WATCHMAN™
INTEGRATED LAAC SOLUTIONS

Boston Scientific
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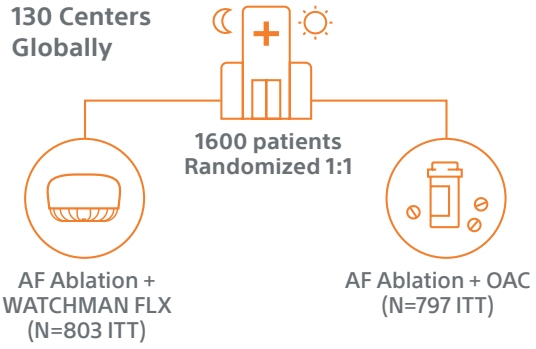
OPTION Randomized Clinical Trial: Primary Endpoints Met

The OPTION Clinical Trial is the first randomized, head-to-head study comparing LAAC to OAC (95% DOACs) after cardiac ablation to determine if LAAC with the WATCHMAN FLX™ Device is a reasonable alternative in patients after AFib ablation.†

Efficacy

Safety

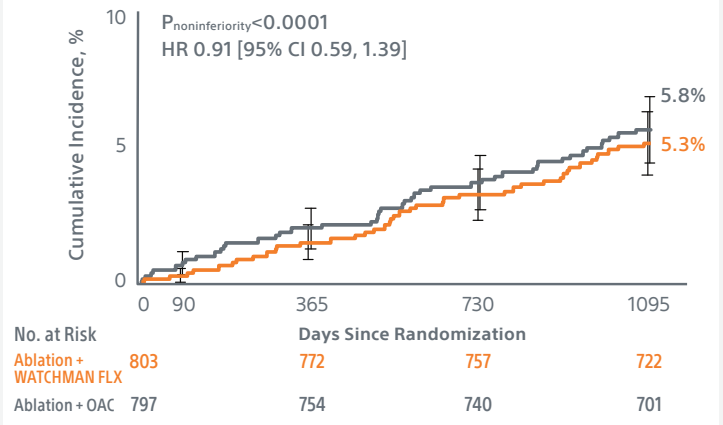
1600
Patients Randomized



Primary efficacy endpoint

WATCHMAN FLX was non-inferior for the primary efficacy endpoint of stroke, all-cause death, and systemic embolism at 36 months

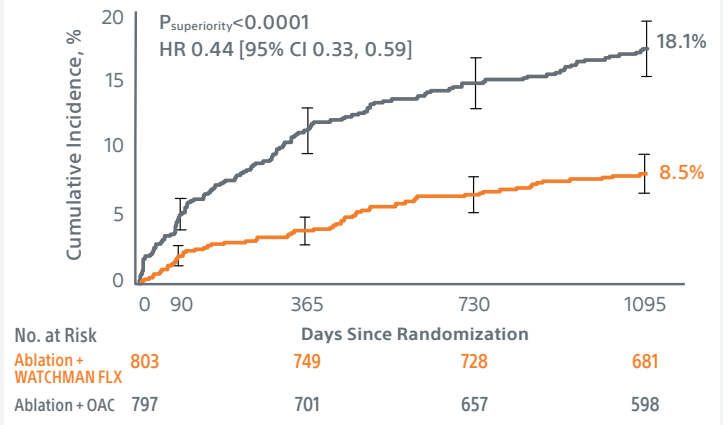
Primary Efficacy: Stroke, Mortality, Systemic Embolism



Primary safety endpoint

WATCHMAN FLX was superior for the primary safety endpoint of non-procedural bleeding* at 36 months

Primary Safety: Non-procedural Bleeding



**ISTH major and clinically relevant non-major bleeding*

WATCHMAN FLX was non-inferior for the secondary safety endpoint of ISTH major bleeding (including procedural) (HR 0.77 [95% CI 0.48, 1.24]) Pnon-inferiority<0.0001)

1.2%
cumulative ischemic stroke rate at 36 months

98.8%
LAAC success (device successfully deployed and released)

† Thermal AFib ablation only

WATCHMAN FLX is an FDA approved device being studied for an expanded indication as a first line therapy vs NOAC for NVAF patients. The use of WATCHMAN or WATCHMAN FLX as a first-line therapy for stroke risk reduction in NVAF patients is considered investigational. Caution: Investigational Device. Limited by US law to investigational use only. Not available for sale.

