AP VALVES 2018
Seoul, Korea, Aug 9-11, 2018

TAVR Outcome of Venus / Venibri Valve

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Disclosures

Physician name	Company	Relationship
Horst Sievert	Abbott, Ablative Solutions, Ancona Heart, Bioventrix, Boston Scientific, Carag, Cardiac Dimensions, Celonova, Cibiem, CGuard, Comed B.V., Contego, CVRx, Edwards, Gardia, Hemoteq, InspireMD, Kona Medical, Lifetech, Maquet Getinge Group, Medtronic, Occlutech, pfm Medical, Recor, St. Jude Medical, Terumo, Trivascular, Vascular Dynamics, Venus, Veryan	Consulting fees, Travel expenses, Study honoraria

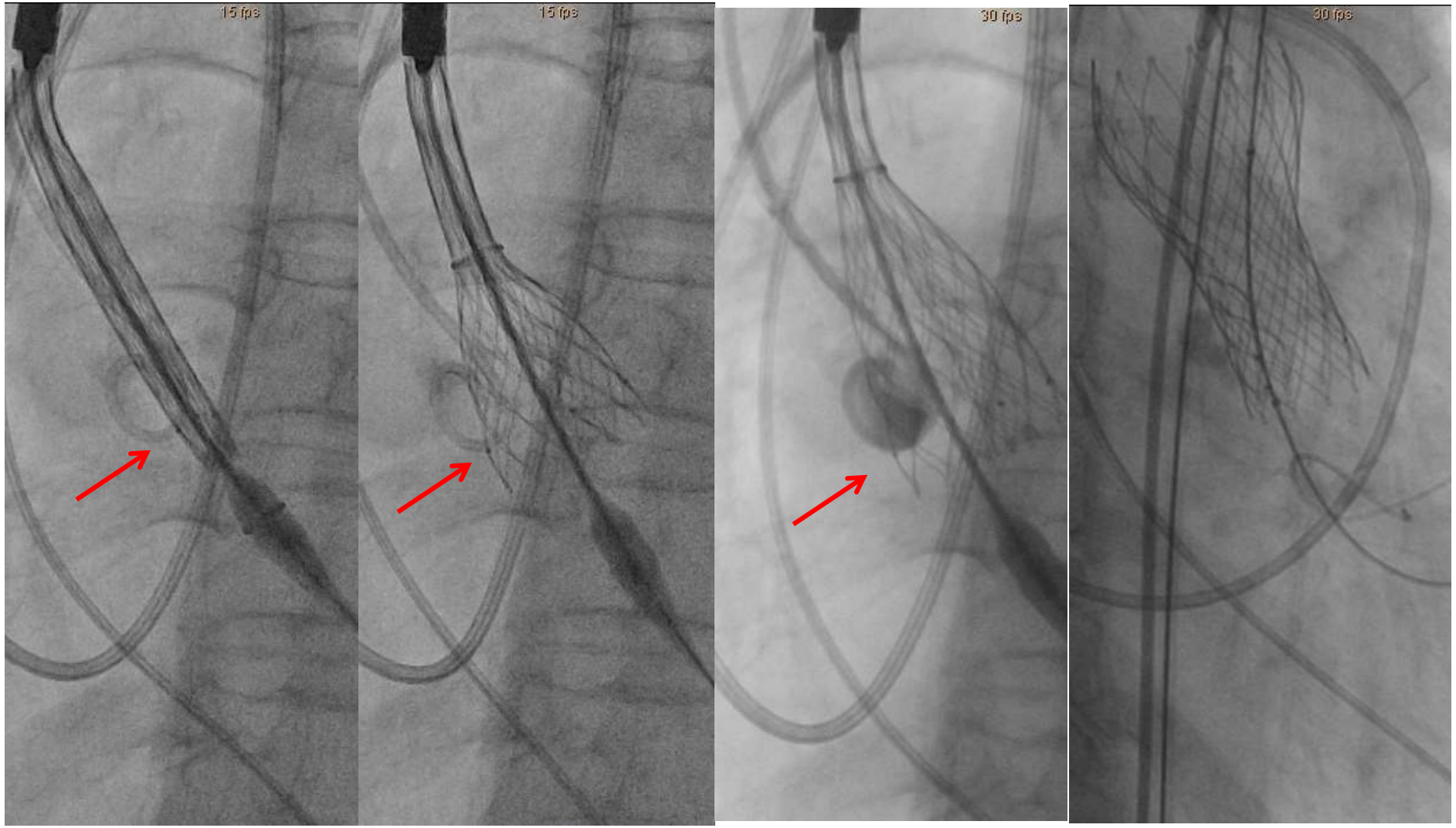
Venus A-Valve System

- Self-expanding frame
- Porcine pericardial valve
- Supra-annular leaflets
- 23, 26, 29 and 32mm
- 19 F, but can be used without sheath
  - "15 F comparable"

Venus A-Valve compared to Evolut

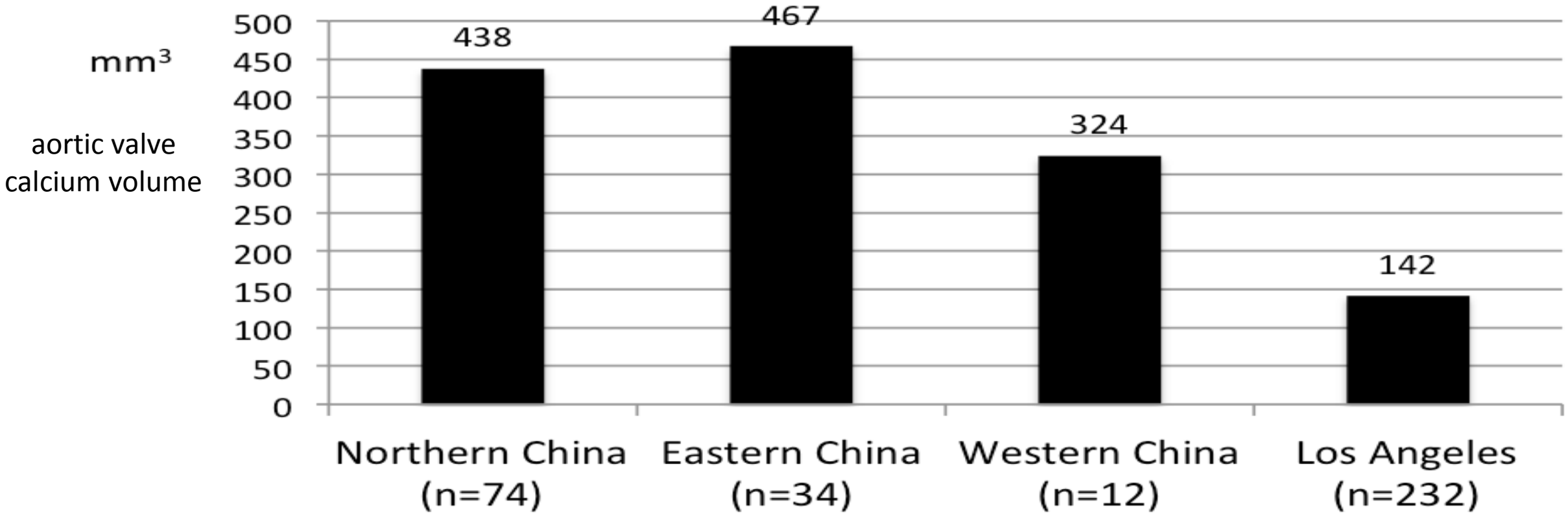
- Advantages
  - Positioning marker for easier placement
  - More stable deployment
  - Higher radial force
- Disadvantage
  - Not retrievable

