NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1889 Insertion of neo-chordae into the beating heart for mitral regurgitation**

Your information

Name:	Reubendra Jeganathan
Job title:	Consultant Cardiac Surgeon/Clinical Director for Specialist Surgery
Organisation:	Royal Victoria Hospital, Belfast Health and Social Care Trust, Grosvenor Road, Belfast BT12 6BA
Email address:	[redacted]
Professional organisation or society membership/affiliation:	Society of Cardiothoracic Surgery of Great Britain and Ireland, European Association of Cardiothoracic Surgery, Royal College of Surgeons (Ireland)
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	GMC 4706647

How NICE will use this information:

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

☐ 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with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.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 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	Yes, I am familiar with the technology and the procedure. I have done 2 cases under the supervision of a proctor. We were the second unit after Royal Brompton to start using this technology. This procedure is performed by the cardiac surgeon with multidisciplinary support from a trans-oesophageal specialist (cardiologist) and under general anaesthesia in the setting of a cardiac theatre environment. All cases require heart team discussion with input from mitral valve repair surgeons/structural heart cardiologist. If felt appropriate for the procedure, then a dedicated TOE if not already performed is analysed to ensure the patient is suitable for the procedure.

	procedure/technology, please indicate your experience with it.	
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 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 (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 – but could also consider “Beating Heart Neochord Insertion for Mitral Regurgitation” Similar concept of inserting neochord onto prolapsing/flail segment of the mitral valve during open-heart surgery. The difference is beating heart vs still heart on CPB/cardioplegic arrest and the neochords are secured onto the ventricle (against a pledget on the outside surface of the ventricle) as opposed to the papillary muscle. 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.
4	Does this procedure/technology have the potential to replace current standard care or	Unlikely to replace the current standard of care (Conventional mitral valve repair) until proven safety and efficacy (current trial Rechord enrolling, previous Mitrachord study stopped). However,

	would it be used as an addition to existing standard care?	I think this would be an appropriate alternative for patients who are not suitable for conventional surgery due to comorbidities.

Current management

6	Please describe the current standard of care that is used in the NHS.	All patients with severe MR due to degenerative mitral valve disease should be offered mitral valve surgery (repair) by a dedicated mitral valve surgeon. These procedures are done utilising cardiopulmonary bypass with cardioplegia with different access options based on expertise (conventional sternotomy or minimally invasive surgery)
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?	In terms of repair, the Neochord device which utilised artificial chordae made out of Gortex to correct a prolapsing of flail segment or the Mitral Clip, utilises a transcatheter technique (transeptal) to secure a prolapsing segment to a corresponding segment on the opposite leaflet. Not until recently, there was the potential of Harpoon (Edwards Lifesciences), that uses a different device but similar concept to Neochord but this has been withdrawn.

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?	The potential benefit would be time spent in hospital and recovery to baseline. Other potential benefits which will need to be assessed is blood transfusion, arrhythmia and infection +/- pain.
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	With limited data on this procedure against standard of practise, all patients will need to be discussed at heart team, and if felt due to comorbidities, such as previous cardiac surgery, then only considered for this procedure provided it meets criteria for Neochord.
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?	Not at present until evidence for it safety and efficacy is available.
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Theatre will need to ensure appropriate imaging facilities with up to date TOE machine for interpretation and 3D reconstruction.
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes, vitally important that the team are proctored for all the cases until sign-off. Would be beneficial visiting dedicated training centres or bio-simulation initially.

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:	• Air embolism • Allergic reaction • Arrhythmias • Bleeding (with or without requiring transfusion) • Broken ribs • Conversion to standard valve repair surgery • Damage to cardiovascular or nervous tissue • Infection

	Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	• Failure to deliver ePTFE artificial chord to intended leaflet site • Mitral regurgitation (>3) • Mitral valve injury • Pericardial damage • Peripheral embolism • Pulmonary embolism • Stroke (CVA) or TIA • Death
14	Please list the key efficacy outcomes for this procedure/technology?	Freedom from recurrent MR and re-operation. Symptomatic improvement/resolution and survival benefit.
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Patient selection is crucial as only treating leaflet prolapse/flail segment with this technique. However, not addressing annular dilatation, which is standard of care in conventional mitral valve surgery following correction of leaflet prolapse.
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Not to my knowledge.
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. 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).	https://doi.org/10.1093/icvts/ivac053 Randomized Trial of the Neochord DS1000 System Versus Open Surgical Repair (ReChord) . ClinicalTrial.Gov NCT02803957. https://doi.org/10.1093/icvts/ivac139

