Summary of Safety and Clinical Performance (SSCP)

AtriCure Dissectors (MID1, GPD1)

28 June 2024

CEM-285 Rev D

OVERVIEW

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device.

The SSCP is not intended to replace the Instructions for Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

INFORMATION INTENDED FOR USERS/ HEALTHCARE PROFESSIONALS:

1. Device Identification and General Information

Product Name:	AtriCure Wolf™ Lumitip™ Dissector (MID1) and Wolf™ Glidepath™ Dissector (GPD1)
Product Group/Family Basic UDI-DI	08401439000000000000019ZW
Manufacturer Legal Name and Address: Single Registration Number (SRN)	AtriCure 7555 Innovation Way Mason, OH 45040 USA SRN: US-MF-000002974
EU Auth Representative: Single Registration Number (SRN)	AtriCure Europe B.V. De entree 260 1101 EE Amsterdam The Netherlands SRN: NL-AR-000000165
Medical Device Scope Expression and Code:	CND code: K0201010201 – Electrosurgical Dissectors, Open Surgery, Single Use EMDN Code: C0699 Cardiac Surgery Instruments, Single Use, Other
Product Classification and Rule (per MDR):	Class III, Rule 6
Year when the first certificate (CE) was issued covering the device:	2009
Notified Body Name, Address & Number:	BSI Group The Netherlands BV Say Building John M. Keynesplein 9 1066 EP Amsterdam The Netherlands +31 20 346 0780 CE 2797

2. Intended Use of the Device

2.1. Intended Purpose

The AtriCure Dissector is intended to dissect cardiac tissue during cardiac and/or thoracic procedures

2.2. Indication(s) and target populations

Indication: The AtriCure Dissector is intended to dissect cardiac tissue for treatment of cardiac arrhythmias, including atrial fibrillation

Target population: Adult patients undergoing treatment of cardiac arrhythmias, including atrial fibrillation

2.3. Contraindications and/ or limitations

None

3. Device Description

3.1. Description of the device

The AtriCure Wolf Lumitip and Wolf Glidepath Dissectors, henceforth referred to as the Dissector(s), are single patient use surgical instruments designed to dissect cardiac tissue during cardiac and/or thoracic surgical procedures. Dissector's battery-powered light source is used to navigate tissue for identification and isolation of anatomic structures.

Figure 1 MID1 Dissector

Figure 2 GPD1 Dissector

3.2. A reference to previous generation(s) or variants if such exist, and a description of the differences

2009: Initial CE marking with BSI
2020: A new Loctite used for bonding was qualified due to discontinuation of prior Loctite by supplier
2023: New LED from same supplier due to obsoletion; modification of resistor to maintain equivalent light intensity, and pull tab modification to improve tensile strength

3.3. Description of any accessories which are intended to be used in combination with the device

None

3.4. Description of any other devices and products which are intended to be used in combination with the device

The Dissectors may be used in combination with the AtriCure Glidepath Tapes associated with the Isolator Synergy Clamps.

4. Risks and warnings

4.1. Residual risks and undesirable effects

Residual risks associated with use of the Dissectors are listed in the Instructions for Use and in the following table.

Potential Harm	Peri-procedural estimated residual risk occurrence
Infection	<0.1%, less than 1 in 1,000 patients
Bleeding resulting in death or permanent impairment	<0.1%, less than 1 in 1,000 patients
Stenosis of a vessel	<0.5% and ≥0.1%, between 1 and 200 patients and 1 in 1,000 patients
Inconvenience/confusion	<0.5% and ≥0.1%, between 1 and 200 patients and 1 in 1,000 patients
Temporary injury or impairment not requiring medical intervention	<0.1%, less than 1 in 1,000 patients
First degree burn	<0.1%, less than 1 in 1,000 patients
Bleeding requiring stitches/intraoperative change to pre-operative plan	<0.1%, less than 1 in 1,000 patients
Bleeding that resolves itself/with minimal pressure (i.e. gauze cover or sponge stick pressure)	<0.5% and ≥0.1%, between 1 and 200 patients and 1 in 1,000 patients
Discomfort	<0.1%, less than 1 in 1,000 patients
Bleeding requiring cautery/intraoperative drainage / stiches within standard of care per medical assessment	<0.1%, less than 1 in 1,000 patients
Systematic adverse reaction	<0.1%, less than 1 in 1,000 patients
Pleural effusion	<0.1%, less than 1 in 1,000 patients
Third degree burn	<0.1%, less than 1 in 1,000 patients
Note: estimated residual risk occurrence rates are based on commercial complaint rates per AtriCure risk management files and may be underestimated.	

