

Single-shot di PFA

Ottimizzazione dell'accesso transettale nelle procedure single-shot di PFA

Dott Paolo China

Responsabile UOS Elettrofisiologia ed Elettrostimolazione

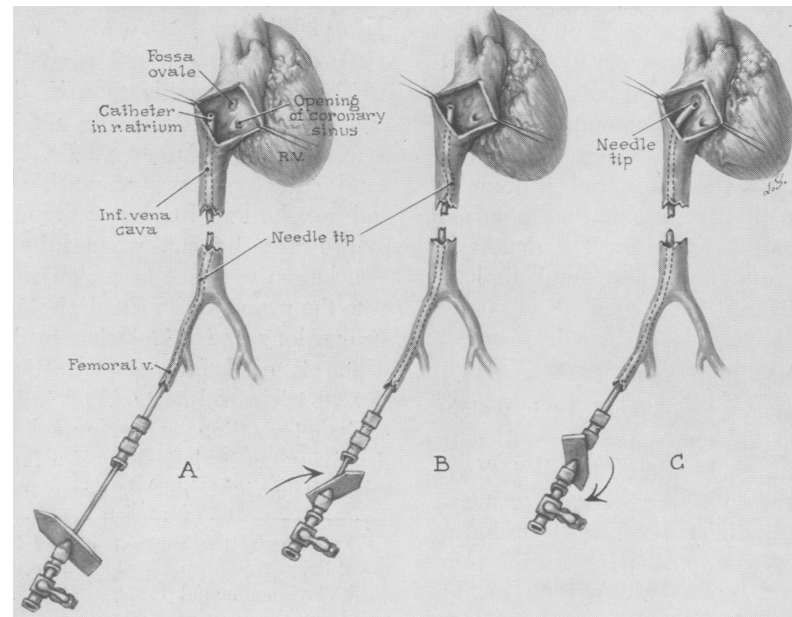
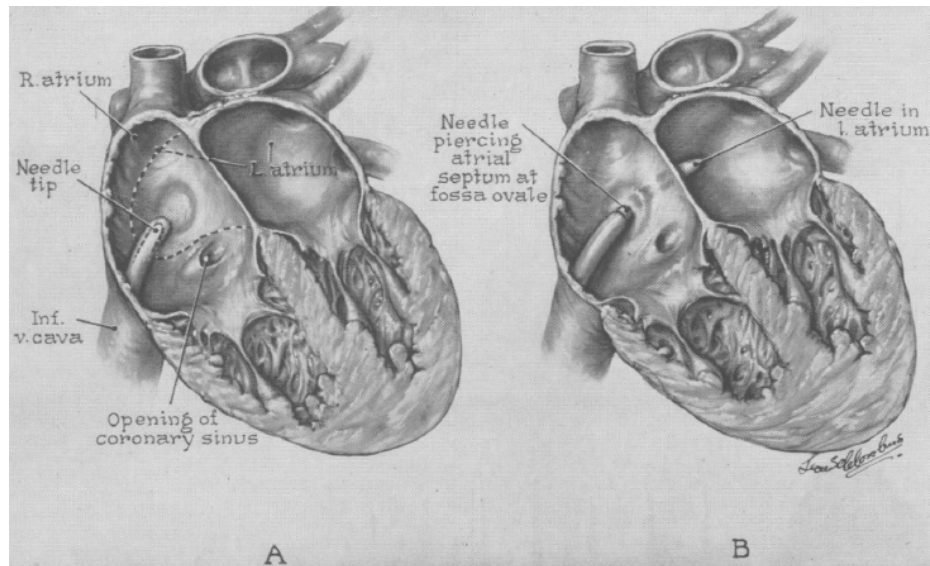
UOC Cardiologia

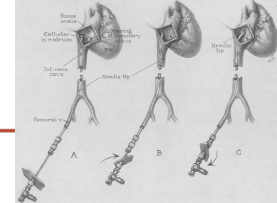
Dip. CardioToracoVascolare con Attività Interventistica e Terapia Intensiva

Ospedale dell'Angelo, Mestre-Venezia, AULSS3 Serenissima



Background: Trans-septal puncture





1957 Manfredi

1959 Ross John Jr: first in dogs

1959 Ross, Braunwald, Morrow: first in human

1960 Transeptal experience in 130 pts

1980 Large experience for *mitral valvuloplasty* and after for *RF catheter ablation*

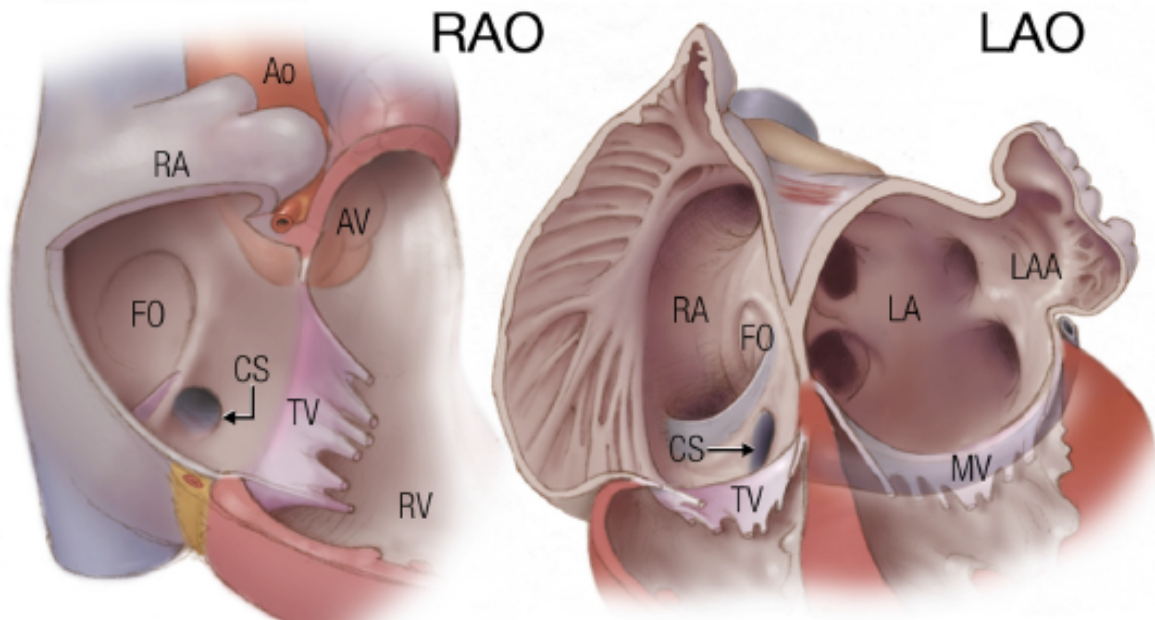
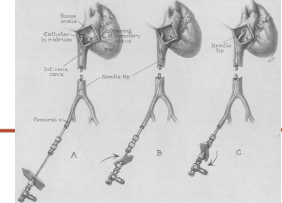
“When these precautions are observed the procedure is technically simple and can be performed by anyone trained in the usual right heart catheterization”

“Precautions:

- 1) The operator must be well acquainted with the ***detailed relation of these structures*** to the atrial septum
- 2) Before undertake the procedure in this clinic it had been utilized ***extensively both in dogs and in cadavers***
- 3) Furthermore, the ***chest roentgenogram*** of each patient should be studied before, in order to know the position of the aorta, the size of the atria, and any anomalies of position or rotation of the heart ...”

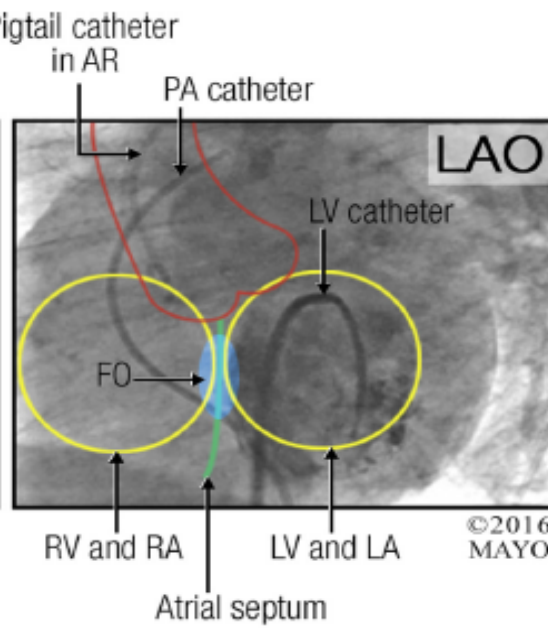
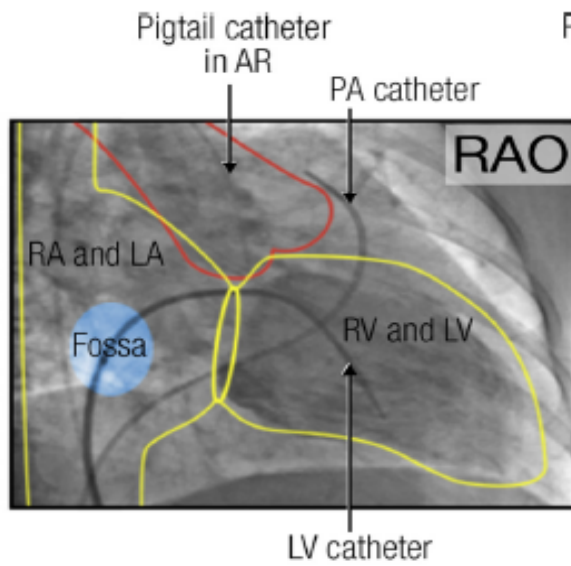


Structures: Fossa Ovalis

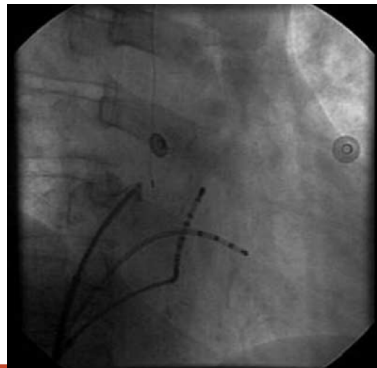
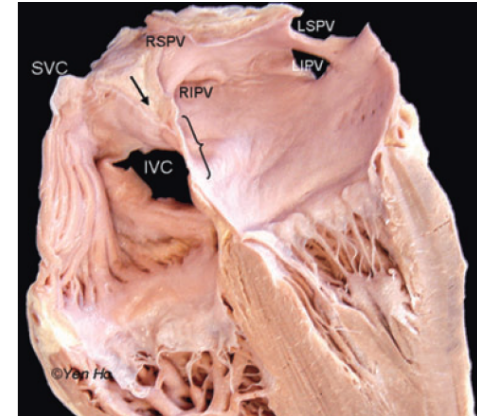


