


Transforaminal/Posterior Lumbar Interbody Fusion
with the
FlareHawk® Expandable Interbody Fusion Device:
A Retrospective Chart Review Study

NCT04057235

November 15, 2019

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1. PURPOSE:


1.1. This retrospective study will evaluate the clinical outcomes of patients who have undergone a TLIF or PLIF procedure with a FlareHawk expandable interbody fusion cage(s) to assess the device’s performance and safety when used in accordance with its intended use.

2. SCOPE:

2.1. This study will include patients who underwent 1 or 2 contiguous level TLIF or PLIF procedure with the FlareHawk expandable interbody fusion cage. A total of at least 100 patients from at least three sites will be enrolled based on inclusion/exclusion criteria.

3. REFERENCES:

- 3.1. EN ISO 14155, Clinical investigation of medical devices for human subjects - Good clinical practice
- 3.2. CER-00001, FlareHawk Interbody Fusion System Clinical Evaluation Report
- 3.3. MEDDEV 2.7/1 rev.4, Clinical evaluation: Guide for manufacturers and notified bodies
- 3.4. Bridwell KH, Lenke LG, McEnery KW, Baldus C, Blanke K: Anterior fresh frozen structural allografts in the thoracic and lumbar spine. Do they work if combined with posterior fusion and instrumentation in adult patients with kyphosis or anterior column defects? Spine (Phila Pa 1976) 20:1410–1418, 1995
- 3.5. Noshchenko A, Hoffecker L, Lindley EM, Burger EL, Cain CM, Patel VV. Long-term Treatment Effects of Lumbar Arthrodeses in Degenerative Disk Disease: A Systematic Review With Meta-Analysis. J Spinal Disord Tech. 2015;28(9):E493-521
- 3.6. Ostelo RW, Deyo RA, Stratford P, et al. Interpreting change scores for pain and functional status in low back pain: towards international consensus regarding minimal important change. Spine. 2008;33(1):90-4
- 3.7. Yavin D, Casha S, Wiebe S, et al. Lumbar Fusion for Degenerative Disease: A Systematic Review and Meta-Analysis. Neurosurgery. 2017; 80(5):701-715

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4. METHODS/PROCEDURE:

4.1. Study Hypothesis

The primary hypothesis is that study subjects who received the FlareHawk expandable cage(s) through a TLIF or PLIF procedure experienced fusion by 12 months (+/- 3 mo) follow-up, with improvements in clinical outcomes related to pain and/or disability compared to pre-operative scores. Further, the subjects are hypothesized to have not experienced any unforeseen device- or procedure-related adverse events

4.2. Primary Outcome


Proportion of subjects with radiographic arthrodesis at 12 months +/- 3 months as determined using plain radiographic images with assessment based on the Bridwell-Lenke grading system [Bridwell and Lenke et al, 1995].

4.3. Secondary Outcomes

- Change in VAS Leg from preoperative baseline to 12 months +/- 3 months
- Change in VAS Back from preoperative baseline to 12 months +/- 3 months
- Change in Oswestry Disability Index (ODI) from baseline to 12 months +/- 3 months
- Intra-operative and post-operative adverse events

4.4. Study Population

A total of at least 100 patients from at least three sites will be enrolled based on inclusion/exclusion criteria. Homogeneity of data collection and treatment procedures will be ensured prior to combining data from multiple sites. The retrospective chart review will include the full consecutive series of patients who received TLIF or PLIF surgery using the FlareHawk expandable interbody fusion cage between December 1, 2017, and May 31, 2018. Subjects from that consecutive series will be included in the study based on the pre-defined inclusion and exclusion criteria. If at least 100 patients are not included after screening through the pre-defined inclusion / exclusion criteria, the date range will be extended, and the full consecutive series of patients within the new date range will be considered for inclusion. The date range will be extended, as necessary, until at least 100 patients are included. All subjects will have been diagnosed with degenerative disc disease of the lumbar spine that required lumbar interbody fusion procedure at one or two levels as per the opinion of the treating surgeon. All

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subjects who meet the inclusion criteria and do not meet any of the exclusion criteria will be included in the study.

4.5. Study Procedure

Refer to **Attachment A** for the detailed study protocol.

5. WORST CASE RATIONALE:

5.1. Not applicable

6. SAMPLE SIZE:

6.1. The primary outcome of this study, radiographic arthrodesis, is commonly observed in approximately 80-100% of study subjects for TLIF/PLIF surgeries [FlareHawk CER-00001 Rev C]. With 100 subjects included, if an 88% fusion rate is observed, the 95% confidence interval for fusion success will be 80.2%-93.0%, placing the performance results within the anticipated range. Further, the inclusion of at least 100 subjects will enable the likely detection of adverse events that have a probability of occurrence of at least 1.6%, assuming a power of 80% [MedDev 2.7.1, rev 4]. This detection rate is adequate for this device and study based on the severity and frequency of anticipated adverse events associated with the FlareHawk device [FlareHawk CER-00001 Rev C]. The target sample size for inclusion will be 118 patients, assuming that up to 15% will not have data at the 12 months follow-up, yielding at least 100 patients with data.


7. ACCEPTANCE CRITERIA:

7.1. Inclusion Criteria

Subjects must meet all of the inclusion criteria to be included in this study.

To be a part of this study, the subject must:

- Have been at least 18 years of age and skeletally mature at the time of surgery
- Have had clinical and radiological evidence of degenerative disc disease of the lumbar spine
- Have been treated with PLIF or TLIF surgery using the FlareHawk expandable interbody cage(s) at 1 or 2 contiguous levels from L2 to S1

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- Have been treated using the FlareHawk expandable interbody fusion cage, according to the approved labeling, between December 1, 2017, and May 31, 2018

7.2. Exclusion Criteria

Subjects must not meet any of the following exclusion criteria to be included in the study:

- Have a history of fusion surgery at the study level(s) prior to treatment with the FlareHawk device(s)
- Have had spondylolisthesis unable to be reduced to grade 1 as part of the surgical procedure
- Have had surgery with the FlareHawk device(s) at more than 2 levels
- Have had surgery with the FlareHawk device(s) at levels outside the range of L2 to S1
- Have been treated with any bone grafting material other than autogenous or allogenic bone graft in the FlareHawk device(s) and surrounding disc space
- Have any contraindications listed in the approved labeling

8. PERSONNEL/EQUIPMENT:

8.1. Proposed Study Site List

8.1.1. Carolina Neurosurgery & Spine Associates, Charlotte, NC

Principal Investigator: Domagoj Coric MD

8.1.2. NYU Langone Health, New York NY

Principal Investigator: Jeffrey A Goldstein MD

8.1.3. Northeast Ohio Spine Center, Akron, OH


Principal Investigator: Mark Grubb MD

8.1.4. Chatham Orthopaedic Associates, Savannah GA

Principal Investigator: Raphael R Roybal MD

8.2. Clinical Research Organization

8.2.1. Telos Partners LLC, Lakeland, FL

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8.3. Institutional Review Board

8.3.1. WIRB (Western Institutional Review Board), Puyallup, WA

9. DATA ANALYSIS:

9.1. Primary Outcome

The proportion of levels achieving arthrodesis at 12 months (+/- 3 months) will be summarized as a percentage and 95% confidence interval, based on the Wilson score method for binomial confidence intervals. Integrity Implants engineering to determine if the criteria for success was met.

9.2. Secondary Outcomes


Continuous variables, such as baseline demographics and change in patient-reported outcomes from preoperative baseline to 12 months, will be summarized using mean, standard deviation, minimum and maximum values. Paired t-test or a non-parametric equivalent (if data does not satisfy assumptions of normality) will be used to determine if changes in VAS or ODI scores are statistically significant from preoperative baseline to 12 months (+/- 3 months) follow-up. Responder analyses for changes in patient-reported outcomes at 12 months (+/- 3 months) will be conducted using minimum clinically important differences (MCID). Significant clinical improvements from preoperative baseline to 12 months (+/- 3 months) follow-up will be determined on a per-patient basis using the following MCID values:

- Improvement in ODI \geq 10 points [Ostelo et al. 2008]
- Improvement in VAS leg pain \geq 15 points [Ostelo et al. 2008]
- Improvement in VAS back pain \geq 15 points [Ostelo et al. 2008]

The proportion of patients with improvements exceeding the MCID values will be summarized as a percentage and 95% confidence interval.