4.2. Warnings and precautions

Warnings

- Use of the Dissector should be limited to properly trained and qualified medical personnel. Failure to follow proper instructions can cause improper functioning of the

device which may lead to death or serious injury.

- This device contains small amounts of Nickel (CAS# 7440-02-0) and Cobalt (CAS# 7440-48-4). Do not use the device if the patient has sensitivity to Nickel or Cobalt as this may result in an adverse patient reaction.
- To avoid the risk of patient infection, inspect the product packaging prior to opening to ensure that the sterility barrier is not breached. If the sterility barrier is breached, do not use the Dissector.
- Do not use excessive force when articulating the Dissector. Using excessive force when articulating may damage the tissue.
- Use caution during device insertion, removal and articulation of the shaft to avoid device catching or failure to insert. Unintended tissue perforations can be caused if awareness is not taken.
- Being unaware of variations in patient anatomy can cause tissue perforations.
- During a surgical procedure, ensure that the Dissector hinge point remains visible at all times. The hinge point should always be visible for the frame of reference of the tip location.
- The dissector includes an LED light source intended to indicate the device position and orientation, not to support visualization of structures. Appearance shifts occur during the use of LED light sources due to the difference in color, temperature, and CRI characteristics of the LED light from those of normal white light sources.
- The Dissector contains a Lithium disposable battery. Do not recharge, disassemble, heat above 100ºC, incinerate, or expose the battery directly to water. No modification of this equipment is allowed.
- Ensure device is disposed of following local governing ordinances and recycling plans to prevent biohazard exposure.
- Do not re-sterilize or reuse the Dissector. Single Patient use only. Reuse can cause patient injury and/or the communication of infectious disease(s) from one patient to another.

Cautions

- Medical electrical equipment needs special precautions regarding EMC and needs to be installed according to EMC information.
- Avoid contacting LED lens with other devices.
- Do not immerse any part of the Dissector in liquids as this may damage the device.
- Do not touch the Dissector tip against metal staples or clips. This may cause damage to the light source lens.
- Avoid contacting the Dissector with electrodes of any electrosurgical device. This may damage the Dissector, the electrosurgical device, or tissue.
- To avoid damage to the device, do not drop or toss the Dissector. If the Dissector is dropped, do not use. Replace with a new Dissector.
- Do not look directly into the light source when illuminated.
- The Dissector is not a sealed device and is not intended for insertion through ports which maintain insufflation.
- It is the responsibility of the health care institution to adequately prepare and identify the products for shipment.

4.3. Other relevant aspects of safety, including a summary of any field safety corrective action (FSCA including FSN) if applicable

None

5. Summary of clinical evaluation and post-market clinical follow-up (PMCF)

This section is intended to summarise, in a comprehensive manner, the clinical evaluation results and the clinical data forming the clinical evidence for the confirmation of conformity with relevant general safety and performance requirements, the evaluation of undesirable side-effects and the acceptability of the benefit-risk ratio. It shall be an objective and balanced summary of the clinical evaluation results of all the available clinical data related to the device in question, whether favourable, unfavourable, and/or inconclusive.

5.1. Summary of clinical data related to equivalent device, if applicable

The conformity of the Glidepath Dissector (GPD1) was assessed and endorsed by the Notified Body on the basis of equivalency to the Lumitip Dissector (MID1). The clinical data described in section 5.2, 5.3, and 5.4 are thus applicable to both devices.

5.2. Summary of clinical data from conducted investigations of the device before the CE-Marking, if applicable

Identity of the investigation/study	Feasibility Trial of a Staged Epicardial & Endocardial Approach for Treatment of Patients With Persistent or Long Standing Persistent Atrial Fibrillation With Radiofrequency Ablation (Staged DEEP); clinicaltrials.gov NCT01661205
Identity of the device	Isolator Synergy Clamps (EMR2, EML2, EMT) and Glidepath Tapes Ablation and Sensing Unit and Source Switch (ASU2/ASB) AtriCure Isolator Pens MAX1, MAX5, MCR1, MLP1 Dissector MID1 AtriCure AtriClip: LAA0, PRO1, CGG100 (Selection Guide)
Intended use of the device in the investigation	Cardiac ablation for persistent or longstanding persistent AF
Objectives of the study	To assess the safety and technical feasibility of treating subjects with persistent or longstanding persistent atrial fibrillation using a minimally invasive thoracoscopic ablation procedure utilizing the AtriCure Bipolar System.
Study design and duration of follow-up	Feasibility, open label, single arm
Primary and secondary endpoint(s)	The primary safety endpoint was a composite of the following adjudicated endpoint events that met the definition of a serious adverse event, and are attributed to any of the following: • AtriCure Bipolar System investigational devices; or • Epicardial surgical procedure; or • Endocardial procedure.

