Health Technology Assessment (HTA) Decision Summary

FlowTriever® catheter-directed mechanical thrombectomy system for intermediate-risk or high-risk pulmonary embolism

SAPACT MEETING DATES	32nd SAPACT Meeting (24 November 2023)
APPLICATION #	2312
TECHNOLOGY	Australian Sponsor: ACRA Regulatory Services Pty Ltd Manufacturer: Inari Medical Inc, 6001 Oak Canyon Suite 100 Irvine, CA, 92618, USA FlowTriever retrieval/aspiration system - Embolectomy/thrombectomy suction catheter The FlowTriever is a single-use large bore (vascular sheath 20 - 24 Fr) catheter-directed mechanical thrombectomy (CDMT) device for the treatment of intermediate-risk or high-risk pulmonary embolism (PE). Theflowsystem consists of 2 main components: (1) FlowTriever catheter comprised of self-expanding nitinol disks designed to engage the thrombus for removal via aspiration and the (2) Triever aspiration catheter used for controlled aspiration of thromboemboli. Radiopaque markers are positioned to aid fluoroscopic visualization. The procedure is typically a one-hour procedure that is completed under conscious sedation. The device's mechanism of action is to disrupt and aspirate clots using large lumen aspiration catheters to rapidly remove the clot and restore blood flow.
TECHNOLOGY CLASSIFICATION	TGA class III high-risk
PATIENT INDICATION (TGA)	TGA intended purpose: The FlowTriever is intended for use in the peripheral vasculature, pulmonary arteries, and for use in the treatment of PE. It is indicated for the non-surgical removal of emboli and thrombi from blood vessels, and injection, infusion, and/or aspiration of contrast media and other fluids into or from a blood vessel. It is comprised of FlowTriever catheter and Triever catheter of varying sizes and compatibility.

SAPACT DECISION

☒ Restricted recommendation for clinical use with financial or operational restrictions and under LHN clinical governance/audit conditions.

SAPACT Advisory Recommendations

☒ Restricted recommendation for clinical use with financial or operational restrictions and under audit conditions.

Currently, SAPACT does not support the FlowTriever for routine clinical use in SA Health. Rather, SAPACT recommends for the restricted use of the FlowTriever for intermediate-risk or high-risk pulmonary embolism in a total of 10 cases across both SALHN and CALHN, with requirement to monitor and report the clinical outcomes back to SAPACT at the completion of these 10 cases. It is recommended that SALHN and CALHN agree on a standardised protocol and ensure that agreed data is being collected for monitoring.

SAPACT Evidence Review Conclusion

United States-based industry-supported, non-randomised, non-comparative, short-term (48-hour and 30-day) cohort studies formed the main published evidence base for the Flowtriever. No published Australian data is available. A few FlowTriever procedures are conducted in NSW public hospitals, however no clinical outcome data has been made available. It is difficult to evaluate or ascertain the effect of the FlowTriever due to the study design limitations, lack of comparative data and bias. Most clinical evidence is for intermediate-risk PE; there is a paucity of data regarding the use of FlowTriever in high-risk patients. There is enough evidence that the FlowTriever procedure reduces the extent of clot in the circulation but not enough evidence of improvement in short- and long-term outcomes. The low quality of evidence (NHMRC level III-3 and IV) records the observational measures on mortality, major adverse events, injuries/complications, clinical outcomes, patient-reported outcomes and hospital quality measures. The review found a risk of major life-threatening bleeding, the need for ICU admission and no significant decrease in hospital LOS and all-cause 30-day hospital readmission. These outcomes will be useful to inform future RCTs on FlowTriever/CDMT. RCTs (such as the PEERLESS study) are underway to confirm the efficacy of the FlowTriever device in the treatment of acute PE.

It is unclear whether the FlowTriever demonstrates value for money, as only a cost-comparison analysis paper authored by Inari Medical consultants was published. It found no clear cost advantage of MT (FlowTriever) over CDT, with observed cost differences influenced by variations in practice and institutions.

