SPONSORED RESEARCH AND COLLABORATION AGREEMENT
BETWEEN 7D SURGICAL, INC. AND HOSPITAL FOR SPECIAL SURGERY

(This is Addendum 1 to that certain Sponsored Research and Collaboration Agreement (SRCA) between the parties dated November 20, 2017, and this Addendum is subject to the terms of that SRCA, including but not limited to all the rights and obligations of the parties stated in such SRCA.)

ADDENDUM 1

A Single Center, Cohort Study Of The MvIGS Spine Navigation System

Addendum Approved:

Hospital for Special Surgery	7D Surgical, Inc.
By: _____	By: _____
Name: Vincent L. Grassia, Jr.	Name: _____
Title: VP, Research Administration	Title: _____
Date: _____	Date: _____

Read, acknowledged and agreed:

By: _____

Name: Frank P. Cammisa, Jr., MD, FACS

Title: Chief Emeritus, Spinal Surgical Service
Principal Investigator

Date: _____

7D Surgical Protocol

A Single-Center, Cohort Study of the MvIGS Spine Navigation System

Protocol Approval Date:

March 2, 2018

Sponsor

7D Surgical
60 Scarsdale Road Unit 118
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Confidentiality Statement

EU CLINICAL STUDY PROTOCOL SYNOPSIS

Sponsor: 7D Surgical

Product: Machine-vision Image guided Surgery Navigation System

Title of Study: "A Single-Center, Prospective Cohort Study of the MvIGS (MvIGS) Spine Navigation System"

Number of Centers Planned: 1

Planned Study Period: 1Q2018-1Q2019

Primary Objective: To prospectively investigate clinical outcomes following implementation of the Machine-vision Image Guided Surgery (MvIGS) spine navigation system in patients requiring posterior instrumentation.

General Design and Methodology: This is a single center, prospective, non-randomized cohort study to assess clinical outcomes following the use of the MvIGS spine navigation system for treatment of spinal stenosis and degenerative spondylolisthesis of the lumbar spine. There will be separate study arms for cases utilizing the three-dimensional (3D) MvIGS spine navigation system and cases that utilize conventional two-dimensional (2D) fluoroscopy.

Study Arm 1: One, two and three-level posterior spine fusion surgery using bilateral pedicle screw instrumentation under 3D MvIGS intraoperative navigation guidance.

Study Arm 2: One, two and three-level posterior spine fusion surgery using bilateral pedicle screw instrumentation under 2D fluoroscopy.

Primary Endpoint: The primary endpoint is based on the mean reduction in total length of operative time. Operative time will be determined by the official recorded operative notes.

Secondary Endpoints: Secondary endpoints include:

- Length of stay
    - Aim: Decrease length of hospital stay
    - Measured: Time (Hours)
- Length of time for initial image processing
    - Aim: Decrease disturbance to surgeon workflow
    - Measured: Time (Minutes)
- Length of time to place all screws
    - Aim: Reduce the time for screw placement
    - Measured: Time (Minutes)
- Length of time to confirm screw placement
    - Aim: Reduce the time needed for confirmation of screw location
    - Measured: Time (Minutes)
- Length of time to register images
    - Aim: To reduce time for registration of reference images
    - Measured: Time (Seconds)
- Estimated Blood Loss (EBL)

    - Aim: To reduce the EBL of each case
    - Measured: Milliliters (mL)
- Incidence of Malalignment
    - Aim: To decrease the incidence of pedicle screw malalignment
    - Measured: Misalignment angle between pilot hole and screw trajectory (degrees)
- Complications: Neurological Deficits, Dural Tears, deep wound infections, etc.
    - Aim: To decrease the incidence of intraoperative complications
    - Measured: number of reported complications while hospitalized
- Measurement of 2D fluoroscopy radiation exposure
    - Aim: to reduce patient and surgeon exposure to radiation
    - Measured: Exposure measured by Dose Area Product (DAP)

Exploratory Analyses: Exploratory analyses include the number of vertebral levels involved, radiographic evaluations of anterior disc height, implant migration, and stability, and preservation of motion at the adjacent, un-instrumented level.

Number of Patients Planned: A total of 130 patients, with 65 patients per group.

Criteria for Inclusion: Patients are included in the study if all of the following criteria are met:

1) Diagnosis of spinal stenosis of the lumbar spine with ≤ grade 2 degenerative spondylolisthesis
2) Skeletally mature adults between the ages of 18-85 years at the time of surgery;
3) Has completed at least 6 months of conservative therapy;
4) Personally signed and dated informed consent document prior to any study-related procedures indicating that the patient has been informed of all pertinent aspects of the study.

