

Product Catalogue

**Disposable surgical gowns,
drapes and packs**





NUREL MEDİKAL, established in Bursa /TÜRKİYE in 2004 shows activity in a 5.000 sqm closed production area which covers all the standards of medical sector.

The Euroset brand is the leader in Turkish market with its disposable medical textile product range, including surgical gowns, drapes and sets.

Our production area is a clean room which meets Class 100.000 standards and all process and products are certified with ISO 9001, ISO 13485, EN13795 and CE marking.

We use latest technology and full automatic spreading, cutting, packaging and labelling machines in our production and manage our sterilization process on our own site according to EN11135-1 standards.

Our sterilization machines are latest technology and working with paramethric release system. The capacity of our sterilization unit is 48 m³ per cycle.

Nurel Medical, Euroset brand, with its fastest response to customer demand; next-generation technology, total quality management system, innovation and lean manufacturing principles adopted by an experienced management team and trained employees, is moving rapidly towards its goal of becoming one of the key players in the global market.

Our production is based on customized product which are designed according to the customer's and hospital's demands or their technical specification.

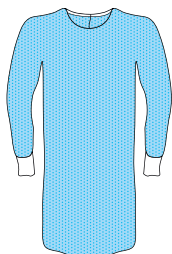
We provide various options for our customers to choose, rather than force them to accept the product that we designate; we do provide professional advice & sufficient information for our customers reference.

Today, we export to 50 different countries, and the share from the global market is growing day by day.

PRODUCTS

Surgical Gowns.....	6-7
General Surgery Packs	8-11
Angiography Packs	12-13
Cardiovascular Packs.....	14-15
ENTPacks.....	16-19
General / Abdominal Packs.....	20-21
Gynaecology Packs.....	22-25
Neuro Packs.....	26-27
C-Section / Delivery Packs.....	28-31
Ophthalmic Packs.....	32-33
Orthopaedic Packs.....	34-44
Urology Packs.....	45-46
Components.....	47-50

SMS Gowns



■ SMS



■ SMS ■ Reinforced



■ SMS

Size	Type	Reference Number
L	Standart	0003 - SMS
XL	Standart	0004 - SMS
XXL	Standart	0005 - SMS
L XLong	Standart	0006 - SMS
XL XLong	Standart	0007 - SMS
XXL XLong	Standart	0008 - SMS
Standart gown : for relatively dry procedures		
L	Polyethylene reinforced (PRF)	0202 - SMS
XL	Polyethylene reinforced (PRF)	0203 - SMS
XXL	Polyethylene reinforced (PRF)	0204 - SMS
L XLong	Polyethylene reinforced (PRF)	0205 - SMS
XL XLong	Polyethylene reinforced (PRF)	0206 - SMS
XXL XLong	Polyethylene reinforced (PRF)	0207 - SMS
Polyethylene reinforced (PRF): proofed at sleeves and chest/abdominal section, for high level wet procedures.		
Lenghts SMS: L is 120 cm, XL is 132 cm, XXL is 142		
(XLong is about 12 cm longer than the regular version)		
Elastic cuffs		
Velcro neck closure		
Sterile gown is packed with towel in a paper wrap and peelable bag		
Gowns are latexfree		
Complies with the EN 13795 norm		

Spunlace Gowns



Spunlace



Spunlace Reinforced

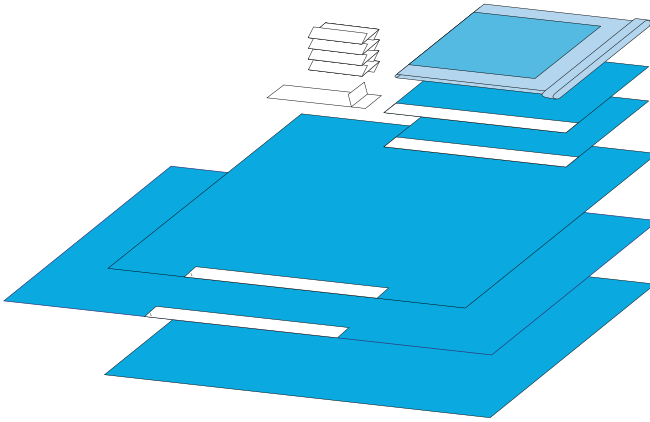


Spunlace

Size	Type	Reference Number
L	Standart	0003 - SPL
XL	Standart	0004 - SPL
XXL	Standart	0005 - SPL
L XLong	Standart	0006 - SPL
XL XLong	Standart	0007 - SPL
XXL XLong	Standart	0008 - SPL
Standart gown : for relatively dry procedures		
L	Polyethylene reinforced (PRF)	0202 - SPL
XL	Polyethylene reinforced (PRF)	0203 - SPL
XXL	Polyethylene reinforced (PRF)	0204 - SPL
L XLong	Polyethylene reinforced (PRF)	0205 - SPL
XL XLong	Polyethylene reinforced (PRF)	0206 - SPL
XXL XLong	Polyethylene reinforced (PRF)	0207 - SPL
Polyethylene reinforced (PRF): proofed at sleeves and chest/abdominal section, for high level wet procedures.		
Lenghts SMS: L is 120 cm, XL is 132 cm, XXL is 142		
(XLong is about 12 cm longer than the regular version)		
Elastic cuffs		
Velcro neck closure		
Sterile gown is packed with towel in a paper wrap and peelable bag		
Gowns are latexfree		
Complies with the EN 13795 norm		

GENERAL SURGERY PACK - 1

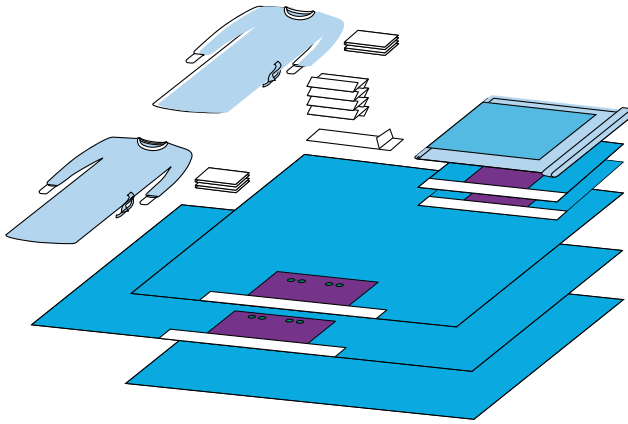
REF NO : 2000



- 1 Mayo stand cover 79x145 cm
- 4 Cellulose towel 38x38 cm
- 1 Op-tape 9x49 cm
- 2 Adhesive drape 90x75 cm
- 1 Adhesive drape 180x180 cm
- 1 Adhesive drape 240x150 cm
- 1 Table cover 150x190 cm , 75x190 cm absorbent

GENERAL SURGERY PACK - 2

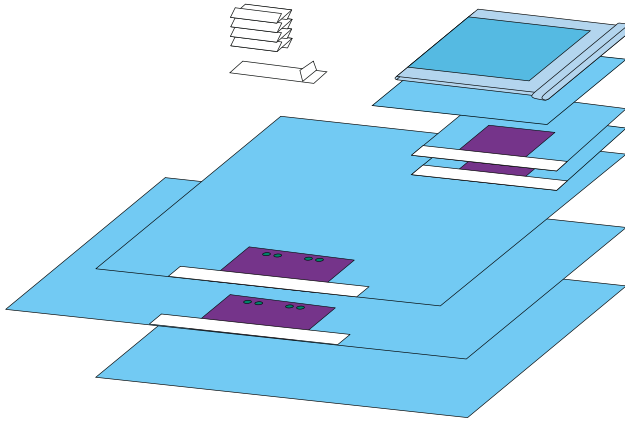
REF NO : 2018



- 1 Surgical gown L + 2 hand towel 38x38 cm
- 1 Mayo stand cover 79x145 cm
- 4 Celluose towel 38x38 cm
- 2 Adhesive drape 90x75 cm
- 1 Surgical gown L + 2 hand towel 38x38 cm
- 1 Op - tape 9x49 cm
- 1 Adhesive drape 180x180 cm
- 1 Adhesive drape 240x150 cm
- 1 Table cover 150x190 cm

