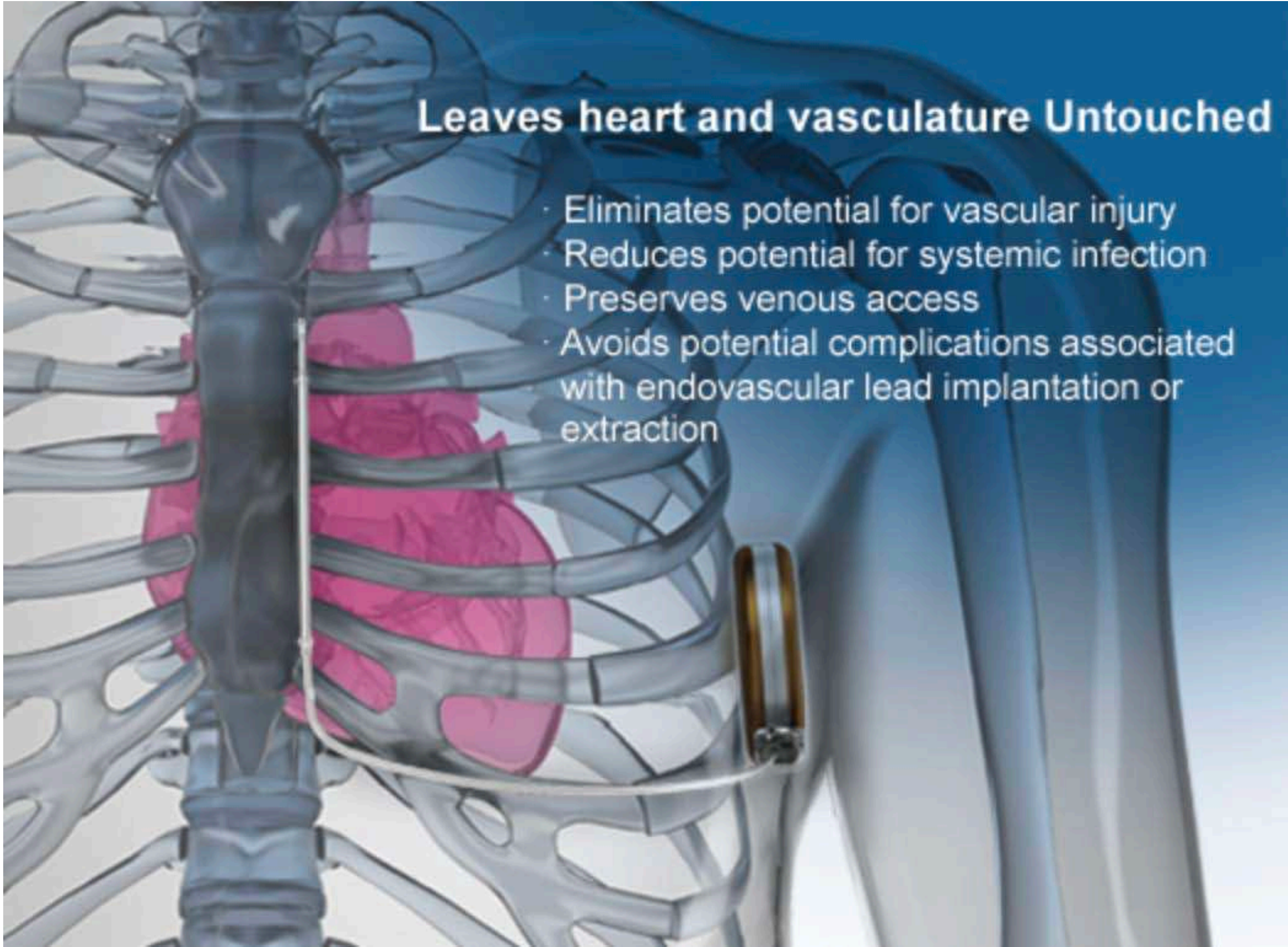


SUBCUTANEOUS ICD AND ITS ROLE AND ADVANTAGE IN PREVENTION OF SUDDEN CARDIAC DEATH

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BAKU HEALTH CENTER



Leaves heart and vasculature Untouched

- Eliminates potential for vascular injury
- Reduces potential for systemic infection
- Preserves venous access
- Avoids potential complications associated with endovascular lead implantation or extraction

Effective defibrillation without transvenous leads

- Effective detection and conversion of induced and spontaneous VT/VF episodes^{1,2}
- Low rates of significant clinical complications¹
- Effective discrimination of AF and SVT from VT/VF^{1,2,3}
- Rate of inappropriate therapy is consistent with transvenous ICDs^{1,2,3}

Sophisticated technology

- Identifies and classifies the heart rhythm, rather than individual beats
- Revolutionary approach to sensing the subcutaneous signal
- INSIGHT™ algorithm effectively discriminates between treatable and other high-rate supra-ventricular events
- Designed to allow self-termination of non-sustained tachyarrhythmia

Durable subcutaneous electrode design

- Subcutaneous placement avoids intra-cardiac biomechanical stresses
- Multistrand cable-core design provides exceptional tensile strength
- Durable polyurethane body is highly resistant to abrasion

