INTERVIEW with Frank Trautwein / Dr. Heuer: The DCI™ implant provides a stabilizing effect but maintains motion at the treated segment without affecting the kinematics of the adjacent segments.

ISASS 12 & Spine Week Review

The Cure Academy
The DCI™ implant is designed to be functionally dynamic. It provides stability and controlled motion to protect the adjacent segments.

- Physiological center of rotation
- Controlled rotational stability
- Shock absorption capabilities
- Anatomical design
- Single-piece implant – no wear debris

The implant has been in clinical use since 2002.

DCI™

Dynamic Cervical Implant

Controlled motion, functionally dynamic

www.paradigmspine.com

Product not available in the USA.
Dear business partners, dear customers, dear friends,

The market for medical devices is in a process of change. Currently, we observe several major trends: A continuous erosion of market prices and increased market entrance barriers due to more complex quality and regulatory requirements. Combined with the need for clinical studies and evidence based medicine, the successful product in the future is characterized by a simple design, easy and reliable surgical technique with short learning curve and cost effectiveness. It has low inventory and is fully traceable and has shown superiority compared to the standard of care in various aspects.

Great examples: coflex™ and DCI™.

This issue of the Spinal Column will bring you up to speed as it relates to the DCI™. This device is still the only dynamic stabilization device for the cervical spine - between fusion and total disc.

Easy - reliable – safe – effective.

Kind Regards & Good Selling,

[Signature]

Guntmar Eisen
President International Paradigm Spine
Stabilization of the Cervical Spine

By René Rothacker

The gold standard treatment for cervical disc disease involves anterior cervical decompression and stabilization, most commonly in the form of an anterior cervical discectomy and fusion (ACDF). The well-documented potential complications of ACDF, including symptomatic adjacent segment disease (ASD), pseudarthrosis, subsidence, loss of sagittal balance and instrumentation-related problems, have led to the search for motion-preserving alternatives that will provide adequate motion segment stabilization while eliminating the problems encountered with ACDF. Recent results of several multicenter, prospective, randomized US FDA Investigational Device Exemption (IDE) trials comparing cervical total disc replacement (C-TDR) systems with ACDF have demonstrated equivalence or superiority with C-TDR over ACDF with respect to clinical outcomes, reduced re-operation rates at the index level, and lower rates of revision for symptomatic ASD. In properly selected patients, conservative estimates suggest that up to 47% of patients requiring cervical spine surgery meet the strict inclusion criteria to be candidates for C-TDR.

While C-TDR has shown to reduce adjacent level intradiscal pressures, provide a more physiologic distribution of total cervical range of motion and normal motion at the operative and adjacent levels, while maintaining sagittal alignment, recent studies have also highlighted potential limitations of C-TDR. With keel-based devices like the ProDisc-C, the integrity of the mechanical endplate may be compromised. The potential for device subsidence with keel and flange-based devices has led to the search for optimal interface mechanics between the device and bony endplate. Further, clinical, finite elemental analysis (FEA) and kinematic studies have revealed that certain C-TDR designs may actually increase the loads experienced by the facet joints. Consequently patients with facet arthrosis are currently not candidates for C-TDR devices. Facet joint stresses can also be exacerbated with poor implant positioning, thus highlighting how technical error in device placement, despite excellent neural decompression, may lead to a suboptimal outcome due to facet arthrosis.

Consequently, there is a distinct role for a motion-preserving strategy that acts as a solution between rigid fixation achieved with fusion and non-physiologic, position-dependent motion provided by C-TDR that may exacerbate facet degeneration. DCTM™ also addresses another important shortcoming of C-TDR namely wear and tear.

Shortcomings ACDF & C-TDR

Fusion and Adjacent Level Disease
- Clinical studies indicated an increased likelihood of adjacent level disc disease after fusion (Goffin et al., 1995; Hilibrand et al., 1999)
- It has been suggested that the cause is associated with an altered mechanical environment (Matsunaga et al., 1999)

Cervical Total Disc Replacement (C-TDR)
- Disc replacements have been introduced as an alternative to fusion (Chang et al., 2007)
- Cervical disc replacement has demonstrated maintenance of adjacent level RoM (Park et al., 2010)
- However, clinical data indicates the potential for progression of facet arthrosis at the index level (Ryu et al., 2010)
- Heterotopic Ossification (Mehren et al., 2006)
- Wear debris were found in surrounding tissue (Pitzen et al., 2007)
- Implant Failure due to broken polyurethane (Fan et al., 2011)

ISASS Poster 241 – G. Matgé
Proof of Concept: Why Dynamic Cervical Stabilization with DCITM is an alternative to ACDF and C-TDR!

By René Rothacker

The concept of dynamic cervical stabilization with DCITM was introduced in 2004 as a treatment option that aimed to facilitate controlled, limited index level motion to prevent transfer of stresses to adjacent levels, while aiming to minimize motion that may exacerbate facet joint stresses. By limiting axial rotation and lateral bending, motions that significantly contribute to facet forces and by only allowing limited subaxial flexion and extension, the DCITM allows for motion-preservation while limiting stresses applied to the posterior elements. In contrast to other motion-preserving systems, the device functions as a shock absorber. With its restoring force it allows for axial compression in flexion, limits extension, and is protected from fatigue overload via a mechanical stop during maximal flexion. Thus, the DCITM is capable of motion segment stabilization and protecting the posterior elements from excessive motion.

The DCITM is a single-piece, MRI compatible titanium implant. The C-shaped implant is placed into the disc space and secured to the endplate with serrated teeth, thus obviating the need for fixation via vertebral body screws or keels which may compromise the mechanical integrity of the vertebral endplate. To date, more than 7,000 patients have been treated with the DCITM since the launch of the second implant generation during SPINEWEEK in Geneva 2008. 200 patients have been followed-up within the Clinical Data Collection of Dres. Matgé, Herdmann and Eif. To date more than 90% of the patients have reached the 24 month mark. So far the results indicate that DCITM is safe and effective and facilitates excellent clinical outcomes.

This year’s workshop at SPINEWEEK in Amsterdam showed once more that Dynamic Cervical Stabilization with DCITM is THE alternative treatment option to ACDF and C-TDR. It has been demonstrated that it combines the advantages of both treatment options but avoids their shortcomings. For this reason DCITM offers the surgeon a wide range of indications in the treatment of degenerated cervical spine.

