



**NRG™**

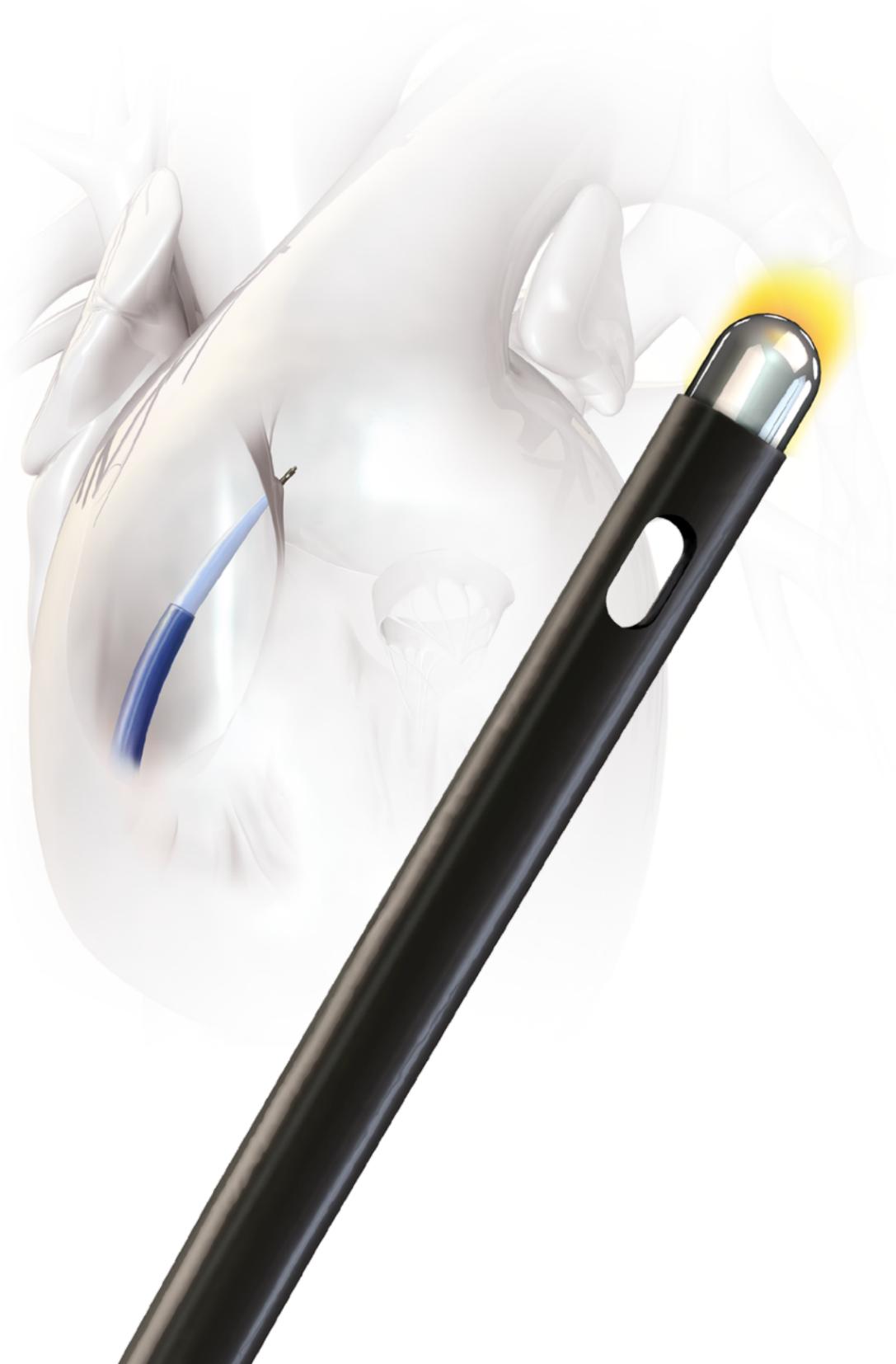
Transseptal Needle

Economic Analysis of  
**RF Transseptal Puncture**



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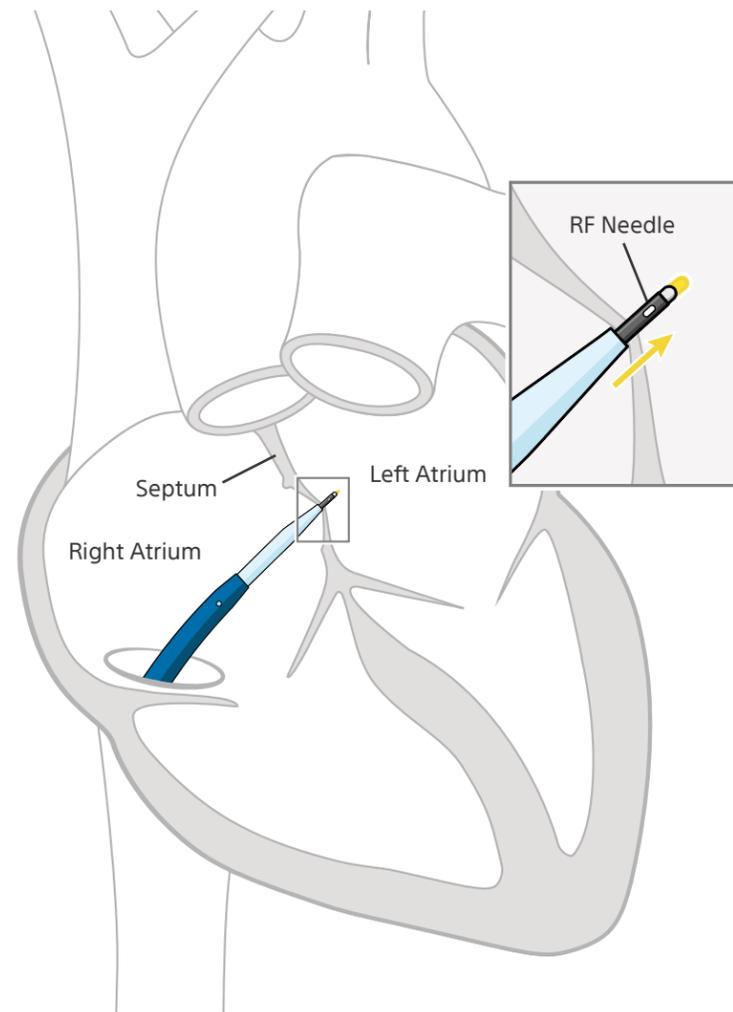
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# Executive Summary

## Save up to \$1,856 per case

through improved clinical outcomes with use of Boston Scientific RF transseptal technologies



Transseptal puncture is a well-known and widely-used procedure, providing percutaneous access to the left atrium of the heart.

Transseptal puncture is often required for treating a variety of pathologies (e.g., atrial fibrillation, atrial flutter, mitral valve regurgitation, stroke prevention) and for performing common cardiac procedures such as electrophysiology catheter ablation (e.g., radiofrequency, cryoballoon, pulsed field ablation) and structural heart interventions (e.g., left atrial appendage closure (LAAC), mitral valve repair).

Transseptal puncture has been historically performed by pushing a sharp, mechanical needle across the interatrial septum. The transseptal puncture process has been associated with serious complications such as tissue injury, cardiac tamponade, and pericardial effusion, requiring medical intervention and prolonging hospital stay. Transseptal puncture can also be time consuming and unpredictable due to differences in patient anatomy.

The undesirable clinical events associated with catheter ablation procedures have been shown to add substantial incremental healthcare expenditures.

