Literature

4. Iprenburg M; Percutaneous Transforaminal Endoscopic Discectomy; The Learning Curve to Achieve a more than 90% Success Rate. In: Program Abstract at the 19th Annual Meeting of the International Intradiscal Therapy Society, Phoenix, 2006
7. AWMF Online, „Leitlinien der Deutschen Gesellschaft für Neurochirurgie“


Lewandrowski KU; Yeung CA; Spoonamore MJ; McLain RF; Minimally Invasive Spinal Fusion Techniques, 2008

The use of endoscopic surgery on a daily basis began in the 1980s in the fields of laparoscopy and arthroscopy. In the 1990s endoscopic and minimally invasive neuro and cardiac surgery followed[1]. Evolution of these technologies has made more sophisticated and targeted applications possible, and as a result endoscopic spine surgery has become a reality.

“Endoscopic techniques may speed recovery, minimize postoperative pain and improve the final outcome. What once required 3 to 6 months to recover from now only requires 3 to 6 weeks!”

The Cleveland Clinic Foundation

Acknowledgments:
The pictures and documentation material shown in this product usage guide are a compilation of different types of L3-L4, L4-L5 and L5-S1 disc herniations, courtesy of Dr. Guntram Krzok, Dr. Florian Maria Alfen, Dr. Michael Schubert, Dr. Rudolf Morgenstern, Dr. Menno Ipenburg, Prof. Dr. Jürgen Kiwit, Dr. Moshe Levinkopf and Dr. Kai-Uwe Lewandrowski.

Sincere thanks are given to them all.

Note: For TESSYS® beginners we recommend focusing on the treatment of L3-L4 and L4-L5 disc hernias. Cranial or caudal sequestered hernias or free fragments are not the best indications to start with, as the TESSYS® method – like all new surgical techniques - has a learning curve dependent on the surgeon.
**The TESSYS® Concept**

The TESSYS® procedure utilizes a lateral, transforaminal, endoscopic approach for the removal of herniated intervertebral disc material, resulting in a less traumatic approach for the patient than the usual dorsal approach. With the TESSYS® technique, sequestered disc material is removed completely and directly through the foramen, which is gradually widened using specialized reamers and instruments. The patient can be placed in either the prone or lateral position, and is awake during the entire operation, which is carried out under local anaesthesia. This allows communication with the patient throughout the entire procedure.[2, 3, 4, 5, 6]

**Surgical Indications**

The TESSYS® method can be used to remove almost all herniated discs and sequesters – irrespective of their position – through the lateral, transforaminal access under analgesic sedation.

The TESSYS® surgery is indicated for all radicular symptoms caused by herniated discs that cannot be improved by conservative therapeutical methods. Cauda equina syndrome indicates immediate grounds for surgery. Every surgical procedure on a spinal disc, including the TESSYS® surgery, has to be carefully prepared by using Magnetic Resonance Imaging (MRI) and/or computer tomography (CT), as well as multiple conventional x-ray images.

Intraoperative discography and chromography provide final certainty in the accurate determination of the herniated disc position. They are conducted using the needle included in the TESSYS® disposable set.
Schematic illustration of the relation between the localisation of a L4-L5 hernia and its corresponding neural compression

Whilst a medial prolapse in L4-L5 (pos. 1) compresses the dura mater and lower nerve roots, a medio-lateral prolapse affects the nerve roots of L5 (pos. 2). An intra- or extraforaminaly located prolapse (pos. 3) compresses the L4 root. The L4 root can also be affected by a more cranially located prolapse (pos. 4). Rarely, in the case of a far caudal dislocated hernia, the root of S1 can become compressed (pos. 5).[7]
The Preoperative Planning

**STEP 1**

When accessing with TESSYS instruments and cutters, observe the herniated disc’s clear position. Sagittal and axial MRT images are required for determination of the herniated disc’s exact location. A lateral x-ray of the spine is also required to determine the size of the foramen and the height of the iliac crest, especially for L5-S1 access.

