Achieve Left Heart Access with
Globally Trusted Baylis RF Technologies
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Background

Baylis RF transseptal technologies have over 10+ years of globally recognized clinical studies that demonstrate them as the technologies of choice to cross the septum in a controlled, precise, and reliable manner. The Baylis RF technologies are built for left heart access:

NRG
RF Needle-Based Platform†

† Includes NRG® Transseptal Needle

VersaCross
RF Wire-Based Platform‡

‡ Includes VersaCross® RF Wire
**Reliable Transseptal**

**NRG® Transseptal Needle has been associated with improved rate of successful transseptal puncture.**¹²

**RFP100A** radiofrequency generator is purpose-built to:

- **Optimize RF delivery for perforation of the atrial septum.**³ RF settings that are not optimized for tissue perforation cause more extensive areas of tissue desiccation and preservation of collagenous structures, which leads to coagulative necrosis.⁴
- **Protect against contact with metal.**⁵ The Baylis **RFP100A** generator is designed to detect changes in impedance and auto-terminate with metal contact, such as with nitinol septal occluders.
Adaptable: Transseptal Puncture from Any Approach

Baylis dedicated RF generator RFP100A optimizes the power delivered on all Baylis RF delivery systems to enable facile transseptal puncture from any approach:

- **Femoral vein access**
  - Right femoral venous access is typically used to introduce the NRG® Transseptal Needle® or VersaCross® RF Transseptal Solution® to perform transseptal puncture.

- **Subclavian or jugular vein access**
  - In patients with absent or interrupted inferior vena cava (IVC), the internal jugular vein, subclavian vein or axillary veins can be used to access the right atrium and perform transseptal puncture.
  - The SupraCross® RF Solution uses a specialized RF wire and steerable sheath to enable angle correction from the subclavian or jugular vein approach to optimize positioning on the fossa ovalis and tenting of the interatrial septum.42
  - Use of the SupraCross® RF Solution has been demonstrated in both RF ablation42-44 and transcatheter mitral valve repair (i.e. MitraClip™ procedure, Abbott).40

- **Hepatic vein access**
  - An alternative approach in the absence of IVC access is using the hepatic vein, which offers operators an inferior access route that is similar to femoral vein access.
  - Transhepatic access has been used to access the right atrium and perform transseptal puncture using the SupraCross® RF Solution in both RF ablation45,46 and left atrial appendage occlusion procedures.46
Improved Crossing for Any Anatomy

Baylis RF technologies reduce the need for forward force and tissue tenting during atrial septal puncture\textsuperscript{1,6-10} and have been associated with lower rates of pericardial effusion and cardiac tamponade.\textsuperscript{2,6}

- Round atraumatic tip of Baylis RF technologies reduces the incidence of plastic particle skiving (0%) when compared to the conventional mechanical needle (33.3% or more)\textsuperscript{*,7,11}
- Baylis RF has been associated with reduced incidence of cardiac tamponade (0% vs 0.92%, respectively)\textsuperscript{9} and pericardial effusion (0% vs 3.06%, respectively)\textsuperscript{6} when compared to a mechanical needle group.
- \textit{NRG}\textsuperscript{®} Transseptal Needle  has been associated with 40% lower incidence of silent acute cerebral embolism vs mechanical needle.\textsuperscript{12}

\textbf{FIBROTIC (THICKENED) SEPTUM}

Cross \textit{fibrotic septum} while reducing mechanical force.\textsuperscript{49}

\textbf{ANEURYSMAL (ELASTIC) SEPTUM}

Cross thin \textit{aneurysmal septum} while reducing excessive tenting.\textsuperscript{8}

\*Based on ex vivo findings.
Characterized Tissue Healing

Baylis RF technologies are optimized for improved puncture of the atrial septum, without coagulative necrosis or prolonged healing.³

- **No coagulative necrosis.** Study by Veldtman et al showed similar pattern of injury when using Baylis RF puncture technology as mechanical needle puncture. Minimal mural thrombus and thermal injury were restricted to the myocardium adjacent to the puncture lumen immediately post-puncture, and fell short of coagulative necrosis characteristic of ablative RF (radiofrequency) energy.³

- **Well-developed healing.** The extent of acute injury using Baylis RF puncture technology was similar to that seen with conventional mechanical needle puncture. Minimal inflammation and homogenous fibrosis observed at 1 month post-puncture.³

**Low rate of persistent atrial septal defects (8.4%)** in patients at 15.5 months following the use of the NRG® Transseptal Needle,¹⁶ similarly to mechanical needle puncture.¹⁵⁰ All patients were asymptomatic, and persistence was correlated with atrial septal angle.¹⁶
Time Savings

Baylis RF technologies have been associated with time savings$^{2,8,13}$ and improved success rate for transseptal puncture.$^{2,8}$

- **NRG® Transseptal Needle**: Significantly lower total instrumentation time reported from procedure start to transseptal puncture (27.1 ± 10.9 min) compared to the conventional mechanical needle systems (36.4 ± 17.7 min).$^9$

- **VersaCross® RF Transseptal Solution**: Significantly faster time reported from femoral access to transseptal puncture (4.1 ± 2.5 min) compared to conventional mechanical needle system (8.4 ± 4.0 min), leading to 2x faster therapy delivery sheath access.$^{13}$$^*$

$^*$ Based on initial retrospective comparative study which found that VersaCross® RF Transseptal Solution delivered LAAC sheath in a mean time of 6.7 mins as compared to 13.4 mins (p=0.002) using BRK™ needle and SL1 sheath. Inohara et al. J Interv Card Electrophys. 2021 DOI: 10.1007/s10840-020-00931-7
Reduced Exchanges

Catheter manipulation, device exchange and procedure time have been associated with incidence of embolism due to air bubbles and/or dislodgment of cardiac thrombus.

