INSTRUCTIONS FOR USE

This Clinical Policy provides assistance in interpreting Oxford benefit plans. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members. Oxford reserves the right, in its sole discretion, to modify its policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice. The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies.

When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Clinical Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Clinical Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Clinical Policy. Other Policies may apply.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

APPLICABLE LINES OF BUSINESS/PRODUCTS

This policy applies to Oxford Commercial plan membership.

BENEFIT CONSIDERATIONS

Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable.

Essential Health Benefits for Individual and Small Group

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits (“EHBs”). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.
Non-Coverage Rationale

Thermal intradiscal procedures (TIPs) are unproven and not medically necessary for treating discogenic pain. TIPs include the following procedures:

- Intradiscal electrothermal therapy (IDET)
- Intradiscal biacuplasty (IDB)
- Percutaneous intradiscal radiofrequency thermocoagulation (PIRFT)
- Percutaneous intradiscal annuloplasty

Percutaneous discectomy and decompression procedures are unproven and not medically necessary for treating discogenic pain. Percutaneous discectomy and decompression procedures include, but are not limited to, the following procedures:

- Nucleoplasty [percutaneous disc decompression (PDD) or percutaneous plasma discectomy]
- Laser discectomy [laser disc decompression (PLDD); laser-assisted disc decompression (LADD); or percutaneous endoscopic discectomy, with or without laser (PELD)]
- Yeung endoscopic spinal surgery (YESS) [arthroscopic microdiskectomy or percutaneous endoscopic diskectomy (PELD)]
- Transforaminal (TESSYS®) and/or interlaminar (iLESSYS®) (transforaminal and interlaminar approach)

Overall, the evidence regarding the efficacy of TIPs and percutaneous discectomy procedures for the treatment of low back pain is insufficient to demonstrate beneficial health outcomes. Available clinical studies are weakened by the lack of randomization, lack of comparator groups, and lack of long-term follow-up. Well-designed studies with larger patient populations are needed to evaluate the relative safety and effectiveness of these procedures.

Annulus fibrosus repair following spinal surgery is unproven and not medically necessary.
Further studies are needed to establish whether annulus fibrosus repair is beneficial for health outcomes in patients with low back pain following spinal surgery.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies may apply.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>22526</td>
<td>Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; single level</td>
</tr>
<tr>
<td>22527</td>
<td>Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; 1 or more additional levels (List separately in addition to code for primary procedure)</td>
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<tr>
<td>62287</td>
<td>Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, any method utilizing needle based technique to remove disc material under fluoroscopic imaging or other form of indirect visualization, with discography and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar</td>
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<tr>
<td>62380</td>
<td>Endoscopic decompression of spinal cord, nerve root(s), including laminotomy, partial facetectomy, foraminotomy, discectomy and/or excision of herniated intervertebral disc, 1 interspace, lumbar</td>
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<th>HCPCS Code</th>
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<tr>
<td>S2348</td>
<td>Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, using radiofrequency energy, single or multiple levels, lumbar</td>
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Description of Services

Back pain is a frequent cause of chronic pain and disability, affecting approximately 15% of the population in the United States. Most episodes of low back pain improve within one month without formal medical intervention. However, some patients may experience persistent and disabling low back pain. Management of low back pain that fails to resolve spontaneously or respond to conservative treatment is challenging. As a result, a number of diagnostic
and therapeutic injections, and other interventional and surgical treatments, have been proposed for the treatment of back pain.

**Thermal Intradiscal Procedures (TIPs)**

In general, percutaneous thermal intradiscal procedures (TIPs) involve the insertion of a catheter or probe into the spinal disc, under fluoroscopic guidance, to produce or apply heat within the disc to relieve low back pain. TIPs remove unwanted tissue, such as herniated discs; create a seal to limit expression of matrix components; shrink collagen tissue; and destroy nociceptors.

**Intradiscal Electrothermal Therapy (IDET)**

Intradiscal electrophoretic therapy (IDET) is one type of TIP. Since degeneration of the intervertebral disc can be the source of severe low back pain, IDET has been proposed as an alternative treatment to spinal fusion for those patients with symptomatic internal disc disruption, who are nonresponsive to conservative medical care. IDET is a minimally invasive, outpatient procedure, during which patients are administered local anesthesia and mild sedation. Under x-ray imaging (fluoroscopy), a disposable flexible catheter and a heating element is inserted into the spinal disc, directly to the annulus fibrosus, the outer component of the intervertebral discs. IDET destroys the nerve fibers and “toughens” the disc tissue, sealing any small tears. The heating of the electrode denatures the collagen of the annulus and coagulates the nerve endings with the goal of alleviating pain.

**Intradiscal Biacuplasty (IDB) or Biacuplasty**

Intradiscal biacuplasty (IDB) or biacuplasty is a modification of IDET that destroys the nerve fibers that generate pain sensations. IDB is a minimally invasive outpatient procedure that requires local anesthesia or mild sedation. IDB uses radiofrequency energy to heat the tissue, while circulating water is used to cool the tissue near the disc. This bilateral approach is intended to facilitate controlled lesioning between the electrodes in the disc.

**Percutaneous Intradiscal Radiofrequency Thermocoagulation (PIRFT)**

Percutaneous intradiscal radiofrequency thermocoagulation (PIRFT) is a minimally invasive method similar to IDET. PIRFT is also known as intradiscal electrothermal annuloplasty (IEA), intradiscal radiofrequency thermomodulation, radiofrequency (RF) annuloplasty, or radiofrequency posterior annuloplasty. Compared with IDET, PIRFT uses a radiofrequency probe that is placed into the center of the disc, rather than around the annulus. The device is activated for 90 seconds at a temperature of 70°C Celsius. PIRFT does not ablate the disc material, but instead alters the biomechanics of the disc or destroys nociceptive pain fibers. PIRFT is performed using the Radionics RF Disc Catheter System. The Radionics catheter system is designed for patients with chronic discogenic back pain for the coagulation and decompression of disc material to treat symptomatic patients with annular disruption of contained herniated disks. This is an outpatient procedure utilizing either sedative or local anesthesia.

