

ABBREVIATED STATEMENT

WATCHMAN™ TruPlan™ CT Imaging Software

INDICATIONS FOR USE/INTENDED USE

WATCHMAN TruPlan enables visualization and measurement of structures of the heart and vessels for:

- Pre-procedural planning and sizing for the left atrial appendage closure (LAAC) procedure
- Post-procedural evaluation for the LAAC procedure

To facilitate the above, WATCHMAN TruPlan provides general functionality such as:

- Segmentation of cardiovascular structures
- Visualization and image reconstruction techniques: 2D review, Volume Rendering, MPR
- Simulation of TEE views, ICE views, and fluoroscopic rendering
- Measurement and annotation tools
- Reporting tools

WATCHMAN TruPlan’s intended patient population is comprised of adult patients.

IMPORTANT:

- TruPlan is intended to be used as a pre-procedural planning aid, and LAAC procedures should be performed per the chosen LAAC device’s approved IFU.
- TruPlan is intended to be used as a post-procedural assessment aid, and all clinical decisions should be made per the chosen LAAC device’s approved IFU.

CONTRAINDICATIONS

None known.

WARNINGS

- TruPlan should not be used for purposes other than those indicated in the Indications for Use/Intended Use section.
- Please review the patient and study information carefully to ensure the correct patient case is being evaluated.
- The TruPlan software is not intended to perform a diagnosis, nor to replace any duties of the physician.
- Measurements made in TruPlan should only provide additional information to, not replace, measurements made during the typical clinical workflow (e.g., intra-procedural imaging using fluoroscopy, TEE, and/or ICE).
- The Fluoro, TEE, and ICE modules provide simulated, not real, images of fluoroscopic, TEE, and ICE views, respectively.
- Quantitative analysis is dependent on the quality and correctness of the image source data (i.e, CT scans).
- Software may slow down when other software applications are being run on the same machine.
- Operating system updates might require an updated version of TruPlan (see System Requirements).
- Any serious incident that has occurred in relation to this software as a medical device should be reported to the Circle Cardiovascular Imaging Inc. and the competent authority of the Member State in which you are established, see Support section for contact information.

WATCHMAN™ TruPlan™ is developed and owned by Circle Cardiovascular Imaging Inc. (Calgary, AB, Canada), and Boston Scientific is the exclusive reseller of WATCHMAN TruPlan.

©2023 Boston Scientific Corporation or its affiliates. All rights reserved. All trademarks are property of their respective owners. SH-900405-AB

NOTE: In the U.S., the use of ICE and CT Follow Up Imaging with WATCHMAN is outside of WATCHMAN’s labeled indications.

WATCHMAN™ TruPlan™
CT IMAGING SOFTWARE

**Boston
Scientific**
Advancing science for life™

EASY.
PRECISE.
OPTIMIZED FOR,
WATCHMAN FLX™.

In a study assessing the safety and feasibility of CT-based preprocedural sizing methodology for WATCHMAN FLX™ left atrial appendage closure device among 136 patients, Filby et al. reaffirmed the proven safety and predictability of the WATCHMAN FLX procedure using WATCHMAN TruPlan CT Imaging software. All cases were performed under ICE guidance.¹

“

TruPlan allows our team to have an in depth, accurate understanding of the appendage anatomy. This has translated into smoother procedures with fewer attempted devices.

– Dr. Stephen Filby

PATIENT DEMOGRAPHICS		STUDY RESULTS	
N	136	Procedural Success	98.5%
Age	76 ± 8.4	Correct Device Size*	91.1%
CHA ₂ DS ₂ -VASc	4.4 ± 1/3	No Leaks (≤ 5mm) at 45 Day Follow-Up	99.3%

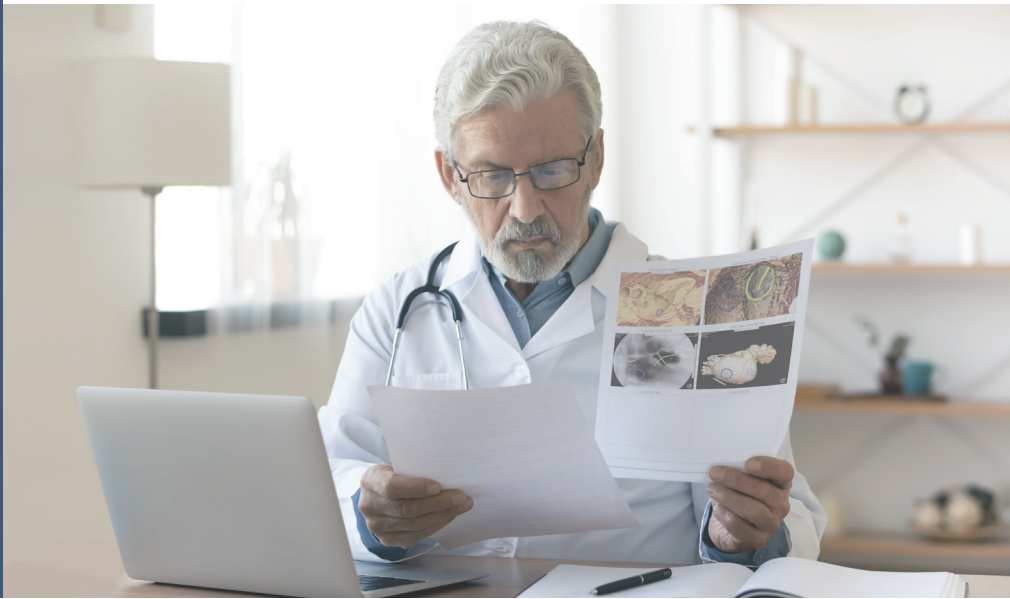
*N=10 or 7.4% required another device size; N = 2 or 0.1% aborted cases.

