Technical Data Sheet

ANGIOGRAPHY COVER (Femoral)

(EU) 2017/745 Annex XI-Part A Production Quality Assurance.

Angiography Drape Features

Product Description	Protective equipment used by doctors or nurses for surgical operations to prevent the possible risk of infection.
Product Class	(EU) 2017/745 Medical Device Regulation – Class Business Rule I
Manufacturer's Location	Tio Medikal 2/20 st. No.:53 (Begos 3. North Entrance, 35400 Buca OSB/Buca/İzmir
Purpose of usage	It is used for angiography operations. The fluoroscopy sheath in the set is used to protect the existing device from contamination during the operation.

Quality

- Manufactured under ISO 13485:2016 and 13795-1 quality management standards.
- It has CE certificate.

Bio-Compatibility

- Does not contain latex.
- Sterilized with ethylene oxide.

Related Standard

- ISO 13485:2016 Medical Medical Devices Quality Management System
- 9001:2015 Quality Management System
- TS EN 13795 Surgical Clothing and Drapes
- TS EN ISO 11607-1:2017 Packaging for finally sterilised medical devices - Part 1: Rules for materials, sterile barrier systems and packaging systems / Products are made in accordance with the relevant standard.
- TS EN ISO 11607-2:2017 Packaging of medical devices-Finally sterilised-

Part 2: Validation requirements for forming, sealing and joining processes/ Products are made in accordance with the relevant standard.

