AVEIR™ VR LEADLESS PACEMAKER (LP) : Patient Selection and Implant Considerations Case based Approach

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Disclosures

Advisory Board, Consultant, Honoraria

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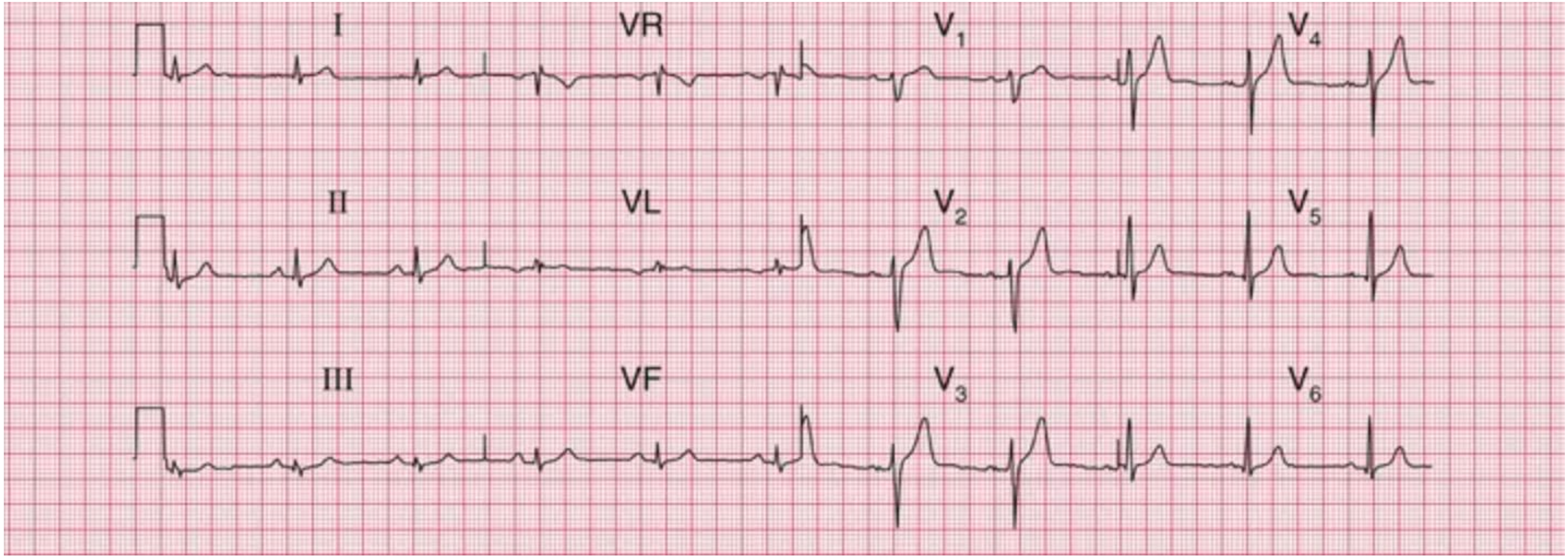
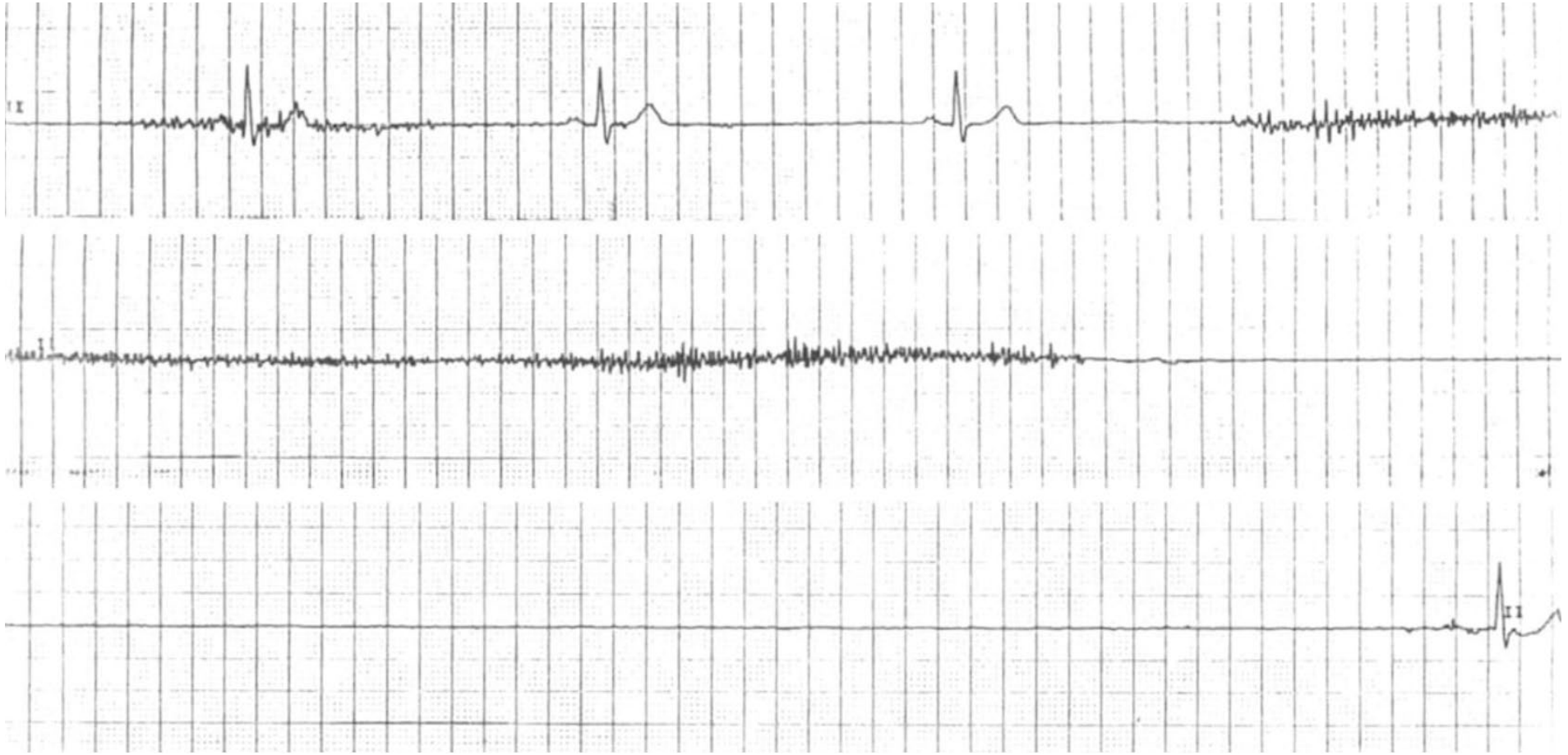
- 22 yr young healthy female with recurrent syncope, more recently accompanied with seizure like activity
- Minimal prodromal symptoms
- Most recent episodes with head trauma
- Echo – Normal , EF 60-65%
- No significant Cardiac Family History
- Tilt testing – No syncope , mild hypotension and sinus bradycardia, no pauses

