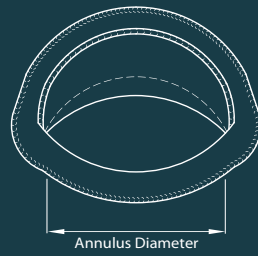
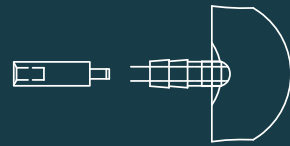


MitroFix™ Device



Model Number	Valve Size (mm)
NRMF-00028	28
NRMF-00030	30
NRMF-00032	32
NRMF-00034	34
NRMF-00036	36
NRMF-00038	38

MitroFix™ Sizer Kit



Model Number	Size(mm)
NRMF-SK028	28
NRMF-SK030	30
NRMF-SK032	32
NRMF-SK034	34
NRMF-SK036	36
NRMF-SK038	38

REFERENCES

- 1 Average EOA from 2.8 to 3.2 cm² observed in various clinical experience with the MitroFix device compares favorably to 2.0 cm² range seen frequently with mechanical mitral valves.
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- 3 Victor O. Morell and Peter A. Wearden, "Experience With Bovine Pericardium for the Reconstruction of the Aortic Arch in Patients Undergoing a Norwood Procedure," *Ann Thorac Surg* 84, no. 4 (October 1, 2007): 1312-1315.
- 4 Michele Musci, et al. "Surgical therapy in patients with active infective endocarditis: seven-year single centre experience in a subgroup of 255 patients treated with the Shelhigh stentless bioprosthesis," *European Journal of Cardiothoracic Surgery* 34 (2008) 410-417.
- 5 Pelosi, MA II, Pelosi MA III. "A new nonabsorbable adhesion barrier for myomectomy," *Am J Surg.* 2002 Nov;184(5):428-32.
- 6 Dohmen et al., "Endothelial Cell-Seeded Bovine Internal Mammary Artery for Complete Revascularization," *Ann Thorac Surg* 83, no. 3 (March 1, 2007): 1168-1169.
- 7 Mishra PK, Sharma AD, Smallwood KG, Spyt TJ, "A new approach to the treatment of mitral valve prolapse using the MitroFast valvular stenting device," *Heart*, 2009 May; 95(5):384.
- 8 Oertel, et al., "Possible Indications for the MitroFast," Presented at the 18th WSCTS World Congress, April 30th - May 3, 2008. Kos, Greece.
- 9 Clinical communications, data on file.

CAUTION: Refer to the Instructions For Use provided with each device for complete information regarding indications for use, contraindications, warnings, precautions, and potential complications.

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MITROFIX™

MITRAL VALVE RESTORATION SYSTEM

See your local representative for ordering



No compromise . . .

The No-React® MitroFix™ Restoration System

A system inspired by emulating the naturally closed posterior mitral leaflet in order to maximize the anterior leaflet's optimal function. The device is combined with a functional sizer to test coaptation and save surgical time, while retaining the clinical benefits of using the patient's own valve.

Turn the art of repair into the science of restoration

The MitroFix™ system allows a surgeon to quickly and easily create a monoleaflet valve - the goal of current repair techniques. Instead of restricting the mitral annulus with traditional annuloplasty, you can now maximize it. The MitroFix™ has shown to deliver a greater EOA than expected with repair or replacement¹.

Durable: 5 years and counting

- ▶ 5 years human clinical experience
- ▶ A pliable stent covered in No-React®-treated porcine pericardium duplicates the natural closed posterior leaflet
- ▶ No erosion of the device or the anterior leaflet has been reported

The No-React® treatment. BioIntegral Surgical manufactures devices using the No-React® treatment. No-React® is a proprietary detoxification of glutaraldehyde-treated tissue.

12 years of clinical experience with No-React® devices show:



- ▶ reduced toxicity, enhanced biocompatibility
- ▶ lower rates of infection, adhesion, and calcification
- ▶ the promotion of endothelial lining²⁻⁶

Restoration Goes Beyond Repair: MitroFix™ is a system, not just a device

- ▶ Test before you commit: a functional sizer demonstrates the likely outcome of the restoration before full commitment is made
- ▶ An effective tool for promotes simplified, reproducible results⁷
- ▶ The system's goal is to maximize EOA, not to constrict or undersize
- ▶ No need to compensate for tethering⁸



Major Indications

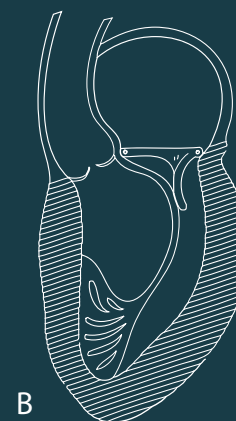
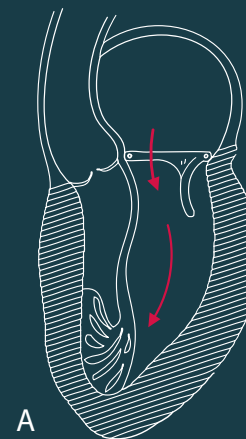
Restore in cases where repair is impossible

Clinical experience indicates that approximately 25% of cases which are beyond repair and would require replacement can be restored with the MitroFix⁸.

- ▶ Ischemic
- ▶ Destruction or infection of the posterior leaflet
- ▶ Complex etiology where repair is impossible or not feasible

Save time when essential for outcome/survival

Experience indicates markedly reduced cross-clamp times compared with repair or replacement alternatives⁹. If performing complex repairs or multiple procedures, the MitroFix™ should be part of your armamentarium.



Implanted BioIntegral MitroFix™ with open anterior leaflet (A) and closed anterior leaflet (B)