



# Improved left atrial catheterization efficiency and consistency using a novel steerable transseptal puncture sheath

## HIGHLIGHTS

- ▶ Using the **VersaCross™** Steerable Access Solution (steerable sheath + RF wire) for both transseptal puncture (TSP) and radiofrequency (RF) ablation procedures in atrial fibrillation patients is safe and efficient.
- ▶ Compared to the standard workflow (fixed curve sheath + RF needle, then exchange to a steerable sheath), the zero-exchange VersaCross Steerable workflow resulted in:
  - 34% faster time to TSP from venous access.
  - 40% faster left atrial (LA) catheterization.
  - 14.2 minutes (min) faster overall procedure time.

## INTRODUCTION

- ▶ Steerable sheaths offer optimal contact force during RF catheter ablation, yet their usage for TSP has not been evaluated in terms of safety and workflow efficiency.
- ▶ This study compared LA catheterization and ablation time of a RF wire-based steerable transseptal system to the standard needle-based workflow.

## METHODS

- ▶ Single-center, retrospective study of 30 consecutive patients with atrial fibrillation (AF) undergoing low fluoro/fluorless RF ablation.
- ▶ **Standard workflow (n=15):**
  - TSP performed using an 8.5F **TorFlex™** Fixed Sheath (Boston Scientific) and **NRG™** RF Needle (Boston Scientific).
  - **ProTrack™** Pigtail Wire (Boston Scientific) used to exchange the transseptal assembly for the Agilis™ Steerable Sheath (Abbott).
- ▶ **VersaCross Steerable workflow (n=15):**
  - VersaCross Steerable Access Solution, comprised of a pigtail RF wire and steerable sheath, was used to perform TSP and ablation with no sheath exchanges.
- ▶ TSP and catheter manipulations were guided by intracardiac echocardiography (ICE) and electroanatomic mapping (EAM) using the CARTO 3 System (Biosense Webster).
- ▶ **Primary endpoint:** Time to TSP and steerable sheath access into the LA.
- ▶ **Secondary endpoint:** RF ablation time, LA dwell time, acute procedural success, procedure time, procedural complications, and fluoroscopy use.

## RESULTS

### LA Access

- ▶ 34% faster time to TSP from venous access with VersaCross Steerable workflow vs. standard workflow (Figure 1A).
  - Less variability between cases in the VersaCross group.
- ▶ 40% faster steerable sheath placement in the LA with VersaCross Steerable workflow vs. standard workflow (Figure 1B).

### RF Ablation

- ▶ Acute procedural success was achieved in all patients with no complications and comparable LA dwell time.
- ▶ Overall procedure time was shorter in the VersaCross Steerable workflow vs. standard workflow (Figure 1C).
- ▶ No difference in fluoroscopy use between groups.

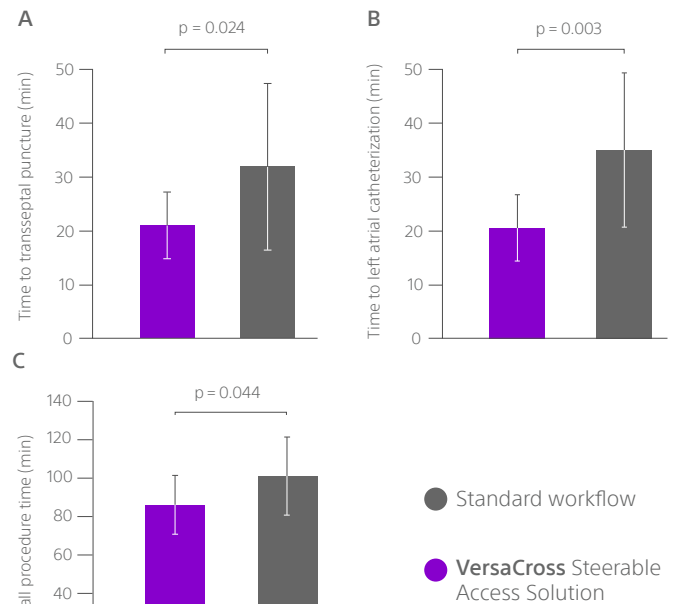


Figure 1. Improved workflow efficiency using VersaCross Steerable workflow vs. standard workflow.