Sub-group analyses will be performed based on the implant version (split-shim vs. "Version B"), history of previous surgery at the index level, patient co-morbidities, and demographic variables.

For any adverse events, the observed rate of each type of event will be summarized as a percentage with the 95% confidence interval and compared with rates observed in

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the literature describing the current state of the art with other PLIF and TLIF interbody cages.

10. ATTACHMENTS:

Attachment A - Clinical Investigation Plan, Transforaminal/Posterior Lumbar Interbody Fusion with the FlareHawk® Expandable Interbody Fusion Device:
A Retrospective Chart Review Study, Protocol Date July 18, 2019, V1

Attachment B - FlareHawk Retrospective Study Case Report Forms

Clinical Investigational Plan

Transforaminal/Posterior Lumbar Interbody Fusion with the
FlareHawk® Expandable Interbody Fusion Device:
A Retrospective Chart Review Study

Protocol Date: July 18, 2019

Sponsor




**Integrity Implants Inc.
354 Hiatt Drive
Palm Beach Gardens, Florida 33418 USA**

Sponsor Protocol Approval Page

Study Title: Transforaminal/Posterior Lumbar Interbody Fusion with the FlareHawk® Expandable Interbody Fusion Device:
A Retrospective Chart Review Study

Short Title: Integrity Implants FlareHawk® Study

Protocol Date: July 18, 2019

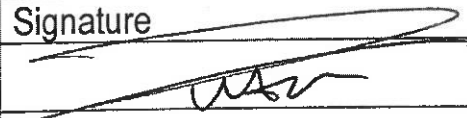
Name	Title	Signature	Date
Rohit Vasani M.D.	Chief Medical Officer, Integrity Implants Inc.	See attached ^{LEA} 22 JUL 2019	
Chris Walsh	Chief Executive Officer, Integrity Implants Inc.		7/22/19
Blake Stone	Chief Administrative Officer & General Counsel, Integrity Implants Inc.		7/18/19
Lauren Kamer	Director of Regulatory, Integrity Implants Inc.		22 JUL 2019

Sponsor Protocol Approval Page

Study Title: Transforaminal/Posterior Lumbar Interbody Fusion with the FlareHawk® Expandable Interbody Fusion Device:
A Retrospective Chart Review Study

Short Title: Integrity Implants FlareHawk® Study

Protocol Date: July 18, 2019

Name	Title	Signature	Date
Rohit Vasan M.D.	Chief Medical Officer, Integrity Implants Inc.		7-18-19
Chris Walsh	Chief Executive Officer, Integrity Implants Inc.		
Blake Stone	Chief Administrative Officer & General Counsel, Integrity Implants Inc.		
Lauren Kamer	Director of Regulatory, Integrity Implants Inc.		

Investigator Protocol Approval Page

Study Title: Transforaminal/Posterior Lumbar Interbody Fusion with the FlareHawk® Expandable Interbody Fusion Device:
A Retrospective Chart Review Study

Short Title: Integrity Implants FlareHawk® Study

Principal Investigator: Domagoj Coric MD

Co-Investigators: Not Applicable

Study Site: Carolina Neurosurgery & Spine Associates, Charlotte, NC

Protocol Date: July 18, 2019

The signature of the investigator below constitutes approval of this protocol and provides the necessary assurances that this Outcomes Study will be conducted according to Good Clinical Practices and to all stipulations, clinically and administratively, as stated in the protocol, including all statements as to confidentiality.

It is agreed that the protocol contains all necessary information required to conduct the Outcomes Study as outlined in the protocol.

PRINCIPAL INVESTIGATOR:

Print Name

Signature

Date

Investigator Protocol Approval Page

Study Title: Transforaminal/Posterior Lumbar Interbody Fusion with the FlareHawk® Expandable Interbody Fusion Device:
A Retrospective Chart Review Study

Short Title: Integrity Implants FlareHawk® Study

Principal Investigator: Jeffrey A Goldstein MD

Co-Investigators: Aaron J Buckland MD

Study Site: NYU Langone Health, New York NY

Protocol Date: July 18, 2019

The signature of the investigator below constitutes approval of this protocol and provides the necessary assurances that this Outcomes Study will be conducted according to Good Clinical Practices and to all stipulations, clinically and administratively, as stated in the protocol, including all statements as to confidentiality.

It is agreed that the protocol contains all necessary information required to conduct the Outcomes Study as outlined in the protocol.

PRINCIPAL INVESTIGATOR:

Print Name

Signature

Date

Investigator Protocol Approval Page

Study Title: Transforaminal/Posterior Lumbar Interbody Fusion with the FlareHawk® Expandable Interbody Fusion Device:
A Retrospective Chart Review Study

Short Title: Integrity Implants FlareHawk® Study

Principal Investigator: Mark Grubb MD

Co-Investigators: Not Applicable

Study Site: Northeast Ohio Spine Center, Akron, OH

Protocol Date: July 18, 2019

The signature of the investigator below constitutes approval of this protocol and provides the necessary assurances that this Outcomes Study will be conducted according to Good Clinical Practices and to all stipulations, clinically and administratively, as stated in the protocol, including all statements as to confidentiality.

It is agreed that the protocol contains all necessary information required to conduct the Outcomes Study as outlined in the protocol.

PRINCIPAL INVESTIGATOR:

Print Name

Signature

Date

Investigator Protocol Approval Page

Study Title: Transforaminal/Posterior Lumbar Interbody Fusion with the FlareHawk® Expandable Interbody Fusion Device:
A Retrospective Chart Review Study

Short Title: Integrity Implants FlareHawk® Study

Principal Investigator: Raphael R Roybal MD

Co-Investigators: Not Applicable

Study Site: Chatham Orthopaedic Associates, Savannah GA

Protocol Date: July 18, 2019

The signature of the investigator below constitutes approval of this protocol and provides the necessary assurances that this Outcomes Study will be conducted according to Good Clinical Practices and to all stipulations, clinically and administratively, as stated in the protocol, including all statements as to confidentiality.

It is agreed that the protocol contains all necessary information required to conduct the Outcomes Study as outlined in the protocol.

PRINCIPAL INVESTIGATOR:

Print Name

Signature

Date

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Integrity Implants Study Summary

Study Title:	Transforaminal/Posterior Lumbar Interbody Fusion with the FlareHawk® Expandable Interbody Fusion Device: A Retrospective Chart Review Study
Study Design:	Retrospective study – chart review
Study Purpose:	To evaluate the clinical outcomes of patients undergoing transforaminal or posterior lumbar interbody fusion (TLIF or PLIF) procedures using a FlareHawk expandable interbody fusion cage
Study Population:	Patients who underwent 1 or 2 contiguous level TLIF or PLIF procedure with the FlareHawk expandable interbody fusion cage. A total of at least 100 patients from at least three sites will be enrolled based on inclusion/exclusion criteria.
Minimum Follow-up:	12 months +/- 3 months
Primary Outcome:	Proportion of subjects with radiographic arthrodesis at 12 months +/- 3 months
Secondary Outcomes:	<ul style="list-style-type: none">• Change in VAS Leg pain from preoperative baseline to 12 months +/- 3 months• Change in VAS Back pain from preoperative baseline to 12 months +/- 3 months• Change in Oswestry Disability Index (ODI) from preoperative baseline to 12 months +/- 3 months• Other intra-operative or post-operative adverse events

1. Introduction

1.1 Background

Degenerative disc disease (DDD) of the lumbar spine is commonly defined by discogenic pain with degeneration of the disc confirmed by patient symptom history (e.g. back and lower extremity pain) and radiographic findings (e.g. disc space collapse and stenosis). DDD is sometimes accompanied by spondylolisthesis (vertebral “slipping”) of varying extent, with Grade I being the most mild. The most common therapies available for lumbar DDD are conservative care (e.g. injections, chiropractic manipulations), decompression without fusion, posterolateral fusion (PLF), or lumbar interbody fusion (LIF). With more than 6 months of failed conservative care, patients may be indicated for surgical intervention and LIF is often regarded as the mainstay of surgical care for degenerative disc disease [Noshchenko et al. 2015; Yavin et al. 2017]. Transforaminal lumbar interbody fusion (TLIF) and posterior lumbar interbody fusion (PLIF) are two variants of LIF surgery that utilize a posterior approach.

