Economic Analysis of
RF Transseptal Puncture

NRG® Transseptal Needle
USA
Save up to $1,856 per case

in savings through improved clinical outcomes with use of Baylis Medical's RF transseptal puncture technology.*

* Refer to page 9 for analysis.
Clinical studies have highlighted the reliability and consistency provided by Baylis Medical RF needle transseptal puncture 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*

*Refer to page 9 for analysis.
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Transseptal puncture is a well-known and widely-used procedure, providing percutaneous access to the left atrium of the heart. This enables performing common cardiac procedures such as:

- Catheter ablation to treat cardiac arrhythmias
- Structural heart procedures such as transcatheter left atrial appendage occlusion and mitral valve repair

Transseptal puncture has historically involved pushing a sharp, “mechanical needle” across the interatrial septum to gain left-heart access. Despite its common use, the transseptal puncture process can be:

- Associated with serious complications, such as cardiac tamponade
- Unpredictable and associated with procedure termination when the septum cannot be crossed
- Time consuming

_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._

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**Figure:** Baseline cost in year after AF ablation and incremental cost of clinical events

*Approximate percentages

Clinical Value of RF Transseptal Needles

Baylis Medical Company Inc. has developed radiofrequency (RF) transseptal needle technology.

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:

- Cardiac tamponade is a serious complication associated with transseptal puncture
- It is a medical emergency and can be fatal
- Studies comparing mechanical and RF transseptal needles have shown that use of RF needles can lower the rate of cardiac tamponade by up to 100%²,³
- A randomized controlled trial showed that 27.8% of mechanical needle cases required crossover to RF needle due to concern that further effort could lead to perforation of lateral wall⁴

- When septum cannot be crossed, case is cancelled and patient is typically rescheduled for re-attempt at ablation procedure
- Studies comparing mechanical and RF transseptal needles have shown that use of RF needles can lower the rate of procedure termination by up to 100%²,³
- A randomized controlled trial showed that 27.8% of mechanical needle cases required crossover to RF needle due to concern that further effort could lead to perforation of lateral wall⁴

- Crossing the septum can be difficult and time consuming, prolonging the case and delaying the beginning of the therapeutic intervention
- It has been shown that use of the RF needle can lower the time to cross the septum by up to 9 minutes⁴

Reduce Rate of Serious Complications

Reduce Rate of Failed Transseptal Crossings Resulting in Procedure Termination

Reduce Procedure Time

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2. Jauvert et al. Heart Lung Circ. 2015
4. Hsu et al. J Am Heart Assoc. 2013. With RF needle available for crossover, no cases in this study resulted in cardiac tamponade or procedure termination.

* Based on an absolute reduction in incidence of up to 2% in study populations.
Economic Value of Improved Transseptal Outcomes

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

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

Summary of Economic Benefits of RF Needles

**Cost savings** offered by Baylis Medical RF Transseptal Needles:

<table>
<thead>
<tr>
<th>Lower Rate of Tamponade</th>
<th>Lower Rate of Procedure Termination</th>
<th>Shorter, More Predictable Transseptal Procedure Times</th>
</tr>
</thead>
<tbody>
<tr>
<td>Up to $16,764* per 100 cases</td>
<td>Up to $58,056** per 100 cases</td>
<td>Minimize time delays</td>
</tr>
<tr>
<td>$168 per case</td>
<td>$581 per case</td>
<td>Up to $1,107† per case</td>
</tr>
</tbody>
</table>

Total healthcare savings provided by improved clinical outcomes with use of RF transseptal puncture technology:

*Up to $1,856 per case

*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


