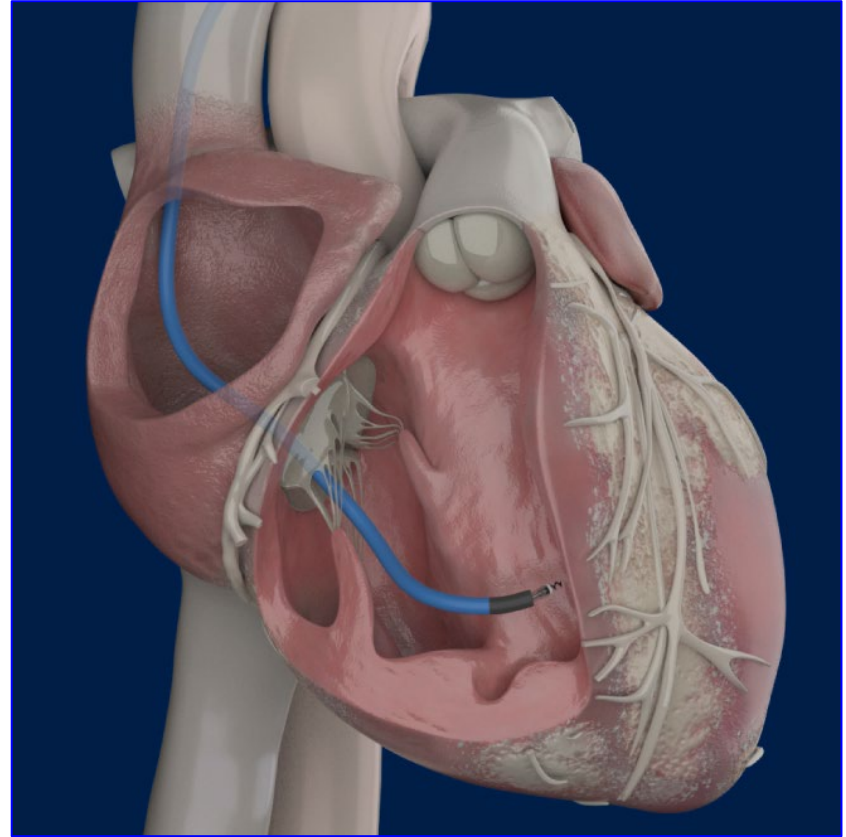


Insertion of a Lumenless Small Diameter Defibrillation Lead

Chad Bounds
Principal Systems Engineer



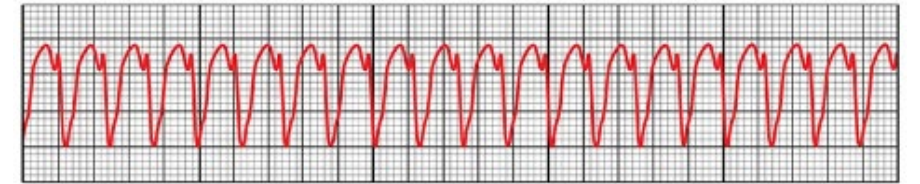
**ICD-10 Coordination and Maintenance Committee
Fall 2025**

Implantable Cardioverter Defibrillators

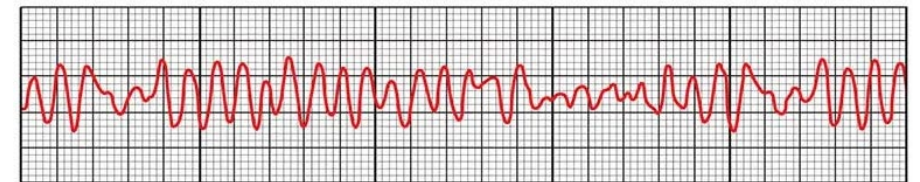
- ❖ Defibrillators treat life-threatening ventricular tachyarrhythmias:
 - ventricular tachycardia
 - ventricular fibrillation
- ❖ The defibrillation lead delivers a shock to terminate the tachyarrhythmia.
- ❖ Most defibrillators can also deliver anti-tachycardia pacing which can sometimes terminate the tachyarrhythmia by itself without shocking.
- ❖ When part of cardiac resynchronization therapy (CRT-D), defibrillators also treat heart failure.



normal EKG (sinus rhythm)



ventricular tachycardia



ventricular fibrillation



ventricular fibrillation

-shock-

sinus rhythm

Lead Technology

Lumenless

- ❖ Eliminating the central stylet in the lead's lumen allows for a small diameter lead.

