# DISCOGENIC PAIN TREATMENT

**Policy Number:** 2014T0105L
**Effective Date:** September 1, 2014

**Table of Contents** **Page**



**Related Policies:**
Surgical Treatment for Spine Pain

***INSTRUCTIONS FOR USE***

*This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee's document (e.g., Certificate of Coverage (COC) or Summary Plan Description (SPD) and Medicaid State Contracts) may differ greatly from the standard benefit plans upon which this Medical Policy is based. In the event of a conflict, the enrollee's specific benefit document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the enrollee specific plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.*

*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.*

## BENEFIT CONSIDERATIONS

**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 (such as maternity benefits), 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 guideline, it is important to refer to the enrollee's specific plan document to determine benefit coverage.

## COVERAGE RATIONALE

**The following thermal intradiscal procedures (TIPs) and percutaneous discectomy using other methods are unproven and not medically necessary for the treatment of discogenic pain:**

- Intradiscal electrothermal therapy (IDET)
- Intradiscal biacuplasty (IDB)
- Percutaneous intradiscal radiofrequency thermocoagulation (PIRFT)
- Nucleoplasty (percutaneous disc decompression)
- Percutaneous lumbar discectomy (by other method)
- Percutaneous laser disc decompression (PLDD)
- Percutaneous endoscopic diskectomy with or without laser (PELD)
- Yeung Endoscopic Spinal Surgery (YESS)
- Percutaneous intradiscal annuloplasty

The evidence is insufficient to demonstrate short or long-term health benefits. Studies are primarily uncontrolled and limited to small sample size. Larger comparative studies are needed to evaluate the safety and effectiveness of these procedures**.**

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

## APPLICABLE CODES

The Current Procedural Terminology (CPT®) codes and Healthcare Common Procedure Coding System (HCPCS) codes listed in this policy are for reference purposes only. Listing of a service code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the enrollee specific benefit 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 claims payment. Other policies and coverage determination guidelines may apply. This list of codes may not be all inclusive.

| CPT® Code | Description |
|---|---|
| 22526 | Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; single level |
| 22527 | Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; 1 or more additional levels (List separately in addition to code for primary procedure) |
| 62287 | 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 the use of an endoscope, with discography and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar |



| HCPCS Code | Description |
|---|---|
| S2348 | Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, using radiofrequency energy, single or multiple levels, lumbar |

## DESCRIPTION OF SERVICES

Back pain is a frequent cause of chronic pain and disability, affecting approximately 15% of the U.S. population during their lifetime. Most episodes of low back pain improve substantially within a month without formal medical intervention. In a small minority of patients, back pain may be persistent and disabling.

Management of back pain that is persistent and disabling despite the use of recommended conservative treatment is challenging. Numerous diagnostic and therapeutic injections and other interventional and surgical treatments have therefore been proposed for the treatment back pain.

**Percutaneous thermal intradiscal procedures (TIPs)** involve the insertion of a catheter(s)/probe(s) in the spinal disc under fluoroscopic guidance for the purpose of producing or applying heat and/or disruption within the disc to relieve low back pain.

The goals of thermal disc treatments are to remove unwanted tissue such as herniated discs, create a seal to limit expression of matrix components, shrink collagen tissue, and destroy nociceptors.

TIPs are also identified or labeled based on the name of the catheter/probe that is used (e.g., SpineCath, discTRODE, Accutherm, TransDiscal electrodes)

**Examples of electrothermal intradiscal therapies include, (but are not being limited to)** the following:

**Annuloplasty** may be done with any of 3 techniques: intradiscal electrothermal therapy (IDET), intradiscal biacuplasty (IDB), and intradiscal radiofrequency thermocoagulation (IRFT). Percutaneous procedures are performed through stab incisions in the skin using a large bore needle and maybe other devices to expand the opening.

**Intradiscal electrothermal therapy (IDET) or intradiscal electrothermal annulorrhaphy (IEA)**
Degeneration of the intervertebral disc can be the source of severe low back pain. IDET has been proposed as a treatment option for patients with low back pain; symptomatic internal disc disruption that is nonresponsive to conservative medical care.
This is a procedure that uses x-ray imaging (fluoroscopy). This is an outpatient procedure using local anesthesia and mild sedation so the patient is awake and can provide feedback to the physician during the procedure). During the procedure a disposable flexible catheter (SpineCATH) and a heating element is inserted into the spinal disc, directly to the annulus fibrosis, 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 ultimate goal of relieving back pain. This is a minimally invasive procedure that has been proposed as an alternative to spinal fusion for the treatment of chronic discogenic low back pain.

**Intradiscal biacuplasty (IDB) (also referred to as biacuplasty)** is a modification of IDET that destroys the nerve fibers that generate pain sensations. IDB is a minimally invasive procedure that uses radiofrequency energy to heat the tissue while circulating water is used to cool the tissue that is near the disc. The bilateral approach is intended to facilitate controlled lesioning between the electrodes in the disc. This is an outpatient procedure utilizing either sedative or local anesthesia.

**Percutaneous intradiscal radiofrequency thermocoagulation (PIRFT)**, also known as intradiscal electrothermal annuloplasty (IEA), intradiscal radiofrequency thermomodulation, radiofrequency (RF) annuloplasty, or radiofrequency posterior annuloplasty, is a minimally invasive method similar to IDET. One difference, however, 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 degrees 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 disk material to treat symptomatic patients with annular disruption of contained herniated disks. This is an outpatient procedure utilizing either sedative or local anesthesia.

**Nucleoplasty, also known as percutaneous disc decompression (PDD)** or percutaneous plasma discectomy uses x-ray images (fluoroscopy) for guidance to insert a multifunctional device called a SpineWand™ to reach the disc nucleus. Radiofrequency energy is used to ablate (coablate) 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 abasis with minimal anesthesia requirements.

**Laser Discectomy (Percutaneous or Laparoscopic), Laser Disc Decompression/Laser Assisted Disc Decompression (LADD) and Percutaneous endoscopic discectomy:** Laser-assisted discectomy, also called laser-assisted disc decompression (LADD) or laser disc decompression, is a minimally-invasive procedure proposed as an alternative to discectomy/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.

