**Intended Purpose**

Intended Use:

The wound care sets are single-use, sterile sets made with various components, intended to help a wound healing.

During a wound care procedure, such operations can be done:

· dressing renewal

· wound cleaning

· prepration of the area

The care is performed by a healthcare professional in institution or for homecare on all kinds of patient without restriction on age or gender.

The wound care set is used less than 60 minutes. But some components contained can remain in place on the wound after the pose until several days (depending on the dressing and the recommendation of the manufacturer).

There is no accumulated use of the set but it might have accumulated use of a dressing which will be always less than 30 days (based on the qualified dressings).

The components might be in contact with skin, mucosal membranes, injured skin, for a maximum of short-term use (depending of the composition of the set).

Target user/group: Healthcare professionals

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

“The MediSet is a procedure pack.”

**Application/Indication**

The indication results from the necessity to perform a care allowing the healing of a wound.

That could include only the cleaning or the various steps of the wound care:

- Old dressing removal

- Wound cleaning

- New dressing

**Reference Number**

4800362

|  |  |  |
| --- | --- | --- |
| **Quantity** | **Component description** | **Included substances** |
| 5 | Pagasling No. 3 plum-size 20x20 cm | See set label |
| 5 | Medicomp 7,5 cm 7,5 cm 4 ply | See set label |
| 1 | ECO Drape 45 cm 37,5 cm  | See set label |
| 1 | Forceps atraumatic straight 12,5 cm | See set label |
| 1 | Forceps atraumatic straight 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 MediSet ® 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 ProductsEN 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 3 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 Identification (UDI) for the set:



Single Sterile Barrier Symstem



Sterile Barrier System with Protective Packaging In- Outside



Double Sterile Barrier System



**Packaging: Multivac in Hard Blister in 3 Alveolas**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Primary packaging/transport carton** | Primary packaging/dispenser | transport carton/pallet | Primary packaging dimension | **Dispenser dimension** | **Transport carton dimension** | **Pallet dimension** |
| 84 | n.a. | 28 | 145 x 140 x 34 mm | n.a  | 587 x 387 x 234 mm | 1200 x 800 x 1928 mm |

**Latest Date of Revision: 2024-12-19**