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 Prelude Prestige™ Splittable Sheath Introducer.

The SSCP is not intended to replace the Instructions for Use (IFU) as the main document to ensure the safe use of the Prelude Prestige Splittable Sheath Introducer, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The English version of this SSCP document (SSCP 0212) 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 name(s):

The devices and model numbers covered by this SSCP are presented in Table 1. The trade name for the device is Prelude Prestige Splittable Sheath Introducer.

Table 1. Devices Included in this SSCP

Product Code	Size (F)	Sheath Length	Hub Color
PLPS-1005	5 F	13 cm	Grey
PLPS-1006	6 F	13 cm	Green
PLPS-1007	7 F	13 cm	Orange
PLPS-1008	8 F	13 cm	Blue
PLPS-1008.5	8.5 F	13 cm	Light Blue
PLPS-1009	9 F	13 cm	Black
PLPS-1009.5	9.5 F	13 cm	Grey
PLPS-1010	10 F	13 cm	Fuchsia
PLPS-1010.5	10.5 F	13 cm	Light Fuchsia

Product Code	Size (F)	Sheath Length	Hub Color
PLPS-1011	11 F	13 cm	Yellow
PLPS-1012	12 F	13 cm	Brown
PLPS-1012.5	12.5 F	13 cm	Light Brown
PLPS-1013	13 F	13 cm	Purple
PLPS-1014	14 F	13 cm	Red
PLPS-1015	15 F	13 cm	Grey
PLPS-1016	16 F	13 cm	Green
PLPS-2505	5 F	25 cm	Grey
PLPS-2506	6 F	25 cm	Green
PLPS-2507	7 F	25 cm	Orange
PLPS-2508	8 F	25 cm	Blue
PLPS-2509	9 F	25 cm	Black
PLPS-2510	10 F	25 cm	Fuchsia
PLPS-2511	11 F	25 cm	Yellow
PLPS-2512	12 F	25 cm	Brown
PLPS-2513	13 F	25 cm	Purple
PLPS-2514	14 F	25 cm	Red
PLPS-2515	15 F	25 cm	Grey
PLPS-2516	16 F	25 cm	Green

Abbreviations: cm = centimeter; F = French

1.2 Manufacturer Information

The name and address of the manufacturer of the Prelude Prestige Splittable Sheath Introducer are provided in Table 2.

Table 2. Manufacturer Information

Subject Device	Legal Manufacturer
Prelude Prestige Splittable Sheath	Merit Medical Systems, Inc.

Subject Device	Legal Manufacturer
Introducer	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) key is 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 device are listed in Table 3.

1.6 Risk Class of Device

The EU device risk classification for the Prelude Prestige Splittable Sheath Introducer is listed in Table 3.

Table 3. Device Identification Information

Device Name	EU Device Class	Product Numbers	Basic UDI-DI	Single Registration Number (SRN)	EMDN/CND Code	EMDN/CND Terms
Prelude Prestige Splittable Sheath Introducer	Class III (Rule 6)	PLPS-1005, PLPS-1006, PLPS-1007, PLPS-1008, PLPS-1008.5, PLPS-1009, PLPS-1009.5, PLPS-1010, PLPS-1010.5, PLPS-1011, PLPS-1012, PLPS-1012.5, PLPS-1013, PLPS-1014, PLPS-1015, PLPS-1016,	088445048819EA	SRN-US-MF-000001366	C0503	CARDIOVASCULAR INTRODUCER SHEATHS, PEEL-AWAY

Device Name	EU Device Class	Product Numbers	Basic UDI-DI	Single Registration Number (SRN)	EMDN/CND Code	EMDN/CND Terms
		PLPS-2505, PLPS-2506, PLPS-2507, PLPS-2508, PLPS-2509, PLPS-2510, PLPS-2511, PLPS-2512, PLPS-2513, PLPS-2514, PLPS-2515, PLPS-2516				

Abbreviations: CND = Classificazione Nazionale Dispositivi medici; EMDN = European Medical Device Nomenclature; EU = European Union; SRN = Single Registration Number; UDI -DI = Unique Device Identification – Device Identification

1.7 Year of EU Market Introduction

The year that the Prelude Prestige Splittable Sheath Introducer was first placed on the European Union (EU) market is presented in Table 4.

1.8 Authorised Representative (if applicable)

The name of the authorized representatives and, if applicable, the SRN are provided in Table 4.

1.9 Notified Body

The Notified Body (NB) involved in the conformity assessment of the Prelude Prestige Splittable Sheath Introducer 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
Prelude Prestige Splittable Sheath Introducer	29 November 2017; first EU sales, 2018	Merit Medical Ireland Ltd.	SRN- IE-AR-000001011	BSI	2797

Abbreviations: BSI = British Standards Institution; EU = European Union; NB = Notified Body; SRN = Single Registration Number

2.0 Intended Use of the Device

2.1 Intended Purpose

The intended purpose of the device is to facilitate the introduction of various types of pacing/defibrillator leads and catheters into the venous vasculature.

