A POST MARKET SURVEILLANCE VALIDATION TO EVALUATE THE CLINICAL PERFORMANCE OF THE MaxAn® Anterior Cervical Plate System

Protocol Number CP-059-04

February 2, 2012

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The signatures of the investigator and representative of the sponsor below constitute their approval of this protocol and provide the necessary assurances that this Post Market Surveillance Validation will be conducted according to Good Clinical Practices and to all stipulations, clinically and administratively, as stated in the protocol, including all statements as to confidentiality.

It is agreed that the protocol contains all necessary information required to conduct the Post Market Surveillance Validation as outlined in the protocol.

It is agreed that all participants in this post market surveillance will provide written informed consent and/or a HIPAA Authorization (addendum to be provided by sponsor) and agree to the Post Market Surveillance Validation procedures as agreed by the Institutional Review Board or Independent Ethics Committee, if applicable.

SPONSOR:

_____

Print Name

_____ _____

Signature Date

PRINCIPAL INVESTIGATOR:

_____

Print Name

_____ _____

Signature Date

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1 STUDY PURPOSE

The purpose of this Post Market Surveillance Validation is to document the performance and clinical outcomes of the MaxAn® Anterior Cervical Plate System. Dr. Park, et.al conducted a retrospective review and found a positive association between adjacent-level ossification following anterior cervical plate procedures and the plate-to-disc distance. [1] They concluded that when the anterior cervical plates were placed at least 5mm away from the adjacent disc spaces, there was a decrease in the likelihood of moderate-to-severe adjacent-level ossification. The design of the MaxAn Anterior Cervical Plate and accompanying technique allows this type of plate placement; therefore we will be looking at the radiographic outcomes of these subjects and comparing them to the retrospective chart review conducted by Dr. Park. Using the MaxAn Technique allows you to achieve plate placement of 5mm from the supraadjacent level which will help minimize the risk of adjacent level ossification.

2 PRODUCT DESCRIPTION

Device Name: MaxAn® Anterior Cervical Plate System

The MaxAn® Anterior Cervical Plate System provides a simple, efficient and innovative approach to anterior cervical plating. The system offers a decompression-based technique for cervical spine stabilization and introduces an innovative one-level plate technique that provides a direct relationship between the bone graft/spacer size and the position of the plate holes. The unique ability to obtain maximum screw angulation and place a fixed screw at any angle up to 30° cephalad on the superior end of the plate and up to 30°caudal on the inferior end of the plate allows for versatile screw placement close to the endplates. Note that the screws converge at 10° in the transverse plane and are not intended to have additional variability in that plane. The significant cephalad-caudal angulation affords the surgeon the opportunity to choose a smaller plate to help minimize the potential for adjacent level ossification.

The plate is low profile and allows for excellent intra-operative visualization of the vertebral end plate and graft. The system also provides a choice of fixed and variable self-drilling screws to provide the surgeon with multiple options.

The MaxAn® Anterior Cervical Plate System is an anterior cervical spinal fixation device made from titanium alloy (Ti-6Al-4VELI). Pre-contoured plates that conform to the natural lordotic curvature of the spine are available in one, two, or three level configurations. These offerings also range from 8.0mm to 72mm in length when measured from screw hole to screw hole. The system includes variable and fixed bone screws, which are available in 4.0mm and 4.5mm diameters in various lengths. The MaxAn® Anterior Cervical Plate System is cleared under K080646.

Indications For Use: The MaxAn® Anterior Cervical Plate System is intended for anterior interbody screw fixation of the cervical spine. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as 'kyphosis, lordosis, or scoliosis), pseudarthrosis, and/or failed previous fusions. The intended levels for treatment range from C2 -T1.

Contraindications for Use: The MaxAn® Anterior Cervical Plate System is contraindicated in patients with spinal infection or inflammation; morbid obesity; mental illness, alcoholism or drug abuse; pregnancy; metal sensitivity/foreign body sensitivity; inadequate tissue coverage over the operative site, open wounds local to the operative area, or rapid joint disease, bone absorption, osteopenia and/or osteoporosis. Osteoporosis is a relative contraindication since the condition may limit the degree of obtainable correction, the amount of mechanical fixation and/or intolerance.