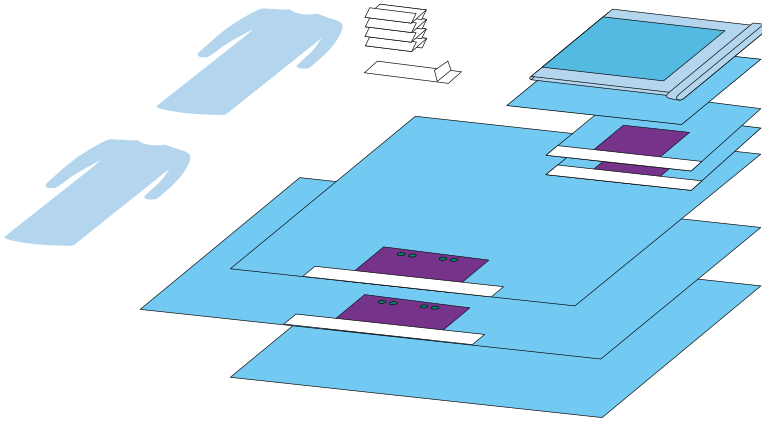
GENERAL SURGERY PACK - 3

REF NO : 2900



- 1 Mayo stand cover 79x145 cm
- 1 Adhesive drape 75x90 cm
- 4 Cellulose towel 38x38 cm
- 2 Adhesive drape 75x75 cm
- 1 Op - tape 9x49 cm
- 1 Adhesive drape 180x180 cm
- 1 Adhesive drape 240x150 cm
- 1 Table cover 150x190 cm

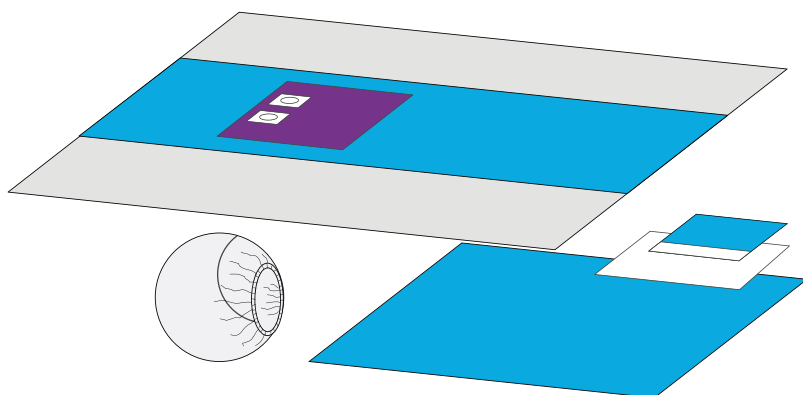
GENERAL SURGERY PACK - 4 REF NO : 2900-1



- 1 Mayo stand cover 79x145 cm
- 1 Adhesive drape 75x90 cm
- 4 Cellulose towel 38x38 cm
- 2 Standard Surgical Gown L
- 2 Adhesive drape 75x75 cm
- 1 Op - tape 9x49 cm
- 1 Adhesive drape 180x180 cm
- 1 Adhesive drape 240x150 cm
- 1 Table cover 150x190 cm

ANGIOGRAPHY PACK - FEMORAL

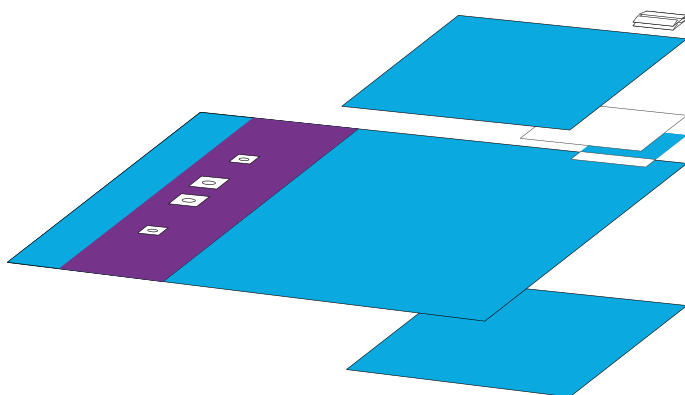
REF NO : 3200



- 1 Angiography drape 240x330cm, reinforcement 70x70cm 2 apertures 7x10 cm
- 1 Adhesive drape 50x50 cm
- 1 Fluoroscopy Cover 85x105 cm
- 1 Absorption drape 60x90 cm
- 1 Table cover 150x190 cm

ANGIOGRAPHY PACK - RADIAL & FEMORAL

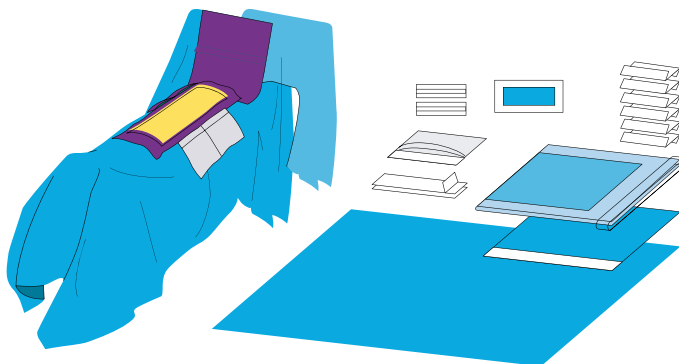
REF NO : 3208



- 1 Table cover 150x140 cm
- 2 Cellulose towel 38x38 cm
- 1 Absorption drape 60x90 cm
- 2 Adhesive drape 50x50 cm
- 1 Angiography drape 240x330 cm apertures 5x7 cm (2) and 7x9 cm (2)
- 1 Table cover 150x140 cm

THORACIC PACK

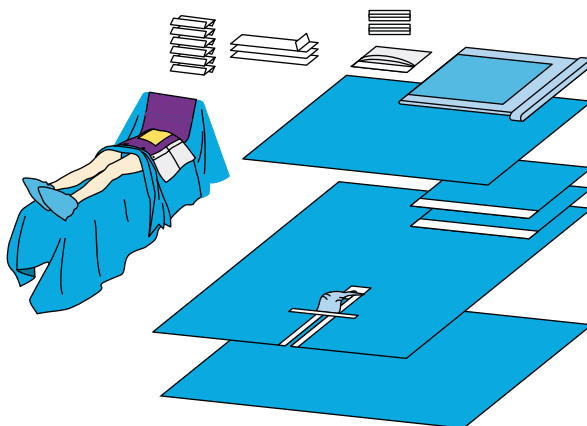
REF NO : 2005



- 1 Mayo stand cover reinforced 79x145 cm
- 1 Genital cover 18x40 cm
- 6 Cellulose towel 38x38 cm
- 2 Tube holder velcro 2,5x11 cm
- 1 Adhesive drape 75x75 cm
- 1 Suture bag 33x38 cm
- 2 Op-tape 9x49 cm
- 1 Acute thoracic drape 200/300x340cm incise area 37x65cm
- 1 Table cover 150x240 cm

CARDIOVASCULAR PACK

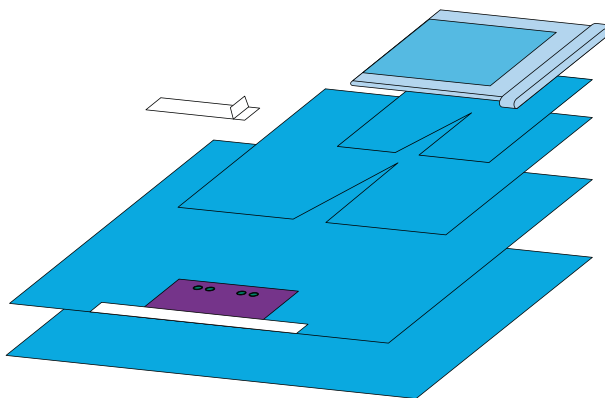
REF NO : 2604



- 1 Mayo stand cover reinforced 79x145 cm
- 6 Cellulose towel 38x38 cm
- 1 Table cover 150x190 cm
- 2 Adhesive Drape 75x90 cm
- 1 Suture bag 33x38 cm
- 2 Tube holder velcro 2,5x11 cm
- 3 Op-tape 9x49 cm
- 2 Foot cover
- 1 Lower vascular drape 200x260 cm, split 20x102 cm
- 1 Thoracic drape 200/300x330 cm incise area 32x40 cm
- 1 Table cover 150x240 cm

HEAD PACK

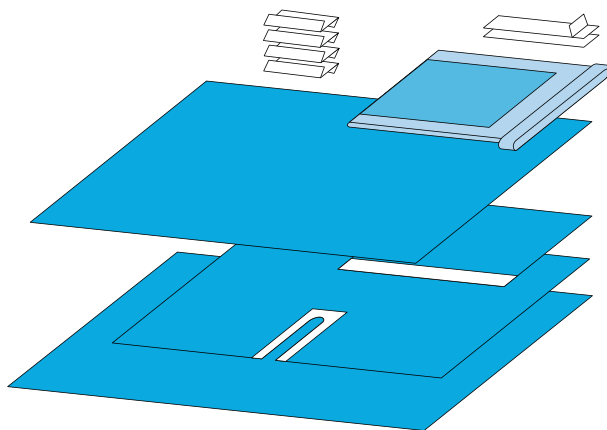
REF NO : 3808



- 1 Mayo stand cover 79x145 cm
- 1 Op-tape 9x49 cm
- 1 Head drape 150x175 cm
- 1 Head drape 106x103 cm
- 1 Adhesive drape 175x175 cm
- 1 Table cover 150x190 cm

