

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Interventional Procedures Programme

Procedure Name: **Electrotherapy for the treatment of haemorrhoids (1125/1)**

Name of Specialist Advisor: **Charles Maxwell-Armstrong**

Specialist Society: **British Association of Coloproctology of Great Britain and Ireland**

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. In so much as I have extensive knowledge of treating haemorrhoids.

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

Yes.

**Comments:**

### **2 Your involvement in the procedure**

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

Yes.

**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

**Comments:**

I have banded and operated on a large number of haemorrhoids but have never used electrotherapy per se

**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 take part in patient selection or refer patients for this procedure regularly.

**Comments:**

That is banding or operating of haemorrhoids ....

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

Other (please comment)

**Comments:**

I wrote a paper that looked at pain after haemorrhoidal banding

**3 Status of the procedure**

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

Definitely novel and of uncertain safety and efficacy.

**Comments:**

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

Banding and operating on haemorrhoids

**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.

**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

Pain. The idea of electrotherapy being applied too low within the anal canal doesn't bear thinking about - assuming this is an office/outpatient procedure

2. Anecdotal adverse events (known from experience)

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

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

Does it cure the haemorrhoid....

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

Yes. I don't understand how it is going to work in grade 4 haemorrhoids wherer there is a significant external component to the haemorrhoid

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

No idea

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

None as far as I am aware

**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?**

none as far as I am aware

## **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):**

**Patient reported symptom improvement at 6 weeks after the procedure**

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

**Pain, bleeding**

**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.

**Comments:**

Will depend on efficacy adverse events and alaos cost...

**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:**

Moderate.

**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?

## 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  **NO**
- Fee-paid work** – any work commissioned by the healthcare industry – **this includes income earned in the course of private practice**  **YES**
- Shareholdings** – any shareholding, or other beneficial interest, in shares of the healthcare industry  **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  **NO**
- Investments** – any funds which include investments in the healthcare industry  **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?  **NO**
- Do you have a **non-personal** interest? The main examples are as follows:
- Fellowships** endowed by the healthcare industry  **YES**
- Support by the healthcare industry or NICE** that benefits his/her position or department, eg grants, sponsorship of posts  **YES**

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

**Comments:**

Our laparoscopic colorectal fellow is funded by ethicon endosurgery

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.

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Interventional Procedures Programme

Procedure Name: **Electrotherapy for the treatment of haemorrhoids (1125/1)**

Name of Specialist Advisor: **David Humes**

Specialist Society: **British Association of Coloproctology of Great Britain and Ireland**

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:**

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

Formal haemorrhoidectomy

#### 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

Burning or electrocution

2. Anecdotal adverse events (known from experience)

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

Most reports suggest it is safe and painless.

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

Recurrent bleeding leading multiple interventions, pain post procedure

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

It is not clear how many treatments are needed and what the recurrence rates are.

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

The procedure can be performed on an outpatient basis. Training would be required in terms of the optimum application technique and duration along with how the electrotherapy device works.

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

I am not aware of any currently.

- 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.

[Gastrointest Endosc.](#) 1991 Nov-Dec;37(6):621-3.

### **A prospective crossover trial of direct current electrotherapy in symptomatic hemorrhoidal disease.**

[Wright RA<sup>1</sup>](#), [Kranz KR](#), [Kirby SL](#).

[Am J Gastroenterol.](#) 1989 May;84(5):482-7.

### **Direct current electrotherapy of internal hemorrhoids: an effective, safe, and painless outpatient approach.**

[Norman DA<sup>1</sup>](#), [Newton R](#), [Nicholas GV](#).

There are few recent studies I can see on a brief search. The majority are case series with no direct comparison or small RCTs.

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

The effectiveness is unknown.

## **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):

Pain post procedure, recurrence of bleeding, need for surgical intervention.



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

**Failure of treatment.**

## **6 Trajectory of the procedure**

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

The procedure was first described in the late 1980's it does offer the advantage of being repeated and relatively painless however its long term efficacy is unknown.

