DIAM™ Spinal Stabilization System – Instructions for Use

Particular attention to this Instructions for Use (IFU) is strongly recommended to ensure a safe transfer of information from the manufacturer to the intended users.

Caution: Federal law restricts this device to sale by or on the order of a physician.

GENERAL INFORMATION ABOUT DIAM™/DEVICE DESCRIPTION

The DIAM™ Spinal Stabilization System device consists of 3 main components: the H-shaped interspinous process spacer (spacer assembly), the spinous process tethers (ligament assembly), and the tether crimps. The device is packaged with the tethers pre-attached to the interspinous spacer implant. The tethers, crimps, and needles remain the same regardless of the spacer size.

The DIAM™ Spinal Stabilization System is provided by Companion Spine and made of 3 components as follows:

Component Designation		Size	Raw Material	Type of Contact with the Patient	Sterility
Spacer assembly	Core	8 to 14 mm	Dimethyl siloxane (silicone)	Long-term contact with spinous process, blood, and soft tissue	Single-use device sterilized by Gamma irradiation
	Jacket		Polyethylene terephthalate (PET)		
Ligament Assembly	Needle	Unique size	Stainless steel	Limited contact with blood and soft tissues	
	Tether		PET	Long-term contact with spinous process, blood, and soft tissue	
Crimp		Unique size	Type 2 Commercially Pure Titanium		

INDICATIONS FOR USE FOR US ONLY

The DIAM™ Spinal Stabilization System is indicated for skeletally mature patients that have moderate to severe primary low back pain (greater than leg pain) secondary to lumbar degenerative disc disease (DDD), at a single level from L2-L5 with current episode refractory to at least 6 months non-operative care.

Symptomatic disc disease is confirmed by patient history, physical examination, and radiographic evaluation with one or more of the following factors:

- Greater than 2mm of decreased disc height (average disc height) compared to the adjacent level
- Scarring/thickening of the ligamentum flavum, annulus fibrosus, or facet joint capsule
- Non-extruded herniated nucleus pulposus

The DIAM™ device is implanted via a minimally invasive posterior approach.

CONTRAINDICATIONS

The DIAM Spinal Stabilization System is contraindicated in patients with:

- An allergy to silicone, polyethylene terephthalate, or titanium;
- Spinal anatomy or disease that would prevent implantation of the device or cause the device to be unstable in situ, such as: Instability of the lumbar spine, e.g., isthmic spondylolisthesis or degenerative spondylolisthesis (anterolisthesis with more than 2mm of translation) or retrolisthesis at the involved level;
- Disc height loss greater than 67% (average disc height) at the involved level compared to the next adjacent spinal level;
- Scoliosis (Cobb angle greater than 10 degrees), flat back or kyphotic spine at the operative level;
- Severe anatomical alterations at the operative levels including congenital abnormalities, spinal tumor or evidence of prior or existing lumbar spine trauma;
- Prior surgery at operative level;
- Cauda equina syndrome defined as neural compression causing neurogenic bladder or bowel dysfunction;
- Disc degeneration requiring treatment at more than one lumbar level;
- Extruded or sequestered disc herniations;
- Large osteophytes and/ or severe hypertrophy between the vertebral bodies and/ or the facet articular process with or without severe subarticular bone erosions and/ or subchondral cysts;
- Diagnosis of osteoporosis, defined as a DEXA bone mineral density T-score equal to or less than -2.5;
- Pregnancy;
- Active systemic infection, or infection localized to the site of implantation;
- Morbid obesity defined as body mass index (BMI) greater than 40.

WARNINGS

The DIAM™ Spinal Stabilization System should only be used by physicians who are experienced and have undergone training in the use of the device. **Only physicians who are familiar with the device, instruments, procedure, clinical applications, biomechanics, adverse events, and risks associated with the DIAM™ Spinal Stabilization System should use this device. A lack of adequate experience and/or training may lead to a higher incidence of adverse events**.

- The safety and effectiveness of this device has not been established in skeletally immature patients, patients less than 22 years old, or greater than 60 years old.
- Certain anatomical characteristics have been associated with an increased risk of spinous process fractures, including patients with Baastrup sign (close approximation of adjacent spinous

processes). Distraction should always be performed gradually and carefully since the risk of spinous process fracture exists.

- This device was designed for single patient use only. Do not reprocess or reuse this product. Reuse or reprocessing may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.

PRECAUTIONS

The supraspinous ligament should be carefully preserved during surgery to avoid overstressing the bone-implant interface.

The safety and effectiveness of the DIAM™ Stabilization System has not been established in patients with the following conditions:

- More than one spinal level requiring surgical intervention.
- More than one surgical procedure at any combination of lumbar levels.
- Prior surgery at any lumbar vertebral level with instrumentation.
- Prior surgery at an adjacent lumbar vertebral level without instrumentation.
- History of Paget's disease, osteomalacia, or other metabolic bone disease.
- History of an autoimmune disease.
- Psychiatric or cognitive impairment.
- Current or recent history of illicit drug or alcohol abuse, or dependence as defined as the continued use of alcohol despite the development of social, legal, or health problems.

POTENTIAL ADVERSE EVENTS

All of the possible adverse effects or complications associated with spinal surgery are possible. The following potential adverse events may occur during the use of the DIAM™ Spinal Stabilization System:

Risks Associated with any Surgical Procedure Include:

- Anesthesia complications including allergic reaction, anaphylaxis, or other reactions to anesthesia
- Anemia
- Blood loss/ hemorrhage possibly requiring a blood transfusion with possible transfusion reaction
- Myocardial infarction
- Blood clots including pulmonary emboli
- Phlebitis
- Injury to blood vessels
- Septicemia
- Cerebral Vascular Accident (Stroke)
- Pulmonary complications including atelectasis, pneumothorax or pneumonia, pulmonary edema and respiratory distress
- False aneurysm
- Infection (wound, local, and/or systemic) abscess, cellulitis, localized or systemic, fever
- Soft tissue damage or fluid collections, including edema, hematoma or seroma, which may require drainage, aspiration, or debridement or other intervention
- Surgical wound dehiscence, necrosis, or scarring of tissue around the wound
- Impairment of the gastrointestinal system including ileus or bowel obstruction, nausea or vomiting
- Impairment of the genitourinary system including incontinence, bladder dysfunction, urinary tract infection, or reproductive system complications
- Neurological complications including nerve damage, paralysis, seizures or convulsions, changes to mental status, or reflex sympathetic dystrophy
- Numbness
- Complications of pregnancy including miscarriage or congenital defects
- Pain at surgical site
- Death.

Risks Associated with Lumbar Spine Surgery Include:

- Risks to neurological structures:
  - Dural tear dural leak and/or dural injury with or without CSF leakage
  - Arachoiditis
  - Neurologic deterioration - injury to nerves or nerve roots associated with the spinal cord (resulting in pain, weakness, paralysis (partial or complete), paresthesia, altered reflexes, numbness, tingling, or other changes in sensation)
  - Gait disturbance
  - Cerebrospinal fluid leakage
  - Cerebrospinal fistula
  - Reflex Sympathetic Dystrophy (RSD)

- New or worsening back or leg pain
- Damage to nerves, blood vessels, and nearby tissues
- Impaired muscle or nerve function
- Epidural bleeding, hematoma, or fibrosis
- Surgery at incorrect level
- Osteolysis
- Loss of bowel or bladder function
- Fracture of the vertebrae, spinous process, or other damage to bony structures during or after surgery
- Postoperative muscle and tissue pain
- Development of degenerative changes at adjacent levels
- Scarring or soft tissue damage
- Spinal instability
- Post-surgical Spondylolisthesis (vertebral slippage)
- Retrolisthesis
- Spinal stenosis (narrowing of the spinal canal)
- Spondylosis
- Infection of the bone, or surrounding soft tissue
- Perineural fibrosis
- Pain and discomfort associated with the presence of implants
- Pain and discomfort associated with the surgical procedure (e.g., cutting of muscles, ligaments, and tissue) and healing
- The spine may undergo adverse changes or deterioration including loss of proper spinal curvature, correction, height, and/or reduction, or malalignment, and another surgery may be required
- Adverse bone/implant interface reaction
- Instruments breaking or malfunctioning which may cause damage to the operative site or adjacent structures

Risks Associated with Lumbar Spine Implants (including the DIAM™ Spinal Stabilization System) Include:

- Sensitivity or allergy to the implant material [Polyethylene Terephthalate (PET), and silicone, and titanium]
- Failure of the device/procedure to improve symptoms and/or function
- Pain and discomfort associated with the operative site or presence of implants
- Implant malposition or incorrect orientation
- Sizing issues with components
- Uncrimping of the needle instrument leading to increased operation time
- Anatomical or technical difficulties implanting the device
- Spinous process fracture
- Spinous process bone resorption
- Bone loss or decrease in bone density, possibly caused by stress shielding

- Production of wear debris which may damage surrounding soft tissues including muscle or nerve
- Foreign body reaction to implant material or material debris and/or autoimmune disease
- Deep infection
- Formation of scar tissue at implant site
- Implantation at the wrong spinal level
- Migration or dislodgement of the implant from the original position so that it becomes ineffective or causes damage to adjacent bone or soft tissues including nerves
- Reoperation including revision, removal, or supplemental fixation
- Loosening, fatigue, deformation, breakage or disassembly of the implant, which may require another operation to remove the implant and may require another treatment method.

CLINICAL STUDY

A clinical study was conducted to establish a reasonable assurance of safety and effectiveness of the DIAM™ Spinal Stabilization System for treatment of primary low back pain at a symptomatic, single level (L2-L5) in the US under Investigational Device Exemption (IDE) G050025. Data from this clinical study were the basis for the PMA approval decision. This primary dataset was further supplemented with data provided from a long-term follow-up (LTFU) study, 'DIAM™ Spinal Stabilization System Long Term Follow Up Clinical Plan' (NCT 05201573). The goal of this additional study was to collect LTFU data on subjects who participated in the DIAM™ Spinal Stabilization System IDE Study and received the investigational device. A large cohort of subjects treated with the investigational device during the IDE study were evaluated at a mean final follow-up of 11.5 years. A summary of the clinical study conducted under G050025 is presented directly below.

A. Study Design

Subjects were treated between 2007 and 2014. The database for this PMA reflected data collected through 2018 and included 283 subjects. The study was a prospective, multi-center, open label, randomized, controlled clinical trial comparing the DIAM™ Spinal Stabilization System to a control group of subjects treated with non-operative care. Subjects were randomized in a ratio of 2:1 to receive either surgical implantation of the investigational DIAM™ Spinal Stabilization System or non-operative care (control group). The control group received an individualized non-operative regimen of standard of care treatments tailored specifically to each individual subject's needs. Non-operative care included patient education, as well as physical therapy, spinal injections, and medications. Control subjects were permitted to cross over to surgical treatment with the DIAM™ Spinal Stabilization System after 6-months of follow-up if their Oswestry Disability Index (ODI) score remained above 30, and a 15-point improvement in ODI was not achieved from baseline.

1. Clinical Inclusion and Exclusion Criteria

Enrollment in this clinical study was limited to subjects that met the following inclusion criteria:

- Has moderate low back pain secondary to lumbar degenerative disc disease at a single level from L2-L5. Low back pain is defined as persistent back pain, with or without radicular pain, with current episode of less than one year duration. Degenerative disc disease is confirmed by patient history, physical examination, and radiographic studies with one or more of the following factors (as measured radiographically by MRI scans or x- rays):

    - Decreased disc height >2mm, compared to the disc space at the next adjacent (superior or inferior, whichever has greater disc height) spinal level;
    - Scarring/thickening of the ligamentum flavum, annulus fibrosis, or facet joint capsule;
    - Herniated nucleus pulposus.
- Is 18-70 years of age, inclusive, and is skeletally mature.
- Has pre-treatment ODI score ≥ 30.
- Has pre-treatment back Numerical Rating Scale (NRS) pain score of ≥ 8 based on the Pre-Treatment Back and Leg Pain Questionnaire (Back Pain Intensity + Back Pain Frequency).
- Has been treated non-operatively (e.g., bed rest, physical therapy, medications, TENS, manipulation, and/or spinal injections) within a period of at least 6 weeks and not more than 6 months prior to enrollment in the clinical study.
- If of child-bearing potential, patient is not pregnant or nursing and agrees not to become pregnant during the study period.
- Is willing and able to participate in either of the randomized treatments for the duration of the study follow-up period. If the patient is randomized to the investigational group, he/she is willing to undergo surgery and receive the DIAM™ device. If the patient is randomized to the control group, he/she is willing to undergo all four non-operative treatments.
- Is willing and able to comply with the study plan and able to understand and sign the Patient Informed Consent Form.

Subjects were <u>not</u> permitted to enroll in this clinical study if they met any of the following exclusion criteria:

- Has disc height loss > 67% at the involved level, compared to the next adjacent (superior or inferior, whichever has greater disc height) spinal level.
- Has arachnoiditis.
- Has a primary diagnosis of a spinal disorder other than degenerative disc disease at the involved level.
- Requires treatment of degenerative disc disease at more than one lumbar level.
- Has had all of the following non-operative treatments (prescribed medications, active physical therapy, spinal injections, and patient education) within the past 6weeks.
- Has a sequestered herniated nucleus pulposus.
- Has had any previous surgery at the involved or adjacent spinal levels (including procedures such as a rhizotomy).
- Has received any intradiscal ablation therapy, such as intradiscal electrothermal therapy (IDET).
- Has congenital or iatrogenic posterior element insufficiency (e.g., facet resection, spondylolysis, pars fracture, or spinal bifida occulta).
- Has back pain (with or without leg, buttock, or groin pain) that is not alleviated in any spinal position.
- Has a motor deficit of the lower extremity.
- Has cauda equina syndrome.
- Has compression of nerve roots with neurogenic bowel (fecal incontinence) or bladder (urinary retention or incontinence) dysfunction.
- Has been previously diagnosed with clinically significant peripheral neuropathy.
- Has significant vascular disease causing vascular claudication.
- Has a medical contraindication that prevents the patient from receiving spinal injections (i.e., allergy to contrast media used to aid in placement of the needle in the epidural space).
- Has anterolisthesis with more than 2mm of translation at the involved level.
- Has evidence of prior fracture or trauma to the L1, L2, L3, L4, or L5 levels in either compression or burst.
- Has lumbar scoliosis with a Cobb angle of greater than 15°.

- Has lumbar kyphosis or flat back syndrome.
- Has sustained a hip fracture within the last year.
- Has any of the following (if “Yes” to any of the below risk factors, a lumbar spine DEXA Scan will be required to determine eligibility):
  - Previous diagnosis of osteoporosis, osteopenia, or osteomalacia.
  - Postmenopausal non-black female over 60 years of age who weighs less than 140 pounds.
  - Postmenopausal female who has sustained a non-traumatic hip, spine, or wrist fracture.
  - Male over the age of 60 who has sustained a non-traumatic hip or spine fracture.
  - If the level of DEXA T-score is -1.0 or lower (i.e., - 1.5, -2.0, etc.), the patient is excluded from the study.
- Has obesity defined by BMI greater than or equal to 40.
- Has a documented allergy to silicone, polyethylene, titanium or latex.
- Has overt or active bacterial infection, either local or systemic, and/or potential for bacteremia.
- Has a suppressed immune system or has taken steroids daily for more than one month within the last year (excluding low dose inhalers for the treatment of asthma).
- Has a history of autoimmune disease.
- Has presence of active malignancy or prior history of malignancy within the last 5 years (except for basal cell carcinoma of the skin).
- Has presence or prior history of a spinal malignancy.
- Has chronic or acute renal and/or hepatic failure or prior history of renal and/or hepatic parenchymal disease.
- Has any disease (e.g., neuromuscular disease) that would preclude accurate clinical evaluation of the safety and effectiveness of the treatment regimens in this study.
- Has received treatment with an investigational therapy (device and/or pharmaceutical) within 30 days prior to entering the study or such treatment is planned during the 24 months following enrollment in the study.
- Has an implantable metal device (e.g., stimulator, pacemaker) and is unable to have an MRI.
- Is an alcohol and/or drug abuser, as defined by currently undergoing treatment for alcohol and/or drug abuse.
- Is mentally incompetent. If questionable, obtain psychiatric consult.
- Has a Waddell Signs of Inorganic Behavior score of 3 or greater.
- Is a prisoner.

2. Follow-up Schedule

All subjects were scheduled to return for follow-up examination at 6 weeks, 3 months, 6 months, 12 months, 24 months post-operatively. Pre-operatively, subjects were confirmed to meet the enrollment criteria, to have given Informed Consent, along with other pre-treatment evaluations. Post-operatively, the objective parameters measured during the study included ODI, back and leg pain assessment, neurological assessment, and radiological evaluation. AEs and complications were recorded at all visits. **Table 1** includes detailed information regarding the schedule of study assessments and data collected at each timepoint. The key timepoints are shown below in the tables summarizing safety and effectiveness. Crossover subjects were assessed at the same follow-up timepoints, after being implanted with the DIAM™ Spinal Stabilization System, as investigational and control subjects originally enrolled in the study. Therefore, all presentations of safety and effectiveness results for crossover subjects below represent data collected from the point the subject received the crossover treatment, For example, 6-month crossover data represent results 6 months after subjects received the crossover treatment and not 6 months after crossover subjects were originally enrolled in the control arm of the study.

Table 1: Schedule of Study Assessments

Procedure	Study Time Period							
	Pre-Operative/ On Treatment	Surgery / Hospital / Discharge#	6Wks ± 2Wks	3M ± 2Wks	6M ± 1M	12M ± 2M	24M ± 2M & Annually Until Required Follow-Up Complete	Additional Evaluation***
Pre-Treatment Information								
Confirm subject eligibility	X							
Obtain informed consent	X							
Case Report Forms								
Medical history	X							
Pre-treatment concomitant medications	X							
Neurological status	X	X	X	X	X	X	X	X
Surgery data# and hospital discharge		X						
Non-operative treatment data (control only)	X		X	X	X	X	X	
Patient data	X		X	X	X	X	X	X
Additional medications / injections (if applicable)			X	X	X	X	X	X
Patient survey	X		X	X	X	X	X	X
ODI	X		X	X	X	X	X	X
Back & leg pain (NRS)	X		X	X	X	X	X	X
SF-36	X		X	X	X	X	X	X

Procedure	Study Time Period							
	Pre-Operative/ On Treatment	Surgery / Hospital / Discharge#	6Wks ± 2Wks	3M ± 2Wks	6M ± 1M	12M ± 2M	24M ± 2M & Annually Until Required Follow-Up Complete	Additional Evaluation***
Adverse event assessment (as needed)		X	X	X	X	X	X	X
Study deviation-patient or site (if applicable)	X	X	X	X	X	X	X	
Patient disposition**	X	X	X	X	X	X	X	
Radiologic Procedures								
Anterior/posterior	X	X	X	X	X	X	X	
Lateral	X	X	X	X	X	X	X	
Lateral Flexion/extension	X		X	X	X	X	X	
MRI	X					X	X*	
Lumbar spine DEXA scan+	X							

* Only collected through 24 months

** Filled out only once at time of subject completion or withdrawal

*** Additional Evaluation CRF's were required for subjects who were scheduled for surgery based on the unsatisfactory outcome of their original Treatment if the subject had not had an evaluation within the last 2 months prior to surgery.

applies to investigational subjects and crossover subjects

+ as required by exclusion criteria #22.

3. Clinical Endpoints

With regards to safety, the DIAM™ Spinal Stabilization System was assessed by comparison to the non-operative care control group with respect to the nature and frequency of adverse events (overall and in terms of severity and relationship to the implant), subsequent index level surgical procedures, and maintenance or improvement in neurological status. Given the ability of control subjects to cross over to the investigational group, all data available for subjects treated with the investigational device were also assessed.

With regards to effectiveness, the DIAM™ Spinal Stabilization System was assessed by comparison to the non-operative care control group with respect to a primary composite endpoint, as described below. Effectiveness was further assessed by assessing improvement in ODI, absence of Serious AEs (SAEs) that were treatment associated, and absence of subsequent surgical procedures at the index level.

Primary Endpoint

The primary composite endpoint was defined as follows:

- Pain/disability success measured as greater than or equal to 15-point improvement in ODI score relative to baseline
- No SAE classified as “implant associated,” “implant-/surgical procedure associated,” or non-operative treatment associated, and
- No additional surgical procedure at the involved level classified as a failure.

Subject success was evaluated using the primary composite endpoint above at 24 months post-operatively (Month 24).

Secondary Endpoints

Additional secondary endpoints were evaluated to further define the safety and effectiveness of the DIAM™ Spinal Stabilization System. Secondary effectiveness variables include, but were not limited to:

- ODI
- Medical Outcomes Study 36-Item Short Form Health Survey (SF-36) Physical Component Summary (PCS)
- NRS Back Pain Intensity
- Radiographic Evaluations
  - Disc Height
  - Intervertebral Angle and Angular Motion
  - Implant Location
  - Integrity of Spinous Process
- Subject Satisfaction with Study Treatment
- Subject Global Perceived Effect
- Work Status

B. Accountability of PMA Cohort

At the time of database lock, 311 subjects were enrolled in the PMA study, with n=207 randomized to the investigational group, and n=104 randomized to the non-operative control group (Intent-to-Treat (ITT) population). 90.7% (253/279) of subjects were available for analysis at Month 24.