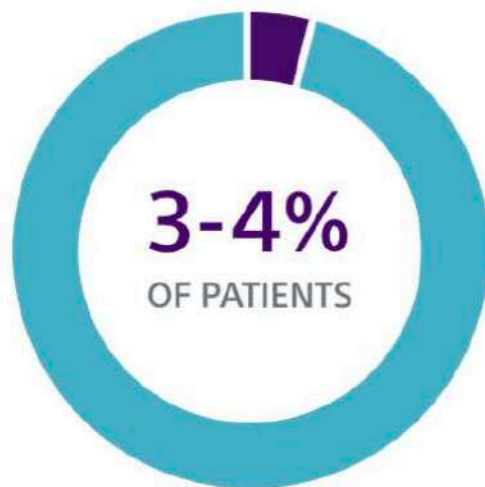
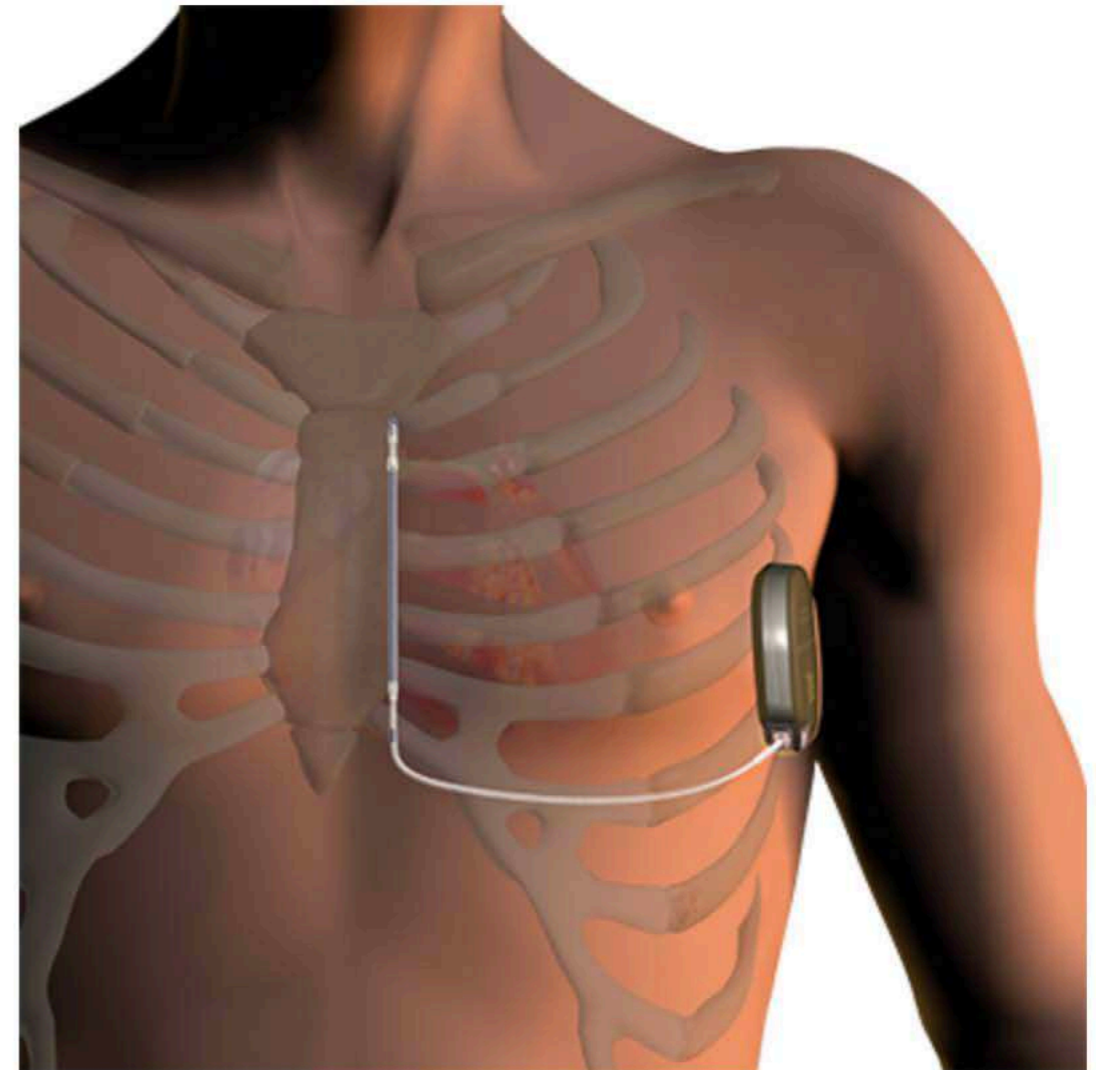
New Solution for a broad range of patients at risk for SC

- Effective for a majority of primary and secondary ICD candidates*
- Alternative for TV-ICD replacements due to lead malfunction/infection
- Ideal for primary electrical or structural heart disease
- Appropriate for a broad range of body types

