

Achieve Left Heart Access with **Globally Dedicated RF Transseptal Technologies**



Contents

- Background 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 11
- Conclusion..... 12
- References..... 13



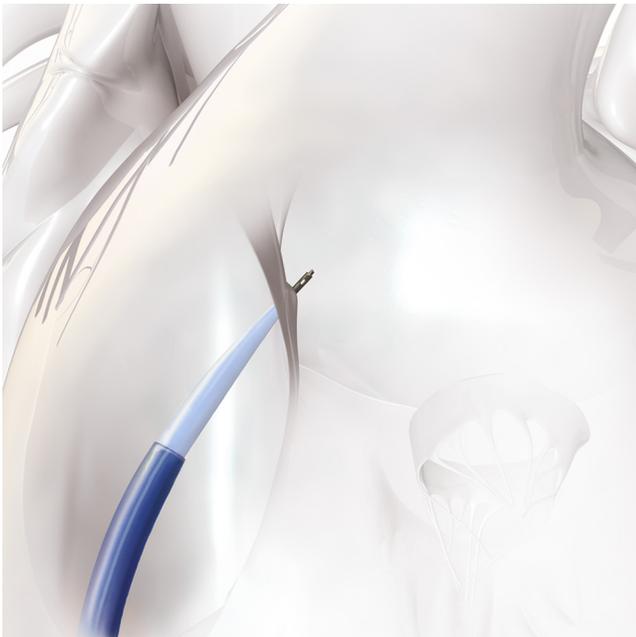
Background

Over 10 years of globally recognized clinical studies demonstrate Boston Scientific RF transseptal technologies are the preferred choice for reliable, consistent, controlled, and precise crossing of the septum.

Boston Scientific RF transseptal technologies built for left-heart access include:

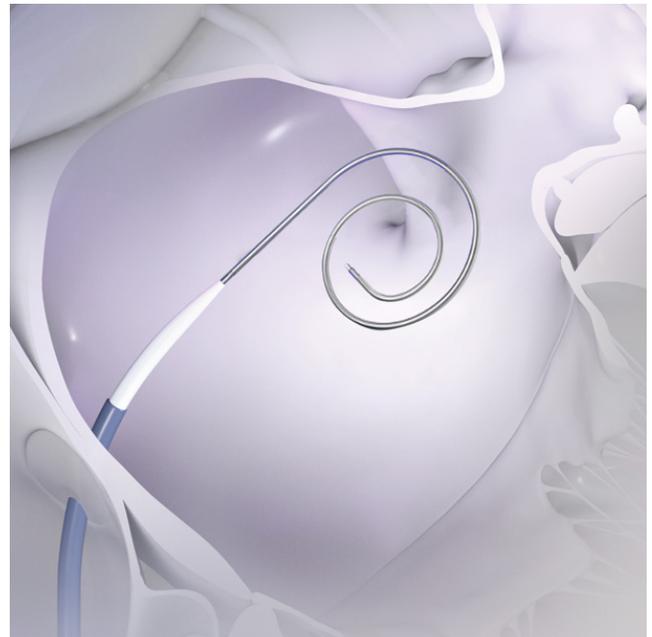
NRG™

RF Needle-Based Platform*



VersaCross™

RF Wire-Based Platform†



*Includes NRG™ Transseptal Needle

†Includes VersaCross™ RF Wire

Reliable Transseptal

The **NRG™** Transseptal Needle has been associated with an improved rate of successful transseptal puncture.^{1,2}

The RFP-100A RF Puncture 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 **RFP-100A generator*** is designed to detect changes in impedance and auto-terminate with metal contact, such as with nitinol septal occluders.



