CardioVascular Learning Network

New Modalities for Ablation and How They Impact Vascular Closure Mechanisms

Faculty

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Faculty Disclosures

- **David DeLurgio, MD, FACC, FHRS**: Consultant—Haemonetics, Boston Scientific, Medtronic, AtriCure, Abbott Medical; Speaker—Haemonetics, Boston Scientific, AtriCure
- **Larry Chinitz, MD**: Consultant—Abbott, Medtronic, Biotronik, Biosense Webster Inc; Speaker—Abbott, Medtronic, Biotronik, Biosense Webster Inc
- **Tom McElderry, MD, FACC, FHRS**: Consultant—Boston Scientific, Medtronic, Haemonetics, Biosense Webster Inc, Abbott; Speaker—Haemonetics

This CME activity includes brand names for participant clarity purposes only. No product promotion or recommendation should be inferred.

Program Information

- This program is provided by HMP Education, an HMP Global company
- Supported by an educational grant from Haemonetics Corporation

Learning Objectives

- Understand the evolving landscape of electrophysiology and the new technology available
- Identify which closure modality is applicable to each ablation modality
- Understand options for large bore vascular closure

Current Changes to the EP Landscape

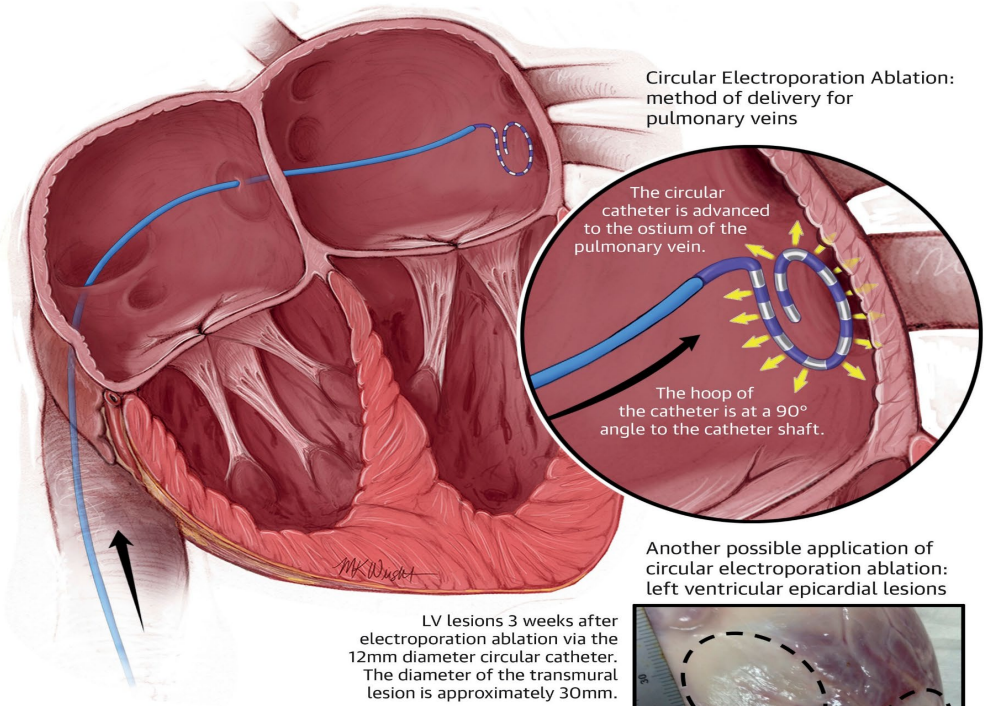
Larry Chinitz, MD

New Technology

- Pulsed field ablation
- Left atrial appendage occlusion
- Leadless pacemaker
- Conduction system pacing
- Subcutaneous and substernal ICD

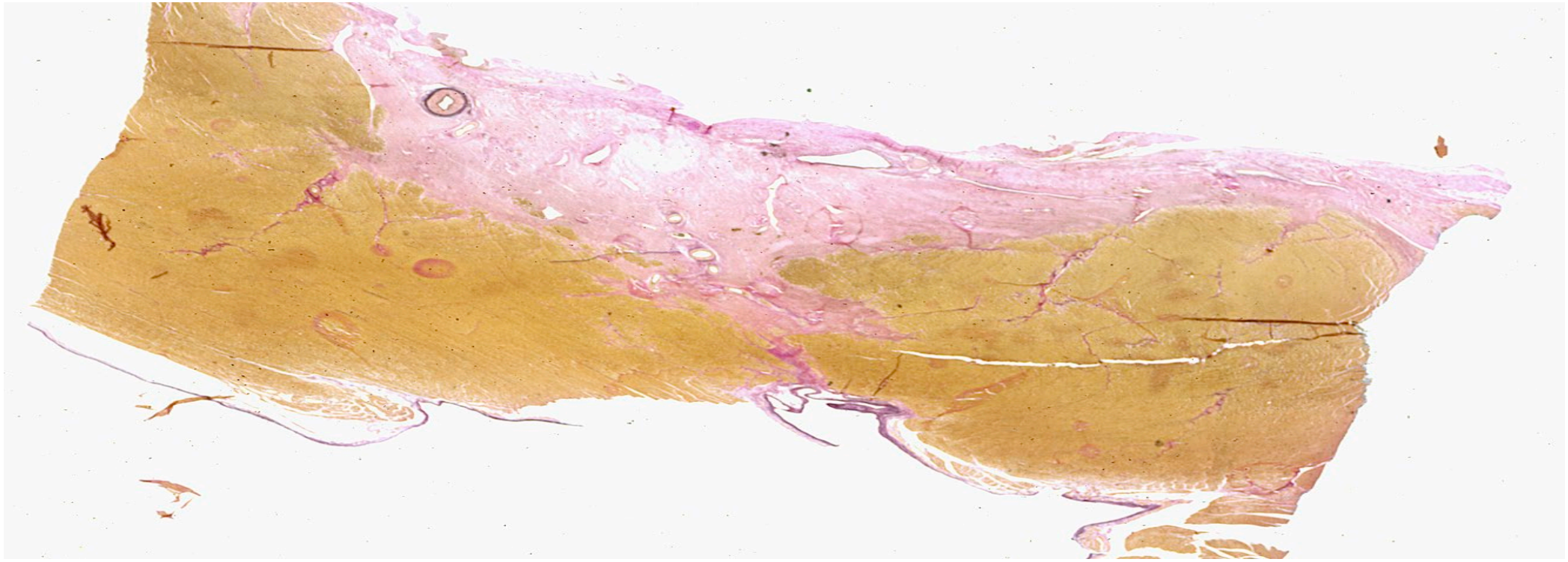
ICD = implantable cardioverter-defibrillator.

Cardiac Electroporation



LV = left ventricle; PV = pulmonary vein; AVNRT = atrioventricular nodal reentrant tachycardia.
Wittkampf FHM, et al. *JACC Clin Electrophysiol*. 2018;4(8):977-986.

PFA Spares Vessels and Nerves



PFA = pulsed field ablation.
Wittkampf FHM, et al. *JACC Clin Electrophysiol*. 2018;4(8):977-986.

Ablation of Atrial Fibrillation With Pulsed Electric Fields

An Ultra-Rapid, Tissue-Selective Modality for Cardiac Ablation

Vivek Y. Reddy, MD,[a,b] Jacob Koruth, MD,[a] Pierre Jais, MD,[c] Jan Petru, MD,[b] Ferdinand Timko, MD,[d] Ivo Skalsky, MD,[d] Robert Hebeler, MD,[e] Louis Labrousse, MD,[f] Laurent Barandon, MD,[f] Stepan Kralovec,[b] Moritoshi Funosako, MD,[b] Boochi Babu Mannuva, MD,[b] Lucie Sediva, MD,[b] Petr Neuzil, MD, PhD[b]

ABSTRACT

OBJECTIVES The authors report the first acute clinical experience of atrial fibrillation ablation with PEF—both epicardial box lesions during cardiac surgery, and catheter-based PV isolation.

BACKGROUND Standard energy sources rely on time-dependent conductive heating/cooling and ablate all tissue types indiscriminately. Pulsed electric field (PEF) energy ablates nonthermally by creating nanoscale pores in cell membranes. Potential advantages for atrial fibrillation ablation include: 1) cardiomyocytes have among the lowest sensitivity of any tissue to PEF—allowing tissue selectivity, thereby minimizing ablation of nontarget collateral tissue; 2) PEF is delivered rapidly over a few seconds; and 3) the absence of coagulative necrosis obviates the risk of pulmonary vein (PV) stenosis.

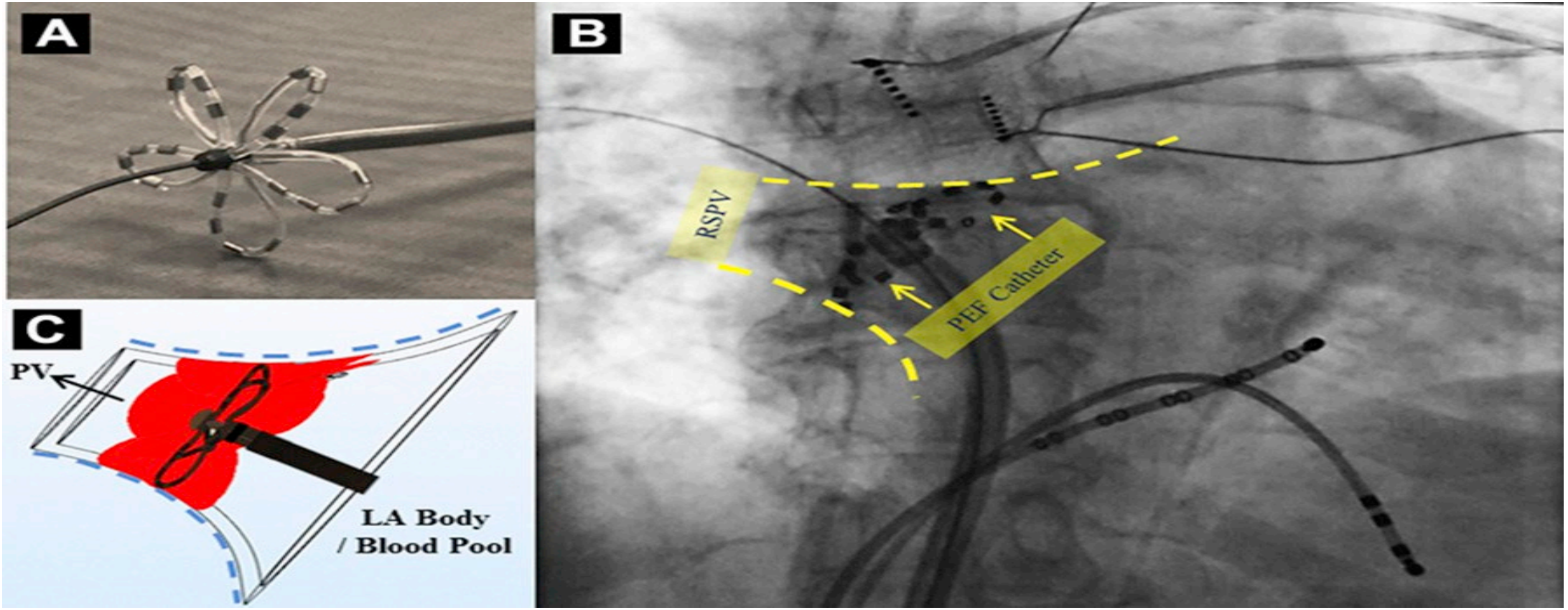
METHODS PEF ablation was performed using a custom over-the-wire endocardial catheter for percutaneous transseptal PV isolation, and a linear catheter for encircling the PVs and posterior left atrium during concomitant cardiac surgery. Endocardial voltage maps were created pre- and post-ablation. Continuous and categorical data are summarized and presented as mean ± SD and frequencies.

RESULTS At 2 centers, 22 patients underwent ablation under general anesthesia: 15 endocardial and 7 epicardial. Catheter PV isolation was successful in all 57 PVs in 15 patients (100%) using 3.26 ± 0.5 lesions/PV: procedure time 67 ± 10.5 min, catheter time (PEF catheter entry to exit) 19 ± 2.5 min, total PEF energy delivery time <60 s/patient, and fluoroscopy time 12 ± 4.0 min. Surgical box lesions were successful in 6 of 7 patients (86%) using 2 lesions/patient. The catheter time for epicardial ablation was 50.7 ± 19.5 min. There were no complications.

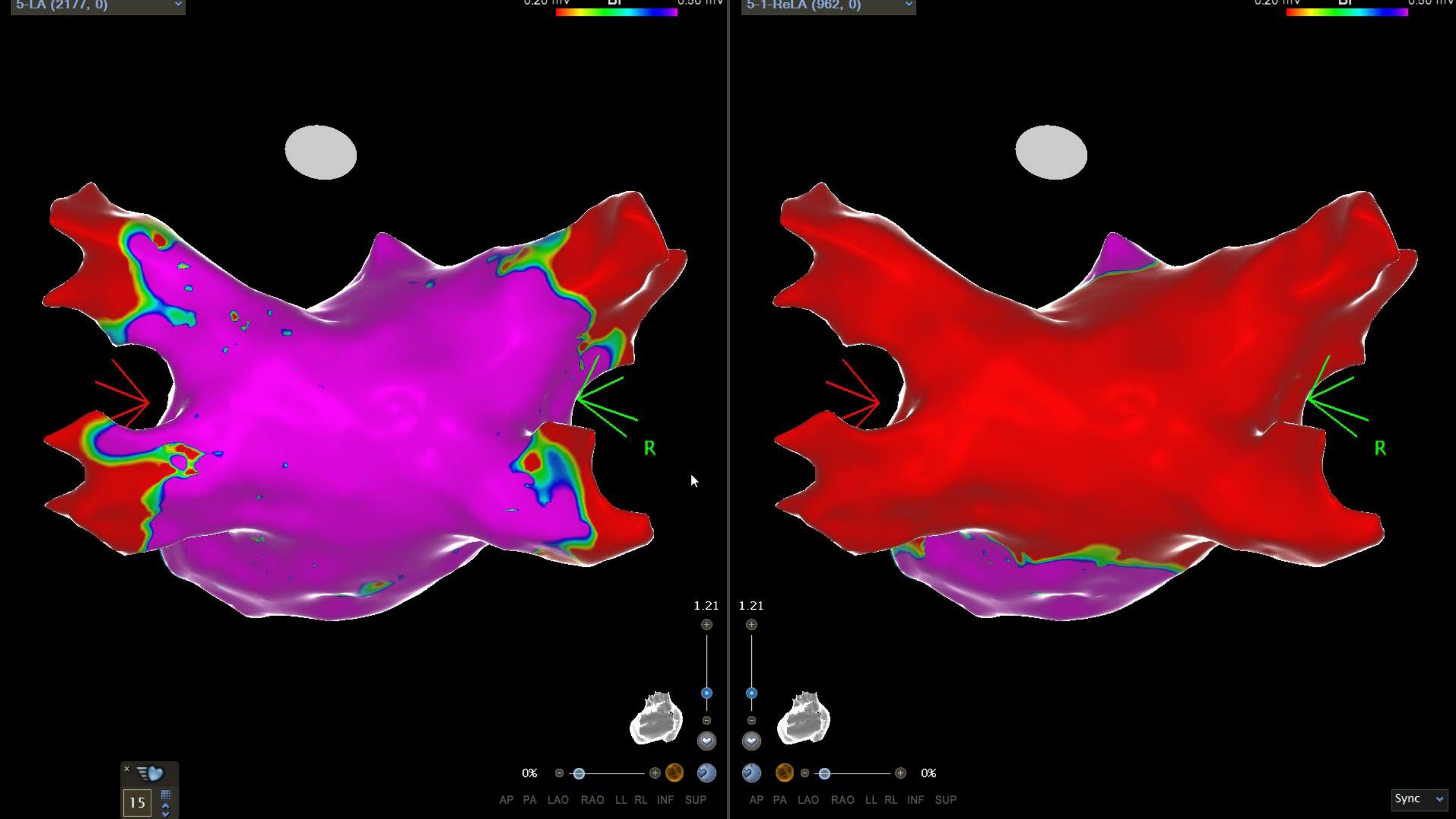
CONCLUSIONS These data usher in a new era of tissue-specific, ultrarapid ablation of atrial fibrillation.

Reddy VY, et al. *JACC Clin Electrophysiol*. 2018;4(8):987-995.

FARAPULSE



LA = left atrium; RSPV = right superior pulmonary vein; PEF = pulsed electric field.
Reddy VY, et al. *JACC Clin Electrophysiol*. 2018;4(8):987-995.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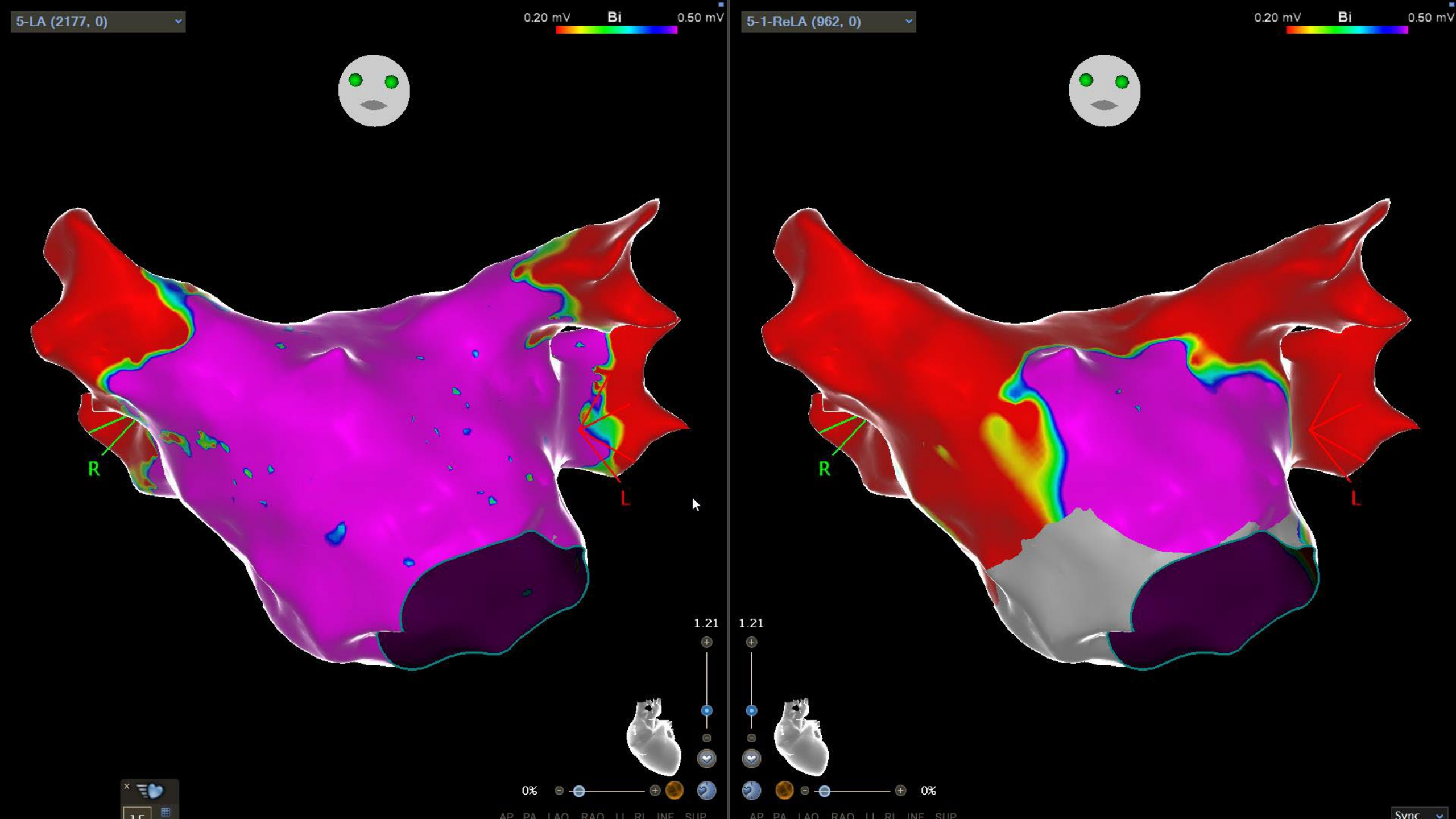
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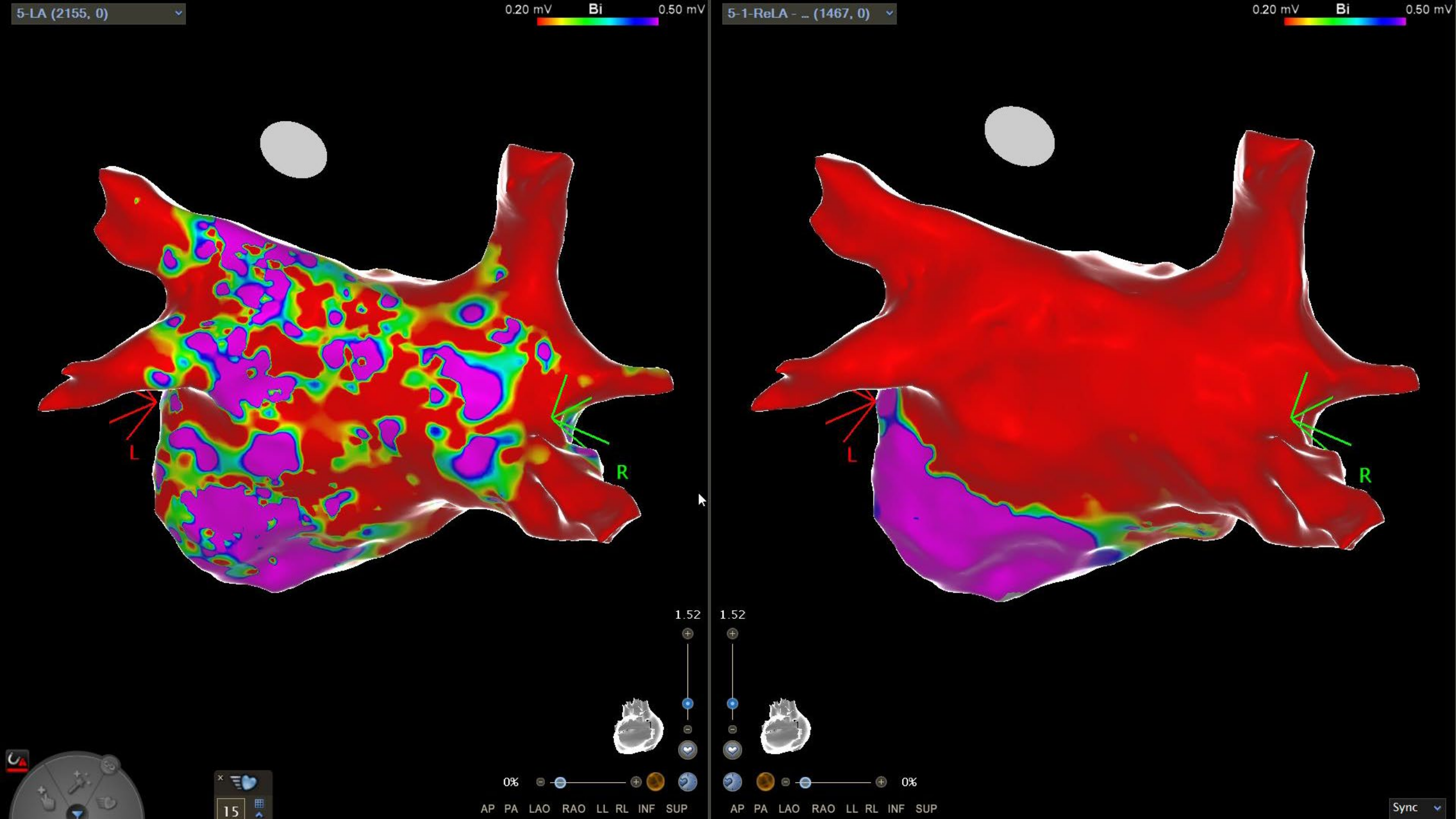
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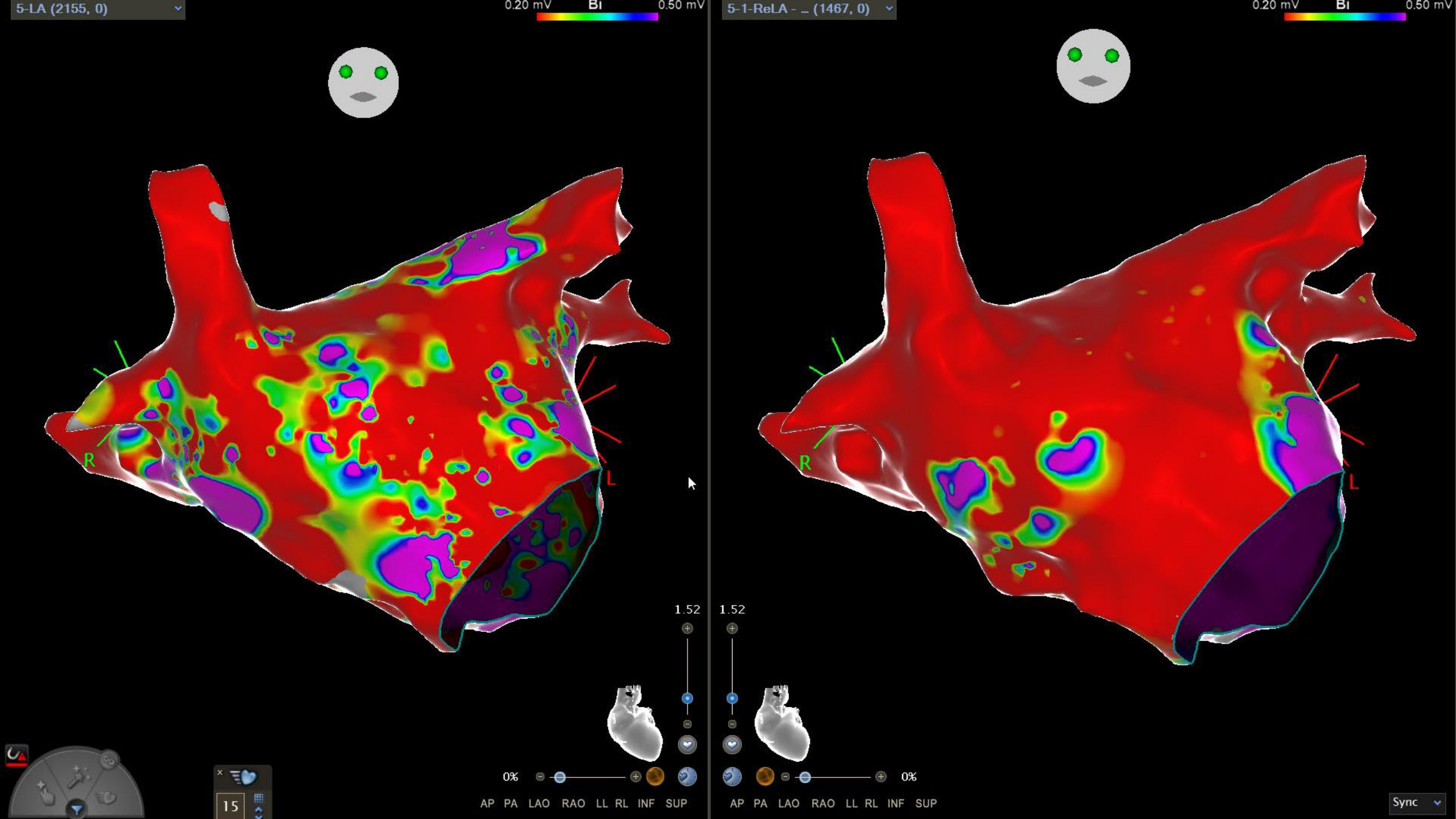
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Dual-Energy Focal Catheter Concept