More recently, expandable interbody cages have been introduced for use in TLIF or PLIF procedures. Expandable cages, in general, have the potential advantage of facilitating more minimally invasive surgery while achieving substantial disc height and neuroforaminal height restoration as well as lordosis. Designs that expand in the transverse plane (medially-laterally) may also reduce subsidence risk due to their larger footprint. The FlareHawk expandable interbody fusion cage offers a simple expansion mechanism to achieve biplanar (cranial-caudal and medial-lateral) expansion in situ. This device is currently FDA-cleared in the United States and has been adopted into standard clinical practice beginning in August 2016, with over 3800 devices implanted to date. This study is a retrospective chart review to assess the performance and safety of the FlareHawk expandable cage under its intended use.

1.2 Device Description

The Integrity Implants FlareHawk Interbody Fusion System is an expandable lumbar intervertebral body fusion device intended for use in the lumbosacral spine from L2-S1 and is intended for intervertebral lumbar fusion. The FlareHawk implant consists of a Shell and a Shim component that are offered in a range of sizes to accommodate variation in patient anatomy. The Shell component is a rectangular frame with struts on all four sides that allow for insertion into the intervertebral body space in a non-expanded form, and subsequent expansion following the insertion of the Shim component. The Shim component has a tapered front end that inserts into and expands the Shell component to the desired vertical and horizontal dimensions. When fully inserted, the Shim locks within the Shell to provide structural stability for interbody fusion. An integrated “Core” in the Shell serves to anchor the delivery instrument during Shim insertion. Protrusions on the superior and inferior surfaces of the implant grip the adjacent vertebral endplates to resist expulsion. The FlareHawk implant is to be filled with autogenous and/or allogenic bone graft composed of cancellous and/or corticocancellous bone. Once implanted, the FlareHawk

implant is designed to restore intervertebral disc height, provide anterior column support and maintain structural stability of the motion segment to facilitate intervertebral body fusion.

2. Purpose of the Study:

The purpose of this study is to evaluate the clinical outcomes of patients who have undergone a TLIF or PLIF procedure with a FlareHawk expandable interbody fusion cage(s) to assess the device's performance and safety when used in accordance with its intended use.

3. Study Design

3.1 Study Hypothesis:

The primary hypothesis is that study subjects who received the FlareHawk expandable cage(s) through a TLIF or PLIF procedure experienced fusion by 12 months (+/- 3 mo) follow-up, with improvements in clinical outcomes related to pain and/or disability compared to pre-operative scores. Further, the subjects are hypothesized to have not experienced any unforeseen device- or procedure-related adverse events.

3.2 Study Description:

This is a retrospective clinical study (chart review) of patients who have previously undergone TLIF or PLIF surgery with the FlareHawk expandable interbody fusion cage at one or two contiguous levels.

3.3 Primary Outcome:

Proportion of subjects with radiographic arthrodesis at 12 months +/- 3 months as determined using plain radiographic images with assessment based on the Bridwell-Lenke grading system [Bridwell and Lenke et al, 1995].

3.4 Secondary Outcomes:

- Change in VAS Leg from preoperative baseline to 12 months +/- 3 months
- Change in VAS Back from preoperative baseline to 12 months +/- 3 months
- Change in Oswestry Disability Index (ODI) from baseline to 12 months +/- 3 months
- Intra-operative and post-operative adverse events

3.5 Study Population:

A total of at least 100 patients from at least three sites will be enrolled based on inclusion/exclusion criteria. Homogeneity of data collection and treatment procedures will be ensured prior to combining data from multiple sites. The retrospective chart review will include the full consecutive series of patients who received TLIF or PLIF surgery using the FlareHawk expandable interbody fusion cage between December 1, 2017, and May 31, 2018. Subjects from that consecutive series will be included in the study based on the pre-defined inclusion and exclusion

criteria, detailed below. If at least 100 patients are not included after screening through the pre-defined inclusion / exclusion criteria, the date range will be extended, and the full consecutive series of patients within the new date range will be considered for inclusion. The date range will be extended, as necessary, until at least 100 patients are included. All subjects will have been diagnosed with degenerative disc disease of the lumbar spine that required lumbar interbody fusion procedure at one or two levels as per the opinion of the treating surgeon. All subjects who meet the inclusion criteria and do not meet any of the exclusion criteria will be included in the study.

Two versions of the device have been on the market recently. The “Split Shim” version was introduced to the market in January 2018. This version supersedes the previous version, “Version B”, which has been on the market since January 2017. These two versions of the device have subtle differences and are equivalent from the clinical, technical, and biological perspective, and are expected to demonstrate equivalent safety and performance. Therefore, data will be collected from patients treated with either version of the device. A subgroup analysis will be performed to confirm poolability of the data.

3.6 Sample Size Justification

The primary outcome of this study, radiographic arthrodesis, is commonly observed in approximately 80-100% of study subjects for TLIF/PLIF surgeries [FlareHawk CER-00001 Rev C]. With 100 subjects included, if an 88% fusion rate is observed, the 95% confidence interval¹ for fusion success will be 80.2%-93.0%, placing the performance results within the anticipated range. Further, the inclusion of at least 100 subjects will enable the likely detection of adverse events that have a probability of occurrence of at least 1.6%, assuming a power of 80% [MedDev 2.7.1, rev 4]. This detection rate is adequate for this device and study based on the severity and frequency of anticipated adverse events associated with the FlareHawk device [FlareHawk CER-00001 Rev C]. The target sample size for inclusion will be 118 patients, assuming that up to 15% will not have data at the 12 months follow-up, yielding at least 100 patients with data.

3.7 Proposed* Study Site List and Justification

1. Carolina Neurosurgery & Spine Associates, Charlotte, NC

Principal Investigator: Domagoj Coric MD

Carolina Neurosurgery & Spine Associates is the largest neurosurgical group in the country, employing almost thirty (30) neurosurgeons across Charlotte and part of South Carolina. Patient demographics range from simple degenerative to very complex adult deformity. Dr. Coric has been the lead investigator or co-investigator of many investigational products and is an authority on expandable spacers. He was an early pioneer using StaxxD, the first commercially available expandable lumbar interbody device, and has

¹ Based on the Wilson score method for binomial confidence intervals

* Proposed sites are pending site qualifications and clinical trial agreements

collaborated with other companies, such as Globus, Stryker, and Expanding Orthopedics, on their expandable technologies. Dr. Coric prefers PLIF over TLIF, as he has always been a proponent of maximum surface area for the most stable construct while being able to maximize graft delivery.

2. NYU Langone Health, New York NY

Principal Investigator: Jeffrey A Goldstein MD

Dr. Goldstein is an NYU-based orthopedic surgeon in Manhattan, and is nationally recognized in several disciplines including MIS, artificial disc, and robotic surgery. Dr. Goldstein's cases vary from degenerative to complex adult deformity. Dr. Goldstein uses a TLIF approach and will approach the spine MIS or Open based on the pathology. Dr. Goldstein also has an interest in nerve health and is interested in devices that could potentially reduce nerve injuries when approaching the spine posteriorly.

3. Northeast Ohio Spine Center, Akron, OH

Principal Investigator: Mark Grubb MD

Dr. Grubb is a private practice orthopedic surgeon, with a distinct focus on treating patients and pathology with minimally invasive surgeries. Dr. Grubb is a respected surgeon teaching Kambin's triangle approach both in the US and abroad. Dr. Grubb prefers a TLIF approach. Due to Dr. Grubb's emphasis on minimally invasive techniques, he uses percutaneous pedicle screws for posterior fixation.