2.2 Indication(s) and Intended Patient Groups

The Prelude Prestige Splittable Sheath Introducer is intended for adult patients who require the introduction of various types of pacing/defibrillator leads and catheters into the venous vasculature.

The Prelude Prestige Splittable Sheath Introducer is indicated for use in adult patients requiring implantation of cardiac rhythm management devices as treatment for arrhythmias, congestive heart failure, or other conditions requiring pacing or defibrillation.

2.3 Contraindications:

There are no known contraindications associated with this device.

3.0 Device Description

3.1 Materials/Substances in Contact with Patient Tissues

The Prelude Prestige Splittable Sheath has no medicinal substances and no tissue or cells of human or animal origin. It also has no substances that

are intended to be absorbed locally or dispersed in the human body. The materials comprising the device are identified in Table 5. The Introducer Sheath and the Dilator have transitory contact with human tissue and blood. The Holder and Straightener has no direct patient contact. The Prelude Prestige Splittable Sheath Introducer is intended for single use only. The device configuration is shown in Figure 1 and Figure 2.

Table 5. Prelude Prestige Splittable Sheath Materials

Product Component	Subcomponent	Material
Introducer Sheath	Sheath	PEBAX® Medical Grade Durometer: 55D
	Radiopaque material	24% $BaSO_4$
	UV stabilizer	0.15% – 0.20% TINUVIN®
	Heat stabilizer	0.08% - 0.12% Irganox®
Dilator	Hub	Polycarbonate
	Dilator tubing 6 F – 10.5 F	HDPE
	Dilator tubing 11 F – 12.5 F	MDPE
	Dilator tubing 13 F – 16 F	LDPE
	Radiopaque material	24% $BaSO_4$ (HDPE, 6 F – 10.5 F)
	Radiopaque material	20% $BaSO_4$ (MDPE, 11 F – 12.5 F)
	Radiopaque material	24% $BaSO_4$ (LDPE, 13 F – 16 F)
Holder and Straightener (Tube Guard)	Holder	HDPE
	J-straightener	Polypropylene

Abbreviations: $BaSO_4$ = barium sulfate; F = French; HDPE = high density polyethylene; LDPE = low density polyethylene; MDPE = medium density polyethylene; UV = ultraviolet

Figure 1. Prelude Prestige Splittable Sheath Introducer™ Splittable Sheath

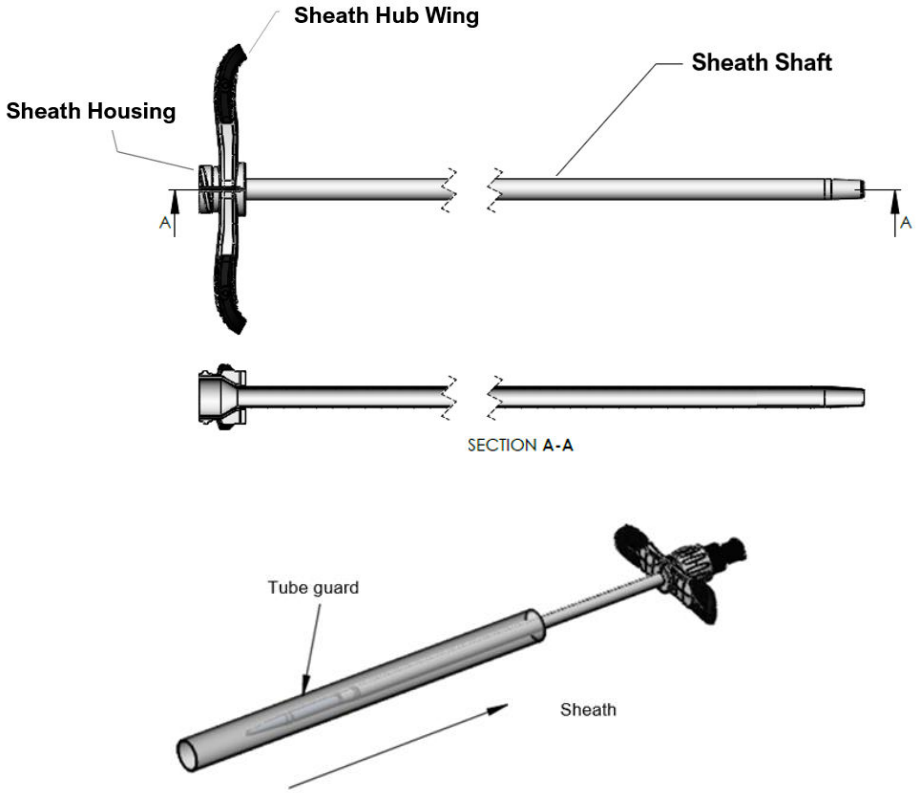
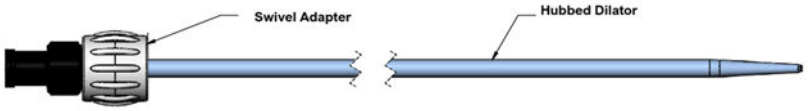