View NEJM Publication

Brief Summary

Intended Use

WATCHMAN FLX Pro is intended for percutaneous, transcatheter closure of the left atrial appendage.

Indications for Use

The WATCHMAN FLX Pro Device is indicated to reduce the risk of thromboembolism from the left atrial appendage in patients with non-valvular atrial fibrillation who:

- Are at increased risk for stroke and systemic embolism based on CHA_2DS_2-VASc scores and are recommended for anticoagulation therapy;
- Are deemed by their physicians to be suitable for anticoagulation therapy; and
- Have an appropriate rationale to seek a non-pharmacologic alternative to anticoagulation therapy, taking into account the safety and effectiveness of the device compared to anticoagulation therapy.

Contraindications

Do not use the WATCHMAN FLX Pro Device if:

- Intracardiac thrombus is present.
- An atrial septal defect repair or closure device is present.
- A patent foramen ovale repair or closure device is present.
- The LAA anatomy will not accommodate a Closure Device (see Step 7 in the IFU).
- The patient has a known hypersensitivity to any portion of the device material or the individual components (see Device Description section) such that the use of the WATCHMAN FLX Pro Device is contraindicated.
- Any of the customary contraindications for other percutaneous catheterization procedure (e.g., patient size too small to accommodate TEE probe or required catheters) or conditions (e.g., active infection, bleeding disorder) are present.
- There are contraindications to the use of anticoagulation therapy, aspirin, or P2Y12 inhibitor.

Warnings

Implantation of the WATCHMAN FLX Pro Device should only be performed by interventional cardiologists and/or electrophysiologists who are proficient in percutaneous procedures, transseptal procedures, the imaging modality utilized and who have completed the WATCHMAN FLX Pro Physician Training program.

- For single use only. Do not reuse, reprocess, or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the Closure Device and/or lead to Closure Device failure which, in turn, may result in patient injury, illness, or death. Reuse, reprocessing, or resterilization may also create a risk of contamination of the Closure Device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the Closure Device may lead to injury, illness, or death of the patient.
- This device has not been studied in pregnant or breastfeeding women. Careful consideration should be given to use of the Closure Device in pregnant and/or breastfeeding women due to the risk of significant exposure to x-rays and the use of anticoagulation medication.
- Device selection should be based on accurate LAA measurements obtained using transesophageal or intracardiac echocardiographic imaging guidance in multiple views to avoid improper Closure Device sizing. For TEE recommended in multiple angles [e.g., 0°, 45°, 90°, 135°]; For ICE imaging, visualization of the LAA is recommended with the following anatomical structures: aortic valve (short-axis), mitral valve (long-axis), and pulmonary artery (short-axis), to assess the minimum and maximum diameter of the LAA ostium.
- Do not release (i.e., unscrew) the WATCHMAN FLX Pro Device from the core wire unless all release criteria (Step 15 in the IFU) are satisfied to avoid suboptimal results.
- Potential for Closure Device embolization exists with cardioversion < 30 days following Closure Device implantation; verify Closure Device position after cardioversion during this period.
- If thrombus is observed on the device, anticoagulation therapy is recommended until resolution of thrombus is demonstrated by TEE.
- Appropriate post-procedure drug therapy should be followed. See Post-Procedure Information section for further detail.
- Do not use if the temperature exposure indicator dot on the pouch label is red or missing, indicating Closure Device performance may have been compromised.

Precautions

- The safety and effectiveness (and benefit-risk profile) of the WATCHMAN FLX Pro Device has not been established in patients for whom long-term anticoagulation is determined to be contraindicated.
- The LAA is a thin-walled structure. Use caution when accessing the LAA and deploying, recapturing, and repositioning the Closure Device.
- Use caution when introducing a WATCHMAN Access System to prevent damage to cardiac structures.
- Use caution when introducing the Delivery System to prevent damage to cardiac structures.
- To prevent damage to the Delivery Catheter or Closure Device, do not allow the WATCHMAN FLX Pro Device to protrude beyond the distal tip of the Delivery Catheter when inserting the Delivery System into the Access Sheath.
- If using a power injector, the maximum pressure should not exceed 690 kPa (100 psi).
- Use caution when manipulating the Delivery System. Excessive counterclockwise rotation of the deployment knob or Delivery System hub independent from the rest of the Delivery System can cause premature implant detachment.