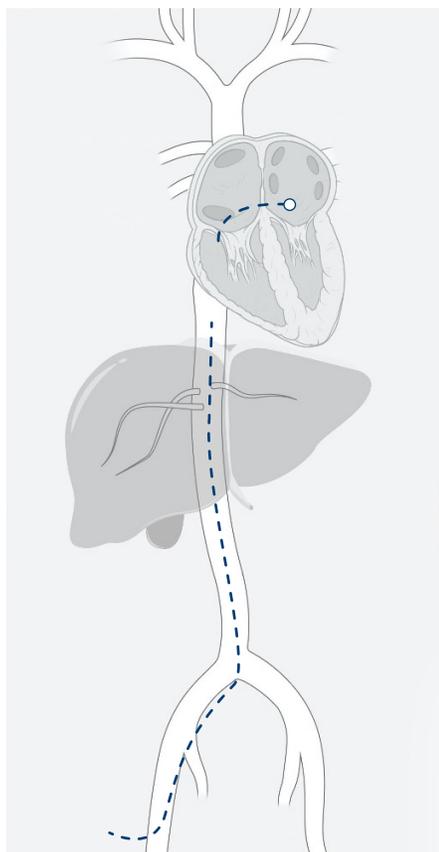
*Baylis Medical Company Radiofrequency Puncture Generator RFP-100A.
Baylis Medical Company is a wholly-owned subsidiary of Boston Scientific Corporation.

Adaptable: Transseptal Puncture from Any Approach

The RFP-100A RF Puncture Generator* optimizes the power delivered on all Boston Scientific RF transseptal solutions to enable facile transseptal puncture from any approach:

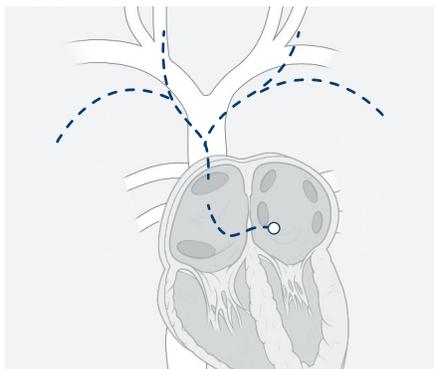
Femoral vein access

- Right femoral venous access is typically used to introduce the **NRG™** Transseptal Needle⁷ or **VersaCross™** RF Transseptal Solution¹⁴ to perform transseptal puncture.



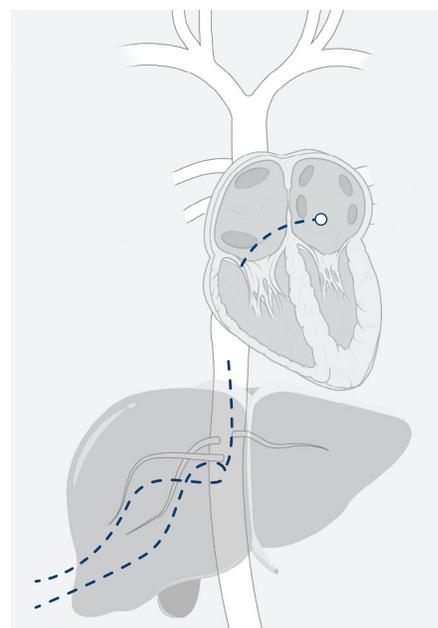
Subclavian or jugular vein access

- 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 ablations⁴²⁻⁴⁴, and transcatheter mitral valve repair⁴⁰ (i.e. MitraClip™ procedure, Abbott).



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 ablation^{45,46}, and left atrial appendage occlusion procedures⁴⁶.



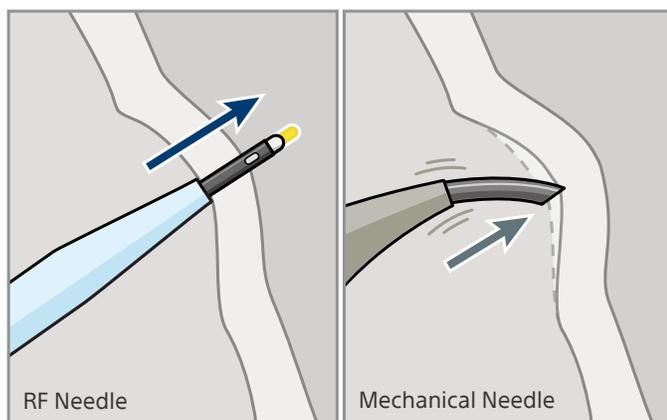
*Baylis Medical Company Radiofrequency Puncture Generator RFP-100A.
Baylis Medical Company is a wholly-owned subsidiary of Boston Scientific Corporation.

