



# Choice of Steerable Sheath Impacts Contact Force Consistency During Pulmonary Vein Isolation

## INTRODUCTION

- ▶ Contact force (CF) consistency during radiofrequency ablation (RFA) for pulmonary vein isolation (PVI) is associated with formation of effective lesions.
- ▶ In experimental studies, different steerable sheaths have shown better precision.
- ▶ This study evaluated CF consistency during RFA using two different steerable sheaths.

## METHODS

- ▶ A single-center retrospective analysis of catheter stability was performed on 30 patients undergoing first time RFA procedures using two sheaths:
  - Agilis™ NxT Steerable Introducer (Abbott; 15 patients)
  - **SureFlex™** Steerable Guiding Sheath (Baylis Medical\*; 15 patients)

### Imaging

- ▶ EnSite Precision™ Mapping System (Abbott) was used for catheter guidance and contact force measurement.

### Radiofrequency ablation

- ▶ Ablations were performed using the TactiCath™ CF-sensing Catheter (Abbott).
- ▶ CF was measured for each lesion at ~ 10 ms intervals.
- ▶ High-power short-duration ablation was used to achieve a local impedance drop of ~ 10 Ω.

### Data analysis

- ▶ CF consistency around each pulmonary vein (PV) was assessed based on the following parameters:
  1. Mean CF for each lesion
  2. CF variability (i.e. CF variability in each lesion)
  3. Inefficient lesions (i.e. lesions with a CF < 5g ≥ 10% of the total RF time)

## RESULTS

- ▶ Baseline parameters were similar in both groups with an exception of higher BMI and percentage of females in the **SureFlex™** group (p<0.05).
- ▶ Both sheaths achieved similar operator-targeted mean CF.
- ▶ Trend of 12.8% lower overall CF variability (p=0.08) was seen using the **SureFlex™** Sheath compared to Agilis™ NxT.
- ▶ In general, right PVs showed greater CF variability compared to the left PVs.
  - Trend of lower CF variability among individual PVs with the **SureFlex™** Sheath compared to Agilis™ NxT.
- ▶ Fewer inefficient lesions with the **SureFlex™** Sheath:
  - Higher odds ratio for inefficient lesions with Agilis™ NxT than the **SureFlex™** Sheath over entire procedure (OR=0.605, p=0.03).
  - Similar trend among individual PVs and most significantly in the right inferior PV (OR=0.607, p=0.009).

## DISCUSSION AND CONCLUSIONS

- ▶ This study suggests that the choice of steerable sheath can affect the quality of RFA lesions.
- ▶ Preliminary results from this study suggest:
  1. MA trend of lower CF variability using the **SureFlex™** Steerable Guiding Sheath than the Agilis™ NxT, specifically for the right-sided veins.
  2. Significant reduction in inefficient lesions using the **SureFlex™** Steerable Guiding Sheath than the Agilis™ NxT.

## Brief Summary | SureFlex™ Steerable Guiding 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 SureFlex™ Steerable Guiding 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 use of echocardiography is recommended. • The SureFlex™ Steerable Guiding Sheath kit is intended for single patient use only. Do not attempt to sterilize and reuse the SureFlex™ 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. • Maintain continuous hemodynamic monitoring throughout procedure • Provide continuous heparinized saline infusion while the introducer remains in vessel. • 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. Echocardiographic guidance is also recommended. 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. • Do not attempt to use the guidewire with electrocautery tools. • 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.

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

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