

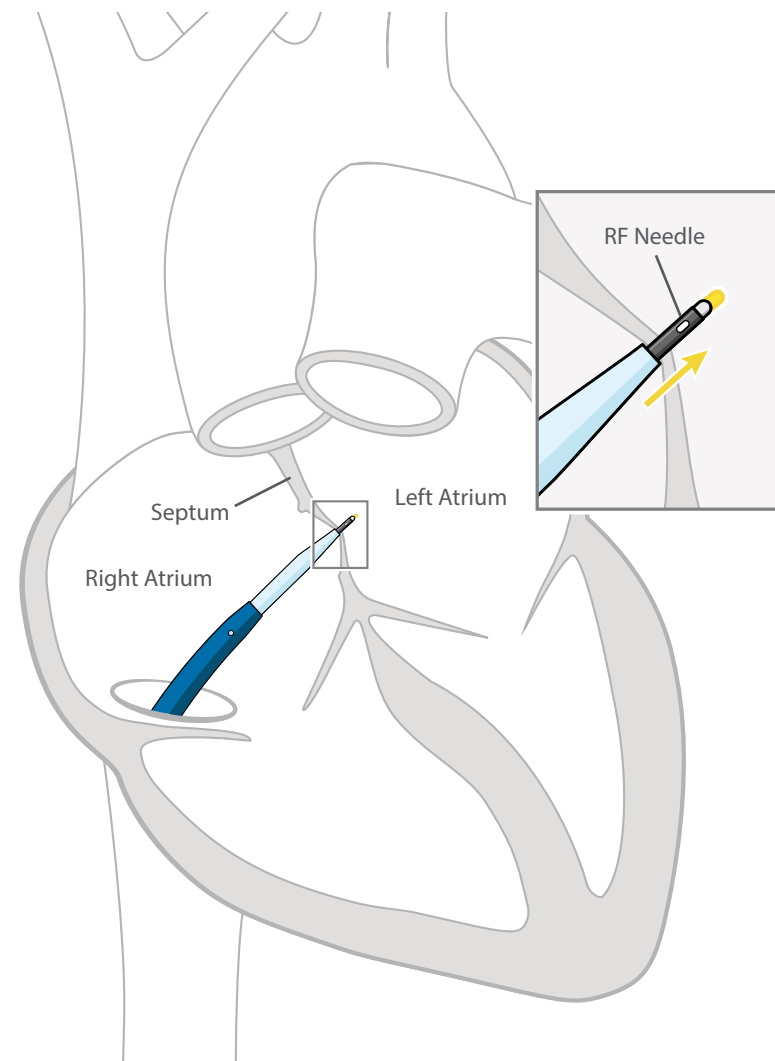
Economic Analysis of **RF Transseptal Puncture**

NRG™ Transseptal Needle
Europe

Save €271 per case

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

* Refer to page 8 for analysis.



Executive Summary

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 cardiac tamponade, requiring medical intervention and prolonging hospital stay. Transseptal puncture can also be time consuming and unpredictable.

To overcome these shortcomings, Baylis Medical developed RF needle transseptal puncture technology.

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.

By using the NRG™ Transseptal Needle with RF transseptal puncture technology, the physician benefits from:

- Reduced rate of serious complications (pericardial tamponade)
- Reduced rate of procedure termination

These clinical benefits translate into a cost savings of €271 per case by allowing the avoidance of missed payments and unnecessary costs.

The NRG™ Transseptal Needle can increase the quality of care provided to patients undergoing common percutaneous cardiac procedures such as catheter ablation for atrial fibrillation, and additionally provide excellent value to the hospital.

