

MediSet[®], stérile

Nahtentfernung mit Schere, 4756995

Intended Purpose

Intended Use:

The suture/thread removal sets are single-use, sterile sets made with various components, intended to perform a suture or to remove the threads or the staples of a suture out of OP room.

During a suture/thread removal procedure, such operations can be done:

- general suture
- gynecology suture
- removal of threads or staples.

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

The suture/thread removal care set is used more than 60 minutes but less than 1 day (no suture material). There is no accumulated use of the care set.

The components might be in contact with skin, mucosal membranes, injured skin, blood 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 suture or to remove the threads or the staples of a suture.

That could include the preparation or the realization during:

- General suture
- Gynecology suture
- Removal of threads or staples

Reference Number

4756995

Quantity	Component description	Included substances
2	Gauze swab 5 cm 5 cm 8 ply	See set label
1	Forceps Micro Adson anatomic straight 12 cm	See set label
1	Scissors Iris 11,5 cm straight straight	See set label

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



Consult instructions for use



Caution

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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 re-sterilize

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.

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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 sterile 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 Management 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
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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 System



Single sterile barrier system

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
88	n.a.	64	175 x 70 x 18 mm	n.a.	380 x 280 x 200 mm	1200 x 800 x 1928 mm

Latest Date of Revision: 2024-07-03