The selection of the lateral access distance from the spinal process line depends on the size of the intervertebral foramen and the patient’s physique. An access of approximately 10 cm from the center line is sufficient for existing large foramens, as is usually the case in levels L2-3 and L3-4. Levels L4-5 and L5-S1 can usually be approached laterally 12-14 cm from the midline for a normal sized foramen. Select an appropriately larger distance from the spinal process line for obese patients or a very narrow foramen. Experience has shown that caudally positioned herniated discs should be approached from a more cranial and lateral access point.

The Positioning & Fluoroscopy

**STEP 2**

A TESSYS operation can be performed in the prone or lateral position. The former is generally known and will not be described in detail at this point.

**Lateral Position**

Position the patient laterally on the operating table with the treatable side facing upwards. Support the waist with a cushion roll. Position the patient’s legs at an angle to achieve desired straightening of the lumbar spine. Then disinfect and aseptically cover the patient’s back. Use the image converter to display the treatable vertebra segments at two levels.

**Anaesthesia**

Please read through our anaesthesia scheme (page 27), which is used in many reference centers.
Access Planning

**STEP 3**

Following the preparation of the operation area, cover the patient with the sterile joimax® patient isolation drape.

Mark the spinal process line (center line) and then the iliac crest line (fig. 1). To reach level L5-S1, the lateral distance (distance line) is 12-14 cm from the center line to the access point (fig. 3). Now position a long instrument (e.g. alligator forceps) in the C-arm's lateral path of rays, level to the herniated disc (fig. 3-5). Once this position is accurately met, mark it (directional line). The intersection made up of the horizontal distance line, the diagonal directional line and the iliac crest line results in the access point (fig. 6).

**TESSYS® Disposable Access Kits:**
The TESSYS® Disposable Access Kits include all single use items and materials for a successful TESSYS® surgery.

**The Kit includes the following components:**
- Marker
- 18 G Needle
- 21 G Needle
- 2 ml, 5 ml and 2 x 10 ml Syringes
- 20 G and 27 G Injection Needles
- 3 x 90 ml Dishes (Contrast medium, NaCl, drugs)
- 2 Guide Wires (0.7 mm x 400 mm)
- Scalpel

**The following instruments and components are necessary for this step:**
- Steel ruler
- Endoscopic Forceps
- Reamer – coarse, dark red 7.5 mm
- Reamer – fine, light red 7.5 mm
- Reamer – coarse, dark yellow 6.5 mm
- Reamer – fine, light yellow 6.5 mm
- Reamer – coarse, dark green 5.0 mm
- Reamer – fine, light green 5.0 mm
- Sealing Cap for Foraminoscopes
- Suture

**TESSYS® Instrument Set**

**TESSYS® Disposable Access Kit**
The Discography / Chromography*

STEP 4

Now perform a discography. It serves differential diagnostic purposes, but also determines the extent of the annulus rupture. Anaesthetize the skin and muscles with approx. 5 ml Xylocain and additional adrenalin (local anaesthesia). Use the 18 G access needle to puncture the posterior lateral disc segment diagonally at an angle of approx. 60° via the isthmus through the neuroforamen (fig. 1). Now use the 21 G needle, inserted through the previously positioned 18 G needle, to puncture the herniated disc (fig. 2-4). Inject approx. 2 ml contrast agent, mixed with indigo carmine, through the thin 21 G needle into the disc to make the pathology fully visible (fig. 5-8).

*Note: A chromography is a discography whereby indigo carmine is added to the contrast agent to color the disc (blue-green).

The 5 types of discogram (classification by Adams MA et al.)


The following components are necessary for this step:
> 18 G Needle  > 21 G Needle  > Syringes
> 20 G and 27 G Injection Needles  > Dishes (contrast medium, NaCl, drugs)

TESSYS® Disposable Access Kit

> Fragmentectomy > Foraminoplasty > Decompression > Nucleotomy > Annuloplasty > Discography
**Placement Guiding Rod I (green)**

**STEP 5**

Now push the first 18 G access needle further over the reclining second 21 G needle. Retract the thin 21 G discography needle and replace it with one of the two guide wires. Finally, retract the first 18 G needle.