Detailed Analysis

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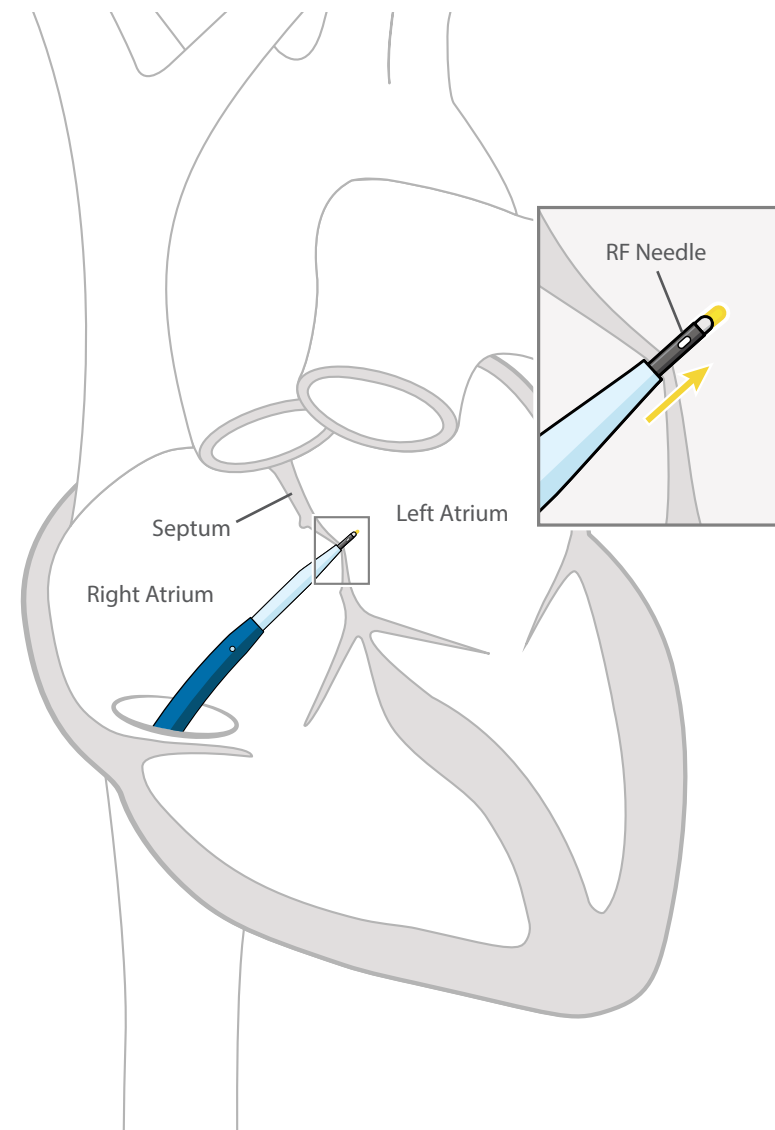
Background

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 cardiac tamponade, requiring medical intervention and prolonging hospital stay. Transseptal puncture can also be time consuming and unpredictable.

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Reduced rates of pericardial tamponade and procedure termination with Baylis Medical technology.

Two comparative studies have examined the use of Baylis Medical RF transseptal puncture needle technology, as compared to mechanical transseptal needles, in groups of ≥ 100 patients per needle type.

Data from these studies showed reductions in the rates of pericardial tamponade and procedure termination with use of the RF needle.

These results are summarized in the following table:

	Winkle et al.	Jauvert et al.
Study Details	<p>In this American study, Winkle et al. 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.</p> <p>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.</p>	<p>In this French study, Jauvert et al. 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.</p>

* RF transseptal punctures were performed using a flexible RF needle: the Toronto RF Septostomy Catheter (later renamed the Toronto Transseptal Catheter) was the predecessor to the NRG™ Transseptal Needle.