MRI Safety Information

A person with the Boston Scientific WATCHMAN FLX Pro Closure Device may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Device Name	WATCHMAN FLX Pro Closure Device
Static Magnetic Field Strength (Bo)	1.5 T or 3.0 T
Maximum Spatial Field Gradient	40 T/m (4,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	There are no Transmit Coil restrictions
RF Receive Coil Type	Any
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)
Scan Duration	2 W/kg whole-body average SAR for 60 minutes of continuous RF (a sequence or back-to-back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact of up to 8 mm.

If information about a specific parameter is not included, there are no conditions associated with that parameter.

Adverse Events

Potential adverse events which may be associated with the use of a left atrial appendage closure device or implantation procedure include but are not limited to: Air embolism, Airway trauma, Allergic reaction to the contrast media, anesthetic, WATCHMAN Implant material, or medication, Altered mental status, Anemia requiring transfusion, Anesthesia risks, Angina, Anoxic encephalopathy, Arrhythmias, Atrial septal defect, Bruising, hematoma, or seroma near the catheter insertion site, Cardiac perforation, Chest pain/discomfort, Confusion post-procedure, Congestive heart failure, Contrast-related nephropathy, Cranial bleed, Death, Decreased hemoglobin, Deep vein thrombosis, Device embolism, Device fracture, Device thrombosis, Edema, Embolism, Excessive bleeding, Fever, Fistula, Groin pain, Groin puncture bleed, Hematuria, Hemoptysis, Hypotension, Hypoxia, Improper wound healing, Inability to reposition, recapture, or retrieve the device, Infection/pneumonia, Interatrial septum thrombus, Intratracheal bleeding, Major bleeding requiring transfusion, Misplacement of the device/improper seal of the appendage/movement of device from appendage wall, Myocardial erosion, Myocardial infarction, Nausea, Oral bleeding, Pericardial effusion/tamponade, Pleural effusion, Prolonged bleeding from a laceration, Pseudoaneurysm, Pulmonary edema, Radiation injury, Renal failure, Respiratory insufficiency/failure, Stroke – Hemorrhagic, Stroke – Ischemic, Surgical removal of the device, TEE complications (e.g., throat pain, bleeding, esophageal trauma), Thrombocytopenia, Thrombosis, Transient ischemic attack (TIA), Valvular or vascular damage, Vasovagal reactions.

There may be other potential adverse events that are unforeseen at this time.

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 "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

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CE 2797

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings, and instructions for use can be found in the product labeling supplied with each device or at www.IFU-BSCI.com. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. This material not intended for use in France.

