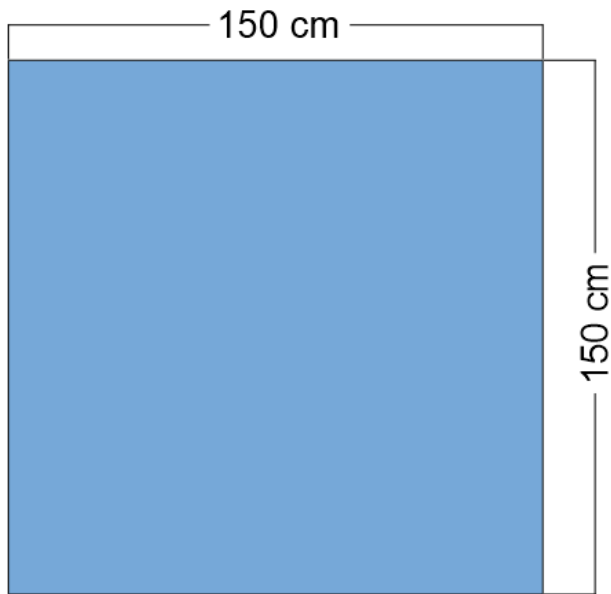


**STERILE ELECTROPHYSIOLOGY
INTERVENTIONS SET
PRODUCT DATA SHEET**

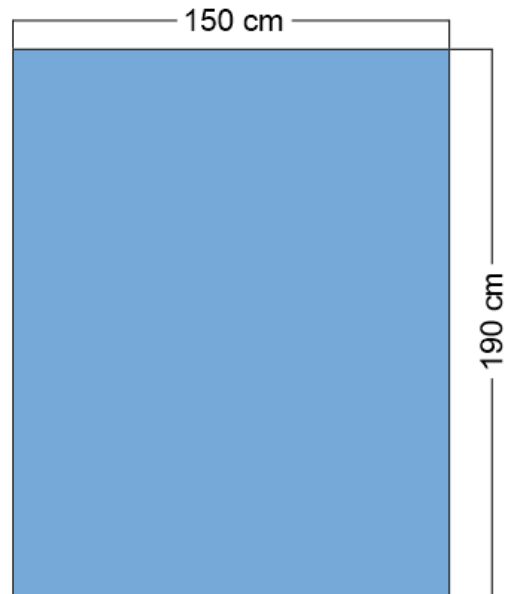
(REF. NO. : 10.028.07)

