

COBRA FUSION™

Une Nouvelle Technique d'Ablation



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The Maze III Operation

J Thorac Cardiovasc Surg 1991;101:584-592

The cut and sew technique



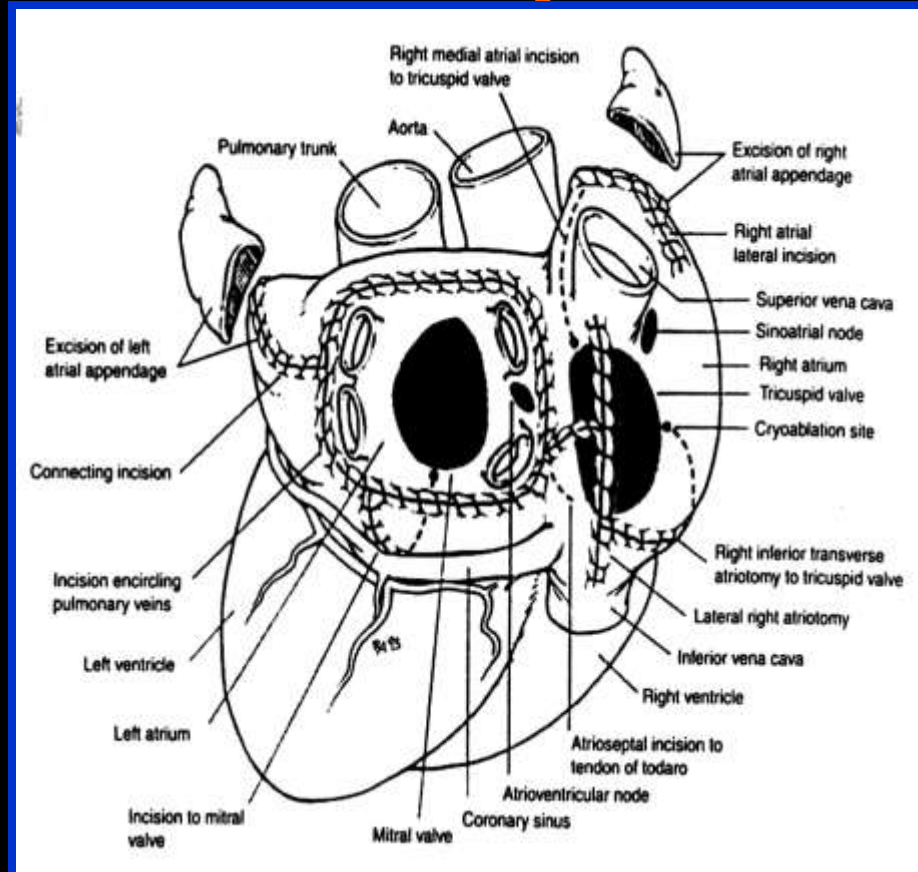
James COX

The Maze III Operation (1988)

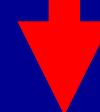
J Thorac Cardiovasc Surg 1991;101:584-592

The cut and sew technique

- Left side lesions
 - PV encircling
 - LAA resection + LAA line
- Right side lesions
 - Inter-caval line
 - RAA resection + RAA line
 - Tricuspid line
- Cryo-application for mitral line



GOLD STANDARD



| Author | Year | N | Parox % | Duration (y) | Lone AF % | SR % | FU (m) | PM % |
|---------------------|------|-----|---------|--------------|-----------|---------------|--------|------|
| Cox JTCVS | 1995 | 74 | 76 | 9 | 55.3 | 75 | 3 | 25 |
| McCarthy Semin TCVS | 2000 | 100 | 22 | 8.0 | 23 | 90 | | 6 |
| Schaff Semin TCVS | 2000 | 221 | 21 | 5.1 | 22.6 | 82 | | 3.2 |
| Izumoto EJCTS | 2000 | 104 | 0 | ? | 0 | 72 | 44.6 | 5.8 |
| Cox JTCVS | 2002 | 308 | 58 | 8.8 | 55.8 | 97 | | 15 |
| Bando JTCVS | 2002 | 258 | 4 | >20: 15-10 | 0 | 84 | 36 | 5.8 |
| Damiano JTCVS | 2003 | 47 | 60 | 7.6 | 0 | 84 no drug | 68.4 | 19 |
| Prasad JTCVS | 2003 | 198 | 64 | 8.5 / 11.6 | 56.6 | 97 | 64.8 | 23 |

KEYS OF SUCCESS

PERSISTENT TRANSMURALITY?

LESION SETS

But

- **Relatively Poor adoption**

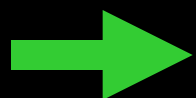
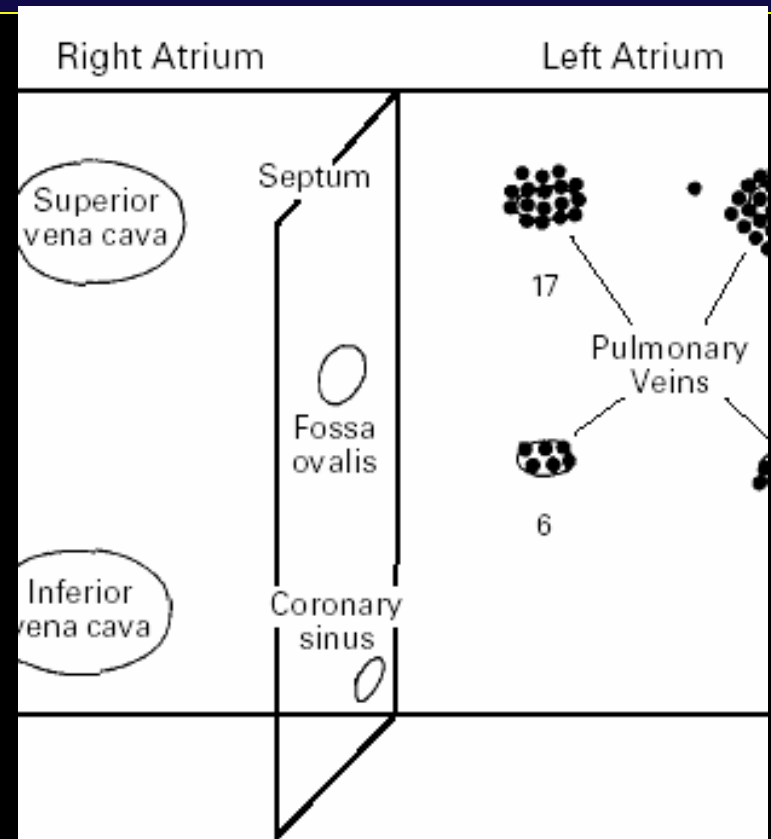
- **Surgical Difficulties ++**
- **Number of atrial incisions, postop bleeding**
- **Extra time on bypass (163 mn)**
- **Extra time of clamp (93 mn)**
- **PM in >20% patients**
- **Impose to open heart surgery (CABG?)**
- **Reproducibility?**

