NICE National Institute for Health and Care Excellence

IP2107 Surgical insertion of a catheter-based left ventricular microaxial flow pump for cardiogenic shock

IPAC date: 22/01/2026

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1.	Consultee 2 British Cardiovascular Intervention Society (BCIS)	Not specified	The British Cardiovascular Intervention Society supports the recommendation.	Thank you for your comment. Consultee agrees with main recommendation.
2.	Consultee 7 Newcastle Upon-Tyne Hospitals NHS Foundation Trust	1.1	No comments but I agree with the recommendations	Thank you for your comment. Consultee agrees with main recommendation.
3.	Consultee 5 Company JnJ Heart Recovery	1.1	J&J welcomes the endorsement of this procedure for use in the NHS as an option for the management of cardiogenic shock. Surgical insertion of the Impella 5.0 was employed as an escalation option in the DanGer SHOCK study (Møller JE et al. Microaxial Flow Pump or Standard Care in Infarct Related Cardiogenic Shock. N Engl J Med. 2024 Apr 18;390(15):13821393), where it was used alongside other mechanical circulatory support (MCS) devices — most	Thank you for your comment. Kanwar (2025) was identified in the update literature search and has been added to the key evidence. Møller (2024) has been added to table 5 of the overview because it describes 12 people who had Impella 5.0 implanted as an escalation option.

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			commonly veno-arterial ECMO (VA-ECMO) and permanent left ventricular assist devices (LVADs). Although relatively infrequent, use of Impella 5.0 in DanGer SHOCK was associated with fewer escalations to other MCS devices in the Impella CP™ arm; and among those who did require escalation, fewer progressed to Impella 5.0™. The Cardiogenic Shock Working Group (CSWG) has since published two important reports in summer 2025 that are relevant to this guidance. The first — addressing Impella 5.5™ with durations shorter and longer than 14 Days — reported an in-hospital survival rate of 72.3% (670 survivors of 927) for all patients and a 30 day post discharge survival of 98.9% among the 187 patients with follow up data (Kanwar MK et al. J Heart Lung Transplant. 2025 Oct;44(10):15831594). Outcomes in patients supported for more than 14 days were more likely to have native heart recovery, or receive heart transplantation, without any notable increase in adverse events. The second CSWG analysis examined VA-ECMO, including cases combined with Impella (Hernandez Montfort J et al. J Heart Lung Transplant. 2025 Jul 24:S10532498(25)021205). For patients treated for HF-CS, mortality was 42.1%. In the overall cardiogenic shock cohort treated with VA-ECMO,	The use of combined VA ECMO and Impella was not included in this assessment. The overview states: 'Evidence was excluded from studies that primarily used microaxial flow pumps as support during high-risk PCI, or for left ventricular unloading during VA-ECMO support.' Data from the SURPASS study is included in the key evidence (Abraham, 2025). Freer (2025) was identified in the update literature search and has been added to table 5 because most of the microaxial flow pumps in the studies were implanted percutaneously. Gill (2023) is included in the key evidence. The committee discussed this comment but decided more evidence is needed before a more

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			mortality reached 51%, with 37.7% of patients in SCAI stage D and 62% in stage E. Although direct comparisons are limited by baseline differences, this is notably higher than the mortality rates in SURPASS (Abraham 2025; previously referenced) which reported 25% (111/444 patients expired) overall. Among the patients that received only Impella 5.5™, 86.5% (179/207) were discharged alive. Safety data also compare favourably to other in-use MCS devices such as VA-ECMO In the CSWG cohort, patients on VA-ECMO alone experienced limb ischaemia in 11.4%, bleeding in 43.9%, and stroke in 12.5%. In SURPASS, the Impella 5.5™ cohort reported 0% limb ischaemia, 23.7% bleeding, and 3.4% stroke — indicating at least favourable safety profile for Impella 5.5™ relative to VA-ECMO, notwithstanding SURPASS reporting solely on HF-CS patients. Some of the aforementioned comparability concerns have been addressed by the recent frequentist network meta-analysis by Freer R et al. (Eur Heart J Qual Care Clin Outcomes. 2025 Nov 4;11(7):1184119), which evaluated mortality and complications using only randomised controlled trials. Across 18 RCTs (n=1,907), intraaortic balloon pump (IABP), Impella™, ECMO, and TandemHeart were analysed. Impella™ reduced 6–12 month mortality compared with	permissive recommendation can be made for this procedure.