PRODUCT SPECIFICATION
STERILE ELECTROPHYSIOLOGY INTERVENTIONS SET

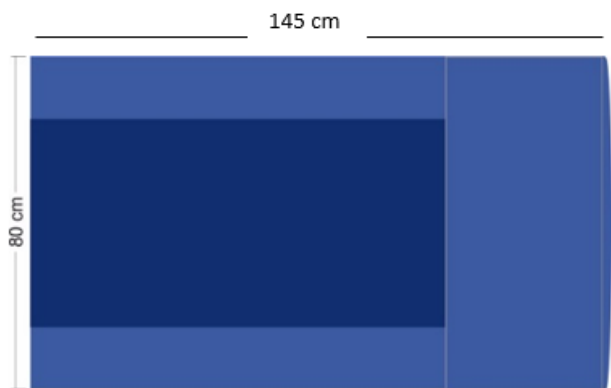
1) PRODUCT COMPONENTS



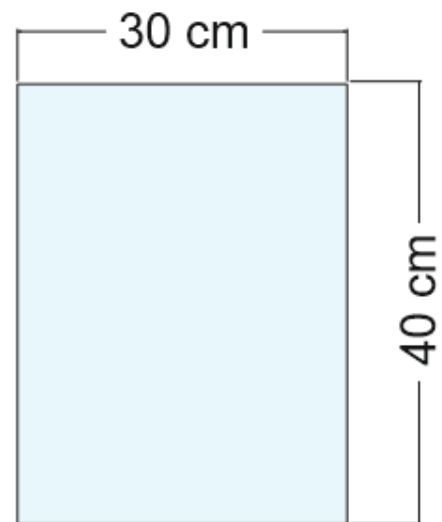
ITEM NO:1
PLAIN DRAPE
150X150 CM



ITEM NO:2
BACK TABLE COVER
150X190 CM

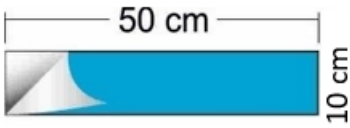


ITEM NO:3
MAYO STAND COVER
80X145 CM



ITEM NO:4
TOWEL
30X40 CM

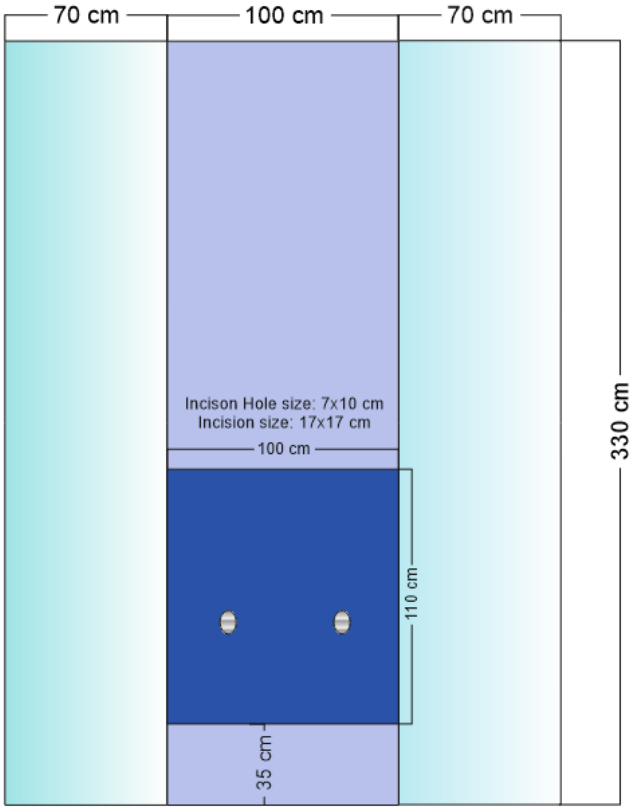
PRODUCT SPECIFICATION
STERILE ELECTROPHYSIOLOGY INTERVENTIONS SET



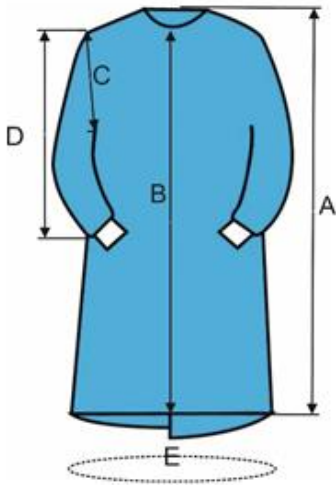
ITEM NO:5
OP-TAPE
10X50 CM



ITEM NO:6
GAUZE COMPRESS
10X10 CM, 4 PLY



ITEM NO:7
ANGIOGRAPHY DRAPE
240X330 CM



MEASUREMENT (cm) Tolerance (+/-3)							
SIZE	A	B	C	D	E	F	G
XL	135	125	32	62	150	50	80

