Australian Government

Department of Health and Ageing

Australia and New Zealand Horizon Scanning Network

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Horizon Scanning Technology Prioritising Summary

Subcutaneous implantable cardioverter-defibrillator (ICD) for patients at risk of sudden cardiac death

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AHTA

Adelaide
Health Technology
Assessment

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PRIORITISING SUMMARY

REGISTER ID: **000526**

NAME OF TECHNOLOGY: SUBCUTANEOUS IMPLANTABLE CARDIOVERTER-DEFIBRILLATOR (ICD)

PURPOSE AND TARGET GROUP: FOR PATIENTS AT RISK OF SUDDEN CARDIAC DEATH

STAGE OF DEVELOPMENT (IN AUSTRALIA):

☒	Yet to emerge	☐	Established
☐	Experimental	☐	Established *but* changed indication or modification of technique
☐	Investigational	☐	Should be taken out of use
☐	Nearly established		

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

☐	Yes	ARTG number
☒	No	
☐	Not applicable	

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Multicentre: USA, New Zealand, UK, Italy, Russia, Germany, Netherlands	✓		
Portugal		✓	

IMPACT SUMMARY:

Cameron Health Inc (USA) provides the S-ICD fully subcutaneous implantable cardioverter defibrillator system with the aim of correcting abnormal heart rhythms by delivering an electrical shock. The technology would be made available through specialised cardiac centres for patients at risk of sudden cardiac death from ventricular arrhythmia.

BACKGROUND

Cardiovascular disease is second only to cancer in its contribution to the burden of disease in Australia and remains the major cause of mortality, mainly due to the

number of deaths it causes amongst older Australians. Coronary heart disease, stroke, heart failure and peripheral vascular disease are the major contributors to the burden of cardiovascular disease (AIHW 2010a). Sudden cardiac death (SCD) resulting from ventricular arrhythmias is a leading cause of mortality in patients with ischemic heart disease and left ventricular dysfunction (Greenberg et al 2004). Individuals at the highest risk of ventricular arrhythmias and SCD are those with a history of myocardial infarction, congestive heart failure, coronary artery disease, left ventricular ejection fraction of less than 40 per cent and cardiomyopathies. In addition, individuals with a family history of SCD or genetic defects such as long QT syndrome are also at a high risk of SCD (Lopshire & Zipes 2006). As reported by the MADIT-II trial (Moss et al 2002)and the Sudden Cardiac Death in Heart Failure trial (Bardy et al 2005), an implantable cardioverter defibrillator (ICD) may result in a decrease in mortality in patients with ischemic or non-ischemic heart disease and left ventricular arrhythmias, when compared to conventional pharmacological therapy alone.
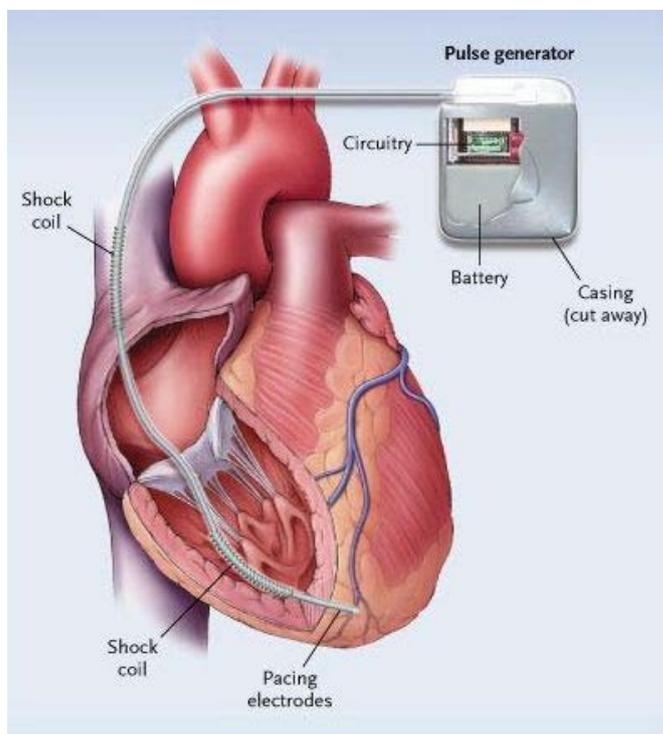
Figure 1   A single chamber ICD (DiMarco 2003)