A total of 59 subjects randomized to the non-operative control group met the pre-defined conditions and elected to crossover and receive the investigational device. This subset of subjects was then followed for at least 24 months post-operatively, using the same follow-up timepoints as the originally enrolled subjects, and assessed for primary overall success separately from the

investigational cohort. At Month 24, 98.3% (58/59) of the crossover subjects were available for analysis of the Composite Clinical Success (CCS).

A summary of the subject accounting and follow-up compliance (**Table 2**) and subject accounting tree (**Figure 1**) are presented below, followed by a description of the analysis populations.

Table 2: Subject Accounting and Follow-up Compliance for Investigational, Control, and Crossover mITT-Followed

	Month 12			Month 24		
	I	C	Crossover	I	C	Crossover
Accounting						
(1) Theoretical follow-up*	182	97	59	182	97	59
(2) Cumulative Death	0	0	0	0	1	0
(3a) Crossover	0	48	0	0	55	0
(3b) Cumulative Non-Crossover SSI Failures	6	7	1	12	9	3
(4) Not Yet Overdue	0	0	0	0	0	0
(5) Deaths + SSI Failures + Crossover among Theoretically Due	6	55	1	12	65	3
(6) Expected Due [(6)=(1)-(4)-(5)][A]	176	42	58	170	32	56
(7) SSI Failures + Crossover among Theoretically Due	6	55	1	12	64	3
(8) Expected Due + SSI Failures + Crossover among Theoretically Due [(8)=(6)+(7)]	182	97	59	182	96	59
All Evaluated Accounting (Actual[B])						
(9) Procedures with any clinical data in interval[C]	170	33	55	156	20	54
(10) Visit Compliance (%)[D]	97%	79%	95%	92%	63%	96%
(11) ODI Evaluation (censored for SSI)	170	33	55	156	20	54
(12) Back Pain Evaluation (censored for SSI)	169	33	55	155	20	53
(13) Leg Pain Evaluation (censored for SSI)	170	33	55	156	19	53
(14) Neurological Evaluation (not censored for SSI)	174	39	56	166	26	57
(15) Composite Clinical Success (CCS)	176	88	57	169	84	58
(16) Actual[B] % Follow-up for CCS[E]	97%	91%	97%	93%	88%	98%
Within Window Accounting (Actual[F])						
(17) Procedures with any clinical data in interval[C]	163	27	53	146	18	50
(18) Visit Compliance (%)[D]	93%	64%	91%	86%	56%	89%
(19) ODI Evaluation (censored for SSI)	163	27	53	146	18	50
(20) Back Pain Evaluation (censored for SSI)	162	27	53	145	18	49
(21) Leg Pain Evaluation (censored for SSI)	163	27	53	146	17	49
(22) Neurological Evaluation (not censored for SSI)	167	33	54	156	24	53
(23) Composite Clinical Success (CCS)	169	83	55	160	82	54
(24) Actual[F] % Follow-up for CCS[E]	93%	86%	93%	88%	85%	92%

* Note, 56 control subjects crossed over prior to Month 24 (n=1 had a treatment surgery first, and is captured in row (3b)). Three (3) additional subjects crossed over after Month 24 (Day 790); therefore, all 59 crossover subjects are included above.

[A] Includes subjects with no SSI prior to the visit specified.

[B] Patients with any follow-up data reviewed or evaluated by investigator ("all evaluated" accounting).

[C] Defined as ODI, back pain, or leg pain data after censoring for SSI.

[D] Denominator is row (6).

[E] Denominator is row (8).

[F] Patients with complete data for each endpoint, within window.

(1) Theoretical follow-up: The theoretical follow-up is the number of subjects that would be theoretically due for Month 12 and Month 24 follow-up before database closure. All subjects in the mITT-Followed population were theoretically due.

(2) Cumulative deaths: Cumulative deaths up to the date of the exact anniversary defining the current interval.

(3a) Crossover: Subjects who had crossover surgery prior to specified visit and the end of visit window.

(3b) Cumulative Non-Crossover SSI Failures: Subjects who had any non-crossover SSI prior to specified visit and the end of visit window. This includes revisions, removals, re-operations, supplemental fixations, and treatment surgeries.

(4) Not Yet Overdue: Includes subjects whose clinical data has not been collected, but they are in between surgical/treatment anniversary and protocol specified follow-up window. Such subjects may not yet be observed, and

follow-up compliance estimates account for this by removing such subjects from the denominator when determining compliance ratios. There are no subjects Not Yet Overdue at the time of this database lock.
(5) Deaths + SSI Failures + Crossover among Theoretically Due: This row records the sum of deaths and all SSI failures, including crossovers. The SSIs, including crossovers, must have occurred prior to the specified visit and before the end of the visit window to be counted in this row. This row is subtracted from theoretically due to determine the number expected due for clinical evaluation.
(6) Expected Due: This row is the number of subjects expected for a given time interval. This includes the theoretical number of subjects due to be evaluated minus the number who died, were SSI/Crossover failures, or were not yet overdue. **Expected = Theoretical – [Death + Failures + Not yet overdue]**. This row serves as the denominator for Visit Compliance and includes subjects lost to follow-up.
(7) SSI Failures + Crossover among Theoretically Due: SSI Failures, including crossovers, that need to be "added back" to the number of expected due to serve as the denominator for CCS counts when determining CCS follow-up compliance.
(8) Expected Due + SSI Failures + Crossover among Theoretically Due: Expected due plus theoretical due failures is computed by adding rows (6) and (7). This row serves as the denominator for CCS outcomes because CCS status is known for subjects with an SSI.
(9) and (17) Procedures with any clinical data in interval: These rows indicate the number of subjects with any ODI, back pain, or leg pain data after SSI censoring for all evaluated subjects **(9)** and for all subjects that are within window **(17)** among expected due subjects.
(10) and (18) Visit Compliance (%): These rows indicate the percentage of subjects compliant with the specified visit scheduled. **(10)** is the percentage of all evaluated among expected due subjects [**(9)** out of **(6)**], and **(18)** is the percentage of subjects within window among expected due subjects [**(17)** out of **(6)**].
(11) and (19) ODI Evaluation (censored for SSI): These rows indicate the number of subjects with any ODI data after SSI censoring for all evaluated subjects **(11)** and for all subjects that are within window **(19)** among expected due subjects.
(12) and (20) Back Pain Evaluation (censored for SSI): These rows indicate the number of subjects with any back pain data after SSI censoring for all evaluated subjects **(12)** and for all subjects that are within window **(20)** among expected due subjects.
(13) and (21) Leg Pain Evaluation (censored for SSI): These rows indicate the number of subjects with any leg pain data after SSI censoring for all evaluated subjects **(13)** and for all subjects that are within window **(21)** among expected due subjects.
(14) and (22) Neurological Evaluation (not censored for SSI): These rows indicate the number of subjects with any neurological evaluations for all evaluated subjects **(14)** and for all subjects that are within window **(22)** among expected due subjects.
(15) and (23) Composite Clinical Success (CCS): These rows indicate the number of subjects evaluable for CCS at specified visit for all evaluated subjects **(15)** and for all subjects that are within window **(23)**. Subjects are evaluable for CCS if they had any SSI or treatment-associated AE before the end of the visit window or if they had an ODI evaluation at the specified visit.
(16) and (24) Actual % Follow-up for CCS: These rows indicate the percentage of subjects evaluable for CCS at specified visit for all evaluated subjects **(16)** and for all subjects that are within window **(24)**. Subjects are evaluable for CCS if they had any SSI or treatment-associated AE before the end of the visit window or if they had an ODI evaluation at the specified visit. The denominator for percentages is expected due plus SSI failures, including crossovers **(8)**.

The subject accounting tree for the DIAM™ IDE study is depicted below in **Figure 1**.

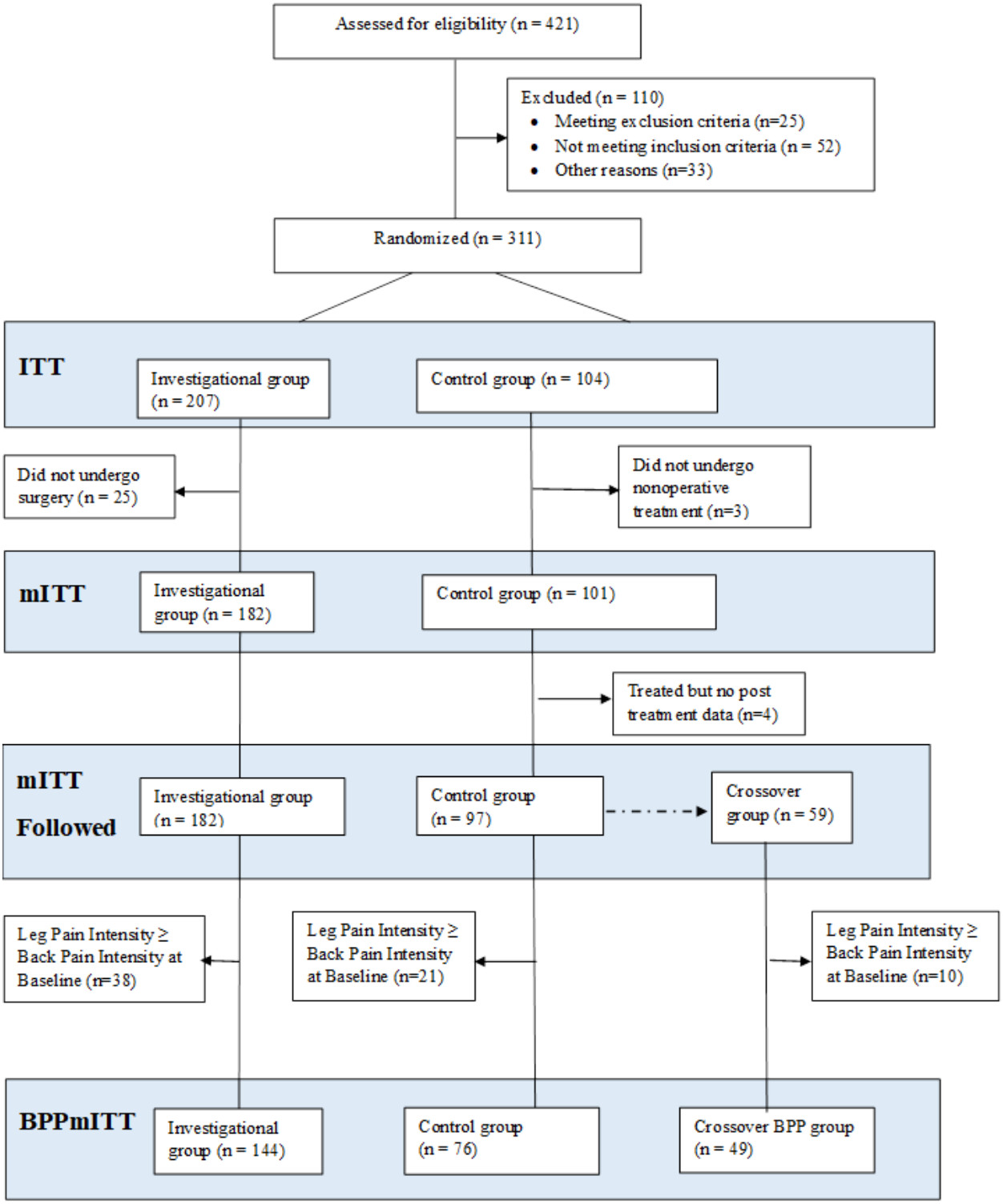


Figure 1: Subject Accounting Tree

Analysis Populations

For the purpose of assessing safety and effectiveness, the following analysis populations were used:

- ***ITT Analysis Set – 311 Subjects:*** The ITT analysis set included all subjects randomized to either the DIAM™ Spinal Stabilization System or non-operative care. This included 207 subjects randomized to DIAM™ Spinal Stabilization System and 104 subjects randomized to non-operative care.

- ***Modified Intent-to-Treat (mITT) Analysis Set – 283 Subjects:*** The mITT analysis set includes all subjects in the ITT analysis set for which treatment was attempted. This includes 182 DIAM™ Spinal Stabilization System subjects and 101 non-operative care subjects. The DIAM™ Spinal Stabilization System mITT analysis set includes one subject in which treatment was initiated and but not completed due to an intraoperative adverse event. This subject was defined as a composite endpoint failure. The non-operative care mITT analysis set includes 4 subjects that initiated non-operative care but for whom there was no follow-up.

- ***Modified Intent-to-Treat Followed (mITT-Followed) Analysis Set – 279 Subjects:*** The mITT-Followed analysis set includes all subjects in the mITT analysis set with any follow-up. Therefore, this is the mITT analysis set excluding the 4 controls that completed treatment but who had no post treatment follow-up. The sample sizes are 182 DIAM™ Spinal Stabilization System subjects and 97 non-operative care controls.

Safety data are presented for the mITT-Followed analysis set.

- ***Back Pain Predominate Modified Intent-to-Treat (BPPmITT) Analysis Set – 220 Subjects:*** The BPPmITT analysis set is a subset of the mITT-Followed dataset which excludes subjects with leg pain intensity scores ≥ back pain intensity scores at baseline. This analysis set comprises 144 DIAM™ Spinal Stabilization System subjects and 76 non-operative care controls. The BPPmITT analysis set was designated the primary endpoint analysis population.

Effectiveness data are presented for the BPPmITT analysis set due to the retrospective modification to the Indications for Use Statement for the DIAM™ Spinal Stabilization System.

- ***Crossover Analysis Set – 59 Subjects:*** This analysis set includes all subjects who were randomized to the control group and elected to receive the DIAM™ Spine Stabilization System as a treatment surgery. A total of 59 control subjects ultimately crossed over to receive the DIAM™ Spinal Stabilization System treatment: 56 within 24-months and 3 additional after the 24-month visit. For crossover subjects, outcome measurements after implanting the investigational device were summarized as crossover cohort and compared to measurements obtained immediately prior to surgery.

Effectiveness data are also presented for a subset of crossover subjects (Crossover BPP), including 49 crossover subjects with back pain intensity scores > leg pain intensity scores.

C. Study Population Demographics and Baseline Parameters

Demographics and baseline parameters are provided for the mITT analysis set (182 investigational; 101 non-operative care) (all randomized subjects in whom study treatment was attempted) and all 59 subjects included in the crossover sub-group. All available demographics and baseline data are presented. As shown below, overall, the treatment groups had similar mean age, height, weight, and BMI, gender distribution, race distribution, education level distribution, proportion of subjects with ongoing spinal litigation, history of prior back surgery, and smoking history. In addition to the similarities in demographics, the investigational and non-operative care control groups had similar

baseline scores, including mean ODI scores, NRS back pain, SF-36 mental scores and SF-36 physical scores. In summary, randomization was effective in providing a well-balanced study population, with similar demographic, baseline, and clinical characteristics between the investigational and non-operative care control groups.

The baseline and demographics for the mITT analysis population are summarized in **Table 3**, **Table 4**, **Table 5**, and **Table 6** for continuous variables, categorical variables, clinical endpoints, and neurological status, respectively. The data demonstrate the two treatment groups have no major difference in terms of characteristics of enrolled subjects. The demographics of the study population are typical for a spine study performed in the US.

Table 3: Summary of Baseline and Demographic Continuous Variables – Investigational, Control, and Crossover mITT

	Investigational						Control						Crossover					
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max
Age (years)	182	42.5	11.0	43.5	18.0	69.0	101	44.6	10.4	44.0	23.0	70.0	59	45.8	10.2	45.0	23.0	70.0
Height (in)	182	67.5	3.6	67.0	59.0	78.0	101	67.8	4.3	68.0	60.0	77.0	59	67.9	4.4	68.0	60.0	77.0
Weight (lbs)	182	183.7	39.6	181.0	108.0	320.0	101	188.2	44.5	185.0	108.0	318.0	59	186.9	47.8	185.0	108.0	311.0
BMI (kg/m^2)	182	28.3	5.2	27.4	18.5	41.1	101	28.6	5.6	27.8	17.4	39.7	59	28.3	5.9	27.3	17.4	39.3

Table 4: Summary of Baseline and Demographic Categorical Variables – Investigational, Control, and Crossover mITT

	Investigational			Control			Crossover		
	N	n	%	N	n	%	N	n	%
Sex									
Female	182	105	57.7%	101	50	49.5%	59	29	49.2%
Male	182	77	42.3%	101	51	50.5%	59	30	50.8%
Race									
Caucasian	182	167	91.8%	101	92	91.1%	59	55	93.2%
Black	182	3	1.6%	101	5	5.0%	59	1	1.7%
Asian	182	1	0.5%	101	0	0.0%	59	0	0.0%
Hispanic	182	11	6.0%	101	1	1.0%	59	1	1.7%
Other	182	0	0.0%	101	3	3.0%	59	2	3.4%
Education Level									
< High School	182	13	7.1%	101	7	6.9%	59	3	5.1%
High School	182	50	27.5%	101	22	21.8%	59	11	18.6%
> High School	182	117	64.3%	101	72	71.3%	59	45	76.3%
Not Reported	182	2	1.1%	101	0	0.0%	59	0	0.0%
Spinal Litigation									
Yes	182	25	13.7%	101	11	10.9%	59	7	11.9%
No	182	157	86.3%	101	90	89.1%	59	52	88.1%
Back Surgery Hx									
Yes	182	1	0.5%	101	4	4.0%	59	2	3.4%
No	182	181	99.5%	101	97	96.0%	59	57	96.6%
Tobacco									
Yes	182	46	25.3%	101	34	33.7%	59	18	30.5%
No	182	134	73.6%	101	65	64.4%	59	40	67.8%
Not Reported	182	0	0.0%	101	0	0.0%	59	1	1.7%

Table 5: Comparison of Baseline Clinical Endpoints – Investigational, Control, and Crossover mITT

	Investigational						Control						Crossover					
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max
Back Pain*	182	16.8	2.3	17.0	9.0	20.0	101	16.2	2.8	17.0	8.0	20.0	59	16.4	2.7	17.0	8.0	20.0
Leg Pain*	182	10.3	6.2	12.0	0.0	20.0	101	9.1	6.5	10.0	0.0	20.0	59	10.3	6.9	12.0	0.0	20.0
ODI	182	50.4	13.9	48.0	30.0	94.0	101	50.4	13.2	50.0	30.0	82.0	59	55.4	13.1	54.0	32.0	96.0
SF36: MCS	181	36.0	9.0	36.6	13.4	54.0	101	35.9	9.7	37.0	11.0	56.0	59	35.2	10.1	35.8	16.3	51.9
SF36: PCS	181	31.5	6.3	30.5	16.4	47.8	101	30.5	5.7	29.8	19.8	46.5	59	29.7	5.3	28.5	21.7	43.1

*Baseline Back Pain and Leg Pain Scores were each evaluated on a 0-20 scale comprising pain intensity (0-10) and pain frequency (0-10) components.

Table 6: Summary of Baseline Neurological Status – Investigational, Control, and Crossover mITT

	Investigational			Control			Crossover		
	N	n	%	N	n	%	N	n	%
Normal Motor Function	182	182	100.0%	101	101	100.0%	59	58	98.3%
Normal Sensory Function	182	164	90.1%	101	95	94.1%	59	56	94.9%
Normal Reflexes	182	164	90.1%	101	92	91.1%	59	54	91.5%
Normal Straight Leg Raise	182	151	83.0%	101	79	78.2%	59	49	83.1%

Data was collected on the type of non-operative care received by control subjects in the mITT population. Treatments received by control subjects at the initial treatment included: education (99% - 100/101); medication (82.2% - 83/101); physical therapy (68.3% - 69/101); and spinal injection (36.6% - 37/101).

The continuous operative variables are summarized in **Table 7** for subjects randomized to the investigational group and subjects who were randomized to the non-operative care control group and subsequently elected to crossover**.** The average operative times were 62.6 minutes and 59.5 minutes with mean blood loss of 31.4 mL and 35.6 mL in the investigational and crossover groups, respectively. Most subjects were discharged from the hospital in less than a day with a mean length of stay of 0.8 days reported in both the investigational and crossover cohorts. General anesthesia was utilized for all investigational and crossover subjects with a reported anesthesia type. In both the investigational and crossover cohorts, the majority of subjects were treated at L4-L5. In the investigational cohort, 4.9% (9/182) subjects were treated at L2-L3, 7.1% (13/182) were treated at L3-L4, and 87.9% (160/182) were treated at L4-L5. The distribution of levels treated was similar in the crossover subjects: 3.4% (2/59) at L2-L3, 5.1% (3/59) at L3-L4, 89.8% (53/59) at L4-L5, and 1.7% (1/59) at L5-L6 (anatomic variant). Regarding surgery site, 62.1% (113/182) and 59.3% (35/59) of subjects were treated in outpatient procedures, and 37.9% (69/182) and 40.7% (24/59) were inpatient procedures in the investigational and crossover groups, respectively.

