

Product Catalogue



ABOUT US

ZEYNI MEDİKAL, based in Bursa, Turkey, is a medical company that encompasses all standards of the healthcare sector. Under the Zeyni brand, they produce disposable medical textile products, surgical gowns, surgical drapes, and sets. The entire production process takes place in Class 100,000 Clean Rooms and adheres to ISO 9001, ISO 13795, ISO 13485, and CE standards.

The company utilizes the latest technology throughout the production, and their EO sterilization process is managed according to EN11135-1 standards within their own factory.

ZEYNI MEDİKAL holds the distinction of being the first company in Turkey to pass the initial inspection smoothly under the (EU) 2017/745 Medical Device Regulation. By promptly and accurately responding to customer requests, they are rapidly progressing toward becoming a leading company in both regional and global markets.

Their production, influenced by the company owners' background as surgical branch doctors, is tailored to meet the technical specifications requested by customers, distributors, hospitals, doctors, and government institutions. Rather than delivering products in predefined standards and sizes, they provide customized solutions based on professional advice and knowledge. ZEYNI MEDİKAL offers contract manufacturing for disposable surgical gowns, drapes, and sets, as well as services like OEM and OBL.

They export to 27 different countries across 5 continents, continually increasing their market share in regional and global markets.

BASIC PRODUCT INFORMATION

Resistance

Two and three layer materials, used for gowns and drapes production, are laminated with plastic film that works as a perfect barrier against body fluids and microorganism penetration.

Linting

The surface is resistant to abrasion, material does not release any fibres.

Absorbency

The drape surface is made from absorbent viscose with high capacity of absorbency
250 ml water/sqm.

Adhesive Zones

Sides of drapes and apertures are lined with adhesive zones, which allow simple effective and safe fixation of the drape to patient body.

Accessories

Following elements may be integrated in the drape upon request:

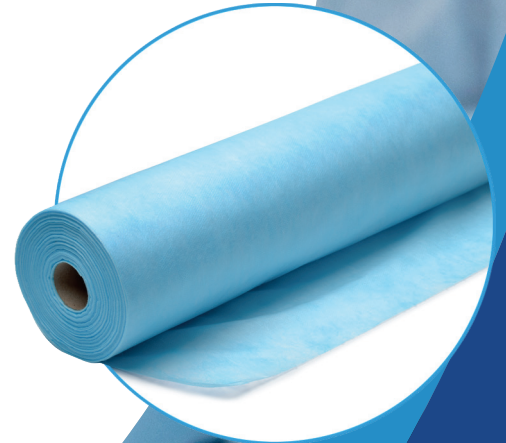
- Incision drape
- Complements for tubes and cables fixation
- Equipment pouch
- Fluid collection bags, etc.

Folding and Packing

Special folding technique enables that drapes and integrated accessories are applied without any contact with sterile and non-sterile surfaces.

Functional Properties

- Each part is anatomically shaped
- Materials perfectly adhere to the surface
- All components are ranked into logic sets which include all that is necessary for a surgery preparation
- Always ready to use



USED MATERIAL



1-TWO LAYER LAMINATE 54gsm

Two layer laminate, upper layer is made of absorbent viscose 28g/sqm, bottom layer is bacterial barrier polyethylene foil 25µm.

Application:

- Drapes & Reinforcement Zones
- Equipment Cover

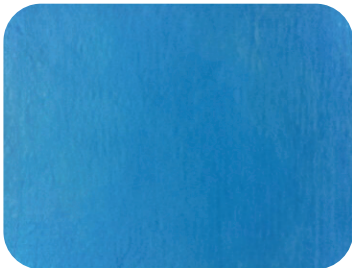


2-TWO LAYER SPUNBOND LAMINATE 56gsm

Non-woven material composed of two layers, upper layer is absorbent spunbond 30g/sqm, bottom layer polyethylene foil 25µm.

Application:

- Drapes & Reinforcement Zones
- Equipment Cover

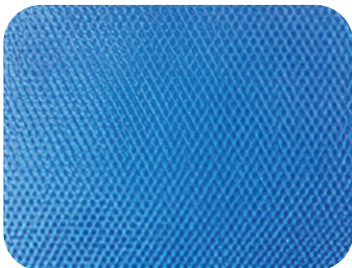


3-THREE LAYER LAMINATE 70gsm

Three layer laminate, upper layer is made of absorbent viscose 28g/sqm, middle layer is made of polyethylene foil 25µm and bottom layer is made of absorbent non-woven textile.

Application:

- Drapes & Reinforcement Zones

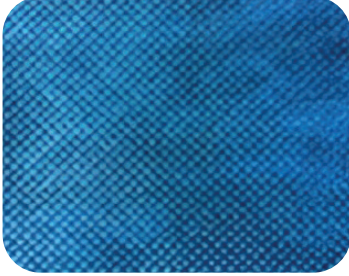


4-SMMS 40-43gsm

SMMS fabrics is composed of two layer of spunbonded fabrics and two layer of Meltblown fabrics. With good tensile strength, high filtration and remarkable softness. It prevent and isolate dust particle, alcohol, blood, bacteria and virus.

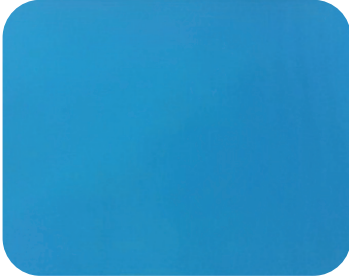
Application:

- Gowns / Drapes
- Sterilization Wraps



5-SPUNBOND 35gsm

Spunbond material which doesn't show resistance to liquid is used in the production of non-sterile gowns and textiles.



6-POLYETHYLENE FOIL 60µm (PE 60 micron)

A turquoise very drapeable, micro embossed PE coex film, Impermeable to fluids, non toxic, very high strength.

Application:

- Back Table Cover & Mayo Stand Cover
- Equipment Covers



7-TOWEL 63gsm

It has high absorbency and lint free. It is used for drying the hands of surgeons before operation.



8-STERILIZATION WRAP 60gsm

It is used for covering and keeping of drape packs during the sterilization process, and it supplies Hygienic security and tight packing.

SURGICAL DRAPES



SMMS Drapes

Main Material Feature	Repellent
	Breathable
Adhesive	No
Type of Product	Individual Drape
Main Material	SMS-40 Gsm
Packaging	Single Peel-Open Pack
Colour of surgical drape	Medical Blue
Single Use	Yes
Sterile	Yes
	No(if requested)

Triplex Drapes

Main Material Feature	Repellent
	Absorbent
	Breathable
Adhesive	No
Type of Product	Individual Drape
Main Material	Triplex-70 Gsm
Packaging	Single Peel-Open Pack
Colour of surgical drape	Medical Blue
Single Use	Yes
Sterile	Yes
	No(if requested)

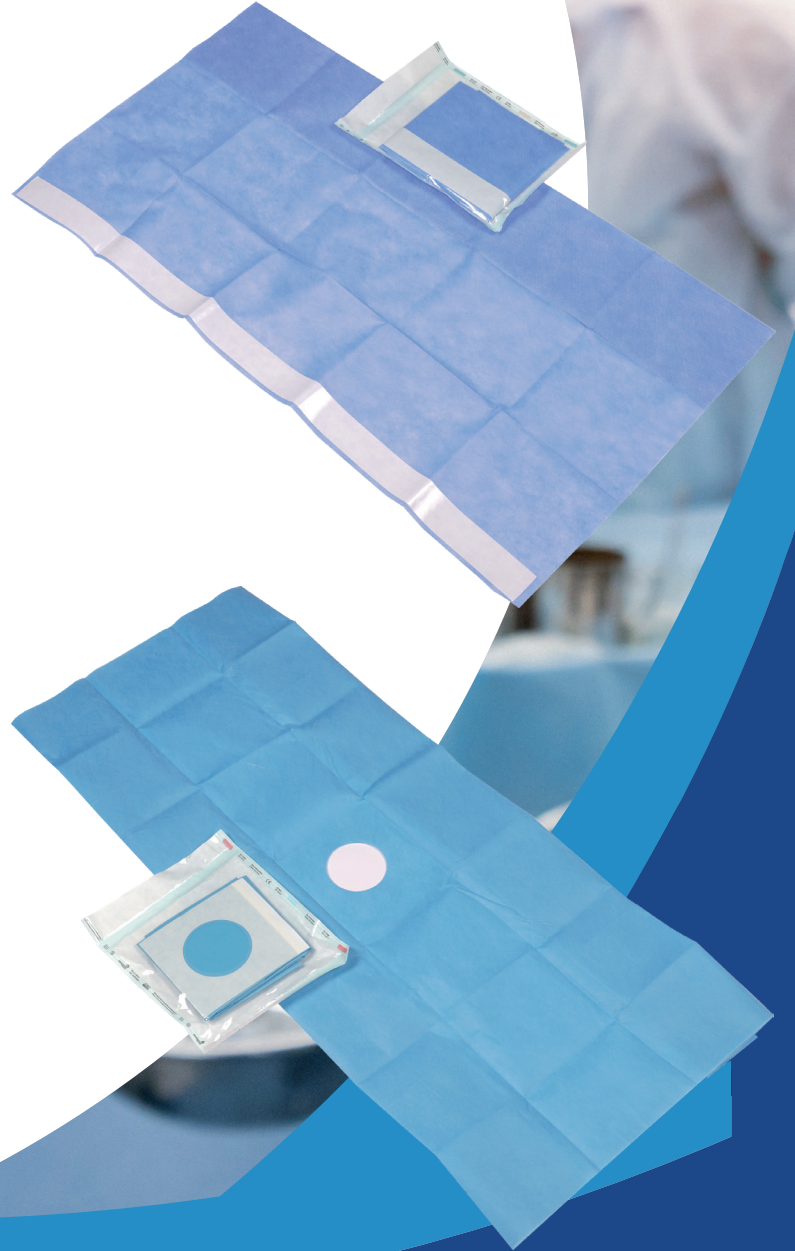
Biflex Drapes

Main Material Feature	Repellent
	Absorbent
	Breathable
Adhesive	No
Type of Product	Individual Drape
Main Material	Biflex-56 Gsm
Packaging	Single Peel-Open Pack
Colour of surgical drape	Medical Blue
Single Use	Yes
Sterile	Yes
	No(if requested)