3 STUDY DESIGN

This post market surveillance study will enroll up to two hundred (200) subjects at up to 15 clinical centers within the United States with subjects followed for 24 months post-surgery. All subjects enrolled in the study will be recruited from the pool of subjects presenting to each investigational site for an anterior cervical fusion procedure. The up to 15 surgeons chosen to participate in this study will be thoroughly knowledgeable in the medical, surgical and mechanical aspects of the MaxAn® Anterior Cervical Plate System. The following inclusion and exclusion criteria must be met for a patient to be considered eligible for participation in this study.

3.1 Inclusion Criteria

- Subject is scheduled to undergo a one to three-level primary spinal fusion surgery between the levels of C2-T1 (Cervical 2 to Thoracic 1) using the MaxAn® Anterior Cervical Plate System.
- Subject has agreed to participate in this study, sign the informed consent and have agreed to return for the 6, 12 and 24 month follow-up visits.
- Subjects or their representative must be willing and able to give informed consent.

3.2 Exclusion Criteria

- Subject has spinal infection or inflammation at any level.
- Subject is morbidly obese, defined as a BMI greater than 40.
- Subject has a mental illness, alcoholism or drug abuse.
- Subject has a metal sensitivity/foreign body sensitivity.
- Subject has inadequate tissue coverage over the operative site.
- Subject has an open wound local to the operative area, or rapid joint disease, bone absorption, osteopenia and/or osteoporosis.
- Female subjects who are pregnant or plan to become pregnant in the next 24 months or who are lactating.
- Subject who does not meet the specific indications for use of the MaxAn® Anterior Cervical Plate System.
- Subjects participating in another clinical research study.
- Any previous cervical spinal surgery.

4 STUDY PROCEDURES

All subjects who have agreed to participate in this study, have signed the informed consent and who meet the inclusion / exclusion criteria will be considered enrolled and assigned a subject ID number. Once a Subject ID number has been issued, it can not be reassigned or used for another subject.

Subjects will be followed pre-operatively, intra-operatively and postoperatively at 6, 12 and 24 months. The following data will be recorded on the Case Report Forms (CRFs) and in addition, electronic data entry will be employed via an Internet connection when possible using an Electronic Data Capture (EDC) program.

The subject number will be assigned to the subject as they are enrolled in the subject and be recorded in the study binder, which will remain at the clinical site. The monitors will only have access to the Subject Number Assignment List while they are at a clinical site reviewing the data.

4.1 Pre-Operative Assessment

4.1.1 Consent

All subjects over the age of 18 will be provided with an informed consent form and will be given ample time to review, ask questions, and sign the document. All subjects who meet all of the entry criteria will be considered for inclusion in this study. All subjects meeting any one of the exclusion criteria will be excluded from the study.

4.1.2 Medical History

Within 60 days prior to the surgery date, the following information will be collected according to the parameters described by the MaxAn Post Market CRFs:

- Demographics
- Medical history, including a complete history of spinal disorder(s) (non-operative or operative treatments performed)
- Physical examination (including height, weight)
- X-Rays
- Current pain medications and other drug therapies.
- Pain/Function Disability Assessment (Neck Disability Index (NDI) form).
- Health Assessment SF-36
- Neck and Shoulder/Arm Visual Analog Scale (VAS)

4.1.3 Clinical Assessment

The subject will undergo the following pain and function assessments within 60 days prior to the surgery date:

Pain/Function Disability Assessment: Pre-operatively the subject will complete the Neck Disability Index Questionnaire. The questionnaire is a combined pain and function index. It will be used to assess the subject's neck pain and how that pain affects the subject's ability to manage in everyday life.

The questionnaire is divided into ten sections designed to assess limitations of various activities of daily living. Each section contains six statements and each statement describes a greater degree of difficulty in that activity than the preceding statement. The subject marks the one statement in each section, which describes his/her limitations most accurately. Each section is scored on a 0-5 scale, 5 representing the greatest disability. The scores for all sections are added together, giving a possible score of 50. The total is doubled and expressed as a percentage. If a subject marks two statements, the highest scoring statement is recorded as a true indication of his disability. If a section is not completed because it is inapplicable, the final score is adjusted to obtain a percentage.

