



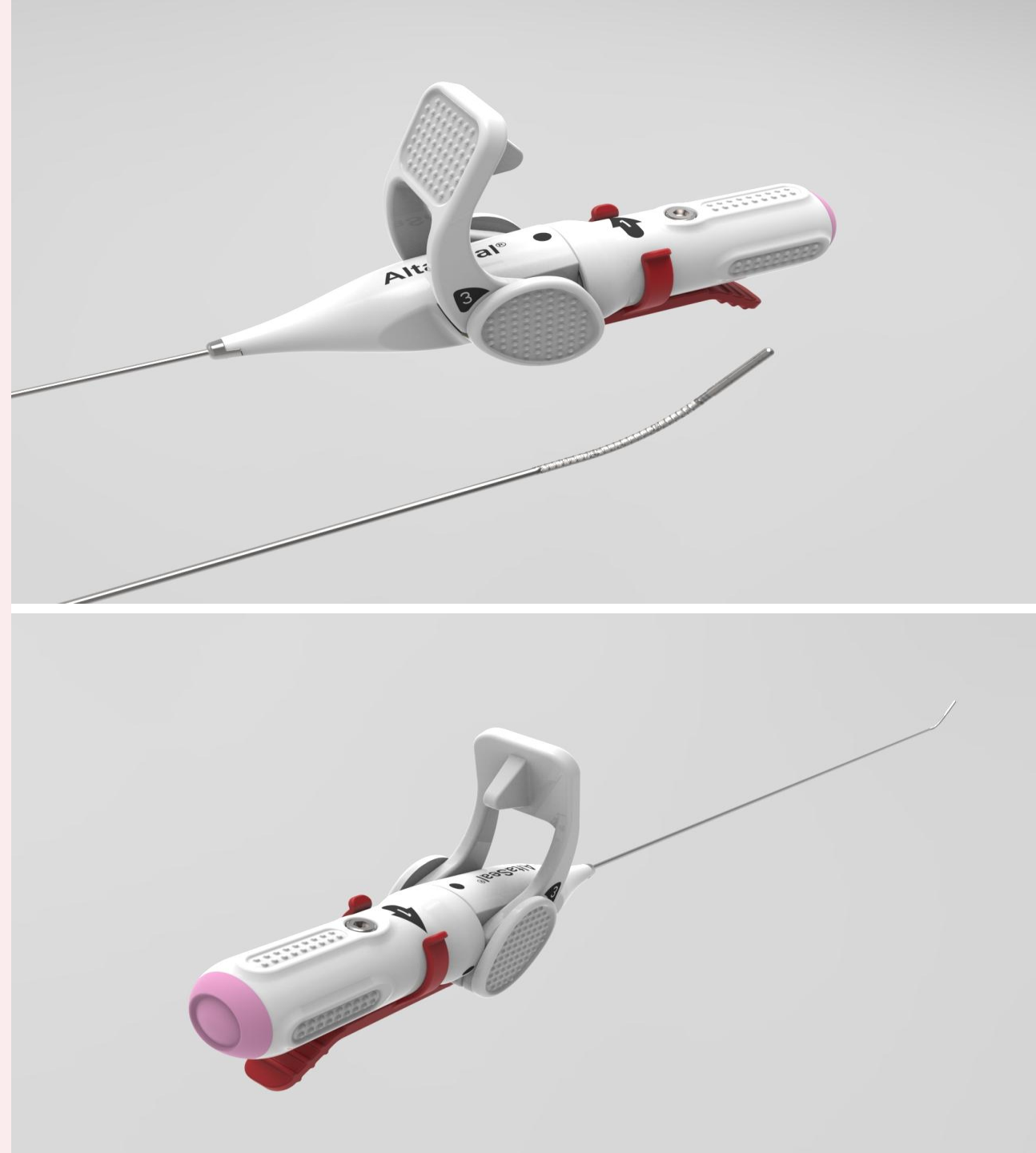
# Redefining Permanent Contraception

**AltaSeal<sup>®</sup>**  
**Office-based Fallopian Tube Occlusion Device**

**Gavin Cooper – CEO**  
[gavin.cooper@altascience.ie](mailto:gavin.cooper@altascience.ie)

**AltaScience Inc.**  
**Incorporated in State of Delaware US in April 2023**

2025



# The Team

## Medical Advisory Board of Key Opinion Leaders in the US and EU.



**Prof. Barbara Levy**

**Clinical Professor of Obstetrics and Gynecology, GW Uni School of Medicine and Health Sciences, UCSD Health, California, USA**



