Healthy Blue

Clinical UM Guideline

Subject:	Cardioverter Defibrillators		
Guideline #:	CG-SURG-97	**Publish Date:**	04/12/2023
Status:	Reviewed	**Last Review Date:**	02/16/2023

Description

This document addresses the use of implantable transvenous and subcutaneous cardioverter-defibrillator devices to monitor the heart rhythm and deliver an electrical shock when a life-threatening ventricular arrhythmia is detected.

For information regarding other technologies for cardiac disease, see:

- MED.00055 Wearable Cardioverter Defibrillators
- CG-SURG-63 Cardiac Resynchronization Therapy with or without an Implantable Cardioverter Defibrillator for the Treatment of Heart Failure

Clinical Indications

Medically Necessary:

Implantable transvenous cardioverter-defibrillator (ICD) therapy is considered **medically necessary** for the treatment of ventricular tachyarrhythmias and for the prevention of sudden cardiac death (SCD) in individuals who are receiving optimal medical therapy and have a reasonable expectation of survival with a good functional status for more than 1 year when **ONE** of the following indications is present (A through K):

A. After evaluation to define the cause of the event and to exclude any completely reversible causes in survivors of cardiac arrest due to either ventricular fibrillation (VF) or hemodynamically unstable sustained ventricular tachycardia (VT); **or**
B. Those with structural heart disease and spontaneous sustained VT, whether hemodynamically stable or unstable; **or**
C. Those with syncope of undetermined origin with clinically relevant, hemodynamically significant sustained VT; **or**
D. Those with nonischemic dilated cardiomyopathy (NIDCM) who have an LVEF (left ventricular ejection fraction) less than or equal to 35% after 3 months of Guideline-directed medical therapy (GDMT) and who are in New York Heart Association (NYHA) functional Class II or III Heart Failure (HF); **or**
E. Those with ischemic cardiomyopathy due to a prior myocardial infarction (MI) who are at least 40 days or more post-MI, with LVEF less than or equal to 30% and are in NYHA functional Class I HF after 3 months of GDMT or with an LVEF less than or equal to 35% and in NYHA Class II or III HF after 3 months of GDMT; **or**
F. Those with nonsustained VT due to prior MI, LVEF less than 40%, and inducible VF or sustained VT at electrophysiological study; **or**
G. Those with long-QT syndrome who are experiencing either syncope or VT while receiving beta blockers; **or**

H. Those with confirmed hypertrophic cardiomyopathy (HCM) with *greater than or equal to 1* of the following **major risk factors** for sudden cardiac death (SCD):
   1. Personal history of cardiac arrest or sustained ventricular arrhythmias; **or**
   2. Personal history of syncope suspected by clinical history to be arrhythmic within the previous 12 months; **or**
   3. Family history of HCM-related sudden death in one or more 1st or 2nd degree relatives who are less than or equal to 50 years of age or in two or more 3rd degree relatives who are less than or equal to 50 years of age; **or**
   4. LV apical aneurysm, independent of size; **or**
   5. LV systolic dysfunction (LVEF less than 50%); **or**
   6. Nonsustained VT episodes on ECG or continuous ambulatory electrocardiographic monitoring; **or**
   7. Left ventricular (LV) wall thickness greater than or equal to 30 mm in any LV segment; **or**

I. For individuals with symptomatic sustained VT in association with congenital heart disease who have undergone hemodynamic and electrophysiological evaluation; (catheter ablation or surgical repair may offer possible alternatives in carefully selected individuals); **or**

J. For individuals with congenital heart disease with recurrent syncope of undetermined origin in the presence of either ventricular dysfunction or inducible ventricular arrhythmias at electrophysiological study; **or**

K. For individuals with cardiac sarcoidosis when **one (1) or more** of the following are met:
   1. Sustained VT **or** survivors of sudden cardiac arrest **or** with an LVEF of 35% or less; **or**
   2. LVEF of greater than 35% with syncope **or** evidence of myocardial scar by cardiac MRI or PET scan; **or**
   3. LVEF of greater than 35% with inducible sustained ventricular arrhythmias.

Implantable transvenous cardioverter-defibrillator (ICD) therapy is considered **medically necessary** for individuals with a confirmed Brugada syndrome diagnosis when either of the following criteria is met (A or B):

A. History of unexplained syncope, documented spontaneous sustained VT with or without syncope, or survivor of a cardiac arrest; **or**

B. Family history of a first- or second-degree relative with sudden cardiac death due to Brugada syndrome or that is unexplained.

Subcutaneous cardioverter-defibrillator (S-ICD) devices are considered **medically necessary** for the following at-risk individuals when the medically necessary criteria above for implantable transvenous cardioverter-defibrillator (ICD) therapy have been met and the individual does not require cardiac pacing:

A. Individuals with a lack of venous access; **or**
B. Individuals who are immunocompromised; **or**
C. Individuals with prosthetic valves; **or**
D. Individuals with recurrent transvenous lead-related, device-pocket or systemic infections; **or**
E. Individuals with endocarditis; **or**
F. Pediatric individuals.*****

****The FDA interprets pediatrics as individuals who are 21 years of age or younger (that is, up to, but not including, the 22nd birthday). See the Discussion/General Information section for additional information about use of ICD therapy in children.***

Note: *For use of combined ICD/Biventricular pacing (CRT-ICD) devices, in cases of NYHA Class IV heart failure and for other indications, see CG-SURG-63 Cardiac Resynchronization Therapy (CRT), with or without an Implantable Cardioverter Defibrillator (CRT/ICD) for the Treatment of Heart Failure.*

Not Medically Necessary:

The use of an implantable transvenous cardioverter-defibrillator is considered **not medically necessary** when the criteria above are not met and for any other indications.

The use of a subcutaneous ICD (S-ICD) is considered **not medically necessary** for all indications when the above criteria are not met.

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

CPT	
33202	Insertion of epicardial electrode(s); open incision (eg, thoracotomy, median sternotomy, subxiphoid approach) [when specified as ICD]
33203	Insertion of epicardial electrode(s); endoscopic approach (eg, thoracoscopy, pericardioscopy) [when specified as ICD]
33216	Insertion of a single transvenous electrode, permanent pacemaker or implantable defibrillator [when specified as ICD]
33217	Insertion of 2 transvenous electrodes, permanent pacemaker or implantable defibrillator [when specified as ICD]
33230	Insertion of implantable defibrillator pulse generator only; with existing dual leads
33231	Insertion of implantable defibrillator pulse generator only; with existing multiple leads
33240	Insertion of implantable defibrillator pulse generator only; with existing single lead
33249	Insertion or replacement of permanent implantable defibrillator system with transvenous lead(s), single or dual chamber
33270	Insertion or replacement of permanent subcutaneous implantable defibrillator system, with subcutaneous electrode, including defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters, when performed
33271	Insertion of subcutaneous implantable defibrillator electrode
93640	Electrophysiologic evaluation of single or dual chamber pacing cardioverter-defibrillator leads including defibrillation threshold evaluation (induction of arrhythmia, evaluation of sensing and pacing for arrhythmia termination) at time of initial implantation or replacement;

93641	Electrophysiologic evaluation of single or dual chamber pacing cardioverter-defibrillator leads including defibrillation threshold evaluation (induction of arrhythmia, evaluation of sensing and pacing for arrhythmia termination) at time of initial implantation or replacement; with testing of single or dual chamber pacing cardioverter-defibrillator pulse generator

HCPCS

C1721	Cardioverter-defibrillator, dual chamber (implantable)
C1722	Cardioverter-defibrillator, single chamber (implantable)
C1777	Lead, cardioverter-defibrillator, endocardial single coil (implantable)
C1882	Cardioverter-defibrillator, other than single or dual chamber (implantable)
C1895	Lead, cardioverter-defibrillator, endocardial dual coil (implantable)
C1896	Lead, cardioverter-defibrillator, other than endocardial single or dual coil (implantable)
G0448	Insertion or replacement of a permanent pacing cardioverter-defibrillator system with transvenous lead(s), single or dual chamber with insertion of pacing electrode, cardiac venous system, for left ventricular pacing

ICD-10 Procedure

02H40KZ-02H44KZ	Insertion of defibrillator lead into coronary vein [by approach; includes codes 02H40KZ, 02H43KZ, 02H44KZ]
02H60KZ-02H74KZ	Insertion of defibrillator lead into atrium [right or left, by approach; includes codes 02H60KZ, 02H63KZ, 02H64KZ, 02H70KZ, 02H73KZ, 02H74KZ]
02HK0KZ-02HL4KZ	Insertion of defibrillator lead into ventricle [right or left, by approach; includes codes 02HK0KZ, 02HK3KZ, 02HK4KZ, 02HL0KZ, 02HL3KZ, 02HL4KZ]
02HN0KZ-02HN4KZ	Insertion of defibrillator lead into pericardium [by approach; includes codes 02HN0KZ, 02HN3KZ, 02HN4KZ]
0JH608Z-0JH838Z	Insertion of defibrillator generator into subcutaneous tissue and fascia [chest or abdomen, by approach; includes codes 0JH608Z, 0JH638Z, 0JH808Z, 0JH838Z]
0JH60FZ-0JH63FZ	Insertion of subcutaneous defibrillator lead into chest subcutaneous tissue and fascia [by approach; includes codes 0JH60FZ, 0JH63FZ]

ICD-10 Diagnosis

	All diagnoses including, but not limited to, the following:
D86.85	Sarcoid myocarditis
I21.01-I21.A9	Acute myocardial infarction
I22.0-I22.9	Subsequent ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction
I24.0-I24.9	Other acute ischemic heart disease
I25.10-I25.119	Atherosclerotic heart disease of native coronary artery
I25.2	Old myocardial infarction
I25.5	Ischemic cardiomyopathy
I25.810-I25.9	Other forms of chronic ischemic heart disease
I42.0-I42.9	Cardiomyopathy
I45.81	Long QT syndrome

I46.2-I46.9	Cardiac arrest
I47.0	Re-entry ventricular arrhythmia
I47.20-I47.29	Ventricular tachycardia
I49.01-I49.02	Ventricular fibrillation, ventricular flutter
Q24.8	Other specified congenital malformations of heart [Brugada syndrome]
Q24.9	Congenital malformation of heart, unspecified (congenital disease of heart)
R55	Syncope and collapse
Z82.41	Family history of sudden cardiac death
Z86.74	Personal history of sudden cardiac arrest

When services are Not Medically Necessary:
For the procedure codes listed above when criteria are not met or for situations designated in the Clinical Indications section as not medically necessary.

Discussion/General Information

Implantable cardioverter defibrillators (ICDs) are an important treatment option for individuals with a history of life-threatening ventricular arrhythmias. Randomized clinical trials have shown that ICD use significantly reduces mortality rates for those with coronary artery disease (CAD) and/or a prior myocardial infarction (MI) who have poor ventricular function. Although ICDs for the treatment of atrial fibrillation (AF) have been used in studies, evidence on efficacy and long-term outcomes is limited, and ICD therapy for AF is not considered to be in accordance with generally accepted standards of medical practice at this time.

