



Choice™

every child desired

Choice ONE

Hormone-free
Fertility Freedom
For Life

Investor Pitch Deck
September 2023



Problem *40% of pregnancies are unwanted*

Current contraception is mid 20th century technology

Despite classic contraception 121 million unintended pregnancies (UPs) annually, averaging 331,000 per day,

- **1 in 4** pregnancies is aborted
- **1 in 5** children is unwanted

Current contraception is choosing the lesser evil:

- **The pill** - possible side effects, effectivity in practice lower
- **IUD** - side effects, often not tolerated
- **Condom** - unreliable, cumbersome
- **Sterilization** - irreversible, surgical procedure



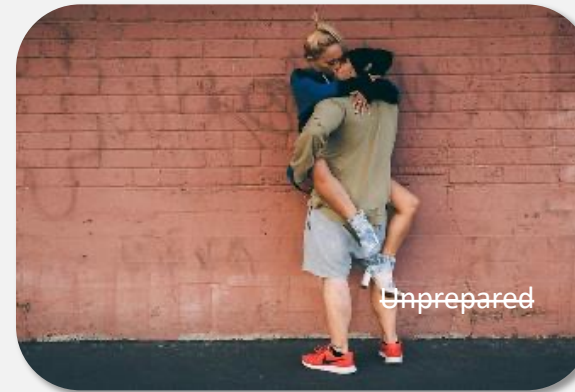
Ideal contraception is:

Hormone-/chemical free



Pill
IUD

Passion Proof



Unprepared

Discipline free



Pill
Condom

Long Acting

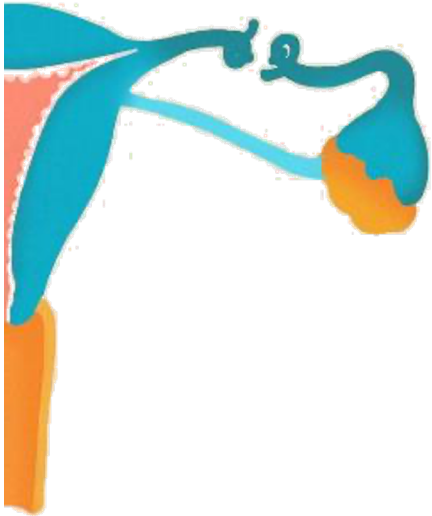


Pill
Condom

So that **every child is desired**



Easy sterilization *and then reversible*



Sterilization is the most frequently used form of contraception worldwide, but it **is a surgical procedure**

First: Choice makes a **superior method of sterilization**:

- Minimally invasive, as **easy** as placing an IUD
- **Lower cost** (from +/-1600 € to 1000 €)
- **Safe**, because we made it **removeable**.

Second: Choice makes the sterilization **reversible**, many times over, so it becomes **contraception**.



Risks during
Surgical
procedure



Potential
regret



Failure of
procedure

Sources: UN, Guttmacher Institute, Gates Foundation, UN Global Health Data
Exchange as of 2019

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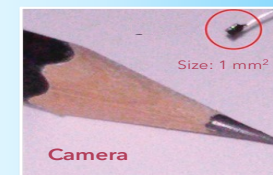
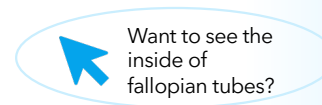
Solution – Choice One *Reversible sterilization*

Choice One consists of three elements:

- Two mechanical **valve** implants placed at the proximal end of the fallopian tubes, **closed prevents conception, open enables conception.**
- A **delivery catheter**, with the smallest **endoscope** in the world at its heart for **easy & reliable placement.**
- A **removal catheter**, only for those rare cases where Choice is not tolerated - insurance policy.

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The device is placed during an outpatient (IUD-like) procedure within 30 min with the **patented Choice ONE delivery endoscope**, fitted with a camera.