Haissaguere

Clustering of foci triggering AF in 45 pts

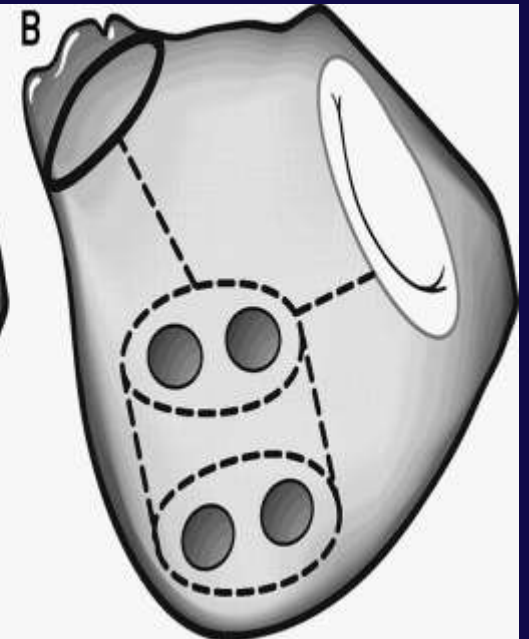
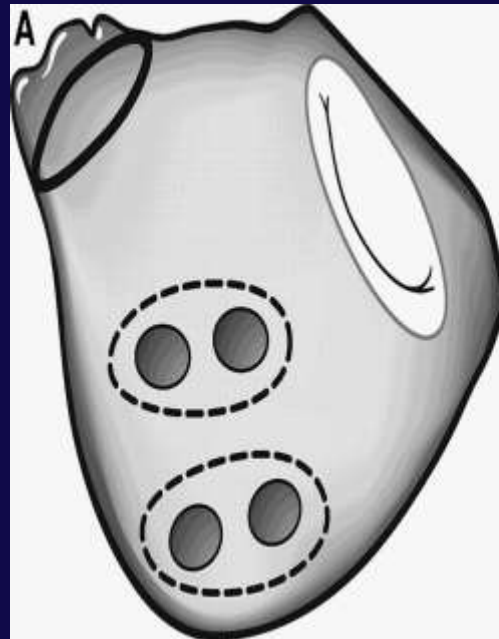
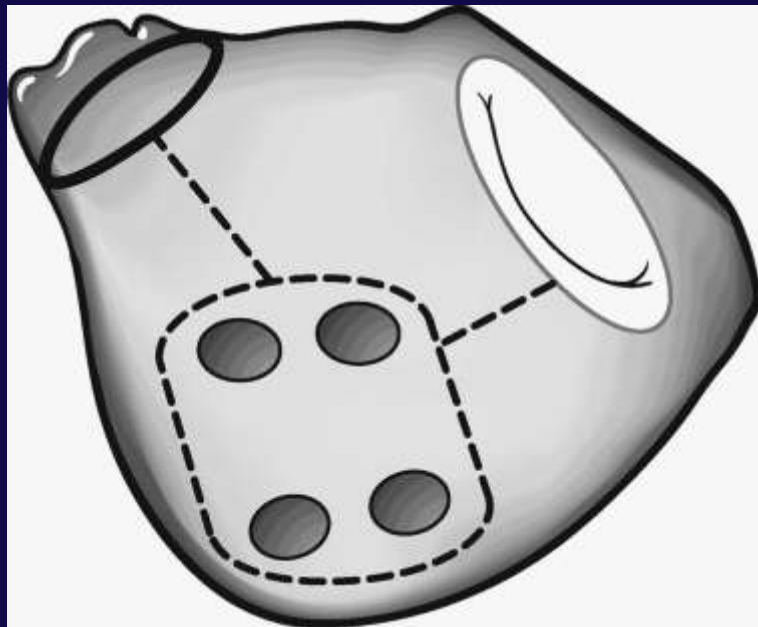
N Engl J Med. 1998;339:659-66

- Premature atrial beats around PV orifices triggering PAF
- Respond to local catheter RF ablation
- Substrate and triggers needed for sustained AF



Basis for PV Isolation Technologies

LEFT MAZE



Les mêmes inconvénients que le Maze

Alternatives to conventional Maze

- **Goals**

- **Create atrial conduction block**
 - **Similar to the “cut & sew”**
- **Create a transmural lesion**
 - **EP effective ?**
- **Create a Faster, Easier and Safer lesion / maze +++**

Ways of Success?