ITEM NO:8
STANDARD SURGICAL GOWN
XL

PRODUCT SPECIFICATION
STERILE ELECTROPHYSIOLOGY INTERVENTIONS SET



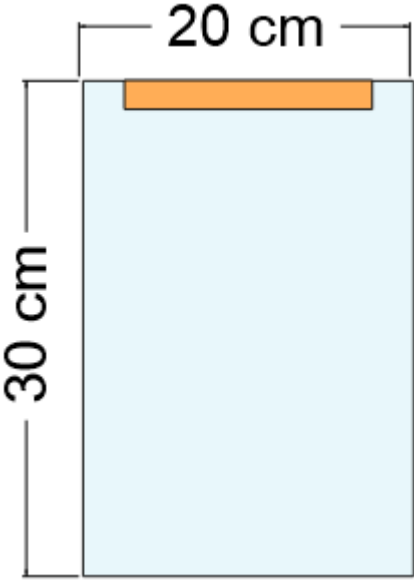
ITEM NO:9
GLOVES (POWDER-FREE)
NO:7



ITEM NO:10
GLOVES (POWDER-FREE)
NO:8

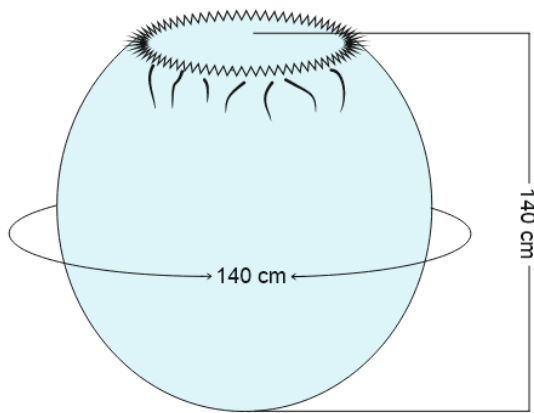


ITEM NO:11
LAMP HANDLE
STD

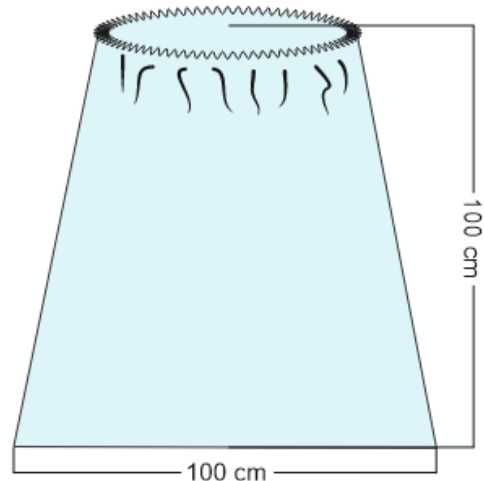


ITEM NO:12
INSTRUMENT POCKET
20X30 CM

PRODUCT SPECIFICATION
STERILE ELECTROPHYSIOLOGY INTERVENTIONS SET



ITEM NO:13
 PE COVER
 140 CM



ITEM NO:14
 PE COVER
 100X100 CM



ITEM NO:15
 SPONGE STICK
 15 CM



ITEM NO:16
 BOWL
 250 ML



ITEM NO:17
 URINE CONTAINER
 120 ML



ITEM NO:18
 SCALPEL
 NO:11

PRODUCT SPECIFICATION
STERILE ELECTROPHYSIOLOGY INTERVENTIONS SET



ITEM NO:19
BOWL
150 ML



ITEM NO:20
LUERLOCK SYRINGE
5 ML



ITEM NO:21
LUERLOCK SYRINGE
20 ML



ITEM NO:22
NEEDLE
21G

PRODUCT SPECIFICATION
STERILE ELECTROPHYSIOLOGY INTERVENTIONS SET



ITEM NO:23
 NEEDLE
 22G



ITEM NO:24
 EXTENSION LINE
 180 CM



ITEM NO:25
 FOOT COVER
 -



ITEM NO:26
 MASK
 -



ITEM NO :27-28
 CAP
 -

PRODUCT SPECIFICATION
STERILE ELECTROPHYSIOLOGY INTERVENTIONS SET

2) DETAILS OF PRODUCT COMPONENTS

ITEM	QTY	PRODUCT	FABRIC TYPE	DIMENSION	COLOUR
1	1	Plain Drape	Biflex (2-layers) 56 gr/m ² (+/-1)	150X150 cm	Blue
2	1	Back Table Cover	Biflex (2-layers) 56 gr/m ² (+/-1)	150X190 cm	Blue
3	1	Mayo Stand Cover	PE+nonwoven	80X145 cm	Blue
4	5	Towel	Cellulose	30x40 cm	White
5	1	Op-Tape	Sms+Hotmelt+Silicon Paper	10X50 cm	Blue
6	70	Gauze Compress	Cotton	10x10 cm, 4 PLY	White
7	1	Angiography Drape	Triplex (3-layers) 73 gr/m ² (+/-1)	240X330 cm	Blue
8	3	Standard Surgical Gown	SMMS 40 gr/m ² (+/-1)	XL	Blue
9	1	Gloves (Powder-Free)	Latex	No:7	White
10	2	Gloves (Powder-Free)	Latex	No:8	White
11	1	Lamp Handle	Pe	Std	Transparent
12	1	Instrument Pocket	Pe	20x30 cm	Transparent
13	1	Pe Cover	PE	140 cm	Transparent
14	1	Pe Cover	PE	100x100 cm	Transparent
15	4	Sponge Stick	-	15 cm	White
16	2	Bowl	PP	250 ml	Transparent
17	1	Urine Container	PP	120 ml	Transparent
18	1	Scalpel	-	No:11	Blue
19	2	Bowl	PP	150 ml	Transparent
20	3	Luerlock Syringe	PP	5 ml	Transparent
21	1	Luerlock Syringe	PP	20 ml	Transparent
22	2	Needle	-	21G	Green
23	2	Needle	-	22G	Black
24	1	Extension Line	pp	180 cm	Transparent
25	5 double	Foot Cover	Biflex (2-layers) 56 gr/m ² (+/-1)	-	Blue
26	5	Mask	-	-	Blue
27-28	7	Cap	SMMS 40 gr/m ² (+/-1)	-	Blue