Average vertical diameter of $18.5 \pm 6.9\text{mm}$
Average horizontal diameter of $10.0 \pm 2.4\text{mm}$



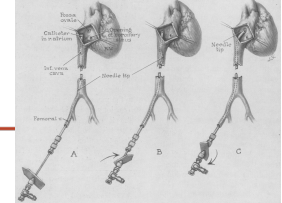


Nearby structures:



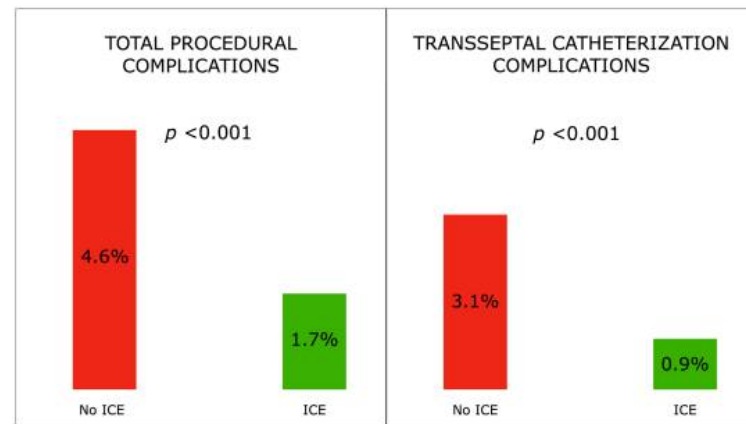
	Total Procedures <i>n</i> = 2181	ICE Group <i>n</i> = 1134	No ICE Group <i>n</i> = 1047	<i>p</i> Value
Periprocedural complications:	67 (3.1%)	19 (1.7%)	48 (4.6%)	<0.001
Transseptal catheterization complications	42 (1.5%)	10 (0.9%)	32 (3.1%)	<0.001
- Vascular access complications, total:	20 (0.9%)	5 (0.4%)	15 (1.4%)	0.028
- Groin hematoma, total:		4	14	
- Major groin hematoma		1	3	
- Retroperitoneal hematoma		1	1	
- Arterio-venous fistula		0	1	
- Aortic root puncture, total:	8 (0.4%)	0 (0%)	8 (0.8%)	0.003
- No consequences		0	2	
- Pericardiocentesis		0	2	
- Cardiac surgery		0	4	
- Atrial wall injury, total:	14 (0.6%)	0 (0%)	14 (1.3%)	<0.001
- Contrast in pericardium		0	10	
- Pericardiocentesis		0	4	
- Cardiac perforation		0	0	
- Pericarditis and/or pericardial effusion	12 (0.6%)	6 (0.5%)	6 (0.6%)	0.89
- Thromboembolism, total:	7 (0.3%)	5 (0.4%)	3 (0.3%)	0.51
- Transient ischemic attack	2	1	1	
- Stroke	4	3	1	
- Systemic embolism	1	0	1	
- Acute coronary injury	6 (0.3%)	2 (0.2%)	4 (0.4%)	0.69
- Hemidiaphragm paresis	1	1 (0.1%)	0 (0%)	0.34
- Death	0	0	0	1.00

ICE for safety

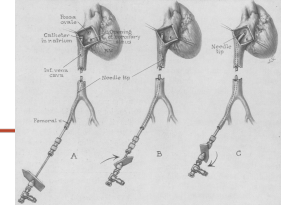


Trans-septal puncture: Success and Complications

Success rate greater than 95-98%
3-5% complication



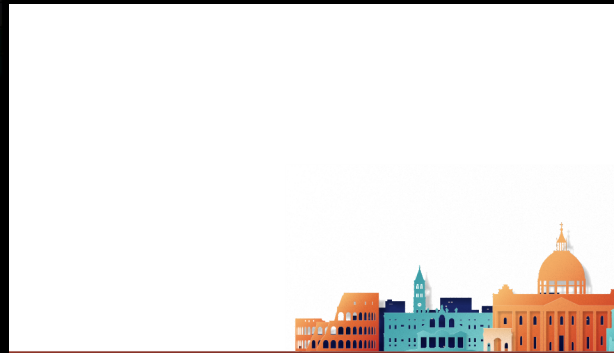
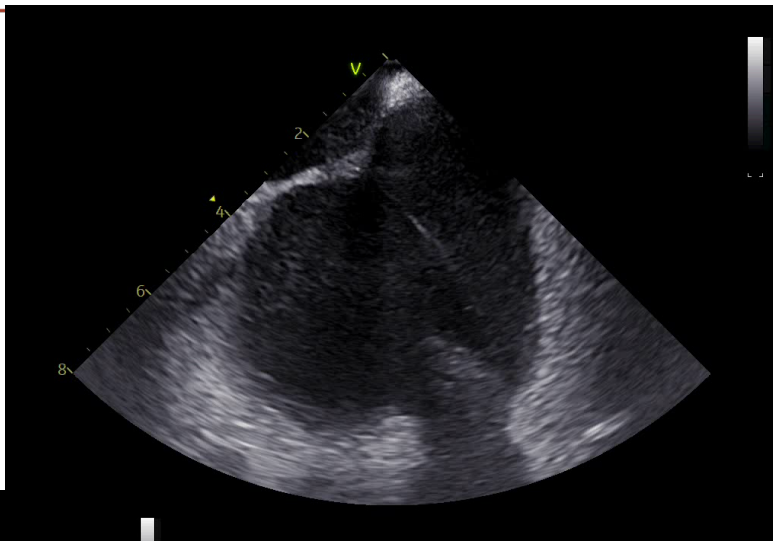
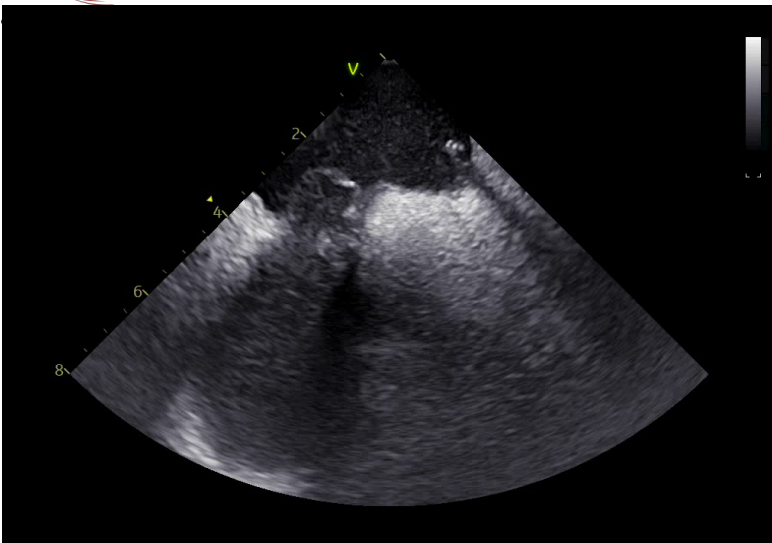
ICE... when?

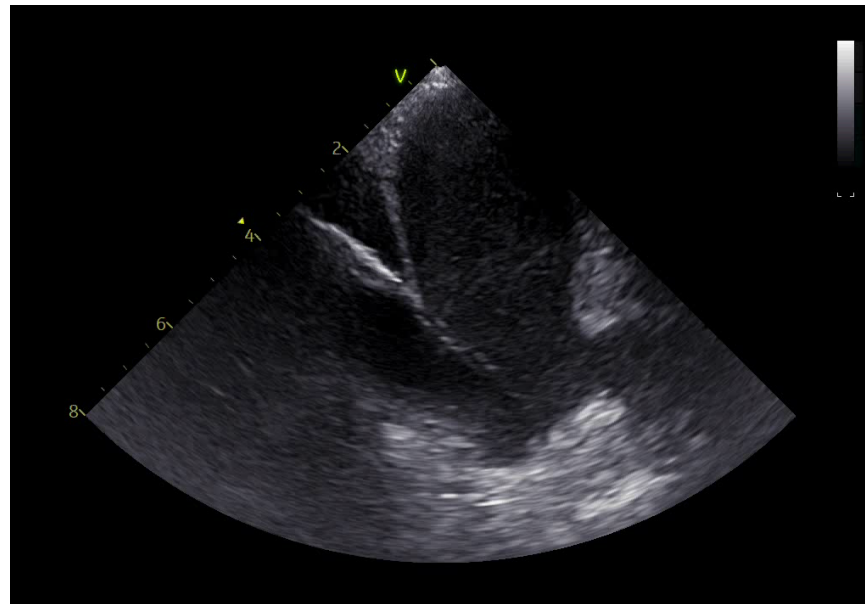
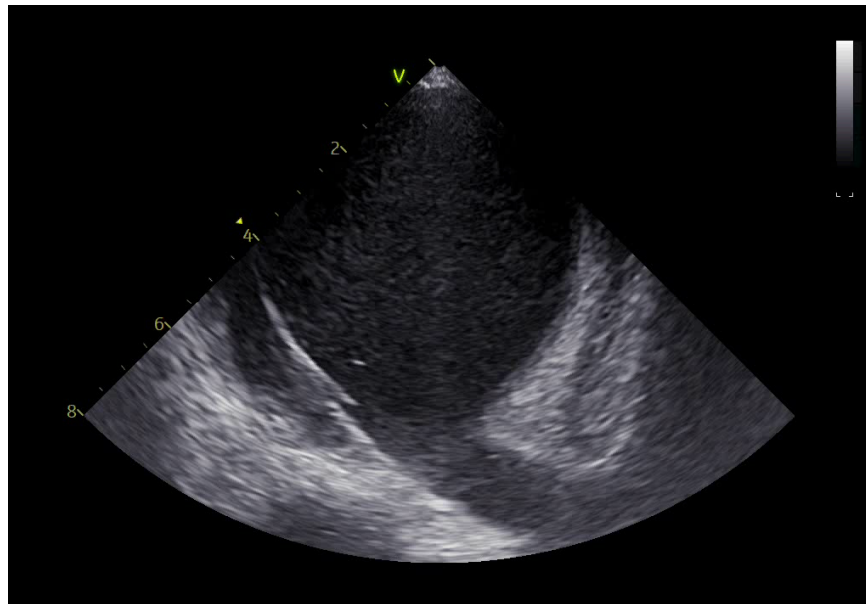


