

5.3.3.4 Selection of Study Population; Inclusion / Exclusion Criteria

(Content from P060021/A011, November 2007 Amendment, SSED, Section 9.3, Pages 27-28)

5.3.3.4 Selection of Study Population; Inclusion / Exclusion Criteria

Pivotal Study S01-01US

Patients were included in study S01-01US only if they met all of the following criteria:

1. The patient or legal guardian was willing and able to understand, sign and date the study specific Patient Informed Consent, which was approved by the Institutional Review Board.
2. The patient was a skeletally mature male or female less than 85 years of age.
3. The patient had a diagnosis of degenerative lumbar spondylolisthesis of Grade 1 or 2 with spinal stenosis demonstrated by medical history, physical examination, and radiographic imaging. Radiographic diagnosis was performed showing a cross sectional image using a CT scan or MRI demonstrating an intact pars interarticularis with evidence of central or lateral recess stenosis accompanied by an anterolisthesis on upright lateral radiographs. The patient had leg and/or back pain and the manifestation of one or more of the following phenomena:
 - radiculopathy
 - sensory deficit
 - motor weakness
 - reflex changes
 - disc herniation
 - neurogenic claudication
 - instability (defined as > 0% and < 50% translation of the vertebrae and/or > 10 degrees and < 20 degrees angular motion) measured on flexion/extension radiographs
 - osteophyte formation or hypertrophy of the facet joint
4. The patient was a candidate for decompression and spinal fusion with the use of autograft from the iliac crest.
5. The patient required one level lumbar fusion (L-3 to S-1).
6. The patient agreed to participate in post-operative clinical and radiographic evaluations and required rehabilitation regimen.
7. The patient had no history of previous fusion attempt(s) to the affected spinal level.
8. The patient was non-responsive to at least 6 months of non-operative treatment prior to study enrollment.
9. The patient had a preoperative Oswestry Disability Index (ODI) of 30-100.

Patients were excluded from study S01-01US if they met any of the following criteria:

1. The patient had non-degenerative spondylolisthesis of any grade at the affected level.
2. The patient had degenerative spondylolisthesis of Grade 3 or 4.

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3. The patient had active spinal and/or systemic infection.
4. The patient had a systemic disease or condition, which affected his/her ability to participate in the study requirements or the ability to evaluate the efficacy of the investigational product (i.e., active malignancy, neuropathy).
5. The patient was a prisoner, a transient, or had been treated for alcohol and/or drug abuse in an inpatient substance abuse program within 6 months prior to proposed study enrollment.
6. The patient had participated in clinical trials evaluating investigational devices, pharmaceuticals, or biologics within 3 months of enrollment in the study.
7. The patient was a woman able to bear children, e.g., not post-menopausal, had not had a hysterectomy, etc.
8. The patient was morbidly obese (defined as weight \geq 60% over the recommended ideal weight as described in the 1996 Metropolitan Height and Weight Tables for Men and Women).
9. The patient had a known sensitivity to any component of OP-1[®] Putty.
10. The patient was known to require at the time of treatment, additional surgery to the lumbar spinal region within the next 6 months.
11. The patient had spinal instability measured on flexion/extension radiographs of \geq 50% translation of the vertebrae or \geq 20 degrees of angular motion.
12. The patient used tobacco or nicotine or was prescribed steroids such as cortisone.

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(Content from P060021, Original PMA, CSR 06-UPLF-01 Section 9.3.1 and 9.3.2)

Extension Study 06-UPLF-01

Inclusion Criteria

To be eligible for study participation, a patient must have met all of the following criteria:

1. The patient was treated in Stryker Biotech clinical protocol S01-01US (Pivotal IDE study) and was not a retreatment failure at the time of completion of the Pivotal IDE study.
2. The patient or legal guardian was willing and able to understand, sign and date the study-specific Patient Informed Consent, which had been approved by the Institutional Review Board (IRB).
3. The patient agreed to complete the necessary clinical and radiographic evaluations. Radiographic evaluations were not required if the patient was pregnant.

Exclusion Criteria

There were no exclusion criteria for participation in this study. Patients who died subsequent to the Pivotal IDE study S01-01US were considered missing for analyses of data at 36+ months.