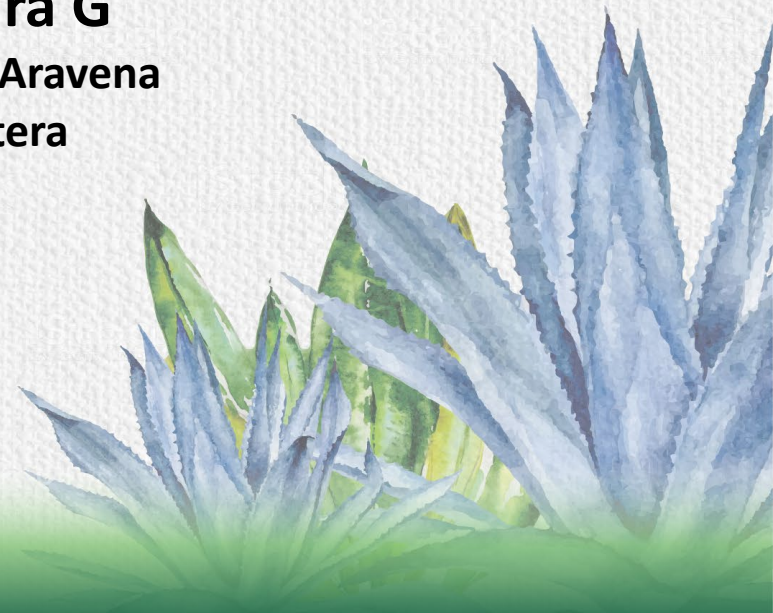


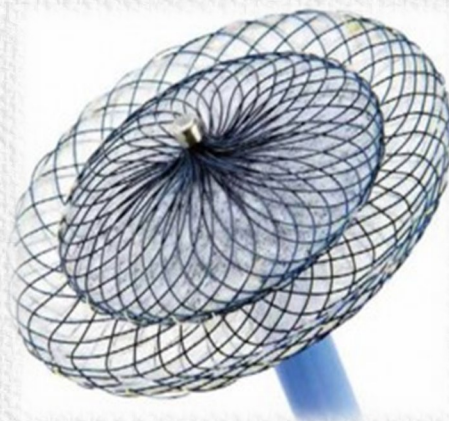
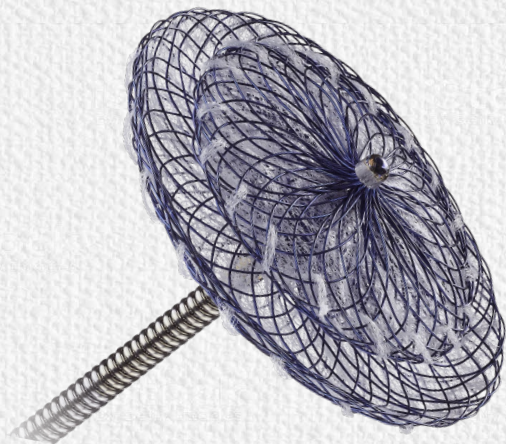
Closure of Patent Foramen Ovale in adults with a bioresorbable device: a case series

Dr. Leonardo Vergara G
Hospital Hernán Henríquez Aravena
Universidad de la Frontera
Temuco, CHILE



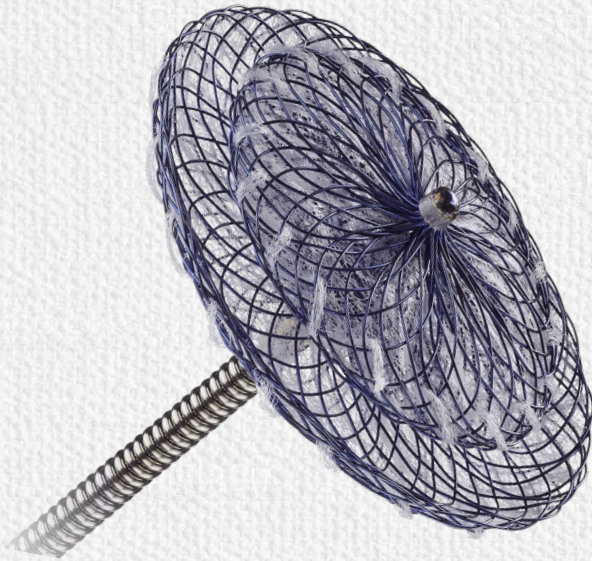
Patent foramen ovale (PFO) Occluder devices

Concept design
“Double metal disc”



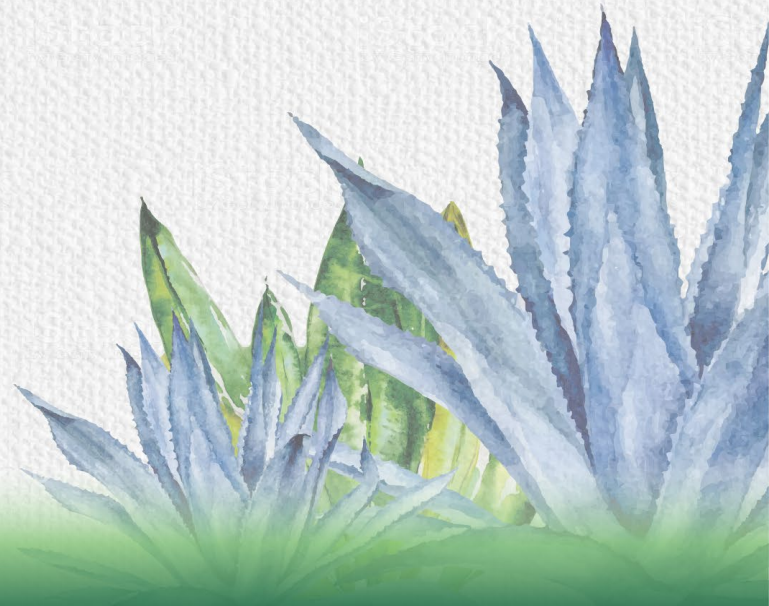
Patent foramen ovale occluders

Concept design
“Double metal disc”



- ✓ Safe & Simple
- ✓ High effective
- ✓ Wide experience
- ✓ Excellent long-term results

So... Why a biodegradable occluder in PFO?



