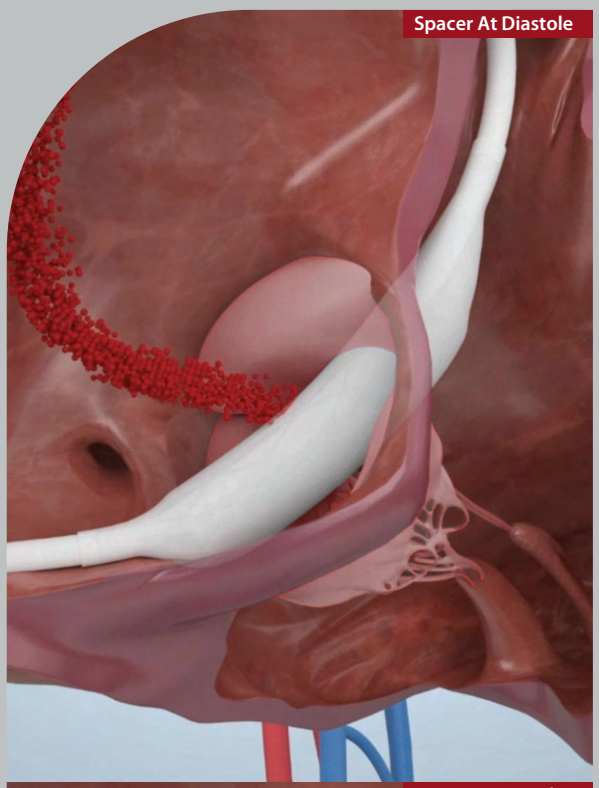
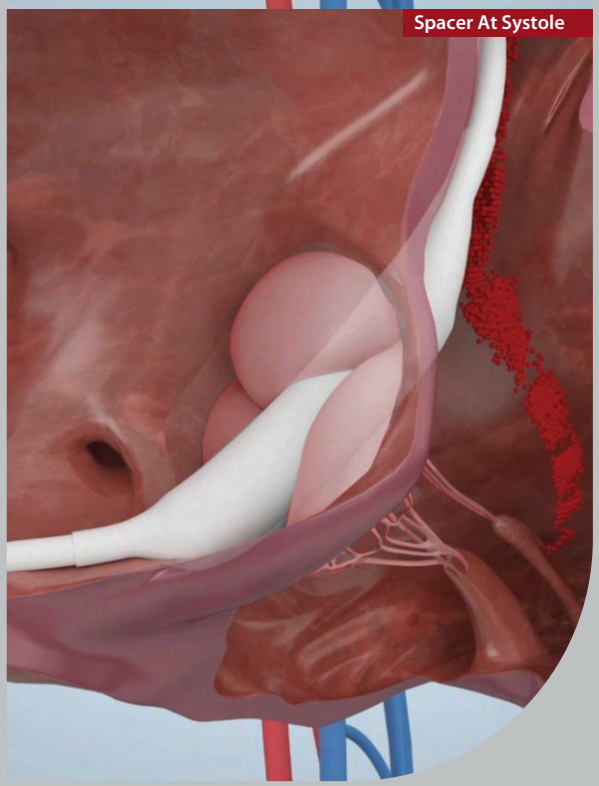




Pivot-TR®

A new class of minimally invasive intervention
designed to restore leaflet coaptation
through dynamic support
for hard-to-treat secondary tricuspid regurgitation.

