



Device Description

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Medline surgical pack are designed to isolate potential contaminants (e.g., microorganisms, particulate matter) present on the operating room personnel from the surgical site. Single use products manufactured by Medline are considered non-invasive devices for short term use.

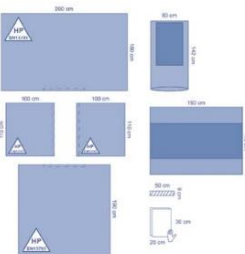
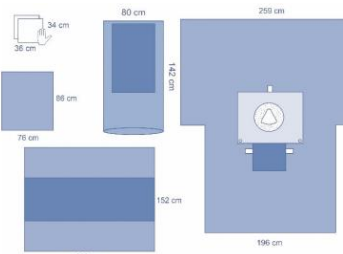
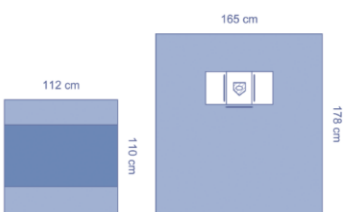
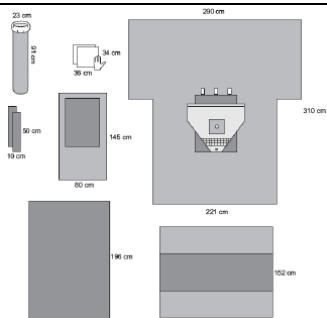
Product Code	Product Description	GMDN Code
ES10116CE	OPS Essential Universal Pack Large	62934
ES10856CE	OPS Essential Caesarean birth pack	62934
DYJPEOPHPSM3	OPS™ Advanced Ophthalmology Pack	62934
DYJPECSEPSM1	OPS Advanced C-section Pack	62934
DYJPEARPSM1	OPS Advanced Arthroscopy pack	62934
DYNJPE9010SM	OPS Advanced Gynecology/Urology Pack	62934
TB29095CE	OPS™ Ultimate Hand Pack	62934
TB29453CE	OPS™ Ultimate Cæsarean Birth Pack	62934
CP29032CE	OPS™ Ultimate Extremity Pack, reinforced	62934
TB29973CE	OPS™ Ultimate Extremity Pack, reinforced	62934
DYNJP1050B	UNIVERSAL PACK I	62934
DYNJP6110	C-BIRTH PACK II	62934

List of Products

The product image and characteristics of the mask are provided in Table 1.

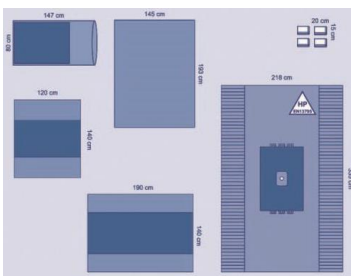
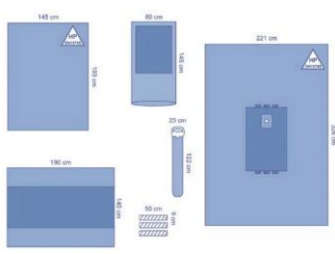
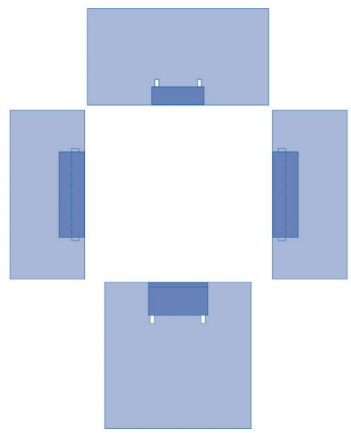
Table 1. Product Image and Characteristics

Product Image	Product Number	Product Name	Product Characteristics
	ES10856CE	OPS Essential Caesarean birth pack	A SMS wrap, 120x120 cm, contains: - 1 back table cover, 140x190 cm, 50 µm containing: - 4 absorbent towels, 30x20 cm unfolded - 2 adhesive tapes, 9x50 cm - 1 baby blanket, 100x105 cm - 1 back table cover, 140x120 cm, 50 µm, folded - 1 bi-laminate cesarean birth drape, 190/260x311 cm, 32x38 cm fenestration

