

TECHNICAL DATASHEET FOR EASY SURGICAL SERIES

Reference

10610023

*** Same sets are available as NON-STERILE with reference 10620023.

Designation

Craniotomy Surgery Set

Description

Craniotomy Surgery Set available with a standard set of contents which may be also customized upon request.

Usage

EASY SURGICAL Craniotomy Surgery Set is used to reduce risk of infection and create a focus on operation area in general surgical operations while offering safety and comfort to surgeons. Craniotomy Surgery Set is designed for use in craniotomy operations.

Transport

Sets are transported in a carton boxes. Basic warnings and information is printed on cartons with manufacturer information and contact details. CE marking & name of set are on carton boxes.

Reference No	Carton Dimensions (W x D x H – mm)	Number of Sets / Carton
10610023	600 x 450 x 600 mm	8

Packing

All components are packed in operational order so that efficiency is ensured. Depending on the preference 2 options are available:

- Pouch Pack: Pouch has necessary peeling opening available.
- PE Pouch with Tyvek Window: Pouch has a peeling side marked.

Packages show the information below:

- Product series name & product name
- Set contents with quantities
- Manufacturing date
- Date of expiry
- Lot number
- Reference number
- Sterilization indicator
- Method of sterilization
- Warnings (don't use open packages, for single use only, latex free)
- Manufacturer contact & company information

Sterility

Craniotomy Surgery Set (Ref: 10610023) is sterilized with EO sterilizer in house. Sterilization is documented and monitored through necessary forms, biological indicators, chemical indicators, dosimeters and data loggers.

It is possible upon request to have gamma sterilized products upon request. Please request information from your Agent / Sales Representative for getting more information on gamma sterilized **EASY SURGICAL** series.

It is possible to have NON-STERILE products upon request. (Ref: 10620023)

Shelf Life

Product has been tested for stability. Test reports show that Craniotomy Surgery Sets have a shelf life of 3 years.

Quality Certification & Compliance

All process across SUBMED is run in compliance with EN ISO 9001 & EN ISO 13485.

Independent third party laboratories tested **EASY SURGICAL** series for packing sealing strength is in compliance with EN ISO 868-5, stability according to ASTM F 1980 and package leak tests according to ASTM F 1929. Thermoforming line is validated for temperature and pressure settings according to EN ISO 17025.

Sterilization process has been validated according to EN ISO 11135-1, for sterilization by Ethylene Oxide. Sterilizer is also validated by IQ and OQ tests.

Our manufacturing plant and clean room is in compliance and been tested for EN ISO 11605, EN ISO 14644-1, EN ISO 14644-2, EN ISO 14698-1 and EN ISO 14698-2 tests for bio contamination levels in order to assure relevant safety levels in all products.

EASY SURGICAL series are tested for bio-burden according to EN ISO 11737-1. To achieve highest quality EO residue is also tested according to EN ISO 10993-7.

EASY SURGICAL series are manufactured in compliance with EN 13795:2011. According to EN 13795:2011, **EASY SURGICAL** series comply with EN ISO 22610:2006, EN ISO 11737-1:2006 + AC:2009, EN ISO 22612:2005, EN ISO 9073-10:2003, , EN 20811:1992, EN 13938:1999 and EN 29073-3:1992.

Craniotomy Surgery Sets are CE Class IS products and have been certified by independent third parties from EU for compliance with standards.

Content

Description	Qty.
Table Cover, 140 x 190 cm.	1
Mayo Stand Cover, 80 x 145 cm.	1
Craniotomy Drape, 230 x 300 cm.	2
Adhesive Drape, 50 x 50 cm.	4
OP Tapes, 10 x 50 cm.	2
Hand Towel, 40 x 40 cm.	2
Reinforced Surgical Gown, L Size	2
Bundle Cover, 100 x 100 cm.	1

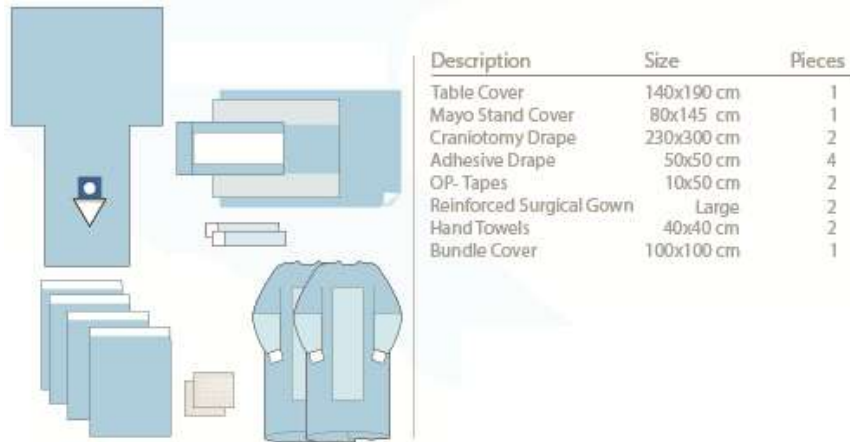
Materials of Selection

All set components are made of absorbent fabrics in order to maximize protection while offering comfort for surgeons. Materials used can be made of from one of the below listed selections:

- 2 Ply (Standard)
- 3 Ply (Optional)

Please request information from your Agent / Sales Representative for getting more information on tailor made solutions of **EASY SURGICAL** series.

Technical Drawing



Storage

Store the product under normal conditions for healthcare material, in a cool and dry place protected from light. The use of medical grade paper and film guarantees its sterility for the duration of its shelf life under normal transport and storage conditions.

Comments

The product must be used by specialised personnel only. Check the package's integrity before use. Do not use if the package is open or damaged.