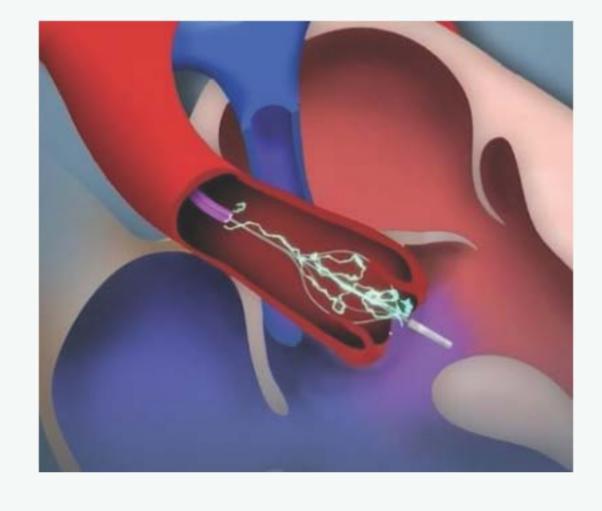
## Valvublator

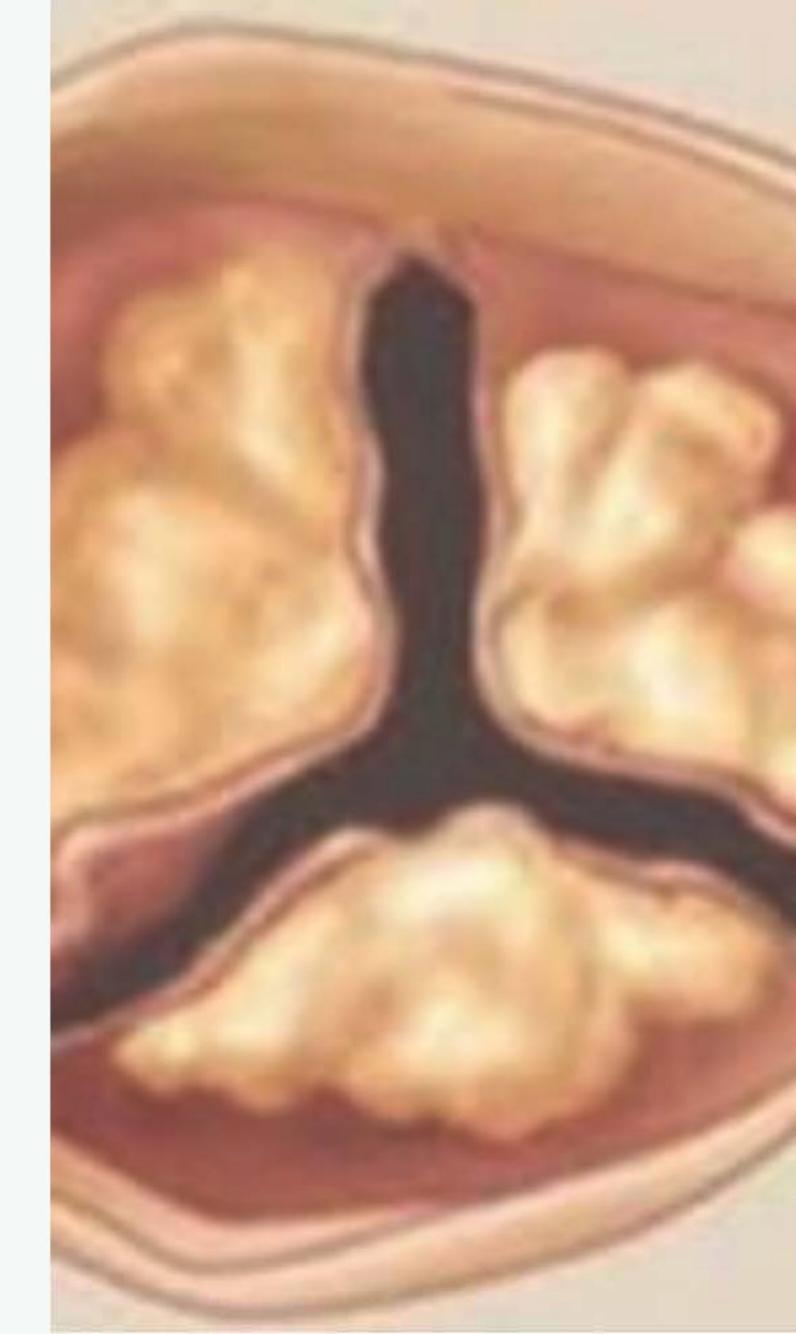
**Regenerate your** own heart valve early so you do not need a cow, pig, steel or plastic artificial implant later.



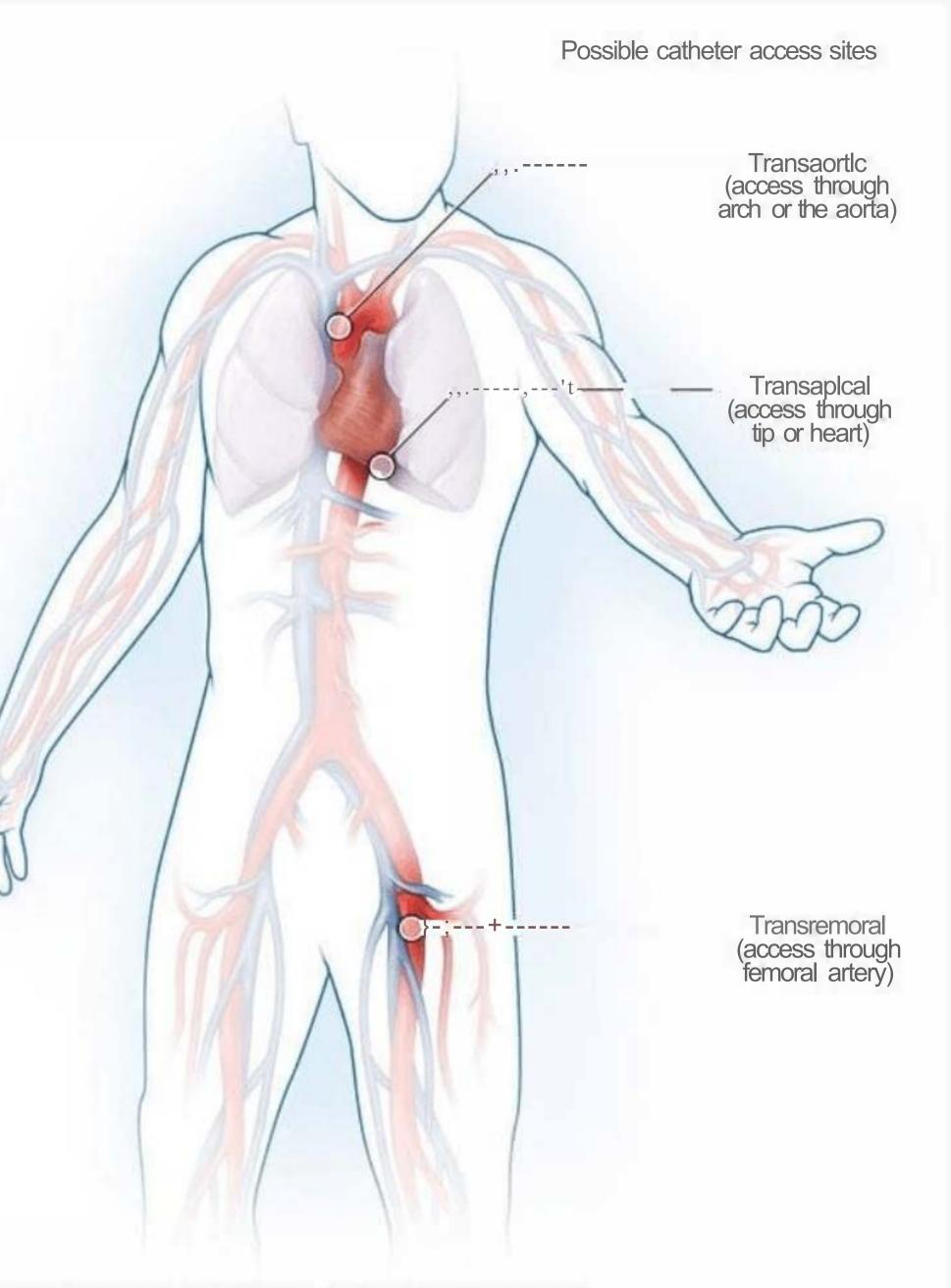
Howard J. Leonhardt, **Executive Chairman & CEO** www.valvublator.com

# Valvublator HEART VALVE REGENE RATION





Helping people keep their ov,n heart valves instead of getting a cov,, pig, steel or plastic artificial implant.



**'0 FOUNDATION FOR M ICAL EDUCATION ANO AESEAACH ALL RIGHTS RESI, RVEO** 

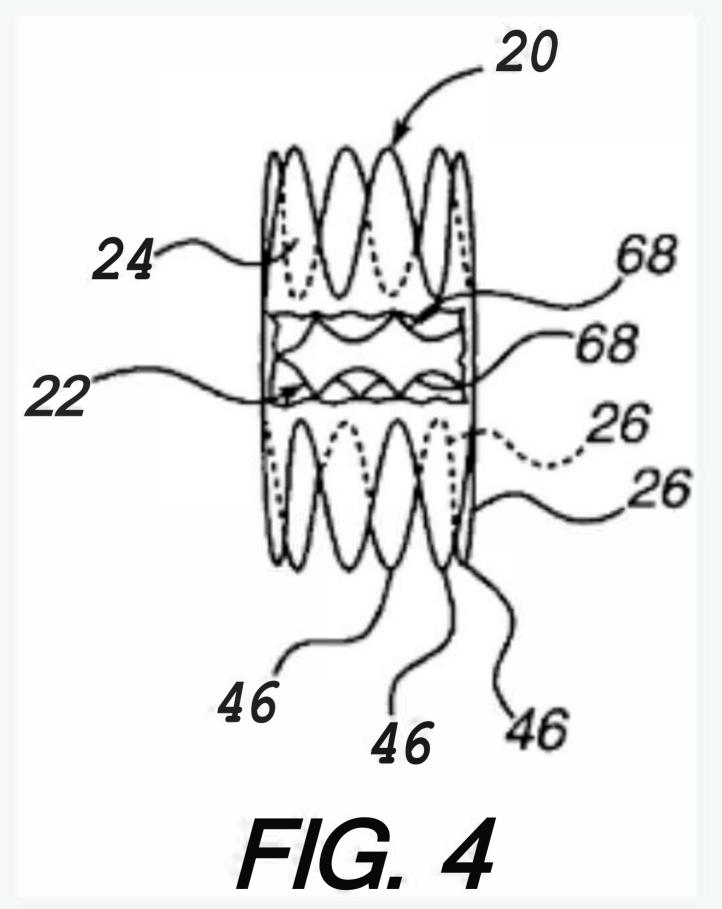
### From the Team that Patented and Developed the First Percutaneous Heart Valve

United States Patent 5,957,949 Leonhardt, et al. filed May 1, 1997 based on 1988 notebook recorded invention

### Percutaneous placement valve stent

#### Abstract

An artificial valve stent for maintaining patent one way flow within a biological passage is disclosed. The artificial valve includes a tubular graft having radially compressible annular spring portions for biasing proximal and distal ends of the graft into conforming fixed engagement with the interior surface of a generally tubular passage. A method of implanting the artificial valve is also disclosed.



Inventors: Leonhardt; Howard J, Greenan; Trevor

# AND... The world's leading endovascular stent graft system



# Introducing Valvublator II Simplified Design

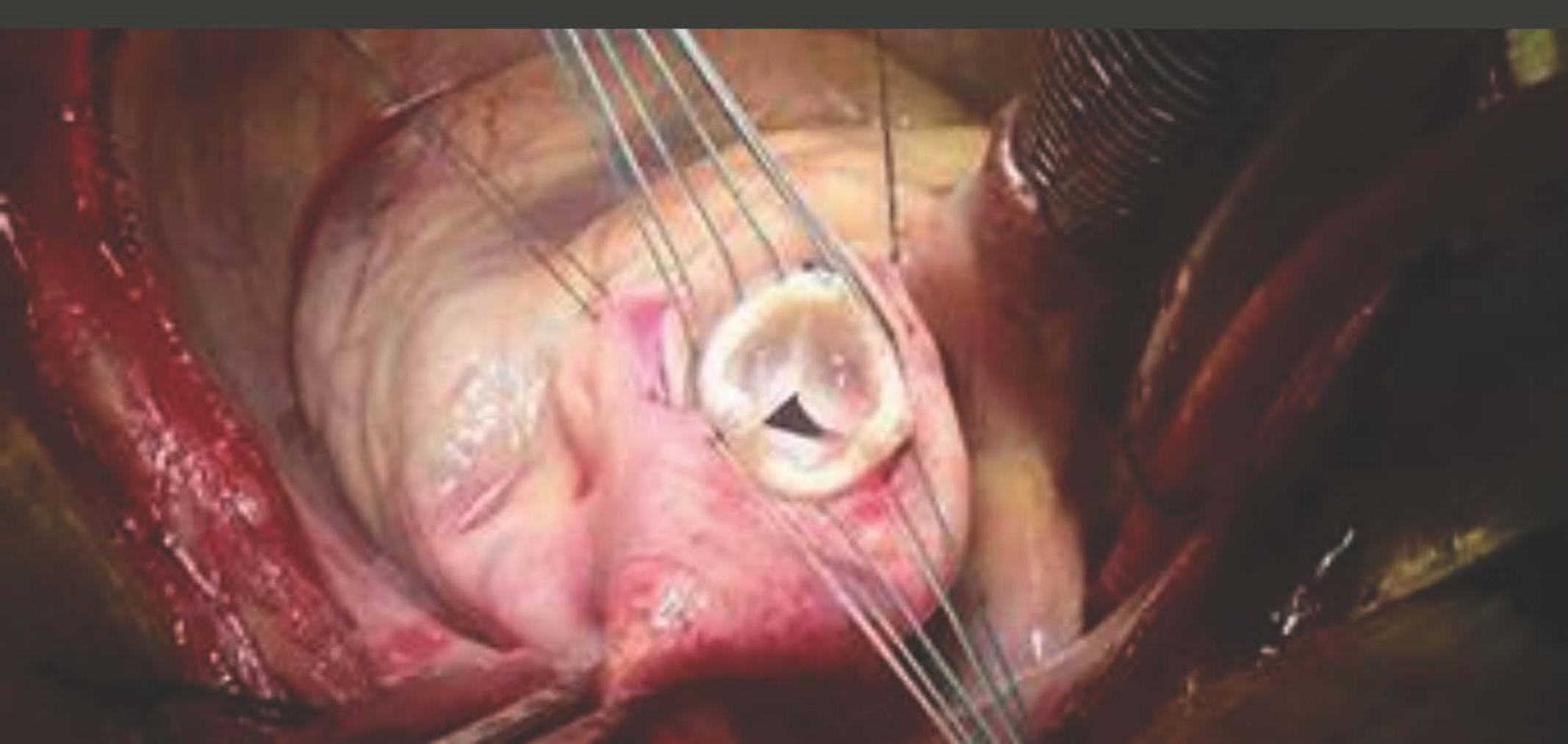


#### Valvublator 11

#### Simplified design

Placed in minutes. Open cage push button >decalcify. Push 2nd button >initiate regeneration.

# Over 300,000 heart valve replacements are completed each year. Over 12 million people worldwide have calcified heart valves.



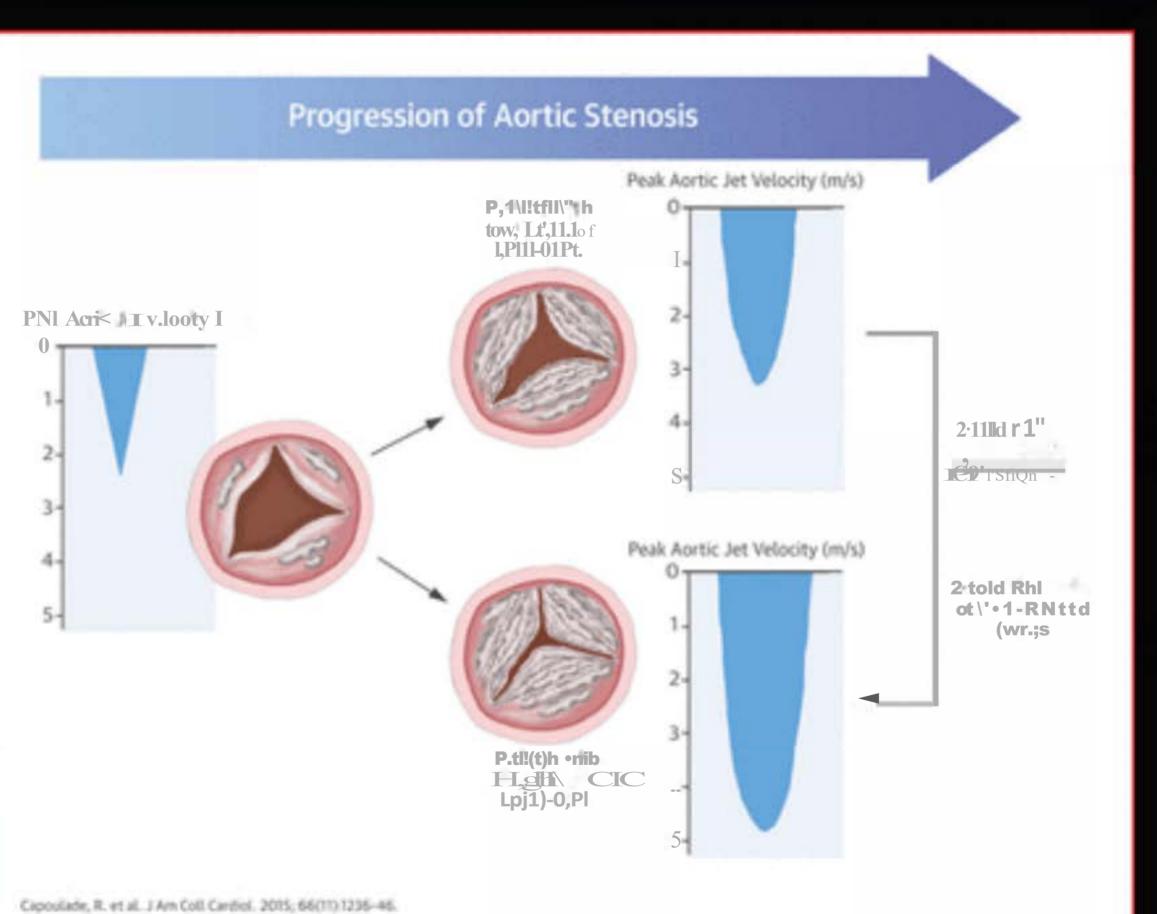
### **Progressive Risk Factors to Disease**

Metabolic Syndrome Obesity Hypertension Smoking Renal Failure Hyperlipidemia Male Gender Oxidative Stress Age

Normal Aortic Valve



#### **Calcific Aortic Valve Disease**





## Valvublator

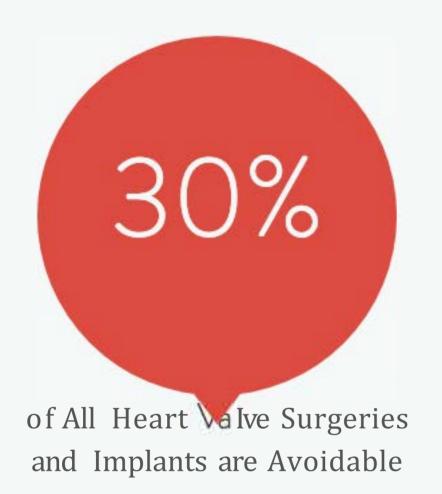
The New Paradigm in Heart Valve Care



You don't wait until your teeth are falling out and you need an implant to go to the dentist. Why wait until you need an implant to get your heart valves rejuvenated?

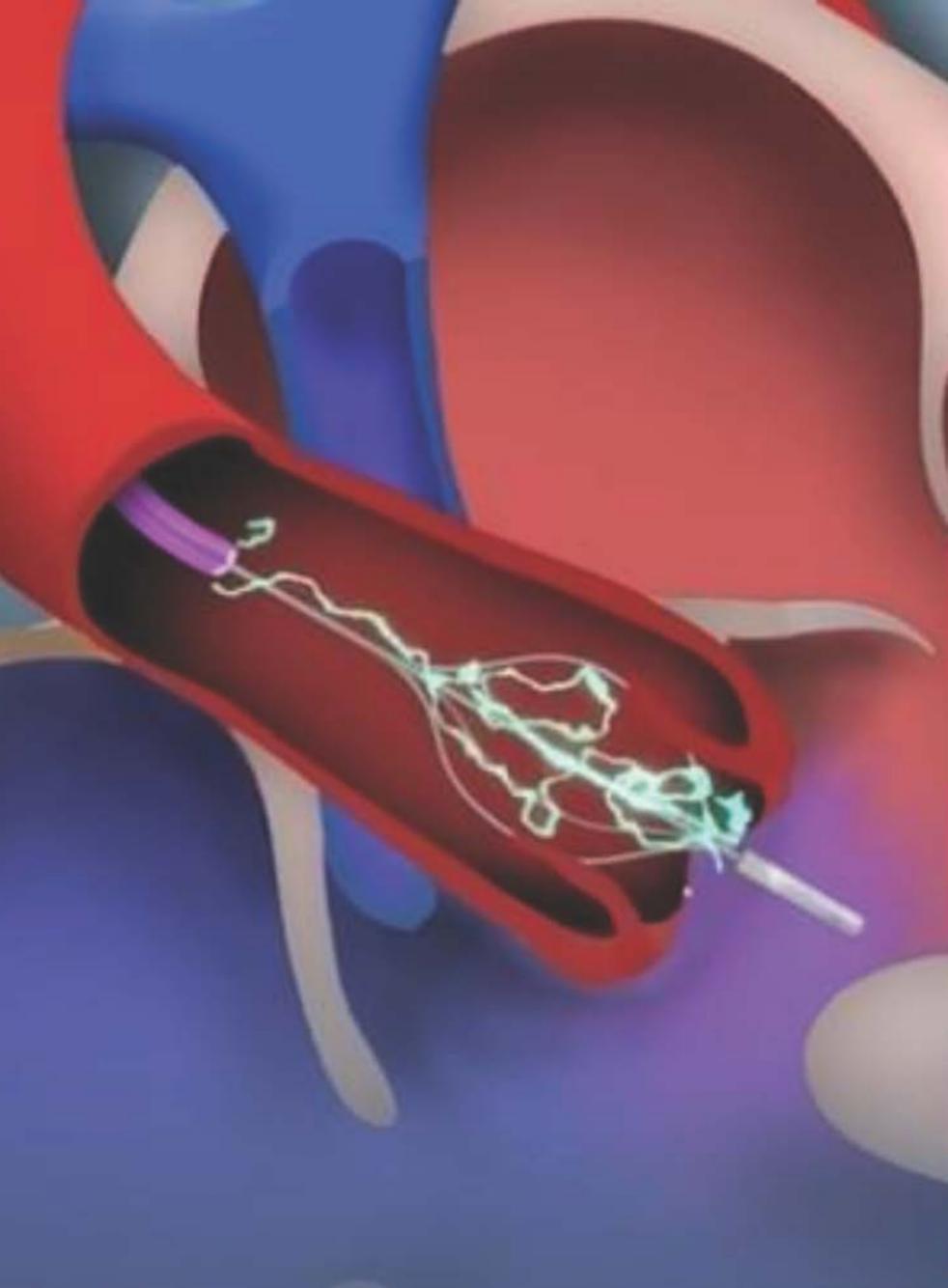
"It is better to keep your own heart valve then to get an implant" Dr. Domingos Moraes Cardiac Surgeon

### Heart Valves Should Be Regenerated NOT Replaced!

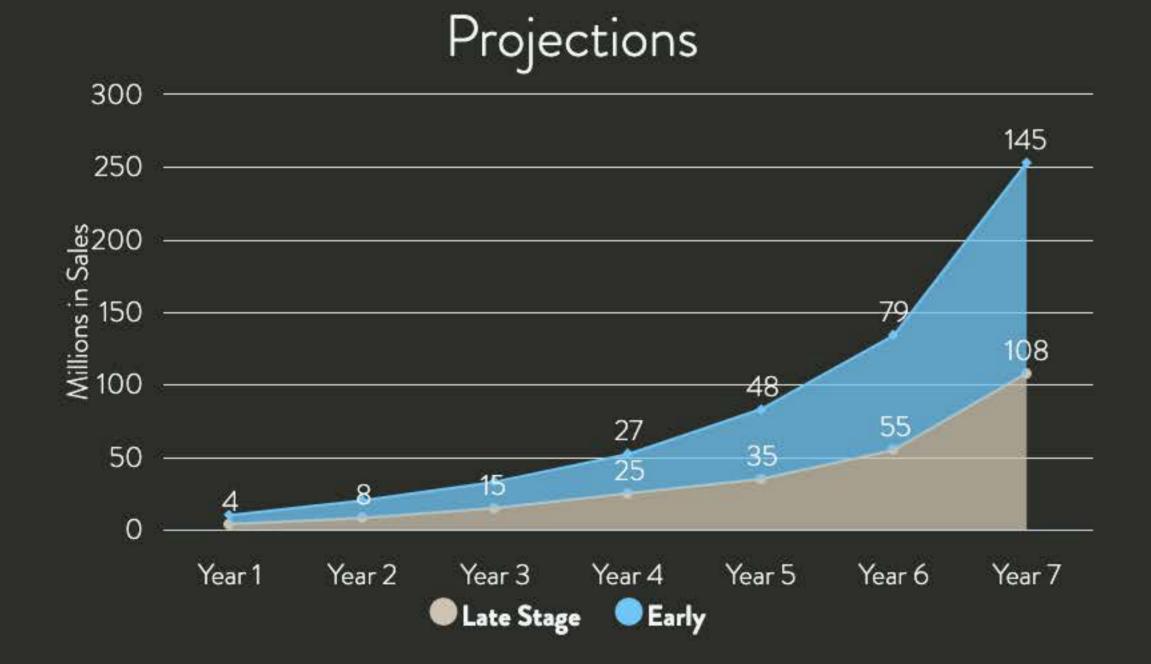


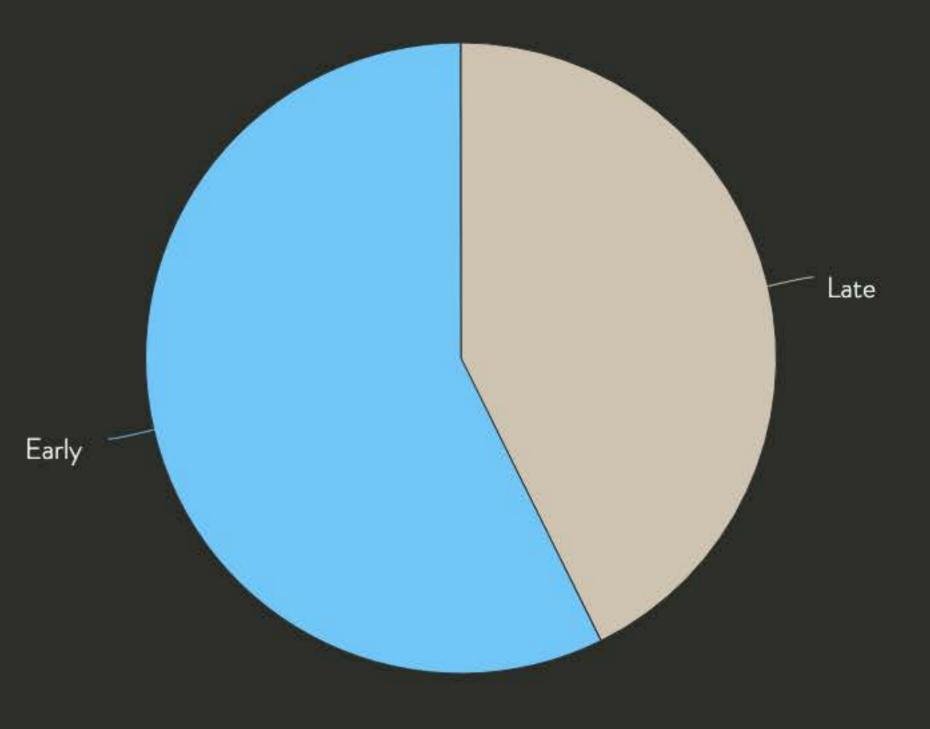
,, You are always better off keeping your own heart valve

Dr. Domingos Moraes, Heart Surgeon



# Revenue Growth First 7 Years Post Market Approval









USD \$9.83 billion is the projected heart valve market for 2023 not even considering the totally unmet market of early rejuvenation.

Source: <u>ResearchandMarkets.com</u>

### **Problem**

Artificial heart valves re-calcify or require blood thinners. Placement has other associated risks (see below).

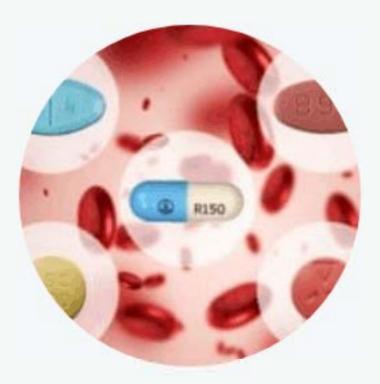
Percutaneous heart valve complications include <u>major/minor</u> **<u>stroke</u>**, life-threatening and major bleeding, vascular injYry., Stage 3 kidney. disease, new p.acemaker imp.lantation, and p.erivalvular leak



Biological heart valves

re-calcify in 3 to 10 years

Problem 1



Problem 2:

Steel heart valves

require blood thinners

# Features of Valvublator

- 1. Easy to use.
- 2. Decalcifles heart valves quickly.
- 3. Regenerates heart valves.
- 4. Prevents re-calciflcation.

Via small puncture in groin valves are decalcified and regenerated within minutes. Simply followp periodic infusions and non-invasive electric stimulation controlled relase of klotho (patent pending) prevents re-calcification.

#### Note- Designed p..erf.ormance claims intended not y.et p..roven in studies.

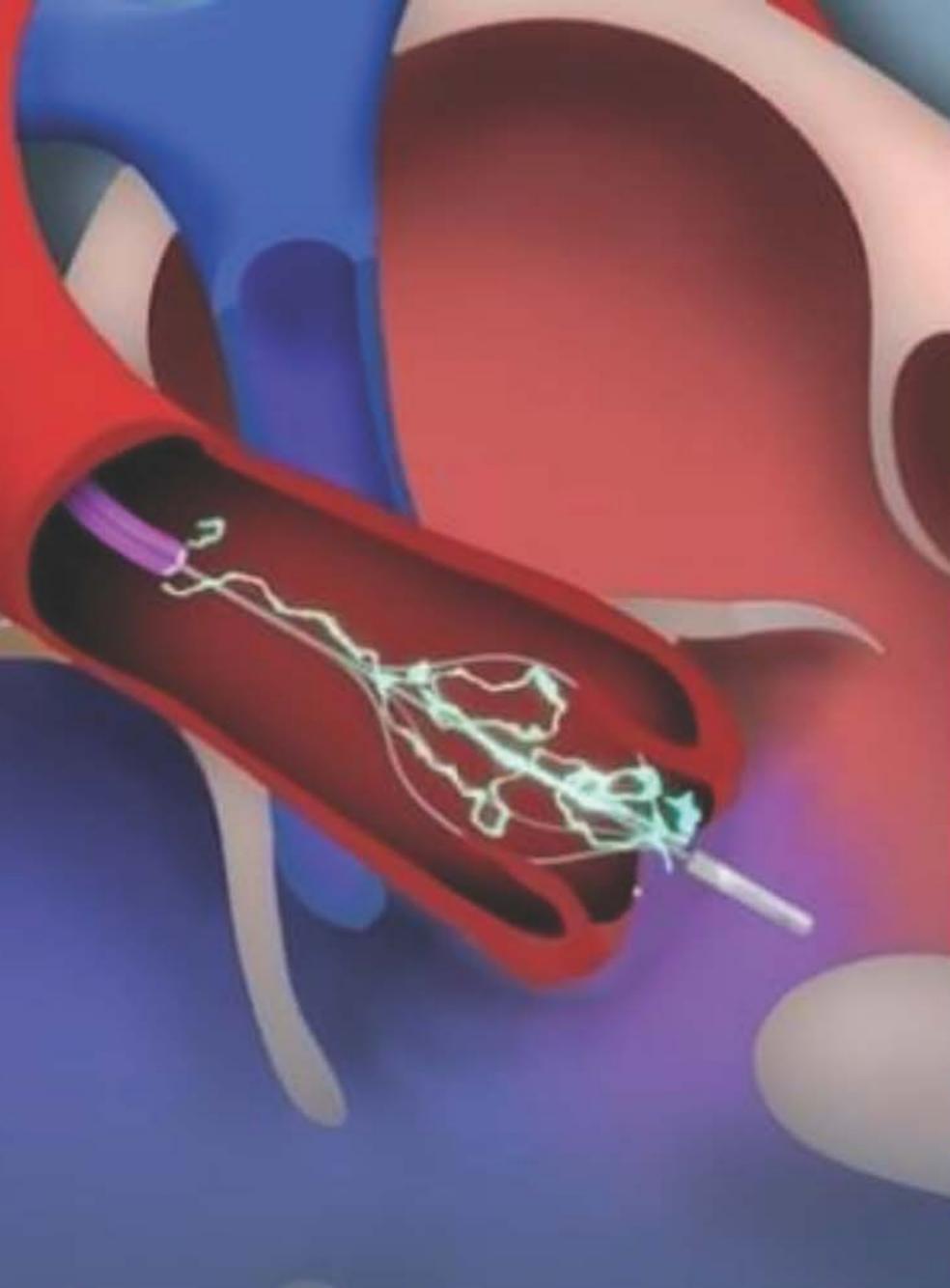


# Valvublator

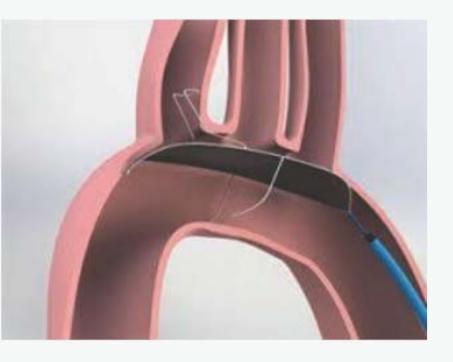
#### Simple to Use



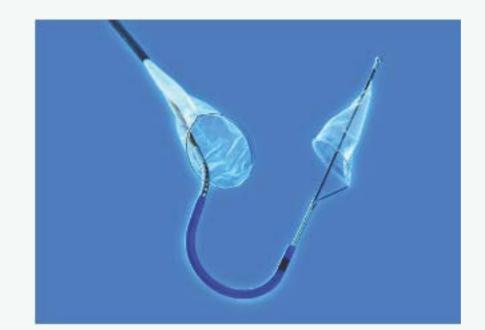
In place within minutes.

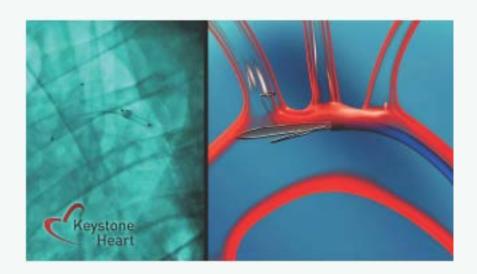


# FDA Cleared Embolitic Protection Device Use is Mandatory in Every Valvublator Case.



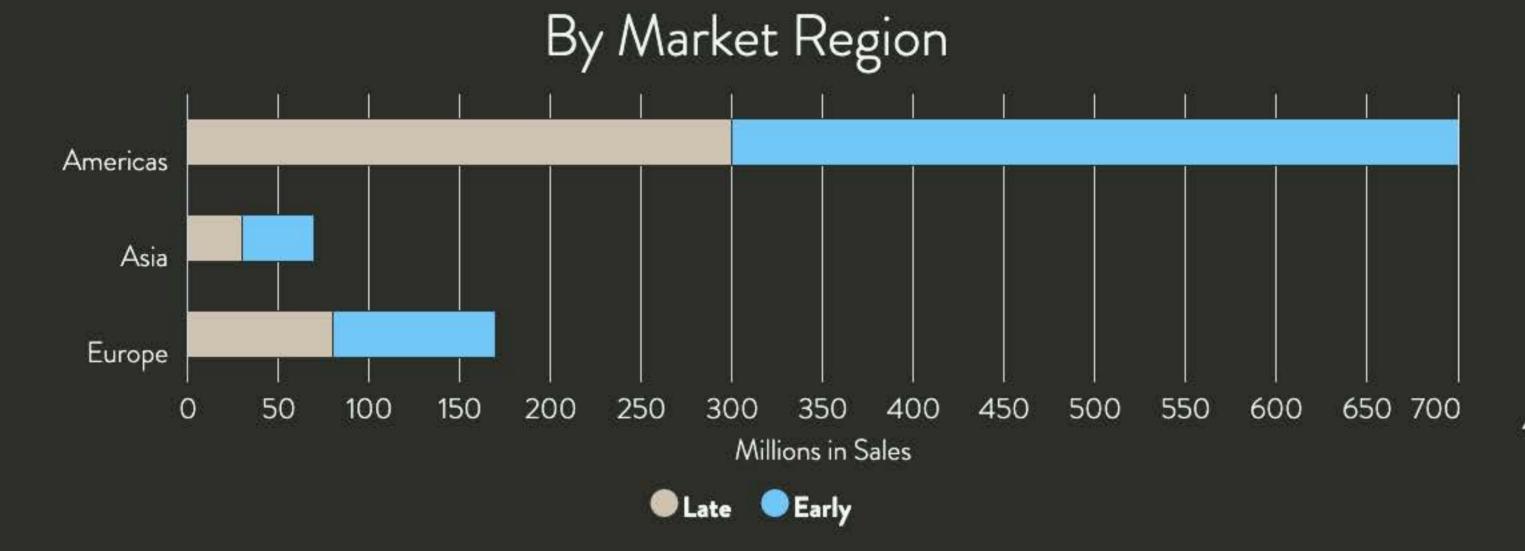






# **Business Model**

- Early Stage Intervention
- Late Stage Intervention



#### The Americas will be the lions share of the market for this product due to high pricing strategy \$23K.

# \$23,000

#### Per Patient

Average Revenue per Patient to Company

# Highlights

Simple Method to **Regenerate Heart** Valves

#### EASY PLACEMENT QUICK

Easy to place via small puncture in groin.

**DE-CALCIFICATION** SIMPLIFIED

De-calcifies heart valve in minutes.

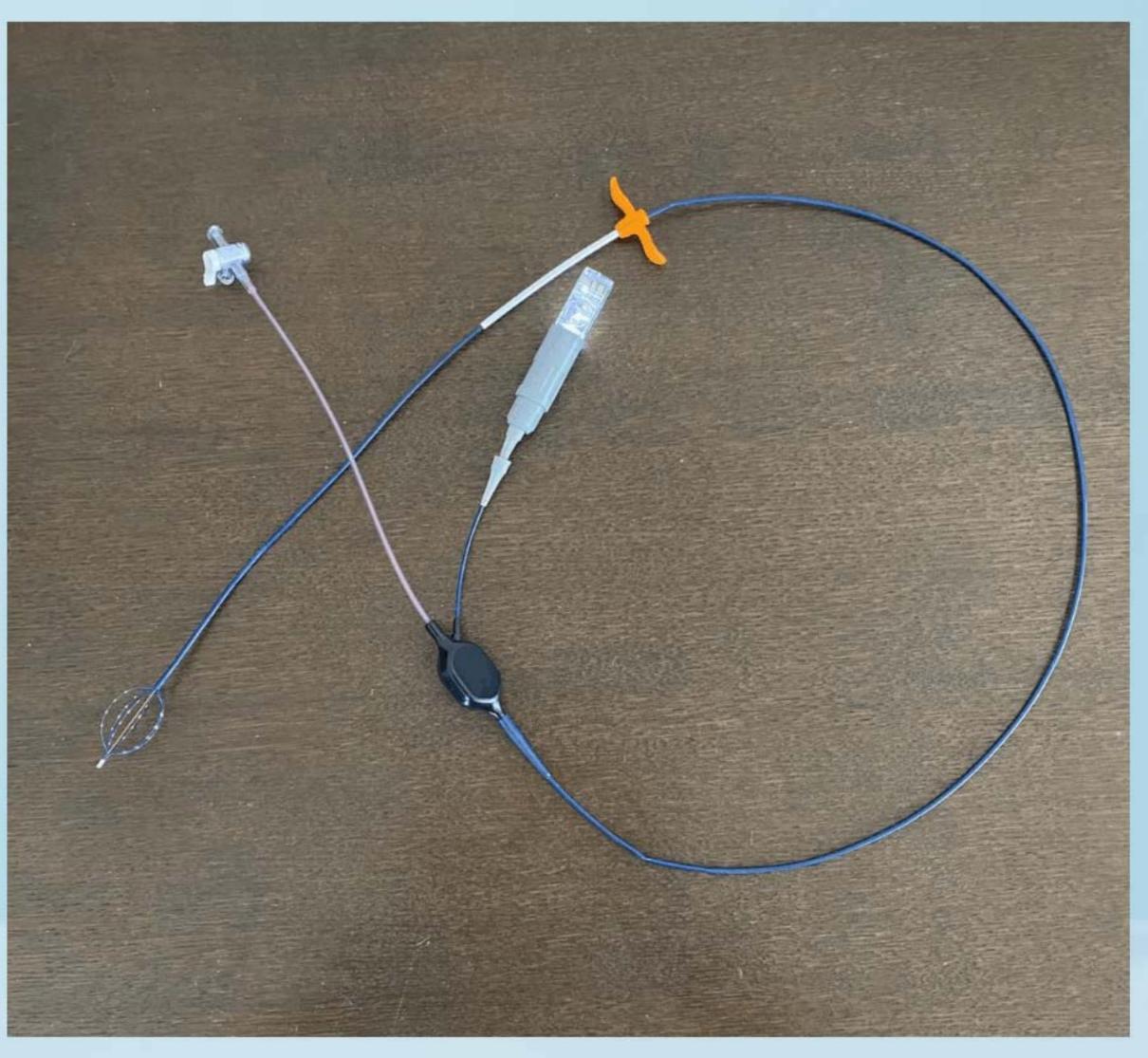
Valvublator the first and only heart valve regeneration system.

Transapical (access through tip of heart)

#### **REGENERATION STARTS** WITH ONE CLICK

Simple one b'utton click to In1t1ateregeneration

Transfemoral access through femoral artery)



Valvublator 11Catheter Adapted from Oscor Medical EP Basket Catheter



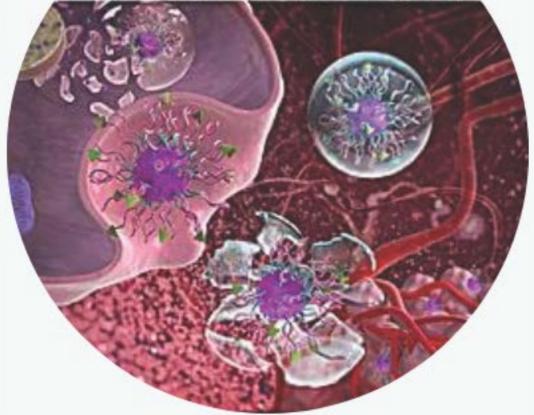
Conductive electrodes deliver patented and patent pending bioelectric signaling sequences designed to promote heart valve regeneration and prevention of recalcification.

### Prevention of Re-Calcification

#### Two proprietary technologies



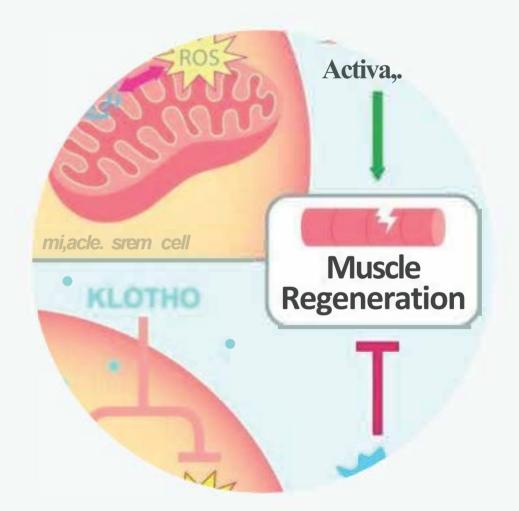
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#### **Periodic infusions of Elastrin Therapeutics Nano-particles**

Animal study data available upon re9uest.

Elastrin Therapeutics nanoparticles and klotho have both been demonstrated in animal studies to reduce calcification. The Valvublator team has an exclusive option or license to pioneering IP related to both.



#### **Non-Invasive Bioelectric Stimulation Controlled Klotho Release**

Site-specific chelation therapy v, ith nanoparticles reverses calcification Abstract - In this study, we tested a targeted nanoparticle-based EDTA chelation therapy to reverse CKD-associated MAC. Intravenous delivery of DiR dye-loaded nanoparticles confirmed targeting to vascular degraded elastin and calcification sites within 24 hours. Next, EDTA-loaded albumin nanoparticles conjugated with an anti-elastin antibody were intravenously injected twice a week for two weeks. The targeted nanoP-articles delivered EDTA at the site of vascular calcification and reversed mineral deP-osits without anx untoward effects. Systemic EDTA injections or blank nanoparticles were ineffective in reversing MAC. Reversal of calcification seems to be stable as it did not return after the treatment was stOP-P-edfor an additional four weeks. Targeted EDTA chelation theraP-Y. successful lx reversed calcification in this adenine rat model of CKD. Sci Rep 9, 2629 (2019) doi: 10.1038/s41598-019-39639-8

# Founding Team

Proven veteran leadership

Howard J. Leonhardt

ExecutiveChairman, CEO

Inventor 22 issued U.S. patents, patented and developed first percutaneous heart valve and leading stent graft system. Led team that completed first nonsurgical heart regeneration.

Dr. Leslie Miller

241 publications, 80+ clinical tria Is, Cardiologist, Co-Editor leading text book on cardiovascular and heart regeneration.

#### Chief Medial Officer

Dr. Brett Burton

#### Vice PresidentR & D

PhD Bioengineering, 8 years experience

# Founding Team

Proven veteran leadership





Dr. Mark Cunningham,

#### **Board Director, Chief Technology Officer**

CardioThoracic Surgeon U.S.C. Keck Medical Center, Director Heart Valve Program, Degreed Engineer, 25 years experience

Former Director Cardiology Minneapolis Heart Institute and Cedars Sinai Hospital Los Angeles, Current Chair and Medical Director Christ Hospital Cincinnati, Leading heart regeneration investigator, 30 years experience

Dr. Tim Henry

#### **Chief Interventional Cardiology** Advisor



Kapil Sharma

#### **Director Bioengineering**

M.S. Bioengineering, 5 years experience, multiple startup launches

# Valvublator is being Developed in Collaboration with Oscor Medical





Deflecting tip catheter

Bleeding prevention introducers



#### PACE 101H

40 Years Bioelectric Stimulation Experience

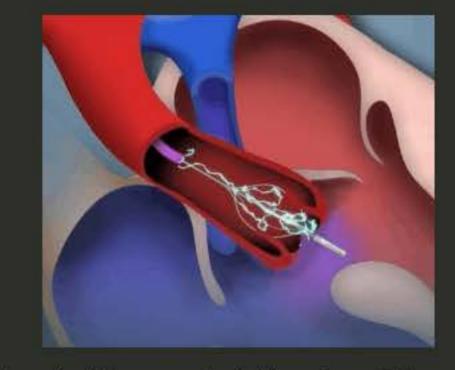


# Highlights

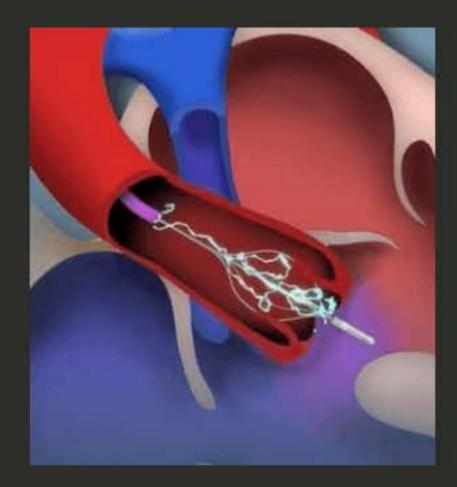
Simple Method

to

De-Calcify and Regenerate Heart Valves



Simple Ultrasonic Vibrational Energy Decalcification

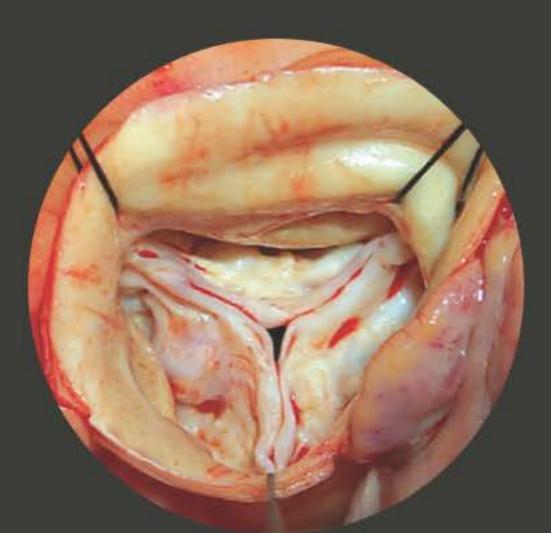


# Heart valve ultrasonically cleaned in minutes.

Simple **Bioelectric Energy** Driven Release of Regeneration Promoting Proteins including Stem Cell Homing Factors, Klotho, Tropoelastin and Follistatin

# Target Market

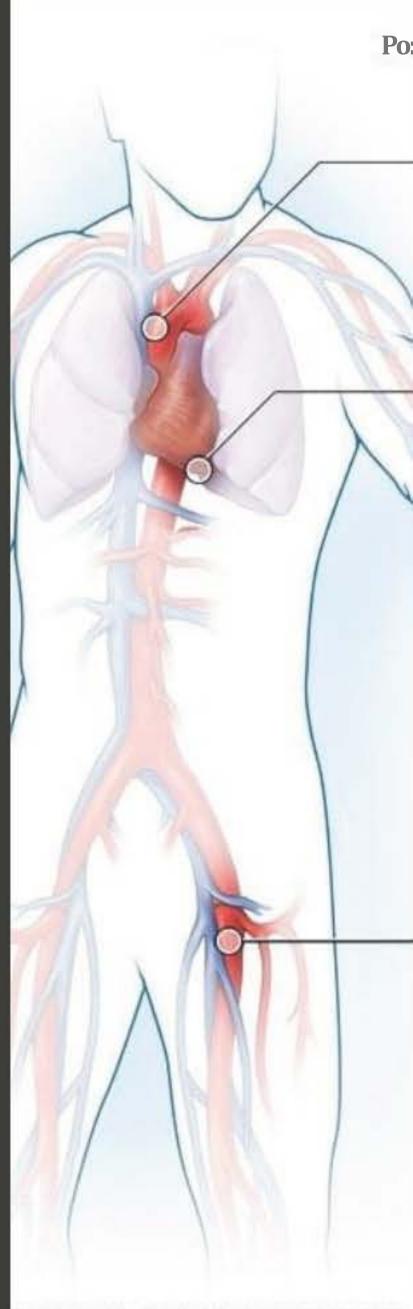
#### Interventional Cardiologists



Early Decalcifying and Regeneration to Avoid Future Need for Implants



Late Decalcification and Regeneration to Avoid Immediate Imminent Surgery or Implant



EDUCATION AND RESEARCH. ALL RIGHTS RESERVED.

## Market exceeds \$10 billion



Total Addressable Market

Million

Min. Capital Needed to Get to First in Human Studies

Sources: European Heart Journal

Transapical (access through tip of heart)

# 15%

Expected Annual Growth Rate of Market

> Transfemoral (access through femoral artery)









Build and test prototypes in lab. File patents.

Complete large animal studies and surgical feasibility study.

Complete first in human studies



Secure strategic partnership.

# Rough Budgets 4 Year



2020

2021

Build and test prototypes in lab. File patents.

BUDGET = \$500,000

Complete large animal studies and surgical feasibility study.

BUDGET = \$500,000

**Complete first in human studies** BUDGET = \$2,500,000



2022





Secure strategic partnership.

BUDGET = \$750,000

# Valvublator 2019-2023



63X ROI

Team focused on completing large animal studies followed by first in human studies.

Target goal is very difficult to achieve 63X ROI for Seed Round Investors

The Valvublator core team has brought other technologies from concept to market leadership in the cardiovascular space and believes they have a reasonable chance to do it again.

The goal of seeking 63X ROI will be very difficult to achieve but if the technology works as intended the market size is there to justify a high valuation. There will be many obstacles to overcome to reach this high goal.

### **Financial Details**

- 3,000,000 total shares authorized.
- Current share price = \$1 per share. Valuation \$3 million.
- Raising \$1 million in four \$250K tranches.
- Legal structure Licensable Technology Platform (LTP) within the Leonhardt's Launchpads accelerator until startup is ready to be self reliant financially. At which time will it be converted to a C corporation. Capital may only be raised via the accelerator at this time.
- The accelerator has filed a Form D part c permitting public advertising of offering limited to verified accredited investors.
- Price per share will rise as milestones are reached.
- Successful prototype lab tests = \$2 per share
- Successful large animal studies = \$25 per share
- Regulatory clearance to begin clinical studies = \$35 per share
- Successful first in human studies = \$63 per share
- Successful prevention re-calcification = \$140 per share.
- Minimal estimated budget to get up to regulatory filings for first in human studies= \$1 million (highly subject to change)

#### Patents & Patents Pending



- &PDGF

- 1nvas1ve.

# • Bioelectric signaling stem cell homing via SDF1

• Combination ultrasonic cleaning and bioelectric regeneration catheter.

• Chelation nanoparticles for preventing re-

calcification + combination therapies.

• Citric acid sprayer for dissolving calcification.

• Bioelectric klotho expression for regeneration AND prevention of calcification > non-

• 30 bioelectric signaling sequences for regeneration promoting protein expressions.



#### Valvublator

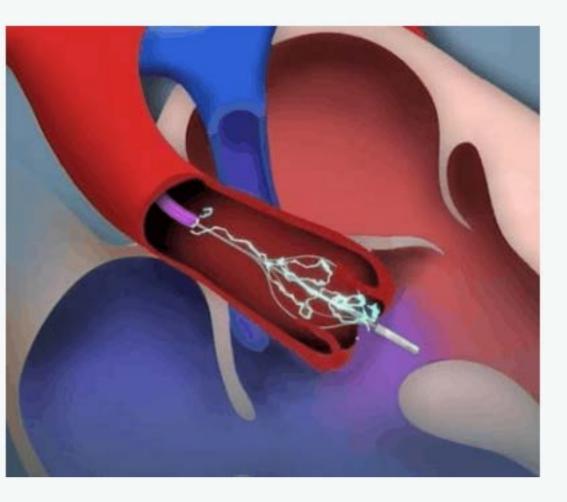
www.valvublator.com



#### email: <u>howard@leonhardtventures.com</u>

• Simple re-calcification prevention.

Business model = secure strategicpartnership after firstin human studies.



#### • Simple heart valve decalcification.

• Simple heart valve regeneration.

# Risk Warnings & Disclaimers

 Product is not y.et p..roven eithersafe or eff\_ective. Patents p...endingmay. not be issued. **Product may be found to infringe other patents.** Patents licensed or optioned may not be maintained. Comp.any. lacks sufficient resources in all forms to bring\_p..roductto clinicalt • Founding team has many other obligations which reduce focus on this project.

#### longerb many. y.ears.

- As an investment this is in the highestrisk category fortotalloss. Chances of blockbustersuccess statisticall are very.very.low.
- Investment is only possible through Cal-X Stars Business Accelerator, Inc. OBA Leonhardt's Launchpads.
- Other rms have substantiall higherbudgets than those we have forecasted.

No other company has succeeded in de calcifying or regenerating heart valves

• All forward looking statements are subject to change without notice. Timeline