



OPTIMAL PLACEMENT

IMPROVING OUTCOMES FOR PATIENTS

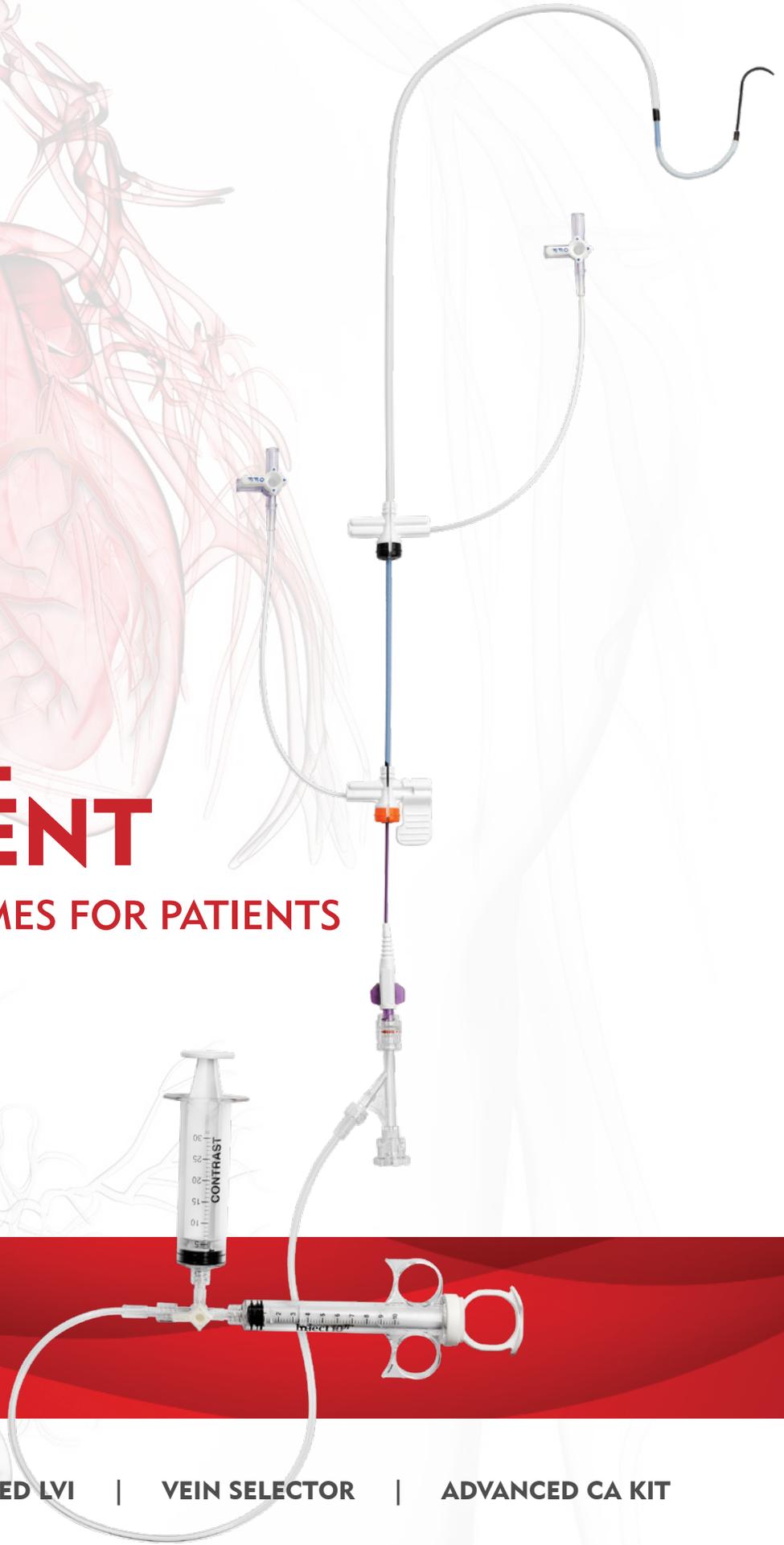
INTERVENTIONAL
CRT TOOLS

ADVANCED CSG

ADVANCED LVI

VEIN SELECTOR

ADVANCED CA KIT



RELIABLE ACCESS & ACCURATE DELIVERY

Cardiac resynchronization therapy (CRT) requires a system that delivers consistency for standard implants while also offering advanced options for complex anatomy. The Worley™ Advanced LV Lead Delivery System is designed to offer both reliability and flexibility when you need it, accurately placing LV leads at the target location.



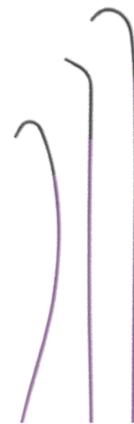
The **Worley Advanced LV Lead Delivery System** is made up of four main parts. Each component plays an intricate role in helping you efficiently and accurately place your LV lead.



Advanced CSG



Advanced LVI



Vein Selector



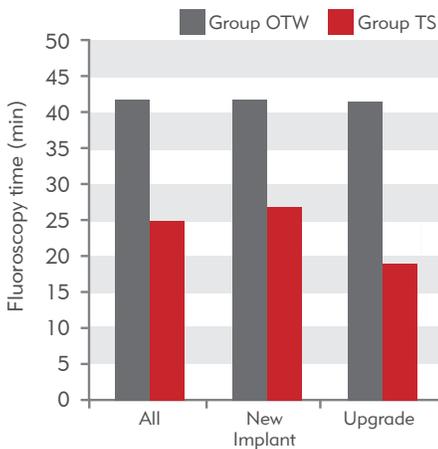
CA Kit

CLINICAL EVIDENCE

In a clinical study conducted at Duke University involving 437 patients who received CRT implantation, two study groups were compared, one group using a standard over-the-wire (OTW) implant technique catheter while the other used a 9F telescoping support catheter system (TS).¹

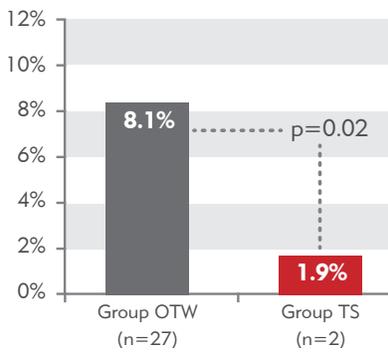
Shorter Fluoro Time

42.1 minutes vs. 26.3 minutes
($p < 0.01$) 38% Improvement



Failed LV Lead Placement

was lower 1.9% vs. 8.1%
($p=0.02$)



Reduce fluoro time by
38%

Reduce failed LV lead placement by
77%

Achieve
87% optimal lead positioning

Optimal Lead Positioning 87% vs. 75% ($p=0.01$)

Left Ventricular Lead Location According to Implantation Technique

	Group OTW	Group TS	P Value
Posterior or Lateral vs. Anterior (%)	92/8	99/1	0.01
Basal or Mid vs. Apical (%)	82/18	87/13	0.22
Optimal vs. Non-optimal (%)*	75/25	87/13	0.01

* Optimal lead location posterior/lateral and Basal or Mid Non-optimal lead location anterior or apical. OTW = over-the-wire; TS = telescoping support.

IN CONCLUSION

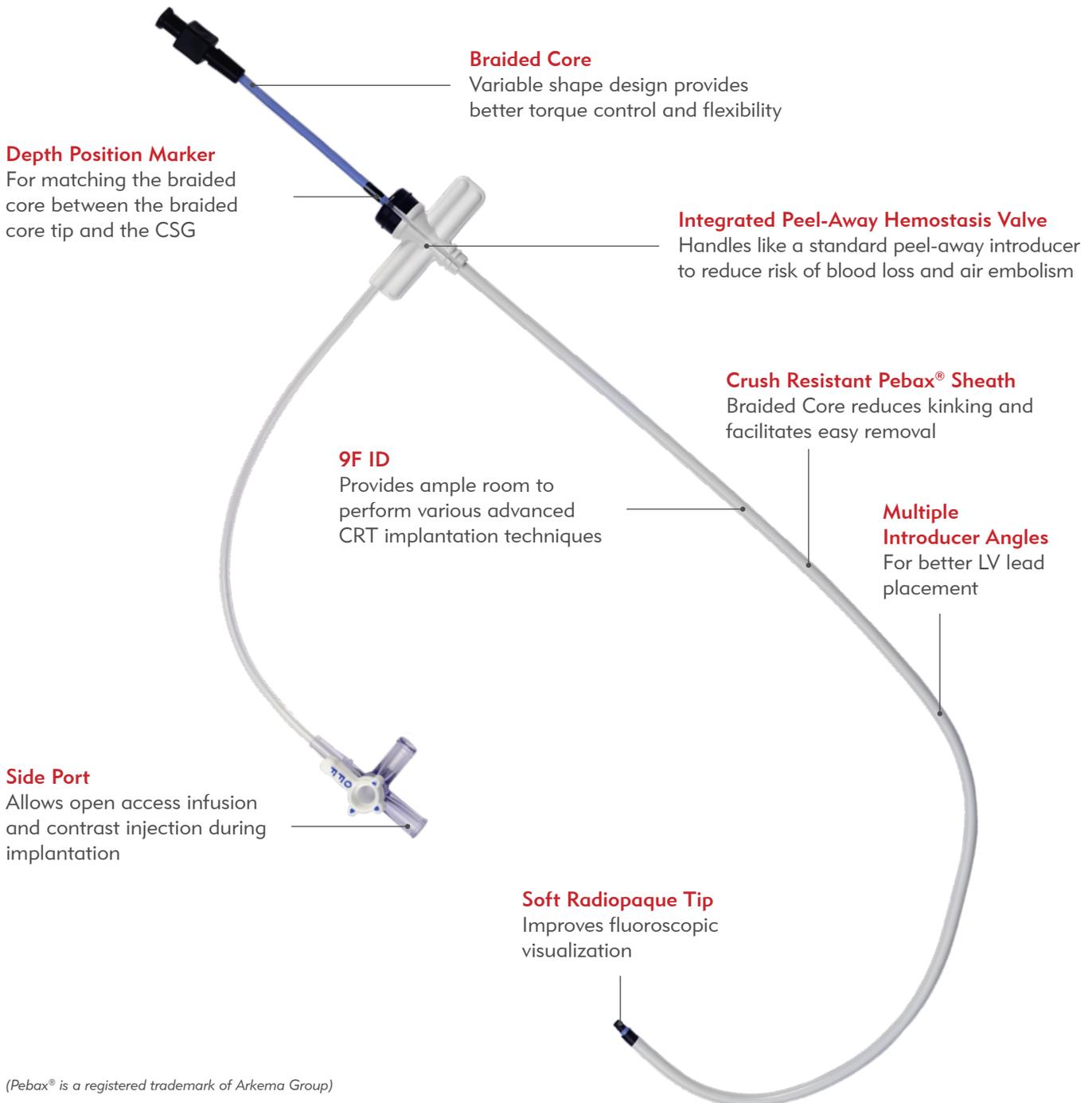
*"A CRT-implant approach using contrast injection and a telescoping-support catheter system results in **FEWER** failed LV lead implants, **IMPROVED** LV lead location, and **SHORTER** procedure times."*

1. Jackson, Kevin P., et al. "Impact of Using a Telescoping-Support Catheter System for Left Ventricular Lead Placement on Implant Success and Procedure Time of Cardiac Resynchronization Therapy." *Pacing and Clinical Electrophysiology* 36.5 (2013): 553-558

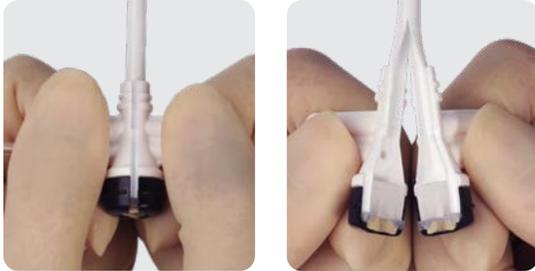
ADVANCING POSSIBILITIES FOR CORONARY SINUS CANNULATION

ONE CATHETER WITH MULTIPLE SHAPE OPTIONS

The Worley™ Advanced Coronary Sinus Guide's unique curve used in conjunction with the Braided Core helps you match your patient's anatomy to the length and curve of the Coronary Sinus Guide. The Braided Core inner catheter can be advanced and manipulated to reduce the number of sheaths needed to facilitate a successful implantation.



