

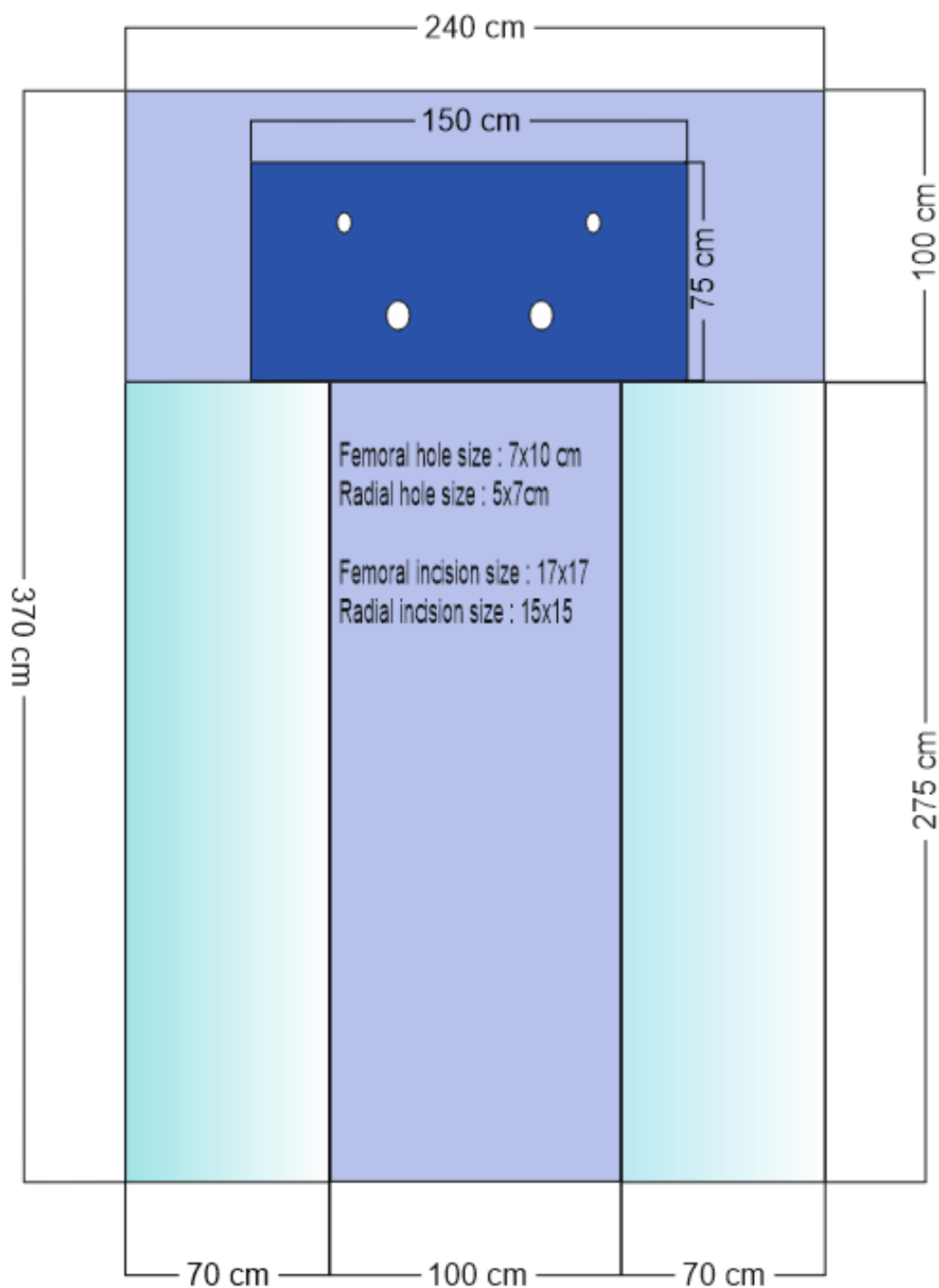


STERILE MAJOR ANGIOGRAPHY SET PRODUCT DATA SHEET

(REF. NO. : 10.028.03)

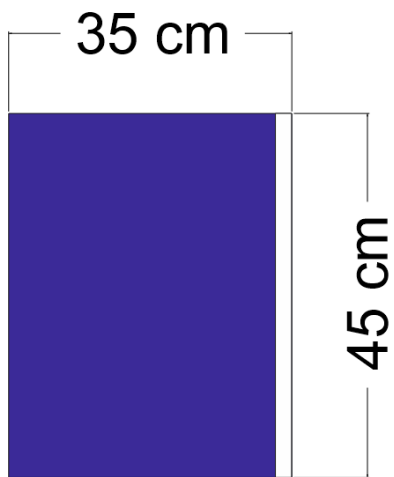
PRODUCT SPECIFICATION
STERILE MAJOR ANGIOGRAPHY SET

