



Australian Government

Department of Health

MSAC Application 1374.1

Subcutaneous implantable cardioverter defibrillator therapy for the prevention of sudden cardiac death

This application form is to be completed for new and amended requests for public funding (including but not limited to the Medicare Benefits Schedule (MBS)). It describes the detailed information that the Australian Government Department of Health requires to determine whether a proposed medical service is suitable.

Please use this template, along with the associated Application Form Guidelines to prepare your application. Please complete all questions that are applicable to the proposed service, providing relevant information only. Applications not completed in full will not be accepted.

Should you require any further assistance, departmental staff are available through the Health Technology Assessment Team (HTA Team) on the contact numbers and email below to discuss the application form, or any other component of the Medical Services Advisory Committee process.

Email: hta@health.gov.au

Website: www.msac.gov.au

PART 1 – APPLICANT DETAILS

1. Applicant details (primary and alternative contacts)

Corporation / partnership details (where relevant):

Corporation name: Boston Scientific

ABN: Redacted

Business trading name: **REDACTED**

Primary contact name: REDACTED

Primary contact numbers

Business: **REDACTED**

Mobile: **REDACTED**

Email: **REDACTED**

Alternative contact name: REDACTED

Alternative contact numbers

Business: **REDACTED**

Mobile: **REDACTED**

Email: **REDACTED**

2. (a) Are you a lobbyist acting on behalf of an Applicant?

Yes

No

(b) If yes, are you listed on the Register of Lobbyists?

Yes

No

PART 2 – INFORMATION ABOUT THE PROPOSED MEDICAL SERVICE

3. Application title

Subcutaneous implantable cardioverter defibrillator (ICD) therapy for the prevention of sudden cardiac death (SCD). This Application is a resubmission of MSAC Application 1374 and is subject to the same PICO ratified in the final protocol (Attachment A).

4. Provide a succinct description of the medical condition relevant to the proposed service (no more than 150 words – further information will be requested at Part F of the Application Form)

ICDs represent a highly effective therapy for primary and secondary prevention of SCD and the treatment of life-threatening ventricular arrhythmias. The S-ICD system provides the same clinical benefits as transvenous ICDs (TV-ICDs) without the risks associated with transvenous lead placement and extraction. As such, S-ICD is primarily indicated for patients with underlying congenital or structural cardiac abnormalities, or with limited or difficult vascular access. Often these patients are quite young and may require multiple replacements of transvenous ICD leads over the course of their lives, leading to an elevated risk of serious complications, especially infection. A functional limitation of current S-ICD devices is that they cannot provide long-term bradypacing or antitachycardia pacing (ATP). S-ICD is therefore only indicated in patients who do not have symptomatic bradycardia, incessant VT, or spontaneous, frequently occurring VT that is reliably terminated with ATP.

5. Provide a succinct description of the proposed medical service (no more than 150 words – further information will be requested at Part 6 of the Application Form)

The proposed service involves the insertion of S-ICD leads. Insertion of the S-ICD system is clinically similar to the insertion of a TV-ICD; however, the subcutaneous lead does not need to be inserted into the vasculature of the heart. Rather, it is placed under the skin of the patients' chest. The implantation of S-ICD leads requires the use of a compatible ICD generator; however, the procedure for implanting the generator remains unchanged (i.e. subcutaneous). Therefore, a new or amended service for implantation of a subcutaneous ICD generator is not requested.

6. (a) Is this a request for MBS funding?

- Yes
 No

(b) If yes, is the medical service(s) proposed to be covered under an existing MBS item number(s) or is a new MBS item(s) being sought altogether?

- Amendment to existing MBS item(s)
 New MBS item(s)

(c) If an amendment to an existing item(s) is being sought, please list the relevant MBS item number(s) that are to be amended to include the proposed medical service:

Not applicable

(d) If an amendment to an existing item(s) is being sought, what is the nature of the amendment(s)?

Not applicable

(e) If a new item(s) is being requested, what is the nature of the change to the MBS being sought?

- i. A new item which also seeks to allow access to the MBS for a specific health practitioner group
- ii. A new item that is proposing a way of clinically delivering a service that is new to the MBS (in terms of new technology and / or population)
- iii. A new item for a specific single consultation item
- iv. A new item for a global consultation item(s)

(f) Is the proposed service seeking public funding other than the MBS?