**The Yeung Endoscopic Spinal Surgery (YESS), also known as arthroscopic microdiskectomy or percutaneous endoscopic diskectomy (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 have not been demonstrated in the medical literature. There are no prospective controlled clinical trials of the YESS or PELD, nor are there any prospective studies with long-term follow-up. The efficacy of endoscopic spinal surgery and surgery with the YESS system has not been established in the peer-reviewed medical literature.

**Annulus fibrosis repair systems** 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 fibrosis of the intervertebral disc.

## CLINICAL EVIDENCE

Chou et al. (2009) conducted a systematic review assessing the benefits and harms of nonsurgical interventional therapies for low back and radicular pain and found that there are few nonsurgical interventional therapies for low back pain that have been shown to be effective in randomized, placebo-controlled trials.

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

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.

Helm at 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.

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.

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 electrothermal 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.

Freeman, et al. (2005) reported on 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.

Pauza et al. (2004) reported a randomized, placebo-controlled, prospective trial of IDET (3). Of 64 enrolled patients, 37 were treated by IDET and 27 by sham treatment. Patients in both groups showed improvement; however mean improvements in pain, disability and depression were significantly greater in patients treated with IDET. The investigators are the developers of the technology and they have a financial investment in Oratec, the developer of the device, now owned by Smith & Nephew.

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.

A prospective study by Derby et al. (2000) reported results for 32 patients with back pain for longer than 6 months, who underwent IDET. One-year results were reported on outcome measures of 1) pain relief, using a 10-point VAS scale, and 2) a 24-point Roland and Morris (RM) Disability Questionnaire. Mean decrease in VAS scores was 1.84 and in RM score was 4.03. Seventy-eight percent of patients reported that they would undergo the procedure again, with 53.1% of patients believing their condition was better than before the procedure, 34.4% perceiving no change in condition, and 12.5% believing their condition worse. However, the investigators reported that 62.5% of patients had a favorable outcome, 25% no change, and 12.5%, an unfavorable outcome.

A prospective case series by Lutz et al., (2003) reported results for 33 patients with chronic constant lumbar discogenic pain who have not responded to at least 6 months of aggressive nonoperative care, who underwent IDET. Fifteen months results were reported on outcome measures of 1) pain relief, using the Roland and Morris (RM) Disability Questionnaire, 2) visual analog scale (VAS) pain scores for the back and for the lower extremity, and 3) North American Spine Society Patient Satisfaction Index. Relief of pain and improvement in physical function were associated with a mean change in the VAS score of 3.9, a mean change in the lower-extremity VAS score of 3.7, and a mean change in the RMDQ of 7.3. For patient satisfaction, 75.7% reported that they would undergo the same procedure for the same outcome. Complete pain relief was achieved in 24% of the patients, and partial pain relief in 46% of the patients. The authors concluded that IDET offers a safe, minimally invasive treatment option for carefully selected patients with chronic lumbar discogenic pain who have not responded to aggressive nonoperative care. The study is limited by subjective outcomes with greater than one-forth of the patients reporting no pain relief.

Saal and Saal (2000a) reported the results of 25 consecutive patients with chronic back pain (duration 10 months to 11 years) who were followed at 6 and 12 months post-IDET. The authors reported pre- and post-treatment (minimum, 6 months) means for a 10-point visual analogue pain

scale (VAS), sitting tolerance, physical function (SF-36), and bodily pain scale. Statistically significant changes were reported for all four measures. There was a mean reduction in VAS of 3.74, a mean increase of 15 points on the SF-36, and a mean increase of 14 points on the bodily pain scale. Eighteen of 25 patients reported an improvement in sitting tolerance (from 23.6 minutes pretreatment to 47.2 minutes post-treatment). Weaknesses of the study include the small sample size, that the trial was not blinded or randomized, the short follow-up, and reliance on subjective measures of improvement. In addition, the investigators reported that "co-intervention was kept to a minimum, and consisted of noncreative treatments to which they already had been exposed without success before thermal treatment," but no further description of potentially confounding therapy was provided.

In another study by Saal and Saal (2000b), results of IDET were reported for 62 consecutive patients with chronic low back pain. Again, outcome measures included visual analogue scale (VAS) pain scores, Short Form (SF-36) Health Status Questionnaire Physical Function subscale and SF-36 Bodily Pain subscale scores at baseline and at least one year later. It appears that there is probable overlap in the subjects reported in the series above and in this series of patients, i.e. that the results of the above study are not additional to, but are included in these results. Mean preoperative duration of symptoms was reported as 5 years, and mean follow-up as 16 months. Mean changes in VAS score was 3.0, in SF-36 physical function was 20, and in bodily pain was 17. Twelve (19%) of the patients did not show improvement on any scale. The investigators suggested that while a cohort of patients demonstrated statistically significant and clinically meaningful improvement at one year post-operatively, the results should be validated with "placebo-controlled randomized trials and studies comparing IDET with alternative treatments." This study's design and weaknesses were similar to those described in the earlier study.

Karasek and Bogduk (2004) reported results of a case-controlled study of 53 patients with back pain caused by internal disc disruption. 35 of the patients whose insurance would cover the procedure received IDET, and 17 of the patients who did not have insurance that would cover the procedure were deemed "controls," and received physical therapy, education and counseling. Outcomes evaluated were pain using a 10-point VAS scale, return to work, and use of opioid analgesics. In the control group, at three months, VAS scores were improved in 3, unchanged in 4, and worsened in 9. The remaining measures included reporting of only 15 patients, but the investigators did not explain why 17 three-month VAS scores were reported, but only 15 return-to-work and 16 opioid use scores were obtained. Five patients discontinued opioids, 7 continued to use them, and 4 began use.

In a case series (n=33) by Bryce et al., statistically significant improvement of pain and functional capacity was strongly associated with female gender and age. Males did not retain significant improvement beyond 6 months.

In a study reported by Cohen et al. (2007), nine consecutive patients with discogenic low back pain who obtained excellent pain relief from intradiscal electrothermal therapy were treated with a repeat procedure after the beneficial effects had diminished. Although 4 of 9 patients obtained > or =50% pain relief and were satisfied with the results, both the degree and duration of benefit were less pronounced than after the first procedure. Prospective studies are needed to identify the best candidates for repeat intradiscal electrothermal therapy.