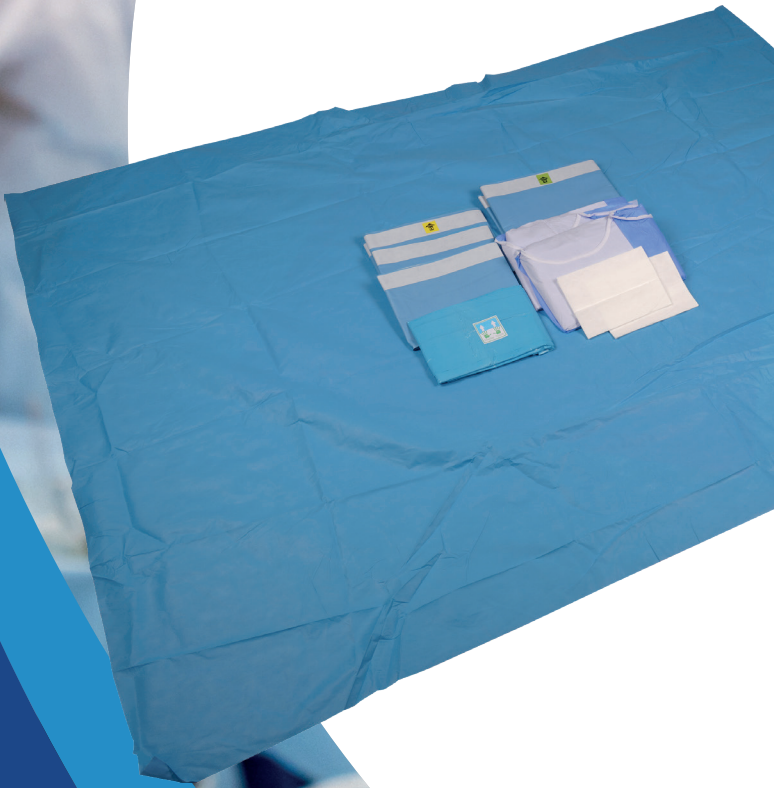
SURGICAL DRAPES

Adhesive Drapes	
Main Material Feature	Repellent
	Absorbent
	Breathable
Adhesive	Yes
Type of Product	Individual Drape
Main Material	SMS-40 Gsm
	BIFLEX-56 Gsm
	TRIPLEX-70 Gsm
Packaging	Single Peel-Open Pack
Colour of surgical drape	Medical Blue
Single Use	Yes
Sterile	Yes
	No(if requested)

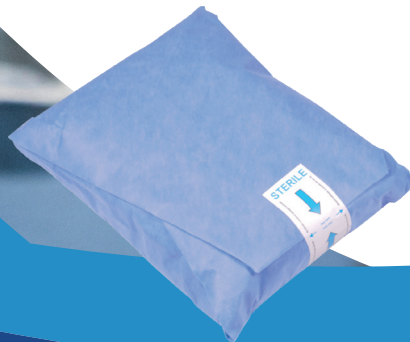
Fenestrated Drapes	
Main Material Feature	Repellent
	Absorbent
	Breathable
Adhesive	Yes
	No(if requested)
Type of Product	Individual Drape
Main Material	SMS-40 Gsm
	BIFLEX-56 Gsm
	TRIPLEX-70 Gsm
Packaging	Single Peel-Open Pack
Colour of surgical drape	Medical Blue
Single Use	Yes
Sterile	Yes
	No(if requested)



GENERAL SURGERY PACK

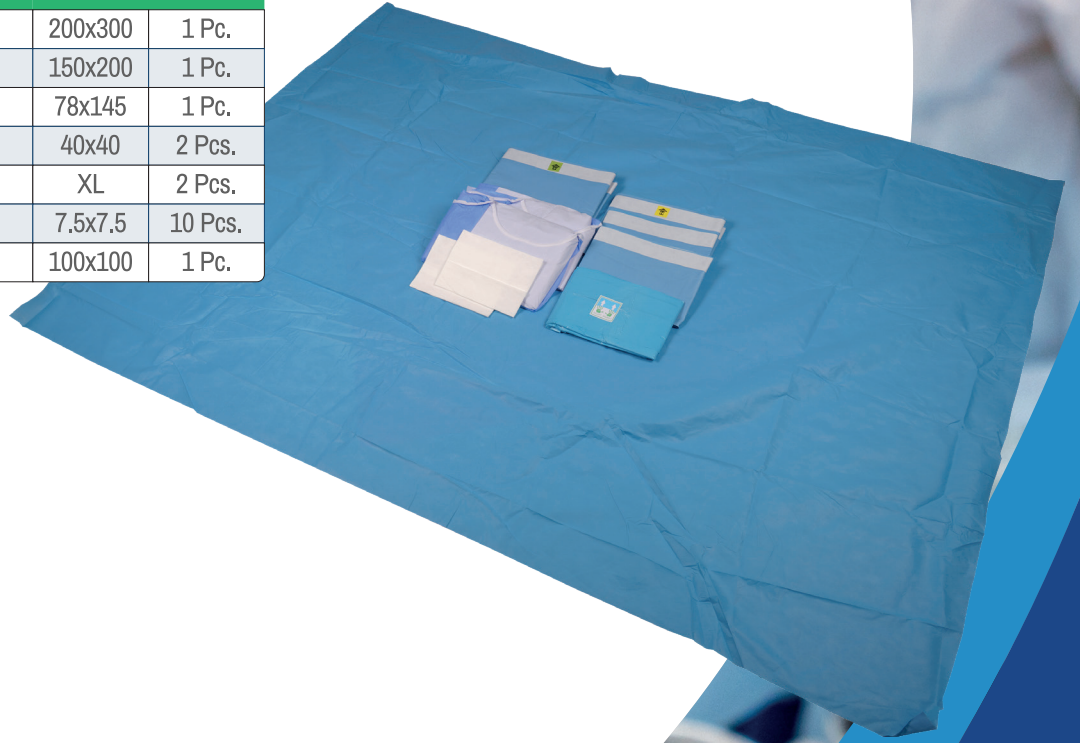


Content	Size	Pcs.
Anesthesia Drape	150x240	1 Pc.
Foot Drape	150x180	1 Pc.
Back Table Cover	150x200	1 Pc.
Mayo Stand Cover	78x145	1 Pc.
Drape with Adhesive Tape	75x90	2 Pcs.
Reinforced Surgical Gown	XL	2 Pcs.
Medical Towel	40x40	2 Pcs.
Sterilization Wrap	100x100	1 Pc.



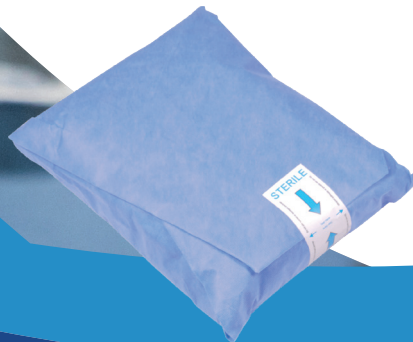
LAPAROSCOPY DRAPE PACK

Content	Size	Pcs.
Laparoscopy Drape	200x300	1 Pc.
Back Table Cover	150x200	1 Pc.
Mayo Stand Cover	78x145	1 Pc.
Medical Towel	40x40	2 Pcs.
Reinforced Surgical Gown	XL	2 Pcs.
Sponge	7,5x7,5	10 Pcs.
Sterilization Wrap	100x100	1 Pc.



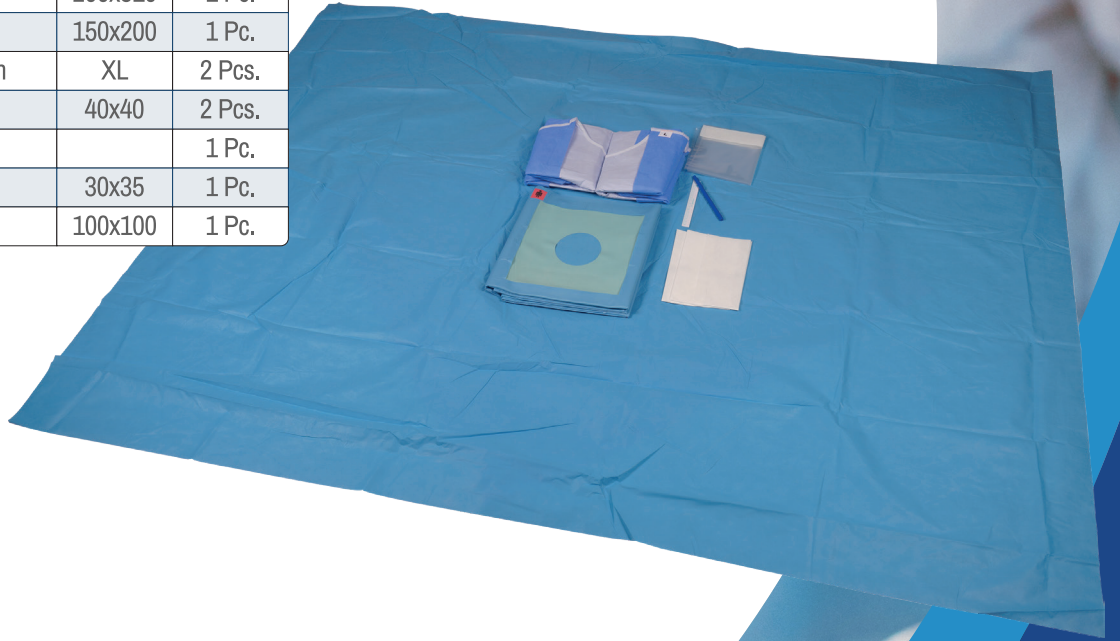
ARTHROSCOPY DRAPE PACK

Content	Size	Pcs.
Arthroscopy Drape with Liquid Collection Pouch	200x300	1 Pc.
Back Table Cover	150x200	1 Pc.
Legging	40x75	2 Pcs.
Medical Towel	40x40	2 Pcs.
Skin Marker & Ruler		1 Pc.
Reinforced Surgical Gown	XL	2 Pcs.
Elastic Bandage	15x150	1 Pc.
Universal Bag	30x35	2 Pcs.
Op-Tape	10x50	2 Pcs.
Sterilization Wrap	100x100	1 Pc.



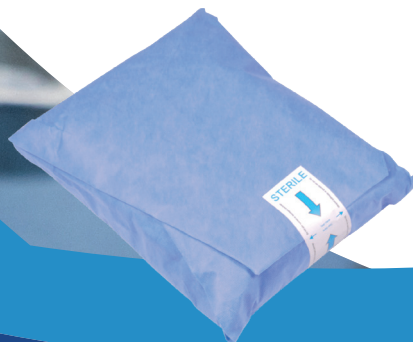
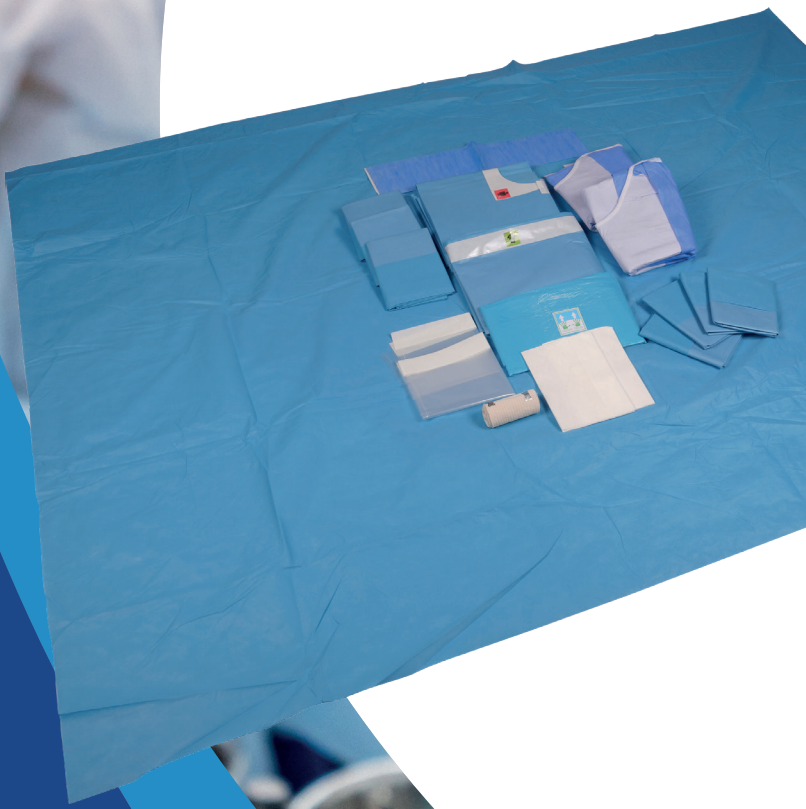
EXTREMITY DRAPE PACK

Content	Size	Pcs.
Extremity Knee Drape	200x310	1 Pc.
Back Table Cover	150x200	1 Pc.
Reinforced Surgical Gown	XL	2 Pcs.
Medical Towel	40x40	2 Pcs.
Skin Marker & Ruler		1 Pc.
Universal Bag	30x35	1 Pc.
Sterilization Wrap	100x100	1 Pc.



