

Meril

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MILTONIATM

Bi-Leaflet Mechanical Valve

Device Description

The MILTONIA™ Mechanical valve is a Bi-Leaflet Heart Valve made up of highly durable Pyrolytic Carbon on a Graphite substrate. The Pyrolytic Carbon is Silicon (Si) alloyed and contains around 3 to 8 % of Silicon(Si) and around 12% Tungsten(W) for radiopacity.

The Polished Silicon alloyed varieties of Pyrolytic Carbon exhibit an excellent degree of thromboresistance while improving resistance to wear, offering excellent and durable results.

The Orifice ring consists entirely of Pyrolytic Carbon. In the full open position, the plane of each leaflet forms a nominal angle of 85° relative to the plane of the orifice ring.

The valve Sewing cuff is made up of Double Velour Polyester fabric and is mounted on the orifice using a Titanium(Ti) Stiffening ring and secured with two Titanium(Ti) Lock rings and Lock wire. This method of Sewing cuff attachment to the orifice allows for rotation of the carbon orifice in-situ during implantation.

Three markers are located in the aortic Sewing ring and four markers are located in the mitral sewing ring to assist in the uniform placement of sutures around the valve annulus.



Components



LEAFLET

Pyrolytic carbon coating over graphite substrate, Tungsten(W) impregnated leaflets for radio-opacity



SEWING RING

Made of double velour polyester that encourages endothelialisation, gives ease in suturing and avoids suture looping and suture knots



PIVOT

Open pivot design - Convex hinge mechanism which protrudes slightly from the inside of the valve orifice on which the leaflets rest



CARBON RIM

Carbon rim made of pyrolytic carbon. Sewing ring is mounted with the help of a Titanium(Ti) stiffening ring and secured with Titanium(Ti) lock ring and lock wire. This allows for the creation of a track for rotation of the carbon rim.

Performance Parameters

Durability



Pyrolytic Carbon coated leaflets:

The leaflets of the MILTONIA valves are made of Pyrolytic Carbon over Graphite substrate and Tungsten(W) impregnation. The presence of Tungsten(W) provides better radiopacity allowing a non invasive diagnostic observation of the leaflet motion through fluoroscopy or similar methodologies.

The Pyrolytic Carbon consists of 3-8% Silicon(Si) and this adds to the strength of the Pyrolytic Carbon.

An open pivot design provides Passive Washing mechanism of pivot which minimizes thrombotic events. The Orifice ring consists entirely of Pyrolytic Carbon with a Titanium(Ti) Stiffening ring. The Titanium(Ti) Stiffening ring increases the strength multiple times and thus minimizes the risk of deformation of the Carbon rim .

The method of Sewing cuff attachment to the Orifice allows for rotation of the sewing ring in-situ, during surgical placement.

Hemodynamics

- In the full open position, the plane of each leaflet forms a nominal angle of 85° relative to the plane of the Orifice ring
- Suspended leaflet design ensures full opening providing large Effective Orifice Area and Minimal trans-valvular gradients to guarantee fulfilling the physiological needs of the patient
- The valve has a thin Carbon Orifice and unique pivot axis from which the leaflets are suspended
- There are Two aortic models- Miltonia Aortic and Miltonia AP Aortic. The Miltonia AP comes with a modified cuff that allows for supra-annular seating

1.2sqcm

16AP/ 19A

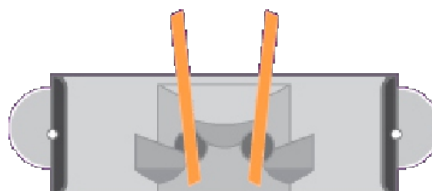
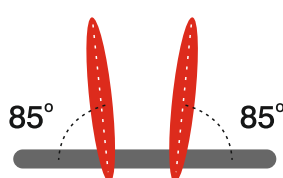
1.5sqcm