Background

SAPACT received a SALHN clinician's application from the SALHN New Health Technology & Clinical Practice Innovation (NHT&CPI) Committee to evaluate the potential use of the FlowTriever system in SA Health. The applicant has proposed to use this technology in 10-12 patients in SALHN per year.

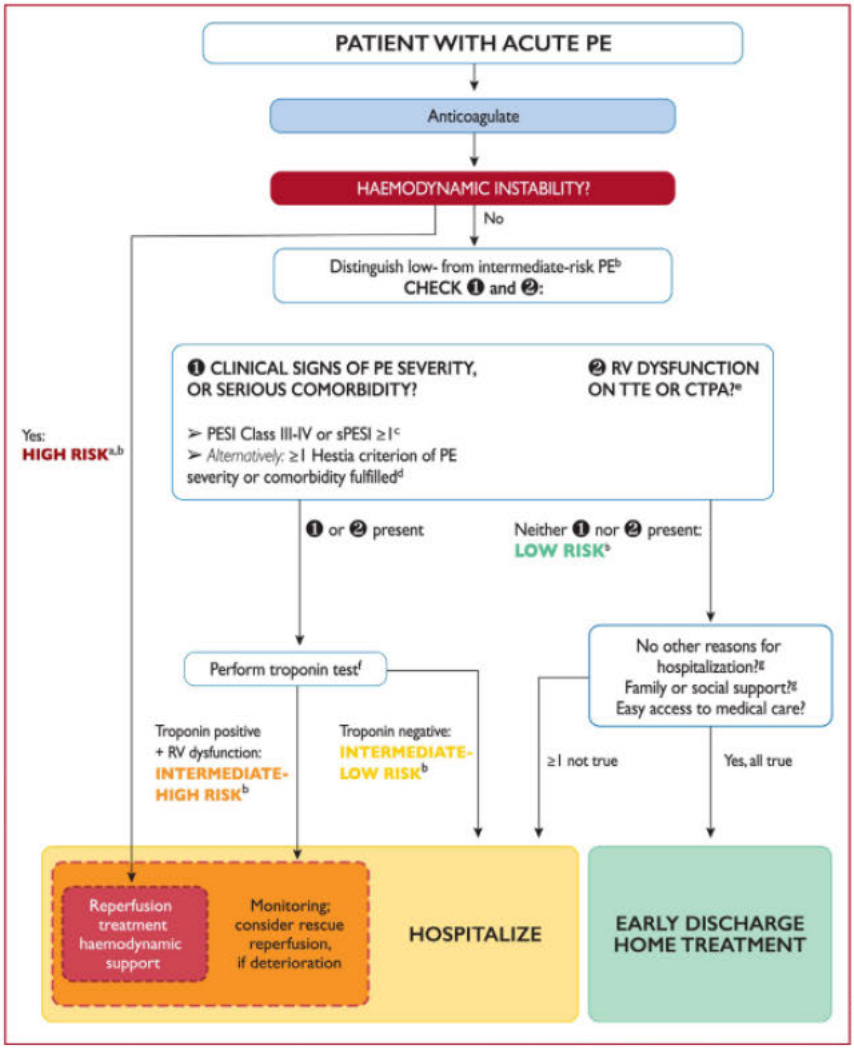
REGULATORY APPROVALS		
☒ **Australia ARTG**: 5/10/2022; Class III; 396997 FlowTriever Retrieval/Aspiration System	☒ **US FDA**: 5/4/2021; Class II; K211013; 510(K) approval granted based on predicate device, the Inari FlowTriever Retrieval/Aspiration System (K202345)	☒ **EU CE mark**: FlowTriever approved. (Exact date is unclear, estimated before October 2021)