Available literature indicates that ICDs are now widely used for the *secondary* prevention of sudden cardiac death (SCD), due to ventricular fibrillation (VF) or ventricular tachycardia (VT). ICD implantation is the generally accepted treatment for those who have experienced an episode of VF not accompanied by an acute MI or other transient or reversible cause. Accepted guidelines prefer this treatment in individuals with sustained VT, causing syncope or hemodynamic compromise. As *primary* prevention, the literature shows that ICD use is superior to conventional antiarrhythmic drug therapy for those who have survived an MI and who have spontaneous, non-sustained VT (NSVT), a low left ventricular ejection fraction (LVEF), and inducible VT at electrophysiological study (EPS).

Several national and international specialty societies have longstanding published guidelines addressing indications for ICD implantation. These include:

- 2002 - American College of Cardiology (ACC)/American Heart Association (AHA)/NASPE (North American Society of Pacing and Electrophysiology) guideline for implantation of cardiac pacemakers and antiarrhythmia devices (Gregoratos, 2002);
- 2003 - ACC/ European Society of Cardiology (ESC) Clinical Expert Consensus Document on Hypertrophic Cardiomyopathy (Maron, 2003);
- 2006 – ACC/AHA/ ESC/European Heart Rhythm Association (EHRA)/ Heart Rhythm Society (HRS) practice guidelines for the management of patients with ventricular arrhythmias and the prevention of SCD (Zipes, 2006);

- 2008 - ACC/AHA/HRS updated guideline for device-based therapy of cardiac rhythm abnormalities (Epstein, 2008);
- 2009 – ACC/AHA Guideline for Management of Heart Failure in Adults (Hunt, 2009);
- 2011 - ACCF/AHA Guideline for the Diagnosis and Treatment of Hypertrophic Cardiomyopathy (Gersh, 2011);
- 2017 AHA/ACC/HRS Guideline for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death (Al-Khatib, 2017);
- 2019 ACC/AHA Strategy for Prevention of Sudden Cardiac Death in High-Risk Patients with Hypertrophic Cardiomyopathy (Maron, 2019);
- 2020 AHA/ACC Guideline for the Diagnosis and Treatment of Patients with Hypertrophic Cardiomyopathy (Ommen, 2020).

The 2008 ACC/AHA/HRS guideline addressed use of ICDs for children and adolescents with congenital heart disease:

> The indications for ICD implantation in young patients and those with congenital heart disease have evolved over the past 15 years based on data derived primarily from adult randomized clinical trials. Similar to adults, ICD indications (for pediatric patients) have evolved from the secondary prevention of SCD to the treatment of patients with sustained ventricular arrhythmias to the current use of ICDs for primary prevention in patients with an increased risk of SCD. However, in contrast to adults, there are minimal prospective data regarding ICD survival benefit, because fewer than 1% of all ICDs are implanted in pediatric or congenital heart disease (CHD) patients. Considerations, such as the cumulative lifetime risk of SCD in high-risk patients and the need for decades of antiarrhythmic therapy, make the ICD an important treatment option for young patients. Prospective identification and treatment of young patients at risk for sudden death is crucial because compared with adults, a very low percentage of children undergoing resuscitation survive to hospital discharge…Because of concern about drug-induced proarrhythmia and myocardial depression, an ICD (with or without cardiac resynchronization therapy [CRT]) may be preferable to antiarrhythmic drugs in young patients with dilated cardiomyopathy (DCM) or other causes of impaired ventricular function who experience syncope or sustained ventricular arrhythmias…The role of ICDs in primary prevention for children with genetic channelopathies, cardiomyopathies, and congenital heart defects should be defined more precisely and is an area in need of further research (Epstein, 2008).

In 2009, the ACC/AHA published a focused update to the 2005 guidelines for the diagnosis and management of heart failure (HF) in adults which gave a Class IIa recommendation for ICD placement in individuals with ischemic dilated cardiomyopathy (IDCM) who are at least 40 days post-MI, have an LVEF of 30% or less, are in NYHA functional class I HF on chronic optimal medical therapy, and have a reasonable expectation of survival with a good functional status for more than 1 year (Hunt, 2009). This was based, in part, on the findings of the SCD-HeFT trial previously described (Bardy, 2005) and has been incorporated into the medical necessity criteria for adult indications.

The decision to place an ICD in an individual with IDCM or nonischemic dilated cardiomyopathy (NIDCM) is based, in part, on the measured LVEF. This measurement is subject to change over time based on medical interventions. The placement of an ICD should be reserved for individuals who have received an adequate trial of optimal medical management (Al-Khatib, 2011). In 2012, the term "Guideline-directed medical therapy" (GDMT) was adopted by the writing groups for the major specialty medical societies, (such as found in Tracy, 2012 and Yancy, 2013) to replace "Optimal medical therapy."

Regarding the timeframe generally considered by consensus as adequate to determine if GDMT has been effective prior to ICD placement is 3 to 6 months. In 2013, a report of the American College of Cardiology Foundation (ACCF) Appropriate Use Criteria Task Force, HRS, AHA, American Society of Echocardiography (ASE), Heart Failure Society of America (HFSA), Society for Cardiovascular Angiography and Interventions (SCAI), Society of Cardiovascular Computed Tomography (SCCT), and Society for Cardiovascular Magnetic Resonance (SCMR) was issued, in which the following is noted regarding the timeframe for GDMT:

> Patients who are going to receive substantial benefit from medical treatment alone usually show some clinical improvement during the first 3 to 6 months. Medical therapy is also assumed to include adequate rate control for tachyarrhythmias, including atrial fibrillation. Therefore, it is recommended that GDMT be provided for at least 3 months before planned reassessment of LV function to consider device implantation. If LV function improves to the point where primary prevention indications no longer apply, then device implantation is not indicated (Russo, 2013).

Beginning in 2003, a series of clinical expert consensus documents on hypertrophic cardiomyopathy (HCM) have been published by the ACC, ESC, the ACCF Task Force, and the ESC Committee for Practice Guidelines (Maron, 2003; Maron, 2010; Gersh, 2011). These documents have identified major risk factors for SCD in individuals with HCM, including:

- Family history of at least one HCM-related SCD (defined as SCD in at least 1 first-degree relative);
- At least one episode of unexplained recent syncope (defined as 1 or more episodes of unexplained loss of consciousness within the previous 12 months);
- Massive left ventricular (LV) hypertrophy (thickness greater than or equal to 30 mm);
- Nonsustained VT on ambulatory 24-hour (Holter) ECG (defined as a run of 3 or more consecutive ventricular beats at a rate of at least 120 beats/minute, lasting less than 30 seconds);
- Hypotensive or attenuated BP response to exercise (defined as failure of BP to rise, or as a fall in BP) (Elliott, 2000; Maron, 2010).

The 2011 ACCF and AHA guidelines for the diagnosis and treatment of HCM noted that the decision to implant an ICD must be individualized to the unique circumstances of each individual with HCM. They note that each of the identified SCD risk factors has low positive predictive value and propose that a combination of conventional risk factors and other risk modifiers may give the best indication of who should receive an ICD.

In 2020, the ACC/AHA issued an updated guideline for the diagnosis and treatment of patients with HCM, which is considered a full guideline revision intended to replace the former Gersh, 2011 guideline (Ommen, 2020). This document provides a comprehensive guide to the evaluation and management of HCM in adults and children, which is based on the current evidence, including relevant studies and other specialty society guidelines. Numerous modifications were made including recommendations for ICD therapy. The following updated recommendations

for ICD therapy and risk stratification for SCD have been incorporated into the criteria for ICD therapy in this document:

> Class I, LOE: B-NR:
> For patients with HCM and previous documented cardiac arrest or sustained VT, ICD placement is recommended.
>
> Class IIa, LOE: B-NR:
> For adult patients with HCM with ≥ 1 major risk factors for SCD, it is reasonable to offer an ICD. These major risk factors include:
> a. Sudden death judged definitively or likely attributable to HCM in ≥ 1 first-degree or close relatives who are ≤ 50 years of age;
> b. Massive LVH ≥ 30 mm in any LV segment;
> c. ≥ 1 Recent episodes of syncope suspected by clinical history to be arrhythmic (i.e., unlikely to be of neurocardiogenic [vasovagal] etiology, or related to LVOTO);
> d. LV apical aneurysm, independent of size;
> e. LV systolic dysfunction (EF < 50%).
>
> For children with HCM who have ≥ 1 conventional risk factors, including unexplained syncope, massive LVH (left ventricular hypertrophy), NSVT, or family history of early HCM-related SCD, ICD placement is reasonable after considering the relatively high complication rates of long-term ICD placement in younger patients (Bharucha, 2015; Kamp, 2013; Maron, 2013, 2016; Miron, 2020; Moak, 2011; Norrish, 2017; Yetman, 1998).
>
> For patients ≥ 16 years of age with HCM and with ≥ 1 major SCD risk factors, discussion of the estimated 5-year sudden death risk and mortality rates can be useful during the shared decision-making process for ICD placement (Ommen, 2020).

The following rationale is excerpted for the above recommendations:

> Over the past several decades, retrospective observational studies have identified a number of noninvasive clinical risk markers associated with increased risk for SCD events in HCM. In association with clinical judgment and shared decision-making, patients with HCM are considered potential candidates for primary prevention ICDs by virtue of ≥ 1 major risk markers, which together have a high sensitivity in predicting those patients with HCM at greatest future risk for SCD events…
> Patients with HCM who have experienced a previous documented cardiac arrest or hemodynamically significant VT/VF remain at significantly increased risk for future life-threatening ventricular tachyarrhythmias and should, therefore, be considered for secondary prevention ICD therapy.
> Identification of adult patients with HCM at high risk for SCD should be guided by the presence of a number of acknowledged noninvasive SCD risk factors. Because each of these major risk factors individually is associated with increased risk, **it would be reasonable to consider primary prevention ICD for patients with ≥ 1 SCD risk factor(s)** (Arnett, 2019; Elliott, 1999; Maron, 2019, 2007; O'Mahony, 2013; Vriesendorp, 2013; Yancy, 2013).

Regarding ICD therapy in less prevalent cardiac conditions, such as Brugada syndrome (BrS), the 2008 ACC/AHA/HRS guidelines for device-based therapy of cardiac rhythm abnormalities provide a Class IIa recommendation for, "ICD implantation as reasonable for patients with BrS who have had syncope" and for, "ICD implantation as reasonable for patients with BrS who have documented VT that has not resulted in cardiac arrest" (Level of Evidence: C). The following is provided as the basis for these recommendations:

> Primary electrical conditions, (in reference to genetic syndromes that predispose to sustained VT or VF, such as BrS), typically exist in the absence of any underlying structural heart disease and predispose to cardiac arrest. Although controversy still exists with regard to risk factors for SCD in these conditions, there is consensus that those with prior cardiac arrest or syncope are at very high risk for recurrent arrhythmic events. On the basis of the absence of any clear or consistent survival benefit of pharmacological therapy for individuals with these genetic arrhythmia syndromes, the ICD is the preferred therapy for those with prior episodes of sustained VT or VF and may also be considered for primary prevention for some with a very strong family history of early mortality… Individuals with syncope and the ECG pattern of spontaneous ST segment elevation (associated with BrS) have a 6-fold higher risk of cardiac arrest than those without syncope and the spontaneous ECG pattern (Epstein, 2008).