The workshop was moderated by the DCITM inventor Dr. Guy Matgé who opened the session with a retrospection of DCITM’s 10 years history. Josh Auerbach, MD and Dr. Dorothea Daentzer presented the findings of their Finite Element Analysis (FEA) and their Biomechanical Investigation respectively, comparing DCITM with ACDF and C-TDR. Dr. Jörg Herdmann from St. Vinzenz Krankenhaus Düsseldorf - one of the three centers taking part in the DCITM clinical data collection - presented his clinical experience. He concluded: “The results after 24 months follow-up are as good as or better than in ACDF. Adjacent segment protection may be the reason for this improvement, which is associated with enhanced life quality”. Last but not least, Frank Trautwein from ACES GmbH closed the session with a motion analysis of the DCITM utilizing a new functional X-ray analysis method. The FXA™ analysis is one of four studies which proves Dr. Matgés concept (see ppt slides “DCITM Product Information”). The study was performed to characterize and quantify the kinematic signature of the DCITM implant.

On the following pages you will find the TAKE HOME MESSAGES of the SPINEWEEK workshop session in brief as well as other supporting documents for discussions with your surgeons. All meeting abstracts and posters are available on the distributor extranet for your information and download.
## Finite Element Analysis (1st Proof of Concept)

**SAS 2011 Poster and Meeting Abstract**

Finite Element Analysis: Comparison between Cage Fusion, Total Disc Replacement and Dynamic Cervical Implant (DCT™)

J. Auerbach et al.

**Biomechanical Testing (2nd Proof of Concept)**

**ISASS 2012 Meeting Abstract**

Biomechanical Investigation of the DCT™ Dynamic Cervical Implant in Comparison to Fusion and Total Disc Replacement

D. Daentzer et al.

### TAKE HOME MESSAGE

**Results:** In general, TDR resulted in increased mobility at the index level during both load and displacement scenarios. The increased RoM after TDR observed for flexion and extension, axial rotation and lateral bending was associated with increased facet contact loading. Conversely, DCT™ maintained limited RoM at the index level compared with TDR but prevented facet contact. Displacement control indicated increased loading at the adjacent segments for fusion when compared to both DCT™ and TDR.

**In conclusion:** DCT™ protects the facet joints. It is a motion-preserving alternative to patients with pre-existing facet arthrosis who are contra-indicated for Total Disc Replacement (TDR).

**Results/Discussion:** Based on the experimental findings, it can be concluded that from a biomechanical perspective the DCT™ can indeed provide an alternative to ACDF and C-TDR in the cervical spine. In particular, the facet joint osteoarthritis and kyphotic deformity, as a contraindication to the arthroplasty, could be a clinical application of the dynamic DCT™.

**In conclusion:** Both DCT™ and TDR protect adjacent segments. DCT™ additionally protects the facet joints. In contrast to the unconstrained TDR designs DCT™ has a restoring force which works like a shock absorber that allows for axial compression.

## Clinical Experience I (3rd Proof of Concept)

**ISASS 2012 Poster 241**

Dynamic Cervical Implant (DCT™) - The Alternative between Cage Fusion and Total Disc Replacement

G. Matgé

**Brtispine 2012 e-Poster 20**

Dynamic Stabilization with DCT™ - Clinical Data Collection

G. Matgé, M. Eif, H. Schenke, P. Buddenberg, J. Herdmann

### TAKE HOME MESSAGE

**Clinical Results:** There was maintenance of index-level motion in about 90% of all patients. NDI and VAS neck and arm pain scores were significantly reduced. More than 90% of patients were very satisfied, while 100% would elect to have the surgery again at 12 and 24 months. Preliminary results indicate that DCT™ is safe and facilitates excellent clinical outcomes, maintains index-level range of motion, and may be suitable for patients with facet degeneration who would otherwise not be candidates for C-TDR.

**Prospective study at three sites with 250 patients. Patient case report forms and X-rays were reviewed at 3, 6, 12 and 24 months. As of today, 90% were seen for their 24 months follow-up. Clinical results after 24 months follow-up are as good as or better than ACDF.**

- Sustainable improvement in neck pain
- Arm pain also improved significantly
- Patient satisfaction 95%
Clinical Experience II (3rd Proof of Concept)

DWG Posters and ISASS 2012 Meeting Abstract (288)
Can Dynamic Cervical Disc Replacement compete with ACDF? Results of a Prospective Clinical Data Collection with up to 24 month follow-up. Dr. Jörg Herdmann et. al

ISASS 2012 Poster 264
Comparison of Dynamic Cervical Implant and Prestige LP: clinical results, range of motion and intervertebral height L. Zou et. al

TAKE HOME MESSAGE

Conclusions: The change of implant footprint after an initial trial has significantly reduced the long-term fusion rate. Clinical results after 24 months follow-up are as good as or better that anterior cervical fusion. Adjacent segment protection may be the reason for this improvement, which is associated with enhanced life quality. Best results to be achieved following these guidelines:
- Do not touch anterior osteophytes
- Sufficient posterior decompression
- Use the largest possible footprint
- Place the implant all the way back to line up with posterior edge

Conclusion: Clinical results as good as TDR but DCI™ with its semi-constrained design serves as a protection for the facet joints of the operated level compared to unconstrained TDR's.

Functional X-Ray Analysis (4th Proof of Concept)

ISASS 2012 and SPINEWEEK 2012 Lunch Workshop session
Kinematic Signature of the DCI™ Implant: Motion Analysis of a functionally Dynamic Cervical Implant utilizing a new functional X-ray Analysis Method. Frank Trautwein / Dr. Frank Heuer

TAKE HOME MESSAGE

The kinematic signature of the DCI™ implant can be summarized as follows: DCI™ provides a stabilizing effect yet maintains motion at the treated segment without affecting the kinematics of the adjacent segments:
- It reduced the RoM in the index level while still maintaining motion after 24 months
- The decrease of the RoM over time was comparable to that reported for Total Disc Replacement technologies
- The disc height was restored by the implant and maintained over time
- The quality of motion in adjacent segment was not affected

Read in detail about the findings and results of the FXA Analysis in an interview with Frank Trautwein and Dr. Frank Heuer from ACES GmbH who is the "brain" behind the Functional X-Ray Analysis software.
The Kinematic Signature of the DCI™ Implant: Motion Analysis of a Functionally Dynamic Cervical Implant Utilizing a New Functional X-Ray Analysis Method

By René Rothacker

Dear Mr. Trautwein,

The roots of the ACES GmbH reach back to the year 1994, when you started developing medical devices for the spine. Can you give us a little background of your history and which services you offer?

