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## Project Canary

Teaser

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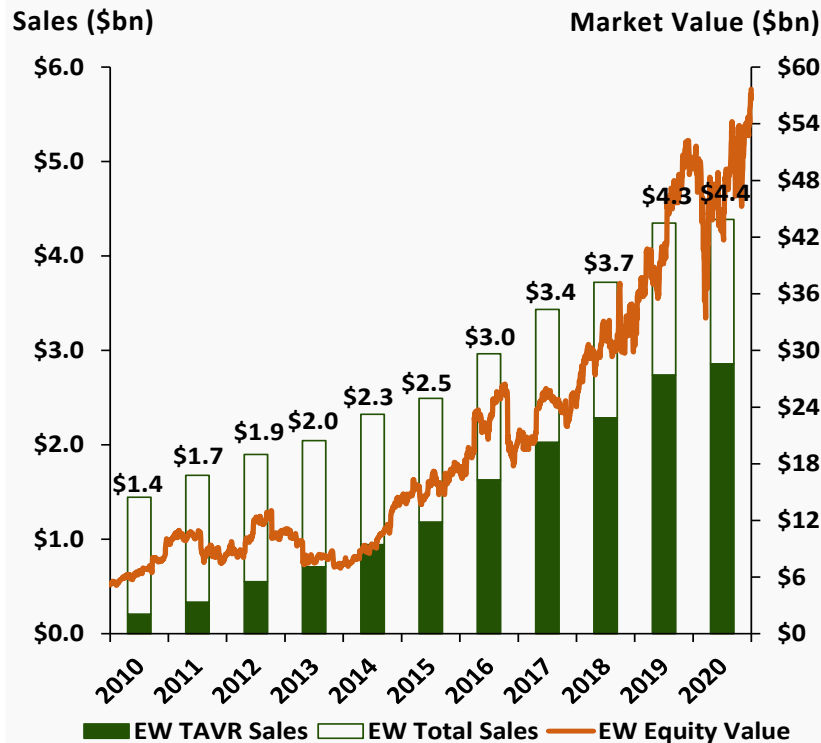
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# Canary is Positioned to be the Leader in Transcatheter Tricuspid Valve Repair – The Next Cardiology Mega Market

Canary's patented technology positions it for leadership in Tricuspid Valve Repair, mirroring the trail blazed by Edwards Lifesciences (EW) in Transcatheter Aortic Valve Replacement (TAVR)

## EW Led the Last Big Revolution in Cardio Devices with TAVR...

- EW has driven TAVR sales growth at a 30% CAGR over the last 10 years and has created \$53bn of market value



## ...Setting the Stage for the Next Big Revolution with Transcatheter Tricuspid and Mitral Valve Treatments

- Prevalence of Tricuspid Regurgitation (TR) is ~2x greater than aortic stenosis (treated by TAVR)
- Current standard of care for moderate to severe TR is invasive, and often risky, open-heart surgery
  - Competitors have failed to develop minimally invasive, transcatheter-based devices that emulate the “gold-standard” of a surgical annuloplasty ring
- Canary has the proven, patented technology to treat TR
  - Built on the foundation of the surgical gold standard for TR Therapy
  - Early results of ongoing first-in-human<sup>(1)</sup> indicate a robust safety profile, TR and annular reduction, and positive right heart remodeling maintained post-adjustment
  - Canary's complete ring solution allows for treatment of TR – dramatically expanding the already sizable tricuspid and mitral valve market
- Canary is initially targeting and has designed its device specifically for treatment of the Tricuspid valve – an underpenetrated segment
  - Leadership in TR will enable quick expansion with a trans-femoral device into the MR market, providing structural heart specialists with a similar platform across both valves

**Canary presents an opportunity to invest in a world-class, industry-changing technology for the treatment of TR, emulating the success of TAVR for the treatment of aortic stenosis**

