

## **SAMPLE OPERATIVE REPORT**

### **X-STOP® Interspinous Process Decompression (IPD®) Procedure (Reference Material Only)**

**Please note:** The following sample is for illustrative purposes only, and reflects one of several treatment options that may be available in this hypothetical case.

**Patient Name:** Mary Smith  
**Date of birth:** January 1, 1957  
**Pre-op Diagnosis:** L4-5 spinal stenosis with neurogenic claudication  
**Post-op Diagnosis:** L4-5 spinal stenosis with neurogenic claudication  
**Procedure:** X-STOP® Interspinous Process Decompression (IPD®) – L4-5 level  
**Surgeon:**  
**Assistant:**  
**Anesthesia:** Spinal (local), or general

**Indications:** Mrs. Smith presents with an 8 month history of spinal stenosis (spondylolisthesis-Grade I) with symptoms of intermittent neurogenic claudication which she states are relieved when she is in a sitting position and has moderate physical impairment. This diagnosis has been confirmed on [X-Ray, MRI, and/or CT scan]. The patient has failed to receive long term relief with non-operative therapy including medications and physical therapy which she has undergone for the 8 months. Epidural steroid injections have also failed to give significant lasting relief. The risks, benefits and alternatives to surgery were discussed with the patient and she wishes to proceed with the planned surgery. These risks include, but are not exclusive of, infection, myocardial infarction, blood loss, neurological system compromise, and dislodgement of implant, fracturing of the spinous process, and the need for aborting the planned surgery and the need for additional surgery for relief of symptoms.

#### **Description of Procedure:**

A time out was performed and we confirmed we had the correct patient, the correct procedure was planned, and the correct antibiotics were given. The patient was administered a spinal anesthetic and then placed in the right lateral decubitus position. The patient's hips and knees were flexed to flex the lumbar spine. The patient was then secured into position. The C-Arm was moved into position to visualize the spine in the lateral position and swung around to visualize the spine in the AP position. The back was then sterilely prepped and draped. Utilizing the C-Arm, the incision, approximately 4-8 cm was centered over the L4-5 spinous process. It was carried thru the subcutaneous tissue to the lumbodorsal fascia. Measuring a width of 1.5-2 cm from the midline supraspinous ligament the fascia was then incised with electrocautery preserving the mid-line ligament.

The paraspinous muscles were elevated from the underlying lamina with Cobb elevators and packed with tapes for hemostasis. The small initial curved dilator was placed along the lamina in line with the spinous process on the right hand side and then rotated clockwise to pass the blunt tip through the base of the interspinous ligament. The position of the dilator was confirmed with the C-Arm. The small dilator was removed and the hole was expanded with the large curved dilator. Again proper positioning was confirmed with the C-Arm. The sizing distractor was inserted making sure it was positioned as far anterior as possible to minimize the risk of implant dislodgement. The handle was squeezed slowly until resistance was encountered. The size of the implant on the handle was confirmed and read aloud. The supraspinous ligament was palpated and optimal sizing was achieved when the ligament was taut. Time was taken to slowly stretch the ligament to allow for ligamentotaxis. This step was carefully performed to make sure that the ligament was not ruptured and the spinous process was not fractured. The position was confirmed with the C-Arm. The correct size sterile implant was then opened and the spacer

*KYPHON, X-STOP, X-STOP, and IPD* are registered trademarks, and *Ahead of the Curve* is a trademark, of Kyphon Inc. © 2008 Kyphon Inc. All Rights Reserved. 16000991-01

placed on the insertion device. The wing was placed on the wing insertion device. Care was taken to make sure that the area around the interspinous ligament was cleared of muscular tissue. The spacer was passed from right to left through the channel that was created in the interspinous ligament. The implant was fit snugly with the rounded edge of the locking screw visible to receive the wing assembly. The handle of the wing assembly was rotated clockwise engaging the spacer and screwing it into the spacer. Using a Kocher instrument, the wings on the right and left sides were compressed to minimize migration and movement of the implant. The long cephalad wings are rotated towards the lamina to maintain proper position. The final tightening was then accomplished. The instruments were then removed.

Final images were then visualized with the C-Arm in the lateral and AP position. The C-Arm was removed. Copious amounts of irrigation were used and the fascia was re-approximated on both the right and left sides with running 0-Vicryl. The subcutaneous tissue was re-approximated with 2-0 Vicryl and the skin with 3-0 sub-cuticular Vicryl. Steri-strips were applied along with a sterile dressing the patient was then turned to the supine position and taken to the recovery room in stable condition.

If a second level is performed the first implant is inserted at the caudal level to prevent this implant from migrating (rotating) after the cephalad (second) implant is placed.

