**VersaCross Radiofrequency System Reduces Time to Left Atrial Access versus Conventional Mechanical Needle**

**HIGHLIGHTS**

The study found LAAC sheath delivery with the VersaCross™ RF Transseptal Solution was:

- Efficient: Transseptal puncture and LAAC sheath delivery on average in under 7 mins.
- Exchangeless: Faster LA access by combining a starter wire, RF transseptal device, and exchange rail in a 3-in-1 solution.
- Effortless: Controlled RF puncture with a single wire.

**INTRODUCTION**

- Left atrial (LA) catheterization requires numerous device exchange steps, and has associated risks and safety concerns.
- The VersaCross™ RF Transseptal Solution (Baylis Medical®) enables vascular cannulation, transseptal puncture (TSP), and device exchange using a single RF-tipped pigtail wire.

**METHODS**

- Consecutive series of left atrial appendage closure (LAAC) using WATCHMAN™ (Boston Scientific) or Amulet™ (Abbott) devices were retrospectively evaluated.
- Femoral access was obtained for inferoposterior TSP using two methods:
  
  **Conventional approach (n=10):**
  - Requiring a starter wire, sharp mechanical needle (BRK-1™ Transseptal Needle, Abbott), fixed curve sheath (Swartz™ Transseptal Guiding Introducers, Abbott), and stiff exchange wire (Amplatz Super Stiff™, Boston Scientific or ProTrack™ Pigtail Wire, Baylis Medical)

  **VersaCross™ RF Transseptal Solution (n=10):**
  - Comprised of the VersaCross™ RF Wire, Sheath, and Dilator

  Efficiency was assessed in terms of time from femoral access to TSP, delivery of LAAC sheath in the LA, device release, overall procedure, and fluoroscopy use.

  Safety was assessed in terms of intra-procedural and in-hospital complications.

**RESULTS**

- LAAC success was 100% using both methods, with no complications.
- Significant improvement in LA access times using VersaCross™ RF Transseptal Solution vs. conventional method:
  - Shorter time to TSP [4.1±2.5 min vs. 8.4±4.0 min (p=0.009)]
  - Less time for LAAC delivery sheath into LA [6.7±2.4 min vs. 13.4±5.4 min (p=0.002; Figure 1)]

- Trend for overall procedural improvement using VersaCross™ RF Transseptal Solution vs. conventional method:
  - Shorter time to device release [23.7±6.4 min vs. 31.2±10.0 min (p=0.062)]
  - Less fluoroscopy use [7.2±2.2 min vs. 11.4±5.9 min (p=0.061)]

**DISCUSSION & CONCLUSIONS**

- VersaCross™ RF Transseptal Solution combines a starter wire, transseptal needle, and exchange guidewire for faster LA access, and may improve overall procedural efficiency.

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* A wholly-owned subsidiary of Boston Scientific Corporation.
† From femoral access to LAAC sheath delivery using VersaCross™ RF Transseptal Solution compared to a conventional mechanical needle and fixed curve sheath (Inohara et al., 2021).

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**Time for LAAC Sheath Delivery**

- **VersaCross™ RF Solution**: 6.7 min.
  - 2x Faster†
  - p=0.002
- **BRK™ needle + SL sheath**: 13.4 min.

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**Figure 1.** LAAC sheath delivery is two times faster using the VersaCross™ RF Transseptal Solution than the conventional workflow."
**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 use in the treatment of atrial septal defects. It is also indicated for use with the VersaCross™ Transseptal Sheath and Dilator kit for the creation of an atrial septal defect.

**CONTRAINDICATIONS:** There are no known contraindications for this device.

**WARNINGS:** Laboratory staff and patients can undergo significant x-ray exposure during RF puncture procedures due to the continuous use 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 device. Do not use the VersaCross™ RF Wire with electrodes or other devices unless specifically indicated. Do not use the VersaCross™ RF Wire with electrocautery or electrocardiography. Do not use the VersaCross™ RF Wire with an accessory device unless specifically indicated.

**PRECAUTIONS:** In order to prevent the risk of infection, ensure that flammable materials are not present in the room during RF power application. Careful manipulation of the VersaCross™ RF Wire may result in vessel trauma, particularly when operating the device.

**ADVERSE EVENTS:** Adverse events that may occur while using the VersaCross™ RF Wire include: Infection, Air embolus, Local nerve damage, Hemorrhage, Vascular thrombosis, Perforation of the myocardium, Hematomas, Allergic reaction to contrast medium, Ventricular fibrillation, Pain and tenderness, Arteriovenous fistula, Pseudoaneurysm, and Aortic puncture.

**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 use with the VersaCross™ Transseptal Sheath for the creation of an atrial septal defect.

**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 use 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™ Transseptal Dilator is intended for single patient use only. Do not attempt to sterilize and reuse the VersaCross™ Transseptal Dilator.

**PRECAUTIONS:** Careful manipulation must be performed to avoid cardiac damage, vessel injury, and 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 VersaCross™ Transseptal Dilator.

**ADVERSE EVENTS:** Adverse events that may occur while using the VersaCross™ Transseptal Dilator include: Infection, Air embolus, Local nerve damage, Hemorrhage, Vascular thrombosis, Perforation of the myocardium, Hematomas, Allergic reaction to contrast medium, Ventricular fibrillation, Pain and tenderness, Arteriovenous fistula, Pseudoaneurysm, and Aortic puncture.

**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 use 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.

**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 kit is compatible with introducer sheaths ≥11Fr or larger. The VersaCross™ Transseptal Sheath and Dilator are compatible with transseptal devices and guidewires ≥0.035" or smaller.

**ADVERSE EVENTS:** Adverse events that may occur while using the VersaCross™ Transseptal Sheath include: Infection, Air embolus, Local nerve damage, Hemorrhage, Vascular thrombosis, Perforation of the myocardium, Hematomas, Thromboembolic events, Stroke, Valve damage, Myocardial infarction, Pacemaker/defibrillator lead displacement, Pulmonary edema, Coronary artery spasm and/or damage, Vessel trauma, Pseudoaneurysms, or Pseudoaneurysm formation.