PRODUCT SPECIFICATION
STERILE ELECTROPHYSIOLOGY INTERVENTIONS SET

3)GENERAL INFORMATION

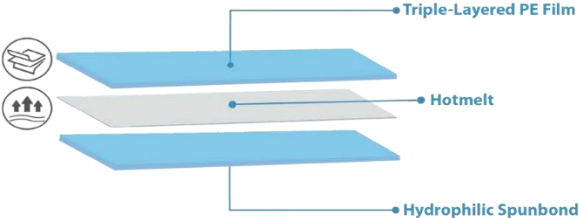
Product Description	STERILE ELECTROPHYSIOLOGY INTERVENTIONS SET
Sterilization	EO (Ethylene Oxide)
Certificates	EC Certificate
	ISO 13485
Standards	ISO15223-1
	ISO11135
	EN556-1
	EN ISO 11737
	EN ISO 10993
	EN ISO 11607
	EN ISO 14644
Instructions For Usage	This set can be used during the surgery operations. This product is disposable and it prevents the bacterial transfer between the medical team and the patient, reduces the occurring of possible contamination and infection between the patient and the medical team.
Expiration Date	3 years
Notes	This product does not contain latex.

PRODUCT SPECIFICATION
STERILE ELECTROPHYSIOLOGY INTERVENTIONS SET

4) QUALITY CONTROL RESULTS FOR FABRIC

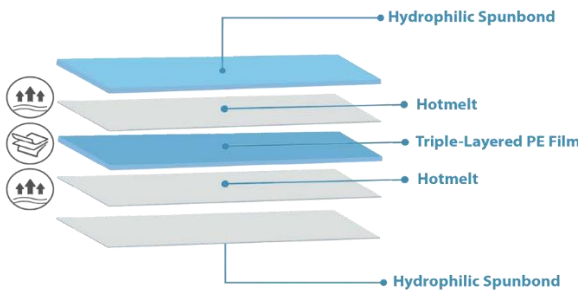
Fabric Type	Characteristic	Test Method	Unit	Requirement (High Performance/Critical Area)	Test Result
SMMS 40 gr/m²	Microbial Cleanliness (Bioburden)	EN ISO 11737-1	CFU/dm ²	≤ 300	0,27
	Resistance to Microbial Penetration-Dry	EN ISO 22612	CFU	Not Required	81,1
	Resistance to Bacterial Penetration-Wet	EN ISO 22610	I _B	6,0 ^{bc}	6
	Tensile Strength – Dry	EN 29073-3	N	≥20	Width: 65,5 Length: 124,8
	Tensile Strength – Wet	EN 29073-3	N	≥20	Width: 53 Length: 129,7
	Bursting Strength - Dry	EN ISO 13938-1	kPa	≥40	169
	Bursting Strength - Wet	EN ISO 13938-1	kPa	≥40	185
	Water Permeability	EN 811:2018	cmH ₂ O	≥20	83,5
	Linting	EN ISO 9073-10	log ₁₀ (lint count)	≤ 4,0	1,36
	Flammability	US CPSC 16 CFR PART 1610:2021	Class I		