Very stable and precise deployment



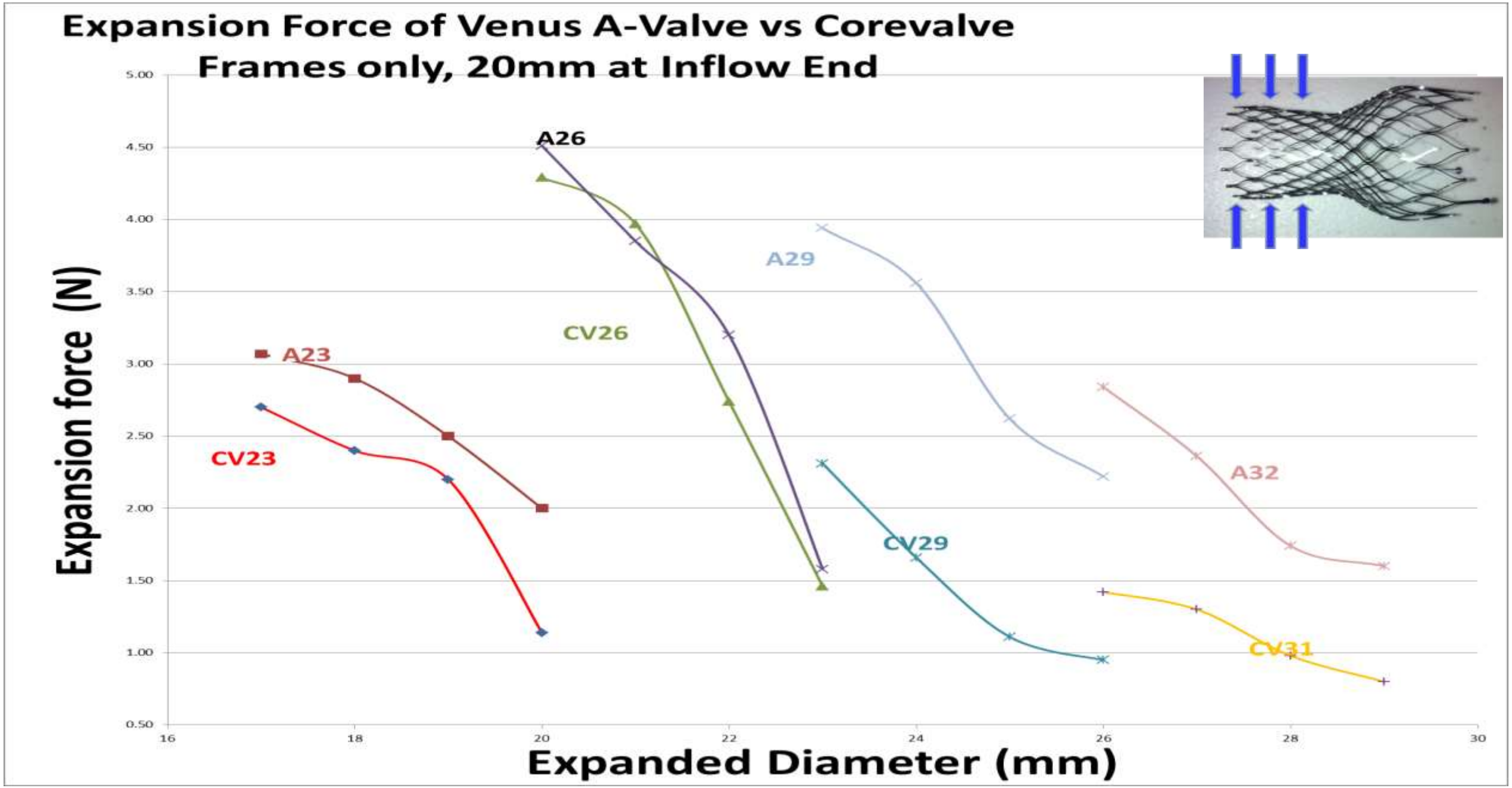
More calcified valves in China

(contrast CT scans; HU-850 threshold)