	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.	
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	ReChord MitraChord - Withdrawn
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)?	Our current practise is to consider this procedure in those not suitable for conventional surgery, but also bearing in mind the other alternative, MitraClip. Therefore, heart team discussion vitally important to ensure these patients are appropriately selected given limited data at present. I would expect <10%.
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.	Beneficial outcome measures: Symptoms – NYHA – 30 days;6 months;12 months;18months, annually 2-5 years QOL - SF-36/KCCQ – change from baseline 1 and 6 months

	– Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Adverse outcome measures: Safety – Freedom from all cause mortality, disabling stroke and life threatening bleeding at 30 days post-implant Performance – procedure success measured at 30days post-treatment as measured by technical success with reduction of MR to mild or less and absence of major device and procedure related SAE. Annually Freedom from re-operation up to 5 years Freedom from moderate or more MR annually up to 5 years

Further comments

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

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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
Non-financial professional	Assessment of the Safety and performance of the Harpoon Beating Heart Mitral Valve Repair System; a multi-centre post market study (Ascend)- PI of UK component	**1/12/2020**	**25/10/2022**
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:	**Reubendra Jeganathan**
Dated:	**29/12/2022**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1889 Beating heart mitral valve repair by artificial chordae insertion for mitral regurgitation**

Your information

Name:	Mr Rana Sayeed
Job title:	Consultant Cardiac Surgeon
Organisation:	Oxford University Hospitals NHS Foundation Trust
Email address:	[redacted]
Professional organisation or society membership/affiliation:	Society for Cardiothoracic Surgery in Cardiothoracic Surgery in Great Britain & Ireland (SCTS)
Nominated/ratified by (if applicable):	SCTS
Registration number (e.g. GMC, NMC, HCPC)	3556494

How NICE will use this information:

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

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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 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	I have not used the technology but have had discussions with a company representative about introducing it to our centre. I am familiar with the literature describing the slowly accruing clinical experience since its introduction about 10 years ago. The technology is only used within adult cardiac surgery, but cases are selected by a multi-disciplinary heart valve team including cardiac surgeons and cardiologists. Cardiologists refer patients with mitral regurgitation to cardiac surgeons, or directly to a Mitral MDT, and the MDT would usually recommend this technology if indicated. The technology is in use in a handful of UK centres. There are two systems in clinical use: the Edwards HARPOON and the NeoChord DS1000 devices. Both use a similar less-invasive approach for beating heart mitral valve repair.

	procedure/technology, please indicate your experience with it.	
2	– Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have had no involvement in research on this procedure.
3	Does the title adequately reflect the procedure? Is the proposed indication appropriate? If not, please explain. Does this have a multi-indication? 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 The indication is appropriate, in selected case as recommended by a Mitral MDT/Heart Valve Team The technology represents a novel approach based on an established concept. Artificial chordae have been used for repair of mitral regurgitation for over 30 years but with an open approach on an arrested heart. However, the technology only addresses one component of the pathology underlying mitral regurgitation; artificial chordae replace elongated or ruptured native chordae but do not address the mitral annular dilatation that accompanies chronic mitral regurgitation Definitely novel and of uncertain medium and long-term (>2-3 years) safety and efficacy.
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?	Currently, this technology would be used as an addition to the existing standard of care – surgical mitral valve replacement, whether by sternotomy, minimally invasive, or robotic approaches – in selected cases as recommended by a Mitral MDT, usually because of high surgical risk. Depending upon the results of ongoing clinical studies, this technology may be suitable for a wider range of clinical cases, but never replace the current standard of care because of the limitations described above.

