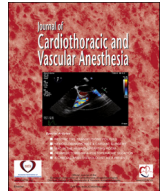


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Review Article

## Update on Cardiovascular Implantable Electronic Devices for Anesthesiologists

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With the advent of “wireless” endocardial pacing, the subcutaneous implantable cardioverter defibrillator, and leadless pacemakers comes an added layer of complexity to the perioperative management of cardiovascular implantable electronic devices (CIED). Since no formal recommendations currently exist for these new CIED technologies, preoperative identification of these devices, understanding their functionality, and developing an individualized perioperative management plan are imperative for the anesthesiologist. The following review is intended to provide the background information required to devise a successful perioperative management strategy for newer CIEDs.

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**Key Words:** pacemaker; cardiovascular implantable electronic device; implantable cardioverter defibrillator; automatic implantable cardioverter defibrillator; transvenous implantable cardioverter defibrillator; subcutaneous implantable cardioverter defibrillator; leadless pacemaker; Micra; transcatheter pacing system; wireless pacing; ultrasound endocardial pacing

RECENT ADVANCEMENTS in cardiovascular implantable electronic device (CIED) technology have resulted in the production of wireless, subcutaneous, and leadless devices. Even though the new devices represent exciting new territories in CIED technology, they also present new challenges for anesthesiologists. Historically, perioperative CIED (ie, transvenous pacemaker and implantable cardioverter defibrillator [ICD]) management has been inconsistent; the addition of subcutaneous implantable cardioverter defibrillators (S-ICDs), wireless pacing, and leadless pacemakers further complicate patient care (Table 1). Although society guidelines for traditional CIEDs exist, there currently are no formal society perioperative management recommendations or guidelines for these novel devices. Therefore, it is essential that anesthesiologists thoroughly understand subcutaneous, wireless, and leadless devices in order to provide safe and effective anesthetics for patients who possess them. This review is

intended to provide anesthesiologists with the information required to devise a perioperative management plan for these newer devices.

### Permanent Transvenous Pacemakers

Improvements in technology have resulted in smaller and more sophisticated devices since permanent pacemakers initially were implanted more than 6 decades ago. These advancements, the improvement in quality of life, and reduction in mortality in specific patient populations have led to approximately 250,000 devices being implanted in the United States annually.<sup>1</sup> Even though a detailed description of all the devices and programming options available would be impractical, a review of a few specifics regarding conventional transvenous pacemakers is provided as they relate to the implantation, function, and management of the new wireless and leadless alternatives.

### Pacemaker Indications and Lead Configurations

Common indications for permanent pacing include symptomatic bradycardia from sinus node or atrioventricular (AV)

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Table 1  
Novel Cardiovascular Implantable Electronic Devices

Device	Description
Wireless pacing	Wireless ultrasound endocardial pacing relies on a subcutaneous generator that transmits ultrasonic acoustic energy to a small endocardial receiver in the left ventricle, which converts the acoustic energy to electrical pacing pulses.
Leadless pacemaker	A self-contained, percutaneously implanted ventricular pacing system, which lacks transvenous lead(s) and a subcutaneous generator.
Subcutaneous implantable cardioverter defibrillator	A single subcutaneous lead and generator that provides sensing, detection, and defibrillation therapy of malignant ventricular tachyarrhythmias.

node disease, long QT syndrome, hypertrophic obstructive cardiomyopathy, and dilated cardiomyopathy.<sup>2</sup> Traditional transvenous pacemaker configurations include devices with leads in single or multiple chambers (eg, biventricular pacing), which is denoted by the North American Society of Pacing and Electrophysiology/British Pacing and Electrophysiology Group Generic Pacemaker Code (NBG) (Table 2).<sup>3</sup> Pacing and sensing can occur in the right atrium (RA), the ventricles (right ventricle [RV] and coronary sinus [CS]), or both depending on the lead configuration (Fig 1) and programming (Table 2). More complicated multichamber pacing and sensing schemes (eg, dual-chamber pacing or cardiac resynchronization therapy [CRT; cardiac resynchronization therapy]) may provide for AV or ventricular synchronicity and increase cardiac output.<sup>4</sup>

#### Lead Fixation

Leads can be differentiated by their fixation mechanism. The distinction is important because active fixation leads are at risk of perforating thin-walled structures such as the RA during placement. Perforation can result in significant pain, pneumomediastinum, and/or effusions. Occasionally diaphragmatic pacing is associated with lead perforation. Leads placed with passive fixation, such as tined leads (ie, prongs that hook onto myocardium or trabeculae), are difficult to reposition or remove because of their fixation mechanism, scar tissue formation, and length of time in situ.<sup>5–9</sup> The CS lead is another passive fixation lead that facilitates epicardial pacing of the left ventricle (LV) for CRT. Instead of tines, however, the CS lead is stabilized in the CS by its preformed shape and therefore can be dislodged easily. In general, the highest risk of lead dislodgement occurs in the first 3 months after lead placement, with atrial and CS leads being affected more frequently than ventricular leads. During this high-risk period, practitioners should remain vigilant for changes in device

function when inserting guidewires, central venous catheters, or pulmonary artery catheters. However, lead dislodgement also may occur during generator replacements and device upgrades.<sup>10</sup>

#### Rate Modulation

Rate modulation, or rate adaptation, denoted by “R” in the fourth position of the NBG code (Table 2), describes a pacemaker’s ability to automatically change the pacing rate in response to certain monitored parameters in patients with chronotropic incompetence. Given that an estimated 85% of pacemakers implanted in the United States are rate responsive and 99% have this capability, anesthesiologists should be familiar with rate modulation.<sup>11,12</sup>

There are a number of physiologic parameters that can be monitored and may induce heart rate changes. Of these physiologic parameters, acceleration, minute ventilation via thoracic impedance, and/or physiologic impedance are the most common. Specifically, transvenous pacemakers that correlate an increase in respiratory rate and tidal volume with exercise and a need for increased cardiac output pose a challenge for anesthesiologists. Because of the monitored parameter (ie, respiratory rate and tidal volume via thoracic impedance), the paced rate in these devices inappropriately may increase in response to mechanical hyperventilation, external respiratory rate monitoring, or even electrocautery.<sup>13–16</sup>

In the 2011 American Society of Anesthesiologists (ASA) Practice Advisory, the ASA and Heart Rhythm Society (HRS) recommended that rate adaptive therapy be disabled preoperatively if “advantageous.”<sup>17</sup> Device manufacturers previously had made more definitive recommendations that minute ventilation–driven rate adaptive therapy should be programmed “off” during mechanical ventilation.<sup>16</sup> Intraoperative rate changes, which result from elective continuation of rate modulation or a lack of CIED programming resources, usually

Table 2  
North American Society of Pacing and Electrophysiology/British Pacing and Electrophysiology Group Revised (2002) Generic Pacemaker Code

Pacing Chamber	Sensing Chamber	Response	Rate Modulation	Multisite Pacing
O = none	O = none	O = none	O = none	O = none
A = atrium	A = atrium	I = inhibited	R = rate modulation	A = atrium
V = ventricle	V = ventricle	T = triggered		V = ventricle
D = dual	D = dual	D = dual		D = dual

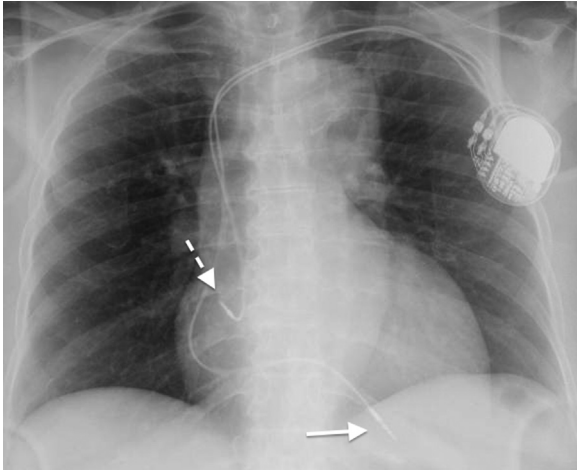


Fig 1. Supine frontal chest radiograph demonstrating a transvenous dual-chamber pacemaker with leads in the right atrium (dashed arrow) and right ventricle (solid arrow) and the generator in the classic left pectoral location.

are benign. However, an increase in paced heart rate can be hemodynamically significant; may be mistaken for a rhythm change (eg, ventricular tachycardia); may be unfavorable for certain pathologies (eg, coronary disease); or may be misinterpreted as patient discomfort.<sup>18,19</sup>

Should active rate modulation result in an intolerable or undesirable increase in heart rate, there are a number of treatment options, including the following: the eliciting stimulus (eg, hyperventilation or electrocautery) can be withdrawn; a magnet can place the pacemaker into an asynchronous mode; or CIED programming can disable rate modulation.