FARAVIEW™

Software Module

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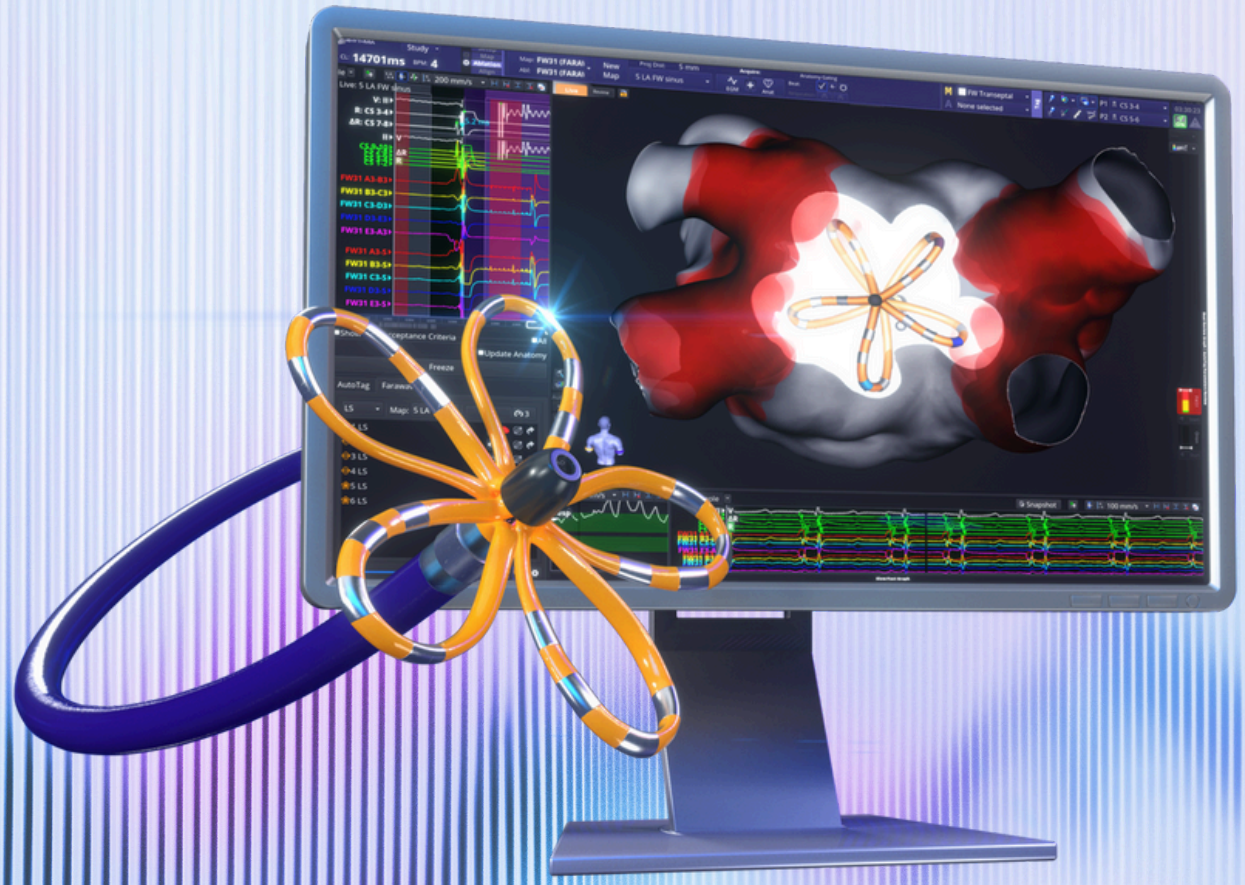

Hier mehr erfahren:

FARAVIEW™
Software Module

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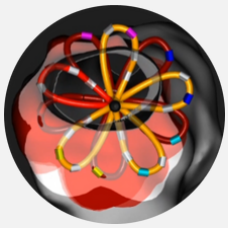
Modulare Erweiterung des FARAPULSE™ PFA Systems mit dem OPAL HDx™ 3D-Mapping-System

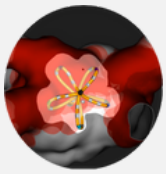
- Neuer FARAWAVE NAV™ Katheter mit verbessertem Handling und genauem Tracking durch impedanzbasierte und elektromagnetische Sensoren
- FARAVIEW™ Software Modul zur navigierten PVI mit 3D-Map

Optimierung Ihres FARAVIEW™ Workflows



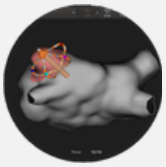
Dynamische Visualisierung

- Präzise Darstellung der Katheterposition
- Überprüfung der korrekten Rotation des Katheters zwischen den PFA-Applikationen in Flower und Basket Konfiguration
- Reduzierung der Fluoroskopiezeit



Field Tagging

- Speziell entwickelt für FARAPULSE™ PFA
- Projektion und Dokumentation der Ablationsfelder und Auschluss von Gaps
- Sicherstellung antraler Läsionsbildung



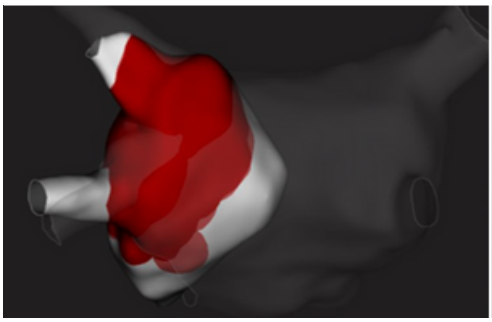
Map & Ablate

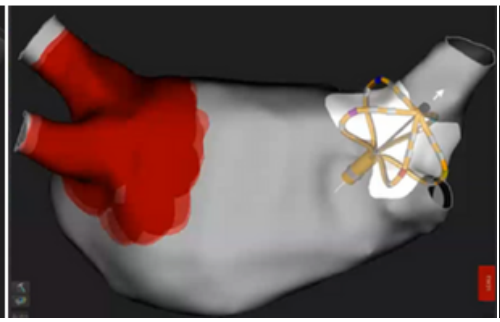
- All-in-One Solution, ein Katheter für Diagnostik und Therapie
- Einfache Darstellung der Venenanatomien durch variable Katheter-konfiguration und optionale Integration des Führungsdrahts für das Mapping