In the very beginning, back in 1994, I started developing spinal implants right after I received my engineering diploma from the University of Applied Sciences in Esslingen. In those days, the design process was just switching from paper drawings to 2D CAD systems, and only the aerospace and automotive industries utilized 3D CAD commonly. Coming from the automotive side, I realized the benefits of being able to design implants with a computer and bringing the components together in the three-dimensional space to see their interaction and dimensioning with structures of the spine. A few years later, I added simulation capabilities by implementing an advanced FEa software package into the design process and the offered services. Over time, these methods became the golden standard. As with most other technologies, the medical device developments became more and more technically challenging where special expert knowledge is essential. Over the years, we have developed from a general engineering office doing CAD work to a specialized R&D service provider, conducting nonlinear FEa studies and providing biomechanical materials and device testing. Very recently, we added the capabilities of an imaging core lab. With our FXA® Software (which stands for Functional X-ray Analysis) we are able to analyze even the most subtle changes in radiographic images, either on functional X-ray images to assess kinematics or in a series of images over time to evaluate changes such as implant subsidence, disc height or even the remodeling of bone resulting from surgical interventions.

Dear Dr. Heuer,

You are the developer of the FXA® software. What is your background?

My background is a mix between basic research in biomechanics, medical engineering and programming. The first time I got in touch with biomechanics was in 2000. At this time, I worked on my diploma thesis studying the safety and efficacy of a temporary pelvic stabilization device at the Legacy Biomechanics Laboratory in Portland, OR, USA. Due to the big success of these experiments, I continued my studies and performed my master thesis at the Fraunhofer Institute, IPA in Stuttgart. In this period, I have developed a 3D laser scanning endoscope together with image processing software that was able to visualize the measurement outcome. In 2003, I completed my PhD thesis in the spine department of the Institute for Orthopedic Research and Biomechanics in Ulm, headed by Prof. Wilke. During this time, I learned a lot of spinal biomechanics and how tricky it can be obtaining the right parameters from a complex biomechanical structure like the spinal column in a precise manner. In the team of Prof. Wilke, I have performed several in vitro studies addressing clinical questions, investigating new spinal implants and conducting parametrical analyses to establish a database required for the validation of the finite element models for the spine. I have also built a 3D laser scanning device that is capable of measuring the 3D disc bulging during spinal movements produced in a spine tester. For this, I also formulated an imaging processing software that made it possible determining the 3D disc bulging and disc surface strains the very first time. All study results were published with the goal that everybody has access to the data.
What was your idea and motivation to develop the FXA software?

Trautwein: Today the analysis of medical images (X-ray, CT, MRI) is typically concentrating on static characteristics. For example, in order to diagnose a disease of the spine, the disk height, the translational shift of vertebrae or the narrowing of the spinal canal is determined based on medical images. Due to the lack of feasible tools, it is hardly possible in the daily routine to evaluate further parameters such as, for example, the location of the center of rotation (CoR) or angular and translational relative motion. However, these parameters give valuable information on the current state of degeneration of a spinal segment. With the FXA®-software it is now possible for the first time to utilize these parameters as part of the diagnosis. Moreover, this software is ideally suited to assess the radiographic outcome of orthopedic treatments within clinical studies or post-market surveillance.

Can you explain how the software works?

Heuer: Basically the software program can read radiographs and detect changes in the position of objects shown on these images. For this purpose, individual areas, such as for example the C5 vertebra is selected by drawing a box around it with a few mouse clicks. This is done in both, the flexion and extension radiograph. Then the software matches the vertebra from one image over the other, and compensates for out of plane and scaling errors. A transformation matrix is saved for each matching process, which is repeated with either an implant or and adjacent vertebra. The relative motion between the matched objects can then be determined by looking at the differences in the transformation matrices. With the relative motion information, we can finally reveal and visualize a lot of information about the kinematics of a spinal segment, such as for example the range of motion, or the center of rotation.

What is the trick behind the accuracy of the FXA™ software?

Trautwein: This is a good question. The key element is the matching process, which registers an object of interest in different images and superimpositions the regions with sub-pixel precision. The main advantage of our proprietary algorithm is that the matching works independent from manual landmark placement, contour identification routines or a manual alignment between the images. For this reason, the analysis results of the FXA®-method are operator independent and foster a reliable reproducibility. Furthermore, this algorithm is (to a certain level) robust against projection errors due to out-of-plane effects and can inherently compensate for these. This has been confirmed by receiving our FDA 510(k) approval last year.

In terms of accuracy, your FXA® analysis presents information that has never been shown before. How does your FXA®- technology change the way we need to look at radiographic information and interpret range of motion data?

Heuer: The accuracy of the FXA®-software with +/-0.13° has a great importance for experts in the field of clinical research, because FXA™ study results can directly influence future treatment strategies. Most results arise from a radiological evaluation which might be accompanied by statistically significant errors due to manual measurements. Therefore, it is important to select a proper method for the data evaluation process that is independent of the operator. For this, the FXA®-software enables highly precise insight into the kinematic relationships, biomechanics and remodeling processes which have never been available before in daily practice. With this new insight, implants may be designed in a way that enables them to perform better, for a longer period of time and with improved clinical outcome. We see the clinical study support with our FXA®-software as one important aspect of our mission to improve knowledge and understanding of the kinematics of the human musculoskeletal system and thereby improve the quality of orthopedic treatment for the patients.
Recently you had a closer look at the DCI™ implant with your FXA®-software – what were your findings?

Heuer: The FXA®-study was performed to characterize and quantify the motion of the DCI™ implant. We looked at the functional x-rays of 51 patients, 49 of them had a follow-up time of 12 months and 27 were seen for their 24 months follow-up. All patients were treated by Dr. Jörg Herdmann and his team from the St. Vinzenz Krankenhaus, Düsseldorf, which is one of three centers taking part in the DCI™ Clinical Data Collection since 2007. (The data collection is expected to be finalized by the end of this year). The average patient age was 50 +/- 8.5 years. We measured a ROM of 7.4° for the index level in the pre-op situation. After 3 months post-surgery, the ROM reduced to a median value of 5.6°. A statistically significant reduction was obtained after 12 and 24 months after surgery, with a RoM of 4.4° and 3.3°, respectively. We did not find a correlation between the implant size (length and/or height) and RoM. The adjacent levels provided a RoM between 10°-11° for the pre-op condition. The RoM was only slightly increased after 12/24 months post implantation.

The typical indicator for the breakdown of a segment is loss of disc height. What were the findings of your radiographic analysis regarding disc height in the segments above and below the DCI™ implant?

Heuer: As a result from the FXA®-evaluation, we could see that the adjacent segments maintained the disc height, CoR location and RoM after 24 months post-surgery. The index segments showed a statistically significant increase of disc height at all regions (anterior, middle and posterior) after implantation, which is due to the C-shaped design of the DCI™ implant and proper height sizing. A reduction of height in the posterior third of the index level was observed, which however can most likely be attributed to a measurement artifact due to some bony bridging in cases where the implant seems to be not positioned deep enough. The DCI™ implant was able to maintain both segmental and foraminal height over time.

