

Cardiologia Estrutural

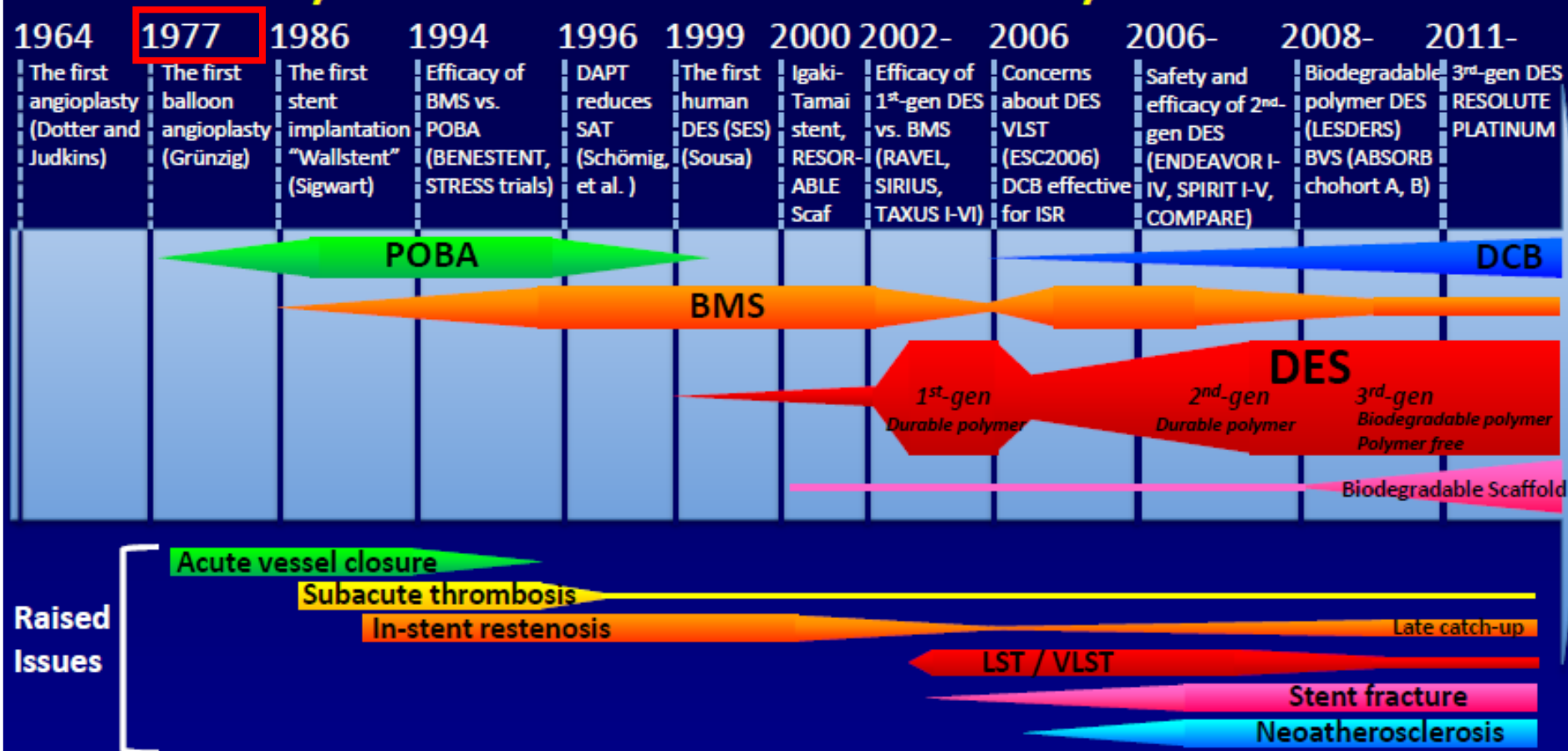
O Santo Graal da década?

R. Seabra Gomes

Congresso Novas Fronteiras em Cardiologia

Ericeira, 9 de Fevereiro 2013

History of Percutaneous Coronary Intervention

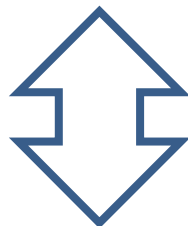


	Balloon Angioplasty	BMS	DES
Success rate	70-85%	>95%	>95%
Restenosis	40-45%	20-30%	<10%
Early Thrombosis (≤ 30 days)	3-5%	1-2%	1-2%
Late Thrombosis (> 30 days, ≤ 1 y)	NA	<0.5%	1%
Very Late Thrombosis (> 1 y)	NA	$\approx 0\%$	1-2%

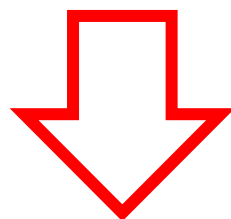
Cardiologia de Intervenção

Evolução

Intervenção Coronária Percutânea

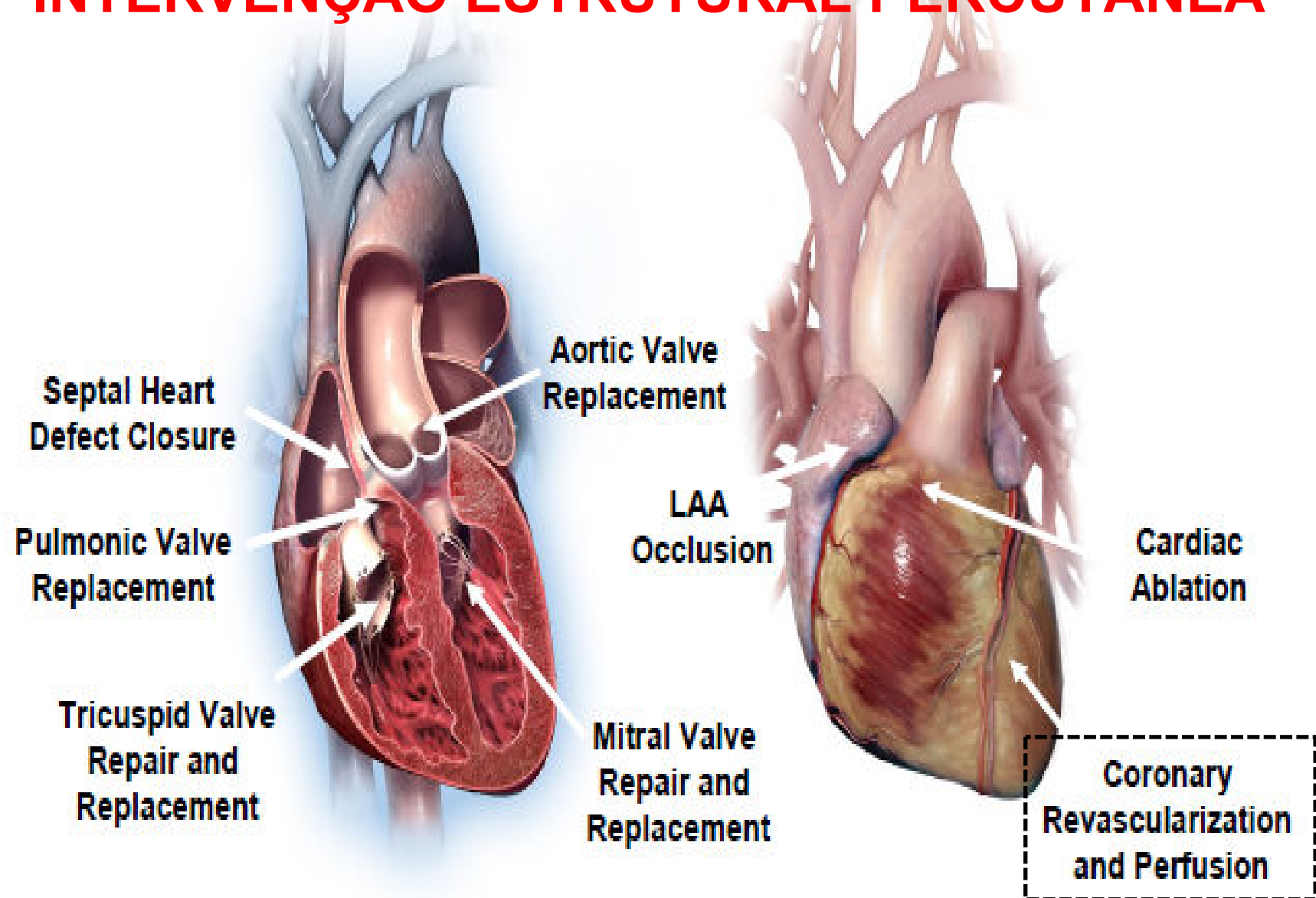


Intervenção Vascular Percutânea



Intervenção Estrutural Percutânea

INTERVENÇÃO ESTRUTURAL PERCUTÂNEA



INTERVENÇÃO ESTRUTURAL PERCUTÂNEA

A implantação percutânea de válvulas aórticas como paradigma

Pulmonic Valve
Replacement

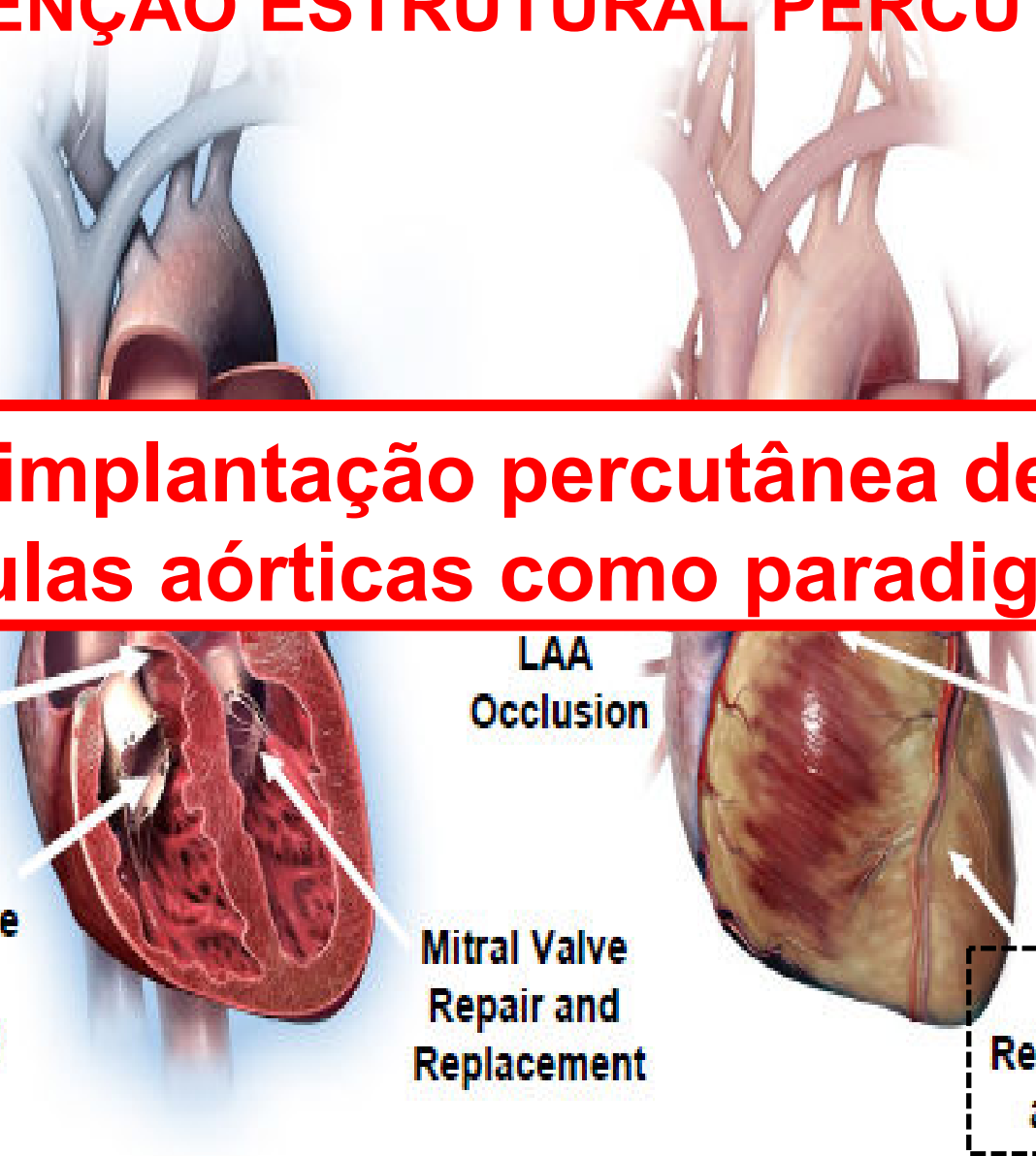
Tricuspid Valve
Repair and
Replacement

LAA
Occlusion

Mitral Valve
Repair and
Replacement

Cardiac
Ablation

Coronary
Revascularization
and Perfusion

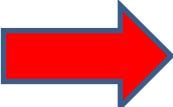


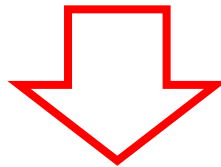
Cardiologia de Intervenção

Evolução

Intervenção Coronária Percutânea

Intervenção Vascular Percutânea

 **Essencialmente uma prática individual**

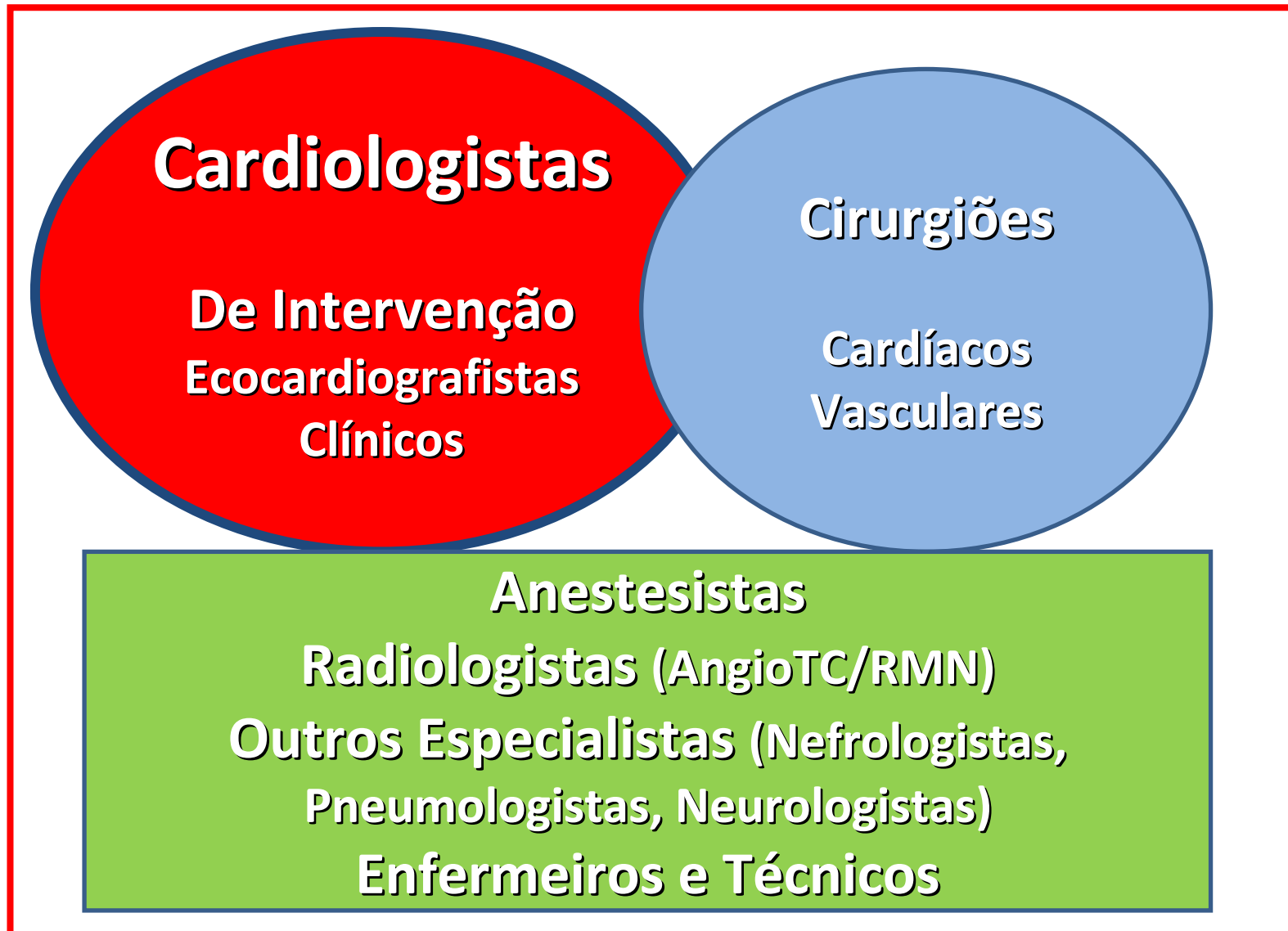


Intervenção Estrutural Percutânea

 **Multidisciplinar - Requer um “Team Approach”**

Intervenção Estrutural Percutânea

HEART TEAM

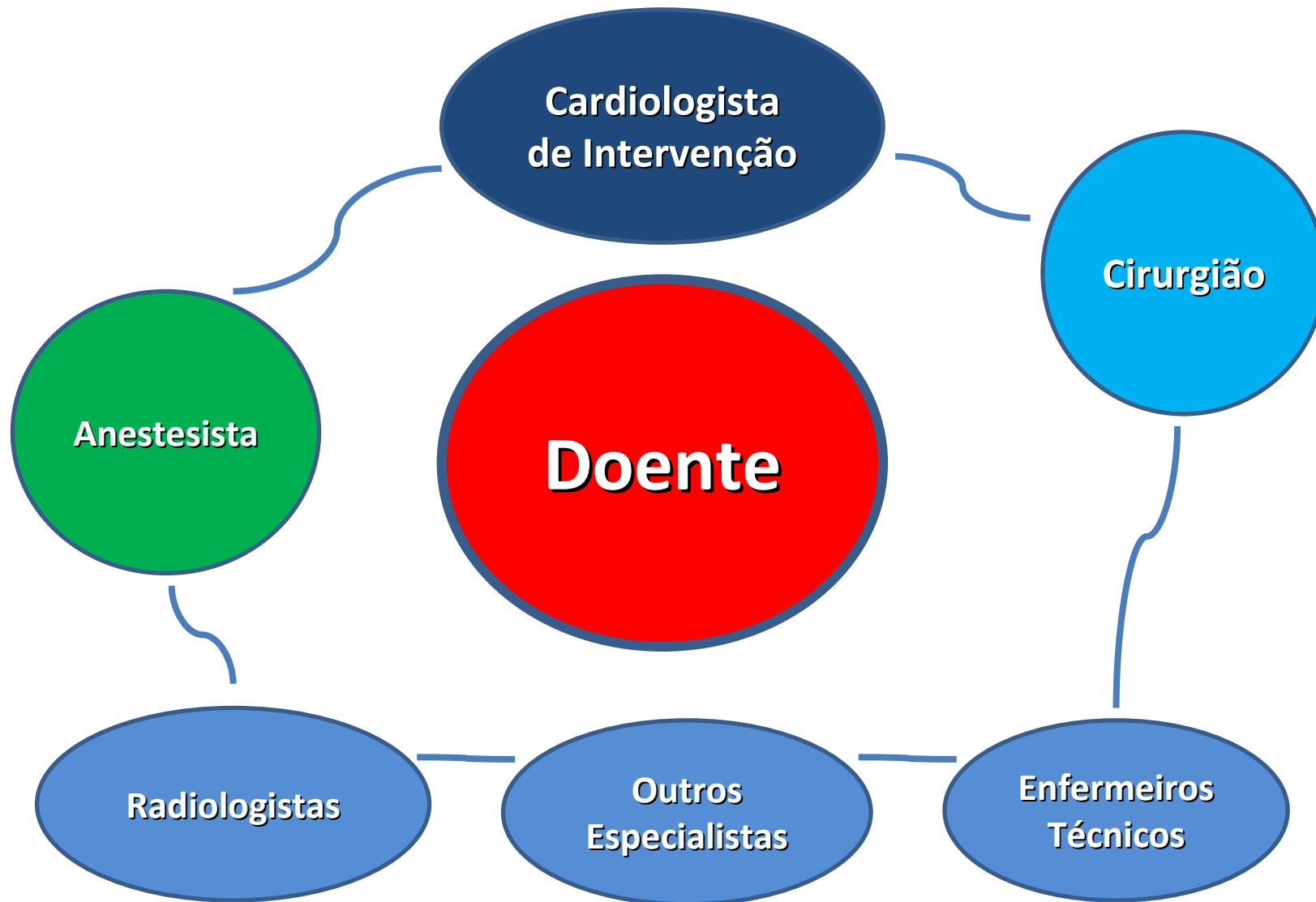




"We like the teamwork idea, but Mr. Superstar won't let us play with his ball."