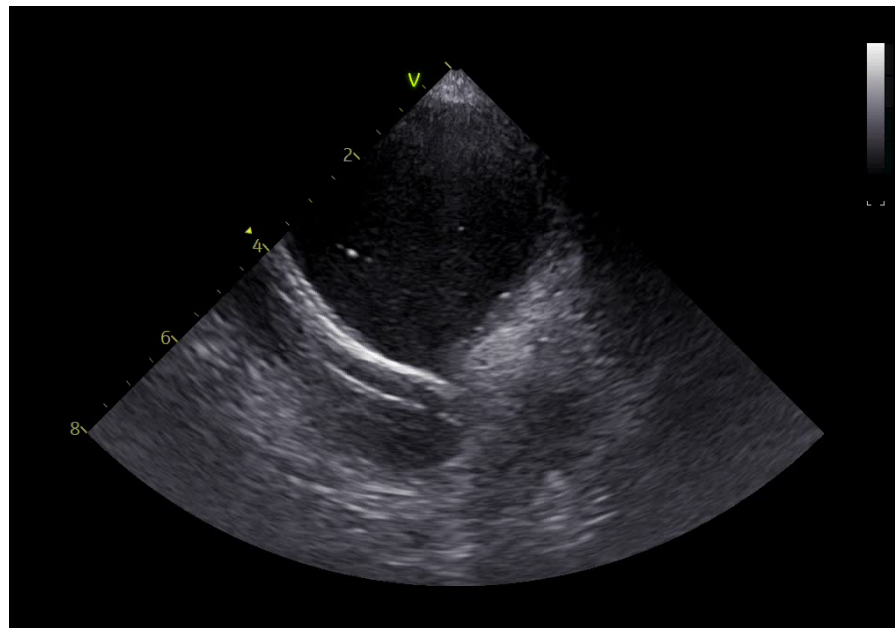
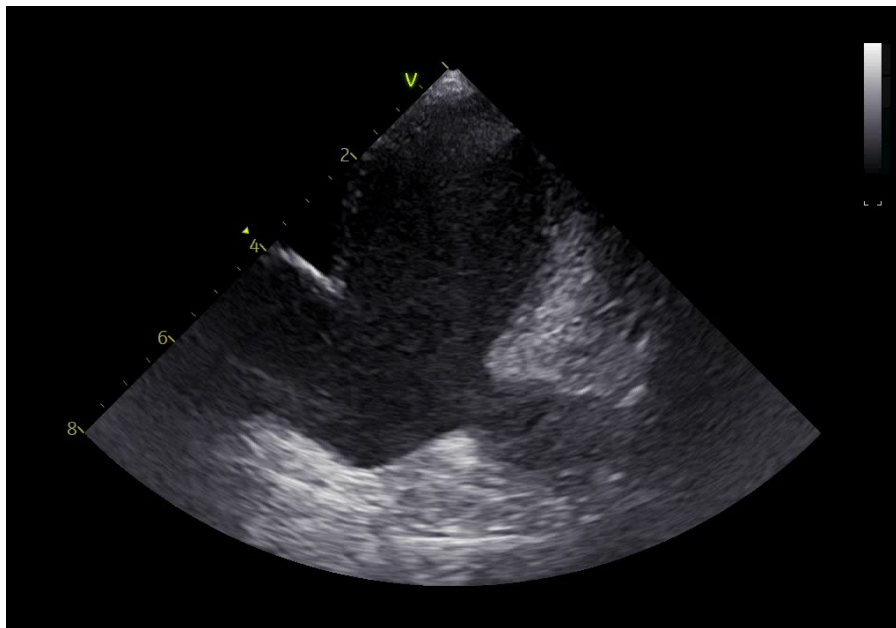
- ***Dilated aortic root***
- ***Real huge septal aneurism***
- ***Very small left atrium / (very large)***
- ***Trans-septal puncture previously performed (resultant scarring)***
- ***Lipomatous hypertrophy***
- Congenital heart disease (ex Fallot/Ebstein/cor triatriatum)
- Large coronary sinus (i.e. left superior vena cava persistence)
- Thoracic spine deformities/cardiac malposition
- Previous septal interventions: ASD/ PFO occluder



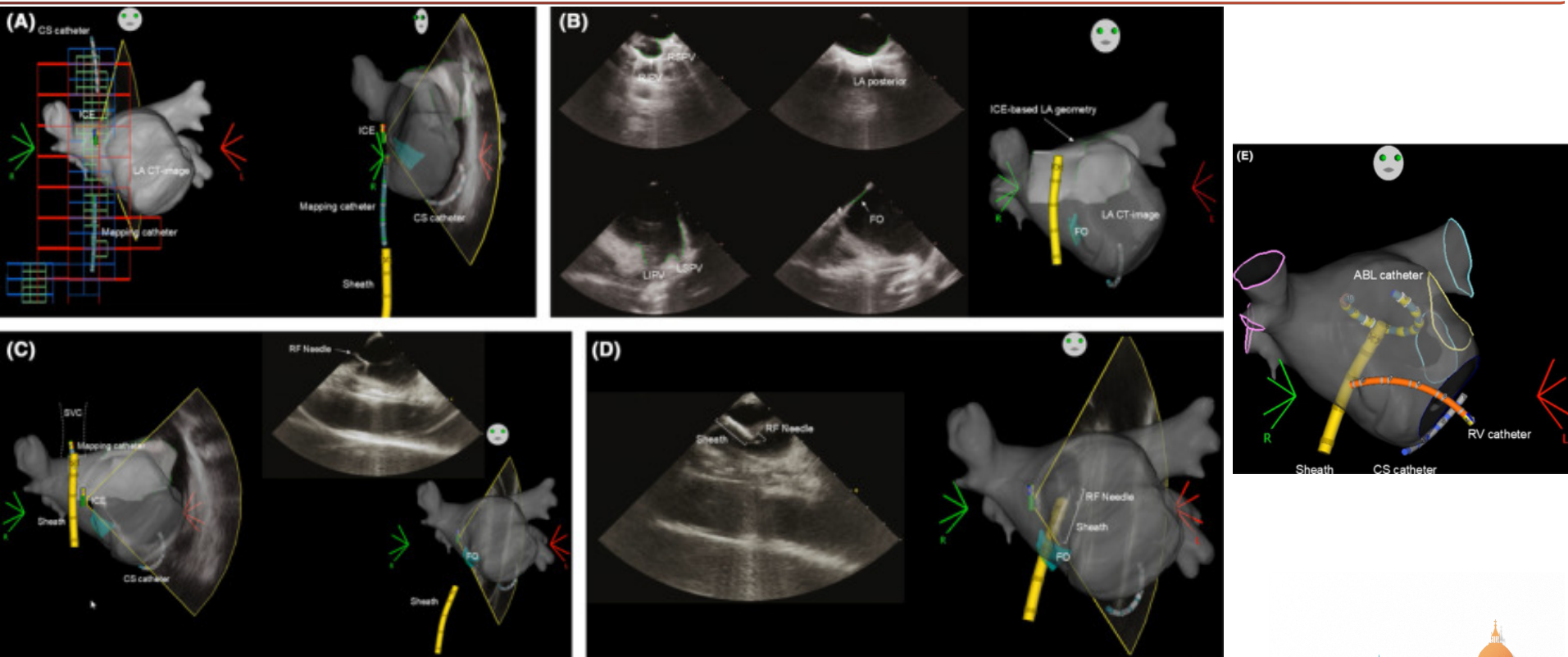
ICE use for safety and to reduce Rx exposure







Zero-fluoroscopy: VIZIGO and ICE

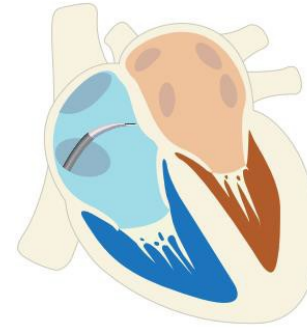


Since the geometry of the FO was created, the transeptal puncture can be done easily by simply pulling back the VIZIGO sheath so that the tip of the VIZIGO overlaps the FO, as monitored by the ICE

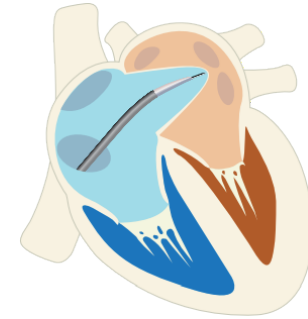


Left heart access challenges with conventional mechanical needles:

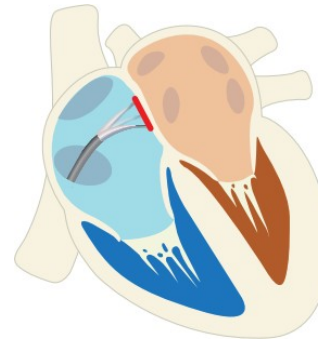
- Momentum of mechanical force required to ***cross the septum***
- Difficulty crossing challenging anatomy (***aneurysmal and fibrotic septa***)
- Difficulty crossing the septum at ***a precise location***
- Skiving and embolism risk



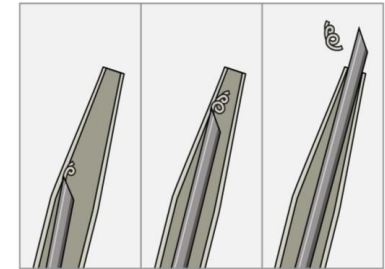
Excessive Force



Excessive Tenting



Lack of Precision

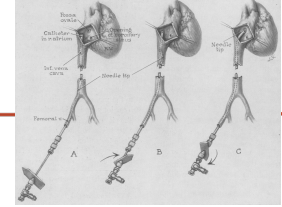


Skiving



Trans-septal puncture:

Different types of commonly used tip designs



Brockenbrough- BRK XS NRG-CO VERSACROSS



ESC

Europace (2026) 28, euag021

<https://doi.org/10.1093/europace/euag021>

EHRA DOCUMENT



EHRA
European Heart
Rhythm Association

Transseptal puncture in cardiovascular interventions: a clinical consensus statement of the European Heart Rhythm Association, the Heart Failure Association, the European Association of Percutaneous Cardiovascular Interventions, the European Association of Cardiovascular Imaging of the ESC, and the Association for European Paediatric and Congenital Cardiology

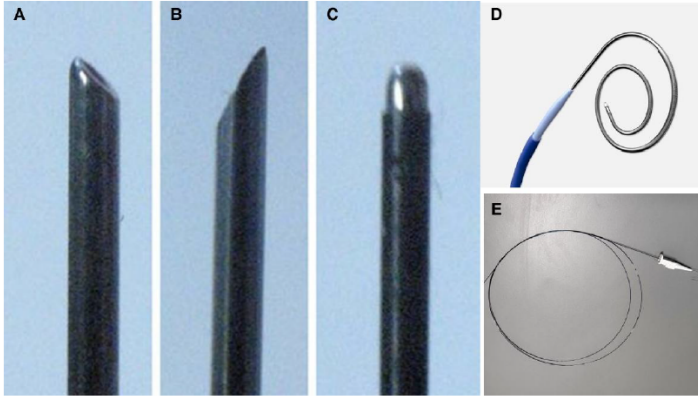


Figure 7 Different types of commonly used needle tip designs. Different types of commonly used needle tips: A. BRK, B. BRK XS, C. NRG-CO, D: VersaCross® wire system with tip configurations J-tip (9 mm) and pigtail (24 mm), diameter 0.035", length 180 cm, 230 cm. (E) SafeSept® wire, with a sharp distal tip and a preformed J shape.