**Percutaneous Discectomy Procedures**

**Nucleoplasty**

Nucleoplasty, also known as percutaneous disc decompression (PDD) or percutaneous plasma discectomy] uses x-ray images (fluoroscopy) for guidance to insert a specialized catheter to reach the disc nucleus. Radiofrequency energy is used to ablate (coagulate) nuclear material and create small channels within the disc. This decompresses the disc, reducing the pressure both inside the disc and on nerve roots. Typically patients are awake and able to speak to the physician during the procedure. Nucleoplasty is performed on an outpatient basis with minimal anesthesia requirements.

**Laser Discectomy**

Laser discectomy [also known as laser disc decompression (PLDD), laser-assisted disc decompression (LADD), or percutaneous endoscopic discectomy, with or without laser (PELD)] is a minimally-invasive procedure proposed as an alternative to discectomy or microdiscectomy. These procedures are performed under local anesthesia since patient cooperation is required during the procedure. The disc space is punctured with a cannula and the tip of the needle is placed into the center of the disc. A second cannula is placed on the opposite lateral side of the disc. Parts of the nucleus pulposus are removed to allow for examination. The remaining disc material is vaporized using a laser.

**Yeung Endoscopic Spinal Surgery (YESS)**

Yeung Endoscopic Spinal Surgery (YESS) [also known as arthroscopic microdiskectomy or percutaneous endoscopic discectomy (PELD)], is a minimally-invasive procedure designed to relieve symptoms caused by herniated discs pressing on nerves. The YESS system uses an endoscopic approach to selectively remove the nucleus pulposus within annular tears. This is an outpatient procedure utilizing either sedative or local anesthesia. The Yeung Endoscopic Spinal System (Richard Wolf Surgical Instrument Corporation) is a specialized endoscope developed for percutaneous spinal endoscopy and discectomy. This endoscope has multichannel inflow and outflow ports, allowing visualization through one port and suction or other therapeutic services through the working port. The purported advantages of endoscopic discectomy or its superiority over microsurgical discectomy has not been demonstrated in the peer-
The efficacy of endoscopic spinal surgery and surgery with the YESS system has not been established due to the lack of sufficient evidence.

**Transforaminal (TESSYS®) and/or Interlaminar (iLESSYS®)**

The TESSYS® approach focuses on the endoscopic visualization of the foramen and a transforaminal approach in order to resect the herniated disc. The surgeon performs a foraminoplasty through which neural elements can be decompressed. Disc material is removed completely and directly through the foramen, which is gradually widened using specialized reamers and instruments. The iLESSYS® method uses endoscopic interlaminar access for the removal of herniated discs or the treatment of lumbar spinal stenosis. Generally all lumbar levels can be treated with either approach.

**Annulus Fibrosus Repair**

The annulus fibrosus is a ring of fibrocartilage and fibrous tissue around the intervertebral disc, surrounding the nucleus pulposus of the spine. During a surgical discectomy or some other spine surgeries, an open pathway or hole (defect) is made in the annulus fibrosus, which is then left to heal. Annulus fibrosus repair systems are designed to reinforce or bridge material to form a strong flexible wall between the annulus and nucleus of the herniated region to close the defect and repair the annulus fibrosus of the intervertebral disc. Three basic types of annulus fibrosus repair have been developed to overcome the potential problems of a hole in the annulus fibrosus, including 1) direct manual suture with standard surgical needles and sutures, 2) soft-tissue reapproximation using specialized tissue anchors and surgical sutures, and 3) surgical devices.

**CLINICAL EVIDENCE**

**Thermal Intradiscal Procedures (TIPs)**

**Intradiscal Electrothermal Therapy (IDET) and Intradiscal Biacuplasty (IDB)**

A prospective, randomized, crossover, multicenter trial for the evaluation of comparative effectiveness of intradiscal biacuplasty (IDB) versus conventional medical management (CMM) in the treatment of lumbar discogenic pain was conducted. The primary outcome measure was the change in visual analog scale (VAS) 12-months after the initiation of each method. Secondary outcome measures included the SF36-Physical Functioning (SF36-PF), Owestry Disability Index (ODI), Beck's Depression Index (BDI), Patient Global Impression of Change (PGIC) and Quality of Life Index (EQ-5D). CMM included physical therapy, pharmacological management, interventional procedures (lumbar epidural injections, sacroiliac joint injections, and facet interventions), and lifestyle changes such as behavioral therapy, weight loss, and acupuncture. Sixty-three patients who had been treated with IDB and CMM for chronic low back pain of discogenic origin were originally randomized to the IDB+CMM group (N=29) or CMM-alone (N=34). Six months following continuous CMM-alone treatment, participants in this study group were permitted to "cross-over" to IDB+CMM (N=25), and followed for an additional 6 months. The original IDB+CMM study subjects were followed for a total of 12 months (N=22). The VAS mean baseline score was 6.7 and at 12 months the mean score was 4.4. The SF36-PF mean baseline score was 48 and at 12 months 62; ODI was 42/30; BDI 8/8; PGIC 4.4/2.9 and EQ-5D 0.57/0.71. Desai et al. (2017) concluded that pain reduction at 12 months was statistically significant and clinically meaningful in the original IDB+CMM group compared to baseline. Limitations of this randomized comparison included the lack of study subjects’ blinding to the study arm within which they were randomized. Study eligibility was also restricted to patients with single-level discogenic pain.

In follow-up of an earlier randomized controlled trial (Kapural et al., 2005), the same investigators evaluated the use of radiofrequency intradiscal biacuplasty for the treatment of discogenic back pain over a period of 12 months. (Kapural et al., 2015) This clinical study evaluated a small patient population (n=27) and evaluate physical functioning, pain relief, and disability. A total of 22 of 27 were followed for 12 months. These patients had clinically meaningful improvements in physical function and pain, and results were durable at 9 and 12 months. Of the 30 patients who were in the same group, 24 crossed over into the treatment group, and 20 of these patients completed the follow-up period at 6 months. However, patients in the crossover group did not experience statistically significant improvements in physical functioning and pain when compared with patients in the initial treatment group. The study was limited by the small number of patients followed, which may have limited the overall power of the study to accurately detect differences between groups.