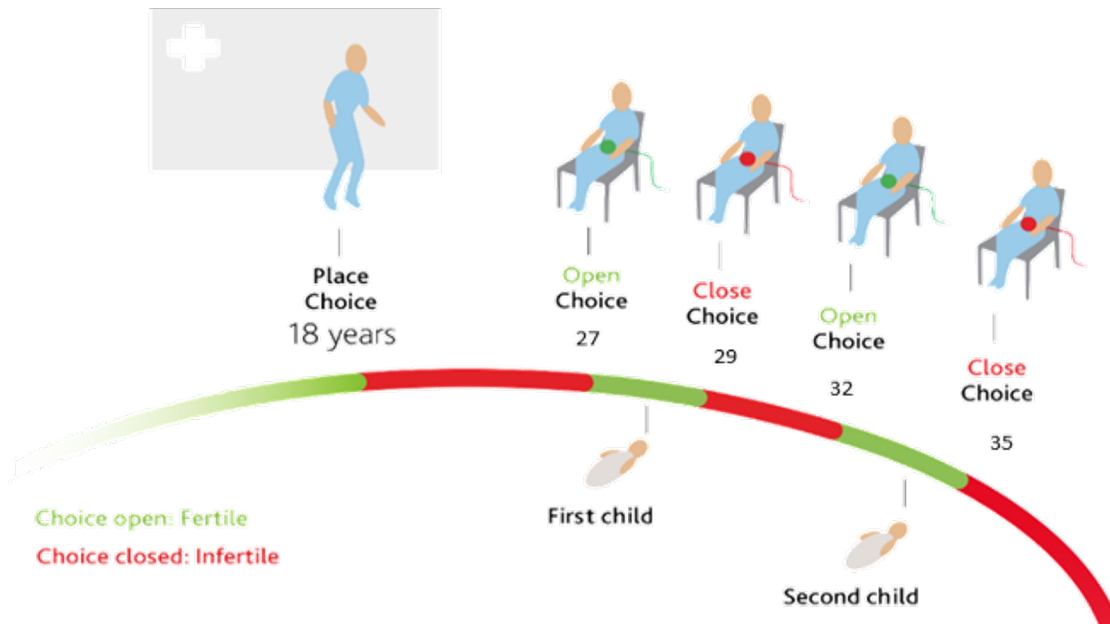
Choice strategically develops Choice One for **sterilization first**, before moving into **contraceptive purposes.**

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Life with Choice makes birth control easy



Using our devices, women can decide their ideal moments in life to be fertile

We envision Choice as a **lifetime solution** for women, **easily implanted** in a one-time 30-minute outpatient procedure and the valves **easily reversed** whenever having a child is desired.