QUALITY OF EVIDENCE	
Quality of Evidence	A comprehensive systematic search for best available HTA and policy evidence was conducted in 7 published and 25 grey literature sources. Since a current comprehensive HTA report and a systematic review were available (NICE Guidance 2023; finalised version obtained from NICE directly, ahead of publication; European Austrian Institute HTA 2023 systematic review, commissioned by Austrian Ministry of Health), no development of a SAPACT Evidence Review was required. No results from an RCT (level I evidence) were identified. Cohort studies conducted in the United States form the published evidence for the FlowTriever; the observational study design does not support a claim of efficacy. The draft NICE Evidence Review 2023 covered Flowtriever in four (488 patients) out of their 6 included studies; the other 2 included studies (Sista 2021 and Sedhom 2021) reviewed the Penumbra Indigo Aspiration System. The Austrian systematic review covered FlowTriever in three out of the 4 studies; and the remaining study (Sista 2021) evaluated the Indigo system. The key trial studies (8) included in the SAPACT review are: • Elmoghrabi 2023 PEITHO retrospective cohort study (n=38), with 48-hour and 30-day results. 13% high-risk PE. • Horowitz 2023 FLASH substudy (n=63), with 48-hour and 30-day results. High-risk PE only. • Khandhar 2023 FLASH prospective registry (n=799), with 6-month results. 75% patients completed study (missing data bias); 8% (64 patients) high-risk PE. Excluded patients include those with life expectancy of <30 days (selection bias, favouring more positive results). • Morrow 2023 FLAME prospective cohort study (n=50), with 45-day results • Toma 2022*^ FLASH prospective registry (n=250), with 48-hour and 30-day results • Buckley 2022* retrospective comparative study (n=58), routine care: mainly anticoagulation, with 30-day results. 36% high-risk PE. • Jaber 2020* FLARE-ED single-arm trial substudy (n=76), with 48-hour and 30-day results. Intermediate risk PE only. • Tu 2019*^ FLARE single-arm trial (n=104), with 48-hour and 30-day results **Results are synthesised in the draft NICE HTA report.* *^ Results are synthesised in the Austrian systematic review.* All the included trial studies are conducted in the United States, no Australian data is available. Industry-funded research bias - the FLASH, FLARE studies are funded by Inari Medical. Morrow 2023 received grant support from Inari. Only Elmoghrabi 2023 and Buckley 2022 declared no conflicts of interest. In most studies (except Horowitz 2023 and Jaber 2020), the study population included a mix of patients with intermediate and high-risk PE, which may serve as a confounding factor for the treatment effect and complication rates. Only one cost-comparison analysis paper (Tran 2023) authored by Inari Medical consultants was published related to the FlowTriever. The PEERLESS study (NCT05111613) is an ongoing RCT (n=550) aiming to compare FlowTriever System versus CDMT (using any commercially available system) in acute intermediate high-risk PE patients. Composite primary outcome will include all-cause mortality, or major bleeding, intracranial haemorrhage, haemodynamic collapse, or ICU admission. Estimated completion date of the PEERLESS study is March 2024. The application, consultations and inputs from the Chief Applicant, industry, LHN New Technology Committees, SA Health HTA, Economics Experts, Procurement, UK NICE and New South Wales (NSW) Health also informed the SAPACT Advisory Recommendations.
CLINICAL NEED	
Burden of Illness	Acute PE is the third leading cause of cardiovascular death and can result in significant morbidity and mortality. Blood clots are responsible for an estimated 10% of all deaths in Australia, and yet up to 70% of these are preventable. Around 30,000 Australians develop PE and deep vein thrombosis every year, including, costing the Australian health system $3.8 billion per year (Access Economics 2008). The Australian Bureau of Statistics recorded 340 deaths (0.2% of all deaths) related to PE in 2015.
Need	*The 2019 European Society of Cardiology (ESC) Guidelines for the diagnosis and management of acute PE* stratifies PE into high-risk, intermediate risk, and low risk. High risk (massive) PE involves patients who are hemodynamically unstable, and in these patients systemic thrombolysis is recommended. Anticoagulation is recommended in cases of PE that are not high risk (Konstantinidis 2019). Thrombolysis is the active breaking down of clots after they are formed, whereas anticoagulation prevents clots from forming. Recommended treatment of ESC intermediate-high or high risk patients include hospital admission, systemic anticoagulation, when possible, plus respiratory and

haemodynamic support as needed. Adjunctive reperfusion treatments for hemodynamically unstable and elevated-risk patients include systemic thrombolysis, percutaneous catheter-directed treatments, and/or surgical embolectomy depending on the clinical situation and institutional availability (Buckley 2022).

