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THE SHAPE OF STROKE PREVENTION

WELCOME
RESEARCH COORDINATORS

James Reinstein, President & CEO

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Developing the Next Generation of LAAO Technology.

The CLAAS® AcuFORM™ System is designed to reduce the risk of stroke without the need for anticoagulants.

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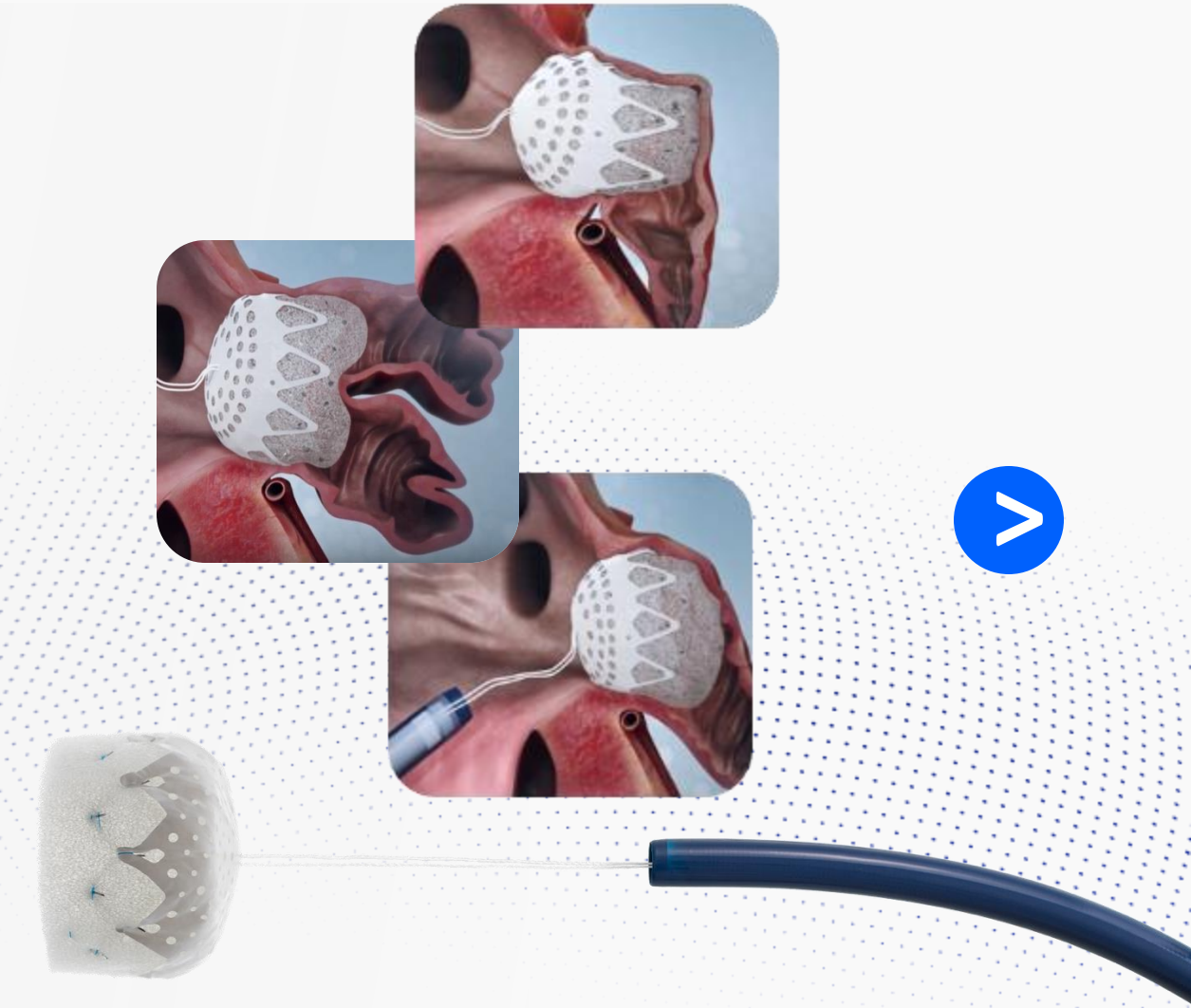
Claas® AcuFORM™

The First & Only LAAO Device to Use Conformable Foam to Seal The LAA

Designed to reduce the risk of stroke without the need for anticoagulants.



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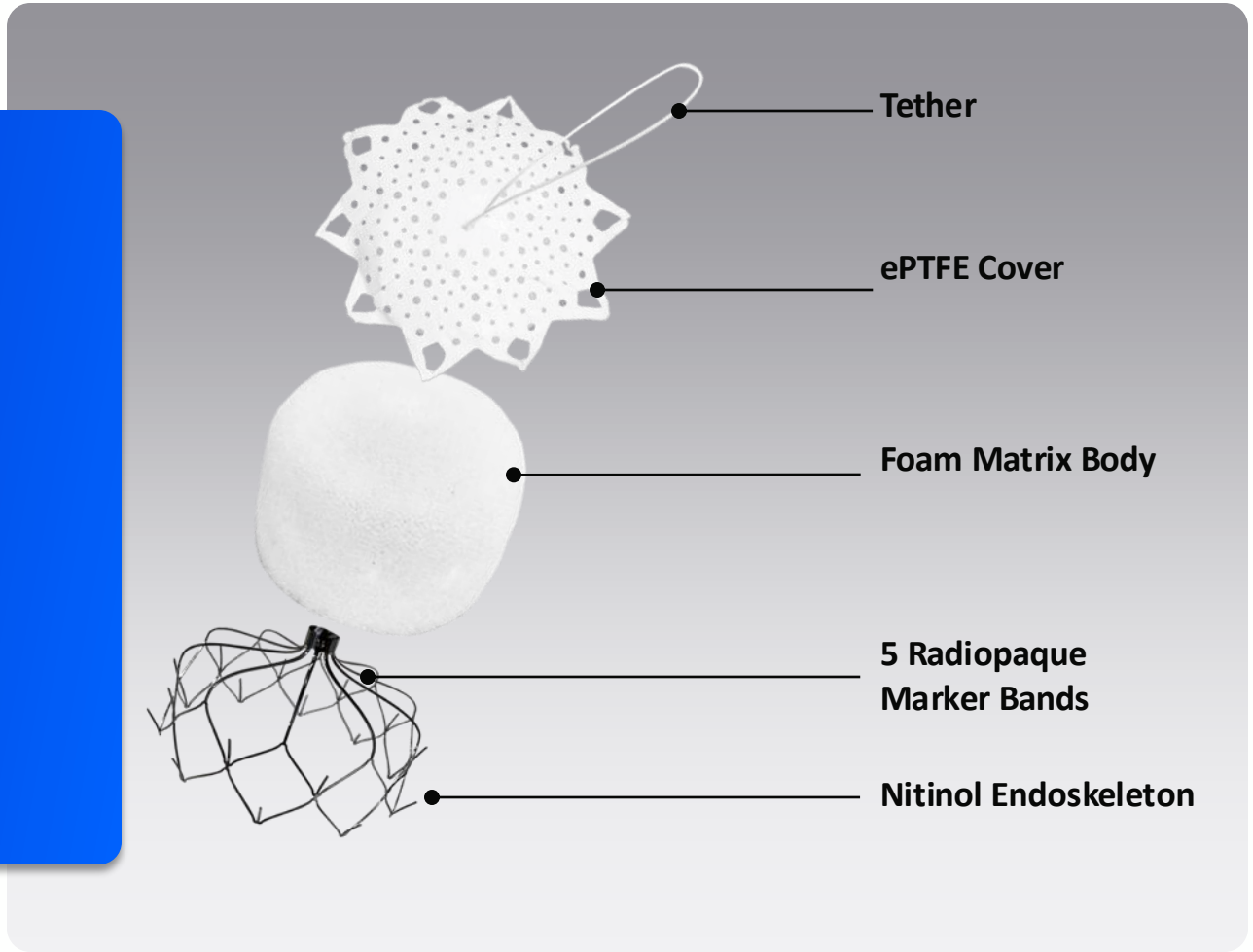
The Shape of Stroke Prevention

claas® AcuFORM™

- Smooth dual-layered ePTFE cover for improved strength and enhanced healing
- No exposed metal, covered with highly conformable foam matrix body, designed to form and fill gaps
- Compliant nitinol endoskeleton that forms to fit the appendage
- Optimized low-profile anchors
- 1 size addresses >90% of patients



Conformal Product Evolution

CLAAS® AcuFORM™ builds upon the novel CLAAS platform with enhanced clinical performance and ease of use

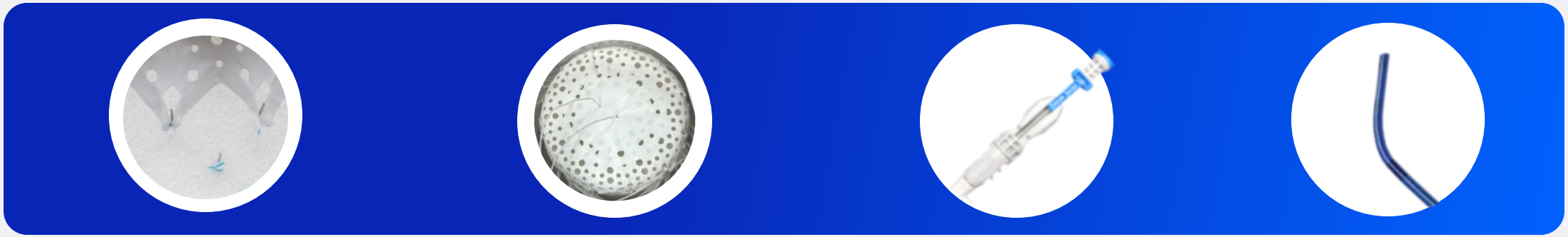
CLAAS® System *(1st Gen)*

- Elevated Pericardial Effusion Rates

CLAAS® AcuFORM™ *(2nd Gen)*

- Redesigned Anchors
- Improved Delivery Experience

Next-Generation LAAO System



Modified Anchors
50% Reduction in Penetration

ePTFE Fluoropolymer
Low Thrombogenicity
High Strength & Durability

Intuitive Handle
Cable & Tether Modes

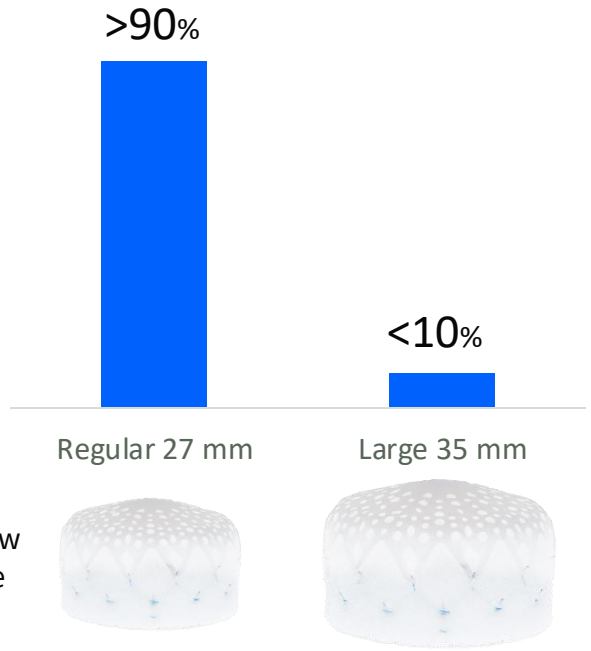
Steerable Sheath
Precise Coaxial Deployment

7

Simplified Sizing

CONFORMAL Vs. WATCHMAN

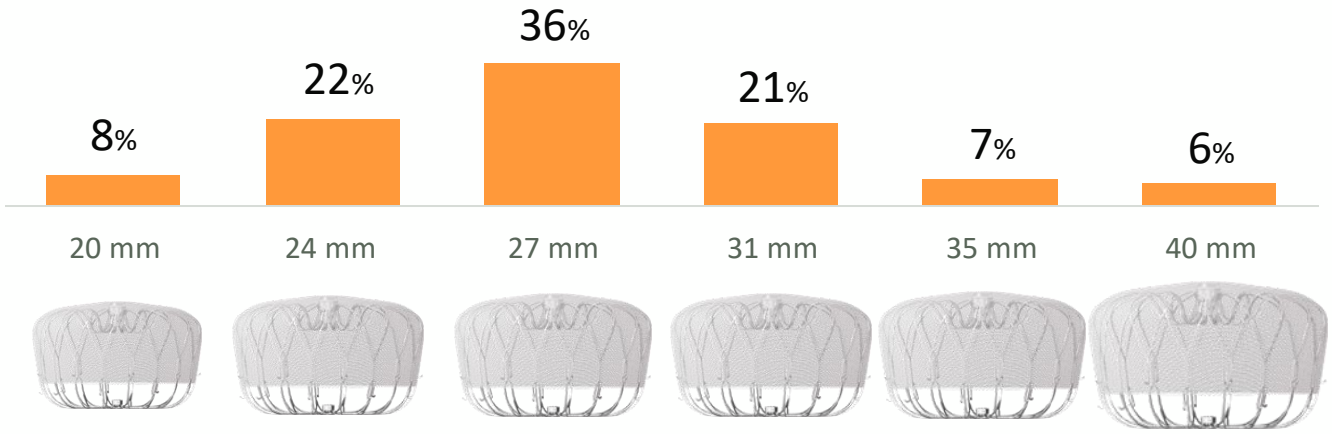
Implant size and percentage used



10 mm shallow landing zone

CONFORMAL-CLAAS AcuFORM[1]

1 size treats >90% of patients



Variable landing zone (requires half the LAA depth or longer)*

BSC-WATCHMAN FLX[2]

6 sizes required

**IFU BSC-WATCHMAN*

1. Conformal Medical Data on File

2. Alli, S., et. al; Left atrial appendage closure with a novel fluoropolymer-coated device: Primary safety and efficacy endpoints of the HEAL-LAA post-approval clinical study. Presented at TCT 2024

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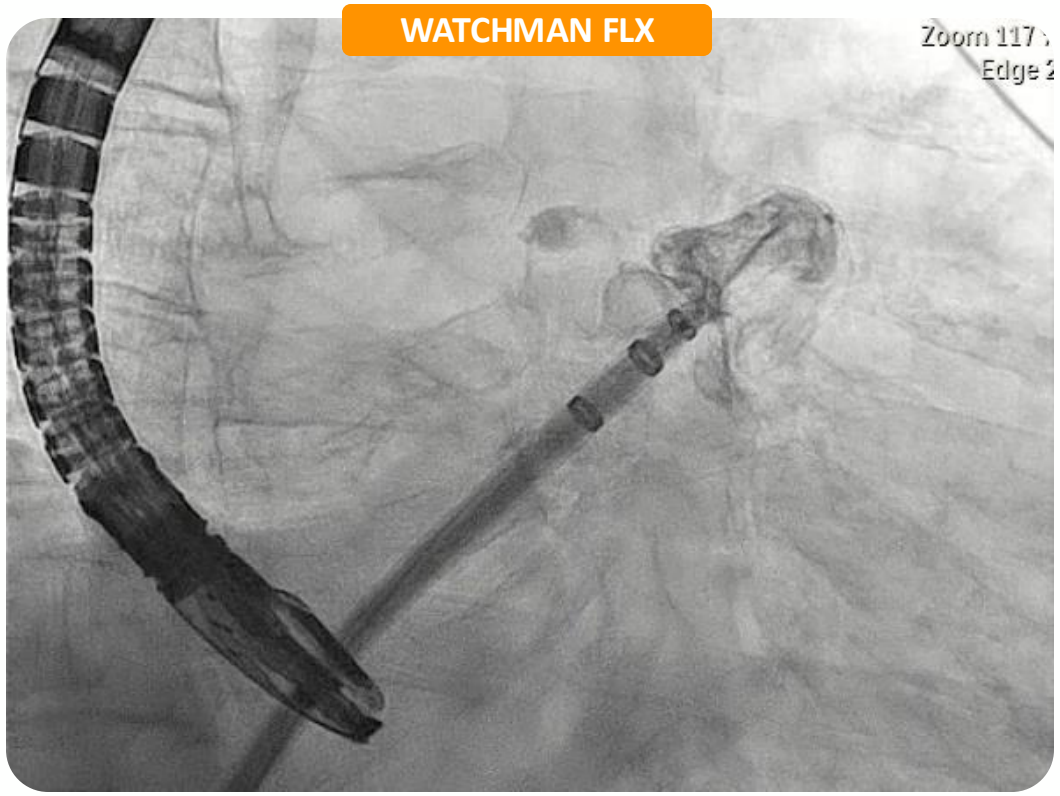
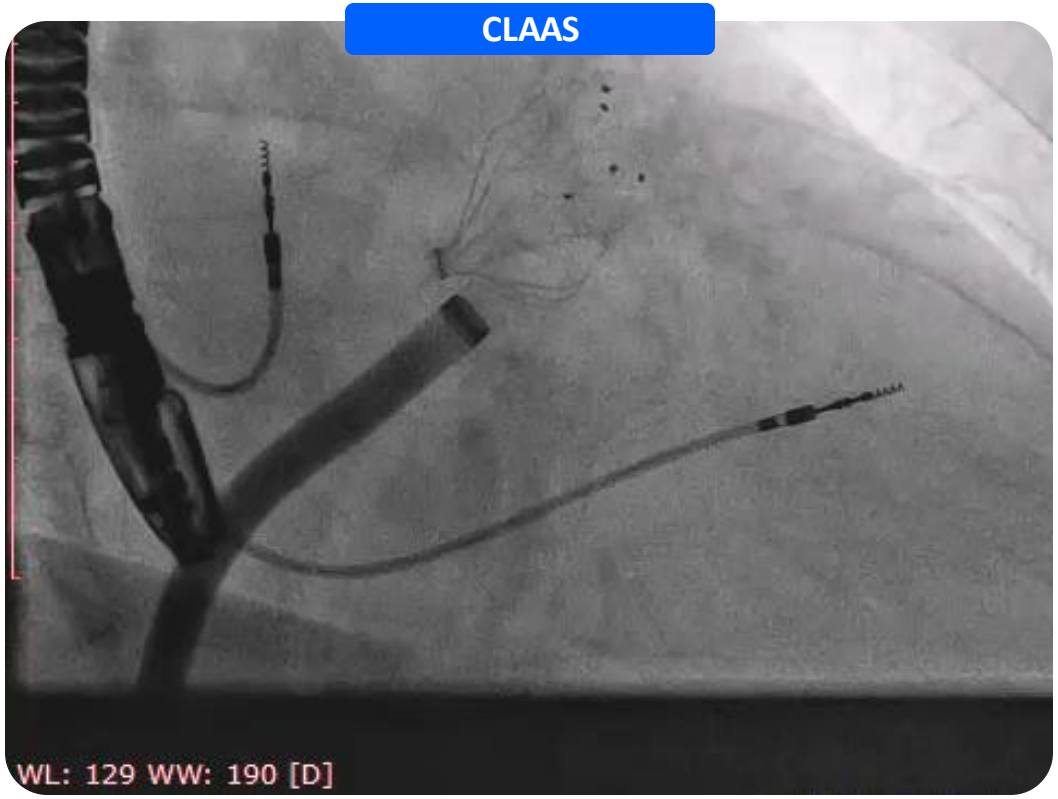
Simplified Seal and Confirmation





97.5% Seal Rate without significant (>3mm) leaks at 12 months, comparing favorably with marketed devices.[1]

1. Gray W, Conformal Early Feasibility Study: 12 Months Results. TCT 2023

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Company Update

CLAAS® System clinical experience in >400 patients

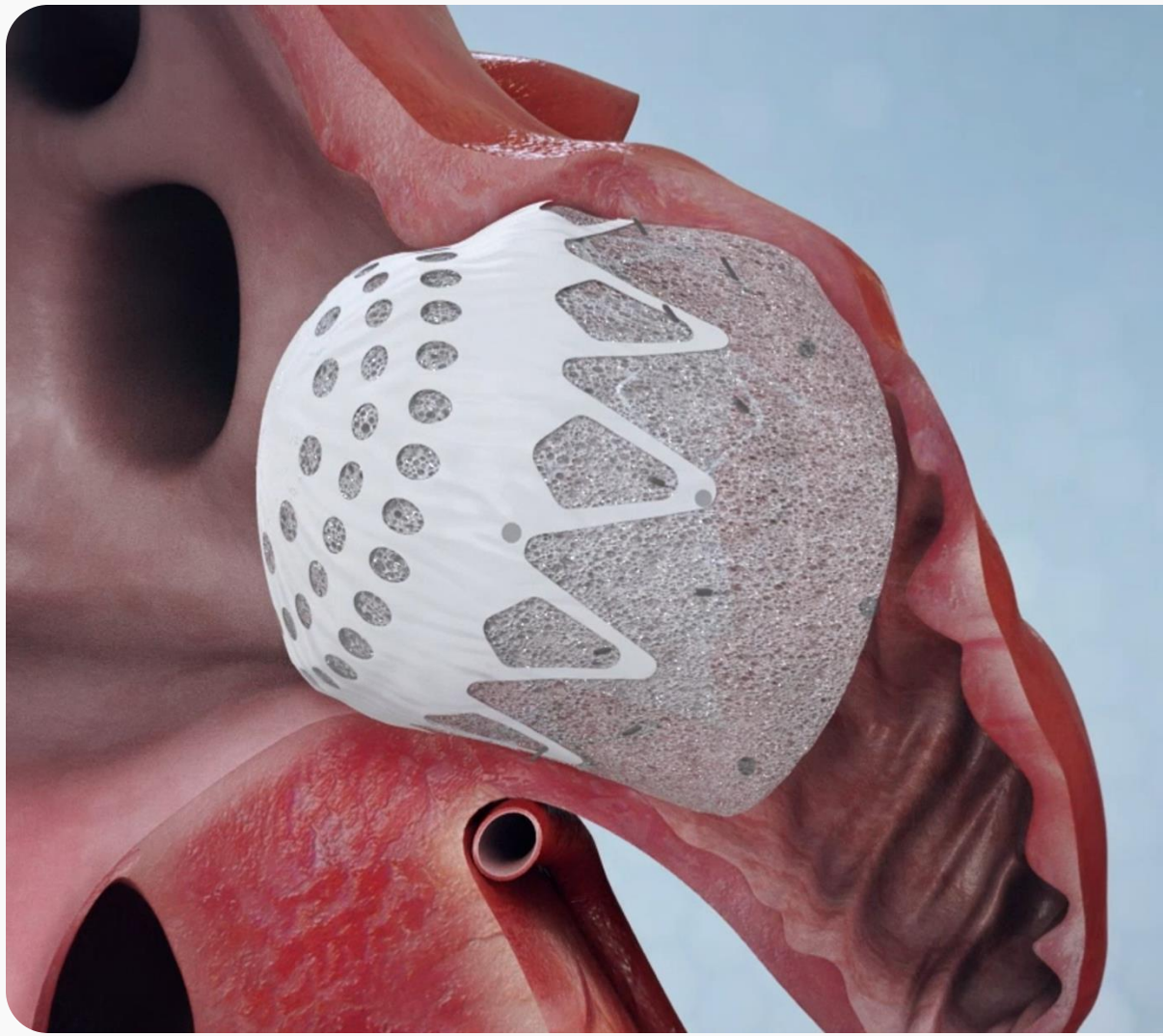
Pivotal Trial: 460 Randomized + 86 Roll-ins*

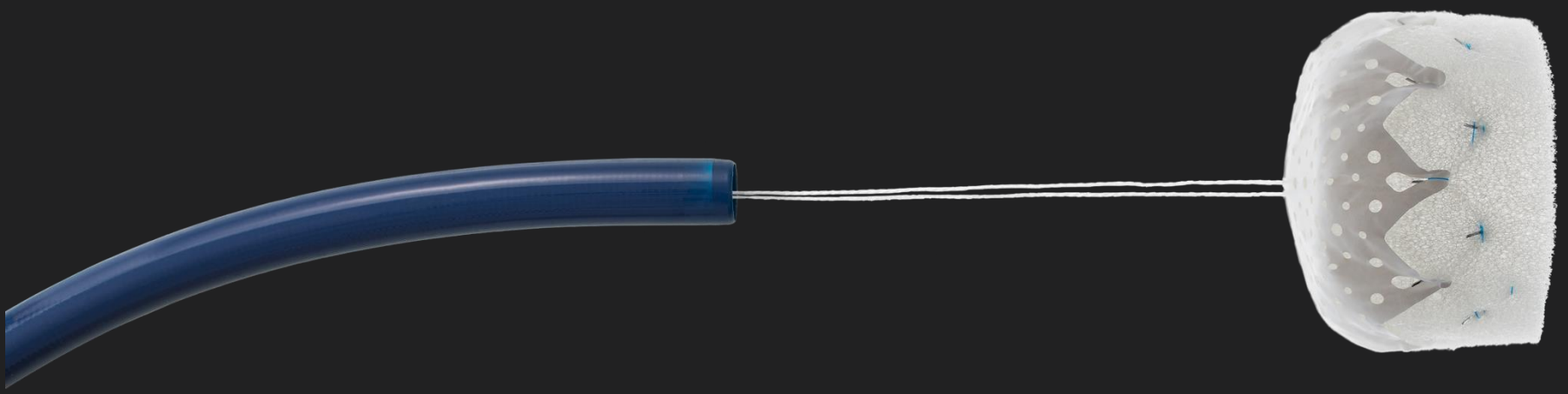
AcuFORM used in 75 patients*

Funded into 2026

Expect to close a new funding round this summer

**As of 05/28/2025*





THE UNSUNG HERO OF CLINICAL RESEARCH

The Critical Importance of Relationship between Clinical Research Coordinator and Sponsor

Deborah Reasner, Director Clinical Affairs

Research Coordinators: Why This Role Matters

Key Impact to Data Quality and Data Integrity

- Accurate and timely data entry into the EDC
- Source documentation retrieval completeness
- Query resolution
- Adverse event tracking and reporting

Outcome: Higher-quality data and minimizes potential audit findings

Why This Role Matters

Front Line Assessment for Regulatory Compliance & Risk Mitigation

- Ensures IRB submissions, renewals/ notifications are on time
- Maintains delegation logs, screening logs, and staff training records
- Supports site audit readiness

Without you, noncompliance risk increases.