Figure 2. Prelude Prestige™ Splittable Sheath Introducer Dilator



3.2 Operating Principals

Splittable Sheath Introducers are typically placed using the Seldinger technique that employs an introducer needle to gain initial vessel access. A guide wire is manually placed through the needle and into the vessel. The needle is then removed, leaving the guide wire in place to preserve vascular access. A sheath introducer / vessel dilator assembly is advanced over the guide wire and into the vessel. The guide wire 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. 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 Previous Generation(s) or Variant(s)

No previous generation of the Prelude Prestige Splittable Sheath Introducer exists. This medical device was developed as a response to physician feedback indicating that a side port—a feature of the Prelude Snap Splittable Sheath Introducer—was not always necessary.

3.4 Accessories:

The accessories described in Table 6 are not included with the Prelude Prestige Splittable Sheath Introducer; but are necessary for use of the device in accordance with the instructions for use.

Table 6. Accessory Devices

Accessory Description
18 g XTW introducer needle: 18-gauge, 7 cm long Merit Advance or equivalent. Needle hub must have a Luer lock
Luer slip syringe. Clear with standard graduations, syringe volume: minimum 19 mL, syringe must have a Luer conical fitting (male)
0.38-inch (0.97 mm) diameter guidewire made of stainless steel. Either 13 cm: 50 cm, 25 cm: 80 cm

Abbreviations: cm = centimeter; g = gauge; mL = milliliter; mm = millimeter

3.5 Devices Used in Combination

Generic devices used with the subject device are listed in Table 6.

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 Prelude Prestige Splittable Sheath Introducer has 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 Prelude Prestige Splittable Sheath Introducer has indirect clinical benefits for patients by facilitating the introduction and placement of pacing/defibrillator leads and catheters.

The Prelude Prestige Splittable Sheath Introducer is used for the introduction of various types of pacing/defibrillator leads and catheters into the venous vasculature.

Articles published between 01 January 2012 to 07 October 2022, were reviewed for the Prelude Prestige Splittable Sheath Introducer and benchmark competitor devices There was no clinical literature found pertaining to the Prelude Prestige Splittable Sheath Introducer. However, the indirect clinical benefits for the subject device have been substantiated via objective evidence from Post Market Clinical Follow-Up (PMCF) data. The Prelude Prestige Splittable Sheath Introducer has been successfully used to facilitate placement of various pacing/defibrillator leads and catheters into the venous vasculature. For the clinical evaluation, the performance outcomes were defined as follows:

- Technical success: Rate of successful placement of pacing leads and/or other catheter into the venous vasculature when using the subject device

Technical success rates from PMCF (subject device) and clinical literature (benchmark devices) are very high. Overall, the technical success rate was 100% (197/197) for the Prelude Prestige Splittable Sheath Introducer and 100% (119/119) for the benchmark devices.

The potential complications associated with the Prelude Prestige Splittable Sheath Introducer, as identified in the IFU, are summarized in Table 7. In addition, the device related adverse events (AEs) identified in PMCF, and corresponding to risk assessment harms are presented in Table 8.

Table 7. Prelude Prestige Splittable Sheath Introducer: Potential Complications

Product Configuration	Potential Complications
Prelude Prestige Splittable Sheath Introducer	• Blood loss/air embolism • Vessel damage • Infection • Hematoma formation • Pneumothorax* • Hemothorax* • Catheter displacement

*The risk of hemothorax and pneumothorax is related to the use of the with the needle.

Table 8. Adverse Events: Post Market Clinical Follow-Up Data

Adverse Events	Device Related	Procedure Related	IFU Complications	Identified Harms from Risk Management File
Vessel Damage (device-related)	X		• Vessel Damage	• Soft Tissue Injury (2)

The Prelude Prestige Splittable Sheath Introducer has been used with a high level of safety during endovascular procedures in patients. Based on the PMCF data, the reported device-related AE rate for the Prelude Prestige Splittable Sheath Introducer is 0.51% (1/197). Incidence of device-related AEs for benchmark competitor devices is 0.00% (0/119). Based on the comparative analysis, the upper bound limit (UBL) of the 1-sided 95% confidence interval (CI) for p1-p2 is less than 0.10 (10%) Therefore, the null hypothesis (H_0) is rejected and the device-related AE rate for the subject device is established as non-inferior to the comparable benchmark splittable sheath introducers at a 95% CI. Safety data for the Prelude Prestige Splittable Sheath Introducer from the PMCF, and for comparable benchmark sheath introducers from the clinical literature, are summarized in Table 9.