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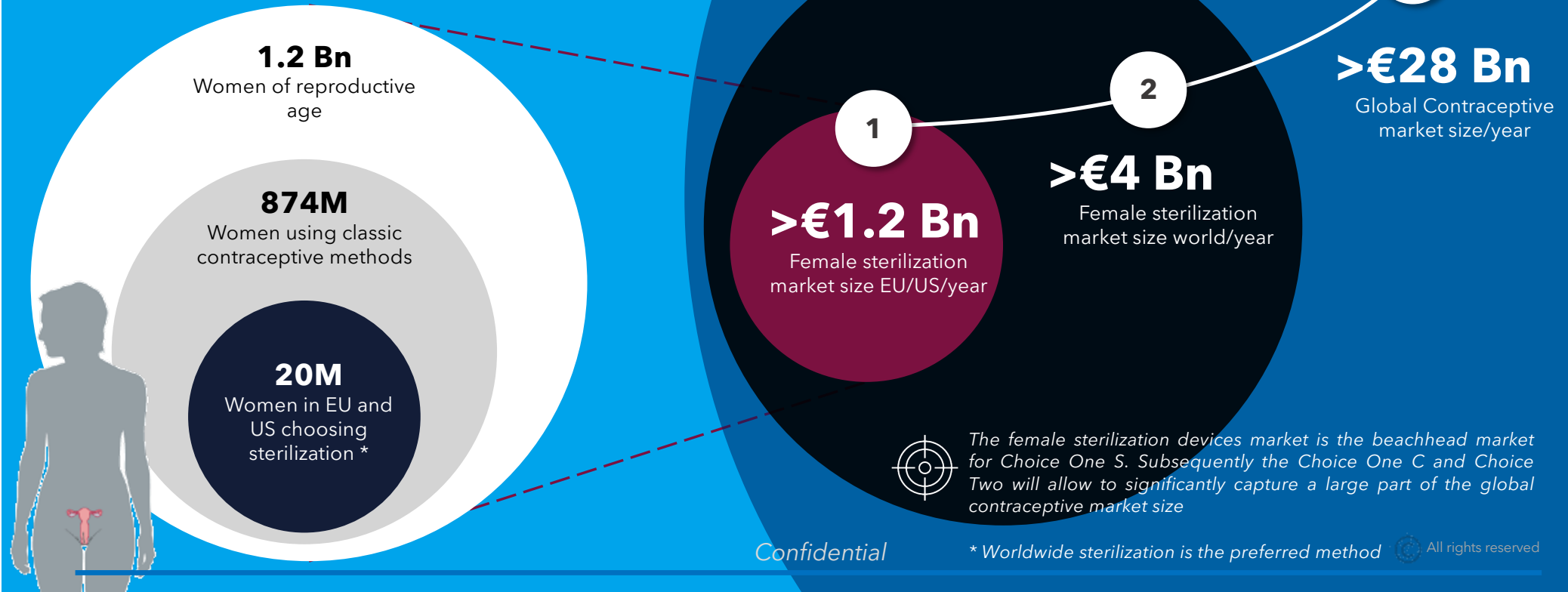




Market Opportunity

Sterilization as beachhead

Choice is uniquely placed in the market as the sole nonsurgical option for sterilization and, in the future, reversible contraception.



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* Worldwide sterilization is the preferred method  All rights reserved

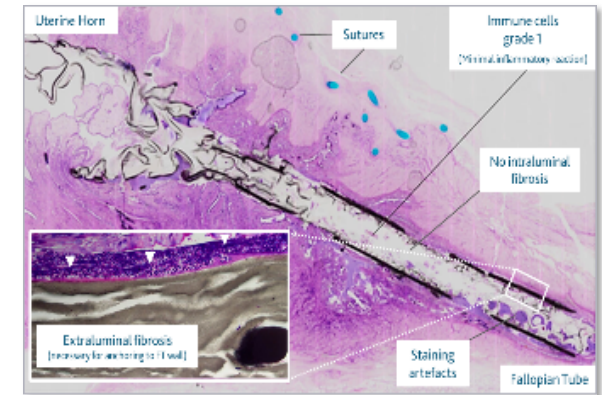


Proof-of-Concept *Excellent biocompatibility*

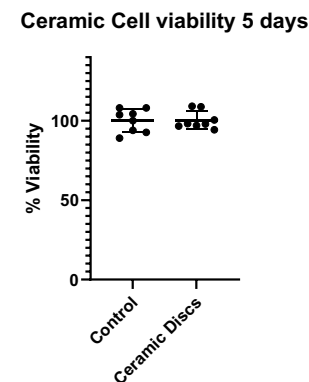
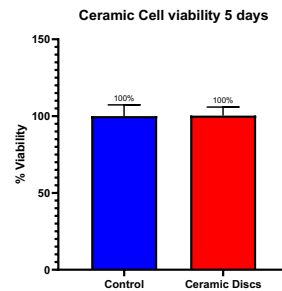
- *In vitro* tests show **valve watertight** of extremely high pressure (80mmHg), showing valve functionality - *completed*
- **Flow modelling study** showing air bubbles cannot block the hydrophobic duct wall - *completed*
- **Animal studies** showing implants well tolerated
- *In vitro* tests to study **interactions of the implant with human gametes** - *ongoing*
- **Organoid tests** with primary human tissue to confirm biocompatibility of ceramic materials with fallopian tubes. - *ongoing with first results shown*

28-day study in rabbits with Choice ONE followed by removal

- No signs of toxicity
- No effect on mortality
- Limited to no signs of fibrosis
- Mild to no host reaction



Representative histological staining of a rabbit fallopian tube after placement of Choice ONE



Cell viability of fallopian tube and endometrial organoids unaffected by exposure to ceramic components Choice implant.