Transcatheter & Removable

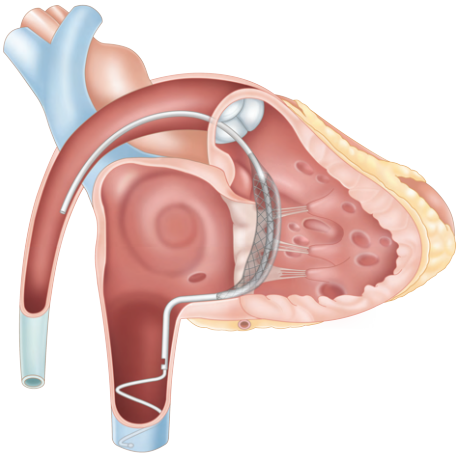
Non-Fixated Yet Stable

Fluid Dynamic Self-Centering

Massive & Torrential TR Inclusive

TAU MEDICAL

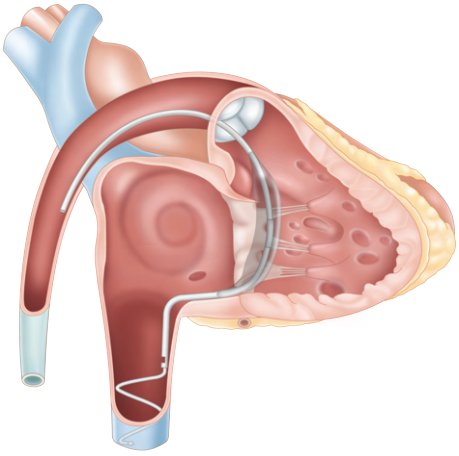
Pivot Extend®



A **permanent** spacer therapy for tricuspid regurgitation. Its flow-guided, self-centering design adapts with the heart and delivers lasting relief without leaflet or annular fixation.

- Permanent, anatomy-conforming therapy
- Adapts naturally; maintains effectiveness over time
- Simple procedure with no leaflet or annular fixation
- Patient-specific sizing to each patient

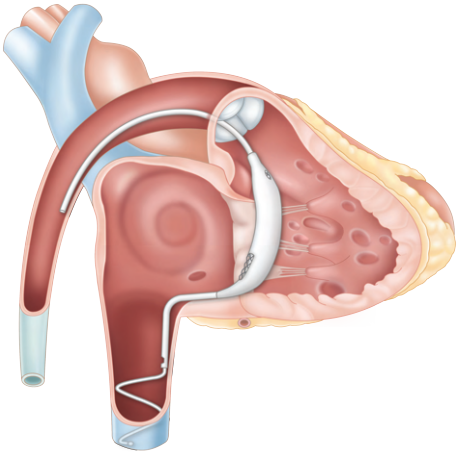
Pivot Long-Bridge



A **temporary** spacer with up to 1-month dwell; sustained relief via the same flow-guided, self-centering design—giving time to stabilise and plan surgery/device therapy while preserving options.

- Sustained TR reduction for up to 30 days
- Bridge-to-surgery or bridge-to-device
- Simple procedure with no leaflet or annular fixation
- Customized to each patient thanks to adjustable balloon

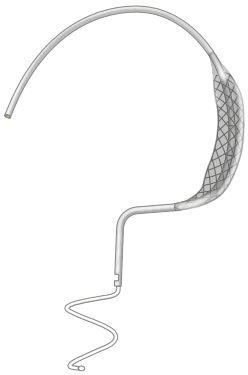
Pivot Bridge®



A **temporary** spacer therapy for tricuspid regurgitation. It provides immediate relief with the same flow-guided, self-centering design while preserving future treatment options.

- Rapid TR reduction for immediate clinical improvement
- Ideal as bridge-to-decision or bridge-to-therapy
- Preserves future treatment options
- Flexible patient management