SAFESEPT



Needle-based transseptal

Wire-based transseptal

Mechanical

Radiofrequency

Mechanical needle

NRG™ Transseptal Needle

VersaCross™ Access Solution



★ RF Energy Electrode

Easily cross thin aneurysmal septa while reducing excessive tenting and cross fibrotic septa while reducing mechanical force

★ Radiopaque Tip

Allows for precise positioning and visualization

★ Rounded Atraumatic Tip

Reduces scraping and skiving of the dilator

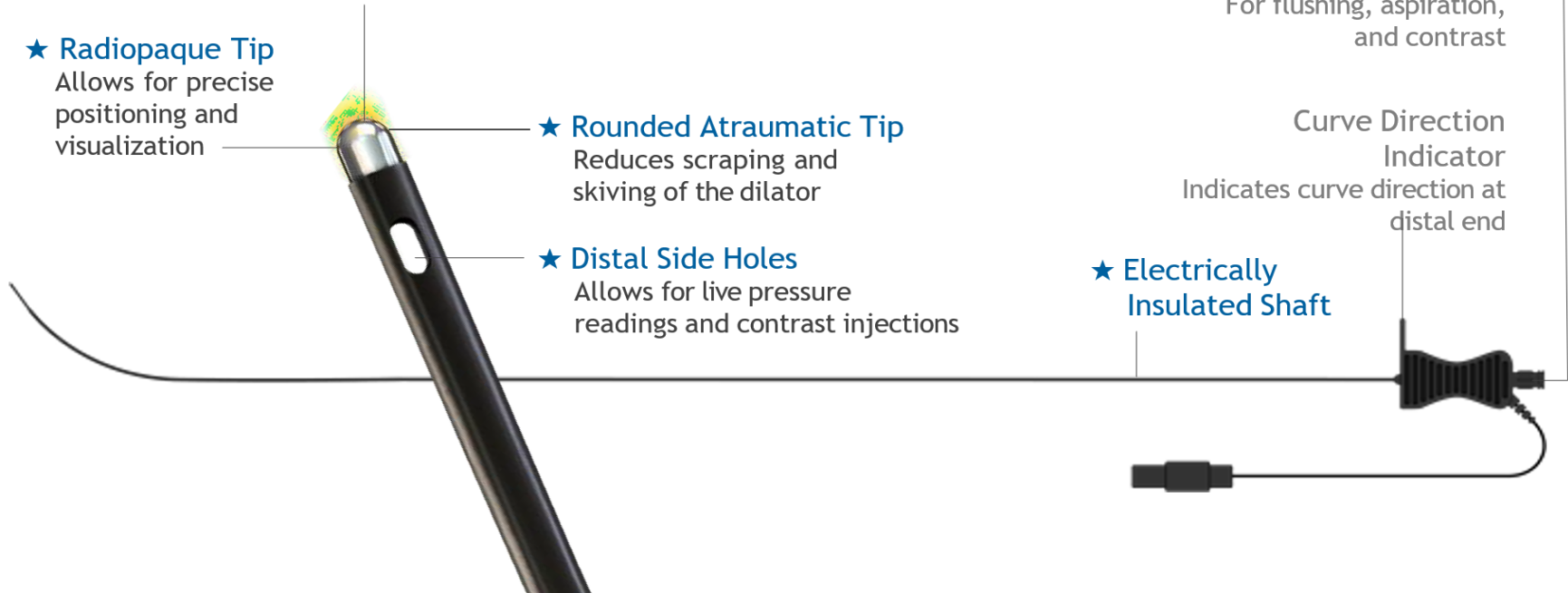
★ Distal Side Holes

Allows for live pressure readings and contrast injections

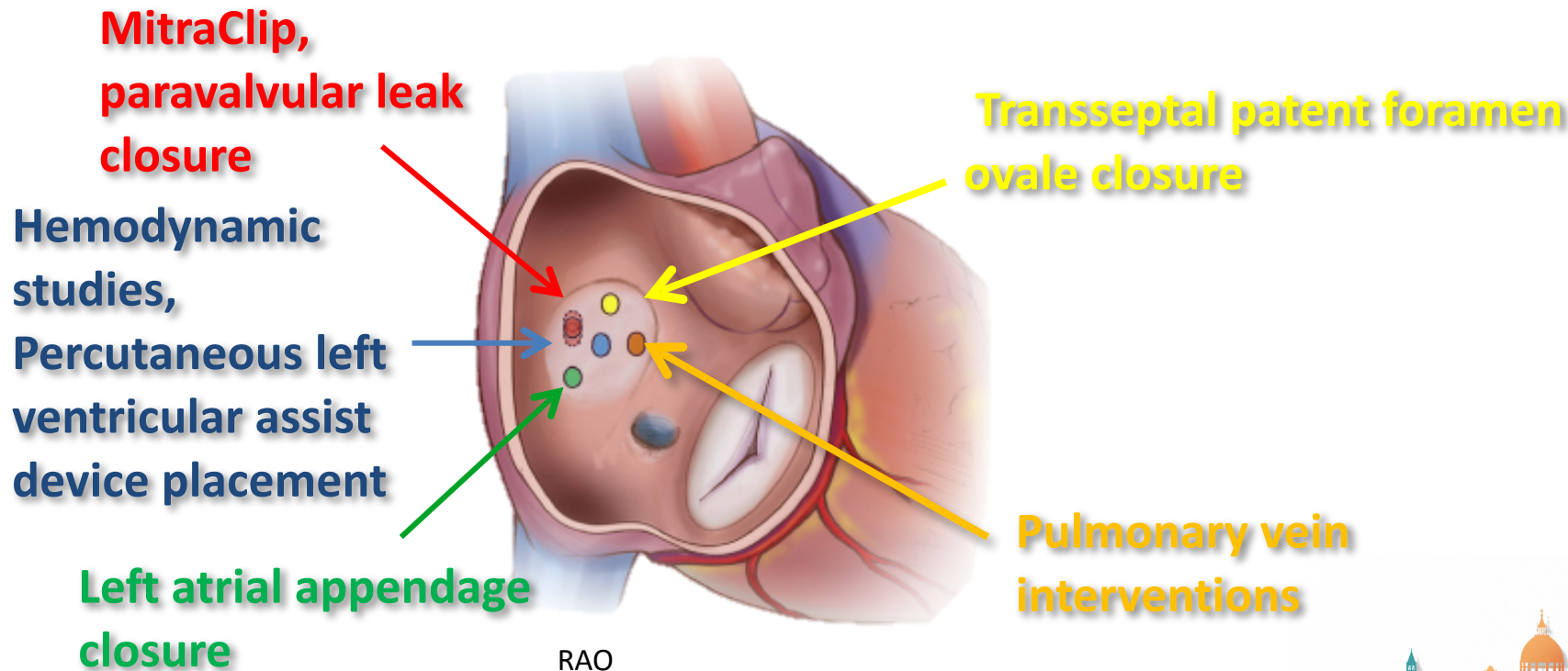
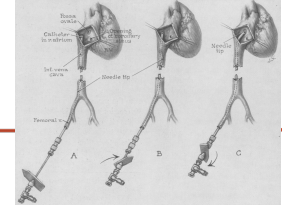
Luer Connector
For flushing, aspiration,
and contrast