HIP PACK

Content	Size	Pcs.
HIP Drape with U-Shaped	200x240	1 Pc.
Back Table Cover	150x200	1 Pc.
Reinforced Surgical Gown	XL	2 Pcs.
Medical Towel	40x40	2 Pcs.
Op-Tape	10x50	2 Pcs.
Drape with Adhesive Tape	150x240	1 Pc.
Mayo Stand Cover	78x145	1 Pc.
Legging	40x75	2 Pcs.
Universal Bag	30x35	2 Pcs.
Elastic Bandage	10x150	1 Pc.
Sterilization Wrap	100x100	1 Pc.



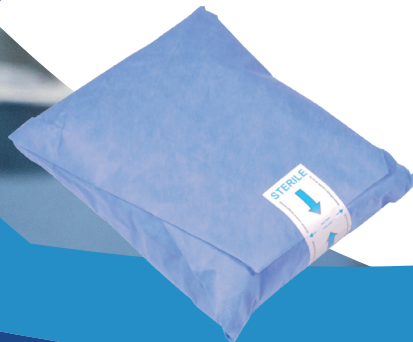
MINOR SURGERY PACK

Content	Size	Pcs.
Minor Surgery Drape	75x75	1 Pc.
Medical Towel	40x40	1 Pc.
Back Table Cover	40x50	1 Pc.
Sterilization Wrap	100x100	1 Pc.



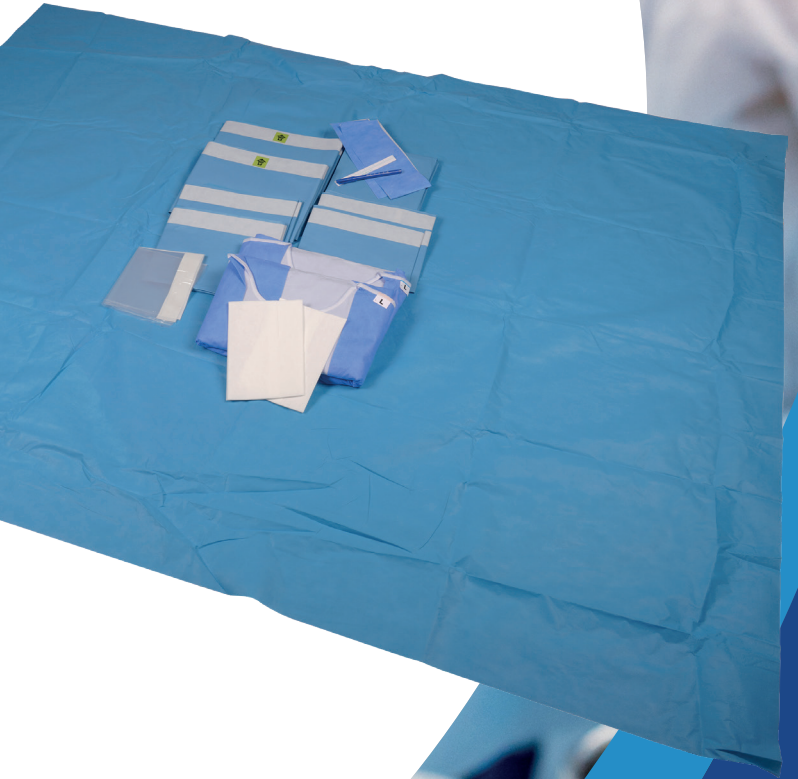
DRESSING PACK

Content	Size	Pcs.
Fenestrated Drape with Adhesive Tape	60x60	1 Pc.
Solution Cap	250 CC	1 Pc.
Betadine Sponge		1 Pc.
Universal Bag	30x35	1 Pc.
Sponge	7.5x7.5	5 Pcs.
Gloves		1 Pair
Medical Towel	40x40	1 Pc.
Sterilization Wrap	100x100	1 Pc.



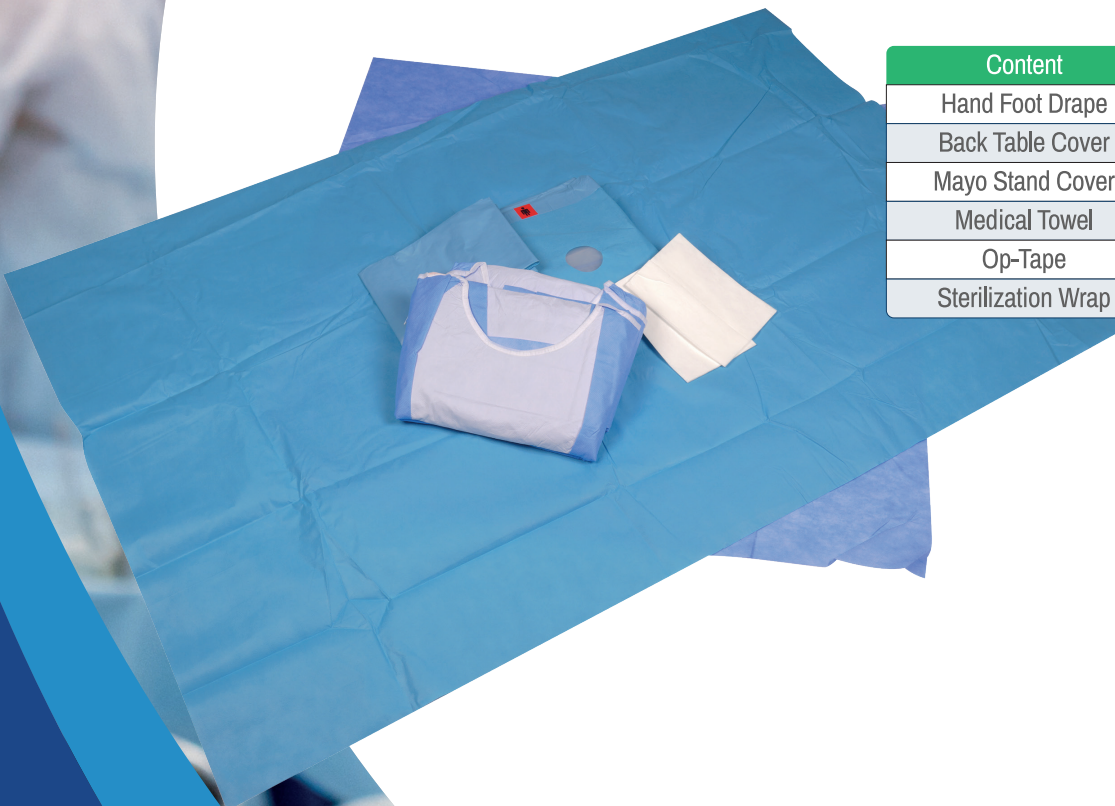
VERTEBRA PACK

Content	Size	Pcs.
Drape with Adhesive Tape	150x240	2 Pcs.
Drape with Adhesive Tape	50x120	2 Pcs.
Drape with Adhesive Tape	100x120	2 Pcs.
Back Table Cover	150x200	2 Pcs.
Universal Bag	30x35	1 Pc.
Skin Marker & Ruler		1 Pc.
Reinforced Surgical Gown	XL	2 Pcs.
Medical Towel	40x40	2 Pcs.
Op-Tape	10x50	2 Pcs.
Sterilization Wrap	100x100	1 Pc.



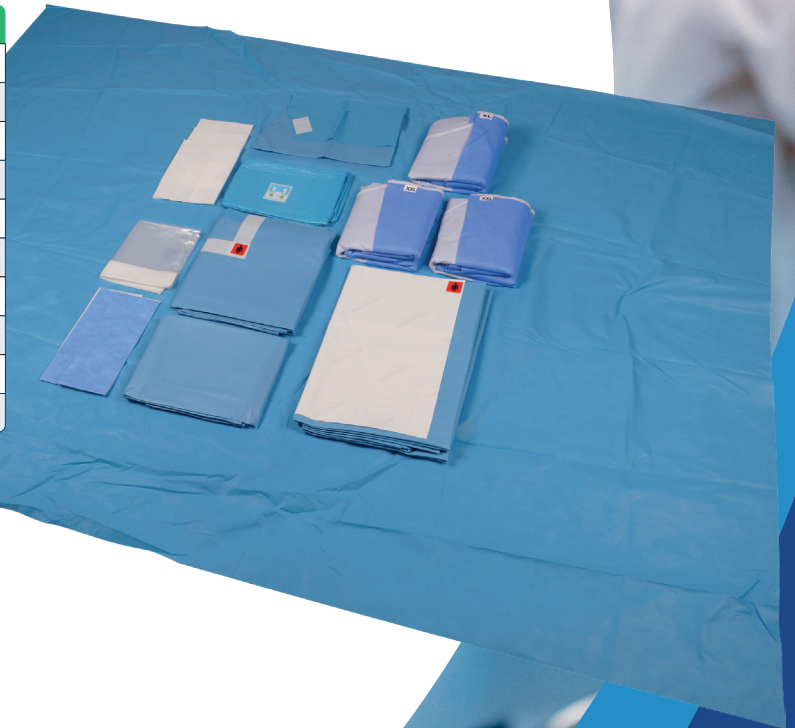
HAND FOOT PACK

Content	Size	Pcs.
Hand Foot Drape	200x300	1 Pc.
Back Table Cover	150x200	1 Pc.
Mayo Stand Cover	78x145	1 Pc.
Medical Towel	40x40	3 Pcs.
Op-Tape	10x50	1 Pc.
Sterilization Wrap	100x100	1 Pc.

