The coflex™ success story continues...

**DISTRIBUTOR STORIES**

General Care International - Entry to the Dragon Market

**EVENTS**

Eurospine 2009 - Paradigm Spine Announcement
The coflex™ implant is ideal for spinal stabilization after surgical decompression of degenerative spinal stenosis.

- Compressible in extension; allowing flexion
- Stress reduction on facet joints
- Maintenance of foraminal height
- Less invasive, tissue-sparing procedure
- Easy and precise application

15 years of clinical history and more than 50,000 implantations worldwide have proven the clinical success of this interspinous implant.

coflex™
Interspinous Implant
Controlled motion, functionally dynamic
www.paradigmspine.com

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

In many countries worldwide, we have now set a new standard for the treatment of lumbar spinal stenosis with coflex™ and decompression. In Germany, about 5,000 devices are implanted per year, which represents about 50% of the interspinous market. More than 25 (!) different interspinous devices are available, just on the German market. Globally, we have implanted more than 50,000 devices since we launched the coflex™ implant in May 2005.

We have brought two important randomized prospective studies on the way. A German multicenter prospective study comparing decompression alone against decompression with coflex™; the second study is performed in the US to obtain FDA approval comparing decompression with fusion against decompression with coflex™. The early results are very promising; these studies will result in landmark publications after completion.

Over the last years, we have learned that the coflex™ wing design can be disadvantageous in 2-level surgeries. We see a lot of overlapping wings, sometimes resulting in implant dislocations. In many cases the 2nd device can not be put deep enough; optimal interlaminar positioning is not always possible.

This is the reasons why we designed the “coflex™ bi-segmental”, which eliminates these problems. After a controlled launch in Germany, we have only received positive response; the device is a significant improvement in two-level cases. This is why we have decided to totally swap to this new coflex™ design in Germany.

Depending on your individual market and regulatory situation, this might be interesting to consider, you will be contacted by our regulatory department to initiate the registrations, if necessary.

I am very much looking forward to meeting many of you at the EUROSPINE 2009 in Warsaw – let us spend some time together to discuss how our new product extensions can be successfully introduced in your market.

Kindest regards,

Guntmar

Guntmar Eisen
President International Paradigm Spine
A new chapter in the coflex™ success story:
coflex™ with a new wing design – be different

By René Rothacker

Product History

The coflex™ interspinous implant was invented by Dr. Jacques Samani in 1994 and has been in continuous use since 1995 outside the United States. Initially, the product was known as the “Interspinous U” and was marketed by Fixano SAS (Péronnas, France). Transfer of ownership to Paradigm Spine was finalized in early 2005. The product then was renamed “coflex interspinous implant” which aimed to express the unique product feature of “COntrolled FLEXibility” of this interspinous implant. The design and material have not changed, although two new sizes have been added. Since then continuous growth can be reported. Today we have 15 years of clinical history and more than 50,000 implantations worldwide that have proven the clinical success of this interspinous implant. In more than 40 countries Paradigm Spine has set a new standard for the treatment of lumbar spinal stenosis with coflex™ and decompression. The key success factor for this outstanding sales history is that all communication towards the surgical indication remained very specific. Being indication specific separated coflex™ from the remaining market players from the very beginning. Nevertheless in some markets saturation along with an increasing number of competitors can be observed. This must encourage us all to not only focus on the new products DCITM, DSS™ or coflex-F™ but also to continue the coflex™ success story together, in order to be the interspinous market leader now and in the future.

Competitive Landscape

When Paradigm Spine started its business activities in 2005 only 3 more interspinous devices have been marketed at that time: Namely the DIAM from Medtronic Sofamor Danek, the WALLIS-System from Abbott Spine (today Zimmer Spine), and the X-STOP from St. Francis Medical (today Medtronic). Since then a multitude of new players have entered this lucrative market segment. An internal market analysis in the 2nd quarter of 2008 has revealed that more than 20 different interspinous device concepts and various copycats are competing on that market. The majority of those interspinous devices do follow the X-Stop design – being a simple extension blocker. The newer designs strive to reduce the morbidity by being less-invasive (even percutaneous; i.e. In-Space from Synthes).

