FEHLING Osteobioptome	
NKS-6 Osteobioptome 3.0 x 200 mm, sterile	
	The osteobioptome is a **single-use device** and must not be reprocessed or reused. Due to the instrument's mechanical design, proper reprocessing cannot be ensured. Risk of tumour cell seeding if the instrument is reused!
	The osteobioptome may only be used and disposed of by qualified medical personnel!

1) Intended purpose

Osteobioptomes are used to obtain tissue samples for fine-tissue examination, particularly for biopsies of soft bone tissue (e.g. cancellous bone) during procedures such as kyphoplasty.

Additional information regarding the intended purpose

Duration of application: Osteobioptomes are intended for temporary use.

Field of application: Osteobioptomes are used in all patients who require tissue sampling, particularly bone sampling, for fine-tissue examination.

User profile: The osteobioptome may only be used by medically trained personnel (e.g. specialist surgeons).

Application environment: Osteobioptomes may only be used in controlled environments (e.g. in the operating room).

Target patient population: No restrictions

2) Indications

Required biopsy of soft bone tissue (e.g. cancellous bone), for example in cases of
- suspected primary or secondary tumour
- pathological compression fracture
- suspected inflammation or infection

3) Contraindication

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

Any use that is incompatible with the physical and/or mechanical properties of the respective osteobioptome is contra-indicated. Furthermore, due consideration must be given to any increased risks arising from the patient's anatomical and physiological characteristics and underlying conditions.

4) Possible side effects

The following side effects are described in the medical literature and may also occur during the intended use of the instruments:
- Infections
- Wound healing disorders
- Injury to structures (tissues, organs, nerves, vessels)

	Medical devices may contain, for example, PEEK, chromium, nickel and/or titanium. The materials used are biocompatible; however, they may cause allergic reactions or intolerances.

5) Before use	
	Sterile. Check packaging for integrity! There is a risk of infection if products from damaged packaging are used! Do not use products from damaged packaging. Return them to the manufacturer! Do not use products from accidentally opened packaging. Dispose of them properly!
	Observe the expiry date! Do not use products after the stated expiry date. Return them to the manufacturer! Risk of infection!
	Use only intact and sterilised products!
	Always perform a safety check before using an osteobioptome. Check for scratches, notches, cracks, deformation, and legible labelling. Check the osteobioptome for proper functioning by opening and closing it several times! Visually inspect the osteobioptome for sharp edges and signs of damage!
	Handle the osteobioptome with care during storage and transport! Avoid mechanical shock and point loading on the osteobioptome to prevent secondary damage! Do not overload functional parts!

6) Configuration and use
The osteobioptome consists of a tubular shaft (a) with a welded-on handle (b), at the distal end of which are the movable jaws. By pressing the arms of the handle (b) together or spreading them apart, the jaws can be closed or opened via the inner pull mechanism (c) running through the tubular shaft (a). Figure 1 shows an osteobioptome with closed (A) and open (B) jaws.

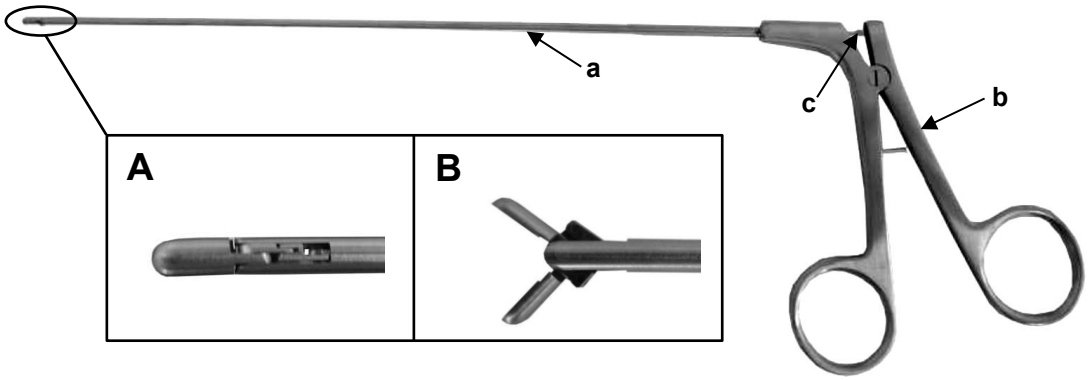


Fig. 1: Osteobioptome with closed (A) and open (B) jaws

	Use only intact and sterilised products!
	Before inserting the osteobioptome, ensure that the surgical field has been appropriately prepared.
	Do not expose medical devices made of ferromagnetic materials to magnetic fields or external electromagnetic interference.
	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 patient's anatomy and physiology and on the field of application.Ensure that the osteobioptome used has the correct size and geometry and is sufficiently stable.

During application

A working channel may be required when using the osteobioptome. For this purpose, a working sleeve with an inner diameter of 3.2 mm can be used, for example.

For instance, a trocar may be used to insert a working sleeve under fluoroscopic guidance through the pedicle into the bone to be examined.

With the jaws closed, insert the osteobioptome into the vertebral body through the working channel. Open the jaws of the osteobioptome by pulling the handle arms apart. When the handle arms are pressed together, the sharp jaws close and cut free the tissue between them. The biopsy specimen can then be retrieved through the working channel and examined.

The procedure must be performed under fluoroscopic guidance. The positions of the working channel and osteobioptome must be monitored continuously!

⚠	Ensure that the jaws of the osteobioptome are fully closed when withdrawing the instrument through the working channel! Do not force the jaws closed! → Risk of breakage → Risk of injury!
⚠	Do not rotate the osteobioptome while its jaws are firmly gripping tissue! Do not force the jaws closed! → Risk of breakage → Risk of injury!

Special notes:

If the osteobioptome cannot be withdrawn through the working channel, open the jaws and pull the instrument back slightly to release the biopsy specimen if necessary. Then withdraw the instrument through the working channel. In this case, the instrument must be discarded. Do not continue using the instrument. Its mechanism may be damaged, and it may no longer function correctly!

After use

	Do not reprocess, do not reuse! Single-use device – risk of infection if reused!
⚠	Dispose of the osteobioptome in accordance with the hospital's own regulations for infectious waste!

7) Storage

In accordance with § 4 MPBetreibV (Medical Devices Operator Ordinance) and the standards of the DIN EN 868, DIN EN ISO 11607 and DIN 58953 series.
To prevent condensation and damage, store the instruments in a clean, dry place at room temperature, protected from damage, sunlight and mechanical stress.

	Observe the expiry date! Do not use products after the stated expiry date. Return them to the manufacturer!

8) Required accessories

No accessories are required to use the osteobioptome.

9) Obligation to report serious incidents

The user is obliged to report serious incidents which 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 domiciled.

Symbols		
Where shown on the medical device, medical device label or instructions for use, the symbols have the following meanings according to DIN EN ISO 15223-1:		
Manufacturer	Consult instructions for use or consult electronic instructions for use	Caution
REF Catalogue number	LOT Batch code	SN Serial number
MD Medical device	UDI Unique device identifier	STERILE EO Sterilised using ethylene oxide
Do not re-use	Use-by date	Date of manufacture
Keep dry	Single sterile barrier system	Double sterile barrier system
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 device or any deviation from these Instructions for Use will result in exclusion of liability. Subject to change without notice.		

Manufacturer's contact information		
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