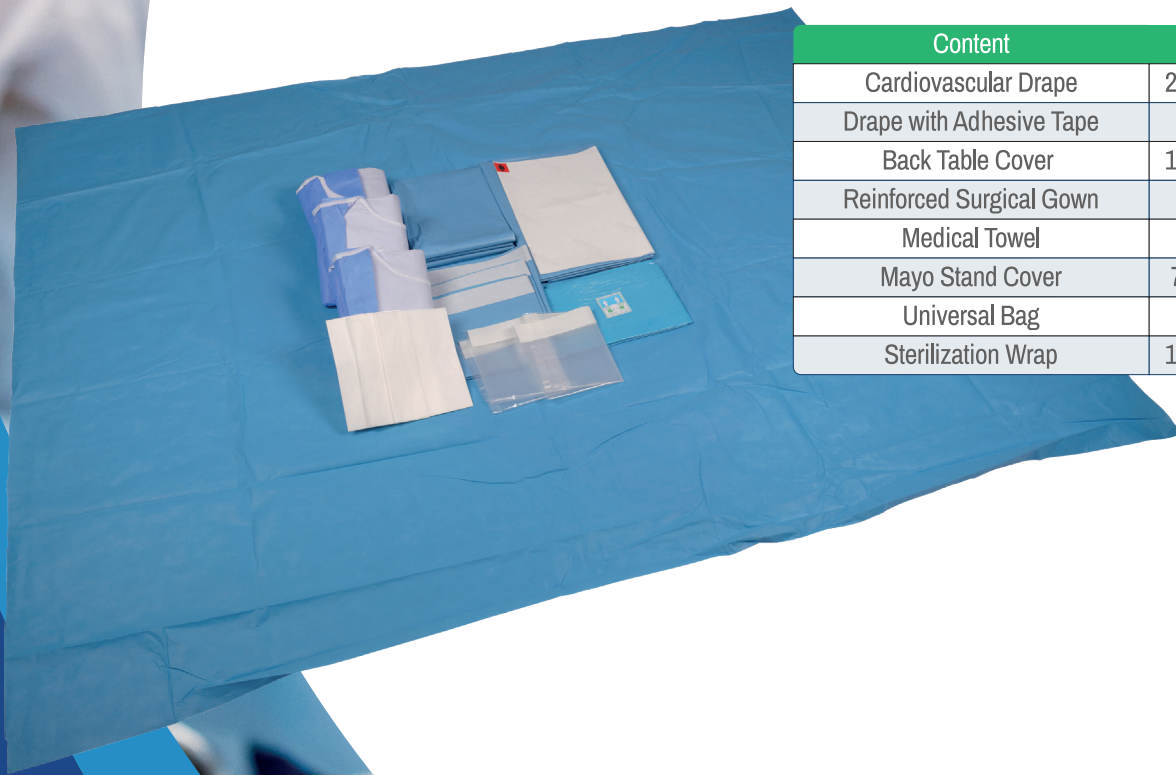


BY-PASS DRAPE PACK

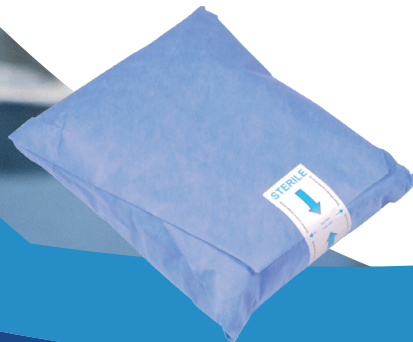
Content	Size	Pcs.
By Pass Drape	240x340	1 Pc.
Perineum Drape with U-Shaped	150x240	1 Pc.
Back Table Cover	150x200	2 Pcs.
Reinforced Surgical Gown	XL	3 Pcs.
Medical Towel	40x40	3 Pcs.
Op-Tape	10x50	2 Pcs.
Mayo Stand Cover	78x145	1 Pc.
Legging	40x75	2 Pcs.
Universal Bag	30x35	2 Pcs.
Sterilization Wrap	100x100	1 Pc.



CVC DRAPE PACK

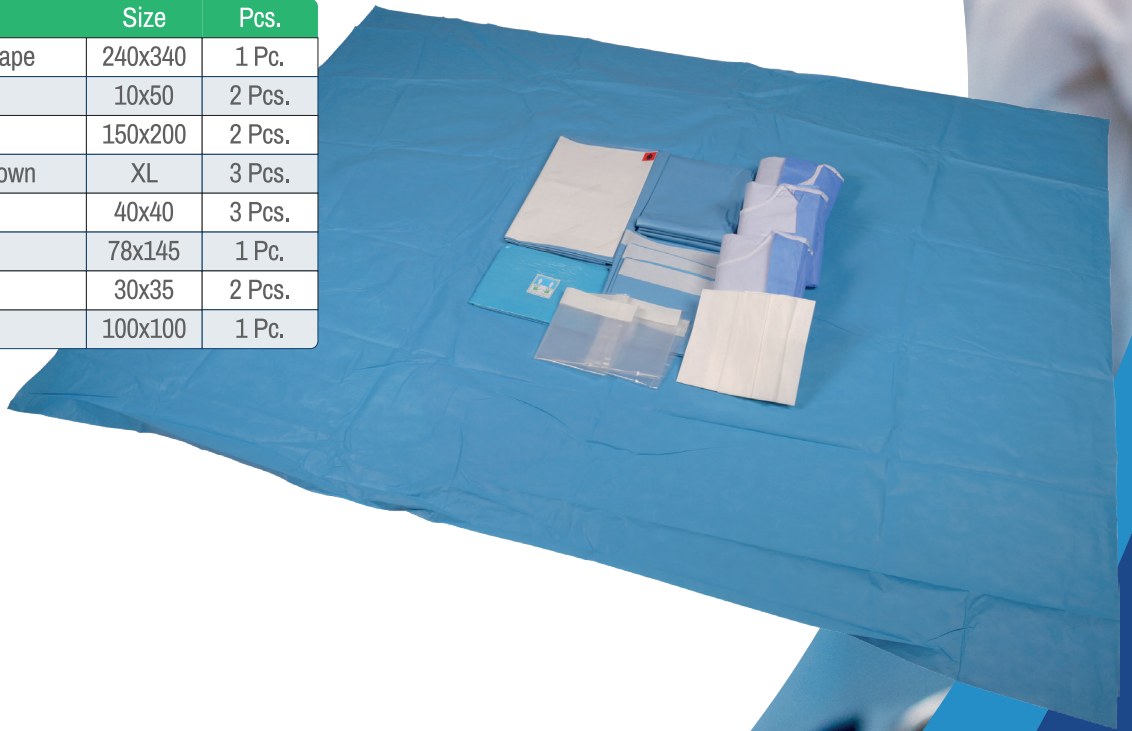


Content	Size	Pcs.
Cardiovascular Drape	200x300	1 Pc.
Drape with Adhesive Tape	75x90	3 Pcs.
Back Table Cover	150x200	2 Pcs.
Reinforced Surgical Gown	XL	3 Pcs.
Medical Towel	40x40	3 Pcs.
Mayo Stand Cover	78x145	1 Pc.
Universal Bag	30x35	2 Pcs.
Sterilization Wrap	100x100	1 Pc.



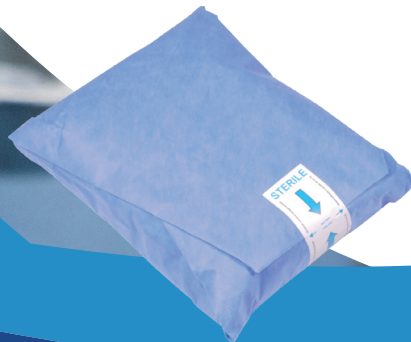
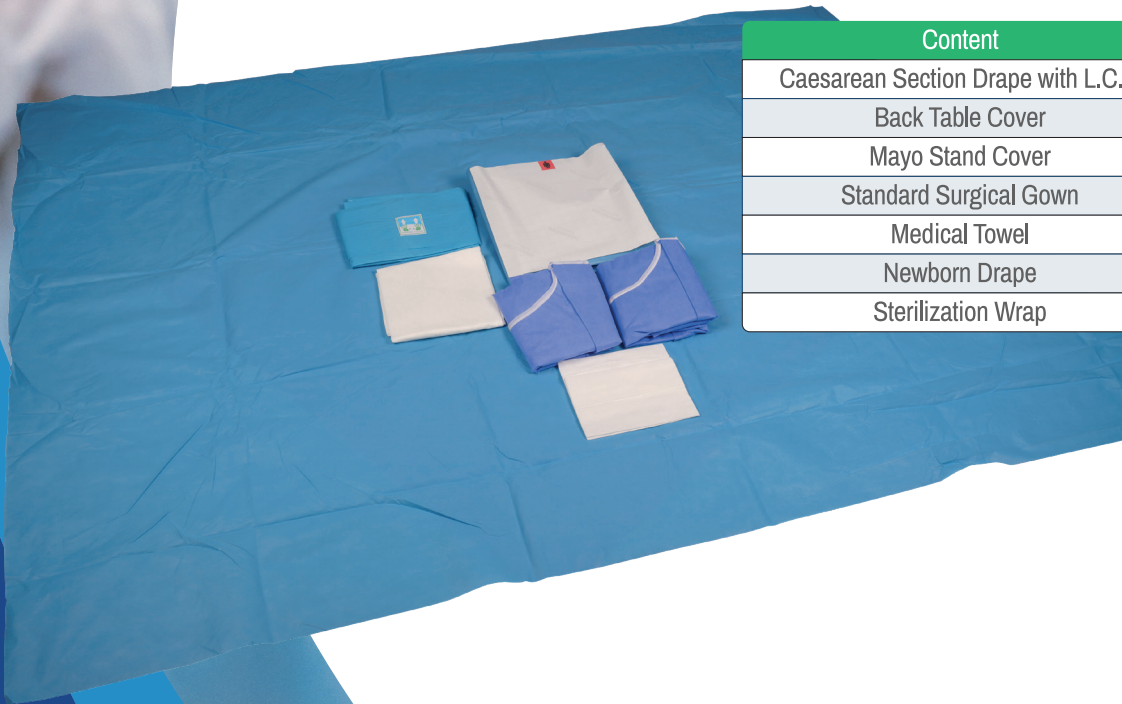
VALVE REPLACEMENT PACK

Content	Size	Pcs.
Valve Replacement Drape	240x340	1 Pc.
Op-Tape	10x50	2 Pcs.
Back Table Cover	150x200	2 Pcs.
Reinforced Surgical Gown	XL	3 Pcs.
Medical Towel	40x40	3 Pcs.
Mayo Stand Cover	78x145	1 Pc.
Universal Bag	30x35	2 Pcs.
Sterilization Wrap	100x100	1 Pc.



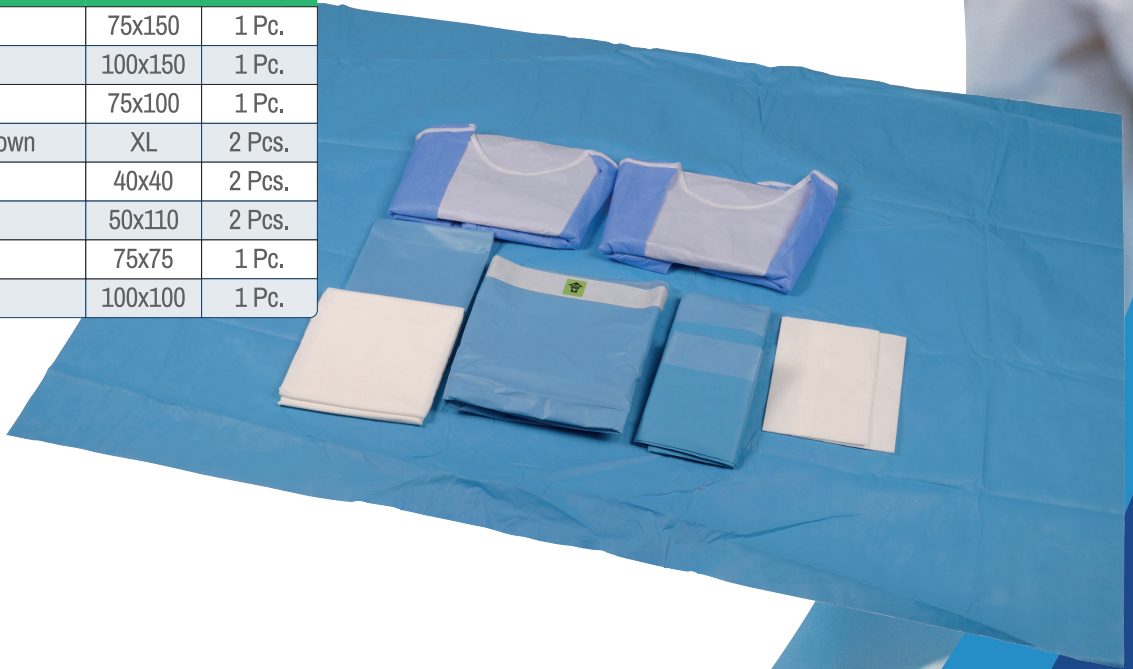
CAESAREAN SECTION DRAPE PACK

Content	Size	Pcs.
Caesarean Section Drape with L.C.P.	200x300	1 Pc.
Back Table Cover	150x200	1 Pc.
Mayo Stand Cover	78x145	1 Pc.
Standard Surgical Gown	XL	2 Pcs.
Medical Towel	40x40	2 Pcs.
Newborn Drape	75x75	1 Pc.
Sterilization Wrap	100x100	1 Pc.



