Boston Scientific
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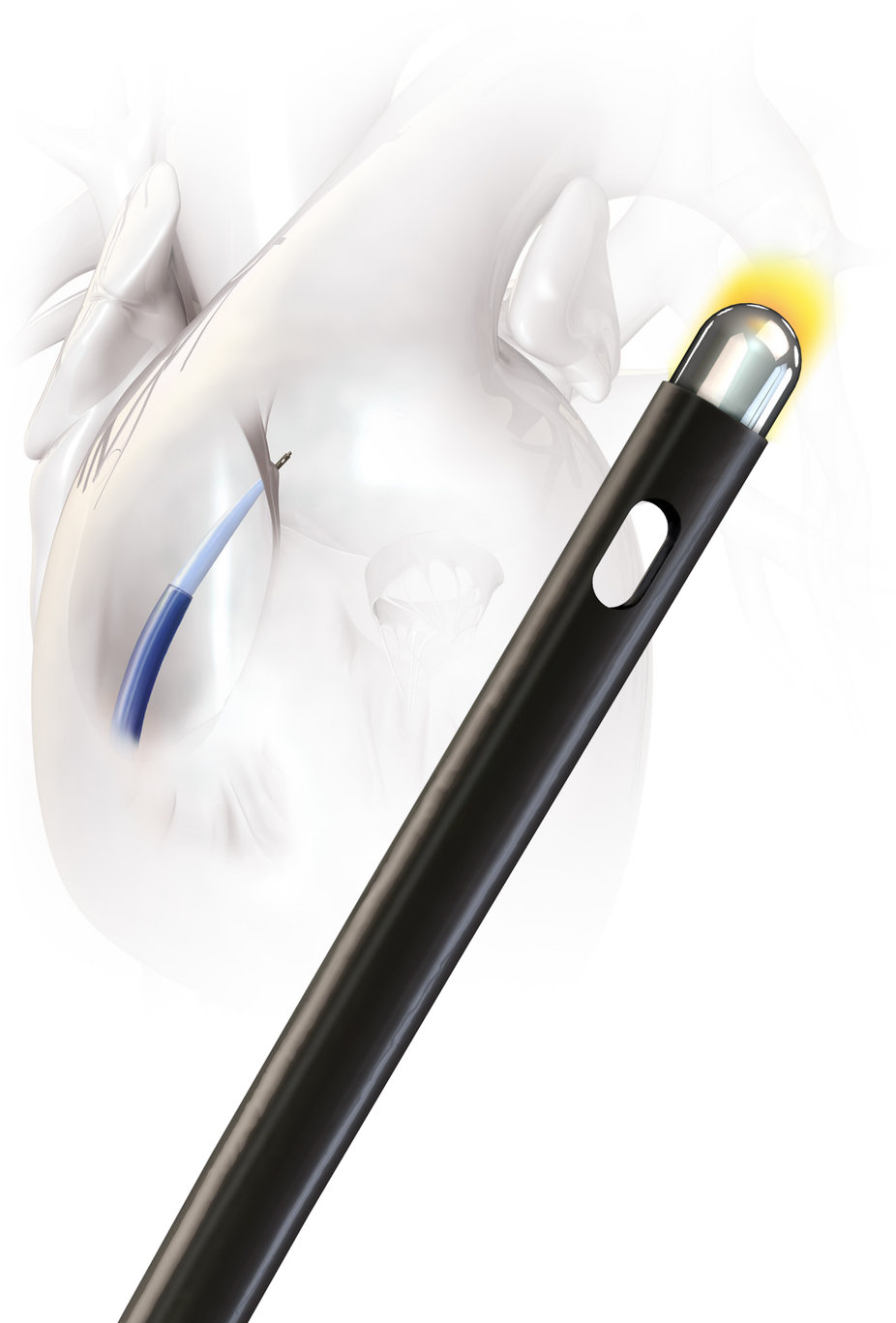
NRG™
Transseptal Needle

Clinical Analysis of
RF Transseptal Punture

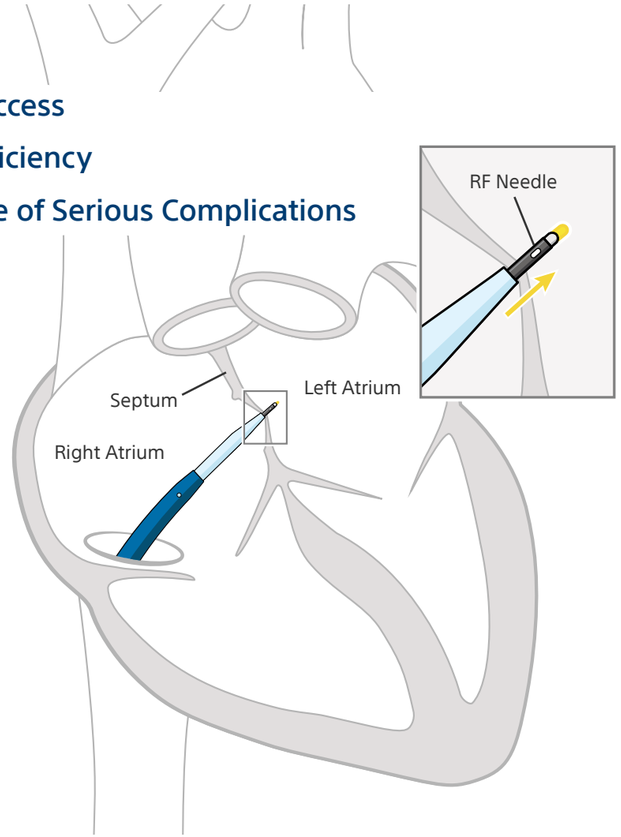
Contents



Executive Summary

Published clinical evidence shows that transseptal puncture using Boston Scientific RF transseptal technologies:

- Increases Success
- Increases Efficiency
- Reduces Rate of Serious Complications



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.

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. Improved success with challenging anatomy
2. Reduced rate of failed transseptal crossings
3. Reduced procedure time
4. Reduced rate of serious complications
5. Reduced time of exposure to fluoroscopic radiation
6. Prevention of skiving/generation of visible plastic particles

These benefits reduce burden on the hospital, patient, and physician, and may be realized across all levels of physician expertise.

Background

Transseptal Puncture

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 was first described in the 1960s. Historically, a sharp, mechanical needle has been used to push across the interatrial septum and gain left-heart access.

Common Challenges

Despite its common use, the transseptal puncture process can be:

- Associated with serious complications, such as cardiac tamponade
- Unpredictable
- Time consuming

Radiofrequency Solution

A dedicated radiofrequency (RF) transseptal needle was developed to address these challenges.

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.

The RF technology of the NRG Transseptal Needle delivers benefits that reduce burden on the hospital, patient, and physician.

