Two implant options to treat your MR patients

Giuseppe Tarantini, MD, PhD, FESC

Director Interventional Cardiology

University of Padua Medical School, Padua (Italy)

Potential conflicts of interest

Speaker's name: Giuseppe Tarantini, MD, PhD

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

Lecture Fees for Edwards LifeSciences

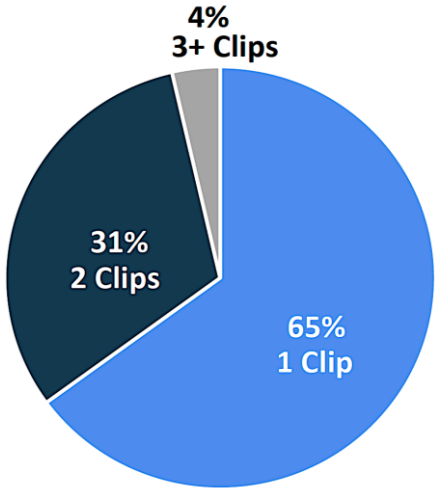
Expert opinion disclaimer

- Expert opinions, advice and all other information expressed represent contributors' views and not necessarily those of Edwards Lifesciences.

DO WE REALLY NEED 4 SIZES? EXPAND G4 Registry[1]

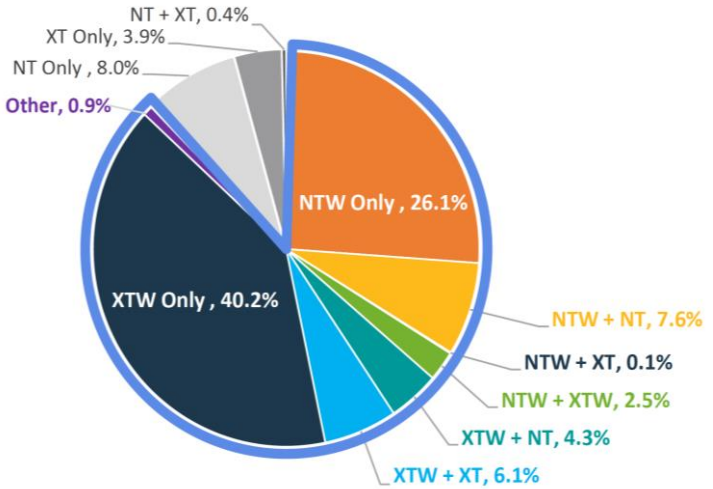
N° OF IMPLANTED CLIPS/PTS[2]

96% ≤ 2 clips per pts



14 CLIP COMBINATIONS[2]

66% used NTW or XTW only



88% used NTW and/or XTW[3]

→ Mostly, only two implant options are used

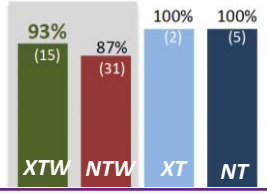
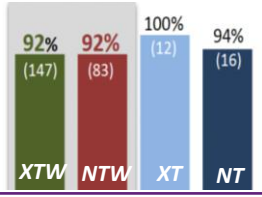
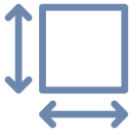
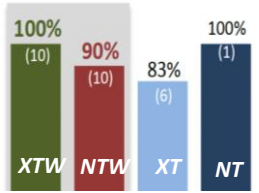
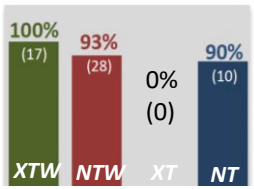
[1]Multicenter registry, with 60 sites, 1164 patients enrolled, 42% having degenerative mitral regurgitation. [2]1141 subjects with at least 1 clip implanted

[3]Von Bardeleben R.S., Contemporary Clinical and Echocardiographic Outcomes of 1000+ Patients Treated with MitraClip™ G4: Results from the EXPAND G4 Post Approval Study. TCT 2022

Based on: Tarantini G., Two implant options to treat all your MR patients. Edwards TNT "Treating diverse mitral regurgitation anatomies: the power of versatility", EuroPCR 2023, May 16th.

DO WE REALLY NEED 4 SIZES? EXPAND G4 Registry[1]

PRECONCEPTs ABOUT THE NEED FOR MORE OPTIONS

	Consensus-based recommendations for clip selection[2]	PRIMARY MR 30-d MR ≤1+	SECONDARY MR 30-d MR ≤1+	Most used
1)  *Leaflet Lenght ≤ 9 mm*	• NTW • NT			**Primary MR:** • 58% **NTW** **Secondary MR:** • 57% **XTW**
2)  *Mitral valve area ≤ 4 cm²*	• NT			**Primary MR:** • 37% **NTW** & 37% **XTW** **Secondary MR:** • 51% **NTW**

XTW and NTW are preferred as 1st clip option[2], despite the recommendations for clip selection

No significant differences in MR reduction, despite the use of different clips

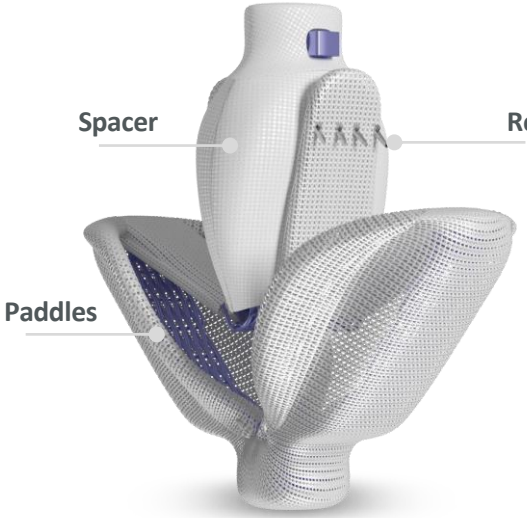
[1]Multicenter registry, with 60 sites, 1164 patients enrolled, 42% having degenerative mitral regurgitation. MR: mitral regurgitation

[2]Maisano F. et al., Clip Selection Strategy with 4th Generation MitraClipTM: Evidence-Based Recommendations from the Global EXPAND G4 Study. PCR London Valves 2022

Based on: Tarantini G., Two implant options to treat all your MR patients. Edwards TNT "Treating diverse mitral regurgitation anatomies: the power of versatility", EuroPCR 2023, May 16th.

Edwards PASCAL Transcatheter Valve Repair System*

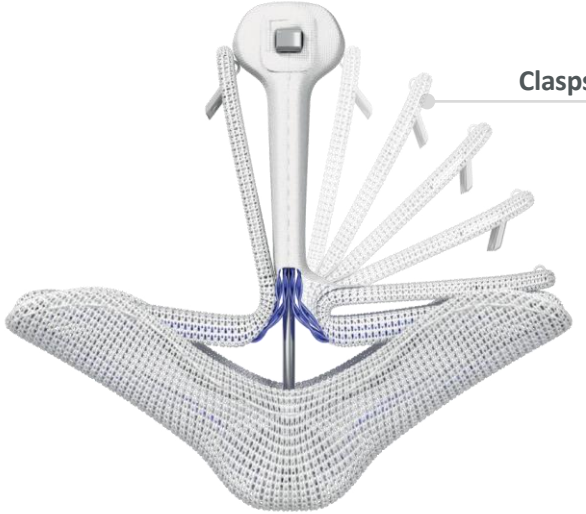
PASCAL Implant



Retention elements

Single row of retention elements to clasp, reclasp, and preserve leaflets

PASCAL Ace Implant



Wide contoured paddles with a larger central spacer

Close the implant to conform to native anatomy and flex during the cardiac cycle

Independent grasping & atraumatic clasp and closure

Allow for staged leaflet capture and adjustment and help you preserve leaflet integrity

* Performance, design and simulation data on file. Note: Images are not actual size

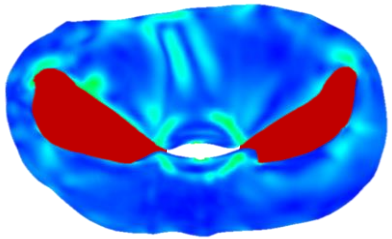
OVERARCHING PRINCIPLES FOR DEVICE SELECTION

1) Ensuring adequate MR reduction for both FMR and DMR
2) Provide preservation of MVA and stability of the implant with adequate leaflet capture

Finite Element Analysis (FEA) in a mitral valve simulates leaflet response to an implant

Implant without spacer

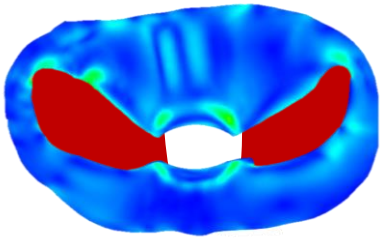
Open orifice area = 156.3 mm² *



- Lower stress concentration
- Higher stress concentration
- Diastolic open orifice area

PASCAL implant

Open orifice area = 188.1 mm² *



- Reduced stress on leaflets*
- 20% increase in open orifice area during diastole *

* Simulation data on file; MR: mitral regurgitation; FMR: functional MR; aFMR: atrial FMR; DMR: degenerative MR; MVA: mitral valve area

TWO IMPLANT OPTIONS FOR YOUR MR PATIENTS

Latest experts' recommendations[1]

EuroIntervention 2023

Anatomical features		NT	XT	NTW	XTW	PASCAL	PASCAL ACE
Length of the mobile leaflet in the grasping zone	<9 mm	✓		✓		✓	✓
	>9 mm		✓		✓	✓	✓
Broad gap size				✓	✓	✓	
Small MVA (<4.5 cm^2)		✓		✓			✓
Thin leaflet structure		✓		✓		✓	✓
Commissural jet		✓		✓			✓
Barlow's disease			✓		✓	✓	✓

MVA: mitral valve area; PMR: primary mitral regurgitation; SMR: secondary mitral regurgitation

PASCAL Ace implant seems to be the workhorse

MR: mitral regurgitation

[1]Hausleiter J. et al. Mitral valve transcatheter edge-to-edge repair. EuroIntervention. 2023 Jan 23;18(12):957-976

Thank You!

Giuseppe.tarantini.1@gmail.com

@interventionalcardiologyteampadova

@giuseppetarantinimdphd

@G_Tarantini01

Thank You!

Expert opinions, advice and all other information expressed represent contributors' views and not necessarily those of Edwards Lifesciences.

Medical device for professional use. For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use (consult eifu.edwards.com where applicable).

Edwards Lifesciences • Route de l'Etraz 70, 1260 Nyon, Switzerland • edwards.com

PCRonline.com