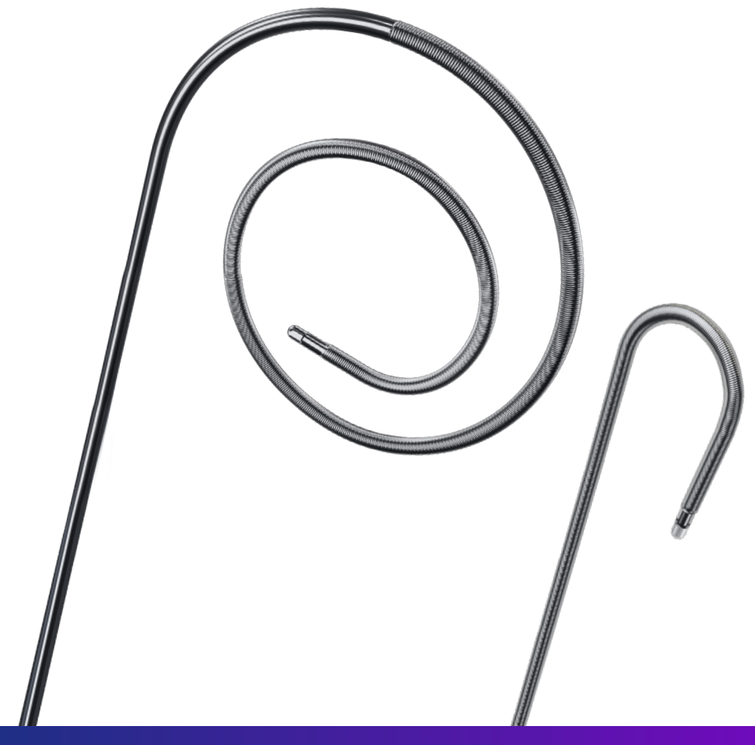

Boston Scientific
Advancing science for life™
VersaCross™
Transseptal Platform
For the Hospital Purchasing Committee
Boston Scientific

Contents



Product Overview

What is transseptal access?

Transseptal puncture is necessary to gain access to the left atrium and left ventricle for therapeutic procedures such as radiofrequency ablation, cryoablation, left atrial appendage closure, and mitral valvuloplasty.

Traditional left atrial catheterization using the transseptal approach requires numerous device exchange steps and has associated risks and safety concerns.

What makes this product unique?

The **VersaCross**™ RF Transseptal Solution enables vascular cannulation, transseptal puncture, and therapy device delivery with a 3-in-1 radiofrequency (RF) wire that uses purpose-built RF puncture technology to cross the fossa ovalis. Purpose-built RF puncture technology optimizes the energy required to puncture the septum by using a built-in electrode on the tip of the RF wire. The electrode delivers low energy from the dedicated Baylis Medical Company* Radiofrequency Puncture Generator RFP-100A, resulting in consistent and reliable puncture of the septum. This unique system uses high-frequency RF currents (>500 kHz) of short duration and high voltage to minimize tissue damage while creating a small tissue opening in the fossa ovalis.

In addition, **TruForm**™ Shapeable Technology was developed to support the **VersaCross**™ RF Wire. This feature allows shaping of the dilator to match the patient's anatomy, resulting in a precise, optimized transseptal puncture location.

* Baylis Medical Company is a wholly owned subsidiary of Boston Scientific Corporation.

Technology Overview

The VersaCross RF Wire can be used, without exchanges, as a guidewire, transseptal puncture device, and as an exchange rail for delivering therapy sheaths. This 3-in-1 solution reduces the steps required for transseptal puncture, rewiring (if needed), and therapy sheath delivery into the left atrium (Figure 1).

The **VersaCross Connect™** Transseptal Platform further reduces procedure steps by using a customized **VersaCross Connect™** Transseptal Dilator designed to fit inside a dedicated therapy sheath. Because the therapy sheath can be used directly in the transseptal procedure, this solution requires zero exchanges for delivery of the sheath into the left atrium (Figure 1).

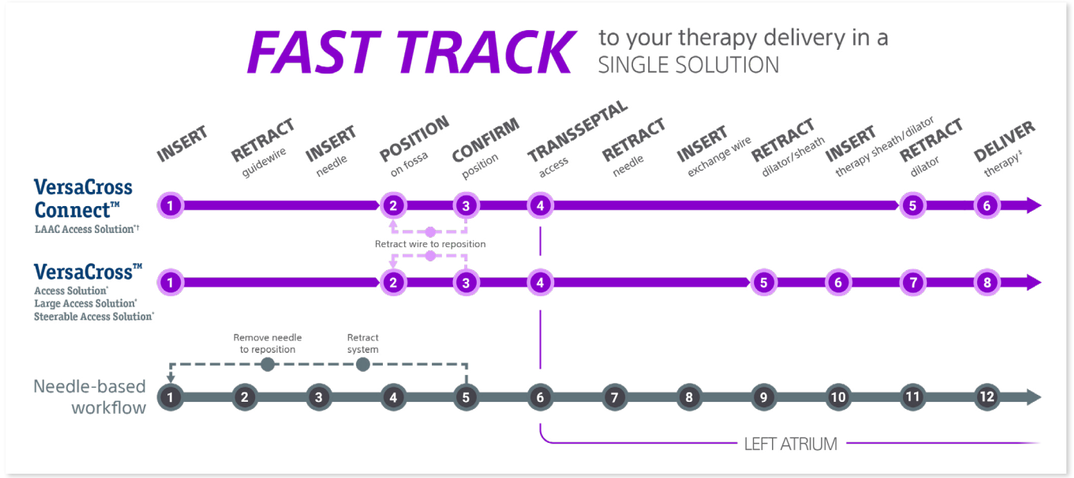
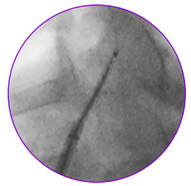


Figure 1. The VersaCross Transseptal Platform reduces the exchanges required for transseptal puncture.

OMNIviz™ Technology

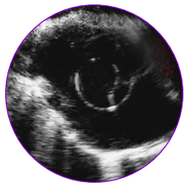
OMNIviz Technology comprises four unique features that allow the physician to know where they are at all times (Figure 2):

1. The entire solution can be visualized using fluoroscopy.
2. The echogenic wire allows visualization on ultrasound.
3. Proximal markers on the wire allow physicians to determine the approximate location of the wire in relation to the dilator.
4. When used with the **DuoMode™** Cable, the RF tip can be tracked on mapping systems.



Radiopaque

Visualize your entire solution on fluoroscopy

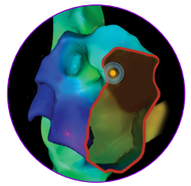


Echogenic

Reliably locate your VersaCross Transseptal Platform on ultrasound to facilitate fluoro reduction

Positional Marker

Visibly confirm position of RF tip within dilator



Mapping

Track and mark RF tip position on your mapping system

Figure 2. Know where you are at all times with OMNIviz Technology.

TRUform™ Shapeable Technology

TRUform Shapeable Technology is built into the dilator of all products within the VersaCross Transseptal Platform (Figure 3). This technology allows the dilator to be shaped with true-to-form curve retention so that a precise location for transseptal puncture can be achieved regardless of patient anatomy.

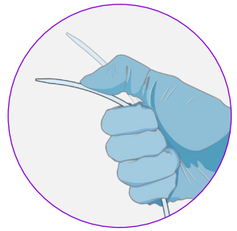


Figure 3. All VersaCross dilators have built-in TRUform Shapeable Technology.

* VersaCross Connect™ LAAC Access Solution includes VersaCross Connect™ Transseptal Dilator and VersaCross™ RF Wire. VersaCross™ Steerable Access Solution includes VersaCross™ Steerable Sheath, VersaCross™ Transseptal Dilator, and VersaCross™ RF Wire. VersaCross™ Large Access Solution includes VersaCross™ Large Access Transseptal Dilator and VersaCross™ RF Wire. VersaCross™ RF Transseptal Solution includes VersaCross™ Transseptal Sheath, VersaCross™ Transseptal Dilator and VersaCross™ RF Wire.

† The VersaCross Connect™ Transseptal Dilator is for use with a 12F (4.2 mm) ID WATCHMAN™ Access Sheath that is 75 cm in length or the WATCHMAN TruSteer Access Sheath that is 67 cm in length, specifically: WATCHMAN™ Access System [Models: M635TU40060, M635TU10060, M635TU20060]; WATCHMAN™ TruSeal™ Access System [Models: M635TU70010, M635TU70040, M635TU70020]; WATCHMAN FXD Curve™ Access System [Models: M635TU80010, M635TU80020]; WATCHMAN TruSteer™ Access System [Model: M635TU90050].

‡ The therapy referred to here may be one of several left heart procedures that require transseptal access. Additional procedural steps and/or devices may be required to deliver the therapy. Before use, consult Instructions for Use for any devices accordingly.

Technology Specifications

All **VersaCross Transseptal Platform** kits contain the VersaCross RF Wire, available in a pigtail or J-tip configuration, dilator and/or sheath, and compatible disposable generator connector cable. The specific dilator/sheath included depends on the ordered kit configuration (Fixed, Steerable, Large Access, or Connect systems). All kits and products in the VersaCross family utilize proprietary technology that is consistent across the platform. Please see "Ordering Information" for specific product configurations. All kits are compatible with the RFP-100A Generator, available separately.

VersaCross™ RF Wire

Feature	Specifications
Tip configurations	J-tip, Pigtail
Curve shape	9 mm (J-tip), 24 mm (Pigtail)
Wire diameter	0.035"
Overall length	180 cm, 230 cm

VersaCross™ Transseptal Sheath

Feature	Specifications
French size	8.5F (2.83 mm)
Sheath usable length	63 cm, 81 cm
Sheath curves	45°, 55°, 90°
Dilator usable length	67 cm, 85 cm
Dilator curves	D0 (Standard curve), D1 (Large curve)
Guidewire max. outer diameter	0.035"

VersaCross™ Steerable Sheath

Feature	Specifications
French size	8.5F (2.83 mm)
Sheath usable length	72 cm
Sheath curves	Small (17 mm), Medium (22 mm), Large (50 mm)
Bidirectional curve angles	90° CCW, 180° CW
Dilator usable length	95 cm
Dilator curves	D0 (Standard curve), D1 (Large curve)
Guidewire max. outer diameter	0.035"

VersaCross™ Large Access Transseptal Dilator

Feature	Specifications
Outer diameter	12.5F (4.17 mm)
Inner diameter	0.035"
Useable length	67 cm
Curve	D0, D1
Guidewire max. outer diameter	0.035"

VersaCross Connect™ Transseptal Dilator* – WATCHMAN™ Access Systems

Feature	Specifications
Outer diameter	12F (4.2 mm)
Inner diameter	0.035"
Useable length	85 cm
Curve	D0, D1
Guidewire max. outer diameter	0.035"

VersaCross Connect™ Transseptal Dilator† – POLARSHEATH™ Steerable Sheath

Feature	Specifications
Outer diameter	12F (4.1 mm)
Inner diameter	0.035"
Useable length	84 cm
Curve	D1
Guidewire max. outer diameter	0.035"

VersaCross Connect™ Transseptal Dilator‡ – FARADRIVE™ Steerable Sheath

Feature	Specifications
Outer diameter	13F (4.4 mm)
Inner diameter	0.035"
Useable length	93 cm
Curve	D1
Guidewire max. outer diameter	0.035"

* The VersaCross Connect™ Transseptal Dilator is for use with a 12F (4.2 mm) ID WATCHMAN™ Access Sheath that is 75 cm in length or the WATCHMAN TruSteer Access Sheath that is 67 cm in length, specifically: WATCHMAN™ Access System [Models: M635TU40060, M635TU10060, M635TU20060]; WATCHMAN™ TruSeal™ Access System [Models: M635TU70010, M635TU70040, M635TU70020]; WATCHMAN FXD Curve™ Access System [Models: M635TU80010, M635TU80020]; WATCHMAN TruSteer™ Access System [Model: M635TU90050].

† The VersaCross Connect™ Transseptal Dilator is for use with a 12F (4.1 mm) ID POLARSHEATH™ Steerable Sheath that is 68 cm in length, specifically, Model M004CRBS3150 (USA).

‡ The VersaCross Connect Transseptal Dilator is for use with a 13F (4.4 mm) ID FARADRIVE™ Steerable Sheath which is 74cm in length, specifically, model: M004PF21M402 (USA).

Technology Specifications

RFP-100A RF Puncture Generator*

Feature	Specifications
Adjustable RF delivery modes	Pulse and Constant
Adjustable RF time	1 – 10 s on Pulse 0.4, 0.6, 0.8, or 1 – 3 s on Constant
Impedance range	100 – 6000 ohms
Power	Average: 5 – 15 W Max: 50 W
Operating frequency	Monopolar RF at ~468 kHz
Input voltage (wall socket input)	100 – 240 V
RF delivery voltage	270 V
Weight	20 lbs
Power cord length	10 ft

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

Regulatory Information

FDA Letter – VersaCross RF Wire

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 17, 2015

Baylis Medical Company Inc.
Ms. Meghal Khakhar
Director, Regulatory & Scientific Affairs
2645 Matheson Blvd. East
Mississauga, ON Canada L4W 5S4

Re: K150709
Trade/Device Name: Protrack Rf Anchor Wire
Regulation Number: 21 CFR 870.5175
Regulation Name: Septostomy Catheter
Regulatory Class: Class II
Product Code: DXF
Dated: March 18, 2015
Received: March 19, 2015

Dear Ms. Khakhar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices

Office of Device Evaluation
Center for Devices and Radiological Health

Regulatory Information

FDA Letter – VersaCross Transseptal Sheath

U.S. FOOD & DRUG ADMINISTRATION

May 20, 2019

Baylis Medical Company Inc.
Meghal Khakhar
VP, Regulatory and Scientific
2645 Matheson Blvd. East
Mississauga, L4W 4J1 Canada

Re: K183655
Trade/Device Name: VersaCross Transseptal Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: April 24, 2019
Received: April 25, 2019

Dear Ms. Khakhar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to:

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Silver Spring,
MD 20993
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registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 10001050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Rachel E. Neubrander -S

for Nicole Ibrahim
Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Regulatory Information

FDA Letter – VersaCross Steerable Sheath

U.S. FOOD & DRUG ADMINISTRATION

April 17, 2019

Baylis Medical Company Inc.
May Tsai
Regulatory Affairs Manager
2580 Matheson Blvd. E
Mississauga, Ontario L4W 4J1
Canada

Re: K190688
Trade/Device Name: VersaCross Steerable Sheath, VersaCross Transseptal Dilator
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: March 15, 2019
Received: March 18, 2019

Dear May Tsai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 10001050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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(http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jaime Raben

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Regulatory Information

FDA Letter – VersaCross Large Access Transseptal Dilator

U.S. FOOD & DRUG ADMINISTRATION

June 12, 2020

Baylis Medical Company Inc.
May Tsai
Regulatory Affairs Manager
2580 Matheson Blvd. East
Mississauga, Ontario L4W 4J1
Canada

Re: K201288
Trade/Device Name: ExpanSure Large Access Transseptal Dilator
Regulation Number: 21 CFR 870.1310
Regulation Name: Vessel Dilator For Percutaneous Catheterization
Regulatory Class: Class II
Product Code: DRE
Dated: May 13, 2020
Received: May 14, 2020

Dear May Tsai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

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statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Rachel E. Neubrander -S

Rachel Neubrander
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Regulatory Information

FDA Letter – VersaCross Connect Transseptal Dilator

U.S. FOOD & DRUG ADMINISTRATION

May 9, 2022

Baylis Medical Company Inc.
May Tsai
Director of Regulatory Affairs
5825 Explorer Dr.
Mississauga, Ontario L4W 5P6
Canada

Re: K220414
Trade/Device Name: VersaCross Connect™ Transseptal Dilator
Regulation Number: 21 CFR 870.1310
Regulation Name: Vessel Dilator For Percutaneous Catheterization
Regulatory Class: Class II
Product Code: DRE
Dated: April 11, 2022
Received: April 13, 2022

Dear May Tsai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

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statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Rachel E. Neubrander -S

Rachel Neubrander
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Regulatory Information

FDA Letter – VersaCross Connect Transseptal Dilator for FARADRIVE

U.S. FOOD & DRUG ADMINISTRATION

December 14, 2023

Baylis Medical Company, Inc.
Christina Dowd
Senior Regulatory Affairs Specialist
5825 Explorer Drive
Mississauga, ON L4W5P6
Canada

Re: K233647
Trade/Device Name: VersaCross Connect™ Transseptal Dilator
Regulation Number: 21 CFR 870.1310
Regulation Name: Vessel dilator for percutaneous catheterization
Regulatory Class: Class II
Product Code: DRE
Dated: November 13, 2023
Received: November 14, 2023

Dear Christina Dowd:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register. Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

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Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Rachel Neubrander
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Reimbursement Information

Coverage

VersaCross Transseptal Platform products are used in several catheter-based cardiology procedures that routinely require access to the left atrium and left ventricle. These procedures include cardiac catheter ablations, left atrial appendage closure, and transcatheter mitral valve repair. These are commonly performed procedures in cardiac electrophysiology and catheterization labs, and are covered in accordance with various commercial payer and CMS (Centers for Medicare and Medicaid Services) policies given that the necessary coverage criteria are met. Payer policies will vary and should be verified prior to treatment for limitations on diagnosis, coding, or site of service requirements.

