View results

Respondent

58 Anonymous

43:00
Time to complete

1. Project Number and Name - (Can be found on email) *

Corticosteroid-releasing bioabsorbable stent or spacer insertion during endoscopic sinus surgery to treat chronic rhinosinusitis

Your information

2. Name: *

Mr Amit Shankar

3. Job title: *

Consultant ENT

4. Organisation: *

East Sussex NHS Healthcare Trust

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

GMC

7. Nominated/ratified by (if applicable):

8. Registration number (e.g. GMC, NMC, HCPC) *

7651442

9. I confirm that:

- I am a registered practising professional in the UK/NHS and in good professional standing
- I have specialist knowledge in the technology or disease area
- I will declare all conflicts of interest in relation to the technology under consideration
- I will abide by NICE's governance policies and comply with NICE's processes and methods
- I will abide by the timelines for this topic, as communicated by the coordinator/administrator.

Personal data submitted to NICE can be used for the purposes of carrying out its CHTE outputs. Personal data will be held on NICE's databases and I may be contacted in the future by NICE after the completion of this topic. *

- (●) I agree
- ( ) I do not agree

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice: https://www.nice.org.uk/privacy-notice

10. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

- (●) I agree
- ( ) I disagree

The procedure/technology

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

11. Please describe your level of experience with the procedure/technology, for example:

Are you familiar with the procedure/technology?

Yes

I am doing endoscopic sinus surgery for more than 12 years and I am familiar with this technology very well

12. Have you used it or are you currently using it?

- Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?

- Is this procedure/technology performed/used by clinicians in specialities other than your own?

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

I have not used it at current NHS setting . Used it at other Centre . It would be widely accepted once on the ground . To be used by all endoscopic sinus surgeons for better postoperative outcome

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

- [x] I have done bibliographic research on this procedure.
- [ ] I have done research on this procedure in laboratory settings (e.g. device-related research).
- [ ] I have done clinical research on this procedure involving patients or healthy volunteers.
- [ ] I have published this research.
- [ ] I have had no involvement in research on this procedure.
- [ ] Other

14. Does the title adequately reflect the procedure?

- (●) Yes
- ( ) Other

15. Is the proposed indication appropriate? If not, please explain

Yes

16. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

Novel approach

17. Which of the following best describes the procedure:

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

18. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?

Yes

19. Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?

No

20. Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?

No

21. Do you think the guidance needs updating?

Yes

Current management

22. Please describe the current standard of care that is used in the NHS.

Saline nasal irrigation and topical steroid spray post sinus surgery . Intraoperative use of nasopore for hemostasis , no stent insertion as such

23. Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?

    If so, how do these differ from the procedure/technology described in the briefing?

None

Potential patient benefits and impact on the health system

24. What do you consider to be the potential benefits to patients from using this procedure/technology?

Better control of post operative cavity interms of adhesions, inflammation and patency of ostium .

25. Are there any groups of patients who would particularly benefit from using this procedure/technology?

Chronic rhinosinusitis , revision sinus surgeries

26. Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?

    Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?

Yes it would improve postoperative outcome with less hospital visits or revision procedures

27. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

May be proper insertion device / equipment to allow better insertion of stent

28. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

Would require hands on training before practicing for sure to avoid any kind complications

Safety and efficacy of the procedure/technology

29. What are the potential harms of the procedure/technology?

Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:

- Adverse events reported in the literature (if possible, please cite literature)
- Anecdotal adverse events (known from experience)
- Theoretical adverse events

Adverse events- infection ,stent migration, injury to lamina / cribriform, granulation, biofilm formation, peri orbital cellulitis , absorption of steroid in case of high dose etc

Anecdotal event- stent falling out

30. Please list the key efficacy outcomes for this procedure/technology?

Patent ostium

Less adhesions

Better healing of sinus cavity

Less disease recurrence

31. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

Use of stent in glaucoma patient where we avoid steroids?

32. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

None

33. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- (●) 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.

Abstracts and ongoing studies

34. Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).

    Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.

    A Corticosteroid-Eluting Sinus Implant Following Endoscopic Sinus Surgery for Chronic Rhinosinusitis: A UK-Based Cost-Effectiveness Analysis
    Mehdi Javanbakht et al. Pharmacoecon Open. 2020 Dec.

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

    Not aware of any such trial

36. Please list any other data (published and/or unpublished) that you would like to share.

    None

Other considerations

37. Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?

    More than 300 per year

38. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

    Beneficial outcome measures.

    These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.

    Short and Long term clinical and patient related outcomes , 6 months and 3 years

39. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

    Adverse outcome measures.

    These should include early and late complications. Please state the post procedure timescales over which these should be measured:

    Should be measured in 2 weeks , 4 weeks for early

    6weeks, 12 weeks for late

Further comments

40. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

Cost of the stent and it's sustainability on a longer run at NHS setting

Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

41. Type of interest: *

- [ ] Direct: financial
- [ ] Non-financial: professional
- [ ] Non-financial: personal
- [ ] Indirect
- [x] No interests to declare

42. Description of interests, including relevant dates of when the interest arose and ceased. *

None

43. I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website. *

- (•) I agree
- ( ) I disagree

Signature

44. Name: *

Mr Amit Shankar

45. Date: *

06/05/2024

View results

Respondent

50 Anonymous

132:26
Time to complete

1. Project Number and Name - (Can be found on email) *

Corticosteroid-releasing bioabsorbable stent or spacer insertion during endoscopic sinus surgery to treat chronic rhinosinusitis (IP963/2)

Your information

2. Name: *

Carl Philpott

3. Job title: *

Professor of Rhinology & Olfactology

4. Organisation: *

University of East Anglia

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

British Rhinological Society (ENT UK)

7. Nominated/ratified by (if applicable):

8. Registration number (e.g. GMC, NMC, HCPC) *

4510862

9. I confirm that:

- I am a registered practising professional in the UK/NHS and in good professional standing
- I have specialist knowledge in the technology or disease area
- I will declare all conflicts of interest in relation to the technology under consideration
- I will abide by NICE's governance policies and comply with NICE's processes and methods
- I will abide by the timelines for this topic, as communicated by the coordinator/administrator.