**Prof. Linda Bradley**

**Professor Obstetrics, Gynecology and Reproductive Biology, Cleveland Clinic, Cleveland, Ohio, USA**



**Dr Kelly Wright**

**Director of Minimally Invasive Gynecologic Surgery, Cedars-Sinai Medical Center, Los Angeles, California, USA**



**Dr. Andreas Thurkow**

**Consultant Gynecologist in minimally invasive surgery, Amsterdam Medical Centre, The Netherlands**



**Dr Edward Evantash**

**Principal Consultant for Clinical Affairs, Cambridge Medical Affairs, Cambridge, MA, USA**

## Experienced AltaScience Management Team



**Gavin Cooper**

**Chief Executive Officer**



**Conor Dalton**

**Chief Financial Officer**



**Dr. James Coleman**

**Founder, Medical Director**



**Stephen O'Sullivan**

**Operations Director**



**Triona McNicholl**

**Quality & Reg. Affairs**

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# AltaScience Investment Highlights

1

Category leading medical device

**30**-minute Day Case,  
No Hormones, No  
Anesthesia

2

Large, growing, and  
reimbursed Market

**\$2.4** Billion Market  
1.5m procedures with  
CPT codes in place

3

Clear path to  
market approvals



SAB of World-  
Renowned KOLS

4

Strong safety and  
efficacy record.  
IP protected platform

Proven Device Platform  
**7** years of Clinical Data

5

Proven robust  
manufacturing  
process

High gross margins  
(**> 80%**)

AltaScience's mission is to be category leader in permanent contraception market

# US Market Size p.a.

Worldwide 219 Million Women rely on Female Sterilization.  
(24% of all Contraception Users).

## Our Vision

### #1

Creating category leading device

## The Problem

### 1.5 Million

Projected cases annually

- 1000k sterilizations
- 500k Endometrial ablations

### 45%

of **6M** annual pregnancies in US are unintended

## Our Solution

### 90 Patients

Proven Technology

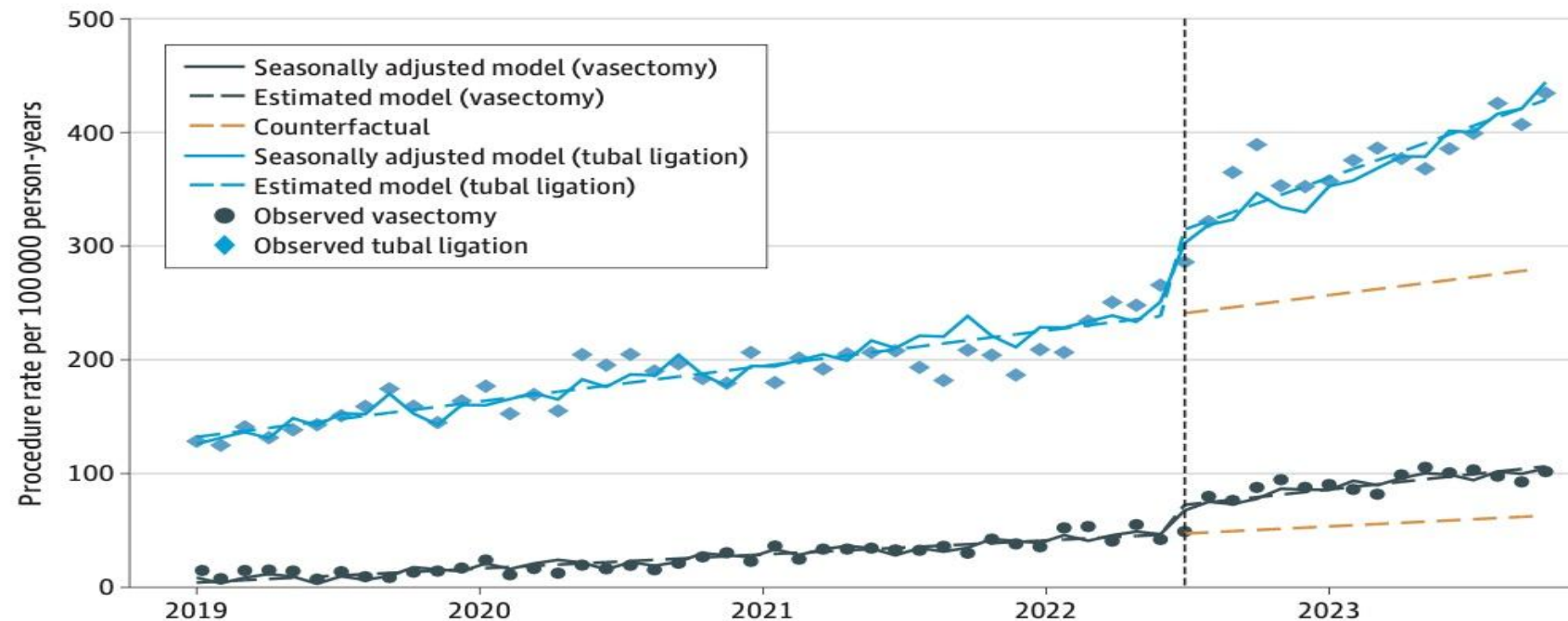
- Across 3 studies
- out to **7** years
- No pregnancies