The coflex™ success story

The coflex™ implant is a functionally dynamic interspinous implant intended to treat patients suffering from lumbar spinal stenosis. Lumbar spinal stenosis is a degenerative condition in which prevalence increases as the population ages. The most severe cases, those that generally require surgical intervention, typically occur in the over-60 population. The coflex™ implant is designed to stabilize the spine after microsurgical decompression of stenosis at the affected level(s), while avoiding fusion.

The coflex™ design allows for a degree of mobility of the spinous process in flexion while preventing anterior or posterior migration. The device is compressible in extension, and spinal balance becomes normalized in the upright position.

Facet pressures are off-loaded at the index level owing to a slight permanent facet distraction resulting from a deeper insertion than for any other interspinous device. This also maintains foraminal distraction. As the coflex™ implant is functionally dynamic, posterior intradiscal pressures are decreased at the index level. The adjacent levels appear not to be adversely affected in their biomechanical parameters. Rotational mobility may possibly be further constrained initially by crimping the wings.

Interlaminar Stabilization
Distinct unique selling propositions

Example of Interspinous vs. Interlaminar positioning

The distinct indication specific positioning of the coflex™ implant separates this device from most of the competitors. In conjunction with this all product features of the coflex™ implant provide a clear benefit to the patient and their treating surgeons. Even more it provides you in your communication to the surgeon’s explicit unique selling propositions.

Large footprint: Optimal stress distribution on the lamina and the spinous processes in combination with the deep insertion of the implant provides maximum stability to the motion segment. Bony erosion can be effectively avoided.

Center of rotation: Due to the ‘U’ configuration the center of rotation of the implant is best approximated to the natural center of rotation when it is deeply inserted.

Interlaminar positioning: The implant design allows a deep insertion to unload the facet joints and to maintain foraminal height over time.

Maintenance of foraminal height: The coflex™ implant provides foraminal distraction and unloading of the facet joints at the facet joint level. Its rigidity anterior maintains the initially achieved clinical result.

Functionally dynamic: Its compressibility in extension protects the adjacent segments from accelerated degeneration and overloading in a truly non-fusion fashion.

In summary no other interspinous implant in the market has a similar large contact surface, is functionally dynamic and can be implanted as deep as coflex™ (besides copycats). To well define this in our/your communication to the surgeon we therefore have changed in the recent past from coflex™ being an interspinous implant only to coflex™ being really a true interlaminar implant.

coflex™ more than a spacer - a functionally dynamic implant

coflex™ in flexion

coflex™ in extension

Example of a static blocker
coflex™ with a new wing design: small difference - big impact

In order to defend your current position in your local market and even win back sales in the interspinous market segment we are happy to introduce to you the next evolution of coflex™. This newly designed coflex™ implant is intended to be used in bisegmental cases to avoid overlapping of the wings and to ensure that surgeons can introduce the implant as anterior as desired. For obvious reasons this has been a technical limitation so far. The adjusted design now perfectly follows the argumentation of true “interlaminar” positioning of the implant by positioning the implant as far anterior as possible. An internal x-ray analysis of double-level cases has revealed that optimal implant positioning between the spinous processes was not possible in a fairly large percentage of the cases. The new solution allows a 3mm deeper insertion of the implant compared to the current design - as shown to the right.

The overall design of the coflex™ bisegmental implant is almost identical to that of the coflex™ implant as shown in the picture above. There have been no changes to the ‘U’ portion of the device or to the ‘teeth’ near the ‘U’ which results in the same tactile “feeling” when placing the implant, nor have there been any changes to the sizes, production process, packaging or sterilization. The only change is a re-configuration of the wings in order to allow better stacking of the implants for bisegmental cases. The coflex™ bisegmental implant does not require any additional instruments.

Proof of Concept:

Before the new concept was introduced to the market Paradigm Spine conducted three tests to verify that the implant concept meets all mechanical requirements. Static Axial Compression testing, Dynamic Compression testing as well as Lateral Wing Bending testing showed that the coflex™ bisegmental implant has met or even exceeded the test results obtained from the clinically proven coflex™ implant. After the implant was mechanically tested but before we started to launch the new implant in our main market Germany the clinical evidence of the concept and market acceptance needed to be evaluated and proven. In the 3rd quarter 2008 we presented the coflex™ bisegmental concept to our coflex™ key users in Germany and first promotion of this new implant was started during the German Spine Congress in Ulm. The concept found a overwhelming acceptance with very positive feedback. Since the introduction in May 2009, more than 900 coflex™ bisegmental implants have been implanted so far with excellent success.
Business aspect and distributor roll-out information:

The coflex™ with the new wing design replaces the current design in a step-wise process. In Germany already more than 40% of all coflex™ active users have been switched to coflex™ bisegmental.