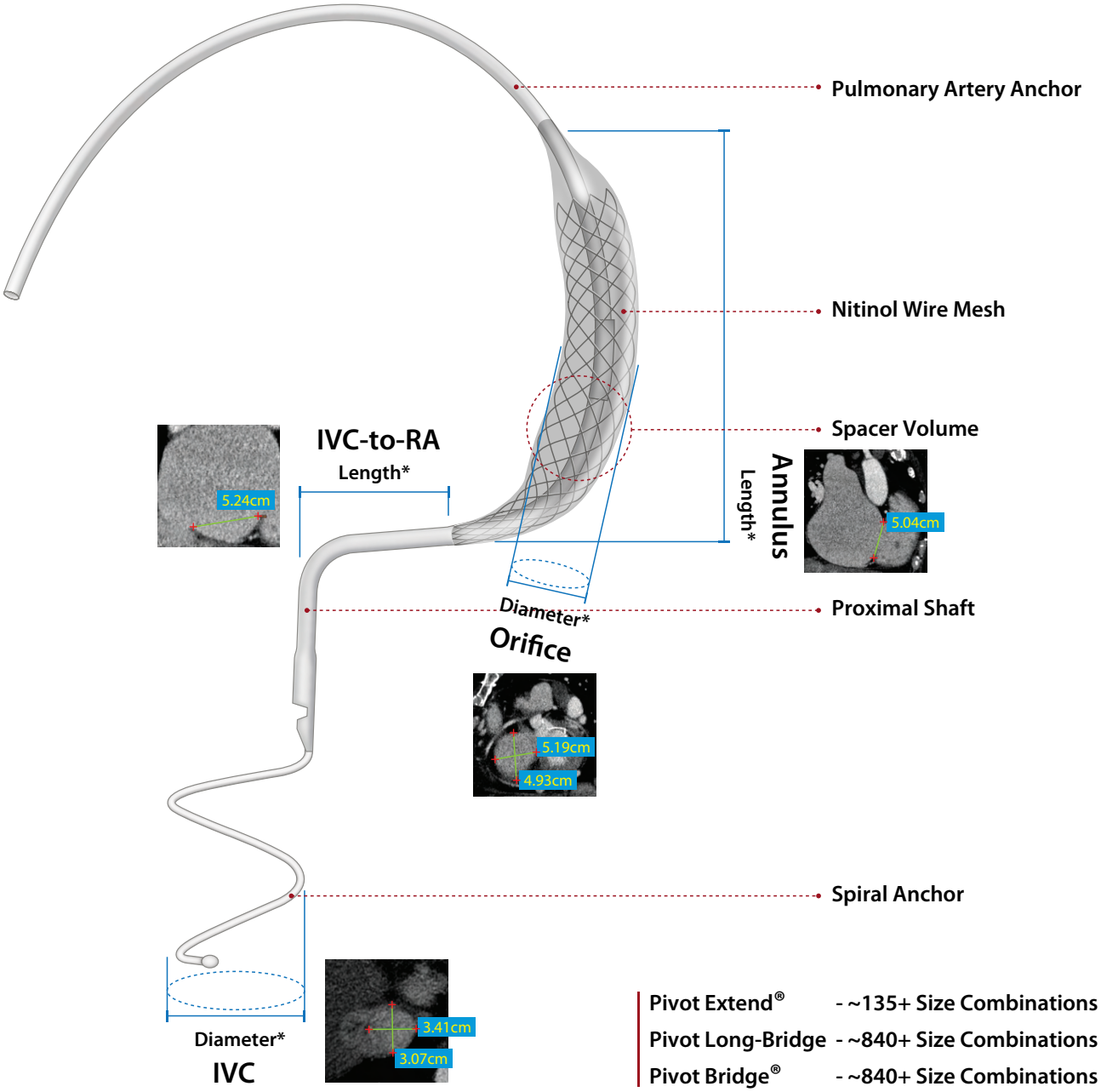
Device Comparison



	Pivot Extend®	Pivot Long-Bridge	Pivot Bridge®
Intended Use	Long-term, definitive therapy	Pre-hab, mid-term bridge therapy	Pre-hab, short-term bridge therapy
Target Disease	Secondary TR	Secondary TR	Secondary TR
TR Severity Treated	Massive & torrential inclusive	Massive & torrential inclusive	Massive & torrential inclusive
Target Population	Patients requiring long-term support	Patients needing stabilization	Patients needing stabilization
Implant Duration	Permanent (~10 years)	Temporary (~4 weeks)	Temporary (~1 week)
Deployment Method	Transfemoral venous access / transcatheter	Transfemoral venous access / transcatheter	Transfemoral venous access / transcatheter
Removal	Intended for long-term implantation; early retrieval possible if needed	Designed for retrieval after stabilization	Designed for retrieval after stabilization
Anchoring	Non-fixated (IVC and PA anchors)	Non-fixated (IVC and PA anchors)	Non-fixated (IVC and PA anchors)
Spacer Design	Oblong nitinol mesh encapsulated in a saline-filled balloon	Oblong saline-filled balloon	Oblong nitinol mesh with ePTFE sheath and flow windows
Spacer Materials	Nitinol mesh, saline-filled balloon	Saline-filled balloon	Nitinol mesh, ePTFE sheath
Valve Interaction	Supports leaflet coaptation without fixation	Supports leaflet coaptation without fixation	Supports leaflet coaptation without fixation
Adaptability	Self-centering and dynamic with heart remodeling	Self-centering and dynamic with heart remodeling	Self-centering and dynamic with heart remodeling
Customization	Balloon volume adjusted during implantation	Balloon volume adjusted during implantation	Spacer size pre-set before implantation

CAUTION: Investigational devices. Limited to investigational use only.