4. Chatham Orthopaedic Associates, Savannah GA

Principal Investigator: Raphael R Roybal MD

Dr. Roybal is a private practice orthopedic surgeon. He represents the majority of orthopedic spine surgeons in the community with an emphasis on degenerative spine and will does some basic deformity. Dr. Roybal uses a mini-open approach for his TLIF insertion, and a specialized retractor for visualization. Dr. Roybal has taught many US courses and is recognized in the Savannah community as one of the top local physicians.

3.8 Subject Eligibility Criteria:

The principal investigator at each site is responsible for verifying that study subjects meet all inclusion/exclusion criteria.

3.9 Inclusion Criteria:

Subjects must meet all of the inclusion criteria to be included in this study.

To be a part of this study, the subject must:

1. Have been at least 18 years of age and skeletally mature at the time of surgery
2. Have had clinical and radiological evidence of degenerative disc disease of the lumbar spine

3. Have been treated with PLIF or TLIF surgery using the FlareHawk expandable interbody cage(s) at 1 or 2 contiguous levels from L2 to S1
4. Have been treated using the FlareHawk expandable interbody fusion cage, according to the approved labeling, between December 1, 2017, and May 31, 2018

3.10 Exclusion criteria:

Subjects must not meet any of the following exclusion criteria to be included in the study:

1. Have a history of fusion surgery at the study level(s) prior to treatment with the FlareHawk device(s)
2. Have had spondylolisthesis unable to be reduced to grade 1 as part of the surgical procedure
3. Have had surgery with the FlareHawk device(s) at more than 2 levels
4. Have had surgery with the FlareHawk device(s) at levels outside the range of L2 to S1
5. Have been treated with any bone grafting material other than autogenous or allogenic bone graft in the FlareHawk device(s) and surrounding disc space
6. Have any contraindications listed in the approved labeling

4. Study Procedure

4.1 Subject Chart Review:

The chart reviews will be conducted by the study investigator or a trained study coordinator at each site. Records from all patients who underwent PLIF or TLIF surgery with the FlareHawk expandable cage between December 1, 2017, and May 31, 2018, will be identified for further screening according to the inclusion and exclusion criteria. Those subjects meeting all of the inclusion criteria and none of the exclusion criteria will be included for data collection. If there are not at least 118 patients included for data collection, the date range will be extended. If there are not at least 100 patients included with follow-up data at 12 (+/- 3) months, the date range will be extended.

4.2 Data Collection Procedure:

All data will be collected on de-identified case report forms (CRF) located at the participating site. Each subject will be identified only by a number which is generated at each site. No PHI will be available or seen by any study personnel with the exception of the investigator or his designee. All printed study records at the site will be maintained in a secure location. The data will be maintained by the investigator and information collected will be available to the study sponsor.

Source Documents

Source data is all information, original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents.

Examples of these original documents, and data records include: hospital records, clinical and office charts, laboratory notes, subjects' diaries or evaluation checklists, copies or transcriptions certified after verification as being accurate and complete, and X-rays.

Case Report Forms

The study case report form (CRF) is the primary data collection instrument for the study. All data requested on the CRF must be recorded. All missing data must be explained. If a space on the CRF is left blank because the procedure was not done or the question was not asked, write "N/D". If the item is not applicable to the individual case, write "N/A". All entries should be printed legibly in black ink. If any entry error has been made, to correct such an error, draw a single straight line through the incorrect entry and enter the correct data above it. All such changes must be initialed and dated. DO NOT ERASE OR WHITE OUT ERRORS. For clarification of illegible or uncertain entries, print the clarification above the item, then initial and date it. The investigator will be responsible for maintaining adequate, accurate CRFs to guarantee the proper interpretation of the data.

4.3 Data to be Collected:

After confirming inclusion in the study based on the above inclusion and exclusion criteria, data collection from the subject record will include the following, as available:

1. Demographics:

- Age
- Gender at birth
- Diagnosis
- BMI
- Co-morbid conditions
 - Hypertension
 - Diabetes
 - Obesity (BMI \geq 30)
 - Hypercholesterolemia
 - Coronary Heart Disease
 - Hypothyroidism
 - Active or history of cancer
 - Other
- Smoking Status

2. Operative data:
 - Date of Surgery
 - Surgical level(s)
 - Description of all implants and graft materials used, including supplemental fixation if described
 - PLIF or TLIF approach
 - Open, mini-open, or minimally invasive procedure
 - Estimated blood loss
 - Length of surgery
 - Fluoroscopic exposure time
 - Intraoperative device- or procedure-related adverse events
 - Device component breakage/fracture
 - Device malfunction
 - Dural tear/injury
 - Nerve root injury
 - Device-related delay of surgery
 - Retained foreign body
 - Other
 - Length of hospitalization
3. Patient reported outcomes surveys at preoperative baseline and each follow-up:
 - Visual Analog Scale (VAS) back and/or leg – Self Administered Questionnaire
 - Oswestry Disability Index (ODI) - Self Administered Questionnaire
4. Radiographs:
 - Intraoperative post-implantation Lateral and AP X-rays of the lumbar spine
 - 12 months (+/- 3 months) follow-up Lateral, AP, and Flexion-Extension X-rays of the lumbar spine
5. Post-operative device- or procedure-related adverse events
 - Infection
 - Donor site pain
 - Complex Regional Pain Syndrome
 - Urinary retention/difficulty
 - Ipsilateral or Contralateral radiculopathy
 - Device component fracture

- Device or device component migration/retropulsion
- Device complication (e.g. loss of expansion)
- Device subsidence
- Loss of fixation
- Non-union
- Vertebral fracture
- Adjacent segment disease
- Other

4.4 Data Management Plan:

Data processing and management will be carried out in accordance with the study-specific data processing plan. The data will be verified per the Monitoring Plan and CRFs will be collected by the clinical research associate (CRA) upon completion. Data will be entered into a password protected and encrypted database by the CRA and will be verified by double data entry.

Any missing, implausible or inconsistent recordings will be referred back to the Investigator using a data query form and will be documented for each individual subject. Responses from the Investigator will be reviewed and updated in the Database. This process will be repeated until no further discrepancies are found. The data will be then be declared as clean.

4.5 Monitoring Plan:

This study will be monitored according to the monitoring plan. The investigator and study staff will allocate adequate time for such monitoring activities. The investigator will also ensure that the monitor or other compliance or quality assurance reviewer is given access to all the above noted study-related documents. A remote pre-qualification assessment will be completed with the investigator and study staff to ensure they are experienced and available to conduct the study. Selected sites will participate in an initiation visit and will be trained on the study protocol and study related responsibilities. Interim remote or onsite monitoring visits will be conducted for cause and one on-site visit will occur once the study site has completed the CRFs, so that the CRA can verify the collected data to the source documents.

5. Adverse Events:

Per EN ISO 14155, an adverse event is defined as any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the investigational medical device as any undesirable deviation from the subject's baseline condition

to include all new conditions or symptoms, or worsening of the pre-existing condition or symptoms regardless of the cause. This definition includes events related to the procedures involved.

The intensity of the adverse event will be determined by the investigator using the following definitions established by the World Health Organization and not necessarily the subject's interpretation:

None: patient outcome is not symptomatic, or no symptoms detected and no treatment is required.

Mild: patient outcome is symptomatic, symptoms are mild, loss of function or harm is minimal or intermediate but short term, and no or minimal intervention (e.g., extra observation, investigation, review or minor treatment) is required.

Moderate: patient outcome is symptomatic, requiring intervention (e.g., additional operative procedure; additional therapeutic treatment), an increased length of stay, or causing permanent or long-term harm or loss of function.

Severe: patient outcome is symptomatic, requiring life-saving intervention or major surgical/medical intervention, shortening life expectancy or causing major permanent or long-term harm or loss of function

Death: on balance of probabilities, death was caused or brought forward in the short term by the incident.