(Pebax® is a registered trademark of Arkema Group)

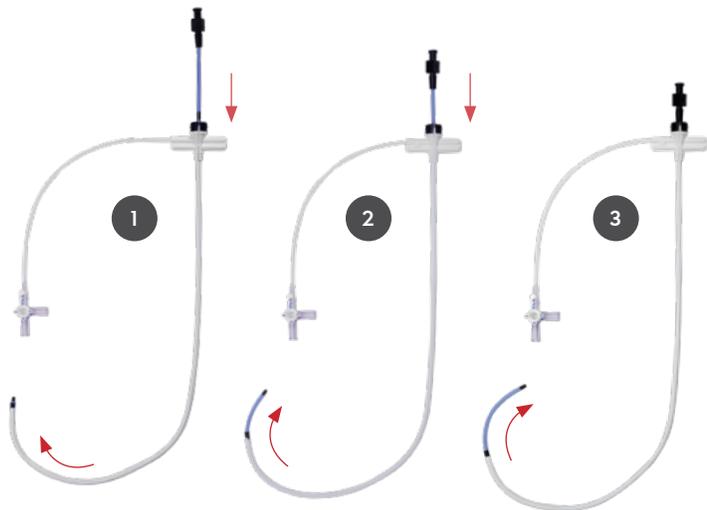
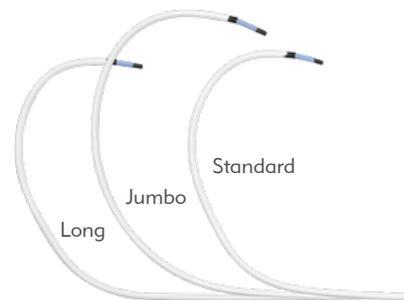


Integrated Peel-Away Hemostasis Valve

- Integrated valve and hub design allows handling like a standard peel-away introducer
- Minimizes the risk of lead movement or dislodgement during catheter removal
- Provides easy removal of the delivery sheath without the need of a slitler

Three Sizes

Size	Length	Purpose
Standard	40 cm	For standard coronary anatomy
Jumbo	50 cm	Large curve for marked atrial enlargement
Long	50 cm	For deep seating and end support



Braided Core Variable Shape Design

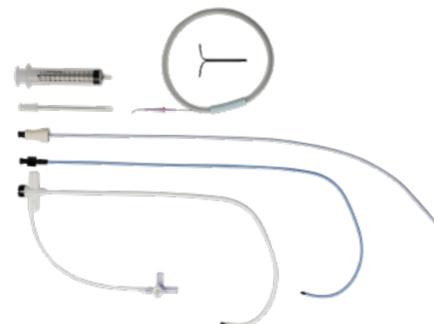
- Reduces the number of sheaths needed to facilitate a successful implantation
- Radiopaque tip for better fluoroscopic visualization
- Inner catheter can be advanced as needed up to 6.5 cm from tip
- CS cannulation in varying anatomy
- Greater torque control when compared to extruded Coronary Sinus Guide
- Proximal black depth-positioning marker for depth guidance and accurate placement

ADVANCED CSG CORONARY SINUS GUIDE

12.1. p.d.

Part Number	Length	Size	Curve	Outer Diameter	Inner Diameter	Tip Diameter
WOR-CSG-B1-09	40 cm	9F	Standard	0.157"	0.130"	0.122"
WOR-CSG-BL1-09	50 cm	9F	Long	0.157"	0.130"	0.122"
WOR-CSG-B2-09	50 cm	9F	Jumbo	0.157"	0.130"	0.122"
WOR-CSG-BR1-09	40 cm	9F	Right	0.157"	0.130"	0.122"

KIT CONTENTS— **PTFE Guide Wire:** 135 Length, 45° angle, 0.035" x 135 cm J tip, **Curved Guiding Core:** 9F introducer, 0.118" OD, 0.095" ID, 0.092" tip, **Straight Vessel Dilator:** 0.038" ID Transvalvular Insertion, **(TVI) Tool:** 1.75", 7F, 0.117" OD, 0.097" ID, **Needle:** 2.75", 18G, **Syringe:** 12 cc



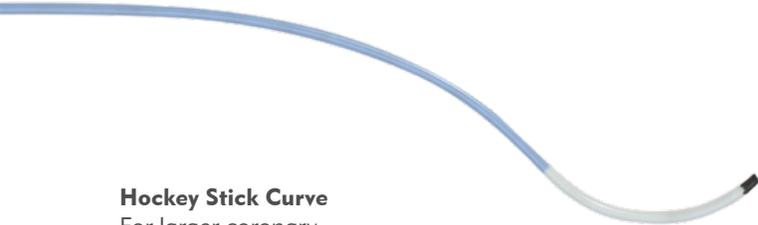
Renal Curve

For most common coronary venous anatomies



Multipurpose Curve

For other coronary venous anatomies



Hockey Stick Curve

For larger coronary venous anatomies



Hook Curve

For smaller challenging coronary venous anatomies



12.2.p.d.

Integrated Valve and Hub Design

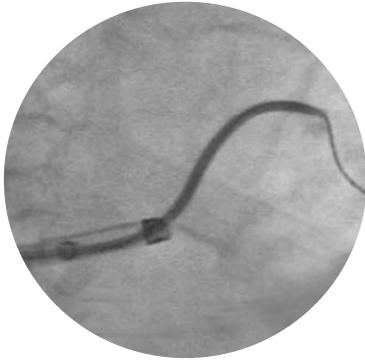
- Breakaway valve provides direct access for the slicer to engage the braided sheath
- Oversized grip reduces risk of lead movement
- Easy-to-use slicer mates to the CSG hub for improved stability during sheath removal



WORLEY ADVANCED LVI

Part Number	Length	Outer Diameter	Inner Diameter	Description
5.5F LVI				
WORLVI-75-5-62-55-RE	62 cm	0.088"	0.072"	Renal
WORLVI-75-5-62-55-HS	62 cm	0.088"	0.072"	Hockey Stick
WORLVI-75-5-62-55-HO	62 cm	0.088"	0.072"	Hook
WORLVI-75-5-62-55-MP	62 cm	0.088"	0.072"	Multipurpose
7F LVI				
WORLVI-75-5-62-07-RE	62 cm	0.120"	0.090"	Renal
WORLVI-75-5-62-07-HS	62 cm	0.120"	0.090"	Hockey Stick
WORLVI-75-5-62-07-HO	62 cm	0.120"	0.090"	Hook
WORLVI-75-5-62-07-MP	62 cm	0.120"	0.090"	Multipurpose

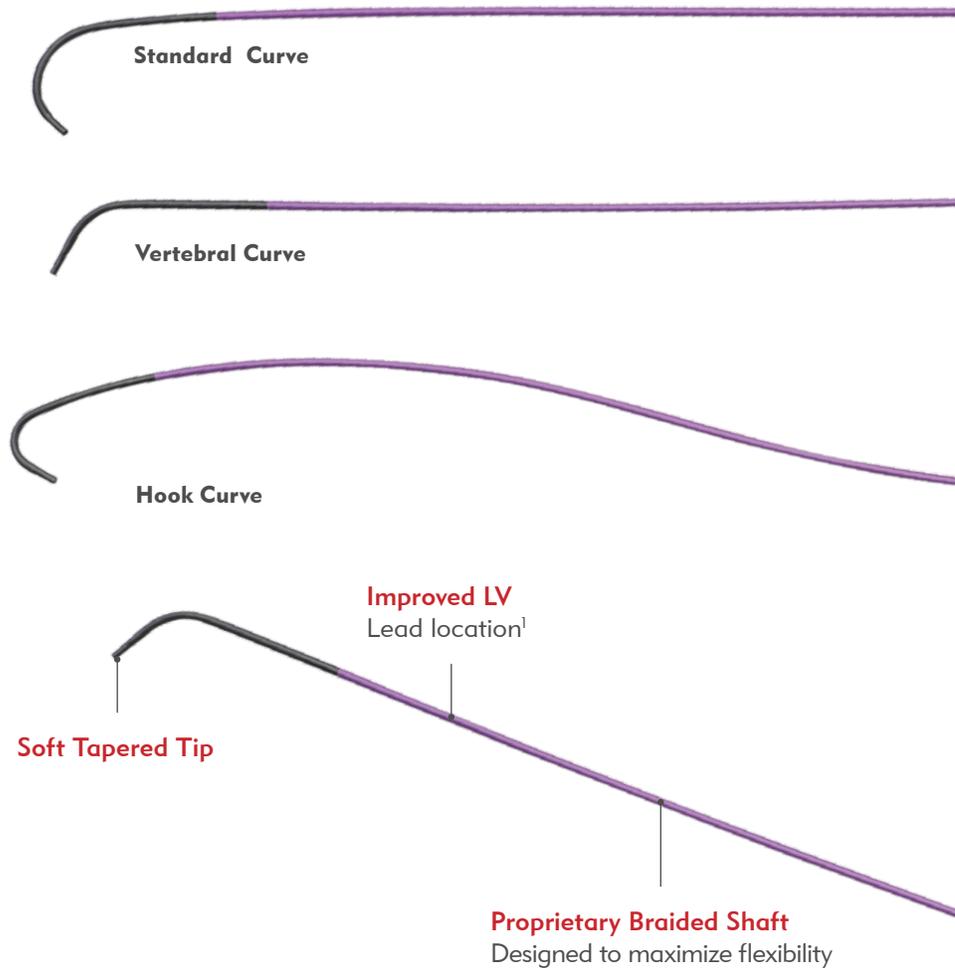
The Worley™ Vein Selector is designed to improve LV lead location. Key features include a unique accordion hub to minimize kinking and enhance steerability, along with a proprietary braided shaft for maximizing torque. The Worley Vein Selector is also highly visible under fluoroscopy.