PFA Characteristics

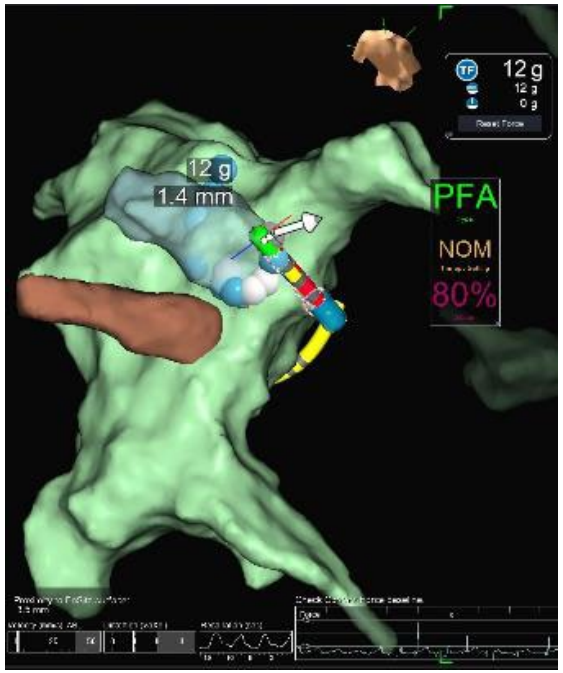
- PF time compatible with HPSD workflow
- Minimal skeletal muscle recruitment – conscious sedation suitability
- Sufficient depth for atrial ablation (>5 mm)
- Maintain existing performance in handling and ablation
- Excellent safety

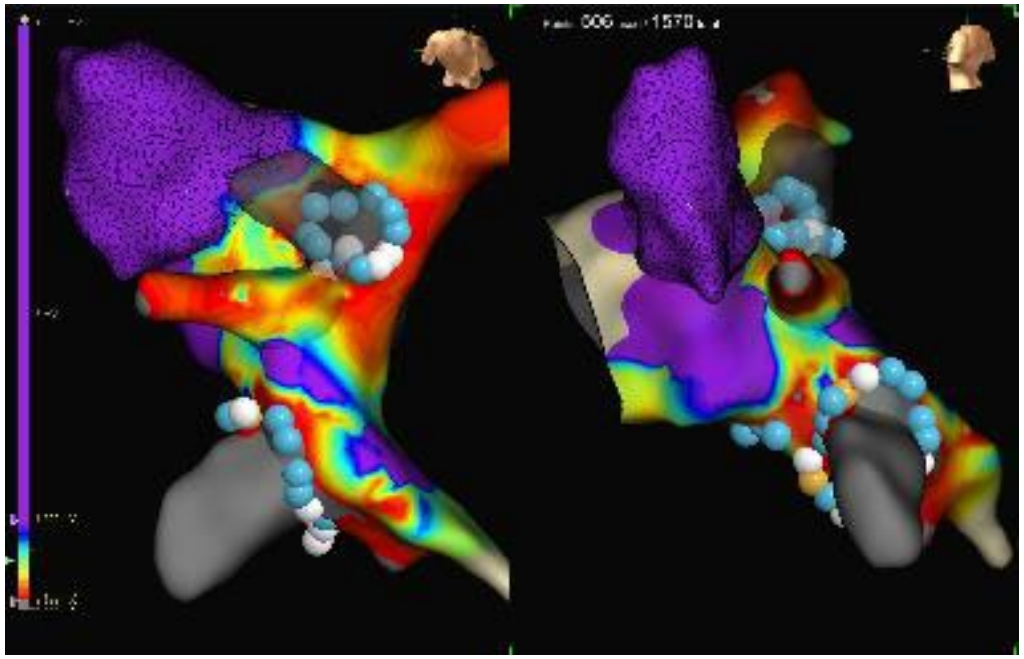
Advantages of RF/PF

- RF titratability + PF post wall safety
- Streamlined connectology
- Mapping integration with established work-flow
- Stable catheter placement for the duration of lesions
- Avoiding spasm along CTI and mitral line

PF = pulsed field; HPSD = high power short duration; RF = radiofrequency; CTI = cavotricuspid isthmus.
Courtesy of Jacob Koruth, Mount Sinai New York.

Dual-Energy Focal Catheter





LIPV = left inferior pulmonary vein.

Volt™ PFA System

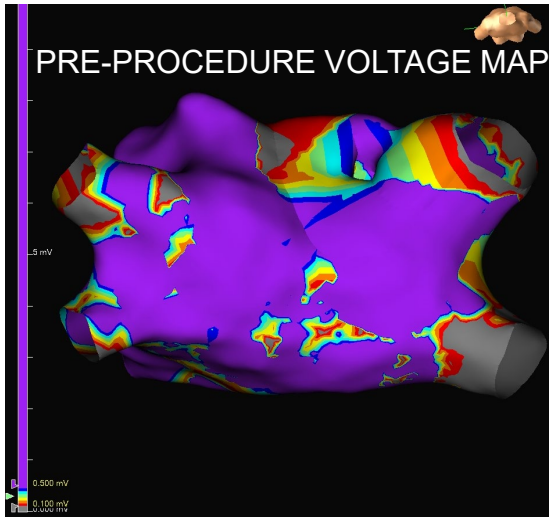
- Volt™ PFA Catheter Sensor Enabled™
- Agilis™ NxT Steerable Introducer Dual-Reach™
- Volt™ PFA Generator
- EnSite™ X EP System with PFA Module

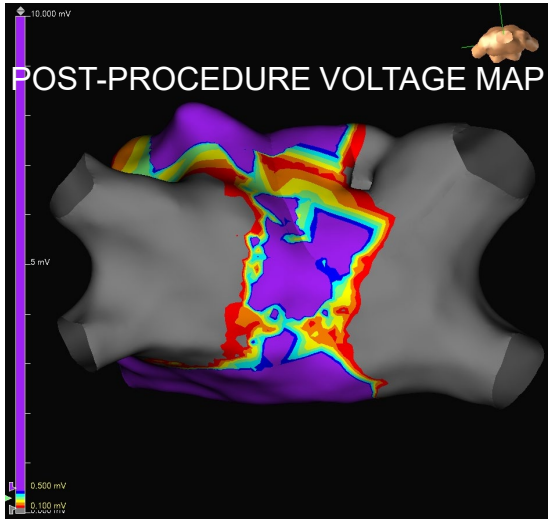
EP = electrophysiology.

NIH. Accessed November 25, 2024. https://clinicaltrials.gov/study/NCT06223789.

The Volt™ PFA System Is a Complete AF Treatment Solution

- Offers acute success and safety paired with ease-of-use
- Differentiators
  - Balloon-in-basket design supports anatomic alignment and conformance to vein for efficient energy transfer reducing required applications
  - This design, paired with electrode selectivity, may protect against hemolysis by limiting energy application to the blood pool
  - Waveform minimizes patient movement and bubble production
  - Full mapping system integration helps support workflows with contact assessment; therapy location tracking with AutoMarks, repositioning, identifying areas for more application

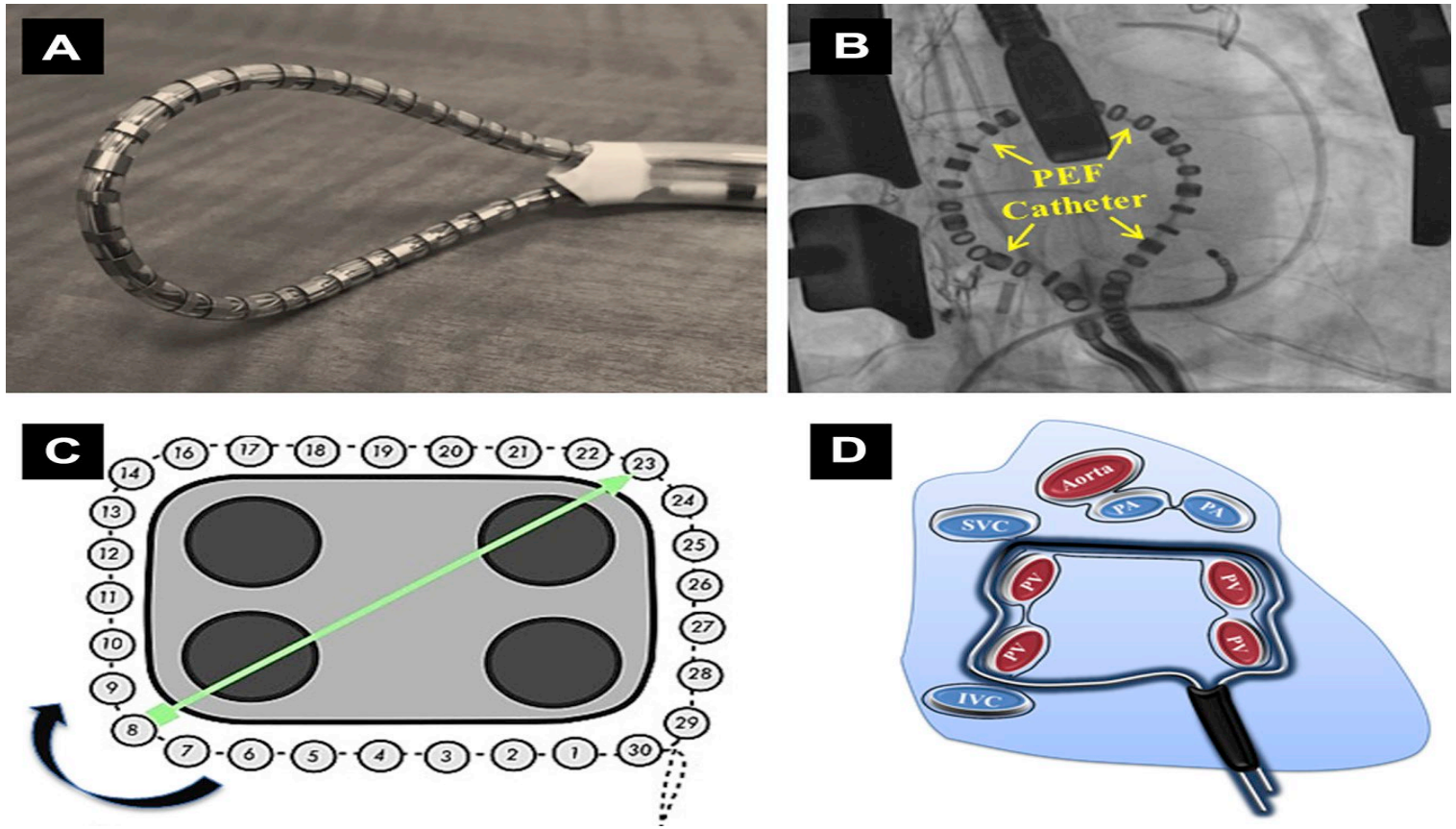




AF = atrial fibrillation.

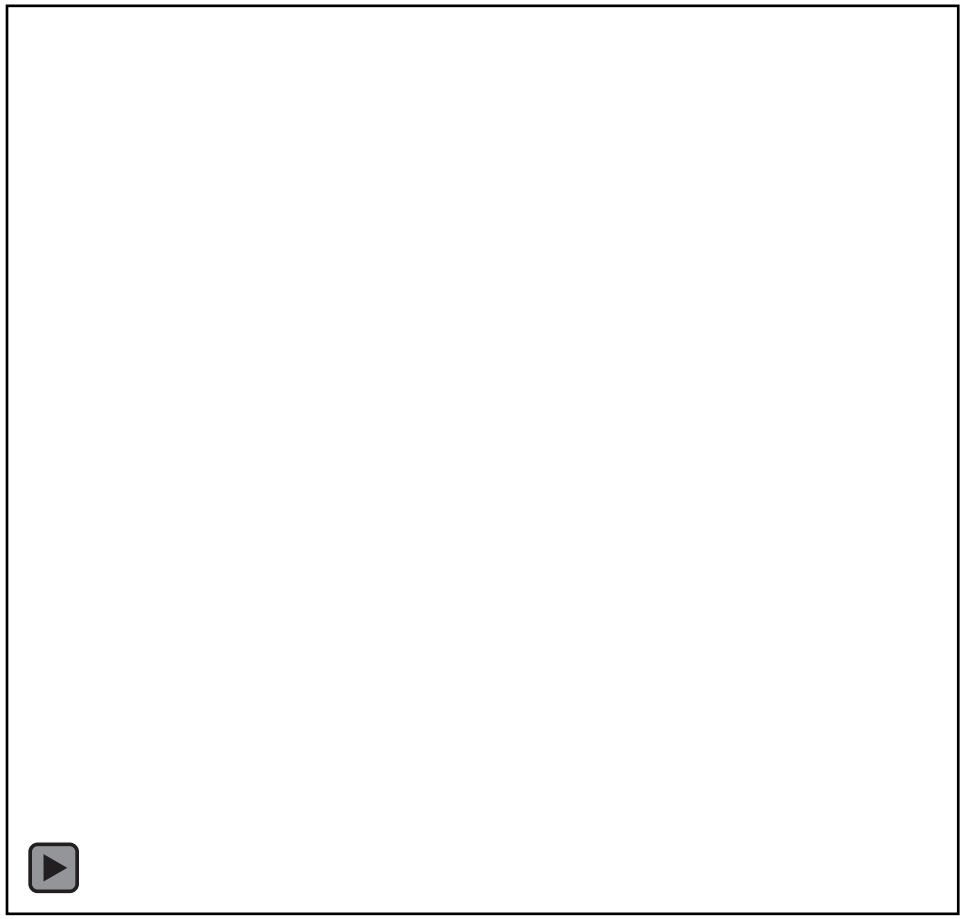
Wittkampf FHM, et al. *JACC Clin Electrophysiol.* 2018;4(8):977-986.

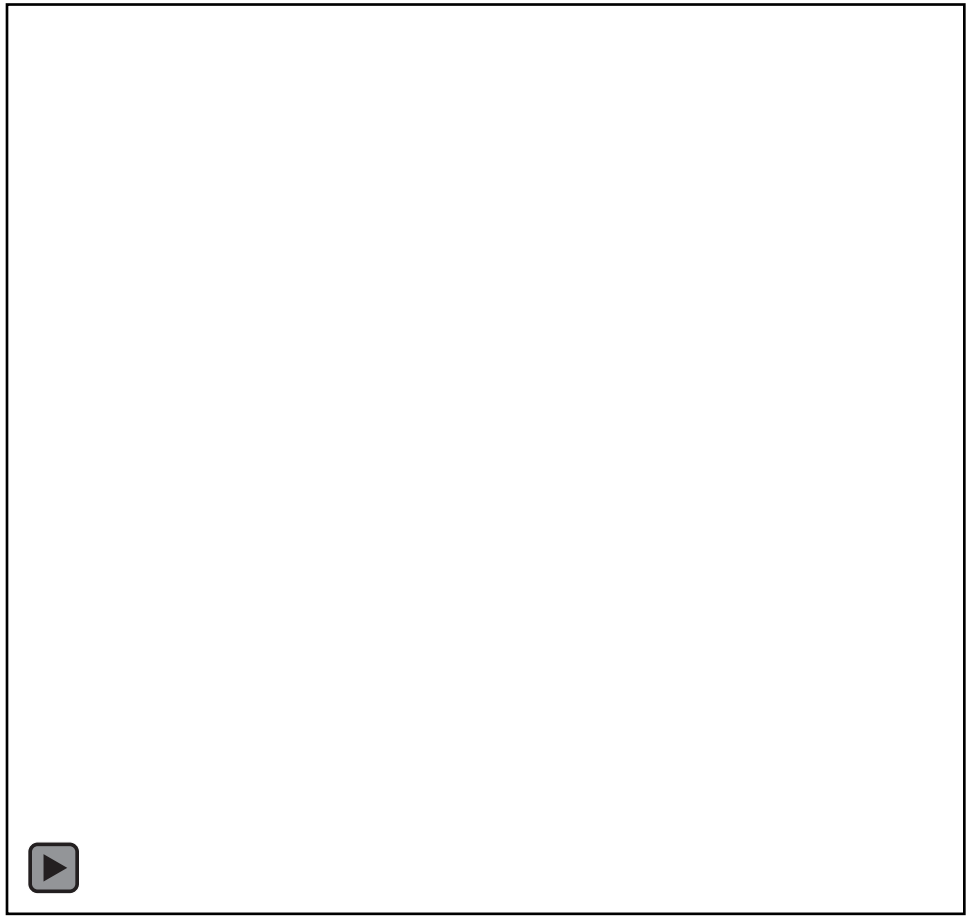
Epicardial Pulsed Field Ablation



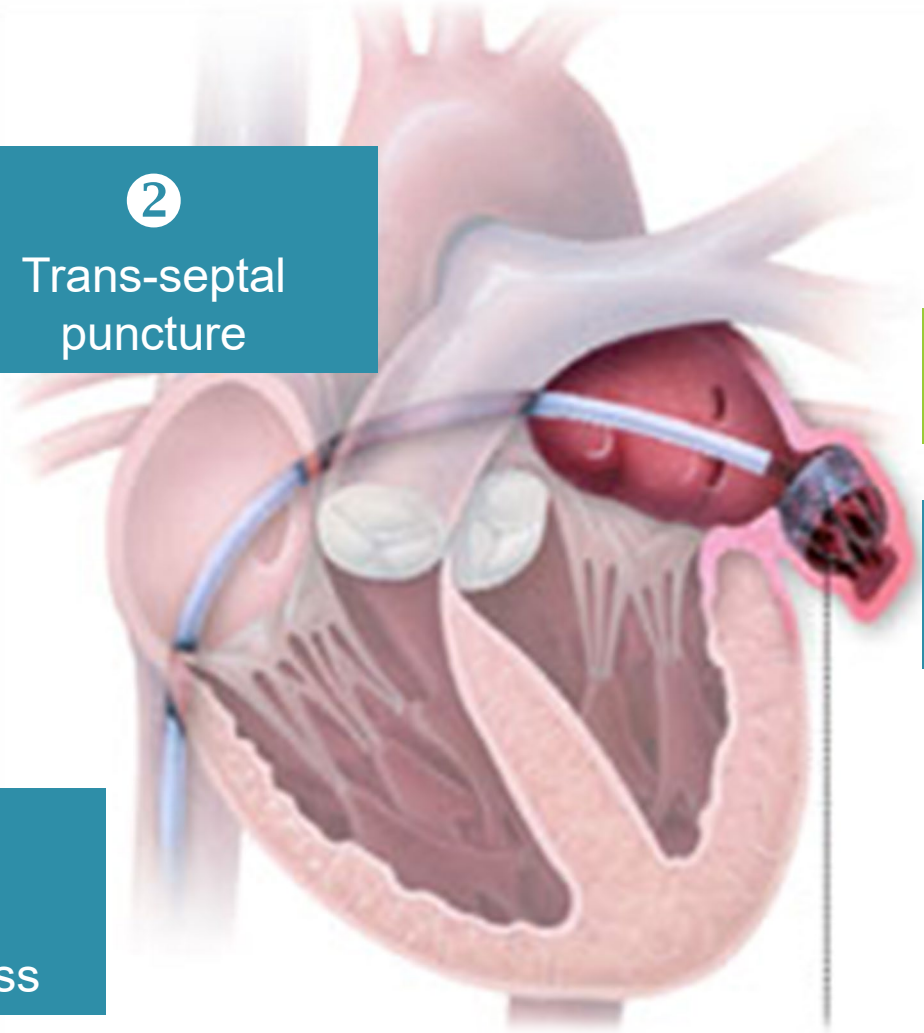
PA = pulmonary artery; SVC = superior vena cava; IVC = inferior vena cava.
Reddy VY, et al. *JACC Clin Electrophysiol*. 2018;4(8):987-995.

Stroke Prevention





Percutaneous LAA Occlusion: Procedural Steps



❷ Trans-septal puncture

LAA size and shape

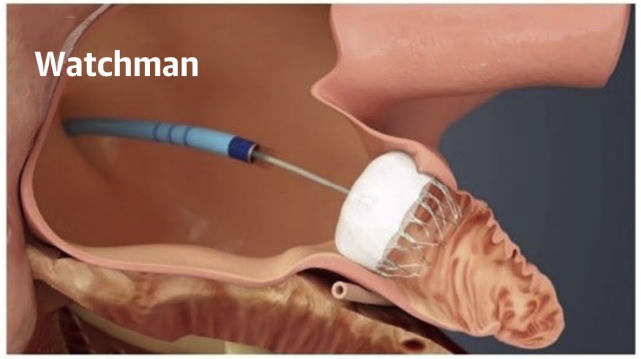
❸ Device deployment

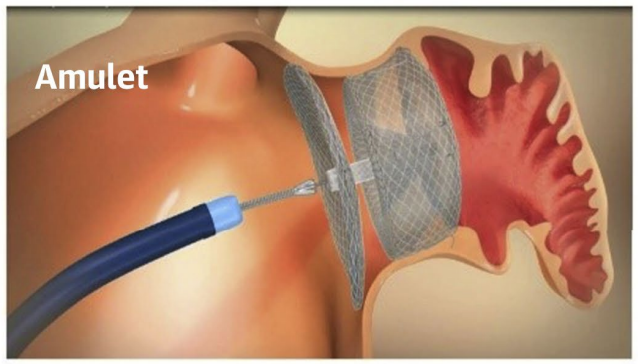
❶ Femoral venous access

LAA = left atrial appendage.