- Yes
 No

(g) If yes, please advise:

Not applicable

7. What is the type of service:

- Therapeutic medical service
 Investigative medical service
 Single consultation medical service
 Global consultation medical service
 Allied health service
 Co-dependent technology
 Hybrid health technology

8. For investigative services, advise the specific purpose of performing the service (which could be one or more of the following):

- i. To be used as a screening tool in asymptomatic populations
ii. Assists in establishing a diagnosis in symptomatic patients
iii. Provides information about prognosis
iv. Identifies a patient as suitable for therapy by predicting a variation in the effect of the therapy
v. Monitors a patient over time to assess treatment response and guide subsequent treatment decisions

Not applicable

9. Does your service rely on another medical product to achieve or to enhance its intended effect?

- Pharmaceutical / Biological
 Prosthesis or device
 No

10. (a) If the proposed service has a pharmaceutical component to it, is it already covered under an existing Pharmaceutical Benefits Scheme (PBS) listing?

- Yes
 No

Not applicable

(b) If yes, please list the relevant PBS item code(s):

Not applicable

(c) If no, is an application (submission) in the process of being considered by the Pharmaceutical Benefits Advisory Committee (PBAC)?

- Yes (please provide PBAC submission item number below)
 No

Not applicable

(d) If you are seeking both MBS and PBS listing, what is the trade name and generic name of the pharmaceutical?

Not applicable

11. (a) If the proposed service is dependent on the use of a prosthesis, is it already included on the Prostheses List?

- Yes
 No

(b) If yes, please provide the following information (where relevant):

Not applicable

(c) If no, is an application in the process of being considered by a Clinical Advisory Group or the Prostheses List Advisory Committee (PLAC)?

- Yes
 No

An application will be made to list Boston Scientific's S-ICD Electrode on the March 2021 Prostheses List

(d) Are there any other sponsor(s) and / or manufacturer(s) that have a similar prosthesis or device component in the Australian market place which this application is relevant to?

- Yes
 No

(e) If yes, please provide the name(s) of the sponsor(s) and / or manufacturer(s):

Not applicable

12. Please identify any single and / or multi-use consumables delivered as part of the service?

Single use consumables:

- ARTG 303348: Boston Scientific Pty Ltd - Pacing/defibrillation lead tunneller
- ARTG 218786: Boston Scientific Pty Ltd - Pacing lead suture sleeve
- ARTG 218786: Boston Scientific Pty Ltd - Cover, ultrasonic probe, body surface

Multi-use consumables:

- ARTG 230414: Boston Scientific Pty Ltd - Latitude Communicator Model 6290 -Transtelephonic implantable pacemaker analysis system
- ARTG 260383: Boston Scientific Pty Ltd - EMBLEM™ S-ICD Programmer Model 3200 Cardiac pulse generator programmer
- ARTG 233613: Boston Scientific Pty Ltd - Telemetry Wand Model 3203 -
- Active-implantable-device communicator
- ARTG 258292: Boston Scientific Pty Ltd - Clinical measurer, ruler

PART 3 – INFORMATION ABOUT REGULATORY REQUIREMENTS

13. (a) If the proposed medical service involves the use of a medical device, in-vitro diagnostic test, pharmaceutical product, radioactive tracer or any other type of therapeutic good, please provide the following details:

- Boston Scientific Pty Ltd - EMBLEM™ MRI S-ICD A219 - Defibrillator, implantable, automatic
- Boston Scientific Pty Ltd - EMBLEM™ S-ICD Subcutaneous Electrode Model 3501 - Lead, defibrillator, implantable

(b) Is the medical device classified by the TGA as either a Class III or Active Implantable Medical Device (AIMD) against the TGA regulatory scheme for devices?

- Class III (S-ICD leads)
 AIMD (S-ICD defibrillator)
 N/A

14. (a) Is the therapeutic good to be used in the service exempt from the regulatory requirements of the *Therapeutic Goods Act 1989*?

- Yes (If yes, please provide supporting documentation as an attachment to this application form)
 No

(b) If no, has it been listed or registered or included in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)?

- Yes (if yes, please provide details below)
 No

ARTG	TGA indication/purpose
ARTG 286705: Boston Scientific Pty Ltd - EMBLEM™ MRI S-ICD A219 - Defibrillator, implantable, automatic	The EMBLEM™ MRI S-ICD pulse generator is a component of the Boston Scientific S-ICD System. The S-ICD System is intended to provide defibrillation therapy for the treatment of life-threatening ventricular tachyarrhythmias in patients who do not have symptomatic bradycardia, incessant ventricular tachycardia, or spontaneous, frequently recurring ventricular tachycardia that is reliably terminated with anti-tachycardia pacing.
ARTG 291908: Boston Scientific Pty Ltd - EMBLEM™ S-ICD Subcutaneous Electrode Model 3501 - Lead, defibrillator, implantable	The EMBLEM™ S-ICD subcutaneous electrode is a component of the Boston Scientific S-ICD System. The S-ICD System is intended to provide defibrillation therapy for the treatment of life-threatening ventricular tachyarrhythmias in patients who do not have symptomatic bradycardia, incessant ventricular tachycardia, or spontaneous, frequently recurring ventricular tachycardia that is reliably terminated with anti-tachycardia pacing.