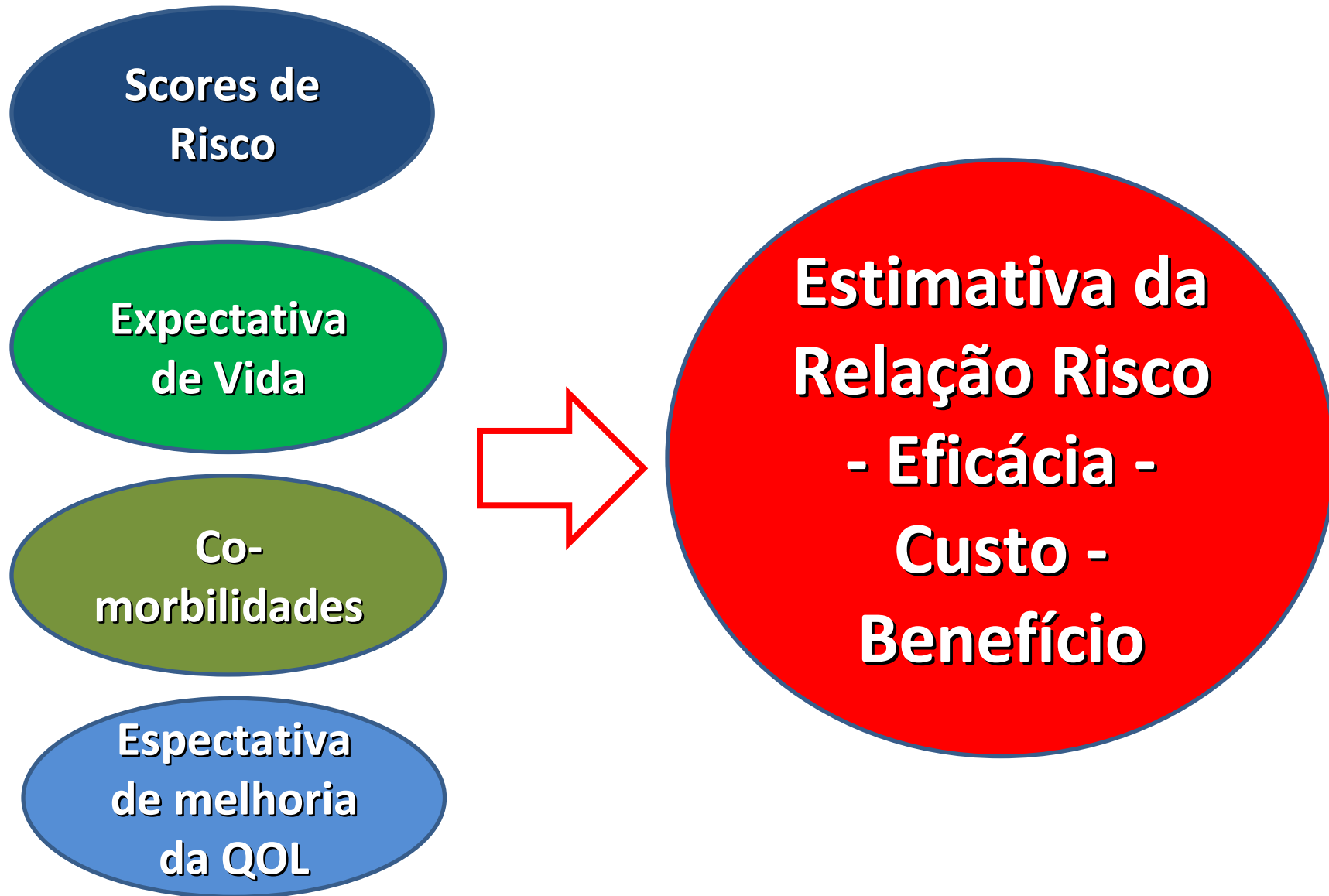
Intervenção Estrutural Percutânea

CENTRADA no DOENTE

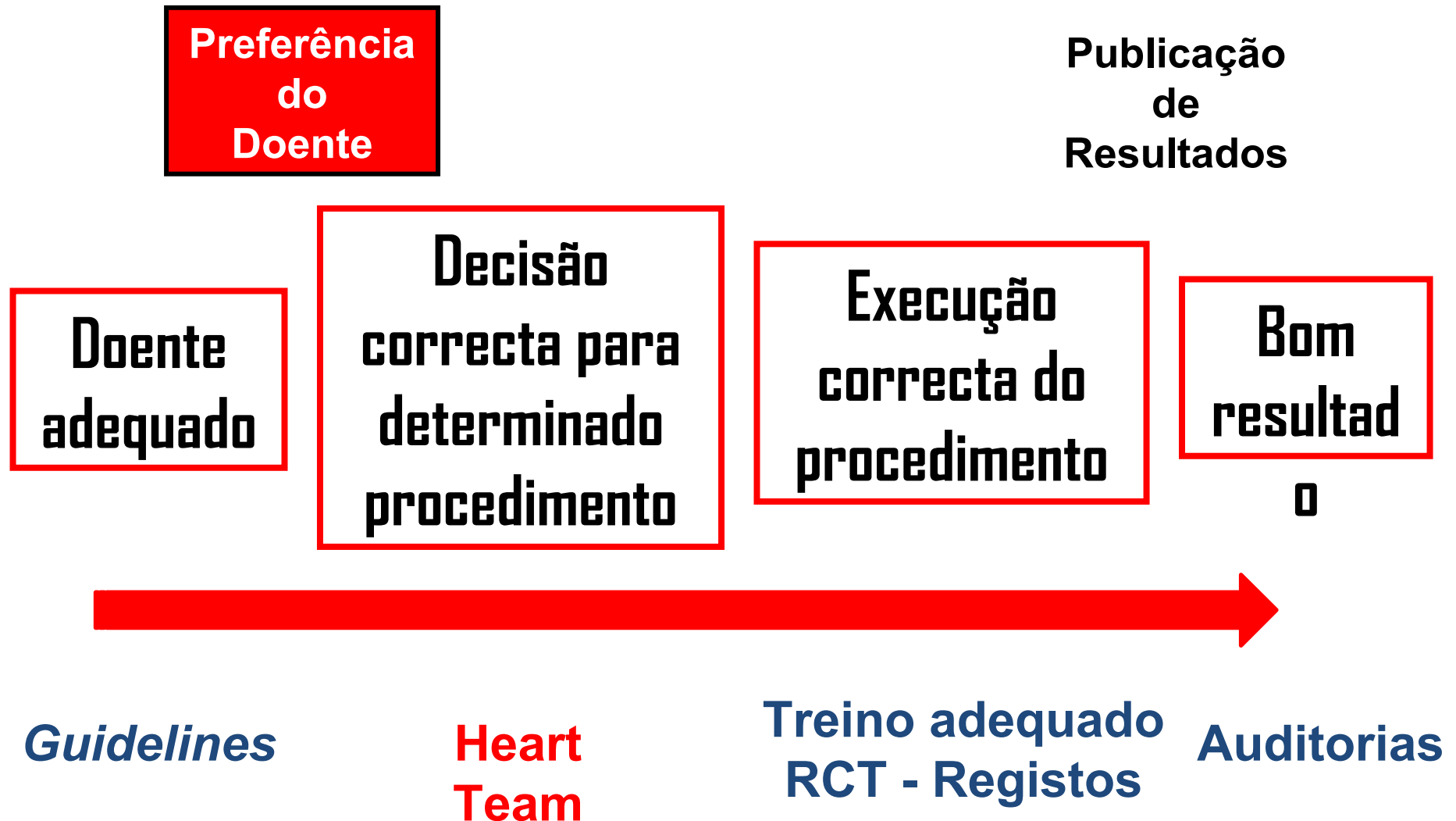


Intervenção Estrutural Percutânea

CENTRADA no DOENTE



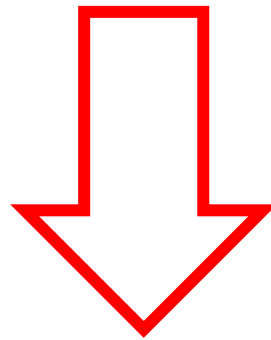
Regras para procedimentos cardiovasculares de alta qualidade



Intervenção Estrutural Percutânea

Necessidades

HEART TEAM



Centros de Excelência

**(concentração de recursos e experiências,
grandes oportunidades para treino de jovens
cardiologistas, etc.)**

Intervenção Estrutural Percutânea

Âmbito Actual

1. Válvula Mitral

- a) Valvotomia mitral
- b) Reparação valvular
- c) Próteses percutâneas

2. Válvula Aórtica

- a) Valvoplastia de balão
- b) Próteses percutâneas

3. Válvula Pulmonar

- a) Valvotomia de balão
- b) Próteses percutâneas

4. Válvula Tricúspide

5. CIA e FOP

6. CIV (pós enfarte)

7. Canal Arterial Permeável

8. Apêndice Auricular Esquerdo

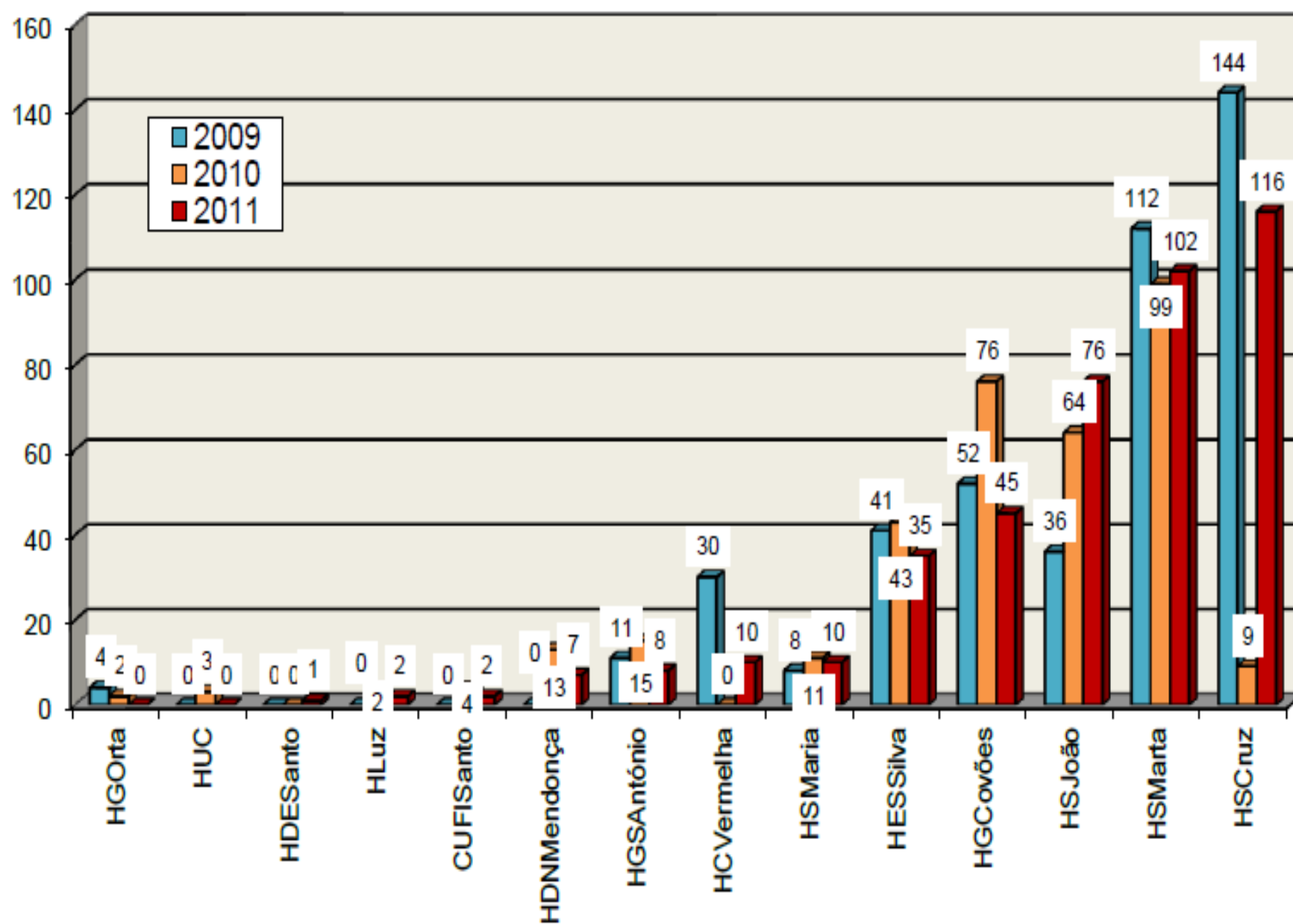
9. *Leaks* para valvulares

10. Ablação septal na CMH

11. Coartação da aorta

12. Aorta (aneurismas)

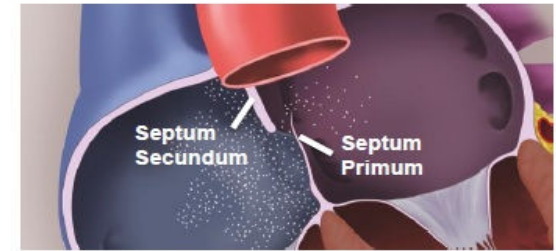
Procedimentos para Encerramento Percutâneo de Shunts: CIAs, FOPs, Canal Arterial





Encerramento de FOP

Agitated saline study demonstrating right to left shunting through the PFO



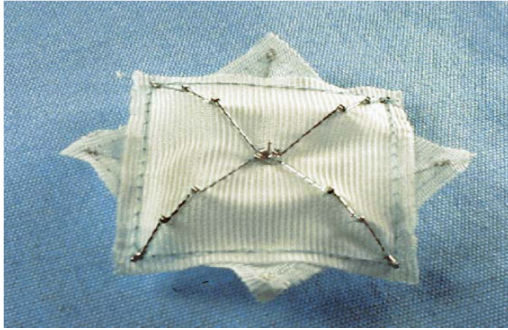
- **Sempre - AVC criptogénico**

(*Orthodeoxia Platypnea* (sat.O₂<92%), Edema pulmonar em alta altitude, abscesso cerebral)

- **Algumas vezes**

(EAM com trombo isolado e coronárias normais por IVUS, doença grave de descompressão, apneia do sono grave, fenómeno de Raynaud, AIT com RMN normal, profilaticamente na presença de trombose venosa profunda ou embolismo pulmonar, Migraine com aura ?)

- **Nunca - FOP assintomático ou achado ecocardiográfico** (20% da população)
(demência ?)



Encerramento de FOP

Possíveis Indicações

- **Prevenção Secundária**

AVC, AIT, EAM embólico,
Embolismo periférico,
Compressão accidental

- **Prevenção Primária**

Potencial agravamento por
existência de FOP (ASIA),
Trombose venosa profunda,
Embolia pulmonar, Cirurgia
de potencial risco
(ortopédica), Gravidez
planeada

- **Por razões terapêuticas**

Migraine, Platypnea –
orthodeoxia, Apneia do
sono, Desaturação
induzida pelo esforço

- **Por razões vocacionais
ou recreativas**

Mergulho em profundidade,
Músicos de sopro, Pilotos de
jacto ou astronautas, Pilotos
ou condutores comerciais

Doentes Submetidos a Valvulotomia Percutânea: Mitral, Aórtica e Pulmonar

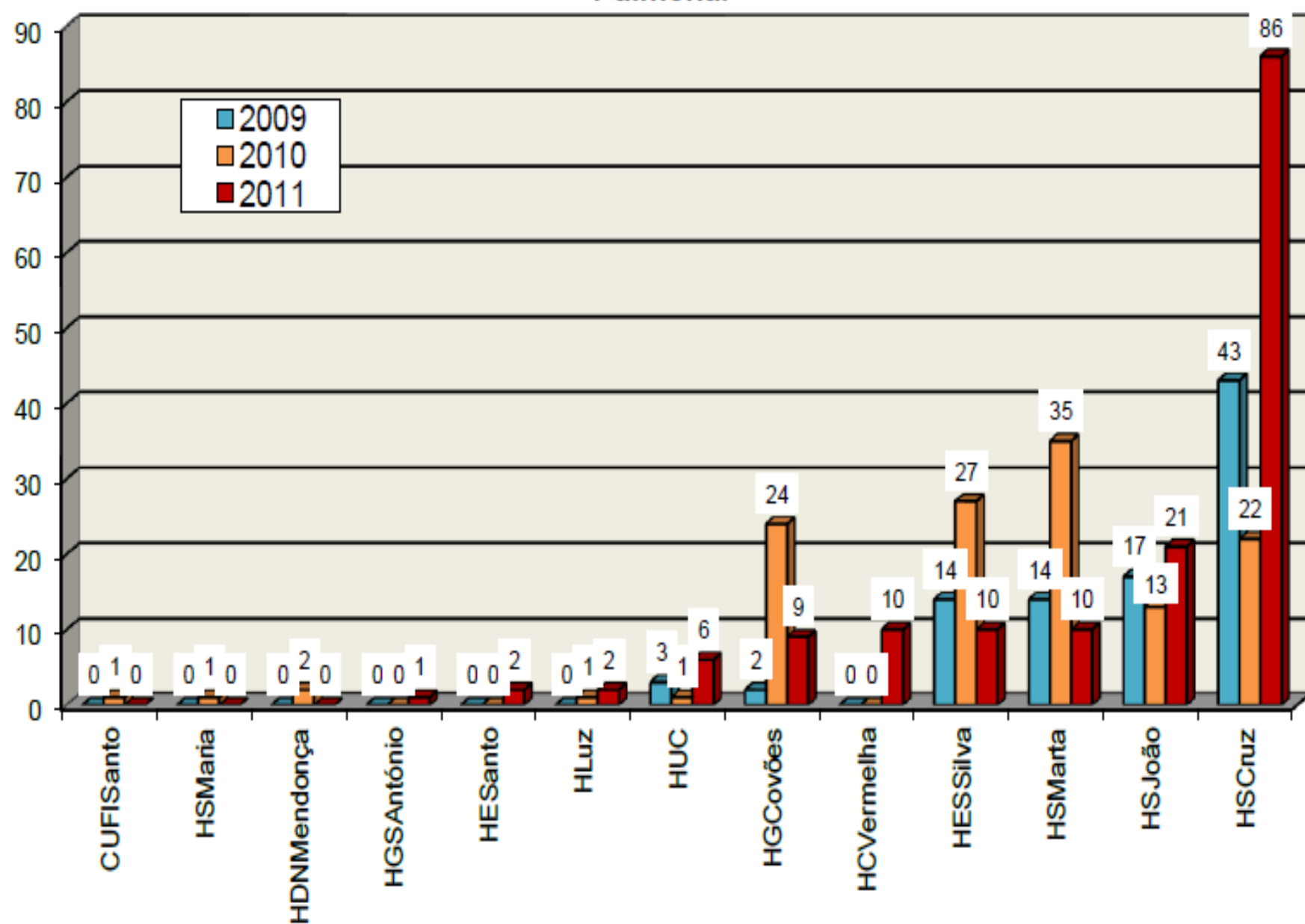


Image size: 512 x 512

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FPS: 24.8

Depth: 6.5 cm

26020764 (-, -) Image size: 512 x 512

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FPS: 24.8

Depth: 6.5 cm

26020764 (-, -)