Coding and Payment

Use of VersaCross Transseptal Platform products does not determine which CPT (Current Procedural Terminology) or ICD (International Classification of Diseases) codes would be applicable. Instead, these codes would be determined based on the services rendered by the site, which often include the transseptal access component. Please see Table 1 (next page) for examples of coding and payment information of index procedures in which VersaCross Transseptal Platform products are used. The coding options listed are commonly used codes and are not intended to be an all-inclusive list. We recommend consulting your relevant manuals for appropriate coding options.

		Physician[1]			ASC[2]	Hospital Outpatient[2]		Hospital Inpatient[3]	
HCPCS/ CPT®[4] Code	HCPCS/CPT Descriptions	Facility Rate	Office Rate	Work RVU Total RVU[5]	ASC Payment[2]	APC Category and Payment[2]	Possible ICD-10-PCS Codes[6]	Possible MS-DRG Assignment	MS-DRG Payment[3]
Intracardiac Electrophysiology Study/Ablation – Atrial Fibrillation									
93656	Comprehensive electrophysiologic evaluation with transseptal catheterizations, insertion and repositioning of multiple electrode catheters, induction or attempted induction of an arrhythmia including left or right atrial pacing/ recording, and intracardiac catheter ablation of atrial fibrillation by pulmonary vein isolation, including intracardiac electrophysiologic 3-dimensional mapping, intracardiac echocardiography with imaging supervision and interpretation, right ventricular pacing/ recording, and His bundle recording, when performed	$897	N/A	17.00 27.72	N/A	APC 5213 $24,532	02583ZZ, 02583ZF	Percutaneous Intracardiac Procedure MS-DRG 273 w/MCC MS-DRG 274 w/o MCC	 $27,906 $22,273
WATCHMAN™ Left Atrial Appendage Closure (LAAC) Procedure									
33340	Percutaneous transcatheter closure of the left atrial appendage with endocardial implant, including fluoroscopy, transseptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, when performed, and radiological supervision and interpretation	$740	N/A	14.00 22.87	N/A	Status C, not paid under OPPS	02L73DK	Percutaneous Intracardiac Procedure MS-DRG 273 w/ MCC MS-DRG 274 w/o MCC	 $27,906 $22,273
Transcatheter Mitral Valve Repair									
33418	Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; initial prosthesis	$1,712	N/A	32.25 52.93	N/A	Status C, not paid under OPPS	02UG3JZ	Endovascular Cardiac Valve Replacement and Supplement Procedures MS-DRG 266 w/ MCC MS-DRG 267 w/o MCC	 $42,754 $33,575

Table 1. Common procedures requiring transseptal left heart access – CY2025/FY2025 Procedural Payment Guide.
Payer policies will vary and should be verified prior to treatment for limitations on diagnosis, coding, or site-of-service requirements. The coding options listed within this guide are commonly-used codes and are not intended to be an all-inclusive list. We recommend consulting your relevant manuals for appropriate coding options.

1. Source: CMS CY2025 Physician Fee Schedule (PFS) Final Rule: CMS-1807-F, including related PFS addenda. Conversion Factor used in calculations = $32.3465. Effective through December 31, 2025.
2. Source: CMS CY2025 Hospital Outpatient Prospective Payment- Notice of Final Rulemaking (NFRM): CMS-1809-FC. Effective through December 31, 2025.
3. Source: CMS FY 2025 IPPS Final Rule: CMS-1808-IFC, including data files. National average (wage index greater than one) MS-DRG rates calculated using the national adjusted full update standardized labor, non-labor and capital amounts. Actual reimbursement will vary for each provider and institution for a variety of reasons including geographic differences in labor and non-labor costs, hospital teaching status, and/or proportion of low-income patients). Effective through September 30, 2025.
4. Current Procedural Terminology (CPT) © 2024 American Medical Association. All Rights Reserved. CPT is a registered trademark of the American Medical Association.
5. Total RVU is the relative value unit total for Facility calculation.
6. Source: CMS ICD-10-CM/PCS MS-DRG v42 Definitions Manual. FY2025 (10/1/2024-09/30/2025). Not intended as an all-inclusive list of MS-DRGs.

Reimbursement Information

C-Codes/HCPCS Codes

The VersaCross Transseptal Platform kits contain a radiofrequency guidewire, connector cable, and one of the following: VersaCross Transseptal Sheath and Dilator (fixed curve); VersaCross Steerable Sheath and Dilator; VersaCross Large Access Dilator; or VersaCross Connect Transseptal Dilator.

- There are no HCPCS (Healthcare Common Procedure Coding System) codes that specifically describe radiofrequency guidewires, connector cables, VersaCross Large Access Transseptal Dilator, or VersaCross Connect Transseptal Dilator.
- C1893 describes introducer/sheath, guiding, intracardiac electrophysiological, fixed-curve, other than peel-away.
- C1766 describes introducer/sheath, guiding, intracardiac electrophysiological, steerable, other than peel-away.
- C1889 describes implantable/insertable device, not otherwise classified.

For questions regarding reimbursement for VersaCross Transseptal Platform products, please contact:
(Email) afs.reimbursement@bsci.com

Please go to https://www.bostonscientific.com/en-US/reimbursement/rhythm-management.html for additional resources.

Important

Note: The Medicare reimbursement amounts shown are currently published national base rate payment amounts. Actual reimbursement will vary for each provider and institution for a variety of reasons including geographic differences in labor and non-labor costs, hospital teaching status, proportion of low-income patients, coverage, and/or payment rules.

Health economic and reimbursement information provided by Boston Scientific Corporation is gathered from third-party sources and is subject to change without notice as a result of complex and frequently changing laws, regulations, rules, and policies. This information is presented for illustrative purposes only and does not constitute reimbursement or legal advice. Boston Scientific encourages providers to submit accurate and appropriate claims for services. It is always the provider's responsibility to determine medical necessity, the proper site for delivery of any services, and to submit appropriate codes, charges, and modifiers for services that are rendered. Boston Scientific recommends that you consult with your payers, reimbursement specialists, and/or legal counsel regarding coding, coverage, and reimbursement matters. It is always the provider's responsibility to understand and comply with national coverage determinations (NCD), local coverage determinations (LCD), and any other coverage requirements established by relevant payers, which can be updated frequently.

Payer policies will vary and should be verified prior to treatment for limitations on diagnosis, coding, or site-of-service requirements. The coding options listed within this guide are commonly used codes and are not intended to be an all-inclusive list. We recommend consulting your relevant manuals for appropriate coding options.

Clinical Summary

Transseptal puncture (TSP) is a well-known and widely used procedure, providing percutaneous access to the left atrium (LA) 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. Using this method, the transseptal puncture process has been associated with serious complications such as tissue injury, cardiac tamponade, and pericardial effusion, sometimes 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 and RF wire-based systems were developed. The **NRG**™ Transseptal Needle uses a blunt-tipped electrode to deliver RF energy, allowing reliable and controlled access to the left atrium without needing to push a sharp mechanical needle across the septum. The VersaCross Transseptal Platform uses the VersaCross RF Wire, which can be used, without exchanges, as a guidewire, an RF transseptal puncture device, and an exchange rail for delivering therapy sheaths. This technology, combined with the dedicated RFP-100A Generator, provides a safe, efficient, cost-effective transseptal crossing and therapy sheath delivery workflow that uses less power (watts) and produces more consistent punctures compared to other TSP modalities.

Clinical studies have highlighted the reliability and consistency provided by Baylis Medical* purpose-built RF technologies (RF needle, RF wire, RFP 100A) by demonstrating:

- Improved success with challenging anatomy
- Reduced rate of failed transseptal crossings
- Reduced procedure time
- Reduced rate of serious complications
- Reduced time of exposure to fluoroscopic radiation
- 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.

* Baylis Medical Company is a wholly owned subsidiary of Boston Scientific Corporation.

Clinical Evidence

Clinical Goal	Clinical Outcome	Clinical Evidence
Safety Reduce complication risk and fluoroscopy time	The VersaCross RF Transseptal Solution eliminates wire exchanges, which may reduce the risk of complications associated with exchanges.	Fewer exchanges may improve safety risks and associated complications.[1,2]
	Purpose-built RF puncture technology may reduce the risk of cerebral embolism.	Incidence of cerebral embolism was lower in patients where TSP was done using an RF needle (19%) vs. non-RF needle (32%).[3]
	Reduced mechanical force and tissue tenting of RF puncture technologies, combined with the rounded atraumatic tip of the RF electrode, may reduce the risk of TSP-related complications such as pericardial effusion or tamponade.	There were no incidents of cardiac tamponade with an RF needle (0%) vs. mechanical needle (0.92%).[4]
	The rounded atraumatic tip on the RF electrode prevents skiving within the dilator.	During ex vivo pr e-procedural tests, advancement of the mechanical needle through a plastic dilator and sheath created visible plastic shavings in 33.3% of tests, compared to 0% with the RF needle.[5] Mechanical needles, with and without a stylet, are associated with more skiving particle formation vs. RF needles.[6]

1. Harada M, Motoike Y, Nomura Y, et al. Factors associated with silent cerebral events during atrial fibrillation ablation in patients on uninterrupted oral anticoagulation. J Cardiovasc Electrophysiol. 2020;31(11):2889-2897. doi:10.1111/jce.14716
2. Deneke T, Nentwich K, Schmitt R, et al. Exchanging Catheters Over a Single Transseptal Sheath During Left Atrial Ablation is Associated with a Higher Risk for Silent Cerebral Events. Indian Pacing Electrophysiol J. 2014;14(5):240-249. Published 2014 Oct 6. doi:10.1016/s0972-6292(16)30795-1
3. Tokuda M, Yamashita S, Matsuo S, et al. Radiofrequency needle for transseptal puncture is associated with lower incidence of thromboembolism during catheter ablation of atrial fibrillation: propensity score-matched analysis. Heart Vessels. 2018;33(10):1238-1244. doi:10.1007/s00380-018-1159-8
4. 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;8(9):1411-1415. doi:10.1016/j.hrthm.2011.04.032
5. Hsu JC, Badhwar N, Gerstenfeld EP, et al. Randomized trial of conventional transseptal needle versus radiofrequency energy needle puncture for left atrial access (the TRAVERSE-LA study). J Am Heart Assoc. 2013;2(5):e000428. Published 2013 Sep 17. doi:10.1161/JAHA.113.000428
6. Feld GK, Tiongson J, Oshodi G. Particle formation and risk of embolization during transseptal catheterization: comparison of standard transseptal needles and a new radiofrequency transseptal needle. J Interv Card Electrophysiol. 2011;30(1):31-36. doi:10.1007/s10840-010-9531-3

Clinical Evidence

Clinical Goal	Clinical Outcome	Clinical Evidence
Safety Reduce complication risk and fluoroscopy time	The radiopaque and echogenic RF electrode enables visibility on imaging such as 3D mapping (using DuoMode Cable), intracardiac echocardiography (ICE), and/or transesophageal echocardiography (TEE).	In cryoballoon ablation procedures, using ICE to visualize the RF needle for TSP helped to minimize fluoroscopy use and radiation exposure over time.[7] Safety and efficacy outcomes of fluoroless TSP were favorable using: • The NRG Transseptal Needle, DuoMode Cable, CARTO® System, and ICE.[8] • The VersaCross RF Transseptal Solution, DuoMode Cable, EAM and/or ICE.[9]
	RF puncture technology reduces fluoroscopy use and radiation exposure.	There was 21% overall lower fluoroscopy time and 67% lower fluoroscopy dose with an RF wire vs. RF needle workflow.[10] Fluoroscopy time and dose were 25% and 60% lower, respectively, with the VersaCross Large Access Solution vs. the NRG needle.[11] There was significantly less fluoroscopy time required for LA access when using an RF needle vs. a mechanical needle. • RF needle 72 s (IQR: 48 – 109 s) vs. mechanical needle 93 s (IQR: 60 – 171 s)[12] • RF needle 1.8 ± 1.3 min vs. mechanical needle 2.9 ± 2.8 min[13]
	Purpose-built RF puncture technology is safer than non-indicated approaches to electrify needles and guidewires.	There was 0% tissue coring with purpose-built RF puncture technology vs. 37% with an electrified open-ended mechanical needle.[14] Larger defects and more tissue charring were observed when using electrified guidewires vs. RF wire for TSP.[15]
	Purpose-built RF puncture technology uses less power, produces smaller puncture defects, and results in less tissue heating vs. electrified guidewires.	Fewer RF applications, lower energy delivery, smaller puncture defects, and lower tissue temperature were observed when using the VersaCross system compared to electrified guidewires.[15]

7. Reiss J, O'Connell H, Getman MK. Achieving contrast-free ultra-low radiation exposure without compromising safety and acute efficacy through evolving AF cryoballoon ablation procedure techniques. Int J Cardiol. 2020;299:153-159. doi:10.1016/j.ijcard.2019.06.018
8. Salam T, Wilson L, Bohannan S, Morin M. Safety and Effectiveness of a Novel Fluoroless Transseptal Puncture Technique for Lead-free Catheter Ablation: A Case Series. J Innov Card Rhythm Manag. 2020;11(4):4079-4085. Published 2020 Apr 15. doi:10.19102/icrm.2020.110405
9. Demo H, Aranda C, Razminia M. Fluoroless left atrial access for radiofrequency and cryoballoon ablations using a novel radiofrequency transseptal wire [published correction appears in J Interv Card Electrophysiol. 2022 Mar 29;:]. J Interv Card Electrophysiol. 2022;64(1):183-190. doi:10.1007/s10840-022-01157-5
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11. Asfour IK, Elchouemi M, Gianni C, et al. Novel streamlined technique for left atrial appendage closure using a radiofrequency wire-based large access system. J Cardiovasc Electrophysiol. 2023;34(8):1690-1697. doi:10.1111/jce.15995
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13. Fromentin S, Sarrazin JF, Champagne J, et al. Prospective comparison between conventional transseptal puncture and transseptal needle puncture with radiofrequency energy. J Interv Card Electrophysiol. 2011;31(3):237-242. doi:10.1007/s10840-011-9564-2
14. Greenstein E, Passman R, Lin AC, Knight BP. Incidence of tissue coring during transseptal catheterization when using electrocautery and a standard transseptal needle. Circ Arrhythm Electrophysiol. 2012;5(2):341-344. doi:10.1161/CIRCEP.111.968040
15. Wasserlauf J, Knight BP. Comparing the safety and effectiveness of dedicated radiofrequency transseptal wires to electrified metal guidewires. J Cardiovasc Electrophysiol. 2022;33(3):371-379. doi:10.1111/jce.15341

Clinical Goal	Clinical Outcome	Clinical Evidence
Efficiency Faster, more efficient clinical workflows	RF puncture technology allows for reduced TSP times.	An RF needle allowed for faster TSP time vs. a mechanical needle: • RF needle 4.8 ± 2.8 min vs. mechanical needle 7.5 ± 8.5 min.[13] • RF needle 27.1 ± 10.9 min vs. mechanical needle 36.4 ± 17.7 min.[4] • RF needle 840 ± 323 s vs. mechanical needle 956 ± 407 s.[12]
	A VersaCross RF wire-based workflow allows for faster TSP than a needle-based workflow.	The RF wire allowed for faster TSP time vs. a mechanical needle: • RF wire 18 min (IQR: 10 – 27 min) vs. mechanical needle 40 min (IQR: 25 – 46 min).[16] • RF wire 4.1 ± 2.5 min vs. mechanical needle 8.4 ± 4.0 min[17] TSP time was 1.3 min faster with an RF wire-based workflow vs. an RF needle-based workflow (6.5 ± 2.3 min vs. 7.8 ± 2.3 min)[10]
	The VersaCross RF Transseptal Solution provides greater procedural efficiency due to reduced exchanges and steps, resulting in time savings.	TSP and LAAC sheath access into LA took less than 7 minutes using the VersaCross system, 2x faster than BRK needles; Fewer wire exchanges contributed to TSP efficiency.[17] Optimized and short TSP time (under 7.5 min) were feasible with the VersaCross system for transcatheter mitral valve repair; this system avoided unnecessary wire changes throughout the procedure.[18] Combined TSP time (first and second TSP) was faster with an RF wire (14.0 min; IQR: 10.6 – 14.6 min) vs. an RF needle (20.5 min; IQR: 14.0 – 27.7 min) due to fewer equipment exchanges.[19] The VersaCross™ RF Wire significantly reduced time to TSP and first PASCAL device deployment and eliminated the need for multiple wires and wire exchanges.[16] VersaCross Connect for WATCHMAN allowed streamlined LA access without requiring sheath exchanges, simplifying the LAAC procedure.[20] The VersaCross Large Access Solution allowed for de novo dilation of the septum for large-bore sheath delivery, reducing device exchanges and delivery sheath manipulation.[11]

