

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Procedure Name: **Percutaneous electrothermal therapy of the intervertebral disc annulus for lower back pain and sciatica (73/3)**

Name of Specialist Advisor: **Alastair Littlewood**

Specialist Society: **British Society of Interventional Radiologists**

Please complete and return to: [azeem.madari@nice.org.uk](mailto:azeem.madari@nice.org.uk) OR [sally.compton@nice.org.uk](mailto:sally.compton@nice.org.uk)

**1 Do you have adequate knowledge of this procedure to provide advice?**

Yes.

No – please return the form/answer no more questions.

**1.1 Does the title used above describe the procedure adequately?**

Yes.

No. If no, please enter any other titles below.

**Comments:**

**2 Your involvement in the procedure**

**2.1 Is this procedure relevant to your specialty?**

Yes.

Is there any kind of inter-specialty controversy over the procedure?

No. If no, then answer no more questions, but please give any information you can about who is likely to be doing the procedure.

**Comments:**

**The next two questions are about whether you carry out the procedure, or refer patients for it. If you are in a specialty that normally carries out the procedure please answer question 2.2.1. If you are in a specialty that normally selects or refers patients for the procedure please answer question 2.2.2.**

**2.2.1 If you are in a specialty which does this procedure, please indicate your experience with it:**

- I have never performed this procedure.
- I have performed this procedure at least once.
- I perform this procedure regularly.

**Comments:**

**2.2.2 If your specialty is involved in patient selection or referral to another specialty for this procedure, please indicate your experience with it.**

- I have never taken part in the selection or referral of a patient for this procedure.
- I have taken part in patient selection or referred a patient for this procedure at least once.
- I take part in patient selection or refer patients for this procedure regularly.

**Comments:**

**2.3 Please indicate your research experience relating to this procedure (please choose one or more if relevant):**

- I have undertaken bibliographic research on this procedure.
- I have undertaken research on this procedure in laboratory settings (e.g. device-related research).
- I have undertaken clinical research on this procedure involving patients or healthy volunteers.
- I have had no involvement in research on this procedure.
- Other (please comment)

**Comments:**

### 3 Status of the procedure

#### 3.1 Which of the following best describes the procedure (choose one):

- Established practice and no longer new.
- A minor variation on an existing procedure, which is unlikely to alter that procedure's safety and efficacy.
- Definitely novel and of uncertain safety and efficacy.
- The first in a new class of procedure.

#### Comments:

Reports and case series available from 2000 onwards

#### 3.2 What would be the comparator (standard practice) to this procedure?

Either no intervention, injection or possible definitive spinal fusion

#### 3.3 Please estimate the proportion of doctors in your specialty who are performing this procedure (choose one):

- More than 50% of specialists engaged in this area of work.
- 10% to 50% of specialists engaged in this area of work.
- Fewer than 10% of specialists engaged in this area of work.
- Cannot give an estimate.

#### Comments:

### 4 Safety and efficacy

#### 4.1 What are the adverse effects of the procedure?

Please list adverse events and major risks (even if uncommon) and, if possible, estimate their incidence, as follows:

##### 1. Theoretical adverse events

Infection of disc

Damage to surrounding structures including spinal cord

2. Anecdotal adverse events (known from experience)

Nil

3. Adverse events reported in the literature (if possible please cite literature)

**4.2 What are the key efficacy outcomes for this procedure?**

VAS and functional outcome scores

**4.3 Are there uncertainties or concerns about the *efficacy* of this procedure? If so, what are they?**

Yes, If the procedure actually works 2 small RCTS and a few case series. Probable short term benefit ? on long term outcomes

**4.4 What training and facilities are required to undertake this procedure safely?**

Need practical experience, Require equipment but no more facilities required than when performing a discogram

**4.5 Are there any major trials or registries of this procedure currently in progress? If so, please list.**

Not that I am aware of

**4.6 Are you aware of any abstracts that have been *recently* presented/ published on this procedure that may not be listed in a standard literature search, e.g. PUBMED? (This can include your own work). If yes, please list.**

No

**4.7 Is there controversy, or important uncertainty, about any aspect of the way in which this procedure is currently being done or disseminated?**

No

## **5 Audit Criteria**

**Please suggest a minimum dataset of criteria by which this procedure could be audited.**

**5.1 Outcome measures of benefit (including commonly used clinical outcomes – both short and long-term; and quality of life measures):**

