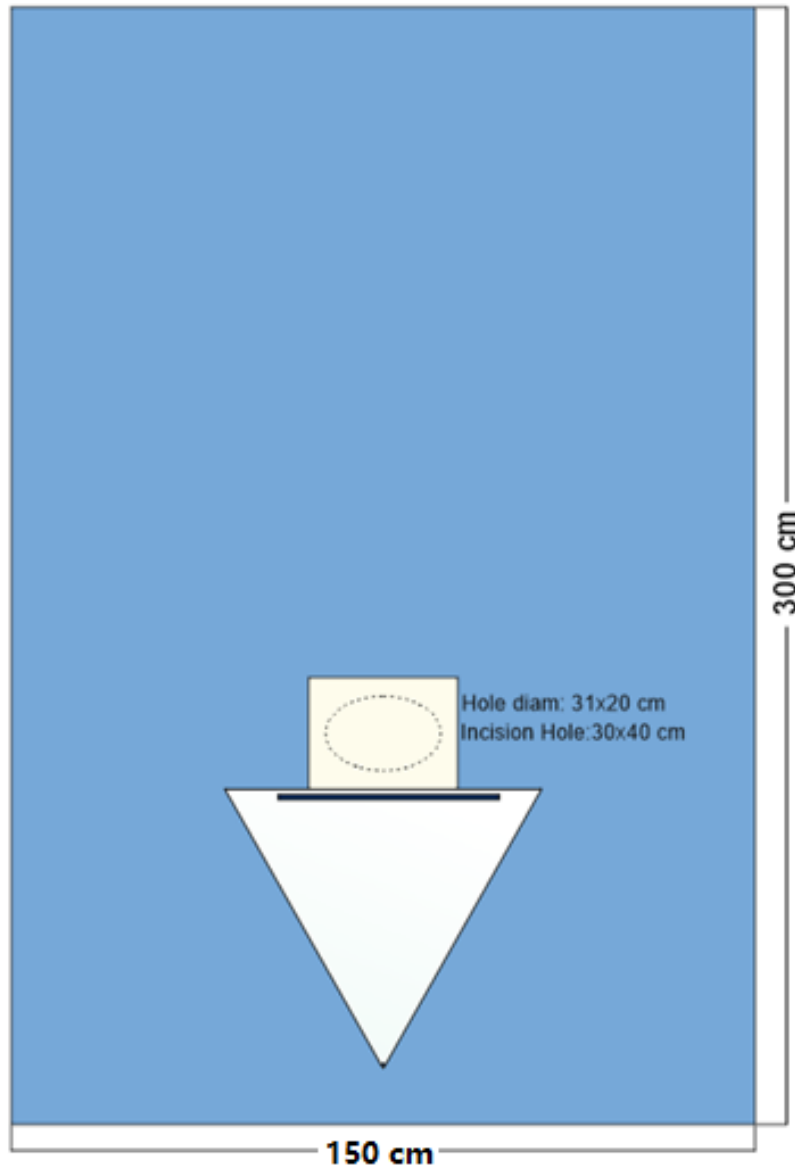


CRANIOTOMY DRAPE PACK
REF.NO:140.001.01
STANDARD PRODUCT DATA SHEET
KY-PD-017



STANDARD PRODUCT DATA SHEET
CRANIOTOMY DRAPE PACK
140.001.01

1) PRODUCT COMPONENTS

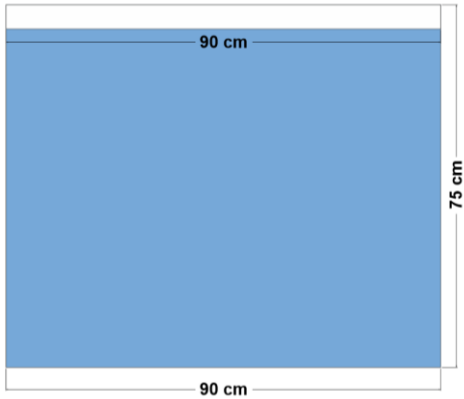


ITEM 1

Craniotomy Drape
150x300 cm



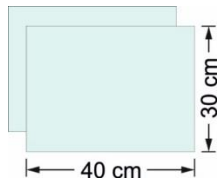
STANDARD PRODUCT DATA SHEET
CRANIOTOMY DRAPE PACK
140.001.01