An ICD is a device designed to detect a life-threatening, rapid heartbeat emanating from the lower chamber of the heart. By delivering an electrical shock to the heart (defibrillation) the abnormal heart rhythm is converted back to normal. Conventional ICDs consist of a generator, which is usually implanted in a pocket in the pectoral region below the left shoulder. The transvenous right ventricular lead contains the shock coils and pacing electrode. Additional leads may be connected for right atrial or left ventricular pacing, sensing and defibrillation (Figure 1). The ICD can be implanted under local anaesthesia with the leads inserted through an incision, into a vein and guided to the heart under fluoroscopy. The lead tip is attached to the heart

muscle, while the other end of the lead is attached to the pulse generator (DiMarco 2003). The majority of ICDs (approximately 80%) are implanted as a means of primary prevention, that is, in patients at risk of SCD but whom have not, as yet, experienced a cardiac event. Dual chamber[1] and biventricular[2] ICDs are now more commonly implanted than single chamber[3] ICDs (Hammill et al 2010).

A number of device related complications may occur with the transvenous systems including: infection or erosion, haematoma, pneumothorax, lead dislodgement, inadequate defibrillation threshold and electromagnetic interference. The greatest number of device-related complications relates to the lead malfunction or lead fracture, which may cause false signals, causing delivery of inappropriate shocks (DiMarco 2003). Failed leads often require removal, which is a procedure associated with a high-degree of morbidity and mortality. If pacing is not required to maintain an adequate heart rate, then a defibrillator which avoids the use of transvenous electrodes may be used (Bardy et al 2010).
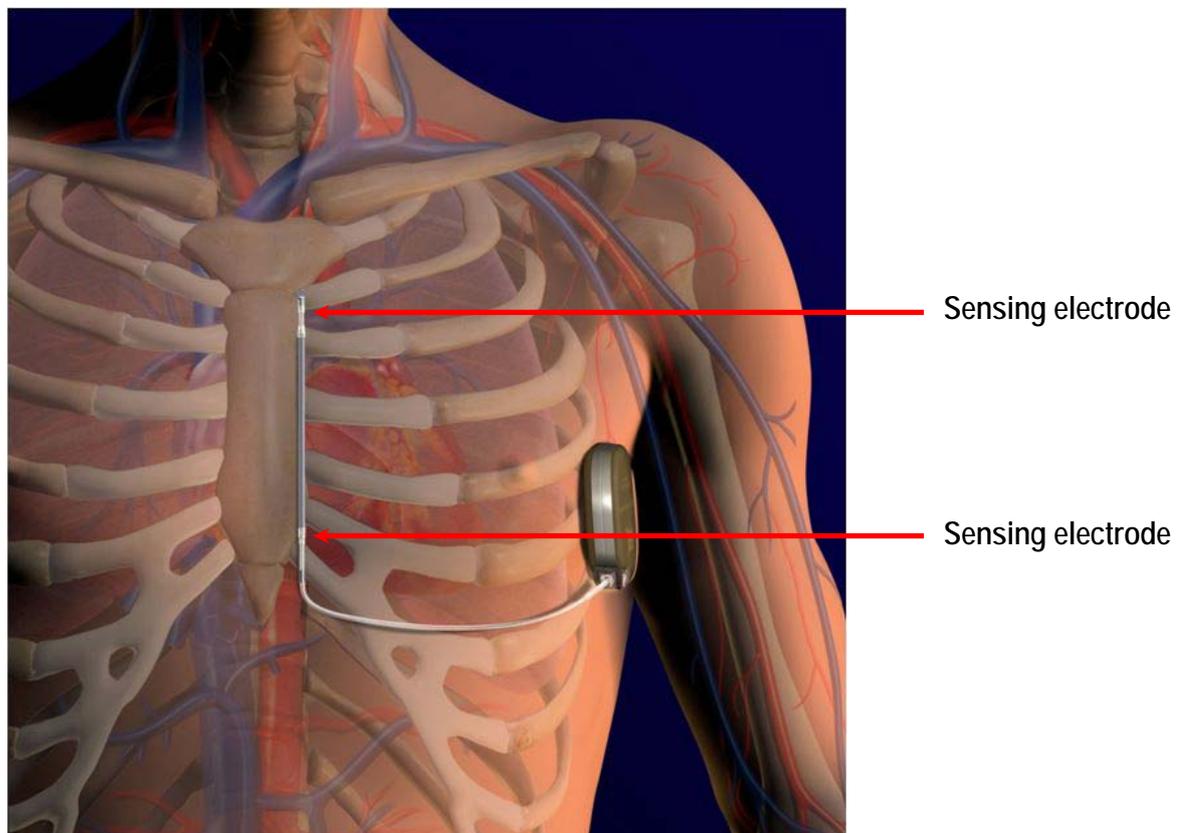
Figure 2   Placement of the S-ICD demonstrating the placement of the leads (printed with permission (Bardy et al 2010)