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- (●) I agree
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10. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

- (●) I agree
- ( ) I disagree

The procedure/technology

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

11. Please describe your level of experience with the procedure/technology, for example:

Are you familiar with the procedure/technology?

I have been using the stents for about 5 years, although mostly in the last year.

12. Have you used it or are you currently using it?

- Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?

- Is this procedure/technology performed/used by clinicians in specialities other than your own?

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

I use it mostly for relapse of sinus disease in case for chronic rhinosinusitis at revision surgery. It can be inserted until local or general anaesthetic. It would not be used in other specialities other than ENT.

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

- [ ] I have done bibliographic research on this procedure.
- [ ] I have done research on this procedure in laboratory settings (e.g. device-related research).
- [ ] I have done clinical research on this procedure involving patients or healthy volunteers.
- [ ] I have published this research.
- [x] I have had no involvement in research on this procedure.
- [ ] Other

14. Does the title adequately reflect the procedure?

- (●) Yes
- ( ) Other

15. Is the proposed indication appropriate? If not, please explain

Yes

16. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

It is a novel design

17. Which of the following best describes the procedure:

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

18. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?

In addition to existing standard of care.

19. Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?

There are currently 3 licenced versions of the stents.

20. Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?

Calvo-Henriquez C, García-Lliberós A, Sánchez-Gómez S, Alobid I. Assessing the effect of absorbable steroid sinus implant: a state-of-the-art systematic review. Eur Arch Otorhinolaryngol. 2024 Mar 9. doi: 10.1007/s00405-024-08531-1. Epub ahead of print. PMID: 38459984.

21. Do you think the guidance needs updating?

Yes

Current management

22. Please describe the current standard of care that is used in the NHS.

Topical steroids of any molecule

23. Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?

If so, how do these differ from the procedure/technology described in the briefing?

No

Potential patient benefits and impact on the health system

24. What do you consider to be the potential benefits to patients from using this procedure/technology?

Maintenance of sinus patency and reduction of symptoms

25. Are there any groups of patients who would particularly benefit from using this procedure/technology?

Patients with severe CRS including Non-steroidal anti-inflammatory Exacerbated Respiratory Disease (NERD), single sinus relapse after sinus surgery and where oral corticosteroids and control-indicated.

26. Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?

Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?

Yes potentially. we are participating in a patient registry to gather more information.

27. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

A rigid nasendoscope and a camera stack.

28. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

Limited training - the technology is easy to deploy.

Safety and efficacy of the procedure/technology

29. What are the potential harms of the procedure/technology?

Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:

- Adverse events reported in the literature (if possible, please cite literature)
- Anecdotal adverse events (known from experience)
- Theoretical adverse events

Migration and exclusion of the stent appears to be most common:

Shah VN, Pasick LJ, Benito DA, Ghiam MK, D'Aguillo C. Complications Associated with PROPEL Mometasone Furoate Bioabsorbable Drug-eluting Sinus Stents From 2012 to 2020. Am J Rhinol Allergy. 2022 Mar;36(2):185-190. doi: 10.1177/19458924211035641. Epub 2021 Aug 3. PMID: 34342518.

A study reporting on a different steroid eluting device cited various complications:Narwani V, Torabi SJ, Kasle DA, Patel RA, Lerner MZ, Manes RP. Adverse Events Associated With Corticosteroid-Eluting Sinus Stents: A MAUDE Database Analysis. Otolaryngol Head Neck Surg. 2022 Jan;166(1):179-182. doi: 10.1177/01945998211006930. Epub 2021 Apr 13. PMID: 33848437.

30. Please list the key efficacy outcomes for this procedure/technology?

Reduced outpatient/GP consultations

31. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

To be explored

32. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

No

33. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- ( ) 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.

Abstracts and ongoing studies

34. Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).

    Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.

    I gave a presentation on patient selection at the first international propel meeting in Wiesbaden on 14th March 2024.

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

    Yes Medtronic are in the process of setting up a registry.

36. Please list any other data (published and/or unpublished) that you would like to share.

    N/A

Other considerations

37. Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?

    perhaps 10% of the 4% of the population with chronic rhinosinusitis with nasal polyposis

38. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

    Beneficial outcome measures.

    These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.

    SNOT-22 scores

39. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

    Adverse outcome measures.

    These should include early and late complications. Please state the post procedure timescales over which these should be measured:

    complications including adverse symptoms

Further comments

40. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

    N/A

Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

41. Type of interest: *

- [x] Direct: financial
- [ ] Non-financial: professional
- [ ] Non-financial: personal
- [ ] Indirect
- [ ] No interests to declare

42. Description of interests, including relevant dates of when the interest arose and ceased. *

I am due to receive an honorarium from Medtronic for the meeting mentioned above.

43. I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website. *

- (●) I agree
- ( ) I disagree

Signature

44. Name: *

Carl Philpott

45. Date: *

17/04/2024

View results

Respondent

48 Anonymous

11:45
Time to complete

1. Project Number and Name - (Can be found on email) *

IP963/2 Corticosteroid-releasing bioabsorbable stent or spacer insertion during endoscopic sinus surgery to treat chronic rhinosinusitis

Your information

2. Name: *

F J Uddin

3. Job title: *

Consultant ENT Surgeon

4. Organisation: *

University Hospitals of Leicester NHS Trust

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

ENT UK

7. Nominated/ratified by (if applicable):

Zoe Jones

8. Registration number (e.g. GMC, NMC, HCPC) *

4514914

9. I confirm that:

- I am a registered practising professional in the UK/NHS and in good professional standing
- I have specialist knowledge in the technology or disease area
- I will declare all conflicts of interest in relation to the technology under consideration
- I will abide by NICE's governance policies and comply with NICE's processes and methods
- I will abide by the timelines for this topic, as communicated by the coordinator/administrator.

Personal data submitted to NICE can be used for the purposes of carrying out its CHTE outputs. Personal data will be held on NICE's databases and I may be contacted in the future by NICE after the completion of this topic. *

(●) I agree

( ) I do not agree

10. I confirm that:

- I am a registered practising professional in the UK/NHS and in good professional standing
- I have specialist knowledge in the technology or disease area
- I will declare all conflicts of interest in relation to the technology under consideration
- I will abide by NICE's governance policies and comply with NICE's processes and methods
- I will abide by the timelines for this topic, as communicated by the coordinator/administrator.

