Highlights from:
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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.

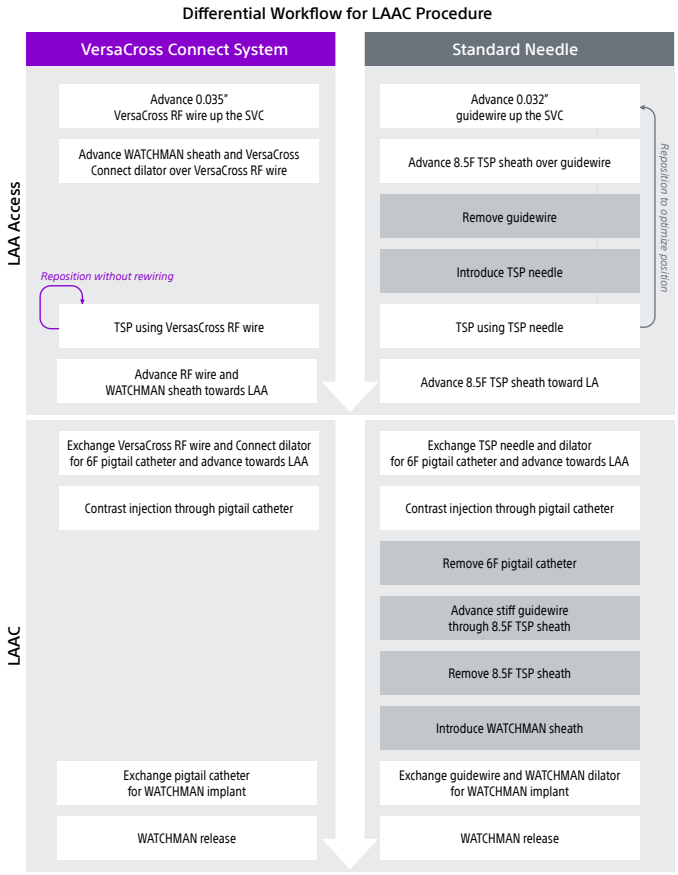

Figure 1. VersaCross Connect™ LAAC Access Solution (Baylis Medical*) eliminates six steps from **WATCHMAN FLX**™ (Boston Scientific) LAAC procedures compared to standard needle workflow. LA: left atria. LAAC: left atrial appendage closure. RF: radiofrequency. SVC: superior vena cava. TSP: transseptal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

*A wholly-owned subsidiary of Boston Scientific Corporation.

Brief Summary | **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: • 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 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.

PRECAUTIONS: • In order to prevent the risk of ignition, ensure that flammable materials are not present in the room during RF power application. • 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. • 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. • 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

EP-1504711-AA

Brief Summary | **VersaCross Connect™** Transseptal Dilator

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 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 results in patient complications. • 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. • 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: • 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. • 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".

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

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