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			medical therapy (RR 0.81; P < 0.05), but was associated with a higher incidence of renal replacement therapy, limb complications, and major bleeding (RR 1.6; P = 0.02; RR 4.8; P = 0.02; RR 2.0; P = 0.004). No other MCS device demonstrated significant mortality benefit versus medical therapy. ECMO increased vascular complications and major bleeding (RR 3.1; P = 0.003; RR 2.4; P = 0.0001), while TandemHeart increased limb complications (RR 19; P = 0.05). Further supporting evidence comes from Gill et al. on Impella 5.0™/5.5™ used as a bridge to transplant or other destination therapies: 70.1% (n=155) survived to their respective destinations — transplant (n=105, 47.5%), durable device (n=30, 13.6%), or recovery (n=86, 38.9%) — with haemodynamic improvements recorded. This publication has been identified by the technical team. Similarly, Fiorelli and Panoulas (Rev Cardiovasc Med. 2021;22(4):1503–1511) compared VAECMO with and without Impella across five studies (n=972 CS patients), finding significantly improved survival with the combination (mortality 56.1% vs 63.7%; RR 0.86; 95% CI 0.76–0.96; p = 0.009), with no significant differences in major bleeding or cerebrovascular accident. For context, SCAI stage specific mortality documented by Jentzer stood at <10% for stages A/B, 15% for C, 50% for D,	

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			and 75% for E (Jentzer JC et al. Influence of cardiac arrest and SCAI shock stage on cardiac intensive care unit mortality. Catheter Cardiovasc Interv. 2020 Dec;96(7):1350-1359). Given the demonstrated equivalence in insertion technique between Impella 5.0™ and Impella 5.5™, the past, longer surgical implantation experience with 5.0™ that can also be viewed as applicable to 5.5, and the recent 5.5-specific procedural safety evidence, J&J believes Impella 5.5™ merits broader patient access in AMI-CS and HF-CS indications.	
4.	Consultee 1	Not specified	There are a few points I would like to highlight. It is not a limited technology as described in the guidance. While not all cardiogenic shock phenotypes require it, Impella, can enable broader access without additional infrastructure. Education and support is needed to make this possible Although it is best to have this in institutions with established cardiogenic shock pathway as part of a nettwork. The 2025 ACC/AHA guidelines upgraded Impella to Class IIa, while downgrading IABP and VA-ECMO to Class III. Meta-analyses show early Impella use before revascularisation improves short- and long-term survival. Its adaptability supports integration into regional shock networks, making it a practical and impactful solution for wider UK implementation.	Thank you for your comment. The 2025 ACC/AHA guidelines are included in the existing assessments section of the overview. The DanGer Shock trial used percutaneous insertion of microaxial flow pumps, which is covered by a separate piece of guidance (IP2042 Percutaneous insertion of a catheter-based left ventricular microaxial flow pump for cardiogenic shock).

