Post-market surveillance study of FLXfit™ TLIF Interbody Fusion Device

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Purpose:this study is a post-market clinical follow-up study. The data collected from this study will serve the purpose of confirming safety and performance of the FLXfit™ implant. The evaluation is based on the following elements.

1. Safety as measured by the rate of serious operative and post-operative complications.
2. Patients quality of life, measured by health-related quality of life questionnaires and patient-reported outcome measures up to 24 months following the procedure, as compared to patient's preoperative baseline.
3. Global and segmental lumbar lordosis (LL)

Therapeutic Indication: Interbody fusion in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. Patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). Patients should be skeletally mature and have completed six months of non-operative treatment.

Study Phase: Post-market

The Devise: FLXfit™ Lumbar Interbody Fusion Devise (Cage) system and surgical instruments

Research Plan/Design: Post market, prospective, non-randomized. The study will be a prospective analysis of patient demographics and baseline characteristics as well as a chart review of in-hospital patient (EPIC) and outpatient information (NextGen). A large number of variables will be collected for each patient, as detailed below. Patients will be de-identified after gathering all patient information. All files will be maintained in a computer at Midwest Orthopaedics at Rush (MOR) under password protection, accessible only by the study personnel. Any addition of research personnel to the study will be notified to the IRB and the person will only participate in this research following IRB approval.

Patient Population: Candidate for spinal fusion procedure as described in indications

No. of Subjects/Sites: Up to 30 patients will be recruited

Study Duration: Up to 24 months follow-up. Data points at 6- and 12-weeks, 6-, 12-, and 24-months.

Data Collection:

- **Demographics**
    - Age

    - Gender
    - Body mass index
    - Race
    - Insurance type
    - Smoking status
    - Comorbidities
- **Perioperative clinical parameters**
    - Operative Time
    - Estimated Blood Loss
    - Hospital Length of Stay
    - Narcotic Consumption
    - Non-narcotic analgesics
    - Anesthetic medications administered
- **Intra-Hospital/Perioperative Complications**
    - Postoperative nausea and vomiting
    - Gastroesophageal reflux
    - Ileus
    - Venous thromboembolic events (pulmonary embolus, deep vein thrombosis)
    - Respiratory depression/airway compromise
    - Myocardial infarction
    - Renal insufficiency
    - Wound complications
    - Admission to ICU
    - Congestive heart failure
    - Mental status changes
    - Intractable Leg pain
    - Dural leak
- **Postoperative Outcomes**
    - Pain scores
    - Mid- to Long-term complications
    - Rates/causes of reoperation
    - Rates of spinal fusion (arthrodesis/pseudarthrosis)
    - Hospital Readmissions/Reoperations
- **Radiographic Analysis**
    - Plain film radiographs
    - Computed tomography (CT)
    - Magnetic resonance imaging (MRI)
- **Patient reported outcomes:** will be collected before and after surgery at the 6-week, 12-week, 6-month, 1-year, and 2-year postoperative follow up visits to characterize any improvements following surgery.
    - Visual Analogue Pain Scale: Back
    - Visual Analogue Pain Scale: Leg
    - Oswestry Disability Index
    - Short Form-12 Health Survey
    - Patient Reported Outcomes Measurement Information System (PROMIS)

- **Safety –** Adverse Events: All adverse events will be assessed by incidence and time to resolution of postoperative device-related complications and serious adverse events/incidence and time to reoperation/incidence and time to revision.
    - All peri-operative adverse events will be noted.
    - Intra-operative – Information will be obtained from the operative note.
        - Blood loss, length of surgery, procedural details, complications
    - Post-operative
        - Nausea, vomiting, wound complications, thromboembolic events
- **Disability –** Obtaining improvement in Oswestry Disability Index (ODI) disease-specific questionnaire up to 24 months following the procedure, as compared to patient's baseline. Mean change in score of the ODI from baseline to 24 months postoperatively.
- **Pain Scores –** Obtaining improvement in Visual Analogue Scale (VAS) Back and Leg pain scores up to 24 months following the procedure as compared to patient's baseline. Mean change in score of the VAS from baseline to 24 months postoperatively.
- **Health-Related Quality of Life Questionnaires**– Obtaining improvement in Short Form-12 health survey up to 24 months following the procedure as compared to patient's baseline. Mean change in score of the SF-12 from baseline to 24 months postoperatively.
- **MCID/SCB** – Minimum clinically important difference (MCID) or Substantial Clinical Benefit (SCB) will be determined based on previously reported values in literature.
- **Fusion Rate –**CT based fusion assessment at 6 months, 12 months, and 24 months with the following criteria: translational motion <3 mm and angular motion <5°
- **Radiographic Outcomes:**
    - **XR**
        - Immediate postoperative – maintenance/improvement of
            - Global Lumbar lordosis (LL)
            - Segmental lordosis at level treated with FLXfit device
        - At follow-up (6-weeks, 12-weeks, 6-months, 12-months, 24-months)