	These events must occur in the first 30 days post-index endocardial EP procedure or hospital discharge, whichever is longer (unless otherwise noted). Serious adverse events included: death (all-cause mortality); myocardial Infarction, stroke or TIA; excess bleeding, intra-procedure: conversion to sternotomy or cardiopulmonary bypass to control bleeding, post-operative excessive bleeding (≥ 2 units blood transfused in a 24 hour period, or reoperation to control bleed, in the first 7 days post-index surgical procedure); pulmonary vein stenosis (from the time of index surgical procedure through 12 month follow-up); atrio-esophageal fistula (from the time of index surgical procedure through 12 month follow-up); phrenic nerve paralysis; pericardial effusion requiring drainage or causing tamponade, vascular access complications including development of a hematoma, an arteriovenous fistula, or pseudoaneurysm that required surgical intervention or transfusion, prolonged hospital stay, or required hospital admission; injury to the specialized conduction system requiring permanent pacemaker implantation; and/or mediastinitis. The primary efficacy endpoint was absence of AF at 12- month follow-up assessment, based on continuous 14-day ECG monitoring (e.g., Holter, ILR, Zio Patch
Inclusion/exclusion criteria for subject selection	Inclusion Criteria: • Age > 18 year • Patients with symptomatic persistent or longstanding persistent AF refractory to a minimum of one Class I or III antiarrhythmic drug (AAD) • Patients with failed catheter ablation attempts are eligible if the patients are symptomatic with persistent or longstanding persistent AF. (catheter ablation procedure must be more than 3 months prior to index procedure) • Life expectancy of at least two years • Patient will and able to provide informed consent • Patient is willing and able to attend

	the scheduled follow-up visits Exclusion Criteria: • Prior Cardiothoracic Surgery • Patient has NYHA (New York Heart Association) Class IV heart failure • Evidence of underlying structural heart disease requiring surgical treatment • Surgical procedure within the 30 days prior to the index procedure • Ejection fraction < 30% • Measured left atrial diameter > 6.0 cm • Renal Failure • Stroke within previous 6 months • Known carotid artery stenosis greater than 80% • Evidence of significant active infection or endocarditis • Pregnant woman or women desiring to become pregnant in the next 24 months • Presence of thrombus in the left atrium determined by echocardiograph • History of blood dyscrasia • Contraindication to anticoagulation, based on Investigator's opinion • Mural thrombus or tumor • Moderate to Severe COPD
Number of enrolled patients	31 (26 treated)
Study population	Mean age : 61.7±9.5 years Male: 21 (80.8%) BMI: 30.8±3.9
Summary of study methods	The first subject was enrolled and treated in the Staged DEEP AF clinical study on September 11, 2012. In total, thirty-one (31) subjects were enrolled. Thirty (30) subjects signed thirty-one (31) consents from six (6) sites. All subjects treated in the Staged DEEP clinical study completed a 30-day follow-up visit and were followed through 24 months post index endocardial EP procedure, as outlined in the clinical protocol.
Summary of results	Primary adverse events occurred in 12% (3/25) of subjects. All three were

	adjudicated to be related to the epicardial procedure. • Death: one (1) subject at 35 days post-procedure • Phrenic nerve paralysis: two (2) subjects Primary efficacy: Primary efficacy was 78.3% (18/23 subjects).
Study Limitations	Feasibility study, small sample size
Any device deficiency or device replacements related to safety or performance during the study	Four device observations/malfunctions associated with the Coolrail linear pen (MCR1) were reported. • Two (2) Coolrail linear pens (MCR1) and two (2) AtriClips were observed to be contaminated or damaged during or prior to the procedure. • Mechanical breakage during the epicardial surgical procedure was reported for 2 additional Coolrail linear pens (MCR1). • In all instances an additional device was used. • No adverse event resulted from any of the observations

Identity of the investigation/study	Feasibility Trial of a Hybrid Approach for Treatment of Patients With Persistent or Longstanding Persistent Atrial Fibrillation With Radiofrequency Ablation (NCT01246466)
Identity of the device	AtriCure Synergy Ablation System: ASU2, ASB3, Isolator Synergy Clamps (EML2, EMR2, EMT1) and Glidepath Tape AtriCure Isolator Pens: MCR1, MAX3/MAX5, MLP1 Dissector MID1 AtriClip PRO1
Intended use of the device in the investigation	Cardiac ablation for persistent and longstanding persistent AF
Objectives of the study	The objective of the study was to assess the safety and technical feasibility of treating subjects with persistent atrial fibrillation or longstanding persistent atrial fibrillation procedure in a minimally invasive thoracoscopic ablation procedure utilizing the AtriCure Bipolar System, with mapping and optimization of lesions provided by currently approved catheter technology.

