Innovations in Interventional Cardiology

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Interventional Cardiology

UNIVERSITY OF MINNESOTA

Driven to Discover®

What I am going to talk about?

1. A story that shows how important/fundamental this speciality is!!
2. An area that is changing rapidly and affecting patients.

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1929 First cath: Werner Forssmann

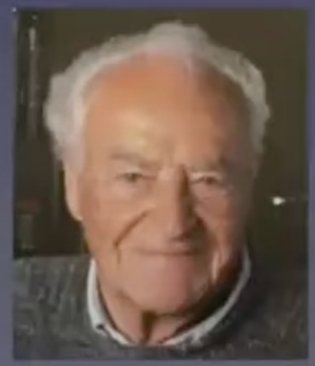
1966 Rashkind: septostomy

1977 Coronary angioplasty

Jean Kan

1982 First balloon valvoplasty

1996 Amplatzer septal occluder



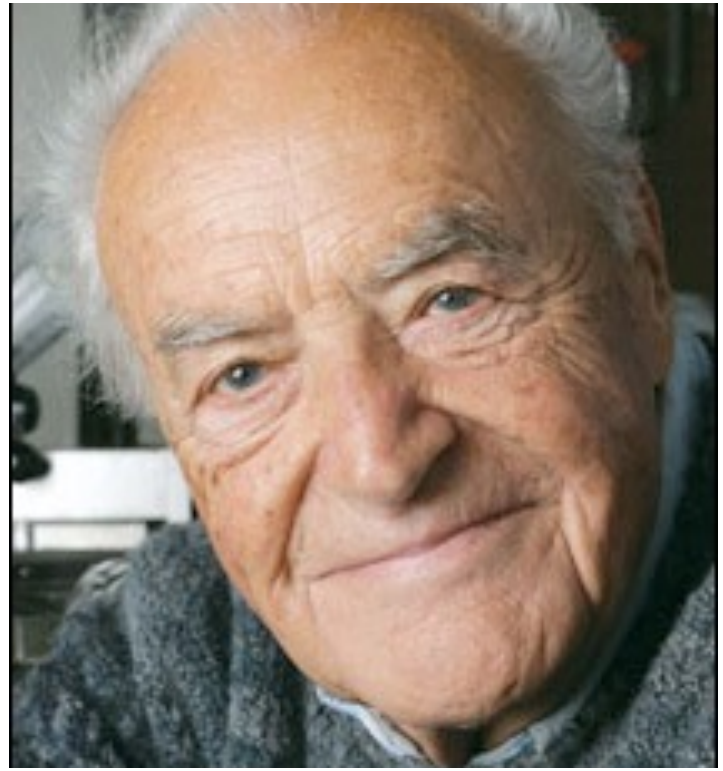
Kurt Amplatz

“Modern” congenital intervention era 2000 onward

CHD: University of Minnesota

C. Walton Lillehai, MD
1918-1999

Kurt Amplatz, MD
1924-2019



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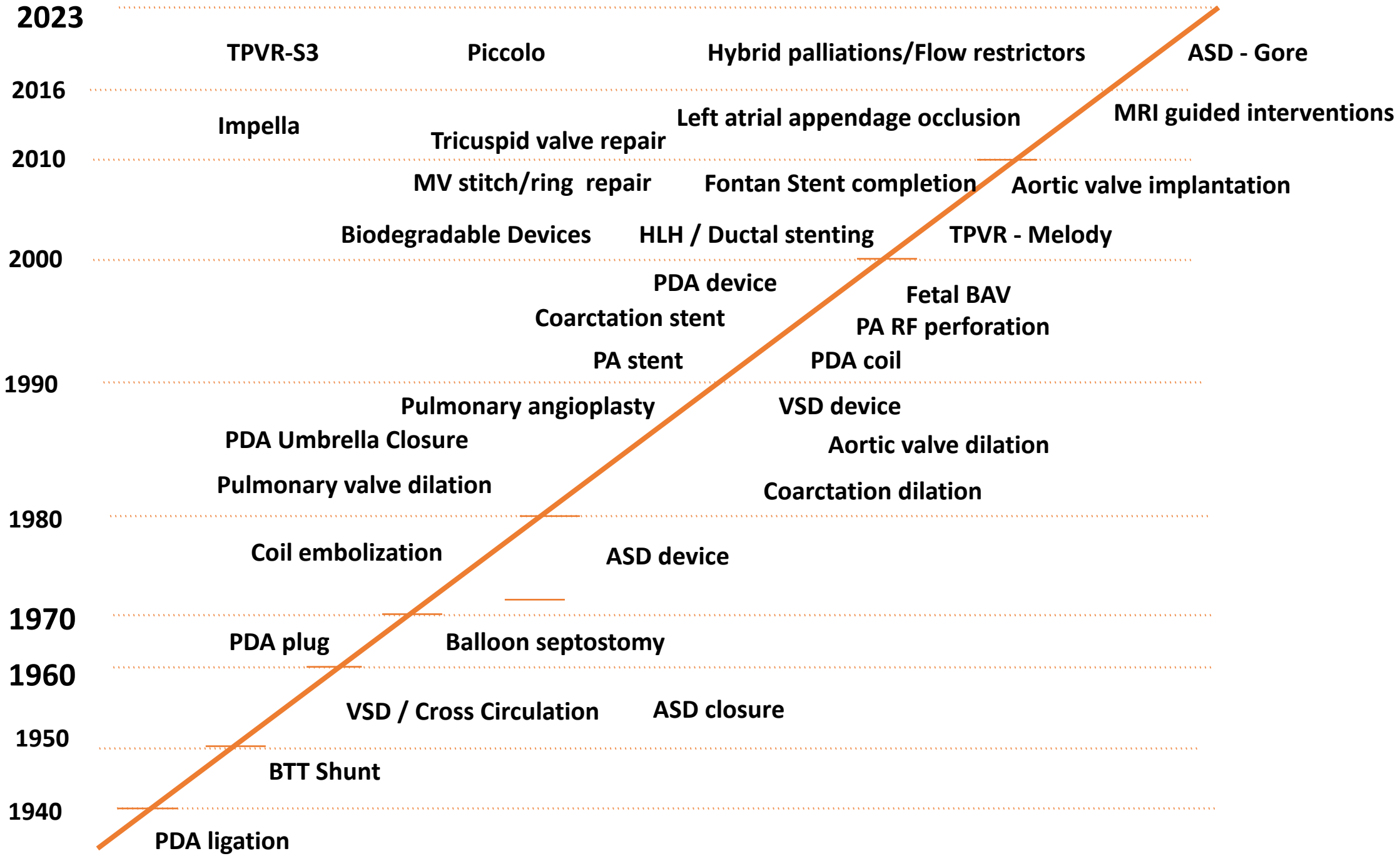
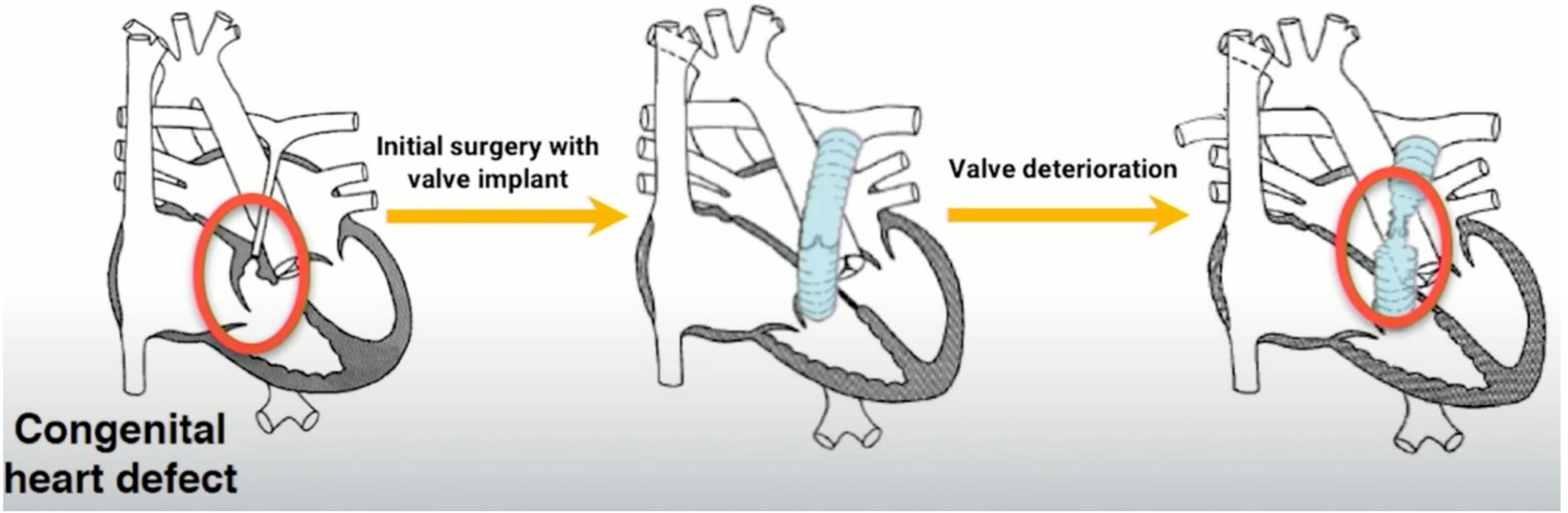

2023
TPVR-S3
Piccolo
Hybrid palliations/Flow restrictors
ASD - Gore
2016
Impella
Left atrial appendage occlusion
MRI guided interventions
Tricuspid valve repair
2010
MV stitch/ring repair
Fontan Stent completion
Aortic valve implantation
Biodegradable Devices
HLH / Ductal stenting
TPVR - Melody
2000
PDA device
Fetal BAV
Coarctation stent
PA RF perforation
PA stent
PDA coil
1990
Pulmonary angioplasty
VSD device
PDA Umbrella Closure
Aortic valve dilation
Pulmonary valve dilation
Coarctation dilation
1980
Coil embolization
ASD device
1970
PDA plug
Balloon septostomy
1960
VSD / Cross Circulation
ASD closure
1950
BTT Shunt
1940
PDA ligation


SURGERY
Dave Tippit


Congenital heart defect
Initial surgery with valve implant
Valve deterioration

The first prototype of a valved stent. This device did not function.

2000
- Bonhoeffer described the use of TPV in France

2003
- First use of Melody TPV in England

2005
- Canada
- 100th patient implant in England

2006
- Europe
- FDA Investigational Device Exemption (IDE) subsmission- first commercially available TPV in North America
- CE Mark- first TPV available commercially, Health Canada approval

2007
- First US IDE study implant
- Use in Saudi Arabia

2009
- First use in Australia
- US FDA panel meeting

2010
- US FDA approval for Melody valve under Humanitarian device exemption (HDE) designation
- First investigational use of Harmony valve in Europe

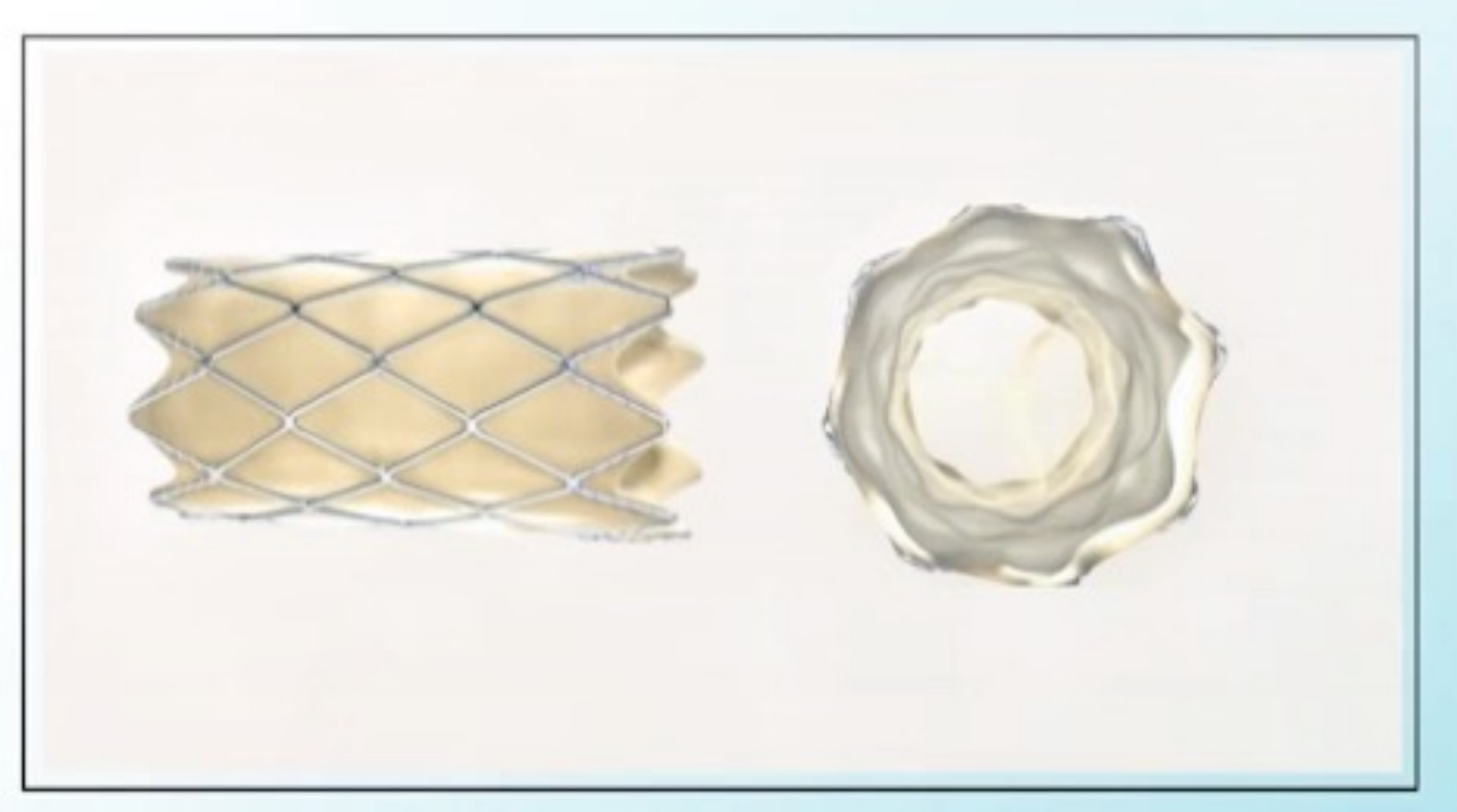
2012
- Use in Bangladesh and Latin America