Inclusion Criteria:

- Adult (18-70 y/o)
- Male or Female
- With the following conditions of the lumbar spine as confirmed by advanced imaging (CT or MRI), who is a candidate for primary spinal fusion procedure according to acceptable criteria for such medical conditions:
    - Degenerative disc disease with up to Grade I spondylolisthesis
    - Spondylolisthesis
- Failure of at least 6-months conservative treatment
- BMI < 40
- Patient to approve no pregnancy during the 24 months of study and no participation in other studies in parallel to this one
- Ability to read, understand, and sign informed consent

Exclusion Criteria:

- Infection, local to the operative site
- Signs of local inflammation
- Fever or leukocytosis

- Pregnancy
- Significant mental disorder or condition that could compromise the patient's ability to remember and comply with preoperative and postoperative instructions (e.g. current treatment for a psychiatric/psychosocial disorder, senile dementia, Alzheimer's disease, traumatic head injury)
- Prior surgical procedure (with the exception of decompression only procedure) at the index level(s) using the desired operative approach
- Prior fusion procedure at an adjacent level
- Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of segmentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count
- Neuromuscular disorder that would engender unacceptable risk of instability, implant fixation failure, or complications in postoperative care
- Active local infection in or near the operative region
- Active systemic infection and/or disease
- Severe osteoporosis or insufficient bone density, which in the medical opinion of the physician precludes surgery or contraindicates instrumentation
- Endocrine or metabolic disorders known to affect osteogenesis (e.g.Paget's disease, renal osteodystrophy, hypothyroidism)
- Systemic disease that requires the chronic administration of nonsteroidal anti-inflammatory or steroidal drugs
- Suspected or documented allergy or intolerance to implant's materials
- Symptomatic cardiac disease
- Patient unwilling to cooperate with postoperative instructions.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- Patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
- Prior fusion at the level to be treated.
- Back VAS <4/10

Statistical Analysis:

The appropriate statistical analysis will be performed for each study derived from this data set. In general, demographic and baseline variables will be presented using descriptive statistics including but not limited to percentile, percentages, mean with standard deviation, median with interquartile range and proportions. Normally distributed (parametric) outcomes will be compared utilizing statistical analyses including but not limited to an unpaired t-test, ANOVA, or linear regressions. Abnormally distributed (non-parametric) outcomes will be compared between groups utilizing statistical analyses including but not limited to Mann-Whitney, Wilcoxin-rank sum test, Kruskal-Wallis, Kaplan-Meier, and Friedman two way tests. Binomial outcomes will be analyzed utilizing chi-squared analysis and multivariate logistic/Poisson regressions. We will specifically analyze patient functional, clinical, and surgical outcomes as well as radiographic outcomesfollowing TLIF with use of the FLXfit interbody device.

Data Collection & Record Keeping:
Data will be recorded from electronic medical records and survey studiesas previously listed. Information will be imported into an excel sheet and maintained in reports included in supplemental documentation. As stated above patient identifiable information (name, MRN, DOB, etc) will be utilized to collect data on the correct patient. Variables collected will be as listed in the study design. After all data has been collected patients will be assigned a study serial number in the excel sheet and de-identified. EPIC and NextGen will be accessed from MOR and collected directly from the patient's charts. All information regarding the nature of the proposed investigation provided to the investigator (with the exception of information required by law or regulations to be disclosed to the IRB, the subject, or the appropriate regulatory authority) will be kept in confidence by the investigator. All personal information will be treated as strictly confidential and not made publicly available. All records and appendices are stored in separate locked filling cabinets as well as a password protected computers which are accessed only by the Principal Investigator and Study Coordinators. All identifiable data will be destroyed a year after the study is complete.

Data Privacy & Confidentiality:
As stated previously all data will be collected directly from the electronic medical records, survey results as previously listed. Information will be imported into an excel sheet. Once all data has been collected patients will be de-identified and provided a database serial number. This serial number will be used to merge files and ensure the data is not mixed up between patients. All data will be recorded and accessed from a password-protected computer at MOR, to which only the study personnel have access.

Potential Benefits:

Direct Benefits:
Patients involved in the study will not directly benefit from our analysis of their outcomes.

Potential Benefits to Society:
This study will provide information regarding postoperative outcomes with use of the FLXfit interbody device. The results from this study can be used to influence future standard practices and provide physicians with information regarding expectations and education for patients who require TLIF and expected outcomes with use of the FLXfit device.