Study design and duration of follow-up	Prospective, multi-center, single arm, feasibility
Primary and secondary endpoint(s)	The primary endpoint for safety was a composite of adjudicated endpoints (e.g., adverse events) occurring within the first 30 days post-procedure or discharge (whichever is longer, unless otherwise noted). These events included death, major bleeding, stroke, transient ischemic attack, myocardial infarction, cardiac tamponade, pulmonary embolism, peripheral embolism, atrioesophageal fistula, diaphragmatic paralysis, pulmonary vein stenosis, serious skin burns, 2nd/3rd degree atrial-ventricular block requiring permanent pacemaker implantation, skin burns occurring within 48 hours after the procedure, emergency conversion to thoracotomy or sternotomy, and serious adverse events related to the catheter and/or the surgical procedure. The primary outcome for determining efficacy was absence of atrial fibrillation (AF) at twelve-month follow-up based on the 14-day auto trigger event monitor i.e., no episodes of AF, atrial flutter, or atrial tachycardia lasting > 30 continuous seconds, while off all Class I and III antiarrhythmic therapy for at least 4 weeks (except amiodarone which must be 12 weeks), prior to assessment.
Inclusion/exclusion criteria for subject selection	Inclusion Criteria: • Age > 18 years • Patients with symptomatic (e.g. palpitations, shortness of breath, fatigue) persistent or longstanding persistent AF Persistent • Patient is willing and able to provide written informed consent. • Patient has a life expectancy of at least 2 years. • Patient is willing and able to attend the scheduled follow-up visits. Exclusion Criteria: • Prior Cardiothoracic Surgery. • Patient has NYHA Class IV heart failure.

	• Evidence of underlying structural heart disease requiring surgical treatment. • Ejection fraction < 30% • Measured left atrial diameter > 6.0 cm • Renal Failure • Stroke within previous 6 months. • Known carotid artery stenosis greater than 80%. • Evidence of significant active infection or endocarditis. • Pregnant woman or women desiring to become pregnant in the next 24 months. • Presence of thrombus in the left atrium determined by echocardiography. • History of blood dyscrasia. • Contraindication to anticoagulation, based on Investigator's opinion. • Mural thrombus or tumor. • Moderate to Severe COPD
Number of enrolled patients	N=24
Study population	Age: 60.1±8.4 years Male: 22 (91.7%) BMI: 30.4±4.2
Summary of study methods	Subjects were followed through twenty-four (24) months with the primary efficacy endpoint evaluated at twelve (12) months.
Summary of results	Primary safety events (adverse event within 30 days post-procedure) occurred in 29.2% (7/24) of the subjects. 12.5% (3/24) were related to the catheter and its procedure. • Conversion to median sternotomy (1/24) • Stroke 20.8% (5/24) were related to the surgical procedure. • Bleeding during the epicardial procedure (1/24): conversion to mini-thoracotomy. • Stroke resulting in death on day 27 • Two subjects had infection at the port site; both were treated with antibiotics. • Vocal cord paralysis occurred in one subject Note: One patient experienced a myocardial infarction that was adjudicated

	to be due to both the endocardial catheter procedure and the epicardial ablation procedure. The primary efficacy endpoint was achieved in 68.4% (13/19) [95% CI 43.4, 87.4].
Study Limitations	Feasibility study, single arm, small sample size
Any device deficiency or device replacements related to safety or performance during the study	Device observations/malfunctions were observed in six (6) subjects: • Isolator Synergy Clamp (EML2) (n=1) - The Glidepath Tape (connection separated from the tip of the clamp jaw. A second EML2 device was used to complete the procedure without incident. • Isolator Transpolar Pen (n=1) - A 60 cycle (e.g., 60 Hertz) interference was noted and thought to be caused by a faulty pen. Use of the device with the associated observation was discontinued and replaced with an additional study device Isolator Transpolar Pen, which was used to complete the procedure without incident. • Coolrail Linear Pen (n=4): • Overheating (n=2) - Use of this device was discontinued and replaced with a commercially available Coolrail Linear Pen, which was used to successfully complete the procedure. • In one patient, a competitive device was used as a backup research device was not available. • In one patient, another Coolrail device from the investigational device inventory was used to complete the procedure without incident. • Mechanical breakage (n=2) – In both cases, the devices were replaced with another Coolrail Linear Pen from the investigational device inventory. • Note: None of these device observations/malfunctions was associated with an adverse event. Despite the temporary interruption of the procedure in

	these cases mentioned above, ablation of the specified lesion set was completed.