2014
- Investigational use of venous-P valve from Chicago and China

2015
- Premarket approval of Melody valve by US FDA

2016
- US FDA approval of SAPIEN XT (pulmonary) for PV replacement
- First data from investigational use of the Medtronic Harmont TPV released

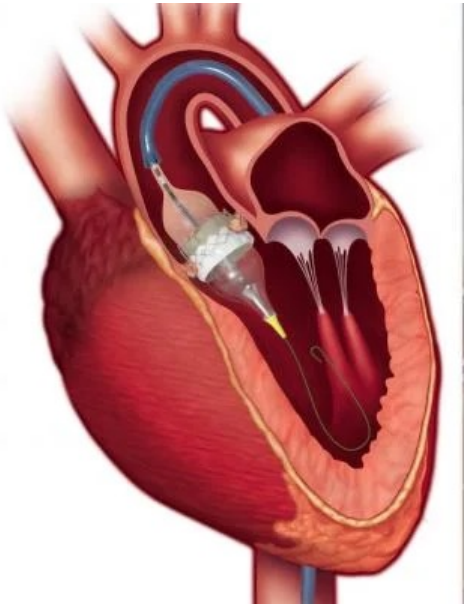
Melody



Animation from Medtronic.com

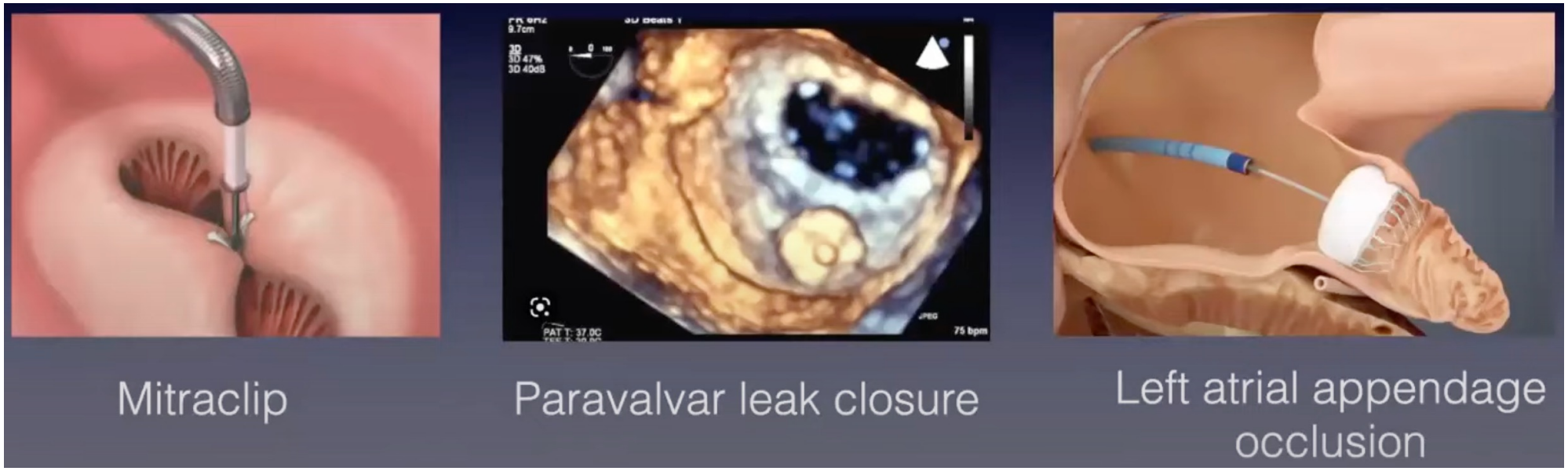
Dr. Bonhoeffer work let directly to …

- TAVR: Transcatheter aortic valve replacement
- Initially for inoperable adult patients but now low-risk population
- Outperforms surgery in every domaine ….
- USA: More than 74,000 TAVRs in the USA
  - Surgical valves: 59, 000



And from there …

The “era” of “structural” cardiac cath interventions was born



Most importantly for us: **Symbiosis**

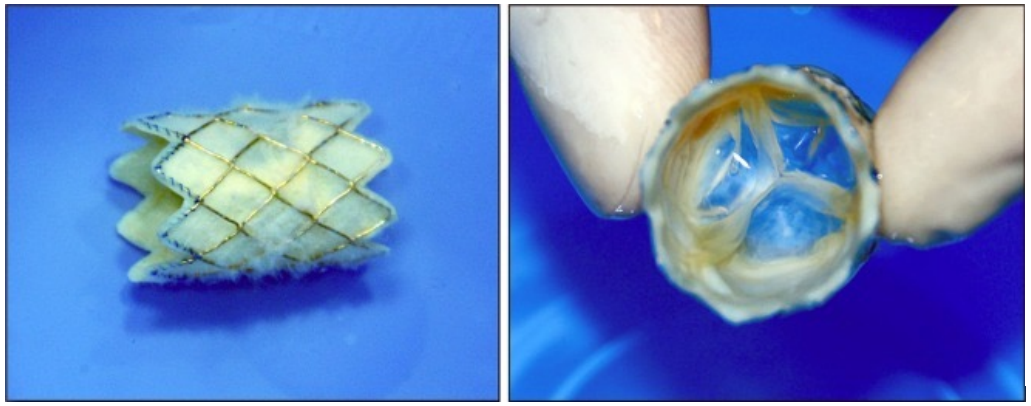
Nothing exists in isolation

The structural intervention dollar brings …

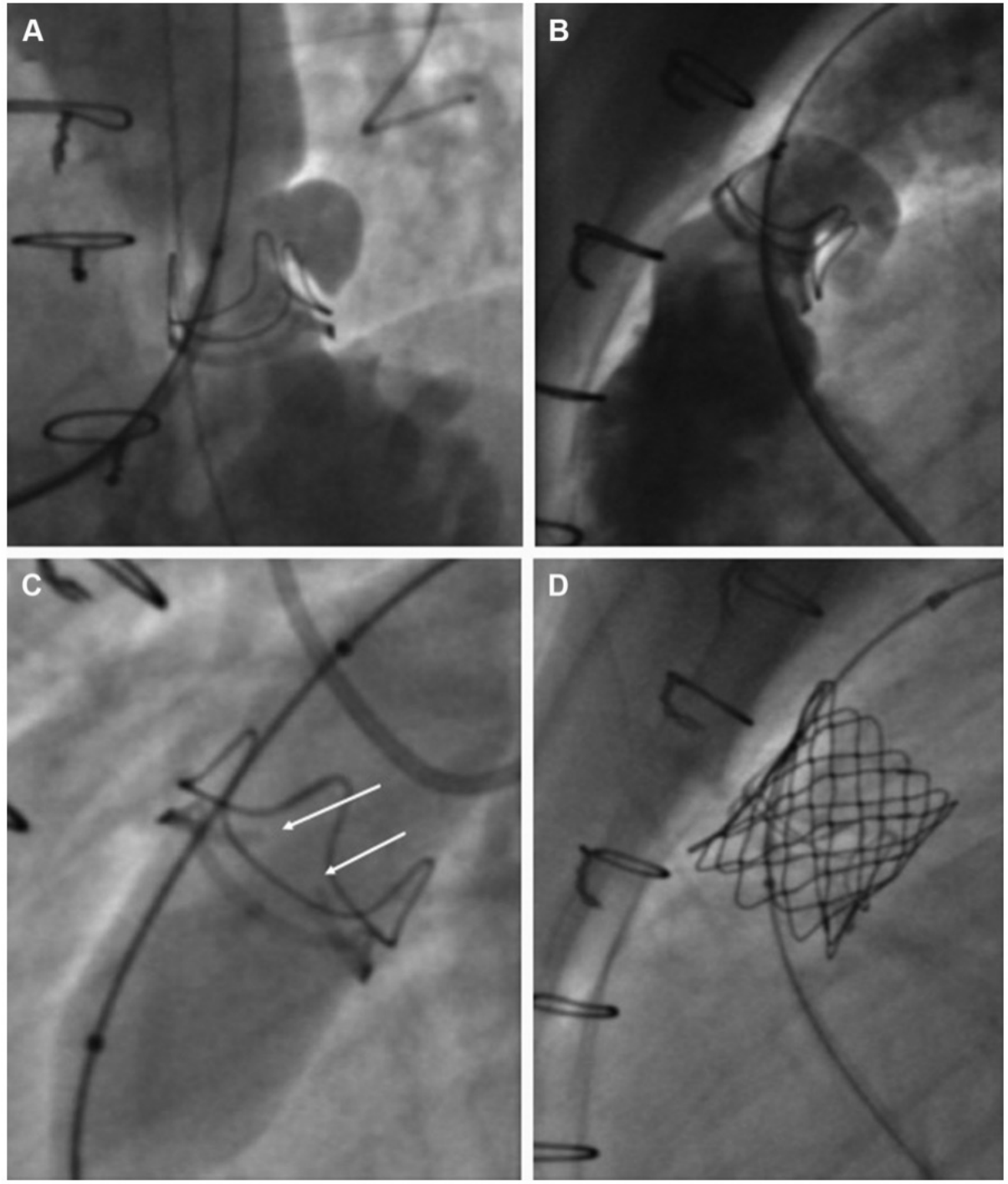
- **Fundamental research**
- Valve longevity
- Materials
- Miniturarisation
- Data collection and organization
- Influence

Transcatheter Pulmonary valve Implantation -Balloon -

The Medtronic Melody® pulmonic valve



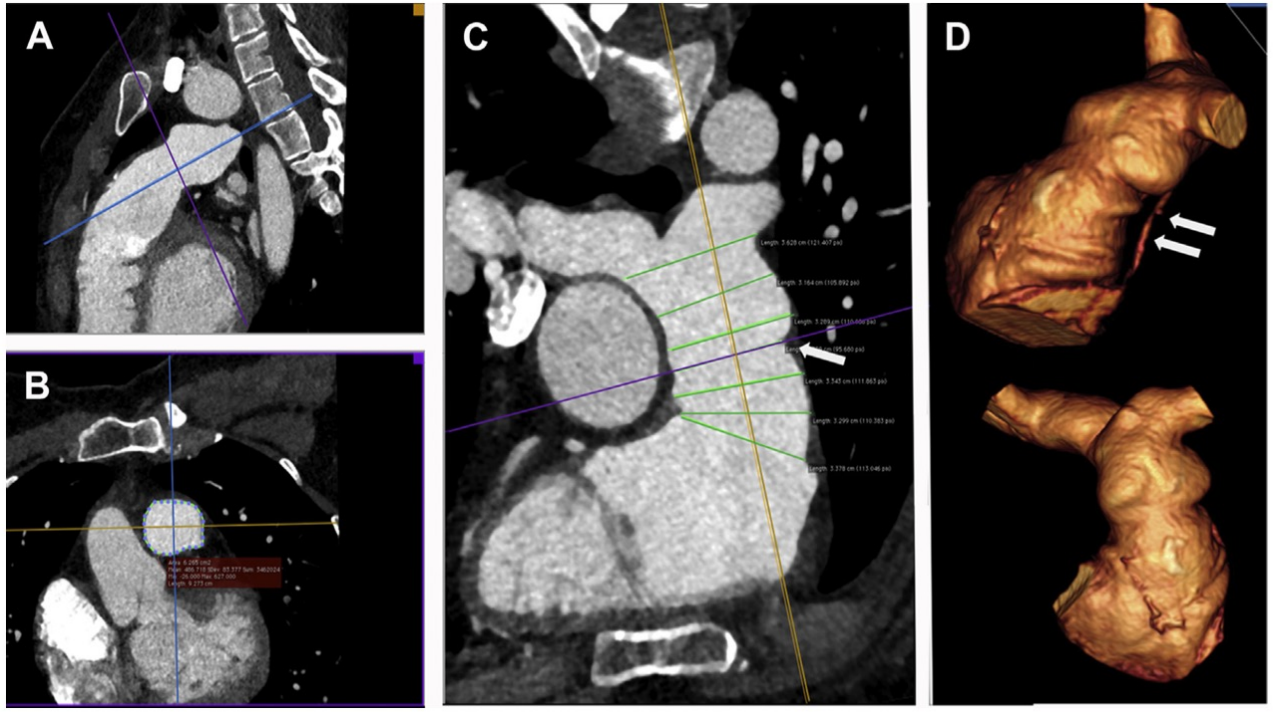
The Edwards Lifesciences SAPIEN™ valve


A
B
C
D

Large native outflow tracts

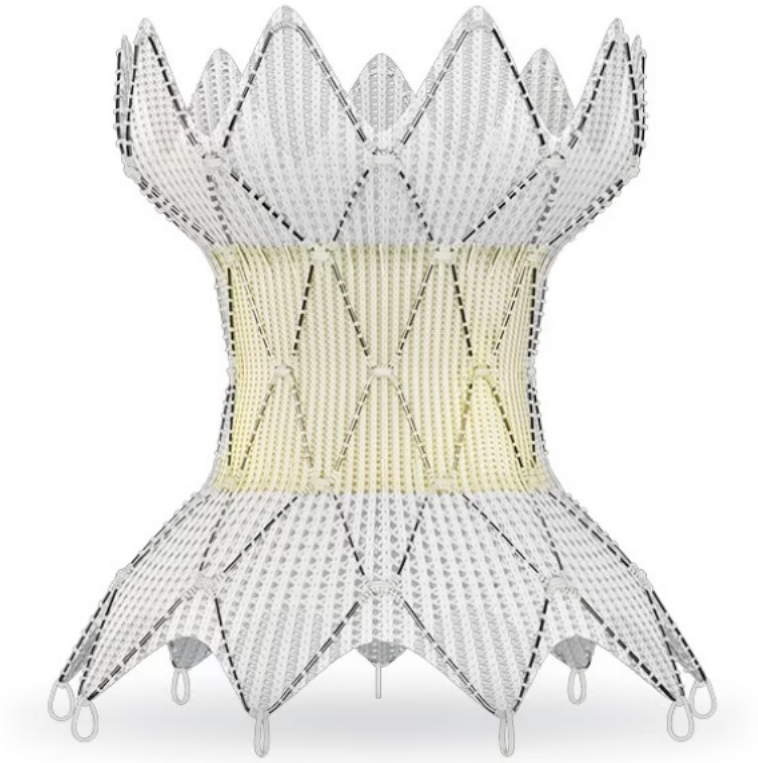
- The majority of native outflow in post-TOF patients are >29 mm