15. If the therapeutic good has not been listed, registered or included in the ARTG, is the therapeutic good in the process of being considered for inclusion by the TGA?

- Yes (please provide details below)
 No

Not applicable

16. If the therapeutic good is not in the process of being considered for listing, registration or inclusion by the TGA, is an application to the TGA being prepared?

Not applicable

PART 4 – SUMMARY OF EVIDENCE

17. Provide an overview of all key journal articles or research published in the public domain related to the proposed service that is for your application (limiting these to the English language only). Please do not attach full text articles, this is just intended to be a summary.

The pivotal evidence for the reapplication is the recently completed PRAETORIAN RCT, which was designed to determine if S-ICD is non-inferior to the TV-ICD with respect to major ICD-related adverse events. This study is yet to be published

18. Identify yet to be published research that may have results available in the near future that could be relevant in the consideration of your application by MSAC (limiting these to the English language only). Please do not attach full text articles, this is just intended to be a summary.

The pivotal evidence for the reapplication is the recently completed PRAETORIAN RCT, which was designed to determine if S-ICD is non-inferior to the TV-ICD with respect to major ICD-related adverse events. This study is yet to be published.

	Type of study design*	Title of research (including any trial identifier if relevant)	Short description of research (max 50 words)**	Website link to research (if available)	Date***
1.	Randomised controlled trial	A prospective, randomised comparison of subcutaneous and transvenous Implantable cardioverter defibrillator therapy (PRAETORIAN) NCT01296022	The objective of PRAETORIAN was to determine if S-ICD is non-inferior to the TV-ICD with respect to major ICD-related adverse events, including: <ul style="list-style-type: none"> • Inappropriate shocks • ICD-related complications requiring intervention • Lead-related complications The trial enrolled 849 patients between March 2011 and January 2017 in the EU and US.	Protocol: https://pubmed.ncbi.nlm.nih.gov/22607851/ Results: not yet published	May 2012

* Categorise study design, for example meta-analysis, randomised trials, non-randomised trial or observational study, study of diagnostic accuracy, etc.

**Provide high level information including population numbers and whether patients are being recruited or in post-recruitment.

***Date of when results will be made available (to the best of your knowledge).

PART 5 – CLINICAL ENDORSEMENT AND CONSUMER INFORMATION

- 19. List all appropriate professional bodies / organisations representing the group(s) of health professionals who provide the service (please attach a statement of clinical relevance from each group nominated):**

The Cardiac Society of Australia and New Zealand

As this is a resubmission the applicant seeks advice whether a new letter of clinical relevance is required

- 20. List any professional bodies / organisations that may be impacted by this medical service (i.e. those who provide the comparator service):**

As above.

- 21. List the consumer organisations relevant to the proposed medical service (please attach a letter of support for each consumer organisation nominated):**

hearts4heart

The applicant is seeking a letter of support from hearts4heart for the proposed medical service

- 22. List the relevant sponsor(s) and / or manufacturer(s) who produce similar products relevant to the proposed medical service:**

Not applicable

- 23. Nominate two experts who could be approached about the proposed medical service and the current clinical management of the service(s):**

Name of expert 1: **REDACTED**

Telephone number(s): **REDACTED**

Email address: **REDACTED**

Justification of expertise: **REDACTED**

Name of expert 2: **REDACTED**

Telephone number(s): **REDACTED**

Email address: **REDACTED**

Justification of expertise: **REDACTED**

Please note that the Department may also consult with other referrers, proceduralists and disease specialists to obtain their insight.

PART 6 – POPULATION (AND PRIOR TESTS), INTERVENTION, COMPARATOR, OUTCOME (PICO)

PART 6a – INFORMATION ABOUT THE PROPOSED POPULATION

24. Define the medical condition, including providing information on the natural history of the condition and a high level summary of associated burden of disease in terms of both morbidity and mortality:

The population requested for reimbursement is consistent with the population described and ratified in the final protocol for MSAC Application 1374.

The main benefit of S-ICD is avoiding some of the risks associated with the highly invasive nature of transvenous lead implantation, which requires leads to be in direct contact with heart tissue. Since intravascular leads become fibrosed in place over time, lead revision and extraction can be associated with even greater risk than implantation. During this procedure, separation of leads from scar tissue can lead to perforation of the heart or surrounding blood vessels, resulting in major bleeding. According to one estimate, patients with ICDs have a 20% chance of lead failure within 10 years, and replacing the leads carries a risk of death of between 2% and 5% (Graham-Rowe, 2008). To avoid some of these risks, broken leads are sometimes left in situ, with a new lead placed alongside. However, veins can only accommodate a limited number of leads, and sometimes, non-functioning leads must be extracted to make space for a new lead. Younger patients sometimes opt for removal of broken leads even if there are no space limitations because they will probably need more leads in the future, and leads are more difficult to extract after a longer time in the body. As a result, the incidence of lead-related complications, infection, and lead failure may be higher in younger, growing, more active patients (Bonney, 2010; Berul, 2008). In Australia, clinicians must be specially certified by the Cardiac Society of Australia and New Zealand (CSANZ) in order to perform extraction of transvenous pacing and defibrillator leads.