Transmurality

Sources of Energy

```
graph TD; A[Sources of Energy] --> B[Conductive Energy]; A --> C[Non Conductive Energy];
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Conductive Energy

Heat (or cold) diffuses via conduction into the tissue

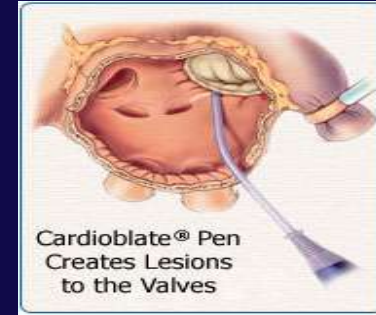
Non Conductive Energy

Real Energy deposit into the tissue

RadioFrequency

Conductive Energy

Cryo



Unipolar

Microwave



Bipolar

Non Conductive Energy

Ultrasounds



Epicor

Comparing to Cox-maze, with Energy sources, results routinely < particularly in Permanent AF

- **At 6 m FU** A.M.Gillinov, Advances in surgical Treatment of AF Stroke 2007; 38: 618-623,

- Uni or Bipolar RF
- 81% paroxysmal, 73% persistent,
- 58% permanent



TRANSMURALITY HAS BEEN PROVED With BP RF

— EP efficacy of bipolar RF in the clinical setting, Benussi & al
J Thorac Cardiovasc Surg, 2010 May;139

- Transmurality obtained after multiple Epicardial applications, attested by block conduction
- But recovery of conduction in 15% after 3 weeks

Good Results using Bipolar Atricure Clamp

Atricure Bipolar Radiofrequency Clamp for Intraoperative Ablation of Atrial Fibrillation

A. Marc Gillinov, MD, and Patrick M. McCarthy, MD (Ann Thorac Surg 2002;74:2165–8)