Neck and Shoulder/Arm Pain: Preoperatively all subjects will assess their neck and/or radicular shoulder/Arm pain in one or both arms using a visual analogue scale (VAS) from 0-100 mm with 100 being considered most painful.

SF-36v2™ Health Survey: Preoperatively all subjects will complete a SF-36v2™ Health Survey as an outcome measure to assess quality of life.

4.2 Perioperative and Postoperative Management

The Surgeon will perform a 1 to 3 level anterior cervical discectomy and fusion per their usual technique. Patient positioning and exposure will be performed by the surgeon as per their usual technique in accordance with the current published MaxAn Anterior Cervical Plate System Surgical Technique. The surgeon will also take care to perform the discectomy(ies) and endplate preparation(s) to their liking and will insert the graft(s) of their choosing per their preferred insertion method. On label indications include use of: machined allograft spacers, with or without bone graft extenders or interbody fusion devices with autogenous bone, with or without bone graft extenders. This study protocol stipulates that screw hole placement will be specific to the MaxAn Anterior Cervical Plate System technique in which screw holes are placed within 1.5mm of the cephalad treated endplate. This helps to enable the hardware to be greater than 5mm from the supradjacent level. Screw hole placement and preparation will be done via one of the following methods for this study:

1. Using the MaxAn System Trial Drill Guide which pre-drills screw holes 1.5mm above and below the endplates in a one level construct and drills the cephalad holes 1.5mm above the endplate in a two or three level construct
2. Using the MaxAn System Endplate Drill Guide which pre-drills the cephalad screw holes 1.5mm above the endplate in a two or three level construct

3. Using the MaxAn Single or Double Barrel Drill Guide which requires that the surgeon take care to place the screw holes within 1.5mm of the cephalad endplate

4. Using no MaxAn drill guide while "free handing" the screws into the plate, requiring the surgeon to take care to place the holes within 1.5mm of the cephalad treated endplate

5. Using no MaxAn drill guide while placing the Punch Awl, requiring the surgeon take care to place the punch awl pilot within 1.5mm of the cephalad treated endplate

Screws will be locked and tightened per the MaxAn System ring locking mechanism and closure will be performed per the surgeon's normal preference in an ACDF. Data will be collected during and immediately after the surgery according to the parameters described by the MaxAn® Anterior Cervical Plate CRFs. This includes: duration of surgery, blood loss, OR time, length of hospital stay, instrumentation used, type of procedure, surgical level, biological augmentation, type of implants and any interbody fixation system used (if applicable). In addition, all intra-operative complications (e.g. excessive blood loss, hematoma, vascular injury, etc.) will be reported and recorded as a complication on the CRF.

Intra-operative (after hardware is completed) or immediate post-operative x-rays need to be obtained at this time point. These images will be provided to Biomet to review along with the data collected from the surgical visit. We will be assessing the position of the plate at this time point at both the plate level and the distance to the adjacent level. Postoperative care will follow the standard of care at each institution for subjects who undergo anterior cervical fusion procedures.

4.3 Follow-up Assessment

Subjects will be asked to return postoperatively at 6 (± 2weeks), 12 (± 1 month) and 24 (± 1 month) months for a clinical and radiographic exam. Data collected during this exam will include:

- Clinical assessment: The investigator will carry out a clinical examination at the 6, 12 and 24 month visit to assess:
  - subject compliance with postoperative care instructions,
  - ability to return to work and normal activity, and

- any procedure related or device related adverse events since discharge form the hospital

- Subject self-assessment:
  - Each subject will be asked to complete a follow-up Neck Disability Index (NDI) form, SF-36 form and a Neck and Shoulder/Arm Pain VAS form at each follow-up visit.
- Radiographic assessment: Each subject will undergo AP, lateral and flexion extension x-rays at the 6, 12 and 24 month visit to assess:
  - Presence / absence of heterotopic bone at the fusion site or at adjacent vertebral levels
  - integrity of the device, with observation for events such as plate and/or spacer migration or subsidence, hardware fracture, and progress towards fusion consolidation

Findings from any additional imaging studies deemed necessary by the investigator will be recorded and reported with study results.