Catheter-Delivered

- ❖ Without a stylet, the lead is delivered by a catheter which enables precise targeting.

Integrated Bipolar

- ❖ Integrating multiple electrodes allows for a small diameter lead.

Small-Diameter

- ❖ Small diameter enables treatment of pediatric adolescents and those with narrowed vessels.

**Conventional
Defibrillator
Lead**



**Lumenless
Catheter-Delivered
Integrated Bipolar
Small-Diameter
Defibrillator Lead**



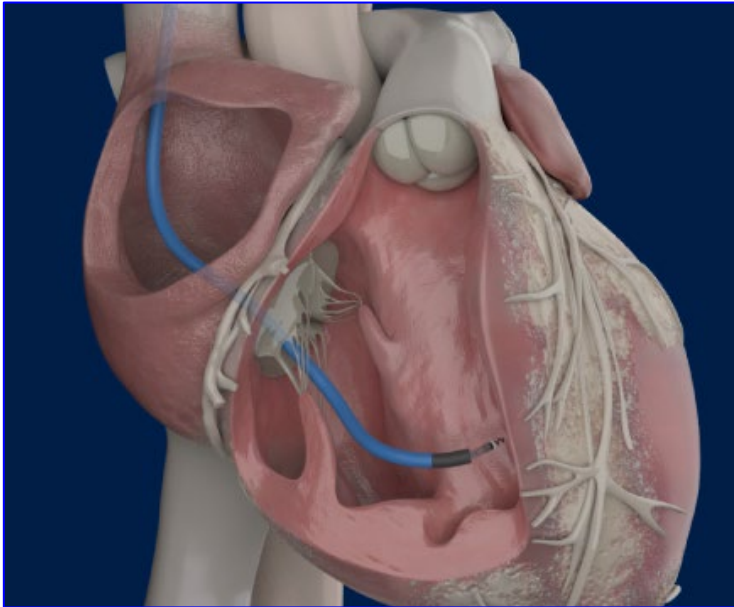
Placement of Lead

- ❖ The lumenless catheter-delivered integrated bipolar small-diameter defibrillation lead is placed transvenously under fluoroscopic guidance.
- ❖ Lead placement is always from the right side (vena cava).
 - From a peripheral insertion site, eg, axillary vein, the catheter is advanced over a guidewire to the vena cava and into the right atrium.
 - The catheter is then advanced through the tricuspid valve and then to the target site in the right ventricle.
 - The lead is advanced through the catheter and secured at the target site.
 - The catheter is then withdrawn leaving the lead in place.

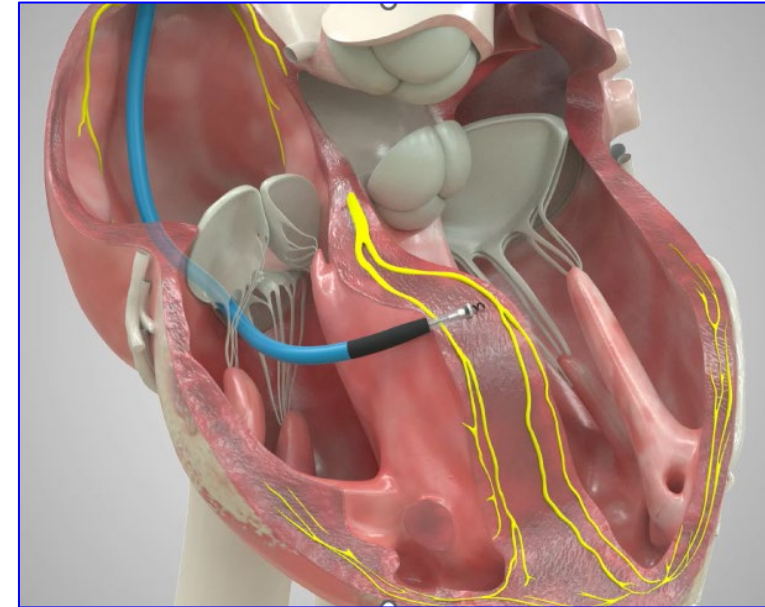
Anatomic Sites for Lead

- ❖ The lead can be placed in two anatomic sites in the heart.