LAA Excluders

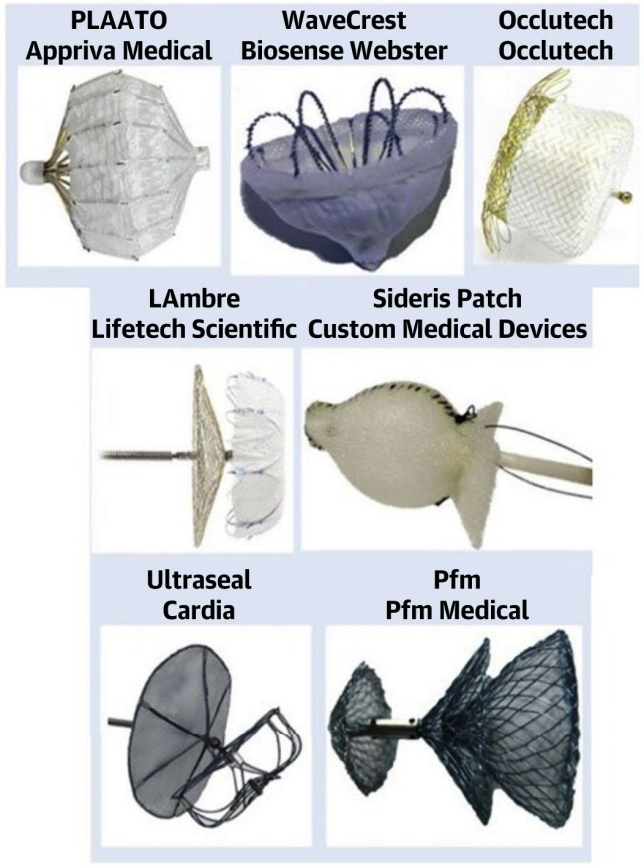
Endocardial LAA Occluders





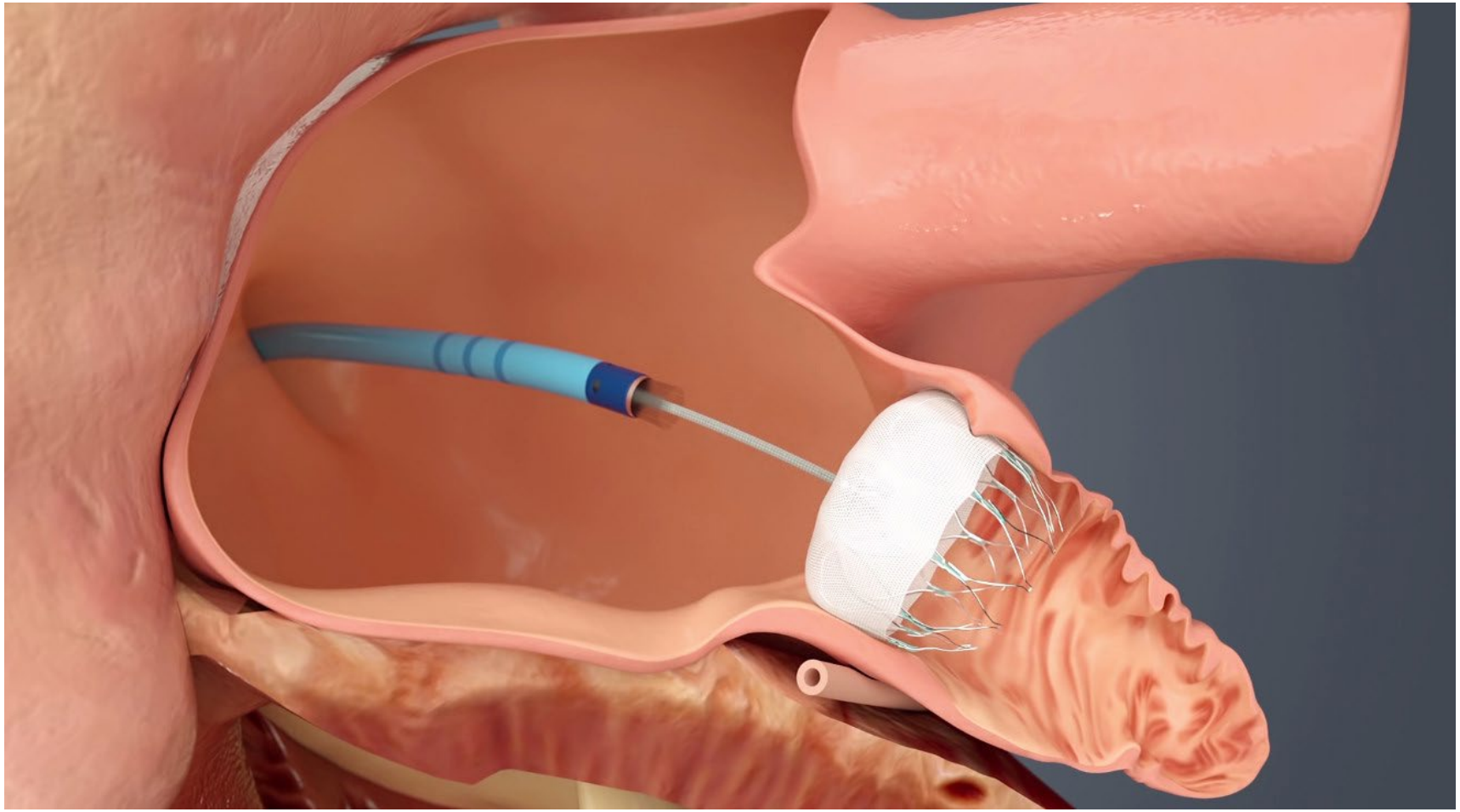
Epicardial LAA Excluders

Other Endocardial LAA Occluders



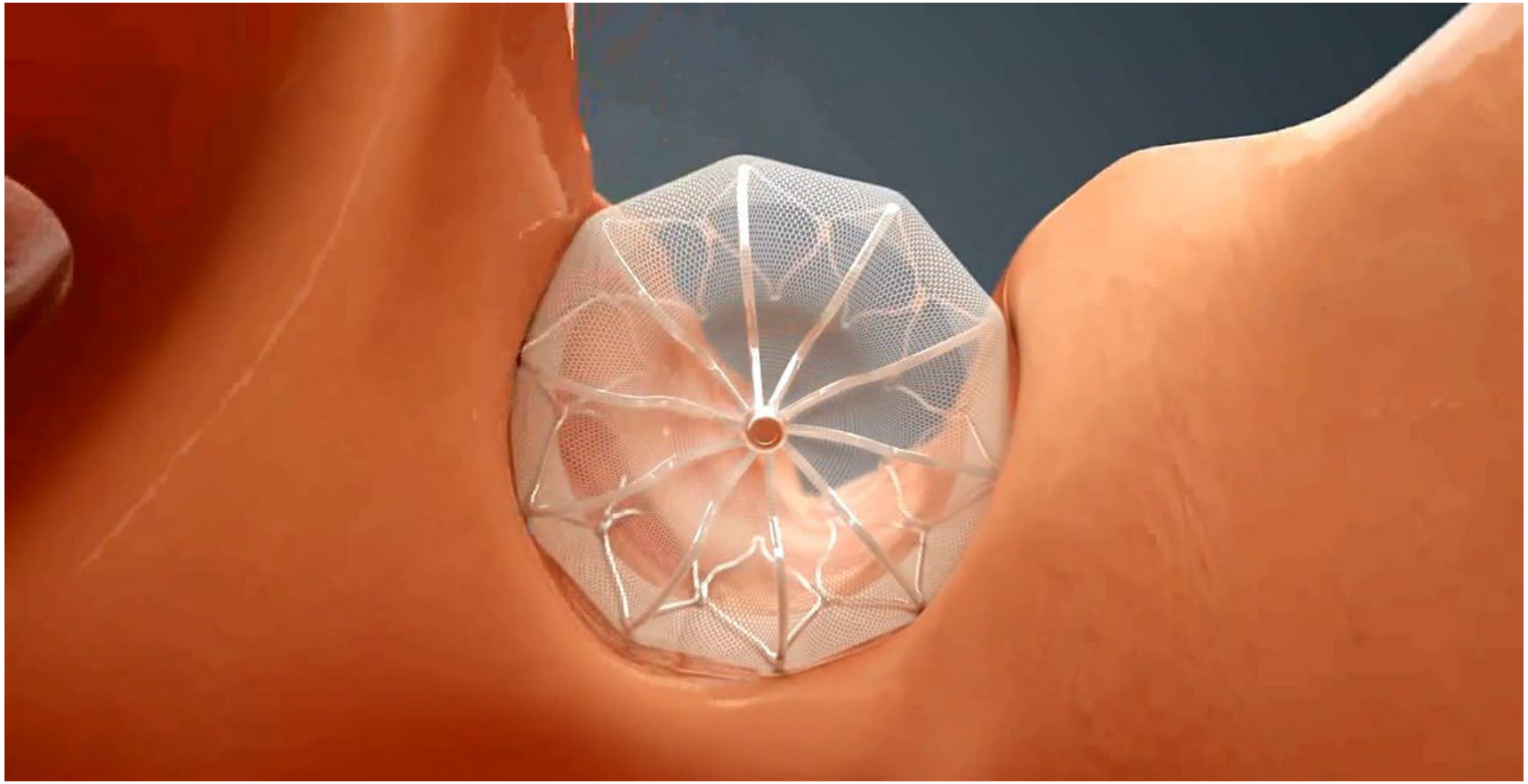
Chung MK, et al. *J Am Coll Cardiol*. 2020;75(14):1689-1713.

Watchman Procedure



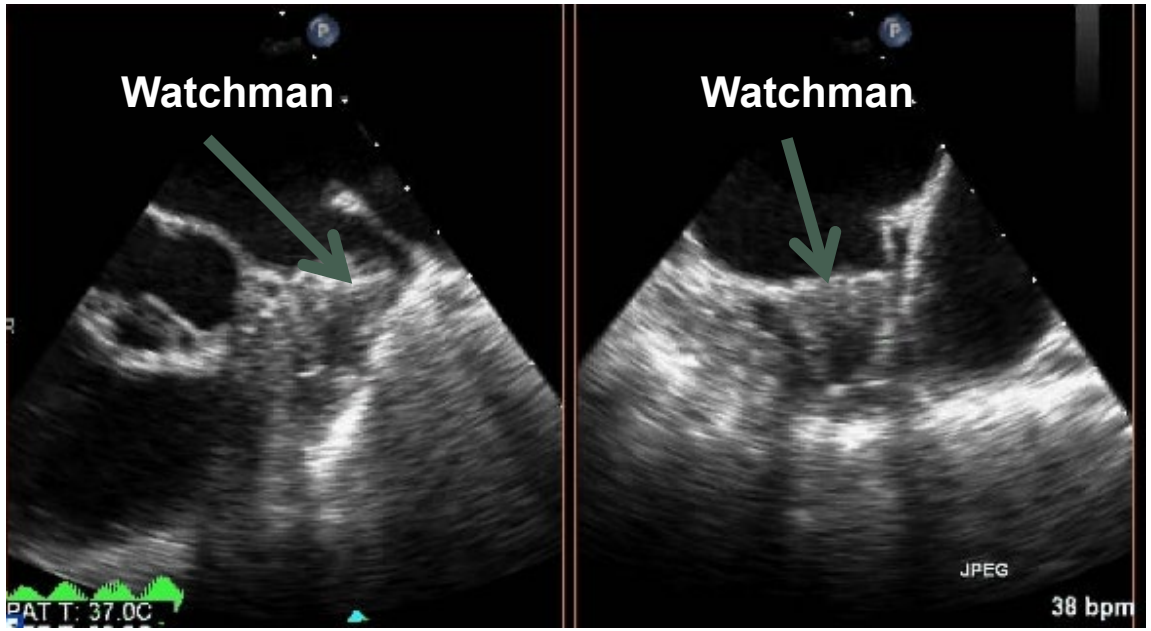
Boston Scientific.

Watchman Procedure

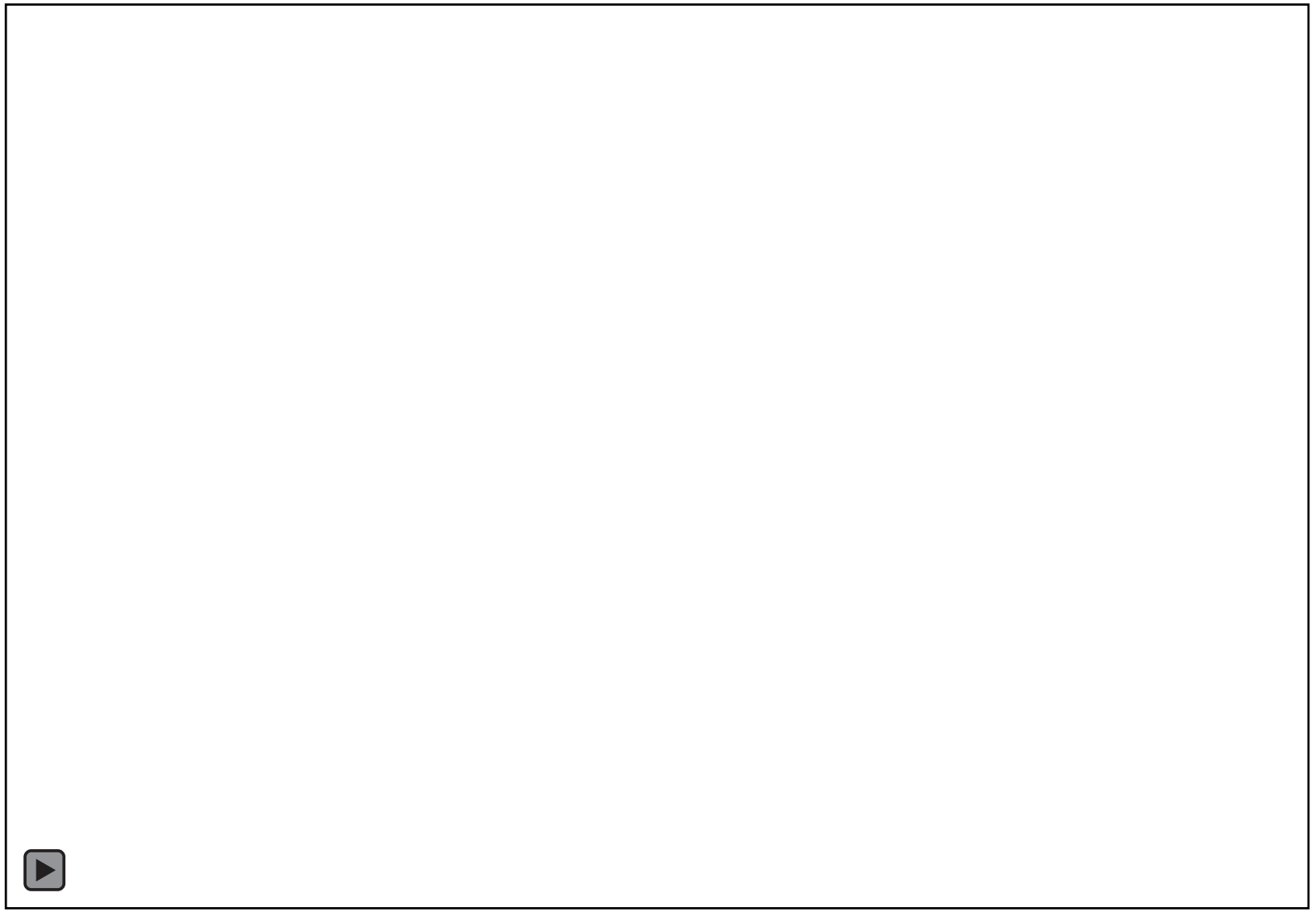


Boston Scientific.

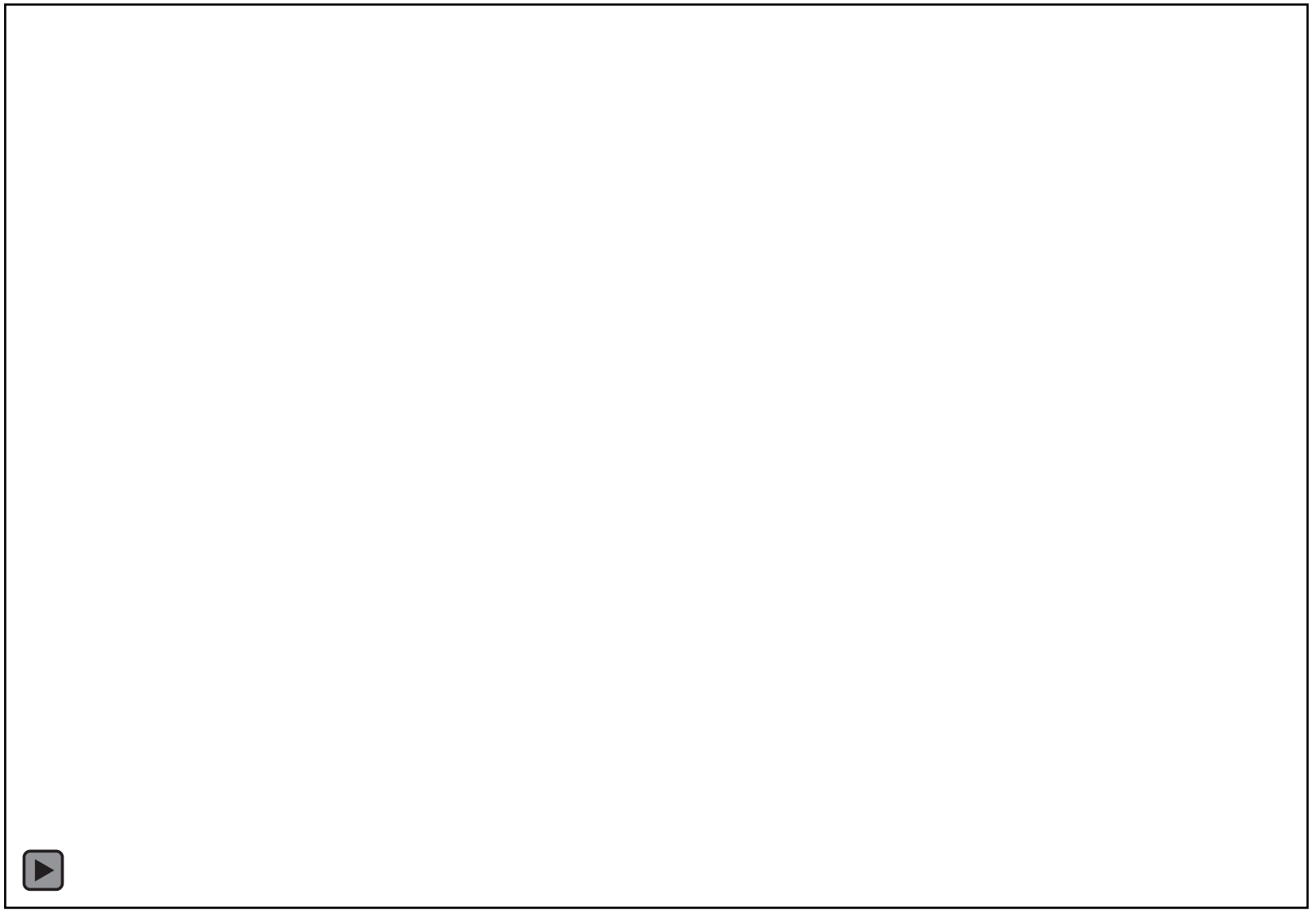
Biplane TEE – Watchman Deployed



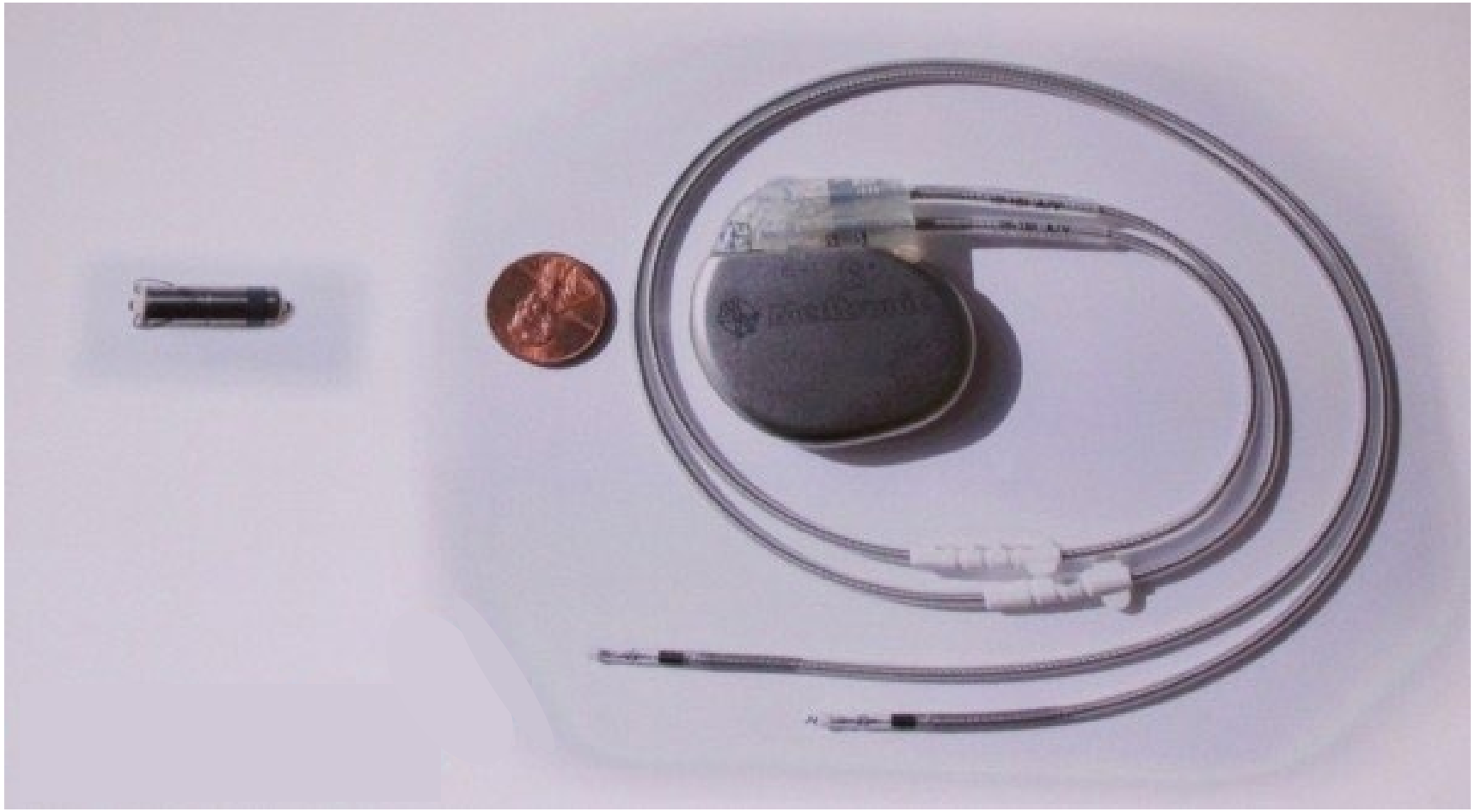
28 mm Amulet



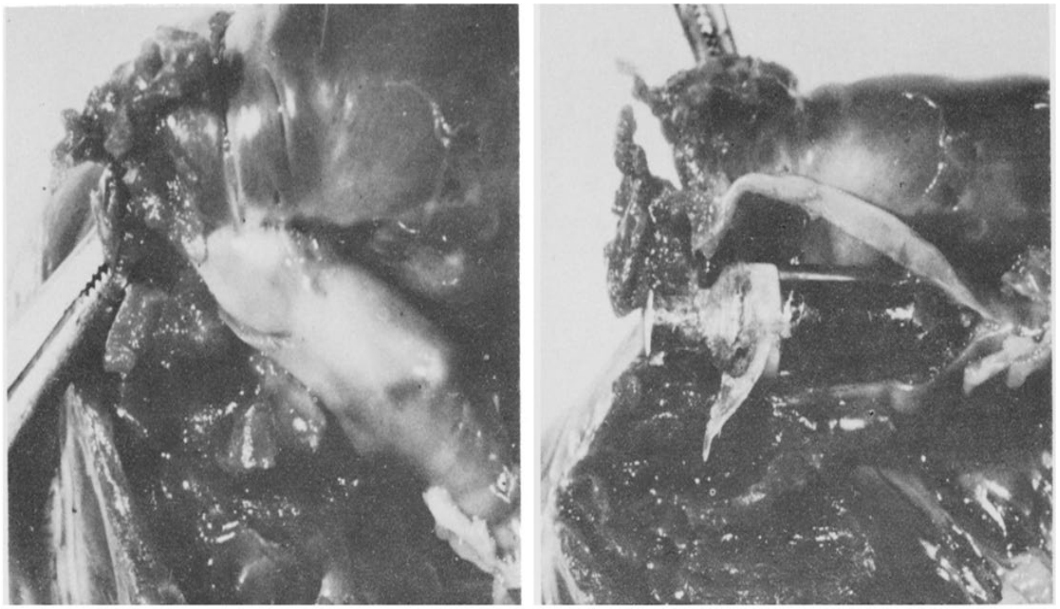
Intraprocedural – 28 mm Amulet

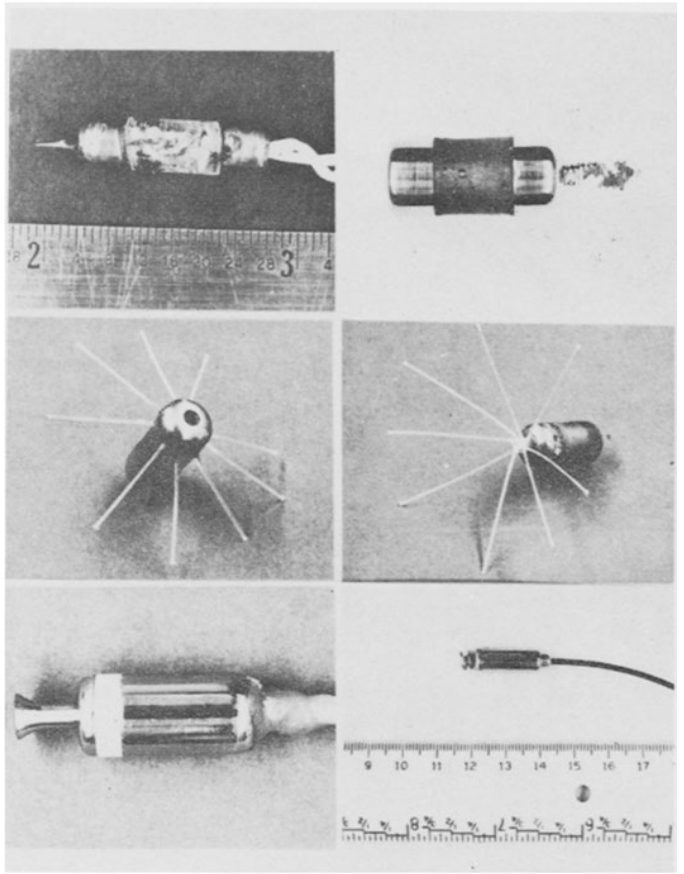


The Future of Cardiac Pacing



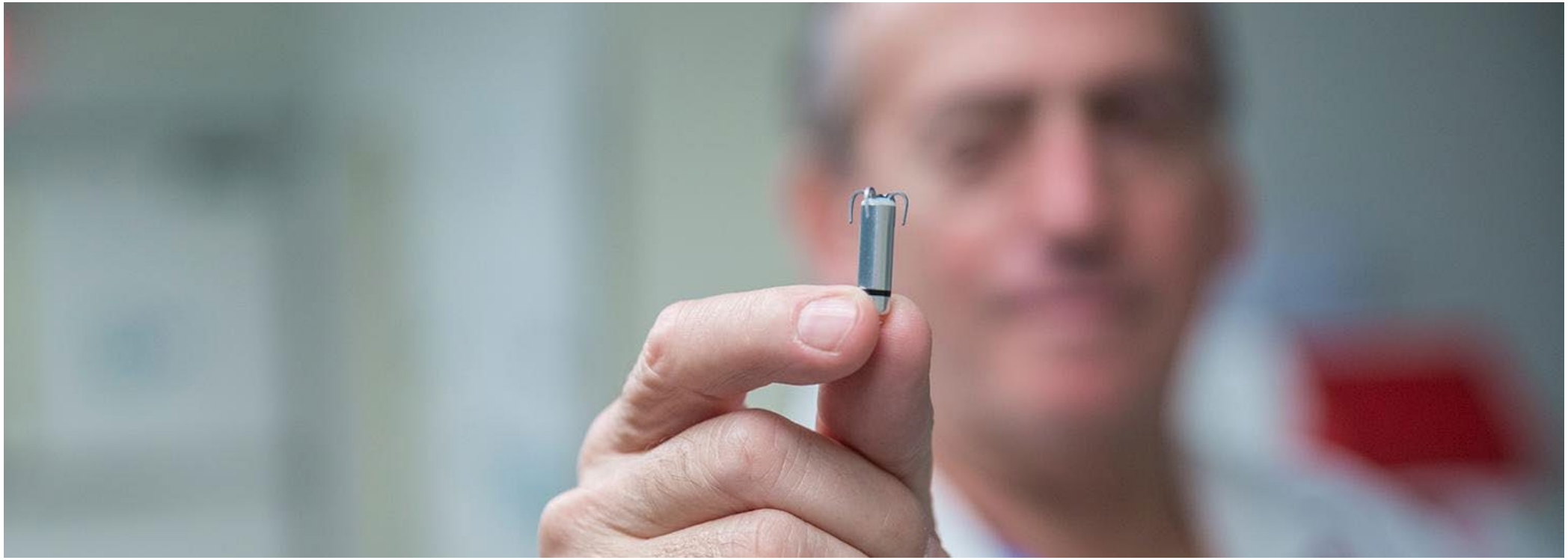
Totally Self-Contained Intracardiac Pacemaker





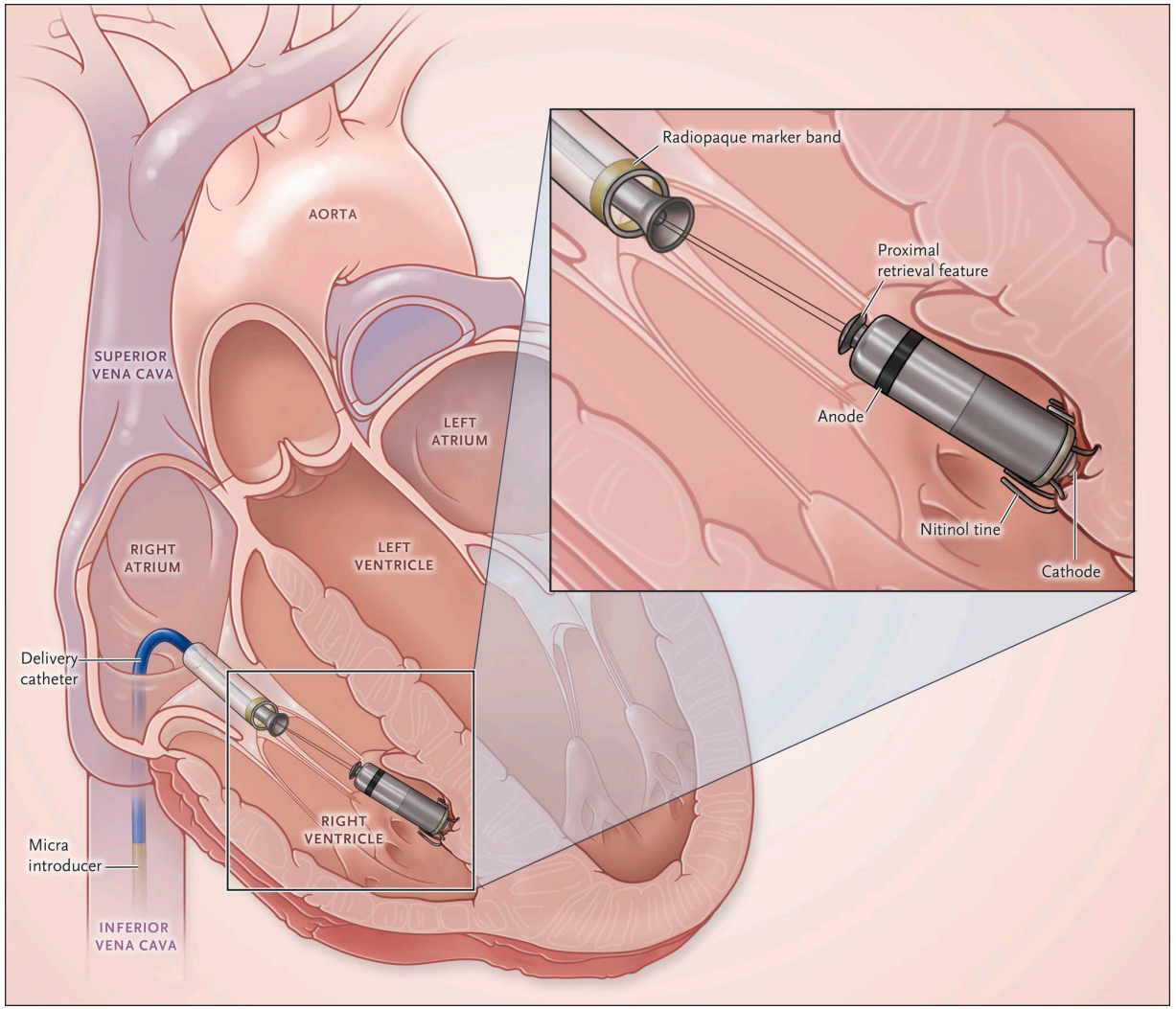
Spickler JW, et al. *J Electrocardiol*. 1970;3(3-4):325-331.