# An Innovative Solution to a Significant Unmet Medical Need...

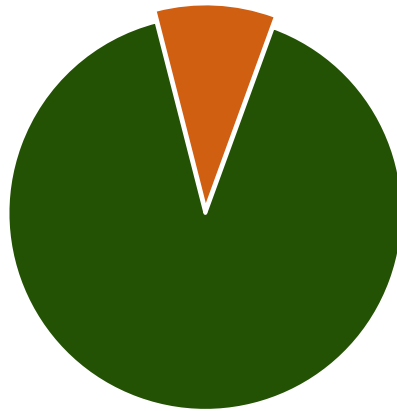
Tricuspid and Mitral Regurgitation affects more patients and is treated less often compared to Aortic Stenosis

Aortic Stenosis

Mitral Regurgitation

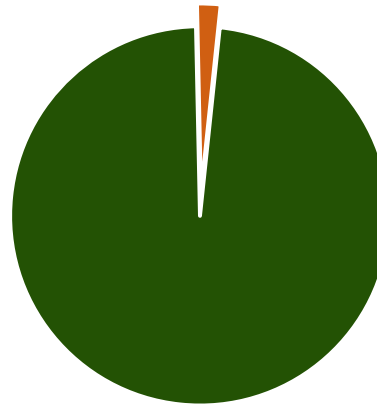
Tricuspid Regurgitation

<10% Treated



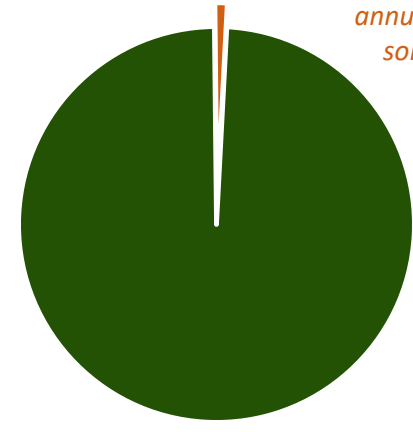
1.2MM Patients in US<sup>(1)</sup>

~2% Treated



4.1MM Patients in US<sup>(2)</sup>

<1% Treated



4.2MM Patients in US<sup>(3)</sup>

*Canary is initially targeting treatment of TR, with a gold standard annuloplasty solution*

***Tricuspid and Mitral patients are in significant need of better treatment options***

(1) Edwards Lifesciences and Stuge et al. Journal of Thoracic Cardiovascular Surgery 2006;132:1258-61.

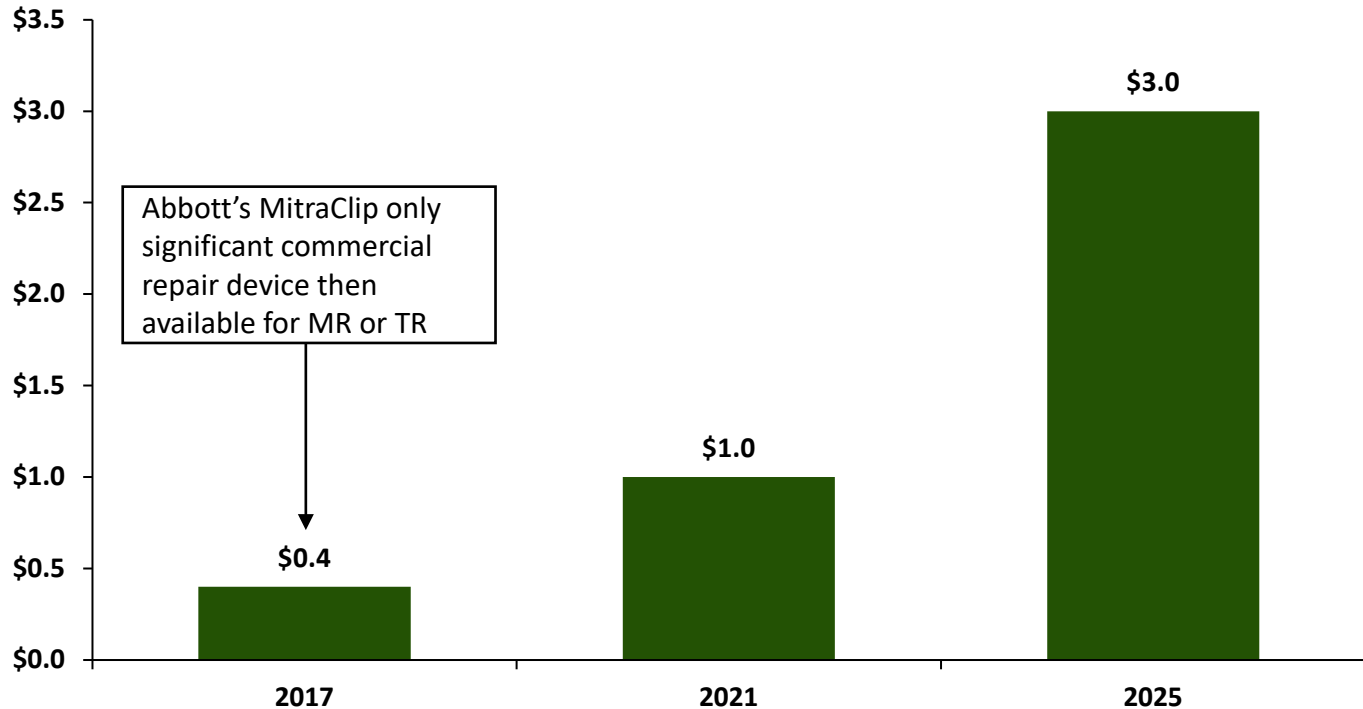
(2) Calculated by taking the median of the implied percentage prevalence of TR and MR from studies by Singh, Topilsky, Suradi, Neovasc, Heartware, Nkomo, and Singh applied to the 2020 Demographic Analysis Estimates by Age and Sex. In: U.S. Census Bureau, 2020.