What is the take-home-message from your center of rotation analysis of the index level and the adjacent segments? What role does the center of rotation play in these investigations?

Trautwein: We looked at the center of rotation (CoR) at each index and adjacent segments. After implantation, it seems to be that the CoR tends to migrate somewhat cranial and posterior in the index segment. The adjacent levels were not influenced regarding their CoR position subsequent implantation of the DCI™ implant at all. In my opinion, the CoR should be maintained or shifted towards the physiological location. Any other deviation of the CoR location could lead to kinematic movements that counteract with the facet joints, which in turn leads to higher stress, degeneration and pain, known as facet joint arthrosis.
Knowing what you know now: How would you describe the kinematic signature of the DCI™ implant and how does it perform compared to total disc replacement technologies? Does DCI™ protect the adjacent segments?

Trautwein: The kinematic signature of the DCI™ implant could be summarized as follows:

The DCI™ implant provides a stabilizing effect but maintains motion at the treated segment without affecting the kinematics of the adjacent segments:

- It reduced the RoM in the index level while still maintaining 3.3° of motion after 24 months
- The decrease of the RoM over time was comparable to that reported for TDR technologies
- The disc height was restored by the implant and maintained over time
- The quality of motion in adjacent segment was not affected

From the current analysis, the DCI™ seems to be a viable treatment option. As with most studies, the results should be verified in long-term studies with TDR and fusion control groups.

About ACES GmbH

ACES GmbH is an engineering service provider and was formed in 1999 with the mission to provide the latest in engineering knowledge and technology to the medical device industry. Being pioneers in the utilization of 3D CAD and advanced FEA simulation, the philosophy of being on the leading edge continues with the recent addition of a novel image analysis software called FXA. Utilizing proprietary, patent pending technology, the FXA software can detect, quantify and analyze even subtle motion within functional radiographs. Typical applications are the quantification of the range of motion, translational and angular instabilities, implant loosening, migration or subsidence, semi-automated measurements of lordosis and cobb angles and fusion assessment, to name a few. Extensive validation studies showed that the measurements are highly reproducible and over ten times more accurate compared to manual measurements by radiologists.

ACES GmbH works in close cooperation with the Steinbeis Transfer Center BWF for mechanical testing of materials and medical implants and with several biomechanical test labs around the world.

Coming from the industry sector, the staff at ACES GmbH understands the processes, needs and time constraints of medical device OEMs. In addition to above services centered around spinal implant and instrument design, ACES GmbH offers expert knowledge and the performance of mechanical and biomechanical preclinical testing for development and validation purposes.

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In conclusion,... stabilization of the degenerated cervical spine using anterior cervical disectomy with fusion is a successful short term option for single level patients. However, long term results often require extension of their fusion. Multi-level ACDF is not as successful as single-level treatments and the incidence of additional surgery is even higher than in single level pathologies.

Motion is better than no motion! The aim of total disc prosthesis is to maintain or restore the natural range of motion and therefore to protect the adjacent levels above and below the affected segment(s). In the past years, there have been a large number of reports on advantages and disadvantages of cervical disc arthroplasty. Limitations for the use of prostheses are restricted indications, secondary fusion (heterotopic ossification), possible over-distraction and a number of other design specific complications. Various studies have indicated that the clinical results are better when the motion pattern of the implant is closest to the physiological motion of the cervical spine.

Dynamic Cervical Stabilization with DCITM is THE alternative treatment option to ACDF and C-TDR. DCITM combines the advantages of both treatment options, the GOLDSTANDARD fusion with the motion preservation philosophy. DCITM is safe and facilitates excellent clinical outcomes, maintains index-level range of motion, and may be suitable for patients with facet degeneration who are no candidates for C-TDR. DCITM therefore offers the surgeon a wider range of indications in the treatment of the degenerated cervical spine.

### Stabilization of the Degenerated Cervical Spine

<table>
<thead>
<tr>
<th>General Goal</th>
<th>Anterior approach, disectomy, decompression, restoration of discal and foraminal height, adjustment of sagittal balance, segmental stabilization</th>
</tr>
</thead>
</table>
| Indication/Stage of Degeneration | Early Stage Degeneration  
· high mobility pre-OP  
· good disc height  
· good facet status  
| Mid Stage Degeneration  
· limited motion pre-OP  
| Late Stage Degeneration  
· no motion pre-OP  
· angular instability  
· translatory instability  
· hypermobility  

| Implant Concepts | Motion Preservation  
Total Disc Replacement  
(Unconstrained) Motion  
| Dynamic Stabilization  
Dynamic Cervical Implant  
(Controlled) Motion  
| Stabilization  
Fusion care / plate  
No Motion  

<table>
<thead>
<tr>
<th>Additional Benefit / Risk</th>
<th>Adjacent Segment Protection</th>
</tr>
</thead>
</table>
| Range of Indication | limited  
wide  
| Risk / Failure Mode | · Facet Arthrosis  
· Wear  
· Migration  
· Subsidence  
· Heterotopic Ossification  
| Adjacent Segment Disease | · Migration  
· Subsidence  
· Nonunion (pseudarthrosis)  

**Why DCITM can replace a lot of ACDF or C-TDR business:**  
DCITM follows the same primary goals as ACDF or C-TDR: anterior approach, disectomy, decompression, restoration of discal and foraminal height as well as adjustment of the sagittal balance and segmental stabilization. The DCITM implant is designed to address the shortcomings of anterior cervical disectomy with fusion by maintaining motion while still providing relief from symptoms. In contrast to C-TDR, it limits the natural range of motion (no lateral bending). With its definitive height posterior it prevents facet contact and therefore protects the facet joints. The DCITM implant offers stable, controlled motion to already degenerated motion segments. Therefore, degenerative arthropathy - a critical cervical pain-generator - remains an indication. In addition the implant is axially compliant offering dampening capabilities to avoid overloading and accelerated degeneration of the adjacent segments above and below the treated segment(s). Extensive radiographic analyses demonstrate that DCITM does not change the Cor (quality of motion) in the adjacent segments and as we all know: Quality of motion is key!
Stop telling, start selling! By Dominik Beck

A sale begins when a customer says “No”. Whether you are cold calling a potential client or making a person-to-person presentation, learn how to close the deal by providing answers to questions the potential client may have. The ability to handle objections is critical for your success. Remember: People do things for their own reasons, not yours.

