# TECHNICAL DATA SHEET

## Craniatomy Cover

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

## Craniotomy 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** | The craniotomy drape set is used for neurosurgery operations. |

### Quality

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

### Bio-Compatibility

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

### Related Standart

- ISO 13485:2016 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.** Craniotomy Drape

# 1. Craniotomy Drape Dimensions

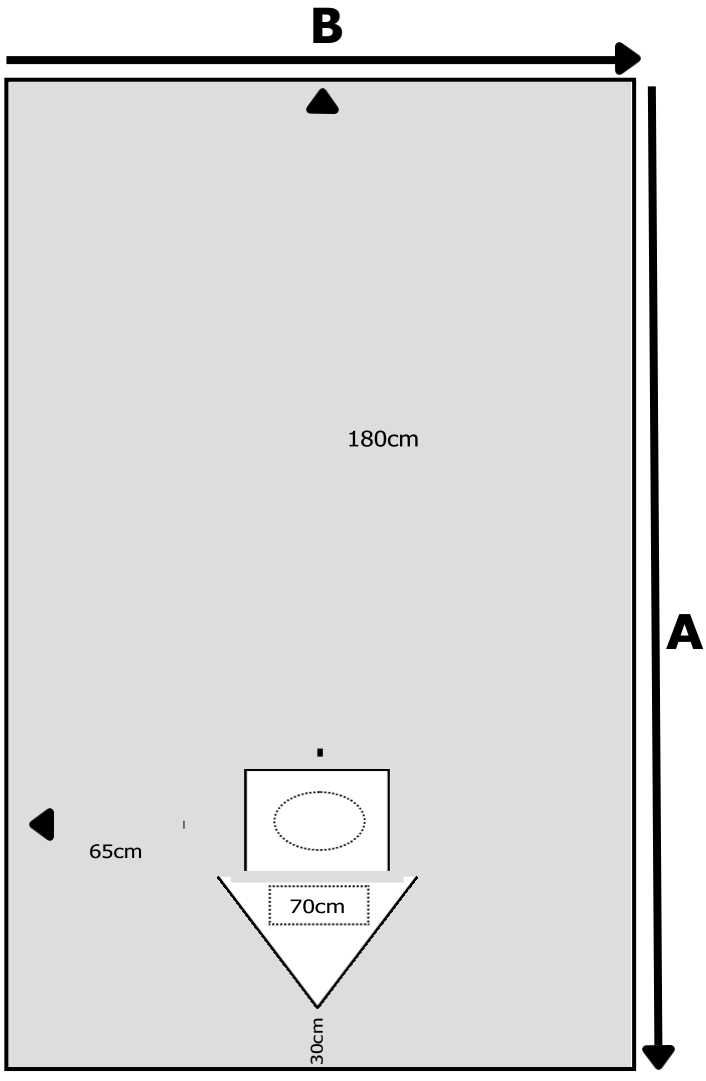



**Figure 1.** Craniotmy Drape Technical Spesifications

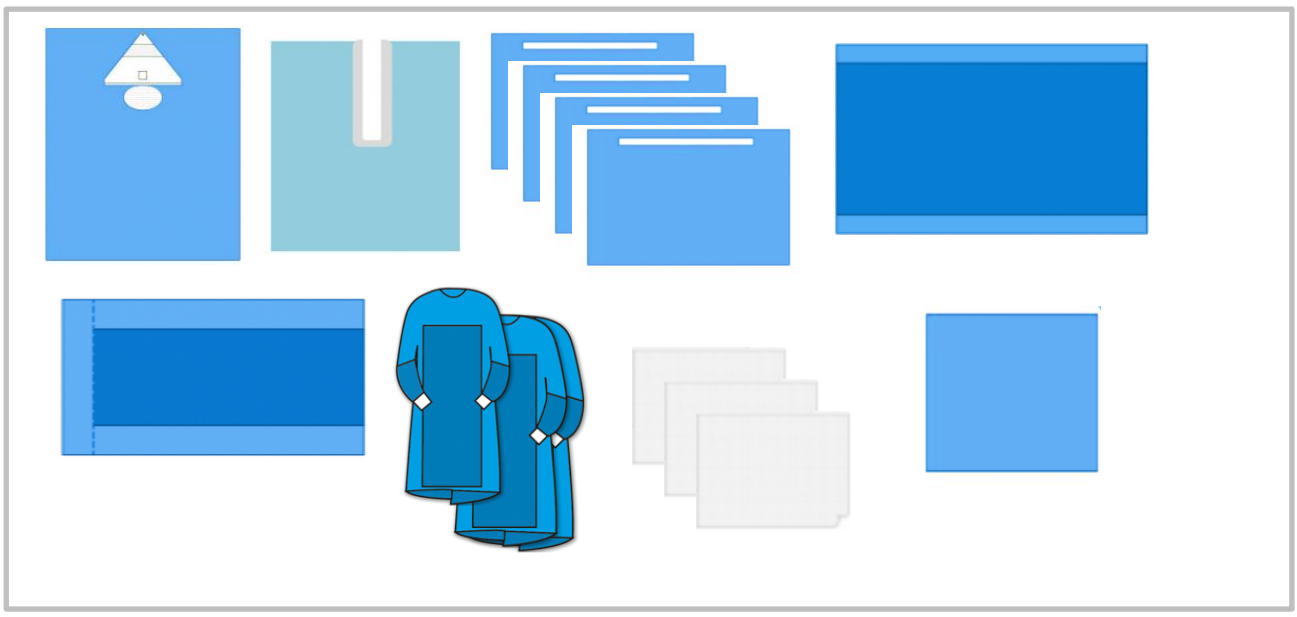
**Avaliable Materials:** 02 Dublex (PE/Viscose or PE/Spunbond PP), 54-56 gr/m2
Incision Film: Fenestration is covered with polyurethane incision film