ENT PACK

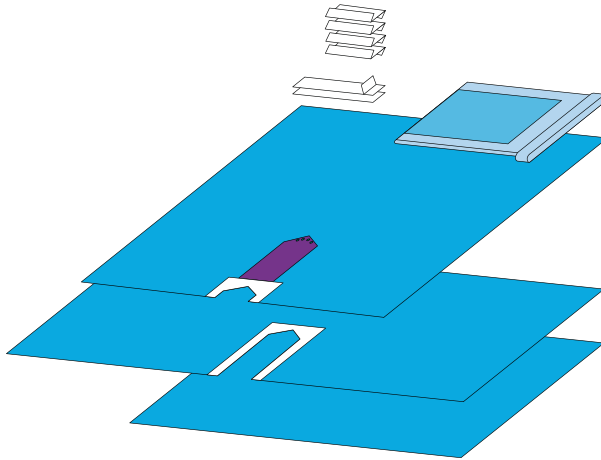
REF NO : 3606



- 1 Mayo stand cover reinforced 79x145 cm
- 4 Cellulose towel 38x38 cm
- 1 Op-sheet 150x175 cm
- 1 Adhesive drape 75x75 cm
- 1 Op-tape 9x49 cm
- 1 Adhesive split sheet 150x125 cm split 7x45 cm
- 1 Table cover 150x240 cm

NECK PACK

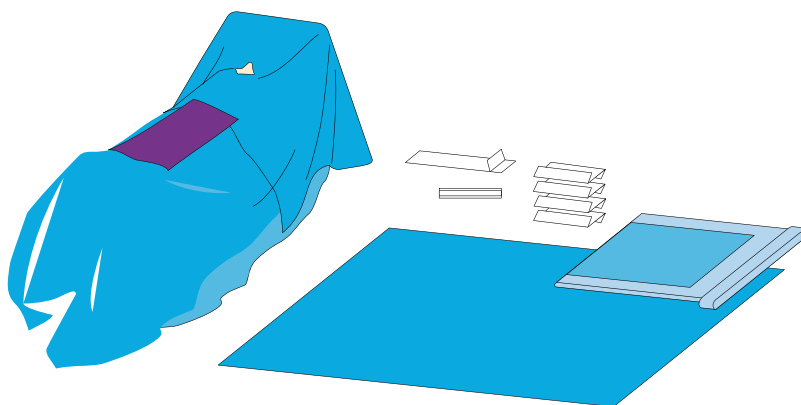
REF NO : 3601



- 1 Mayo stand cover 79x145 cm
- 4 Cellulose towel 38x38 cm
- 1 Op-tape 9x49 cm
- 1 Body drape 180x230 cm, split 20x20 cm
- 1 Head drape 260x150 cm split 20x65 cm
- 1 Table cover 150x190 cm

THYROID PACK

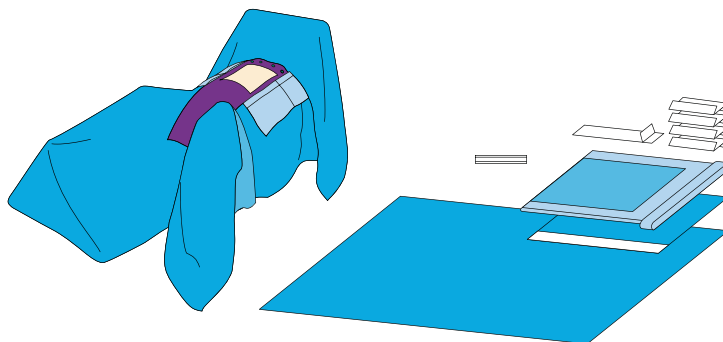
REF NO : 3604



- 1 Mayo stand cover 79x145 cm
- 4 Cellulose towel 38x38 cm
- 1 Op - tape 9x49 cm
- 1 Tube holder velcro 2,5x11 cm
- 1 Adhesive aperture drape 200/280x350 cm aperture 11x11 cm
- 1 Table cover 150x190 cm

LAPAROSCOPY PACK - ABDOMINAL / PERINEAL

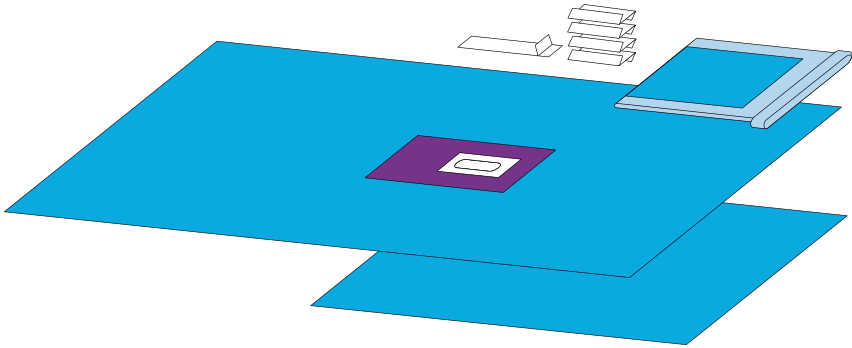
REF NO :2813



- 1 Mayo stand cover 79x145 cm
- 1 cellulose towel 38x38 cm
- 1 Op - tape 9x49 cm
- 1 Tube holder velcro 2,5x11 cm
- 1 Adhesive drape 75x75 cm
- 1 Laparoscopy drape 250/175/270x260 cm
- 25x30 cm and 13x24 cm
- 1 Table cover 150x190 cm

LAPAROTOMY PACK

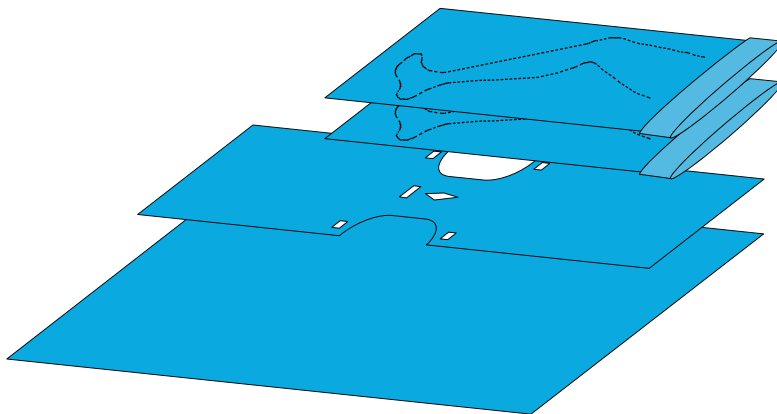
REF NO : 3803



- 1 Mayo stand cover 79x145 cm
- 4 Cellulose towel 38x38 cm
- 1 Op - tape 9x49 cm
- 1 Laparoscopy drape 200x315 cm, aperture 11x22
- 1 Table cover 150x190 cm

CYSTOSCOPY PACK

REF NO :2812



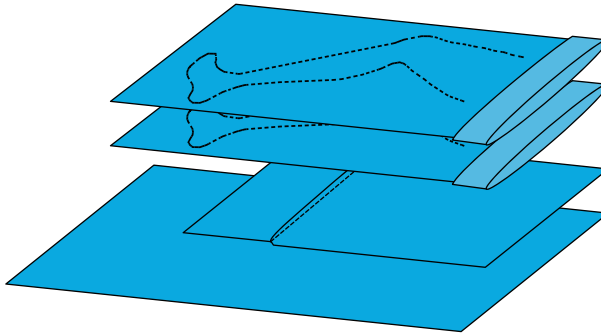
2 Leggings 75x120 cm

1 Aperture drape 75x175 cm, aperture 9x15 cm

1 Table cover 150x190 cm

LITHOTOMY PACK

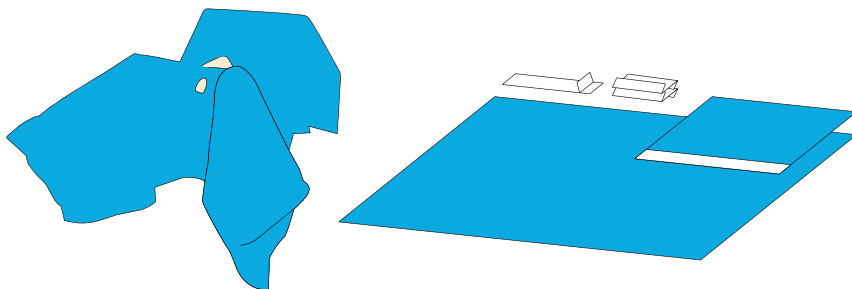
REF NO : 2816



- 2 Leggings 75x120 cm
- 1 Under buttocks drape 75x100 cm
- 1 Drape 90x150 cm
- 1 Back Table Cover 150x190cm