## DISCUSSION AND CONCLUSIONS

- ▶ The VersaCross Steerable Access Solution streamlined the ablation workflow by eliminating 4 procedural steps leading to a faster overall ablation procedure.
- ▶ The atraumatic pigtail wire and rounded dilator tip support direct puncture with a steerable sheath without compromising safety compared to standard steerable sheaths and needles.

## NRG™ Transseptal Needle

**CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. **INDICATIONS FOR USE:** The NRG™ Transseptal Needle is used to create an atrial septal defect in the heart. Secondary indications include monitoring intracardiac pressures, sampling blood, and infusing solutions. **CONTRAINDICATIONS:** The NRG™ Transseptal Needle is not recommended for use with any conditions that do not require cutting or coagulation of soft tissue. **WARNINGS:** • Only physicians with a thorough understanding of angiography and percutaneous interventional procedures should use this device. • Do not alter this device in any way. • The NRG Transseptal Needle is supplied STERILE using an ethylene oxide process. Do not use if the package is damaged. • Laboratory staff and patients can undergo significant x-ray exposure during radiofrequency puncture procedures due to the continuous usage of fluoroscopic imaging. This exposure can result in acute radiation injury as well as increased risk for somatic and genetic effects. Therefore, adequate measures must be taken to minimize this exposure. • The NRG Transseptal Needle is intended for single patient use only. Do not attempt to sterilize and reuse the needle. Reuse can cause the patient injury and/or the communication of infectious disease(s) from one patient to another. Failure to do so may result in patient complications. • The NRG Transseptal Needle must be used with the BMC Connector Cable. Attempts to use it with other connector cables can result in electrocution of the patient and/or operator. • For RFP-100: Do not attempt to puncture with an initial power setting of greater than 10 Watts. The initial attempt should be made with a setting of 10 Watts. In subsequent punctures, the power setting can be increased, if necessary. • The pressure transducer system used with the NRG Transseptal Needle must comply with the electrical safety requirements of IEC 60601. Failure to use compliant pressure transducers may result in patient or operator injury. **PRECAUTIONS:** • Do not attempt to use the NRG Transseptal Needle or ancillary equipment before thoroughly reading the accompanying Instructions for Use. • Radiofrequency puncture procedures should be performed only by physicians thoroughly trained in the techniques of radiofrequency powered puncture in a fully equipped catheterization laboratory. • The sterile packaging should be visually inspected prior to use to detect any compromise. Ensure that the packaging has not been damaged. Do not use the equipment if the packaging has been compromised. • Visually inspect the needle prior to use. Do not use the needle if there is any damage or visibly exposed metal on the shaft where it connects to the handle. • Do not use the NRG Transseptal Needle after the "Use By" date indicated on the label. • The NRG Transseptal Needle is intended for use with only those devices listed in section VII "Equipment Required". • Read and follow the manufacturer's instructions for use of the Disposable Indifferent (Dispersive) Patch (DIP) electrode. Always use DIP electrodes that meet or exceed IEC 60601-2-2 requirements. • Placement of the dispersive electrode on the thigh or hip could be associated with higher impedance. • In order to prevent the risk of ignition make sure that flammable material is not present in the room during RF power application. • Take precautions to limit the effects that the electromagnetic interference (EMI) produced by the Generator may have on the performance of other equipment. Check the compatibility and safety of combinations of other physiological monitoring and electrical apparatus to be used on the patient in addition to the Generator. • Adequate filtering must be used to allow continuous monitoring of the surface electrocardiogram (ECG) during radiofrequency power applications. • Careful needle manipulation must be performed to avoid cardiac damage, or tamponade. Needle advancement should be done under image guidance. If resistance is encountered, DO NOT use excessive force to advance or withdraw the needle. • Do not attempt to puncture until firm position of the active tip has been achieved against the atrial septum. • It is not recommended to exceed five (5) radiofrequency power applications per NRG Transseptal Needle. • Do not bend the NRG Transseptal Needle. Excessive bending or kinking of the needle shaft may damage the integrity of the needle and may cause patient injury. Care must be taken when handling the needle. • The Generator is capable of delivering significant electrical power. Patient or operator injury can result from improper handling of the needle and DIP electrode, particularly when operating the device. • During power delivery, the patient should not be allowed to come in contact with ground metal surfaces. • Apparent low power output or failure of the equipment to function properly at normal settings may indicate faulty application of the DIP electrode, failure to an electrical lead, or poor tissue contact at the active tip. Check for obvious equipment defects or misapplication. Attempt to better position the tip of the needle against the atrial septum. Only increase the power if low power output persists. • Baylis Medical Company relies on the physician to determine, assess and communicate to each individual patient all foreseeable risks of the Baylis Medical Radiofrequency Puncture System. • Ensure the distal tip protruding the dilator/sheath assembly when visualizing on electroanatomic mapping systems. Visualization of the distal tip of the NRG Transseptal Needle may be lost when retracted within the dilator/sheath assembly. **ADVERSE EVENTS:** Adverse events that may occur while using the Baylis Medical Radiofrequency Puncture System include: • Tamponade • Sepsis/Infection • Thromboembolic episodes • Vessel perforation • Atrial Fibrillation • Myocardial Infarction • Vessel Spasm • Sustained arrhythmias • Atrial Flutter • Hemorrhage • Vascular thrombosis • Perforation of the myocardium • Hematoma • Allergic reaction to contrast medium • Ventricular Tachycardia • Pain and Tenderness • Thermal damage to tissue • Arteriovenous fistula • Pericardial Effusion