Freeman, et al. (2005) reported results of 57 patients who were randomized to either IDET (n=38) or sham (n=19). The objective of the study was to test the safety of IDET compared with sham treatment for low back pain of at least 3 months duration. Study participants were chosen from consecutive patients of 3 spine surgeons if they satisfied eligibility criteria. Randomization occurred after catheter placement via sealed envelope by an independent technician who covertly connected the catheter if the patient was to receive active treatment. All subjects followed a common rehabilitation program. Patient evaluations occurred at 6 weeks and 6 months by an independent investigator. Outcomes measures were recorded at baseline and 6 months and included the VAS, low back pain outcome score (LBOS), Oswestry Disability Index (ODI), SF-36, Zung Depression index, the modified somatic perception questionnaire, sitting tolerance, work tolerance, medication, and the presence of any neurologic deficit. Success was
defined a priori as a composite measure: no neurologic deficit resulting from the procedure, an improvement in the LBOS of 7 or more points, and an improvement in the SF-36 subscales of bodily pain and physical functioning of greater than 1 standard deviation from the mean. Sample size was calculated before the study and using a 2:1 allocation with 80% power, 75 patients were required. The authors reported that no serious adverse events in either arm of the study occurred, without defining serious adverse events. The authors also reported, "Transient radiculopathy (less than 6 weeks) was reported in 4 study participants who underwent IDET and in 1 study participant who underwent the sham procedure." The authors concluded that IDET was no more effective than placebo for the treatment of chronic discogenic low back pain.

A small, double-blind, randomized, controlled trial by Kapural et al. (2005) comparing IDET (n=38) to sham catheter (n=19) found that six months after treatment, neither group had experienced statistically significant improvement from baseline. The investigators concluded that IDET was safe, but not demonstrably better than placebo. There was no improvement in pain over sham treatment.

Tsau et al. (2010) evaluated ninety-three consecutive patients undergoing IDET at 134 disc levels from October 2004 to January 2007. All patients had discogenic disease with chronic low back pain (LBP), as determined by clinical features, physical examination and imaging studies, and had failed to improve with conservative treatment for at least 6 months. Follow-up period was from 1 week to 3 or more years postoperatively. There were 50 male and 43 female patients, with a mean age of 46.07 years (range, 21-65 years). The results were classified as symptom free (100% improvement), better (≥50% improvement), slightly better (<50% improvement), unchanged and aggravated. Eighty-nine patients were followed up in the first week; of them, 77 (86.52%) patients had improvement (4, symptom free; 45, better; and 28, slightly better). The improvement rate gradually decreased to 80.90% in 1 year; and 73.91%, in 3 years. In conclusion, IDET offers a safe, minimally invasive therapy option for carefully selected patients with chronic discogenic LBP who have not responded to conservative treatment. Although IDET may provide intermediate-term relief of pain, further studies with long-term follow-up are necessary.

Kapural and Mekhail (2007) reported the treatment of severe axial discogenic pain in a young man using IDB. The investigators reported that there were no intra- and post-operative complications, and significant improvements in patient functional capacity and pain scores were noted. At 6-month follow-up, visual analog scale pain scores decreased from 5 cm to 1 cm, Oswestry disability scores improved from 14 points (28% or moderate disability) to 6 points (12% or minimal disability) and SF-36-PF (physical function) score changed from 67 to 82. These findings need to be confirmed by well-designed controlled clinical studies.

Helm and colleagues (2012) conducted a systematic review of the available evidence evaluating the effectiveness of thermal annular procedures in treating discogenic low back pain. The primary outcome measure was pain relief of at least six months. Secondary outcome measures were improvements in functional status. Three randomized controlled trials and one observation study met the inclusion criteria for thermal annular procedures. No new controlled trials were identified. Using the criteria for successful outcomes, the evidence was found to be fair for IDET and poor for use of the discTRODE probe, a device to deliver thermal energy to the disc, and IDB procedures regarding whether they are effective in relieving discogenic low back pain. The limitations of this systematic review for IDET include the paucity of literature and non-availability of randomized trials.

Helm et al. (2009) conducted a systematic review of the effectiveness of thermal annular procedures in treating discogenic low back pain. A total of 67 articles were reviewed of which 36 were either randomized controlled trials (n=2) or observational studies (n=34). The authors conclude that while the evidence is generally weak, IDET offers functionally significant relief in approximately one-half of appropriately chosen chronic discogenic low back pain patients. There is minimal evidence supporting the use of radiofrequency annuloplasty and IDB.

A systematic review by Urrutia et al. (2007) included six studies with a total of 283 patients. Two open, nonrandomized trials (95 patients) showed positive results for IDET compared with rehabilitation and percutaneous intradiscal radiofrequency therapy (PIRFT). Results from 2 RCTs showed no differences between PIRFT and placebo, and between different PIRFT techniques. Two RCTs compared IDET with placebo. One suggested differences only in pain and in disability, while the best quality RCT showed no differences. The authors concluded that the available evidence does not support the efficacy or effectiveness of percutaneous thermocoagulation intradiscal techniques for the treatment of discogenic low back pain.

A meta-analysis by Appleby et al. (2006) was conducted to determine the representative outcomes of intradiscal electrothermic therapy (IDET) for pain relief, reduction of disability, and risk of complications. The outcomes analyzed were the visual analog scale (VAS) assessment of pain, the bodily pain, and physical functioning subscales of the SF-36 health survey, and the Oswestry disability index. From 1998 to March 2005, 62 peer-reviewed articles were identified regarding the IDET procedure. The authors concluded that although variation exists in the reported outcomes among the various studies of the IDET procedure, the pooled results of the published studies provide
compelling evidence of the relative efficacy and safety of the IDET procedure. However, the studies that were included in this meta-analysis used subjective evaluation of improvement as key outcome measures.

The National Institute for Health and Care Excellence (NICE) 2016 recommendation states that the current evidence on percutaneous electrothermal treatment of the intervertebral disc annulus for low back pain and sciatica raises no major safety concerns but the evidence on efficacy is inconsistent and of poor quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

**Professional Societies**

**American College of Occupational and Environmental Medicine (ACOEM)**
The ACOEM practice guidelines on low back disorders, (2011) states that IDET is not recommended for treatment of acute, subacute, or chronic low back pain, or any other back-related disorder.