Disadvantages of metal devices

- ✓ **Nickel allergy**
- ✓ **Pro-arrhythmic effect (atrial fibrillation)**
- ✓ **Intracardiac tissue erosion**
- ✓ **Incomplete endothelialization (thrombosis risk)**



Patent Foramen ovale (PFO) closure

Main indication

ESUS < 60 years

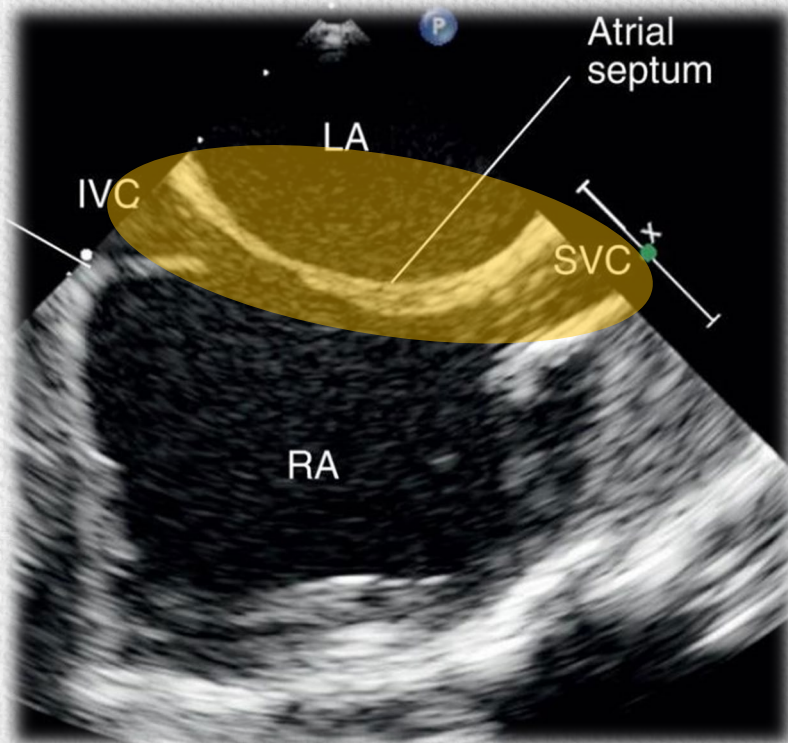


Young population

Metalic device in the atrial septum in the future...

- ✓ Cardiac MRI artifacts
- ✓ Challenging transseptal puncture (EP procedures, LAAC, etc.)

Bioresorbable device in PFO...



**“Free metal
implantation”**

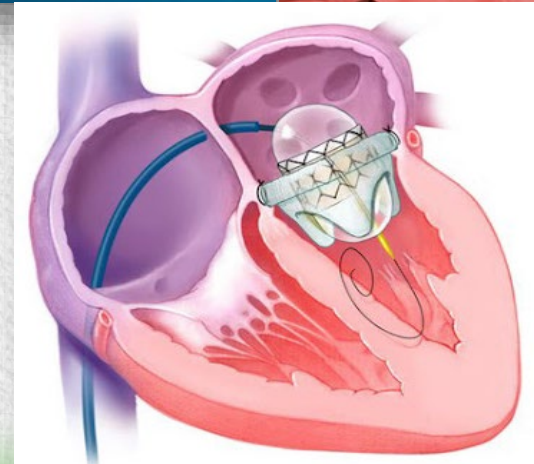
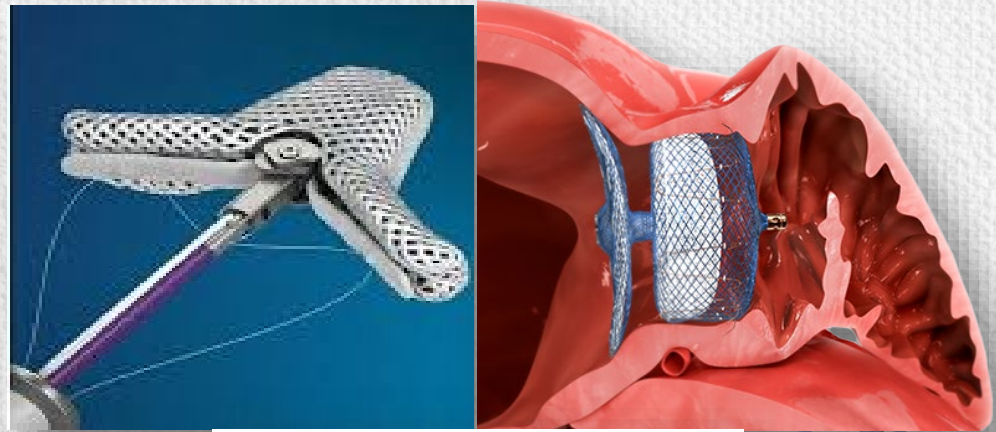
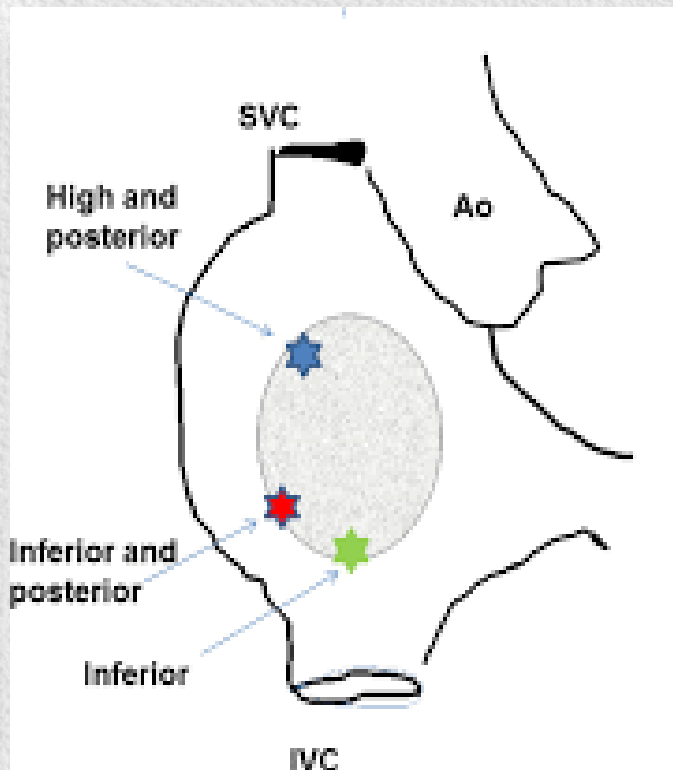
**Assure integrity & crossability
of atrial septum**