**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:**

If safe this procedure could be used widely however this would take time.

## 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?

## 8 Data protection and conflicts of interest

### 8.1 Data protection statement

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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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**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

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- 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.

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Interventional Procedures Programme

Procedure Name: **Electrotherapy for the treatment of haemorrhoids (1125/1)**

Name of Specialist Advisor: **Henry Tilney**

Specialist Society: **British Association of Coloproctology of Great Britain and Ireland**

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:**

This is a novel procedure and not part of routine colorectal surgical practice.



**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:**

This would not be considered a routine outpatient treatment for haemorrhoids.

**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:**

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

Injection or banding of haemorrhoids

**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

Pain, bleeding, thrombosis

2. Anecdotal adverse events (known from experience)

None

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

Not known

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

Effect on bleeding and/or prolapse of haemorrhoids

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

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

Not established but would require specific training on the precise use and safety of the equipment employed

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

Not as far as I am aware

**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?**

Not common enough for such concerns to be widespread

## **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):**

**Effect on volume/frequency of haemorrhoidal bleeding  
Reduction in degree of prolapse**

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

**Pain, bleeding, recurrence of haemorrhoids**

## **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:**

As many well established outpatient treatments for haemorrhoids exist a new technique would have to be significantly more effective to gain significant support in the UK

**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:**

Very common condition for which no current procedure is ideal. A novel and effective procedure might have an impact on a great many patients if found to be superior to current outpatient treatments.

## 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?

Nil

## 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.

---

### 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:**

No conflict of interest to declare.

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.

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Interventional Procedures Programme

Procedure Name: **Electrotherapy for the treatment of haemorrhoids (1125/1)**

Name of Specialist Advisor: **Mark Coleman**

Specialist Society: **British Association of Coloproctology of Great Britain and Ireland**

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:**

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

Banding or haemorrhoidectomy

#### 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

Bleeding, infection

2. Anecdotal adverse events (known from experience)

nil

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

None

<http://www.ncbi.nlm.nih.gov/pubmed/?term=electrotherapy+AND+haemorrhoids>

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

Reduction of bleeding and prolapse of haemorrhoids

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

Whether the treatment will have a significant effect on the above

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

None with accreditation or assessment of competency

**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.**

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?**

None known

## **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):**

**no improvements and no adverse outcomes compared to banding for grade 2-3 haemorrhoids**

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

**as above**

## 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:**

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?

no

## 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.*

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---

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

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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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**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

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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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    - 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).
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    - 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.

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Interventional Procedures Programme

Procedure Name: **Electrotherapy for the treatment of haemorrhoids (1125/1)**

Name of Specialist Advisor: **Mr Paul Mackey**

Specialist Society: **British Association of Coloproctology of Great Britain and Ireland**

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:**

Will be undertaken almost exclusively by colorectal surgeons

**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: New technique useful to supplement the current treatment options available to treat haemorrhoids, especially if patients cannot, or do not want, definitive excisional surgery**

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

Probably would fall between rubber band ligation and excisional haemorrhoidectomy

#### 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: New technique in this country, more established in America**

### 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

Pain, bleeding (maybe at day 5-10 post –procedure), infection, failure to resolve symptoms, discomfort during procedure, need for repeat treatment(s), thrombosed haemorrhoids, vaso-vagal event. Impossible to give a reliable estimate



of incidence, but I would have thought all less than injection sclerotherapy and rubber band ligation

2. Anecdotal adverse events (known from experience)

Occasionally very mild discomfort during the procedure, but no cases of haemorrhage, infection, structuring or severe pain, as far as I am aware

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

I have been informed that no significant adverse events have been reported to the FDA in the USA in the last 4 years. I am not aware of any complications related to Ultroid reported in the literature.

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

Resolution of haemorrhoidal symptoms, namely bleeding and prolapse

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

Impossible to predict what the long/medium-term outcomes, but no reason to believe any less than current treatments such as injection and banding, but avoiding all the risks associated with surgery.

