

TESSYS®

Transforaminal Endoscopic Surgical System

TES® - Transforaminal Endoscopic Surgery with **TESSYS® - The Unique All-in-One System**





The use of endoscopic surgery on a daily basis began in the 1980's in the fields of laparoscopy and arthroscopy. In the 1990's endoscopic / minimally invasive neuro and cardiac surgery followed [1]. Evolution of these technologies has made more delicate and disease-specific 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!

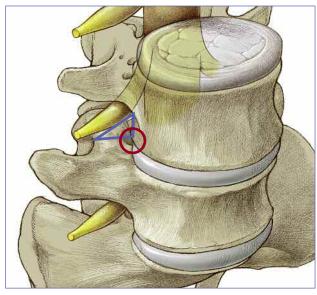
The Cleveland Clinic Foundation

Pioneers in Endoscopic Spinal Column Surgery

Minimally invasive spinal column surgery has developed into an alternative and reliable treatment procedure for a range of spinal column disorders. The surgical technique is used especially for discectomy, for treating herniated discs or in order to stabilize unstable spinal column segments. Mixter, Barr^[2] and Dandy^[3] are known for their work on the diagnosis and treatment of herniated discs and for using laminectomy to expose the lumbar spinal canal. Over the last 40 years, numerous surgeons have sought alternatives to laminectomy and discectomy, such as removal of the nucleus by means of anterior retroperitoneal access^[4], automated percutane nucleotomy^[5] via suction excision for lumbar herniated discs^[6], chemonucleolysis or laser ablation^[7, 8, 9, 10, 11].

In the 1970s, Parviz Kambin [12, 13] and Hijikata [14] began performing surgery with cannulae specially designed for the percutane dorso-lateral nucleotomy, achieving a documented success rate of 75% with their technique. In the 80s, the principle of mechanical nucleotomy was further advanced by other physicians [15, 16].

Thanks to the combination of a growing body of endoscopic know-ledge of the anatomy of the intra- and extraforaminal areas [17, 18], the radiological determination of orientation points for the working zone around the dorsolateral area of the anulus by Kambin [19, 20, 21] and the availability of smaller endoscopes, lateral access became possible. Different types of lateral access have been described by Anthony Yeung [22], Thomas Hoogland [23] and Sang Ho Lee [24], et al. The TESSYS® method and joimax® technology combines the access methods and techniques applied by multiple users, as published in numerous articles, and has been applied successfully in thousands of procedures.



Kambin's triangle and working zone for the TESSYS® access

CONCEPT

To remove a herniated disc, the TESSYS® method uses a lateral, transforaminal, endoscopic access path, classifiable as a surgical access method that minimizes patient trauma. Sequestered herniated disc tissue is completely and directly removed through the foramen, which is gradually extended with special reamers and instruments, while the patient is in a stable lateral or prone position and responsive throughout surgery under analgesic sedation. The TESSYS® surgical method is also performed in hospitals and ambulant surgical centers [25, 26, 27, 28, 29].



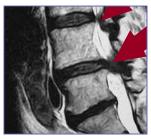


X-ray photograph: lateral

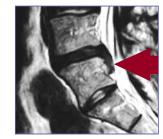


X-ray photograph: a.p.

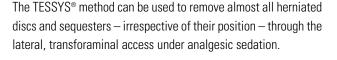




MRI: L3-L4 and L4-L5 lateral

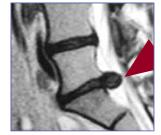


MRI: L4-L5 lateral caudal

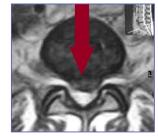


The TESSYS® surgery is indicated for all radicular symptoms caused by herniated discs that were not improved by conservative therapeutical methods. Cauda equina syndrome indicates immediate grounds for surgery. Every surgical procedure on a spinal disc, including the TESSYS® surgery, has to be carefully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

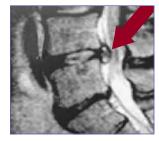
Intraoperative discography and chromography provide final certainty in definitive determination of the herniated disc position. They are conducted using the needle included in the TESSYS® disposable set (see Product Usage Guide page 12-13).



