

Epicardial HIFU For Treating Atrial Fibrillation

Jack Sliwa
Senior Director Of Applied Research
AF Division / SJM

And many others

March 21, 2007
UIA / NPL Joint Meeting-London

Rev 022307

Atrial Fibrillation (AF), what is it and how is it treated-Slides 3,4

Gradient Energy vs. Focused Energy-Slides 5,6

Potential benefits and challenges of HIFU for AF-Slide 7

HIFU for AF, Commercial history-Slide 8

Epicor HIFU, Current experience-Slides 9,10

The Epicor Ultracinch™ and Ultrawand™ disposable devices, ACS Console and Insertion/Sizing PAS Device-Slides 11-18

The Epicor Transducer-Slides 19-24

Movie: Animation of the Epicor Procedure (x min, if time allows)

AF, What Is It And How Is It Treated

Atrial Fibrillation is a heart rhythm irregularity, one of several possible types, which is caused by aberrant electrical circuits in the heart

AF is often a byproduct of thickening heart muscles due to other problems such as failing valves-thus it is often one of several presenting problems

Drugs, including anticoagulants, are usually tried first. They may not work at all and their benefit may also wear off. Drug side effects can be of concern. AF invites blood clots in stagnant regions of flow.

RF catheter ablation, as practiced by an electrophysiologist, has been the most commonly used device intervention for the last 15+ years. RF ablation uses a disposable RF catheter threaded through the body lumens into the heart. There the RF energy burns dots or lines to create thermally necrosed lesions aimed at breaking the aberrant circuits. Hours of electrical mapping and fluoroscopy exposure are typically required.

AF, What Is It And How Is It Treated

- * Thermally necrosed lesions, in general, can be made using heat, cold or chemicals. These lesions are electrically nonconducting and become mechanically compliant scar tissue.
- * Heat-based lesions can be made using RF, microwave, ultrasound and laser devices.
- * Cold-based lesions can be made using cryogenically cooled devices
- * Chemical lesions can be made as by injecting an alcohol (other organs)

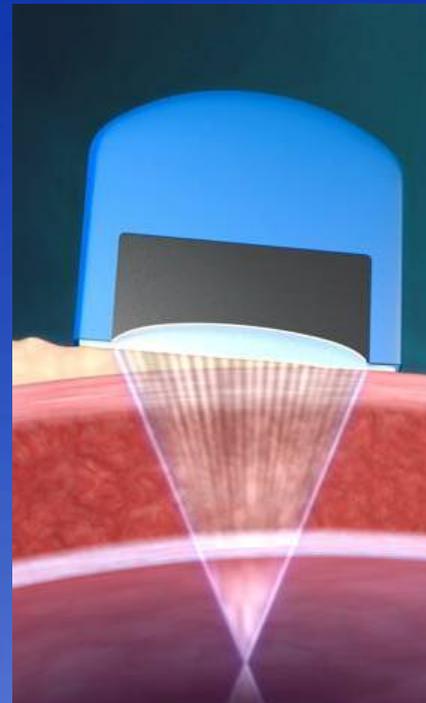
- * Thermal lesions are usually formed in the Cox-Maze manner- a network of intersecting linear lesions is created near and around the pulmonary veins to break the most-likely expected aberrant circuits

- * Most recent lesion sets are subsets or approximations of the original Cox-maze scalpel lesion set

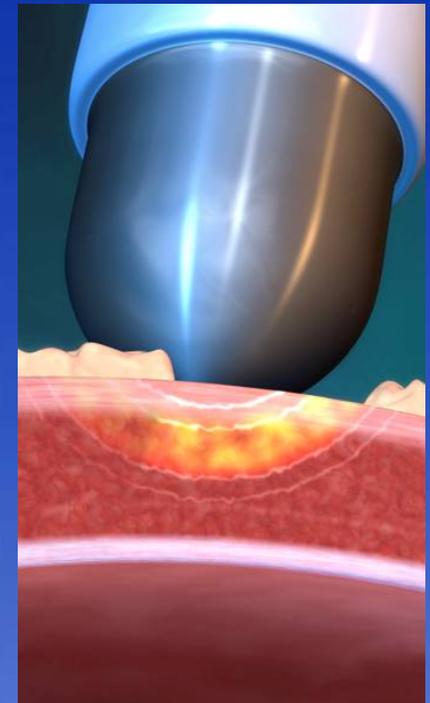
Gradient vs. Focused Energy

Gradient Energy Application Using Thermal Conduction

- Gradient energies are energies transported completely (Cryo) or partly (RF) by a temperature gradient. They:
 - Deposit or remove heat from a point or primarily from the near surface
 - Make lesions with widths comparable to their depths
 - Can't be concentrated at-depth
 - Can cause tissue disruptions (endocardial RF)
 - Can damage coronary arteries
 - Can't be aimed in a direction
 - RF success rate is 26-90% depending on criteria. Lower success rates correspond to most rigid criteria. Many procedures are redone at least once.