- **But:**

Limited to PV

For more open Heart Surgery needed

Fat ++

Impedance control



- **How improve the procedure & effectiveness?**
 - **Using routine more extensive lesion (more effective in permanent AF)**
 - **Producing a Continuous Transmural lesion**
 - **Available for all kind of AF (Lone or combined)**
 - **Easy to use (off pump, beating heart)**
 - **Fast**
 - **Reproducible**
 - **No collateral damage**
 - **Minimally invasive**

**In order to improve use & results
a new device was needed**

The COBRA FUSION™
Estech / Atricure



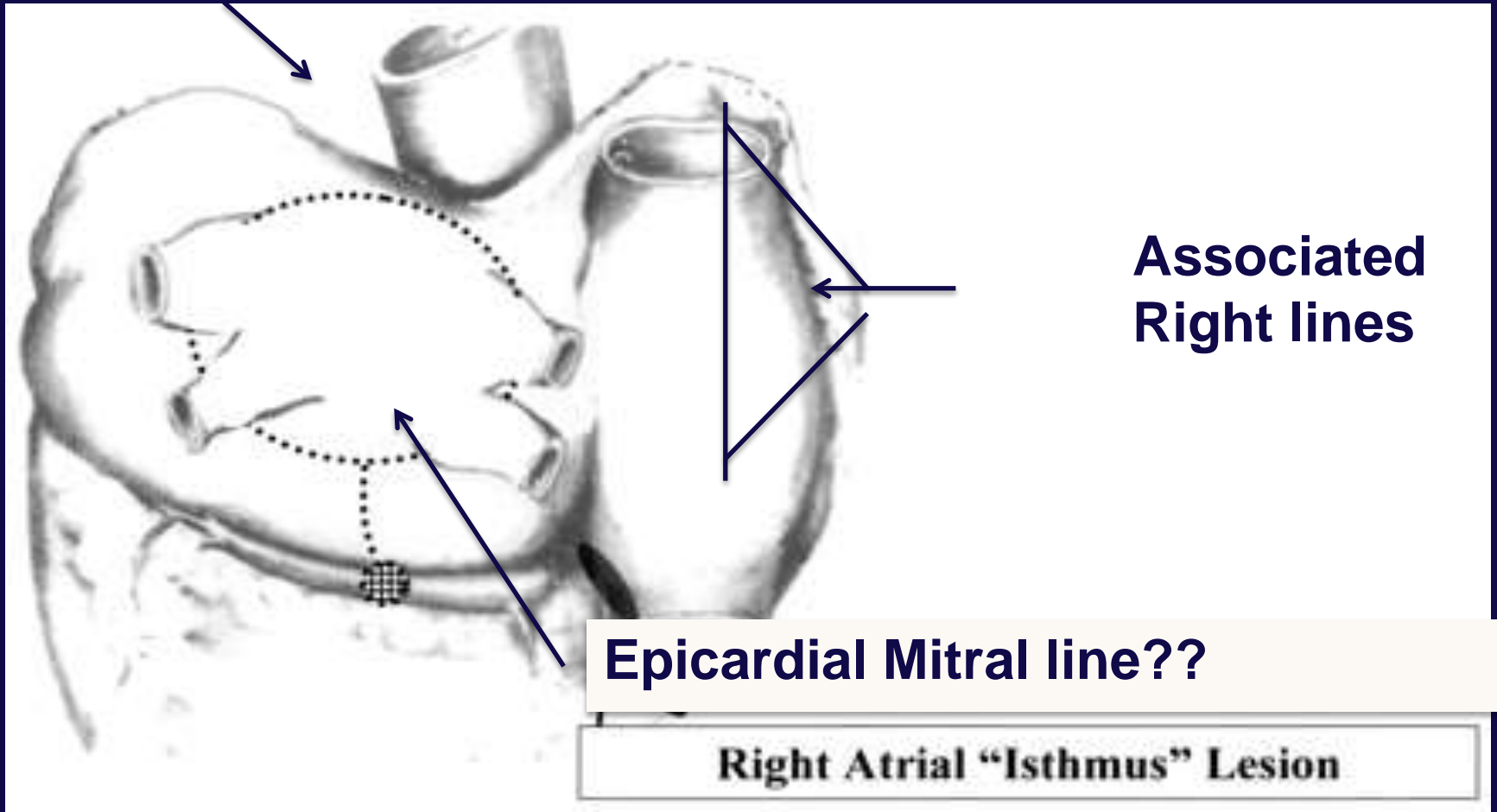
THE CHALLENGE

To create a transmural continuous
circumferential reproducible lesion

using an epicardial application
On beating heart

On Left & Right Atrial

• The EPICARDIAL BOX Lesion

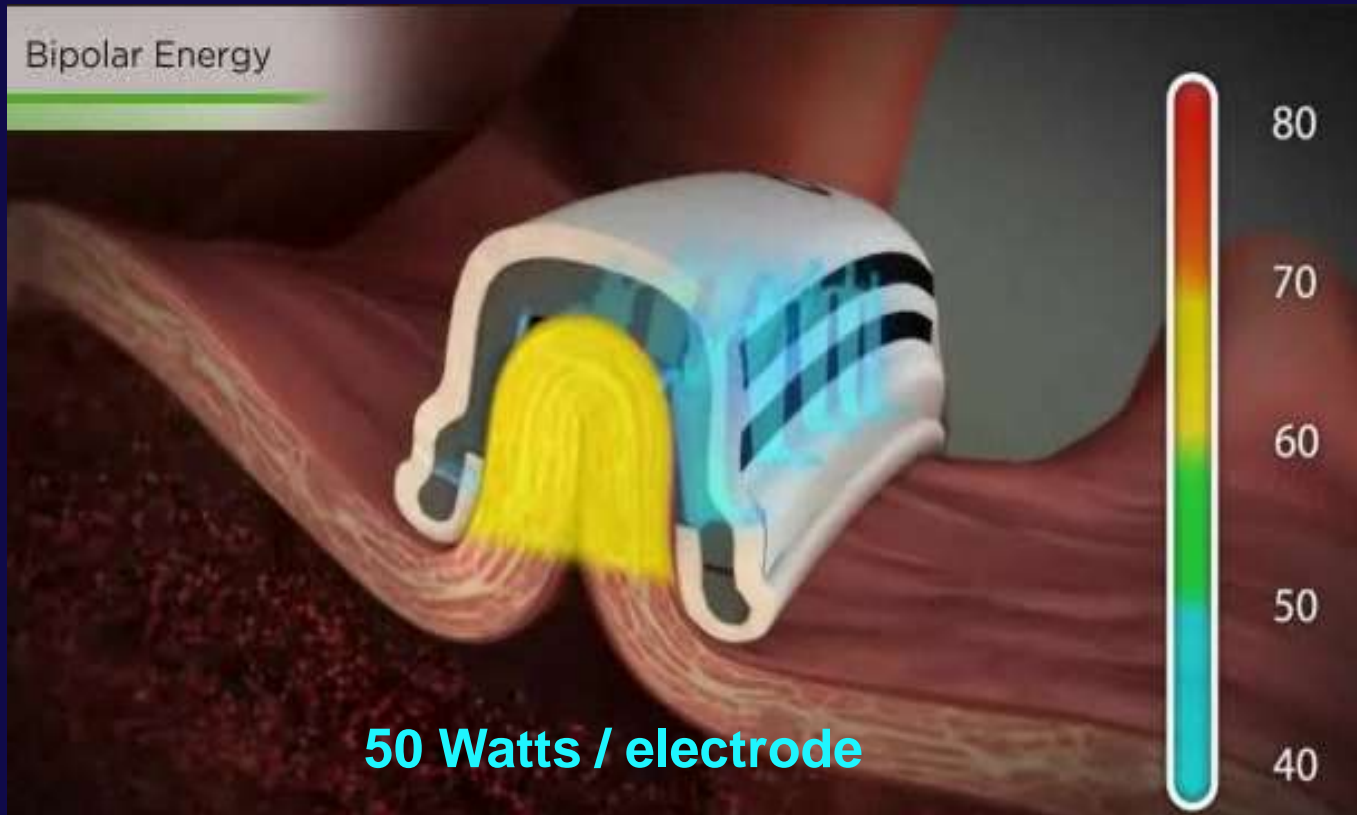


The Energy: Radiofrequency

RF DELIVERY

Flexible probe, including 2 rows of electrodes

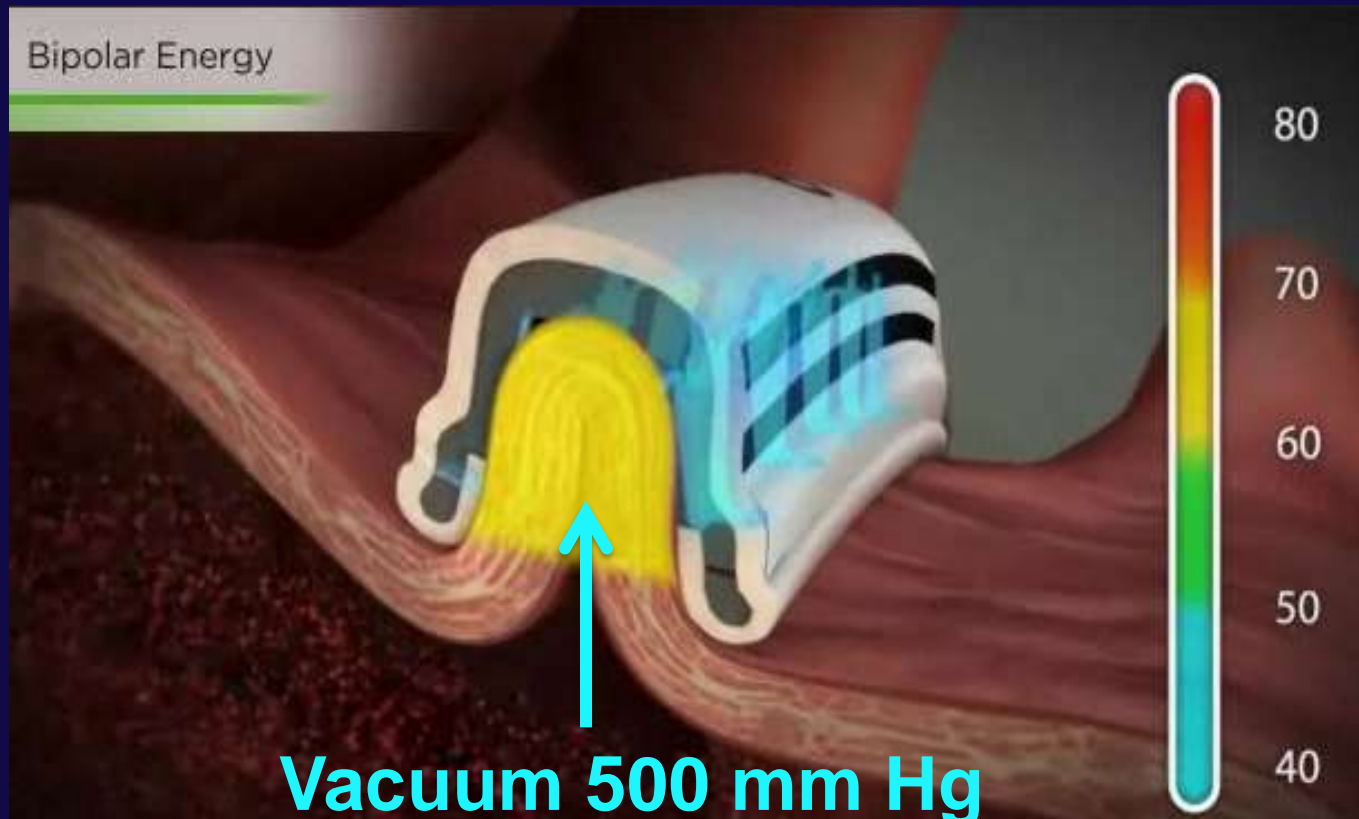
Bipolar Ablation



RF BIPOLAR ACTION

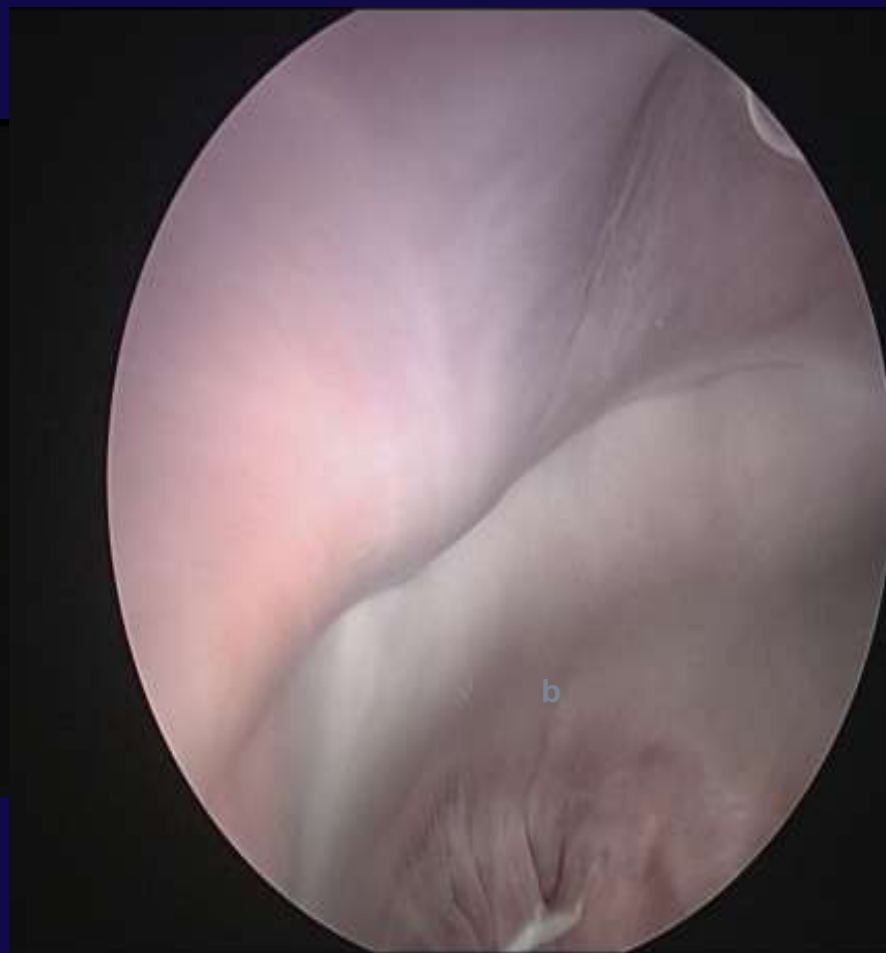
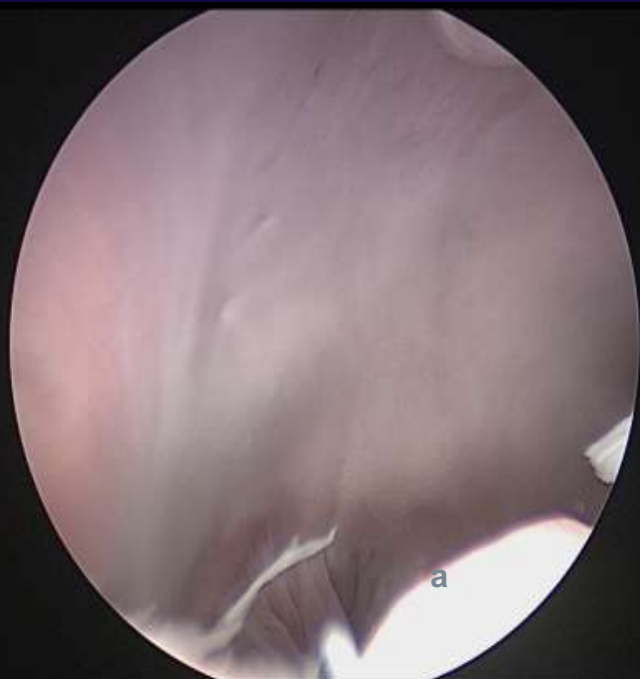
LA tissue included into the probe using vacuum

No Heat Sink effect & better contact



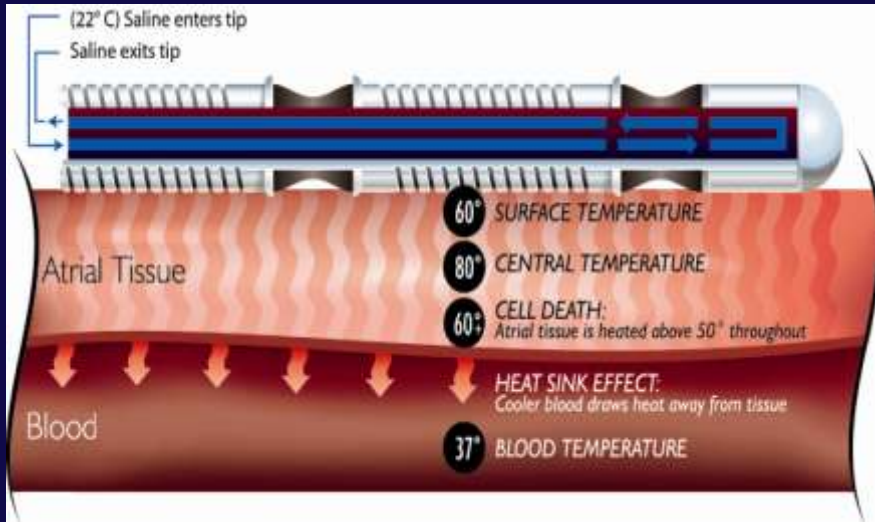
AtriCure®

With Dynamic Suction on a Beating Heart