Proof-of-Concept

Ex vivo studies / First-in-human

Tests in extirpated bovine and sheep uteri



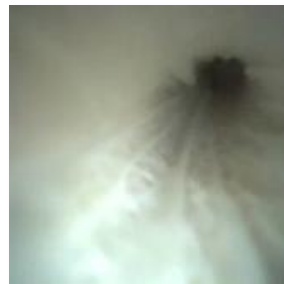
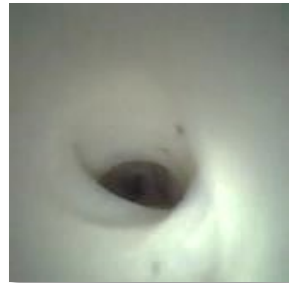
Conducted by professors Bas Veersema (Gynaecology) & Peter Vos (Veterinary Medicine)

View from endoscope

Entrance to FT



Inside FT



Entrance to FT



Inside FT

✓ Excellent visibility

✓ Good light from endoscope

First test in extirpated human uteri



Conducted by professors Marlies Bongers & Bas Veersema (Gynaecology)

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IP: valve & motor granted, 3 patent pending, more in pipeline

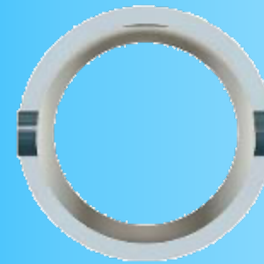
Choice has a handful of **already granted patents**, with more **pending** to maximize coverage in the EU and US

Current granted patents (EU and US):

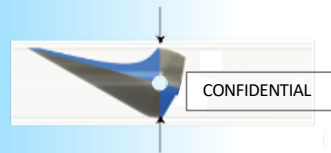
- **EU: EP3188699 US: 11291582 B2**
 - Covering the overall idea, full valve, nitinol wire actuator and central detent
- **NL2026357**
 - Concentric nitinol actuator and detent
- **NL2026354**
 - Halve valve (for Choice One S and Choice One C)

Pending patents

- **P127160**
 - Concentric Motor - Motor folded around tube
- **P128127**
 - Bias Detent - Spring detent creates bistable valve
- **P129989**
 - Half Valve - Half valve allows for incontinence



Central detent



Halve valve

Next batch of patents will involve two packages

Choice One Delivery system

- Choice One - stent/housing/valve/detent - ready
- Switch mechanism - in development
- Endoscope delivery - PoC created, in development
- Construction catheter & controls - in development

Choice One Removal System (concept level) :

- Catheter cutter
- Catheter stent hook
- Chitin filler

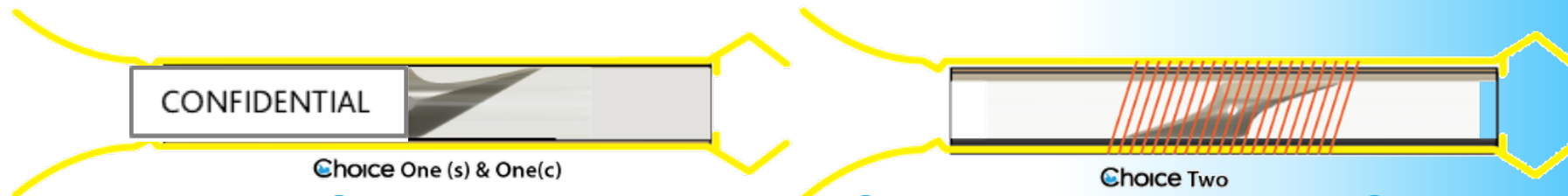
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Product Roadmap

Sterilization quickest road to market



2027

Choice One (S)
(Sterilisation)