### Multisite Pacing

At first glance, the fifth position of the NBG code (Table 2) appears redundant given the possibility of “D” (dual) in the first position. However, the fifth position of the NBG code actually conveys unique and valuable information to the practitioner regarding the performance and location of multisite pacing: pacing both atria, pacing both ventricles, or multiple pacing sites in a single chamber.<sup>3</sup> For example, “A” represents pacing with multiple catheters in either one or both atria, although left atrial pacing via the CS rarely is performed, and “V” indicates pacing with multiple catheters in either one or both ventricles (i.e., CRT).

The goal of CRT is 2-fold—to maintain sequential AV contraction and to synchronize contraction of the RV and LV. A dual-chamber pacemaker successfully maintains sequential AV contraction between the RA and the RV; however, RV pacing often results in delayed depolarization of the left ventricular inferior or inferolateral wall on account of a conduction delay.<sup>20</sup> CRT attempts to address this phenomenon by the placement of a lead in the CS. The CS lead then can be used to pace the LV from the inferolateral position with a goal of synchronized ventricular contraction and increased cardiac output. However, despite optimal CS lead placement, approximately 25% of patients with severe LV systolic dysfunction do not respond to

Table 3  
Indications for CRT

	LVEF (%)	QRS Duration	NYHA Class	Brady, Pacer Dependence
CRT-D	< 35%	> 120 ms	III, IV (I, II)	+/-
CRT-P	< 35%	> 120 ms	III, IV (I, II)	+/-
	(no ICD preferred)			

Abbreviations: Brady, Bradycardia; CRT, cardiac resynchronization therapy; D, Defibrillator; P, Pacemaker; ICD, implantable cardioverter defibrillator; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; QRS.

CRT.<sup>10</sup> Determination of which patients will respond to CRT is an active field of investigation.<sup>21</sup>

Indications for CRT, which also is frequently described as biventricular pacing, have expanded in recent years (Table 3). In 2012, an American College of Cardiology/American Heart Association/HRS update extended a class I indication to New York Heart Association class II patients with left bundle branch block (LBBB) and QRS duration > 150 ms. A class IIa indication was assigned to patients with an LBBB with a QRS duration of 120-to-149 ms or a non-LBBB pattern with a QRS > 150 ms.<sup>2,22</sup> Therefore, CRT devices in patients likely will become more common in the operating room. Patients with CRT devices may be delineated further as either CRT-D or CRT-P. Even though the indications essentially are the same (Table 3), CRT-D (Fig 2) implies pacing for cardiac resynchronization therapy plus an ICD, whereas CRT-P implies no ICD component.

### Pacing Dependence

Determination of pacing dependence is difficult because there is no strict definition (ie, percentage paced). However,

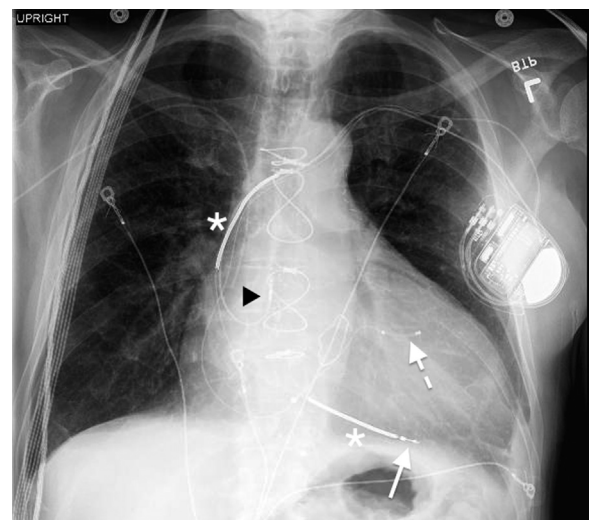


Fig 2. Upright frontal chest radiograph demonstrating a cardiac resynchronization therapy-D device. A cardiovascular implantable electronic device with supraventricular/ventricular shock coils (asterisks) and a bipolar pacing lead in the right ventricle (solid arrow), an atrial lead in the right atrium (black arrowhead), and a coronary sinus lead (dashed arrow) for biventricular pacing.

patients who have undergone AV node ablation, have underlying significant ventricular bradyarrhythmias, and/or have a “high % paced” on examination often are labeled as being “pacemaker dependent.” In addition, a history of temporary pacing wires, syncope from a bradyarrhythmia, or paced rhythm on electrocardiogram (ECG) may suggest dependence.<sup>23</sup> Reprogramming a pacemaker to VVI at 30 bpm (or lowest programmable rate) in the preoperative area can be used to investigate underlying activity and thus determine dependence.<sup>17</sup> Alternatively, Mahlow et al simplified pacemaker dependency in the Pacing And Cardioverting Electronic Devices peri-Operative Protocol (PACED-OP) to individuals who displayed a paced rhythm on preoperative ECG.<sup>24</sup>

CRT devices present a unique challenge for anesthesiologists. Given that the goal of CRT is to increase cardiac output via synchronization of ventricular contraction by pacing, these patients might be considered functionally pacemaker dependent. This is a debatable position because CRT patients often have an “adequate” underlying rhythm. However, inhibition due to electromagnetic interference (EMI) may result in a reduction in cardiac output, hindering the success of CRT.

### Transvenous Implantable Cardioverter Defibrillators

A transvenous ICD is a CIED that is able to sense, detect, and treat malignant ventricular tachyarrhythmias with anti-tachycardia pacing (ATP) or defibrillator shock via shock coils in the RV and occasionally in the superior vena cava. Treatment of identified ventricular tachyarrhythmias via overdrive pacing (ie, ATP) or defibrillation depends on the diagnosis of either ventricular tachycardia or ventricular fibrillation. ATP, or overdrive pacing, typically occurs at lower rates (ie, ventricular tachycardia) and uses less energy. This reduces battery depletion and is less painful and therefore is better tolerated by patients. Given these advantages, most current transvenous ICDs can deliver some form of ATP while the capacitor charges for a shock. However, once a shock has been delivered, no further ATP will take place.<sup>23</sup>

The addition of a supraventricular coil (Fig 2), which is denoted by the North American Society of Pacing and Electrophysiology/British Pacing and Electrophysiology Group Generic Defibrillator Code (Table 4), can be advantageous in differentiating supraventricular tachycardia from ventricular tachyarrhythmias.<sup>13,25</sup> This differentiation is important because atrial fibrillation with rapid ventricular response and supraventricular tachycardia are the most common causes of inappropriate shock therapy, occurring in 10% to 40% of

ICD patients.<sup>26,27</sup> Aside from the negative effects inappropriate shocks have on quality of life, they also have resulted in myocardial injury (elevated troponin levels in the absence of ischemia) and even death.<sup>28</sup> Finally, any inappropriate ICD therapy (ATP or shock) has been associated with increased mortality.<sup>29,30</sup>

In addition to tachyarrhythmia therapies, all transvenous ICDs are equipped with pacing capabilities, and therefore the fourth position of the generic defibrillator code (Table 4) can be expanded to include all 5 pieces of information conveyed by the NBG code (Table 2). This expanded form often is referred to as the “label form.” Even though pacing is advantageous when defibrillation results in a bradyarrhythmia, it also mandates perioperative programming in situations involving pacemaker-dependent patients and electromagnetic interference.