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.

**National Institute for Health and Clinical Excellence (NICE):** NICE evaluated percutaneous intradiscal electrothermal therapy for lower back pain in 2009 and concluded that current evidence on the safety and efficacy of percutaneous intradiscal electrothermal therapy for low back pain is inconsistent. NICE encourages further research which should describe patient selection, use validated measures of long-term pain relief and quality of life, address the role of the procedure in avoiding major surgery, and measure long-term safety outcomes.

**Professional Societies**

**American College of Occupational and Environmental Medicine (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 American Society of Interventional Pain Physicians (ASIPP) Evidence-Based Practice Guidelines in the Management of Chronic Spinal Pain (Manchicanti, et al., 2013) states 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 intra-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 tp 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 can not 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.

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, including the Barendse trial described above, 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.

Barendse et al. (2001) reported on a double-blind trial that randomized 28 patients with chronic low back pain to undergo PIRFT or a sham procedure. The primary outcome was the percentage of success at eight week, as measured by changes in pain level, impairment, Oswestry Disability Scale, and analgesics taken. At the end of the eight weeks, there were two treatment successes in the sham group compared to one in the treatment group. The authors concluded that PIRFT was not better than placebo procedure in reducing pain and disability.

Ercelen et al. (2003) conducted a prospective randomized trial evaluating the efficacy of percutaneous intradiscal radiofrequency thermocoagulation in 39 patients. Patients were randomly selected and divided into two groups. In the first group, treatment was performed for 120 seconds and in the second group for 360 seconds, both at 80C. Evaluations were performed before, immediately after treatment, at 1 and 2 weeks, and at 1, 3, and 6 months after the procedure. There were no statistical differences in pain relief and functional improvement between two groups. The immediate, 1-week and 2- week, and 1-month visual analogue scale (VAS) scores were decreased significantly in both groups when comparing them with the pretreatment scores. However, the final values after 6 months were similar to those measured at the beginning of the study. The authors concluded that percutaneous intradiscal radiofrequency thermocoagulation has been suggested and performed to relieve discogenic pain. In the previous controlled study, no effective pain relief has been obtained. In this study, the authors increased the duration of radiofrequency thermocoagulation to improve the effectiveness of this method. However, the authors have not yet found any significant differences between the application of lesioning at two different times in percutaneous intradiscal radiofrequency thermocoagulation.

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.

**National Institute for Health and Clinical Excellence (NICE):** NICE evaluated the safety and efficacy of percutaneous intradiscal radiofrequency thermocoagulation for lower back pain and concluded that the evidence does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research. (NICE, 2004a)

**Professional Societies**

**American College of Occupational and Environmental Medicine (ACOEM)** practice guidelines on low back disorders, (2007) Updated 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): Interventional Techniques: Evidence-based Practice Guidelines in the Management of Chronic Spinal Pain**

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 (Manchicanti, et al., 2013)** 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**
There are no published randomized controlled trials evaluating nucleoplasty in the medical literature; studies consist primarily of small uncontrolled case series Coblation (ArthroCare Spine, Stockholm, Sweden) technology (Freeman, 2008).

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

Cohen et al., (2003) conducted a nonrandomized controlled trial that evaluated IDET as an adjunct to nucleoplasty for lumbar disc herniations. A total of 7 patients underwent nucleoplasty alone (nucleoplasty group) and 9 patients underwent nucleoplasty combined with IDET (IDET group). Patients were assigned to the IDET group if they had sitting intolerance, degenerative disc disease on MRI, and concurrent axial discogenic pain during provocative discography. At a mean follow-up of 9 months, mean pain scores had decreased from 6.0 2.0 to 4.8 1.8 in the nucleoplasty group and from 7.2 1.8 to 6.3 1.0 in the IDET Group. Using >= 50% pain relief as the definition of clinical success, only 1 (6%) patient had a successful procedure. Due to the poor results obtained, Cohen et al. (2005) recommended that future clinical trials enroll patients who have herniations < 6 mm, annular integrity confirmed by CT discography, and radicular symptoms confirmed by nerve blocks or neurological studies.

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.

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.

Sharps and Isaac (2002) conducted a prospective, single site study that evaluated 49 consecutive patients with complaints of back pain with or without leg pain secondary to a contained focal protrusion. Success was defined as a minimum 2-point reduction on a Visual Analog Scale (VAS), patient satisfaction, absence of narcotic use, and return to work if not working secondary to back pain. The pre-procedure and post- procedure VAS differences were 4.28, 4.66, 4.75, and 3.3 at the one-month, 3- month, 6-month, and 12-month intervals respectively. Overall, there was a 79% success rate, with 67% success in the group of patients that had previous surgery and 82% success in the group that had no prior surgical intervention. The study is limited by mixed diagnoses of study participants and subjective outcomes.

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.

Marin (2005) reported on 64 patients treated with nucleoplasty for discogenic low back and/or leg pain. Improvements in pain scores were recorded in 76% to 83% of patients at all follow-ups to 12 months. The study is limited by small sample size.

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.

A technology assessment by Hayes, Inc. (2007) evaluated evidence that identified 2 nonrandomized controlled trials and 10 uncontrolled case series on nucleoplasty. Results of these studies provide preliminary evidence that nucleoplasty is a safe and effective treatment for patients who have small herniations or protrusions of spinal discs. However, most of this evidence comes from uncontrolled studies and all of the available studies assessed results of nucleoplasty for less than one year after treatment. Therefore, the efficacy of nucleoplasty relative to other treatments for disc disease has not been established and the durability of improvements after nucleoplasty has not been investigated adequately. Further controlled studies with long-term measurement of pain and physical function are needed to establish the efficacy of disc nucleoplasty.

**National Institute for Health and Clinical Excellence (NICE)** evaluated percutaneous disc decompression using coblation for lower back pain in 2006 and concluded that there was some evidence of short-term efficacy; however it was insufficient to support the use of this procedure without special arrangements for consent and for audit or research.

**Professional Societies**

**American College of Occupational and Environmental Medicine (ACOEM)** practice guidelines on low back disorders (Updated 2011), states 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.

**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 (Boswell, 2007).

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**
The number of techniques falling under the rubric of “percutaneous discectomy,” and the variations on each of these techniques are manifold. Furthermore, the terminology used to describe these surgical techniques is equally varied and not fully standardized.