**American Society of Interventional Pain Physicians (ASIPP)**
An updated ASIPP Evidence-Based Practice Guidelines in the Management of Chronic Spinal Pain (Manchikanti, et al., 2013). State that the evidence for intradiscal electrothermal therapy (IDET) is limited to fair.

The safety, efficacy, and long-term outcomes of intradiscal electrothermal annuloplasty in the treatment of patients with chronic discogenic low back pain have not been established in the published medical literature. This procedure has not been proven to achieve equivalent or improved patient outcomes compared to available and established alternatives. In addition, the long-term effect of thermal coagulation of intervertebral discs has not been determined.

**Percutaneous Intradiscal Radiofrequency Thermocoagulation (PIRFT)**
PIRFT may also be referred to as intradiscal radiofrequency thermomodulation or percutaneous radiofrequency thermomodulation. With PIRFT, the catheter is placed into the center of the disc rather than the annulus.

In a prospective, parallel, randomized and gender stratified, double-blind placebo-controlled study, Kvarstein et al (2009) evaluated the long-term effect and safety aspects of PIRFT with the discTRODE probe. A total of 20 patients with chronic LBP and a positive 1-level pressure-controlled provocation discography were randomized to either intran-annular PIRFT or intra-annular sham treatment. A blinded interim analysis was performed when 20 patients had been followed for 6 months. The 6-month analysis did not reveal any trend towards overall effect or difference between active and sham treatment for the primary endpoint: change in pain intensity (0 to 10). The inclusion of patients was therefore discontinued. After 12 months, the overall reduction from baseline pain had reached statistical significance, but there was no significant difference between the groups. The functional outcome measures (ODI, and SF 36 subscales and the relative change in pain) appeared more promising, but did not reach statistical significance when compared with sham treatment. Two actively treated and 2 sham-treated patients reported increased pain levels, and in both groups a higher number was unemployed after 12 months. The study did not find evidence for a benefit of PIRFT, although it cannot rule out a moderate effect. The authors stated that considering the high number reporting increased pain in this study, they would not recommend intra-annular thermal therapy with the discTRODE probe.

Kapural et al. (2005) performed a prospective matched controlled trial of intradiscal thermal annuloplasty versus intradiscal radiofrequency ablation for treatment of discogenic pain. They matched 42 patients with 21 having IDET and 21 having radiofrequency annuloplasty. They reported the IDET group had significantly lower mean pain scores than the radiofrequency annuloplasty group however; there was improvement noted in both groups. VAS pain scores decreased from 6.6+2.0 before to 4.4+2.4 at one year after radiofrequency annuloplasty, whereas in IDET group the average VAS pain score decreased from 7.4+1.9 before IDET to 1.4+1.9 at 1-year follow-up. Similarly, pain disability index scores in the IDET group had a significantly larger improvement than those for patients who received radiofrequency annuloplasty.

Finch et al. (2005) studied 31 patients by heating of their annular tears with a flexible radiofrequency electrode placed across the posterior annulus and compared 15 patients with conservative management. The visual analog scale decreased significantly after the radiofrequency treatment and this decrease persisted at 12 months follow-up. The VAS did not change over 12 months in untreated controlled subjects. The Oswestry Disability Index also decreased in treated patients but not in control group subjects. This study is limited by small sample size.

Urrutia et al. (2007) conducted a systematic review to evaluate the evidence for the percutaneous thermocoagulation intradiscal techniques IDET and PIRFT in the treatment of discogenic low back pain. Six studies with a total of 283 patients were included. Two randomized controlled trials showed no differences between PIRFT and placebo and between different PIRFT techniques. The authors stated that, although previous case reports and nonrandomized trials suggested positive results, results from randomized clinical trials show that PIRFT is not effective for the treatment of discogenic low back pain.
Zhang and colleagues (2016) investigated the safety and efficacy of percutaneous intradiscal radiofrequency thermocoagulation (PIRFT) for the treatment of discogenic low back pain (LBP). Twenty-three patients with LBP who were treated with single level bipolar radiofrequency thermocoagulation (RFTC) were included in the study. The patients were assessed before the procedure and at 1 week, 1 month, 3 months, 6 months, and 1 year after the procedure. The primary outcome included the visual analog scale (VAS) score and the Oswestry Disability Index (ODI) score. The secondary outcome included pain relief, reduction of analgesic dose, and patient satisfaction. VAS and ODI scores were reported as significantly decreased after bipolar RFTC treatment at all-time points of follow-up (p<0.05). A significant change was also reported in all secondary measures, such as pain relief, reduction of analgesic dose, and patient satisfaction. Three patients experienced mild short-term post-dural puncture headache, but the symptom disappeared within 1 week. No serious complications, such as nerve injuries, discitis, and hematoma, or neurological sequelae occurred in any of the patients. The authors concluded that bipolar RFTC treatment can significantly reduce pain and improve the function of patients with discogenic LBP. Limitations of this study include lack of a control group and the small sample size.

**Professional Societies**

*American College of Occupational and Environmental Medicine (ACOEM)*

The ACOEM practice guidelines on low back disorders (originally published in 2007 and updated in 2011) states that PIRFT is strongly not recommended for treatment of acute, subacute, or chronic low back pain, particularly including discogenic low back pain.

*American Society of Interventional Pain Physicians (ASIPP)*

The ASIPP has prepared practice guidelines, and found that the evidence for radiofrequency posterior annuloplasty was limited for short-term improvement, and indeterminate for long-term improvement in managing chronic discogenic low back pain. (Boswell, 2007)

An updated American Society of Interventional Pain Physician (ASIPP) Evidence-Based Practice Guidelines in the Management of Chronic Spinal Pain (Manchikanti, et al., 2013a) state that the evidence is limited for discTRODE (PIRFT).

There is insufficient evidence in the published medical literature to demonstrate the safety, efficacy and long-term outcomes of PIRFT. There is no evidence that this procedure is as effective as established alternatives for the treatment of back pain.

**Nucleoplasty**

Wu et al. (2015) conducted a randomized controlled trial to compare CT-guided nucleoplasty, CT-guided nucleoplasty combined with nerve root injection, and CT-guided transforaminal lumbar epidural injections for patients with lumbar disk herniation and leg pain (n=97). Results of the study demonstrated that the combination of nucleoplasty with nerve root injection produced a significantly greater reduction in the pain score and disability score when compare with only nucleoplasty in the short term, at 1 week, as well at 1 month. The study limitations included lack of blinding, and relatively small patient populations.