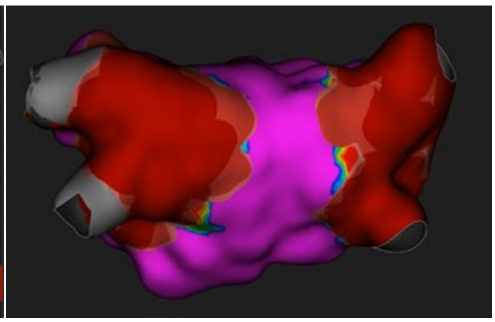
Der passende Workflow für jede Art der Anwendung

- Direktes visuelles Feedback: bessere Orientierung bei komplexen Vorhofanatomien (kann präoperative Bildgebung ersetzen), mehr Sicherheit für Neuanwender
- Unterstützung bei der Katheterpositionierung an schwer erreichbaren Stellen (rechte Pulmonalvenen)
- Ausschluss von Rekonnektion bei Erstablation und Gap-Detektion bei Re-Do Eingriffen
- Möglichkeit der Visualisierung der Hinterwandablation

Effizient	Ausgewogen	Detailliert
Darstellung der Pulmonalvenen	Vollständige anatomische Darstellung des Vorhofs	Vorhofanatomie mit Voltagemap







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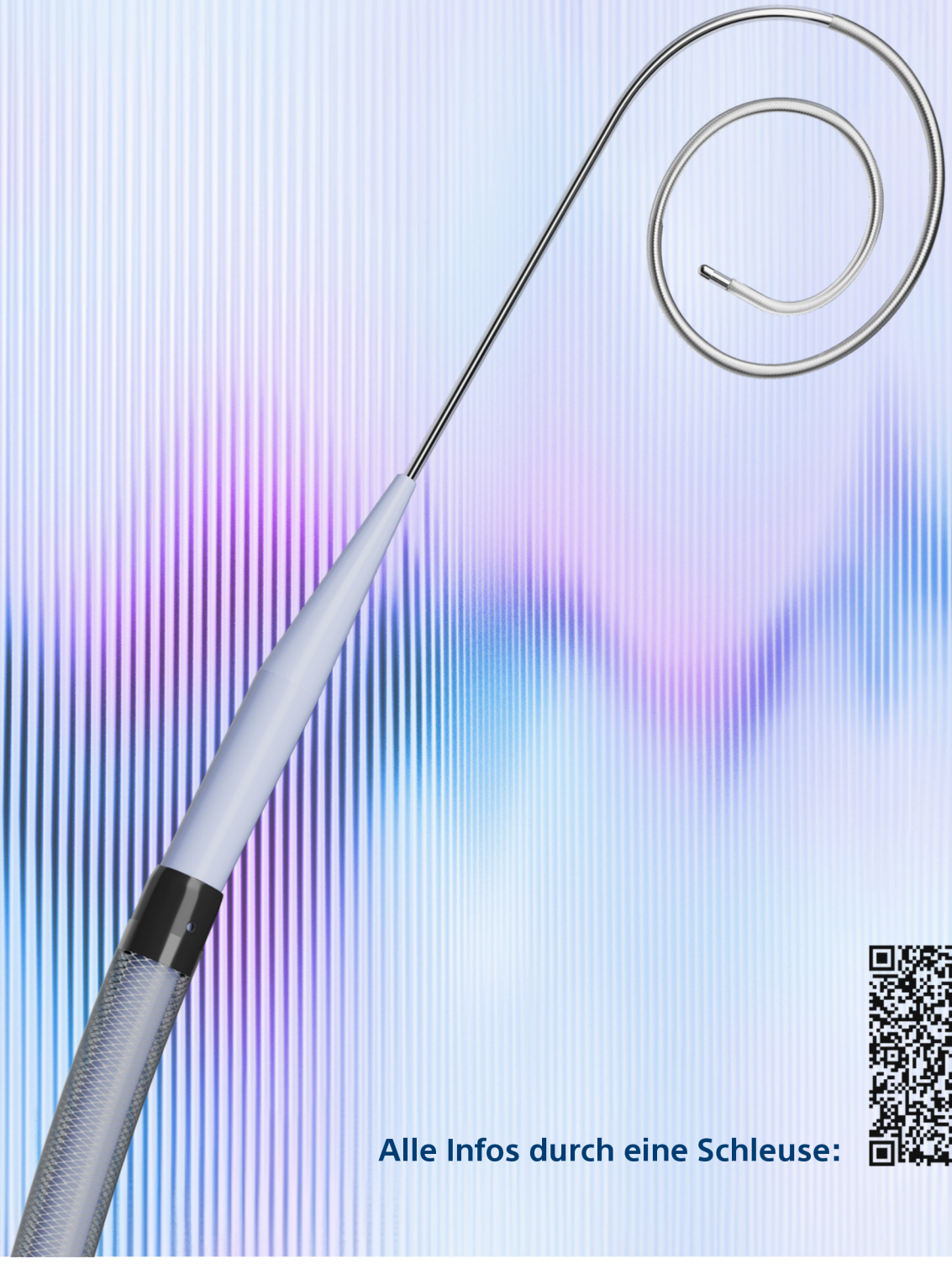
VersaCross Connect™