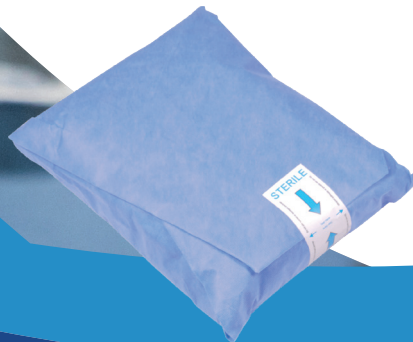
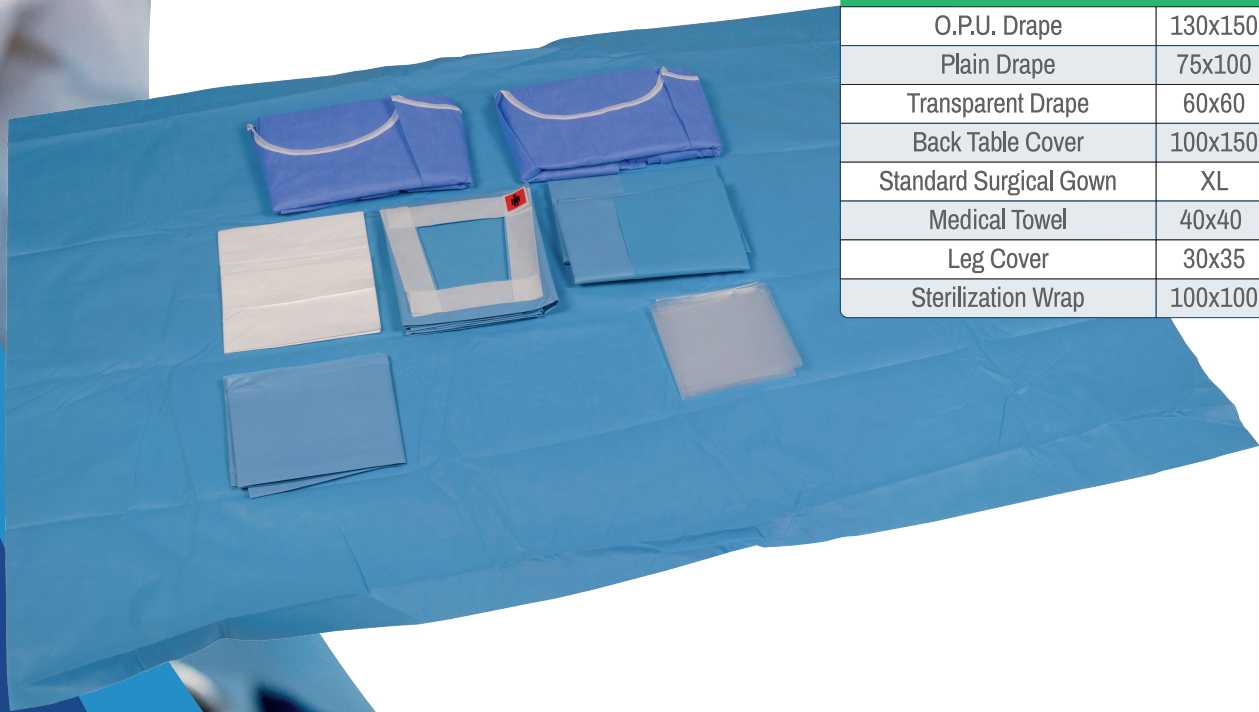
DELIVERY PACK

Content	Size	Pcs.
Abdominal Drape	75x150	1 Pc.
Back Table Cover	100x150	1 Pc.
Plain Drape	75x100	1 Pc.
Reinforced Surgical Gown	XL	2 Pcs.
Medical Towel	40x40	2 Pcs.
Leg Cover	50x110	2 Pcs.
Newborn Drape	75x75	1 Pc.
Sterilization Wrap	100x100	1 Pc.



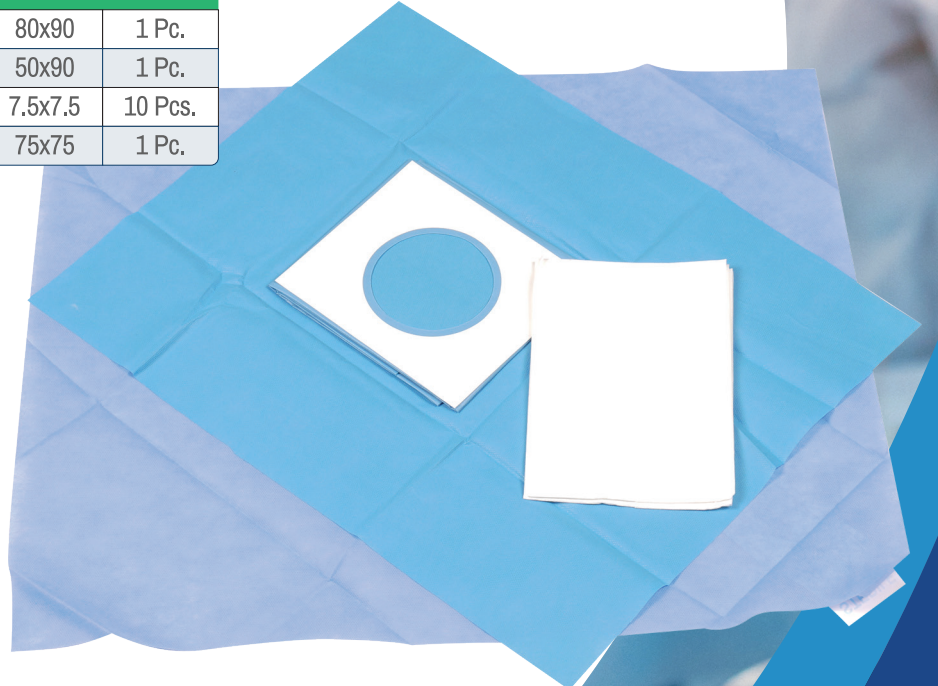
OPU DRAPE PACK

Content	Size	Pcs.
O.P.U. Drape	130x150	1 Pc.
Plain Drape	75x100	1 Pc.
Transparent Drape	60x60	1 Pc.
Back Table Cover	100x150	1 Pc.
Standard Surgical Gown	XL	2 Pcs.
Medical Towel	40x40	2 Pcs.
Leg Cover	30x35	2 Pcs.
Sterilization Wrap	100x100	1 Pc.



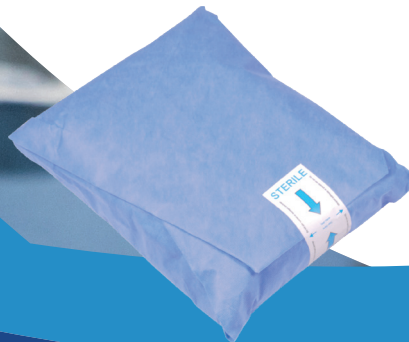
E.T PACK

Content	Size	Pcs.
Fenestrated Drape with Adhesive Tape	80x90	1 Pc.
Drape with Adhesive Tape	50x90	1 Pc.
Sponge	7.5x7.5	10 Pcs.
Sterilization Wrap	75x75	1 Pc.



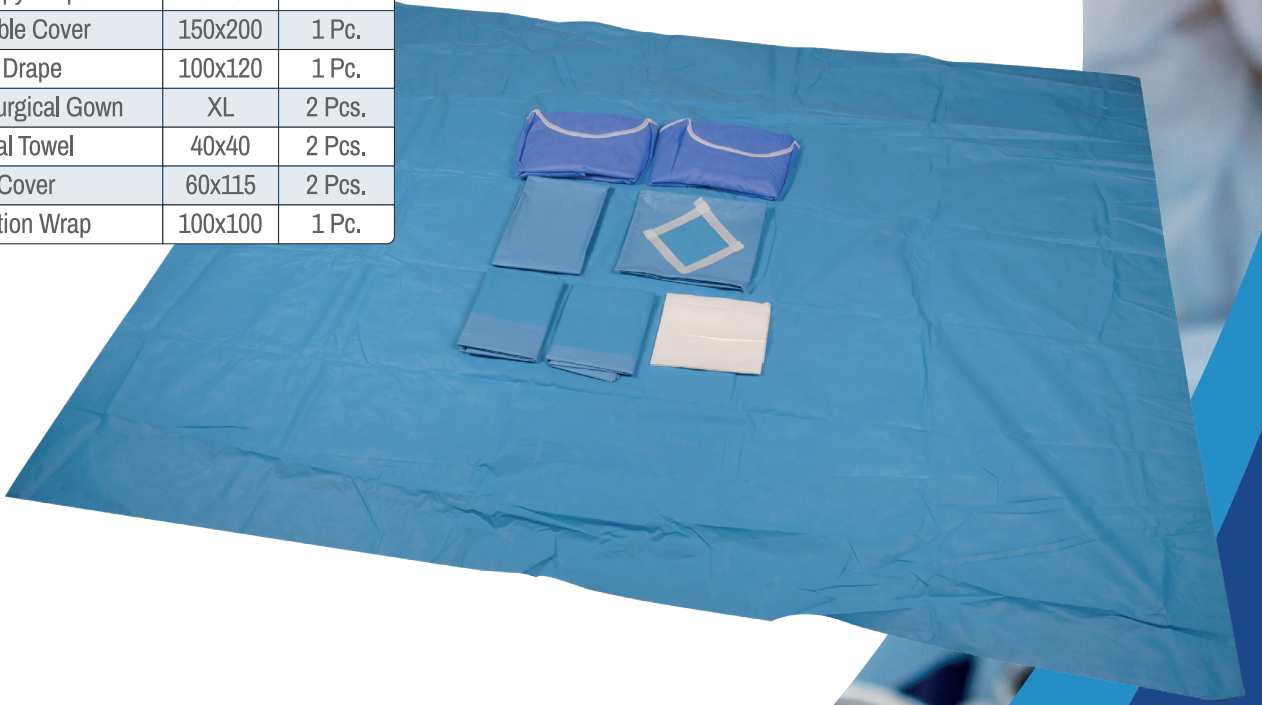
T.U.R. DRAPE PACK

Content	Size	Pcs.
T.U.R. Drape with L.C.P.	180x200	1 Pc.
Back Table Cover	100x150	1 Pc.
Plain Drape	100x120	1 Pc.
Reinforced Surgical Gown	XL	2 Pcs.
Medical Towel	40x40	2 Pcs.
Sterilization Wrap	100x100	1 Pc.