April 2016: First Commercially Approved Leadless Implant – Medtronic Micra



FDA. April 6, 2016. Accessed November 25, 2024. https://www.fda.gov/news-events/press-announcements/fda-approves-first-leadless-pacemaker-treat-heart-rhythm-disorders.

Micra Transcatheter Pacing System Positioned in the Right Ventricle



Reynolds D, et al. *N Engl J Med.* 2016;374(6):533-541.

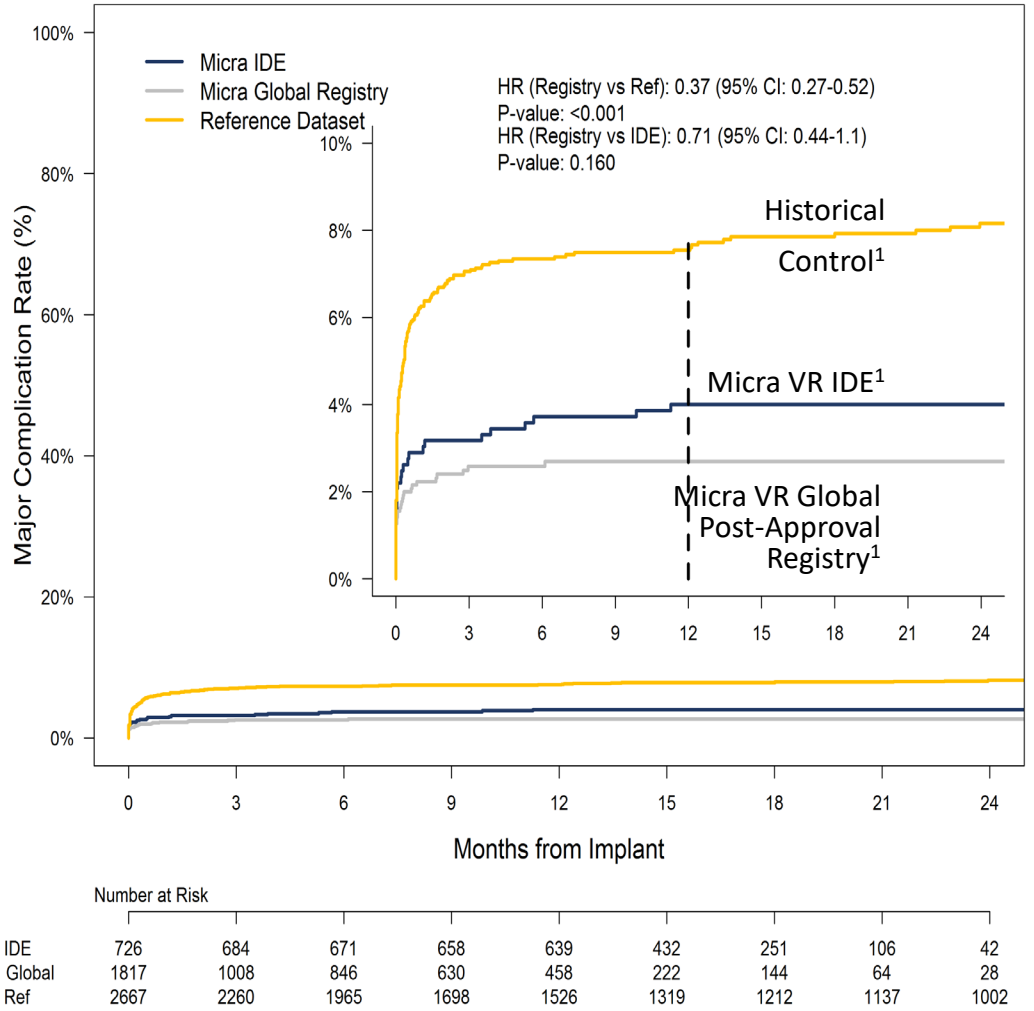
Performance of a Miniaturized Transcatheter Pacing System: First-in-Human Experience

Philippe Ritter, MD; Gabor Z Duray, MD, PhD, FESC; Clemens Steinwender, MD, FESC; Kyoko Soejima, MD; Razali Omar, MD; Lluis Mont, MD; Lucas VA Boersma, MD; Reinoud E Knops, MD;, MD; Shuyang Zhang, MD; Calambur Narasimhan, MD; John D Hummel, MD; Michael S Lloyd, MD; Timothy A Simmers, MD; Andrew H Voigt, MD; Verla Laager, MA; Kurt Stromberg, MS; J Harrison Hudnall, BS; Matthew D Bonner, PhD;

Dwight W Reynolds, MD

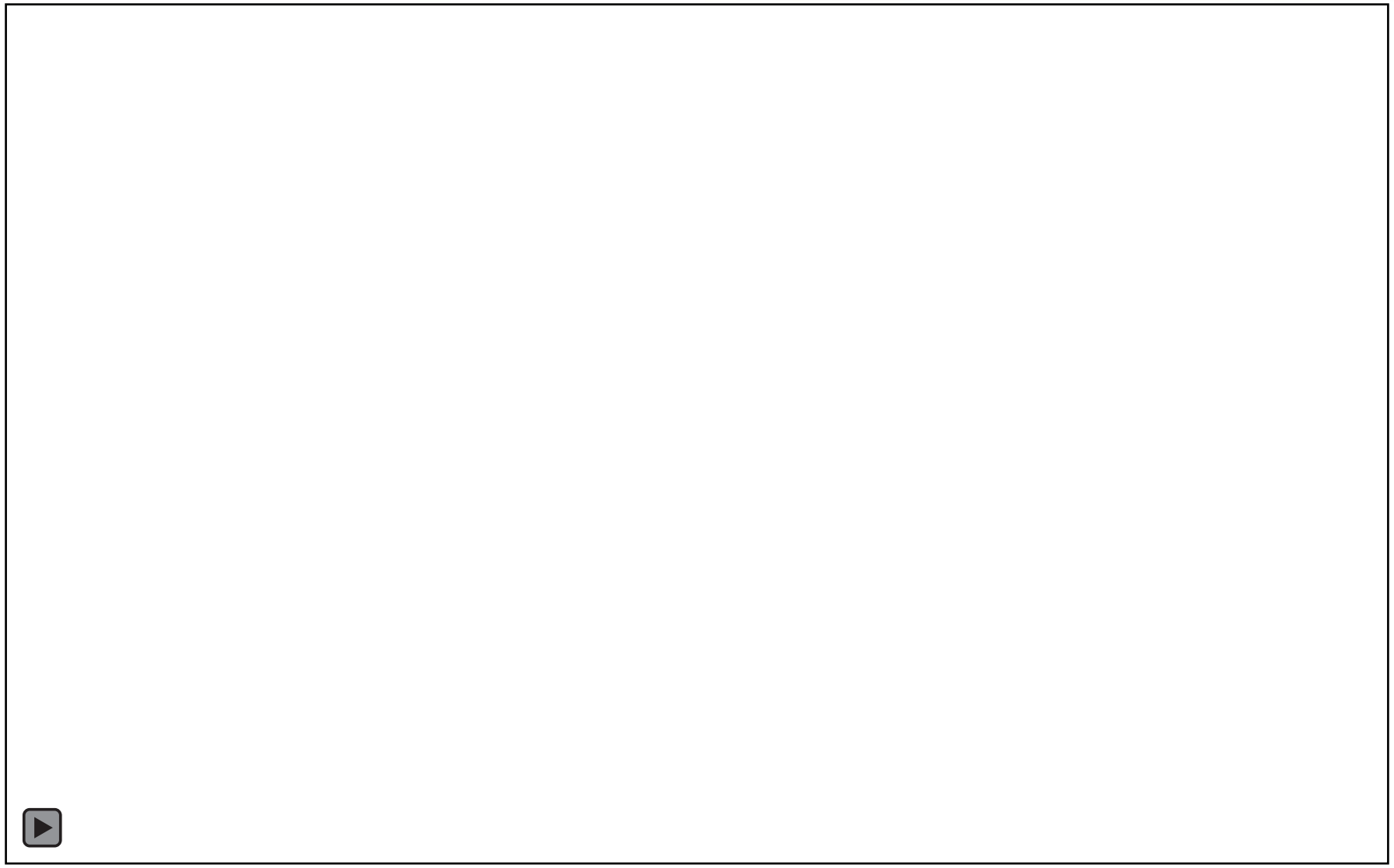
Heart Rhythm 2015 – 36th Annual Scientific Sessions

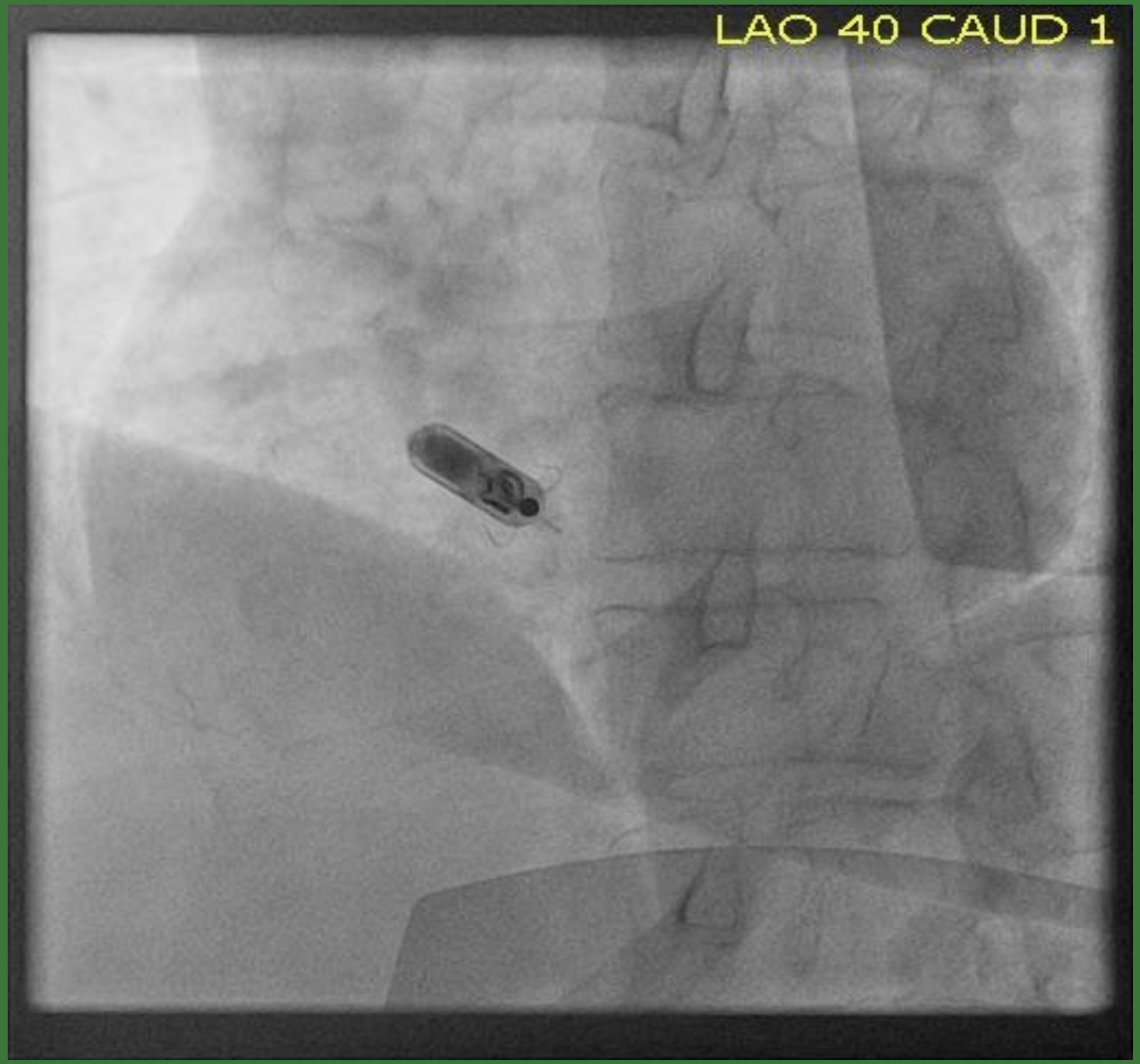
Reduced Major Complications with Micra



El-Chami MF, et al. Presented at: Heart Rhythm Society Scientific Sessions; May 10, 2018; Boston, Massachusetts. Abstract 5741.

Septal Location/Not Apical




LAO 40 CAUD 1

AV Synchronous Pacing With a Ventricular Leadless Pacemaker: Primary Results from the MARVEL Study

Larry A. Chinitz, MD, FHRS; Philippe Ritter, MD; Surinder Kaur Khelae, MBBS, FHRS; Saverio Iacopino, MD; Christophe Garweg, MD; Maria Grazia Bongiorni, MD; Petr Neuzil, MD, PhD; Jens Brock Johansen, MD; Lluis Mont, MD, PhD; Efrain H. Gonzalez, MD; Venkata S. Sagi, MD, FHRS; Gabor Z. Duray, MD, PhD; Nicolas Clementy, MD; Todd J. Sheldon, MS; Vincent Splett, MS; Kurt Stromberg, MS; Nicole Wood, BS; Clemens Steinwender, MD

Heart Rhythm Scientific Sessions; May 11, 2018; Boston, Massachusetts.

Ambulatory AV Synchronous Pacing Over Time Using a Leadless Ventricular Pacemaker: Primary Results from the AccelAV Study

Larry A.Chinitz, MD, FHRS; Mikhael F. El-Chami, MD, FHRS; Venkata Sagi, MD, FHRS; Hector Garcia, MD; F. Kevin Hackett, MD; Miguel Leal, MD, FHRS; Patrick Whalen, MD, FHRS; Charles A. Henrikson, MD, MPH, FHRS; Arnold J. Greenspon, MD; Todd Sheldon, MS; Kurt Stromberg, MS; Nicole Wood, BS; Dedra H. Fagan, PhD; Joseph Yat; Sun Chan, MBBS

HEART RHYTHM JOURNAL 2022

Left Bundle Branch Area Pacing Using a Stylet-Driven, Retractable Helix Lead: Early Results from a Prospective, Multicenter, IDE Trial

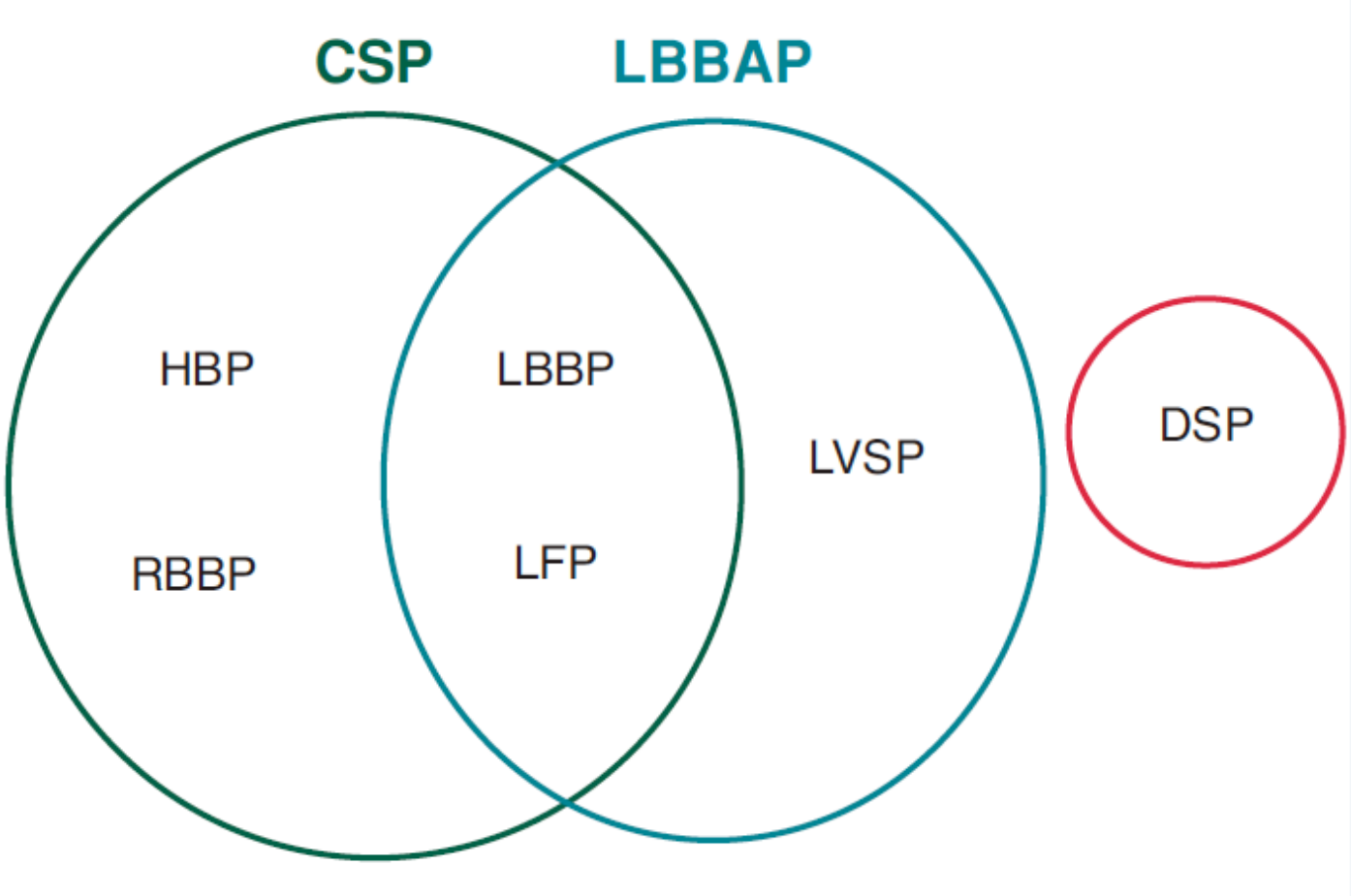
(The BIO-CONDUCT Study)

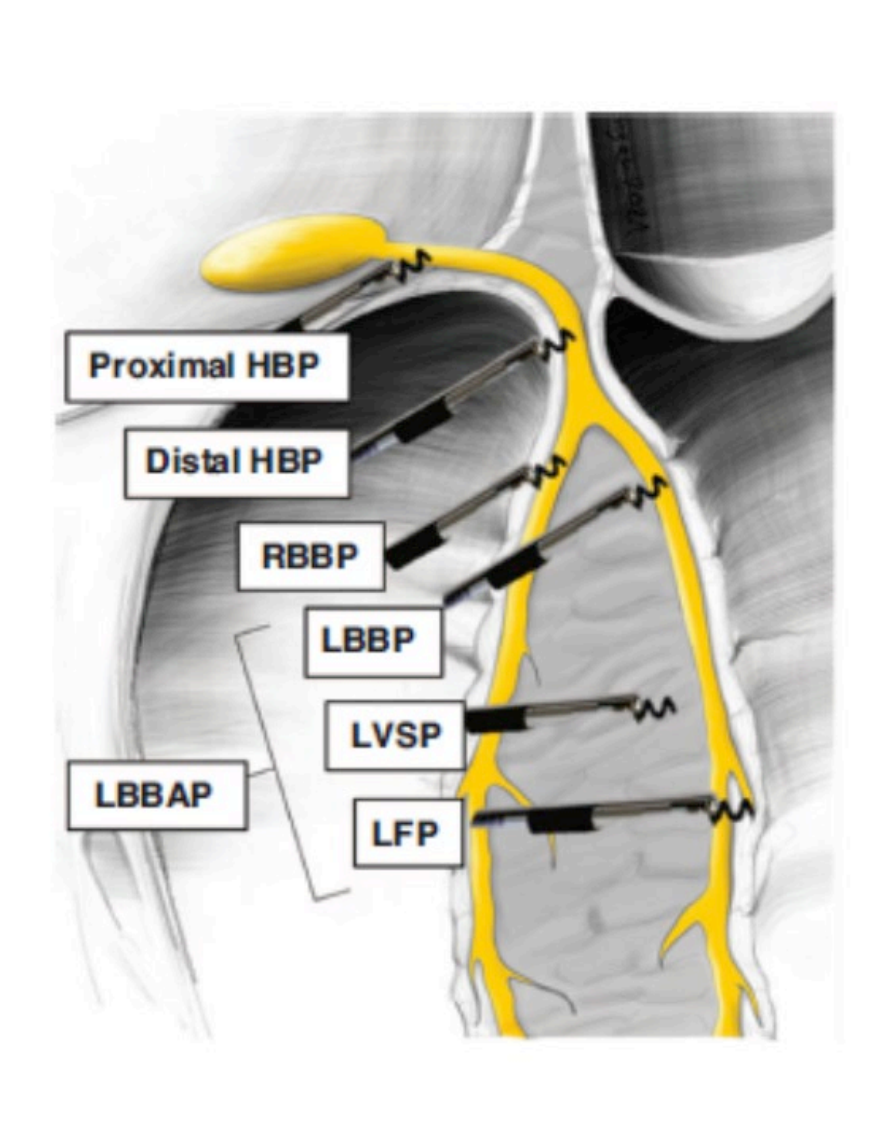
Presented by Dr. Larry Chinitz, MD

on behalf of the BIO-CONDUCT and BIO|MASTER.Selectra 3D study investigators

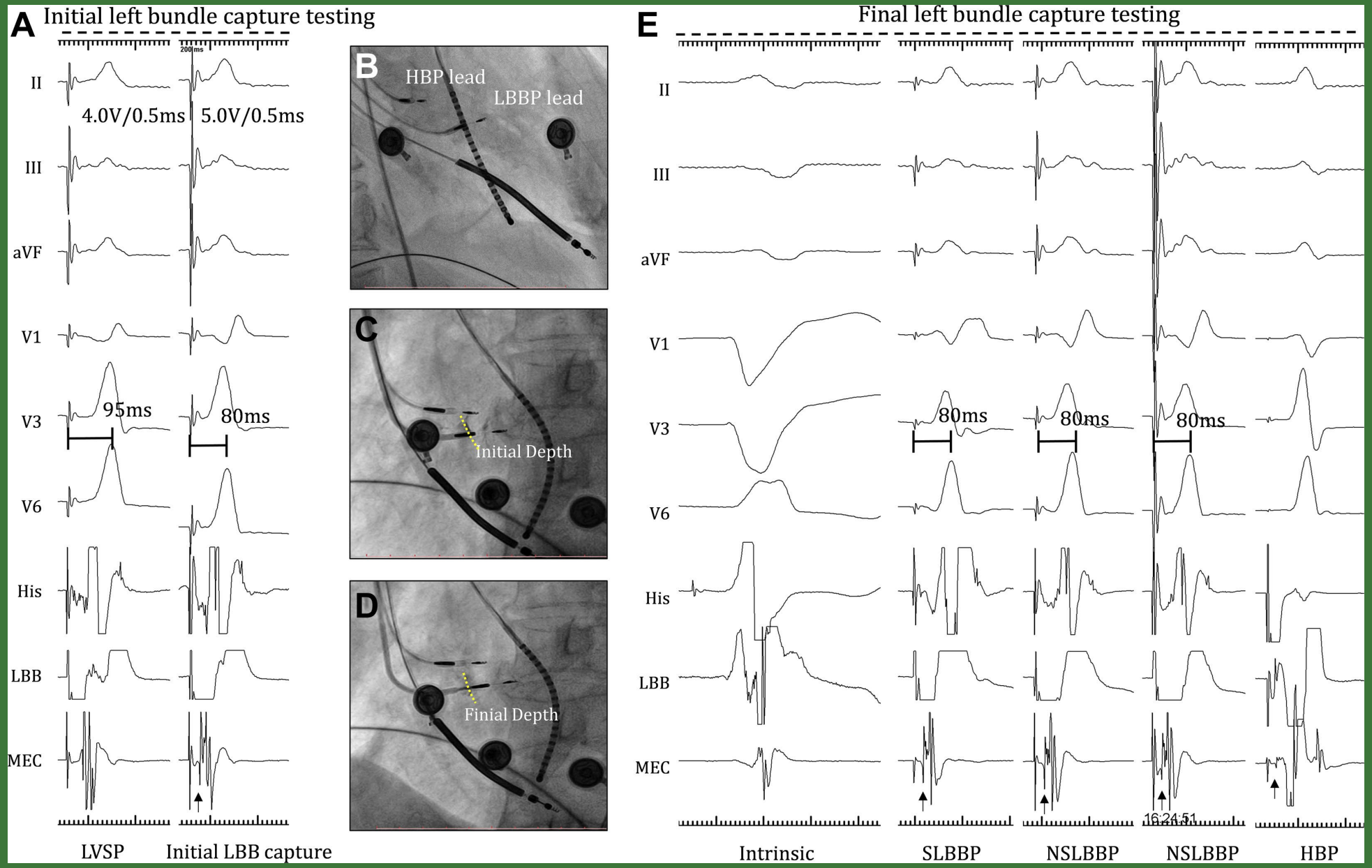
May 19, 2024

Heart Rhythm Scientific Sessions; May 16-19, 2024; Boston, Massachusetts.