(3) Source: Canary.

## ...Creating a Substantial Global Opportunity

Worldwide Transcatheter TR & MR Market Size<sup>(1)</sup> (\$ billions)

*With Canary technology, these market opportunities could grow significantly over and above current estimates below*



*Canary is the developer of a percutaneous annuloplasty system with technical applications for tricuspid and mitral regurgitation, a potential \$3.0bn global market by 2025, approaching the size of today's \$3.4bn TAVR market*

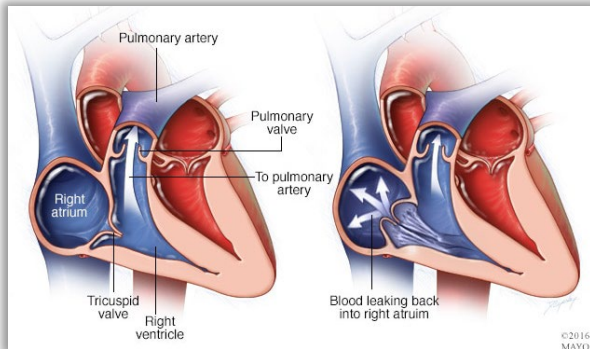
# Tricuspid and Mitral Valve Diseases

Cardiovascular diseases are the leading cause of death globally, claiming ~18 million lives per year<sup>(1)</sup>

## What are Tricuspid Regurgitation and Mitral Regurgitation?

- TR and MR are disorders in which the tricuspid or mitral valves do not close completely, causing some blood to reverse-flow back into the pumping heart chamber
- If severe regurgitation is left untreated, a patient's mortality rate after one year increases to more than 25%<sup>(2)</sup> for tricuspid regurgitation and 20%<sup>(3)</sup> for mitral regurgitation
- 70% of patients diagnosed and only medically managed (i.e. no surgery or interventions) with severe TR die within 5 years<sup>(4)</sup>

Healthy Tricuspid Valve      Tricuspid Valve with Regurgitation into Atrium



## What Treatments are Currently Available?

- Open-heart surgery
  - Annuloplasty ring is the preferred surgical therapy and gold standard for moderate-to-severe TR patients
  - Patients that are too sick or too old to withstand open-heart surgery are left untreated
- Abbot's MitraClip & TriClip
  - May become new standard of care...
  - ... But not a full ring solution
- Valve technologies are being actively developed but hold limited promise for addressing the largest share of the tricuspid market
- Both valve replacement and leaflet plication limit the use for future therapies in cases of MR or TR recurrence



