NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Procedure Name:	**Percutaneous coblation of the intervertebral disc for lower back pain and sciatica (235/2)**
Name of Specialist Advisor:	**Dr Antony Hammond**
Specialist Society:	**British Pain Society**
Please complete and return to:	azeem.madari@nice.org.uk OR 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:

The instrumentation used is the 'spine wand" catheter by Arthrocare. The title given to the procedure by Arthrocare is Coblation "Nucleoplasty" and it is often referred to as nucleoplasy.

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:
I have used coblation in simple form for over 10 years and in adapted form (Disc FX, see below) for 2-3 years.

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:
I maintain and audit of my own outcomes with these procedures

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:

The procedure is not novel in that it has been around for a decade but is in the sense that it is not widely used and requires to be introduced to NHS practice as a wholly new procedure. It does not quitter replace any current procedure except disc chymodiactin injection which is out of use

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

Conservative care including high dose opiate use
Spinal fusion and disc replacement surgery
Other discal procedures including compound disc procedures like 'DiscFX" which employ physical nucleotomy, coblation and intradiscal annulus RF denervation
Mechanical disc nucleotomy "DeKompressor" (Stryker I think)
Possibly laser discectomy
Historically chymodiactin or chymopapain enzymatic nucleus digestion

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
    - Discitis (disc infection) estimate of risk 1 in 2-4000, usually managed by intravenous/intradiscal antibiotics.
    - Nerve injury by needle ‘en route’.
    - Post procedure pain
    - Misadventure, needle misplaced through disc to retroperitoneum or behind to the dura or spinal canal
    - Technical failure at L5/S1 due to difficult access
    - Possibly late disc protrusion (rare)
    - Hospital admission for pain control or assessment of discitis

2. Anecdotal adverse events (known from experience)

Post procedure pain

Discitis – 1 case

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

Major adverse events are rare. The procedure correctly conducted is simple and safe. have read a report of epidural fibrosis attributed to the technique but I find it difficult to understand the link

4.2 What are the key efficacy outcomes for this procedure?

Reduction of back and leg pain, disability, work and domestic productivity

In my own practice I use –

Pain area on a grid
VAS back pain Average and worst
VAS leg pain average and worst
VAS patient global improvement
Oswestry disability (RMDQ could be used)

There are numerous standardised spinal scoring and disability inventories

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

There have been no absolutely definitive long term placebo/sham controlled trials to define the efficacy beyond doubt but there are substantial patient numbers reported in open label and outcome series and some comparative studies.

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

Training:

- Disc access under fluoroscopic guidance
- Use of RF devices
- Sterile technique

Facilities:

- Theatre, fluoroscopy
- Day case facilities
- Preprocedure MRI

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

None

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.

I am aware of a small trial conducted in UK 2 years ago but I have not seen it reported. I have presented my own data but not published it.

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

I have made the following comment previously.
Disc Diagnostics and treatments are controversial Cdonfor the following reasons:

Discogenic pain is said to account for 40% of persisting severe axial spinal pain and affects mainly young adults in the most productive years. None the less it is not diagnosed or treated by the UK pain medicine community. Those who do find it difficult to know how you can comprehensively manage spinal pain without addressing the disc and believe that the process is flawed without it. Patients are misdiagnosed, misinformed and treatment opportunities missed.

This arises in several ways. Disc management is not established and the lack of positive NICE guidance is interpreted as the presence of negative guidance which makes makes clinicians reluctant - “this is ‘not approved’ we shouldn’t do it”, “we must only practice ’evidence based’ medicine”.

Likewise, lack of positive guidance makes it very difficult to access new procedures from NHS purchasers so even those who would cannot. It would be easier for the surgical community to introduce such techniques as less invasive and less expensive alternatives to major surgery but this is not within their remit.

Effective disc therapy depends on correct diagnosis. It is not sufficient to test an empirically suspect disc for positive or negative pain response. In my own series, 30-40% of cases would be misdiagnosed on MR or clinical grounds and the wrong disc treated or a symptomatic disc left untreated. Disc pain is diagnosed by pain provocation discography. This is a disputed technique. The only standardised method is that recommended by the International Spinal Pain Society (ISIS) and that is not widely practiced. It requires testing a non-suspect disc to have an internal negative for absolute specificity. There are legitimate, but perhaps over worked concerns that intervening in radiographically normal discs for the purposes of discography could lead to future disc degeneration. For all of these reasons, the techniques have not been widely disseminated. .