**The guide wire remains in position (fig. 1)!**

Use the scalpel to open the puncture point to no more than 1 cm.

**Attention: The patient’s covering foil should be cut out slightly around the puncture point for the reaming procedure.**

Now push the guiding rod (green) over the guide wire up to the facet joint (fig. 3-5). The special guiding rod I (green) with its curved tip is often advantageous for L5-S1 (fig. 7-8). To dilate the soft tissue, advance the three guiding tubes I/II/III (green/yellow/red) with increasing diameters over the guiding rods (fig. 6).

You can optionally use the 21 G discography needle, whose tip is angled with the needle holder, to infiltrate the facet joint between guiding rod I (green) and guiding rod III (red). A double-canulated guiding rod is also available, offering a further infiltration option.

Finally, remove guiding rods II (yellow) and III (red).

**Traffic Light Principle**

The TESSYS® System uses the recognized world wide traffic light sequence as a reference guide.

- **Red:** Beware, you are working very close to the nerve!
- **Yellow:** Caution, you are approaching the nerve!
- **Green:** Safe, you are working at a safe distance from the nerve!

**The following instruments and components are necessary for this step:**

- Guiding Rod – green (straight/curved)
- Guiding Rod Forceps
- Guiding Tubes – green, yellow and red
- 2 Guide Wires
- Scalpel

**TESSYS® Instrument Set**

**TESSYS® Disposable Access Kit**
**First Reamer I (light green fine or dark green course)**

**STEP 6**

Rotate the crown reamer I (green fine or coarse / 5.0 mm) over the guiding rod I (green) and the guiding tube I (green), (fig. 1 and 2). Now remove the facet joint isthmus bone under medialisation in the direction of the herniated disc in order to expand the neuroforamen.

**Reaming principle:**
All guiding rods, guiding tubes, disposable reamers and reamer ejectors are color-coded according to the Traffic Light Principle: green-yellow-red (page 14). The blue reamer (4.0 mm, in kits 5 and 7) will be required for very narrow foramina. The toothing of the crown reamer is designed in such a way that no soft tissue is caught or trapped while inserting the reamer counter-clockwise. The reamer should be turned clockwise as soon as it comes into contact with bone. Optimal analgesia is crucial for this part of the procedure.

The endo-reamer serves to remove bone tissue under constant endoscopic view. It is inserted through the working channel after positioning the foraminoscope.

Figures 3 and 4 display the position of the crown reamer over the guiding rod and the guiding tube. The position of the instruments and the reaming process are monitored with a.p. lateral control x-rays. Ensure the guiding rod tip is positioned directly against the vertebral body’s top panel in the lateral view (depending on the position of the prolapse) and simultaneously in the center of the spinal canal during a.p. x-ray.

**Reaming depth border line:**
The crown reamers should never be turned deeper than up to the medial interpedicular line (fig. 8).

**The following instruments and components are necessary for this step:**
- Guiding Rod – green
- Guiding Tube – green
- Reamer Ejector – green
- Reamer – green
- Handle for Reamer

**TESSYS® Instrument Set**

**TESSYS® Disposable Access Kit**

> Fragmentectomy > Foraminoplasty > Decompression > Nucleotomy > Annuloplasty > Discography
**Second Reamer (light yellow ± fine or dark yellow ± coarse)**

**STEP 7**

To secure the position of the guide wire, push the blunt guiding rod (green) as counter-support for the conical guiding rod I (green) over the guide wire. Now carefully unscrew the first crown reamer with guiding tube I (green) in a counter-clockwise direction. Remove both the blunt and the conical guiding rod I. Now use the guide wire to bring the second conical guiding rod II (yellow) into the desired position (fig. 1-3). If required, use the hammer to gradually advance the guiding rod. The guiding tube II (yellow) is passed over the guiding rod II (yellow, fig. 4), followed by the crown reamer II (yellow; fine or coarse), both of which are now carefully advanced through the intervertebral foramen (fig. 5-7).