Access Solution für FARADRIVE™



Alle Infos durch eine Schleuse:

VersaCross Connect™

Access Solution für FARADRIVE™

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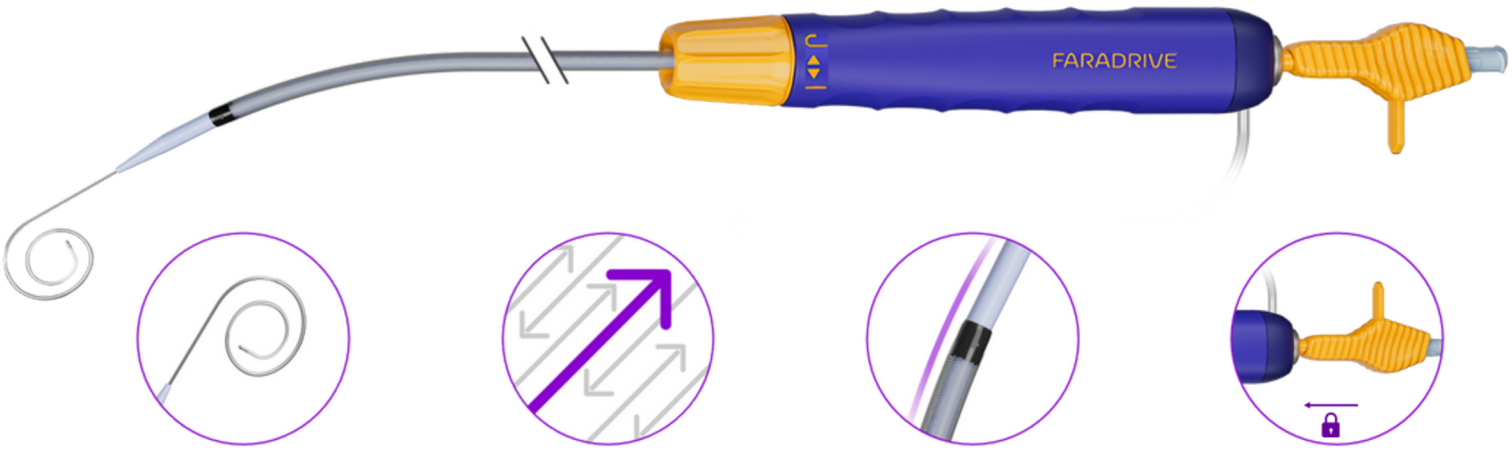
Die transseptale Punktion mit einer RF-Nadel ermöglicht eine präzise und kontrollierte Punktion selbst bei schwieriger Anatomie – mit weniger Kraftaufwand und geringerem Komplikationsrisiko.
Mit dem VersaCross Connect™ System entfällt sogar der Schleusenwechsel – für mehr Sicherheit, Effizienz und spürbare Zeitersparnis im Labor.



