



Centre for
Heart Valve Innovation
St. Paul's Hospital, Vancouver

Mitral and Tricuspid Repair

Current status

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Disclosure

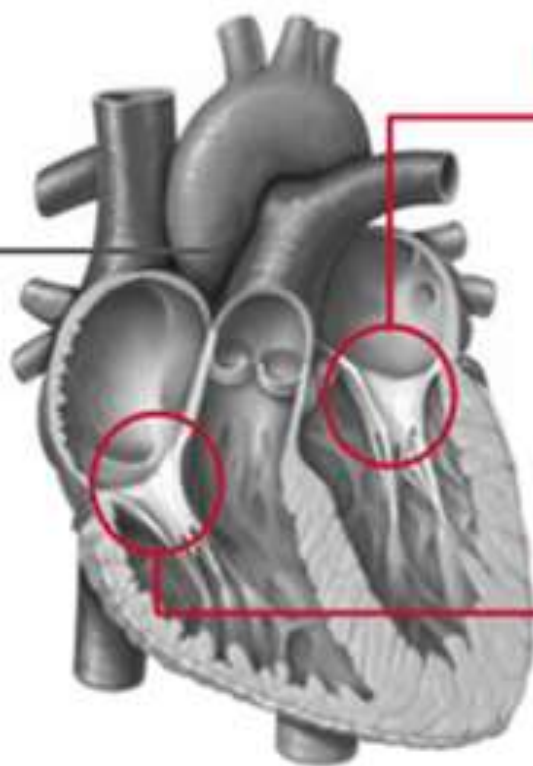
Consultant:

**Edwards Lifesciences
JC Medical Inc.**

Mitral and Tricuspid U.S. Disease Burden is Significant

Severe Symptomatic Aortic Stenosis

~650K patients
~18% treatment



Moderate & Severe Mitral Regurgitation

Degenerative MR

Leaflet lesions cause valve leakage

Functional MR

LV dilatation causes valve leakage

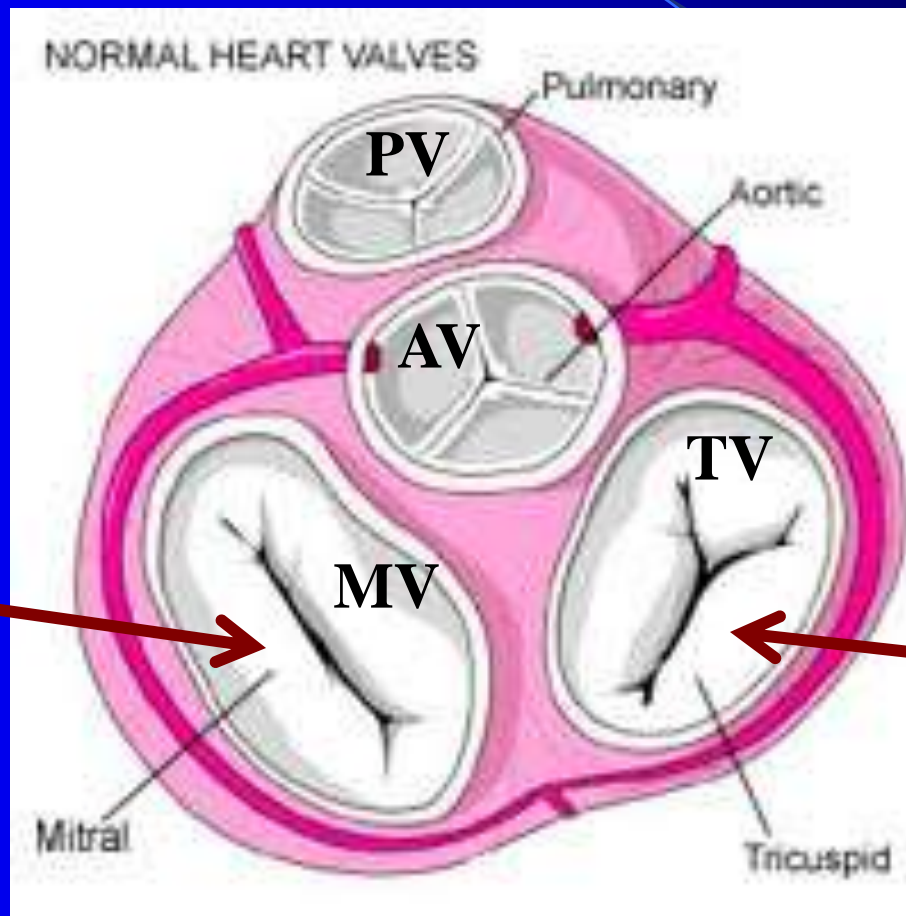
~2.5 M patients^{1,2}
~2% treatment

Moderate & Severe Tricuspid Regurgitation

Annular enlargement causes valve leakage

~1.5 M patients^{1,2}
<1% treatment

Transcatheter Therapies for MV and TV



V-in-V
TMVR
MV repair
Valvuloplasty

V-in-V
TV repair

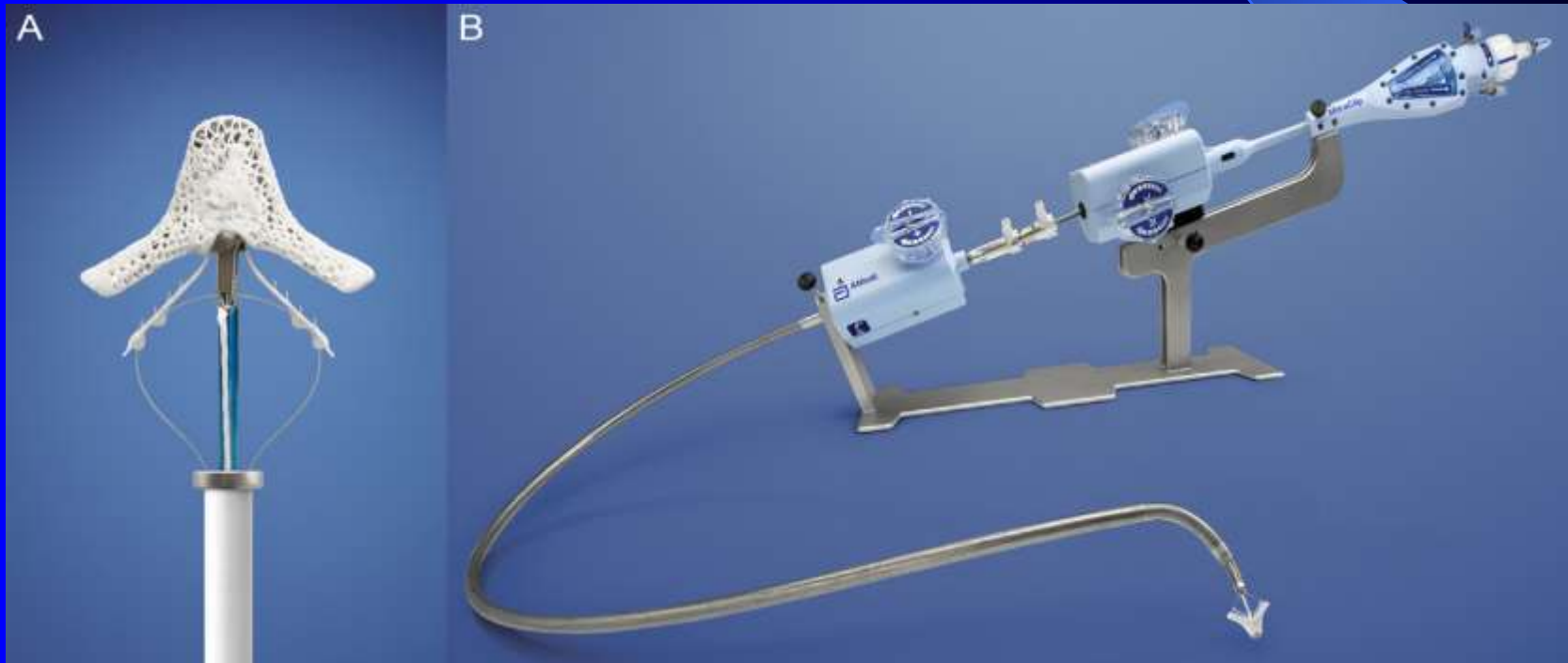
Devices Potentially for Both MV & TV

Device	Target	Regurgitation
MitraClip	Leaflet	Functional Degenerative
PASCAL (mitral only at present)	Leaflet	Functional Degenerative
Cardioband	Annulus	Dilated annulus Functional
Mitralign	Annulus	Dilated annulus Functional
Millipede System	Annulus	Dilated annulus Functional
Spacer	Leaflet coaptation	Dilated annulus Functional

Edge-to-Edge Procedure

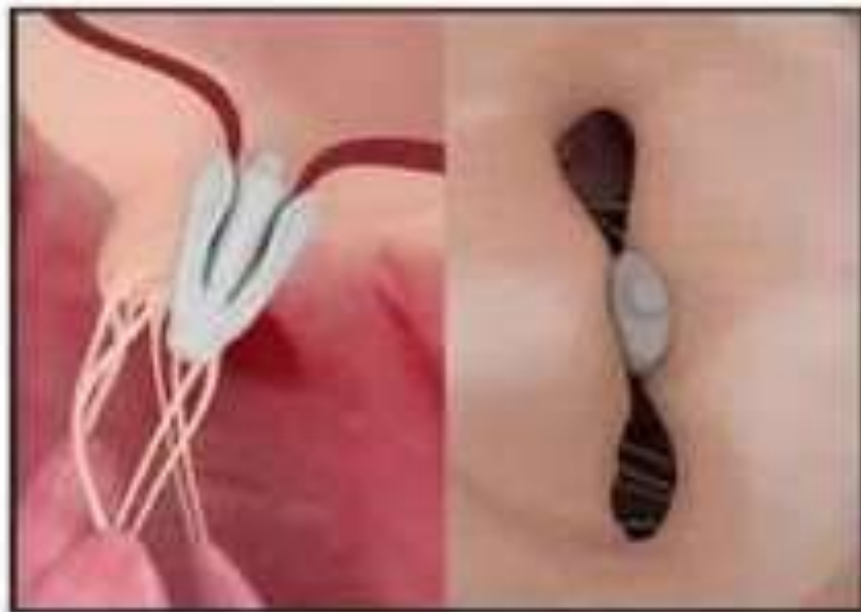
MitraClip

- **FDA approval for degenerative MR**
- **Ongoing clinical trial on the treatment of functional MR**
- **Early clinical experience in the treatment of TR**