**VAS score**

**A quality of life outcome measure eg SF-36**

**Return to work ?**

**5.2 Adverse outcomes (including potential early and late complications):**

**Infections**

**All complications including proceeding to surgery**

## **6 Trajectory of the procedure**

**6.1 In your opinion, what is the likely speed of diffusion of this procedure?**

Relatively slow

**6.2 This procedure, if safe and efficacious, is likely to be carried out in (choose one):**

- Most or all district general hospitals.
- A minority of hospitals, but at least 10 in the UK.
- Fewer than 10 specialist centres in the UK.
- Cannot predict at present.

**Comments:**

**6.3 The potential impact of this procedure on the NHS, in terms of numbers of patients eligible for treatment and use of resources, is:**

- Major.
- Moderate.
- Minor.

**Comments:**



## 7 Other information

7.1 Is there any other information about this procedure that might assist NICE in assessing the possible need to investigate its use?

n/a

## 8 Data protection and conflicts of interest

### 8.1 Data protection statement

*The Institute is committed to transparency. As part of this commitment your name and specialist society will be placed in the public domain, in future publications and on our website ([www.nice.org.uk](http://www.nice.org.uk)) and therefore viewable worldwide. This information may be passed to third parties connected with the work on interventional procedures.*

*A copy of the completed Specialist Adviser advice will be sent to the Specialist Society who nominated the Specialist Adviser.*

Specialist Advisers should be aware that full implementation of the Freedom of Information Act 2000 may oblige us to release Specialist Advice from 2005. The Freedom of Information Act 2000 favours the disclosure of information however requests will be considered on a case by case basis. If information is made available, personal information will be removed in accordance with the Data Protection Act 1998. In light of this please ensure that you have not named or identified individuals in your comments.

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### 8.2 Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee

Please state any potential conflicts of interest, or any involvements in disputes or complaints, relevant to this procedure. Please use the “Conflicts of Interest for Specialist Advisers” policy (attached) as a guide when declaring any conflicts of interest. Specialist Advisers should seek advice if required from the Associate Director – Interventional Procedures.

Do you or a member of your family<sup>1</sup> have a **personal pecuniary** interest?  
The main examples are as follows:

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<sup>1</sup> ‘Family members’ refers to a spouse or partner living in the same residence as the member or employee, children for whom the member or employee is legally responsible, and adults for whom the member or employee is legally responsible (for example, an adult whose full power of attorney is held by the individual).



- Consultancies or directorships** attracting regular or occasional payments in cash or kind  YES  
 NO
- Fee-paid work** – any work commissioned by the healthcare industry – **this includes income earned in the course of private practice**  YES  
 NO
- Shareholdings** – any shareholding, or other beneficial interest, in shares of the healthcare industry  YES  
 NO
- Expenses and hospitality** – any expenses provided by a healthcare industry company beyond those reasonably required for accommodation, meals and travel to attend meetings and conferences  YES  
 NO
- Investments** – any funds which include investments in the healthcare industry  YES  
 NO
- Do you have a **personal non-pecuniary** interest – eg have you made a public statement about the topic or do you hold an office in a professional organisation or advocacy group with a direct interest in the topic?  YES  
 NO
- Do you have a **non-personal** interest? The main examples are as follows:
- Fellowships** endowed by the healthcare industry  YES  
 NO
- Support by the healthcare industry or NICE** that benefits his/her position or department, eg grants, sponsorship of posts  YES  
 NO

**If you have answered YES to any of the above statements please describe the nature of the conflict(s) below.**

**Comments:**

I practice in the private sector but do not perform this procedure.  
 I own a small holding of Astra Zeneca shares

Thank you very much for your help.