[1] Dual chamber: leads are attached in the right atrium and right ventricle with the pulse delivered to the right atrium first to assist the heart to beat in a normal rhythm
[2] Biventricular ICD: 2 or 3 leads are positioned in the right atrium and the right and left ventricles (via the coronary sinus vein)
[3] Single chamber: lead is attached in the right ventricle and pulse assists the ventricle to contract normally

Cameron Health Inc (USA) manufacture an entirely subcutaneous ICD (S-ICD) which consists of the SQ-RX Pulse Generator for patients with cardiac arrhythmias who require defibrillation and the Q-TRAK Subcutaneous, which is implanted subcutaneously, with the distal portion positioned parallel to the left sternal border and the proximal end of the 3mm electrode connected to the pulse generator (Figure 2), avoiding the need to place the sensing and therapy electrodes within or on the heart. A full description of the surgical procedure may be found in the [supplementary appendix](#) of the Bardy et al (2010) paper. The surgical procedure may be conducted in an outpatient setting and is guided by anatomical landmarks, therefore fluoroscopy is not required and the procedure time is markedly shortened compared to the implantation of transvenous ICDs (Bardy et al 2010).

During device operation, the cardiac rhythm is detected by the two sensing electrodes as indicated in Figure 2. The system can be programmed to discriminate between supraventricular tachycardia and ventricular tachycardia to avoid inappropriate treatment of the former. After device testing with the use of 65-Joule (J) shocks, the device will deliver defibrillation shocks at 80-J. Other features include automatic reverse shock polarity if the initial shock fails and demand pacing at 50 beats per minute for 30 seconds after a shock. Data from up to 24 treated episodes can be stored (Bardy et al 2010).

CLINICAL NEED AND BURDEN OF DISEASE

Individuals at the highest risk of ventricular arrhythmias and SCD are those with a history of myocardial infarction, coronary artery disease, left ventricular dysfunction and cardiomyopathies. Individuals with a family history of SCD or genetic defects such as long QT syndrome are also at a high risk of SCD (Lopshire & Zipes 2006). A cross-sectional Australian study investigated the causes of SCD in people less than 35 years of age (Doolan et al 2004). A total of 10,199 autopsies performed in Sydney were reviewed, 193 cases identified as SCDs. Although the cause of SCD was not established it was presumed to be due to a primary arrhythmia in 31 per cent of cases. Coronary artery disease was reported in 24 per cent of cases, hypertrophic cardiomyopathy or unexplained left ventricular hypertrophy in 15 per cent of cases, and myocarditis in 12 per cent of cases.