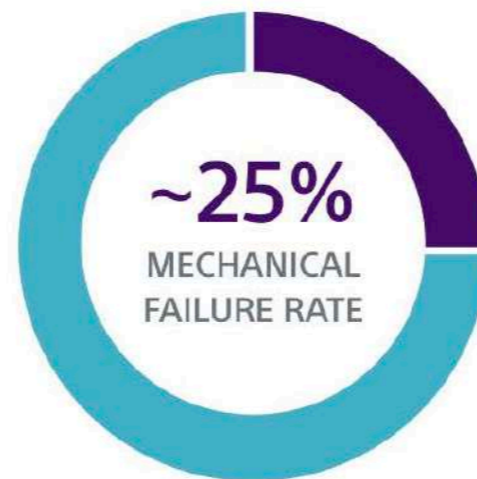
Entirely Subcutaneous ICD

The S-ICD System may be implanted using only anatomical landmarks, thereby eliminating the need for fluoroscopy during implant:

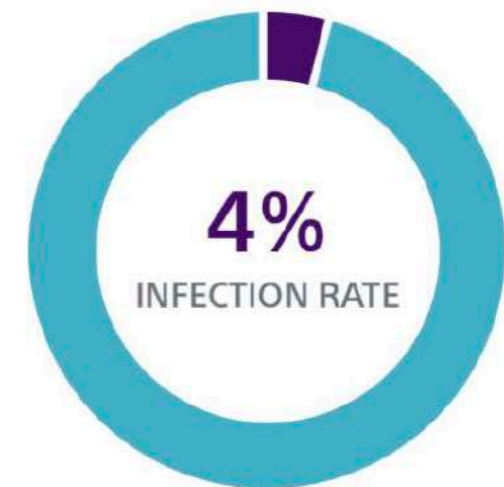
- Reducing radiation exposure for both patients and physicians
- Eliminating the need for lead apron during implant



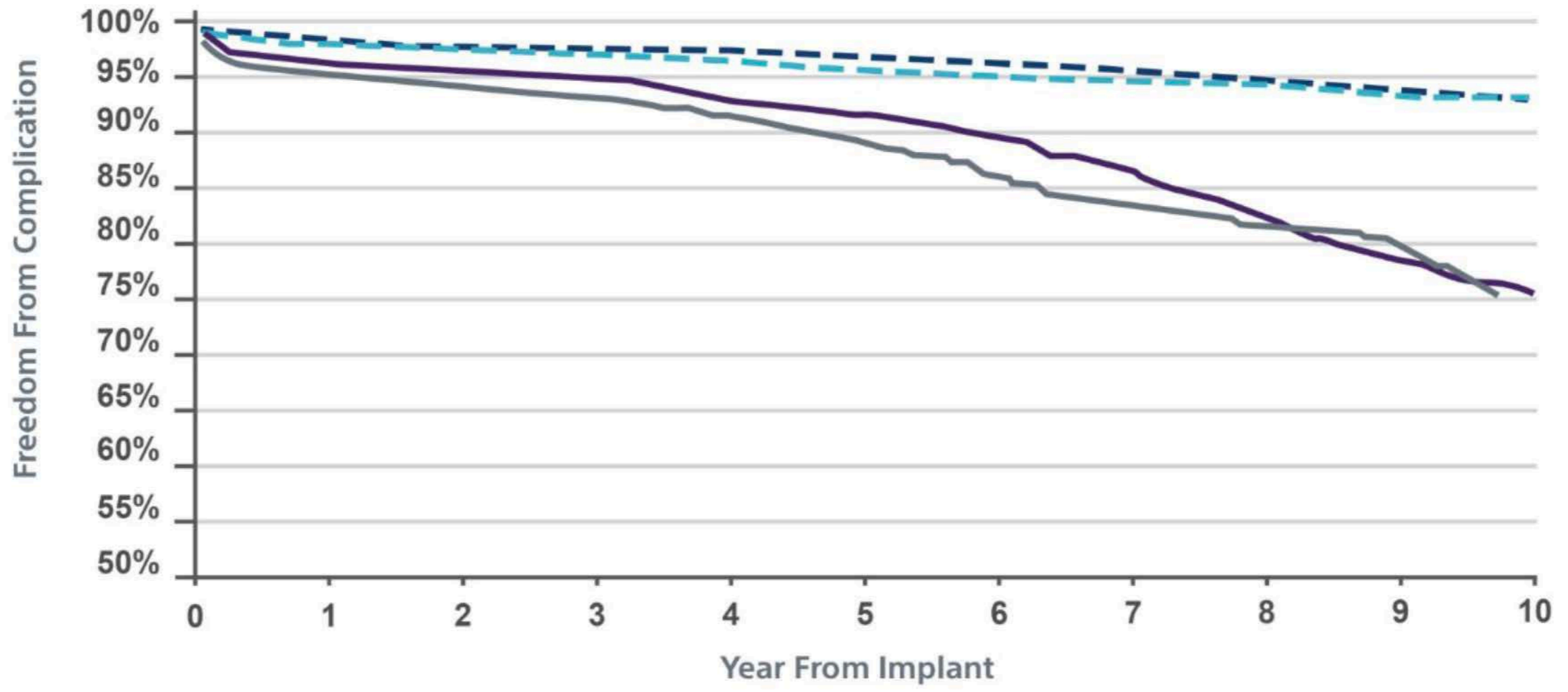
3-4% of patients with TV-ICD suffer lead malfunctions in the first year of implant¹¹