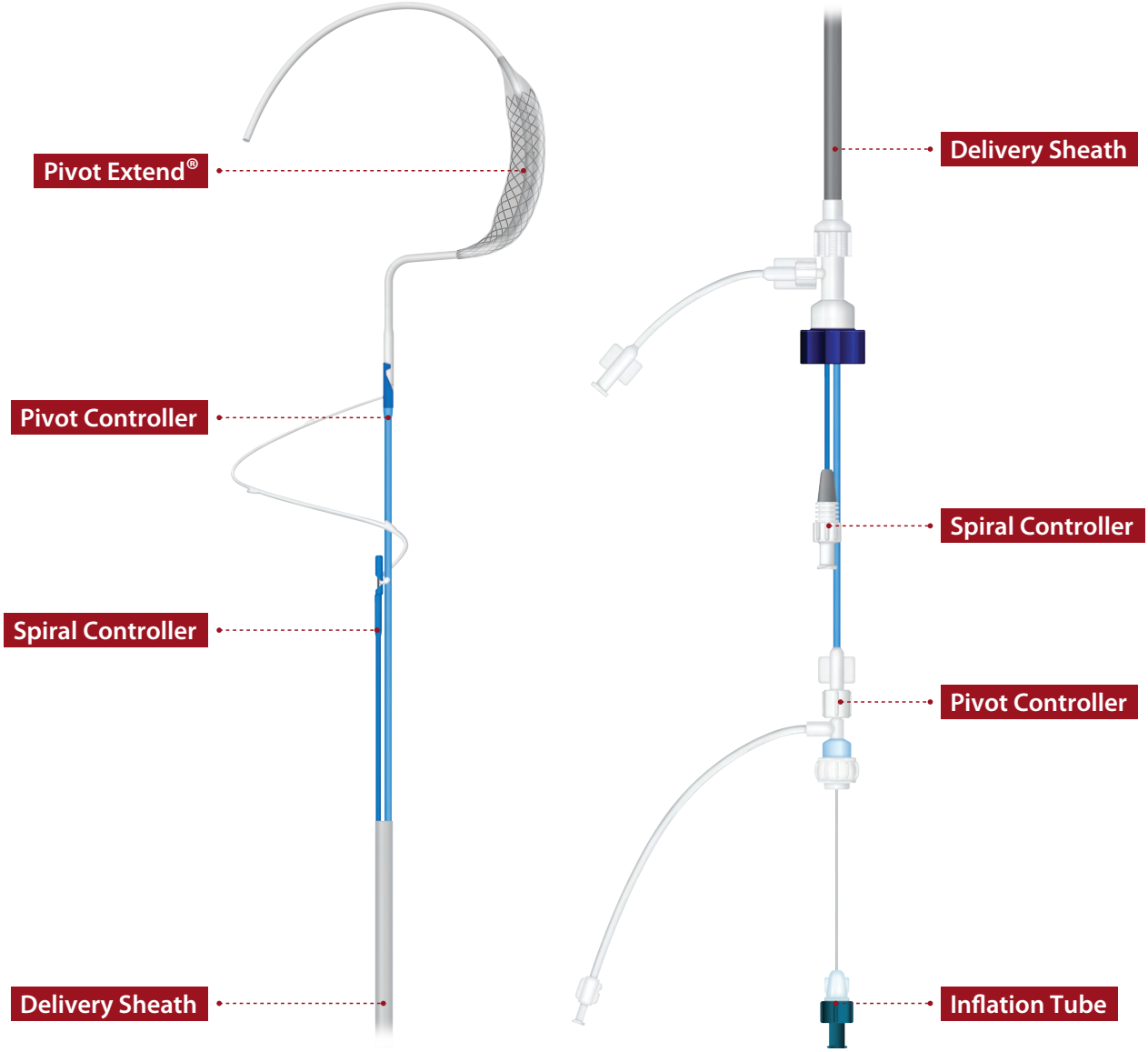
Device Sizing



Pivot Extend®	- ~135+ Size Combinations
Pivot Long-Bridge	- ~840+ Size Combinations
Pivot Bridge®	- ~840+ Size Combinations

Pivot-TR® devices are tailored to match individual anatomy, with key dimensions—including proximal shaft length, spacer diameter, spacer length, and spiral anchor diameter—selected for each patient. This patient-specific sizing creates an optimized device configuration, ensuring effective valve stabilization and maximizing therapeutic benefit.

Device Delivery



Pivot Extend® System

Pivot-TR® is implanted using a 21 Fr transfemoral transcatheter system, relying on familiar catheter techniques and avoiding open-heart surgery. The procedure can typically be completed in under one hour, with a low learning curve for interventional cardiologists, enabling rapid adoption in clinical practice. The device anchors atraumatically without sutures, clips, or tissue penetration, minimizing procedural risk. Its design also allows full retrieval through the same transfemoral access, offering a reversible therapy if patient needs or treatment strategies change.