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			The DanGer Shock RCT demonstrated a 12.7% absolute and 26% relative reduction in mortality at 180 days in patients with STEMI-related cardiogenic shock treated with Impella CP, compared to conventional therapy, with a Number Needed to Treat (NNT) of 8. Long-term data recently published confirmed the survival benefit at 10 years (30% relative reduction in mortality and approximately 600 additional days alive per patient), despite early concerns about statistical fragility. As mentioned, International guidelines have been upgrading percutaneous mAFP (Impella) to Class I and Class IIa, prioritising survival despite increased adverse events such as bleeding, while other device classes (e.g. IABP and VA-ECMO) are being downgraded in Europe and the US to class III. "DanGer" patients represent a sizable and well-scoped phenotype within the overall cardiogenic shock patient population. There is extensive variation in cardiogenic shock aetiology that indeed can lead to uncertainty in evidence applicability among sub-types, and blurred evidence on clinical safety and efficacy. Despite that, for patients developing Cardiogenic Shock because of ST-Elevation Myocardial Infraction without Out-of-Hospital Cardiac Arrest (OHCA) with Glasgow Comma Scale <8 (i.e. “DanGer” patients), the evidence on the risk-benefit of the procedure appears convencing. Moreover, DanGer investigators reported no differences in time from	Cost-effectiveness is not within the remit of NICE IP guidance, so economical evidence is not prioritised for inclusion in the overview. Thiele (2024) is not included in this assessment because it only used microaxial flow pumps that are inserted percutaneously. Terauchi (2025) was identified in the update literature search but was not prioritised and has been added to appendix B because only a small proportion of people had Impella 5.5. The EACTS/STS/AATS guidelines (Potapov 2025) have been added to the existing assessments section of the overview.

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			symptom onset to randomization across the different study regions. With adjustment for patient severity, the hazard ratio in Germany and the United Kingdom as compared with Denmark was 1.06 (95% CI, 0.76 to 1.49). This implies similar results across different healthcare settings and varied populations. Lastly, several key publications supporting the clinical and economic value of Impella are missing from the current NICE documentation. • These include the DanGer Long term outcomes study (Møller et al., 2025) showing a sustained 30% mortality reduction at 10 years, and a network meta-analysis (Freer et al., 2025) confirming long-term survival benefits using only RCT data. • Additional evidence from the Japanese registry (Terauchi et al., 2025) highlights improved outcomes in non-ACS cardiogenic shock, especially myocarditis. • Meta-analyses by Thiele et al., 2024 confirm that unloading devices like Impella offer survival benefits in selected STEMI shock patients, unlike VA-ECMO.	

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			• Recent international guidelines (JCS, EACTS/STS/AATS) and the French HAS appraisal also support Impella use.	
5.	Consultee 3	Not specified	Overall the recommendation and document is balanced and appropriate. There are some additional elements which could be considered in specific areas by the committee. In the complication section it would be helpful to include haemolysis as a specific source of harm. This is at least in part the mechanism for worsening kidney injury and microvascular injury whilst on microaxial flow pumps. As a marker of harm it is easy to measure either directly (plasma free haemoglobin) or indirectly through routinely collected blood samples. Also the distal complications depend upon the route of insertion - clearly leg ischaemia if the femoral artery is used, but also arm ischaemia if the subclavian artery is used. The ability to manage complications on site, especially vascular complications related to insertion or removal should form part of the guidance. Centres should have this ability on-site.	Thank you for your comment. Haemolysis has been added to the list of key safety outcomes. Section 3.6 has been changed from 'leg ischaemia' to 'limb ischaemia'. A committee comment has been added to state that a bleeding management protocol should be in place.

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6.	Consultee 4	Overview (the procedure, condition, current, practice, unmet need)	Unfortunately I couldn't get the link to work.....	Thank you for your comment. The team will ensure that the link to the final guidance will work when it is published.
7.	Consultee 4	Overview (clinical assessment tools)	Just FYI - the SCAI classification is currently being updated. Likely publication early 2026.	Thank you for your comment.
8.	Consultee 4	Overview (evidence summary)	Great evidence summary. I totally take the point regarding transferability to other healthcare systems, however, it would be the right thing if we were able to generate evidence (both within and without transplant pathways) for the 5.5 device wihtin the NHS.	Thank you for your comment. The guidance recommends evidence generation for all people having the procedure.
9.	Consultee 4	Overview (existing assessments)	I was part of the ESC 2021 guidelines. I believe this assessment 2a C remains accurate for this device inserted surgically. I would add however that this should be related to the experience of centres and networked care with expert decision-making	Thank you for your comment. The guidance states that 'Patient selection should be done by a multidisciplinary team. This procedure should only be done in centres that specialise in managing cardiogenic shock and by healthcare professionals with specific training in this procedure.'