**\$2.4 Billion Total Addressable Market (TAM) (1.5M cases x \$1600)**



# Patient request for permanent contraception has increased since Roe V Wade US Court Judgement Reversal

**Figure. Monthly Time Series of Tubal Ligation and Vasectomy Procedure Rates Among Adults Aged 18 to 30 Years**



Published: April 12, 2024. doi:[10.1001/jamahealthforum.2024.0424](https://doi.org/10.1001/jamahealthforum.2024.0424)

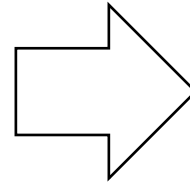
# How we deliver leadership in Permanent Contraception

## Today

Tubal Ligation



- **Cauterized, Tied, Cut and Banded**
- **Operating Room Procedure**
- Large Associated Cost
- Scars, Anesthesia, Infections
- Not suitable for high BMI
- Failure rate: 1.3 -6%
- 2–3-day recovery
- 90-Year-Old Procedure



## Tomorrow

AltaSeal device and implant



- ✓ **No Surgical Incision**
- ✓ **Office Procedure in 30 minutes**
- ✓ Cost Effective
- ✓ No Anesthesia, No Hormones, No Scars
- ✓ Suitable for high BMI
- ✓ No Pregnancies
- ✓ Quick recovery - hours
- ✓ Proven platform & modern technique

# Benefits of AltaSeal® Over Alternative Birth Control Options

	Altaseal	Tubal Sterilization Surgery	Hormonal Implant	IUD (Copper/ Hormonal )	Essure ( Off Market )
Permanent	✓	✓	✗	✗	✓
Office – based Procedure	✓	✗	✓	✓	✓
No Anesthesia	✓	✗	✓	✓	✓
No Hormones	✓	✓	✗	✓ ✗	✓
IVF Still Possible	✓	✓	✓	✓	✓
Patient-device compatibility / biocompatibility	✓	✓	✓	✓	✗ Leading to Market Recall
Failure Rate	0% - to date (See Clinical Results)	1-3* - 6% ** (after 3- 5 Years)	8%	1-3%	1%† - 5%** (after 3- 5 Years)

\* Ref: Peterson, et al; The risk of pregnancy after tubal sterilization: Findings from the U.S. Collaborative Review of Sterilization; AM J OBSTET GYNECOL 1996;174:1161-70

\*\* Ref: Garipey, et al; Fertility and Sterility® Vol. 117, No. 6, June 2022.

† Result from Essure Post Market Surveillance Study PS160001 - [https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm?t\\_id=356&c\\_id=3854](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm?t_id=356&c_id=3854)

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# Emerging Competitor

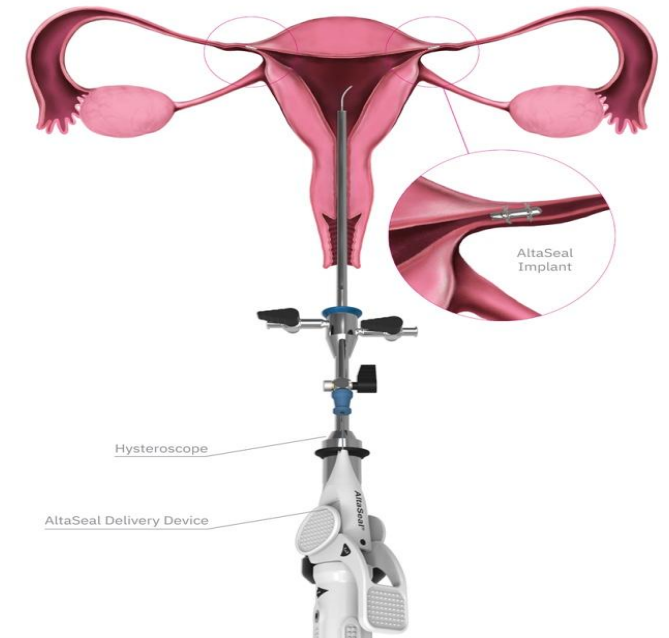
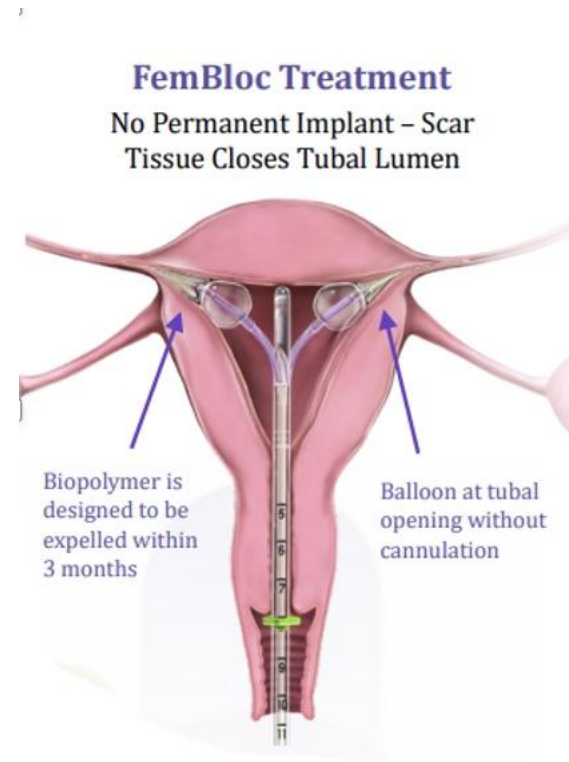
FemBloc is undertaking an FDA IDE process.

