Summary of Safety and Clinical Performance (SSCP)

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 Merit Medical Coronary Sinus Guides (CSGs) and Lateral Vein Introducers (LVIs). The CSGs and LVIs include the following configuration variants:

- CSGs:
  - SafeSheath® CSG® (Coronary Sinus Guide)
  - Worley™ Advanced CSG (Coronary Sinus Guide) (Worley Advanced CSG, Worley Advanced Right-Sided CSG)
- LVIs:
  - SafeSheath® Worley LVI (Lateral Vein Introducer) (5.5 French [F], 7F)
  - Worley™ Advanced LVI (Lateral Vein Introducer) (5.5F, 7F)
  - Situs Target (Lateral Vein Introducer)
  - Situs LDS 2 (Lateral Vein Introducer)

The SSCP is not intended to replace the Instructions for Use (IFU) as the main document to ensure the safe use of the CSGs and LVIs nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The English version of this SSCP document (SSCP 0225) has been validated by the notified body. The following information is intended for users/healthcare professionals.

1.0 Device identification and general information

1.1 Device trade names:

The devices and model numbers covered by this SSCP are presented in Table 1.

Table 1 Devices Included in this SSCP

Device Name	Product Numbers
CSGs	
Safe Sheath CSG*	MDR-FCL-068-00
	MDR-FCL-069-00
	MDR-FCL-069-02
	MDR-FCL-069-03
	MDR-FCL-070-00
	MDR-FCL-070-01
	MDR-FCL-083-00
	MDR-FCL-083-01
	MDR-FCL-083-02
	MDR-FCL-083-03
	MDR-FCL-090-00
Worley Advanced CSG	MDR-CSG-B1-09
	MDR-CSG-B2-09
	MDR-CSG-BL1-09
	MDR-CSG-BR1-09
	MDR-CSG-E-90
LVIs	
SafeSheath Worley LVI*	MDR-FCL-137-00
	MDR-FCL-137-01
	MDR-FCL-137-02
	MDR-FCL-137-03
	MDR-FCL-200-00
	MDR-FCL-200-01

Device Name	Product Numbers
	MDR-FCL-200-02
	MDR-FCL-200-03
Worley Advanced LVI	MDR-LVI-07-HO
	MDR-LVI-07-HS
	MDR-LVI-07-MP
	MDR-LVI-07-RE
	MDR-LVI-55-HO
	MDR-LVI-55-HS
	MDR-LVI-55-MP
	MDR-LVI-55-RE
Situs Target**	MDR-FCL-197-00
	MDR-FCL-197-01
Situs LDS 2**	MDR-FCL-167-00
	MDR-FCL-167-01
	MDR-FCL-167-02
	MDR-FCL-167-03

*OEM sold to Pressure Products, Inc.

**OEM sold to MicroPort

Abbreviations: CSG = Coronary Sinus Guide; LVI = Lateral Vein Introducer

1.2 Manufacturer Information

The name and address of the manufacturer of the CSGs and LVIs are provided in Table 2.

Table 2 Manufacturer Information

Manufacturer Name	Address of Manufacturer
Merit Medical Systems, Inc.	1600 West Merit Parkway South Jordan, Utah 84095-2416 USA

Abbreviations: USA = United States of America

1.3 Manufacturer Single Registration Number (SRN)

The Single Registration Number (SRN) for the manufacturer is included in Table 3.

1.4 Basic UDI-DI

The basic Unique Device Identifier (UDI) with Device Identification (DI) keys are provided in Table 3.

1.5 Medical Device Nomenclature Description / Text

The European Medical Device Nomenclature (EMDN) and Classificazione Nazionale dei Dispositivi medici (CND) codes and descriptors for the subject devices are listed in Table 3.

1.6 Risk Class of Device

The EU device risk classifications for the CSGs and LVIs are listed in Table 3.

Table 3 Device Identification Information

Device Name	EU Device Class	Product Number	Basic UDI-DI	Single Registration Number (SRN)	EMDN/CND Code	EMDN/CND Terms
CSGs						
SafeSheath CSG	Class III	MDR-FCL-068-00, MDR-FCL-069-00, MDR-FCL-069-02, MDR-FCL-069-03, MDR-FCL-070-00, MDR-FCL-070-01, MDR-FCL-083-00, MDR-FCL-083-01, MDR-FCL-083-02, MDR-FCL-083-03, MDR-FCL-090-00	0884450BUDI296Q8	US-MF-000001366	C0503	CARDIOVASCULAR INTRODUCER SHEATHS, PEEL-AWAY
Worley Advanced CSG		MDR-CSG-B1-09, MDR-CSG-B2-09, MDR-CSG-BL1-09, MDR-CSG-BR1-09, MDR-CSG-E-90	0884450BUDI297QA			

Device Name	EU Device Class	Product Number	Basic UDI-DI	Single Registration Number (SRN)	EMDN/CND Code	EMDN/CND Terms
LVIs						
SafeSheath Worley LVI	Class III	MDR-FCL-137-00, MDR-FCL-137-01, MDR-FCL-137-02, MDR-FCL-137-03, MDR-FCL-200-00, MDR-FCL-200-01, MDR-FCL-200-02, MDR-FCL-200-03	0884450BUDI298QC	US-MF-000001366	C0503	CARDIOVASCULAR INTRODUCER SHEATHS, PEEL-AWAY
Worley Advanced LVI		MDR-LVI-07-HO, MDR-LVI-07-HS, MDR-LVI-07-MP, MDR-LVI-07-RE, MDR-LVI-55-HO, MDR-LVI-55-HS, MDR-LVI-55-MP, MDR-LVI-55-RE	0884450BUDI299QE			
Situs Target		MDR-FCL-197-00, MDR-FCL-197-01	0884450BUDI300P6			
Situs LDS 2		MDR-FCL-167-00, MDR-FCL-167-01, MDR-FCL-167-02, MDR-FCL-167-03	0884450BUDI301P8			

Abbreviations: CND = Classificazione Nazionale Dispositivi medici; CSG = Coronary Sinus Guide; EMDN = European Medical Device Nomenclature; EU = European Union; LVI = Lateral Vein Introducer; SRN = Single Registration Number; UDI -DI = Unique Device Identification – Device Identification

1.7 Year of EU Market Introduction

The year that the CSGs and LVIs were first placed on the EU market is presented in Table 4.

1.8 Authorized Representative

The name of the authorized representative and the SRN are provided in Table 4.

1.9 Notified Body

The Notified Body (NB) involved in the conformity assessment of the CSGs and LVIs in accordance with Annex IX or Annex X of the Medical Device Regulation (MDR) and responsible for validating the SSCP is listed in Table 4.

1.10 NB Single Identification Number

The NB Single Identification Number is listed in Table 4.

Table 4 Authorized Representative and Notified Body Information

Device Name	Year Placed on EU Market	Authorized Representative		Notified Body (NB)	
		Name	SRN	Name	ID Number
CSGs					
SafeSheath CSG	2012	Merit Medical Ireland Ltd.	IE-AR-000001011	BSI	2797
Worley Advanced CSG					
LVIs					
SafeSheath Worley LVI	2012	Merit Medical Ireland Ltd.	IE-AR-000001011	BSI	2797
Worley Advanced LVI					
Situs Target					
Situs LDS 2					

Abbreviations: CSG = Coronary Sinus Guide; EU = European Union; LVI = Lateral Vein Introducer; NB = Notified Body; SRN = Single Registration Number

2.0 Intended Use of the Device

2.1 Intended Purpose

The labeled intended purposes for the CSGs and LVIs device configurations are summarized in Table 5.

Table 5 CSGs and LVIs: Intended Purpose

Product Configuration	Intended Purpose
CSGs	
SafeSheath CSG	For the introduction of various types of pacing or defibrillator leads and catheters.
Worley Advanced CSG	
Worley Advanced Right Sided CSG	
LVIs	
SafeSheath Worley LVI (5.5F)	For the introduction of various types of pacing or defibrillator leads and catheters.
SafeSheath Worley LVI (7F)	
Worley Advanced LVI (5.5F)	
Worley Advanced LVI (7F)	
Situs Target	
Situs LDS 2	

Product Configuration	Intended Purpose

Abbreviations: CSG = Coronary Sinus Guide; F = French; LVI = Lateral Vein Introducer

2.2 Indications and Intended Patient Groups

The labeled indications for use and the labeled intended patient population for the CSGs and LVIs device configurations are summarized in Table 6 and Table 7, respectively.

Table 6 CSGs and LVIs: Indications for Use

Product Configuration	Indications
CSGs	
SafeSheath CSG	For use in patients who require the introduction of various types of pacing leads and other tools to deliver cardiac resynchronization therapy for patients with congestive heart failure.
Worley Advanced CSG	
Worley Advanced Right Sided CSG	
LVIs	
SafeSheath Worley LVI (5.5F)	For use in patients who require the introduction of various types of pacing leads and other tools to deliver cardiac resynchronization therapy for patients with congestive heart failure.
SafeSheath Worley LVI (7F)	
Worley Advanced LVI (5.5F)	
Worley Advanced LVI (7F)	
Situs Target	
Situs LDS 2	

Abbreviations: CSG = Coronary Sinus Guide; F = French; LVI = Lateral Vein Introducer

Table 7 CSGs and LVIs: Intended Patients

Product Configuration	Intended Patients
CSGs	
SafeSheath CSG	The intended patient population for the CSG system are adult patients who require the introduction of various types of pacing/defibrillator leads and catheters into the coronary venous system.
Worley Advanced CSG	
Worley Advanced Right Sided CSG	

Product Configuration	Intended Patients
LVIs	
SafeSheath Worley LVI (5.5F)	The intended patient population for the LVI system are adult patients who require the introduction of various types of pacing/defibrillator leads and catheters into the coronary venous system.
SafeSheath Worley LVI (7F)	
Worley Advanced LVI (5.5F)	
Worley Advanced LVI (7F)	
Situs Target	The intended patient population for the Situs Target system are adult patients who require the introduction of various types of pacing/defibrillator leads and catheters into the coronary venous system.
Situs LDS 2	The intended patient population for the Situs LDS 2 system are adult patients who require the introduction of various types of pacing/defibrillator leads and catheters into the coronary venous system.

Abbreviations: CSG = Coronary Sinus Guide; F = French; LVI = Lateral Vein Introducer

2.3 Contraindications:

The labeled contraindications for the CSGs and LVIs device configurations are summarized in Table 8.

Table 8 CSGs and LVIs: Contraindications

Product Configuration	Contraindications
CSGs	
SafeSheath CSG	Use of the CSG system is contraindicated for the following: • Patients with an existing or possible occlusion of the coronary vessels or unsuitable anatomy of the coronary veins • Patients with active systemic infection
Worley Advanced CSG	
Worley Advanced Right Sided CSG	
LVIs	
SafeSheath Worley LVI (5.5F)	Use of the LVI system is contraindicated for the following: • Patients with an existing or possible occlusion of the coronary vessels or unsuitable anatomy of the coronary veins • Patients with active systemic infection
SafeSheath Worley LVI (7F)	
Worley Advanced LVI (5.5F)	
Worley Advanced LVI (7F)	
Situs Target	The Situs Target system is contraindicated for the following: • Patients with an existing or possible occlusion of the coronary vessels or unsuitable anatomy of the coronary veins • Patients with active systemic infection
Situs LDS 2	Use of the Situs LDS 2 is contraindicated for the following: • Patients with an existing or possible occlusion of the coronary vessels or unsuitable anatomy of the coronary veins

Product Configuration	Contraindications
	• Patients with active systemic infection

Abbreviations: CSG = Coronary Sinus Guide; F = French; LVI = Lateral Vein Introducer

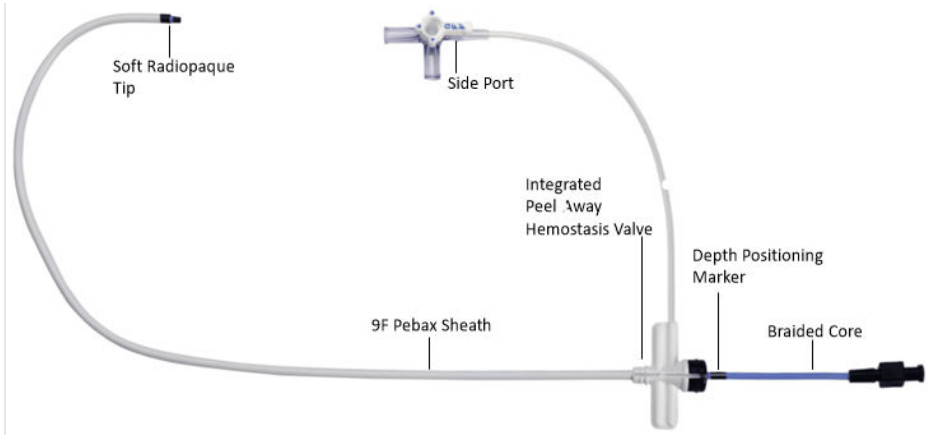
3.0 Device Description

Coronary Sinus Guide

The CSG system includes the Splittable Sheath Introducer, a Guiding dilator (Guiding "Braided" core) and a mating Dilator. The CSG Splittable Sheath Introducer is available in 9F inner diameter (ID) size and multiple lengths from 40 cm to 50 cm. The Guiding core is designed to conform to the ID of the introducer Sheath, and offered in multiple curves and length range from 46 cm to 66 cm. The mating Dilator is designed to conform to the ID of the introducer Sheath and is intended to provide support.