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Zoom: 126% Angle: 0

Im: 115/303

JPEGBaseline

Zoom: 126% Angle: 0

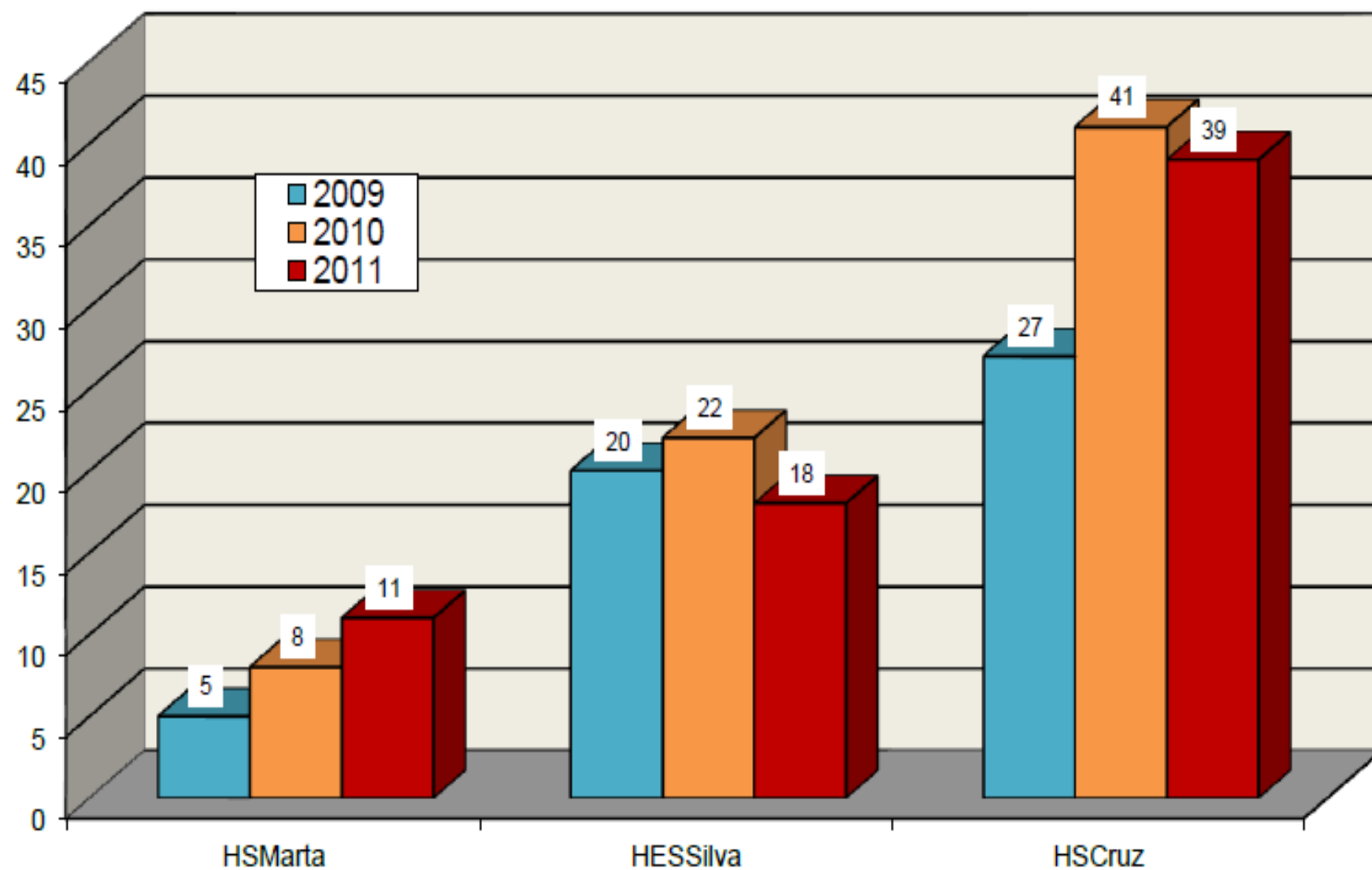
13/01/21 11:08:49 Im: 140/303

Made In OsiriX JPEGBaseline

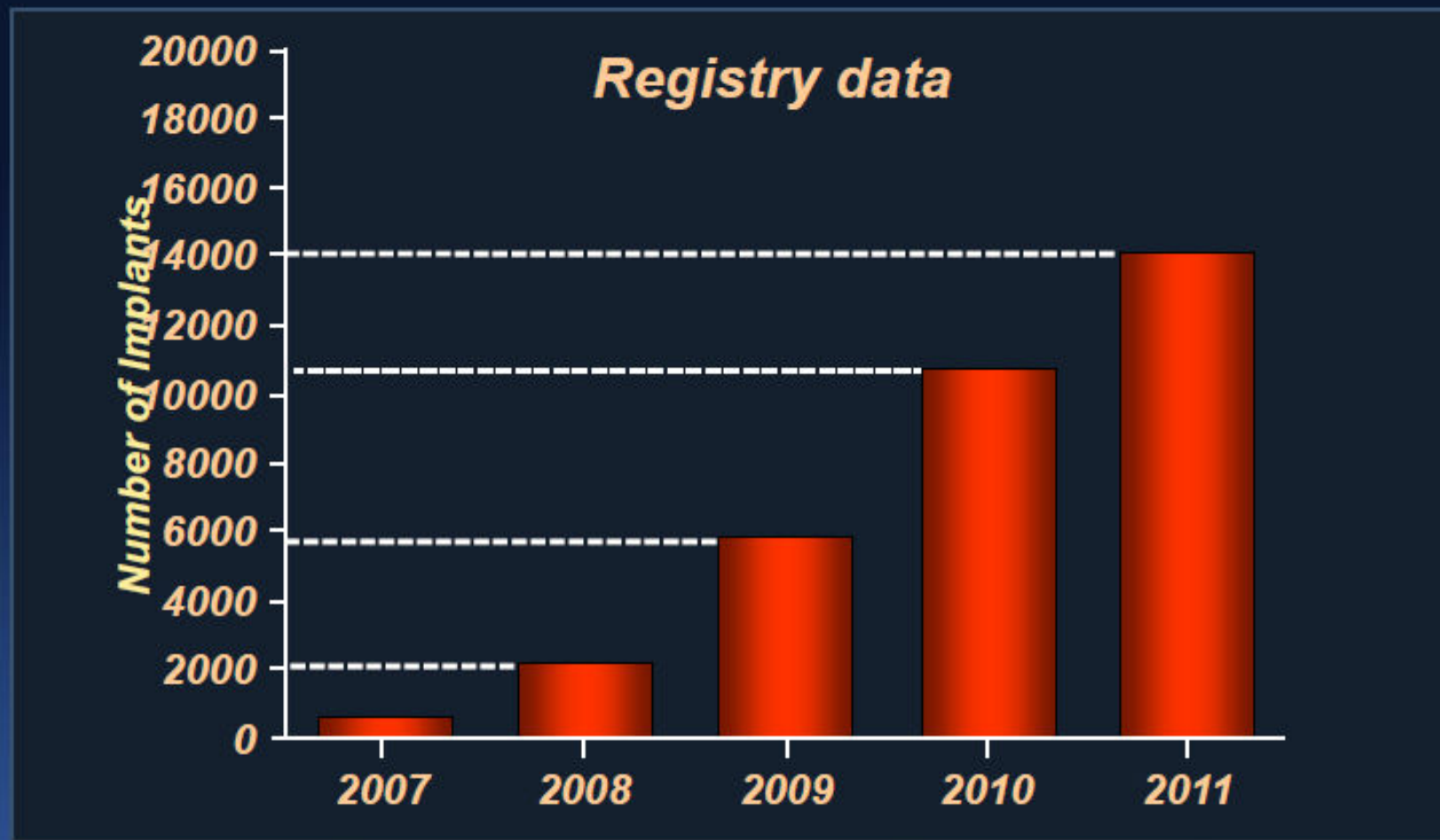
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Implantações de Próteses Valvulares Percutâneas



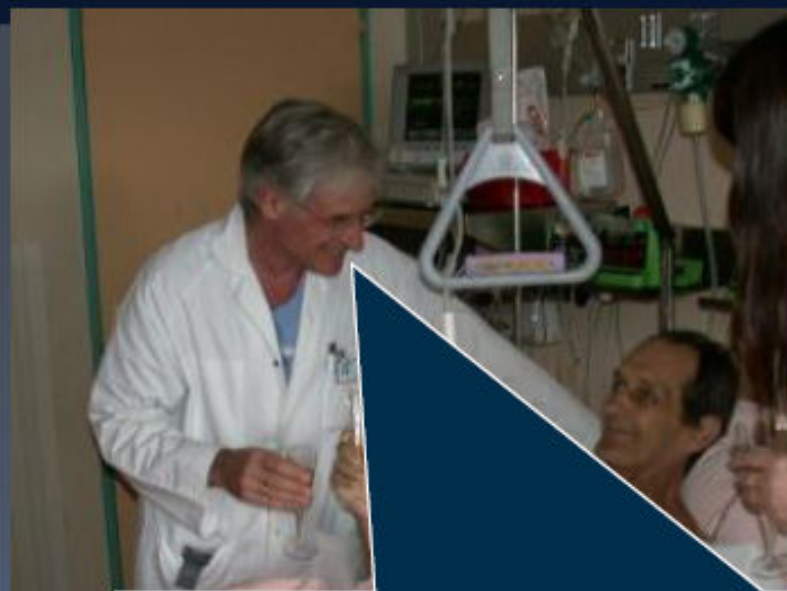
Number of TAVI Implants/Year Across EU-11



VÁLVULA AÓRTICA

Dr. Alain Cribier

First-in-Man PIONEER



Circulation

American Heart
Association
Learn and Live.

Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis

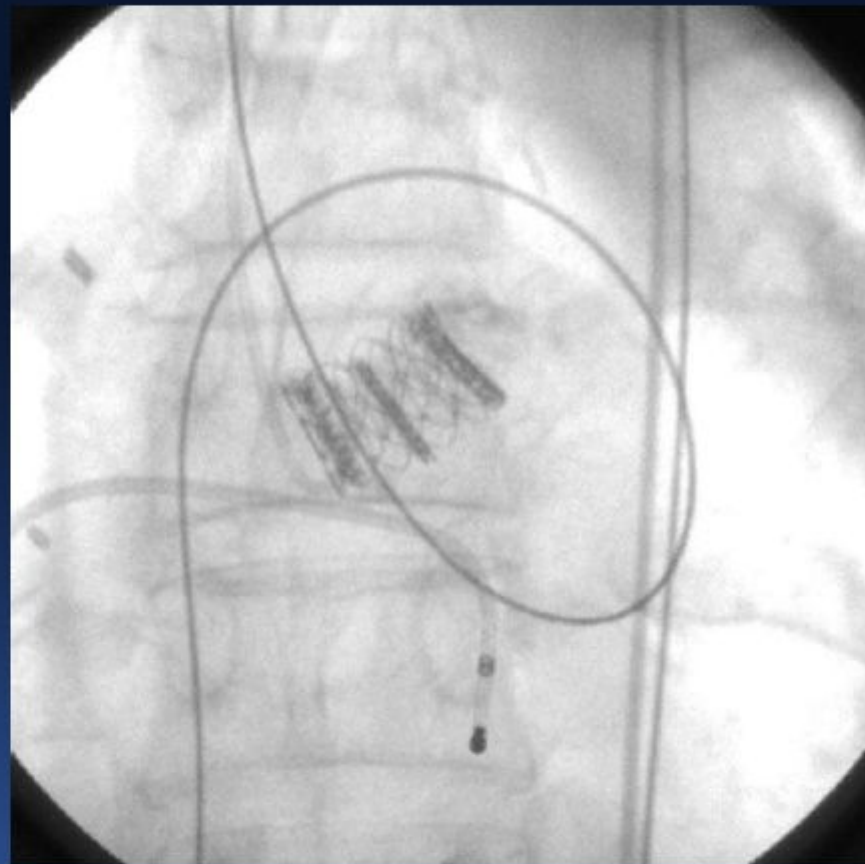
First Human Case Description

*Alain Cribier, MD; Helene Eltchaninoff, MD; Assaf Bash, PhD;
Nicolas Borenstein, MD; Christophe Tron, MD; Fabrice Bauer, MD;
Genevieve Derumeaux, MD; Frederic Anselme, MD; François
Laborde, MD; Martin B. Leon, MD*

Conclusions— *Nonsurgical implantation of a prosthetic heart valve can be successfully achieved with immediate and midterm hemodynamic and clinical improvement.*

April 16, 2002

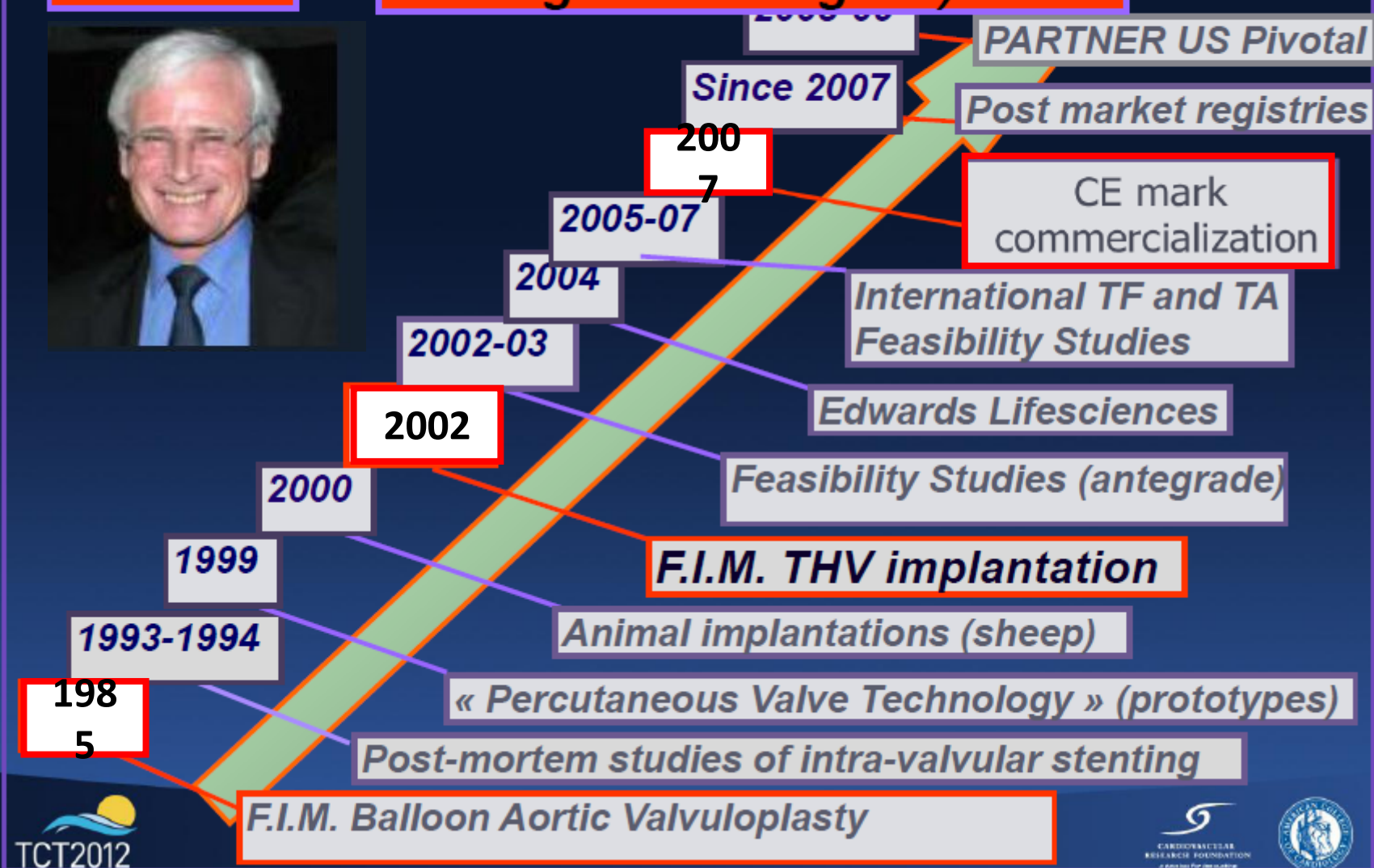
April 16, 2002, FIM-TAVI, Transseptal



Valve deployment

Nov 2011
Oct 2012

**FDA Approval (non-surgical
and high risk surgical)**



Guidelines on the management of valvular heart disease (version 2012)

Recommendations	Class ^a	Level ^b
TAVI should only be undertaken with a multidisciplinary 'heart team' including cardiologists and cardiac surgeons and other specialists if necessary.	I	C
TAVI should only be performed in hospitals with cardiac surgery on-site.	I	C
TAVI is indicated in patients with severe symptomatic AS who are not suitable for AVR as assessed by a 'heart team' and who are likely to gain improvement in their quality of life and to have a life expectancy of more than 1 year after consideration of their comorbidities.	I	B
TAVI should be considered in high-risk patients with severe symptomatic AS who may still be suitable for surgery, but in whom TAVI is favoured by a 'heart team' based on the individual risk profile and anatomic suitability.	IIa	B

Recomendações para TAVR

Classe I

- Requer um HEART TEAM
- Hospitais com cirurgia cardíaca
- Doentes não candidatos a cirurgia

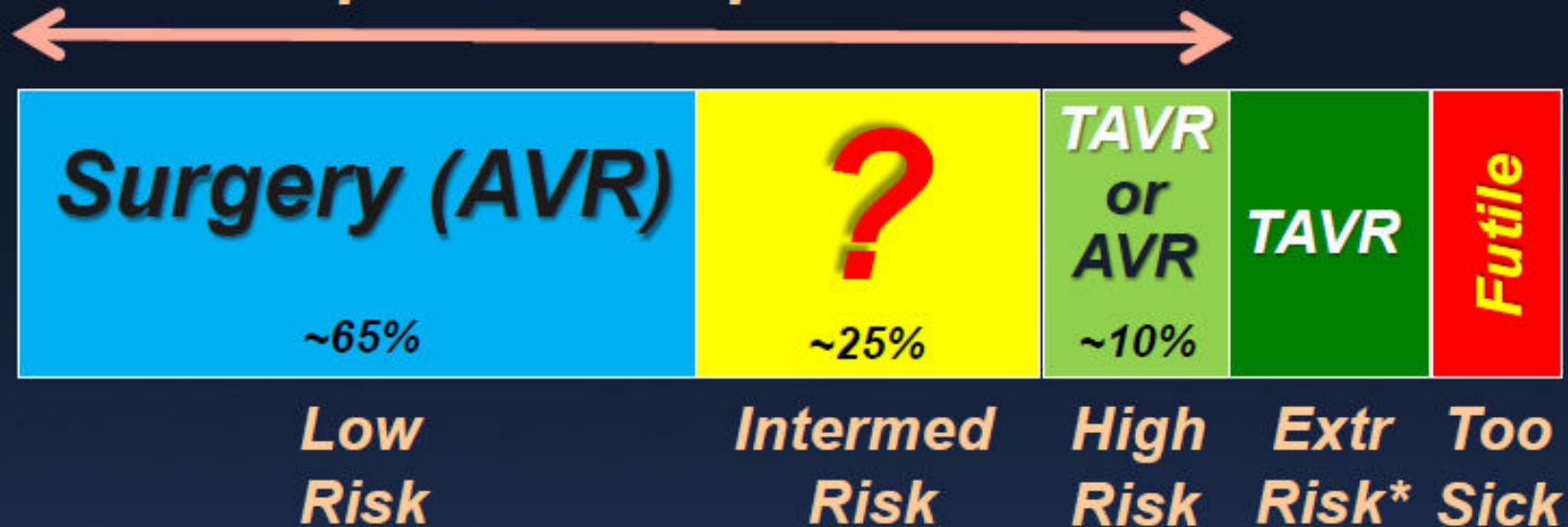
Classe IIa

- Doentes operáveis de alto risco em alternativa à cirurgia
- Avaliação pelo HEART TEAM
- Decisão individualizada

TAVR Categories

(risk is a continuum)

Operable AS patients



TAVR in 2012

*irresponsible,
reckless*

“equipoise” OK preferred No

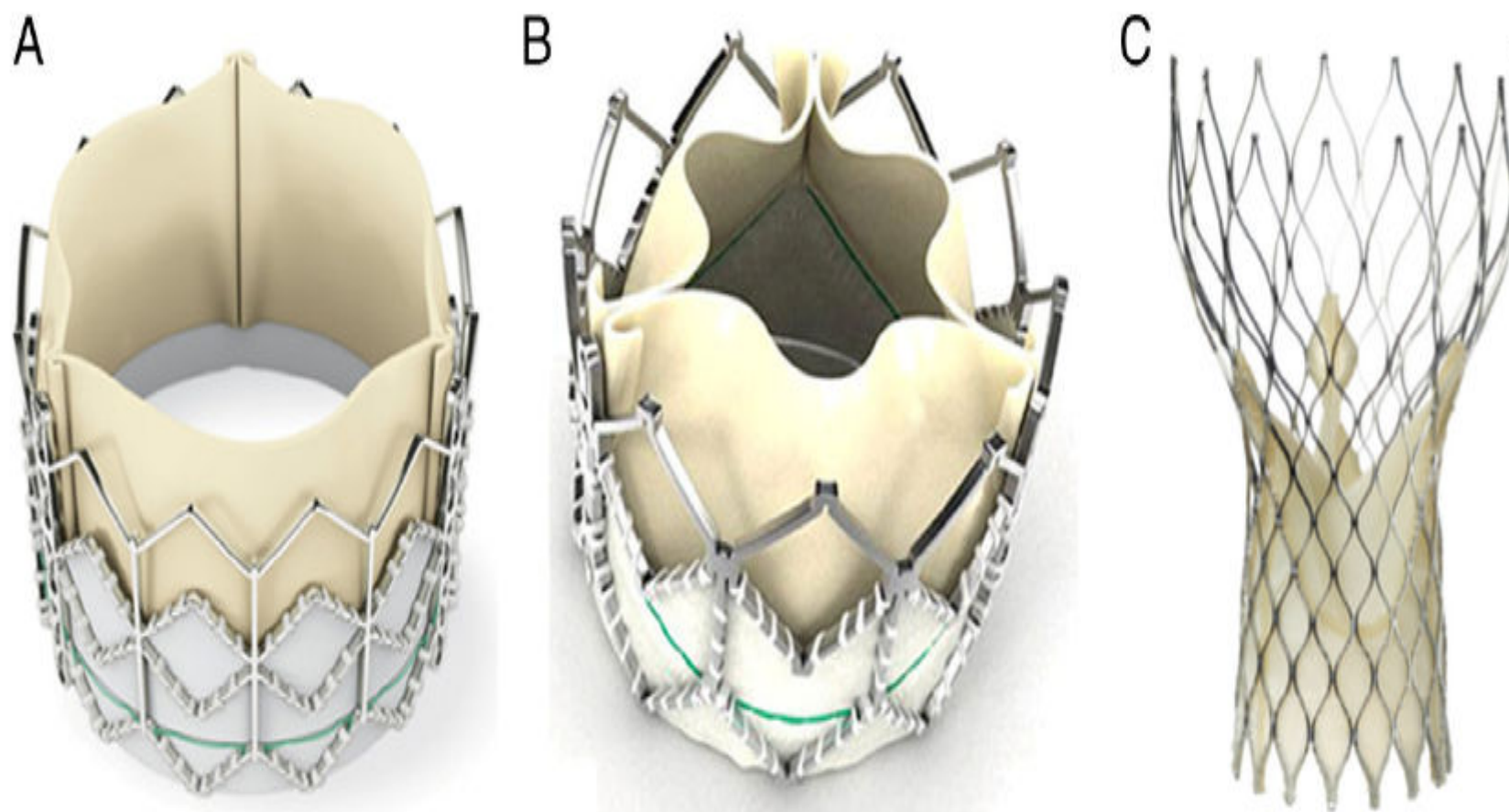


Figure 1 Current Widely Available Transcatheter Valves

(A) The Edwards SAPIEN THV balloon-expandable valve (Edwards Lifesciences, Irvine, California) incorporates a stainless steel frame, bovine pericardial leaflets, and a fabric sealing cuff. (B) The SAPIEN XT THV (Edwards Lifesciences) utilizes a cobalt chromium alloy frame and is compatible with lower profile delivery catheters. (C) The Medtronic CoreValve (Medtronic, Minneapolis, Minnesota) incorporates a self-expandable frame, porcine pericardial leaflets, and a pericardial seal.

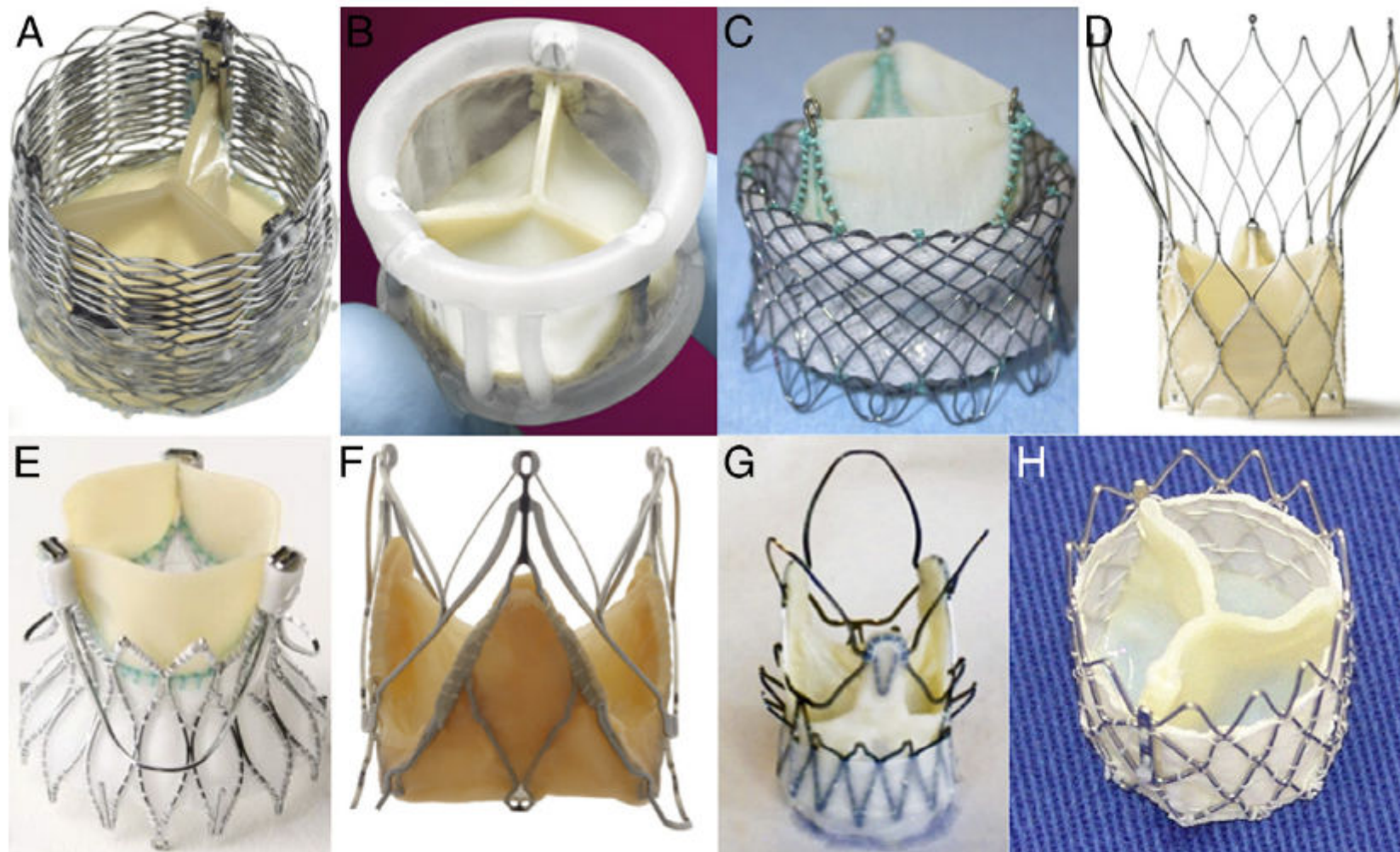


Figure 4 Valves Undergoing Early Evaluation

(A) Lotus (Boston Scientific Inc., Natick, Massachusetts), (B) Direct Flow (Direct Flow Medical Inc., Santa Rosa, California), (C) HLT (Bracco Inc., Princeton, New Jersey), (D) Portico (St. Jude Medical Inc., St. Paul, Minnesota), (E) Engager (Medtronic Inc., Minneapolis Minnesota), (F) JenaClip (JenaValve Inc., Munich, Germany), (G) Acurate valve (Symetis Inc., Ecublens, Switzerland), and (H) Inovare (Braile Biomedica Inc., São José do Rio Preto, Brazil) valves.

Clinical Outcomes After Transcatheter Aortic Valve Replacement Using Valve Academic Research Consortium Definitions

A Weighted Meta-Analysis of 3,519 Patients From 16 Studies

Philippe Généreux, MD,*† Stuart J. Head, MSc,‡ Nicolas M. Van Mieghem, MD,§
Susheel Kodali, MD,* Ajay J. Kirtane, MD, SM,* Ke Xu, PhD,* Craig Smith, MD,*
Patrick W. Serruys, MD, PhD,§ A. Pieter Kappetein, MD, PhD,‡ Martin B. Leon, MD*

New York, New York; Montréal, Québec, Canada; and Rotterdam, the Netherlands



TAVR Outcomes - VARC Meta-Analysis

(16 studies; 3,519 patients)

Endpoint	Pooled Estimate (%)	[95% CI]
----------	---------------------	----------

Mortality

All @ 30 days	7.8	[5.5, 11.1]
CV @ 30 days	5.6	[3.7, 8.3]
All @ 1 year	22.1	[17.9, 26.9]
CV @ 1 year	14.4	10.6, 19.5

Strokes @ 30 days

Major	3.2	[2.1, 4.8]
Major + minor	4.0	[2.4, 6.3]
TIA	1.2	[0.0, 2.3]
All	5.7	[3.7, 8.9]

TAVR Outcomes - VARC Meta-Analysis

(16 studies; 3,519 patients)

<i>Endpoint</i>	<i>Pooled Estimate (%)</i>	<i>[95% CI]</i>
-----------------	----------------------------	-----------------

Vascular events @ 30 days

Major	11.9	[8.6, 16.4]
Minor	9.7	[6.7, 14.0]
All	18.8	[14.5, 24.3]

Bleeding @ 30 days

Life threatening	15.6	[11.7, 20.7]
Major	22.3	[17.8, 28.3]
Minor	9.9	[6.9, 14.3]
All	41.4	[35.5, 47.6]
Transfusion $\geq$ 1 unit	42.6	[19.8, 62.4]

TAVR Outcomes - VARC Meta-Analysis

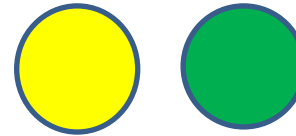
(16 studies; 3,519 patients)

<i>Endpoint</i>	<i>Pooled Estimate (%)</i>	<i>[95% CI]</i>
MI (peri-procedural)	1.1	[0.2, 2.0]
Valve performance @ 30 days		
AVA $\leq 1.2 \text{ cm}^2$	4.8	[3.0, 6.6]
Mean gradient $\geq 20 \text{ mmHg}$	1.0	[0.0, 2.1]
AR $\geq$ moderate (PVL)	7.4	[4.6, 10.2]
Valve-in-valve	2.3	[1.3, 4.5]
Valve embolization	1.7	[0.2, 3.3]
Perm Pacemaker @ 30 days		
Edwards	4.9	[3.9, 6.2]
MDT-Corevalve	28.9	[23.0, 36.0]

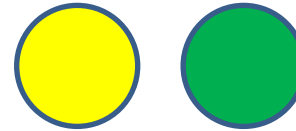
TAVR – Preocupações actuais

Complicações

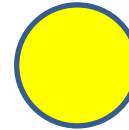
Complicações Vasculares



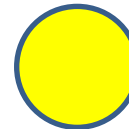
Leaks paravalvulares



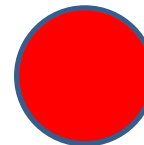
AVC



Necessidade de PM



**Durabilidade da Válvula
a longo-prazo**



TAVR – Aspectos práticos para o médico referenciador

- **Doente assintomático com boa FVE**

Indicadores de gravidade da EA (área valvular < 0,6 cm²; *peak velocity* > 5 m/seg)

Indicadores de progressão da EA - seguimento a 1 ano (diminuição da área valvular > 0,2 cm²; aumento da *jet velocity* > 0,3 m/seg)

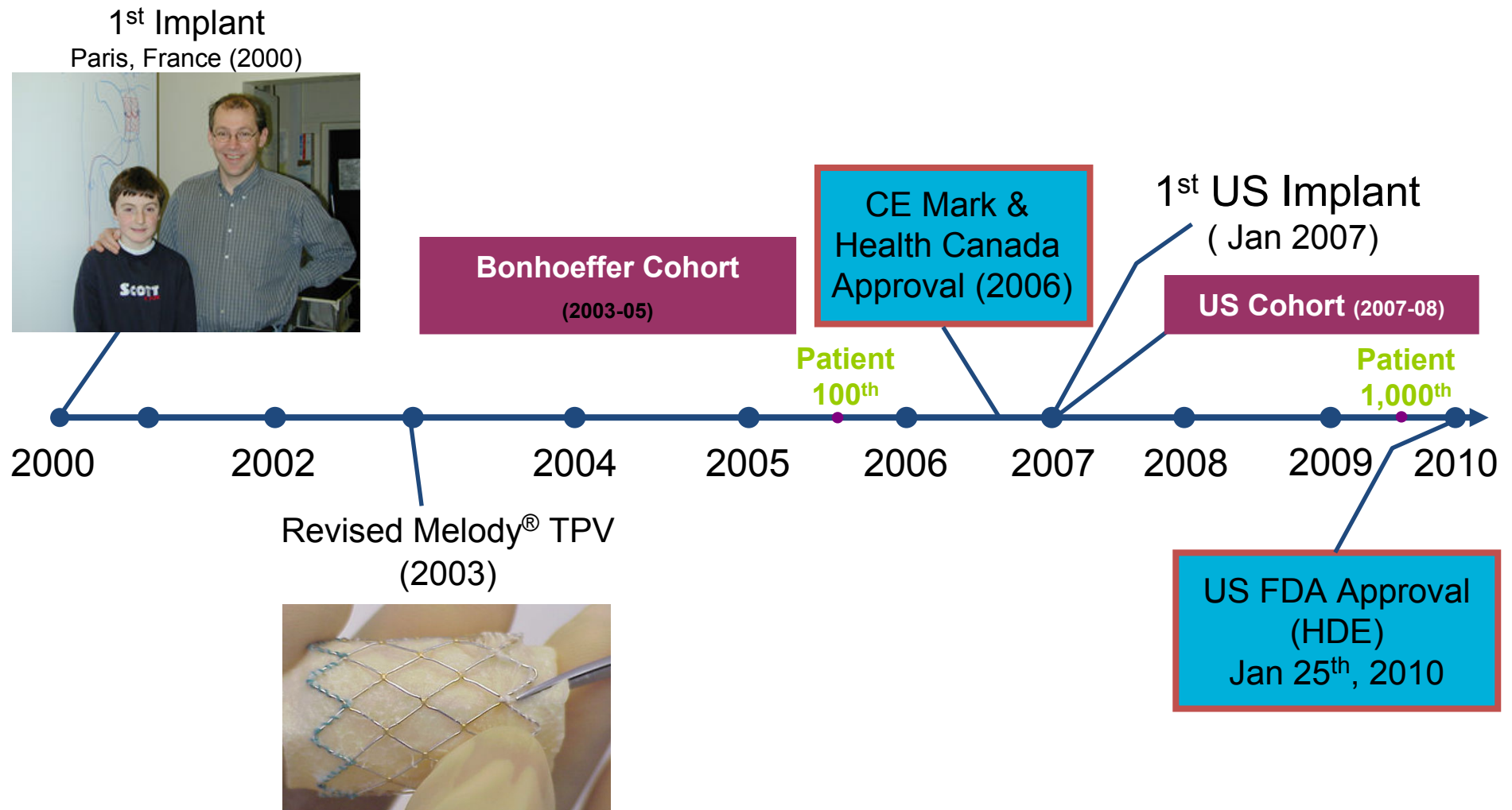
Qual a expectativa de vida e de melhoria da QOL?

O que deseja o doente?

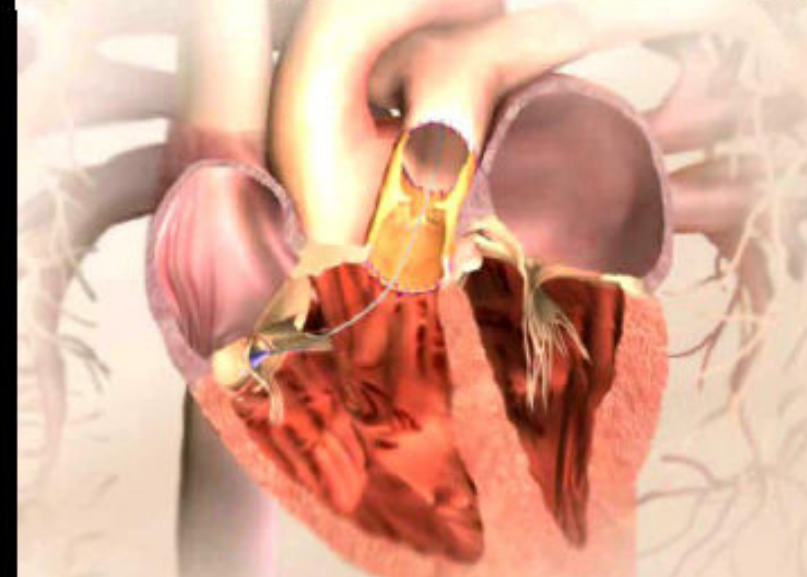
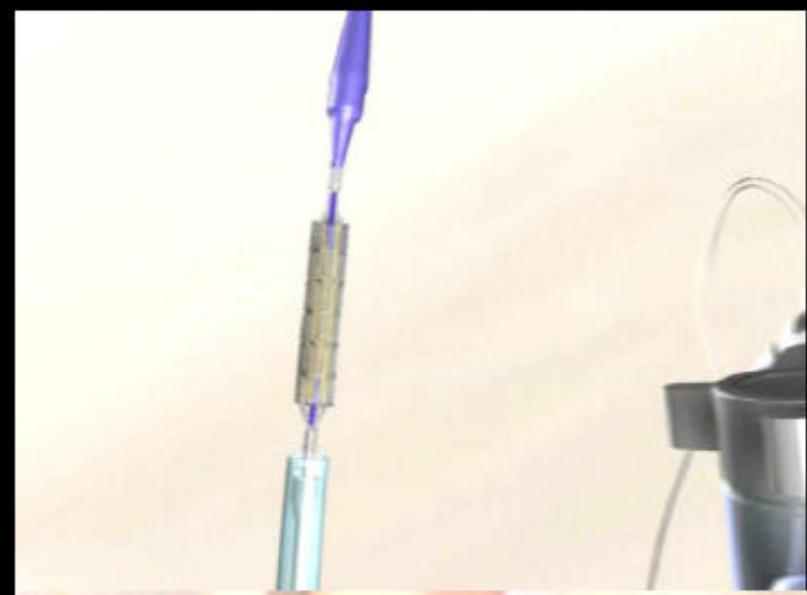
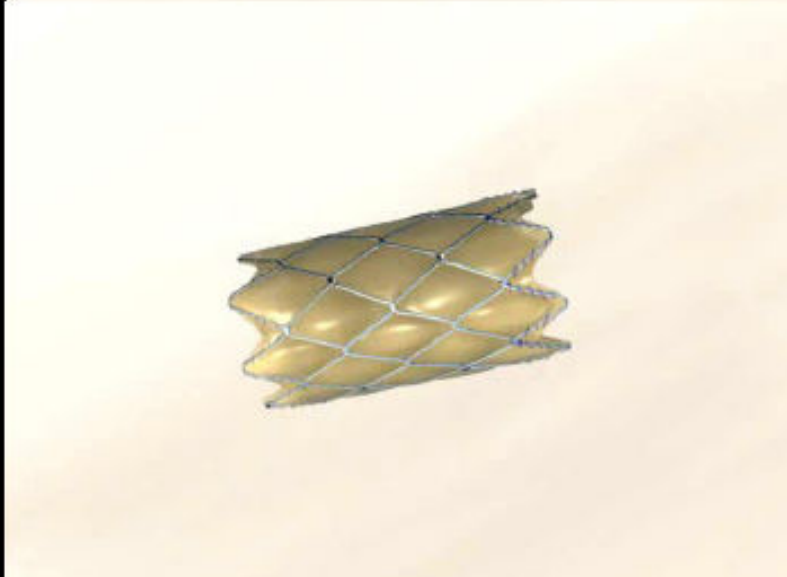
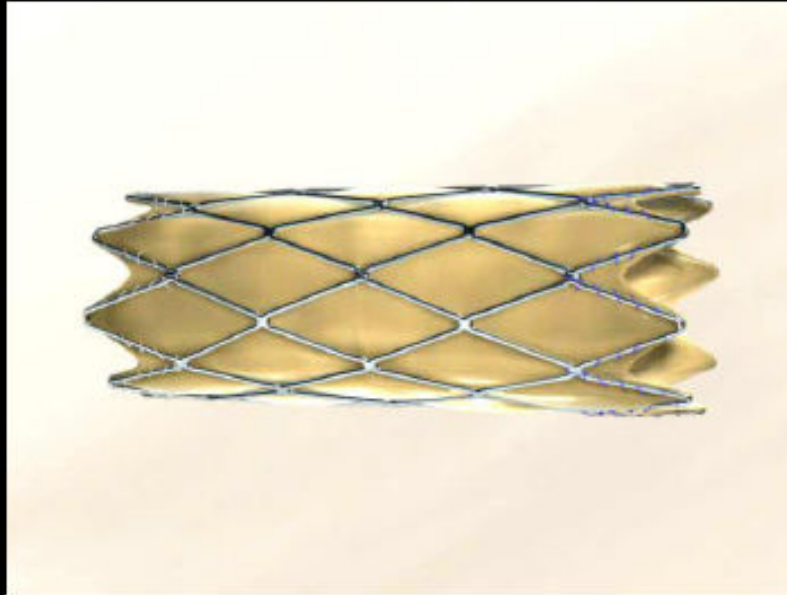
Para onde devo referenciar?

VÁLVULA PULMONAR

Implantação de Válvulas Pulmonares Percutâneas

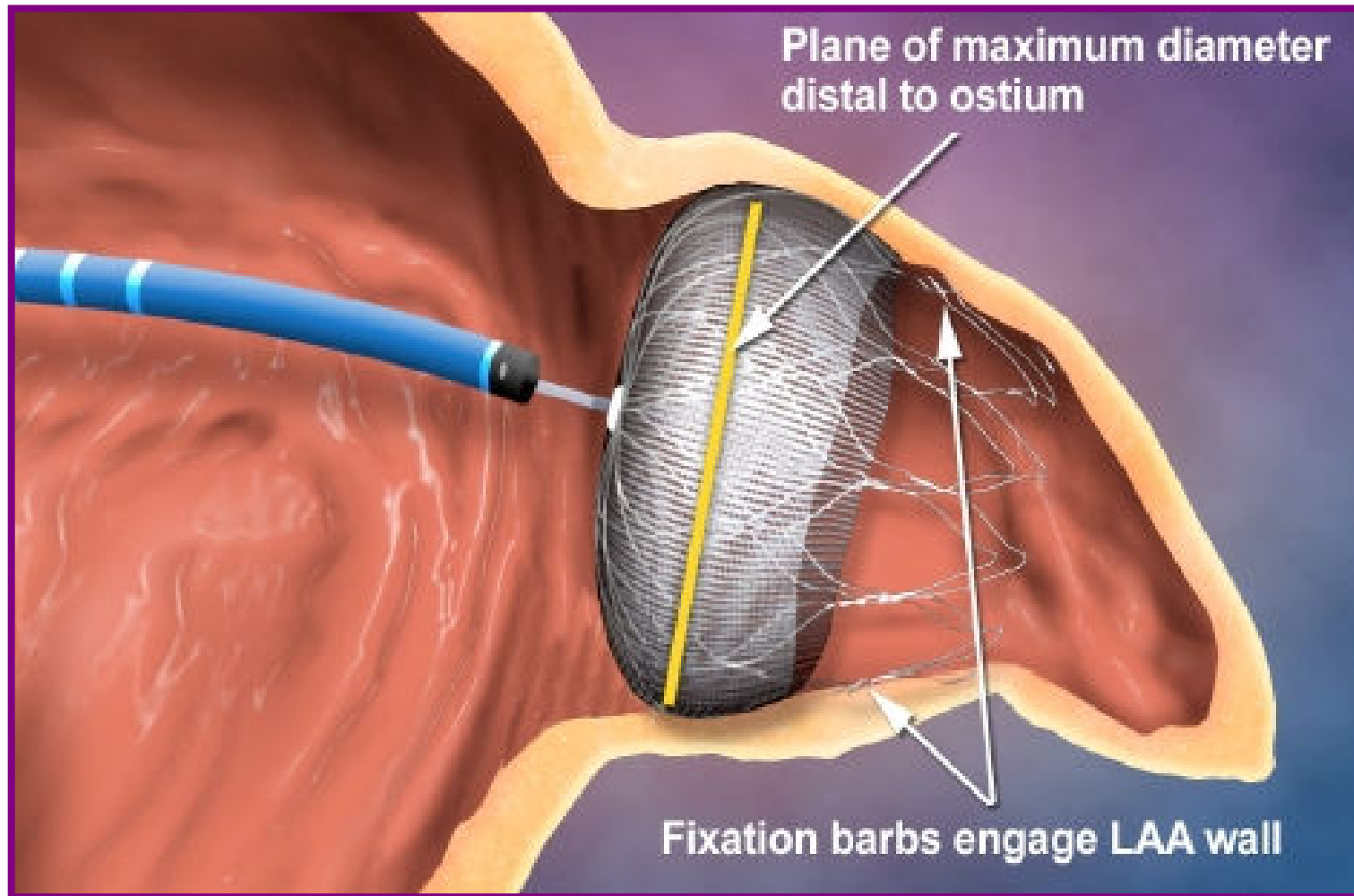


PULMONARY VALVE IMPLANTATION



**ENCERRAMENTO DO
APÊNDICE AURICULAR
ESQUERDO**

WATCHMAN LAA Closure Device in situ

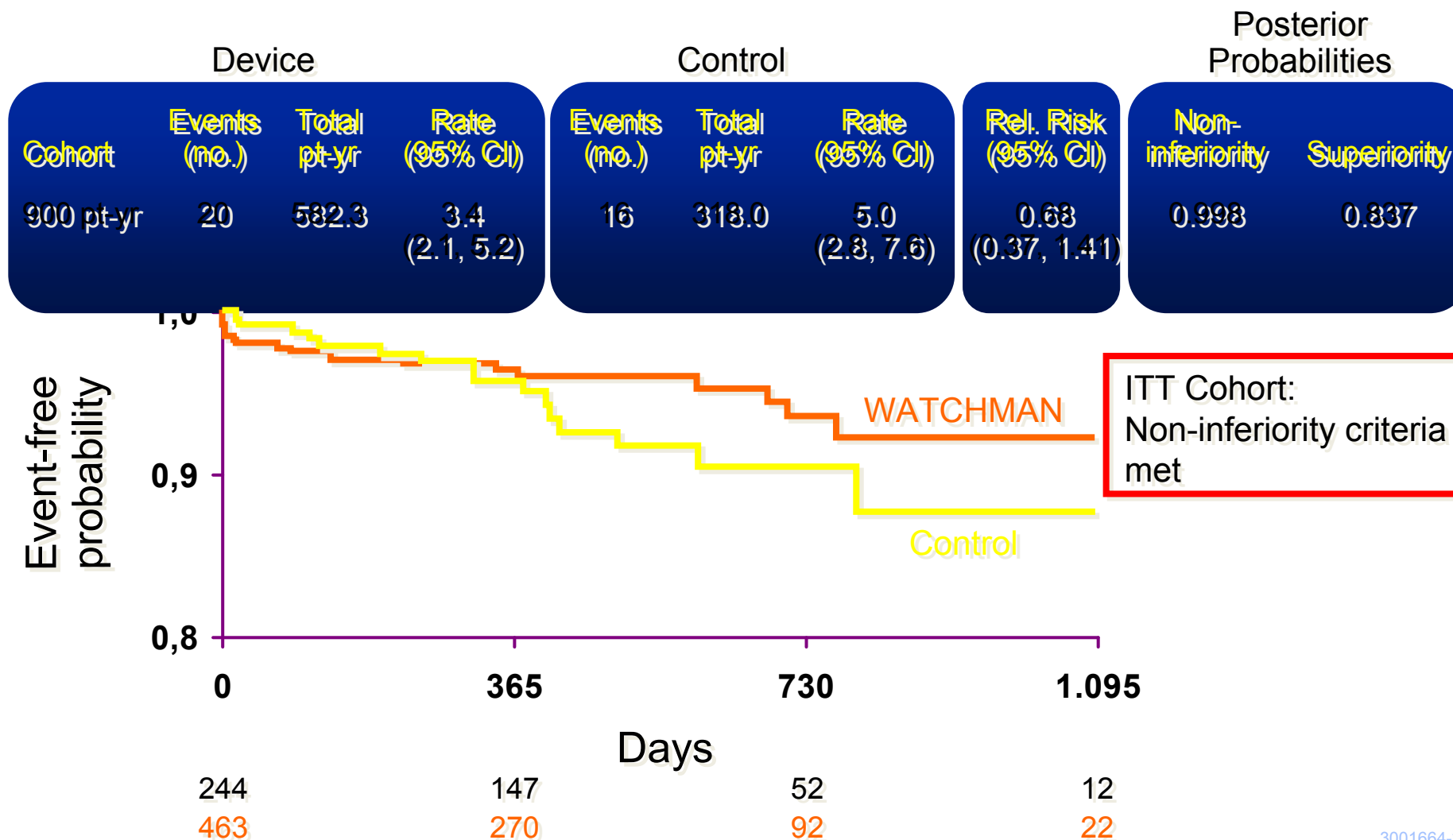


PROTECT- AF Trial

Primary Efficacy Results

Intent-to-Treat

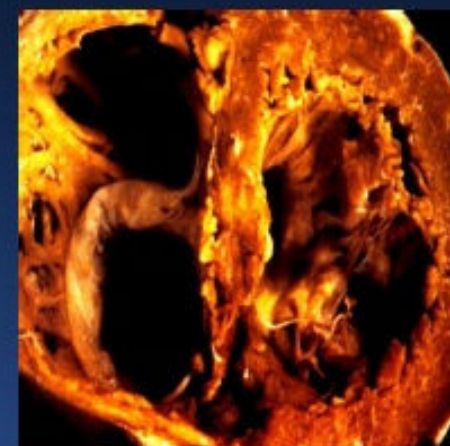
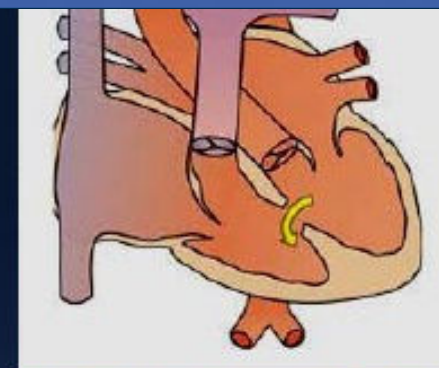
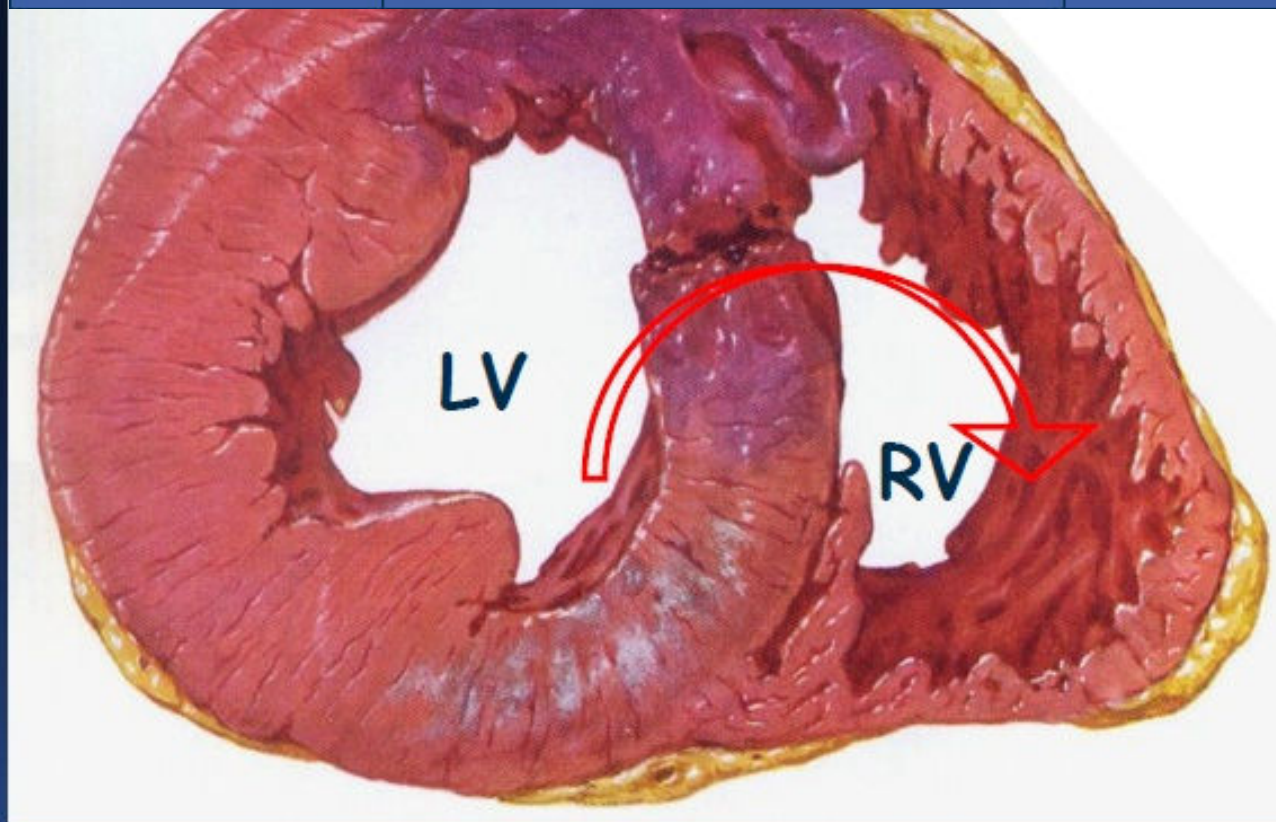
Randomization allocation (2 device : 1 control)



CIV PÓS ENFARTE

ACUTE VENTRICULAR SEPTAL RUPTURE

	Pre-thrombolytic era	Thrombolytic and PCI era
Incidence	1-4 %	0.2 - 0.34 % *
Onset	5-7 days	24 hours *



Post-MI VSD IS NOT A HOLE !

IS A RUPTURE OF THE VENTRICULAR SEPTUM !!

POST-MI VSD CATH CLOSURE

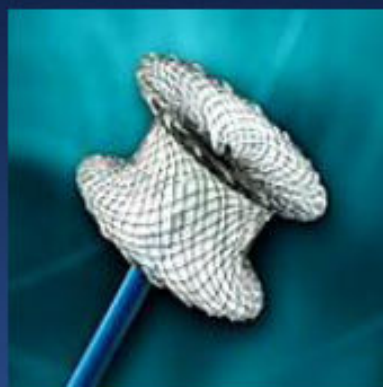
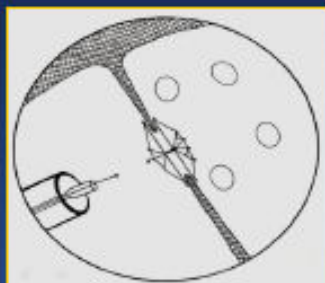
Technically feasible using a variety of septal occluding devices

- ❖ Rashkind double umbrella
- ❖ Clamshell double umbrella
- ❖ CardioSEAL device
- ❖ Different types of Amplatzer devices

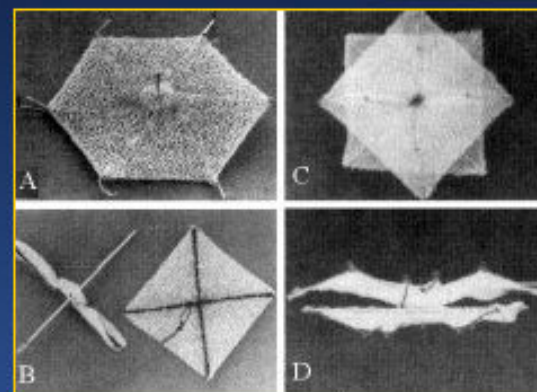
CardioSEAL®



Clamshell Device



Amplatzer Septal Occluder

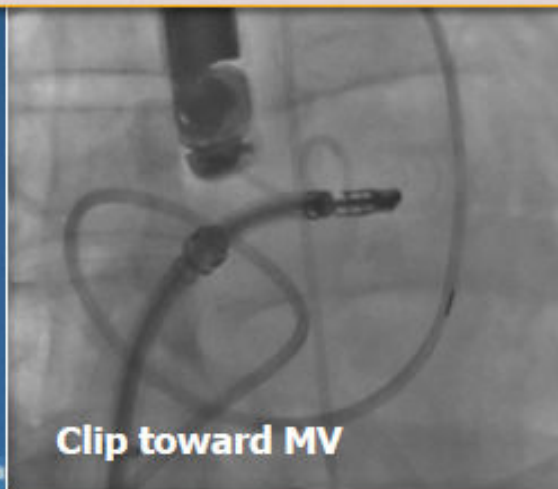
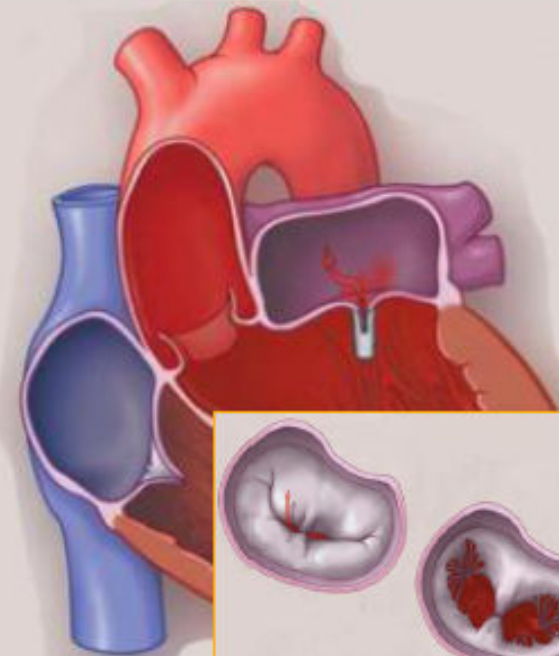
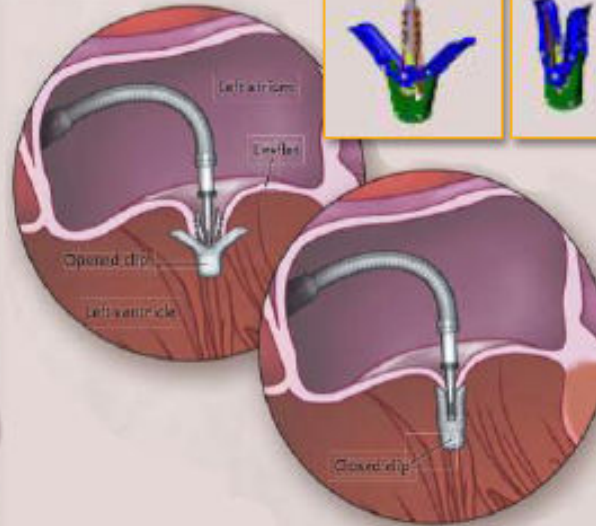
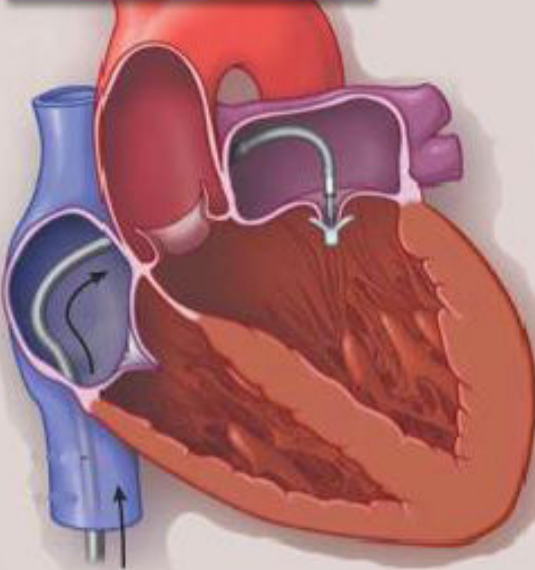


Rashkind double umbrella

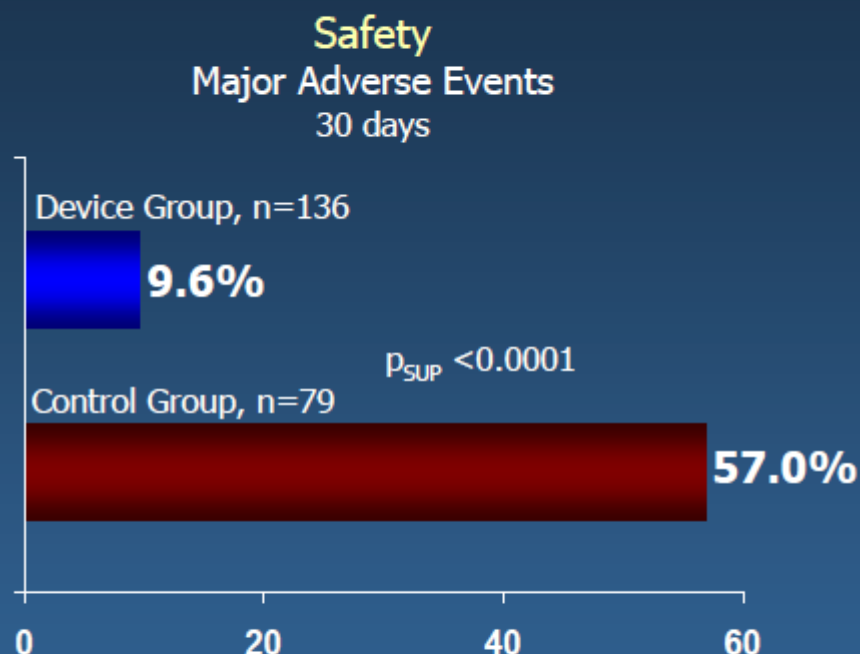
VÁLVULA MITRAL

Catheter-Based Mitral Valve Repair

MitraClip System



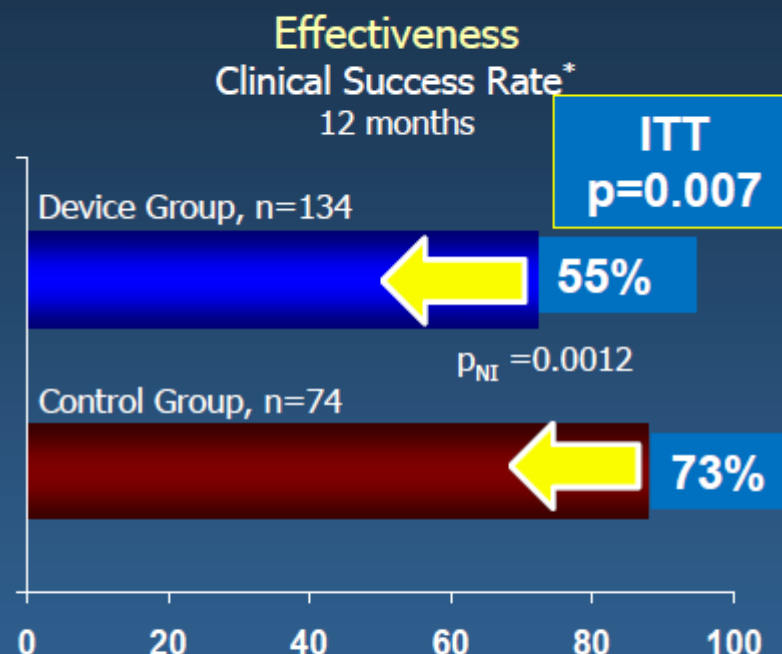
EVEREST II RCT: Primary Endpoints Per Protocol Cohort



Met superiority hypothesis

- Pre-specified margin = 6%
- Observed difference = **47.4%**
- 97.5% LCB = 34.4%

LCB = lower confidence bound
UCB = upper confidence bound



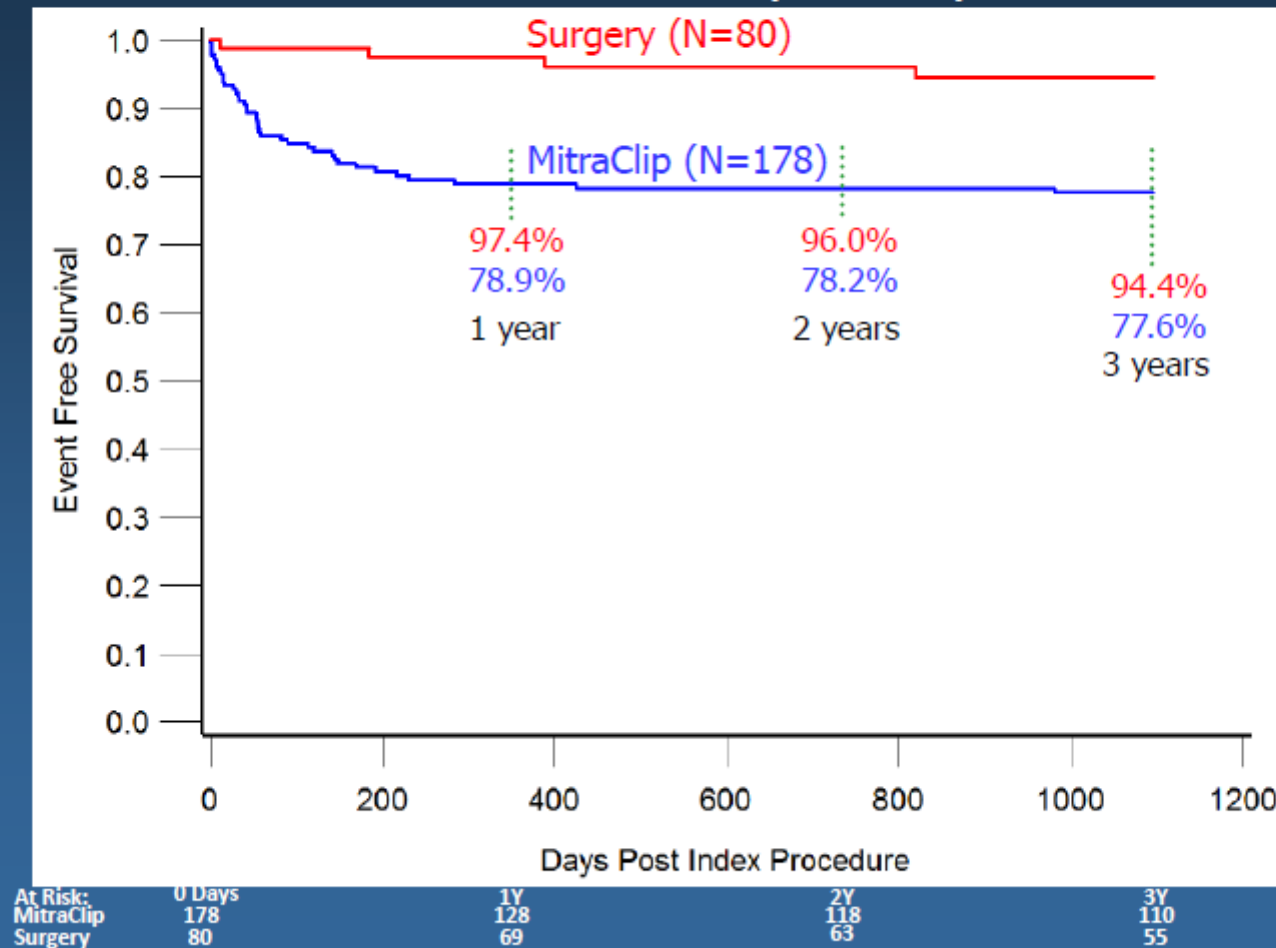
Met non-inferiority hypothesis

- Pre-specified margin = 31%
- Observed difference = **15.4%**
- 95% UCB = 25.4%

* Freedom from the combined outcome of death, MV surgery or re-operation for MV dysfunction, MR >2+ at 12 months

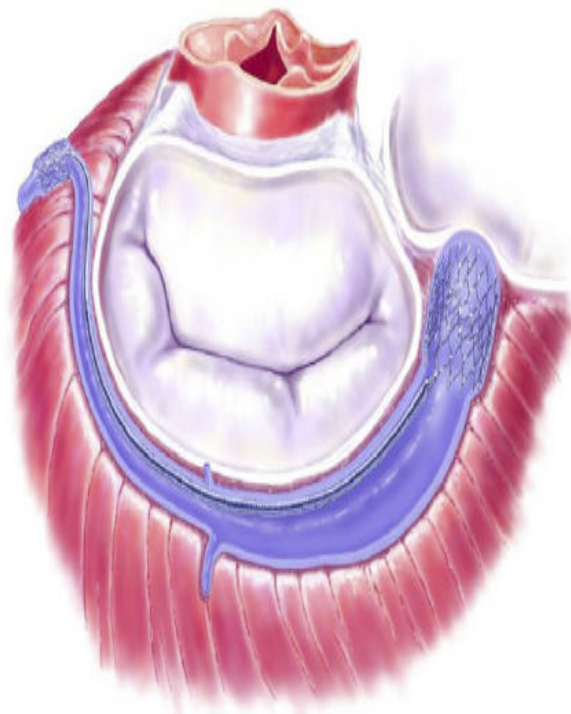
Kaplan-Meier Freedom from MV Surgery in MitraClip group or Re-operation in Surgery group

All Treated Patients (N = 258)

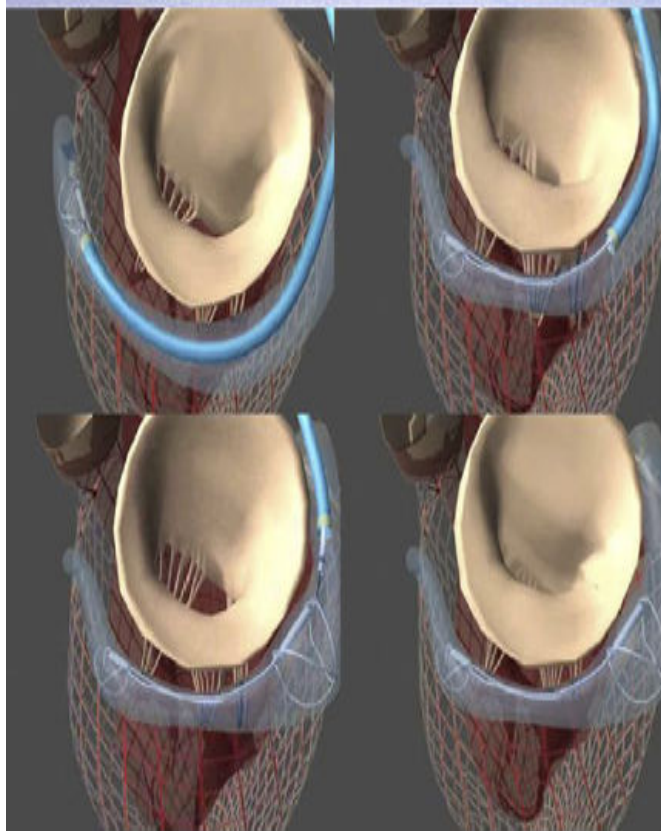


Reparação Percutânea da Válvula Mitral

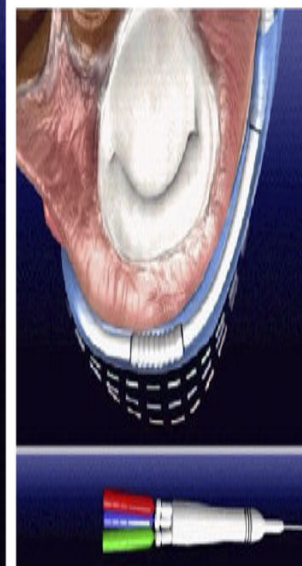
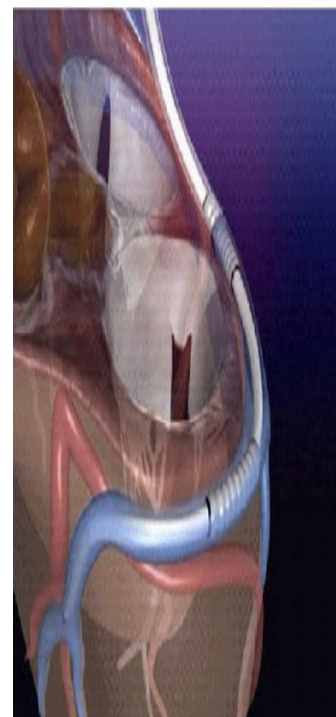
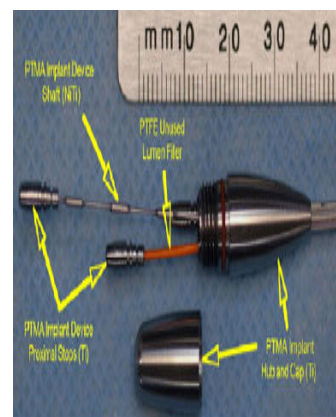
Anuloplastia Indirecta (Seio Coronário) - FIM



Monarc Device



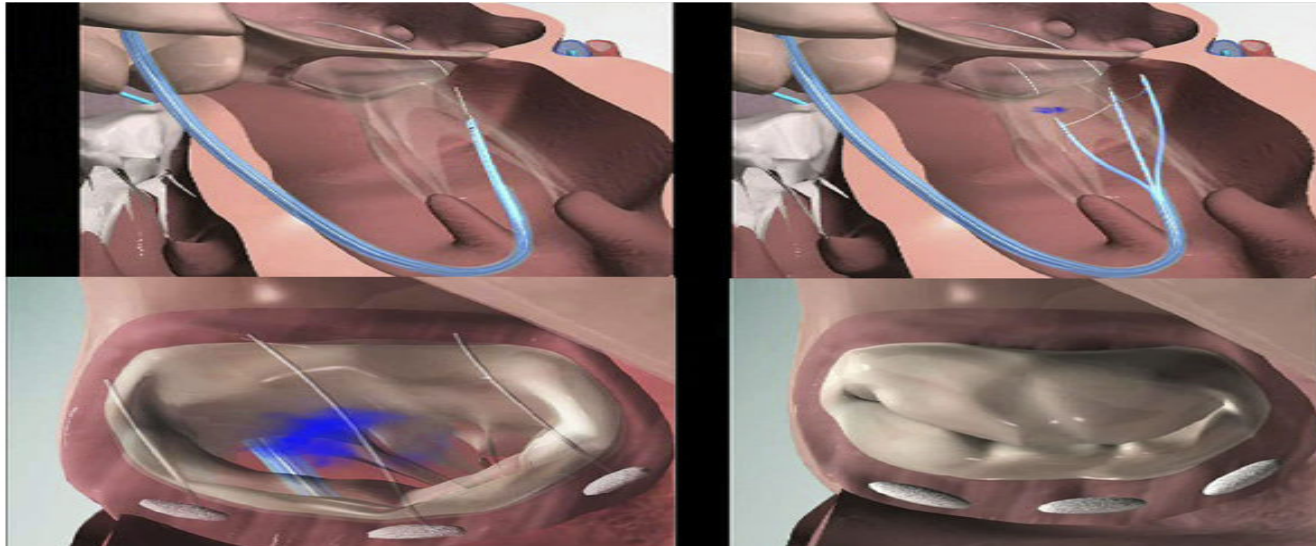
Carillon Device



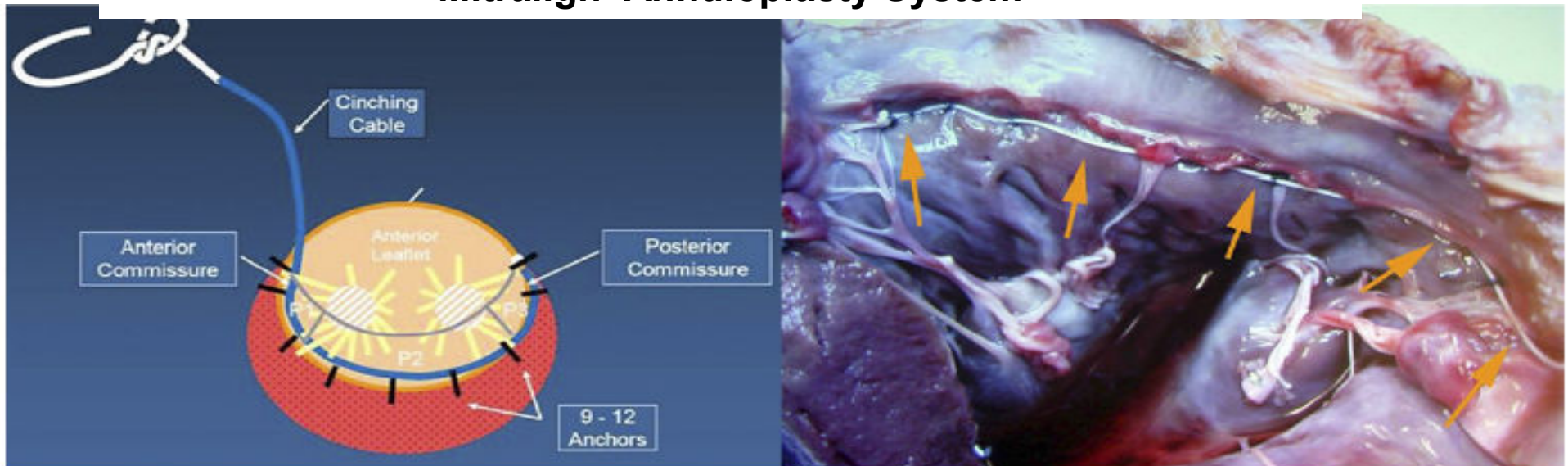
Viacor Device

Reparação Percutânea da Válvula Mitral

Anuloplastia directa - FIM



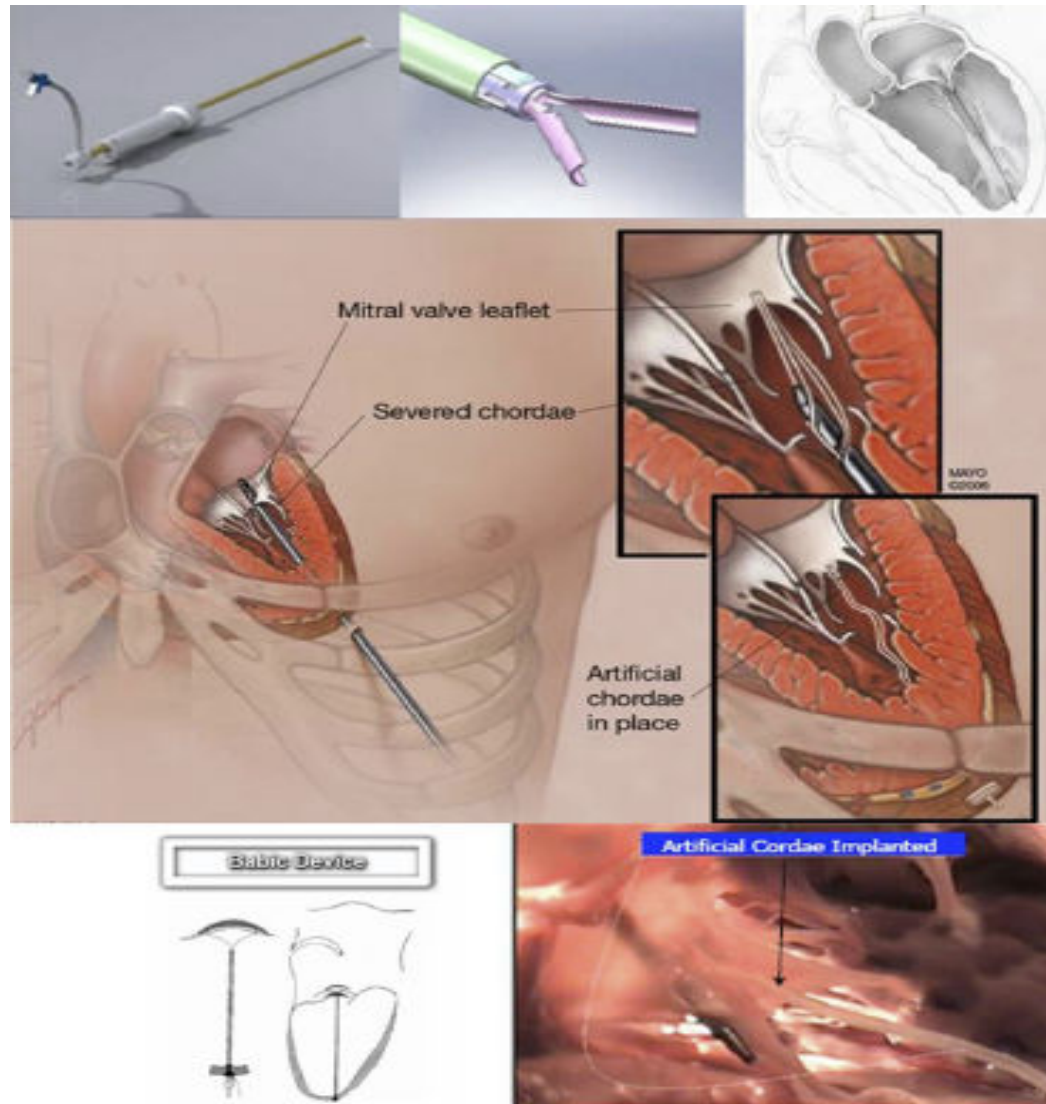
Mitralign Annuloplasty System



Accucinch Annuloplasty System

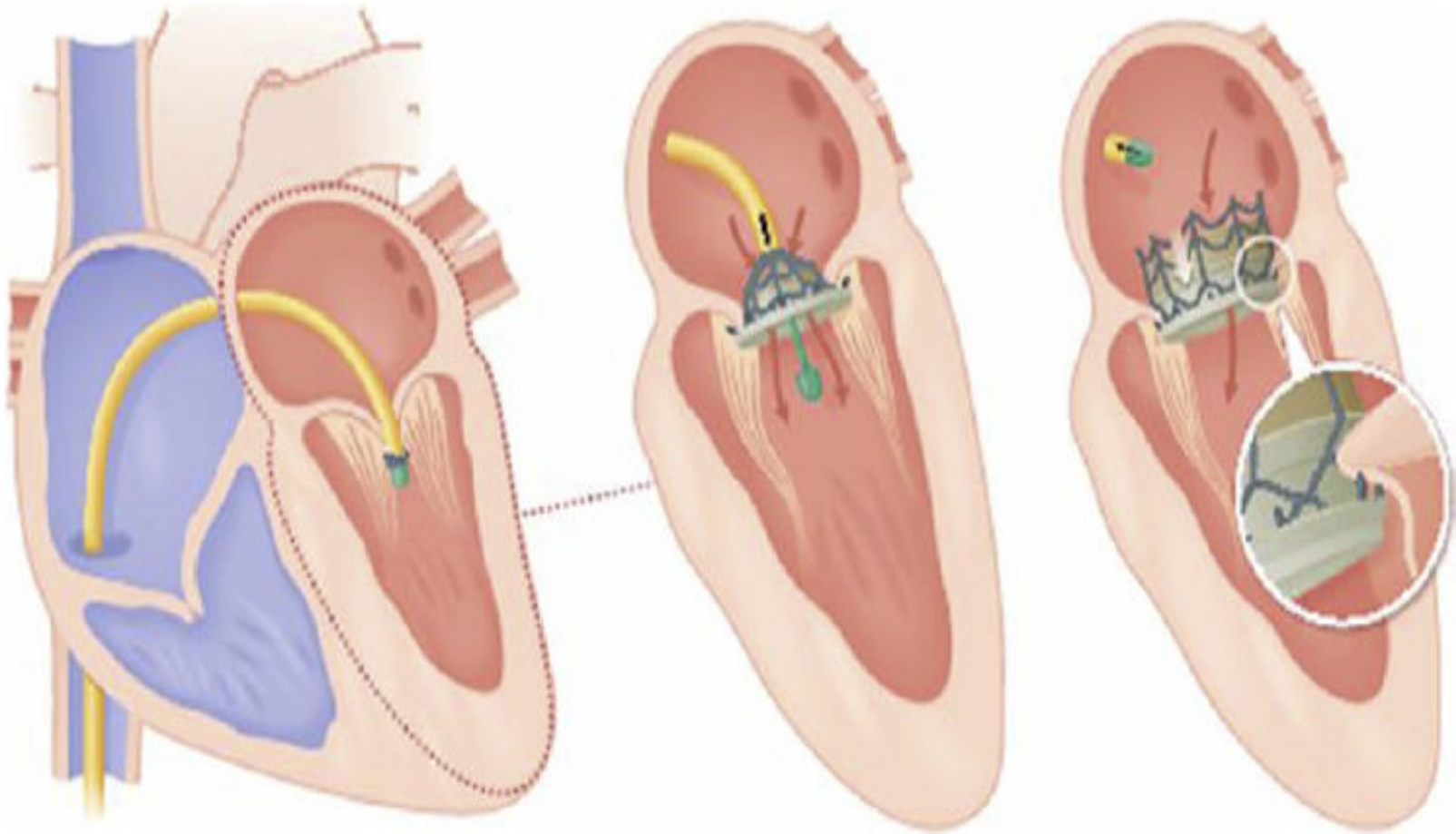
Reparação Percutânea da Válvula Mitral

Implantação de cordas – Estudos pré-clínicos



Reparação Percutânea da Válvula Mitral

Implantação de Válvulas Mitrais – FIM



Prótese CardiAQ – Via transeptal

CardiAQ Valve Technologies

Transcatheter Mitral Valve Implantation



FOR IMMEDIATE RELEASE

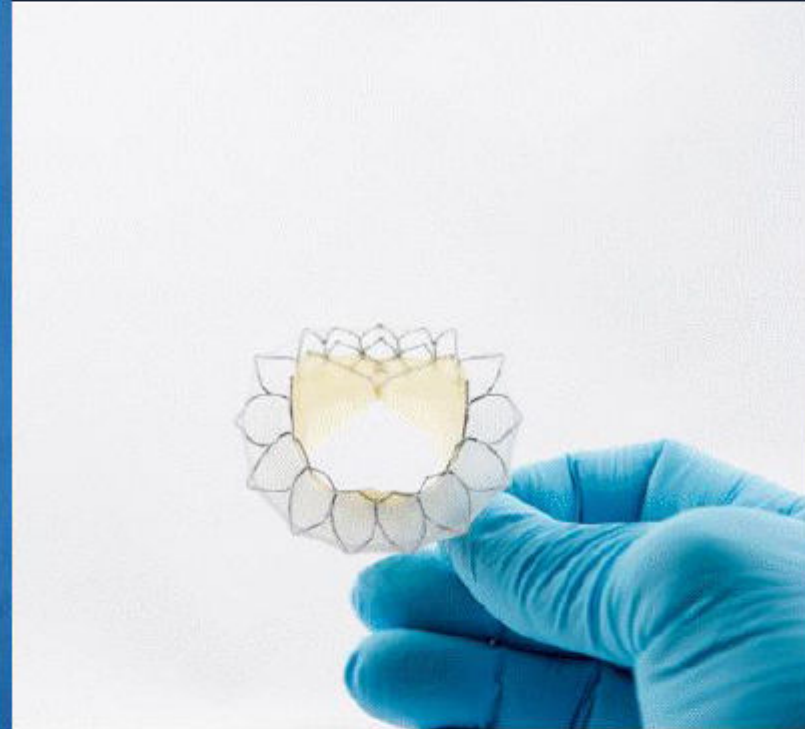
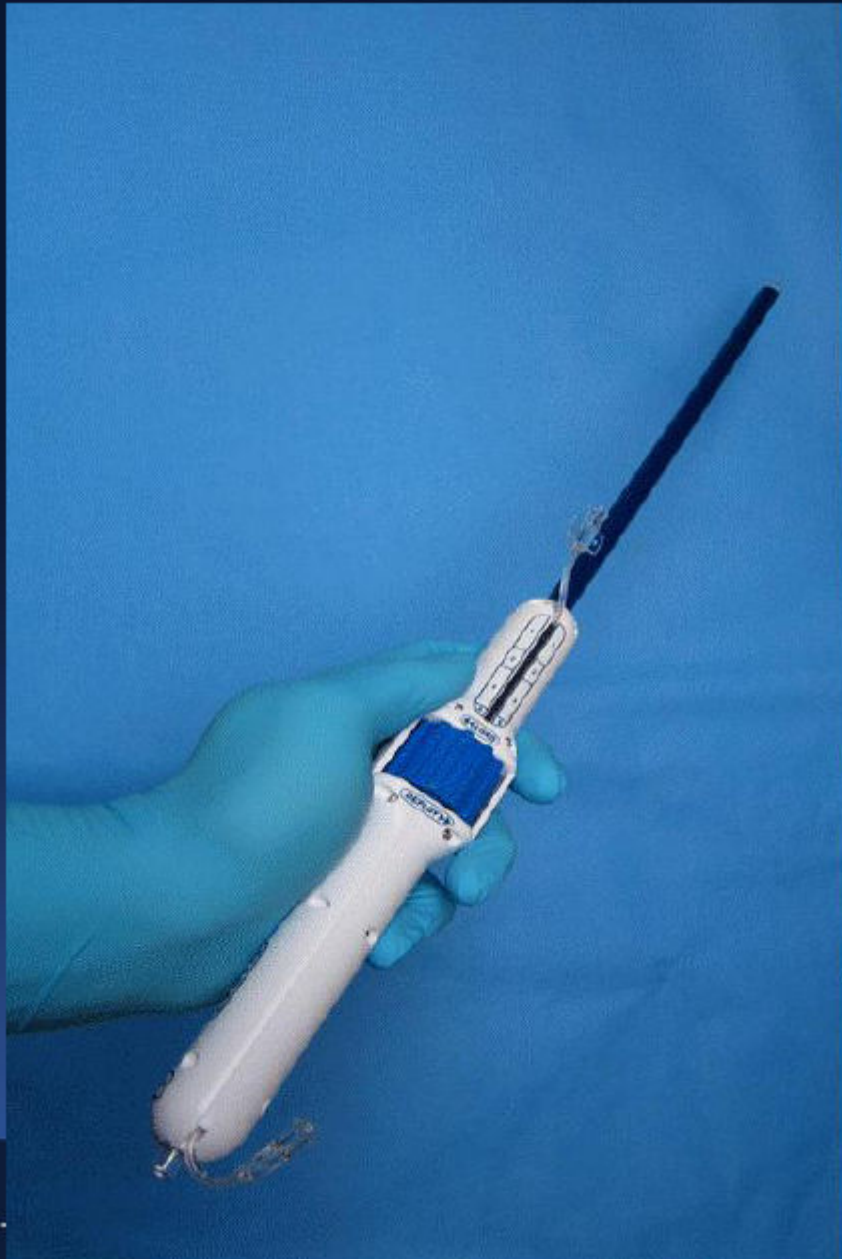
CONTACT: RONALD TRAHAN, APR, RONALD TRAHAN ASSOCIATES, INC., +1 508-359-4005, x108

NEWS RELEASE

CardiAQ™ Valve Technologies reports cardiovascular medicine milestone: first-in-human nonsurgical percutaneous implantation of a bioprosthetic mitral heart valve

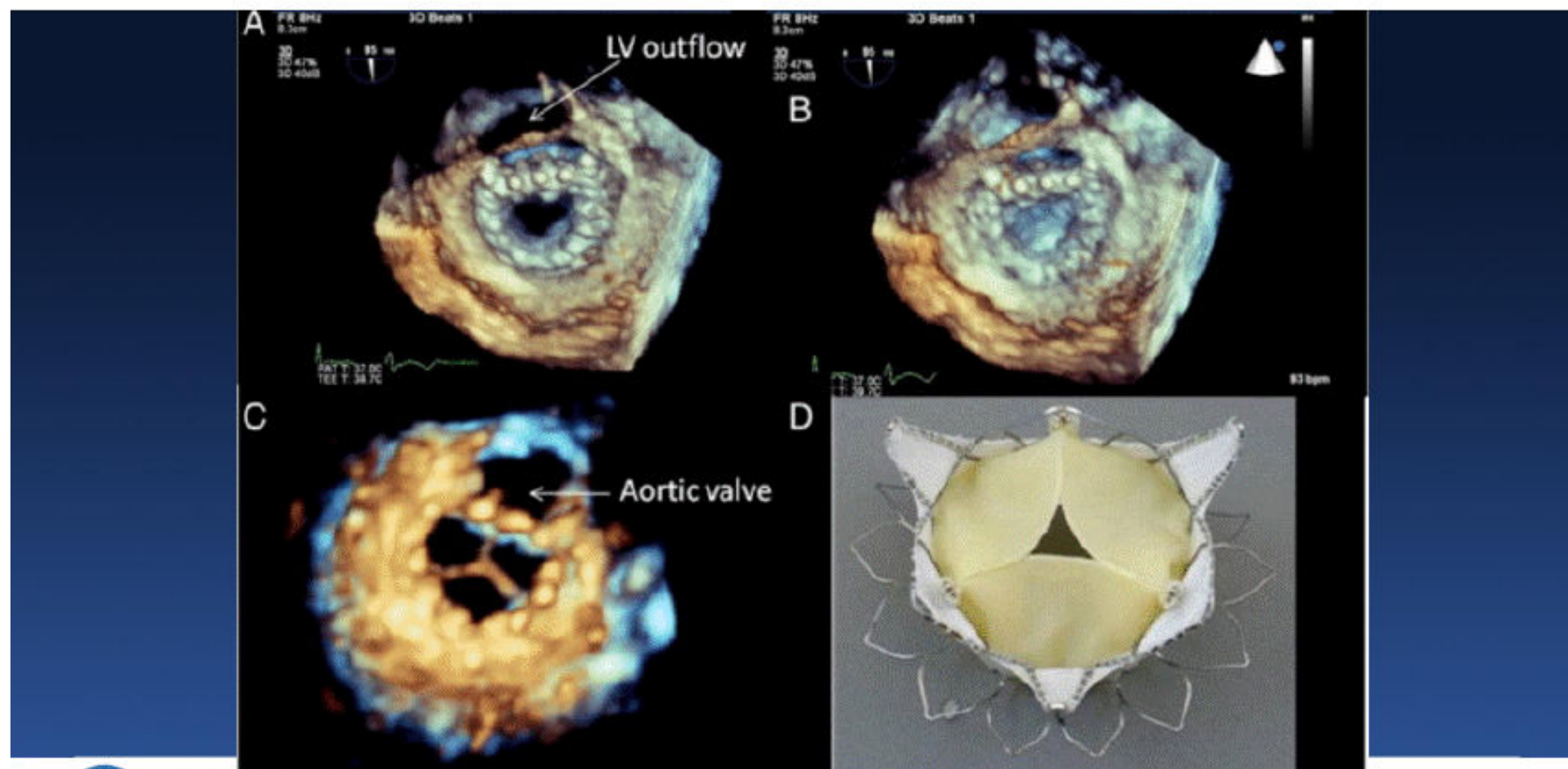
IRVINE, Calif., June 14, 2012—CardiAQ Valve Technologies (CardiAQ), which has developed the world's first self-conforming and self-anchoring technology for nonsurgical Transcatheter Mitral Valve Implantation (TMVI), today announced that the Company has achieved a cardiovascular medicine milestone: a bioprosthetic mitral heart valve was successfully implanted as a compassionate treatment into an 86-year-old male suffering from severe mitral regurgitation (MR 4+). The breakthrough TMVI procedure was performed on June 12, 2012 at The Heart Centre, Rigshospitalet University Hospital, Copenhagen, Denmark, by interventional cardiologists Lars Søndergaard, M.D., and Olaf Franzen, M.D., cardiovascular surgeon Susanne Holme, M.D., anesthesiologist Peter Bo Hansen, M.D., and echocardiographer Nikolaj Ihlemann, M.D.

Tiara and Delivery System



Tiara: A Novel Catheter-Based Mitral Valve Bioprosthesis

Initial Experiments and Short-Term Pre-Clinical Results

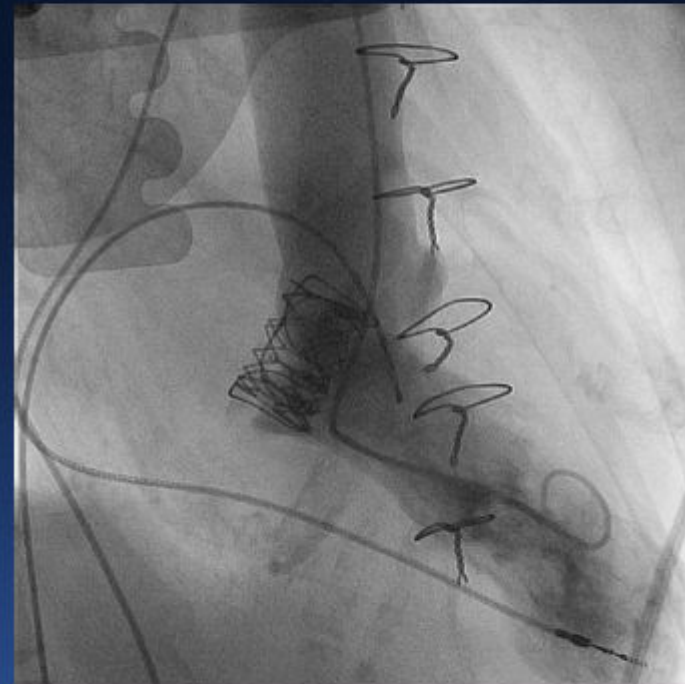
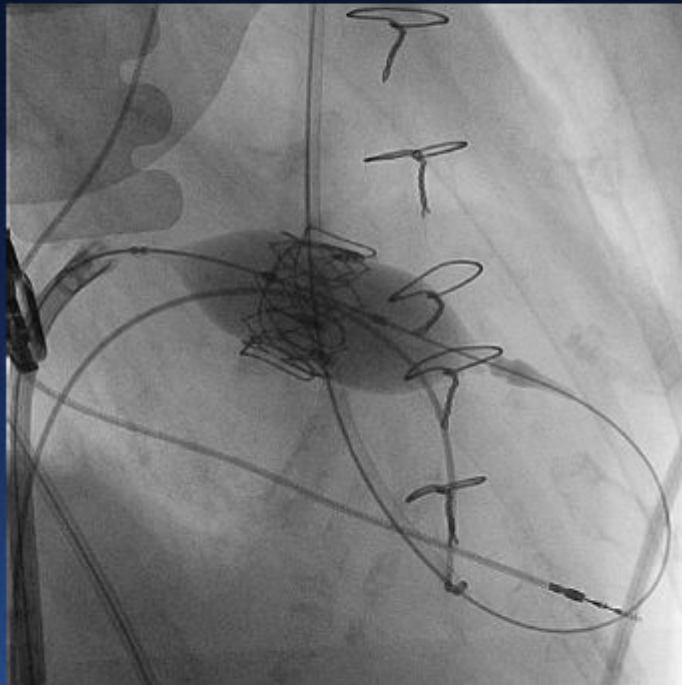


Transapical Mitral V in V

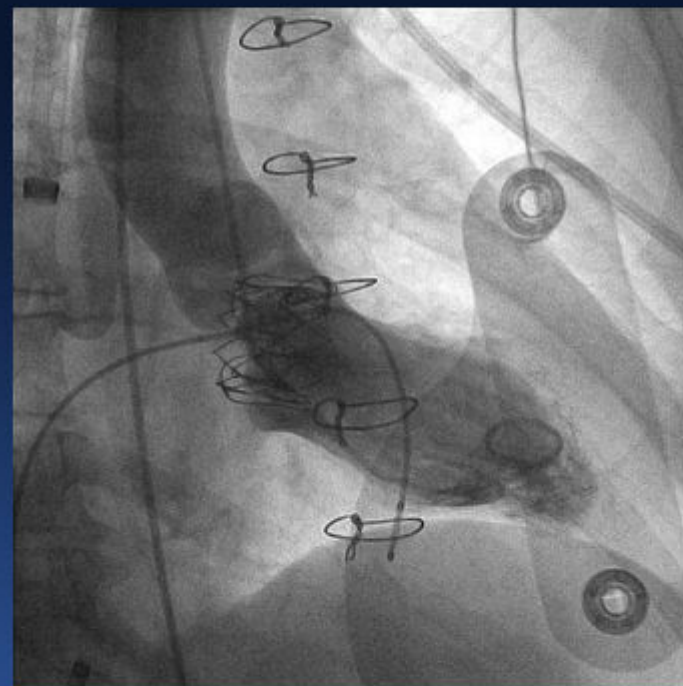
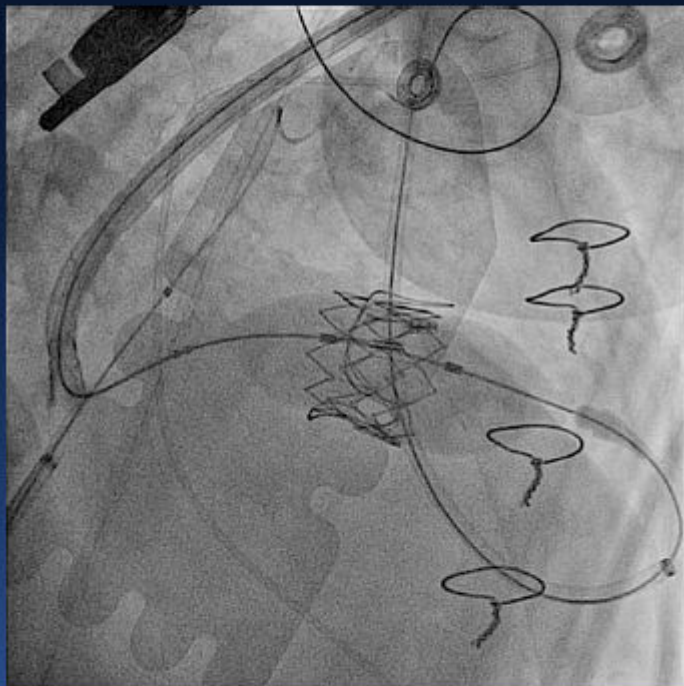


Transfemoral Mitral V in V

before

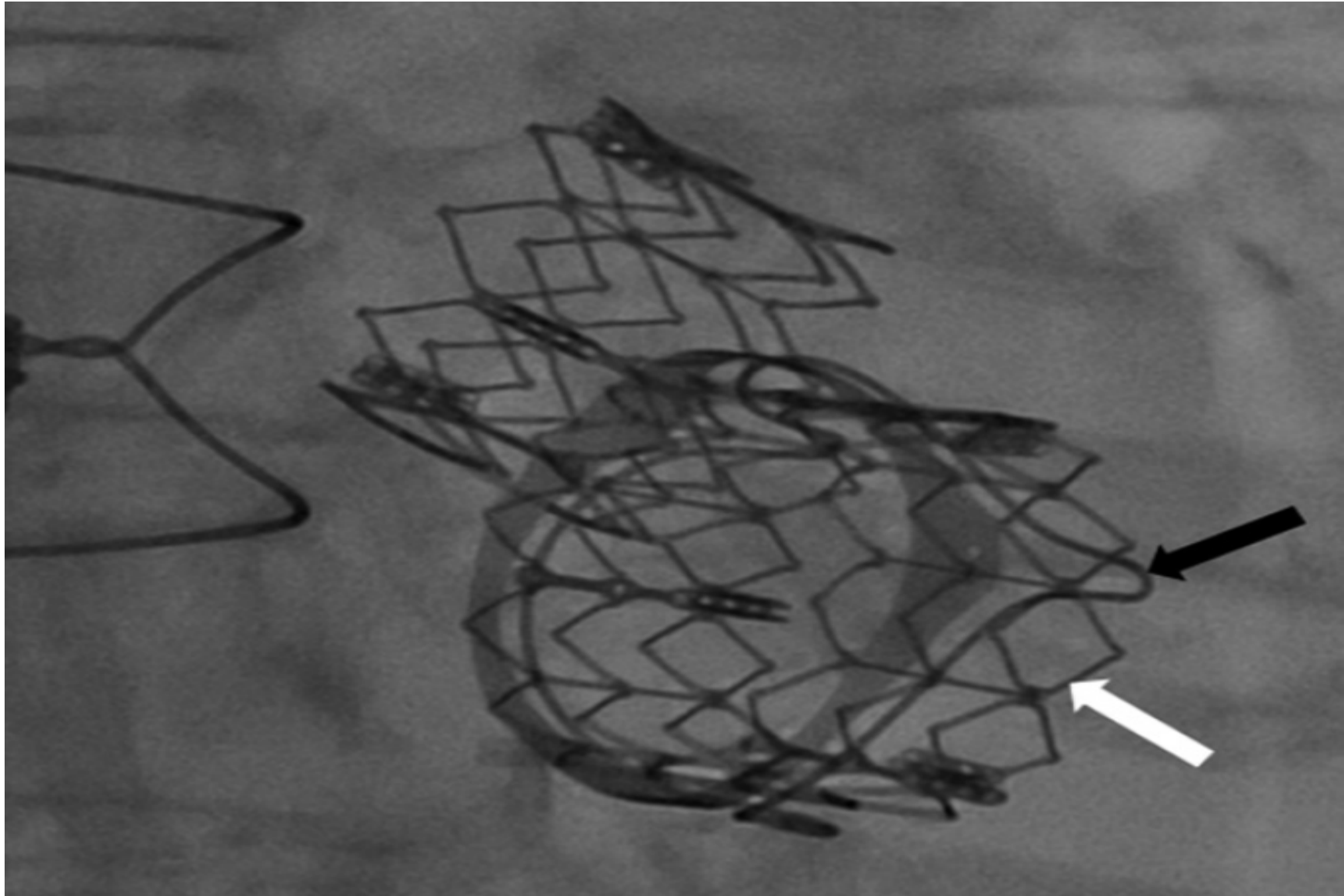


Transjugular Mitral V in V



Dupla implantação valvular percutânea

Aórtica e Mitral (**valve-in-valve**)



VÁLVULA TRICÚSPIDA

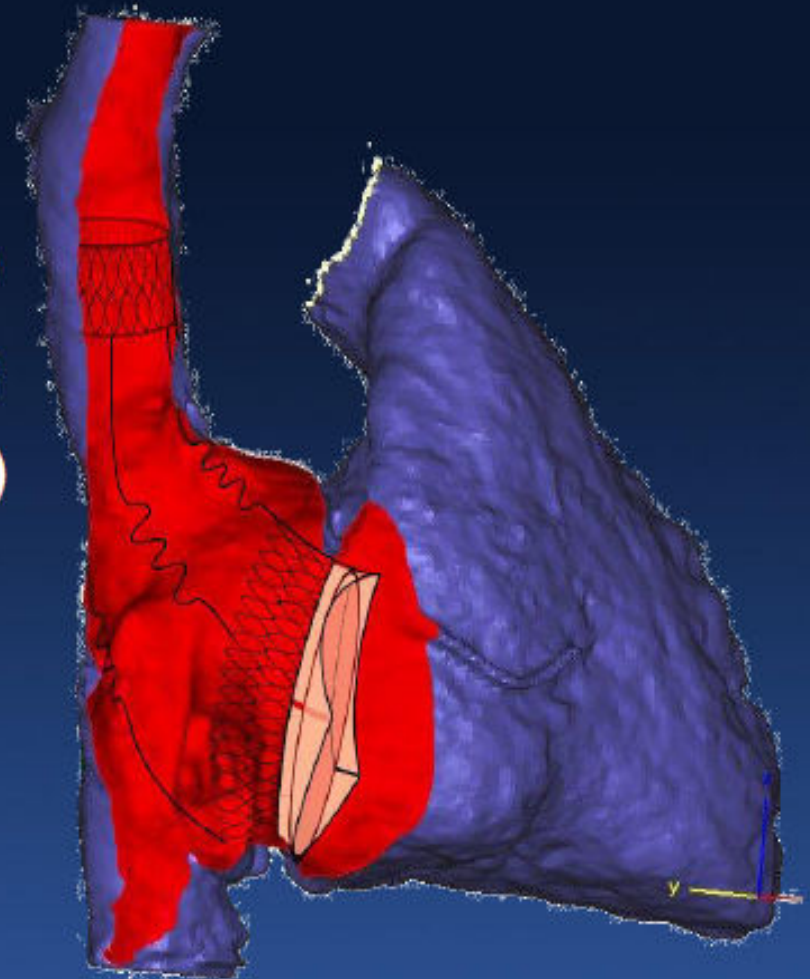
Novel Approach

Interventional therapy

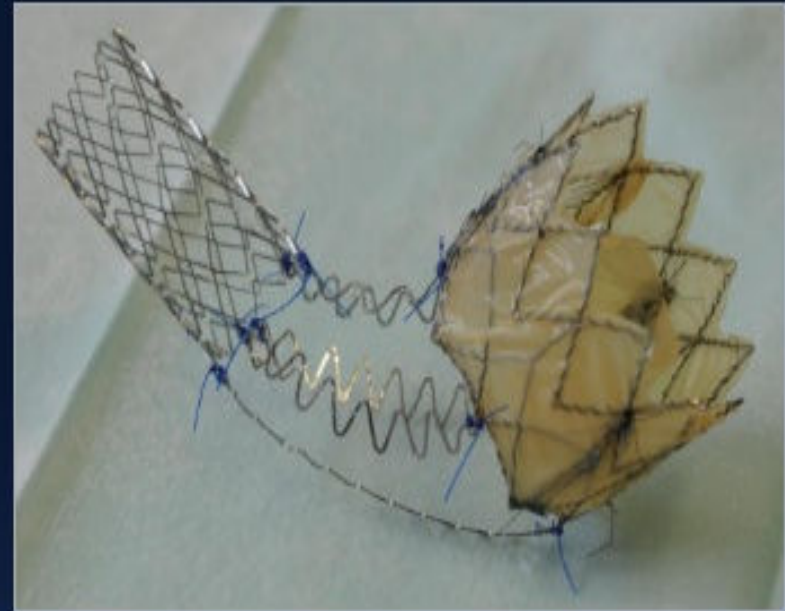


- **Displacement of primary anchoring towards Sup. V. Cava**
- **Two stents, connected by struts**
 - tricuspid valve annulus stent (TVA)
 - Sup. V. Cava stent (SVC)
 - Struts as connectors

Primary anchoring: SVC-stent
Suppl. anchoring: TVA-stent



- **A custom trileaflet heart valve sewn into the TVA-stent**
 - **Bovine and/or porcine pericardium**
- **Stents and struts connected**



- **Arched stent-construct crimped and loaded onto a 24F catheter**



Intervenção Estrutural Percutânea

Conclusões

Mesmo reconhecendo as fases de qualquer nova inovação

**Expansão
Entusiasmo**

**Desilusão
Análise crítica**

**Estabilização
Seleção de Doentes
Melhoria da Técnica
Análises de Custo /
Benefício**

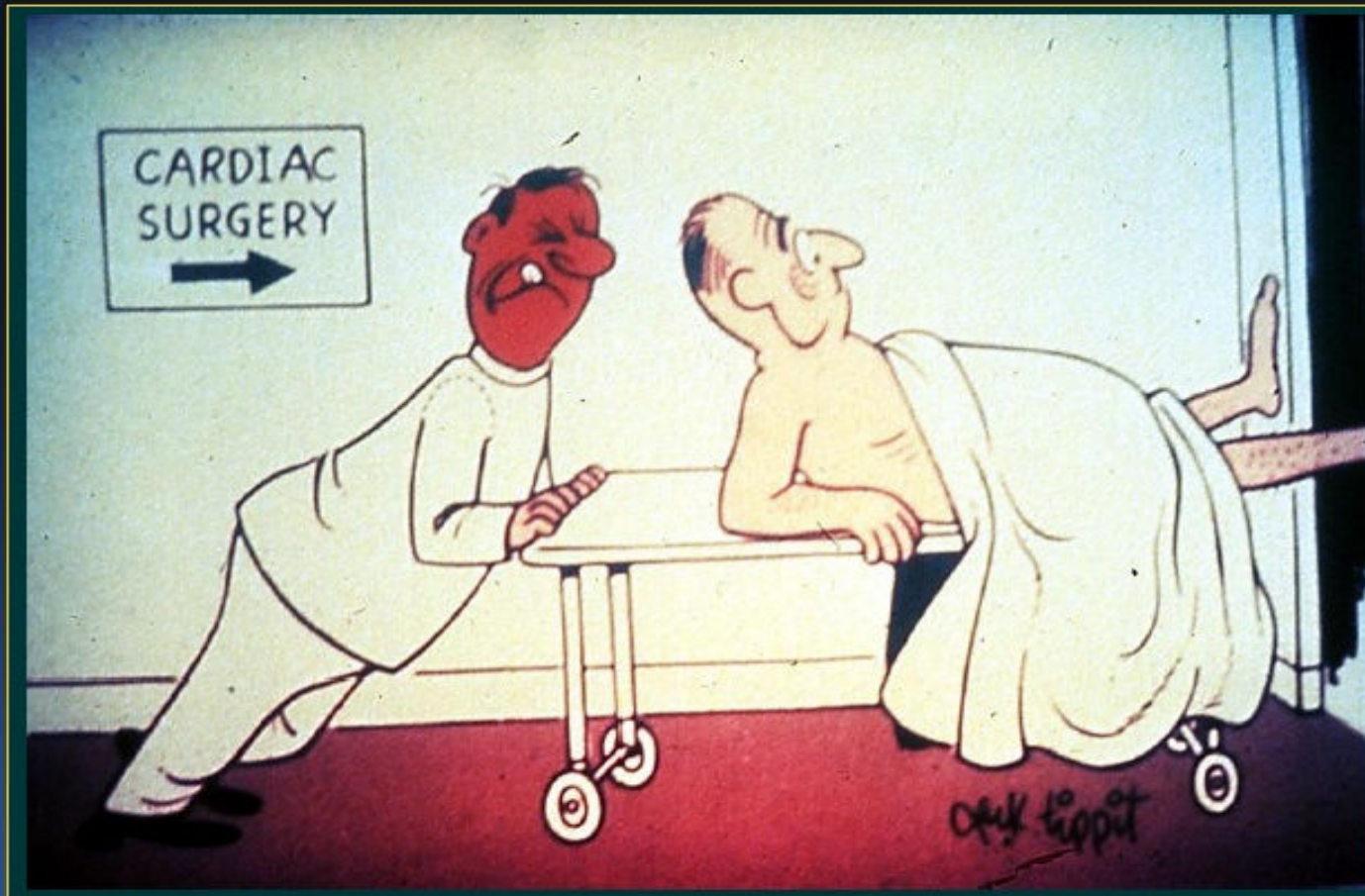
**Descoberta
Início da Técnica**



Tem sido um **TRAJECTO**

FASCINANTE...

***NOONE Likes Surgery
(of any kind)!***



Não é possível esconder a realidade



Cardiologia Estrutural



**Não! O Santo Graal é apenas
um MITO...**

A realidade é que a
INTERVENÇÃO
CARDIOVASCULAR
PERCUTÂNEA

constitui já uma

UMA NOVA
(SUB)ESPECIALIDADE
DA CARDIOLOGIA



OBRIIGADO