- The industry has grown up in this new speciality has given us a new generation of larger self-expanding valves aimed at the pulmonary artery

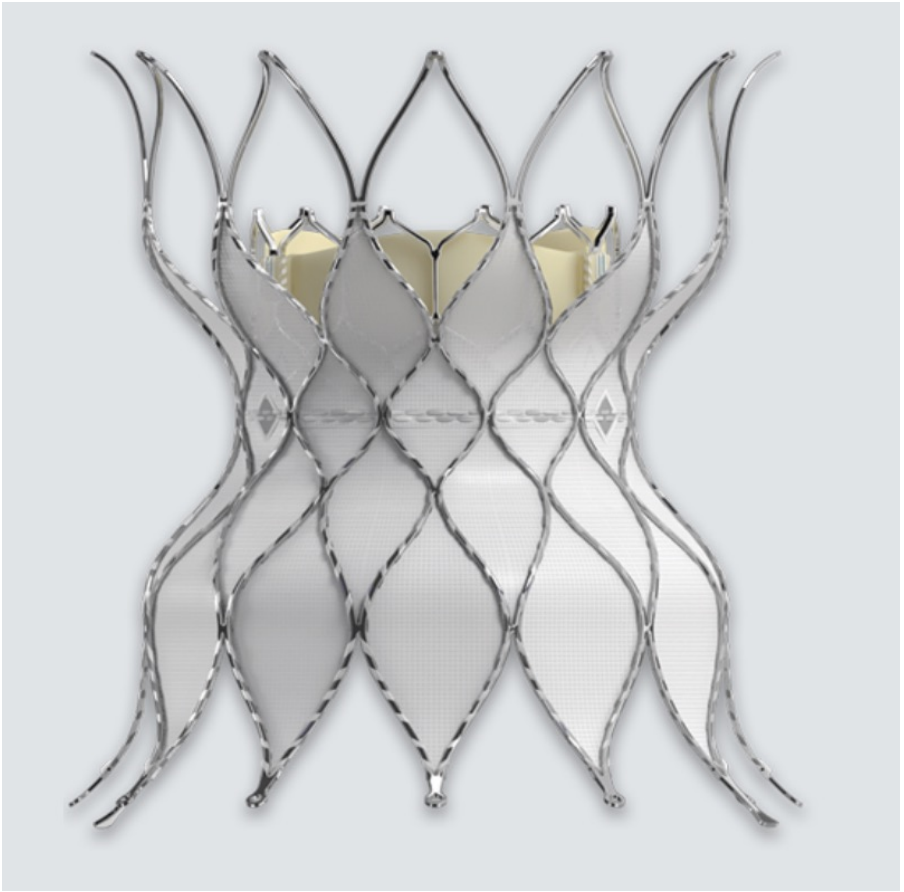


Transcatheter Pulmonary valve Implantation -Other -

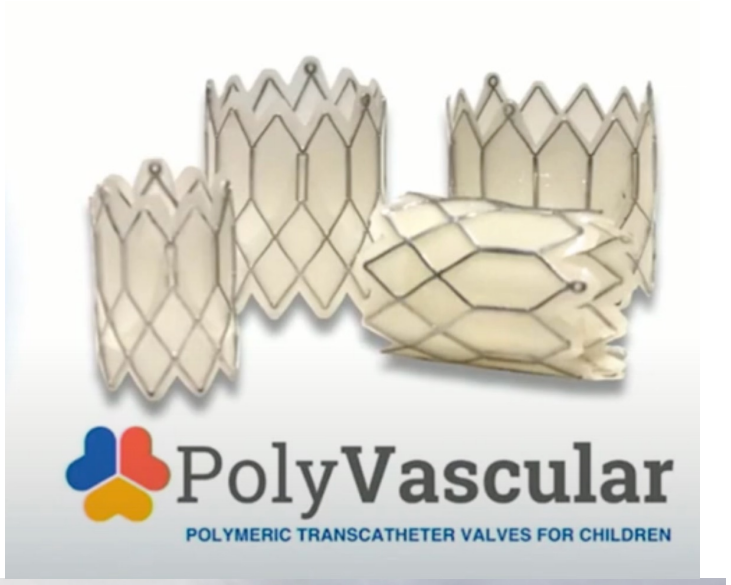
- Medtronic Harmony valve



- Edwards Altera System



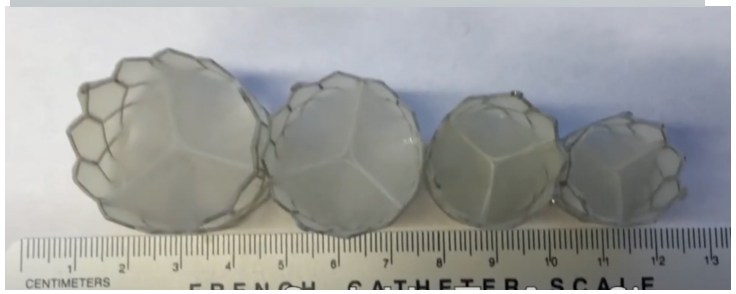
The Future



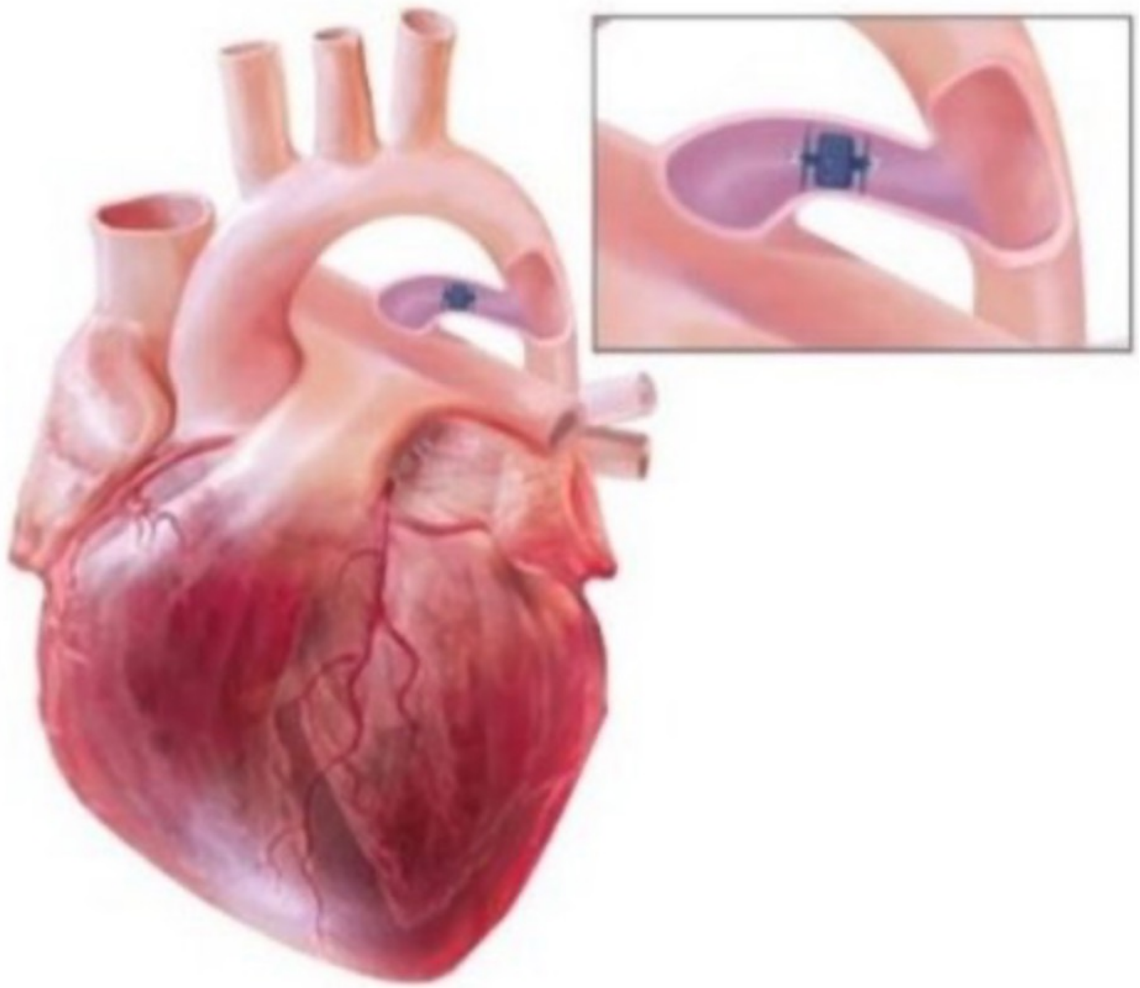
Masa Valve®

THE AUTUS VALVE

- Surgically implanted pulmonary valve replacement
- Novel biomimetic bileaflet design
- Inspired by the geometry of the human venous valve
- Fully synthetic
- Functions across a wide range of diameters
- Customizable implant diameter
- Designed to be balloon expanded via minimally invasive transcatheter approach as the patient grows

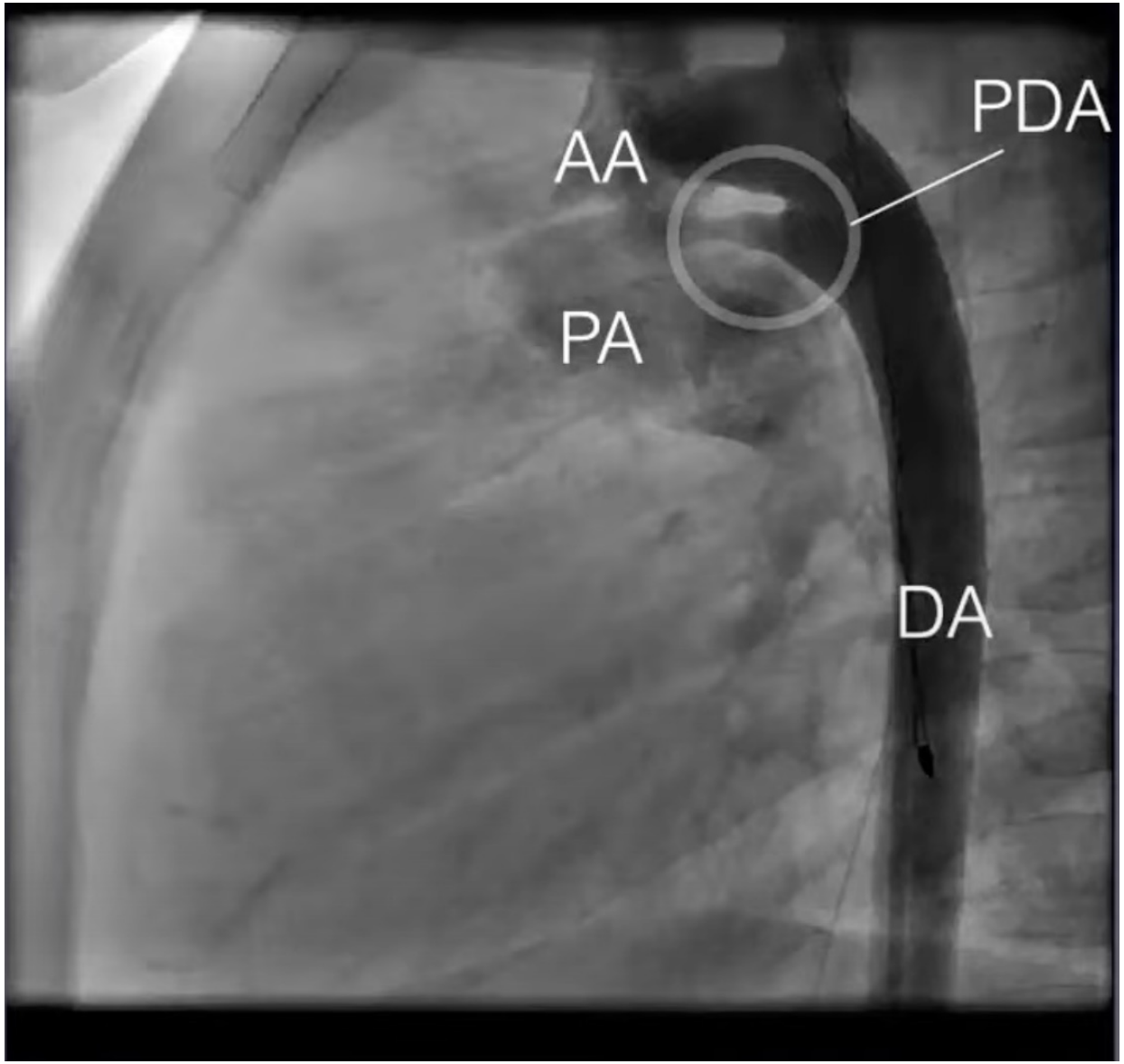


Transcatheter PDA closure in neonates



”Traditional” PDA closure …

- Nearly all cases are done in the cath lab
- At least 5 kg in weight
- Requires:
  - General anesthesia
  - Femoral arterial access
  - Femoral vein access