Improved Crossing for Any Anatomy

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

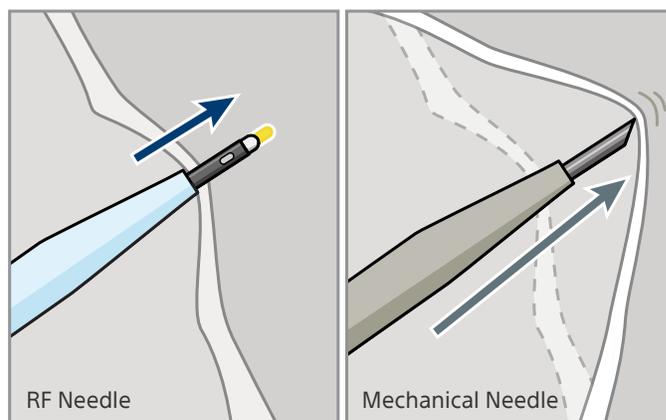
- The round atraumatic tip of Boston Scientific RF transeptal technologies reduces the incidence of plastic particle skiving (0%) when compared to the conventional mechanical needle (33.3% or more)^{7,11}
- Boston Scientific RF transeptal technologies have been associated with reduced incidence of cardiac tamponade (0% vs 0.92%, respectively)⁹, and pericardial effusion (0% vs 3.06%, respectively)⁶ when compared to a mechanical needle group.
- The **NRG™** Transeptal Needle has been associated with 40% lower incidence of silent acute cerebral embolism compared to a mechanical needle.¹²

Fibrotic (thickened) septum



Cross **fibrotic septum** while reducing mechanical force.⁴⁹

Aneurysmal (elastic) septum



Cross thin **aneurysmal septum** while reducing excessive tenting.⁸

*Based on ex vivo findings.

Characterized Tissue Healing

Boston Scientific RF transeptal technologies are optimized for improved puncture of the atrial septum **without coagulative necrosis or prolonged healing.**³

- **No coagulative necrosis:** A study by Veldtman et al. showed a similar pattern of injury when using Boston Scientific RF transeptal 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 energy.³
- **Well-developed healing:** The extent of acute injury using Boston Scientific RF transeptal technology was similar to that seen with conventional mechanical needle puncture. Minimal inflammation and homogenous fibrosis were observed at one month post-puncture.³

There was a low rate of persistent atrial septal defects (8.4%) in patients at 15.5 months following the use of the **NRG™** Transeptal Needle¹⁶, similar to mechanical needle puncture⁵⁰.^{*} All patients were asymptomatic, and persistence was correlated with atrial septal angle.¹⁶

^{*}Results from different clinical investigations are not directly comparable.
Information provided for educational purposes only.

Time Savings

Boston Scientific RF transeptal technologies have been associated with time savings^{2,8,13}, and improved success rate for transeptal puncture^{2,8}.

- **NRG™ Transeptal Needle:** Significantly lower total instrumentation time was reported from procedure start to transeptal puncture (27.1±10.9 min) compared to the conventional mechanical needle system (36.4±17.7 min).⁹
- **VersaCross™ RF Transeptal Solution:** Significantly faster time was reported from femoral access to transeptal puncture (4.1±2.5 min) compared to the conventional mechanical needle system (8.4±4.0 min), leading to two times faster therapy delivery sheath access.^{13*}

*Based on initial retrospective comparative study which found that **VersaCross™** RF Transeptal 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