### Transvenous ICD Indications

Indications for transvenous ICD placement include hemodynamically significant ventricular tachycardia, ventricular fibrillation, and conditions associated with sudden cardiac death (eg, long QT syndrome, Brugada syndrome, arrhythmogenic RV dysplasia, and infiltrative cardiomyopathies).<sup>28,31,32</sup> In addition, recent studies also suggest that ICDs are useful for primary prevention of sudden cardiac death in patients with hypertrophic cardiomyopathy, postmyocardial infarction with an ejection fraction <30%, or cardiomyopathy with an ejection fraction <35%.<sup>33–35</sup> Finally, an ICD may be incorporated with CRT (eg, CRT-D) in patients with dilated cardiomyopathy and prolonged QRS interval. Although CRT has been shown to improve functional status and quality of life while reducing heart failure events, the additional benefit of an ICD (ie, CRT-D) is less certain.<sup>21</sup>

### Device Recognition

Important device information can be obtained from a wallet card provided by the patient, patient history and medical records, or the manufacturing company. Other approaches such as trialing programmers from all 5 device companies to determine the manufacturer, assuming the device is functional, or calling all 5 companies are time consuming and may not yield useful information. Alternatively, magnet application to a pacemaker can narrow the field of potential manufacturers by the magnet mode rate. Even though this magnet mode rate technique requires assumptions regarding the device

Table 4  
North American Society of Pacing and Electrophysiology/British Pacing and Electrophysiology Group Generic Defibrillator Code

Shock Chamber	Antitachycardia Pacing Chamber	Tachycardia Detection	Antibradycardia Pacing Chamber
O = none	O = none	E = electrogram	O = none
A = atrium	A = atrium	H = hemodynamic	A = atrium
V = ventricle	V = ventricle		V = ventricle
D = dual	D = dual		D = dual

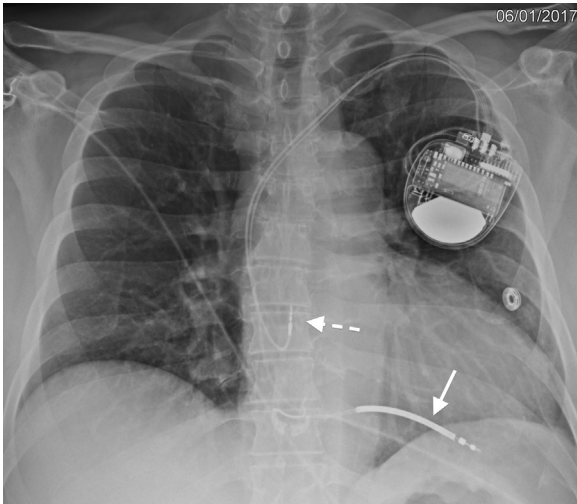


Fig 3. Chest radiograph demonstrating an implantable cardioverter defibrillator. A dual-chamber device with 1 lead in the right atrium (dashed arrow) and another in the right ventricle (solid arrow). A defibrillation coil is present (solid arrow), which differentiates it as an implantable cardioverter defibrillator.

(ie, pacemaker); programmed magnet response (ie, devices from Biotronik, Berlin, Germany; Boston Scientific, Marlborough, MA; and St. Jude Medical, St. Paul, MN); and battery life of the device, it nevertheless can be used to quickly identify a newly implanted Medtronic (Minneapolis, MN) or Sorin (Milan, Italy) pacemaker, given the consistent, unique magnet responses of 85 bpm and 96 bpm, respectively.<sup>28</sup> A chest radiograph can be used to determine the device type (pacemaker v CRT-P v ICD v CRT-D), number of leads implanted, and device company.<sup>36</sup>

The prevalence of preoperative chest radiographs and the ability to magnify sections of radiographs (eg, the generator) makes identifying the device type, the number of leads, and

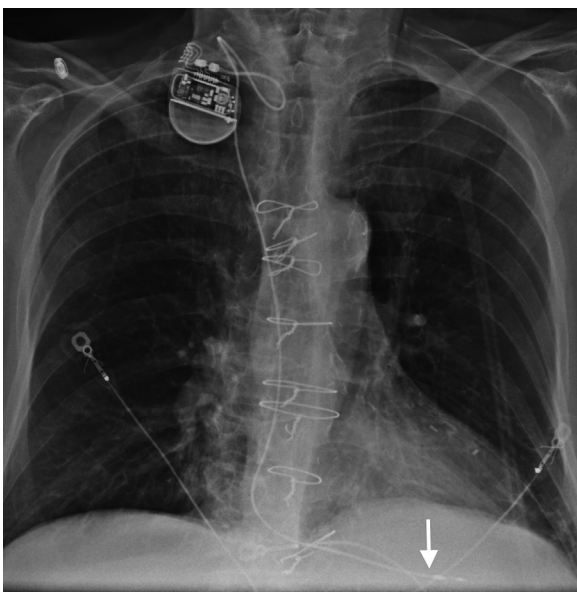


Fig 4. Chest radiograph demonstrating a pacemaker with a single lead in the right ventricle. This likely is a temporary transvenous pacemaker given the position of the generator and venous access (ie, right internal jugular).

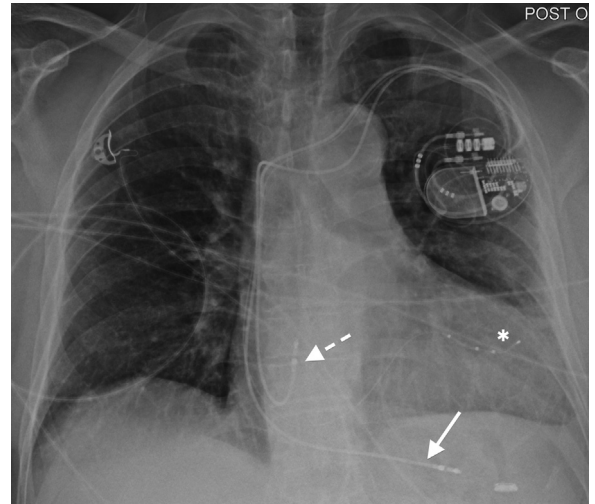


Fig 5. Chest radiograph demonstrating a cardiac resynchronization therapy-pacemaker device with a lead in the right atrium (dashed arrow), right ventricle (solid arrow), and coronary sinus (asterisk).

the device company possible. One should begin by differentiating between a pacemaker (Fig 1) and a transvenous ICD (Fig 3). The number of leads present can then help the practitioner identify the pacing scheme, differentiating between single chamber (Fig 4), dual chamber (Fig 1), or biventricular (Fig 5). The practitioner also can determine whether a transvenous ICD has a single defibrillation coil (Fig 3) or 2 coils (Fig 2) or possesses CRT capability (Fig 2). Finally, radiographic markings (eg, alpha numeric codes); shape of the battery and generator; and/or header orientation can be used to identify the device company (Fig 6).<sup>36</sup>

