Final Topic Refinement Document
Catheter Ablation for Atrial Fibrillation - Project ID: CRDT0913

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Topic: Catheter Ablation for Atrial Fibrillation – Project ID: CRDT0913

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Final Topic Refinement Document

Key Questions

In patients with longstanding persistent atrial fibrillation (AF), persistent AF, or paroxysmal AF (considered separately):

Key Question 1. What is the comparative efficacy and effectiveness of AF catheter ablation on short- (6-12 months) and long- (>12 months) term outcomes in the general adult and Medicare populations? Comparisons of interest include:

a) Catheter ablation compared with medical therapy
b) Comparing ablation using different energy sources

Key Question 2. What are the comparative short- and long-term complications and harms (e.g., periprocedural or device-related harms) associated with AF catheter ablation in the general adult and Medicare populations? Comparisons of interest include:

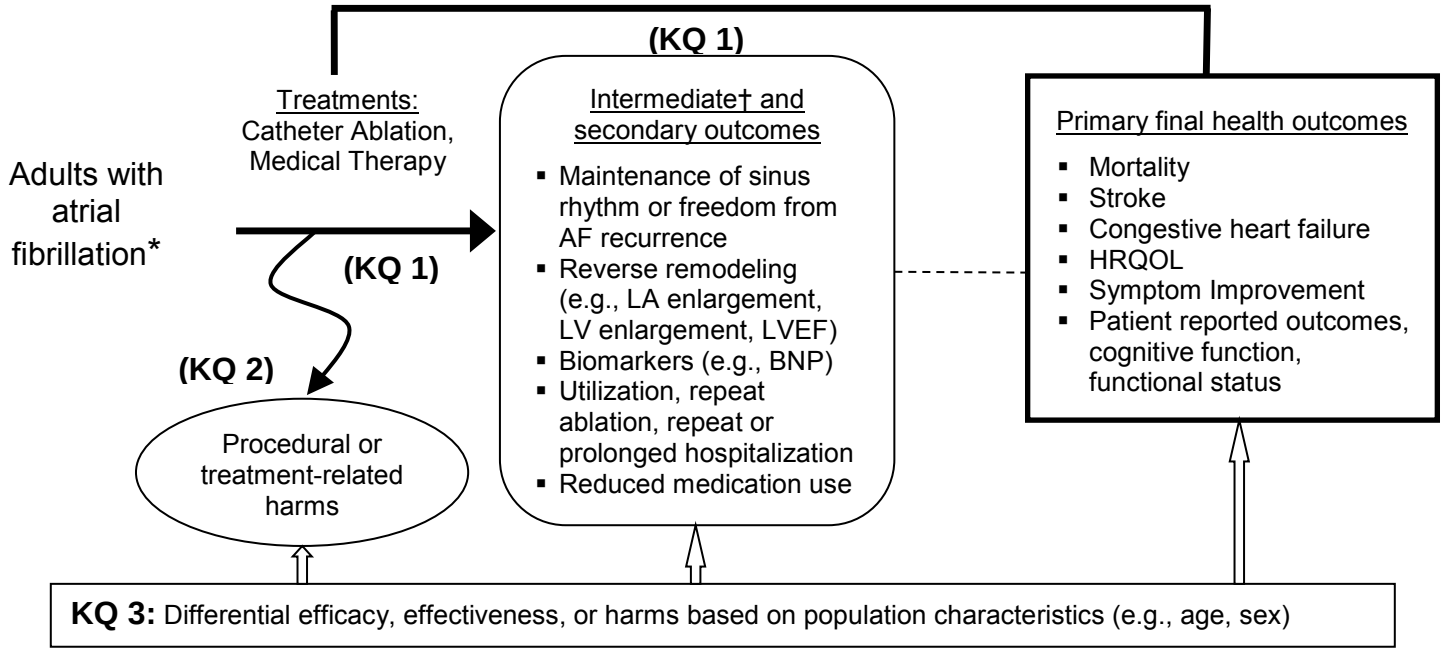
a) Catheter ablation compared with medical therapy
b) Comparing ablation using different energy sources