LAPAROSCOPY PACK

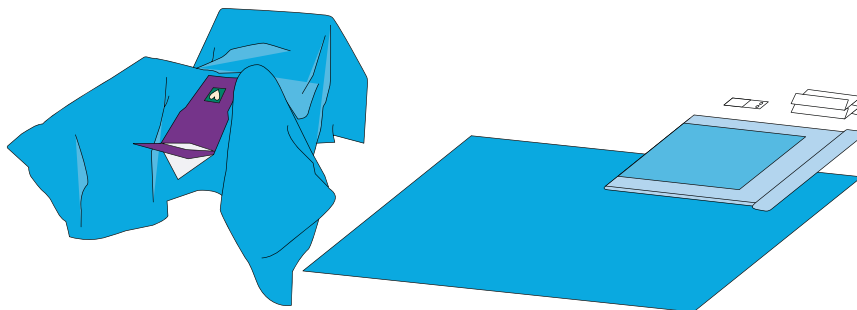
REF NO :2806



- 2 Cellulose towel 38x38 cm
- 1 Op-tape 9x49 cm
- 1 Adhesive drape 75x75 cm
- 1 Laparoscopy drape w/leggings 250/270x310 cm Triangular aperture
26x20 cm 7,5x13 cm
- 1 Table cover 150x190 cm

GYNAECOLOGY PACK

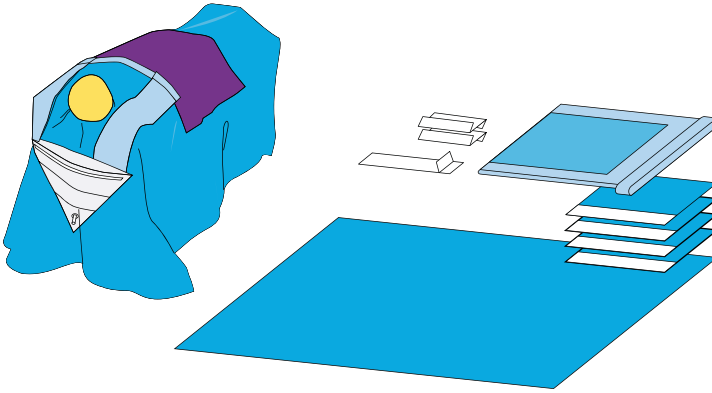
REF NO : 2405



- 1 Mayo stand cover 79x145 cm
- 2 Cellulose towel 38x38 cm
- 1 Tube holder 9x18 cm
- 1 Gyn drape 60x116 cm w/pouch, aperture 8x11 cm
- 1 Base drape w/leggings 200/270x215 cm
- 1 Table cover 150x190 cm

CRANIOTOMY PACK-1

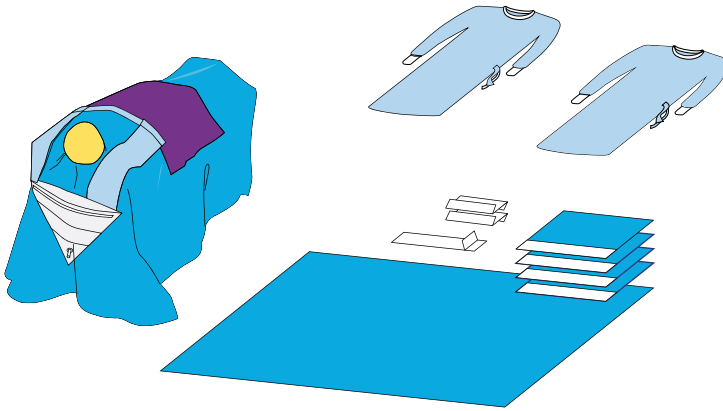
REF NO :3800-1



- 1 Mayo stand cover 79x145 cm
- 2 Cellulose towel 38x38 cm
- 1 Op-tape 9x49 cm
- 4 Adhesive towel 50x50 cm
- 1 Craniotomy drape 230x290 cm incise area 30x20 cm
- 1 Table cover 150x190 cm

CRANIOTOMY PACK-2

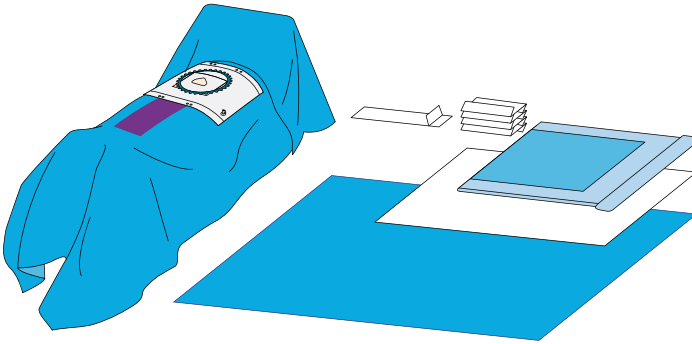
REF NO : 3800-2



- 2 Cellulose towel 38x38 cm
- 1 Op - tape 9x49 cm
- 4 Adhesive towel 50x50 cm
- 1 Craniotomy drape 230x290 cm incise area 30x20 cm
- 1 Table cover 150x190 cm
- 2 Reinforced surgical gown large

C-SECTION PACK -1

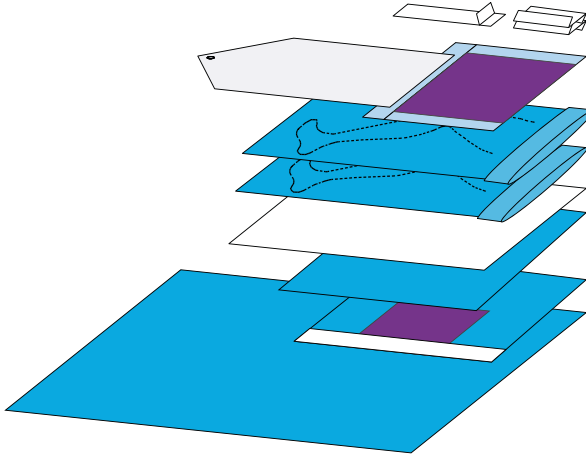
REF NO :2204-1



- 1 Mayo stand cover 79x145 cm
- 4 Cellulose towel 38x38 cm
- 4 Cellulose towel 38x38 cm
- 1 Op - tape 9x49 cm
- 1 Baby wrap 90x120 cm
- 1 Sectio drape 175/250x300cm incise area 38x32cm aperture 18x16cm
- 1 Table cover 150x190cm

DELIVERY PACK

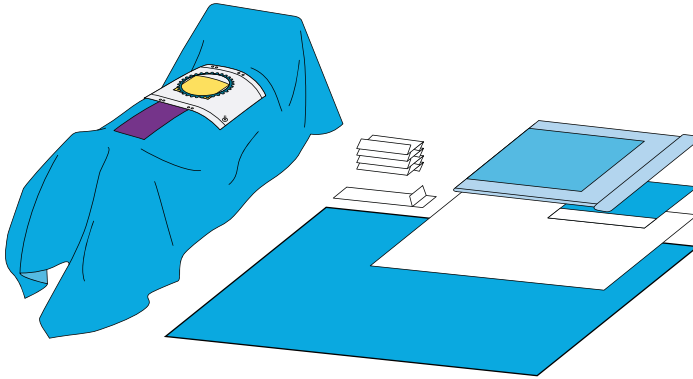
REF NO :2202



- 1 Op-tape 9x49 cm
- 2 Cellulose towel 38x38 cm
- 1 Under buttocks drape 86x112 cm with pouch
- 2 Leggings 75x120 cm
- 1 Baby wrap 100x100 cm
- 1 Utility drape 75x90 cm
- 1 Adhesive drape 75x75 cm
- 1 Table cover 150x190 cm