97185932 (Rev. A.1)

## TorFlex™ Transseptal Guiding Sheath

**CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. **INDICATIONS FOR USE:** The TorFlex™ Transseptal Guiding Sheath kit is used for the percutaneous introduction of various types of cardiovascular catheters and guidewires to all heart chambers, including the left atrium via transseptal perforation / puncture. **CONTRAINDICATIONS:** There are no known contraindications for this device. **WARNINGS:** Laboratory staff and patients can undergo significant x-ray exposure during interventional procedures due to the continuous usage of fluoroscopic imaging. This exposure can result in acute radiation injury as well as increased risk for somatic and genetic effects. Therefore, adequate measures must be taken to minimize this exposure. The use of echocardiography is recommended. • The TorFlex™ Transseptal Guiding Sheath kit is intended for single patient use only. Do not attempt to sterilize and reuse the TorFlex™ Transseptal Guiding Sheath kit. Reuse can cause patient injury and/or the communication of infectious disease(s) from one patient to another. • The TorFlex™ Transseptal Guiding Sheath kit is supplied STERILE using an ethylene oxide process. Do not use if the package is damaged. • The sheath's shaft is coated with a lubricious coating. The following warnings must be considered: o Use of the sheath with introducer sheaths smaller than the size listed in the section below may result in a tight fit that affects device performance, including coating integrity. o Excessive wiping and/or wiping of the sheath with a dry gauze may damage the coating. • The Mechanical Guidewire is coated with a lubricious coating. The following warnings must be considered: o Use with incompatible introducers or dilators may affect device performance and integrity, including coating integrity. o Excessive manual bending and/or shaping of the device may affect the coating integrity. • DO NOT attempt to insert or retract the guidewire through a metal cannula or a percutaneous needle, which may damage the guidewire and may cause patient injury. • Care should be taken to ensure that all air is removed from the sheath before infusing through the side port. • Care should be taken when inserting or removing the dilator and catheters from the sheath. • Do not attempt direct percutaneous insertion of the sheath without the dilator as this may cause vessel injury. • Careful manipulation must be performed to avoid cardiac damage or tamponade. Sheath advancement should be done under fluoroscopic guidance. Echocardiographic guidance is also recommended. **PRECAUTIONS:** • Do not attempt to use the TorFlex™ Transseptal Guiding Sheath kit before thoroughly reading the accompanying Instructions for Use. • Careful manipulation must be performed to avoid cardiac damage, or tamponade. Sheath, dilator and guidewire advancement should be done under fluoroscopic guidance. If resistance is encountered, DO NOT use excessive force to advance or withdraw the device. • The sterile packaging and sheath should be visually inspected prior to use. Do not use the device if it has been compromised or damaged. • Only physicians thoroughly trained in the techniques of the approach to be used should perform interventional procedures. • Only physicians or personnel trained in aseptic techniques should perform aseptic presentation • Note product "Use By" date. • The TorFlex™ Transseptal Guiding Sheath is compatible with introducer sheaths 11Fr or larger. • Do not reshape distal tip or curve of the guidewire. Excessive bending or kinking of the distal curve may damage the integrity of the wire or coating and lead to patient injury. • Only use compatible tip straighteners with the guidewire. • Do not attempt to insert the proximal end of the guidewire as the distal end. • Confirm ancillary devices are compatible with the dilator and guidewire diameters before use. • Individual patient anatomy and physician technique may require procedural variations. • Do not attempt to use the guidewire with electrocautery tools. • Avoid guidewire contact with liquids other than blood, isopropyl alcohol, contrast solution or saline. **ADVERSE EVENTS:** Adverse events that may occur while using the TorFlex™ Transseptal Guiding Sheath kit include: • Infection • Air embolus • Local nerve damage • Hemorrhage • Embolic events • Vessel spasm • AV fistula formation • Atrial septal defect • Pseudoaneurysm • Perforation and/or tamponade • Arrhythmias • Pericardial/pleural effusion • Hematoma • Vessel trauma • Valve damage • Catheter entrapment