CDMT are emerging alternative interventions for the treatment of PE. Thrombectomy devices such as FlowTriever are uniformly larger catheters which advanced over stiffer wires than used for CDMT and theoretically impose a higher risk of intra-procedural complications (Elmoghrabi 2023). The FlowTriever is marketed as the first mechanical thrombectomy device used to remove large clots from large vessels such as the pulmonary arteries without the need for thrombolytic drugs or open heart surgery. With the FlowTriever, patients are purported to have a safer and less invasive treatment, with low bleeding risk, immediate symptom improvement and faster recovery.

Risk-adjusted management strategy for acute PE (as extracted from the 2019 ESC Guidelines)



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CLINICAL BENEFIT	
Safety	**Mortality** In-hospital mortality: 3.6% vs 23.3%, p<0.05 (statistically significantly (stat. sig.) lower in FlowTriever group vs systemic anticoagulation) (Buckley 2022) 48-hour mortality: 5.2% (Elmoghrabi 2023) 30-day mortality: 21.5% (Elmoghrabi 2023); 0.4% (1 of 250 patients unrelated to procedure) (Toma 2022); In high-risk PE patients, 0% (Horowitz 2023) 6-month all-cause mortality: 4.6% (29/628 patients) at study completion. Deaths were adjudicated to be unrelated to FlowTriever. (Khandhar 2023) **Major adverse events (MAE)** 48-hour MAE: 5.26% (2 of 38 patients) – One had procedure-related access site hematoma and life-threatening bleeding, while another developed intraprocedural-related massive hemoptysis and cardiopulmonary arrest. (Elmoghrabi 2023). Similar to FLARE study (Tu 2019), which reported a composite MAE rate (device-related death, major bleeding, treatment-related clinical deterioration, treatment-related pulmonary vascular injury, and treatment-related cardiac injury) of 4% (4 patients) at 48 hours. Toma 2022 reported an MAE rate (device-related death, major bleeding, and device-or procedure-related adverse events) of 1% (n=3) at 48 hours, all major bleeding events but with no device-related injuries, clinical deteriorations or deaths at 48 hours. Jaber (2020), in their sub-study of the FLARE population (Tu 2019), reported an MAE rate (major bleeding, device-related death or clinical deterioration, and vascular or cardiac injury) of 4% (n=3) at 48 hours. 30-day MAE: In high-risk PE patients, 0% (Horowitz 2023) 6-month MAE: 13.2% (Khandhar 2023) Major life-threatening bleeding: 5.26% (Elmoghrabi 2023) – significant blood loss reported, not highlighted in FLARE study. 11.3% (Morrow 2023). Tu 2019 reported 1 major bleeding event in 104 patients at 48 hours. Toma 2022 reported a 1% major bleeding rate (n=3). Buckley 2022 did not classify bleeding complications by severity but reported 3 procedure-related complications in the mechanical thrombectomy group (11%): 1 self-limited hemoptysis and 2 post-procedure transfusions due to aspiration-related blood loss. In the routine care group, the rate was similar with 3 self-limited bleeding complications not requiring transfusion (10%) and 1 significant bleed requiring transfusion (3%). Jaber 2020 reported 1 major bleeding event which was procedure-related at 48 hours in a study of 76 patients. **Injuries/complications** Device-related complications: 0% (Elmoghrabi 2023); 22.6% (with individual components of hemoglobin decrease (15.1%), vascular access hemorrhage (7.5%), and hypotension (1.9%). There were no reported pulmonary vascular injuries or hemorrhagic strokes) (Morrow 2023) Acute kidney injury: 5.26% (Elmoghrabi 2023) Pulmonary vascular injury: 1 in 104 patients at 48-hour (Tu 2019 and Jaber 2020 (likely same patient); 0 (Toma 2022) Cardiac injury: 0 (Tu 2019, Jaber 2020, Toma 2022) Access-site complication: 0.4% (1 access-site hematoma in a patient who also received thrombolytics in 250 patients) (Toma 2022) Clinical deterioration: 15.1% (Morrow 2023); 4% at 48-hour (Tu 2019 and Jaber 2020); 0% at 48-hour (Toma 2022) Pressor support: 7.89% (Elmoghrabi 2023) Other anecdotal/theoretical adverse events not reported in literature: Infection, cardiac complications (tamponade, myocardial infarction, valvular dysfunction); iodine anaphylaxis; contrast nephropathy; hemothorax; puncture site pseudoaneurysm, stroke (NICE 2023)
Effectiveness	**Clinical outcomes**