FemBloc is in clinical stage hysteroscopic, office-based approach to permanent birth control.

Inflammatory response Vs Mechanical occlusion.

Blind Procedure Vs Direct Vision.

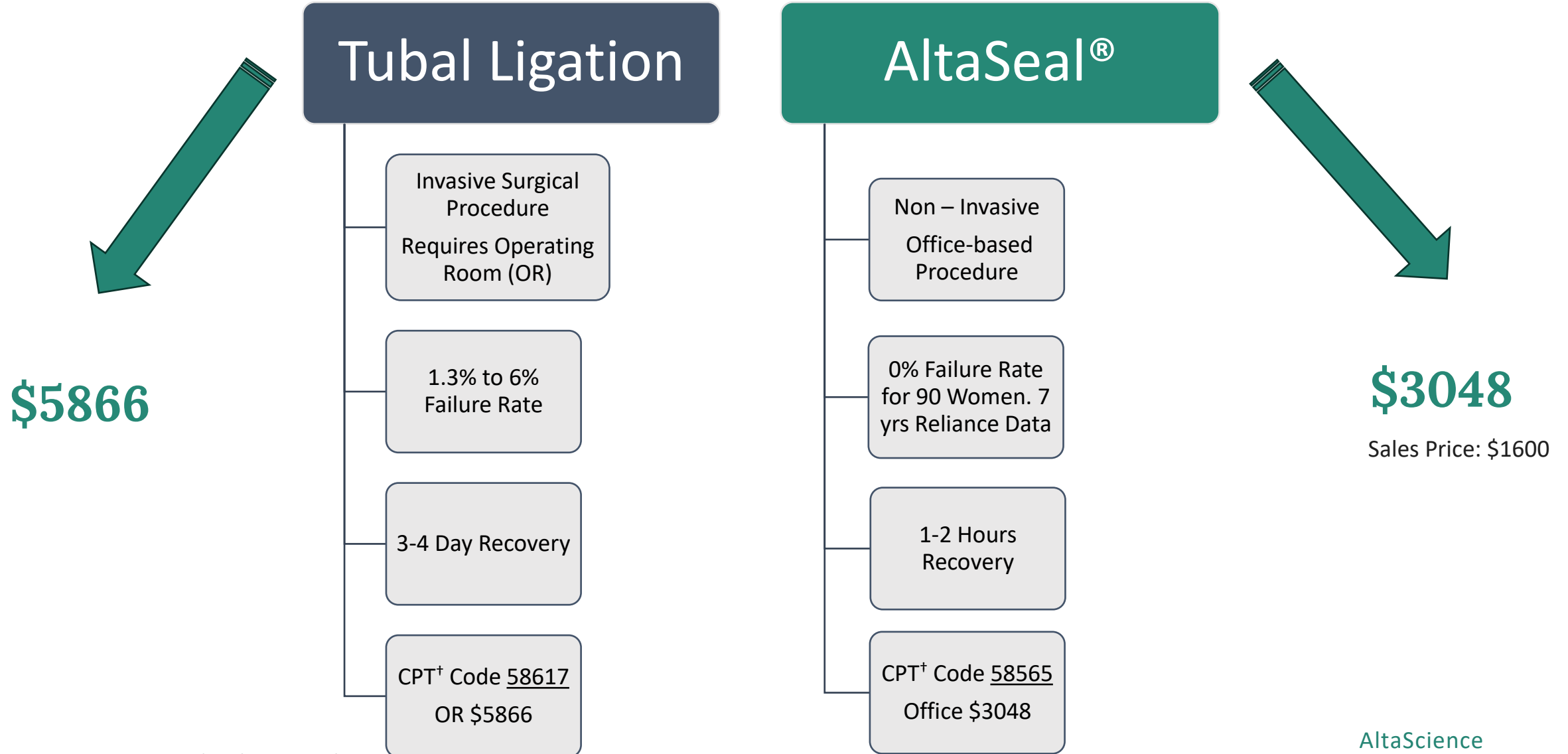
Altaseal has clear advantages and preferred by clinicians in our research.