Benefits of RF Transseptal Puncture

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

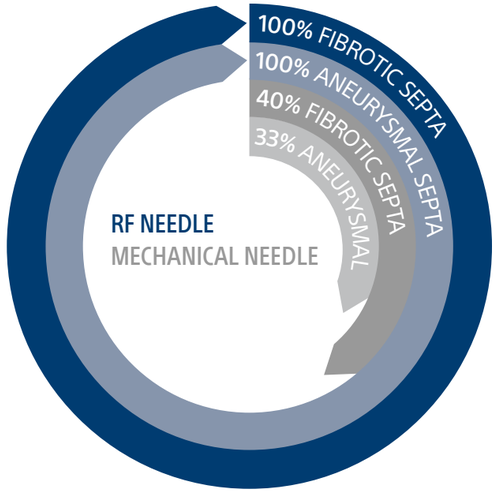
1. **Improved success with challenging anatomy** (such as thickened septum, fibrotic septum, patients who have had a previous transseptal puncture, aneurysmal septum, congenital heart disease)
2. **Reduced rate of failed transseptal crossings**
3. **Reduced procedure time**
4. **Reduced rate of serious complications**
5. **Reduced time of exposure to fluoroscopic radiation**
6. **Prevention of skiving/generation of visible plastic particles**

The following sections describe the evidence that supports the benefits of the RF needle in each of these categories. These benefits may be realized across all levels of physician expertise.

1. Improved Success with Challenging Anatomy

Studies have shown that the RF Needle is consistently successful in crossing challenging anatomy.

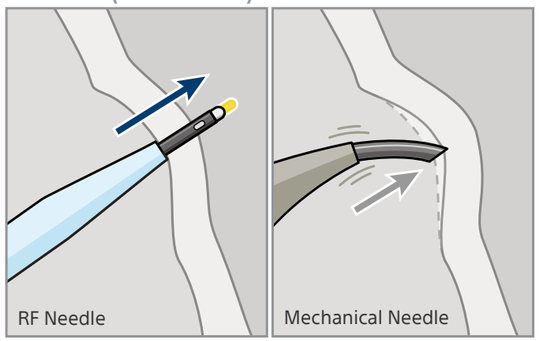
success rates
*crossing challenging anatomy**



Study	RF Needle	Mechanical Needle
	Challenging Case Transseptal Results	Challenging Case Transseptal Results
Fromentin et al.[1]	**n = 119** 100% success in failed (crossover) cases from Mechanical Needle group (4 cases)	**n = 38** - the 4 failed cases included: 2/4 had thick interatrial septum (patients undergoing 3rd transseptal procedure) 1/4 had small fossa ovalis requiring crossing through thicker portion of septum
Hsu et al.[2]	**n = 36** 100% success in failed (crossover) cases from Mechanical Needle group (10 cases)	**n = 36** 4/10 failed cases were in patients who had previous transseptal puncture
Jauvert et al.[3†]	**n = 125** 7/7 (100%) in fibrotic (thickened) septa‡ 3/3 (100%) in aneurysmal septa 1/1 (100%) in small left atrium with small fossa ovalis and split septum	**n = 100** 2/5 (40%) in fibrotic (thickened) septa 1/3 (33%) in aneurysmal septa

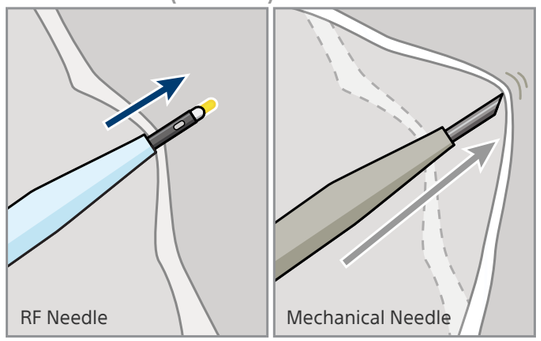
* Figure represents data from the Jauvert et al. study[3]; details in table above and on opposite page.
† RF transseptal punctures were performed using a flexible RF needle, the Toronto RF Septostomy Catheter (later renamed the Toronto Transseptal Catheter), which was the predecessor to the NRG Transseptal Needle.
‡ The mechanical needle failed to cross previously in 2/7 patients.

FIBROTIC (THICKENED) SEPTUM



RF Needle crosses fibrotic (thickened) septum consistently versus mechanical needle.

ANEURYSMAL (ELASTIC) SEPTUM



RF Needle crosses aneurysmal (elastic) septum consistently versus mechanical needle.

Fromentin et al. (2011)
Fromentin et al.[1] conducted a prospective comparison of patients receiving RF transseptal puncture with the NRG Transseptal Needle (n=119) to patients undergoing transseptal puncture with a mechanical needle (n=38). The results showed that the septum was successfully crossed in all patients receiving transseptal puncture with the RF needle, whereas 4/38 patients (11%) in the mechanical needle group required crossover to the RF needle (p=0.003). Two of these patients were undergoing their third transseptal procedure and had a thickened interatrial septum, while another required transseptal puncture through a thicker portion of the septum due to the presence of a very small fossa ovalis. If crossover to the RF needle had not been possible in these cases, the physicians would have had to either try more aggressively to cross with the sharp mechanical needle, which could make the case more prone to complications, or they would have had to abort the case.

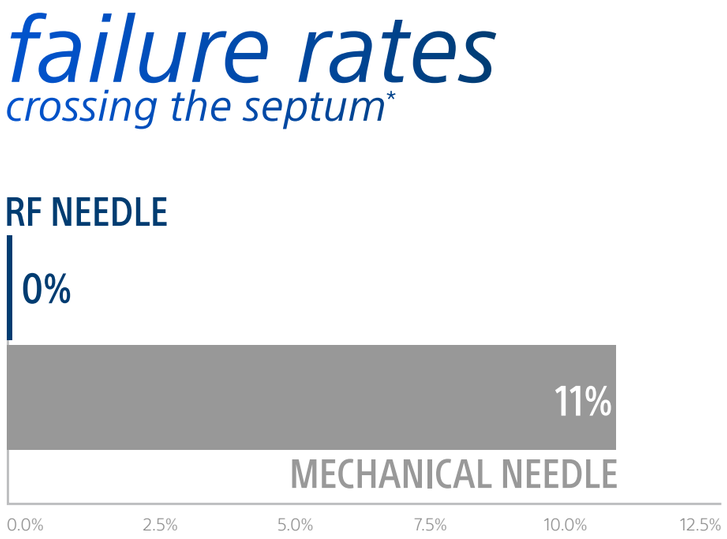
Hsu et al. (2013)
Hsu et al.[2] conducted a RCT with subjects undergoing catheter ablation procedures randomized to RF transseptal puncture with the NRG Transseptal Needle (n=36) or a mechanical transseptal needle (n=36). The authors observed no failures to cross with the assigned needle in the RF needle group (0/36) as compared to 10/36 failures (27.8%) in the mechanical needle group (P<.001). Of these failures, 4 were in patients who had a previous transseptal puncture. The authors acknowledge the previous evidence suggesting that repeat transseptal punctures are more challenging and indicate that the RF needle may be preferred in this patient population.