Choice One S - Closed valve suitable for the application in female sterilization

2030

Choice One (C)
(Contraception)

Choice One C - Bistable valve that can be manually opened or closed by a GP or gynecologist

2032

Choice Two
(Contraception)

Choice Two - Bistable valve that can be externally opened or closed using a mode change antenna and internal motor

- ✓ MDR compliant
- ✓ ISO 13485 certified, notified body 
- ✓ CRO partner 

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Development Roadmap

2022

2023

2024

2025

2026

2027

Q1 Q2 Q3 Q4

Q1 Q2 Q3 Q4

Q1 Q2 Q3 Q4

Q1 Q2 Q3 Q4

Q1 Q2 Q3 Q4

Q1 Q2 Q3 Q4

Choice One S

Preclinical studies

First-in-Woman studies

Regulatory Approval

Market Launch

- 28-day Rabbit Test - Local Biocompatibility**
- Biocompatibility with organoids - ongoing**
- Biocompatibility with gametes - ongoing**
- Ex vivo- Compared Uterus Study (Insemination model selection)**
- Ex vivo endoscope Study - Usability in human uteri and fallopian tubes**
- 28-day Rabbit Test - Immediate Test & Local Biocompatibility - Repeat Study 2.0 (in preparation)
- Efficacy (Rabbit) Insemination Test
- Sheep stent ingrowth leak test
- Sheep removal test

- Permission for tests in women granted (prior to hysterectomy)**
- Falloposcope use / visualization of fallopian tubes in 2 women (in preparation)
- Two-step investigational Clinical Study (Phase II)
 - A: First-in-women - placement and removal
 - B: Pilot Feasibility Trial, demonstrating efficacy/safety
- Pivotal trial - (Phase III) Investigating pregnancy, procedure- and wearing safety

- CE mark - MDR Class III device registration (with contracted German notified body DQS)
- Obtaining FDA approval - Pre-market approval route (PMA)

- Out-licensing in high-income countries (HIC)

Uterus removal procedures allow accelerated clinical testing

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Market Opportunity

Bayer's Essure

The sterilization device market was proven by the **Essure device**, which was developed by Conceptus in 2002.

Essure was acquired by Bayer in 2013 for **\$1.1B**. In total, **750.000 women received Essure**, of which **97% were satisfied**.

Not properly tested with no customer feedback it ran into problems (as pre- MDR products often did). Choice has addressed all Essure shortcomings (to be discussed under NDA).

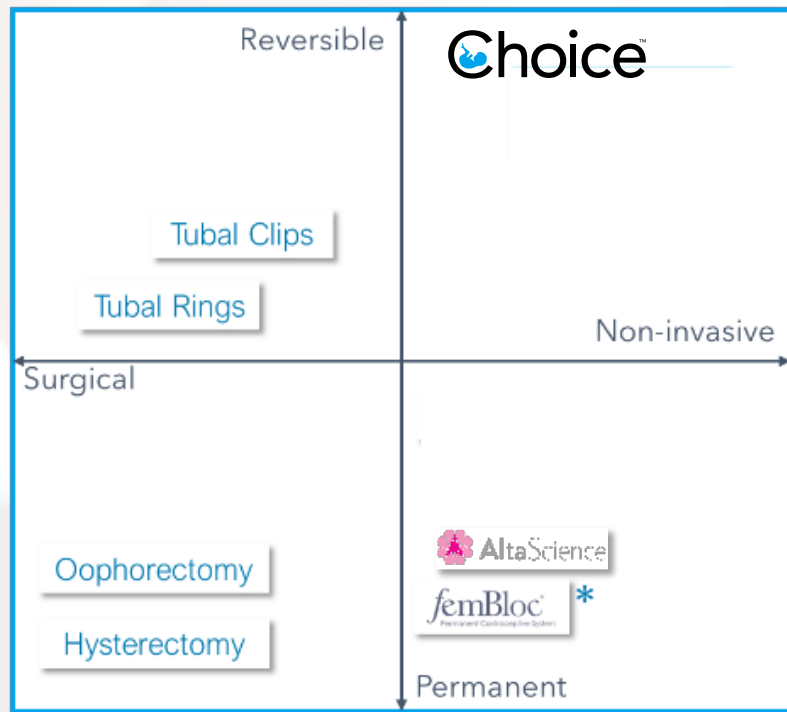
<i>Essure</i>	2013	2014	2016	2018	2020	<i>CAGR</i>
<i>\$ M</i>	92	139	338	497	677	33%