**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 (NICE, 2004). 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)**
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.

Chatterjee et al. (1995) conducted a randomized controlled trial to compare automated percutaneous lumbar discectomy (APLD) with microdiscectomy in 71 patients. In the original study design, the recruitment goal was 160 patients. However, when interim analysis found that results with APLD were inferior to microdiscectomy, further recruitment of subjects to the APLD treatment arm was halted. Of the 31 patients treated with APLD, 9 (29%) had a successful outcome, while 32/40 (80%) patients treated with microdiscectomy had a successful outcome. Grevitt et al. (1995) studied the safety and efficacy of APLD in 115 of 137 patients for whom long-term data was available. Excellent to good results were noted in 45% of this group, although approximately 30% of the patients who were initially rated as successful had deterioration in symptoms and increased disability from back pain at long-term follow-up.

Kotilainen and Valtonen (1994) reported on 2-year follow-up status of 53 patients treated with manual percutaneous discectomy. Both back and leg pain were relieved or markedly diminished in approximately 80% of patients, with the effect seen as largely durable for 2 years. Discitis at the operated disc space was noted in 4% of patients. Mochida et al. (2001) reported the results after long-term follow-up of a group of 42 patients treated with percutaneous nucleotomy. Although 71% of the patients reported relief in the immediate postoperative period, this decreased to 55% after 2 years.

Gronemeyer et al. (2003) provided long-term follow-up on 200 patients with nonsequestered lumbar disc herniation who underwent PLDD. These patients were followed for 4 years, primarily through telephone interviews regarding severity of pain, degree of impairment, use of pain medication, and number of back pain-related sick days, in comparison with presurgical levels. At final follow-up, 73% of patients reported either no pain or a substantial reduction in pain, with 15% reporting no change and 8.5% reporting increased pain. Sensorimotor impairment was also either eliminated or improved in 74% of patients. Approximately half of the patients required some type of pain medication; half of these patients were using levels similar to those required prior to surgery, while half had reduced their consumption. Overall, patient satisfaction was high, 74% of patients were satisfied with the outcome of the therapy, and 81.5% of patients said they would undergo another laser discectomy procedure in the event of another disc herniation. The study is limited by subjective outcomes.

Amoretti et al. (2005) reported on the use of DeKompressor probe for the percutaneous discectomy 10 patients chosen at random. Results were satisfactory with a decrease of the initial VAS by more than 70% and a complete elimination of medical therapy in eight patients. The

authors state their results should be confirmed by a multicentric large series with the criteria of inclusion or exclusion strictly respected.

**Percutaneous Laser Disc Decompression (PLDD)**
An ECRI Health Technology Assessment (Updated 2011) 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 a literature review, Goupille et al. (2007) evaluated the current state of evidence for percutaneous laser disc decompression in treating lumbar disc herniation. The authors noted that the concept of laser disc decompression was based on the percutaneous introduction of an optical fiber into the intervertebral disc. The administered laser energy would allow for the vaporization of portions of the nucleus pulposus, which may reduce intradiscal pressure and relieve radicular pain. The authors note that there is no consensus on the type of laser to use, the wavelength, duration of application, or appropriate energy applied. Study methodology and conclusions are questionable, and no controlled studies were published at the time of the literature review. The authors concluded that while the concept of laser disc decompression is appealing, the treatment cannot be considered effective for disc herniation--associated radiculopathy, refractory to conservative treatment.

Tassi (2004) described the results of PLDD in 92 patients as evaluated with the MacNab criteria with a follow-up range of 5 to 12 months. Good to excellent improvement was achieved in 76 (82.8%), poor improvement was achieved in 16 (17.2%) patients. No complications were observed. The study is limited small sample size and lack of long term follow up.

McMillan et al. (2004) evaluated the short-term efficacy of PLDD in 32 consecutive patients using the standardized symptom score on the American Academy of Orthopedic surgery Outcomes Assessment Questionnaire for neurogenic and back pain. Thirty patients had sciatica at baseline. At 3 months, 24 reported improvement in sciatica symptoms. Thirty-two patients had discogenic pain at baseline, 24 reported improvement at 3 months. The study is limited by small sample size and self-reported outcomes.

Ahn et al. (2004) evaluated posterolateral endoscopic laser-assisted disc excisions in 43 patients. Follow-up was 24 to 39 months with a mean of 31 months. According to the MacNab criteria, 81.4% showed excellent or good outcomes. The mean visual analog scale decreased from 8.72 to 2.58. The study is limited by small sample size and subjective outcomes.

Toyone et al. (2004) reported on 40 consecutive patients. Twenty underwent standard discectomy, 20 underwent microendoscopic discectomy. The mean duration of follow-up was 40 months. No difference was found in the two groups for resolution of leg pain or low back pain. Method of assessment of pain was not reported in the abstract.

A prospective study of 41 patients by Haufe and Mork (2004) evaluated complications associated with cervical endoscopic laser discectomy. Complications included vessel compromise in 2 patients due to the guidewire, 1 episode of discitis, 1 episode of hoarseness potentially related to laryngeal nerve damage, and 2 complaints of a clicking sensation in the neck. The authors concluded that there is the potential for life threatening complications from this procedure.

A retrospective study by Lee et al. (2009) compared percutaneous endoscopic laser diskectomy (n=25 patients) to open lumbar microdiscectomy (OLM) (n=29 patients) for recurrent disc herniation. Clinical outcomes were assessed using Visual Analogue Scale (VAS) score and Oswestry Disability Index (ODI). Radiological variables were assessed using plain radiography and/or magnetic resonance imaging. Mean operating time and hospital stay were significantly shorter in laser group (45.8 minutes and 0.9 day, respectively) than open group (73.8 minutes and 3.8 days, respectively). At a mean follow-up duration of 34.2 months, the laser group had better improvements in back and leg pain, and functional improvement than the open group. Disc height did not change after percutaneous endoscopic laser diskectomy, but significantly decreased after open lumbar microdiscectomy. The authors concluded that both percutaneous endoscopic laser diskectomy and open lumbar microdiscectomy showed favorable outcomes for recurrent disc herniation, but the laser group had advantages in terms of shorter operating time, hospital stay, and disc height preservation. The study is limited by retrospective study design and small number of patients.