Paradigm Spine will present coflex™ bisegmental during this year’s EUROSPINE meeting in October 2009 in Warsaw which will be at the same time the kick-off to launch coflex™ bisegmental in Europe.

Market launch in all other business regions will follow step by step in 2010. You will be contacted by our Business Managers who are in close contact with our Quality Management department to define next steps which are necessary to register coflex™ bisegmental in your country, if necessary.

It is our goal to limit stock and not have two co-existing product lines at the same time. However this may be unavoidable for a certain period as an exchange of existing stocks is not planned.

Paradigm Spine Distributor Extranet

Welcome to the Paradigm Spine Distributor Extranet

Please also check out our Paradigm Spine Distributor Extranet for updates which will be uploaded by our Marketing department on a regular base. There you will not only find the coflex™ presentations with the CEP content (Marketing Positioning, Product Information, Surgical Technique, Sales and Complaint Statistics, etc.) but also published coflex™ literature as well as images of our products. http://paradigm-spine.de/web/login.php

Please note: In case you are missing your username and password please feel free to contact us.

Workshops

Next Meetings

Workshop Eurospine coflex™
Thursday, October 22, 2009

Please join us for our workshops at Eurospine 2009 in Warsaw, Thursday, October 22, 2009 with Dieter Adelt, MD and Rudolf Bertagnoli, MD.
Interlaminar Stabilization: coflex™ - a Functionally Dynamic Implant for the Treatment of Degenerative Spinal Stenosis

By René Rothacker

Dear Dr. Adelt,

The idea of interspinous stabilization after microsurgical decompression seems to intrigue you now for many years. For which indications do you use the coflex™ implant?

We are working with the coflex™ implant now for more than 7 years. As it is a dynamic non-fusion device we use it for the protection of adjacent segments next to fused segments. However, our main indication remains – by far - low back pain associated to leg pain in degenerative spinal stenosis cases. In our series of more than 900 patients, we could clearly see that this device not only stabilized the treated segment after microsurgical decompression but improved significantly low back pain coming from arthritic facet joints seen with degenerative spinal stenosis.

In your eyes - what benefit does this product offer to the patient?

The philosophy is to apply the implant after microsurgical decompression of the spinal canal to stabilize the segment, control motion and to address associated low back pain. The coflex™ implant unloads the facet joints and maintains foraminal height. Due to the implant design it can be positioned nearest to the physiological centre of rotation of the segment. No other implant in the market can achieve such a deep insertion. The range of motion is decreased, resulting in the improvement of low-back-pain due to “controlled restricted motion”.

Some interspinous implants are designed to be used without microsurgical decompression (indirect decompression) which allows an even percutaneous application. How do you see this in comparison to coflex™?

While other implants may claim an indirect therapy of canal stenosis (i.e. X-Stop, Medtronic, In-Space, Synthes), none of them is dynamic. This potentially over-loads the adjacent segments. These type implants only distract posteriorly to increase the diameter of the spinal canal and foramen. In my opinion, this may only be successful in cases of soft stenosis and is not a suitable treatment for more severe stenosis as it does not address the bony (hard) constriction of the spinal canal which is the majority of our cases. Again, the coflex™ implant is ideal to be used for back pain caused by arthritic joints associated to degenerative spinal stenosis. One must not forget that the underlying indication for surgery is the need for decompression of nerve tissue. The support of the painful facet joints by coflex™ is in addition to that. If you just want to treat low back pain you have less invasive methods with good results i.e. denervation of the facet joints (a method which allows multilevel interventions). In our eyes indirect decompression with X-Stop alike implants could never be used in the indication of coflex™ where (bony decompression) is required. Percutanous application here is not a valid argument as it does not address the pathology at all!

What evidence of effectiveness is being recorded in current trials? What are the primary complications being observed and at what rates?