1) PRODUCT COMPONENTS

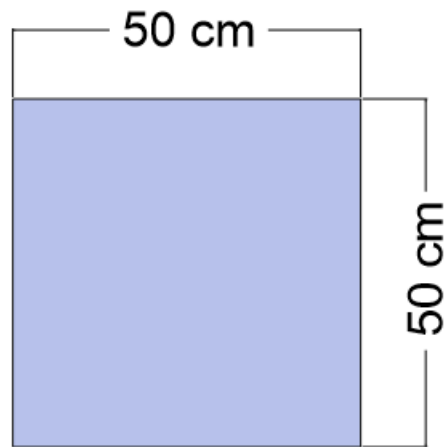


ITEM NO:1
ANGIOGRAPHY DRAPE
240X370 CM

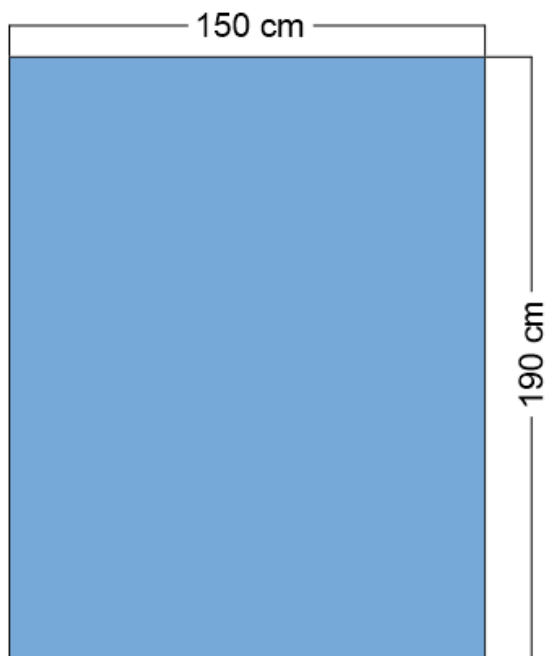
PRODUCT SPECIFICATION
STERILE MAJOR ANGIOGRAPHY SET