16. Doshi SN, Savvoulidis P, Mechery A, et al. VersaCross Transseptal System for Mitral Transcatheter Edge-To-Edge Repair with the PASCAL Repair Platform. Struct Heart. 2023;In Press. doi:10.1016/j.shj.2023.100203.
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Clinical Evidence

Clinical Goal	Clinical Outcome	Clinical Evidence
Predictability Consistent, successful, and reliable crossing	Radiofrequency puncture with the NRG needle and VersaCross RF Transseptal Solution enables successful transseptal crossing regardless of septal anatomy.	Less variability in time-to-transseptal puncture was shown with a VersaCross wire-based workflow (smaller IQRs).[19] There were no failures to cross with an RF needle vs. 28% failures to cross (10/36) with a mechanical needle. Of those failures with the mechanical needle, 40% were in patients who had repeat transseptal punctures.[5] There was a significantly lower rate of failed TSP and case termination with an RF needle (0.17%) vs. mechanical needle (1.23%).[4]
Precision Successful transseptal puncture/crossing at targeted location on septum	RF puncture technology eliminated the need for mechanical force and allowed targeted TSP at the desired location. The radiopaque RF electrode allows for enhanced visibility on imaging for precise positioning within the heart.	An ideal inferior-anterior transseptal location was more often observed in the RF needle group (42.1%) vs mechanical needle group (23.3%).[12] Significant septum tenting was required with the mechanical needle approach vs. the RF needle.[21] NRG[22] and VersaCross[16] allowed for a more precise crossing due to the reduction of force needed to tent the septum. 3D map-guided TSP was successful in 97% of attempts within 7 min with 85.1% of the TSP in a good position on the fossa ovalis.[23]
Cost Effective Controls treatment-associated expenses without compromising patient care quality	Workflows using purpose-built RF puncture technology are cost-effective.	Purpose-built RF systems were shown to be cost-effective compared to mechanical transseptal needles.[24]*

21. Sharma G, Singh GD, Smith TW, Fan D, Low RI, Rogers JH. Accuracy and procedural characteristics of standard needle compared with radiofrequency needle transseptal puncture for structural heart interventions. Catheter Cardiovasc Interv. 2017;89(6):E200-E206. doi:10.1002/ccd.26608
22. Rinaldi MJ, Scherer M, Downey W, et al. Site-specific transseptal puncture for emerging structural heart interventions. Cardiac Interv Today. 2014;March/April:25-29.
23. Bohnen M, Minners J, Eichenlaub M, et al. Feasibility and safety of a three-dimensional anatomic map-guided transseptal puncture for left-sided catheter ablation procedures. Europace. 2023;25(3):1126-1134. doi:10.1093/europace/euac262
24. Sanchez JM, Shah R, Kouassi Y, Chronowic M, Wilson L, Marcus GM. A cost-effectiveness analysis comparing a conventional mechanical needle to a radiofrequency device for transseptal punctures. J Cardiovasc Electrophysiol. 2020;31(7):1672-1677. doi:10.1111/jce.14500

* Cost-effectiveness analysis compared costs/outcomes with NRG RF needles to mechanical transseptal needles. Results may vary when comparing other devices.

Highlights from:

Michifumi Tokuda, MD, PhD, Seigo Yamashita, MD, PhD, Seiichiro Matsuo, MD, PhD, Mika Kato, MD, PhD, Hidenori Sato, MD, Hirotsuna Oseto, MD, Eri Okajima, MD, Hidetsugu Ikewaki, MD, Ryota Isogai, MD, Kenichi Tokutake, MD, Kenichi Yokoyama, MD, Ryohsuke Narui, MD, Shin-ichi Tanigawa, MD, Keiichi Inada, MD, PhD, Michihiro Yoshimura, MD, PhD, and Teiichi Yamane, MD, PhD

Tokuda et al. Heart and Vessels. April 2018 DOI: 10.1007/s00380-018-1159-8

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Radiofrequency needle for transseptal puncture is associated with lower incidence of thromboembolism during catheter ablation of atrial fibrillation: propensity score-matched analysis

INTRODUCTION

- Catheter ablation of atrial fibrillation (AF) is a well-established but not risk-free procedure. Silent ischemic lesions and neuropsychological decline have been observed following these procedures.
- The impact of different approaches to accessing the heart has recently been considered as a risk factor for silent acute cerebral embolism (ACE). This study aimed to compare the incidence of ACE following AF ablation procedures performed with a radiofrequency (RF) needle versus mechanical needle for transseptal puncture.

METHODS

- This retrospective, propensity score-matched analysis of 232 patients who underwent a catheter ablation procedure for AF compared those with transseptal puncture performed with a RF transseptal needle* (n=116) to those with a non-RF (mechanical) transseptal needle (n=116). Cerebral magnetic resonance images were collected following all procedures to assess for ACE.

RESULTS

- Incidence of ACE was significantly lower in the RF needle group than in the mechanical needle group (19% vs. 32%, p=0.02). This represents an approximately 40% lower incidence (see Figure 1).
- Total procedure time was significantly shorter in the RF needle group than in the mechanical needle group (167±50 min. vs. 181±52 min., p=0.01). This represents a 14 min. lower mean procedure time, which suggests economic benefits through improved electrophysiology (EP) lab efficiencies may be achieved.

DISCUSSION AND CONCLUSIONS

- It is speculated that the basis for lower incidence of ACE with RF needles may be associated with reduced skiving† and/or a more predictable transseptal process with the RF needle involving reduced time and interaction with the septum.
- It is widely accepted in the AF ablation and EP community that efforts to help lower the incidence of silent ACE are desirable, despite an incomplete understanding of the clinical consequence of these events.‡
- The results of this study suggest that physicians may consider an RF transseptal needle to help lower incidence of ACE.

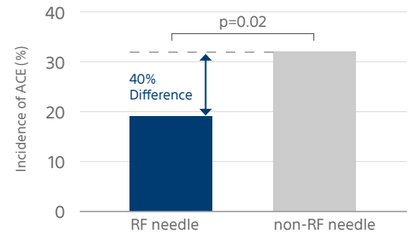

Figure 1. Incidence of acute cerebral embolism (ACE) was lower in patients who had transseptal puncture performed with a radiofrequency (RF) needle than those using a non-RF needle.

* Marketed in US, Canada and EU as **NRG™** Transseptal Needle (Baylis Medical Company, a fully-owned subsidiary of Boston Scientific Corporation).
† As generated by mechanical needles during the catheterization process
‡ Calkins et al. 2017 HRS/EHRA/ECAS/APHRS/SOLAECE expert consensus statement on catheter and surgical ablation of atrial fibrillation. Heart Rhythm. 2017 Oct;14(10):e275-e444

EP-1582604-AA

Clinical Evidence

Highlights from:
Roger A. Winkle, R. Hardwin Mead, Gregory Engel, and Rob A. Patrawala

Winkle et al. Heart Rhythm, Volume 8, Issue 9, Sept 2011 DOI: 10.1016/j.hrthm.2011.04.032

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The use of a radiofrequency needle improves the safety and efficacy of transseptal puncture for atrial fibrillation ablation

INTRODUCTION

- This large case series compares the safety and efficacy of transseptal puncture (TSP) using the purpose-built radiofrequency (RF) **NRG™** Transseptal Needle (Baylis Medical*) to a sharp mechanical needle (BRK-1™ or BRK-1™ ES, Abbott) for atrial septal puncture.

METHODS

- 1550 consecutive atrial fibrillation (AF) ablations were retrospectively analyzed.
- Fluoroscopy, intracardiac ultrasound, pressure measurement, and/or contrast injection were used to guide the transseptal puncture.

Transseptal puncture

- Mechanical needle (975 ablations).
  - Forward force was applied for TSP and to advance the transseptal apparatus across the septum.
- **NRG™** RF Needle (575 ablations).
  - RF energy was applied using a dedicated generator (RFP-100-115, Baylis Medical*) to perforate the septum with no significant forward motion of the needle.
  - The transseptal apparatus was then advanced into the left atrium (LA) over the needle.
- After a successful transseptal puncture, all patients underwent standard AF ablation.

Data analysis

- Instrumentation time was recorded from lidocaine injection to heparin injection upon LA access.
- Complications during TSP were assessed, including failure of LA access, pericardial tamponade, inadvertent aortic puncture, death, stroke, or transient ischemia.
- Operator experience over time was assessed by quartile using Cochran-Armitage trend analysis.

RESULTS

- Failure of TSP was lower with RF needle than mechanical needle (0.17% vs. 1.23%; p=0.039).
- No cardiac tamponade occurred with RF needle compared to mechanical needle (0.00% vs. 0.92%; p<0.04).
- With mechanical needle, septal crossing rates (p=0.79) and rate of tamponade (p=0.46) did not improve with operator experience.
- Instrumentation time was shorter with the RF needle than mechanical needle (27.1 ± 10.9 min vs. 36.4 ± 17.7 min; p<0.0001).

DISCUSSION AND CONCLUSIONS

- RF needles reduce the rate of atrial perforation by requiring minimum forward movement to cross the septum compared to sharp mechanical needles.
- RF needles improve the rate of crossing, even in septa that are thick or scarred from prior punctures.
  - Atraumatic tip of RF needle allows verification of needle tip position without tissue penetration.
  - Sharp mechanical needles can create micro-punctures upon tissue contact that may lead to procedure termination to prevent risks from procedural anticoagulation.
- Clean tissue perforation requires a dedicated RF needle and purpose-built generator.
  - Connecting an ablation generator to a mechanical or RF needle may lead to tissue heating, necrosis, and septal damage.
- This study showed that purpose-built RF needles reduce instrumentation times, increase TSP efficacy, and reduce the incidence of pericardial tamponade during AF ablation.

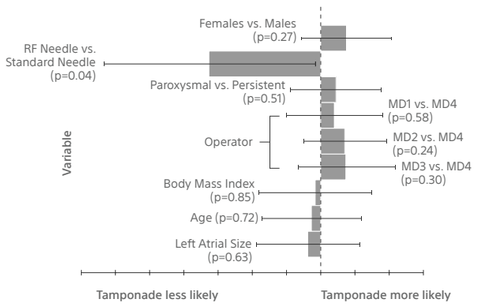

Figure 1. Multivariate analysis of pericardial tamponade indicated that the RF needle is the only variable associated with lower tamponade (95% confidence interval).

* A wholly-owned subsidiary of Boston Scientific Corporation.

EP-1582909-AA

Highlights from:
Jonathan C. Hsu, Nitish Badhwar, Edward P. Gerstenfeld, Randall J. Lee, Mala C. Mandyam, Thomas A. Dewland, Kourtney E. Imburgia, Kurt S. Hoffmayer, Vasanth Vedantham, Byron K. Lee, Zian H. Tseng, Melvin M. Scheinman, Jeffrey E. Olgin, and Gregory M. Marcus

Journal of the American Heart Association, Sept 2013 DOI: 10.1161/JAHA.113000428

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Randomized Trial of Conventional Transseptal Needle Versus Radiofrequency Energy Needle Puncture for Left Atrial Access (the TRAVERSE–LA Study)

METHODS

- Randomized, prospective, and controlled trial. 72 patients were randomized to either the **NRG™** RF Transseptal Needle (Baylis Medical*) or conventional transseptal needle on a 1:1 basis.

RESULTS

Primary Outcome

- Median transseptal procedure time was 68% lower in RF needle group compared with conventional needle group on an intention-to-treat basis.

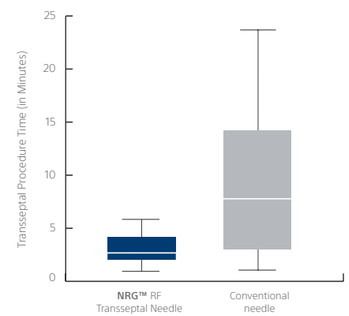
Secondary Outcome

- RF needle group did not experience transseptal procedure failure with assigned needle: 0 out of 36 cases (0%).
- Conventional needle group experienced 10 failures in 36 cases (27.8%). Subsequent crossover to RF needle enabled successful transseptal procedure in all cases.

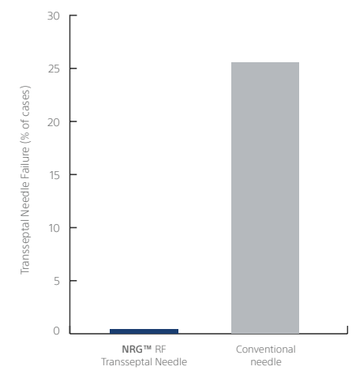
Secondary Outcome

- In pre-procedural ex vivo testing that involved advancement of the needle through the plastic dilator and sheath, the conventional needle produced visible plastic particles in 33.3% of cases whereas the RF needle did not produce visible particles in any cases (0%).

Procedure time



Rate of failure



* A wholly-owned subsidiary of Boston Scientific Corporation.

EP-1582805-AA

Clinical Evidence

Highlights from:
Gregory K. Feld, Jay Tiongson, and Ganiyu Oshodi
Feld et al., J Interv Card Electrophysiol, Jan 2011 DOI: 10.1007/s10840-010-9531-3

Boston Scientific
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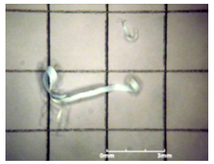
Particle formation and risk of embolization during transseptal catheterization: Comparison of standard transseptal needles and a new radiofrequency transseptal needle

INTRODUCTION

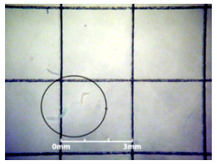
- This study examined the risk of particle formation (due to skiving) during transseptal procedures. A standard needle, a reverse-bevel needle, and a radiofrequency needle were compared.

DISCUSSION AND CONCLUSIONS

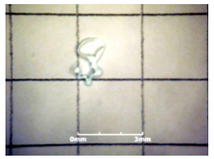
- The standard needle generated clinically relevant, visible particles when used without the stylet. Use of the stylet reduced the amount of visible particles generated but did not eliminate the problem.
- Use of the reverse-bevel needle reduced the amount of visible particles generated but did not eliminate the problem.
- Use of the radiofrequency needle eliminated the problem of visible particles.



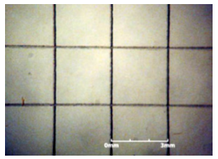
Standard needle without stylet



Standard needle with stylet



Reverse-bevel needle



NRG™ Needle

EP-1613909-AA

Highlights from:
James Reiss, MD, MPH, FACC, FHRS, Heather O'Connell, MHS, and Michael Getman, MS
Reiss et al. International Journal of Cardiology, Jun 2019 DOI: 10.1016/j.ijcard.2019.06.018

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Achieving Contrast-Free Ultra-Low Radiation Exposure Without Compromising Safety and Acute Efficacy Through Evolving AF Cryoballoon Ablation Procedure Techniques

INTRODUCTION

- Due to the detrimental effects of radiation during catheter-based procedures, it should be assumed that a safe level of radiation exposure does not exist.
- This study demonstrates the safety and acute effectiveness of ultra-low fluoroscopy use during cryoballoon ablation for atrial fibrillation.

METHODS

- A retrospective observational analysis was performed on 307 cryoballoon ablation procedures for pulmonary vein isolation (PVI) using ultra-low fluoroscopy.

Imaging

- Pre-procedural planning included cardiac computed tomography or magnetic resonance imaging.
- Transesophageal echocardiography to rule out thrombus.
- Intracardiac echocardiography (ICE; Zonare Ultrasound System, St. Jude Medical) was used for transseptal puncture and catheter guidance.
- 3D electroanatomic mapping (EAM) was used to recreate cardiac geometries and for catheter guidance (Achieve™ Mapping Catheter, Medtronic, Inc.; EnSite™ NavX™ Mapping System, St. Jude Medical).
- "Single-shot" fluoroscopy (3.75 frames/s) was used if resistance was felt during device exchange.