Ren et al. (2015) evaluated the efficacy of percutaneous nucleoplasty using coblation technique for the treatment of chronic nonspecific low back pain (LBP), after 5 years of follow-up. Forty-one patients who underwent percutaneous nucleoplasty for chronic LBP were assessed preoperatively and at 1 week, 1 year, 3 years, and 5 years postoperatively. Pain was graded using a 10-cm Visual Analogue Scale (VAS) and the percentage reduction in pain score was calculated at each postoperative visit. The Oswestry Disability Index (ODI) was used to assess disability related to lumbar spine degeneration, and patient satisfaction was assessed using the modified MacNab criteria. There were significant differences among the preoperative, 1-week postoperative, and 3-year postoperative VAS and ODI scores, but not between the 3- and 5-year postoperative scores. Excellent or good patient satisfaction was achieved in 87.9% of patients after 1 week, 72.4% after 1 year, 67.7% after 3 years, and 63.4% at the last follow-up. The authors concluded although previously published short- and medium-term outcomes after percutaneous nucleoplasty appeared to be satisfactory, the long-term follow-up results showed a significant decline in patient satisfaction over time. This is an uncontrolled study with a small sample size.

Kuman et al. (2014) evaluated the safety and efficacy of annulo-nucleoplasty using Disc-FX for the treatment of lumbar disc pathology (n=24). All patients were non-responsive to non-operative treatment measures. A total of 12 patients had degenerative disc disease and 12 patients had contained lumbar disc herniation. Health outcomes included the VAS, Oswestry Disability Index, and the Short Form-36 scores evaluated before and after the procedure. Study authors reported significant improvement in outcomes relative to baseline. The overall rate of re-intervention for symptoms that continued to persist was about 18%; in the group of patients with lumbar disc herniation, the rate was about 36%. The study was limited by lack of appropriate comparator groups, lack of randomization, and relatively limited follow-up.
Zhu et al (2011) evaluated longer-term efficacy over a 2-year follow-up of coblation nucleoplasty treatment for protruded lumbar intervertebral disc. A total of 42 cases of protruded lumbar intervertebral disc treated by coblation nucleoplasty followed-up for 2 years were analyzed. Relief of LBP, leg pain and numbness after the operation were assessed by VAS. Function of lower limb and daily living of patients were evaluated by the ODI. The authors concluded that coblation nucleoplasty may have satisfactory clinical outcomes for treatment of protruded lumbar intervertebral disc for as long as 2-year follow-up, but longer-term benefit still needs verification.

A prospective, non-randomized, longitudinal, cohort study, Gerszten et al. (2006) assessed pain, functioning, and quality of life (QOL) in 67 patients with radicular leg and back pain who underwent nucleoplasty- based percutaneous disc decompression. Pain relief, functioning, and quality of life (QOL) were evaluated. Patients completed the Medical Outcomes Study 36-Item Short Form (SF-36) Health Survey, EuroQol 5D (EQ5D), and a VAS for pain preoperatively, and at 3 and 6 months after surgery. Compared with pre-operative QOL, there was a statistically significant improvement in QOL at 3 months as measured using the SF-36 Physical Component Summary (PCS) scale, the EQ5D and the VAS for pain. Six-month results in 36 patients continued to reflect improvement as measured using the SF-36 PCS and the EQ5D. The authors concluded that nucleoplasty-based percutaneous disc decompression in patients with symptomatic contained disc herniations is safe and improves QOL as measured by the SF-36, EQ5D, and VAS for pain, three generic QOL outcome instruments. Nucleoplasty is an effective minimally invasive surgical treatment alternative in patients with symptomatic contained disc herniations. They noted that further follow-up evaluation is underway to determine the durability of QOL improvement after nucleoplasty.

The largest available controlled trial of nucleoplasty was performed by Nardi et al. (2005) who assigned 50 patients to nucleoplasty and 20 patients to conventional therapy with anti-inflammatory medications and physical therapy. Unlike most of the other available studies of nucleoplasty, this trial enrolled patients who had herniated or protruding cervical discs rather than damaged lumbar discs. At 60 days post-treatment, complete resolution of cervical and radicular pain was reported by 40 (80%) patients in the nucleoplasty group and by 4 (20%) patients in the conventional group. MRI findings at 4 months after nucleoplasty appeared to correlate with clinical resolution. In contrast, no spontaneous regression of disc herniation was observed in MRI exams of patients in the conventional group. Nardi et al. reported that clinical improvements were statistically significant in the nucleoplasty group but not in the conventional group; however, these investigators do not appear to have performed an intergroup analysis.

The largest available uncontrolled study of nucleoplasty was performed by Alexandre et al. (2005) who assessed outcomes for 1390 patients treated for lumbalgia or lumbosciatica due to disc bulging or partially contained disc herniation. Alexandre et al. reported few details of demographics and no information concerning fraction of patients lost to follow-up. Based on Japanese Orthopedic Association scores, at 1 year of follow-up, improvements were excellent for 56% of patients, good for 25%, scanty for 12%, and none for 7%. No clear trend was observed when outcomes at 15 days, 1 month, 6 months, and 1 year were compared. Findings on MRI and/or CT at 6 months after nucleoplasty showed the elimination of disc bulging in 34% of patients, a reduction in 48%, and no change in 18%. The study is limited by uncontrolled study design.

Bhagia et al. (2006) reported the short-term side effects and complications after percutaneous disc decompression utilizing coblation technology (nucleoplasty) in a retrospective study on 53 patients. The authors reported statistically significant reductions in VAS scores for both back and leg pain. The procedure was associated at 24 hours with short-term increased pain at the needle insertion site (76%), new numbness or tingling (26%), increased preprocedure back pain (15%) and new areas of back pain (15%). By 2 weeks no patients had soreness at injection site or new areas of back pain, and only 2 had increased intensity of preprocedure back pain, while new numbness or tingling was present in 15% of patients. The study is limited by retrospective study design, subjective outcomes and new symptoms in 15% of study participants.