Table 9. Comparative Adverse Event Rates

Attribute	Subject Device	Benchmark Devices
Device-Related AE Rate	1/197(0.51%)	0/119 (0.00%)

Abbreviations: AE = adverse event

This assessment accounts for the various risk factors associated with the Prelude Prestige Splittable Sheath Introducer. 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 pertaining to similar devices. The results of the clinical risk/safety analysis demonstrate that the subject device meets the established acceptance criteria with respect to safety and exhibits 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 Prelude Prestige Splittable Sheath Introducer device configurations are summarized in Table 10.

Table 10. Prelude Prestige Splittable Sheath Introducer: Warnings & Precautions

Product Configuration	Labeling
Prelude Prestige Splittable Sheath Introducer	**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. • Never advance or withdraw the guide wire or sheath when resistance is met. Determine the cause by fluoroscopy and take remedial action. • After use, dispose of device in a manner consistent with standard protocols for biohazard waste disposal. • There are insufficient safety and performance data to support use of the device in pediatric populations.
	Precautions
	• Do not alter this device in any way. • 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. • In the EU, any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the applicable Member State. • Do not leave in patient longer than 60 minutes.

Abbreviations: EU = European Union

4.2 Other Relevant Safety Aspects

The Corrective and Preventive Action (CAPA) process for the subject devices is conducted under QSP 0219 or site-specific procedure. 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 (CAPAs) during the reporting period for this report (Table 11).

Table 11. Corrective Action Report Summary

CAPA Number	CAR Title	CAR Originate Date	CAR Description	CAR Status
23-03875	Sheath did not peel properly	2023-08-14	-Prelude Prestige- On both complaints (A) CASE-2023-00053198-1 & (B) CASE-2023-00056904-1 customer reported "COMPONENT BROKEN/DAMAGED" in which the sheath did not peel properly.	Awaiting, Implementation

Abbreviation: CAPA = Corrective and Preventive Action; 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 Post market Clinical Follow-up

5.1 Summary of Clinical Data for the Equivalent Device

The Prelude Prestige Splittable Sheath Introducer has been commercialized for several years and has an established history of use. In addition, the Prelude Prestige Splittable Sheath Introducer utilizes well-established technology and exhibits a low complaint/incidence rate. The clinical evaluation was based on PMCF of the subject device only.

5.2 Summary of Clinical Investigations of the Subject Device

Conformity of the Prelude Prestige Splittable Sheath Introducer was initially assessed and endorsed by the applicable NB in 2018. No pre-market clinical investigations of the device were conducted in the EU prior to the initial Conformité Européenne (CE) marking. A summary of all available clinical data for the Prelude Prestige Splittable Sheath Introducer is provided in Section 5.4.

5.3 Summary of Clinical Data from Other Sources

Clinical Literature Review

A review of relevant clinical literature for the Prelude Prestige Splittable Sheath Introducer was conducted for the time period of 01 January 2017 to 07 October 2022. No studies were identified for inclusion in the evaluation of the Prelude Prestige Splittable Sheath Introducer.

Post-Market Clinical Follow-Up

The clinical evidence supporting the safety and performance of the Prelude Prestige Splittable Sheath Introducer includes PMCF data from 197 cases/data points from 30 healthcare professionals. The Prelude Prestige Splittable Sheath Introducer was used to facilitate the delivery of a catheter/lead in all cases. The overall safety and performance of the Prelude Prestige Splittable Sheath Introducer reported in the patient-level surveys is summarized in Table 12. The technical success rate for the Prelude Prestige Splittable Sheath Introducer was 100% (197/197) and the device-related AE rate was 0.51% (1/197).

Table 12. PMCF Data

Respondent Identifier	Number of Procedures/Cases	Performance Technical Success n/N (%)	Safety Device-Related AEs n/N (%)
FR01	10	10/10 (100)	0/10 (0)
FR02	10	10/10 (100)	0/10 (0)
FR03	10	10/10 (100)	0/10 (0)
FR04	5	5/5 (100)	0/5 (0)
FR05	5	5/5 (100)	0/5 (0)
FR06	5	5/5 (100)	0/5 (0)
FR07	5	5/5 (100)	0/5 (0)
US01	10	10/10 (100)	0/10 (0)
US02	10	10/10 (100)	0/10 (0)
US03	10	10/10 (100)	0/10 (0)
US04	10	10/10 (100)	0/10 (0)
US05	8	8/8 (100)	0/8 (0)
US06	10	10/10 (100)	0/10 (0)
US07	5	5/5 (100)	0/5 (0)
US08	10	10/10 (100)	0/10 (0)
US09	10	10/10 (100)	0/10 (0)
US10	5	5/5 (100)	1/5 (20)