**Please note:**

**Indications for Use:** The X-STOP® Interspinous Process Decompression (IPD®) System is indicated for treatment of patients aged 50 or older suffering from neurogenic intermittent claudication secondary to a confirmed diagnosis of lumbar spinal stenosis (with X-Ray, MRI and/or CT evidence of thickened ligamentum flavum, narrowed lateral recess and/or central canal narrowing). The X-STOP is indicated for those patients with moderately impaired physical function who experience relief in flexion from their symptoms of leg/buttock/groin pain, with or without back pain, and have undergone a regimen of at least 6 months of non-operative treatment. The X-STOP may be implanted at one or two lumbar levels in patients in whom operative treatment is indicated at no more than two levels.

**Contraindications:** The device is contraindicated in patients with: an allergy to titanium or titanium alloy; spinal anatomy or disease that would prevent implantation of the device or cause the device to be unstable *in situ*, such as: significant instability of the lumbar spine, e.g. isthmic spondylolisthesis or degenerative spondylolisthesis greater than grade 1.0 (on a scale of 1 to 4), an ankylosed segment at the affected level(s), acute fracture of the spinous process or pars interarticularis and significant scoliosis (Cobb angle greater than 25 degrees); cauda equina syndrome defined as neural compression causing neurogenic bowel or bladder dysfunction; diagnosis of severe osteoporosis, defined as bone mineral density (from DEXA scan or some comparable study) in the spine or hip that is more than 2.5 SD below the mean of adult normals in the presence of one or more fragility fractures; and active systemic infection or infection localized to the site of implantation.

**Warnings:** The X-STOP implant must be placed in the concavity between the spinous processes. Posterior positioning of the implant may result in dislodgement. If correct placement of the implant cannot be achieved due to variant anatomy, the surgeon should consider aborting the procedure because incorrect placement may result in device dislodgement, particularly if the patient experiences a traumatic event. **Precautions:** radiological evidence of stenosis must be correlated with the patient's symptoms before the diagnosis can be confirmed; if the spinous processes at the affected level are not distracted in flexion, the X-STOP system may not be indicated; the safety and effectiveness of the X-STOP device has not been studied in patients with the following conditions: axial back pain without leg, buttock or groin pain, symptomatic lumbar spinal stenosis at more than 2 levels, prior lumbar spine surgery, significant peripheral neuropathy, acute denervation secondary to radiculopathy, Paget's disease, vertebral

*KYPHON, X-STOP, X-STOP, and IPD* are registered trademarks, and *Ahead of the Curve* is a trademark, of Kyphon Inc. © 2008 Kyphon Inc. All Rights Reserved. 16000991-01

metastases, morbid obesity, pregnancy, a fixed motor deficit, angina, active rheumatoid arthritis, peripheral vascular disease and advanced diabetes or any other systemic disease that may affect the patient's ability to walk; surgeons should not implant the X-STOP implant until receiving adequate training regarding surgical technique because inadequate training may result in poor patient outcomes and/or increased rates of adverse events; and a stress fracture of the spinous process may occur if strenuous physical activity is resumed too soon postoperatively.

### **Potential Adverse Events**

The following potential adverse events may occur as a result of interspinous process decompression with the X-STOP system; some of these adverse events were reported in the Pivotal Clinical Trial. X-STOP system related: implant dislodgement/migration; implant not positioned correctly; fracture of the spinous process; additional surgery, which could include removal of the X-STOP implant; foreign body reaction; mechanical failure of the device; failure of the device/procedure to improve symptoms and/or function. Surgery Related: reactions to anesthesia; myocardial infarction; infection; blood vessel damage/bleeding; deep vein thrombosis; hematoma; pneumonia; neurological system compromise; stroke; nerve injury or spinal cord damage; paralysis; thrombus formation; wound dehiscence or delayed healing; pain/discomfort at the operative site; and death.

Note: Medication or additional surgery may be necessary to correct some of these potential adverse events.

Medtronic cannot guarantee coverage or reimbursement for X-STOP® IPD® procedure, and Kyphon Inc. makes no other representations as to selecting codes for procedures or compliance with any other billing protocols or prerequisites. As with all claims, individual physicians and hospitals are responsible for exercising their independent clinical judgment in selecting the codes that most accurately reflect the patient's condition and procedures performed for a patient. Physicians and hospitals should refer to current, complete, and authoritative publications such as AMA CPT lists or insurer policies for selecting codes and completing claims forms based on the care rendered to an individual patient, and may wish to contact individual carriers, fiscal intermediaries, or other third-party payers as needed.