VERTECT Jack device

VERTECT Jack device, sterile NKS-1

For single use only.
Do not reprocess.
Do not reuse.

Only trained medical personnel may use or dispose of the VERTECT Jack device.

The VERTECT Jack device is intended for use with the Huber universal handle with force limitation, NKS-5K, that is reusable after reprocessing.
The VERTECT Jack device is intended for transient use only (< 60 minutes).

Intended use:

The VERTECT Jack device is intended for mechanical erection of collapsed vertebral bodies in the thoraco-lumbar spine for the purpose of creating the natural height of the vertebral body for kyphoplasty.

Indications and contraindications for use

The VERTECT Jack device is intended for mechanical erection of collapsed vertebral bodies **in the thoraco-lumbar region** for the purpose of restoring the original height of the vertebral body for kyphoplasty prior to the application of bone cement. Painful compression fractures of the vertebral body can be caused by osteoporosis, benign lesions (hemangioma) and malignant lesions (metastases, myeloma).

Indications:

Kyphoplasty and therefore the use of the VERTECT Jack device is indicated **only in the thoraco-lumbar region** in the following cases:

- painful, acute traumatic compression fractures of the vertebral bodies
- osteoporotic vertebral body compression fractures
- painful vertebral body fractures in association with osteonecrosis (Kummell disease)
- painful vertebral body osteolysis, which can be caused by benign lesions (hemangioma) and malignant lesions (metastases, multiple myeloma).
- The pedicle of the vertebral body to be treated must be large enough to permit the vertebral access cannula to be inserted safely and without risk. If this is not the case, using the device can cause the pedicle to fracture!

Contraindications:

Do not use in the cervical region!

Using the device on vertebrae that are too small can result in the risk of pedicle fracture! (cf. Indications)

Use is also contraindicated in cases of

- old, healed vertebral body fractures
- stable, asymptomatic vertebral body fractures
- partial or complete loss of the posterior margin of the vertebral body
- over 70% or complete loss of the vertebral body height (vertebra plana)
- spinal stenosis
- allergies to components of PMMA cement
- hemorrhagic diathesis
- active systemic infections
- local inflammation (e.g. osteomyelitis)
- vertebral body tumors (cells can be spread through the displacement of cancellous bone during the kyphoplasty)

Possible adverse effects during the treatment of vertebral body fractures using kyphoplasty or vertebroplasty
In the medical literature, the following adverse effects are described that can also occur despite the intended use of FEHLING VERTECT Jack device after performing a kyphoplasty or vertebroplasty: - cement leakage (possibly with subsequent injury of the patient through cement extravasation, such as perforation of vessels or embolism) - vertebral body fractures of the adjacent vertebrae As for adults, the decision to use the FEHLING VERTECT Jack device in children can only be made by the attending physician after considering all the benefits and risks.

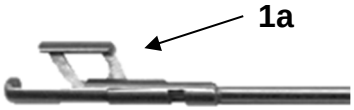
Prior to use:

Observe the expiration date! Do not use after the expiration date!
Check the packaging for integrity.
Do not use products from damaged packaging.
Open and close the VERTECT Jack devices to check that they function properly.
Visually inspect VERTECT Jack devices for sharp edges and damage.
Use only products of sound quality.

Components:

Figure 1

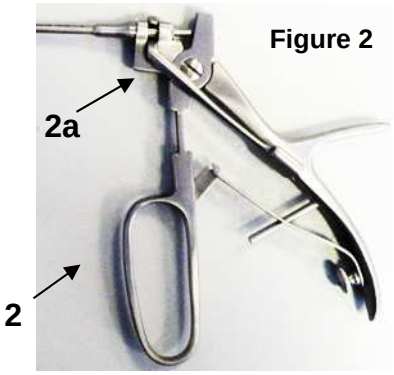
closed



open

	Article no.	Description
1	NKS-1	VERTECT Jack device
1a		Jack plate
1b		Inner cable with ball end
2	NKS-5K	Huber universal handle with force limitation
2a		Locking lever

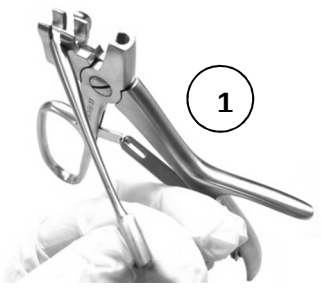
Figure 2



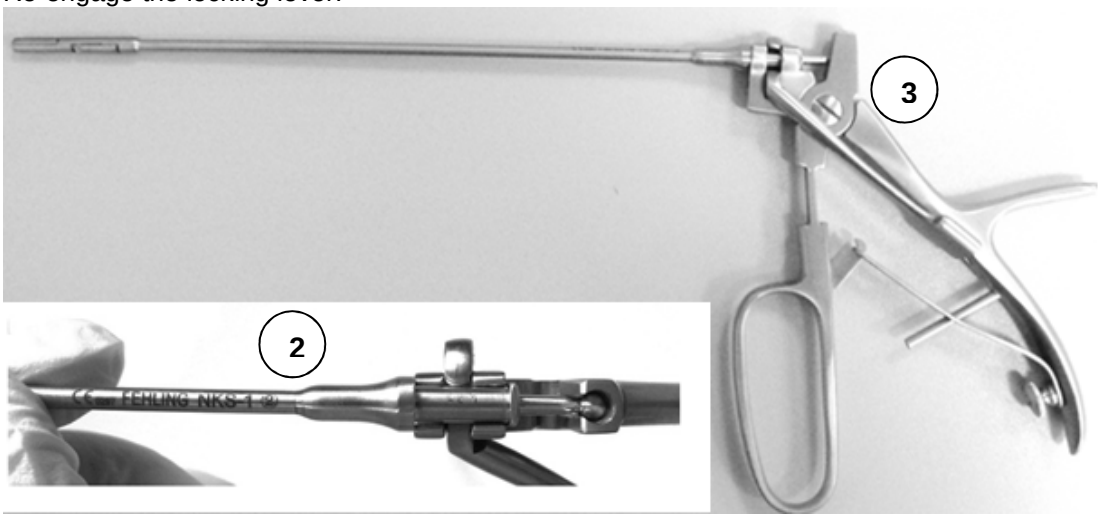
Assembly:

To use the jack device, insert the single-use tubular shank instrument into the reusable Huber universal handle with force limitation.

Assembly steps:
1. Open the locking lever (2a) of the Huber universal handle.



2. Insert the inner cable with the ball end (1b) and the proximal end of the tubular shank instrument into the handle. (If the working end is not completely closed, the length of the inner cable must be adjusted. By turning the inner cable, the distance can be varied as needed.)
3. Re-engage the locking lever.

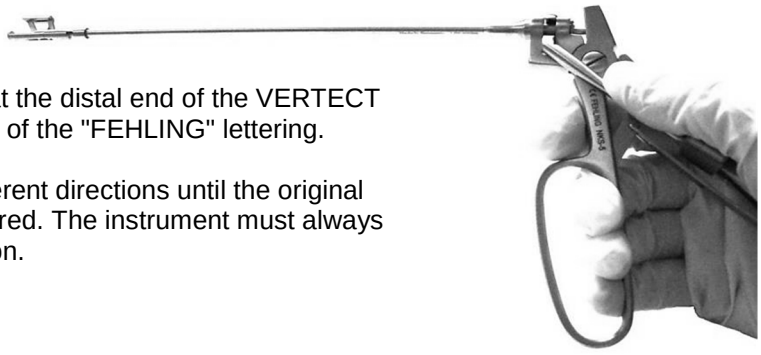


⚠ In order for the working end to open in a defined direction, the lettering "FEHLING" imprinted on the shaft must be facing up.

During use:

The VERTECT Jack device must be used under fluoroscopic control in two directions.
Transpedicular access requires an access system consisting of a trocar and a vertebral access cannula with an internal diameter of at least 4.9 mm. Appropriate vertebral access cannulas are available from the manufacturer.
The trocar is used to insert the vertebral access cannula into the vertebral body through the pedicle. As soon as the vertebral access cannula is in position and the trocar has been withdrawn, the closed VERTECT Jack device is inserted through the vertebral access cannula into the vertebral body and positioned.

Due to its unidirectional orientation, the VERTECT Jack device can specifically erect the vertebral body in various directions and at various positions. Compared to other kyphoplasty methods, with this method, instead of creating a homogeneous cavity, individual notches are compacted in the cancellous bone, which enlarges the contact surface between the bone cement and the cancellous bone.



The handle is now used to spread the jack plate (1a) at the distal end of the VERTECT Jack device. The mechanism is spread in the direction of the "FEHLING" lettering.

This procedure must be repeated several times in different directions until the original height and shape of the vertebral body has been restored. The instrument must always be closed for repositioning and when changing direction.

⚠ **Never rotate the instrument in the vertebral body when the instrument is open.**
In order to prevent the vertebral body from becoming overdistracted, the erection process must be performed under fluoroscopic control (AP and lateral projections).

Once the vertebral body has been re-erected, the VERTECT Jack device must be removed. The device must be completely closed during removal.
Once the VERTECT Jack device has been removed, the vertebral body and the pedicle must be filled with bone cement. The appropriate bone filler is available from the manufacturer.

Special remarks:

Huber handle with force limitation:

Starting from a load of > 15.5 kg, the Huber handle with force limitation opens in order to prevent injury. A return spring presses the parts of the handle apart again; the handle is then again ready for use.

Troubleshooting:

If the handle does not automatically spring back to its starting position, it can be spread mechanically by using two hands to carefully press the two parts of the handle apart. In this case, under fluoroscopic control, double-check that the instrument is completely closed.

If it is not possible to completely close the instrument, it must be withdrawn from the vertebral access cannula while still open. The instrument mechanics are designed so the jack plate is automatically pressed together when the VERTECT Jack device is withdrawn through the vertebral access cannula.

If this method is unsuccessful, the VERTECT Jack device must be closed to the extent possible and must be removed along with the vertebral access cannula.

For single use only.
Do not reprocess.
Do not reuse. Risk of infection.
Only trained medical personnel may dispose of the VERTECT Jack device in accordance with the hospital's own rules.

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.

Storage / Symbols

Store in a cool, dry place. Do not expose to direct sunlight.

	Not intended for reuse		Follow the Instructions for Use.
STERILE R	Sterilized with gamma irradiation	REF	Article number
	Expiration date: Observe the expiration date. Do not use after the expiration date!	LOT	Batch description
	Do not use if packaging is damaged!	CE 0297	Notified Bodies
	Store in a dry place.		Keep away from sunlight.
	Warning	**Manufacturer:**	**FEHLING INSTRUMENTS GmbH & Co. KG** Hanauer Landstr. 7A, 63791 Karlstein, Germany Tel.: +49 (0) 6188 - 957440 Fax: +49 (0) 6188 - 957445 www.fehling-instruments.de