The CSG introducer is packaged stand-alone, this includes the CSG Introducer, Guiding Core and mating Dilator set. A pictorial representation of the CSG Kit is provided in Figure 1.

Figure 1 Coronary Sinus Guide Kit

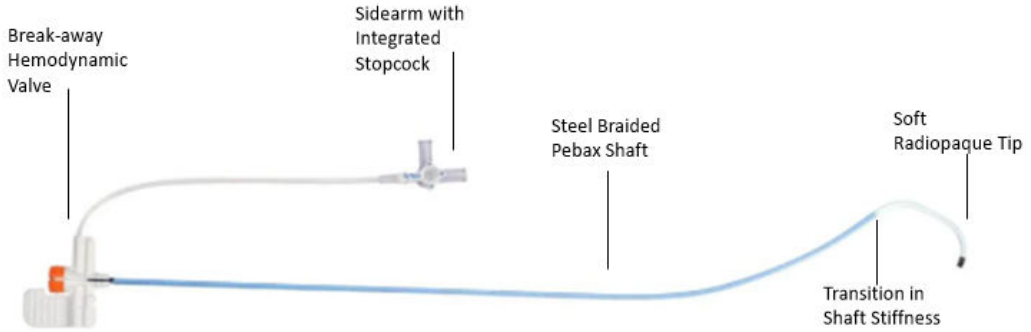


Lateral Vein Introducer

The LVIs are available in 5.5F, 7F, and 9F ID sizes, and lengths from 48 cm to 62 cm, have a shaft design with three (3) gradually decreasing stiffness segmentations from proximal to distal. The shaft is reinforced by a metal braid from the proximal end until approximately 0.175 inch from the distal end. The shaft is coated by a medical-grade coating that provides enhanced lubricity when advanced through the CSG Introducer.

The LVI introducer is packaged stand alone and may include a mating Dilator set as appropriate (e.g., Situs Target does not include a dilator). In addition, other supporting tools (e.g., Sheath, Cutter, and TVI tool) as applicable are also included with the LVI introducer. A pictorial representation of the LVI Kit is provided in Figure 2.

Figure 2 Lateral Vein Introducer Kit



3.1 Materials/Substances in Contact with Patient Tissues

The materials of construction for the CSGs and LVIs are summarized in Table 9. The CSGs and LVIs do not contain any medicinal substances. The biological and toxicological risk associated with the patient-contacting materials of the subject devices are low and acceptable. The CSGs and LVIs are intended for single-use only and are sterilized with ethylene-oxide.

Table 9 CSGs and LVIs: Device Materials

Components	Material Information
SafeSheath CSG, Worley Advanced CSG, Worley Advanced Right-Sided CSG	
9F Sheath Tubing	Pebax 5533 SA01 MED
	Barium Sulfate

Components	Material Information
	Clariant AH52631209, Blue Tint
	Irganox 1010
	Tinuvin 783
Braided Core Outer Wall	Pebax 6333 SA01 MED
	Barium Sulfate
	Irganox 1010
	Tinuvin 783
	Pantone 659C Blue Colorant
Braided Core Inner Wall	Pebax 4033 SA01 MED
	Barium Sulfate
Braided Core Inner Wall	Irganox 1010
	Tinuvin 783
	Pantone 659C Blue Colorant
Dilator Hub	HDPE
	Black Colorant
	HDPE (Chevron HID 9018 HDPE Nat.)
	Lt Blue Colorant (CXB-5011-A)
Dilator Tube	Marlex HHM-5502
	Dow Unival DMDH-6400 NT
	Blue Colorant
	Barium Sulfate
	Resin.POLYE LOW DSYT 1017.
Snap Nut Fitting	Santoprene 8281-65 MED
	White Colorant
RO Tip Segment (0.115”)	Pebax 4533 SA01 MED
	C5 Tungsten
	Irganox 1010
	Tinuvin 783
Soft Tip Segment (0.060”)	Pebax 3533 SA01 MED
	Barium Sulfate

Components	Material Information
	Irganox 1010
	Tinuvin 783
Ink	Pad Printing Ink, Black
	Pad Printing Ink, Thinner
	Pad Printing Ink, Hardener
Valve Body	Isoplast 2510
	White Colorant
Sidearm Tubing	Dow Pellethane 2363-80AE
Stopcock	HDPE MAT-107
	Polycarbonate MAT-315
	Silicone 750-25
Soaked Tearaway Valve	Silicone Rubber
	Dow 360 Medical Grade Silicone
	Silicone Medical Grade 350 cs
Foam Washer	Foamex Grade 900Z Polyurethane
Valve Cap	Isoplast 2510
	Black Colorant
Adhesive	Loctite 4011 Cyanoacrylate Adhesive
Lubricant	Silicone Medical Grade
	Fluid MDX4-4159 Medical Grade
	Silicone, Dow 360 Medical Grade
	DP-200 Silicone Fluid
SafeSheath Worley LVI (5.5F), Worley Advanced LVI (5.5F), Situs Target	
Sheath Section 1	Pebax 7233 SA01 MED
	Barium Sulfate
	Ultramarine Blue Colorant
	Tinuvin 783
	Irganox 1010
Sheath Section 2	Pebax 4533 SA01 MED
	Barium Sulfate

Components	Material Information
	Ultramarine Blue Colorant
	Tinuvin 783
	Irganox 1010
Sheath Section 3	Pebax 4533 SA01 MED
	Tungsten Carbide
	Irganox 1010
	Tinuvin 783
Sheath Section 4	Pebax 4533 SA01 MED
	Barium Sulfate
	Black Colorant
	Tinuvin 783
	Irganox 1010
Liner	PTFE
Valve Housing	Isoplast 2510
	White Colorant
Wing Handle	Isoplast 2510
	White Colorant
Soaked Tearaway Valve	Silicone Rubber
	Dow 360 Medical Grade Silicone
	Silicone Medical Grade 350 cs
Sideport Tube	Dow Pellethane 2363-80AE
3-Way Stopcock	HDPE MAT-107
	Polycarbonate MAT-315
	Silicone 750-25
Foam Washer	Foamex Grade 900Z Polyurethane
Valve Cap	Isoplast 2510
	Gray Colorant
Lubricants	Silicone Medical Grade
	Fluid MDX4-4159 Medical Grade
	Silicone, Dow 360 Medical Grade

Components	Material Information
	DP-200 Silicone Fluid
Adhesive	Loctite 4011 Cyanoacrylate Adhesive
SafeSheath Worley LVI (7F), Worley Advanced LVI (7F), Situs LDS 2	
Sheath Section 1	Pebax 6333 SA01 MED
	Barium Sulfate
	Irganox 1010
	Tinuvin 783
	Pantone 659C Blue Colorant
Sheath Section 2	Pebax 5533 SA01 MED
	Barium Sulfate
	Irganox 1010
	Tinuvin 783
	Pantone 659C Blue Colorant
Sheath Section 3	Pebax 2533 SA01 MED
	Barium Sulfate
	Irganox 1010
	Tinuvin 783
	Pantone 657C Blue Colorant (SafeSheath and Worley LVI [7F])
	Pantone 659C Blue Colorant (Situs LDS 2)
Liner	Pebax 6333 SA01 MED
RO Tip Segment (0.115”)	Pebax 4533 SA01 MED
	C5 Tungsten
	Irganox 1010
	Tinuvin 783
Soft Tip Segment (0.060”)	Pebax 3533 SA01 MED
	Barium Sulfate
	Irganox 1010
	Tinuvin 783
	Black Colorant
Valve Housing	Isoplast 2510

Components	Material Information
	White Colorant
Sideport Tube	Dow Pellethane 2363-80AE
Wing Handle	Isoplast 2510
	White Colorant
3-Way Stopcock	HDPE MAT-107
	Polycarbonate MAT-315
	Silicone 750-25
Soaked Tearaway Valve	Silicone Rubber
	Dow 360 Medical Grade Silicone
	Silicone Medical Grade 350 CS
Foam Washer	Foamex Grade 900Z Polyurethane
Valve Cap	Isoplast 2510
	Orange Colorant
Lubricants	Silicone Medical Grade
	Silicone, Dow 360 Medical Grade
	Fluid MDX4-4159 Medical Grade
	DP-200 Silicone Fluid
Adhesive	Loctite 4011 Cyanoacrylate Adhesive
Dilator Hub	HDPE
	Orange Colorant

Abbreviations: cs = centistoke; CSG = Coronary Sinus Guide; F = French; FEP = fluorinated ethyl propylene; HDPE = high-density polyethylene; LVI = Lateral Vein Introducer; PETG = polyethylene terephthalate glycol; PPS = purchased part specification; PTFE = polytetrafluoroethylene; THF = tetrahydrofuran; UV = ultraviolet

3.2 Operating Principals

The CSGs and LVIs are typically placed using the Seldinger technique that employs an introducer needle to gain initial vessel access. A guidewire is manually placed through the needle and into the vessel. The needle is then removed, leaving the guidewire in place to preserve vascular access. A sheath introducer/vessel dilator assembly is advanced over the guidewire and into the vessel. The guidewire and dilator are removed leaving the sheath introducer as a conduit to the vessel. A hemostasis valve in the sheath hub minimizes blood loss and air ingress. Interventional and diagnostic devices may then be placed through the sheath's hemostasis valve and into the vessel. The sideport extension tubing (if applicable)

provides a means to aspirate air, infuse fluids and sample blood. Once the lead or catheter is in the desired position, the sheath hub is split and the sheath peels away from the implanted device allowing it to maintain position.

3.3 Accessories

No accessories are included with the CSGs and LVIs. Table 10 shows additional accessories that are mentioned in the IFU but are not included with the subject devices.

Table 10 Additional Accessories Not Included with the CSGs and LVIs

Component	Comment
Needle	Needles are used for providing a puncture site in blood vessels for the introduction of vascular access devices such as the Prelude introducers. Needles incorporate a translucent standard female Luer locking connector for immediate bleed back visualization and is color coded for needle gauge identification. To accommodate customer requests, some of the needle configurations have a Seldinger or Cournand shield or may be echo enhanced. Needles are single use devices supplied sterile and non-pyrogenic.
Guidewires	Introducer Guide Wires are used for procedures that require the use of shorter guidewires such as percutaneous drainage, dialysis graft de-clot, micro puncture introducer insertions, routine arterial and venous catheterizations, sheath introducer insertions, and so forth. Introducer wires are typically double-ended with a 3 mm J on one end and a straight, floppy tip on the other.
Syringe	A 10cc or 12 cc Polypropylene Syringe is used to aspirate air, infuse fluids (i.e., saline flushing).
Lead Delivery Catheter	Lead Delivery Catheters are used to provide a pathway through which pacing, or defibrillator leads will be introduced.

Abbreviations: cc = cubic centimeter; CSG = Coronary Sinus Guide; LVI = Lateral Vein Introducer; mm = millimeter

4.0 Risks and Warnings

4.1 Residual Risks and Undesirable Effects

The Merit Risk Management process is conducted in accordance with EN ISO 14971:2019. Risk assessment processes are utilized to analyze risks associated with the use of Merit devices, including possible misuses of a device. This ensures that all foreseeable potential failure modes and associated risks have been considered and addressed in the device design and/or production quality system. The process involves the following key aspects:

- Identifying potential failure modes, and their likely causes and effects
- Evaluating the probability of occurrence, degree of severity and relative detectability of each failure
- Identifying controls and preventive measures

All possible risk control measures have been implemented and verified and the CSGs and LVIs have met all applicable regulations and standards. Through the clinical evaluation process, information relative to the clinical state-of-the-art and potential adverse events are identified based on a review of the pertinent clinical evidence.

Intended clinical benefits:

> The subject devices have no direct clinical benefit to the patient. The indirect clinical benefit to the patient is the successful delivery and placement of cardiac pacing catheters for the treatment of cardiac arrhythmias.

The subject devices are used for the introduction of various types of pacing or defibrillator leads and catheters.

Articles published between 01-January-2012 and 09-January-2023 were reviewed. Based on the literature, the subject devices have been successfully used to introduce of various types of pacing leads and other tools to deliver cardiac resynchronization therapy for patients with congestive heart failure. For the clinical evaluation, the performance outcomes were defined as follows:

> **Technical success:** Successful target access and catheter/lead placement†
>
> † In cases where only procedural success is reported, technical success was assumed.