Curve Direction
Indicator
Indicates curve direction at
distal end

★ Electrically Insulated Shaft

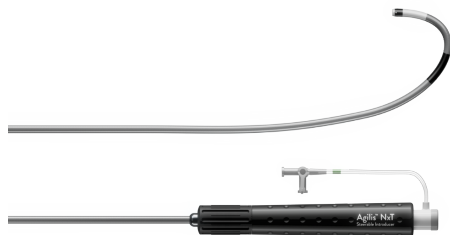


Trans-septal puncture: where

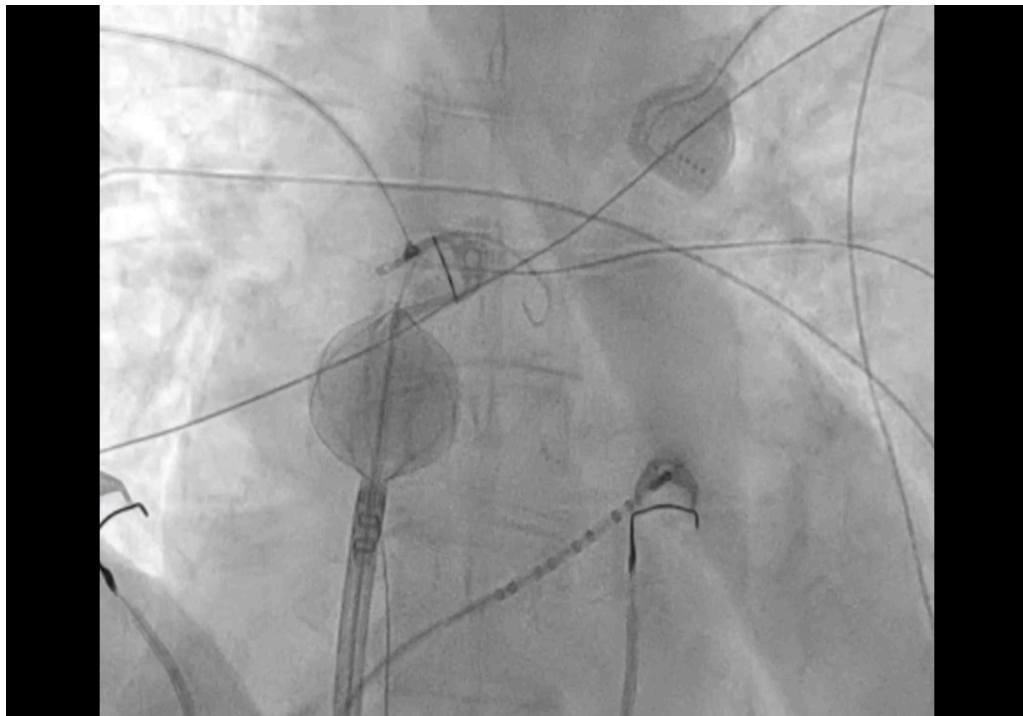


Trans-septal precision: RIPV engagement

INNER DIAMETER 13 Fr | OUTER DIAMETER 17.2 Fr Agilis + VOLT

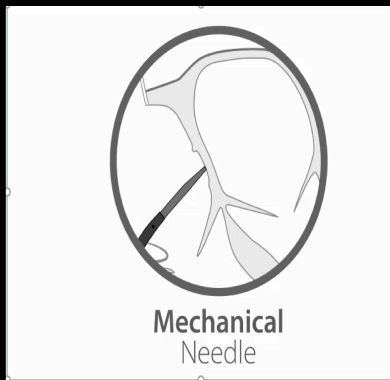


TSP Puncture can be directly performed using the BRK 98 cm needle



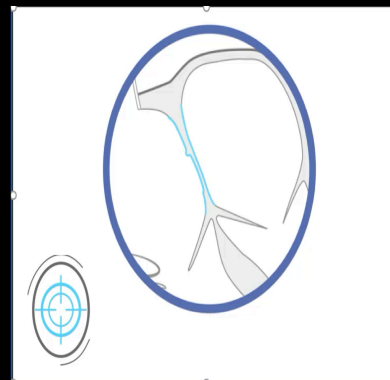
Mechanical Needle

Loss of position

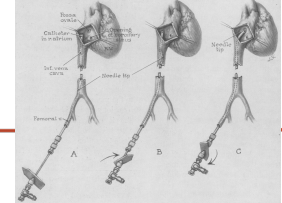


NRG®

Accurate position



Le sfide della puntura tradizionale: precisione



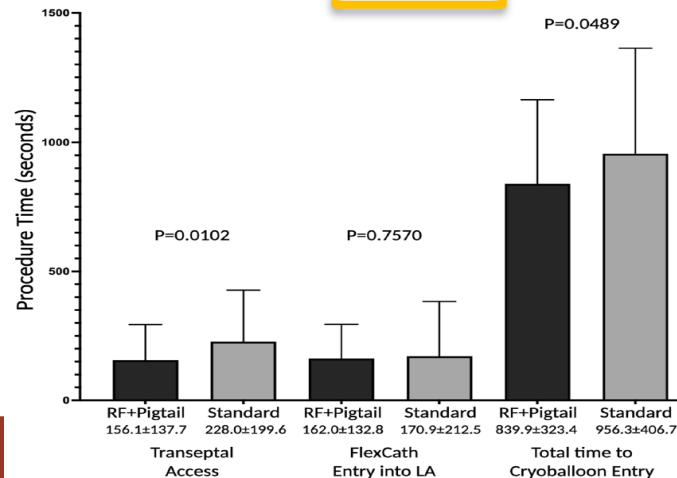
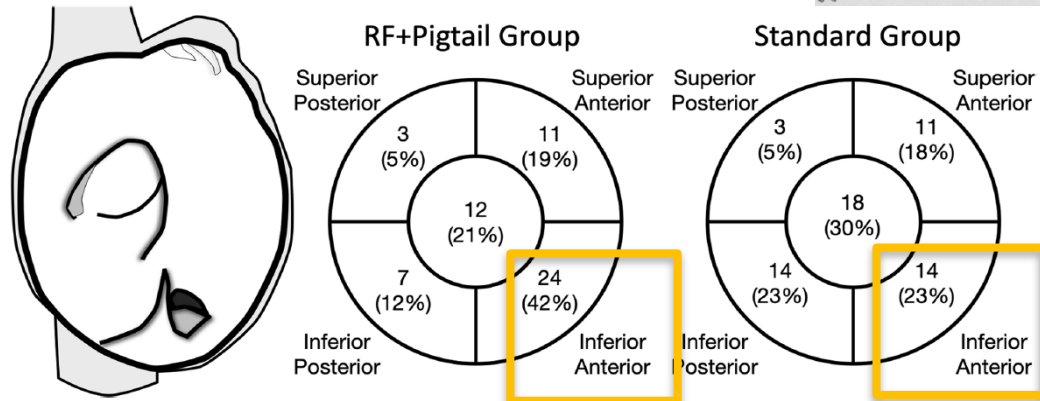
Randomized trial of conventional versus radiofrequency needle transseptal puncture for cryoballoon ablation: the CRYO-LATS trial

Jason G. Andrade^{1,2,3} · Laurent Macle³ · Matthew T. Bennett¹ · Nathaniel M. Hawkins^{1,2} · Vidal Essebag^{4,5} · Jean Champagne⁶ · Jean-Francois Roux⁷ · Bhavanesh Makanjee⁸ · Anthony Tang⁹ · Allan Skanes⁹ · Yaariv Khaykin¹⁰ · Carlos Morillo¹¹ · Umjeet Jolly¹² · Evan Lockwood¹³ · Guy Amit¹⁴ · Paul Angaran¹⁵ · John Sapp¹⁶ · Stephan Wardell¹⁷ · George A. Wells¹⁸ · Atul Verma⁴ · Marc W. Deyell^{1,2}

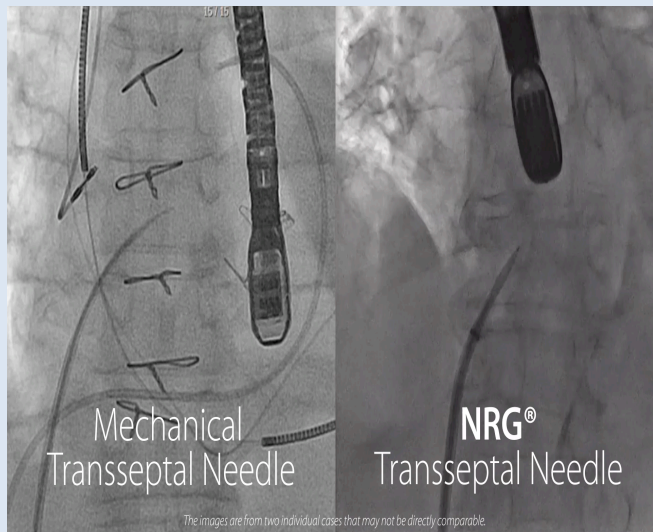
161 pazienti, 74 RF needle/RF wire, 87 standard needle/Safesept

3.4 Transseptal location

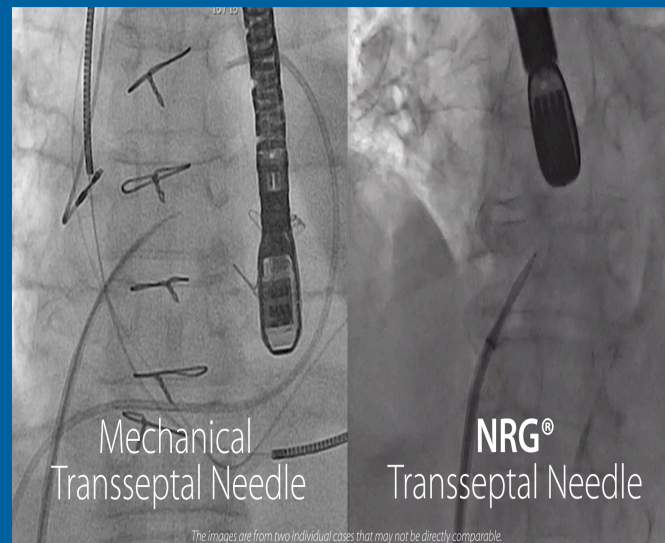
In those patients who underwent echocardiographically guided transseptal puncture, patients in the RF + Pigtail group were more often observed to have an ideal inferior-anterior transseptal location (42.1% vs. 23.3%, $P = 0.0476$, Fig. 4).

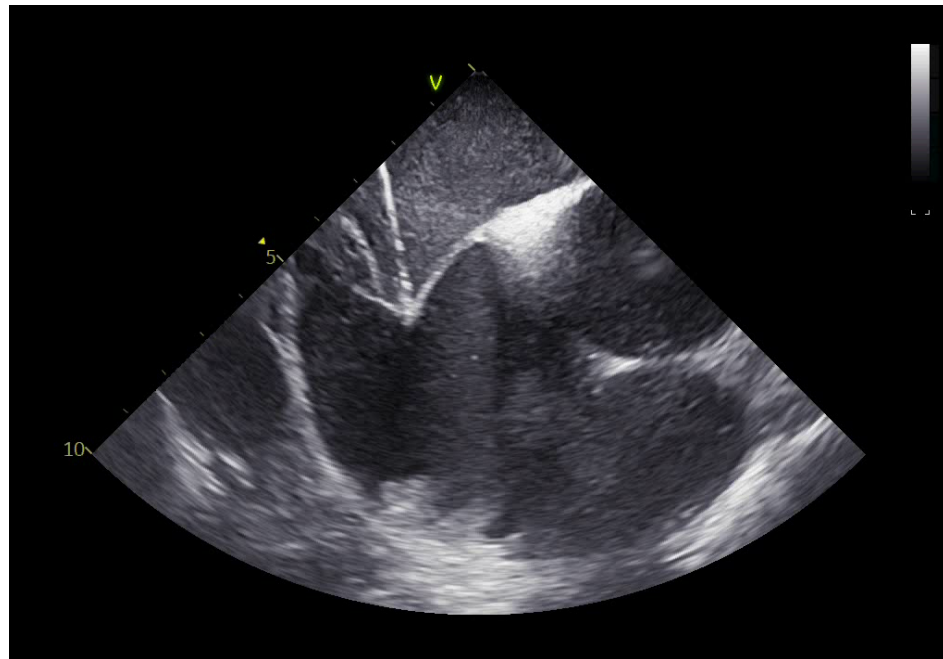
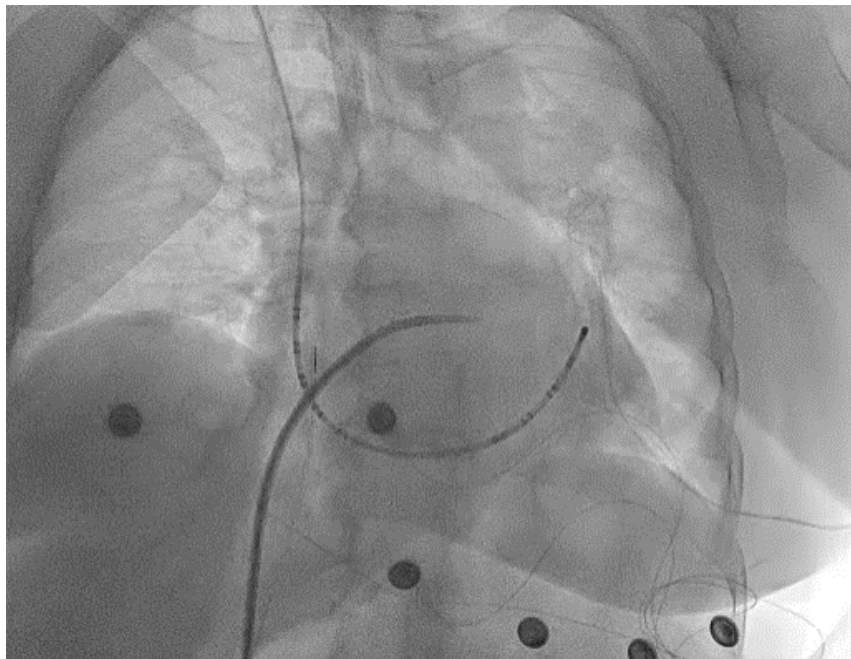