97186431 (Rev. A.1)

## ProTrack™ Pigtail Wire

**CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. **INDICATIONS FOR USE:** The ProTrack™ Pigtail Wires are intended for use in percutaneous transseptal procedures to introduce and position catheters and other interventional devices within the left heart. The device is not intended for use in the coronary arteries. **CONTRAINDICATIONS:** There are no known contraindications for this device. **WARNINGS:** • The pigtail wire is intended for single use only. DO NOT sterilize and/or reuse. • The pigtail wire should only be used by a physician trained in percutaneous, intravascular techniques and procedures. It is important to follow the instructions for use prior to using this product. • The guidewire should only be handled by users who are familiar with aseptic handling techniques. • The pigtail wire is supplied sterile and non-pyrogenic in an unopened package and should be used under sterile conditions. DO NOT use if the package has been damaged or opened. • DO NOT use the pigtail wire after the expiration date indicated on the label. Discard pigtail wires that exceed the expiration date. • Confirm ancillary devices are compatible with the pigtail wire outer diameter before use. • Always exercise care while advancing or withdrawing the pigtail wire to prevent wire breakage, kinking, coil separation or damage. Wire damage may cause complications which may require additional interventions. • DO NOT push, auger, withdraw or torque a pigtail wire against resistance until the cause of the resistance has been determined. Applying excessive force against unexpected resistance may cause damage to the pigtail wire, interventional device and/or vessel/organ. • Utilize proper techniques to prevent air from entering the catheter system while removing and reinserting the pigtail wire. Improper techniques could result in an air embolism. • The Instructions for Use supplied with all interventional devices to be used in conjunction with Baylis Medical Pigtail wires should be consulted for intended use, contraindications, warnings, precautions and potential complications related to such devices. • When the pigtail wire is exposed to the vascular system, it should be manipulated while under high-resolution imaging guidance including fluoroscopy and/or echocardiography. Improper visualization of the guidewire may lead to misplacement, dissection, or perforation. • Inspect the pigtail wire prior to use for coil separation, kinking, appropriate distal tip flexibility or breakage. If the pigtail wire is damaged or defective, do not use it. Using a damaged or defective pigtail wire may cause vasculature damage and/or compromise pigtail wire performance. • Guidewire must always be advanced/withdrawn through a compatible catheter. • The curve of the pigtail wire is not designed to be reshaped and should be handled with care to avoid damaging the distal tip or device. • Laboratory staff and patients can undergo significant X-ray exposure during interventional procedures due to the continuous usage of fluoroscopic imaging. The exposure can result in acute radiation injury as well as increased risk for somatic and genetic effects. Therefore, adequate measures must be taken to minimize this exposure. • DO NOT attempt to deliver electrical signals or RF energy through device. • Failure to abide by the warnings in this labeling might result in damage to the device, which may necessitate intervention or result in serious adverse events. **PRECAUTIONS:** • DO NOT allow the pigtail wire to remain in a prolapsed position as this may result in damage to the pigtail wire. • DO NOT straighten the spiral distal tip of the wire more than 5 times during a procedure. • Use care when removing the pigtail wire from the dispenser to reduce the possibility of pigtail wire damage. **ADVERSE EVENTS:** Potential complications associated with the use of the pigtail wire include, but are not limited to: • Vessel Perforation/Dissection/Trauma or Damage • Vessel Spasm • Hemorrhage • Access Site Complications/Hematoma • Thrombus/Thromboembolism • Allergic reaction • Vascular complication • Cardiac tamponade • Cardiac Perforation/Laceration • Conduction disorder • Embolism • Additional Surgical Procedure • Pericardial/pleural effusion • Sepsis/Infection/Inflammation • Foreign Body/Wire Fracture • Hemolysis • Hypovolemia • Myocardial Ischemia and/or Infarction • Stroke/Transient Ischemic Attack • Vessel Occlusion • Wire Entrapment/Entanglement • Valve Complication

