maxmorespine®

ENGLISH

Disposable maxmorespine® Manual Bone Drill Cat No: 1001-BD 001 and 1001-BD 051

Instructions for use
CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Scope of application

maxmorespine® instruments are exclusively designed for the operative use in the lumbar spine and by physicians experienced and trained in the appropriate specialised procedures. It is the responsibility of the physician to become familiar with the proper techniques.
An accurate diagnosis, patient selection and operative care are critical to the success of the device and avoidance of injury during surgery. In general, careful attention must be paid, especially to asepsis and any anatomical anomalies.
It is important that the physician exercise extreme caution when working in close proximity to vital organs, nerves or vessels.

Appropriate use

- Only use instruments before expiring date and in accordance with this information sheet.
- Bone drill may only be used **manua**l with the manufacturers Ball Handle (Cat. No.: 1001 BH 001).
- CAUTION: Before use check correct connection with Ball Handle.
- Before use the Bone Drill needs to be checked for function and damages.
- Only use instruments which are in perfect technical and sterile condition.
- Damaged instruments (e.g. broken or blunt cutting edges; cracks or corrosion) may not be used.
- CAUTION: Do not contact the cutting edges to avoid contamination and infection.
- Bone Drills are not designed for working on metals (e.g. implants).

Inappropriate use may cause:

- Nerve root damage, paralysis, loss of strength, pain, injury or damage to the spine, soft tissue, inner organs, vital parts or joints.
- Infections if the instruments are not cleaned and sterilized properly (Cat. No.: 1001-BD 001 and 1001-BD 051).
- Dural leakage.
- Injury of vital organs, nerves and vessels.
- Bony fracture, especially in cases of deformed spine or weak bone.
- Cutting of skin or gloves of operating staff.

If the sterile package is damaged, the drill cannot be used anymore

Gripping pressure

- Excessive forces are to be avoided to prevent injury to the patient or deformation to the instrument.
- Optimal grip pressure: approx 2 N (pressure of gripping a fountain pen when writing).

Packaging, Handling and Storage

- Bone Drill is delivered gamma sterilized and is indented for single use only; **DO NOT RESTERILIZE** (1.0mmID)**.**
- Sterile package label contains sterilization and expiration date.
- Inspect sterile packaging for signs of damage. Damaged packages or products shall not be used.
- Package contains adhesive product labels for documentation.
- Products should be stored at room temperature, in a dust, humid and contamination free area until used.
- Wear gloves during disposal to avoid contamination and infection.

Safety and Liability

Before handling, the user must check the suitability and application possibilities for the intended purpose – the use of the instrument is in the users responsibility.
Hoogland Spine Product GmbH does not take any liability or guarantee and does not warrant the use of damaged or re-sterilized instruments, instruments which repair have been attempted or instruments who have not been repaired by our own professional service.

CE 0483 STERILE R

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Pre-Operative Planning:

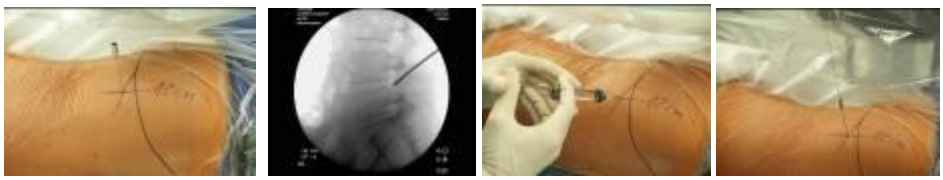
- Sagittal and axial MRI images as well as X-Rays -not older than 3 month- are required to identify size of the intervertebral foramen, the height of the iliac crest as well as the size and location of the herniated fragment
- A C-arm for X-ray imaging of the lumbar spinal segments in two planes is required
- An optimal local anaesthesia control (responsive patient) throughout the entire procedure is essential for the overall outcome

1-2. The herniated fragment at the MRI is plotted into the lateral and AP x-ray view of the lumbar spine; the entrance point is determinate

This procedure can be performed in both prone as well as here shown lateral position.

3.-4.-5.-6. Positioning of the patient in a stable lateral position on the radiolucent operation table, disinfection of the skin and sterile draping; marking of the iliac crest, midline and approach point [L3-4 approx. 9 / cm L4-5 approx. 10cm / L5-S1 approx -12cm] from the midline; as well as marking of the approach angle on the C-arm guidance

7.-8.-9.-10. Determination of the entrance point in the skin and local anaesthesia; positioning of the spinal needle [18G] at the target area of the facet joint; injection of 5cc 1% xylocaine with adrenalin, insertion of a guide wire

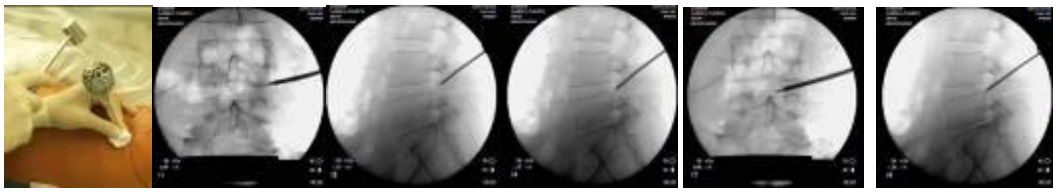


11.-12.-13. Skin incision of 8mm; pre-dilation with a 3.0mm [1001-DC 002] and 6.3mm [1001-DC 001] rod