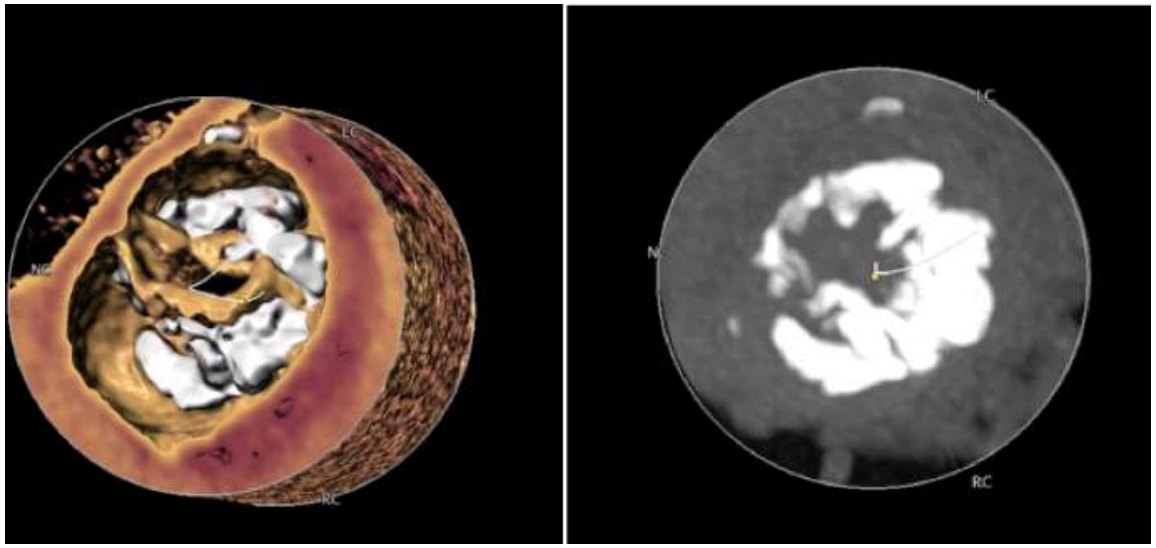
Hasan Jilaihawi, CCH 2014, Beijing

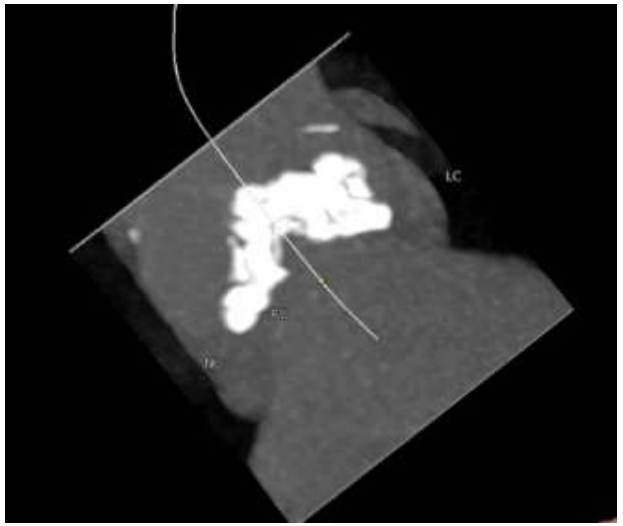
Expansion Force A-Valve vs Corevalve

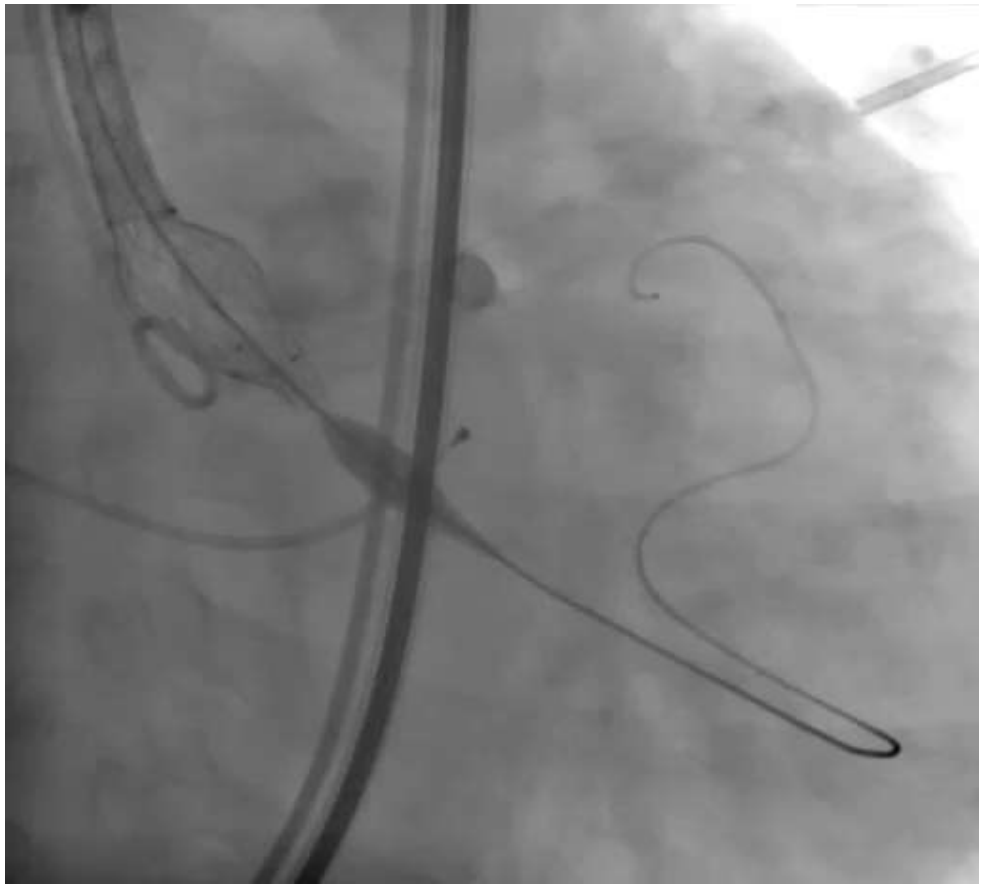


Case Examples

First generation Venus A-Valve (frame comparable to Corevalve) in *extreme* aortic valve calcification