Why This Role Matters

Enhancing Patient Experience

- 1st point of contact for subjects→ A compassionate and familiar face for patients and families
- Ensure patient understanding the study through the complexities of informed consent and study follow-up processes
- Coordinates visit logistics making things easy for the patient

Result: Better subject retention = Better study outcomes

Why This Role Matters

Key Partner in Driving Overall Study Success

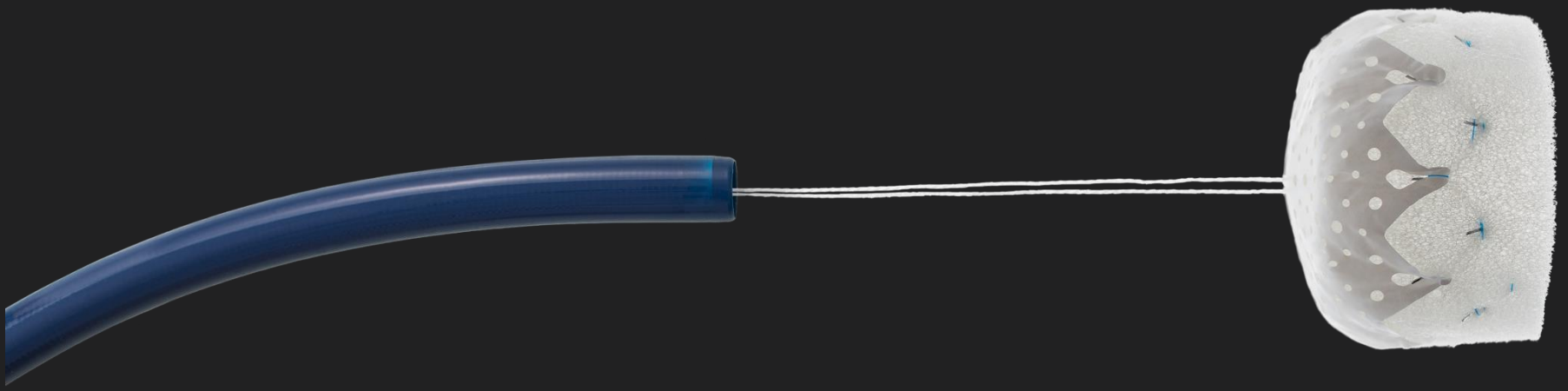
- Enrollment targets are met
- Visit windows maintained
- Noncompliance minimized
- Facilitate frontline communication between sponsor and investigator and patient
- Keeping sponsor informed of challenges in study

Why This Role Matters

Final Thought

Behind every successful clinical trial is a dedicated Clinical Research Professional ensuring that every study detail is accurate, on-time, and compliant.

Your impact on Patients and contribution to Science is Meaningful!!



CONFORM Study Updates

Aly Dechert, Manager Clinical Operations

Site Manager Team

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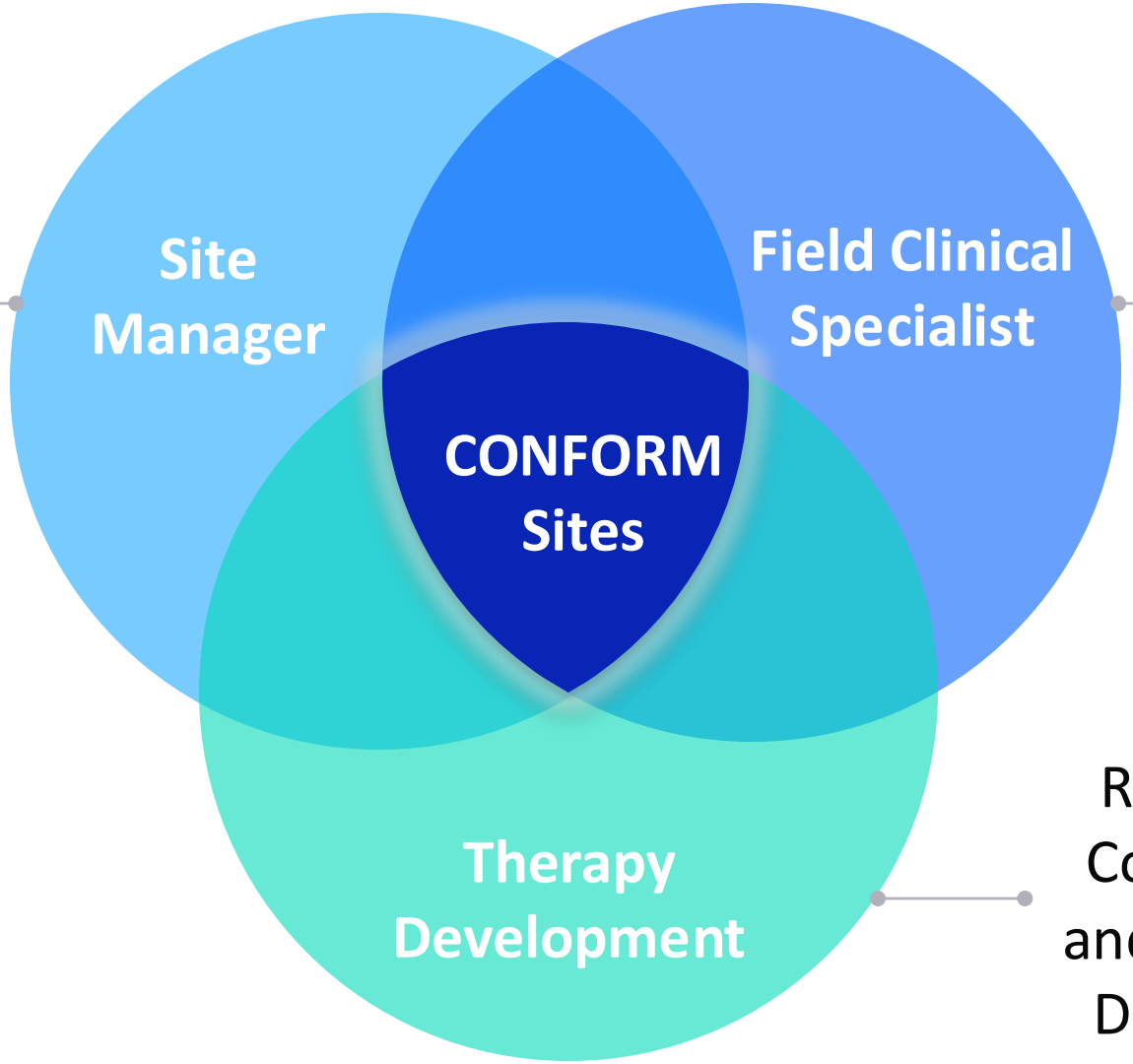
CONFORM Site Team

By working together, we advance the future of LAAO practices

Clinical Trial Support, Protocol Experts



On-site Case Support, Device Experts

Relationship, Collaboration, and Partnership Development

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US Activated Sites

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OUS Activated Sites

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Protocol Update Rev. K

Aly Dechert,
Manager Clinical Operations

Updates to CONFORM Protocol Revision K

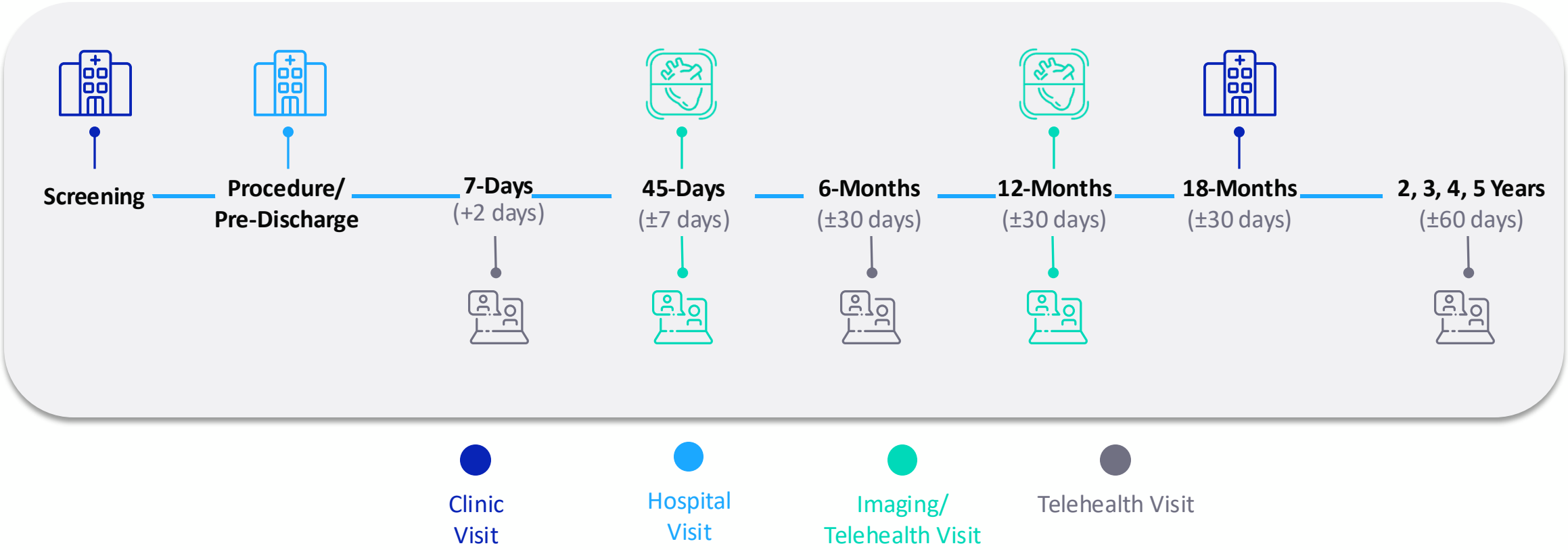
1. **CLAAS AcuFORM:** Next Generation CLAAS device
2. **Roll-In Maximum:** Maximum of 3-4 roll-in patients per site
3. **Study Timeline:** Updated to reflect enrollment pause and GLACE Study
4. **Removal of CHADS2** from eligibility criteria and assessments
5. **Follow Up Schedule - Attempted Population:** Followed for 18-Months (telehealth only)
6. **Screening Imaging: A CT or TEE** is required prior to randomization to properly assess all I/E criteria. Cardiac MRI or TTE alone are not sufficient to randomize the patient
7. **Pre-Discharge TTE: Must be done 4+ hours** after end of procedure
8. **Cardiac CT allowed at 45-day** follow up. Findings of leak or thrombus on CT must be confirmed on TEE and resolution must be documented

Study Design

Sample Size	Prospective, multicenter, randomized control trial Up to **1600 patients randomized; Up to 300 Roll-In Study-Wide** *(maximum 3-4 per site)*
Sites	Up to 100 investigational sites in North America Up to 5 investigational sites in Japan Up to 10 investigational sites in EU/EEA and Central Asia
Randomization	**1:1 randomization**; Non-Inferiority **CLAAS : Any commercially available LAAO device**
Objective	**(1)** To **evaluate the safety and effectiveness** of the CLAAS system by demonstrating non-inferiority to currently marketed LAAO systems in subjects with non-valvular atrial fibrillation **(2)** To demonstrate **the safety of a post-procedure** pharmacologic **antiplatelet regimen** that consists of DAPT alone without concomitant anticoagulation therapy (OAC) **(3)** To demonstrate the **ability to safely deliver the CLAAS Device** using a conscious sedation protocol without general anesthesia. To investigate this objective, a separate sub-study will be conducted after recruitment of the RCT is complete at select, qualified sites based on the experience demonstrated in the RCT **(4)** Support regulatory approval(s) in territories outside US.

Follow Up Requirements

Clinic, Telehealth, and Imaging Visits



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Screening Imaging

Imaging shall be done post-consent prior to randomization.
Historical images within 6 months prior to consent are accepted.

★ TEE

★ Cardiac CT

Cardiac MRI

TTE

Patient with history of stroke or TIA?

Brain
MRI or CT

Anatomical Imaging

Evaluates echo exclusion criteria 1, 5, 6, 8

★ **Required for randomization**

Clinical Imaging

Evaluates echo exclusion criteria 2, 3, 4, 7, 9

May be used as supportive imaging

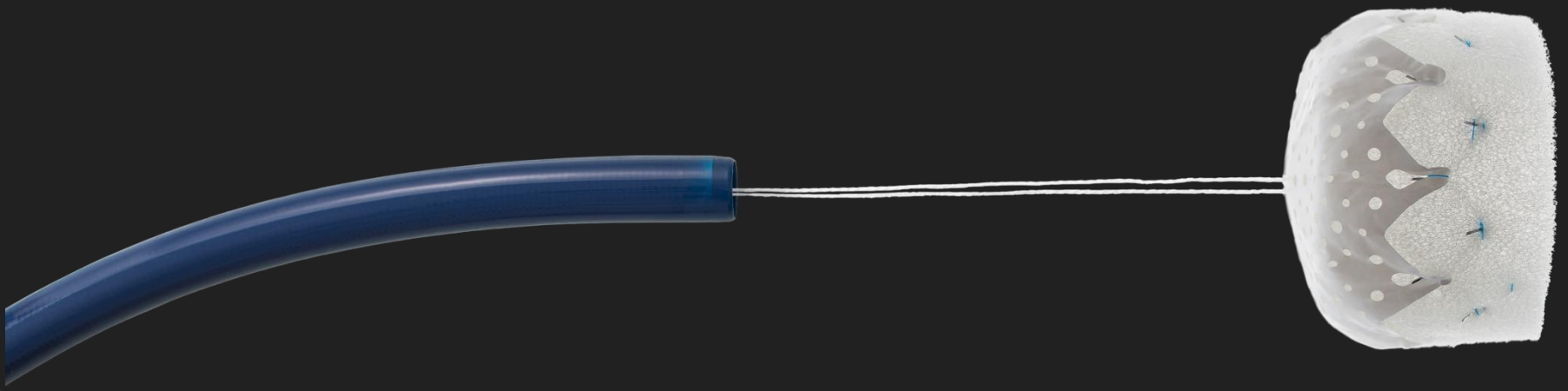
Brain Imaging

If neuro event was ≤ 24 months ago:

Recent brain scan MRI or CT post-neuro event is required

Full Schedule of Assessments

	Screening	Procedure[0]	Pre-Discharge	7-Day	45-Day	6 Month	12 Month	18 Month	2, 3, 4, 5 Year	Stroke/SE Assessment[1]
		Day 0	4 hours	+2 Days	±7 Days	±30 Days	±30 Days	±30 Days	±60 Days	+14 Days
	Clinic	Hospital	Hospital	Telehealth[2]	Clinic Visit/ Telehealth[2]	Telehealth[4]	Clinic Visit/ Telehealth[2]	Clinic Visit	Telehealth[2]	Clinic
Informed Consent	X									
Medical and Surgical History	X									X
Physical Exam/Assessment	X ☆									X
Vital Signs	X									
CHA_2DS_2-VASc	X									
HAS-BLED	X									
Serum Creatinine or GFR/eGFR	X									
CBC, Platelet count and Hgb/Hct	X	X[4] ☆								
ECG 12 Lead	X									
Pregnancy Test	X									
Neuro Assessment	X		X					X		X
QVSFS	X			X	X	X	X	X	X	X
Cardiac CT	X ☆				X[11] ☆		X[11]			
TTE	X[10]		X[10]		X[12]					
TEE		X			X[12]		X[12]			X
Brain Imaging	X									X[14]
AE Assessment	X	X	X	X	X	X	X	X	X	X
Medication Review[15]	X	X	X	X	X	X	X	X	X	X
INR	X	X								
Randomization	X[16]									
LAA Measurements		X								



CLAAS® AcuFORM™

Dana Sullivan, VP Therapy Development

Drivers of A Rapidly Growing LAAO Market

Patients

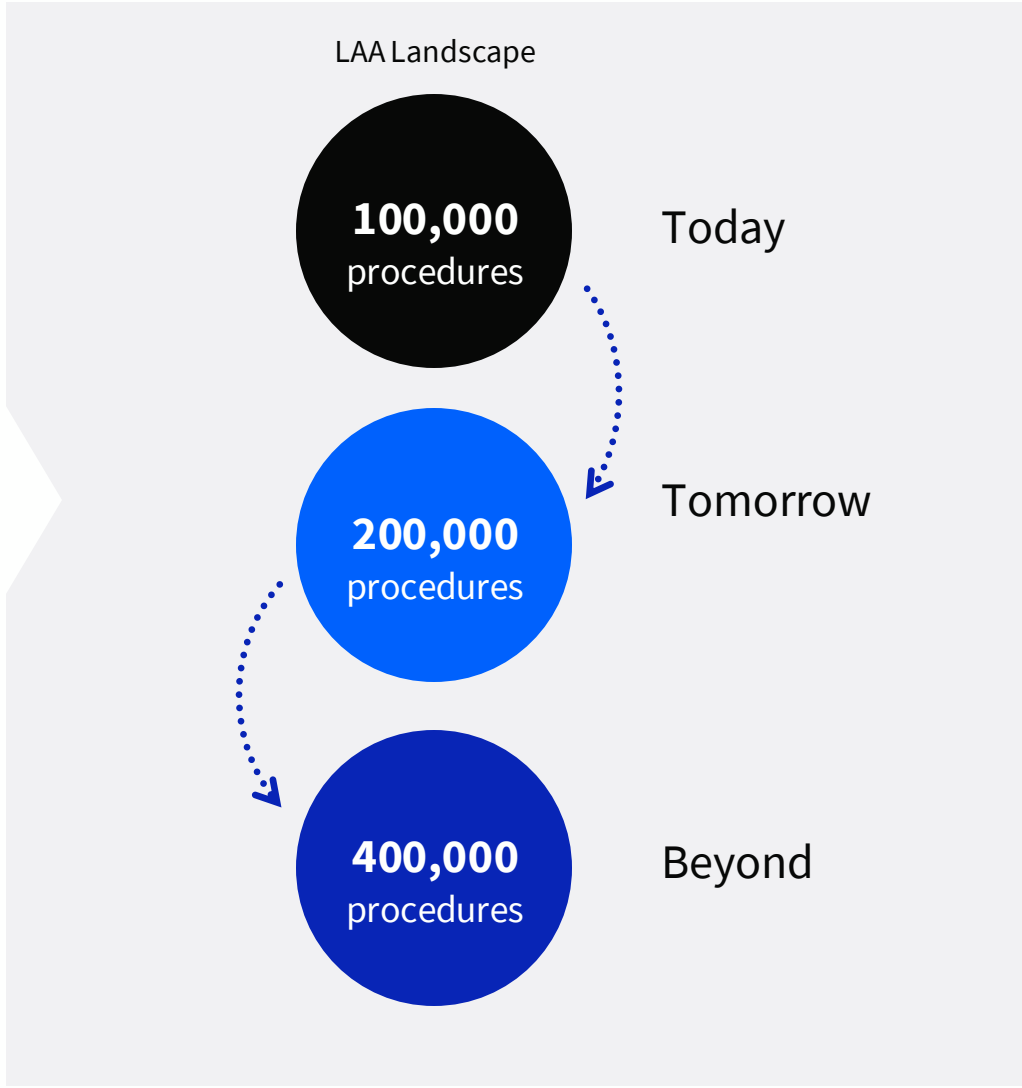
- Increasing Prevalence of Afib
- Evolving Patient Preference

Physicians

- Growing Physician Adoption
- Advancements in LAAO Technology
- Strong Clinical Evidence and Guideline Integration

Payors

- Favorable Reimbursement Policies
- Geographic Market Expansion
- Indication Expansion



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A Rapidly Growing Market Needs An Optimized Solution

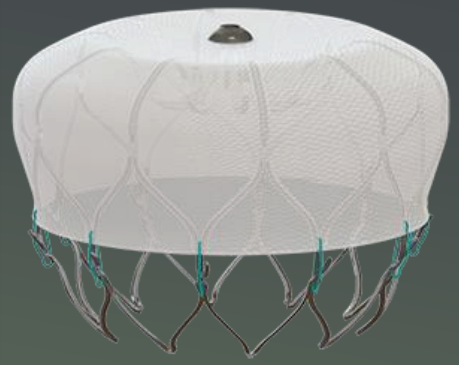
2023[1]
100,000 Patients treated

2025[1]
150,000 Patients forecasted

2030[2]
400,000 Patients forecasted

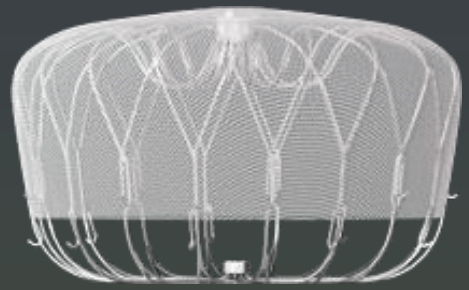
1. Piper Sandler Market Update September 2023
2. Boston Scientific Investor Day September 2023

Watchman



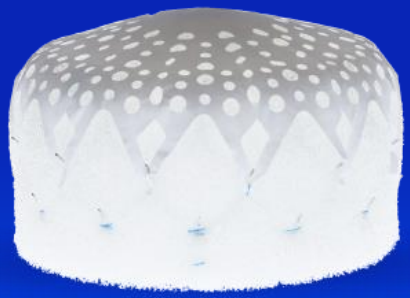
1st GEN
Pioneered Market
PMA Approval
CMS Coverage

Watchman FLX PRO



3rd GEN
Established Market: >$1.2B 2023
TEE/General Anesthesia
3 Physician Procedure

Conformal CLAAS AcuFORM



NEXT GEN
Transforming Market: Improved Closure; Conscious Sedation; Single Physician Procedure

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Claas® AcuFORM™

Next-Generation LAAO Technology.