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 Not applicable, guidance in development

Current management

6	Please describe the current standard of care that is used in the NHS.	Surgical mitral valve repair on an arrested heart using a sternotomy minimally invasive, or robotic approach with a combination of artificial chordae, leaflet resection, and annuloplasty techniques
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?	Trans-catheter edge-to-edge repair is a percutaneous approach to treating mitral regurgitation on a beating heart. TEER has a different mode of action: the prolapsing mitral leaflets are apposed with a clip device to restore mitral competence. It is used in selected higher surgical risk cases as recommended by a Mitral MDT. There is an ongoing international randomised clinical trial comparing TEER with surgical mitral valve repair (PRIMARY). There are percutaneous mitral valve replacement technologies, e.g. Abbott Tendyne, Edwards SAPIEN M3, that treat mitral regurgitation by valve replacement rather than repair.

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?	A less invasive approach allowing a shorter in-hospital stay and faster out-of-hospital recovery with less use of hospital resources, e.g. ICU stay, blood transfusion.
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients at high or prohibitive surgical risk that may not be otherwise treatable, e.g. mitral valve anatomy unsuitable for TEER or percutaneous mitral valve repair.
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?	A less invasive approach allowing a shorter in-hospital stay and faster out-of-hospital recovery with less use of hospital resources, e.g. ICU stay, blood transfusion.
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Standard clinical facilities widely available are suitable; however, more widespread availability of hybrid operating theatres with in-built X-ray screening facilities would facilitate wider uptake.
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Current mitral surgeons would need to undergo bespoke training in devices suitable for this procedure to ensure safe practice. The MDTs recommending this procedure would also need education in the current state of technology, supporting evidence, and case selection.

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:	Mortality < 1% Stroke < 0.3% Myocardial infarction < 0.5% Access and vascular complications < 0.5%

	Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	Bleeding 1% Acute kidney injury 3% Cardiac arrhythmias or conduction disturbance 20% Pericardial effusion 6%
14	Please list the key efficacy outcomes for this procedure/technology?	Technical and procedural success Procedural mortality Residual mitral regurgitation Conversion to open surgical repair Medium and long-term recurrent mitral regurgitation, reintervention, mortality, and heart failure Incidence of significant complications such as stroke, myocardial infarction, access and vascular complications, bleeding, acute kidney injury, arrhythmias or conduction disturbance
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Medium and long-term outcomes – mortality and heart failure Impact of not addressing mitral annular dilatation leading to recurrent mitral regurgitation
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Impact of not addressing mitral annular dilatation leading to recurrent mitral regurgitation
17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	A minority of hospitals, but at least 10 specialist centres in the UK.

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	Unaware of any recent abstracts or conference proceedings

	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.	
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Randomized trial of the Neochord DS1000 system versus open surgical repair (ReChord) NCT02803957 Multicenter post-market observational registry of the Neochord artificial chordae delivery system (AcCHORD) NCT04190602
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)?	< 100 cases each year (< 3% of current surgical mitral repairs) depending upon the results of ongoing clinical trials
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	Beneficial outcome measures: 5-year survival, heart failure readmission rates, and freedom from worse than mild mitral regurgitation, PROMS

	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:	Adverse outcome measures: 5-year mortality – all-cause and cardiovascular, heart failure readmissions, reintervention, recurrent mitral regurgitation, new, tricuspid regurgitation, new atrial fibrillation

Further comments

23	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	None

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Declarations of interests

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Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Choose an item.			
Choose an item.			
Choose an item.			

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

Print name:	**Rana Sayeed**
Dated:	**1-Jun-2025**

View results

Respondent

1 Anonymous

09:46
Time to complete

Your information

1. Name: *

Enoch Akowuah

2. Job title: *

Cardiac Surgeon

3. Organisation: *

South Tees NHS Foundation Trust

4. Email address: *

[redacted]

5. Professional organisation or society membership/affiliation: *

Society for cardiothoracic Surgery in Great Britain and Ireland

6. Nominated/ratified by (if applicable):

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

4399885

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

8. 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.

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

   Are you familiar with the procedure/technology?

   I am familiar with the procedure but haven't performed it personally

10. 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.

    Limited to a small number of units currently

    Uptake likely to be low due to lack of comparative studies proving efficacy

11. 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

12. Does the title adequately reflect the procedure?

- (●) Yes
- ( ) Other

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

A novel approach

14. 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.

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

It could replace current standard if shown to be effective in appropriate RCTs

Current management

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

Surgical mitral valve repair

17. 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?