CSP = conduction system pacing; DSP = deep septal pacing; HBP = His bundle pacing; LBBAP = left bundle branch area pacing; LBPP = left bundle branch pacing; LFP = left fascicular pacing; LVSP = left ventricular septal pacing; RBBP = right bundle branch pacing.
Burri H, et al. *Europace*. 2023;25(4):1208-1236.



MEC = multielectrode linear catheter; SLBPP = selective left bundle branch pacing; NSLBBP = non-selective left bundle branch pacing.
Wu, S et al. *JACC Clin Electrophysiol*. 2021;7(9):1166-1177.

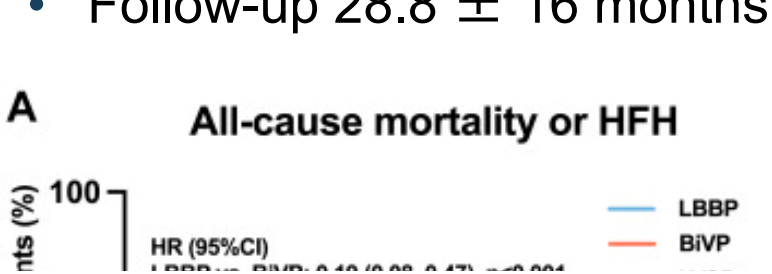
The Importance of the Criteria

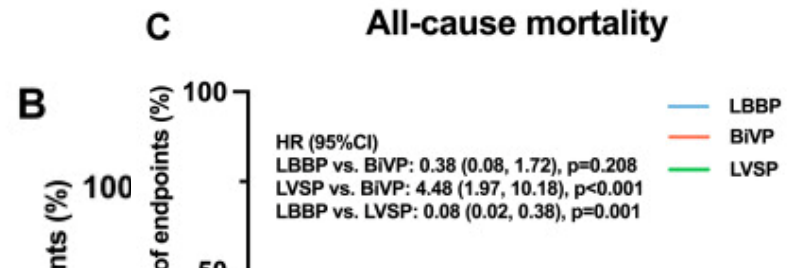
Comparisons of long-term clinical outcomes with left bundle branch pacing, left ventricular septal pacing, and biventricular pacing for cardiac resynchronization therapy

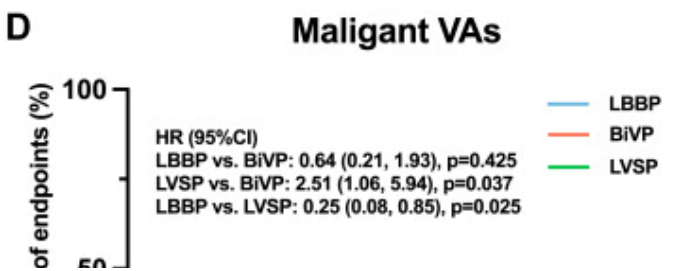
Haojie Zhu, MD, PhD,[1,*] Chaotong Qin, MD,[2,*] Anjie Du, MD,[2] Qian Wang, MD,[1] Chen He, MD,[1] Fengwei Zou, MD,[3] Xiaofei Li, MD,[1] Jin Tao, MD,[4] Chuangshi Wang, PhD,[5] Zhimin Liu, MD,[1] Siyuan Xue, MD,[2] Jiaxin Zeng, MD,[2] Zhiyong Qian, MD, PhD,[2] Yao Wang, MD, PhD,[2] Xiaofeng Hou, MD,[2] Kenneth A. Ellenbogen, MD,[6] Michael R. Gold, MD, PhD,[7] Yan Yao, MD, PhD, FHRS,[1] Jiangang Zou, MD, PhD, FHRS,[2,8] Xiaohan Fan, MD, PhD[1]

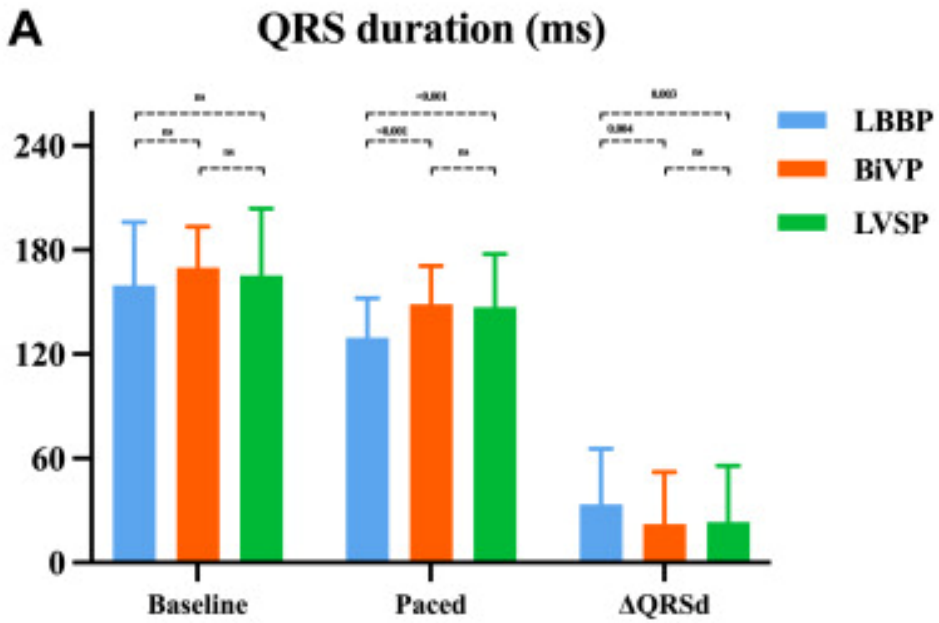
259 patients with LVEF, <50% undergoing CRT, were prospectively enrolled if successful LBBP, LVSP, or biventricular pacing (BiVP) was achieved

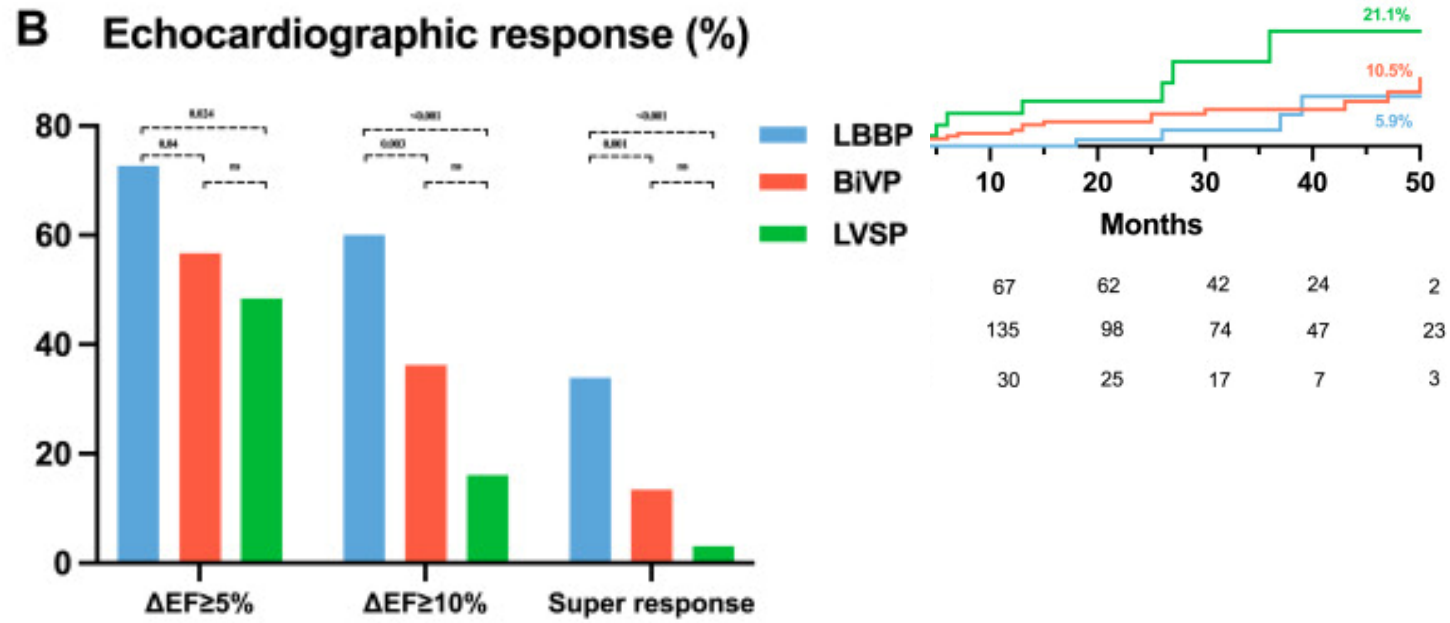
- Follow-up 28.8 ± 16 months











Zhu H, et al. *Heart Rhythm.* 2024;21(8):1342-1353.

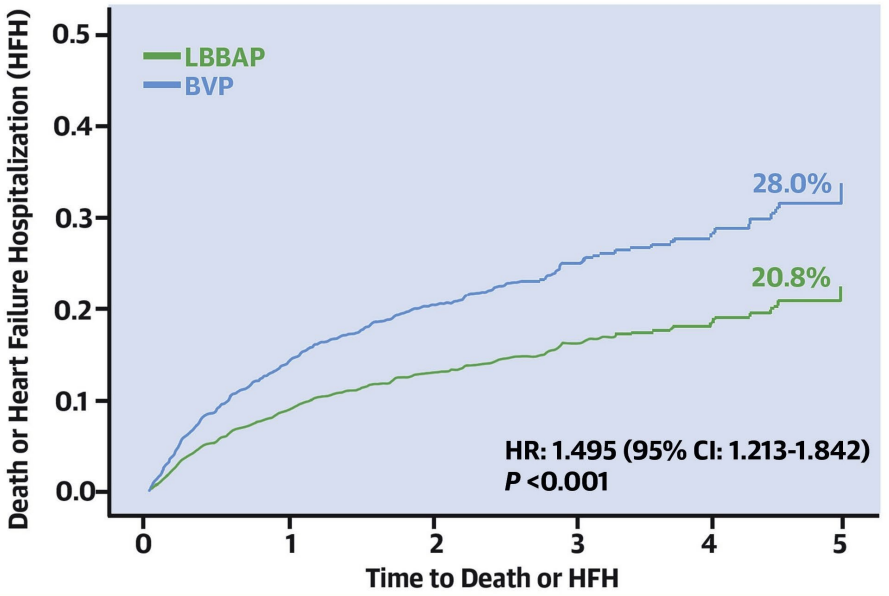
LBBP Criteria

1. Transition
   a) during decremental output pacing
   b) programmed stimulation
2. Physiology based ECG criteria: LBB potential
3. V6RWPT measurement
4. V6:V1 interpeak
5. (Capture beats)
6. Current of injury and QRS morphology (during continuous pacing)
7. Transition patterns (during continuous pacing)

ECG = electrocardiogram; V6RWPT = V6 R-wave peak time.

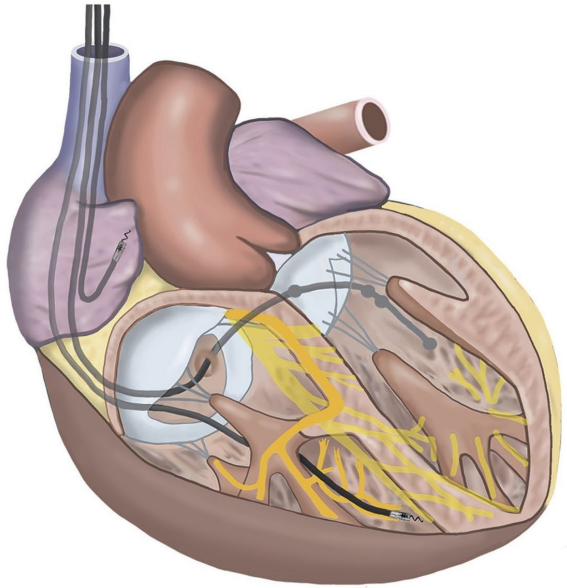
Death or Heart Failure Hospitalization

Time to Death or Heart Failure Hospitalization
All Patients (n = 1,778)

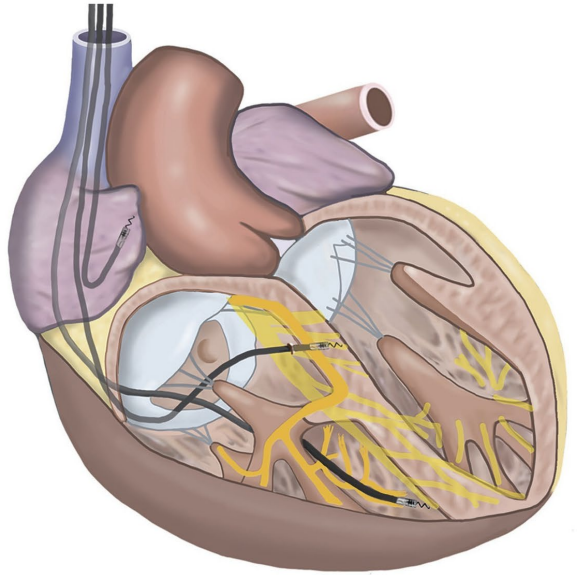


BVP	981	728	546	352	166	18
LBBAP	797	574	342	152	18	0

Biventricular Pacing (BVP)



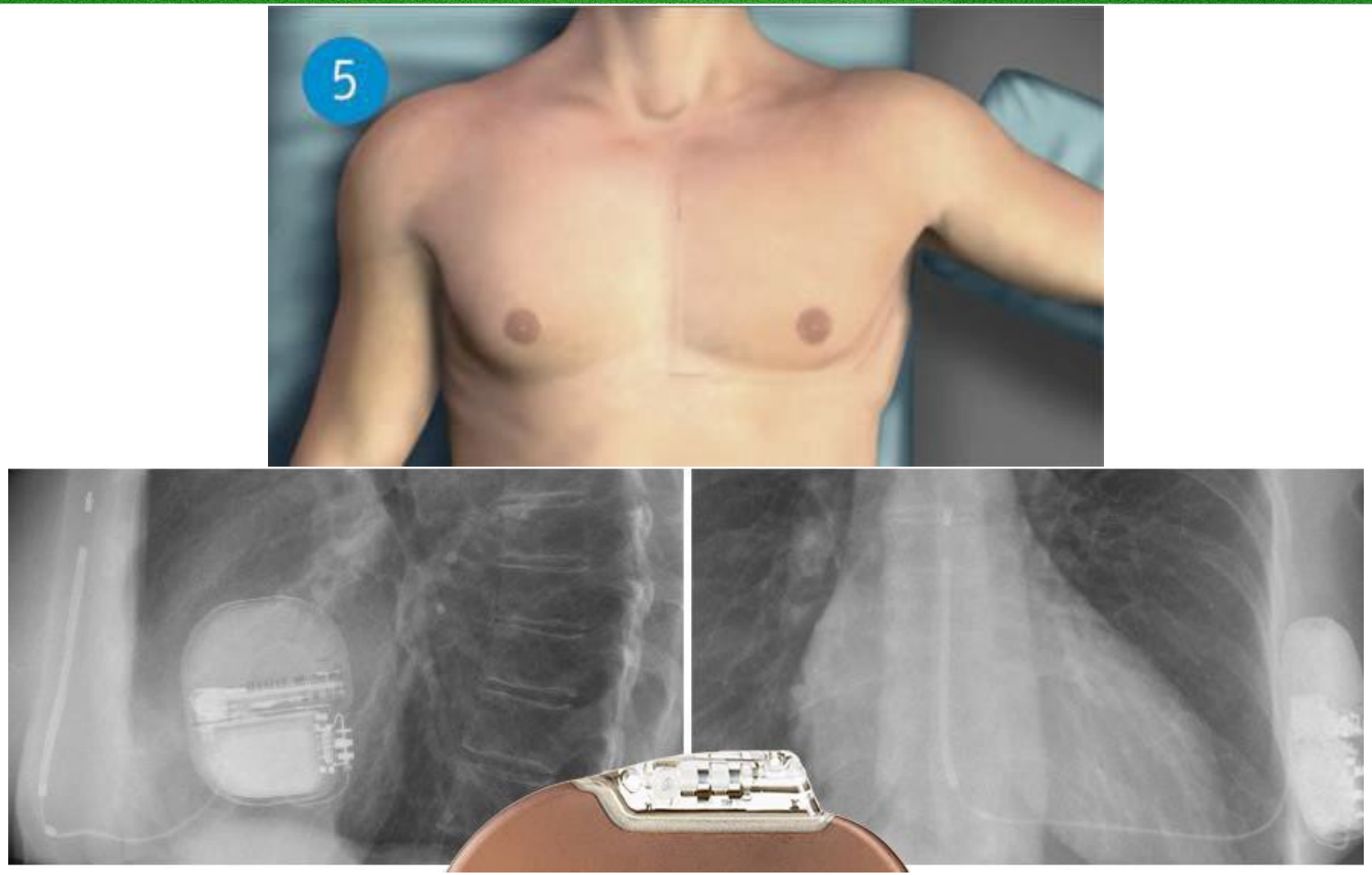
Left Bundle Branch Area Pacing (LBBAP)



HR = hazard ratio; CI = confidence interval.

Vijayaraman P, et al. *J Am Coll Cardiol*. 2023;82(3):228-241.

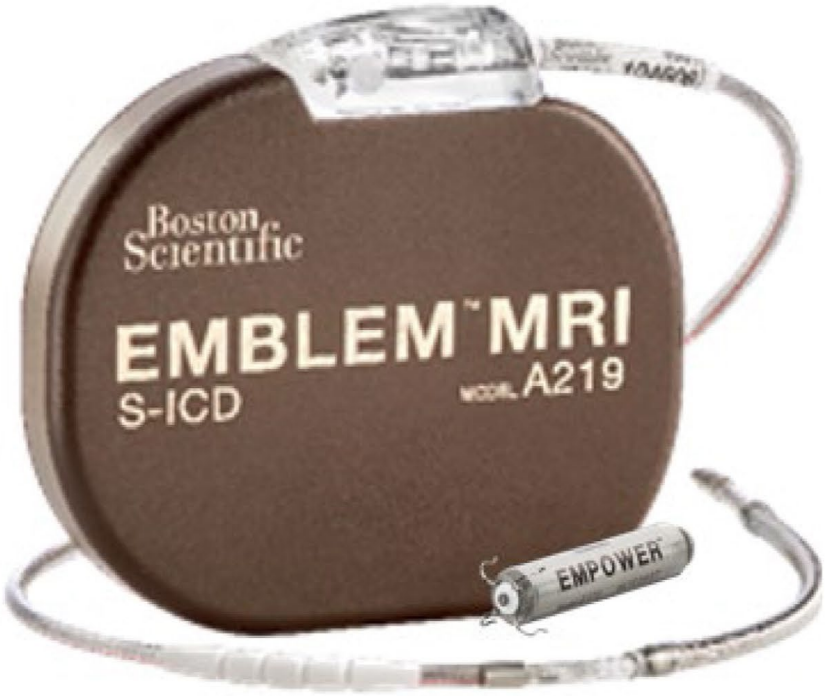
Subcutaneous ICD

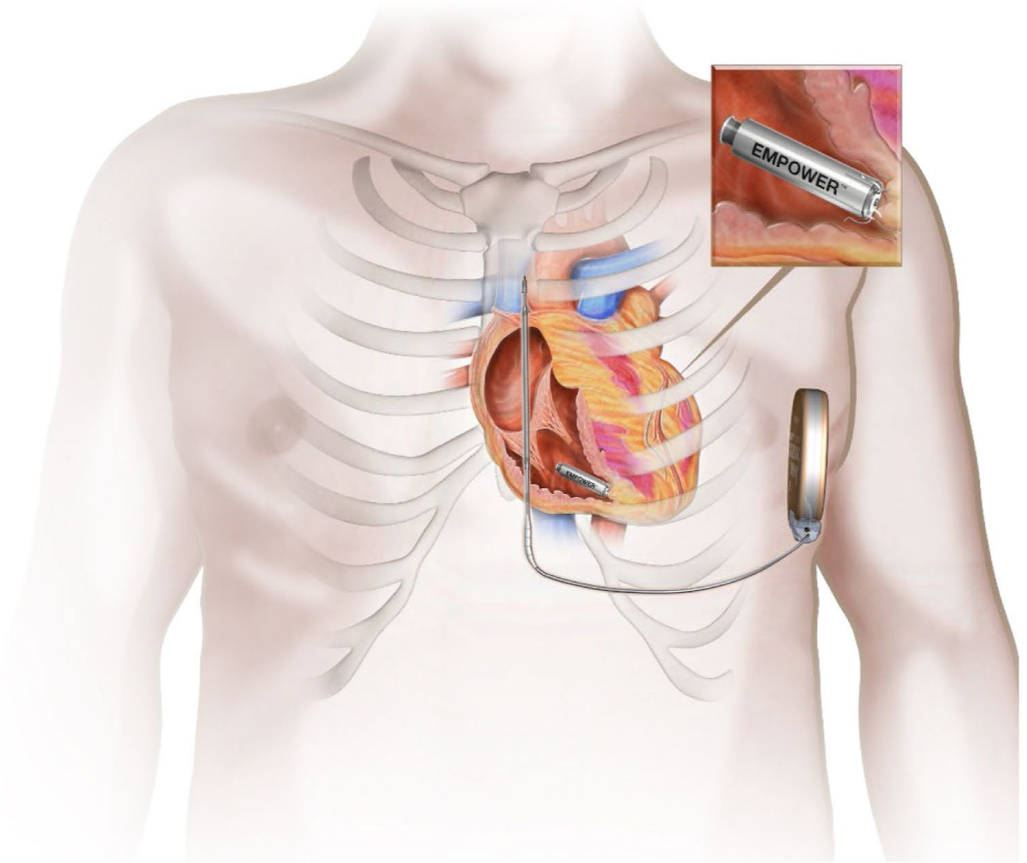


ICD = implantable defibrillator.

FDA. Accessed November 25, 2024. https://www.accessdata.fda.gov/cdrh_docs/pdf11/P110042C.pdf.

Subcutaneous ICD



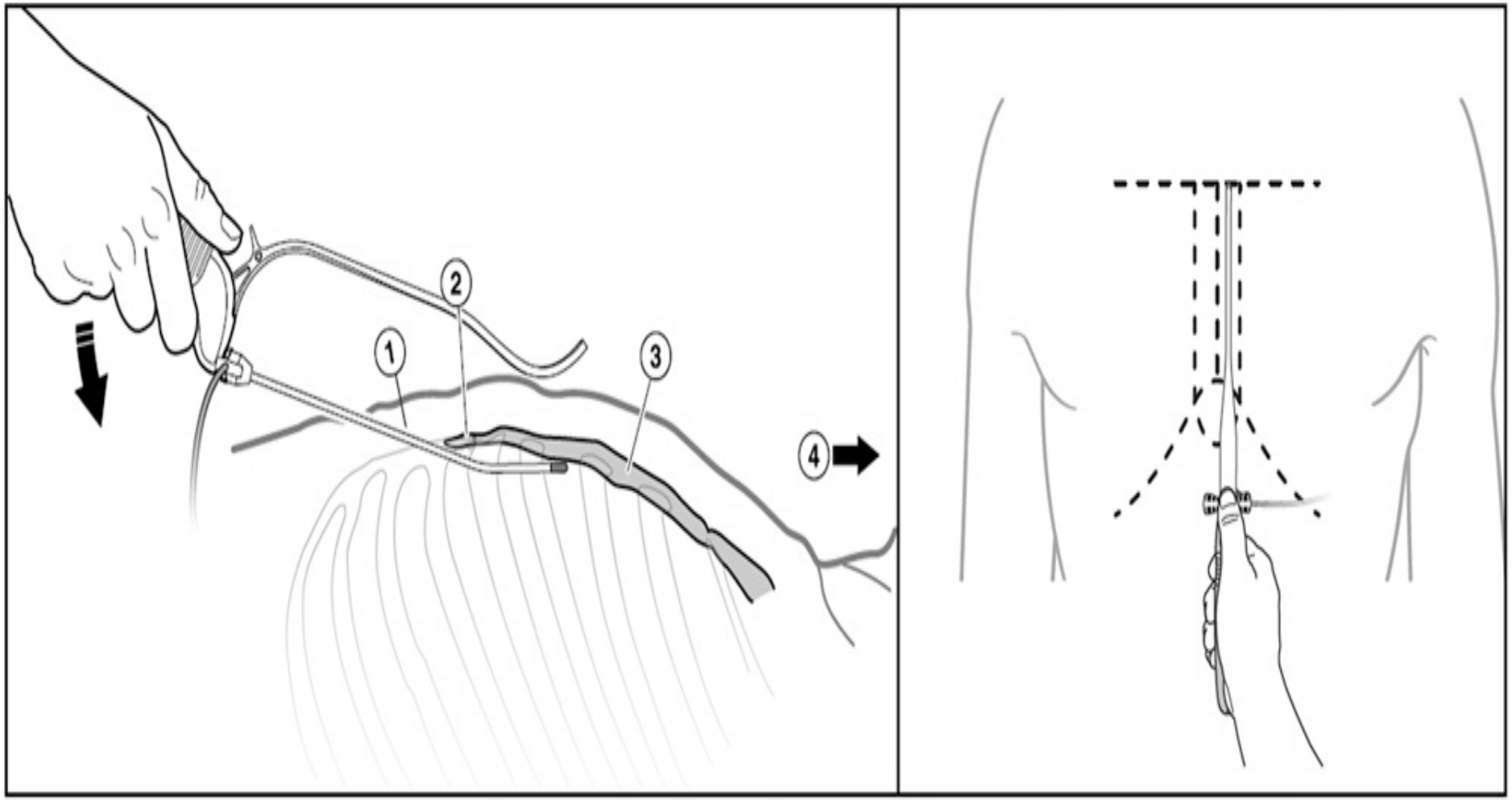


Lloyd MS, et al. *Heart Rhythm O2*. 2023;4(7):448-456.