	Right Ventricle/Left Ventricle (RV/LV) ratio: Stat. sig. reduction in RV/LV ratio from baseline to follow-up (Tu 2019, Toma 2022, Jaber 2020) Right ventricular (RV) function: Stat. sig. increase from 15.1% at baseline to 95.1% at 6 months (P <.0001) (Khandhar 2023) Pre- and post-thrombectomy average mean pulmonary artery pressure (mPAP): Stat. sig. reduction (Elmoghrabi 2023, Toma 2022, Tu 2019); non-sig. reduction (Jaber 2020) Deep vein thrombosis (DVT) right leg: 21.05% (Elmoghrabi 2023) Deep vein thrombosis (DVT) left leg: 36.84% (Elmoghrabi 2023) Hemodynamic measures (mean pulmonary artery pressure; mean hemoglobin, mean systolic blood pressure, mean heart rate: Lowered with the FlowTriever (Elmoghrabi 2023) Cardiac index: No stat. sig. change between pre- and post-procedure, but stat. sig. improvement (by 13% on-table (p=0.005)) in cardiac index in the sub-group with low baseline cardiac index (impaired cardiac function) (Toma 2022) Modified Miller score (thrombus load): Stat. sig. reduction from 20.8±2.4 to 18.9±2.9 (Tu 2019) Prevalence of chronic thromboembolic pulmonary hypertension (CTPH) at 6-month visit: 1% (Khandhar 2023) Prevalence of chronic thromboembolic disease (CTED) at 6-month visit: 1.9% (Khandhar 2023) **Patient-reported outcomes** Khandhar 2023 reported the following patient outcomes improved quickly after treatment and were sustained during follow-up. 6-minute walk test (6MWT) distance: Sig. increase from 180m at 48-hour to 398m at 6 months (P<0.001) (Khandhar 2023) Modified Medical Research Council dyspnea scores (NMRCD): Sig. improvement from 3.0 at baseline to 0.0 at 6 months (P<0.0001) (Khandhar 2023) Median Pulmonary Embolism Quality of Life (PEmb-QoL)) Score: Sig. improvement from 9.38 at 30 days to 4.85 at 6 months (P<0.001) (Khandhar 2023) **Hospital quality measures** ICU admission (%): 52.63% of patients (n = 20) (Elmoghrabi 2023) Average ICU length of stay (LOS; days): • 2.1 ±1.2 vs 6.1±8.6, P<0.05 (stat. sig. lower in FlowTriever group vs systemic anticoagulation) (Buckley 2022) • 1.5±2.1 (Tu 2019) • 1 (median; Jaber 2020) Overall post-procedural LOS *(days): 7.7 ± 5.6 (Elmoghrabi 2023) Hospital LOS (days): 7.7±6.9 vs 6.8±6.9 (no stat. sig. difference; Buckley 2022); 4.1±3.5 (Tu 2019); 3 (Toma 2022) All-cause 30-day readmission (%): 11% (MT) vs 13% (RC), no stat. sig. diff between groups (Buckley 2022); 6% (only 2 related to PE; Toma 2022) Hospital discharge survival (%): 78.9% of patients (n = 30 of 38) survived hospital discharge (Elmoghrabi 2023) Discharged with anticoagulation: 30 patients who survived were discharged with oral anticoagulation. (Elmoghrabi 2023)
SUITABILITY OF PATIENT GROUP	
Suitability of Patient Group	Number of SALHN patients proposed by applicant per year: 10-12 patients [redacted] The applicant proposed the use of FlowTriever in: Patients diagnosed with intermediate-high-risk or high-risk PE via diagnostic imaging, as defined by the 2019 ESC/ERS Guidelines for the diagnosis and management of acute PE, developed in collaboration with the European Respiratory Society (ERS). Methods used in patient selection: PERC / WELLS / sPESI scoring via physical examination, vitals assessment, bloodwork, and performance of diagnostic imaging (e.g., VQ Perfusion Scan, Computed Tomography Pulmonary Angiography, Echocardiography, and/or Pulmonary Angiography) to confirm a filling defect in at least one main or lobar pulmonary artery caused by presence of thromboembolus Exclusion: Patients who are deemed unsuitable for an endovascular procedure; patients who are unable to be safely anticoagulated peri-operatively. Not intended for use in vessels < 8 mm

