

SIMPLICI-T™

Annuloplasty System for Mitral and Tricuspid Repair



Repair Redefined

A first-of-its kind approach to mitral and tricuspid valve repair: the Simplici-T™ Annuloplasty System.

The Simplici-T™ Annuloplasty System is the first flexible band to eliminate the need for sizing, providing a custom fit for every patient and requiring less inventory space.

No More Sizing – Ever

One size is always the right size. The Simplici-T™ System is based on the “no sizing” implant technique of Dr. Tirone David, one of the world’s most outstanding technical cardiac surgeons.

Customized for Every Patient

The flexible band and holder adapts to the unique needs of every patient. The implanted band length is determined by the annular size and degree of plication of the annular tissue.

Reduced Inventory

The flexible annuloplasty band is supplied in a length of 100mm and requires no additional accessories.

What’s more, the Simplici-T™ System delivers the benefits of a flexible band, including:

- Better early postoperative LV systolic function over patients with a rigid ring¹
- Allows annulus size and configuration to adapt to changes throughout cardiac cycle²⁻⁴
- Better diastolic blood flow across the mitral valve, particularly during exercise⁵
- Flexible annuloplasty repair devices place less stress on the sutures during systole, minimizing the likelihood of dehiscence⁶

Contact your Medtronic sales representative for more information about a training site near you.



"I have not sized a mitral valve for an annuloplasty band for more than a decade. Simplici-T™ allows the surgeon to tailor the length of the band according to the pathology."

Tirone E. David, M.D.*

* Tirone E. David receives royalties from Medtronic, Inc. on sales of the Simplici-T™ annuloplasty system.

REFERENCES

1. David TE, Armstrong S, Sun Z. Left Ventricular Function After Mitral Valve Surgery. *J Heart Dis.* 1995;4:5175-80.
2. Tsakiris AG, Von Vernuth G, Rastilli GC, et al. Size and Motion of the Mitral Valve in Anesthetized Intact Dogs. *J Appl Phys.* 1971;30:611
3. Ormiston JA, Shah PM, Tei C, et al. Size and Motion in the Mitral Valve Annulus in Man. *Circulation.* 1981;64:113.
4. Duran CMG, Ubago JLM. Clinical and Hemodynamic Performance of a Totally Flexible Prosthetic Ring for Atrio-Ventricular Valve Reconstruction. *Ann Thorac Surg.* 1976;22:458-63.
5. Okada Y, Shomura T, Yamaura YI, et al. Comparison of the Carpentier and Duran Prosthetic Rings Used in Mitral Reconstruction. *Ann Thorac Surg.* 1995;59:658-63.
6. Duran C. Perspectives for Acquired Valvular Disease. In: *Advanced Cardiac Surgery*, Vol. 4, 1993.

Simplici-T™ Annuloplasty System

Indications: This device is indicated for the reconstruction and/or remodeling of pathological mitral and tricuspid valves. Appropriate repair and annular remodeling may correct combined valvular insufficiency and stenosis. **Contraindications:** Heavily calcified valves, valvular retraction with severely reduced mobility, active bacterial endocarditis. **Warnings/Precautions/Adverse Events:** Only physicians who have received proper training in valve repair should use this device. Adverse events can include: thromboembolic events, band dehiscence, hemolysis, stenosis, heart block, endocarditis, systolic anterior motion, left ventricular outflow tract obstruction, anticoagulant-related bleeding or hemorrhage, uncorrected or recurrent regurgitation, low cardiac output, thrombosis, damage to coronary arteries. For additional information please refer to the Instructions for Use provided with the product or contact your local Medtronic representative. **CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a physician.

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