Transseptal access

- Transseptal puncture was performed using the **NRG™** Transseptal Needle (Baylis Medical*).
- Catheter exchange in the left atrium was initially done using a STORQ® Steerable Guidewire (Cordis) during the first 18 months of the study before switching to the **ProTrack™** Pigtail Wire (Baylis Medical*) for the remaining 28 months.

Cryoballoon ablation

- Ablations were performed using the Arctic Front Advance™ Cryoballoon (Medtronic, Inc.).
- Direct pressure monitoring and Doppler flow were used to confirm pulmonary vein occlusion in place of radiopaque contrast.

RESULTS

- Radiation dose decreased from 6.7 mGy to 2.0 mGy over the study period ($p<0.01$).
- Fluoroscopy time decreased from 0.75 min to 0.2 min over the study period ($p<0.0001$).
- Use of a 28-mm cryoballoon required significantly lower fluoroscopy use than both the 23-mm cryoballoon and combination of 23-mm and 28-mm cryoballoons.
- Acute procedural success was achieved in 99% of patients with a 2.0% complication rate, consistent with other cryoballoon studies.
- One incidence of left atrial appendage perforation leading to cardiac tamponade was attributed to the STORQ® Steerable Guidewire, and prompted the switch to the **ProTrack™** Pigtail Wire.

DISCUSSION AND CONCLUSIONS

- This study describes a method for ultra-low fluoroscopy cryoballoon ablation compared to other large sponsored studies, and demonstrates safety and effectiveness.
- The best practices for fluoroscopy reduction include:
  - ICE to visualize the **NRG™** Transseptal Needle for transseptal puncture and **ProTrack™** Pigtail Wire for wiring across the left atrium
  - 3D EAM, ICE, pressure waveform, and Doppler imaging for catheter navigation
  - Cryoballoon dosing algorithm to minimize freezing beyond acute PVI
  - Slow fluoroscopy frame rate when needed
- These tools and techniques are common within electrophysiology labs and require minimal additional operator training.

* A wholly-owned subsidiary of Boston Scientific Corporation.

EP-1579304-AA

Clinical Evidence

Highlights from:
Tariq Salam, MD, FHRS, Lane Wilson, RCIS, CEPS, CCDS, Sara Bohannan, RCES, CEPS, and Michael Morin, LPN, RCES

Salam et al., Journal of Innovations in Cardiac Rhythm Management, Volume 26, Issue 5, April 2020
DOI: 10.19102/icrm.2020.110405

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A Large Case Series Demonstrating Safety and Effectiveness of a Novel Fluoroless Transseptal Puncture Technique for Lead-Free Catheter Ablation

INTRODUCTION

- This large series of 382 consecutive cases demonstrates the safety and effectiveness of fluoroless transseptal puncture (TSP) and radiofrequency (RF) ablation using 3D electroanatomic mapping (EAM).

METHODS

Visualization setup

- **NRG™** Transseptal Needle (Baylis Medical*) was visualized on the CARTO® 3 System (Biosense Webster) using the **DuoMode™** Extension Cable† (Baylis Medical*) (Figure 1).
- An esophageal temperature probe was sutured to a quadripolar catheter to track on EAM.
- Devices were visualized using preset catheter definitions (20B 4F quad 2-5-2 mm fixed) and by enabling "extended features raw data" on the CARTO® 3 System.

Transseptal puncture and catheter ablation

- Femoral access was used to introduce the ThermCool SmartTouch® Catheter (Biosense Webster) for mapping the superior vena cava (SVC) and right atrium, marking the His bundle, coronary sinus, and fossa ovalis.
- The transseptal sheath was then re-positioned in the SVC to introduce the **NRG™** Needle.
- The sheath and dilator were pulled back to expose the round **NRG™** Needle tip for positional tracking on the CARTO® 3 System during dropdown onto the septum (**DuoMode™** Cable set to "mapping mode").
- Intracardiac echocardiography (ICE) was used to confirm needle position on the fossa ovalis before RF puncture (**DuoMode™** Cable set to "generator mode").
- Left atrial mapping and RF catheter ablation were performed as per usual protocol.

RESULTS

- Double or single TSP was achieved 100% successfully and without fluoroscopy within 28±15 min.
- Total procedure time was 135±34 min without significant complications.
- Recurrence rate was 27% at 3±1 month follow-up.

DISCUSSION AND CONCLUSIONS

- This study demonstrates the safety and effectiveness of non-fluoroscopic TSP using the **NRG™** RF Transseptal Needle, 3D-EAM, and ICE.
- The atraumatic electrode tip of the RF needle allowed exposure during drop-down for positional tracking from the SVC to the fossa ovalis, unlike the sharp tip of a mechanical needle.
- Dedicated RF transseptal needles improve safety, efficiency, precision, and TSP success in diverse septal anatomies, offsetting the material costs.
- Use of electrified mechanical needles is not characterized and presents risks of injury.

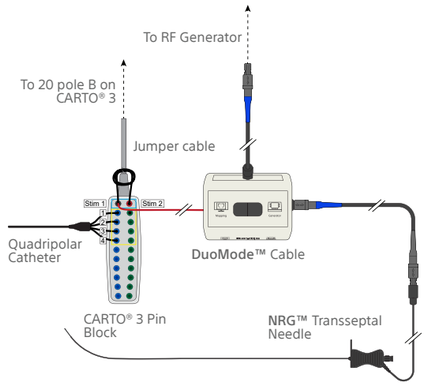

Figure 1. Graphical adaptation of the equipment setup used by Salam et al for device visualization on EAM.

* A wholly-owned subsidiary of Boston Scientific Corporation.
† Consult your mapping system's user manual for connectivity and configuration instructions prior to **DuoMode™** Cable use.

EP-1579305-AA

Highlights from:
Hany Demo, MD, FACC, FHRS, Carla Aranda, Mansour Razminia, MD

Demo et al., Journal of Interventional Cardiac Electrophysiology (JICE), Feb 2022 DOI: 10.1007/s10840-022-01157-5

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Fluoroless Left Atrial Access for Radiofrequency and Cryoballoon Ablations using a Novel Radiofrequency Transseptal Wire

HIGHLIGHTS

- The **VersaCross™ RF Transseptal Solution** can enable fluoroless transseptal puncture in ablation procedures.
- Efficient procedure with average transseptal puncture time under 20 minutes.
- Zero exchanges required for transseptal puncture.

INTRODUCTION

- Procedure efficiency and transseptal puncture (TSP) remain a barrier to the full adoption of fluoroless procedures to reduce radiation exposure and associated health risks.
- This study reports the first clinical experience using the **VersaCross™ RF Transseptal Solution** (Baylis Medical*) for more efficient left atrial (LA) access through reduced device exchanges to facilitate fluoroless radiofrequency ablation (RFA) and cryoballoon ablation (CBA).

METHODS

- Fluoroless RFA and CBA procedures at two centers were retrospectively evaluated for procedural efficiency and safety.
- The **VersaCross™ RF Transseptal Solution**, consisting of a transseptal sheath, shapeable dilator, and RF wire (J-tip or pigtail), was used to cannulate the superior vena cava (SVC), perform RF TSP, and deliver RF ablation or the FlexCath Advance™ Steerable Sheath (Medtronic) in CBA.
- The **VersaCross™ RF Transseptal Solution** was visualized without fluoroscopy using:
  A. Electroanatomic mapping (EAM) using the **DuoMode™ Cable** (Baylis Medical) and EnSite Precision™ Cardiac Mapping System (Abbott), and intracardiac echocardiography (ICE).
  B. ICE only.
- RFA or CBA procedures were then performed as per usual protocol.

RESULTS

- 126 patients underwent RFA (n=72) or CBA (n=54) for left-sided cardiac arrhythmias.
- Fluoroless TSP was successful in 100% of cases regardless of septal anatomy. Device exchanges were not required for TSP or repositioning on the septum.
- All procedures were 100% successful without any intraprocedural complications.
- Average procedure time was 104.4 ± 38.0 min for RFA and 91.1 ± 22.1 min for CBA.
- Transseptal Puncture Time (Figure 1)
  - 2.8 ± 1.0 min for RFA and 3.5 ± 1.6 min for CBA from **VersaCross™ RF Wire** insertion into femoral introducer.
  - 14.5 ± 6.6 min for RFA and 19.2 ± 11.7 min for CBA from initial vascular access.

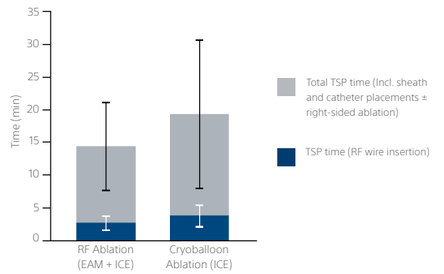

Figure 1. Transseptal puncture time during RF ablation (EAM + ICE) and cryoballoon ablation (ICE) using the **VersaCross™ RF Transseptal Solution** (Baylis Medical).

DISCUSSION & CONCLUSIONS

- RFA and CBA can be performed safely using the **VersaCross™ RF Transseptal Solution** without the use of fluoroscopy or lead.
- The **VersaCross™ RF Transseptal Solution** enabled more efficient and faster catheter ablation procedures compared to conventional techniques by:
  - Effective fluoroless visualization using EAM and/or ICE.
  - Reducing the number of device exchanges for LA access.
- TSP time with fluoroless visualization of the **VersaCross™ RF Wire** are comparable to fluoroscopy-guided TSP using RF wire, suggesting fluoroless visualization does not compromise TSP efficiency.[1]

[1]Sayah N., et al. Initial clinical experience with VersaCross transseptal system for transcatheter mitral valve repair. *Catheter Cardiovasc Interv*. 2021;97(6): 1230-4. https://doi.org/10.1002/ccd.29365.

*A wholly-owned subsidiary of Boston Scientific Corporation.

EP-1525115-AA

Clinical Evidence

Highlights from:
Stéphane Fromentin, Jean-François Sarrazin, Jean Champagne, Isabelle Nault, François Philippon, Franck Molin, Louis Blier, and Gilles O'Hara

Fromentin et al., J Interv Card Electrophysiol, Sept 2011 DOI: 10.1007/s10840-011-9564-2

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Prospective comparison between conventional transseptal puncture and transseptal needle puncture with radio frequency energy

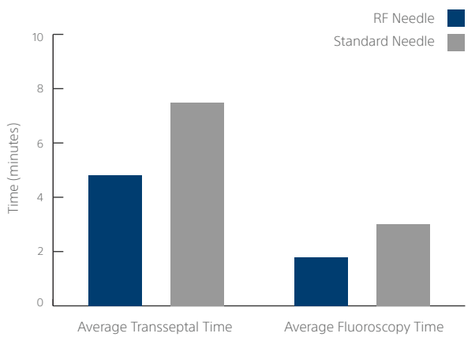
INTRODUCTION

- This study compared the safety and efficacy of radiofrequency (RF) transseptal puncture to the conventional technique.

RESULTS

- The average time for the RF transseptal puncture was 4.8 minutes compared to 7.5 minutes for the conventional technique (p=0.045).
- The average fluoroscopy time for the RF transseptal puncture was 1.8 minutes compared to 2.9 minutes for the conventional technique (p=0.043).
- RF transseptal puncture was successful in all patients. Four patients undergoing the conventional technique required crossover to the RF transseptal puncture (p=0.003).

Comparison between RF Needle and Standard Needle



Highlights from:
Eugene Greenstein, MD, Rod Passman, MD, Albert C. Lin, MD, and Bradley P. Knight, MD

Greenstein et al., Circulation: Arrhythmia and Electrophysiology Feb 2012. DOI: 10.1161/CIRCEP.111.968040

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Incidence of Tissue Coring During Transseptal Catheterization When Using Electrocautery and a Standard Transseptal Needle

INTRODUCTION

- Application of radiofrequency (RF) energy through the open-ended tip of a hollow transseptal needle can cause coring of cardiac tissue and creation of embolic material.
- This study investigated the incidence of tissue coring when RF is delivered through a Brockenbrough needle.

METHODS

- Hearts were harvested from small (<50 kg) and large (>65 kg) swine and immersed in 0.9% saline.
- Transseptal puncture (TSP) was performed ex vivo using adult Brockenbrough needles from Cook Medical, TZ Medical, and St. Jude Medical with or without electrocautery.
- RF was delivered using a Valleylab Force FX™ Electrosurgical Generator (Valleylab Inc).
  - Punctures were performed at 10 and 15 W
  - RF was delivered for 1-2 s using a foot pedal at the time of needle advancement
- Punctures were performed on fossa ovalis (FO), other areas of interatrial septum (non-FO), and aortic sites.
- After each puncture, the needle was manually flushed and inspected for release of cardiac tissue.

RESULTS

- 288 TSPs were performed with electrocautery and 108 TSPs were performed without electrocautery.
- Tissue coring was observed in 37% of the punctures when RF was delivered through a standard Brockenbrough needle as compared to TSP without electrocautery (p<0.001) (Figure 1).
- Tissue coring occurred in 35% of punctures through the FO and 40% of punctures through non-FO. Significantly higher coring was reported in the case of punctures at aortic sites compared to the septal sites (65%, p<0.001) (Figure 1).
- Needle model and power settings did not have a significant effect on the incidence of coring.
- Although not statistically significant, coring occurred 2-9% more often in larger hearts when using electrocautery.

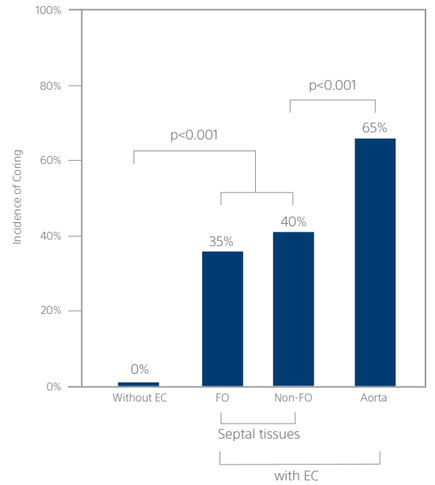

Figure 1. Significantly more coring was observed in septal tissues (i.e. fossa ovalis, FO, and other areas of interatrial septum, non-FO) using Brockenbrough needles with electrocautery (EC) than without electrocautery. In addition, significantly more tissue coring was observed in the aortic sites as compared to septal tissues.

DISCUSSION AND CONCLUSIONS

- Tissue coring occurred on average in 37% of punctures using electrified Brockenbrough needles regardless of tissue thickness, needle type, power delivered, or heart size.
- With increase in the target tissue thickness, the incidence of coring increased.
- Since use of electrocautery to perforate the interatrial septum carries the risk of systemic embolism, an alternative must be considered, such as a purpose-built transseptal RF needle or a sharp-tipped J-shaped guidewire.

Clinical Evidence

Highlights from:
S. N. Doshi, MD, MBChB, FRCP, P. Savvoulidis, MD, PhD, FESC, A. Mechery, MBBS, DM, MRCP, E. Lawton, RN, M. A. Nadir, MD, MRCP, FACC
Doshi et al., Structural Heart, Jun 2023 DOI: 10.1016/j.shj.2023.100203

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VersaCross Transseptal System for Mitral Transcatheter Edge-To-Edge Repair With the PASCAL Repair Platform

HIGHLIGHTS

The **VersaCross™** RF Transseptal Solution is a safe and easy-to-use platform that streamlines transseptal puncture (TSP), and offers many advantages over standard mechanical needles when used in transcatheter edge-to-edge repair (M-TEER) procedures. Compared to a standard mechanical needle-based workflow, a VersaCross RF wire-based workflow:

- Shortened time to TSP and first PASCAL™ Implant release significantly, enabling 2.2x faster TSP and 1.6x faster time to first PASCAL Implant release.
- Allowed a more precise crossing to be achieved due to the reduction of force needed to tent the septum at the time of crossing.
- Improved M-TEER procedural efficiency by reducing the number of wires and wire exchanges required.

INTRODUCTION

- Precise positioning and puncture of the fossa ovalis is critical for efficient access to the left atrium (LA) and successful mitral transcatheter edge-to-edge repair.
- This study is the first to compare use of the **VersaCross™** Radiofrequency (RF) Wire (Baylis Medical*) to conventional mechanical puncture for M-TEER using the PASCAL Precision™ Transcatheter Valve Repair System (Edwards Lifesciences).

METHODS

- This single-center, retrospective study included 33 consecutive patients undergoing M-TEER with the PASCAL Precision system using two TSP methods:
- **Mechanical Needle Group (n = 10):**
  - A 150-cm J-tipped 0.032" guidewire was used to introduce a Mullins (Medtronic) or SL1 (Abbott) sheath and dilator.
  - The guidewire was then exchanged for the BRK1™ Transseptal Needle (Abbott) to drop down to the septum for performing TSP.
  - After TSP, the dilator and needle were exchanged for an Amplatz Super Stiff™ Guidewire (Boston Scientific) for subsequent delivery of the 22F PASCAL™ Guide Sheath.
- **VersaCross RF Wire Group (n = 23):**
  - The 0.035" VersaCross RF pigtail wire was used to introduce the dedicated VersaCross transseptal sheath and dilator and position on the fossa ovalis.
  - The VersaCross wire was then used to perform RF TSP.
  - After crossing, the VersaCross wire was used to exchange the transseptal sheath for the 22F PASCAL Guide Sheath, which was advanced into the LA.