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

Minimal training required – maybe 2-3 cases just to familiarise oneself with the equipment, for practioners already familiar with treating haemorrhoids. Facilities same as for any colorectal outpatient clinic

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

None that I personally know 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.**

2 presentations at European Society of Coloproctology meeting in Barcelona, copies of which I believe you are in possession of.

**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, not that I am aware of

## **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):**

Ongoing haemorrhoidal symptoms such as bleeding and discomfort

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

Pain, failure to improve or resolve symptoms, post-procedure bleeding, infection, anal stenosis (probably theoretical risk only), haemorrhoidal thrombosis

**6 Trajectory of the procedure**

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

Very 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:**

Haemorrhoidal symptoms currently generally under-treated, as the best treatments are also the most expensive and are associated with risks, which often are unacceptable to patients and surgeons. Less invasive out-patient treatments not universally effective in bringing about resolution of symptoms. Ultroid will hopefully allow patients with troublesome bleeding from 1<sup>st</sup>/2<sup>nd</sup> degree haemorrhoids access to effective treatment, role for prolapsing haemorrhoids led certain, but undoubtedly a role in carefully selected patients

## 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?

Not that I am currently aware of

## 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.*

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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 have offered ultroid treatment to patients in the private sector who I have clinically assessed, and in my opinion, thought would benefit from such treatment. I have discussed my Azeem Madari who advised that I do not need to take any further action at this time.

Thank you very much for your help.

**Professor Bruce Campbell, Chairman, Professor Carole Longson, Director,**

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**Interventional Procedures Advisory  
Committee**

**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.
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    - 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.

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Interventional Procedures Programme

Procedure Name: **Electrotherapy for the treatment of haemorrhoids (1125/1)**

Name of Specialist Advisor: **Mr Pradeep Basnyat**

Specialist Society: **British Association of Coloproctology of Great Britain and Ireland**

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:**

I have performed this procedure about three times

**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:**

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

Injection and/or Banding of Haemorrhoids

**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

Pain

Infection  
Perforation

2. Anecdotal adverse events (known from experience)

Not Known

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

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

No further Rectal Bleeding  
Symptoms related to Haemorrhoids improved

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

Recurrence Rate  
Number of treatment

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

One to one hands on practical training one session is probably sufficient for  
established colorectal surgeons who treat haemorrhoids.  
Treated in an out patient setting

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

Not 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.**

Am aware of an abstract presented at the recent European Society Meeting

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

Procedure needs to be compared with standard treatment of early Haemorrhoids that is Injection and Banding

## **5 Audit Criteria**

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

**Dataset for audit should include patient demographics, symptoms, Grade of Haemorrhoids and other colorectal causes of symptoms excluded, treatment time/duration, patient comfort, patient satisfaction, complications immediate and late, number of treatment sessions, recurrence rate.**

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

**This procedure is probably an alternative to Injection and/or banding of Haemorrhoids. Therefore a randomised trial may give a better idea which is better treatment option.**

**Main benefit would be improvement of Haemorrhoid symptoms mainly bleeding.**

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

**Pain Infection Bleeding Perforation Recurrence Incontinence**

## **6 Trajectory of the procedure**

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

If the audit shows significant improvement in patient symptoms with minimum or no complication with only one or two treatment sessions then this will have a major impact on uptake of this procedure by surgeons around the country however the down side is it takes around 30 minutes to treat one patient with three haemorrhoids at the primary sites compared to injection or banding which in most competent surgeon will take only few minutes.

**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:**

Most Haemorrhoids do not require active treatment. This procedure, in my opinion, has role only for symptomatic first and second degree haemorrhoids (may be some early third degree haemorrhoids)

## 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?

Patient compliance.

Duration of Treatment and frequency of treatment

## 8 Data protection and conflicts of interest

### 8.1 Data protection statement

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The main examples are as follows:

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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 do Private practice and have used this procedure in private patients. I have given an interview to the national newspaper regarding this procedure.

Thank you very much for your help.

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

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

---

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

**February 2010**

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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.