- Single arm, multi-center study
- 401 Patients to be enrolled
- Ultrasound Confirmation of Occlusion at 3-months
- Study commenced in September 2023



# CPT Reimbursement Code For Hysteroscopic Sterilization Currently Exists

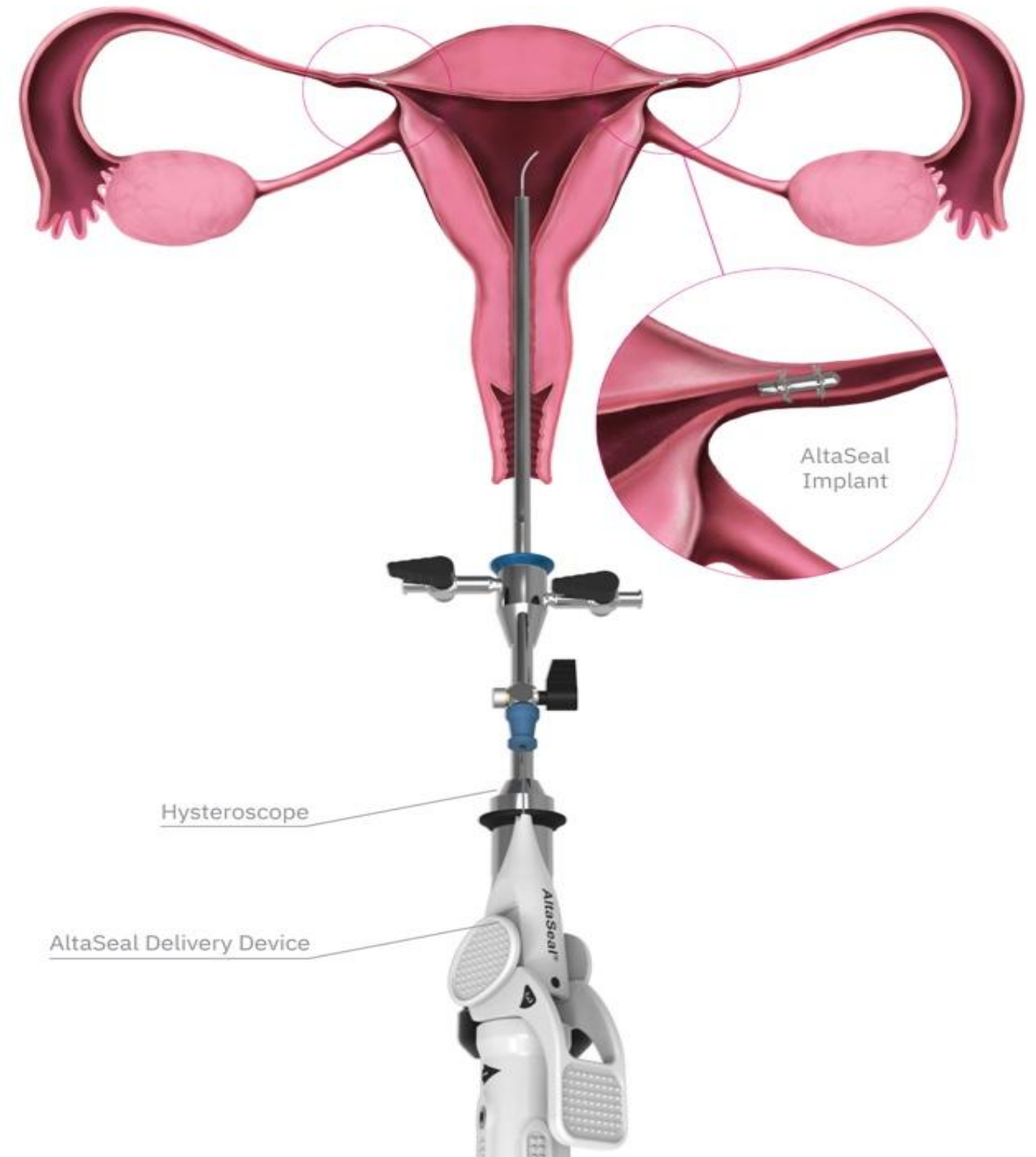


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<sup>†</sup>CPT: Current Procedural Terminology

# The AltaSeal® Implant Results in Permanent, Female Contraception, via Hysteroscopic Delivery

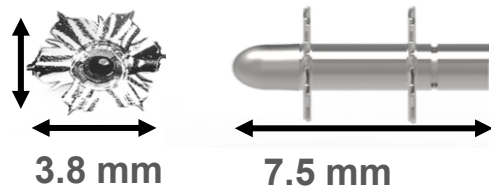
- Ambulatory office-based 30-minute procedure – oral analgesia
- Permanent implant: metallic biomaterial
- Atraumatic & easy-to-use
- Placed in the fallopian tubes by a gynecologist using a hysteroscope.
- The implant mechanically blocks the fallopian tube thus preventing pregnancy.
- Currently no Hysteroscopic Permanent Contraception Device on the Market.