5 Audit Criteria

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

There are well standardised spinal outcomes and amny with expertise in outcomes assessment
In my own practice I use –

Pain area on a grid
VAS back pain Average and worst
VAS leg pain average and worst
VAS patient global improvement
Oswestry disability (RMDQ could be used)

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

Disability with ADL are crucial to measure
Work and home productivity
Return to work
EQ-5D

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

Post procedure severe pain
As per other discal procedures including late relapse of pain
duration of response to 1 year
Hospitalisations post procedure for pain control
Discitis
Any disc protrusion event on the operated level(s)
Any surgeries

6 Trajectory of the procedure

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

If approved it would be quite rapid but in a limited number of centres. In its own right, It is a simple technique for those with the appropriate training and there is substantial unmet need. However, the requirement for prior pain provocation discography is perhaps more of a technical and clinical challenge. The need to establish a system of assessment and a two stage procedural path would be a block in many units.

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:

Potentially there are a lot of patients but there are no robust estimates of prevalence. The available prevalence of 40% of chronic axial spinal pain comes from limited numbers in an American chronic pain clinic. However using that. Chronic back pain is 1% and disc .4 of this hence .4% of adults.

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?

The pathology underpinning discogenic pain is complex and involves a set of inflammatory changes involving both or either nucleus or annulus. It is not possible in a given case to determine which is present, or both. Current diagnostics with pain provocation discography don't really differentiate these factors. Coblation addresses reduction of nuclear volume (and thus direct removal of potentially inflamed tissue), produces positive alteration in cytokine profile (in porcine disc in vivo) and reduces intradiscal pressure but does not treat the annulus directly. I therefore now use the Disc FX system which deploys 3 modalities, mechanical (ronguers) nucleotomy coblation and internal annulus heat denervation) by the same aproach and appears in my experience to be superior to simple coblation. This technique should, if possible be included as a sub analysis of this procedure.

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) 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.

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[1] have a **personal pecuniary** interest? The main examples are as follows:

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 have a £5000 investmetnt in Alloksys lLife Sciences (a biological pharma company)
I own an RF lesion generator currently rented to KIMS hospital

[1] '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).

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.

This applies Equally to 235/2 161/2 43/2

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Procedure Name:	**Percutaneous coblation of the intervertebral disc for lower back pain and sciatica (235/2)**
Name of Specialist Advisor:	**George Verghese**
Specialist Society:	**British Association of Spinal Surgeons**
Please complete and return to:	azeem.madari@nice.org.uk OR 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:

Coblation / Electrothermal therapy / RF thermocapsulat. all apply equally to techniques using heat to coagulate disc Rotors to shrink them, thus reducing the pressure effect of a bulging or prolapsed disc

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:

Performed Mainly by Pain Specialists.

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:

I have been trained but did not see a clinical role in my practice

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:

RRRR -

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

As in (1.1) - Same Principle + Different Manufacturer - Different Names

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

- Thermal effects to surrounding tissue.
- Neurovascular injury / Bleed / Paralysis
- Defect
- Instrument failure → Damage to other structures
- Operator " → " "

2. Anecdotal adverse events (known from experience)

- Visceral / Vascular / Jaw
- worsening Symptoms / RSD.

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

4.2 What are the key efficacy outcomes for this procedure?

These procedures fail to take into consideration the chemical nociceptive nature of Spinal Pain & assume it is all a mass effect of Inflammation causing Pain. This is NOT the case

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

I am unsure this family of techniques works. The cost far out weighs the minimal benefits — to my belief

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

Technique is Essentially same as doing a discogram. But appropriate training would be essential

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

N/A

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.

N/A

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

Nobody seems to be clear as to exactly how this works or if this is better than existing Rx

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 / ODI / EQ5D
- But this has to compare 2 comparable & blinded groups of Pts.

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

- Any possible complications that a Spinal Surgeon can be sued for must be audited. (or his Trust)
- Specifically - PO.T Rx neuropathic pain

6 Trajectory of the procedure

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

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:

only a few trials in very few centres
Should this be allowed
Mod Imp: Is this Cost Effective??