Prospective randomized trials are underway in the U.S. and in Germany. To date we have first interim analysis from the IDE trial which have been previously reported by Pettine et.al. and Davis et. al at the SAS meeting in Miami and at the NASS meeting in Toronto. These results are very promising so far and suggest that coflex™ is not only “non-inferior” but even superior compared to the control group which in the U.S. is fusion. In the German trial we compare patients who receive decompression only with patients who receive decompression and coflex™. The goal of this study is to identify the “added value” for the patient by the implant. Besides well-known patient scores like the Oswestry Disability Index, the Visual Analog Scales and the Zurich Claudication Questionnaire we...
perform in addition a treadmill test with every patient. The hypothesis is that patients with the implant do comparatively better after two years. In total we are investigating on 230 patients with 115 patients in each arm of the study. To date 99 patients have been included in this trial and the first patients reach the one year timepoint.

We also have performed a thorough retrospective analysis of our own patients. In our series of 240 patients, an improvement of low-back-pain was shown in 72% of the patients with 40% demonstrating complete pain relief. An improvement of walking distance due to back pain was found in 87% of the patients. There was a high rate of patient satisfaction with 94% being satisfied or very satisfied and 95% indicating they would have surgery again.

One difficulty is unrecognized instabilities which lead to later fusion operations. Important is the exclusion of instabilities as determined by x-rays in flexion and extension. Unstable segments should not be treated with interspinous devices. This remains the domain of pedicle screw fixation. With all interspinous devices, there are possible postoperative hematomas because of the “dead space” between the implant and the dura. For that reason we always use a drain when applying the coflex™ implant.

How long do you think this device would last and what is your revision strategy?
In our study which originally included the years 2002 to 2005 (now up to 2009), we have not seen any broken implants and only one deformed implant (out of 240 implants). Mechanical testing showed excellent fatigue strength with a 10 million cycles run-out suggesting a duration of life of coflex™ in the long-term. The revision strategy is easy; there is no problem with removing coflex™ even after years. With a chisel you remove overgrowing bone, especially at the wings. When you open the wings with that chisel, you can pull out the implant with any pliers.

Paradigm Spine recently introduced a new design of the coflex™ implant especially addressing the bisegmental application. What is your experience with this implant so far?
Due to the modified wing configuration the newly designed coflex™ implant now allows a deep insertion of the implant also in the second level (which usually is the cranial one). This is beneficial for the patient as described before. Interlaminar positioning simply provides better anatomical stability in comparison to an interspinous application and foraminal distraction and unloading of the facet joints is more effective. The company finally discharged the hole in the wings which – in my eyes - had no functional importance as the implant is primary stable and does not require additional stabilization. I did not observe any difference in the handling during the insertion procedure – on the contrary - it is an even smoother feeling when crimping the wings to the spinous processes. The wings seem to be a little less elastic during crimping which leads to an improved crimping process. Functionally there is no difference to the existing implant. For that reason we use it now in monosegmental cases as well.

As a conclusion…
Retrospective studies confirmed the safety and effectiveness of the coflex™ implant with a high satisfaction rate of the patients. Multicenter prospective studies in Europe and in the U.S. are in process with very promising results so far. The new “bisegmental design” significantly improves the placement of the implant in cases where two implants are needed but can also be used in single level cases. Interlaminar positioning can easily be achieved.

This is a case example of a 74 year old male patient diagnosed with degenerative spinal stenosis at levels L3/4 and L4/5. After decompression of the affected levels implantation of the new design coflex™ implant has been performed. Due to the change in the wing configuration true interlaminar (deep) positioning could be achieved in both levels and any overlapping of the wings avoided.
General Care International – the China success story: Enter the Dragon Market

By Charles Ownn

Chinese market – brief statistics

The Chinese population currently counts to 1.3 billion inhabitants. There are 31 provinces and 56 races and tribes live in China. The land mass is approximately as big as the United States without Alaska. The current government was formed 60 years ago in 1949. China holds the world’s largest foreign reserves. It represents the world’s third largest spine market (after the USA and Japan). The surgeon mentality is the following: “Unless it breaks, do not fix”. Additionally, China has the largest resources of herbs and a long herbal medicine history.