3-in-1 RF Pigtail oder J-Wire

ermöglicht den Zugang über die SVC, die transseptale Punktion und die Einführung der steuerbaren FARADRIVE™ Schleuse.

Zero-Exchange

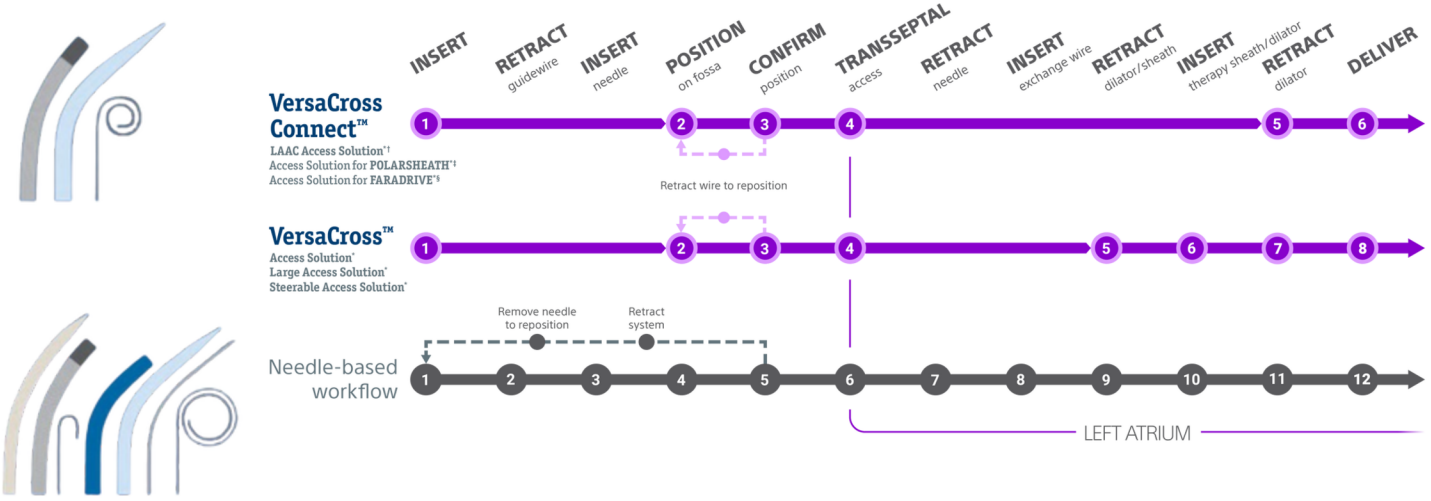
bei der transseptalen Punktion mit Drahtführung ohne Schleusenwechsel (Punktion erfolgt direkt über die FARADRIVE™ Schleuse).

Reibungsloser Übergang

zwischen VersaCross Connect™ Dilatator und der FARADRIVE™ Schleuse.

Snap Fit Lock

für Konsistenz und Zuverlässigkeit verbindet der Snap Fit Lock VersaCross Connect™ mit FARADRIVE™.



OMNIviz™ Technologie

Der VersaCross Connect™ Draht lässt sich zuverlässig unter Fluoroskopie und Ultraschall lokalisieren. Markierungen zeigen die Position der HF-Spitze innerhalb des Dilatators an.
Durch Anschließen des DuoMode™-Kabels ist auch im Mappingsystem eine Visualisierung der HF-Spitze möglich.

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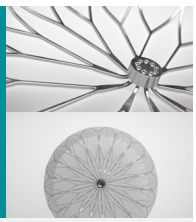
CHAMPION-AF Clinical Trial Results

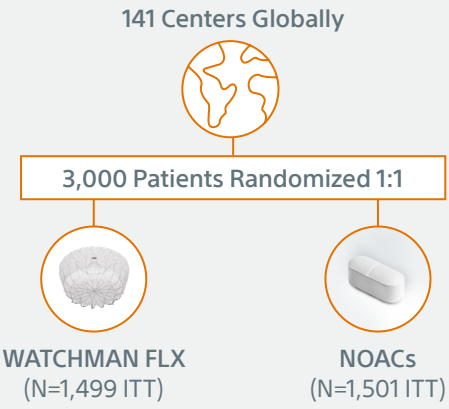
WATCHMAN met all 3-year endpoints as a first-line option vs. NOACs in a broad NVAF population



The CHAMPION-AF clinical trial is the first and largest randomized controlled trial comparing the WATCHMAN FLX™ LAAC Device to NOACs as a first-line option for stroke risk reduction in a broad population of patients with non-valvular atrial fibrillation (NVAF), including those who are at low-to-moderate risk of bleeding from the use of anticoagulation.