Bioresorbable device in PFO

A “normal” interatrial septum

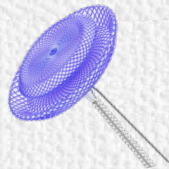
Accurate transeptal
puncture



Bioresorbable PFO occluder

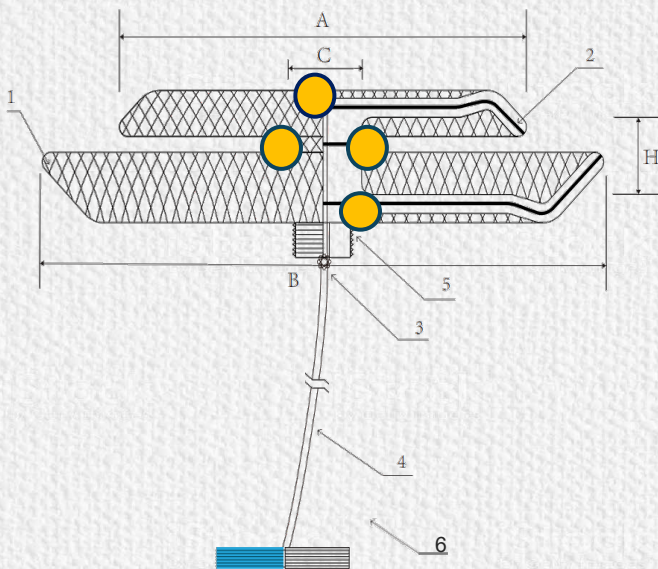
2023

First biodegradable
PFO occluder
implantation



Bioresorbable PFO occluder

Anatomy of the device



✓ Double disk

✓ NO metallic parts

Bioresorbable PFO occluder

Anatomy of the device

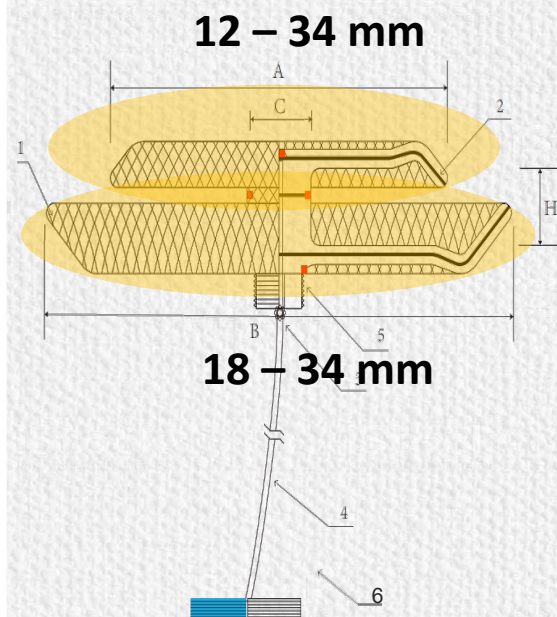
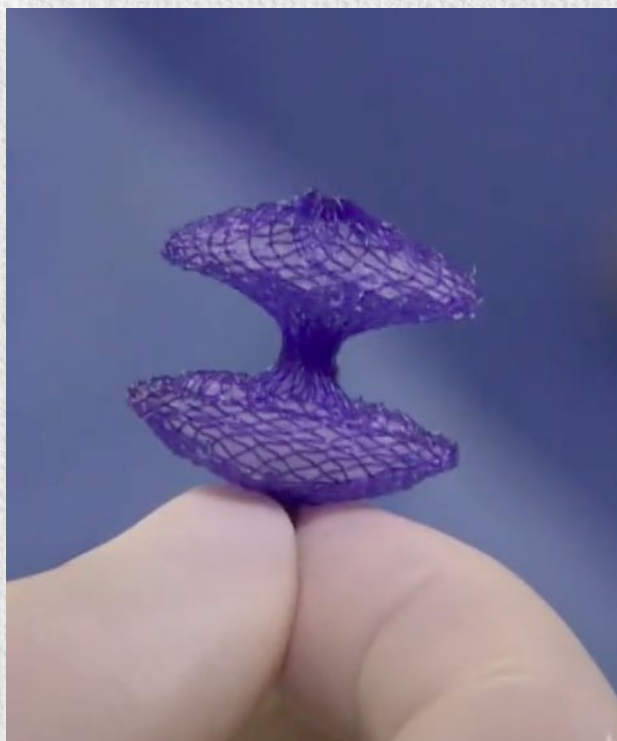


Table 1 Basic sizes of Biodegradable Patent Foramen Ovale Occluder (mm)

Specification & model	Waist diameter C	Waist height H	Upper disk diameter A	Lower disk diameter B
BDPFO-I1218	4.0±2.0	3.0±2.0	12.0±2.5	18.0±2.5
BDPFO-I1818	4.0±2.0	3.0±2.0	18.0±2.5	18.0±2.5
BDPFO-I1824	4.0±2.0	4.0±2.0	18.0±2.5	24.0±2.5
BDPFO-I2424	4.0±2.0	4.0±2.0	24.0±2.5	24.0±2.5
BDPFO-I2228	4.5±2.0	4.0±2.0	22.0±2.5	28.0±2.5
BDPFO-I2828	4.5±2.0	4.0±2.0	28.0±2.5	28.0±2.5
BDPFO-I2534	5.0±2.0	5.0±3.0	25.0±2.5	34.0±2.5
BDPFO-I3434	5.0±2.0	5.0±3.0	34.0±2.5	34.0±2.5