Jauvert et al. (2015)
Jauvert et al.[3] compared 125 consecutive patients who had transseptal puncture performed with a flexible RF needle (Toronto Catheter)† to 100 consecutive patients who had transseptal puncture performed with a mechanical needle. In the mechanical needle group, there were 3 patients with an aneurysmal septum and 5 patients with a fibrotic septum. In this subset of patients, successful transseptal puncture with the mechanical needle was only possible in 1/3 (33%) aneurysmal septa, and 2/5 (40%) fibrotic septa. This is compared to 125/125 successful transseptal punctures in the RF flexible needle group, despite an abnormal septum in 11 (8.8%) patients (7 had unusually thickened septa, 2 of which were patients in whom the mechanical needle had failed to perforate previously; 3 had aneurysmal septa; 1 patient had a small left atrium, small fossa ovalis and a split septum).

Esch et al. (2013)
Esch et al.[4] conducted a retrospective chart review of 10 patients with congenital heart disease (five patients had undergone atrial switch procedures (Mustard/Senning), four had undergone Fontan operations, and one had atrial septal defect repair) who had attempts made using the NRG Transseptal Needle to provide transseptal access to the left heart for mapping/ablation procedures. The authors acknowledge the challenges posed to traditional mechanical needle puncture by the highly distorted anatomy in the congenital heart disease population. However, the RF needle was successful in 9/10 (90%) of these cases, including 2 that had first failed with a mechanical needle. The septal material in these cases was atrial muscle (n = 5), pericardium (n = 3), and synthetic fabric (n = 2). In their Methods section, the authors indicate a number of factors considered for choosing to use the RF needle rather than a mechanical needle for the initial transseptal attempt. These factors included thick septum calcification demonstrated by fluoroscopy, thick septum at the desired puncture site, presence of synthetic atrial patch material, a large pericardial baffle, or an occlusion device in the septum, and a small left atrial chamber size that made forceful tip advancement unadvisable.

2. Reduced Rate of Failed Transseptal Crossing

There was only 1 failure to cross the septum with the RF Needle in published comparative studies.



Study	RF Needle		Mechanical Needle	
	# of Transseptal Punctures	# of Failures to Cross Septum	# of Transseptal Punctures	# of Failures to Cross Septum
Winkle et al.[5]	575	1	975	12†
Fromentin et al.[1]	119	0	38	4
Hsu et al.[2]	36	0	36	10‡
Jauvert et al.[3]	125	0	100	5§
Yoshida et al.[6]	10	0	32	0

* Figure represents data from Fromentin et al. study; details in table above and on opposite page.
† The authors indicate that these failures in the mechanical needle group were due to inadvertent punctures of unintended structures and resulted in the termination of the procedures.
‡ The authors indicate that these failures in the mechanical needle group occurred due to concern that further forward pressure or tenting could lead to perforation of the lateral left atrial wall.
§ The authors indicate that two of these cases were aborted due to an aneurysmal septum that brought the dilator too close to the left atrial roof or free wall, making the procedure too risky.

Winkle et al. (2011)
Winkle et al.[5] conducted a retrospective study comparing transseptal puncture performed with the NRG Transseptal Needle to that performed with a mechanical needle in patients undergoing catheter ablation of atrial fibrillation. A total of 1,167 consecutive patients who underwent 1,550 AF ablations were included in the study. Of these, 975 transseptal punctures were performed using the mechanical needle and 575 with the NRG Transseptal Needle. The authors found the rate of failure to cross the atrial septum was lower for the RF needle (1 of 575 [0.17%] vs. 12 of 975 [1.23%], p = 0.039). Further, the authors indicate that these failures in the mechanical needle group were due to inadvertent punctures of unintended structures (as shown by contrast injection staining) and resulted in the termination of these procedures without sequelae. The single patient in the RF transseptal needle group who experienced a failure to cross was due to a hypertrophic cardiomyopathy and a thick interatrial septum and also required a subsequent procedural session (the paper does not, however, provide data on overall success rates in challenging anatomies for either group).

Because the RF needle was used later in the series of patients, the authors examined their 975 mechanical needle punctures over time for evidence of improved operator performance, but found there was no trend for improved septal crossing rates (p = 0.794). The authors state that this suggests that the better results seen with the RF needle are probably not due to more operator experience.

In the Discussion of the paper, the authors review several differences between the mechanical needle and the RF needle that may account for the improved rate of septal crossing with the RF needle. They indicate that, after crossing with the mechanical needle, they would typically advance the needle tip a few millimeters out of the sheath to measure pressure and inject a small amount of contrast, confirming access, before advancing the larger sheath and dilator; however, in some failed crossings, contrast staining indicated that the sharp needle tip had inadvertently caused a puncture at an unintended location, leading to the decision to not proceed with the case. They contrast this with the blunt-tipped RF needle, which can inject contrast without exposing tissue to a sharp tip. Also, they indicate that RF energy may facilitate septal crossing in thicker portions of the septum or in areas scarred from previous transseptal procedures.

Fromentin et al. (2011)
Fromentin et al.[1] conducted a prospective comparison of patients receiving transseptal puncture with the NRG Transseptal Needle (n=119) to patient undergoing transseptal puncture with a mechanical needle (n=38). The septum was successfully crossed in all patients receiving transseptal puncture with the RF needle; however, four patients (11%) in the mechanical needle group required crossover to the RF needle (p=0.003). Two of these patients were undergoing their third transseptal procedure and had a thickened interatrial septum, while another required transseptal puncture through a thicker portion of the septum due to the presence of a very small fossa ovalis. If crossover to the RF needle had not been possible in these cases, the physicians would have had to either push more aggressively to cross with the sharp mechanical needle, which could make the case more prone to complications, or they would have had to abort the case. In addition, 1/38 subjects (2.6%) in the mechanical needle group experienced an interatrial septum dissection with extension to the aortic root, causing intramural hematoma. This led to the case being aborted.

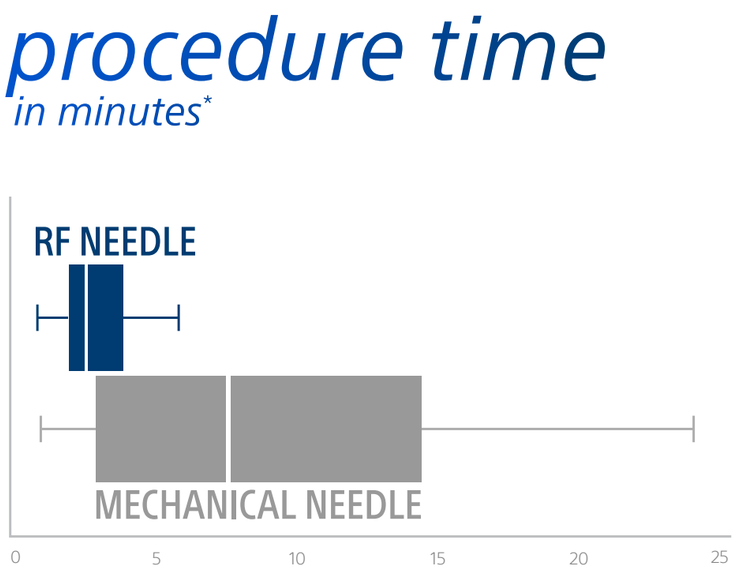
Hsu et al. (2013)
Hsu et al.[2] conducted a RCT of subjects undergoing catheter ablation procedures randomized to transseptal puncture with the NRG Transseptal Needle (n = 36) or a mechanical transseptal needle (n = 36). There were no failures to cross with the assigned needle in the RF needle group (0/36) as compared to 10/36 failures (27.8%) in the mechanical needle group (P < 0.001). The authors indicate that these 10 failures with the mechanical needle occurred due to concern that further forward pressure or tenting could lead to perforation of the lateral left atrial wall. However, all 10 patients that failed transseptal puncture with the mechanical needle had successful transseptal puncture performed after crossing over to the RF needle group. If crossover to the RF needle had not been available in these cases, the physicians would have had to either push more aggressively to cross with the sharp mechanical needle, which could make the case more prone to complications, or they would have had to abort the case.