12 lead ECG – Normal



30 day monitor



Treatment Considerations

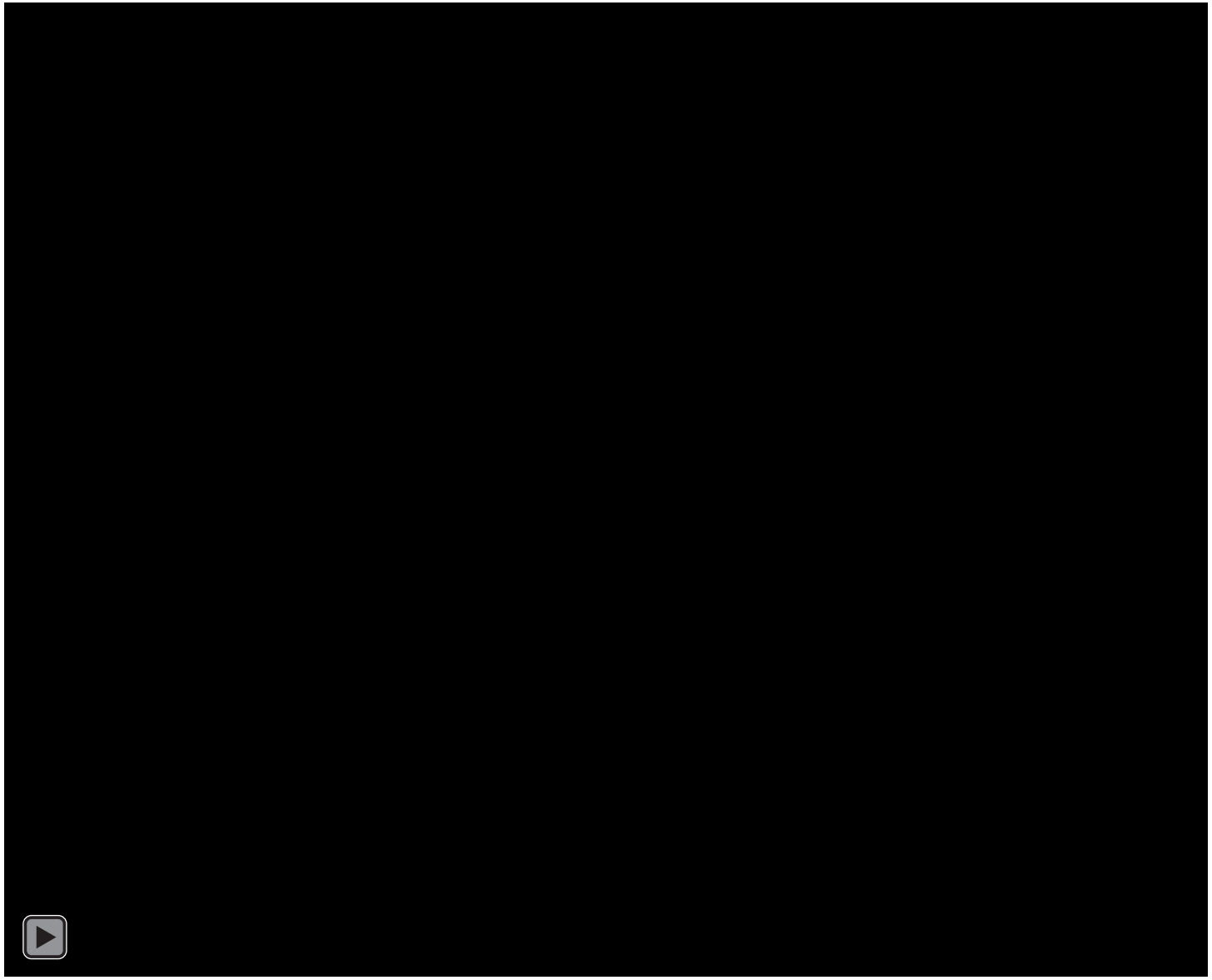
- **Leadless pacing**
  - **Relatively young patient**
  - **Malignant bradycardia**
  - **Infrequent need for pacing**
  - **Desire to preserve vasculature - Concern with long-term transvenous leads, multiple generator changes**
  - **“Visibility of the disease” and psychological impact on a young patient**