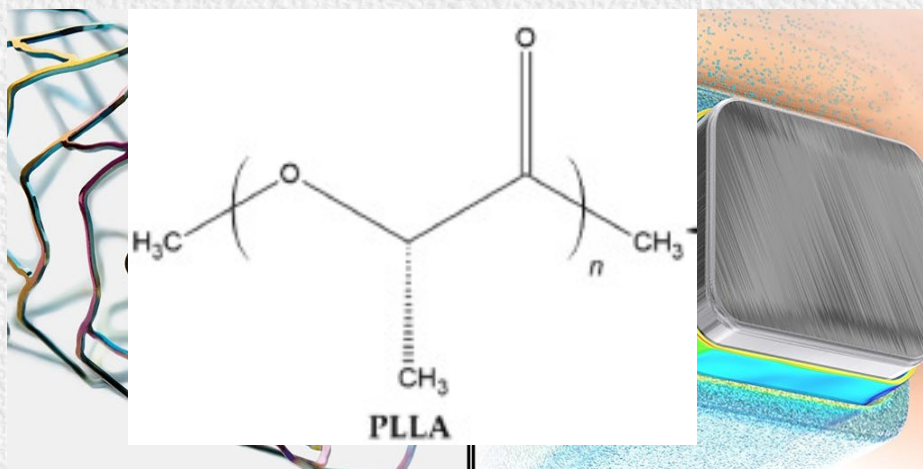
Bioresorbable PFO occluder

Material composition



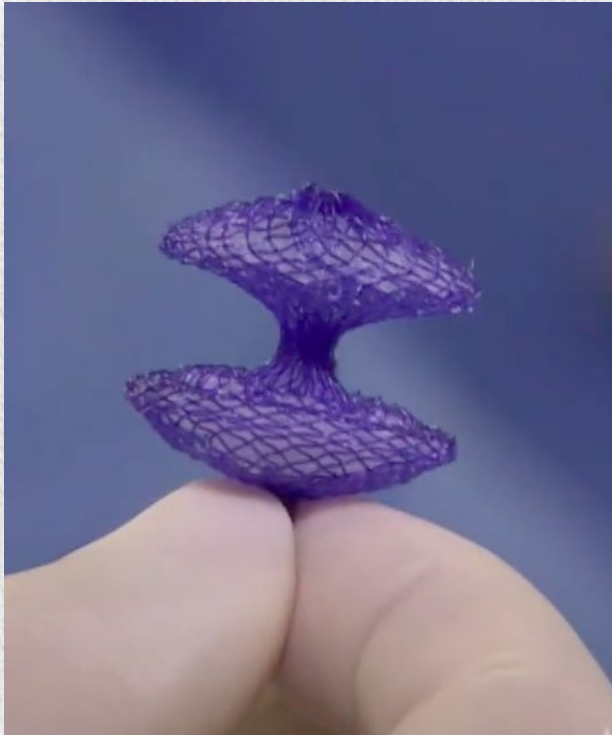
Flow barrier film

Poly(lactic acid) (PLLA)



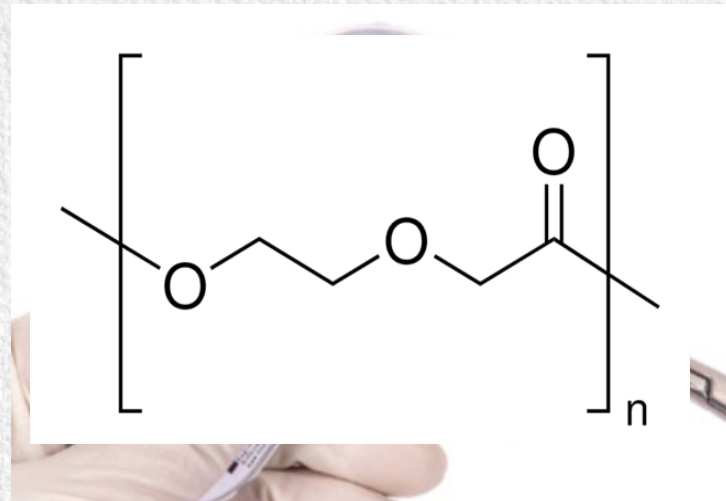
Bioresorbable PFO occluder

Material composition

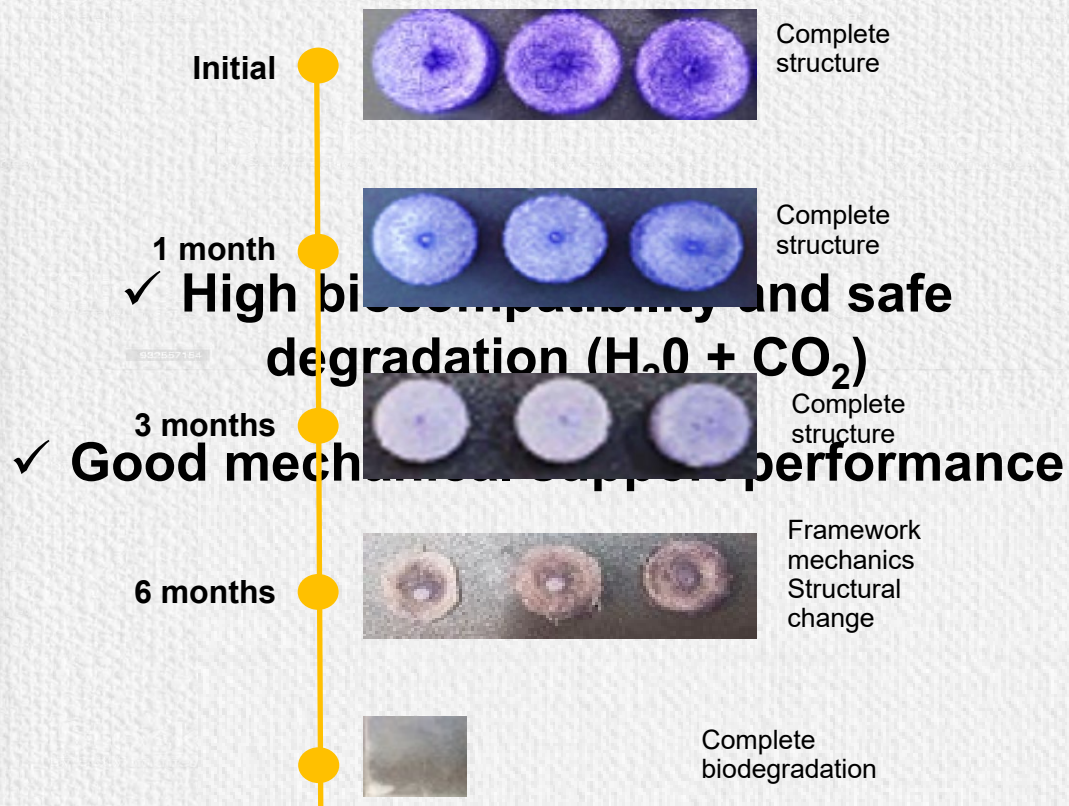
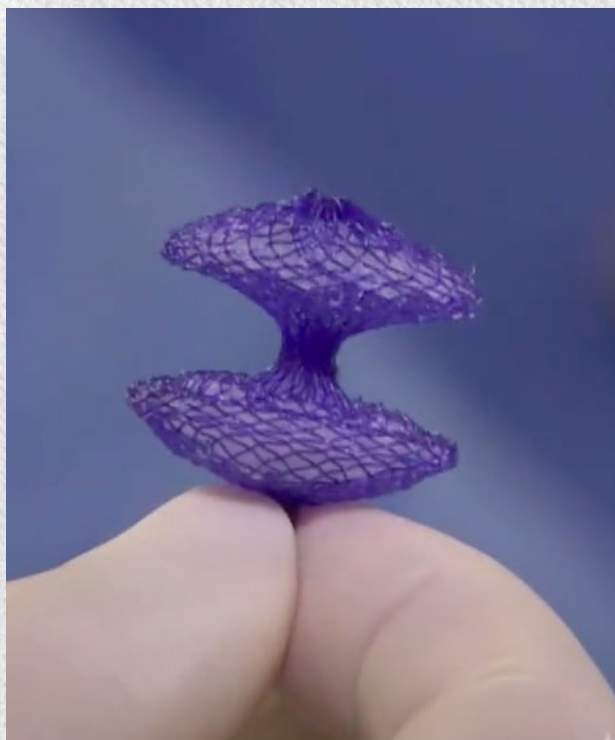