Pre-dominant pressure on non-fusion products

As early as 1970’s, Chinese surgeons tried non-fusion spine products already. Unfortunately either due to patients not listening to surgeons’ advice, wrong choice of size of products, product deficiency, inadequacy, surgeons less correct skill or judgement, or a combination of all above, quite a number of “medical disputes” occurred. Hence “fusion” becomes the Gold Standard, for another reason, to avoid disputes! Consequently, there is an over-bearing pressure to “re-introduce” non-fusion spine products in the 2000!!

Back to basic

So, while it is later than many other places of the world to introduce non-fusion concepts, our market-entry strategy for non-fusion is to play “Safety First”. Stringent control of choice of right product, right size through right skill to the right patient (indication), becomes mandatory. It is along this “Rule of Basic” that we in China introduced coflex™ in late 2007, and DCI™ in this August 2009. While the implants number is not great (close to a thousand), we have luckily maintained a zero medical dispute rate, so far. We shall follow the similar strategy for DCI™ and, hopefully, have more time for beer and wine, than settling screams and cries (from patients and hospitals)!! We know we still have a lot to learn from our fellow-distributors across the world. Above was our limited experience, in limited time, with limited success, to share. Let’s progress together through sharing!!

DISTRIBUTOR STORIES

DCI™ launch meeting at the newest 7-stars grade hotel: The “Pan-Gu 7-stars” Hotel in Beijing, adjacent to the Bird’s Nest - Olympic Stadium in 2008, China

The launch committee members (from left to right: Eddie Chen - Paradigm Spine, Pr. Hai Young - Beijing Capital University Hospital, Pr. SunYu - Beijing University Hospital, Prof Emeritus QIU Qui-xing - President of Chinese Orthopedic Association/COA, Dr. Rudolf Bertagnoli - Past SAS President, Dr. Guy Matgé - Developer of DCITM, Charles Ownn – General Manager of General Care International)

2009国际颈椎非融合技术研讨会
After a series of teamwork and diligence devoted by the team from both General Care International (Paradigm Spine’s distributor in China) and Paradigm Spine, the launch of DCI™ in China finally was successfully made during August 7-11, 2009 with main meeting in Beijing taking advantage of the 3rd China International Congress and Exhibition of Orthopaedics (CICO) which was organized by Peking University Third Hospital (PUTH). It is considered one of the most professional, international and richest academic congress for orthopaedics in China.

With the pleasure and honor to have Dr. Rudolf Bertagnoli introducing the DSS™ system and presenting his three years clinical result of coflex™ as well as Dr. Guy Matgé from Luxembourg, the surgeon designer of the DCI™ implant, introducing the design rationale, feature and benefit, market positioning, surgical technique and clinical result of DCI™, most of those spine surgeons showed up during the roadshow provided positive feedback and considered the first-hand interaction with both invited surgeon champions was enjoyable, productive and valuable.

Followed by meetings in Shanghai and Guangzhou, the DCI™ launch had a even wider penetration covering more core markets in China! With the proven track record for the success of coflex™ in China, the continuous success for Paradigm Spine products in China hopefully will be another legend ongoing.

A special thank you shall be dedicated to Charles Ownn and his whole General Care International team for the perfectly organized roadshow in the various cities and the great hospitality which Dr. Bertagnoli, Dr. Guy Matgé and Eddie Chen were allowed to experience!!
Eurospine 2009 – Paradigm Spine announcement

By Lucia Neininger

This year, the Eurospine 2009, the Annual Meeting of the Spine Society of Europe will take place from Wednesday, October 21, 2009 to Saturday, October 24, 2009. The meeting is hosted at the Palace of Culture and Science in Warsaw, Poland. The Eurospine is the key spine meeting for European spine surgeons and is among the most popular spine meetings in the world. As with all major spine meetings, Paradigm Spine will be represented at Eurospine in Warsaw as well...

Paradigm Spine’s Activities
Paradigm Spine will have various activities during Eurospine 2009. We are more than happy to welcome you at the various functions. Please do not miss this excellent opportunity to get the latest information on our products:

Booth
Paradigm Spine will have a 3m x 9m booth at the second floor of the Palace of Culture and Science. The booth number is 2506+2508+2510. It is located in the neighborhood of all the big players. Our booth team will welcome you during the opening hours from Wednesday to Friday.