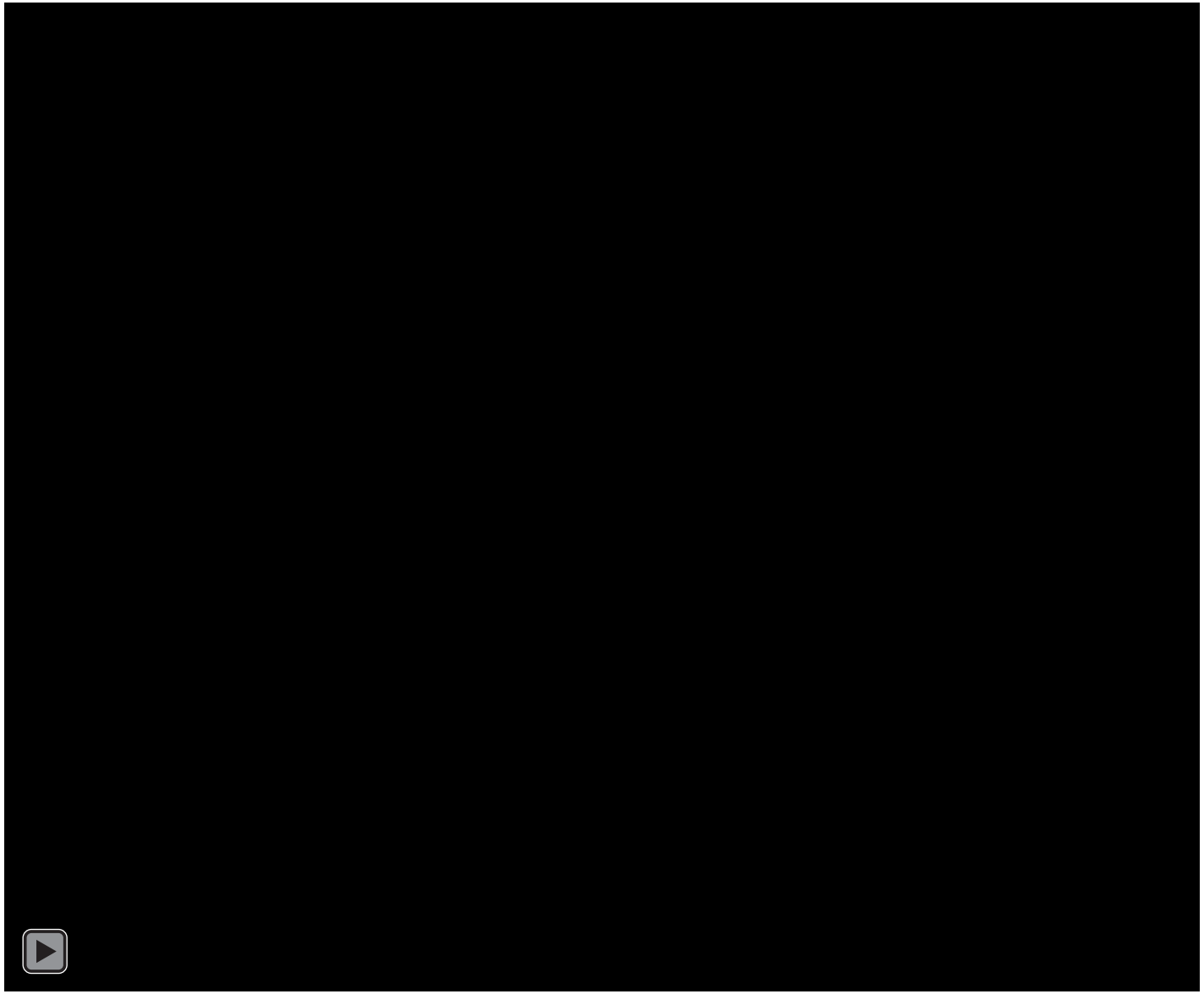
- **Aveir™ VR LP**
  - **Need for chronic retrievability**
  - **Potential for an upgrade to dual in the future***