## Perioperative Management of Transvenous CIEDs

### Current Recommendations

Current recommendations from the ASA and HRS focus on an individualized, multidisciplinary approach with less reliance on direction from industry-employed allied health professionals and increased involvement of the primary CIED management team.<sup>17,37</sup> Alternative protocols for device management, such as the PACED-OP protocol, advocate for more selective criteria for CIED reprogramming in an effort to operate within the confines of restricted resources and to avoid reprogramming errors (Table 5).<sup>24</sup>

### Intraoperative Management

Perioperative management largely relies on determining the patient's CIED dependence and EMI potential. Despite CIED technologic advancements and the trend toward bipolar lead placement, EMI still can occur in the perioperative period. EMI can result from any device that emits radiofrequency waves between 0 and  $10^9$  Hz.<sup>14</sup> The expansive list of potential EMI sources includes, but is not limited to, electrocautery, external defibrillation, electroconvulsive therapy,

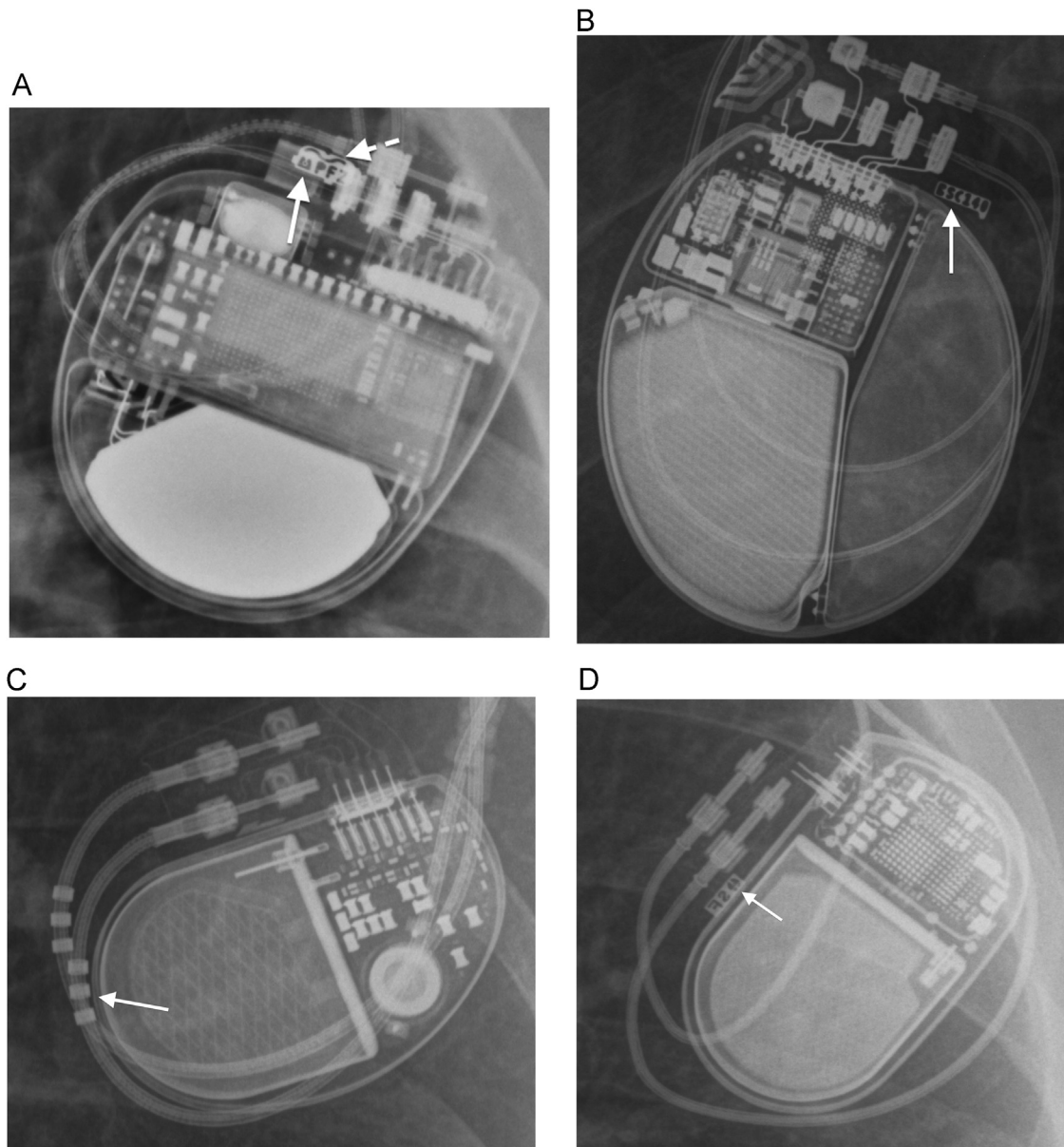


Fig 6. Chest radiographs with magnification of the generator and characteristic radiographic markings. (A) Medtronic device with the Medtronic symbol (solid arrow) and magnetic resonance conditional marking (dashed arrow). (B) Boston Scientific device with characteristic radiographic marking (solid arrow). (C) St. Jude dual-chamber device with magnetic resonance conditional leads denoted by the 3 radiographic rings (solid arrow). (D) Biotronik device and symbol (solid arrow).

transcutaneous electrical nerve stimulation, and radiofrequency waves used in ablation procedures.<sup>17</sup> In addition, the radiofrequency scanning systems commonly used to identify retained surgical towels can interfere with pacemakers.<sup>38,39</sup>

Although a potential source of EMI may be present, EMI still may be unlikely. For example, the potential for interaction is considered to be markedly reduced if the distance from the electrocautery current to the CIED pulse generator and leads is greater than 6 inches.<sup>37,40</sup> Furthermore, it is the current belief that for surgical procedures below the umbilicus, electrocautery will not interfere with a generator and leads that are located in the upper chest.<sup>41</sup>

Additional techniques other than absolute distance can reduce the possibility or effect of EMI, such as the use of

bipolar as opposed to monopolar electrocautery; short bursts of electrocautery (less than 4 seconds, separated by at least 2 seconds); lower electrocautery power settings; nonblended “cutting” electrocautery; use of an ultrasonic cutting device (eg, harmonic scalpel); and proper positioning of the electrocautery return pad to minimize return current interaction with the device.<sup>17,28</sup>

A historic staple of CIED perioperative management has been the application of a magnet. Even though reliance on a magnet may not be the most elegant technique, it is applicable in some situations; however, knowing the magnet mode response for pacemakers and transvenous ICDs before making this decision is vital. It is important to note that when tachyarrhythmia therapies are programmed “off,” external

Table 5  
PACED-OP Protocol Summary

Clinical Situation	Management
1. Pacemaker dependent or AICD + EMI in critical zone	1. Reprogram preoperatively and examine postoperatively
2. AICD + EMI outside the critical zone	2. Apply magnet (exception: devices with reed switch)
3. Pacemaker dependent patient + EMI outside the critical zone + bradycardia postoperatively	3. Examine postoperatively

NOTE. "Critical zone" is the area between the mandible and the xiphoid. Abbreviation: AICD, automatic implantable cardioverter defibrillator; EMI, electromagnetic interference; PACED-OP, Pacing And Cardioverting Electronic Devices peri-Operative Protocol.

defibrillation should be readily available until therapies are re-enabled. Alternatively, if magnet application is used instead of programming a transvenous ICD "off," it can be removed to deliver an internal shock if indicated.<sup>17,37</sup> Reliance on a magnet for the intraoperative management of a transvenous ICD poses a particular challenge because the magnet response may be programmed "off" and the magnet application has previously permanently disabled tachyarrhythmia therapies in certain ICDs (eg, Guidant ICDs [Boston Scientific] before a software update in 2009).<sup>42,43</sup> Moreover, the magnet has to be reliably secured over the device and out of the surgical field to ensure that the ICD is disabled temporarily. These challenges are not to be taken lightly because inappropriate ATP or defibrillation can result in significant battery depletion or myocardial injury.<sup>10,28,29</sup> Navigating these situations is best accomplished through proper preoperative preparation, examination, and reliance on the device company technical support.