Highly Visible
Greater visibility (under fluoroscopy) for reliable access to the target vein



Unique Accordion & Ergonomic Wing Hub
Designed to minimize kinking and enhance handling and control



WORLEY VEIN SELECTOR

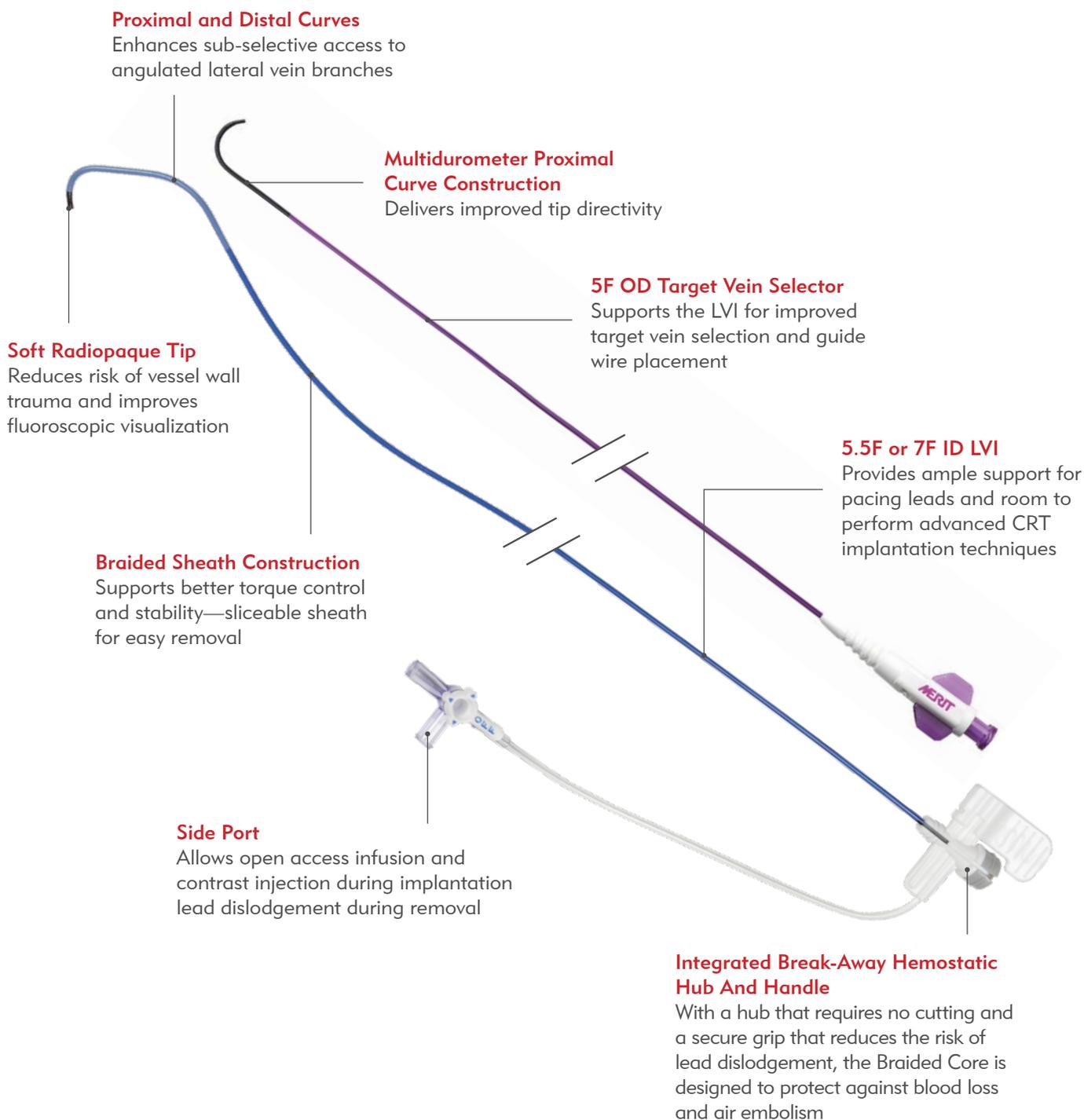
12.3.p.d.

Part Number	French Size	I.D.	Length	Curve
57538CS-WOR	5F	.046"/1.17 mm	75 cm	Standard
57538CSV-WOR	5F	.046"/1.17 mm	75 cm	Vertebral
57538CSHK-WOR	5F	.046"/1.17 mm	75 cm	Hook

1. Jackson KP, Hegland DD, Frazier-Mills C, Piccini JP, Koontz JI, Atwater BD, Daubert JP, Worley SJ. Impact of using a telescoping-support catheter system for left ventricular lead placement on implant success and procedure time of cardiac resynchronization therapy. Pacing Clin Electrophysiol. 2013 May; 36(5):553-8.

ADVANCING EFFICIENT & SUCCESSFUL LV LEAD IMPLANTATION

When used together with the Worley Advanced CSG and Worley Vein Selector, the Worley™ Advanced LVI provides the tools and solutions needed to reduce implantation times, gain easier access to the target vessel, and improve chances for successful CRT implantation.¹



ADVANCING REAL-TIME VISIBILITY FOR ACCURATE PLACEMENT

Inserting Cardiac Resynchronization Therapy (CRT) devices requires accurate placement of LV leads quickly and efficiently. Merit Medical's Worley™ Contrast Administration (CA) Kit combines all of the products you need to gain sustained, clear visibility of coronary venous anatomy. The Worley CA Kit provides real-time visibility during CRT implantation for improved LV lead placement. Labels and a bowl complete the Advanced CA Kit with the accessories you need to meet your clinical needs.

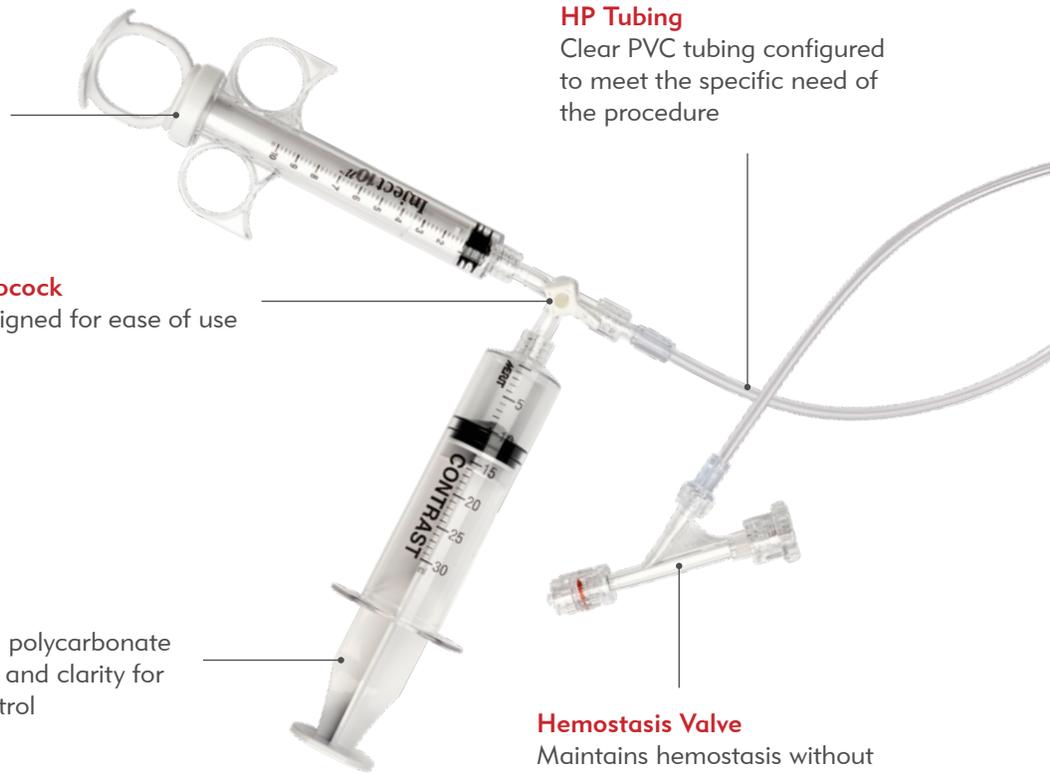
Inject10n™ Coronary Control Syringe
Smaller barrel ID reduces hand fatigue and requires less force to generate high pressure during injections

Stopcock
Designed for ease of use

Medallion® Syringes
Manufactured from strong polycarbonate with glass-like smoothness and clarity for improved visibility and control

HP Tubing
Clear PVC tubing configured to meet the specific need of the procedure

Hemostasis Valve
Maintains hemostasis without compromising catheter movement or restriction of contrast flow