The relationship of the AE to the implant or surgical procedure is determined according to the following definitions:

Device related: The AE can be reasonably associated with the presence or performance of the device and follows a reasonable temporal sequence to the device implant

Procedure related: The AE has been established as a potential risk or complication associated with any type of spinal surgical procedure and not specific to the receipt of the device.

Not related: The AE has no temporal sequence from the receipt of the device or it can be explained by other factors, including underlying disease, concomitant medication or concurrent treatment. This also includes events associated with general surgical procedures (e.g. anesthesia reactions).

5.1 Subject Safety:

The expandable cage used in this study is currently used in standard of care procedures for these lumbar spine disorders. No experimental devices or products were used in this study and all patients were treated according to the standard practices of the study investigators.

5.2 Mitigation of Risks:

This is a retrospective chart review that does not introduce any additional risks to the patient.

6. Image and Data Analysis

6.1 Radiographic Fusion Assessment:

Radiographs will be evaluated by up to three reviewers (two primary reviewers and an adjudicator, as necessary, to evaluate any contradicting reviews by the primary reviewers). Reviewers will be 3rd party board-certified orthopedic surgeons, neurosurgeons, or radiologists.

Fusion status will be determined according to the Bridwell-Lenke grading system [Bridwell and Lenke et al, 1995], with grades 1-2 accepted as “Fused” and grades 3-4 accepted as “Not Fused”:

- Grade 1: Fused with remodeling and trabeculae present
- Grade 2: Graft intact, not fully remodeled and incorporated, but no lucency present
- Grade 3: Graft intact, potential lucency present at top and bottom of graft
- Grade 4: Fusion absent with collapse/resorption of the graft

6.2 Data Analysis:

Primary outcome:

The proportion of levels achieving arthrodesis at 12 months (+/- 3 months) will be summarized as a percentage and 95% confidence interval, based on the Wilson score method for binomial confidence intervals.

Secondary outcomes:

Continuous variables, such as baseline demographics and change in patient-reported outcomes from preoperative baseline to 12 months, will be summarized using mean, standard deviation, minimum and maximum values. Paired t-test or a non-parametric equivalent (if data does not satisfy assumptions of normality) will be used to determine if changes in VAS or ODI scores are statistically significant from preoperative baseline to 12 months (+/- 3 months) follow-up. Responder analyses for changes in patient-reported outcomes at 12 months (+/- 3 months) will be conducted using minimum clinically important differences (MCID). Significant clinical improvements from preoperative baseline to 12 months (+/- 3 months) follow-up will be determined on a per-patient basis using the following MCID values:

- Improvement in ODI \geq 10 points [Ostelo et al. 2008]
- Improvement in VAS leg pain \geq 15 points [Ostelo et al. 2008]
- Improvement in VAS back pain \geq 15 points [Ostelo et al. 2008]

The proportion of patients with improvements exceeding the MCID values will be summarized as a percentage and 95% confidence interval.

Sub-group analyses will be performed based on the implant version (split-shim vs. “Version B”), history of previous surgery at the index level, patient co-morbidities, and demographic variables.

For any adverse events, the observed rate of each type of event will be summarized as a percentage with the 95% confidence interval and compared with rates observed in the literature describing the current state of the art with other PLIF and TLIF interbody cages.

7. Ethical and Regulatory Requirements:

7.1 Code of Conduct

The Investigator will ensure that the clinical study is conducted in accordance with good clinical practice (GCP), EN ISO 41455, and all regulatory and institutional requirements, including those for subject privacy, informed consent, Independent Ethics Committee (IEC)/Institutional Review Board (IRB) approval and record retention, and the Food and Drug Administration (FDA) Guidelines for the conduct of clinical trials. As this study is a retrospective chart review adding no additional risk to the subjects, a waiver of informed consent will be requested from the IEC/IRB.

7.2 Subject Confidentiality

The Sponsor will maintain the confidentiality of the identity of all subjects enrolled in the study and the information contained in their records. The Sponsor will also instruct the study investigators in the importance of maintaining the confidentiality of study records. The subject records will be made available as required for review by governing regulatory agencies and a reviewing IEC/IRB, however to every extent possible; the subject’s identities will not be disclosed. Compliance with EN ISO 14155 and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) is required and data collection must comply with the Standards for Privacy of Individually Identifiable Health Information, 45 CFR Part 160 and Part 164, as amended from time to time (the “Privacy Rule”), under HIPAA.

The case report forms do not include any subject identifying information in accordance with HIPAA. Therefore, once the data is entered on the CRF, a subject can no longer be identified. It is the responsibility of the investigator to maintain a list of subject identification and ID numbers.

7.3 Retention of Records by the Investigator

The investigators will retain records for a period of 2 years following the date of the study conclusion.

8. References

Bridwell KH, Lenke LG, McEnery KW, Baldus C, Blanke K: Anterior fresh frozen structural allografts in the thoracic and lumbar spine. Do they work if combined with posterior fusion and instrumentation in adult patients with kyphosis or anterior column defects? *Spine (Phila Pa 1976)* 20:1410–1418, 1995.

Noshchenko A, Hoffecker L, Lindley EM, Burger EL, Cain CM, Patel VV. Long-term Treatment Effects of Lumbar Arthrodeses in Degenerative Disk Disease: A Systematic Review With Meta-Analysis. *J Spinal Disord Tech.* 2015;28(9):E493-521.

Ostelo RW, Deyo RA, Stratford P, et al. Interpreting change scores for pain and functional status in low back pain: towards international consensus regarding minimal important change. *Spine.* 2008;33(1):90-4.

Yavin D, Casha S, Wiebe S, et al. Lumbar Fusion for Degenerative Disease: A Systematic Review and Meta-Analysis. *Neurosurgery.* 2017; 80(5):701-715.



Clinical Site Number:

Subject Number:

Case Report Form
Integrity Implants FlareHawk® Study
Investigator Approval

STUDY TITLE: Transforaminal/Posterior Lumbar Interbody Fusion with the FlareHawk® Expandable Interbody Fusion Device:

A Retrospective Chart Review Study

PROTOCOL DATE: July 18, 2019

CLINICAL SITE NUMBER:

SUBJECT NUMBER:

PRINCIPAL INVESTIGATOR: _____
(Printed Name)

I am confident that the information supplied in this case report form is complete and accurate data. I confirm that the study was conducted in accordance with the protocol and any protocol amendments and that a waiver for informed consent has been approved by the IRB.

Investigator Signature: _____ **Date:** _____

Case Report Forms Completed By:

Signature: _____ **Date:** _____

Printed Name: _____

NA, the Case Report Forms were completed by the Principal Investigator

Clinical Site Number: Subject Number:

Case Report Form
Integrity Implants FlareHawk® Study
Inclusion/Exclusion Criteria

Page 1 of 1

ALL patients treated with FlareHawk Interbody Fusion Device prior to September 30, 2018 (9/30/2018) will be evaluated with the Inclusion/Exclusion criteria below. However, the remaining CRF data should only be collected for those patients meeting the criteria.

INCLUSION CRITERIA		
1. Was the subject at least 18 years of age and skeletally mature at the time of surgery?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
2. Has the subject been diagnosed with degenerative disc disease of the lumbar spine based on clinical and radiological evidence?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
3. Has the subject been treated with PLIF or TLIF surgery using the FlareHawk expandable cage(s) at 1 or 2 contiguous levels from L2-S1?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
4. Has the subject undergone surgery using the FlareHawk expandable interbody fusion cage, according to approved labeling, prior to September 30, 2018?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
All inclusion criteria must be answered "Yes" to proceed to completing the remaining fields. If any inclusion criteria were answered "No" do not collect additional data.		