Create the Need
After introducing DCI™ to the potential customer, the next step should be to determine if there is a fit between your service and his or her needs. You can achieve this with probing questions to learn more about what your prospect wants and how you can fulfill his or her needs. People appreciate it when you listen to them. Understand what they are saying, then ask relevant follow-up questions, whether you are clarifying something or simply acknowledging their statements. Remember: your ability to close a sale will greatly depend on your skill to make your prospect feel that you have the product or service which is designed for his sole benefit.

Think of your objection handling strategy
You need to thank your lucky stars if your prospects start using the DCI™ Implant without any questions asked. More likely, people will give you reasons why they shouldn’t buy from you, if not try all tactics in the book to get rid of you quickly. But remember this. Prospective customers say “No” as automatic mechanism to get rid of the salesman. As part of your preparation, you need to think as many possible objections your prospect may have, and then have ready answers to counter these objections.

Here is the good news: If somebody has an objection he or she has already thought about your product!
We hope this “handling objections strategy” stimulates your next discussions with surgeons. Please let us know if you have heard of other objections that you need to address. This is a truly dynamic process and we rely on your feedback. Let us get better every day hand in hand!

As the Nike ad says, “Just do it.”

**Objection:** ACDF is a very successful and safe procedure. Why should I leave this?

**Answer:** I really appreciate your honest opinion. Recent FDA C-TDR studies who compare TDR against ACDF in a randomized, controlled set up have presented interesting findings in the mid-to long-term follow-up. The revision rate in the fusion control group was 17.8% after 7 years. 10.3% at the adjacent segment and 7.5% at the index level. Similar findings were found by the Texas Back Institute in Dallas who compared their in-house findings from several trials. After 4 years a rate of 17.6% revisions was found in the ACDF group. In 9.8% the problem was at the adjacent segment and in 7.8% at the index level. So with longer follow-up more and more evidence of clinically relevant problems is presented.

**Objection:** Everything will fuse eventually and it is then nothing but an expensive cage…

**Answer:** I understand your concern. Paradigm Spine performed a prospective post-market surveillance study with up to two year follow-up to learn more about this phenomenon. It was found that after 1 year more than 90% of the implants were mobile and after 2 years more than 80% of all implants were still moving. When we did the functional x-ray analysis, we found out that the DCI™ implant did not alter the center of rotation in the adjacent segments at all which proves that quality of motion was maintained. Also very promising: No Loss of height was found in the adjacent segments above and below (go through FXA slides now when necessary). Nevertheless, surgical technique is important, too, to reduce heterotopic ossification.

1. Avoid aggressive endplate remodeling. DCI™ allows for an atraumatic anchorage!
2. Choose maximum implant footprint. Laterally: reach out all the way to the uncinate processes, in AP leave 1-2mm distance to dura.
3. Do not over-distract with/oversize implant: This generally may create neck pain but also may increase stresses leading to bony reactions.

**Objection:** Continuous loading may lead to subsidence which then leads to subsequent clinical problems!

**Answer:** This is a very interesting thought. In our clinical investigation with n=250 patients and two-year follow-up subsidence was very rare and the rate was comparable to ACDF. Several aspects that are different to ACDF are important to note: The large implant footprint minimizes point loading on the endplate. Placing the implant on the apophyseal ring is important. Endplate remodeling is supposed to be less aggressive. Finally the implant is axially compliant which means that axial loading is transformed into motion and shock can be absorbed.

**Objection:** I don’t believe that DCI™ really is able to mimic the motion pattern of the spine. It seems to be very different to current C-TDR concepts!

**Answer:** I am glad that you are bringing this up. Initially, this was our thought as well. We then started a series of investigations including finite element analysis, biomechanical testing, prospective clinical evaluation and extensive radiographic analysis. What we found is the following:

1. Segmental motion could be restored without any increase of the facet joint forces, one of the problems C-TDR faces.
2. Center of Rotation was not altered at all at the adjacent segments at 2 years
3. Segmental height was not decreased at all at 2 years
4. Segmental stabilization is very similar to ACDF since the implant in only compressible anteriorly. Posteriorly it maintains foraminal height and effectively protects the facet joints.
5. Nice side effect: The surgical technique is as simple as with ACDF. Also it allows for an insertion under compression which minimizes the need for intraoperative (excessive) distraction. This may lower the occurrence of neck pain direct post-op.
Objection: Dynamic implants typically deal with wear and tear which concerns me.

Answer: I truly understand your concern. You are absolutely right that any implant that articulates, i.e. knee implants, hips or C-TDR has to deal with wear and tear eventually. Typically it starts slow and worsens over time which ultimately may require a revision. DCI™ is different though. As you can see it is a single piece implant with no articulation. So no wear and tear must be expected. It is a very simple design that has all the advantages of a cage fusion avoiding shortcomings of current C-TDR concepts (if adequate show example of Bryan failure 8 years post-op at this time).

Objection: I am concerned that the implant may dislocate anteriorly since it is not fixed to the endplate or fuses over time.

Answer: We understand your concern. From our experience of more than 7,000 implantations worldwide we can clearly preclude the risk of anterior luxation if proper surgical technique is applied. The key is to position the implant on the endplates so that the anterior teeth of the implant are within the parameters of the vertebral body and “bite” into the apophyseal ring of the vertebral endplate. This can be easily achieved with the DCI™ instrument set which allows for a precise positioning of the implant. We do recommend a lateral x-ray confirmation before the insertion instrument is disconnected.

Objection: I am concerned that the implant may dislocate posteriorly.

Answer: This is an important question and we understand you concern. The DCI™ implant is in clinical use since 2002. Up to now, more than 7,000 units have been implanted worldwide and no posterior migration has been reported. The convex design of the implant and the teeth anteriorly provide excellent stabilization. In addition, it is important to note that the implant is inserted under compression which provides additional stability once the insertion instrument is disconnected and compression is released.

Objection: Does DCI™ create artifacts on an MRI? I need to be able to have MRI as a diagnostic tool also after implantation.

Answer: This is an excellent question. As a matter of fact DCI™ is probably creating fewer artifacts than most of the current total disc replacements. Here is an example of an MRI after DCI™ has been implanted (show example at this point). What are your thoughts? Do you feel comfortable with this?

Objection: Why does the implant have no surface treatment or coating?

Answer: This is a legitimate question. Do I understand you correctly that you are concerned about sufficient primary and secondary stability of the implant?