K12-WORLEY1



K12-WORLEY2

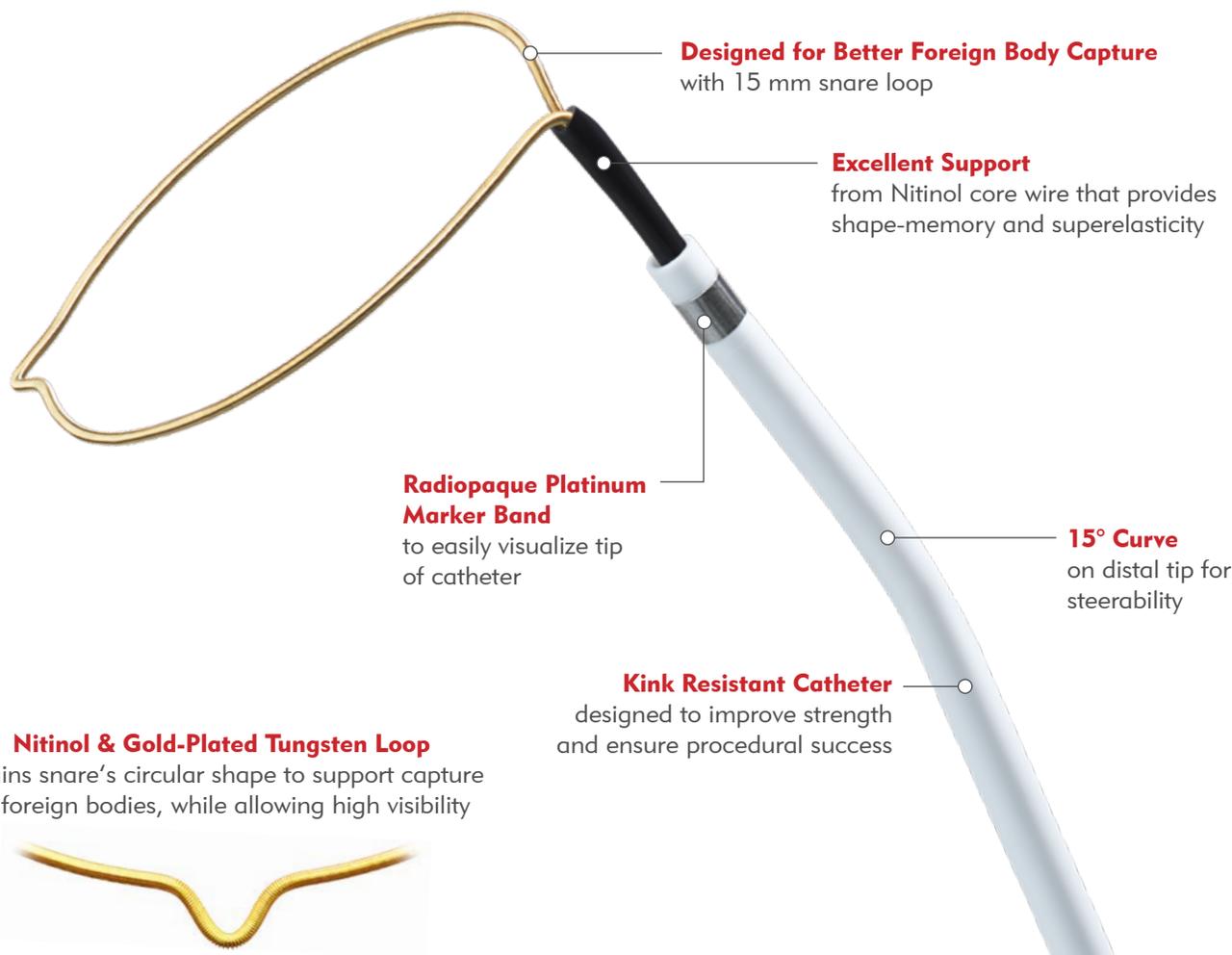


WORLEY KITS

Part Number	Description
K12-WORLEY1	Worley Advanced Contrast Administration Kit 1
K12-WORLEY2	Worley Contrast Administration Kit 2

LV LEAD DELIVERY OPTIONS FOR CHALLENGING ANATOMY

Used with the Worley Advanced LV Delivery system, the ONE Snare System provides another option for placing LV leads during challenging cases. Designed with a 15° tip curve to the 4F catheter and a 15 mm snare loop electrophysiologists can retrieve and manipulate foreign objects in the coronary and peripheral vascular system, allowing for optimal lead position.¹



Nitinol & Gold-Plated Tungsten Loop retains snare's circular shape to support capture of foreign bodies, while allowing high visibility

ONE Snare[®] delivery catheter provides **2.4X more buckle force** than the competition²

ONE SNARE™ SYSTEM

Part Number	Loop Diameter	Snare Length	Catheter Size	Catheter Length
ONE1501	15 mm	80 cm	4F	65 cm

1 Jackson KP, Hegland DD, Frazier-Mills C, Piccini JP, Koontz JI, Atwater BD, Daubert JP, Worley SJ. *Impact of using a telescoping-support catheter system for left ventricular lead placement on implant success and procedure time of cardiac resynchronization therapy.* *Pacing Clin Electrophysiol.* 2013 May; 36(5):553-8.
 2 Data on file, Merit 2012.

PILLARS OF PERFORMANCE

Merit's Amplatz wire provides an increased level of stiffness that delivers support and stability within the vasculature for enhanced navigation.

Flat Wire Outer Coil

Allows a larger inner core to provide additional shaft support

Increased Wire Stiffness

Provides stability within the vasculature for enhanced navigation

Push and Navigation

Without compromising tip flexibility

Proprietary PTFE Coating

Reduces friction along the wire

Extra Support and Stability

Provides extra support to facilitate advancement while maintaining stability and access with the Coronary Sinus Guide

INQWIRE AMPLATZ GUIDE WIRE

Part Number	Diameter	Length	Flexible Tip Length	Description
IQA505	0.035" (0.89)	145 cm (57")	3.5 cm, Short Taper	3mm J
IQA506	0.035" (0.89)	180 cm (71")	3.5 cm, Short Taper	3mm J
IQA507	0.035" (0.89)	260 cm (102")	3.5 cm, Short Taper	3mm J

Ordering Information

ADVANCED CORONARY SINUS GUIDE

Part Number	Length	Size	Curve	Outer Diameter	Inner Diameter	Tip Diameter
WOR-CSG-B1-09	40 cm	9F	Standard	0.157"	0.130"	0.122"
WOR-CSG-BL1-09	50 cm	9F	Standard	0.157"	0.130"	0.122"
WOR-CSG-B2-09	50 cm	9F	Jumbo	0.157"	0.130"	0.122"
WOR-CSG-BR1-09	40 cm	9F	Right	0.157"	0.130"	0.122"

WORLEY ADVANCED LVI

Part Number	Length	Outer Diameter	Inner Diameter	Description
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5.5F LVI

WORLVI-75-5-62-55-RE	62 cm	0.088"	0.072"	Renal
WORLVI-75-5-62-55-HS	62 cm	0.088"	0.072"	Hockey Stick
WORLVI-75-5-62-55-HO	62 cm	0.088"	0.072"	Hook
WORLVI-75-5-62-55-MP	62 cm	0.088"	0.072"	Multipurpose

7F LVI

WORLVI-75-5-62-07-RE	62 cm	0.120"	0.090"	Renal
WORLVI-75-5-62-07-HS	62 cm	0.120"	0.090"	Hockey Stick
WORLVI-75-5-62-07-HO	62 cm	0.120"	0.090"	Hook
WORLVI-75-5-62-07-MP	62 cm	0.120"	0.090"	Multipurpose

WORLEY VEIN SELECTOR

Part Number	French Size	I.D.	Length	Curve
57538CS-WOR	5F	.046"/1.17 mm	75 cm	Standard
57538CSV-WOR	5F	.046"/1.17 mm	75 cm	Vertebral
57538CSHK-WOR	5F	.046"/1.17 mm	75 cm	Hook

WORLEY CONTRAST KITS

Part Number	Description
K12-WORLEY1	Worley Advanced Contrast Administration Kit 1
K12-WORLEY2	Worley Contrast Administration Kit 2

INQWIRE AMPLATZ GUIDE WIRE

Part Number	Diameter	Length	Flexible Tip Length	Description
IQA505	0.035" (0.89)	145 cm (57")	3.5 cm, Short Taper	3mm J
IQA506	0.035" (0.89)	180 cm (71")	3.5 cm, Short Taper	3mm J
IQA507	0.035" (0.89)	260 cm (102")	3.5 cm, Short Taper	3mm J

ONE SNARE™ ENDOVASCULAR SNARE SYSTEM

Part Number	Loop Diameter	Snare Length	Catheter Size	Catheter Length
ONE1501	15 mm	80 cm	4F	65 cm

Before using refer to Instructions for Use for indications, contraindications, warnings, precautions, and directions for use.



Understand. Innovate. Deliver.™

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SEAMLESS CROSSING

HeartSpan[®]
Transseptal Delivery System



HEARTSPAN® STEERABLE SHEATH INTRODUCER

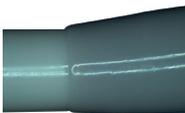
The 180° bi-directional, 8.5F HeartSpan Steerable Sheath Introducer is designed to offer a softer, flexible tip to reduce the risk of atrial wall perforation. The Neutral Position Indicator aids in knowing the direction of the distal tip with a tactile click of the dial. When navigating cardiac chambers, the sheath handle is designed to deliver ergonomic and comfortable control for more precise articulation of the sheath.



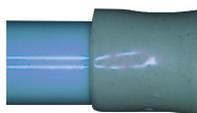
NEUTRAL POSITION INDICATOR
With a tactile click at neutral position, move from 0° to 180° to achieve the desired curve within the atrial chamber.



ULTRA LOW PROFILE
Seamless dilator to sheath transition for smooth advancement across the atrial septum.



Merit Heartspan Sheath



Leading Competitor Sheath

PRODUCT FEATURES



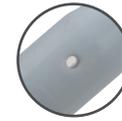
Hemostatic Valve
Reduces bleed back and air embolism



Side Port with 3-Way Stopcock
Allows for flushing and aspiration



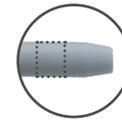
Lubricious Coating
Reduces friction when exchanging EP catheters



Distal Side Holes
Minimize cavitation



Braided Construction
Provides curve durability and support needed for longer cases.



Radiopaque Marker Band
For enhanced visibility under fluoroscopy



Atraumatic Tip
For smooth advancement across atrial septum

HEARTSPAN® STEERABLE SHEATH INTRODUCER

Part Number	Curl Type	Curl Size	Compatible Needle Length
HST-085-00	Small	16.4 mm	98 cm
HST-085-10	Medium	22.4 mm	98 cm
HST-085-20	Large	50.0 mm	98 cm

Packaged 1 kit per box. **Kit Contents include:** (1) Steerable Sheath, (1) Dilator, and (1) 0.032" x 180 cm guidewire.



HEARTSPAN® FIXED CURVE BRAIDED TRANSSEPTAL SHEATH

The HeartSpan Fixed Curve Braided Transseptal Sheath is designed with a seamless dilator to sheath transition to assist with ease of femoral insertion as well as trauma reduction when crossing the atrial septum. Our braided sheath construction allows for curve durability and kink resistance during long procedures.