It is anticipated that S-ICD will be reserved for those patients currently indicated for ICD therapy with a high clinical need for a system that avoids the risks associated with the implantation of leads through the vasculature and directly into the heart anatomy. These include patients with underlying congenital or structural cardiac abnormalities, or with limited or difficult vascular access in whom insertion of transvenous leads is particularly challenging or contraindicated. As lead replacement is a less complicated procedure than TV-ICD lead extraction, S-ICD may also be preferred in younger ICD patients who will likely require a number of lead replacement procedures over their lifetime.

There are several groups of patients that have the greatest clinical need for alternatives to conventional transvenous ICD, and in whom subcutaneous ICD may be preferable:

- Patients with difficult venous anatomy - in patients with left persistent superior vena cava (LPSVC), capped ICD leads, occluded veins and diseased or mechanical tricuspid valves, the implantation of transvenous ICD leads can be technically difficult and is associated with increased procedural risk
- Younger patients - transvenous ICD may not be suitable for children or young adults, due to anatomical challenges within the growing body, risk of dislodgement due to high activity level and risks related to procedure revisions over a long life expectancy
- Patients who are at high risk for infection - patients with a high infection risk may have a lower risk of infection with subcutaneous ICD. This group may include patients with diabetes, renal impairment, or paediatric/small patients
- Patients with congenital heart disease and channelopathies - several conditions commonly categorised as adult congenital heart disease (ACHD) have been associated with sudden cardiac death including: univentricular hearts, transposition of the great arteries, congenitally corrected transposition, tetralogy of fallot, and aortic stenosis. In addition, transvenous ICD leads are associated with a higher failure rate in patients with channelopathies such as Long QT syndrome, Brugada Syndrome, and Catacholaminergic Polymorphic Ventricular Tachycardia (CPVT).

Consistent with the natural history of chronic heart failure, over time a small proportion of patients will develop secondary indications such as bradycardia or tachycardia, which may be terminated with pacing. In some cases, these patients may be effectively managed with anti-arrhythmic medication; however, some will require switching to a TV-ICD system, prior to the elective replacement of their current S-ICD.

25. Specify any characteristics of patients with the medical condition, or suspected of, who are proposed to be eligible for the proposed medical service, including any details of how a patient would be investigated, managed and referred within the Australian health care system in the lead up to being considered eligible for the service:

Identifying individuals at the highest risk of VA and SCD can be a complex process. In general, patients with a history of myocardial infarction, coronary artery disease, left ventricular dysfunction and cardiomyopathies have a high risk of experiencing life-threatening arrhythmias. Individuals with a family history of SCD or genetic defects such as Long QT syndrome are also at a high risk of SCD. Physiological approaches to risk stratification include the use of electrophysiology studies, signal-averaged ECGs and heart rate variability. In addition, increased risk of SCD may also be conferred by the presence of ventricular asynchrony as evidenced by prolonged QRS duration on the ECG. For patients diagnosed with an elevated risk for VA, common treatment options include anti-arrhythmic medications, ICDs and cardiac ablation surgery.

In Australia, patients requiring ICD therapy for primary prevention are required to have an LVEF $\leq 30\%$ at least one month after a MI when the patient has received optimal medical therapy, or chronic heart failure associated with mild to moderate symptoms (NYHA II and III) and a LVEF $\leq 35\%$ when the patient has received OMT (MSAC, 2006). Medicare funding is also available for ICD implantation in patients requiring secondary prevention of SCD. These criteria are consistent with evidence-based US and European practice guidelines, which recommend ICD therapy for primary and secondary prevention of SCD.

26. Define and summarise the current clinical management pathway *before* patients would be eligible for the proposed medical service (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway up to this point):

According to the current clinical management algorithm for the treatment of VA, the appropriate transvenous ICD system (single-chamber, dual-chamber or CRT-D), and the necessary functions of that system (e.g. defibrillation, pacing and resynchronisation) are determined by the treating cardiologist based on the individual needs of the patient. For patients with a clinical indication for resynchronisation therapy the most appropriate treatment option is usually a CRT-D device. At present, all other patients with an ICD indication proceed to single or dual-chamber transvenous ICD, irrespective of their need for long-term bradycardia or tachycardia pacing.

The proposed clinical management algorithm for treating VAs (Attachment B) is identical to the current algorithm, except for the inclusion of subcutaneous ICD as an alternative to single and dual-chamber transvenous ICD in patients without a pacing indication.