Mechanical Needle

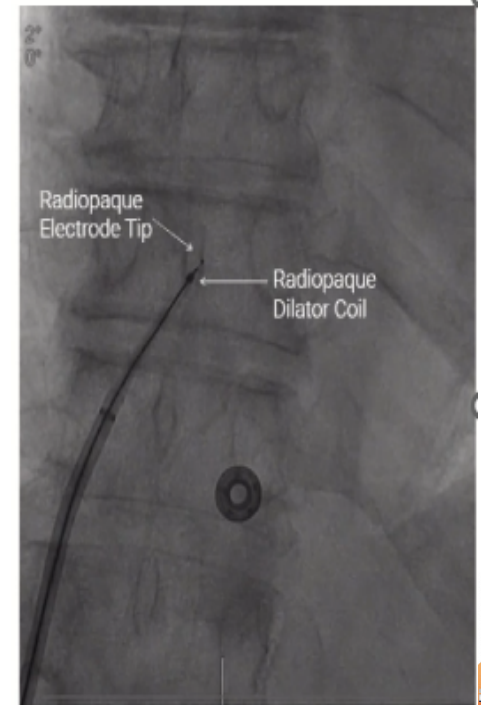
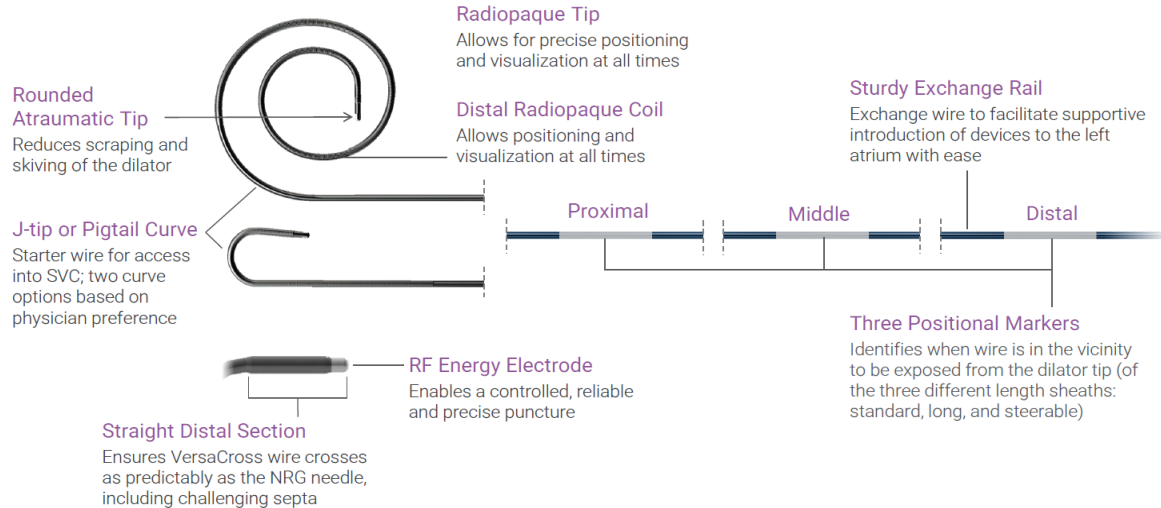


NRG

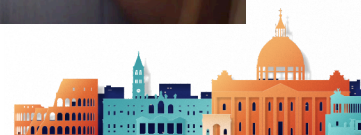
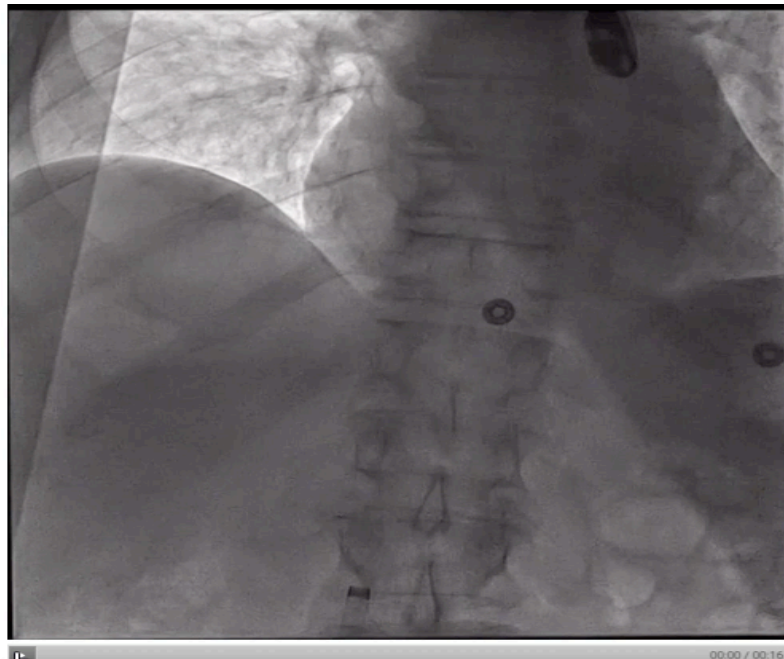


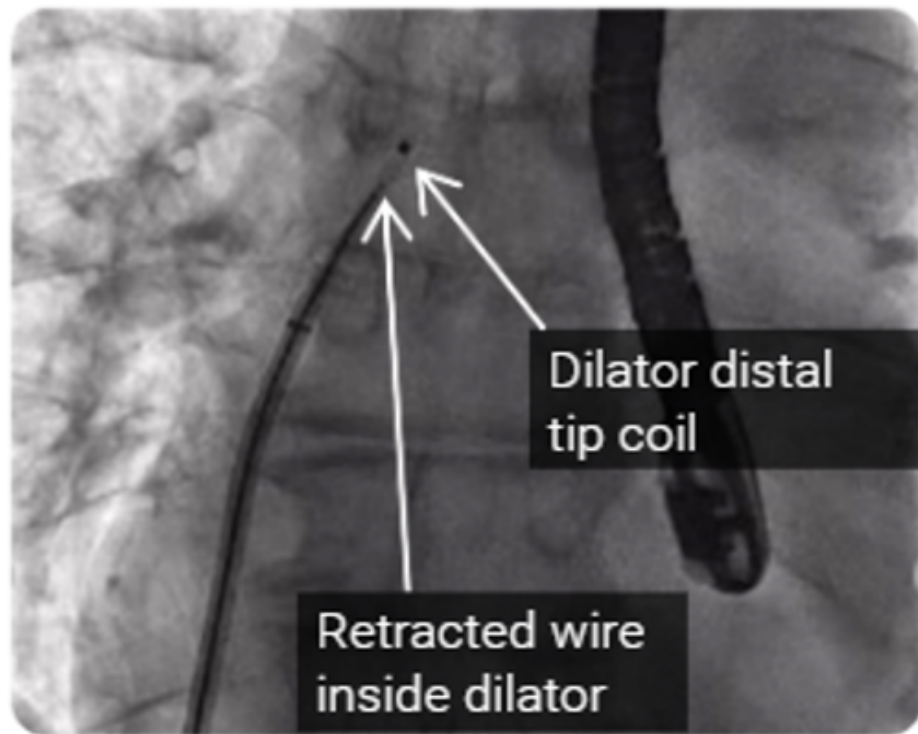
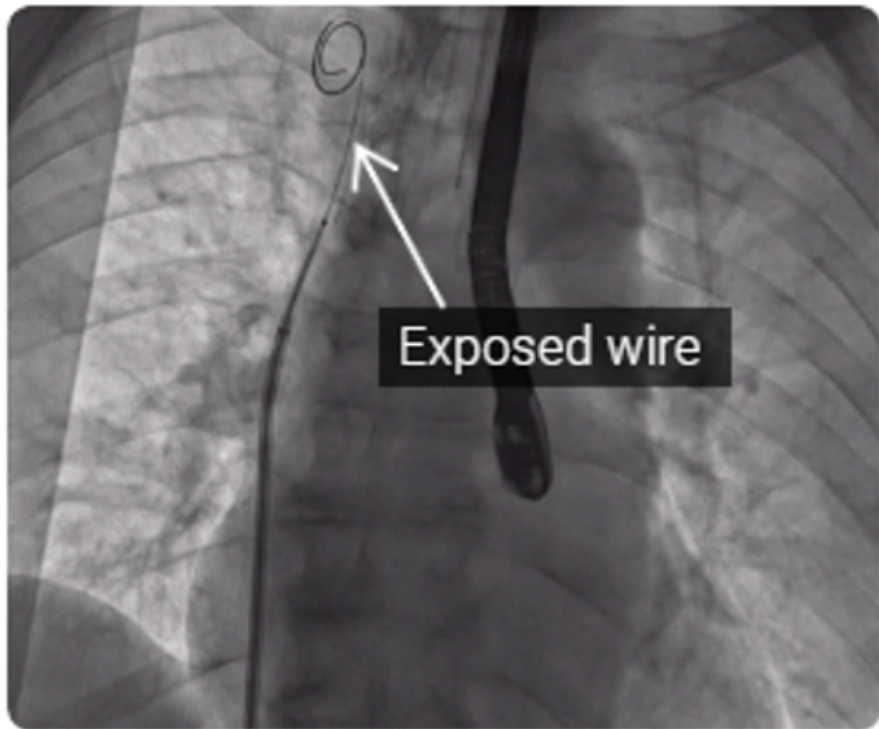


VersaCross™ RF wire Features

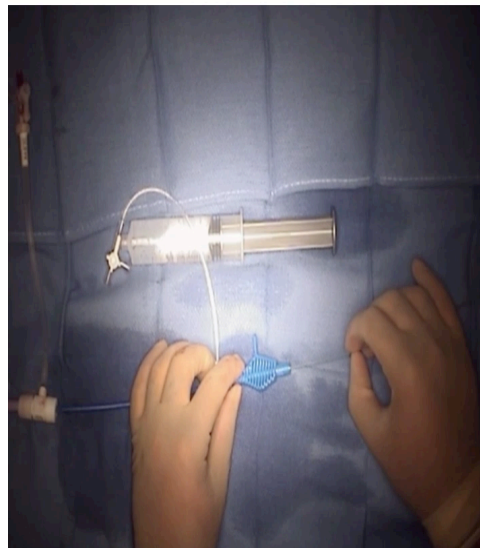
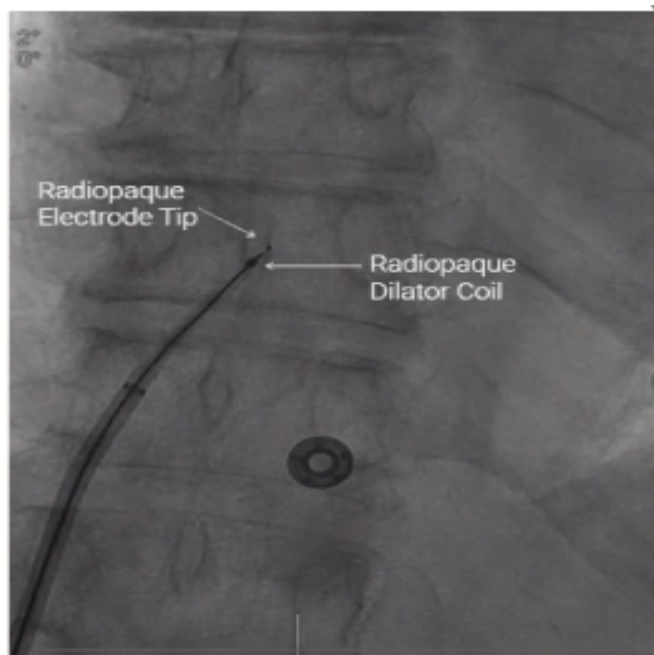


IL SISTEMA VERSACROSS





IL SISTEMA VERSACROSS



Continually advance VersaCross® RF Wire.