# AltaSeal® Fallopian Tube Occlusion Implant

AltaSeal® Delivery System

- ✓ Pre-mounted implant
- ✓ **Easy to use device**
- ✓ Effective when deployed
- ✓ **Patent Claims directed to implant and method**



Deployed Implant

Strong Portfolio of granted US, EU, JP and CN patents including;

- Actuator for deployable implant [US Patent # 9,603,600]
- Devices and methods for occluding or promoting fluid flow (continuation) [US Appln #18/144,817 ; US Patent #11,672,517]

Coverage to December 2035.

Further applications pending.

- Wound Closure and Tissue Coupling Systems and Methods [US Appln #18/087,498]
- Wound Closure and Tissue Coupling Systems and Methods [US Appln #18/087,559]
- Wound Closure and Tissue Coupling Systems and Methods [US Appln #18/977,902]

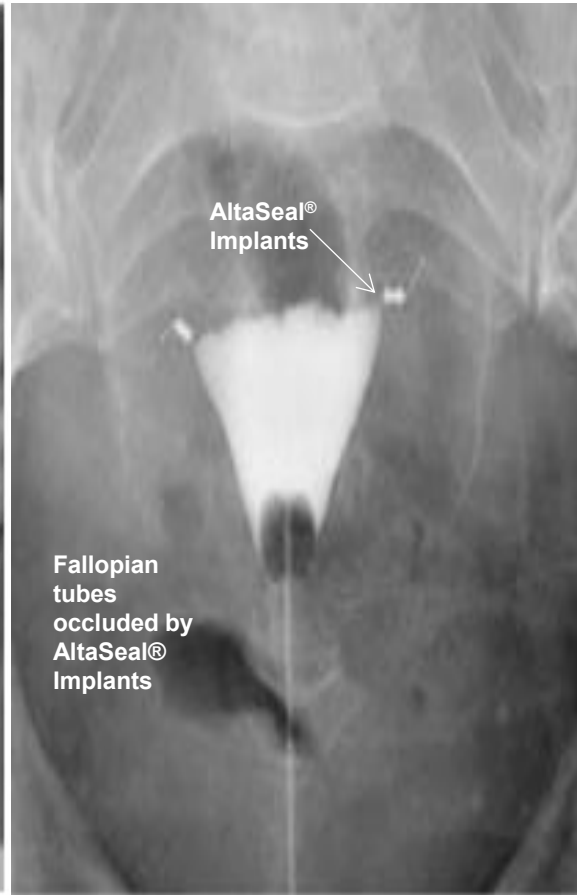
# Video Showing Deployment



# Critical Aspect: Ultrasound Confirmation Check at 3-months



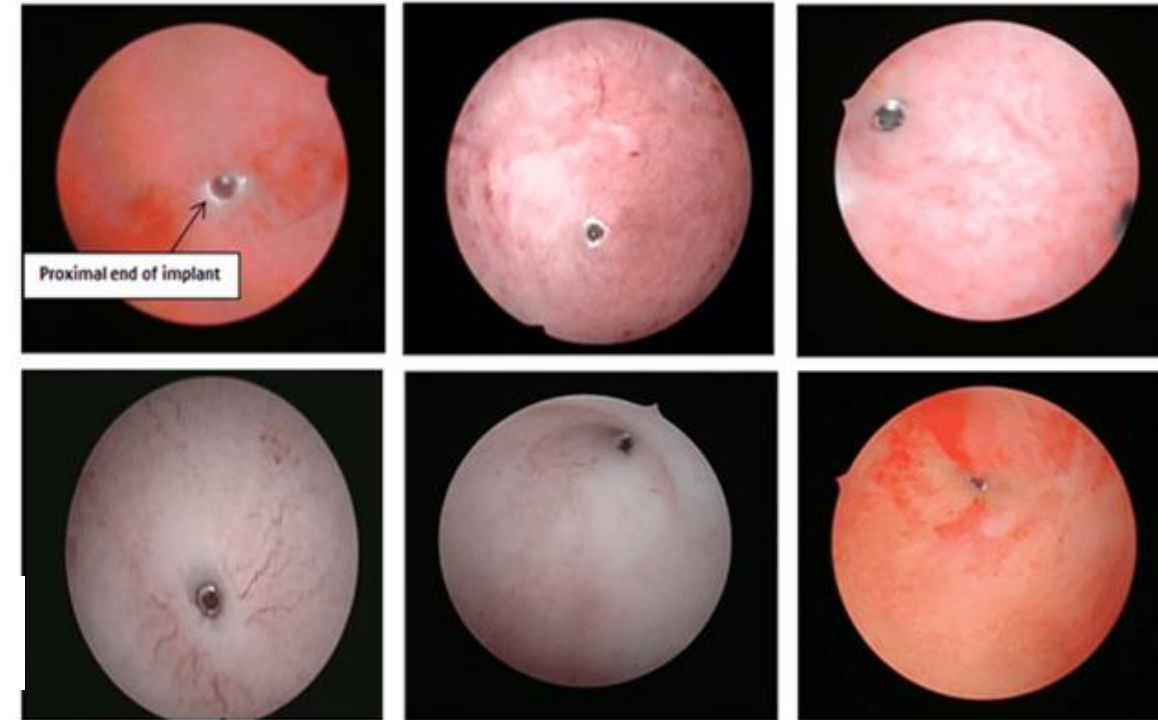
Pre AltaSeal® Procedure



Post AltaSeal® Procedure  
with x-ray HSG

Confirmation test will be performed using Ultrasound HyFoSy { ExEm® Foam } instead of x-ray HSG, in-line with improvements in best standard of care

- <https://pubmed.ncbi.nlm.nih.gov/33368463/>
- <https://www.sciencedirect.com/science/article/pii/S1472648324005698>
- <https://obgyn.onlinelibrary.wiley.com/doi/full/10.1002/uog.17398>



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# Further Clinical Applications of AltaSeal®