18AP/21A

1.7sqcm

20AP/23A

Ref- EOAs are derived from in-vitro performance testing

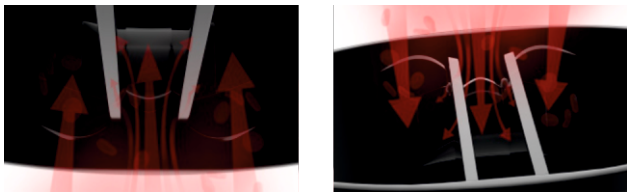


- 85° opening angle
- 60° travel arc

Thromboresistance

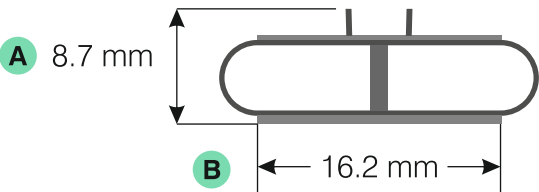
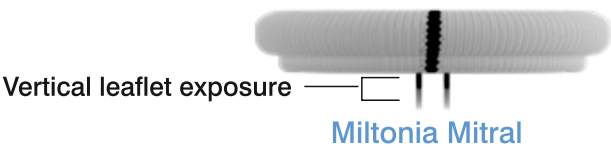
An open pivot design ensures space between the leaflet and the hinge area leading to proper passive washing of the pivot area. This prevents blood stasis and lowers the chances of thrombus formation.

A Smooth Blood contact surface and a laminar flow ensures less turbulence and hence chances of eliciting platelet activation is low.

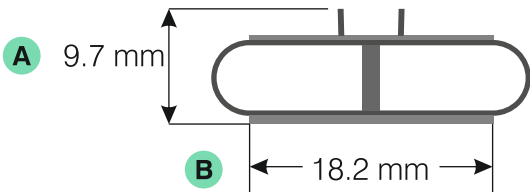


Implantability

- The Miltonia bileaflet valve is a low profile heart valve with minimal vertical leaflet exposure as well as an adequate posterior wall clearance. This minimizes the chances of coronary ostia blockage in the aortic position and the chances of subvalvular impingement in the mitral position are also reduced
- The valve comes with a Titanium(Ti) stiffening ring with two Titanium(Ti) lock rings and a lock wire. This provides a mechanism for the valve to rotate at the time of implantation
- There are two cuff variants in Aortic (compact) and Mitral (flared) for easier implantation



MILTONIA AP 16 mm



MILTONIA AP 18 mm

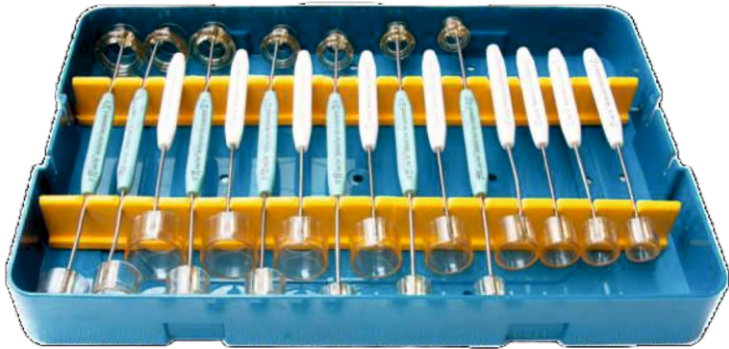
A - Implant Height (mm) | B - Tissue Annulus Diameter (mm)

Specification		Tissue Annulus Diameter (mm)	Overall Height (mm)	Implant Height (mm)	Vertical Leaflet Exposure (mm)	Opening Angle (°)	Posterior Wall Clearance (mm)	
Mitral Valve	Catalog No.						Anatomical Orientation	Anti-anatomical Orientation
	MLT23M	23.8±2	11.5±2	6.7±3	3.8±1	85±5	2.2±1	5.9±2
	MLT25M	25.8±2	12.5±2	7.1±3	4.1±1	85±5	2.5±1	5.7±2
	MLT27M	27.8±2	13.5±2	7.9±3	4.9±1	85±5	2.8±1	5.2±2
	MLT29M	29.8±2	14.4±2	8.9±3	5.9±1	85±5	3.2±1	5±2
	MLT31M	31.8±2	14.4±3	8.9±3	5.9±1	85±5	3.2±1	5±2
	MLT33M	33.8±2	15.4±3	9.1±3	6.1±1	85±5	3.3±1	4.9±2