The largest improvement in mean VAS score was reported in this follow-up study by Masala et al. (2007) who treated 72 patients affected by lumbar disk herniation were treated with nucleoplasty coblation. Average preprocedural pain level for all patients was 8.2, while the average pain level at 12 months follow-up was 4.1. At the 1 year evaluation, 79% of patients demonstrated a statistically significant improvement in numeric pain scores: 17% (12 patients) were completely satisfied with complete resolution of symptoms, and 62% (43 patients) obtained a good result a decrease from 8.2 at baseline to 4.1 (4.1 points) at 1-year follow-up. The study is limited by subjective outcomes with only a 50% decrease in pain and no documentation of improvement in functional status.

Mirzai et al. (2007) evaluated outcomes 2 weeks, 6 months, and 1 year after nucleoplasty in 52 consecutive patients with leg pain and MRI evidence of small and medium-sized herniated discs. Thirty-four patients had one and 18 had two discs treated; a total of 70 procedures were performed. Mean VAS reduced from preprocedure 7.5 to 3.1 at postprocedure 6 months and to 2.1 at the latest follow-up. Mean Oswestry index decreased from 42.2 to 24.8 at 6 months and to 20.5 at the latest examination. Analgesic consumption was stopped or reduced in 42 patients (85%) at 6 months and in 46 patients (94%) 1 year after the procedure. Overall patient satisfaction was 81% at 2 weeks, 85% at 6 months, and 88% at the latest follow-up. The study is limited by subjective outcomes.
The National Institute for Health and Care Excellence (NICE) in 2016, evaluated percutaneous coblation of the intervertebral disc for low back pain and concluded that percutaneous coblation of the intervertebral disc for low back pain may be used for patients with pain caused by contained herniated discs that have not responded to conservative treatment, when open surgery is not suitable.

**Professional Societies**

**American College of Occupational and Environmental Medicine (ACOEM)**

ACOEM practice guidelines on low back disorders, (Updated 2011), state that there is no quality evidence that Coblation therapy is an effective treatment for any back or radicular pain problem.

**American Pain Society**

The evidence-based clinical practice guideline from the American Pain Society, Interventional Therapies, Surgery, and Interdisciplinary Rehabilitation for Low Back Pain, states that there are no trials evaluating Coblation nucleoplasty. The authors were unable to estimate the net benefit of the procedure in the treatment of patients with back pain, with or without radiculopathy. (Chou, 2009)

**American Society of Interventional Pain Physicians (ASIPP)**

Interventional Techniques: Evidence-based Practice Guidelines in the Management of Chronic Spinal Pain. (Updated 2013) The American Society of Interventional Pain Physicians (ASIPP) has prepared practice guidelines, and found that clinical effectiveness of nucleoplasty is limited to fair for nucleoplasty, and that the procedure is recommended in select cases. (Manchikanti, 2013b)

The safety, efficacy and long-term outcomes of nucleoplasty have not been demonstrated in the published medical literature. In addition, the long-term consequences of thermal denervation and tissue damage associated with this procedure are unknown.

**Percutaneous and Endoscopic Laminectomy and Disc Decompression Procedures**

There are a number of techniques described as “percutaneous discectomy,” and the variations on each of these techniques are numerous. Furthermore, the terminology used to describe these surgical techniques is equally varied and not fully standardized.

Li et al. (2015) performed a study to determine the feasibility and effectiveness of percutaneous endoscopic transforaminal discectomy (PETD) for recurrent lumbar disc herniation (RLDH). The study consisted of 56 patients with RLDH who underwent PETD. All the patients had a mean pain-free interval of 5.5 years. The visual analogue scale (VAS) score for back pain was 6.18 ± 1.44 and the VAS score for leg pain was 7.66 ± 1.03. Postoperative effectiveness was assessed based on the VAS score and modified MacNab criteria. The average follow-up was 28.2 months. Patients obtained immediate pain relief postoperatively. The postoperative VAS scores of back and leg pain at 1 month, 3 months, 12 months, and last follow-up were significantly decreased when compared with preoperative score (P < 0.05). Based on the modified MacNab criteria, the results were excellent in 39 cases, good in 9 cases, fair in 5 cases, and poor in 3 cases at 12 months after operation. Surgery-related complications were found in 5 cases. The authors concluded that PETD had several advantages in treating RLDH, such as decreasing operation-related complications, shortening operation time, reducing trauma, and obtaining rapid postoperative recovery and is feasible and effective for RLDH. This was a nonrandomized study design without a control group.

**Automated Percutaneous Lumbar Discectomy (APLD)/Automated Percutaneous Nucleotomy**

Automated percutaneous lumbar discectomy (APLD), also referred to as automated percutaneous nucleotomy, is a minimally-invasive surgical procedure used in the treatment of herniated lumbar intervertebral discs. In this procedure, a cannula is placed in the center of the disc under fluoroscopic guidance using a posterolateral approach. A probe connected to an automated cutting and aspiration device is then introduced through the cannula. The disc is then aspirated until no more nuclear material is obtained. The goal of APLD is to remove herniated disc material that may be pressing on nerve roots and thereby causing pain and other symptoms. There is insufficient evidence in the peer-reviewed medical literature to support the safety and efficacy of APLD. Results of published studies are inconsistent and do not demonstrate long-term improvement. There is no evidence that APLD is as effective as discectomy/microdiscectomy.

**Percutaneous Lumbar Discectomy (PLD)**

Martins et al. (2016) conducted a review of 40 systematic reviews for the surgical treatment of low back pain (LBP) and analyzed their outcomes, quality, and conclusions. There was a heterogeneous group of surgical interventions, including injections, direct repair of the pars interarticularis, arthroplasty, decompression, nucleoplasty, endoscopic discectomy, and fusion. The outcome measures utilized were the AMSTAR (A Measurement Tool to Assess Systematic Reviews) score and PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) questionnaires.
Most systematic reviews for LBP did not reach very good or excellent quality and only 27.5% of them had evidence based conclusions. Including a meta-analysis is a significant factor to improve quality and evidence for systematic reviews and the authors suggested that researchers should concentrate efforts in performing randomized clinical trials in surgical treatment for LBP before attempting secondary studies. Martins and colleagues concluded that although many systematic reviews for LBP surgical treatment are available, there is still no strong evidence favoring most of surgical procedures from an evidence-based approach and surgeons should not blindly trust systematic reviews because the validity of a significant number of them is questioned.

