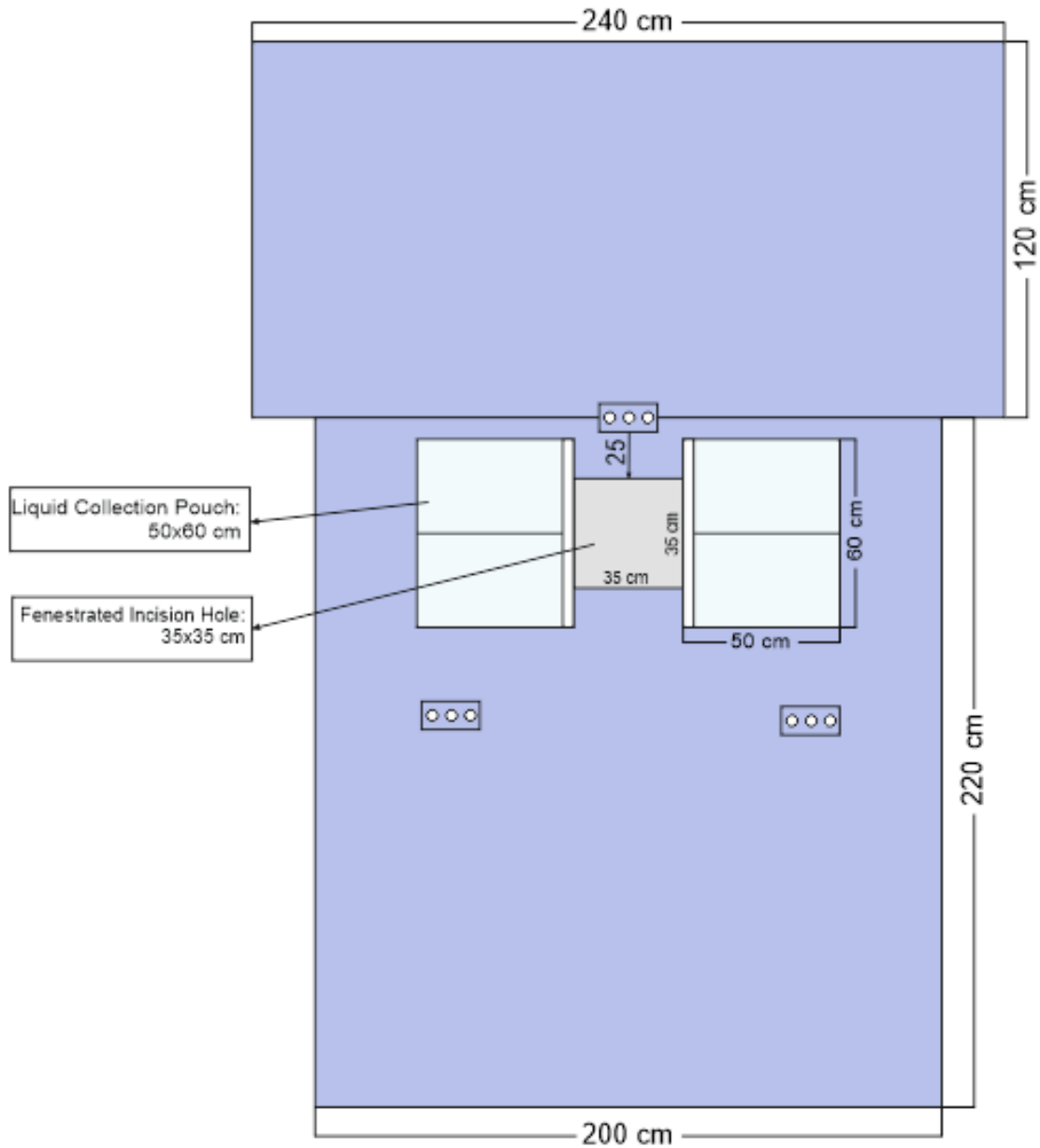


CARDIOVASCULAR DRAPE PACK
REF.NO:130.001.01
STANDARD PRODUCT DATA SHEET
KY-PD-010



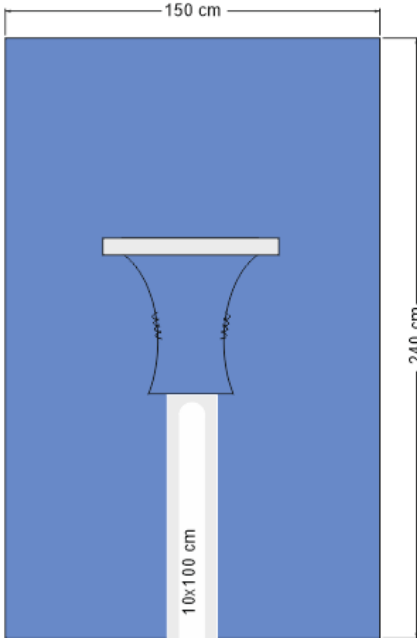

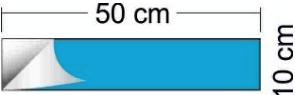
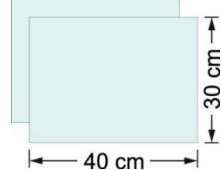


STANDARD PRODUCT DATA SHEET
CARDIOVASCULAR DRAPE PACK
130.001.01

1) PRODUCT COMPONENTS

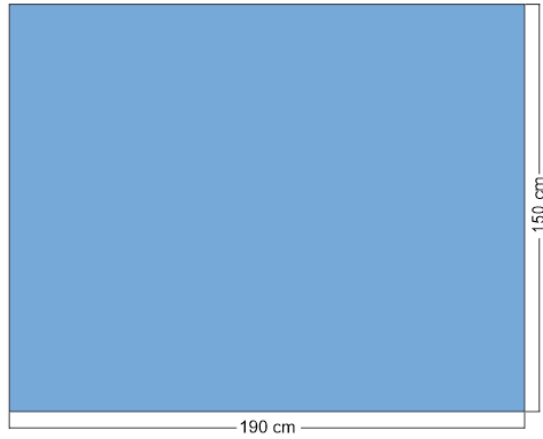


ITEM 1
Cardiovascular Drape
240x340 cm

**STANDARD PRODUCT DATA SHEET
CARDIOVASCULAR DRAPE PACK
130.001.01**

	
<p align="center">ITEM 2 Bypass Split Drape 150x240 cm</p>	<p align="center">ITEM 3 Diathermy Bag 33x30 cm</p>
	
<p align="center">ITEM 4 Op Tape 10x50 cm</p>	<p align="center">ITEM 5 Hand Towel 30x40 cm</p>
	
<p align="center">ITEM 6 Foot Covers</p>	<p align="center">ITEM 7 Mayo Stand Cover 78x145 cm (unfolded)</p>

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ITEM 8

Back Table Cover

150x190 cm

(All of the product components are wrapped into back table cover)