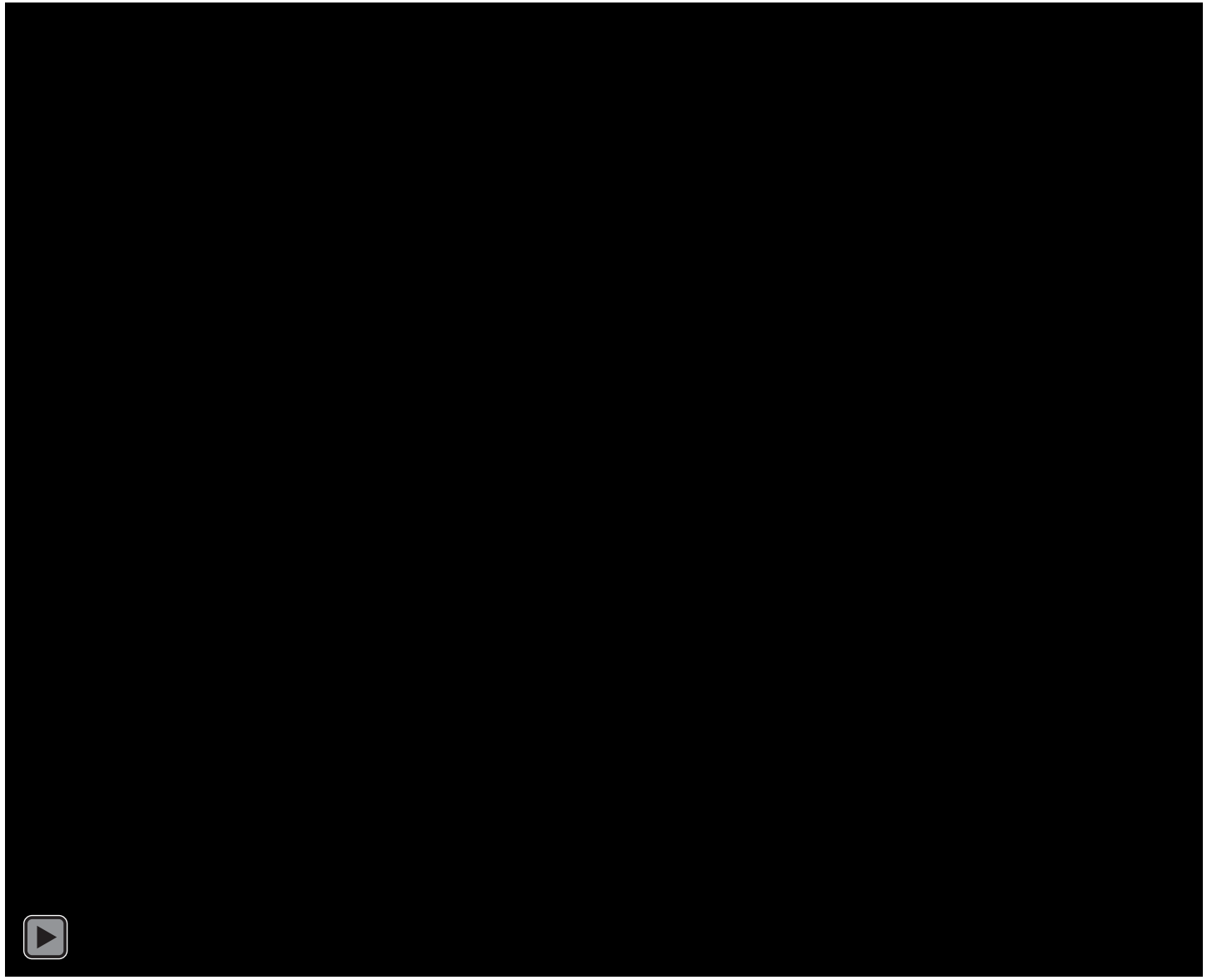
*The LP device electronics are designed to be enabled by future software, upon regulatory approval, to support dual chamber pacing in the future. Dual chamber pacing system is currently in clinical trial (ClinicalTrials.gov NCT #05252702) and limited to investigational use only.

Precise Access with Ultrasound

- Hemostasis with double Perclose™ Suture-Mediated Closure and Repair (SMCR) System
- Preclose SMCR prior to insertion of Amplatzer™ Occluder stiff wire into IVC
- Dilate skin tract
- Introduce the Aveir™ Access sheath into IVC and remove the dilator and wire
- Connect sheath to heparinized Saline bag
- Prep Aveir™ delivery catheter with 3 more heparinized bags prior to introduction into sheath