CAUTION:

- the patient isolation drape shall be slightly cut out puncture site

14. KEY STEP advancing TOM Shidi [1001-TS 001 -003]
Targeting and advancing TOM Shidi in to the herniated fragment (see step 2.) under C-arm control

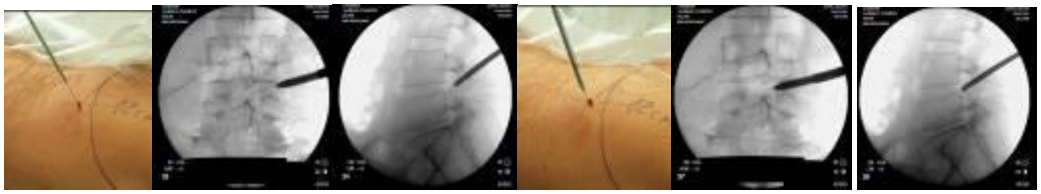


15.-16. Placement of the guide wire [1001-GW 001; 0,7mm] through TOM Shidi; straight line drilling with 1st 4mm **DISPOSABLE** manual bone drill [1001-BD 001; connected with Ball Handle 1001-BH 001] and the 2nd 5mm **DISPOSABLE** manual bone drill [1001-BD 051; connected with Ball Handle 1001-BH 001].

CAUTION:

- the TOM Shidi or bone drills are not to be positioned deeper than the medial interpedicular line to assure that the dura of the spinal cord stays completely untouched
- introduce the manual bone drills counter clock wise to avoid soft tissue damage
- drilling is to be performed manual under X-ray control in two planes, towards the disc fragment in a medial direction
- the Guide Wire stays in place

17.-18.-19. Enlargement of the drill hole with 3rd 6mm manual bone drill [1001-BD 002]; 4th 7mm manual bone drill [1001-BD 003]



19.-20.-21. Enlargement with 5th 8mm manual bone drill [1001-BD 004]; insertion of 6,3mm[1001-DC 001] dilator and working sleeve [1001-ES 001] over guide wire. The working sleeve is inserted under X-ray control into the widened foramen, at disc level, towards the medial interpedicular line with the opening facing the herniated disc fragment located in the epidural space.

22.-23.-24. Endoscopic inspection of spinal canal entrance with endoscope [1002-TS 001]; endoscopic removal of herniated fragment with special forceps [1001-EF 001-004]; control of position of freed nerve, working cannula and forceps.

CAUTION:

- please always check light source and camera on proper working function
- white balance needs to be performed for optimal colour resolution
- appropriate flow- and pressure values have to applied

25. Endoscopic inspection of the spinal nerve: confirmed by free movement of previously compressed nerve root.
[see above]
26. Finally the disc space will be irrigated with an antibiotic containing sodium solution and the working sleeve is removed. The skin puncture access point will be closed with a 3.0 suture.

SYMBOL IDENTIFICATION

Symbol	Used for
	Single-use, Do not reuse
	Batch Number
	Date of Manufacture
	Check Expiration date before use
	Sterility information
	Attention, see instructions for use
CE 0483	CE mark and identification number of notified body

LITERATURE

- Hoogland T. Transforaminal endoscopic discectomy with foraminoplasty for lumbar disc herniation. Elsevier SAS (Paris). All rights reserved. Surgical Techniques in Orthopaedics and Traumatology, 55-120-C-40, 2003, 6p.

- Schubert M., Hoogland T. Die transforaminale endoskopische Nukleotomie mit Foraminoplastik bei lumbalen Bandscheibenvorfällen. Endoscopic Transforaminal Nucleotomy with Foraminoplasty for Lumbar Disk Herniation. Urban & Vogel. Oper Orthop Traumatolog 2005/5:641-661.

- Hoogland T., Schubert M., Miklitz B., Ramirez A. Transforaminal Posterolateral Endoscopic Discectomy With or Without the Combination of a Low-Dose Chymopapain: A Prospective Randomized Study in 280 Consecutive Cases. Spine 2006;31(24):E890-E897.

- Hoogland T., Scheckenbach C. Die endoskopische transforaminale Diskektomie bei lumbalen Bandscheibenvorfällen. Orthopädische Praxis 1998:34;5,16.

- Hoogland T., Scheckenbach C. Endoskopische transforaminale Diskektomie (ETD)- Ergebnisse nach 2 Jahren. Orthopädische Praxis 1999/2;35:104-105.

- Hoogland T., Scheckenbach C., Dekkers H., Endoskopische transforaminale Diskektomie. Ambulant operieren 1999/4.

- Yeung A., Tsou PM. Posterolateral endoscopic excision for lumbar disc herniation. The surgical technique, outcome and complications in 307 consecutive cases. Spine 2002;27(7):722-731.

- Knight MTN, Goswami AKD. Endoscopic laser foraminoplasty. In: Savitz MH, Chiu JC, Yeung AT, eds. The Practice of Minimally Invasive Spinal Technique. 1st ed. Richmond, VA: AAMISMS Education, LLC, 2000;42:337-340.

- Kambin P., Casey K., O´Brien E., Zhou L: Transforaminal arthroscopic decompression of lateral recess stenosis. In: J Neurosurg./ March 1996 Volume 84, pp 462-467.

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