Primary stability is achieved by the convex shape of the implant, the large contact surface, teeth anteriorly and – most importantly – insertion of the implant under compression. Once the insertion instrument is released the implant aligns with the endplates and reaches its maximum stability. Since fusion is not the goal of the procedure the disc is carefully removed (blunt dissections) without destroying the integrity of the endplates. We do not recommend the use of a high-speed burr as this can be too aggressive and may damage the endplates. This technique furthermore is favorable to avoid later stage heterotopic ossification.
Vietnamese Guest Surgeons enjoy the hospitality of Dr. Eif in Görlitz  

By Klaus Schnottz

Springtime in Görlitz. Having just arrived from Southeast Asia, six Vietnamese guest surgeons enjoyed the cool weather in Germany. Mr. Tuong Nguyen, General Manager of Vietsing Medical JSC led the group. He came with his customers to have a profound training in coflex™ and DCITM. Tuong perfectly arranged the trip for the group involving a Vietnamese guide coming from Prague – “right around the corner”.

After a short introduction Dr. Eif left to the O.R. with two surgeons joining him. The rest of the group stayed in the conference room having a perfect view by video transmission. Scheduled were two coflex™ cases.

The first case – double-level coflex™ – was thoroughly followed by our Vietnamese guests. Dr. Eif rejoined the group for a wrap-up and questions and answers session after the surgery. The second case was then presented: Anamnesis and indication followed by therapeutical details with discussion. The surgery was accompanied by another two surgeons. The discussion afterwards was vivid and interesting. Dr. Eif also gave theoretical background and shared his almost 10 years’ experience using coflex™.

After a perfect first O.R.-day, we all left for a visit of the beautiful old town of Görlitz including a walk to Poland right over the bridge. The dinner in a former merchant’s house is the end of a perfect day.

The next day was dedicated to DCITM. Dr. Eif presented the technology and included both the advantages and contra-indications of the DCITM system. This knowledge can be very helpful for the surgeons once they are back home having to choose the correct therapy.

The whole group enjoyed the two days in Görlitz. Dr. Eif perfectly showed his skills as a good neurosurgeon and as a warm-hearted host for his Vietnamese guest surgeons.
Turkey, has seen quite some reimbursement challenges for two years now for non-fusion products. Nevertheless, the approval for GSP™, the Growing Spine Profiler, for treatment of EOS, Early Onset Scoliosis, was received in April 2012.

The first surgeries took place in Malatya, a one-million habitants city in the south-east of Turkey, about 200 kilometers from the Syrian border. Malatya is famous for their dried fruits, apricots, which are exported to all countries.

In Inonu University Faculty of Medicine, Turgut Ozal Medical Center, referring to the University Hospital of Malatya, Dr. Mehmet Fatih Korkmaz, performed the first two GSP™ surgeries with support of Kerstin Kopp, Director International Business Development and former Product Manager for Non-Fusion Scoliosis at Paradigm Spine.

Dr. Korkmaz already performed two more surgeries and the next cases are planned for mid of May. He sees a lot of congenital scoliosis, with severe malformation of the vertebral body, and thinks he can help these children with the GSP™ system, to prevent early fusion of the spine in these young children.

Building on a very friendly and strong partnership in spine business with FerMed headed by President Kamil Bai, it is a further step to enhance business after the problems with reimbursement in the country. We are looking forward to further business with FerMed.
The ISASS 12, the 12th Annual Meeting of the International Society for the Advancement of Spine Surgery, took place from March 20-23, 2012 in Barcelona, Spain. Despite the overall small attendance both from surgeon side as well as industry side, the meeting turned out to be a great success for Paradigm Spine.

During this year’s ISASS 12, Paradigm Spine was very proud to host several podium presentations. Our flagship product, the coflex™ interlaminar implant, was presented in six different podium presentations and four oral/regular posters while the DCI™ was presented in two podium presentation and two regular posters. The coflex-F™ system, the GSP™ system and the DSS™ system were shown in one podium presentation/one oral poster and in one regular poster and one oral poster respectively.

Please check the distributor extranet for full abstract books of all Paradigm Spine product-related abstracts presented at ISASS 12. Above all, it was a great honor that one of the presentations was awarded with “The Kostuik Innovation Award” sponsored by Dr. Thomas Errico. Dr. Joshua Auerbach received the award for his presentation “coflex® Interlaminar Stabilization Compared to Posterior Spinal Fusion for Spinal Stenosis and Spondylolisthesis: Two-year results from the Prospective, Randomized, Multicenter Food and Drug Administration IDE Trial.” Congratulations to Dr. Auerbach and all parties involved in creating this abstract for this great achievement!

The Kostuik Innovation Award sponsored by Dr. Thomas Errico for the presentation “coflex® Interlaminar Stabilization Compared to Posterior Spinal Fusion for Spinal Stenosis and Spondylolisthesis: Two-year results from the Prospective, Randomized, Multicenter Food and Drug Administration IDE Trial.”
The 3rd SPINE WEEK congress took place from May 28 to June 1, 2012. After being held in Porto in 2004 and in Geneva in 2008, the organizers chose Amsterdam, Netherlands as a location. SPINE WEEK aims at synchronizing the annual meetings of leading scientific spine societies in one location, thus simplifying meeting logistics both for delegates and participating industry – amongst others of course it was attended by Paradigm Spine.

The scientific presence of Paradigm Spine was outstanding like at ISASS 12 – Paradigm Spine featured several podium presentations on the coflex™ - the IDE study results were again clearly a highlight of the scientific program and well presented by Dr. Joshua Auerbach - and held three lunch workshops to further promote its products.

The first lunch workshop was focused on the DCI™ and was moderated by Dr. Guy Matgé, the chairman of the session which was kicked-off by Dr. Joshua Auerbach showing a finite element analysis which compared cage fusion, TDR and DCI™. Dr. Dorothea Daentzer followed by her talk about biomechanical investigation of the DCI™ in comparison to fusion and TDR. Afterwards, Dr. Jörg Herdmann presented his results of the prospective clinical data collection with up to 24 months follow-up and Frank Trautwein finalized the workshop by presenting a motion analysis of the DCI™ utilizing a new functional X-ray analysis method.