- One Size Strategy Addresses >90% of patients
- Confirm Seal with Peri-procedural Angio
- Efficiency of Workflow Allows for Scale
- Facilitates Single Operator Procedure

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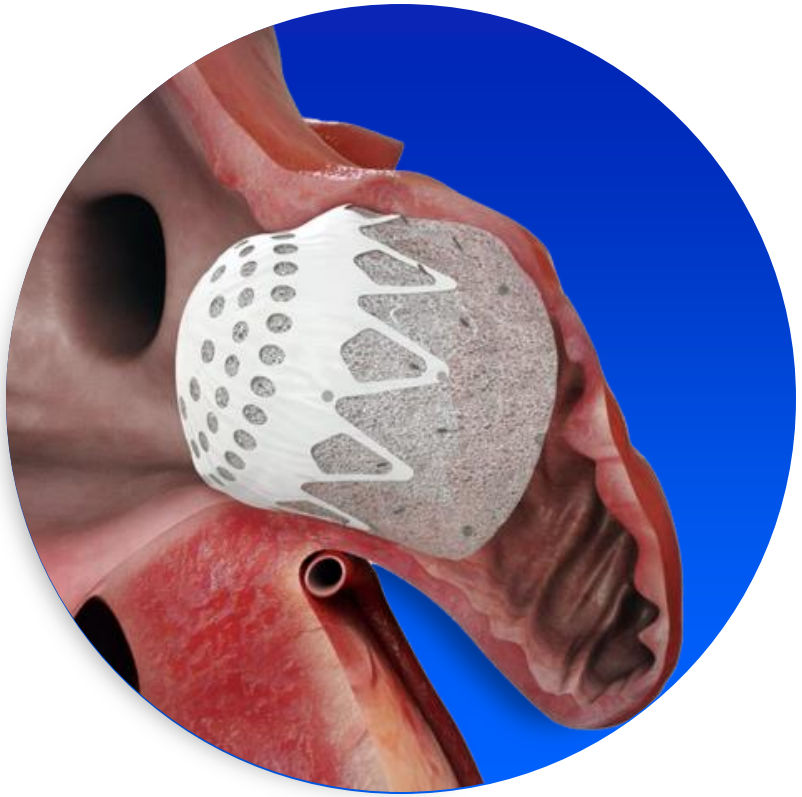
CLAAS® AcuFORM™ Next-Generation LAAO Device



- Builds upon the novel CLAAS device
- Engineered to conform to and seal the LAA
- Only two sizes, one of which effectively treats over 90% of patient anatomies
- A proven delivery technique
  - Potentially eliminating the need for general anesthesia,
  - Enhancing operational efficiency
  - Enabling healthcare providers to easily confirm appendage seal

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CLAAS® AcuFORM™

Left Atrial Appendage Occlusion System

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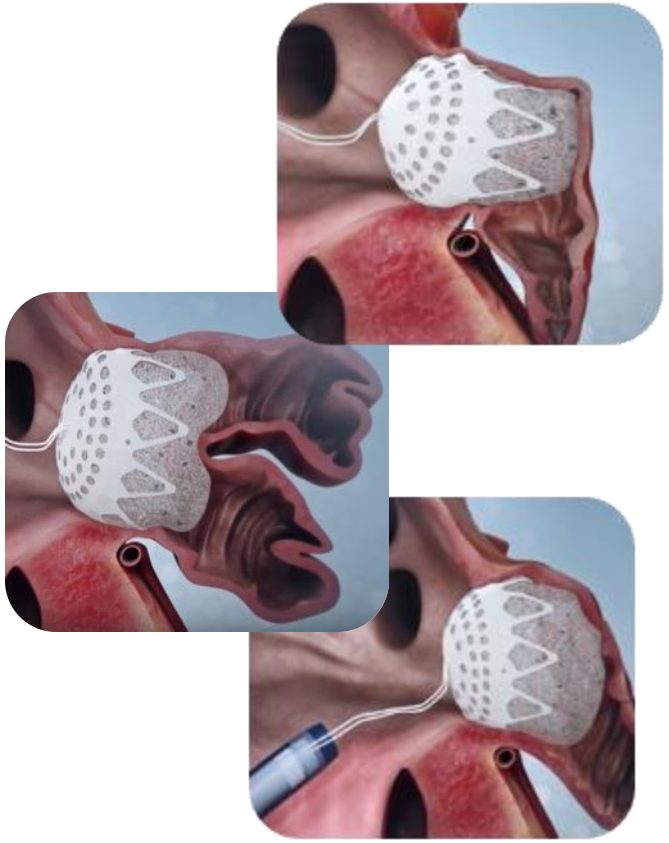

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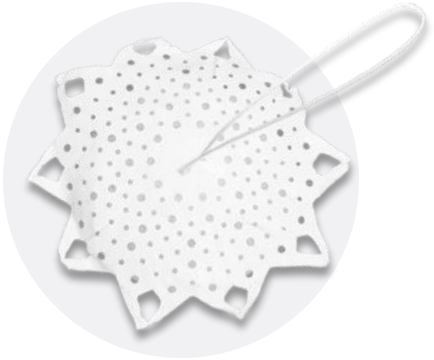
The Conformal CLAAS® AcuFORM™ LAAO Implant

Conformable Implant
Available in 2 sizes

Compliant Nitinol
Endoskeleton

Foam Matrix Body
&
5 Radiopaque
Marker Bands



ePTFE Cover
&
Flexible Tether

Indication for use: To reduce the risk of thromboembolism from the left atrial appendage in patients with non-valvular atrial fibrillation, without the need for oral anticoagulants.

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Simplified Sizing

1 size address >90% of patients

Shallow
10mm landing zone

Regular Size CLAAS® Device
(LAA Ostium Range of 10-33 mm)

Large Size CLAAS® Device
(LAA Ostium Range of 20-40 mm)

WATCHMAN™

Amulet™

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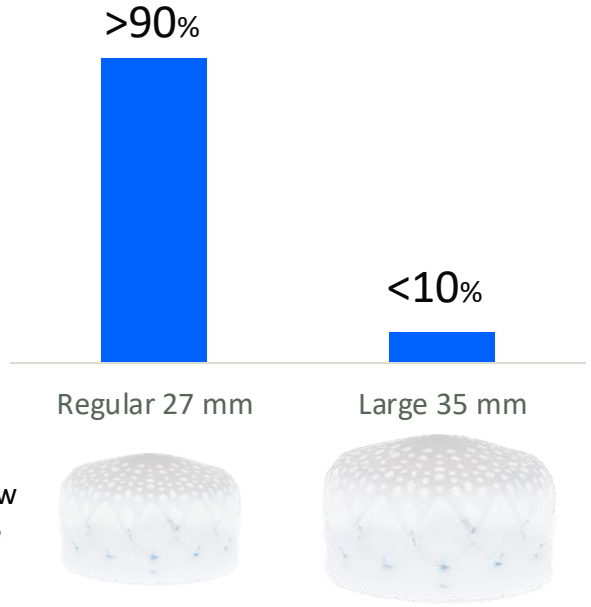
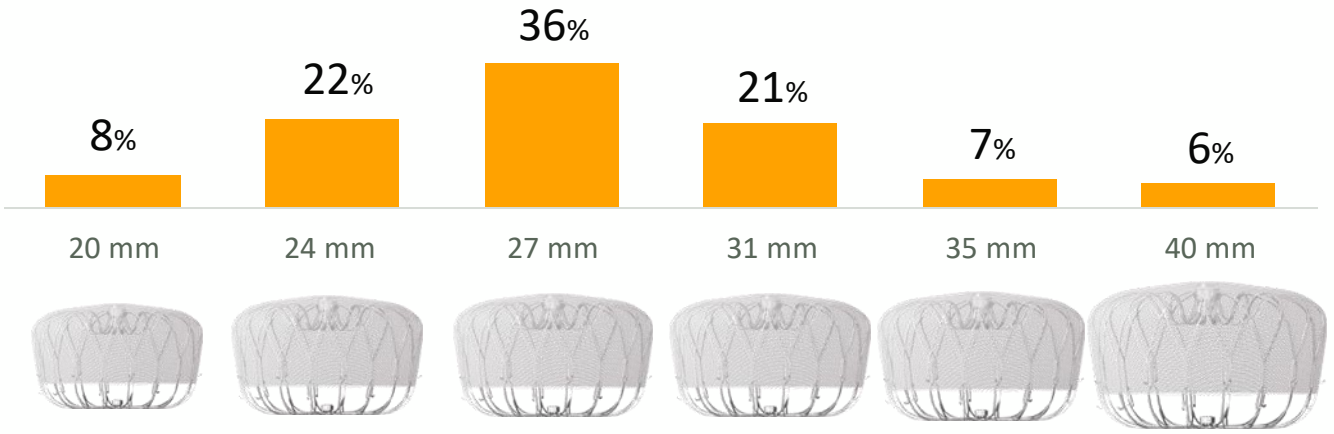
Simplified Sizing

CONFORMAL Vs. WATCHMAN™

Implant size and percentage used



10 mm shallow landing zone



Variable landing zone (requires half the LAA depth or longer)*

CONFORMAL- CLAAS® ACUFORM™[1]

1 size treats >90% of patients

BSC-WATCHMAN FLX™[2]

6 sizes required

*IFU BSC-WATCHMAN

1. Conformal Medical Data on File
2. Doshi SK, et, al; PINNACLE FLX Two-Year Outcomes With a Next-Generation Left Atrial Appendage Device: Final Results of the PINNACLE FLX Trial. J Am Heart Assoc. 2023 Feb 21;12(4):e026295.

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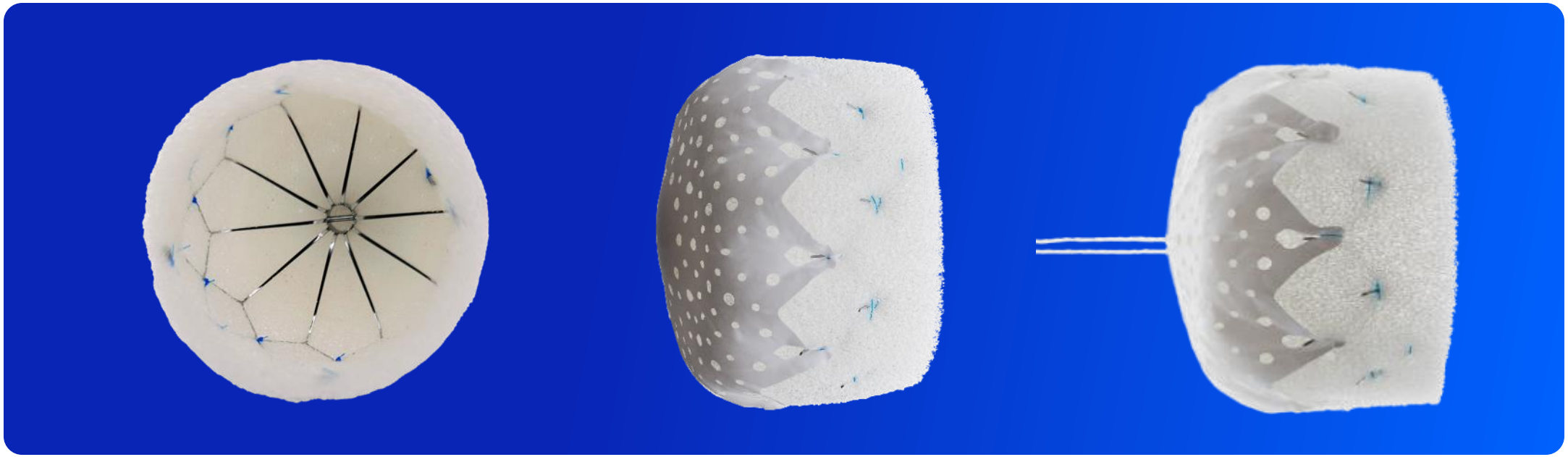
Definitive Seal and a Smooth Surface



Compliant endoskeleton
Conforms

ePTFE cover
Less thrombogenic

Flexible tether
Eliminates cable attachment site
Eliminates cable bias

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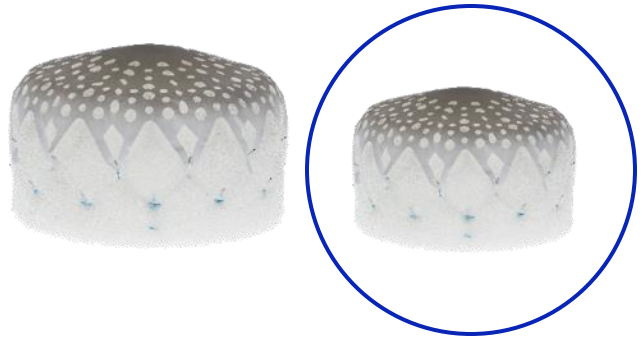
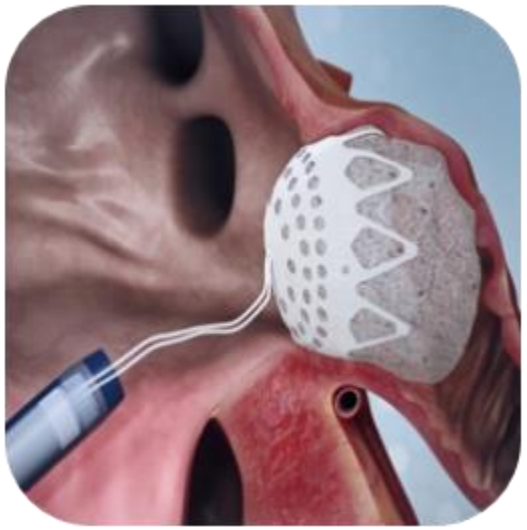
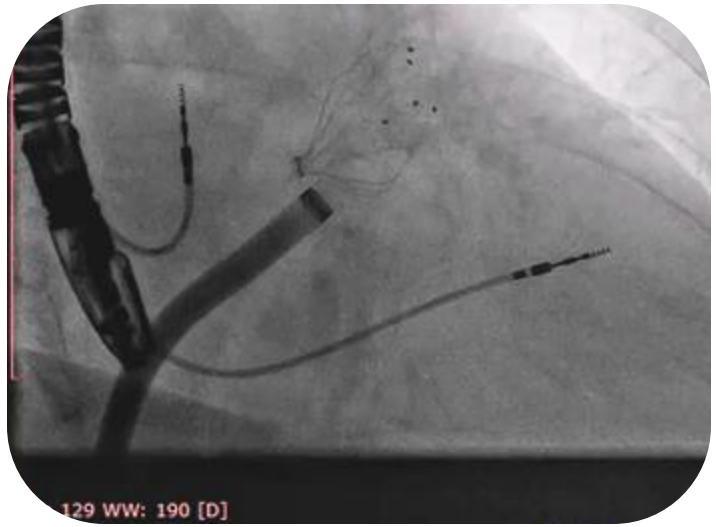
Eliminating TEE Enables Conscious Sedation

Simplified Sizing	Unbiased Positioning	Ability to Test with Angiography



>90%





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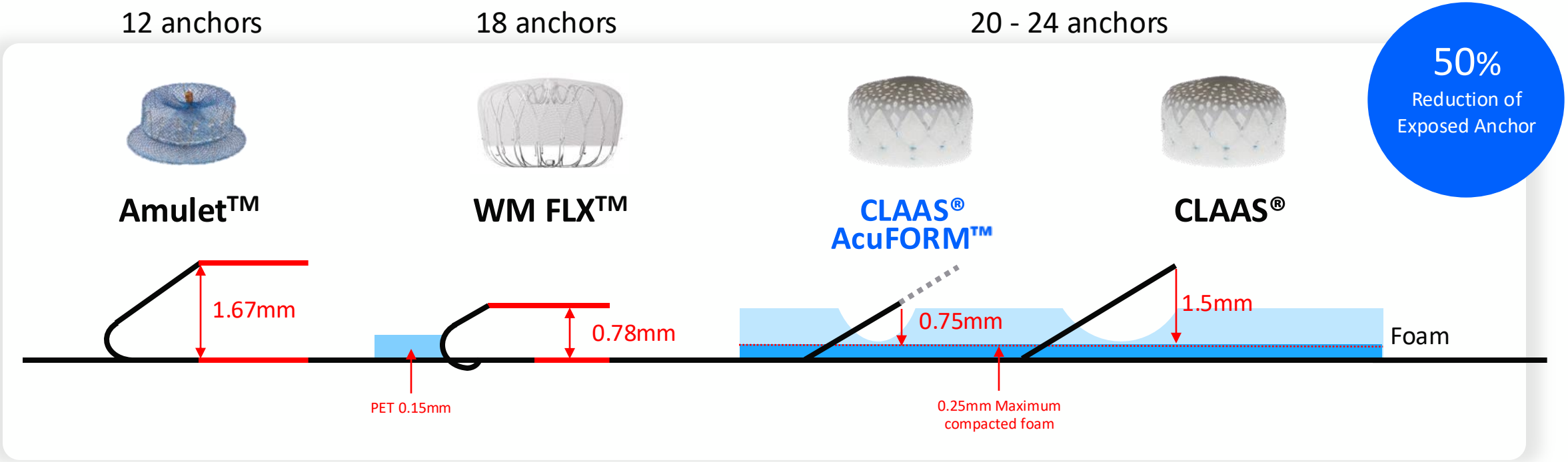
LAAO Device: Anchor Penetration Depth



Drawings are illustrative

CLASS Implant (20 anchors regular) (24 anchors large)

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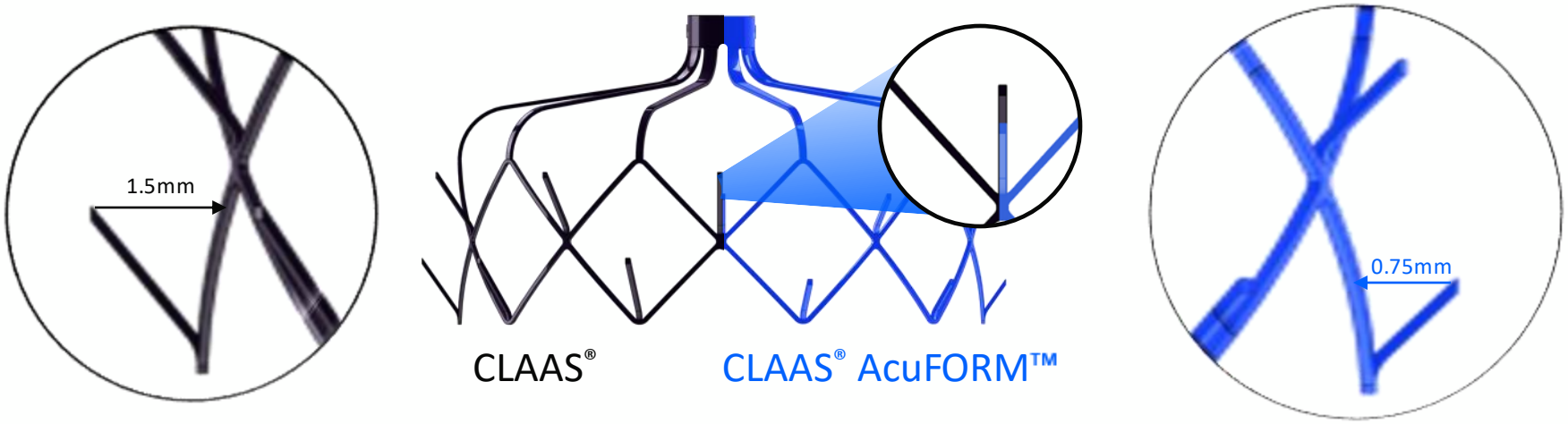
Anchor Pull Forces in Tube & Plate Models[1]

Device	Exposed Anchor Length (mm)	Tube Model* In Pounds	Plate Model In Pounds
CLAAS® (27mm)	1.5	0.65 (25 mm ID)	1.22
CLAAS® AcuFORM™ (27mm)	**.75**	**0.60 (25 mm ID)**	**0.95**
Control (27mm WM FLX™)	**~0.78**	**0.40 (24 mm ID)**	**0.30**