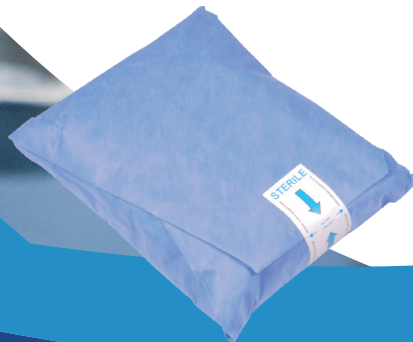
CYSTOSCOPY PACK

Content	Size	Pcs.
Cystoscopy Drape	75x150	1 Pc.
Back Table Cover	150x200	1 Pc.
Plain Drape	100x120	1 Pc.
Standard Surgical Gown	XL	2 Pcs.
Medical Towel	40x40	2 Pcs.
Leg Cover	60x115	2 Pcs.
Sterilization Wrap	100x100	1 Pc.



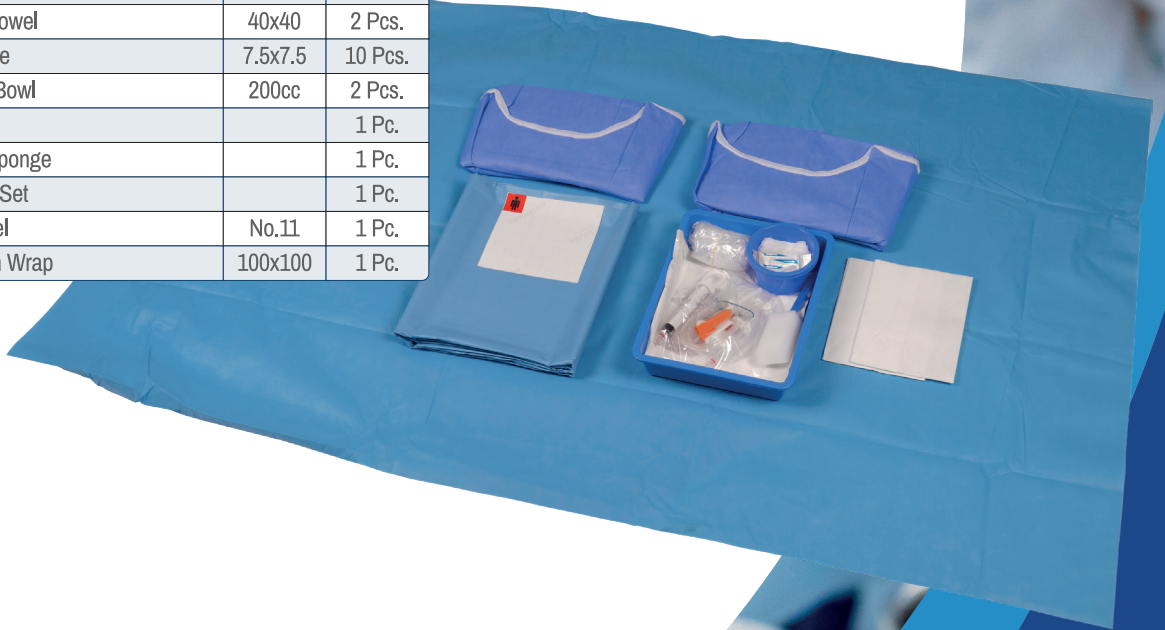
PERCUTANEOUS DRAPE

Content	Size	Pcs.
Percutaneous Drape	130x150	1 Pc.
Camera Cover	14x250	1 Pc.
Scopy Cover	90x120	1 Pc.
Back Table Cover	150x200	1 Pc.
Reinforced Surgical Gown	XL	2 Pcs.
Medical Towel	40x40	2 Pcs.
Op-Tape	10x50	2 Pcs.
Sterilization Wrap	100x100	1 Pc.



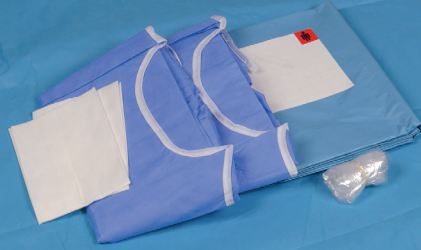
ANGIOGRAPHY DRAPE 1

Content	Size	Pcs.
Angiography Drape with Femoral and Radial Holes	180x300	1 Pc.
Fluoroscopy Cover	86cm	1 Pc.
Back Table Cover	100x150	1 Pc.
Standard Surgical Gown	XL	2 Pcs.
Medical Towel	40x40	2 Pcs.
Sponge	7.5x7.5	10 Pcs.
Solution Bowl	200cc	2 Pcs.
Tray		1 Pc.
Betadine Sponge		1 Pc.
Opaque Set		1 Pc.
Scalpel	No.11	1 Pc.
Sterilization Wrap	100x100	1 Pc.



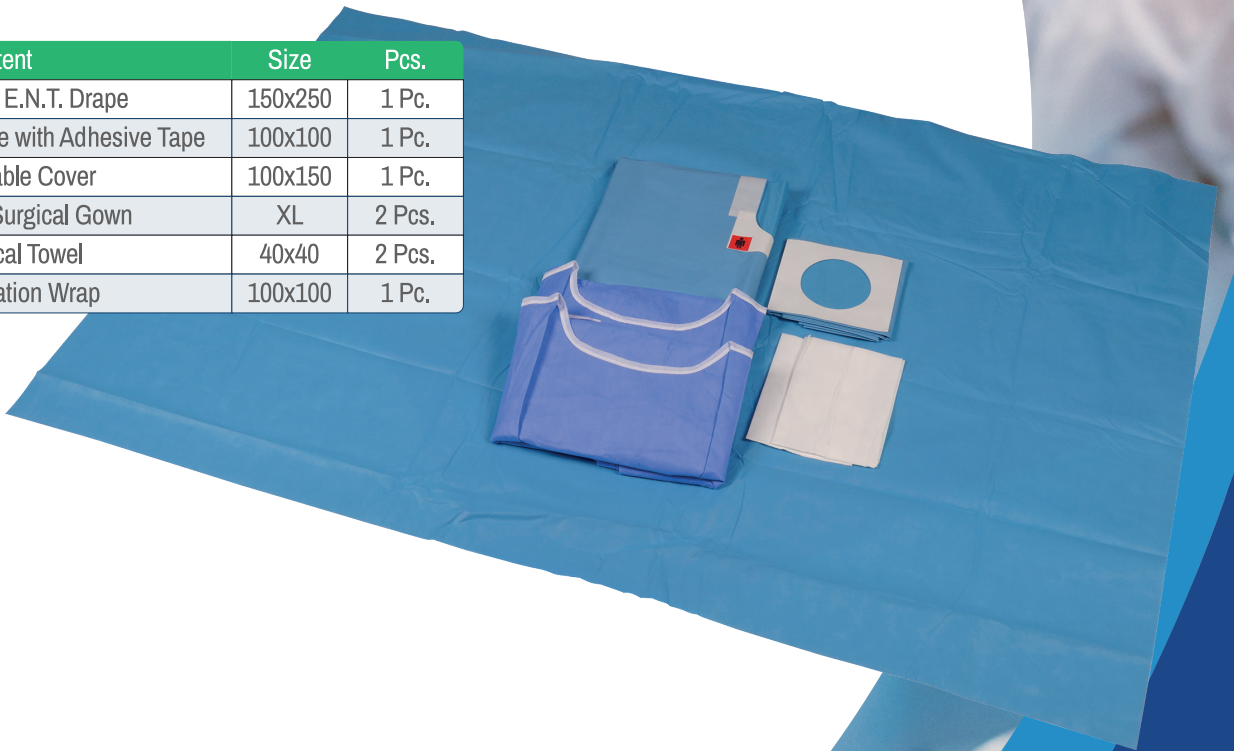
ANGIOGRAPHY DRAPE 2

Content	Size	Pcs.
Angiography Drape with Femoral Holes	150x300	1 Pc.
Fluoroscopy Cover	86cm	1 Pc.
Back Table Cover	100x150	1 Pc.
Standard Surgical Gown	XL	2 Pcs.
Medical Towel	40x40	2 Pcs.
Sterilization Wrap	100x100	1 Pc.

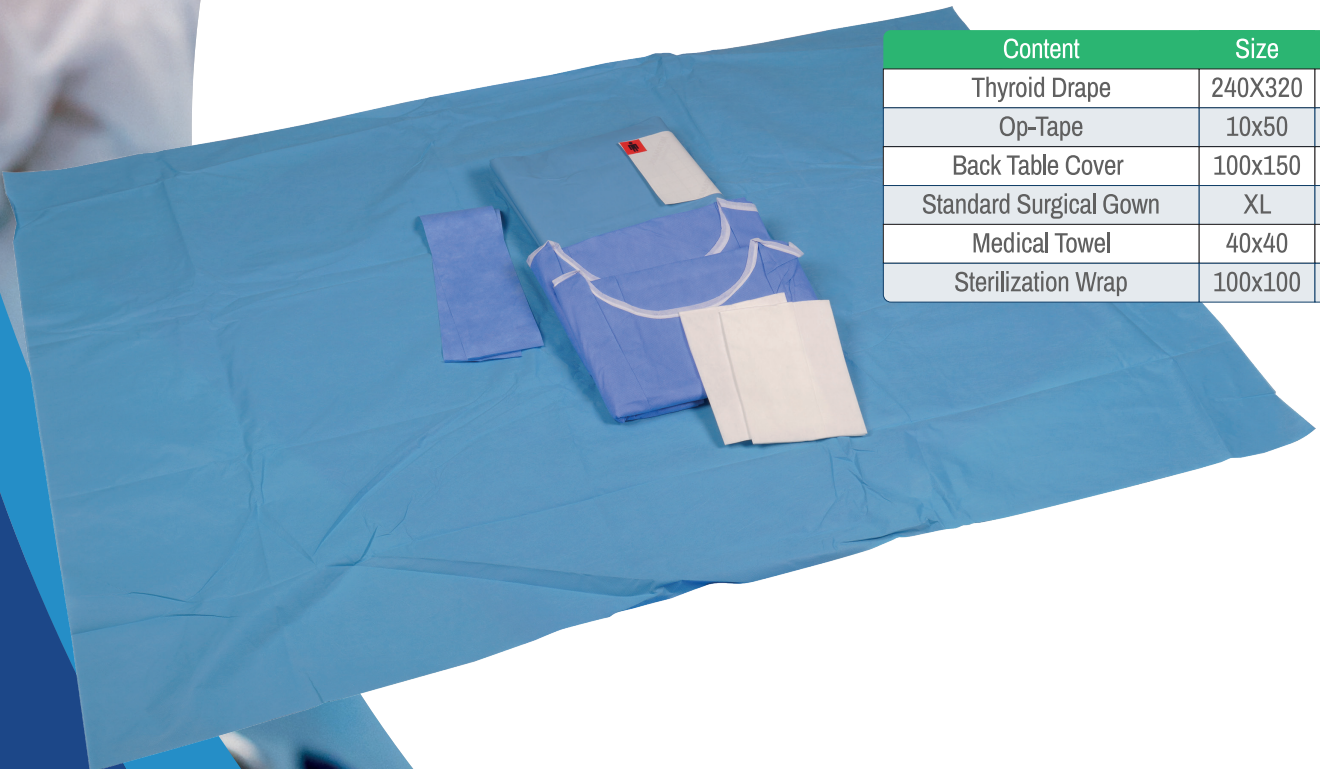


E.N.T

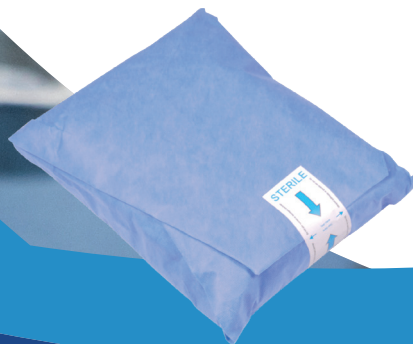
Content	Size	Pcs.
U-Shaped E.N.T. Drape	150x250	1 Pc.
Fenestrated Drape with Adhesive Tape	100x100	1 Pc.
Back Table Cover	100x150	1 Pc.
Standard Surgical Gown	XL	2 Pcs.
Medical Towel	40x40	2 Pcs.
Sterilization Wrap	100x100	1 Pc.



