Peha®-instrument Sharp spoon, sterile; **Peha®-instrument** Curette, sterile

General Product Description/Intended Purpose
Peha-instrument Sharp spoon and Curette are single-use surgical steel instruments for transient treatment in the context of medical intervention such as mechanical wound management by removal of tissue on humans used by healthcare professionals. The devices are intended to be used in a sterile condition.

Application/Indication
Sharp spoon and curette are intended for use in the context of mechanical wound management by removal of tissue on humans during medical interventions.

The detailed indications of Peha-instrument sharp spoons are listed below:

Name	Intended use
Sharp spoon combination 16.5 cm	abrading of tissue
Fox bone curette 14.5 cm	Wound debridement, ablation of bone skin and other (e.g. necrotic) tissue

Reference Numbers

Product PHI	Size	Reference number	Medical device class	Rule
Sharp spoon combination	16.5 cm	991010	IIa	6
Fox bone curette	14.5 cm	991013	IIa	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

Warning: 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.

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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.:

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
	year	month	day

Shelf Life: 5 years

Medical Device

MD Medical Device

Unique Device Identification (UDI)

UDI

Single Sterile Barrier System

Single sterile barrier system

Manufacturer

Peha®-instrument Sharp spoon, sterile; **Peha®-instrument** Curette, sterile

Distributor

CE mark with identification no. 0123

Do not reuse

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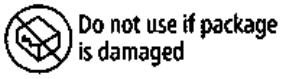

Keep dry

Keep away from sunlight

Sterilized using ethylene oxide

Do not resterilize

Green dot

Symbol of recycling

Triman (France)

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Open the top of the dispenser to find the warning leaflet

Latest Date of Revision: 2021-02-16