Table 7: Summary of Operative Details – Continuous Variables Investigational mITT-Followed and Crossover

	Investigational						Crossover					
	N	Mean	SD	Med	Min	Max	N	Mean	SD	Med	Min	Max
Surgery Time (min)	182	62.6	18.7	60.0	21.0	123.0	59	59.5	20.3	56.0	25.0	138.0
Blood Loss (mL)	182	31.4	26.9	25.0	0.0	100.0	59	35.6	29.9	23.0	9.0	100.0
Length of Stay (days)	182	0.8	0.7	1.0	0.0	3.0	59	0.8	0.9	1.0	0.0	6.0

D. Safety and Effectiveness Results

1. Safety Results

The analysis of safety was based on the mITT-Followed Analysis population of 279 subjects available beyond the Month 24 evaluation (day 790). Note that the listings of days related to

adverse event results (e.g., “day 790”) represents the upper bound of the follow-up window (e.g., 24 months + 2 months). The key safety outcomes for this study are presented below in **Table 8** to **Table 20**.

Adverse Event Summary

The safety endpoint evaluated the rate of AEs, categorized by severity (mild, moderate or severe), relationship to the implant, surgical procedure, or non-operative care, and SAEs. AEs were reviewed by an independent Clinical Events Committee (CEC) and adjudicated for severity and relationship to the non-operative care, implant, and/or surgical procedure in accordance with the definitions provided below.

Severity

AEs were assessed for severity using the following definitions:

- **Mild (Grade 1)** – Noticeable to the subject but did not interfere with routine activity, and for subjects in the investigational group, the AE did not require removal of the implant;
- **Moderate (Grade 2)** – Interfered with routine activity but responded to symptomatic therapy or rest, and for subjects in the investigational group, the AE did not require removal of the implant;
- **Severe (Grade 3)** – Significantly limited the subject’s ability to perform routine activities despite symptomatic therapy, and for subjects in the investigational group, the AE may require removal of the implant; and,
- **Life-threatening (Grade 4)** – The subject is at immediate risk of death, and for subjects in the investigational group, the AE may require removal of the implant.

Serious Adverse Events

An SAE was defined as an AE that: led to a death; led to fetal distress, fetal death, or a congenital abnormality or birth defect; or, led to a serious deterioration in health of the subject that:

- Resulted in a life-threating illness or injury;
- Resulted in permanent impairment of a body structure or function;
- Required in-patient hospitalization or prolongation of existing hospitalization; or
- Resulted in medical or surgical intervention to prevent permanent impairment to body structure or a body function.

Association with Study Treatment

For investigational and crossover subjects (i.e., subjects randomized to non-operative care who elected to undergo implantation with the DIAM™ Spinal Stabilization System), association of an AE with the investigational treatment was assessed according to the following definitions:

- **Implant-Associated AE:** An AE for which there was a reasonable possibility that the event may have been caused primarily by the implant/implant component.
- **Surgical Procedure-Associated AE:** An AE for which there was a reasonable possibility that the event may have been caused primarily by the surgical procedure.
- **Implant/Surgical Procedure-Associated AE:** An AE for which there was a reasonable possibility that the event may have been caused primarily by the implant/implant component and/or the surgical procedure but cannot be definitively associated exclusively with the implant or exclusively with the surgical procedure.
- **Undetermined AE:** An AE for which sufficient information to determine the causality of the event was not available.
- **Not Related AE:** An AE for which sufficient information existed to indicate that the etiology of the event was unrelated to the study treatment.

For non-operative care control subjects, association of an AE with non-operative care treatments was assessed according to the following definitions:

- **Non-operative Treatment Associated AE:** An AE for which there was a reasonable possibility that the event may have been caused primarily by the non-operative treatment.

- **Undetermined AE:** An AE for which sufficient information was not available to determine its causality.
- **Not Related AE:** An AE for which sufficient information existed to indicate that the etiology of the event was unrelated to the study treatment.

For any event categorized by CEC as implant-associated, surgical procedure-associated, implant/surgical procedure-associated, or non-operative care associated, the CEC assigned the following relationship categories.

- **Definitely Associated:** An AE that has a strong causal relationship. An AE that follows a strong temporal relationship, follows a known response pattern, and cannot reasonably be explained by known characteristics of the subject's clinical state or other therapies.
- **Probably Associated:** An AE that potentially has a causal relationship. The AE has a reasonable temporal relationship and alternative etiology is less likely compared to the potential relationship to the use of the investigational device/procedure or non-operative treatment (control only).
- **Possibly Associated:** An AE that potentially has a causal relationship. The AE has a reasonable temporal relationship to the use of the investigational device/procedure, but alternative etiology is equally likely compared to the potential relationship to the use of the investigational device/procedure or non-operative treatment (control only).

Please note, the Month 24 and Month 60 safety tables below present all AEs that occurred within that interval following initial randomized treatment to the investigational or control arms, regardless of whether the subject received additional treatment. Accordingly, AEs presented for the control group include AEs that occurred after crossover treatment. However, AEs presented for the crossover group do not include AEs that occurred prior to subjects receiving the crossover treatment. The tables displaying treatment-associated events provide context on whether events that occurred over the 24-month (day 790) or 60-month (day 1,885) intervals were associated to the implant and/or surgical procedure.

Further, a separate set of select safety tables that list AEs through six months (day 210) are provided since the comparison between the investigational and non-operative care control treatments through 6 months is not impacted by AEs occurring after crossover in the control group at later timepoints.

AEs through Month 6 for the investigational, crossover, and control groups are reported in **Table 8**. The results indicate that through Month 6, 76.9% (140/182) of investigational subjects, 66.0% (64/97) of control subjects, and 76.3% (45/59) of crossover subjects experienced at least one AE. The percentage of subjects who reported at least one SAE was 13.7% (25/182) in the investigational group, 22.7% (22/97) in the control group, and 15.3% (9/59) in the crossover group. While more subjects in the investigational and crossover groups experienced an AE, this is not unexpected for an implant relative to non-operative care.

Table 8: Comparison of Summary of Safety Events up to 6 Months – Investigational and Control mITT-Followed and Crossover

	Investigational (N=182)			Control (N=97)			Crossover (N=59)		
	Events	n	%	Events	n	%	Events	n	%
Any adverse event	319	140	76.9%	117	64	66.0%	92	45	76.3%
Any implant/surgical procedure associated AE	6	6	3.3%	0	0	0.0%	2	2	3.4%
Any implant only associated AE	1	1	0.5%	0	0	0.0%	1	1	1.7%
Any surgical procedure only associated AE	46	44	24.2%	0	0	0.0%	25	22	37.3%
Any nonoperative treatment associated AE	0	0	0.0%	1	1	1.0%	0	0	0.0%
Any serious AE	27	25	13.7%	23	22	22.7%	9	9	15.3%
Any implant/surgical procedure associated SAE	3	3	1.6%	0	0	0.0%	0	0	0.0%
Any implant only associated SAE	0	0	0.0%	0	0	0.0%	0	0	0.0%
Any surgical procedure only associated SAE	10	10	5.5%	0	0	0.0%	6	6	10.2%
Any nonoperative treatment associated SAE	0	0	0.0%	1	1	1.0%	0	0	0.0%
Spinous Process Fracture	13	13	7.1%	0	0	0.0%	5	5	8.5%
Deaths	0	0	0.0%	0	0	0.0%	0	0	0.0%

Only adverse events through the first 210 days are included.

AEs through Month 24 for the investigational, crossover, and control groups are reported in **Table 9**. The results indicate that through Month 24, 92.9% (169/182) of investigational subjects, 89.7% (87/97) of control subjects, and 91.5% (54/59) of crossover subjects experienced at least one AE. It should be noted that some AEs captured under the control group through Month 24 may be related to subjects that crossed over. Nevertheless, the investigational and crossover subjects experienced an AE rate within only a few percent higher than the control group, and this again is to be expected with an implant relative to non-operative care.

Table 9: Comparison of Summary of Safety Events up to 24 Months – Investigational and Control mITT-Followed and Crossover

	Investigational (N=182)			Control (N=97)			Crossover (N=59)		
	Events	n	%	Events	n	%	Events	n	%
Any adverse event	638	169	92.9%	314	87	89.7%	173	54	91.5%
Any implant/surgical procedure associated AE	6	6	3.3%	0	0	0.0%	2	2	3.4%
Any implant only associated AE	4	4	2.2%	0	0	0.0%	1	1	1.7%
Any surgical procedure only associated AE	46	44	24.2%	0	0	0.0%	27	24	40.7%
Any nonoperative treatment associated AE	0	0	0.0%	2	2	2.1%	0	0	0.0%
Any serious AE	69	59	32.4%	47	42	43.3%	19	16	27.1%
Any implant/surgical procedure associated SAE	3	3	1.6%	0	0	0.0%	1	1	1.7%
Any implant only associated SAE	2	2	1.1%	0	0	0.0%	0	0	0.0%
Any surgical procedure only associated SAE	10	10	5.5%	0	0	0.0%	6	6	10.2%
Any nonoperative treatment associated SAE	0	0	0.0%	2	2	2.1%	0	0	0.0%
Spinous Process Fracture	14	14	7.7%	0	0	0.0%	6	6	10.2%
SSI	13	12	6.6%	68	65	67.0%	4	3	5.1%
Deaths	1*	1	0.5%	1**	1	1.0%	0	0	0.0%

Only adverse events through the first 790 days are included.
*Cause of death was acidosis and septic shock at approximately 24 months post-operatively.
**Cause of death was hypertensive cardiomegaly at 23 months post-treatment.

The mITT-Followed population (investigational and non-operative care) and the crossover population also reported comparable rates of AEs through the 60-month follow-up, as shown below. The overall adverse event rate was 96.2% (175/182) in the investigational group, 93.8% (91/97) in the control group, and 94.9% (56/59) in the crossover group. Similar proportions of subjects in the investigational, control, and crossover treatment groups experienced any SAE during the 60-month follow-up. The percentage of subjects who reported at least one SAE was 42.3% (77/182) in the

investigational group, 52.6% (51/97) in the control group, and 40.7% (24/59) in the crossover group. Compared to Month 24, there were no significant differences in the rates of implant-associated, surgical procedure-associated, or implant/surgical procedure-associated SAEs reported in the investigational and crossover subjects at Month 60. A similar trend was observed in the SSI rates reported across all three treatment groups.

Table 10: Comparison of Summary of Safety Events up to 60 Months – Investigational and Control mITT-Followed and Crossover

	Investigational (N=182)			Control (N=97)			Crossover (N=59)		
	Events	n	%	Events	n	%	Events	n	%
Any adverse event	1033	175	96.2%	507	91	93.8%	269	56	94.9%
Any implant/surgical procedure associated AE	6	6	3.3%	0	0	0.0%	2	2	3.4%
Any implant only associated AE	4	4	2.2%	0	0	0.0%	2	2	3.4%
Any surgical procedure only associated AE	46	44	24.2%	0	0	0.0%	27	24	40.7%
Any nonoperative treatment associated AE	0	0	0.0%	2	2	2.1%	0	0	0.0%
Any serious AE	110	75	41.2%	58	47	48.5%	32	24	40.7%
Any implant/surgical procedure associated SAE	3	3	1.6%	0	0	0.0%	1	1	1.7%
Any implant only associated SAE	2	2	1.1%	0	0	0.0%	0	0	0.0%
Any surgical procedure only associated SAE	10	10	5.5%	0	0	0.0%	6	6	10.2%
Any nonoperative treatment associated SAE	0	0	0.0%	2	2	2.1%	0	0	0.0%
Spinous Process Fracture	14	14	7.7%	0	0	0.0%	6	6	10.2%
SSI	20	18	9.9%	71	68	70.1%	7	5	8.5%
Deaths	2*	2	1.1%	1**	1	1.0%	0	0	0.0%

Only adverse events through the first 1,885 days are included.
*Cause of death was acidosis and septic shock at approximately 24 months post-operatively.
**Cause of death was hypertensive cardiomegaly at 23 months post-treatment.

Counts and percentages of subjects with specific AEs through Month 6 are presented in the table below (**Table 11)**. No control subjects received crossover treatment prior to 6 months; therefore, data presented in the table below is a more representative comparison of AE rates between treatment with the investigational subjects and non-operative care subjects as compared to AE rates collected after 6 months (which include crossover and other surgical treatments in the control group). At Month 6, the most commonly reported AEs were: back and/or leg pain (of back etiology) (22.0% - 40/182) and accidental injury/muscle strain (14.3% - 26/182) in the investigational group; spinal event at target level (21.6% - 21/97) and back and/or leg pain (of back etiology) (15.5% - 15/97) in the non-operative care control group; and, back and/or leg pain (of back etiology) (23.7% - 14/59), lower extremity pain (not of back etiology) (11.9% - 7/59) and spinal event at target level (11.9% - 7/59) in the crossover group.

Table 11: Counts and Percentages of Subjects with Specific Safety Events up to 6 Months – Investigational and Control mITT-Followed and Crossover

	Investigational (N=182)			Control (N=97)			Crossover (N=59)		
	Events	n	%	Events	n	%	Events	n	%
All AEs	319	140	76.9%	117	64	66.0%	92	45	76.3%
Accidental Injury/Muscle Strain	26	26	14.3%	4	4	4.1%	5	4	6.8%
Allergic Reaction	1	1	0.5%	0	0	0.0%	1	1	1.7%
Back and/or Leg Pain (of back etiology)	43	40	22.0%	16	15	15.5%	14	14	23.7%
Cancer[1]	1	1	0.5%	0	0	0.0%	0	0	0.0%
Cardiovascular (i.e., M.I., Stroke)	2	2	1.1%	2	2	2.1%	3	3	5.1%
Cervical Spine Event	5	5	2.7%	4	4	4.1%	5	5	8.5%
Depression	7	7	3.8%	1	1	1.0%	1	1	1.7%
Electrolyte Imbalance	4	4	2.2%	0	0	0.0%	0	0	0.0%
Endocrine (i.e., Hypothyroid, etc.)	0	0	0.0%	1	1	1.0%	0	0	0.0%
Gastrointestinal-Other[2]	17	10	5.5%	6	6	6.2%	1	1	1.7%
Hematological	1	1	0.5%	0	0	0.0%	0	0	0.0%
Incision-Related[3]	12	12	6.7%	0	0	0.0%	6	6	10.2%
Infection[4]	13	12	6.6%	8	7	7.2%	3	3	5.1%
Infection UTI	2	2	1.1%	0	0	0.0%	1	1	1.7%
Lower Extremity (not of back etiology, i.e., knee, ankle)	24	20	11.0%	10	7	7.2%	8	7	11.9%
Malpositioned Implant	0	0	0.0%	1	1	1.0%	1	1	1.7%
Neck and Arm Pain	2	2	1.1%	1	1	1.0%	0	0	0.0%
Neurological	9	9	4.9%	4	2	2.1%	1	1	1.7%
Other[5]	20	16	8.8%	10	9	9.3%	1	1	1.7%
Other Pain[6]	11	9	4.9%	2	2	2.1%	0	0	0.0%
Prolonged postoperative sequalae	9	9	4.9%	4	3	3.1%	7	6	10.2%
Psychological	1	1	0.5%	2	2	2.1%	1	1	1.7%
Radiculopathy/Sciatica without back pain	10	9	4.9%	0	0	0.0%	5	5	8.5%
Respiratory	6	6	3.3%	1	1	1.0%	3	3	5.1%
Retrograde Ejaculation	1	1	0.5%	0	0	0.0%	0	0	0.0%
Skin Disorder	1	1	0.5%	1	1	1.0%	0	0	0.0%
Spinal Event at Other Lumbar Level	9	8	4.4%	4	4	4.1%	2	2	3.4%
Spinal Event at Target Level[7]	18	18	9.9%	21	21	21.6%	7	7	11.9%
Subsidence	0	0	0.0%	0	0	0.0%	1	1	1.7%
Superficial Incision Infection	15	15	8.2%	0	0	0.0%	2	2	3.4%
Systemic[8]	1	1	0.5%	1	1	1.0%	6	5	8.5%
Trauma[9]	27	16	8.8%	5	3	3.1%	3	3	5.1%
Upper Extremity Pain (not of neck etiology, i.e., shoulder, arm)	15	12	6.6%	7	6	6.2%	3	3	5.1%
Urogenital	8	6	3.3%	1	1	1.0%	0	0	0.0%
Vascular Event Post-Op Peripheral/DVT	0	0	0.0%	0	0	0.0%	1	1	1.7%

Only adverse events through the first 210 days are included.

[1]Cancer: cervical cancer

[2]Gastrointestinal-Other: nausea, epigastric pain

[3]Incision-Related: pain on the incision site, delayed wound healing, erthema, bruising, hematoma, rash

[4]Infection: viral illness, sinus infection, pneumonia, common cold, otitis, flu, pharyngitis, cough, zona, cold symptoms, respiratroy infection, systemic

[5]Other: needle issue, eye disorder, miscarriage, gynecological disorder, breast surgery, dental surgery

[6]Other Pain: migraine headache, ankylosing spondylitis, extreme low back pain

[7]Spinal Event at Targey Level - bilateral hip pain radiating from surgical site, low back pain with or without leg pain, discogenic pain, disc herniation/stenosis/slip, facet joint changes, spinous process fracture, numbness/paresthesia

[8]Systemic: mental confusion, lupus, hypercholesterolemia, polycythemia, insomnia, hypertension, weight gain, allergies

[9]Trauma: fall or motor vehicle accident or other trauma resulting in a broken or sprained foot, ankle, hand; meniscal tear, or temporary increase in back pain

Counts and percentages of subjects with specific AEs through Month 24 are presented in **Table 12**. Importantly, control group AE counts in **Table 12** include AEs for subjects that received crossover treatment or other surgical interventions after Month 6 and should not be considered representative of AEs associated with non-operative care alone. At Month 24, the most commonly reported AEs were: back and/or leg pain (of back etiology) (36.8% - 67/182) and lower extremity

pain (not of back etiology) (21.4% - 39/182) in the investigational group; spinal event at target level (36.1% - 35/97) and back and/or leg pain (of back etiology) (33.0% - 32/97) in the non-operative care control group; and, back and/or leg pain (of back etiology) (37.3% - 22/59) and lower extremity pain (not of back etiology) (23.7% - 14/59) in the crossover group.

Table 12: Counts and Percentages of Subjects with Specific Safety Events up to 24 Months – Investigational and Control mITT-Followed and Crossover

	Investigational (N=182)			Control (N=97)			Crossover (N=59)		
	Events	n	%	Events	n	%	Events	n	%
All AEs	638	169	92.9%	314	87	89.7%	173	54	91.5%
Accidental Injury/Muscle Strain	42	35	19.2%	16	15	15.5%	11	10	16.9%
Allergic Reaction	5	5	2.7%	3	3	3.1%	2	2	3.4%
Back and/or Leg Pain (of back etiology)	76	67	36.8%	37	32	33.0%	24	22	37.3%
Cancer[1]	3	3	1.6%	0	0	0.0%	0	0	0.0%
Cardiovascular (i.e., M.I., Stroke)	12	12	6.6%	7	7	7.2%	5	5	8.5%
Cervical Spine Event	10	9	4.9%	7	7	7.2%	7	7	11.9%
Death[2]	0	0	0.0%	1	1	1.0%	0	0	0.0%
Depression	12	12	6.6%	3	3	3.1%	3	3	5.1%
Dysphagia	0	0	0.0%	1	1	1.0%	1	1	1.7%
Electrolyte Imbalance	4	4	2.2%	0	0	0.0%	0	0	0.0%
Endocrine (i.e., Hypothyroid, etc.)	4	4	2.2%	3	3	3.1%	1	1	1.7%
Gastrointestinal-Other[3]	46	26	14.3%	7	6	6.2%	6	5	8.5%
Hematological	4	4	2.2%	1	1	1.0%	0	0	0.0%
Incision-Related[4]	10	10	5.5%	8	8	8.2%	7	7	11.9%
Infection[5]	45	29	15.9%	23	16	16.5%	3	3	5.1%
Infection UTI	5	4	2.2%	1	1	1.0%	2	2	3.4%
Lower Extremity (not of back etiology, i.e., knee, ankle)	46	39	21.4%	26	19	19.6%	19	14	23.7%
Malpositioned Implant	0	0	0.0%	1	1	1.0%	1	1	1.7%
Neck and Arm Pain	9	7	3.8%	6	5	5.2%	0	0	0.0%
Neurological	16	15	8.2%	12	10	10.3%	3	3	5.1%
Other[6]	46	33	18.1%	24	17	17.5%	9	8	13.6%
Other Pain[7]	28	22	12.1%	6	6	6.2%	0	0	0.0%
Prolonged postoperative sequelae	9	9	4.9%	5	4	4.1%	7	6	10.2%
Psychological	7	7	3.8%	8	7	7.2%	4	4	6.8%
Radiculopathy/Sciatica without back pain	13	12	6.6%	2	2	2.1%	6	6	10.2%
Respiratory	10	10	5.5%	6	6	6.2%	8	7	11.9%
Retrograde Ejaculation	1	1	0.5%	0	0	0.0%	0	0	0.0%
Skin Disorder	3	3	1.6%	2	2	2.1%	0	0	0.0%
Spinal Event at Other Lumbar Level	14	12	6.6%	6	6	6.2%	4	4	6.8%
Spinal Event at Target Level[8]	33	33	18.1%	36	35	36.1%	9	9	15.3%
Subsidence	0	0	0.0%	0	0	0.0%	1	1	1.7%
Superficial Incision Infection	15	15	8.2%	0	0	0.0%	2	2	3.4%
Systemic[9]	2	2	1.1%	2	2	2.1%	9	7	11.9%
Trauma[10]	54	31	17.0%	29	20	20.6%	6	4	6.8%
Upper Extremity Pain (not of neck etiology, i.e., shoulder, arm)	23	19	10.4%	17	14	14.4%	11	9	15.3%
Urogenital	30	20	11.0%	7	7	7.2%	0	0	0.0%
Vascular Event Post-Op Peripheral/DVT	1	1	0.5%	1	1	1.0%	2	2	3.4%

Only adverse events through the first 790 days are included.