Once again under medialization in the transversal level, ream in the direction of the herniated disc.

The position of the reamer is always monitored at two levels with the C-arm. The dura of the medulla remains completely untouched if the medial interpedicular line (fig. 8) is not transgressed.

**Caution:** A very large foramen may cause the guiding rod and guiding tube to medially advance. This should be avoided as it may lead to irritation or even damage nerve roots.

**The following instruments and components are necessary for this step:**
- Guiding Rod – yellow
- Guiding Tube – yellow
- Reamer Ejector – yellow
- Crown Reamer – yellow
- Handle for Reamer
- Guiding Rod – green, blunt

**TESSYS® Instrument Set**

**TESSYS® Disposable Access Kit**
**Third Reamer (light red & fine or dark-red & coarse)**

**STEP 8**

Once you have completed the reaming process in step 7, remove the guiding rod II (yellow), the guiding tube II (yellow) and the crown reamer. Use the matching blunt guiding rod II for safety reasons. **The guide wire again remains in place!** Now use the guide wire to position the conical guiding rod III (red) correctly over the guide wire (fig. 1). Use this guiding rod to position the guiding tube III (red). The third crown reamer III (red; find or coarse, 7.5 mm) is rotated over this in a counter-clockwise direction, and then clockwise upon contact with the bone, to extend the foramen (fig. 2 and 3). The position of the instruments and the reaming progress are monitored under a.p. and lateral fluoroscopic control. The crown reamer should never be turned over the medial interpedicular line in the a.p. position (fig. 4).

Now remove the crown reamer III (red). Insert one of the fenestrated working tubes (with an outer diameter of 7.5 mm) over the remaining guiding rod and guiding tube. For protection, the protruding lip of the working tube is initially rotated in the direction of the nerve root (fig. 5). Then remove the guide wire, guiding rod III (red) and guiding tube III (red, fig. 6).

Monitor the position of the working tube under x-ray conditions. In the extended foramen, the working tube is positioned at disc level, exactly at the medial interpedicular line (fig. 7) and aimed at the herniated disc fragment in the epidural space (fig. 8).

**The following instruments and components are necessary for this step:**
- Guiding Rod – red
- Guiding Tube – red
- Reamer Ejector – red
- Working Sleeve
- Crown Reamer – red
- Handle for Reamer
- Guiding Rod – yellow and red, blunt

**TESSYS® Instrument Set**

**TESSYS® Disposable Access Kit**

> Fragmentectomy > Foraminoplasty > Decompression > Nucleotomy > Annuloplasty > Discography
The Foraminoscope

STEP 9

After the HDI-lamp of the C-/D-Camsource® has been activated, white balancing is performed for optimum color results. Now insert the joimax® Foraminoscope through the selected working tube (fig. 1 and 2). **Attention: Observe pressure and flow values (see instruction for use for joimax® Multi-Range Irrigation Pump)!** The various tissue structures will become visible. Herniated tissue, colored by chromography (discography), is clearly distinguishable from the nerve root and the dura (fig 3-5).

Should the surgery concern a central spinal canal stenosis, this can be successfully treated using the unique TESSYS® Spinal Stenosis Program according to Dr. Rudolf Morgenstern. Please find further steps for this method in the product usage guide for spinal canal stenosis.

joimax® Foraminoscopes

All Foraminoscopes are available in the versions C = single cable technology (combo) or O = ocular technology (ocular), have an OD of 6.3 mm, a viewing angle of 30° and 1 irrigation channel as well as 1 suction channel, ID 1.5 mm each.

Both versions are available in lengths of 174 mm and 208 mm.

**OD = Outer Diameter, ID = Inner Diameter**
Removal of Extruded Disc Material

STEP 10

For further orientation on the endoscopic image, insert nerve probes, hooks or elevators through the foraminoscope. During removal of the herniation the patient is responsive for the entire time. Now remove loose tissue and free disc fragments gradually with the various instruments such as graspers, forceps and punches (fig. 1-4). Large free fragments should be removed by pulling the endoscope with the fragment out of the working tube (fig. 5). If orientation is clear, the shorter forceps can be used to remove large fragments without the endoscope but under C-arm control.