Identity of the investigation/study	Combined Endoscopic Epicardial and Percutaneous Endocardial Ablation Versus Repeated Catheter Ablation in Persistent and Longstanding Persistent Atrial Fibrillation (CEASE-AF) (NCT02695277)
Identity of the device	AtriCure Bipolar System (MAX5, ASU, ASB, GPT200, MID1, EMR2, EML2) AtriClip PRO LAA Exclusion System (PRO1/PRO2) and CGG100 (Selection Guide)
Intended use of the device in the investigation	Cardiac ablation
Objectives of the study	The objective of this study is to compare the efficacy and safety of two interventional approaches in preventing the recurrence of AF in symptomatic, drug-refractory patients with persistent or longstanding persistent atrial fibrillation.
Study design and duration of follow-up	The prospective 2:1 randomized study is designed to compare the effects of combined epicardial endoscopic surgical and endocardial catheter techniques versus standard endocardial catheter ablation strategies with regard to safety, efficacy, and quality of life. Effects on health economics of the two treatment strategies will also be evaluated. Duration of follow-up is 36 months.
Primary and secondary endpoint(s)	Primary effectiveness: • Number of subjects free from documented Atrial Fibrillation (AF), Atrial Flutter (AFL) or Atrial Tachycardia (AT) episodes >30 seconds in duration through 12-months follow-up, in the absence of Class I or III Antiarrhythmic Drugs (AADs). Secondary effectiveness: • Number of subjects free from documented AF, AFL or AT episodes > 30 seconds in duration through 24- and 36-months follow-up, in the absence of Class I or III AADs. [Time Frame: Through 24- and 36-months post the Endocardial procedure (Hybrid Procedure) or last allowed Catheter Ablation (Catheter Procedure)]

	Safety: Composite major complications and adverse events will be analyzed during follow-up, comparing cumulative complication rates occurring during the repeated procedures in the two study arms. Adverse events may include the following: death, stroke, transient ischemic attack, myocardial infarction in the context of AF Ablation, pericarditis, bleeding, wound infection, atrio-esophageal fistula, esophageal injury, permanent phrenic nerve paralysis, permanent pacemaker, pulmonary vein (PV) stenosis of >70%, cardiac tamponade/cardiac perforation, empyema, superficial wound infections or vascular access complications, pneumonia, and pneumothorax requiring intervention.
Inclusion/exclusion criteria for subject selection	Inclusion criteria: • Patient has a history of symptomatic Persistent AF and a left atrium (LA) > 4cm or Long Standing Persistent AF as defined by the HRS/EHRA/ECAS expert consensus statement • Patient is refractory to or intolerant of at least one antiarrhythmic drug (class I or III) • Patient is mentally able and willing to give informed consent Exclusion criteria: • Patient has longstanding persistent AF > 10 years • Patient presenting with paroxysmal AF • Patient with persistent AF and a LA-diameter ≤ 4cm • AF is secondary to electrolyte imbalance, thyroid disease, or other reversible or non-cardiovascular cause • Patient underwent previous ablation procedure or heart surgery • Patient needs other cardiac surgery procedures besides AF treatment (valve, coronary, others) • Contraindication for either catheter ablation or epicardial surgery (including, but not limited to: previous thoracic radiation, previous perimyocarditis, Previous cardiac tamponade, Pleural adhesions, Prior thoracotomy)