Paradigm Spine will hold two workshops to which we would invite all business partners and their customers. Please find here all the necessary details:

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### Workshops

**Eurospine 2009 | October 21, 2009 | Warsaw, Poland**

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### Lumbar Dynamic Stabilization with DSS™ - “Stand Alone” and Combined with Fusion (“Topping-Off”)

Minimally Invasive Lumbar Fusion - coflex-F™ in Combination with Interbody Fusion Cages

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Round Table Discussion and Hands-On Workshop
Workshops

**Eurospine 2009 | October 22, 2009 | Warsaw, Poland**

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**Motion Control in the Treatment of the Degenerative Spine: Cervical Dynamic Stabilization with DCI™**

**Interlaminar Stabilization: coflex™ - a Functionally Dynamic Implant for the Treatment of Degenerative Spinal Stenosis**

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Round Table Discussion and Hands-On Workshop with the DCI™-System

**Distributor Meeting**

Paradigm Spine would like to invite all distributors to join our Distributor-Only Meeting during Eurospine. Please attend this meeting and take the chance to receive a thorough feedback of the introduction of our new products DCI™, DSS™ and coflex-F™ in the international markets. Don’t miss the opportunity to share your thoughts and experiences and use the opportunity to hear from Dr. Bertagnoli (DSS™) and Dr. Afshar (coflex-F™) about their experience with the Paradigm Spine’s products. The meeting will take place at the Holiday Inn Warsaw Hotel which is only 2 minutes walking distance from the congress center. The meeting room is the room Sonata at the Holiday Inn Warsaw Hotel.

**Distributor Dinner**

After the distributor meeting, our well-known Distributor Dinner will take place on Thursday, October 22, 2009 starting from 7.30pm. Please contact Lucia Neininger at Lucia.Neininger@paradigmspine.de for further details and for reservations.

We are looking forward to seeing you in Warsaw at Eurospine!
This year, the North American Spine Society 24th Annual Meeting will take place from Tuesday, November 10, 2009 to Saturday, November 14, 2009 in San Francisco, California, USA. Located at the Moscone Convention Center, the NASS Annual Meeting is the leading conference addressing the latest spine surgical and non-surgical treatment options and research findings. Leading authorities such as orthopedic spine surgeons, neurosurgeons and other health care professionals who are dedicated to the advancement of spine care will unite to exchange ideas in spine education, research and innovation.

The purpose of the annual meeting is to foster research and training through interactive panel discussions, present current research and data, and promote discussion of new scientific developments and best practices among a multidisciplinary group of spine specialists. Pre-meeting courses and technique workshops will begin on Tuesday, November 10, 2009. On Wednesday, the exhibit hall opens at 9am and Paradigm Spine will host a 20ft x 20ft booth on the floor. The booth number is 317 and is located in Hall A. Paradigm Spine’s team members will welcome you any time during opening hours. The exhibit hall closes on Friday, November 13, 2009 at 2pm.

The Viscogliosi Brothers will kick off the meeting by hosting their annual cigar party. Taking place at the stunning Waterbar restaurant located on The Embarcadero, the invite-only guest list will consist of Paradigm Spine team members and well-respected spine specialists. With beautiful views of the Bay Bridge, Oakland city lights and San Francisco Bay, the setting provides a perfect place to discuss timely topics that are surgeon centric, indication specific, and data driven - the movement of spine care.

Please contact Steven Seegers at: Steven.Seegers@paradigmspine.com or at +1-212-583-9700 ext. 2163 for further information and reservations.

We are looking forward to meeting you in San Francisco at NASS 2009!

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<td>IMAST</td>
<td>Canada, Toronto</td>
<td>Booth</td>
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<td>September 15-17</td>
<td>Eurospine</td>
<td>Austria, Vienna</td>
<td>Booth, Workshops, Distributor-Only Meeting, Distributor Dinner</td>
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<tr>
<td>October 5 - 9</td>
<td>NASS</td>
<td>USA, Orlando, FL</td>
<td>Booth</td>
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In May, July and August 2009, the US team was pleased to host both Bernhard Holtkamp (Senior Design Engineer and DSS™ Project Leader) and Reinhold Knebel (Product Manager for the DSS™ system). Paradigm Spine is a global company and we are committed to the exchange of information between team members and customers in the US and outside the US. Bernhard and Reinhold left colleagues, friends and family to observe the DSS™ system in use by US surgeons, spend quality time in clinical discussions, and explore topics that will advance the adoption of DSS™ both in the US and internationally.