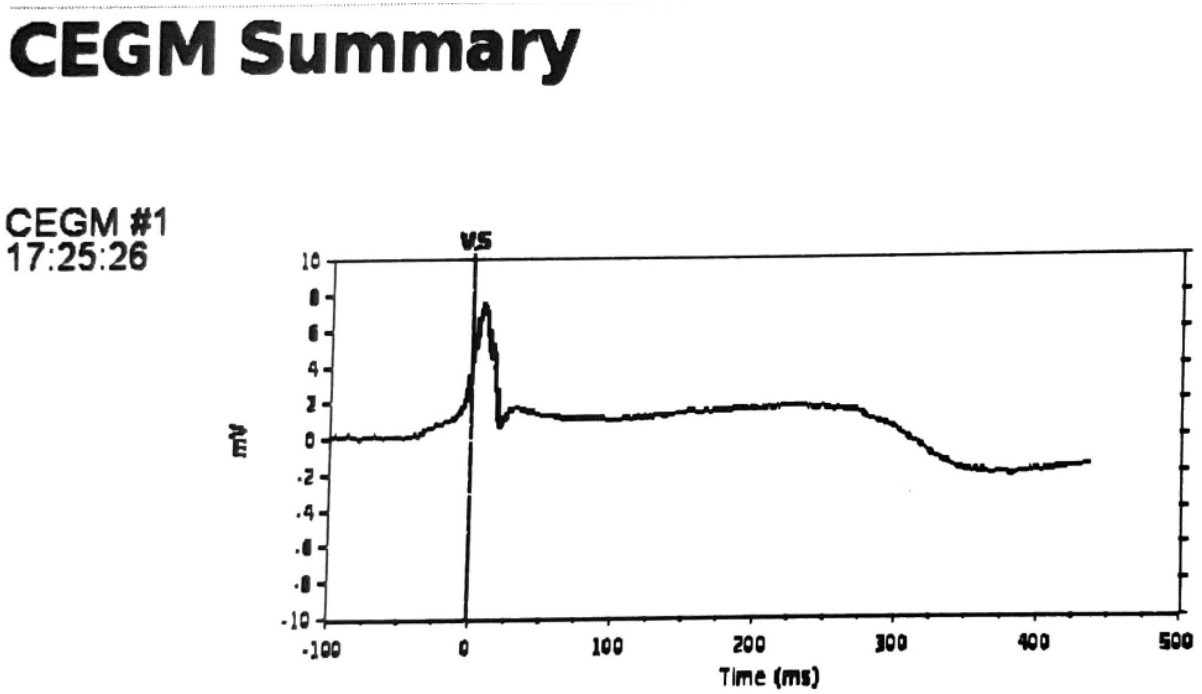


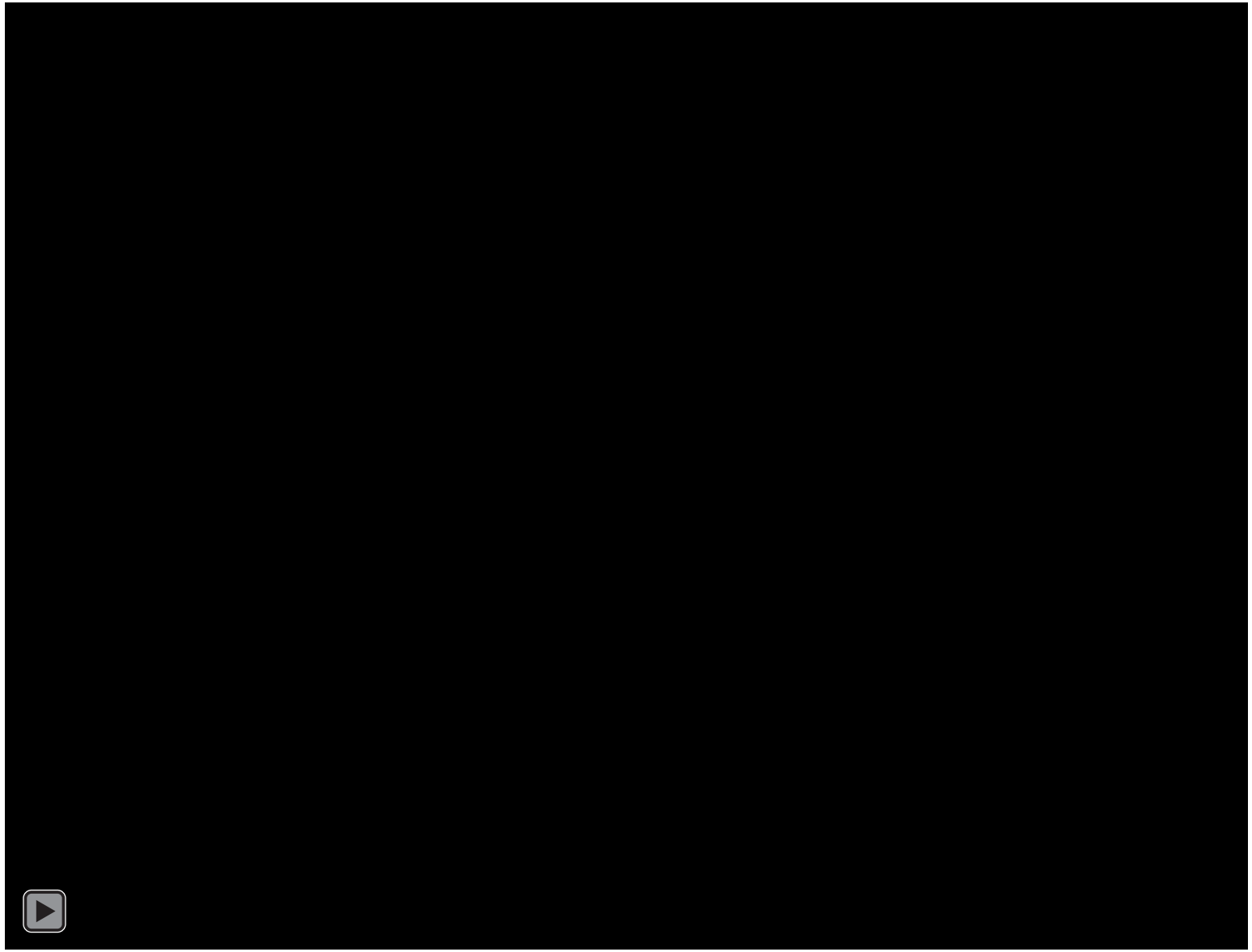


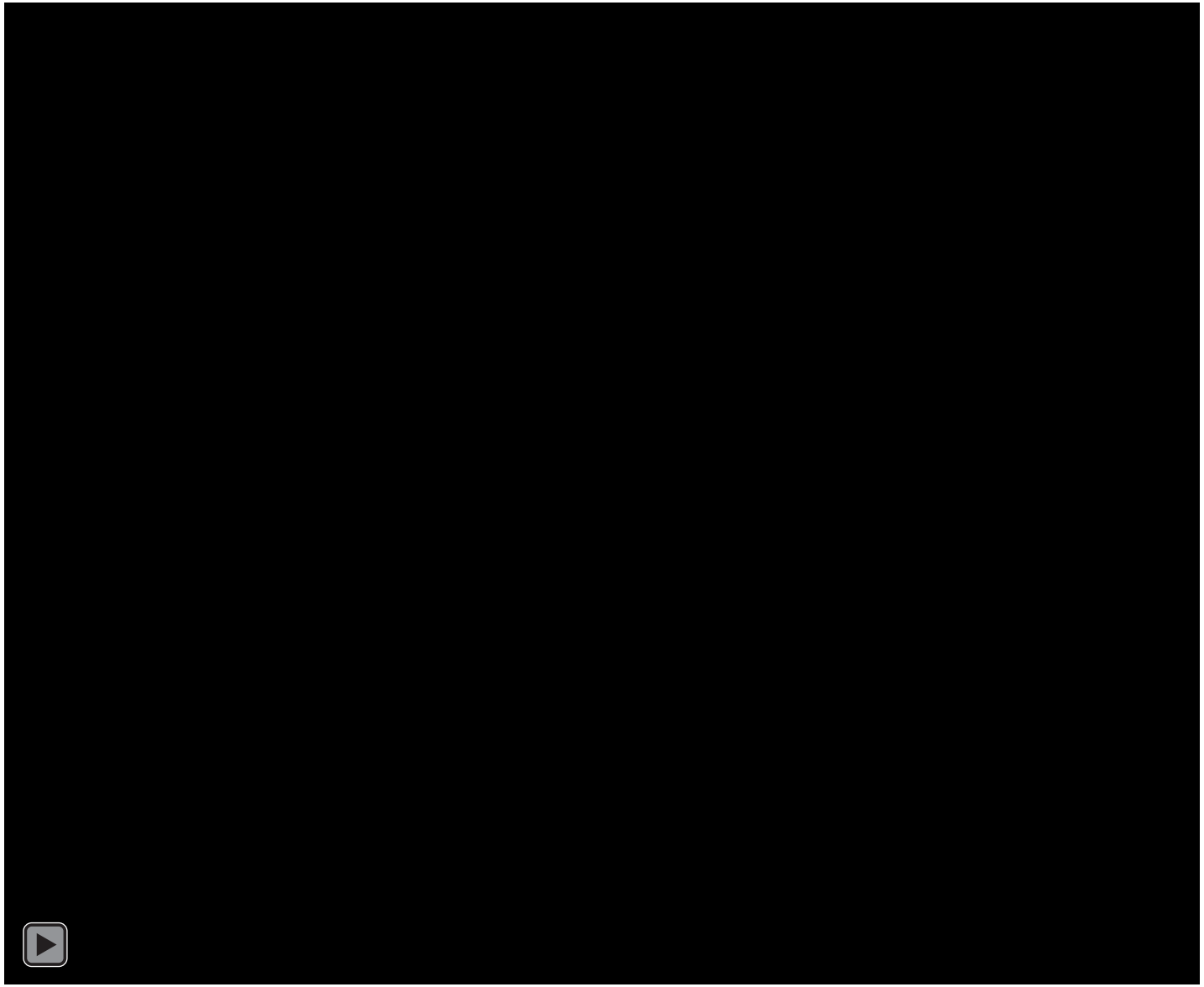
MAPPING

Acute mapping parameters

- **Sensing 8.0 mV**
- **Threshold 1.0 V @ 0.5 ms**
- **Impedance 300 ohms**







Implant Characteristics and Follow-up

Acute mapping parameters

Sensing 8.0 mV
Theshold 1.0 V 0.5 ms ,
Impedance 300 ohms

During implant

Sensing 6.0 mV
Threshold 2.25 V 0.5 ms
Impedance 550 ohms

Subsequent rise 2 hrs later

Sensing 10.0 mV
Threshold 1.5 V @ 0.5ms
Impedance 420 ohms

THANK YOU

Rx Only

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Indications: The Aveir™ Leadless Pacemaker system is indicated for patients with significant bradycardia and:

- Normal sinus rhythm with rare episodes of A-V block or sinus arrest
- Chronic atrial fibrillation
- Severe physical disability

Rate-Modulated Pacing is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity.

Intended Use: The Aveir™ Leadless Pacemaker (LP) is designed to provide bradycardia pacing as a pulse generator with built-in battery and electrodes for implantation in the right ventricle. The LP is intended to provide sensing of intrinsic cardiac signals and delivery of cardiac pacing therapy to the target patient population.

The Aveir™ Delivery Catheter system is intended to be used in the peripheral vasculature and the cardiovascular system to deliver and manipulate an LP. Delivery and manipulation includes implanting an LP within the target chamber of the heart.

