IP1889 Off-pump minimal access mitral valve repair by artificial chordae insertion to treat mitral regurgitation

IPAC date: 11/12/2025

Com. no.	Consultee name and organisation	Sec. no.	Comments [sic]	Response
1.	Consultee 1 Cardiac Surgeon	Not specified	I am a cardiac surgeon who has used this device in the last 2 years in first time and redo patients. My specialist area is mitral repair and minimal access surgery. I have had laboratory training in Neochord and been proctored when performing cases. The procedural success is high as it is a relatively straightforward device to use. Patient selection is important and the COREecho lab at Neochord are very helpful in delineating measurements to predict post procedure success. This is key. I think it important to look at cases in the redo setting - patients who have had previous successful mitral repair who now have repeat flail or prolapse. I have found this device particularly useful in this context. These are a very separate group of patients.	Thank you for your comment. Consultee highlights their view on the usefulness of the procedure in re-repair mitral valve cases, noting their view on good procedural outcomes and reduced hospital stay. Consultee states that this group faces higher surgical risks and suggests recognising them as a distinct subgroup. In section 3.7 the committee have acknowledged that the procedure can be used in people who have previously undergone surgical mitral valve repair. It was agreed that

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			Conventional surgery has risks in literature of 6-10% depending on patient demographics. Having been able to use this device has been very useful in these patients. My experience has shown a good procedural success and a less than 3 day postprocedural stay with no mortality. The neochord device does not preclude further intervention and provides a lower risk option in these patients. It restores anatomical configuration of the leaflets in the same way as the initial surgical repair. Other interventions such as Edge to edge clips leave thrombogenic material attached to the leaflets and preclude any future repair, and have variable results. The Neochord results are predictable if the algorithms from the company are followed. It would be useful in the document to have a separate section for these patients. I have contributed data to the international registry (OMNI) which was presented at AATS this year and to the paper being presented in New York Dec 2025 at the Mitral Conclave in New York (Lead author for that is Salizzoni) on using Neochord in the redo setting. It provides good results with low risk and short post procedure stay.	further evidence generation on the use of the procedure in re-repair cases would be valuable, particularly given the higher surgical risk in this group. Please also note that the definition of 'unsuitable' in recommendation 1.1 reflects a risk-benefit assessment between the patient and the cardiac surgeon. If a patient (whether for a first procedure or a re-repair case) is deemed to be at too high surgical risk, they would be eligible for this procedure under this recommendation. The company submitted new evidence relating to the use of this procedure in re-repair cases, which the committee considered at the second interventional procedures advisory committee.

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				Committee discussed potential amendment to the recommendation. Committee amended the recommendation to '***considered*** unsuitable by the multidisciplinary team' for recommendation 1.1, and '***considered*** suitable by the multidisciplinary team' for recommendation 1.2 to highlight the importance of a multidisciplinary team when making decisions regarding patient selection.
2.	Consultee 2 Dot Medical	Not specified	NICE Technology evaluations New Data presented by Prof. Stefano Salizzoni in 2025 at AATS demonstrates unequivocable evidence of the benefits of Neochord over Conventional Surgical Mitral Valve re-repair (Redo). Conventional Surgical Mitral Valve Redo v Neochord is as follows: Mortality Post-op at 30 days: 13% v 1.4% ICU Stay: 4 days v 18 hours General Ward Stay: 15 days v 4 days AF Post procedure: 39% v 4.1%	Thank you for your comment. Consultee highlights new data which they think shows improved outcomes with the procedure compared to conventional surgical mitral valve re-repair. The consultee stated that the procedure should be recommended as an option for