Patient Selection

Pivot Extend® and Pivot Bridge® are non-fixated, fully repositionable devices that restores tricuspid valve leaflet coaptation.

Compassionate Use / Expanded Access of Pivot Extend® or Pivot Bridge® requires the patient be diagnosed with serious secondary symptomatic tricuspid regurgitation for which no satisfactory alternative therapies are available. Reasons for lack of therapeutic options may include but are not limited to: intolerance and / or contraindications to existing treatments, failure of alternate or approved therapies, and others etc.

Patients are **not** automatically precluded by prior heart transplantation, pacemaker-lead–induced tricuspid regurgitation, markedly reduced left- or right-ventricular ejection fraction, or a failed edge-to-edge repair in which the device could not be fully implanted.

Inclusion Criteria

- Suitable for Pivot-TR® devices according to anatomic criteria evaluated via computed tomography
- Massive (4+) or Torrential (5+) tricuspid regurgitation demonstrated by echocardiography and leading to NYHA class III or IV
- Deemed a candidate for Pivot Extend® implantation by an interventional cardiologist
- Patient/authorized legal guardian understands the nature of the procedure, is willing to comply with associated follow-up evaluation, and provides written informed consent.

Exclusion Criteria

- Evidence of calcification of the tricuspid valve leaflets as assessed by echocardiogram of CT
- Preexisting pulmonary valve prosthesis or a right ventricle to pulmonary artery (RV-PA) conduit
- Has anatomy incompatible with Pivot TR® device implantation

Contraindications

Pivot Extend® and Pivot Bridge® are contraindicated in patients who have any of the following:

- Evolutionary or recent stroke;
- Cerebrovascular accident (CVA) within 30 days;
- Transient ischemic attacks (TIA) within 30 days;
- Myocardial infarction (MI) within 30 days;
- Sepsis, including active endocarditis;
- Known hypersensitivity, allergy or contraindication to implant's components, e.g. nitinol;
- Known hypersensitivity to vitamin K antagonists, heparin and other oral anticoagulants;
- Sensitivity to contrast medium that cannot be adequately premedicated;
- Patients with Creatinine clearance < 20 ml / min;
- Patients with thrombocytopenia of platelet count < 50,000 / µL;
- Patients with bleeding diathesis or coagulopathy or patient refusing blood transfusion;
- Patients with active GI bleeding;
- Thrombosis of the lower venous system or vena cava filter;
- Patients with vascular conditions that make insertion and endovascular access impossible;
- Pregnancy

A Growing Unmet Need

One in Sixteen*

Significant **tricuspid regurgitation (TR)** affects approximately 1 in 16 older adults, with incidence rising with age and comorbid cardiac disease. Despite its progressive nature and strong association with adverse outcomes—including hospitalizations and excess mortality—TR remains markedly undertreated.

For patients with **symptomatic secondary severe to torrential TR** who are unsuitable for open-heart surgery, valve replacement, or other available transcatheter options, therapeutic alternatives are extremely limited.