Bayer's projected growth path





Competition



Choices' products demonstrate superiority in terms of **reversibility** and **non-invasiveness** compared to conventional/ marketed sterilization procedures and contraceptive products.

Choice ONE S

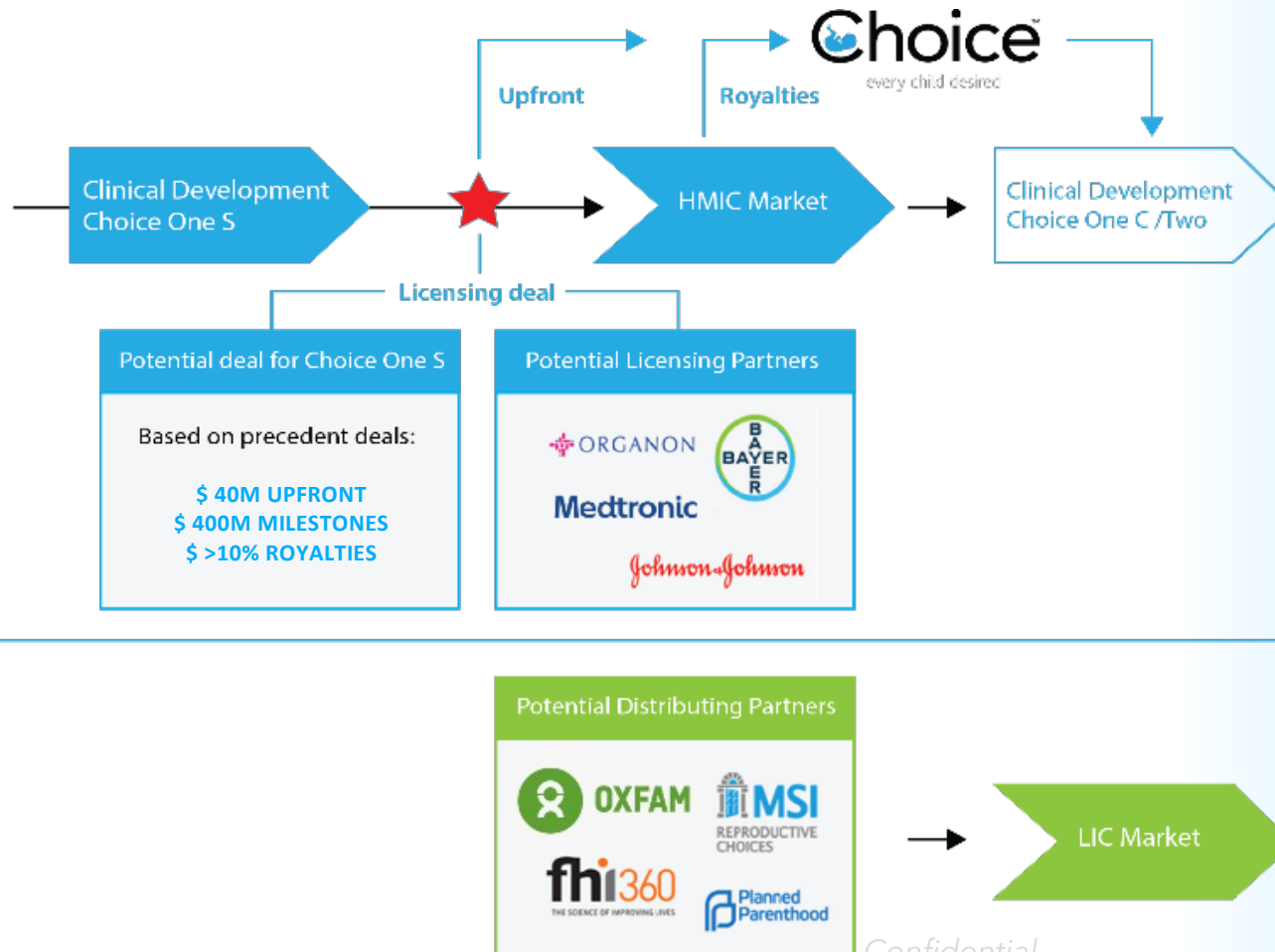
	Choice	Tubal clips/Rings	
Reversible	✓	~	<u>Hormone Free</u>
Non-surgical	✓	✗	<u>Discipline free</u>
Office Procedure	✓	✗	<u>Passion proof</u>
No Anesthesia	✓	✗	<u>One Time Cost</u>
Easy removal	✓	✗	Highly Reliable (>90%)

