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VersaCross Transseptal System for Mitral Transcatheter Edge-To-Edge Repair With the PASCAL Repair Platform

HIGHLIGHTS

The **VersaCross™** RF Transseptal Solution is a safe and easy-to-use platform that streamlines transseptal puncture (TSP), and offers many advantages over standard mechanical needles when used in transcatheter edge-to-edge repair (M-TEER) procedures. Compared to a standard mechanical needle-based workflow, a VersaCross RF wire-based workflow:

- Shortened time to TSP and first PASCAL™ Implant release significantly, enabling 2.2x faster TSP and 1.6x faster time to first PASCAL Implant release.
- Allowed a more precise crossing to be achieved due to the reduction of force needed to tent the septum at the time of crossing.
- Improved M-TEER procedural efficiency by reducing the number of wires and wire exchanges required.

INTRODUCTION

- Precise positioning and puncture of the fossa ovalis is critical for efficient access to the left atrium (LA) and successful mitral transcatheter edge-to-edge repair.
- This study is the first to compare use of the **VersaCross™** Radiofrequency (RF) Wire (Baylis Medical*) to conventional mechanical puncture for M-TEER using the PASCAL Precision™ Transcatheter Valve Repair System (Edwards Lifesciences).

METHODS

- This single-center, retrospective study included 33 consecutive patients undergoing M-TEER with the PASCAL Precision system using two TSP methods:
- **Mechanical Needle Group (n = 10):**
  - A 150-cm J-tipped 0.032" guidewire was used to introduce a Mullins (Medtronic) or SL1 (Abbott) sheath and dilator.
  - The guidewire was then exchanged for the BRK1™ Transseptal Needle (Abbott) to drop down to the septum for performing TSP.
  - After TSP, the dilator and needle were exchanged for an Amplatz Super Stiff™ Guidewire (Boston Scientific) for subsequent delivery of the 22F PASCAL™ Guide Sheath.
- **VersaCross RF Wire Group (n = 23):**
  - The 0.035" VersaCross RF pigtail wire was used to introduce the dedicated VersaCross transseptal sheath and dilator and position on the fossa ovalis.
  - The VersaCross wire was then used to perform RF TSP.
  - After crossing, the VersaCross wire was used to exchange the transseptal sheath for the 22F PASCAL Guide Sheath, which was advanced into the LA.

RESULTS

- TSP was successful in all patients in both groups, with no cases of pericardial effusion or tamponade.
- Fewer guidewires were used in the VersaCross procedure workflow (1) than the mechanical needle workflow (2).
- Median time to TSP was shorter using the VersaCross system than mechanical needle (18 min [IQR: 10–27 min] vs. 40 min [IQR: 25–46 min]; p = 0.048) (Figure 1).
- Median time to first PASCAL Implant release was shorter using the VersaCross system than mechanical needle (94 min [IQR: 73–130 min] vs. 146 min [IQR: 115–175 min]; p = 0.029) (Figure 1).

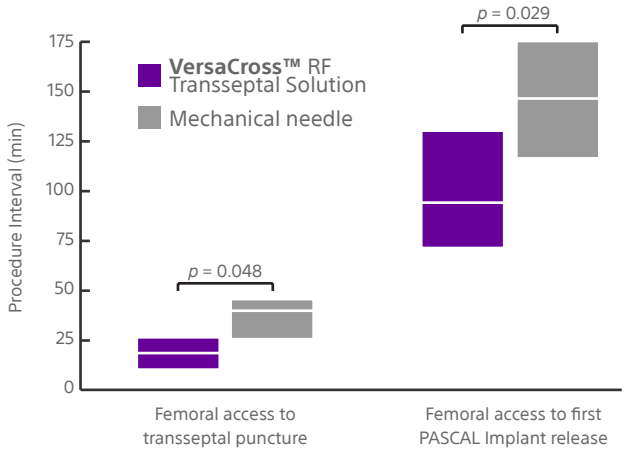

Figure 1. Time from femoral access to transseptal puncture and first PASCAL Implant release using a mechanical needle (n = 10) vs. the VersaCross RF system (n = 23). Results are the median ± inter-quartile range (IQR).

DISCUSSION AND CONCLUSIONS

- The VersaCross system eliminated the need for an additional supportive guidewire for large therapy sheath exchange.
- Compared to a mechanical needle, the VersaCross system significantly reduced transseptal puncture time and time to PASCAL Implant release.
- Overall, the authors report the VersaCross RF Transseptal Solution is a safe and effective system that can streamline structural heart interventions requiring large-bore sheath delivery to the LA.

*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™** 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™ Transseptal Dilator 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 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. Failure to follow this instruction may result in patient complications • Maintain continuous hemodynamic monitoring throughout procedure • Provide continuous heparinized saline infusion while the introducer remains in vessel.

PRECAUTIONS: • 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.

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 • Thromboembolic events • Stroke • Valve damage • Myocardial infarction • Pacemaker/defibrillator lead displacement • Pulmonary edema • Coronary artery spasm and/or damage • Vessel trauma • Pericardial/pleural effusion

EP-1506213-AA

Brief Summary | **VersaCross™** Transseptal 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™ Transseptal 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 VersaCross™ Transseptal Sheath kit is intended for single patient use only. Do not attempt to sterilize and reuse the VersaCross™ Transseptal Sheath kit. Reuse can cause patient injury and/or the communication of infectious disease(s) from one patient to another. • 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: • 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™ Transseptal Sheath is compatible with introducer sheaths 11Fr or larger. • The VersaCross™ Transseptal Sheath and Dilator are compatible with transseptal devices and guidewires .035" or smaller. • The VersaCross™ Transseptal Sheath kit is NOT compatible with transseptal needles such as the "NRG™ Transseptal Needle".

ADVERSE EVENTS: Adverse events that may occur while using the VersaCross™ Transseptal 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

EP-1506605-AA

EP-1696104-AA