

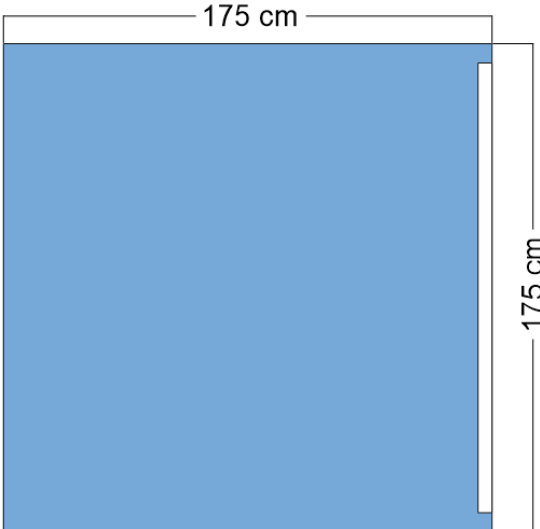


**STERILE PACEMAKER IMPLANTATION SET
PRODUCT DATA SHEET**

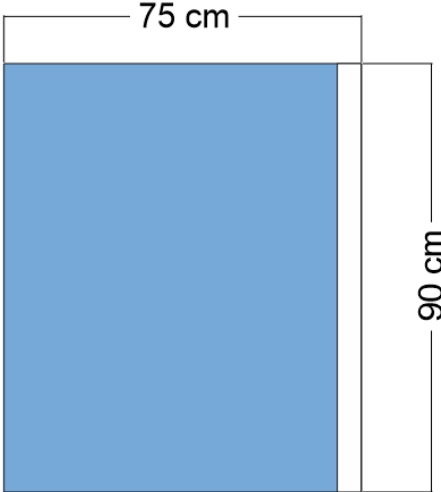
(REF. NO. : 10.028.05)

PRODUCT SPECIFICATION
STERILE PACEMAKER IMPLANTATION SET

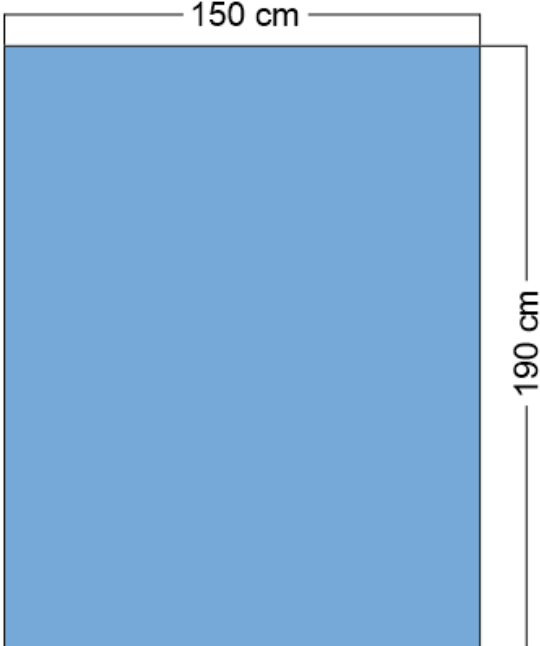
1) PRODUCT COMPONENTS



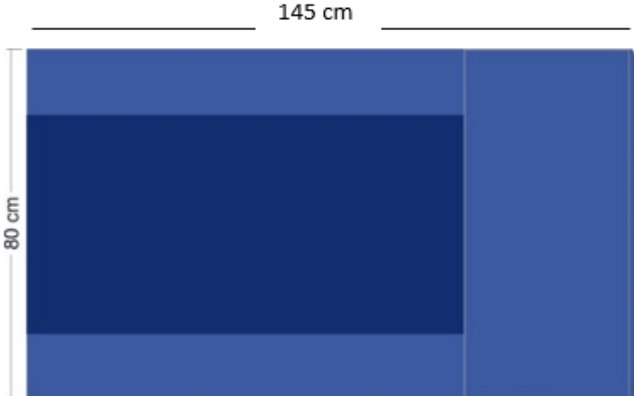
ITEM NO:1
ADHESIVE DRAPE
175x175 CM



ITEM NO:2
ADHESIVE DRAPE
75X90 CM

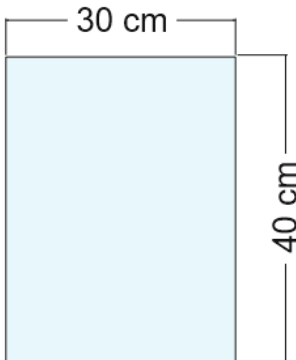
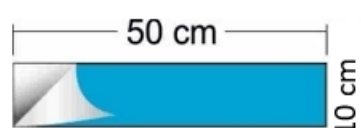

