

General Product Information:

- Storage Temperature

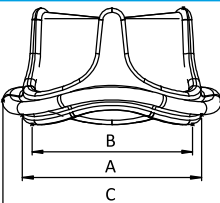
: 10 °C to 25 °C (50-77 °F)
- Storage Solution

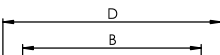
: Glutaraldehyde
- Rinse Procedure

: 1 min rinse each in first 3 bowl and store the valve in 4th bowl prior to implantation.
- MRI Safety Information

: Testing of this device in a magnetic field of 1.5 and 3.0 Tesla has shown that this device is MR conditional.

Technical Specification:

|  | Nominal Specifications (mm)           |    |    |    |      |      |
|-----------------------------------------------------------------------------------|---------------------------------------|----|----|----|------|------|
|                                                                                   | Size                                  | 19 | 21 | 23 | 25   | 27   |
|                                                                                   | A Tissue Annulus Diameter             | 20 | 22 | 24 | 26.5 | 28.5 |
|                                                                                   | B Internal Stent Post Diameter (Base) | 18 | 20 | 22 | 24   | 26   |
|                                                                                   | C External Sewing Ring Diameter       | 27 | 28 | 31 | 33   | 36   |

| Mitral                                                                            | Nominal Specifications (mm)            |      |      |      |      |      |
|-----------------------------------------------------------------------------------|----------------------------------------|------|------|------|------|------|
|  | Size                                   | 23   | 25   | 27   | 29   | 31   |
|                                                                                   | A. Stent Diameter (Wire Form)          | 23   | 25   | 27   | 29   | 29   |
|                                                                                   | B. External Stent Post Diameter (Base) | 26.5 | 28.5 | 29.5 | 32.5 | 32.5 |
|                                                                                   | C. External Stent Post Diameter (Tip)  | 27   | 29   | 31   | 33   | 33   |
|                                                                                   | D. External Sewing Ring Diameter       | 33   | 36   | 38   | 41   | 43   |

| Available Bioprosthesis Diameter (mm) | Ordering Information |              |
|---------------------------------------|----------------------|--------------|
|                                       | Aortic Model         | Mitral Model |
| 19                                    | FLOM19A              | N.A          |
| 21                                    | FLOM21A              | N.A          |
| 23                                    | FLOM23A              | FLOM23M      |
| 25                                    | FLOM25A              | FLOM25M      |
| 27                                    | FLOM27A              | FLOM27M      |
| 29                                    | N.A                  | FLOM29M      |
| 31                                    | N.A                  | FLOM31M      |

| Available Sizer Set | Ordering Information |
|---------------------|----------------------|
| Aortic sizer set    | FLOMA1927            |
| Mitral sizer set    | FLOMM2331            |



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Flomero<sup>TM</sup>  
Pericardial Bioprosthesis

Protected by



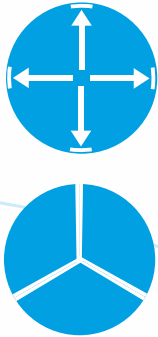


Tri-leaflet stented bioprosthesis



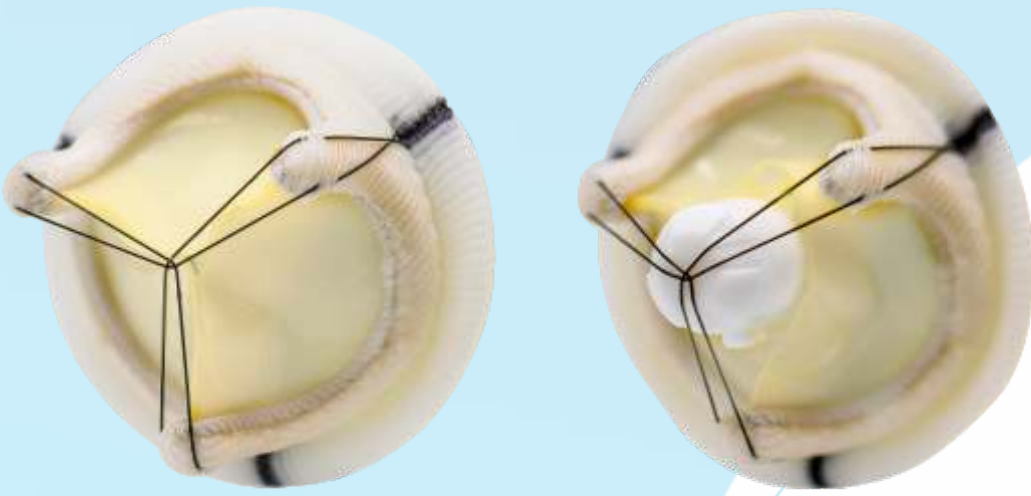
HEMODYNAMICS SUPPORT

- Triple-Composite design provides optimal Effective Orifice Area (EOA)
- The three separate leaflets are matched for better leaflet Coaptation which helps minimize Intra-Valvular Regurgitation.



EASE OF IMPLANTABILITY

- Black sutures in Mitral valves helps reduce the profile of the commissures, easing the bioprosthesis implantation in the Mitral annulus.

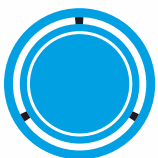


TRUSTED DURABILITY

- Leaflets are treated with proprietary anti-calcification process to increase valve's long term durability.
- Three independent pericardial leaflets are laser cut to provide absolute uniformity realizing a Triple-composite design.
- Triad-frame design with elgiloy alloy wireform provides Robustness via Superior spring efficiency, Fatigue and Corrosion resistance.



- Sewing ring designed for better approximation to patient's annulus and for ease of implantability.
- Commissural markers on sewing ring facilitates suture placement and valve orientation.
- Elgiloy alloy wireform provides excellent Radio-Opacity and handling characteristics.



Aortic Valve Placement

Mitral Valve Placement