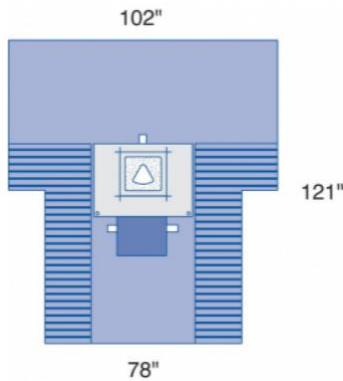
Product Image	Product Number	Product Name	Product Characteristics
			with incise film with a pear-shaped-opening 18x18 cm, 360° fluid collection pouch with malleable bars, armboard covers, with 2 cord holding tabs
	ES10116CE	OPS Essential Universal Pack Large	A back table cover, 140x190 cm, 50 µm contains: - 1 bi-laminate adhesive head drape, 260x160cm - 1 bi-laminate adhesive foot drape, 190x190cm - 2 bi-laminate adhesive side sheets, 110x100 cm - 1 adhesive tape, 9x50 cm - 2 absorbent towels, 30x20 cm unfolded - 1 Mayo stand cover, 80x142 cm
	DYJPECSEPS M1	OPS Advanced C-section Pack	A back table cover, 152x190 cm contains : - 2 absorbent towels, 34x36 cm, unfolded - 1 baby blanket, 76x86 cm - 1 mayo stand cover reinforced, 80x142 cm - 1 SMMMS C-section drape 196/259x307 cm, absorbent reinforcement 38x51 cm, incise film with pear shaped fenestration 18x18 cm, fluid collection pouch with exit ports, 3 hook & loop tube holders, armboard covers
	DYJPEOPHP SM3	OPS Advanced Ophthalmology Pack	A SMS wrap, 91x91 cm contains: 1 back table cover 112x110 cm, 50 µm containing: - 1 ophthalmic drape 165x178 cm, 11x13 cm fenestration, fenestrated incise film, ophthalmic pouch with formable tape strip
	DYJPEARPS M1	OPS Advanced Arthroscopy pack	A back table cover, 152x190 cm, 50µm contains***: - 1 Mayo stand cover 80x145 cm, 61x85 cm absorbent reinforcement, *** - 2 Absorbant towel, 34x36 cm, unfolded - 2 bilaminate OP tapes, 9x50cm, - 1 impervious stockinette, 23x91 cm*** - 1 wetlaid drape sheet, 135x196 cm*

Product Image	Product Number	Product Name	Product Characteristics
			- 1 SMS arthroscopy drape 221/290x310 cm, absorbent reinforcement 74x91.5 cm, 6 cm diameter elastic fenestration, armboard covers, 3 hook & loop tube holders, 1 fluid collection pouch with filter and exit port**
	DYNJPE9010 SM	OPS Advanced Gynecology/ Urology Pack	A back table cover, 125x229 cm contains : - 2 hand towels 43x50 cm unfolded - 2 wetlaid leggings 74x109 cm with cuff, 15 cm - 1 SMMMS utility drape 38x66 cm, with adhesive - 1 blue PE under buttocks drape 89x119 cm, with wetlaid reinforcement 18x89 cm - 1 SMMMS abdominal drape 135x97 cm, adhesive, absorbent reinforcement 46x53 cm
	TB29095CE	OPS™ Ultimate Hand Pack	A sterile wrap 86x86 cm contains: - 1 back table cover, 140x190 cm, 50 µm containing*: - 1 tri-laminate hand drape, 196x373 cm, 43x86 cm reinforcement, 3 cm diameter elastic fenestration, 4 cord holding tabs, with table extension* - 1 back table cover, 140x190 cm, 50 µm, folded*
	TB29453CE	OPS™ Ultimate Cæsarean Birth Pack	A back table cover 140x190 cm, 50 µm*contains: - 1 Baby blanket, 100x105 cm - 1 tri-laminate Cesarean birth drape, 196/249x300 cm, arm board covers, 2 reinforcements : 52x67 cm and 43x57 cm, fluid collection pouch, 30x36 cm fenestration with fenestrated incise film 17x19cm and extra adhesives, 4 cord holding tabs* - 1 Mayo stand cover, 80x142 cm, 55x88 cm reinforcement* - 2 absorbent towels, 30x20 cm unfolded



Product Image	Product Number	Product Name	Product Characteristics
	CP29032CE	OPS™ Ultimate Extremity Pack, reinforced	The pack contains: 1 Trilaminare extremity drape, reinforced, 218 x 335 cm, with a 6-cm diameter elastic fenestration and 6 cord-holding tabs 1 Trilaminare 3/4 quarter drape, 145 x 193cm 4 Hand towels, unfolded, 39 x 30 cm 1 Mayo stand cover, heavy duty, 80 x 145 cm 1 Back table cover, 140 x 120 cm, 50 µm 1 Back table cover, 140 x 190 cm, 75 µm.
	TB29973CE	OPS™ Ultimate Extremity Pack, reinforced	A back table cover 140x190 cm, 50 µm* contains: - 1 tri-laminare Extremity drape, 221x326 cm, 77x114 cm reinforcement, 6 cm diameter elastic fenestration, 6 cord holding tabs* - 1 tri-laminare Three quarter drape, 145x193 cm* - 3 adhesive tapes, 9x50 cm (folding in half) - 1 impervious stockinette, 23x122 cm* - 1 Mayo stand cover 80x145 cm, 61x85 cm absorbent reinforcement*
	DYNJP1050B	UNIVERSAL PACK I	Pack includes: reinforced table cover, 50" x 90" (127 x 229 cm); Mayo stand cover, 24" x 53" (61 x 135 cm); two side drapes with adhesive, 35" x 79" (89 x 201 cm); bottom drape with adhesive, 70" x 75" (178 x 191 cm); top drape with adhesive, 102" x 53" (259 x 135 cm) and suture bag (paper) Top, side and bottom drapes feature absorbent reinforcement: top drape 29" x 10" (74 x 25 cm), bottom drape 29" x 16" (74 x 41 cm), side drape 8" x 40" (20 x 102 cm); adhesive along reinforced edge; hook-and-loop line holders on top and bottom drapes; side drapes have 4" x 40" fabric trough (10 x 102 cm); top drape available separately as DYNJP4002, sterile; bottom drape and side drape not available sterile