Transcatheter edge to edge surgery

Potential patient benefits and impact on the health system

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

minimally invasive

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

Unceratin

20. 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

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

hybrid O

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

Yes
likely to have a significant learning curve

Safety and efficacy of the procedure/technology

23. 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

lack of efficacy
bleeding
heart failure
Emergency surgery

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

Prolonged freedom form mitral regurgitation, heart failure, repeat interventions, death

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

No adequately powered RCTS have been published comparing this to standard care

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

yes

27. 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

28. 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.

Not aware

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

Not aware

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

N/A

Other considerations

31. 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)?

>1000

32. 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.

33. 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:

Recurrent mitral regurgitation
emergency/urgent surgery
repeat intervention
heart failure
death

Further comments

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

Non

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.

35. Type of interest: *

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

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

NA

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- (•) I agree
- ( ) I disagree

Signature

38. Name: *

Enoch Akowuah

39. Date: *

30/11/2022

View results

Respondent

124 Anonymous

67:40
Time to complete

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

Interventional Procedures Programme Invitation to act as a professional expert Beating heart mitral valve repair by artificial chordae insertion for mitral regurgitation (IP1889)

Your information

2. Name: *

Alison Duncan

3. Job title: *

Associate Specialist

4. Organisation: *

The Royal Brompton Hospital, part of Guy's and St. Thomas's foundation trust

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

British heart valve Society (Secretary), cardiovascular Society, ISMICS, PCR Mitral Focus Group, PCR Tricuspid Focus Group, CSI Frankfurt, British Society of heart failure, BISMICS, EACTS, TCT, ACC

7. Nominated/ratified by (if applicable):

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

GMC registration #4202105

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, which have been communicated by Zoe Jones.

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 am familiar with this technology. I am the Lead Interventional Echocardiologist at the Royal Brompton Hospital, and I have image-guided 50 transventricular Neochord procedures, with my first procedure being performed in 2016. I am also the only UK imaging Proctor for this procedure, guiding procedures at the Royal Sussex County Hospital, Wolverhampton Hospital, Kings College London, and Blackpool Hospitals

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 used and I am currently using this procedure
Currently, the procedure is predominantly performed at the Royal Brompton Hospital.
It is not used in specialties other than cardiothoracic surgery.

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).
- [x] I have done clinical research on this procedure involving patients or healthy volunteers.
- [x] 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
- ( ) No
- ( ) Other

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

It is appropriate

16. Does this have a multi-indication?

No

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?

This procedure has been available in the UK since 2016
The concept of mitral valve repair using neocords is not new, but the transventricular approach, using a beating heart rather than cardiopulmonary bypass, is the variation on a tried untested surgical technique

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?

In patients who have recurrent mitral regurgitation following previous surgical mitral valve repair, particularly if there is prolapse of the posterior mitral valve leaflet, this procedure has the potential to replace current standard of care of redo mitral valve repair surgery. Currently it is used in addition to existing standard of care

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

No

21. Do you think guidance would be helpful on this topic?

- (●) Yes
- ( ) No

Current management

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

There are 2 situations to describe
1. Native mitral valve regurgitation due to degenerative mitral valve disease. The current standard of care for these patients is conventional mitral valve repair with cardiac surgery cardiac surgery (using either a minimal access technique or via median sternotomy) to repair the mitral valve. During mitral valve repair surgery, an annuloplasty ring is usually implanted into the mitral valve annulus, and the degenerated mitral valve leaflet repaired using surgical neochords.
2. Recurrent mitral valve regurgitation following previous mitral valve repair surgery. The standard of care for these patients is redo cardiac surgery (either minimal access or via median sternotomy).

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?

1. To treat native mitral valve regurgitation: Transcatheter mitral valve edge-to-edge (MV-TEER) intervention is a potential alternative to this procedure in patients who deemed not clinically suitable or fit for conventional mitral valve surgery
2. To treat recurrent mitral valve regurgitation following previous mitral valve repair surgery: MV-TEER can be considered, but is frequently not technically achievable to perform in patients with previous annuloplasty ring due to the potential risk of developing mitral stenosis, particularly if the previous annuloplasty ring is small

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?

Insertion of tansventricular neochords avoids the need for cardiopulmonary bypass.
It is a less invasive procedure than conventional cardiac surgery
For both of the reasons above, the recovery time is therefore potentially faster than conventional mitral valve surgery
Furthermore, undergoing transventricular Neochord does not prohibit future conventional cardiac surgery.