Reliable confirmation of appropriate magnet placement and suspension of antitachyarrhythmia therapies are only present in Boston Scientific (beeping tone) and Sorin (pacing rate, but not the mode, change to 90 bpm if new or 80 bpm if the battery is at elective replacement) transvenous ICDs.<sup>28</sup> Even though appropriate magnet application typically disables tachyarrhythmia therapies, it will not change the pacing function to an asynchronous mode. Therefore, perioperative programming to asynchronous mode may be required for pacemaker-dependent patients with a transvenous ICD when high-density EMI is likely. Similarly, reprogramming CRT-D devices to an asynchronous mode would be required to

guarantee continued pacing in the perioperative period when EMI is anticipated.<sup>17</sup>

## Cardiovascular Implantable Electronic Device Milestones

Since the first pacemaker was implanted in 1958, there have been many improvements in the programming, leads, battery life, and sizing of CIEDs.<sup>44</sup> However, reliance on the transvenous placement of leads has persisted through the development and implantation of the ICD and CRT. Even though slight deviations from the transvenous model have occurred (eg, epicardial pacing) since its introduction, it has taken nearly 50 years for the leadless pacemaker to come to market (Fig 7).<sup>1</sup> The production of wireless, subcutaneous, and leadless devices represents not only a significant change in CIED technology, but also new challenges for perioperative management.<sup>21,28,45</sup>

### Leadless Transcatheter-Deployed Intracardiac Pacemakers

Short-term risks of the traditional transvenous CIED system (lead and pulse generator) include pneumothorax or cardiac perforation (1%-2.7%), deep vein thrombosis, and lead dislodgement within 30 days (2.4%-3.3%).<sup>46-48</sup> More long-term, transvenous leads can fracture (1%-4%), be plagued by intra-system connection errors or insulation failure, contribute to significant tricuspid regurgitation (5%), result in venous obstruction (8%-21%), and/or become infected (1%-2%).<sup>44,49</sup> Furthermore, the number of lead(s) in place may directly affect the ability to obtain central venous access or place a pulmonary artery catheter. Finally, hematoma, skin erosion, or infection can result from creation of the pocket required for generator placement.<sup>45</sup> Reports suggest that 2.5% of single-chamber pacing systems, which have a lower risk than dual-chamber systems, require surgical intervention within the first 3 months, and 1.25% of those are lead related.<sup>46,47</sup> Overall, the traditional transvenous pacing system has a 10% short-term and 20% 5-year complication rate.<sup>48-50</sup> Therefore, a self-contained, leadless pacing system that avoids the complications associated with transvenous systems is an appealing alternative.

The Micra Transcatheter Pacemaker System (Medtronic) is a single-chamber ventricular pacemaker that is 26 mm long × 6.7 mm in diameter with accelerometer-based rate modulation capabilities and 4 functional modes (eg, VVIR, VVI, VOO,

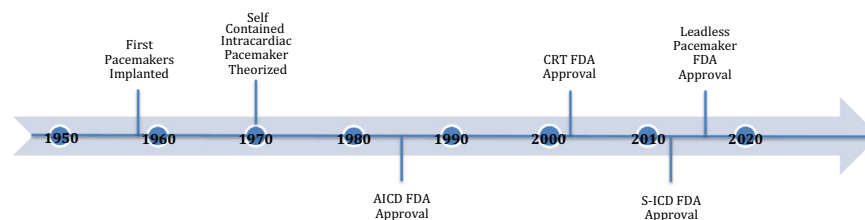


Fig 7. Timeline of cardiovascular implantable electronic device milestones. AICD, automatic implantable cardioverter defibrillator; CRT, cardiac resynchronization therapy; FDA, Food and Drug Administration; ICD, implantable cardioverter defibrillator; S-ICD, subcutaneous implantable cardioverter defibrillator.

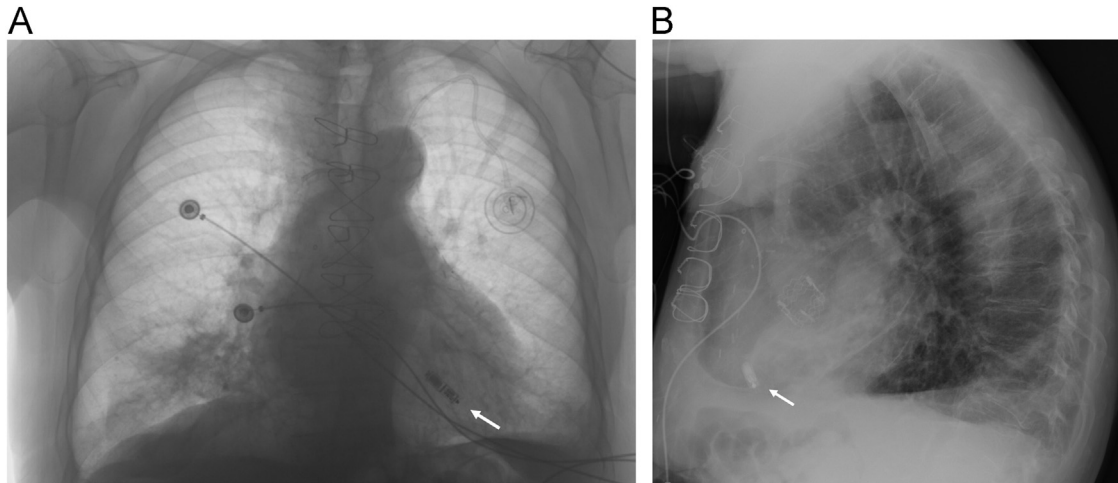


Fig 8. (A) Posteroanterior chest radiograph demonstrating a Medtronic Micra device (solid arrow). (B) Lateral chest radiograph demonstrating a Medtronic Micra device (solid arrow) at the apex.

With permission from Mickus et al.<sup>51</sup>.

OVO) (Fig 8).<sup>49</sup> In addition, the Micra has a “device off” mode, which may be useful should a malfunctioning device become irretrievable. In the event of a device reset, the default setting is VVI at 65 bpm. Similar to traditional transvenous pacemakers, the device contains a dexamethasone acetate-impregnated tip, which helps maintain low thresholds after placement, and interactions between EMI and the leadless system can result in oversensing, tachyarrhythmias, tissue damage, etc.<sup>10,20</sup> However, unlike many older traditional transvenous pacemakers, the Medtronic leadless device has received “magnetic resonance imaging conditional” approval.

Although estimated to be equivalent to other generators at greater than 10 years, the longevity of the leadless device is unknown. The manufacturer has estimated the battery life to be 12.5 years based on VVIR/VVI mode and signal amplitude. Because nearly 20% of pacemakers implanted in the United States are VVIR systems, this may represent a reasonable estimation; however, only time will tell.<sup>51</sup> In the event that the battery is exhausted or near exhaustion, the manufacturer contends that utilization of the “device off” mode and placement of a second neighboring device are options. Other options would include percutaneous retrieval, which represents one of the highest-risk procedures in interventional cardiology, or surgical explantation of the device.<sup>44,51</sup> Even though percutaneous retrieval has been documented, prior experience with the percutaneous extraction of chronic passive fixation transvenous leads would imply comparable difficulty with a long-term Micra device.<sup>1,53,54</sup> This assumption is based on the characteristic fibrosis of chronically implanted devices and the similar fixation mechanism of the Micra device (ie, 4 self-expanding electrically inactive nitinol tines) (Fig 9).