C-SECTION PACK-2

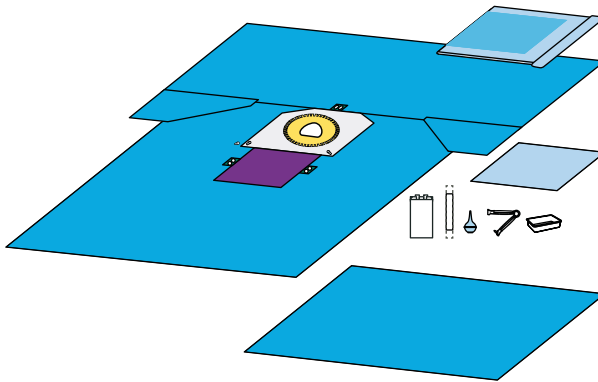
REF NO :2204-2



- 1 Mayo stand cover 79x145 cm
- 4 Cellulose towel 38x38 cm
- 1 Op-tape 9x49 cm
- 1 Adhesive towel 50x50 cm
- 1 Baby wrap 90x120 cm
- 1 C- section drape 175/250x300cm folded length wise,
- 1 Table cover 150x190 cm

C-SECTION PACK-3

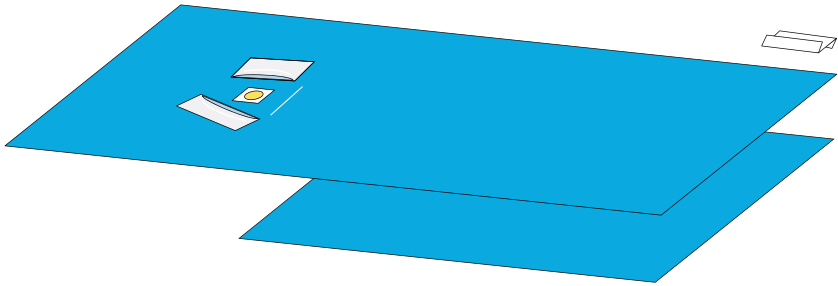
REF NO :2204-3



- 1 Mayo stand cover 79x145 cm
- 1 Suture bag 16.5x28.5 cm
- 1 Bulb syringe 60 ml
- 1 Towel
- 1 Cord clamp 6 cm
- 1 Placenta basin
- 1 C-section drape 196/257x325cm pouch 77x71cm, incise area 38x30cm, aperture 20x15 cm
- 1 Baby blanket 77x77 cm
- 1 Table cover 150x200 cm

OPHTHALMIC PACK-1

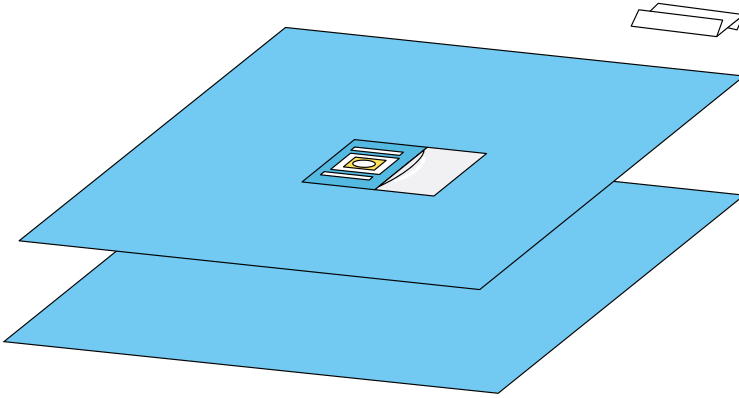
REF NO :4000-1



- 1 Cellulose towel 38x38 cm
- 1 Ophthalmic drape 150x300 cm w/pouches, incise area 8x10 cm
- 1 Table cover 150x190 cm

OPHTHALMIC PACK-2

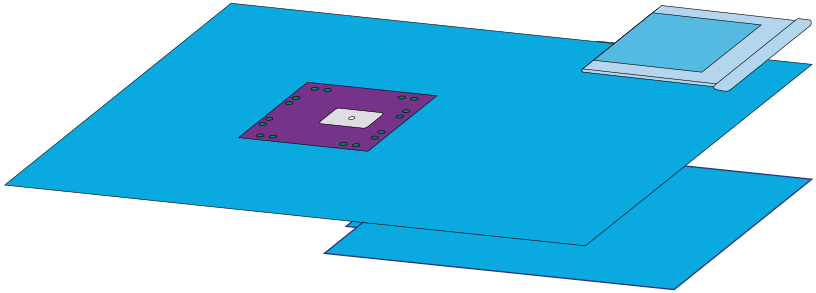
REF NO :4000-2



- 1 Cellulose towel 38x38 cm
- 1 Ophthalmic drape 140x150cm w/pouches, incise area 8x10cm, aperture 3,5x6,5cm
- 1 Table cover 150x190 cm

HAND / FOOT PACK

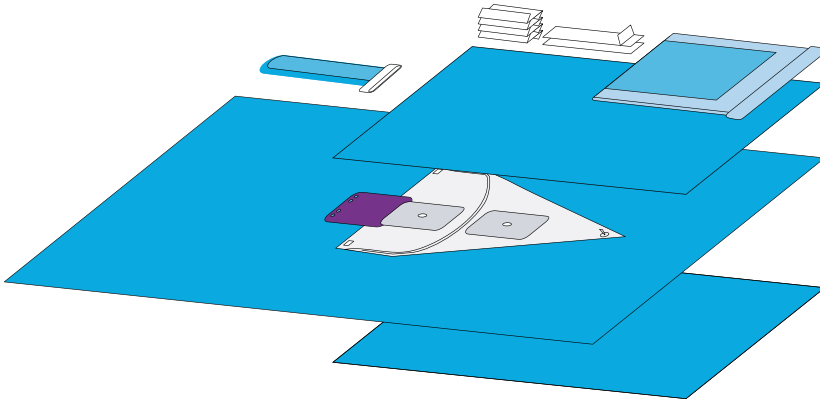
REF NO :2016



- 1 Mayo stand cover 79x145 cm
- 1 Hand & foot drape 230x315 cm 3,5 cm elastic
- 1 Table cover 150x190 cm

KNEE ARTHROSCOPY PACK

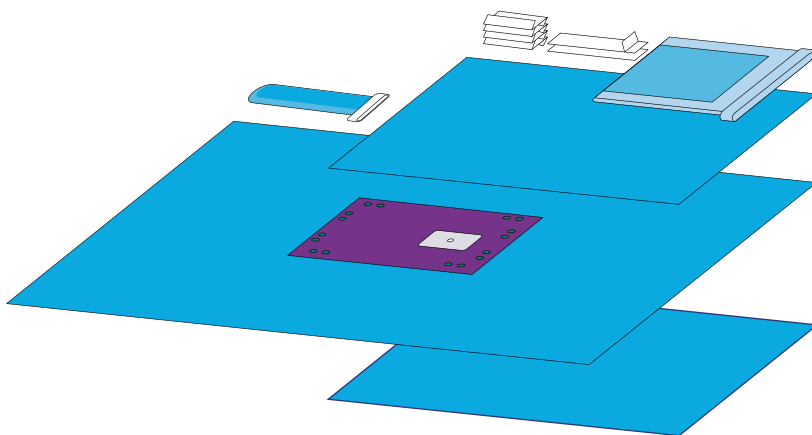
REF NO :3007



- 1 Mayo stand cover 79x145 cm
- 4 Cellulose towel 38x38 cm
- 1 Table cover 150x190 cm
- 1 Op-tape 9x49 cm
- 1 Stockinet small 22x75 cm
- 1 Knee arthroscopy drape 200x320 cm aperture 5 cm elastic
- 1 Table cover 150x190 cm

EXTREMITY PACK

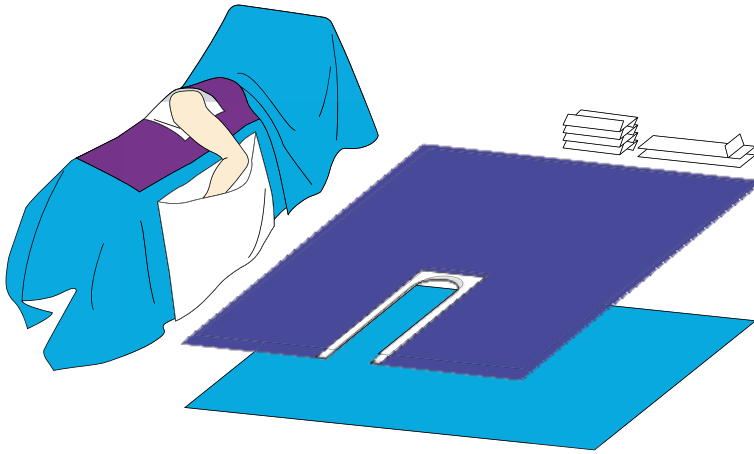
REF NO :3002-1



- 1 Mayo stand cover 79x145 cm
- 1 Table cover 150x190 cm
- 4 Cellulose towel 38x38 cm
- 1 Op-tape 9x49 cm
- 1 Stockinet small 22x75 cm
- 1 Extremity drape 230x315 cm, aperture 7 cm elastic
- 1 Table cover 150x190 cm