Shelf Life

- 3 years

Figure 1. Angiography Drape

1. Angiography Drape Dimensions

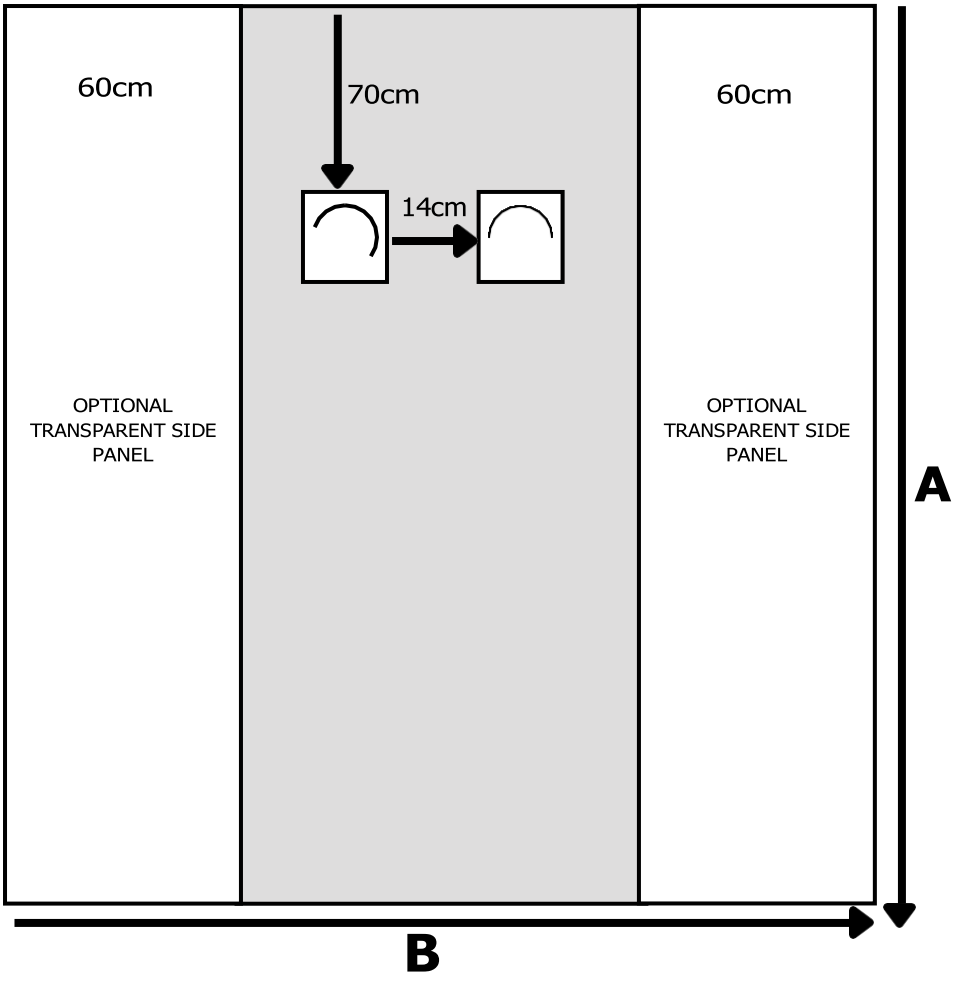


Figure 1. Angiography Drape Technical Spesifications

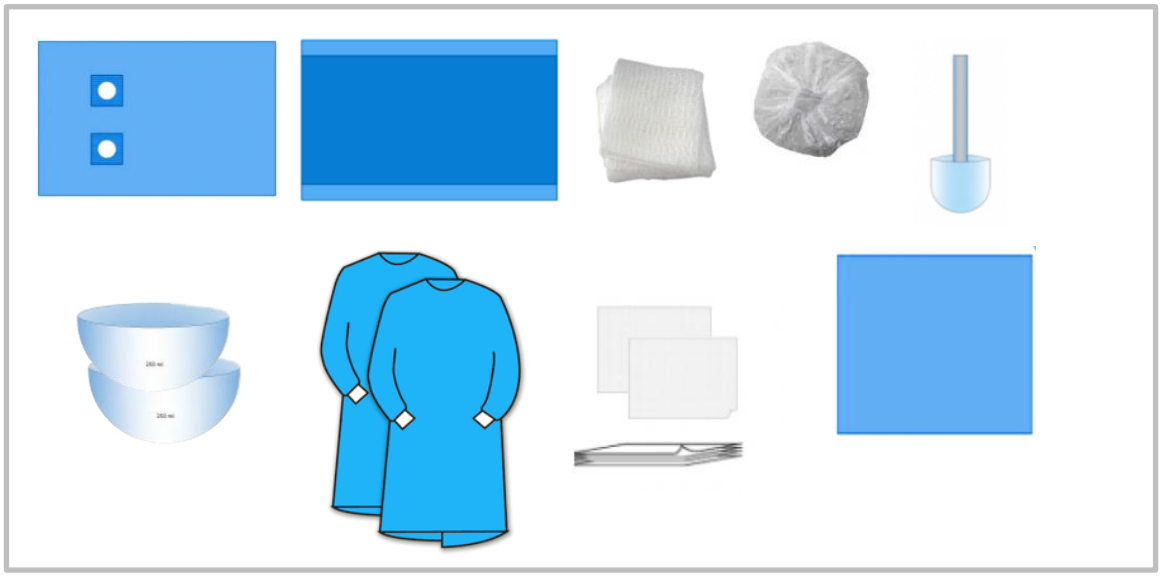
Available Materials: 03 Triplex (Spunbond PE Viscose/Spunbond) , 64 gr/m2 01 Dublex (PE/Viscose) or PE/Spunbond PP) ,54- 56 gr/m2
Incision Film: PU , Both holes are covered with polyurethane incision film

REF . CODES	DIMENSIONS (CM)		NUMBER İN COLUMN	
	A	B	50×80×50	40×60×40
453.0X.001.01	300	150	75	25
453.0X.002.01	330	220	50	25

Tolerances: -+3% (ALL SIZES ARE PRODUCED & CUSTOMISATION)

2. Angiography Pack Content

Angiography Pack	Size	QTY
Angiography drape	150*300cm	1x
Back table cover	100*150cm	1x
Gauzes	7,5*7,5cm	10x
Betadine sponge with handle		1x
Fluoroscopy cover	86cm	1x
Solution cup	350 cc	2x
Surgical gown	L	2x
Medical towel	40*40cm	2x
non-woven wrap	75*75cm	1x