In 2017, an updated AHA/ACC/HRS guideline for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death (Al-Khatib) was published which was based on systematic reviews of the available evidence-based data and additional guidance from specialty societies (Birnie [HRS], 2014; Kron, 2013; Mohsen, 2014; Schuller, 2012; Shen [ACC/AHA/HRS], 2017). This document provided Class I and IIa recommendations for ICD therapy in those with cardiac sarcoidosis and specific clinical indications when there is reasonable expectation of meaningful survival of greater than 1 year. The recommendations with the strongest indications for benefit from ICD therapy have been incorporated into the medically necessary criteria within this document.

In 2022, the ACC/AHA/HFSA (Heart Failure Society of America) updated its guideline for the management of HF (Heidenreich, 2022). This update retains the 2009 recommendations for ICD therapy and includes a Class IIa Level of Evidence B-R recommendation stating that implantation of an ICD is reasonable for individuals with risk factors, LVEF less than or equal to 45%, and genetic arrhythmogenic cardiomyopathy. This is consistent with a IIa B-NR recommendation in the 2017 AHA/ACC/HRS Guideline for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death (Al-Khatib, 2017) stating that ICD implantation can be beneficial for individuals with risk factors, LVEF less than or equal to 45%, and NIDCM due to a Lamin A/C gene mutation. Heidenreich, et al. do not cite RCTs to support their recommendation and Al-Khatib, et al. specifically state that there are no studies that test the effects of ICD implantation on long-term survival for individuals with a Lamin A/C mutation.

On September 28, 2012 the U.S. Food and Drug Administration (FDA) granted clearance for the first subcutaneous ICD device, the S-ICD® System, (developed by Cameron Health®, Inc., now owned by Boston Scientific Corp., San Clemente, CA). According to the FDA press release:

> The S-ICD System is cleared to provide an electric shock to the heart (defibrillation) when the individual's heart is beating at a dangerous level or abnormally fast (ventricular tachyarrhythmias). It is approved only for individuals who do not require a pacemaker or pacing therapy.

This press release went on to say: "The S-ICD System provides an alternative for treating patients with life-threatening heart arrhythmias for whom the routine ICD placement procedure is not ideal," said Christy Foreman, director of the Office of Device Evaluation at the FDA Center for Devices and Radiological Health (CDRH). "Some patients with anatomy that makes it challenging to place one of the implantable defibrillators currently on the market may especially benefit from this device" (CDRH, 2012).

On March 13, 2015 the EMBLEM™ S-ICD System (Boston Scientific Corp., St. Paul, MN) obtained pre-market clearance from the FDA for indications very similar to the original S-ICD System for individuals who are at risk for SCD but who do not also require a pacemaker or pacing therapy. The FDA required that a post-approval study be conducted by the manufacturer. This prospective cohort study (of 1616 subjects from approximately 50 investigational centers [including up to 140 in the US]), the PRAETORIAN trial, is underway with final 5 year follow/up data planned and interim reports submitted to the FDA at 6 months, 1 year, 18 months, 2, and 3 years. Interim safety data as of Jan. 24, 2018 reported no high impedance alerts and no adverse events, to date, for the 140 enrolled subjects in the U.S (Gold, 2017). At follow-up of 49.1 months, Knops reported interim data that showed primary end-point events occurred in 68 subjects in the S-ICD group and in 68 subjects in the transvenous ICD (TV-ICD) group (48-month Kaplan-Meier estimated cumulative incidence, 15.1% and 15.7%, respectively; hazard ratio [HR], 0.99; 95% confidence interval [CI], 0.71 to 1.39; p=0.01 for noninferiority; p=0.95 for superiority). Device-related complications occurred in 31 subjects in the S-ICD group and in 44 in the TV-ICD group (HR, 0.69; 95% CI, 0.44 to 1.09); inappropriate shocks occurred in 41 and 29 subjects, respectively (HR, 1.43; 95% CI, 0.89 to 2.30). Death occurred in 83 subjects in the S-ICD group and in 68 in the TV-ICD group (HR, 1.23; 95% CI, 0.89 to 1.70); appropriate shocks occurred in 83 and 57 subjects, respectively (HR, 1.52; 95% CI, 1.08 to 2.12) (Knops, 2020). Additional information is available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma_pas.cfm?t_id=612348&c_id=4601. Accessed on January 26, 2023.

On August 9, 2016 the FDA cleared the Emblem MRI S-ICD System, which allows individuals with this subcutaneous device to safely undergo magnetic resonance (MR) imaging. The FDA has also allowed for MR conditional labeling for all previously implanted Emblem S-ICD Systems. According to the manufacturer, the company is also actively pursuing MRI compatibility for their currently approved ICD and CRT (cardiac resynchronization therapy) systems via the global ENABLE MRI study.

The criteria within this document for use of ICD therapy are consistent with generally accepted standards of medical practice and are clinically appropriate to treat the cardiac conditions described in the Clinical Indications section of this document.

ICD THERAPY IN CHILDREN

There remains limited data on the clinical utility of ICD in children for many conditions which would commonly be treated with ICD in adults. As such, the potential risks and evidence of benefit from ICD therapy in children is not

as well described in the medical literature. Studies have shown higher inappropriate shock rates and lead failure (Berul, 2008) and reduced quality of life (Sears, 2011) in children who have received an ICD. Based on specialty society input and opinions from the practice community, it was determined that ICD therapy should be made available to children based on the currently accepted adult indications for ICD, subject to the expert evaluations and treatment discretion of the treating physician in collaboration with the child's parents or legal guardians (Alexander, 2004; Berul, 2008; Decker, 2009; Dimitrow, 2010; Epstein, 2008; Gersh, 2011; Monserrat, 2003; Silka, 1993). Prior to ICD implantation in a child, the informed consent discussion that the treating provider conducts with the family/guardian should include documentation of a thorough discussion of the probability of a life threatening event, based on the underlying condition, as well as the potential benefits and harms of the ICD and the family's/guardian's understanding of the information provided.

Definitions

Abnormal blood pressure (BP) response during upright exercise testing: Failure of BP to rise by more than 25 mmHg (flat) or a fall in BP more than 15 mmHg (considered to be a hypotensive response) that occurs during upright exercise stress testing.

Arrhythmia (or dysrhythmia): Problems that affect the electrical system of the heart muscle, producing abnormal heart rhythms and may be classified as either atrial or ventricular, depending on which part of the heart they originate from.

Atrial Fibrillation: A condition in which the atrium (the heart's two upper chambers) produce uncoordinated electrical signals.

Brugada syndrome (BrS): An autosomal-dominant inherited arrhythmic disorder characterized by ST elevations with successive negative T waves in the right precordial leads without structural cardiac abnormalities. Individuals with BrS are at risk for sudden cardiac death (SCD) due to ventricular fibrillation (VF). Mutations in the SCN5A gene represent the most common genotype responsible for BrS but mutations in additional genes have also been associated with BrS and risk for SCD.

Cardiac Sarcoidosis: A multisystem granulomatous disease of unknown etiology. Myocardial involvement occurs in at least 25% of individuals with sarcoidosis who are at increased risk for sudden death from ventricular arrhythmias.

Cardiomyopathy (CM): A disease in which the heart muscle becomes inflamed affecting cardiac function. There are multiple types of CM, (with the three main types being dilated, hypertrophic, and restrictive [see below]):

- Dilated - This is the most common form, in which the heart cavity is enlarged and stretched (cardiac dilation). The heart is weak and doesn't pump normally, and most individuals develop congestive heart failure. Abnormal heart rhythms and disturbances in the heart's electrical conduction may also occur.
- Hypertrophic (HCM) - In this condition, the muscle mass of the left ventricle enlarges or "hypertrophies." In one form of the disease, the wall between the two pumping chambers becomes enlarged and obstructs the blood flow from the left ventricle. In the other form of the disease, non-obstructive hypertrophic cardiomyopathy, the enlarged muscle doesn't obstruct blood flow.

- Ischemic Dilated (IDCM) - Left ventricular systolic dysfunction (or disease of the heart muscle) associated with at least 75% narrowing of at least one of the three major coronary arteries (marked stenosis) or a documented history of MI.
- Nonischemic Dilated (NIDCM) - Left ventricular systolic dysfunction (or disease of the heart muscle) that is not associated with Coronary Artery Disease (CAD) or narrowing of the coronary arteries. There are a few different types of NIDCM but all involve thickening (abnormal enlargement) of the walls of the heart and progressive weakening of the pumping efficiency of the heart.
- Restrictive - This is the least common type in the United States. The myocardium (heart muscle) of the ventricles becomes excessively "rigid," making it more difficult for the ventricles to fill with blood between heartbeats. This type of cardiomyopathy is usually due to another disease process.

Congestive Heart Failure (CHF), also referred to as Heart Failure (HF): This is a condition in which the heart can't pump enough blood to the body's other organs. The "failing" heart keeps working but not as efficiently as it should. As blood flow out of the heart slows, blood returning to the heart through the veins backs up, causing congestion in the tissues.

Coronary Artery Disease (CAD): Heart problems caused by narrowed heart arteries. When arteries are narrowed, less blood and oxygen reaches the heart which can ultimately lead to a heart attack (myocardial infarction - MI).

Defibrillation: A process in which an electronic device (a defibrillator) gives the heart an electric shock, helping to re-establish normal contraction rhythms in a heart that is not properly beating. This may be done using an external device or by a device implanted in the body.

Ejection Fraction (EF) or Left Ventricular Ejection Fraction (LVEF): The percentage of blood ejected from the left ventricle with each heartbeat. Normal readings would be in the 58-70% range and lower values would indicate ventricular dysfunction.

Electrophysiology Studies (EPS): These studies evaluate the electrophysiological properties of the heart, such as automaticity, conduction, and whether the condition is refractory to management with medications. Additional capabilities of this testing include: ability to initiate and terminate tachycardia to map activation sequences and to evaluate individuals for various forms of therapy and to judge response to therapy.

Myocardial Infarction (MI): This is the medical term for “heart attack.” A MI occurs when the blood supply to part of the heart muscle (the myocardium) is severely reduced or blocked (stenosed).

According to the 2012 European Society of Cardiology, American College of Cardiology Foundation, American Heart Association, and the World Heart Federation (ESC/ACCF/AHA/WHF) Expert Consensus Document: Third Universal Definition of Myocardial Infarction, the following definitions are provided for acute evolving MI and prior MI:

Acute MI is defined as – Detection of a rise and/or fall of cardiac biomarker values (preferably cardiac troponin [cTn]) with at least one value above the 99th percentile upper reference limit (URL) and with at least one of the following:

- Symptoms of ischemia;

- New, or presumed new, significant ST-segment-T wave (ST-T) changes or new left bundle branch block (LBBB);
- Development of pathological Q waves in the EKG;
- Imaging evidence of new loss of viable myocardium or new regional wall motion abnormality;
- Identification of an intracoronary thrombus by angiography or autopsy.