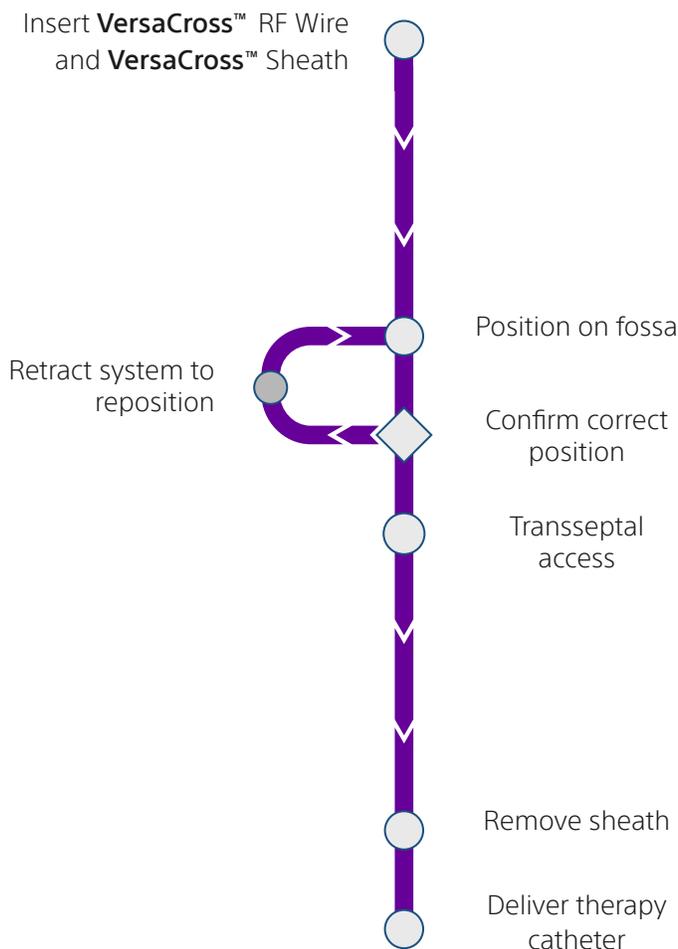
Reduced Exchanges

Catheter manipulation^{17,18}, device exchange^{19,20}, and procedure time²¹ have been associated with incidence of embolism due to air bubbles, and/or dislodgment of cardiac thrombus.

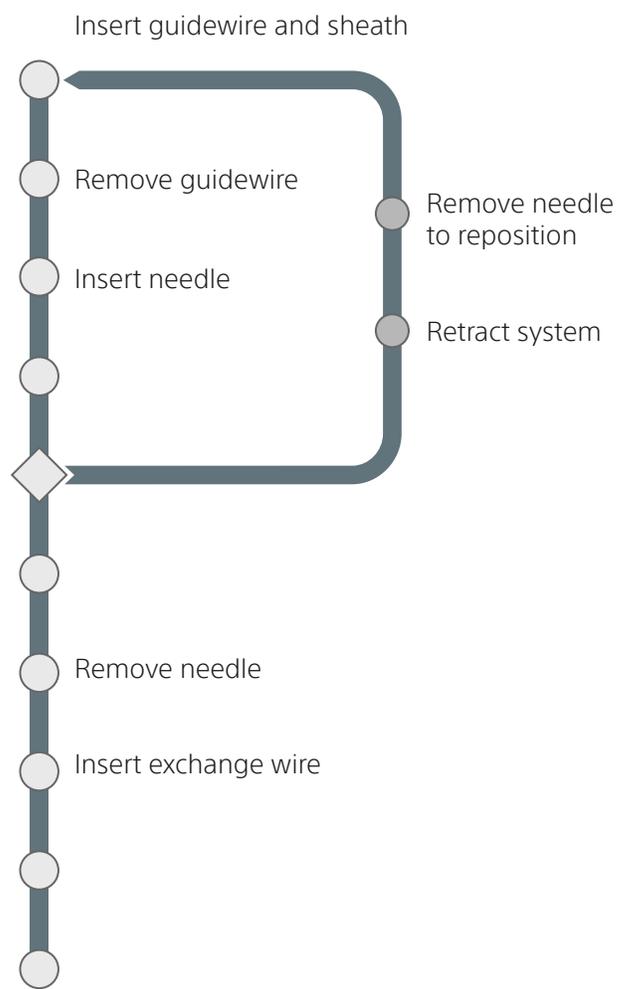
Catheter ablation procedures have been associated with silent cerebral embolism²², which may cause long-term cognitive dysfunction^{23,24}.

The **VersaCross™** RF Transseptal Solution reduces the number of device exchanges through exchangeless vascular cannulation, transseptal puncture, and catheter delivery into the left atrium.^{13,14}

VersaCross™ Workflow



Standard Needle Workflow



Enhanced Visualization

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

OMNIVIZ™ Technology



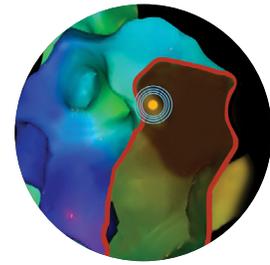
Radiopaque

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 approximately 15 mSv of radiation (the equivalent of 750 chest X-rays) per procedure, and staff to 5 mSv (the equivalent of 250 chest X-rays) per year.²⁵

- Radiation exposure presents a risk of **acute skin injuries**²⁶ and **fatal malignancies** to patients²⁵.
- 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 transseptal 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 Boston Scientific RF transseptal technologies in non-fluoroscopic procedures have been well studied in:

- Double transseptal punctures for RF ablation³⁴
- Single transseptal puncture for cryoballoon ablation^{35,36}
- Complex anatomies^{31,33}
- Without echocardiography³¹

Fluoroscopy Reduction (continued)

Zero Fluoro. Zero Compromise.™

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 were reported during fluoroless transseptal puncture.^{34,37}

Maintain efficient transseptal access **without fluoroscopy***

NRG™ Needle
zero fluoro used³⁴

27.8 min ± 15.1 min.

