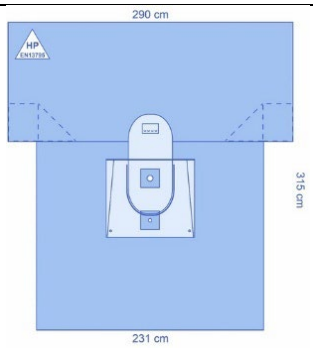
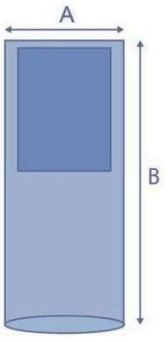
Identifier	Product Name	Raw Material
TB29630CE	OPS Ultimate Orthopaedic Split Pack, reinforced	Tri-laminated material (polypropylene + polyethylene + polypropylene)
DYJPEARDTB	OPS Ultimate Arthroscopy Sheet	Tri-laminated material (polypropylene + polyethylene + polypropylene)
8339CCE	Mayo Stand Cover, 80cm x 142cm	Polyethylene, Polypropylene
DYNJPE2314	Table Cover, 152cm x 229cm	Polyethylene, Cellulose
ES29561CE	OPS Essential Cardiovascular Pack	Bi-laminated material (polyethylene + polypropylene) Cardiac drape reinforcement (polyester + viscose) Peri-groin drape reinforcement (polypropylene)
TB29081CE	OPS Ultimate TUR Pack	Tri-laminated material (polypropylene + polyethylene + polypropylene)
TB29429CE	OPS Ultimate Hip Drape with Pouches	Tri-laminated material (polypropylene + polyethylene + polypropylene)

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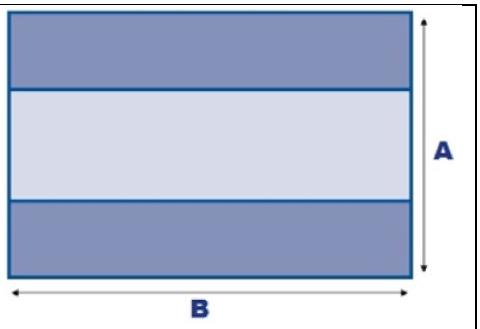
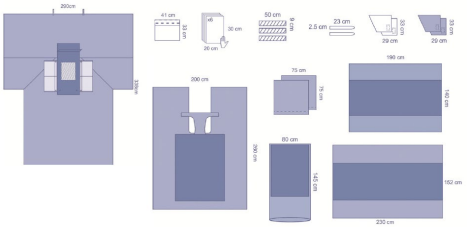
13. Product specifications

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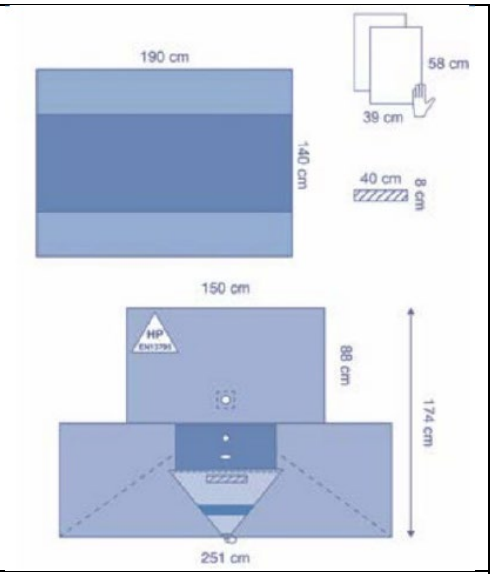
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