A comprehensive survey of the number of pacemakers and implantable cardioverter defibrillators was undertaken in Australia and New Zealand for the year 2005. Data were obtained via a survey of all companies that sold and registered ICDs throughout Australia and via individual hospitals in New Zealand. During 2005 there were 68 Australian and four New Zealand centres routinely performing the implantation ICDs.

A total of 3,284 ICDs were sold in Australia during 2005, of which 2,864 were new implants and 420 (12.8%) were replacement devices. This figure represents a 194 per cent increase in the number of devices implanted in the year 2001 (1,115). Of these

devices, 35 per cent were biventricular ICDs with the remaining 65 per cent an equal mix of single- and dual-chamber models. In New Zealand for the same year, there were a total of 179 ICDs implanted which was a 57 per cent increase in the number implanted in 2001 (n=114). Of these, the majority were new implants (n=134) with 25 per cent (n=45) being replacement ICDs. Of these devices, 10 per cent were biventricular ICDs with the remaining being an equal mix of single- and dual-chamber models. The survey did not report on the clinical indications for implantation nor the complications arising from ICD implantation (Mond & Whitlock 2008).

The prevalence of ICDs in the community is unclear in either Australia or New Zealand.

In Australia, the number of implantations or replacement of ICDs conducted in public hospitals has steadily increased from 606 in 1998-99 to 4,074 2007-08 (AR-DRG F01A[4] and F01B). The average length of stay for the implantation procedure has decreased over time at 11.5 days in 1998-99 down to 7.5 days in 2007-08 for F01A and from 6.6 down to 2.4 days for F01B for the same time periods (AIHW 2010b). According to the Medicare Australia Statistics web site a total of 576 ICDs were implanted in the private sector, using the MBS item number 38371, for the calendar year 2009.

DIFFUSION

The S-ICD is currently being implanted in two centres in New Zealand: Auckland and Christchurch, under the auspices of the IDE trial (ClinicalTrials.gov Identifier NCT01064076), which is being conducted to gain Food and Drug Administration regulatory approval. The device received the European CE Mark in June 2009, which allows Cameron Health to register the product for commercial distribution in New Zealand. Although interest in the product has been expressed in Australia, the company states that their limited resources do not allow broad scale commercial distribution and therefore they have elected not to register the product with Australian TGA (personal communication Cameron Health Inc).

COMPARATORS

Patients who have experienced a cardiac event such as cardiac arrest or an episode of documented sustained ventricular tachycardia, or those at risk of sudden cardiac would be implanted with a conventional transvenous ICD, as described in the background section. The implantation of transvenous ICDs is associated with acute and chronic complication rates of 10 and 30 per cent, respectively. In addition, lead survival rates are estimated to be 85 and 60 per cent at five and eight years, respectively, with a reported 20 per cent survival rate at 10-years. Removal of the transvenous leads, with

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[4] F01A = with catastrophic or severe complication or comorbidity, F01B = without catastrophic or severe complication or comorbidity

its associated risks of morbidity and mortality, is a growing problem with the increased survival age of patients implanted with ICDs and the increasing use of ICDs in younger patients. The estimated lifespan of an ICD is up to eight years (Sousa et al 2010).

SAFETY AND EFFECTIVENESS ISSUES

Radbill et al (2010) reported on a cohort of 39 paediatric patients implanted with a "non-transvenous" (NVT) ICD and compared the system longevity to patients implanted with a conventional transvenous (TV) ICD (n=78) (level III-2 intervention evidence). The NVT device was not specifically made for subcutaneous implantation but consisted of a generator, a pace-sense lead and at least one NTV ICD coil in the subcutaneous, pericardial or pleural space. The primary indication for implantation in the NTV group was small patient size, with the mean weight in this group being 23 kg (range 14-60 kg), a mean age of seven years (range 3-19 years) and a mean body surface area of 0.88 m^2 (range 0.63-1.66 m^2). Patients in the TV group differed significantly in all of these characteristics ($p<0.001$) with a mean age of 20 years (range 15-27 years), mean weight 68 kg (range 56-85 kg) and mean body surface area of 1.75 m^2 (range 1.58-2.01 m^2). The indications for ICD implantation also varied significantly between the two groups with the majority of patients in the TV group implanted for reasons of primary prevention (85%) and the majority of patients in the NTV group implanted due to aborted cardiac arrest (33%) or sustained ventricular tachycardia (23%).

