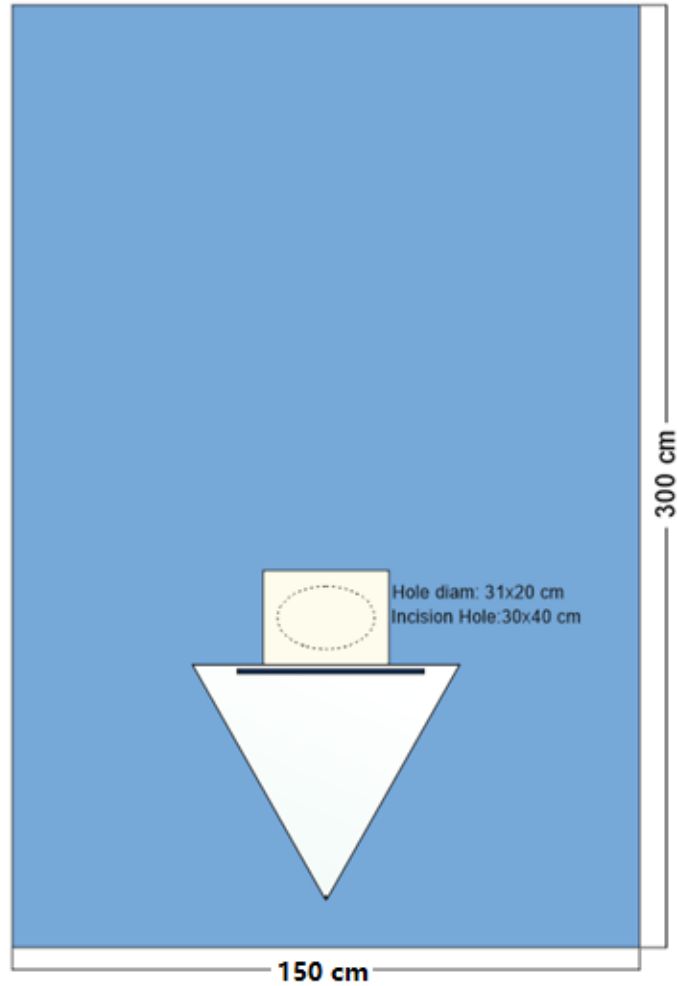


CRANIOTOMY DRAPE
REF.NO:240.001.01
STANDARD PRODUCT DATA SHEET
KY-PD-019



**STANDARD PRODUCT DATA SHEET
CRANIOTOMY DRAPE
240.001.01**

1) PRODUCT COMPONENTS



ITEM 1
Craniotomy Drape
150x300 cm

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 80 Micron (+/-5)	75x85 cm	Transparent

**STANDARD PRODUCT DATA SHEET
CRANIOTOMY DRAPE
240.001.01**

3)GENERAL INFORMATION

Product Description	CRANIOTOMY DRAPE
Reference Code	240.001.01
Packing Quantity	1 pc
Quantity Per Box	-
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 product 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

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CRANIOTOMY DRAPE
240.001.01

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>	