Once all free disc fragments have been removed, check endoscopically whether the affected nerve root has been freed (fig. 6). Now turn the opening of the working tube (window) so that the nerve root is protected and the opening points towards the disc space. Further free fragments can be removed from the interim disc space under x-ray control. Often both nerve roots are visible at the end.

RF Trigger-Flex™ Probe

The radiofrequency Trigger-Flex™ probe can be used to stop any bleeding and remove tissue (e.g. scars). Through tissue shrinkage, the annulus ruptures can be closed by up to 3 mm (fig. 7 and 8). See instructions for use for joimax® Trigger-Flex™.

The following instruments are necessary for this step:

- Endoscopic Forceps
- Other Bipolar Forceps and Graspers

The following instruments are necessary for this step:
Irrigation and Wound Closure

**STEP 11**

Finally, irrigate the disc space with saline-antibiotic solution and remove the remaining working tube. Close the small skin incision with a 3.0 suture.

**Additional instruments**

The affected vertebral endplates can be skimmed with a straight or curved tip awl. A rise of the fluid content of the nucleus pulposus (high intensity in the MRI) can be seen in the first clinical trials after 3 and 6 months.

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**TESSYS® Anaesthesia Recommendation**

The following TESSYS® Centers use the anaesthesia regime below:

- ATOS Klinik, Munich/Germany; Dr. Michael Schubert
- HELIOS-Klinik, Volkach/Germany; Dr. Florian Maria Alfen
- Marienstift, Arnsstadt/Germany; Dr. Guntram Krok
- HELIOS-Klinik, Berlin-Buch/Germany; Prof. Dr. Jürgen Kiwit
- Bethanien-Krankenhaus, Frankfurt/Germany; Dr. Ralf Wagner
- Rugkliniek Iprenburg, Veenhuizen/Netherlands; Dr. Menno Iprenburg
- Centro Médico Teknon, Barcelona/Spain; Dr. Rudolf Morgenstern
- Sheeba-Hospital, Tel Aviv/Israel; Dr. Moshe Levinkopf
- Rush Copley Aurora, Chicago, IL/USA; Dr. Daniel Laich
- Mid Atlantic Spine, Maryland/USA; Frank J. E. Falco, M.D.
- Seashore Surgical Institute, New Jersey/USA; Gabriel P. Jasper, M.D.
- Middlesex Surgery Center, New Jersey/USA; Doug Spiel, M.D.

All doses mentioned below are recommended by **Dr. Alexander Godschalx** (anaesthesiologist, Rugkliniek-Iprenburg, Veenhuizen / Netherlands), and correspond to the respective patient:

**Analgo Sedation:**

- Preoperative:
  - Analgetic: Piritramid (e.g.: 15 mg Dipidolor® i.m.)
  - Sedation: Midazolam (e.g.: 1-2 mg Dormicum®)

- Intraoperative Analgo Sedation:
  - Antibiotic: Cefalozin (e.g.: 2.0 g Gramaxin® i.v.)
  - Sedation: Midazolam (e.g.: 3-5 mg Dormicum® i.v.)
  - Central Sedation: Remifentanyl (e.g.: 0.05 μg / kg BW / min Ultiva® i.v.)

- Postoperative:
  - Analgetic: Individual decision depends on the patient

- Discography / Chromography:
  - Contrast Medium e.g.: Lohexol (e.g.: Omnipaque®) mixed with Indigo Carmine (5ml / 1ml) for improved tissue differentiation, particularly important in the starting phase.

- Additional Drugs:
  - Local anaesthesia: e.g.: Xylonest® 2 % plus Adrenaline – if required:
    - Bacitracin 2500 I.E. (e.g.: Nebacetin®) and Neomycin Sulfate 35,000 I.E. (e.g.: Bivacin®)