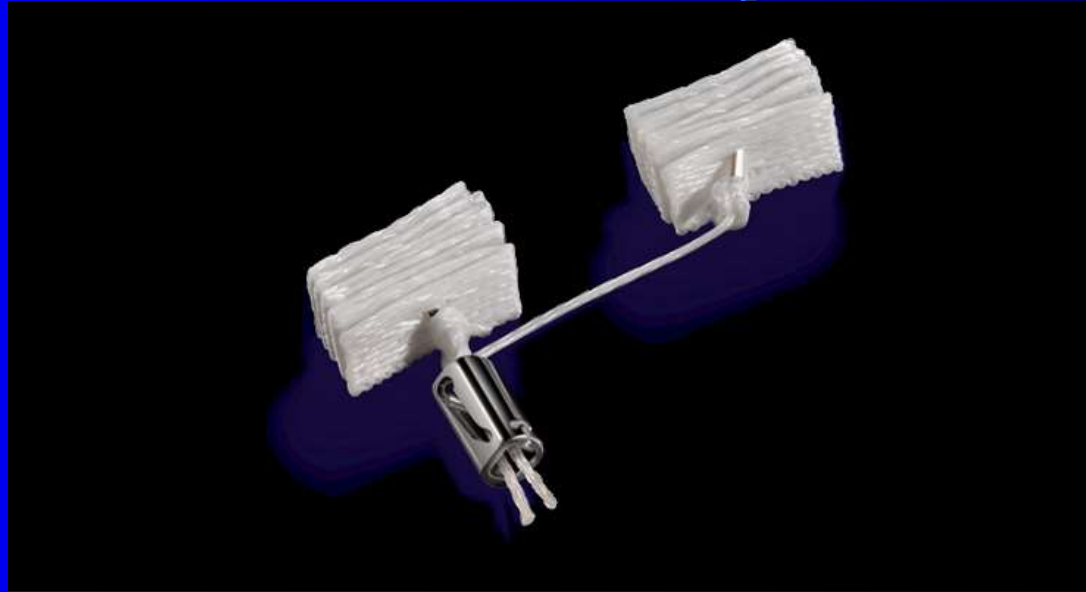


Edge-to-Edge ± Spacer Edwards PASCAL Repair System

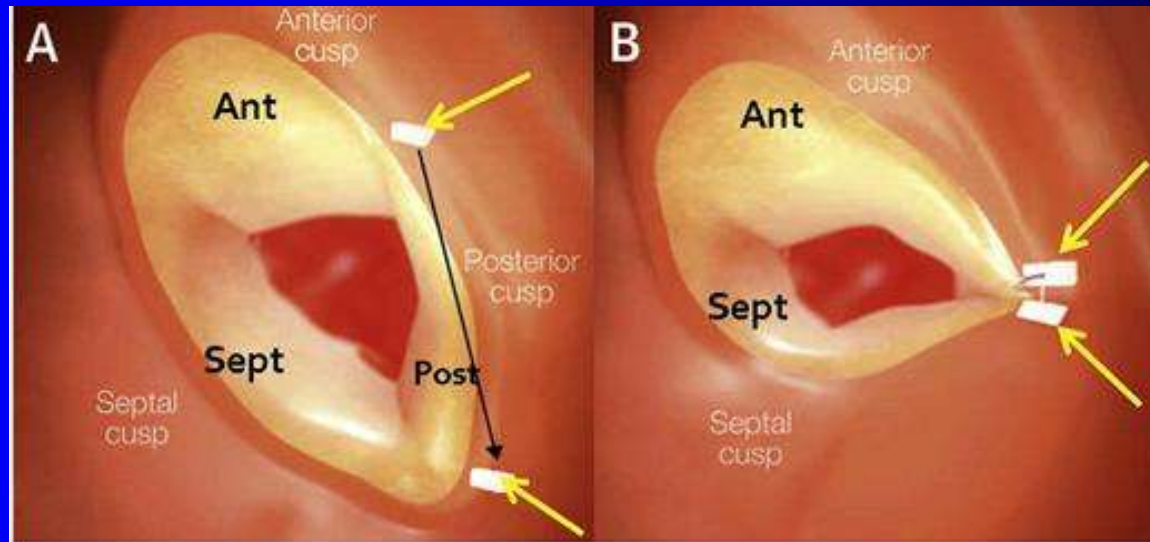
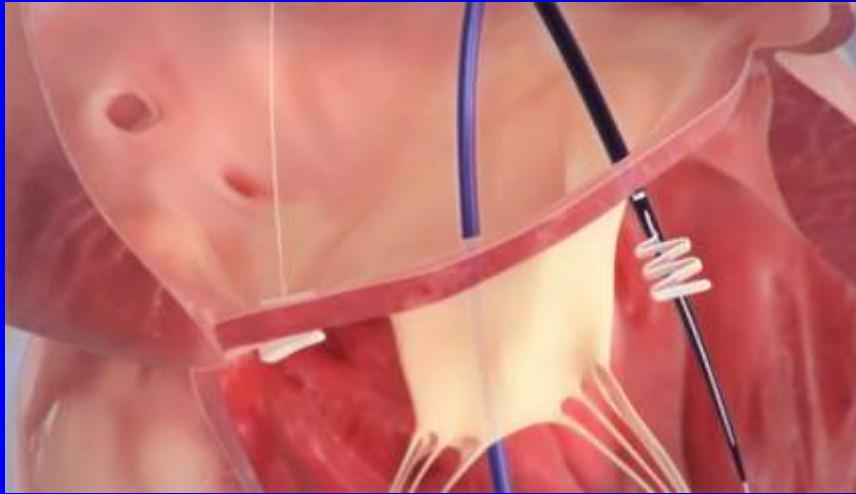
- Spacer is clasped between both Mitral Valve leaflets
- Independent leaflet claspings
- Simple "Commander-like" delivery system
- Conventional transfemoral/transseptal approach



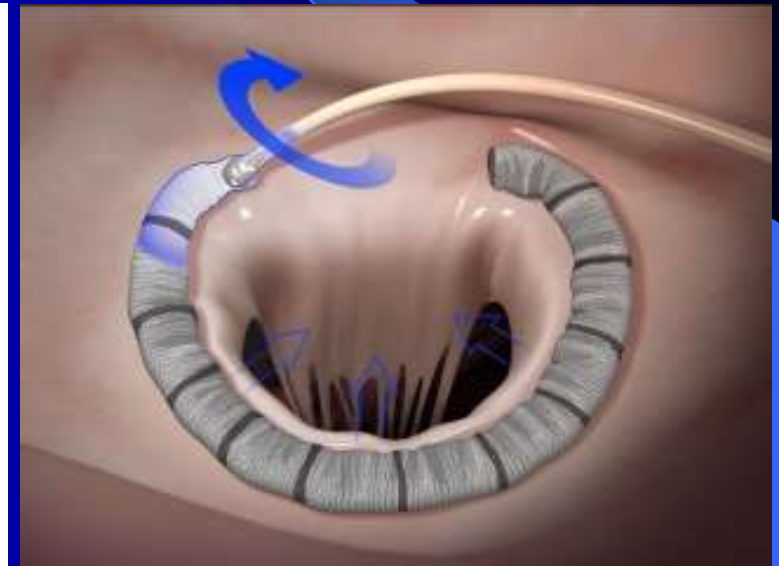
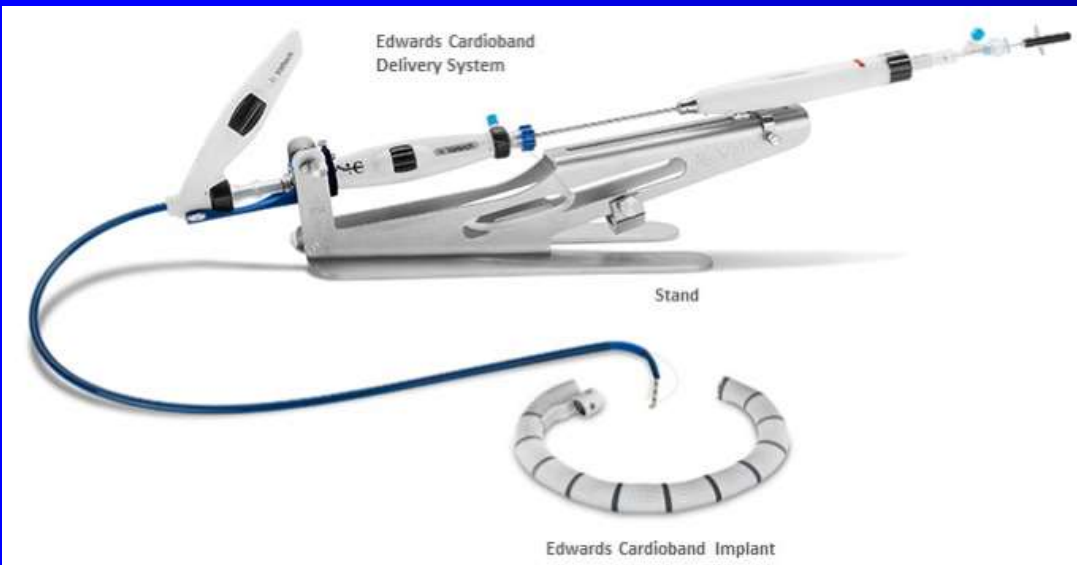
Plication of Annulus Mitralign and Trialign System



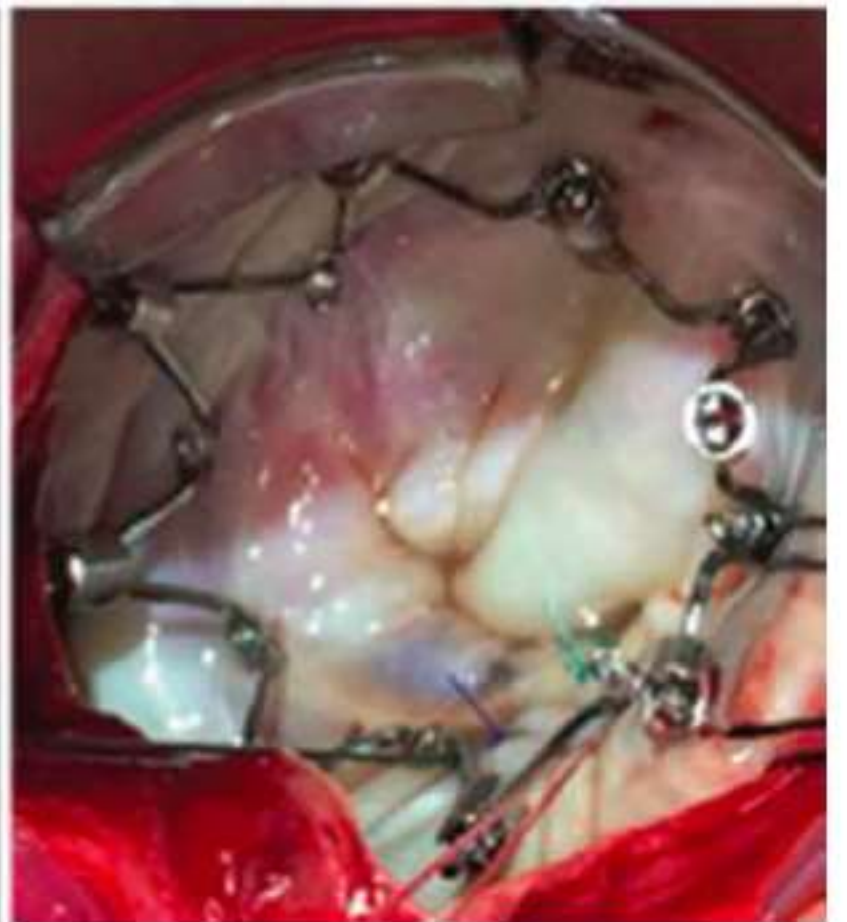
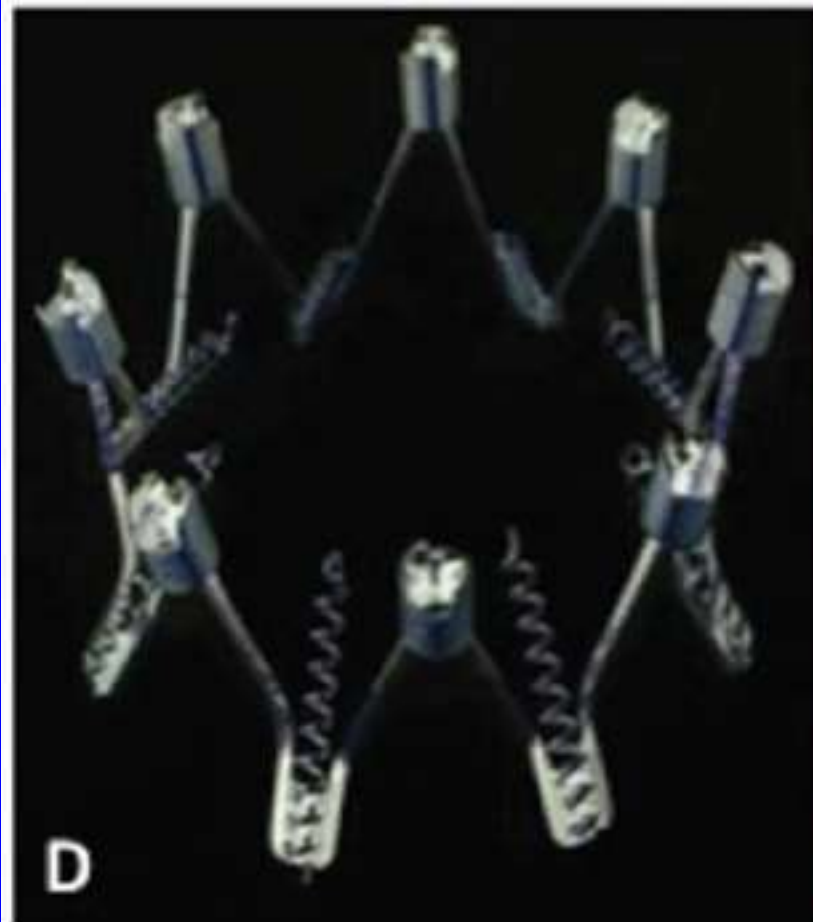
Plication of Annulus Mitralign and Trialign System



Annuloplasty Band Edwards Cardioband System



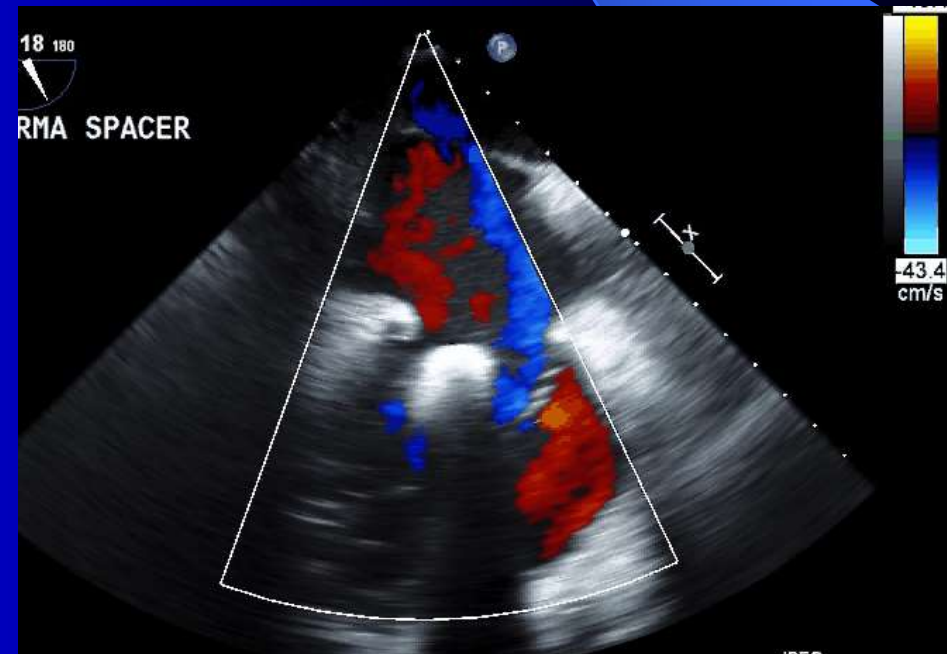
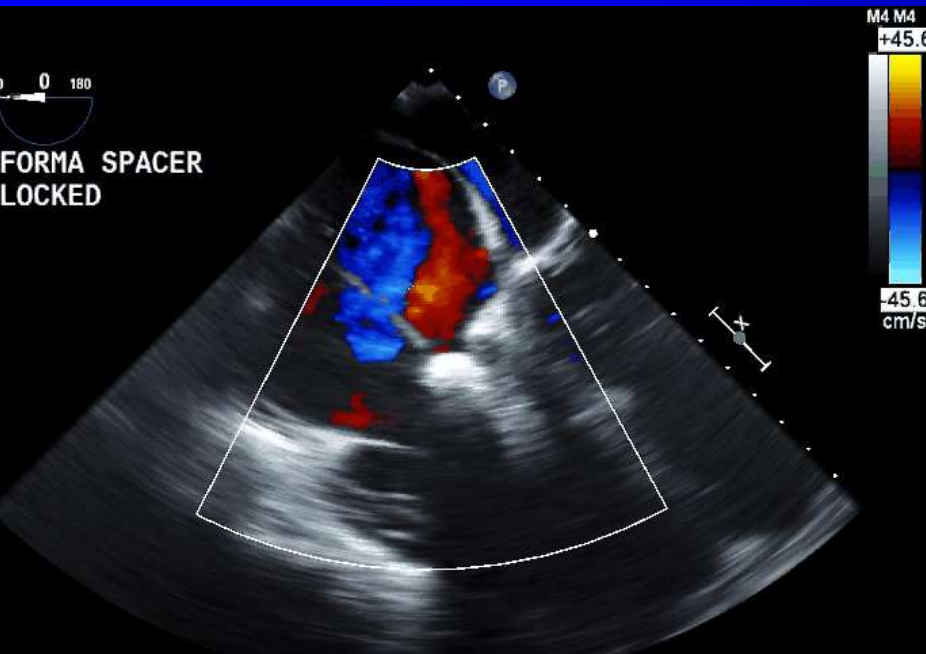
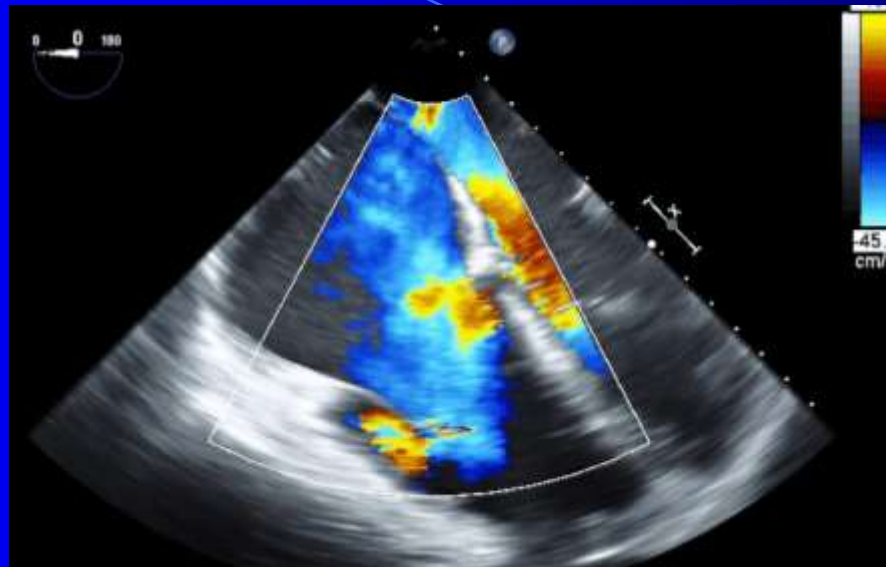
Annuloplasty Ring Millipede System



Edwards FORMA TV Device



TR reduction with Spacer in place



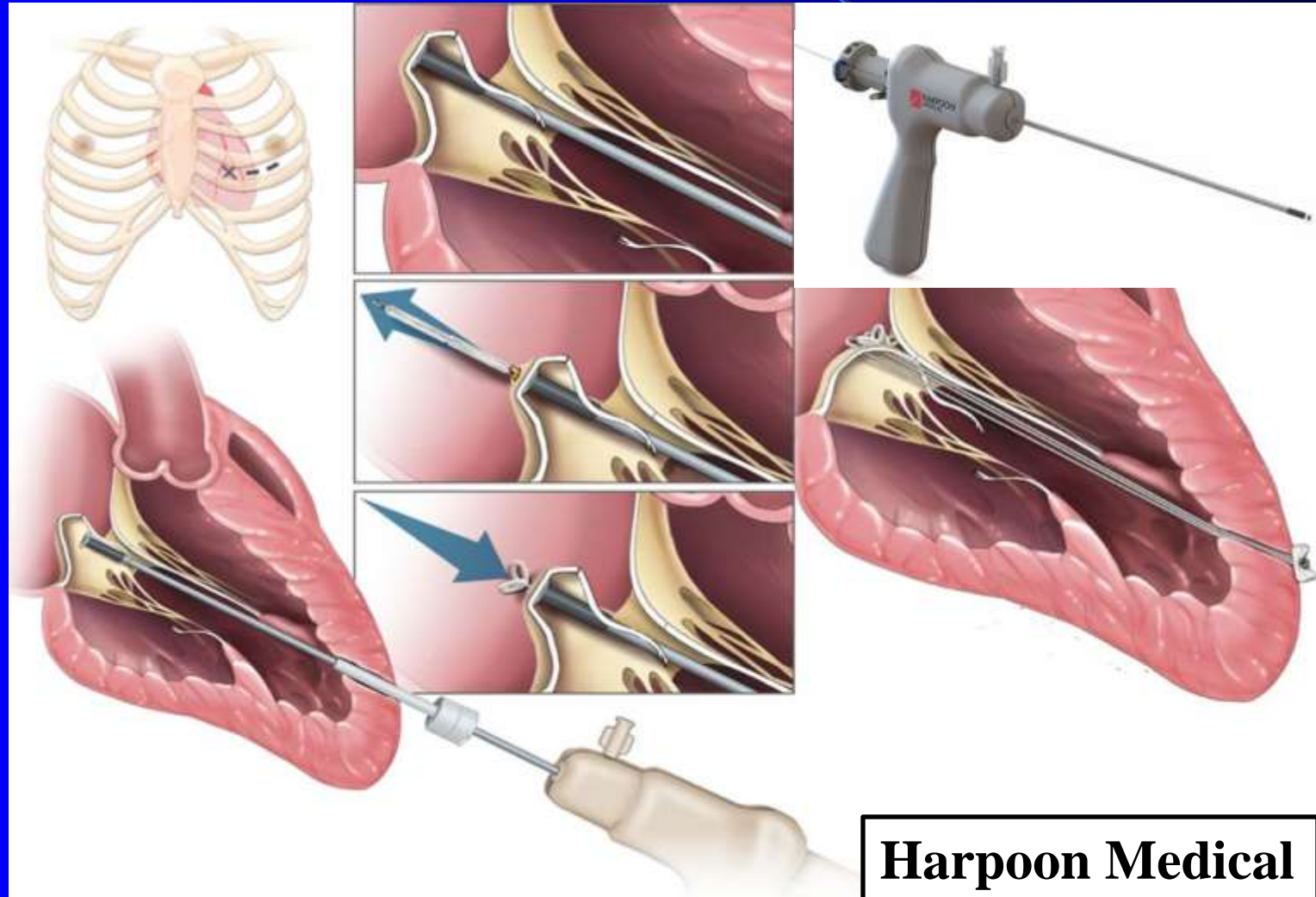
Devices for MV or TV Repair

Device	Valve Disease	Target	Similar Surgery Procedure
NeoChord	Degenerative MR	Chordae	Chordal replacement
Harpoon TSD-5	Degenerative MR	Chordae	Chordal replacement
Amend annuloplasty ring	MR	Annulus	Annuloplasty ring
TriCinch	Functional TR	Annulus	Reduction of annulus

Chordal Replacement NeoChord DS1000 Device



Chordal Replacement Harpoon TSD-5



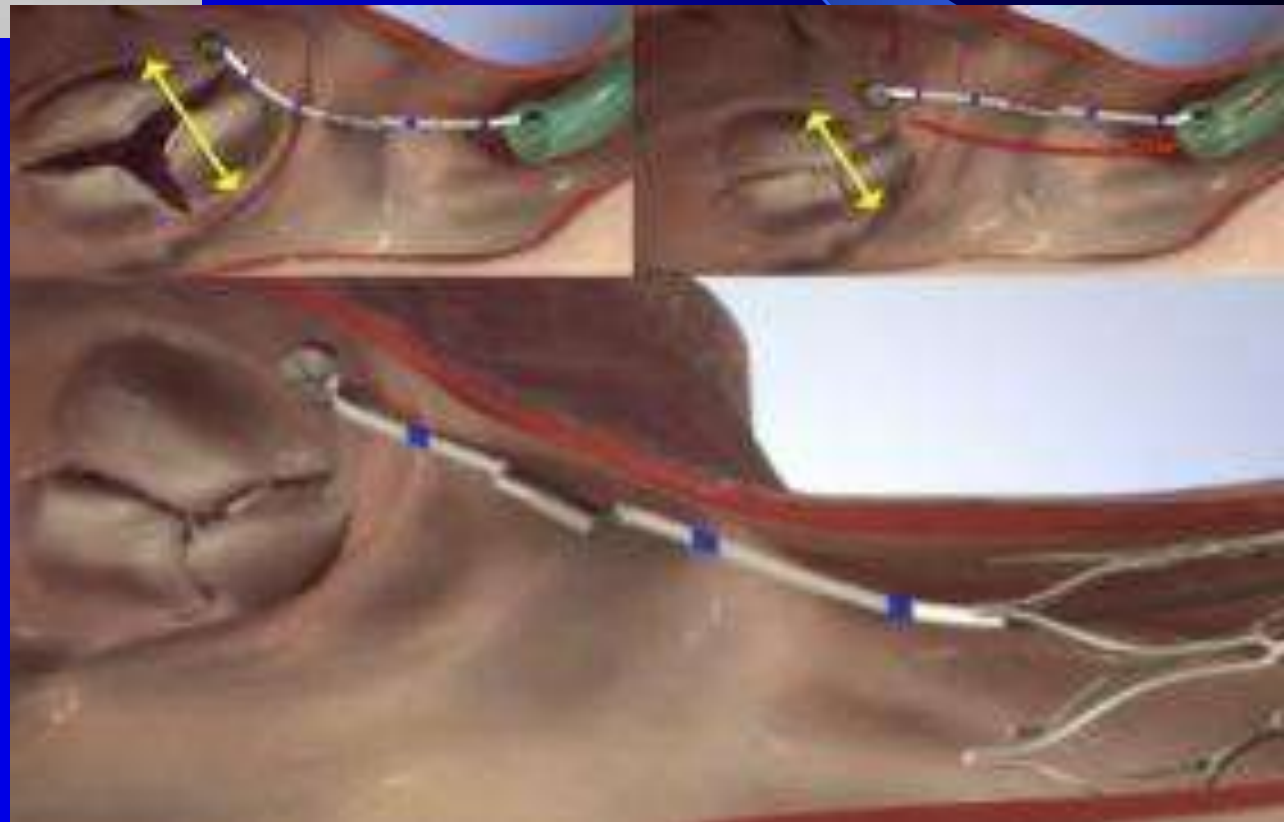
Harpoon Medical

Annuloplasty Amend Mitral Repair System



The Valcare Medical (Israel)

Reduction of A-P Distance **TriCinch System**



Ongoing Clinical Trials – MV Repair

Study	Device	Type of MR	N. of patient	Country	Year of completion
COAPT	MitraClip	Functional MR	610		2024
Randomized trial	NeoChord (vs surgical repair)	Degenerative MR	585	US	2023
MITRACHORD	NeoChord	Degenerative MR	194	EU	2019
SCOUT	Mitralign system	Functional MR			
ALIGN	Mitralign	50	30	EU	2017
REPAIR	Cardioband system	Functional MR	50	EU	2019
ACTIVE (Randomized)	Edwards Cardioband (vs medical Tx)	Functional MR	375	US	2023
Safety study	Amend annuloplasty ring	MR	40	EU	2018
Safety study	Millipede IRIS	MR	10	EU	2017
CLASP	Edwards PACAL	MR	130	Canada	2021

Ongoing Clinical Trials – TV Repair

Study	Device	Type of TR	N. of patient	Country	Year of completion
HOVER	Edwards SAPIEN XT	TR	15	US	2021
PREVENT	TriCinch system	Functional TR	24	EU	2017
US feasibility trial	Edwards FORMA Saper	Funcitonal aor secondary TR	30	US	2020
SCOUT	Mitralign system	Functionanal TR	30	EU	completed
SCOUT- II	Trialign system	Functional TR	60	EU	2022
TRI-REPAIR	Cardioband	Functional TR	30	EU	2019
SPACER	Fdwards FORMA	TR	75	CA and EU	2020
TVrepair	MitraClip	TR	100	EU	2017

Challenges and Concerns

- **Challenging anatomy and complexity of mitral and tricuspid valve structure**
- **Safety and effectiveness:**
 - **very limited clinical experience**
 - **considerable mortality and complications**
- **Highly selected patients**
 - **difficulty in finding right patients**
- **Survival benefit is more difficult to be demonstrated in TR and MR patients than in AS patients**
- **Every case must be evaluated by a Heart Team**

THANKS!