97186432 (Rev. A.1)

## VersaCross™ Steerable Sheath

**CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. **INDICATIONS FOR USE:** The VersaCross™ Steerable Sheath kit is indicated for introducing various cardiovascular catheters to the heart, including the left side of the heart through the interatrial septum. **CONTRAINDICATIONS:** There are no known contraindications for this device. **WARNINGS:** • Laboratory staff and patients can undergo significant x-ray exposure during interventional procedures due to the continuous usage of fluoroscopic imaging. This exposure can result in acute radiation injury as well as increased risk for somatic and genetic effects. Therefore, adequate measures must be taken to minimize this exposure. The use of echocardiography is recommended. • The VersaCross Steerable Sheath kit is intended for single patient use only. Do not attempt to sterilize and reuse the VersaCross Steerable Sheath kit. Reuse can cause the patient injury and/or the communication of infectious disease(s) from one patient to another. • Care should be taken to ensure that all air is removed from the sheath before infusing through the side port. • Care should be taken when inserting or removing the dilator and catheters from the sheath. • Do not attempt direct percutaneous insertion of the sheath without the dilator as this may cause vessel injury. • Maintain continuous hemodynamic monitoring throughout procedure. • Provide continuous heparinized saline infusion while the introducer remains in vessel. • To minimize vacuum effects during withdrawal, remove components/aspirate slowly. Refrain from aspiration if a wire is directly through the valve. • Avoid contact with liquids other than blood, isopropyl alcohol, contrast solution or saline. • Prior to sterilization of the sheath's delivery and removal, ensure distal section is as straight as possible. • Do not kink, stretch or severely bend steerable sheath. • Do not use surgical instruments to handle sheath. • The sheath device shaft in its entirety is coated with a hydrophobic lubricious coating for smoother device manipulation. The following warning must be considered: o Excessive wiping and/or wiping with a dry gauze may damage the coating. • The guidewire is coated with a lubricious coating. The following warnings must be considered: o Use with incompatible introducers or dilators may affect device performance and integrity, including coating integrity. o Excessive manual bending and/or shaping of the device may affect the coating integrity. • DO NOT attempt to insert or retract the guidewire through a metal cannula or a percutaneous needle, which may damage the guidewire and may cause patient injury. **PRECAUTIONS:** • Do not attempt to use the VersaCross Steerable Sheath kit before thoroughly reading the accompanying Instructions for Use. • Careful manipulation must be performed to avoid cardiac damage, or tamponade. Sheath, dilator and guidewire advancement should be done under fluoroscopic guidance. If resistance is encountered, DO NOT use excessive force to advance or withdraw the device. • The VersaCross Steerable Sheath kit is supplied STERILE using an ethylene oxide process. • The sterile packaging and all components should be visually inspected prior to use. Do not use if the device, packaging or sterile barrier have been compromised or damaged. • Only physicians thoroughly trained in the techniques of the approach to be used should perform interventional procedures. • Do not use device after its "Use By" date. • Avoid deflecting distal end of sheath during delivery and removal, otherwise damage to vessels may occur. • The VersaCross Steerable Sheath kit is not compatible with transseptal needles such as the "NRG™ Transseptal Needle". • Do not reshape distal tip or curve of the guidewire. Excessive bending or kinking of the distal curve may damage the integrity of the wire or coating and lead to patient injury. • Only use compatible tip straighteners with the guidewire. • Do not attempt to insert the proximal end of the guidewire as the distal end. • Confirm ancillary devices are compatible with the dilator and guidewire diameters before use. • Individual patient anatomy and physician technique may require procedural variations. • Do not attempt to use the guidewire with electrocautery tools. • Avoid guidewire contact with liquids other than blood, isopropyl alcohol, contrast solution or saline. **ADVERSE EVENTS:** Adverse events that may occur while using the VersaCross™ Sheath include: • Infection • Air embolus • Local nerve damage • Vasovagal reaction • Dissection • Vessel spasm • AV fistula formation • Atrial septal defect • Pseudoaneurysm • Aortic puncture • Arrhythmias • Perforation and/or tamponade • Hematoma • Hemorrhage • Catheter entrapment • Embolic events • Stroke • Valve damage • Myocardial infarction • Pericardial/pleural effusion • Pulmonary edema • Coronary artery spasm and/or damage • Vessel trauma • Pacemaker/defibrillator lead displacement