Jauvert et al. (2015)
Jauvert et al.[3] compared 125 consecutive patients who had transseptal puncture performed with a flexible RF needle (Toronto Catheter) to 100 consecutive patients who had transseptal puncture performed with a mechanical needle. In the flexible RF needle group 125/125 (100%) of subjects has successful transseptal puncture performed, as compared to 95/100 (95%) in the mechanical needle group (p=0.01). Of the 5 failures in the mechanical needle group, 2 transseptal punctures were aborted due to an aneurysmal septum that brought the dilator too close to the left atrial roof or free wall with the authors determining that transseptal puncture in these cases would be too risky. The other 3 failures in the mechanical needle group were related to a fibrotic septum, 2 of which were in patients that had previously had a transseptal puncture performed.

Yoshida et al. (2016)
Yoshida et al.[6] conducted a retrospective study on paediatric patients (n = 43) weighing less than 30 kg undergoing transseptal puncture for the purpose of catheter ablation. Eight patients (n = 8) in this study had the transseptal puncture performed with the NRG Transseptal Needle. All reported cases were successful in crossing the septum.

3. Reduced Procedure Time

All comparative studies that measured time showed a shorter, more predictable time for transseptal puncture with the RF Needle.



Study	RF Needle		Mechanical Needle	
	# of Transseptal Punctures	Time Required for Puncture	# of Transseptal Punctures	Time Required for Puncture
Winkle et al.[5]	575	27.1 ± 10.9 minutes†	975	36.4 ± 17.7 minutes†
Fromentin et al.[1]	119	7.5 ± 4.2 min‡	38	12.3 ± 9.3‡
Hsu et al.[2]	36	2.3 min [IQR, 1.7 to 3.8 min]§	36	7.3 min [IQR, 2.7 to 14.1 min]§

* Figure represents data from Hsu et al. study[2]; details in table above and on opposite page. Box plots show IQR of transseptal puncture procedure time, with white lines indicating median values; whiskers represent extremes within 1.5 times IQR; outliers are not shown.
† Time from lidocaine injection at the start of the case to time of successful septal crossing. Reported values were mean ± standard deviation.
‡ Time from initial insertion of the needle into the long sheath and when the sheath reached the left atrium (with removal of needle and dilator). Reported values were mean ± standard deviation.
§ Time from pull-down of needle/dilator/sheath from the superior vena cava, until confirmation in left atrium. Reported values were median [interquartile range].

Winkle et al. (2011)
In the Winkle et al.[5] retrospective study comparing 975 transseptal punctures done with the mechanical needle and 575 done with the RF transseptal needle, the authors found that the time from lidocaine injection at the start of the case to time of successful septal crossing was shorter for the RF needle compared with the mechanical needle (27.1 ± 10.9 minutes vs. 36.4 ± 17.7 minutes, P < 0.0001). They attribute this shorter instrumentation time to the more expeditious transseptal puncture afforded by the RF mode of action.

Fromentin et al. (2011)
Fromentin et al.[1] conducted a prospective comparison of patients receiving transseptal puncture with the NRG Transseptal Needle (n = 119) to patient undergoing transseptal puncture with a mechanical needle (n = 38). It was observed that the average transseptal time with the NRG Transseptal Needle was shorter than that with the mechanical needle (7.5 ± 4.2 min versus 12.3 ± 9.3 min; p=0.005).

Hsu et al. (2013)
Hsu et al.[2] conducted a RCT of subjects undergoing catheter ablation procedures randomized to transseptal puncture with the NRG Transseptal Needle (n = 36) or a mechanical transseptal needle (n = 36). A significantly shorter median transseptal time was seen in the RF needle group (2.3 minutes [IQR, 1.7 – 3.8 minutes]) as compared to the mechanical needle group (7.3 minutes [IQR, 2.7 – 14.1 minutes] (p = 0.005). Further, the authors noted a greater variability in time required for transseptal puncture in the mechanical needle group, with the authors attributing this to a more uniform experience in the RF needle group. The authors' use of multivariate models found that older patient age predicted longer transseptal times, which they speculate was possibly due to more distorted cardiac anatomy or more fibrosis of the interatrial septum.

4. Reduced Rate of Serious Complications

no serious complications

attributed to the RF Needle in published comparative studies.

About Cardiac Tamponade

One of the serious complications associated with transseptal puncture is cardiac tamponade (also known as pericardial tamponade).

This is when blood (or other fluid) accumulates in the sac surrounding the heart (the pericardium). This puts pressure on the heart and prevents normal functioning.

Cardiac tamponade is a medical emergency. It can be fatal.

Treatment includes:

- Emergency pericardiocentesis (insertion of needle into pericardium and fluid aspiration)

or

- Open heart surgery (pericardial window created to cut open pericardium)

Study	RF Needle			Mechanical Needle		
	# of Transseptal Punctures	# of Pericardial Tamponades	# of Septum Dissections with Aortic Root Hematoma	# of Transseptal Punctures	# of Pericardial Tamponades	# of Septum Dissections with Aortic Root Hematoma
Winkle et al.[5]	575	0	0	975	9†	0
Jauvert et al.[3]	125	0	0	100	2‡	0
Fromentin et al.[1]	119	1§	0	38	0	1‖
Hsu et al.[2]	36	0	0	36	0	0
Yoshida et al.[6]	10	0	0	32	0	0

* Published clinical literature typically characterizes pericardial effusion as a minor complication.
† The authors state that their data indicate that the majority of pericardial tamponades occurring during AF ablation are likely related to transseptal puncture. 8 tamponades were managed with emergency pericardiocentesis; 1 required an open surgical procedure.
‡ The authors attribute these events to overshooting following the sudden release of the septum, thereby leading to a micro puncture with bleeding worsened by anticoagulation.
§ The authors indicate that this was related to a pop observed during catheter ablation and not related to the transseptal puncture.
‖ Occurred during contrast injection and led to the case being aborted.

