

Peha[®]-instrument Scissors, sterile

General Product Description/Intended Purpose

Peha–instrument Scissors are single-use surgical steel instruments intended for transient treatment in the context of medical interventions such as cutting and preparation of tissue, suture, dressings, etc. on humans used by healthcare professionals. The devices are intended to be used in a sterile condition.

Application/Indication

Scissors are intended for use in the context of medical interventions such as cutting and preparation of tissue on humans, suture, dressings, etc. Bandage scissors are intended only for cutting of dressing.

The detailed indication of Peha-instrument scissors is listed below:

Name	Intended use
Braun-Stadler episiotomy scissors 14.5 cm	Episiotomy
Operating scissors sharp/blunt straight 14.5 cm	cutting of threads, dressing etc. cutting/preparation of tissue; incision
Operating scissors blunt/blunt straight 14.5 cm	cutting of threads, dressing, hair etc.; cutting/preparation of tissue; incision
Operating scissors sharp/sharp straight 13 cm	cutting of threads, dressing etc. cutting/preparation of tissue; incision
Metzenbaum scissors blunt/blunt curved 14.5 cm	cutting/preparation of tissue
Iris scissors straight 11.5 cm	Preparation of tissue, also in plastic and eye surgery
Iris scissors curved 11.5 cm	Preparation of tissue, also in plastic and eye surgery
Bandage scissors 16 cm	Cutting of threads and dressing
Micro-scissors 11 cm	Cutting and preparation of tissue; used in hand, plastic and eye surgery

Reference Numbers

Product PHI	Size	Reference number	Medical device class	Rule
Bandage scissors	16 cm	991090	I	1
Operating scissors sharp/blunt straight	14.5 cm	991081	Ila	6
Braun-Stadler episiotomy scissors	14.5 cm	991080	Ila	6
Iris scissors curved	11.5 cm	991087	Ila	6
Micro-scissors	11 cm	991085	Ila	6
Metzenbaum scissors blunt/blunt curved	14.5 cm	991084	Ila	6
Operating scissors sharp/sharp straight	13 cm	991083	Ila	6
Operating scissors blunt/blunt straight	14.5 cm	991082	Ila	6
Iris scissors straight	11.5 cm	991086	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: Finger pain and fatigue, injuries due to dull instruments or due to incorrect application

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)

Peha®-instrument Scissors, sterile

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.

Product Characteristics

Property	Material name	Reference
Steel quality	AISI 420A	Refer to standards (ASTM F899 and DIN EN ISO 7153-1)

Labelling

Lot-No. with 8-Digit Code

e.g.:



0

12

XXXXX

year

week of production

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)



Peha[®]-instrument Scissors, sterile

Single Sterile Barrier System



Manufacturer



Distributor



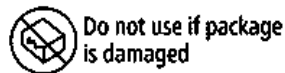
CE mark with identification no. 0123



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



Peha[®]-instrument Scissors, sterile

Symbol of recycling



Triman (France)



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



Latest Date of Revision: 2021-02-25