



## Highlights from:

Jonathan C. Hsu, Nitish Badhwar, Edward P. Gerstenfeld, Randall J. Lee, Mala C. Mandyam, Thomas A. Dewland, Kourtney E. Imburgia, Kurt S. Hoffmayer, Vasanth Vedantham, Byron K. Lee, Zian H. Tseng, Melvin M. Scheinman, Jeffrey E. Olgin, and Gregory M. Marcus

# Randomized Trial of Conventional Transseptal Needle Versus Radiofrequency Energy Needle Puncture for Left Atrial Access (the TRAVERSE-LA Study)

## METHODS

- ▶ Randomized, prospective, and controlled trial. 72 patients were randomized to either the **NRG™** RF Transseptal Needle (Baylis Medical\*) or conventional transseptal needle on a 1:1 basis.

## RESULTS

### Primary Outcome

- ▶ Median transseptal procedure time was 68% lower in RF needle group compared with conventional needle group on an intention-to-treat basis.

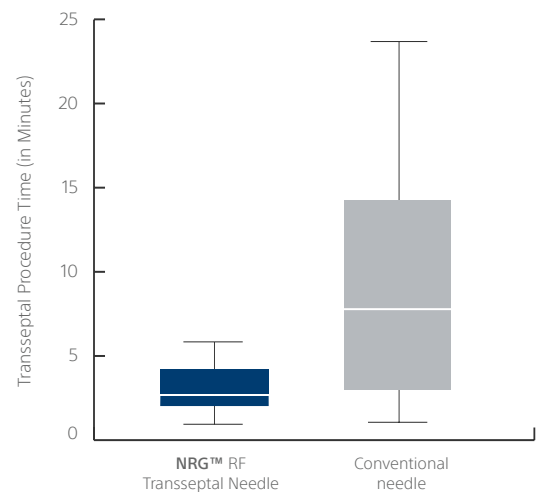
### Secondary Outcome

- ▶ RF needle group did not experience transseptal procedure failure with assigned needle: 0 out of 36 cases (0%).
- ▶ Conventional needle group experienced 10 failures in 36 cases (27.8%). Subsequent crossover to RF needle enabled successful transseptal procedure in all cases.

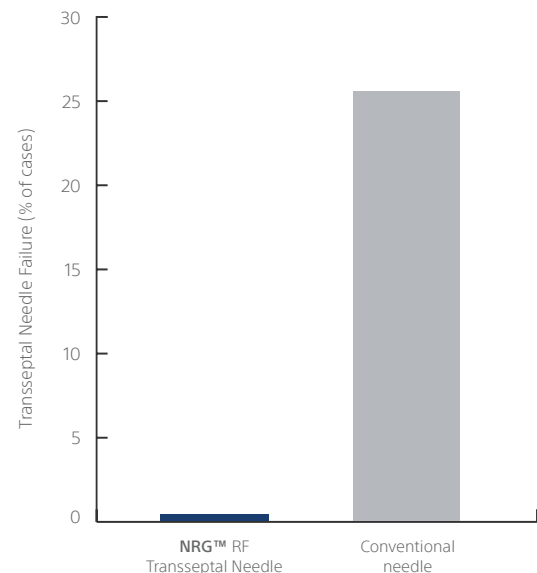
### Secondary Outcome

- ▶ In pre-procedural ex vivo testing that involved advancement of the needle through the plastic dilator and sheath, the conventional needle produced visible plastic particles in 33.3% of cases whereas the RF needle did not produce visible particles in any cases (0%).

## Procedure time



## Rate of failure



## 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-1582805-AA