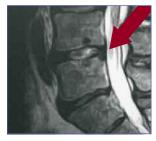
MRI: L5-S1 lateral



MRI: L5-S1 axial

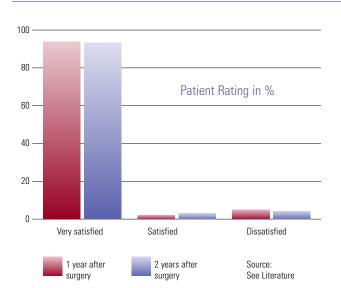


MRI: L3-L4 lateral pre operatively



MRI: L3-L4 lateral post surgically

STATISTICS

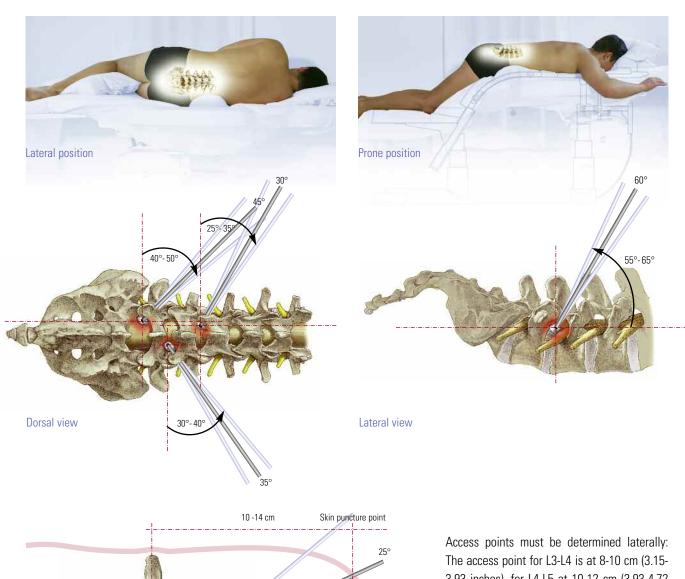


International medical literature reports a success rate of 75-85% [30, 31] for percutaneous nucleotomy. Many centers achieve approximately 90% [32, 33, 34] success rates by using microscopic surgeries for herniated discs. Using the endoscopical TESSYS® method for removing herniated disc problems results in a success rate of over 93% [35], as documented in 1-year, 2-year and most recently 3-year studies. The early recurrence rate can be maintained at under 4%. The success rate for patients with recurring herniated disc incidents is over 86% [36, 37, 38, 39].



As the figure below shows, correct positioning of the patient and careful planning of the main point of access to the herniated disc is crucial for positive surgical results.

The combination of the TESSYS® method with the TESSYS® technology permits access to practically all spinal disc sequestra and herniations, and therefore also allows for their removal along the complete lumbar spine including L5-S1, regardless of their position. This special direct access to the herniated disc occurs through the intervertebral foramen, which contains the nerve roots and may be anatomically narrow. In order to ensure safe access into the spinal canal and avoid irritation of the nerves in the foramen, the caudal part of the intervertebral foramen is widened millimeter by millimeter using special reamers (see also Product Usage Guide, starting page 16).

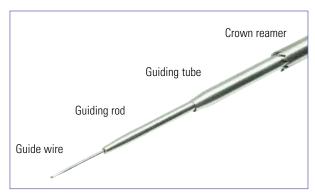


The access point for L3-L4 is at 8-10 cm (3.15-3.93 inches), for L4-L5 at 10-12 cm (3.93-4.72 inches) and for L5-S1 at 12-14 cm (4.72-5.51 inches). The figures to the left show the entrance angle from the dorsal, lateral and axial views.

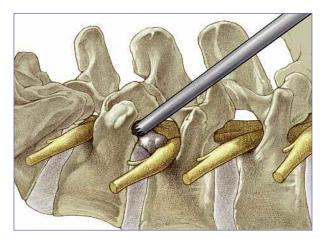
Axial view

. 10°- 40°





Three-step guide wire concept



Widening of intervertebral foramen with crown reamer

Access to the prolapse is effected via a 3-step guide wire concept (see figure on left). The (soft) tissue is gradually dilated under permanent x-ray monitoring and the foramen stretched step by step using the reamers described. This permits safe, tissue-conserving access to the spinal canal and the prolapse.