About 25% mechanical failure rate for TV-ICD at 10 years¹¹

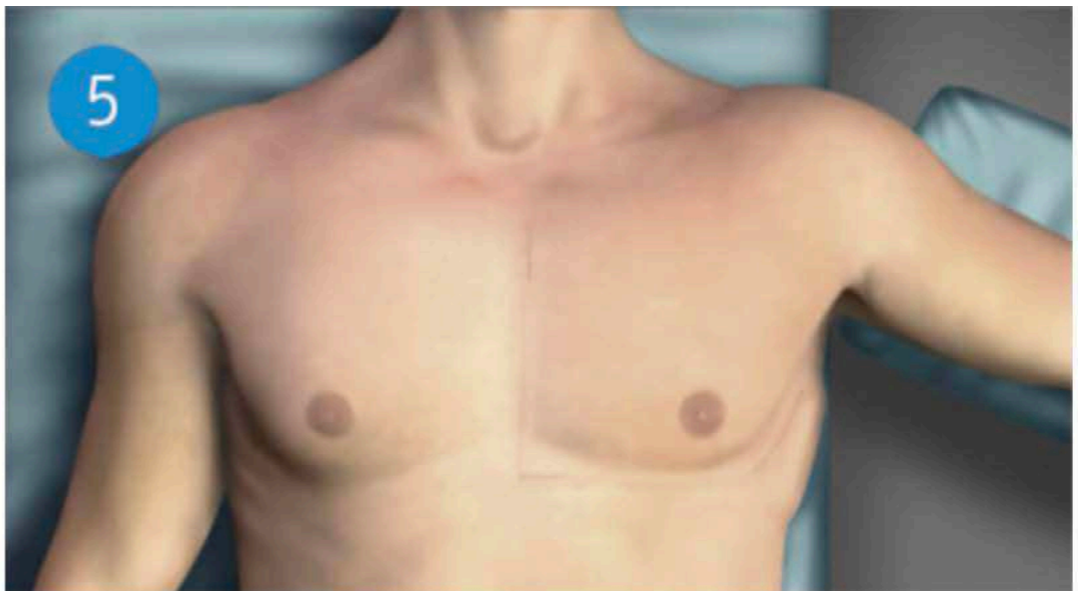
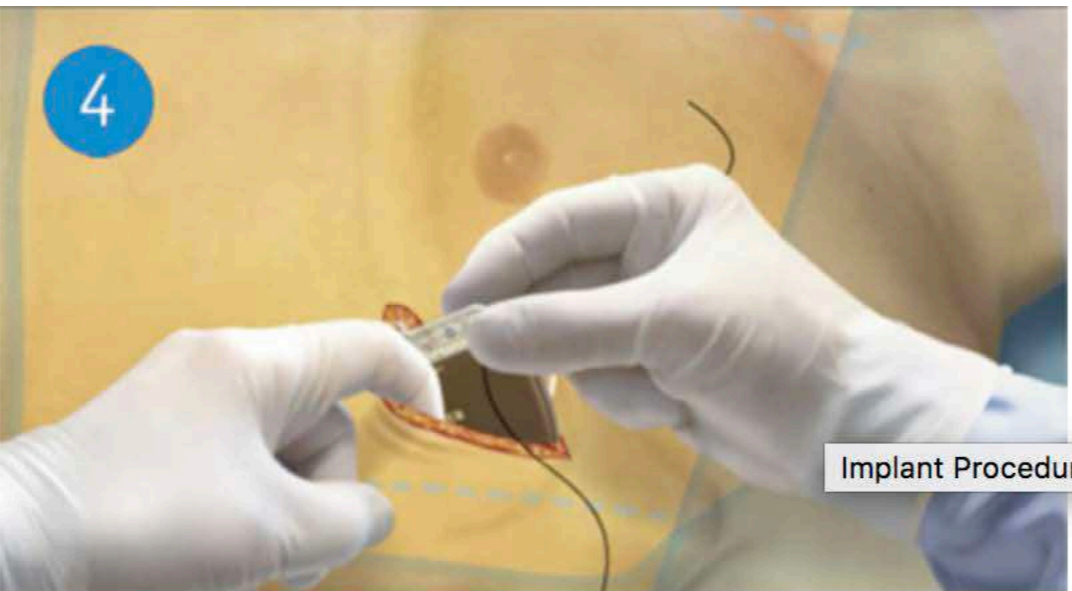