Prior MI is defined as – Any one of the following:

- Pathological Q waves with or without symptoms in the absence of non-ischemic causes;
- Imaging evidence of a region of loss of viable myocardium that is thinned and fails to contract in the absence of a non-ischemic cause;
- Pathological findings of a prior MI (Thygesen, 2012).

New York Heart Association (NYHA) Definitions:
The NYHA classification of heart failure is a 4-tier system that categorizes based on subjective impression of the degree of functional compromise. The four NYHA functional classes are as follows:

- Class I - individuals with cardiac disease but without resulting limitation of physical activity; ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain; symptoms only occur on severe exertion;
- Class II - individuals with cardiac disease resulting in slight limitation of physical activity; they are comfortable at rest; ordinary physical activity, (e.g., moderate physical exertion, such as carrying shopping bags up several flights of stairs) results in fatigue, palpitation, dyspnea, or anginal pain;
- Class III - individuals with cardiac disease resulting in marked limitation of physical activity; they are comfortable at rest; less than ordinary activity causes fatigue, palpitation, dyspnea or anginal pain;
- Class IV - individuals with cardiac disease resulting in inability to carry on any physical activity without discomfort; symptoms of heart failure or the anginal syndrome may be present even at rest; if any physical activity is undertaken, discomfort is increased.

Non-sustained/Sustained Ventricular Tachycardia: Ventricular tachycardia is considered non-sustained (NSVT) when 3 or more consecutive ventricular beats occur at a rate of at least 120 beats/minute which lasts less than 30 seconds. If the rhythm lasts more than 30 seconds, it is known as a sustained ventricular tachycardia (even if it terminates on its own, [that is, without medical intervention] after 30 seconds).

QRS Complex: The portion of an electrocardiogram (EKG) reading, which represents the spread of the electrical impulse through the ventricles.

Structural Heart Disease: A general or umbrella term that encompasses the full scope of conditions caused by defects or abnormalities in the heart's valves, walls and/or muscle. Heart valve conditions are either congenital (present at birth) or can form later in life, due to aging, infection or a correlated underlying condition, and affect the cardiac structure and proper pumping function of the myocardium. The term, structural heart disease, has also been described as, "Non-coronary cardiovascular disease processes and related interventions" (DeMaria, 2014). This refers to heart disease for which some therapy, surgical or percutaneous, exists. Examples include aortic stenosis, hypertrophic cardiomyopathy, some arrhythmias and coronary artery disease where an abnormality of the cardiac structure interferes with normal function (Portions excerpted from UChicago Medicine Valvular & Structural Heart

Disease 2019; available at: https://www.uchicagomedicine.org/conditions-services/heart-vascular/valve-disease. Accessed on January 17, 2023).

Sudden Cardiac Arrest (SCA): Refers to a sudden cessation of cardiac activity such that the victim becomes unresponsive with no normal breathing and no signs of circulation. If corrective measures are not taken rapidly, this condition progresses to SCD.

Sudden Cardiac Death (SCD also called sudden death): Death resulting from an abrupt loss of heart function (cardiac arrest).

Syncope: An episode where the individual experiences loss of consciousness lasting at least several seconds. If the person only experiences extreme dizziness but with no actual loss of consciousness, this is termed "Pre-Syncope."

Ventricular Fibrillation (Vfib or VF): This is a condition in which the heart's electrical activity becomes disordered, resulting in the heart's lower (pumping) chambers contract in a rapid, unsynchronized fashion, (that is, the ventricles "flutter" rather than beat), and the heart pumps little or no blood.

Ventricular Tachyarrhythmias: This medical term refers to a rapid heartbeat that may be regular or irregular and arises from the ventricle or pumping chamber of the heart. Two common tachyarrhythmias are ventricular tachycardia and ventricular fibrillation.

Ventricular Tachycardia (Vtach or VT): This is a fast regular heart rate (usually of 100 or more beats per minute) that starts in the lower chambers (ventricles) and may result from serious heart disease that usually requires prompt treatment.

References

Peer Reviewed Publications:

1. Agrawal S, Garg L, Nanda S, et al. The role of implantable cardioverter-defibrillators in patients with continuous flow left ventricular assist devices - A meta-analysis. Int J Cardiol. 2016; 222:379-384.
2. Alexander ME, Cecchin F, Walsh EP, et al. Implications of implantable cardioverter-defibrillator therapy in congenital heart disease and pediatrics. J Cardiovasc Electrophysiol. 2004; 15(1):72-76.
3. Al-Khatib SM, Hellkamp A, Curtis J, et al. Non-evidence-based ICD implantations in the United States. JAMA. 2011; 305(1):43-49.
4. Al-Khatib SM, Hellkamp AS, Fonarow GC, et al. Association between prophylactic implantable cardioverter-defibrillators and survival in patients with left ventricular ejection fraction between 30% and 35%. JAMA. 2014; 311(21):2209-2215.
5. Amara N, Boveda S, Defaye P, et al. Implantable cardioverter-defibrillator therapy among patients with non-ischemic vs. ischemic cardiomyopathy for primary prevention of sudden cardiac death. Europace. 2018; 20(1):65-72.
6. Bardy GH, Lee KL, Mark DB, et al. Amiodarone or an implantable cardioverter–defibrillator for congestive heart failure (SCD-HeFT Trial). N Engl J Med. 2005; 352(3):225-237.

7. Bardy GH, Smith WM, Hood MA, et al. An entirely subcutaneous implantable cardioverter-defibrillator. N Engl J Med. 2010; 363(1):36-44.
8. Berul CI, Van Hare GF, Kertesz NJ, et al. Results of a multicenter retrospective implantable cardioverter-defibrillator registry of pediatric and congenital heart disease patients. J Am Coll Cardiol. 2008; 51(17):1685-1691.
9. Bharucha T, Lee KJ, Daubeney PEF, et al. Sudden death in childhood cardiomyopathy: results from a long-term national population-based study. J Am Coll Cardiol. 2015; 65:2302-2310.
10. Boehmer JP. Device therapy for heart failure. Am J Cardiol. 2003; 91(6A):53D-59D.
11. Boersma L, Burke MC, Neuzil P, et al. Infection and mortality after implantation of a subcutaneous ICD after transvenous ICD extraction. Heart Rhythm. 2016; 13(1):157-164.
12. Boersma L, El-Chami MF, Bongiorni MG, et al. Understanding outcomes with the EMBLEM S-ICD in primary prevention patients with low EF study (UNTOUCHED): clinical characteristics and perioperative results. Heart Rhythm. 2019; 16(11):1636-1644.
13. Bristow MR, Saxon LA, Boehmer J, et al. Cardiac-resynchronization therapy with or without an implantable defibrillator in advanced chronic heart failure. N Engl J Med. 2004; 350(21):2140-2150.
14. Brouwer TF, Yilmaz D, Lindeboom R, et al. Long-term clinical outcomes of subcutaneous versus transvenous implantable defibrillator therapy. J Am Coll Cardiol. 2016; 68(19):2047-2055.
15. Bunch TJ, Hohnloser SH, Gersh BJ. Mechanisms of sudden cardiac death in myocardial infarction survivors: insights from the randomized trials of implantable cardioverter-defibrillators. Circulation. 2007; 115(18):2451-2457.
16. Burke MC, Aasbo JD, El-Chami MF, et al. 1-Year prospective evaluation of clinical outcomes and shocks: The Subcutaneous ICD Post Approval Study. JACC Clin Electrophysiol. 2020; 6(12):1537-1550.
17. Burke MC, Gold MR, Knight BP, et al. Safety and efficacy of the totally subcutaneous implantable defibrillator: 2-year results from a pooled analysis of the IDE Study and EFFORTLESS Registry. J Am Col Cardiol. 2015; 65(16):1606-1615.
18. Buxton AE, Lee KL, Fisher JD, et al. A randomized study of the prevention of sudden death in patients with coronary artery disease. N Engl J Med. 1999; 341(25):1882-1890.
19. Buxton AE, Lee KL, Hafley GE, et al.: MUSTT Investigators. Limitations of ejection fraction for prediction of sudden death risk in patients with coronary artery disease: lessons from the MUSTT study. J Am Coll Cardiol. 2007; 50(12):1150-1157.
20. Buxton AE, Sweeney MO, Wathen MS, et al. QRS duration does not predict occurrence of ventricular tachyarrhythmias in patients with implanted cardioverter-defibrillators. J Am Coll Cardiol. 2005; 46(2):310-316.
21. Carbucicchio C, Santamaria M, Trevisi N, et al. Catheter ablation for the treatment of electrical storm in patients with implantable cardioverter-defibrillators: short- and long-term outcomes in a prospective single-center study. Circulation. 2008; 117(4):462-469.
22. Cha YM, Gersh BJ, Maron BJ, et al. Electrophysiologic manifestations of ventricular tachyarrhythmias provoking appropriate defibrillator interventions in high-risk patients with hypertrophic cardiomyopathy. Cardiovasc Electrophysiol. 2007; 18(5):483-487. Comment in: J Cardiovasc Electrophysiol. 2007; 18(5):488-489.
23. Chow AW, Lane RE, Cowie MR. New pacing technologies for heart failure. BMJ. 2003; 326(7398):1073-1077.
24. Christiaans I, van Engelen K, van Langen IM, et al. Risk stratification for sudden cardiac death in hypertrophic cardiomyopathy: systematic review of clinical risk markers. Europace. 2010; 12(3):313-321.