Winkle et al. (2011)
In the Winkle et al.[5] retrospective study comparing 575 transseptal punctures done with the RF transseptal needle and 975 done with the mechanical needle, the authors found that there were fewer pericardial tamponades with the RF needle (0 of 575 [0.00%] vs. 9 of 975 [0.92%], p = 0.031). Of the 9 instances of pericardial tamponade in the mechanical needle group, one case required an open surgical procedure and 8 were managed with emergency pericardiocentesis. In the Discussion of the paper, the authors indicate that even though pericardial tamponade can be caused by steam pops during catheter ablation or excessive catheter contact force, their data indicate that the majority of pericardial tamponades occurring during AF ablation are likely related to transseptal puncture.

Because the RF needle was used later in the series of patients, the authors examined their 975 mechanical needle punctures over time for evidence of improved operator performance, but ***found that there was no trend for fewer tamponades with more operator experience (p = 0.456). The authors state that this suggests that the better results seen with the RF needle are probably not due to more operator experience.*** Also, the results of the authors' multivariate analysis on the influence of gender, type of transseptal puncture needle utilized, primary physician operator, BMI, age, and LA size on the occurrence of pericardial tamponade found that ***only the use of the RF transseptal needle was associated with a reduced incidence of tamponade (p = 0.04).***

In the Discussion of the paper, the authors discuss the various advantages of the RF needle that may contribute to reducing the rate of atrial perforation. These stated advantages include the fact that, after tenting of the atrial septum with a mechanical needle, the sharp needle tip must be further advanced toward the far wall of the left atrium in order to puncture the septum. In contrast, the RF Needle uses RF energy to cross the septum without the need to push the needle forward after tenting is achieved. Instead, RF puncture allows the septum to move back towards its non-tented position, while the RF needle remains stationary. Another advantage of the RF needle stated by the authors is its blunt tip, which makes perforation unlikely if it were to contact the left atrial roof, posterior wall, or appendage after crossing the septum.

Jauvert et al. (2015)
Jauvert et al.[3] compared 125 consecutive patients who had transseptal puncture performed with a flexible RF needle (Toronto Catheter) to 100 consecutive patients who had transseptal puncture performed with a mechanical needle. In the mechanical needle group, 3 (3.0%) pericardial effusions* were observed with 2 (2.0%) of these developing into tamponade, as compared to none (0%) in the RF flexible needle group (p = 0.04). The authors attribute two of these events in the mechanical needle group to overshooting following the sudden release of the septum, thereby leading to a micro puncture with bleeding worsened by anticoagulation. They attribute the third event in the mechanical needle group to the dilator sliding upward while pushing the needle.

Fromentin et al. (2011)
Fromentin et al.[1] conducted a prospective comparison of patients receiving transseptal puncture with the NRG Transseptal Needle (n = 119) to patient undergoing transseptal puncture with a mechanical needle (n = 38). One tamponade occurred in the NRG Transseptal Needle group (0.84%), but the authors indicate that this was related to a pop observed during catheter ablation and not related to the transseptal puncture.

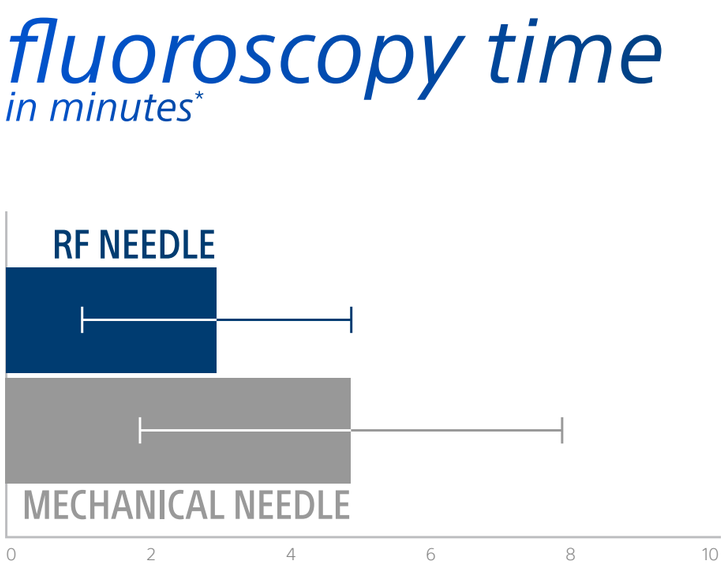
In addition, 1/38 subjects (2.6%) in the mechanical needle group experienced an interatrial septum dissection with extension to the aortic root, causing intramural hematoma, during contrast injection. This led to the case being aborted.

Hsu et al. (2013)
Hsu et al.[2] conducted a randomized controlled trial with subjects undergoing catheter ablation procedures randomized to transseptal puncture with the NRG Transseptal Needle (n = 36) or a mechanical transseptal needle (n = 36). In the RF needle arm, after completion of the LA ablation procedure (3 hours after the transseptal puncture), 1 patient was found to have a pericardial effusion* detected by ICE. In the mechanical needle arm, 1 patient experienced a transient ischemic attack, with a brain MRI consistent with embolic etiology.

Yoshida et al. (2016)
Yoshida et al.[6] conducted a retrospective study on paediatric patients (n = 43) weighing less than 30kg undergoing transseptal puncture for the purpose of catheter ablation. Eight patients (n = 8) in this study had the transseptal puncture performed with the NRG Transseptal Needle. No serious complications were observed in either group.

5. Reduced Time of Exposure to Fluoroscopic Radiation

Comparative studies showed a significantly shorter fluoroscopy time for transseptal puncture using the RF needle.



Study	RF Needle		Mechanical Needle	
	# of Transseptal Punctures	Fluoroscopy Time Required for Transseptal Puncture	# of Transseptal Punctures	Fluoroscopy Time Required for Transseptal Puncture
Fromentin et al.[1]	119	3.0 ± 1.8 min†	38	4.8 ± 3.1 min†
Yoshida al.[6]	10	24.5 (18.5–32.8) min‡	32	30.5 (17.9–52.0) min‡

* Figure represents data from Fromentin et al. study[1] (mean ± standard deviation); details in table above and on opposite page.
† Reported values were mean ± standard deviation.
‡ Reported values were median (range).

Fromentin et al. (2011)
Fromentin et al.[1] conducted a prospective comparison of patients receiving transseptal puncture with the NRG Transseptal Needle (n = 119) to patients undergoing transseptal puncture with a mechanical needle (n = 38). It was observed that the total fluoroscopy time for transseptal access with the NRG Transseptal Needle was shorter than that with the mechanical needle (3.0 ± 1.8 min versus 4.8 ± 3.1 min; p = 0.009).

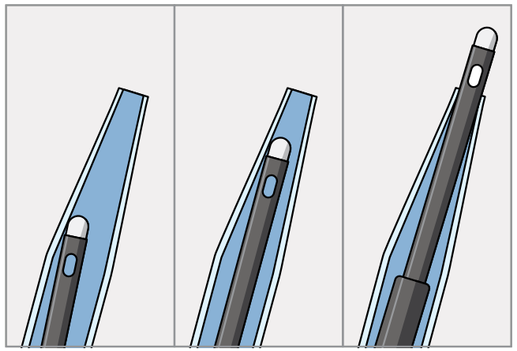
Yoshida et al. (2016)
Yoshida et al.[6] conducted a retrospective study on paediatric patients (n = 43) weighing less than 30 kg undergoing transseptal puncture for the purpose of catheter ablation. Eight patients (n = 8) in this study had the transseptal puncture performed with the NRG Transseptal Needle. The results demonstrated that the RF transseptal group showed a significantly lower fluoroscopy time compared to the mechanical needle group (24.5 [18.5 – 32.8] min versus 30.5 [17.9 – 52.0] min; p = 0.036).