AtriCure®

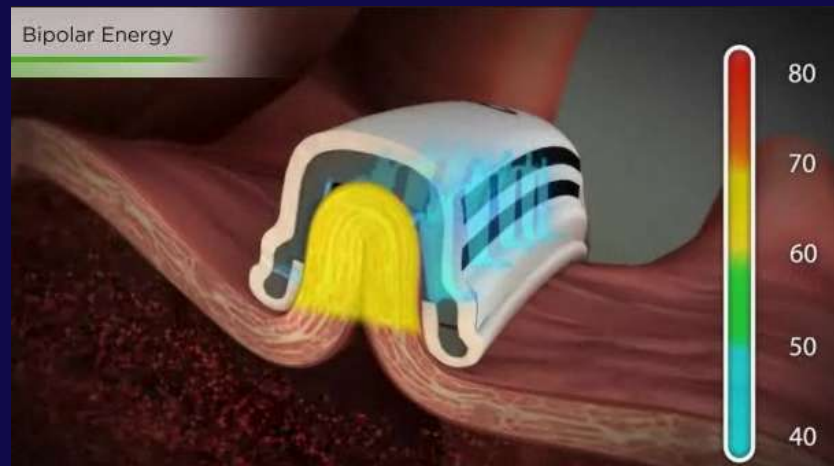
Reduce Heat Sink Effect



Monopolar



Bipolar Clamp ++ but limited PV



All around
the box

Cobra Fusion +++

- **Which Temperature?**
- **Which Duration?**

RF: 2 mechanisms of action

1/ Resistive heating (Temperature)

Tissues = resistor, generating heat

Occurs for only 1mm of depth

Superficial lesion very high surface θ

2/ Conductive heating (Time)

To heat at deeper level

Passive heat transfer from high temperature tissue to surrounding low temperature tissue

Lesion is function of the tissue conduction

Effects of Temperature on Tissue

| Temperature (°C) | Cellular Effect |
|------------------|---------------------------------|
| < 40 | No significant cell damage |
| 40-49 | Reversible cell damage |
| 50-70 | Irreversible cell damage |
| 71-99 | Coagulation |
| 100-200 | Desiccation (Boiling) |

Irreversible cell injury that is unable to propagate electrical signals occurs at sustained temperatures exceeding 50 °C.

For safety reasons, cell temperatures must never exceed 90 °C.

The Vacuum Effect:

AtriCure® Constant Epicardial Contact

Unipolar Approach



Suction Applied RF



TECHNICAL IMPROVEMENT (1)

Temperature Controlled RF (TCRF)