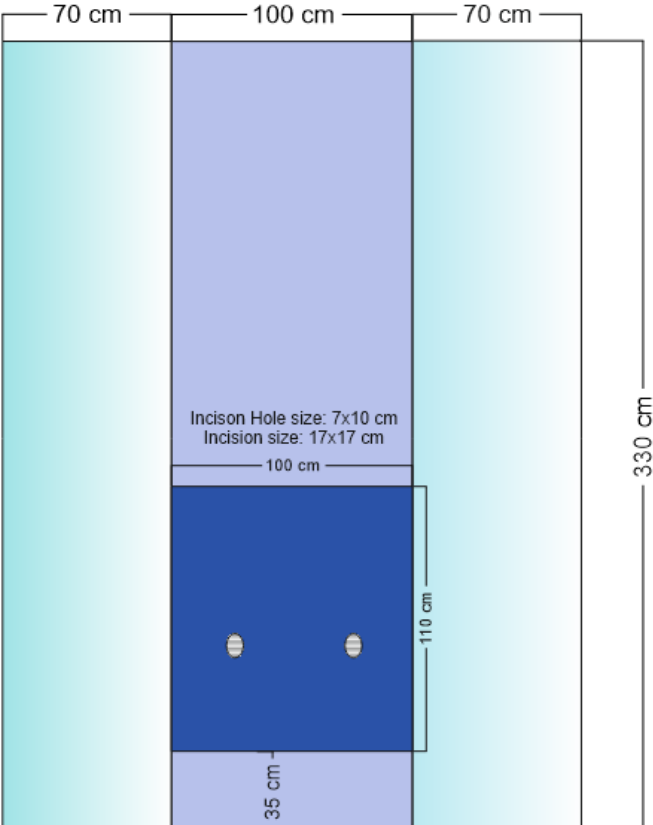


ITEM NO:3
BACK TABLE COVER
150X190 CM

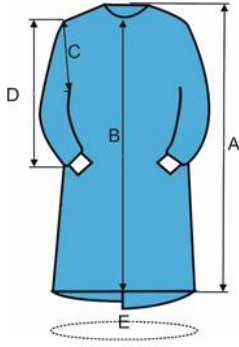


ITEM NO:4
MAYO STAND COVER
80X145 CM

**PRODUCT SPECIFICATION
STERILE PACEMAKER IMPLANTATION SET**

	
<p align="center">ITEM NO:5 TOWEL 30X40 CM</p>	<p align="center">ITEM NO:6 OP-TAPE 10X50 CM</p>
	
<p align="center">ITEM NO:7 GAUZE COMPRESS 10X10 CM, 4 PLY</p>	<p align="center">ITEM NO:8 ANGIOGRAPHY DRAPE 240X330 CM</p>

**PRODUCT SPECIFICATION
STERILE PACEMAKER IMPLANTATION SET**

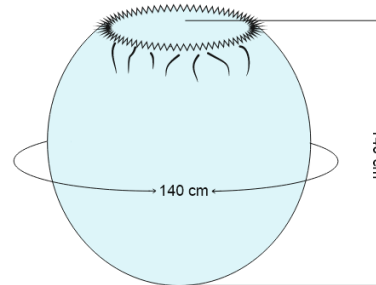


MEASUREMENT (cm) Tolerance (+/-3)							
SIZE	A	B	C	D	E	F	G
XL	135	125	32	62	150	50	80