**Tube ID closest size available (without exceeding) to max ostium width from IFU*



1. Conformal technical report TR-89 Anchor Shortening Analysis.

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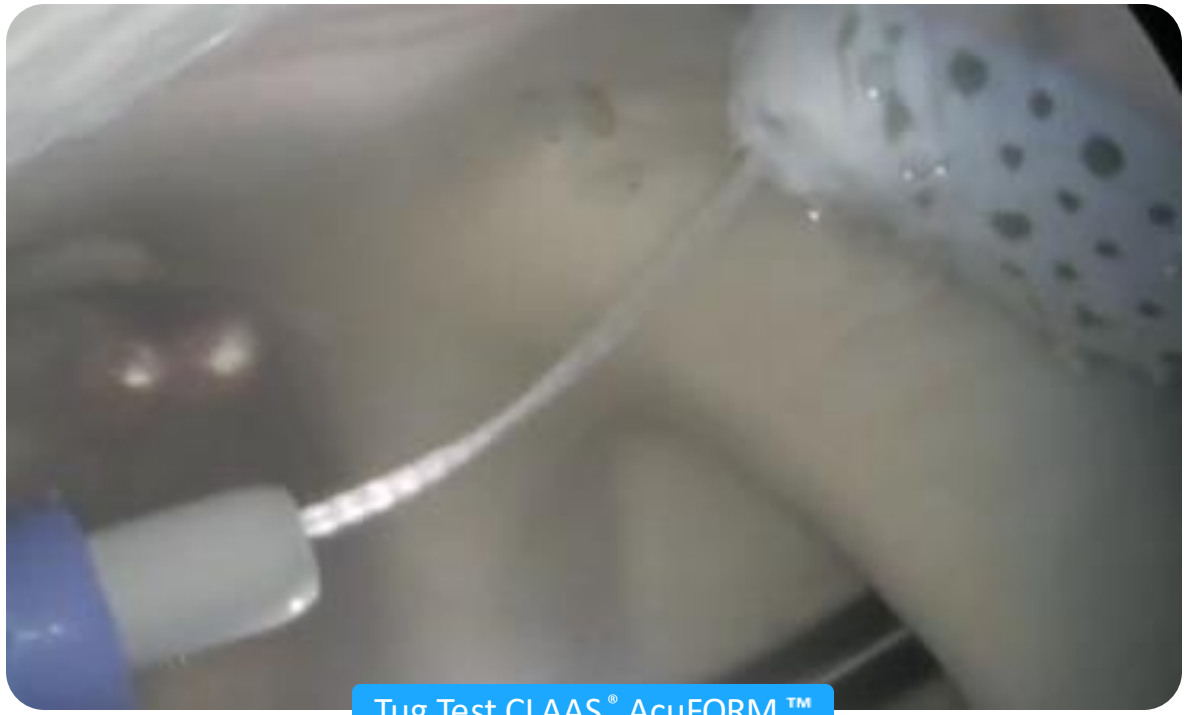
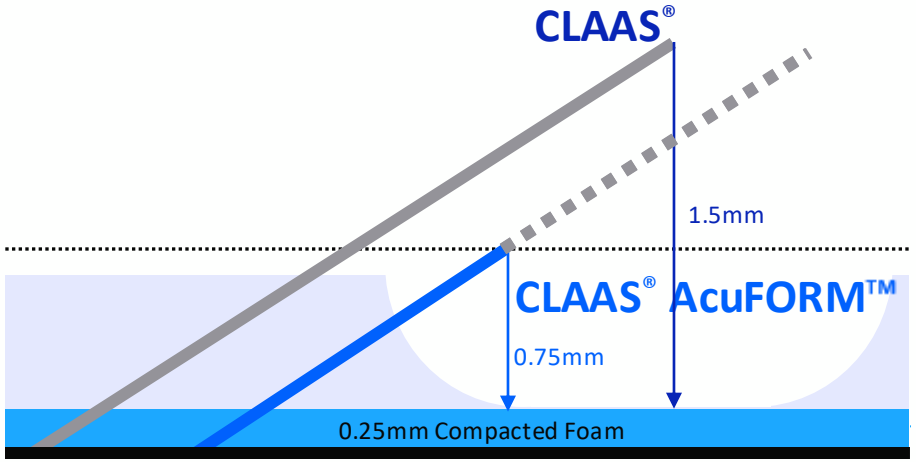
CLAAS® AcuFORM™ Tug Test



Tug Test CLAAS® AcuFORM ™



Drawings are illustrative

- 50% shorter anchors
- Reduced tissue penetration (0.75mm)
- Two rows of anchors (regular=20, large =24)

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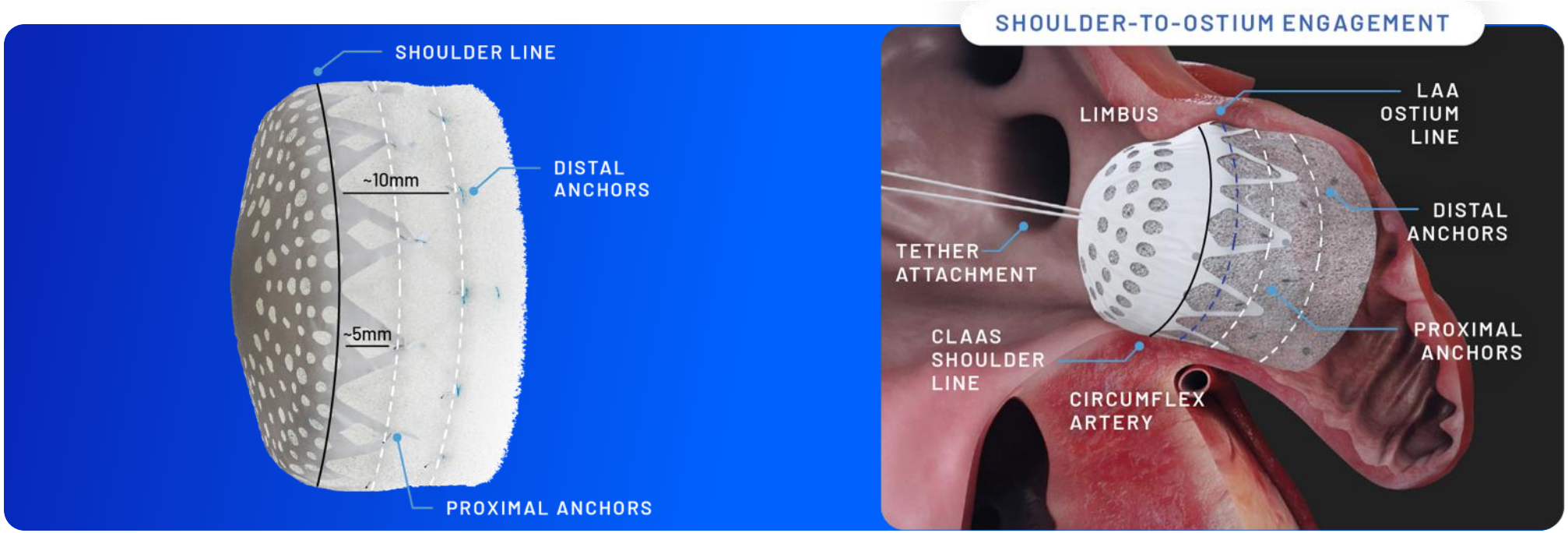
CLAAS® AcuFORM™ Anchoring System

- Shoulder line to be <5mm proximal to the LAA ostium and not to exceed 8mm
- Both rows of anchors should engage tissue
- The distance from the shoulder to the anchors does NOT change with compression



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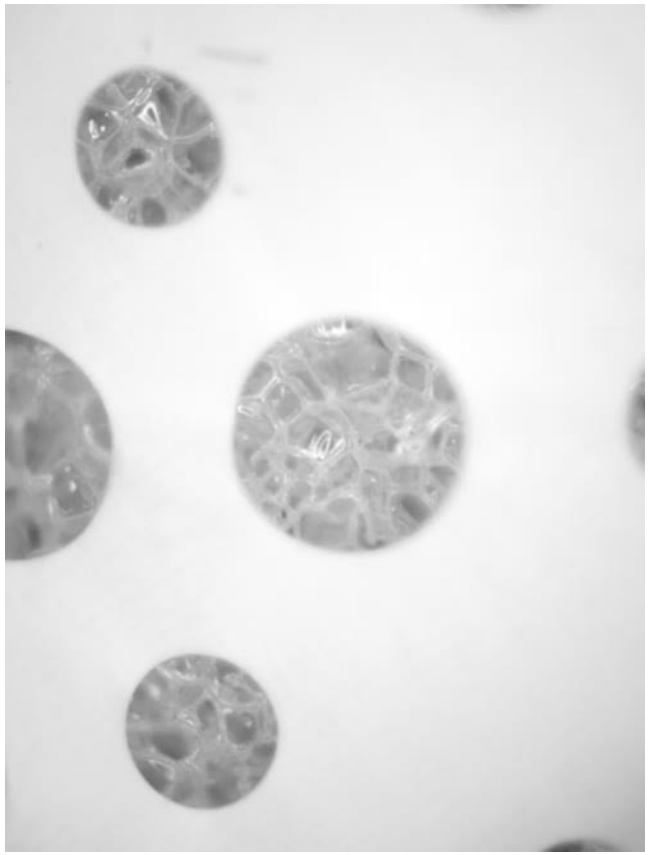
WM FLX vs. CLAAS®

WM FLX

PET



CLAAS AcuFORM

ePTFE

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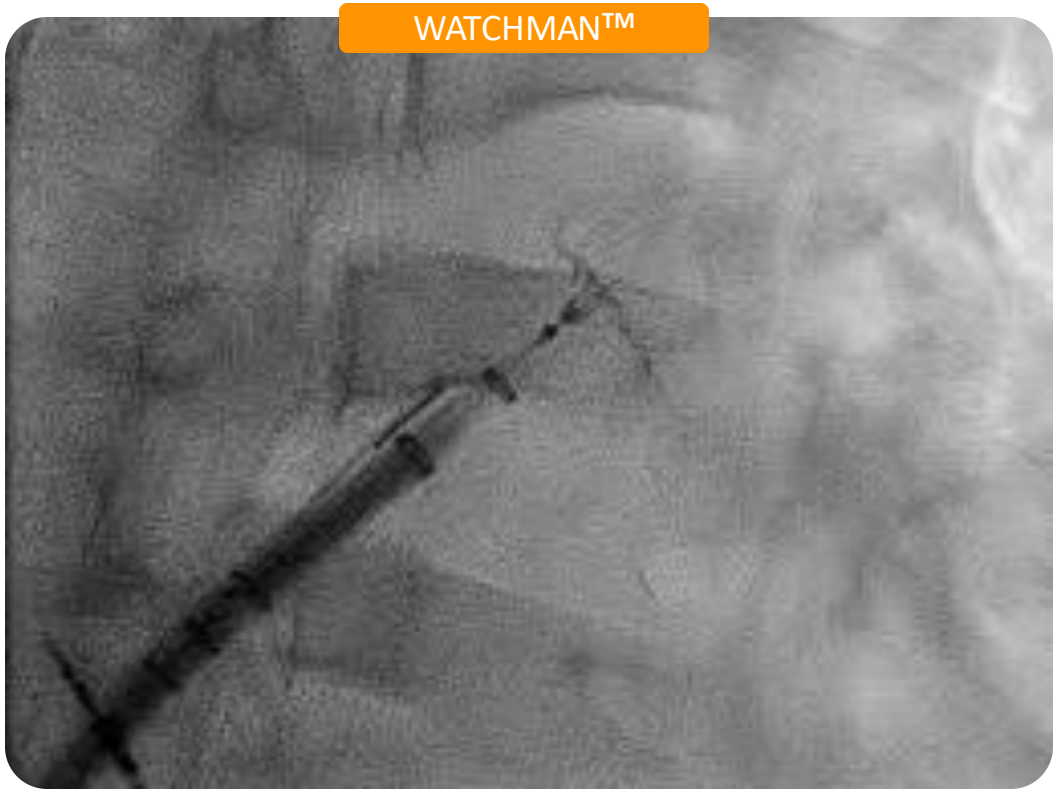
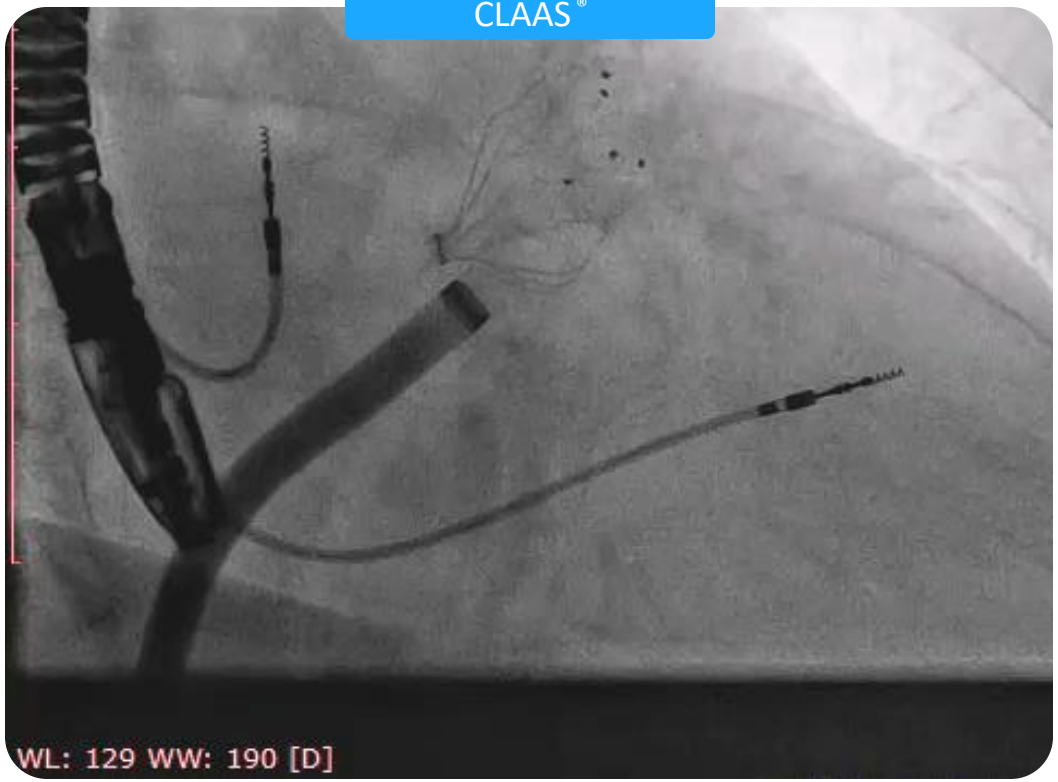
Confirming Seal

WATCHMAN™



CLAAS®



97.7% Seal Rate without significant (>3mm) leaks at 12 months, comparing favorably with marketed devices.[1]

1. Gray W, Conformal Early Feasibility Study: 12 Months Results. TCT 2023 Study Details | The CONFORMAL Early Feasibility Study | ClinicalTrials.gov

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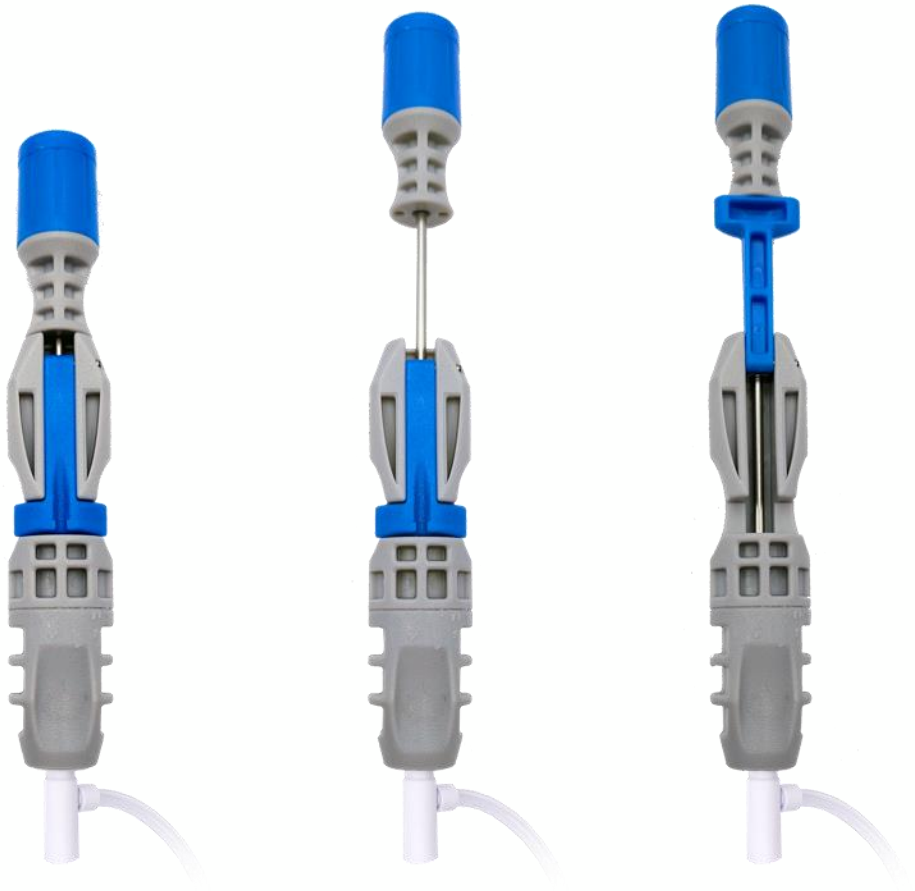
Intuitive Handle



- Simple and easy to use
- Improved ergonomics
- Effortless tether management
- Increased durability
- Enhanced deployment & confirmation
  - Cable-like delivery
  - Tether permits placement without cable bias

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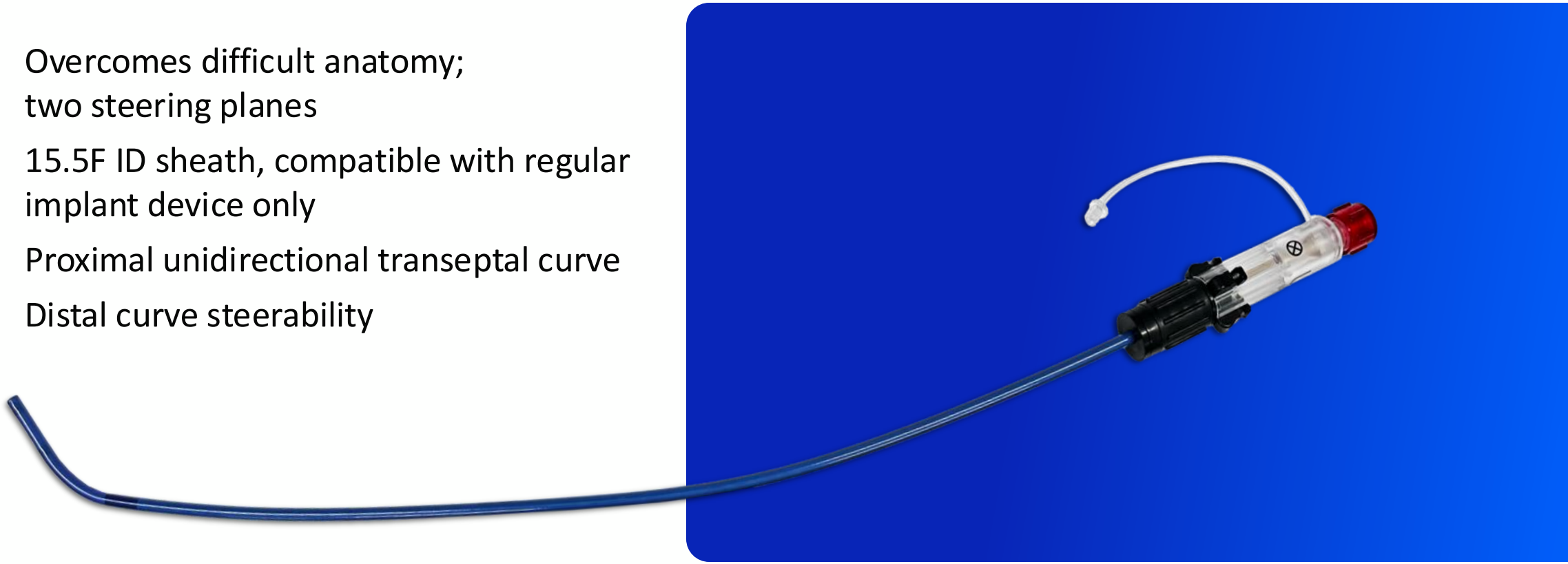
OEM Steerable Sheath

- Overcomes difficult anatomy; two steering planes
- 15.5F ID sheath, compatible with regular implant device only
- Proximal unidirectional transeptal curve
- Distal curve steerability



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CONFORM Pivotal Trial Early Feasibility Data

claas®

97.7% Seal Rate

Seal without significant (>3mm) leaks at 12 months, comparing favorably with marketed devices.[1]

1. Data on file, based on core lab evaluable images, study in progress N=40

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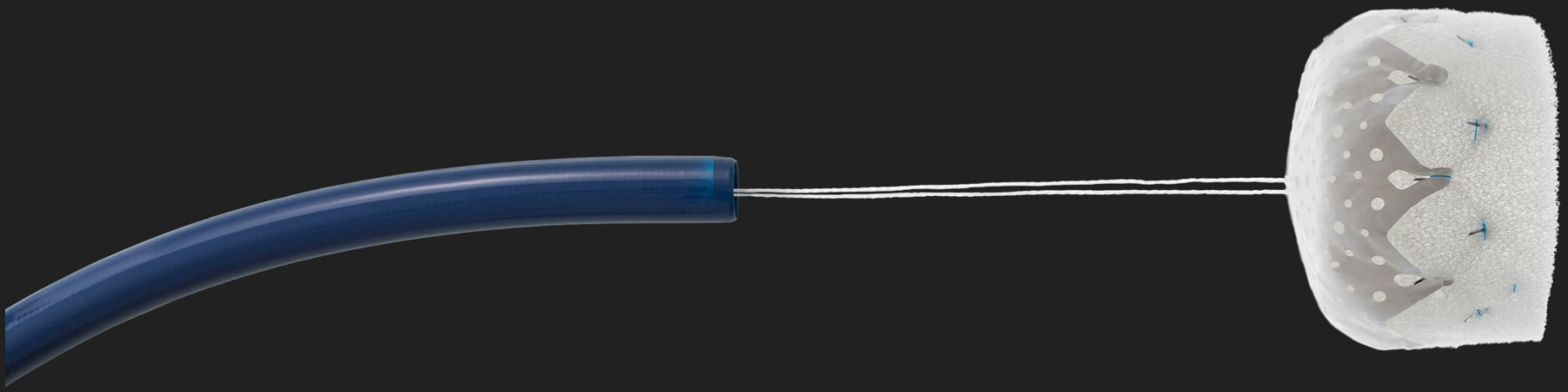
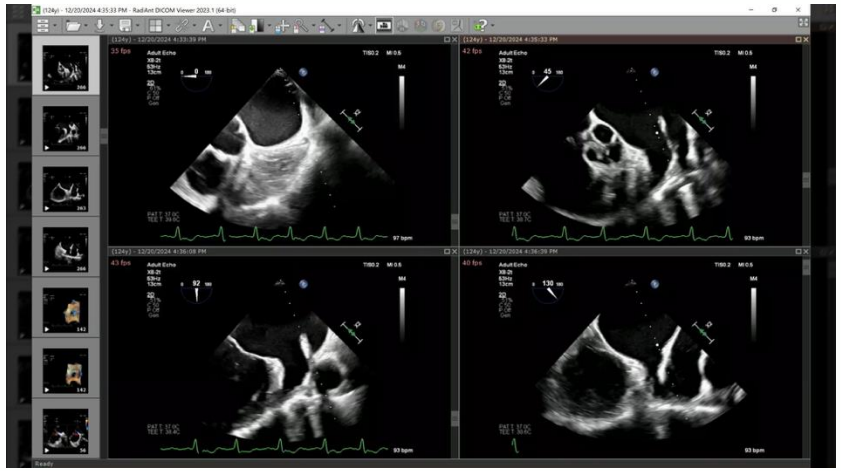