Respondent Identifier	Number of Procedures/Cases	Performance Technical Success n/N (%)	Safety Device-Related AEs n/N (%)
US11	5	5/5 (100)	0/5 (0)
US12	5	5/5 (100)	0/5 (0)
US13	5	5/5 (100)	0/5 (0)
US14	2	2/2 (100)	0/2 (0)
US15	5	5/5 (100)	0/5 (0)
US16	5	5/5 (100)	0/5 (0)
US17	5	5/5 (100)	0/5 (0)
US18	2	2/2 (100)	0/2 (0)
US19	5	5/5 (100)	0/5 (0)
US20	5	5/5 (100)	0/5 (0)
US21	5	5/5 (100)	0/5 (0)
US22	5	5/5 (100)	0/5 (0)
US23	5	5/5 (100)	0/5 (0)
Total	**197**	**197/197 (100)**	**1/197 (0.51)**

Abbreviations: AE = adverse event

5.4 Overall Summary of Clinical Performance and Safety

Data to support the safety and performance of the Prelude Prestige Splittable Sheath Introducer have been analyzed and provide evidence to support all the safety and performance outcomes. Based upon a review of the clinical data, the overall benefits to patients of using the device for its intended purpose outweigh the overall risks.

5.5 Ongoing Post market Clinical Follow-up

The need to conduct PMCF activities is subject to annual review as part of the Post-Market Surveillance (PMS) process and also based on merging 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

Heart Failure

Heart failure (HF) is a complex clinical syndrome caused from functional or structural impairment of ventricular filling or ejection.[5] 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. 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.[5,6] As presented in Table 13, 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 (see Table 14). HF can be classified based on ejection fraction (EF). The four main classifications are HF with reduced EF (HFrEF) (where left ventricular ejection fraction [LVEF] is ≤40%), HF with mildly reduced EF (HFmrEF) (where LVEF ranges between 41 to 49%), HF with preserved EF (HFpEF) (where LVEF is ≥50%), and HF with improved EF (HFimpEF).[7] HFimpEF is characterized by a ≥ 10-point increase from a baseline LVEF of ≤40%, coupled with an LVEF of >40% at the second measurement.[7]

Table 13. ACCF/AHA Stages of HF[5]

ACCF/AHA Stages of HF	
A	At high risk for HF but without structural heart disease or symptoms of HF
B	Structural heart disease but without signs or symptoms of HF
C	Structural heart disease with prior or current symptoms of HF
D	Refractory HF requiring specialized interventions

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

Table 14. NYHA Functional Classification of HF[5,8]

NYHA Classification			
Class	Patient Symptoms	Class	Objective Assessment
I	No limitation of physical activity. Ordinary physical activity does not cause symptoms of HF.	A	No objective evidence of cardiovascular disease. No symptoms and no limitation in ordinary physical activity.

NYHA Classification			
II	Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in symptoms of HF.	B	Objective evidence of minimal cardiovascular disease. Mild symptoms and slight limitation during ordinary activity. Comfortable at rest.
III	Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea.	C	Objective evidence of moderately severe cardiovascular disease. Marked limitation in activity due to symptoms, even during less-than-ordinary activity. Comfortable only at rest.
IV	Unable to carry on any physical activity without symptoms of HF, or symptoms of HF at rest.	D	Objective evidence of severe cardiovascular disease. Severe limitations. Experiences symptoms even while at rest.

Abbreviations: HF = heart failure; NYHA = New York Heart Association

HF is a prominent disease worldwide, affecting 1% to 2% of adults in developed countries.[6] From 2013 to 2016, HF affected an estimated 6.2 million American adults ≥20 years of age, an increase of roughly 5 million people when compared to 2009 to 2012. Prevalence is expected to increase 46% from 2012 to 2030 in people over 18 years old.[9] Factors that increase the risk of HF include the following:

Increased age: HF affects more than 10% of adults greater than 70 years old

Sex: Lifetime risk of developing HF is 33% for 55-year-old males and 28% for 55-year-old females[6]

Hypertension

Obesity

History of cardiovascular disease[9]

African Americans are at highest risk for developing HF, followed by Hispanic, Caucasians, and Chinese Americans. 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.[9]

Congenital Heart Disease

Definitions of congenital heart disease (CHD) differ among guidelines and reports.[10] 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, or anatomic variants such as patent foramen ovale.[11,12] CHD can be classified by disease complexity as mild, moderate, or severe (see Table 15). 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.[10,13]

Table 15. ESC Classification of CHD complexity[12]

ESC CHD Complexity Classifications
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 residue or sequalae, 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 - sub valvular 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