HIP PACK -1

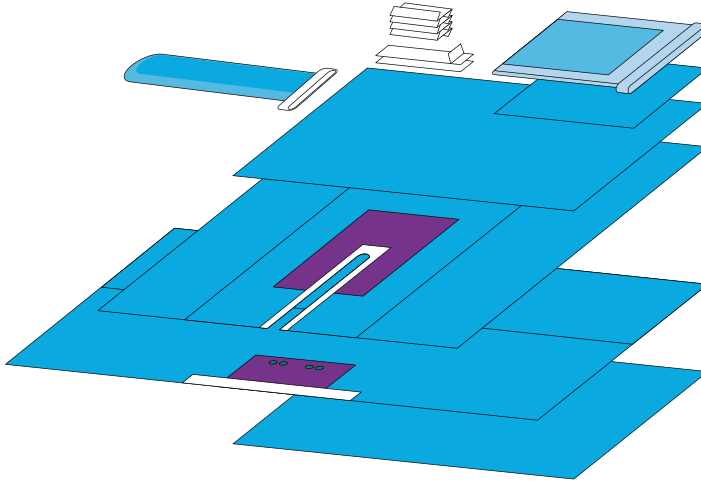
REF NO :3003-1



- 4 Cellulose towel 19x25 cm
- 2 Op-tabe 9x49 cm
- 1 Adhesive split drape 150x200 cm plastic, split 20x80 cm
- 1 Hip drape 230/300x350 cm, aperture 16x19 cm elastic
- 1 Table cover 150x190 cm

HIP PACK -2

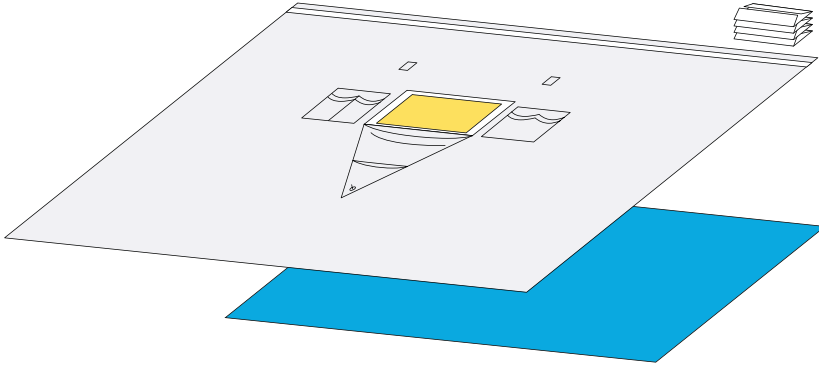
REF NO :3003-2



- 1 Mayo stand cover 79x145 cm
- 4 Cellulose towel 38x38 cm
- 1 Utility drape 75x90 cm
- 1 Table cover 150x190 cm
- 1 Stockinet large 32x120 cm
- 2 Op - tape 9x49 cm
- 1 Adhesive split sheet 200x260 cm split 7x102 cm
- 1 Adhesive op - sheet 300x180 cm
- 1 Table cover 150x190 cm

VERTICAL ISOLATION PACK

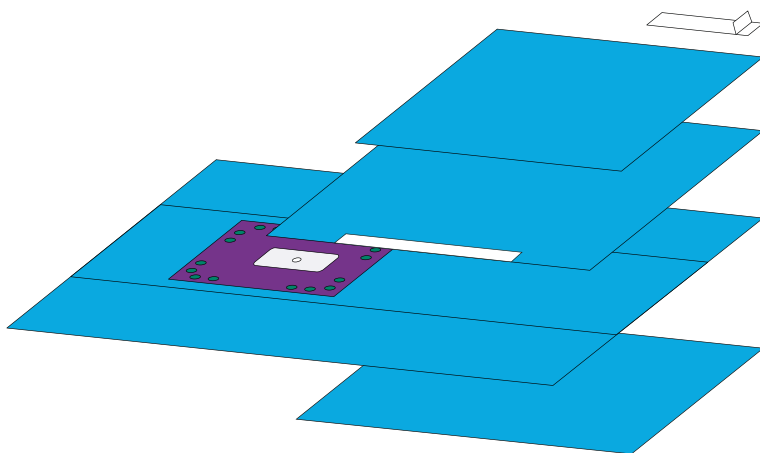
REF NO :1259



- 4 Cellulose towel 38x38 cm
- 1 Vertical isolation drape 330x240 cm, incise area 30x40 cm
- 1 Table cover 150x190 cm

UPPER EXTREMITY PACK

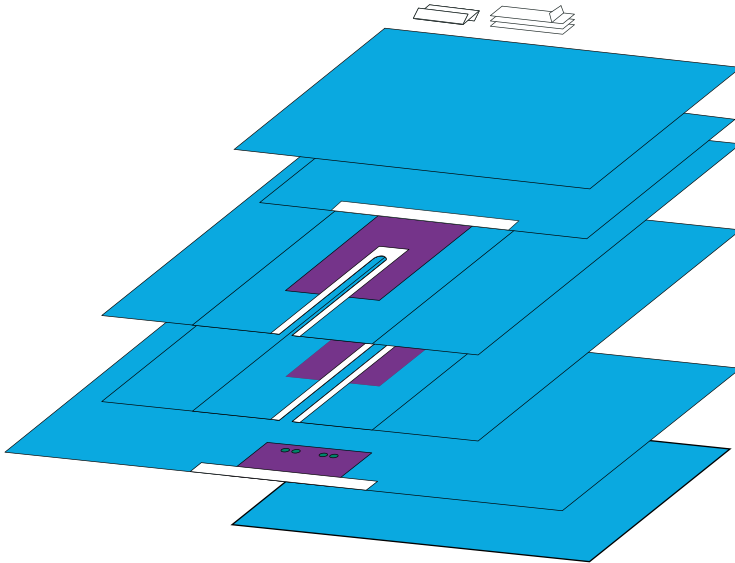
REF NO :3011



- 1 Op-tape 9x49 cm
- 1 Drape 150x175 cm
- 1 Adhesive drape 180x180 cm
- 1 Hand & foot drape 230x315 cm aperture 3,5cm elastic, patch 70x70cm
- 1 Table cover 150x190 cm

ORTHOPAEDIC PACK

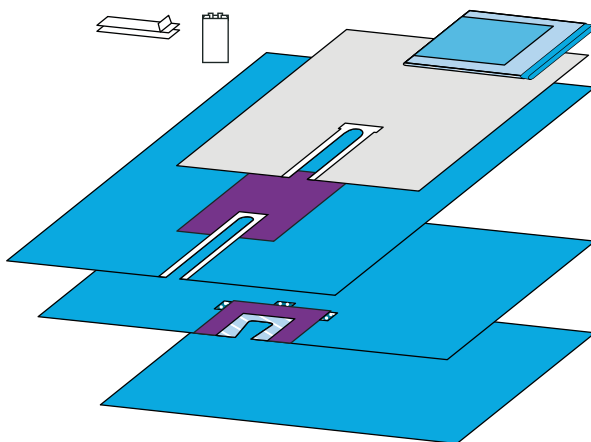
REF NO :3004



- 2 Cellulose towel 38x38 cm
- 1 Table cover 150x190 cm
- 1 Adhesive drape 175x150 cm
- 3 Op - tape 9x49 cm
- 2 Split drape 200x260 cm split 7x102 cm
- 1 Adhesive drape 300x180 cm
- 1 Table cover reinforced 150x190 cm
- 1 Wrap 100x100 cm

SHOULDER ARTHROSCOPY PACK

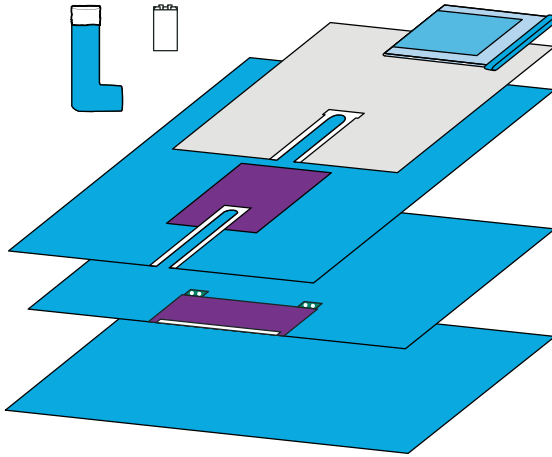
REF NO :3011-2



- 1 Mayo stand cover 79x145 cm
- 2 Op - tape 9x49 cm
- 1 Suture bag 16.5x28.5 cm
- 1 Adhesive split drape 150x190 cm plastic, split 15x61 cm
- 1 Body split drape 200x295 cm reinforcement 61x91 cm split 10x69 cm
- 1 Shoulder split sheet 254x180 cm split 15x20 cm
- 1 Table cover reinforced 150x200 cm

