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Procedural simplification of left atrial appendage occlusion using the VersaCross connect system: First in-human experience

HIGHLIGHTS

- First in-human experience using the **VersaCross Connect**™ LAAC Access Solution for **WATCHMAN FLX**™ implantation was successful in all patients with no procedural complications.
- **VersaCross Connect**™ improved procedure efficiency and saved six steps compared to the standard needle-based workflow.

INTRODUCTION

- Left atrial appendage closures (LAAC) traditionally require several device exchanges from transseptal puncture (TSP) to device delivery.
- The new **VersaCross Connect**™ LAAC Access Solution (Baylis Medical*) is designed to integrate with the **WATCHMAN FLX**™ delivery sheath (Boston Scientific) to access the left atrium (LA).
- This study reports the first in-human experience using the **VersaCross Connect**™ LAAC Access Solution.

METHODS

- Prospective case series using the **VersaCross Connect**™ system for **WATCHMAN FLX**™ LAAC device at two different centers.
- Preprocedural planning involved cardiac computed tomography for all patients and all LAAC procedures were guided by transesophageal echocardiography (TEE).
- After vascular access, the **VersaCross Connect**™ system, comprised of the **VersaCross**™ RF Wire and the **VersaCross Connect**™ dilator, was used in conjunction with the WATCHMAN sheath to canulate the superior vena cava (SVC), and perform infero-posterior TSP to access the LA (Figure 1).
- The WATCHMAN sheath was placed in the left atrial appendage (LAA) over the pigtail **VersaCross**™ RF Wire for **WATCHMAN FLX**™ device placement.

RESULTS

- Nine consecutive cases of **WATCHMAN FLX**™ LAAC were performed using the **VersaCross Connect**™ system.
- LAAC was successful in 100% of patients with no procedural complications.
  - Time from TSP to **WATCHMAN FLX**™ release was 12.2 ± 1.9 min.
  - Overall procedure time was 31 ± 6.3 min.
  - Fluoroscopy time was 6.7 ± 4.9 min.
- The **VersaCross Connect**™ system was directly inserted into the right femoral vein in all but one patient.