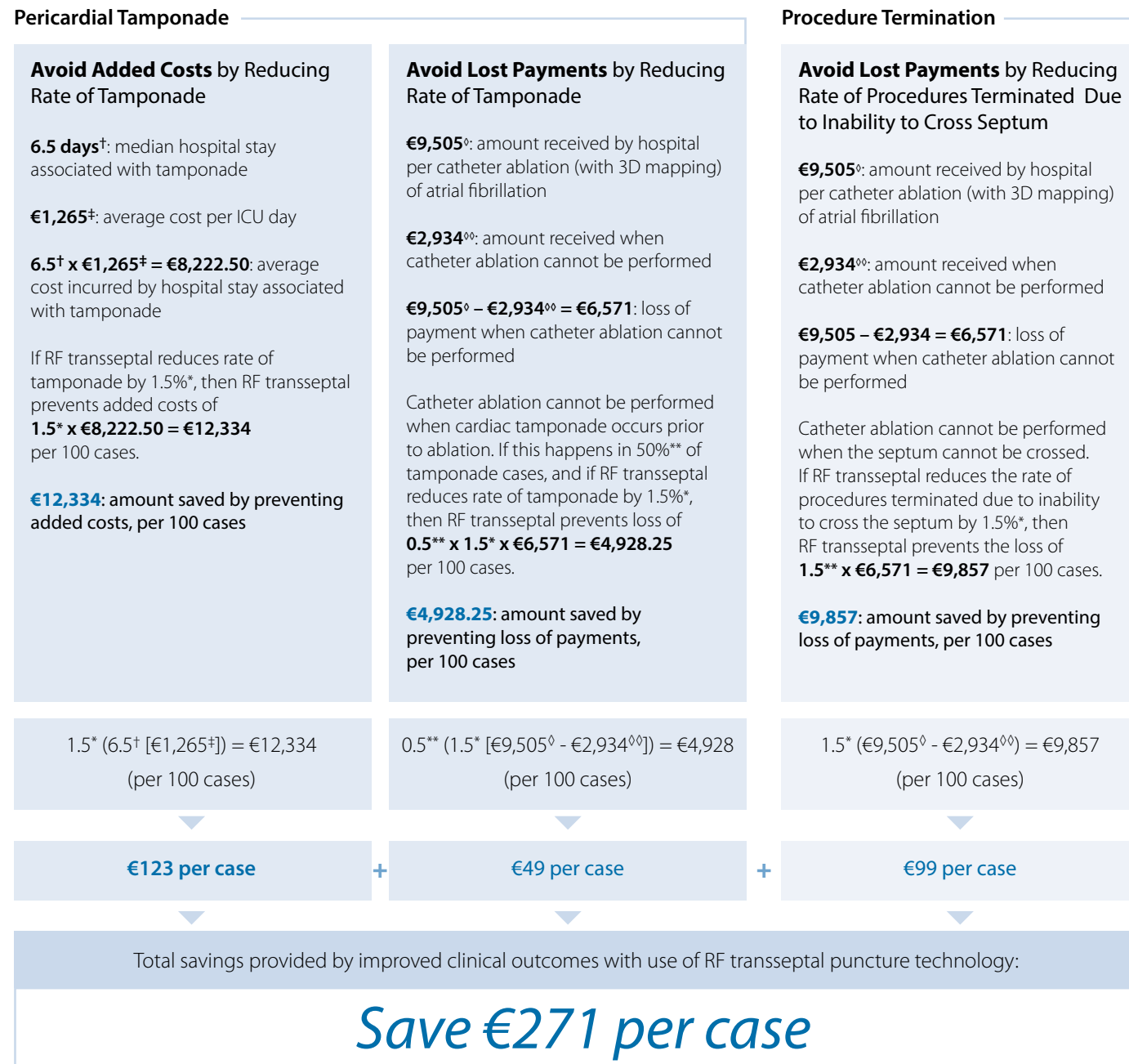
	Winkle et al.	Jauvert et al.
Study Outcome: Pericardial Tamponade	<p>The results demonstrated fewer pericardial tamponades with the RF needle (0 of 575; [0.00%]) as compared to the mechanical needle (9 of 975; [0.92%]) (p=0.031).</p> <p>Of the 9 instances of pericardial tamponade in the mechanical needle 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.</p> <p>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).</p>	<p>The results demonstrated fewer pericardial tamponades with the RF flexible needle (0 of 125; [0.00%]) as compared to the mechanical needle (2 of 100; [2.00%]). (The 2 tamponades in the mechanical needle group developed from a total of 3 pericardial effusions [p=0.04]).</p> <p>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.</p>
Study Outcome: Procedure Termination	<p>The results demonstrated that the rate of failure to cross the atrial septum leading to procedure termination was lower for the RF needle (1 of 575; [0.17%]) as compared to the mechanical needle (12 of 975; [1.23%]) (p=0.039).</p> <p>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).</p> <p>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.</p> <p>The authors indicate that RF energy may facilitate septal crossing in thicker portions of the septum or in areas scarred from previous transseptal procedures.</p>	<p>The results demonstrated that the rate of failure to cross the atrial septum was lower for the flexible RF needle (0 of 125; [0.00%]) as compared to the mechanical needle (5 of 100; [5.00%]) (p=0.01); of these failures in the mechanical needle group, 2 procedures (2 of 100; [2.00%]) were aborted.</p> <p>Procedures terminated in the mechanical needle group were 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.</p>

