

- 
- > Fragmentectomy
 - > Foraminoplasty
 - > Decompression
 - > Nucleotomy
 - > Annuloplasty
 - > Discography

TESSYS[®]

Transforminal Endoscopic Surgical System



**TES - Transforaminal Endoscopic Surgery
with TESSYS[®] – the Unique All-in-One System**

INTRODUCTION

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!'

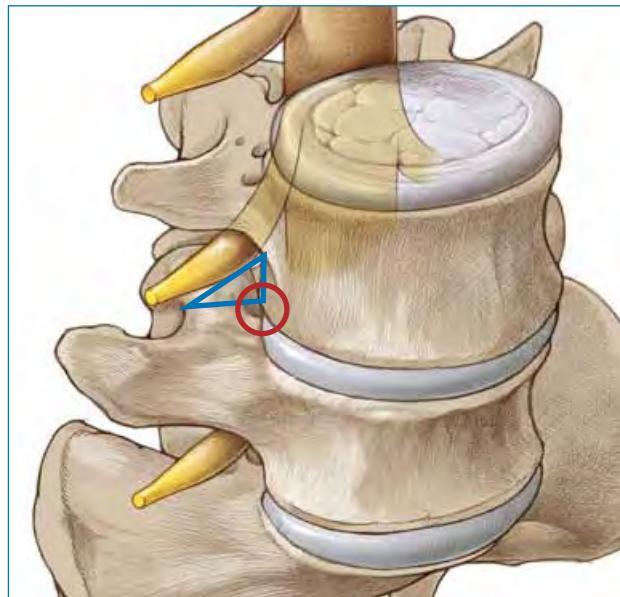
The Cleveland Clinic Foundation

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 percutaneous 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 percutaneous dorsolateral 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 knowledge 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 annulus 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].

INDICATION



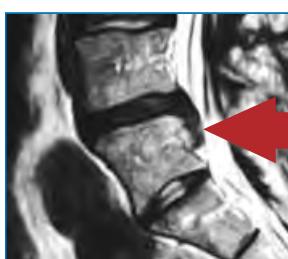
X-ray photograph: lateral



X-ray photograph: a.p.



MRI: L3-L4 and L4-L5 lateral



MRI: L4-L5 lateral



MRI: L5-S1 lateral

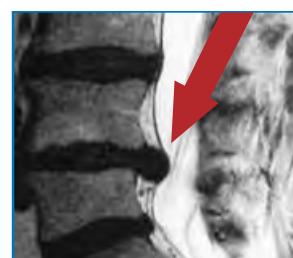


MRI: L5-S1 axial

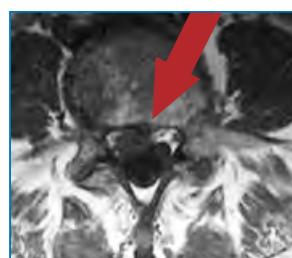
The TESSYS® method can be used to remove almost all herniated discs and sequesters – irrespective of their position – through the lateral, transforaminal access under analgesic sedation.

The TESSYS® surgery is indicated for all radicular symptoms caused by herniated discs that 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).