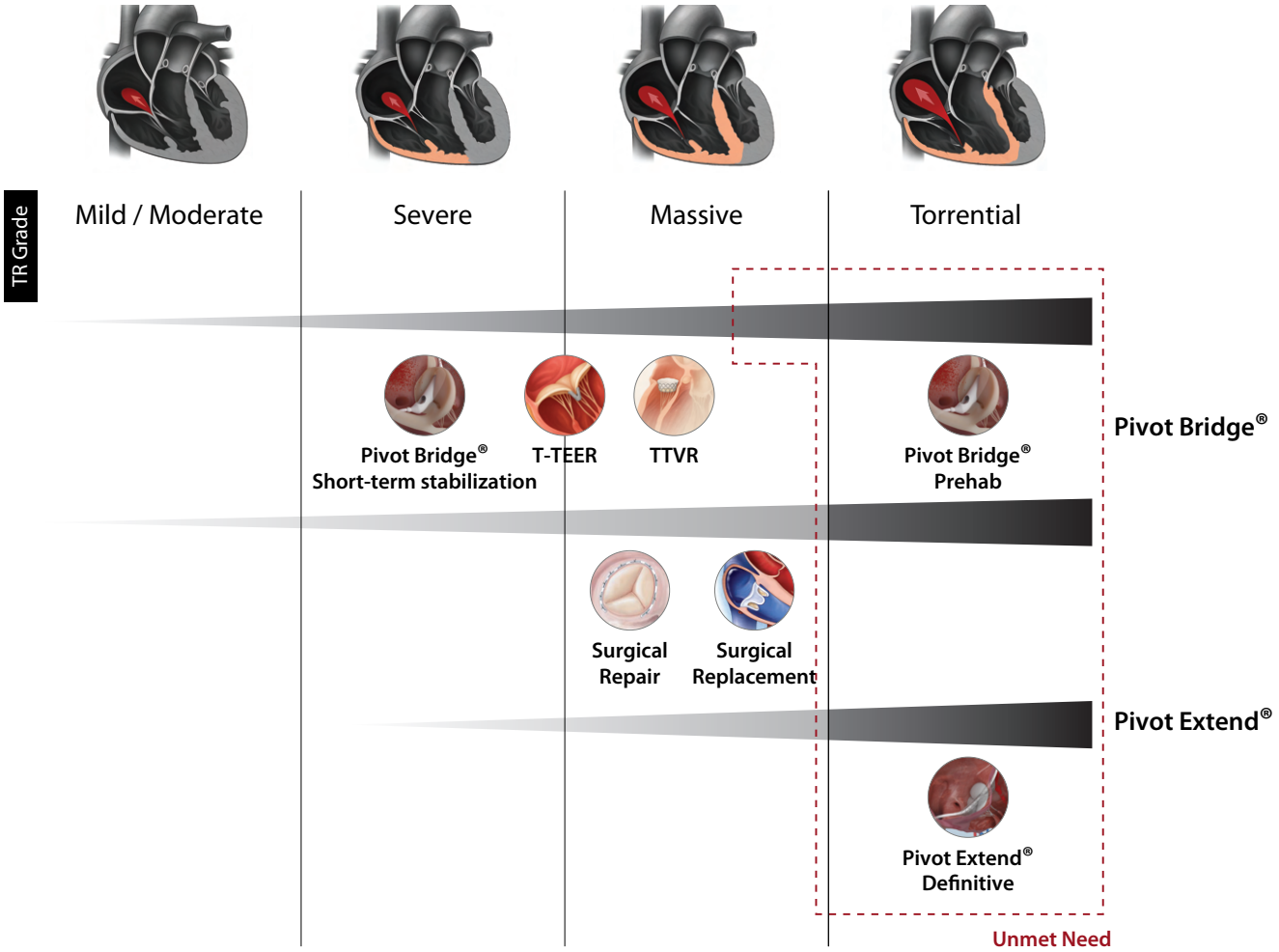
This highlights a critical unmet **need for low-risk, durable, minimally invasive interventions** capable of providing **effective treatment while preserving future therapeutic pathways.**

Target Patient Population

Pivot-TR® is designed for patients with massive to torrential tricuspid regurgitation, where outcomes with the device have been especially strong. These patients often present with marked annular dilation that excludes them from T-TEER or other transcatheter options, and many are too frail or high-risk for surgical repair or replacement. By addressing this severely ill, previously untreatable group, Pivot-TR® fills a critical gap in current TR therapy.

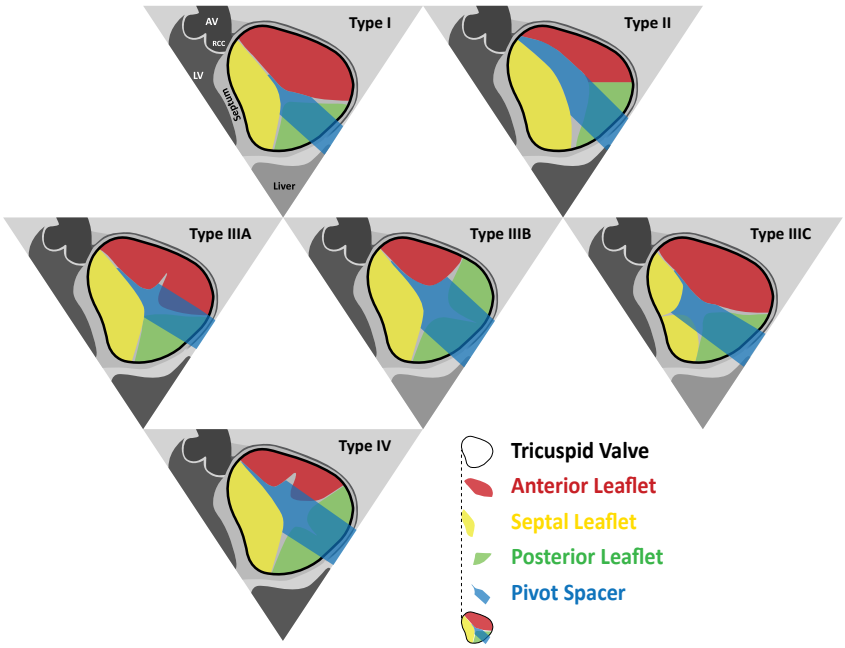
*Dernektsi, Chrisoula, Tetsu Tanaka, Johanna Vogelhuber, Georg Nickenig, and Fabien Praz. “Tricuspid Regurgitation – Part 1: Evaluation and Risk Stratification.” European Society of Cardiology, June 11, 2024.