**Novel, transcatheter-based treatments are emerging as one of the most important MedTech growth markets. Competing efforts are inadequate and predicated on technology for the mitral valve.**

(1) World Health Organization. 2017 figure – Cardiovascular diseases account for 31% of global deaths.  
(2) TRI-REPAIR: 30-Day Outcomes of Transcatheter TV Repair in Patients With Severe Secondary Tricuspid Regurgitation; Georg Nickenig, University of Bonn Germany, Oct 24, 2017.  
(3) Prevalence and Outcomes of Unoperated Patients With Severe Symptomatic Mitral Regurgitation and Heart Failure: Comprehensive Analysis to Determine the Potential Role of MitraClip for This Unmet Need; Sachin S. Goel, Samir R. Kapadia, et al.; Sep 11, 2013.  
(4) Chorin E, Rozenbaum Z, Topilsky Y, et al. Tricuspid regurgitation and long-term clinical outcomes. European Heart Journal - Cardiovascular Imaging 2019; 21(2): 157-65.

# Canary's Percutaneous Annuloplasty System will be the First Full Ring Solution for Treating TR without Open-Heart Surgery

By harnessing the body's natural healing process, Canary has the first and thus far only solution designed to overcome the challenges of dehiscence

The Canary System functions by implanting and later tightening an annuloplasty ring to restore proper functioning of the tricuspid valve, leveraging the body's natural healing process

- The Ring Delivery System (RDS) delivers a small and flexible ring implant to the heart via the jugular vein – far less invasive and strenuous than traditional surgical procedures
- The RDS is positioned around the annulus of the valve and calibrated using fluoroscopy and echocardiography to assure optimal fit
- Following the attachment to the annulus, a cord tethered to the original implant site is left in place
- After a 90-day healing period, the Adjustment Tool (AT) delivers a proprietary locking clip that adjusts the ring to achieve the desired physiologic reduction of the annulus
- Patented healing process will prove to be an effective, safe, and durable solution to the challenges of treating TR and MR

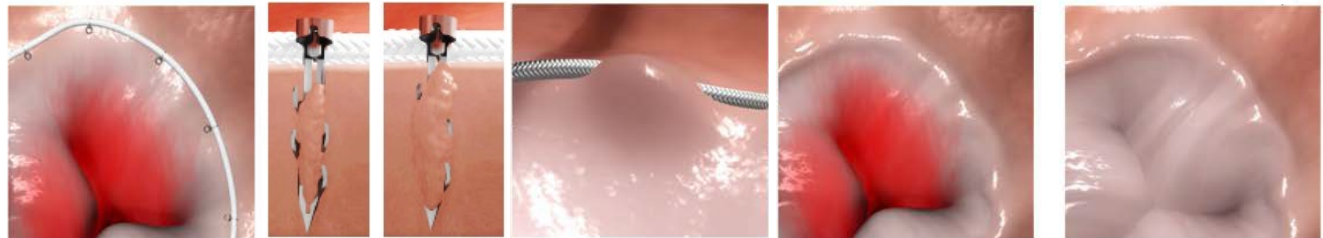
Ring  
Implantation

Anchor  
Attachment

Anchor  
Encapsulation

Ring  
Encapsulation

Ring  
Adjustment



***Canary's percutaneous annuloplasty is designed to be less invasive than open-heart surgery, offer a shortened hospital stay and recovery, and provide equally effective therapy compared to the gold standard for TR treatment (surgery)***

# Advantages of Canary's Percutaneous Annuloplasty System

Canary's unique approach to anchoring an annuloplasty ring to the valve annulus will achieve the three essential requirements for a successful transcatheter valve repair device

## 1 Safety

- Low-profile anchors
- Reduce risk of damage to structures of heart
- Healing secures the ring implant