Peng et al. (2009) indicated that while percutaneous endoscopic lumbar discectomy (PELD) is a relatively new technique, few studies have reported the clinical outcome of PELD regarding quality of life and return to work. In a retrospective study of 55 subjects, clinical outcomes were reviewed using the North American Spine Score (NASS), Medical Outcomes Study Short Form-36 scores (SF-36), the Visual Analogue Scale (VAS) and return to work. The treatment sites varied as well as the disc status. Thirty nine (70.9%) subjects had L4-L5 discectomy, 12 (21.8%) had L5-S1 discectomy, 2 (3.6%) had L3-L4 and 2 (3.6%) had two levels L4-L5 and L5-S1 performed. There were 44 (80%) disc protrusions, 10 (18.2%) extrusions and 1 (1.8%) sequestrated disc. The mean follow-up period was 3.4 years (range 2.0 – 6.5 years). All who were working preoperatively returned to work. The mean time to return to work was 24.3 days (range 10 – 60 days). Back pain and lower limb symptoms were reduced NASS and VAS, (p less than 0.05) at 6 months and 2 years. There were improvements in Quality of Life (SF-36, p less than 0.05) scores except for general health at 6 months and 2 years post surgery. The recurrence rate was 5% or 3 subjects who subsequently underwent lumbar fusion for persistent back pain. The limitations of this study were that it was retrospective, uncontrolled and limited in size.

The National Institute for Health and Clinical Excellence (NICE) evaluated the safety and efficacy of percutaneous endoscopic laser lumbar and cervical discectomy in 2009 and found the current evidence inadequate to conclude that this is a safe and effective treatment.

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.

In 2003, the National Institute for Health and Clinical Excellence (NICE) evaluated the safety and efficacy of endoscopic laser foraminoplasty 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.

The Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (2000) found that there is insufficient evidence surrounding the use of percutaneous endoscopic laser discectomy to draw any conclusions about the safety or effectiveness of this procedure.

There is insufficient evidence in the published medical literature to demonstrate the safety, efficacy and long-term outcome of laser discectomy. There are no randomized controlled trials that evaluate laser discectomy and compare this procedure to established treatment methods.

**Annulus Fibrosis Repair**

Hayes (2013) reported there is insufficient published evidence to assess the safety and/or impact on health outcomes or patient management of the Xclose Plus Tissue Repair System for repair of the annulus fibrosus.

A prospective, multicenter, single-blind, randomized, controlled clinical study by Bailey (2013) et.al. compared outcomes associated with repairing the anulus 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 anulus fibrosus after discectomy, current practice has been to leave the anulus 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.

In a narrative review, Bron and colleagues (20089) observed that lumbar discectomy is an effective therapy for neurological decompression due to herniated disc. However, there are high recurrence rates of reherniation and persisting post-operative low back pain. The author's conclusion proposes that development of techniques that deal with the damaged annulus fibrosus, such as tissue engineering and annulus repair are needed in order to prevent re-herniation.

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

The SpineCATH™ Intradiscal Catheter and the SpineCATH™ Intradiscal Catheter, Model 92002 received FDA 510(k) clearance (product code GEI) for marketing in the US in 1998 and 1999.

There were two 510(k) approvals for the SpineWand device. There are additional approvals for the Controller (radiofrequency electrosurgical generator); these listings are available from the Center for Devices and Radiological Health 510(k):

- PercD Spinewand. Arthrocare Corporation. [Decision date 04/16/03]
- PercD Spinewand. Arthrocare Corporation. [Decision date 05/31/01]

The ArthroCare System 2000 (K001588) received 510(k) approval on August 17, 2000. It is a bipolar, high-frequency electrosurgical system that has three components: an electrosurgical generator (Controller), disposable, single use Wand, and a reusable cable. The ArthroCare 8000S Coblator Surgery System received a special 510(k) approval on December 6, 2005. The Perc™ received 510(k) approval (K010811) on May 30, 2001 for ablation, coagulation, and decompression of diFsc material to treat symptomatic patients with contained herniated discs.

Three subsequent 510(k) approvals (K020621, K030954, and K053447) were issued for the

ArthroCare® Perc-D® SpineWand™ on March 28, 2002, April 16, 2003, and December 27 2005, respectively, noting modifications in dimensional and performance specifications, materials, and labeling for the device. Indications for both approvals for use, technology, principle of operation, packaging, and sterilization parameters of the wands were unchanged from those of the predicate device. The ArthroCare System 2000 received CE marking. Endoscopes, catheters, and needles that can be used for epidural lysis of adhesions are regulated by the FDA as Class II devices and a number of these devices have been approved via the FDA 510(k) process. The Racz Catheter received FDA approval on October 8, 1996 (K954584). The Myelotec Myeloscope received 510(k) approval on September 4, 1996 (K960194).

Other examples include the PercScope, Yeung Endoscopic Spine System, and The Spine Endoscope, discTRODE, Accutherm and TransDiscal electrodes.

Additional information, under product codes GEI, HRX, BSO and BSP, is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. Accessed May 29, 2014

The Radionics RF Disc Catheter Electrode System received FDA 510(k) clearance in October 2000. See the following Web site for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf/K001741.pdf. Accessed May 29, 2014

There are 3 commercially marketed devices indicated for closure of the annulus fibrosis:

- The Inclose Surgical Mesh System (Anulex Technologies, Inc., Minnetonka,
- MN) received FDA 510(k) clearance on August 18, 2005 and is proposed as an alternative procedure for annular repair following discectomy to re-approximate the compromised tissue of the annulus fibrosus. The device is comprised of a mesh implant and two suture assemblies referred to as anchor bands. The surgical mesh implant is comprised of polyethylene terephthalate (PET) monofilament expandable braided material that is preloaded on a disposable delivery tool inserted through the aperture of the tissue defect and affixed to surrounding soft tissue with the anchor bands. To date, no evidence was found in the peer-reviewed medical literature evaluating the efficacy and safety of the Inclose Surgical Mesh System for any indication. Additional information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf5/K050969.pdf. Accessed May 20, 2014
- Anchor Band Suturing System, Model SR-AB (Anulex Technologies, Inc., Minnetonka,
- MN) received FDA 510(k) clearance on July 2006. Additional information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf6/K061386.pdf. Accessed May 20, 2014.
- The Xclose Tissue Repair System (Anulex Technologies, Inc., Minnetonka, MN) received U.S. Food and Drug Administration (FDA) 510(k) clearance on August 7, 2006. The FDA labeled indications state the system is used for soft tissue approximation in general and orthopedic surgery procedures. The Xclose Tissue Repair System (modified sutures with anchors) was subsequently proposed for re-approximation of the annulus fibrosus after a lumbar discectomy procedure. In February 2011, the FDA required the manufacturer submit a premarket approval application (PMA) supported by clinical data from an investigational device exemption (IDE) study for this application. The FDA considered the annulus fibrosus repair indication to be investigational and outside the scope of Anulex Technologies, Inc. 510(k) clearance for the Xclose Tissue Repair System as described in an ongoing clinical trial evaluating use of the device for repair of the annulus fibrosus after discectomy. Additional information available at: http://www.accessdata.fda.gov/cdrh_docs/pdf6/K062307.pdf Accessed May 20, 2014

## CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does not cover Thermal Intradiscal Procedures (TIPs). Effective for services performed on or after September 29, 2008, CMS has determined that Thermal Intradiscal Procedures (TIPs)

are not reasonable and necessary for the treatment of low back pain. Refer to the National Coverage Determination (NCD) for Thermal Intradiscal Procedures (TIPS) (150.11). Local Coverage Determinations (LCDs) for TIPs do not exist at this time.

Medicare does not have a National Coverage Determination (NCD) for percutaneous discectomy procedures including: Intradiscal electrothermal therapy (IDET), Intradiscal biacuplasty (IDB), Percutaneous intradiscal radiofrequency thermocoagulation (PIRFT), Nucleoplasty (percutaneous disc decompression), Percutaneous lumbar discectomy (by other method), Percutaneous laser disc decompression (PLDD), Percutaneous endoscopic diskectomy with or without laser (PELD), Yeung Endoscopic Spinal Surgery (YESS) and Percutaneous intradiscal annuloplasty. Local Coverage Determinations (LCDs) for do not exist at this time.

Medicare does not have a NCD for annulus fibrosis repair following spinal surgery. Local Coverage Determinations (LCDs) do not exist at this time.

(Accessed June 3, 2014)

## REFERENCES


Ahn Y, Lee SH, Park WM, et al. Percutaneous endoscopic lumbar discectomy for recurrent disc herniation: surgical technique, outcome, and prognostic factors of 43 consecutive cases. Spine. 2004 Aug 15;29(16):E326-32.

Alexandre A, Coro L, Azuelos A, et al. Percutaneous nucleoplasty for discoradicular conflict. Acta Neurochir Suppl. 2005;92:83-86.

American College of Occupational and Environmental Medicine. Occupational medicine practice guidelines: evaluation and management of common health problems and functional recovery of workers, low back disorders. 2nd ed. Glass L, editor. Beverly Farms, MA: OEM Press Updated 2011.

Amoretti N, Huchot F, Flory P, et al. Percutaneous nucleotomy: preliminary communication on a decompression probe (Dekompressor) in percutaneous discectomy. Ten case reports. Clin Imaging. 2005 Mar-Apr;29(2):98-101.

Appleby D, Andersson G, Totta M. Meta-analysis of the efficacy and safety of intradiscal electrothermal therapy (IDET). Pain Med. 2006 Jul-Aug;7(4):308-16.

Australian Safety and Efficacy of New Interventional Procedures – Surgical (ASERNIP-S). Barendse GA, van Den Berg SG, Kessels AH, et al. Randomized controlled trial of percutaneous intradiscal radiofrequency thermocoagulation for chronic discogenic back pain: lack of effect from a 90-second 70 C lesion. Spine. 2001 Feb 1;26(3):287-92.

Bailey A, Araghi A, Blumenthal S, et.al. Anular Repair Clinical Study Group.
Spine (Phila Pa 1976). 2013 Jun 15;38(14):1161-9

Bailey A, Araghi A, Blumenthal S, Huffmon GV. Prospective, multicenter, randomized, controlled study of anular repair in lumbar discectomy: two-year follow-up. Spine (Phila Pa 1976). 2013; 38(14):1161-1169.

Bhagia SM, Slipman W, Nirschl M, et al. Side effects and complications after percutaneous disc decompression using coblation technology. Am J Phys Med Rehabil. 2006;85(1):6-13.

Boswell MV, Trescot AM, Datta S, et al. American Society of Interventional Pain Physicians. Interventional techniques: evidence-based practice guidelines in the management of chronic spinal pain. 2007 Mar;10(2):381.

Bron JL, Helder MN, Meisel HJ, et al. Repair, regenerative and supportive therapies of the annulus fibrosus: achievements and challenges. Eur Spine J. 2009;18(3):301-313.

Chatterjee S, Foy PM, Findlay GF. Report of a controlled clinical trial comparing automated percutaneous lumbar discectomy and microdiscectomy in the treatment of contained lumbar disc herniation. Spine. 1995;20(6):734-738.

Chou R, Atlas SJ, Stanos SP, et al. Nonsurgical interventional therapies for low back pain: a review of the evidence for an American Pain Society clinical practice guideline. Spine (Phila Pa 1976). 2009 May 1;34(10):1078-93.

Cohen SP, Shockey SM, Carragee EJ. The efficacy of repeat intradiscal electrothermal therapy. Anesth Analg. 2007 Aug;105(2):495-8.

Cohen S, et al. Nucleoplasty in the treatment of lumbar herniated disk: A pilot study. Reg Anesth Pain Med. 2003; 28.

Derby R, Eek B, Chen Y, et al., Intradiscal electrothermal annuloplasty (IDET): a novel approach for treating chronic discogenic back pain. Neuromodulation. 2000:3(2): 82-88. In: ECRI Technology Assessment - Target report #767. Intradiscal electrothermal therapy for discogenic pain**.** (Updated 2009).

ECRI Institute. Hotline Report. Surgical Devices for Anulus Fibrosus Repair after Spinal Surgery. April 2009.