In their conclusions, the authors indicate that they consider the use of RF needles as one method of increasing the safety of transseptal puncture in children.

6. Prevention of Skiving/Generation of Visible Plastic Particles

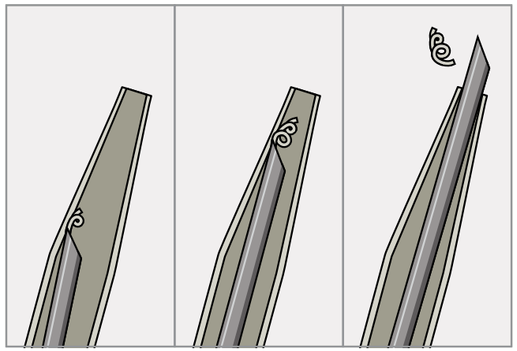
Testing has demonstrated that the RF Needle does not generate visible plastic particles as it is advanced through the sheath and dilator.

RF NEEDLE



RF Needle does not generate visible plastic particles as it is advanced through the sheath and dilator.

MECHANICAL NEEDLE



Mechanical Needle generates visible plastic particles as it is advanced through the sheath and dilator. Plastic particle illustrated above is to scale with a 2 mm long coil.

Study	RF Needle	Mechanical Needle
	Percentage of Tests That Found Visible Plastic Particles*	Percentage of Tests That Found Visible Plastic Particles*
Hsu et al.[2†]	0%	33%
Feld et al.[7‡]	0%	100%

* Study results are not necessarily indicative of clinical performance.
† Preprocedural ex vivo testing. Transseptal needles were placed through dilator and sheath, then removed and the dilator and sheath were flushed with heparinized saline to check for grossly visible plastic particles.
‡ In vitro study simulating transseptal catheterizations. Any particles generated from advancement of the transseptal needles through the sheath and dilator were collected and analyzed.

Hsu et al. (2013)
Hsu et al.[2] conducted a randomized controlled trial of subjects undergoing catheter ablation procedures randomized to transseptal puncture with the NRG Transseptal Needle (n = 36) or a mechanical transseptal needle (n = 36). They conducted preprocedural ex vivo testing of both needle groups that involved placing the transseptal needle through the dilator and sheath, then removing the needle and flushing the dilator and sheath with heparinized saline to check for grossly visible plastic particles. Plastic particles were grossly visible in 0 (0%) of RF needle cases and 12 (33.3%) of mechanical needle cases (P < 0.001). The authors provide an example of one of these particles which, in its coiled configuration, measures approximately 2 mm x 3 mm in size.

Feld et al. (2011)
Feld et al.[7] conducted an in vitro study simulating transseptal catheterizations performed using mechanical needles and the NRG Transseptal Needle. Any particles generated from advancement of the transseptal needles through the sheath and dilator were collected and analyzed. A light microscope was used to identify particles in the visible range (50 µm – 4 mm), and particles in the sub-visible range (10 µm – 50 µm) were counted using a light obscuration method. The results demonstrated that all simulated procedures using the mechanical transseptal needles generated visible particles, whereas the RF transseptal needle generated no visible particles. The visible particles generated by the mechanical needles measured up to 6 mm in length (uncoiled) and over 0.3 mm in width. All needles tested generated sub-visible particles, but one mechanical needle type generated a significantly greater number than all other needles tested (p < 0.01). The authors indicate that the results of this testing confirm the generation of particles, which they suggest could potentially lead to embolism.

Conclusion

The radiofrequency (RF) puncture technology offered by the NRG Transseptal Needle allows access to the left atrium in a reliable and consistent manner.

This is supported by published clinical evidence showing that transseptal puncture using Boston Scientific RF transseptal technology:

Increases Success

Improves success with challenging anatomy

Reduces failure to cross septum

Increases Efficiency

Enables shorter and more predictable procedure time

Reduces time of exposure to fluoroscopic radiation

Reduces Rate of Serious Complications

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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: • Only physicians with a thorough understanding of angiography and percutaneous interventional procedures should use this device. • Do not alter this device in any way. • The NRG Transseptal Needle is supplied STERILE using an ethylene oxide process. Do not use if the package is damaged. • 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. • For RFP-100: Do not attempt to puncture with an initial power setting of greater than 10 Watts. The initial attempt should be made with a setting of 10 Watts. In subsequent punctures, the power setting can be increased, if necessary. • The pressure transducer system used with the NRG Transseptal Needle must comply with the electrical safety requirements of IEC 60601. Failure to use compliant pressure transducers may result in patient or operator injury.

PRECAUTIONS: • Do not attempt to use the NRG Transseptal Needle or ancillary equipment before thoroughly reading the accompanying Instructions for Use. • Radiofrequency puncture procedures should be performed only by physicians thoroughly trained in the techniques of radiofrequency powered puncture in a fully equipped catheterization laboratory. • The sterile packaging should be visually inspected prior to use to detect any compromise. Ensure that the packaging has not been damaged. Do not use the equipment if the packaging has been compromised. • Visually inspect the needle prior to use. Do not use the needle if there is any damage or visibly exposed metal on the shaft where it connects to the handle. • Do not use the NRG Transseptal Needle after the "Use By" date indicated on the label. • The NRG Transseptal Needle is intended for use with only those devices listed in section VII "Equipment Required" • Read and follow the manufacturer's instructions for use of the Disposable Indifferent (Dispersive) Patch (DIP) electrode. Always use DIP electrodes that meet or exceed IEC 60601-2-2 requirements. • 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. • Take precautions to limit the effects that the electromagnetic interference (EMI) produced by the Generator may have on the performance of other equipment. Check the compatibility and safety of combinations of other physiological monitoring and electrical apparatus to be used on the patient in addition to the Generator. • Adequate filtering must be used to allow continuous monitoring of the surface electrocardiogram (ECG) during radiofrequency power applications.• 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. • Do not attempt to puncture until firm position of the active tip has been achieved against the atrial septum. • It is not recommended to exceed five (5) radiofrequency power applications per NRG Transseptal Needle. • Do not bend the NRG Transseptal Needle. Excessive bending or kinking of the needle shaft may damage the integrity of the needle and may cause patient injury. Care must be taken when handling the needle. • The Generator is capable of delivering significant electrical power. Patient or operator injury can result from improper handling of the needle and DIP electrode, particularly when operating the device. • During power delivery, the patient should not be allowed to come in contact with ground metal surfaces. • Apparent low power output or failure of the equipment to function properly at normal settings may indicate faulty application of the DIP electrode, failure to an electrical lead, or poor tissue contact at the active tip. Check for obvious equipment defects or misapplication. Attempt to better position the tip of the needle against the atrial septum. Only increase the power if low power output persists. • Baylis Medical Company relies on the physician to determine, assess and communicate to each individual patient all foreseeable risks of the Baylis Medical Radiofrequency Puncture System. • Ensure the distal tip is protruding the dilator/sheath assembly when visualizing on electroanatomic mapping systems. Visualization of the distal tip of the NRG Transseptal Needle may be lost when retracted within the dilator/sheath assembly.

