Valve ASSIST 2 and VIVID™ E95
Utilizing advanced imaging to Plan, Guide, and Assess
Left Atrium Appendage Closure procedures.

Dr. Garot and Dr. Cormier
Institut Cardiovasculaire Paris Sud, Massy (France)
The interventional field is growing with ever-expanding capabilities and is migrating to less invasive, safer, and more cost-efficient procedures. With the new generation of GE’s advanced interventional imaging solution, ASSIST*, you can expand your clinical versatility and successfully plan, guide, and assess increasingly sophisticated procedures with greater precision and dose efficiency.

**ACHIEVE CLINICAL EXCELLENCE IN LAAC**

**Greater precision and dose efficiency**

**POWER UP YOUR CLINICAL CAPABILITIES AND SERVICE LINE**

ASSIST enables you collect more clinical information, helping you precisely plan, guide, and assess even the most complex interventional procedures.

**POWER UP PRODUCTIVITY**

The portfolio of ASSIST clinical packages provide intuitive planning tools, designed to make your procedures easier, safer, and more efficient.

**POWER UP PATIENT CARE**

By optimizing for minimal dose exposure and maximum IQ quality, your patients will benefit from exceptional diagnostic accuracy and therapeutic efficacy.

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Introduction

Dr. Philippe Garot
Interventional Cardiologist, Head of Institut Cardiovasculaire Paris Sud (ICPS), Massy - France
Plan
Segment the 3D CT images of the left atrium to precisely plan the intervention, including:
- Morphology
- Ideal landing zone
- Optimal device size

Guide
Significantly reduce procedure time with the help of CT/X-Ray image fusion, while decreasing contrast media & X-ray dose. Use Valve ASSIST 2 to guide each step with confidence, from the trans-septal puncture to the device deployment 1.

Assess
Once the device is deployed, employ echocardiography to confirm the device location and evaluate compression before releasing the device.

Ultrasound imaging is not included in Valve ASSIST 2
Introduction

Dr. Bertrand CORMIER
Echocardiographer at the Institut Cardiovasculaire Paris Sud (ICPS), Massy - France
Biplane Views from 4D Dataset with Live FlexiSlice

Reconstruct 2D planes from the 4D-volume dataset in real time, accessing biplane views that cannot be achieved by manipulating the TOE probe.

Better 4D-Orientation with HDlive™

Display virtual light and shadow effects inside the body for better 4D-orientation, with the help of a highly developed software-algorithm.
Streamlined Collaboration

Given that soft tissue is not visible by x-ray alone, the LAAC procedure requires simultaneously x-ray and ultrasound imaging to execute each step of the intervention. Clear communication and strong collaboration across medical disciplines are essential to achieve positive clinical outcomes.
Image guidance tools

To facilitate communication within the heart team, CT, X-rays, ultrasound images are visible in real time to both interventional cardiologist and echocardiographer. Thanks to these live images guidance tools, the procedure is smoother and performed quicker.
Typical Clinical Challenges

- LAA and surrounding structures can have a wide variability in their morphology and angulations.
- LAAC procedures require the use of multiple imaging techniques to perform occlusions in a safe and effective way, reduce risks of complications.
- Optimal trajectories, working angulation, trans-septal puncture zone and accurate device delivery location are essential for a positive patient outcome.

Benefits of the solution

- **Enhanced Planning** of 3D CT images to better visualize the anatomy of the LAA, make key measurements and help select the optimal implantation C-Arm angulation.
- **Optimal trajectories & device optimal landing zone** overlaid on X-Ray images help improve navigation throughout key steps of the procedure & deliver the device with increased accuracy.
- **CT/X-Ray images fusion facilitates communication** with the echocardiographer.
Patient information

- Male, 85 years old.
- Medical history:
  - CKD on dialysis (2015+), nephroangiosclerosis.
  - Permanent AF (non-valvular).
- Rectal bleeding episodes after starting a double antiplatelet therapy.
- CHA2DS2-VASc: score 4.
1. PLAN

Pre-Procedural Planning Using CT-Scan

The CT volume rendering view allows a strong visualization of the Fossa Ovalis (FO) location (green line, upper-left image). There are two LAA lobes, the deepest one follows the green line and seems better for the procedure (bottom right image). CT scanner images also provide information about the ideal working angulation (RAO and CRA), the morphology of the LAA, as well as the location and diameter of the landing zone (orange circle), helping to pre-determine the ideal device size.
Per Procedure Planning Using Ultrasound

The Live FlexiSlice feature enables biplane views that could otherwise not be achieved by manipulating the TOE probe. This helps reach complex angulation, aligned with the LCx, and helps improve accuracy of the device measurement. It also allows to be in the same angulations than the CT images.
2. GUIDE

Valve ASSIST 2 and Vivid E95 are complementary to guide each step of the procedure.