ECRI Institute. Laser discectomy for the treatment of herniated lumbar discs. Plymouth Meeting (PA); ECRI institute Health Technology Assessment information Service; 2011 Mar 8. Available at URL address: http://www.ecri.org

Ercelen O, Bulutcu E, Oktenoglu T, et al. Radiofrequency lesioning using two different time modalities for the treatment of lumbar discogenic pain: a randomized trial. Spine. 2003 Sep 1;28(17):1922-7.

Finch PM, Price LM, Drummond PD. Radiofrequency heating of painful annular disruptions: one-year outcomes. J Spinal Disord Tech 2005; 18:6-13.

Freeman, B. J., Fraser, Robert D. et al., A Randomized, Double-Blind, Controlled Trial: Intradiscal Electrothermal Therapy versus Placebo for the Treatment of Chronic Discogenic Low Back Pain. Spine. November 2005; v30 (21):2369-2377.

Freeman BJ, Mehdian R. Intradiscal electrothermal therapy, percutaneous discectomy, and nucleoplasty: what is the current evidence? Curr Pain Headache Rep. 2008 Jan;12(1):14-21.

Gibson JNA, Grant IC, Waddell G. Surgery for lumbar disc prolapse. Cochrane Database Syst Rev. 2006;(2):CD001350.

Goupille P, Mulleman D, Mammou S, et al. Percutaneous laser disc decompression for the treatment of lumbar disc herniation: a review. Semin Arthritis Rheum. 2007;37(1):20-30.

Grevitt MP, McLaren A, Shackleford IM, Mulholland RC. Automated percutaneous lumbar discectomy. An outcome study. J Bone Joint Surg Br. 1995;77(4):626-629.

Gronemeyer DH, Buschkamp H, Braun M, et al. Image-guided percutaneous laser disk decompression for herniated lumbar disks: a 4-year follow-up in 200 patients. J Clin Laser Med

Surg. 2003;21(3):131-138.

Haufe SM, Mork AR. Complications associated with cervical endoscopic discectomy with the holmium laser. J Clin Laser Med Surg. 2004;22(1):57-58

Hayes, Inc. Health Technology Brief. Arthroscopic Microdiscectomy for Lumbar Disc Herniation. Lansdale, PA: Hayes, Inc.; June 2007. Updated June 2009.

Hayes, Inc. Health Technology Brief. Endoscopic Laser-Assisted Discectomy for Cervical Disc Herniation. Lansdale, PA: Hayes, Inc.; February 2009. Last updated February 2010.

Hayes, Inc. Medical Technology Directory. Intradiscal Electrothermal Therapy (IDET). Lansdale, PA: Hayes, Inc.; February 2010. Updated January 30, 2013

Hayes, Inc. Health Technology Brief. Disc Nucleoplasty (ArthroCare-D SpineWand) for Percutaneous Disc Decompression. Lansdale, PA: Hayes, Inc.; December 2007. Last updated December 2009.

Hayes Inc. Technology Brief. Percutaneous Sacroplasty for Treatment of Sacral Insufficiency Fractures. Lansdale, PA: Hayes, Inc.; May 2009a.

Hayes Inc. Technology Brief. Xclose Plus Tissue Repair System (Anulex Technologies, Inc.) for Repair of the Annulus Fibrosus Lansdale, PA: Hayes, Inc.; June 2013.

Helm Ii S, Deer TR, Manchikanti L, et al. Effectiveness of thermal annular procedures in treating discogenic low back pain. Pain Physician. 2012; 15(3):E279-304.

Helm S, Hayek SM, Benyamin RM, et al. Systematic review of the effectiveness of thermal annular procedures in treating discogenic low back pain. Pain Physician. 2009 Jan-Feb;12(1):207-32.

Hirsch JA, Singh V, Falco FJ, et al. Automated percutaneous lumbar discectomy for the contained herniated lumbar disc: a systematic assessment of evidence. Pain Physician. 2009 May-Jun; 12(3):601-20.

Kapural L, Hayek S. Malak O, et al. Intradiscal thermal annuloplasty versus intradiscal radiofrequency ablation for the treatment of discogenic pain: a prospective matched control trial. Pain Med. 2005; 6(6):425-31.

Kapural L, Mekhail N. Novel intradiscal biacuplasty (IDB) for the treatment of lumbar discogenic pain. Pain Pract. 2007; 7(2):130-134.

Karasek M, Bogduk N. Twelve-month follow-up of a controlled trial of intradiscal thermal anuloplasty for back pain due to internal disc disruption. Spine. 2000(Nov.) ;25(20): 2601-2607.

Kotilainen E, Valtonen S. Percutaneous nucleotomy in the treatment of lumbar disc herniation results after a mean follow-up of 2 years. Acta Neurochir (Wien). 1994;128(1-4):47-52.

Kvarstein G, Måwe L, Indahl A, et al. A randomized double-blind controlled trial of intra-annular radiofrequency thermal disc therapy -- a 12-month follow-up. Pain. 2009; 145(3):279-286.

Lee DY, Shim CS, Ahn Y, et al. Comparison of Percutaneous Endoscopic Lumbar Discectomy and Open Lumbar Microdiscectomy for Recurrent Disc Herniation. J Korean Neurosurg Soc 46 : 515-521, 2009.

Lutz C, Lutz GE, and Cooke PM. Treatment of chronic lumbar diskogenic pain with intradiskal

electrothermal therapy: A prospective outcome study. Arch Phys Med Rehabil. 2003(Jan.); 84(1):23-8.

Manchikanti L, Abdi S, Atluri S,Benyamin RM,Bowell MV,Buenaventura RM, et al. An update of comprehensive evidence-based guidelines for interventional techniques in chronic sp inal pain. Part ll: guidance and recommendations. PainPhysiucian. 2013 Apr; 16(2Suppl):S49-283

Manchikanti L, Datta S, Gupta S, Munglani R, Bryce DA, Ward SP, Benyamin RM, Sharma ML, Helm S 2nd, Fellows B, Hirsch JA. A critical review of the American Pain Society clinical practice guidelines for interventional techniques: part 2. Therapeutic interventions. Pain Physician. 2010 Jul-Aug; 13(4):E215-64. Review

Marin FZ. CAM versus nucleoplasty. Acta Neurochir Suppl. 2005;92:111-114.