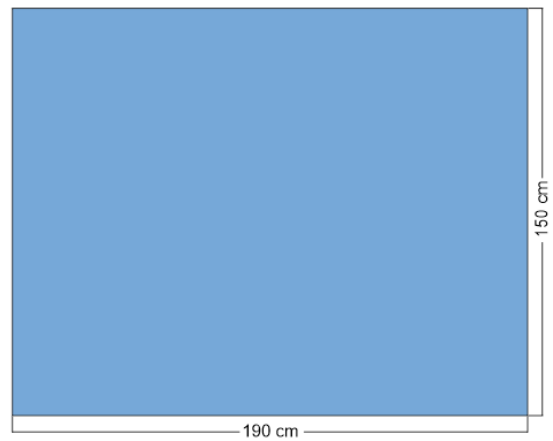
ITEM 2
Adhesive Drape (90 cm band)
75x90 cm



ITEM 3
Mayo Stand Cover
78x145 cm (unfolded)



ITEM 4
Hand Towel
30x40 cm



ITEM 5
Back Table Cover
150x190 cm
(All of the product components are wrapped into back table cover)

**STANDARD PRODUCT DATA SHEET
CRANIOTOMY DRAPE PACK
140.001.01**

2) DETAILS OF PRODUCT COMPONENTS					
ITEM	QTY	PRODUCT	FABRIC TYPE	DIMENSION	COLOUR
1	1	Craniotomy Drape	Biflex 56gr/m2 (+/-3)	150x300 cm	Blue
		Liquid Collection Pouch	PE 50 Micron (+/-3)	75x85 cm	Transparent
2	4	Adhesive Drape (90 cm band)	Biflex 56gr/m2 (+/-3)	75x90 cm	Blue
3	1	Mayo Stand Cover	Pe+nonwoven+PE Blue film	78x145 cm	Blue
4	2	Hand Towel	Cellulose	30x40 cm	White
5	1	Back Table Cover <i>(All of the product components are wrapped into back table cover)</i>	Biflex 56gr/m2 (+/-3)	150x190 cm	Blue

**STANDARD PRODUCT DATA SHEET
CRANIOTOMY DRAPE PACK
140.001.01**

3)GENERAL INFORMATION

Product Description	CRANIOTOMY DRAPE PACK
Reference Code	140.001.01
Packing Quantity	1 pc
Quantity Per Box	10 pcs
Sterilization	EO (Ethylene Oxide)
Certificates	EC Certificate
	ISO 13485:2016
Standards	EN ISO 14971:2019
	EN 13795-1:2019
	EN ISO 11135:2014
	EN 556-1:2001
	EN ISO 15223-1:2016
	EN ISO 11737-1:2018
	EN ISO 11737-2:2020
	EN ISO 14644-1:2015
	EN ISO 14644-2:2015
	EN 17141:2020
	EN ISO 10993-1:2020
	EN ISO 10993-5:2009
	EN ISO 10993-7:2008
	EN ISO 10993-10:2010
	EN ISO 20417:2021
	EN ISO 11607-1:2020
	EN ISO 11607-2:2020
	EN 62366-1:2015
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.
Expiry Date	3 years

**STANDARD PRODUCT DATA SHEET
CRANIOTOMY DRAPE PACK
140.001.01**

5) PACKAGING

All production	Clean Room Conditions, Medical Folding, Sterilization Bag, Peelable label,	
Labelling of product	Each unit <ul style="list-style-type: none"> - Article number, - Lot number, - Manufacturer , - Production date, - Expiry date, - EO Sterilization, - Single use, - CE, - Other customer requests, 	
Packaging	<u>Pallet system</u>	<u>Carton</u>
	Height (cm) -A	40
	Width (cm) - B	60
	Length (cm) - C	40
		
Storage Instructios	<p>HANDLING AND STORAGE: Products are sterile and must be stored in its original closed carton box, in a dry place. The products must be used as soon as the package is opened in the operation room. Do not expose to humidity and direct heat or sunlight.</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;"> <p>45°C</p>  <p>Upper limit of temperature</p> </div> <div style="text-align: center;"> <p>% 70</p>  <p>Humidity Limitation</p> </div> </div>	