EXCLUSION CRITERIA		
1. Does the subject have a history of fusion surgery at the study level(s) prior to treatment with the FlareHawk device(s)?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
2. Did the subject have spondylolisthesis unable to be reduced to grade 1 as part of the surgical procedure?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
3. Has the subject had surgery with the FlareHawk device(s) at more than 2 levels?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
4. Has the subject had surgery with the FlareHawk device(s) at levels outside the range of L2- S1?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
5. Has the subject been treated with any bone grafting material other than autogenous or allogenic bone graft in the FlareHawk device(s) and surrounding disc space?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
6. Did the subject have any contraindications listed in the approved labeling?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
All exclusion criteria must be answered "No" to proceed to completing the remaining fields. If any exclusion criteria were answered "Yes" do not collect additional data		

ELIGIBILITY		
Did the Subject meet the Eligibility Criteria?	<input type="checkbox"/> Yes	<input type="checkbox"/> No

Clinical Site Number: Subject Number:

Case Report Form
Integrity Implants FlareHawk® Study
Baseline Data – Visit 1

Page 1 of 3

VISIT 1 – BASELINEDATE OF VISIT: //
MM DD YYYY**DEMOGRAPHIC DATA**Date of Birth: //
MM DD YYYY Gender at Birth: Female
Male
Height: in. Weight: lb.**SMOKING STATUS**Non-smoker Active smoker History of smoking Not Recorded **COMORBID CONDITIONS**Hypertension Diabetes Obesity (BMI ≥ 30)
Hypercholesterolemia Coronary Heart Disease Hyperthyroidism
Active Cancer History of Cancer
If checked, type of cancer: _____ If checked, type of cancer: _____
None recorded **VISUAL ANALOG SCALE (VAS)**Please enter the VAS score as documented at the baseline visit in the medical records for the level of **RIGHT LEG** pain.VAS **Right Leg** Pain Score: _____ Not Recorded Please enter the VAS score as documented at the baseline visit in the medical records for the level of **LEFT LEG** pain.VAS **Left Leg** Pain Score: _____ Not Recorded Please enter the VAS score as documented at the baseline visit in the medical records for the level of **BACK** pain.VAS **Back Pain** Score: _____ Not Recorded

Clinical Site Number: Subject Number:

Case Report Form
Integrity Implants FlareHawk® Study
Baseline Data – Visit 1

OSWESTRY DISABILITY INDEX (ODI)

Please transcribe answers directly from the patient's medical record.
(Circle score for each section recorded)

Not Recorded

Section 1 – Pain Intensity	
0	I have no pain at the moment
1	The pain is very mild at the moment
2	The pain is moderate at the moment
3	The pain is fairly severe at the moment
4	The pain is very severe at the moment
5	The pain is the worst imaginable at the moment

Section 4 – Walking	
0	Pain does not prevent me walking any distance
1	Pain prevents me from walking more than 1 mile
2	Pain prevents me from walking more than ½ mile
3	Pain prevents me from walking more than 100 yards
4	I can only walk using a cane or crutches
5	I am in bed most of the time

Section 2 – Personal Care (washing, dressing, etc.)	
0	I have no pain at the moment
1	The pain is very mild at the moment
2	The pain is moderate at the moment
3	The pain is fairly severe at the moment
4	The pain is very severe at the moment
5	The pain is the worst imaginable at the moment

Section 5 – Sitting	
0	I can sit in any chair as long as I like
1	I can only sit in my favorite chair as long as I like
2	Pain prevents me from sitting more than one hour
3	Pain prevents me from sitting more than 30 minutes
4	Pain prevents me from sitting more than 10 minutes
5	Pain prevents me from sitting at all

Section 3 – Lifting	
0	I can lift heavy weights without extra pain
1	I can lift heavy weights but it gives extra pain
2	Pain prevents me from lifting heavy weights off the floor, but I manage if they are conveniently placed e.g. on a table
3	Pain prevents me lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned
4	I can lift very light weights
5	I cannot lift or carry anything at all

Section 6 – Standing	
0	I can stand as long as I want without extra pain
1	I can stand as long as I want but it gives me extra pain
2	Pain prevents me from standing more than 1 hour
3	Pain prevents me from standing more than 30 minutes
4	Pain prevents me from standing for more than 10 minutes
5	Pain prevents me from standing at all



Clinical Site Number:

Subject Number:

Case Report Form
Integrity Implants FlareHawk® Study
 Baseline Data – Visit 1

OSWESTRY DISABILITY INDEX (ODI) Continued

Please transcribe answers directly from the patient's medical record.
 (Circle score for each section recorded)

Not Recorded

Section 7 – Sleeping	
0	My sleep is never disturbed by pain
1	My sleep is occasionally disturbed by pain
2	Because of pain I have less than 6 hours sleep
3	Because of pain I have less than 4 hours sleep
4	Because of pain I have less than 2 hours sleep
5	Pain prevents me from sleeping at all

Section 8 – Sex Life (if applicable)	
0	My sex life is normal and causes no extra pain
1	My sex life is normal but causes some extra pain
2	My sex life is nearly normal but is very painful
3	My sex life is severely restricted by pain
4	My sex life is nearly absent because of pain
5	Pain prevents any sex life at all

Section 9 – Social Life	
0	My social life is normal and gives me no extra pain
1	My social life is normal but increases the degree of pain
2	Pain has no significant effect on my social life apart from limiting my more energetic interests e.g. sports
3	Pain has restricted my social life and I do not go out as often
4	Pain has restricted my social life to my home
5	I have no social life because of pain

Section 10 – Traveling	
0	I can travel anywhere without pain
1	I can travel anywhere but it gives me extra pain
2	Pain is bad but I manage journeys over two hours
3	Pain restricts me to journeys of less than one hour
4	Pain restricts me to short necessary journeys under 30 minutes
5	Pain prevents me from traveling except to receive treatment

Clinical Site Number: Subject Number: **Case Report Form**
Integrity Implants FlareHawk® Study
Surgery – Visit 2

Page 1 of 3

VISIT 2 – SURGERYDATE OF SURGERY: / /
MM DD YYYYTotal Operative Time: min.
(Open to Close)Estimated Blood Loss: cc./ml.Length of Hospitalization: daysFluoroscopic Exposure Time: min.**TYPE OF PROCEDURE**Operative Procedure: Open Mini-open Minimally Invasive Operative Approach: PLIF TLIF Number of Levels: One Two Surgery Levels: L2-L3 L3-L4 L4-L5 L5-S1 **IMPLANT(S) USED****Implant #1**

Shell Catalog # _____

Shim Catalog # _____

Shell Lot # _____

Shim Lot # _____

Implant #2NA

Shell Catalog # _____

Shim Catalog # _____

Shell Lot # _____

Shim Lot # _____

Implant #3NA

Shell Catalog # _____

Shim Catalog # _____

Shell Lot # _____

Shim Lot # _____

Implant #4NA

Shell Catalog # _____

Shim Catalog # _____

Shell Lot # _____

Shim Lot # _____

GRAFT MATERIALGraft Materials Used: Allograft Autograft Mix of Allograft/Autograft



Clinical Site Number:

Subject Number:

Case Report Form
Integrity Implants FlareHawk® Study
Surgery – Visit 2

SUPPLEMENTAL FIXATION

Supplemental Fixation Used (check one): Unilateral Bilateral

Description of Construct: _____

ADVERSE EVENTS (AEs)

Did any intra-operative adverse events occur? Yes No

If "Yes", add adverse event to **Intra-Operative AE Log**.

DELAY OF SURGERY

Device Related Delay of Surgery: Yes No

If yes, how many minutes? min.