**ITEM NO:9
STANDARD SURGICAL GOWN
XL**

**ITEM NO:10
GLOVES (POWDER-FREE)
NO:7**



**ITEM NO:11
GLOVES (POWDER-FREE)
NO:8**







**ITEM NO:12
PE COVER
140 CM**



**ITEM NO:13
LAMP HANDLE
STD**

**ITEM NO:14
BOWL
500 ML**

PRODUCT SPECIFICATION
STERILE PACEMAKER IMPLANTATION SET

	
<p>ITEM NO:15 BOWL 250 ML</p>	<p>ITEM NO:16 URINE CONTAINER 120 ML</p>
	
<p>ITEM NO:17 SPONGE STICK 15 CM</p>	<p>ITEM NO:18 SCALPEL NO:22</p>
	
<p>ITEM NO:19 FORCEPS -</p>	<p>ITEM NO:20 TWEEZER -</p>

PRODUCT SPECIFICATION
STERILE PACEMAKER IMPLANTATION SET



ITEM NO:21
FOOT COVER

-



ITEM NO:22
MASK

-



ITEM NO:23-24
CAP

-

**PRODUCT SPECIFICATION
STERILE PACEMAKER IMPLANTATION SET**

2) DETAILS OF PRODUCT COMPONENTS					
ITEM	QTY	PRODUCT	FABRIC TYPE	DIMENSION	COLOUR
1	1	Adhesive Drape	Biflex (2-layers) 56 gr/m ² (+/-1)	175x175 cm	Blue
2	1	Adhesive Drape	Biflex (2-layers) 56 gr/m ² (+/-1)	75X90 cm	Blue
3	1	Back Table Cover	Biflex (2-layers) 56 gr/m ² (+/-1)	150X190 cm	Blue
4	1	Mayo Stand Cover	PE+nonwoven	80X145 cm	Blue
5	3	Towel	Cellulose	30x40 cm	White
6	1	Op-Tape	Sms+Hotmelt+Silicon Paper	10X50 cm	Blue
7	200	Gauze Compress	Cotton	10x10 cm, 4 PLY	White
8	1	Angiography Drape	Triplex (3-layers) 73 gr/m ² (+/-1)	240X330 cm	Blue
9	3	Standard Surgical Gown	SMMS 40 gr/m ² (+/-1)	XL	Blue
10	1	Gloves (Powder-Free)	Latex	No:7	White
11	2	Gloves (Powder-Free)	Latex	No:8	White
12	1	Pe Cover	PE	140 cm	Transparent
13	1	Lamp Handle	-	Std	Transparent
14	2	Bowl	PP	500 ml	Transparent
15	2	Bowl	PP	250 ml	Blue
16	1	Urine Container	PP	120 ml	Transparent
17	5	Sponge Stick	-	15 cm	White
18	1	Scalpel	-	No:22	-
19	1	Forceps	PP	-	Blue
20	4	Tweezer	pp	-	Blue
21	5 double	Foot Cover	Biflex (2-layers) 56 gr/m ² (+/-1)	-	Blue
22	5	Mask	-	-	Blue
23-24	7	Cap	SMMS 40 gr/m ² (+/-1)	-	Blue

PRODUCT SPECIFICATION
STERILE PACEMAKER IMPLANTATION SET

3)GENERAL INFORMATION

Product Description	STERILE PACEMAKER IMPLANTATION 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.

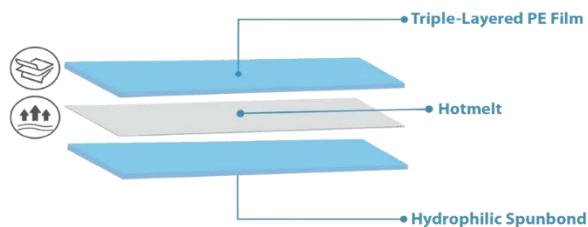
**PRODUCT SPECIFICATION
STERILE PACEMAKER IMPLANTATION SET**

4) QUALITY CONTROL RESULTS FOR FABRIC

Fabric Type	Characteristic	Test Method	Unit	Requirement (High Performance/Critical Area)	Test Result
SMMS 40 gr/m ²	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	l _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	

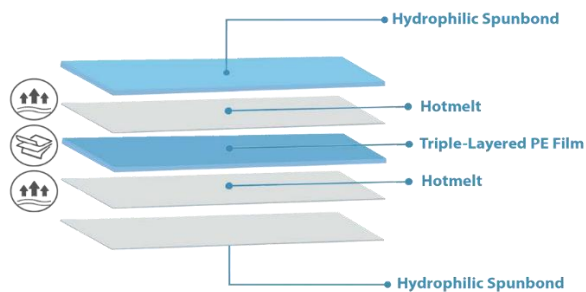
PRODUCT SPECIFICATION
STERILE PACEMAKER IMPLANTATION SET

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/m²	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 PACEMAKER IMPLANTATION 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/100cm ²	≤ 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 H ₂ O	≥ 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		



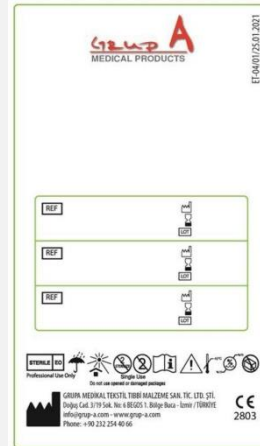
**PRODUCT SPECIFICATION
STERILE PACEMAKER IMPLANTATION SET**

5) PACKAGING

All production Clean Room Conditions
 Medical Folding
 Sterilization Bag
 Standard label

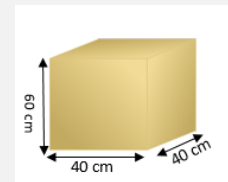
Labelling of product Each unit

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



Packaging

	<u>Carton</u>
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.