PART 6b – INFORMATION ABOUT THE INTERVENTION

27. Describe the key components and clinical steps involved in delivering the proposed medical service:

Implantation of the pulse generator

The process for implanting a pulse generator for use with subcutaneous leads is the same as the process currently used for the implantation of conventional transvenous ICD. The only difference being that the S-ICD canister is implanted in the left lateral thoracic region, while the optimum location for a conventional ICD canister is the right or left pectoral region. Currently, this service is performed using either MBS item 38387 (primary prevention) or MBS item 38393 (secondary prevention).

Implantation of subcutaneous ICD leads

The subcutaneous ICD leads are tunnelled under the skin into a pre-determined position planned during pre-surgical X-rays. Lead placement occurs via anatomical incisions made at the mid-axillary line, xiphoid mid-line and superior parasternal area. An incision and pocket are created in the vicinity of the left 5th and 6th intercostal spaces at the mid-axillary line where the ICD generator is implanted. Once connected

to the lead, it is placed in the pocket and sutured closed. The lead has an 8cm shocking coil, flanked by two sensing electrodes. The device automatically chooses the most appropriate sensing vector for avoiding QRS double-counting and T-wave over-sensing. A conditional shock zone can also be programmed between heart rates of 170 to 240 bpm to distinguish supraventricular from ventricular tachycardia, thereby avoiding inappropriate shocks caused by the former. New MBS items are requested for this service.

Replacement procedures

Leads usually last longer than device batteries, so leads are simply reconnected to each new pulse generator (battery) at the time of replacement i.e. for routine generator replacement there is no additional cost for technology or physician fee for replacement of a subcutaneous ICD lead. Should lead replacement be required (e.g. as a result of infection of lead failure) it is proposed that the procedure would be carried out using the same service as that proposed for subcutaneous lead implantation.

28. Does the proposed medical service include a registered trademark component with characteristics that distinguishes it from other similar health components?

N/A

29. If the proposed medical service has a prosthesis or device component to it, does it involve a new approach towards managing a particular sub-group of the population with the specific medical condition?

The use of S-ICD leads in eligible patients does not involve any changes to the manner in which patients at risk of SCD are managed.

30. If applicable, are there any limitations on the provision of the proposed medical service delivered to the patient (i.e. accessibility, dosage, quantity, duration or frequency):

In terms of staffing, procedure time and training, implantation of a subcutaneous ICD device is clinically similar to the insertion of a transvenous ICD. As such, the necessary capabilities to perform subcutaneous ICD implantation are already established at the relevant clinics and institutions.

31. If applicable, identify any healthcare resources or other medical services that would need to be delivered at the same time as the proposed medical service:

S-ICD system implantation is commonly provided under conscious or general sedation, as is transvenous ICD. An anaesthetist may be required to provide the appropriate level of sedation. As with TV-ICD, follow-up testing of the ICD (MBS item 38213) is also performed at the same time as S-ICD lead implantation.

32. If applicable, advise which health professionals will primarily deliver the proposed service:

S-ICD implantation will be performed by a cardiothoracic surgeon or interventional cardiologist

33. If applicable, advise whether the proposed medical service could be delegated or referred to another professional for delivery:

Not applicable

34. If applicable, specify any proposed limitations on who might deliver the proposed medical service, or who might provide a referral for it:

Not applicable

35. If applicable, advise what type of training or qualifications would be required to perform the proposed service, as well as any accreditation requirements to support service delivery:

No further training would be required.

36. (a) Indicate the proposed setting(s) in which the proposed medical service will be delivered (select ALL relevant settings):

- Inpatient private hospital (admitted patient)
- Inpatient public hospital (admitted patient)
- Private outpatient clinic
- Public outpatient clinic

- Emergency Department
- Private consulting rooms - GP
- Private consulting rooms – specialist
- Private consulting rooms – other health practitioner (nurse or allied health)
- Private day surgery clinic (admitted patient)
- Private day surgery clinic (non-admitted patient)
- Public day surgery clinic (admitted patient)
- Public day surgery clinic (non-admitted patient)
- Residential aged care facility
- Patient’s home
- Laboratory
- Other – please specify below

37. Where the proposed medical service is provided in more than one setting, please describe the rationale related to each:

The procedure is performed as an inpatient service, either in the public or private hospital setting.