RESULTS

- TSP was successful in all patients in both groups, with no cases of pericardial effusion or tamponade.
- Fewer guidewires were used in the VersaCross procedure workflow (1) than the mechanical needle workflow (2).
- Median time to TSP was shorter using the VersaCross system than mechanical needle (18 min [IQR: 10–27 min] vs. 40 min [IQR: 25–46 min]; p = 0.048) (Figure 1).
- Median time to first PASCAL Implant release was shorter using the VersaCross system than mechanical needle (94 min [IQR: 73–130 min] vs. 146 min [IQR: 115–175 min]; p = 0.029) (Figure 1).

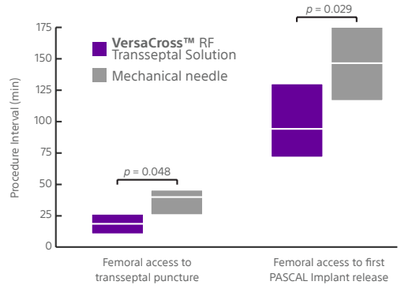

Figure 1. Time from femoral access to transseptal puncture and first PASCAL Implant release using a mechanical needle (n = 10) vs. the VersaCross RF system (n = 23). Results are the median ± inter-quartile range (IQR).

DISCUSSION AND CONCLUSIONS

- The VersaCross system eliminated the need for an additional supportive guidewire for large therapy sheath exchange.
- Compared to a mechanical needle, the VersaCross system significantly reduced transseptal puncture time and time to PASCAL Implant release.
- Overall, the authors report the VersaCross RF Transseptal Solution is a safe and effective system that can streamline structural heart interventions requiring large-bore sheath delivery to the LA.

*A wholly-owned subsidiary of Boston Scientific Corporation.

EP-1696104-AA

Highlights from:
Taku Inohara, MD, Thomas Gilhofer, MD, Christina Luong, MD, Michael Tsang, MD, Jacqueline Saw, MD
Inohara et al., J Interv Card Electrophys, Jan 2021 DOI: 10.1007/s10840-020-00931-7

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VersaCross Radiofrequency System Reduces Time to Left Atrial Access versus Conventional Mechanical Needle

HIGHLIGHTS

The study found LAAC sheath delivery with the **VersaCross™** RF Transseptal Solution was:

- Efficient: Transseptal puncture and LAAC sheath delivery on average in under 7 mins.
- Exchangeless: Faster LA access by combining a starter wire, RF transseptal device, and exchange rail in a 3-in-1 solution.
- Effortless: Controlled RF puncture with a single wire.

INTRODUCTION

- Left atrial (LA) catheterization requires numerous device exchange steps, and has associated risks and safety concerns.
- The **VersaCross™** RF Transseptal Solution (Baylis Medical*) enables vascular cannulation, transseptal puncture (TSP), and device exchange using a single RF-tipped pigtail wire.

METHODS

- Consecutive series of left atrial appendage closure (LAAC) using WATCHMAN™ (Boston Scientific) or Amulet™ (Abbott) devices were retrospectively evaluated.
- Femoral access was obtained for inferoposterior TSP using two methods:

Conventional approach (n=10):

- Requiring a starter wire, sharp mechanical needle (BRK-1™ Transseptal Needle, Abbott), fixed curve sheath (Swartz™ Transseptal Guiding Introducers, Abbott), and stiff exchange wire (Amplatz Super Stiff™, Boston Scientific or **ProTrack™** Pigtail Wire, Baylis Medical)

VersaCross™ RF Transseptal Solution (n=10):

- Comprised of the **VersaCross™** RF Wire, Sheath, and Dilator

- Efficiency was assessed in terms of time from femoral access to TSP, delivery of LAAC sheath in the LA, device release, overall procedure, and fluoroscopy use.
- Safety was assessed in terms of intraprocedural and in-hospital complications.

RESULTS

- LAAC success was 100% using both methods, with no complications.
- Significant improvement in LA access times using **VersaCross™** RF Transseptal Solution vs. conventional method:
  - Shorter time to TSP [4.1±2.5 min vs. 8.4±4.0 min (p=0.009)]
  - Less time for LAAC delivery sheath into LA [6.7±2.4 min vs. 13.4±5.4 min (p=0.002; Figure 1)]
- Trend for overall procedural improvement using **VersaCross™** RF Transseptal Solution vs. conventional method:
  - Shorter time to device release [23.7±6.4 min vs. 31.2±10.0 min (p=0.062)]
  - Less fluoroscopy use [7.2±2.2 min vs. 11.4±5.9 min (p=0.061)]

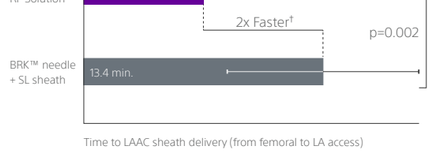

Figure 1. LAAC sheath delivery is two times faster using the **VersaCross™** RF Transseptal Solution than the conventional workflow.†

DISCUSSION & CONCLUSIONS

- **VersaCross™** RF Transseptal Solution combines a starter wire, transseptal needle, and exchange guidewire for faster LA access, and may improve overall procedural efficiency.

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† From femoral access to LAAC sheath delivery using **VersaCross™** RF Transseptal Solution compared to a conventional mechanical needle and fixed curve sheath (Inohara et al., 2021).

EP-1548701-AA

Clinical Evidence

Highlights from:
Neila Sayah, MD, Francois Simon, MD, Patrick Garceau, MD, Anique Ducharme, MSc, MD, Arsene Basmadjian, MD, MSc, Denis Bouchard, MD, PhD, Michel Pellerin, MD, Raoul Bonan, MD, Anita W. Asgar, MD, MSc
Sayah et al. Catheter Cardiovasc Interv. Nov 2020 DOI: 10.1002/ccd.29365

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Initial Clinical Experience with VersaCross Transseptal System for Transcatheter Mitral Valve Repair

HIGHLIGHTS

The novel **VersaCross™** Radiofrequency (RF) Transseptal Solution enabled MitraClip™ Guide delivery in under 7.5 minutes.* The initial experience shows using the **VersaCross™** RF Transseptal Solution is:

- Efficient: Achieved TSP and MitraClip™ Guide delivery under 7.5 mins.
- Exchangeless: Reduced number of wire exchanges.
- Effortless: Repositioned on the fossa without rewiring.

INTRODUCTION

- Transseptal puncture (TSP) location is critical for transcatheter mitral valve repair success.
- Brockenbrough needles can cause excessive tenting of the septum, leading to unpredictable TSP location and complications.
- Purpose-built RF devices avoid excessive septal tenting or slippage to allow crossing at the desired location and have increased in use during MitraClip™ procedures (Abbott).
- The **VersaCross™** RF Transseptal Solution (Baylis Medical†) utilizes an RF wire and shapeable dilator for targeted TSP while reducing wire exchanges to improve procedural efficiency.
- This study describes the initial clinical experience using the **VersaCross™** RF Transseptal Solution in 25 prospective consecutive MitraClip™ procedures.

METHODS

- Right femoral vein access was obtained using standard techniques.
- The **VersaCross™** RF Wire (pigtail configuration) was used to introduce the transseptal sheath and dilator, perform RF TSP, and introduce the MitraClip™ Guide into the LA with no wire exchanges.
- Procedural efficiency was evaluated in terms of time from **VersaCross™** RF Wire insertion to (A) TSP and (B) MitraClip™ Guide in the left atrium (LA).
- Major adverse events were assessed at hospital discharge.

RESULTS

- TSP using the **VersaCross™** RF Transseptal Solution was 100% successful with no major adverse procedural events.
- TSP was achieved within 3.3 ± 1.6 min (Figure 1) or 1.2 ± 0.5 attempts.
- MitraClip™ guide catheter was placed in the LA within 3.8 ± 3.0 min.

DISCUSSION & CONCLUSIONS

- The **VersaCross™** RF Transseptal Solution combines several tools to minimize exchanges that are typically required to insert the MitraClip™ Guide into the LA, including:
  - Shapeable dilator to optimize position on the fossa ovalis
  - Soft pigtail wire for easy repositioning
  - RF puncture device for targeted TSP
  - Long supportive wire to advance the MitraClip™ sheath
- Case series demonstrates the safety and feasibility of targeted TSP using the **VersaCross™** RF Transseptal Solution in under 5 min.
- Outcomes suggest a potential improvement in procedural efficiency using the **VersaCross™** RF Transseptal Solution.

Transseptal Time for MitraClip™ Procedures

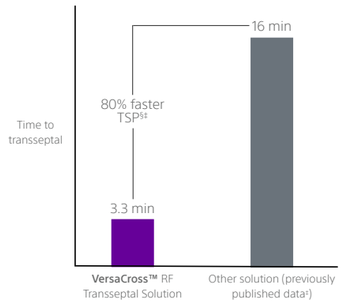

Figure 1. TSP time for MitraClip™ procedures reported by Sayah et al using the **VersaCross™** RF Transseptal Solution is 80% faster, as compared to previously published data.‡§

* From femoral access; based on 3.3 min for TSP and 3.8 min for subsequent MitraClip™ guide exchange.

† A wholly-owned subsidiary of Boston Scientific Corporation.

‡ Results from different clinical investigations are not directly comparable. Information provided for educational purposes only. Sayah et al compared the time to transseptal puncture in their case series to data previously published by Maisano et al.[5]

§ Maisano, et al. Transseptal access for MitraClip™ procedures using surgical diathermy under echocardiographic guidance. EuroIntervention. 2012;8(5):579-86.

EP-1557902-AA

Highlights from:
T. A. Dewland, MD, E. P. Gerstenfeld, MD, J. D. Moss, MD, A. C. Lee, MBBS, V. Vedantham, MD, PhD, R. J. Lee, MD, PhD, Z. H. Tseng, MD, MAS, H. H. Hsia, MD, B. K. Lee, MD, MAS, G. C. Wall, BA, K. R. Chang, BS, M. H. Yang, BS, and G. M. Marcus, MD, MAS
Dewland et al., JACC Clinical Electrophysiology, Nov 2022 DOI: 10.1016/j.jacep.2022.10.017

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Randomized comparison of a radiofrequency wire versus a radiofrequency needle system for transseptal puncture

HIGHLIGHTS

- RF wire-based transseptal technique resulted in a faster time to transseptal puncture, with fewer equipment exchanges, compared to an RF-needle-based workflow.

INTRODUCTION

- The overall efficiency and safety of many electrophysiology and structural interventions are dependent on the success of the transseptal puncture (TSP), which can be improved using radiofrequency (RF) energy.
- The **VersaCross™** RF solution (Baylis Medical*) system uses a single RF wire to position the TSP assembly into the superior vena cava (SVC), perform RF TSP, and then lead the TSP assembly into the left atrium (LA), eliminating the need for a transseptal needle and wire/needle exchange.
- The WIRE-IT (**W**ire **I**nstrumentation with **R**F **E**nergy to **I**mpact **T**SP) is a randomized controlled trial comparing the use of a standard needle-based workflow to the **VersaCross™** wire based-workflow in patients undergoing left atrial catheter ablation.

METHODS

- Single-center single-blinded randomized trial comparing efficacy and safety of two TSP workflows:
  - **NRG™** needle-based workflow: TSP was performed using an **NRG™** transseptal needle (Baylis Medical*) with an Agilis™ NXT (Abbott) or Vizigo™ (Biosense Webster) steerable sheath. In some cases, a second TSP was performed using a separate **NRG™** transseptal needle with an SL1™ sheath (Abbott).
  - **VersaCross™** wire-based workflow: TSP performed using a **VersaCross™** pigtail RF transseptal wire with a **VersaCross™ Steerable Sheath**. A second TSP was performed using the same RF wire and an 8.5F fixed curve **VersaCross™ Transseptal Sheath**.
- **Primary outcome:** Time to first TSP from wire insertion to removal of the dilator and transseptal needle or wire after LA access.
- **Secondary outcome:** Times to second and combined TSP, TSP fluoroscopy time, number of equipment exchanges, and complications.

RESULTS

- 75 patients underwent TSP using either the **NRG™** needle-based workflow (n=36) or the **VersaCross™** wire-based workflow (n=39).
- Double TSP was performed in 83% of participants in the needle workflow group vs. 90% in the wire workflow group (p=0.41). Device exchanges were not required for TSP or repositioning on the septum.
- The wire-based workflow resulted in 25% shorter time to first TSP compared to the needle-based workflow (p=0.03, Figure 1A).
- 29% shorter time to second TSP (median 6.0 [IQR: 4.9-7.8] min vs. 8.4 [IQR: 5.5-13.4] min, p=0.04) and 32% shorter combined TSP time (p=0.007) in the wire-based workflow compared to needle-based workflow (Figure 1B).
- Lower trend (30%, p=0.06) for overall TSP fluoroscopy time for the wire-based workflow vs. the needle-based workflow (Figure 1C).
- More equipment exchanges in the needle-based workflow (one) compared to the wire-based workflow (none) for first TSP; 28% of needle-based workflow patients required two or more exchanges on the first TSP.
- No complications in the wire-based workflow compared to one transient ventricular asystole due to atrioventricular (AV) block in the needle-based workflow (mechanical injury to the AV node caused by the steerable sheath).

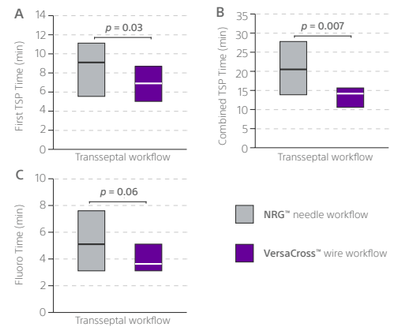

Figure 1. Outcomes following randomization to **NRG™** needle-based workflow or **VersaCross™** wire-based workflow in patients undergoing double TSP for left atrial catheter ablation. A) First TSP time, B) Combined TSP time, C) Overall fluoroscopy time. Values are the median ± interquartile range (IQR).

DISCUSSION & CONCLUSIONS

- **VersaCross™** wire-based workflow resulted in shorter time to TSP and fewer device exchanges, eliminating guidewire removal, sheath flushing, and needle insertion after positioning in SVC.
- **VersaCross™** wire-based workflow allowed easy repositioning for TSP assembly without rewiring to optimize TSP location.
- TSP procedural variability was limited with **VersaCross™** wire-based workflow (smaller IQRs) resulting in a more consistent experience and an overall positive procedural efficiency.

*A wholly-owned subsidiary of Boston Scientific Corporation.

EP-1519202-AA

Clinical Evidence

Highlights from:
Nils Perrin, MD, Cameron McAlister, MD, Michael Tsang, MD, Blandine Mondésert, MD, Réda Ibrahim MD, Jaqueline Saw, MD Perrin et al., Catheter Cardiovasc Interv, Nov 2022 DOI: 10.1002/ccd.30503

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Procedural simplification of left atrial appendage occlusion using the VersaCross connect system: First in-human experience

HIGHLIGHTS

- First in-human experience using the **VersaCross Connect**™ LAAC Access Solution for **WATCHMAN FLX**™ implantation was successful in all patients with no procedural complications.
- **VersaCross Connect**™ improved procedure efficiency and saved six steps compared to the standard needle-based workflow.

INTRODUCTION

- Left atrial appendage closures (LAAC) traditionally require several device exchanges from transseptal puncture (TSP) to device delivery.
- The new **VersaCross Connect**™ LAAC Access Solution (Baylis Medical*) is designed to integrate with the **WATCHMAN FLX**™ delivery sheath (Boston Scientific) to access the left atrium (LA).
- This study reports the first in-human experience using the **VersaCross Connect**™ LAAC Access Solution.

METHODS

- Prospective case series using the **VersaCross Connect**™ system for **WATCHMAN FLX**™ LAAC device at two different centers.
- Preprocedural planning involved cardiac computed tomography for all patients and all LAAC procedures were guided by transesophageal echocardiography (TEE).
- After vascular access, the **VersaCross Connect**™ system, comprised of the **VersaCross**™ RF Wire and the **VersaCross Connect**™ dilator, was used in conjunction with the WATCHMAN sheath to canulate the superior vena cava (SVC), and perform infero-posterior TSP to access the LA (Figure 1).
- The WATCHMAN sheath was placed in the left atrial appendage (LAA) over the pigtail **VersaCross**™ RF Wire for **WATCHMAN FLX**™ device placement.