The Extravascular Implantable Cardioverter-Defibrillator: The Pivotal Study Plan

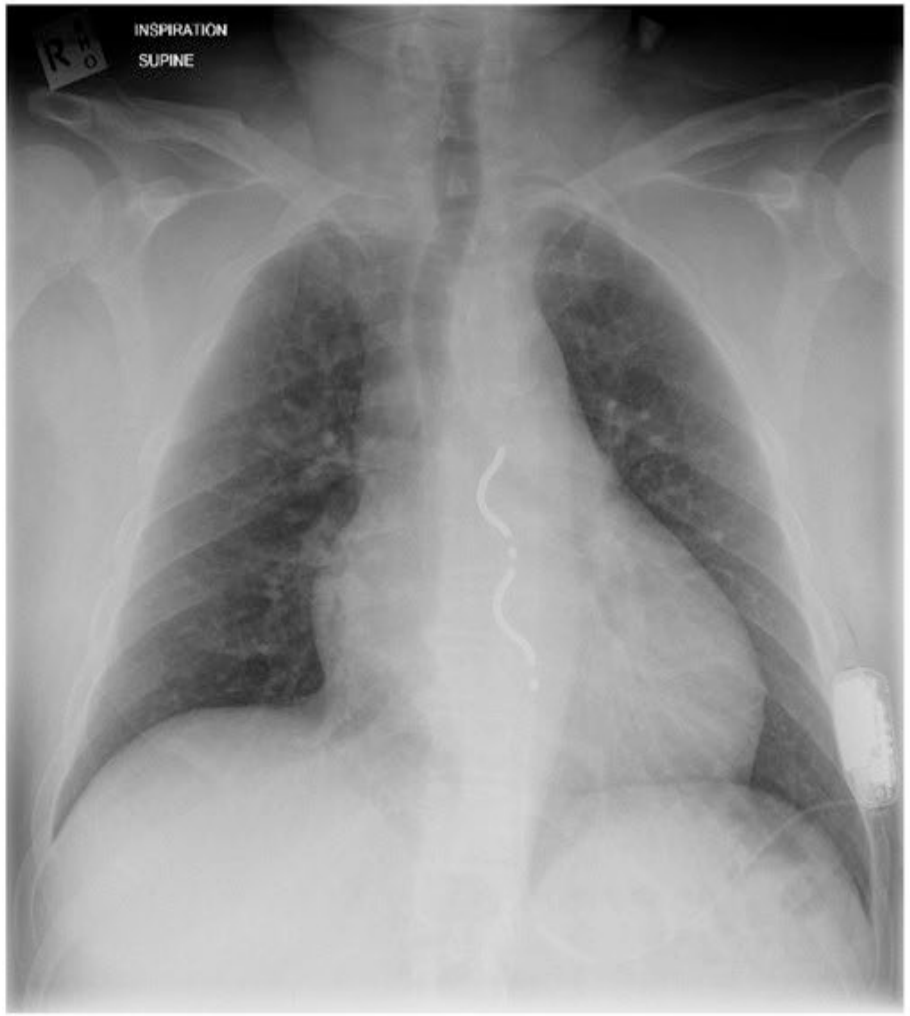
Crozier I, et al. *J Cardiovasc Electrophysiol.* 2021;32(9):2371-2378.

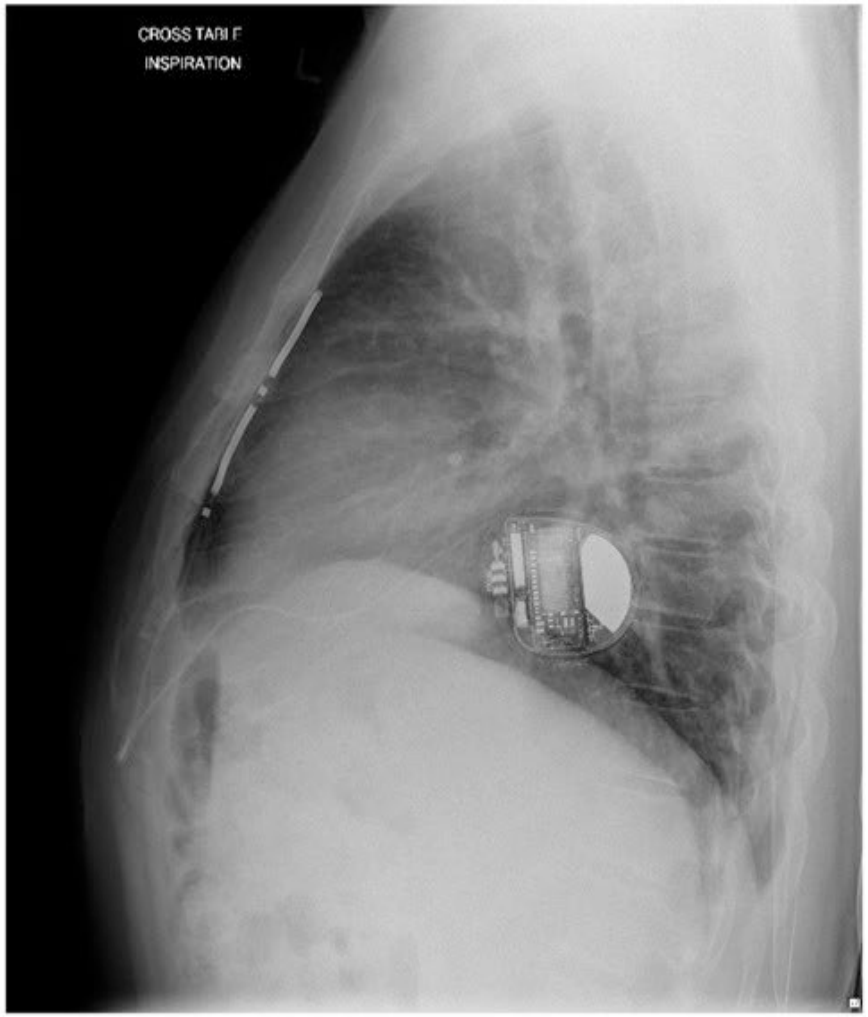
The Extravascular Implantable Cardioverter-Defibrillator: The Pivotal Study Plan



Crozier I, et al. *J Cardiovasc Electrophysiol.* 2021;32(9):2371-2378.

The Extravascular Implantable Cardioverter-Defibrillator: The Pivotal Study Plan





Crozier I, et al. *J Cardiovasc Electrophysiol.* 2021;32(9):2371-2378.

How New Ablation Modalities Impact Vascular Closure

David DeLurgio, MD, FACC, FHRS

AMBULATE Pivotal Trial

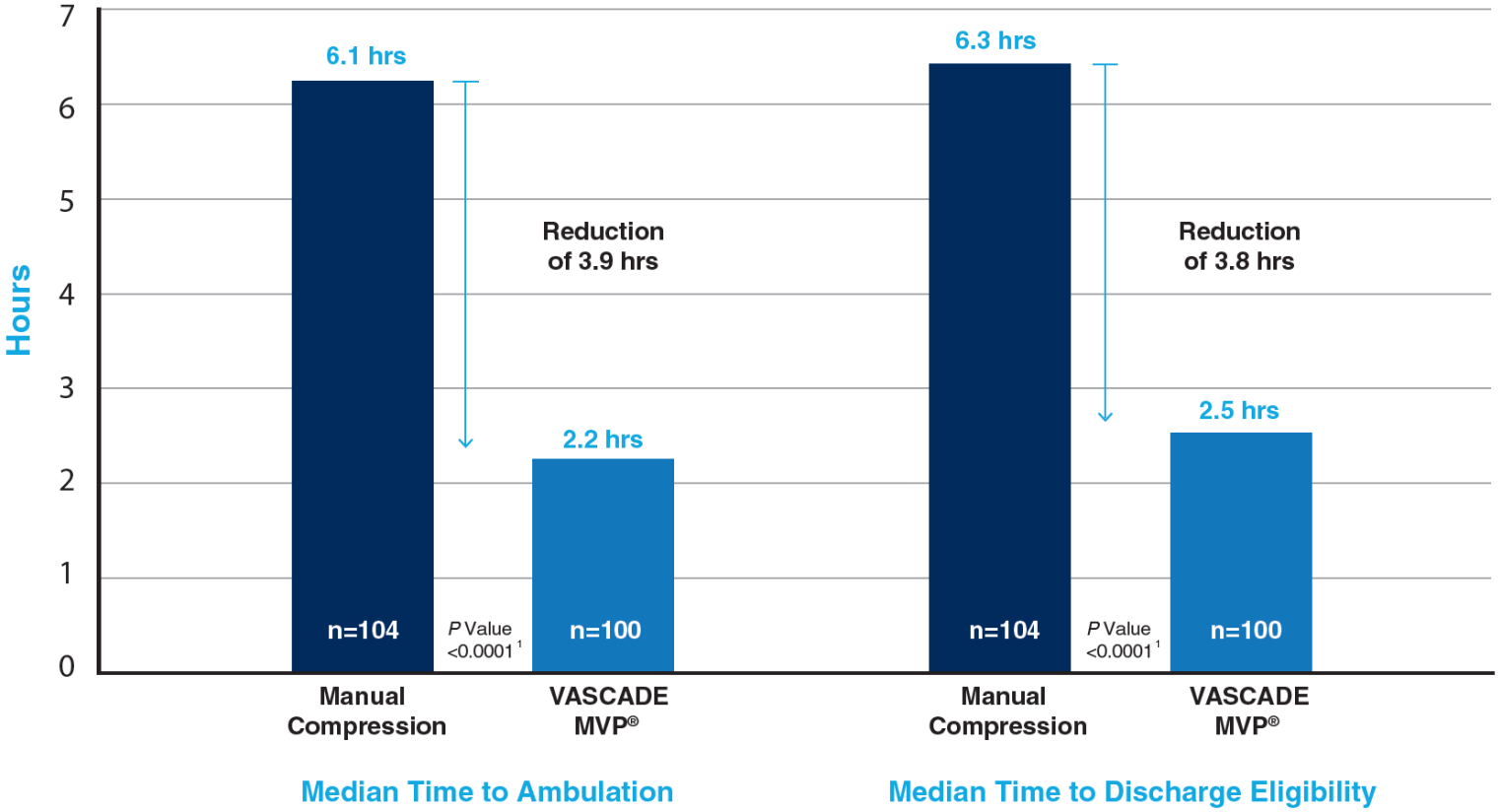
Prospective, Multicenter, Randomized 1:1 Clinical Trial

- **Randomized clinical trial:** 204 patients, 13 sites, 28 physicians, randomized 1:1 against manual compression
- **Primary endpoints:** time to ambulation, major access site complications
- **Secondary endpoints:** time to hemostasis, total post-procedure time, time to discharge eligibility, time to discharge, time to closure eligibility, procedure success, device success, minor access site complications
- **Additional data:** patient satisfaction, pain meds

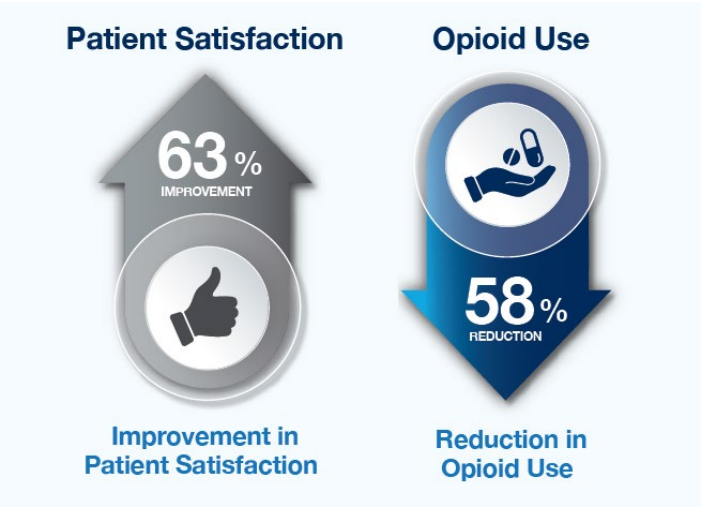
Natale A, et al. *JACC Clin Electrophysiol.* 2020;6(1):111-124.

AMBULATE Pivotal Trial

VASCADE MVP® System Compared to Manual Compression



SAFETY ENDPOINT	VASCADE MVP® n=199 limbs	Manual Compression n=209 limbs	*P* Value
Major complications	0%	0%	–
Minor complications	1.0%	2.4%	0.45[2]



[1]P-values from 2-sided Wilcoxon rank-sum test for medians, unadjusted for stratification factor; [2]P-value for two-sided t-test, non-inferiority analysis; *Patient satisfaction surveys administered prior to discharge. Rated on sale of 0-10, with 10 being very satisfied.

Natale A, et al. *JACC Clin Electrophysiol.* 2020;6(1):111-124. NIH. Accessed November 11, 2024. https://clinicaltrials.gov/study/NCT03193021.

AMBULATE

Portfolio of Studies

AMBULATE
Pivotal Trial

- Randomized clinical trial: 204 subjects, 13 sites, 28 enrolling physicians
- Pivotal for FDA approval
- JACC EP: Natale et al, Oct 2019

AMBULATE CAP
Continued Access Protocol

- Single arm venous closure in EP cases; 3 sites,168 patients
- Endpoints: same calendar day discharge, Foley use, protamine usage, complications
- JCE: Al-Ahmad et al, Jan 2021

AMBULATE
Same Day Discharge Clinical Studies

- Retrospective SDD
- Prospective SDD 1
- Prospective SDD 2
- JCE: Eldadah et al, Nov 2022

SDD = same day discharge.

Natale A, et al. *JACC Clin Electrophysiol*. 2020;6(1):111-124. Al-Ahmad A, et al. *J Cardiovasc Electrophysiol*. 2021;32(2):191-199. Eldadah ZA, et al. *J Cardiovasc Electrophysiol*. 2023;34(2):348-355. NIH. Accessed November 12, 2024. https://clinicaltrials.gov/study/NCT03193021; NCT03573206; NCT04538781; NCT04203329.

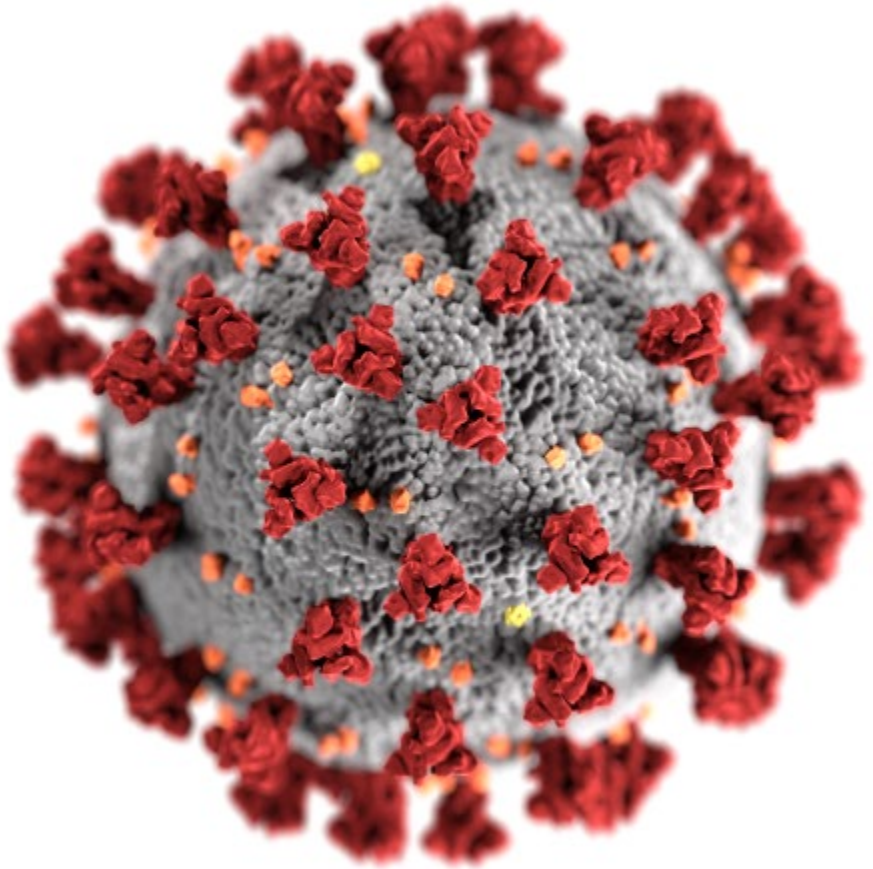
EP Vessel Closure Using VASCADE MVP® System

Procedures within Indication

Procedure*	Femoral Sheath Inner Diameter
VASCADE MVP System is indicated for percutaneous closure of femoral venous access sites and can be used in 6F to 12F inner diameter (15F maximum outer diameter) introducer sheaths.	
AF Ablation, including cryoablation (12F inner diameter)	6F-12F
SVT/Atrial Flutter Ablation	6F-11F
VT Ablation – Venous	6F-11F
LAAC (Watchman™, 12F AMULET™)	12F
ASD/PFO Repair	6F-12F
Pulmonary Pressure Monitoring (CardioMEMS™)	12F
Post-Venous Stent	8F-10F

***The procedures listed are for informational use only as an example of procedures that may fall within the indicated venotomy sizes. Please consult manufacturers' package inserts and instructions for use for more detailed product and safety information.**
F = French size catheter scale; SVT = supraventricular tachycardia; VT = ventricular tachycardia; LAAC = left atrial appendage closure; ASD = atrial septal defect; PFO = patent foramen ovale.
FDA. Accessed November 12, 2024. https://www.accessdata.fda.gov/cdrh_docs/pdf12/P120016c.pdf. Natale A, et al. *JACC Clin Electrophysiol*. 2020;6(1):111-124. Al-Ahmad A, et al. *J Cardiovasc Electrophysiol*. 2021;32(2):191-199. NIH. Accessed November 12, 2024. https://clinicaltrials.gov/study/NCT03193021; NCT03573206.

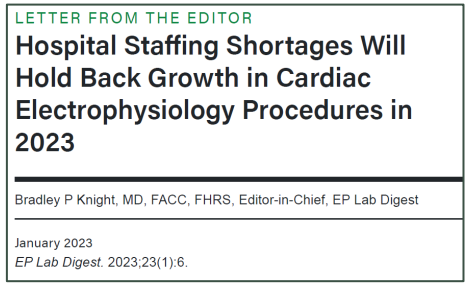
Disruption Number 1



Eckert A and Higgins D. Public Health Image Library. 2020. Accessed November 11, 2024. https://phil.cdc.gov/Details.aspx?pid=23312.

Nursing and Staff Shortages

The Importance of Addressing Staff Efficiencies in EP



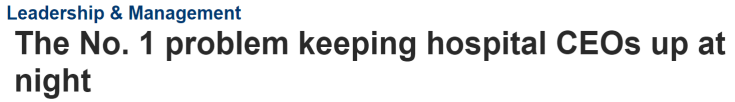
LETTER FROM THE EDITOR

Hospital Staffing Shortages Will Hold Back Growth in Cardiac Electrophysiology Procedures in 2023

Bradley P Knight, MD, FACC, FHRS, Editor-in-Chief, EP Lab Digest

January 2023
EP Lab Digest. 2023;23(1):6.

- Approximately 18% of healthcare workers have quit since the COVID-19 pandemic
- Hospitals have had to rely on contract travel nurses to fill this gap, with salaries that are typically 3X higher than employed nurses
- Hospital administrators are unable/unwilling to pay for added staffing – even for programs with high potential for revenue growth, such as EP
- *"The volume of hospital-based rhythm procedures, such as AF ablation and LAAC procedures, will not be able to grow unless hospital and electrophysiology lab staffing shortages improve."*



Leadership & Management

The No. 1 problem keeping hospital CEOs up at night

- 2022 American College of Healthcare Executives annual survey of hospital CEOs' concerns
- Workforce challenges are ranked the highest concern for CEOs
  - 90% said nursing shortages are most pressing
  - 83% said technician shortages are an issue
  - 80% concerned about burnout of non-physician staff

Knight BP. *EP Lab Dig*. 2023;23(1):6. Becker's Hospital Review. Accessed February 13, 2023. https://www.beckershospitalreview.com/hospital-management-administration/the-no-1-problem-keeping-hospital-ceos-up-at-night.html?origin=BHRE&utm_source=BHRE&utm_medium=email&utm_content=newsletter&oly_enc_id=4835D4750201B8Y. American College of Healthcare Executives. Accessed February 4, 2023. https://www.ache.org/learning-center/research/about-the-field/top-issues-confronting-hospitals/top-issues-confronting-hospitals-in-2021.

AF Ablation Workflow and Same Day Discharge: Value vs Cost

A New Approach Post-COVID

WORKFOW	BEFORE	Using VASCADE MVP® n=700 AF patients
Pull Sheaths	Recovery	EP Lab
Closure Methods	Manual Compression	VASCADE MVP
Time To Ambulation	4 hours	2 hours
SDD for AF Patients	0%	95%

Our Paradigm Flipped → Same Day Discharge for all AF ablation patients except for travel issues or a specific medical reason

Average per-patient savings of ~$2,500 (including cost of VASCADE MVP® devices)

Disruption Number 2

LIFETIME RISK for AF
1 in 3 individuals

Catheter ablation or medical therapy to delay progression of atrial fibrillation: the randomized controlled atrial fibrillation progression trial (ATTEST)

Karl-Heinz Kuck [1]*, Dmitry S. Lebedev [2], Evgeny N. Mikhaylov [2], Alexander Romanov[3], László Gellér[4], Oskars Kalējs[5], Thomas Neumann[6], Karapet Davtyan [7], Young Keun On[8], Sergey Popov[9], Maria Grazia Bongiorni [10], Michael Schlüter [11], Stephan Willems[12], and Feifan Ouyang[1]*

Comparative risk of dementia among patients with atrial fibrillation treated with catheter ablation versus anti-arrhythmic drugs

Emily P. Zeitler, MD, MHS[a], T. Jared Bunch, MD[b], Rahul Khanna, BPharm, MBA, PhD[c], Xiaozhou Fan, MD, PhD[c], Maximiliano Iglesias, MBA[d], and Andrea M. Russo, MD[c] *Lebanon, NH; Salt Lake City, UT; New Brunswick, NJ; Irvine, CA; Camden, NJ*

Effect of Catheter Ablation vs Antiarrhythmic Drug Therapy on Mortality, Stroke, Bleeding, and Cardiac Arrest Among Patients With Atrial Fibrillation

The CABANA Randomized Clinical Trial

2023 ACC/AHA/ACCP/HRS Guideline for the Diagnosis and Management of Atrial Fibrillation: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines

Developed in Collaboration With and Endorsed by the American College of Clinical Pharmacy and the Heart Rhythm Society

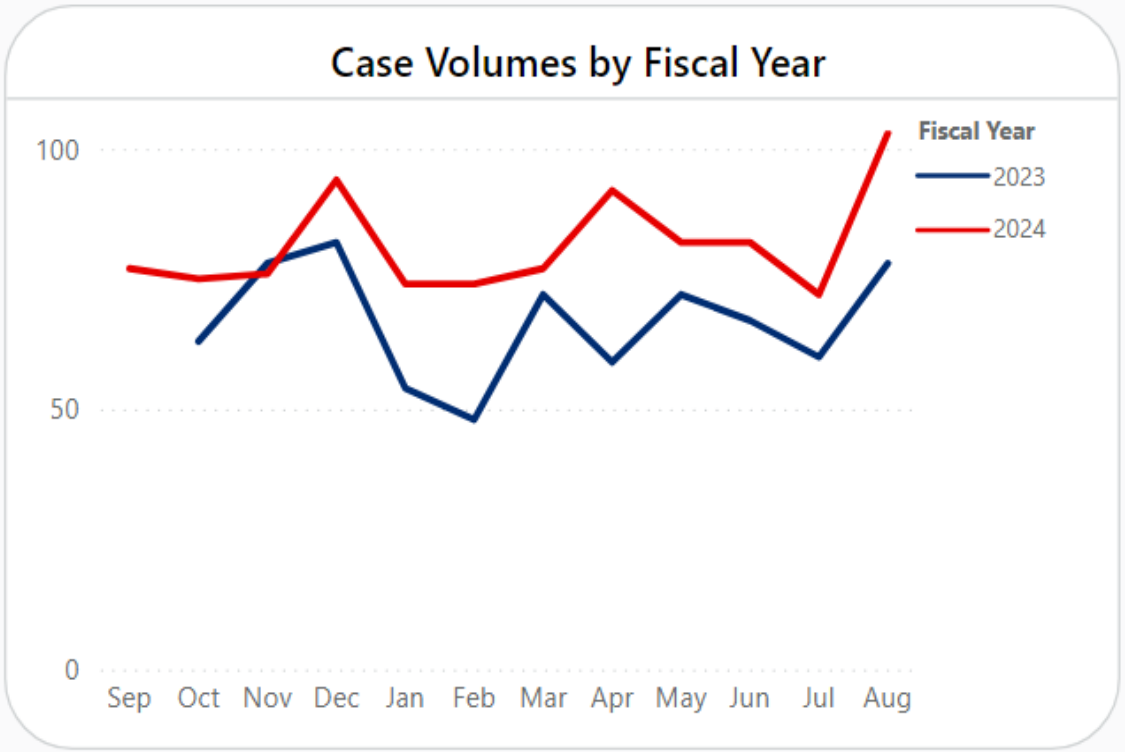
Writing Committee Members*

José A. Joglar, MD, FACC, FAHA, FHRS, Chair; Mina K. Chung, MD, FACC, FAHA, FHRS, Vice Chair; Anastasia L. Armbruster, PharmD, FACC†; Emelia J. Benjamin, MD, ScM, FACC, FAHA; Janice Y. Chyou, MD, FACC, FAHA, FHRS; Edmond M. Cronin, MB, BCh, BAO, FHRS; Anita Deswal, MD, MPH, FACC, FAHA†; Lee L. Eckhardt, MD, MS, FHRS; Zachary D. Goldberger, MD, FACC, FAHA, FHRS; Rakesh Gopinathannair, MD, MA, FACC, FAHA, FHRS; Bulent Gorenek, MD, FACC; Paul L. Hess, MD, MHS‡; Mark Hlatky, MD, FACC, FAHA; Gail Hogan§; Chinwe Ibeh, MD; Julia H. Indik, MD, PhD, FACC, FAHA, FHRS; Kazuhiko Kido, PharmD, PhD, MS, FCCP‖; Fred Kusumoto, MD, FACC, FAHA, FHRS; Mark S. Link, MD, FACC, FAHA, FHRS; Kathleen T. Linta § Gregory M. Marcus, MD, MAS, FACC, FAHA, FHRS; Patrick M. McCarthy, MD, FACC; Nimesh Patel, MD; Kristen K. Patton, MD, FACC, FAHA, FHRS; Marco V. Perez, MD, FAHA; Jonathan P. Piccini, MD, MHS, FACC, FAHA, FHRS; Andrea M. Russo, MD, FACC, FAHA, FHRS¶; Prashanthan Sanders, MBBS, PhD, FAHA, FHRS; Megan M. Streur, PhD, MN, ARNP; Kevin L. Thomas, MD, FACC, FHRS; Sabrina Times, DHSC, MPH#; James E. Tisdale, PharmD, FACC, FAHA, FCCP; Anne Marie Valente, MD, FACC, FAHA**; David R. Van Wagoner, PhD, FAHA, FHRS