Personal data submitted to NICE can be used for the purposes of carrying out its CHTE outputs. Personal data will be held on NICE's databases and I may be contacted in the future by NICE after the completion of this topic. *

(●) I agree

( ) I do not agree

How NICE will use this information:

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For more information about how we process your data please see our privacy notice: https://www.nice.org.uk/privacy-notice

11. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

(●) I agree

( ) I disagree

The procedure/technology

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

12. Please describe your level of experience with the procedure/technology, for example:

    Are you familiar with the procedure/technology?

    Aware of technology but never used it

13. Have you used it or are you currently using it?

    - Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?

    - Is this procedure/technology performed/used by clinicians in specialities other than your own?

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

    Not currently used in my NHS trust
    I am the lead rhinologist in my institution.

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

    - [ ] I have done bibliographic research on this procedure.
    - [ ] I have done research on this procedure in laboratory settings (e.g. device-related research).
    - [ ] I have done clinical research on this procedure involving patients or healthy volunteers.
    - [ ] I have published this research.
    - [x] I have had no involvement in research on this procedure.
    - [ ] Other

15. Does the title adequately reflect the procedure?

    - (•) Yes
    - ( ) Other

16. Is the proposed indication appropriate? If not, please explain

17. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

18. Which of the following best describes the procedure:

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

19. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?

addition to standard care

20. Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?

21. Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?

22. Do you think the guidance needs updating?

Current management

23. Please describe the current standard of care that is used in the NHS.

Maximum medical treatment followed by endoscopic sinus surgery (when required)

24. Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?

If so, how do these differ from the procedure/technology described in the briefing?

Potential patient benefits and impact on the health system

25. What do you consider to be the potential benefits to patients from using this procedure/technology?

Better long term control of symptoms

26. Are there any groups of patients who would particularly benefit from using this procedure/technology?

Patient swith CRSwNP and underlying chonic lung disease

27. Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?

    Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?

potentially better control of symptoms and reduced need for surgical intervention

28. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

No additional apart from device

29. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

Guidance on technique of insertion

Safety and efficacy of the procedure/technology

30. What are the potential harms of the procedure/technology?

    Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:

    - Adverse events reported in the literature (if possible, please cite literature)
    - Anecdotal adverse events (known from experience)
    - Theoretical adverse events

Possible foreign body reaction

31. Please list the key efficacy outcomes for this procedure/technology?

Improved patient symptom scores

32. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

33. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

It is a new technique

34. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- ( ) 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.

Abstracts and ongoing studies

35. Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).

    Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.

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

37. Please list any other data (published and/or unpublished) that you would like to share.

Other considerations

38. Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?

    I would guess approximately 30 per year in my unit

39. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

    Beneficial outcome measures.

    These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.

40. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Adverse outcome measures.

These should include early and late complications. Please state the post procedure timescales over which these should be measured:

Further comments

41. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

This is an exciting area of development in a continually evolving field of research.

Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

42. Type of interest: *

- [ ] Direct: financial
- [ ] Non-financial: professional
- [ ] Non-financial: personal
- [ ] Indirect
- [x] No interests to declare

43. Description of interests, including relevant dates of when the interest arose and ceased. *

None

44. I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website. *

- (●) I agree
- ( ) I disagree

Signature

45. Name: *

F J Uddin

46. Date: *

16/04/2024

View results

Respondent

56 Anonymous

26:16
Time to complete

1. Project Number and Name - (Can be found on email) *

Corticosteroid-releasing bioabsorbable stent or spacer insertion during endoscopic sinus surgery to treat chronic rhinosinusitis (IP963/2)

Your information

2. Name: *

Jonathan Joseph

3. Job title: *

Consultant Rhinologist and Head and Neck Surgeon

4. Organisation: *

University College London Hospitals NHS Trust

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

ENTUK, British Rhinologic Society,

7. Nominated/ratified by (if applicable):

Invited by Zoe Jones

8. Registration number (e.g. GMC, NMC, HCPC) *

GMC 6105465

9. I confirm that:

- I am a registered practising professional in the UK/NHS and in good professional standing
- I have specialist knowledge in the technology or disease area
- I will declare all conflicts of interest in relation to the technology under consideration
- I will abide by NICE's governance policies and comply with NICE's processes and methods
- I will abide by the timelines for this topic, as communicated by the coordinator/administrator.

Personal data submitted to NICE can be used for the purposes of carrying out its CHTE outputs. Personal data will be held on NICE's databases and I may be contacted in the future by NICE after the completion of this topic. *

- (●) I agree
- ( ) I do not agree

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice: https://www.nice.org.uk/privacy-notice

10. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

- (●) I agree
- ( ) I disagree

The procedure/technology

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

11. Please describe your level of experience with the procedure/technology, for example:

Are you familiar with the procedure/technology?

I have been shown the technology by the company that produces it. I am aware of the indications for use and how to deploy the device

12. Have you used it or are you currently using it?

- Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?

- Is this procedure/technology performed/used by clinicians in specialities other than your own?

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

I have only used it In demonstration models.
It is now available in my department so my colleagues and I will be using it imminently.
There are a small number of specialist centres starting to use the device in the NHS.
It is only used by ENT specialists.
My department has a rhinology MDT where all cases for this device are discussed and approved.

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

- [ ] I have done bibliographic research on this procedure.
- [ ] I have done research on this procedure in laboratory settings (e.g. device-related research).
- [ ] I have done clinical research on this procedure involving patients or healthy volunteers.
- [ ] I have published this research.
- [x] I have had no involvement in research on this procedure.
- [ ] Other

14. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) Other

15. Is the proposed indication appropriate? If not, please explain

It has potential application in the awake setting under local anaesthetic. This would be in addition to the stated indications.

16. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

This is a novel concept in the treatment of nasal polyps

17. Which of the following best describes the procedure:

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

18. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?

This would be an addition to standard care

19. Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?