Key Question 3. Are there modifications of efficacy, effectiveness, or harms of catheter ablation by patient-level characteristics such as age, sex, type of AF, comorbidities, risk for stroke or bleeding events, condition (i.e., patients with significant left ventricular dysfunction/heart failure or patients with significant left atrial enlargement or left ventricular hypertrophy), provider/setting characteristics or technique/approach? Comparisons of interest include:

a) Catheter ablation compared with medical therapy
b) Comparing ablation using different energy sources

Draft Analytic Framework

Figure 1. DRAFT analytic framework: Catheter Ablation for Atrial Fibrillation



*Patients with longstanding persistent AF, persistent AF, or paroxysmal AF (considered separately); includes general population and Medicare population.
†Intermediate outcomes are those which may be along the causal pathway to final health outcomes.
BNP = brain natriuretic peptides; HRQOL = health-related quality of life; LA = left atrium; LV = left ventricle; LVEF = left ventricular ejection fraction.

Background

Nature and burden of atrial fibrillation

AF is a major public health concern in the United States, affecting an estimated 2.3 million Americans.[1] It has been projected that the prevalence of AF will reach 5.6 to 12.1 million by the year 2050.[2] AF is the most common sustained arrhythmia seen in clinical practice and accounts for approximately one third of hospitalizations for cardiac dysrhythmias.[3]

AF is characterized by uncoordinated atrial activation with resulting deterioration of atrial mechanical function.[4] While AF can occur in isolation, it may also be associated with other arrhythmias such as atrial flutter or atrial tachycardia. Atrial fibrillation can be paroxysmal, persistent, or permanent. The 2011 American College of Cardiology/American Heart Association/European Society of Cardiology AF guidelines define paroxysmal AF as recurrent AF that terminates spontaneously, persistent AF as one that is sustained beyond seven days, and permanent AF as long-standing AF in which restoring and/or maintaining sinus rhythm has failed or has been foregone. Long-standing persistent AF is usually defined as AF that persists

for over a year. Long-standing persistent and permanent AF are more commonly seen in older patients with structural heart disease.[5]

A number of factors have been associated with increased risk of AF. The prevalence of AF increases with age and affects 8 to 10 percent of patients older than 80 years of age.[2, 6, 7] AF is also more common in males: data from the Framingham Heart Study suggest that men are 1.5 times as likely to develop AF than are women after controlling for age and comorbidities.[2] Obesity increases the risk of developing AF. Data from community-based cohorts suggests that obese persons have a 1.5 to 2.3 fold greater risk of developing AF. Furthermore, obesity increases the likelihood that AF will progress from paroxysmal to permanent AF.[7] Additional factors that have been suggested to increase the risk of AF include smoking, hypertension, hyperthyroidism, obstructive sleep apnea, diabetes, myocardial infarction, heart failure, and cardiac surgery.[7]

AF is associated with significant mortality, morbidity, and health care costs. Patients with AF have twofold greater risk of death than do those without this disease. AF is associated with an increased risk of stroke, which affects five percent of non-rheumatic AF patients and nearly seven percent of AF patients with heart failure each year.[8] Furthermore, ischemic stroke that occurs in the setting of AF tends to be either fatal or of moderate to high severity in most patients.[9] AF can also cause a number of cardiac conditions, including myocardial ischemia or infarction, exacerbation of heart failure, and cardiomyopathy if the ventricular rate is insufficiently controlled.[10-13] Although some patients with AF are asymptomatic, other patients experience symptoms like shortness of breath, intractable fatigue, and near-syncope, which can severely affect overall quality of life.[14-17] In total, the management of AF and its complications costs the U.S. health care system approximately $16 billion each year.[18]

Management of AF

Treatment of AF involves rate control, rhythm control, prevention of thromboembolic events, and treating the underlying disease if applicable.[5] Typically, pharmacologic therapy is the primary treatment for rate and rhythm control, while catheter ablation is the second choice for rhythm control.[4] The proposed report will focus on the effectiveness and harms of catheter ablation for treating atrial fibrillation. AF ablation is typically recommended only for symptomatic patients; asymptomatic patients are usually managed with anticoagulation and/or rate control as needed.[5]