38. Is the proposed medical service intended to be entirely rendered in Australia?

- Yes
- No – please specify below

PART 6c – INFORMATION ABOUT THE COMPARATOR(S)

39. Nominate the appropriate comparator(s) for the proposed medical service, i.e. how is the proposed population currently managed in the absence of the proposed medical service being available in the Australian health care system (including identifying health care resources that are needed to be delivered at the same time as the comparator service):

The proposed comparator is consistent with the final protocol for MSAC Application 1374. S-ICD is expected to provide a direct substitute for TV-ICD in patients without symptomatic bradycardia, incessant ventricular tachycardia, or spontaneous, frequently recurring ventricular tachycardia that is reliably terminated with ATP. In some of these patients, conventional TV-ICD devices can be programmed to provide defibrillation only, with back-up bradycardia pacing support. It is assumed that all patients implanted with a CRT-D device would have a clinical indication for resynchronisation therapy and would therefore not be candidates for S-ICD.

On this basis, the proposed comparator for S-ICD is single or dual-chamber TV-ICD.

40. Does the medical service (that has been nominated as the comparator) have an existing MBS item number(s)?

- Yes (please list all relevant MBS item numbers below)
- No

The relevant MBS item numbers of TV-ICD lead insertion are 38384 (primary prevention) and 38390 (secondary prevention), as described below.

Category 3 – Therapeutic Procedures
<p>MBS: 38384</p> <p>AUTOMATIC DEFIBRILLATOR, insertion of patches for, or insertion of transvenous endocardial defibrillation electrodes for, primary prevention of sudden cardiac death in:</p> <ul style="list-style-type: none"> - patients with a left ventricular ejection fraction of less than or equal to 30% at least one month after a myocardial infarct when the patient has received optimised medical therapy; or - patients with chronic heart failure associated with mild to moderate symptoms (NYHA II and III) and a left ventricular ejection fraction less than or equal to 35% when the patient has received optimised medical therapy. <p>Not being a service associated with a service to which item 38213 applies</p>

<p>Multiple Services Rule (Anaes.) (Assist.)</p> <p>Fee: \$1,052.65</p> <p>Explanatory note:</p> <p>T8.67 Implantable Cardioverter Defibrillator (Items 38384 and 38387)</p> <p>Items 38384 and 38387 apply only to patients who meet the criteria listed in the item descriptor, and to patients who do not meet the criteria listed in the descriptor but have previously had an ICD device inserted and who prior to its insertion met the criteria and now need the device replaced.</p>
<p>Category 3 – Therapeutic Procedures</p>
<p>MBS: 38390</p> <p>AUTOMATIC DEFIBRILLATOR, insertion of patches for, or insertion of transvenous endocardial defibrillation electrodes for - not for patients with heart failure or as primary prevention for tachycardia arrhythmias. Not being a service associated with a service to which item 38213 applies</p> <p>Multiple Services Rule (Anaes.) (Assist.)</p> <p>Fee: \$1,052.65</p> <p>(No explanatory notes)</p>

- 41. Define and summarise the current clinical management pathway/s that patients may follow *after* they receive the medical service that has been nominated as the comparator (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway that patients may follow from the point of receiving the comparator onwards, including health care resources):**

In patients who are implanted with ICDs the pulse generator will need to be replaced due to battery depletion once every 5-10 years. Leads usually last longer than device batteries, so leads are simply reconnected to each new pulse generator (battery) at the time of replacement. In cases where lead replacement is required (e.g. as a result of infection or lead failure) the procedure is carried out using the same service as that proposed for transvenous lead implantation.

- 42. (a) Will the proposed medical service be used in addition to, or instead of, the nominated comparator(s)?**

- In addition to (i.e. it is an add-on service)
- Instead of (i.e. it is a replacement or alternative)

- (b) If instead of (i.e. alternative service), please outline the extent to which the current service/comparator is expected to be substituted:**

Current S-ICD cannot provide long-term bradypacing or ATP. Australian expert clinical opinion estimates that between 20% and 25% of ICD patients present with a pre-existing indication for cardiac pacing (i.e. bradycardia, tachycardia). As S-ICD cannot currently provide long-term bradypacing or ATP, these patients would not be considered suitable for S-ICD therapy. Thus, the proportion of patients suitable for S-ICD treatment is expected to be approximately 75% of the total eligible ICD population.

As S-ICD is primarily of benefit to patients who have a high risk of complications using TV-ICD, the actual uptake is likely to be further restricted to a specific subset including younger patients, those with difficult venous anatomy, patients with a high risk of infection (e.g. with diabetes) and those with congenital heart disease and channelopathies. Overall, the maximum uptake in patients aged less than 55 years is expected to be 10% in prevalent patients (undergoing lead replacement procedures) and 15% in incident patients (receiving an ICD for the first time). In those aged 55 years or over, the maximum uptake is expected to be 5% in prevalent patients (undergoing lead replacement procedures) and 10% in incident patients (receiving an ICD for the first time).

43. Define and summarise how current clinical management pathways (from the point of service delivery onwards) are expected to change as a consequence of introducing the proposed medical service, including variation in health care resources (Refer to Question 39 as baseline):

Following delivery of the intervention, patient management for patients receiving TV-ICD and S-ICD is unchanged, with the exception of fewer complications (e.g. infections, bleeding and pneumothorax) in the latter. The reduction in complications is itself associated with decreased resource use, including hospitalisations.