[1]Cancer: cervical cancer

[2]Death: cardiac arrest

[3]Gastrointestinal Other: gastrointestinal illness such as epigastric or abdominal pain, nausea and vomiting, stomach virus, constipation, abdominal cramping, hernia, cholecystitis, pancreatitis

[4]Incision-Related: pain on the incision site, delayed wound healing, erythema, bruising, hematoma, rash

[5]Infection: viral illness, sinus infection, pneumonia, common cold, otitis, flu, pharyngitis, cough, zona, cold symptoms, respiratory infection, mononucleosis, varicella-zoster, systemic

[6]Other: needle issue, eye disorder, miscarriage, gynecological disorder, sinusitis, ENT disorder, breast surgery, opioid dependence

[7]Other Pain: (migraine) headache, ankklyosing spondylitis, extreme low back pain, fibromyalgia, panic attack, eye injury, pain post childbirth

[8]Spinal Event at Target Level: bilateral hip pain radiating from surgical site, low back pain with or without leg pain, discogenic pain, disc herniation/stenosis/slip, facet joint changes, spnious process fracture, spinous process bony erosion, numbness/paresthesia

[9]Systemic: mental confusion, luppus, hypercholesterolemia, polycythemia, insomnia, hypertension, weight gain, allergies

[10]Trauma: fall or motor vehicle accident or other trauma resulting in a broken or sprained foot, ankle, nose, hand, or tooth; meniscal tear, rotator cuff tear, bruising, contusion or temporary increase in back pain

Table 13 provides a comparison of all AEs through Month 24 (day 790) reported in the investigational, non-operative care control, and crossover groups, classified as mild, moderate, severe, or life-threatening. At Month 24, 17.7% (113/182) of investigational subjects, 22.6% (71/97) of non-operative care control subjects, and 11.6% (20/59) of crossover subjects experienced AEs categorized as severe. However, it should be noted that control group AE counts after Month 6 included AEs for subjects that received crossover treatment or other surgical interventions, and should not be considered representative of AEs associated with non-operative treatment alone.

Table 13: Comparison of All Safety Events by Severity Through 24 Months – Investigational and Control mITT-Followed and Crossover

	Mild		Moderate		Severe		Life-Threatening		Total
	Events	%*	Events	%*	Events	%*	Events	%*	Events
Investigational (n=182)	152	23.8%	372	58.3%	113	17.7%	1	0.2%	638
Non-Operative Care (n=97)	81	25.8%	160	51.0%	71	22.6%	2	0.6%	354
Crossover (n=59)	113	65.3%	40	23.1%	20	11.6%	0	0.0%	173
*Percentage of total events									

Treatment-Associated Adverse Events

Below, the counts and percentages of all implant- and surgical procedure-associated AEs, in the investigational and crossover groups are shown in **Table 14.** There were 2 AEs (both SAEs) in 2 subjects (2.1%) that were non-operative care-associated, which were both classified as worsening back pain.

Table 14: Counts and Percentages of Implant- and Surgical Procedure-Associated Adverse Events Through 24 Months - Investigational mITT-Followed and Crossover

	Investigational (N=182)			Crossover (N=59)		
	Events	n	%	Events	n	%
All AEs	56	52	28.6%	30	25	42.4%
Accidental Injury/Muscle Strain	1	1	0.5%	0	0	0.0%
Allergic Reaction	0	0	0.0%	1	1	1.7%
Back and/or Leg Pain (of back etiology)	3	3	1.6%	0	0	0.0%
Cardiovascular (i.e., M.I., Stroke)	0	0	0.0%	1	1	1.7%
Gastrointestinal-Other[1]	1	1	0.5%	0	0	0.0%
Incision-Related[2]	11	11	6.0%	7	7	11.9%
Infection[3]	0	0	0.0%	1	1	1.7%
Lower Extremity (not of back etiology, i.e., knee, ankle)	1	1	0.5%	0	0	0.0%
Malpositioned Implant	0	0	0.0%	1	1	1.7%
Other[4]	1	1	0.5%	1	1	1.7%
Prolonged postoperative sequelae[5]	9	9	4.9%	7	6	10.2%
Radiculopathy/Sciatica without back pain	4	4	2.2%	3	3	5.1%
Respiratory	1	1	0.5%	0	0	0.0%
Skin Disorder	1	1	0.5%	0	0	0.0%
Spinal Event at Other Lumbar Level	1	1	0.5%	0	0	0.0%
Degeneration of Adjacent Level	1	1	0.5%	0	0	0.0%
Spinal Event at Target Level[6]	8	8	4.4%	4	4	6.8%
Back Pain	0	0	0.0%	1	1	1.7%
Disc Herniation/Stenosis/Slip	4	4	2.2%	0	0	0.0%
Spinous Process Bony Erosion	1	1	0.5%	0	0	0.0%
Spinous Process Fracture	1	1	0.5%	0	0	0.0%
Worsening Back Pain	1	1	0.5%	2	2	3.4%
Superficial Incision Infection	14	14	7.7%	2	2	3.4%
Systemic[7]	0	0	0.0%	1	1	1.7%
Vascular Event Post-Op Peripheral/DVT	0	0	0.0%	1	1	1.7%

Only adverse events through the first 790 days are included.
[1]Gastrointestinal-Other: abdominal pain
[2]Incision-Related: infection, pain on the incision site, delayed wound healing, erythema, bruising, hematoma, rash
[3]Infection:Varicella-zoster
[4]Other: needle issue, opioid dependence
[5]Prolonged postoperative sequelae: post-operative low back pain, tightness in chest, constipation, fever, ENT issue, headache, tachycardia, low potassium, hyperglycemia
[6]Spinal Event at Target Level: bilateral hip pain radiating from surgical site, low back pain with or without leg pain
[7]Systemic: insomnia

Serious Adverse Events

A listing of all specific serious adverse events (SAEs) that occurred through Month 6 is presented in **Table 15**. In total, 27 SAEs occurred in 13.7% (25/182) of investigational subjects, 23 SAEs occurred in 22.7% (22/97) of non-operative care control subjects, and 9 SAEs occurred in 15.3% (9/59) of crossover subjects.

Table 15: Counts and Percentages of Subjects with Specific Serious Adverse Events at 6 Months – Investigational and Control mITT-Followed and Crossover

	Investigational (N=182)			Control (N=97)			Crossover (N=59)		
	Events	n	%	Events	n	%	Events	n	%
All AEs	27	25	13.7%	23	22	22.7%	9	9	15.3%
Back and/or Leg Pain (of back etiology)	1	1	0.5%	7	7	7.2%	0	0	0.0%
Cancer[1]	1	1	0.5%	0	0	0.0%	0	0	0.0%
Cardiovascular (i.e., M.I., Stroke)	0	0	0.0%	0	0	0.0%	1	1	1.7%
Cervical Spine Event	1	1	0.5%	0	0	0.0%	0	0	0.0%
Depression	1	1	0.5%	0	0	0.0%	0	0	0.0%
Gastrointestinal-Other[2]	2	2	1.1%	0	0	0.0%	0	0	0.0%
Infection[3]	0	0	0.0%	0	0	0.0%	1	1	1.7%
Lower Extremity (not of back etiology, i.e., knee, ankle)	1	1	0.5%	1	1	1.0%	0	0	0.0%
Malpositioned Implant	0	0	0.0%	0	0	0.0%	1	1	1.7%
Neurological	1	1	0.5%	0	0	0.0%	0	0	0.0%
Other[4]	1	1	0.5%	3	3	3.1%	0	0	0.0%
Prolonged postoperative sequelae[5]	5	5	2.7%	3	3	3.1%	4	4	6.8%
Radiculopathy/Sciatica without back pain	1	1	0.5%	0	0	0.0%	0	0	0.0%
Respiratory	2	2	1.1%	0	0	0.0%	0	0	0.0%
Superficial Incision Infection	4	4	2.2%	0	0	0.0%	0	0	0.0%
Spinal Event at Target Level[6]	3	3	1.6%	8	8	8.2%	1	1	1.7%
Trauma[7]	2	2	1.1%	0	0	0.0%	0	0	0.0%
Upper Extremity Pain (not of neck etiology, i.e., shoulder, arm)	0	0	0.0%	1	1	1.0%	0	0	0.0%
Urogenital	1	1	0.5%	0	0	0.0%	0	0	0.0%
Vascular Event Post-Op Peripheral/DVT	0	0	0.0%	0	0	0.0%	1	1	1.7%

Only adverse events through the first 210 days are included.
[1]Cancer: cervical cancer
[2]Gastrointestinal-Other: epigastric pain, abdominal pain
[3]Infection: systemic
[4]Other: gynecological issue, dental surgery
[5]Prolonged postoperative sequelae: post operative low back pain, tightness in chest, fever, ENT issue, hyperglycemia
[6]Spinal Event at Target Level: back pain with or without leg pain, discogenic back pain, disc herniation/stenosis/slip, numbness/paresthesia
[7]Trauma: fall or motor vehicle accident or other trauma resulting in a broken or sprained foot or hand

A listing of all specific serious adverse events (SAEs) that occurred through Month 24 is identified in **Table 16** below. In total, sixty-nine (69) SAEs occurred in 32.4% (59/182) of investigational subjects, 47 SAEs were reported in 43.3% (42/97) of non-operative control subjects, and 19 SAEs occurred in 27.1% (16/59) of crossover subjects.

Table 16: Counts and Percentages of Subjects with Specific Serious Adverse Events at 24 Months – Investigational and Control mITT-Followed and Crossover

	Investigational (N=182)			Control (N=97)			Crossover (N=59)		
	Events	n	%	Events	n	%	Events	n	%
All AEs	69	59	32.4%	47	42	43.3%	19	16	27.1%
Back and/or Leg Pain (of back etiology)	3	3	1.6%	12	12	12.4%	1	1	1.7%
Cancer[1]	3	3	1.6%	0	0	0.0%	0	0	0.0%
Cardiovascular (i.e., M.I., Stroke)	1	1	0.5%	1	1	1.0%	1	1	1.7%
Cervical Spine Event	2	2	1.1%	0	0	0.0%	2	2	3.4%
Death[2]	0	0	0.0%	1	1	1.0%	0	0	0.0%
Depression	1	1	0.5%	0	0	0.0%	0	0	0.0%
Gastrointestinal-Other[3]	9	9	4.9%	0	0	0.0%	0	0	0.0%
Infection[4]	1	1	0.5%	1	1	1.0%	1	1	1.7%
Infection UTI	1	1	0.5%	0	0	0.0%	0	0	0.0%
Lower Extremity (not of back etiology, i.e., knee, ankle)	7	7	3.8%	1	1	1.0%	0	0	0.0%
Malpositioned Implant	0	0	0.0%	0	0	0.0%	1	1	1.7%
Neurological	2	2	1.1%	0	0	0.0%	0	0	0.0%
Other[5]	4	4	2.2%	4	4	4.1%	1	1	1.7%
Other Pain[6]	1	1	0.5%	0	0	0.0%	0	0	0.0%
Prolonged postoperative sequelae[7]	5	5	2.7%	4	4	4.1%	4	4	6.8%
Radiculopathy/Sciatica without back pain	1	1	0.5%	0	0	0.0%	0	0	0.0%
Respiratory	2	2	1.1%	1	1	1.0%	0	0	0.0%
Spinal Event at Target Level[8]	11	11	6.0%	19	18	18.6%	5	5	8.5%
Superficial Incision Infection	4	4	2.2%	0	0	0.0%	0	0	0.0%
Trauma[9]	3	3	1.6%	1	1	1.0%	1	1	1.7%
Upper Extremity Pain (not of neck etiology, i.e., shoulder, arm)	3	3	1.6%	1	1	1.0%	0	0	0.0%
Urogenital	5	5	2.7%	0	0	0.0%	0	0	0.0%
Vascular Event Post-Op Peripheral/DVT	0	0	0.0%	1	1	1.0%	2	2	3.4%

Only adverse events through the first 790 days are included.
[1]Cancer: cervical cancer
[2]Death: cardiac arrest
[3]Gastrointestinal Other: epigastric pain, hernia, abdominal pain, pancreatitis
[4]Infection: systemic, cough
[5]Other: breast surgery, dental surgery, gynecological disorder
[6]Other Pain: headache
7Prolonged postoperative sequelae: post operative low back pain, tightness in chest, fever, ENT issue, hyperglycemia
[8]Spinal Event at Target Level: low back pain with or without leg pain, disc herniation/stenosis/slip, spinous process bony erosion, facet joint changes
[9]Trauma: Trauma: fall or motor vehicle accident or other trauma resulting in a broken or sprained foot, ankle, hand; compression fracture, rotator cuff tear, or temporary increase in back pain

Treatment-Associated Serious Adverse Events

Table 17 shows the counts and percentages of all implant-associated and surgical procedure-associated SAEs, in the investigational and crossover groups. The counts and percentages of all non-operative treatment-associated SAEs in the non-operative care control group are discussed below. In the control group, there were 2 SAEs in 2 subjects (2.1%) that were non-operative treatment-associated, which were both classified as Worsening Back Pain.

Table 17: Counts and Percentages of Subjects with Serious Implant- and Surgical Procedure-Associated Adverse Events Through 24 Months - Investigational mITT-Followed and Crossover

	Investigational (N=182)			Crossover (N=59)		
	Events	n	%	Events	n	%
All AEs	15	14	7.7%	7	6	10.2%
Malpositioned Implant	0	0	0.0%	1	1	1.7%
Prolonged postoperative sequelae[1]	5	5	2.7%	4	4	6.8%
Radiculopathy/Sciatica without back pain	1	1	0.5%	0	0	0.0%
Respiratory	1	1	0.5%	0	0	0.0%
Spinal Event at Target Level	4	4	2.2%	1	1	1.7%
Back Pain	3	3	1.6%	0	0	0.0%
Disc Herniation/Stenosis/Slip	0	0	0.0%	1	1	1.7%
Spinous Process Bony Erosion	1	1	0.5%	0	0	0.0%
Superficial Incision Infection	4	4	2.2%	0	0	0.0%
Vascular Event Post-Op Peripheral/DVT	0	0	0.0%	1	1	1.7%

Only adverse events through the first 790 days are included.
[1]Prolonged postoperative sequelae: postoperative back pain, ENT disorder, hyperglycemia, tightness in chest, fever

Unanticipated Device Adverse Effects

Adverse events were reviewed by the CEC to confirm or reclassify the severity, seriousness, relationship to the device or procedure, and whether it was anticipated or unanticipated. No unanticipated adverse device effects were reported during the course of this study or adjudicated as such by the CEC.

Secondary Surgical Interventions

In the investigational group, procedures performed at the index level at or before Month 24 were considered secondary surgical intervention (SSI) failures in the clinical study. For the control group, SSI failure was defined as receiving an index level surgery (subsequent to poor response to the non-operative care provided) to treat the subject's original condition. After 6 months of non-operative care treatment, control subjects were permitted to cross over and undergo surgical treatment if their ODI score remained above 30 and their ODI score failed to improve by 15 points from baseline. It is important to note that while surgical interventions in the control group were technically classified as SSIs, these procedures represent *primary* surgical interventions for control subjects.

In the mITT-Followed analysis cohorts, there were a total of 13 SSIs in 12/182 (6.6%) of investigational subjects compared to 68 SSIs in 65/97 (67.0%) in non-operative care control subjects. Importantly, 56 of the 68 SSIs in the control group were crossover surgeries. Time course listings of secondary surgical interventions (SSIs) reported in the investigational and non-operative care control groups are provided in the tables below.

In the investigational group, 12/182 (6.6%) subjects had 13 additional surgeries at the index level, including 5 removals in 5/182 (2.7%) subjects, and 6 reoperations in 6/182 (3.3%) subjects, and 2/182 (1.1%) subjects had lumbar supplemental fixation procedures.

Table 18: SSI by Time of Occurrence – DIAM™ Spinal Stabilization System Investigational mITT-Followed

SSI Type	Event Time Course (Months)				Total (Events)
	0-3	3-6	6-12	12-24	
Removal and Decompression	1	1	0	1	3
Debridement and Wound Care	3	0	0	0	3

SSI Type	Event Time Course (Months)				Total (Events)
	0-3	3-6	6-12	12-24	
Decompression	1	1	0	1	3
TDR Placement (No Device Removal)	0	0	1	0	1
Removal	0	0	0	1	1
Removal, TDR Placement	0	0	0	1	1
Fusion	0	0	0	1	1
TOTAL	**5**	**2**	**1**	**5**	**13**

*To be consistent with the inclusion period for each time visit, events occurring with 104 days, 210 days, 425 days, 790 days are captured within the 0-3 months, 3-6 months, 6-12 months, and 12-24 months follow-up timepoints, respectively.

In the non-operative care control group, 68 SSIs were performed in 65/97 (67.0%) subjects through 24 months. Fifty-six (56/97, 57.7%) of these subjects received crossover surgery to the investigational device with 29 subjects receiving crossover surgery at the 6-month follow-up, 23 subjects between 6- and 12-months follow-up, and 9 subjects between 12 and 24 months. An additional 12 SSIs were considered treatment surgeries at the index level. Importantly, although classified as SSIs in the study, the 68 surgical procedures listed in the control group are *primary* surgical interventions.

Table 19: SSI by Time of Occurrence – Control mITT-Followed

SSI Type	Event Time Course (Months)				Total (Events)
	0-3	3-6	6-12	12-24	
Crossover Surgery	0	29	23	4	56
Instrumentation (Pedicle Screws) Removal and Decompression	0	0	0	1	1
Decompression	1	0	0	1	2
Fusion	1	0	1	2	4
Fusion and Decompression	0	1	2	1	4
Fusion and Arthroplasty**	0	0	1	0	1
TOTAL	**2**	**30**	**27**	**9**	**68**

* To be consistent with the inclusion period for each time visit, events occurring with 104 days, 210 days, 425 days, 790 days are captured within the 0-3 months, 3-6 months, 6-12 months, and 12-24 months follow-up timepoints, respectively.

** Subject experienced worsening severe discogenic low back pain and MRI showed L4-L5 advanced DDD with vascular fibrosis of adjacent vertebral bodies and a new disc herniation at L5-S1. The SSI included L4-L5 ALIF and L5-S1 arthroplasty.

Crossover subjects were followed for at least 24 months, and all secondary surgical interventions (SSIs) throughout the 24-month follow-up period from the time of crossover surgery were documented and adjudicated in accordance with the same criteria applied to the investigational cohort.

There were 4 SSIs in 3 crossover subjects (3/59, 5.1%). Two SSIs were classified as supplemental fixation procedures (fusion), and two were classified as removal procedures (Device Removal and Fusion; Device Removal, Fusion and decompression). One subject (1/59, 1.7%) underwent both supplemental fixation and removal procedures.

Neurological Status

Neurological status was evaluated prior to study treatment and at each follow-up visit

(surgery/discharge assessment conducted for investigational and crossover subjects only). Neurological status was based on four types of measurements: motor, sensory, reflexes, and straight leg raising. Below, **Table 20** presents a summary of the proportion of investigational, control, and crossover subjects determined to have maintained or improved neurological functional status in the respective neurological domains at baseline and Month 24.

At Month 24, the overall assessment of neurologic function indicates that there are similar rates of maintenance or improvement of neurologic function in each of the treatment groups at all timepoints. The results demonstrate no acute or longer-term neurological deterioration (particularly in terms of motor function) after implantation of the DIAM™ Spinal Stabilization System.