1 Filby et al. "Novel computed tomography-based sizing methodology for WATCHMAN FLX device in left atrial appendage closure", Journal of Cardiovascular Electrophysiology, May 2022.

Easy to Access

Built for accessibility and collaboration to make pre/peri/post case assessments easier and more efficient.*

**Talk to your Boston Scientific representative about how you can access WATCHMAN TruPlan at no additional cost.*



ACCESS ANYWHERE WITH UNLIMITED USER LICENSES*



- Your clinic
- Your office
- Your laptop
- Control room



More Real-World Results

The Valley Health Hospital, a non-academic regional medical center located in Ridgewood, NJ, supports 100 LAAC procedures annually while using WATCHMAN TruPlan CT imaging software to help drive faster procedure times and increase the number of daily procedures.

“ Our data, for the first time, show the value of using a dedicated cardiac CT software for pre-procedure planning of LAAC with the WATCHMAN FLX device. By reducing the number of devices used, procedure times decreased by 29%, which translated into a 50% improvement in lab efficiency. – Mittal et al.

21%

Reduction in Devices
Used Per Procedure²

29%

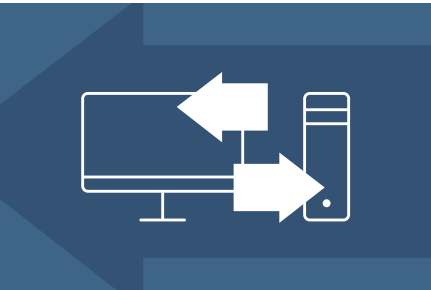
Decrease in
Procedural Time²

50%

Increase in Capacity &
Procedures Per Day²

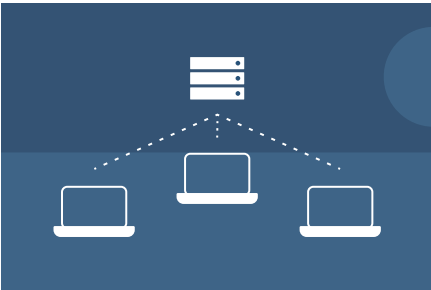
2 Mittal et al. "Impact of Pre-Procedural Planning with a Novel Cardiac CT Software Platform on the Efficiency of a Left Atrial Appendage Closure Procedure" Heart Rhythm Society, Abstract, Vol 19, Issue 5, Supplement, S221, May 2022.

PACS INTEGRATION READY



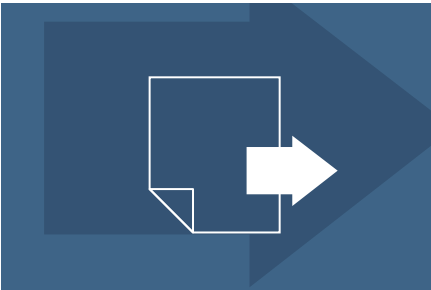
- CT data becomes readily available

NEW CLIENT SERVER DEPLOYMENT MODEL



- Improved image database management and work collaboration versus a standalone desktop application
- Simplifies IT and security management

ENHANCED COLLABORATION



- Access workups across workstations and collaborate with others with saved session files (~2 MB)
- MAC and PC compatible

Actionable LAAC Insights

Unique tools and features provide helpful clinical guidance for optimal outcomes.

- Plan your transseptal using any WATCHMAN™ Access Sheath models
- Unique thrombus assessment tool
- First-to-market ICE simulator
- **NEW** Follow-Up model

With WATCHMAN TruPlan, Boston Scientific's industry leading WATCHMAN clinical specialists will be by your side to support your software in addition to supporting your procedures.

Contact your Boston Scientific representative to learn more about WATCHMAN TruPlan.



What is WATCHMAN™ TruPlan™?

A purpose-built CT imaging software that includes comprehensive tools to guide your LAAC clinical decisions more precisely.

WATCHMAN TruPlan offers a full feature set that facilitates patient screening, procedure planning, and accurate diagnosis for LAAC.



YOU'RE IN CONTROL WITH WATCHMAN TRUPLAN

- Dedicated LAAC workflow with AI predicted landing zone
- Automated 3D segmentation
- Fluoro, TEE and ICE* simulated views
- Transseptal planning
- Thrombus assessment tool
- Estimated device sizing and compression
- Follow-Up workflow and assessment tools*
- Automated planning and Follow-Up reports
- Unlimited user licenses

**In the U.S., the use of ICE and CT Follow Up with WATCHMAN is outside of WATCHMAN's labeled indications.*

Easy to Use

Intuitive controls and automation make CT analysis simple and user friendly.



NEW AI PREDICTED
LANDING ZONE



AUTOMATIC 3D
SEGMENTATION



ESTIMATED DEVICE
COMPRESSION AND SIZING



AUTOMATIC REPORT
GENERATION