The coflex™/coflex-F™ workshop was highlighted by the coflex™ presentations of Dr. Joshua Auerbach titled “Direct Decompression and Interlaminar Stabilization Compared to Laminectomy and Posterior Spinal Fusion with Pedicle Screw Instrumentation for Spinal Stenosis with Back Pain or Degenerative Spondylolisthesis: Two-Year Results from the Prospective, Randomized, Multi-Center FDA IDE Trial.” and Prof. Dr. H. Michael Mayer talking about modern fusion concepts and the philosophy of interlaminar stabilization. The second part was dedicated to the coflex-F™ presentation by Dr. Joshua Auerbach about the clinical and radiographic evaluation of the coflex-F™. The DSST™ system and the newly developed HPSTM system were the topics of the third workshop on Thursday, May 31, 2012. The speakers involved were Dr. Joshua Auerbach, Dr. Eberhard Mayer, Dr. Aldemar Hegewald and Prof. Rudolf Bertagnoli. Dr. Auerbach started the workshop by presenting a finite element analysis comparing DSST™, PEEK and titanium posterior stabilization systems with each other followed by Dr. Eberhard Mayer presenting his new surgical percutaneous and mini-open approach. Dr. Hegewald continued the session presenting the biomechanical effect of dynamic stabilization adjacent to single level fusion and Prof. Bertagnoli finished the workshop with elaborating on indications for adjacent segment protection with the HPS™ system as a hybrid construct.

As a regular “institution” at international spine congresses, Paradigm Spine held a distributor meeting for all its distribution partners. The highlights certainly were a coflex™ ideas/opinions/knowledge/experience exchange with Dr. Joshua Auerbach and the two Paradigm Spine Partnership presentation by Maciej Zaczeniuk for Paradigm Spine Polska and Jirí Hrdina from BBraun in the Czech Republic.

See you next year at EuroSpine 2013!
The scientific program and the podium presentations/posters were well accompanied by two lunch workshops. The first lunch workshop on Wednesday, March 21, 2012 was dedicated to “New Ways in Spinal Stabilization and Adjacent Segment Protection”. Dr. William Sears kicked the session off and talked about his early experience with the HPS™ system, while Dr. Auerbach presented in-depth the two-to-four-year clinical results on adjacent segment protection when using the coflex™. The workshop was completed by Frank Trautwein and Dr. Dorothea Daentzer presenting about the kinematic signature of the DCI™ implant and the biomechanical investigation of the DCI™ compared to fusion and TDR.

The second workshop was dedicated to coflex™ and coflex-F™ and titled “Interlaminar Stabilization with the coflex™ Family of Implants – Rigid and Dynamic Solutions Following Direct Decompression.” Due to some shortcomings arising last minute, Dr. Reginald Davis was unfortunately not able to make it to ISASS 12, therefore, his workshop presentation was held by Dr. Joshua Auerbach presenting in more detail the two-year clinical data on coflex™ of the FDA IDE trial. This part was followed by an in-vivo load analysis by Frank Trautwein. Dr. Christoph Siepe from Munich then took over presenting modern fusion concepts and philosophy of interlaminar implants. The workshop was rounded out by Dr. Auerbach’s talk about the clinical and radiographic evaluation of the coflex-F™ system.

Besides the booth, the workshops and the podium presentations, Paradigm Spine and its team members took the chance to meet and discuss with its distribution partners the various product updates, news and challenges. This was done not only in single business meetings but also in a combined distributor meeting during which as a highlight Mr. Carlos del Campo, representing his company BioProPeru, held a presentation showing his success story of Paradigm Spine products in Peru. Another highlight was a clinical exchange meeting between Paradigm Spine faculty member and Chinese surgeons discussing and debating about the coflex™ interlaminar implant and the DCI™ dynamic cervical implant.

Paradigm Spine is looking forward to next year’s ISASS 13, which is going to take place in Vancouver, BC, Canada from April 2-5, 2013!
DCI™ Clinical Round - Stabilization of the cervical spine with dynamic implants  By Norbert Schmidt, Sales Representative Paradigm Spine Germany

A small scientific highlight took place on March 28, 2012 in the Klinik Helle Mitte, in the Berlin town district Hellersdorf. Organized by Paradigm Spine an internal continuing education of the clinicians was carried out on the subject „Stabilization of the cervical spine with dynamic implants“. 12 doctors took part in the event and followed with much interest the presentations. Our aim was to make the doctors DCI™ users who implant up to now only cages and prosthesis.

Dr. Heinitz, neurosurgeon of the clinic, spoke of the functional anatomy of the cervical spine and the surgical consequences arising from it. By his many years’ work as a leading senior physician in a big neurosurgical clinic he has much surgical experience. He showed the possibilities in his presentation how patients with different illnesses of the cervical spine can receive the best treatment for them. A huge number of different operating technologies and implants make this possible.

Dr. Koennecke, a lowered neurosurgeon, spoke in the second part of the event about “Possibilities of the stabilization of the cervical spine with dynamic implants”; especially of his experiences with the DCI™. He showed in his presentation very persuasive the advantages of DCI™ in the treatment of degenerative illnesses in the cervical vertebra column. Particularly the simplicity of the implantation and the evident function of the implant persuaded the listeners.

The long working day was finished with a small snack during which the participants had opportunity to discuss with the advisers. Dr. Heinitz still wants to implant in the 2nd quarter his first DCI™. This was a successful event and proved once more Paradigm Spine’s leading scientific role being surgeon centric, indication specific and data driven.

DSS™ International Cadaver Lab in Frankfurt  By Tino Schulz, Sales Representative Paradigm Spine Germany

High buildings and a phenomenal skyline are what Frankfurt am Main, Germany’s capital city of finance, is famous for. But not just that- also the well-known orthopedic spine department of the University Hospital Friedrichsheim with its chief of surgery Prof. Dr. Rauschmann is located in this town.

On March 2 and 3, 2012, the international DSS™ Cadaver Lab Course took place at the anatomic institute of the local Goethe University in Frankfurt. Many spine-surgeons, orthopedic surgeons and neurosurgeons from Latin America, Italy, Egypt and India, but also physicians from Germany followed the invitation of Paradigm Spine.

The modified Wiltse-Approach, which causes less muscle damage, the classic surgical technique, and Dr. Eberhard Mayer’s Mini open Technology with its special instruments designed by Paradigm Spine engineers were the focus of the course.

On Friday, March 2, 2012, the course started with the theoretical part. Prof. Rauschmann and Dr. Mayer gave lectures about indications, samples and cases as well advices and tricks for the usage of the DSS™ system. Besides, they talked about limits of the dynamic stabilization system from experienced surgeons’ points of view. Afterwards, Kerstin Kopp of Paradigm Spine introduced an overview of product features of the DSS™ system to the participants. After that, participants and speakers had the possibility to discuss some cases and the instructors presented some radiographic pictures and provided an overview of the patients’ medical conditions with the question: what would you have done? In the evening, there was a get-together-meeting and dinner at a historic sight restaurant called “Gerbermühle”. Over a glass of wine and provided with delicious food, attendees developed lively conversations about the indications and advantages of lumbar dynamic stabilization.