Currently approved indications for the Micra leadless pacemaker by the American College of Cardiology/American Heart Association are class I and II bradycardia. These include tachycardia-bradycardia syndrome, symptomatic paroxysmal or permanent second- or third-degree AV block, bilateral bundle branch block, and paroxysmal or transient sinus node

dysfunction with or without an AV conduction disorder.<sup>28,51</sup> Contraindications to device implantation include the presence of another implanted cardiac device (eg, pacemaker, defibrillator, or left ventricular assist device); mechanical tricuspid valve; or an inferior vena cava (IVC) filter. Additional contraindications may include morbid obesity because this may preclude telemetry communication, unfavorable venous anatomy (ie, placement requires a 23-F introducer sheath); abnormal cardiac anatomy; or hypersensitivity to medications used during placement (eg, heparin, contrast dye, dexamethasone).<sup>51,55</sup>

Even though the presence of an IVC filter has been deemed a contraindication to placement, a Medtronic leadless device has been placed successfully in the apical septum of a patient with an IVC filter.<sup>56</sup> As an argument for transfemoral percutaneous placement, the authors of the case report cited previous reports regarding the passage of sheaths up to 8-F in

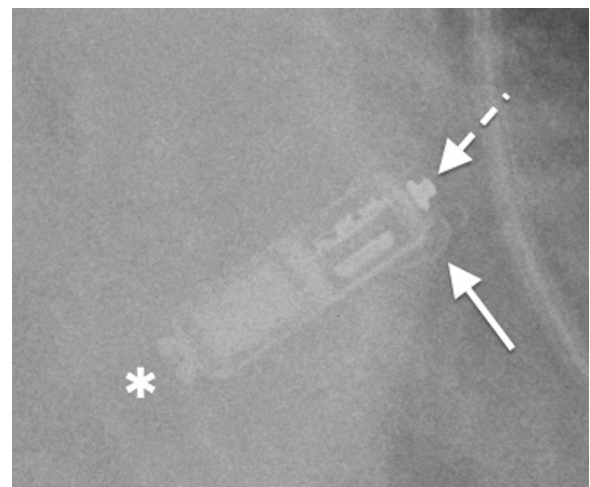


Fig 9. Chest radiograph (magnified view) with a Medtronic Micra device in situ. One of the self-expanding nitinol tines is clearly visible (solid arrow) as are the cathode (dashed arrow) and proximal retrieval feature (asterisk).



diameter (the Micra Transcatheter Pacing System eventually was placed with a 23-F introducer sheath) and the fact that there is no sheath size upper limit in patients with IVC filters.<sup>57</sup> Even though the leadless device ultimately was placed successfully, it was conceded that damage to the IVC filter's function could not be definitely excluded.

Many of the complications (eg, hematoma formation, infection, nerve injury) associated with traditional transvenous lead placement also are possible during the percutaneous placement of a leadless device, but it is theorized that the overall rate will be lower due to greater use of ultrasound guidance and compressibility of the inguinal region.<sup>51</sup> In a large study of 725 patients, the device was implanted successfully in 99% of participants. Complications included cardiac perforation (1.6%), vascular injury (0.7%), and poor thresholds (0.3%).<sup>53</sup>

Even though the advent and use of the Micra system in the United States is exciting, it also poses new challenges for preoperative radiographic identification of leadless devices and perioperative management because there is no guideline, expert consensus statement, or practice advisory. Reports have indicated that appropriate interrogation software has not been readily available, which requires greater coordination with device representatives, and no magnet sensor. Medtronic has addressed the device interrogation issues; however, given the lack of a magnet response, early identification of these patients and proper interrogation are essential for perioperative management. Previous reports have advocated for reprogramming the device to an asynchronous mode (VOO) if dependent, the use of short bursts of electrocautery, or the use of bipolar electrocautery to minimize device interference.<sup>51</sup>

An alternative to the Medtronic device is the St. Jude Nanostim leadless intracardiac pacemaker. Even though the Nanostim is approved for implant in countries outside the United States, it currently is awaiting approval for implantation in the United States. The Nanostim is a cylindrical device (42 mm × 6 mm) with a proximal docking interface and distal nonretractable helix for fixation. The Nanostim device interacts with the Merlin Programmer (St. Jude Medical) via conductive communication with 5 surface ECG electrodes. This differs from the Micra, which uses the conventional radiofrequency approach.<sup>1</sup> Programming options for an implanted Nanostim device include RV blood-temperature rate responsiveness, which can increase the heart rate in response to exercise.<sup>52</sup>

Due to a lack of ferrous material, the St. Jude device has magnetic resonance imaging conditional approval and is implanted in the RV via a percutaneous approach similar to that for the Micra; however, the Nanostim only requires an 18-F sheath for delivery.<sup>45</sup> Indications for placement in the LEADLESS and LEADLESS II trials were atrial fibrillation with AV block; sinus rhythm with high-grade AV block (ie, second- or third-degree AV block) and limited expected activity or life span; or sinus bradycardia with infrequent pauses, syncope, or His-Purkinje disease.<sup>45</sup> Exclusions to placement included an existing CIED, pacemaker dependence, a prosthetic tricuspid valve, pulmonary hypertension, and/or an

IVC filter.<sup>52,58</sup> Overall, the device was placed successfully in 95.8% of participants in the LEADLESS II trial with a favorable complication rate of 6.7%. Complications included dislodgment (1.7%), cardiac perforation (1.3%), poor thresholds (1.3%), and vascular injury (0.7%). Finally, battery life was estimated to be 15 years at a 6-month evaluation.<sup>58</sup> Despite this battery life estimate, St. Jude recently released a battery advisory because 0.5% of patients who had received a Nanostim experienced a battery malfunction within approximately 3 years, which resulted in battery depletion and loss of pacing/communication.<sup>1</sup>

From a perioperative management perspective, the Nanostim device may have a slight advantage over the Micra; it has a magnet sensor and response. Assuming appropriate battery life, a Nanostim device will respond to a magnet applied over the apex of the heart by pacing at 100 bpm for 8 beats followed by an asynchronous mode at 90 bpm (65 bpm elective replacement indicator). Furthermore, the fixation helix (the device uses an active screw in helix and secondary fixation of 3 angled nitinol tines) may be superior to the Micra self-expanding tines when it comes to long-term retrieval.<sup>45</sup> In fact, the longest implant duration of a retrieved St. Jude device currently is documented as 1,188 days.<sup>58,59</sup> Although the fixation mechanism and dedicated steerable retrievable catheter of the Nanostim may facilitate percutaneous device extraction, the depth of penetration (ie, 1.3 mm maximum depth of penetration) also may increase the risk of its dislocation compared with the Medtronic device.<sup>1,52</sup>

The most significant current limitation of these devices is the restriction to single-chamber, RV pacing, which represents only approximately 10% to 20% of devices currently implanted in the United States. Single-chamber, RV pacing also could potentially result in pacemaker syndrome and heart failure. The inability to deliver tachyarrhythmia therapies or CRT further limits their utility.<sup>49</sup> Another potential disadvantage is their limited electrogram storage space. Even though this limited storage affords energy efficiency and a smaller size, it is at the cost of rhythm analysis.<sup>45</sup> Finally, long-term complications (eg, dislodgment, failure rates); management (eg, retrieval); arrhythmogenic potential; accuracy of rate responsiveness; and battery longevity have yet to be confirmed.

