

# The ENCIRCLE Trial

NCT04153292

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<b>Status</b>	RECRUITING
<b>Phase</b>	Not Applicable
<b>Sponsor</b>	Edwards Lifesciences
<b>Enrollment</b>	900 participants

## Key Eligibility Criteria

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### Inclusion (6)

- years of age or older
- MR e 3+
- NYHA functional class e II
- Per the Heart Team, commercially available surgical or transcatheter treatment options are deemed unsuitable due to clinical, anatomic or technical considerations.
- Subject's heart failure management has been optimized based on subject characteristics and applicable guidelines, and stable for at least 30 days prior to enrollment.

... and 1 more (see full listing online)

### Exclusion (28)

- Mitral/cardiac anatomy that would preclude appropriate delivery and deployment of the SAPIEN M3 dock or valve
- Inappropriate anatomy for femoral introduction and delivery of the SAPIEN M3 dock and valve
- Presence of any device that will contact or interfere with the SAPIEN M3 System during delivery or after implantation
- Left ventricular ejection fraction  $\lt 25\%$
- Severe right ventricular dysfunction

... and 23 more (see full listing online)

## Locations (68 total)

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Heart Center Hospital, Huntsville, Alabama, United States  
Banner University Medical Center, Phoenix, Arizona, United States  
Saint Josephs Hospital Medical Center Dignity Health, Phoenix, Arizona, United States  
... and 65 more locations