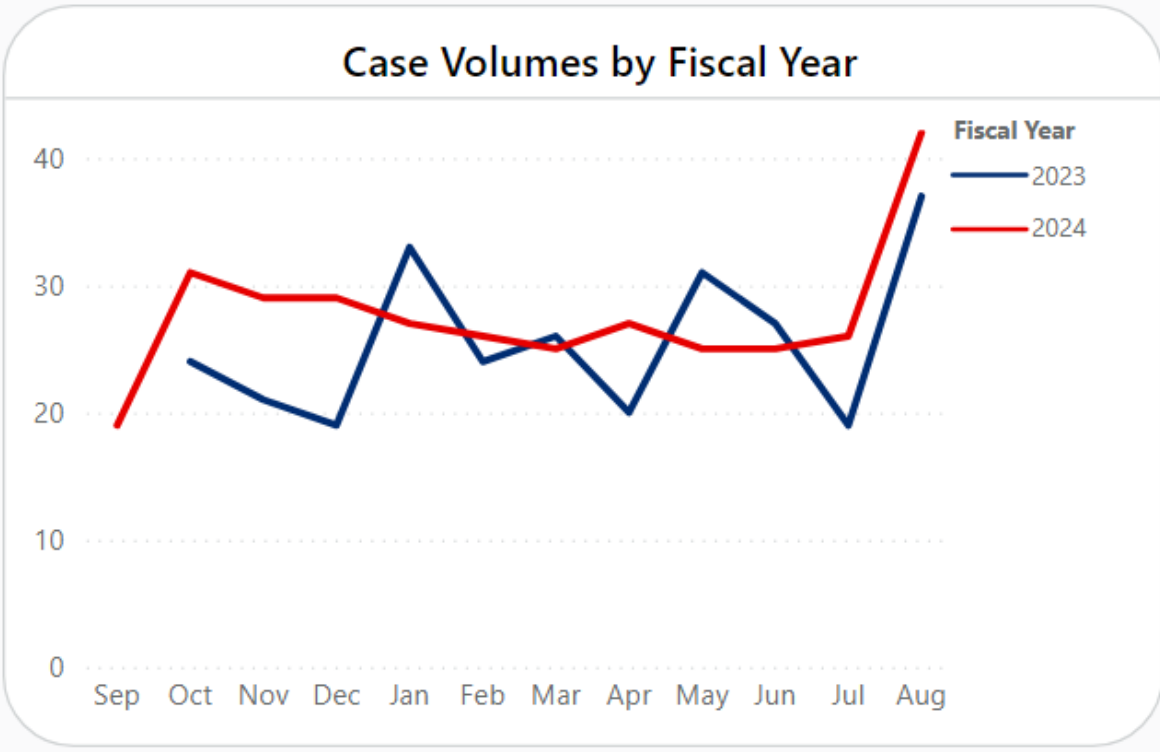
Kuck KH, et al. *Europace.* 2021;23(3):362-369. Zeitler EP, et al. *Am Heart J.* 2022;254:194-202. Joglar JA, et al. *Circulation.* 2024;149(1):e1-e156. NIH. Accessed November 12, 2024. https://clinicaltrials.gov/study/NCT00578617.

AFIB vs LAAC Case Volumes

AFIB Ablation Volume



LAAC Volume



How to Answer These Challenges

Safety, Efficacy, and Efficiency

- Increased volume
- Younger patients
- Redo volume
- Strain on pre-post areas
- Limited hospital beds

Ablation centers must continue to seek safer, more effective procedures that optimize efficiency and resource utilization.

Large Bore Modalities

Tom McElderry, MD, FACC, FHRS

What Is “Large Bore”?

Tools for EP Are Changing (Sheath OD)

New Ablation Technology

Farapulse	17F
Affera	11F
Pulse Select	14F
Volt	17F
Varipulse	11F

Left Atrial Appendage Occlusion

Watchman	17F
Amulet	18F

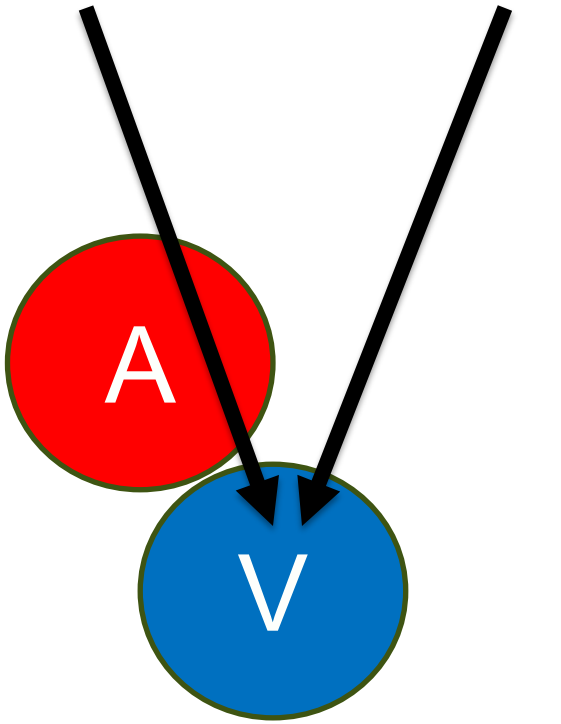
Leadless Pacing

Aveir	27F
Micra	28F

OD = outer diameter.

FDA. Accessed December 3, 2024. https://www.accessdata.fda.gov/cdrh_docs/pdf23/P230030C.pdf; pdf13/P130013S035C.pdf; pdf24/P240013C.pdf; pdf23/P230017C.pdf; pdf15/P150033C.pdf; pdf15/P150035C.pdf; pdf20/P200049C.pdf; pdf24/P240006C.pdf.

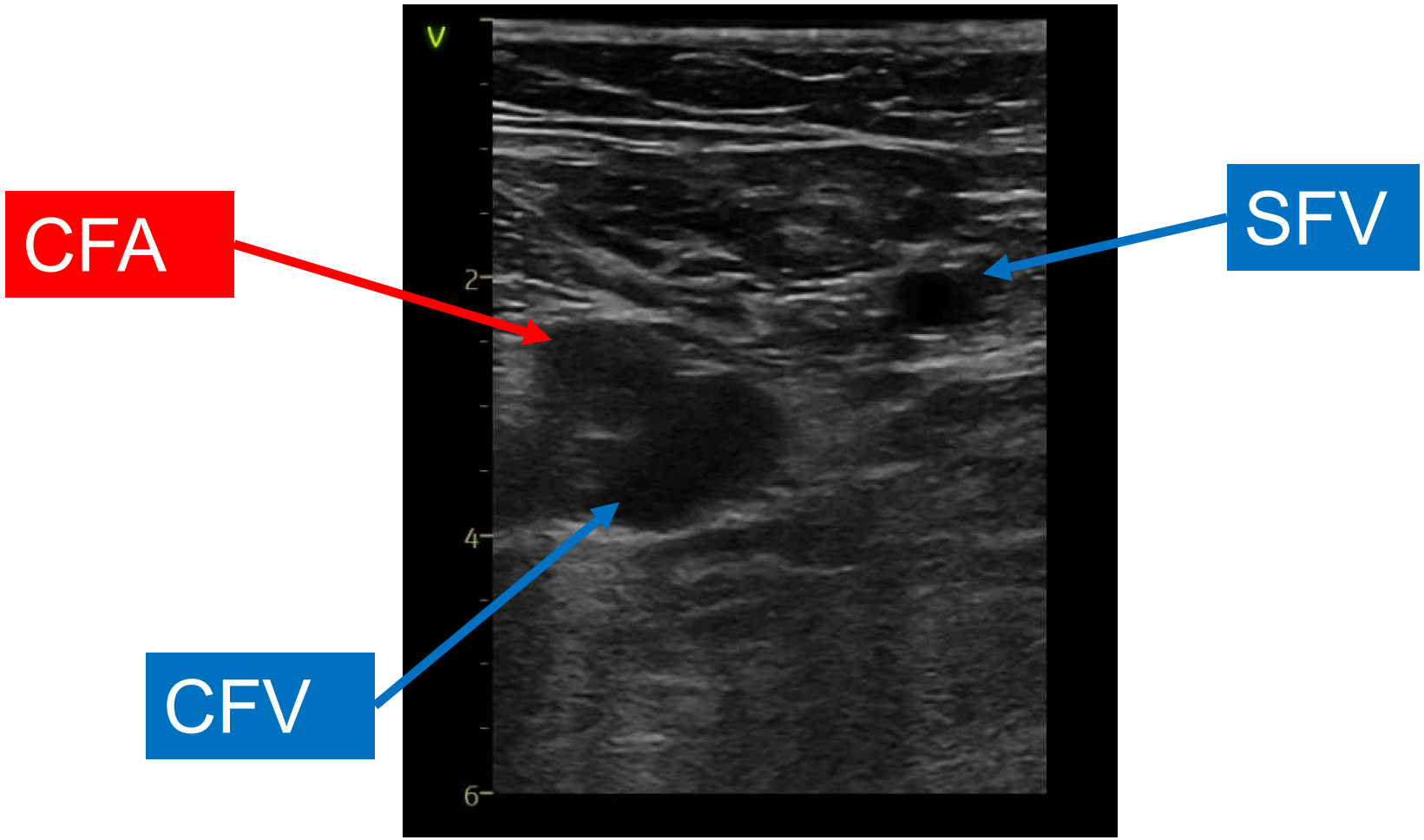
Closure Begins with Access



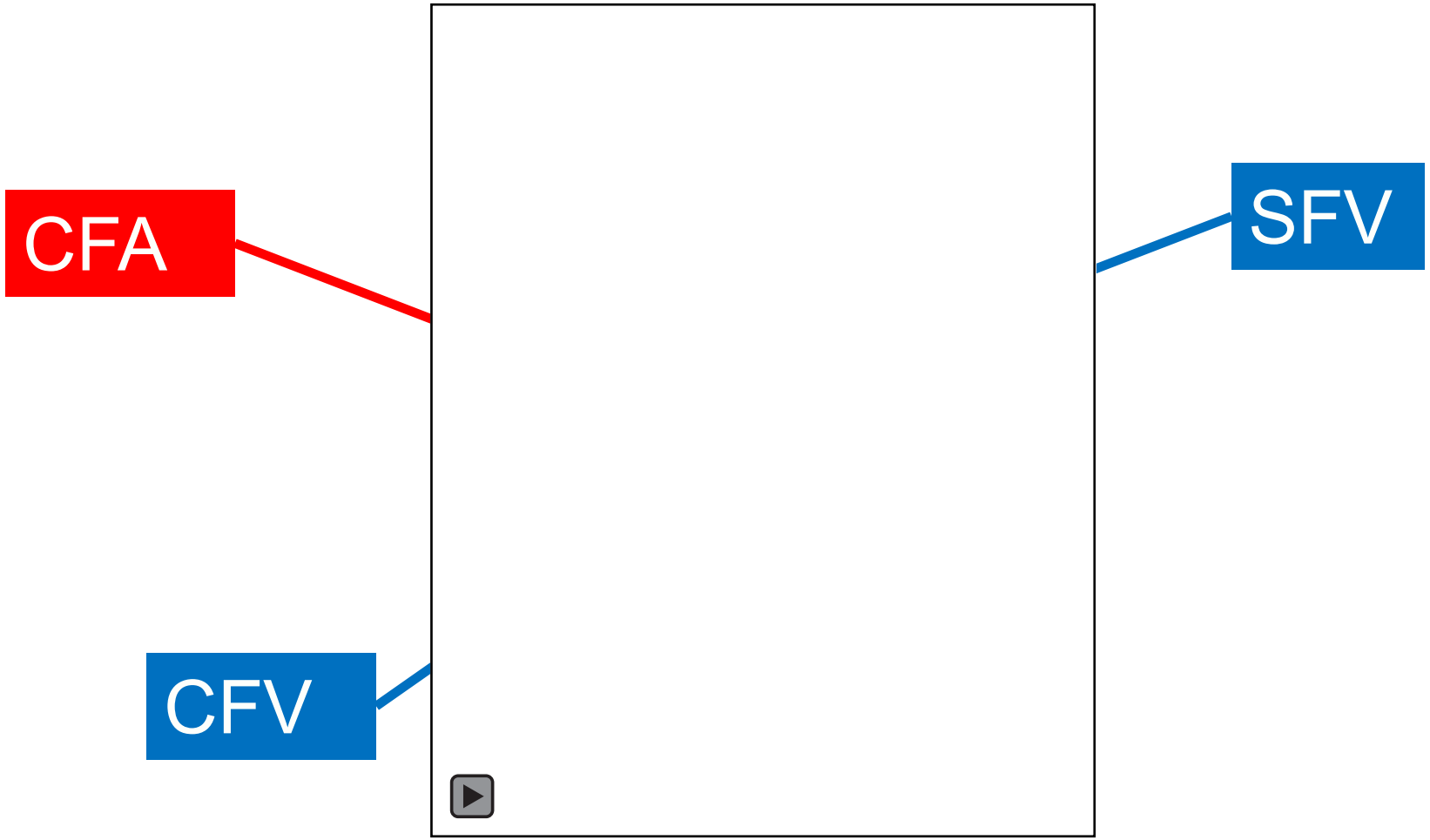
Better for hemostasis

- Direct visualization
- Smaller
- Fewer
- Lower pressure

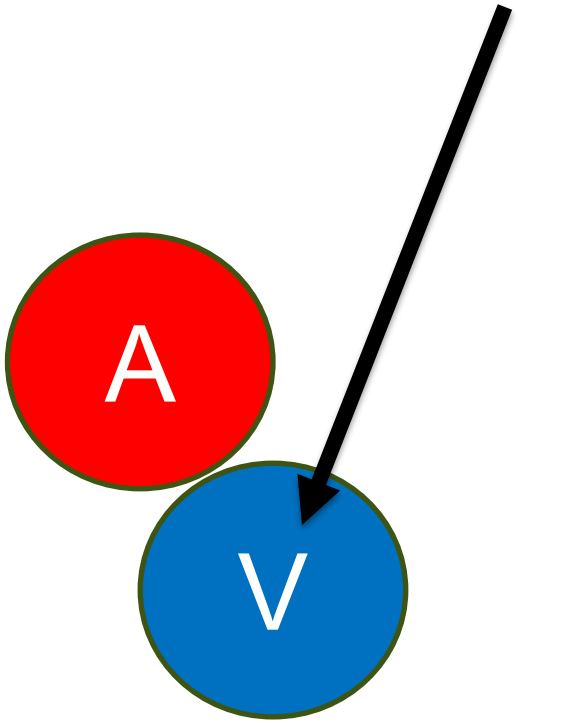
Ultrasound Venous Access



Ultrasound Venous Access

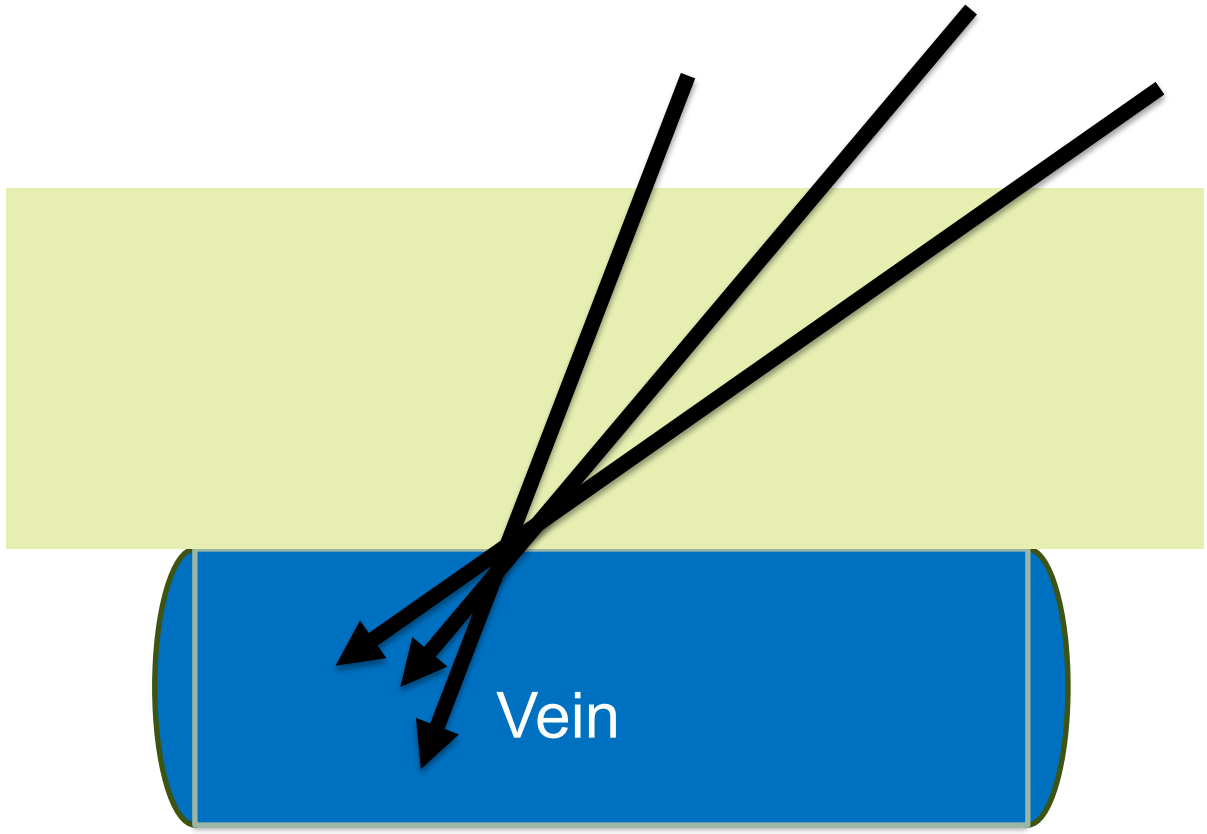


Closure Begins with Access

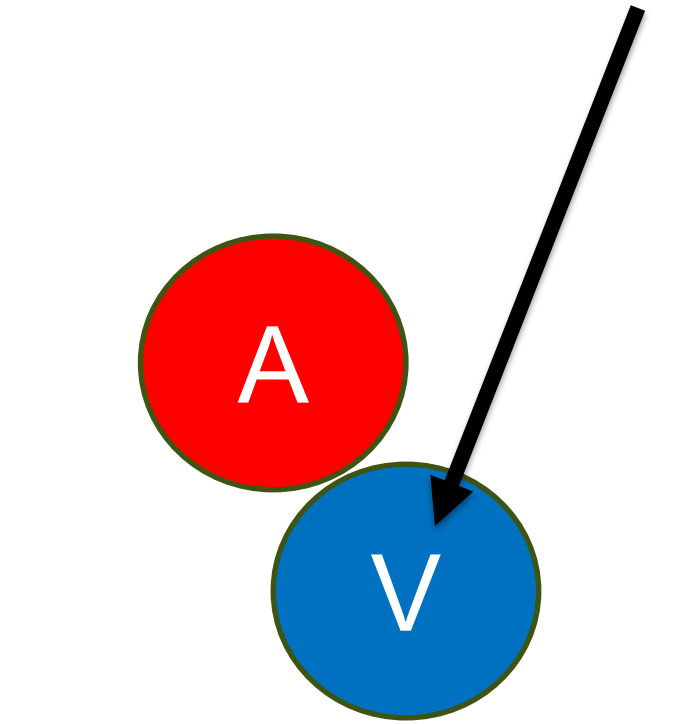


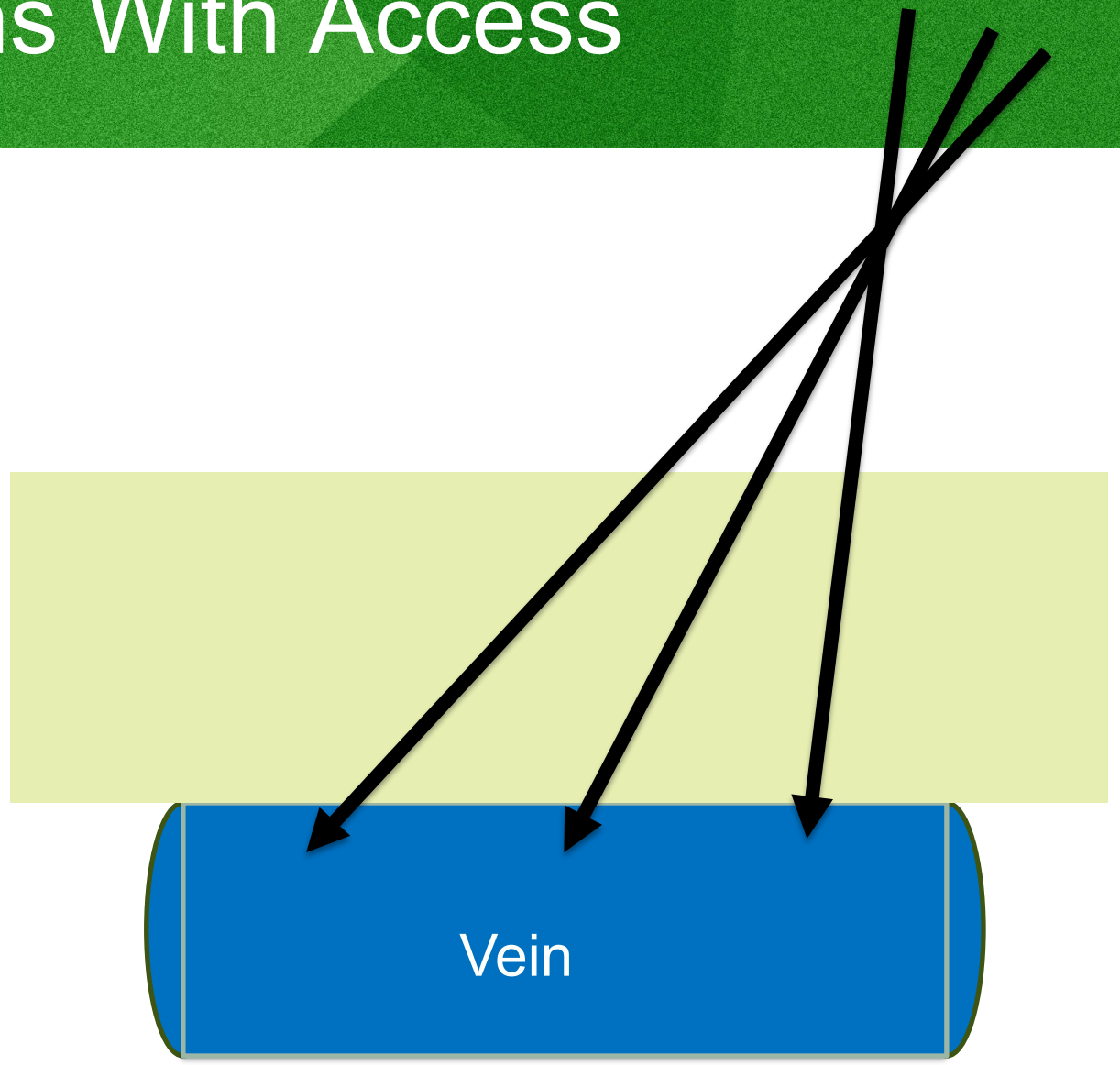
Lateral Medial

Right Leg

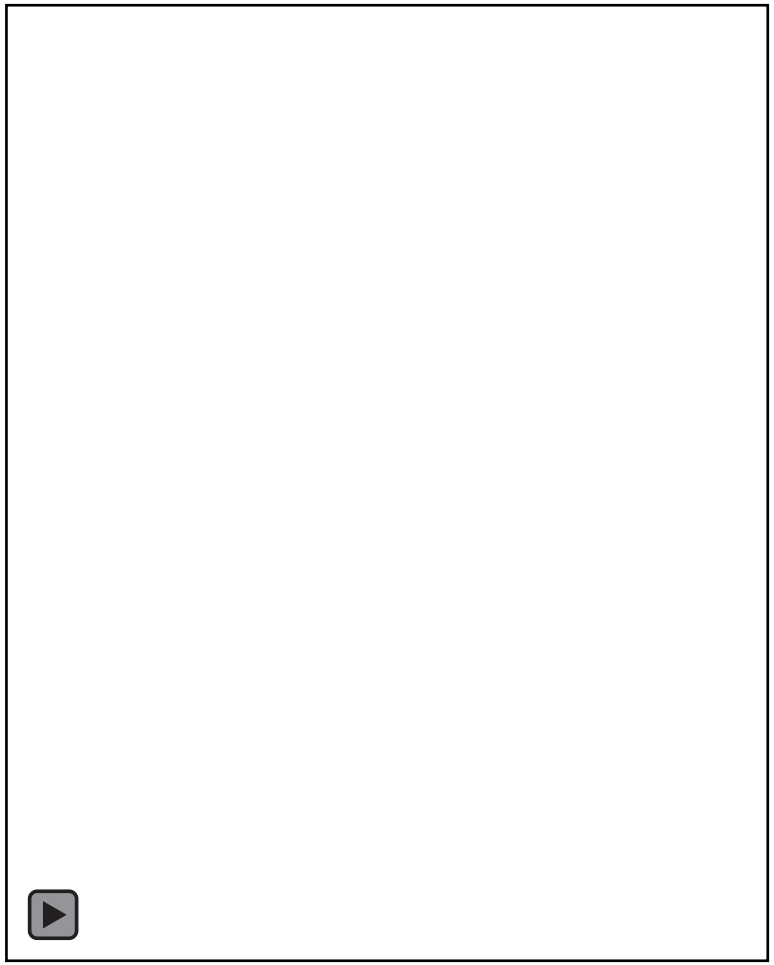


Closure Begins With Access





Separate Puncture Sites along the Vein



Large Bore Venous Closure

Manual Compression

- No additional device cost
- Nursing cost
- As we move to less femoral access and manual pressure, I think we are collectively losing this skill set
- Longer bedrest and time to ambulation
- Less desirable in anticoagulated patients