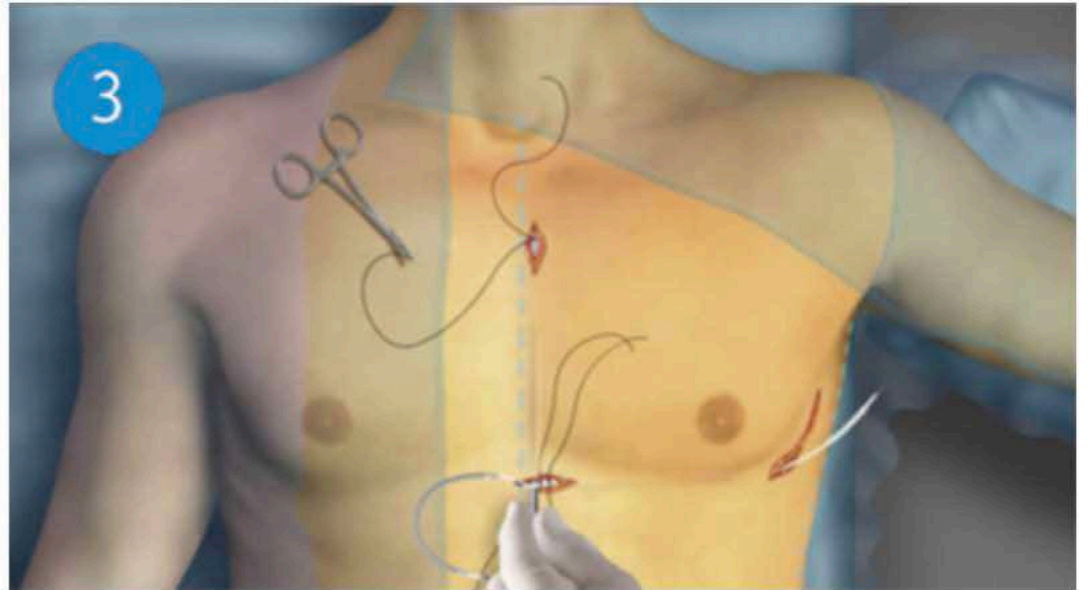
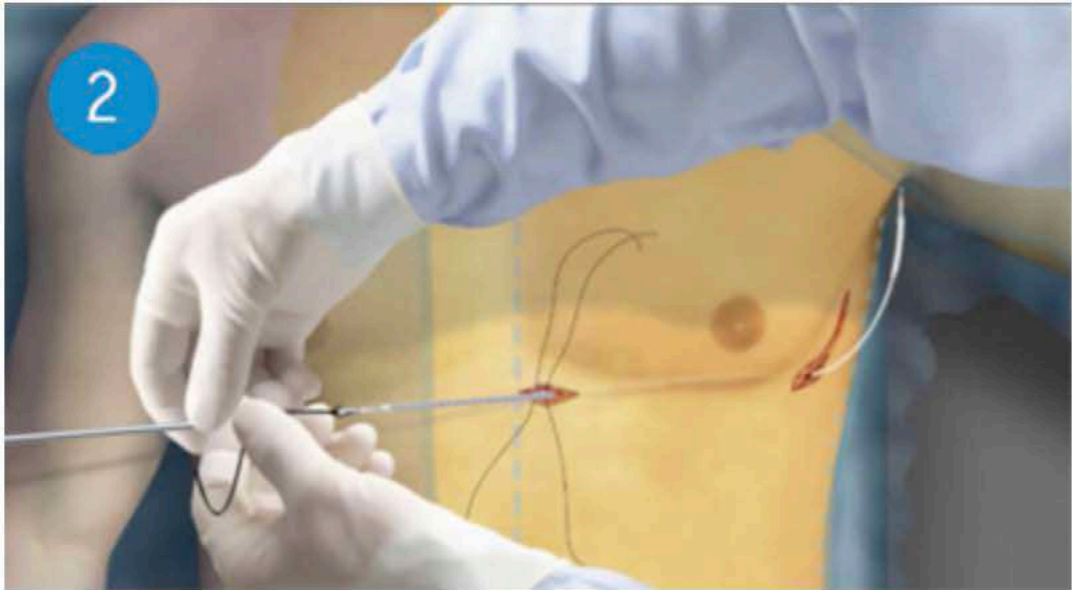
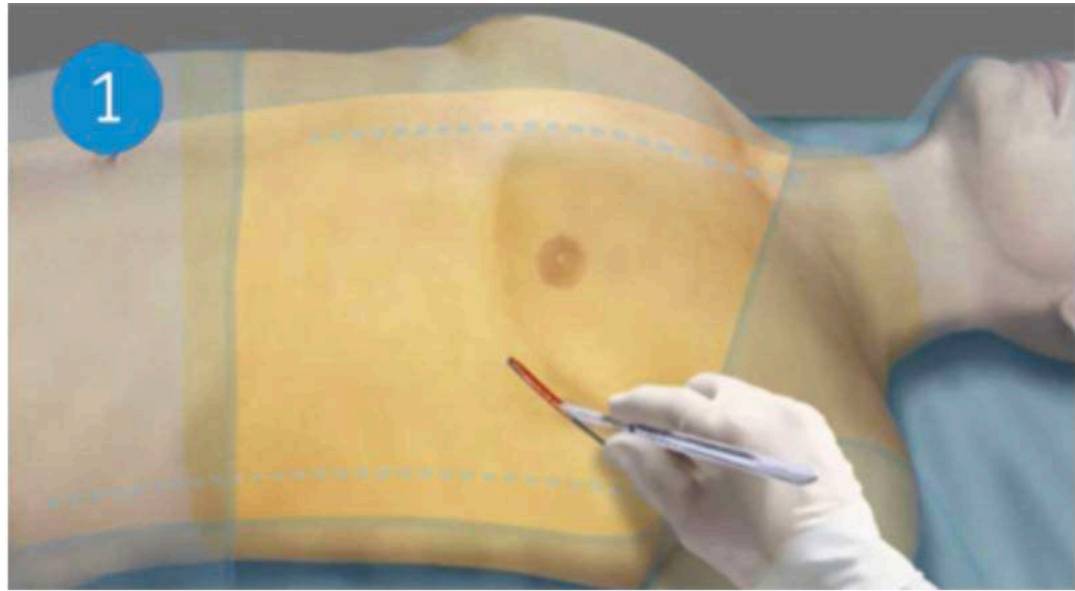