RESULTS

- Nine consecutive cases of **WATCHMAN FLX**™ LAAC were performed using the **VersaCross Connect**™ system.
- LAAC was successful in 100% of patients with no procedural complications.
  - Time from TSP to **WATCHMAN FLX**™ release was 12.2 ± 1.9 min.
  - Overall procedure time was 31 ± 6.3 min.
  - Fluoroscopy time was 6.7 ± 4.9 min.
- The **VersaCross Connect**™ system was directly inserted into the right femoral vein in all but one patient.

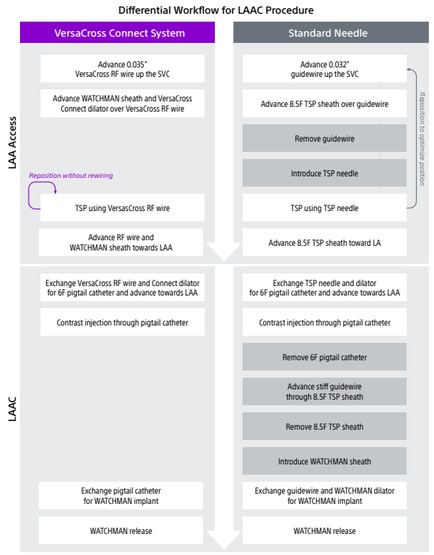

Figure 1. VersaCross Connect™ LAAC Access Solution (Baylis Medical*) eliminates six steps from **WATCHMAN FLX**™ (Boston Scientific) LAAC procedures compared to standard needle workflow. LA: left atria. LAAC: left atrial appendage closure. RF: radiofrequency. SVC: superior vena cava. TSP: transseptal puncture

DISCUSSION & CONCLUSIONS

- Streamlining LA access and simplifying LAAC procedures by eliminating multiple sheath exchanges can reduce the risk of air embolism and perforation.
- Short overall procedure time (31 min) and interval between LAA access and device deployment (12 min) were observed with the **VersaCross Connect**™ Access Solution system.
- The **VersaCross Connect**™ LAAC Access Solution allowed for safer and more efficient **WATCHMAN FLX**™ LAAC procedures.

*A wholly-owned subsidiary of Boston Scientific Corporation.

EP-1508701-AB

Highlights from:
Gaurav Sharma, MD, Gagan D. Singh, MD, Thomas W. Smith, MD, Dali Fan, MD, Reginald I. Low, MD, and Jason H. Rogers, MD

Poster #703 at Transcatheter Cardiovascular Therapeutics, San Francisco, CA, Oct 2015
Sharma et al., Catheter Cardiovasc. Interv., May 2016 DOI: 10.1002/ccd.26608

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Accuracy and Procedural Characteristics of Standard Needle Compared with Radiofrequency Needle Transseptal Puncture for Structural Heart Interventions

INTRODUCTION

- This retrospective, single-center study compared the performance and accuracy of a mechanical needle and the **NRG™** RF Transseptal Needle (Baylis Medical*) in gaining left-sided access via transseptal puncture in 52 structural heart procedures, including left atrial appendage occlusions and mitral valve repairs.

RESULTS

- The punctures attempted using the unassisted mechanical needle were successful in 88% of cases while the **NRG™** RF Needle was successful in 100% of cases (Figure 1). Two cases in which the mechanical needle failed required crossover to the **NRG™** RF Needle to achieve successful transseptal puncture.
- The average extent to which the septum was tented was reduced by 51% with the **NRG™** RF Needle compared to the mechanical needle (Figure 2, p<0.05).

DISCUSSION AND CONCLUSIONS

- The **NRG™** RF Needle resulted in a higher overall transseptal puncture success rate, decreased puncture time, and reduced tenting.

Successful Punctures

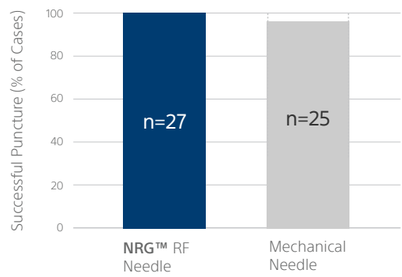

Figure 1. Successful transseptal punctures performed with the **NRG™** RF Needle vs. an unassisted mechanical needle.

Tenting Distance

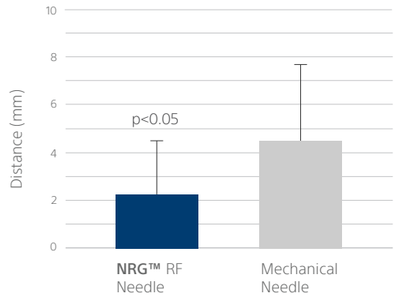

Figure 2. Pre-to-maximum tenting at the transseptal site using the **NRG™** RF Needle vs. a mechanical needle (p<0.05).

* A wholly-owned subsidiary of Boston Scientific Corporation.

EP-1583405-AA

Clinical Evidence

Highlights from:
Michael J. Rinaldi, MD, FACC, FSCAI, Markus Scherer, MD, FACC, FSCCT, William Downey, MD, FACC, FSCAI, and Geoffrey Rose, MD, FACC, FASE

Rinaldi et al., Cardiac Interventions Today, p.25-29, Mar/Apr 2014

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Site-Specific Transseptal Puncture for Emerging Structural Heart Interventions

INTRODUCTION

- This article reviews the importance of precision in transseptal puncture to optimize left-sided structural heart procedures such as mitral valve (MV) repair, left atrial appendage (LAA) occlusion, and mitral paravalvular leak closure. In addition, the article discusses the importance of guidance by various views on transesophageal echocardiography (TEE) and intracardiac echocardiography (ICE) and how these imaging modalities help guide site-specific transseptal puncture for structural heart interventions.

METHODS

- A slightly superior-posterior transseptal puncture (Figure 1) optimizes the MitraClip™ procedure to achieve the adequate 3.5–4 cm height above the MV annulus.
- A posterior and mid to slightly inferior transseptal puncture (Figure 1) optimizes the LAA procedure to enhance the coaxial sheath orientation towards the LAA.

DISCUSSION AND CONCLUSIONS

- Repeat transseptal punctures can result in a thick and fibrotic septum, making subsequent transseptal punctures challenging. The **NRG™** Transseptal Needle (Baylis Medical*) provides added value to these cases by providing targeted RF delivery for safe passage into the left atrium without needing the force required with mechanical needles.
- Precision in transseptal puncture is critical for success in many structural heart procedures.

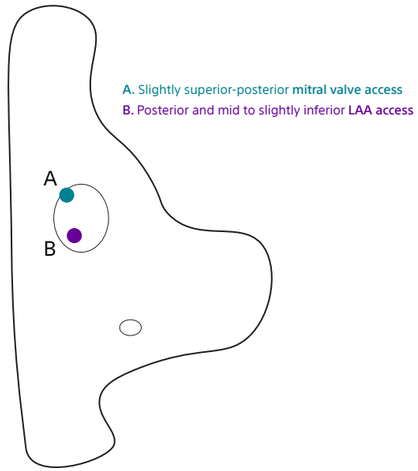

Figure 1. Approximate transseptal puncture locations on the fossa ovalis for structural heart procedures (right anterior oblique view).

* A wholly-owned subsidiary of Boston Scientific Corporation.

EP-1613706-AA

Highlights from:
Marius Bohnen, Jan Minners, Martin Eichenlaub, Reinhold Weber, Hans-Jürgen Allgeier, Amir Jadidi, Franz-Josef Neumann, Dirk Westermann, Thomas Arentz, and Heiko Lehrmann

Bohnen et al., Europace, Jan 2023 DOI: 10.1093/europace/euac262

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Feasibility and safety of a three-dimensional anatomic map–guided transseptal puncture for left-sided catheter ablation procedures

HIGHLIGHTS

- Transseptal puncture: Zero fluoro, zero compromise.
- Completely fluoroless TSP for PVI point-by-point ablation is feasible with the **NRG™** Transseptal Needle.
- First study validating feasibility and safety of stand-alone 3D mapping-guided TSP using the **NRG™** Transseptal Needle, which might be relevant in the context of European workflow (often without echo-guidance).

INTRODUCTION

- Transesophageal and intracardiac echocardiography (TEE and ICE) can be used to reduce radiation exposure and risks of inadvertent puncture; however, they can be associated with their own risks and added costs.
- This study assessed the feasibility and safety of three-dimensional (3D) mapping-guided Transseptal Puncture (TSP) using the **NRG™** Transseptal Needle (Baylis Medical*).

METHODS

- Prospective single-center feasibility study in patients undergoing radiofrequency (RF) ablation for paroxysmal or persistent atrial fibrillation.
- CARTO® 3 Electroanatomic Mapping System (Biosense Webster) was used to visualize:
  - Circular Mapping Catheter (Lasso®, Biosense Webster) for creation of right atrial (RA) map and identification of fossa ovalis (FO) (protrusion technique)
  - RF Ablation Catheter (ThermoCool Smarttouch®, Biosense Webster)
- TSP was performed using the RF **NRG™** Transseptal Needle connected via a pinbox to the 3D mapping system – defined as a bipolar catheter – for real time visualization.
  - The operator was first blinded for positioning on the FO. TEE was then used to confirm TSP site on the FO before applying RF energy (TEE unblinding)
  - Puncture position was assessed using a scoring system (good, adequate, out-of-FO, or dangerous)
- Anatomical parameters: 3D map vs TEE calculated FO area (mm^2), 5% atrial septal aneurysm, and 13% patent foramen ovale.

RESULTS

- TSP was performed in 104 patients following 3D RA mapping to identify the FO. The latter was achieved using the protrusion technique.
- Reliable identification of FO in 98% of patients (n=102), with majority showing good and adequate positioning after TEE unblinding (Figure 1).
  - Failure in the remaining two cases was attributed to thickened and fibrous interatrial septum
- Successful TSP was achieved in 97% of 3D map-guided attempts, with no TSP-related complications, and in 99% of all fluoroless attempts (Figure 1).
  - Four attempts with adequate positioning required further adjustment prior to TSP and one attempt required fluoroscopy to confirm the presence of unusual anatomy
- Secure guidewire position within the left pulmonary vein (PV) was confirmed using fluoroscopy and TEE in 57% and 43% of attempts, respectively.
  - Completely fluoroless TSP was more commonly achieved in the second half versus the first half of the cohort (60% attempts vs 28% attempts, respectively, p=0.003)

DISCUSSION AND CONCLUSIONS

- 3D map-guided TSP is feasible and safe using the RF **NRG™** Transseptal Needle:
  - The rounded atraumatic tip allows safer exposure and visualization on the mapping system in real time compared to conventional TSP needles with sharp tips
  - The RF transseptal needle connects to existing 3D mapping systems without the added costs of TEE and ICE
- Visualized wires, such as the **VersaCross™** RF Wire (Baylis Medical*), can be used to overcome fluoroscopy needs for guidewire placement in the left PV and sheath crossing into the left atrium.

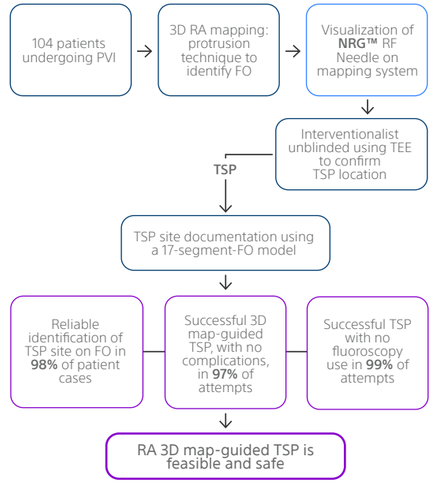

Figure 1. Graphical summary of study workflow and main findings. TSP: Transseptal Puncture. FO: Fossa Ovalis. 3D: Three-Dimensional. RA: Right Atria. TEE: Transesophageal Echocardiography. PVI: Pulmonary Vein Isolation. RF: Radiofrequency.

* A wholly-owned subsidiary of Boston Scientific Corporation.

EP-1559402-AA

Clinical Evidence

Highlights from:
Sanchez J. M., MD, Shah R., PharmD, Kouassi Y., PharmD, Chronowic M., MSc, Wilson L., PhD, and Marcus G. M., MD, MAS

Sanchez et al., Journal of Cardiovascular Electrophysiology, Volume 31, Issue 7, Jul 2020 DOI: 10.1111/jce.14500

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A Cost-Effectiveness Analysis Comparing a Conventional Mechanical Needle to a Radiofrequency Device for Transseptal Punctures

INTRODUCTION

- Previous studies have demonstrated that use of a dedicated radiofrequency (RF) transseptal puncture (TSP) device (**NRG™** Transseptal Needle, Baylis Medical*) is associated with reductions in transseptal complications, failures to cross the septum, and transseptal access time, as compared to use of a mechanical transseptal needle (BRK™, Abbott).
- While the upfront cost of the RF TSP device is more than the mechanical needle, the cost-effectiveness of the two options has not previously been evaluated.

METHODS

- A decision tree was prepared to evaluate the cost-effectiveness of the RF TSP device and the mechanical needle, as used during pulmonary vein isolation (PVI) procedures, in three different clinical scenarios: single TSP with one device (base case), double TSP with one device, and double TSP with two devices.
- Probability and clinical cost inputs were located in peer-reviewed literature and healthcare databases, while costs of TSP materials were obtained from the University of California, San Francisco electrophysiology lab.
- The total cost at 30 days was the sum of PVI procedure costs and costs of TSP-related complications.
- Effectiveness was defined as probability of survival at day 30 following TSP success.
- Incremental cost-effectiveness ratios (ICER) were calculated for these four scenarios.
- One-way and Monte-Carlo probabilistic sensitivity analyses were then performed, with the latter used to prepare a cost-effectiveness acceptability curve (CEAC).

RESULTS

- The cost-effectiveness rankings of the four scenarios are shown in Table 1.
- In all scenarios the RF TSP device was found to be dominant, as compared to the mechanical needle.
- The probabilistic sensitivity analysis and CEAC found that the RF TSP device was more cost-effective at any willingness-to-pay threshold.

DISCUSSION AND CONCLUSIONS

- When all costs are accounted for, the RF TSP device is less costly and more effective than the mechanical needle, despite a greater upfront equipment cost.
- The modified base case analysis suggested that the shorter time-to-transseptal with the RF TSP device may further increase cost savings, which may enable faster lab turn-over and more efficient use of personnel and space.
- It is noted that variations in procedural and equipment costs between centers could influence the level of dominance or cost-effectiveness reported.

Table 1. Cost-Effectiveness of RF TSP device compared to mechanical needle

Scenario	Incremental Total Cost at 30 Days for RF TSP device ($)†	Incremental Effectiveness at 30 Days for RF TSP Device (%)†	ICER‡
Single TSP with 1 device (base case)	-41	+0.9	Dominant
Double TSP with 1 device	-338	+1.1	Dominant
Double TSP with 2 devices	-158	+1.1	Dominant
Single TSP with 1 device (modified base case, with PVI costs adjusted for transseptal time savings)	-774	+0.9	Dominant

* A wholly-owned subsidiary of Boston Scientific Corporation.
† As compared to mechanical transseptal needle
‡ The term "Dominant" indicates a device was associated with higher effectiveness and lower cost TSP denotes transseptal puncture; RF, radiofrequency; ICER, incremental cost-effectiveness ratio; PVI, pulmonary vein isolation

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Economic Value

Economic Value

Clinical studies have highlighted the reliability and consistency provided by Boston Scientific purpose-built RF Transseptal systems (RF needle, RF wire, RF generator) by demonstrating advanced transseptal performance (Table 2).

As such, these purpose-built RF systems enable interventional programs to:

- **Increase** operational efficiencies.
- **Optimize** patient scheduling and throughput.
- **Strengthen** quality outcomes.
- **Enhance** patient experience.
- **Improve** financial health.

Efficiency	Predictability	Safety	Cost-Effectiveness
Allows for reduced and more consistent transseptal access time vs. a mechanical needle[1,2,3]	Improves the efficacy and predictability of transseptal crossing vs. a mechanical needle[1,2,3]	Has been associated with reduced incidence of cardiac tamponade, pericardial effusion, and silent acute cerebral embolism vs. a mechanical needle[1,4,5]	Purpose-built RF systems have been demonstrated to be cost-effective vs. mechanical transseptal needles.6*
Promotes a reduction in fluoroscopy time vs. TSP procedures performed with a mechanical needle[2,5,7]	Provides quicker and more precise site-specific crossing of the interatrial septum in cryoballoon (large bore catheter) cases[8]	Requires less force/tenting for targeted transseptal crossing in challenging septal anatomy and large-bore mitral cases[9]	
		Reduces the incidence of tissue coring vs. electrified mechanical needles[10]	

Table 2. Summary of clinical evidence for advanced performance of purpose-built RF puncture solutions.