	• Body mass index > 35 • LA Diameter > 6 cm • Left ventricular ejection fraction < 30 % • Severe mitral regurgitation (>II) • Patient unable to undergo TransEsophageal Echocardiogram (TEE) • Presence of LA thrombus by TEE, CT scan, MRI or angiography • History of cerebrovascular disease, including stroke or transient ischemic attack (TIA) within 6 months prior to enrollment • Active infection or sepsis • Other clinical conditions precluding inclusion (e.g., organ disease, disturbances of hemostasis) • Contraindication to anticoagulant therapy, or inability to comply with anticoagulant therapy • Pregnancy, planned pregnancy or breastfeeding • Life expectancy is less than 12 months • Patient is involved in another study involving an investigational drug or device
Number of enrolled patients	N=170
Study population	N=154
Summary of study methods	From November 2015 to May 2020, 170 patients from 9 centers in Czechia (Czech Republic), Germany, the Netherlands, Poland, and the United Kingdom were enrolled and randomized 2:1 to Hybrid Ablation (N=114) or repeat Catheter Ablation (N=56). Of enrolled patients, 152 were treated with the index procedure (intention to treat, ITT, population). The modified ITT population consistent of 146 patients had at least one follow-up visit after T0 (6-months post index procedure).
Summary of results	Primary effectiveness (N=146 patients, n=95 Hybrid Ablation; n=51 Catheter Ablation) • Freedom from AF/AFL/AT in the absence of Class I/III AADs except those not exceeding previously failed doses through 12-months visit post-T0 was 71.6% (68/95) in the Hybrid

	Ablation arm versus 39.2% (20/51) in the repeat Catheter Ablation arm (absolute benefit increase 32.4%, p<0.001) • Persistent AF/enlarged left atrium subgroup: Freedom from AF/AFL/AT in the absence of Class I/III AADs except those not exceeding previously failed doses through 12-months visit post-T0 was 72.7% (56/77) in the Hybrid Ablation arm versus 41.9% (18/43) in the repeat Catheter Ablation arm (absolute benefit increase 30.9%, p<0.001). • Longstanding persistent AF subgroup: Freedom from AF/AFL/AT in the absence of Class I/III AADs except those not exceeding previously failed doses through 12-months visit post-T0 was 66.7% (12/18) in the Hybrid Ablation arm versus 25.0% (2/8) in the repeat Catheter Ablation arm (absolute benefit increase 41.7%, p=0.090). • Safety (N=154): Composite major complication rates through 30-days post-index and second stage/repeat endocardial catheter ablation were 7.8% (8/102) in the Hybrid Ablation arm and 5.8% (3/52) in the Catheter Ablation arm (n=0.751); Composite major complication rates through 1-year post index procedure were 8.8% (9/102) and 5.8% (3/52) (p=0.752). No device-related complications occurred per Clinical Events Committee adjudication
Study Limitations	• Minimal lesion sets were required in each arm, but additional epicardial or endocardial lesions could be made per institutional practice or physician discretion
Any device deficiency or device replacements related to safety or performance during the study	There was one (1) generator malfunction, which did not result in any adverse event or adverse outcome. The patient was treated by an alternative method and exited from the study protocol following the procedure.

Additional clinical study data outside of these manufacturer-sponsored clinical trials was identified through systematic literature searches as part of the Clinical Evaluations. This data is summarised in section 5.3.

5.3. Summary of clinical data from other sources, if applicable

Based on a comprehensive, systematic literature search performed as part of the Clinical Evaluation for the subject devices, 10 published literature studies specifically describe the safety and/or performance of the AtriCure Dissectors used in procedures with the AtriCure Pens and/or Clamps in cardiac ablation procedures in patients with atrial fibrillation[1-10]. Based on published clinical data in which the AtriCure Dissectors were used to create tissue plans during cardiac ablation procedures with AtriCure RF Clamps and Pens, the pooled incidence of major adverse events related to the device or procedure was <9% in >500 patients with AF. For performance, restoration of sinus rhythm/freedom from atrial arrhythmias was >80% in >400 patients.

5.4. An overall summary of the clinical performance and safety

The clinical benefit of the AtriCure Dissectors is to dissect and create tissue planes for AtriCure device placement to achieve their clinical benefit. Based on clinical trials and published literature, the AtriCure Dissectors were used to create tissue planes during cardiac ablation procedures for placement of AtriCure radiofrequency devices, including Pens and Clamps. The clinical benefits of the AtriCure Pens and Clamps are to return to normal sinus rhythm, reduce arrhythmia symptoms and improve quality of life. Based on the Clinical Evaluations of the AtriCure Dissectors, Pens, and Clamps, together the safety and performance objectives were met to achieve return to normal sinus rhythm rates (>55%) after cardiac ablation procedures and safety objectives were met for <19% major adverse events within 30 days.

5.5. Ongoing or planned post-market clinical follow-up

The AtriCure Dissector MID1 is used in ongoing clinical trials CEASE-AF (mid/long-term follow-up), DEEP Pivotal, and HEAL-IST, which will provide post-market clinical follow-up data. The information generated from these studies and AtriCure's post-market surveillance program will be used to monitor and identify residual risks from use of the devices or performance-related impacts to the benefit-risk ratio.