The Move Away from Manual Pressure

Figure 3.1 Overall time to achieve hemostasis

Study or Subgroup	Figure of 8 Mean	SD	Total	Manual compression Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI	Year
Issa 2015	6.8	5.7	123	50.7	12.2	253	25.0%	-43.90 [-45.71, -42.09]	2015
Lakshmanadoss 2017	15.4	4.7	179	15.7	4.2	105	25.1%	-0.30 [-1.36, 0.76]	2017
Pracon 2018	0.3	0.1	60	12.25	1.46	30	25.1%	-11.95 [-12.47, -11.43]	2018
Payne 2018	7.92	5.69	62	36.09	10.37	42	24.8%	-28.17 [-31.61, -24.73]	2018
Total (95% CI)			**424**			**430**	**100.0%**	**-21.04 [-35.66, -6.42]**	

Heterogeneity: $Tau^2 = 221.51$; $Chi^2 = 1748.19$, df = 3 ($P < 0.00001$); $I^2 = 100\%$
Test for overall effect: $Z = 2.82$ ($P = 0.005$)

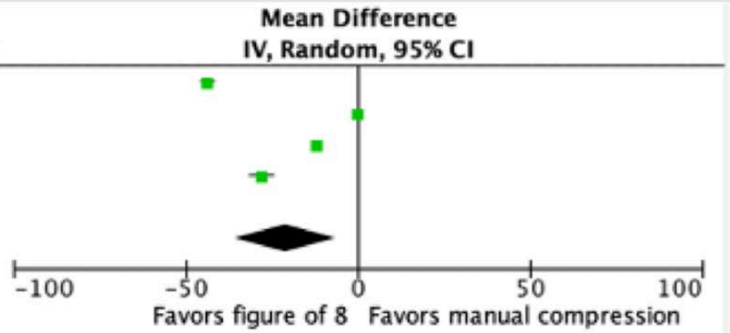
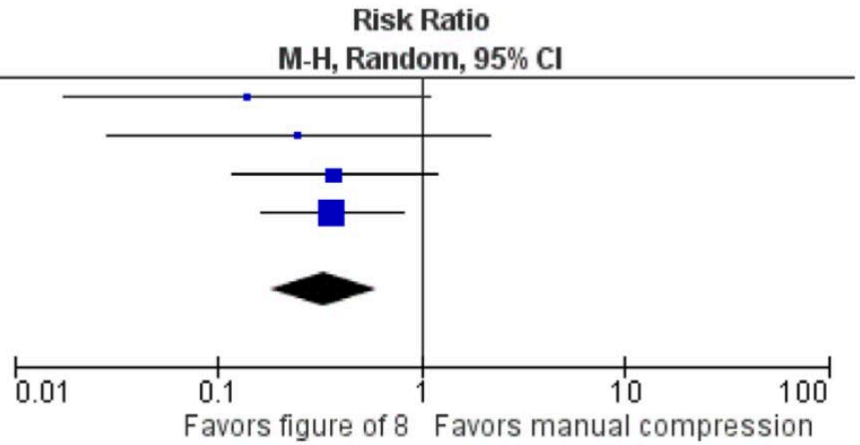


Figure 3.3 Access site complications for sheaths ≥ 10 Fr

Study or Subgroup	Figure of 8 Events	Total	Manual Compression Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Akkaya 2017	1	96	7	94	8.4%	0.14 [0.02, 1.12]
Aytemir 2016	1	100	4	100	7.7%	0.25 [0.03, 2.20]
Jensen 2020	4	158	9	132	27.1%	0.37 [0.12, 1.18]
Pracon 2018	8	60	11	30	56.8%	0.36 [0.16, 0.81]
Total (95% CI)		**414**		**356**	**100.0%**	**0.33 [0.18, 0.60]**
Total events	14		31			

Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 0.86$, df = 3 ($P = 0.84$); $I^2 = 0\%$
Test for overall effect: $Z = 3.63$ ($P = 0.0003$)



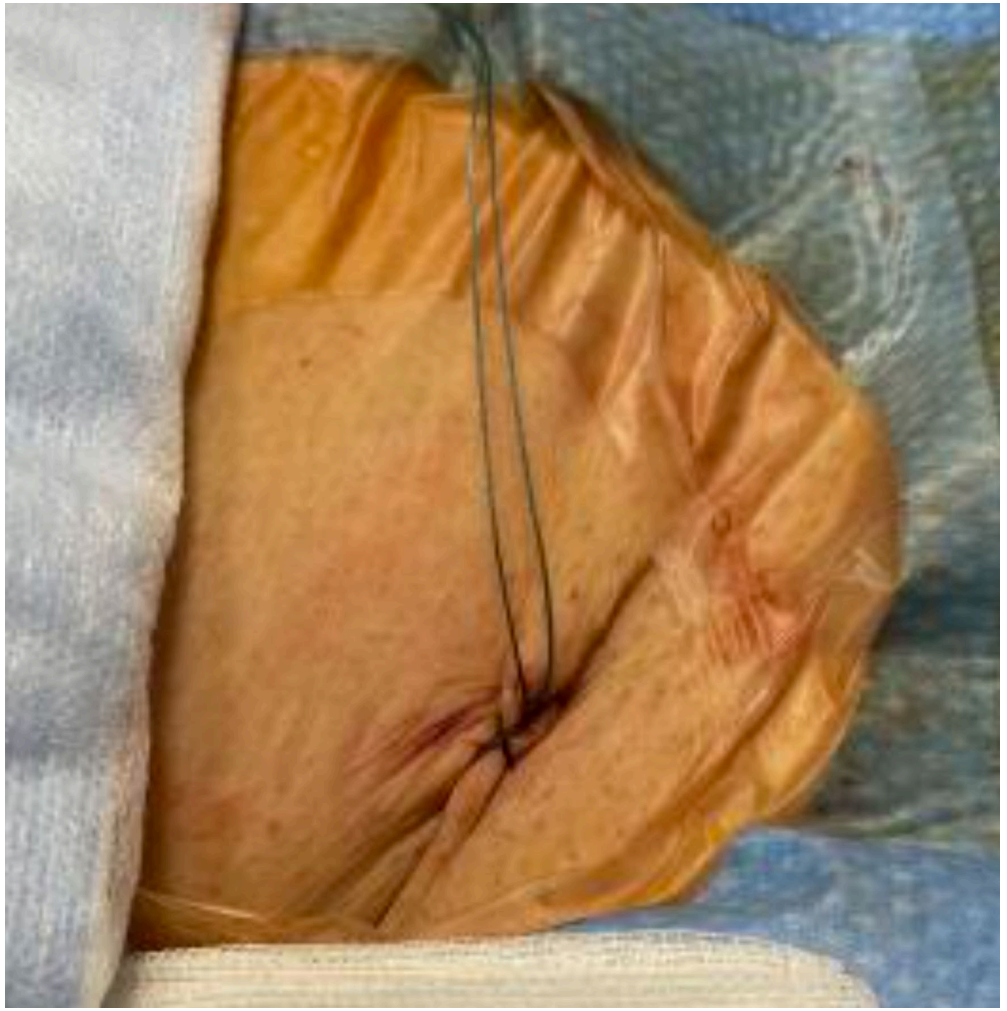
Mujer MT, et al. *Pacing Clin Electrophysiol.* 2020;43(8):856-865.

Large Bore Venous Closure

Manual Compression

Figure of Eight Closure

- Fisherman's Knot

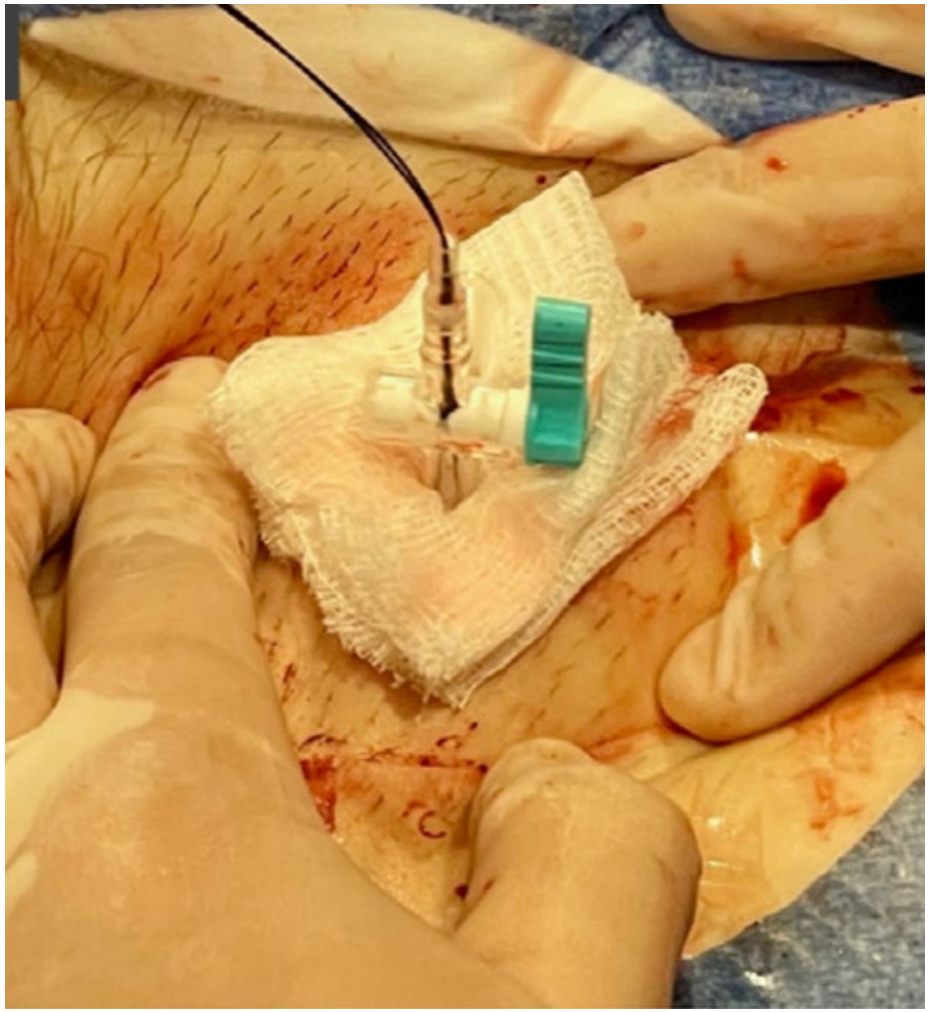


Large Bore Venous Closure

Manual Compression

Figure of Eight Closure

- Fisherman's Knot
- Stopcock



Katamreddy A, et al. *Heart Rhythm O2*. 2024;5(7):468-473.

Large Bore Venous Closure

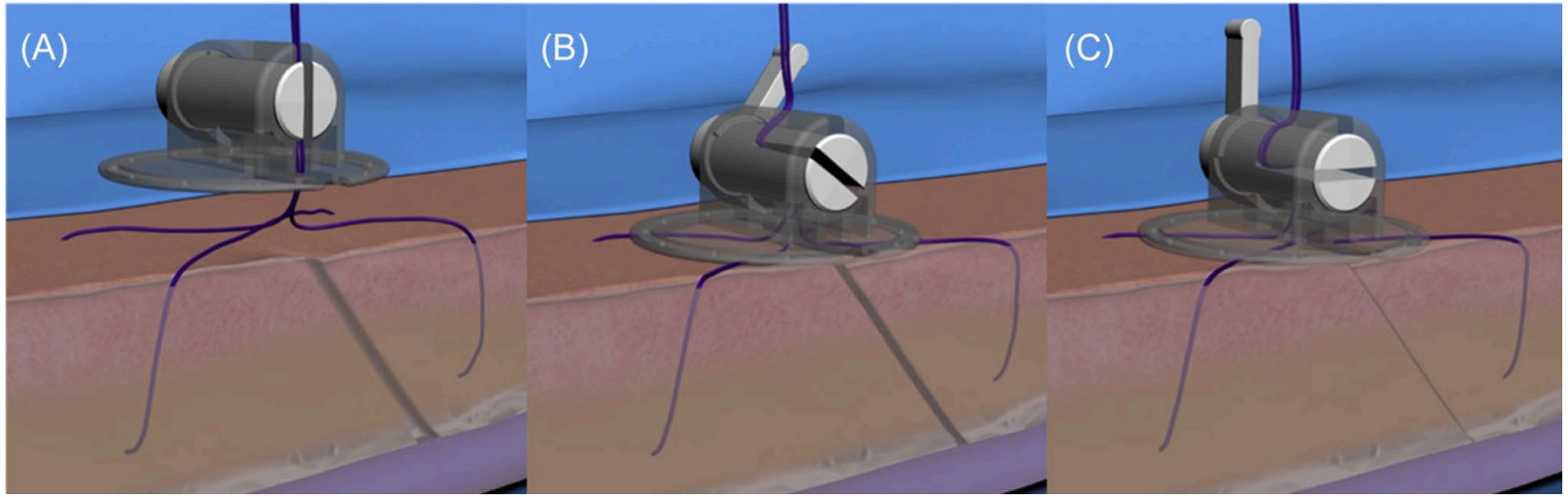
Manual Compression

Figure of Eight Closure

- Fisherman's Knot
- Stopcock
- "Advanced" Stopcock

Other issues

- Patient comfort
- Time to ambulation
- Time to discharge



Katapadi A, et al. *J Cardiovasc Electrophysiol*. 2024;35(10):1952-1959.

Large Bore Venous Closure

Manual Compression

Figure of Eight Closure

Mechanical Closure (current FDA approved devices)

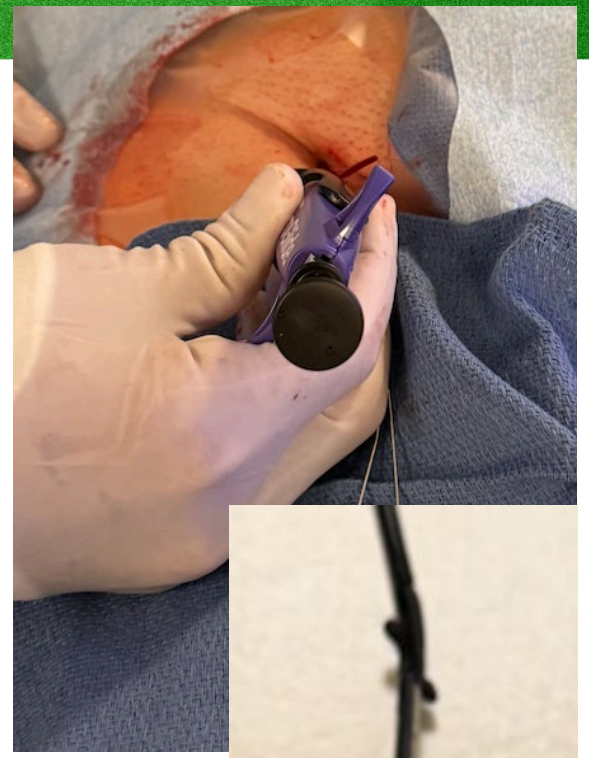
- Perclose Proglide™ – 29F Max OD with “pre-close” and multiple devices (>14F)
- Vascade XL™ – 15F Max OD
- Mynx Control™ – 12F Max ID

ID = inner diameter.

FDA. Accessed December 3, 2024. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P960043S122; https://www.accessdata.fda.gov/cdrh_docs/pdf12/P120016C.pdf; https://www.accessdata.fda.gov/cdrh_docs/pdf4/P040044S097C.pdf.

Suture-Mediated Closure

- Need to “pre-close”
  - Deploy the devices prior to upsizing to the larger sheath
- Suture is permanent
- Inconsistent results



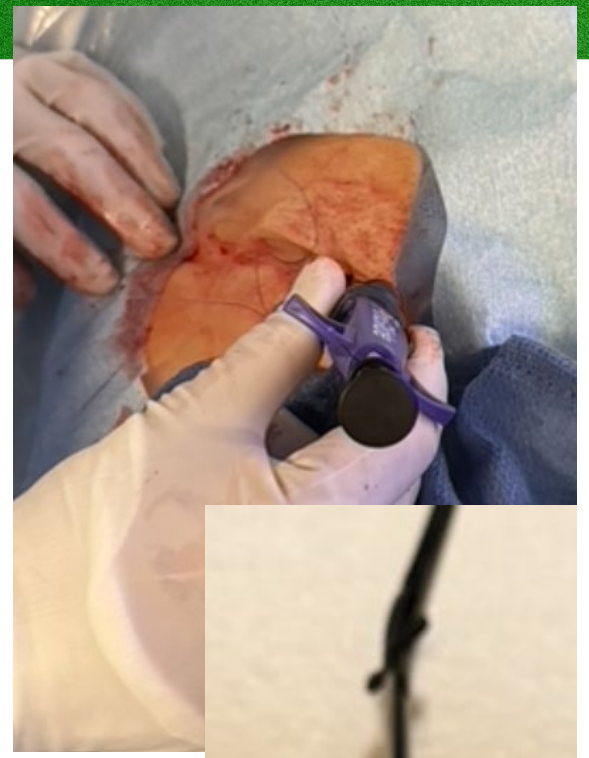


Figure of Eight vs Device

Table 2
Outcomes in the two study arms

Outcomes n (%)	Perclose (n=20)	Figure-of-8 (n=20)	P-value
Ecchymosis >5 cm	0 (0%)	3 (15%)	0.23
Hematoma	0 (0%)	2 (10%)	0.49
Manual Hold	2 (10%)	1 (5%)	1.00
Ipsilateral Venous Ultrasound	1 (5%)	0 (0%)	1.00
Blood Transfusion	1 (5%)	1 (5%)	1.00
Access site Pain	0 (0%)	1 (5%)	1.00
Access Site Infection	0 (0%)	0 (0%)	1.00
Total Events	4 (20%)	7 (35%)	0.48

Lodhi H, et al. *Am J Cardiol*. 2023;209:181-183

Variable	VCS group N = 63	F8 group N = 62	P-value
Energy source			
Cryoballoon, *n* (%)	51 (81.0%)	49 (79.0%)	0.826
PFA, *n* (%)	11 (17.5%)	9 (14.5%)	0.808
Laser, *n* (%)	1 (1.6%)	1 (1.6%)	1
RF, *n* (%)	0 (0.0%)	3 (4.8%)	0.119
Number of punctures			
1, *n* (%)	9 (14.3%)	8 (12.9%)	1
2, *n* (%)	54 (85.7%)	52 (83.9%)	0.808
3, *n* (%)	0 (0.0%)	2 (3.2%)	0.243

Table 3 Times

Variable	VCS group N = 63	F8 group N = 62	P-value
TTA, min	109.0 (82.0, 160.0)	269.0 (243.8, 340.5)	<0.001*
TTH, min	1 (1, 2)	5 (2, 10)	<0.001*
TTDe, min	270 (270, 270)	340 (300, 458)	<0.001*
TTD, days	2 (2, 3)	2 (2,3)	0.690
Same-day discharge, *n* (%)	9 (14.3%)	7 (11.3%)	0.789

Tilz RR, et al. *EP Europace*. 2024;26(5):euae105.

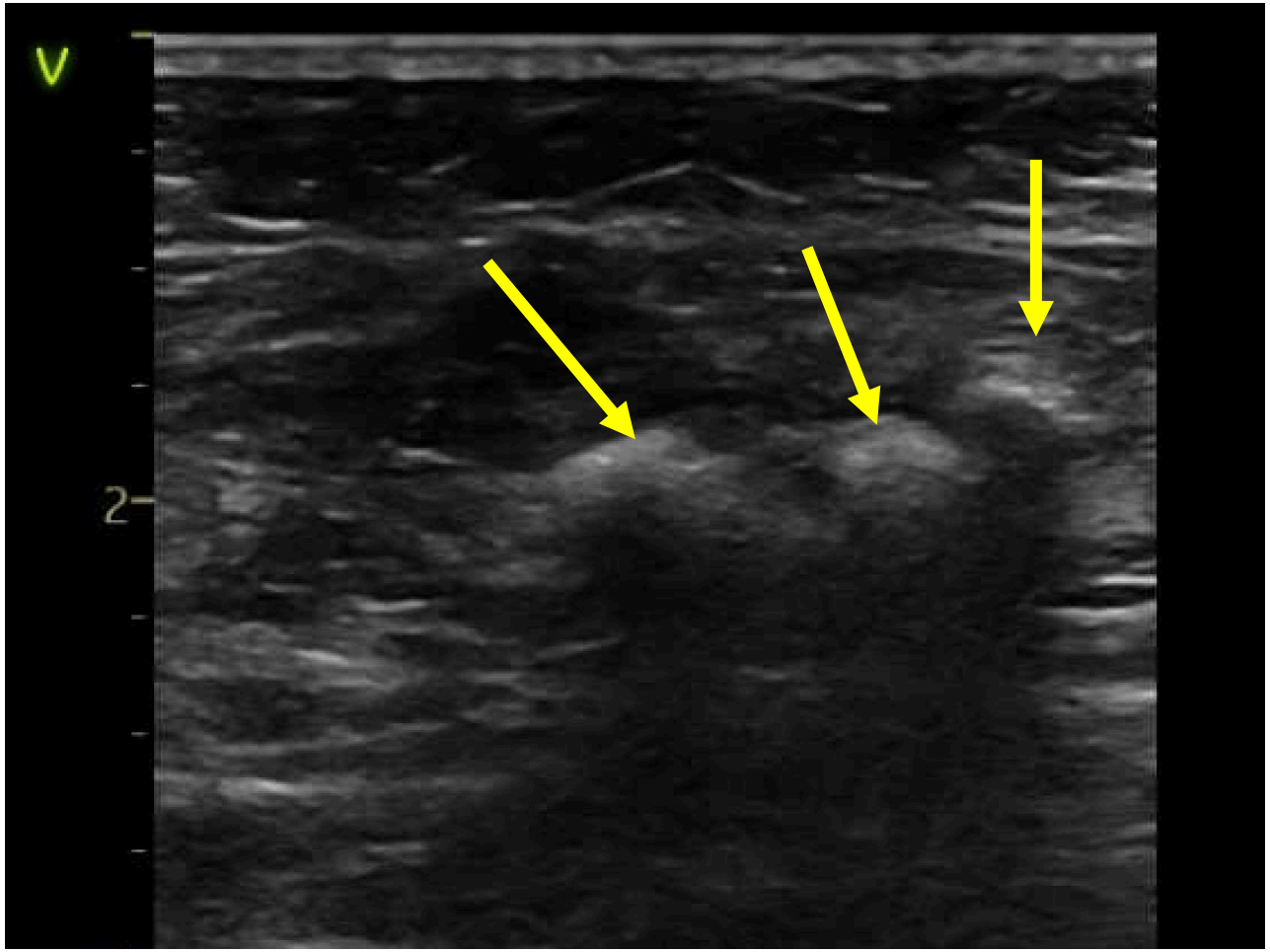
Vascade XL?

- Downsize from 13-18F sheath to a 12F sheath
  - For those of you using a 18F ID sheath for your LAAO cases, I would not personally recommend this technique
- Elastic recoil of the vein allows for this in almost all patients
- Vascade XL™ closure as normal

LAAO = left atrial appendage occlusion.

Vascade XL x 2 and MVP x 1

1. 17F (OD) PFA sheath
2. 11F (ID) ICE sheath
3. 6F (ID) Decapolar catheter



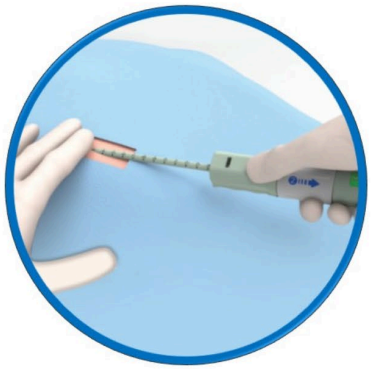
ICE = intracardiac echocardiography.

The Future – NOT FDA Approved

New indications for current device(s)

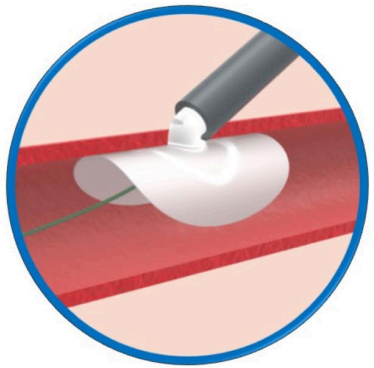
New devices → PerQseal Elite

Designed for purpose



Suitable for arteriotomies up to 24F
No pre-procedural steps – OTW delivery
One device per arteriotomy
Fully synthetic absorbable implant
No sutures, no collagen, no metal

Simple and secure device deployment



Automatic loading – Simple and intuitive delivery
Safety Guidewire remains in situ until implant release
Dedicated 0.035" compatible introducer

Patch based fully absorbable implant

Ultra-low profile patch, rapidly endothelialised
Implant fully absorbed within 180 days
Abluminal surface matrix promotes adherence and healing

OTW = over-the-wire.

Fumedica. Accessed December 3, 2024. https://www.fumedica.ch/custom/data/ckEditorFiles/Produkte/Closure_device/PERQSEAL%20brochure%20-%20%20MK-DP2-1%20Rev%20AA%20%20-%20Final.pdf.

Questions and Discussion