- **Constant temperature monitoring for added safety and control (70°C)**
- **Permanent feedback between energy delivery and tissue temperature +++**
- **Adjusts electrode output to accommodate varying tissue thicknesses+++**

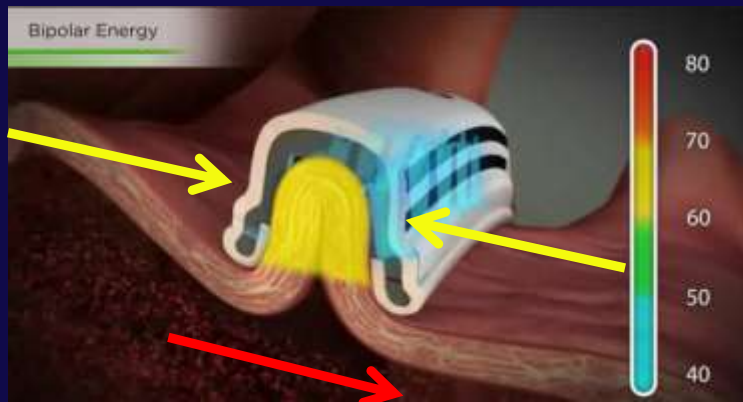
TCRF vs Impedance

- Pulsed RF halts RF delivery momentarily to keep tissue temp lower and conductance as high as possible

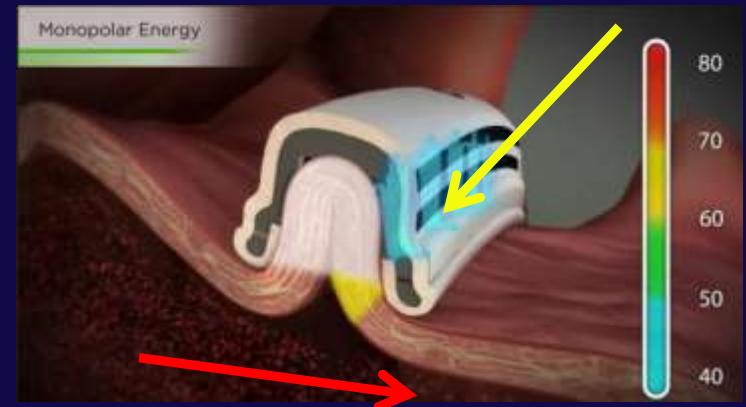
Technical Improvement (2)

AtriCure®

Uni or Bipolar Power Delivery: The Cobra Fusion Versapolar™ Technology



Bipolar energy creates transmural lesions for tissue within the device (up to 7mm tissue wall thickness)



For thicker tissue monopolar energy creates transmural lesions with energy from active electrodes to ground pad





Your Partner
in Afib Solutions

DURATION: Cobra Fusion Settings

AtriCure®

Ablation Time (seconds) COBRA Fusion
at 50W/Electrode, -500 mmHg of vacuum

| Tissue Thickness | 60°C | | 70°C | |
|------------------|---|--|---|---|
| Mode |  |  |  |  |
| 5mm | 60 | 30 | 60 | 30 |
| 7mm | 120 | 120 | 120 | 90 |

Times based on mode of energy delivery selected by surgeon

The DEVICE

2 kind of PROBES

Cobra Fusion 50

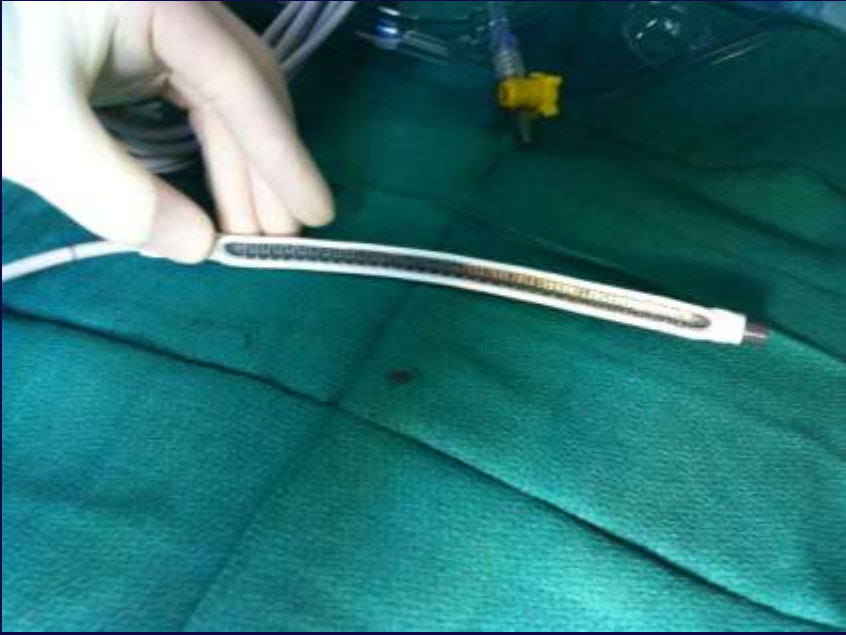


- 50 mm in length
- 2 segments of electrodes