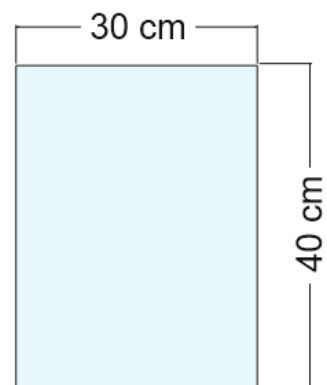
ITEM NO:2
ADHESIVE DRAPE
35X45 CM



ITEM NO:3
PLAIN DRAPE
50X50 CM

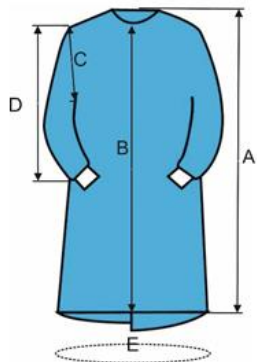


ITEM NO:4
BACK TABLE COVER
150X190 CM



ITEM NO:5
SCRIM TOWEL
30X40 CM

PRODUCT SPECIFICATION
STERILE MAJOR ANGIOGRAPHY SET



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

ITEM NO:6
STANDARD SURGICAL GOWN
XL



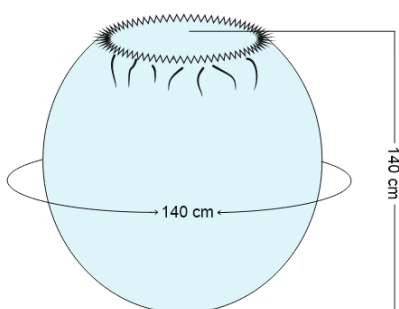
ITEM NO:7
GLOVES (POWDER-FREE)
NO:7



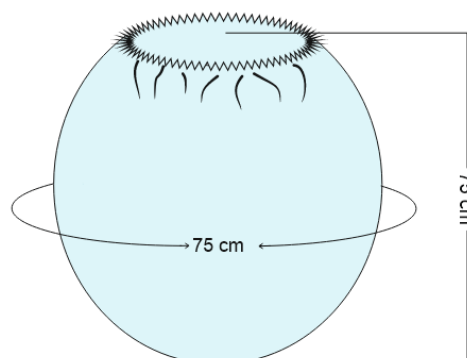
ITEM NO:7
GLOVES (POWDER-FREE)
NO:7.5



ITEM NO:7 GLOVES (POWDER-FREE)
NO:8



ITEM NO:8
PE COVER
140 CM

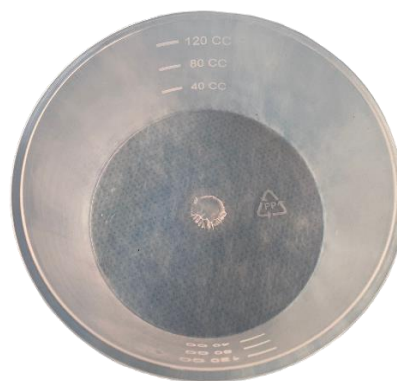


ITEM NO:9
PE COVER
75 CM

PRODUCT SPECIFICATION
STERILE MAJOR ANGIOGRAPHY SET



ITEM NO:10
URINE CONTAINER
120 ML



ITEM NO:11
BOWL
100 ML



ITEM NO:12
BOWL
250 ML



ITEM NO:13
KIDNEY TRAY
800 ML



ITEM NO:14
FORCEPS
-



ITEM NO:15 CLAMP
-

PRODUCT SPECIFICATION
STERILE MAJOR ANGIOGRAPHY SET



ITEM NO:16
GUIDEWIRE BOWL
2500 ML



ITEM NO:17
Y- CONNECTOR
STD



ITEM NO:18
SCALPEL
NO:11



ITEM NO:19
GUIDE WIRE LINE
175 CM



ITEM NO:20
GAUZE COMPRESS
10X10 CM, 8 PLY



ITEM NO:21
NEEDLE
18G

PRODUCT SPECIFICATION
STERILE MAJOR ANGIOGRAPHY SET



ITEM NO:22
NEEDLE
21G



ITEM NO:23
NEEDLE
22G



ITEM NO:24
LUERLOCK SYRINGE
20 ML



ITEM NO:25
LUERLOCK SYRINGE
10 ML



ITEM NO:26
LUERLOCK SYRINGE
5 ML

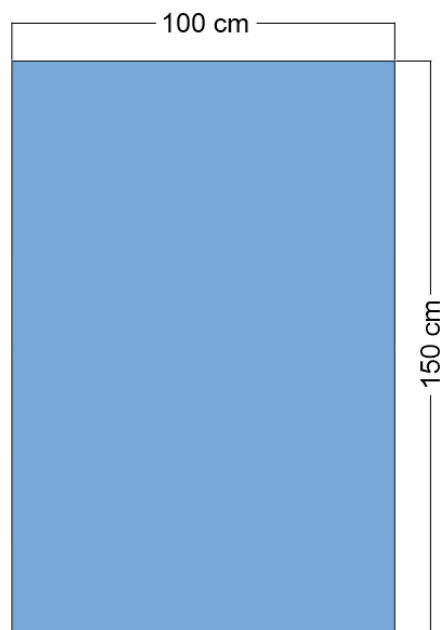


ITEM NO:27
LUERLOCK SYRINGE
2 ML

PRODUCT SPECIFICATION
STERILE MAJOR ANGIOGRAPHY SET



ITEM NO:28
TRAY
30X30 CM



ITEM NO:29
PLAIN DRAPE
100X150 CM

PRODUCT SPECIFICATION
STERILE MAJOR ANGIOGRAPHY SET

2) DETAILS OF PRODUCT COMPONENTS					
ITEM	QTY	PRODUCT	FABRIC TYPE	DIMENSION	COLOUR
1	1	Angiography Drape	Triplex (3-layers) 73 gr/m ² (+/-1)	240X370 cm	Blue
2	1	Adhesive Drape	MVA 110gr/m ² (+/-1)	35x45 cm	Blue
3	1	Plain Drape	Triplex (3-layers) 73 gr/m ² (+/-1)	50x50 cm	Blue
4	1	Back Table Cover	Biflex (2-layers) 56 gr/m ² (+/-1)	150X190 cm	Blue
5	4	Scrim Towel	Cellulose	30x40 cm	White
6	2	Standard Surgical Gown	SMMS 40 gr/m ² (+/-1)	XL	Blue
7	1	Gloves (Powder-Free)	Latex	No:7	White
7	2	Gloves (Powder-Free)	Latex	No:7.5	White
7	1	Gloves (Powder-Free)	Latex	No:8	White
8	2	Pe Cover	PE	140 cm	Transparent
9	1	Pe Cover	PE	75 cm	Transparent
10	1	Urine Container	PP	120 ml	Transparent
11	1	Bowl	PP	100 ml	Transparent
12	1	Bowl	PP	250 ml	Blue
13	1	Kidney Tray	PP	800 ml	Blue
14	1	Forceps	PP	-	Blue
15	1	Clamp	pp	-	Blue
16	1	Guidewire Bowl	PP	2500 ml	Blue
17	1	Y- Connector	Std	-	Transparent
18	1	Scalpel	-	No:11	-
19	1	Guide Wire Line	PP	175 cm	Transparent
20	50	Gauze Compress	Cotton	10x10 cm, 8 PLY	White
21	2	Needle	-	18G	Pink
22	1	Needle	-	21G	Green
23	1	Needle	-	22G	Black
24	2	Luerlock Syringe	PP	20 ml	Transparent