Imaging Requirements

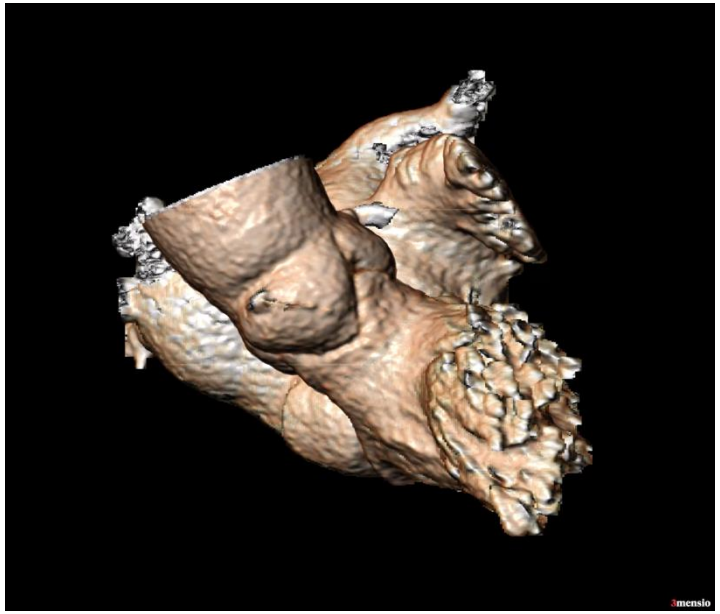
Alyssa Smith, Imaging Manager

Screening Imaging & Pre-Procedure Review Process



★ TEE

★ Cardiac CT



Anatomical Imaging

Evaluates echo exclusion criteria 1, 5, 6, 8

★ **Required for randomization**

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Screening Imaging & Pre-Procedure Review Process

U.S. Sites with **LESS than 5 Enrollments **FIRST PATIENT****

- Site Manager issues Pre-Procedure Review Template Deck to Site for Site & Subject Demographic Information
- FCS Team assesses anatomic suitability of LAA
- **TD assists to arrange a 1:1 w/ PI & Exec Committee (EC)**

Site returns deck to Site Manager

PDF of completed deck and notification of suitability is provided to site

- FCS embeds assessed dynamic & static images from TEE or CT
  - **1:1 call**
- EC and/or designate at CMI indicates suitability

- Site completes the remaining screening process, confirms general I/E criteria are met

Proceed to Procedure or Study Exit

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Screening Imaging & Pre-Procedure Review Process

U.S. Sites with **LESS than 5 Enrollments **PATIENT 2-5****

- Site Manager issues Pre-Procedure Review Template Deck to Site for Site & Subject Demographic Information
- FCS Team assesses anatomic suitability of LAA

Site returns deck to Site Manager

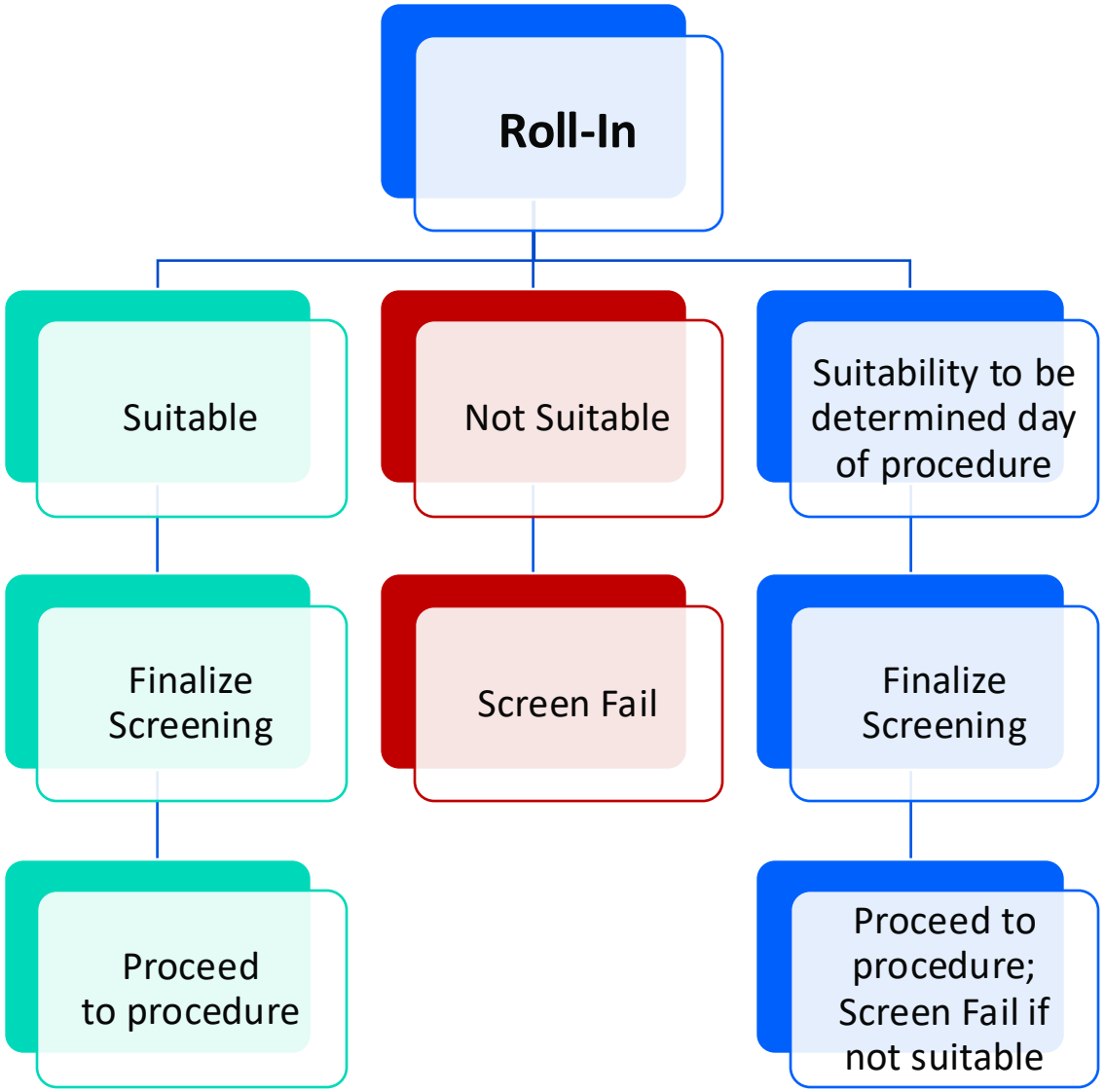
PDF of completed deck and notification of suitability is provided to site

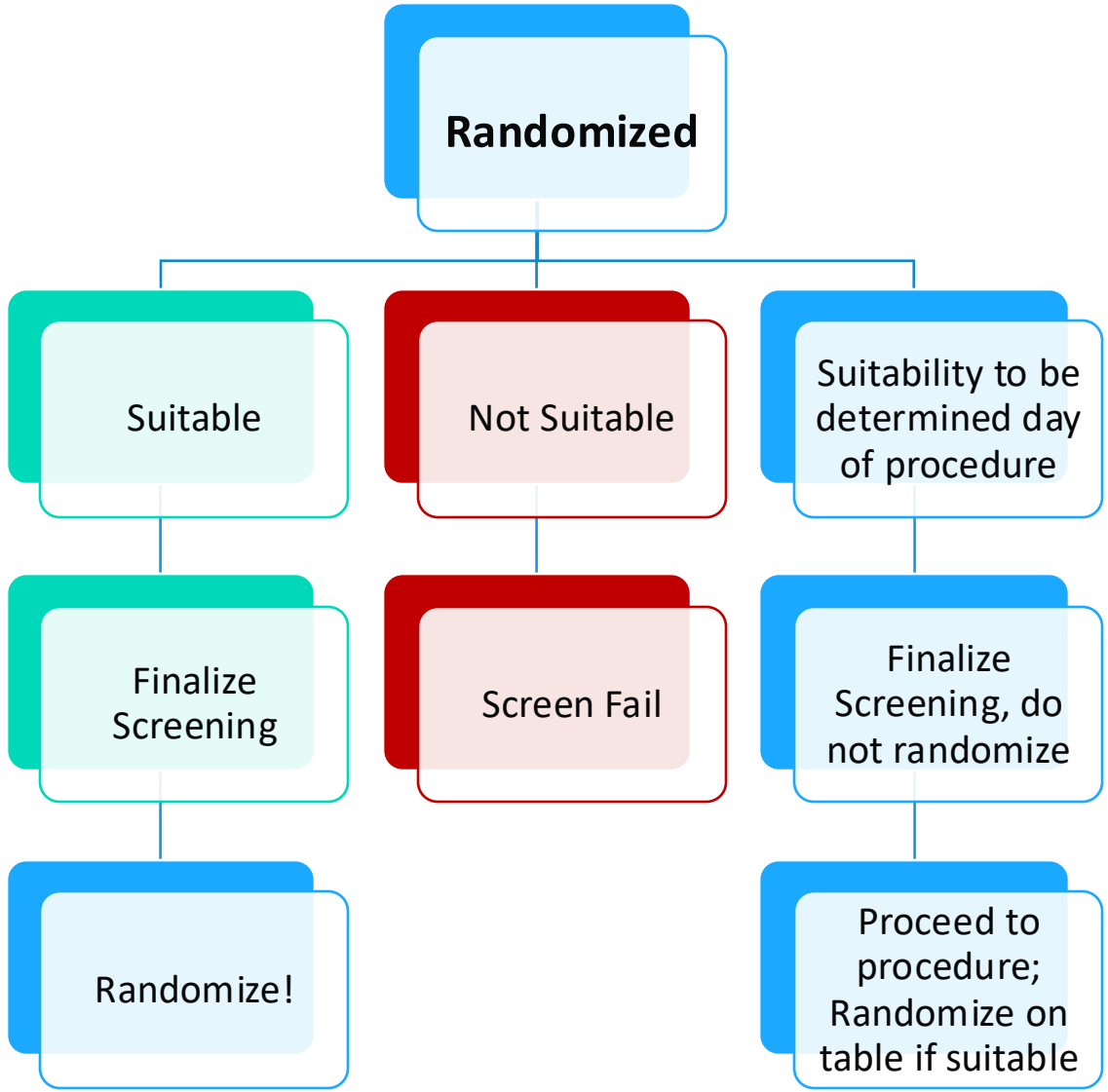
- FCS embeds assessed dynamic & static images from TEE or CT
- EC and/or designate at CMI indicates suitability

- Site completes the remaining screening process, confirms general I/E criteria are met

Proceed to Procedure or Study Exit

Screening Imaging & Pre-Procedure Suitability





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Screening & Pre-Procedure Review Process

U.S. Sites with **MORE THAN 5 Enrollments**

Conformal Field Clinical Support (FCS) Team reviews images for anatomy & imaging per Inclusion/Exclusion criteria within 48 hours

Is the Patients anatomy appropriate for the CONFORM Trial?

YES

FCS Team notifies site to move forward

NO

Patient anatomy requires additional review

FCS Team notifies Designated Clinical Exec Committee reviewer

Is the Patient anatomy appropriate?

YES

FCS Team notifies site to move forward

NO

FCS or Clinical Exec Committee reviewer notifies site of exclusion rationale

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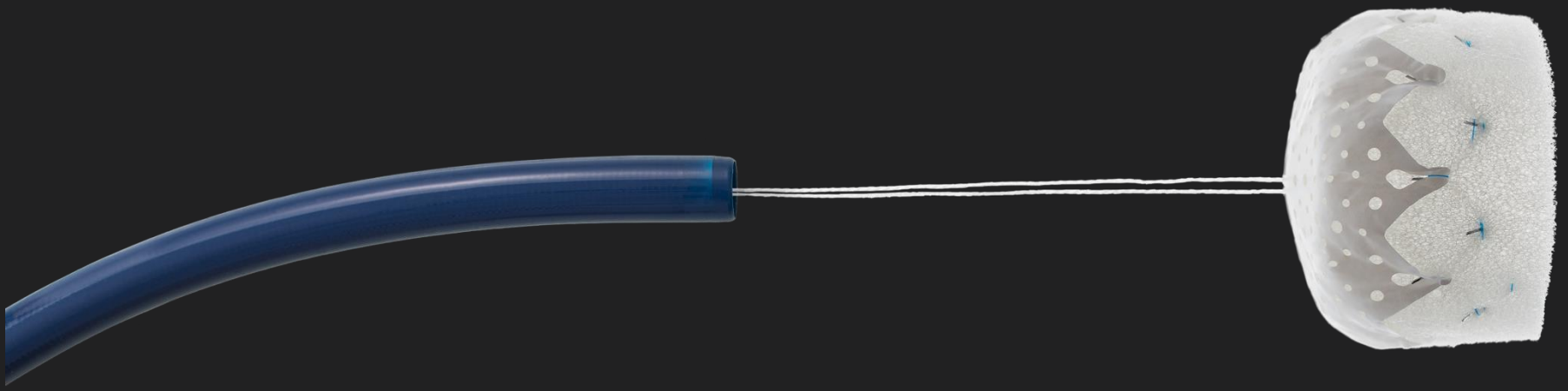

AE Reporting, EDC Updates and Source Worksheets

Melissa Ricketts & Eileen Berbary, Senior CRAs

AE Reporting, EDC Updates & Source Worksheets

AE Reporting

- The Basics
- Comp Check

EDC

- CCGs
- Tips

Source worksheets

- DTT vs Source
- Updates

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Adverse Event Reporting

- An adverse event (AE) is **any untoward medical occurrence, unintended disease or injury or untoward clinical signs (including an abnormal laboratory finding)** in a subject, whether related to the study device and whether anticipated or unanticipated.
- A reported AE **does not imply** that there is **a relationship between the AE and the study device.**
- Source documentation related to an AE is **only required** if selected for Clinical Events Committee Adjudication.
- **Roll-In** adverse events collection occurs from the **time of the consent** through subject **study completion.**
- **Randomized** adverse events collection occurs from the **time of randomization** through subject **study completion.**
- For subjects who **did not have an implant, study completion is at 45 days.**

Adverse Event Reporting

- An **unanticipated adverse device effect (UADE)** is any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death **was not previously identified in nature, severity, or degree of incidence in the clinical investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.**

- Must be reported to Conformal and your IRB/REB **as soon as possible** but no later than within **2 working days** after you (site personnel) first learn of the event

Adverse Event Reporting

- All serious adverse events (SAEs)
- All device and procedure-related adverse events
- Unanticipated adverse device effects (UADEs)
- Pre-procedure events (i.e., events related to pre-procedure medication changes)
- The following events regardless of seriousness or relatedness will be collected:
  - Bleeding events
  - Myocardial Infarction
  - Pericardial Effusion Requiring Drainage
  - Embolic events (e.g., stroke, TIA, Systemic Embolism)
  - Neurologic events
  - Device embolization
  - Device Related Thrombus

Adverse Events of Special Interest

Adverse Event of Special Interest?	☐ Yes ☐ No	If yes, check all that apply	☐ Bleeding Event ☐ Myocardial Infarction Were cardiac enzymes drawn? ☐ Yes (Complete Cardia Enzyme Form) ☐ No ☐ Unknown ☐ Neurological Event ☐ Vascular Complication ☐ Systemic Embolization

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CONFORM Bleeding Event Source Worksheet

Site Number: _____ Subject ID: _____

Note: This form is not required to be completed if information is readily available on medical records.

Date of Event:	__/__/____ (DD/MMM/YYYY)
Was the subject on antiplatelet therapy at the time of the bleeding event?	☐ Yes *If Yes, ensure ConMed Log is completed* ☐ No
Was the subject on anticoagulation therapy at the time of the bleeding event?	☐ Yes *If Yes, ensure ConMed Log is completed* ☐ No
Is the INR level at the time of bleeding event known?	☐ Yes, enter INR Level: _____ ☐ Not applicable ☐ Unknown

_____ Site Personnel Signature

__/__/____ Date (DD/MMM/YYYY)

If an AE is deemed not to be related to the device, procedure implant or medications and is not cardiovascular or neurological in nature **AND**; does not meet serious adverse criteria..... **it does not need to be reported.**

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Adverse Event Reporting Examples

Are these events reportable per CONFORM Pivotal protocol?

1. Subject did not receive the roll-in implant and was hospitalized for pre-planned procedure s/p 75 days from index procedure.
2. Randomized subject was hospitalized for less than 24 hours after the 18 month follow up visit occurred.
3. Subject received commercial implant and had a worsening condition that was not neurological or cardiovascular in nature.
4. Roll In subject had a medication change during a prolonged hospitalization and was started on an anticoagulant due to new elevated labs for a blood clotting disorder.
5. Roll-In subject baseline laboratory results report hypomagnesemia and 18 month follow up visit reports a reduction in magnesium levels.

Adverse Event Reporting Answers

Are these events reportable per CONFORM Pivotal protocol?

1. Subject did not receive the roll-in implant and was hospitalized for pre-planned procedure s/p 75 days from index procedure. **Yes**
2. Randomized subject was hospitalized for less than 24 hours after the 18 month follow up visit occurred. **No**
3. Subject received commercial implant and had a worsening condition that was not neurological or cardiovascular in nature. **No**
4. Roll In subject had a medication change during a prolonged hospitalization and was started on an anticoagulant due to new elevated labs for a blood clotting disorder. **Yes**
5. Roll-In subject baseline laboratory results report hypomagnesemia and 18 month follow up visit reports a reduction in magnesium levels. **No**

Adverse Event Reporting

The following adverse events will be reported for this study:	Screening through 18-Month Follow-up	2, 3, 4, 5 Year Visits
All serious adverse events	☑	☑
All device and procedure-related adverse events	☑	
Unanticipated adverse device effects	☑	☑
Pre-procedure events (e.g., events related to pre-procedure medication changes)	☑	
All adverse events of special interest, regardless of seriousness or relatedness: • Bleeding events • Embolic events (e.g., stroke, TIA, systemic embolism) • Neurologic events • Device embolizations • Device Related Thrombus	☑	☑

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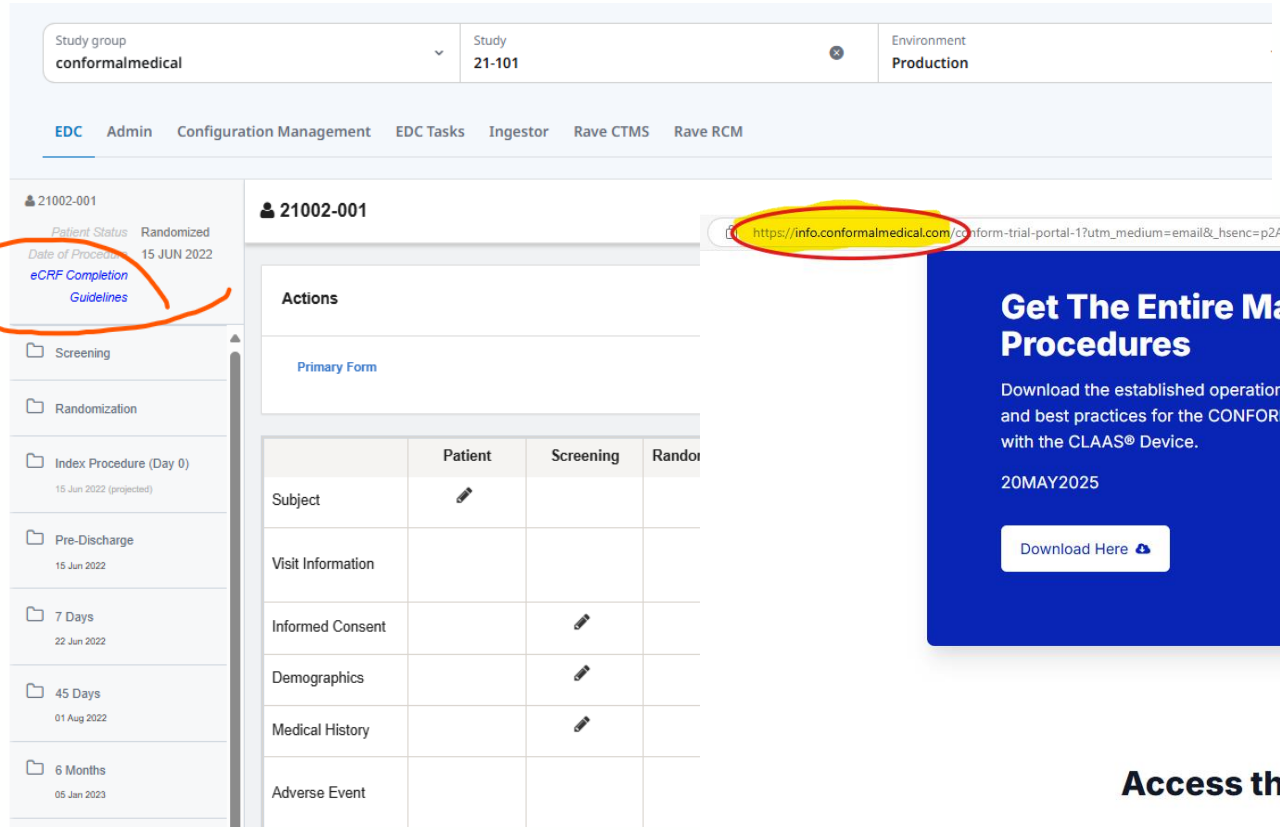
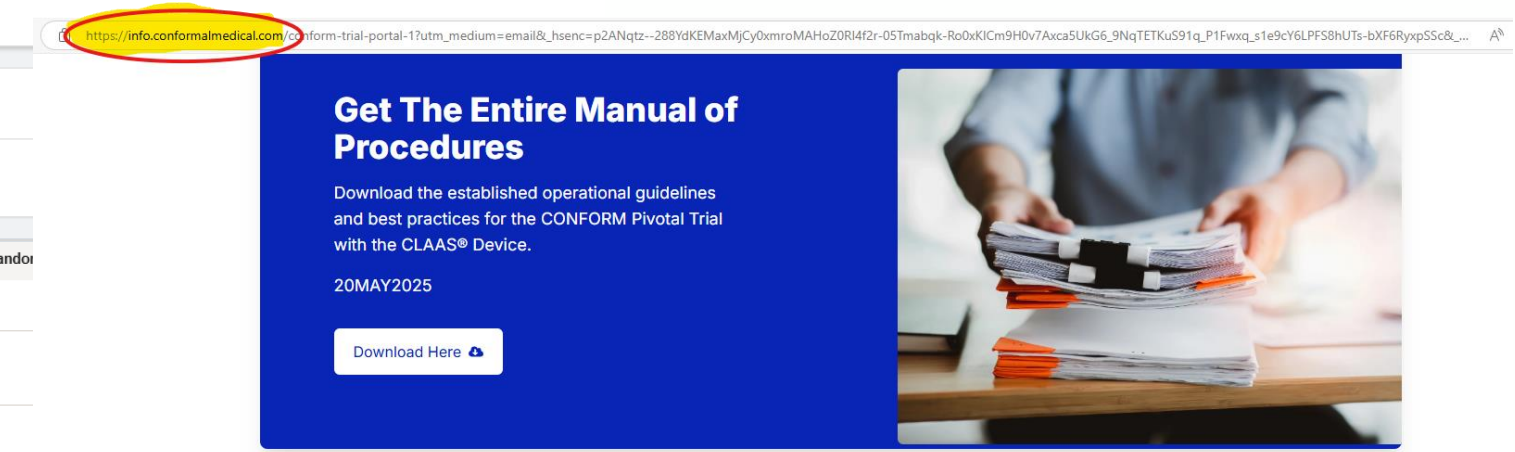
Reporting Timelines

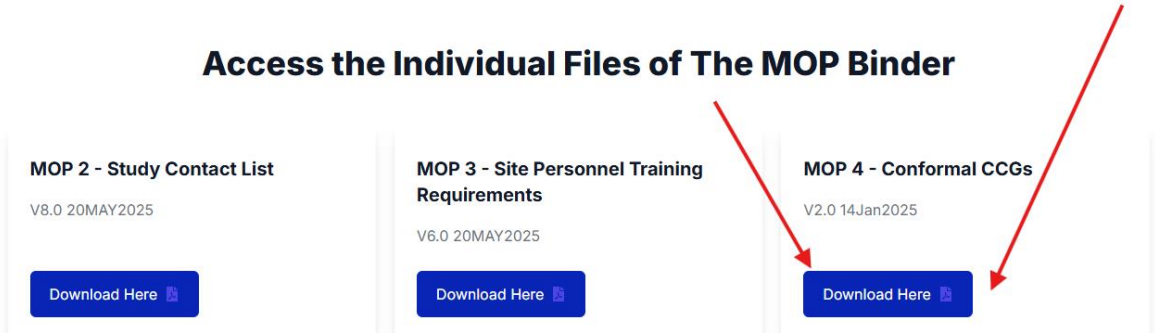
Event	Reporting Window to Sponsor
Adverse Event	As soon as possible, but **no later than 10 days working days from the date of awareness** and per your IRB/EC requirements
Serious Adverse Event	No later than **2 working days from the date of awareness** and per your IRB/EC requirements
Protocol deviations in emergencies	No later than **5 working days** and per IRB/EC requirements
Unanticipated Adverse Device Effect	No later than **2 working days from the date of awareness**
Unscheduled Visit	No later than **5 working days**
AE Requested for Adjudication	Upload source within **5 days working days of request**

EDC Tips – CCGs

Case Report Form Completion Guidelines







[CONFORM TRIAL PORTAL]

[21002-001]

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EDC Tips

If you need additional support with eCRF Completion Guidelines, or if you encounter issues, *please* reach out to **your assigned Site Manager**.