PRODUCT FEATURES



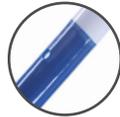
Radiopaque Dilator
Enables visualization



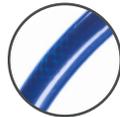
Smooth Transition, Soft Tip
Atraumatic distal tip with seamless dilator to sheath transition for smooth advancement across the atrial septum



Embedded Platinum Marker
For enhanced visibility under fluoroscopy



Dual Side Holes
Minimize cavitation



Radiopaque Braided Sheath
Braided steel core for controlled torqueability made with Pebax®



Lubricious Coating
Reduces friction when exchanging EP catheters



3-Way Stopcock
Allows for flushing and aspiration



Integrated Hemostatic Valve
Designed to reduce air introduction and backflow



Locking Dilator
Sheath and dilator lock to provide a smooth crossing profile during transseptal puncture

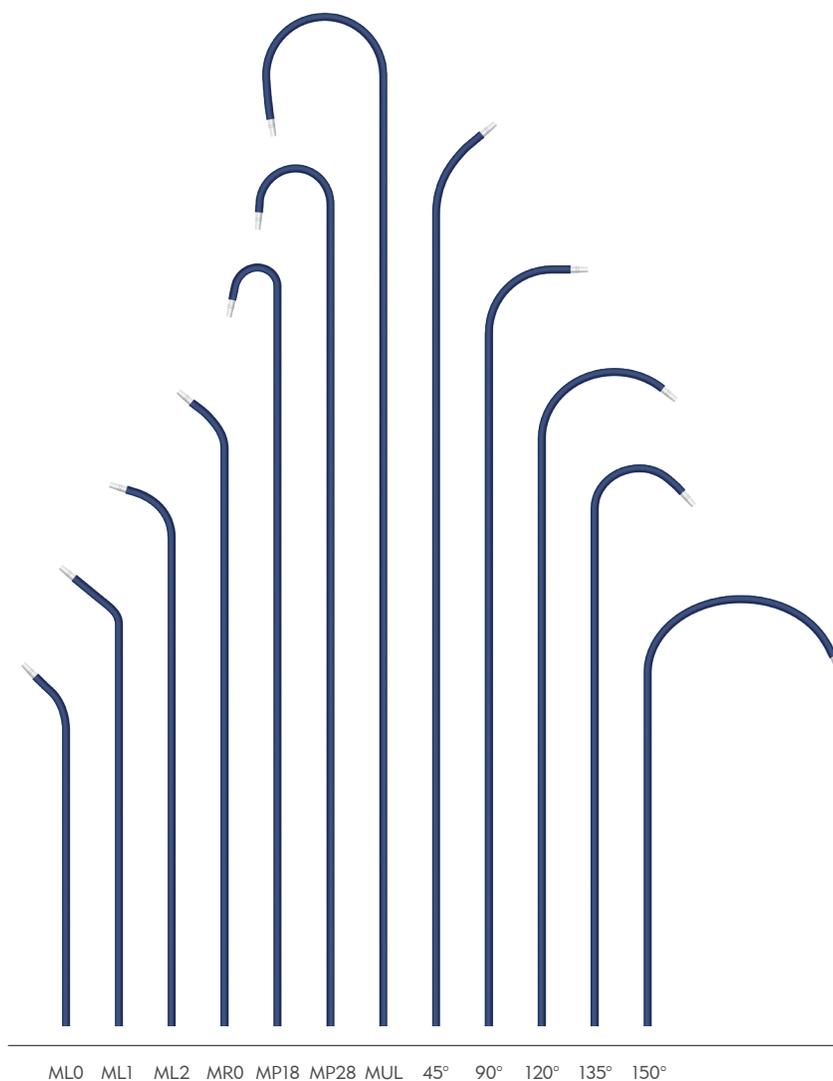
Pebax® is a registered trademark of Arkema Group



FIVE NEW CURVES AVAILABLE



12 AVAILABLE CURVES PROVIDING OPTIONS



HEARTSPAN® FIXED CURVE BRAIDED SHEATH

Part Number	French Size	Length	Curve Type	Compatible Needle Length
FCB8560MP18	8.5F	60 cm	MP18	71 cm
FCB8560MP28	8.5F	60 cm	MP28	71 cm
FCB8561MUL	8.5F	61 cm	MUL	71cm
FCB8563ML0	8.5F	63 cm	ML0	71 cm
FCB8563ML1	8.5F	63 cm	ML1	71 cm
FCB8563ML2	8.5F	63 cm	ML2	71 cm
FCB8563MR0	8.5F	63 cm	MR0	71 cm
FCB856345	8.5F	63 cm	45°	71 cm
FCB856390	8.5F	63 cm	90°	71 cm
FCB8563120	8.5F	63 cm	120°	71 cm
FCB8563135	8.5F	63 cm	135°	71 cm
FCB8563150	8.5F	63 cm	150°	71 cm
FCB8581ML0	8.5F	81 cm	ML0	89 cm
FCB8581ML1	8.5F	81 cm	ML1	89 cm
FCB8581ML2	8.5F	81 cm	ML2	89 cm
FCB8581MR0	8.5F	81 cm	MR0	89 cm
FCB858145	8.5F	81 cm	45°	89 cm
FCB858190	8.5F	81 cm	90°	89 cm
FCB8581120	8.5F	81 cm	120°	89 cm
FCB8581135	8.5F	81 cm	135°	89 cm
FCB8581150	8.5F	81 cm	150°	89 cm

Packaged (1) kit per box. **Kit Contents include:** (1) Fixed Curve Braided Sheath, (1) Dilator, and (1) 0.032" x 180 cm guidewire.

HEARTSPAN® TRANSSEPTAL NEEDLE

The HeartSpan Transseptal Needle combines familiar curve angles with advanced materials, along with an ergonomic handle design engineered to enhance tactile and visual feedback during the transseptal puncture.

PRODUCT FEATURES

TRANSPARENT HANDLE

Allows direct visualization of bubbles before they travel distally



Orientation Arrow

Gives direction



Pre-established Distal Curves

Providing options



Locking Stylet

Provides guidance with needle advancement through dilator to reduce the risk of skiving



Ergonomic Handle Design

Offers excellent handling characteristics



Exceptionally Responsive

Needle backed up with enhanced stiffness



Tapered for Strength



Compatible with the HeartSpan Fixed Curve or Steerable Transseptal Sheath Offering a comprehensive solution



HEARTSPAN® TRANSSEPTAL NEEDLES

Part Number	Length	Curve Angle	Tip Gauge
FND-019-01	71 cm	50° Curve	21
FND-019-02	71 cm	86° Curve	21
FND-019-03	89 cm	50° Curve	21
FND-019-04	89 cm	86° Curve	21
FND-019-05	98 cm	50° Curve	21
FND-019-06	98 cm	86° Curve	21

Packaged 1 kit per box. **Kit Contents include:** (1) Transseptal Needle and (1) Stylet.

13.p.d.



HeartSpan®

Transseptal Delivery System

FULL TRANSEPTAL PORTFOLIO PROVIDING OPTIONS WITH SUPERB FEATURES.

HEARTSPAN® FIXED CURVE BRAIDED SHEATH

Part Number	French Size	Length	Curve Type	Compatible Needle Length
FCB8560MP18	8.5F	60 cm	MP18	71 cm
FCB8560MP28	8.5F	60 cm	MP28	71 cm
FCB8561MUL	8.5F	61 cm	MUL	71 cm
FCB8563ML0	8.5F	63 cm	ML0	71 cm
FCB8563ML1	8.5F	63 cm	ML1	71 cm
FCB8563ML2	8.5F	63 cm	ML2	71 cm
FCB8563MR0	8.5F	63 cm	MR0	71 cm
FCB856345	8.5F	63 cm	45°	71 cm
FCB856390	8.5F	63 cm	90°	71 cm
FCB8563120	8.5F	63 cm	120°	71 cm
FCB8563135	8.5F	63 cm	135°	71 cm
FCB8563150	8.5F	63 cm	150°	71 cm
FCB8581ML0	8.5F	81 cm	ML0	89 cm
FCB8581ML1	8.5F	81 cm	ML1	89 cm
FCB8581ML2	8.5F	81 cm	ML2	89 cm
FCB8581MR0	8.5F	81 cm	MR0	89 cm
FCB858145	8.5F	81 cm	45°	89 cm
FCB858190	8.5F	81 cm	90°	89 cm
FCB8581120	8.5F	81 cm	120°	89 cm
FCB8581135	8.5F	81 cm	135°	89 cm
FCB8581150	8.5F	81 cm	150°	89 cm

Packaged (1) kit per box. **Kit Contents include:** (1) Fixed Curve Braided Sheath, (1) Dilator, and (1) 0.032" x 180 cm guidewire.

HEARTSPAN® STEERABLE SHEATH INTRODUCER

Part Number	Curl Type	Curl Size	Compatible Needle Length
HST-085-00	Small	16.4 mm	98 cm
HST-085-10	Medium	22.4 mm	98 cm
HST-085-20	Large	50.0 mm	98 cm

Packaged 1 kit per box. **Kit Contents include:** (1) Steerable Sheath, (1) Dilator, and (1) 0.032" x 180 cm guidewire.

13.p.d.

HEARTSPAN® TRANSEPTAL NEEDLES

Part Number	Length	Curve Angle	Tip Gauge
FND-019-01	71 cm	50° Curve	21
FND-019-02	71 cm	86° Curve	21
FND-019-03	89 cm	50° Curve	21
FND-019-04	89 cm	86° Curve	21
FND-019-05	98 cm	50° Curve	21
FND-019-06	98 cm	86° Curve	21

Packaged 1 kit per box. **Kit Contents include:** (1) Transseptal Needle and (1) Stylet.

All trademarks and registered trademarks are the property of their respective owners.

Before using refer to Instructions for Use for indications, contraindications, warnings, precautions, and directions for use.



Understand. Innovate. Deliver.™

merit.com

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South Jordan, Utah 84095
1.801.253.1600
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Galway, Ireland
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SEAMLESS CROSSING

HeartSpan[®]
Transseptal Delivery System



HEARTSPAN® STEERABLE SHEATH INTRODUCER

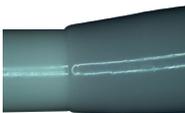
The 180° bi-directional, 8.5F HeartSpan Steerable Sheath Introducer is designed to offer a softer, flexible tip to reduce the risk of atrial wall perforation. The Neutral Position Indicator aids in knowing the direction of the distal tip with a tactile click of the dial. When navigating cardiac chambers, the sheath handle is designed to deliver ergonomic and comfortable control for more precise articulation of the sheath.



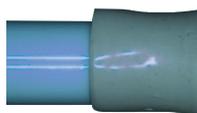
NEUTRAL POSITION INDICATOR
With a tactile click at neutral position, move from 0° to 180° to achieve the desired curve within the atrial chamber.



ULTRA LOW PROFILE
Seamless dilator to sheath transition for smooth advancement across the atrial septum.



Merit Heartspan Sheath



Leading Competitor Sheath

PRODUCT FEATURES



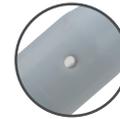
Hemostatic Valve
Reduces bleed back and air embolism



Side Port with 3-Way Stopcock
Allows for flushing and aspiration



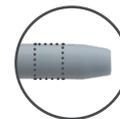
Lubricious Coating
Reduces friction when exchanging EP catheters



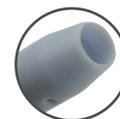
Distal Side Holes
Minimize cavitation



Braided Construction
Provides curve durability and support needed for longer cases.



Radiopaque Marker Band
For enhanced visibility under fluoroscopy



Atraumatic Tip
For smooth advancement across atrial septum

HEARTSPAN® STEERABLE SHEATH INTRODUCER

Part Number	Curl Type	Curl Size	Compatible Needle Length
HST-085-00	Small	16.4 mm	98 cm
HST-085-10	Medium	22.4 mm	98 cm
HST-085-20	Large	50.0 mm	98 cm

Packaged 1 kit per box. **Kit Contents include:** (1) Steerable Sheath, (1) Dilator, and (1) 0.032" x 180 cm guidewire.