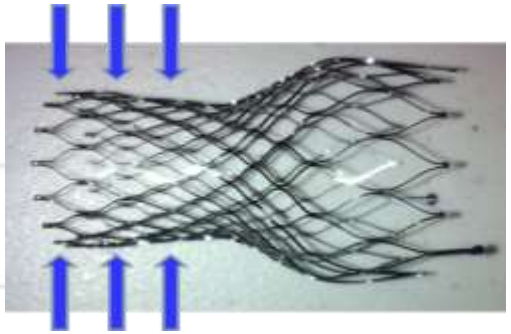


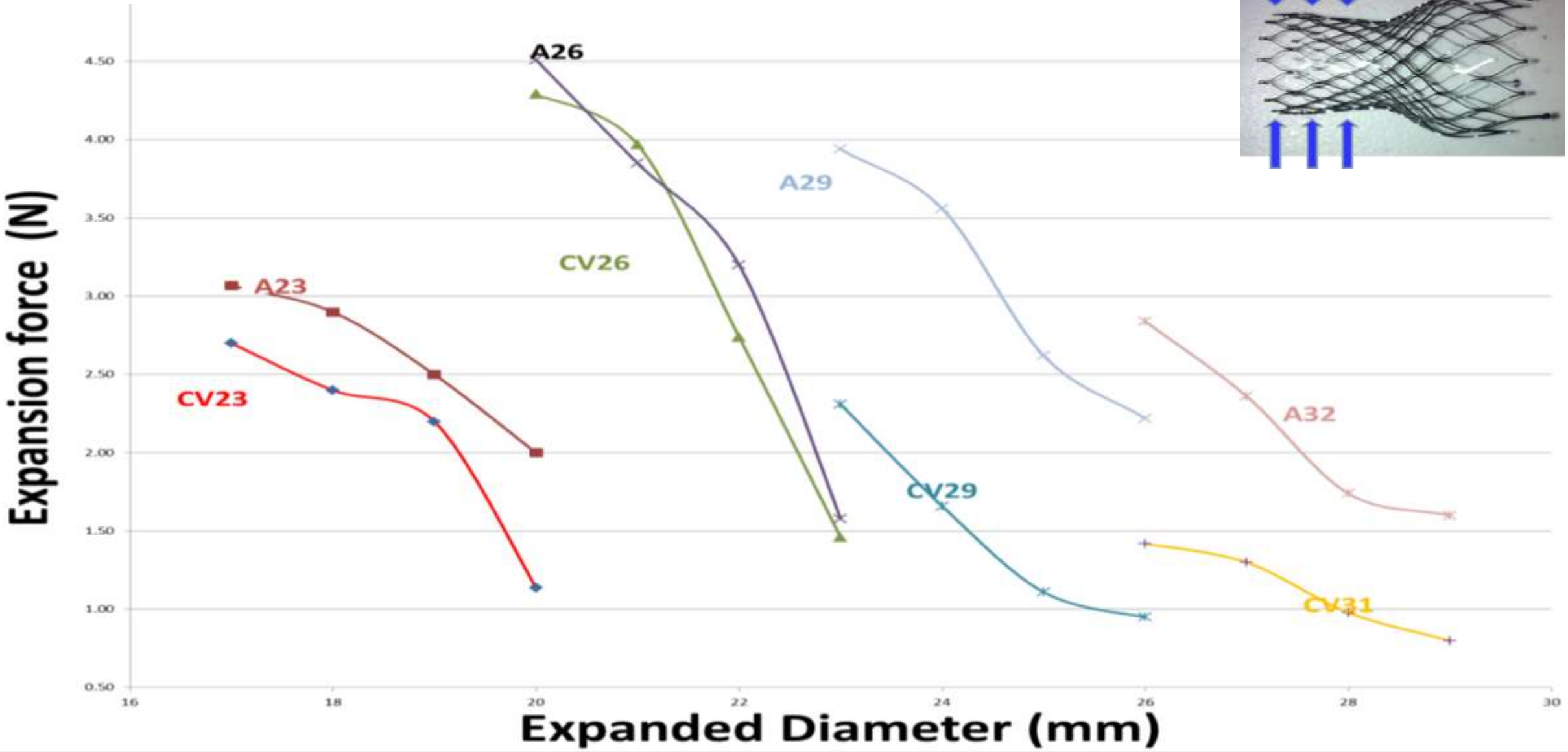




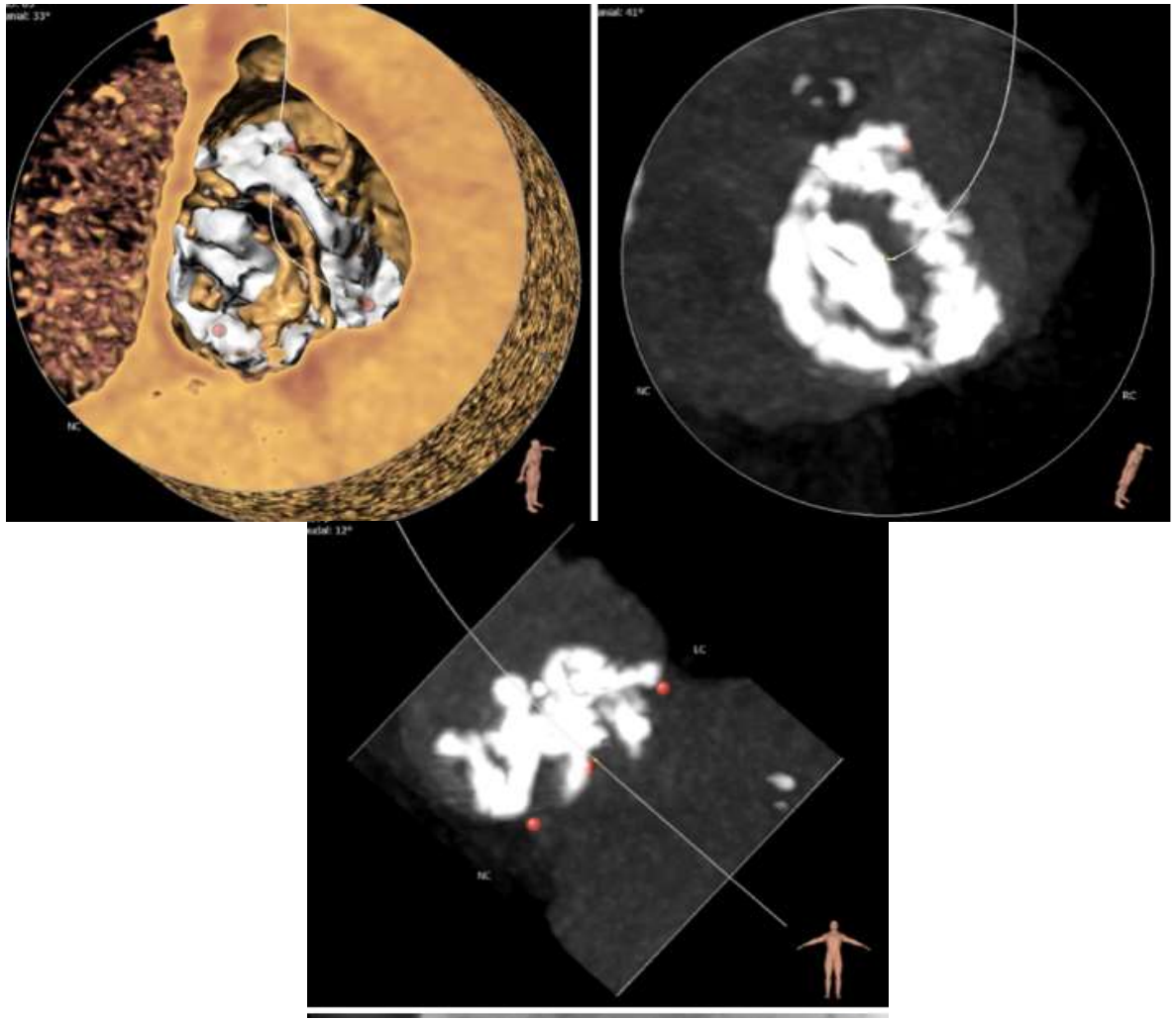
Valve not expanding

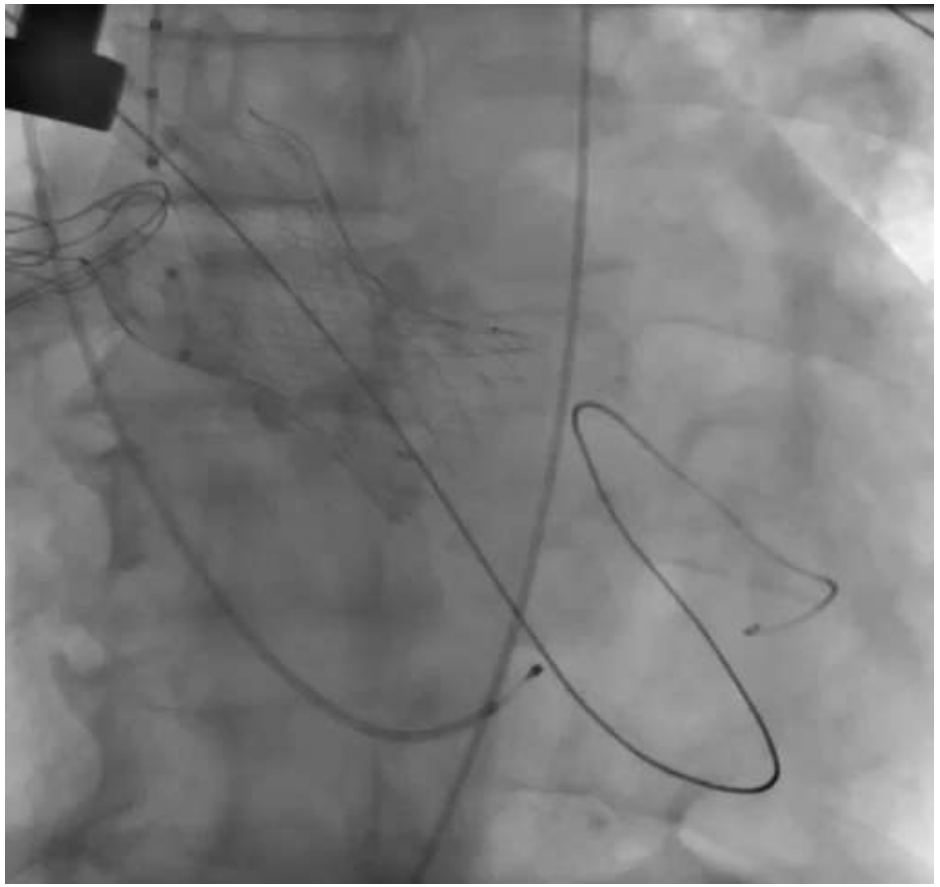
Expansion Force: second generation Venus A-Valve vs Corevalve





Second generation Venus A-Valve (frame with increased radial force) in *extreme* aortic valve calcification