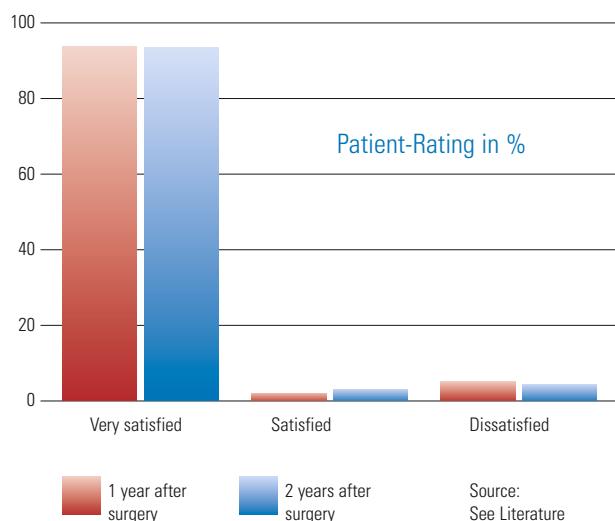


MRI: L4-L5 lateral and axial



44-year-old woman: radicular pain for over 5 months

STATISTICS

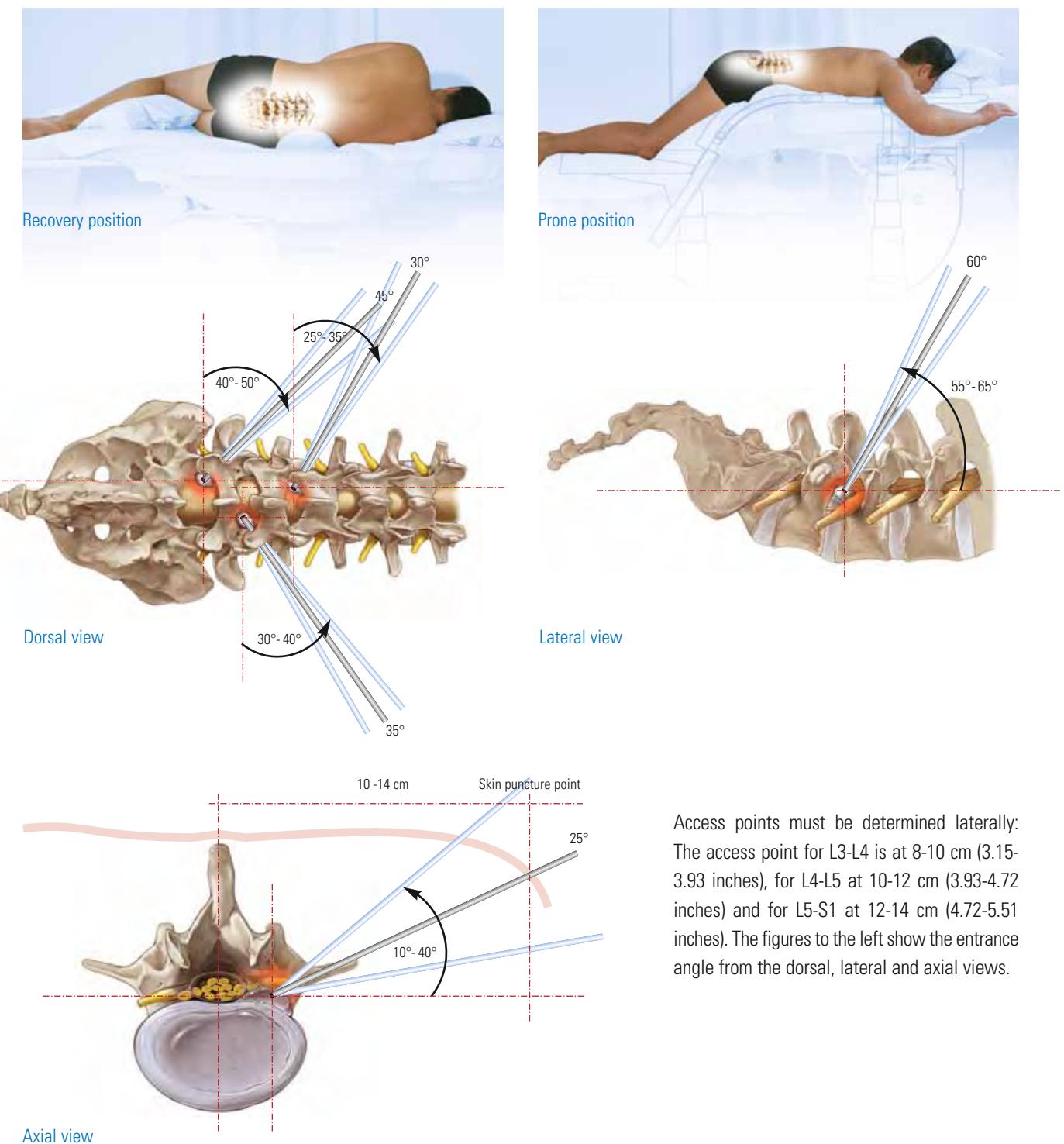


International medical literature reports a success rate of 75-85% [30, 31] for percutaneous nucleotomy. Many centers achieve approximately 90% [32, 33, 34] success rates by using microscopic surgeries for herniated discs. Using the endoscopical TESSYS® method for removing herniated disc problems results 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].

S U R G I C A L T E C H N I Q U E

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 ingress 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).



RESULTS

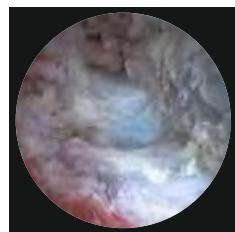
Before the operation:



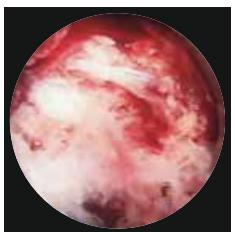
After the operation:



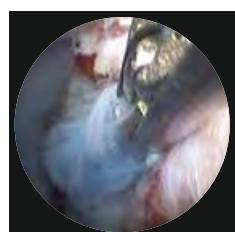
43-year-old man: L3-L4, lateral cranial



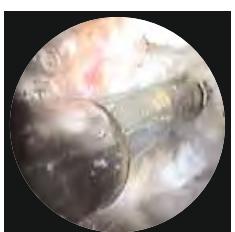
Herniated disc



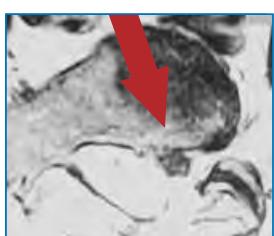
Herniated disc



Removal of the prolapse
using endoscopic forceps



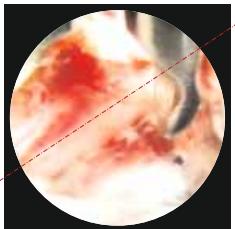
Surgi-Max™ Trigger-Flex™
Radio frequency probe