Criteria for Exclusion: Patients are excluded from participating in this study if any of the following criteria are met:

1) Gross instability, defined as > 3 mm translational motion on flexion/extension studies;
2) Degenerative spondylolisthesis > grade 2
3) Degenerative scoliosis > 10° at any level in lumbar spine;
4) Congenital lumbar spinal stenosis;
5) Endplate changes;
6) Visible change in disc height;
7) Radiographic confirmation of facet joint disease or degeneration;

8) Prior surgery at any lumbar level including the level being treated except for: Lamino/Foraminotomy, Microdiscectomy, IDET, and Percutaneous Discectomy;

9) Any evidence of a prior/current fracture, compromised vertebra, current or past trauma, or tumor at affected level or the spinous processes at the adjacent levels;

10) Requires destabilizing surgical decompression that adversely affects the functioning of the facets;

11) Cauda equina syndrome defined as neural compression causing neurogenic bowel (rectal incontinence) or bladder dysfunction (bladder retention or incontinence);

12) Significant peripheral neuropathy or acute denervation secondary to radiculopathy, caused by conditions other than spinal stenosis;

13) Significant peripheral vascular disease (diminished dorsalis pedis or tibial pulses);

14) Morbid obesity, defined as BMI > 40 kg/m^2;

15) Active systemic or local infection;

16) Active Hepatitis (receiving medical treatment within two years);

17) Immunocompromised such as but not limited to Acquired Immunodeficiency Syndrome (AIDS), HIV infection, Severe Combined Immunodeficiency Syndrome, Thymic Hypoplasia;

18) Insulin dependent diabetes mellitus or any other medical condition(s) that would represent a significant increase in surgical risk or interfere with normal healing;

19) Immunologically suppressed, or has received systemic steroids, excluding nasal steroids, at any dose daily for > 1 month within last 12 months;

20) History of Paget's disease, osteomalacia, or any other metabolic bone disease;

21) Active malignancy. A patient with a history of any invasive malignancy (except non-melanoma skin cancer), unless treated with curative intent and there has been no clinical signs or symptoms of the malignancy >5 years;

22) Involved in study of another investigational product that may affect outcome;

23) Women who are pregnant, lactating or anticipate becoming pregnant within 24 months post-surgery;

24) Patients who are incarcerated;

25) Worker's compensation cases;

26) Patients involved in active litigation relating to his/her spinal condition;

Duration of Follow-up: Patients will be clinically followed throughout the course of their hospital admission.

1 INTRODUCTION

1.1 Background Information

Medicine and technology have long enjoyed a symbiotic relationship whereby the success of one directly advances the other. In the past few decades, innovations in surgical equipment have dramatically enhanced proficiency and improved patient safety in the operating room, thus leading to precipitous reductions in complication rates. In spine surgery, where the inherent risks are great, recent advancements in pre and intraoperative imaging technology have been heavily relied upon for guidance in complex cases. Improvements from two-dimensional (2D) plain radiographs to three-dimensional (3D) real-time imaging have given surgeons accessible accuracy in multiple planes of vision. Though there are many advantages to intraoperative imaging, there exist a number of drawbacks that have been extensively studied, most notably radiation exposure to both surgeon and patient and prolongation of operative time. In hopes to eliminate these drawbacks, an emergent technology in intraoperative spine navigation imaging, and the focus of this study, emits no radiation while simultaneously integrating into the surgeon driven workflow of the operating room.

1.2 Treatment Options

Currently, there are a number of intraoperative imaging options available to aid spine surgeons. By far, the most commonly used modality is 2D fluoroscopy. A worldwide survey conducted in 2013 by Hartl et al. reported that 78% of surgeons utilize routine fluoroscopy during spine surgery as either a control at the end of a procedure or for active monitoring used throughout the procedure. Two dimensional anterior/posterior (AP) and lateral fluoroscopic views provide reasonable accuracy measurements but also subject the patient and surgeon to additional ionizing radiation exposure and increased operative timing.