Masala S, Massari F, Fabiano S, et al. Nucleoplasty in the treatment of lumbar diskogenic back pain: one year follow-up. Cardiovasc Intervent Radiol. 2007;30(3):426-432.

McMillan MR, Patterson PA, Parker V. Percutaneous laser disc decompression for the treatment of discogenic lumbar pain and sciatica: a preliminary report with 3-month follow-up in a general pain clinic population. Photomed Laser Surg. 2004 Oct;22(5):434-8.

Mirzai H, Tekin I, Yaman O, et al. The results of nucleoplasty in patients with lumbar herniated disc: a prospective clinical study of 52 consecutive patients. Spine J. 2007;7(1):88-93.

Mochida J, Toh E, Nomura T, et al. The risks and benefits of percutaneous nucleotomy for lumbar disc herniation. A 10-year longitudinal study. J Bone Joint Surg Br. 2001;83(4):501-505.

Nardi PV, Cabezas D, Cesaroni A. Percutaneous cervical nucleoplasty using coblation technology. Clinical results in fifty consecutive cases. Acta Neurochir Suppl. 2005;92:73-78.

National Institute for Clinical Excellence (NICE). Interventional Procedures Percutaneous intradiscal thermocoagulation for lower back pain. London, UK: NICE; August 2004a. Available at: http://www.nice.org.uk/guidance/IPG83 Accessed. May 20, 2014.

National Institute for Health and Clinical Excellence (NICE). Percutaneous disc decompression using coblation for lower back pain. Interventional Procedures Consultation Document. London, UK: NICE; 24 May 2004b. Available at: http://www.nice.org.uk/guidance/IPG173 Accessed May 20, 2014.

National Institute for Health and Clinical Excellence (NICE). Percutaneous intradiscal electrothermal therapy for lower back pain. London, UK: NICE; November 2009. Available at: http://www.nice.org.uk/guidance/IPG319 . Accessed May 20, 2014.

National Institute for Clinical Excellence (NICE). Percutaneous endoscopic laser lumbar discectomy. London, UK: NICE; May 2009. Available at: http://www.nice.org.uk/nicemedia/pdf/IPG300Guidance.pdf. Accessed May 20, 2014.

National Institute for Clinical Excellence (NICE). Percutaneous endoscopic laser cervical discectomy. London, UK: NICE; June 2009. Available at: http://www.nice.org.uk/nicemedia/pdf/IPG303Guidance.pdf. Accessed May 20, 2014.
National Institute for Clinical Excellence (NICE). Endoscopic laser foraminoplasty. London, UK: NICE; December 2003. Available at: http://www.nice.org.uk/guidance/IPG31 . Accessed May 20, 2014.

Ogbonnaya S, Kaliaperumal C, Qassim A, O'Sullivan M. Outcome of nucleoplasty in patients with radicular pain due to lumbar intervertebral disc herniation. J Nat Sci Biol Med. 2013;4(1):187-190.

Pauza KJ, Howell S, Dreyfuss P, et al. A randomized, placebo-controlled trial of intradiscal electrothermal therapy for the treatment of discogenic low back pain. Spine J. 2004 Jan-Feb; 4(1):27-35.

Peng C, Yeo W, Tan S. Percutaneous endoscopic lumbar discectomy: clinical and quality of life outcomes with a minimum 2 year follow-up. J Orthop Surg Res. 2009; v4 (20).

Saal J, Saal J. Intradiscal electrothermal treatment for chronic discogenic low back pain: a prospective study with minimum one-year follow-up. Spine. 2000b(Nov.);25(20): 2622-2627.

Saal J, Saal J. Management of chronic discogenic low back pain with a thermal intradiscal catheter. Spine. 2000a(Feb.);25(3): 382-388.

Sharps L and Isaac Z. Percutaneous disc decompression using nucleoplasty. Pain Physician. 2002;5(2):121-126.

Tassi GP. Preliminary Italian experience of lumbar spine percutaneous laser disc decompression according to Choy's method. Photomed Laser Surg. 2004 Oct;22(5):439-41.

Toyone T, Tanaka T, Kato D, et al. Low-back pain following surgery for lumbar disc herniation. A prospective study. J Bone Joint Surg Am. 2004 May;86-A(5):893-6.
Tsou HK, Chao SC, Kao TH, et al. Intradiscal electrothermal therapy in the treatment of chronic low back pain: Experience with 93 patients. Surg Neurol Int. 2010 Aug 4;1 (37).

Urrutia G, Kovacs F, Nishishinya MB, et al. Percutaneous thermocoagulation intradiscal techniques for discogenic low back pain. Spine. 2007 May 1;32(10):1146-54.

Whitlow CT, Mussat-Whitlow BJ, Mattern CW, et al. Sacroplasty versus vertebroplasty: comparable clinical outcomes for the treatment of fracture-related pain. AJNR Am J Neuroradiol. 2007;28(7):1266-1270.

Yeung AT, Porter J. Minimally invasive endoscopic surgery for the treatment of discogenic pain. In: Pain Management: A Practical Guide for Clinicians. 6th ed. RS Weiner, ed. Boca Raton, FL: CRC Press; 2002; Ch. 87:1073-1078.

Zhu H, Zhou XZ, Cheng MH, et al. The efficacy of coblation nucleoplasty for protrusion of lumbar intervertebral disc at a two-year follow-up. Int Orthop. 2011 Jan 15.

## POLICY HISTORY/REVISION INFORMATION

| Date | Action/Description |
|---|---|
| 09/01/2014 | • Reorganized policy content<br>• Added benefit considerations language for *Essential Health Benefits for Individual and Small Group plans* to indicate:<br>o 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")<br>o 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 (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non- |

| Date | Action/Description |
|---|---|
| | Grandfathered plans<br>o The determination of which benefits constitute EHBs is made on a state by state basis; as such, when using this guideline, it is important to refer to the enrollee's specific plan document to determine benefit coverage<br>• Updated coverage rationale:<br>o Added language to indicate the unproven services are "not medically necessary"<br>o Removed reference to specific product names used for annulus fibrosis repair<br>• Updated supporting information to reflect the most current clinical evidence, FDA and CMS information, and references<br>• Archived previous policy version 2013T0105K |