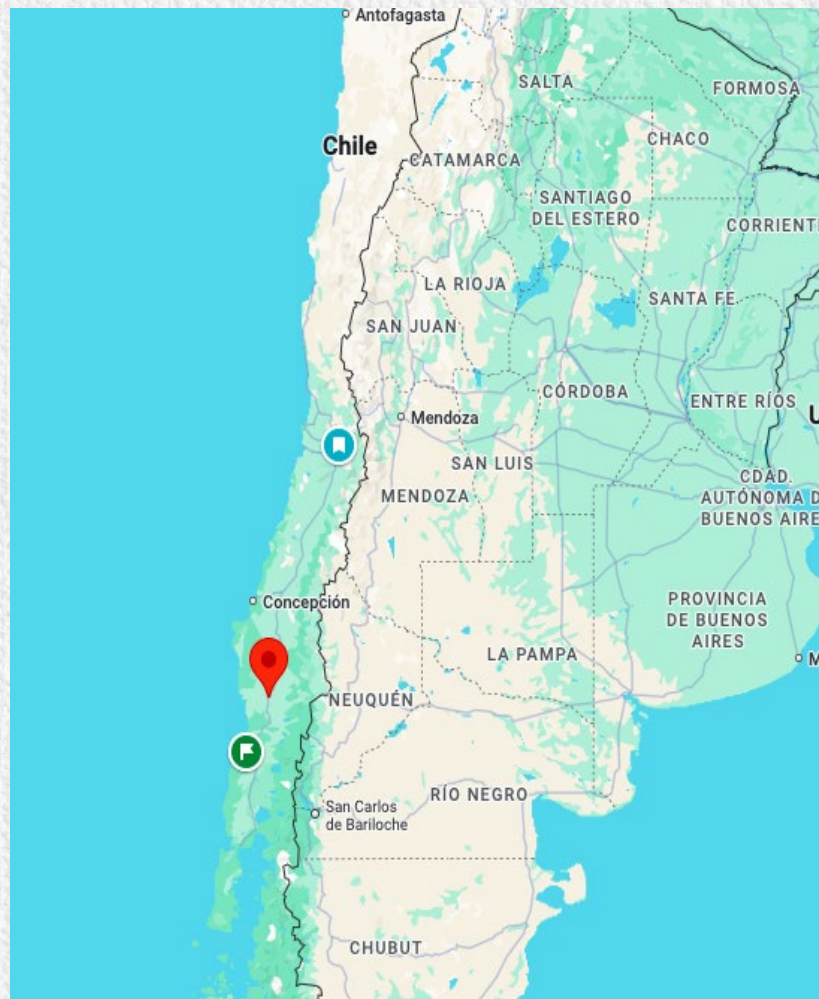
Frame

Polydioxanone



Complete degradation $\approx$ 12 month







Our experience

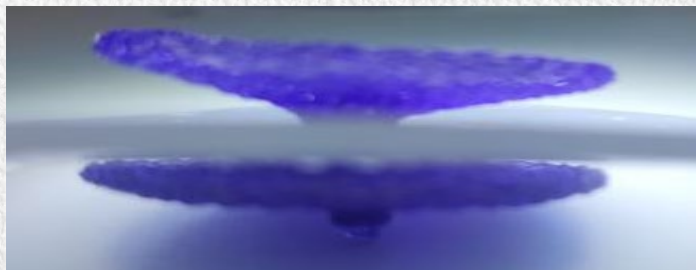
- ✓ Six adult patients with PFO (Sept/2024) / TE-Echo assessment
- ✓ Indication: secondary prevention of stroke (cryptogenic)
- ✓ Mean age: 57 y.o.
- ✓ Mean ROPE score: 7 points

Overview

- ✓ **Lidocaine 2%**
- ✓ **Femoral venous access (Delivery sheath 10 – 12 Fr)**
- ✓ **Heparin 100 UI/kg**
- ✓ **Intracardiac echo (ICE) assisted**

Loading process

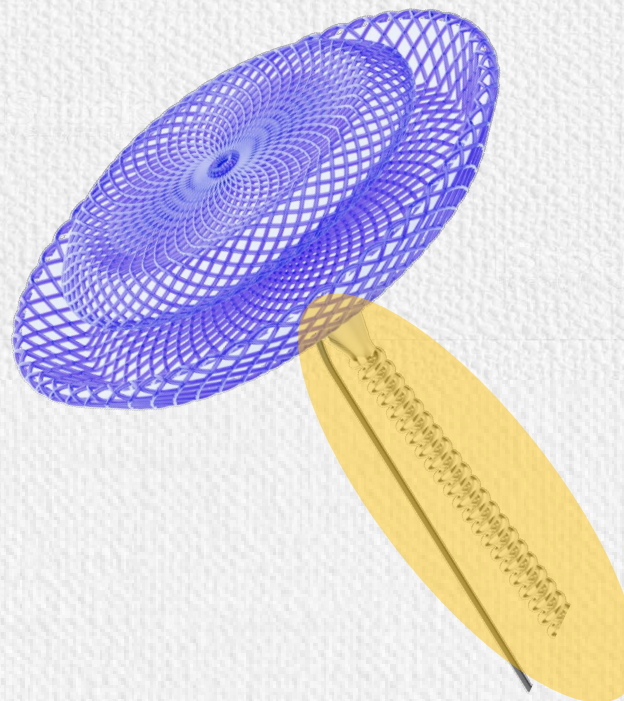
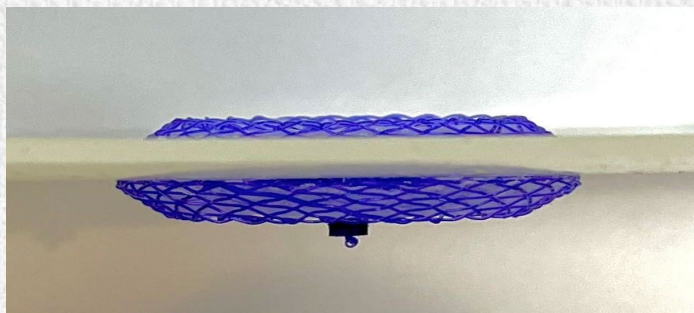
1.



