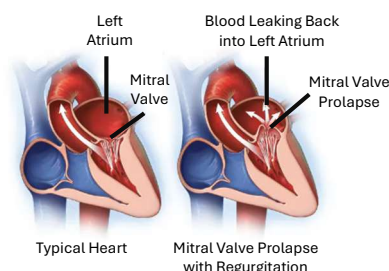


Cath Concept XION

What is Mitral Regurgitation (MR)?

A condition where the **mitral valve**, located between the left atrium and left ventricle of the heart, **does not close properly**, allowing blood to flow backward into the left atrium.



Market Validation & Market Size

MR is considered the most common valvular heart disease:

- **6,000,000 Patients**
 - 1.7% of the US population has moderate or severe mitral regurgitation. This percentage increases with age, reaching 9.3% for people over 75.¹
 - **120,000 Treated Annually**
 - Only about 2% of US patients with MR receive surgery.¹
- **\$1.87 billion**
 - Global mitral valve disease market size in 2023.²
- **\$16.65 billion**
 - Projected market size by 2032 (CAGR of 27.2%).²

Our Solution

	Market Leaders	Cath Concept Xion
Outer Sheath Size	22F (0.290")	18F (0.240")
Procedure	• Percutaneous transseptal puncture • Insert Guidewire • Insert Dilator w/ Guide Sheath (22F) • Remove Dilator • Insert & position Delivery Catheter (18F) w/ Clip implant • Position and deploy Clip implant via Actuation Catheter (11F)	• Percutaneous transseptal puncture • Insert, position, and deploy
Clip Removal	Separate Systems and/or Methods	Same Xion system
Max Clip Grip Surface Area	2 leaflets X 12mm X 6mm	2 leaflets X 14mm x 7mm
Max Clip Size	18mm X 6mm X 6mm	16mm X 4mm (Ø)
Components	Guide Catheter (22F) • 1X & 2X Liners • 16X Round Braid Wires & 1X Coil • 1X Pull Ring Assembly • 7X Durometer Segments • 1 X Marker Band • 1X Hydrophilic Coat Delivery Catheter (18F) • 1X & 1X Liners • 8X Flat Braid Wires • 1X Pull Ring Assembly • 1X Compressed Coil • 2X Hypotube • 6X Durometer Segments Actuation Catheter (11F) • 1X & 4X Liners • 48X & 16X Round Braid Wires • 1 Hypotube • 5X Durometer Segments Stabilizer System • Multiple support mechanisms	Delivery Catheter (18F) • 1X & 1X Liners • 16X Round Braid Wires & 1X Coil • 1X Pull Ring Assembly • 5X Durometer Segments • 1 X Marker Band • Hydrophilic Coat Central Core Shaft (10F) • 5X Liners • 16X Round Braid Wires • 1 Hypotube • 5X Durometer Segments
	Clip: 20+ Components	Clip: 10 Components
	Handles: 3X Separate Systems	Handle: 1X System
Manufacturing Cost	X	1/4 th X

1. https://www.cms.gov/medicare/coverage/determinationprocess/downloads/stewart_comment_07302020.pdf

2. <https://www.businessresearchinsights.com/market-reports/transcatheter-mitral-valve-repair-and-replacement-tmvr-market-108286>

Cath Concept XION

		Complete	Target
Phase 1: Project Planning	Project Plan	X	
	User Requirements Specification	X	
	Risk Management Plan	X	
Phase 2: Design Input	Prototype Designs	X	
	Product Specification	X	
	Map Manufacturing Procedures	X	
	Clinical Use FMEA	X	
	Patent Assessment	X	
	Competitive Benchmarking & Analysis	X	
	Equipment Capital Requirements & Technology Assessment	X	
	Design Freeze	X	
Phase 3: Design Process	Design Verification Protocol, Test Method, & Report	X	
	Design FMEA	X	
	Specifications (Components)	X	
	Inspection Procedures	X	
	Process/Specification Flow Chart	X	
	Manufacturing Procedures	X	
	IQ & OQ Equipment, Fixtures, & Tooling	X	
	Equipment Maintenance Procedures	X	
	Device Master Record	X	
	Tolerance Analysis	X	
Phase 4: Design Output	Design Validation Plan	X	
	Biocompatibility Protocol & Report		Q2, 2025
	Shelf Life Protocol & Report		Q4, 2025
	Sterilization Validation Protocol & Report		Q3, 2025
	Specifications (Package, Label, IFU)		Q4, 2025
	Package Validation Protocol & Report		Q4, 2025
	Animal Study Protocol & Report		TBD ³
	Clinicals Protocol & Report		TBD ³
Phase 5: Design Transfer / Commercial Release	Process Validation Plan		TBD ³
	Process FMEA		TBD ³
	Process Capability Assessment		TBD ³
	Sterilization Strategy		TBD ³
	Regulatory Clearance to Market		TBD ³
	Device Registration and Listing		TBD ³
	Design Transfer		TBD ³

3. Target completion date will depend on Seed & Series A funding.