25. Coats AJ. MADIT II, the Multi-center Autonomic Defibrillator Implantation Trial II stopped early for mortality reduction, has ICD therapy earned its evidence-based credentials? Int J Cardiol. 2002; 82(1):1-5.
26. Cook JR, Rizo-Paton C, et al. Effect of surgical revascularization in patients with coronary artery disease and ventricular tachycardia or fibrillation in the antiarrhythmias versus implantable defibrillation registry. Am Heart J. 2002; 143(5):821-826.
27. Cooper JM, Katcher MS, Orlov MV. Current concepts: implantable devices for the treatment of atrial fibrillation. N Eng J Med. 2002; 346(26):2062-2028.
28. David Investigators. dual-chamber pacing or ventricular backup pacing in patients with an implantable defibrillator: the dual chamber and VVI implantable defibrillator (DAVID) trial. JAMA. 2002; 288(24):3115.
29. Day JD, Doshi RN, Belott P, et al. Inductionless or limited shock testing is possible in most patients with implantable cardioverter-defibrillators/cardiac resynchronization therapy defibrillators: results of the multicenter ASSURE Study (Arrhythmia Single Shock Defibrillation Threshold Testing Versus Upper Limit of Vulnerability: Risk Reduction Evaluation With Implantable Cardioverter-Defibrillator Implantations). Circulation. 2007; 115(18):2382-2389. Comment in: Circulation. 2007; 115(18):2370-2372.
30. Decker JA, Rossano JW, Smith EO, et al. Risk factors and mode of death in isolated hypertrophic cardiomyopathy in children. J Am Coll Cardiol. 2009; 54(3):250-254.
31. Defaye P, Boveda S, Klug D, et al. Dual- vs. single-chamber defibrillators for primary prevention of sudden cardiac death: long-term follow-up of the Défibrillateur Automatique Implantable-Prévention Primaire registry. Europace. 2017; 19(9):1478-1484.
32. Delise P, Allocca G, Marras E, et al. Risk stratification in individuals with the Brugada type 1 ECG pattern without previous cardiac arrest: usefulness of a combined clinical and electrophysiologic approach. Eur Heart J. 2011; 32(2):169-176.
33. DeMaria AN. Structural heart disease. J Am Col Cardiol. 2014; 63(6):603-604.
34. Desai AS, Fang JC, Maisel WH, et al. Implantable defibrillators for the prevention of mortality in patients with nonischemic cardiomyopathy: a meta-analysis of randomized controlled trials. JAMA. 2004; 292(23):2874-2879.
35. Dhutia H, Malhotra A, Parpia S, et al. The prevalence and significance of a short QT interval in 18,825 low-risk individuals including athletes. Br J Sports Med. 2016; 50(2):124-129.
36. Dimitrow PP, Chojnowska L, Rudzinski T, et al. Sudden death in hypertrophic cardiomyopathy: old risk factors re-assessed in a new model of maximalized follow-up. Eur Heart J. 2010; 31(24):3084-3093.
37. Earley A, Persson R, Garlitski AC, et al. Effectiveness of implantable cardioverter defibrillators for primary prevention of sudden cardiac death in subgroups: a systematic review. Ann Intern Med. 2014; 160(2):111-121.
38. El-Chami MF, Burke MC, Herre JM, et al. Outcomes of subcutaneous implantable cardioverter-defibrillator in dialysis patients: Results from the S-ICD post-approval study. Heart Rhythm. 2020; 17(9):1566-1574.
39. El-Chami MF, Levy M, Kelli HM, et al. Outcome of subcutaneous implantable cardioverter defibrillator implantation in patients with end-stage renal disease on dialysis. J Cardiovasc Electrophysiol. 2015; 26(8):900-904.
40. Ellenbogen KA, Levine JH, Berger RD, et al. Are implantable cardioverter defibrillator shocks a surrogate for sudden cardiac death in patients with nonischemic cardiomyopathy? Circulation. 2006; 113(6):776-782.
41. Elliott PM, Poloniecki J, Dickie S, et al. Sudden death in hypertrophic cardiomyopathy: identification of high risk patients. J Am Coll Cardiol. 2000; 36(7):2212-2218.
42. Elliott PM, Sharma S, Varnava A, et al. Survival after cardiac arrest or sustained ventricular tachycardia in patients with hypertrophic cardiomyopathy. J Am Coll Cardiol. 1999; 33(6):1596-1601.

43. Engelstein ED. Prevention and management of chronic heart failure with electrical therapy. Am J Cardiol. 2003; 91(9):62.
44. Exner DV, Klen GJ, Prytowsky EN. Primary prevention of sudden cardiac death with implantable defibrillator therapy in patients with cardiac disease: can we afford to do it? (Can we afford not to?). Circulation. 2001; 104(13):1564-1570.
45. Ezekowitz JA, Armstrong PW, McAlister FA. Implantable cardioverter-defibrillators in primary and secondary prevention: a systemic review of randomized, controlled trials. Ann Intern Med. 2003; 138(6):445-452.
46. Ezekowitz JA, Rowe BH, Dryden DM, et al. Systematic review: cardioverter defibrillators for adults with left ventricular systolic dysfunction. Ann Intern Med. 2007; 147(4):251-262.
47. Ezzat VA, Lee V, Ahsan S, et al. A systematic review of ICD complications in randomized controlled trials versus registries: is our 'real-world' data an underestimation? Open Heart. 2015; 2(1):e000198.
48. Fisher JD, Buxton AE, Lee KL, et al. Designation and distribution of events in the Multicenter UnSustained Tachycardia Trial (MUSTT). Am J Cardiol. 2007; 100(1):76-83.
49. Fong KY, Ng CJR, Wang Y, et al. Subcutaneous Versus Transvenous Implantable Defibrillator Therapy: A Systematic Review and Meta-Analysis of Randomized Trials and Propensity Score-Matched Studies. J Am Heart Assoc. 2022; 11(11):e024756.
50. Fontenla A, Martinez-Ferrer JB, Alzueta J, et al. Incidence of arrhythmias in a large cohort of patients with current implantable cardioverter-defibrillators in Spain: results from the UMBRELLA Registry. Europace. 2016; 18(11):1726-1734.
51. Friedman P, Murgatroyd F, Boersma LVA, et al. Efficacy and Safety of an Extravascular Implantable Cardioverter–Defibrillator. N Engl J Med. 2022; 387:1292-1302.
52. Friedman DJ, Parzynski CS, Varosy PD, et al. Trends and in-hospital outcomes associated with adoption of the subcutaneous implantable cardioverter defibrillator in the United States. JAMA Cardiol. 2016; 1(8):900-911.
53. Frommeyer G, Dechering DG, Kochhauser S, et al. Long-time "real-life" performance of the subcutaneous ICD in patients with electrical heart disease or idiopathic ventricular fibrillation. J Interv Card Electrophysiol. 2016; 47(2):185-188.
54. Gigli M, Merlo M, Graw SL, et al. Genetic risk of arrhythmic phenotypes in patients with dilated cardiomyopathy. J Am Coll Cardiol. 2019; 74:1480–1490.
55. Gold MR, Aasbo JD, El-Chami MF, et al. Subcutaneous implantable cardioverter-defibrillator Post-Approval Study: Clinical characteristics and perioperative results. Heart Rhythm. 2017; 14(10):1456-1463.
56. Gold MR, Aasbo JD, Weiss R, et al. Infection in patients with subcutaneous implantable cardioverter-defibrillator: Results of the S-ICD Post Approval Study. Heart Rhythm. 2022; 19(12):1993-2001.
57. Gold MR, Lambiase PD, El-Chami MF, et al. Primary results from the understanding outcomes with the S-ICD in primary prevention patients with low ejection fraction (UNTOUCHED) trial. Circulation. 2021; 143(1):7-17.
58. Gold MR, Theuns DA, Knight BP, et al. Head-to-head comparison of arrhythmia discrimination performance of subcutaneous and transvenous ICD arrhythmia detection algorithms: the START study. J Cardiovasc Electrophysiol. 2012; 23(4):359-366.
59. Gold MR, Weiss R, Theuns DA, et al. Use of a discrimination algorithm to reduce inappropriate shocks with a subcutaneous implantable cardioverter-defibrillator. Heart Rhythm. 2014; 11(8):1352-1358.

60. Goldenberg I, Gillespie J, Moss AJ, et al. Long-term benefit of primary prevention with an implantable cardioverter-defibrillator: an extended 8-year follow-up study of the Multicenter Automatic Defibrillator Implantation Trial II. Circulation. 2010; 122(13):1265-1271.
61. Goldenberg I, Moss AJ, Hall, J, et al. Causes and consequences of heart failure after prophylactic implantation of a defibrillator in the multicenter automatic defibrillator implantation trial II. Circulation. 2006; 113(24):2810-2817.
62. Goldenberg I, Vyas AK, Hall WJ, et al. Risk stratification for primary implantation of a cardioverter-defibrillator in patients with ischemic left ventricular dysfunction. J Am Coll Cardiol. 2008; 51(3):288-296.
63. Gradaus R, Wollmann C, Köbe J, et al. Potential benefit from implantable cardioverter-defibrillator therapy in children and young adolescents. Heart. 2004; 90(3):328-329.
64. Greenberg H, Case RB, Moss AJ, et al.: MADIT-II Investigators. Analysis of mortality events in the Multicenter Automatic Defibrillator Implantation Trial (MADIT-II). J Am Coll Cardiol. 2004; 43(8):1459-1465.
65. Healey JS, Krahn AD, Bashir J, et al. Perioperative safety and early patient and device outcomes among subcutaneous versus transvenous ICD implantation: a randomized, multi-center trial. Ann Intern Med. 2022; 175(12):1658-1665.
66. Heidenreich PA, Keefe B, McDonald KM, et al. Overview of randomized trials of antiarrhythmic drugs and devices for the prevention of sudden cardiac death. Am Heart J. 2002; 144(3):422-430.
67. Hernandez-Ojeda J, Arbelo E, Borras R, et al. Patients with Brugada syndrome and implanted cardioverter-defibrillators: long-term follow-up. J Am Coll Cardiol. 2017; 70(16):1991-2002.
68. Hlatky MA. Evidence-based use of cardiac procedures and devices. N Engl J Med. 2004; 350(21):2126-2128.
69. Hodgkinson KA, Parfrey PS, Bassett AS, et al. The impact of implantable cardioverter-defibrillator therapy on survival in autosomal-dominant arrhythmogenic right ventricular cardiomyopathy (ARVD5). J Am Col Cardiol. 2005; 45(3):400-408.
70. Hohnloser SH, Kuck KH, Dorian P, et al. Prophylactic use of an implantable cardioverter-defibrillator after acute myocardial infarction. N Engl J Med. 2004; 351(24):2481-2488.
71. Huang DT, Sesselberg HW, McNitt S, et al. Improved survival associated with prophylactic implantable defibrillators in elderly patients with prior myocardial infarction and depressed ventricular function: a MADIT-II substudy. J Cardiovasc Electrophysiol. 2007; 18(8):833-838.
72. Jarman JW, Lascelles K, Wong T, et al. Clinical experience of entirely subcutaneous implantable cardioverter-defibrillators in children and adults: cause for caution. Eur Heart J. 2012; 33(11):1351-1359.
73. Kadish A, Dyer A, Daubert JP, et al. Prophylactic defibrillator implantation in patients with nonischemic dilated cardiomyopathy. N Engl J Med. 2004; 350(21):2151-2158.
74. Kadish A, Schaechter A, Subacius H, et al. Patients with recently diagnosed nonischemic cardiomyopathy benefit from implantable cardioverter-defibrillators. J Am Coll Cardiol. 2006; 47:2477-2482.
75. Kamp AN, Von Bergen NH, Henrikson CA, et al. Implanted defibrillators in young hypertrophic cardiomyopathy patients: a multicenter study. Pediat Cardiol. 2013; 34:1620-1627.
76. Kaski JP, Tome Esteban MT, Lowe M, et al. Outcomes after implantable cardioverter-defibrillator treatment in children with hypertrophic cardiomyopathy. Heart. 2007; 93:372-374.
77. Khairy P, Harris L, Landzberg MJ, et al. Implantable cardioverter-defibrillators in tetralogy of Fallot. Circulation. 2008; 117(3):363-370.
78. Kirkfeldt RE, Johansen JB, Nohr EA, et al. Complications after cardiac implantable electronic device implantations: an analysis of a complete, nationwide cohort in Denmark. Eur Heart J. 2014; 35(18):1186-1194.