ESC CHD Complexity Classifications
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.[13] The number of severe CHD cases is decreasing in developed countries due to fetal screening and pregnancy termination, yet cases are rising globally.[12] For every 3 of 1000 births, catheter- or surgical- based treatment is required early in life.[14] Additionally, due to surgical and technological advancement, greater than 90% of CHD patients survive to adulthood (at least 18 years old).[12] 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.[14] Furthermore, early intervention does not typically cure CHD; many adult CHD patients incur complications including arrhythmias, HF, endocarditis, pulmonary hypertension, and need for reintervention.[13]

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.[9] 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.[15] 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.[9] 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.[16] DCM has a mixed etiology and may occur from environmental, infectious, and systemic factors but 25% to 35% cases are genetic.[16] Approximately 50% of ARVC cases are genetic mutations and in most cases of desmosomal proteins leading to myocardial thinning and ventricular wall ballooning.[16] ARVC symptoms include palpitation, syncope, and occasionally sudden cardiac death.[9] RCM is the least common representing 2% to 5% of cardiopathies cases. RCM is considered mixed etiology and presents with ascites or peripheral edema.[16]

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.[9] HCM incidence rate is 1 in 250 to 500 people with similar prevalence among all races. HCM often presents in adolescents and young adults.[17] Risk of mortality for patients with HCM is 3-fold higher than age matched healthy individuals.[9] 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.[17] 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.[9] ARVC is known to increase risk of sudden cardiac death and patients are recommended not to participate in endurance sports.[16]

Myocardial Infarction

Myocardial infarction (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 onset of MI.[18] 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 16.[18]

Table 16. MI Classifications[18]

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.

MI Type	Etiology
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 United States (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.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.[9]

Arrhythmia

Supraventricular tachycardia (SVT) and ventricular arrhythmias are defined as the disruption of electrical conduction within in the myocardium resulting in irregular, uniform, and chaotic contraction. SVTs 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.[19] The etiology of arrhythmia includes cardiac structural deformities that disrupt automaticity and conduction properties,[19] or disruptions of cardiac function due to genetic mutations[20,21]or pharmacological agents.[21,22]Risk factors for arrythmias include cardiomyopathy, age, hypertension, obesity, sleep apnea, alcohol consumption, and diabetes.[20]

SVTs are estimated to affect 3.6 per 10,000 in the United States, approximately 6% of adults (>65 years old).[19,22]Atrial fibrillation (AF) is the most common SVT and in 2010 was reported to affect 2.6 to 6.1 million people in United States 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 sudden cardiac death, and 35.8% due to non-cardiovascular related death.[9] Additionally, AF is associated with fatigue, reduced exercise capability, reduced quality of life.[20] Ventricular arrhythmias including ventricular fibrillation and ventricular tachycardia are reported to severely reduce or cease cardiac output[23] and are associated with increased risk of sudden cardiac arrest.[21] Progressive HF is known to increase the risk of developing ventricular arrythmias.[24,25]

6.2 Treatment Options and Interventions

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.[26] A pacemaker usually consists of 3 main components[26] (Figure 3):

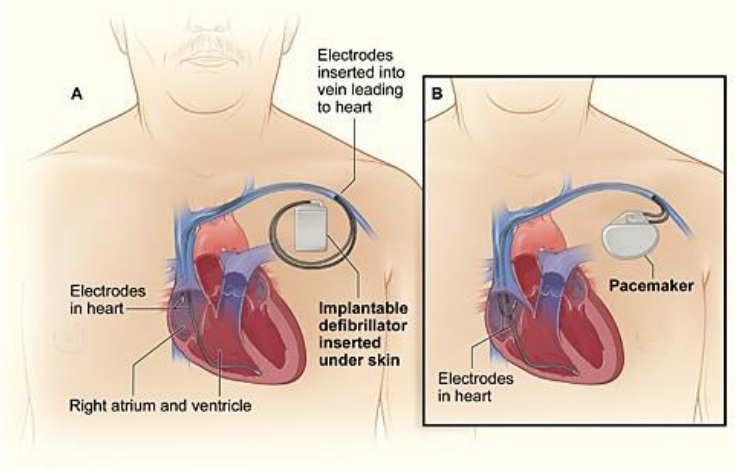
A pulse generator, which generates electrical signals

Wires/leads, which carry the electrical signals to the chambers of the heart

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 left ventricle (LV), pacemakers can be used to coordinate electrical signaling between the 2 ventricles and help restore normal pumping action.[26,27] Pacemaker leads are placed in both ventricles and an atrium, in a configuration called cardiac resynchronization therapy (CRT). 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.[28]

Figure 3. Cross-section of chest and heart with (A) implantable cardioverter defibrillator, and (B) pacemaker[29]



Implantable Cardioverter Defibrillators

Implantable cardioverter defibrillators (ICDs) are devices placed in the chest or abdomen that check for arrythmias and send electrical shocks to correct arrythmias.[29] 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.[29] 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.[29]

Implantation Approach

Splittable sheath introducers are widely recognized as standard devices for the placement of cardiac leads, electrodes, and catheters. These devices incorporate a tearaway sheath with a break-away hub affixed to the proximal end of the sheath. The peel-away feature is accomplished by pre-scoring along two opposing sides of the sheath body, ensuring a clean, easy peel after pacing lead or catheter placement.