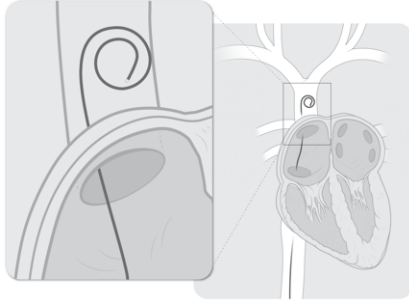


Use imaging to confirm pigtail/
J formation.

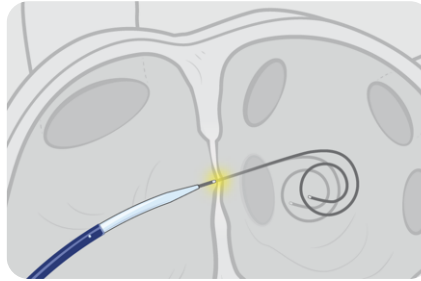


VersaCross™ RF Transseptal Solution eliminates exchanges: Left heart access with a single solution from start to finish

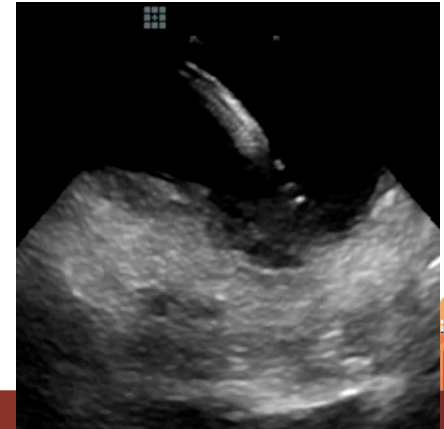
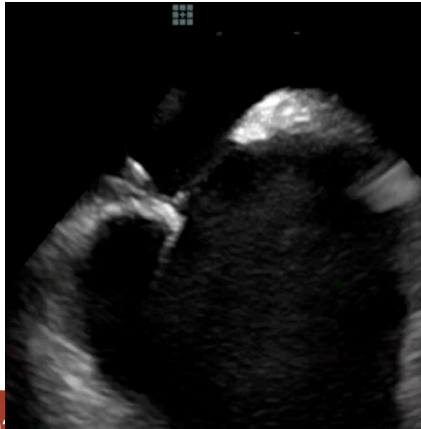
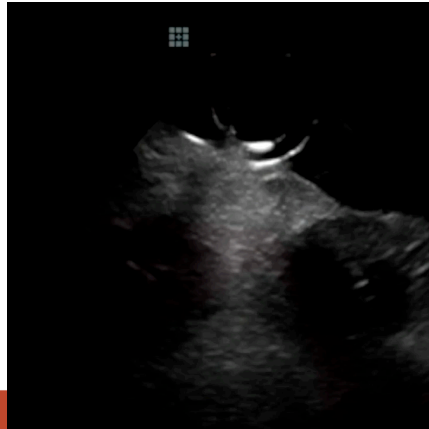
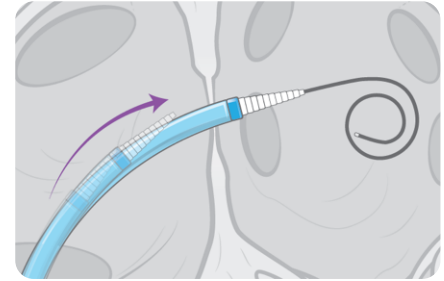
Use as a
starter wire



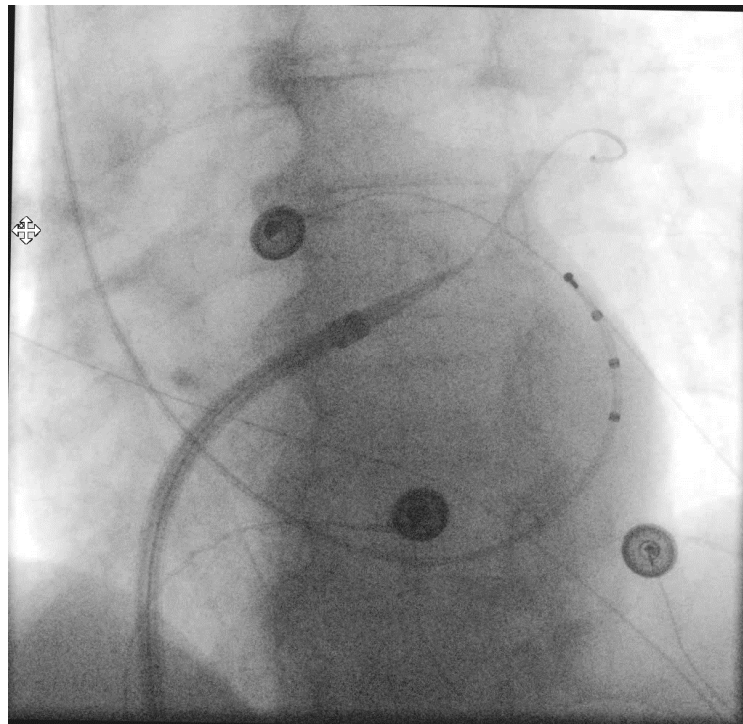
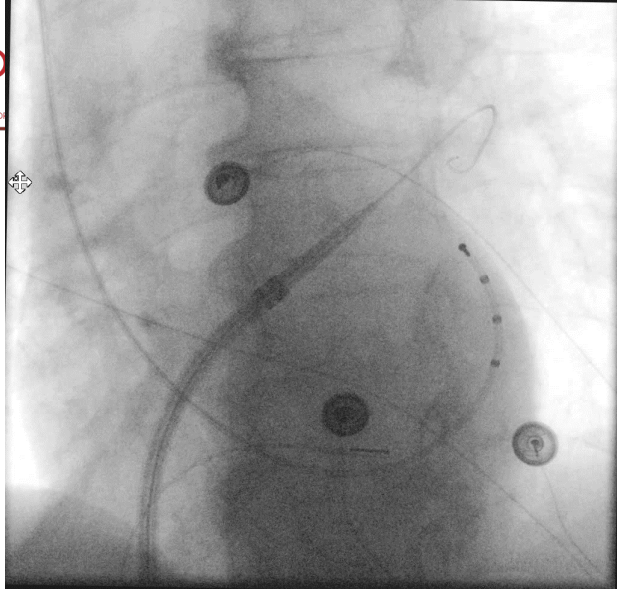
Access with
RF puncture technology



Deliver
therapy device



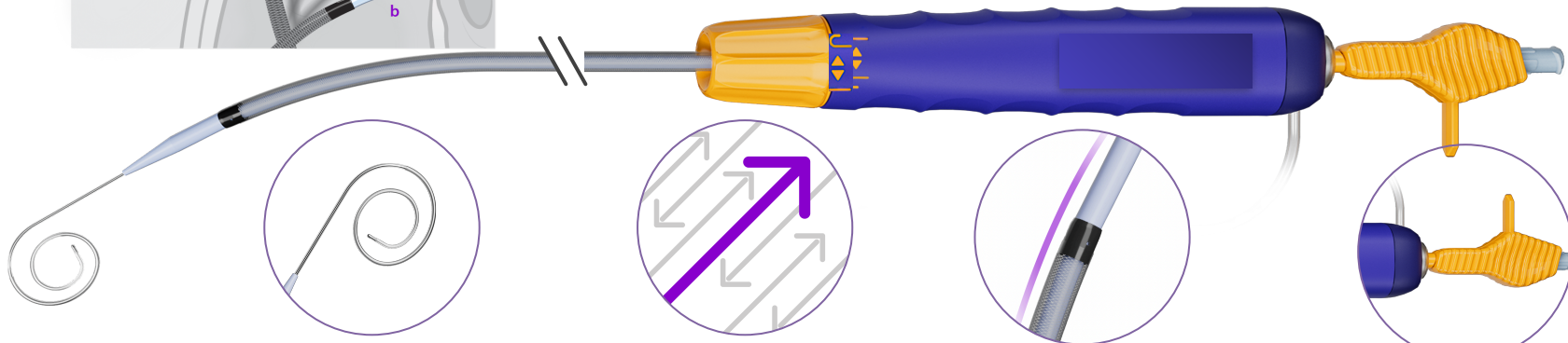
Difficoltà puntura tradizionale: spinta nel
passaggio allo scambio 2° introduttore



TRUform Shapeable Technology

Consider Dilator Curve Modification

TRUform Shapeable Technology allows to personalize the shape of the dilator curve



3-in-1 RF Pigtail* Wire

Allows advancement to SVC, RF transseptal puncture, and delivery of FARADRIVE Steerable Sheath

*J-tip option is also available.