Cong et al. (2016) conducted a systematic review to compare the effectiveness and safety of endoscopic discectomy (ED) with open discectomy (OD) for the treatment of recurrent lumbar disc herniation (LDH). A search was used to identify all published randomized controlled trials (RCT) up to August 2014. Cochran methodological was used for the results of this meta-analysis. Nine relevant RCTs involving 1,092 patients were identified. Compared with OD, ED results in slightly better clinical outcomes which were evaluated by the Macnab criteria without clinical significance (ED group: 95.76; OD group: 80%; P=0.10), a significantly greater patient satisfaction rate (ED group: 93.21%; OD group: 86.57%; P=0.03), lower intraoperative blood loss volume, and shorter length of hospital stay. The authors conclude that from the existing outcomes, ED surgery could be viewed as a sufficient and safe supplementation and alternative to standard open discectomy. The cost-effectiveness analyses still remain unproved from the existing data. More independent high-quality RCTs using sufficiently large sample sizes with cost-effectiveness analyses are needed.

A 2017 Hayes Health Technology Brief evaluated the use of percutaneous endoscopic lumbar discectomy (PELD) for the treatment of recurrent lumbar disc herniation in adults. The literature search identified 6 clinical studies (n=41-401 patients). Overall, the low-quality body of evidence suggests that PELD may be inferior to comparison treatments for reducing back pain. While some studies suggest no statistically significant differences between PELD and comparator treatments for a majority of key outcomes, in a small number of studies minimally invasive transforaminal lumbar interbody fusion or microendoscopic discectomy was favored over PELD on evaluations of back pain and recurrence. The poor quality of the individual studies, small samples, small numbers of studies evaluating individual key outcomes and comparisons, and variability in index surgeries all contributed to the low-quality body of evidence.

A Hayes (2017) Health Technology Brief literature search identified 8 clinical studies (n=20-15,817 patients) that evaluated the efficacy and safety of percutaneous endoscopic lumbar discectomy (PELD) for primary surgical intervention for symptomatic lumbar disc herniation (LDH). Overall, a low-quality body of evidence suggests that PELD performs similarly to other surgical alternatives in patients with symptomatic LDH that has failed conservative management. Substantial uncertainty exists regarding appropriate patient-selection criteria. PELD has a significant learning curve, requiring specific instruction and training. The bulk of the literature with PELD is in the lower lumbar spine (L4-L5, L5-S1), with less available evidence with use of the technology in upper LDH.

Pan et al. (2016) performed a prospective cohort study to investigate the clinical outcomes of transforaminal endoscopic system (TESSYS) for discogenic low back pain (DLBP). Consecutive patients (n=62) with one-level DLBP underwent TESSYS from January 2010 to December 2013 with a mean follow-up of 26.8 ± 4.2 months. The visual analog scale (VAS) was used for back pain, the Oswestry Disability Index (ODI) for lumbar function, and the modified Macnab criteria for clinical global outcomes. Twenty-four patients showed only inflammatory granuloma on annulus tear tissues (Group A), 16 patients showed no annulus tear but adhesion and inflammatory granuloma among the intracanal annulus fibrous(AF), posterior longitudinal ligament(PLL) and the abdomen side of the dura sac(Group B) and 22 patients showed both(Group C). The success rate of group C was much higher than A and B. The whole success rate was 75.8%. Of the 4 patients with poor result, 2 refused further surgical treatment and showed either no improvement or worsening. The remaining 2 patients had spinal fusion surgery and achieved better results. VAS and ODI had significantly improved after surgery (P < 0.01). No unexpected complications were seen. The authors concluded that TESSYS is an effective method in treating DLBP. The findings of this study need to be validated by well-designed studies.

In a prospective cohort study, McCormick et al. (2016) determined long-term outcomes of Dekompressor percutaneous lumbar disc decompression (PLDD) for discogenic radicular pain. Consecutive patients (n=70) with discogenic lumbosacral radicular pain who underwent PLDD with Dekompressor were included in the study. Numerical Rating Scale (NRS) leg pain score and Oswestry Disability Index (ODI) score data were collected at 6 months and 1 year. These 2 measures, 5-point Likert scale patient satisfaction, and surgical rate data were collected at 8 years. Forty and twenty-five patients were successfully contacted at 1-year and 8-year follow-up, respectively. At 1 year and 8 years, NRS leg pain scores were reduced greater than 50 % in 47 % and 29 % of patients, respectively; ODI score improved greater than 30 % in 43 % and 26 % of patients, respectively. Of the patients who were followed-up at 8 years, 36 % had undergone surgery and the median satisfaction was “4” (interquartile range of 2 to 5). The authors concluded that while limited by loss-to-follow-up, the findings of this study suggested that treatment of discogenic lumbosacral radicular pain with Dekompressor resulted in decreased leg pain and disability and favorable satisfaction at long-term follow-up. They stated that further study with adequate follow-up retention is needed to confirm that Dekompressor spares open spinal surgery.
Sanusi et al. (2015) conducted a two year retrospective assessment of patients (n=201) who underwent transforaminal endoscopic discectomy at a tertiary neurosurgical center in the United Kingdom by a single surgeon. Mean time of onset of symptoms was 5.5 months and the most common level was L4/5 (53%). All endoscopic discectomies were performed under local anesthesia. The visual acuity score of the pain dropped from an average of 7/10 pre-operatively to 0-1/10 in 95% of patients two weeks post operatively. Eighty-seven percent of the patients went back to their normal daily activities within two weeks. There were no cases of CSF leak, hematoma formation or wound infection. One percent of patients developed a nerve root injury. 6% of patients had recurrent herniation and required microdiscectomy. The authors concluded that endoscopic discectomy can be an alternative approach to microdiscectomy and the data shows that the far lateral endoscopic discectomy using the TESSYS technique has comparable outcomes to microdiscectomy. The study is limited by its retrospective observations.