Not that I am aware of.

20. Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?

No

21. Do you think the guidance needs updating?

Yes

Current management

22. Please describe the current standard of care that is used in the NHS.

Nasal polyps are treated using a combination of nasal steroids and sinus surgery. This device will reduce reliance of these treatments.

23. Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?

    If so, how do these differ from the procedure/technology described in the briefing?

No

Potential patient benefits and impact on the health system

24. What do you consider to be the potential benefits to patients from using this procedure/technology?

This will make the effect of sinus surgery longer lasting so patients are symptom free for longer and require less frequent surgery

25. Are there any groups of patients who would particularly benefit from using this procedure/technology?

Those with recurrent nasal polyps with poor response to treatment.

26. Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?

    Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?

    This would lead to a reduction in the prescriptions for nasal steroids and may reduce the number of polyp operations required per patient.

27. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

    Other than the device itself, no additional facilities or changes are required.

28. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

    The surgeon should practice on a model before using it. The nursing staff should be taught how to prepare the device.

Safety and efficacy of the procedure/technology

29. What are the potential harms of the procedure/technology?

    Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:

    - Adverse events reported in the literature (if possible, please cite literature)
    - Anecdotal adverse events (known from experience)
    - Theoretical adverse events

    No known adverse events

30. Please list the key efficacy outcomes for this procedure/technology?

    1. Presence of nasal polyps
    2. Size of polyps
    3. Subjective patient outcomes reporting nasal blockage and effect on sense of smell
    4. Use of nasal steroids.
    5. Duration of efficacy of polypectomy surgery
    6. Objective measures of nasal airflow such as Peak nasal inspiratory flow, acoustic rhinometry

31. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

    Whether there is continued effect after the device has been fully absorbed is unclear.

32. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

    Indications for use is not clearly defined

33. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- ( ) 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.

Abstracts and ongoing studies

34. Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).

    Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.

    None that I am aware of

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

    None that I am aware of

36. Please list any other data (published and/or unpublished) that you would like to share.

    N/A

Other considerations

37. Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?

    500-1000 people per year in the UK

38. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

    Beneficial outcome measures.

    These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.

    Outcome measures :
    Requirement for nasal steroid sprays
    Time to next polyp operation
    Endoscopic view of size of polyps
    SNOT-22 questionnaire and NOSE questionnaire for patient reported outcomes

39. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Adverse outcome measures.

These should include early and late complications. Please state the post procedure timescales over which these should be measured:

steroid related side effects
Presence of adhesions or stenosis
Failure to insert device correctly

Further comments

40. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

N/A

Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

41. Type of interest: *

- [ ] Direct: financial
- [ ] Non-financial: professional
- [ ] Non-financial: personal
- [ ] Indirect
- [x] No interests to declare

42. Description of interests, including relevant dates of when the interest arose and ceased. *

N/A

43. I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website. *

- (●) I agree
- ( ) I disagree

Signature

44. Name: *

Jonathan Joseph

45. Date: *

01/05/2024

View results

Respondent

47 Anonymous

30:44
Time to complete

1. Project Number and Name - (Can be found on email) *

Corticosteroid-releasing bioabsorbable stent or spacer insertion during endoscopic sinus surgery to treat chronic rhinosinusitis (IP963/2)

Your information

2. Name: *

Martyn Barnes

3. Job title: *

Consultant Rhinologist

4. Organisation: *

Mid and South Essex NHS Foundation Trust

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

FRCS-ORL (RCSEd), ENT-UK, BRS, BSFPS

7. Nominated/ratified by (if applicable):

NA

8. Registration number (e.g. GMC, NMC, HCPC) *

4652126

9. I confirm that:

- I am a registered practising professional in the UK/NHS and in good professional standing
- I have specialist knowledge in the technology or disease area
- I will declare all conflicts of interest in relation to the technology under consideration
- I will abide by NICE's governance policies and comply with NICE's processes and methods
- I will abide by the timelines for this topic, as communicated by the coordinator/administrator.

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(●) I agree

( ) I do not agree

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- I have specialist knowledge in the technology or disease area
- I will declare all conflicts of interest in relation to the technology under consideration
- I will abide by NICE's governance policies and comply with NICE's processes and methods
- I will abide by the timelines for this topic, as communicated by the coordinator/administrator.

Personal data submitted to NICE can be used for the purposes of carrying out its CHTE outputs. Personal data will be held on NICE's databases and I may be contacted in the future by NICE after the completion of this topic. *

(●) I agree

( ) I do not agree

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11. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

(●) I agree

( ) I disagree

The procedure/technology

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

12. Please describe your level of experience with the procedure/technology, for example:

    Are you familiar with the procedure/technology?

    Yes - I have used these devices twice, and have many years of experience providing surgery for patients that might benefit from their use.

13. Have you used it or are you currently using it?

    - Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?

    - Is this procedure/technology performed/used by clinicians in specialities other than your own?

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

    I believe it's use is rapidly expanding within the NHS, although not widespread yet.

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

    - [ ] I have done bibliographic research on this procedure.
    - [ ] I have done research on this procedure in laboratory settings (e.g. device-related research).
    - [ ] I have done clinical research on this procedure involving patients or healthy volunteers.
    - [ ] I have published this research.
    - [ ] I have had no involvement in research on this procedure.
    - [x] I have extensive experience in the procedure within which the device is intended for use, as well as within the disease and patients involved, but have

15. Does the title adequately reflect the procedure?

    - (●) Yes
    - ( ) Other

16. Is the proposed indication appropriate? If not, please explain

    You mean the indications that the reps are proposing? - you have not provided any 'indication' yourself. Anyway, yes, it seems reasonable.

17. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

    Minor variation

18. Which of the following best describes the procedure:

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

19. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?

An addition

20. Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?

No.

21. Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?

What guidance??

22. Do you think the guidance needs updating?

I have no idea - you have not sent me any pre-existing guidance.

Current management

23. Please describe the current standard of care that is used in the NHS.

Medical treatment (steroid nasal sprays and saline douches) first line, then surgery second line as an adjunct to ongoing medical treatment.

24. Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?

If so, how do these differ from the procedure/technology described in the briefing?