If yes, cause of delay? _____

INSTRUMENTATION

Were there any reported issues with instrument(s)? Yes No

If yes, please provide the catalog and lot number below as well as the description of the issue with the instrument(s):

Catalog # _____ Description of issue: _____

Lot # _____

Not Recorded



Clinical Site Number:

Subject Number:

Case Report Form
Integrity Implants FlareHawk® Study
Surgery – Visit 2

RADIOGRAPHS

Are intra-operative, post-implantation X-rays available on CD? Yes No

X-ray views taken (*check those that apply*): AP Lateral

If X-rays are available, has the CD been provided to the evaluators? Yes No

ADDITIONAL COMMENTS

Please add any other pertinent information regarding the surgical procedure, the device/instruments or any safety concerns:



Clinical Site Number:

Subject Number:

Case Report Form
Integrity Implants FlareHawk® Study
Follow-up – Visit 3

Page 1 of 3

VISIT 3 – 12 MONTHS (+/- 3MONTHS)

DATE OF VISIT: / /
MM DD YYYY

RADIOGRAPHS

Are 12-month X-rays available on CD? Yes No

X-ray views taken (check those that apply): AP Lateral Flexion/Extension

If X-rays are available, has the CD been provided to the evaluators? Yes No

ADVERSE EVENTS (AEs)

Did any post-operative adverse events occur? Yes No

If "Yes", add adverse event to **Post-Operative AE Log**.

VISUAL ANALOG SCALE (VAS)

Please enter the VAS score as documented at the follow-up visit in the medical records for the level of **RIGHT LEG** pain.

VAS **Right Leg** Pain Score: _____ Not Recorded

Please enter the VAS score as documented at the follow-up visit in the medical records for the level of **LEFT LEG** pain.

VAS **Left Leg** Pain Score: _____ Not Recorded

Please enter the VAS score as documented at the follow-up visit in the medical records for the level of **BACK** pain.

VAS **Back Pain** Score: _____ Not Recorded



Clinical Site Number:

Subject Number:

Case Report Form
Integrity Implants FlareHawk® Study
 Follow-up – Visit 3

OSWESTRY DISABILITY INDEX (ODI)

Please transcribe answers directly from the patient's medical record.
 (Circle score for each section recorded)

Not Recorded

Section 1 – Pain Intensity	
0	I have no pain at the moment
1	The pain is very mild at the moment
2	The pain is moderate at the moment
3	The pain is fairly severe at the moment
4	The pain is very severe at the moment
5	The pain is the worst imaginable at the moment

Section 4 – Walking	
0	Pain does not prevent me walking any distance
1	Pain prevents me from walking more than 1 mile
2	Pain prevents me from walking more than ½ mile
3	Pain prevents me from walking more than 100 yards
4	I can only walk using a cane or crutches
5	I am in bed most of the time

Section 2 – Personal Care (washing, dressing, etc.)	
0	I have no pain at the moment
1	The pain is very mild at the moment
2	The pain is moderate at the moment
3	The pain is fairly severe at the moment
4	The pain is very severe at the moment
5	The pain is the worst imaginable at the moment

Section 5 – Sitting	
0	I can sit in any chair as long as I like
1	I can only sit in my favorite chair as long as I like
2	Pain prevents me from sitting more than one hour
3	Pain prevents me from sitting more than 30 minutes
4	Pain prevents me from sitting more than 10 minutes
5	Pain prevents me from sitting at all

Section 3 – Lifting	
0	I can lift heavy weights without extra pain
1	I can lift heavy weights but it gives extra pain
2	Pain prevents me from lifting heavy weights off the floor, but I manage if they are conveniently placed e.g. on a table
3	Pain prevents me lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned
4	I can lift very light weights
5	I cannot lift or carry anything at all

Section 6 – Standing	
0	I can stand as long as I want without extra pain
1	I can stand as long as I want but it gives me extra pain
2	Pain prevents me from standing more than 1 hour
3	Pain prevents me from standing more than 30 minutes
4	Pain prevents me from standing for more than 10 minutes
5	Pain prevents me from standing at all

Clinical Site Number: Subject Number:

Case Report Form
Integrity Implants FlareHawk® Study
Follow-up – Visit 3

Page 3 of 3

OSWESTRY DISABILITY INDEX (ODI) Continued

Please transcribe answers directly from the patient's medical record.

Not Recorded **Section 7 – Sleeping**

0	My sleep is never disturbed by pain
1	My sleep is occasionally disturbed by pain
2	Because of pain I have less than 6 hours sleep
3	Because of pain I have less than 4 hours sleep
4	Because of pain I have less than 2 hours sleep
5	Pain prevents me from sleeping at all

Section 8 – Sex Life (if applicable)

0	My sex life is normal and causes no extra pain
1	My sex life is normal but causes some extra pain
2	My sex life is nearly normal but is very painful
3	My sex life is severely restricted by pain
4	My sex life is nearly absent because of pain
5	Pain prevents any sex life at all

Section 9 – Social Life

0	My social life is normal and gives me no extra pain
1	My social life is normal but increases the degree of pain
2	Pain has no significant effect on my social life apart from limiting my more energetic interests e.g. sports
3	Pain has restricted my social life and I do not go out as often
4	Pain has restricted my social life to my home
5	I have no social life because of pain

Section 10 – Traveling

0	I can travel anywhere without pain
1	I can travel anywhere but it gives me extra pain
2	Pain is bad but I manage journeys over two hours
3	Pain restricts me to journeys of less than one hour
4	Pain restricts me to short necessary journeys under 30 minutes
5	Pain prevents me from traveling except to receive treatment

Clinical Site Number: Subject Number: **Case Report Form**
Integrity Implants FlareHawk® Study
Follow-up Visit – ODI Score**FOLLOW-UP VISIT**DATE OF VISIT: //
MM DD YYYY**OSWESTRY DISABILITY INDEX (ODI)**Please transcribe answers directly from the patient's medical record.
(Circle score for each section recorded)Not Recorded **Section 1 – Pain Intensity**

0	I have no pain at the moment
1	The pain is very mild at the moment
2	The pain is moderate at the moment
3	The pain is fairly severe at the moment
4	The pain is very severe at the moment
5	The pain is the worst imaginable at the moment

Section 4 – Walking

0	Pain does not prevent me walking any distance
1	Pain prevents me from walking more than 1 mile
2	Pain prevents me from walking more than ½ mile
3	Pain prevents me from walking more than 100 yards
4	I can only walk using a cane or crutches
5	I am in bed most of the time

Section 2 – Personal Care (washing, dressing, etc.)

0	I have no pain at the moment
1	The pain is very mild at the moment
2	The pain is moderate at the moment
3	The pain is fairly severe at the moment
4	The pain is very severe at the moment
5	The pain is the worst imaginable at the moment

Section 5 – Sitting

0	I can sit in any chair as long as I like
1	I can only sit in my favorite chair as long as I like
2	Pain prevents me from sitting more than one hour
3	Pain prevents me from sitting more than 30 minutes
4	Pain prevents me from sitting more than 10 minutes
5	Pain prevents me from sitting at all

Section 3 – Lifting

0	I can lift heavy weights without extra pain
1	I can lift heavy weights but it gives extra pain
2	Pain prevents me from lifting heavy weights off the floor, but I manage if they are conveniently placed e.g. on a table
3	Pain prevents me lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned
4	I can lift very light weights
5	I cannot lift or carry anything at all

Section 6 – Standing

0	I can stand as long as I want without extra pain
1	I can stand as long as I want but it gives me extra pain
2	Pain prevents me from standing more than 1 hour
3	Pain prevents me from standing more than 30 minutes
4	Pain prevents me from standing for more than 10 minutes
5	Pain prevents me from standing at all



Clinical Site Number:

Subject Number:

Case Report Form
Integrity Implants FlareHawk® Study
 Follow-up Visit – ODI Score

OSWESTRY DISABILITY INDEX (ODI) Continued

Please transcribe answers directly from the patient's medical record.
 (Circle score for each section recorded)

Not Recorded

Section 7 – Sleeping	
0	My sleep is never disturbed by pain
1	My sleep is occasionally disturbed by pain
2	Because of pain I have less than 6 hours sleep
3	Because of pain I have less than 4 hours sleep
4	Because of pain I have less than 2 hours sleep
5	Pain prevents me from sleeping at all

Section 8 – Sex Life (if applicable)	
0	My sex life is normal and causes no extra pain
1	My sex life is normal but causes some extra pain
2	My sex life is nearly normal but is very painful
3	My sex life is severely restricted by pain
4	My sex life is nearly absent because of pain
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Section 9 – Social Life	
0	My social life is normal and gives me no extra pain
1	My social life is normal but increases the degree of pain
2	Pain has no significant effect on my social life apart from limiting my more energetic interests e.g. sports
3	Pain has restricted my social life and I do not go out as often
4	Pain has restricted my social life to my home
5	I have no social life because of pain

Section 10 – Traveling	
0	I can travel anywhere without pain
1	I can travel anywhere but it gives me extra pain
2	Pain is bad but I manage journeys over two hours
3	Pain restricts me to journeys of less than one hour
4	Pain restricts me to short necessary journeys under 30 minutes
5	Pain prevents me from traveling except to receive treatment



Clinical Site Number:

Subject Number:

Case Report Form
Integrity Implants FlareHawk® Study
Follow-up Visit – VAS Score

Page 1 of 1

FOLLOW-UP VISIT

DATE OF VISIT: / /
MM DD YYYY

VISUAL ANALOG SCALE (VAS)

Please enter the VAS score as documented at the follow-up visit in the medical records for the level of **RIGHT LEG** pain.