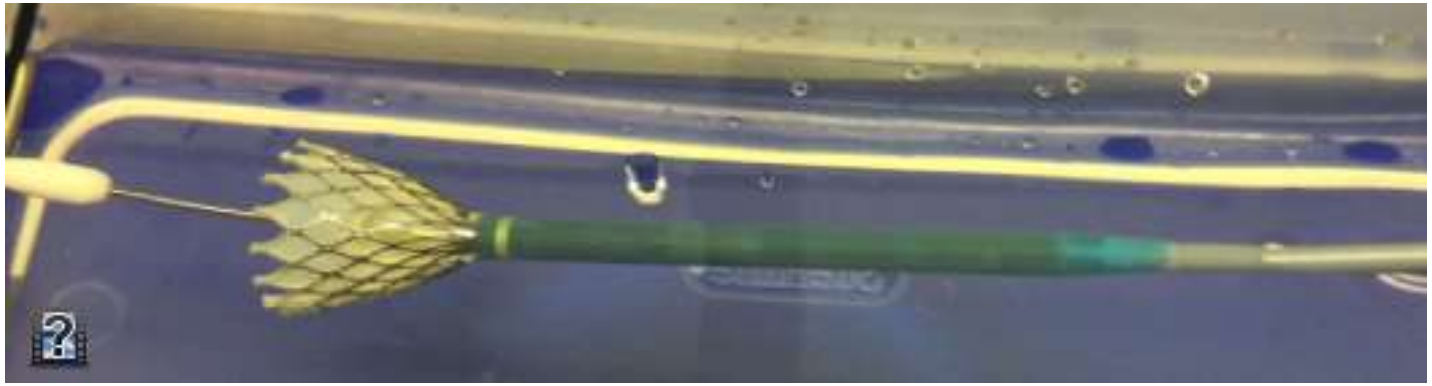


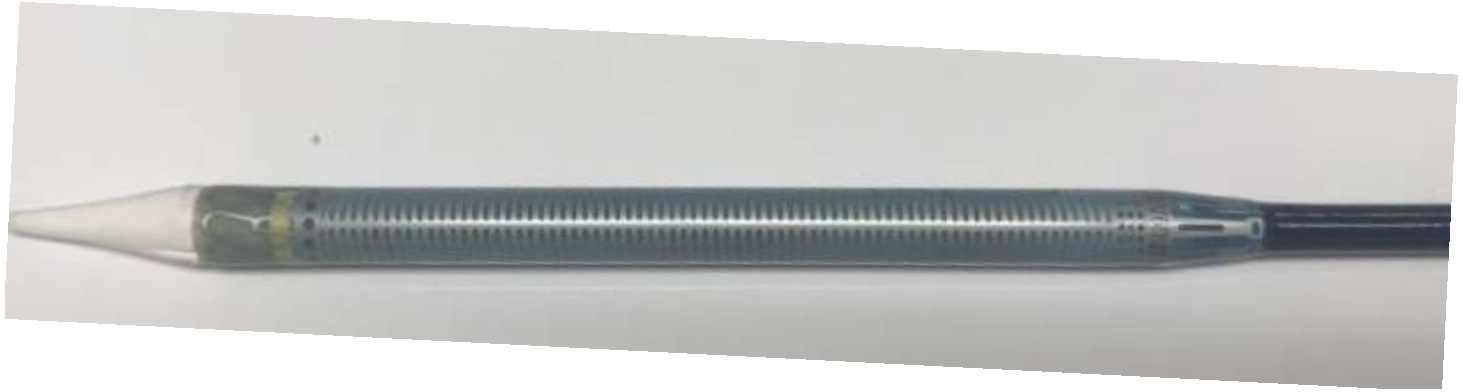
Valve expanding

Venus A trial

- 2012 to 2015
- N = 101
- 75.4 ± 6.4 years
- median STS score 5.5%
- 97 native valves, 4 valve in valve
- 45.4% bicuspid and 54.6% tricuspid aortic valve
- 30 day outcome
  - Mortality 5.3%
  - Stroke 1%