2. **Threads: “locking mode”**



Stable shaping without deformation



Courtesy of live case in CSI Frankfurt 2024

Loading process

**Step 1. Threading
threads over the
release cable**

Loading process

Step 2. Pull the threads completely to the end

Step 3. Screw the device onto the cable

Extra-support GW

Sheathed

03/05/2025 15:04



Deployment



Device liberation

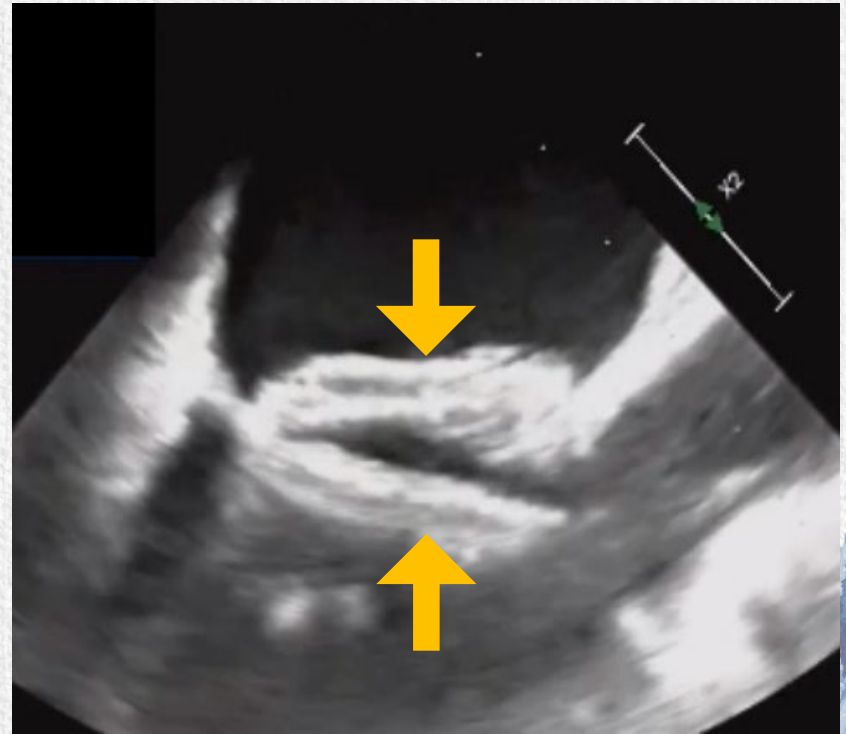
There is no fluoroscopic view of the discs, which is why the implant assistance guided by ICE or TEE is essential.

Device liberation

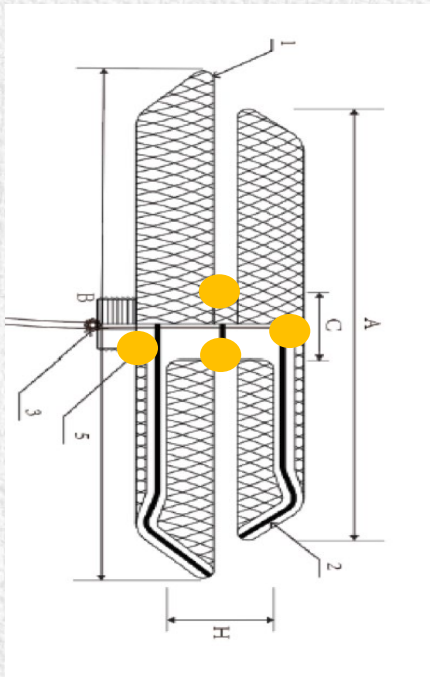
**Pull the threads to
“lock”**



No retrievable

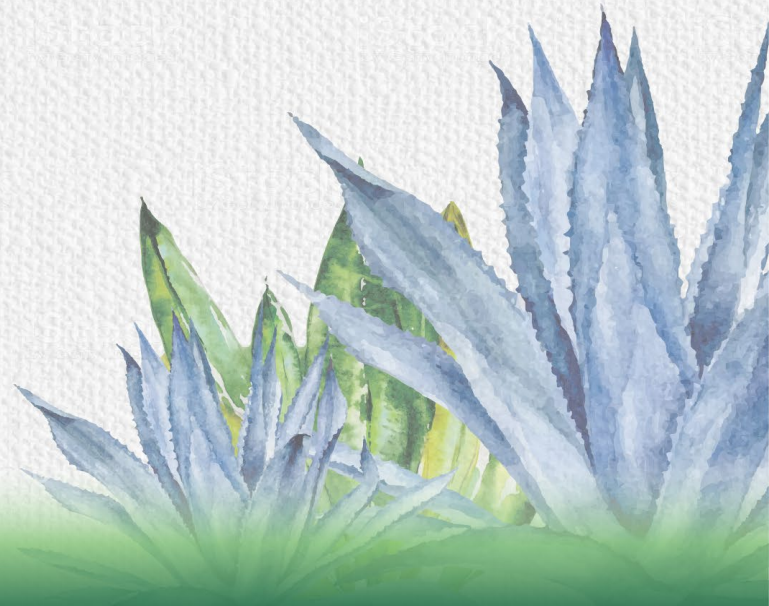


Post-liberation

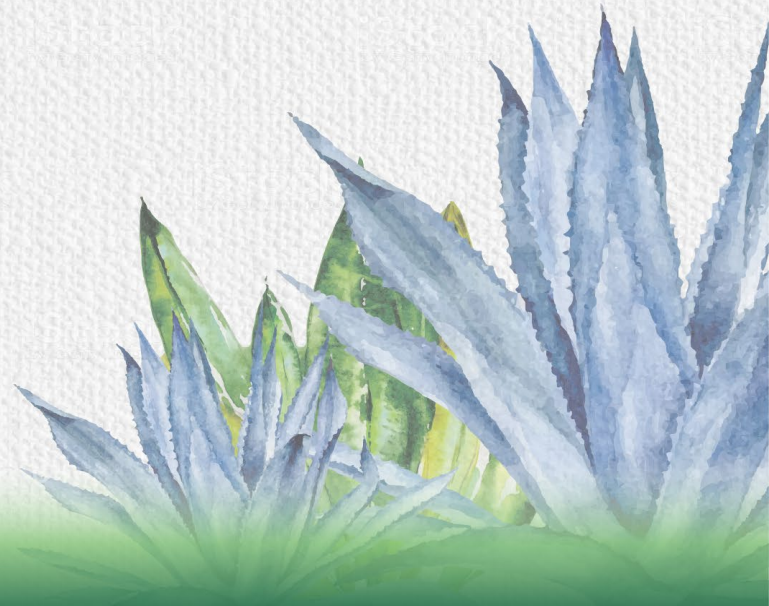


Follow up

SOCIME'15



- ✓ **Dual antiplatelet therapy for 3 month (ASA + Clopidogrel), followed only by ASA until 12 month.**



Bed-side Echo

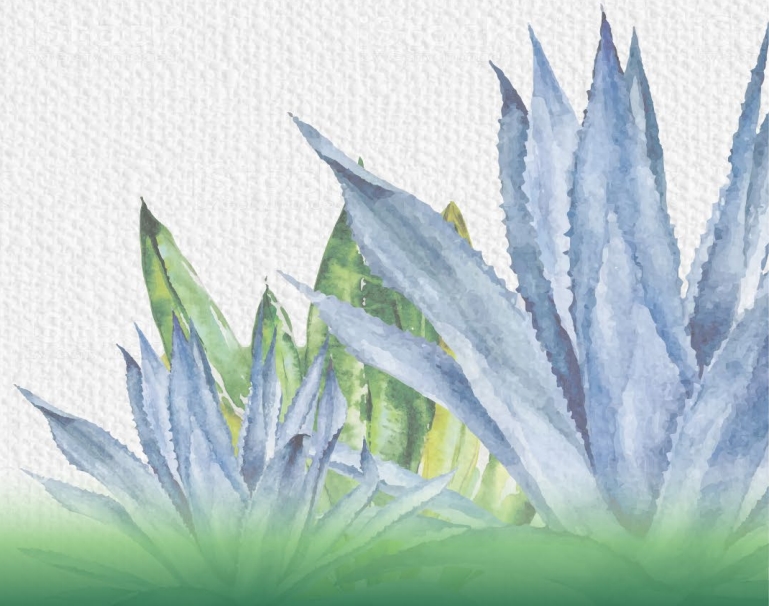
1 month

TT Echo

6 month

11 month

SOCIME '15

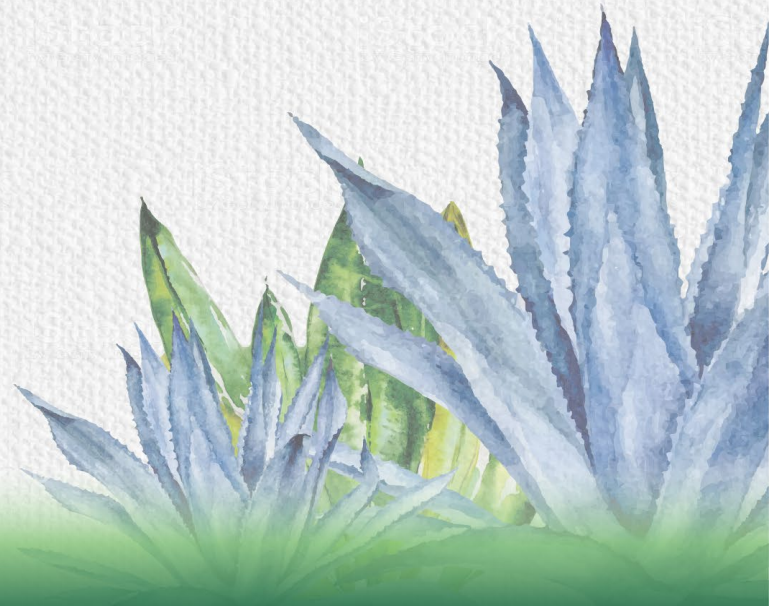


TT Echo

6 month

11 month

SOCIME '15



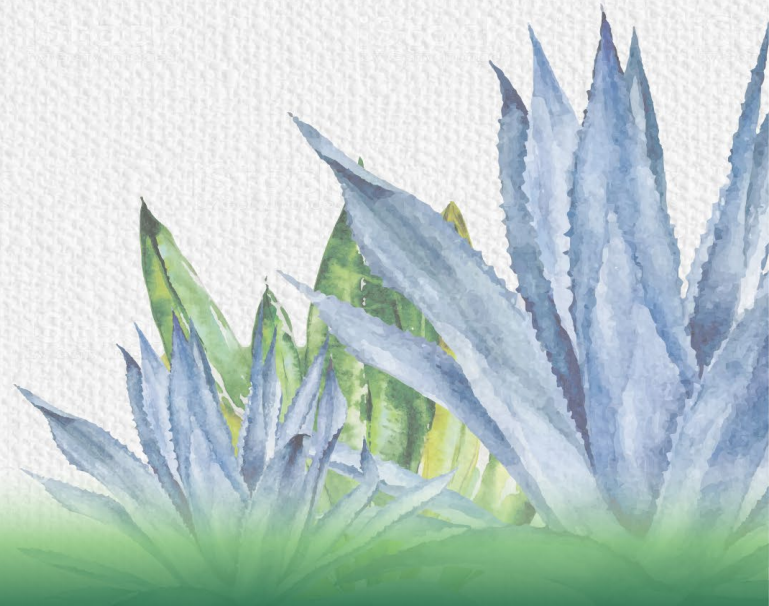
TT Echo

Bubbles Test

6 month

11 month

SOCIME '25



Cardiac MRI

6 month



Follow up: until now...

- ✓ **NO adverse clinical events**
- ✓ **NO dislodgement**
- ✓ **NO residual shunt / device thrombosis**



Gap of know

- ✓ Real cinetic of degradation
- ✓ Reappearance sh
- ✓ Septum fi
- Hard transseptal puncture?
- Thrombosis risk?
- Local and imagenologic strategy

RCT Randomized control trial

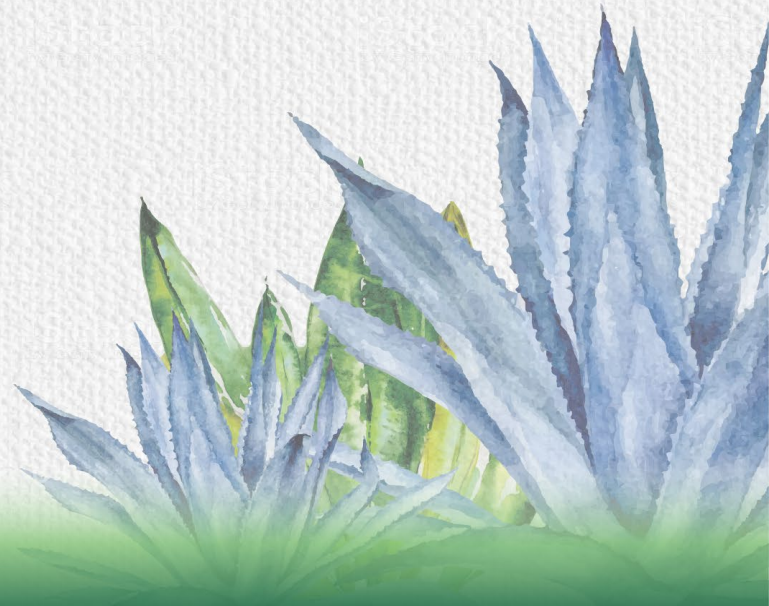


Closure of patent foramen ovale in adults with a bioresorbable device: a case series

Leonardo Vergara G.
Fellow of Interventional Cardiology
Hospital Hernán Henríquez Aravena
Universidad de la Frontera
Temuco, CHILE



Intracardiac Echo (7 mo)



Bioresorbable PFO occluder

Anatomy of the device

Table 1 Basic sizes of Biodegradable Patent Foramen Ovale Occluder (mm)

Specification & model	Waist diameter C	Waist height H	Upper disk diameter A	Lower disk diameter A
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BDPFO-I3434	5.0±2.0	5.0±3.0	34.0±2.5	34.0±2.5

Discos simétricos

18/18 24/24
28/28 34/34

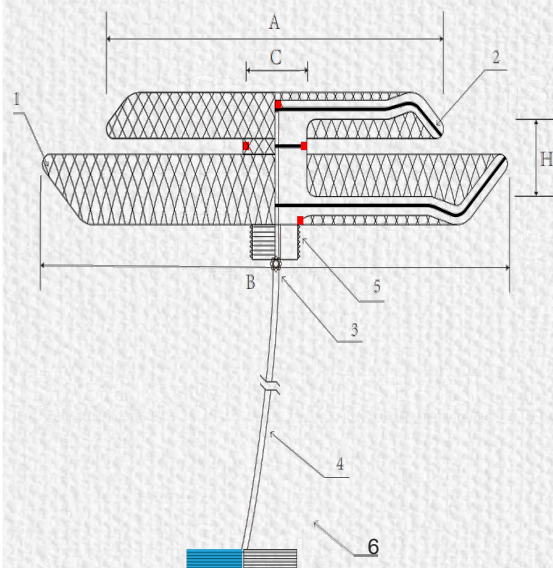


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BDPFO-I3434	5.0±2.0	5.0±3.0	34.0±2.5	34.0±2.5

**Septum primum
Menor 20 mm**

FOP estándar

ASA ≥ 10 con túnel largo

ASA ≥ 20 mm

Hipertrofia lipomatosa

Loading process

Step 4. Attach the distal end of the wires to the distal end of the cable

Loading process

**Step 5. Charge the
device onto the pusher**

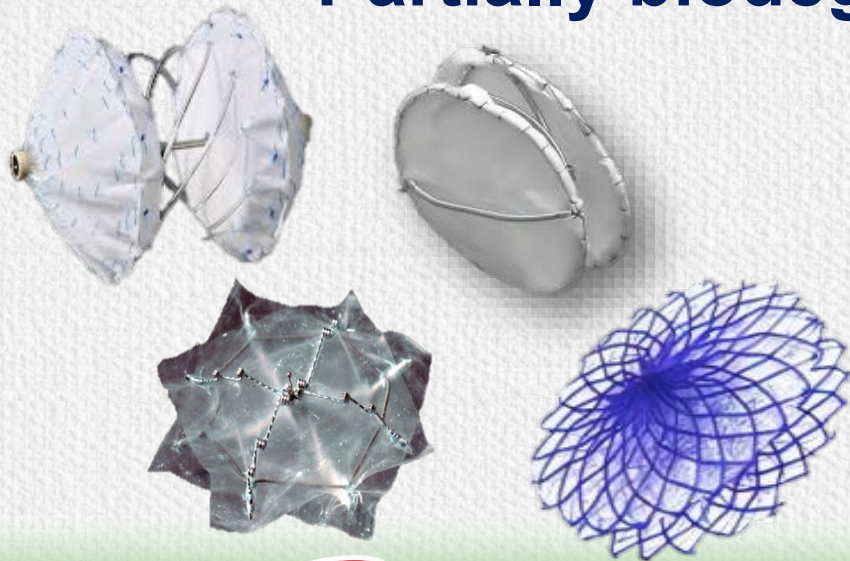
SOLACI SOCIME '25

Septal defects

Metal devices



Partially biodegradable

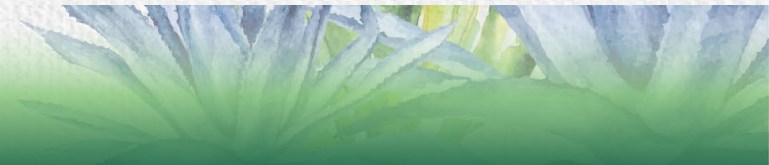


Fully biodegradable



Device liberation

**Advance and attach
the sheath to device
for support**



Metal v/s Bioresorbable



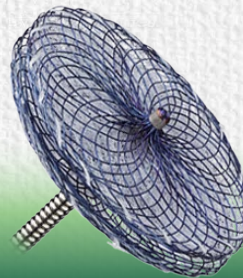
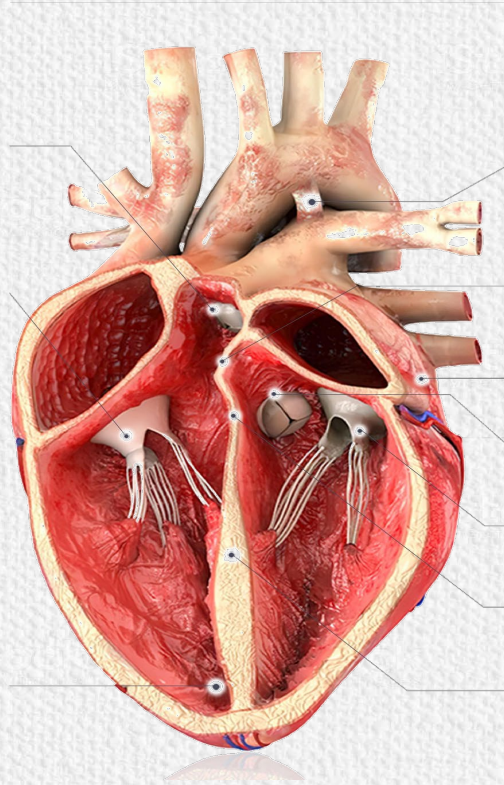
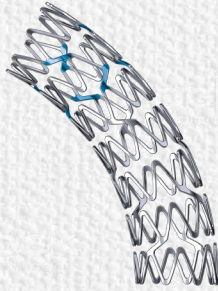
**How Old
is a
Sugar
Daddy?**

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written by
Bonnie Pearson
Author sugar-lifestyle.com



“Steel heart”

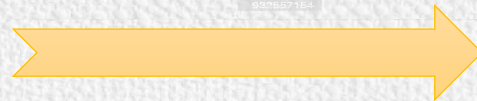
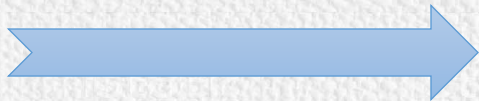


Bioresorbable milestones

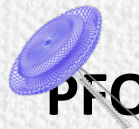
2018



The world's first fully
biodegradable
occluder implanted
in the human body

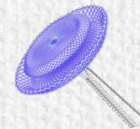


2023



First biodegradable
PFO occluder implantación

2024



First biodegradable
ASD occluder
implantation