**STANDARD PRODUCT DATA SHEET
CARDIOVASCULAR DRAPE PACK
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2) DETAILS OF PRODUCT COMPONENTS

ITEM	QTY	PRODUCT	FABRIC TYPE	DIMENSION	COLOUR
1	1	Cardiovascular Drape	Biflex 56gr/m2 (+/-3)	240x340 cm	Blue
2	1	Bypass Split Drape	Biflex 56gr/m2 (+/-3)	150x240 cm	Blue
3	2	Diathermy Bag	PE 45 Micron (+/-5)	33x30 cm	Transparent
4	4	Op Tape	Sms+hotmelt+silicon paper	10x50 cm	Blue
5	4	Hand Towel	Cellulose	30x40 cm	White
6	2	Foot Covers	-	-	Blue
7	1	Mayo Stand Cover	Pe+nonwoven	78x145 cm	Blue
8	1	Back Table Cover	Biflex 56gr/m2 (+/-3)	150x190 cm	Blue

**STANDARD PRODUCT DATA SHEET
CARDIOVASCULAR DRAPE PACK
130.001.01**

3)GENERAL INFORMATION

Product Description	CARDIOVASCULAR DRAPE PACK
Reference Code	130.001.01
Packing Quantity	1 pc
Quantity Per Box	12 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
CARDIOVASCULAR DRAPE PACK
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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>	