Right Ventricle



RV Septum - Left Bundle Branch

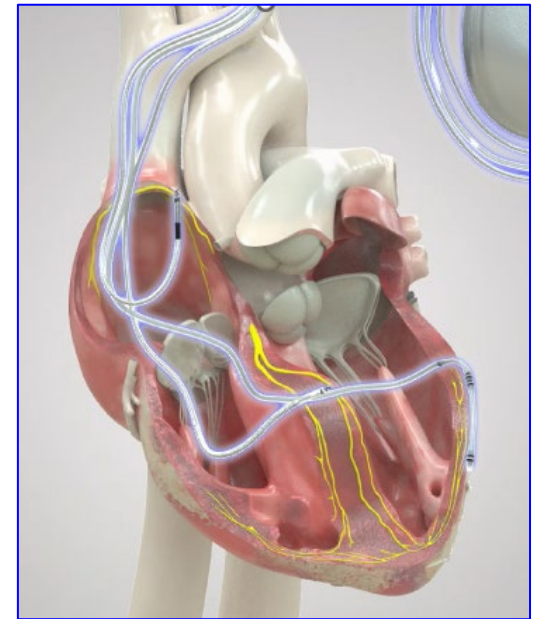
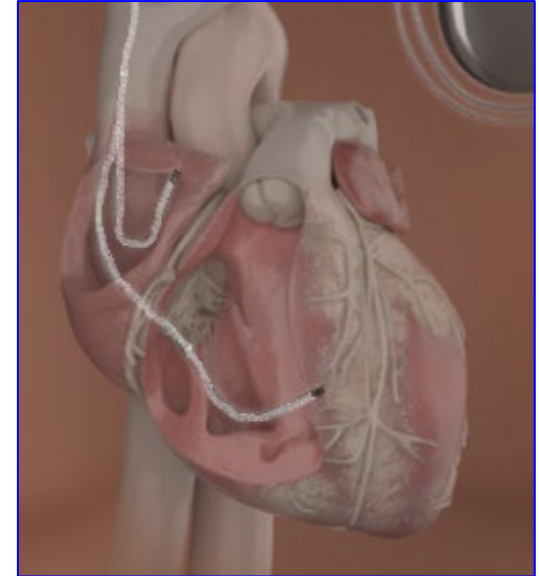


Placement in the LBB of the ventricular septum is not yet FDA approved

- ❖ Placement in the septum at the left bundle branch engages the heart's intrinsic conduction system.
- ❖ This more closely approximates the heart's natural electrical physiology.

Configurations

- ❖ The lumenless small-diameter defibrillation lead may be placed together with conventional leads in other sites.
 - The lumenless small-diameter defibrillator lead may be placed with a conventional lead in the right atrium.
 - For CRT-D, the lumenless small-diameter defibrillation lead may be placed with a conventional lead in the right atrium and a conventional lead in the coronary sinus.
- ❖ Regardless of the configuration, only one lumenless small-diameter defibrillation lead is placed, always in the right ventricle.



Procedure Documentation

- ❖ Placement of a lumenless catheter-delivered integrated bipolar small-diameter defibrillation lead is documented in the procedure report.
- ❖ The procedure report may particularly note use of a delivery catheter for lead placement.
- ❖ The lead model used in the US is the OmniaSecure™ (aka OmniaSecure™ MRI SureScan™, 3930M) defibrillation lead
- ❖ This may be documented by model name in the procedure report and/or the operative equipment/supply list.



FDA Information

FDA Breakthrough Device Designation

- ❖ The lumenless catheter-delivered integrated bipolar small-diameter defibrillation lead received FDA Breakthrough Device designation in November 2021.
- ❖ This reflects its use in adolescent pediatric patients as well as zero lead fractures and high reliability in the pivotal trial despite the lead's significantly smaller size.

FDA Approvals

- ❖ The lumenless catheter-delivered integrated bipolar small-diameter defibrillation lead was FDA approved for placement in the right ventricle in April 2025.
- ❖ FDA approval for placement in the left bundle branch is anticipated in 2026.