All TESSYS® instruments (guiding rods, guiding tubes, disposable reamers and reamer ejectors) are color-coded in the logical sequence of a traffic light: red-yellow-green. The instruments marked green have the smallest diameter and the red ones the largest.



Red: Caution, you are working very close to the nerve! **Yellow:** Caution, you have approached the nerve!

Green: You are working at a safe distance from the nerve!

Crown reamer toothing is designed in such a way that soft tissue is not injured during counter-clockwise rotation. As soon as the reamer meets bone, which is easily felt, clockwise rotation is applied to drill the bone. Special attention must be paid to the dosage of the analgesic, especially during the reaming process (patient responsiveness).

Once the gradual stretching of the tissue and the foramen is completed, loose tissue and prolapsed material is removed with novel foraminoscopes, under full endoscopic view and with the help of specially designed gripping, cutting and punching forceps. Once all spinal disc fragments are removed, an endoscopic check will be performed to verify that all affected nerve roots are free.

In-depth knowledge of the TESSYS® surgical method can be acquired in special training programs (see Education Program). For further information, please contact us directly via email, telephone or fax, or contact your local joimax® representative.



Colored prolapse tissue (discography/chromography)

Spinal disc sequester: 4 cm

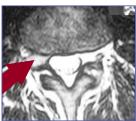


Pre operatively:







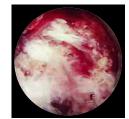




43-year-old man: L3-L4, lateral cranial (intraforaminal)







Herniated disc



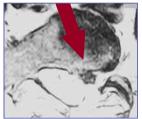


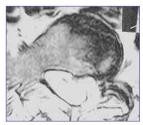
Removal of the prolapse using endoscopic forceps

 $Surgi\text{-}Max^{^{\text{\tiny{TM}}}} Trigger\text{-}Flex^{^{\text{\tiny{TM}}}}$ Radio frequency probe









49-year-old man: L5-S1, left caudal



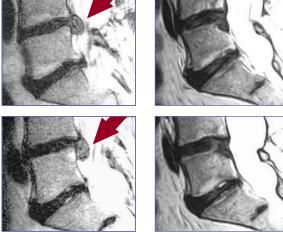


A. Gibson: "Mean bed stay was

Exposed nerve root

Exposed nerve root from 8 am to 2 pm









Exposed nerve root

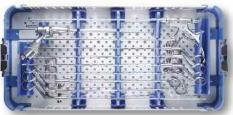


The TESSYS® System











TESSYS® Instrument Set



Disposable access set - modular & specific

The TESSYS Access Set® contains all the products and aids necessary to perform consistent and successful TESSYS® surgery: puncture needles (20 G and 27 G), discography needles (18 G and 21 G), syringes, preparation bowl, marking pen, scalpel, guide wire, sealing cap and surgical suturing material.

We offer a range of Access Sets with various types of reamers depending on purpose. We differentiate between fine and coarse crown reamers, which, like the guiding rods and tubes, are also color-coded for easier handling (green = 5.0 mm, yellow = 6.5 mm and red = 7.5 mm). Additional disposable reamers are available separately in undersize 4.0 mm (blue) and oversize 8.5 mm (purple).

Instrument Set - high precision, high durability

The TESSYS® Instrument Set contains all necessary instruments for secure minimally invasive surgery and for the removal of spinal disc material, plus a range of different grasping, cutting and punching forceps for removing of free nucleus material, scar tissue and facet joint capsule tissue.

joimax® Foraminoscope - perfect view

All foraminoscopes are available as version C = singlecable technology (Combo) or O = occular funnel technology (Occular) and have an exterior diameter of 6.3 mm, an optical angle of 30°, and flush and suction channels with an interior diameter of 1.5 mm.