Aware no, but there may be alternatives. Some surgeons soak dissolvable nasal packs in corticosteroid solutions, which may provide some similar effects.

Potential patient benefits and impact on the health system

25. What do you consider to be the potential benefits to patients from using this procedure/technology?

Depends on the patient group covered - in some of the most severe cases, these stents might make a significant difference to morbidity and healthcare expense. Indeed, we do not understand how effective these are yet, so that statement may even apply much more widely than I have suggested.

26. Are there any groups of patients who would particularly benefit from using this procedure/technology?

Refractory Chronic Rhinosinusitis - especially in patients likely to need repeated episodes of surgery.

27. Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?

    Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?

Yes - potentially far fewer surgical episodes, and reduced patient morbidity

28. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

It is used during routine sinus surgery in existing facilities for this.
It COULD be used in an awake surgery setting and provide much more efficient treatment options.

29. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

very little.

Safety and efficacy of the procedure/technology

30. What are the potential harms of the procedure/technology?

    Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:

    - Adverse events reported in the literature (if possible, please cite literature)
    - Anecdotal adverse events (known from experience)
    - Theoretical adverse events

Theoretical (I am unaware of any specific reports) :
Risks are intrinsic to this surgical group, but just possibly could be slightly higher.
Orbital injury (problems with eye movements, blindness, double vision)
Skullbase injury and csf leak / meningitis.

31. Please list the key efficacy outcomes for this procedure/technology?

Resolution of symptoms (nasal blockage, anosmia, rhinorrhoea, facial pain / pressure) and in particular the duration of resolution.
To quote a recent publication : "Three randomized controlled trials and a meta-analysis support the efficacy and safety of the use of steroid-eluting implants in chronic rhinosinusitis. Implants placed in the ethmoid sinuses at the time of surgery have been found to significantly reduce postoperative adhesions, recurrence of polyposis, middle turbinate lateralization, the need for postoperative oral steroids and the need for postoperative interventions. Studies also support the ocular safety of steroid-eluting implants."

32. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

By comparison to existing surgical and medical therapies, I have very little concern with regard to safety, and I have some confidence that efficacy is greater with these devices.

33. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

Very little.

34. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- (●) 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.

Abstracts and ongoing studies

35. Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).

Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.

I would suggest you start with Campbell RG, Kennedy DW. What is new and promising with drug-eluting stents in sinus surgery? Curr Opin Otolaryngol Head Neck Surg. 2014 Feb;22(1):2-7. doi: 10.1097/MOO.0000000000000012. PMID: 24275800.

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

Not that I know of.

37. Please list any other data (published and/or unpublished) that you would like to share.

None.

Other considerations

38. Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?

Depends what use it is put to - in my centre it might be considered essential in a few patients a year, or it might considered helpful for 50 or more.

39. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Beneficial outcome measures.

These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.

Endoscopy appearances following surgery at 6 months, 24 months, 5 years.
Return to theatre (for recurrence) - average interval.
Systemic Corticosteroid use over 2 or 5 year interval following surgery.

40. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Adverse outcome measures.

These should include early and late complications. Please state the post procedure timescales over which these should be measured:

Corticosteroid systemic effects - HPA Axis suppresion outcomes. I am no expert to advise on these.
Surgical risks- / complications.

Further comments

41. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

These devices might save us a fortune if they are genuinely effective in preventing returns to theatre for repeated surgery. They may also allow less extensive surgery which can be far more efficiently offered through awake surgery settings.

Declarations of interests

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42. Type of interest: *

- [ ] Direct: financial
- [ ] Non-financial: professional
- [ ] Non-financial: personal
- [ ] Indirect
- [x] No interests to declare

43. Description of interests, including relevant dates of when the interest arose and ceased. *

Nil

44. I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website. *

- (●) I agree
- ( ) I disagree

Signature

45. Name: *

Martyn Barnes

46. Date: *

15/04/2024

View results

Respondent

51 Anonymous

06:12
Time to complete

1. Project Number and Name - (Can be found on email) *

IP963/2

Your information

2. Name: *

Peter Andrews

3. Job title: *

Consultant Rhinologist, Facial Plastic and Anterior Skull Base Surgeon (Professor of RHinology)

4. Organisation: *

University College London Hospitals NHS Trust

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

GMC, BRS, BMA, BSFPS, ERS

7. Nominated/ratified by (if applicable):

N/A

8. Registration number (e.g. GMC, NMC, HCPC) *

4020895

9. I confirm that:

- I am a registered practising professional in the UK/NHS and in good professional standing
- I have specialist knowledge in the technology or disease area
- I will declare all conflicts of interest in relation to the technology under consideration
- I will abide by NICE's governance policies and comply with NICE's processes and methods
- I will abide by the timelines for this topic, as communicated by the coordinator/administrator.

Personal data submitted to NICE can be used for the purposes of carrying out its CHTE outputs. Personal data will be held on NICE's databases and I may be contacted in the future by NICE after the completion of this topic. *

- (●) I agree
- ( ) I do not agree

How NICE will use this information:

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10. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

- (●) I agree
- ( ) I disagree

The procedure/technology

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

11. Please describe your level of experience with the procedure/technology, for example:

Are you familiar with the procedure/technology?

Yes have experience in using and am aware of the technology/indicatons/use.

12. Have you used it or are you currently using it?

- Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?

- Is this procedure/technology performed/used by clinicians in specialities other than your own?

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

Yes used and use in courses etc. we are starting its use in UCLH from May 2024 again.

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

- [ ] I have done bibliographic research on this procedure.
- [x] I have done research on this procedure in laboratory settings (e.g. device-related research).
- [x] I have done clinical research on this procedure involving patients or healthy volunteers.
- [ ] I have published this research.
- [ ] I have had no involvement in research on this procedure.
- [ ] Other

14. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) Other

15. Is the proposed indication appropriate? If not, please explain

yes

16. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

novel concept and dsign and approach, good uses.

17. Which of the following best describes the procedure:

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

18. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?

addition

19. Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?

no

20. Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?

no

21. Do you think the guidance needs updating?

no

Current management

22. Please describe the current standard of care that is used in the NHS.

refractiory crs disease
revision crs surgery
mucocoele
frontal sinus surgry

23. Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?