Choice ONE C

	Choice	Pill	Condom	IUDs
	✓	✗	✓	✓✗
	✓	✗	✗	✓
	✓	✓	✗	✓
	✓	✗	✗	✗
	✓	✓	✗	✓
	✓	✓	✗	✓



Business and revenue model



- **Choice** will adopt **licensing deals**, First EU & US, then India & China (HMIC), to scale & Africa for impact
- Choice expects an **upfront payment** and **royalties** on net sales
- Choice continues as a **R&D centre** for future versions & applications
- Choice ONE will be introduced to **low income countries (LIC)** in collaboration with **NGOs**.

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TEAM *An experienced, multi-disciplinary team*

TEAM



Peter van de Graaf *CEO/Founder*
Designer and innovator with 25 years of experience and multiple patents in medical product design. Full-time CEO of Choice.



Leonie van de Kamer *CCA*
Very experienced **Clinical Research Professional** with 7+ year (served 8 projects and >20 clients in strategic decisions) of experience in the field of Medical Devices.
Investor Choice



Jörg Stroetzel *COO*
Career in the development, sales and roll-out of modular optical telecom systems, from development engineer to deputy CEO and board member.
Investor Choice

COLLABORATORS



Thomas Nissl
Eminent stent designer at TNTech



Bram van Dijck
a.o. Global Group Director Fertility at Organon

SCIENTIFIC ADVISORY BOARD



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Gynaecologist
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Michiel de Haan
Venture Capitalist
45 years experience in Venture Capital firms, Aescap Venture Amsterdam



Dr. Joris Bannenberg
Clinical advisor, Investor Choice
25 years med. device regulatory and clinical affairs. Founder of Avania & Bevinced Clinical Research Organizations.

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PARTNERS

TECHNICAL



CLINICAL



SOCIETAL



FINANCIAL



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Summary

Choice™



TEAM & MISSION

- FemTech product developer from Eindhoven, Netherlands
- Highly experienced team with extensive technological, business and clinical experience.
- Development of reversible and non-invasive sterilization and contraceptive devices for women
- Mission: **Every Child Desired**



TECHNOLOGY

- Valve based implants inserted in the fallopian tubes, blocking sperm and ova migration.
- Can easily be placed during outpatient procedure with endoscope.
- Achieved proof-of-principle ex vivo, biocompatibility, in rabbit tests, and in human extirpated uteri + fallopian tubes



OPPORTUNITY

- Seeking **€2.5M** equity financing in current round to:
 - First-in-women studies
 - MVP design freeze
 - Perform first insemination test
 - Start conversation with FDA
- Targeting a licensing with Pharma/MedTech in 2027



Large, unserved market opportunity



Best-in-class innovative technology



Established experienced team and network



Tremendous societal impact

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ChoiceTM


every child desired

Realizing lifetime hormone-free fertility freedom

Looking for a €2.5M investment targeting a €28B market

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 <https://www.choice.nu/>

 <https://www.linkedin.com/company/choice-every-child-desired/>

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August 2023