Littleford et al.[30] first reported on the application of peel-away introducer sheaths in 1979.[30] Prior to this, permanent transvenous electrode implantation with an introducer sheath was performed with either a disposable catheter introducer for implantation of hubless electrode wires, or with a no. 9 Desilets-Hoffman sheath for implantation of small unipolar electrodes.[30] This new method modified a Seldinger sheath, commonly

used in cardiac catheterization, to create a device that included a permanent metal hub which allowed for placement of the larger connecting terminal of the pacing lead.[31] This device consisted of a "presplit", semirigid, radiopaque, polyethylene sheath, a needle, a J-tip spring guidewire, and a vessel dilator. This new design allowed for the introduction of various types of transvenous electrodes through the subclavian vein.[30]

With the introduction of the peel-away sheath, subclavian cannulation became the most popular method for implantation of permanent pacemakers due to the technique's speed, relatively atraumatic nature, and suitability for placement of multiple leads.[32] Splittable sheath introducers are now manufactured with a wide variety of materials and features including hemostatic valves (both nondetachable and detachable), suture rings, and radiopaque tip markers to allow for visibility during fluoroscopy. Implantation approaches for pacemakers or ICD leads may leverage these splittable sheaths to navigate the device leads into the chambers of the heart. Different implantation approaches are described below.

Transvenous Implantation

In the majority of cases, the leads are advanced through the subclavian vein and superior vena cava (SVC), into the right atrium, then placed in the right atrium, or passed through the tricuspid valve and placed in the right ventricle (RV), or advanced into the coronary sinus and it's tributary veins (CRT only).[33] Leads and electrodes are commonly introduced via the subclavian vein using an introducer or sheath assembly.[34] 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.[34]

While implantation of leads in the RV and right atrium are straightforward, optimal placement of the LV lead for CRT is considered challenging.[35] Consequently, several tools have been developed for accurate LV lead placement. Prior to LV lead placement, the anatomy of the coronary sinus (CS) is assessed using imaging techniques such as coronary angiograms, cardiac computed tomography (CT) angiograms, cardiac magnetic resonance (MR) angiograms, and echocardiography.[35] The LV lead can sometimes be implanted using just a soft coronary guidewire, in a technique called over-the-wire. Pre-shaped telescoping sheaths can be useful in engaging the vein of interest, particularly in challenging venous anatomy.[35] 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.[35] The transvenous implant success rate for CRT via the CS has been reported to be around 90% in major clinical trials.[35]

Although less common, transvenous implantation via femoral vein access is also feasible.[36] Guerrero et al. (2017)[36] 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. Similar results were achieved by Griffiths et al using the femoral route. In this study, the complication rate at a mean of 6.8 years was 29.0%.[37]

Alternative Implantation Approach

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.[33,38] Further, around 30%–40% of patients do not respond to conventional CRT.[33,38] In these cases, alternate methods of pacemaker implantation are often used.

One alternative method to address unfavorable venous anatomy is a snare technique, where a second catheter is introduced. The second catheter is used to insert a snare, which is used to capture the first catheter. This technique allows the practitioner to maneuver around tortuous venous anatomy.[39]

The most frequently used alternative 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.[26] In a retrospective study, Hejjel et al. (2017)[38] investigated the feasibility of epicardial CRT via mini thoracotomy in 57 patients. The authors reported no serious intraoperative complications. Estimated 5-year survival rates were 40% for patients who received a CRT defibrillator and 61% in patients who received a CRT pacemaker. Other studies have reported increased rate of complications like renal insufficiency and infections associated with epicardial lead placement.[36] Thoracoscopic surgery for lead placement has also been documented by Kim et al.[41] In this study, video-assisted thoracoscopic surgery (VATS) was used to place CRT leads. The authors concluded that VATS can be an effective and safe alternative to the standard transvenous approach in CRT patients with challenging anatomy.

