**Intended Purpose**

Intended Use:

Cardiac & Thoracic/Hybrid

The CombiSets for cardiac & thoracic / hybrid surgery are single-use, sterile component sets, customized for various interventions on humans in the field of cardiac & thoracic / hybrid surgery such as

- Angiocardiography - all interventions where coronary arteries with X-ray contrast agents via X-ray are shown

- Bypass - all bypass interventions due to constrictions or stenosis of the coronary arteries

- Heart surgery - all interventions of the open heart

- Lung surgery - all interventions of the lung (open and laparoscopic)

- MIC valve replacement - minimal invasive heart valve replacement.

- Operation on thorax - all surgery on the thorax

- Thoracoscopy - all laparoscopic interventions of the thorax

- Thoracotomy - all open interventions of the thorax

- Valve replacement - open heart valve replacement

performed by healthcare professionals within an operating theater; the single components might get in contact with skin, mucosal membranes, injured skin, circulatory system, bone and blood, and it is intended for long term use.

Target user/group: Healthcare professionals

Medical device class of the set (based on component with the highest classification): II b

“The CombiSet is a procedure pack.”

**Application/Indication**

The medical indication results from the necessity to perform an operation in the field of cardiac & thoracic / hybrid surgery by , e.g., angiocardiography (method of following the passage of blood through the heart and great vessels) , bypass (to treat coronary artery disease) , heart surgery (e.g., after heart failure, vegetations and embolic risk or fungal infective endocarditis), lung surgery (e.g. to treat chronic lung infection (multiple abscesses, bronchiectasis, fungal infection, tuberculosis), minimal invasive heart valve replacement (to replace a poorly working aortic valve with an artificial valve) , operation on thorax (e.g. pneumothorax or malignant effusions (pleurodesis) , thoracoscopy (e.g., workup and diagnosis of idiopathic pleural effusions, staging of lung cancer), thoracotomy (to treat lung cancer) or valve replacement (for patients diagnosed with severe aortic stenosis)

**Reference Number**

2622333

|  |  |  |
| --- | --- | --- |
| **Quantity** | **Component description** | **Included substances** |
| 1 | Needle Holder 14 cm Mayo Hegar with adjustment | See set label |
| 1 | Scissors 14,5 cm straight straight | See set label |
| 1 | Scissors Mayo 15,5 cm straight curved | See set label |
| 1 | Safety Scalpel Fig. 11 normal | See set label |
| 1 | Forceps surgical straight 14 cm | See set label |
| 1 | Fenestrated drape adh PE 78 cm 100 cm 7 cm | See set label |
| 5 | Pagasling No. 3 plum-size 20x20 cm | See set label |
| 1 | Forceps splinter anatomic straight 9 cm | See set label |
| 1 | Dagrofil 1 USP 4 metric braided, non absorbable | See set label |
| 1 | Hemostatic Forceps Kocher traumatic straight 14 cm | See set label |
| 1 | Forceps anatomic straight 14,0 cm | See set label |
| 3 | Hemostatic Forceps Halstead Mosquito atraumatic curved 12,5 cm | See set label |

**Instuction for use, Contra-Indications and Undesirable Side Effects, Warnings:**

Consult instructions for use

Caution

For possible contraindications please follow the instructions/warning hints of the individual set items listed in the instructions for use enclosed within the set.

**Sterile Device:**

Sterilized using ethylene oxide

Do not use if package is damaged

 Do not resterilize

**Single Use Device:**

Do not re-use

Reusing a single-use medical device is dangerous. Reprocessing devices, in order to reuse

them, may seriously damage their integrity and their performance. Information available

on request.

**Product Disposal**

To minimize the risk of potential infection hazards, or environmental pollution, disposable

components of CombiSet ® should follow disposal procedures according to applicable and

local laws, rules, regulations and infection prevention standards.

**Incident Reporting**

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the kitpacker.

**Product Performance Characteristics**

|  |  |
| --- | --- |
| **Property** | **Applicable standard** |
| Manufacturing practice in cleanroom conditions | FDA Guide on sterie Drug Products  EN ISO 14644 |
| Packaging | DIN EN ISO 11607 |
| Sterilization | DIN EN ISO 11135-1 |
| Transport | DIN EN ISO 11607, ISO/TS 16775, ASTM D4169, ISTA Test procedures 2A, 3A & 3B |
| Biological evaluation | DIN EN ISO 10993 |
| Risk management | EN ISO 14971 |
| Symbols medical devices | EN ISO 15223-1 |
| Quality Managemetn System | EN ISO 13485 |

**Labelling**

For complete Set labeling see set label.

The set is offered with a repositionable sticker showing barcode for the traceability. It can be stuck on patients file.

Data matrix according to GS1: EAN-128 codes readable on each packaging level.

Lot-No. with 8-Digit Code

e.g.:

|  |  |  |  |
| --- | --- | --- | --- |
|  | 0 | 12 | XXXXX |
|  | year | week of production | for internal purposes only |

Manufacturing Date

e.g.:  2015 04 07

year month day

Use-by-Date



e.g.: 2015 04 07

year month day

Shelf Life: Maximum 5 years, or the shelf life of the component with the shortest shelf-life

Medical Devices in the set are indicated by following symbol



Unique Device Indetification (UDI) for the set:



Single Sterile Barrier Symstem



Sterile Barrier System with Protective Packaging In- Outside



**Packaging: Multivac**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Primary packaging/transport carton** | Primary packaging/dispenser | transport carton/pallet | Primary packaging dimension | **Dispenser dimension** | **Transport carton dimension** | **Pallet dimension** |
| 26 | n.a. | 16 | Multivac | n.a | 570 x 367 x 418 mm | 1200 x 800 x 1950 mm |

**Latest Date of Revision: 2023-04-21**