A systematic review by Hirsch et al. (2009) evaluated the effectiveness of APLD and concluded that APLD is a safe procedure and may provide relief in properly selected patients with contained disc herniation. The authors also stated that the effectiveness of APLD appears to compare favorably with the results of chymopapain injection and open discectomy, however assumptions have not been proven in randomized trials.

A meta-analysis by Gibson et al. (2006) analyzed 27 randomized controlled trials of surgery for lumbar disc prolapse that included 3 trials evaluating the effect of APLD for lumbar herniation. Analysis of the pooled data from these trials indicated there is moderate evidence that APLD results in poorer clinical outcomes than standard discectomy or chymopapain treatment.

**Percutaneous Laser Disc Decompression (PLDD)**

Brouwer and colleagues (2015) conducted a randomized controlled trial with non-inferiority study design (n=115) to evaluate PLDD compared with conventional surgery for the treatment of low back pain. The non-inferiority analysis showed that PLDD resulted in non-inferior outcomes compared with conventional surgery; however, the number of reoperations required was significantly higher in the PLDD group (38%) compared with conventional surgery group (16%).

Lee et al. (2015) conducted a small pilot study to evaluate the safety and effectiveness of the L’DISQ device in patients with lumbar discogenic pain (n=20). Preliminary results of the L’DISQ device showed that at 48 weeks, the VAS improved, while the disability index, range of motion, and quality of life (QOL) index decreased significantly when compared with baseline values. However, the study was limited by the before-and-after study design, lack of randomization, and blinding, as well as lack of a comparator group. Additional studies are necessary to definitively evaluate the safety and efficacy of the L’DISQ device for treatment of lumbar discogenic pain.

An ECRI Health Technology Assessment (Updated 2016) evaluating laser discectomy for the treatment of herniated lumbar discs noted a lack of controlled trials comparing this procedure to either continued conservative care or other operative procedures such as open discectomy or microdiscectomy. Since laser discectomy is considered an alternative to open discectomy, the absence of a trial comparing these procedures is noteworthy. The authors stated that controlled trials are important when evaluating pain-relieving treatments to determine the influence of nonspecific effects and regression to the mean on pain-related outcome measures. Considering the natural history of herniated lumbar discs, pain relief may be as likely without invasive treatment as with invasive treatment. A controlled trial is needed to determine the actual extent to which laser discectomy achieves pain relief beyond the natural course of the disorder.

In 2003, the National Institute for Health and Care Excellence (NICE) evaluated the safety and efficacy of endoscopic laser foraminoablation and found the evidence inadequate to support the use of this procedure. Additionally, the NICE guidance stated that further research was needed to evaluate safety and efficacy to reduce uncertainty of this procedure.

**Professional Societies**

**American Society of Interventional Pain Physicians (ASIPP)**

American Society of Interventional Pain Physicians (ASIPP) (Updated 2013) Practice Guidelines for the Management of Chronic Spinal Pain stated that the evidence for percutaneous laser discectomy is moderate for short-term relief and limited for long-term relief.

**North American Spine Society (NASS)**

In their evidence-based guideline, NASS states that percutaneous endoscopic discectomy may be considered as an option for the treatment of lumbar disc herniation and radiculopathy to reduce early postoperative disability and opioid use compared with open discectomy [Grade of Recommendation – B(fair-quality evidence)]. (NASS, 2012)
**Annulus Fibrosus Repair**

A prospective, multicenter, single-blind, randomized, and controlled clinical study by Bailey et al. (2013) compared outcomes associated with repairing the annulus fibrosus after lumbar discectomy for the surgical management of herniated nucleus pulposus. A total of 750 patients were treated for herniated lumbar discs and randomly assigned in a 2:1 ratio to discectomy with the Xclose Tissue Repair System (Anulex Technologies, Minnetonka, MN) for annular repair or discectomy without annular repair. Patient self-reported measures included visual analogue scales for leg and back pain, Oswestry Disability Index, and Short Form-12 Health Survey. Adverse events and subsequent reherniation surgical procedures were documented. Preoperative outcome measures were compared with follow-up visits at 2 weeks, 6 months, 1 year, and 2 years. The authors concluded that without a safe and effective method for closing the annulus fibrosus after discectomy, current practice has been to leave the annulus in a compromised state. This study demonstrated that, while not statistically significant, annular repair may reduce the need for subsequent reherniation surgery while retaining the benefits of discectomy with no increased risk for patients.

Bailey et al. (2013) completed two year follow up evaluation to outcomes associated with repairing annulus fibrosus after lumbar discectomy. The primary outcome measure, reherniation surgery rates at 3 months, 6 months, and 2 years, did not differ statistically between the experimental and control groups. However the difference between the two groups in reoperation for disc reherniation was not seen at two years. Limitations of this study include the use of a post-hoc analysis, the lack of consecutive enrollment of participants at each site because certain individuals did not meet the inclusion/exclusion criteria and declined to participate in the randomized study, and the declining numbers of participants who were available at the two-year follow-up for inclusion in the analysis. The authors concluded that the addition of annulus fibrosus repair did not induce a significant reduction in reoperation for recurrent herniation. Additional randomized controlled studies with participants reporting statistically significant improvement in clinical outcomes and a decrease in overall complication rates are needed to determine the long term safety and efficacy of the Xclose Tissue Repair System in reducing the need for subsequent reherniation surgery after post-discectomy annular repair.

**U.S. FOOD AND DRUG ADMINISTRATION (FDA)**

Percutaneous endoscopic lumbar discectomy (PELD) is a procedure and, therefore, not subject to FDA regulation. However, any medical devices, drugs, biologics, or tests used as a part of this procedure may be subject to FDA regulation. Please see the following website for more information on devices used for PELD (search by product code HRX): [http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm) (Accessed June 14, 2017)

Additional information for marketed devices indicated for closure of the annulus fibrosus can be found under the following product codes:
- Product code: FTL (surgical mesh, polymeric)
- Product code: FTM (mesh, surgical)
- Product code: GAT (suture, nonabsorbable, synthetic, polyethylene)


**REFERENCES**

The foregoing Oxford policy has been adapted from an existing UnitedHealthcare national policy that was researched, developed and approved by UnitedHealthcare Medical Technology Assessment Committee. [2017T0105R]


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