- > Standard working length: 171 mm, working channel (interior diameter): 3.7 mm
- > XT working length: 208 mm, working channel (interior diameter): 3.7 mm

RF Trigger-Flex™ Probe

The radio-frequency Trigger-Flex™ probe can be used to stop bleeding and remove scar tissue. Anular ruptures of up to 3 mm are easy to seal by means of tissue shrinking.

We offer additional disposable material for optimum surgery success, such as the special incision foil for covering the patient. A special tubing set with Y-connectors is available for the joimax® low-pressure irrigation pump.



Spinal Stenosis Program: Broad Minimally Invasive Treatment Solutions



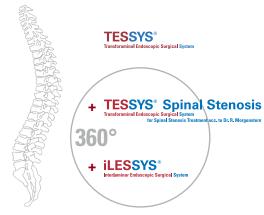
360° Lumbar Spinal Treatment Program

The TESSYS®, TESSYS® Stenosis and iLESSYS® Program

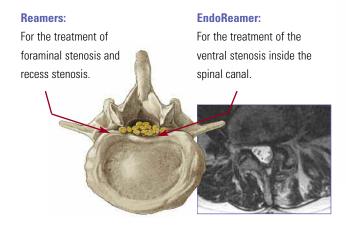
All three instrumentations enable a 360° all around exposure and hence pressure release of the spinal canal under full endoscopic control!

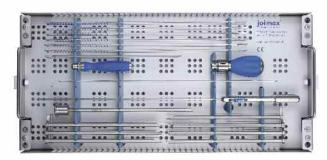
Advantages for the patients:

- > Minimal destabilization
- > Minimal traumatization
- > Minor scarring
- > Fast recovery



TESSYS® Stenosis Instruments, the perfect complement to TESSYS®





TESSYS® Spinal Stenosis Set





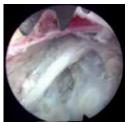
Working sleeves in 2 lengths and 7 different types

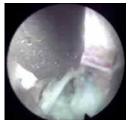
for optimal protection of nerval structures





EndoReamer guided over: EndoAwl, EndoElevator, EndoChisel





EndoReamer in the spinal canal



EndoReamer: Removal of an osteophyte under endoscopic control

Flexible nerve probe



Shrill® Shaver Drill System

The joimax® Shrill®-System was developed for the resection of tissue, both soft as well as solid structures, primally in the area of the spine. For optimal tissue-conserving and safest working in immediate proximity of the nerve.



A whole variety of shaver blades: For optimal tissue preserving resection of bony structures inside the spinal canal.

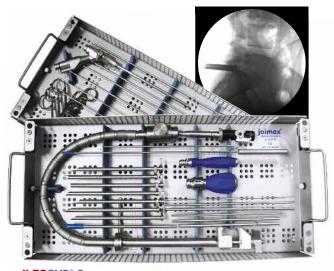


Shrill® Acorn Trimmer: Resection of bone proliferations under endoscopic control

iLESSYS[®] interLaminar Endoscopic Surgical System

The iLESSYS® instrumentarium consists of an access tray and a resection tray. It contains special instruments for the full endoscopic access through the lamina (laminotomy) or for the ligamentum flavum (flavectomy). The working length of the standard laminoscope is 171 mm but it is also available as short version (125 mm).

iLESSYS® is especially suitable for the treatment of disc herniations in level L5/S1 which are well accessible through the lamina. For the treatment of the lumbal spinal stenosis iLESSYS® with its various versions offers a complete endoscopic platform base.



iLESSYS® Set



The TESSYS® surgical technique enables high-precision treatment to be performed whilst minimizing tissue trauma. This results in minor wound pain and very little scar tissue. In addition, spine stability is unimpaired. Because this technique utilizes analgesic sedation, it is suitable for all age groups and is an outpatient procedure, allowing the patient to leave the hospital on the same day for a faster return to everyday life.