Pacemaker leads can 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.[42] 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.[43]

Another approach for LV lead placement is through the LV apex, called the transapical approach.[43] This procedure is performed under general anesthesia, with access to the LV apex obtained through a mini-thoracotomy.[43,44] Advantages of this technique include the minimally invasive surgical approach, endocardial stimulation, and low risk of damage to the mitral valve.[43] Kis et al. (2017)[43] reported on a prospective study evaluating transapical LV lead implantation in a cohort of 26 patients receiving CRT with previously failed transvenous lead placement. 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.[43]

Finally, wireless or leadless pacemakers are gaining popularity as they eliminate the need for leads and complications associated with lead

implantation.[27,45] 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.[27] 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.[27] Early clinical studies have shown feasibility of leadless pacemakers with high implantation success rates and low complication rates compared to patients receiving transvenous pacemakers.[27] Leadless pacemakers have been used successfully in instances where lead removal was necessary due to infection.[45]

7.0 Suggested Profile and Training for Users

The Prelude Prestige Splittable Sheath Introducer should be used by clinicians trained in cardiac intervention including pacing therapy, cardiac resynchronization therapy, and defibrillation. The devices are intended to be used by trained health professionals.

8.0 Applicable Harmonized Standards and Common Specifications

Table 17 provides a summary of the harmonized standards and guidance documents that were applied or considered during the design and development of the Prelude Prestige Splittable Sheath Introducers.

Table 17. Harmonized Standards and Guidance Documents

Title	State of the Art Date/Version	Merit Compliance Date/Version	Merit Compliance* to State of the Art (Full/Full*/Partial**/No)	Evidence for Compliance to State of the Art	Justification for Full* OR Partial** Compliance	Actions (if gap identified)	Comment
Design Control - Catheter							
Sterile single-use intravascular introducers, dilators and guidewires - Second Edition	ISO 11070: 2014, Amd 2018	2014, Amd. 2018	Full	DHF 0213, Design Verification Report, Rev. 002. ESR-21039. PROM-210202	N/A	N/A	N/A
Conical fittings with 6 % (Luer) taper for syringes, needles and	594-2	1998	Full	DHF 0213, Design Verification Report, Rev. 002 PROM-210202	N/A	N/A	N/A

Title	State of the Art Date/Version	Merit Compliance Date/Version	Merit Compliance* to State of the Art (Full/Full*/Partial**/No)	Evidence for Compliance to State of the Art	Justification for Full* OR Partial** Compliance	Actions (if gap identified)	Comment
certain other medical equipment — Part 2: Lock fittings							
Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or	EN ISO 80369-7:2017 ISO 80369-7:2016 (EQV)	2021	Partial	PROM 210294	FDA recognition of ISO 594-1 First edition 1986-06-15 [Rec# 6-11] and ISO 594-2 Second edition 1998-09-01 [Rec# 6-129] will be superseded by recognition of ISO 80369-7 Second edition 2021-05 [Rec# 5-133]. FDA will accept declarations of conformity, in support of premarket submissions, to [Rec# 6-11] and [Rec# 6-129] until December 17, 2023. After this transition period, declarations of conformity to [Rec# 6-11] and [Rec# 6-129] will not be accepted.	PRJ 0572 23-MEMO-0090	Full compliance testing is expected to be completed by July 2024
Biological Safety							
Biological Evaluation of	ISO 10993-1:2018	2018	Full	Biocompatibility,	N/A	N/A	N/A

Title	State of the Art Date/Version	Merit Compliance Date/Version	Merit Compliance* to State of the Art (Full/Full*/Partial**/No)	Evidence for Compliance to State of the Art	Justification for Full* OR Partial** Compliance	Actions (if gap identified)	Comment
Medical Devices – Part 1: Evaluation and testing	& EN ISO 10993-1:2009, OJ Pub: 02Dec2009 & EN ISO 10993-1:2009/AC:2010, OJ Pub: 18Jan2011			TDF0212, Section 25.0			
Sterilization							
Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide sterilization residuals	EN ISO 10993-7:2008, OJ Pub: 19Feb2009 & EN ISO 10993-7:2008/AC:2009, OJ Pub: 07Jul2010	2019	Full	Lab report # 367962-S01 Sterilization, TDF0212, Section 18.0	N/A	N/A	N/A

*Note: Per (EU) 2017/745 Articles 8 & 9, 'Full' compliance is claimed for compliance with all requirements or the relevant part of the standard or common specification.

Note: 'Partial' compliance is claimed where the standard allows an alternative process, e.g., UOUP per Annex C under IEC 62366-1.

Abbreviations: FDA = Food and Drug Administration; ISO = International Organization for Standardization; N/A = not applicable

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10.0 Revision History

SSCP Revision	ECN Number	Date Issued DD/MM/YYYY	Change Description	Revision Validated by the Notified Body
REV 001	ECN166449	15/FEB/2024	Initial release of the Prelude Prestige SSCP to support CE marking under MDR	☒ Yes Validation language: English ☐ No
REV 001	ECN189201	02/11/2024		☐ Yes Validation language: English ☒ No