

# Protocol

## Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, and Biacuplasty

(70172)

<b>Medical Benefit</b>		<b>Effective Date:</b> 04/01/09	<b>Next Review Date:</b> 09/19
<b>Preauthorization</b>	No	<b>Review Dates:</b> 02/07, 02/08, 01/09, 01/10, 01/11, 09/11, 09/12, 09/13, 09/14, 09/15, 09/16, 09/17, 09/18	

***This protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.***

*The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"><li>• Discogenic back pain</li></ul>	Interventions of interest are: <ul style="list-style-type: none"><li>• Intradiscal electrothermal annuloplasty</li></ul>	Comparators of interest are: <ul style="list-style-type: none"><li>• Conservative management</li><li>• Surgical spinal decompression</li></ul>	Relevant outcomes include: <ul style="list-style-type: none"><li>• Symptoms</li><li>• Functional outcomes</li><li>• Quality of life</li><li>• Treatment-related morbidity</li></ul>
Individuals: <ul style="list-style-type: none"><li>• Discogenic back pain</li></ul>	Interventions of interest are: <ul style="list-style-type: none"><li>• Intradiscal radiofrequency annuloplasty</li></ul>	Comparators of interest are: <ul style="list-style-type: none"><li>• Conservative management</li><li>• Surgical spinal decompression</li></ul>	Relevant outcomes include: <ul style="list-style-type: none"><li>• Symptoms</li><li>• Functional outcomes</li><li>• Quality of life</li><li>• Treatment-related morbidity</li></ul>
Individuals: <ul style="list-style-type: none"><li>• Discogenic back pain</li></ul>	Interventions of interest are: <ul style="list-style-type: none"><li>• Intradiscal biacuplasty</li></ul>	Comparators of interest are: <ul style="list-style-type: none"><li>• Conservative management</li><li>• Surgical spinal decompression</li></ul>	Relevant outcomes include: <ul style="list-style-type: none"><li>• Symptoms</li><li>• Functional outcomes</li><li>• Quality of life</li><li>• Treatment-related morbidity</li></ul>

### DESCRIPTION

Electrothermal intradiscal annuloplasty therapies use radiofrequency energy sources to treat discogenic low back pain arising from annular tears. These annuloplasty techniques are designed to decrease pain arising from the annulus by thermocoagulating nerves in the disc and tightening of annular tissue.

### SUMMARY OF EVIDENCE

For individuals who have discogenic back pain who receive intradiscal thermal annuloplasty, radiofrequency annuloplasty, or biacuplasty, the evidence includes a small number of randomized controlled trials (RCTs). Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Two RCTs on intradiscal electrothermal annuloplasty have reported conflicting results, with one reporting benefit for intradiscal electrothermal annuloplasty and the other reporting no benefit. There is a lack of evidence to support a

role for radiofrequency annuloplasty with either a single or a double (biacuplasty) probe. One sham-controlled RCT assessing biacuplasty has suggested that this procedure may provide modest benefit to highly select patients; confirmation of these results in a broader population is needed. Further study in a sham-controlled trial with a representative population of patients is needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

## POLICY

Percutaneous annuloplasty (e.g., intradiscal electrothermal annuloplasty, intradiscal radiofrequency annuloplasty, or intradiscal biacuplasty) for the treatment of chronic discogenic back pain is considered **investigational**.

## BACKGROUND

### DISCOGENIC LOW BACK PAIN

Discogenic low back pain is a common, multifactorial pain syndrome that involves low back pain without radicular symptoms findings, in conjunction with radiologically confirmed degenerative disc disease.

#### Treatment

Typical treatment includes conservative therapy with physical therapy and medication management, with potential for surgical decompression in more severe cases.

A number of electrothermal intradiscal procedures have been introduced to treat discogenic low back pain; they rely on various probe designs to introduce radiofrequency (RF) energy into the disc. It has been proposed that heat-induced denaturation of collagen fibers in the annular lamellae may stabilize the disc and potentially seal annular fissures and that pain reduction may occur through the thermal coagulation of nociceptors in the outer annulus.

Some electrothermal intradiscal procedures are briefly described next.

With the intradiscal electrothermal annuloplasty procedure, a navigable catheter with an embedded thermal resistive coil is inserted posterolaterally into the disc annulus or nucleus. Using indirect RF energy, electrothermal heat is generated within the thermal resistive coil at a temperature of 90° C; the disc material is heated for up to 20 minutes. Proposed advantages of indirect electrothermal delivery of RF energy with intradiscal electrothermal annuloplasty include precise temperature feedback and control, and the ability to provide electrothermocoagulation to a broader tissue segment than would be allowed with a direct RF needle.

Percutaneous intradiscal radiofrequency thermocoagulation uses direct application of RF energy. With percutaneous intradiscal radiofrequency thermocoagulation, the RF probe is placed into the center of the disc, and the device is activated for only 90 seconds at a temperature of 70° C. The procedure is not designed to coagulate, burn, or ablate tissue. The Radionics RF Disc Catheter System has been specifically designed for this purpose.

Intradiscal biacuplasty uses two cooled RF electrodes placed on the posterolateral sides of the intervertebral annulus fibrosus. It is believed that, by cooling the probes, a larger area may be treated than could occur with a regular needle probe.

Annuloplasty using a laser-assisted spinal endoscopy kit to coagulate the disc granulation tissue (percutaneous endoscopic laser annuloplasty) has also been described.

## REGULATORY STATUS

A variety of RF coagulation devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA), some of which are designed for disc nucleotomy. In 2002, the Oratec Nucleotomy Catheter (ORATEC Interventions, Menlo Park, CA, acquired by Smith & Nephew in 2002) was cleared for marketing by FDA through the 510(k) process. The predicate device was the SpineCATH® Intradiscal Catheter, which received FDA clearance for marketing in 1999. The Radionics (a division of Tyco Healthcare group) RF (Radiofrequency) Disc Catheter System received marketing clearance by FDA through the 510(k) process in 2000. FDA product code: GEI.

In 2005, the Baylis Pain Management Cooled Probe was also cleared for marketing by FDA through the 510(k) process. It is intended for use "in conjunction with the Radio Frequency Generator to create radiofrequency lesions in nervous tissue." FDA product code: GXI.

**Note:** This protocol does not address disc nucleoplasty, a technique based on the bipolar RF device (Coblation®; ArthroCare, Austin, TX, acquired by Smith & Nephew, 2014). With the coblation system, a bipolar RF device is used to provide lower energy treatment to the intervertebral disc, which is designed to provide tissue removal with minimal thermal damage to collateral tissue. Disc nucleoplasty is closer in concept to a laser discectomy in that tissue is removed or ablated to provide decompression of a bulging disc. Disc nucleoplasty and laser discectomy are considered in the Decompression of the Intervertebral Disc Using Laser Energy (Laser Discectomy) or Radiofrequency Coblation (Nucleoplasty) Protocol.

## RELATED PROTOCOLS

Automated Percutaneous and Percutaneous Endoscopic Discectomy

Decompression of Intervertebral Discs Using Laser Energy (Laser Discectomy) or Radiofrequency Coblation (Nucleoplasty)

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Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

## REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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