Product Image	Product Number	Product Name	Product Characteristics
	DYNJP6110	C-BIRTH PACK II	Pack includes: reinforced table cover, 50" x 90" (127 x 229 cm); Mayo stand cover, 24" x 53" (61 x 135 cm); Eclipse poly-reinforced gown (L), with towel in outer wrap; two Eclipse poly-reinforced gowns (L); ear/ulcer syringe, 2 oz.; umbilical cord clamp; suture bag (paper); C-section drape with pouch and fenestrated incise, 102" x 121" x 78" (259 x 307 x 198 cm); baby blanket, 30" x 34" (76 x 86 cm); two OB pads, 11" (28 cm); placenta basin and four hand towels 14" x 22" (35.6cm x 56 cm)

Intended Use

A surgical pack is designed to isolate potential contaminants (e.g., microorganisms, particulate matter) present on the operating room personnel from the surgical site.

Intended users

Healthcare professionals uses these products in perating room during surgery.

Instructions for Use

Caution

Do not expose to a flame or high intensity heat sources

Directions for disposal

There's no specific instruction for the product disposal. Follow the institutional policy.

Product Stability and Shelf Life

Product Shelf Life

The products duration of use is the same as the duration of the surgery, in average few hours.
The shelf-life of the products is five(5) years.

Contra-indications and Warnings

There are no contra-indications for surgical packs.

List of materials

Materials of construction of the Suction Canister System are summarized in Table 2.

Part Name	SKUs	Material Description
OPS Essential Surgical Pack	ES10116CE ES10856CE	SMS material (PP), with repellent treatment
OPS Advanced	DYNJPE9010SM	SMS Material(PP), with soft treatment

Surgical Pack	DYJPEARPSM1 DYJPEOPHPSM3 DYJPECSEPSM1	
OPS Ultimate Surgical Pack	TB29453CE TB29095CE TB29973CE CP29032CE	Trilaminate material(3 layer of material: SPP+PP+SPP), breathable
C-Birth Pack	DYNJP6110	SMS material, Spunlace(blend of PET(45%)+woodpulp(55%))
Universal Pack	DYNJP1050B	SMS material

Packaging System Components and Materials of Pack

Part Name	Material Description
Sterilization Bag	Polyliner bag
Case	Carton Box

Sterilization/Microbiological Information

Surgical packs are sterilized using ethylene oxide gas.

Storage condition

General warehouse conditions, keep dry.

Clinical Evaluation and Post-Market Clinical Follow-Up

There is no post-market clinical study planned / applicable for surgical packs based on the available data and post market surveillance.

Medline standard operating procedures and quality control ensures that any customer complaints are collected through product vigilance reporting. The extremely high frequency of use of these devices and no incidence of failure reports/ customer complaint (an indication of appropriate device performance) justify the non-applicability of post-market clinical study.



Complete List of Various Configuration of Surgical Gown and Drape and Pack

No.	Product Name	Model no.
1	OPS™ Advanced Cæsarean birth pack	DYJPECSEPSM1
2	OPS™ Advanced Ophthalmology Pack	DYJPEOPHPSM3
3	OPS™ Essential Universal Pack Large	ES10116CE
4	OPS™ Ultimate Hand Pack	TB29095CE
5	OPS™ Ultimate Cæsarean Birth Pack	TB29453CE
6	OPS™ Ultimate Extremity Pack, reinforced	CP29032CE
7	OPS™ Advanced Arthroscopy Pack	DYJPEARPSM1
8	OPS™ Advanced Gynecology/Urology Pack	DYNJPE9010SM
9	OPS™ Ultimate Extremity Pack, reinforced	TB29973CE
10	OPS™ Essential Caesarean birth pack	ES10856CE
11	C-BIRTH PACK II	DYNJP6110
12	UNIVERSAL PACK I	DYNJP1050B