VersaCross™ Wire
zero fluoro used³⁷

14.2 min ± 6.0 min.

Time to Transseptal

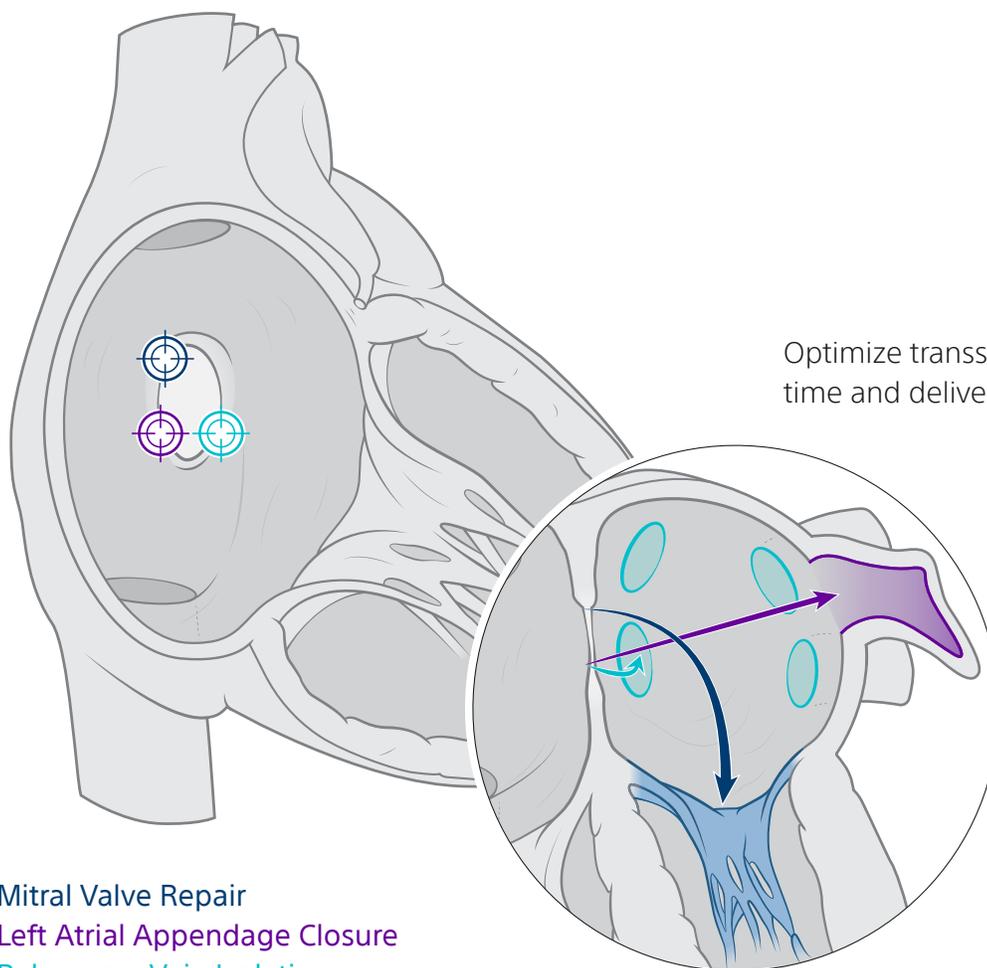
(from femoral to LA access) includes RA mapping time

*Based on transseptal times from femoral to LA access from two non-comparative fluoroless case series^{34,37} compared to using conventional fluoroscopy-guided procedures².