HEARTSPAN® FIXED CURVE BRAIDED TRANSSEPTAL SHEATH

The HeartSpan Fixed Curve Braided Transseptal Sheath is designed with a seamless dilator to sheath transition to assist with ease of femoral insertion as well as trauma reduction when crossing the atrial septum. Our braided sheath construction allows for curve durability and kink resistance during long procedures.

PRODUCT FEATURES



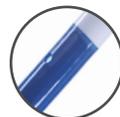
Radiopaque Dilator
Enables visualization



Smooth Transition, Soft Tip
Atraumatic distal tip with seamless dilator to sheath transition for smooth advancement across the atrial septum



Embedded Platinum Marker
For enhanced visibility under fluoroscopy



Dual Side Holes
Minimize cavitation



Radiopaque Braided Sheath
Braided steel core for controlled torqueability made with Pebax®



Lubricious Coating
Reduces friction when exchanging EP catheters



3-Way Stopcock
Allows for flushing and aspiration



Integrated Hemostatic Valve
Designed to reduce air introduction and backflow



Locking Dilator
Sheath and dilator lock to provide a smooth crossing profile during transseptal puncture

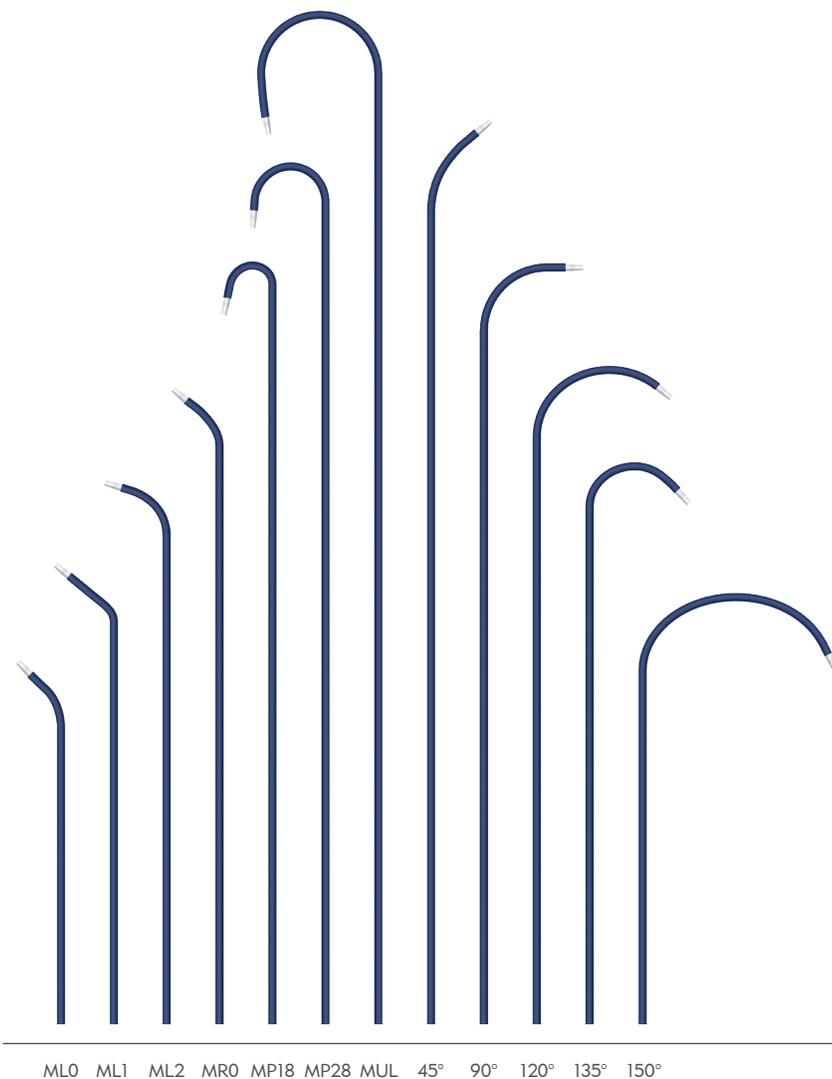
Pebax® is a registered trademark of Arkema Group



FIVE NEW CURVES AVAILABLE



12 AVAILABLE CURVES PROVIDING OPTIONS



HEARTSPAN® FIXED CURVE BRAIDED SHEATH

Part Number	French Size	Length	Curve Type	Compatible Needle Length
FCB8560MP18	8.5F	60 cm	MP18	71 cm
FCB8560MP28	8.5F	60 cm	MP28	71 cm
FCB8561MUL	8.5F	61 cm	MUL	71cm
FCB8563ML0	8.5F	63 cm	ML0	71 cm
FCB8563ML1	8.5F	63 cm	ML1	71 cm
FCB8563ML2	8.5F	63 cm	ML2	71 cm
FCB8563MR0	8.5F	63 cm	MR0	71 cm
FCB856345	8.5F	63 cm	45°	71 cm
FCB856390	8.5F	63 cm	90°	71 cm
FCB8563120	8.5F	63 cm	120°	71 cm
FCB8563135	8.5F	63 cm	135°	71 cm
FCB8563150	8.5F	63 cm	150°	71 cm
FCB8581ML0	8.5F	81 cm	ML0	89 cm
FCB8581ML1	8.5F	81 cm	ML1	89 cm
FCB8581ML2	8.5F	81 cm	ML2	89 cm
FCB8581MR0	8.5F	81 cm	MR0	89 cm
FCB858145	8.5F	81 cm	45°	89 cm
FCB858190	8.5F	81 cm	90°	89 cm
FCB8581120	8.5F	81 cm	120°	89 cm
FCB8581135	8.5F	81 cm	135°	89 cm
FCB8581150	8.5F	81 cm	150°	89 cm

Packaged (1) kit per box. **Kit Contents include:** (1) Fixed Curve Braided Sheath, (1) Dilator, and (1) 0.032" x 180 cm guidewire.

HEARTSPAN® TRANSSEPTAL NEEDLE

The HeartSpan Transseptal Needle combines familiar curve angles with advanced materials, along with an ergonomic handle design engineered to enhance tactile and visual feedback during the transseptal puncture.

PRODUCT FEATURES

TRANSPARENT HANDLE

Allows direct visualization of bubbles before they travel distally



Orientation Arrow

Gives direction



Pre-established Distal Curves
Providing options



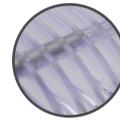
Locking Stylet

Provides guidance with needle advancement through dilator to reduce the risk of skiving



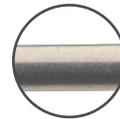
Ergonomic Handle Design

Offers excellent handling characteristics



Exceptionally Responsive

Needle backed up with enhanced stiffness



Tapered for Strength



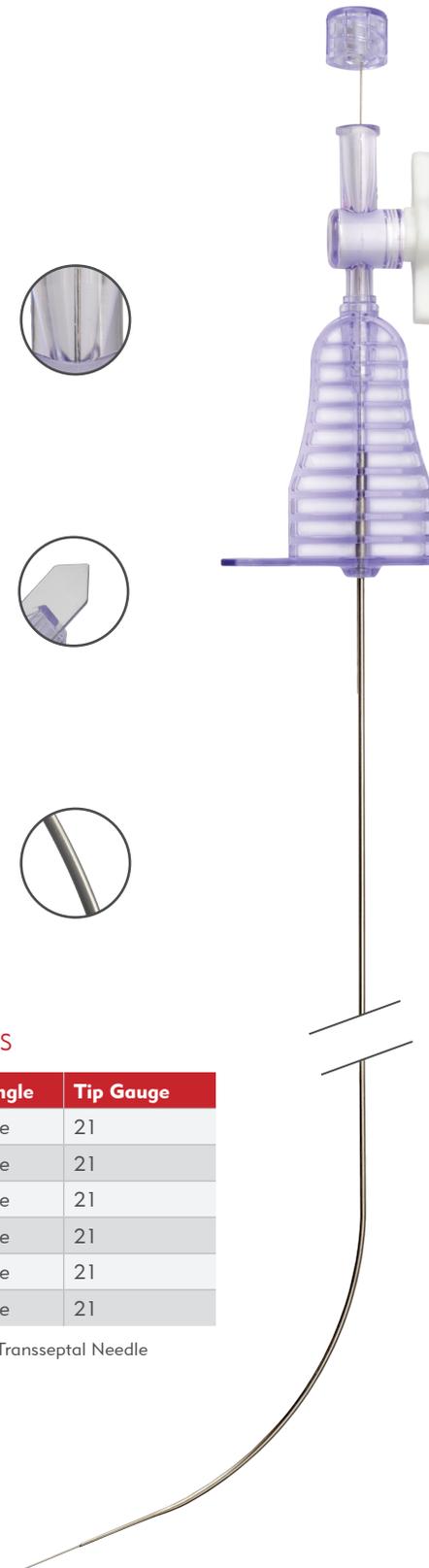
Compatible with the HeartSpan Fixed Curve or Steerable Transseptal Sheath
Offering a comprehensive solution



HEARTSPAN® TRANSSEPTAL NEEDLES

Part Number	Length	Curve Angle	Tip Gauge
FND-019-01	71 cm	50° Curve	21
FND-019-02	71 cm	86° Curve	21
FND-019-03	89 cm	50° Curve	21
FND-019-04	89 cm	86° Curve	21
FND-019-05	98 cm	50° Curve	21
FND-019-06	98 cm	86° Curve	21

Packaged 1 kit per box. **Kit Contents include:** (1) Transseptal Needle and (1) Stylet.



HeartSpan®

Transseptal Delivery System

FULL TRANSEPTAL PORTFOLIO PROVIDING OPTIONS WITH SUPERB FEATURES.

HEARTSPAN® FIXED CURVE BRAIDED SHEATH

14.p.d.

Part Number	French Size	Length	Curve Type	Compatible Needle Length
FCB8560MP18	8.5F	60 cm	MP18	71 cm
FCB8560MP28	8.5F	60 cm	MP28	71 cm
FCB8561MUL	8.5F	61 cm	MUL	71 cm
FCB8563ML0	8.5F	63 cm	ML0	71 cm
FCB8563ML1	8.5F	63 cm	ML1	71 cm
FCB8563ML2	8.5F	63 cm	ML2	71 cm
FCB8563MR0	8.5F	63 cm	MR0	71 cm
FCB856345	8.5F	63 cm	45°	71 cm
FCB856390	8.5F	63 cm	90°	71 cm
FCB8563120	8.5F	63 cm	120°	71 cm
FCB8563135	8.5F	63 cm	135°	71 cm
FCB8563150	8.5F	63 cm	150°	71 cm
FCB8581ML0	8.5F	81 cm	ML0	89 cm
FCB8581ML1	8.5F	81 cm	ML1	89 cm
FCB8581ML2	8.5F	81 cm	ML2	89 cm
FCB8581MR0	8.5F	81 cm	MR0	89 cm
FCB858145	8.5F	81 cm	45°	89 cm
FCB858190	8.5F	81 cm	90°	89 cm
FCB8581120	8.5F	81 cm	120°	89 cm
FCB8581135	8.5F	81 cm	135°	89 cm
FCB8581150	8.5F	81 cm	150°	89 cm

Packaged (1) kit per box. **Kit Contents include:** (1) Fixed Curve Braided Sheath, (1) Dilator, and (1) 0.032" x 180 cm guidewire.