System survival was the primary outcome assessed, and was 73, 55 and 49 per cent in the NTV group at 12, 24 and 36 months, respectively. System survival was significantly higher in the TV group at all time points with 91, 83 and 76 per cent survival at 12, 24 and 36 months, respectively. Shock coil failure occurred in four of the NTV and in none of the TV patients, and twice as many patients (n=4) experienced inappropriately high defibrillation thresholds in the NTV group than in the TV group (n=2). In a univariate hazard analysis for variables associated with system failure, having a NTV had an overall hazard ratio (HR) of 3.09 (95% CI [1.42, 6.69], $p= 0.004$), being 5-10 years of age at implant had a HR of 3.84 (95% CI [1.66, 8.89] p= 0.002) and a larger body surface had a non-significant decreased hazard of 0.53 (95% CI [0.28, 1.01], $p=0.06$). A multivariate analysis that controlled for body surface area and age at implant found that being implanted with a NTV had a significant increased risk of system failure (HR 2.92 $p=0.04$). Although it was reported that 23 and 18 per cent of NTV patients received appropriate and inappropriate shocks, respectively; these values were not reported for the TV group. It is of note that one patient in the TV group died after failure to shock. Of the 14 system failures, 13 underwent revision with four of these converting to TV systems (Radbill et al 2010).

Bardy et al (2010) has conducted the largest study to date using the Cameron Health S-ICD, which has been specifically designed to be implanted subcutaneously. The initial study was designed to identify the best configuration of the leads: left lateral pulse generator with a 8cm electrode positioned at the left parasternal margin; a left pectoral pulse generator with a 4 cm left parasternal electrode positioned at the inferior sternum; a left pectoral pulse generator with a 8 cm electrode curving from the left inferior parasternal line across to the inferior margin of the sixth rib; and a left lateral pulse generator with a left parasternal 5 cm^2 disk. A total of 78 patients (mean age 61 ± 11 years, mean LVEF = 0.35 ± 0.14) were all temporarily implanted with one of these configurations, later explanted and implanted with a conventional transvenous ICD (level IV intervention evidence). Testing of each of these configurations revealed that the first configuration (left lateral pulse generator with a 8cm electrode positioned at the left parasternal margin, Figure 2) had the lowest delivered defibrillation threshold energy of 32.5 ± 17.0 J (95% CI [27.8, 37.3]) and was therefore chosen as the standard configuration for future studies.

The second phase of the S-ICD evaluation involved the simultaneous implantation of the S-ICD and a conventional TV ICD in the same 49 consecutive patients (mean age 64 ± 11 years, mean LVEF = 0.37 ± 0.13). After completion of the trial the S-ICD was explanted (level III-2 intervention evidence). Defibrillation thresholds were randomly tested in both devices. The S-ICD was as effective as the TV ICD for terminating induced ventricular fibrillation, however, a significantly higher mean energy was required to do so (36 ± 18.8 vs 11.1 ± 8.5 J, p<0.001). One TV ICD in one patient and one S-ICD in another failed to terminate induced fibrillation. In the S-ICD patient this failure was due to incorrect positioning of the electrode (Bardy et al 2010).