Targeted Precision

Precise crossing is necessary to avoid unintended perforation of nearby structures. Targeted transseptal puncture (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.³⁸
- The **NRG™** Transseptal Needle was used to provide controlled site-specific crossing of the interatrial septum without complications.³⁹
- Boston Scientific RF transseptal technology enables site-specificity even in the presence of atrial septal occluders.⁴⁰



Mitral Valve Repair
Left Atrial Appendage Closure
Pulmonary Vein Isolation

Conclusion

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

1. Reliable Transeptal
2. Adaptable Transeptal 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

1. Sharma et al. Catheter. Cardiovasc. Interv. 2017.
2. Winkle et al. J. Interv. Card. Electrophysiol. 2013.
3. Veldtman et al. Catheter. Cardiovasc. Interv. 2005.
4. Whittaker et al. Lasers Surg. Med. 2000.
5. Anderson et al. Catheter. Cardiovasc. Interv. 2020.
6. Jauvert et al. Heart Lung Circ. 2015.
7. Hsu et al. J. Am. Heart Assoc. 2013.
8. Fromentin et al. J. Interv. Card. Electrophysiol. 2011.
9. Winkle et al. Heart Rhythm 2011.
10. Yoshida et al. EP Eur. 2016.
11. Feld Et al. J. Interv. Card. Electrophysiol. 2011.
12. Tokuda et al. Heart Vessels 2018.
13. Inohara et al. J. Interv. Card. Electrophysiol. 2021.
14. Sayah et al. Catheter. Cardiovasc. Interv. 2020.
15. Greenstein et al. Circ. Arrhythm. Electrophysiol. 2012.
16. Watanabe et al. Heart Vessels 2018.
17. Takami et al. Circ. Arrhythm. Electrophysiol. 2016.
18. Sugrue Alan et al. J. Interv. Card. Electrophysiol. 2020.
19. Deneke et al. Indian Pacing Electrophysiol. J. 2014.
20. Tokuda et al. Heart Vessels 2018.
21. Harada et al. J. Cardiovasc. Electrophysiol. 2020.
22. Miyazaki et al. Heart Rhythm 2019.
23. Medi et al. J. Am. Coll. Cardiol. 2013.
24. Shwarz et al. Heart Rhythm 2020.
25. Venneri et al. Am. Heart J. 2009.
26. Picano et al. J. Atr. Fibrillation 2014.
27. Roguin et al. Am. J. Cardiol. 2013.
28. Gerber et al. Circulation 2009.
29. Orme et al. J. Am. Coll. Cardiol. 2015.
30. Attanasio et al. EP Eur. 2012.
31. Guarguagli et al. Cardiol. Res. Pract. 2020.
32. Imnadze et al. Cardiol. J. 2020.
33. Shah et al. Heart Rhythm Case Rep. 2019.
34. Salam et al. J. Innov. Card. Rhythm Manag. 2020.
35. Reiss et al. Int. J. Cardiol. 2020.
36. Demo et al. Card. Electrophysiol. Clin. 2019.
37. Demo and Razminia. J. Cardiovasc. Electrophysiol. 2021.
38. Singh et al. Interv. Cardiol. Clin. 2015.
39. Poulin et al. Catheter. Cardiovasc. Interv. 2019.
40. Yap et al. Catheter. Cardiovasc. Interv. 2020.
41. Inohara et al. J. Cardiovasc. Electrophysiol. 2021.
42. Hernandez-Ojeda et al. Heart Rhythm Case Rep. 2020.
43. Liang et al. Clin. Electrophysiol. 2020.
44. Santangeli et al. J. Cardiovasc. Electrophysiol. 2020.
45. Suryanarayana et al. Heart Rhythm Case Rep. 2020.
46. Hanley et al. J. Cardiovasc. Electrophysiol. 2020.
47. Rich et al. J Vis Exp. 2015.
48. Rinaldi et al. Cardiac Interv Today. 2014.
49. Smelley et al. J Cardiovasc Electrophysiol. 2010.
50. Singh et al. Circ. Arrhythm. Electrophysiol. 2011.



*Baylis Medical Company Radiofrequency Puncture Generator RFP-100A. Baylis Medical Company is a wholly-owned subsidiary of Boston Scientific Corporation.
All trademarks are property of their respective owners. Patents Pending and/or issued. Caution: The law restricts this device to sale by or on the order of a physician. Indications, Contraindications, Warnings, and Instructions For Use can be found in the product labelling supplied with each device or at 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**
Advancing science for life™

© 2023 Boston Scientific Corporation
or its affiliates. All rights reserved.
EP-1589209-AA