Table 20: Neurological Functional Status – Investigational and Control mITT-Followed and Crossover

	Pre-Op									Month 24								
	Investigational			Control			Crossover			Investigational			Control			Crossover		
	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%	N	n	%
Motor Functions	182	182	100.0%	97	97	100.0%	59	58	98.3%	166	162	97.6%	26	26	100.0%	57	55	96.5%
Sensory Functions	182	164	90.1%	97	91	93.8%	59	56	94.9%	166	152	91.6%	26	24	92.3%	57	52	91.2%
Reflexes	182	164	90.1%	97	88	90.7%	59	54	91.5%	166	160	96.4%	26	25	96.2%	57	54	94.7%
Straight Leg Raise	182	151	83.0%	97	75	77.3%	59	49	83.1%	166	161	97.0%	26	23	88.5%	57	55	96.5%

Implant Migration

Implant location of the investigational device and the positions of the left and right crimps were evaluated on anterior-posterior (AP) and lateral radiographs at each post-operative visit starting at 6 weeks, and were compared with radiographs obtained at surgery discharge to determine if migration of any component had occurred. No subjects treated with the DIAM™ Spinal Stabilization System device experienced a migration of any component through 24 months.

Spinous Process Fractures

In the investigational group, spinous process fractures were observed in 0 subjects pre-operatively, 5 subjects (2.9%; 5/171) at discharge, 8 subjects (4.5%; 8/179) at 6 weeks, 9 subjects (5.1%; 9/177) at 3 months, 8 subjects (4.6%; 8/173) at 6 months, 7 subjects at (4.0%; 7/157) at 12 months, and 3 subjects (1.9%; 3/157) at 24 months. Cumulatively, there were 14 (7.7%; 14/182) subjects with spinous process fractures within 24 months. Most spinous process fractures occurred by 6 weeks (64.3%; 9/14), and most were healed by Month 24 (78.6%; 11/14). No spinous process fractures were reported in the non-operative care control group at any point during the 24-month follow-up duration.

2. Effectiveness Results

Primary Endpoint

The primary endpoint analysis reported the CCS event rate at Month 24 in the mITT-Followed cohort (182 DIAM™ Spinal Stabilization System and 97 Non-operative Care subjects). At Month 24, the CCS rate was 63.9% (108/169) for the investigational group, and 11.9% (10/84) for the non-operative care control group based on evaluable subjects.

All subsequent effectiveness analyses are shown for the Back Pain Predominate Modified Intent-to-Treat (BPPmITT) analysis set (144 DIAM™ Spinal Stabilization System and 76 Non-operative Care subjects).

The BPPmITT analysis population was utilized due to a retrospective modification to the Indications for Use Statement for the DIAM™ Spinal Stabilization System, which limits use of the device to subjects with pre-operative back pain intensity greater than leg pain intensity. This change better defines the target population intended to be treated by the DIAM™ Spinal Stabilization System and helps to exclude subjects with predominate leg pain with radiculopathy. In line with this change, it was determined that presentation of effectiveness data from the BPP subset, which included a

majority of study subjects, was most appropriate. It is important to note, however, that the effectiveness results for the BPPmITT analysis population were not substantially different from the mITT analysis population.

Similarly, the subsequent effectiveness analyses for the crossover subjects are shown for the Crossover Back Pain Predominant (Crossover BPP) analysis set, including 49 crossover subjects.

Table 21 and **Table 22** present the overall effectiveness evaluation for the BPPmITT and Crossover BPP analysis populations at Month 24 and Month 60, respectively.

Table 21: Overall Success Rates at 24 Months – Investigational and Control BPPmITT and Crossover BPP

	Investigational			Control			Crossover		
	N	n	%	N	n	%	N	n	%
Composite Clinical Success	135	91	67.4%	67	8	11.9%	48	33	68.8%
(1) No Secondary Surgical Intervention	144	136	94.4%	76	23	30.3%	49	46	93.9%
No Revision	144	144	100.0%	76	76	100.0%	49	49	100.0%
No Removal	144	139	96.5%	76	76	100.0%	49	48	98.0%
No Re-operation	144	139	96.5%	76	76	100.0%	49	49	100.0%
No Supplemental Fixation	144	140	97.2%	76	76	100.0%	49	46	93.9%
No Crossover/Treatment Surgery	144	144	100.0%	76	23	30.3%	49	49	100.0%
(2) ODI Responder	126	97	77.0%	15	8	53.3%	45	36	80.0%
(3) No Related Serious AEs	144	134	93.1%	76	75	98.7%	49	44	89.8%
No Implant Associated	144	143	99.3%	76	76	100.0%	49	49	100.0%
No Implant/Surgical Procedure Associated	144	143	99.3%	76	76	100.0%	49	49	100.0%
No Surgical Procedure Associated	144	136	94.4%	76	76	100.0%	49	44	89.8%
No Nonoperative Treatment Associated	144	144	100.0%	76	75	98.7%	49	49	100.0%

Table 22: Overall Success Rates at 60 Months – Investigational and Control BPPmITT and Crossover BPP

	Investigational			Control			Crossover		
	N	n	%	N	n	%	N	n	%
Composite Clinical Success	101	64	63.4%	64	7	10.9%	30	21	70.0%
(1) No Secondary Surgical Intervention	144	131	91.0%	76	20	26.3%	49	45	91.8%
(2) ODI Responder	84	66	78.6%	8	7	87.5%	24	22	91.7%
(3) No Related Serious AEs	144	133	92.4%	76	75	98.7%	49	44	89.8%

At 24 months, the CCS rate for the BPPmITT cohort was 67.4% (91/135) for investigational subjects, 11.9% (8/67) for non-operative care control subjects, and 68.8% (33/48) for crossover subjects. At 60 months, the CCS rates were largely maintained with a 63.4% (64/101) success rate for investigational subjects, 10.9% (7/64) for non-operative care control subjects, and 70.0% (21/30) for crossover subjects. The low CCS success rates in the control group at Month 24 and Month 60 is largely driven by the high number of crossover subjects, and other surgical procedures that occurred after 6 months.

Secondary Endpoints

This section focuses on secondary clinical endpoints from a number of relevant domains including ODI, back pain intensity (NRS), general health status (SF-36), subject work status and satisfaction assessments which were assessed preoperatively (baseline) and at prescribed clinical intervals throughout the follow-up period. Note that the high crossover rate in the control group makes interpretation of secondary endpoint success rates difficult after 6 months.

For each continuous clinical endpoint, summary tables were designed to present clinical outcomes for the investigational, control, and crossover groups over time. These tables include the individual sample sizes for each group at each timepoint as well as the mean, standard deviation (SD), and percentage of subjects meeting the pre-specified responder criteria at each timepoint. Overall,

subjects treated with the investigational device exhibited improvement across a spectrum of secondary analyses.

Table 23 below presents the responder rates for ODI, Back Pain Intensity, and SF-36 PCS at 24 and 60 months for both treatment groups in the BPPmITT analysis set (144 DIAM™ Spinal Stabilization System and 76 Non-operative Care subjects) and the Crossover BPP analysis set (n=49).

Table 23: Secondary Effectiveness Subject Outcomes at Month 24 and Month 60 Compared to Baseline - Investigational and Control BPPmITT and Crossover BPP

Secondary Effectiveness Endpoint	Investigational (N=144)		Control (N=76)		Crossover (N=49)	
	Month 24	Month 60	Month 24	Month 60	Month 24	Month 60
ODI Improvement ≥ 15-point Responder Rate (out of 100)	77.0% (97/126)	78.6% (66/84)	53.3% (8/15)	87.5% (7/8)	80.0% (36/45)	91.7% (22/24)
Back Pain Intensity ≥ 2-point Responder Rate (out of 10)	83.2% (104/125)	85.7% (72/84)	46.7% (7/15)	75.0% (6/8)	90.9% (40/44)	87.5% (21/24)
SF-36 PCS ≥ 5-point Responder Rate (out of 100)	75.6% (93/123)	71.1% (59/83)	40.0% (6/15)	75.0% (6/8)	86.4% (38/44)	79.2% (19/24)

ODI Results

Table 24 presents the mean ODI scores and the ODI responder rates through the Month 60 follow-up for both treatment groups comprising the BPPmITT analysis set (144 DIAM™ Spinal Stabilization System and 76 non-operative care), as well as the Crossover BPP analysis set (n=49).

ODI is scored on a 50-point scale (10 questions with a score of 0-5 for each) and is then normalized to a scale of 100 percentage points. Higher ODI is representative of greater disability. In the investigational and crossover groups, mean ODI scores were improved at all time-points compared to baseline. The ODI responder rates (defined as a ≥ 15-point decrease in ODI) at all follow-up timepoints up through Month 48 were higher in the investigational group than the control group. At Month 60 the control group had a higher responder rate (87.5%) than the investigational group (78.6%); however, significant attrition in the control group limits interpretation of longer-term outcomes. The responder rate for the crossover group was similar to the investigational group through Month 60.

Table 24: Mean ODI Score and ODI Responder Rates Over 60 Months – Investigational and Control BPPmITT and Crossover BPP

	Investigational					Control					Crossover				
	N	Mean	SD	Responder		N	Mean	SD	Responder		N	Mean	SD	Responder	
				n	%				n	%				n	%
Pre-Op	144	49.9	14.1	N/A	N/A	76	50.8	13.4	N/A	N/A	49	55.2	13.3	N/A	N/A
Week 06	140	26.4	16.6	92	65.7%	73	43.3	15.1	17	23.3%	49	25.7	15.7	35	71.4%
Month 03	139	22.1	16.4	111	79.9%	73	42.6	15.9	21	28.8%	49	22.2	17.3	36	73.5%
Month 06	140	20.7	16.9	110	78.6%	71	50.5	16.3	12	16.9%	49	22.2	17.3	39	79.6%
Month 12	137	21.6	19.7	105	76.6%	24	41.1	18.1	9	37.5%	47	21.1	16.9	38	80.9%
Month 24	126	20.2	17.0	97	77.0%	15	35.9	20.1	8	53.3%	45	20.5	17.9	36	80.0%
Month 36	120	20.1	18.9	91	75.8%	12	33.2	18.1	6	50.0%	40	18.8	16.0	33	82.5%
Month 48	103	18.0	17.4	85	82.5%	8	32.0	18.2	6	75.0%	35	19.7	13.7	31	88.6%
Month 60	84	19.3	18.8	66	78.6%	8	32.3	21.6	7	87.5%	24	17.5	12.6	22	91.7%

Back Pain Results

Table 25 shows mean back pain intensity scores and back pain intensity responder rates over 60 months. Subjects rated their back pain intensity on the Numerical Rating Scale (NRS) from 0-10, with a score of 0 representing “no pain” and a score of 10 representing “pain as bad as it could be.”

In the investigational and crossover groups, mean back pain intensity scores decreased at all follow-up timepoints as compared to baseline. Back pain intensity responder rates (defined as a ≥ 2-point decrease on NRS) were above 75% at all follow-up timepoints in the investigational and crossover groups.

Table 25: Mean Back Pain Intensity Scores and Back Pain Intensity Responder Rates Over 60 Months – Investigational and Control BPPmITT and Crossover BPP

	Investigational					Control					Crossover				
	N	Mean	SD	Responder		N	Mean	SD	Responder		N	Mean	SD	Responder	
				n	%				n	%				n	%
Pre-Op	144	8.1	1.6	N/A	N/A	76	7.9	1.7	N/A	N/A	49	7.5	1.7	N/A	N/A
Week 06	140	3.3	2.5	126	90.0%	73	6.3	2.4	33	45.2%	49	2.8	2.3	43	87.8%
Month 03	139	3.4	2.7	117	84.2%	73	6.1	2.6	29	39.7%	48	2.9	2.5	43	89.6%
Month 06	139	3.3	2.7	117	84.2%	71	6.8	2.3	28	39.4%	49	3.0	2.9	39	79.6%
Month 12	137	3.6	3.2	107	78.1%	24	5.9	2.8	11	45.8%	47	3.0	2.9	36	76.6%
Month 24	125	3.4	3.1	104	83.2%	15	5.5	3.3	7	46.7%	44	2.5	2.4	40	90.9%
Month 36	119	3.4	3.2	99	83.2%	12	5.1	3.2	7	58.3%	40	2.8	2.7	31	77.5%
Month 48	103	2.8	3.0	84	81.6%	8	5.1	2.9	6	75.0%	35	3.2	2.7	28	80.0%
Month 60	84	2.9	2.9	72	85.7%	8	4.4	3.0	6	75.0%	24	2.7	2.4	21	87.5%

SF-36 PCS Results

Table 26 shows mean SF-36 Physical Component Score (PCS) scores and SF-36 PCS responder rates over 60 months for the BPPmITT analysis set (144 DIAM™ Spinal Stabilization System and 76 non-operative care), and Crossover BPP analysis set (n=49). In the investigational and crossover groups, mean SF-36 PCS scores increased at all follow-up timepoints from baseline. SF-36 PCS responder rates (defined as an improvement of ≥ 5 points in SF-36 PCS) were above 70% at all follow-up timepoints 3 months and after for the investigational and crossover subjects.

Table 26: Mean SF-36 PCS Scores and SF-36 PCS Responder Rates Over 60 Months – Investigational and Control BPPmITT and Crossover BPP

	Investigational					Control					Crossover				
	N	Mean	SD	Responder		N	Mean	SD	Responder		N	Mean	SD	Responder	
				n	%				n	%				n	%
Pre-Op	143	31.9	6.3	N/A	N/A	76	30.4	5.8	N/A	N/A	49	29.5	5.0	N/A	N/A
Week 06	137	39.5	7.4	76	55.5%	73	32.8	6.4	26	35.6%	49	39.7	7.6	35	71.4%
Month 03	138	41.5	8.3	97	70.3%	72	32.6	6.6	20	27.8%	48	41.1	8.5	35	72.9%
Month 06	139	42.8	8.6	103	74.1%	71	30.8	6.4	18	25.4%	48	41.3	8.7	37	77.1%
Month 12	135	43.0	9.3	102	75.6%	24	33.5	8.0	6	25.0%	47	42.4	8.0	39	83.0%
Month 24	123	43.2	9.4	93	75.6%	15	36.4	9.0	6	40.0%	44	42.9	9.1	38	86.4%
Month 36	117	43.4	9.4	86	73.5%	12	36.3	10.2	6	50.0%	39	42.0	9.0	30	76.9%
Month 48	102	44.0	9.3	76	74.5%	8	36.9	9.9	5	62.5%	35	41.1	8.1	28	80.0%
Month 60	83	43.5	9.3	59	71.1%	8	38.7	10.0	6	75.0%	24	41.8	7.1	19	79.2%

Subject Satisfaction with Treatment

At the 24 month follow-up timepoint, 81.2% (108/133) of investigational subjects and 57.9% (11/19) of control subjects were satisfied with the results of their non-operative care or surgical intervention; 76.7% (102/133) of investigational subjects and 57.9% (11/19) of control subjects said that it was "definitely true" or "mostly true" that they were helped as much as they expected; and 81.2% (108/133) of investigational subjects said that they would have the treatment again for the same condition, as compared to 42.1% (8/19) of control subjects. Based on these results, investigational subjects were more satisfied with their treatment than the subjects in the control group.

Global Subject Perception of Treatment Effectiveness

At 24 months, the success rate of subject global perception of treatment effect was 86.2%

(112/130) for the investigational subjects and 57.9% (11/19) for the control subjects.

Work Status

Subjects were asked to provide work status at preoperative and each postoperative follow-up through 24 months. Preoperatively, 68.8% (99/144) of investigational subjects and 69.7% (53/76) of control subjects reported working. At 24 months following surgery, 72.5% (95/131) of investigational subjects and 52.6% (10/19) of control subjects reported working.

Pain Medication Usage

At baseline, the number of subjects who were taking narcotic pain medications in some capacity was 49.3% (69/143) among investigational subjects and 58.7% (44/75) among non-operative care subjects. At Month 24, these rates dropped to 28.6% (38/133) among investigational subjects and 36.8% (7/19) among non-operative care subjects. Furthermore, the number of investigational subjects who were taking narcotic pain medications daily decreased from 23.1% (33/143) at baseline to 15.0% (20/133) at 24 months while the percentage of control subjects also decreased (baseline: 30.7% (23/75); 24 months: 21.1% (4/19)). The decreasing trend in daily narcotic pain medication usage compared to baseline in investigational subjects was consistent at later timepoints where 18.9% (24/127), 17.0% (19/112), and 14.1% (13/92) of investigational subjects reported daily use at the 36-, 48-, and 60-month follow-up visits.

Disc Height and Angular Range of Motion

Radiographic analyses are presented in the following tables. Note that significant attrition in the control group limits the ability to compare results across groups.

Posterior disc height was measured between the posterior-inferior corner of the superior vertebra and the posterior-superior corner of the inferior vertebra. Average disc height was calculated as the simple mean of the posterior and anterior disc heights.

Mean posterior disc height as shown in **Table 27** was numerically higher through Month 12 in subjects treated with the DIAM™ Spinal Stabilization System as compared to the non-operative care control. Mean average disc height was maintained across all groups through 24 months.

Table 27: Mean Posterior Disc Height (mm) at Target Level up to 24 Months – Investigational and Control BPPmITT and Crossover BPP

	Investigational			Control			Crossover		
	N	Mean	SD	N	Mean	SD	N	Mean	SD
Pre-Op	141	7.0	1.7	76	7.0	2.0	49	7.0	2.0
Week 06	139	7.8	1.9	70	6.9	1.9	49	7.9	2.2
Month 03	141	7.8	2.0	74	6.7	2.0	48	7.8	2.4
Month 06	136	7.6	1.9	71	6.8	1.9	49	7.6	2.1
Month 12	138	7.5	2.0	27	6.6	2.0	46	7.3	2.0
Month 24	122	7.3	1.9	16	7.5	2.1	46	7.0	2.2

Mean intervertebral angle in extension was reduced in subjects treated with DIAM™ Spinal Stabilization System as compared to non-operative care at Week 6 through Month 24.

Table 28: **Mean Intervertebral Angle (degrees) at Extension Position up to 24 Months – Investigational and Control BPPmITT and Crossover BPP**

	Investigational			Control			Crossover		
	N	Mean	SD	N	Mean	SD	N	Mean	SD
Pre-Op	141	9.5	3.8	73	9.4	4.2	49.0	9.7	3.9
Week 06	136	6.0	3.7	70	9.5	4.2	49.0	7.1	3.9
Month 03	139	6.5	3.9	73	9.5	4.1	47.0	6.6	3.7
Month 06	136	7.3	4.3	69	9.9	4.1	49.0	7.5	3.7
Month 12	136	7.6	4.3	27	10.0	5.0	46.0	8.6	3.7
Month 24	122	7.4	4.4	15	8.6	4.2	45.0	8.3	3.8

No meaningful difference in mean intervertebral angle in flexion was seen through Month 24 between groups.

Table 29: Mean Intervertebral Angle (degrees) at Flexion Position up to 24 Months – Investigational and Control BPPmITT and Crossover BPP

	Investigational			Control			Crossover		
	N	Mean	SD	N	Mean	SD	N	Mean	SD
Pre-Op	141	2.0	5.7	73	1.2	5.2	49	2.3	5.6
Week 06	135	0.6	4.3	70	1.6	5.4	49	1.7	3.8
Month 03	139	0.8	4.6	73	1.8	5.3	47	1.2	4.0
Month 06	136	0.9	5.1	70	1.9	5.3	49	1.7	4.9
Month 12	136	1.1	5.1	27	2.6	5.3	46	2.5	5.7
Month 24	122	1.1	5.4	16	0.4	5.9	45	1.4	5.3

PACKAGING AND STERILIZATION

Devices are supplied sterile, sterilized with gamma radiation. Packages for each of the components should be intact upon receipt. Once the seal on the sterile package is broken, the product should not be re-sterilized. If a loaner set is used, all sets, and components should be carefully checked for completeness and to ensure there is no damage prior to use. Damaged packages or products should not be used and should be returned to Companion Spine.

Storage

The shelf-life of the medical device is 1 year keeping it in a dry place, without sunlight, and in an ambient atmosphere to ensure the integrity of the implant and its packaging.

Visual Inspection

Visually inspect:

- All sterile-barrier packaging before use. If the sterile barrier is damaged or the integrity has been compromised, do not use the product. Contact Companion Spine for return information.
- The device before use. If the device is damaged, do not use the product.
- The Use-by date to guarantee the maintenance of the sterile state and the integrity of the product.

Contact Companion Spine for return information.

INSTRUCTIONS FOR USE

Intra-Operative Instructions:

The DIAM™ Spinal Stabilization System implants must be used with the instruments designed and supplied for the purposes of performing the implantation and/or removal of the device, as specified in the surgical technique manual. The available surgical technique manual also instructs the user on proper implantation and removal techniques. The user must be familiar with the recommended surgical technique prior to implanting the DIAM™ Spinal Stabilization System device. Please consult the surgical technique manual for further information on the DIAM™ Spinal Stabilization System implantation procedure.

Post-Operative Instructions in Case of Removal:

When explanting and/or disposing of a device, avoid exposure to bodily substances such as blood, tissue, etc., as contact could lead to infection or disease. Always wear and use proper equipment, taking special care with sharp objects and needles. Follow your healthcare center's policy regarding both the disposal of devices and any events of exposure. Please consult the surgical technique manual for further information on the DIAM™ Spinal Stabilization System explantation procedure when device removal is necessary.