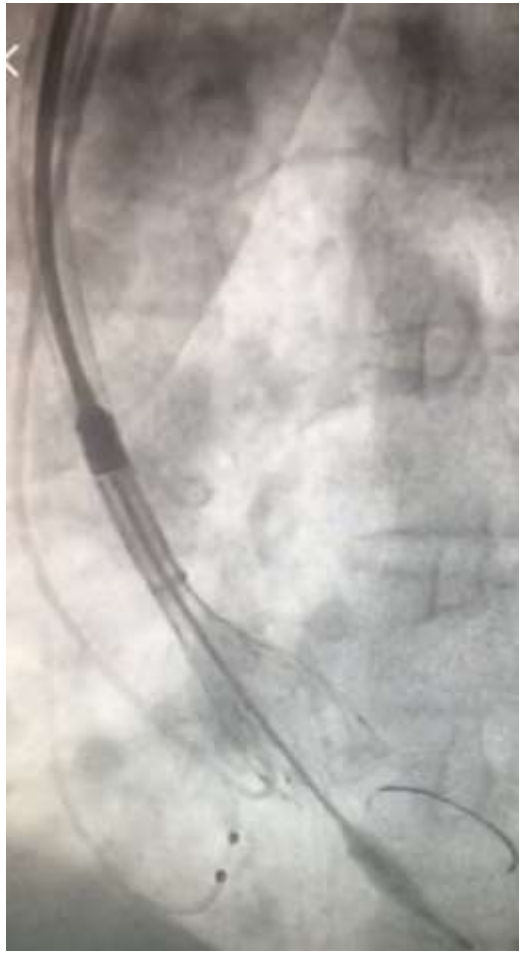
Venus A+ Retrievable System

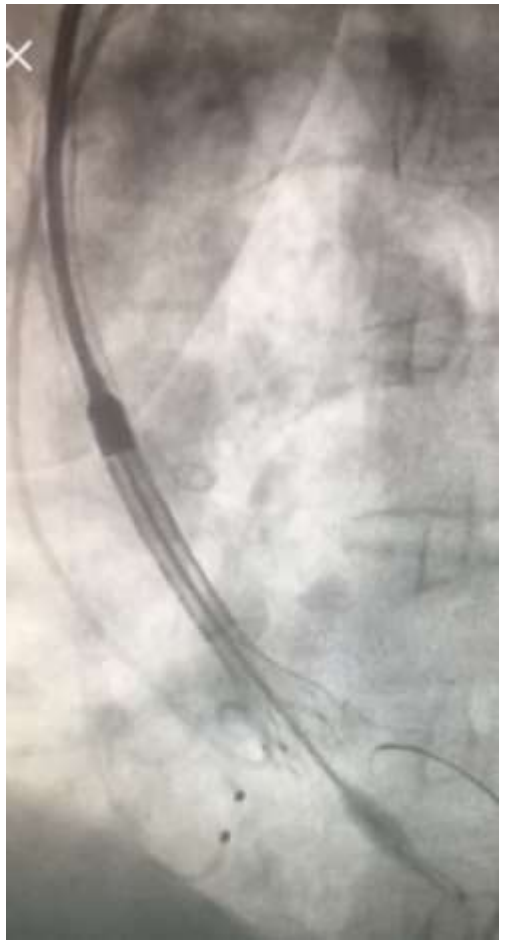


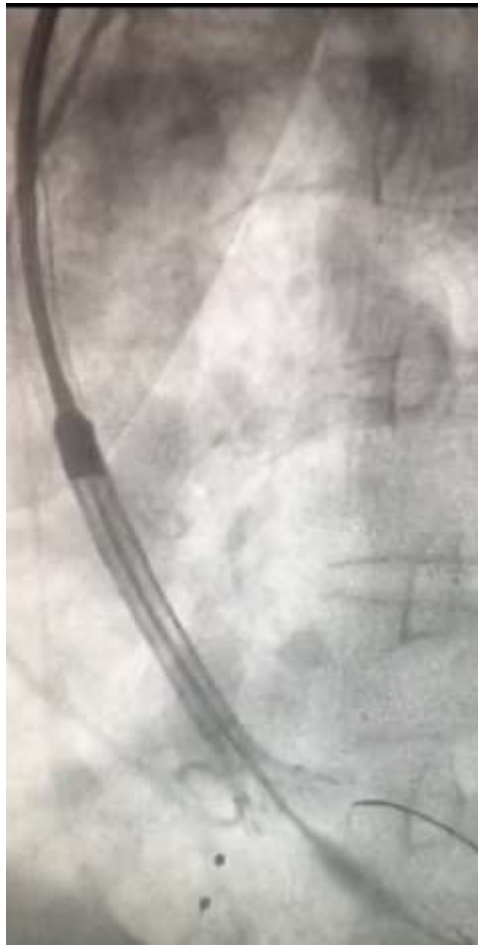


Reinforced Capsule

Venus A+ Retrievable System in clinical trial in China







V-Sheath – Expandable Sheath

Lumen 14 F expandable to 19 F
Lumen 17 F expandable to 24 F

VENIBRI I

- Same Nitinol frame as Venus A valve
- Dry Tissue Technology (Colibri)
- 18Fr delivery system
- Prepackaged at factory
- 17 human implants to date