PRODUCT SPECIFICATION
STERILE MAJOR ANGIOGRAPHY SET

25	2	Luerlock Syringe	PP	10 ml	Transparent
26	2	Luerlock Syringe	PP	5 ml	Transparent
27	1	Luerlock Syringe	PP	2 ml	Transparent
28	1	Tray	PP	30x30 cm	White
29	1	Plain Drape	Biflex (2-layers) 56 gr/m ² (+/-1)	100x150 cm	Blue

3)GENERAL INFORMATION

Product Description	STERILE MAJOR ANGIOGRAPHY 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.

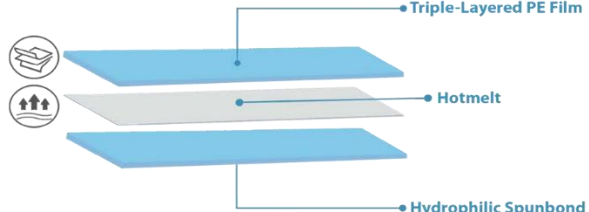
PRODUCT SPECIFICATION
STERILE MAJOR ANGIOGRAPHY SET

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		

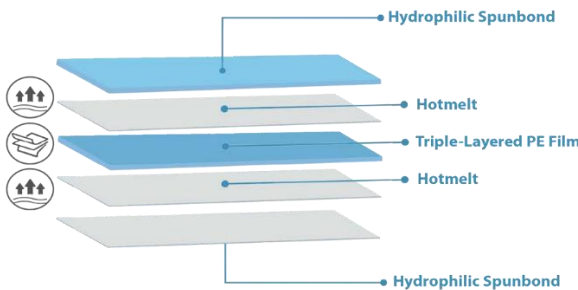
PRODUCT SPECIFICATION
STERILE MAJOR ANGIOGRAPHY SET

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 MAJOR ANGIOGRAPHY 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 MAJOR ANGIOGRAPHY SET

MVA X 110

Fiber Composition
Material Description
Base structure
Colours
PHYSICAL TESTS

Viscose
Nonwoven /PE Film
Chemicallybonded/Spunlace/PE Film
Blue

			Critical Product Area	Less Critical Product Area
Total Weight	gr/m2	TS EN 29073-1	110 ±%10	
Viscose Nonwoven Weight		TS EN 29073-1	28	
Spunlace Nonwoven Weight		TS EN 29073-1	50	
Pe Film Weight		TS EN 29073-1	24	
Hotmelt			4	
Resistance to microbial penetration-dry	CFU	EN ISO 22612	12	13
Resistance to microbial penetration-wet		EN ISO 22610	6	6
Cleanliness-Particulate Matter	IPM	EN ISO 9073-10	3,4	3,4
Cleanliness-Microbial				
Total aerobic mesophilica bacteria (30 C/48-120 hr)	CFU	ISO 11737-1	36	43
Total anaerobic mesophilica bacteria (30 C/48-120 hr)			0	0
Total Yeast-Mould (22 C/120-168hr)			0	0
Negative Control (30 C/48-120 hr)			No Growth	No Growth
Total Viable Count			36	43
Linting	log10	EN ISO 9073-10	3,5	3,5
Resistance to liquid Penetration	100 cm H2O Pressure	EN 20811-EN 13795	No liquid Penetration	No liquid Penetration
Bursting Strength – Dry	kpa	EN ISO 13938	280,3	
Bursting Strength - Wet	kpa	EN ISO 13938	252	
Liquid Wicking Rate	mm/5min	ISO 9073-6	MD:90mm/5min	CD : 65mm/5min
CERTIFICATES	OekoTex®Standard 100 Product II ISO 9001: 2008			

PRODUCT SPECIFICATION **STERILE MAJOR ANGIOGRAPHY SET**

5) PACKAGING

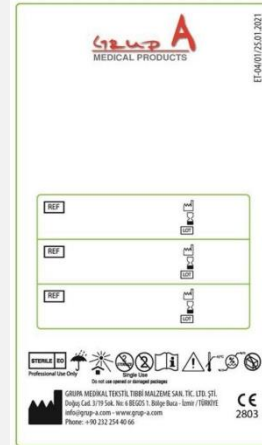
All production

Clean Room Conditions
Medical Folding
Sterilization Bag
Standard label

Labelling of product

Each unit

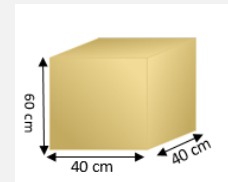
- Article number,
- Lot number,
- Manufacturer,
- Production date,
- Expiry date,
- Sterilization and sterilization date,
- Single use,
- CE,
- Other customer requests,



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.