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			Post-op dialysis: 14% v 0% Return to theatre for Post-op bleeding: 8.3% v 0% The data for Conventional Surgical Mitral Valve Redo is readily available at "Reoperative mitral valve surgery in the UK: 20-year trends and early outcomes" – International journal of cardiology – 2025. It examines 1239 patients over a 20 year period. Professor Salizzoni's data for Neochord Mitral Valve Redo from 26 centers was presented at AATS in 2025. It examines 72 patients, 13 of which are from the UK. In total there have been over 100 publications (1000+ patients) involving Neochord. Neochord has been used in over 2500 mitral valve repairs world-wide. There is no question that on reduction of mortality, hospital stay, complications, dialysis, Post-op AF, Neochord should be recommended as a critical tool available for Mitral Valve repair and in particular Re-repair (redo). References: Micro-invasive, off-pump, trans-ventricular neochordae implantation in recurrent mitral valve regurgitation after open heart surgical repair (Stefano Salizzoni, AATS 2025) Reoperative mitral valve surgery in the UK: 20-year trends and early outcomes – International journal of cardiology – 2025	mitral valve repair, particularly in redo cases. Please see response to comment 1. Committee discussed potential amendment to recommendation. Committee recognised the potential value of this procedure in the re-repair population. However, it noted that the evidence for the use of this procedure for re-repair is limited, uncertain and based on a highly selected population. It recommended that further evidence should be collected to better understand the potential benefits and harms of the procedure in this group. Please see committee comment 3.14 in final guidance.

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			With best wishes	
3.	Consultee 3 Dot Medical	Not specified	In response to the email received stating the summary of opinion during the NeoChord evaluation I would like to appeal, requesting further consideration that the procedure be recommended, especially for the redo (re-repair) mitral valve patient population. It was a surprise for all involved in preparing and representing the NeoChord submission to the NICE recommendation committee to receive this unfavourable outcome, which states that NeoChord could only be considered if there were no other option for a patient. For the redo (re-repair) patient population, favouring conventional surgical (open chest) mitral valve repair over this safe, quick procedure demonstrating such promise in numerous studies, including UK patients, seems to vote against the overwhelming data in its favour. For further clarity, these patients have had previous mitral valve repair through a traditional sternotomy, and are at a much higher risk of death, AF, stroke, and much longer recovery than by using a safe and effective mitral valve repair tool such as NeoChord. We are pleading with you to evaluate this technology further, to take into consideration all of the research done to prove safety and efficacy, and also the impact that offering this procedure has for the patients, which holds the greatest importance in everything that we do. Over 2500 patients have been treated with NeoChord across Europe with over 65 of those patients being treated in the UK. There are over 100 studies, published from 2013 – present day, all demonstrating correlation in their data. I have helped	Thank you for your comment. Consultee requests that this procedure be recommended for re-repair mitral valve procedures, citing observational/registry evidence and UK experience which they think demonstrates that it is a safer and less invasive option than conventional re-repair surgery. Please see response to comment 1. Committee discussed potential amendment to recommendation. Please see response to comment 2. Consultee mentions appeal. To be clear on the process, the topic was at the consultation stage when this

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			numerous surgeons establish their practices with NeoChord over the last 8 years and seen first-hand the incredible results the procedure can offer, often with symptoms diminishing right after the procedure. This surgical technique has provided patients with an improved recovery, and most importantly the ability to live a normal life again, often being able to play with their grandchildren carrying out activities that they never thought possible. Conventional surgical mitral valve re-repair requires another major surgery involving prolonged times on a ventilator, re-opening the patient's sternum, arresting the heart, placing them again on cardiopulmonary bypass (CPB) to access and re-repair the valve. CPB, especially for valve surgeries, is also associated with longer cross clamp times, major recovery times and has potential for cognitive impairment, organ impairment, and organ failure (Madigan E. Stanley, 2022) making the time the patient is on a ventilator under CPB a major factor in determining their surgical risk for re-operation. Patients that are requiring treatment following a failed previous surgical mitral valve repair are faced with a difficult decision to undergo a second open surgery with higher operative risks that most likely will result in a replacement of the patient's valve, or possibly be deemed ineligible or high risk for a second open surgery. The current transcatheter options (ViR, TEER) may not be anatomically feasible or durable and carry additional substantial risks, and fail to preserve the native anatomy for future intervention if needed. The majority of redo surgeries also result in valve replacement which carries higher risk of adverse events (Luke J. Rogers, 2025) including risk	comment was received. This stage gives consultees an opportunity to comment on the draft guidance. It is not an appeal stage of the process.