Treating the Worst Cases



Patients with advanced TR grades are often excluded from T-TEER, surgical repair, or TTVR due to frailty and associated pathophysiology. Pivot Bridge® offers stabilization, risk prediction, and procedural facilitation in advanced patients prior to definitive treatment, while Pivot Extend® provides a destination therapy designed to restore valve competence even for the worst cases.

Anatomically Agnostic



Pivot-TR® is uniquely designed to accommodate the wide variability of tricuspid valve leaflet morphologies. This adaptability expands eligibility to patients who are often excluded from other device-based therapies such as T-TEER.

Filling the Gap

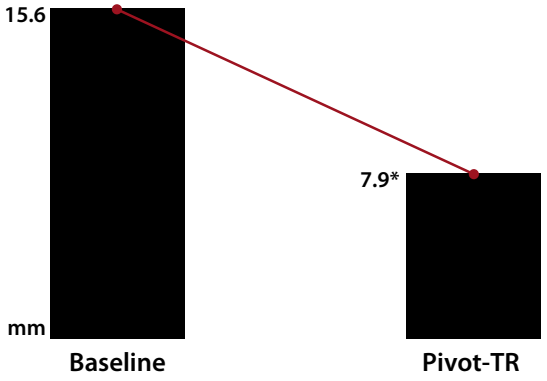
	Surgical Repair	T-TEER	TTVR	Pivot-TR®
Coaptation Gap > 7mm	▲	✕	●	●
Complex Subvalvular Anatomy	▲	✕	▲	●
Difficult TEE Imaging	✕	✕	▲	●
Large Annulus	✕	●	✕	●
Poor RV Function	▲	▲	▲	●
Anticoagulation C/I	●	●	▲	●

Pivot-TR® remains effective even in patients with markedly dilated right ventricles and inferior vena cava. In the early feasibility study, 67% of patients had large coaptation gaps (>7 mm), 93% had large annuli (>52 mm), and 67% had large IVC diameters (>35 mm)—features that typically exclude patients from edge-to-edge repair, TTVR, or heterotopic valve options.†