INFORMATION TO PROVIDE TO THE PATIENT

The surgeon should inform the patient about restrictions and expectations that are involved in the use of this device. While not all inclusive, this discussion should include instructions on back care education, physical therapy, proper use of any prescribed orthotics, and activity expectations. It is particularly important to mention the topics of premature load bearing, limitations of physical activities, and the necessity of regular medical follow-up.

The patient should be informed of the surgical risks, benefits, and limitations associated with the use of the DIAM™ Spinal Stabilization System device. General limitations of the device include but are not limited to; the device not reproducing spine flexibility, resistance, strength or have the durability of a normal healthy tissue. The effect of the device may also be limited by the amount of degeneration of the disc at the time of implantation resulting in a diminished pain relief and a shorter length of effective treatment than anticipated. In addition, disc degeneration progresses with age which may limit the effectiveness of the device as a person ages. Patient controlled activities such as smoking and excessive weight gain may diminish the effectiveness of the device to relieve back pain.

Engaging in activity that involves repetitive or excessive load, or trauma on the implant (for example, extensive walking, running, lifting weights, or extensive muscular effort), may result in damage to the device and subsequent surgical revision.

The patient should inform health professionals of the DIAM™ Spinal Stabilization System implantation when being evaluated for radiographic (X-rays, CT scans, MRI) or invasive procedures. If there are any concerns regarding progressive back pain, weakness, numbness, signs of swelling or infections in the back the patient should contact their treating physician.

SYMBOLS

Symbol	Meaning	Symbol	Meaning
MD	Medical device		Do not re-sterilize
REF	Catalogue number	STERILE R	Sterilized using irradiation
LOT	Batch code	Rx Only	Prescription use only
UDI	Unique Device Identifier		Legal manufacturer
	Use-by date (last day of month displayed)		Consult instructions for use or consult electronic instructions for use
Mat	Raw materials		Caution, indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences
	Do not use if package is damaged and consult instructions for use		Patient identification
	Keep away from sunlight	31	Surgery date
	Keep dry		Health care center or doctor
MR	MR Conditional		Patient information website
	Do not re-use / Single use device		Double sterile barrier system

MRI SAFETY INFORMATION

MR Conditional

The DIAM™ implant is MR Conditional.

The DIAM™ Spinal Stabilization System was determined to be MR Conditional according to the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503-05, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, Pennsylvania, 2005.

Product comparison demonstrated that the DIAM™ Spinal Stabilization System is MR Conditional.

A patient with this device can be scanned immediately after placement under the conditions presented below.

MRI Safety Information

A person implanted with the DIAM™ Spinal Stabilization System may be safely scanned anywhere in the body at 1.5T and 3.0T under the following conditions. Failure to follow these conditions may result in injury.

Device Name	DIAM™ Spinal Stabilization System
Static Magnetic Field Strength (B_0)	1.5T or 3T
Maximum Spatial Field Gradient	30 T/m (3000 Gauss/cm)
RF Excitation	Circularly polarized (CP)
RF Transmit Coil Type	Integrated whole body transmit/ Receive coil
Operating Mode	Normal or first level controlled operating mode
Maximum Whole-Body SAR	4 W/kg
Scan Duration	4 W/kg whole-body average SAR for 60 minutes of continuous RF (a sequence or back-to-back series/ scan without breaks).
Scan Region	Any landmark is acceptable
MR Image Artifact	The maximum artifact beyond the implant was 5 mm for the spin echo sequence and 9 mm for the gradient echo sequence in a 3-Tesla MR system (GE Signa HDxt MR System). Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary. The presence of other implants or the health state of the patient may require a modification of the MR conditions.

During an MRI, the patient may notice a warming sensation around the implant or feel a tingling sensation. If the warming or tingling sensation is uncomfortable the patient should communicate this to the MR technologist, the MRI should be stopped, and the settings adjusted to reduce or eliminate the sensation. The highest temperature change above the background observed in non-clinical testing was +3.2°C (associated with specific conditions listed above).

If information about a specific parameter is not included, there are no conditions associated with that parameter.

PRODUCT COMPLAINTS

To report any issues with the product, please contact Companion Spine: customerservice@companion-spine.com.

Patients experiencing a serious incident in relation to the device should contact Companion Spine: customerservice@companion-spine.com.

FURTHER INFORMATION

Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request. If further information is required, contact Companion Spine.

LEGAL MANUFACTURER

COMPANION SPINE France
Immeuble le Bridge-Etage 5
5 allée des Acacias
33 700 Mérignac- France
www.companion-spine.com

US Contact

COMPANION SPINE LLC
505 Park Avenue, 14th floor
New York, NY 10022 USA

Date of first product on the market by Companion Spine: XX/XX/XXXX

Date of publication of the current version of the IFU by Companion Spine: 03/09/2025

CS001E0001 (DOC-884) Ver. 2

Approved By:

(CO-496) CS001E0001

Description

DIAM Spinal Stabilization System_Physicians and Patient Labeling_US_Update 04SEP2025

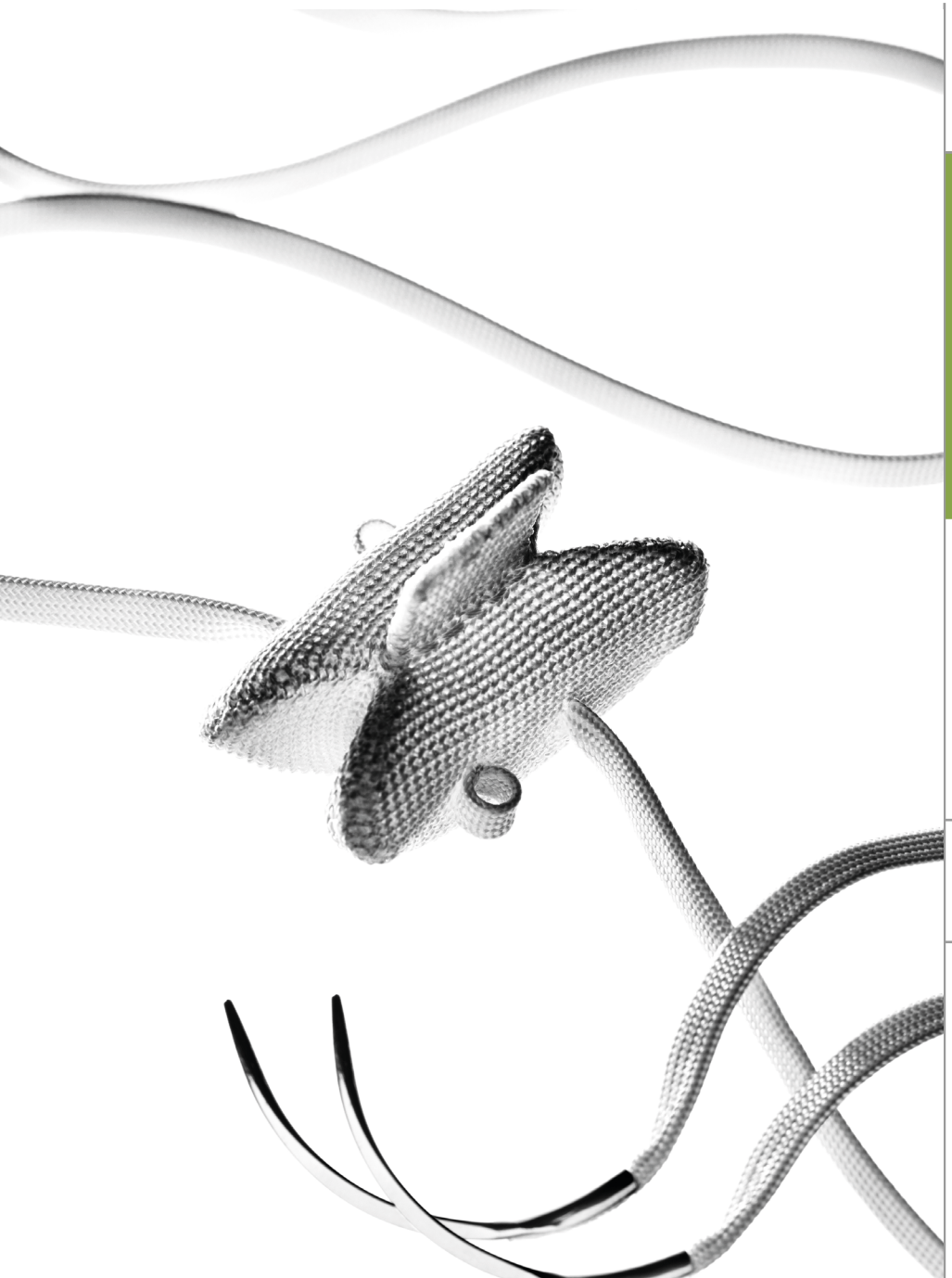
Justification

This Change Order has been submitted following FDA's request to specify the indications, contraindications and precautions for DIAM US.

Assigned To:	Initiated By:	Priority:	Impact:
Arnaud Malet	Camille COMBE	Urgent	Minor

Version History:

Author	Effective Date	CO#	Ver.	Status
Camille COMBE	September 10, 2025 3:52 PM CEST	CO-496	2	Published
Jeremy Mejane	October 3, 2024 1:30 PM CEST	CO-372	1	Superseded
Simon Menand	February 9, 2023 12:35 PM CET	Not Available	0	Superseded



DIAM™

SPINAL STABILIZATION SYSTEM

US

Surgical Technique Manual

COMPANION SPINE

Changing spine care for good.

COMPANION SPINE

Changing spine care for good.

DIAM™
Spinal Stabilization System

Surgical Technique Manual

The DIAM™ Spinal Stabilization System is provided by Companion Spine.

Indications

The DIAM™ Spinal Stabilization System is indicated for skeletally mature patients that have moderate to severe primary low back pain (greater than leg pain) secondary to lumbar degenerative disc disease (DDD), at a single level from L2-L5 with current episode refractory to at least 6 months of non-operative care.

Symptomatic disc disease is confirmed by patient history, physical examination, and radiographic evaluation with one or more of the following factors:

- Greater than 2mm of decreased disc height (average disc height) compared to the adjacent level
- Scarring/thickening of the ligamentum flavum, annulus fibrosus, or facet joint capsule
- Non-extruded herniated nucleus pulposus

The DIAM™ Spinal Stabilization System is implanted via a minimally invasive posterior approach.

Contraindications

The DIAM™ Spinal Stabilization System is contraindicated in patients with:

- An allergy to silicone, polyethylene terephthalate, or titanium;
- Spinal anatomy or disease that would prevent implantation of the device or cause the device to be unstable in situ, such as: Instability of the lumbar spine, e.g., isthmic spondylolisthesis or degenerative spondylolisthesis (anterolisthesis with more than 2mm of translation) or retrolisthesis at the involved level;
- Disc height loss greater than 67% (average disc height) at the involved level compared to the next adjacent spinal level;
- Scoliosis (Cobb angle greater than10 degrees), flat back or kyphotic spine at the operative level;
- Severe anatomical alterations at the operative levels including congenital abnormalities, spinal tumor or evidence of prior or existing lumbar spine trauma;
- Prior surgery at the operative level;
- Cauda equina syndrome defined as neural compression causing neurogenic bladder or bowel dysfunction;
- Disc degeneration requiring treatment at more than one lumbar level;
- Extruded or sequestered disc herniations;
- Large osteophytes and/ or severe hypertrophy between the vertebral bodies and/ or the facet articular process with or without severe subarticular bone erosions and/ or subchondral cysts.

- Diagnosis of osteoporosis, defined as a DEXA bone mineral density T-score equal or less than -2.5;
- Pregnancy;
- Active systemic infection, or infection localized to the site of implantation;
- Morbid obesity defined as body mass index (BMI) greater than 40.

Warnings

The DIAM™ Spinal Stabilization System should only be used by physicians who are experienced and have undergone training in the use of the device. **Only physicians who are familiar with the device, instruments, procedure, clinical applications, biomechanics, adverse events, and risks associated with the DIAM™ Spinal Stabilization System should use this device. A lack of adequate experience and/or training may lead to a higher incidence of adverse events.**

- The safety and effectiveness of this device has not been established in skeletally immature patients, patients less than 22 years old, or greater than 60 years old.
- Certain anatomical characteristics have been associated with an increased risk of spinous process fractures, including patients with Baastrup sign (close approximation of adjacent spinous processes). Distraction should always be performed gradually and carefully since the risk of spinous process fracture exists.
- This device was designed for single patient use only. Do not reprocess or reuse this product. Reuse or reprocessing may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.

Precautions

The supraspinous ligament should be carefully preserved during surgery to avoid overstressing the bone-implant interface.
The safety and effectiveness of the DIAM™ Spinal Stabilization System has not been established in patients with the following conditions:

- More than one spinal level requiring surgical intervention.
- More than one surgical procedure at any combination of lumbar levels.
- Prior surgery at any lumbar vertebral level with instrumentation.
- Prior surgery at an adjacent lumbar vertebral level without instrumentation.
- History of Paget's disease, osteomalacia, or other metabolic bone disease.
- History of an autoimmune disease.
- Psychiatric or cognitive impairment.
- Current or recent history of illicit drug or alcohol abuse, or dependence as defined as the continued use of alcohol despite the development of social, legal, or health problems.

Potential Adverse Events

All of the possible adverse effects or complications associated with spinal surgery are possible. The following potential adverse events may occur during the use of the DIAM™ Spinal Stabilization System:

Risks Associated with any Surgical Procedure Include:

General surgical risks include, but are not limited to:

- Anesthesia complications including allergic reaction, anaphylaxis, or other reactions to anesthesia
- Anemia
- Blood loss/ hemorrhage possibly requiring a blood transfusion with possible transfusion reaction
- Myocardial infarction
- Blood clots including pulmonary emboli
- Phlebitis
- Injury to blood vessels
- Septicemia
- Cerebral Vascular Accident (i.e., stroke)
- Pulmonary complications including atelectasis, pneumothorax or pneumonia, pulmonary edema and respiratory distress
- False aneurysm
- Infection (wound, local, and/or systemic) abscess, or cellulitis, localized or systemic, fever
- Soft tissue damage or fluid collections, including edema, hematoma or seroma, which may require drainage, aspiration, or debridement or other intervention
- Surgical wound dehiscence, necrosis, or scarring of tissue around the wound
- Impairment of the gastrointestinal system including ileus or bowel obstruction, nausea or vomiting
- Impairment of the genitourinary system including incontinence, bladder dysfunction, urinary tract infection, or reproductive system complications
- Neurological complications including nerve damage, paralysis, seizures or convulsions, changes to mental status, or reflex sympathetic dystrophy
- Numbness
- Complications of pregnancy including miscarriage or congenital defects
- Pain at surgical site
- Death.

Risks Associated with Lumbar Spinal Surgery Include:

- Risks to neurological structures:
  - Dural tear dural leak and/or dural injury with or without CSF leakage
  - Arachnoiditis
  - Neurologic deterioration - injury to nerves or nerve roots associated with the spinal cord (resulting in pain, weakness, paralysis (partial or complete), paresthesia, altered reflexes, numbness, tingling, or other changes in sensation)
  - Gait disturbance
  - Cerebrospinal fluid leakage
  - Cerebrospinal fistula
  - Reflex Sympathetic Dystrophy (RSD)
- New or worsened back or leg pain
- Damage to nerves, blood vessels, and nearby tissues
- Impaired muscle or nerve function
- Epidural bleeding, hematoma, or fibrosis
- Surgery at incorrect levels
- Osteolysis
- Loss of bowel or bladder function
- Fracture of the vertebrae, spinous process, or other damage to bony structures during or after surgery
- Postoperative muscle and tissue pain
- Development of degenerative changes at adjacent levels
- Scarring or soft tissue damage
- Spinal instability
- Post-surgical spondylolisthesis (vertebral slippage)
- Retrolisthesis
- Spinal stenosis (narrowing of the spinal canal)
- Spondylosis
- Infection of the bone, or surrounding soft tissue
- Perineural fibrosis
- Pain and discomfort associated with the presence of implants
- Pain and discomfort associated with the surgical procedure (e.g., cutting of muscles, ligaments, and tissue) and healing
- The spine may undergo adverse changes or deterioration including loss of proper spinal curvature, correction, height, and/or reduction, or malalignment, and another surgery may be required
- Adverse bone/implant interface reaction
- Instruments breaking or malfunctioning which may cause damage to the operative site or adjacent structures

Risks Associated with Lumbar Spine Implants (including the DIAM™ Spinal Stabilization System):

- Sensitivity or allergy to the implant material [Polyethylene Terephthalate (PET), silicone, and titanium]
- Failure of the device/procedure to improve symptoms and/or function
- Pain and discomfort associated with the operative site or presence of implants
- Implant malposition or incorrect orientation
- Sizing issues with components
- Uncrimping of the needle instrument leading to increased operation time
- Anatomical or technical difficulties implanting the device
- Spinous process fracture
- Spinous process bone resorption
- Bone loss or decrease in bone density, possibly caused by stress shielding
- Production of wear debris which may damage surrounding soft tissues including muscle or nerve
- Foreign body reaction to implant material or material debris and/or autoimmune disease
- Deep infection
- Formation of scar tissue at implant site
- Implantation at the wrong spinal level
- Migration or dislodgement of the implant from the original position so that it becomes ineffective or causes damage to adjacent bone or soft tissues including nerves
- Reoperation including revision, removal, or supplemental fixation
- Loosening, fatigue, deformation, breakage or disassembly of the implant, which may require another operation to remove the implant and may require another treatment method.

Notes

Training

Physicians who intend to use the DIAM™ Spinal Stabilization System must undergo training to ensure they have the necessary background and skills to use the device safely and effectively. This training typically includes both didactic (classroom-style) and laboratory components.

During the didactic portion of the training, physicians learn about the implant components, including their design, materials used, and functions. They also familiarize themselves with the manual instruments employed in the implantation process. This training ensures that physicians understand the various components and instruments associated with the DIAM™ Spinal Stabilization System.

Throughout this session, participants will also explore an extensive array of scientific evidence pertaining to the product. This encompasses a multitude of published studies evaluating the safety and effectiveness of the device in vivo.

The training also covers the implantation procedure itself, providing step-by-step instructions on how to correctly position and insert the device. Physicians learn the surgical technique, patient positioning, incision placement, and other procedural details to ensure safe and successful implantation.

Clinical applications of the DIAM™ Spinal Stabilization System are discussed, highlighting the conditions or situations where the device is suitable for use. This information helps physicians identify appropriate patients and understand the potential benefits of the device.

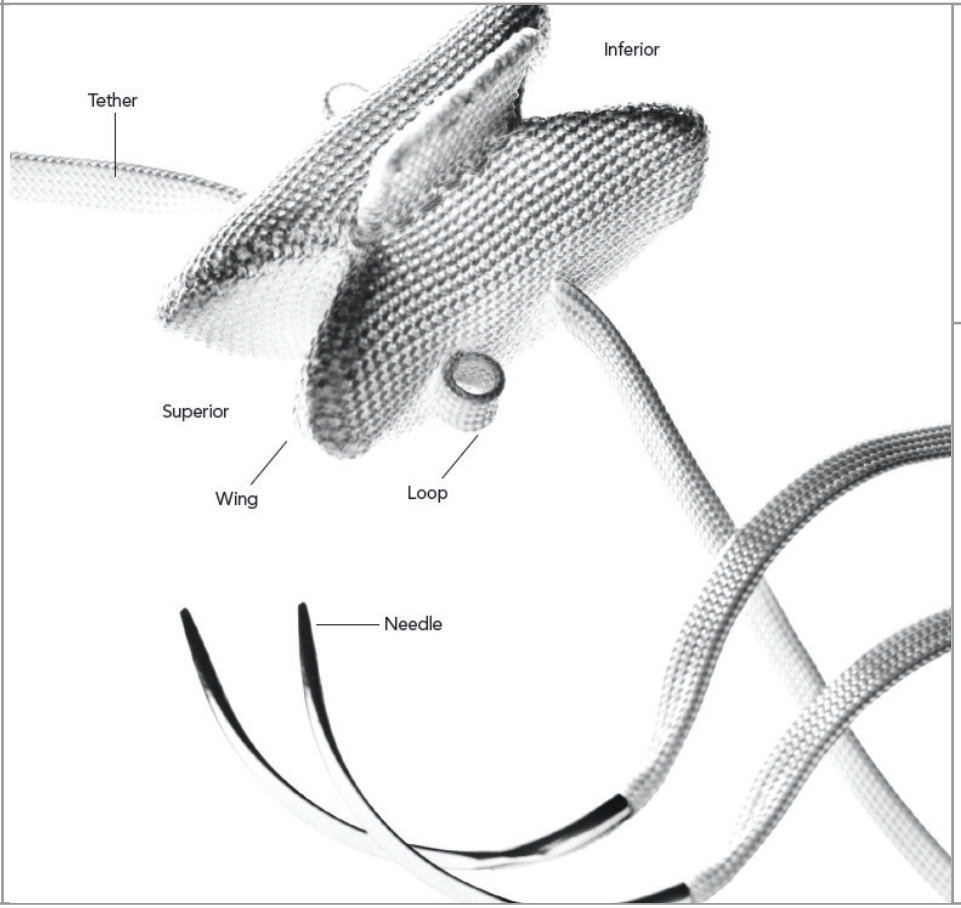
Biomechanics of the device are also covered in the training. Physicians learn how the DIAM™ Spinal Stabilization System interacts with the spine and affects its biomechanical properties. Understanding these principles is crucial for selecting the appropriate patients and optimizing outcomes.

