

Peha[®]-instrument Needle holder, sterile

General Product Description/Intended Purpose

Peha-instrument Needle holders are single-use surgical steel instruments used for short-term treatment in the context of suturing tissue on humans and used by healthcare professionals in combination with needles and threads. The devices are intended to be used in a sterile condition.

Application/Indication

Needle holders are intended for use in the context of suturing tissue on humans and used by healthcare professionals in combination with needles and threads.

The detailed indication of Peha-instrument needle holder is listed below:

Name	Intended use
Mayo-Hegar needle holder 12 cm	holding needles
Mayo-Hegar needle holder 14 cm	holding needles
Mayo-Hegar needle holder 16 cm	holding needles

Reference Numbers

Product PHI	Size	Reference number	Medical device class	Rule
Mayo-Hegar needle holder	12 cm	991031	Ila	6
Mayo-Hegar needle holder	14 cm	991030	Ila	6
Mayo-Hegar needle holder	16 cm	991034	Ila	6

Residual Risks, Contra-Indications and Undesirable Side Effects, Warnings

Residual Risk: Several risks were evaluated in the risk management file. No significant risk remained after design risk mitigation strategies.

Contra-Indications: None

Side Effects: Not known

Important safety instructions: It is essential to ensure a precise use and continuous monitoring/check of the correct functioning of the instruments during the entire use

Sterile Device

Do not use if package is damaged (peel pouch)

Single Use Device

Reusing a single-use medical device is dangerous. Reprocessing devices, in order to reuse them, may seriously damage their integrity and performance. Reuse of the product could lead to microbiological contamination and/or mild infections of the skin. The flawless functionality of the product is no longer given, and it could be contaminated with non-biocompatible materials. Information available on request.

Product Disposal

To minimize the risk of potential infection hazards, or environmental pollution, disposable components of Peha-instrument needle holder should follow disposal procedures according to applicable and local laws, rules, regulations and infection prevention standards.

Peha[®]-instrument Needle holder, sterile

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 manufacturer and/or its authorized representative and to your national authority.

Product Characteristics

Property	Material name	Reference
Steel quality	AISI 430	Refer to standards (ASTM F899 and DIN EN ISO 7153-1) 1)

Labelling

Lot-No. with 8-Digit Code

e.g.:



0

year

12

week of
production

XXXXX

for internal purposes only

Manufacturing Date

e.g.:


2015
year

04
month

07
day

Use-by-Date

e.g.:


2015
year

04
month

07
day

Shelf Life: 5 years

Medical Device


Medical
Device

Unique Device Identification (UDI)



Single Sterile Barrier System


Single sterile
barrier system

Manufacturer



Distributor



Distributor

Peha[®]-instrument Needle holder, sterile

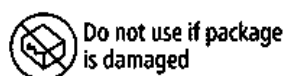
CE mark with identification no. 0123



Do not reuse



Do not use if package is damaged (peel pack)



Keep dry



Keep away from sunlight



Sterilized using ethylene oxide



Do not resterilize



Green dot



Symbol of recycling



Triman (France)



Important safety instructions: It is essential to ensure a precise use and continuous monitoring/check of the correct functioning of the instruments during the entire use



Peha[®]-instrument Needle holder, sterile

Open the top of the dispenser to find the important safety instructions



Latest Date of Revision: 2021-02-25