HEARTSPAN® STEERABLE SHEATH INTRODUCER

Part Number	Curl Type	Curl Size	Compatible Needle Length
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HST-085-20	Large	50.0 mm	98 cm

Packaged 1 kit per box. **Kit Contents include:** (1) Steerable Sheath, (1) Dilator, and (1) 0.032" x 180 cm guidewire.

HEARTSPAN® TRANSEPTAL NEEDLES

Part Number	Length	Curve Angle	Tip Gauge
FND-019-01	71 cm	50° Curve	21
FND-019-02	71 cm	86° Curve	21
FND-019-03	89 cm	50° Curve	21
FND-019-04	89 cm	86° Curve	21
FND-019-05	98 cm	50° Curve	21
FND-019-06	98 cm	86° Curve	21

Packaged 1 kit per box. **Kit Contents include:** (1) Transseptal Needle and (1) Stylet.

All trademarks and registered trademarks are the property of their respective owners.

Before using refer to Instructions for Use for indications, contraindications, warnings, precautions, and directions for use.



Understand. Innovate. Deliver.™

merit.com

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Merit Medical Ireland Ltd.
Parkmore Business Park West
Galway, Ireland
+353 (0) 91 703 733



EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No.**CE 541900**

Issued To:

**Merit Medical Systems, Inc.
1600 West Merit Parkway
South Jordan
Utah
84095
USA**

In respect of:

See certificate scope page.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):



Stewart Brain, Head of Compliance & Risk -
Medical Devices

First Issued: **2008-10-03**Date: **2018-10-01**Expiry Date: **2023-10-02****...making excellence a habit.™**

Page 1 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI. This certificate was issued electronically and is bound by the conditions of the contract.

Certificate No: CE 541900

Certificate Scope:

The design, development and manufacture of sterile angiographic, angioplasty and other procedure kits/packs, angiographic catheters, cardiac catheters, vascular catheters, peripheral catheters, guiding catheters, guide wires (coated and uncoated), vascular trocars, introducer needles, angiographic needles, hemodialysis catheters, introducer devices, dilators, transducers, drainage devices, contrast management devices, embolectomy devices, snare devices, hemostasis devices, balloon inflation systems, scalpels, tubing, manifolds/stopcocks, valves, syringes, tracheobronchial stent systems, esophageal stent systems, biliary stent systems, stent positioning system intended for coronary or renal interventional procedures, Peritoneal Dialysis Catheters, accessories and kits, embolization particles, biopsy instruments and accessories, vascular grafts, graft accessory component kits, orthopedic bone cement, bone cement delivery devices/accessories, orthopedic surgical instruments and RF tumor ablation systems for orthopedic applications, percutaneous transluminal angioplasty (PTA) catheters, caps for the disinfection of vascular access connectors.

Those aspects of Annex II related to securing and maintaining sterility in the manufacture of angiographic, angioplasty and other procedure kits/packs, anesthesia conduction catheter fixation devices, catheter flush devices, infusion systems, syringes, suture retention devices, torque devices, drainage/waste/sharps collection devices, surgical/general purpose organizers, abdominal binders, labeling sets, compression devices, balloon inflation systems, non-vascular balloon catheter systems and all related accessories.

Those aspects of Annex II related to metrology in the manufacture of syringes, pressure monitors, tracheal measuring devices, balloon inflation systems and all related accessories.

First Issued: **2008-10-03**Date: **2018-10-01**Expiry Date: **2023-10-02**

...making excellence a habit.™

Page 2 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.



**Merit Medical Systems Inc.
1600 West Merit Parkway
South Jordan, Utah 84095
USA**

Your ref.	N/A
Our ref.	CA-3834999
Tel.	+31 88 96 83009
Fax	+31 88 96 83100
E-mail	medical.nl@dekra.com

September 13, 2023

Subject: Extension of validity of DEKRA Certification B.V. Certification Agreement for continuation of MDD 93/42/EEC surveillance activities, in reference to Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulation (EU) 2017/745 as regards the transitional provision for certain medical devices

Dear Gamaliel Figueroa:

Introduction:

Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulation (EU) 2017/745 as regards the transitional provision for certain medical devices has been published on 20 March 2023 and came into force on the same day.

This Regulation (EU) 2023/607 has amended Regulation (EU) 2017/745 (from here referred to as MDR 2017/745) to now identify that under certain conditions certificates issued by notified bodies in accordance with Directive 93/42/EEC that were still valid on 26 May 2021 and that have not been withdrawn afterwards shall remain valid after the end of the period indicated on the certificate under certain conditions. Additionally should the manufacturer intend to make use of the extension of the validity of the certificates, involvement of a notified body for continued surveillance is required.

This agreement identifies the devices and certificates for which the required conditions are met and that the manufacturer intends to make use of the options for extension of the validity of the certificates. The agreement also identifies the conditions under which DEKRA Certification B.V. will be the notified body responsible for continued surveillance. In order for DEKRA Certification B.V. to continue these surveillance activities the Certification Agreement in place with the manufacturer will be extended, as detailed further below.

Agreement:

Merit Medical Systems, Inc. has identified the intention to make use of the options for extension of the validity of the certificates as detailed in the amendment of the MDR 2017/745 by Regulation (EU) 2023/607.

Evidence has been provided by Merit Medical Systems, Inc. that they meet the following condition(s) for the certificates issued by DEKRA Certification B.V. in accordance with Directive 93/42/EEC to remain valid:

- Merit Medical Systems, Inc. holds certificates issued by DEKRA Certification B.V. in accordance with Directives 90/385/EEC and/or 93/42/EEC that were still valid on 26 May 2021 and that have expired before 20 March 2023, and has in place
EITHER:
 - (a) Before the date of expiry of the certificate, the manufacturer and a notified body have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII of MDR 2017/745 for the conformity assessment in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device;
 - OR
 - (b) A competent authority of a Member State has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) of this Regulation or has required the manufacturer, in accordance with Article 97(1) of this Regulation, to carry out the applicable conformity assessment procedure
- Merit Medical Systems, Inc. holds certificates issued by DEKRA Certification B.V. in accordance with Directive 93/42/EEC that were still valid on 26 May 2021 and that have not been withdrawn afterwards and were not expired on 20 March 2023 and:
 - (a) Has already lodged a formal application with a notified body in accordance with MDR 2017/745 Section 4.3, first subparagraph, of Annex VII for conformity assessment in respect of the device or in respect of the device intended to substitute that device.
 - (b) A written agreement in accordance with MDR 2017/745 Section 4.3, second subparagraph, of Annex VII, is already in place between the notified body to which the formal application has been made and Merit Medical Systems, Inc.
- Merit Medical Systems, Inc. holds certificates issued by DEKRA Certification B.V. in accordance with Directive 93/42/EEC that were still valid on 26 May 2021 and that have not been withdrawn afterwards and were not expired on 20 March 2023 and:
 - (a) Commits to ensure that no later than 26 May 2024, Merit Medical Systems, Inc. or their authorised representative will lodge a formal application with a notified body in accordance with MDR 2017/745 Section 4.3, first

subparagraph, of Annex VII for conformity assessment in respect of the device or in respect of the device intended to substitute that device. Should this commitment not be met by 26 May 2024 the certificate cannot be considered valid.

- (b) For the conditions to be met for the certificate to remain valid the notified body to which the formal application has been made and Merit Medical Systems, Inc. must have signed a written agreement in accordance with MDR 2017/745 Section 4.3, second subparagraph, of Annex VII, by no later than 26 September 2024. Should this agreement not be signed the certificate cannot be considered valid.

Based on evidence provided by Merit Medical Systems, Inc. it has been determined that the following 93/42/EEC DEKRA Certification B.V. certificates of Merit Medical Systems, Inc. for the devices indicated below meet the requirements to remain valid:

Certificate number	Scope and product categories	Annex	Class & rule
3809162CE01 Expiry: 01-Jul-2023	Introducers and Accessories <ul style="list-style-type: none"> • Transseptal Access System • Introducer Sheath Kits and Accessories <ul style="list-style-type: none"> ○ Tear Away Introducer Kits ○ Coronary Sinus Guide Introducer Kits ○ Lateral Vein Introducer Kits ○ Large Bore Introducer Kits ○ Tear Away Sealing Adapters ○ Transvalvular Insertion Tool ○ Braided Tube Cutter ○ Braided Tube Slitter ○ Steerable Sheath Introducer Kits 	Annex II	Class III rule 6 Class III rule 6 Class III, rule 6 Class III, rule 6 Class IIa, rule 6 Class IIa, rule 2 Class Is, rule 2 Class Is, rule 2 Class Is, rule 2 Class III, rule 7
3809162CE02 Expiry: 01-Jul-2023	Splittable Sheath Introducers	II	Class III Rule 6
3809162CE03 Expiry: 26-May-2024	Non-vascular catheter introduction set (GMDN:62391)	II	Class IIa Rule 6
3809162DE01 Expiry: 01-Jul-2023	Introducer Sheath Kits(GMDN:58865) <ul style="list-style-type: none"> • Introducer Sheath Kit: <ul style="list-style-type: none"> ○ ID: 5F – 13.5F ○ Length: 13 – 25 cm • Coronary Sinus Guide Introducer: <ul style="list-style-type: none"> ○ ID : 7F - 9F ○ Length : 40 – 59 cm • Lateral Vein Introducer: <ul style="list-style-type: none"> ○ ID :5.5F, 7F ○ Length : 48 - 66 cm 	Annex II	Class III, rule 6
3809162DE02 Expiry: 01-Jul-2023	Transseptal Devices <ul style="list-style-type: none"> • Transseptal Needle Kit(GMDN:47248) <ul style="list-style-type: none"> ○ Tip Gage: 21-22 ga ○ Length : 56-98 cm 	Annex II	Class III, rule 6

	<ul style="list-style-type: none"> ○ Curve: 50-86° • Fixed Curve Braided Transseptal Sheath Introducer (GMDN:47247) <ul style="list-style-type: none"> ○ Diameter : 8.5 F ○ Length: 60 – 101.5 cm ○ Curve: 15 – 180° and multiplanar (ML1 and ML2) 		
3809162DE03 Expiry: 01-Jul-2023	Steerable Transseptal Access Systems [GMDN: 47247] <ul style="list-style-type: none"> • HeartSpan Steerable Sheath Introducer Kit <ul style="list-style-type: none"> • ID: 8.5F • Length: 74cm 	Annex II	Class III, rule 7
3809162DE04 Expiry: 01-Jul-2023	Splittable Sheath Introducers(GMDN:58865) <ul style="list-style-type: none"> • Prelude SNAP Splittable Sheath Introducer <ul style="list-style-type: none"> ○ ID: 6F– 12.5F ○ Length: 13 – 25cm • Hydrophilic Prelude SNAP Splittable Sheath Introducer <ul style="list-style-type: none"> ○ ID: 6F – 12.5F ○ Length: 13 – 25cm 	II	Class III Rule 6
3809162DE05 Expiry: 01-Jul-2022	Splittable Sheath Introducers <ul style="list-style-type: none"> • Prelude Prestige Splittable Sheath Introducer <ul style="list-style-type: none"> ○ ID: 5 - 16F ○ Length: 13 – 25cm 	II	Class III Rule 6

By signing this agreement Merit Medical Systems, Inc. also confirms that the following additional requirements of MDR 2017/745 Article 120 3c, as amended by Regulation (EU) 2023/607, are met, and will continue to be met, for all products listed above which will continue to be placed on the market:

- those devices continue to comply with Directive 93/42/EEC, as applicable;
- there are no significant changes in the design and intended purpose;
- the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;

Additionally Merit Medical Systems, Inc. also commits that no later than 26 May 2024, the manufacturer has put in place a quality management system in accordance with MDR 2017/745 Article 10(9).

