

Peha[®]-instrument Wound hooks, sterile

General Product Description/Intended Purpose

Peha - instrument Wound hook is a single-use surgical steel instrument for short-term treatment in the context of surgical interventions such as holding and separation of tissue and/or organs on humans used by healthcare professionals. The devices are intended to be used in a sterile condition.

Application/Indication

Wound hooks are intended for use in the context of holding and separation of tissue on humans during medical interventions.

The detailed indication of Peha-instrument wound hooks is listed below:

Name	Intended use
Wound hook combination 16 cm	holding of tissue

Reference Numbers

Product PHI	Size	Reference number	Medical device class	Rule
Wound hook combination	16 cm	991012	Ila	6

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

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

Peha[®]-instrument Wound hooks, sterile

Product Characteristics

Property	Material name	Reference
Steel quality	AISI 410	Refer to standards (ASTM F899 and DIN EN ISO 7153-1)

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



Unique Device Identification (UDI)



Single Sterile Barrier System



Manufacturer



Distributor



CE mark with identification no. 0123

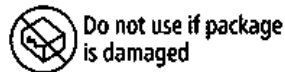


Peha[®]-instrument Wound hooks, sterile

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



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



Latest Date of Revision: 2021-02-25