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

97185932 (Rev. A.1)

TorFlex™ Transseptal Guiding Sheath

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 TorFlex™ Transseptal Guiding Sheath kit is used for the percutaneous introduction of various types of cardiovascular catheters and guidewires to all heart chambers, including the left atrium via transseptal perforation / puncture.

CONTRAINDICATIONS: There are no known contraindications for this device.

WARNINGS: Laboratory staff and patients can undergo significant x-ray exposure during interventional 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 use of echocardiography is recommended. • The TorFlex™ Transseptal Guiding Sheath kit is intended for single patient use only. Do not attempt to sterilize and reuse the TorFlex™ Transseptal Guiding Sheath kit. Reuse can cause patient injury and/or the communication of infectious disease(s) from one patient to another. • The TorFlex™ Transseptal Guiding Sheath kit is supplied STERILE using an ethylene oxide process. Do not use if the package is damaged. • The sheath's shaft is coated with a lubricious coating. The following warnings must be considered: o Use of the sheath with introducer sheaths smaller than the size listed in the section below may result in a tight fit that affects device performance, including coating integrity. o Excessive wiping and/or wiping of the sheath with a dry gauze may damage the coating. • The Mechanical Guidewire is coated with a lubricious coating. The following warnings must be considered: o Use with incompatible introducers or dilators may affect device performance and integrity, including coating integrity. o Excessive manual bending and/or shaping of the device may affect the coating integrity". • DO NOT attempt to insert or retract the guidewire through a metal cannula or a percutaneous needle, which may damage the guidewire and may cause patient injury. • Care should be taken to ensure that all air is removed from the sheath before infusing through the side port. • Care should be taken when inserting or removing the dilator and catheters from the sheath. • Do not attempt direct percutaneous insertion of the sheath without the dilator as this may cause vessel injury. • Careful manipulation must be performed to avoid cardiac damage or tamponade. Sheath advancement should be done under fluoroscopic guidance. Echocardiographic guidance is also recommended.

PRECAUTIONS: • Do not attempt to use the TorFlex™ Transseptal Guiding Sheath kit before thoroughly reading the accompanying Instructions for Use. • Careful manipulation must be performed to avoid cardiac damage, or tamponade. Sheath, dilator and guidewire advancement should be done under fluoroscopic guidance. If resistance is encountered, DO NOT use excessive force to advance or withdraw the device. • The sterile packaging and sheath should be visually inspected prior to use. Do not use the device if it has been compromised or damaged. • Only physicians thoroughly trained in the techniques of the approach to be used should perform interventional procedures. • Only physicians or personnel trained in aseptic techniques should perform aseptic presentation • Note product "Use By" date. • The TorFlex™ Transseptal Guiding Sheath is compatible with introducer sheaths 11Fr or larger. • Do not reshape distal tip or curve of the guidewire. Excessive bending or kinking of the distal curve may damage the integrity of the wire or coating and lead to patient injury. • Only use compatible tip straighteners with the guidewire. • Do not attempt to insert the proximal end of the guidewire as the distal end. • Confirm ancillary devices are compatible with the dilator and guidewire diameters before use. • Individual patient anatomy and physician technique may require procedural variations. • Do not attempt to use the guidewire with electrocautery tools. • Avoid guidewire contact with liquids other than blood, isopropyl alcohol, contrast solution or saline.

ADVERSE EVENTS: Adverse events that may occur while using the TorFlex™ Transseptal Guiding Sheath kit include: • Infection • Air embolus • Local nerve damage • Hemorrhage • Embolic events • Vessel spasm • AV fistula formation • Atrial septal defect • Pseudoaneurysm • Perforation and/or tamponade • Arrhythmias • Pericardial/pleural effusion • Hematoma • Vessel trauma • Valve damage • Catheter entrapment

97186431 (Rev. A.1)

ProTrack™ Pigtail Wire

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 ProTrack™ Pigtail Wires are intended for use in percutaneous transseptal procedures to introduce and position catheters and other interventional devices within the left heart. The device is not intended for use in the coronary arteries.

CONTRAINDICATIONS: There are no known contraindications for this device.

WARNINGS: • The pigtail wire is intended for single use only. DO NOT resterilize and/or reuse. • The pigtail wire should only be used by a physician trained in percutaneous, intravascular techniques and procedures. It is important to follow the instructions for use prior to using this product. • The guidewire should only be handled by users who are familiar with aseptic handling techniques • The pigtail wire is supplied sterile and non-pyrogenic in an unopened package and should be used under sterile conditions. DO NOT use if the package has been damaged or opened. • DO NOT use the pigtail wire after the expiration date indicated on the label. Discard pigtail wires that exceed the expiration date. • Confirm ancillary devices are compatible with the pigtail wire outer diameter before use. • Always exercise care while advancing or withdrawing the pigtail wire to prevent wire breakage, kinking, coil separation or damage. Wire damage may cause complications which may require additional interventions. • DO NOT push, auger, withdraw or torque a pigtail wire against resistance until the cause of the resistance has been determined. Applying excessive force against unexpected resistance may cause damage to the pigtail wire, interventional device and/or vessel/organ. • Utilize proper techniques to prevent air from entering the catheter system while removing and reinserting the pigtail wire. Improper techniques could result in an air embolism. • The Instructions for Use supplied with all interventional devices to be used in conjunction with Baylis Medical Pigtail wires should be consulted for intended use, contraindications, warnings, precautions and potential complications related to such devices. • When the pigtail wire is exposed to the vascular system, it should be manipulated while under high-resolution imaging guidance including fluoroscopy and/or echocardiography. Improper visualization of the guidewire may lead to misplacement, dissection, or perforation. • Inspect the pigtail wire prior to use for coil separation, kinking, appropriate distal tip flexibility or breakage. If the pigtail wire is damaged or defective, do not use it. Using a damaged or defective pigtail wire may cause vasculature damage and/or compromise pigtail wire performance. • Guidewire must always be advanced/withdrawn through a compatible catheter. • The curve of the pigtail wire is not designed to be reshaped and should be handled with care to avoid damaging the distal tip or device. • Laboratory staff and patients can undergo significant X-ray exposure during interventional procedures due to the continuous usage of fluoroscopic imaging. The 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. • DO NOT attempt to deliver electrical signals or RF energy through device • Failure to abide by the warnings in this labeling might result in damage to the device, which may necessitate intervention or result in serious adverse events.