6. Possible diagnostic or therapeutic alternatives

The AtriCure Dissectors are used to dissect cardiac tissue during surgery for treatment or cardiac arrhythmias including atrial fibrillation. Other tissue dissectors are made by other manufacturers. The rest of this section describes therapeutic alternatives for cardiac arrhythmia treatment.

Atrial fibrillation

Rhythm control can be pursued pharmacologically among some patients with AF. The 2020 ESC Guidelines recommend amiodarone for long-term rhythm control in all AF patients, but urge trying other AADs first due to the extracardiac toxicity[11]. These guidelines also recommend rhythm control be pursued by AF catheter ablation for pulmonary vein isolation after one failed or intolerant class I or class III anti-arrhythmic drug in patients with paroxysmal AF or persistent AF with or without major risk factors for AF recurrence ("Catheter or surgical ablation should be considered in patients with symptomatic persistent or long-standing persistent AF refractory to AAD therapy to improve symptoms")[11]. Although antiarrhythmic drugs are useful, the Journal of American College of Cardiology described AF ablation as the primary therapeutic strategy in their 2020 Council Perspective paper[12]. A variety of ablative procedures have been investigated as potentially curative approaches, or as modifiers of the arrhythmia such that drug therapy becomes more effective. Further,

ablation may be a suitable treatment option in patients for whom AAD treatment has not been successful or is not well tolerated.

Ablative approaches focus on interruption of the electrical pathways that contribute to atrial fibrillation, through modifying the triggers of atrial fibrillation and/or the myocardial substrate that maintains the aberrant rhythm. The most common types of energy for ablation include radiofrequency, high-intensity ultrasound, laser, cryoenergy, and microwave. These energy sources ablate the cardiac tissue by scarring and creating lesion sets which disrupt the electrical signals. Among the various energy sources, RF and cryothermal energy are the most applied to ablate cardiac tissue[12]. Various RF ablation devices are on the market, and several also have cardiac electrophysiology diagnostic capabilities; these devices enable the physician to monitor (e.g., sensing, pacing, and recording) the success of the lesions in real-time[13]. Surgical ablation can be performed as either part of an open-heart surgery with a concomitant cardiac procedure or as a standalone thoracoscopic procedure. Both types of procedures have been assessed for safety and performance outcomes in clinical trials, some of which are reviewed in this SSCP. The frequency of surgical ablation performance and durable rhythm success, as a primary or stand-alone procedure, has steadily increased. Current guidelines from multiple physician societies have evaluated the use of surgical ablation to treat AF[11, 13-15].

Inappropriate Sinus Tachycardia

Currently, there is no FDA approved therapy for the treatment of IST. According to the 2015 Heart Rhythm Society (HRS) Expert Consensus Statement, evidence-based treatment options for IST are limited and there is no standard of care therapy for this debilitating disease[16].

Drug treatments such as beta blockers or calcium channel blockers are generally chosen as the first line of treatment but have not proven effective. Ivabradine, an inhibitor of the hyperpolarizing sodium current, is a more recent drug that has exhibited better results. Data has suggested that a combination of ivabradine and metoprolol might be safe and effective or Ivabradine may also provide benefits when added to a beta-blocker therapy.
RF catheter ablation involving sinus node (SN) ablation has been a potential alternative in patients with IST refractory to medical therapy. Often, the symptoms worsen or necessitate a permanent pacemaker. Other complications include phrenic nerve damage or transient superior vena cava syndrome. It is generally felt that the risks involved outweigh the benefit of this treatment.

Because of the complex psychosocial relationship to IST, treatment often involves a multi-disciplinary approach. Managing the heart rate does not always relieve the distress the patient has been experiencing. Other treatment options have included, erythropoietin, fludrocortisone, volume expansion, compression garments, phenobarbital, clonidine, psychiatric evaluation, and exercise training.

7. Suggested profile and training for users

The intended users for the AtriCure Pens are licensed medical doctors who perform cardiac and/or thoracic surgical procedures. AtriCure offers additional comprehensive education and training on the use of the AtriCure Dissectors as per the device instructions for use. This may include didactic review with an experienced operator and optional simulator/cadaver lab.