Computer assisted spine surgery is another imaging modality that has grown popular since its advent in the early 1990's (Kalfas et al.). In computer assisted cases, surgeons are provided with patient specific and real-time three-dimensional (3D) images. Spine navigation systems typically integrate recently acquired pre-operative computer-tomography (CT) images with proprietary software to help orient the surgeon through real-time 3D reconstructed images. Numerous studies have shown a significant reduction in pedicle screw malalignment rates in cases where spine navigation systems are used versus conventional 2D fluoroscopic imaging, thus confirming an increase in accuracy (Patel et al, Hartl et al, 2012). Despite this reduction in pedicle screw malalignment, spine navigation imaging systems do have inherent drawbacks. As is common in most new technologies, the computer assisted surgery (CAS) systems are more expensive than 2D fluoroscopy. CAS systems also require the use of proprietor specific probes and tools during surgery and, therefore, subject the surgeon to a learning curve that initially may prolong operative times. It was that projected disturbance in workflow that Hartl et al. reported as the reason nearly 80% of surgeons did not use CAS more frequently.

In an effort to address the growing concerns of current computer assisted spine navigation systems, an emergent technology has been developed that does not require intraoperative

ionizing radiation exposure. In addition to sparing the patient and surgeon to radiation exposure, this new spine navigation system, named the Machine-vision Image Guided Surgery (MvIGS) system, is also projected to not increase mean operative. By use of Instant Flash™ registration, localizing reference images are generated in a matter of seconds, as opposed to minutes, and thereby mitigate the disturbance to normal surgeon-defined workflow.

1.3 Name of the Device and Intended Use

The name of the device is the Machine-vision Image Guided Surgery (MvIGS) spine navigation system. The intended use of this device is to provide patient specific high quality intraoperative imaging with no radiation exposure. Use of the proprietary integrated surgical light with embedded tracking technology and Instant Flash™ registration allows for continuous and direct visualization of the surgical field with no disturbance to surgeon workflow.

1.4 Objective of Study

The main objective of this study is to prospectively compare operative time of patients requiring posterior instrumentation utilizing the MvIGS spine navigation system to patients requiring posterior instrumentation under the guidance of conventional 2D fluoroscopy.

1.5 Clinical Study Rationale

Posterior fixation is the standard of care for spinal instability and deformity. Of paramount importance are the accurate placement of transpedicular screws and the avoidance of adjacent neurovascular structures. Intraoperative 3D navigation systems are becoming increasingly popular yet conventional 2D fluoroscopy remains the more widely used modality (Hartl). Worldwide consensus from 677 spine surgeons reported the need for more data regarding surgical precision, operative time and radiation exposure, among other factors, for computer-assisted surgery (CAS) to become more widely accepted.

The purpose of this study is to evaluate the use of the MvIGS spine navigation system for pedicle screw fixation guidance and its effect on the length of operation. It is projected that the length of operation will remain similar to cases where conventional 2D fluoroscopy is utilized.

2 CLINICAL ASSESSMENTS

2.1 Primary Endpoint

The primary endpoint is based on the mean reduction in total length of operative time. Operative time will be determined by the official recorded operative notes.

2.2 Secondary Endpoints

- Length of stay
    - Aim: Decrease length of hospital stay
    - Measured: Time (Hours)
- Length of time for initial image processing
    - Aim: Decrease disturbance to surgeon workflow
    - Measured: Time (Minutes)
- Length of time to place all screws
    - Aim: Reduce the time for screw placement
    - Measured: Time (Minutes)
- Length of time to confirm screw placement
    - Aim: Reduce the time needed for confirmation of screw location
    - Measured: Time (Minutes)
- Length of time to register images
    - Aim: To reduce time for registration of reference images
    - Measured: Time (Seconds)
- Estimated Blood Loss (EBL)
    - Aim: To reduce the EBL of each case
    - Measured: Milliliters (mL)
- Incidence of Malalignment
    - Aim: To decrease the incidence of pedicle screw malalignment
    - Measured: Misalignment angle between pilot hole and screw trajectory (degrees)
- Complications: Neurological Deficits, Dural Tears, deep wound infections, etc
    - Aim: To decrease the incidence of intraoperative complications
    - Measured: number of reported complications while hospitalized
- Measurement of 2D fluoroscopy radiation exposure
    - Aim: to reduce patient and surgeon exposure to radiation
    - Measured: Exposure measured by Dose Area Product (DAP)

3 STUDY DESIGN

3.1 General Overview of the Study Design

This is a single center, non-randomized, prospective cohort study to comparatively evaluate the implementation of the MvIGS spine navigation system to conventional 2D fluoroscopy for pedicle screw fixation for the treatment of spinal stenosis with degenerative spondylolisthesis of the lumbar spine.

3.2 Duration of the Study

The patients will be clinically followed throughout the course of their hospital admission. The data collected during surgery and postoperative course will be used to evaluate the efficacy of the MvIGS spine navigation system.