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			of future prosthetic valve failures and does not align with the clinical standard of care that repair is superior to replacement. A multi-centre registry aimed at evaluating the feasibility, safety, and outcomes of re-repair using the NeoChord procedure was conducted across 26 centres (Stefano Salizzoni, 2025) and studies 72 consecutive cases. The patients included in this registry all had severe recurrent MR at baseline due to leaflet prolapse following a failed previous surgical repair including ring annuloplasty. The key efficacy outcomes were technical success and MR at follow up. Safety outcomes included operative mortality, and 30-day composite of cardiovascular death, recurrence of severe MR, and need for reintervention. This study recently presented by the study investigators at The American Association for Thoracic Surgery | AATS 2025, showed that the NeoChord procedures were completed with 100% technical success with no operative mortality. At latest follow-up, nearly 90% of patients had mild or less mitral regurgitation and 92.8% of the patients were in NYHA I, indicating significant improvement in quality of life. Perioperative complications were rare. 30-day mortality included one death: a compassionate-use patient who had requested not to be resuscitated in case of complications. Follow up (6 months-10 years) showed freedom from reoperation at 93.1%. The NeoChord technique showed excellent results in terms of safety (low mortality and complications), efficacy (high success of re-repair) and encouraging durability of the repair. Though published long-term clinical follow up beyond 10 years remain limited, these results indicate excellent safety	

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			outcomes and patient benefits which outweigh any risk for this patient population. The NeoChord DS1000 procedure used in a mitral valve repair procedure, is not a valve replacement procedure and as such it replicates the native chordal support, preserving the native valve and avoiding valve replacement that carries additional risks including risk of future prosthetic valve failures. I have summarised a table below demonstrating the risk involved by offering a patient redo open chest mitral valve repair and NeoChord minimal access through a mini thoracotomy. Table1 – Comparison of outcomes in Redo conventional surgery vs NeoChord repair Factor Redo conventional MV repair (1239) Redo MV Repair with NeoChord (72 including 13 from UK centers) % Mortality post op 13% 30-day mortality 0% but 1.4% 30-day mortality ICU stay 4 days 18 hours General ward	

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			stay 15 days 4 days AF post procedure 39% 4.1% The study to confirm these findings has been attached with the submission. The study carried out over 20 years of redo mitral valve procedures in the UK, containing a patient pool of n=1239 states an overall mortality of 5.2% in a primary open chest mitral valve repair, increasing to 13% when carrying out conventional open chest redo mitral valve repair. With NeoChord, our redo mitral valve mortality is 1.4% at 30-days. This is without considering the other post op complications associated with redo mitral valve conventional surgery, such as 14% of patients requiring dialysis, 8.3% of patients requiring a return to theatre immediately post op for bleeding, and finally an increase in post op length of hospital stay of 15 days, compared to an average of 4 days post operative stay when using the NeoChord technology. A new study, presented at AATS by Prof. Stefano Salizzoni in 2025 detailing his registry of multicentre results, n=72 is summarised below. Table 2 – Summary of Salizzoni presentation Overall Surgical Time, min 138.5 (+/- 61.0)	

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			Average Number of Chords 3 (2-6) End Procedure mild MR 19/26 patients (the rest moderate, with none severe) No ICU Stay 20/26 patients Post op AF 4.1% 4 (4-5) 30-day mortality 1.4% (1 patient with other complications) MVARC Procedure success 95.8% Conventional surgical mitral valve repair is associated with increased mortality, complications and recovery time. NeoChord should be a viable and acknowledged option to treat this patient group, safely and effectively. It should also be considered for primary prevention in a suitable patient group, but an essential tool for the treatment in patients with failed traditional mitral valve repair.	
4.	Consultee 3 Dot Medical	Not specified	Safety and efficacy In total, 21 articles which reported clinical performance and/or safety outcomes were included in the literature review for the NeoChord DS1000, covering the period between December 2013 and September 2024. These studies included 1,290 patients in total. On average (median), the age of	Thank you for your comment. Evidence on safety and efficacy has already been considered in developing the draft recommendations. Additional

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			the patients was 64 years, and the majority of patients (72%) were males. All studies were restricted to primary (i.e., degenerative) MR. The majority of patients had severe MR (grade 4+) at the time of inclusion. The mean follow-up time after the procedure was 12 months. As well as attaching the publications on safety and efficacy, the summary of the findings in these essential documents are detailed below. Table 3 – Summary of performance data Performance Endpoint References Median Range Technical Success rate % 13 99% 83-100% Patient success rate % (6 months/12 months/2 years/3 years)	evidence provided by the company has been included in table 2, table 3 and appendix B of the overview. No change to guidance.

