WELLEX™

Post Market Survey Results

February 2011

CONFIDENTIAL INFORMATION MEMORANDUM

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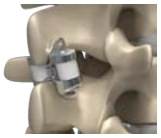
POST MARKET SURVEY RESULTS

Eden Spine Europe's mission is to develop and distribute globally innovative spinal solutions, with research and development efforts focused on motion preservation technologies to the benefit of patients worldwide.

Product Description

The WELLEX™ is CE Marked. It is indicated for the treatment of degenerative disc disease with intractable radiculopathy associated with mild stenosis. It was developed to perfect the balance between motion and stability, maintaining the neutral zone.



The Wellex™ Interspinous Technology fills the gap between conservative less effective care & fusion. It is an extension controller, positioned between the Interspinous processes, uniquely designed to provide better long term results by dynamically controlling extension, reducing the loading on the disc and facets, increasing the space in the spinal canal and foramen, thus relieving patient's symptoms.

Introduction

As a part of the WELLEX™ CE Mark, Eden Spine has done a scientific study, Post Market Survey ("PMS"), to analyze, on a random group of patients, the clinical effects of the technology, following implantation.


Dr. Sivaraman

The PMS gathered clinically relevant data on the safety and efficacy of the WELLEX™ Interspinous Technology in a real-world British population of 42 patients in the U.K. All subjects were being followed for three year period. The surgeries were performed by Dr. A. Sivaraman, an Orthopedic Spinal Surgeon in the U.K, at The Royal London, The St Bartholomew's and The London Independent Hospitals.

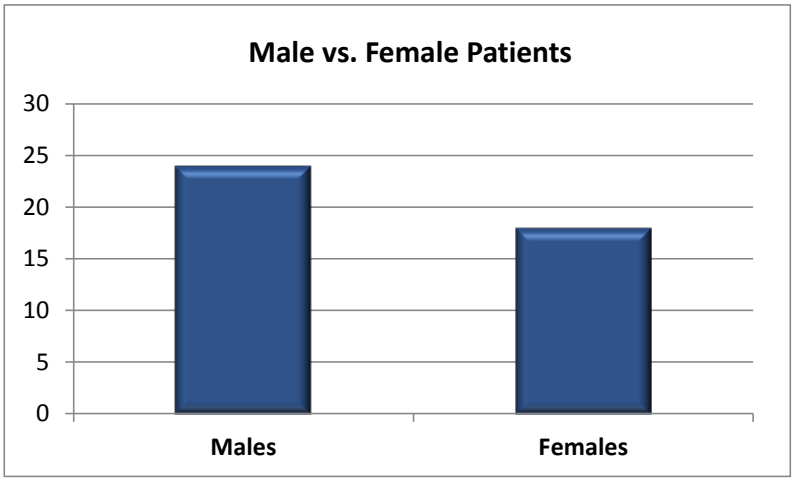
The PMS' primary goals are to observe (i) the reliability of the WELLEX™ Technology following implantation (ii) the patient's clinical evolution before and after the surgery, using classical criteria such as length of hospital stay, pain medication treatments, return to work.

PMS Analysis: Geography

The WELLEX™ PMS took place in U.K where Dr. Sivaraman performed spinal surgeries at The Royal London, The St. Bartholomew's and The London Independent Hospitals.

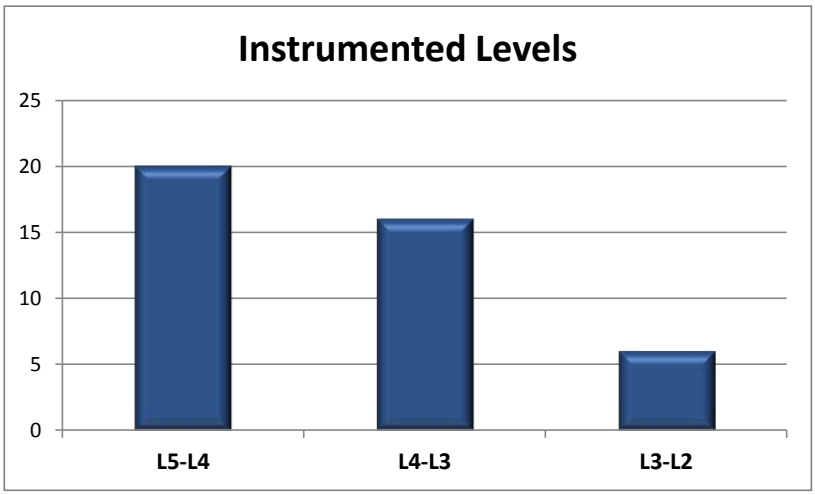
PMS Analysis: Gender

The population of 42 patients was balanced with 57% of patients being males and 43% being females.