As designed, a total of 130 patients are to be enrolled in the study, with 65 patients per treatment group. Based on this sample size, rate of patient accrual, and the prescribed follow-up time, the total duration of the study is projected to be approximately 9 months.

3.3 Outcome Measures Recorded During the Study

Time point measurements in surgery, including total operative length, will be recorded on the day of surgery. Radiographic measurements of the misalignment angle will be retrospectively recorded and analyzed.

3.4 Clinical Visits: Scheduling and Requirements

No clinical visits will be required for patients enrolled in this study following discharge of index admission.

3.5 Selection of Patients

3.5.1 Criteria for Inclusion

Patients are included in the study if all of the following criteria are met:

1) Diagnosis of spinal stenosis of the lumbar spine with ≤ grade 2 degenerative spondylolisthesis
2) Skeletally mature adults between the ages of 18-85 years at the time of surgery;
3) Has completed at least 6 months of conservative therapy;
4) Personally signed and dated informed consent document prior to any study-related procedures indicating that the patient has been informed of all pertinent aspects of the study.

3.5.2 Criteria for Exclusion

Patients are excluded from participating in this study if any of the following criteria are met:

1) Gross instability, defined as > 3 mm translational motion on flexion/extension studies;
2) Degenerative spondylolisthesis > grade 2
3) Degenerative scoliosis > 10° at any level in lumbar spine;
4) Congenital lumbar spinal stenosis;
5) Endplate changes;

6) Visible change in disc height;

7) Radiographic confirmation of facet joint disease or degeneration;

8) Prior surgery at any lumbar level including the level being treated except for: Lamino/Foraminotomy, Microdiscectomy, IDET, and Percutaneous Discectomy;

9) Any evidence of a prior/current fracture, compromised vertebra, current or past trauma, or tumor at affected level or the spinous processes at the adjacent levels;

10) Requires destabilizing surgical decompression that adversely affects the functioning of the facets;

11) Cauda equina syndrome defined as neural compression causing neurogenic bowel (rectal incontinence) or bladder dysfunction (bladder retention or incontinence);

12) Significant peripheral neuropathy or acute denervation secondary to radiculopathy, caused by conditions other than spinal stenosis;

13) Significant peripheral vascular disease (diminished dorsalis pedis or tibial pulses);

14) Morbid obesity, defined as BMI > 40 kg/m^2;

15) Active systemic or local infection;

16) Active Hepatitis (receiving medical treatment within two years);

17) Immunocompromised such as but not limited to Acquired Immunodeficiency Syndrome (AIDS), HIV infection, Severe Combined Immunodeficiency Syndrome, Thymic Hypoplasia;

18) Insulin dependent diabetes mellitus or any other medical condition(s) that would represent a significant increase in surgical risk or interfere with normal healing;

19) Immunologically suppressed, or has received systemic steroids, excluding nasal steroids, at any dose daily for > 1 month within last 12 months;

20) History of Paget's disease, osteomalacia, or any other metabolic bone disease;

21) Active malignancy. A patient with a history of any invasive malignancy (except non-melanoma skin cancer), unless treated with curative intent and there has been no clinical signs or symptoms of the malignancy >5 years;

22) Involved in study of another investigational product that may affect outcome;

23) Women who are pregnant, lactating or anticipate becoming pregnant within 24 months post-surgery;

24) Patients who are incarcerated;

25) Worker's compensation cases;

26) Patients involved in active litigation relating to his/her spinal condition;

3.6 Description of MvIGS Spine Navigation System

3.6.1 Materials

The equipment includes:

1. Proprietary imaging software
2. Integrated surgical light with embedded tracking technology
3. Cart with Arm and Head attachments
4. Surgical Instruments: reference clamp, awl tip, and pedicle probe

3.6.2 Intended Use of the Device

The MvIGS spine navigation system is intended for spatial positioning and orientation of surgical instruments during pedicle screw implantation in patients undergoing posterior fixation in single or multiple levels. The surgical light is intended to be the sole luminaire during image guided surgery.

3.6.3 Indication for Use under Study

The MvIGS spine navigation system is a stereotaxic image guidance system indicated for use in posterior approach spine surgery where reference to a rigid anatomical structure can be identified.