To overcome these shortcomings, a radiofrequency (RF) transseptal needle was developed. The NRG™ Transseptal Needle uses a blunt-tipped electrode to deliver RF energy, allowing reliable, controlled access to the left atrium without needing to push a sharp, mechanical needle across the septum.

Clinical studies have highlighted the reliability and consistency provided by Boston Scientific RF transseptal technology by demonstrating:

1. Reduced rate of serious complications
2. Reduced rate of failed transseptal crossings resulting in procedure termination
3. Reduced procedure time

These clinical benefits can translate into healthcare cost savings of up to \$1,856 per case.

# Background

Transseptal puncture is often required for treating a variety of pathologies (e.g., atrial fibrillation, atrial flutter, mitral valve regurgitation, stroke prevention) and for performing common cardiac procedures such as electrophysiology catheter ablation (e.g., radiofrequency, cryoballoon, pulsed field ablation) and structural heart interventions (e.g., left atrial appendage closure (LAAC), mitral valve repair).

Transseptal puncture has been historically performed by pushing a sharp, mechanical needle across the interatrial septum. The transseptal puncture process has been associated with serious complications such as tissue injury, cardiac tamponade, and pericardial effusion, requiring medical intervention and prolonging hospital stay. Transseptal puncture can also be time consuming and unpredictable due to differences in patient anatomy.