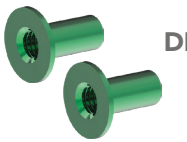
Lastly, the training covers the potential adverse events and risks associated with using the DIAM™ Spinal Stabilization System. Physicians learn about the possible complications, contraindications, and precautions they need to be aware of when using the device. This knowledge helps physicians identify and manage any complications or adverse events that may arise during or after implantation.

Overall, the training ensures that physicians have a comprehensive understanding of the DIAM™ Spinal Stabilization System, its implantation procedure, clinical applications, biomechanics, and associated risks. This knowledge is essential for the safe and effective use of the device in patient care.

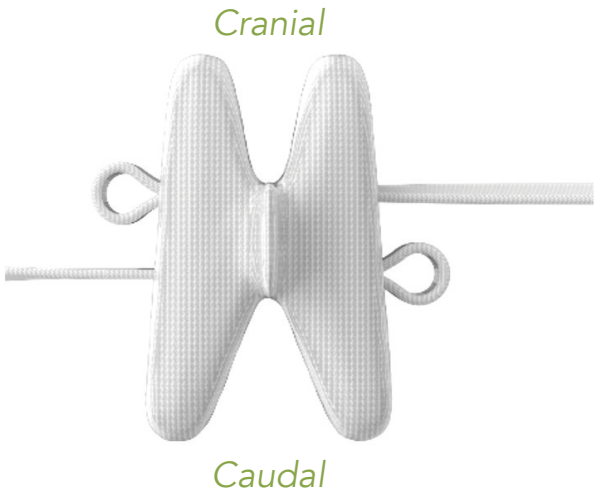
To learn more about the DIAM™ Spinal Stabilization System training, please contact Customer Service at customerservice@companion-spine.com

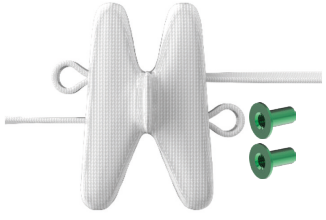
Implant



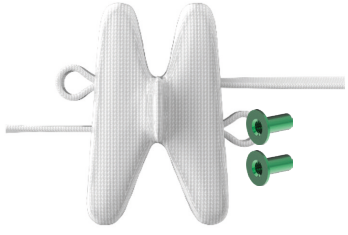


DIAM™ Spinal Stabilization System Crimps
CS001A0015

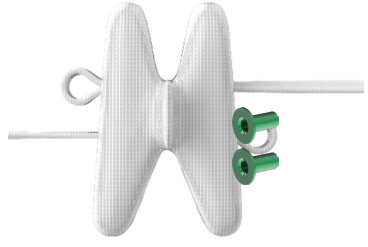




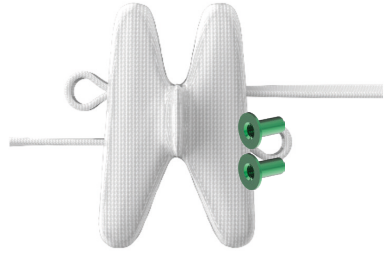
DIAM™ Spinal Stabilization System Spinal Device 08
CS001A0008



DIAM™ Spinal Stabilization System Spinal Device 10
CS001A0010



DIAM™ Spinal Stabilization System Spinal Device 12
CS001A0012



DIAM™ Spinal Stabilization System Spinal Device 14
CS001A0014

Instrument Set

Option 1

Case and Tray parts:
CS001C0031 – Outer Case
CS001C0032 – Outer Case Lid
CS001C0034 – Upper Instrument Tray

DIAM™ Spinal Stabilization System, Tissue Resector-Left
CS001B0027

DIAM™ Spinal Stabilization System, Tissue Resector-Right
CS001B0028

DIAM™ Spinal Stabilization System, Bi-lateral Impactor
CS001B0025

DIAM™ Spinal Stabilization System, Sicard
CS001B0021 (small)
CS001B0022 (large)

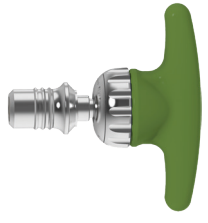
DIAM™ Spinal Stabilization System, Crimper
CS001B0026

DIAM™ Spinal Stabilization System, Small Distractor w/Knob
CS001B0029 (small)

DIAM™ Spinal Stabilization System, Template (four included)
CS001B0008 (8mm)
CS001B0010 (10mm)
CS001B0012 (12mm)
CS001B0014 (14mm)

OPTION 1

DIAM™ Spinal Stabilization System, Unilateral Inserter
CS001B0024



DIAM™ Spinal Stabilization System, Ratcheting T-handle
CS001B0030

Instrument Set
Option 2

Case and Tray parts:
CS001C0035 – Outer Case (alt inserter)
CS001C0032 – Outer Case Lid
CS001C0034 – Upper Instrument Tray

DIAM™ Spinal Stabilization System, Tissue Resector-Left
CS001B0027

DIAM™ Spinal Stabilization System, Sicard
CS001B0021 (small)
CS001B0022 (large)

DIAM™ Spinal Stabilization System, Template (four included)
CS001B0008 (8mm)
CS001B0010 (10mm)
CS001B0012 (12mm)
CS001B0014 (14mm)

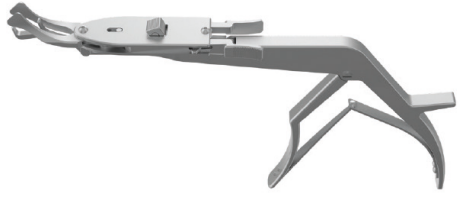
DIAM™ Spinal Stabilization System, Tissue Resector-Right
CS001B0028

DIAM™ Spinal Stabilization System, Crimper
CS001B0026

DIAM™ Spinal Stabilization System, Bi-lateral Impactor
CS001B0025

DIAM™ Spinal Stabilization System, Small Distractor w/Knob
CS001B0029 (small)

OPTION 2



DIAM™ Spinal Stabilization System, Implant Inserter
CS001B0031

Step 1: Patient Positioning and Approach

DIAM™ Spinal Stabilization System procedures are performed under spinal or general anesthesia. The patient is positioned prone with the spine slightly flexed to aid in the intraoperative exposure of the interlaminar space. The table and frame should be compatible with lateral fluoroscopy and/or x-ray imaging.

Identify the appropriate operative level utilizing manual palpation and imaging techniques. Make a midline incision above the spinous processes at the appropriate levels and retract the soft tissue. Elevate the musculature and other soft tissues to expose the spinous processes (Figure 1). **The supraspinous ligament should be preserved.**

Figure 1: Patient positioning

Step 2: Implant Site Preparation

The musculature is elevated bilaterally from the lamina to the level of the apophyseal joint capsules utilizing a standard technique. **The apophyseal joint capsules and supraspinous ligament should be carefully preserved.** The interspinous space is prepared all the way to the ligamentum flavum using blunt dissection, only removing the necessary interspinous ligament to properly insert the DIAM™ Spinal Stabilization System implant. The ligamentum flavum should be preserved.

The implantation site should be cleared of soft tissue using the sicard (Figure 2) and tissue resectors (Figure 3). First, the sicard is used and then tissue resectors are introduced into the interspinous space to free the muscular and ligamentous attachments of the spinous process and lamina. This will ensure a good fit of the wings of the DIAM™ Spinal Stabilization System implant

No bony resection should be performed in order to preserve the integrity of the spinous process (Figure 4).

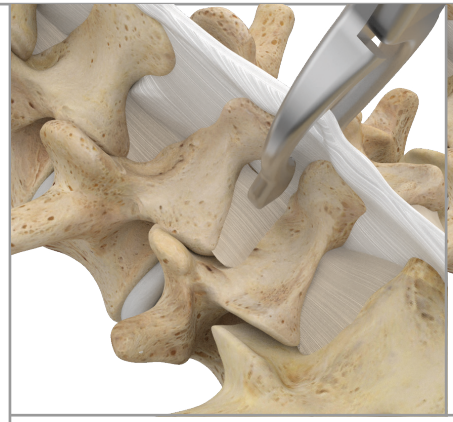


Figure 2: Sicard insertion to remove the necessary interspinous ligament

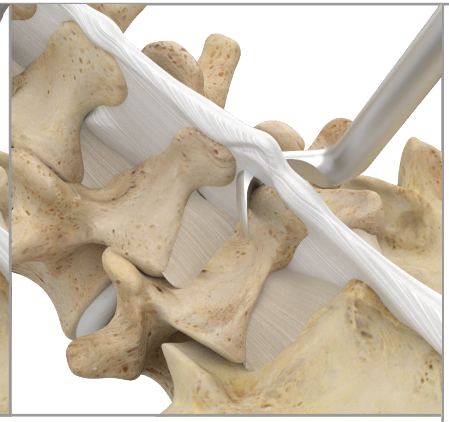


Figure 3: Tissue resectors insertion to free the muscular and ligamentous attachments.

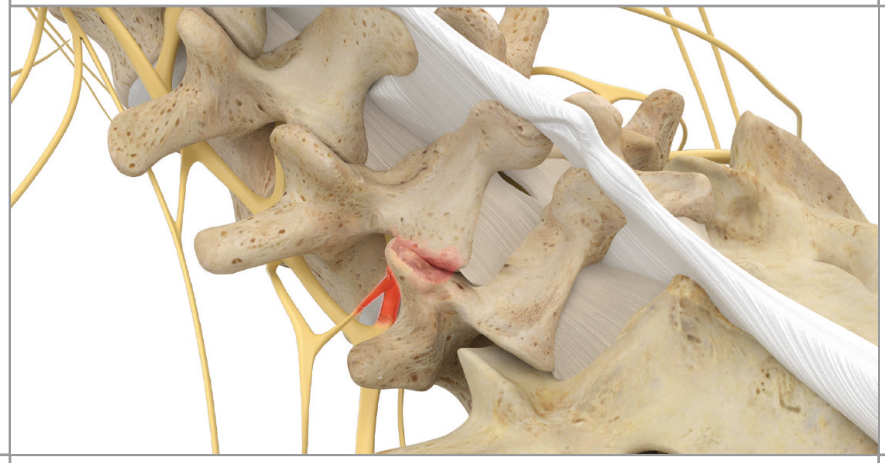


Figure 4: Implantation site fully cleared

Step 3: Distraction

Reduction of the anatomy at the indicated level will optimize adequate decompression and proper lumbar spinal alignment. The reduction is achieved through distraction.

The distractor should be positioned as far anteriorly as possible, ideally at the junction of the spinous process and lamina. Distraction is applied until an appropriate degree of tension is achieved in the supraspinous ligament and capsules, and proper realignment of the facets and the interlaminar space is achieved (Figure 5). Desired anatomic reduction should be verified with fluoroscopy or x-ray imaging. The DIAM™ Spinal Stabilization System device will replace the distractor and maintain adequate decompression while allowing motion and stabilizing the treated segment

NOTE
Do not use the DIAM™ Spinal Stabilization System implant in cases of "kissing spine" where bony bridges must be broken off.

NOTE
Distraction should not put the patient into kyphosis. This can be controlled by ensuring facet re-alignment and that the vertebral body end plates do not exceed parallel alignment.

Figure 5: Distractor insertion to get proper alignment and tension

Step 4: Implant Selection

A series of templates is used to select the proper size DIAM™ Spinal Stabilization System implant. The appropriate template should fit firmly within the interspinous space when positioned above the arms of the distractor (Figure 6).
The templates come in 8, 10, 12 and 14mm sizes.

NOTE

If the physician hesitates between two sizes, he must choose the smaller one to avoid placing the patient in kyphosis.

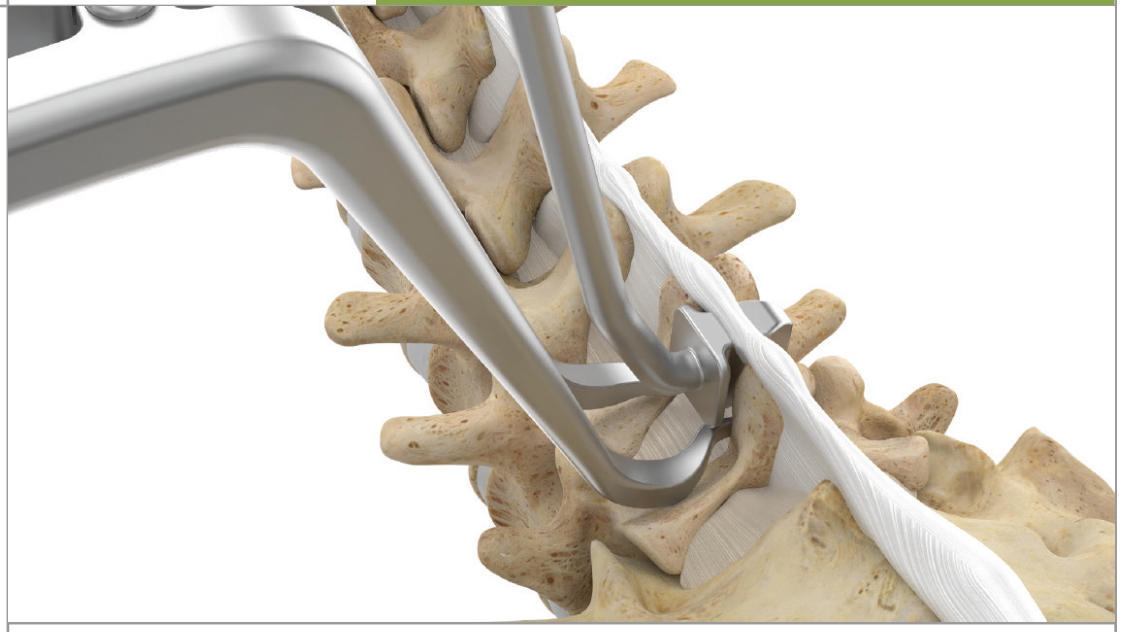


Figure 6: Templates insertion to select the proper implant size

Step 5: Implant Preparation

Option 1 : Unilateral Inserter

Fully open the arms of the Inserter by turning the inserter knob until the open position indicator is in line with the indicator hole on the side of the instrument (Figure 7a). Remove the implant from its packaging and place it in the cradle of the Inserter between the compression arms (Figure 7b). Ensure the proper implant orientation with the implant tab facing toward the handle end of the instrument. The caudal end of the implant is slightly larger than the cranial end (see page 10). While holding the implant in place, begin to compress/fold the wings of the implant by turning the inserter knob clockwise (Figure 7c) until implant is fully compressed (Figure 7d).

An optional Ratcheting T-handle is provided and can be attached to the end of the Inserter if desired. Fully compress the implant wings between the compression arms to facilitate insertion of the implant between the spinous processes and under the supraspinous ligament.

NOTE

Be careful to pull out the ratchet part of the T-handle and insert it **all the way/fully** onto the unilateral inserter.

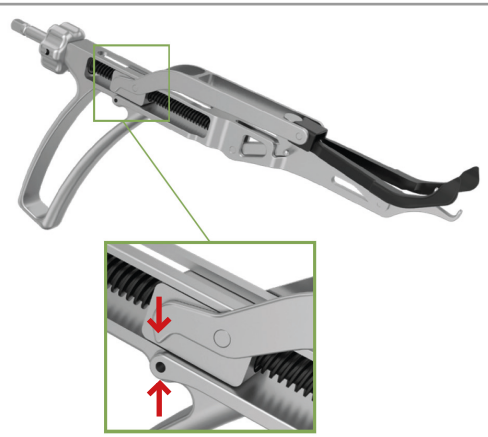


Figure 7a: Inserter indicator hole

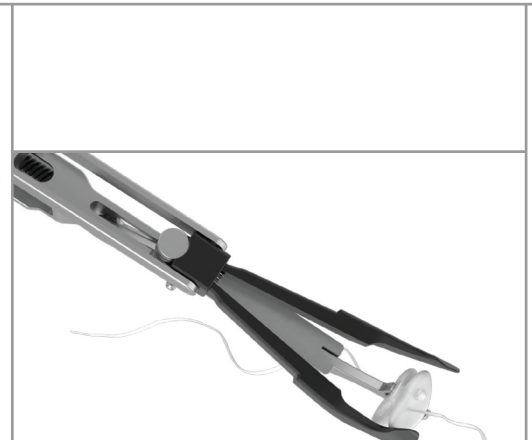


Figure 7b: Implant placed on the open inserter

Figure 7c: Folding implant wings

Figure 7d: Fully compressed implant wings

Step 5: Implant Preparation

Option 2: Implant Inserter

To prepare the implant for insertion, place it on the open inserter (Figure 8a). The wings of the implant will fold as the inserter arms are compressed (Figure 8b). Fold the inserter arms until implant wings are fully compressed on one side (Figure 8c) to facilitate insertion under the supraspinous ligament. Care should be taken to properly position the implant in the appropriate cranial/caudal orientation. The superior (cranial) end of the device is slightly smaller than the inferior (caudal) end (see page 10).

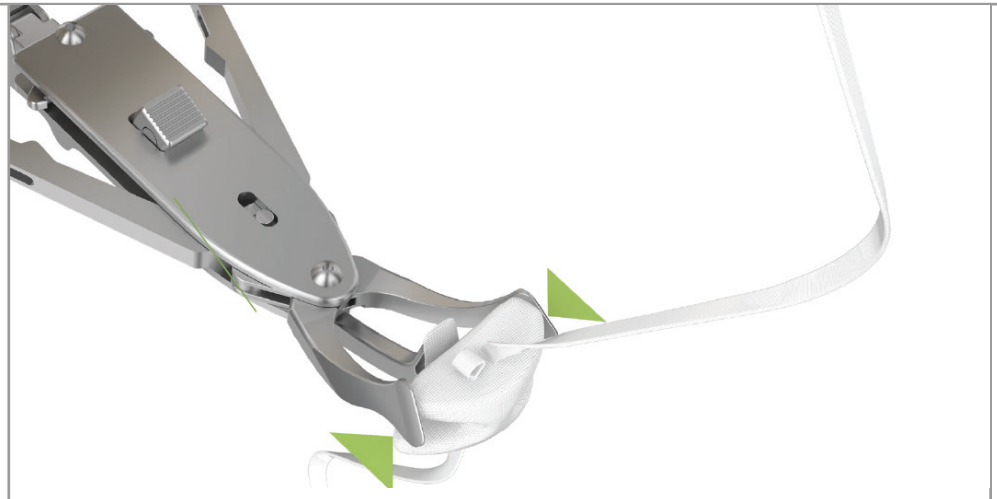


Figure 8a: Implant placed on the open inserter

Figure 8b: Folding implant wings

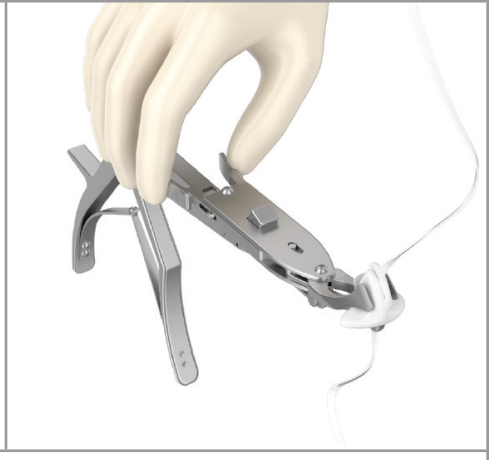


Figure 8c: Fully compressed implant wings

Step 6: Implant Insertion

Additional distraction may be applied temporarily to facilitate insertion of the DIAM™ Spinal Stabilization System implant. The contralateral tether is passed through the interspinous space. The DIAM™ Spinal Stabilization System implant/inserter combination is then positioned above the grooves of the distractor and advanced until the jaws of the inserter are in contact with the spinous process (Figure 9a and 9b - option 1 or Figure 9c and 9d - option 2).

The implant is then advanced and its wings deployed along the contralateral side by squeezing the inserter handle (or rotating the inserter knob counterclockwise - option 1). The distractor is then removed.

NOTE

If needed, the bilateral impactor can be used to secure the implant while removing the distractor.

