MediSet®, stérile

Urinkatheter-Set Standard Superior 1, 4800711

Intended Purpose
Intended Use:
The urinary catheterization sets are single-use, sterile sets made with various components.
During the urinary catheterization procedure, such operation can be done:

- Preparation of the area
- Insertion of an urethral catheter (not included) into the urinary bladder
- removal of urethral catheter

The care is performed by a healthcare professional in institution and for homecare on all kinds of patient without restriction on age or gender.
The urinary catheterization kits can be used more than 60 minutes (if jelly relevant) but always less than 30 days. The frequency of renewal depends of the clinician prescription.
There is no accumulated use of the care set. Some components can have an accumulated use but they can be separately provided or not and the accumulated use is under the clinician decision.
The components might be in contact with skin, mucosal membranes, injured skin for a short-term use.
Target user/group: Healthcare professionals
Medical device class of the set (based on component with the highest classification): III
“The MediSet is a procedure pack.”

Application/Indication

The indication results from the necessity to perform an urinary catheterization or to remove an urethral catheter.

Reference Number

4800711

Quantity	Component description	Included substances
2	Sterilux ES compresse 7,5 cm 7,5 cm 8 ply	See set label
1	Actolind W solution 50 ml bottle Polyhexanide, Poloxamer	See set label
4	Pagasling No. 3 plum-size 20x20 cm	See set label
1	Nitrile Powderfree Examination Gloves L latex-free PHAG	See set label
1	Catheter Gel 12 ml filled syringe 2 % Lidocain	See set label
1	ECO Drape 55 cm 50 cm	See set label
2	Nitrile Powderfree Examination Gloves L latex-free PHAG	See set label
1	ECO Fenestrated Drape 75 cm 60 cm 10 Ø cm	See set label
2	Forceps atraumatic straight 12,5 cm	See set label
1	Farco-fill Aqua-Glycerol 10 ml filled syringe 10% Glycerin	See set label

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


Consult instructions for use

MediSet®, stérile

Urinkatheter-Set Standard Superior 1, 4800711

 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.

MediSet®, stérile

Urinkatheter-Set Standard Superior 1, 4800711

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 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.:

LOT	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

MediSet®, stérile

Urinkatheter-Set Standard Superior 1, 4800711

---

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

MD

Unique Device Identification (UDI) for the set:

UDI

Sterile Barrier System with Protective Packaging In- Outside

Packaging: Multivac in Hard Blister in 2 Alveolas

Primary packaging /transport carton	Primary packaging /dispenser	transport carton/pallet	Primary packaging dimension	**Dispenser dimension**	**Transport carton dimension**	**Pallet dimension**
12	n.a.	35	260 x 135 x 70 mm	n.a	530 x 220 x 320 mm	1200 x 800 x 1928 mm

Latest Date of Revision: 2025-01-10