Technical success rates from the clinical literature and Post Market Clinical Follow-Up (PMCF) are very high. Overall technical success was 98.9% for the CSGs and LVIs and 95.9% for the benchmark devices.

The potential complications/adverse events related to the subject device as identified in the Instructions For Use (IFU) are summarized in Table 11. In addition, the device-related events identified in the literature and Post Market Clinical Follow-Up (PMCF), and the corresponding risk assessment harms are presented in Table 12.

Table 11 CSGs and LVIs: Potential Complications

Product Configuration	Potential AEs
CSGs	
SafeSheath CSG Worley Advanced CSG Worley Advanced Right Sided CSG	Complications which may be associated with the use of catheter introducer systems include, but are not limited to, the following: • Air embolism • Bleeding • Cardiac arrhythmias • Cardiac tamponade

Product Configuration	Potential AEs
	• Damage to the heart valves • Hematoma at the puncture site • Infection • Local tissue response, fibrotic tissue formation • Myocardial damage • Myocardial infarction • Plaque dislodgement • Pneumothorax • Stroke and death • Thrombus formation/emboli • Vascular occlusion • Venous or cardiac perforation
LVIs	
SafeSheath Worley LVI (5.5F) SafeSheath Worley LVI (7F) Worley Advanced LVI (5.5F) Worley Advanced LVI (7F) Situs Target Situs LDS 2	Complications which may be associated with the use of catheter introducer systems include, but are not limited to, the following: • Air embolism • Bleeding • Cardiac arrhythmias • Cardiac tamponade • Damage to the heart valves • Hematoma at the puncture site • Infection • Local tissue response, fibrotic tissue formation • Myocardial damage • Myocardial infarction • Plaque dislodgement • Pneumothorax • Stroke and death • Thrombus formation/emboli• • Vascular occlusion • Venous or cardiac perforation

Abbreviations: CSG = Coronary Sinus Guide; F = French; LVI = Lateral Vein Introducer

Table 12 Adverse Events: Clinical Literature Data

Complications from the Clinical Literature Data	Incident Rate n/N (%)	Device Related	Procedure Related	IFU Complications	Identified Harms from Risk Management File	Typical Timing
Clinical Literature – CSGs and LVIs						
CS dissection[1]	1/273 (0.4%)		X	Not applicable	• Not applicable	Periprocedural
LV-lead dislodgment[1]	1/273 (0.4%)		X	Not applicable	• Not applicable	3 weeks post-procedure
Infection[1]	1/273 (0.4%)		X	Not applicable	• Not applicable	3 weeks post-procedure
PMCF – CSGs and LVIs						
Bleeding	2/273 (0.7%)	X	X	Bleeding	• Hemorrhage	Not reported
Cardiac arrhythmia	5/273 (1.8%)	X	X	Cardiac arrhythmia	• Cardiac Event	Not reported
Infection	1/273 (0.4%)	X		Infection	• Infection	Not reported
Vascular occlusion	1/273 (0.4%)	X		Vascular occlusion	• Foreign body, vascular	Not reported
Benchmark Devices						
Pocket hematoma[2,3]	4/266 (1.5%)		X	Not applicable	• Not applicable	< 24 hours
Sheath breakage[4]	1/266 (0.4%)	X		Air Embolism	• Foreign body, vascular	Periprocedural

The CSGs and LVIs have been used with a high level of safety for the introduction of various types of pacing or defibrillator leads and catheters in patients. Based on the literature data and PMCF data, the reported device-related Adverse Event (AE) rate for the subject devices is 0.7%. Safety data for the subject devices from the literature data, PMCF data, and for comparable benchmark guidewires from the clinical literature are summarized in Table 13. The overall device-related AE rate for the comparable benchmark devices is 0.4%.

Table 13 Comparative Adverse Event Rates

Attribute	Subject Devices	Benchmark Devices
AE Rate	2/273 (0.7%)	1/266 (0.4%)

This assessment accounts for the various risk factors associated with the CSGs and LVIs. Given that the complication rates are low and generally transient in nature, patients are assumed to accept the risks associated with endovascular diagnostic or interventional procedures based on the probable benefits.

In summary, the safety of the subject device has been substantiated via objective evidence from post-market clinical follow-up data and clinical literature data. The results of the clinical risk/safety analysis demonstrate that the subject device meets the established acceptance criteria with respect to safety and exhibit an acceptable overall safety profile. No new safety concerns specific to the subject device were identified in this evaluation, and the rates reported in the literature are consistent with available data for state-of-the-art alternative treatments.

4.2 Warnings and Precautions

The labeled warnings and precautions for the CSGs and LVIs device configurations are summarized in Table 14.

Table 14 CSGs and LVIs: Warnings & Precautions

Product Configuration	Labeling
CSGs	
SafeSheath CSG Worley Advanced CSG Worley Advanced Right Sided CSG	**Warnings**
	• This product is sensitive to light. Do not use if stored outside the protective outer carton. Store in a cool, dark, and dry place. • Infusion through the side port can be done only after all air is removed from the unit. Improper use of the transvalvular insertion tool (TVI) can cause air embolism and back bleeding. • Do not use this device in patients who cannot be appropriately anticoagulated. • After use, dispose of device in a manner consistent with standard protocols for biohazard waste disposal.
	Precautions
	• Do not alter this device in any way. • Read instructions prior to use. • For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

Product Configuration	Labeling
	• Aspiration and saline flushing of the sheath, dilator, and valve should be performed to help minimize the potential for air embolism and clot formation. • Indwelling introducer sheaths should be internally supported by a catheter, pacing lead, or dilator.
	• Dilators, wires, catheters, and pacing leads should be removed slowly from the sheath. Rapid removal may damage the valve members resulting in blood flow though the valve. Never advance or withdraw guide wire or sheath when resistance is met. Determine cause by fluoroscopy and take remedial action. • When injecting or aspirating through the sheath, use the side port only. • When using the TVI always keep the exposed proximal end covered to prevent air embolization and back bleeding.
LVIs	
SafeSheath Worley LVI (5.5F) Worley Advanced LVI (5.5F)	**Warnings**
	• This product is sensitive to light. Do not use if stored outside the protective outer carton. Store in a cool, dark, and dry place. • Infusion through the side port can be done only after all air is removed from the unit. Improper use of the transvalvular insertion tool (TVI) can cause air embolism and back bleeding. • Do not use this device in patients who cannot be appropriately anticoagulated. • After use, dispose of device in a manner consistent with standard protocols for biohazard waste disposal.
	Precautions
	• Do not alter this device in any way. • Read instructions prior to use. • For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. • Aspiration and saline flushing of the sheath, dilator, and valve should be performed to help minimize the potential for air embolism and clot formation. • Indwelling introducer sheaths should be internally supported by a catheter, electrode pacing lead, or dilator wire. • Dilators, wires, catheters, and pacing leads should be removed slowly from the sheath. Rapid removal may damage the valve members resulting in blood flow through the valve. Never advance or withdraw guide wire or sheath when resistance is met. Determine cause by Fluoroscopy and take remedial action. • When injecting or aspirating through the sheath, use the side port only. • When using the TVI always keep the exposed proximal end covered to prevent air embolization and back bleeding.

Product Configuration	Labeling
SafeSheath Worley LVI (7F) Worley Advanced LVI (7F)	**Warnings** • This product is sensitive to light. Do not use if stored outside the protective outer carton. Store in a cool, dark, and dry place. • Infusion through the side port can be done only after all air is removed from the unit. Improper use of the transvalvular insertion tool (TVI) can cause air embolism and back bleeding. • Do not use this device in patients who cannot be appropriately anticoagulated. • After use, dispose of device in a manner consistent with standard protocols for biohazard waste disposal. **Precautions** • Do not alter this device in any way. • Read instructions prior to use. • For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. • Aspiration and saline flushing of the sheath, dilator, and valve should be performed to help minimize the potential for air embolism and clot formation. • Indwelling introducer sheaths should be internally supported by a catheter, electrode pacing lead, or dilator wire. • Dilators, wires, catheters, and pacing leads should be removed slowly from the sheath. Rapid removal may damage the valve members resulting in blood flow through the valve. Never advance or withdraw guide wire or sheath when resistance is met. Determine cause by Fluoroscopy and take remedial action. • When injecting or aspirating through the sheath, use the side port only. • When using the TVI always keep the exposed proximal end covered to prevent air embolization and back bleeding.
Situs Target	**Warnings** • This product is sensitive to light. Do not use if stored outside the protective outer carton. Store in a cool, dark, and dry place. • Infusion through the side port can be done only after all air is removed from the unit. Improper use of the Transvalvular Insertion Tool (TVI) can cause air embolism and back bleeding. • Do not use this device in patients who cannot be appropriately anticoagulated. • After use, dispose of device in a manner consistent with standard protocols for biohazard waste disposal. **Precautions** • Do not alter this device in any way. • Read instructions prior to use. • For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or

Product Configuration	Labeling
	cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. • Aspiration and saline flushing of the sheath, dilator, and valve should be performed to help minimize the potential for air embolism and clot formation. • Indwelling introducer sheaths should be internally supported by a catheter, electrode pacing lead, or dilator wire. • Dilators, wires, catheters, and pacing leads should be removed slowly from the sheath. Rapid removal may damage the valve members resulting in blood flow through the valve. Never advance or withdraw guide wire or sheath when resistance is met. Determine cause by fluoroscopy and take remedial action. • When injecting or aspirating through the sheath, use the side port only. • When using the TVI always keep the exposed proximal end covered to prevent air embolization and back bleeding.
Situs LDS 2	**Warnings** • This product is sensitive to light. Do not use it if stored outside the protective outer carton. • Store in a cool, dark, and dry place. • Infusion through the side port can be done only after all air is removed from the unit. Improper use of the transvalvular insertion tool (TVI) can cause air embolism and back bleeding. • Do not use this device in patients who cannot be appropriately anticoagulated. • After use, dispose of device in a manner consistent with standard protocols for biohazard waste disposal.
	Precautions • Do not alter this device in any way. • Read instructions prior to use. • For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. • Aspiration and saline flushing of the guide catheter, dilator, and valve should be performed to help minimize the potential for air embolism and clot formation. • Indwelling introducer sheaths should be internally supported by a catheter, electrode pacing lead, or dilator wire. • Dilators, wires, catheters, and pacing leads should be removed slowly from the guide catheter. Rapid removal may damage the valve components resulting in blood flow though the valve. Never advance or withdraw guide wire or guide catheter when resistance is met determine cause by fluoroscopy and take remedial action • When injecting or aspirating through the guide catheter, use the side port only. • When using the TVI always keep the exposed proximal end covered with your thumb to prevent air embolization and back bleeding.

Abbreviations: cm = centimeter; CSG = Coronary Sinus Guide; F = French; LVI = Lateral Vein Introducer; mm = millimeter; TVI = transvalvular Insertion

4.3 Other Relevant Safety Aspects

The Corrective and Preventive Action (CAPA) process for the subject devices is conducted under GPS 999.092. In accordance with the procedure, a risk assessment is conducted to evaluate the significance of the risk of the issue and its associated impact. If the CAPA requires escalation, the appropriate management representatives are required to review and assess the escalation based on their scope of responsibility.

Merit has created 1 Corrective Action Reports (CARs) during the reporting period for this report (Table 15).

Table 15 Corrective Action Report Summary

CAR Number	CAR Title	CAR Originate Date	CAR Description	CAR Status
20-02683	Complaint Trend	18 August 2020	When the customer splits the sheath, the foam does not split in half. the customer must cut manually.	Closed

Abbreviations: CAR = Corrective Action Report

There have been no field escalations or product recalls during the period of this report.

5.0 Summary of Clinical Evaluation and Postmarket Clinical Follow-up (PMCF)

5.1 Summary of Clinical Data for the Equivalent Device

To adequately support S&P with sufficient clinical data for the CSGs and LVIs, equivalence was established between the following subject devices:

- The SafeSheath CSG (subject device) plus the Worley Advanced Right-Sided CSG (subject device) and the Worley Advanced CSG (equivalent comparator)
- The SafeSheath Worley LVI (5.5F) (subject device) and the Worley Advanced LVI (5.5F) (equivalent comparator)
- The SafeSheath Worley LVI (7F) (subject device) and the Worley Advanced LVI (7F) (equivalent comparator)

The clinical, technical, and biological characteristics were analyzed between the subject devices and equivalent comparators and no differences are anticipated to significantly affect clinical safety or performance. In accordance with MEDDEV 2.7/1 Rev 4 Appendix A1, MDCG 2020-5, and MDR, Annex XIV, Part A, Section 3, the clinical, technical, and biological equivalence of the above-listed subject and equivalent comparator devices has been established through this analysis. Therefore, clinical data collected in this evaluation pertaining to the equivalent devices may be used to support the safety and performance of the subject devices. All clinical data for the equivalent and subject devices is listed in Section 5.3.

5.2 Summary of Clinical Investigations of the Subject Device

Conformity of the CSGs and LVIs is pending assessment and endorsement by the applicable notified body. No pre-market or post-market clinical investigations of the device were conducted in the EU prior to the initial CE marking. A summary of all available clinical data for the CSGs and LVIs is provided in Section 5.4.