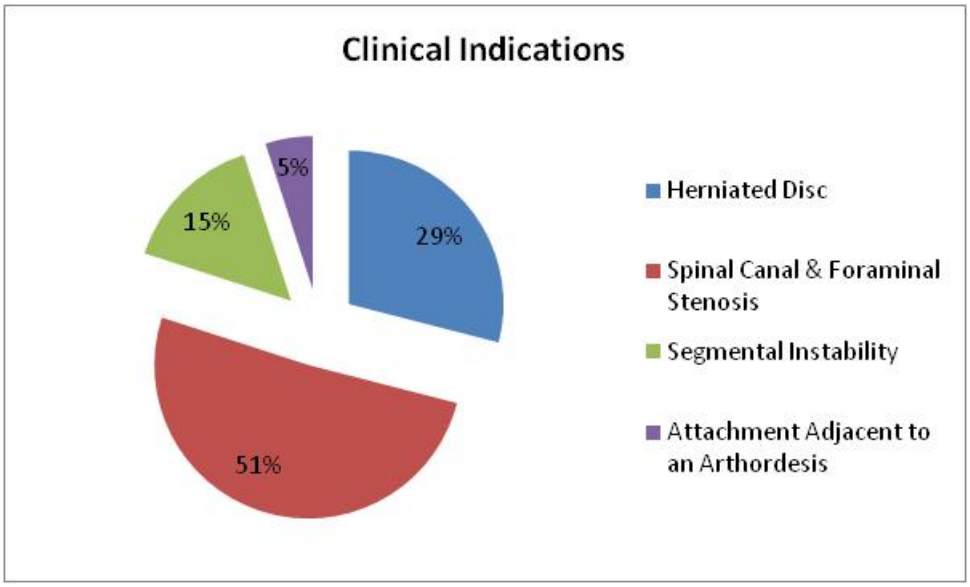
PMS Analysis: Instrumented Levels

Dr. Sivaraman performed 38 one level procedures and 4 two level procedures. Average time taken to perform the surgeries was 30 minutes. On an average a patient had to stay overnight for post-operative care. As expected, 86% of the WELLEX™ surgeries took place at L5-L4 & L4-L3; only 14% at L3-L2.



PMS Analysis: Clinical Indications of Instrumented Population

The WELLEX™ is primarily indicated for the treatment of early stage degenerative disc disease with intractable radiculopathy associated with mild stenosis.

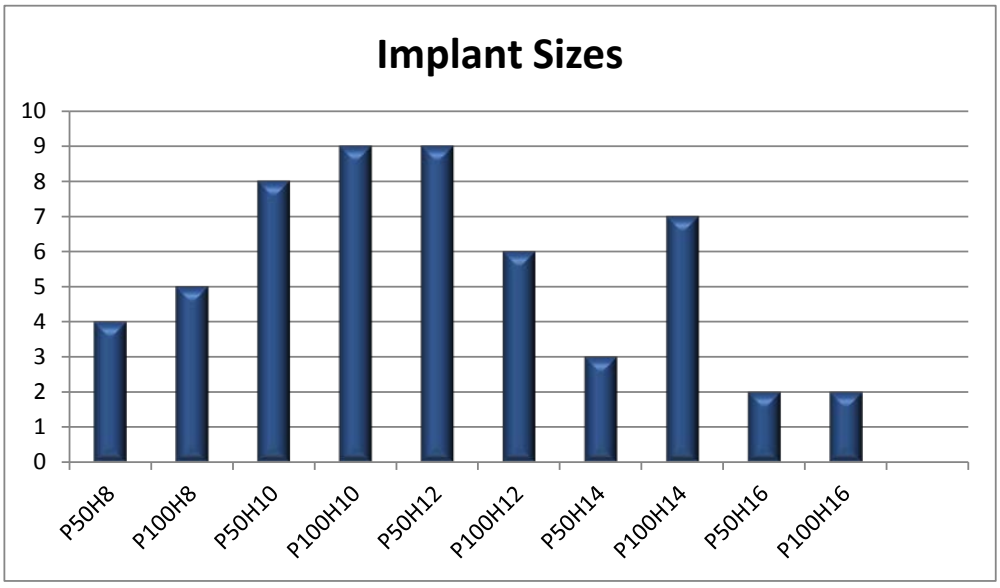


PMS Analysis: Implant Sizes

WELLEX™ implants are available in 5 different sizes/heights:

- 8mm
- 10mm
- 12mm
- 14mm
- 16mm

Each size is available in 2 stiffness's: 50 N and 100 N

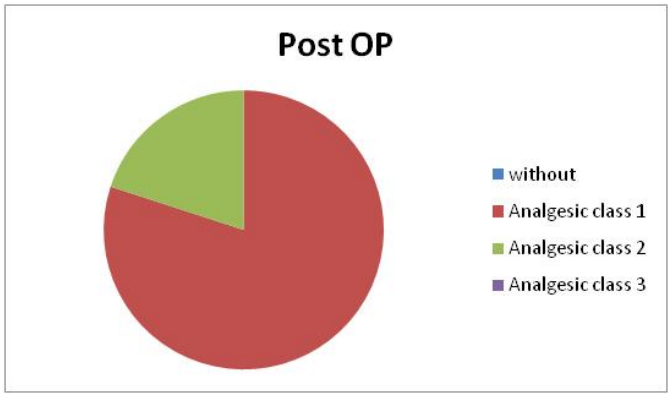


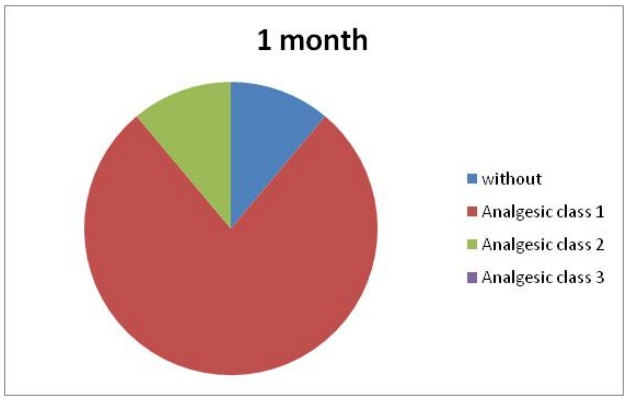
Size 10, 12 and 14 represent 76% of the implants during the study.

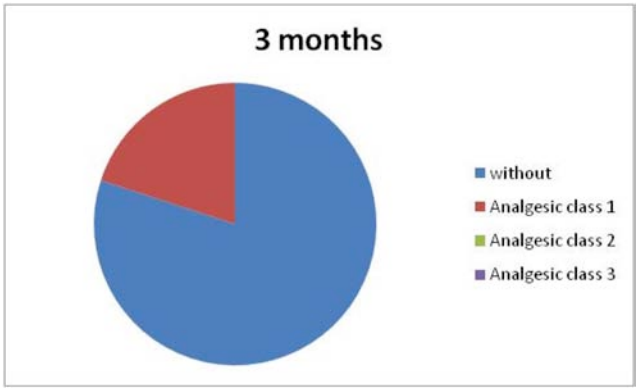
PMS Analysis: Per Operative Surgery

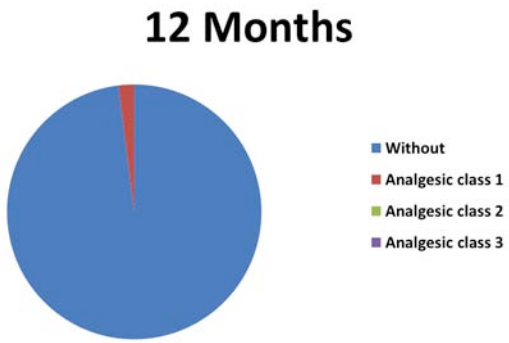
Technical problems	Yes	☒	No
Per operative complications	Yes	☒	No

PMS Analysis: 42 Patients Clinical Evaluation









PMS Analysis: Patients Professional Activity

Duration of medical leave of absence following surgery: All 42 patients back to work within 2 months following surgery.

Patient's types of work:

Sedentary work	52%
Active work	27%
Very active work (Heavy labor)	21%

Hours:

Full time	95%
Part time	5%

Impact of surgery on professional activity:

Same activity	96%
Change of job position	4%

PMS Analysis: Post-Operative Surgery Complications

Implant breakage	Yes	☒	No
Spinous process breakage	Yes	☒	No
Implant disassembling	Yes	☒	No

No post-operative nor per operative complications were observed during the trial. Superficial infection was observed in only one surgery.

Conclusion

The Post Market Survey shows that when the WELLEX™ Interspinous Technology is used in compliance with the indications and contra-indications recommended by Eden Spine Europe SA, it complies with Annex I.3 MDD and presents a benefit/risk analysis favorable to the patients.