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10	Consultee 5 Company JnJ Heart Recovery	Not specified	J&J welcomes the development of this IPG on the surgical insertion of a catheter-based intravascular micro-axial flow pump for cardiogenic shock and appreciates the opportunity to provide comments. Cardiogenic shock (CS) is a life-threatening condition, presenting in multiple distinct phenotypes. This draft guidance outlines the varied clinical pathologies that can lead to the syndrome, with cardiogenic shock following acute myocardial infarction (AMI-CS) being the better studied in relation to Impella™ use. In broad terms, these devices are also employed in CS secondary to heart failure (HF-CS) and other forms of CS, with post-cardiotomy cardiogenic shock (PCCS) representing the predominant type within the latter category. Other variants of CS have likewise been investigated. Overall, J&J concurs that multiple unresolved questions remain regarding surgical insertion in this complex therapeutic area, where several device models and configurations may need to be deployed to save lives and optimise outcomes. We further believe that certain patient subpopulations have stronger supporting evidence than others, particularly in relation to device safety. We have highlighted these within our comments throughout the draft guidance and have sought to address some of the open	Thank you for your comment. Consultee notes that the safety data for surgical insertion of the Impella 5.0 is relevant to the Impella 5.5. and efficacy outcomes are at least equivalent, if not superior. Murugiah (2025) was not identified in the search. It will not be included in the overview because it is a commentary and not suitable for inclusion as per the Interventional procedures programme manual. Potapov (2025) has been added to the existing assessments section of the overview. Pahuja (2021) was identified in the literature search but was excluded because it is not a systematic review.

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			research questions raised by the committee during the drafting process. Since the literature review in May 2025, several new studies have been published in peer-reviewed journals which may prove valuable. Regarding individual device models and how their evidence applies to this guidance, we note the technical team's consideration of different implantation techniques. Impella 5.0™ permitted femoral access for insertion; Impella 5.5™ does not, as this access route prevents mobilisation, regarded as a key component to rehabilitation. Given that longer-term support is an important factor in patient recovery, mobilisation is regarded as the standard scenario for patients supported with Impella 5.5™. For surgical techniques—where the axillary approach is predominant—it was anticipated that the two technologies would be equivalent in terms of insertion safety, if not safer (Pahuja, M et al. 2021. Device profile of the Impella 5.0 and 5.5 system for mechanical circulatory support for patients with cardiogenic shock: overview of its safety and efficacy. Expert Review of Medical Devices, 19(1), 1–10). This safety equivalence was acknowledged during regulatory approval of the Impella 5.5™ under the MDR, and is consistent with MEDDEV 2.7.1 Rev 4, MDCG 202005, and Regulation (EU) 2017/745. We, therefore, consider the safety data for surgical insertion of the Impella 5.0™ to be relevant	

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			to the Impella 5.5. Efficacy outcomes are at least equivalent, if not superior. Several recent clinical guideline updates — particularly from the United States — have increasingly upgraded the strength of recommendations for Impella™ use, especially in AMI-CS, while downgrading other mechanical circulatory support (MCS) devices such as VA-ECMO and intra-aortic balloon pump (IABP). A concise and up-to-date overview of this shift is provided in Murugiah K, McDonagh T, Cohen D, et al. Mechanical Circulatory Support in Acute Myocardial Infarction–Cardiogenic Shock: 2025 Acute Coronary Syndrome Guideline in Context. JACC. 2025 Jun;85(22):2103–2106. In the context of the surgical implantation this guidance will address, it is vitally important to highlight the recent guidelines developed by the world's three leading cardiac surgery societies (European Association for Cardio-Thoracic Surgery "EACTS", Society of Thoracic Surgeons "STS" and American Association of Thoracic Surgery "AATS"). EACTS, STS and AATS have jointly made temporary MCS a Class I recommendation in patients with CS while recognizing the key role that micro-axial flow pumps like Impella™ play. These guidelines recognise micro-axial flow pumps like Impella™ for a wide range of clinical scenarios, providing	