5.3 Summary of Clinical Data from Other Sources

Scientific Literature Review

A review of relevant clinical literature for the CSGs and LVIs was conducted for the time period of 01-January-2012 and 09-January-2023. Five articles were identified as pivotal data. Table 16 summarizes the study characteristics of the pivotal articles. Table 17 summarizes the safety and performance of the CSGs and LVIs in the articles that were reviewed.

Table 16 CSGs and LVIs: Summary Study Characteristics

Author (Year) LOE Study Type	Primary Clinical Indication	Device Application, Access	Patients, n/N (%)*	Devices Used (N)	Gender (M/F) Age (years)	Follow-up
Worley Advanced CSG						
Foerst (2017)[5] LOE: C Case report	BiV pacemaker upgrade	Introduction of lead Subclavian vein access	2/2 (100%)	Worley sheath§ (2)	2M / 0F Patient 1: 63 years Patient 2: 88 years	NR
SafeSheath CSG						
Kumar (2018)[6] LOE: C Case report	Complete heart block	Introduction of pacemaker lead Subclavian vein access	1/1 (100%)	SafeSheath CSG (1)	0M / 1F 47 years	NR
Golian (2016)[7] LOE: C Case series	Patient 2: ischemic cardiomyopathy	Introduction of pacemaker lead Subclavian vein access	1/1 (100%)	9F SafeSheath (1)‡	1M / 0F Patient 2: 57 years	NR
Worley (2012)[8] LOE: C Retrospective, single-center	Patients requiring CRT	Introduction of lead Access NR	11/11 (100%)	9F SafeSheath CSG (11)	NR	6–10 months

Author (Year) LOE Study Type	Primary Clinical Indication	Device Application, Access	Patients, n/N (%)*	Devices Used (N)	Gender (M/F) Age (years)	Follow-up
SafeSheath Worley LVIs (7F)						
Golian (2016)[7] LOE: C Case series	Patient 1: AV block	Introduction of pacemaker lead Subclavian vein access	1/1 (100%)	7F, 25-cm SafeSheath (1)	1M / 0F Patient 1: 84 years	NR
Worley Catheters						
Vinther (2021)[1] LOE: A2 Prospective, randomized controlled study, single-center	HF and LBBB	Introduction of lead Access NR	32/50 (64%)	Worley catheters (32)	24M / 7F** Mean age 67.4 ± 9.1 years**	6 months

* n = number of patients treated with device; N = total patients

§ Device reported as "Worley Sheath", most likely referring to the Worley Advanced CSG due to reported French size (9F) and/or use in implanting coronary sinus lead

‡ Reported device sizes and application likely indicate a SafeSheath LVI was used in patient 1 and SafeSheath CSG in patient 2

** Does not include 1 patient who was switched over to His-CRT

Abbreviations: AV = atrioventricular; BiV = biventricular; cm = centimeter; CRT = cardiac resynchronization therapy; CSG = Coronary Sinus Guide; F = female; F = French; HF = heart failure; ICD = implantable cardioverter defibrillator; LBBB = left bundle branch block; LOE = level of evidence; LVI = Lateral Vein Introducer; M = male; NR = not reported

Table 17 CSGs and LVIs: Safety and Performance Summary

Author (Year) LOE Study Type	Device	Technical Success n/N (%)	Device-Related AE Rate n/N (%)	Complications	Other Notes
Worley Advanced CSG					
Foerst (2017)[5] LOE: C Case report	Worley sheath (Merit Medical)	2/2 (100%)	NR	NR	Device reported as "Worley Sheath", most likely referring to the Worley Advanced CSG due to use in implanting CS lead. Device size reported as 9F in case 2.
SafeSheath CSG					
Kumar (2018)[6] LOE: C Case report	SafeSheath CSG (Merit Medical)	1/1 (100%)	NR	NR	Complications were not discussed.
Golian (2016)[7] LOE: C Case series	9F SafeSheath (Pressure Products)	1/1 (100%)	0/1 (0%)	No early complications	Patient had subclavian vein occlusion requiring percutaneous revascularization prior to lead implantation. Reported device size and application likely indicate a SafeSheath CSG was used in patient 2.

Author (Year) LOE Study Type	Device	Technical Success n/N (%)	Device-Related AE Rate n/N (%)	Complications	Other Notes
Worley (2012)[8] LOE: C Retrospective, single-center	9F SafeSheath CSG (Pressure Products)	11/11 (100%)	0/11 (0%)	No complications	There were no lead dislodgements or lead fractures. Time for CS lead placement was <5 min in all patients. There were no complications including CS blood flow problems, lead function, or venous obstruction.
SafeSheath Worley LVIs (7F)					
Golian (2016)[7] LOE: C Case series	7F, 25-cm SafeSheath (Pressure Products)	1/1 (100%)	0/1 (0%)	No early complications	Patient had subclavian vein occlusion requiring percutaneous revascularization prior to lead implantation. Reported device size and application likely indicate a SafeSheath LVI was used in patient 1.
Worley Catheters					
Vinther (2021)[1] LOE: A2 Prospective, randomized controlled study, single-center	Worley catheters (Merit Medical)	31/32 (96.9%)	0/32 (0%)	CS ostium dissection: 1 Dislodgement of the LV lead: 1 Infection: 1	In one patient in the BiV-CRT group (group that received the subject device), CS access was difficult and resulted in a small CS dissection before operators switched to placing a His lead instead. At follow-up, 1 patient experienced dislodgment of the LV lead and another patient experienced infection with positive blood cultures for *Staphylococcus aureus*.

Abbreviations: AE = adverse event; BiV-CRT = biventricular cardiac resynchronization therapy; cm = centimeter; CS = coronary sinus; CSG = Coronary Sinus Guide; EP = electrophysiology; F = French; LOE = level of evidence; LV = left ventricular; LVI = Lateral Vein Introducer; min = minute; NR = not reported

Proactive Post-Market Clinical Follow-up

A total of 228 cases/data were collected for the CSGs and LVIs from healthcare professionals. The dates of the surveys ranged from 30 September 2022 to 01 December 2022. Target locations for the subject devices were the CS in 134 patients (86 CSG, 48 LVI) and the lateral vein in 94 patients (29 CSG, 65 LVI). The S&P rates of CSGs and LVIs are summarized in Table 18. The subject devices were successfully placed in 99.1% of post-market clinical follow-up (PMCF) cases. Two reports of unsuccessful access to the target location were reported. The first patient had failed access to the coronary sinus using the CSG as a result of the coronary sinus anatomy. The second patient had failed access to the coronary sinus using the LVI as a result of vessel size. A total of 2 device-related AEs occurred in patients for an overall PMCF device-related AE rate of 0.9%. Both patients were treated with the CSG. Reported device-related AEs included bleeding and infection in one patient and cardiac arrythmia and vascular occlusion in a second patient. No additional details were provided in the PMCF survey response.

Table 18 Summary PMCF Performance and Safety Data

Device	Technical Success n/N (%)	Device-Related AE Rate n/N (%)
CSG		
Worley Advanced CSG	114/115 (99.1%)	2/115 (1.7%)
LVI		
Worley Advanced LVI	79/79 (100%)	0/79 (0%)
Situs Target	10/11 (90.9%)	0/11 (0%)
Situs LDS 2	23/23 (100%)	0/23 (0%)
LVI Overall	112/113 (99.1%)	0/113 (0%)
Overall	**226/228 (99.1%)**	**2/228 (0.9%)**

Abbreviations: AE = adverse event; CSG = Coronary Sinus Guide; F = French; LVI = Lateral Vein Introducer; NR = not reported

5.4 Overall Summary of Clinical Performance and Safety

Data to support the safety and performance of the CSGs and LVIs have been analyzed and provide evidence to support all the safety and performance outcomes. The clinical data demonstrate that the risks associated with the CSGs and LVIs are acceptable when weighed against the clinical benefits to the patient. All introduction of pacing leads and tools modalities have a risk of complications and/or failure, and the risks for an individual are an unpredictable combination of patient, the primary surgical/interventional procedure, and device-related interactions. The subject devices are intended to facilitate introduction of pacing leads and tools in patients who require or elect pacemaker implantation or CRT as their treatment modality. The subject devices were deemed consistent with the SOA benchmark devices for S&P in this patient population. The devices in the CSGs and LVIs are well established, having demonstrated acceptable S&P profile subject devices were first commercialized in 2012. Based on design verification/validation testing results, S&P outcomes in the literature, and Post-Market Surveillance (PMS) data, there are no known uncertainties regarding S&P of the subject devices or the intended use. The known risks are well-documented, and the risk of occurrence is low and not associated with any safety or performance signals.

The clinical indications identified in the IFUs for the CSGs and LVIs product configurations are supported by the clinical evidence presented in the CER. Furthermore, the IFUs contain correct and sufficient information to reduce the risk of user error as well as information on residual risks and their management as supported by clinical evidence (e.g., handling and use instructions, description of risks, warnings, precautions, cautions, indications and contraindications, and instructions for managing foreseeable unwanted situations). The overall clinical benefits to the patient of the CSGs and LVIs substantially outweigh any residual risks associated with their clinical use. In accordance with the Acceptable Benefit/Risk Requirement, an evaluation of clinical data and informational materials demonstrates the following:

- The positive impact to patient health and well-being through the use of the CSGs and LVIs to facilitate undergoing introduction of pacing leads and tools is fully described.
- Specific measurable clinical outcomes (e.g., device-related AEs, technical success) are associated with the use of the CSGs and LVIs.
- The technical success rate for the CSGs and LVIs is high and comparable to alternative therapies/devices.
- The device-related AE rate for the CSGs and LVIs are low, and these rates are consistent with the SOA benchmark devices in all cases.
- The incidence of AEs based on PMS/vigilance reporting as well as the lack of CSGs and LVIs field actions/recalls is considered clinically acceptable.

Based on a review of the clinical data, the overall benefits to patients of using the device for its intended purpose outweigh the overall risks. The risk/benefit assessment for the CSGs and LVIs is summarized in Table 19.

Table 19. Summary of Benefit/Risk Assessment

Summary of the Benefit(s)	Summary of the Risk(s)	Summary of Other Factors
CSGs		
The CSGs are intended for the introduction of various types of pacing or defibrillator leads and catheters. The CSG devices have no direct clinical benefit to the patient. The indirect clinical benefit to the patient is the successful delivery and placement of cardiac pacing catheters for the treatment of cardiac arrhythmias. CSGs Technical success rate: 99.2% Benchmark CSGs (SOA) Technical success rate: 95.9% Subject device technical success rate is non-inferior to the comparable benchmark catheters at a 95% confidence level.	No device-related AEs occurred in the clinical literature. PMCF data reported device-related AEs in 2 patients, which included bleeding, infection, vascular occlusion, and cardiac arrythmia. None of the device-related AEs required additional treatment. Subject Device Device-related AE rate from clinical literature: 0/12 (0%) Device related AE rate from PMCF: 2/115 (1.7%) Global complaint rate from PMS: 0.0282% Benchmark Competitor Device-related AE rate from clinical literature: 1/266 (0.4%) Device-related AE rate for the subject device is non-inferior to benchmark competitor devices.	The CSGs provide a safe and effected method for introduction of various types of pacing or defibrillator leads and catheters.

Summary of the Benefit(s)	Summary of the Risk(s)	Summary of Other Factors
LVIs		
The LVIs are intended for the introduction of various types of pacing or defibrillator leads and catheters. The LVI devices have no direct clinical benefit to the patient. The indirect clinical benefit to the patient is the successful delivery and placement of cardiac pacing catheters for the treatment of cardiac arrhythmias. LVIs Technical success rate: 98.6% Benchmark LVIs (SOA) Technical Success rate:95.9% Subject device technical success rate is non-inferior to the comparable benchmark catheters at a 95% confidence level.	No device-related AEs occurred in the clinical literature or PMCF data. Subject Device Device-related AE rate from clinical literature: 0/33 (0%) Device related AE rate from PMCF: 0/113 (0%) Global complaint rate from PMS: 0.0716% Benchmark Competitor Device-related AE rate from clinical literature: 1/266 (0.4%) Device-related AE rate for the subject device is non-inferior to benchmark competitor devices.	The LVIs provide a safe and effected method for introduction of various types of pacing or defibrillator leads and catheters.

5.5 Postmarket Clinical Follow-up (PMCF)

The need to conduct PMCF activities is subject to annual review as part of the PMS process and also based on emerging data. The Merit Tech Team group actively monitors all after-market field data. All data are subject to a risk review from which a determination is made regarding the requirements for PMCF.