Canary's Percutaneous Annuloplasty Ring

## 2 Ease-of-Use

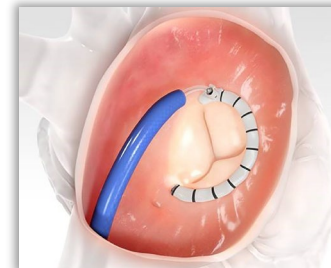
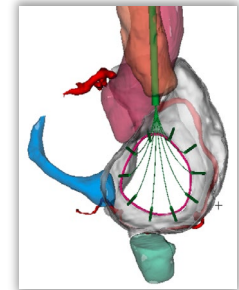
- Patented Ring Delivery System and Adjustment Tool designed to provide a familiar and easy-to-use experience
- Single shot delivery
- Short procedure time

## 3 Predictable and Durable Results

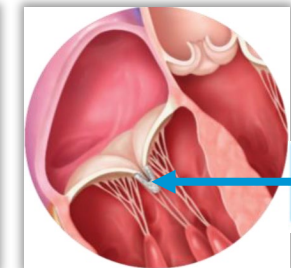
- Circumferential ring can be fully adjusted to provide optimal therapy
- Fixed internal cord designed to prevent further dilation for durable repair

## Proprietary Cloud Based Clinical Software

- Canary has taken procedure development one step further with its custom-built planning and analysis software reflecting Canary's deep roots in the 3D/4D anatomical analysis upon which its single shot delivery system is built
- Supports the operator with unique dynamic views of the patient's heart to optimize the implant process



Edwards CardioBand


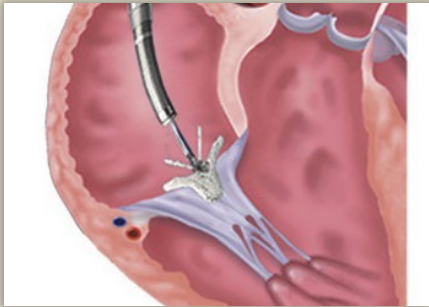
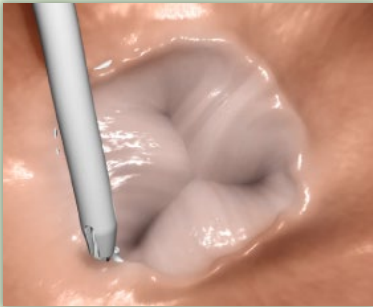