In addition, the following potential resource utilisation consequences of S-ICD will be explored in the submission:

- Differences in lead and generator longevity between S-ICD and TV-ICD, and the impact on the lifetime costs of the device
- The number of patients suitable for subcutaneous ICD and the number of those patients expected to develop a need for pacing overtime
- Lead failure/migration

PART 6d – INFORMATION ABOUT THE CLINICAL OUTCOME

44. Summarise the clinical claims for the proposed medical service against the appropriate comparator(s), in terms of consequences for health outcomes (comparative benefits and harms):

Evidence from the PRAETORIAN study suggests that there is a statistically significant reduction in lead-related complications for patients treated with S-ICD compared to TV-ICD. Nonetheless, to be conservative, the main clinical claim in the submission will be that S-ICD is non-inferior to TV-ICD, in terms of clinical efficacy and safety.

45. Please advise if the overall clinical claim is for:

- Superiority
 Non-inferiority

46. Below, list the key health outcomes (major and minor – prioritising major key health outcomes first) that will need to be specifically measured in assessing the clinical claim of the proposed medical service versus the comparator:

Safety Outcomes:

Primary outcome

Number of participants with implantable cardioverter defibrillator (ICD) related adverse events

Secondary outcomes

Number of inappropriate shocks

Number of complications individually

Hospitalisation rate

Clinical Effectiveness Outcomes:

Number of Major Adverse Cardiac Event (MACE)

Number of appropriate shocks

Cardiac (pre-)syncope events

Cardiac decompensation

Quality of life

Time to successful therapy

First shock conversion efficacy

PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION

47. Estimate the prevalence and/or incidence of the proposed population:

The table below presents the number of patients undergoing TV-ICD lead insertion from 2010 to 2019, (based on Medicare Statistics). The data suggest a small annual average increase in the utilisation of TV-ICD lead insertion services in the primary setting and relatively stable use of TV-ICD services in the secondary setting. Overall, in 2019, there were 2,006 TV-ICD lead insertion procedures performed in Australia. These numbers include patients receiving an ICD implantation for the first time (incident population), and a smaller proportion of patients requiring lead replacement due to complications (prevalent population).

Year	MBS item 38384 (primary)	MBS item 38390 (secondary)	Total
2010	855	794	1,649
2011	1,100	877	1,977
2012	999	761	1,760
2013	1,053	962	2,015
2014	1,279	911	2,190
2015	1,306	974	2,280
2016	1,323	916	2,239
2017	1,119	825	1,944
2018	1,209	837	2,046
2019	1,198	808	2,006

48. Estimate the number of times the proposed medical service(s) would be delivered to a patient per year:

The insertion of a subcutaneous ICD lead and associated generator is a once-off procedure and the therapy is for the lifetime of the patient. If the patient requires a new generator (in the event that the battery expires) then the new generator can be connected to the existing subcutaneous ICD lead i.e. there is no additional cost for technology or physician fee for replacement of a subcutaneous ICD lead. This is no different to insertion and replacement of a transvenous ICD generator.

In addition to the incident population described above, there is also expected to be a smaller proportion of patients (prevalent population) undergoing lead replacement (e.g. due to lead failure) who may choose to switch from TV-ICD to S-ICD. This would also be a one-off procedure.

49. How many years would the proposed medical service(s) be required for the patient?

Both incident and prevalent patients are likely to require one medical service per lifetime; however, in instances where patients experience lead-related complications additional services for lead replacement may be required.

50. Estimate the projected number of patients who will utilise the proposed medical service(s) for the first full year:

Based on the Medicare utilisation statistics from 2010 to 2019 presented above, the average rate of growth across all TV-ICD insertion procedures is approximately 33 additional services per year. This rate of growth translates to 2,104 services in 2022 – the likely first full year of listing.

Current S-ICD cannot provide long-term bradypacing or ATP. Australian expert clinical opinion estimates that between 20% and 25% of ICD patients present with a pre-existing indication for cardiac pacing (i.e. bradycardia, tachycardia). As S-ICD cannot currently provide long-term bradypacing or ATP, these patients would not be considered suitable for S-ICD therapy. Thus, the proportion of patients suitable for S-ICD treatment is expected to be approximately 75% of the total eligible ICD population.

As noted above, the overall uptake of S-ICD is likely to be limited to those with a high clinical risk using TV-ICD leads. Based on expert opinion, the maximum uptake in patients aged less than 55 years is expected to be 10% in prevalent patients and 15% in incident patients. In those aged 55 years or over, the maximum uptake is expected to be 5% in prevalent patients and 10% in incident patients.