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



Exposed nerve root

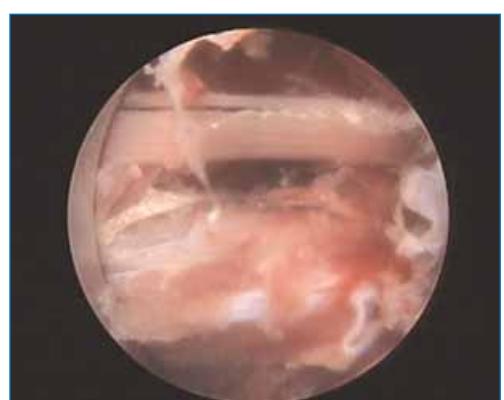


Exposed nerve root
from 8 am to 12 pm

S. Ruetten: "Recovery time can be reduced from 49 days to 25 by using endoscopic surgery instead of microsurgery." [39]



L4-L5, bilateral view



Exposed nerve root

TESSYS® ADVANTAGES AT A GLANCE

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 stays ^[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



Participation

Experience TESSYS® live

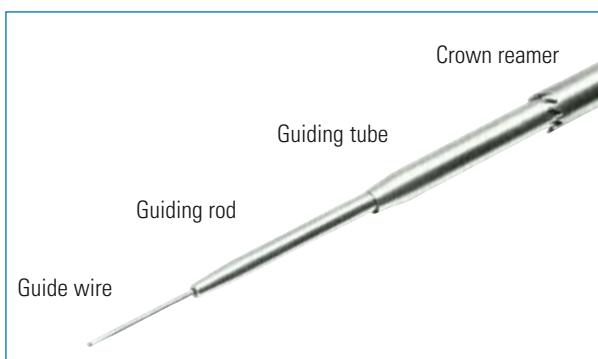
- > Participation in surgical operations at selected training centers
- > Indication related application of all instruments and devices
- > TESSYS® Step by Step – Exchange of experiences with surgeons, anesthesiologists and surgical staff as well as patient contact

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

S U R G I C A L T E C H N I Q U E

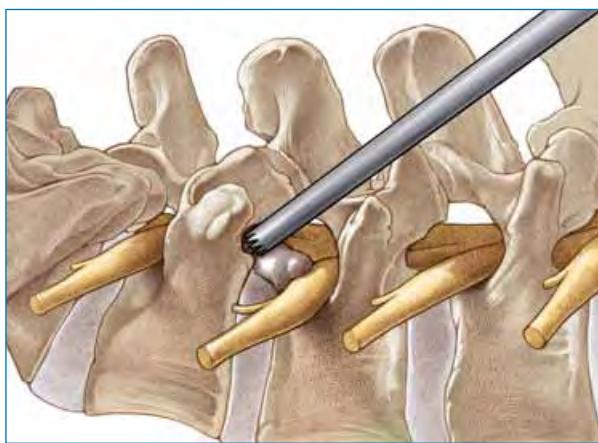


Three-step guide wire concept

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.

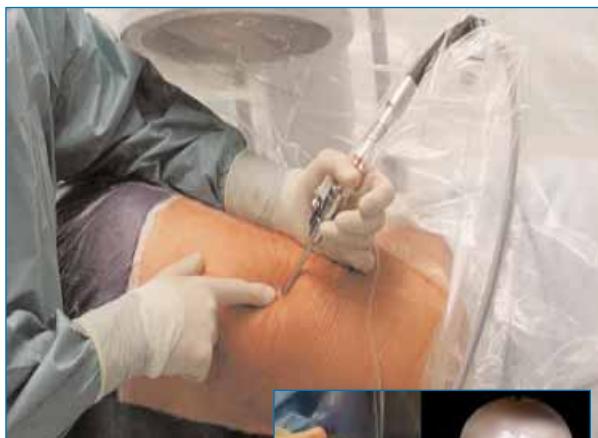
All TESSYS® instruments (guiding rods, guiding tubes, disposable reamers and reamer ejectors) are color-coded in the logical sequence of a traffic light: red-yellow-green. The instruments marked green have the smallest diameter and the red ones the largest.

- Red:** Caution, you are working very close to the nerve!
- Yellow:** Caution, you have approached the nerve!
- Green:** All OK, you are working at a safe distance from the nerve!