Rhythm control

While the initial management of AF often includes management of ventricular rate using pharmacological agents (i.e., beta-blockers or nonhydropyridine calcium channel blockers), it is common for the long-term management strategy to focus on restoring and maintaining normal heart rhythm.[5] AF patients who continue to have significant symptoms despite adequate rate control, who desire long-term rhythm control, or who are of younger age (<65 years) should be considered for treatment using a rhythm control strategy.

Pharmacological treatment

For rhythm control in patients with AF, pharmacologic therapy is typically the first choice, with catheter ablation being the second choice.[4] Selecting the first line antiarrhythmic medication is largely driven by the presence or absence of structural heart disease. For example, the 2011 Focused Update of the Guidelines for the Management of Patients with Atrial Fibrillation give a

Class I recommendation for treatment with flecainide, dofetilide, propafenone, or ibutilide; and a Class IIa recommendation for administration of amiodarone for patients with no structural heart disease.[5] In patients with heart failure, the guidelines recommend only two antiarrhythmic medications as first line therapy; namely, dofetilide and amiodarone.[5]

Catheter ablation

Catheter ablation for the treatment of AF is a commonly performed procedure for symptomatic patients in whom rhythm control medications are either ineffective or not tolerated.[5, 19, 20] This procedure restores normal sinus rhythm by delivering energy (commonly radiofrequency energy) through catheters to targeted points in the heart at which the arrhythmia originates; this energy ablates or destroys these small focal areas of the heart and disrupts the abnormal electrical activity. Other types of catheter ablation are becoming available, such as cryoablation, which uses a pressurized refrigerant in the catheter tip to ablate the source of the arrhythmia, cryoballoon ablation, which involves cooling and freezing of the targeted tissue using coolant inside a balloon to alter abnormal electrical activity. The procedure is typically performed in a catheter lab and involves guided insertion of catheters from the arm, groin, or neck through the blood vessel and into the heart.

Three catheter devices have been approved by the FDA for use in AF specifically, starting in 2008. Two are RF devices manufactured by Stereotaxis and Biosense Webster and utilize catheter tips of 4 mm without irrigation. The third FDA-approved device is a cryoablation catheter produced by Medtronic Cryocath. This system uses a balloon with a diameter of 23–29 mm.

A number of other catheter devices, both RF and cryoablation, have been approved for other indications and may be used for the treatment of AF. A list of FDA-approved devices and their manufactures can be found in the Appendix.

The most commonly used catheter ablation approaches to treat AF are pulmonary vein isolation (PVI) and pulmonary vein antrum isolation (PVAI).[21] The Heart Rhythm Society Task Force has recommended that ablation strategies that target the pulmonary veins and/or pulmonary antrum be used, since AF initiation has been mapped within the pulmonary veins.[19] If the pulmonary veins are targeted, complete electrical isolation should be achieved. Other approaches are also used, including wide area circumferential ablation (WACA) and complex fractionated atrial electrograms (CFAE).[4] Additional lines can be ablated, depending on where the sources of the arrhythmia have been mapped.[19]

Current state of the evidence

In 2009, AHRQ published a comparative effectiveness review that evaluated both short- and long-term clinical effectiveness and harms of RF catheter ablation for AF.[21] Six RCTs enrolling a total of 693 patients were available The report found moderate quality evidence based on three RCTs that patients treated with RF catheter ablation after failing medical therapy had a threefold greater likelihood of maintaining freedom from AF recurrence at 12 months compared with patients who received medical therapy alone. There was low quality evidence that suggested that ablation resulted in greater quality of life and required less anticoagulation compared with medical treatment alone. However, there was low quality evidence to suggest no differences

between the two treatment groups in terms of the risk of stroke and the rate of readmission. The report found high level evidence that age wasn't significantly associated with AF recurrence after ablation, however, the vast majority of patients studied were between the ages of 40 and 70 with mean and/or median age in the fifties, and the evidence was insufficient to estimate whether older age affected outcome. A number of issues remain and were lacking evidence at the time of the 2009 report, including health outcomes at one year or longer, whether ablation reduces the risk of death and stroke, and what the evidence is regarding the comparative effectiveness and harms of catheter ablation in the Medicare population (age 65 years or older, females).