3.7 Investigator Training

The utilization of the MvIGS spine navigation system should be performed only by experienced spinal surgeons with specific training. Implantation of pedicle screw spinal systems is a technically demanding procedure presenting a risk of serious injury to the patient. All warnings, precautions, and recommendations must be fully understood by the operating surgeon prior to surgery. Investigators will use a posterior surgical approach. The use of the intraoperative spine navigation does not alter the surgical technique so much as it is a tool in which the surgeon can utilize to further refine their surgical technique.

3.8 Study Procedures

3.8.1 Enrollment/Preoperative Visit

Patients who meet all the inclusion criteria and who do not meet any of the exclusion criteria specified on the eligibility form will be asked to enroll in the study. Information on screening failures will be collected in a screening log. Patients agreeing to participate in this study must then sign the informed consent.

3.8.2 Post-Operative Visits

Patients will be clinically followed throughout the course of their hospital admission. No visits following discharge will be required.

3.8.3 Patient Disposition

Patients will either complete all the necessary study requirements or their participation in the study may end prematurely for one or more reasons.

Patients will be termed **"discontinued"** from the study for the following reasons:

- **Patient voluntarily withdraws from the study:** A patient may voluntarily withdraw from the study at any time.

3.8.4 Withdrawal Documentation

The reason for patient withdrawal must be fully documented. Study numbers assigned to patients who do not complete the study or discontinue will not be reassigned to newly enrolled patients. Patients who have discontinued should be requested to maintain contact and continue to have assessments whenever possible.

4. STATISTICS

4.1 Sample Size Analysis

- **Student's t-test, ANOVA, chi-square, regression, etc.:** Independent samples T-test
- **Alpha level:** 0.05
- **Beta or power level:** 0.883
- **Primary outcome variable estimate (mean +/- s.d. for continuous outcome, frequency/ percentage for categorical variable):** Total length of operative time (minutes) as determined by the official recorded operative notes
- **Number of groups being compared (use 1 for paired analysis within the same subjects):** 2
- **Effect size or change expected between groups:** Estimated change difference in length of operative time of five (5) minutes with equivalence margins of 40 minutes
- **Resulting number per group:** 65 per group; 130 patients total

A priori power analysis is based on recorded estimates of operative time for 1, 2, and 3-level fusion surgeries. Average length of surgery for 1, 2, and 3-level fusion surgeries are 230, 275, and 325 minutes, respectively. Estimated pooled standard deviation was set at 70 minutes, representing 22 to 30% of the mean operation time for the single and multi-level surgeries. In a non-inferiority model using an independent sample t-test, group sample sizes of 65 patients in two study groups achieves 88% power (with statistical significance defined as alpha equal to 0.05) to detect non-inferiority where the margin of equivalence is 40 minutes and the true difference between study groups is estimated to be 5 minutes.

4.2 Data Analysis

Data analysis of the study will include:

Descriptive statistics will report means and standard deviations for continuous variables of the study population. Frequencies and percentages will be used to report all discrete variables. Tests of normality for continuous variables will be evaluated using Shapiro-Wilks tests. For those that are non-parametric, Mann-Whitney U tests will be used.

Analysis of the primary outcome will use independent samples t-tests to compare the mean length of surgery between the two study arms.

Comparison of secondary outcomes between patients who undergo posterior spine fusion surgery using 2D fluoroscopy versus those who undergo the same procedure under 3D MvIGS intraoperative navigation guidance will use independent samples t-tests to analyze length of hospital stay; time for initial image processing; time to place all pedicle screws; time to confirm screw placement; time to register images; estimated blood loss; and amount of radiation exposure. Chi-square (or Fisher's exact) tests will be used to compare differences in incidence of malalignment and rate of complications between the two study groups.

To adjust for any potential confounding, multivariable regression models will be generated to report the adjusted effect of which spine navigation technique is used on length of surgical time.

5. ASSESSMENT OF SAFETY

The events reported during the entire course of the study for patients will be evaluated. The data will be examined for the types of events reported and their frequency of occurrence. Re-operations, revisions, removals or supplemental fixation will be assessed at each post-surgical follow-up visit.

5.1 Adverse Events

An Adverse Event (AE) is any untoward medical occurrence in a clinical study patient. All AEs will be recorded in this study. An AE can be any unfavorable and unintended sign, symptom, or disease regardless of the relationship to the product.

5.2 Recording and Reporting Adverse Events

For the purpose of AE recording, the study period is defined as the time period from surgery through discharge from the hospital. All AEs will be reported to 7D Surgical. Any reported AE that occurs after the study follow-up period (regardless of time after study participation) will be assessed for its relationship to the patient's participation in the study. If an AE occurs after the study follow-up period and is considered by the investigator to be possibly related to study participation, it must be recorded and reported.