Stretching of intervertebral foramen with crown reamer

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).



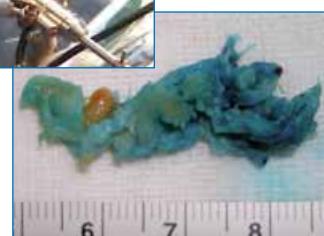
Removal of spinal disc sequester with endoscopic view

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

The TESSYS® System

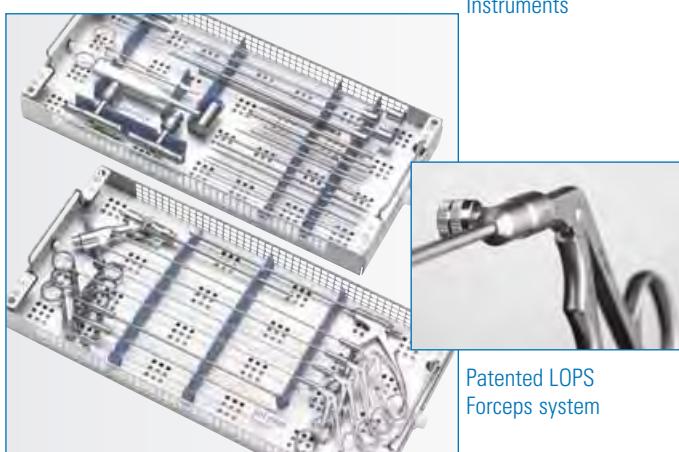


TESSYS® Disposable Access Sets

Color-coded reamers in a range of sizes



Color-coded Instruments



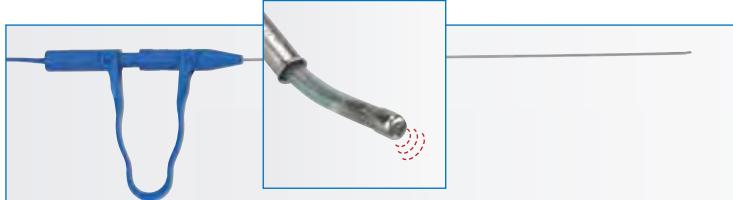
TESSYS® Instrument Set

Patented LOPS Forceps system



TESSYS® Foraminoscope

Laser Sidefire Probe



Surgi-Max™ Trigger-Flex™ RF Probes

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), discectomy needles (18 G and 21 G / 22 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 gripping, cutting and punching forceps for removing scar tissue and facet joint capsule tissue.

joimax® Foraminoscope - perfect view

All foraminoscopes are available as version C = single-cable technology (Combo) or O = ocular funnel technology (Ocular) 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.

- > Working length: 171 mm, working channel (interior diameter): 3.7 mm
- > 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.

INSTRUMENT SYSTEM

joimax® Digital Endoscopic System

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

1 Vitegra® HD

Visual Integration System

- > Fully integrated 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 Video TWISTER

360° Image Rotation & Zoom-in Magnification

- > Infinitely adjustable 360° image rotation
- > Zoom and image-centering function
- > Text generator (optional)

3 C-Camsource®

Combined Camera & Light Source System

- > Single-cable technology: light guide and camera in one
- > Miniature camera with integrated optical coupler
- > High-intensity light source with long-life lamp and optimized color temperature

4 Surgi-Max™

Dual High Radio Frequency System

- > Dual radio frequency system with bipolar disposable probes to arrest bleeding and remove scar tissue
- > Bipolar tweezers 0.5-2.0 mm
- > Trigger-Flex™ endoscopic bipolar disposable probe

5 JIFP 2000

Multi-Range Irrigation Pump System

- > Pressure-controlled arthroscopy and spinal column flush pump (low-pressure)
- > Flush performance: 0-2000ml/min
- > Pressure area: 0-200 mmHg

6 JFMS 1910

High Resolution Flatscreen Monitor

joimax® Flatscreen Monitor, HD-ready

- > joimax® Flatscreen TFT Monitor, EMC-resistant
- > 1280x1024 dpi (or higher), 16 million colors, 250 cd/m²
- > High resolution, high refresh rate



SPOT™

Spinal Operating Table

- > Completely radiolucent
- > Low-maintenance plastic parts
- > Two-column technique
- > Motor-driven height adjustment



Patents pending

FDA CE 0483



CESSYS™ Cervical Endoscopic Surgical System

TESSYS®
Transforminal Endoscopic Surgical System

+ **TESSYS® Spinal Stenosis**
Transforminal Endoscopic Surgical System
for Spinal Stenosis Treatment acc. to Dr. R. Morgenstern

360°

+ **iLESSYS™**
Interlaminar Endoscopic Surgical System

+ **New MISS Implants**

+ **Neuro Monitoring**

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joined minimal access technologies

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