



## Highlights from:

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# Direct Hepatic Vein Puncture and Transseptal Access for Atrial Flutter and Fibrillation Ablation in a Patient with Prior Ligation of the Inferior Vena Cava

## INTRODUCTION

- ▶ This case report describes a novel technique for left atrial (LA) access and radiofrequency (RF) ablation using hepatic vein access in a patient with surgically ligated inferior vena cava (IVC).

## METHODS

### Hepatic vein access

- ▶ The middle hepatic vein was punctured along the right costal margin between the midclavicular and right anterior axillary line under ultrasound guidance and support from interventional radiology.

### Transseptal puncture

- ▶ First attempt to access the septum using the Agilis™ EPI Steerable Introducer (Abbott) failed to position the sheath tip on the septum from the challenging hepatic vein trajectory.
- ▶ Second attempt using the **SupraCross™** Steerable Sheath (Baylis Medical\*) with a flexible dilator supported access of the dedicated Baylis RF pigtail wire† on the septum.
- ▶ Transseptal puncture was performed using the Baylis RF wire† under intracardiac echocardiography guidance.
- ▶ The **SupraCross™** Sheath was advanced into the LA over the RF pigtail wire for mapping and ablation.

### Catheter ablation

- ▶ Three-dimensional electroanatomic maps of the left and right atria were created using the CARTO® 3 System (Biosense Webster).
- ▶ Pulmonary vein isolation and cavo-tricuspid isthmus ablation for right atrial flutter were performed using the Thermocool Smarttouch® SF Catheter (Biosense Webster).

### Access site closure

- ▶ An approximately 4 cm Gelfoam® Plug (Pfizer) was pushed through the 12F sheath to seal the hepatic vein entry site.

## DISCUSSION AND CONCLUSIONS

- ▶ Hepatic vein access can be used for left atrial catheterization in patients with surgically ligated IVC.
  - This is facilitated by an inferior approach that is familiar to operators experienced in using femoral access but require catheter manipulation to reach the septum.
- ▶ The **SupraCross™** Sheath with a flexible dilator provided a tight angle of curvature to enable positioning on the septum.
- ▶ While force translation may be impacted by altered catheter trajectory, the use of a RF transseptal system minimized force and tissue tenting.
- ▶ RF puncture reduces the risk of complications in comparison to conventional mechanical needles.
- ▶ RF wires improve workflow efficiency by allowing repositioning on the septum without rewiring.
- ▶ Use of a steerable sheath with a flexible dilator and RF wire for TSP can improve the feasibility and safety of transhepatic approach for LA access to allow more patients to receive treatment.

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† RF transseptal puncture was performed in the case described in this article using the **SupraCross™** RF Wire (Baylis Medical\*).

## Brief Summary | SupraCross™ 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 SupraCross™ 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 SupraCross™ Steerable Sheath kit is intended for single patient use only. Do not attempt to sterilize and reuse the SupraCross™ Steerable Guiding 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. • Do not attempt direct percutaneous insertion of the sheath without the dilator as this may cause vessel injury. • 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:** • 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. • Avoid deflecting distal end of sheath during delivery and removal, otherwise damage to vessels may occur. • The SupraCross™ Steerable Sheath kit is not compatible with transeptal needles such as the "NRG™ Transeptal Needle". • Do not reshape the 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.

**ADVERSE EVENTS:** Adverse events that may occur while using the SupraCross™ Steerable 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 • Pacemaker/defibrillator lead displacement • Pulmonary edema • Coronary artery spasm and/or damage • Vessel trauma • Pericardial/pleural effusion

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## Brief Summary | SupraCross™ 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 SupraCross™ RF Wire is indicated for creation of an atrial septal defect in the heart.

**CONTRAINDICATIONS:** The SupraCross™ 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 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 SupraCross™ 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 SupraCross™ 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 SupraCross™ 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 SupraCross™ RF Wire. Attempts to use it with other RF Generators and devices can result in electrocution of the patient and/or operator. • The SupraCross™ RF Wire must be used with 0.035" compatible transeptal sheath and/or dilator devices. Use of incompatible accessory devices may damage the integrity of the SupraCross™ RF Wire or accessory devices and may cause patient injury. • The SupraCross™ RF Wire has only been validated for transeptal puncture use through SupraCross™ dilators which have been demonstrated to provide the required support for optimal function. • The SupraCross™ 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 SupraCross™ 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. • Do not bend the SupraCross™ 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 SupraCross™ RF Wire and Connector Cable. • Careful manipulation of the SupraCross™ RF Wire must be performed to avoid vessel trauma. If resistance is encountered, DO NOT use excessive force to advance or withdraw the SupraCross™ 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. • Avoid RF energy delivery of the SupraCross™ RF Wire with incompatible dilator or cannula devices, which may lead to patient burns, ineffective puncture or failure to puncture. • The Baylis RF Generator is capable of delivering significant electrical power. Patient or operator injury can result from improper handling of the SupraCross™ 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.

**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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