Because catheter ablation is increasingly being used to treat AF patients in the Medicare population, and there is uncertainty regarding the efficacy and harms of this procedure in this population in particular, a systematic review to re-evaluate the current state of evidence, identify and evaluate inconsistencies in the evidence, and identify important research gaps is warranted to help inform clinical practice and policy.

Draft PICOTS

PICOTS	Include	Exclude
Populations	• Humans • Adults (age ≥ 18 years) • Patients with atrial fibrillation (AF) o Long-standing, persistent AF (an ongoing, long-term episode) (main focus of this report) o Persistent AF (recurrent episodes that last > 7 days) o Paroxysmal AF (recurrent episodes that self-terminate in < 7 days) • Subgroups of potential interest: o Medicare population (≥ 65 years of age and < 65 years of age who are permanently disabled) (primary interest) o Age o Sex (women) o Race/ethnicity o Different types of AF (long-term persistent, persistent, paroxysmal) o Specific comorbidities (heart failure, hypertension, coronary artery disease, diabetes, kidney disease, hypertrophic cardiomyopathy, thyroid disease, pulmonary disease; obstructive sleep apnea) o Enlarged left atrium (LA) (e.g., measured via LA volume index) o Other heart disease including left ventricular (LV) systolic function; meaningful valvular disease, LV hypertrophy o Prior rate- or rhythm-control pharmacological strategy was ineffective o High risk for stroke or bleeding events (patients with diabetes, heart failure, hypertension) o Stroke risk categories (e.g., using	• Patients < 18 years of age • Isolated Atrial flutter (AFI) • Atrial tachycardia (including focal and multifocal) • Patients in whom treatment of AF is not the primary goal • Focal junctional ectopic tachycardia and nonparoxysmal junctional tachycardia • Ventricular tachycardia and paroxysmal ventricular tachycardia • Bradycardia • Patients with prior catheter ablation • Patients who have known reversible causes of AF (including but not limited to postoperative, post-myocardial infarction, hyperthyroidism)

PICOTS	Include	Exclude
	$CHADS_2$ or CHA_2DS_2VASc criteria) and history of prior stroke o Obesity o Patients with atrial fibrosis	
Interventions	• Catheter ablation: o Devices available for use in the U.S. o Main focus on pulmonary vein isolation (PVI) alone; however, PVI with additional lines, PVI plus cavotricuspid isthmus ablation vs. PVI only will also be included – targeting of the pulmonary vein antrum and use of irrigated or 8 mm catheter tips o Ablation (including standalone radiofrequency ablation) of complex fractionated atrial electrograms (CFAE) and linear ablations o Ablation of ganglionated plexi) o Wide area circumferential ablation (WACA) o PVAC (pulmonary vein ablation catheter) system; multi-electrode RF catheter o Michel Haissaguerre approach o Ablation of non-pulmonary vein foci o Cryoablation o Cryoballoon ablation o Laser balloon o Ablating rotors/FIRM (focal impulse and rotor modulation)	• Ablation as an adjunct to surgery, intraoperative ablation • Right atrial ablation for atrial flutter • Use of non-Food and Drug Administration (FDA) approved devices or devices not in final stages for FDA approval • Studies in which PV electrical isolation was not the goal of ablation as well as studies of ablation of the atrioventricular (AV) junction • Complete AV node ablation requiring pacemaker implantation
Comparators	• Medical therapy only • Pharmacological agents for rate control: o Beta blockers (e.g., acebutolol, atenolol, bisoprolol, carvedilol, esmolol [acute rate lowering only], metoprolol, nadalol, nebivolol, timolol) o Non-dihydropyridine calcium channel blockers (verapamil, diltiazem) o Other (digoxin, amiodarone, dronedarone) • Pharmacological agents for rhythm control: o Amiodarone o Disopyramide o Dofetilide o Dronedarone o Flecainide o Ibutilide (acute conversion only) o Propafenone o Sotalol	• Comparisons of different techniques used in catheter ablation (i.e., imaging, types of catheter tips) • Cardioversion alone (i.e., in the absence of antiarrhythmic medical therapy) • Cox-Maze procedure; surgical ablation • Antiarrhythmic agents: o Quinidine o Procainamide
Outcomes	<u>Primary efficacy/effectiveness</u>: • Prevention of mortality, embolic events, stroke (any type), transient ischemic attack (TIA), and congestive heart failure • Improvement of symptoms (including palpitation, tachypnea, chest stuffiness, syncope, anxiety, exercise capacity) • Quality of life, cognition, functional status and other patient-reported outcomes • Hospitalization/readmission for cardiovascular events (including AF) • Repeat ablation for AF <u>Intermediate and secondary outcomes</u>	• Nonclinical outcomes • Outcomes from neuroimaging studies