MILTONIA™ Ordering Information

Specification		Tissue Annulus Diameter(mm)	Sewing Ring Diameter (mm)	Orifice Inner Diameter (mm)	Geometric Orifice Area (cm²)	Overall Height (mm)
Aortic Valve	Catalog No.					
	Standard					
	MLT19A	19±2	19.8±2	14.8±1	1.55±1	8.7±1
	MLT21A	21±2	21.8±2	16.8±1	2.02±1	9.7±1
	MLT23A	23±2	23.8±2	18.8±1	2.56±2	10.9±1
	MLT25A	25±2	25.8±2	20.8±1	3.17±2	12.1±1
	MLT27A	27±2	27.8±2	22.8±1	3.84±2	13.1±1
	Advanced Performance (AP)					
	MLT16AP	16.2±2	19.8±2	14.8±1	1.55±1	8.7±1
	MLT18AP	18.2±2	21.8±2	16.8±1	2.02±1	9.7±1
	MLT20AP	20.2±2	23.8±2	18.8±1	2.56±1	10.9±1
	MLT23M	23.8±2	31±2	18.8±1	2.56±2	11.5±2
Mitral Valve	MLT25M	25.8±2	33±2	20.8±1	3.17±2	12.5±2
	MLT27M	27.8±2	35±2	22.8±1	3.84±2	13.5±2
	MLT29M	29.8±2	37±2	24.8±1	4.59±2	14.4±2
	MLT31M	31.8±2	39±2	26.8±1	5.37±2	14.4±3
	MLT33M	33.8±2	41±2	26.8±1	5.37±2	15.4±3

Sizer Set

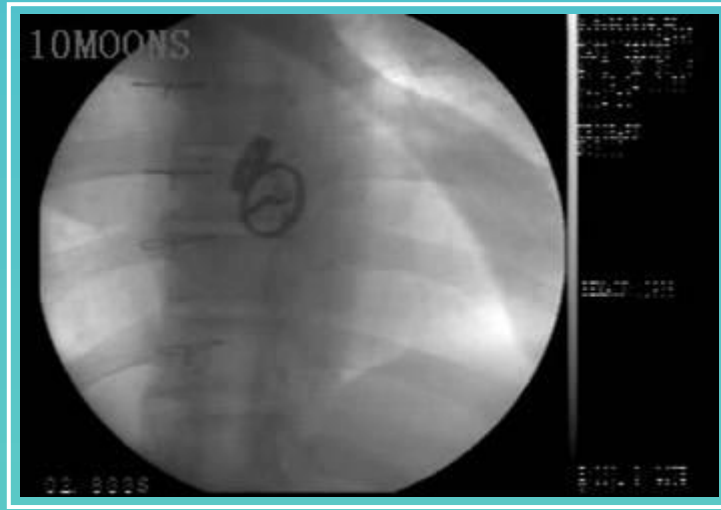


MRI Statement

The MILTONIA™ Mechanical Bi-Leaflet Heart Valve has been shown in non-clinical testing to be MRI Conditional. MRI test conditions used to evaluate this valve were: for magnetic field interactions, a static magnetic field strength of 3 Tesla with a maximum spatial gradient magnetic field of 1000 Gauss/cm for MRI-related heating, a maximum whole body averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of MR imaging. While a single valve produced a temperature rise of less than 1°C and should not migrate under these conditions, non-clinical testing has not been performed to rule out the possibility of valve migration at field strengths higher than 3 Tesla. MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the valve.

The MRI in-vivo testing has not yet been carried out.
If MRI is necessary in clinical situations,
careful evaluation is required.

Flouroscopy and X Ray Visualisation



The leaflets consist of Pyrolytic Carbon coated over a Graphite substrate
The Graphite substrate for the leaflets is Tungsten(W) impregnated for radiopacity

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Meril's Global Presence

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