		EN 13795 requirements			
Characteristic	Test Method	High performance		Results	Main fabric
		Critical product area	Less critical product area		
Resistance to microbial penetration - Dry (CFU)	EN ISO 22612	Not required	<300	Conformed	- SS Hydrophobic Spunbond - SS Hydrophylic Spunbond - Surgigal drape and gowns-Blue/white non woven - Surgigal drape and gowns-Blue laminated non woven
Resistance to microbial penetration - Wet (I/B)	EN ISO 22610	6,0	Not required	Conformed	- SS Hydrophobic Spunbond - SS Hydrophylic Spunbond - Surgigal drape and gowns-Blue/white non woven - Surgigal drape and gowns-Blue laminated non woven
Cleanliness - Microbial (CFU/100cm²)	EN ISO 11737-1	<300	<300	Conformed	- SS Hydrophobic Spunbond - SS Hydrophylic Spunbond - Surgigal drape and gowns-Blue/white non woven - Surgigal drape and gowns-Blue laminated non woven
Cleanliness - Particulate matter (IPM)	EN ISO 9073-10	<3,5	<3,5	Conformed	- SS Hydrophobic Spunbond - SS Hydrophylic Spunbond - Surgigal drape and gowns-Blue/white non woven - Surgigal drape and gowns-Blue laminated non woven
Linting (Log10 (lint count))	EN ISO 9073-10	<4,0	<4,0	Conformed	- SS Hydrophobic Spunbond - SS Hydrophylic Spunbond - Surgigal drape and gowns-Blue/white non woven - Surgigal drape and gowns-Blue laminated non woven
Resistance to liquid penetration	EN 13795	≥ 100	≥ 10	Conformed	- SS Hydrophobic Spunbond - SS Hydrophylic Spunbond - Surgigal drape and gowns-Blue/white non woven - Surgigal drape and gowns-Blue laminated non woven
Bursting strength - dry	EN 13795	≥ 40	≥ 40	Conformed	- SS Hydrophobic Spunbond - SS Hydrophylic Spunbond - Surgigal drape and gowns-Blue/white non woven - Surgigal drape and gowns-Blue laminated non woven
Bursting strength - wet	EN 13795	Not required	≥ 40	Conformed	- SS Hydrophobic Spunbond - SS Hydrophylic Spunbond - Surgigal drape and gowns-Blue/white non woven - Surgigal drape and gowns-Blue laminated non woven
Tensile strength - dry	EN 13795	≥ 20	≥ 20	Conformed	- SS Hydrophobic Spunbond - SS Hydrophylic Spunbond - Surgigal drape and gowns-Blue/white non woven - Surgigal drape and gowns-Blue laminated non woven
Tensile strength - wet	EN 13795	Not required	≥ 20	Conformed	- SS Hydrophobic Spunbond - SS Hydrophylic Spunbond - Surgigal drape and gowns-Blue/white non woven - Surgigal drape and gowns-Blue laminated non woven

BIOCOMPATIBILITY

Biocompatability studies has been done, and test results are given in the below table. Test results are within limits.

Table 31 Biocomtability Study Documentation

Test Name	***Test Method***	***Test facility***	***Report No***	***Report Date***	***Result***
Cytotoxicity	ISO10993-5:2010	HACETTEPE UNIVERSITY	ARGEDS-2016/37	01.08.2016	*Confirmed*
Sensitizasyon *Sensitization*	ISO10993-10: 2014	HACETTEPE UNIVERSITY	ARGEDS-2016/37	24.10.2016	*Confirmed*
Cilt İrritasyon *Skin Irritation*	ISO10993-10: 2014	HACETTEPE UNIVERSITY	ARGEDS-2016/37	11.06.2016	*Confirmed*

Instruction for use:

1. The package of product shall be opened in sterile and aceptic conditions.
2. For a clean peel, open the package from the direction of the arrow slowly .
3. There are labels or marks on the drapes, which helps the user to follow the patient direction and unfolding directions.
4. For the is incision film or adhesive tape on the drapes,first of all peel the paper carrier and fix the drape on the operational area of the patient. After then unfold the drape by following the directions.
5. Surgical drapes are ready for the operation, when they are completely unfolded.

	Do not use if package is damaged		Manufacturer		Single Use (Do not re-use)		Use by date
	Do not expose the product to sunlight.	REF	Catalogue number		Consult instructions for use	10 °C 30 °C	Temperature Limitation
	Do not re-sterilize		Manufacturing Date	STERILE EO	Sterilized using Ethyleneoxide and Single sterile barier system	CE 2696	CE Marking
	Keep Dry	LOT	Batch Code		Caution	MD	Medical device
	Unique device identifier						