Option 1: Unilateral Inserter

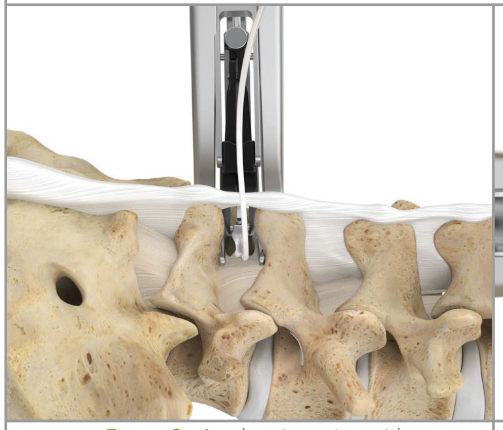


Figure 9a: Implant insertion with Unilateral Inserter - lateral view

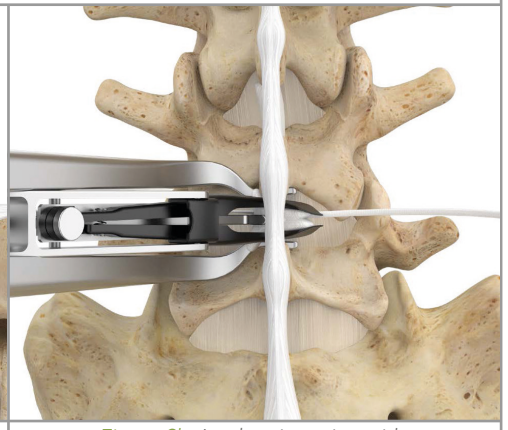


Figure 9b: Implant insertion with Unilateral Inserter - top view

Option 2: Implant Inserter

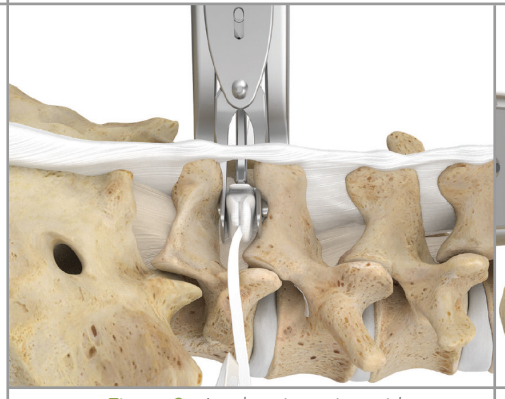


Figure 9c: Implant insertion with Implant Inserter - lateral view

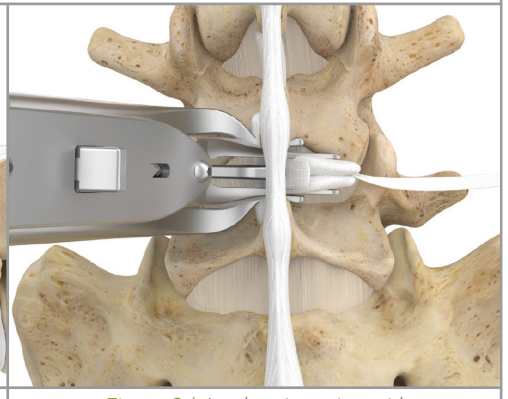


Figure 9d: Implant insertion with Implant Inserter - top view

Step 7: Implant Positioning

The DIAM™ Spinal Stabilization System implant is driven as far anterior as possible using the unilateral or bilateral impactor (Figure 10).

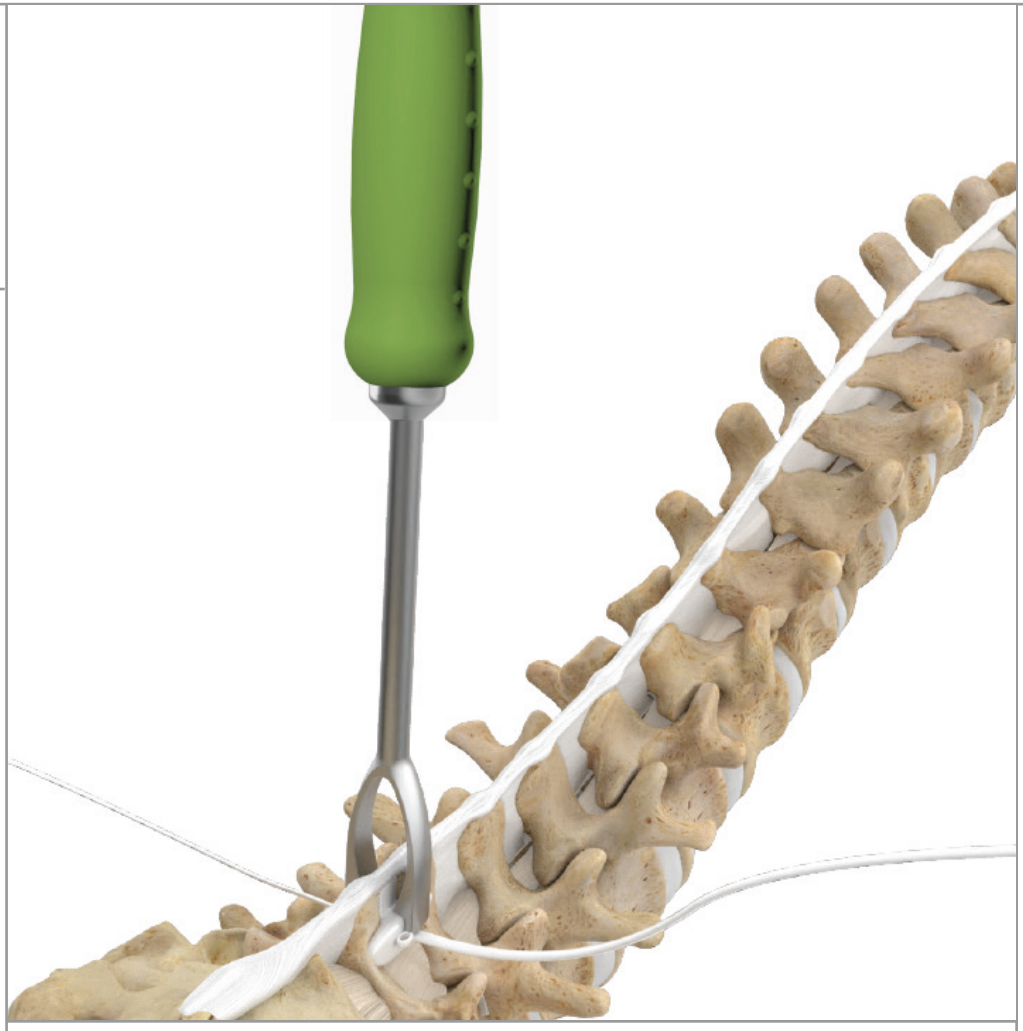


Figure 10: Bilateral impactor insertion to position the implant

Step 8: Tether Attachment

The DIAM™ Spinal Stabilization System device is secured to the adjacent spinous processes by the implant tethers. A contralateral exposure is necessary to allow passage of the tethers around the supra-adjacent and sub-adjacent spinous processes. The tether should avoid being twisted when placed around the spinous processes. The tethers are passed through the loops on each side of the implant (Figure 11). Next, slide the crimps onto each tether and apply longitudinal tension (Figure 12). The crimper is then used to secure the crimps (Figure 13). The excess tether length is then cut just distal to the crimp.

Figure 11: Tethers passed through the loops

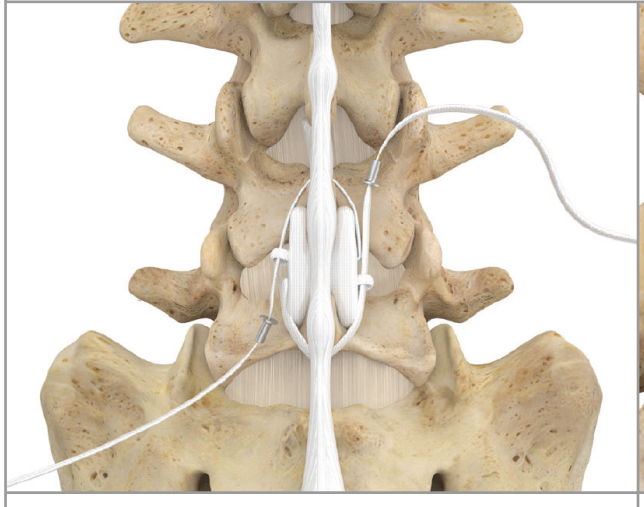


Figure 12: Crimps slid onto each tether

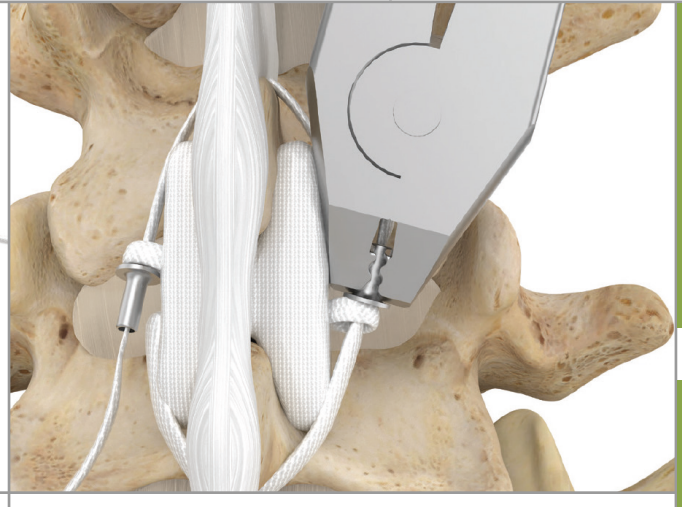


Figure 13: Crimper used to secure the crimps

NOTE

Once the needle is through the interspinous ligament, grab directly the tethers using a suitable suturing instrument (needle holder / tweezers) to slide it completely through the ligament to then apply tension. Do not use the needle to pull or apply tension.

NOTE

Only depress the crimper one time. Over crimping could result in an unsecured tether.

Step 9: Closure

The final implant position (Figures 14 and 15) should be verified prior to closure.

The closure is performed following standard procedure. A surgical drain may be left in place in accordance with the surgeon's decision.

Preoperative and postoperative antibiotics should be administered per the surgeon's standard of care.

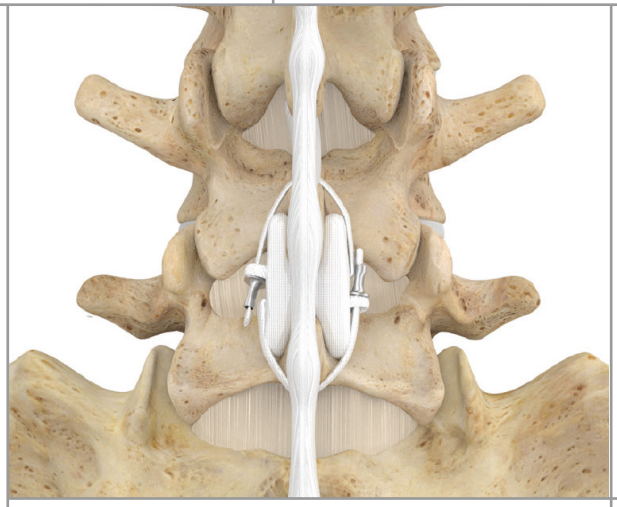


Figure 14: Final implant position - top view

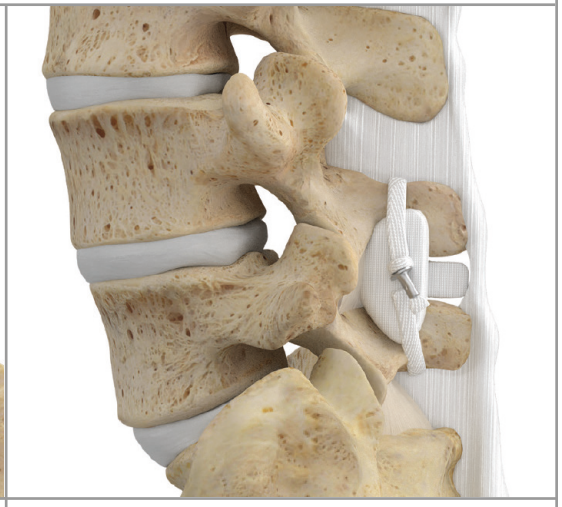


Figure 15: Final implant position - lateral view

Explant Technique

Contact Companion Spine (at customerservice@companion-spine.com) when planning DIAM™ Spinal Stabilization System removal to facilitate device retrieval and complaint handling.

In the event that the surgeon has determined that the DIAM™ Spinal Stabilization System implant needs to be removed, the surgeon would decide on the best course of action.

The patient is positioned prone with the spine slightly flexed to aid in the intraoperative exposure of the interlaminar space, under local, spinal or general anesthesia (Figure 16).

Figure 16: Patient positioning

EXAMPLE OF SURGICAL INSTRUMENTS THAT COULD BE USED:

- Retractor (Weitlaner for example)
- Scalpel
- Bone-Cutting Forceps (or Pince Gouge)

If the device must be removed, the surgeon performs a midline incision over the initial implant site and retracts the soft tissue until the implant can be seen (Figure 17).

The surgeon removes the supraspinous ligament posterior to the device at the implanted motion segment. Once the implant is exposed, the secured tethers above and below the spacer are cut (Figure 18).

Then, the entire implant is simply pulled out utilizing an appropriate forceps (Figure 19).

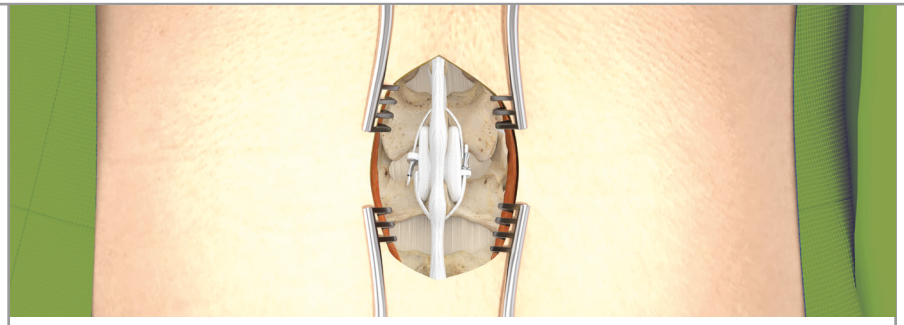


Figure 17: Implant view after soft tissue retraction

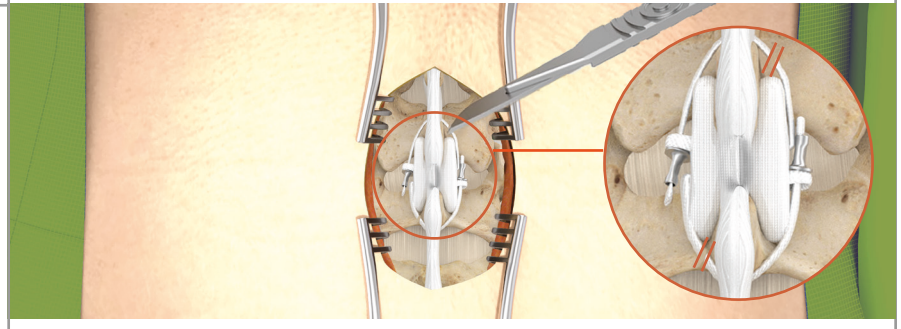


Figure 18: Supraspinous ligament removed above the implant and tethers cut

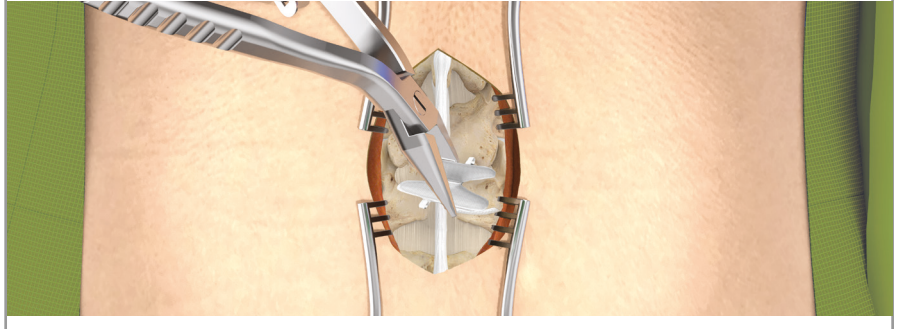


Figure 19: Removal of the implant

Product Ordering Information

DIAM™ Spinal Stabilization System

Instrument Set 1

Item Number	Description
CS001B0008	DIAM™ Spinal Stabilization System, 8mm Template
CS001B0010	DIAM™ Spinal Stabilization System, 10mm Template
CS001B0012	DIAM™ Spinal Stabilization System, 12mm Template
CS001B0014	DIAM™ Spinal Stabilization System, 14mm Template
CS001B0021	DIAM™ Spinal Stabilization System, Sicard Small
CS001B0022	DIAM™ Spinal Stabilization System, Sicard Large
CS001B0024	DIAM™ Spinal Stabilization System, Unilateral Inserter
CS001B0025	DIAM™ Spinal Stabilization System, Bi-Lateral Impactor
CS001B0026	DIAM™ Spinal Stabilization System, Crimper
CS001B0027	DIAM™ Spinal Stabilization System, Tissue Resector-Left
CS001B0028	DIAM™ Spinal Stabilization System, Tissue Resector-Right
CS001B0029	DIAM™ Spinal Stabilization System, Small Distractor W/Knob
CS001B0030	DIAM™ Spinal Stabilization System, Ratcheting T-Handle

Instrument Set 2

Item Number	Description
CS001B0008	DIAM™ Spinal Stabilization System, 8mm Template
CS001B0010	DIAM™ Spinal Stabilization System, 10mm Template
CS001B0012	DIAM™ Spinal Stabilization System, 12mm Template
CS001B0014	DIAM™ Spinal Stabilization System, 14mm Template
CS001B0021	DIAM™ Spinal Stabilization System, Sicard Small
CS001B0022	DIAM™ Spinal Stabilization System, Sicard Large
CS001B0031	DIAM™ Spinal Stabilization System, Implant Inserter
CS001B0025	DIAM™ Spinal Stabilization System, Bi-Lateral Impactor
CS001B0026	DIAM™ Spinal Stabilization System, Crimper
CS001B0027	DIAM™ Spinal Stabilization System, Tissue Resector-Left
CS001B0028	DIAM™ Spinal Stabilization System, Tissue Resector-Right
CS001B0029	DIAM™ Spinal Stabilization System, Small Distractor W/Knob

Product Ordering Information

DIAM™ Spinal Stabilization System

Implants

Item Number	Description
CS001A0008	DIAM™ Spinal Stabilization System Spinal Device 08
CS001A0010	DIAM™ Spinal Stabilization System Spinal Device 10
CS001A0012	DIAM™ Spinal Stabilization System Spinal Device 12
CS001A0014	DIAM™ Spinal Stabilization System Spinal Device 14
CS001A0015	DIAM™ Spinal Stabilization System Crimps

The DIAM™ Spinal Stabilization System is made of the 3 following components:

Component Designation		Size	Raw Material	Type of Contact with the Patient	Sterility
Spacer assembly	Core	8 to 14 mm	Dimethyl siloxane (silicone)	Long-term contact with spinous process, blood, and soft tissue	Single-use device sterilized by Gamma irradiation
	Jacket		Polyethylene terephthalate (PET)		
Ligament assembly	Needle	Unique size	Stainless steel	Limited contact with blood and soft tissues	
	Tether		PET	Long-term contact with spinous process, blood, and soft tissue	
Crimp		Unique size	Type 2 Commercially Pure Titanium		

Not of human or animal origin

STORAGE

The shelf-life of the medical device is 1 year keeping it in a dry place, without sunlight, and in an ambient atmosphere to ensure the integrity of the implant and its packaging.

PACKAGING AND STERILIZATION

Devices are supplied sterile, sterilized with gamma radiation. Packages for each of the components should be intact upon receipt. Once the seal on the sterile package is broken, the product should not be re-sterilized. If a loaner set is used, all sets, and components should be carefully checked for completeness and to ensure there is no damage prior to use. Damaged packages or products should not be used and should be returned to Companion Spine.

PRODUCT COMPLAINTS

To report any issues with the product, please contact Companion Spine: customerservice@companion-spine.com.

Patients experiencing a serious incident in relation to the device should contact Companion Spine: customerservice@companion-spine.com.

FURTHER INFORMATION

Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request.

If further information is required, contact Companion Spine.

COMPANION SPINE

Changing spine care for good.

The surgical technique shown is for illustrative purposes only.
The technique(s) actually employed in each case will always depend upon the medical judgment of the physician exercised before and during surgery as to the best mode of treatment for each patient.

Please see the package insert for the complete list of indications, warnings, precautions and other important medical information: *https://www.ifu-oem.com/ifu/C17 (link to be edited)*

Caution: Federal law restricts this device to sale by or on the order of a physician.

DEVICES MANUFACTURER BY:

COMPANION SPINE France
Immeuble le Bridge - Étage 5
5 Allée des Acacias
33 700 Mérignac, France
TEL: +33 5 32 26 25 70
FAX: +33 5 32 26 25 79
www.companion-spine.com

US CONTACT:

COMPANION SPINE LLC
505 Park Avenue, 14th floor
New York, NY 10022 USA

DISTRIBUTED BY:

CS001E0006_2