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: Cost v. Effectiveness!
Remember Scott Para SCIA !!
& - Metal-on-Metal thigh replacements.
- Polar plastic & Bipolar Pedial #'s
etc, etc (DRAFT Study)

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?

1.1 + 6.3.

8 Data protection and conflicts of interest

8.1 Data protection statement

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Do you or a member of your family[1] have a **personal pecuniary** interest? The main examples are as follows:

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[1] '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:

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

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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).

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- 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.

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Procedure Name:	**Percutaneous coblation of the intervertebral disc for lower back pain and sciatica (235/2)**
Name of Specialist Advisor:	**Dr Sam Stuart**
Specialist Society:	**British Society of Interventional Radiologists**
Please complete and return to:	azeem.madari@nice.org.uk OR sally.compton@nice.org.uk

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

X Yes.

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

1.1 Does the title used above describe the procedure adequately?

X 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?

X 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:

X 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.

X 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.

XI 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):

X 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:

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

Medication (analgesia)
Possibly surgery

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.

X 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
2. discitis, Infection
3. instability,
4. increased back pain,

5. reherniation.
6. Epidural fibrosis
7. Nerve damage
8. Bleeding

<1% complication rate from literature

9. Anecdotal adverse events (known from experience)

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

discitis, Infection

instability,

increased back pain,

reherniation.

Epidural fibrosis

Nerve damage

Bleeding

- **Side effects and complications after** percutaneous disc **decompression using** coblation **technology**

  by Bhagia, Sarjoo M; Slipman, Curtis W; Nirschl, Monica; more...

  American journal of physical medicine & rehabilitation / Association of Academic Physiatrists, 01/2006, Volume 85, Issue 1

- **Epidural fibrosis following** percutaneous disc **decompression with** coblation **technology**

  by Smuck, Matthew; Benny, Benoy; Han, Alice; more...

  Pain physician, 09/2007, Volume 10, Issue 5

- **Lumbar** disc **nucleoplasty using** coblation **technology: clinical outcome**

  by Azzazi, Alaa; AlMekawi, Sherif; Zein, Mostafa

  Journal of neurointerventional surgery, 09/2011, Volume 3, Issue 3

4.2 What are the key efficacy outcomes for this procedure?

Improvement in pain

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

Yes. There are no large high quality studies demonstrating this invasive technique is more effective than medical treatment of back pain or other percutaneous methods of disc decompression.

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

Understanding of imaging
Safe use of x ray equipment and understanding of risks of Ionising radiation
Available fluoroscopy or CT scanner

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?

Uncertainty over who would benefit best from this treatrment – i.e. patient selection.

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):

Quality of life measures (including pain measures)

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

Infection

Nerve damage

Bleeding

6 Trajectory of the procedure

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

Slow. The procedure has been described for many years (at least 2006) and to my knowledge has not been widely taken up by the medical community.

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

X 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:

If safe, effective and cost efficiency is proven then most hospitals could provide this service with appropriately trained individuals. There are many unanswered questions however.

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:

X Major.

☐ Moderate.

☐ Minor.

Comments:

Back pain and disc herniation are very common.

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?

More information about the efficacy of the procedure and cost effectiveness is needed before it can be seen if it's use should be widespread.

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) 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.

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[1] have a **personal pecuniary** interest? The main examples are as follows:

[1] '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

Consultancies or directorships attracting regular or occasional payments in cash or kind	☐	**YES**
	x	**NO**
Fee-paid work – any work commissioned by the healthcare industry **– this includes income earned in the course of private practice**	☐	**YES**
	x	**NO**
Shareholdings – any shareholding, or other beneficial interest, in shares of the healthcare industry	☐	**YES**
	x	**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**
	x	**NO**
Investments – any funds which include investments in the healthcare industry	☐	**YES**
	x	**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**
	x	**NO**

Do you have a **non-personal** interest? The main examples are as follows:

Fellowships endowed by the healthcare industry	☐	**YES**
	x	**NO**
Support by the healthcare industry or NICE that benefits his/her position or department, eg grants, sponsorship of posts	☐	**YES**
	x	**NO**

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

Comments:

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

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whom the member or employee is legally responsible (for example, an adult whose full power of attorney is held by the individual).

Conflicts of Interest for Specialist Advisers

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