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			support for left and right ventricular failure, and bridging patients to recovery, transplant, or decision (Potapov EV, et al. EACTS/STS/AATS Guidelines on temporary mechanical circulatory support in adult cardiac surgery, European Journal of Cardio-Thoracic Surgery. 2025; ezaf330, https://doi.org/10.1093/ejcts/ezaf330). Finally, thank you, again, for this guidance that represents an important step in enabling equitable patient access to this much needed technology across the NHS.	
11	Consultee 5 Company JnJ Heart Recovery	What evidence generation is needed	J&J provides publications confirming the equivalence of the insertion technique between Impella 5.0™ and Impella 5.5™, as well as a recent Cardiogenic Shock Working Group "CSWG" report indicating enhanced efficacy with longer durations of support, without any corresponding increase in patient safety risk.	Thank you for your comment. Kanwar (2025) was identified in the update literature search and has been added to the key evidence. Pahuja (2021) was identified in the literature search but was excluded because it is not a systematic review.
12	Consultee 5 Company JnJ Heart Recovery	Unmet need	J&J concurs with this statement, which captures the key advantage of surgical insertion for higher flow Impella™ pumps. As noted above, Kanwar MK et al. have demonstrated that prolonged durations of haemodynamic	Thank you for your comment. Kanwar (2025) was identified in the update literature search and has been added to the key evidence.

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			support with Impella™ are associated with improved outcomes compared to shorter periods of support.	
13	Consultee 5 Company JnJ Heart Recovery	What evidence generation is needed	J&J concurs that patient selection is a critical requirement. Despite the multiple CS phenotypes and wide variation in the research base, certain phenotypes—such as AMICS patients resembling those enrolled in DanGer SHOCK—appear to benefit from Impella CP™ and Impella 5.5™ when used as an escalation device. Similarly, HF-CS patients with characteristics matching those enrolled in SURPASS reported high survival rates, particularly among those who subsequently received heart replacement therapy (HRT) following Impella™ support. Other patients also seem to compare favourably compared to similar cohorts receiving VA-ECMO alone, as reported in the recent Cardiogenic Shock Working Group "CSWG" publication, notwithstanding the naivety of the comparison (Hernandez Montfort J et al., elaborated elsewhere).	Thank you for your comment. Hernandez-Montfort (2025) describes outcomes associated with with VA-ECMO support, so it is not included in the overview.
14	Consultee 5 Company JnJ Heart Recovery	What evidence generation is needed	We wish to highlight a recent quality of life study involving patients receiving surgically implanted Impella™ devices via the common axillary approach. This prospective longitudinal analysis, conducted in 15 HF-CS patients where Impella™ was used as a bridge to transplant, was published by Mautong H et al. (Health Related Quality of Life Measures in Patients with Heart Failure Cardiogenic Shock Following	Thank you for your comment. Mautong (2025) was identified in the update literature search but was excluded because the sample size was less than 20. The evidence base for this assessment was large