PICOTS	Include	Exclude
	• Freedom from recurrence of AF • Maintenance of sinus rhythm, • Parameters suggesting reverse remodeling (e.g., LA size, LV size, LV ejection fraction) • Effect on biomarkers (e.g., brain natriuretic peptide) • Health care utilization • Reduced medication use (e.g., need for anticoagulants, antiarrhythmic drugs) <u>Harms or adverse events *(procedure or treatment related)*</u> • In-hospital and 30-day mortality (all-cause, cardiovascular) • In-hospital and 30-day stroke (any, by type), TIA • In-hospital and 30-day embolic events • In-hospital and 30-day myocardial infarction • Procedural complications (pulmonary vein stenosis, atrioesophageal fistula, major bleeding complications/hemorrhage, phrenic nerve palsy, pericardial effusion or cardiac tamponade, deep vein thrombosis and pulmonary embolism, peripheral vascular complication [including pseudoaneurysm, hematoma at catheter insertion site, vascular injury, infection leading to prolonged hospitalization or sepsis, pulmonary edema]) • Adverse events from drug therapies (e.g., hypotension, hypothyroidism and hyperthyroidism, arrhythmias [bradyarrhythmias, tachyarrhythmias, or proarrhythmias], allergic reactions, hepatotoxicity, neurotoxicity, pulmonary toxicity, ophthalmological toxicity, dermatological toxicity) • Hemorrhage (after 30 days peri-procedural time) • Radiation exposure	
Timing	• Timing of followup not limited o Primary focus will be on long-term (>12 months) outcomes o Short-term (6–12 months) outcomes	None
Setting	• Inpatient and outpatient	None
Study Design	• Focus will be on evidence from comparative studies with the least potential for bias (i.e., high quality systematic reviews with or without meta-analysis), randomized controlled trials, controlled observational studies, registry studies • Case series or uncontrolled observational studies may be considered in the evaluation of harms if specifically designed to evaluate harms and/or adverse events, have a minimum of 100 patients and followup of at least 80%	• Nonclinical studies of technique • Studies reporting only on the technical aspects of ablation (e.g., imaging, type of catheter) • Uncontrolled observational studies • Non-systematic reviews • Narrative reviews • Abstracts, editorials, letters • White papers • Articles identified as preliminary reports when results are published in later versions • Case series • Case reports
Publication	• Studies published in English in scholarly	• Studies with a publication date prior to

PICOTS	Include	Exclude
	journals, published health technology assessments, or publicly available FDA reports • Gray literature (e.g., ongoing or unpublished clinical trial data)	2005 (to exclude outdated technologies) • Single reports from multicenter trials • Duplicate publications of the same study which do not report on unique outcomes

Definition of Terms

Catheter ablation: Procedure used to treat some types of heart arrhythmias. Restores normal sinus rhythm by delivering energy through catheters guided from the arm, groin, or neck through blood vessels to targeted points in the heart at which the arrhythmia originates. This energy ablates or destroys these small focal areas of the heart and disrupts the abnormal electrical activity.