    If so, how do these differ from the procedure/technology described in the briefing?

no

Potential patient benefits and impact on the health system

24. What do you consider to be the potential benefits to patients from using this procedure/technology?

less need for oral steroids' and antibiotics
less need for revision surgery
less need for more invasive surgery

25. Are there any groups of patients who would particularly benefit from using this procedure/technology?

refractory crs patient
type 2 disease

26. Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?

    Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?

    yes - improved outcomes, fewer hospital visits or less invasive treatment

27. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

    nil

28. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

    yes - minor training takes 10 mins

Safety and efficacy of the procedure/technology

29. What are the potential harms of the procedure/technology?

    Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:

    - Adverse events reported in the literature (if possible, please cite literature)
    - Anecdotal adverse events (known from experience)
    - Theoretical adverse events

    nil

30. Please list the key efficacy outcomes for this procedure/technology?

    beneficial outcomes including less disease severity and less surgery

31. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

    nil

32. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

    cost

33. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

    - (●) 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.

Abstracts and ongoing studies

34. Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).

    Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.

    nil

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

    nil

36. Please list any other data (published and/or unpublished) that you would like to share.

    nil

Other considerations

37. Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?

    500 across the UK per annum

38. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

    Beneficial outcome measures.

    These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.

    N/A

39. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

    Adverse outcome measures.

    These should include early and late complications. Please state the post procedure timescales over which these should be measured:

    Pain, infection rates, need for oral steroids and antibiotics

Further comments

40. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

nil

Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

41. Type of interest: *

- [ ] Direct: financial
- [ ] Non-financial: professional
- [ ] Non-financial: personal
- [ ] Indirect
- [x] No interests to declare

42. Description of interests, including relevant dates of when the interest arose and ceased. *

n/a

43. I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website. *

- (•) I agree
- ( ) I disagree

Signature

44. Name: *

Peter Andrews

45. Date: *

17/04/2024

View results

Respondent

49 Anonymous

25:29
Time to complete

1. Project Number and Name - (Can be found on email) *

Corticosteroid-releasing bioabsorbable stent or spacer insertion during endoscopic sinus surgery to treat chronic rhinosinusitis (IP963/2)

Your information

2. Name: *

Ssan

3. Job title: *

Sunkaraneni

4. Organisation: *

Royal Surrey NHS Foundation Trust

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

GMC

7. Nominated/ratified by (if applicable):

8. Registration number (e.g. GMC, NMC, HCPC) *

4639040

9. I confirm that:

- I am a registered practising professional in the UK/NHS and in good professional standing
- I have specialist knowledge in the technology or disease area
- I will declare all conflicts of interest in relation to the technology under consideration
- I will abide by NICE's governance policies and comply with NICE's processes and methods
- I will abide by the timelines for this topic, as communicated by the coordinator/administrator.

Personal data submitted to NICE can be used for the purposes of carrying out its CHTE outputs. Personal data will be held on NICE's databases and I may be contacted in the future by NICE after the completion of this topic. *

- ○ I agree
- ◉ I do not agree

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice: https://www.nice.org.uk/privacy-notice

10. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

- ◉ I agree
- ○ I disagree

The procedure/technology

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

11. Please describe your level of experience with the procedure/technology, for example:

Are you familiar with the procedure/technology?

Yes; I have used it on more than 20 patients

12. Have you used it or are you currently using it?

- Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?

- Is this procedure/technology performed/used by clinicians in specialities other than your own?

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

I am currently using it. I'm unclear how widespread its use is, but it is increasing.

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

- [x] I have done bibliographic research on this procedure.
- [ ] I have done research on this procedure in laboratory settings (e.g. device-related research).
- [x] I have done clinical research on this procedure involving patients or healthy volunteers.
- [ ] I have published this research.
- [ ] I have had no involvement in research on this procedure.
- [ ] Other

14. Does the title adequately reflect the procedure?

- (●) Yes
- ( ) Other

15. Is the proposed indication appropriate? If not, please explain

Yes

16. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

This is novel in the sense that it is a bioabsorbable device; steroid eluting stents for the sinuses have previously been used.

17. Which of the following best describes the procedure:

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

18. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?

An addition to current standard care

19. Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?

No

20. Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?

Not that I am aware of

21. Do you think the guidance needs updating?

Yes

Current management

22. Please describe the current standard of care that is used in the NHS.

Standard endoscopic sinus surgery

23. Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?

    If so, how do these differ from the procedure/technology described in the briefing?

I do not

Potential patient benefits and impact on the health system

24. What do you consider to be the potential benefits to patients from using this procedure/technology?

Increased likelihood of patency of the sinuses

25. Are there any groups of patients who would particularly benefit from using this procedure/technology?

All patients undergoing sinus surgery

26. Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?

    Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?

Yes, to improved outcomes and fewer hospital visits. No to the degree of invasiveness, but hopefully fewer procedures would be required.

27. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

A standard operating theatre

28. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

Yes, but very basic training

Safety and efficacy of the procedure/technology

29. What are the potential harms of the procedure/technology?

Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:

- Adverse events reported in the literature (if possible, please cite literature)
- Anecdotal adverse events (known from experience)
- Theoretical adverse events

The most common adverse events to patients included infection, oropharyngeal obstruction, and headache/pain. The most common device malfunction reported was migration and expulsion of the stent.

Shah VN, Pasick LJ, Benito DA, Ghiam MK, D'Aguillo C. Complications Associated with PROPEL Mometasone Furoate Bioabsorbable Drug-eluting Sinus Stents From 2012 to 2020. Am J Rhinol Allergy. 2022 Mar;36(2):185-190. doi: 10.1177/19458924211035641. Epub 2021 Aug 3. PMID: 34342518.

30. Please list the key efficacy outcomes for this procedure/technology?

Frontal sinus ostial patency
SNOT-22 score (a PROM)

31. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

None

32. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

None

33. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- ( ) 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.

Abstracts and ongoing studies

34. Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).

    Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.