6.0 Diagnostic or Therapeutic Alternatives

6.1 Review of Medical Conditions

6.1.1 Heart Failure

Heart failure (HF) is a complex clinical syndrome caused from functional or structural impairment of ventricular filling or ejection.[9] Typical symptoms of HF include dyspnea orthopnea, fatigue, limited exercise capability, and fluid retention that can lead to pulmonary and/or splanchnic congestion and/or peripheral edema.[9] However, not all patients with HF experience symptoms. HF can be caused by a variety of conditions including disorders of the pericardium, myocardium, endocardium, heart valves, or great vessels, specific metabolic conditions, and arrhythmias.[9,10] As presented in Table 20, the American College of Cardiology Foundation/American Heart Association (ACCF/AHA) describes stages of HF with disease development and progression, and the New York Heart Association (NYHA) describes classifications of HF with disease symptoms and

ability to exercise.[9] HF can also be classified based on left ventricular ejection fraction (LVEF). The 2 main classifications are HF with preserved ejection fraction (HFpEF) when ejection fraction (EF) is ≥50% and HF with reduced EJ (HFrEF) when EF is less than ≤40%.[9] HF with mid ranged EF (HFmrEF) has recently been used to classify patients with EF ranging from 40 to 49%.[10] HFpEF and HFrEF classifications vary in patient demographics, comorbidities, disease prognosis, and recommendation of therapies.[9]

Table 20 ACCF/AHA Stages of HF and NYHA Functional Classification[9]

ACCF/ AHA Stages of HF		NYHA Functional Classification	
A	At high risk for HF but without structural heart disease or symptoms of HF	None	
B	Structural heart disease but without signs or symptoms of HF	I	No limitation of physical activity. Ordinary physical activity does not cause symptoms of HF.
C	Structural heart disease with prior or current symptoms of HF	I	No limitation of physical activity. Ordinary physical activity does not cause symptoms of HF.
		II	Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in symptoms of HF.
		III	Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in symptoms of HF.
		IV	Unable to carry on any physical activity without symptoms of HF, or symptoms of HF at rest.
D	Refractory HF requiring specialized interventions	IV	Unable to carry on any physical activity without symptoms of HF, or symptoms of HF at rest.

Abbreviations: ACCF = American College of Cardiology Foundation; AHA = American Heart Association; HF = heart failure; NYHA = New York Heart Association

HF is a prominent disease worldwide, affecting 1% to 2% of adults in developed countries.[10] From 2013 to 2016, HF affected an estimated 6.2 million American adults ≥20 years of age, compared to 5.7 million adults in the period between 2009 to 2012.[11] Prevalence is expected to increase 46% from 2012 to 2030 in people over 18 years old.[12] Factors that increase the risk of HF include the following:

- Increased age: HF affects more than 10% of adults greater than 70 years old[10]
- Sex: Risk of developing HF is 33% for 55-year-old males and 28% for 55-year-old females[10]
- Hypertension[11]
- Obesity[11]
- History of cardiovascular disease[12]

African Americans are at highest risk for developing HF, followed by Hispanic, Caucasians, and Chinese Americans.[11] HFpEF is more common than HFrEF (50% of diagnoses compared to 39%). Despite improved survival following HF diagnosis, mortality rates remain high with overall 5-year mortality rates of 52.6% and more specifically, 24.4% and 54.4% for 60-year-olds and 80-year-olds, respectively.[12]

6.1.2 Congenital Heart Failure

Definitions of congenital heart disease (CHD) differ among guidelines and reports.[13] The ACC/AHA defines CHD as wide variety structural cardiac defects present prior to birth and developed during fetal cardiac development. The European Society of Cardiology (ESC) definition of CHD also includes inherited disorders and abnormalities that may have led to cardiac abnormalities, such as Marfan syndrome or hypertrophic cardiomyopathy (HCM), or anatomic variants such as patent foramen ovale.[14,15] CHD can be classified by disease complexity as mild, moderate, or severe (see Table 21). Only 15% of CHD etiology is known, whereas most cases (8% to 10%) are due to chromosomal aneuploidies causing malformation syndromes such as Down syndrome, trisomy 13, trisomy 18, Turner syndrome, and DiGeorge syndrome. An estimated 3% to 5% of CHD cases are due to single gene defect such as Alagille syndrome, Holt-Orman syndrome, and Noonan syndrome, followed by 2% of cases caused by environmental factors. The 2 major risk factors of CHD are maternal diabetes and phenylketonuria. Additional risk factors include maternal obesity, alcohol use, rubella infection, febrile illness, use of drug such as thalidomide and retinoic acid, and exposure to organic solvents.[13,16]

Table 21 ESC Classification of CHD complexity[15]

Mild:
• Isolated congenital aortic valve disease and bicuspid aortic disease • Isolated congenital mitral valve disease (except parachute valve, cleft leaflet) • Mild isolated pulmonary stenosis (infundibular, valvular, supravalvular) • Isolated small ASD, VSD, or PDA • Repaired secundum ASD, sinus venosus defect, VSD, or PDA without residuae or sequelae, such as chamber enlargement, ventricular dysfunction, or elevated PAP
Moderate: (Repaired or unrepaired where not specified; alphabetical order)
• Anomalous pulmonary venous connection (partial or total) • Anomalous coronary artery arising from the PA • Anomalous coronary artery arising from the opposite sinus • Aortic stenosis - subvalvular or supravalvular • AVSD, partial or complete, including primum ASD (excluding pulmonary vascular disease) • ASD secundum, moderate or large unrepaired (excluding pulmonary vascular disease) • Coarctation of the aorta • Double chambered right ventricle

• Ebstein anomaly • Marfan syndrome and related HTAD, Turner Syndrome • PDA, moderate or large unrepaired (excluding pulmonary vascular disease) • Peripheral pulmonary stenosis • Pulmonary stenosis (infundibular, valvular, supravalvular), moderate or severe • Sinus of Valsalva aneurysm/fistula • Sinus venosus defect • Tetralogy of Fallot repaired • Transposition of the great arteries after arterial switch operation • VSD with associated abnormalities (excluding pulmonary vascular disease) and/or moderate or greater shun
Severe: (Repaired or unrepaired where not specified; alphabetical order)
• Any CHD (repaired or unrepaired) associated with pulmonary vascular disease (including Eisenmenger syndrome) • Any cyanotic CHD (unoperated or palliated) • Double-outlet ventricle • Fontan circulation • Interrupted aortic arch • Pulmonary atresia (all forms) • Transposition of the great arteries (except for patients with arterial switch operation) • Univentricular heart (including double inlet left/right ventricle, tricuspid/mitral atresia, hypoplastic left heart syndrome, any other anatomic abnormality with a functionally single ventricle) • Truncus arteriosus • Other complex abnormalities of atrioventricular (AV) and ventriculoarterial connection (i.e., crisscross heart, heterotaxy syndromes, ventricular inversion).

Abbreviations: ASD = atrial septal defect; AV = atrioventricular; AVSD = atrioventricular septal defect; CHD = congenital heart disease; HTAD = heritable thoracic aortic disease; PA = pulmonary artery; PAP = pulmonary artery pressure; PDA = patent ductus arteriosus; VSD = ventricular septal defect

Although prevalence of CHD varies geographically, on average 9 of 1000 newborns (range: 3 to 10 cases per 1000 newborns) are diagnosed with CHD worldwide.[16] The number of severe CHD cases is decreasing in developed countries due to fetal screening and pregnancy termination, yet cases are rising globally.[15] For every 3 of 1000 births, catheter- or surgical- based treatment is required early in life.[17] Additionally, due to surgical and technological advancement, greater than 90% of CHD patients survive to adulthood (at least 18 years old).[15] Long-term survival into adulthood varies based on CHD complexity and is estimated to be 95%, 90%, and 80% for mild, moderate/severe, and severe complexity, respectively; however, specific types of complexities may further affect survival.[17] Furthermore, early intervention does not typically cure CHD; many adult CHD patients incur complications including arrhythmias, HF, endocarditis, pulmonary hypertension, and need for reintervention.[16]

6.1.3 Cardiomyopathy

The AHA and ESC define cardiomyopathy as myocardial disorders leading to functional and structural abnormalities. Diseases such as coronary artery disease, hypertension, valvular disease, and CHD cannot be the cause of the myocardial abnormality for the disorder to considered be cardiomyopathy.[12] Cardiomyopathy can be divided based on morphological and functional phenotypes including arrhythmogenic right ventricular cardiomyopathy (ARVC), dilated cardiomyopathy (DCM), hypertrophic cardiomyopathy (HCM), restrictive cardiomyopathy (RCM), and unclassified cardiomyopathies such as left ventricular non-compaction (LVNC) or takotsubo cardiomyopathy.[18] These subtypes are then further classified into genetic, non-genetic, or mixed etiologies. HCM is most commonly caused by genetic mutations of sarcomere proteins, accounting for approximately 20-30% of cases, and genetic mutations leading to glycogen storage diseases leading to myocardial thickening.[12] HCM is usually asymptomatic; symptomatic HCM can present as atypical chest pain or, if DCM or RCM, symptoms present similar to HFrEF (i.e., peripheral edema, fatigue, orthopnea, dyspnea, presyncope, and cardiac ischemia.[19] DCM has a mixed etiology and may occur from environmental, infectious, and systemic factors but 25% to 35% cases are genetic.[19] Approximately 50% of ARVC cases are genetic mutations and in most cases of desmosomal proteins leading to myocardial thinning and ventricular wall ballooning.[19] ARVC symptoms include palpitation, syncope, and occasionally sudden cardiac death (SCD).[12] RCM is the least common representing 2% to 5% of cardiopathies cases. RCM is considered mixed etiology and presents with ascites or peripheral edema.[19]

Globally, cardiomyopathy is responsible for a death rate of 5.2 per 100,000 and prevalence rate 88.9 per 100,000 with the highest measures in Central and Eastern Europe.[12] HCM incidence rate is 1 in 250 to 500 people with similar prevalence among all races. HCM often presents in adolescents and young adults.[20] Risk of mortality for patients with HCM is 3-fold higher than age matched healthy individuals.[12] DCM typically presents in the first year of life at a rate of 4.58 per 100,000 compared to 0.34 per 100,000 in ages 1 to 18 years old.[20] Although ARVC prevalence has not been formally studies, ARVC is estimated to affect 1 in 1000 to 5000 and presents most often during adolescence and early childhood.[12] ARVC is known to increase risk of sudden SCD and patients are recommended not to participate in endurance sports.[19]

6.1.4 Myocardial Infarction

Myocardial infraction (MI) defined clinically by ESC, ACC, AHA, and World Heart Federation (WHF) is the presence of abnormal levels of cardiac biomarkers indicating myocardial injury following acute myocardial ischemia. Pathologically, MI refers to myocardial necrosis from prolonged ischemia. Ischemia symptoms including chest, upper extremity, mandibular, or epigastric discomfort, dyspnea, or fatigue can indicate the onset of MI.[21] To determine appropriate intervention, MI can be classified based on electrocardiogram (ECG) signals into ST-segment elevation MI (STEMI), non-ST-elevation MI (NSTEMI), or unstable angina. MI can also be classified based on etiology and biomarker levels, as described in Table 22.[21]

Table 22 MI Classifications[21]

MI Type	Etiology
Type 1	MI due to disruption in atherosclerotic plaque such as rupture or erosion leading to myocardium necrosis and potentially to distal coronary embolism. Elevated or reduced cTn values must be detected with at least 1 value above the 99th percentile URL.
Type 2	Ischemic myocardial injury due to disruption in balance of supply and demand of oxygen. This imbalance can be caused by limited myocardial perfusion not from plaque disruption or increased oxygen demand. Potential causes of reduced perfusion include atherosclerosis, vasospasm or coronary microvascular dysfunction, non-atherosclerotic coronary dissection, or oxygen supply and demand balance alone. Potential causes for increased oxygen demand include tachyarrhythmia or severe hypertension with or without left ventricular hypertrophy. Elevated or reduced cTn values must be detected with at least 1 value above the 99th percentile URL.
Type 3	Sudden cardiac death suspected to be caused by acute myocardial ischemia. MI can be suspected from new ischemic ECG changes or ventricular fibrillation; however, cardiac biomarker test results may not be available or indicative of MI due to death prior to blood collection or death prior to elevation in biomarkers. MI can be detected during an autopsy.
Type 4	4a: Ischemic myocardial injury due to percutaneous coronary intervention. 4b: Percutaneous coronary intervention caused MI from stent or scaffold thrombosis. 4c: Percutaneous coronary intervention caused MI from in-stent restenosis or balloon angioplasty restenosis. Elevated postprocedural cTn values must be detected with 5 times above the 99th percentile URL.
Type 5	MI caused by coronary artery bypass grafting procedure. Elevated postprocedural cTn values must be detected with 10 times above the 99th percentile URL.