Contact Information	
Organization	Name
NAMSA	conformalsupport@namsa.com
Conformal Medical, Inc. (Sponsor)	**Aly Dechert** Manager of Clinical Operations adechert@conformalmedical.com 15 Trafalgar Square, Ste. 101 Nashua, NH 03063 **Michelle Pappas** Associate Director, Clinical Safety mpappas@conformalmedical.com 15 Trafalgar Square, Ste. 101 Nashua, NH 03063

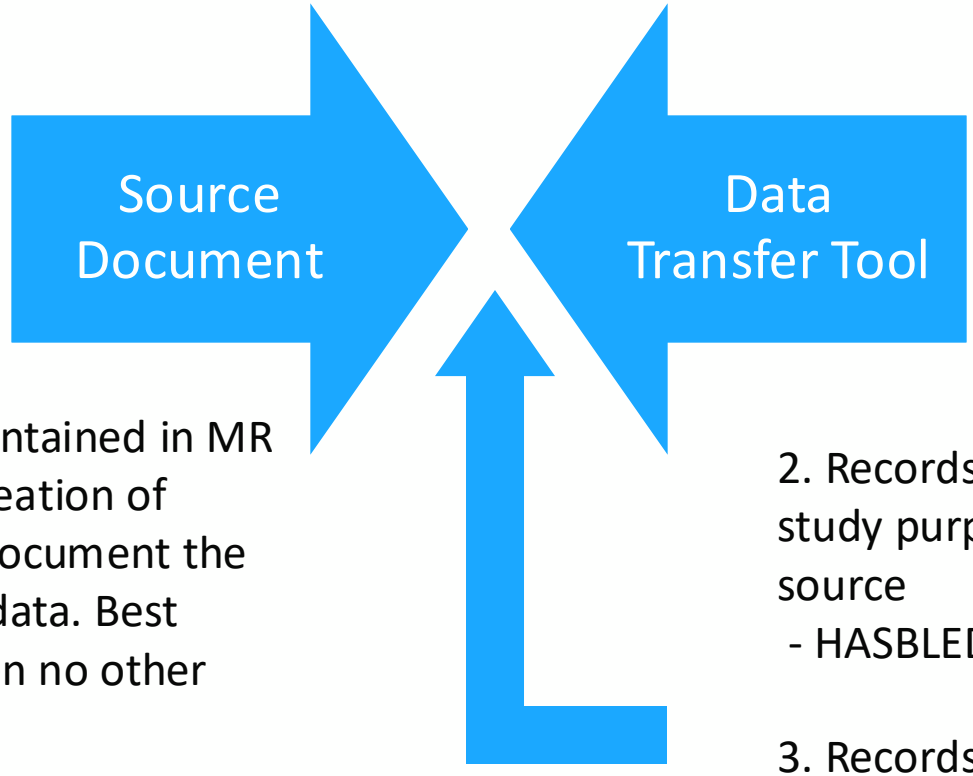
Source Documents & Source Data

Source Documents are those documents where data regarding study subjects are first recorded and serve as the basis for the information submitted to the Sponsor on the case report forms.

Source documents are '*original* documents, data and records' and include documents such as hospital records, laboratory reports, academic records, memoranda, subject diaries, assessment measures, and device labels or device use records. Source data is the information recorded in a source document, such as clinical findings and observations.

Source Document	Corresponding Source Data
QVSFS	Stroke Assessment number change
TTE Report	Presence of pericardial effusion
Laboratory Report	Platelet Count
Medication list in EMR	Did study medication change ?

Source Document vs Data Transfer Tool



1. Some procedures, by virtue of their conduct, will result in corresponding source documentation
   - laboratory surveys
   - current medication listings maintained in MR
2. Some procedures will require creation of study- specific source in order to document the conduct of procedure resulting in data. Best Practice: Should only be used when no other option for study documentation:
   - Eligibility Criteria
   - documentation of study-specific procedures/data
   - support compliance

1. Records data that was originally collected for another purpose
   - recording weight from MR
   - recording physical exam notes

2. Records data that was originally collected for study purposes from another study-specific source
   - HASBLED score or Chads2VASC score

3. Records original data
   - Implanter records LAA measurements

try to avoid unnecessary duplication of documentation !!

Source Document vs Data Transfer Tool

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CONFORM Patient Population
Directions & Data Transfer Tool

Site Number: _____ Subject ID: _____

Did Subject meet eligibility criteria before Procedure Day ?	☐ **Yes** ☐ **No** *(Complete the Study Exit form accordingly. Classify subject as "Screen Failure" -- Subject did not meet I/E criteria prior to index procedure.)*
Did Subject undergo Procedure TEE ?	☐ **Yes** ☐ **No** *(Complete the Study Exit form accordingly. If the subject did not undergo the procedural TEE, the subject should be exited and classified as a "Screen Failure – Subject did not meet I/E criteria prior to index procedure" (or "Withdrawn" if the subject withdrew).*

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CONFORM ECG
☐ Source ☐ Data Transfer Tool
Site Number: _____ Subject ID: _____

Was ECG performed?	☐ Yes ☐ No *(Complete a protocol deviation form)*		
Date of ECG	__ __ / __ __ __ / __ __ __ __ (DD/MMM/YYYY)		
Sinus rhythm	☐ Yes ☐ No		
Atrial Arrhythmia	☐ Yes ☐ No	Atrial fibrillation	☐ Yes ☐ No
		Atrial flutter	☐ Yes ☐ No
		Paroxysmal atrial fibrillation/flutter	☐ Yes ☐ No
		Atrial tachycardia	☐ Yes ☐ No
Junctional rhythm	☐ Yes ☐ No	if yes, what degree?	☐ 1st Degree ☐ 2nd Degree ☐ 3rd Degree
AV node conduction disturbance/heart block	☐ Yes ☐ No		
Paced Rhythm	☐ Yes ☐ No		
Q-Wave present	☐ Yes ☐ No		
Left bundle branch block present	☐ Yes ☐ No		
Right bundle branch block present	☐ Yes ☐ No		

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CONFORM Adverse Event
Source
Site Number: _____ Subject ID: _____

AE #	AE Term	AE Status	Cause	Date Aware	Date Entered	Severity	Serious	Onset Date	Resolved Date
		☐ New ☐ Pre-Existing				☐ Mild ☐ Moderate ☐ Severe	☐No ☐ Yes * Circle all that apply 1 2 3 4 5 6 7		
	Relationship to implant?	**Relationship to access sheath?**		**Relationship to delivery system?**		**Relationship to Study Procedure?**		**Relationship to Study Medication?**	
	☐ Not related ☐ Possible ☐ Probable ☐ Causal relationship	☐ Not related ☐ Possible ☐ Probable ☐ Causal relationship		☐ Not related ☐ Possible ☐ Probable ☐ Causal relationship		☐ Not related ☐ Possible ☐ Probable ☐ Causal relationship		☐ Not related ☐ Possible ☐ Probable ☐ Causal relationship	
	Investigator Signature:					**Date (DD/MMM/YYYY):**			

AE #	AE Term	AE Status	Cause	Aware	Notified	Severity	Serious	Onset	Resolved Date
		☐ New ☐ Pre-Exist				☐ Mild ☐ Moderate ☐ Severe	☐ No ☐ Yes * Circle all that apply 1 2 3 4 5 6 7		
	Relationship to implant?	**Relationship to access sheath?**		**Relationship to delivery system?**		**Relationship to Study Procedure**		**Relationship to Study Medication**	
	☐ Not related ☐ Possible ☐ Probable ☐ Causal relationship	☐ Not related ☐ Possible ☒ Probable ☐ Causal relationship		☐ Not related ☐ Possible ☐ Probable ☐ Causal relationship		☐ Not related ☐ Possible ☐ Probable ☐ Causal relationship		☐ Not related ☐ Possible ☐ Probable ☐ Causal relationship	
	Investigator Signature:					**Date (DD/MMM/YYYY):**			

* Serious : 1. Led to chronic disease 2. Led to subject death 3. Resulted in life-threatening illness or injury 4. Resulted in permanent impairment of a body structure or body function 5. Resulted in medical or surgical intervention to prevent life-threatening illness, injury or permanent impairment of body structure or function 6. Required in-subject hospitalization or prolongation of existing hospitalization 7. Led to fetal distress, fetal death or congenital anomaly or birth defect

Version 3.0, Date: 06DEC2024 Page **1** of **1**

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CONFORM Procedure Lab Assessments
☐ Source ☐ Data Transfer Tool
Site Number: _____ Subject ID: _____

Original source should be obtained from a direct laboratory report from Subject Medical Record. Laboratory results to be reviewed by delegated investigator (either directly on lab report or as Source here) as relates to subject safety and general INC/EXC Criteria.

Pre-procedure oral anticoagulation should be managed as per site protocol. Warfarin should be discontinued in accordance with site standard of care practices including INR levels on the day of the procedure. We are not collecting day of procedure INR levels.

Laboratory Collection at Procedure required **within 48 hours of implant.**

Date of Hematology __ __ / __ __ __ / __ __ __ __ (DD/MMM/YYYY)

☐ Not Done (ENTER PD)

Assessment	Results Value/ unit	Clinically Significant
Platelet Count		☐ Yes ☐ No
		☐ Yes ☐ No
		☐ Yes ☐ No

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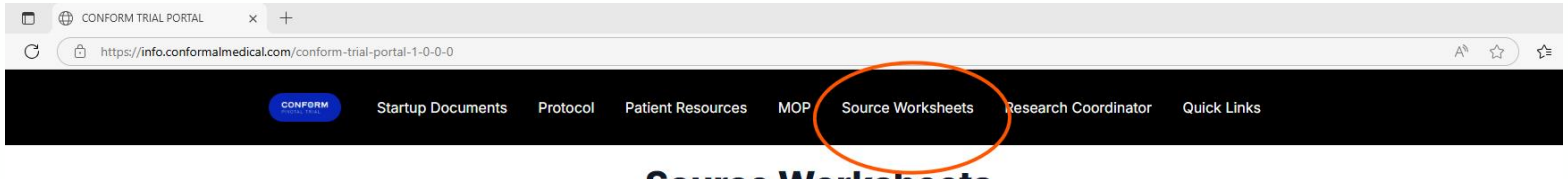
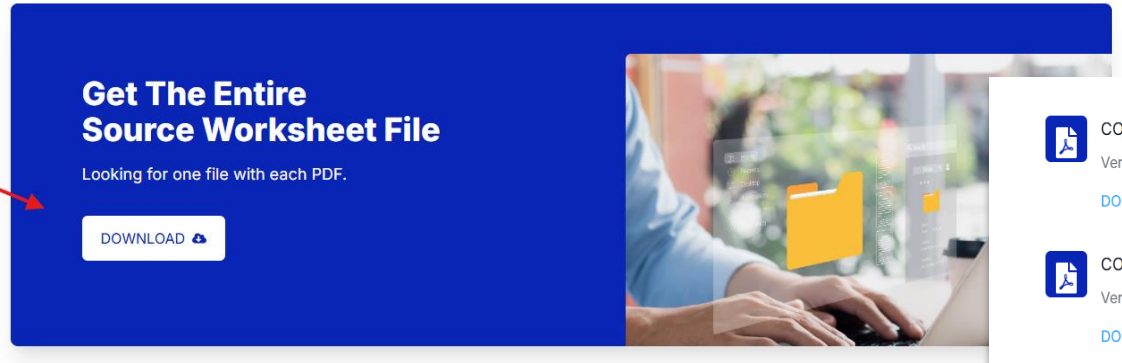
Source Document vs Data Transfer Tool



Source Worksheets

CONFORM IDE Trial NCT05147792



DIGITAL DOWNLOAD

CONFORM Source Worksheet Documents

- CONFORM L1 - Concomitant Medication
  Version 3.0, Date: 06DEC2024
  DOWNLOAD HERE
- CONFORM L2 - Protocol Deviations
  Version 3.0, Date: 06DEC2024
  DOWNLOAD HERE
- CONFORM P01 - Procedure Source Worksheet
  Version 5.0, Date: 06DEC2024
  DOWNLOAD HERE
- CONFORM P02 - CLASS Implant
  Version 2.0, Date: 06DEC2024
  DOWNLOAD HERE
- CONFORM P03 - CLASS Delivery System
  Version 2.0, Date 06DEC2024
  DOWNLOAD HERE
- CONFORM P04 - CLAAS Device Deficiency Worksheet
  Version 2.0, Date: 06DEC2024
  DOWNLOAD HERE
- CONFORM P05 - Control Implant
  Version 3.0, Date: 06DEC2024
  DOWNLOAD HERE
- CONFORM P06 - Echo Exclusion Criteria
  V3.0, 06DEC2024
  DOWNLOAD HERE
- CONFORM P07 - Additional Procedure Source Worksheet
  Version 1.0, Date: 06DEC2024
  DOWNLOAD HERE
- CONFORM P08 - Patient Population
  V 1.0 06DEC2024
  DOWNLOAD HERE
- CONFORM P09 - Procedure Lab Assessments
- CONFORM Pivotal Trial TEE TTE Sonographer Worksheet

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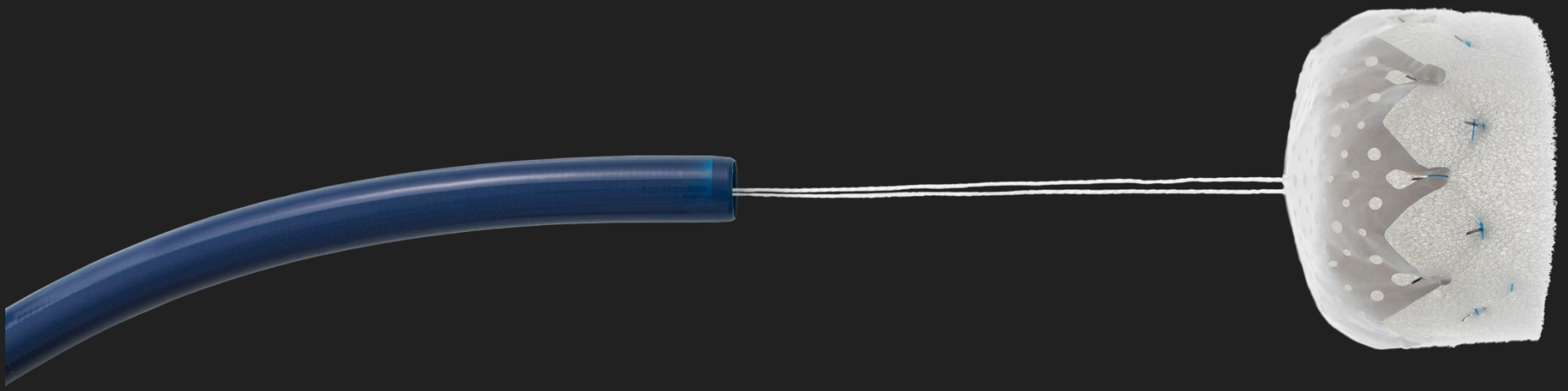
CONFORM Source Worksheet Documents

New formatting / New Forms ★

- Concomitant Medications ★
- CLAAS Implant & CLAAS Delivery System ★
- Echo Exclusion Criteria *(for procedure day only if needed)*
- Additional Procedure Source Worksheet ★
- Patient Population ★
- Procedure Lab Assessments
- Shared Decision - Making Source ★
- Physical Examination – Review of Symptoms
- LAA Measurements
- Adverse Event Source ★
- Death ★
- Study Exit



Research Coordinator Presentation:
Tips for a Successful CONFORM Program

Maddie Peek, BS, CET, CPT
Lead RC at Memorial Hermann Medical Center
(West Houston Area Clinical Trial Consultants)

Disclosures

- No disclosures

west houston area
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About Me

- *8.5 years as a CRC, 5 years working on LAAC Trials*
- *Coordinate all aspects from start-up and regulatory to enrollment and follow-up for anywhere from 10-12 drug and device studies at a time*
- *Goal of presentation: Help other CRCs be able to streamline enrollment and implant process and help retain patients long term*

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About us *(some ideas)*

- Locations in Katy, TX and Houston, TX
- We work in partnership with Memorial Hermann's Memorial City Hospital. Memorial Hermann is the largest not-for-profit health system in southeast Texas and consists of 17 hospitals, 8 Cancer Centers, 3 Heart & Vascular Institutes, and 27 sports medicine and rehabilitation centers, in addition to other outpatient and rehabilitation centers
- Began LAAO in 2015 with Watchman

- ~400 LAAO annually
- Top 5 highest enrollers in multiple drug and device studies

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Enrollment Strategies

- **The WHO**: Afib patients who are no longer a candidate for long-term OAC (bleeding event, stroke/other embolic event.
- **The WHERE:** Our own patients. Our non-implanting Sub-I or other physician partners referrals. Patients referred directly by their PCP with a new AF diagnosis. Look at ALL patients who have been referred for evaluation for LAAC. We as CRCs don't do chart review for CONFORM. Our LAAC clinic is relatively busy, so there hasn't been a need.
- **EDUCATION:** Have a very in-depth conversation with any potential patients about CONFORM vs commercial implant before they are scheduled to screen (
- **SCHEDULING:** Whenever possible, a CRC is at the same location as PI during clinic hours to streamline scheduling for the patient
- **HANDLING MULTIPLE STUDIES:** Review all options with patients who may qualify for multiple trials to help the patient make an informed decision on the best fit for them

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Overcoming Common Challenges

- **Clinical trial vs commercial device** – Some patients once they learn of other options are excited to be part of moving medicine forward and make excellent trial participants. PI can tell from discussion with patients who is and is not open to an alternative and those truly not open to another device are not referred. **Never push or talk a patient into being part of a trial**.
- **Patient retention strategies – Talk to in person**, give a physical copy of the ICF, and get a screening visit on the schedule versus patients who we call later and schedule over the phone. Flexibility and communication go a long way!
- **Follow up schedule** – Explain that the on-site follow-up visits are very similar to standard of care and all other follow-up can be easily completed by phone. We also make every effort to have a **list of available implant dates** at screening visit, so patients will know approximate follow-up schedule from the first visit.
- **Patient consent** – PI has an in-depth discussion before patients are referred to a trial. CRC and PI review again at screening and ensure patients understand randomization, follow-up schedule and their rights in relationship to the study before they decide to sign ICF.

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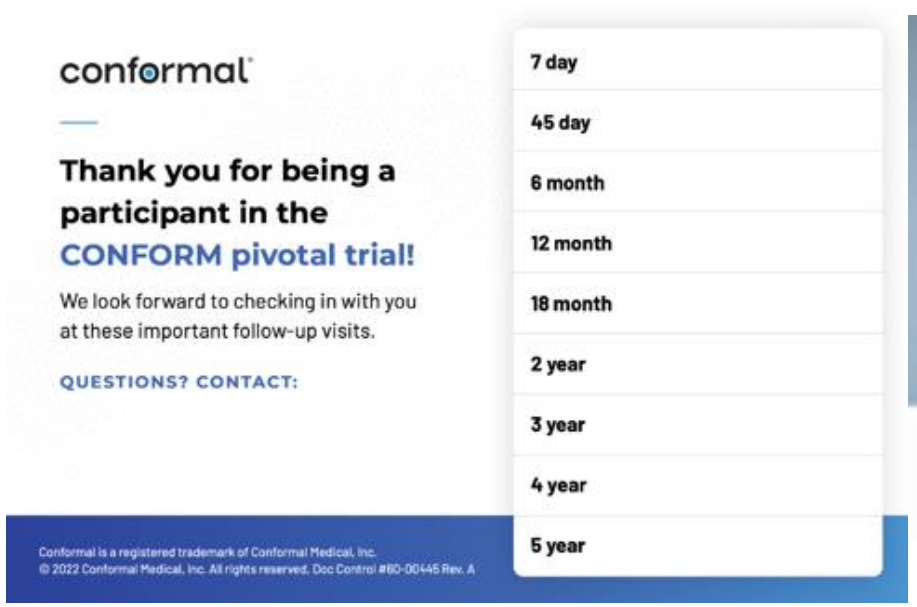
Helpful Conformal Tools

- Demo device – PI will show patients. They get a “hands on” visual
- Patient schedule magnets – many patients find these helpful
- Flip books for education



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Key Lessons Learned

- Try to have **dates available for pre-planning imaging** (if historical will not be available) and index procedure ready to review and confirm with patient day of screening visit. Everything goes MUCH smoother for both patient and site staff when majority of schedule can be set at screening visit.
- When PI is open to this, it's best for CRC to have **multiple cases on one day**.
- Record in real time and **enter data in a timely manner**, for implant specifically – verify all CRC collected data against procedure log for Index Procedure
- **Patient Education!** This is a team effort! Begins with PI, but CRCs play a big roll here as well.

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More Key Lessons

- **Know your people!** Get to know your scheduling nurses, cath lab staff, billing/auth staff, imaging staff, etc. Any unforeseen issues are much easier to solve when everyone is working as a team. Understand how much time each team needs to get things scheduled.
- If you manage **multiple studies**, reference your protocols and use your resources. No one can keep the finer details of multiple protocols straight from memory. Knowing how **to search your protocols and manuals** saves time and stress.
- **Network with other coordinators!** Always helpful to have a sounding board when you run into an issue!