Following from the above information and commitments from Merit Medical Systems, Inc. DEKRA Certification B.V. agrees to be the notified body responsible for the continued appropriate surveillance in accordance with applicable requirements, and in the respect of the applicable devices identified above, as stipulated in MDR 2017/745 Article 120 3e, as amended by Regulation (EU) 2023/607, DEKRA Certification B.V.. This appropriate surveillance shall include at least:

- Surveillance audits in accordance with Directive 93/42/EEC (as applicable), considering also MDR 2017/745 requirements for post market surveillance, vigilance, registration of economic operators and of devices as required by MDR 2017/745 Article 120
- Assessment of reportable changes
- Assessment of reportable adverse events (vigilance) for impact on certification status

For the specific devices given above for which the certificate can still be considered valid, the certificate validity date and dates until when the products may be placed on the market or put into service are as follows.

Type of Device	Date until which certificate can still be considered valid
Class III Class IIb implantable devices excluding well-established technologies (sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)	31 December 2027
Class IIb devices Class IIb implantable devices which are well-established technologies (sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors) Class IIa devices Class I sterile devices Class I devices with a measuring function	31 December 2028

The table above thus also defines the dates until which DEKRA Certification B.V. is responsible for the appropriate surveillance, unless one of the following situations applies:

- Merit Medical Systems, Inc. provides a Notification of Change to inform DEKRA Certification B.V. that devices will no longer be placed on the market or put into service and the certificate should no longer be considered to be valid
- DEKRA Certification B.V. is not the notified body with which the written agreement has been signed for conformity assessment of the device or substitute device in accordance with MDR 2017/745. In this case the notified body with which the written agreement has been signed for conformity assessment of the device or substitute device must take responsibility for surveillance of the device which has a certificate that was issued in accordance with Directive 93/42/EEC. This should be no later than 26 September 2024 as detailed in MDR 2017/745 Article 120 3e, as amended by Regulation (EU) 2023/607. Thus DEKRA Certification B.V.'s responsibility for surveillance will end on 26 September



2024 in this case, or before if a Notification of Change is provided to confirm that the surveillance activities are now carried out by another Notified Body.

Finally, by signing this agreement DEKRA Certification B.V. and Merit Medical Systems, Inc. agree that current Certification Agreement 3827127CN which covers the products under the Directive 93/42/EEC certificates listed above will thus continue to remain valid until the dates as stipulated above, in order for DEKRA Certification B.V. to meet the required surveillance responsibilities. This also includes that the manufacturer will continue to meet the following responsibilities as stipulated in that Certification Agreement:

- Allowing DEKRA to carry out appropriate surveillance activities in respect of the applicable requirements
- Reporting of significant changes to DEKRA Certification B.V. for assessment
- Reporting of adverse events (vigilance) to DEKRA Certification B.V. for assessment

Should you agree with the above please confirm this through a signature below.

Thus duly agreed, drafted and signed:

Company Name

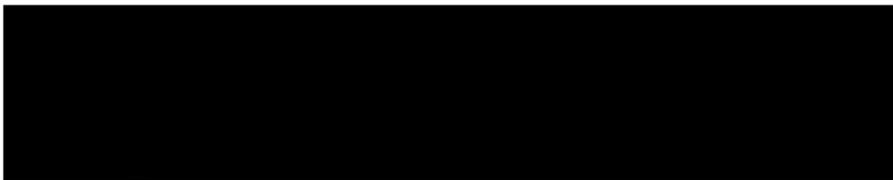
DEKRA Certification B.V.

South Jordan (place)

Arnhem (place)

13-Sep-2023 (date)

September 13, 2023 (date)



(signature)

Cory Marsh (name)

B.T.M. Holtus (name)

Director, RA operations (title)

Managing Director (title)

MDD CE Mark Self-Declaration Memo (EU) 2023/607

Identification of the device(s) (e.g., device name, family/group name)	Directive Certificate number(s) to which this confirmation is made	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity	Notified Body name and number that issued the Directive Certificate	Notified Body name and number where the MDR application was lodged/contract signed	End date of extended validity / transition period	Substitute Device(s) (if applicable)
HeartSpan Fixed Curve Braided Sheath	3809162CE01 EC Certificate	01 July 2023	DEKRA (NB# 0344)	BSI (NB# 2797)	31 Dec 2027	N/A
HeartSpan Transseptal Needle	3809162DE02 EC Design Certificate					

Prepared By: (print)	Desiree Bond Senior Regulatory Affairs Specialist		
Prepared by: (sign)		Date:	Jul 11, 2023
Approved by: (print)		Regulatory Affairs	Date:
Approved by: (sign)		Date:	Jul 11, 2023

With respect to the certificates issued under Council Directive 93/42/EEC on medical devices (“MDD”), (“Directive Certificates”) and their validity per Article 120.2 of Regulation (EU) 2017/745 on medical devices as amended by Regulation 2023/607 of 20 March 2023 (“MDR”) and with respect to the Devices’ and its Manufacturer’s compliance with the conditions to continued placing on the market or putting into service per Article 120.3 of the MDR:

We, as the Manufacturer confirm

- the above listed product and associated certificates meet the conditions for the legal extension of validity as required in Article 120.2 of the MDR.
- the **Device(s)** listed above are in compliance with the conditions listed in Article 120.3 of the MDR for continued placing on the market and putting into service

Namely, the Directive Certificate covering the listed Devices:

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

Expired/expires *after* 20 March 2023:

Choose one applicable statement:

- Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- We do not intend to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

Quality Management System (QMS)

Choose one applicable statement:

- A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
- A QMS in accordance with Article 10(9) MDR is in place.
- A notified body has issued the attached certificate for the MDR-compliant QMS.

Device(s) as listed above

- The Device(s) continue to comply with the MDD.
- The Device(s) have not been significantly changed in its design and intended purpose since 26 May 2021.
- The Device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

EU Authorized Representative: Merit Medical Ireland Ltd.
Parkmore Business Park West
Galway, Ireland

Merit Medical SRN Number for the Device(s) listed: US-MF-000001366

MDD Extension HeartSpan Transseptal Devices

Final Audit Report

2023-07-11

Created:	2023-07-11
By:	Jennifer Fordham (jfordham@merit.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAALrBvexbEyNMKbuxgp_XLWZr9VeMPiJi

"MDD Extension HeartSpan Transseptal Devices" History

-  Document created by Jennifer Fordham (jfordham@merit.com)
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-  Document e-signed by Desiree Bond (desiree.bond@merit.com)
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-  Document emailed to Tom Haueter (tom.haueter@merit.com) for signature
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-  Agreement completed.
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MDD CE Mark Extension Memo (EU) 2023/607

Product Name(s)	TEC/TDF	MDD Certificate(s)	Notified Body	EU MDR Class	Extended MDD Date
Hemostatic Splittable Sheath Intducers, Coronary Sinus Guide (CSG)	TDF0181	3809162CE01 3809162DE01 (Both Certificates Expiring 01 July 2023)	DEKRA Certification B.V. (Notified Body Number 0344)	Class III	31-Dec-2027
Lateral Vein Introducer (LVI)				Class III	31-Dec-2027

Prepared By: (print)	Nan McIntosh, Senior Regulatory Affairs Specialist		
Prepared by: (sign)		Date:	Jun 21, 2023
Approved by: (print)	Tom Haueter, Director, Regulatory Affairs		
Approved by: (sign)		Date:	Jun 21, 2023

With respect to the certificates issued under Council Directive 93/42/EEC on medical devices ("MDD"), ("Directive Certificates") and their validity per Article 120.2 of Regulation (EU) 2017/745 on medical devices as amended by Regulation 2023/607 of 20 March 2023 ("MDR") and with respect to the Devices' and its Manufacturer's compliance with the conditions to continued placing on the market or putting into service per Article 120.3 of the MDR:

We, as the Manufacturer confirm

- the above listed product and associated certificates meet the conditions for the legal extension of validity as required in Article 120.2 of the MDR.
- the **Device(s)** listed above are in compliance with the conditions listed in Article 120.3 of the MDR for continued placing on the market and putting into service.

Namely, the Directive Certificate covering the listed Devices:

- Has been issued after 25 May 2017.
- Has not been withdrawn by 20 March 2023.
- Was valid on 26 May 2021 and did not expire before 20 March 2023.

- The Device(s) continue to comply with the MDD.
- The Device(s) have not been significantly changed in its design and intended purpose since 26 May 2021.
- The Device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.
- A quality management system in accordance with Article 10(9) MDR has been put in place.
- A formal application to the Notified Body in accordance with Section 4.3, first subparagraph, of Annex VII, MDR for conformity assessment has been made for the Device(s) listed or their substitutes, and a corresponding written agreement in accordance with Section 4.3, second subparagraph, of Annex VII has been signed by us and the Notified Body.
- Post-market surveillance, market surveillance, vigilance, registration of economic operators in accordance with the MDR – as far as possible and required - is in place for the Device(s) listed.

EU Authorized Representative: Merit Medical Ireland Ltd.
Parkmore Business Park West
Galway, Ireland

Merit Medical SRN Number for the Device(s) listed: US-MF-000001366

MDD CE Mark Extension (CSG, LVI) for Abbott

Final Audit Report

2023-06-21

Created:	2023-06-21
By:	Kirk McIntosh (Kirk.McIntosh@merit.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAImeM5895aAYH0xwsZTcG_I4tfHk6ukyA

"MDD CE Mark Extension (CSG, LVI) for Abbott" History

-  Document created by Kirk McIntosh (Kirk.McIntosh@merit.com)
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