Radiofrequency catheter ablation: Uses radiofrequency energy sent from an external device through the catheters to ablate the source of the arrhythmia.

Cryoablation: Uses a pressurized refrigerant in the catheter tip to ablate the source of the arrhythmia.

Cyroballoon ablation: Involves cooling and freezing of the targeted tissue using a coolant inside a balloon to alter abnormal electrical activity.

Paroxysmal AF: Recurrent AF (≥2 episodes) that terminates spontaneously within 7 days. Episodes of AF of ≤ 48 hours' duration that are terminated with electrical or pharmacologic cardioversion should also be classified as paroxysmal AF episodes.

Persistent AF: Continuous AF that is sustained beyond 7 days. Episodes of AF in which a decision is made to electrically or pharmacologically cardiovert the patient after ≥ 48 hours of AF, but prior to 7 days, should also be classified as persistent AF episodes.

Longstanding Persistent AF: Continuous AF of greater than 12 months' duration.

Summary of disposition of public comments to Draft Key Questions and supporting material

The draft Key Questions, developed during the Topic Refinement phase with input from Key Informants, were available for public comment on the Effective Health Care Program Web site. We are grateful to those who provided comments and constructive suggestions on the Draft Key Questions and related materials. The comments highlighted some of the challenges inherent in a review of this topic. The summary below, in response to the public comments, provides additional details regarding the scope of the report.

Overall, commenters affirmed the importance of reviewing this topic and some remarked on the thoroughness of key question and topic development. A number of commenters pointed out that there may be variations in actual practice that may influence outcomes, some of which may be related to provider skill/experience and differences in practice between tertiary/academic centers and other settings. Suggestions regarding evaluation of such provider characteristics as well as specific patient factors, procedural factors/characteristics, energy sources and type of atrial fibrillation were made. These will be captured in data abstraction and evaluated to the extent possible from the included literature.

Commenters remarked that a variety of definitions and classifications of atrial fibrillation (AF) and arrhythmias may be used. Definitions recommended by the American College of Cardiology and Heart Rhythm Society will be used in describing types of AF. Definitions used by included studies may, however, differ. Comments regarding the need to consider timing of post-procedural arrhythmia evaluation and care were also made. Data abstraction will capture definitions of arrhythmias and their timing relative to the procedure, information on how recurrent AF was monitored and measured, and periprocedural care (including use of anticoagulation strategies and post-ablation AAD use). Analysis planning will include consideration of how to best synthesize available information.

Some commenters suggested evaluation of cost-effectiveness of catheter ablation be included. AHRQ does not consider inclusion of cost-effectiveness studies, but resource utilization will be considered.

Some commenters suggested that the report include comparison of catheter ablation techniques and approaches to each other and that evaluation on the influence of mapping to guide ablation be included. Our main analyses will synthesize the evidence for catheter ablation compared with medical therapy. We will, however, abstract data concerning the type of device and techniques used for the catheter ablation and as possible explore whether our findings differ by ablation type or approach. Any FDA- approved devices (or devices in final stages of approval) that are used for catheter ablation in patients with AF will be included whether or not they have been specifically approved for treatment of AF. The review will not formally evaluate the comparative effectiveness of ablation types with each other. The review will not include evaluation of hybrid strategies. Diagnostic evaluation studies and studies focused on mapping alone or those comparing mapping techniques are not part of the scope of this review.

Some commenters provided literature citations. These will be considered and evaluated based on final inclusion/exclusion criteria for the systematic review. At the start of the systematic review process, AHRQ will send a request for scientific information to industry stakeholders. (http://effectivehealthcare.ahrq.gov/index.cfm/submit-scientific-information-packets/scientific-information-packet-guidelines/) Industry stakeholders who provided comment will be added to the list to receive this if they had not been previously identified.

Minor amendments to the key questions were made.