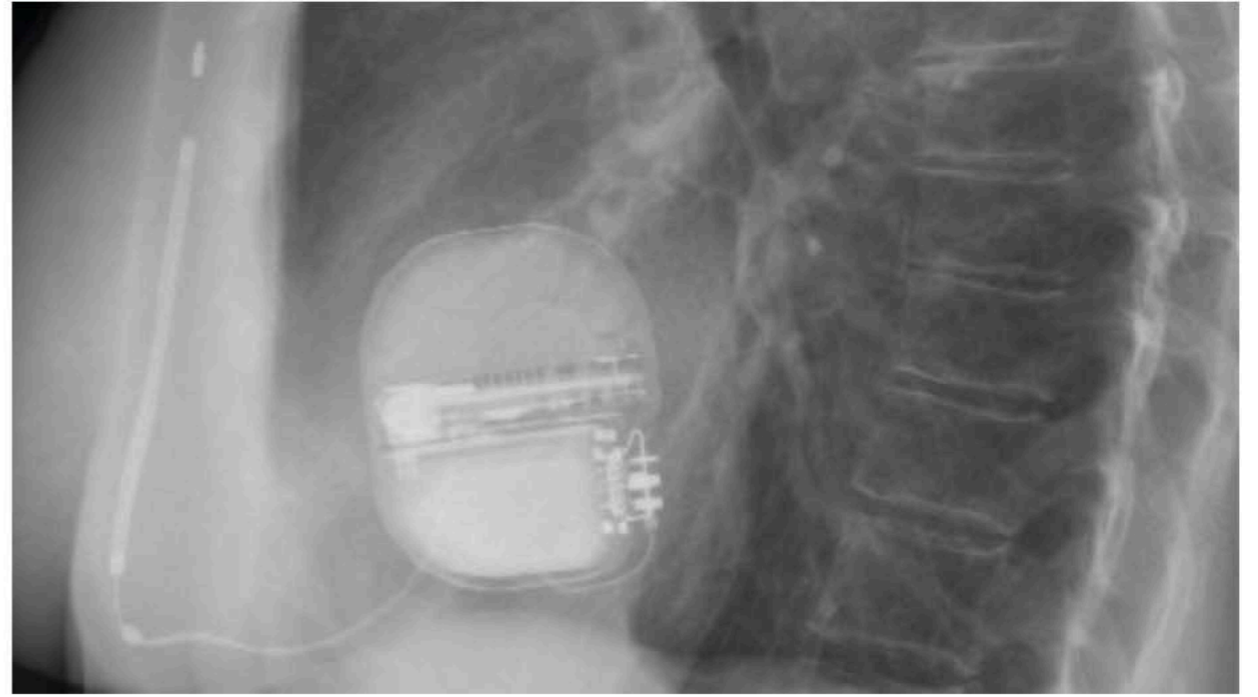
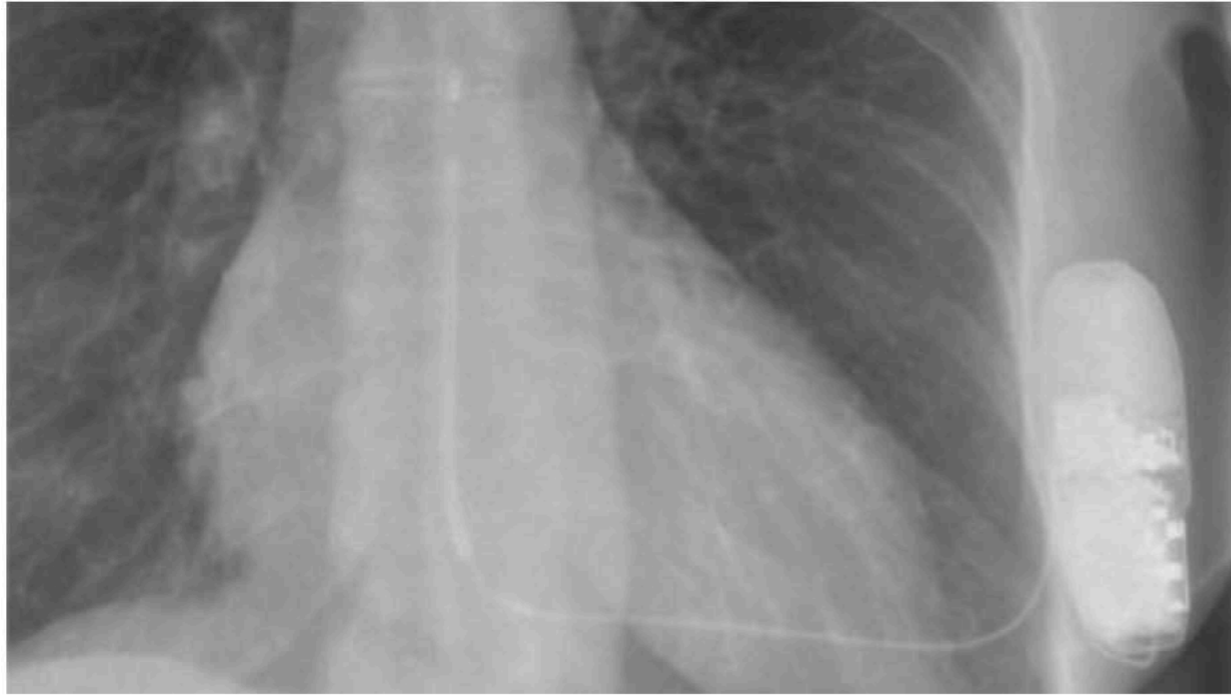
4% infection rate for TV-ICD at 10 years¹¹