## Use with Endometrial Ablation

500k Cases Per Annum in US

minerva  
SURGICAL



Medtronic



@operSurgical

IDOMAN  
TEORANTA

OLYMPUS

HOLOGIC®

## Use with In-Vitro Fertilization (IVF)

50k Cases Per Annum in US

**Up to 30% of women with infertility have hydrosalpinx as a cause.**

### The Solution

- AltaSeal can occlude the fallopian tube(s), stopping the fluid from entering the uterine cavity from the hydrosalpinx and damaging the embryo during IVF (greatly increasing chance of full-term pregnancy).

### Clinical Effectiveness

- 17 women received AltaSeal® prior to IVF.
- 10 healthy babies were born to 8 women.

# Excellent AltaSeal® Clinical Data

- Combination of 3 clinical studies
- 90 women relying on AltaSeal® for up to 7 years\*
  - \* { > 5000 months cumulative }
- 0 pregnancies in patients with proven occlusion and advised to rely.
- Excellent Safety Profile



# AltaSeal® EU-MDR Regulatory Pathway for CE-Mark

## EU-MDR Pathway:

- Single arm, multi-center study
- Ca. 220 Patients to be enrolled – with ca. 180 to 12-Month Pregnancy Endpoint
- Ultrasound Confirmation of Occlusion at 3-months in Pivotal



Pilot (UK)

Class III  
Permanent  
Implant

Multi-Center

Non-Randomized, single arm Trial

180 Patients

Primary End points

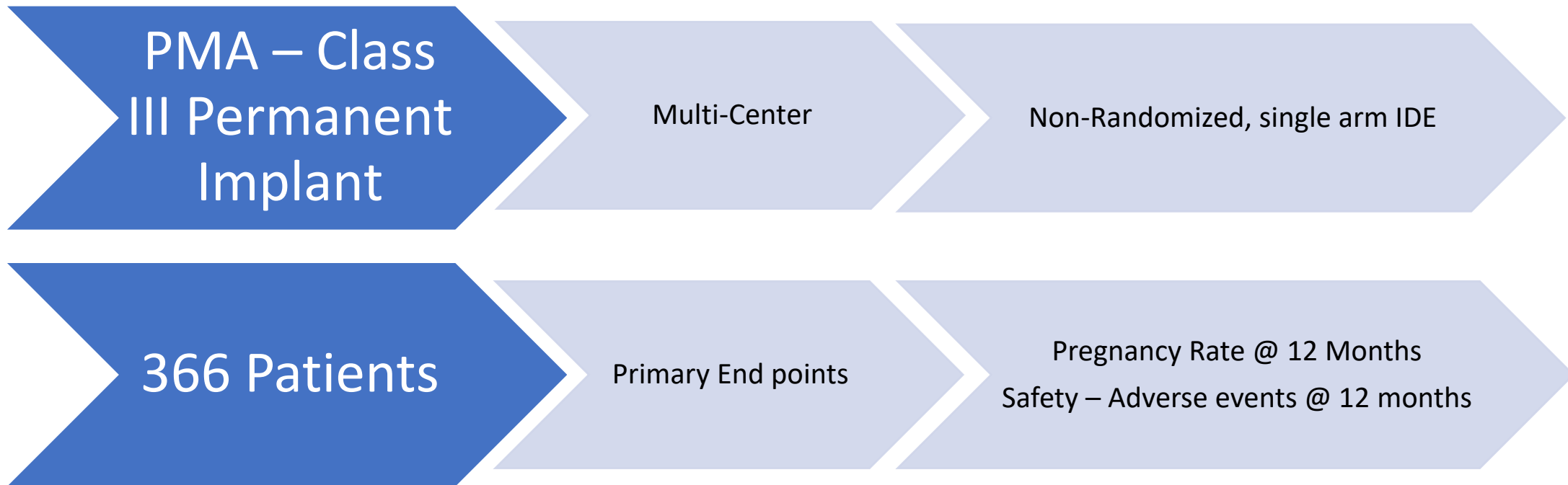
Pregnancy Rate @ 12 Months  
Safety – Adverse events @ 12 months

