



## Highlights from:

Gaurav Sharma, MD, Gagan D. Singh, MD, Thomas W. Smith, MD, Dali Fan, MD, Reginald I. Low, MD, and Jason H. Rogers, MD

Poster #703 at Transcatheter Cardiovascular Therapeutics, San Francisco, CA, Oct 2015  
Sharma et al., Catheter Cardiovasc. Interv., May 2016 DOI: 10.1002/ccd.26608

# Accuracy and Procedural Characteristics of Standard Needle Compared with Radiofrequency Needle Transseptal Puncture for Structural Heart Interventions

## INTRODUCTION

- ▶ This retrospective, single-center study compared the performance and accuracy of a mechanical needle and the **NRG™** RF Transseptal Needle (Baylis Medical<sup>1</sup>) in gaining left-sided access via transseptal puncture in 52 structural heart procedures, including left atrial appendage occlusions and mitral valve repairs.

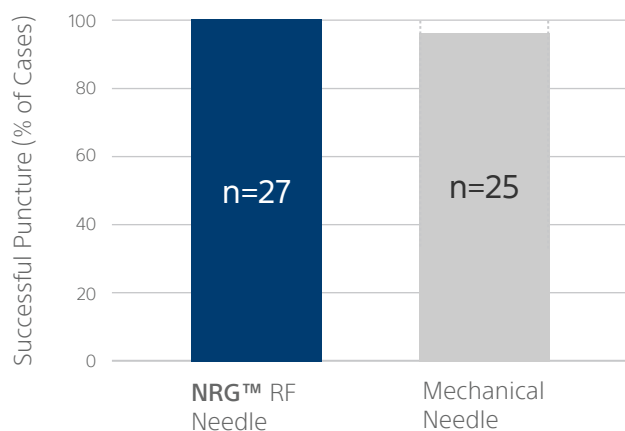
## RESULTS

- ▶ The punctures attempted using the unassisted mechanical needle were successful in 88% of cases while the **NRG™** RF Needle was successful in 100% of cases (Figure 1). Two cases in which the mechanical needle failed required crossover to the **NRG™** RF Needle to achieve successful transseptal puncture.
- ▶ The average extent to which the septum was tented was reduced by 51% with the **NRG™** RF Needle compared to the mechanical needle (Figure 2,  $p < 0.05$ ).

## DISCUSSION AND CONCLUSIONS

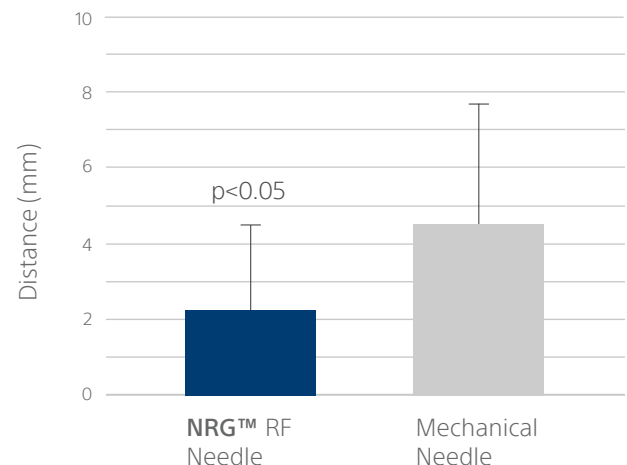
- ▶ The **NRG™** RF Needle resulted in a higher overall transseptal puncture success rate, decreased puncture time, and reduced tenting.

### Successful Punctures



**Figure 1.** Successful transseptal punctures performed with the **NRG™** RF Needle vs. an unassisted mechanical needle.

### Tenting Distance



**Figure 2.** Pre-to-maximum tenting at the transseptal site using the **NRG™** RF Needle vs. a mechanical needle ( $p < 0.05$ ).

## 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

EP-1506305-AA

All trademarks are property of their respective owners. Patents Pending and/or issued. CAUTION: The law restricts these devices to sale by or on the order of a physician. Rx only. Indications, Contraindications, Warnings, and Instructions For Use can be found in the product labelling supplied with each device or at [www.baylismedical.com](http://www.baylismedical.com).

Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries.  
This material not intended for use in France.

Boston Scientific is a Global Company. Please note that model numbers, indications, contraindications, warnings and specifications may differ depending on geographic region. Not all information displayed in this brochure may be licensed in accordance with Canadian law. Please contact your Boston Scientific representative for local labeling, product specifications and licensed model numbers.

**Boston  
Scientific**  
Advancing science for life™

© 2023 Boston Scientific Corporation  
or its affiliates. All rights reserved.

EP-1583405-AA