- Superior Net Clinical Benefit*
- Non-inferior Efficacy
- Superior Bleeding Reduction

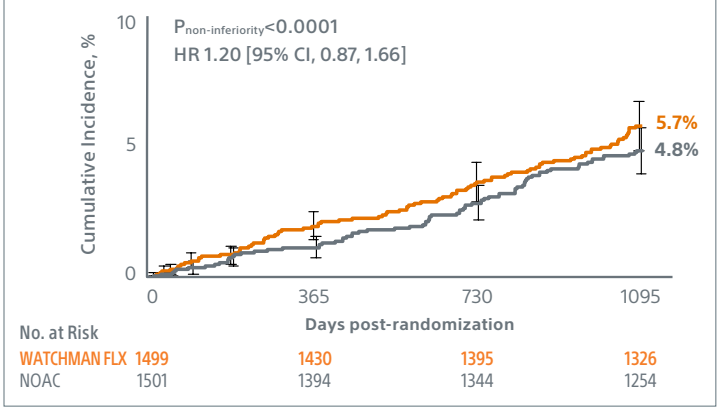
*Net clinical benefit endpoint includes a composite of cardiovascular death, stroke, systemic embolism, and non-procedural ISTH major and modified clinically-relevant non-major bleeding



Primary Efficacy Endpoint Met

WATCHMAN FLX demonstrated statistical non-inferiority to NOACs for the occurrence of cardiovascular (CV) death (hemorrhagic and/or unexplained death), stroke (ischemic and/or hemorrhagic), and systemic embolism (5.7% vs. 4.8%; $P_{non\text{-}inferiority}$ <0.0001)

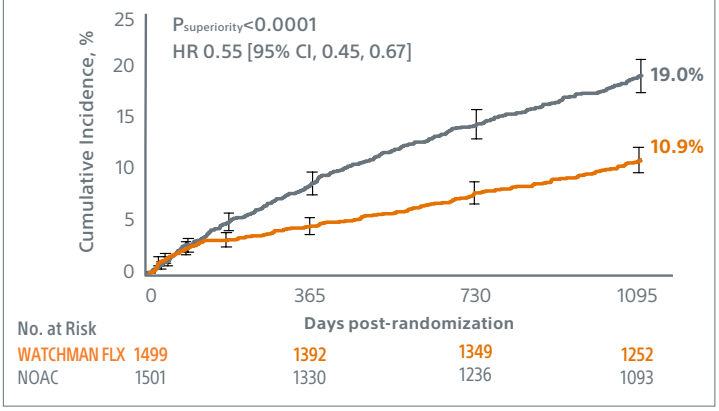
Primary Efficacy: CV Death, Stroke, Systemic Embolism



Primary Safety Endpoint Met

WATCHMAN FLX demonstrated statistical superiority to NOACs for the occurrence of ISTH non-procedural major bleeding and modified* clinically relevant non-major bleeding (10.9% vs. 19.0%; $P_{superiority}$ <0.0001)

Primary Safety: ISTH Non-procedural Bleeding



*Modified ISTH clinically relevant non-major bleeding was defined as any sign or symptom of hemorrhage (e.g., more bleeding than would be expected for a clinical circumstance, including bleeding found by imaging alone) that does not fit the criteria for the ISTH definition of major bleeding but does meet at least one of the following criteria.
- Requiring medical intervention by a healthcare professional
- Leading to hospitalization or increased level of care (e.g., ER visit, diagnostic procedures, medication change)

34% Reaffirming superiority of the primary safety endpoint, WATCHMAN FLX demonstrated a **statistically significant 34% risk reduction in ISTH bleeding (including procedural)** at 36 months (12.8% vs. 19.0% (HR 0.66 [0.54, 0.80]); P<0.0001).

1.1% Annualized Ischemic Stroke Rate

98.8% Procedural Success

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WATCHMAN FLX Pro LAAC Device Implanter- Indications, Safety and Warnings