Following these initial trials, a pilot study was commenced with six patients permanently implanted with a S-ICD (mean age 60 ± 11 years, mean LVEF = 0.23 ± 0.07). A total of 18 episodes of ventricular fibrillation were induced, with all episodes detected and defibrillated with 65-J sub-maximal shocks. No device-related complications or inappropriate shocks occurred during 488 days of follow-up, nor did any spontaneous episodes of ventricular tachycardia or ventricular fibrillation occur. These successful results led onto a larger series of patients (mean age 56 ± 13 years, mean LVEF = 0.34 ± 0.13) being permanently implanted with the S-ICD (level IV intervention evidence). Of the 55 patients, the majority (n=37) had coronary artery disease or non-ischaemic cardiomyopathy (n=10). In addition, the majority of patients were implanted as a means of primary prevention (n=43) rather than after a cardiac event (n=12).

Defibrillation testing was not possible in two patients due to intra-operative haemodynamic instability in one patient and a failure to induce ventricular fibrillation in the other. A total of 137 episodes of ventricular fibrillation were induced in 53 patients, with all being detected by the S-ICD. The mean time from time of induced fibrillation to delivery of shock was 14.0 ± 2.5 seconds. In one patient, the first

episode of induced fibrillation was converted at 65-J, however the subsequent consecutive episode failed to be converted, and therefore this patient was converted to a transvenous ICD. Failure to terminate induced fibrillation in another patient occurred due to incorrect positioning of the electrode, which was then repositioned. Total procedure time for practitioners performing the implantation procedure for the first time was 67 ± 33 minutes, which was reduced to 55 ± 23 minutes for practitioners who had performed three or more procedures. Procedure time included implantation and time taken to perform at least two induction and termination tests (Bardy et al 2010).

During follow-up, one patient died due to causes unrelated to the implantation of the device (renal failure). Two patients developed a pocket infection, with only one patient undergoing a revision, the other opting to discontinue therapy. Within one week of surgery, three patients experienced lead dislodgement due to inadequate anchoring, which then required repositioning. Six months post-surgery, lead dislodgement occurred in an additional patient after vigorous physical activity. No cases of lead fracture, generator migration or pocket erosion were noted in the 10 ± 1 months follow-up, however two patients experienced minor lead migration. During follow-up, only 12 episodes of spontaneous ventricular tachycardia were detected in three patients, all of which were detected and successfully treated. Inappropriate sensing occurred in three patients due to muscle noise and was rectified by reprogramming of the device and no further inappropriate shocks were noted (Bardy et al 2010).

Concerns have been raised regarding the higher energy (3 times higher than transvenous ICDs) required to deliver an adequate shock to terminate fibrillation. The increase in energy required may cause damage to the myocardium or other tissues. In addition, long-term use of the S-ICD may induce fibrosis which may impede the ability to deliver an adequate shock. For these reasons it has been suggested that the S-ICD may be a good choice of device to treat patients who experience infrequent events but may not be the appropriate therapeutic device for patients with substantial ventricular dysfunction (Buga et al 2010, Kleijn & van der Veldt 2010). In addition, pacing with the S-ICD is transthoracic which makes anti-tachycardia pacing impossible and also makes bradycardia support pacing painful (Sousa et al 2010)

Several case reports have described the use of the purpose built S-ICD. A 31-year old implanted with a transvenous ICD experienced three lead fractures and underwent laser lead extraction and re-implantation of a new ICD and leads. Ventricular over-sensing resulted in two inappropriate ICD shocks and a new lead fracture was noted. Tachycardia therapies of the ICD were switched off, the device was left in place with atrial pacing at 55 beats per minute and a S-ICD was then implanted. The patient was successfully discharged with no interference from the ICD's atrial pacing noted by the S-ICD (van Opstal et al 2010). Sousa et al (2010) described a similar case in a 18-year old male who had experienced five inappropriate ICD shocks as a consequence of

lead fracture. After lead extraction a S-ICD was implanted without incident. McLeod and McLean (2010) described the successful implantation of the S-ICD device in two children (aged 10 and 11 years), both of whom had experienced a cardiac arrest. The implantation procedures were uncomplicated and both children remained well at > five months follow-up. The authors felt that the size of generator and the lead length meant that the device should not be implanted in a child who weighed less than 30 kg. It remains to be seen whether or not the device withstands the effects of growth in such young children.