	Additional information provided by applicant - multidisciplinary team (MDT) High-risk or intermediate-high-risk patients selected for treatment consideration SA Health Referral to vascular surgery Urgent "Bedside" case conference regarding appropriateness of treatment. Conference includes the following specialists: • If under care of ICCU, discussion between Intensive Care Specialists and Vascular Surgery • If under care of Respiratory Medicine, discussion (including in ICCU) to include Respiratory Medicine Specialists Decision during case conference to proceed if: • Agreement of 2 ICU specialists and 2 vascular surgeons to proceed • Agreement of 2 respiratory medicine specialists and 2 vascular surgeons + ICU specialist to proceed Note: In the setting of patient not in ICCU or deemed to have intermediate-low-risk PE but benefit considered in the individual case, the MDT conference will occur to decide if there is benefit from intervention. This is in consideration of benefit from intervention as preventive strategy for CTED or CTEPH. This team should primarily include 2 consultant respiratory physicians in agreement that benefit could be gained in consultation with 2 consultant vascular surgeons. As the patient will likely be managed post-procedurally in the ICCU, or if the patient was in ICU, the decision-making team should include the treating intensivist and a second intensivist in agreeance that treatment would be supported on a case-by-case decision basis.
FINANCIAL CONSIDERATIONS	
Device costs	Since this is a single use catheter device, no capital equipment is required. Procedure costs: Inari FlowTriever™ System components and consumables are covered under a PE-PPP (Price Per Procedure) for which allows for multiple combinations and quantities per procedure without impacting cost. The current PE-PPP is [redacted], excluding GST. Number of patients per year: [redacted] Total costs in SALHN per year: 12 x [redacted]
Value for Money	It is unclear whether the FlowTriever demonstrates value for money. Tran 2023 is a US-based multicentre cost-comparison analysis paper authored by Inari Medical consultants. It compared the hospital costs of 146 intermediate-risk PE patients who underwent mechanical thrombectomy (FlowTriever) and 226 patients who underwent CDT (Craig-McNamara perfusion catheter by Medtronic or the EKOS ultrasound-facilitated thrombolysis system by Boston Scientific) and found there was no clear cost advantage of a treatment over another, with observed cost differences influenced by variations in practice and institutions. Although some cost savings are anticipated due to lower in-hospital mortality, lower ICU stay and fewer complications related to use of thrombolysis, hardly any published evidence has been found to support these claims. Tran 2023 concluded that future efforts should focus on strategies to reduce the length of stay, improve efficiency and minimize overall cost of care for intermediate-risk PE patients.
Australian or Overseas Funding Approvals	The FlowTriever has not been considered by the Commonwealth Medical Services Advisory Committee (MSAC) or the Commonwealth Prosthesis List Advisory Committee (PLAC). Interstate experiences: The FlowTriever system has only been used in New South Wales, particularly in Liverpool, Westmead and Wollongong public hospitals [redacted] Overseas experiences a) UK National Institute for Health and Care Excellence (NICE) Guidance (29 November 2023): High-risk pulmonary embolism (PE) when alternative treatments are not suitable There is an unmet need for people with high-risk PE when alternative treatments are not suitable or have failed, and this procedure is the only treatment option. For high-risk PE in people who cannot have thrombolysis, or when there are no other suitable treatment options or alternative treatments have failed, percutaneous thrombectomy should only be used with special arrangements for clinical governance, informed consent and audit. Intermediate-risk PE or high-risk PE when alternative treatments are suitable For intermediate-risk PE or high-risk PE when alternative treatments are suitable, pulmonary thrombectomy should only be used in research. b) Europe HTA Austria (March 2023) In 2023, the Austrian Institute for HTA (HTA Austria) was commissioned by the Austrian Ministry of Health to conduct a HTA review on "Percutaneous aspiration thrombectomy (FlowTriever and Penumbra Indigo systems) for PE.". It did