Key Question changes:
Public comments were discussed with CMS and AHRQ in December as part of topic refinement and during the systematic review kick off call with the new CMS representative. Based on these calls, the revised KQs listed below clarify comparison of catheter ablation (using any energy source) with medical therapy and inclusion of comparison of energy sources. Additionally, KQ 3 was revised to add identification of provider/setting and techniques/approaches that included studies report as modifying treatment effect or safety. These changes were made in keeping with the scope of a small review and PICOTS inclusion/exclusion established during the topic refinement process.

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APPENDIX
Topic Refinement Document Part 3

Table of FDA-approved catheter ablation devices

Device (PMA #)	Date approved	Manufacturer
Atrial Fibrillation		
Helios II Ablation Catheter (P050029)	2008	Stereotaxis, Inc.
NAVISTAR® THERMOCOOL® and EZ Steer THERMOCOOL® Nav Irrigated Deflectable Diagnostic/Ablation Catheter for Treatment of Paroxysmal Atrial Fibrillation (P030031S011)	2009	Biosense Webster, Inc.
Arctic Front® Cardiac CryoAblation Catheter (P100010) Includes models 2AF232 and 2AF282; Freezor® *MAX* Cardiac CryoAblation Catheter (Models 239F3 and 239F5); CryoConsole (Model 106A2); Manual Retraction Kit (Model 20MRK)	2010	Medtronic Cryocath, LP
Atrial Flutter		
NaviStar DS and Celsius DS Diagnostic/Ablation Catheters, Stockert 70 RF Generator and accessories (P010068)	2002	Biosense Webster, Inc.
Blazer II XP™ Cardiac Ablation Catheter, EPT-1000 XP Cardiac Ablation Controller and Accessories (P020025)	2003	Boston Scientific Corporation, Electrophysiology Division
NAVISTAR™ and CELSIUS™ THERMOCOOL® Irrigated Deflectable Diagnostic/Ablation Catheter (P030031)	2004	Biosense Webster, Inc.
IBI Therapy™ Dual 8™ Ablation Catheter and IBI 1500T6 (USA) Cardiac Ablation Generator (P040042)	2005	Irvine Biomedical, Inc.
IBI Therapy™ Cool Path™ Ablation Catheter and IBI 1500T9 RF Generator (P060019)	2007	Irvine Biomedical, Inc.
CryoCor Cryoablation System (CryoBlator Catheters & Model 2020 Console) (P050024)	2007	CryoCor, Inc.
Therapy Cool Path Duo™ Ablation Catheter, Safire BLU Duo™ Ablation Catheter, and IBI1500T9-CP V1.6 Cardiac Ablation Generator (P110016)	2012	Irvine Biomedical, Inc.
Other indications		
Blazer II™ Cardiac Ablation Catheter, EPT-1000 Cardiac Ablation Controller and Accessories (P920047)	1994	Boston Scientific Corporation, Electrophysiology Division
Atakr™ Radiofrequency Catheter Ablation (RFCA) System (P930029)	1995	Medtronic, Inc.
Webster Diagnostic/Ablation Deflectable Tip Catheter (P950005)	1997	Cordis Corporation
Chilli Cooled RF Ablation System (P980003) Includes Chilli Cooled Ablation Catheter, Standard Curve, and Chilli Cooled Ablation Catheter, Large Curve	1999	Boston Scientific Corporation
Livewire TC® Steerable Electrophysiology Catheter	1999	Daig Corporation

and Accessory Cables (P960016)		
Stinger™ Ablation Catheter and TempLink™ Extension Cable (P000020**)**	2000	C.R. Bard, Inc., Bard Electrophysiology Division
NAVISTAR™ Diagnostic/Ablation Deflectable Tip Catheter (P990025)	2000	Biosense Webster, Inc.
7F Freezor® Cardiac Cryoablation Catheter and CCT.2 CryoConsole System (P020045)	2003	Medtronic Cryocath, LP
IBI Therapy™ Cardiac Ablation System (P040014)	2005	Irvine Biomedical
NAVISTAR™ THERMOCOOL® Deflectable Diagnostic/Ablation Catheter (P040036)	2006	Biosense Webster, Inc.