In the future, leadless devices may not be limited to single-chamber, ventricular pacing because dual-chamber and multi-chamber pacing are under development. In addition, these devices may not be limited by their lack of tachyarrhythmia therapy because coimplantation with an S-ICD has been documented in the literature.<sup>60</sup> In the future, leadless device may be able to deliver antitachycardia pacing with proper programming.<sup>49,61</sup> Therefore, the future clinical application of these devices is expansive but currently largely unknown.

### *Wireless Ultrasound Endocardial Pacing*

Wireless ultrasound endocardial pacing represents a break from traditional transvenous pacemakers; however, it differs significantly from the previously described leadless devices.

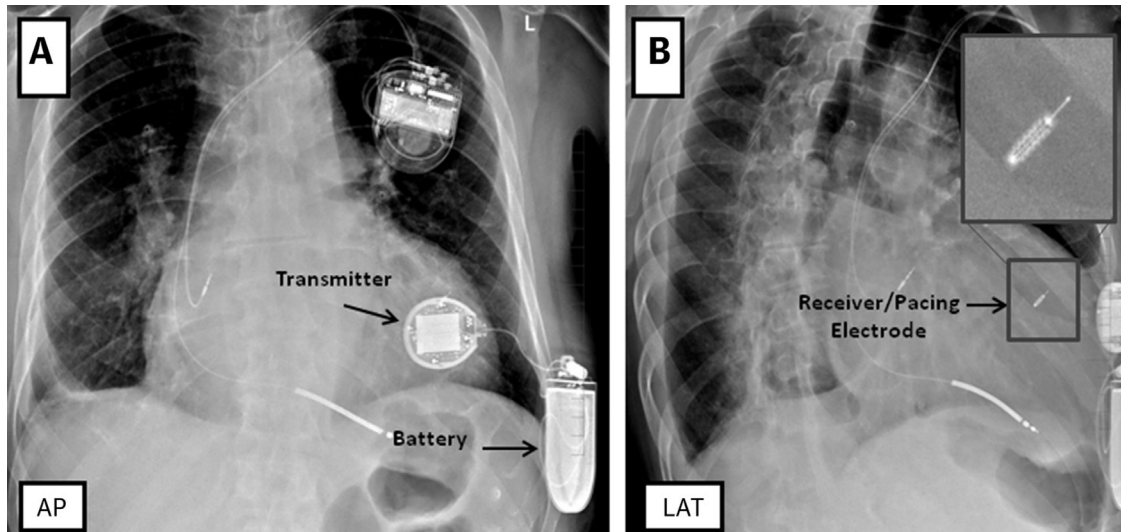


Fig 10. Anteroposterior and lateral chest radiographs demonstrating a wireless ultrasound endocardial pacing system. In addition, a dual-chamber device is present. With permission from Miller et al.<sup>45</sup>.

Wireless ultrasound endocardial pacing relies on a subcutaneous generator that transmits ultrasonic acoustic energy to a small endocardial receiver, which converts the acoustic energy to electrical pacing pulses, and a coimplanted traditional pacemaker or defibrillator to detect an RV pacing impulse (Fig 10). Therefore, it is a multicomponent, not self-contained, system and only the small endocardial receiver is technically leadless.<sup>44</sup>

Despite the significant challenges (eg, the generator must be optimally positioned subcutaneously on the thorax so that ultrasonic energy can be delivered reliably to the endocardial receiver) and risks of placement (eg, the endocardial receiver is placed using a percutaneous transaortic approach into the LV cavity), it is theorized that endocardial pacing of the LV may be worthwhile. Proponents contend that the endocardial-to-epicardial activation is more physiologic; less arrhythmogenic; lacks phrenic nerve stimulation; requires lower energy output; and, in contrast to a transvenous coronary sinus lead, would permit LV activation from multiple sites.<sup>44,45</sup>

Given the potential benefits, the feasibility of pacing the LV from an endocardial location was investigated by the authors of the Wireless Stimulation Endocardially for Cardiac Resynchronization Therapy (WiSE-CRT) study. Even though the initial results were promising, the WiSE-CRT study was halted due to safety concerns (eg, development of significant pericardial effusion during placement).<sup>62</sup> After the premature termination of the WiSE-CRT study, the delivery system was redesigned. The redesigned system was the focus of the Safety and Performance of Electrodes implanted in the Left Ventricle study, which also showed promising results (ie, clinical and echocardiographic improvement at 6 months) with significantly fewer procedure-related complications (ie, significant pericardial effusions, inability to place the device successfully, and failure to capture).<sup>63</sup> Despite recent positive results, this technology remains largely investigational.

In addition to the risks identified in the WiSE-CRT study (ie, challenging placement and the possibility of vascular or cardiac perforation), questions regarding the potential long-term biothermal effects of ultrasound energy delivered at a mechanical index of 1.9 (the highest mechanical index considered safe for cardiac ultrasound imaging), thrombogenic nature of the endocardial device, embolic risk, environmental interference, and battery longevity remain unanswered.<sup>44,45</sup>

Because the current wireless ultrasound endocardial pacing system requires a coimplanted transvenous pacemaker or defibrillator system to function and is largely under investigation, it is strongly recommended that the ultrasound endocardial pacing system be disabled perioperatively. The coimplanted transvenous CIED can be used for the management of chronotropic incompetence. Perioperatively, the practitioner must keep in mind that a loss of LV endocardial pacing may result in hemodynamic deterioration due to a reduction in cardiac output.

### Subcutaneous Implantable Cardioverter Defibrillator

#### Indication and Features

The S-ICD system (Boston Scientific) consists of a single subcutaneous electrode and a pulse generator and has emerged as an excellent alternative to conventional transvenous ICD systems for the prevention of sudden cardiac death. The S-ICD provides sensing, detection, and defibrillation therapy (synchronous, biphasic shock energy of 80 J) of malignant ventricular tachyarrhythmias in patients who have no need for ATP or bradycardia pacing and avoids complications associated with chronic transvenous leads such as infections, endocarditis, cardiac perforation, and vascular occlusion.<sup>64,65</sup> It is important to note that despite the lack of permanent pacing capabilities, the S-ICD provides transient bradycardia

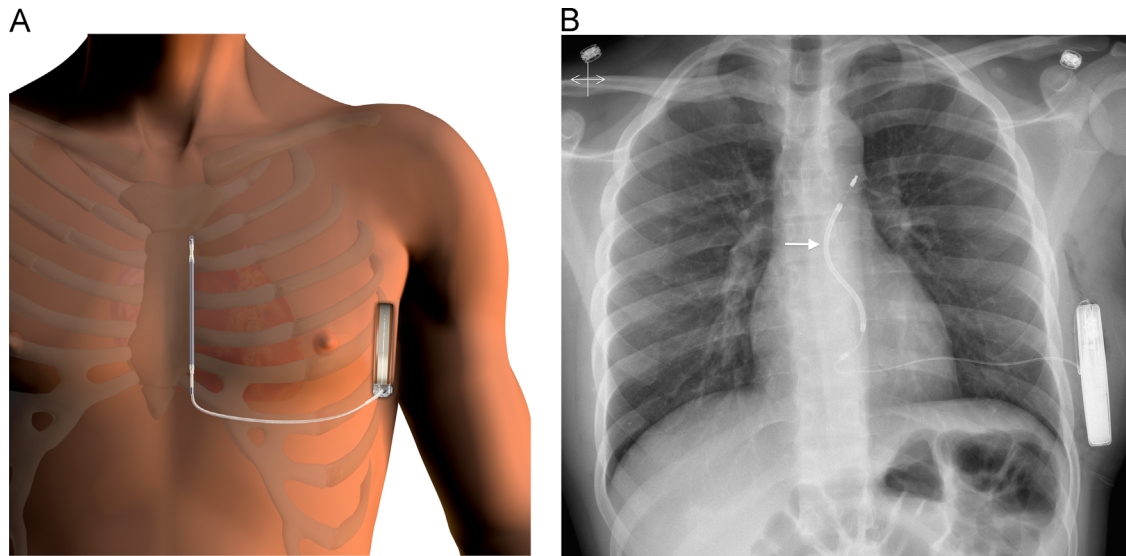


Fig 11. (A) Location of the pulse generator and the subcutaneous electrode after implantation of the subcutaneous implantable cardioverter defibrillator system. (B) Anteroposterior chest radiograph demonstrating a subcutaneous implantable cardioverter defibrillator system in situ with the single subcutaneous electrode delineated (arrow).