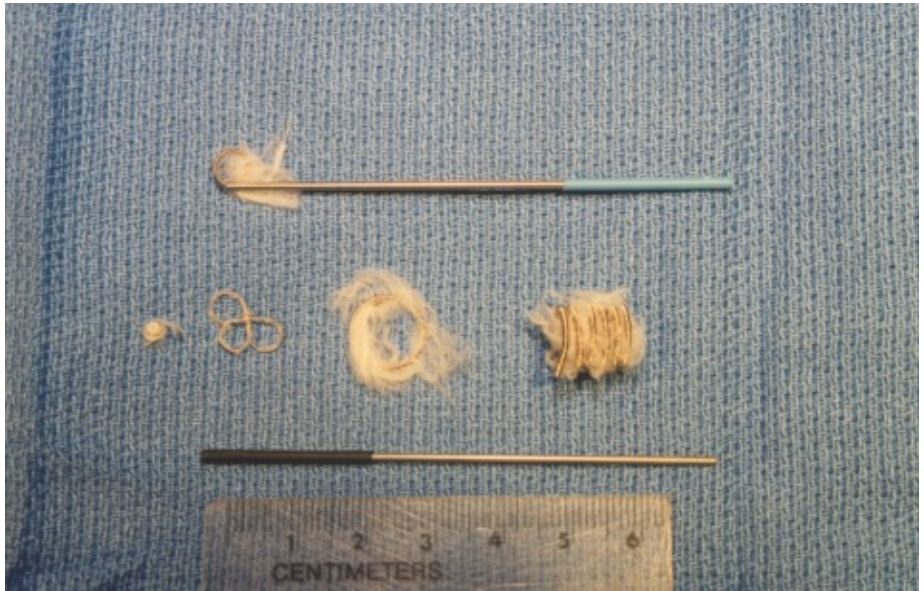
Current Devices

ADO-1

ADO-II

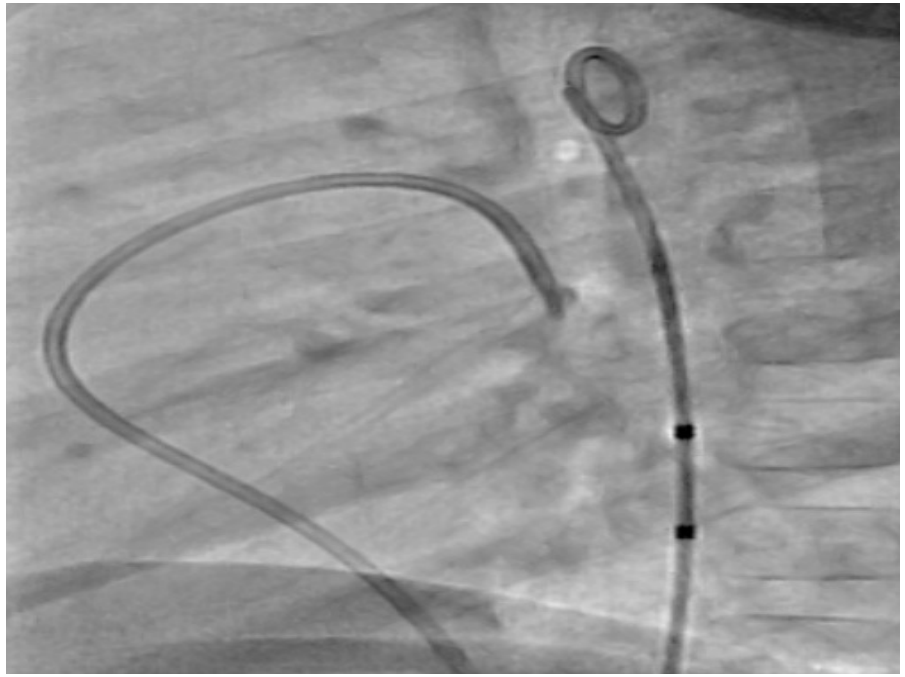
AVP-II

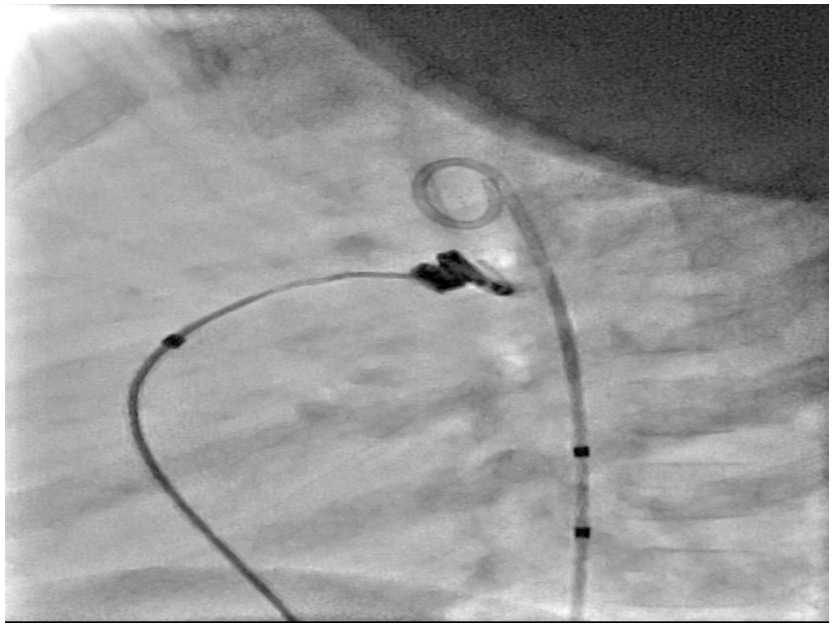
Coils



Nit-occlud

PDA closure is one of the common transcatheter procedures in children





PDA Closure in “Premies”

- Very small
- Very young
- Very fragile
- PDA associated with
  - Pulmonary Hypertension
  - Bronchopulmonary dysplasia
  - NEC
  - IVH
  - Retinopathy
  - Renal problems

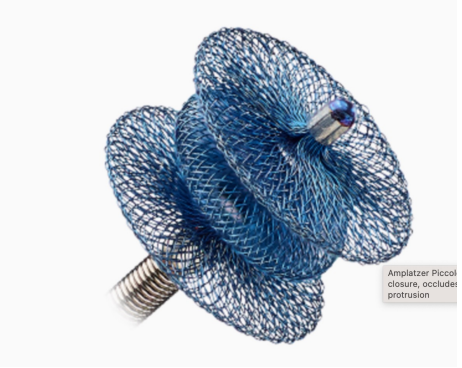
Affects more than 24,000 infants each year in the USA

Deciding which PDA to close is NOT always easy …

- When a duct is “significant”?
- Is there a role for observation?
- Or other forms of treatment first?

PIVOTAL

PICCOLO
Abbott



WHAT IS AMPLATZER PICCOLO?

Amplatzer Piccolo is the only U.S. approved device specifically designed and indicated for PDA closure in premature infants. Only Piccolo:

Has been developed for babies as small as 700g and ≥ 3 days old

Has the most clinical data, proving excellent outcomes

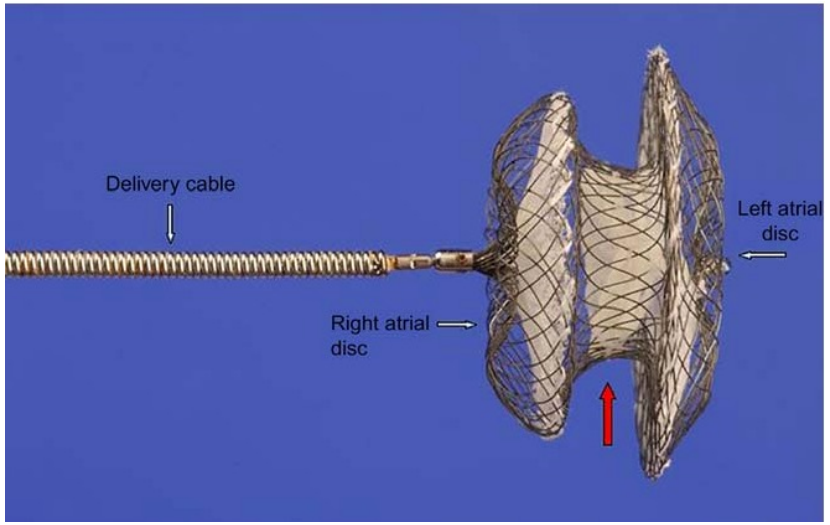
Offers the widest range of sizes, enabling treatment of all duct types and sizes

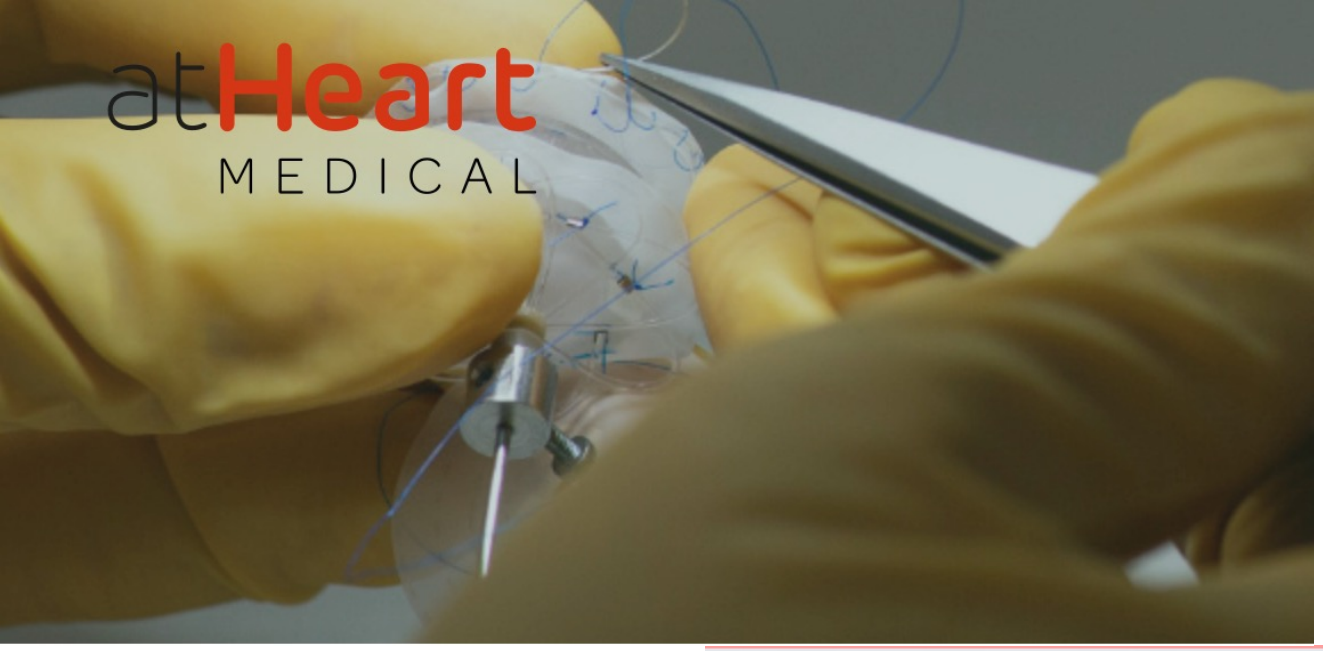
Is compatible with infant size, offering a low profile device and delivery system

ASD Closure Devices

Closure devices

- Amplatzer
  - septal occluder
  - PFO occluder
  - Cribriform
- Gore cardioform septal occluder





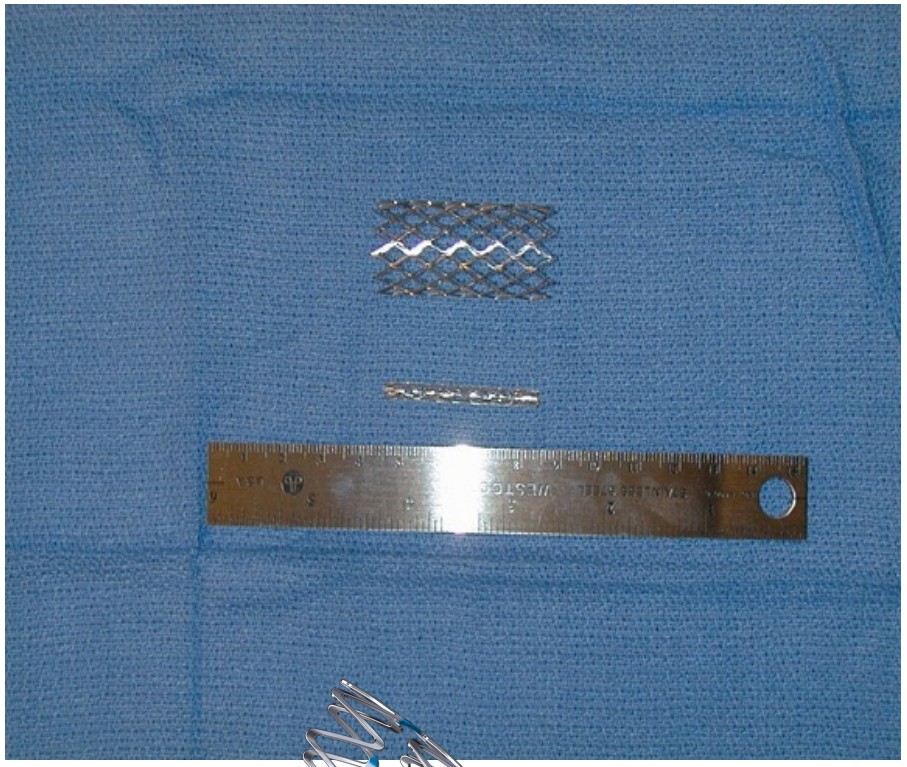
LESS METAL, MORE OPTIONS

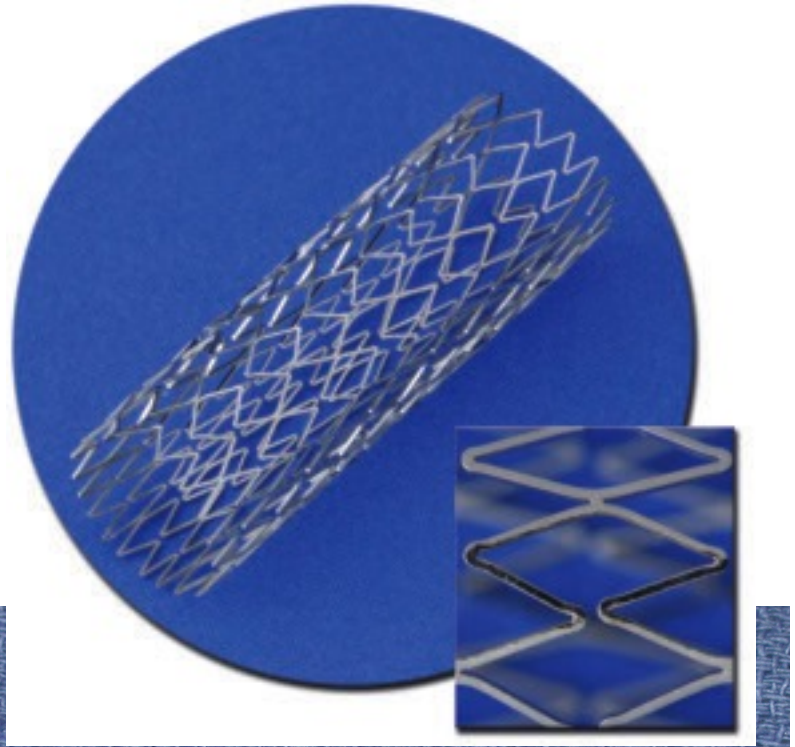
The **reSept™ ASD Occluder** is the first device with a metal-free, bioresorbable frame. This novel device aims to overcome the limitations of current ASD treatment options and offers the potential to:

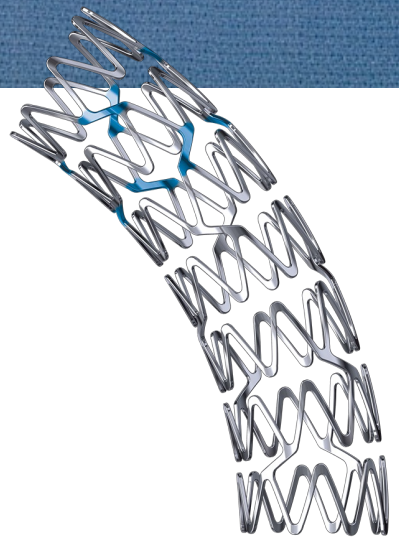
- Help reduce the risk of complications due to long-term presence of bulky metal in the heart.
- Enable future interventions that may not otherwise be possible due to metal barriers.

Stents

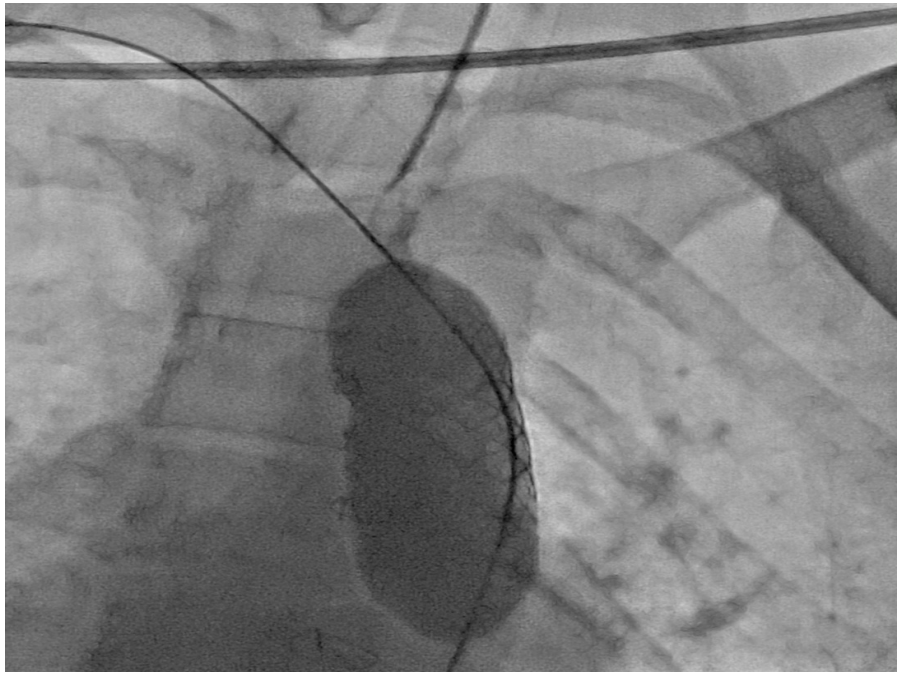
STENT IMPLANTATION

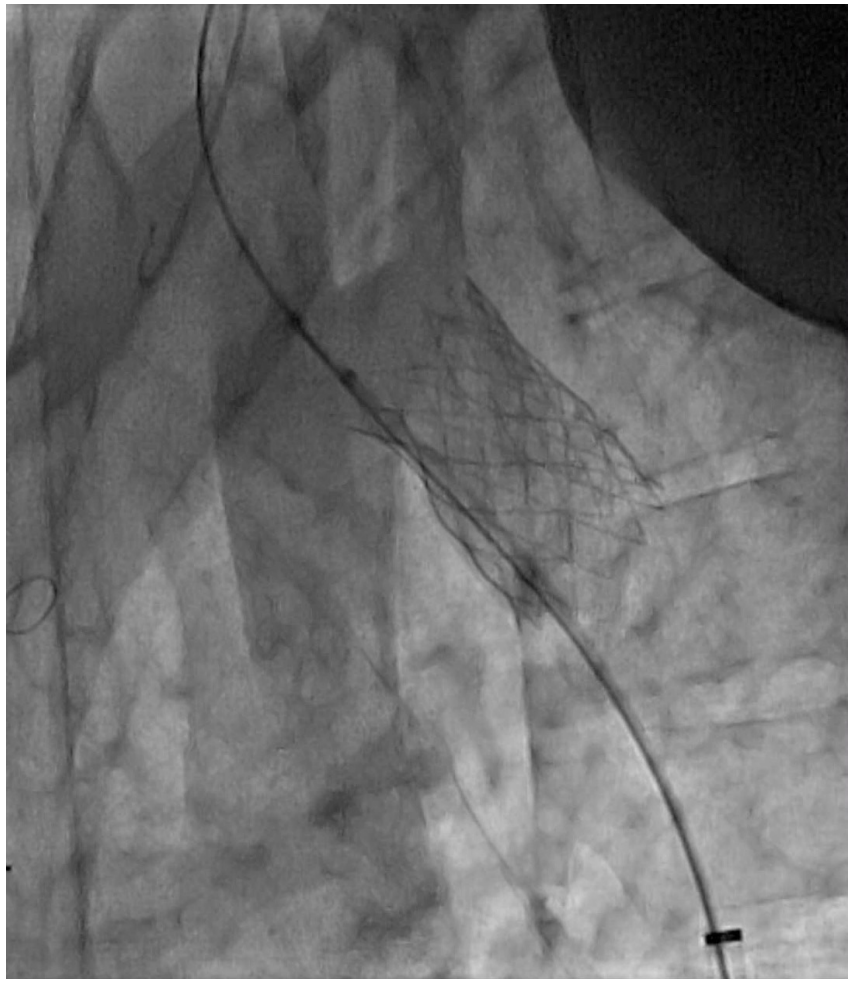




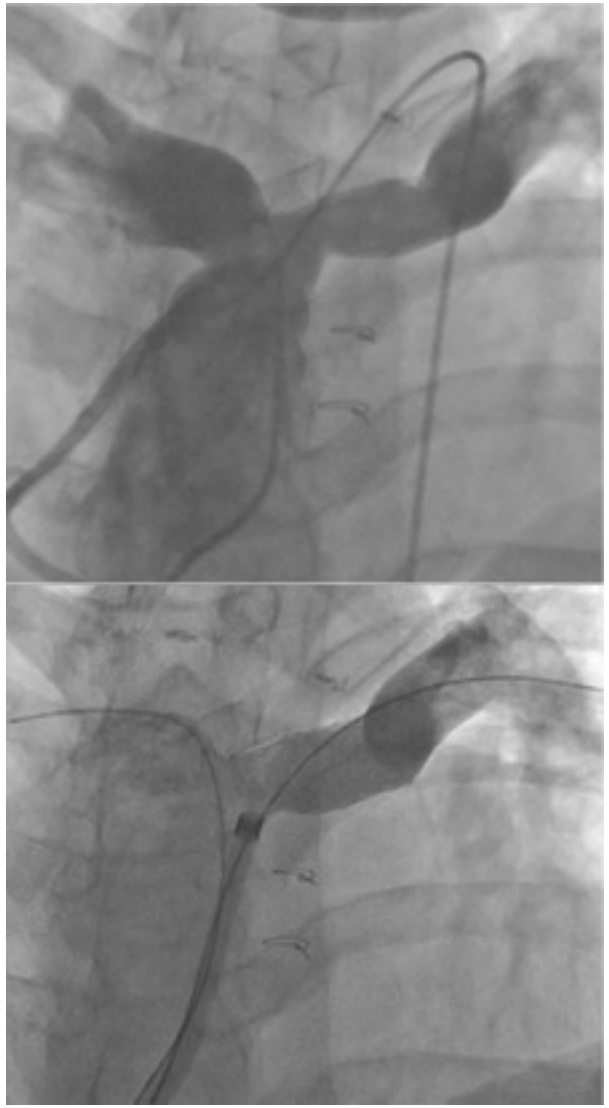


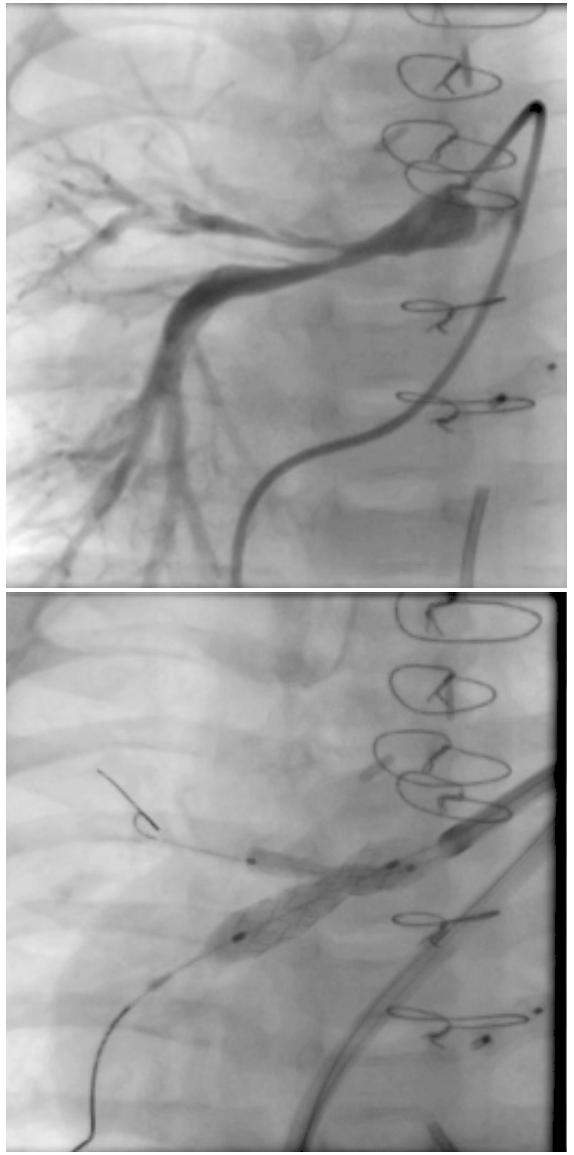
Coarctation stent placement





Pulmonary artery stenosis

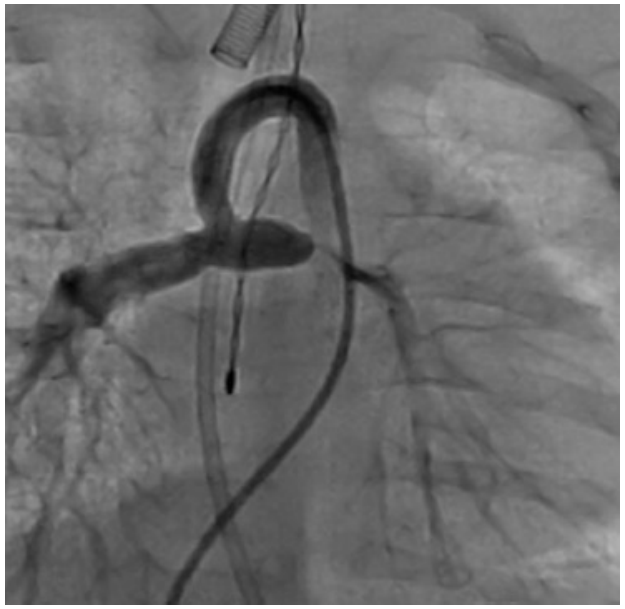


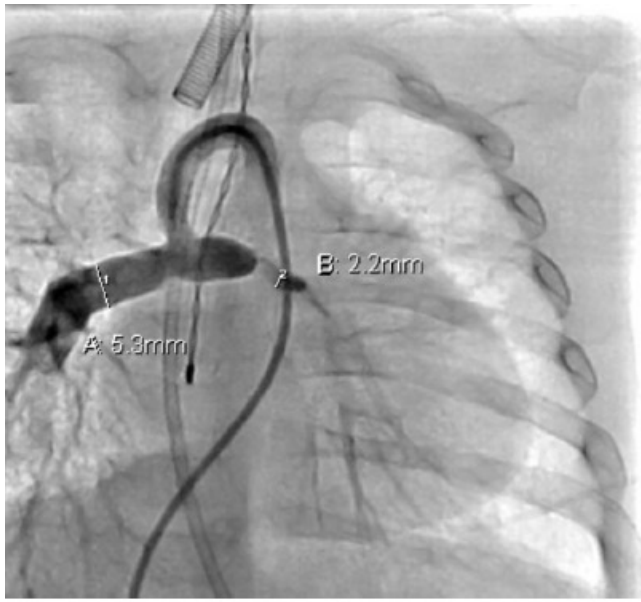


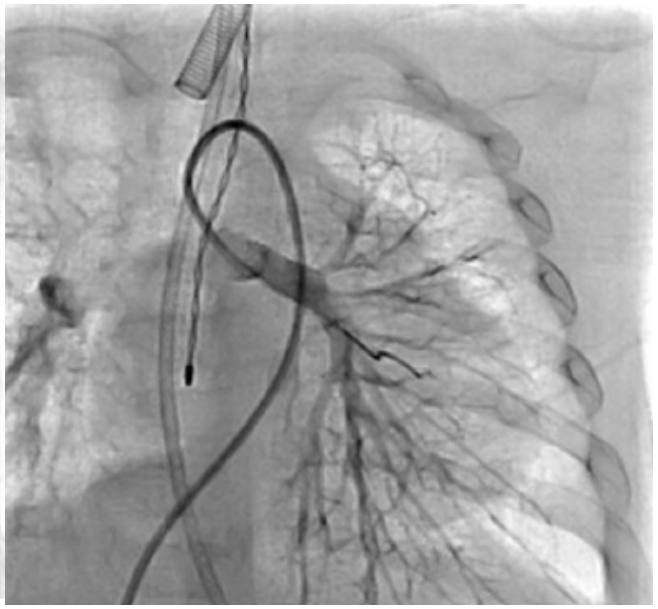
Limitations of stent therapy

- Stents don’t grow, children do..