**Professor Bruce Campbell, Chairman,  
 Interventional Procedures Advisory  
 Committee**

**Professor Carole Longson, Director,  
 Centre for Health Technology  
 Evaluation.**

**February 2010**

## Conflicts of Interest for Specialist Advisers

- 1 **Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee**
  - 1.1 Any conflicts of interest set out below should be declared on the questionnaire the Specialist Adviser completes for the procedure.
  - 1.2 Specialist Advisers should seek advice if required from the Associate Director – Interventional Procedures.
- 2 **Personal pecuniary interests**
  - 2.1 A personal pecuniary interest involves a current personal payment to a Specialist Adviser, which may either relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as ‘**specific**’ or to the industry or sector from which the product or service comes, in which case it is regarded as ‘**non-specific**’. The main examples are as follows.
    - 2.1.1 **Consultancies** – any consultancy, directorship, position in or work for the healthcare industry that attracts regular or occasional payments in cash or kind (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).
    - 2.1.2 **Fee-paid work** – any work commissioned by the healthcare industry for which the member is paid in cash or in kind (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).
    - 2.1.3 **Shareholdings** – any shareholding, or other beneficial interest, in shares of the healthcare industry that are either held by the individual or for which the individual has legal responsibility (for example, children, or relatives whose full Power of Attorney is held by the individual). This does not include shareholdings through unit trusts, pensions funds, or other similar arrangements where the member has no influence on financial management.
    - 2.1.4 **Expenses and hospitality** – any expenses provided by a healthcare industry company beyond that reasonably required for accommodation, meals and travel to attend meetings and conferences (this includes both those which have been undertaken in the 12 months preceding the point at which the declaration is made and which are planned but have not taken place).
    - 2.1.5 **Investments** – any funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.
  - 2.2 No personal interest exists in the case of:
    - 2.2.1 assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds) and where

the fund manager has full discretion as to its composition (for example, the Universities Superannuation Scheme)

2.2.2 accrued pension rights from earlier employment in the healthcare industry.

### 3 **Personal family interest**

3.1 This relates to the personal interests of a family member and involves a **current payment** to the family member of the Specialist Adviser. The interest may relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as '**specific**', or to the industry or sector from which the product or service comes, in which case it is regarded as '**non-specific**'. The main examples include the following.

3.1.1 Any consultancy, directorship, position in or work for a healthcare industry that attracts regular or occasional payments in cash or in kind.

3.1.2 Any fee-paid work commissioned by a healthcare industry for which the member is paid in cash or in kind.

3.1.3 Any shareholdings, or other beneficial interests, in a healthcare industry which are either held by the family member or for which an individual covered by this Code has legal responsibility (for example, children, or adults whose full Power of Attorney is held by the individual).

3.1.4 Expenses and hospitality provided by a healthcare industry company (except where they are provided to a general class of people such as attendees at an open conference)

3.1.5 Funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.

3.2 No personal family interest exists in the case of:

3.2.1 assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds) and where the fund manager has full discretion as to its composition (for example, the Universities Superannuation Scheme)

3.2.2 accrued pension rights from earlier employment in the healthcare industry.

### 4 **Personal non-pecuniary interests**

These might include, but are not limited to:

4.1 a clear opinion, reached as the conclusion of a research project, about the clinical and/or cost effectiveness of an intervention under review

4.2 a public statement in which an individual covered by this Code has expressed a clear opinion about the matter under consideration, which could reasonably be interpreted as prejudicial to an objective interpretation of the evidence

- 4.3 holding office in a professional organisation or advocacy group with a direct interest in the matter under consideration
- 4.4 other reputational risks in relation to an intervention under review.

## **5 Non-personal interests**

5.1 A non-personal interest involves payment that benefits a department or organisation for which a Specialist Advisor is responsible, but that is not received by the Specialist Advisor personally. This may either relate to the product or service being evaluated, in which case it is regarded as '**specific,**' or to the manufacturer or owner of the product or service, but is unrelated to the matter under consideration, in which case it is regarded as '**non-specific**'. The main examples are as follows.

5.1.1 **Fellowships** – the holding of a fellowship endowed by the healthcare industry.

5.1.2 **Support by the healthcare industry or NICE** – any payment, or other support by the healthcare industry or by NICE that does not convey any pecuniary or material benefit to a member personally but that does benefit his/her position or department. For example:

- a grant from a company for the running of a unit or department for which a Specialist Advisor is responsible
- a grant, fellowship or other payment to sponsor a post or member of staff in the unit for which a Specialist Adviser is responsible. This does not include financial assistance for students
- the commissioning of research or other work by, or advice from, staff who work in a unit for which the specialist advisor is responsible
- one or more contracts with, or grants from, NICE.

5.2 Specialist Advisers are under no obligation to seek out knowledge of work done for, or on behalf of, the healthcare industry within departments for which they are responsible if they would not normally expect to be informed.