Economic Analysis

As summarized in the preceding Clinical Outcomes section of this document, literature shows that Baylis Medical RF transseptal puncture technology can:

- Prevent approximately 1-2 tamponades per 100 cases
- Prevent approximately 1-2 procedure terminations due to inability to cross septum per 100 cases

The figure below shows how these clinical benefits provide cost savings, making the technology cost-effective to the hospital.¹



Sites with higher tamponade rates and procedure termination rates would save even more per case.

¹ Payment information published by InEK GmbH (Institut für das Entgeltsystem im Krankenhaus) at www.G-DRG.de as of 25-Nov-2016.

[†] Assumes that all 6.5 days are spent in ICU. Data from Mujović et al. 2016.

[‡] Martin et al. 2008.

* Assumes 1.5 of each, tamponade and procedure termination, prevented per 100 cases.

[◇] G-DRG F50A. For ICD-10: I48.0; OPS Codes 8-835.83, 8-831.0 and 1-274.3.

^{◇◇} G-DRG F49F. For ICD-10: I48.0; OPS Codes 8-831.0, 1-274.3 and 5-995.

** Assumes that 1/2 of cases with tamponade will not receive catheter ablation.

Conclusion

By using the NRG™ Transseptal Needle with RF transseptal puncture technology, the physician benefits from:

- Reduced rate of serious complications (pericardial tamponade)
- Reduced rate of procedure termination

As shown in the Economic Analysis in this document, these clinical benefits translate into a cost savings of €271 per case by allowing the avoidance of missed payments and unnecessary costs.

Therefore, the NRG™ Transseptal Needle can increase the quality of care provided to patients undergoing common percutaneous cardiac procedures such as catheter ablation for atrial fibrillation, and additionally provide excellent value to the hospital.

References

Jauvert G, Grimard C, Lazarus A, Alonso C. Comparison of a radiofrequency powered flexible needle with a classic rigid Brockenbrough needle for transseptal punctures in terms of safety and efficacy. *Heart Lung Circ.* 2015 Feb;24(2):173-8.

Martin J, Neurohr C, Bauer M, Weiss M, Schleppers A. Cost of intensive care in a German hospital: cost-unit accounting based on the InEK matrix. *Anaesthesist.* 2008 May;57(5):505-12.

Mujović N, Marinković M3, Marković N, Kocijančić A, Kovačević V, Simić D, Ristić A, Stanković G, Miličić B, Putnik S, Vujisić-Tešić B, Potpara TS. Management and Outcome of Periprocedural Cardiac Perforation and Tamponade with Radiofrequency Catheter Ablation of Cardiac Arrhythmias: A Single Medium-Volume Center Experience. *Adv Ther.* 2016 Oct;33(10):1782-96. Epub 2016 Aug 23.

Winkle RA, Mead RH, Engel G, Patrawala RA. The use of a radiofrequency needle improves the safety and efficacy of transseptal puncture for atrial fibrillation ablation. *Heart Rhythm.* 2011 Sep;8(9):1411-5.



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