    Calvo-Henriquez C, García-Lliberós A, Sánchez-Gómez S, Alobid I. Assessing the effect of absorbable steroid sinus implant: a state-of-the-art systematic review. Eur Arch Otorhinolaryngol. 2024 Mar 9. doi: 10.1007/s00405-024-08531-1. Epub ahead of print. PMID: 38459984.

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

    I believe Medtronic have set up a European registry

36. Please list any other data (published and/or unpublished) that you would like to share.

Other considerations

37. Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?

    90% of the target population

38. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

    Beneficial outcome measures.

    These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.

    SNOT-22 scores (3 months, and 12 months)
    Frontal sinus ostial patency (based on ability to cannulate frontal sinus in out-patient setting) (5 years)
    Rates of revision surgery/rescue medication over a 5 year period

39. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

    Adverse outcome measures.

    These should include early and late complications. Please state the post procedure timescales over which these should be measured:

    Infection (1 week)
    Stent irritation (2 weeks)
    Stent migration (2 months)
    Oropharyngeal displacement (2 months)

Further comments

40. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

A further multi centre RCT would help to understand the benefits in the UK population

Declarations of interests

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41. Type of interest: *

- [x] Direct: financial
- [ ] Non-financial: professional
- [ ] Non-financial: personal
- [ ] Indirect
- [ ] No interests to declare

42. Description of interests, including relevant dates of when the interest arose and ceased. *

Expenses paid invitation to attend a conference on the Propel implant in Germany 14-15th March 2024.

43. I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website. *

- (•) I agree
- ( ) I disagree

Signature

44. Name: *

VS Sunkaraneni

45. Date: *

16/04/2024

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP963/2 Corticosteroid-releasing bioabsorbable stent or spacer insertion during endoscopic sinus surgery to treat chronic rhinosinusitis**

Your information

Name:	Yujay Ramakrishnan
Job title:	ENT Skull base consultant
Organisation:	Nottingham University Hospital
Email address:	[redacted]
Professional organisation or society membership/affiliation:	Secretary British Rhinological Society
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	6040055

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

x☐ Please tick this box if you would like to receive information about other NICE topics.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice.

x☐ I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below:

Click here to enter text.

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? Have you used it or are you currently using it? – Do you know how widely this procedure/technology is used in the	I am familiar with the technology of drug-eluting stents in sinus surgery eg Medtronic 'Propel' stents. I am not currently using it. I am also aware that very limited rhinology colleagues in the UK are using this due concerns regarding cost-effectiveness. The speed of uptake within NHS can be rapid if not carefully rationed.

	NHS or what is the likely speed of uptake? − Is this procedure/technology performed/used by clinicians in specialities other than your own? − If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.	 No n/a
2	− Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done bibliographic research on this procedure. I have attended rhinology meetings (BACO 2023) where surgeons from the USA have shared their experience with drug-eluting stents. As always, there are proponents and detractors. The USA and Europe are often initial adopters of new technology. It is often useful for them to share their experience with the UK, as they are more advanced on the learning curve and experience with respect to stents.
3	Does the title adequately reflect the procedure? Is the proposed indication appropriate? If not, please explain. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	Yes Yes It is not established practice in the UK but has been used in USA and Europe for at least 5 years. The manufacturers claim that the drug elution lasts for approximately 30 days. What confounds the clinical outcomes is the need to use of nasal steroids after 30 days. It is therefore challenging to ascertain if the stent or routinely used nasal steroids postoperatively, are actually influencing clinical outcomes. A stent costing £500-1000 and lasting for 30 days, in my opinion, represents poor value, compared to current nasal steroid regimes (spray, drops, nasules, respules) Definitely novel but of uncertain cost-effectiveness

4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	Addition to existing standard care
5	Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure? Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	No More studies on adverse events are available.

Current management

6	Please describe the current standard of care that is used in the NHS.	Comprehensive sinus surgery (definition varies depending on surgeon) Postoperative nasal steroids (spray, drops, nasules, respules, budesonide nasal rinses) Aspirin desensitisation (for Samter triad- available in limited centres nationally).

7	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	No

Potential patient benefits and impact on the health system

8	What do you consider to be the potential benefits to patients from using this procedure/technology?	Niche indication as outlined below
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Limited utility in sinuses with a higher risk of stenosis following sinus surgery eg frontal sinus, to maintain sinus patency. Also patients with refractory sinus disease eg Samter triad to minimise disease recurrence in early postoperative phase.
10	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	Yes Very niche indication as outlined above. It should <u>not</u> be used routinely for all sinus surgery patients due to cost-effectiveness and limited duration of drug elution of the stent. The stent cannot substitute non-comprehensive sinus surgery. It should be used as an adjunct to comprehensive sinus surgery in select patients.

11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Limited training as stent is easily deployed with support from company representatives
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	See above

Safety and efficacy of the procedure/technology

13	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	Migration of stent, fragmentation of the stent which does not dissolve quickly Postoperative infection
14	Please list the key efficacy outcomes for this procedure/technology?	Frontal sinus patency (photo documentation where possible), resolution of frontal sinus symptoms Good symptom control of refractory sinus disease (eg Samter) with PROMS eg SNOT scores
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	n/a

16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	n/a
17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Fewer than 10 specialist centres in the UK with advanced rhinology/anterior skull base surgeons

Abstracts and ongoing studies

18	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	Eur Arch Otorhinolaryngol . 2024 Mar 9. doi: 10.1007/s00405-024-08531-1. Online ahead of print. Assessing the effect of absorbable steroid sinus implant: a state-of-the-art systematic review Christian Calvo-Henriquez et al Otolaryngol Head Neck Surg. 2022 Jan;166(1):179-182 Adverse Events Associated With Corticosteroid-Eluting Sinus Stents: A MAUDE Database Analysis Vishal Narwani 1, Sina J Torabi 1, David A Kasle 1, Rahul A Patel 2, Michael Z Lerner 1, R Peter Manes 1
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	n/a
20	Please list any other data (published and/or unpublished) that you would like to share.	n/a

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	If limited to frontal sinus or refractory sinus disease following comprehensive sinus surgery, across 10 centres nationally, assuming 10-15 cases per centre, the total is 150 cases annually. Once data has been audited and analysed for cost-effectiveness and safety, this may be rolled out to other centres undertaking similar procedures.
22	Please suggest potential audit criteria for this procedure/technology. If known, please describe: − Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. − Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: Please see earlier notes Adverse outcome measures: Please refer to publications listed

Further comments

23	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	There is no doubt about new technologies and drugs making an impact on the management of sinus disease. However, these cannot substitute comprehensive sinus surgery and cheaper treatment options postoperatively like steroid nasal rinses. The NHS is also not investing in aspirin desensitisation programmes nationally for Samter patients, leading to recurrent disease and repeated surgery and oral steroids. The basic management of comprehensive surgery, supporting aspirin desensitisation locally and patient adherence to postoperative nasal steroid regimes remains the cost effective option for the vast majority of sinus disease.