Abbott TriClip

**Competitive approaches do not provide a full-ring solution (gold standard for surgical therapy)**

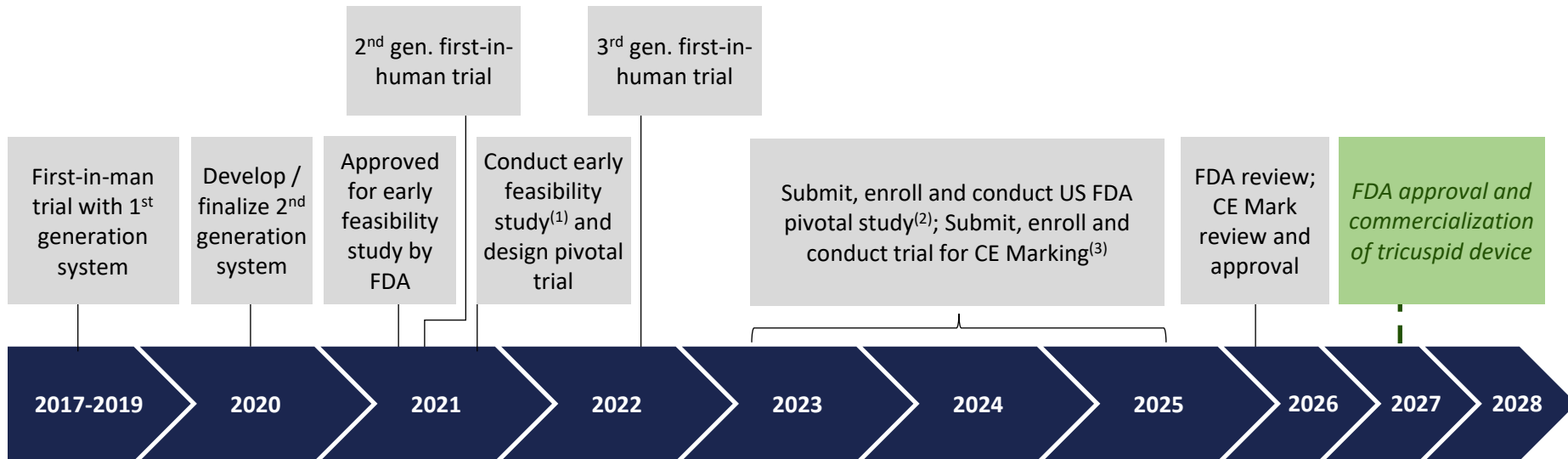


# Canary's Percutaneous Annuloplasty System Positioned to Become Gold Standard Treatment Option

Open-Heart Ring Annuloplasty	Leaflet Plication	Percutaneous Annuloplasty System
<ul style="list-style-type: none"> <li>+ Gold standard therapy for TR</li> <li>+ Mechanically optimal, complete annuloplasty ring</li> <li>+ Widely adopted solution with physician familiarity</li>   <li>- Highly invasive procedure – involves cutting through the breastbone</li> <li>- Substantial operative risk in sick and elderly patients</li> <li>- Many patients left untreated</li> </ul>	<ul style="list-style-type: none"> <li>+ Incumbent mitral transcatheter device</li> <li>+ Recently expanded FDA label for secondary MR</li> <li>+ Minimally invasive</li> <li>Safe and easy to use</li> <li>+ TriClip pivotal study for FTR underway (TRILUMINATE)</li>   <li>- Incomplete solution – alters leaflets rather than repairing the valve</li> <li>- Challenging to image leaflets, may limit general adoption</li> <li>- Prevents future transcatheter intervention</li> </ul>	<ul style="list-style-type: none"> <li>+ Applicable for both TR and MR</li> <li>+ Mechanically optimal, complete annuloplasty ring</li> <li>+ Minimally invasive</li> <li>+ Safe and easy-to-use as demonstrated by interim findings from first-in-human</li> <li>+ Adjustment process designed to make the implementation patient-specific</li> <li>+ Harnesses body's healing process</li> <li>+ Transcatheter equivalent of surgical annuloplasty ring (the gold standard)</li> </ul>
		

Moving towards less invasive but proven therapies

# Canary's Path to Commercialization



Source: Canary.

(1) An early feasibility study (EFS) is a limited clinical investigation of a device early in development. It typically: enrolls a small number of subjects; is used to evaluate the device design concept with respect to initial clinical safety and device functionality; and may guide device modifications.

(2) US FDA = United States Food and Drug Administration.

(3) CE marking is the regulatory approval to commercially market a medical product within the European Economic Area (EEA).

# Unique Opportunity for Leadership in TR and MR Markets

## Significant Unmet Clinical Need

- 1-2% of TR and MR patients are currently treated<sup>(1),(2)</sup>
- Need is likely even greater than initially thought as studies show value of early intervention and prevention of TR before it reaches moderate to severe levels<sup>(3)</sup>
- Many patients cannot undergo current standard of care (open-heart surgery) due to risks imposed

## Large Addressable Market

- 4.2MM potential patients for the treatment of TR in the US alone. In addition, a further 4.1MM suffer from MR
- Global revenue from current transcatheter devices for treatment of TR and MR expected to increase from \$0.4bn in 2017 to \$3bn in 2025<sup>(1)</sup>
  - With Canary's percutaneous annuloplasty system, these markets should increase substantially

## Canary's Novel Solution Superior to Alternatives

- Significantly less invasive and safer than open-heart surgery
- Complete, full ring solution using same functional mechanism as surgical annuloplasty for valve repair
- Harnesses the body's natural healing process, mitigating common problems with alternative transcatheter-based technologies
- With a broad portfolio of issued patents, Canary has exclusive rights to the key features enabling its breakthrough solution for transcatheter valve annuloplasty, and a strong foundation for a portfolio of transcatheter atrioventricular valve repair and replacement products

## De-risked Technology

- Ongoing first-in-human trial for treatment of TR across 6 sites in the EU
- Six cases conducted to date with 1<sup>st</sup> generation delivery system
- New cases to use 2<sup>nd</sup> generation delivery system with broadened sizing matrix
- Early feasibility study approved by FDA in March 2021