VAS **Right Leg** Pain Score: _____ Not Recorded

Please enter the VAS score as documented at the follow-up visit in the medical records for the level of **LEFT LEG** pain.

VAS **Left Leg** Pain Score: _____ Not Recorded

Please enter the VAS score as documented at the follow-up visit in the medical records for the level of **BACK** pain.

VAS **Back Pain** Score: _____ Not Recorded



Clinical Site Number:

Subject Number:

Case Report Form
Integrity Implants FlareHawk® Study
 Intra-Operative Adverse Event Log

INTRA-OPERATIVE ADVERSE EVENT (AE) LOG			No AEs Recorded <input type="checkbox"/>			
If Adverse Events have occurred, check “yes” or “no” for each event listed below. If “yes” is marked for an Adverse Event below, please complete all of the columns to the right.						
Adverse Events	Yes / No		Severity	Relatedness	Action Taken	Outcomes
			1- None 2- Mild 3- Moderate 4- Severe 5- Death	1- Device related 2- Procedure related 3- Not related	1- None 2- Medication/Therapy 3- Revision Surgery 4- Additional Surgery 5- Other	1- Resolved 2- Ongoing at 12-month (+/- 3 month) Follow-up 3- Unknown
Device component breakage/fracture	Yes <input type="checkbox"/>	No <input type="checkbox"/>				
Device malfunction	Yes <input type="checkbox"/>	No <input type="checkbox"/>				
Dural tear/injury	Yes <input type="checkbox"/>	No <input type="checkbox"/>				
Nerve root injury	Yes <input type="checkbox"/>	No <input type="checkbox"/>				
Other Adverse Events <i>(Describe event below)</i>			Severity	Relatedness	Action Taken	Outcomes



Clinical Site Number:

Subject Number:

Case Report Form
Integrity Implants FlareHawk® Study
 Post-Operative Adverse Event Log

POST-OPERATIVE ADVERSE EVENT (AE) LOG **No AEs Recorded**

If Adverse Events have occurred, check “yes” or “no” for each event listed below. If “yes” is marked for an Adverse Event below, please complete all of the columns to the right.

Adverse Events	Yes / No		Onset Date	Resolution Date	Severity	Relatedness	Action Taken	Outcomes
			MM/DD/YYYY	MM/DD/YYYY	1- None 2- Mild 3- Moderate 4- Severe 5- Death	1- Device related 2- Procedure related 3- Not related	1- None 2- Medication/ Therapy 3- Revision Surgery 4- Additional Surgery 5- Other	1- Resolved 2- Ongoing at 12-month (+/- 3 month) Follow-up 3- Unknown
Infection	Yes <input type="checkbox"/>	No <input type="checkbox"/>	/ /	/ /				
Donor site pain	Yes <input type="checkbox"/>	No <input type="checkbox"/>	/ /	/ /				
Complex regional pain syndrome	Yes <input type="checkbox"/>	No <input type="checkbox"/>	/ /	/ /				
Urinary retention/difficulty	Yes <input type="checkbox"/>	No <input type="checkbox"/>	/ /	/ /				
Ipsilateral or contralateral radiculopathy	Yes <input type="checkbox"/>	No <input type="checkbox"/>	/ /	/ /				
Device component breakage/fracture	Yes <input type="checkbox"/>	No <input type="checkbox"/>	/ /	/ /				
Device or device component migration/retropulsion	Yes <input type="checkbox"/>	No <input type="checkbox"/>	/ /	/ /				
Device complication (e.g. loss of expansion)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	/ /	/ /				
Device subsidence	Yes <input type="checkbox"/>	No <input type="checkbox"/>	/ /	/ /				
Loss of fixation	Yes <input type="checkbox"/>	No <input type="checkbox"/>	/ /	/ /				
Non-union	Yes <input type="checkbox"/>	No <input type="checkbox"/>	/ /	/ /				
Vertebral fracture	Yes <input type="checkbox"/>	No <input type="checkbox"/>	/ /	/ /				
Adjacent segment disease	Yes <input type="checkbox"/>	No <input type="checkbox"/>	/ /	/ /				



Clinical Site Number:

Subject Number:

Case Report Form
Integrity Implants FlareHawk® Study
 Post-Operative Adverse Event Log

POST-OPERATIVE ADVERSE EVENT (AE) LOG Continued

No AEs Recorded

Please complete all columns below if additional Adverse Events are recorded.

Other Adverse Events <i>(Describe event below)</i>	Onset Date MM/DD/YYYY	Resolution Date MM/DD/YYYY	Severity 1- None 2- Mild 3- Moderate 4- Severe 5- Death	Relatedness 1- Device related 2- Procedure related 3- Not related	Action Taken 1- None 2- Medication/ Therapy 3- Revision Surgery 4- Additional Surgery 5- Other	Outcomes 1- Resolved 2- Ongoing at 12-month (+/- 3 month) Follow-up 3- Unknown
	/ /	/ /				
	/ /	/ /				
	/ /	/ /				
	/ /	/ /				
	/ /	/ /				

Clinical Site Number: Subject Number:

Case Report Form
Integrity Implants FlareHawk® Study
Radiographic Reviewer

CRF TO BE COMPLETED BY RADIOGRAPHIC REVIEWER ONLYDATE OF X-RAY: / /
MM DD YYYY**RADIOGRAPHS**X-ray views evaluated (check all that apply): AP Lateral Flexion/Extension **RADIOGRAPHS**

Using the Bridwell-Lenke grading system, what is the X-ray fusion status at L2 - L3?	Grade 1	<input type="checkbox"/>
	Grade 2	<input type="checkbox"/>
	Grade 3	<input type="checkbox"/>
	Grade 4	<input type="checkbox"/>
NA – Subject not implanted with FlareHawk device at L2-L3		<input type="checkbox"/>

Using the Bridwell-Lenke grading system, what is the X-ray fusion status at L3 – L4?	Grade 1	<input type="checkbox"/>
	Grade 2	<input type="checkbox"/>
	Grade 3	<input type="checkbox"/>
	Grade 4	<input type="checkbox"/>
NA – Subject not implanted with FlareHawk device at L3-L4		<input type="checkbox"/>

Using the Bridwell-Lenke grading system, what is the X-ray fusion status at L4 – L5?	Grade 1	<input type="checkbox"/>
	Grade 2	<input type="checkbox"/>
	Grade 3	<input type="checkbox"/>
	Grade 4	<input type="checkbox"/>
NA – Subject not implanted with FlareHawk device at L4-L5		<input type="checkbox"/>

Using the Bridwell-Lenke grading system, what is the X-ray fusion status at L5- S1?	Grade 1	<input type="checkbox"/>
	Grade 2	<input type="checkbox"/>
	Grade 3	<input type="checkbox"/>
	Grade 4	<input type="checkbox"/>
NA – Subject not implanted with FlareHawk device at L5-S1		<input type="checkbox"/>

Was any magnification adjustment used by the radiographic reviewer to grade fusion status? Yes No

If "Yes", describe below: _____

APPROVAL

Reviewer Signature: _____

Date: _____