	not recommend Austrian Ministry of Health to include the technology in the country's catalogue of benefits ("currently not recommended"). The HTA review concluded that: In the absence of robust comparative data, no conclusions can be drawn regarding the comparative effectiveness of aspiration thrombectomy compared with other procedures (such as catheter-based thrombolysis). Re-evaluation is recommended in 2025, when results from PEERLESS will be available.
FEASIBILITY OF ADOPTION	
Organizational Feasibility	The applicant outlined that SALHN has an established model of care for acute PE based on international guidelines where interventional therapy is beneficial in changing the course of outcome for high risk and intermediate risk PE, with also hope to reduce the long-term consequences of PE such as Chronic thromboembolic pulmonary hypertension (CTEPH). This is a careful change in management taking into account developments in this area. The application for FlowTriever sits within this program as a device that is specifically engineered to do this procedure and has published good outcomes when utilised compared to other established techniques. The application states that the removal of PE with the FlowTriever System is performed in a suitable Hybrid Operating Suite or Cardiac Catheterization Lab. The average procedure time is approximately 60 minutes. Since thrombolytics are not required, an ICU stay is not obligatory following a FlowTriever procedure and is often unnecessary. Refer to "suitability of patient group" section for more details on MDT. <u>Clinical outcomes reporting</u> Outcomes reporting were not covered in the application.
Credentialing and Competency	CDMT using the FlowTriever is known to be a complex or technically difficult procedure, without the need use of general anaesthesia. It requires operators to have the experience and knowledge of passing and manipulating large-diameter catheters within the right ventricle and pulmonary arteries (Kopec 2023). The applicant noted that in Australia, the FlowTriever procedure is performed by Vascular Surgeons and Interventional Radiologists. Vascular Surgeons have to undergo a 5-year training program with endovascular surgery/interventions before becoming qualified. Interventional Radiologists do a 1-year fellowship after receiving their fellowship. In USA and Europe, interventional cardiologists may be involved as they sometimes branch into peripheral vascular work. The applicant explained that there is no credentialling pathway well established for this in Australia. In South Australia this is the case, and then it will depend on LHN pathways. The different LHNs will be slightly different due to skill mix/interest in treatment algorithms. • SALHN has an established an PE therapy pathway in combination with our Interventional Radiologists and ICU/Respiratory Medicine. • CALHN is in the process of establishing a PE therapy pathway. Physician training consists of three phases: an online training, in person didactic and hands on, as well as continuing training. All cases where an Inari FlowTriever product is used, are supported by trained Inari representatives 24/7. If approved for use, the FlowTriever procedure should only be done by clinicians with specific training and accreditation. The clinicians should be appropriately credentialed and approved by the SA Health Credentialing and Scope of Practice Committee to use the FlowTriever (refer to paragraph 3.4.3 New Clinical Procedures, Technologies and Treatments of the SA Health Credentialing Policy Directive).
CONSISTENCY WITH EXPECTED SOCIETAL/ ETHICAL/ LEGAL VALUES	
Values	Consistent with expected societal, ethical and legal values at this time. Certain religious patients may require extra care and explanation concerning the FlowSaver blood filtration and return device.
QUERIES TO	Dr Deborah Chen Manager, Health Technology Assessment (HTA) Program SAPACT, Medicines and Technology Programs, SA Department for Health and Ageing Level 8, Citi Centre Building, 11 Hindmarsh Square, Adelaide, SA 5000 Tel: +61 8 7117 9807; Email: Health.SAPACT@sa.gov.au
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