Published data from the current literature will be gathered for purposes of comparing operating room time and the surgeon's assessment of fusion compared with that reported in this study.

4.4 Independent Radiologist Assessment

An independent radiographic analysis will be performed to evaluate all images and assess subjects' radiographic status. The following quantitative and qualitative assessments will be performed.

4.4.1 Plate Location Measurements

Plate location measurements including the distance from end of plate to adjacent level at both the cephalad and caudal ends of the plate, distance from the point of screw insertion (center line of screw) to endplate of affected level at both the cephalad and caudal ends of the plate and screw angulation at both the cephalad and caudal ends of the plate at each time point will be assessed quantitatively using validated computer-assisted measurement tools.

4.4.2 Disc Height

Anterior and posterior disc height will be assessed quantitatively using validated computer-assisted measurement tools. Disc height will be calculated from neutral lateral radiographs. Anterior (posterior) disc height is defined as the distance between the anterior-inferior (posterior-inferior) corner of the superior vertebra, and the corresponding corner of the inferior vertebra. This distance is measured perpendicular to the superior endplate of the inferior vertebra. Average disc height is calculated as the simple average of the anterior and posterior disc heights. Disc Height will be reported in units of millimeters.

4.4.3 Change in Disc Height

Change in disc height is defined as the change in distance between the anterior-inferior (posterior-inferior) corner of the superior vertebra, and the corresponding corner of the inferior vertebra. This change is measured perpendicular to the superior endplate of the inferior vertebra. Change in average disc height is calculated as the simple average of the change in anterior and posterior disc heights. Change in disc height is calculated by subtracting the measured disc height at one time point from a baseline disc height measurement. The results will be recorded in units of millimeters.

4.4.4 Disc Degeneration

Disc Degeneration, including Adjacent Level Degeneration, will be qualitatively graded in accordance with the following definitions (adapted from Weiner et al [3], Lane et al [4] and Wilke et al [5]):

0. **None:** No disc space narrowing, no osteophytes, no endplate sclerosis
1. **Mild:** < 33% disc space narrowing, mild osteophytes, no endplate sclerosis
2. **Moderate:** 33% - 66% disc space narrowing, moderate osteophytes, mild to moderate endplate sclerosis
3. **Severe:** ≥ 67% disc space narrowing, severe osteophytes or bridging, severe endplate sclerosis

It should be observed that Disc Degeneration is assessed from an evaluation of 3 component factors: Disc Space Narrowing, Osteophyte Formation, and Endplate Sclerosis. Disease severity will be defined by the most severe radiographic component.

4.4.5 Adjacent Level Ossification

The severity of adjacent level ossification will be measure on the last follow-up (24 month) lateral radiograph as:

- Grade 0 – None
- Grade 1 – Mild (if the ossification extended across <50% of the disc space)
- Grade 2 – Moderate (if the ossification extended across ≥ 50% of the disc space)
- Grade 3 – Severe (if there is complete bridging of the adjacent disc space)

4.4.6 Fusion Determination

Fusion will be assessed by an independent radiographer when data collection is complete at each site. The radiographic report (if available) and the x-rays will be sent to an independent radiologist for review at the end of the study. X-rays will be evaluated at each visit for fusion determination. The grading system is as follows:

- Grade 1 - No graft incorporation
- Grade 2 - Incomplete graft incorporation
- Grade 3 - Graft Incorporation
- Grade 4 - Solid fusion with graft incorporation

Radiographic Success: Radiographic success is defined by graft incorporation or solid fusion with graft incorporation (Grade 3 or 4)

Radiographic Failure: Radiographic failure is defined by incomplete graft incorporation or no graft incorporation (Grade 1 or 2).