Abbreviations: cTn = cardiac troponin; ECG = electrocardiogram; MI = myocardial infarction; URL = upper reference limit

From 2013 to 2016, MI has been reported to affect 3% of the entire US population with higher prevalence in males (4%) than females (2.3%). MI is most commonly present in Caucasian and African American males followed by Hispanic males.[12] Prevalence also increases with age; the highest rates are reported in patients ≥80 years old (17.3% and 12.3% for males and females, respectively). In pooled analyses of randomized controlled trials, following percutaneous coronary intervention patients with STEMI had increased risk of death for 30 days after intervention, whereas NSTEMI patients had increased risk for 2 years after intervention. STEMI patients are subject to greater in-hospital risk compared to NSTEMI patients, including death, cardiogenic shock, and bleeding: 6.4%, 4.4%, and 8.5% versus 3.4%, 1.6%, and 5.5%, respectively. Based on race and gender, mortality rates within the first 5 years after first MI range from 36% to 47%, 11% to 28%, 25% to 44%, and 55% to 64% for patients ≥45 years old, 45 to 64 years old, 65 to 74 years old, and ≥75 years old, respectively.[12]

6.1.5 Arrhythmia

Supraventricular arrhythmias (e.g., supraventricular tachycardia [SVT]) and ventricular arrhythmias (VAs) are defined as the disruption of electrical conduction within the myocardium resulting in irregular, uniform, and chaotic contraction. SVT are limited to atria causing rapid and spontaneous contraction, whereas ventricular arrythmias are confined to the ventricles causing abnormal conduction patterns, however, it may pass between both chambers.[22] The etiology of arrhythmia includes cardiac structural deformities that disrupt automaticity and conduction properties,[22] or

disruptions of cardiac function due to genetic mutations[23,24] or pharmacological agents.[24,25] Risk factors for arrythmias include cardiomyopathy, age, hypertension, obesity, sleep apnea, alcohol consumption, and diabetes.[23]

SVTs are estimated to affect 3.6 per 10,000 in the US, and approximately 6% of adults (>65 years old).[22,25] Atrial fibrillation (AF) is the most common SVT and in 2010 was reported to affect 2.6 to 6.1 million people in the US and 8.8 million people over the age of 55 in the EU. The highest prevalence was reported in the Caucasian population followed by Hispanic, African American, and Chinese people, and was more prevalent in females. In 2016, the reported mortality rate from AF was 6.5 per 100,000 people. Death rates related to complications of AF include 7.0% due to stroke, 15.1% due to progressive HF, 22.25% due to SCD, and 35.8% due to non-cardiovascular related death.[12] Additionally, AF is associated with fatigue, reduced exercise capability, and reduced quality of life.[23] VAs including ventricular fibrillation (VF) and ventricular tachycardia (VT) are reported to severely reduce or cease cardiac output[26] and are associated with increased risk of sudden cardiac arrest (SCA).[24] Progressive HF is known to increase the risk of developing ventricular arrythmias.[27,28]

6.1.6 Treatment Options and Interventions

Annually, 1.2 to 1.4 million cardiovascular implantable electronic devices (CIEDs) are implanted worldwide to improve quality-of-life and treat heart disease.[29] CIEDs include pacemakers and implantable cardiac defibrillators, which function to prevent and monitor disease.[29] However, because CIEDs are implanted for lifelong treatment,[29] complications may arise leading to lead extraction.[29,30] Studies have reported lead extraction due to infection, system upgrade, malfunction, and pain at the site.[30] Lead dislodgement is one of the most frequent complications following CIED implantation.[31,32] Mlynarski et al. 2022 examined predictors of early lead dislodgement in 14,293 patients across 14 years. Atrial lead dislodgement occurred most frequently with higher incidence in the elderly. In both male and female patients, frailty was predictive of early lead dislodgement.[31] Qin et al 2022 also examined risk factors of lead dislodgement following CIED implantation. The retrospective cohort analysis review 20,683 patients who underwent CIED implantation between 2010 and 2020. A total of 1.69% of patients experienced lead dislodgement. Variables associated with increased risk of lead dislodgement included passive fixation type, lower sense amplitude, and lower lead impedance at implant. However, lead dislodgement was not associated with significant changes in long-term risks of overall and cardiac mortality.[32]

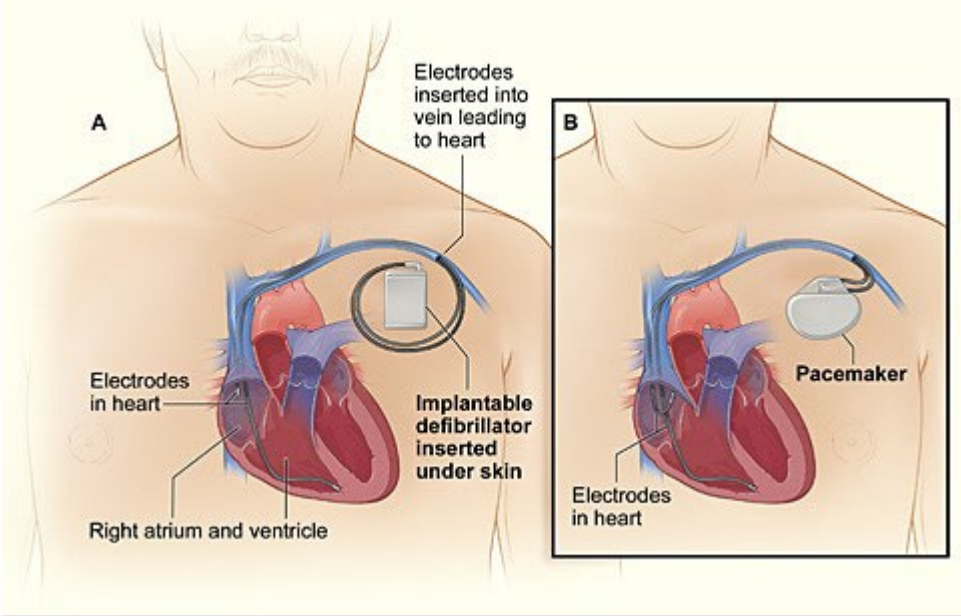
6.1.6.1 Permanent Pacemakers

A permanent pacemaker is a device placed in the chest or abdomen that sends low-energy electrical signals to the heart to help it beat at a normal rhythm and pace.[33] A pacemaker usually consists of 3 main components[33] (Figure 3):

1. A pulse generator, which generates electrical signals
2. Wires/leads, which carry the electrical signals to the chambers of the heart
3. Electrodes, which sense natural heartbeat and deliver electrical signals to the heart

Pacemakers have historically been used to treat heart arrythmias like bradycardia and tachycardia. In patients with HF who experience delay in contraction of certain segments of the LV, pacemakers can be used to coordinate electrical signaling between the 2 ventricles and help restore normal pumping action.[33,34]

Figure 3 Cross-section of chest and heart with (A) implantable cardioverter defibrillator, and (B) pacemaker[35]



6.1.6.2 Cardiac Resynchronization Therapy

In a configuration called CRT, transvenous leads are placed in the right atrium (RA) and both ventricles.[36] CRT is considered a clinically proven treatment for HF, with conclusive evidence of beneficial effects on symptoms, exercise capacity, LV function, and hospitalization/mortality risk.[37]

Current guidelines recommend that QRS width and morphology be evaluated to optimally select patients for CRT.[38] CRT is contraindicated in patients with a narrow QRS width (<130 ms), and the greatest benefits from CRT are observed in patients who have a QRS width >150 ms.[37] In terms of QRS morphology, studies have reported that the presence of left bundle branch block (LBBB) is associated with a reduction in mortality, whereas the presence of non-LBBB is associated with no clinical benefits from CRT.[37,39]

In a survey carried out between 2015 and 2016 in 272 European centers with a total of 10,664 patients, it was reported that CRT device

implantation was successful at the time of first attempt in 99.3% of patients, and periprocedural complications occurred in 5.5% of patients.[40] Major complications associated with CRT include access site bleeding and pocket hematoma (2.5%), lead dislodgement (2.9% – 10%), infection (3.3%), pneumothorax (0.66%), and CS perforation/dissection (0.28%).[41]

In CRT, the LV lead is placed in a tributary of the CS via lead delivery catheters.[42] Success rates of LV lead implantation vary between 88.0% – 92.4%, with more recent studies reporting success rates between 89.0% – 97.6%.[42] CRT success heavily depends on the positioning of the LV lead, with different LV lead locations being associated with different long-term outcomes.[43] A retrospective analysis with 2,087 patients who underwent CRT implantation reported that lateral LV lead implantation was associated with a significant decrease in risk of all-cause mortality in comparison to posterior (hazard ratio: 0.84; 95% confidence interval [CI]: 0.74 – 0.96; $P < 0.01$) and anterior (hazard ratio: 0.69; 95% CI: 0.55 – 0.87; $P < 0.01$) lead implantations.[38] In patients with challenging venous anatomies for implantation, the snare technique may be utilized.[44] A study with 262 patients compared the snare technique to the conventional technique and reported that CRT response rates (62.5% vs. 60.6%) were similar between the two groups. Additionally, no immediate complications occurred following LV lead implantation with the snare technique.[44]

CRT device implantation may not be possible in 2.5% – 10% of patients due to unstable or unsuitable lead positions and difficulties with accessing the CS.[45] The anatomy of the coronary venous system can vary significantly between patients; for example, some may have site branches that are accessible, whereas others may only have one tributary that allows for suitable lead positioning.[46] Additionally, hindrances such as kinking and valves in the veins are frequent.[47] Another limitation of CRT is clinical non-responsiveness, which is reported in 16% – 48% of patients, and may be attributed to insufficient CRT device programming, HF etiology, or suboptimal LV lead placement.[48,49]

The most challenging part of CRT is obtaining transvenous LV epicardium pacing, which starts with trying to locate and cannulate the CS.[50] CS cannulation is usually performed by advancing a hydrophilic wire through a guide catheter to the CS ostium.[51] However, inability to visualize the CS can make locating the CS ostium difficult.[51] In this case, a telescoping guide system coupled with a contrast injection system can be employed to aid with CS visualization.[51] Telescoping sheaths can help decrease procedural time and provide extra stability to the CS outer sheath during positioning of the lead.[52] Occlusive venography can also be used to facilitate lead implantation and provide information on which inner guide catheters to use for cannulation.[51]

6.1.6.3 Implantable Cardioverter Defibrillators

ICDs are devices placed in the chest or abdomen that check for arrythmias and send electrical shocks to correct arrythmias.[35] ICD implantation follows the same steps used for pacemaker implantation, and left-sided implantation is preferred due to decreased defibrillation thresholds and mortality rates.[53] ICDs deliver low-energy shocks to correct abnormally slow (bradycardia) or fast (tachycardia) heart rates. If normal heart rhythm is not restored with low-energy electrical signals, or if ventricles start to quiver instead of contracting, the ICD switches to high-energy shocks to correct irregular heartbeats.[35] Similar to pacemakers, ICDs consist of a generator, wires/leads, and electrodes to monitor and deliver electrical

signals to 1 or 2 chambers of the heart.[35] ICDs are effective in preventing SCD, but complications may arise from lead failure.[54] Studies have reported that the most common type of lead failure is high-rate sensing, which can result in unwanted shock therapy.[54]

6.1.6.4 Implantation Approach

The process of implanting a pacemaker or ICD typically involves inserting leads of the pacemaker or ICD in the chambers of the heart. Different implantation approaches are described below.

6.1.6.4.1 Transvenous Implantation

In the majority of cases, the leads and electrodes of a pacemaker or ICD are implanted in the heart transvenously via the CS, a collection of veins between the LV and LA.[55] The CS is formed when the main posterior lateral vein merges with the great cardiac vein, and includes other major tributaries such as the middle cardiac vein and inferior LV vein.[41] Leads and electrodes are commonly introduced via the subclavian vein using an introducer or sheath assembly.[56] An introducer assembly is typically supplied as a kit consisting of, at a minimum, a needle (to create a puncture in the subclavian vein), a guidewire, and a sheath (or introducer), which is a plastic tube through which the leads are inserted and advanced into the desired location in the heart.[56] While implantation of leads in the right ventricle (RV) and RA are straightforward, optimal placement of the LV lead for CRT is considered challenging,[57] and at least 11% of patients have suboptimal LV lead placements despite successful transvenous LV lead implantations.[58] Consequently, a number of tools have been developed for accurate LV lead placement. Prior to LV lead placement, the anatomy of the CS is assessed using imaging techniques such as coronary angiograms, cardiac computed tomography (CT) angiograms, cardiac magnetic resonance (MR) angiograms, and echocardiography.[57] The LV lead can sometimes be implanted using just a soft coronary guidewire, in a technique called over-the-wire.[57] Pre-shaped telescoping sheaths can be useful in engaging the vein of interest, particularly in challenging venous anatomy.[57] Other tools that facilitate successful transvenous implantation through the CS include splittable guide catheters, splittable subselector guides, balloon-tipped angiography catheters, and steerable electrophysiology (EP) catheters.[57] Additionally, in cases where there are difficulties with advancing the lead delivery sheath, snaring of the guidewire can be performed.[51] Snaring involves using a gooseneck snare to capture the distal end of the guidewire, which then allows for traction of the lead through tortuous or narrow CS branches.[51,58] A prospective study with 566 patients that used a modified snare technique when the standard LV implantation technique failed reported a success rate of 97.9%.[58] Additionally, the study also reported a lower re-intervention rate at 4 years due to a reduction in LV implant failure and dislodgement when compared to the standard technique.[58] Overall, the transvenous implant success rate for CRT via the CS has been reported to be around 90% in major clinical trials.[57]

Although less common, transvenous implantation via femoral vein access is also feasible.[59] Guerrero et al. (2017)[59] retrospectively analyzed outcomes in 50 patients who received permanent pacemakers via the femoral approach. There were no acute or long-term complications associated with the procedure, and the mortality rate in the 46 patients for whom follow-up data was available was 46% at a mean follow-up time of 50 months.