- Trans-Septal Puncture
- Guide the Stiff Wire in the LSPV
- Introduction of the Pigtail in the LAA
- Device Deployment
Trans-septal Puncture

With the 3D CT image overlay on the live X-Ray, Valve ASSIST 2 helps the interventional cardiologist visualize the Fossa Ovalis (blue line, upper image), and more effectively guide the sheath to the optimal zone for the trans-septal puncture. The puncture position is then fine-tuned with the help of echocardiography.

This innovative image overlay proved to reduce procedure time, facilitate communication between the echocardiographer and the interventional cardiologist, as well as reduce X-Ray exposure².
Guide the stiff wire in the LSPV

The 3D CT images are used to overlay the contours of the left atrium onto the Live X-Ray images, helping the interventional cardiologists guide the stiff wire in the PV while avoiding the LAA reducing the risk of perforation and tamponade. Echocardiography is then used to confirm that the stiff wire is well positioned.
Introduction of the pigtail in the LAA

3 CT overlay allows to visualize the contours of the LA and helps the interventional cardiologist position the pigtail with a better accuracy.
Moving to the working angulation

The C arm is moved to the working angulation perpendicular to the landing zone. A quick injection of contrast media helps to precisely align the 3D CT image on angiographic images from table side.

In addition, the volume rendering view is used to better visualize the 3D anatomy with the two projection of the LAA paths defined during CT planning.
Deployment of the device

Radiopaque marker bands of the delivery sheath help to adjust its placement/depth in the LAA regarding to the landing zone easily visible thanks to the overlay.

The device is brought to the landing zone. While unsheathing the device, the overlay helps to keep the position of the proximal part of the device stable at the level of the landing zone.
The device is finally deployed and positioned as expected at the level of the landing zone.
3. ASSESS
Final assessment

Valve ASSIST 2 allowed to easily guide the procedure and the device deployment. Thus, the position, the anchor, the size and the seal of the device are well confirmed by the echocardiographer utilizing different views.

- The device is stable, checked with the «tug test»
- The device position is distal relative to LAA ostium as planned with CT planning
- The size is measured with its in-situ compression
- There is no residual flow

At the end of the procedure:

Exposure time - Rx time: 0:08:07 - mGy: 230 - Gy.cm²: 23.28
ACHIEVE CLINICAL EXCELLENCE IN LEFT ATRIAL APPENDAGE CLOSURE

Challenging Complexity
Transcatheter LAA closure has been associated with potentially serious complications due to the necessity of trans-septal puncture, manipulation of stiff wires and guide catheters in the left atrium and the release of the device in the LAA².

Imaging solutions
Echocardiography guidance is mandatory for LAAC procedures. In performing a trans-septal puncture, a step by step and methodical patient approach is recommended. For example a properly selected puncture location reduces procedure time and improves the chances of procedural success³.

Limiting Dose
Personnel not previously exposed to ionizing radiation are now frequently close to the X-ray field⁴. Protecting both patients and practitioners from X-Ray dose is critical.
VALVE ASSIST 2 brings new opportunities to improve outcomes in LAAC procedures

-28% Procedure Time
-25% Fluoro Time
-78% Contrast Media

Fusion of 3D CT images together with live X-ray gives additional information to the interventional cardiologist that help reduce the procedure time, fluoro time, and use contrast media. The procedure is faster, with less dose and helps improve confidence through better image guidance. The decrease of the dose is very beneficial for the echocardiographer who plays a key role in the procedure.
A COMPLETE PORTFOLIO, to address your structural heart procedure

**Innova IGS 520**
Advanced Visualization
Advanced PCI, complex procedures

**Innova IGS 530**

**Innova IGS 620**
See the vessels from two different positions with 1 injection in 1 shot

**Innova IGS 630**

**Discovery IGS 730**
Rediscover space and movement. Structural heart and Hybrid OR
Vivid E95

Premium 4D cardiovascular ultrasound system designed to help you rise above some of today’s complex healthcare challenges.

Vivid iq

Directly addresses your changing needs with a combination of portability and power that fits right in.
### ASSIST,
solutions for interventional procedures

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4. Radiation Safety for the Interventional Cardiologist—A Practical Approach to Protecting Ourselves From the Dangers of Ionizing Radiation. Jan 04, 2016   Gautam Kumar, MD, FACC; Syed Tanveer Rab, MBBS, FACC.
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Data subject to change.

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