Same participants for European Clinical supporting CE-Mark as for FDA IDE supporting PMA [AltaScience](#)

# AltaSeal® US PMA Regulatory Pathway

## PMA Regulatory Pathway based on Competitor IDE approval:

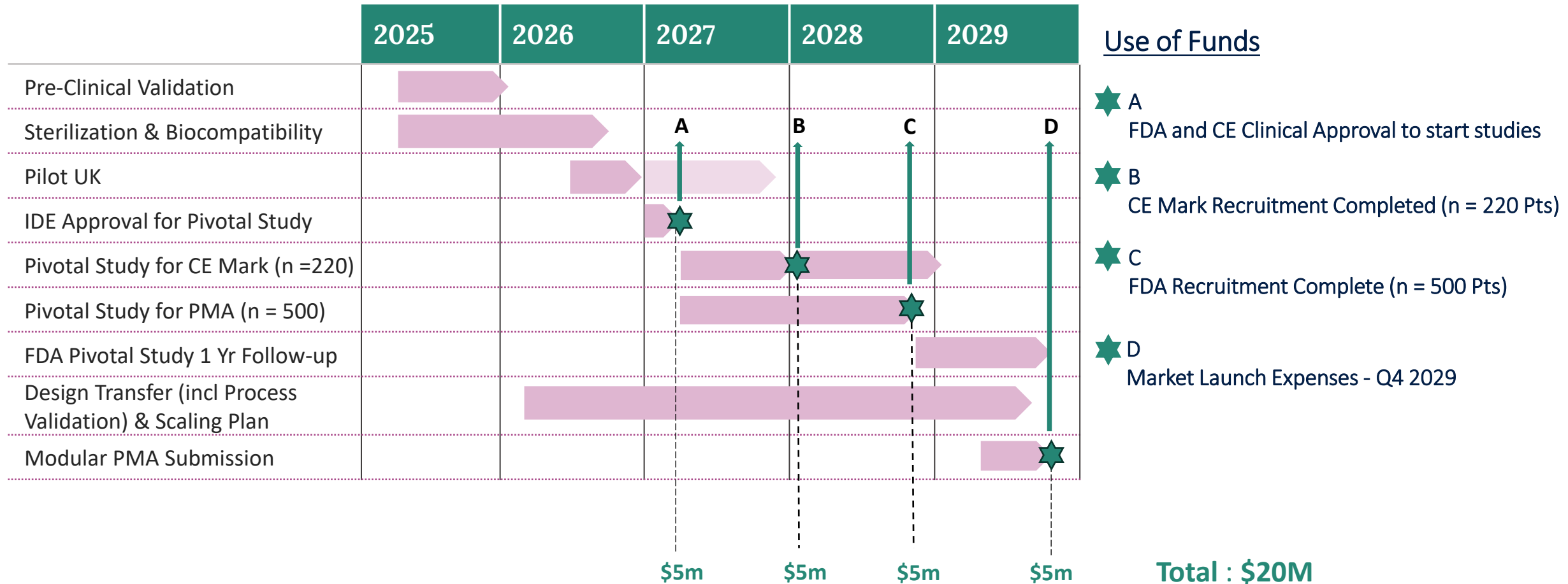
- Initiates after Pilot Study (UK)
- Single arm, multi-center study
- Ca. 500 Patients to be enrolled – with ca. 366 to 12-Month Pregnancy Endpoint
- Ultrasound Confirmation of Occlusion at 3-months



**Same participants for IDE supporting PMA as for European Clinical supporting CE-Mark**

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# AltaScience Funding Strategy and Milestones



\$4m of Convertible Loan Note (CLN) finances development program to achieve FDA IDE And CE-Mark Pivotal Trial Initiation



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Strong safety and  
efficacy record.  
IP protected platform

Proven Device Platform  
**7** years of Clinical Data

5

Proven robust  
manufacturing  
process

High gross margins  
(**> 80%**)

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