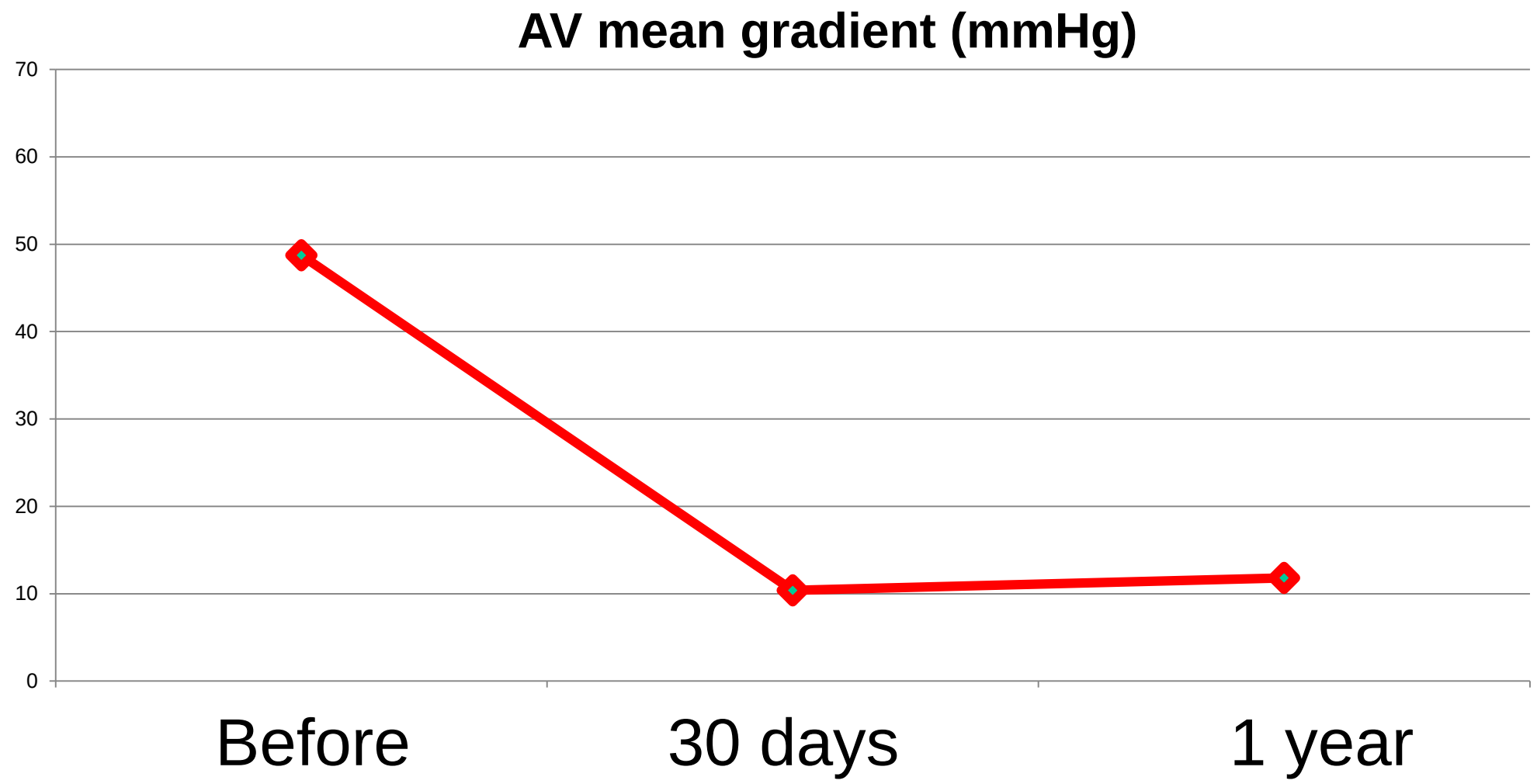
Venibri is the joint venture project of Venus MedTech and Colibri Heart Valve

Venibri I - Baseline

Characteristic	N=17
Age（year）	81±4
Male	70% (N=12)
STS >4	100% (N=17)
NYHA class III or IV	100% (N=17)
Diabetes	17% (N=3)
Prior Stroke	5% (N=1)
Chronic Obstructive Pulmonary Disease	11% (N=2)
Creatinine >2 mg/dl	11% (N=2)
Prior Myocardial Infarction	11% (N=2)
Prior Coronary Intervention	29% (N=5)
Pre-pacemaker	5% (N=1)

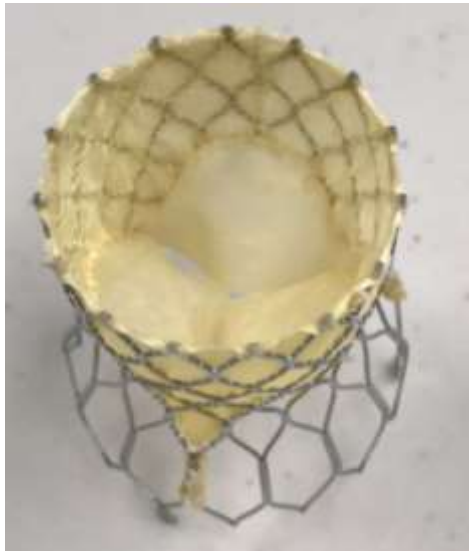
Venibri I - Outcomes

N = 17	30 days	1 year
Technical success	100% (N=17)	=
ModeratePVL	6% (N=1)	12% (N=2)
New pacemaker	12% (N=2)	=
Vascular complication	6% (N=1, false aneurysm, contralateral)	=
New hemodialysis	6% (N=1, pt with pre-existing renal failure)	=
Death	6% (N=1)	18% (N=3)
Stroke	0% (N=0)	=