4.5 Post Validation Follow-Up Meeting

Upon completion of the post market surveillance, the sponsor will compile the results and organize a meeting in of all participating clinicians to review and discuss the study results including the intra-operative assessment of instruments and implants and clinical outcomes of the MaxAn® Anterior Cervical Plate System. Tabular presentations of the data and descriptive statistics will be used to report outcomes.

4.6 Subject Withdrawal

It is recognized that the subject's participation in this post market surveillance study is entirely voluntary, and that he or she may refuse to participate and may withdraw from participation at any time without jeopardy to any future medical care. It is also recognized that the surgeon, at his/her discretion, may withdraw a subject from this post market

surveillance study based upon his/her professional judgment. If the subject is withdrawn a final evaluation form will be completed.

Other Conditions for Withdrawal:

Any subject who develops a severe concurrent medical illness during the post market surveillance study should be withdrawn. This type of illness is defined as any illness that would hinder the subject's ability to return for scheduled follow-up appointments. Such a withdrawal will not be counted for the purposes of determining success or failure.

5 COMPLICATIONS

In addition to the standard operating procedures for reporting complications per hospital/physician protocol, all clinical events, including both observed or volunteered problems, complaints, symptoms, physical signs or disease which either occur during the study, having been absent at baseline, or, if present at baseline, appear to worsen during the clinical outcomes collection study are to be recorded as complications in the subject's medical record and on the appropriate case report form. In addition for any cleared device, a Product Experience Report (PER) must be completed per the manufacturer's customary complaint procedure (SOP 114.0.1 – Product Complaint Procedure).

5.1 Definition

A complication is any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, performance, or any indication of the failure of a device to meet a user or customer's expectations. The complaint may be the possible failure of a device, labeling, or packaging to meet any of its specifications after it is released for distribution.

6 Primary Objective and Sample Size Justification

The primary objective of this study is to obtain a precise estimate of the proportion of patients who have moderate-to-severe adjacent-level ossification at 24 months, indicated by a severity of Grade 1, 2, or 3 at any level on the 24-month lateral radiograph. A point estimate and two-sided, 95% confidence interval for this endpoint will be calculated using the normal approximation to the binomial, as follows:

$$\hat{p} \pm z_{1-\frac{\alpha}{2}} \sqrt{\frac{\hat{p}(1-\hat{p})}{n}}$$

Where:

$\hat{p}$ = the proportion of soft tissue masses found

n = the total number of patients

α = 0.05

The sample size for this study was based on the number of patients needed in order to calculate, within a precision of 10%, a 95% confidence interval for the proportion of patients with moderate-to-severe adjacent-level ossification. The "precision" of a confidence interval refers to the distance from the estimated proportion (point estimate) to the upper and lower limits of the confidence interval. The full width of the confidence interval is twice the precision. This sample size assumes that the rate of incidence will be approximately what was observed in a study conducted by Park, et.al[2]. This study indicates that rate of incidence of moderate-to-severe adjacent-level ossification observed in this study for patients with a PDD of > 5mm is 45.5%. Under this assumption, a sample size of 96 patients will allow a precision of 10% to be achieved. Accounting for possible attrition of up to 15% gives a sample size of 113 patients.

7 ETHICAL AND REGULATORY REQUIREMENTS

7.1 CODE OF CONDUCT

The Investigator will ensure that the clinical study is conducted in accordance with good clinical practice (GCP) and all regulatory and institutional requirements, including those for subject privacy, informed consent, Institutional Review Board (IRB) approval and record retention, the Food and Drug Administration (FDA) Guidelines for the conduct of clinical trials, and the CPMP/ICH/135/95.

6.2 REPORTS

Clinical investigators must make the following required reports:

- Unanticipated Adverse Device Effects
- Withdrawal of IRB Approval
- Informed consent

- Other reports requested by a reviewing IRB or FDA

7.3 INSTITUTIONAL REVIEW BOARDS

The Investigator must obtain appropriate Institutional Review Board (IRB) approval before the study can be initiated. A copy of the written approval from the IRB and a copy of the approved informed consent form must be sent to the Sponsor. A list of the IRB members (including their Institution affiliations, gender makeup, and occupations); or a statement from the IRB specifying that the membership comply with applicable regulations is to be provided to the sponsor.