79. Knops RE, Brouwer TF, Barr CS, et al. The learning curve associated with the introduction of the subcutaneous implantable defibrillator. Europace. 2015; 18(7):1010-1015.
80. Knops RE, Olde Nordkamp LRA, Delnoy PHM, et al. Subcutaneous or transvenous defibrillator therapy. N Engl J Med. 2020; 383(6):526-536.
81. Knops RE, van der Stuijt W, Delnoy PP, et al. Efficacy and safety of appropriate shocks and antitachycardia pacing in transvenous and subcutaneous implantable defibrillators: an analysis of all appropriate therapy in the PRAETORIAN trial. Circulation. 2022; 145:321–329.
82. Köbe J, Reinke F, Meyer C, et al. Implantation and follow-up of totally subcutaneous versus conventional implantable cardioverter-defibrillators: a multicenter case-control study. Heart Rhythm. 2013; 10(1):29-36.
83. Kober L, Thune JJ, Nielsen JC, et al. Defibrillator implantation in patients with nonischemic systolic heart failure. N Engl J Med. 2016; 375(13):1221-1230.
84. Kron J, Sauer W, Schuller J, et al. Efficacy and safety of implantable cardiac defibrillators for treatment of ventricular arrhythmias in patients with cardiac sarcoidosis. Europace. 2013; 15(3):347-354.
85. Kumar S, Sivagangabalan G, Zaman S, et al. Electrophysiology-guided defibrillator implantation early after ST-elevation myocardial infarction. Heart Rhythm. 2010; 7(11):1589-1597.
86. Kupersmith J. The past, present, and future of the implantable cardioverter-defibrillator. Am J Med. 2002; 113(1); 82-84.
87. Kusumoto, FM, Goldschlager N. Device therapy for cardiac arrhythmias. JAMA. 2002; 287(14):1848-1852.
88. Lambiase PD, Barr C, Theuns DA, et al. Worldwide experience with a totally subcutaneous implantable defibrillator: early results from the EFFORTLESS SICD Registry. Eur Heart J . 2014; 35(25):1657-1665.
89. Lambiase PD, Gold MR, Hood M, et al. Evaluation of subcutaneous ICD early performance in hypertrophic cardiomyopathy from the pooled EFFORTLESS and IDE cohorts. Heart Rhythm. 2016; 13(5):1066-1074.
90. Lambiase PD, Theuns DA, Murgatroyd F, et al. Subcutaneous implantable cardioverter-defibrillators: long-term results of the EFFORTLESS study. Eur Heart J. 2022:ehab921.
91. Lewandowski M, Sterlinski M, Maciag A, et al. Long-term follow-up of children and young adults treated with implantable cardioverter-defibrillator: the authors' own experience with optimal implantable cardioverter-defibrillator programming. Europace. 2010; 12(9):1245-1250.
92. Lin G, Nishimura RA, Gersh BJ, et al. Device complications and inappropriate implantable cardioverter defibrillator shocks in patients with hypertrophic cardiomyopathy. Heart. 2009; 95(9):709-714.
93. Magnusson P, Gadler F, Liv P, et al. Hypertrophic cardiomyopathy and implantable defibrillators in Sweden: inappropriate shocks and complications requiring surgery. J Cardiovasc Electrophysiol. 2015; 26(10):1088-1094.
94. Marchlinski FE, Jessup M. Timing the implantation of implantable cardioverter-defibrillators in patients with nonischemic cardiomyopathy. J Am Coll Cardiol. 2006; 47(12):2483-2485.
95. Mark DB, Anstrom KJ, Sun JL, et al.; Sudden Cardiac Death in Heart Failure Trial Investigators. Quality of life with defibrillator therapy or amiodarone in heart failure. N Engl J Med. 2008; 359(10):999-1008.
96. Maron BJ. Contemporary insights and strategies for risk stratification and prevention of sudden death in hypertrophic cardiomyopathy. Circulation. 2010; 121(3):445-456.
97. Maron BJ, Rowin EJ, Casey SA, et al. Hypertrophic cardiomyopathy in children, adolescents, and young adults associated with low cardiovascular mortality with contemporary management strategies. Circulation. 2016; 133(1):62-73.
98. Maron BJ, Spirito P, Ackerman MJ, et al. Prevention of sudden cardiac death with implantable cardioverter defibrillators in children and adolescents with hypertrophic cardiomyopathy. J Am Coll Cardiol. 2013; 61(14): 1527-1535.

99. Maron BJ, Spirito P, Shen WK, et al. Implantable cardioverter-defibrillators and prevention of sudden cardiac death in hypertrophic cardiomyopathy. JAMA. 2007; 298(4):405-412.
100. McClellan MB, Tunis SR. Medicare coverage of ICDs. N Engl J Med. 2005; 352(3):222-224.
101. Miron A, Lafreniere-Roula M, Fan CS, et al. A validated model for sudden cardiac death risk prediction in pediatric hypertrophic cardiomyopathy. Circulation. 2020; 142(3):217-229.
102. Mithani AA, Kath H, Hunter K, et al. Characteristics and early clinical outcomes of patients undergoing totally subcutaneous vs. transvenous single chamber implantable cardioverter defibrillator placement. Europace. 2018; 20(2):308-314.
103. Mizusawa Y, Wilde AA. Brugada Syndrome. Circ Arrhythm Electrophysiol. 2012; 5(3):606-616. Available at: http://circep.ahajournals.org/content/5/3/606.full.pdf+html. Accessed on January 18, 2023.
104. Moak JP, Leifer ES, Tripodi D, et al. Long-term follow-up of children and adolescents diagnosed with hypertrophic cardiomyopathy: risk factors for adverse arrhythmic events. Pediatr Cardiol. 2011; 32(8):1096-1105.
105. Mohsen A, Jimenez A, Hood RE, et al. Cardiac sarcoidosis: electrophysiological outcomes on long-term follow-up and the role of the implantable cardioverter-defibrillator. J Cardiovasc Electrophysiol. 2014; 25(2):171-176.
106. Monserrat L, Elliott PM, Gimeno JR, et al. Non-sustained ventricular tachycardia in hypertrophic cardiomyopathy: an independent marker of sudden death risk in young patients. J Am Coll Cardiol. 2003; 42(5):873-879.
107. Moss AJ, Hall WJ, Cannom DS, et al. Improved survival with an implanted defibrillator in patients with coronary disease at high risk for ventricular arrhythmia. Multicenter Automatic Defibrillator Implantation Trial Investigators. N Engl J Med. 1996; 335(26):1933-1940.
108. Moss AJ, Zareba W, Hall WJ, et al. Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. N Engl J Med. 2002; 346(12):877-883.
109. Nagahara D, Nakata T, Hashimoto A, et al. Predicting the need for an implantable cardioverter defibrillator using cardiac metaiodobenzylguanidine activity together with plasma natriuretic peptide concentration or left ventricular function. J Nucl Med. 2008; 49(2):225-233.
110. Nanthakumar K, Dorian P, Paquette M, et al. Is inappropriate implantable defibrillator shock therapy predictable? J Interv Cardiac Electrophysiol. 2003; 8(3):215-220.
111. Norrish G, Cantarutti N, Pissaridou E, et al. Risk factors for sudden cardiac death in childhood hypertrophic cardiomyopathy: a systematic review and meta-analysis. Eur J Prev Cardiol. 2017; 24(11):1220-1230.
112. Nso N, Nassar M, Lakhdar S, et al. Comparative assessment of transvenous versus subcutaneous implantable cardioverter-defibrillator therapy outcomes: An updated systematic review and meta-analysis. Int J Cardiol. 2022; 349:62-78.
113. Olde Nordkamp LR, Knops RE, Bardy GH, et al. Rationale and design of the PRAETORIAN trial: a Prospective, RAndomizEd comparison of subcuTaneOus and tRansvenous ImplANtable cardioverter-defibrillator therapy. Am Heart J. 2012; 163(5):753-760.
114. Olde Nordkamp LR, Postema PG, Knops RE, et al. Implantable cardioverter-defibrillator harm in young patients with inherited arrhythmia syndromes: a systematic review and meta-analysis of inappropriate shocks and complications. Heart Rhythm. 2016; 13(2):443-454.
115. Pahl E, Sleeper LA, Canter CE, et al. Incidence of and risk factors for sudden cardiac death in children with dilated cardiomyopathy: a report from the Pediatric Cardiomyopathy Registry. J Am Coll Cardiol. 2012; 59(6):607-615.

116. Parkes JB, Milne AR. Implantable cardioverter-defibrillators in arrhythmias: a rapid and systematic review of effectiveness. Heart. 2002; 87(5):438-442.
117. Passman R, Subacius H, Ruo B, et al. Implantable cardioverter defibrillators and quality of life: results from the defibrillators in nonischemic cardiomyopathy treatment evaluation study (DEFINITE). Arch Intern Med. 2007; 167(20):2226-2232.
118. Pedersen SS, Mastenbroek MH, Carter N, et al. A comparison of the quality of life of patients with an entirely subcutaneous implantable defibrillator system versus a transvenous system (from the EFFORTLESS S-ICD Quality of Life Substudy). Am J Cardiol. 2016; 118(4):520-526.
119. Persson R, Earley A, Garlitski AC, et al. Adverse events following implantable cardioverter defibrillator implantation: a systematic review. J Interv Card Electrophysiol. 2014; 40(2):191-205.
120. Piccini JP, Al-Khatib SM, Hellkamp AS, et al. Mortality benefits from implantable cardioverter-defibrillator therapy are not restricted to patients with remote myocardial infarction: An analysis from the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT). Heart Rhythm. 2011; 8(3):393-400.
121. Poole JE, Johnson GW, Hellkamp AS, et al. Prognostic importance of defibrillator shocks in patients with heart failure. N Engl J Med. 2008; 359(10):1009-1017.
122. Pouleur AC, Barkoudah E, Uno H, et al. Pathogenesis of sudden unexpected death in a clinical trial of patients with myocardial infarction and left ventricular dysfunction, heart failure, or both. Circulation. 2010; 122(6):597-602.
123. Probst V, Veltmann C, Eckardt L, et al. Long-term prognosis of patients diagnosed with Brugada Syndrome: results from the FINGER Brugada Syndrome Registry. Circulation. 2010; 121(5):635-643.
124. Providencia R, Kramer DB, Pimenta D, et al. Transvenous implantable cardioverter-defibrillator (ICD) lead performance: a meta-analysis of observational studies. J Am Heart Assoc. 2015; 4(11):pii: e002418.
125. Pugh TJ, Kelly MA, Gowrisankar S, et al. The landscape of genetic variation in dilated cardiomyopathy as surveyed by clinical DNA sequencing. Genet Med. 2014; 16:601–608.
126. Raviele A, Bongiorni MG, Brignole M, et al. Early EPS/ICD strategy in survivors of acute myocardial infarction with severe left ventricular dysfunction on optimal beta-blocker treatment. The BEta-blocker STrategy plus ICD trial. Europace. 2005; 7(4):327-337.
127. Reddy VY, Reynolds MR, Neuzil P, et al. Prophylactic catheter ablation for the prevention of defibrillator therapy. N Engl J Med. 2007; 357(26):2657-2665. Comment in: N Engl J Med. 2007; 357(26):2717-2719.
128. Sacher F, Probst V, Iesaka Y, et al. Outcome after implantation of a cardioverter-defibrillator in patients with Brugada syndrome: a multicenter study. Part 1. Circulation. 2006; 114(22):2317-2324.
129. Sacher F, Probst V, Maury P, et al. Outcome after implantation of a cardioverter-defibrillator in patients with Brugada syndrome: a multicenter study-Part 2. Circulation. 2013; 128(16):1739-1747.
130. Sarkozy A, Boussy T, Kourgiannides G, et al. Long-term follow-up of primary prophylactic implantable cardioverter-defibrillator therapy in Brugada syndrome. European Heart Journal. 2007; 28(3):334-344.
131. Saxon LA. The subcutaneous implantable defibrillator: a new technology that raises an existential question for the implantable cardioverter defibrillator. Circulation. 2013; 128(9):938-940.
132. Saxon LA, Hayes DL, Gilliam FR, et al. Long-term outcome after ICD and CRT implantation and influence of remote device follow-up: the ALTITUDE Survival Study. Circulation. 2010; 122(23):2359-2367.
133. Schaechter A, Kadish AH, et al. Defibrillators in non-ischemic cardiomyopathy treatment evaluation (DEFINITE). Card Electrophysiol Rev. 2003; 7(4):457-462.
134. Scheinman MM, Keung E. The year in clinical cardiac electrophysiology. J Am Coll Cardiol. 2007; 49(20):2061-2069.