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

Patients who have recurrent mitral regurgitation following previous mitral valve cardiac 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?

Redo surgery can be challenging in patients who have previously undergone cardiac surgery. There are longer procedural times, risk of adhesions, risk of bleeding. Therefore alternative therapies that can treat recurrent mitral regurgitation that avoid the need for redo surgery or cardiopulmonary bypass would be of potential benefit.

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

The transventricular neochord procedure is already a relatively safe procedure, particularly compared to redo cardiac surgery. A important ongoing clinical risk is that of bleeding at the puncture site into the left ventricle, as the neochord introducer does not have a haemostatic valve. Nevertheless, any bleeding can be auto transfused back into the patient. The other limiting factor is the low number of trained interventional echo cardiologists to image-guided the procedure.

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

Yes. Both the operating surgeon and interventional cardiologist need specific 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 procedure is a relatively low risk procedure. The main clinical side effect is of bleeding at the site of the introducer into the left ventricle.

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

Reduction in mitral regurgitation, avoiding the need for cardiopulmonary bypass
Short hospital stay
Short recovery time

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?

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.

    1. Gammie JS, et al. beating heart mitral valve repair using a novel ePTFE chordal implantation device. JACC 2018; 71: 25-36
    2. Salizzoni S et al. Microinvasive, off-pump, transventricular neochord implantation in recurrent mitral valve regurgitation after open heart surgical repair. Presented at the AATS meeting Seattle 2025

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

    Not that I am aware of

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

    See above

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)?

    Possibly 20-30% of all patients being considered for redo mitral valve cardiac surgery

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.

    Length of hospital stay
    Durability of procedure in terms of absence from recurrent mitral regurgitation on echocardiography

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:

    Bleeding risk (in hospital)
    Rates of recurrent mitral regurgitation (first 5 years following intervention)

Further comments

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

    None

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 have been a Proctor and therefore have received consultation fees from Neochord

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: *

Alison Duncan

45. Date: *

09/05/2025

View results

Respondent

126 Anonymous

15:40
Time to complete

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

Beating heart mitral valve repair by artificial chordae insertion for mitral regurgitation (IP18

Your information

2. Name: *

Ee Ling Heng

3. Job title: *

Consultant Cardiologist Structural Heart Intervention

4. Organisation: *

Royal Brompton & Harefield Hospitals

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

BCIS

7. Nominated/ratified by (if applicable):

BCIS

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

6148852

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, which have been communicated by Zoe Jones.

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

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 - undertaken by surgeon within my institution.
Regular discussions about the technology as a potential treatment option within our cross site Mitral MDT/Heart team.

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 not aware of how widely this is being used in the NHS - I believe it is currently limited to dedicated specific centres.

Yes - performed by consultant cardiac surgical colleagues

Involved in patient selection on regular basis as part of our twice weekly Mitral Heart team discussions as a potential treatment option.

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
- ( ) No
- ( ) Other

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

Yes

16. Does this have a multi-indication?

No

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 on established surgical Neochordae technique - safety and efficacy relative to established surgical techniques to be determined

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 existing standard of care

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

No

21. Do you think guidance would be helpful on this topic?

- (●) Yes
- ( ) No

Current management

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

Standard of care for management of severe symptomatic mitral regurgitation determined by patient's age, valve anatomy, co-morbidities as to whether conventional surgical repair of mitral valve/replacement, transcatheter techniques or beating heart artificial chordae can be offered.

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?

Options include Neochord and Harpoon (not currently commercially available in the UK)
Not substantially different

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?

Minimally invasive approach compared to conventional surgery via median sternotomy

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

Multi-morbid patients who may be too frail for conventional cardiac surgery
Patients with suitable anatomy (typically centrally at A2/P2)

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?

