

Company

Boston Scientific | Baylis Medial

Drug or Device Name

VersaCross Transseptal Platform

Category

Medical Technology

Compound/Technical Name

Cardiovascular device

Trade Name

VersaCross

Date of Approval

04/17/2019

Therapeutic Categories

Structural Heart Intervention

Indications

"Creation of an atrial septal defect in the heart" is the formal regulatory Canada indication for Versa Cross, but in practice the VersaCross system is used to facilitate access to the left atrium, via the inter-atrial septum, of various catheter-based devices for interventions procedures performed in the left atrium, including electrical ablation, left atrial appendage occlusion, percutaneous left ventricular assist, and mitral valve repair or replacement. In concise terms the Versa cross system is used for non-surgical "trans-septal access". The term "trans-septal puncture" has been used historically but in modern practice, access to the left atrium involves more than simply a puncture of the septum - it also requires dilation of the newly-created septal defect, placement of a support wire, and positioning of a sheath or guiding catheter. Each of the various left atrial procedures has a unique requirement for puncture location on the atrial septum. Furthermore, some of these procedures, particularly those involving the mitral valve, use very large devices (up to 40 Fr or 14 mm). These factors demand a high level of precision and safety in creating the septal puncture and facilitating access of the relevant interventional device. In a more operational and less anatomic sense, the role of the VersaCross system could be described as facilitating the safe and effective performance of several high-impact cardiac procedures needing non-surgical access to the left atrium.

Background

Trans-septal puncture (TSP) for catheter-based access to the left atrium was developed in the late 1950's but was little used until the development of ablation to treat atrial fibrillation. Over the past 15 years, other catheter-based procedures requiring access to the left atrium (LA) are now widely performed (eg MitraClip), all requiring TSP as the initiating step. Precise positioning of the puncture

site is vital and is procedure-specific. The traditional method involves a long needle introduced via the femoral vein inside a sheath-dilator assembly. Guided by fluoroscopy and ultrasound, the tapered dilator is positioned against the right side of the atrial septum; the needle tip is then advanced to puncture the septum, the whole system then advanced slightly across the septum, with the dilator-needle acting as a stiff "rail" over which the less rigid sheath slides forward to a stable position in the LA. Shortcomings of the traditional method include both safety and efficiency. Good training and imaging mitigate but do not eliminate the risk of serious complications; this is particularly germane as LA procedures become more widespread. A thick, fibrotic, or redundant (floppy) septum – each relatively common – poses particular challenges. Workflow using traditional equipment is far from ideal even absent the anatomic challenges. If an acceptable position on the septum is not achieved with the sheath-dilator-needle, a repeat attempt requires at least five additional steps to remove the needle, reinsert the guide wire, re-advance the system, remove the wire and reinsert the needle. Even though each step adds a small incremental risk and takes time, the real drawback on workflow from the traditional method is the lack of integration of the TSP with the primary left atrial procedure; even after successful TSP has been achieved, none of the equipment for the primary procedure is yet in place.

Development

The VersaCross system draws on technology developed by Baylis and on insightful observation and analysis of the workflow of contemporary trans-septal puncture (TSP). VersaCross consists of a sheath, a dilator, and a highly sophisticated wire that serves multiple functions detailed below. While there are multiple engineering triumphs, the VersaCross wire represents the greatest technological advance. The compelling innovative achievement is the deep understanding Baylis acquired of existing workflow, the imagination to envision a better alternative, and the technical know-how to create and perfect the components needed for that alternative. An earlier Baylis innovation consisted of a trans-septal needle that used a rounded rather than sharp tip within an otherwise conventional sheath-dilator assembly. The puncture was created by a short burst of RF energy delivered at the tip of the blunt needle positioned against the septum. The VersaCross system does away with the rigid needle altogether and replaces it with an ingenious multi-functional stiff support wire with a floppy atraumatic distal segment and an RF electrode at the tip. This completely transforms the workflow and is thus far more than an incremental enhancement to any prior technology for TSP. The floppy segment is used to guide the system up the vena cava and to reposition when necessary without a wire exchange. The wire tip, constrained in shape by the dilator, delivers RF energy to create the puncture then assumes its curved atraumatic shape as it exits the dilator into the LA, where it can be safely advanced for anchoring. The stiff segment provides support to advance not only the sheath-dilator to the LA, but also the large procedural catheter that will follow (for example the 28 Fr MitraClip Steerable Guide). This achieves the goals outlined in the Background section of safety, efficiency, and integration of TSP with the primary procedure.

Innovation

I feel compelled to nominate VersaCross because it has a significant impact and typifies the very best in innovation. Impact because several left atrial procedures that have been shown to benefit patients are increasingly used and require trans-septal access as a starting point. Complications, frustrations, and delays induced by ancillary equipment can have an insidious undermining effect on otherwise successful therapies. The consistently safe, precise, and efficient access to the left atrium provided by VersaCross is a critical enabler of the benefits provided by the primary procedures. Innovative because it starts not with a vague or incremental goal to “improve” trans-septal puncture, but rather with a

crystal clear understanding of an unmet need - more clear perhaps than the cardiologist operators (myself included) may have been able to understand or articulate. It then makes that leap of insight and imagination that separates true innovation from routine progress, envisioning an elegant solution based on a multi-function wire that upends the 60-year reliance on a rigid needle to make the puncture. Finally, it delivers on the theoretic solution with a high-quality cost-effective product that performs as promised. Commercial success on its own does not equate to true innovation of true benefit, but in the case of VersaCross I believe the market success – achieved quickly by a relatively small company based in Canada – attests to the genuine benefits of the product rather than to a marketing campaign. I am a practising structural interventionist and have been involved in the evaluation and dissemination of many cardiovascular devices over the past three decades. I also served as chair of the selection committee for a national innovation award spanning all sectors, not just medicine. Rarely if ever have I seen a medical device like VersaCross that provides such an elegant and impactful solution to a focused but highly relevant problem.

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1. J Interv Card Electrophysiol. 2021 Jan 22. doi: 10.1007/s10840-020-00931-7. Online ahead of print. VersaCross radiofrequency system reduces time to left atrial access versus conventional mechanical needle. Inohara T(1), Gilhofer T(1), Luong C(1), Tsang M(1), Saw J(2). DOI: 10.1007/s10840-020-00931-7 PMID: 33479854 2. Catheter Cardiovasc Interv. 2021 May 1;97(6):1230-1234. doi: 10.1002/ccd.29365. Epub 2020 Nov 11. Initial clinical experience with VersaCross transseptal system for transcatheter mitral valve repair. Sayah N(1), Simon F(1), Garceau P(1), Ducharme A(1), Basmadjian A(1), Bouchard D(2), Pellerin M(2), Bonan R(1), Asgar AW(1). DOI: 10.1002/ccd.29365 PMID: 33175452

Attachments