AV mean gradient (mmHg)
70
60
50
40
30
20
10
0
Before
30 days
1 year

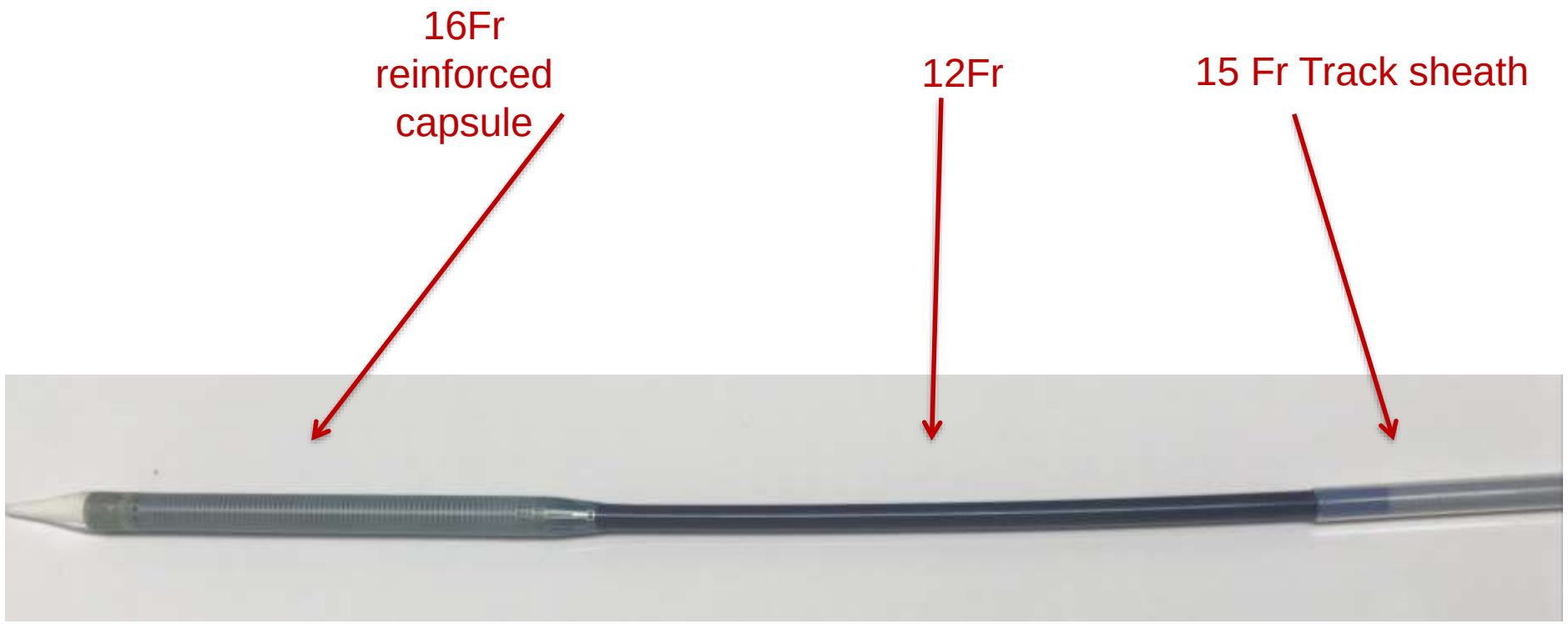
VENIBRI II - Third Generation Aortic Valve

- New frame design
- Porcine pericardium, Dry tissue technology
- Pre-packaged ， 16Fr system, Retrievable
- Integrated cerebral protection
- Sealing skirt

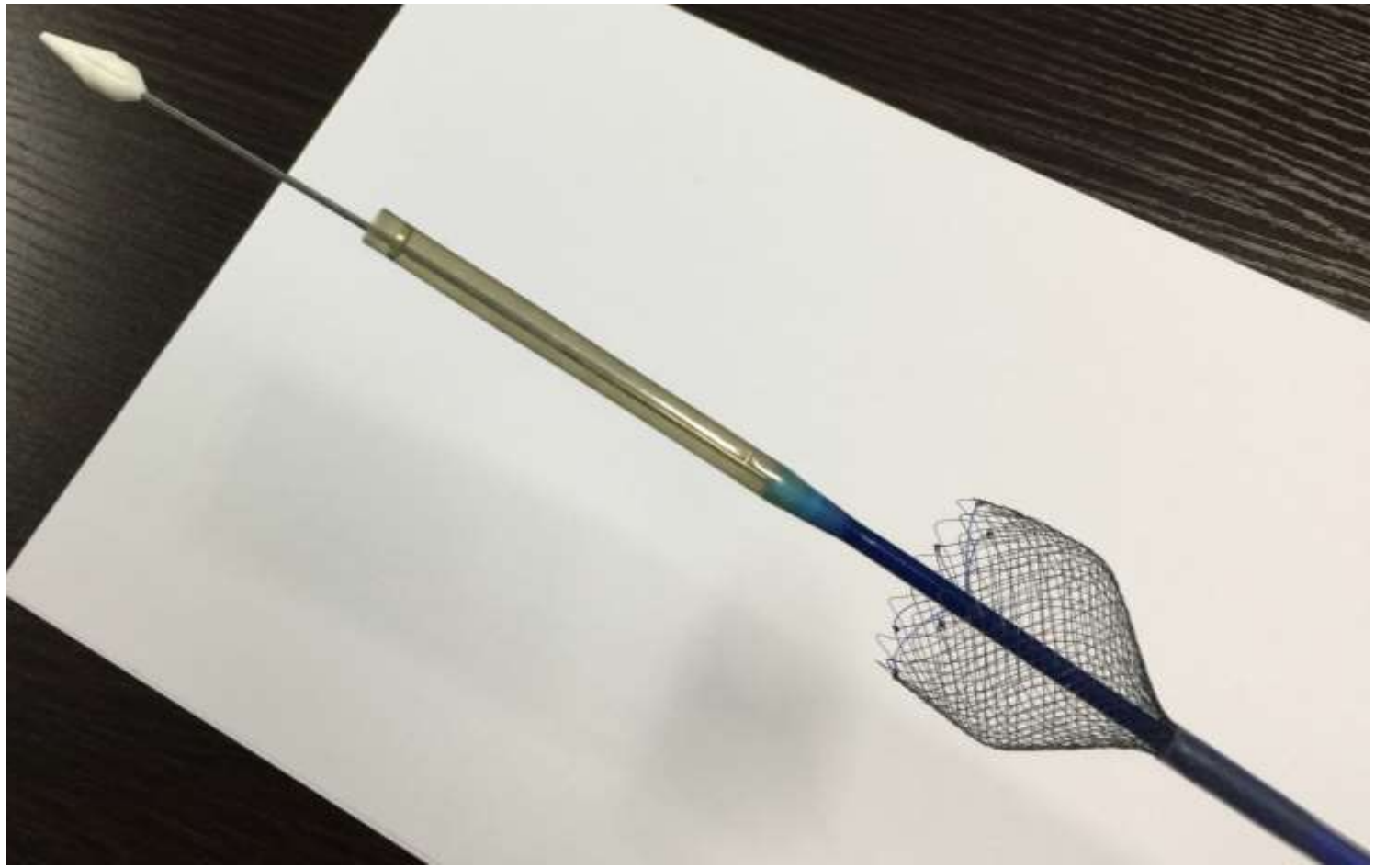


In pre-clinical

Retrievable System for VENIBRI II



Integrated Cerebral Protection



Cerebral Protection

1. Introduce

2. Deploy

3. Capture

4. Retract

Sealing Skirt (I)

When crimped, low profile

Expansion and pull mechanism to form a seal ring

Thank you!

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