LOWER EXTREMITY PACK

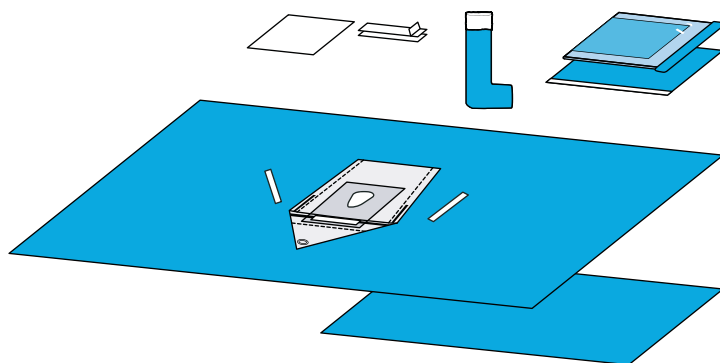
REF NO :3002-2



- 1 Mayo stand cover 79x145 cm
- 1 Adhesive split drape 150x190 cm plastic, split 15x61 cm
- 1 Stockinet 31x122 cm
- 1 Suture bag 16.5x28.5 cm
- 1 Adhesive split drape 200x254 cm reinforcement 46x91 cm
- 1 Adhesive Drape 150x240cm
- 1 Table cover reinforced 150x215 cm

BEACH CHAIR SHOULDER PACK

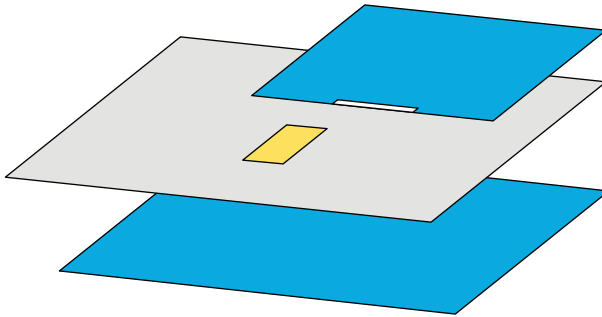
REF NO :3011-1



- 1 Mayo stand cover 79x145 cm
- 1 Stockinet 18x86 cm
- 2 Op-tape 9x50 cm
- 1 Adhesive utility drape 90x75 cm
- 1 Cellulose towel 50x50 cm
- 1 Beach chair shoylder drape 257x406 cm aperture 15x15 cm, elastic
- 1 Table cover reinforced 150x230 cm

SPINAL PACK

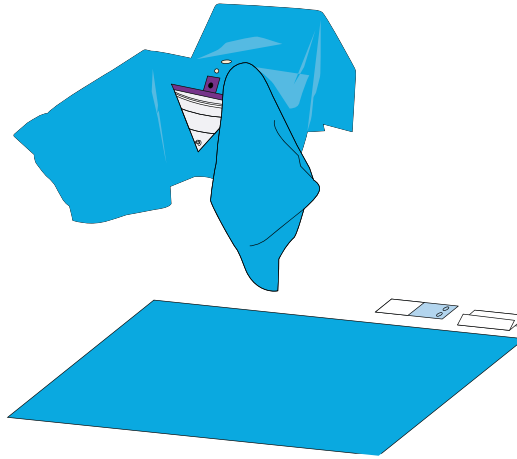
REF NO :3806



- 1 Adhesive patient drape 180x150 cm
- 1 Spinal drape 240x320 cm, incise area 30x60 cm
- 1 Table cover reinforced 150x200 cm

TUR PACK

REF NO :2814



- 1 Cellulose towel 38x38 cm
- 1 Tube holder 9x18 cm
- 1 Tur drape 175x215 cm w/pouch, apertures 8 cm and 5 cm, finger cot
- 1 Table cover 150x190 cm

COMPONENTS



YANKUER SET



TRAY



TRAY OF 3



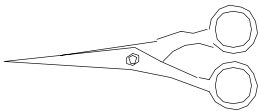
TOURNIQUET ADULT



SYRINGE LUER LOCK
20 ML



SUTURE BAG



STAINLESS STEEL SCISSOR



SPONGE FORCEPS
ROUND TIP



SKIN STAPLER



SCALPEL WITH HANDLE
NO:11



SCALPEL NO:15



3 WAY TAP



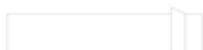
PURPLE SKIN MARKER



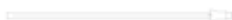
PROTECTIVE COVER SQUARE



SURGICAL CAP



OP TAPE 10x50 CM



NEEDLE CABEL



NEEDLE NEST



NEEDLE 18 G



MONIFOLD SET



FACE MASK



KIDNEY BASIN 700 ML



CAMERA COVER



NEEDLE BOX



INSTRUMENT POUCH 2
COMPARTMENTS



HEMOSTATIC VALVE



GUIDEWIRE 0,038*150 3 MM JTP



GUIDEWIRE BOWL 2500 ML



GAUZE SWAPS



FORCEP



FOOT COVER



FLOUROSCOPY COVER



ELECTRIC CAUTERY PEN



ELASTIC BANDAGE



SWAB STICK



6F RADIAL INTRODUCER



BAND BLUE AND PINK



CAMERA COVER



CAMERA COVER



CANNULA FREIZER 12 FR



BOWL 500 CC



CELLULOSE 5 SPEARS
STERILE IN ONE PACK



COTTON APPLICATOR



DISPOSABLE SHOE COVER



BETADINE SPONGE



COVER HANDLEBARS



COVER HANDLEBARS



ASPIRATION TUBE

CERTIFICATE



Device	Trademark	Model	Risk class
Sterile Single Use Surgical Gowns	EUROSET	Standard Surgical Gowns	Class Is
		Reinforced Surgical Gowns	

Device	Trademark	Model	Risk class
Sterile Single Use Surgical Drapes	EUROSET	Specialty Surgical Drapes	Class Is
		Equipment Drapes	

Device	Trademark	Model	Risk class
Sterile Single Use Surgical Drape-Gown Sets	EUROSET	Specialty Procedure Sets (Drape and Gowns)	Class Is

Limitation on Certificate / Conditions

-

Certificate History

No	Date	Cause of Revision
00	2024.06.14	First Issue



**NOTİCE BELGELENDİRME
MUAYENE VE DENETİM
HİZMETLERİ A.Ş.**

Esentepe Mahallesi Milangaz Caddesi
No:75/A/92 Kartal / İstanbul / TÜRKİYE
www.notice.com.tr

CERTIFICATE

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

According to (EU) 2017/745 Medical Device Regulation Annex IX – Chapter I & Chapter III

Certificate number : 3QMS-MDR-0001/06/2024

Manufacturer : NUREL MEDİKAL SANAYİ VE TİCARET ANONİM ŞİRKETİ

Address(es) : Demirtaş Dumlupınarosb Mah. Karanfil Sk. No:4
Osmangazi/Bursa/Türkiye

Single Registration Number : TR-MF-000015944

Authorized Representative : N/A(Not Applicable.)

Authorized Representative Address : N/A(Not Applicable.)

Device(s) : Sterile Single Use Surgical Gowns, Surgical & Equipment
Drapes, Surgical Drape-Gown Sets

See page 2 for device details.

Final Report Number : CE-MDR-C-0001-1STA-CFR.01

This report includes reference to relevant CS, harmonized standards and test report.

Initial Issue Date and Place : 2024.06.14 & İstanbul

Revision No. and Date : 00 / --

Detailed information on certificate revision and history is given in the last section of the certificate.

Validity Date : 2029.06.13

NOTICE with Notified Body No. 2764 declares that the above-mentioned manufacturer implements a quality management system in accordance with Annex IX, Chapter I and III of (EU) 2017/745 the Medical Device Regulation, and that the quality management system fulfills the requirements for establishing, securing and maintaining sterile conditions. The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis. This approved quality management system is subject to periodic surveillance and unannounced on-site audits in accordance with Annex IX, Chapter I, Section 3 of the (EU) 2017/745 Medical Device Regulation. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. The evaluation and approval performed by NOTICE is limited to the parts of the quality management system that establish, secure, and maintain sterile conditions.