THYROID PACK



Content	Size	Pcs.
Thyroid Drape	240X320	1 Pc.
Op-Tape	10x50	2 Pcs.
Back Table Cover	100x150	1 Pc.
Standard Surgical Gown	XL	2 Pcs.
Medical Towel	40x40	2 Pcs.
Sterilization Wrap	100x100	1 Pc.



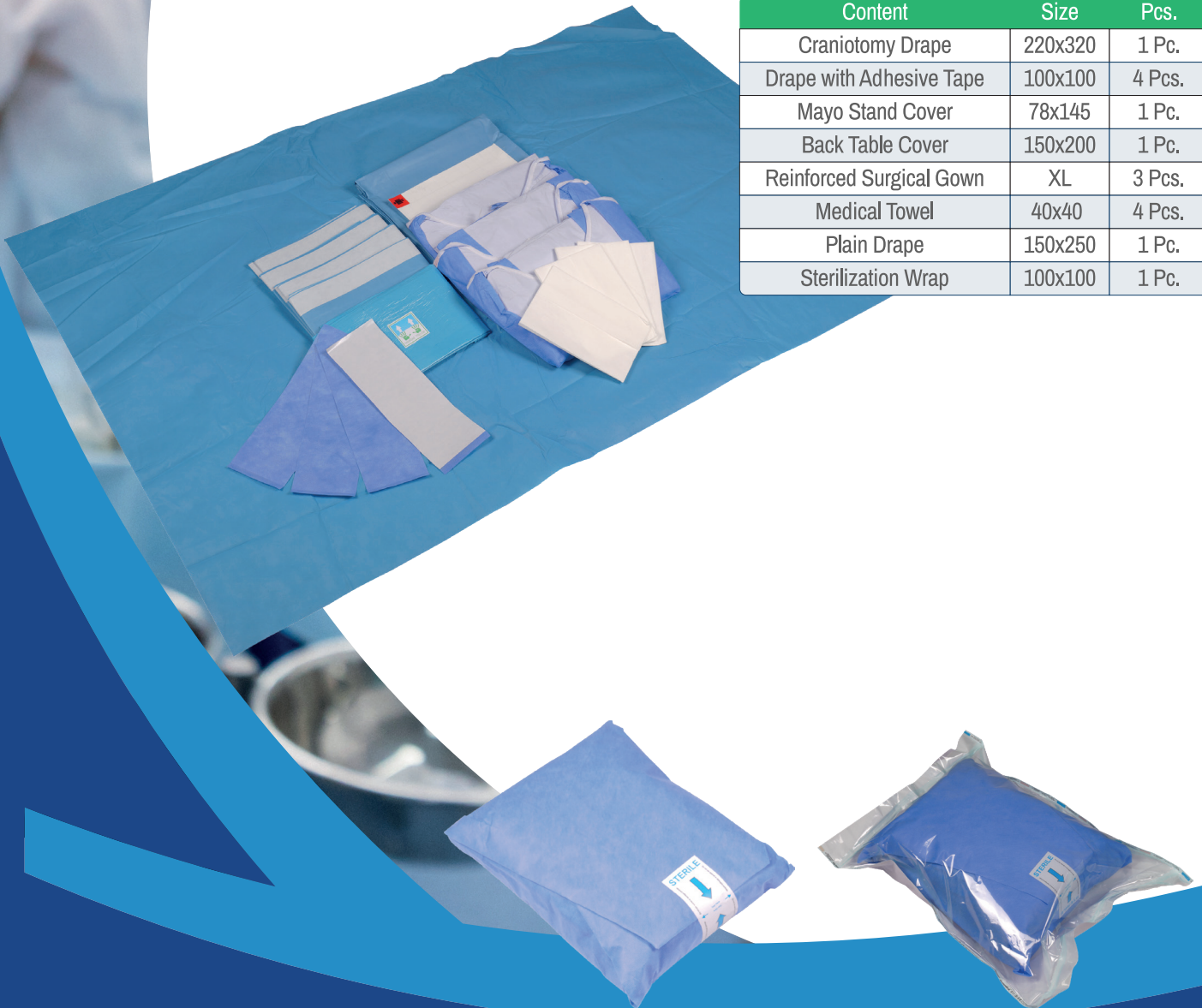
SPINAL DRAPE

Content	Size	Pcs.
Spinal Laminectomy Drape	160x300	1 Pc.
Drape with Adhesive Tape	100x120	4 Pcs.
Mayo Stand Cover	78x145	1 Pc.
Back Table Cover	100x150	1 Pc.
Reinforced Surgical Gown	XL	3 Pcs.
Medical Towel	40x40	4 Pcs.
Op-Tape	10x50	4 Pcs.
Sterilization Wrap	100x100	1 Pc.



CRANIOTOMY PACK

Content	Size	Pcs.
Craniotomy Drape	220x320	1 Pc.
Drape with Adhesive Tape	100x100	4 Pcs.
Mayo Stand Cover	78x145	1 Pc.
Back Table Cover	150x200	1 Pc.
Reinforced Surgical Gown	XL	3 Pcs.
Medical Towel	40x40	4 Pcs.
Plain Drape	150x250	1 Pc.
Sterilization Wrap	100x100	1 Pc.



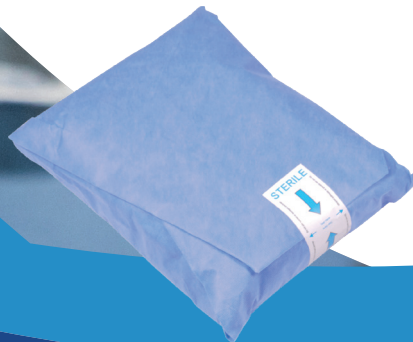
SHUNT PACK

Content	Size	Pcs.
Shunt Drape	150x300	1 Pc.
Anesthesia Drape	150x240	1 Pc.
Mayo Stand Cover	78x145	1 Pc.
Back Table Cover	150x200	1 Pc.
Reinforced Surgical Gown	XL	3 Pcs.
Medical Towel	40x40	4 Pcs.
Drape with Adhesive Tape	75x90	4 Pcs.
Plain Drape	150x180	4 Pcs.
Sterilization Wrap	100x100	1 Pc.



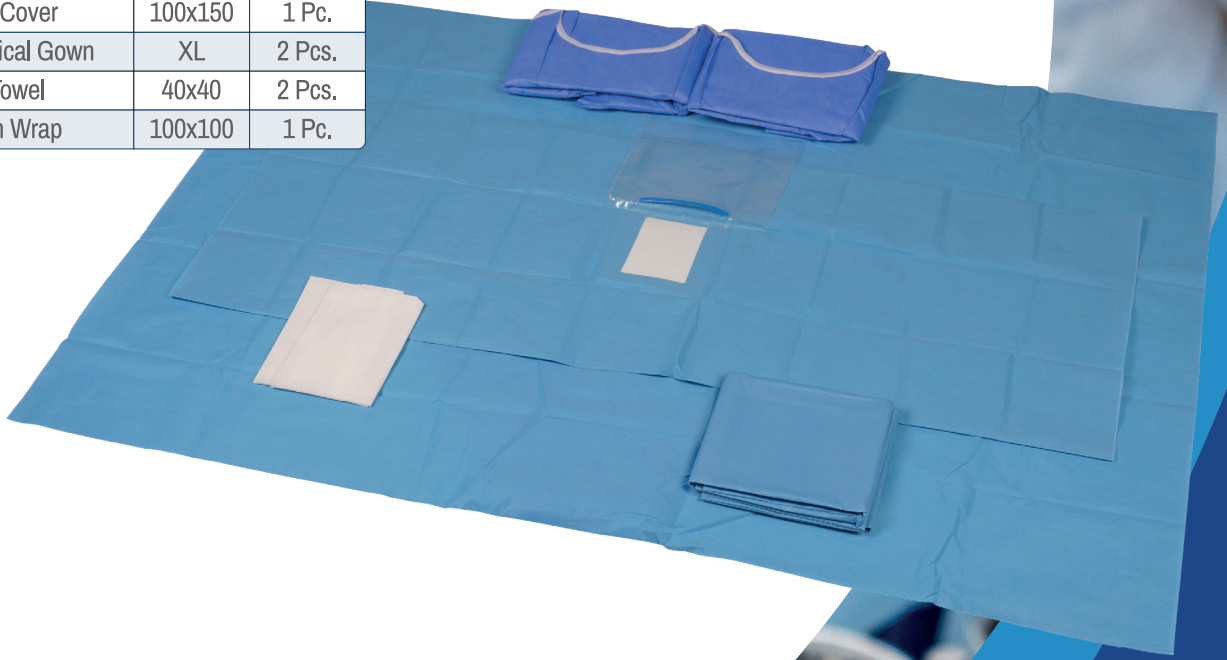
BIOPSY PACK

Content	Size	Pcs.
Biopsy Drape	120x150	1 Pc.
Sponge	7.5x7.5	10 Pcs.
Betadine Sponge		1 Pc.
Back Table Cover	100x150	1 Pc.
Standard Surgical Gown	XL	2 Pcs.
Medical Towel	40x40	2 Pcs.
Solution Bowl	500 CC	1 Pc.
Sterilization Wrap	100x100	1 Pc.



OPHTHALMIC PACK

Content	Size	Pcs.
Ophthalmic Drape with Pouch	100x130	1 Pc.
Plain Drape	150x170	1 Pc.
Back Table Cover	100x150	1 Pc.
Standard Surgical Gown	XL	2 Pcs.
Medical Towel	40x40	2 Pcs.
Sterilization Wrap	100x100	1 Pc.



SURGICAL GOWN

Compliance With Legal Requirements

Medical Device Regulation (EU) 2017/745, MDR class Is

Compliance With Product Standards

EN ISO 11135, EN 13795-1 Standard performance

Quality Standards

EN ISO 13485

Good protection with high breathability

Super comfort with soft SMS

Antistatic and alcohol repellent treated

Very high abrasion resistance

Extra soft stretchable neckline material for higher comfort

Ultrasonic sealed sleeves to increase comfort by reducing excessive materials causing discomfort

Gown with overlapping back and adjustable

Velcro in the neck enables optimal fit for individual adjustments

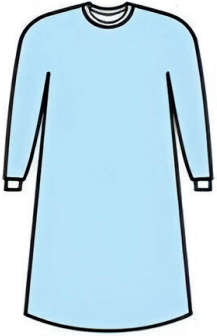
Clear stamp with size and performance type

Belt card with clear indications of sterile / non-sterile for secure donning

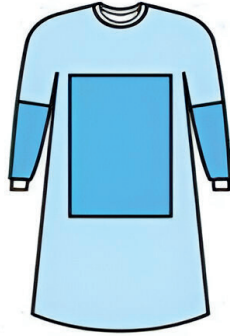


Material

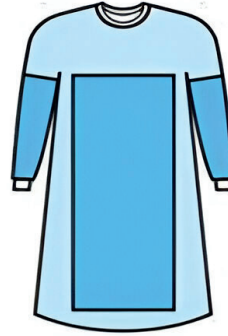
Product Part	Raw Material & Characteristics
Body, Sleeve, Belt	PP SMS Nonwoven, Blue
Cuff	PES, Rib Knitted Fabric
Neck Ribbon	PP Spunbond Nonwoven, White
Velcro Band	PA Woven Ribbon With Hook or Loop
Belt Card	Cellulose Pulp (ECF), White
Wrapping Crepe	Pulp (ECF), White
Sewing Thread	PES, White
Hand Towel	Scrim Reinforced Tissue, White



STANDARD



REINFORCED



FULL REINFORCED

UROLOGY GOWN

Zeyni's Urology Surgical Gown offers improved technology in the operating theatre and professional-level protection during surgeries. The universal gown, made of a threelayer material, provides high-level fluid protection, is impervious and keeps the user cool by way of breathable film technology.