If the Investigator advertises for subjects, whether in a professional or consumer publication, radio, television or community notices, all advertising must receive prior approval by the Sponsor and the IRB.

Any changes to the protocol must be discussed and approved by the Sponsor in writing unless the change is made to assure the safety of the subject. In the non-emergent setting, after agreement on the changes has been reached, an amendment to the protocol will be provided by the Sponsor for submission to the IRB for review and approval prior to initiation of the change. Any change made emergently must be documented in the subject's medical record.

The Investigator must immediately forward to the IRB any written safety reports or updates from the Sponsor.

The Investigator must keep the IRB informed of the progress of the study as required by the IRB but at least annually.

7.4 INFORMED CONSENT

An investigator is responsible for obtaining informed consent under 21 CFR Part 50. The Investigator must observe the requirements of the IRB by obtaining written informed consent by the subject prior to any study procedures. The Sponsor will supply a sample informed consent form to the principle investigator of each clinical site prior to the IRB submission. The informed consent form must be approved by a registered IRB. Copies of the informed consent form used in the study must contain the IRB-approval stamp (if applicable) and version date.

Subjects will be informed of new information learned during the study, which may affect the subject's decision to continue participation in the study.

The study informed consent form must be obtained prior to the initiation of any study procedures. The subject (or the subject's legally authorized representative) must be allowed sufficient time to thoroughly read (or have explained to them), the information within the informed consent form. The Investigator should answer any questions that the subject/representative might have. If the subject agrees to participate in the study, the subject/representative must sign two copies of the informed consent form. The witness and the Investigator must also sign both copies of the informed consent form. One copy of the informed consent form should be given to the subject/representative. The study staff should adequately and accurately document the sequence of actions in the consenting process as well as the date and time of the subject's signature on the informed consent form in the subject's medical chart to document that informed consent was obtained prior to initiating any study procedures. The other copy will be kept with the investigational site.

A Subject Enrollment Log (DD0157) will be completed to document the existence of the signed informed consent form. The log will contain: Subject ID, subject initials and date and time informed consent form signed. Signed informed consent forms (or copies) are to be maintained in the study file and must be available for verification by monitors or inspectors.

7.5 SOURCE DOCUMENTATION REQUIREMENTS

Source documentation for this study will be maintained to document the treatment and study course of a subject and to substantiate the integrity of the trial data submitted for review and analysis. Source documentation will include, but not be limited to, signed and dated consent form, worksheets, hospital and/or clinic or office records documenting subject visits including study and other treatments or procedures, medical history and physical examination information, laboratory and special assessments results, pharmacy records, and medical consultations (as applicable).

7.6 SUBJECT CONFIDENTIALITY

The Sponsor will maintain the confidentiality of the identity of subjects enrolled in the study and the information contained in their study records. The Sponsor will also instruct the study investigators in the importance of maintaining the confidentiality of study records. The records will be made available as required for review by governing regulatory agency such as FDA and a reviewing IEC/IRB, however to the extent possible; the subject's identity will not be disclosed.

Compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) is required and data collection must comply with the Standards for Privacy of Individually Identifiable Health Information, 45 CFR Part 160 and Part 164, as amended from time to time (the "Privacy Rule"), under HIPAA.

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

By assigning subjects a unique DataAssist ID number, their identity is protected in DataAssist, the online database. The database is restricted, allowing a doctor to only view and enter data from his own subjects. User authentication is required to view research data. The data is transmitted to a centralized database through a secured (SSL) channel on the Internet. Data in transit is in 128-bit encryption. The access to the centralized database is limited to those who are responsible for maintaining the database.

7.7 RETENTION OF RECORDS BY THE INVESTIGATOR

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

7.8 MONITORING

The Investigator must allow regular inspection of all study records including CRFs, source documents and regulatory documents during the study by the monitor or a representative of the Sponsor. This measure is to ensure that the study is carried out

and documented in accordance with the terms of this protocol, GCPs, ICH, IRB and if applicable federal regulations. The Investigator also agrees to allow inspections by staff members of the IRB or other regulatory agencies before, during or after the study has concluded, if such inspections are requested.