> Outpatient Treatment

- Analgo sedation Conscious during surgery
- Patient's reaction to possible pain
- Well-suited for patients with heart disease and for older patients

> Minimally invasive access - "gentle surgery"

- 3-level guide wire concept
- Gentle tissue dilation
- Spine stability remains unimpaired
- Minor wound pain and very little scar tissue
- Reduced risk of infection

> Cost savings - solo surgery

- Shorter hospital stavs [39]
- Lower therapy costs

TESSYS® EDUCATION PROGRAM

Dynamic "3-step concept" to learn the TESSYS® surgical technique - Training for the surgeon and the surgical team as a whole



Cadaver Workshop

Step by Step

- > TESSYS® Guidelines: Anatomy, Indication and Contraindication, Anesthesiology, Step by Step surgical technique, Instruments
- > Hands-on Anatomical Specimen Training
- > Exchange of experiences



First Surgery

Your own patients

- > Ongoing support will be provided by a joimax® application specialist and/or a referring physician
- > Guaranteed surgical success and satisfied patients
- > Training for the entire surgical team in the use of the TESSYS® technology

Participation

Experience TESSYS® live

- > Participation in surgical operations at selected training centers
- > Indication related application of all instruments and devices
- > TESSYS® Step by Step Exchange of experiences with surgeons, anesthesiologists and surgical staff as well as patient contact



joimax® Digital Endoscopic System

joimax® provides the latest digital technology for endoscopic surgery, particularly for innovative "joined minimal access" procedures.

1 Vitegra® pro **Visual Integration System**

- > Fully integrated HD image and video data recording with multi-task navigation
- > Touch-screen monitor, CD/DVD/USB, HDD
- > Speech recognition & audio recording
- > Up to 4 signal sources

² C-Camsource HD

- > The 5-in-1System **7wister**
 - HD-system
 - Light source (100 W Xenon)
 - Twister function
 - USB documentation
 - Text generator

³ Shrill[®]

- > Multi-functional drill and resection system
- > Uniquely designed spine-shaver
- > Easy handling
- > Tissue-specific shaver blades

4 Versicon **Versatile Irrigation Control**

- > For endoscopic spinal surgery and arthroscopy
- > Spinal Program:
 - Irrigation range: 0 750 ml/min
 - Pressure: 0 100 mmHg

5 Surgi-Max **Dual High Radio Frequency System**

- > Dual radio frequency system to stop bleeding and remove scar tissue
- > Trigger-FlexTM: twistable bipolar disposable probe usage through foraminoscopes/laminoscopes

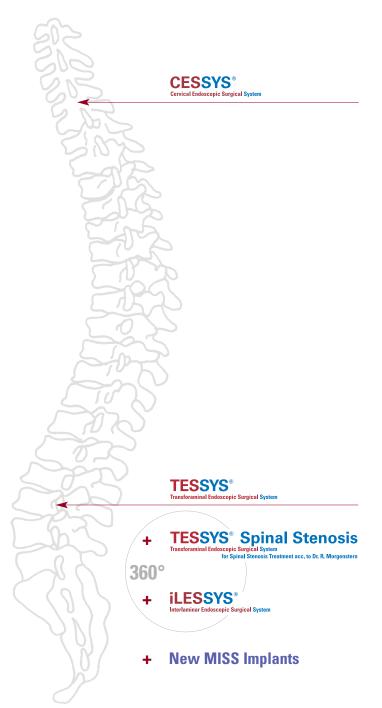
joimax® Flatscreen Monitor, Full HD

- > joimax® flat screen TFT Monitor, EMC resistant
- > picture in picture function
- > 24" and 42"

joimax® goes HD

- HD-Camera
- HD-Scope
- HD-Monitors





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joined minimal access

technologies

joimax® GmbH

Amalienbadstrasse 41 RaumFabrik 61

76227 Karlsruhe - Germany

PHONE +49 (0) 721 255 14-0 +49 (0) 721 255 14-920 FAX MAIL info@joimax.com NET www.joimax.com

joimax®, Inc.

14 Goodyear, Suite 145 Irvine, CA 92618-3759, USA

PHONE +1 949 859 3472 FAX +1 949 859 3473 MAIL info@joimaxusa.com NET www.joimaxusa.com

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