Contraindications: Use of the Aveir™ Leadless Pacemaker is contraindicated in these cases:

Use of any pacemaker is contraindicated in patients with a co-implanted ICD because high-voltage shocks could damage the pacemaker and the pacemaker could reduce shock effectiveness.

Single-chamber ventricular demand pacing is relatively contraindicated in patients who have demonstrated pacemaker syndrome, have retrograde VA conduction, or suffer a drop in arterial blood pressure with the onset of ventricular pacing.

Programming of rate-responsive pacing is contraindicated in patients with intolerance of high sensor-driven rates.

Use is contraindicated in patients with an implanted vena cava filter or mechanical tricuspid valve because of interference between these devices and the delivery system during implantation.

Persons with known history of allergies to any of the components of this device may suffer an allergic reaction to this device. Prior to use on the patient, the patient should be counseled on the materials (listed in Product Materials section in IFU) contained in the device and a thorough history of allergies must be discussed.

Adverse Events: Potential complications associated with the use of the Aveir™ Leadless Pacemaker system are the same as with the use of single chamber pacemakers with active fixation pacing leads including, but not limited to: Cardiac perforation, Cardiac tamponade, Pericardial effusion, Pericarditis, Valve damage and/or regurgitation, Heart failure, Pneumothorax/hemothorax, Cardiac arrhythmias, Diaphragmatic/phrenic nerve stimulation / extra-cardiac stimulation, Palpitations, Hypotension, Syncope, Cerebrovascular accident, Infection, Hypersensitivity reaction to device materials, medications, or direct toxic effect of contrast media on kidney function, Pacemaker syndrome, Inability to interrogate or program the LP due to programmer or LP malfunction, Intermittent or complete loss of pacing and/or sensing due to dislodgement or mechanical malfunction of the LP (non-battery related), Loss of capture or sensing due to embolization or fibrotic tissue response at the electrode, Increased capture threshold, Inappropriate sensor response, Interruption of desired LP function due to electrical interference, either electromyogenic or electromagnetic, Battery malfunction/ premature battery depletion, Device-related complications (Premature deployment, Device dislodgement/embolization of foreign material, Helix distortion), Death.

As with any percutaneous catheterization procedure, potential complications include, but are not limited to: Vascular access complications (such as perforation, dissection, puncture, groin pain), Bleeding or hematoma, Thrombus formation, Thromboembolism, Air embolism, Local and systemic infection, Peripheral nerve damage, General surgery risks and complications from comorbidities (such as hypotension, dyspnea, respiratory failure, syncope, pneumonia, hypertension, cardiac failure, reaction to sedation, renal failure, anemia, and death)

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