		There are select patients who may benefit from new technologies eg stents or biological agents. This may include refractory patients with Samter triad/nons-Samter who have undergone comprehensive sinus surgery and aspirin desensitisation and/or are high risk of oral steroid exposure (significant osteoporosis, cataract, glaucoma). NICE in conjunction with specialist societies can work collaboratively this niche of patients to ensure that the limited financial resources are spent wisely with robust audit mechanism to capture efficacy and safety. National level negotiation on pricing can also tilt the balance of cost-effectiveness, rather following the pricing model set by the distributors/manufacturers.

NICE National Institute for Health and Care Excellence

Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Choose an item.	none		
Choose an item.			
Choose an item.			

x ☐ I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website.

Print name:	**Yujay Ramakrishnan**
Dated:	**23/4/24**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP963/2 Corticosteroid-eluting bioabsorbable stent or spacer insertion during endoscopic sinus surgery to treat chronic rhinosinusitis**

Your information

Name:	Hesham Saleh
Job title:	Professor of Practice (Rhinology)
Organisation:	Imperial College
Email address:	[redacted]
Professional organisation or society membership/affiliation:	ENT-UK, ERS, BRS, BSFPS. EAFPS. RSE, BAAPS
Nominated/ratified by (if applicable):	NICE
Registration number (e.g. GMC, NMC, HCPC)	4244772

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

X☐ Please tick this box if you would like to receive information about other NICE topics.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public

consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice.

X☐ I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below:

Click here to enter text.

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?	Yes. I have use it for regularly for few years now
	Have you used it or are you currently using it? – Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? – Is this procedure/technology performed/used by clinicians in specialities other than your own?	I personally use it almost every week. I am aware that other centres are also using it regularly but I am not sure if it is widely used in the NHS yet. I expect that it will gradually been taken up more. The technology is applicable to other parts of the upper airway. I understand it has been used in other areas in ENT such as surgery for choanal atresia.

	− If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.	I use it for frontal sinus surgery and polyp surgery.
2	− Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done bibliographic research on this procedure. *Yes* I have done research on this procedure in laboratory settings (e.g. device-related research). I have done clinical research on this procedure involving patients or healthy volunteers. *Currently involved in a multicentre study* I have published this research. *Yes (Javanbakht M, Saleh H, Hemami MR, Branagan-Harris M, Boiano Met al., 2020, A corticosteroid-eluting sinus implant following endoscopic sinus surgery for chronic rhinosinusitis: a UK-based cost-effectiveness analysis., PharmacoEconomics - Open, Vol: 4, Pages: 679-686, ISSN: 2509-4254)* I have had no involvement in research on this procedure. Other (please comment)
3	Does the title adequately reflect the procedure? How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	Yes Novel approach Established practice and no longer new. A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.

		Definitely novel and of uncertain safety and efficacy. Yes but safety has been proven The first in a new class of procedure.
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	Addition
5	Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure? Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	No No significantly but more evidence is becoming available.

Current management

6	Please describe the current standard of care that is used in the NHS.	Occasionally degradable dressings (such as Nasopre) soaked in triamcinolone are inserted postoperatively but they only last for maximum of 2 weeks in contrast to 4 to 6 weeks for the stent which makes them less effective

7	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	Sinuva is a similar implant that lasts for 90 days but is not available in the UK

Potential patient benefits and impact on the health system

8	What do you consider to be the potential benefits to patients from using this procedure/technology?	Less recurrence of sinus disease and potentially less need for surgery
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	CRS with or without nasal polyps, Samter's triad, Allergic fungal sinusitis, CRS in cystic fibrosis…..
10	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	Yes
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	None more than what is available
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes simple taining

Safety and efficacy of the procedure/technology

13	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:	Similar to intranasal steroid sprays and drops. e.g nasal irritation, nose bleed, increased intraocular pressure…

	Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	Displacement, inhalation
14	Please list the key efficacy outcomes for this procedure/technology?	Less recurrence oof disease, less need for topical and systemic steroids. Less need for surgery
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Displacement
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	None that I know of
17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Most or all district general hospitals. Yes A minority of hospitals, but at least 10 in the UK. Fewer than 10 specialist centres in the UK. Cannot predict at present.

Abstracts and ongoing studies

18	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent	Details study reviews and clinical experiences (including mine) were presented in CEORL-HNS conference iin Milan in October 2022

	abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	There is currently a multicentre open interventional study that I am contributing in
20	Please list any other data (published and/or unpublished) that you would like to share.	

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	Between 50 and 80 in y practice
22	Please suggest potential audit criteria for this procedure/technology. If known, please describe: − Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. − Adverse outcome measures. These should include early and late complications. Please state the post	Beneficial outcome measures: SNOT 22, SF-36, NIPF: pre op, 6 weeks, 6 months and 12 months post po, Adverse outcome measures: Ocular pressure, bleeding estimates, same as above

	procedure timescales over which these should be measured:	

Further comments

23	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	N/A

NICE National Institute for Health and Care Excellence

Declarations of interests

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Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Non-financial professional	Received samples of the device	**2017**	**2017**
Non-financial professional	Been involved in publications on the device	**2021**	**2021**
Direct - financial	Gave paid lectures	**2022**	**2022**

x ☐ I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website.

Print name:	**Hesham Saleh**
Dated:	**23-11-2023**