6.1.6.4.2 Alternative Implantation Approaches

In about 8% – 10% of patients undergoing CRT, transvenous implantation is not suitable due to unfavorable coronary venous anatomy, phrenic nerve stimulation, or due to scarring preventing effective pacing.[55,60] Additionally, conventional transvenous lead implantation can lead to problems such as lead fracture, lead-related endocarditis, and systematic infections.[61] In these cases, alternate methods of pacemaker or ICD implantation are often used.

The most frequently used alternative pacemaker implantation method is epicardial implantation through an open surgical approach or mini-thoracotomy. In this technique, the pacemaker electrodes are attached to the surface of the heart in a surgical procedure performed under general anesthesia.[33] In a retrospective study, Hejjel et al. (2017) investigated the feasibility of epicardial CRT via mini-thoracotomy in 57 patients.[60] The authors reported no serious intraoperative complications.[60] Estimated 5-year survival rates were 40% for patients who received a CRT defibrillator and 61% in patients who received a CRT pacemaker.[60] Other studies have reported an increased rate of complications like renal insufficiency and infections associated with epicardial lead placement.[52]

An alternative to the transvenous/epicardial system is the subcutaneous approach, which avoids vascular access and involves ICD implantation outside of the thoracic cavity.[62,63] With this approach, the electrode lead and generator are both placed subcutaneously.[63] Benefits to implantation outside of the thoracic cavity include evasion of vessel-associated problems, cardiac complications, and tissue damage.[62] Additionally, fluoroscopy time is decreased, and issues related to complex venous access can be avoided.[61,62] A registry with 985 patients who underwent subcutaneous ICD implantation reported that the complication-free rate was 99.7% and 98% after 30 days and 1 year, respectively.[61] Another study with 1,160 patients that compared subcutaneous ICD implantation to transvenous ICD implantation reported that there was a significant decrease in lead-related complications in the subcutaneous group (0.8%) compared to the transvenous group (11.5%).[61] However, there was no significant difference in the total complication rate between the subcutaneous group (13.7%) and the transvenous group (18%), and the subcutaneous group had a significantly higher rate of non-lead-associated complications (9.9%) compared to the transvenous group (2.2%).[61]

Pacemaker leads can also be implanted through the interatrial septum in an approach called the transseptal approach. The Alternate Site Cardiac Resynchronization (ALSYNC) study evaluated the feasibility and safety of the transseptal approach in 138 patients with HF.[64] Lead implant success rate was 89.4%, and freedom from complications at 6 months was observed in 82.2% of patients. A total of 23 deaths occurred during the study follow-up, but none were related to the transseptal approach. However, other studies have shown that transseptal approaches are associated with a high risk of device-related infective endocarditis requiring hazardous surgical lead extraction and repair or replacement of the mitral valve when affected.[65] Jastrzębski et al. conducted a registry-based observational study of 2,533 patients across 14 European centers who underwent permanent transseptal left bundle branch area pacing device implantation. The average success rate for lead implantation was 89.6%. Independent predictors of lead implantation failure were heart failure, broad baseline QRS, and left ventricular end-diastolic diameter. The overall complication

rate was 11.7%, and complication rate specific to the ventricular transseptal route pacing lead was 8.3%. Authors found that this alternate method was feasible as a primary pacing technique in patients with bradyarrhythmia and heart failure indications.[66]

Another approach for LV lead placement is through the LV apex, called the transapical approach.[65] This procedure is performed under general anesthesia, with access to the LV apex obtained through a mini-thoracotomy.[65,67] Advantages of this technique include the minimally invasive surgical approach, endocardial stimulation, and low risk of damage to the mitral valve.[65] Kis et al. (2017) reported on a prospective study evaluating transapical LV lead implantation in a cohort of 26 patients receiving CRT with previously failed transvenous lead placement.[65] While the mortality rate of 47% at a median follow-up of 40 ± 24.5 months was comparable to conventional CRT, there was a high rate of thromboembolic complications, with 2 cases of major acute ischemic stroke and one case of transient ischemic stroke.[65]

Finally, wireless or leadless pacemakers are gaining popularity as they eliminate the need for leads and complications associated with lead implantation.[34] Single-component wireless pacemakers contain the pulse generator and pacing and sensing electrodes in a single capsule usually delivered via a sheath through the femoral vein.[34] Multi-component systems typically comprise a small receiver electrode "seed" placed within a cardiac chamber and a subcutaneous pulse generator that generates ultrasound pulses transduced into electrical pulses by the seed.[34] Early clinical studies have shown feasibility of leadless pacemakers with high implantation success rates and low complication rates compared to patients receiving transvenous pacemakers.[34]

6.2 Professional Guidelines and Recommendations

Clinical practice guidelines and consensus statements issued by the following professional societies were reviewed to inform on pacemaker implantation and defibrillation.

- 2021 ESC Guidelines for the Diagnosis and Treatment of Acute and Chronic Heart Failure[68]
- 2017 American Heart Association/American College of Cardiology/Heart Rhythm Society (AHA/ACC/HRS) Guideline for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death[69]
- 2018 ESC Guidelines for the Diagnosis and Management of Syncope[70]
- 2018 ACC/AHA/HRS Guideline on the Evaluation and Management of Patients with Bradycardia and Cardiac Conduction Delay[71]

The relevant standard of care and clinical practice guidelines pacemaker implantation and defibrillation have been extrapolated into Table 23. These guidelines inform on appropriate and relevant safety and performance measures for target therapy and alternative therapies.

6.2.1 Standard of Care Recommendations

Table 23 Standard of Care Guidelines and Recommendations for the Management of Medical Condition

Recommendation	LOE	Grade/Strength of Recommendation
2021 ESC Guidelines for the Diagnosis and Treatment of Acute and Chronic Heart Failure[68]		
An ICD is recommended to reduce the risk of sudden death and all-cause mortality in patients who have recovered from a ventricular arrhythmia causing haemodynamic instability, and who are expected to survive for >1 year with good functional status, in the absence of reversible causes or unless the ventricular arrhythmia has occurred <48 h after a MI.	A	I
An ICD is recommended to reduce the risk of sudden death and all-cause mortality in patients with symptomatic HF (NYHA class II-III) of an ischaemic aetiology (unless they have had a MI in the prior 40 days), and an LVEF ≤35% despite ≥3 months of OMT, provided they are expected to survive substantially longer than 1 year with good functional status.	A	I
An ICD should be considered to reduce the risk of sudden death and all-cause mortality in patients with symptomatic HF (NYHA class II-III) of a non-ischaemic aetiology, and an LVEF ≤35% despite ≥3 months of OMT, provided they are expected to survive substantially longer than 1 year with good functional status.	A	IIa
Patients should be carefully evaluated by an experienced cardiologist before generator replacement, because management goals, the patient's needs, and clinical status may have changed.	B	IIa
A wearable ICD may be considered for patients with HF who are at risk of sudden cardiac death for a limited period or as a bridge to an implanted device.	B	IIb
ICD implantation is not recommended within 40 days of a MI as implantation at this time does not improve prognosis.	A	III
ICD therapy is not recommended in patients in NYHA class IV with severe symptoms refractory to pharmacological therapy unless they are candidates for CRT, a VAD, or cardiac transplantation.	C	III
CRT is recommended for symptomatic patients with HF in SR with a QRS duration ≥150 ms and LBBB QRS morphology and with LVEF ≤35% despite OMT in order to improve symptoms and reduce morbidity and mortality.	A	I
CRT rather than RV pacing is recommended for patients with HFrEF regardless of NYHA class or QRS width who have an indication for ventricular pacing for high degree AV block in order to reduce morbidity. This includes patients with AF.	A	I
CRT should be considered for symptomatic patients with HF in SR with a QRS duration ≥150 ms and non-LBBB QRS morphology and with LVEF ≤35% despite OMT in order to improve symptoms and reduce morbidity and mortality.	B	IIa
CRT should be considered for symptomatic patients with HF in SR with a QRS duration of 130-149 ms and LBBB QRS morphology and with LVEF ≤35% despite OMT in order to improve symptoms and reduce morbidity and mortality.	B	IIa
Patients with an LVEF ≤35% who have received a conventional pacemaker or an ICD and subsequently develop worsening HF despite OMT and who have a significant proportion of RV pacing should be considered for 'upgrade' to CRT.	B	IIa
CRT may be considered for symptomatic patients with HF in SR with a QRS duration of 130-149 ms and non-LBBB QRS morphology and with LVEF ≤35% despite OMT in order to improve symptoms and reduce morbidity and mortality.	B	IIb

Recommendation	LOE	Grade/Strength of Recommendation
CRT is not recommended in patients with a QRS duration <130 ms who do not have an indication for pacing due to high degree AV block.	A	III
2017 AHA/ACC/HRS Guideline for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death[69]		
In patients with ischemic heart disease, who either survive SCA due to VT/VF or experience hemodynamically unstable VT (LOE: B-R) or stable sustained VT (LOE: B-NR) not due to reversible causes, an ICD is recommended if meaningful survival greater than 1 year is expected.	B-R/B-NR	I
In patients with ischemic heart disease and unexplained syncope who have inducible sustained monomorphic VT on electrophysiological study, an ICD is recommended if meaningful survival of greater than 1 year is expected.	B-NR	I
In patients resuscitated from SCA due to coronary artery spasm in whom medical therapy is ineffective or not tolerated, an ICD is reasonable if meaningful survival of greater than 1 year is expected.	B-NR	IIa
In patients resuscitated from SCA due to coronary artery spasm, an ICD in addition to medical therapy may be reasonable if meaningful survival of greater than 1 year is expected.	B-NR	IIb
In patients with LVEF of 35% or less that is due to ischemic heart disease who are at least 40 days' post-MI and at least 90 days postrevascularization, and with NYHA class II or III HF despite GDMT, an ICD is recommended if meaningful survival of greater than 1 year is expected.	A	I
In patients with LVEF of 30% or less that is due to ischemic heart disease who are at least 40 days' post-MI and at least 90 days postrevascularization, and with NYHA class I HF despite GDMT, an ICD is recommended if meaningful survival of greater than 1 year is expected.	A	I
In patients with NSVT due to prior MI, LVEF of 40% or less and inducible sustained VT or VF at electrophysiological study, an ICD is recommended if meaningful survival of greater than 1 year is expected.	B-R	I
In nonhospitalized patients with NYHA class IV symptoms who are candidates for cardiac transplantation or an LVAD, an ICD is reasonable if meaningful survival of greater than 1 year is expected.	B-NR	IIa
An ICD is not indicated for NYHA class IV patients with medication-refractory HF who are not also candidates for cardiac transplantation, an LVAD, or a CRT defibrillator that incorporates both pacing and defibrillation capabilities.	C-EO	III
In patients with incessant VT or VF, an ICD should not be implanted until sufficient control of the VA is achieved to prevent repeated ICD shocks.	C-LD	III
In patients with NICM who either survive SCA due to VT/VF or experience hemodynamically unstable VT (LOE: B-R) or stable sustained VT (LOE: B-NR) not due to reversible causes, an ICD is recommended if meaningful survival greater than 1 year is expected.	B-R/B-NR	I
In patients with NICM who experience syncope presumed to be due to VA and who do not meet indications for a primary prevention ICD, an ICD or an electrophysiological study for risk stratification for SCD can be beneficial if meaningful survival greater than 1 year is expected.	B-NR	IIa
In patients with NICM, HF with NYHA class II–III symptoms and an LVEF of 35% or less, despite GDMT, an ICD is recommended if meaningful survival of greater than 1 year is expected.	A	I
In patients with NICM due to a *Lamin A/C* mutation who have 2 or more risk factors (NSVT, LVEF <45%, nonmissense mutation, and male sex), an ICD can be beneficial if meaningful survival of greater than 1 year is expected.	B-NR	IIa