PRODUCT SPECIFICATION
STERILE ELECTROPHYSIOLOGY INTERVENTIONS SET

Material Type:	56 gsm / NONBREATHABLE TEXTILE BACKSHEET				
Color:	Blue				
Material Structure:	30 gsm Blue Hydrophilic NW + 2 gsm Hotmelt + 24 gsm Blue NBRT Film				
Fabric Type	Characteristic	Test Method	Unit	Requirement (High Performance/Critical Area)	Test Result
BIFLEX (2-Layers) 56 g/m ²	Microbial Cleanliness (Bioburden)	EN ISO 11737-1	Log (10) CFU/dm ²	≤ 300	0,44
	Resistance to Microbial Penetration-Dry	EN ISO 22612	CFU	Not Required	1,2
	Resistance to Bacterial Penetration-Wet	EN ISO 22610	I _B	6,0 ^{bc}	0,08
	Tensile Strength – Dry	EN 29073-3	N	≥20	Width: 36,6 Length: 66,7
	Tensile Strength – Wet	EN 29073-3	N	≥20	Width: 79,5 Length: 46,1
	Bursting Strength - Dry	EN ISO 13938-1	kPa	≥40	166
	Bursting Strength - Wet	EN ISO 13938-1	kPa	≥40	171
	Water Permeability	EN 811:2018	cmH ₂ O	≥20	184
	Linting	EN ISO 9073-10	log ₁₀ (lint count)	≤ 4,0	1,23
	Flammability	US CPSC 16 CFR PART 1610:2021	Class I		
  					

PRODUCT SPECIFICATION
STERILE ELECTROPHYSIOLOGY INTERVENTIONS SET

Material Type:	73 gsm / NONBREATHABLE TEXTILE BACKSHEET				
Color:	Blue				
Material Structure:	30 gsm Blue Hydrophilic NW + 3 gsm Hotmelt + 25 gsm Blue NBRT Film + 3 gsm Hotmelt + 12 gsm White Hydrophilic NW				
Fabric Type	Characteristic	Test Method	Unit	Requirement (High Performance/Critical Area)	Test Result
TRIPLEX (3-Layers) 73 g/m²	Resistance to Microbial Penetration-Dry	EN ISO 22612	CFU	Not Required	1
	Resistance to Microbial Penetration-Wet	EN ISO 22610	lb	6,0 bc	6
	Cleanliness-Microbial	EN ISO 11737-1	CFU/100cm2	≤ 300	45
	Cleanliness-Particulate Matter	EN ISO 9073-10	IPM	≤ 3,5	2,4
	Linting	EN ISO 9073-10	log 10 (lint count)	≤ 4,0	1,3
	Resistance to Liquid Penetration	EN 20811	cm H2O	≥ 100	130
	Bursting Strength –Dry	EN ISO 13938-1	kPa	≥40	140
	Bursting Strength -Wet	EN ISO 13938-1	kPa	≥40	128
	Tensile Strength- Dry	EN 29073-3	N	≥20	70
	Flammability	US CPSC 16 CFR PART 1610:2021	Class I		



PRODUCT SPECIFICATION **STERILE ELECTROPHYSIOLOGY INTERVENTIONS SET**

5) PACKAGING

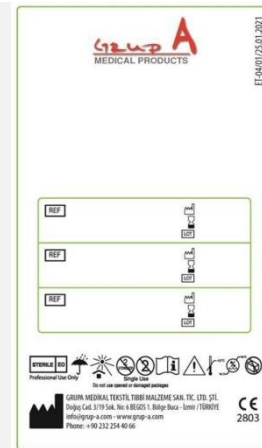
All production

Clean Room Conditions
 Medical Folding
 Sterilization Bag
 Standard label

Labelling of product

Each unit

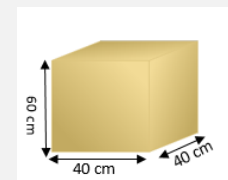
- Article number,
- Lot number,
- Manufacturer,
- Production date,
- Expiry date,
- Sterilization and sterilization date,
- Single use,
- CE,
- Other customer requests,



Packaging

Carton

Height (cm) -A	40
Width (cm) - B	60
Length (cm) - C	40
Empty Weight (kg)	~ 1,1



Storage Instructions

Our disposable products have to be kept without unwrapping the outer package. If it will be stored in a warehouse, then it has to be stored with its inner packaging in sterile conditions. In order to keep the product's sterile conditions, it has to be unwrapped from its inner packaging before using it.

Products have to be kept away from humidity, excess air flow and direct sunshine.