It could indeed lead to less invasive treatment (compared to surgery via median sternotomy)
Durability data less certain in terms of its impact on long term clinical outcomes
Given the technology is only applicable to specific anatomies of the mitral valve, there is currently limited scope for extending it across a broader range of mitral valve pathologies

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

Surgical expertise and training
Development of image guidance by interventional echo colleagues to ensure optimal imaging peri-procedurally

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

Yes - surgical 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

Neochord rupture leading to recurrence of significant mitral regurgitation
Durability requires further clarification - recurrence of MR does not seem uncommon
Recognised surgical complications - bleeding, infection, conversion to median sternotomy

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

Efficient and durable reduction in severity of mitral regurgitation
Incidence of surgical related adverse outcomes
Patient symptom improvement

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

No concerns, but the efficacy/durability of the technology requires further clarification

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.

NA

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

Not aware of

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

NA

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)?

I would estimate <10% of patients with severe symptomatic mitral regurgitation given the specific screening/anatomical criteria

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.

Procedural success - successful placement of artificial chordae intra procedurally, degree of MR reduction
Procedural safety parameters
Efficacy of therapy in achieving reduction in mitral regurgitation severity
Durability of repair via this method

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:

Further comments

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

None

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. *

not applicable

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: *

Ee Ling Heng

45. Date: *

15/05/2025

View results

Respondent

125 Anonymous

34:56
Time to complete

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

IP1889 Artificial chord insertion for mitral valve repair

Your information

2. Name: *

ishtiaq ahmed

3. Job title: *

Consultant Cardiac Surgeon

4. Organisation: *

University Hospitals Sussex

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

SCTS BISMICS RCS(Eng)

7. Nominated/ratified by (if applicable):

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

4194671

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, which have been communicated by Zoe Jones.

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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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

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 used myself. Uptake currently is limited to a few centres. It is used extensively in Europe also. There are specific requirements for suitability in terms of measurements of the mitral apparatus based on Trans oesophageal echo. Currently it i snot a first line treatment in the UK for primary degenerative mitral valve disease but has been used as part of patient choice. There is increasing evidence to use in redo mitral procedures providing a lower risk option with good results (recently presented at AATS 2025)

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).
- [x] I have done clinical research on this procedure involving patients or healthy volunteers.
- [x] 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
- ( ) No
- ( ) Other

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

yes

16. Does this have a multi-indication?

yes

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?

It is innovative. Involves small incisions. No cardiopulmonary bypass is needed. The risks are lower than a conventional mitral procedure - esp in the redo setting. Longer term results are dependent on the mitral valve pathology and anatomy with better results in simple lesions associated with P2

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. It would be another option available to the multidiciplinary team and patient

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

no

21. Do you think guidance would be helpful on this topic?

- (●) Yes
- ( ) No

Current management

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

European guidelines - mitral repair by stermotomy or mini Right thoracotomy. In high risk cases edge to edge catheter techniques

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?

Low risk. Micro invasive. Keeps options open for all other procedures in the future. Short length of stay. Faster return to activity

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

Redo mitral procedures and those where the mitral anatomy fits the desired anatomic measurements

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 - less invasive treatment and shorter hospital stay

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

Staffing infrastructure - need for imaging specialist and surgeon in the same theatre aswell as anesthetist. Other equipment is routinely available

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

Yes. Training with the device to become familiar with deployment of the goretex sutures and training in the echo views

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

Bleeding. Recurrent mitral regurgitation

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

Microinvasive. Lower risk in redo procedures. Shorter length of stay

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

Long term efficacy in complex lesions of the mitral valve

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

I would not call it controversy but there is definitely training needed and a learning curve. Would be best done I think in a limited number of centres by surgeons who have had the training and who all work together to imptove outcomes

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.

AATS 2025 Neochord in recurrent MR after MV repair with ring

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

ReCHORD trial

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

EJCTSurgery An early eurpean experience of transapical off pump Mitral valve repair
A Colli

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)?

10%

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.

Length of stay
ITU stay
Pain
Mortality
Recurrent mitral regurgitation at 1 year
Reduction of LV volume at 1 year

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:

Recurrent mitral regurgitation at 6 months and 1 year

Further comments

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

It is a good technology. It definitely needs training and there is a learning curve. Would be best introduced by surgeons who have training in a small number of centres probably by having a consistency of operators. There is now accumulating evidence of its benefit in redo procedures.

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. *

I use the technology and have produced patient information material to help inform patients. In addition data from my patients have been part of the manuscript presented at AATS 2025

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: *

Ishtiaq Ahmed

45. Date: *

08/05/2025