Bernhard and Reinhold were accompanied by Aaron LaCasse (US Product Manager for the DSS™ system), John Maynard (Areas Sales Director Southeast US) and Jim Elia (US Senior Marketing Manager for the DSS™ system). During their stay in the US, Bernhard and Reinhold were very active, traveling to many destinations in the US, including Baltimore, MD, Nashville, TN, New York City, Pensacola, FL, Denver CO…just to name a few of the sites they visited.

The main purpose for the visits were to introduce new DSS™ system instruments and implants (measuring caliper adapters, compression and distraction instruments, DSS™ coupler template and DSS™ slotted coupler holder, threadless spacers, etc.) to key opinion leaders and US surgeon advisors with extensive DSS™ experience. Additionally, Bernhard and Reinhold were interested in learning more about US surgeon preferences and specific technique issues with which US surgeons encounter.

The US surgeons really appreciated the extra time and attention provided by our colleagues from PS GmbH. Clinical and technical dialogues spanned many topics. These topics included the universal system, use of anterior column support for fusion, posterior spine stabilization market dynamics and competitive systems.

In mid-May 2009, Aaron and Bernhard traveled to Loveland, Colorado to meet with Dr. Kenneth Pettine. Dr. Pettine invited the intrepid travelers to his home for dinner. Upon arrival, Dr. Pettine played the perfect host and made Bernhard and Aaron feel quite ‘at home’ including a short list ‘chores’ to do before dinner. They proceeded to feed the Dr. Pettines’ exotic assortment of Koi fish and then headed up stairs to change the battery in the smoke detector at the peak of Ken’s home. Once the chores were completed they had an amazing dinner prepared by Chef Ken.

The next day was spent in the OR with Dr. Pettine observing and supporting DSS™ cases. Of particular note, Dr. Pettine was the first US surgeon to evaluate the new DSS™ threadless spacers. Dr. Pettine appreciated the new design, and commented that the threadless spacers would become his ‘spacer of choice’. The case went very well, and the scene was repeated the next day with similar positive comments and support for the revisions and updates to the DSS™ instruments and implants. This was a great way to kick-off the US Tour of VIP surgeons!

Bernhard returned to the US in July 2009. On July 20, 2009, he spent the entire day with Dr. Melvin Law at Centennial Hospital in Nashville, TN. Dr. Law performed a multi-level DSS™ case, and Bernhard and Dr. Law discussed the sequencing of implants, biomechanical and mechanical testing data and clinical experiences outside the US. Late that night, John Maynard joined Dr. Law and Bernhard for an engaging dinner meeting to download on the earlier case and share a delicious steak dinner!

The next morning John and Bernhard flew to Pensacola to support two DSS™ cases with Dr. Marcus Schmitz. Again, the cases went very smoothly, and the team reviewed previous cases performed by Dr. Schmitz to discuss pre-op planning and follow-up imaging.
Reinhold Knebel visited with PSLLC in early August 2009. He took a bite out of the Big Apple with the Senior Marketing Manager for the DSS™ system in the US, Jim Elia. Reinhold attended and actively assisted in the initial case for a new DSS™ user, Dr. Sundaresan on August 3, 2009 at Lincoln Hospital in the Bronx. This was an involved case in which previously implanted traditional spine fixation implants were removed, and then replaced by the DSS™ system to provide stabilization for fusion. Jim and Reinhold worked together as team, and the case went smoothly despite its complexity and the fact that it was the surgeon’s first case with the DSS™ system. This is a great testament to attributes of the DSS™ system and the value of technically expert OR support from Paradigm Spine. Dr. Sundaresan was very pleased with the post-op X-rays and commented on the value of DSS™ modularity.

The evening was capped-off by another delicious steak dinner in the Meat Packing District of New York City (West Side) where Reinhold was able to experience all the sights and sounds of “The City that Never Sleeps”.

The entire US team extends its sincerest thanks and appreciation to Guntmar Eisen, President International at Paradigm Spine, Bernhard Holtkamp and Reinhold Knebel for reaching ‘across the pond’ to bring the expertise, enthusiasm and perspective of our German-based colleagues and their broad experiences from around the world to the shores of the US. The US team benefited greatly from their visit and knowledge, and our surgeon customers felt the special VIP treatment for which Paradigm Spine is known globally.

