

OPU PACK

REF.NO:163.001.01

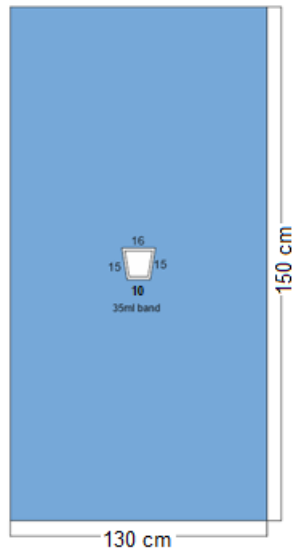
STANDARD PRODUCT DATA SHEET

KY-PD-033

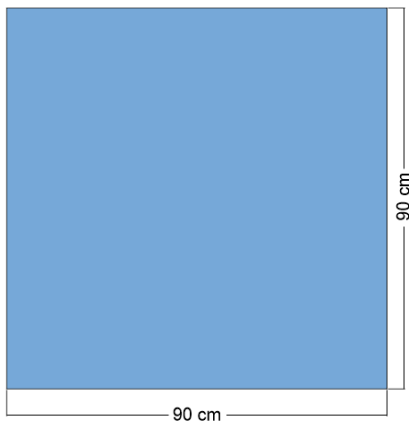


STANDARD PRODUCT DATA SHEET
OPU PACK
163.001.01

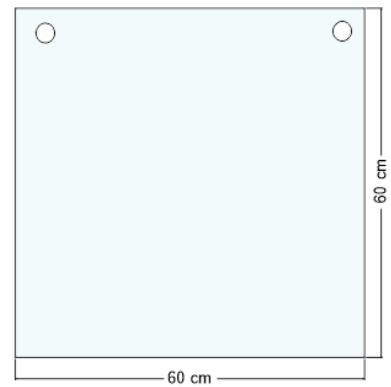
1) PRODUCT COMPONENTS



ITEM 1
OPU Drape
130x150 cm

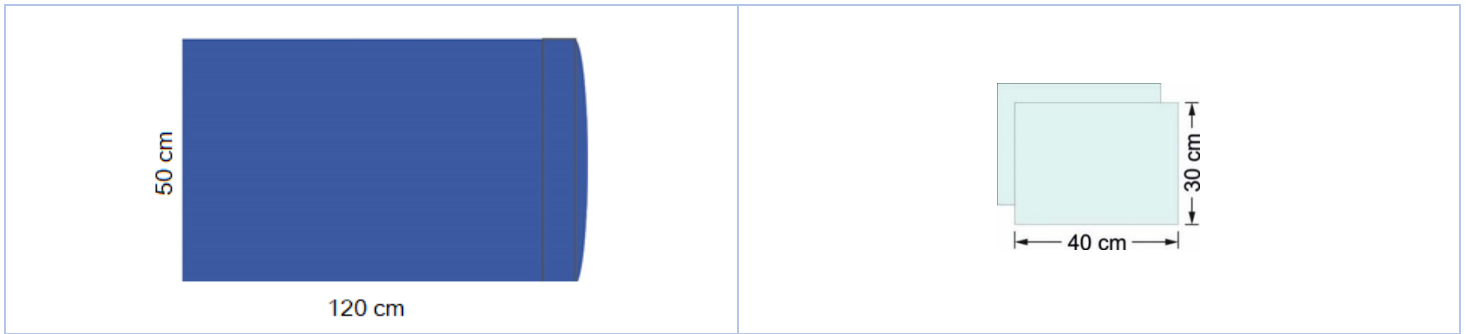


ITEM 2
Plain Drape
90x90 cm



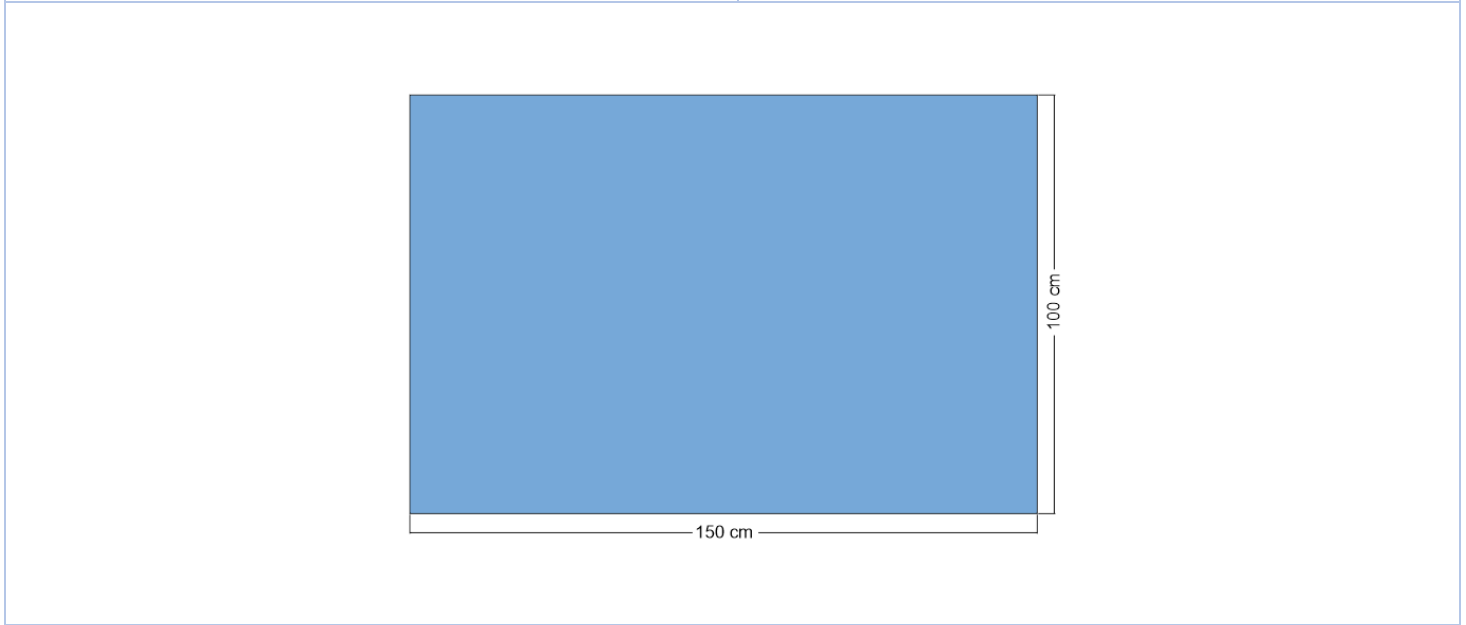
ITEM 3
Transparent Drape
60x60 cm

STANDARD PRODUCT DATA SHEET
OPU PACK
163.001.01



ITEM 4
 Leggings
 50x120 cm (unfolded)

ITEM 5
 Hand Towel
 30x40 cm



ITEM 6
 Back Table Cover
 100x150 cm
(All of the product components are wrapped into back table cover)

2) DETAILS OF PRODUCT COMPONENTS

ITEM	QTY	PRODUCT	FABRIC TYPE	DIMENSION	COLOUR
1	1	OPU Drape	Biflex 56gr/m2 (+/-3)	130x150 cm	Blue
2	1	Plain Drape	Biflex 56gr/m2 (+/-3)	90x90 cm	Blue
3	1	Transparent Drape	PE 45 Micron (+/-5)	60x60 cm	Transparent
4	2	Leggings	Biflex 56gr/m2 (+/-3)	50x120 cm	Blue
5	2	Hand Towel	Cellulose	30x40 cm	White
6	1	Back Table Cover	Biflex 56gr/m2 (+/-3)	100x150 cm	Blue

STANDARD PRODUCT DATA SHEET

OPU PACK

163.001.01

3)GENERAL INFORMATION

Product Description	OPU PACK
Reference Code	163.001.01
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 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

**OPU PACK
163.001.01**

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>	