TR Reduction

50% Average Length Reduction in TR

Vena Contracta — **Pivot-TR**

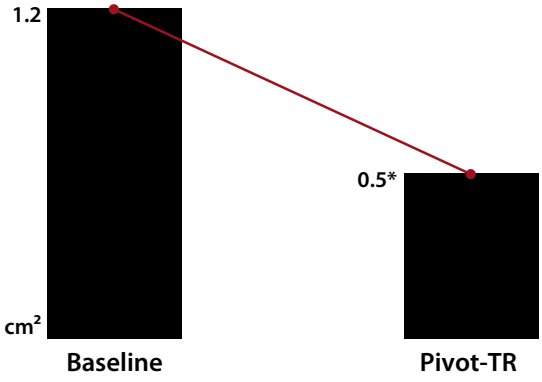


Average 1/2-Length Reduction in TR
*(n=15; *p<0.01 vs. baseline)*

50% Average Area Reduction in TR

EROA*— **Pivot-TR**

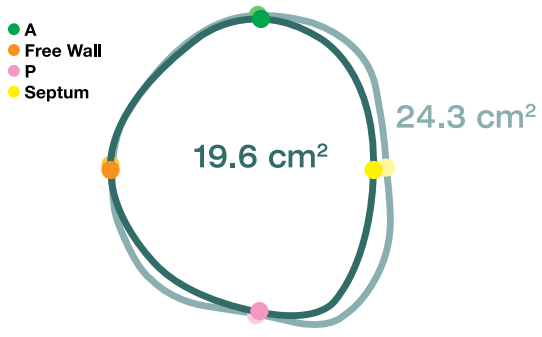
*Effective Regurgitant Orifice Area



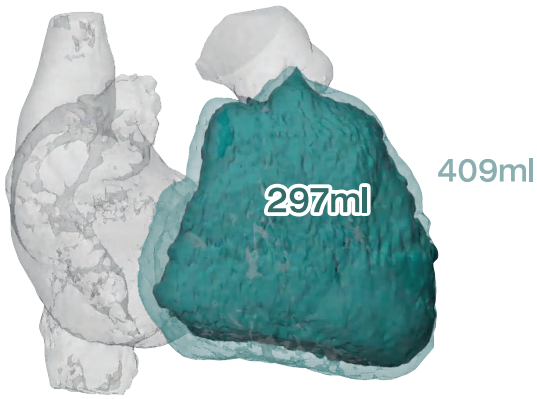
Average 1/2-Area Reduction in TR
*(n=15; *p<0.01 vs. baseline)*

Pivot-TR® achieved a 2-grade average reduction in tricuspid regurgitation severity, corresponding with marked decreases in effective regurgitant orifice area and vena contracta. This rapid improvement demonstrates not only symptom relief but also meaningful reversal of disease burden in patients with severe secondary TR.†

Anatomical Stabilization



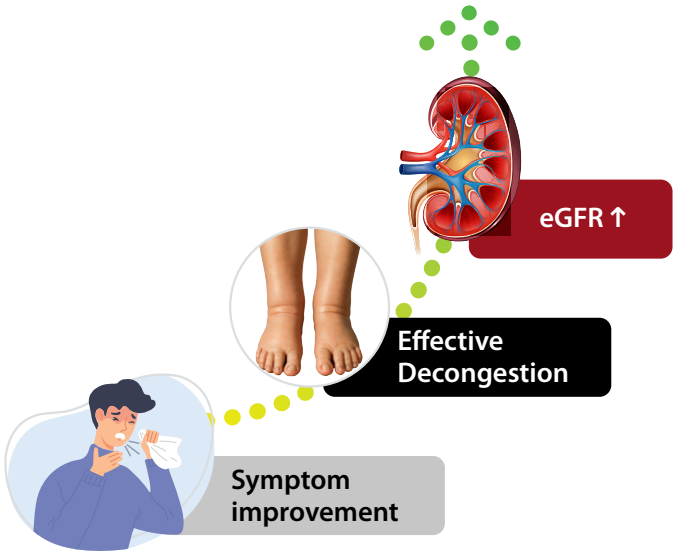
Measurable TV Annulus Reduction



Measurable RV Volume Reduction

Pivot-TR® has shown to induce rapid anatomical stabilization of the maladaptive remodeling associated with tricuspid regurgitation. Within just one week of implantation, patients demonstrated a **14% average reduction in tricuspid annulus diameter** and an **8% average reduction in right ventricular volume,** highlighting the device's ability to address the pathophysiology of TR.†

Symptom Improvement



On average, patients experienced a one-grade NYHA class improvement (from 2.5 to 1.5, $p<0.05$), along with reduced body weight from better fluid management (–1.6 kg, $p<0.05$). Importantly, kidney function improved, with a 10% increase in eGFR ($p<0.05$), reflecting restored hemodynamic stability and multi-organ benefit.[†]

Seamless with Standard NOAC

Pivot-TR® does not require any additional or intensified anticoagulation therapy beyond what is already standard for most patients with tricuspid regurgitation. The majority of TR patients are already receiving NOACs (non–vitamin K oral anticoagulants) for coexisting atrial fibrillation, and Pivot-TR® can be managed under this same regimen. No device-specific anticoagulation protocol is needed, allowing physicians to maintain patients on their usual therapy without modification

[†] Data from a multi-center, single-arm study conducted at 11 hospitals in South Korea, involving 15 patients with severe symptomatic secondary TR. Devices were implanted temporarily for up to 7 days, with outcomes assessed by core lab–reviewed echocardiography and cardiac CT.

Watch

Live-in-a-Box | Pivot Extend® at CSI Frankfurt 2025

Pivot Extend® Procedure Animation

Pivot Bridge® Procedure Animation

Contact For More

E-Mail: INFO@tau-medical.com
https://www.tau-medical.com/

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CAUTION: Investigational devices. Limited to investigational use only.