Osteobioptome, sterile **REF:** **NKS-6,** **NKS-7**	
	Disposable product – intended for single use only. Due to the instrument'sdesign and construction, safe reprocessing cannot be guaranteed. **Do not reprocess. Do not reuse. Risk of tumor cell spread if reused.**

Only trained medical personnel may use or dispose of the osteobioptome.

The osteobioptome is intended for transient use only (< 60 minutes).

Intended use:

The osteobioptome is intended to be used to remove tissue specimens for histological examination, for example biopsies of bone tissueduring kyphoplasty.

Indications and contraindications

Indication: When bone tissue biopsy is required, for e.g.

- suspected primary or secondary tumor
- pathological compression fracture
- suspected inflammation or infection

Contraindications: none known

Prior to use:

	Check the packaging for damage. **Do not use products with damaged packaging.**
	Do not use products after their expiration date. **Check the products for damage and proper performance prior to use. Use only products in perfect condition.**

During use:

To use the osteobioptome, a vertebral access cannula with an internal diameter of 3.2 mm (for NKS-6) or 4.9 mm (for NKS-7) is required. Appropriate vertebral access cannulas are available from the manufacturer.

Under fluoroscopic control, a trocar is used to insert the vertebral access cannula into the bone to be examined through the pedicle.

The osteobioptome is inserted into the vertebral body through the vertebral access cannula. The distal end of the bioptome is spread apart by operating the handle (i.e. pulling apart the arms). Pressing the arms together causes the jaw to close. The collet can now be removed through the vertebral access cannula.

The osteobioptome must be used under fluoroscopic control. Continuously check the position of the vertebral access cannula and of the osteobioptome during the procedure.

	Please note that the osteobioptome must be completely closed in order for it to be withdrawn through the vertebral access cannula. **Do not use force to close the instrument! This could cause damage to the instrument and injury to the patient.**

Special remarks:

If the osteobioptome cannot be withdrawn through the vertebral access cannula, open the distal end and withdraw it slightly in order to release the biopsy sample (if applicable). Then withdraw the instrument through the vertebral access cannula. In this situation, the instrument must be discarded as it will no longer function effectively or safely.

After use:	
	The osteobioptome is intended for single use and must not be reprocessed or reused after use. It must be disposed of properly.
To contact the manufacturer:	FEHLING INSTRUMENTS GmbH & Co. KG Hanauer Landstr. 7A 63791 Karlstein, Germany Tel.: +49 (0) 6188 - 957440 Fax: +49 (0) 6188 - 957445 Email: info@fehling-instruments.de

Storage/Symbols:

Protect from excessive heat.	Follow the instructions for use	Store in a dry place. No long-term storage below +5 °C or above +40 °C.	Not intended for reuse	Warning	Do not use if packaging is damaged.
REF Article number	LOT Batch description	Expiration date: Observe the expiration date! Do not use after the expiration date.	STERILE R Sterilized by irradiation.	CE 0297 Notified Bodies	

Any modification to the device or deviation from these Instructions for Use will exclude the manufacturer from all legal liability for the use of the device

Subject to change without notice.

Manufacturer:

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