A study led by researchers at Massachusetts General Hospital, Boston has shown that undesirable clinical events associated with catheter ablation procedures add substantial incremental healthcare expenditures (Figure 1).<sup>1</sup>

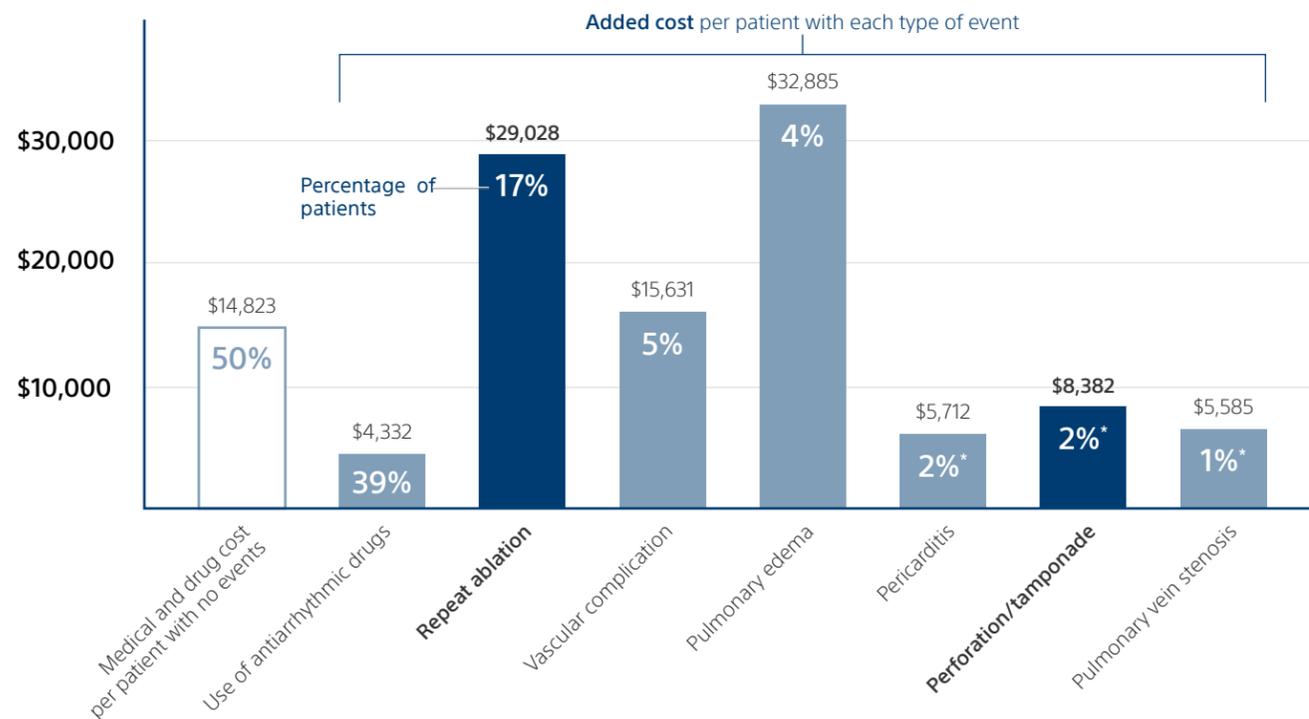


Figure 1. Baseline cost in year after AF ablation and incremental cost of clinical events.

\* Approximate percentages

# Clinical Value of RF Transseptal Needles

A dedicated RF transseptal needle was developed to address the challenges associated with mechanical transseptal puncture.

The NRG™ Transseptal Needle uses a blunt-tipped electrode to deliver a short and highly focused RF energy pulse, allowing a reliable, controlled puncture without needing to push through the septum using a sharp, mechanical needle.

Clinical studies have demonstrated the value of RF transseptal needle technology:

Reduce Rate of Serious Complications	Reduce Rate of Failed Transseptal Crossings Resulting in Procedure Termination	Reduce Procedure Time
<ul style="list-style-type: none"> <li>Cardiac tamponade is a serious complication associated with transseptal puncture</li> <li>It is a medical emergency and can be fatal</li> <li>Studies comparing mechanical and RF transseptal needles have shown that use of RF needles can lower the rate of cardiac tamponade by <b>up to 100%</b><sup>*2,3</sup></li> <li>A randomized controlled trial showed that <b>27.8%</b> of mechanical needle cases required crossover to RF needle due to concern that further effort could lead to perforation of lateral wall<sup>4</sup></li> </ul>	<ul style="list-style-type: none"> <li>When septum cannot be crossed, case is cancelled and patient is typically rescheduled for re-attempt at ablation procedure</li> <li>Studies comparing mechanical and RF transseptal needles have shown that use of RF needles can lower the rate of procedure termination by <b>up to 100%</b><sup>*2,3</sup></li> <li>A randomized controlled trial showed that <b>27.8%</b> of mechanical needle cases required crossover to RF needle due to concern that further effort could lead to perforation of lateral wall<sup>4</sup></li> </ul>	<ul style="list-style-type: none"> <li>Crossing the septum can be difficult and time consuming, prolonging the case and delaying the beginning of the therapeutic intervention</li> <li>It has been shown that use of the RF needle can lower the time to cross the septum by <b>up to 9 minutes</b><sup>3,4</sup></li> </ul>

\* Based on an absolute reduction in incidence of up to 2% in study populations.