Zero-Exchange

Predictable wire-based transseptal puncture with no exchanges to FARADRIVE Steerable Sheath introduction

Smooth Transition

Smooth dilator-sheath transition between VersaCross Connect and delivery sheath

Snap-Fit Lock

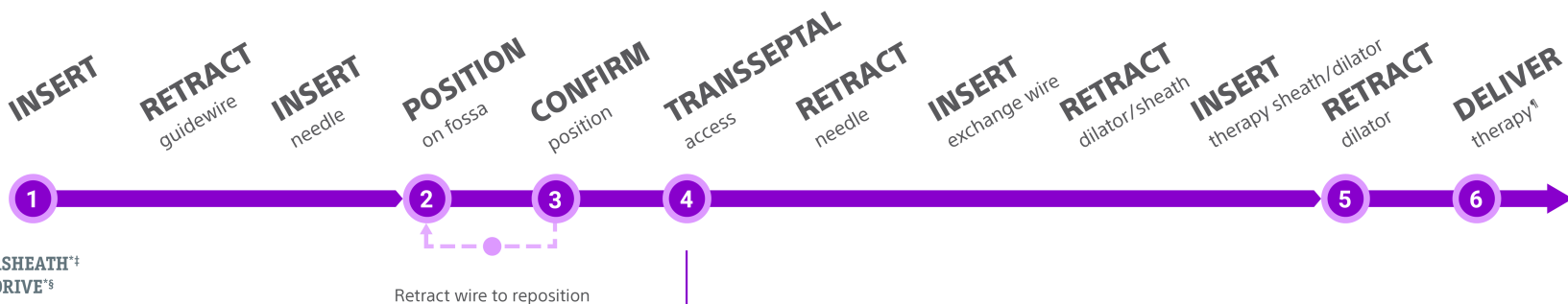
Designed for consistency and reliability
Does NOT provide *rotational lock*



Needle-based workflow versus wire-based workflow

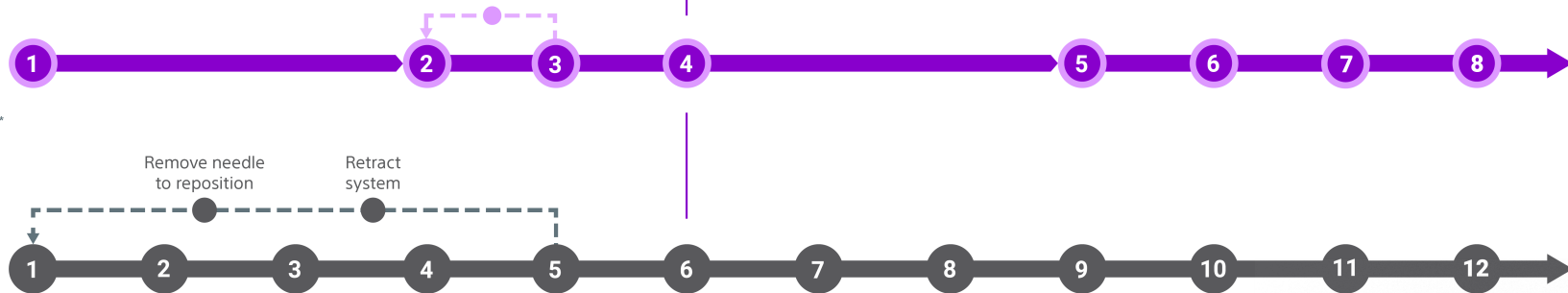
VersaCross Connect™

LAAC Access Solution†
Access Solution for POLARSHEATH‡
Access Solution for FARADRIVE§



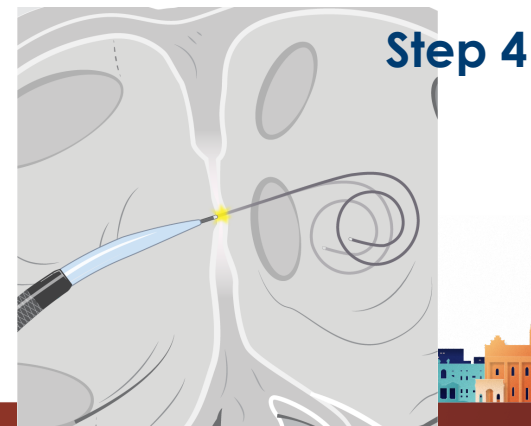
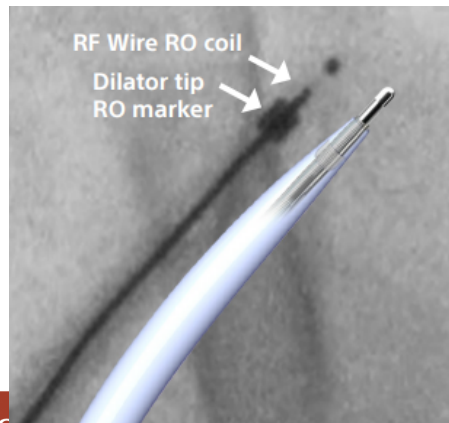
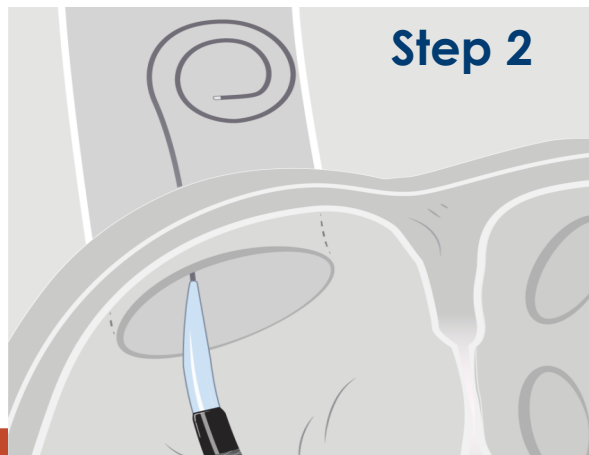
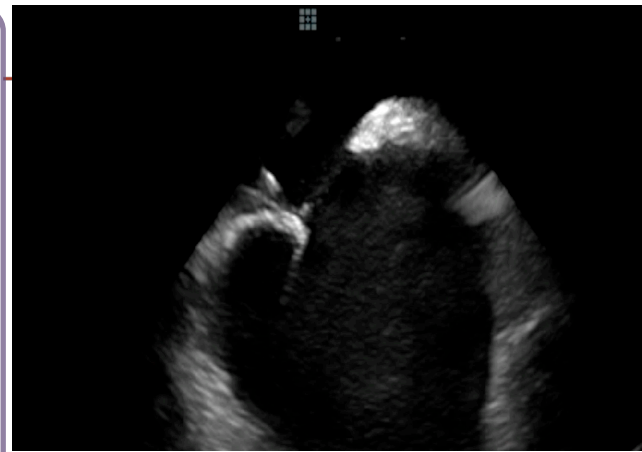
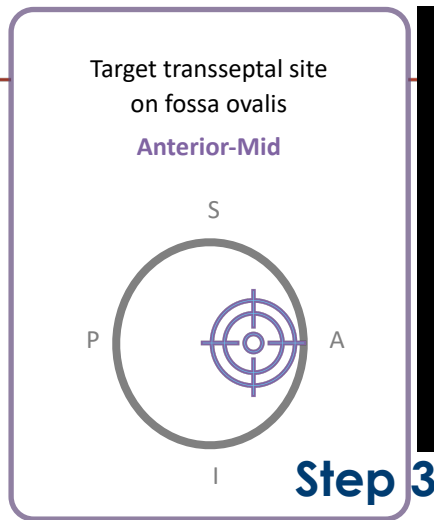
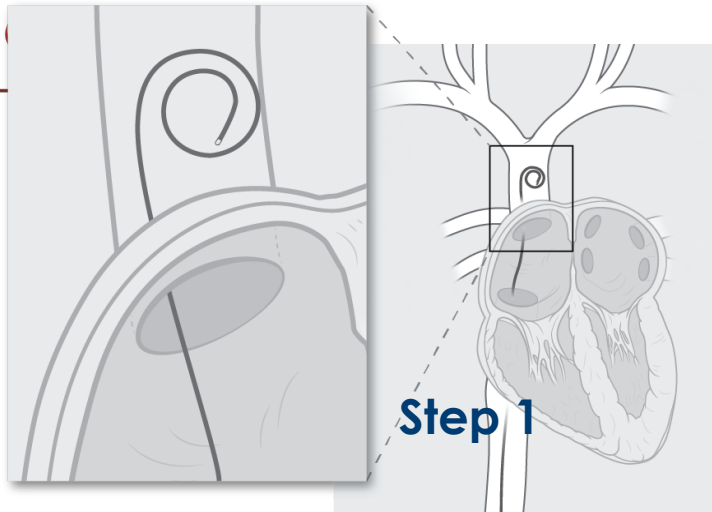
VersaCross™

Access Solution*
Large Access Solution*
Steerable Access Solution*



Needle-based workflow





Screening

1

Workflow

2

Study Endpoints

3

First Time PVI
Age 18 – 85 years
Written informed
consent

Cardiac MRI:
LA Anatomy eligible for
PFA



Primary Endpoint

Procedural Workflow Efficiency
(total procedural time)

Secondary Endpoints

TSP characteristics

- Number of TSP Attempts
- First-pass success

Radiation exposure

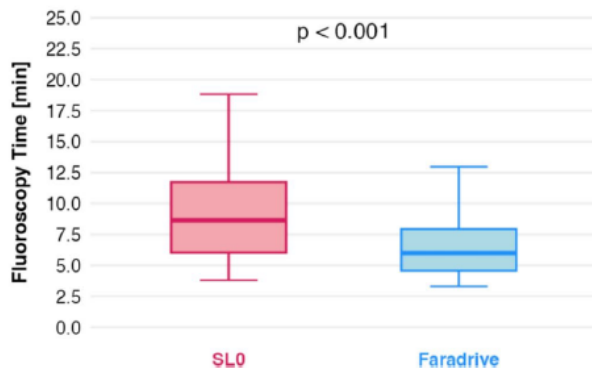
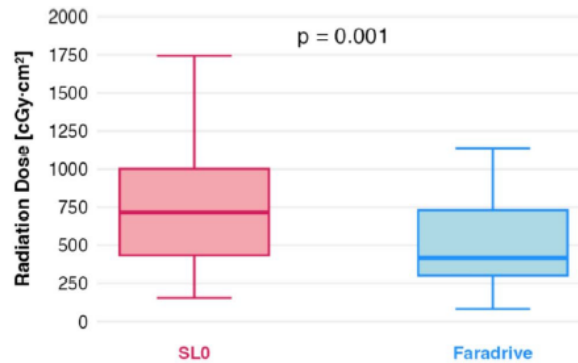
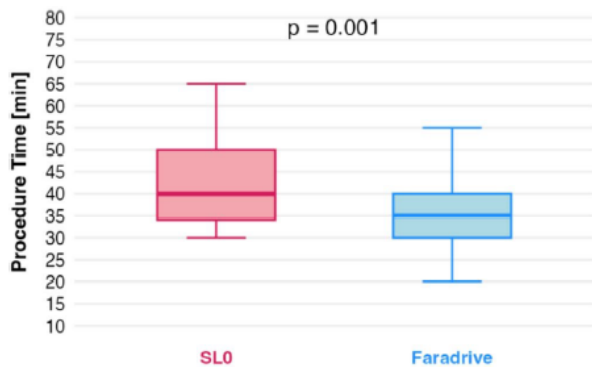
- Fluoroscopy Time
- Radiation Dose

Safety outcomes

- Procedural complications

Workflow resource utilization

- Sheath crossover
- Cost effectiveness



Conclusions

- ICE-use improves safety and accuracy even in single-shot ablation with PFA
- Single-shot PFA is a simple procedure and trans-septal puncture must also be
- Workflow can be improved with different techniques and technologies, but perfect knowledge of anatomy and the experience of the center are critical to improving safety