| | DIMENSIONS (CM) | | NUMBER İN COLUMN | |
|---|---|---|---|---|
| REF . CODES | A | B | 50×80×50 | 40×60×40 |
| 571.0X.000.01 | 350 | 200 | 75 | 25 |
| 571.0X.000.01 | 290 | 230 | 75 | 25 |

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

## 2. Craniotomy Pack Content

| Craniotomy Pack | Size | QTY |
|---|---|---|
| Craniotomy drape | 200*350cm | 1x |
| U split drape | 150*250cm | 1x |
| Drape w/adhesive | 75*90cm | 4x |
| Back table cover | 150*200cm | 1x |
| Mayo stand cover | 75*145cm | 1x |
| Reinforced surgical gown | L | 3x |
| Medical towel | 40*40cm | 3x |
| non-woven wrap | 100*100cm | 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<br>- SS Hydrophylic Spunbond<br>- Surgigal drape and gowns-Blue/white non woven<br>- Surgigal drape and gowns-Blue laminated non woven |
| Resistance to microbial penetration - Wet (/ B) | EN ISO 22610 | 6,0 | Not required | Conformed | - SS Hydrophobic Spunbond<br>- SS Hydrophylic Spunbond<br>- Surgigal drape and gowns-Blue/white non woven<br>- Surgigal drape and gowns-Blue laminated non woven |
| Cleanliness - Microbial (CFU/100cm²) | EN ISO 11737-1 | <300 | <300 | Conformed | - SS Hydrophobic Spunbond<br>- SS Hydrophylic Spunbond<br>- Surgigal drape and gowns-Blue/white non woven<br>- Surgigal drape and gowns-Blue laminated non woven |
| Cleanliness - Particulate matter (IPM) | EN ISO 9073-10 | <3,5 | <3,5 | Conformed | - SS Hydrophobic Spunbond<br>- SS Hydrophylic Spunbond<br>- Surgigal drape and gowns-Blue/white non woven<br>- Surgigal drape and gowns-Blue laminated non woven |
| Linting (Log10 (lint count)) | EN ISO 9073-10 | <4,0 | <4,0 | Conformed | - SS Hydrophobic Spunbond<br>- SS Hydrophylic Spunbond<br>- Surgigal drape and gowns-Blue/white non woven<br>- Surgigal drape and gowns-Blue laminated non woven |
| Resistance to liquid penetration | EN 13795 | ≥ 100 | ≥ 10 | Conformed | - SS Hydrophobic Spunbond<br>- SS Hydrophylic Spunbond<br>- Surgigal drape and gowns-Blue/white non woven<br>- Surgigal drape and gowns-Blue laminated non woven |
| Bursting strength - dry | EN 13795 | ≥ 40 | ≥ 40 | Conformed | - SS Hydrophobic Spunbond<br>- SS Hydrophylic Spunbond<br>- Surgigal drape and gowns-Blue/white non woven<br>- Surgigal drape and gowns-Blue laminated non woven |
| Bursting strength - wet | EN 13795 | Not required | ≥ 40 | Conformed | - SS Hydrophobic Spunbond<br>- SS Hydrophylic Spunbond<br>- Surgigal drape and gowns-Blue/white non woven<br>- Surgigal drape and gowns-Blue laminated non woven |
| Tensile strength - dry | EN 13795 | ≥ 20 | ≥ 20 | Conformed | - SS Hydrophobic Spunbond<br>- SS Hydrophylic Spunbond<br>- Surgigal drape and gowns-Blue/white non woven<br>- Surgigal drape and gowns-Blue laminated non woven |
| Tensile strength - wet | EN 13795 | Not required | ≥ 20 | Conformed | - SS Hydrophobic Spunbond<br>- SS Hydrophylic Spunbond<br>- Surgigal drape and gowns-Blue/white non woven<br>- 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 | | | | | | |