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			Axillary Mechanical Circulatory Support. Medical Sciences. 2025;13(3):146). On admission, most patients reported an overall health related quality of life (HRQoL) of poor to fair (46.7%), as assessed by the Kansas City Cardiomyopathy Questionnaire12 (KCCQ-12) summary score. The median overall summary score increased significantly after Impella 5.5 support (50.52 vs 28.13; p = 0.005). Symptom frequency (70.83 vs 43.75; p = 0.009) and quality of life domains (50.00 vs 12.50; p = 0.023) improved significantly; while physical limitation showed a positive trend and social limitation remained unchanged. These HRQoL improvements occurred in parallel with a marked shift towards lower SCAI shock stages, significant increases in cardiac output and cardiac index, and no escalation in vasoactive inotropic support requirements.	and non-randomised studies with fewer than 20 people were excluded. This is stated in the overview. The validity and generalisability section of the overview has been amended to clarify that no quality-of-life data was identified in the prioritised evidence.
15	Consultee 5 Company JnJ Heart Recovery	Why the committee made this recommendation	J&J welcomes the recognition of the urgent need within this complex and difficult to treat patient population affected by cardiogenic shock. There remains a notable paucity of randomised controlled trials (RCTs) in this therapy area, largely due to the difficulties these studies encounter in recruitment. This issue is not unique to Impella™ devices; other relevant technologies have	Thank you for your comment. Consultee notes that they are not aware of any upcoming randomised controlled trials in people with AMICS that do not offer Impella as a therapeutic option to the control group and that it was deemed

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			been similarly affected. Over the past decade, several industry-sponsored RCTs—both in the United States and Europe—have been discontinued due to low enrolment (including the "FRENCH TRIAL" NCT00314847; "IMPRESS in STEMI" NTR1079 trialregister.nl; "RECOVER II" NCT00972270; and "IMPRESS Cardiac Arrest" NTR3450 trialregister.nl). At present, DanGer SHOCK (Møller JE et al., 2024; see references above) is the only RCT in this space to reach completion. By contrast, RECOVER IV (NCT05506449) was discontinued following the recommendation of its independent Data Safety and Monitoring Board (DSMB). The DSMB's decision followed the positive results of DanGer SHOCK, which demonstrated that routine use of Impella™ CP improved survival in STEMI-related cardiogenic shock. Given these findings, it was deemed no longer ethical to randomise patients to the non-Impella™ arm of RECOVER IV, as this could potentially deprive them of a therapy now supported by robust trial evidence (see further details via TCTMD: https://www.tctmd.com/news/recover-iv-impella-trial-halted-wake-danger-shock). As the sponsor of RECOVER IV, J&J adhered to the DSMB recommendation and does not plan any further RCTs to prove Impella™ efficacy in this patient population.	unethical to randomise people to a non-Impella arm. The guidance recommends that more data should be collected but it does not stipulate that this should be in the form of randomised controlled trials.

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			Consequently, we are not aware of any upcoming RCTs in the AMI-CS population that do not offer Impella™ as a therapeutic option to control group patients. Considering the recently published Cardiogenic Shock Working Group "CSWG" evidence, we believe Impella 5.5™ can be assessed both safe and efficacious as an escalation device in AMI-CS. Similarly, it can be viewed as comparing favourably with VA-ECMO in HF-CS.	
16	Consultee 5 Company JnJ Heart Recovery	Overview (population and studies description)	Thank you for elaborating on the Khalil et al. publication based on the US MAUDE database. J&J wishes to contend that the use of the MAUDE database by Khalil et al. is problematic, as this database is not fit for the purpose of determining adverse events or complication rates. This limitation has been described in multiple publications — one example being Sandberg JM et al. (An evaluation of the Manufacturer And User Facility Device Experience database that inspired the United States Food and Drug Administration's reclassification of transvaginal mesh. Investig Clin Urol. 2018;59(2):126132). The MAUDE database is an FDA database designed to capture, via passive surveillance, cases of suspected device-associated adverse events. While it can be very useful and important part of reporting, the FDA has made very clear that this database cannot be used to "establish rates of events,	Thank you for your comment. The limitations of the FDA MAUDE database are described in the 'Population and studies description' section of the overview. The study was selected as part of the key evidence because it describes adverse events that may not have been captured elsewhere. The data was not used to establish rates of adverse events.