In cooperation with the on-site staff, monitors will:

- Review all study documentation to ensure compliance with the protocol.
- Review data recording for each visit to verify the accuracy and completeness of the information on the CRFs against appropriate source documents.
- Review adequacy of enrollment rate.
- Review required regulatory documentation.

7.8.1 Data Quality Assurance

Standardized subject case report forms will be provided for use at all Investigational Sites. The Investigator is responsible for completion and timely submission of the forms to the study Sponsor for data processing.

Data will be collected on all subjects pre-operatively, intra-operatively and postoperatively at 6, 12 and 24 months. Electronic data entry will be employed via an Internet connection when possible, using our Electronic Data Capture (EDC). Access to the EDC program is limited to the physician or physician's assistant. All users will be given a unique user name and password and will be assigned a specific role. The role determines the level of access granted to each user. Study monitors will have access to subject numbers only; any subject identifying information will be blocked. In the event the site does not have Internet access, data will be recorded on paper Case Report Forms (CRFs).

Incoming data are reviewed to identify inconsistent or missing data and Adverse Events. Data inconsistencies will be addressed through telephone calls, faxes, or emails to the Investigational Sites and during site visits. All hard copy forms and data files will be secured to ensure confidentiality.

7.8.2 Screened Subjects Who are Not Enrolled

Only data for enrolled subjects will be monitored and entered into the database. Subjects who are screened for the study but are not enrolled for any reason will not be followed

and the Sponsor will not evaluate their data. The sites may retain the screening case report forms for these subjects, at their discretion.

8 BIBLIOGRAPHY

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4. Lane NE, Nevitt MC, Genant HK, Hochberg MC. Reliability of new indices of radiographic osteoarthritis of the hand and hip and lumbar disc degeneration. *J Rheumatol* 1993; 20(11):1911–1918

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APPENDIX 1: Data Collection Forms

The designated protocol visits occur pre-operatively, intra- and post-operatively and 3-months post-operatively.

Informed Consent Form – Signed by subject at pre-op visit.
Demographics & Physical Exam –. Completed by STAFF, information found in Medical History. This form is completed only once.
Medical History - Completed by STAFF, information found in Medical History. This form is completed only once.
Previous Spine Surgery History - Completed by STAFF. This form is completed only once.
Non-Operative Treatment - Completed by STAFF. This form is completed only once.
Current Surgery - Completed by STAFF, information taken from Operative Notes and Discharge Report. This form is completed only once after the subject has had surgery.
Post Market Follow-Up Survey – to be completed by operating SURGEON at the 6, 12 and 24 month follow-up visits.
Neck Disability Index Form – To be completed by the subject at the pre-operative and 6, 12 and 24 month follow-up visits.
SF-36 Health Survey – To be completed by the subject at the pre-operative and 6, 12 and 24 month follow-up visits.
Neck and Shoulder/Arm Pain VAS – To be completed by the subject at the pre-operative and 6, 12 and 24 month follow-up visits.
Medication Log - Completed by STAFF. This form is completed and updated pre-operatively, intra-operatively, post-operatively, and at the 6, 12 and 24-month follow-up visits.
Complications Form - Completed by STAFF or SURGEON only if this occurs.

APPENDIX 2: Surgical Technique

CLINICAL PROTOCOL CHANGE HISTORY

From Version	To Version	New Version Date	Change Page No.	Description of Changes
CP-059-01	CP-059-02	13-Jun-2011	4 8	Split of a run-on sentence toward the end of study purpose. Addition of the following sentence: Choices of grafting material are limited to machined allograft spacers, (e.g. OsteoStim) with or without bone graft extenders or interbody fusion devices, (e.g. Biomet C-Thru) with autogenous bone only.
CR-059-02	CP-059-03	20-Jun-2011	8	Delete the new sentence added on 13-Jun-2011 and replaced it with: On label indications include use of: machined allograft spacers, with or without bone graft extenders or interbody fusion devices with autogenous bone, with or without bone graft extenders.