Cobra Fusion 150

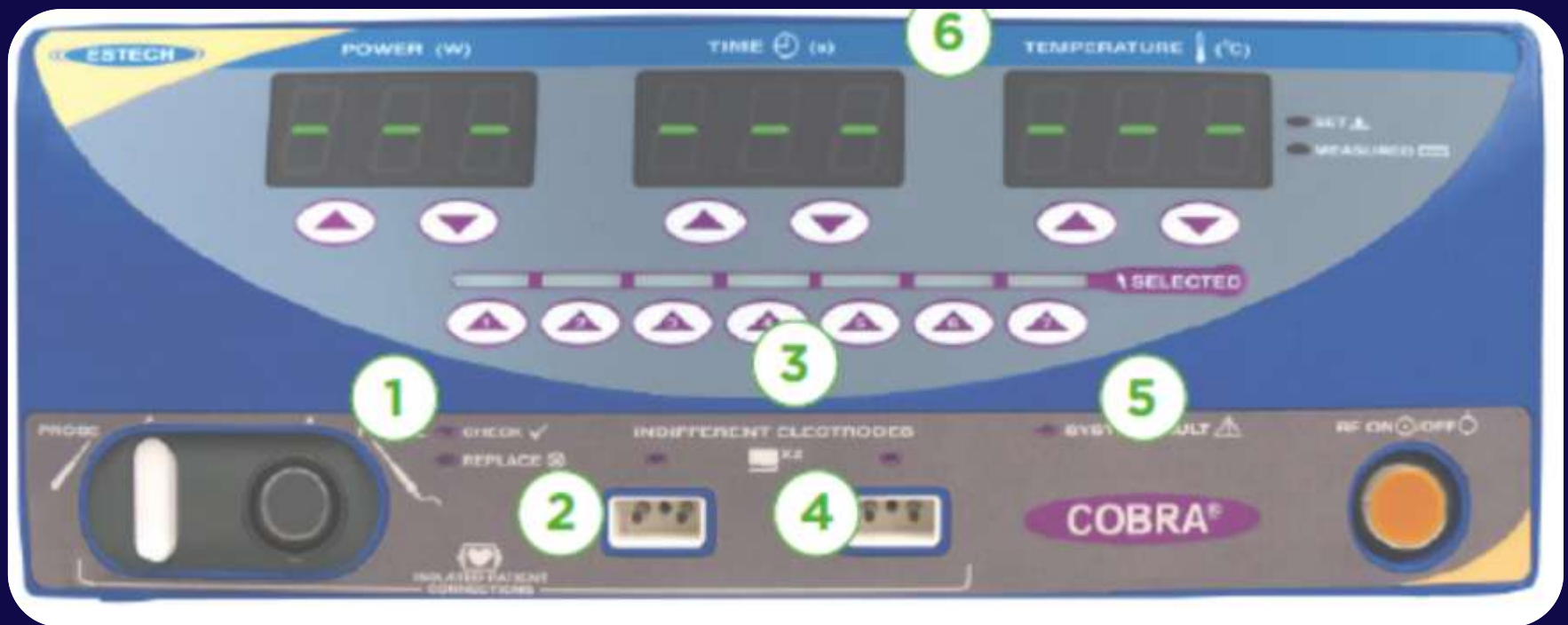


- 150 mm in length
- 6 electrodes
- 25mm each in length
(3 can ablate at one time)



The Generator

- Temperature Controlled RF ++

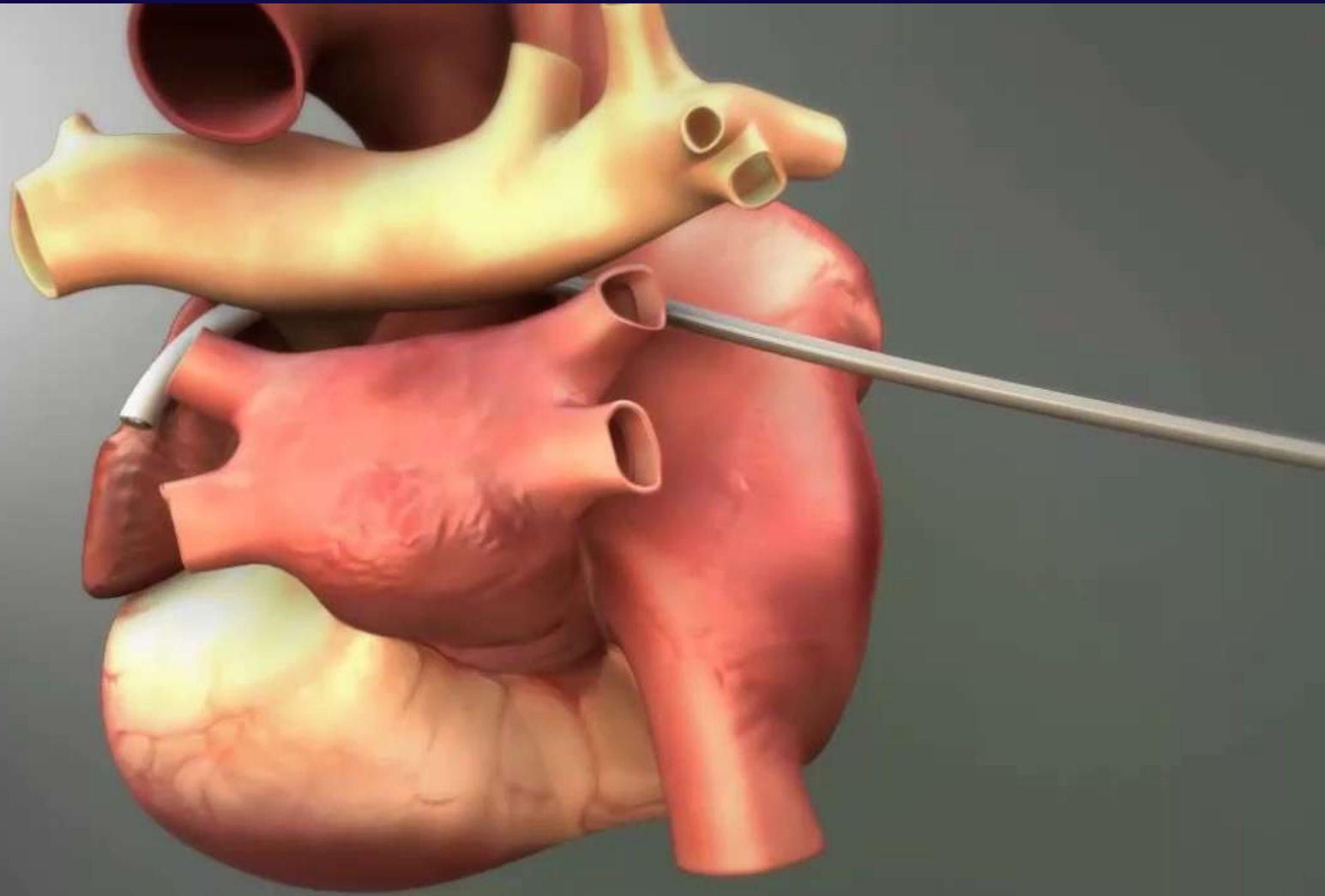


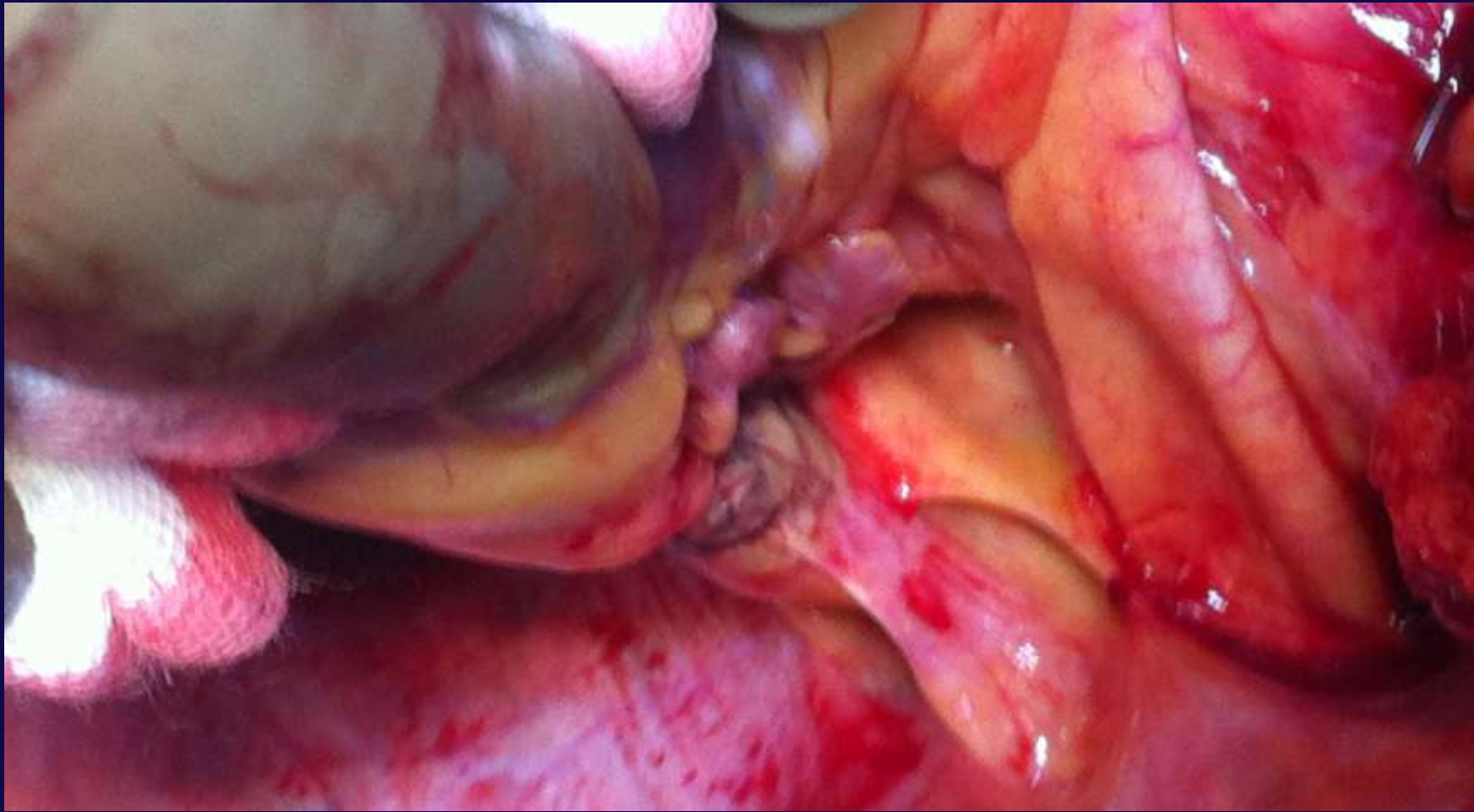
RF EPICARDIAL LESION

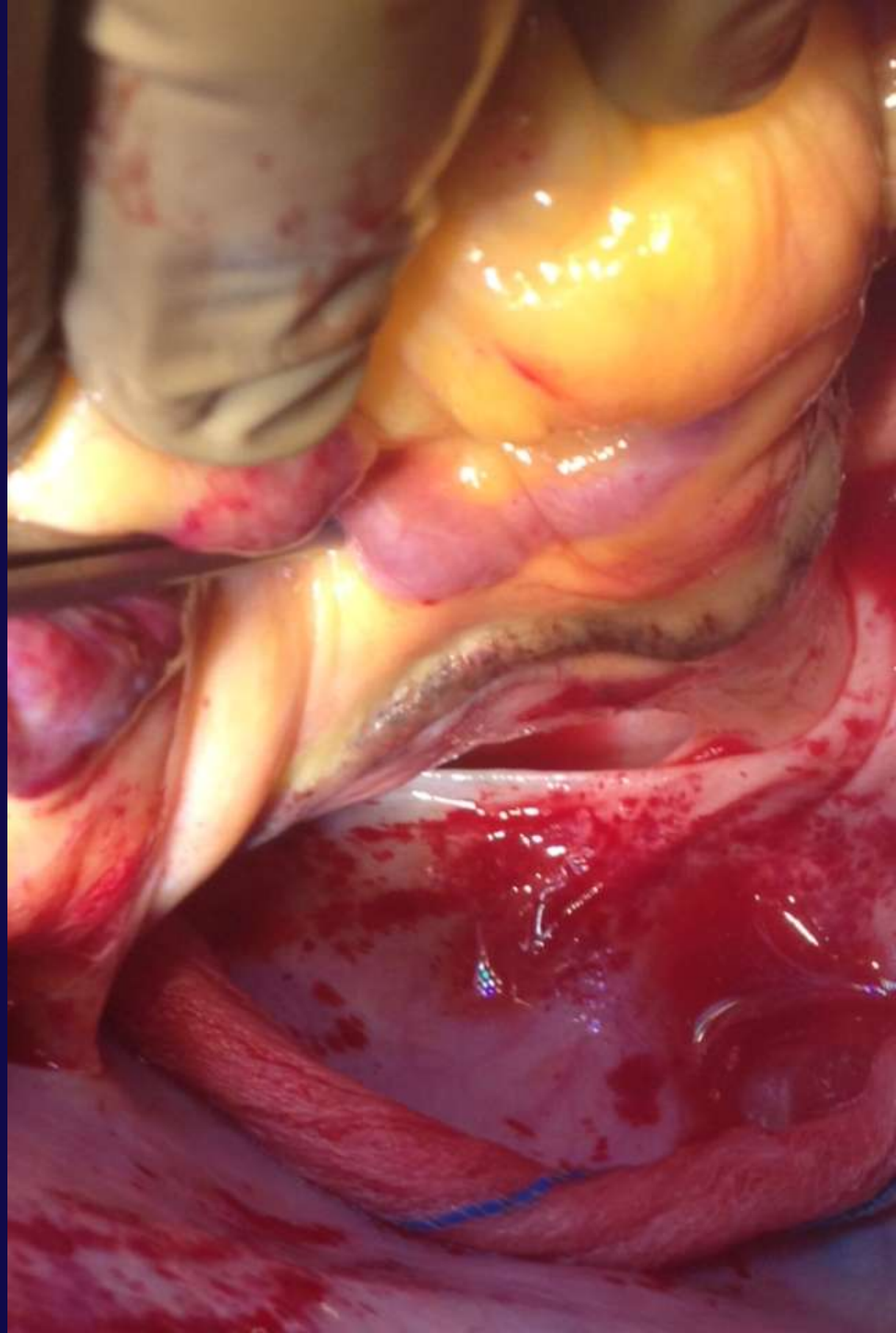
All around the LA \longrightarrow BOX LESION



+/- Right Lines

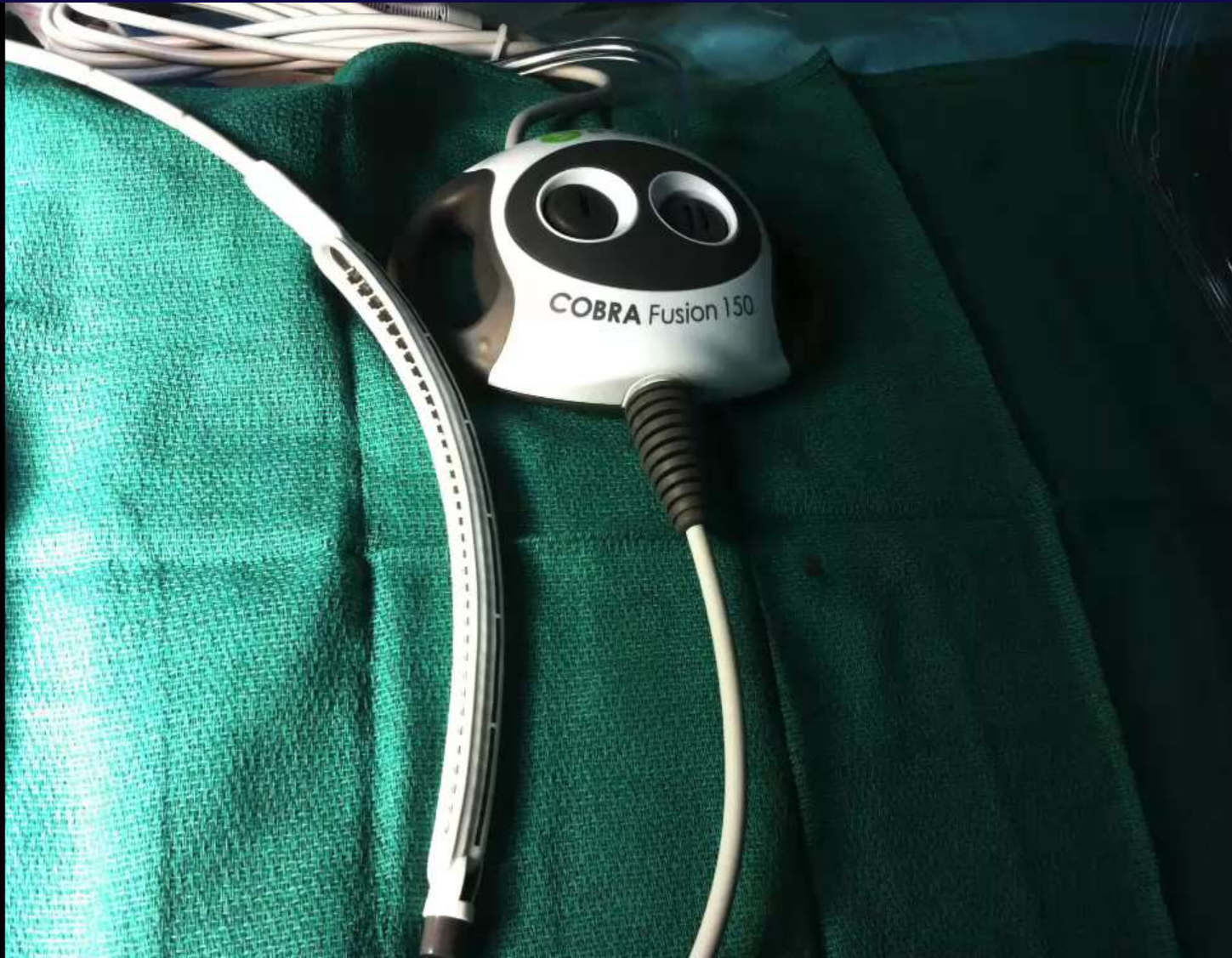






How to prove Conduction Block?

- **Integrated Pacing and Sensing** – Immediate conduction block testing upon completion of lesion sets with Fusion 50



PRELIMINARY RESULTS

EXPERIMENTAL STUDY

Performance of a Novel Bipolar/Monopolar Radiofrequency Ablation Device on the Beating Heart in an Acute Porcine Model. Lindsey L.Saint & AI, Innovations, Vol 8 n 4 July/August 2013

N=6 pigs

Ablation lines on R & LA

N=270 cross sections

Transmurality : 94% of all cross section

96% middle section

89% end section (P=0.04)

Failure associated with low body temperature

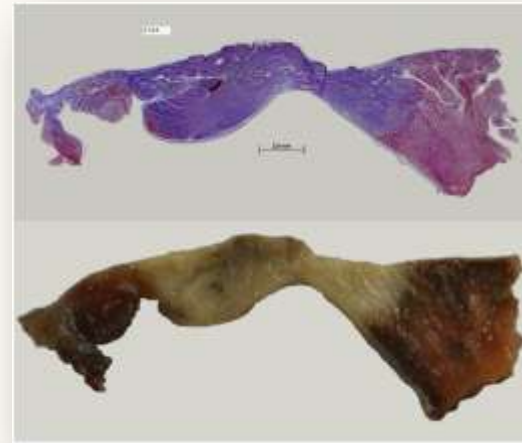
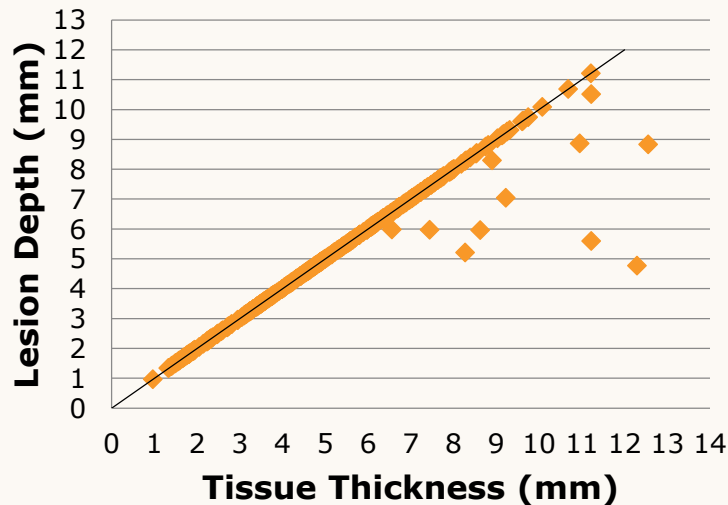
EXPERIMENTAL DATA

AtriCure®

UNC Kiser Fusion Animal Study

Transmurality 96.4% (294/305)

Fusion



Data courtesy of Dr. Andy C. Kiser, Chief, Division of Cardiothoracic Surgery