NB 2764
Özlem WCDAN AKDAG
Chairman of the Board

**NOTİCE BELGELENDİRME
MUAYENE VE DENETİM
HİZMETLERİ A.Ş.**

Esentepe Mahallesi Milangaz Caddesi
No:75/A/92 Kartal / İstanbul / TÜRKİYE
www.notice.com.tr



NOTICE BELGELENDİRME MUAYENE ve DENETİM HİZMETLERİ A.Ş.

Hereby certifies that

NUREL MEDİKAL SANAYİ VE TİCARET ANONİM ŞİRKETİ

With the address(es) below:

Address : Demirtas Dumlupınarosb Mah. Karanfil Sk. No:4 Osmangazi/Bursa/Türkiye

has implemented a quality management system according to

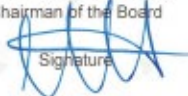
EN ISO 13485:2016

The scope of this Quality Management System includes:

Manufacture and sales of sterile and non-sterile disposable surgical drapes, surgical gowns, surgical drape packs, examination gowns and apparels, clean air suits for patients, sterile and nonsterile plastic medical devices and their sets, sterilization of the medical devices

Certificate Number : ISO.MED.0007.06.2024
Issue Date : 2024.06.14
Validity Date : 2027.06.13
Revision : --
Revision Date : --

Approved by
Özlem VİCDAN AKDAĞ
Chairman of the Board


Signature

According to ISO/IEC 17021 rules, the company is subject to surveillance audits. This certificate is valid as long as the company complies with NOTICE certification rules. You can check the validity of this certificate through contacting the phone number and email address given below. The validity can also be verified via Certificate Query part in our website: www.notice.com.tr

NOTICE BELGELENDİRME MUAYENE VE DENETİM HİZMETLERİ A.Ş.
Esenyol Mahallesi Mıngazı Caddesi No:75/A/52 Kartal / İstanbul / TÜRKİYE
Tel: 00 90 216 504 16 98 - e-posta: info@notice.com.tr



TÜRKAK BDS NO
YS-D5A4-4B6A



Supplementary Information to ISO.MED.0007.06.2024

Audited Addresses

Sterilization	:	Demirtas Dumlupınarosb Mah. Karanfil Sk. No:4
	:	Osmangazi/Bursa/Türkiye

Issue Date	:	2024.06.14
Validity Date	:	2027.06.13
Revision	:	--
Revision Date	:	--

According to ISO/IEC 17021 rules, the company is subject to surveillance audits. This certificate is valid as long as the company complies with NOTICE certification rules. You can check the validity of this certificate through contacting the phone number and email address given below. The validity can also be verified via Certificate Query part in our website: www.notice.com.tr

NOTICE BELGELENDİRME MUAYENE VE DENETİM HİZMETLERİ A.Ş.
Esenyol Mahallesi Mıngaz Caddesi No:75/A/52 Kat:1 / İstanbul / TÜRKİYE
Tel: 00 90 216 504 16 98 - e-posta: info@notice.com.tr



2020

CERTIFICATE OF REGISTRATION

This certifies that:

Nurel Medikal Sanayi Ve Ticaret A S
Dosab Laranfil Sok No 4 B
No. 4/B Osmangazi
Osmangazi Bursa, TR TR-16245

is registered with the U.S. Food and Drug Administration for FY 2020 pursuant to Title 21, 807 et seq. of the United States Code of Federal Regulations:

Establishment Owner/Operator Number:

10076043

DUNS No.:

35-564-2172

Device Classification Name:

NON-SURGICAL ISOLATION
GOWN

Product Code:

OEA

Regulation Number:

878.4040

Official Correspondent
and U.S. Agent:

Registrar Corp
144 Research Drive, Hampton, Virginia,
23666, USA
Telephone: +1-757-224-0177 • Fax:
+1-757-224-0179

Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. Registrar Corp assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding."

The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. Registrar Corp is not affiliated with the U.S. Food and Drug Administration.

Registrar Corp ★ ★

144 Research Drive, Hampton, Virginia, 23666, USA
Telephone: +1-757-224-0177 • Fax: +1-757-224-0179
info@registrarcorp.com • www.registrarcorp.com

David Lennarz
David Lennarz
Executive Director
Registrar Corp
Dated: July 13, 2020



Certificate

ISO 9001 : 2015

NUREL MEDİKAL SAN. VE TİC. A.Ş.

Demirtaş Dumlupınar OSB. Mah. Karanfil Sok. No:4 İç Kapı No:1
Osmangazi/Bursa/TÜRKİYE

This certificate shows that the quality management system of the above company was approved by PCA Sertifikasyon for the following scope, the validity of the certificate depends on the company's pass the annual surveillance audits and company's maintenance the related management system conditions according to international accreditation criteria.

SCOPE

Manufacture and sales of sterile & non-sterile disposable surgical drapes, surgical gowns, surgical drape packs, examination gowns & apparels, clean air suits for patients, sterile & non-sterile plastic medical devices and their sets, sterilization of the medical devices

EA CODE

23

Certificate No	: KKY-24023
Registration Date	: 05.12.2017
Release Date	: 08.12.2023
Expiry Date	: 04.12.2024
Certificate Period	: 3 Years (From the date of registration)
Exclusion	: 0.3

IAS
ACCREDITED
Management
Systems
Certification Body
MSCB-103

PCA Certification Approval

PCA Sertifikasyon Hizmetleri Limited Şirketi
Orta Mah. Çiftçi SK. Toprak Ç. Blok No:26/23 Kertül / İSTANBUL
Tel: +90 216 518 63 40-48 Fks: +90 216 517 63 40
www.pca-tr.com info@pca-tr.com

FR/SG Rev 4



BELGE NUMARASI REFERENCE NUMBER OF LICENCE	032856-TSE-01/03
BELGENİN İLK VERİLİŞ TARİHİ DATE OF FIRST ISSUE OF LICENCE	27.04.2007
BELGENİN SON GEÇERLİLİK TARİHİ LICENCE VALID UNTIL	27.04.2025
BELGE SAHİBİ KURULUŞUN ADI NAME OF THE LICENCE HOLDER	NUREL MEDİKAL SANAYİ VE TİCARET ANONİM ŞİRKETİ
BELGE SAHİBİ KURULUŞUN ADRESİ ADDRESS OF THE LICENCE HOLDER	DEMİRTAŞ DÜMLÜPINAROSB MAH. KARANFIL SK. NO:4 OSMANGAZI BURSA / TÜRKİYE
ÜRETİM YERİ ADI NAME OF THE MANUFACTURING PLACE	NUREL MEDİKAL SANAYİ VE TİCARET A.Ş.
ÜRETİM YERİ ADRESİ ADDRESS OF THE MANUFACTURING PLACE	DEMİRTAŞ DÜMLÜPINAROSB MAH. KARANFIL SOK. NO:4 OSMANGAZI BURSA / TÜRKİYE
İFTAL EDİLEN BELGE NUMARASI (Varsa) INDICATION OF SUPERSEDED LICENCE (if any)	032856-TSE-01/02
TESCİLLİ TİCARİ MARKASI REGISTERED TRADE MARK	EUROSET
İLGİLİ TÜRK STANDARDI RELATED TURKISH STANDARD	TS EN 13795-1 / 30.09.2019
BELGE KAPSAMI SCOPE OF LICENCE	SURGICAL DRAPES-HIGH PERFORMANCE, DISPOSABLE SURGICAL DRAPES-STANDARD PERFORMANCE, DISPOSABLE SURGICAL GOWNS-HIGH PERFORMANCE, DISPOSABLE SURGICAL GOWNS -STANDARD PERFORMANCE, DISPOSABLE USED AS A MEDICAL DEVICE FOR PATIENTS, CLINICAL STAFF AND EQUIPMENTS

e-imza ile onaylanmıştır

18.04.2024

On Behalf Of The Head Of Certification Center
ASU KORNOŞOR

TSE BURSA CERTIFICATION MANAGER

*This certificate also shows that the production place of the certified product meets the requirements of the institute.
*This certificate under any circumstances cannot be changed, duplicated partially or in a way that makes it difficult to read and reuse cannot be done.
*TSE * Adres: Organize Sanayi Bölgesi Kırıkkale Cad. No:16 16140 BURSA * Telefon: 02242438000/5417 Faks: 02242438324
*TSE HEAD OF CERTIFICATION CENTER: Address: Necatibey Cad. No:112 06100 Sıhhiye/ANKARA - Telephone: 0 312 416 64 61 / 416 64 27, Fax: 0 312 416 66 17 E-mail: info@tse.org.tr , web : www.tse.org.tr

Please check the accuracy and validity of the certificate from <https://www.kontrol.tse.org.tr/BelgeDogrulama.aspx?g=kgp&f=y>



1 / 1



NOTES

This image shows a single sheet of white paper with horizontal blue ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.