PRECAUTIONS: • DO NOT allow the pigtail wire to remain in a prolapsed position as this may result in damage to the pigtail wire. • DO NOT straighten the spiral distal tip of the wire more than 5 times during a procedure. • Use care when removing the pigtail wire from the dispenser to reduce the possibility of pigtail wire damage.

ADVERSE EVENTS: Potential complications associated with the use of the pigtail wire include, but are not limited to: • Vessel Perforation/Dissection/Trauma or Damage • Vessel Spasm • Hemorrhage • Access Site Complications/Hematoma • Thrombus/Thromboembolism • Allergic reaction • Vascular complication • Cardiac tamponade • Cardiac Perforation/Laceration • Conduction disorder • Embolism • Additional Surgical Procedure • Pericardial/pleural effusion • Sepsis/Infection/Inflammation • Foreign Body/Wire Fracture • Hemolysis • Hypovolemia • Myocardial Ischemia and/or Infarction • Stroke/Transient Ischemic Attack • Vessel Occlusion • Wire Entrapment/Entanglement • Valve Complication

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Baylis Medical Company Radiofrequency Puncture Generator RFP-100A

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.

INTENDED USE/INDICATIONS FOR USE: The Baylis Medical Company Radiofrequency Puncture Generator & Footswitch (optional accessory) is to be used with separately approved radiofrequency devices in general surgical procedures to cut soft tissues.

CONTRAINDICATIONS: The BMC Radiofrequency Puncture Generator is not recommended for uses other than the indicated use.

WARNINGS: • DO NOT attempt to operate the Generator before thoroughly reading this User's Manual. It is vital that the operating instructions for the equipment be read, understood, and followed properly. For future reference, retain this User's Manual in a convenient, readily accessible place. • The Generator is intended for use with separately cleared BMC RF Devices, BMC connector cables, and the accessory footswitch only. For respective devices/accessories, refer to individual IFUs for more information. • To avoid risk of electric shock, Generator must only be connected to supply mains with protective earth. • Do not remove the cover of the Generator. Removal of the cover may result in injury and/or damage to the Generator. • When the Generator is activated, conducted and radiated electrical fields may interfere with other medical and electrical equipment. Care should be taken to limit the effects that electromagnetic interference (EMI) produced by the Generator has on other equipment. • Laboratory staff and patients can undergo significant x-ray exposure during RF 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. • Do not attempt to perform an RF puncture with an initial cut setting other than that recommended by the BMC RF Device Instructions for Use. The cut setting (and therefore output power) should be as low as possible (as recommended for BMC RF device) to avoid any unintended result. • Failure of the Generator could result in an unintended increase of output power. • Place monitoring electrodes as far away from the surgical site as possible, to avoid burns or interference with other equipment. The use of needle monitoring electrodes (or other small area electrodes) during RF output is not recommended. In all cases, incorporating high frequency current limiting devices are recommended. • Skin-to-skin contact (for example between the arms and body of the patient) should be avoided, for example by insertion of dry gauze. • During RF output, implanted devices such as pacemakers may be affected. Qualified advice should be obtained as necessary, to minimize the risk from injury due to implanted device malfunction. • Unless a compatible monitoring return electrode that meets or exceeds IEC 60601-2-2 is used with the contact quality monitor, loss of safe contact between the return electrode and patient will not result in an auditory alarm. • The Generator should not be operated if the display area (LCD screen) is cracked or broken. • Devices should be checked for exposed metal between shaft and handle, as well as check for any connection issues prior to use. • Devices should not be used in the presence of flammable materials, chemicals, and substances (anesthetics, oxygen, etc.). • No modification of Generator is allowed. Modification may result in patient or operator harm. • Flammable solutions may pool under the patients or in body depressions such as the umbilicus, and in body cavities such as the vagina. • Generator failure can lead to neuromuscular stimulation. • When using RF On/Off switch, the Generator can deliver RF energy without continuous depression of RF On/Off switch for the specified treatment time. Failure to specify correct treatment time could result in an unintended RF delivery.

PRECAUTIONS: • The Generator is intended for use with separately cleared BMC RF Devices, BMC connector cables and an optional accessory footswitch only. Ensure that the rated accessory voltage is equal to or greater than the Generator's maximum output voltage. • Ensure that the Generator connector cables and dispersive electrode cables are positioned in such a way that contact with the patient or other leads is avoided. • Ensure the application and connections of dispersive electrode before selecting a higher output setting on generator. • Temporarily unused Devices should be disconnected from the Generator, from the Connector Cable or they should be stored in a location that is isolated from the patient. • It is recommended not to exceed the specified number of RF energy applications per BMC RF Device, as indicated within the BMC RF Device's specific instructions for use. • Only physicians thoroughly trained in RF Puncture techniques, in a fully equipped catheterization laboratory, should perform RF Puncture procedures. • Read and follow the manufacturer's instructions for use of the return (dispersive) electrode. Only use dispersive electrodes that meet or exceed IEC 60601-2-2 requirements. The entire area of the dispersive electrode should be reliably attached to the patient's body and as close to the operating field as possible. • The Generator is capable of delivering significant electrical power. Patient or operator injury can result from improper handling of the BMC RF Device and dispersive electrode, particularly when operating the BMC RF Device. • During RF energy delivery, the patient should not be allowed to come in contact with grounded metal surfaces or metal surfaces which have an appreciable capacitance to earth (for example operating table supports, etc.). The use of antistatic sheeting is recommended for this purpose. • Apparent failure of the equipment to function properly at normal settings may indicate faulty application of the dispersive electrode or failure of an electrical lead. Do not increase power before checking for obvious defects or misapplication. • Regularly inspect and test re-usable connector cables and accessory footswitch. • Perform regular inspections of all system components, including separately cleared BMC RF Devices and BMC Connector Cables, for damage to insulations. • Associated equipment and BMC RF Devices should be selected with a rated accessory voltage equal to or greater than the maximum output voltage of the mode it is to be used for. • Baylis Medical Company relies on the physician to determine, assess, and communicate to each individual patient all foreseeable risks of the Generator. • The mains power cord of the Generator must be connected to a properly grounded receptacle to avoid the risk of electric shock. Extension cords, portable multiple socket outlets and/or adapter plugs must not be used. The mains power cord assembly should be periodically checked for damaged insulation or connectors. • Although the BMC RF Device and BMC Connector Cables are sterilized, the Generator is not. The Generator must not enter the surgical sterile field. • Fluids pooled in the body depressions and cavities should be mopped up before RF energy is delivered. • There is a danger of ignition of endogenous gases (e.g., cotton and gauze saturated with oxygen may be ignited by sparks produced) during normal use of Generator. • The use of a smoke-plume extractor is recommended for the operator during RF procedures.

ADVERSE EVENTS: Adverse events that may occur while using the Generator include: • Atrial Fibrillation and/or Atrial Flutter • Myocardial Infarction • Sustained Arrhythmias leading to Ventricular Tachycardia • Neuromuscular stimulation • Electric shock • Thermal damage to tissue • Thromboembolic Episodes • Sepsis and Infection • Unintended Perforation

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EP-1725606-AA

CAUTION: The law restricts this device 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.IFU-BSCI.com.

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