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			evaluate a change in event rates over time or compare event rates between devices." Reasons include the following: • The denominator (total number of cases) is unknown • The numerator (total cases reported) is difficult to interpret because: • MAUDE entries may be incomplete and/or inaccurate. • There may be multiple entries for the same event. • The events may not have been verified. • The FDA itself acknowledges that this system "has limitations" due to "the potential submission of incomplete, inaccurate, untimely, unverified, or biased data." For the 43 MAUDE reports identified by Khalil et al, it cannot be ascertained whether these cases relate to the same or different patients, because there can be multiple reports for the same case. • Sandberg et al. (referenced above) provides a good analysis of these limitations. Using as an example the transvaginal mesh, Sandberg et al identified 1,103 MAUDE reports, of which 47% did not identify a source, 28% reported on devices that were no longer on the market and at least 64 were duplicates.	

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17	Consultee 5 Company JnJ Heart Recovery	Overview (validity and generalisability)	Please note the recently published quality of life study, already highlighted elsewhere in our comments, by Mautong H et al. That prospective longitudinal analysis, conducted in 15 HF-CS patients where Impella™ was used as a bridge to transplant, was published over the summer 2025 period (Mautong H et al. Health Related Quality of Life Measures in Patients with Heart Failure Cardiogenic Shock Following Axillary Mechanical Circulatory Support. Medical Sciences. 2025;13(3):146).	Thank you for your comment. Mautong (2025) was identified in the update literature search but was excluded because the sample size was less than 20. The evidence base for this assessment was large and non-randomised studies with fewer than 20 people were excluded. This is stated in the overview (see Appendix B). The validity and generalisability section of the overview has been amended to clarify that no quality-of-life data was identified in the prioritised evidence.
18	Consultee 5 Company JnJ Heart Recovery	Overview (validity and generalisability)	Thank you for the intensive focus on issues of perceived bias, which are also of concern to J&J. We would emphasise that in this complex therapy area, physician training is essential to ensure optimal safety outcomes, and J&J — alongside others in the field — is committed to supporting education of the highest standard. For this reason, within a space of complicated and evolving techniques, we work in close partnership with clinicians who	Thank you for your comment. It is usual practice for the overview to include details of potential conflicts of interest reported in the prioritised studies.

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			develop expertise that can be shared through peer-to-peer educational events. Such activities may necessitate the provision of appropriate honoraria. It should also be noted that investigators have similarly partnered with other manufacturers offering solutions that could be regarded as therapeutic alternatives to our own. We believe that this transparency, combined with the involvement of a broad range of partners, ensures that no inappropriate bias exists.	
19	Consultee 5 Company JnJ Heart Recovery	Overview (ongoing trials)	We were pleased to alert the committee to several Cardiogenic Shock Working Group "CSWG" publications since the original IPG literature review that may provide additional clarity on the comparative safety and efficacy of Impella 5.5™.	Thank you for your comment.
20	Consultee 6 Harefield Hospital	Overview (validity and generalisability)	It is true that the majority of these studies are US based. In Harefield we have the biggest experience in Impella 5.5 and indeed 5.0. Our 5.0 data had been published before (M Monteagudo-Vela et al) and were truly exceptional given that we were implanting this device in patients that had no other option other than death. They were SCAI D.E or Intermacs !/II and on inotropes with worsening multiorgan failure. Regarding 5.5 in our institution we have done around 20 Impella 5.5 and we will publish those in the near future. It is true that 5.5 is a device that has a learning curve and needs	Thank you for your comment. Consultee notes that the procedure had exceptional results in people with no other treatment options. Monteagudo-Vela (2021) was identified in the literature search but was excluded because only 8 people were bridged with Impella 5.0 to heart transplant.

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			specialised input, however when treated with best practices in can truly save patient's lives, encourage recovery in patients naive to medical therapy and bridge appropriately candidates to transplantation or LVADs. In contrast bivad levitronix devices are far more invasive, with much higher bleeding rates and other complication rates and do not promote recovery of native heart.	

"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."