MitroFix™ Device

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<th>Valve Size (mm)</th>
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MitroFix™ Sizer Kit

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REFERENCES

1. Average EOA from 2.8 to 3.3 cm² observed in various clinical experience with the MitroFix device compares favorably to 2.0 cm² range seen frequently with mechanical mitral valves.

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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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.

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