97184084 (Rev. A.1)

## VersaCross™ RF Wire

**CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. **INDICATIONS FOR USE:** The VersaCross™ RF Wire is indicated for creation of an atrial septal defect in the heart. **CONTRAINDICATIONS:** The VersaCross™ RF Wire is not recommended for use with any conditions that do not require the creation of an atrial septal defect. The Connector Cable is not recommended for use with any other Baylis RF Generator or any other device. **WARNINGS:** • Only physicians with a thorough understanding of angiography and percutaneous interventional procedures should use this device. It is recommended that physicians avail themselves of pre-clinical training, a review of pertinent literature and other appropriate education before attempting new interventional procedures. • The VersaCross RF Wire and Connector Cable are supplied STERILE using an ethylene oxide process. Do not use if the package is damaged. • Laboratory staff and patients can undergo significant x-ray exposure during RF puncture procedures due to the continuous usage of fluoroscopic imaging. This exposure can result in acute radiation injury as well as increased risk for somatic and genetic effects. Therefore, adequate measures must be taken to minimize this exposure. • The VersaCross RF Wire and Connector Cable are intended for single patient use only. Do not attempt to sterilize and reuse either devices. Reuse can cause patient injury and/or the communication of infectious disease(s) from one patient to another. Reuse may result in patient complications. • The VersaCross RF Wire must be used with the Connector Cable provided. Attempts to use it with other connector cables can result in electrocution of the patient and/or operator. • Do not use the VersaCross RF Wire with electrocautery or electrosurgery generators, connector cables or accessories as attempted use can result in patient and/or operator injury. • The Connector Cable must only be used with the RFP-100A Baylis RF Generator and the included VersaCross RF Wire. Attempts to use it with other RF Generators and devices can result in electrocution of the patient and/or operator. • The VersaCross RF Wire must be used with 0.035" compatible transseptal sheath and/or dilator devices. Use of incompatible accessory devices may damage the integrity of the VersaCross RF Wire or accessory devices and may cause patient injury. • The VersaCross RF Wire has only been validated for transseptal puncture use through VersaCross dilators which have been demonstrated to provide the required support for optimal function. • The active tip and distal curve of the VersaCross RF Wire are fragile. Be careful not to damage the tip or the distal curve while handling the VersaCross RF Wire. If the tip or the distal curve becomes damaged at any time during its use, discard the VersaCross RF Wire immediately. Do not attempt to straighten the active tip if bent. Damage to device can lead to patient injury. • The VersaCross RF Wire is not intended for use with neonatal patients (i.e. less than one month of age). Do not attempt to treat neonatal patients with the VersaCross RF Wire. • Do not attempt to insert or retract the VersaCross RF wire through a metal cannula or a percutaneous needle, which may damage the device and may cause patient injury. **PRECAUTIONS:** • Do not attempt to use the VersaCross RF Wire and the Connector Cable before thoroughly reading the accompanying Instructions for Use. • RF puncture procedures should be performed only by physicians thoroughly trained in the techniques of RF-powered puncture in a fully equipped catheterization laboratory. • The sterile packaging should be visually inspected prior to use. Do not use the devices if the packaging has been damaged or compromised. • Visually inspect the VersaCross RF Wire and Connector Cable prior to use to ensure there are no cracks or damage to the insulating material. Do not use the wire or the cable if there is any damage. • Do not use the VersaCross RF Wire and/or Connector Cable after the use-by date indicated on the label. • The VersaCross RF Wire and Connector Cable are intended for use with only those devices listed in Section VIII, Equipment Required. • Read and follow the manufacturer's Instructions For Use for the DIP electrode. Always