On Saturday morning, March 3, 2012, at the anatomic institute, there were three cadavers with whose help, the participants were taught different approaches to the spine and how to place pedicle screws for dynamic stabilization with the DSS™ system the right way and they had the possibility to practice this by themselves. Both Prof. Rauschmann’s table and Dr. Mayer’s table were well visited and the participants practiced the mini open approach under Dr. Mayer’s instruction. So after directly getting a really positive feedback from the attendees, we are proud that we were again able to organize a very successful event.
Established in the year 1995 in New Delhi, India, Cure Surgicals is one of the leading healthcare service providers covering various verticals of Orthopaedics, Spine, Neurosciences, Biologics and modern medical devices. Over the past 15 years, Cure Surgicals has been consistently offering quality products and healthcare solutions to the medical fraternity along with superior service. We continuously strive to introduce niche products and technologies in India by collaborating with leading multinational companies. In our endeavor to promote training and education we organize various educational and courses under CURE ACADEMY.

On behalf of Cure Surgicals, it gives me great pleasure of informing you that we had a very successful launch of Cure Academy–Education Beyond Boundaries.

Cure Academy is an initiative to promote training and education in the field of spine surgery by providing an opportunity to aspiring surgeons to enhance their surgical skills.

Cure Academy offers a unique educational package to equip surgeons with skill sets necessary to deal with common and difficult spine surgical situations through the model of didactic, hands on workshop and cadaver sessions.

Our first program event was held in Pune (2hrs drive from Mumbai) on 28th-29th January 2012. The event comprised of 2 live surgeries using the Bone Scalpel by Dr. Rajesh Parasnis and 1 live surgery on Balloon Kyphoplasty by Dr. Abhay Nene and Dr. Vishal Peshatiwar. Over 50 surgeons witnessed the case live in the auditorium of Oyster and Pearl Hospital, Pune. Surgeons were impressed by the precision of the instrument in both the cases. As it was a new technology which was being used, the Cure Academy launch was well appreciated by esteemed surgeons of Pune Orthopaedic Society. The exciting curriculum and agenda attracted media coverage. The event also had debating sessions on various spinal procedures.

We at Cure Surgicals have ploughed in a lot of effort and time for making this event and product a success in all corners of the country.

ASSICON Congress 2012
It is with great pleasure and pride to share the 25th ASSICON at Hotel Le Meridien, New Delhi. The Association of Spine Surgeons of India has grown in strength and numbers in the last few years. With more than 650 life members is now one of the largest professional bodies in the world. The association also has numerous academic and educational activities which foster training to younger surgeons and up-gradation of skill to all its members. The annual meeting of the association is a premier event and this year’s meeting is going to a special event to commemorate the 25th year.

In keeping with the special occasion, the Scientific program was different from that of previous ASSICONS with multiple prestigious international and national societies like Scoliosis Research Society (SRS), International Society for Study of Lumbar Spine (ISSLS), International Spinal Cord Society (ISCoS), World Society for Endoscopic Navigated & Minimal Invasive Spine Surgery (WENMISS), International...
Group for Advancement in Spinal Science (IGASS) and Neurological Society of India (NSI) participated in the conference and conducted sessions during the conference. The conference was an academic feast.

This platform was used to launch the DCI™ Kick Off meeting.

Cure Surgicals, India is all set to execute a multi-centric, prospective, non-randomized, investigator initiated registry to assess the motion preservation, effectiveness, stabilization and functional improvement in subjects with DCI™ for use in one-level symptomatic cervical disc disease. The idea was conceptualized between Paradigm Spine, Cure Surgicals and Dr. Bipin Walia- Head of Spinal Surgery, Max Hospital, New Delhi around a year and a half ago and was recently given a final shape for its delivery. The project will be controlled and funded by Cure Surgicals in collaboration with Paradigm Spine.

The DCI™ registry will be conducted across 10 investigating centers in India, covering different geographical locations, under the supervision of the lead investigator - Dr. Bipin Walia. The registry design includes a total sample size of 125 DCI™ and 125 ACDF cases with the duration of one year of patient enrolment and one year of patient follow up. The results will then be sent for publication in different national and international journals.

A kick-off meeting was organized on February 24, 2012 at Hotel Le Meridien during the annual conference of ASSICON which was attended by all principle investigators, Dr. Walia and Mr. Kapil Malhotra-CEO, Cure Surgicals. The meeting covered all important aspects of the registry protocol followed by a product demonstration by René Rothacker, product manager with Paradigm Spine.

In all, it was a Unique Academic Feast

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**Event Calendar 2012**

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<tr>
<th>Date</th>
<th>Event</th>
<th>Location</th>
<th>Paradigm Spine’s Activities</th>
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</thead>
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<tr>
<td>July 18-21</td>
<td>IMAST</td>
<td>Turkey, Istanbul</td>
<td>Booth</td>
</tr>
<tr>
<td>September 17+18</td>
<td>DSS™ Cadaver Course</td>
<td>Czech Republic, Prague</td>
<td>DSS™ Theoretical Training &amp; Hands-on Cadaver Course with Prof. Stulik &amp; Prof. Rauschmann &amp; Dr. E Mayer</td>
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<tr>
<td>September 21-23</td>
<td>SMISS</td>
<td>USA, Miami, FL</td>
<td>Booth</td>
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<tr>
<td>October 6-10</td>
<td>CNS</td>
<td>USA, Chicago, IL</td>
<td>Booth</td>
</tr>
<tr>
<td>October 23-27</td>
<td>NASS</td>
<td>USA, Dallas, TX</td>
<td>Booth</td>
</tr>
<tr>
<td>November 11+12</td>
<td>DSS™ Cadaver Course</td>
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</tr>
<tr>
<td>December 6-8</td>
<td>German Spine Congress (DWG)</td>
<td>Germany, Stuttgart</td>
<td>Booth and Workshops</td>
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**PARADIGM SPINE U.S. REGULATORY STATUS**

<table>
<thead>
<tr>
<th>Device</th>
<th>Status</th>
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<tbody>
<tr>
<td>coflex™ implant</td>
<td>Investigational device. For investigational use only.</td>
</tr>
<tr>
<td>DCI™ implant</td>
<td>Not approved.</td>
</tr>
<tr>
<td>coflex-F™ system</td>
<td>FDA cleared.</td>
</tr>
<tr>
<td>HPS™ system</td>
<td>Not approved.</td>
</tr>
<tr>
<td>DSS™ system</td>
<td>510(k) cleared – Hybrid use not cleared in the US. See US package insert for labeling limitations.</td>
</tr>
<tr>
<td>orthobiom™ system</td>
<td>Not approved.</td>
</tr>
<tr>
<td>GSP™ system</td>
<td>Not approved.</td>
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**IMPRESSUM**

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