* Cost-effectiveness analysis compared costs/outcomes of NRG RF needles to mechanical transseptal needles. Results may vary when comparing other devices.

1. 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;8(9):1411-1415. doi:10.1016/j.hrthm.2011.04.032
2. Inohara T, Gilhofer T, Luong C, Tsang M, Saw J. VersaCross radiofrequency system reduces time to left atrial access versus conventional mechanical needle. J Interv Card Electrophysiol. 2022;63(1):9-12. doi:10.1007/s10840-020-00931-7
3. Hsu JC, Badhwar N, Gerstenfeld EP, et al. Randomized trial of conventional transseptal needle versus radiofrequency energy needle puncture for left atrial access (the TRAVERSE-LA study). J Am Heart Assoc. 2013;2(5):e000428. Published 2013 Sep 17. doi:10.1161/JAHA.113.000428
4. 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;24(2):173-178. doi:10.1016/j.hlc.2014.07.073
5. Tokuda M, Yamashita S, Matsuo S, et al. Radiofrequency needle for transseptal puncture is associated with lower incidence of thromboembolism during catheter ablation of atrial fibrillation: propensity score-matched analysis. Heart Vessels. 2018;33(10):1238-1244. doi:10.1007/s00380-018-1159-8
6. Sanchez JM, Shah R, Kouassi Y, Chronowic M, Wilson L, Marcus GM. A cost-effectiveness analysis comparing a conventional mechanical needle to a radiofrequency device for transseptal punctures. J Cardiovasc Electrophysiol. 2020;31(7):1672-1677. doi:10.1111/jce.14500
7. Demo H, Aranda C, Razminia M. Fluoroless left atrial access for radiofrequency and cryoballoon ablations using a novel radiofrequency transseptal wire [published correction appears in J Interv Card Electrophysiol. 2022 Mar 29;:]. J Interv Card Electrophysiol. 2022;64(1):183-190. doi:10.1007/s10840-022-01157-5
8. Andrade JG, Macle L, Bennett MT, et al. Randomized trial of conventional versus radiofrequency needle transseptal puncture for cryoballoon ablation: the CRYO-LATS trial. J Interv Card Electrophysiol. 2022;65(2):481-489. doi:10.1007/s10840-022-01277-y
9. Smelley MP, Shah DP, Weisberg I, et al. Initial experience using a radiofrequency powered transseptal needle. J Cardiovasc Electrophysiol. 2010;21(4):423-427. doi:10.1111/j.1540-8167.2009.01656.x
10. Greenstein E, Passman R, Lin AC, Knight BP. Incidence of tissue coring during transseptal catheterization when using electrocautery and a standard transseptal needle. Circ Arrhythm Electrophysiol. 2012;5(2):341-344. doi:10.1161/CIRCEP.111.968040

Ordering Information

Note: UPNs shown are effective as of March 10, 2025

VersaCross™ Access Solution with J-Tip RF Wire

Product Code	Product Specifications					Barcode
	RF Wire		Transseptal Sheath		Dilator	
VXSK0101	J-tip	180 cm	63 cm	45°	D0	
VXSK0102	J-tip	180 cm	63 cm	45°	D1	
VXSK0103	J-tip	180 cm	63 cm	55°	D0	
VXSK0104	J-tip	180 cm	63 cm	55°	D1	
VXSK0106	J-tip	180 cm	63 cm	90°	D1	
VXSK0111	J-tip	230 cm	63 cm	45°	D0	
VXSK0112	J-tip	230 cm	63 cm	45°	D1	

Note: UPNs shown are effective as of March 10, 2025

VersaCross™ Access Solution with Pigtail RF Wire

Product Code	Product Specifications					Barcode
	RF Wire		Transseptal Sheath		Dilator	
VXSK0121	Pigtail	180 cm	63 cm	45°	D0	
VXSK0122	Pigtail	180 cm	63 cm	45°	D1	
VXSK0123	Pigtail	180 cm	63 cm	55°	D0	
VXSK0124	Pigtail	180 cm	63 cm	55°	D1	
VXSK0125	Pigtail	180 cm	63 cm	90°	D0	
VXSK0131	Pigtail	230 cm	63 cm	45°	D0	
VXSK0132	Pigtail	230 cm	63 cm	45°	D1	
VXSK0133	Pigtail	230 cm	63 cm	55°	D0	
VXSK0134	Pigtail	230 cm	63 cm	55°	D1	
VXSK0137	Pigtail	230 cm	81 cm	45°	D0	

Ordering Information

Note: UPNs shown are effective as of March 10, 2025

VersaCross™ Steerable Access Solution with J-Tip RF Wire

Product Code	Product Specifications					Barcode
	RF Wire		Transseptal Sheath		Dilator	
VSTK0102	J-tip	180 cm	72 cm	L	D1	
VSTK0103	J-tip	180 cm	72 cm	M	D0	
VSTK0104	J-tip	180 cm	72 cm	M	D1	
VSTK0106	J-tip	180 cm	72 cm	S	D1	

Note: UPNs shown are effective as of March 10, 2025

VersaCross™ Steerable Access Solution with Pigtail RF Wire

Product Code	Product Specifications					Barcode
	RF Wire		Transseptal Sheath		Dilator	
VSTK0114	Pigtail	180 cm	72 cm	L	D1	
VSTK0115	Pigtail	180 cm	72 cm	M	D0	
VSTK0116	Pigtail	180 cm	72 cm	M	D1	
VSTK0117	Pigtail	180 cm	72 cm	S	D0	
VSTK0118	Pigtail	180 cm	72 cm	S	D1	
VSTK0120	Pigtail	230 cm	72 cm	L	D1	
VSTK0121	Pigtail	230 cm	72 cm	M	D0	
VSTK0122	Pigtail	230 cm	72 cm	M	D1	
VSTK0123	Pigtail	230 cm	72 cm	S	D0	
VSTK0124	Pigtail	230 cm	72 cm	S	D1	

Ordering Information

Note: UPNs shown are effective as of March 10, 2025

VersaCross™ Large Access Solution

Product Code	Product Specifications				Barcode
	RF Wire		Transseptal Dilator		
VLAK0102	J-tip	180 cm	67 cm	D1	
VLAK0109	Pigtail	180 cm	67 cm	D0	
VLAK0110	Pigtail	180 cm	67 cm	D1	
VLAK0113	Pigtail	230 cm	67 cm	D0	
VLAK0114	Pigtail	230 cm	67 cm	D1	

Note: UPNs shown are unchanged (effective prior to March 10, 2025)

VersaCross Connect™ Access Solution for POLARSHEATH™ Steerable Sheath

Product Code	Product Specifications				Barcode
	RF Wire		Transseptal Dilator		
VXAK0035	J-tip	180 cm	84 cm	D1	
VXAK0031	Pigtail	180 cm	84 cm	D1	

Note: UPNs shown are effective as of March 10, 2025

VersaCross Connect™ Access Solution for WATCHMAN™ Access Systems

Product Code	Product Specifications				Barcode
	RF Wire		Transseptal Dilator		
VXAK0109	J-tip	180 cm	85 cm	D0	
VXAK0101	Pigtail	180 cm	85 cm	D0	
VXAK0103	Pigtail	180 cm	85 cm	D1	
VXAK0105	Pigtail	230 cm	85 cm	D0	
VXAK0107	Pigtail	230 cm	85 cm	D1	

Note: UPNs shown are unchanged (effective prior to March 10, 2025)

VersaCross Connect™ Access Solution for FARADRIVE™ Steerable Sheath

Product Code	Product Specifications				Barcode
	RF Wire		Transseptal Dilator		
VXAK0045	J-tip	180 cm	93 cm	D1	
VXAK0041	Pigtail	180 cm	93 cm	D1	

Ordering Information

Note: UPNs shown are effective as of March 10, 2025

VersaCross™ Transseptal Sheath

Product Code	Product Specifications			Barcode
	Transseptal Sheath		Dilator	
VXS0201	63 cm	45°	D0	
VXS0202	63 cm	45°	D1	
VXS0203	63 cm	55°	D0	
VXS0204	63 cm	55°	D1	
VXS0206	63 cm	90°	D1	

Note: UPNs shown are effective as of March 10, 2025

VersaCross™ Steerable Sheath

Product Code	Product Specifications			Barcode
	Steerable Sheath		Dilator	
VST0205	72 cm	S	D1	
VST0202	72 cm	M	D0	
VST0203	72 cm	M	D1	
VST0201	72 cm	L	D1	

VersaCross™ RF Wire

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner. Rx only. Prior to use, please refer to all applicable "Instructions for Use" for more information on Intended Use/ Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator's Instructions. **INTENDED USE/INDICATIONS FOR USE:** The VersaCross™ RF Wire is indicated for creation of an atrial septal defect in the heart. **CONTRAINDICATIONS:** The VersaCross™ RF Wire is not recommended for use with any conditions that do not require the creation of an atrial septal defect. The Connector Cable is not recommended for use with any other Baylis RF Generator or any other device. **WARNINGS:** • Only physicians with a thorough understanding of angiography and percutaneous interventional procedures should use this device. It is recommended that physicians avail themselves of pre-clinical training, a review of pertinent literature and other appropriate education before attempting new interventional procedures. • The VersaCross RF Wire and Connector Cable are 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 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. • The VersaCross RF Wire and Connector Cable are intended for single patient use only. Do not attempt to sterilize and reuse either devices. Reuse can cause patient injury and/or the communication of infectious disease(s) from one patient to another. Reuse may result in patient complications. • The VersaCross RF Wire must be used with the Connector Cable provided. Attempts to use it with other connector cables can result in electrocution of the patient and/or operator. • Do not use the VersaCross RF Wire with electrocautery or electrosurgery generators, connector cables or accessories as attempted use can result in patient and/or operator injury. • The Connector Cable must only be used with the RFP-100A Baylis RF Generator and the included VersaCross RF Wire. Attempts to use it with other RF Generators and devices can result in electrocution of the patient and/or operator. • The VersaCross RF Wire must be used with 0.035" compatible transseptal sheath and/or dilator devices. Use of incompatible accessory devices may damage the integrity of the VersaCross RF Wire or accessory devices and may cause patient injury. • The VersaCross RF Wire has only been validated for transseptal puncture use through VersaCross dilators which have been demonstrated to provide the required support for optimal function. • The active tip and distal curve of the VersaCross RF Wire are fragile. Be careful not to damage the tip or the distal curve while handling the VersaCross RF Wire. If the tip or the distal curve becomes damaged at any time during its use, discard the VersaCross RF Wire immediately. Do not attempt to straighten the active tip if bent. Damage to device can lead to patient injury. • The VersaCross RF Wire is not intended for use with neonatal patients (i.e. less than one month of age). Do not attempt to treat neonatal patients with the VersaCross RF Wire. • Do not attempt to insert or retract the VersaCross RF wire through a metal cannula or a percutaneous needle, which may damage the device and may cause patient injury. **PRECAUTIONS:** • Do not attempt to use the VersaCross RF Wire and the Connector Cable before thoroughly reading the accompanying Instructions for Use. • RF puncture procedures should be performed only by physicians thoroughly trained in the techniques of RF-powered puncture in a fully equipped catheterization laboratory. • The sterile packaging should be visually inspected prior to use. Do not use the devices if the packaging has been damaged or compromised. • Visually inspect the VersaCross RF Wire and Connector Cable prior to use to ensure there are no cracks or damage to the insulating material. Do not use the wire or the cable if there is any damage. • Do not use the VersaCross RF Wire and/or Connector Cable after the use-by date indicated on the label. • The VersaCross RF Wire and Connector Cable are intended for use with only those devices listed in Section VIII, Equipment Required. • Read and follow the manufacturer's Instructions For Use for the DIP electrode. Always use DIP electrodes that meet or exceed IEC 60601-2-2 requirements. • Placement of the DIP electrode on the thigh could be associated with higher impedance. • In order to prevent the risk of ignition, ensure that flammable materials are not present in the room during RF power application. • Take precautions to limit the effects that the electromagnetic interference (EMI) produced by the Baylis RF 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 Baylis RF Generator. • Adequate filtering must be used to allow continuous monitoring of the surface electrocardiogram (ECG) during RF power applications. • Do not attempt to insert and use the proximal end of the VersaCross RF Wire as the active tip. • Do not bend the VersaCross RF Wire or the Connector Cable. Excessive bending or kinking of the wire shaft, distal curve of the wire and/ or the Connector Cable may damage the integrity of the device components and may cause patient injury. Care must be taken when handling the VersaCross RF Wire and Connector Cable. • Careful manipulation of the VersaCross RF Wire must be performed to avoid vessel trauma. If resistance is encountered, DO NOT use excessive force to advance or withdraw the VersaCross RF Wire or ancillary sheath and/or dilator assembly. Excessive force may lead to bending or kinking of the device limiting advancement and retraction of sheath and/or dilator device. • VersaCross RF Wire and ancillary sheath and/or dilator assembly advancement should be done under imaging guidance. The use of visible markers on the wire body are only an approximate guide for positioning the wire tip with the distal end of the dilator. • Do not attempt to deliver RF energy until the active tip of the VersaCross RF Wire is confirmed to be in good contact with the target tissue. • Avoid RF energy delivery of the VersaCross RF Wire with incompatible dilator or cannula devices, which may lead to patient burns, ineffective puncture or failure to puncture. • It is recommended not to exceed five (5) RF power applications per VersaCross RF Wire. • Never disconnect the Connector Cable from the Baylis RF Generator while RF power is being delivered. • Never disconnect the Connector Cable from the Baylis RF Generator by pulling on the cable. Failure to disconnect the cable properly may result in damage to the cable. • Do not twist the Connector Cable while inserting or removing it from the Isolated Patient Connector on the Baylis RF Generator. Twisting the cable may result in damage to the pin connectors. • The Baylis RF Generator is capable of delivering significant electrical power. Patient or operator injury can result from improper handling of the VersaCross RF Wire and/or 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 active tip of the VersaCross RF Wire against the atrial septum. Only increase the power if low power output persists. • If using electroanatomical mapping guidance, it is recommended to use it along with alternative imaging modality in the event there is loss of visibility of the device. **POTENTIAL ADVERSE EVENTS:** Adverse events that may occur while creating an atrial septal defect 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 • Arteriovenous fistula • Pericardial/pleural effusion • Tachycardia • Vascular Trauma • Additional Surgical Procedure • Wire entrapment/Entanglement • Foreign body/wire fracture 97184047 (Rev. C.5)

VersaCross™ Transseptal 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 VersaCross™ Transseptal 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 VersaCross Transseptal Sheath kit is intended for single patient use only. Do not attempt to sterilize and reuse the VersaCross Transseptal Sheath kit. Reuse can cause patient injury and/or the communication of infectious disease(s) from one patient to another. • The VersaCross Transseptal 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. o Manual shaping of the sheath distal curve shall be done with smooth motions along the curve without applying excessive pressure. Excessive manual bending and/or shaping of the sheath shaft may affect the coating integrity. • 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. • Damage to guidewire may result if withdrawn through a metal needle cannula. • Careful manipulation must be performed to avoid cardiac damage or tamponade. Sheath advancement should be done under fluoroscopic guidance. Echocardiographic guidance is also recommended. • 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. **PRECAUTIONS:** • Do not attempt to use the VersaCross Transseptal 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 VersaCross Transseptal Sheath is compatible with introducer sheaths 11Fr or larger. • The VersaCross Transseptal Sheath and Dilator are compatible with transseptal devices and guidewires .035" or smaller. • The VersaCross Transseptal Sheath kit is NOT compatible with transseptal needles such as the "NRGTM Transseptal Needle". • 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 VersaCross™ Transseptal 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 97184142 (Rev. A.1)