5.3 Relationship to the Imaging System

The investigator will evaluate the relationship of the AE to the MvIGS spine navigation system according to the following definitions:

Definite The AE is clearly related to the spine navigation system: the event has a temporal relationship, and no alternative cause is present.

Probable The AE is likely related to the spine navigation system: the event has a temporal relationship, follows a known or suspected pattern of response, or is otherwise logically related, but an alternative cause may be present.

Not Related The AE is clearly not related to the spine navigation system: the event has no temporal or other relationship to the use of navigation, follows no known or suspected pattern of response, and an alternative cause is present.

Unknown Unable to determine the relationship based on all available information.

6 DIRECT ACCESS TO SOURCE DATA/DOCUMENTS

The investigator(s) must maintain, at all times, the primary records (i.e., source documents) of each patient's data. Examples of source documents are hospital records, office visit records, films, examining physician's finding or notes, consultant's written opinion or notes.

The investigator(s) will maintain a confidential patient identification list that allows the unambiguous identification of each patient. All study-related documents must be kept until notification by 7D Surgical

7 QUALITY CONTROL AND QUALITY ASSURANCE

7.1 Protocol Amendments, Protocol Deviations and Violations

7.1.1 Protocol Amendments

No changes from the final approved protocol will be initiated without prior written approval or favorable opinion of a written amendment by 7D Surgical, except when necessary to eliminate immediate hazards to the patients or when the change involves only logistics or administration.

7.2 Information to Study Personnel

The investigator is responsible for giving information about the study to all staff members involved in the study or in any element of patient management, both before starting the practical performance of the study and during the course of the study (e.g., when new staff become involved). The investigator must ensure that all study staff members are qualified by education, experience, and training to perform their specific responsibilities. The monitor is responsible for explaining the protocol to all study staff, including the investigator, and for ensuring their compliance with the protocol.

8 ETHICS

8.1 Informed Consent

Written informed consent will be obtained from each patient before any study-specific procedures or assessments are done, and after the aims, methods, anticipated benefits, and potential hazards are explained. The patient's willingness to participate in the study will be documented in writing in a consent form, which will be signed by the patient with the date of that signature indicated. The investigator will keep the original consent forms and copies will be given to the patients. It will also be explained to the patients that they are free to refuse entry into the study and free to withdraw from the study at any time without prejudice to future treatment.

Written and/or oral information about the study will be provided in understandable language to all patients.

8.2 Institutional Review Board (IRB)

Before commencement of this study, the protocol will be submitted to the CRP and IRB for evaluation. As required, the study will not start before approval to proceed.

9 REPORTING AND PUBLICATION OF RESULTS

All unpublished information given to the investigator by 7D Surgical shall not be published or disclosed to a third party without the prior written consent of 7D Surgical.

When 7D Surgical generates reports from the data collected in this study for presentation to regulatory authorities, drafts may be circulated to the investigator for comments and suggestions. An endorsement of the final report will be sought from the investigator when required by local regulatory agencies.

All information concerning the MvIGS, 7D Surgical operations, patent application drawings or formulas, manufacturing processes, basic scientific data and design or formulation information, supplied by the sponsor to the investigator and not previously published, is considered confidential and remains the sole property of 7D Surgical. No patent application(s) based on the results of the study may be made by the investigator nor

may assistance be given to any third party to make such an application without the written authorization of 7D Surgical.

The following is a listing of the reports the investigator shall submit to 7D Surgical:

- Adverse event reports as required;
- Progress reports on the clinical study;
- A final report must be provided within 6 months following termination or completion of the investigation or the investigator's part of the investigation.

10 REFERENCES

1. Härtl R, Lam KS, Wang J, Korge A, Kandziora F, Audigé L. Worldwide Survey on the Use of Navigation in Spine Surgery. *World Neurosurgery*. 2013;79(1):162-172. doi:10.1016/j.wneu.2012.03.011.

2. Kalfas IH, Kormos DW, Murphy MA, et al. Application of frameless stereotaxy to pedicle screw fixation of the spine. *Journal of Neurosurgery*. 1995;83(4):641-647. doi:10.3171/jns.1995.83.4.0641.

3. Patil S, Lindley EM, Burger EL, Yoshihara H, Patel VV. Pedicle Screw Placement With O-arm and Stealth Navigation. *Orthopedics*. 2012;35(1):e61-e65. doi:10.3928/01477447-20111122-15.