COST IMPACT

The cost of the S-ICD device is approximately US$23,500, which compares favourably with the current average price for a transvenous ICD. However, savings in the actual implantation procedure may be made as the procedure can be conducted in an outpatient setting, the procedure time is shorter and there is no need for fluoroscopy or an electrophysiology laboratory (personal communication Cameron Health Inc).

A 2006 MSAC report found that the use of ICDs in addition to optimal pharmacological treatment is associated with an increase in survival and an increase in costs. When increased costs are balanced against life years saved, the estimated incremental cost per life year saved by adding ICD to optimal pharmacological treatment is approximately $18,681 based on public hospital costs and $44,479 based on private hospital costs and undiscounted life years. There was a significant amount of uncertainty with the assumptions regarding long-term mortality rates. It was assumed that observed mortality rates would remain the same, however it is possible that lower mortality rates may occur. No long term mortality data are currently available to address this uncertainty. Long-term incremental annual costs for annual cohorts of 1,560 *new* patients are expected to be $120,461,419 for ICD use based on public hospital costs and $288,765,004 for ICD use based on private hospital costs, representing an annual incremental cost per patient of $5,800 and $13,904 in the public and private sector, respectively (MSAC 2006).

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified/raised in the sources examined.

OTHER ISSUES

Cameron Health Inc is currently recruiting patients to participate in a multicentre clinical trial (29 locations in the United States, United Kingdom, the Netherlands and New Zealand). This non-comparative, uncontrolled case series aims to enrol 330 adult patients who require, but do not already have, an ICD. The study expects to be completed in 2015 (ClinicalTrials.gov Identifier NCT01064076). In addition, Cameron Health has registered a post-market S-ICD registry to evaluate the first

1,000 patients implanted with the S-ICD for the treatment of ventricular tachyarrhythmias. The primary outcome measures will be the perioperative S-ICD complication free rate (30-days post implant), 1-year S-ICD complication free rate and the percentage of inappropriate shocks for atrial fibrillation/supraventricular tachycardia. In addition, an exploratory analysis of resource utilisation and costs based on measures of clinical outcome such as complication rates, unscheduled hospitalisations and length of stay will be conducted to enable comparison of costs of the S-ICD system versus a standard transvenous system (ClinicalTrials.gov Identifier NCT01085435).

SUMMARY OF FINDINGS

Preliminary results indicate that the S-ICD has the potential to detect and eliminate episodes of ventricular tachycardia, however data are required to assess the long-term benefits of S-ICD implantation. Long-term data are also required to be able to assess the stability of leads in comparison to conventional transvenous ICDs. A number of post-implantation complications were noted, including over-sensing and lead dislodgement, and although these complications were rectified, patients needed to undergo revision procedures. In addition, the S-ICD cannot provide long-term pacing and is therefore not an alternative to transvenous ICDs when antibradycardia pacing is required.

HEALTHPACT ASSESSMENT:

Preliminary results of this device appear promising and it would be prudent to await the results from the large clinical trial currently being conducted. Therefore HealthPACT have recommended that this technology be monitored for further information in 24 months.

NUMBER OF INCLUDED STUDIES

Total number of studies
Level III-2 intervention evidence   2
Level IV intervention evidence   2
Case reports   3

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SEARCH CRITERIA TO BE USED:

Defibrillators, Implantable
Electrodes, Implanted
Prosthesis Implantation/*methods

Heart Defects, Congenital/radiography/*therapy
Heart Diseases/*therapy
Ventricular Fibrillation/physiopathology/*therapy
Heart Diseases/physiopathology/*therapy

HEALTH PACT DECISION:

☐ Horizon Scanning Report   ☐ Full Health Technology Assessment

☐ Monitor   ☐ Archive

☐ Refer   ☐ Decision pending

PRIORITY RATING

☐ **High**   ☐ **Medium**   ☐ **Low**