A with permission from Boston Scientific.

pacing at 50 pulses/min for a maximum duration of 30 seconds in the event that post-shock therapy bradycardia occurs.

The S-ICD system is implanted subcutaneously in the left hemithorax with no direct contact with any cardiovascular structures. The pulse generator is implanted at the sixth intercostal space along the left midaxillary line and has a battery life of 7.3 years (Fig 11).<sup>66</sup> The electrode is tunneled from the pulse generator pocket to the xyphoid process and then superiorly to the manubriosternal junction (Fig 12). After implantation, S-ICD programming is performed—the electrophysiologist selects the best of 3 sensing vectors (subcutaneous ECGs) to avoid T-wave oversensing, which may cause inappropriate shock therapy. The device uses heart rate, ECG morphology, and QRS width discriminators during rhythm analysis before shock therapy is delivered to avoid inappropriate shock therapy of supraventricular tachycardia and other noise-related arrhythmias. Common practice is to use a dual-zone heart rate strategy—a heart rate of 200 beats/min for ventricular tachycardia (optional conditional shock zone) and a heart rate of 220 beats/min for ventricular fibrillation (shock zone).<sup>66</sup> The S-ICD provides a maximum of 5 shocks/episode of ventricular tachyarrhythmia.<sup>66</sup>

#### Perioperative Management of S-ICDs

Even though S-ICDs are less prevalent than transvenous ICDs, their implantation is increasing. A post-approval follow-up study of the S-ICD system registry identified 1,637 S-ICD implants between 2013 and 2016.<sup>65</sup> Management of the S-ICD in the perioperative period is challenging due to the lack of society guidelines or recommendations and the aforementioned features. Moreover, the S-ICD system is different from transvenous ICDs and may be more prone to EMI considering the wider sensing region (left hemithorax) and the use of

subcutaneous ECGs (similar to surface ECGs) for sensing. However, the principles of current guidelines for the perioperative management of transvenous ICDs may be transferable to S-ICDs.

The anesthesiologist should determine the reason for S-ICD implantation—primary versus secondary prevention of sudden cardiac death. Primary prevention patients have no history of ventricular tachyarrhythmias, whereas secondary prevention

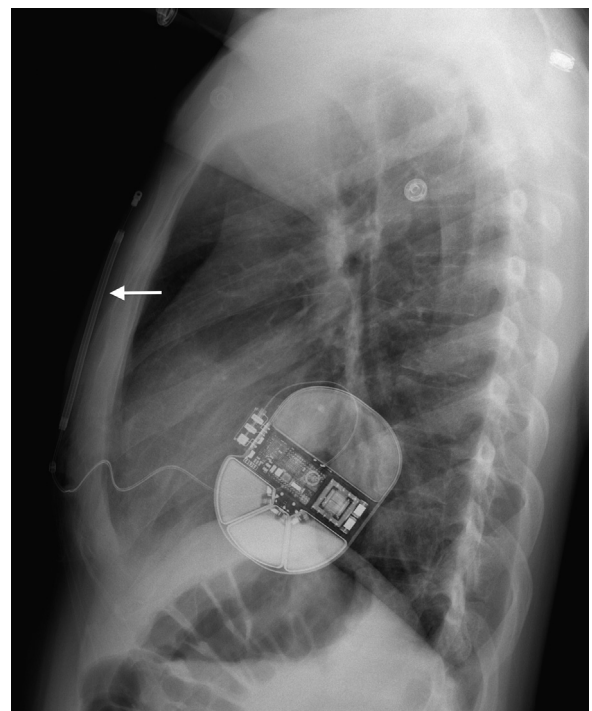


Fig 12. Lateral chest radiograph of a subcutaneous implantable cardioverter defibrillator system. Note that the electrode is tunneled into position anterior to the manubrium (arrow).



Fig 13. Recommended positions for magnet placement for suspension of arrhythmia therapy.  
With permission from Boston Scientific.

patients have a prior history of life-threatening ventricular tachyarrhythmias. This data can be helpful when deciding whether to suspend therapy before surgery, especially in secondary prevention patients. Preoperative examination by a CIED team verifies the integrity of the S-ICD system and battery life and provides vital data stored in the pulse generator. The EMBLEM S-ICD (Model A209; Boston Scientific) stores subcutaneous ECGs for 25-treated and 20-untreated tachyarrhythmia episodes, whereas the EMBLEM MRI S-ICD (Model A219) stores up to 20-treated and 15-untreated tachyarrhythmia episodes and provides guidance to the anesthesiologist.

Similar to the perioperative management of traditional transvenous ICDs, clinicians are faced with the difficult decision of either programming the S-ICD to the “therapy off” mode before surgery or applying a magnet to prevent EMI-induced inappropriate shock therapy. Reprogramming devices to “therapy off” in the perioperative period is strongly supported by HRS and the ASA for transvenous ICDs. One can assume that this recommendation extends to S-ICDs. However, unlike traditional transvenous ICDs, S-ICDs cannot provide bradycardia pacing or antitachycardia pacing. If bradycardia pacing is a perioperative concern, then the application of external pads or temporary transvenous pacing is required.

Another strategy is to leave the S-ICD in the “therapy on” mode and temporarily suspend ventricular tachyarrhythmia therapy intraoperatively with a standard doughnut-shaped magnet. It is noteworthy that magnet application to the S-ICD is different from that for transvenous ICDs: the manufacturer recommends magnet placement over the header or over the lower edge of the pulse generator to suspend therapy (Fig 13). Optimal S-ICD suspension with a magnet occurs if the device emits a beeping tone for 60 seconds after magnet application.<sup>66</sup> Failure to hear the beeping sound implies that the applied magnet has not disabled the S-ICD and magnet reposition is warranted in the recommended target zones (Fig 13). Arrhythmia detection and shock therapy are

restored immediately upon magnet removal. Heart rhythm monitoring not only with surface ECGs, but also with pulse oximetry and arterial lines, is essential with the 2 approaches just described to ensure rapid diagnosis and therapy of sustained ventricular arrhythmias. Regardless of the strategy adopted for perioperative S-ICD management, external defibrillation/cardioversion and transcutaneous pacing should be readily available in the event that S-ICD failure and/or post-shock refractory bradycardia occur. External defibrillator pads (or paddles) should, however, be applied with caution. Direct application of a defibrillator pad/paddle over the pulse generator or the electrode may damage the S-ICD system and should be avoided.

## Conclusions

CIED technology is evolving rapidly and presents challenges to anesthesiologists. This evolution has led to newer devices that are implanted in the myocardium or extrathoracically and have different functionality from traditional transvenous CIEDs. Similarly, there is room for the role of the anesthesiologist in CIED management to expand and evolve. Progress already is under way at some large academic centers where comprehensive perioperative CIED services are staffed by anesthesiologists.<sup>67,68</sup> Even though it seems unreasonable to expect that every anesthesiologist will possess an intimate knowledge of devices, it is important for anesthesiologists to have a basic understanding of the CIEDs in circulation to ensure optimal communication with consultants and thus improve patient care.

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