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			2/3/2/1 94%, 91%, 87%, 81% 84-100% Acceptable MR reduction (MR<2) -leaving OR 9 100% 97-100% -1 year 10 94% 86-100% -3 year 2 87% 79-94% Reintervention at any time over 5 years 10 7% 0-32% Conversion to open repair 13 1% 0-17% Table 4 – Adverse events recorded in NeoChord data	

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			Safety Endpoint References Median Range Mortality rate (at any time from procedure to 5 years) 16 0.7% 0-6.7% Myocardial infarction 13 0% 0-2% Bleeding complications 10 1.3% 0-15% New arrhythmias or conduction disturbances 15 22.5% 0-41.2% Acute kidney injury 13 2.6% 0-14% Outcomes of transapical mitral valve repair with neochordae implantation – completed by the Padova NeoChord group in 2023 detailed over 100 patients during a 3-year period of all suitability's. Mortality at 30-days was 2%, procedure success was 98%, and severe mitral valve regurgitation	

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			reoccurrence at 5 years was 14%. Patients were a mixture of favourable and unfavourable anatomies. In the acute safety and efficacy of the NeoChord procedure study by Colli et al in 2015, 62 patients were evaluated in a 1-year period, where procedural success was achieved in all patients. At 30-days mitral regurgitation was still absent in half of patients, and only 8 patients were at 2+ or more which all had successful retensioning of the chords. Safety outcomes include low rates of major complications, and efficacy is supported by the reduction of mitral regurgitation (MR) and improved clinical status in the short to medium term.	
5.	Consultee 3 Dot Medical	Not specified	Conclusion NeoChord has been demonstrated as a safe and effective treatment for mitral valve repair. We offer a thorough training platform which ensures that every surgeon offering the technology can confidently perform the procedure on the patient with a high degree of expert ability. Support from the whole NeoChord surgical family is always available. We have numerous publications highlighting case success rate, mortality and procedure longevity. In order to correct a statement in the response from NICE, we do not have control over the patients submitted to us, and there is no bias in our studies. We have included patients of all types and have clearly indicated that procedure results will vary on patient type and suitability. However, we	Thank you for your comment. Consultee emphasised that this procedure is safe and effective and supported by published evidence and highlighted its potential value in re-repair cases. Please see response to comment 1.

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			will always support a surgeon, especially if they tell us that the patient has no other option and so have included these ‘compassionate’ cases for full transparency. NeoChord are a wonderful company to represent in the UK, I take so much pride in my role for them. They are passionate, caring, compassionate and strive for the best outcome for every patient submitted to us as a potential NeoChord candidate. Our patients are so grateful for what we have done for them and this can be shown in our case studies and patient video: Of course, it is always important to note that as well as a safe and effective tool at repairing the mitral leaflet functionality, the NeoChord procedure doesn’t limit any future treatment options, it is a physiological procedure, simply replacing the chords that nature intended to be there re-creating a beautifully functioning cardiac system. We appreciate your time and consideration when evaluating this critical procedure, with emphasis on the redo mitral valve repair patient population where we truly feel this device shines the brightest, giving patients a safer, effective alternative to conventional, open chest cardiac surgery. Thank you for your time and consideration of this appeal, and if any queries arise do not hesitate to contact me, the representing surgeons, or any of my NeoChord colleagues as we would all be delighted to help build the picture of how remarkable this technology truly is.	Committee discussed potential amendment to recommendation. Please see response to comment 2.

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6.	Consultee 3 Dot Medical	3.15	The company is not involved in reviewing every person who will have the procedure. Only during the proctoring period (approx. 10 cases). After that, the surgeon is free to treat patients who he/she thinks is suitable for the therapy, but the company can always be consulted for a second opinion or advice.	Thank you for your comment. Change to section 3.13: 'the company reviews transoesophageal echocardiograms for every person who will have the procedure ***during the proctoring period*** and ***is available to*** provide advice about the procedure's technical feasibility.'

"Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees."