

# Complex Cases in TAVI

## Our Experience With the Last Generation Valves

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# Potential Conflicts of Interest

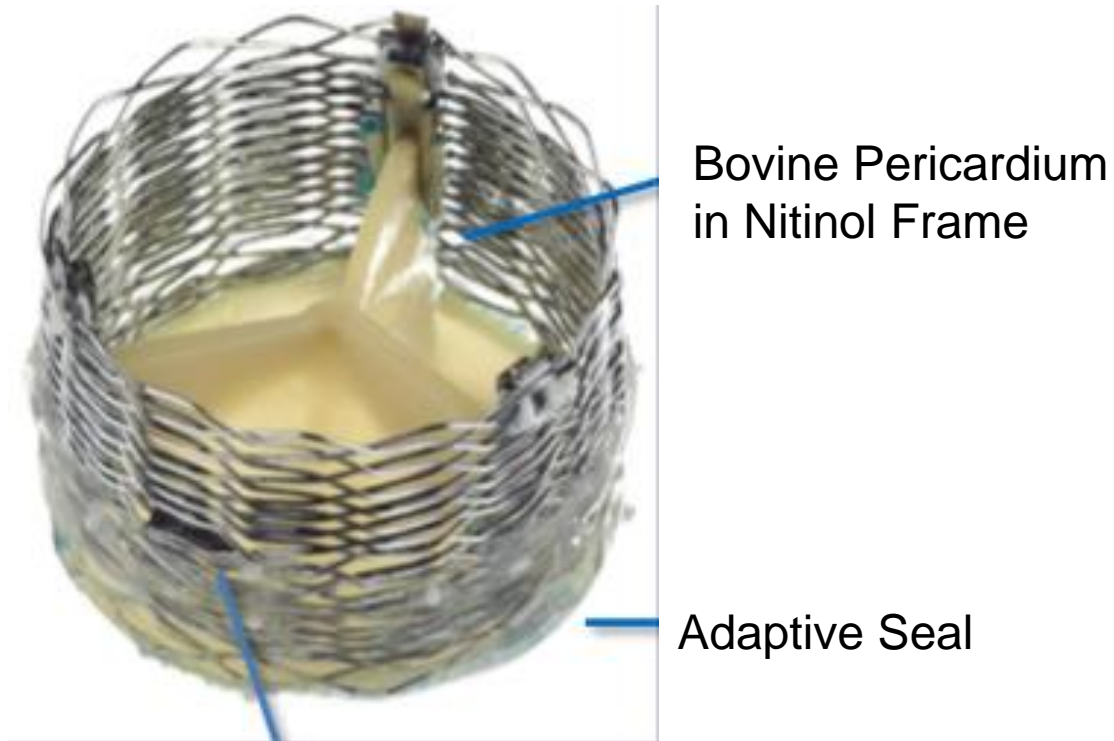
Speaker's name: Vinícius Esteves

✓ I have the following potential conflicts of interest to report:

- ✓ Boston Scientific – Proctor
  - ✓ TAVI – Lotus™ Valve System
  - ✓ IVUS - ILab™
  - ✓ Atherectomy - Rotablator



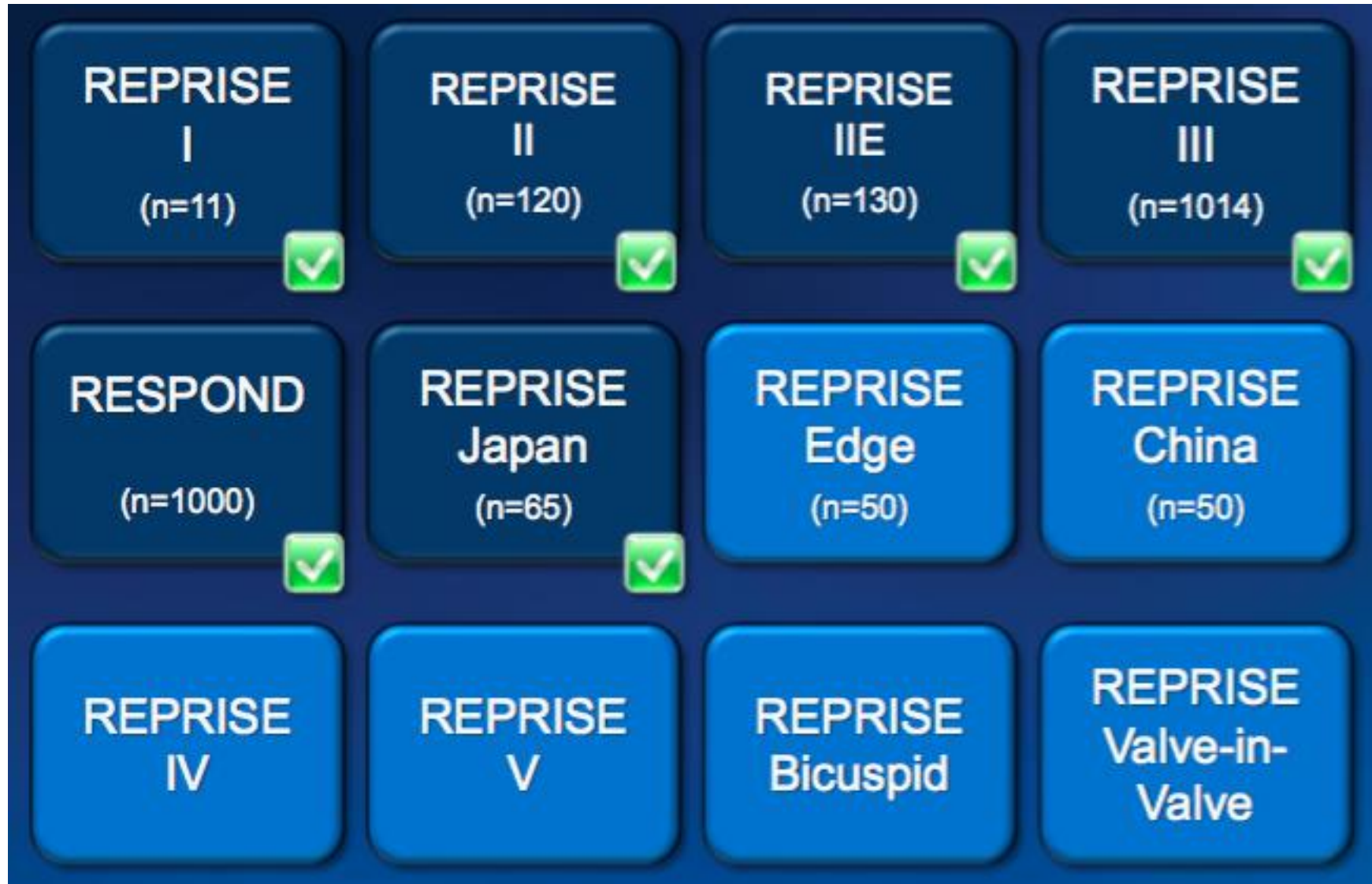
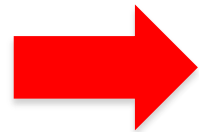
# Lotus™ Valve System



Radiopaque Marker

- . **Controlled mechanical expansion**
- . **Valve functions early in deployment to provide hemodynamic stability**
- . **Valve is fully repositionable and retrievable throughout the entire deployment process.**
- . **Adaptive seal conforms to irregular anatomic surfaces to minimize paravalvular leak.**

# REPRISE Clinical Program



# RESPOND Trial

**1014 Patients Between May 2014 and February 2016 – Multicentric**

**30 Days Follow Up**

DEVICE SUCCESS – VARC-2	
All Cause Mortality	2,6%
Disabling Stroke	2,2%
Correct positioning of one valve in proper location	99,7%
Mean aortic valve gradient < 20 mmHg	96,4% (903/937)
Peak velocity < 3 m/s	96,1% (900/937)
No moderate/severe prosthetic valve regurgitation	99,6% (941/945)

# Transcatheter Aortic Valve Implantation – Initial Brazilian Experience With the Second Generation Lotus™ Device

## 31 patients – In Hospital End Points

DEVICE SUCCESS – VARC-2	RESPOND (1014)	BRAZILIAN EXPERIENCE (31)
All Cause Mortality	2,6%	3,2%
Disabling Stroke	2,2%	0%
Correct positioning of one valve in proper location	99,7%	100%
Mean aortic valve gradient < 20 mmHg	96,4%	96,8%
No moderate/severe prosthetic valve regurgitation	99,6%	100%
Permanent Pacemaker	30%	38%

**Esteves V; Marchini JF; Bernardi G; Tebet MA; Bernardi F; Kreimer S; Prates P; Mariani J; Leite RS; Mattos LA; Grube E; Lemos PA. RBCI E pub ahead**



# Complex Cases in TAVI

## Our Experience With the Last Generation Valves

### Esperança/Recife

Luiz Alberto Mattos  
Jorge Lorena  
Rosário Leite



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### São Luiz Morumbi/SP

Luiz Alberto Mattos  
Vinícius Esteves  
Marden Tebet  
Sergio Kreimer  
Pedro Beraldo



### HMB Brasil/St André



### Santa Casa/Marilia



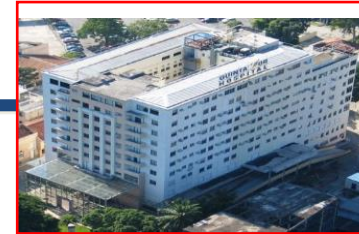
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### Copa D'or/RJ

Luiz Alberto Mattos  
Cleverson Zukowski  
Felipe Maia  
Mauricio Oliveira  
Vinícius Esteves



### Quinta D'or/RJ



1

12 cases

## Our Exp

### ESTRATÉGIA MINIMAMENTE INVASIVA PARA O IMPLANTE PERCUTÂNEO DE BIOPRÓTESE AÓRTICA DE SEGUNDA GERAÇÃO LOTUS®

## Valves

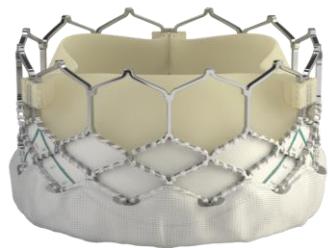
DEVICE SUCCESS – VALVES	MINIMALLY INVASIVE STRATEGY FOR IMPLANT OF PERCUTANEOUS AORTIC BIOPROSTHESIS SECOND GENERATION LOTUS®			REDE D'OR (12)
All Cause Mortality				0%
Disabling Stroke	Marden André Tebet <sup>1</sup> , Vinicius Borges Cardoso Esteves <sup>1</sup> , Sergio Kreimer <sup>1</sup> , Cleverson Zukowski <sup>2</sup> , Felipe Maia <sup>2</sup> , Maurício Oliveira <sup>2</sup> , Jorge Lorena <sup>3</sup> , Pedro Beraldo de Andrade <sup>4</sup> , Luiz Alberto Piva e Mattos <sup>1</sup>			0%
Correct positioning of one valve in proper location				100%
Mean aortic valve gradient < 20 mmHg	1 – Rede D'OR – São Luiz – São Paulo – Hospitais Brasil (Santo André) e Morumbi			100%
No moderate/severe prosthetic valve regurgitation	2 – Rede D'OR – São Luiz – Rio de Janeiro – Hospitais Copa e Quinta D'OR			100%
Permanent Pacemaker	3 - Rede D'OR - São Luiz – Recife – Hospital Esperança			
	4 - Santa Casa de Misericórdia de Marília			33%
Conscious Sedation	NA	16%		83%



# Moderate/Severe Paravalvular Leak

## 1 Month Follow Up – TAVI Clinical Trials

Sapien 3  
PARTNER II S3



**3.8%**

Kodali.ACC2015

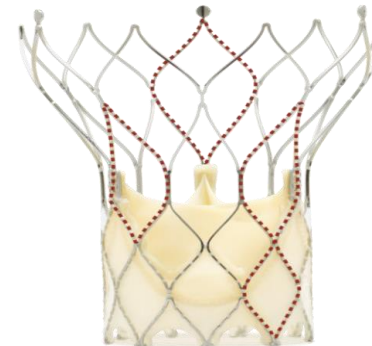
Evolut R



**3.4%**

Meredith.ACC2015

Portico  
CE Study



**4%**

Manoharam.TCT2014

Lotus  
RESPOND



**0.4%**

Falk.PCR2016

# Lotus™ Valve System

**Unique  
Features**

**100% REPOSITIONABLE AND RETRIEVABLE**

**+**

**EARLY FUNCTIONING**

**+**

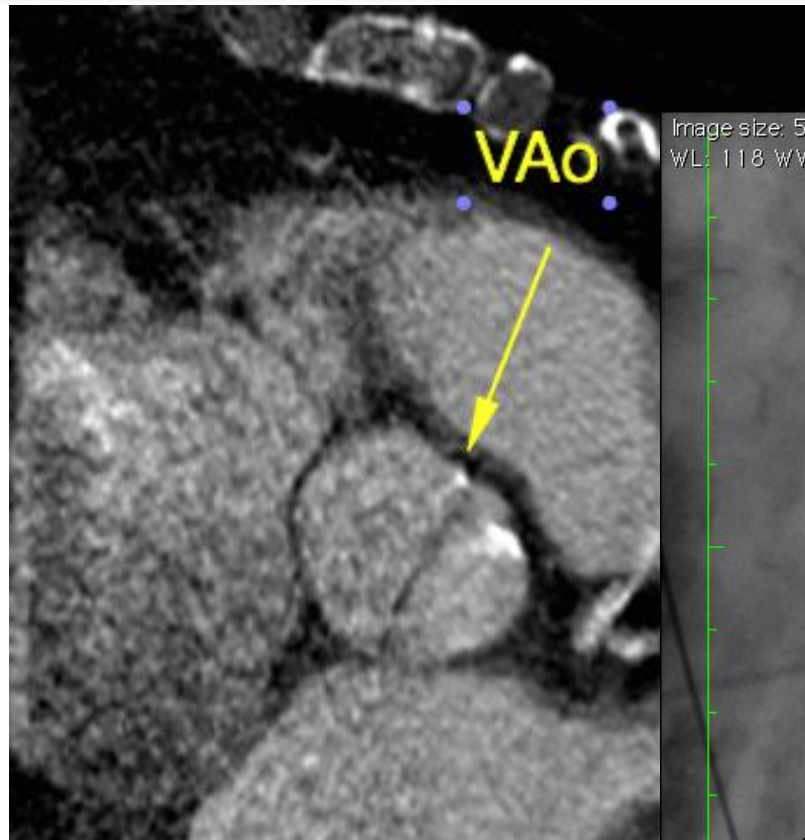
**ADAPTIVE SEAL – PREVENTING PVL**



**IDEAL DEVICE FOR COMPLEX CASES (Calcium; Bicuspid; Horizontal  
Aorta; Low Flow Low Gradient)**

**Aortic Regurgitation (?) / Valve in Valve (?)**

# Bicuspid Calcified Valve



**Area: 526 mm<sup>2</sup>**





# Low Flow Low Gradient Aortic Stenosis

How to keep the procedure safe without clinical instability? Which strategy? LVEF: 23%

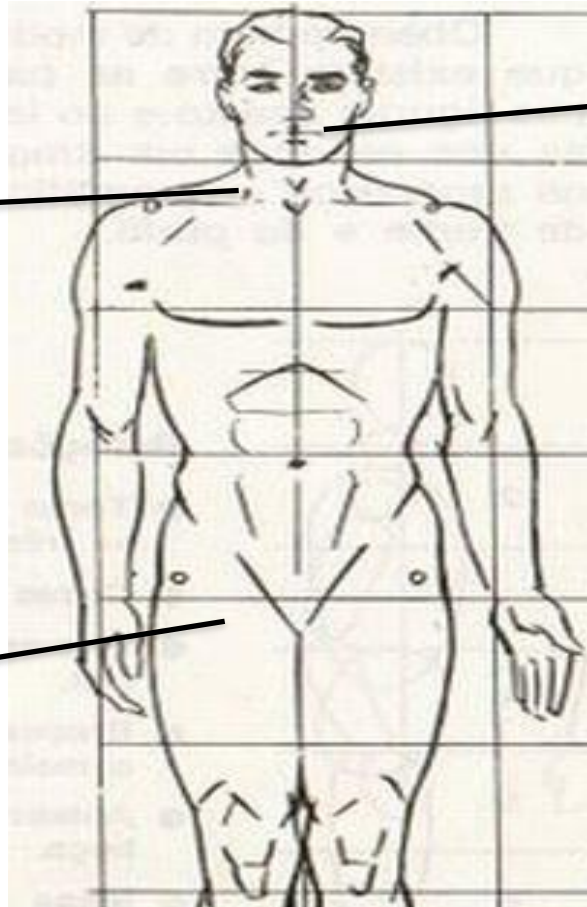
## MINIMALLY INVASIVE

Internal Jugular Vein

- . 6F introducer
- . 5F pacemaker
- . Central Venous Line

Right Femoral Artery  
Main Access

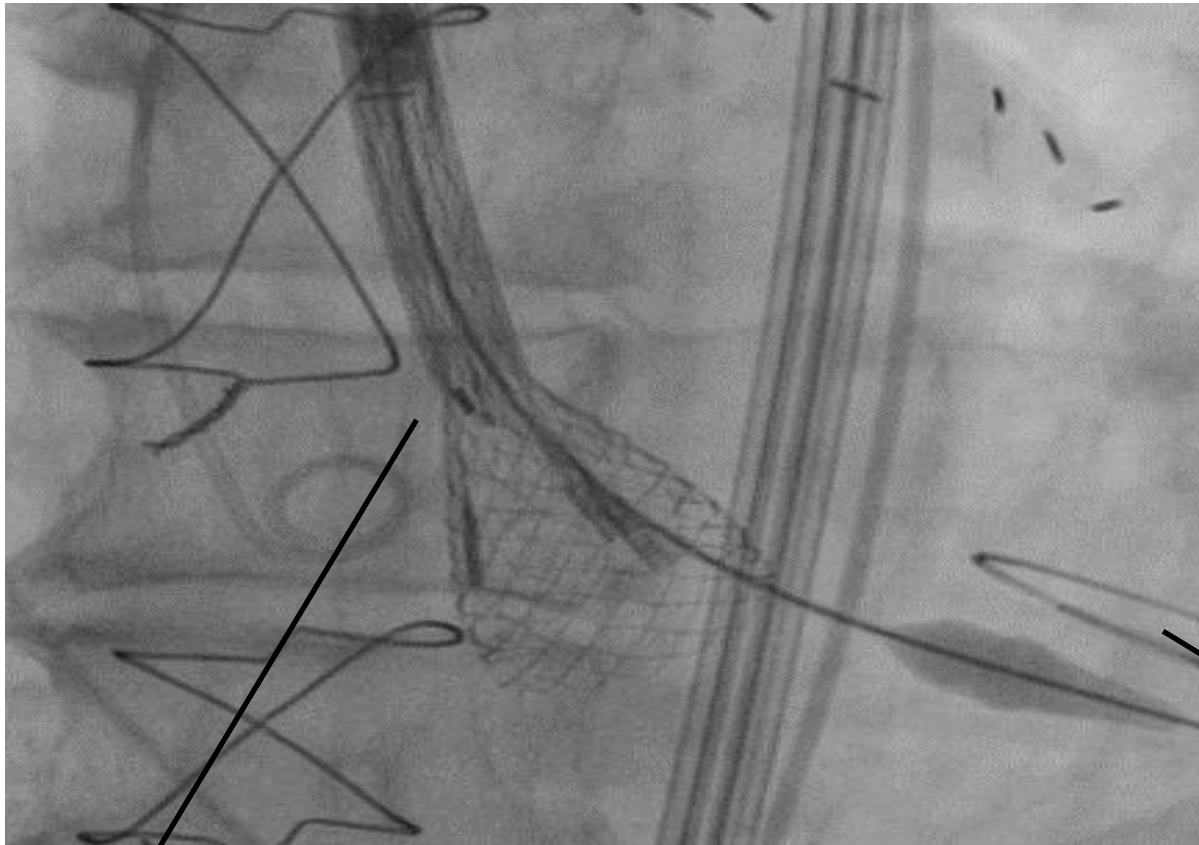
- . 18F introducer
- . 2 Proglides™



Conscious Sedation

- . Fentanyl
- . No endotracheal intubation
- . No Foley catheter
- . No TEE
- . TTE at the end

# Low Flow Low Gradient Aortic Stenosis



**Direct TAVI**  
**No Predilation – No Rapid Pacing**  
**No Instability**

**Early Valve Functioning**  
**No Instability**

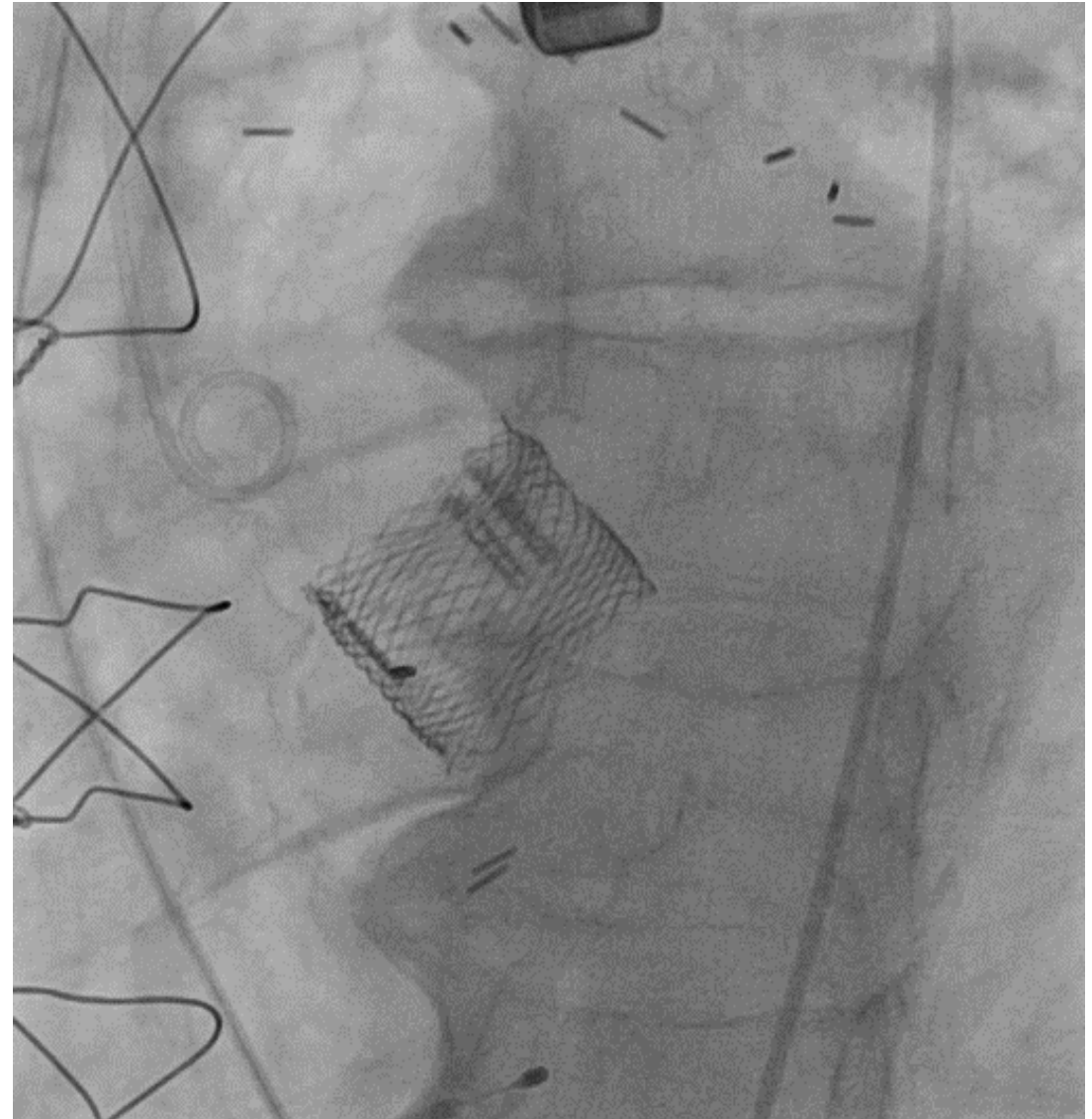
**Safari Wire™**  
**More Stability**

# Low Flow Low Gradient Aortic Stenosis

**No post dilation - No instability  
Without Aortic Regurgitation**

**.24 h ICU**

**. 48h Hospital  
Discharge**

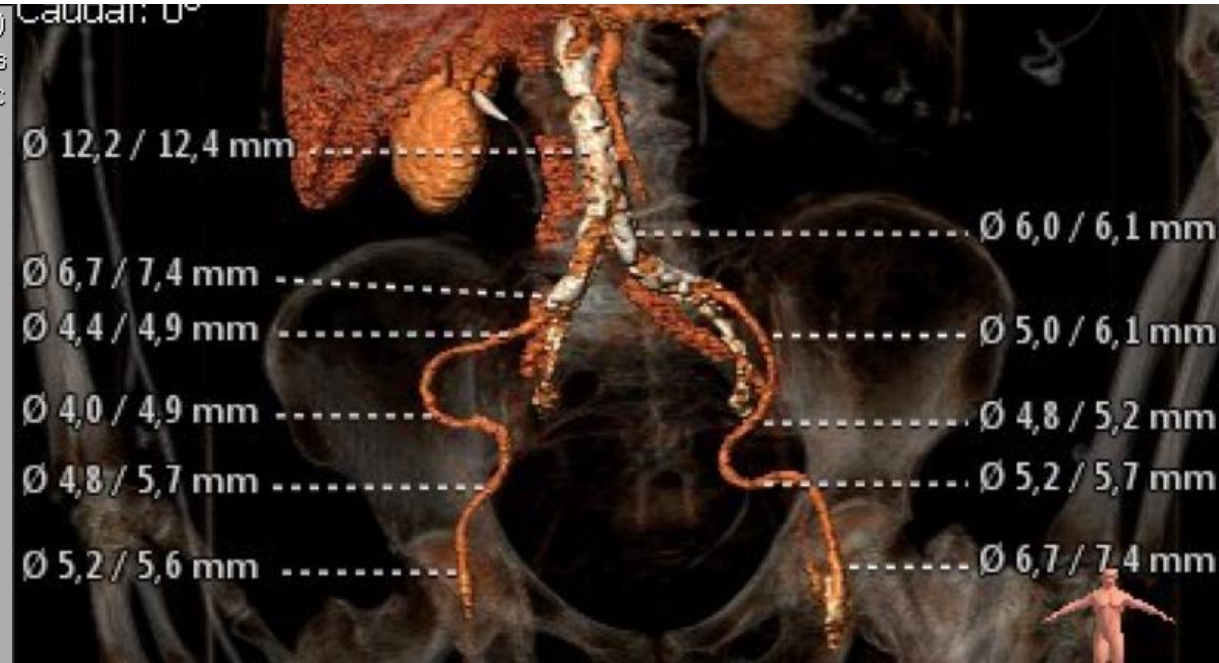




# Small and Calcified Vascular Access

Image size: 512 x 512  
WL: 128 WW: 256

13387 ( -, - )  
Special Procedures  
Cardiac



## Contralateral Protection

Zoom: 113%

Im: 1/15 Series: 25

LittleEndianExplicit

09/05/16 10:48:11

Made In OsiriX



## iSleeve™

- Ultra-thin walled expandable sheath
- Low Profile (14F) introduction and removal
- Transient expansion to minimize vessel trauma
- Designed to work with LOTUS Edge™



## Bolt™

- Direct access aortic sheath
- Reduced length
- Uncoated
- Multiple radio-opaque markers



6 – FUTURE: Lotus Edge™ (Q4 2017)



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## Our Experience With the Last Generation Valves

**Hospital Brasil – Santo André**



**Hospital São Luiz – Morumbi**



**Thank You**

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