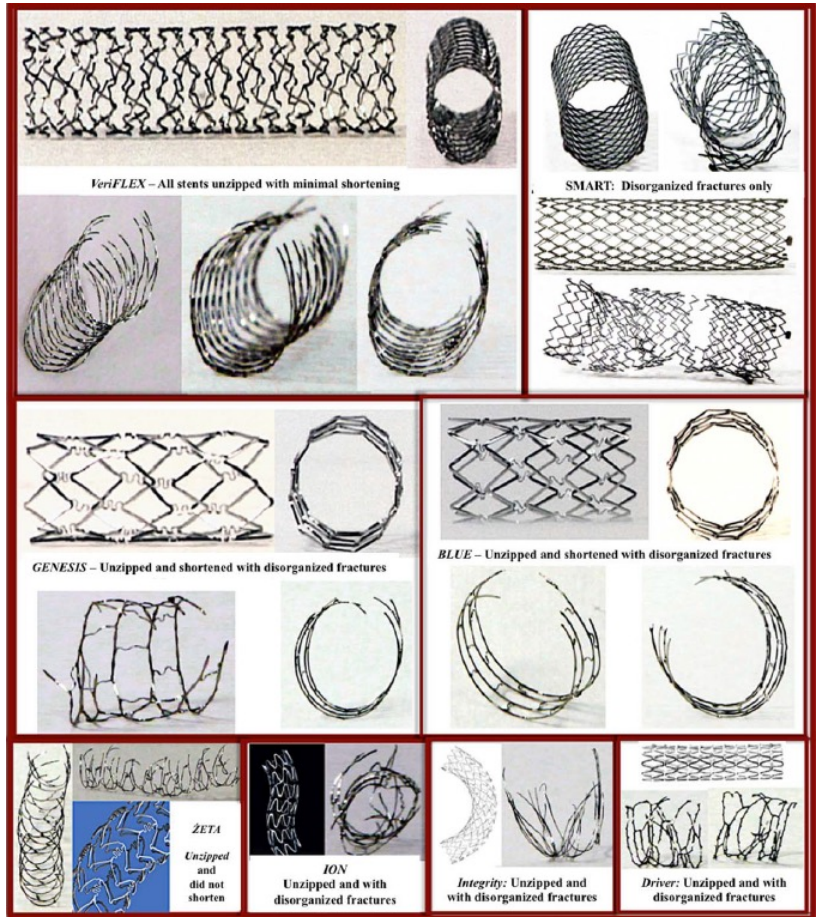
4 month old LPA stenosis s/p surgery
Treated with 4mm cobalt chromium coronary stent
Doesn’t reach final adult dimension (12-14mm)





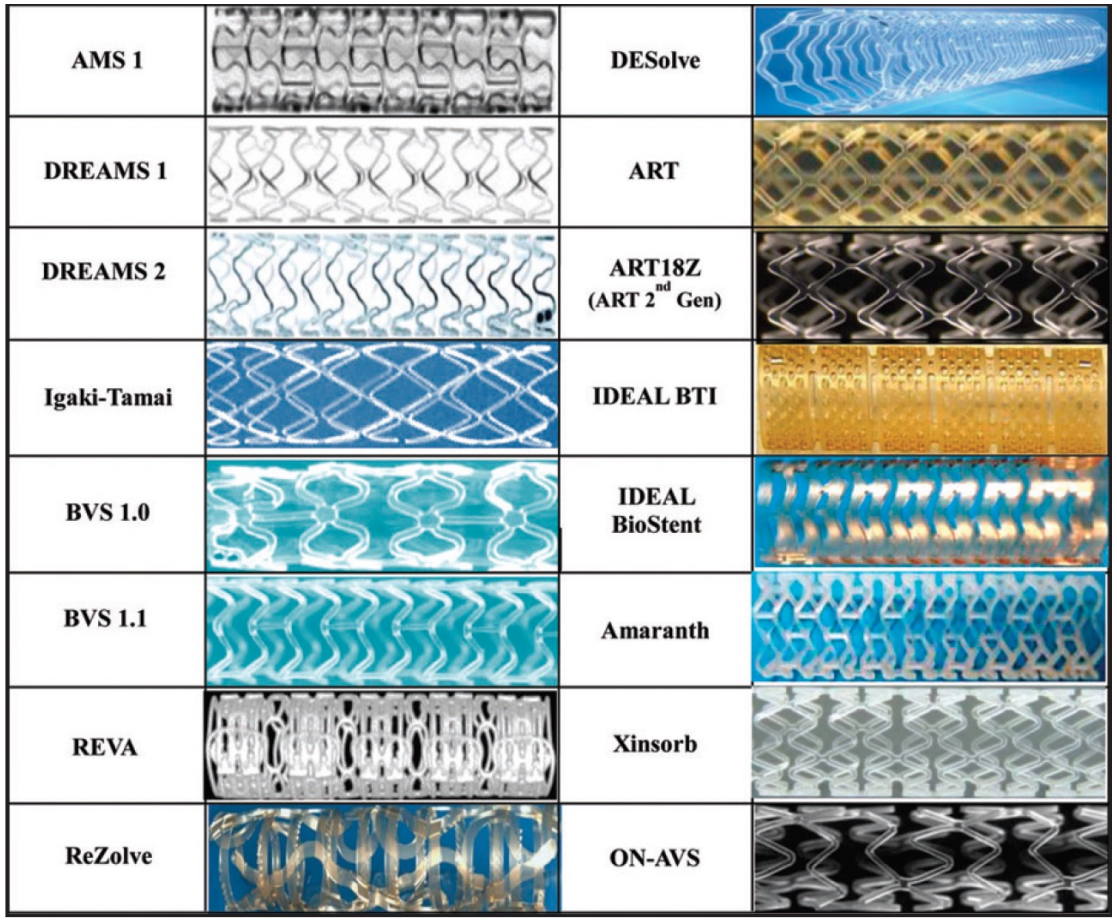


Solutions



- Surgery
- Intentional stent fracture
- Use stents that ‘unzip’

Biodegradable Stents

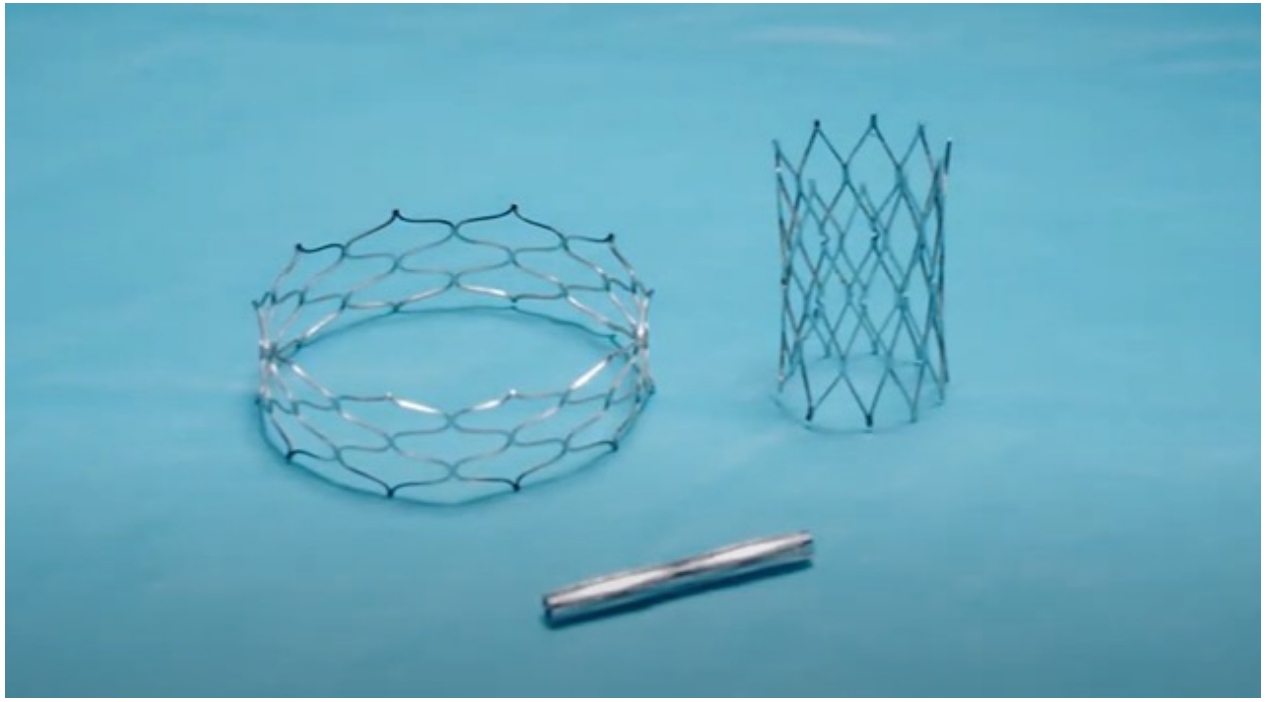


At the present time, there are NO biodegradable stents available for use in pediatric patients with congenital heart disease

1. Illusicor stent (Tremedics Medical Devices LLC, TX, USA)
2. 480 Biomedical stent (480 Biomedical Inc)
3. ZeBRa stent, Pediastent LLC, Cleveland, OH, USA

ZeBRa Stent implanted in the aorta in a preclinical model.

Renata STENT



(Actual Size)

<2MM

We implant the device at birth with the initial device size at less than 2mm.

(Actual Size)

8MM - 12MM

As the patient grows into an adolescent, the device can be gradually expanded.

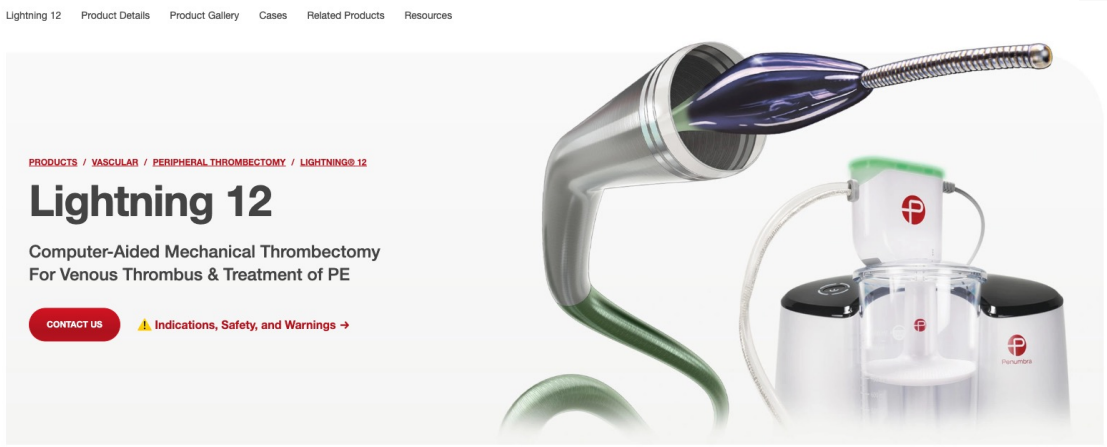
(Actual Size)

>18MM

When the patient reaches adulthood, the device will have the capability to expand to over 18mm.