VersaCross™ Steerable 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 VersaCross™ Steerable Sheath kit is indicated for introducing various cardiovascular catheters to the heart, including the left side of the heart through the interatrial septum. **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 VersaCross Steerable Sheath kit is intended for single patient use only. Do not attempt to sterilize and reuse the VersaCross Steerable Sheath kit. Reuse can cause the patient injury and/or the communication of infectious disease(s) from one patient to another. • 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. • Maintain continuous hemodynamic monitoring throughout procedure • Provide continuous heparinized saline infusion while the introducer remains in vessel. • To minimize vacuum effects during withdrawal, remove components/aspirate slowly. Refrain from aspiration if a wire is directly through the valve. • Avoid contact with liquids other than blood, isopropyl alcohol, contrast solution or saline. • Prior to steerable sheath's delivery and removal, ensure distal section is as straight as possible. • Do not kink, stretch or severely bend steerable sheath. • Do not use surgical instruments to handle sheath. • The sheath device shaft in its entirety is coated with a hydrophobic lubricious coating for smoother device manipulation. The following warning must be considered: o Excessive wiping and/or wiping with a dry gauze may damage the coating. • The 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. **PRECAUTIONS:** • Do not attempt to use the VersaCross Steerable 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 VersaCross Steerable Sheath kit is supplied STERILE using an ethylene oxide process. • The sterile packaging and all components should be visually inspected prior to use. Do not use if the device, packaging or sterile barrier have been compromised or damaged. • Only physicians thoroughly trained in the techniques of the approach to be used should perform interventional procedures. • Do not use device after its "Use By" date. • Avoid deflecting distal end of sheath during delivery and removal, otherwise damage to vessels may occur. • The VersaCross Steerable Sheath kit is not compatible with transseptal needles such as the "NRGTM Transseptal Needle". • 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 VersaCross™ Sheath include: • Infection • Air embolus • Local nerve damage • Vasovagal reaction • Dissection • Vessel spasm • AV fistula formation • Atrial septal defect • Pseudoaneurysm • Aortic puncture • Arrhythmias • Perforation and/or tamponade • Hematoma • Hemorrhage • Catheter entrapment • Embolic events • Stroke • Valve damage • Myocardial infarction • Pericardial/pleural effusion • Pulmonary edema • Coronary artery spasm and/or damage • Vessel trauma • Pacemaker/defibrillator lead displacement 97184084 (Rev. A.1)

VersaCross™ Large Access Transseptal Dilator

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 VersaCross™ Large Access Transseptal Dilator is indicated for use in procedures where access to the left atrium via the transseptal technique is desired. **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 VersaCross Large Access Transseptal Dilator and accompanying guidewire are intended for single patient use only. Do not attempt to sterilize and reuse the VersaCross Large Access Transseptal Dilator or accompanying guidewire. Reuse can cause the patient injury and/or the communication of infectious disease(s) from one patient to another. Failure to do so may results in patient complications. • The Mechanical Guidewire is coated with a lubricious coating. The following warnings must be considered: i. Use with incompatible introducers or dilators may affect device performance and integrity, including coating integrity ii. Excessive manual bending and/or shaping of the device may affect the coating integrity" • The VersaCross Large Access Transseptal Dilator and accompanying guidewire are supplied STERILE using an ethylene oxide process. Do not use if the package is damaged. • The dilator shaft is coated with a lubricious coating. The following warnings must be considered: o Use with 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 with a dry gauze may damage the coating. o Manual shaping of the distal curve shall be done with smooth motions along the curve without applying excessive force and/ or pressure. Excessive manual bending and/or shaping of the shaft may affect the coating integrity. • Care should be taken to ensure that all air is removed from the dilator before infusing through the proximal hub. • Care should be taken when inserting or removing the dilator from introducer sheaths. • Care should be taken when inserting or removing compatible guidewires from the dilator lumen. • Do not attempt direct percutaneous insertion of the dilator without a guidewire as this may cause vessel injury. • Damage to guidewire may result if withdrawn through a metal needle cannula. • Careful manipulation must be performed to avoid cardiac damage or tamponade. Dilator advancement should be performed under imaging guidance. Fluoroscopic or echocardiographic imaging is recommended. **PRECAUTIONS**: • Do not attempt to use the VersaCross Large Access Transseptal Dilator or accompanying guidewire before thoroughly reading the accompanying Instructions for Use. • Careful manipulation must be performed to avoid cardiac damage, or tamponade. Dilator and guidewire advancement should be performed under imaging guidance, such as fluoroscopy or echocardiography. If resistance is encountered, DO NOT use excessive force to advance or withdraw the device. • The sterile packaging, dilator, and guidewire 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. • Note product "Use By" date. • The VersaCross Large Access Transseptal Dilator is compatible with introducer sheaths 12.5Fr or larger. • The VersaCross Large Access Transseptal Dilator is compatible with .035" transseptal devices and guidewires • The VersaCross Large Access Transseptal Dilator is NOT compatible with transseptal needles such as the "NRG™ Transseptal Needle". • 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 VersaCross™ Large Access Transseptal Dilator and accompanying guidewire include: • Infection • Air embolus • Local nerve damage • Vessel trauma • Vessel spasm • Pseudoaneurysm • AV fistula formation • Atrial septal defect • Arrhythmias • Perforation and/or tamponade • Hematoma • Hemorrhage • Catheter entrapment • Embolic events • Valve damage • Pericardial/pleural effusion 97184070 (Rev. A.1)

VersaCross Connect™ Transseptal Dilator – WATCHMAN™ Access Systems

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner. Prior to use, please refer to all applicable "Instructions for Use" for more information on Intended Use/Indications, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator's Instructions. **INTENDED USE/INDICATIONS FOR USE:** The VersaCross Connect Transseptal Dilator 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. United States: The VersaCross Connect Transseptal Dilator is indicated for use in procedures where access to the left atrium via the transseptal technique is desired. **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 VersaCross Connect Transseptal Dilator and accompanying guidewire are intended for single patient use only. Do not attempt to sterilize and reuse the VersaCross Connect Transseptal Dilator or accompanying guidewire. 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 VersaCross Connect Transseptal Dilator and accompanying guidewire are supplied STERILE using an ethylene oxide process. Do not use if the package is damaged. • Care should be taken to ensure that all air is removed from the dilator before infusing through the proximal hub. • Care should be taken when inserting or removing the dilator from access sheaths or introducer sheaths. • Manual shaping of the distal curve shall be done with smooth motions along the curve. Do not use excessive force and/or pressure when reshaping. • Care should be taken when inserting or removing compatible guidewires from the dilator lumen. • Do not attempt direct percutaneous insertion of the dilator without a guidewire as this may cause vessel injury. • Careful manipulation must be performed to avoid cardiac damage or tamponade. Dilator advancement should be performed under imaging guidance. Fluoroscopic or echocardiographic imaging is recommended. If resistance is encountered, DO NOT use excessive force to advance or withdraw the device. • 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. o 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. **PRECAUTIONS**: • Do not attempt to use the VersaCross Connect Transseptal Dilator or accompanying guidewire before thoroughly reading the accompanying Instructions for Use. • The sterile barrier system, dilator, and guidewire should be visually inspected prior to use. Do not use if the sterile barrier integrity or devices have been compromised or damaged. • Only physicians thoroughly trained in the techniques of the approach to be used should perform interventional procedures. • The VersaCross Connect Transseptal Dilator is compatible with introducer sheaths 12.5F or larger. • The VersaCross Connect Transseptal Dilator is for use with specified models of 12F ID WATCHMAN™ Access Sheath that are 75cm in length or the WATCHMAN TruSteer Access Sheath that is 67 cm in length. • The VersaCross Connect Transseptal Dilator is compatible with 0.035" transseptal devices and guidewires or smaller. • The VersaCross Connect Transseptal Dilator is NOT compatible with transseptal needles such as the "NRG™ Transseptal Needle". • 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. **POTENTIAL ADVERSE EVENTS:** Adverse events that may occur while using the VersaCross Connect Transseptal Dilator and accompanying guidewire include: • Infection • Local nerve damage • Vessel spasm • AV fistula formation • Arrhythmias • Hematoma • Catheter entrapment • Valve damage • Air embolus • Vessel trauma • Pseudoaneurysm • Atrial septal defect • Perforation and/or tamponade • Hemorrhage • Embolic events • Pericardial/pleural effusion 97184051 (Rev. D.3)

VersaCross Connect™ Transseptal Dilator – POLARSHEATH™ Steerable Sheath

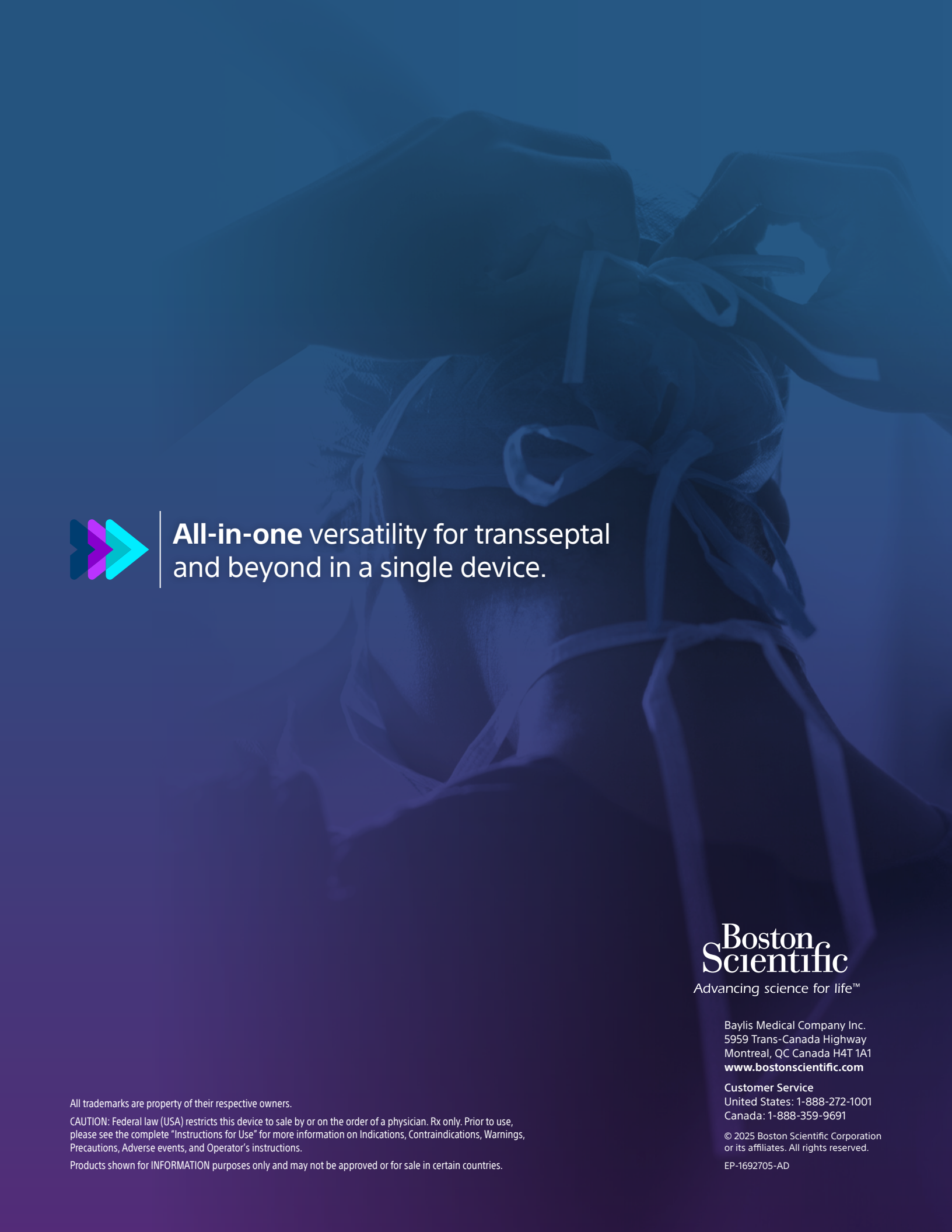
CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner. Prior to use, please refer to all applicable "Instructions for Use" for more information on Intended Use/Indications, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator's Instructions. **INTENDED USE/INDICATIONS FOR USE:** The VersaCross Connect Transseptal Dilator 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. United States: The VersaCross Connect Transseptal Dilator is indicated for use in procedures where access to the left atrium via the transseptal technique is desired. **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 VersaCross Connect Transseptal Dilator is intended for single patient use only. Failure to do so may result in patient complications. • Do not attempt to sterilize and reuse the VersaCross Connect Transseptal Dilator. Reuse can cause the patient injury and/or the communication of infectious disease(s) from one patient to another. • The VersaCross Connect Transseptal Dilator is supplied STERILE using an ethylene oxide process. Do not use if the package is damaged. • Care should be taken to ensure that all air is removed from the dilator before infusing through the proximal hub. • Care should be taken when inserting or removing the dilator from access sheaths or introducer sheaths. • Manual shaping of the distal curve shall be done with smooth motions along the curve. Do not use excessive force and/or pressure when reshaping. • Care should be taken when inserting or removing compatible guidewires from the dilator lumen. • Do not attempt direct percutaneous insertion of the dilator without a guidewire as this may cause vessel injury. • Careful manipulation must be performed to avoid cardiac damage or tamponade. Dilator advancement should be performed under imaging guidance. Fluoroscopic or echocardiographic imaging is recommended. If resistance is encountered, DO NOT use excessive force to advance or withdraw the device. **PRECAUTIONS**: • Do not attempt to use the VersaCross Connect Transseptal Dilator before thoroughly reading the accompanying Instructions for Use. • The sterile barrier system and dilator should be visually inspected prior to use. Do not use if the sterile barrier integrity or device have been compromised or damaged. • Only physicians thoroughly trained in the techniques of the approach to be used should perform interventional procedures. • The VersaCross Connect Transseptal Dilator is compatible with introducer sheaths 12.5F or larger. • The VersaCross Connect Transseptal Dilator is for use with the 12F ID POLARSHEATH™ Steerable Sheath, which is 68 cm in length. • The VersaCross Connect Transseptal Dilator is compatible with 0.035" transseptal devices and guidewires or smaller. • The VersaCross Connect Transseptal Dilator is NOT compatible with transseptal needles such as the "NRGTM Transseptal Needle". **POTENTIAL ADVERSE EVENTS:** Adverse events that may occur while using the VersaCross Connect Transseptal Dilator include: • Infection • Local nerve damage • Vessel spasm • AV fistula formation • Arrhythmias • Hematoma • Catheter entrapment • Valve damage • Air embolus • Vessel trauma • Pseudoaneurysm • Atrial septal defect • Perforation and/or tamponade • Hemorrhage • Embolic events • Pericardial/pleural effusion 97108419 (Rev. B.3)

VersaCross Connect™ Transseptal Dilator – FARADRIVE™ Steerable 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 VersaCross Connect Transseptal Dilator 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. United States: The VersaCross Connect Transseptal Dilator is indicated for use in procedures where access to the left atrium via the transseptal technique is desired. **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 VersaCross Connect Transseptal Dilator is intended for single patient use only. Failure to do so may result in patient complications. • Do not attempt to sterilize and reuse the VersaCross Connect Transseptal Dilator. Reuse can cause the patient injury and/or the communication of infectious disease(s) from one patient to another. • The VersaCross Connect Transseptal Dilator is supplied STERILE using an ethylene oxide process. Do not use if the package is damaged. • Care should be taken to ensure that all air is removed from the dilator before infusing through the proximal hub. • Care should be taken when inserting or removing the dilator from access sheaths or introducer sheaths. • Manual shaping of the distal curve shall be done with smooth motions along the curve. Do not use excessive force and/or pressure when reshaping. • Care should be taken when inserting or removing compatible guidewires from the dilator lumen. • Do not attempt direct percutaneous insertion of the dilator without a guidewire as this may cause vessel injury. • Careful manipulation must be performed to avoid cardiac damage or tamponade. Dilator advancement should be performed under imaging guidance. Fluoroscopic or echocardiographic imaging is recommended. If resistance is encountered, DO NOT use excessive force to advance or withdraw the device. **PRECAUTIONS:** • Do not attempt to use the VersaCross Connect Transseptal Dilator before thoroughly reading the accompanying Instructions for Use. • The sterile barrier system and dilator should be visually inspected prior to use. Do not use if the sterile barrier integrity or device have been compromised or damaged. • Only physicians thoroughly trained in the techniques of the approach to be used should perform interventional procedures. • The VersaCross Connect Transseptal Dilator is compatible with introducer sheaths 13F or larger. • The VersaCross Connect Transseptal Dilator is for use with the 13F (4.31 mm) ID FARADRIVE Steerable Sheath, which is 74cm in length. • The VersaCross Connect Transseptal Dilator is compatible with 0.035" transseptal devices and guidewires or smaller. • The VersaCross Connect Transseptal Dilator is NOT compatible with transseptal needles such as the "NRGTM Transseptal Needle". **ADVERSE EVENTS:** Adverse events that may occur while using the VersaCross Connect Transseptal Dilator include: • Infection • Air embolus • Local nerve damage • Vessel trauma • Vessel spasm • Pseudoaneurysm • AV fistula formation • Atrial septal defect • Arrhythmias • Perforation and/or tamponade • Hematoma • Hemorrhage • Catheter entrapment • Embolic events • Valve damage • Pericardial/pleural effusion 97157448 (Rev. A.1)

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 97185373 (Rev. A.1)



All-in-one versatility for transseptal and beyond in a single device.

Boston Scientific

Advancing science for life™

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