use DIP electrodes that meet or exceed IEC 60601-2-2 requirements. • Placement of the DIP electrode on the thigh could be associated with higher impedance. • In order to prevent the risk of ignition, ensure that flammable materials are not present in the room during RF power application. • Take precautions to limit the effects that the electromagnetic interference (EMI) produced by the Baylis RF Generator may have on the performance of other equipment. Check the compatibility and safety of combinations of other physiological monitoring and electrical apparatus to be used on the patient in addition to the Baylis RF Generator. • Adequate filtering must be used to allow continuous monitoring of the surface electrocardiogram (ECG) during RF power applications. • Do not attempt to insert and use the proximal end of the VersaCross RF Wire as the active tip. • Do not bend the VersaCross RF Wire or the Connector Cable. Excessive bending or kinking of the wire shaft, distal curve of the wire and/or the Connector Cable may damage the integrity of the device components and may cause patient injury. Care must be taken when handling the VersaCross RF Wire and Connector Cable. • Careful manipulation of the VersaCross RF Wire must be performed to avoid vessel trauma. If resistance is encountered, DO NOT use excessive force to advance or withdraw the VersaCross RF Wire or ancillary sheath and/or dilator assembly. Excessive force may lead to bending or kinking of the device limiting advancement and retraction of sheath and/or dilator device. • VersaCross RF Wire and ancillary sheath and/or dilator assembly advancement should be done under imaging guidance. The use of visible markers on the wire body are only an approximate guide for positioning the wire tip with the distal end of the dilator. • Do not attempt to deliver RF energy until the active tip of the VersaCross RF Wire is confirmed to be in good contact with the target tissue. • Avoid RF energy delivery of the VersaCross RF Wire with incompatible dilator or cannula devices, which may lead to patient burns, ineffective puncture or failure to puncture. • It is recommended not to exceed five (5) RF power applications per VersaCross RF Wire. • Never disconnect the Connector Cable from the Baylis RF Generator while RF power is being delivered. • Never disconnect the Connector Cable from the Baylis RF Generator by pulling on the cable. Failure to disconnect the cable properly may result in damage to the cable. • Do not twist the Connector Cable while inserting or removing it from the Isolated Patient Connector on the Baylis RF Generator. Twisting the cable may result in damage to the pin connectors. • The Baylis RF Generator is capable of delivering significant electrical power. Patient or operator injury can result from improper handling of the VersaCross RF Wire and/or DIP electrode, particularly when operating the device. • During power delivery, the patient should not be allowed to come in contact with ground metal surfaces. • Apparent low power output or failure of the equipment to function properly at normal settings may indicate faulty application of the DIP electrode, failure to an electrical lead, or poor tissue contact at the active tip. Check for obvious equipment defects or misapplication. Attempt to better position the active tip of the VersaCross RF Wire against the atrial septum. Only increase the power if low power output persists. • If using electroanatomical mapping guidance, it is recommended to use it along with alternative imaging modality in the event there is loss of visibility of the device. **ADVERSE EVENTS:** Adverse events that may occur while creating an atrial septal defect include: • Tamponade • Sepsis/Infection • Thromboembolic episodes • Vessel perforation • Atrial Fibrillation • Myocardial Infarction • Vessel spasm • Sustained arrhythmias • Atrial Flutter • Hemorrhage • Vascular thrombosis • Perforation of the myocardium • Hematoma • Allergic reaction to contrast medium • Ventricular Tachycardia • Pain and Tenderness • Arteriovenous fistula • Pericardial effusion • Tachycardia • Vascular Trauma • Additional Surgical Procedure • Wire entrapment/ entanglement • Foreign body/wire fracture

97184047 (REV. B)

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EP-1841105-AA