Other

Penumbra Lightning indigo aspiration system



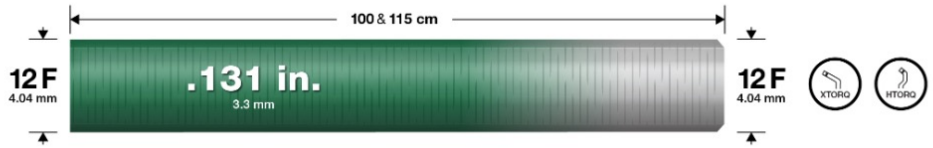
Computer-Aided, Maximized Clot Engagement

Designed for frontline venous thrombus removal and for the treatment of pulmonary embolism

Product Technology & Features

Specs & Compatibility

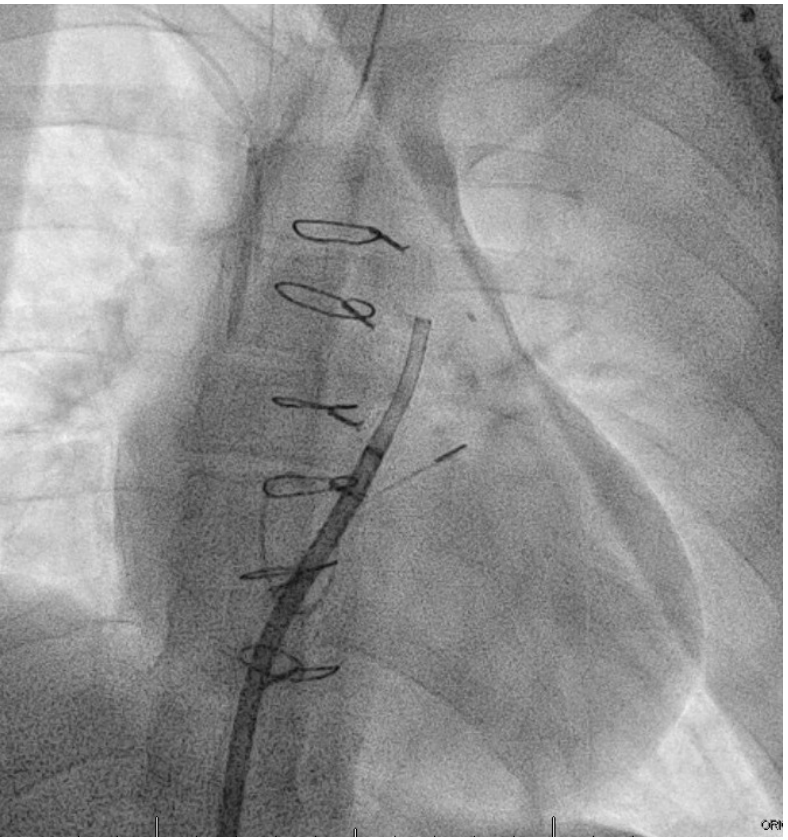
- 12 F (4.04 mm) sheath compatibility
- 100 cm (HTORQ and XTORQ Tips) and 115 cm (HTORQ Tip) working lengths
- .014–.038″ (.36–.97 mm) wire platform
- Compatible with Separator™ 12
- Packaged with Lightning® Aspiration Tubing



Indigo System
Lightning Arterial, Venous, and Pulmonary Applications
Learn More →

Moving the Field Forward with Computer-Aided Aspiration
EVT, July 2022
Learn More →

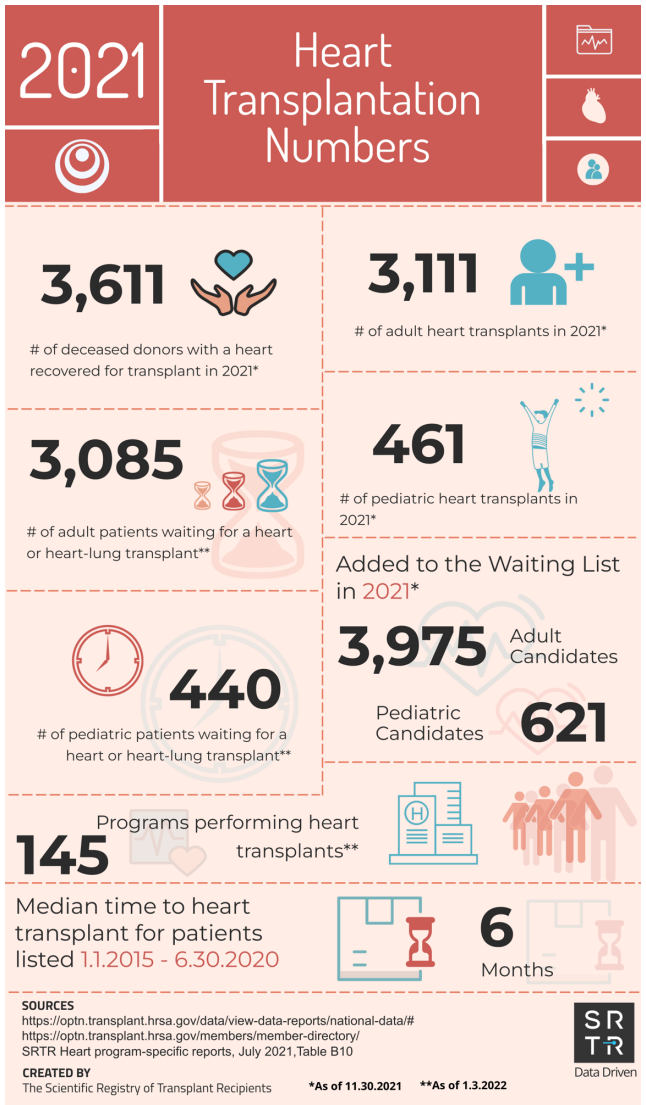
https://youtu.be/DwrTQHcGuUQ

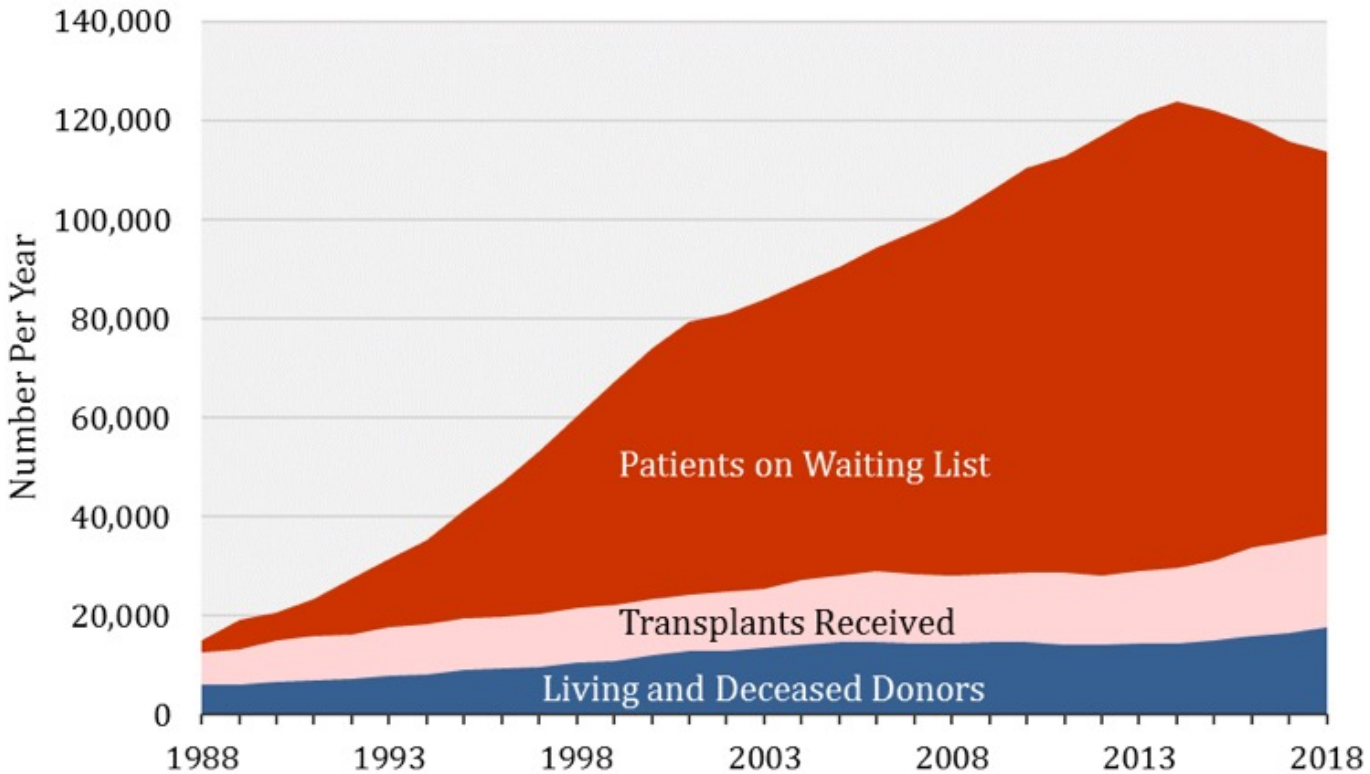


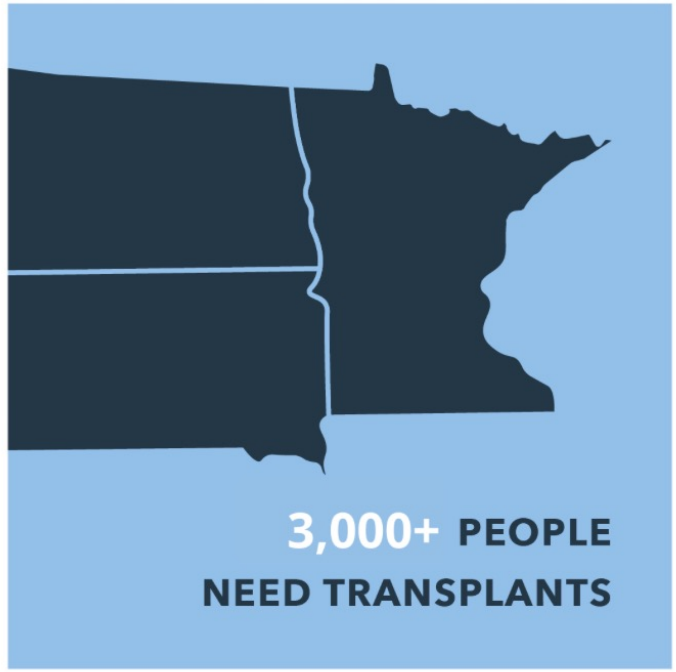
Before

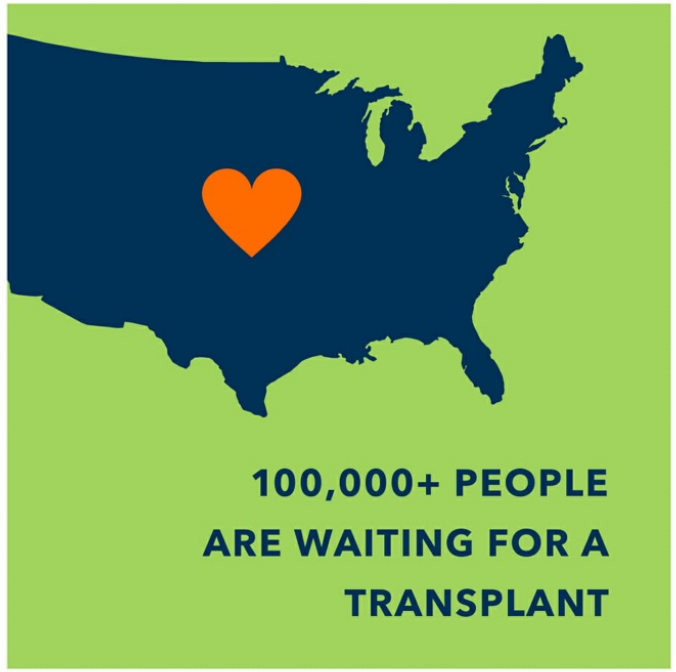
After

How we support those in need of transplantation









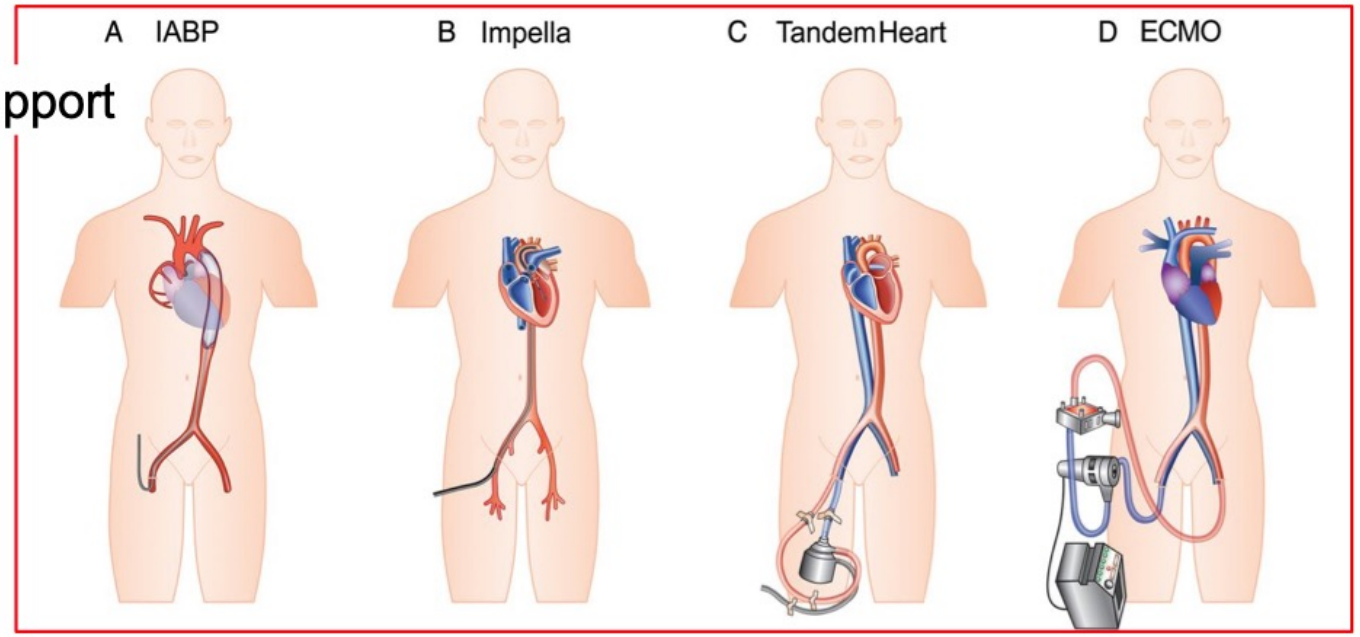
On the Waiting List	National	Minnesota	North Dakota	South Dakota
Total Patients Waiting	103,817	2,279	126	365
Kidney	88,607	1,910	126	334
Liver	10,429	178	–	32
Pancreas	841	96	–	3
Kidney-Pancreas	1,955	170	–	4
Heart	3,397	89	–	–
Lung	991	34	–	–
Heart-Lung	35	2	–	–
Intestine	205	–	–	–

Waiting list data provided by Organ Procurement and Transplantation Network (OPTN) as of April 18, 2023. Data subject to change based on future data submission or correction.

Totals may be less than the sums due to patients included in multiple categories.