In the interest of time and column space, we have chosen not to chronicle every surgeon interaction and case experience. However, we must say that both Bernhard and Reinhold were real ‘Road Warriors’ and were constantly on the move. I extend my thanks to the US team for making our colleagues feel welcomed and appreciated, One trend seemed apparent…Steak dinners were the preferred selection throughout each visit!

We look forward to hosting future visits in the US from our PS GmbH Team members, and hope to be able to reciprocate with visits outside the US to advance our knowledge and expertise on the DSS™ system, and provide a point-of-view that may be of some value to customers worldwide.
Recently, Australian distributor Paige Schwartz, the National Sales Manager for Lifehealthcare visited the United States for DSS™ product training, clinical and customer visits.

Her first visit was in Dallas at the Texas Back Institute with Dr. Scott Blumenthal and the local Paradigm Spine distributor, Trase Mahan. Dr. Blumenthal graciously gave Paige and Trase a couple hours of his time to discuss his views on motion preservation, his practice and his thoughts in regards to the America surgical marketplace.

Next, Paige joined the Paradigm Spine team in Memphis, Tennessee for the first official DSS™ training program. She stated that this was one of the most organized and well run training programs she has had the pleasure to be involved with. The insight and knowledge she gained during these three days equipped her with an in-depth knowledge of the DSS™ system and the scientific theories around motion preservation. Not only did she gain valuable product knowledge she established key relationship with the Paradigm Spine USA team.

In Baltimore, Paige met up with Dr. Reginald Davis to observe two hybrid DSS™ surgeries. This afforded Paige the opportunity to see the system’s clinical strengths. Dr. Davis took time to explain the clinical benefit of DSS™ and the theory behind motion preservation. Dr. Davis stated, “think of DSS™ as one step below motion, whereas Dynesys is one step above fusion.”

Following Baltimore, Paige travelled to Loveland, Colorado to spend theatre time with Dr. Ken Pettine. He performed two DSS™ surgeries which again afforded Paige the opportunity to gain knowledge and surgical tips regarding DSS™. The good doctor had just celebrated his 100th case with the dynamic stabilization system during Paige’s visit. Dr. Pettine was a world of information in regards to outcomes data and surgical pearls of wisdom with this system.

Lastly, she attended surgery in Colton, California with Dr. Darren Bergey. He performed a DSS™ case where she gained additional insight into nuances of the system and valuable practical surgical tips. Dr. Bergey met with Paige, Mark Roady, Western US Area Sales Manager, Paradigm Spine and Chris Hughes, US President, Paradigm Spine, prior to the case where he shared his thoughts in regards to the DSS™ system, motion preservation and the indications in which he utilizes DSS™ in his practice.

During her USA trip Paige gained knowledgeable insight into Paradigm Spine and the DSS™ product. Australia is now well positioned for a full scale launch of DSS™.

Lifehealthcare brings a 20 year history of relationships, product development and clinical consultation to the Australian market. It employs over 120 people with an employee network in every Australian state and New Zealand. Lifehealthcare has strong and successful partnerships from all corners of the globe (including Paradigm Spine), with some of the world’s most established medical device manufacturers.

Amongst different therapy units, Lifehealthcare operates in the Australian spinal market. Lifehealthcare now provides innovations across lumbar degenerative disc disease, cervical disc herniation, spinal fractures and spinal stenosis perfectly fitting Paradigm Spine providing dynamic stabilization systems (DSS™ and coflex™) to enrich its product portfolio. Paradigm Spine is looking forward to the successful market introduction of DSS™ in the Australian spine market.
Right: Dr. Darren Bergey performing a DSS™ case

Left: Dr. Kenneth Pettine, Right: His surgical assistant, Gina Klapproth

Right: Dr. Reginald Davis during surgery
PARADIGM SPINE U.S. REGULATORY STATUS

coflex™ implant .......... Investigational device. For investigational use only.

DSS™ system ............. 510(k) cleared – Hybrid use not cleared in the US. See US package insert for labeling limitations.

coflex-F™ implant .......... Not approved.

DCI™ implant ............ Not approved.