Catheter ablation procedures have been associated with silent cerebral embolism which may cause long-term cognitive dysfunction.

The VersaCross® RF Transseptal Solution reduces the number of device exchanges through exchangeless vascular cannulation, transseptal puncture and catheter delivery into the left atrium.

VersaCross® Workflow

Insert VersaCross® RF Wire & VersaCross® Sheath
Retract system to reposition
Position on fossa
Confirm correct position
Transseptal access
Remove sheath
Deliver therapy catheter

Standard Needle Workflow

Insert guidewire & sheath
Remove guidewire
Insert needle
Retract system
to reposition
Remove needle
Insert exchange wire
Enhanced Visualization

The NRG® Transseptal Needle and VersaCross® RF Transseptal Solution are engineered with OMNIviz™ Technology to enable visualization of RF tip on fluoroscopy, ultrasound, and electrical anatomical mapping.

OMNIviz™ Technology

Radiopaque
Visualize your entire solution on fluoroscopy

Echogenic
Reliably locate your devices on ultrasound to reduce reliance on fluoroscopy

Mapping
Track and mark RF tip position on your mapping system
Fluoroscopy Reduction

Catheter ablation procedures expose patients to approx. 15 mSv of radiation (i.e. 750 chest X-rays) per procedure and staff to 5 mSV (i.e. 250 chest X-rays) per year.25

- Radiation exposure presents a risk of acute skin injuries26 and fatal malignancies to patients.25
- Electrophysiology staff have an elevated risk of brain tumor and cancers.27,28
- Staff have a risk of orthopedic injuries from prolonged use of heavy protective lead apparel.29

Electroanatomic mapping (EAM) and intracardiac echocardiography (ICE) have been used to reduce radiation exposure during catheter ablation procedures; however, transseptal puncture remains one of the critical steps that requires fluoroscopy due to inadequate visualization of the transeptal needle.30

Studies show that transseptal puncture can be performed safely using the NRG® Transseptal Needle or VersaCross® RF Transseptal Solution by visualizing the unique RF tip under 3-dimensional EAM, ICE and/or transesophageal electrocardiography (TEE).31-33

Successful use of Baylis RF technologies in various non-fluoroscopic procedures has been well published:

- Double transseptal punctures for RF ablation34
- Single transseptal puncture for cryoballoon ablation35,36
- Complex anatomies31,33
- Without echocardiography31
Transseptal efficiency was maintained in fluoroless procedures, demonstrated by short left heart access times using:

- **NRG® Transseptal Needle**: 27.8 ± 15.1 min\(^{34}\)
- **VersaCross® RF Transseptal Solution**: 14.2 ± 6.0 min\(^{37}\)

No procedure-related complications reported during fluoroless transseptal puncture.\(^{34,37}\)

Maintain efficient transseptal access **without fluoroscopy**

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Time</th>
</tr>
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<tbody>
<tr>
<td>NRG® Needle</td>
<td>27.8 min ± 15.1 min (^{34})</td>
</tr>
<tr>
<td>VersaCross® Wire</td>
<td>14.2 min ± 6.0 min (^{37})</td>
</tr>
</tbody>
</table>

*Based on transseptal times from femoral to LA access from two non-comparative fluoroless case series\(^{34,37}\) compared to using conventional fluoroscopy-guided procedures.\(^2\)
Targeted Precision

Precise crossing is necessary to avoid unintended perforation of nearby structures. Targeted TSP at the intended location on the interatrial septum is necessary to ensure optimal trajectory for therapy sheaths in transcatheter structural heart procedures:

- Off-target TSP can add complexity and time to a procedure.\textsuperscript{38}
- The NRG\textsuperscript{®} Transseptal Needle was used to provide controlled site-specific crossing of the interatrial septum without complications.\textsuperscript{39}
- Baylis RF enables site-specificity even in the presence of atrial septal occluders.\textsuperscript{40}

Mitral Valve Repair
Left Atrial Appendage Closure
Pulmonary Vein Isolation

Optimize transseptal location to save time; deliver therapy on target.\textsuperscript{47,48}
Conclusion

The Baylis RF puncture technology enables access to the left atrium in a reliable and consistent manner. This is supported by published clinical evidence showing that transseptal puncture using Baylis RF technology provides:

1. Reliable Transseptal
2. Adaptable: Transseptal from Any Approach
3. Improved Crossing for Any Anatomy
4. Characterized Tissue Healing
5. Time Savings
6. Reduced Exchanges
7. Enhanced Visualization
8. Fluoroscopy Reduction
9. Targeted Precision
References

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