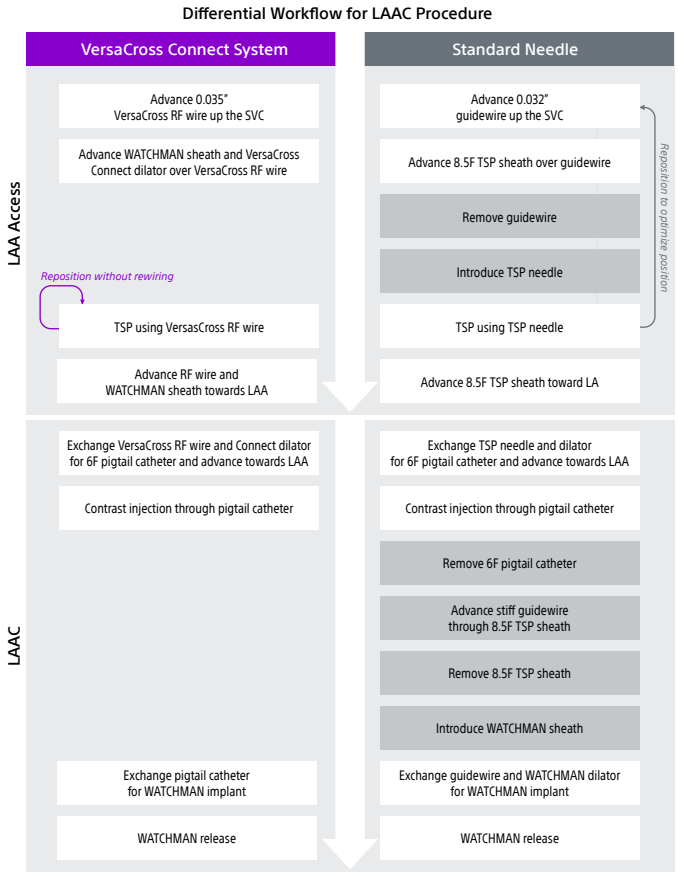

Figure 1. VersaCross Connect™ LAAC Access Solution (Baylis Medical*) eliminates six steps from **WATCHMAN FLX**™ (Boston Scientific) LAAC procedures compared to standard needle workflow. LA: left atria. LAAC: left atrial appendage closure. RF: radiofrequency. SVC: superior vena cava. TSP: transseptal puncture

DISCUSSION & CONCLUSIONS

- Streamlining LA access and simplifying LAAC procedures by eliminating multiple sheath exchanges can reduce the risk of air embolism and perforation.
- Short overall procedure time (31 min) and interval between LAA access and device deployment (12 min) were observed with the **VersaCross Connect**™ Access Solution system.
- The **VersaCross Connect**™ LAAC Access Solution allowed for safer and more efficient **WATCHMAN FLX**™ LAAC procedures.

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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

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VersaCross Connect™ Transseptal Dilator

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner. Prior to use, please refer to all applicable "Instructions for Use" for more information on Intended Use/Indications, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator's Instructions.

INTENDED USE/INDICATIONS FOR USE: The VersaCross Connect Transseptal Dilator 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. United States: The VersaCross Connect Transseptal Dilator is indicated for use in procedures where access to the left atrium via the transseptal technique is desired.**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 Connect Transseptal Dilator and accompanying guidewire are intended for single patient use only. Do not attempt to sterilize and reuse the VersaCross Connect Transseptal Dilator or accompanying guidewire. 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 VersaCross Connect Transseptal Dilator and accompanying guidewire are supplied STERILE using an ethylene oxide process. Do not use if the package is damaged. • Care should be taken to ensure that all air is removed from the dilator before infusing through the proximal hub. • Care should be taken when inserting or removing the dilator from access sheaths or introducer sheaths. • Manual shaping of the distal curve shall be done with smooth motions along the curve. Do not use excessive force and/or pressure when reshaping. • Care should be taken when inserting or removing compatible guidewires from the dilator lumen. • Do not attempt direct percutaneous insertion of the dilator without a guidewire as this may cause vessel injury. • Careful manipulation must be performed to avoid cardiac damage or tamponade. Dilator advancement should be performed under imaging guidance. Fluoroscopic or echocardiographic imaging is recommended. If resistance is encountered, DO NOT use excessive force to advance or withdraw the device. • 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. o 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 Connect Transseptal Dilator or accompanying guidewire before thoroughly reading the accompanying Instructions for Use. • The sterile barrier system, dilator, and guidewire should be visually inspected prior to use. Do not use if the sterile barrier integrity or devices have been compromised or damaged. • Only physicians thoroughly trained in the techniques of the approach to be used should perform interventional procedures. • The VersaCross Connect Transseptal Dilator is compatible with introducer sheaths 12.5F or larger. • The VersaCross Connect Transseptal Dilator is for use with specified models of 12F ID WATCHMAN™ Access Sheath that are 75cm in length or the WATCHMAN TruSteer Access Sheath that is 67 cm in length. • The VersaCross Connect Transseptal Dilator is compatible with 0.035" transseptal devices and guidewires or smaller. • The VersaCross Connect Transseptal Dilator 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.

POTENTIAL ADVERSE EVENTS: Adverse events that may occur while using the VersaCross Connect Transseptal Dilator and accompanying guidewire include: • Infection • Local nerve damage • Vessel spasm • AV fistula formation • Arrhythmias • Hematoma • Catheter entrapment • Valve damage • Air embolus • Vessel trauma • Pseudoaneurysm • Atrial septal defect • Perforation and/or tamponade • Hemorrhage • Embolic events • Pericardial/pleural effusion

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