In addition, with our gown, the following features apply:

A better fit on the user, the neck part is adjustable and closes with a hook and loop

Wider coverage in seated surgeries with the integrated pleat.



Product Specification

Color	Blue
Fabric	Nonwoven
	Biflex
	SMMS
Sterile	Yes
Disposable	Yes
Breathing	Easy
Latex Free	Yes
Skin Friendly	Yes
Recycleable	Yes
En Barrier Level	HP
Reinforcement Type	Fully Impervious
Alcohol Repellent Material	Level 10
Asepsis	Sterile
Antiseptic Present	Yes

DISPOSABLE VISITOR PATIENT GOWN

Products	Visitor Gown, Assure Air Permeability Adjustable, With Tie Closure At The Neck, It is Provided With 2 Ties. Validity 5 years from the date of production.
Fabric	PP+PE Material
Weight	40gr/m ²
Color	Medical Blue
Size	S, M, L, XL, 2XL, 3XL, 4XL

PRODUCT CONFIRMITIES

ISO 9001, ISO 13485, EN 13795, ISO 11135:2014
ISO 146443:2019, ISO 14791:2012, ISO 14937: 2009,
ISO 109937:2008, EN 20811



DISPOSABLE SCRUB SUITS

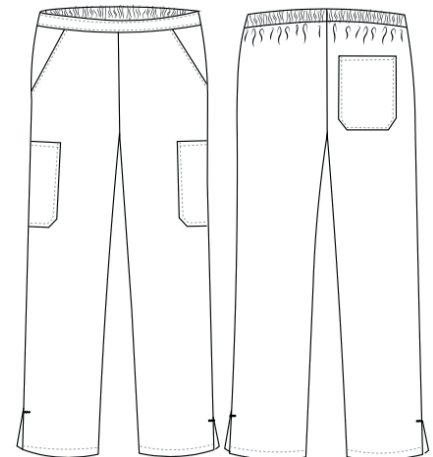
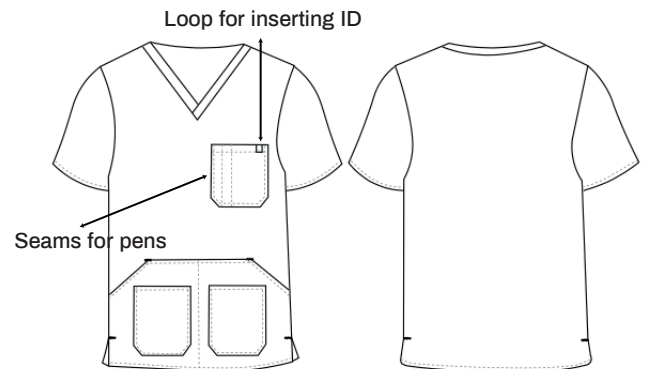


Top

- V-neck
- Short and loose sleeves
- Pockets (main fabric)
- Seams for pens
- Loop for inserting ID-card

Barteck

- Strengthen sticking at pockets
- Open pockets
- Logotype on the chest



Bottom

- Straight model
- Pockets on the sides
- Diagonal pocket
- No buttons or zippers
- Smocking elastic on the back
- Opening at the buttons of pants and top



Size Range: XS- XXXL

Color: Navy and Military green

Fabric: breathable, comfortable, sustainable, recyclable, and disposable. (Open formultiple uses).

Weight: 35-45 g/m2

COLONOSCOPY SHORTS / PANTS

Product Specification	
Color	Blue, Dark Blue, Black
Fabric	Nonwoven
	SMMS
DisposableY	Es
Breathing	Easy
Latex FreeT	Yes
Skin FriendlyY	Es
RecycleableY	Es



OVERSHOE

Non-Slip Sole
Water Resistant
Durable Elastic Band
Breathable TNT



Product Conformities

ISO 9001

ISO 13485

EN 13795

ISO 11135:2014

ISO 14644-3:2019

ISO 14791:2012

ISO 14937: 2009

ISO 10993-7:2008



EU Quality Assurance Certificate

Medical Devices Regulation (EU) 2017/745 Annex XI Part A
(Class Is, Im and Ir Devices)



Certificate Number: M.2022.MDR.1007

Manufacturer Name : Zeyni Medikal Tekstil İnş. San. Ve Tic. Ltd. Şti.
Manufacturer Address : Yunusemre Mah. 12. Yıldırım Sk. No:17 Yıldırım BURSA / TURKEY

Single registration number-SRN : TR-MF-000017474

Authorised Representative Name
(If applicable) : NA

Authorised Representative Address : NA

Product Scope : See the product list on the following page(s).

Based on the conformity assessment for the abovementioned manufacturer's quality assurance system in accordance with (EU) 2017/745 Medical Devices Regulation Annex XI Part A, UDEM Adriatic d.o.o hereby declares that the requirements of Annex XI Part A of the Regulation (EU) 2017/745 have been met for the listed products in this certificate.

The manufacturer has established, documented and implemented a quality management system, which is subject to periodic surveillance assessments by UDEM Adriatic d.o.o. according Annex XI Part A Section 7 of the aforementioned Regulation.

For the devices covered by this certificate, the involvement of UDEM Adriatic d.o.o. in the conformity assessment procedures is limited: in the case of devices placed on the market in sterile condition, to the aspects relating to establishing, securing and maintaining sterile conditions; in the case of devices with a measuring function, to the aspects relating to the conformity of the devices with the metrological requirements; in the case of reusable surgical instruments, to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

The report referenced below summarizes the result of assessments/examinations and includes reference to relevant CS, harmonized standards and test reports.

Report Number : MDR.1130
Date of Issue : 22/11/2022
Recertification Date : -
Reissue Date/No : -
Date of Expiry : 21/11/2027

UDEM Adriatic d.o.o.
General Manager



If any, Previous Certificate(s) No: NA

UDEM Adriatic d.o.o. is a Notified Body (identification no 2696) under (EU) 2017/745 Medical Devices Regulation.

Address: Rađnička cesta 54/ R3 Zagreb- Croatia
E-Mail: info@udemadriatic.com Web: www.udemadriatic.com

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UDFRH.03.M-4/00-00/30.03.2022



CERTIFICATE

ZEYNI MEDİKAL TEKSTİL İNŞAAT SANAYİ VE TİCARET LİMİTED ŞİRKETİ

YUNUSEMRE MAH. 12. YILDIRIM SOK. NO:17
YILDIRIM / BURSA / TÜRKİYE

Has been assessed and found to comply with the requirements of:
Denetlenmiş ve aşağıdaki standardın gerekliliklerine uygunluğu görülmüştür:

ISO 9001:2015

The Quality Management System is applicable to:
Kalite Yönetim Sistemi:

MANUFACTURE AND SALES OF DISPOSABLE SURGICAL STERILE GOWNS, DRAPES
AND COVER SETS, NON-STERILE MEDICAL TEXTILE PRODUCTS

TEK KULLANIMLIK CERRAHİ STERİL ÖRTÜ, ÖNLÜKLER VE ÖRTÜ SETLERİ, NON-
STERİL MEDİKAL TEKSTİL ÜRÜNLERİN ÜRETİMİ VE SATIŞI

Certificate Number: QMS-001072
Belge Numarası: QMS-001072

Initial Certification Date: 01.04.2024
İlk Belgelendirme Tarihi: 01.04.2024

Certification Period: 3 Years
Belgelendirme Periyodu: 3 Yıl

Certificate Validity Date: 31.03.2025
Belge Geçerlilik Tarihi: 31.03.2025



IQR Sertifikasyon Onayı



Health meets innovation



CERTIFICATE

ZEYNI MEDİKAL TEKSTİL İNŞAAT SANAYİ VE TİCARET LİMİTED ŞİRKETİ

YUNUSEMRE MAH. 12. YILDIRIM SOK. NO:17
YILDIRIM / BURSA / TÜRKİYE

Has been assessed and found to comply with the requirements of:
Denetlenmiş ve aşağıdaki standardın gerekliliklerine uygunluğu görülmüştür:

ISO 13485:2016

Medical Devices-Quality Management System is applicable to:
Tıbbi Cihazlar Kalite Yönetim Sistemi

MANUFACTURE AND SALES OF DISPOSABLE SURGICAL STERILE GOWNS, DRAPES
AND COVER SETS, NON-STERILE MEDICAL TEXTILE PRODUCTS

TEK KULLANIMLIK CERRAHİ STERİL ÖRTÜ, ÖNLÜKLER VE ÖRTÜ SETLERİ, NON-
STERİL MEDİKAL TEKSTİL ÜRÜNLERİN ÜRETİMİ VE SATIŞI

Certificate Number: 2024/MDQMS/000540 Initial Certification Date: 01.04.2024
Belge Numarası: 2024/MDQMS/000540 İlk Belgelendirme Tarihi: 01.04.2024

Certification Period: 3 Years
Belgelendirme Periyodu: 3 Yıl

Certificate Validity Date: 31.03.2025
Belge Geçerlilik Tarihi: 31.03.2025



IQR
IQR Sertifikasyon Onayı



CERTIFICATE

ZEYNI MEDİKAL TEKSTİL İNŞAAT SANAYİ VE TİCARET LİMİTED ŞİRKETİ

YUNUSEMRE MAH. 12. YILDIRIM SOK. NO:17
YILDIRIM / BURSA / TÜRKİYE

Has been assessed and found to comply with the requirements of:
Denetlenmiş ve aşağıdaki standardın gerekliliklerine uygunluğu görülmüştür:

ISO 14001:2015

The Environmental Management System is applicable to:
Çevre Yönetim Sistemi:

MANUFACTURE AND SALES OF DISPOSABLE SURGICAL STERILE GOWNS, DRAPES
AND COVER SETS, NON-STERILE MEDICAL TEXTILE PRODUCTS

TEK KULLANIMLIK CERRAHİ STERİL ÖRTÜ, ÖNLÜKLER VE ÖRTÜ SETLERİ, NON-
STERİL MEDİKAL TEKSTİL ÜRÜNLERİN ÜRETİMİ VE SATIŞI

Certificate Number: EMS-001072
Belge Numarası: EMS-001072

Initial Certification Date: 01.04.2024
İlk Belgelendirme Tarihi: 01.04.2024

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Belgelendirme Periyodu: 3 Yıl

Certificate Validity Date: 31.03.2025
Belge Geçerlilik Tarihi: 31.03.2025



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IQR Sertifikasyon Onayı



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Yunusemre Mah. 12. Yıldırım Sok. No:17

Yıldırım / BURSA