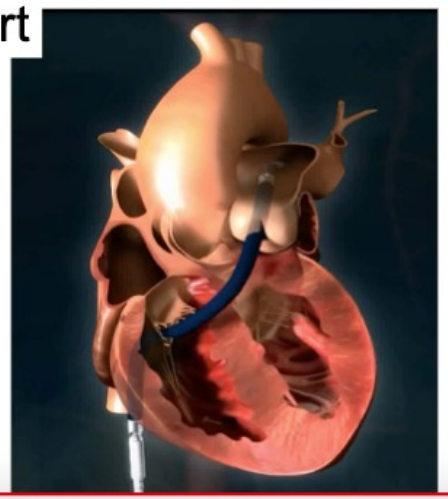
Percutaneous Temporary Support Options

LV Support

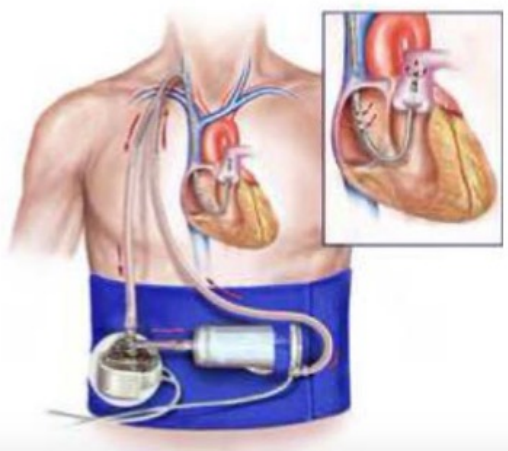


RV Support

Impella RP



Tandem Heart-Protek-Duo



Goals of use TMCS in CS

- Circulatory Support
- Ventricular Support
- Coronary Perfusion
- Provide Time: to define treatment strategy

ABIOMED®

Recovering hearts. Saving lives.™

CHILDREN'S IMPELLA PRESENTATION

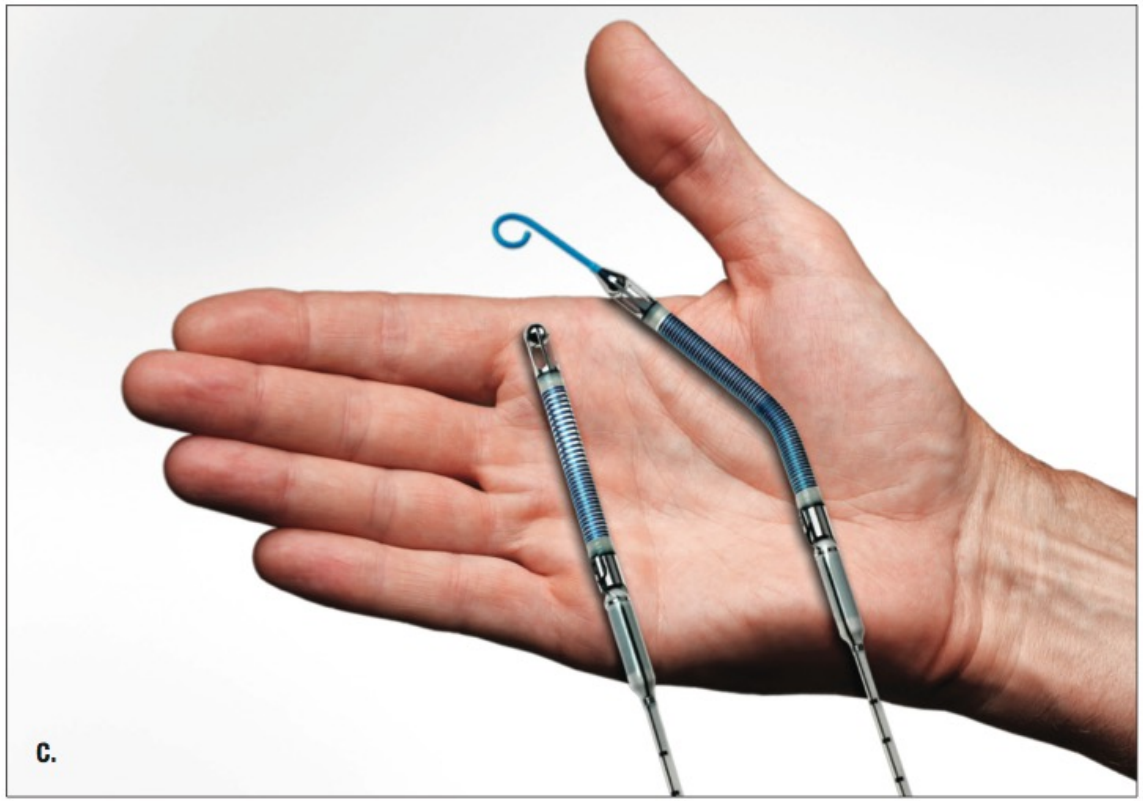
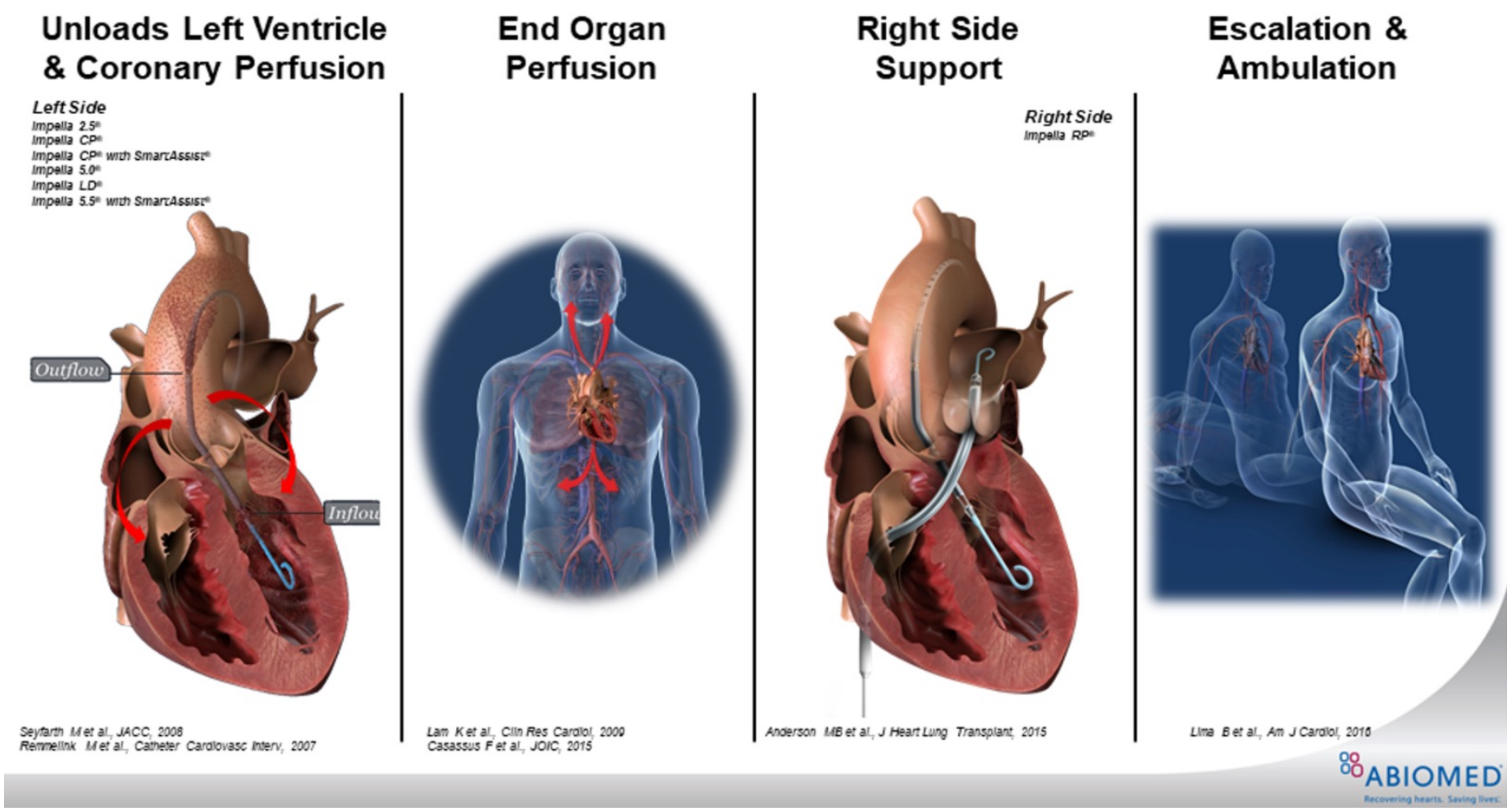


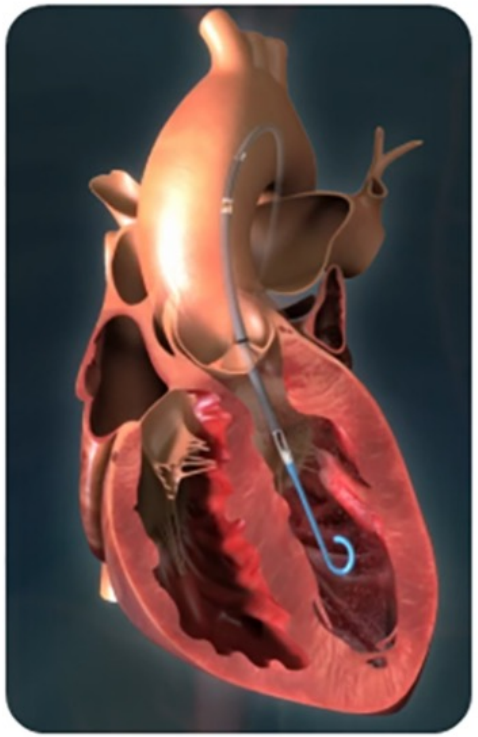
Figure 1C. A comparison between the Impella LD and 5.0.

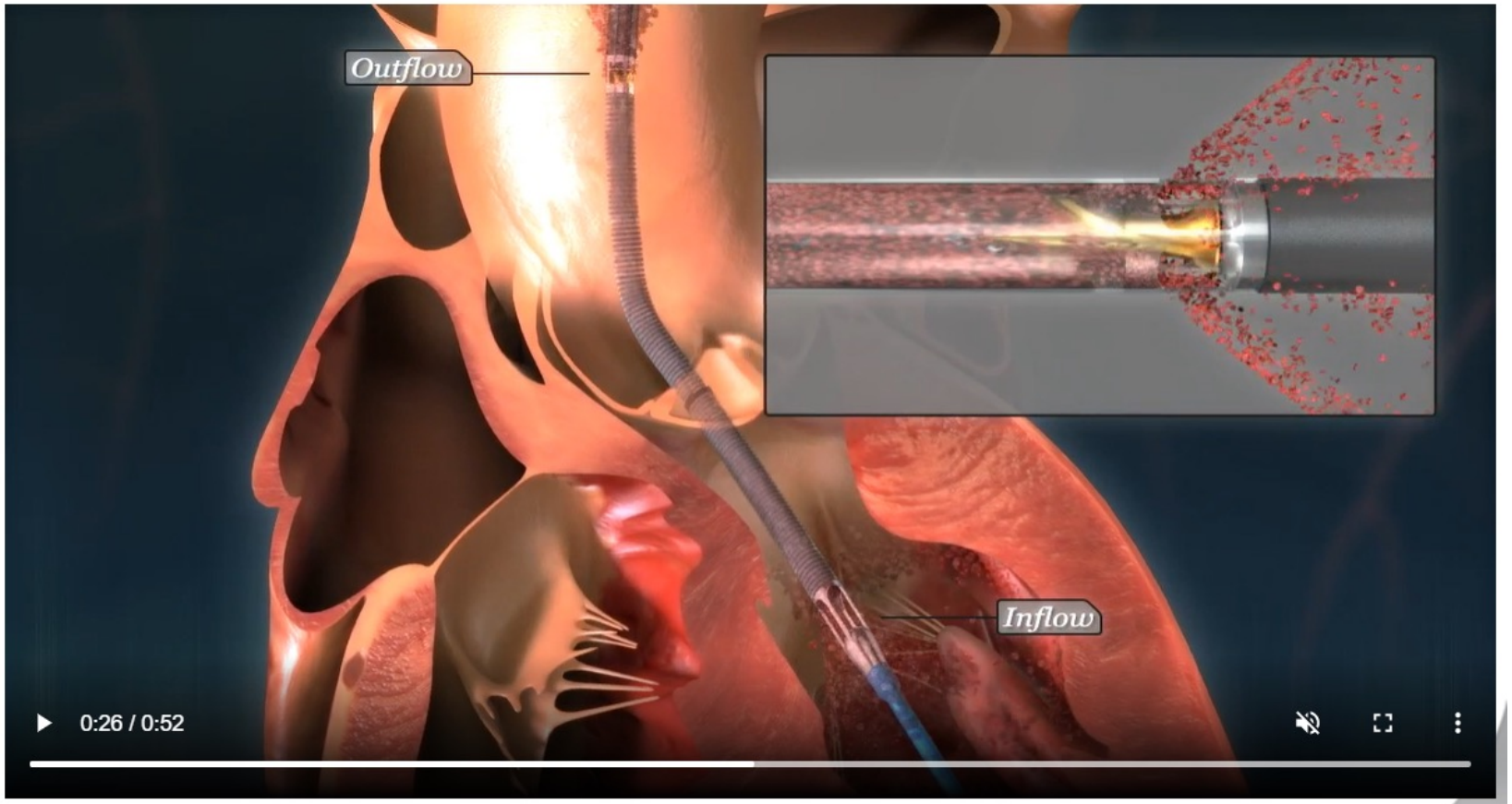


2.5/CP/5.5 can all be placed axillary via cutdown for ambulation

IMPELLA® HEART PUMP: HOW IT WORKS

Placement in Left Ventricle





Conclusion

- A quick “run” through a couple of aspects of trans-catheter intervention in congenital heart disease
- A fundamental and exciting area of medicine
- Continually changing and developing over the last 30 years
- Many things that people (surgeons!) told us were impossible are now routine !

University of Minnesota

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