8. Reference to any harmonized standards and CS applied

Standard	Compliance – Full, Partial, or No	Justification if Partial or No
BS EN ISO 13485: 2016 + A11 2021 Medical devices — Quality management systems – Requirements for regulatory purposes	Full	N/A
BS EN ISO 14971:2019+A11:2021 Medical devices - Application of Risk Management to Medical Devices	Full	N/A
BS EN ISO 14155: 2020 Clinical investigation of medical devices for human subjects - Good clinical practice	Full	N/A
BS EN 62366-1: 2015 + A1 2020 Medical devices - Application of usability engineering to medical devices	Full	N/A
BS EN 60601-1: 2006+A2:2021 Medical electrical equipment Part 1: General requirements for basic safety and essential performance	Full	N/A
BS EN 60601-1-2: 2015+A1:2021 Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests	Full	N/A
BS EN 60601-1-6: 2010+A2:2021 Medical electrical equipment: Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability	Full	N/A
BS EN ISO 10993-1:2020 Biological evaluation of medical devices – Part 1: Evaluation and testing	Full	N/A
BS EN ISO 10993-3: 2014: Biological evaluation of medical devices – Part 3: Genotoxicity, Carcinogenicity and Reproductive Toxicity	Full	N/A
BS EN ISO 10993-4: 2017 Biological evaluation of medical devices – Part 4: interactions with Blood	Full	N/A
BS EN ISO 10993-5: 2009 Biological evaluation of medical devices – Part 5: Cytotoxicity	Full	N/A
BS EN ISO 10993-7: 2008 Biological evaluation of medical devices –Part 7 EO Residuals	Full	N/A
BS EN ISO 10993-9: 2021 Biological evaluation of medical devices. Framework for identification and quantification of potential degradation products	Full	N/A
BS EN ISO 10993-10: 2013 Biological evaluation of medical devices – Part 10: Skin irritation/sensitization	Full	N/A
BS EN ISO 10993-11: 2018 Biological evaluation of medical devices – Part 11: Test for systemic toxicity	Full	N/A
BS EN ISO 10993-12: 2021 Biological evaluation of medical devices – Part 12: Sample Prep	Full	N/A
BS EN ISO 10993-13: 2010Biological evaluation of medical devices. Identification and quantification of degradation products from polymeric medical devices	Full	N/A
BS EN ISO 10993-15: 2009 Biological evaluation of medical devices. Identification and quantification of degradation products from metals and alloys	Full	N/A
BS EN ISO 10993-16: 2017 Biological evaluation of medical devices. Toxicokinetic study design for degradation products and leachables	Full	N/A

EN ISO 10993-17: 2009 Biological evaluation of medical devices Establishment of allowable limits for leachable substances	Full	N/A
BS EN ISO 10993-18: 2020 Biological evaluation of medical devices – Chemical characterization	Full	N/A
BS EN ISO 10993-23 2021 Biological evaluation of medical devices — Part 23: Tests for irritation	Full	N/A
ISTA 3A: 2018 Performance testing of Shipping Containers and Systems	Full	N/A
BS EN ISO 11135:2014:+A1 2019 Sterilization of health-care products -Ethylene Oxide	Full	N/A
BS EN ISO 11607-1: 2020+A11:2022: Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier Systems, and packaging Systems	Full	N/A
BS EN ISO 11607-2:2020+A11: 2022: Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes	Full	N/A
BS EN ISO 11737-1 2018/A1:2021 Sterilization of health care products. Microbiological methods	Full	N/A
ASTM F88/F88M-21: 2021 Standard Test Method for Seal Strength of Flexible Barrier Materials	Full	N/A
ASTM F1980: 2021 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	Full	N/A
ASTM F1929-15: 2015 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration	Full	N/A
BS EN ISO 15223-1: 2021 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements	Full	N/A
BS EN ISO 20417:2021 Medical Devices – Information to be supplied by the manufacturer	Full	N/A
BS EN IEC 62366-1: 2015 + A1 2020 Medical devices - Application of usability engineering to medical devices	Full	N/A
N/A – not applicable		

9. Revision history

SSCP Revision Number	Date Issued	Change Description	Validated by Notified Body (Yes or No)	Validation Language
A	See AtriCure MasterControl CEM-285.A for release date	Initial Release	No	English
B	See AtriCure MasterControl CEM-285.B for release date	- The notified body information was update in Section 1 - A statement was added to Section 3.4 regarding the devices that may be used with the Dissectors in alignment with the IFU - A statement for the equivalence claim between MID1 and GPD1 was added to Section 5.1.	No	English
C	28 June 2024	- Update to change validation status. Cover page date reflects Rev B approval date. Translations to be attached on Rev D.	Yes	English
D	See AtriCure MasterControl CEM-285.D for release date	- Revised to CEM-2858.D to attach translations files. Cover page date reflects Rev B approval date.	Yes	English

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