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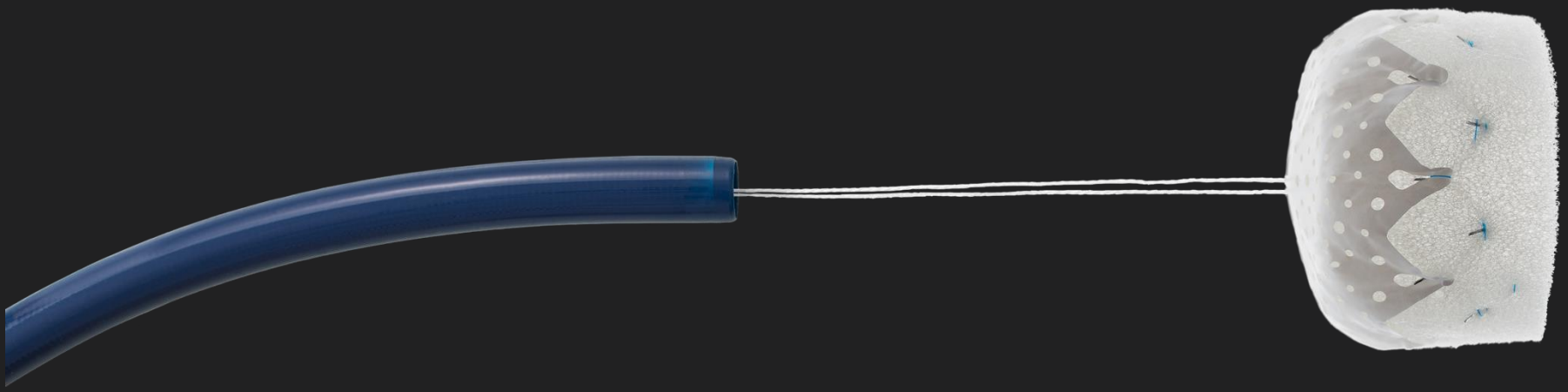

Training Requirements

Lizzy Raskulinecz, CRA II

Training Requirements At-A-Glance

Site Personnel Training Requirements

	Principal Investigator	Implanting Sub-Investigator	Non-Implanting Sub-Investigator	Research Coordinator	Regulatory
Training Required to:					
CONFORM Protocol & Amendments	X	X	X	X	
CONFORM TEE Imaging Acquisition Protocol	O	O			
Protocol Synopsis & Amendments					X[3]
Didactic Device Training	X[1]	X			
Hands on Device Training	X[1]	X			
Device Accountability App				X	
EDC System/ AE Adjudicate / Imaging Module				X	
EDC – Sign Off	X				
Documents Maintained:					
Listed on the DOA	X	X	X	X	O
Financial Disclosure	X	X	X		
Investigator Agreement	X	X	X		
GCP Certification	X	X	X	X	X[3]
CV (signed/dated within past 2 years)	X	X	X	X	X[3]
Active Medical License	X	X	O	O	
NIHSS and mRS[2]				X	
Key:					

X = Required
O = Optional
[1] = Didactic training must be completed by a Conformal FCS team member prior to the first implant.
[2] = Training/certification must be current; at least one member of study team must have NIHSS/mRS certification
[3] = Only required if listed on DOA

Source: MOP03 Site Training Personnel Requirements V6.0 20May2025

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Imaging Personnel Training Requirements

Role	Imager for Screening Imaging (CT[1], TEE[1], TTE, MRI)	Imager for Procedural TEE	Imager for Pre-Discharge TTE	Imager for Follow-up TEEs (45 D, 6 M[2], 12 M, Unscheduled)	Lead Echo-cardiographer
Training Required to:					
CONFORM Protocol Synopsis & Amendments[4]	O	X	O	X	X
CONFORM TEE Imaging Acquisition Protocol[4]	O	X	O	X	X
Protocol & Amendments[4]	O	O	O	O	O
Didactic Device Training	O	O	O	O	O
Hands on Device Training	O	O	O	O	O
Documents Maintained:					
GCP Certification	O	X[3]	X[3]	X[3]	X
CV (signed/dated within past 2 years)	O	X[3]	X[3]	X[3]	X
Active Medical License	O	X[3]	X[3]	X[3]	X
FAQs:					
Does this person need to be listed on the DOA?	No	No	No	No	Yes
Does this person need to be a physician?	No	Yes	No	Yes	Yes
Can the PI also act as this role?	Yes	No	Yes	Yes	No
Can this person be the same as Procedural Implanter?	Yes	No	Yes	Yes	No
Key:					

X = Required
O = Optional
[1] = Required prior to randomization
[2] = 6 Month imaging only required if 45 Day TEE has findings of leak or thrombus
[3] = Only required for Imagers on DOA
[4] = Read & Acknowledge training permitted

Source: MOP03 Site Training Personnel Requirements V6.0 20May2025

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Takeaways Re: Echocardiographer

- At least one echocardiographer must be on the DOA at your site
- If one or more echocardiographers is/are not on the DOA, your site must delegate a “Lead Echocardiographer”
- If all echocardiographers are on the DOA, no “Lead Echocardiographer” required
- Training is same for echocardiographers on the DOA and not on the DOA
  - CONFORM Protocol Synopsis
  - CONFORM TEE Imaging Acquisition Protocol
  - *Applies for Procedural TEE and all follow-up TEEs*

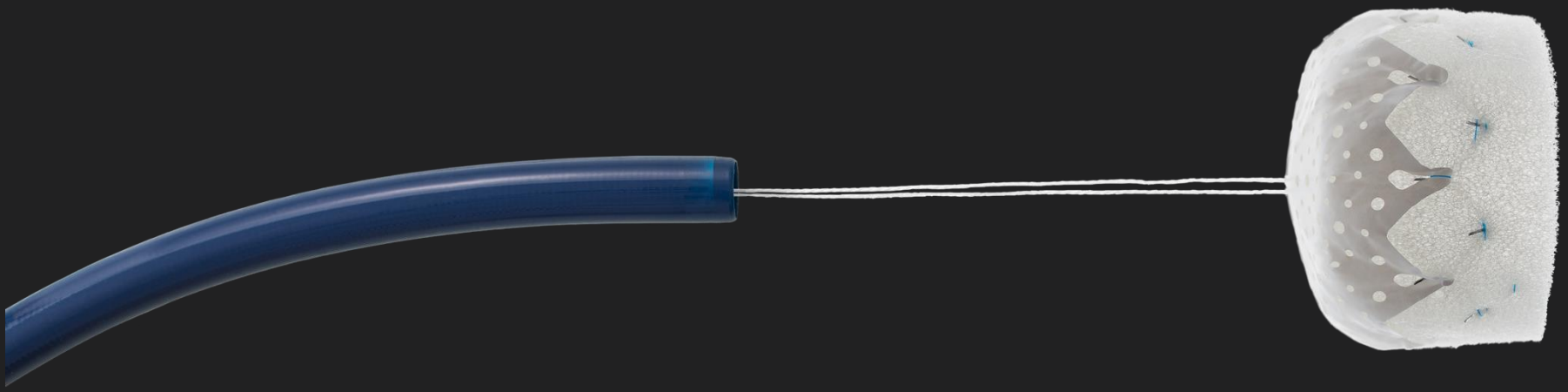
Your Training Team

FCS trains personnel to:

- Didactic Device Training (required for Implanting Investigator)
- Hands-on Device Training (required for Implanting Investigator)
- TEE Imaging Acquisition Protocol (required for Procedural TEE imager)

Site Manager trains personnel to:

- CONFORM Protocol
- Medidata (EDC, AE Adjudicate, Intelemage)
- Device Accountability App

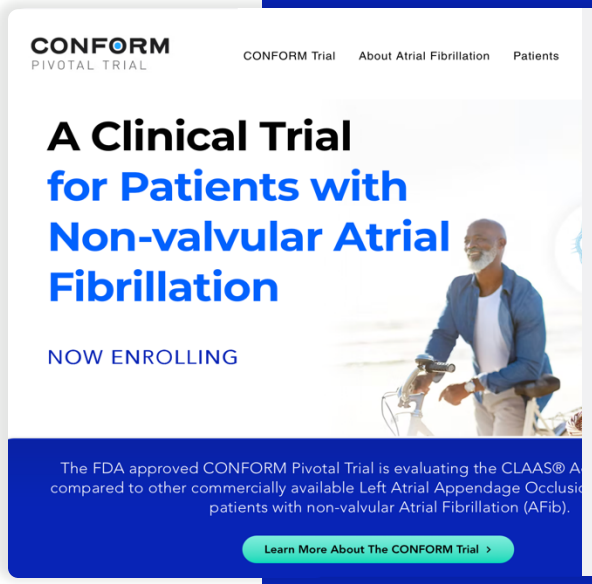


CONFORM Trial Digital Resources

Alexander Smith, Marketing Manager

CONFORM Trial
Digital Resources

Alexander Smith, Marketing Manager



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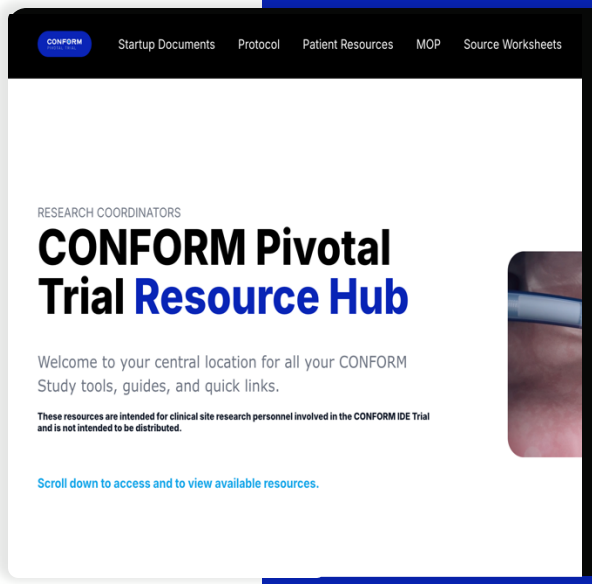
CONFORMTrial.com

A new site to help inform and educate prospective patients seeking an alternative to long-term blood thinners for stroke risk reduction in non-valvular atrial fibrillation.

Launched 2025



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Research Coordinator Portal/Hub

A new site to help inform and educate prospective patients seeking an alternative to long-term blood thinners for stroke risk reduction in non-valvular atrial fibrillation.

Launched 2024

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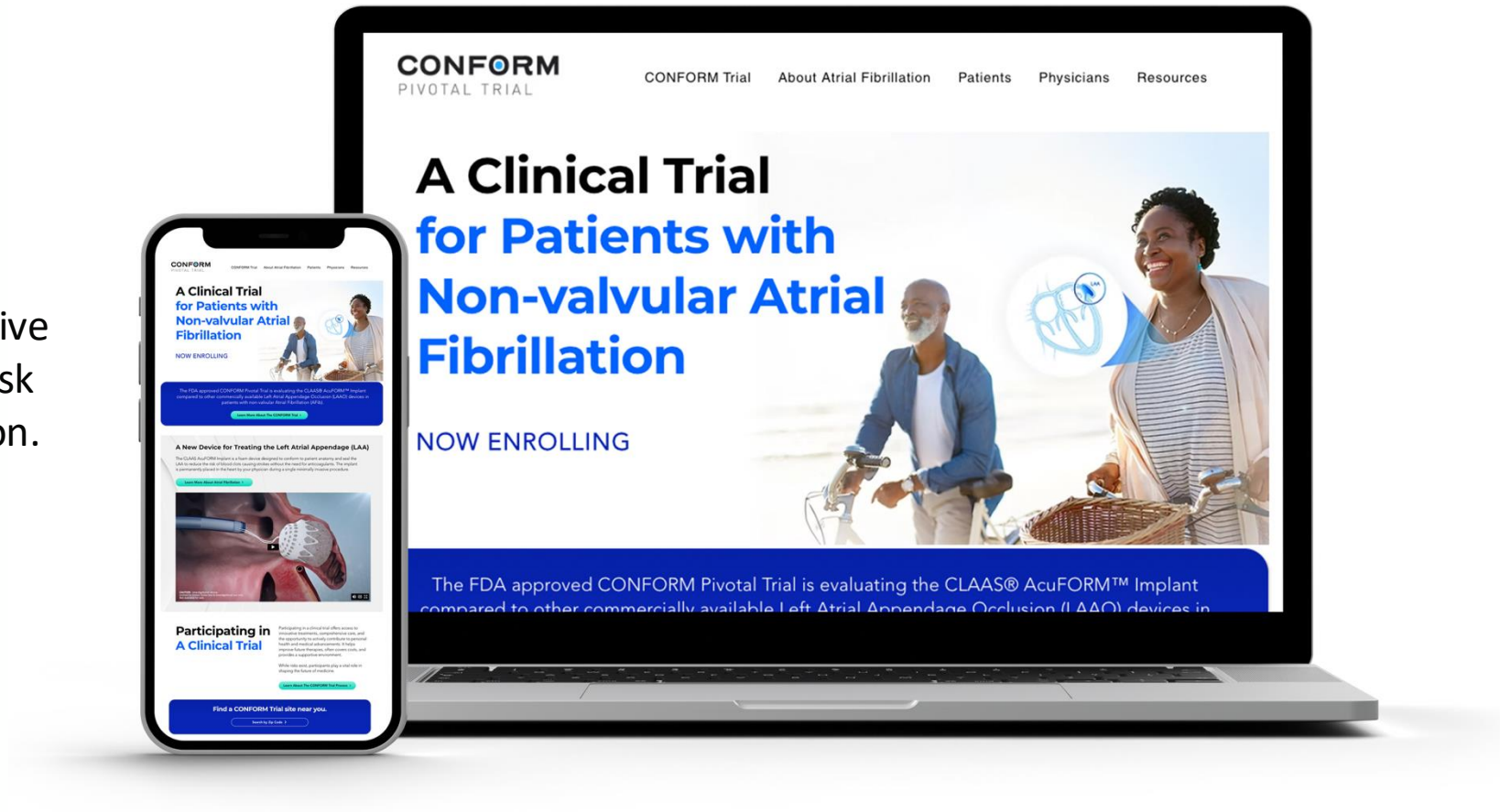
Launched May 2025

THE

NEW CONFORMTRIAL.COM

A new site to help inform and educate prospective patients seeking an alternative to long-term blood thinners for stroke risk reduction in non-valvular atrial fibrillation.

CONFORMTrial.com **offers study information in one digital location.**



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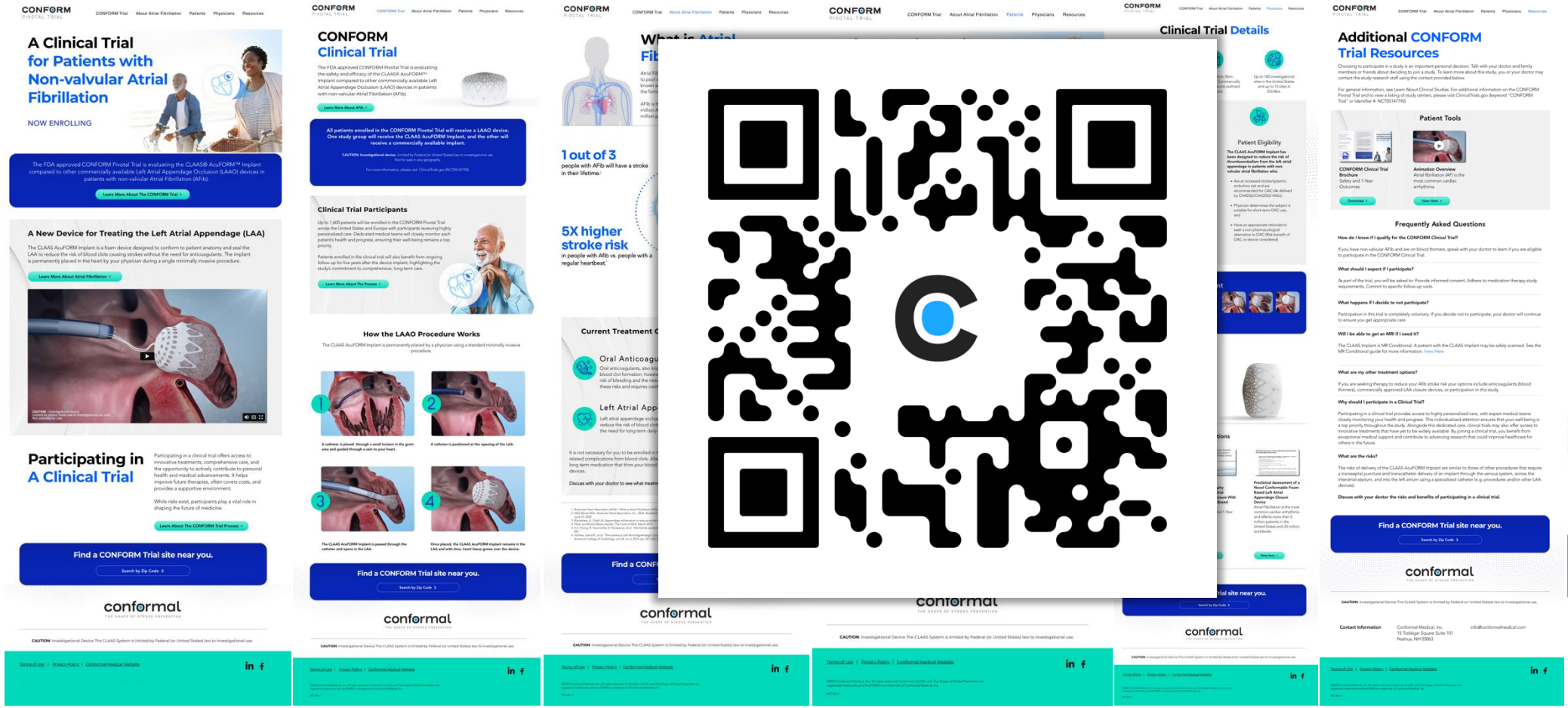
Walkthrough of CONFORMTrial.com



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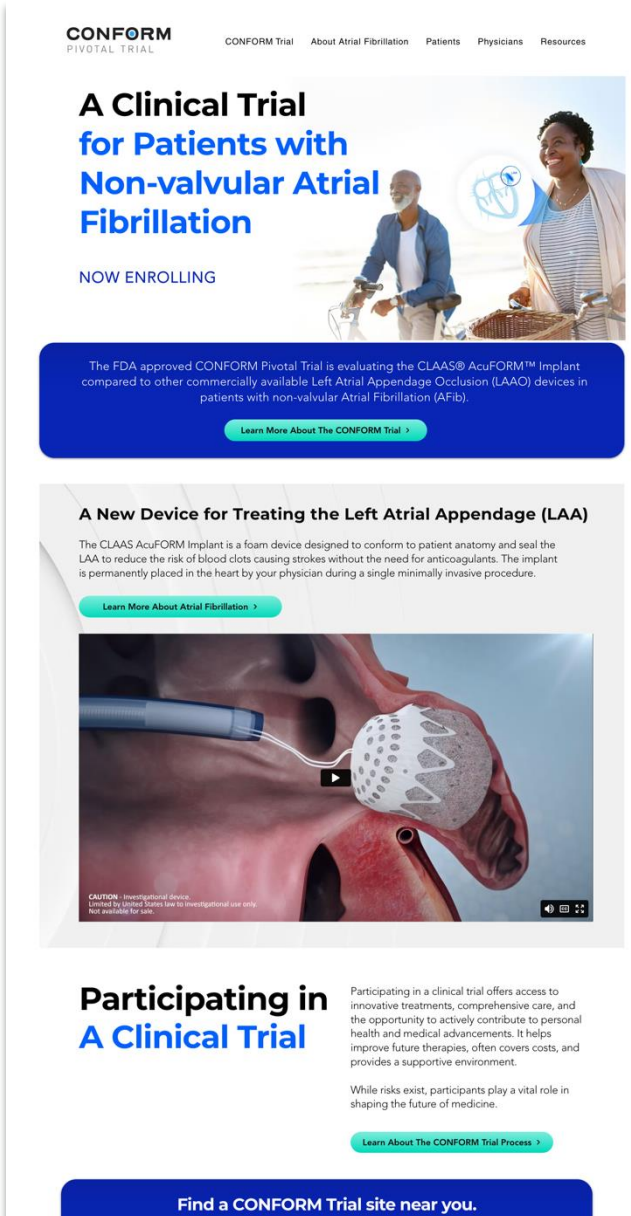
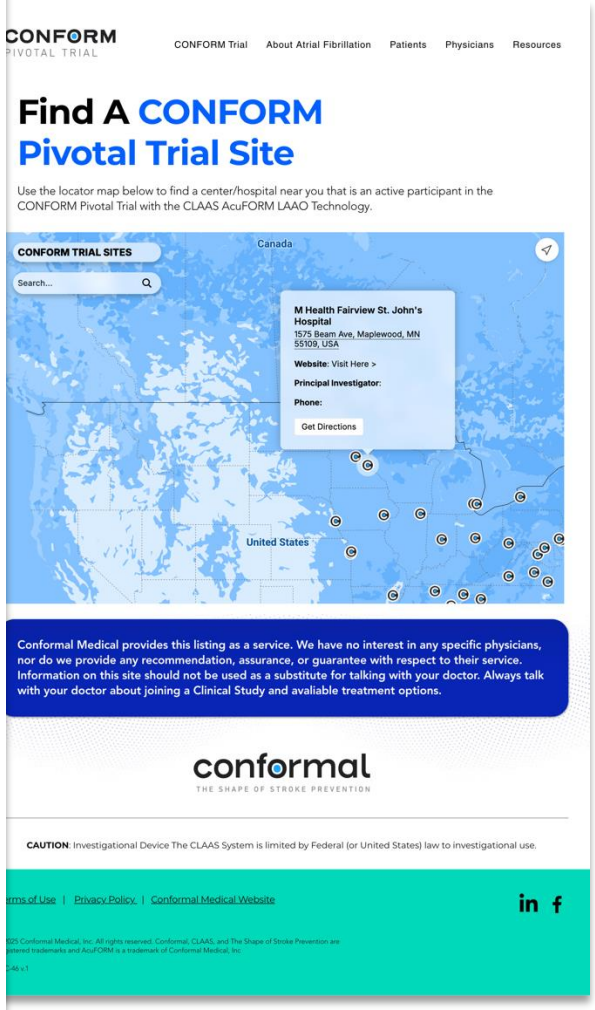
Benefits For You and Patients

- Easier access to information about the CONFORM Trial
- Trial details and animation
- Participating in a clinical trial overview
- Site finder tool
- FAQ Section and downloadable resources





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Launched March 2024

THE

CONFORM RC Portal/Hub

Exclusive access to the following tools:

- Study Startup package for those new to the trial
- Clinical investigational protocol and associated resources
- Patient facing materials for prospective subjects
- Established operational guidelines and best practices
- Source worksheet PDFs in one file
- Safety information, inventory applications, and more!