135. Schinkel AF, Vriesendorp PA, Sijbrands EJ, et al. Outcome and complications after implantable cardioverter defibrillator therapy in hypertrophic cardiomyopathy: systematic review and meta-analysis. Circ Heart Fail. 2012; 5(5):552-559.
136. Schlapfer J, Rapp F, Kappenberger L, et al. Electrophysiologically guided amiodarone therapy versus the implantable cardioverter-defibrillator for sustained ventricular tachyarrhythmias after myocardial infarction: results of long-term follow-up. J Am Coll Cardiol. 2002; 39(11):1813-1819.
137. Schuller JL, Zipse M, Crawford T, et al. Implantable cardioverter defibrillator therapy in patients with cardiac sarcoidosis. J Cardiovasc Electrophysiol. 2012; 23(9):925-929.
138. Sears SF, Hazelton AG, St Amant J, et al. Quality of life in pediatric patients with implantable cardioverter defibrillators. Am J Cardiol. 2011; 107(7):1023-1027.
139. Shamshad F, Kenchaiah S, Finn PV, et al. Fatal myocardial rupture after acute myocardial infarction complicated by heart failure, left ventricular dysfunction, or both: the VALsartan In Acute myocardial iNfarcTion Trial (VALIANT). Am Heart J. 2010; 160(1):145-151.
140. Sieira J, Ciconte G, Conte G, et al. Asymptomatic Brugada Syndrome clinical characterization and long-term prognosis. Circ Arrhythm Electrophysiol. 2015; 8(5):1144-1150.
141. Silka MJ, Kron J, Dunnigan A, et al. Sudden cardiac death and the use of implantable cardioverter-defibrillators in pediatric patients. Circulation. 1993; 87(3):800-807.
142. Sponder M, Khazen C, Dichtl W, et al. Specific indications and clinical outcome in patients with subcutaneous implantable cardioverter-defibrillator (ICD) - A nationwide multicenter registry. Eur J Intern Med. 2018; 48:64-68.
143. Steinbeck G, Andresen D, Seidl K, et al. Defibrillator implantation early after myocardial infarction. N Engl J Med. 2009; 361(15):1427-1436.
144. Steinberg JS, Martins J, et al. Antiarrhythmic drug use in the implantable defibrillator arm of the antiarrhythmics versus implantable defibrillator (AVID) study. Am Heart J. 2001; 142(3):520-529.
145. Sterns LD, Meine M, Kurita T, et al. Extended detection time to reduce shocks is safe in secondary prevention patients: the secondary prevention sub-study of PainFree SST. Heart Rhythm. 2016; 13(7):1489-1496.
146. Su L, Guo J, Hao Y, Tan H. Comparing the safety of subcutaneous versus transvenous ICDs: a meta-analysis. J Interv Card Electrophysiol. 2021; 60(3):355-363.
147. Swygman C, Wang PJ, Link MS, et al. Advances in implantable cardioverter-defibrillators. Curr Op Card. 2002; 17(1):24-28.
148. Syska P, Przybylski A, Chojnowska L, et al. ICD in patients with HCM: efficacy and complications of the therapy in long-term follow-up. J Cardiovasc Electrophys. 2010; 21(8):883-889.
149. Varma N. Rationale and design of a prospective study of the efficacy of a remote monitoring system used in implantable cardioverter defibrillator follow-up: the Lumos-T reduces routine office device follow-up study (TRUST). Am Heart J. 2007; 154(6):1029-1034.
150. Vetta G, Parlavecchio A, Magnocavallo M, et al. Subcutaneous versus transvenous implantable cardioverter defibrillators in children and young adults: A meta-analysis. Pacing Clin Electrophysiol. 2022; 45(12):1409-1414.
151. Von Bergen NH, Atkins DL, Dick M, et al. Multicenter study of the effectiveness of implantable cardioverter defibrillators in children and young adults with heart disease. Ped Cardiol. 2011; 32(4):399-405.
152. Vriesendorp PA, Schinkel AF, Van Cleemput J, et al. Implantable cardioverter-defibrillators in hypertrophic cardiomyopathy: patient outcomes, rate of appropriate and inappropriate interventions, and complications. Am Heart J. 2013; 166(3):496-502.

153. Weiss R, Knight BP, Gold MR, et al. Safety and efficacy of a totally subcutaneous implantable-cardioverter defibrillator. Circulation. 2013; 128(9):944-953.
154. Wilber DJ, Zareba W, Hall WJ, et al. Time dependence of mortality risk and defibrillator benefit after myocardial infarction. Circulation. 2004; 109(9):1082-1084.
155. Yap SC, Roos-Hesselink JW, Hoendermis ES, et al. Outcome of implantable cardioverter defibrillators in adults with congenital heart disease: a multi-center study. Eur Heart J. 2007; 28(15):1854-1861.
156. Yetman AT, Hamilton RM, Benson LN, et al. Longterm outcome and prognostic determinants in children with hypertrophic cardiomyopathy. J Am Coll Cardiol. 1998; 32(7):1943-1950.
157. Zecchin M, Merlo M, Pivetta A, et al. How can optimization of medical treatment avoid unnecessary implantable cardioverter-defibrillator implantations in patients with idiopathic dilated cardiomyopathy presenting with "SCD-HeFT criteria?" Am J Cardiol. 2012; 109(5):729-735.

Government Agency, Medical Society, and Other Authoritative Publications:

1. Academisch Medisch Centrum - Universiteit van Amsterdam (AMC-UvA), Boston Scientifioc Corporation. A PRospective, rAndomizEd Comparison of subcuTaneOous and tRansvenous ImplANtable Cardioverter Defibrillator Therapy (PRAETORIAN). NCT01296022. Last updated Aug. 10, 2020. Available at: https://clinicaltrials.gov/ct2/show/NCT01296022?term=NCT01296022&draw=2&rank=1. Accessed on January 18, 2023.
2. Al-Khatib SM, Stevenson WG, Ackerman MJ, et al. 2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. Heart Rhythm. 2018; 15(10):e190-e252.
3. Antzelevitch C, Brugada P, Borggrefe M, et al. Brugada syndrome: report of the second consensus conference: endorsed by the Heart Rhythm Society and the European Heart Rhythm Association. Circulation. 2005; 111(5):659-670.
4. Arnett DK, Blumenthal RS, Albert MA, et al. 2019 ACC/AHA guideline on the primary prevention of cardiovascular disease: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol. 2019; 74:e177-232.
5. Birnie DH, Parkash R, Exner DV, et al. Clinical predictors of Fidelis lead failure: report from the Canadian Heart Rhythm Society Device Committee. Circulation. 2012; 125(10):1217-1225.
6. Birnie DH, Sauer WH, Bogun F, et al. Heart Rhythm Society (HRS) expert consensus statement on the diagnosis and management of arrhythmias associated with cardiac sarcoidosis. Heart Rhythm. 2014; 11:1305-1323.
7. Boston Scientific Corporation. Understanding outcomes with the EMBLEM™ S-ICD in primary prevention patients with low ejection fraction (UNTOUCHED). NCT02433379. Last updated August 17, 2021. Available at: https://clinicaltrials.gov/ct2/show/NCT02433379?term=NCT02433379.&draw=2&rank=1. Accessed on January 18, 2023.
8. Boston Scientific Corporation. S-ICD® System Post Approval Study. NCT01736618. Last updated May 17, 2022. Available at: https://clinicaltrials.gov/ct2/show/NCT01736618?term=NCT01736618&draw=2&rank=1. Accessed on January 18, 2023.
9. Brugada J, Blom N, Sarquella-Brugada G, et al. Pharmacological and non-pharmacological therapy for arrhythmias in the pediatric population: EHRA and AEPC-Arrhythmia Working Group joint consensus statement. Europace. 2013; 15(9):1337-1382.