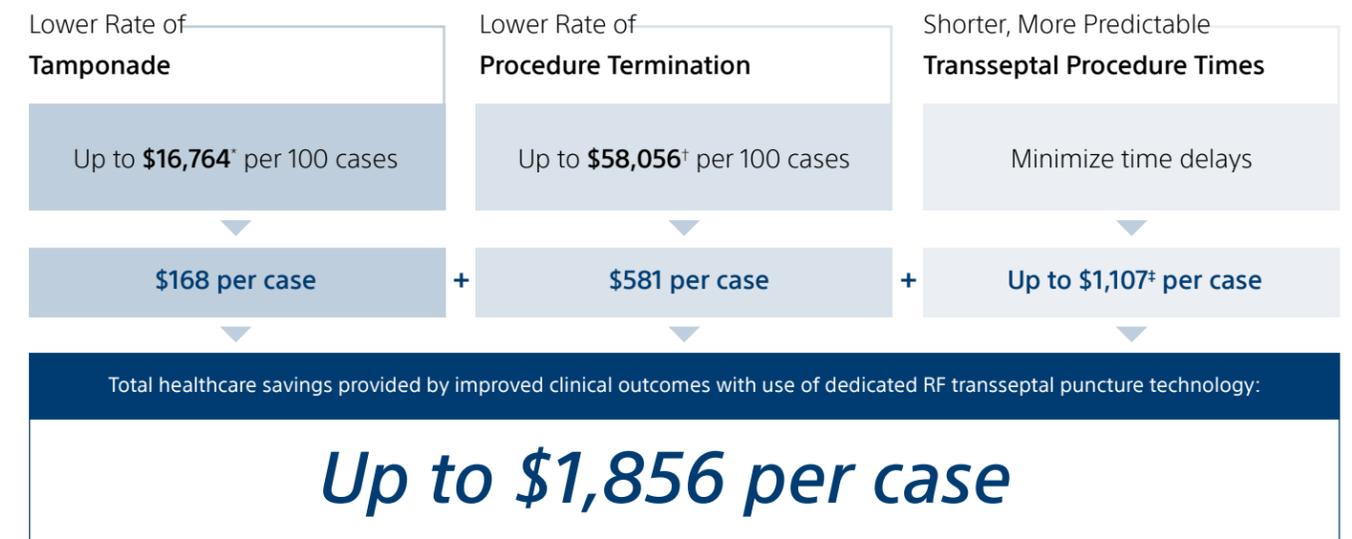
## Economic Value of Improved Transseptal Outcomes

## Summary of Economic Benefits of RF Needles

Avoiding undesirable clinical events during transseptal puncture can have positive economic effects:

Cardiac Tamponade Cost	Repeat Ablation Cost	Procedure Time Cost
The incremental cost per event of cardiac tamponade to the healthcare system has been reported to be:	The incremental cost per event of repeat ablation to the healthcare system has been reported to be:	Literature has shown the cost per minute of time used in electrophysiology catheter ablation procedures to be:
<b>\$8,382 USD<sup>1</sup></b>	<b>\$29,028 USD<sup>1</sup></b>	<b>\$105/minute</b> for procedural reimbursement  <b>and</b> <b>\$14/minute</b> for personnel fees <sup>5</sup>

Cost savings offered by the NRG Transseptal Needle:



\* Calculated as 2 x \$8,382. Data from Jauvert et al. Heart Lung Circ. 2015 and Mansour et al. HRS Scientific Sessions. 2016.

† Calculated as 2 x \$29,028. Data from Jauvert et al. Heart Lung Circ. 2015 and Mansour et al. HRS Scientific Sessions. 2016. Assumes terminated cases are paid in full because induction of anesthesia has already occurred upon termination.

‡ Calculated as \$119/minute x 9.3 minutes. Data from Winkle et al. Heart Rhythm. 2011 and Capone et al. PACE. 2015.

# References

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# 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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