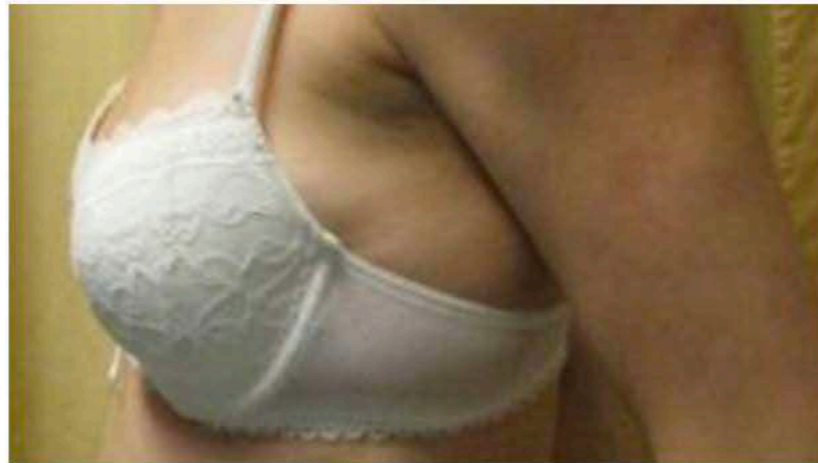
		Total	Year									
			0	1	2	3	4	5	6	7	8	9
Infection	ICD	28,505	18,080	11,968	7,853	5,382	3,699	2,387	1,489	1,035	532	275
	CRT-D	12,285	7,619	4,948	3,077	1,960	1,300	778	683	319	179	179
			98.8%	98.4%	97.9%	97.4%	97.1%	96.6%	95.9%	95.1%	94.3%	93.2%
			98.4%	98.1%	97.8%	97.0%	96.1%	95.4%	94.8%	94.5%	93.6%	93.6%
Mechanical	ICD	28,505	17,784	11,624	7,643	5,137	3,374	2,242	1,352	769	432	247
	CRT-D	12,285	7,402	4,626	2,929	1,865	1,166	705	419	279	134	75
			96.9%	96.1%	95.0%	93.6%	92.0%	90.0%	86.5%	83.1%	79.1%	76.1%
			95.0%	94.6%	93.4%	91.7%	89.3%	86.2%	84.1%	82.1%	79.5%	75.2%

