FEHLING Osteobioptome	
NKS-6..... Osteobioptome 3.0 x 200 mm, sterile	
	The osteobioptome is a **single-use product** and must not be reprocessed and reused! Due to the mechanics of the instrument, proper reprocessing cannot be guaranteed. Risk of tumor cell carryover when reused!
	The osteobioptome may only be used and disposed of by qualified medical personnel!

1) Intended purpose

Osteobioptomes are used to take tissue samples for fine-tissue examination, in particular biopsies of soft bone tissue (e.g., cancellous bone), for example, in the course of kyphoplasty.

Additional information regarding the intended purpose

Duration of use: Osteobioptome is intended for temporary use.

Field of application: Osteobioptomes are used in all patients in whom tissue samples, especially bone tissue, must be taken for fine tissue examination.

User profile: The osteobioptomes may only be used by medically trained personnel (e.g., specialists).

Application environment: Osteobioptomes are only used under controlled environmental conditions (e.g., OR).

2) Indications

Necessary biopsy of soft bone tissue (e.g. cancellous bone), for example in the case of
- suspected primary or secondary tumor
- pathological compression fracture
- suspected inflammation or infection

3) Contraindication

The osteobioptome must not be used on structures that are too hard (e.g. cortical bone).

Contraindicated are all applications that are contrary to the physical and/or mechanical properties of the individual osteobioptome. In addition, attention must be paid to increased risks that could result from the anatomical and physiological conditions as well as the patient's clinical picture.

4) Possible side effects

The following side effects are described in the medical literature, which may possibly also occur during the intended use of the instruments:
- Infections
- Wound healing disorders

	Medical devices may contain chromium and/or nickel, for example. The materials used are bio-compatible, but they may cause allergic reactions or intolerances.

5) Before use

	Sterile, check packaging for integrity!

	There is a risk of infection when using products from damaged packaging! Do not use products from damaged packaging and return them to the manufacturer! Do not use products from accidentally opened packaging and dispose of them properly.
	Observe the use by date! Do not use products after the use by date! Risk of infection!
	Only use faultless and sterilized products!
	A safety check must be performed before use. Check osteobioptomes for proper functioning by opening and closing them several times! Check osteobioptomes for sharp edges and damage by visual inspection!
	Handle osteobioptomes with care during storage and transport! Avoid blows and punctual loads on the osteobioptome to prevent possible consequential damage! Do not overload functional parts!

6) Configuration and application

The osteobioptome consists of a tube shaft (a) with a welded handle (b), at the distal end of which the movable jaws are located. By pressing the handle (b) together or apart, the jaws can be closed or opened via the inner cable (c) running in the tube shaft (a). Figure 1 shows an osteobioptome with closed (A) and opened (B) jaws.

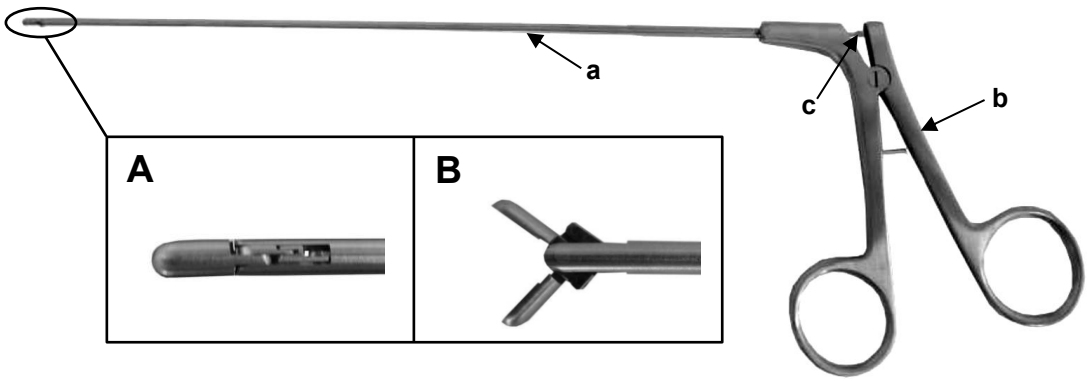

Fig. 1: Osteobioptome with closed (A) and opened (B) jaws.

	Only use faultless and sterilized products!
	Before inserting the osteobioptome, ensure that the surgical field is appropriately prepared.
	Medical devices made of ferromagnetic materials must not be exposed to a magnetic field or electromagnetic external influences.
	Medical devices containing metals are electrically conductive and must not be exposed to a power source or external electrical influences.
	The choice of osteobioptome depends on the anatomical and physiological conditions as well as the area of application. Care must be taken to ensure that the osteobioptomes used are the correct size and have sufficient stability.

During use
A working channel may be required for the application of the osteobioptome. For this purpose, a working sleeve with an inner diameter of 3.2 mm can be used, for example. With the aid of a trocar, a working sleeve, for example, can be inserted through the pedicle into the bone to be examined under fluoroscopic control. The osteobioptome is inserted into the vertebral body through the working channel with the jaws closed. The jaws of the osteobioptome are spread open by actuating the handle (pulling the branches apart). When the branches are squeezed together, the jaw closes and the tissue in between is separated by the sharp jaw parts. Now the biopsy specimen can be removed through the working channel and examined. The application must be performed under fluoroscopic control. The position of the working channel and osteobioptome must be constantly checked!

⚠	Please note that the osteobioptome must be completely closed if it is to be retracted through the working channel! Do not close by force! → Risk of breakage→ Risk of injury!
⚠	Please note that no rotating movement may be performed with the osteobioptome while firmly grasping it! Do not close by force! → Risk of breakage→ Risk of injury!

Special Notes:
If the osteobioptome cannot be retracted through the working channel, open the distal end and retract it slightly to release the biopsy material if necessary. Then retract the instrument through the working channel. In this case, the instrument must be discarded. Do not continue to use the instrument, as the mechanics may be damaged and the instrument can no longer fulfill its function properly!

After use	
⊘2	Do not reprocess, do not reuse! Disposable product - risk of infection if reused!
⚠	Dispose of osteobioptomes according to the clinic's own regulations for infectious waste!

7) Storage

According to § 4 MPBetreibV and standards of the series DIN EN 868, DIN EN ISO 11607 and DIN 58953.
Instruments must be stored in a dry place, at room temperature, clean, protected from damage and mechanical influences (avoid condensation, damage).

⌛	Observe the use-by date! Do not use products after the use-by date!

8) Required Accessories

No accessories are required for the use of the osteobioptome.

9) Obligation to Report Serious Incidents

The user is obliged to report serious incidents that have occurred in connection with the medical device to the manufacturer either by e-mail to vigilance@fehling-instruments.de or via the complaint form at https://www.fehling-instruments.de/en/complaint/ and to the competent authority of the Member State in which the user is established.

Symbols		
As far as shown on the medical device or medical device label or instructions for use, the symbols have the following meaning according to DIN EN ISO 15223-1:		
Manufacturer	Consult instructions for use or consult electronic instructions for use	Caution
REF Catalog number	LOT Batch code	SN Serial number
MD Medical Device	UDI Unique Device Identifier	STERILE R Sterilized using irradiation
Do not re-use	Use-by date	Date of manufacture
Single sterile barrier system	Double sterile barrier system	Keep dry
Keep away from sunlight	Do not use if package is damaged and consult instructions for use	CE 0297 CE marking
CE marking		
Any modification to the product or deviation from these instructions for use will result in exclusion of liability! Subject to change without notice.		

Contact the manufacturer	
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