University of North Carolina Center for Heart and Vascular Care, Chapel Hill, NC

- The COBRA Fusion ablation device achieved 100% transmural lesion formation at sites of tissue <6mm
- Thin tissue represents a significant impediment to transmural lesion formation since the endocardial blood rapidly cools the targeted tissue.
- Fusion overcomes this challenge by excluding the endocardial blood flow

Reliable Transmurality on Thin and Thick Tissue

L
A
A



S
V
C



EPICARDIAL

ENDOCARDIAL



CLINICAL DATA

Preliminary Results from the Historic-AF Trial: A European prospective multicenter study. Muneretto C. & Al, presented STS meeting January 2014

- **N= 50pts June 2012 – Nov 2013**
- **Lone Persistent AF**
- **Ablation & assessment perop Conduction block**
- **72h Holter Monitoring**

- **At 6 & 12 m FU: SR 86.8 & 85.7%**
- **14% EP evaluation & ablation**

CONCLUSION : COBRA FUSION™

- **Feasibility**

- Off-pump, beating heart, Left & Right lesions
- Reproducible
- Fast, Easy to use

- **Safety**

- No collateral damage,
- No device related complication,

- **Transmurality - Efficacy** awaiting more results

- **Real minimally-invasive approaches (Lone AF)**

Tout peut s'appivoiser même la FA!!