Assuming an average of 10% across all age groups and indications, it is expected that approximately 158 patients would be considered appropriate for treatment in the first full year of listing (2,104 x 75% x 10%). Assuming the rate of uptake in this population in the first year of listing is 80%, it is estimated that 121 patients would actually use the service in 2022 (2,104 x 75% x 10% x 80%).

Actual data from the applicant shows lower implant data than the estimates provided above. The last several years have shown private implant data to be less than 90 implants per calendar year. With the introduction of an S-ICD lead MBS code this number would see growth; however, this would be modest given the technology is already available in the private market.

51. Estimate the anticipated uptake of the proposed medical service over the next three years factoring in any constraints in the health system in meeting the needs of the proposed population (such as supply and demand factors) as well as provide commentary on risk of ‘leakage’ to populations not targeted by the service:

Based on the same rates of eligibility described above, but assuming that the uptake of S-ICD increases from 80% to 100%, it is expected that the uptake of the proposed service will increase from 158 to 163 in the first three years of listing (2022-2024). Implant data from the applicant has shown that actual implant data is lower than the estimates presented.

There is unlikely to be any leakage outside the populations discussed in this application form, and given the similarities between S-ICD and TV-ICD lead insertion, there are unlikely to be substantial resource constraints.

Population	2022	2023	2024
Estimated patients with TV-ICD leads inserted	2,104	2,136	2,169
No requirement for long-term bradypacing or ATP	75%	75%	75%
Likely to benefit from S-ICD	10%	10%	10%
Uptake	80%	90%	100%
Total expected utilisation	158	160	163

PART 8 – COST INFORMATION

52. Indicate the likely cost of providing the proposed medical service. Where possible, please provide overall cost and breakdown:

The clinical claim presented in the submission will be that S-ICD is non-inferior to TV-ICD in terms of efficacy and safety. Therefore, a cost-minimisation analysis between S-ICD lead insertion and conventional TV-ICD lead insertion is presented as the base-case economic evaluation.

A comparison between the processes for inserting S-ICD and TV-ICD devices is presented below. Both procedures take a similar amount of time (approximately one hour); however, the insertion of a transvenous lead is a more complex procedure and is thus associated with a higher level of procedural risk. Despite these differences, both procedures should be undertaken by a highly skilled physician to ensure appropriate lead placement, without over-sensing, lead migration and local infection.

Overall, S-ICD and TV-ICD lead insertion are largely similar procedures, although TV-ICD lead insertion is somewhat more complex. Thus, it is expected that the fee for S-ICD lead insertion will be similar or less than the current fee for TV-ICD lead insertion (\$1,085.55). A complete derivation and justification for this fee will be presented in the submission.

Steps in the delivery of intervention	Proposed Service – Insertion of a subcutaneous ICD lead	Current Service – Insertion of a transvenous ICD lead
Sedation Type	Conscious or general sedation	Conscious or general sedation
Imaging Technique	Fluoroscopy	Fluoroscopy
Procedural Steps	<ul style="list-style-type: none"> • Prep time • Device pocket formation • Subcutaneous lead placement (additional incisions and suturing required) • Electrode terminal pin connection to device • Device programming & testing performed • Pocket closure 	<ul style="list-style-type: none"> • Prep time • Device pocket formation • Transvenous lead placement under fluoroscopy • Electrode terminal pin connection to device • Device programming & testing performed • Pocket closure
Procedure Time	Approx. 1 hour	Approx. 1 hour

53. Specify how long the proposed medical service typically takes to perform:

As stated above, the total procedure for S-ICD lead insertion takes approximately an hour.

54. If public funding is sought through the MBS, please draft a proposed MBS item descriptor to define the population and medical service usage characteristics that would define eligibility for MBS funding.

The proposed item descriptor for subcutaneous ICD in primary and secondary prevention is presented below. The suggested wording for this item descriptor was agreed to in the Final Protocol for Application 1374. The proposed MBS item descriptors specify that the use of subcutaneous ICD should be limited to patients who do not have symptomatic bradycardia, incessant ventricular tachycardia, or spontaneous, frequently occurring VT that is reliably terminated with ATP. The Applicant proposes that physician discretion and patient preference is maintained when deciding between a transvenous and a subcutaneous system, and therefore recommends that no further restriction in patient population to insertion of a subcutaneous ICD lead compared to criteria for insertion of a transvenous ICD lead.

Category 3 – Therapeutic Procedures

MBS: TBD

SUBCUTANEOUS DEFIBRILLATOR LEAD, insertion, removal or replacement of, for prevention of sudden cardiac death in patients who do not have symptomatic bradycardia, incessant ventricular tachycardia, or spontaneous, frequently occurring ventricular tachycardia that is reliably terminated with anti-tachycardia pacing.

Multiple Services Rule (Anaes.) (Assist.)

Fee: TBD