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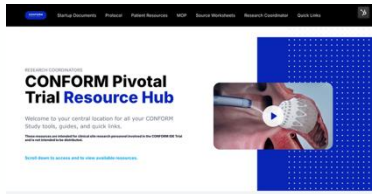
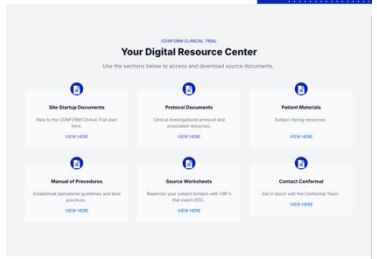
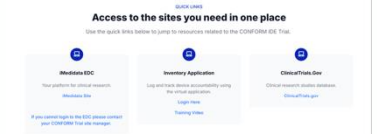
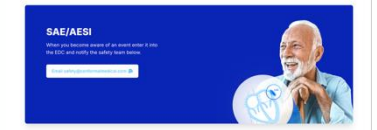
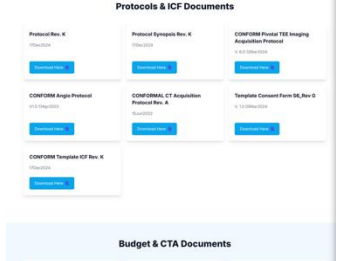
Walkthrough of the RC Portal/Hub

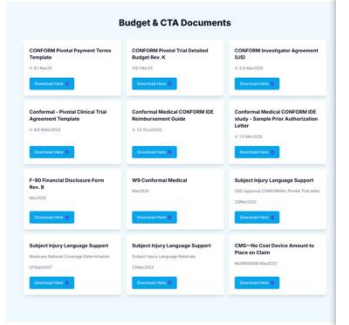


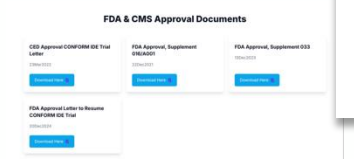


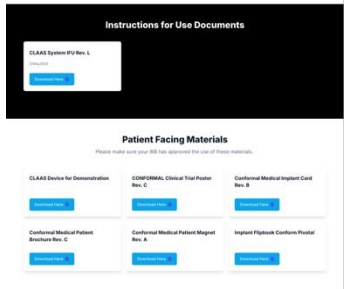


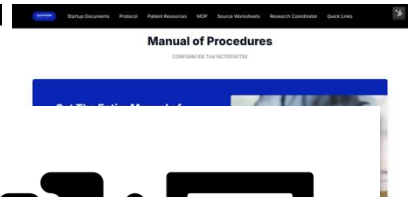


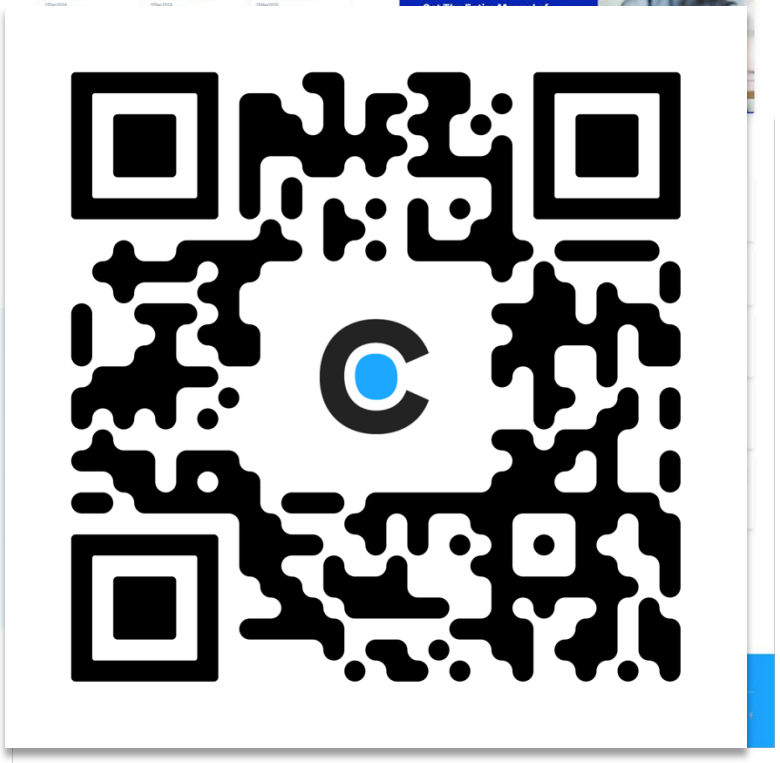




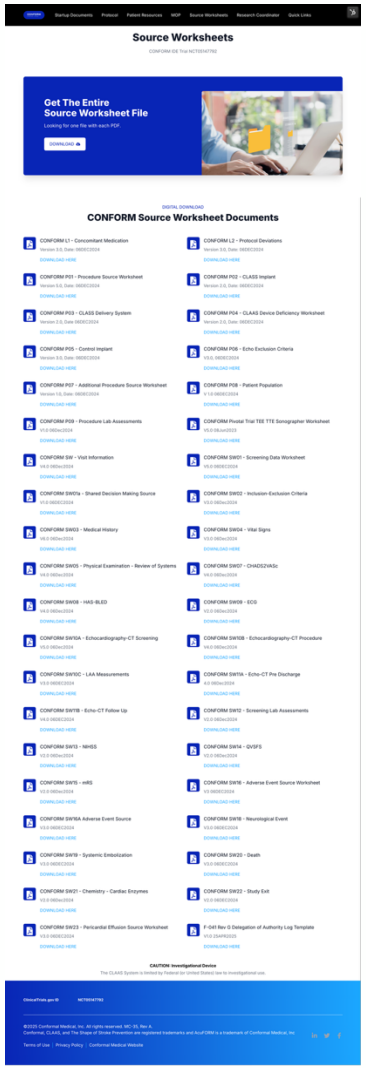


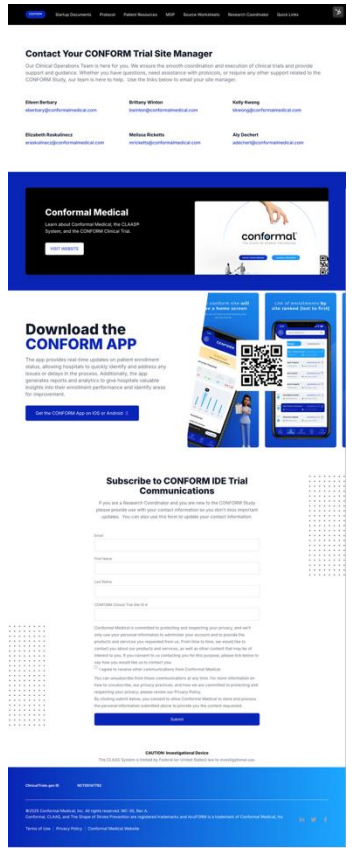






Site Login: AcuFORM2025!





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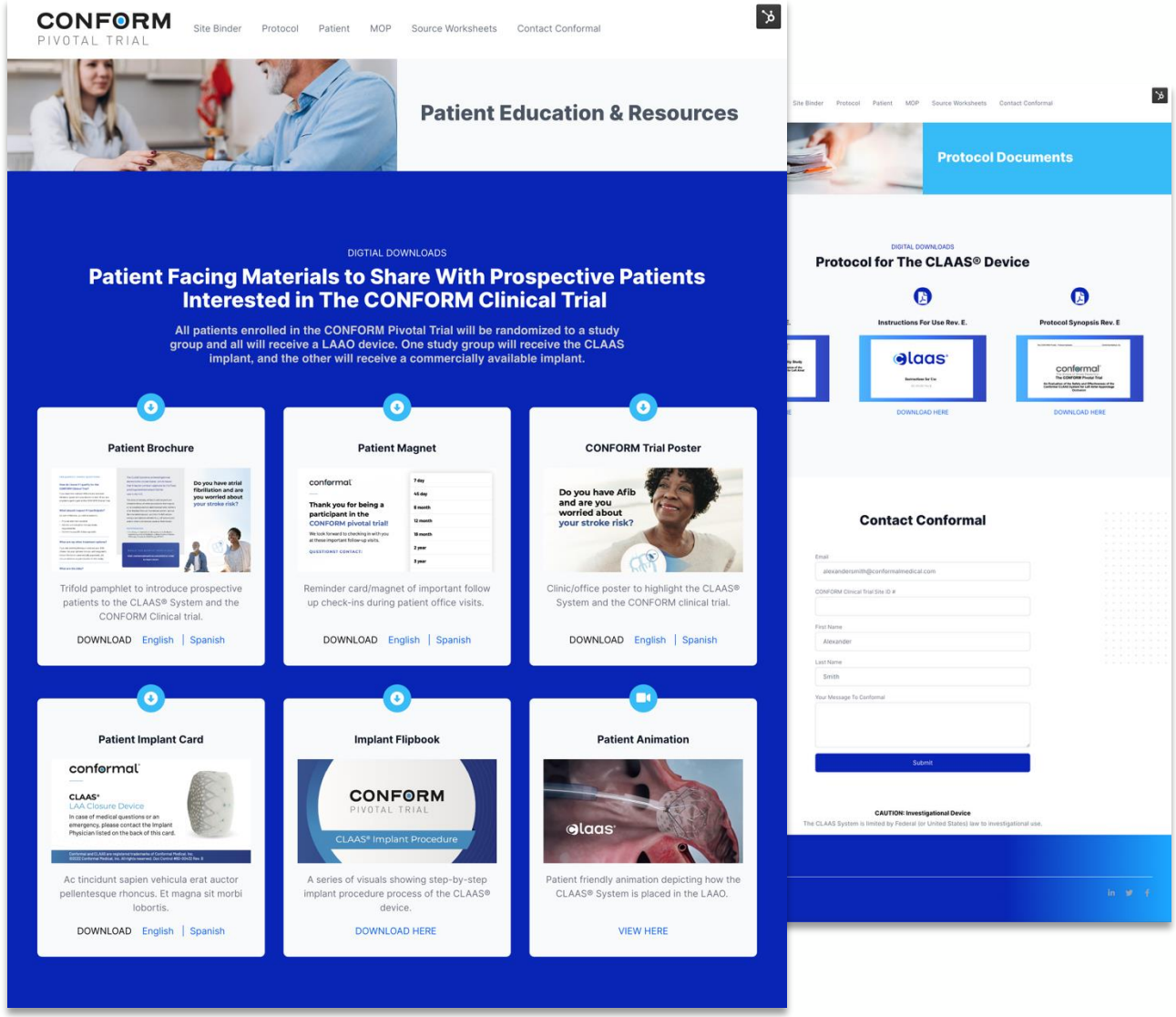
The RC Portal is for You

- Easier access to information
- On-Demand downloads of the most up to date CONFORM Trial documentation
- Study Start-up tools
- Latest Protocol and IFU Revisions
- Request patient facing print materials
- Easy access to CONFORM Clin Ops Team



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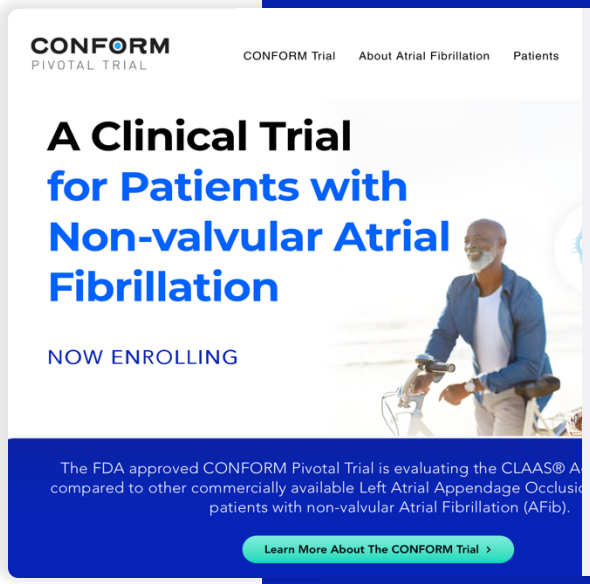
Share with your patients and their caregivers the CONFORMTrial.com site.

We Encourage you to explore these digital tools.



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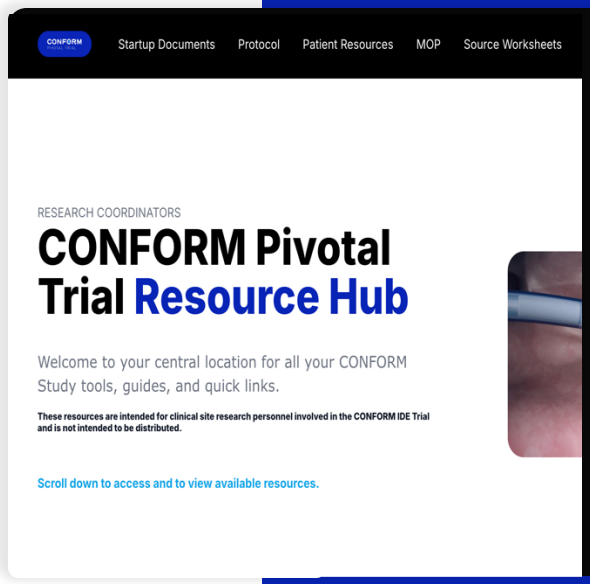

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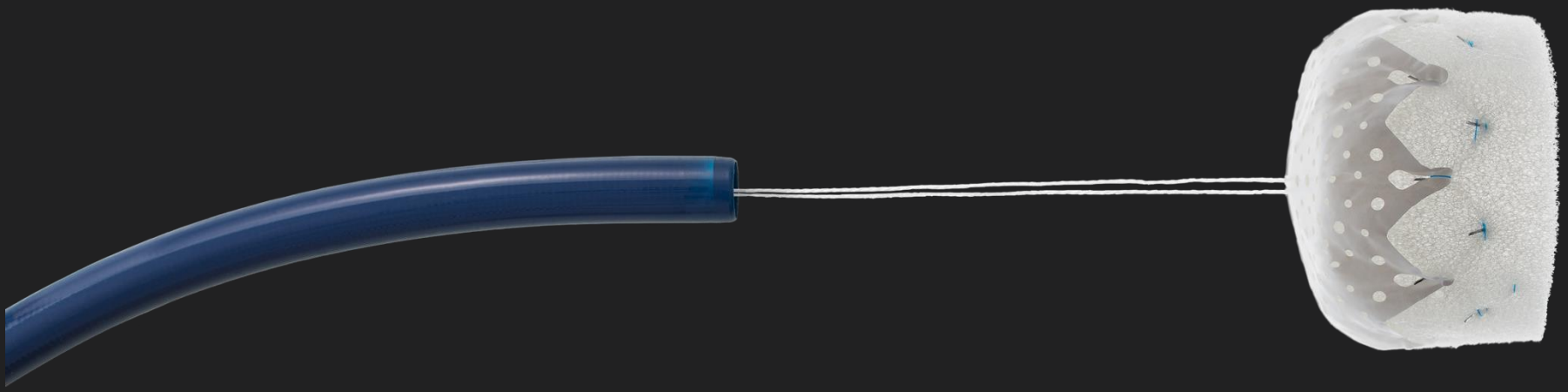


Enrollment Programs & the CONFORM App

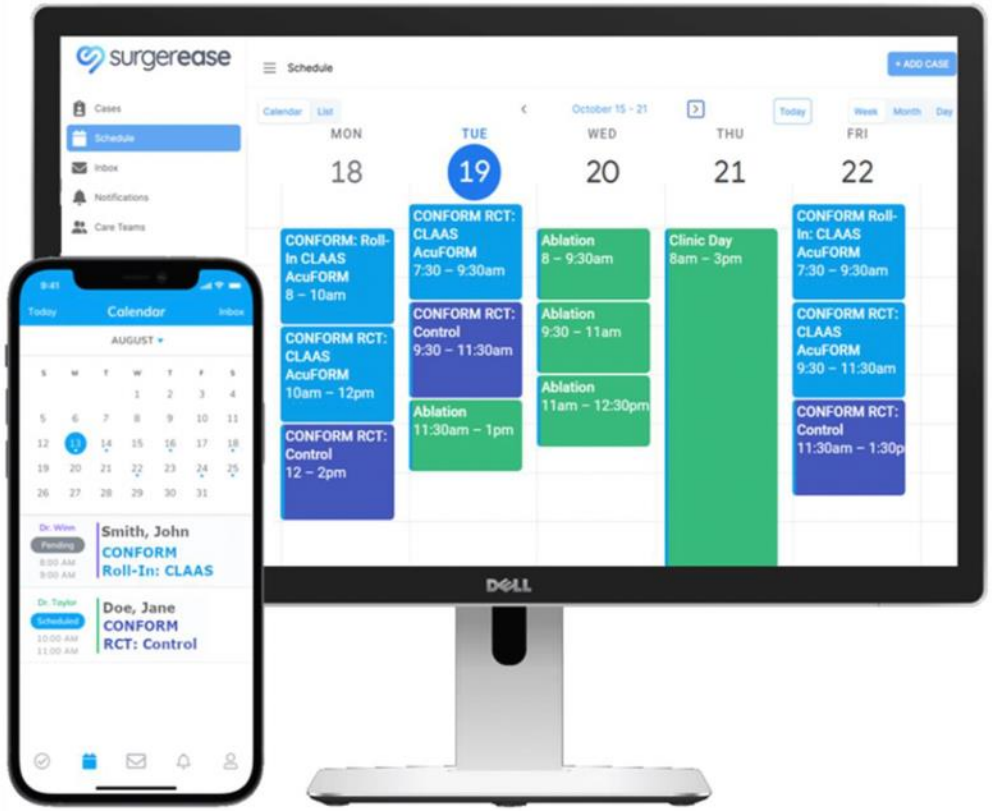
Jeff Bednar, Director of Therapy Development

Single Day Multiple Cases — Recognition Program

Criteria

$1,000 for Each Additional Enrollment in a Single Day!

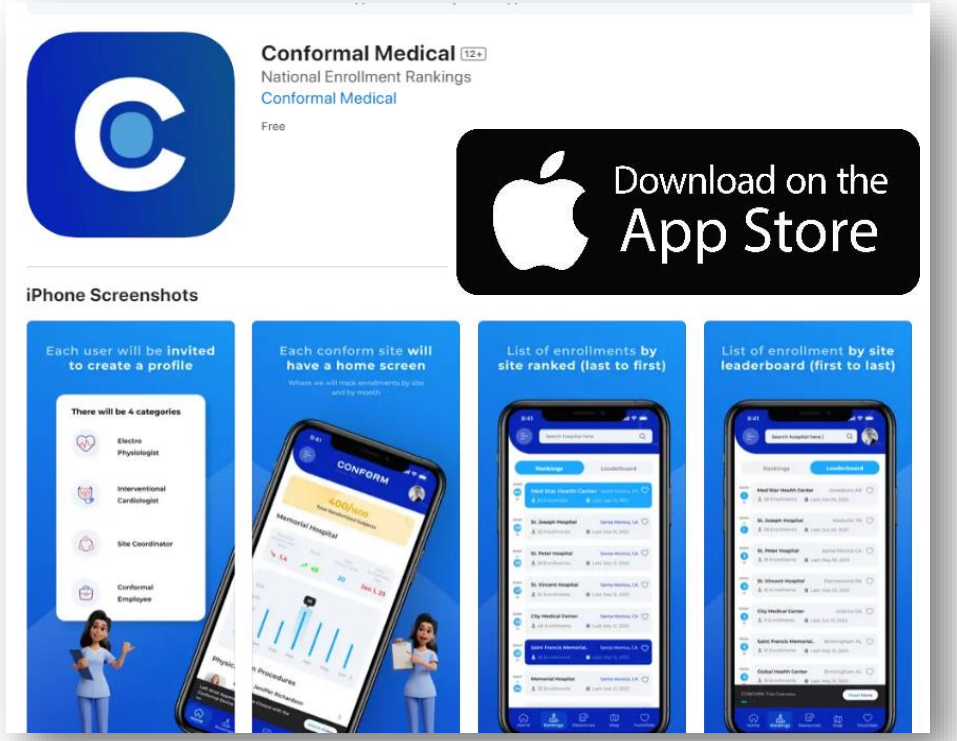
To both encourage the efficient deployment of Conformal resources, as well as recognize the extra work required of staff when scheduling multiple cases in a day, sites will receive **$1,000** for each additional enrollment scheduled on the same day.



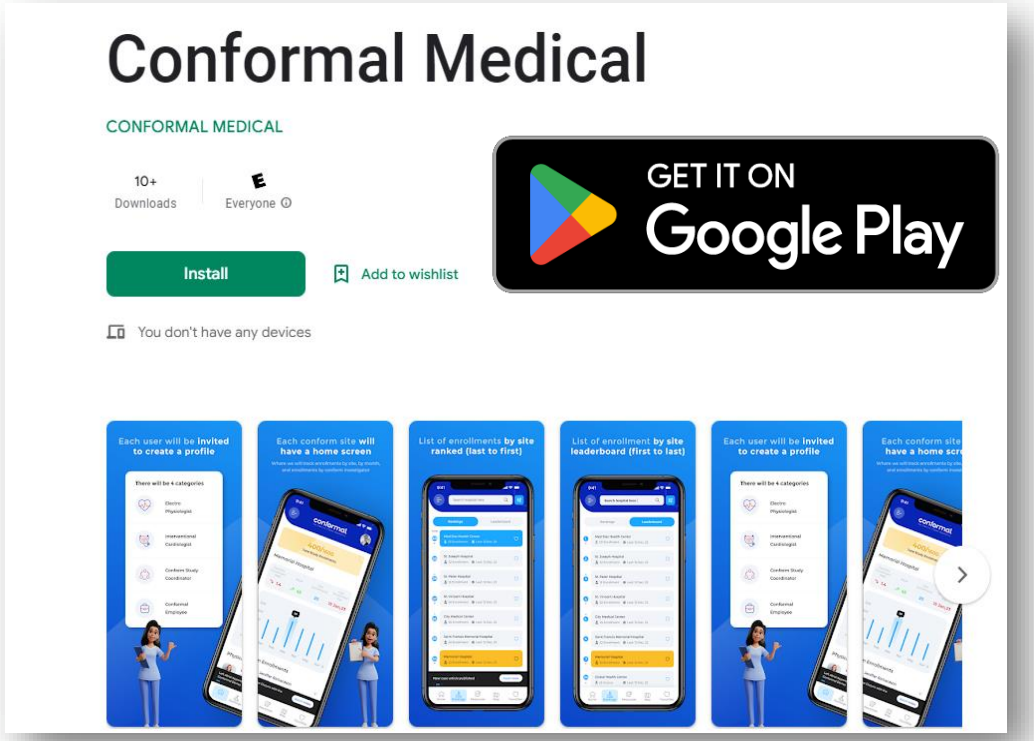
Example:

- 1st CLAAS Roll-in or Randomization to CLAAS *($0)*
- **3 ADDITIONAL CONFORM Enrollments** *(regardless of randomization stratification)*
- As recognition for the extra effort required the **site receives $3,000**

CONFORM Trial App



Scan this QR Code!



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CAUTION: Investigational Device
The CLAAS System is limited by Federal (or United States) law to investigational use.

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