HIFU



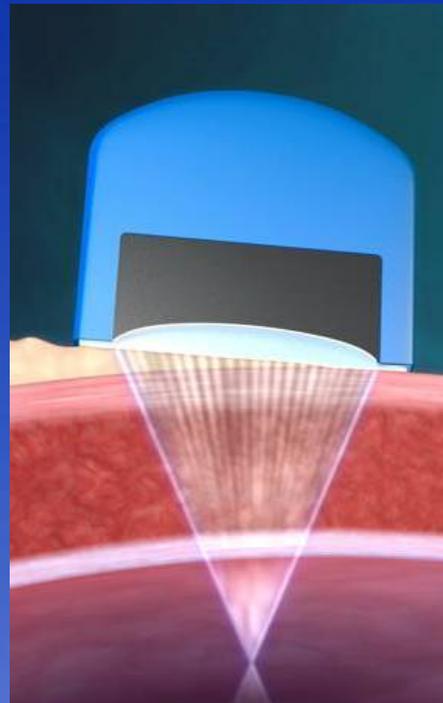
Gradient Energies

Gradient vs. Focused Energy

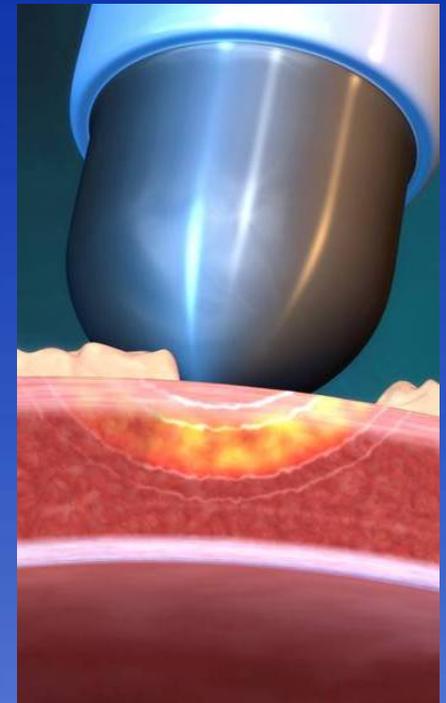
High Intensity Focused Ultrasound (HIFU) via Directed Ultrasound Beams

HIFU energy allows:

- Transmural ablation through cardiac fat or tissue as thick as 14mm with minimal cardiac functional loss
- Ablation without damage to coronary arteries or delicate endocardial tissue
- Deep lesions can be made faster
- Lesions can be oriented in a direction if that is beneficial



HIFU



Gradient Energies

 ST. JUDE MEDICAL

Potential benefits and challenges of HIFU for AF

Can form deep and narrow lesions while minimizing functional loss

Can necrose cardiac tissues epicardially or endocardially without fat trimming or fat popping

Can avoid damaging endocardial surfaces-no char, no clots...

Can avoid damaging cardiac arteries

Could utilize transducer(s) to provide ultrasonic feedback or images

Could be mechanically or phased-array steered if necessary

Lesions formed with the Epicor Cinch typically don't require electrical mapping thereby saving hours of surgical time.

Making a complex disposable at an attractive cost requires true R&D/Mfg teamwork

Technology is new to practitioner and sales force- training required

HIFU for AF, Commercial History

At least one former and one current endo HIFU catheter have been demonstrated by two different commercial entities

Both of these catheters utilize(d) inflatable liquid/gas double balloons as acoustic mirrors and tubular PZT elements to burn annular lesions in the entrances to the four pulmonary veins.

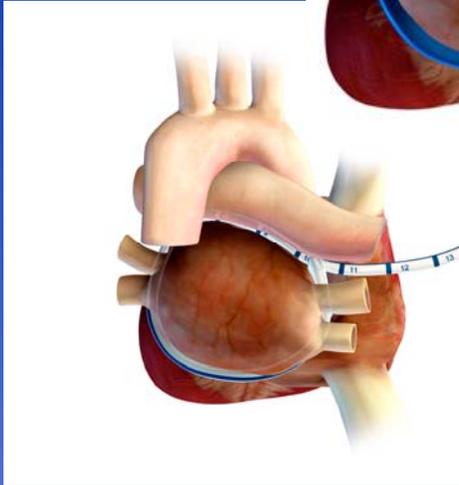
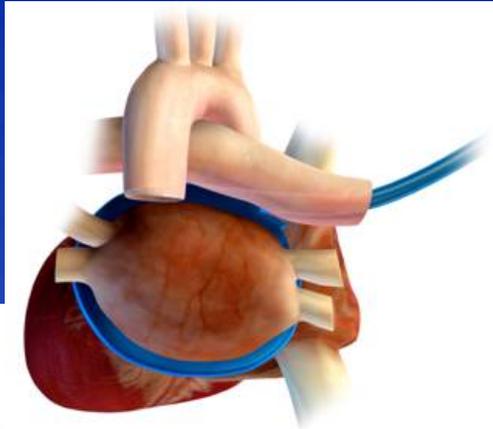
These devices have two difficult anatomical challenges:

- 1) They are of regular shape and the anatomy isn't-several implications
- 2) They must avoid burning the esophagus and other critical nearby organs as has been shown to be possible. Such unintended injuries can be quite dangerous.

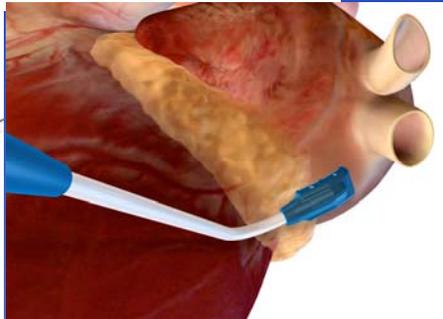
The currently operating entity is doing an FDA trial now. The jury is still out.

The Complete Epicor™ System

UltraCinch™ device



PASTM System



UltraWand™ device



Ablation Control System (ACS)

Epicor HIFU, current experience

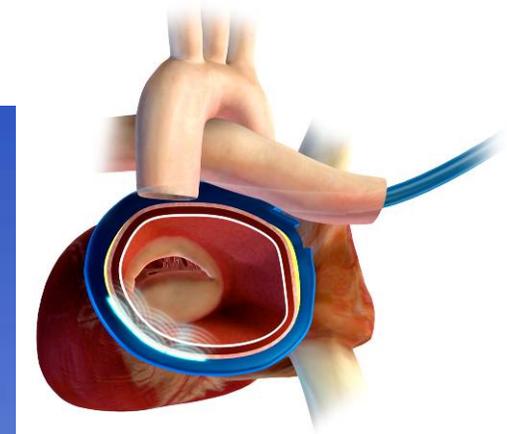
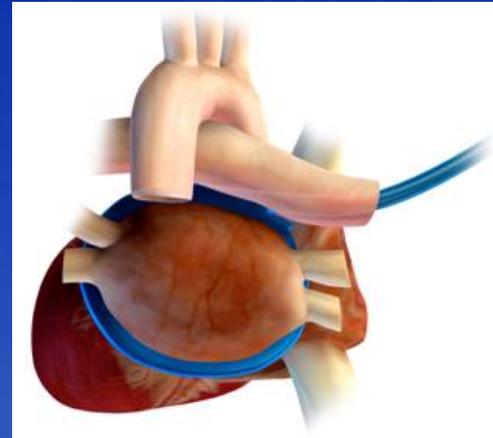
The Epicor device(s) create a version of the Cox-Maze lesion set as follows:

- a) Formation of an encircling closed-loop lesion using the Ultracinch™ disposable belt. This device uses 7-13 cylindrical PZT/ML transducers abutted end to end.
- b) Optionally, an additional connected lesion segment is formed using the Ultrawand™ wand disposable. This device uses 2 of the same type transducers.
- c) The transducers all run a multistep multifrequency algorithm which provides transmural lesions in typical cardiac tissue ranging in thickness from 1.5 mm to 10 or more mm around the closed loop path. Some parallel operation is used. All tissue thicknesses receive the common algorithm.
- d) Overlying fat is not a major issue as it can be for epicardial RF
- e) Transducers are water-cooled and tissue-coupled with slowly flowed saline and individually temperature monitored
- f) Open Chest and Minimally Invasive approaches
- g) Cinch and wand products FDA approved and on the market inside and outside US

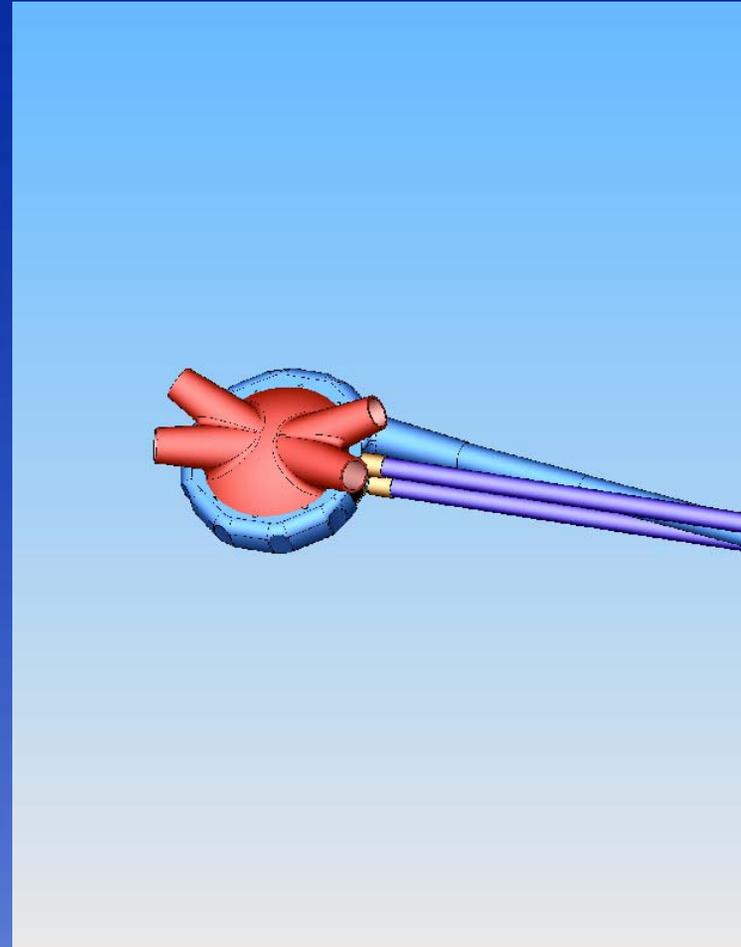
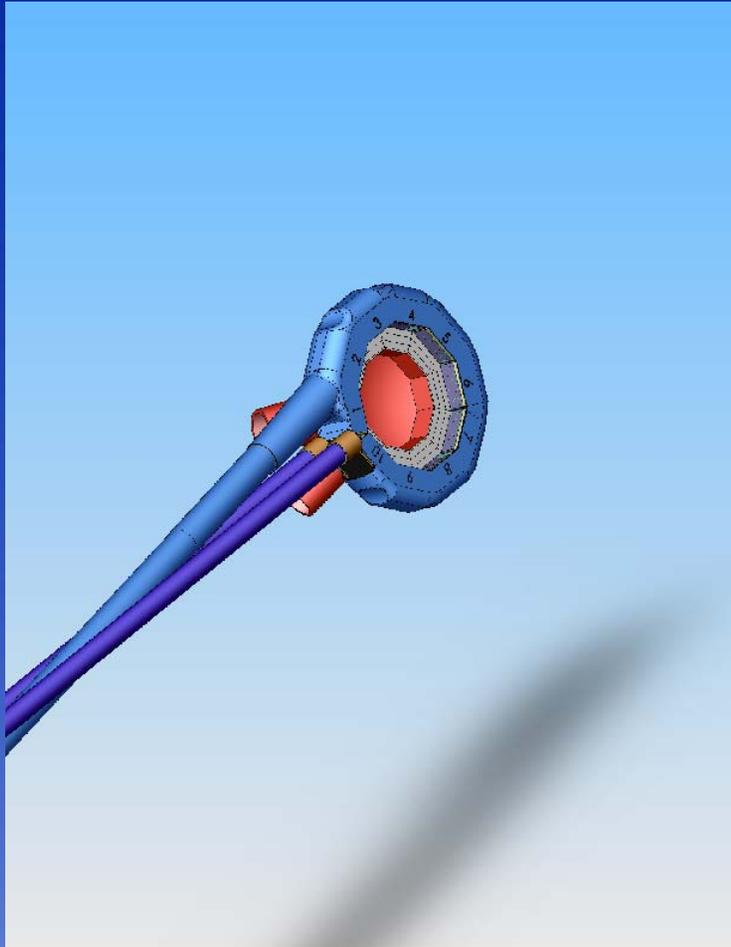
The Epicor™ Belt or Cinch

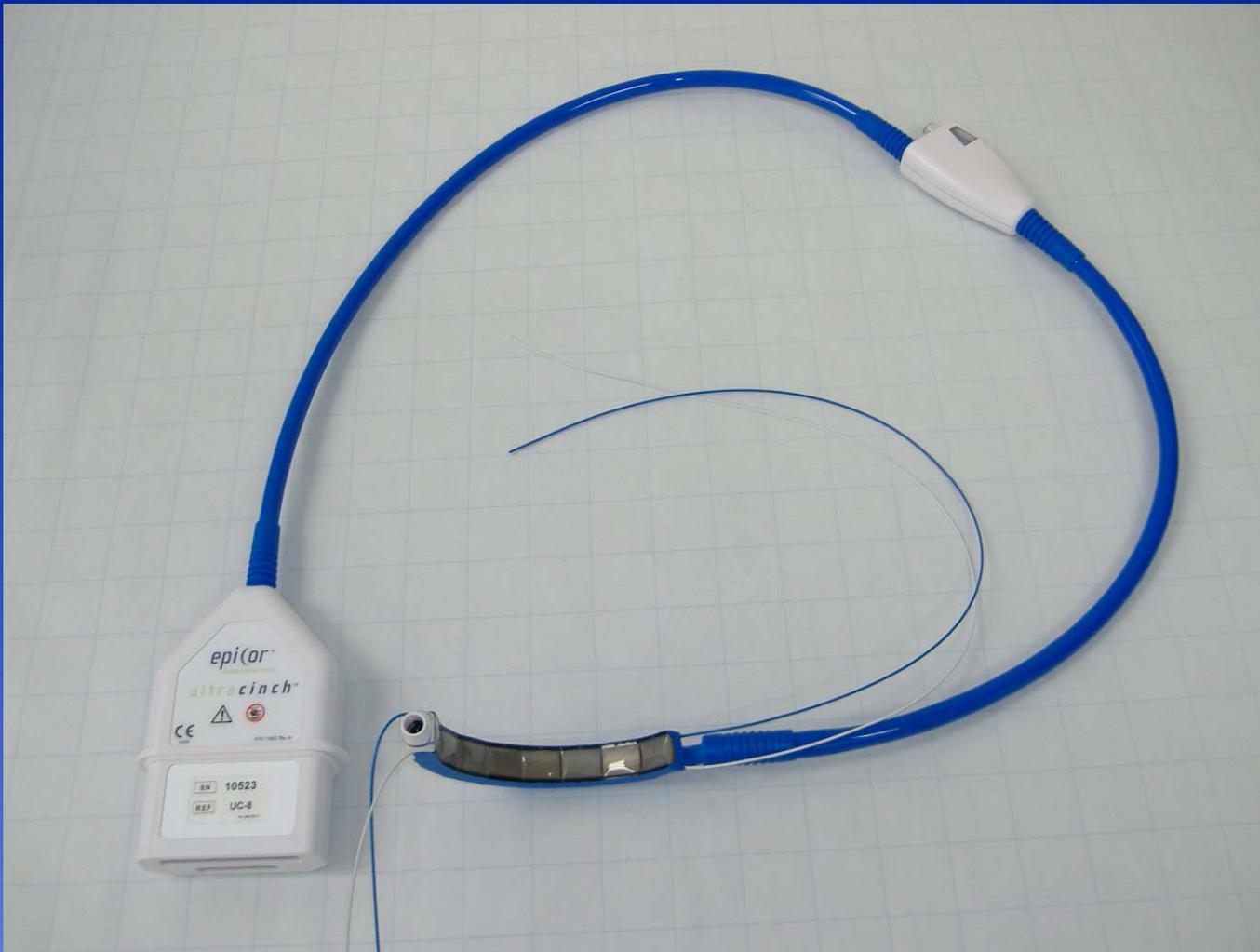
UltraCinch™ Ablation Device

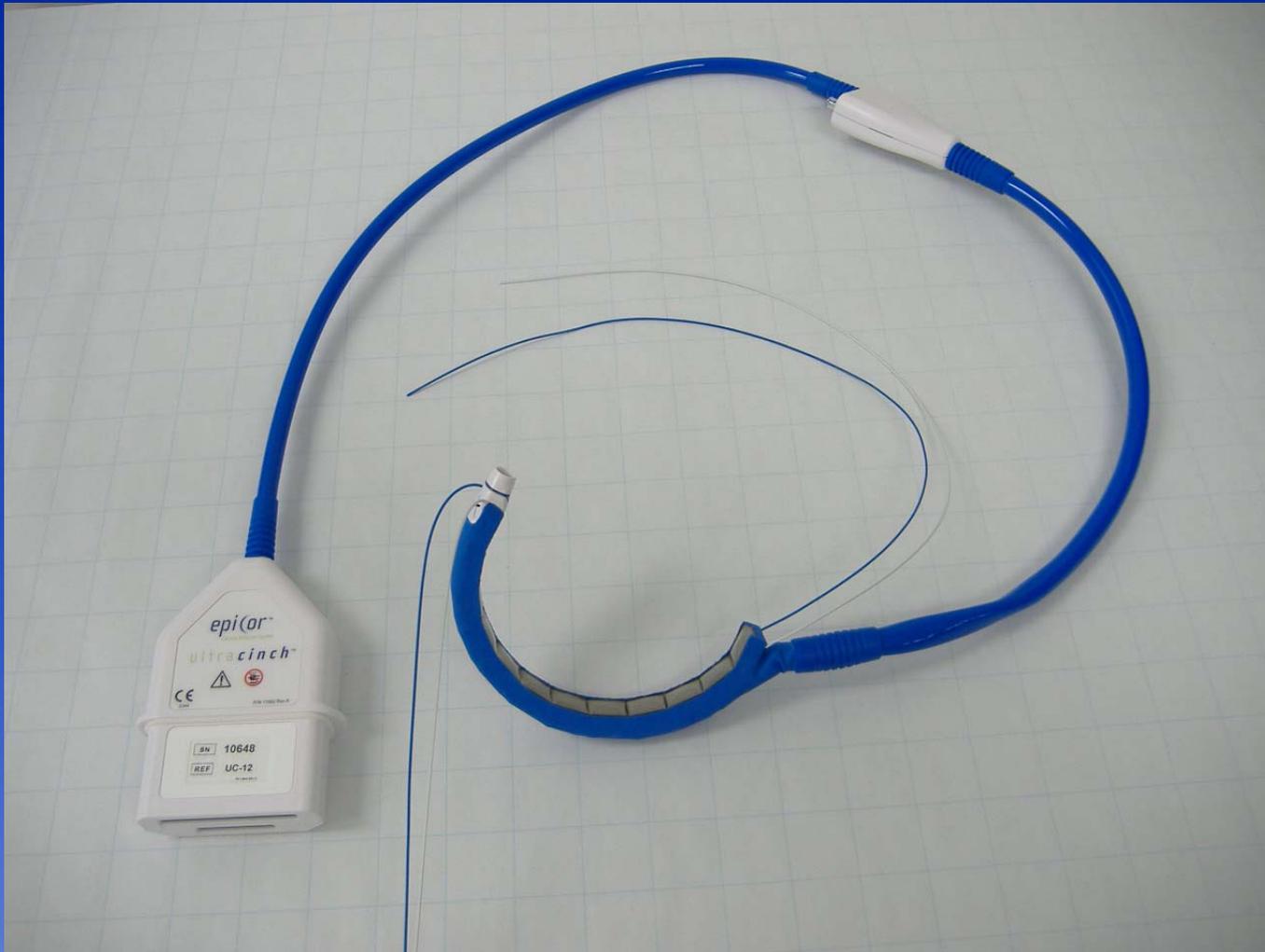
- Linear string of ultrasound transducers, 10 typical, wrapped around heart
- Single step Pulmonary Vein Isolation (PVI)
- Off-pump, epicardial energy delivery
- Continuous encircling transmural lesion
- Stable natural positioning reduces risk of collateral damage
- Downbeam blood pools a safety advantage
- Multiple sizes (7-13 cells) to fit individual patient's anatomy



Ultracinch™ Deployed State





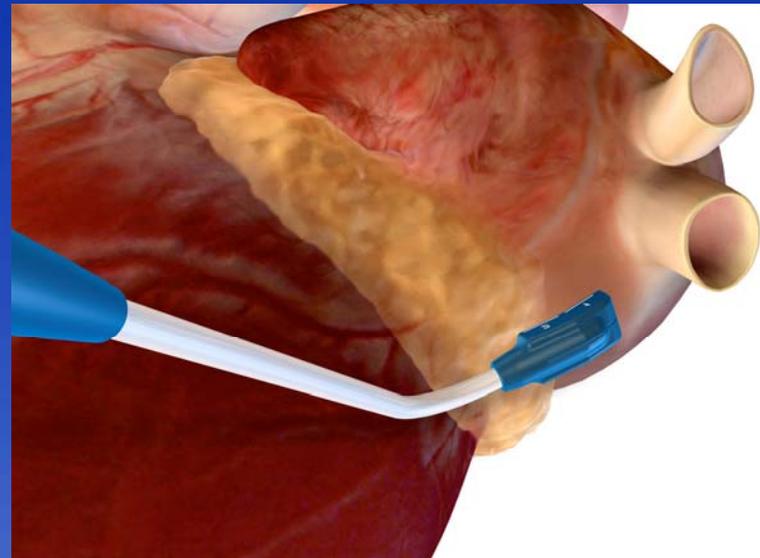


The Epicor™ Wand

UltraWand™ Handheld Ablation Device

Malleable shaft with two transducers

- Creates focused lesions complementing UltraCinch PVI lesion
- Operation similar to Ultracinch™



The Epicor™ System Console (ACS)

Ablation Control System (ACS)™

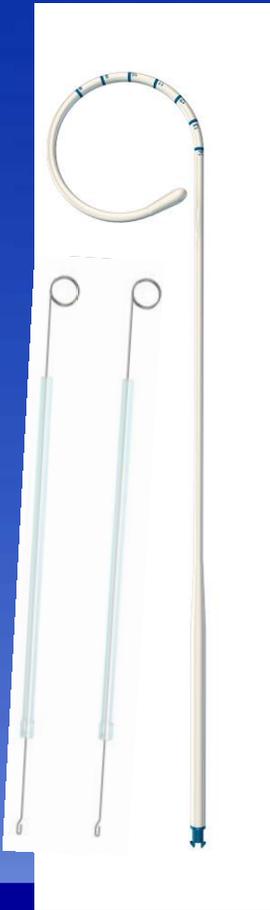
Energy delivery system and user interface

- Preprogrammed multistep algorithm
- Single button operation to run full algorithm
- Real time ablation monitoring and control with safety shut-off, temp monitoring, saline monitoring
- Scalable platform for future system and software upgrades
- Miniaturized RF subsystems
- Procedure data recording
- Customizes driving to take into account transducer to transducer variations using EEPROM data

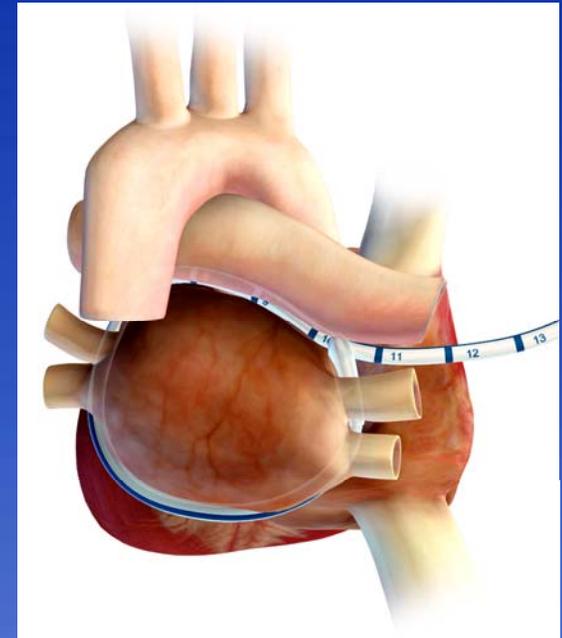


The Epicor™ System

Positioning and Sizing (PAS)™ System



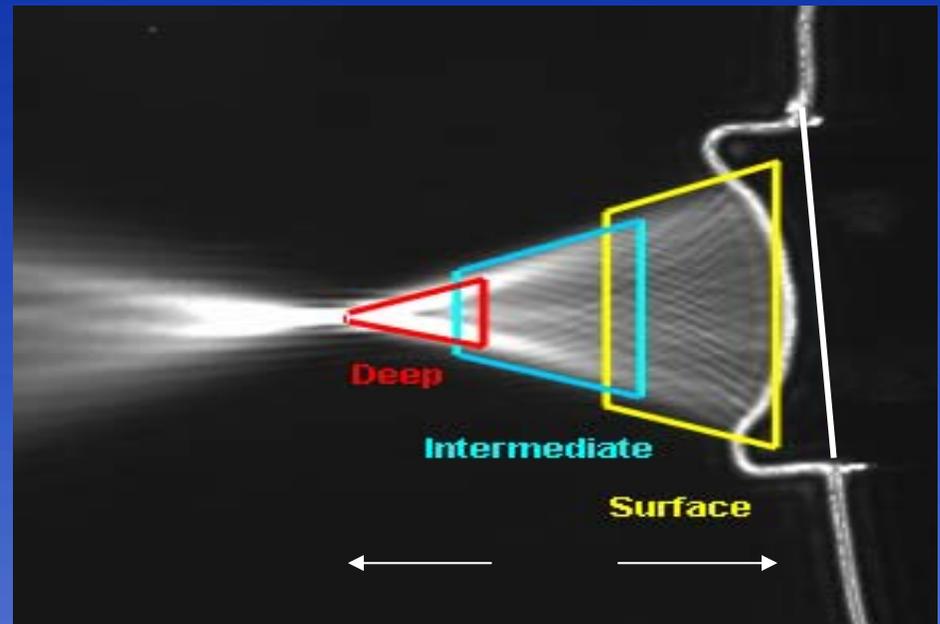
- Tracks through transverse and oblique sinus
- Assures proper sizing of UltraCinch™ device
- Transitions UltraCinch™ into proper position
- Facilitates small access approaches
- Tourniquets secure UltraCinch™ and prevent device migration

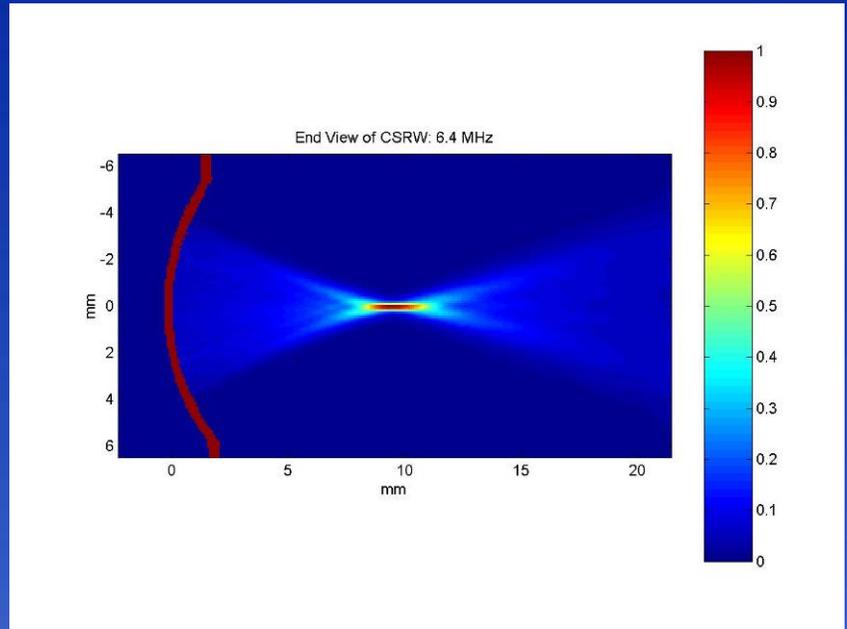
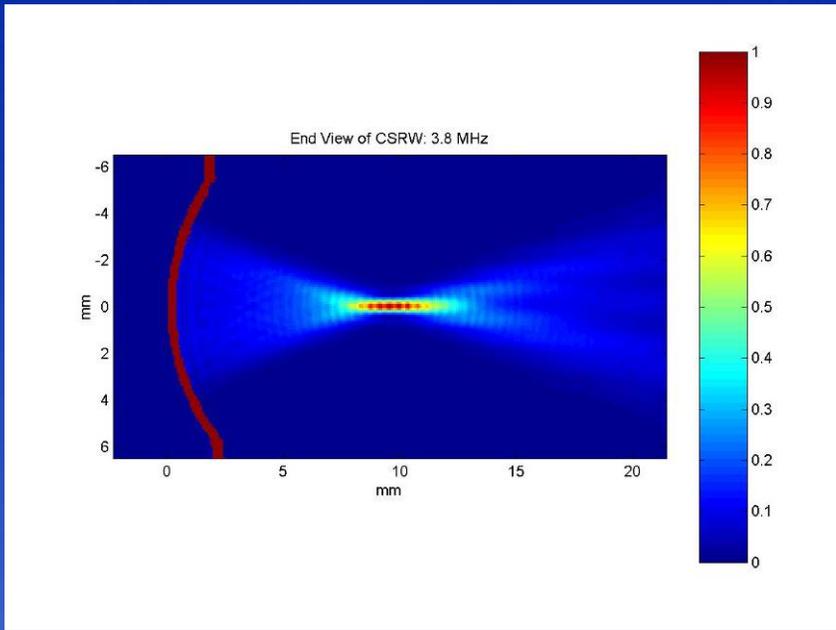


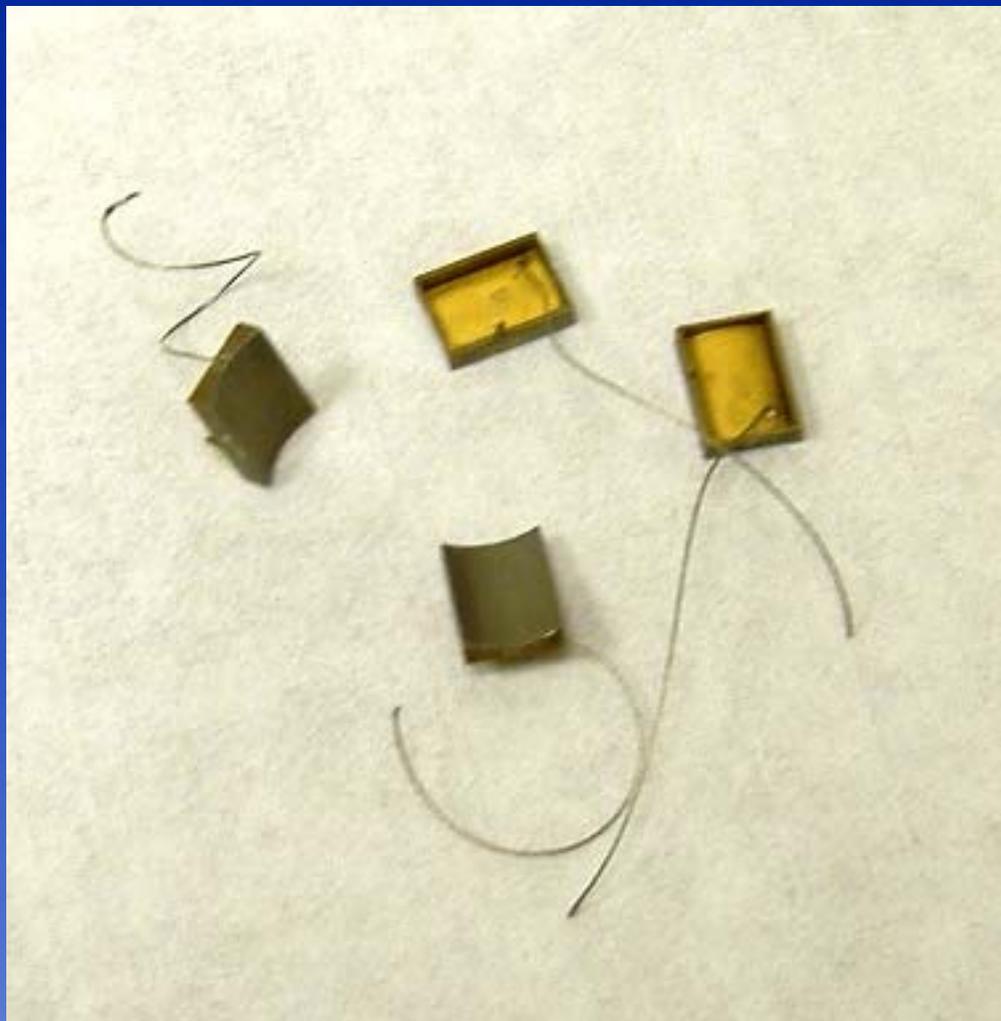
The Epicor Transducer

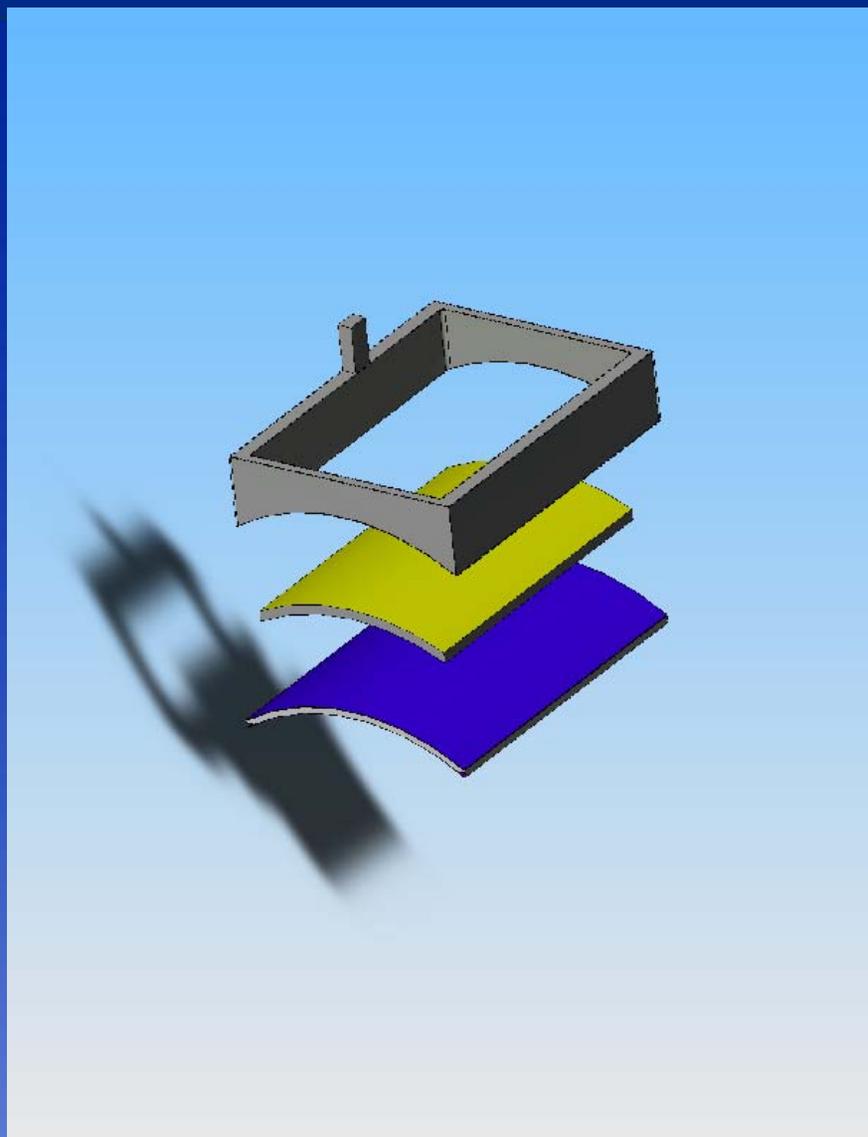
High Intensity Focused Ultrasound (HIFU)

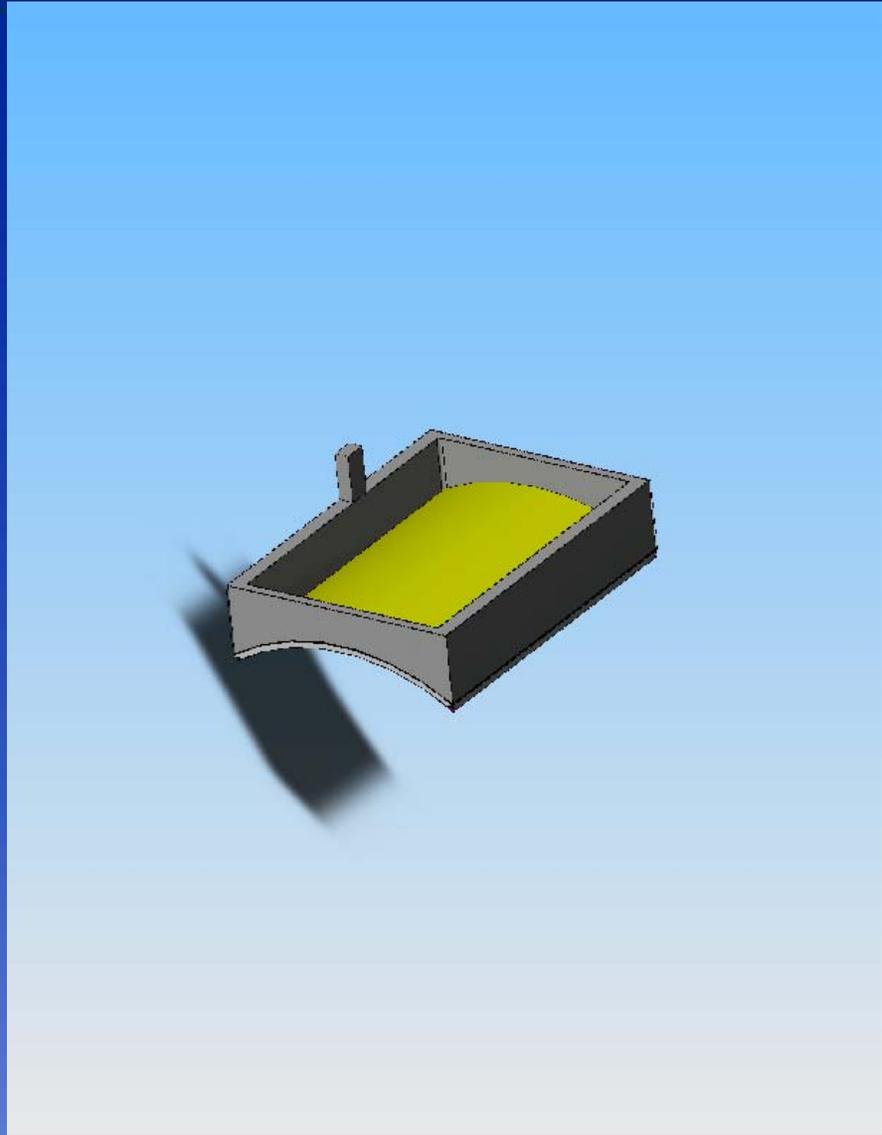
- Multistep algorithm-10 minutes long in total, some simultaneous transducer operation is used, no operator intervention required
- Two Frequencies, approx 3.8 and 6.4 Mhz are used
- Air-backed cylindrical PZT-8 transducers with matching layer and frontside membrane
- Three different time/power combinations directed into 3 zones
- Deeper ablation steps utilize lower frequency and shorter pulses
- Saline filled membrane for coupling and cooling
- Fixed Mechanical Focus

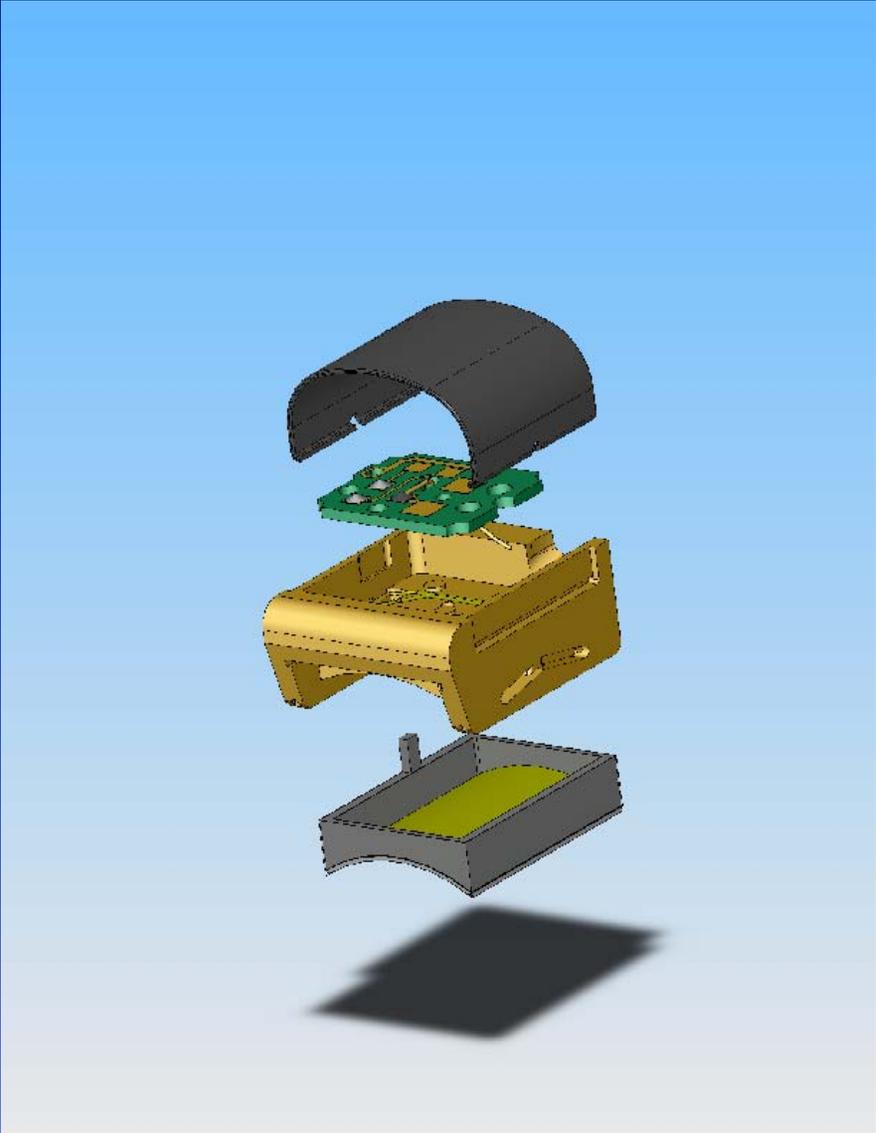












Summary

- HIFU treatment for atrial fibrillation works predictably and offers patient benefits such as improved safety and better procedure success rates
- HIFU disposables can be affordably produced in volume
- The future of Ultrasound Surgery looks very promising