10. Centers for Medicare & Medicaid Services. National Coverage Determination: Implantable Automatic Defibrillators. NCD#20.4. Effective February 15, 2018. Available at: https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=288. Accessed on January 18, 2023.
11. Connolly SJ, Hohnloser SJ, and the DINAMIT Steering Committee and Investigators. DINAMIT: Randomized trial of prophylactic implantable defibrillator therapy versus optimal medical treatment early after myocardial infarction: The Defibrillator in Acute Myocardial Infarction Trial. American College of Cardiology Scientific Session 2004. Bethesda, MD: American College of Cardiology; 2004.
12. Epstein AE, DiMarco JP, Ellenbogen KA, et al. ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the ACC/AHA/NASPE 2002 Guideline Update for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices): developed in collaboration with the American Association for Thoracic Surgery and Society of Thoracic Surgeons. Circulation. 2008; 117(21):e350-408.
13. Gersh BJ, Maron BJ, Bonow RO, et al. 2011 ACCF/AHA guideline for the diagnosis and treatment of hypertrophic cardiomyopathy: A report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2011; 58(25):e212-260.
14. Goldberger JJ, Cain ME, Kadish AH, et al. American Heart Association/American College of Cardiology Foundation/Heart Rhythm Society Scientific Statement on Noninvasive Risk Stratification Techniques for Identifying Patients at Risk for Sudden Cardiac Death. A Scientific Statement from the American Heart Association Council on Clinical Cardiology Committee on Electrocardiography and Arrhythmias and Council on Epidemiology and Prevention. J Am Coll Cardiol. 2008; 52(14):1179-1199.
15. Gregoratos G, Abrams J, Epstein AE, et al. ACC/AHA/NASPE 2002 guideline update for implantation of cardiac pacemakers and antiarrhythmia devices: summary article: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/NASPE Committee to Update the 1998 Pacemaker Guidelines). Circulation. 2002; 106(16):2145-2161.
16. Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA guideline for the management of heart failure: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. J Am Coll Cardiol. 2022; 79:e263–e421. Available at: https://www.jacc.org/doi/pdf/10.1016/j.jacc.2021.12.012?_ga=2.2351088.1537863112.1673283074-1713359233.1673283074. Accessed on January 20, 2023.
17. Hunt SA, Abraham WT, Chin MH, et al. 2009 focused update incorporated into the ACC/AHA 2005 guidelines for the diagnosis and management of heart failure in adults: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2009; 53(15):e1-90.
18. Jessup M, Abraham WT, Casey DE, et al. writing on behalf of the 2005 Guideline Update for the Diagnosis and Management of Chronic Heart Failure in the Adult Writing Committee. 2009 focused update: ACCF/AHA guidelines for the diagnosis and management of heart failure in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2009; 53:1343-1382.
19. Khairy P, Van Hare GF, Balaji S, et al. PACES/HRS expert consensus statement on the recognition and management of arrhythmias in adult congenital heart disease: developed in partnership between the Pediatric and Congenital Electrophysiology Society (PACES) and the Heart Rhythm Society (HRS). Endorsed by the governing bodies of PACES, HRS, the American College of Cardiology (ACC), the American Heart Association (AHA), the European Heart Rhythm Association (EHRA), the Canadian Heart Rhythm Society (CHRS), and the International Society for Adult Congenital Heart Disease (ISACHD). Can J Cardiol. 2014; 30(10):e1-e63.

20. Kulik A, Ruel M, Jneid H, et al; on behalf of the American Heart Association Council on Cardiovascular Surgery and Anesthesia. Secondary prevention after coronary artery bypass graft surgery: A scientific statement from the American Heart Association. Circulation. 2015; 131:927. Available at: https://www.ahajournals.org/doi/pdf/10.1161/CIR.0000000000000182. Accessed on January 18, 2023.
21. Kusumoto FM, Calkins H, Boehmer J, et al. HRS/ACC/AHA expert consensus statement on the use of implantable cardioverter-defibrillator therapy in patients who are not included or not well represented in clinical trials. J Am Coll Cardiol. 2014; 64(11):1143-1177.
22. Lampert R, Hayes DL, Annas GJ, et al. HRS Expert Consensus Statement on the Management of Cardiovascular implantable electronic devices (CIEDs) in patients nearing end of life or requesting withdrawal of therapy. Heart Rhythm. 2010; 7(7):1008-1026.
23. Maron BJ, McKenna WJ, Danielson GK, et al. ACC/ESC clinical expert consensus document on hypertrophic cardiomyopathy: a report of the American College of Cardiology Task Force on Clinical Expert Consensus Documents and the European Society of Cardiology Committee for Practice Guidelines (Committee to Develop an Expert Consensus Document on Hypertrophic Cardiomyopathy). J Am Coll Cardiol. 2003; 42(9):1687-1713.
24. Maron MS, Rowin EJ, Wessler BS, et al. Enhanced American College of Cardiology/American Heart Association strategy for prevention of sudden cardiac death in high-risk patients with hypertrophic cardiomyopathy. JAMA Cardiol. 2019; 4:644-657.
25. McAlister FA, Ezekowitz J, Dryden DM, et al. Cardiac resynchronization therapy and implantable cardiac defibrillators in left ventricular systolic dysfunction. Evid Rep Technol Assess (Full Rep). 2007; (152):1-199.
26. Moss AJ, Zareba W, Hall WJ, et al. Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. N Engl J Med. 2002; 346:877–883.
27. Narins CR, Aktas MK, Chen AY, et al. Arrhythmic and mortality outcomes among ischemic versus nonischemic cardiomyopathy patients receiving primary ICD therapy. JACC Clin Electrophysiol. 2022; 8:1-11.
28. O'Gara PT, Kushner FG, Ascheim DD, et al. 2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction: A report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2013; 61(4):e78-140.
29. O'Mahony C, Jichi F, Ommen SR, et al. International external validation study of the 2014 European Society of Cardiology guidelines on sudden cardiac death prevention in hypertrophic cardiomyopathy (EVIDENCE-HCM). Circulation. 2018; 137(10):1015-1023.
30. Ommen SR, Mital S, Burke MA, et al. 2020 AHA/ACC guideline for the diagnosis and treatment of patients with hypertrophic cardiomyopathy: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. J Am Coll Cardiol. 2020; 76(25):e159-240.
31. Priori SG, Blomstrom-Lundqvist C, Mazzanti A, et al. 2015 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: The Task Force for the Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death of the European Society of Cardiology (ESC) Endorsed by: Association for European Pediatric and Congenital Cardiology (AEPC). Eur Heart J. 2015; 36(41):2793-2867.
32. Priori SG, Wilde AA, Horie M, et al. HRS/EHRA/APHRS Expert consensus statement on the diagnosis and management of patients with inherited primary arrhythmia syndromes. Heart Rhythm, 2013; 10(12):1932-1963.
33. Russo AM, Stainback RF, Bailey SR, et al. ACCF/HRS/AHA/ASE/HFSA/SCAI/SCCT/SCMR 2013 Appropriate use criteria for implantable cardioverter-defibrillators and cardiac resynchronization therapy: A report of the American College of Cardiology Foundation Appropriate Use Criteria Task Force, Heart Rhythm Society, American Heart Association, American Society of Echocardiography, Heart Failure Society of

America, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, and Society for Cardiovascular Magnetic Resonance. Heart Rhythm. 2013; 10(4):e11-58.
34. Shen WK, Sheldon RS, Benditt DG, et al. 2017 ACC/AHA/HRS guideline for the evaluation and management of patients with syncope: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. Circulation. 2017; 136(5):e60-122.
35. Shimizu A. Indication of ICD in Brugada syndrome. J Arrhyth. 2013; 29(2):110-116.
36. Thygesen K, Alpert JS, Jaffe AS, et al.; the Writing Group on behalf of the Joint European Society of Cardiology, American College of Cardiology Foundation, American Heart Association, and the World Heart Federation (ESC/ACCF/AHA/WHF) Task Force for the Universal Definition of Myocardial Infarction. Third universal definition of myocardial infarction. Circulation. 2012; 126(16):2020-2035.
37. Towbin JA, McKenna WJ, Abrams DJ, et al. 2019 HRS expert consensus statement on evaluation, risk stratification, and management of arrhythmogenic cardiomyopathy. Heart Rhythm. 2019; 16:e301–e372.
38. Tracy CM, Epstein AE, Darbar D, et al. 2012 ACCF/AHA/HRS focused update of the 2008 guidelines for device-based therapy of cardiac rhythm abnormalities: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2012; 60(14):1297-1313.
39. Uhlig K, Balk EM, Earley A, et al. Assessment on Implantable Defibrillators and the Evidence for Primary Prevention of Sudden Cardiac Death. Evidence Report/Technology Assessment. (Prepared by the Tufts Evidence-based Practice Center under Contract No. 290-2007-10055-I.) Rockville, MD: Agency for Healthcare Research and Quality (AHRQ). June 2013. Available at: http://www.cms.gov/Medicare/Coverage/DeterminationProcess/Downloads/id91TA.pdf. Accessed on January 18, 2023.
40. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health. Premarket approval for EMBLEM™ S-ICD System (Boston Scientific Corp., St. Paul, MN). P110042/S043. March 13, 2015. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P110042S043. New supplements available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P110042. Accessed on January 18, 2023.
41. Yancy CW, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation. 2013; 128(16):e240-e327.
42. Yancy CW, Jessup M, Bozkurt B, et al. 2017 ACC/AHA/HFSA focused update of the 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. Circulation. 2017; 136(6):e137-161.
43. Zipes DP, Camm AJ, Borggrefe M, et al. ACC/AHA/ESC 2006 guidelines for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: a report of the American College of Cardiology/American Heart Association Task Force and the European Society of Cardiology Committee for Practice Guidelines (Writing Committee to develop guidelines for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death). Circulation. 2006; 114(10):e385-484.

Websites for Additional Information

1. Heart failure Cleveland Clinic web site for member information. Available at: https://my.clevelandclinic.org/health/diseases/17069-heart-failure-understanding-heart-failure. Accessed on January 18, 2023.
2. What is cardiomyopathy? Cleveland Clinic web site. Available at: https://my.clevelandclinic.org/health/diseases/16841-cardiomyopathy. Accessed on January 18, 2023.

Index

Automatic Defibrillator
Cardioverter Defibrillator
EMBLEM S-ICD System
ICD
Implantable Cardioverter-Defibrillator
S-ICD System
Subcutaneous ICD

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
Reviewed	02/16/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. The Discussion and References sections were updated. Updated Coding section, removed CPT 00534 associated anesthesia.
	9/28/2022	Updated Coding section with 10/01/2022 ICD-10-CM changes; added I47.20-I47.29 replacing I47.2.
Reviewed	02/17/2022	MPTAC review. References were updated.
Revised	02/11/2021	MPTAC review. The MN criteria regarding major risk factors in HCM were revised consistent with updated ACC/AHA guideline recommendations (Ommen, 2020) to require 1 or more risk factors as follows: 1. Personal history of cardiac arrest or sustained ventricular arrhythmias; 2. Personal history of syncope suspected by clinical history to be arrhythmic within the previous 12 months; 3. Family history of HCM-related sudden death in one or more 1st or 2nd degree relatives who are less than or equal to 50 years of age or in two or more 3rd degree relatives who are less than or equal to 50 years of age; 4. LV apical aneurysm, independent of size; 5. LV systolic dysfunction (LVEF less than 50%); 6. Nonsustained VT episodes on ECG or continuous ambulatory electrocardiographic monitoring; 7. Left ventricular (LV) wall thickness greater than or equal to 30 mm in any LV segment; Removed "Abnormal BP response during exercise."

		Language was added to the Clinical Indications for the S-ICD for clarification to say: "When the individual does not require cardiac pacing." Minor additional edits were made to the Clinical Indications section for clarification. The Discussion and References sections were updated. Reformatted and updated Coding section.
Reviewed	02/20/2020	MPTAC review. References were updated.
	10/01/2019	Updated Coding section with 10/01/2019 ICD-10-PCS changes; added 0JH60FZ, 0JH63FZ. A definition for structural heart disease was added to the Definitions section and References section was updated.
New	03/21/2019	MPTAC review. Moved content of SURG.00033 Cardioverter Defibrillators to a new clinical utilization management guideline document with the same title. The Note about ICD therapy in children was moved from the Clinical Indications section to the Discussion/Background section. The Discussion and References sections were updated.