



# Achieving Contrast-Free Ultra-Low Radiation Exposure Without Compromising Safety and Acute Efficacy Through Evolving AF Cryoballoon Ablation Procedure Techniques

## INTRODUCTION

- ▶ Due to the detrimental effects of radiation during catheter-based procedures, it should be assumed that a safe level of radiation exposure does not exist.
- ▶ This study demonstrates the safety and acute effectiveness of ultra-low fluoroscopy use during cryoballoon ablation for atrial fibrillation.

## METHODS

- ▶ A retrospective observational analysis was performed on 307 cryoballoon ablation procedures for pulmonary vein isolation (PVI) using ultra-low fluoroscopy.

### Imaging

- ▶ Pre-procedural planning included cardiac computed tomography or magnetic resonance imaging.
- ▶ Transesophageal echocardiography to rule out thrombus.
- ▶ Intracardiac echocardiography (ICE; Zonare Ultrasound System, St. Jude Medical) was used for transseptal puncture and catheter guidance.
- ▶ 3D electroanatomic mapping (EAM) was used to recreate cardiac geometries and for catheter guidance (Achieve™ Mapping Catheter, Medtronic, Inc.; EnSite™ NavX™ Mapping System, St. Jude Medical).
- ▶ "Single-shot" fluoroscopy (3.75 frames/s) was used if resistance was felt during device exchange.

### Transseptal access

- ▶ Transseptal puncture was performed using the **NRG™** Transseptal Needle (Baylis Medical\*).
- ▶ Catheter exchange in the left atrium was initially done using a **STORQ®** Steerable Guidewire (Cordis) during the first 18 months of the study before switching to the **ProTrack™** Pigtail Wire (Baylis Medical\*) for the remaining 28 months.

### Cryoballoon ablation

- ▶ Ablations were performed using the Arctic Front Advance™ Cryoballoon (Medtronic, Inc.).
- ▶ Direct pressure monitoring and Doppler flow were used to confirm pulmonary vein occlusion in place of radiopaque contrast.

## RESULTS

- ▶ Radiation dose decreased from 6.7 mGy to 2.0 mGy over the study period ( $p < 0.01$ ).
- ▶ Fluoroscopy time decreased from 0.75 min to 0.2 min over the study period ( $p < 0.0001$ ).
- ▶ Use of a 28-mm cryoballoon required significantly lower fluoroscopy use than both the 23-mm cryoballoon and combination of 23-mm and 28-mm cryoballoons.
- ▶ Acute procedural success was achieved in 99% of patients with a 2.0% complication rate, consistent with other cryoballoon studies.
- ▶ One incidence of left atrial appendage perforation leading to cardiac tamponade was attributed to the **STORQ®** Steerable Guidewire, and prompted the switch to the **ProTrack™** Pigtail Wire.

## DISCUSSION AND CONCLUSIONS

- ▶ This study describes a method for ultra-low fluoroscopy cryoballoon ablation compared to other large sponsored studies, and demonstrates safety and effectiveness.
- ▶ The best practices for fluoroscopy reduction include:
  - ICE to visualize the **NRG™** Transseptal Needle for transseptal puncture and **ProTrack™** Pigtail Wire for wiring across the left atrium
  - 3D EAM, ICE, pressure waveform, and Doppler imaging for catheter navigation
  - Cryoballoon dosing algorithm to minimize freezing beyond acute PVI
  - Slow fluoroscopy frame rate when needed
- ▶ These tools and techniques are common within electrophysiology labs and require minimal additional operator training.

## Brief Summary | **NRG™** Transseptal Needle

**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 NRG™ Transseptal Needle is used to create an atrial septal defect in the heart. Secondary indications include monitoring intracardiac pressures, sampling blood, and infusing solutions.

**CONTRAINDICATIONS:** The NRG™ Transseptal Needle is not recommended for use with any conditions that do not require cutting or coagulation of soft tissue.

**WARNINGS:** • Laboratory staff and patients can undergo significant x-ray exposure during radiofrequency 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 NRG™ Transseptal Needle is intended for single patient use only. Do not attempt to sterilize and reuse the needle. Reuse can cause the patient injury and/or the communication of infectious disease(s) from one patient to another. Failure to do so may result in patient complications. • The NRG™ Transseptal Needle must be used with the BMC Connector Cable. Attempts to use it with other connector cables can result in electrocution of the patient and/or operator.

**PRECAUTIONS:** • Placement of the dispersive electrode on the thigh or hip could be associated with higher impedance. • In order to prevent the risk of ignition make sure that flammable material is not present in the room during RF power application. • Careful needle manipulation must be performed to avoid cardiac damage, or tamponade. Needle advancement should be done under image guidance. If resistance is encountered, DO NOT use excessive force to advance or withdraw the needle. • During power delivery, the patient should not be allowed to come in contact with ground metal surfaces. • Thoroughly flush the NRG™ Transseptal Needle with heparinized saline solution prior to use. • If using electroanatomical mapping guidance it is recommended to confirm tip placement on the fossa ovalis and septal tenting before RF puncture with graphic imaging or another imaging modality.

**ADVERSE EVENTS:** Adverse events that may occur while using the Baylis Medical Radiofrequency Puncture System 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 • Thermal damage to tissue • Arteriovenous fistula • Pericardial Effusion

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## Brief Summary | **ProTrack™** Pigtail 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 ProTrack™ Pigtail Wires are intended for use in percutaneous transseptal procedures to introduce and position catheters and other interventional devices within the left heart. The device is not intended for use in the coronary arteries.

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

**WARNINGS:** • DO NOT push, auger, withdraw or torque a pigtail wire against resistance until the cause of the resistance has been determined. Applying excessive force against unexpected resistance may cause damage to the pigtail wire, interventional device and/or vessel/organ. • When the pigtail wire is exposed to the vascular system, it should be manipulated while under high-resolution imaging guidance including fluoroscopy and/or echocardiography. Improper visualization of the guidewire may lead to misplacement, dissection, or perforation. • Inspect the pigtail wire prior to use for coil separation, kinking, appropriate distal tip flexibility or breakage. If the pigtail wire is damaged or defective, do not use it. Using a damaged or defective pigtail wire may cause vasculature damage and/or compromise pigtail wire performance. • Laboratory staff and patients can undergo significant x-ray exposure during interventional procedures due to the continuous usage of fluoroscopic imaging. The 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.

**ADVERSE EVENTS:** Potential complications associated with the use of the pigtail wire include, but are not limited to: • Vessel Perforation/Dissection/Trauma or Damage • Vessel Spasm • Hemorrhage • Access Site Complications/Hematoma • Thrombus/Thromboembolism • Allergic reaction • Vascular complication • Cardiac tamponade • Cardiac Perforation/Laceration • Conduction disorder • Embolism • Additional Surgical Procedure • Pericardial/pleural effusion • Sepsis/Infection/Inflammation • Foreign Body/Wire Fracture • Hemolysis • Hypovolemia • Myocardial Ischemia and/or Infarction • Stroke/Transient Ischemic Attack • Vessel Occlusion • Wire Entrapment/Entanglement • Valve Complication

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