

THE VALLEY HOSPITAL CASE STUDY

WATCHMAN™ TruPlan™ CT IMAGING SOFTWARE

HOSPITAL OVERVIEW

- Non-Academic Regional Medical Center in Ridgewood, NJ
- 450 beds
- 3 implanters: all EPs
- 100 procedures annually
- Suburban area



CHALLENGES

- Difficult to get patients to undergo pre-procedure TEE imaging
- Suboptimal transseptal puncture necessitating a repeat puncture at alternate site

PATIENT DEMOGRAPHICS

N	AGE	CHA ₂ DS ₂ -VASc
136	76 ± 8.4	4.4 ± 1/3

OUTCOMES

- Pre-procedural planning led to higher procedural completion rate and faster procedure times
- Increased daily procedures from 4 to 6
- Optimal transseptal placement for every patient identified before the procedure
- Reduced transseptal recross rate. No recrosses needed post-implementation of WATCHMAN TruPlan CT Imaging Software

STUDY RESULTS

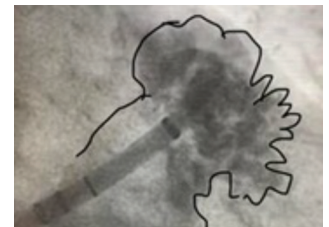
PROCEDURAL SUCCESS	CORRECT DEVICE SIZE*	NO LEAKS (≤ 5MM) AT 45 DAY FOLLOW-UP
98.5%	91.1%	99.3%

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

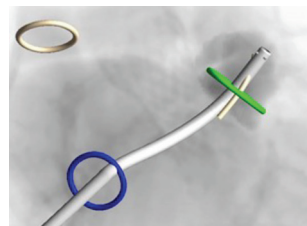
EXPECTATION VS. REALITY | Fluoroscopic Images



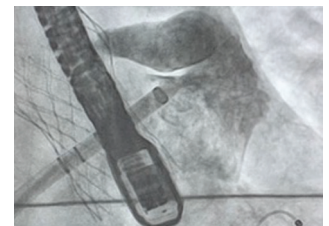
LAA Morphology (CT)



LAA Morphology (Fluoro)



Optimal TS Puncture



WATCHMAN FLX™ Left Atrial Appendage Closure Device

SUMMARY

29%

Decrease in Procedural Time¹

50%

Increase in Capacity and Procedures Per Day¹

EASY. PRECISE. OPTIMIZED FOR WATCHMAN FLX™.

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.

1 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.

Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

Please visit www.circlecvi.com/watchman-truplan for a summary of safety information and to download the full Directions for Use (User Manual). Rx Only.

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

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