Recommendation	LOE	Grade/Strength of Recommendation
In patients with NICM, HF with NYHA class I symptoms and an LVEF of 35% or less, despite GDMT, an ICD may be considered if meaningful survival of greater than 1 year is expected.	B-R	IIb
In patients with medication-refractory NYHA class IV HF who are not also candidates for cardiac transplantation, an LVAD, or a CRT defibrillator that incorporates both pacing and defibrillation capabilities, an ICD should not be implanted.	C-EO	III
In patients with arrhythmogenic right ventricular cardiomyopathy and an additional marker of increased risk of SCD (resuscitated SCA, sustained VT, significant ventricular dysfunction with RVEF or LVEF ≤35%), an ICD is recommended if meaningful survival greater than 1 year is expected.	B-NR	I
In patients with arrhythmogenic right ventricular cardiomyopathy and syncope presumed due to VA, an ICD can be useful if meaningful survival greater than 1 year is expected.	B-NR	IIa
In patients with HCM who have survived an SCA due to VT or VF, or have spontaneous sustained VT causing syncope or hemodynamic compromise, an ICD is recommended if meaningful survival greater than 1 year is expected.	B-NR	I
In patients with giant cell myocarditis with VF or hemodynamically unstable VT treated according to GDMT, an ICD and/or an antiarrhythmic medication may be considered if meaningful survival of greater than 1 year is expected.	C-LD	IIb
In patients with cardiac sarcoidosis who have sustained VT or are survivors of SCA or have an LVEF of 35% or less, an ICD is recommended, if meaningful survival of greater than 1 year is expected.	B-NR	I
In patients with cardiac sarcoidosis and LVEF greater than 35% who have syncope and/ or evidence of myocardial scar by cardiac MRI or positron emission tomographic scan, and/or have an indication for permanent pacing, implantation of an ICD is reasonable, provided that meaningful survival of greater than 1 year is expected.	B-NR	IIa
In patients with cardiac sarcoidosis and LVEF greater than 35%, it is reasonable to perform an electrophysiological study and to implant an ICD, if sustained VA is inducible, provided that meaningful survival of greater than 1 year is expected.	C-LD	IIa
In patients with cardiac sarcoidosis who have an indication for permanent pacing, implantation of an ICD can be beneficial.	C-LD	IIa
In patients with HFrEF who are awaiting heart transplant and who otherwise would not qualify for an ICD (e.g., NYHA class IV and/or use of inotropes) with a plan to discharge home, an ICD is reasonable.	B-NR	IIa
In patients with an LVAD and sustained VA, an ICD can be beneficial.	C-LD	IIa
In patients with a cardiac channelopathy and SCA, an ICD is recommended if meaningful survival of greater than 1 year is expected.	B-NR	I
In high-risk patients with symptomatic long QT syndrome in whom a beta blocker is ineffective or not tolerated, intensification of therapy with additional medications (guided by consideration of the long QT syndrome type), left cardiac sympathetic denervation, and/or an ICD is recommended.	B-NR	I
In asymptomatic patients with long QT syndrome and a resting QTc greater than 500 ms while receiving a beta blocker, intensification of therapy with medications (guided by consideration of the long QT syndrome type), left cardiac sympathetic denervation or an ICD may be considered.	B-NR	IIb

Recommendation	LOE	Grade/Strength of Recommendation
In patients with catecholaminergic polymorphic ventricular tachycardia and recurrent sustained VT or syncope, while receiving adequate or maximally tolerated beta blocker, treatment intensification with either combination medication therapy (e.g., beta blocker, flecainide), left cardiac sympathetic denervation, and/or an ICD is recommended.	B-NR	I
In patients with Brugada syndrome with spontaneous type 1 Brugada electrocardiographic pattern and cardiac arrest, sustained VA or a recent history of syncope presumed due to VA, an ICD is recommended if meaningful survival of greater than 1 year is expected.	B-NR	I
In patients with early repolarization pattern on ECG and cardiac arrest or sustained VA, an ICD is recommended if meaningful survival greater than 1 year is expected.	B-NR	I
In patients with short QT syndrome who have a cardiac arrest or sustained VA, an ICD is recommended if meaningful survival greater than 1 year is expected.	B-NR	I
In patients resuscitated from SCA due to idiopathic polymorphic VT or VF, an ICD is recommended if meaningful survival greater than 1 year is expected.	B-NR	I
In patients with adult congenital heart disease and hemodynamically unstable VT, an ICD is recommended after evaluation and appropriate treatment for residual lesions/ventricular dysfunction if meaningful survival of greater than 1 year is expected.	B-NR	I
In patients with adult congenital heart disease with SCA due to VT or VF in the absence of reversible causes, an ICD is recommended if meaningful survival of greater than 1 year is expected.	B-NR	I
In adults with repaired tetralogy of Fallot physiology and inducible VT/VF or spontaneous sustained VT, implantation of an ICD is reasonable if meaningful survival greater than 1 year is expected.	B-NR	IIa
In patients with repaired moderate or severe complexity adult congenital heart disease with unexplained syncope and at least moderate ventricular dysfunction or marked hypertrophy, either ICD implantation or an electrophysiological study with ICD implantation for inducible sustained VA is reasonable if meaningful survival of greater than 1 year is expected.	B-NR	IIa
In patients with adult congenital heart disease and severe ventricular dysfunction (LVEF <35%) and symptoms of heart failure despite GDMT or additional risk factors, ICD implantation may be considered if meaningful survival of greater than 1 year is expected.	B-NR	IIb
In patients who meet criteria for an ICD who have inadequate vascular access or are at high risk for infection, and in whom pacing for bradycardia or VT termination or as part of CRT is neither needed nor anticipated, a subcutaneous implantable cardioverter-defibrillator is recommended.	B-NR	I
In patients who meet indication for an ICD, implantation of a subcutaneous implantable cardioverter-defibrillator is reasonable if pacing for bradycardia or VT termination or as part of CRT is neither needed nor anticipated.	B-NR	IIa
In patients with an indication for bradycardia pacing or CRT, or for whom antitachycardia pacing for VT termination is required, a subcutaneous implantable cardioverter-defibrillator should not be implanted.	B-NR	III
In patients with an ICD and a history of SCA or sustained VA in whom removal of the ICD is required (as with infection), the wearable cardioverter-defibrillator is reasonable for the prevention of SCD.	B-NR	IIa
In patients at an increased risk of SCD but who are not ineligible for an ICD, such as awaiting cardiac transplant, having an LVEF of 35% or less and are within 40 days from an MI, or have newly diagnosed NICM, revascularization within the	B-NR	IIb

Recommendation	LOE	Grade/Strength of Recommendation
past 90 days, myocarditis or secondary cardiomyopathy or a systemic infection, the wearable cardioverter-defibrillator may be reasonable.		
2018 ESC Guidelines for the Diagnosis and Management of Syncope[70]		
It is recommended that decisions for ICD implantation in patients with unexplained syncope are made according to the ESC HCM Risk-SCD score.	B	I
ICD implantation may be considered in patients with ARVC and a history of unexplained syncope.	C	IIb
ICD implantation in addition to beta-blockers should be considered in LQTS patients who experience unexplained syncope while receiving an adequate dose of beta-blockers.	B	IIa
ICD implantation should be considered in patients with a spontaneous diagnostic type 1 ECG pattern and a history of unexplained syncope.	C	IIa
2018 ACC/AHA/HRS Guideline on the Evaluation and Management of Patients with Bradycardia and Cardiac Conduction Delay[71]		
In patients with permanent or persistent AF in whom a rhythm control strategy is not planned, implantation of an atrial lead should not be performed.	C-LD	III
In patients undergoing isolated coronary artery bypass surgery, routine placement of temporary epicardial pacing wires is reasonable.	B-NR	IIa
In patients undergoing coronary artery bypass surgery who will likely require future CRT or ventricular pacing, intraoperative placement of a permanent epicardial LV lead may be considered.	C-EO	IIB
In patients undergoing surgery for AF, routine placement of temporary epicardial pacing wires is recommended.	B-NR	I
In patients who have new postoperative SND, or atrioventricular block associated with symptoms or hemodynamic instability that does not resolve after surgery for AF, permanent pacing is recommended before discharge.	B-NR	I
In patients undergoing surgery for AF who will likely require future CRT or ventricular pacing, intraoperative placement of a permanent epicardial LV lead may be considered.	C-EO	IIb
In patients undergoing surgical aortic valve replacement or repair, routine placement of temporary epicardial pacing wires is recommended.	C-LD	I
In patients undergoing aortic valve surgery who will likely require future CRT or ventricular pacing, intraoperative placement of a permanent epicardial LV lead may be considered.	C-EO	IIb
In patients undergoing mitral valve surgery, routine placement of temporary epicardial pacing wires is reasonable.	C-LD	IIa
In patients undergoing surgical mitral valve repair or replacement who will likely require future CRT or ventricular pacing, intraoperative placement of a permanent epicardial LV lead may be considered.	C-EO	IIb
In patients undergoing tricuspid valve surgery, routine placement of temporary epicardial pacing wires is recommended.	C-LD	I
In patients who are undergoing tricuspid valve replacement or tricuspid repair with high risk for postoperative atrioventricular block, intraoperative placement of permanent epicardial leads at the time of cardiac surgery is reasonable.	C-LD	IIa

Recommendation	LOE	Grade/Strength of Recommendation
In adults with ACHD with preexisting sinus node and/or atrioventricular conduction disease who are undergoing cardiac surgery, intraoperative placement of epicardial permanent pacing leads is reasonable.	C-EO	IIa
In selected adults with ACHD and venous to systemic intracardiac shunts, placement of endocardial pacing leads is potentially harmful.	B-NR	III
In patients who require permanent pacing therapy, before implantation, an assessment of the risk of future ventricular arrhythmias and need for an ICD should be performed.	B-NR	I
In patients with indications for permanent pacing but also with significant comorbidities such that pacing therapy is unlikely to provide meaningful clinical benefit, or if patient goals of care strongly preclude pacemaker therapy, implantation or replacement of a pacemaker should not be performed.	C-LD	III

Abbreviations: ACC = American College of Cardiology; ACHD = adult congestive heart disease; AF = atrial fibrillation; AHA = American Heart Association; ARVC = arrhythmogenic right ventricular cardiomyopathy; AV = atrioventricular; CRT = cardiac resynchronization therapy; ECG = electrocardiogram; EO = expert opinion; ESC = European Society of Cardiology; GDMT = guideline-directed management and therapy; h = hour; HCM = hypertrophic cardiomyopathy; HF = heart failure; HFrEF = heart failure with reduced ejection fraction; HRS = Heart Rhythm Society; ICD = implantable cardioverter-defibrillator; LBBB = left bundle branch block; LD = limited data; LOE = level of evidence; LQTS = long QT syndrome; LV = left ventricular; LVAD = left ventricular assist device; LVEF = left ventricular ejection fraction; MI = myocardial infarction; MRI = magnetic resonance imaging; ms = millisecond; NICM = nonischemic cardiomyopathy; NR = nonrandomized; NSVT = nonsustained ventricular tachycardia; NYHA = New York Heart Association; OMT = optimal medical therapy; QRS = Q, R, and S waves of an ECG; R = randomized = RV = right ventricular; RVEF = right ventricular ejection fraction; SCA = sudden cardiac arrest; SCD = sudden cardiac death; SND = sinus node dysfunction; SR = sinus rhythm; VA = ventricular arrhythmia; VAD = ventricular assist device; VF = ventricular fibrillation; VT = ventricular tachycardia

7.0 Suggested profile and training for users

The labeled intended physicians for the CSGs and LVIs device configurations are summarized in Table 24.

Table 24 CSGs and LVIs: Intended Physicians

Product Configuration	Intended Physicians
CSGs	
SafeSheath CSG	The CSG system is intended for use by electrophysiologists and interventional cardiologists familiar with percutaneous catheter introduction.
Worley Advanced CSG	
Worley Advanced Right Sided CSG	
LVIs	
SafeSheath Worley LVI (5.5F)	The LVI system is intended for use by electrophysiologists and interventional cardiologists familiar with percutaneous catheter introduction.
SafeSheath Worley LVI (7F)	
Worley Advanced LVI (5.5F)	
Worley Advanced LVI (7F)	

Product Configuration	Intended Physicians
Situs Target	The Situs Target system is intended for use by electrophysiologists and interventional cardiologists familiar with percutaneous catheter introduction.
Situs LDS 2	The Situs LDS 2 system is intended for use by electrophysiologists and interventional cardiologists familiar with percutaneous catheter introduction.

Abbreviations: CSG = Coronary Sinus Guide; F = French; LVI = Lateral Vein Introducer

8.0 Applicable Harmonized Standards and Common Specifications

The following harmonized standards and guidance documents were applied or considered during the design and development of the CSGs and LVIs.

- ISO 10993-1:2018, Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process
- ISO 11070:2014, Sterile Single-Use Intravascular Introducers, Dilators, and Guidewires
- ISO 10555-1:2013, Intravascular Catheters – Sterile and Single-Use Catheters – Part 1: General Requirements
- ISO 80369-7, Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications
- ISO 11135: 2014, Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices

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10.0 Revision History

SSCP Revision	ECN Number	Date Issued	Change Description	SSCP Author	Revision Validated by the Notified Body
REV 001	ECN 166323	MAR 2023	Initial SSCP for the CSGs/LVIs	Alyssa Jimenez	☒ Yes Validation language: English ☐ No