- ICD Infection
- CRT-D Infection
- ICD Mechanical
- CRT-D Mechanical





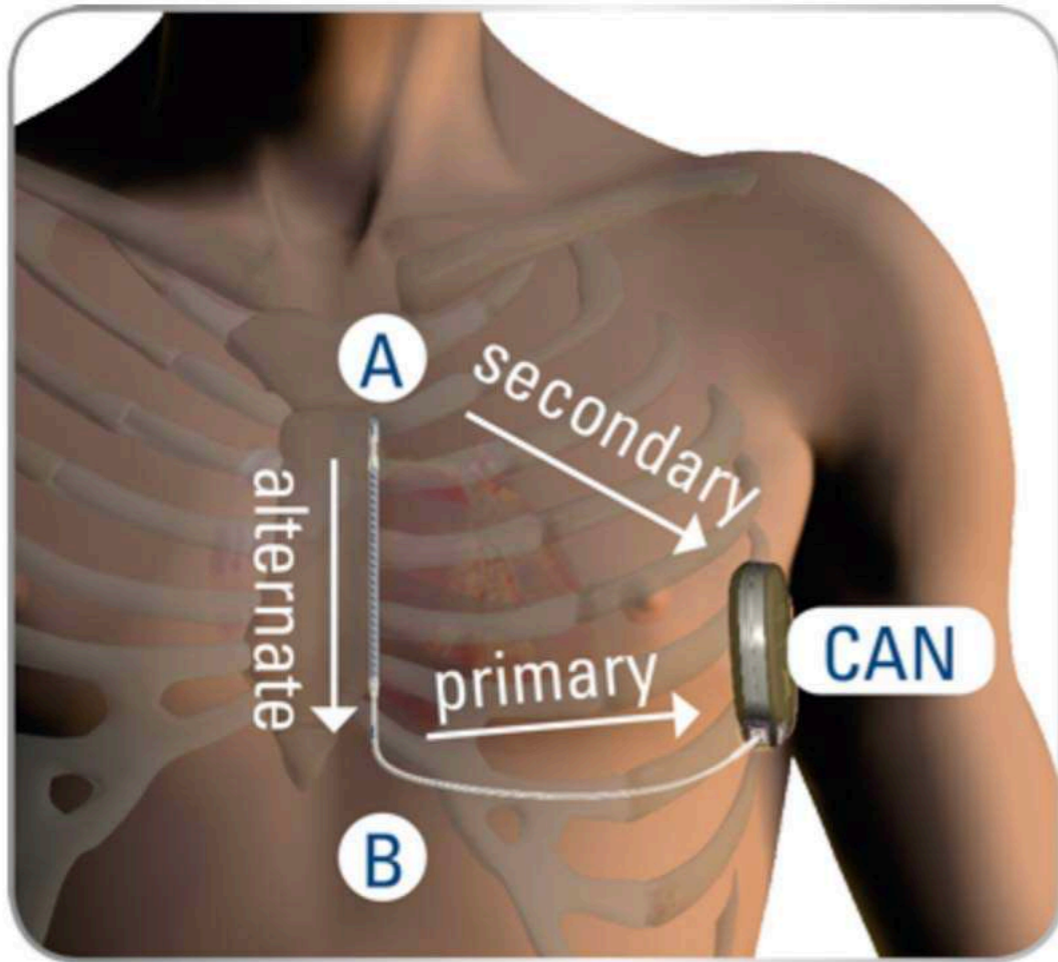
Post-op 30 days



Post-op 30 days



Post-op 60 days



PHASE I
Detection

Subcutaneous signal
detection

PHASE II
Certification

Heart rate
determined

PHASE III
Therapy
Decision

Heart rhythm assessed and
confirmation for therapy

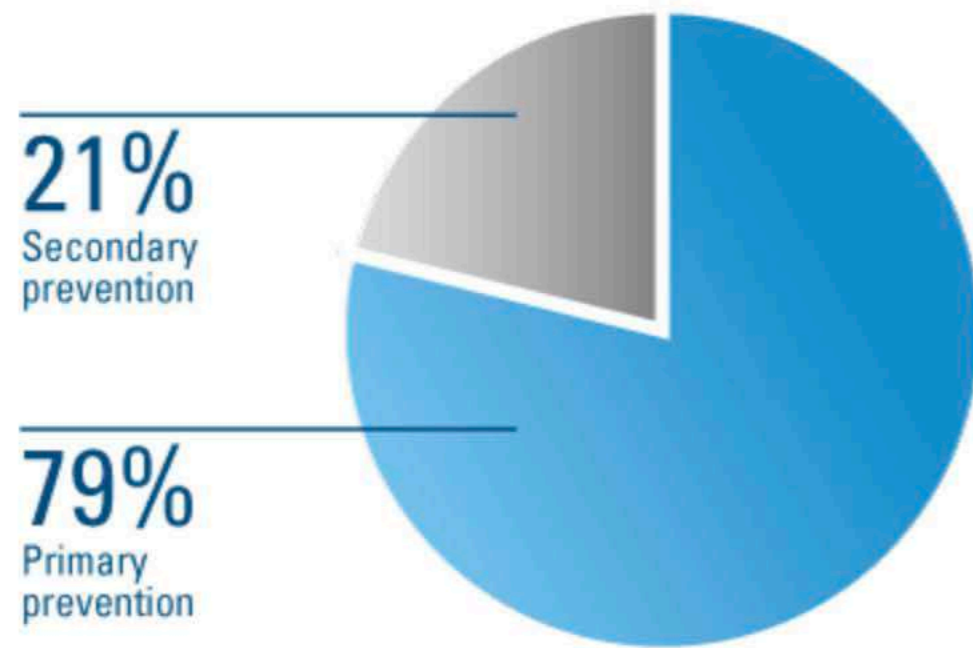
THREE SIMULTANEOUS RHYTHM ANALYSES:

- **Static morphology analysis** identifies nonshockable rhythms, utilizing the NSR (normal sinus rhythm) template.
- **Dynamic morphology analysis** identifies shockable polymorphic rhythms by comparing each complex to the previous ones.
- **QRS width analysis** compares the QRS width to the NSR QRS width.

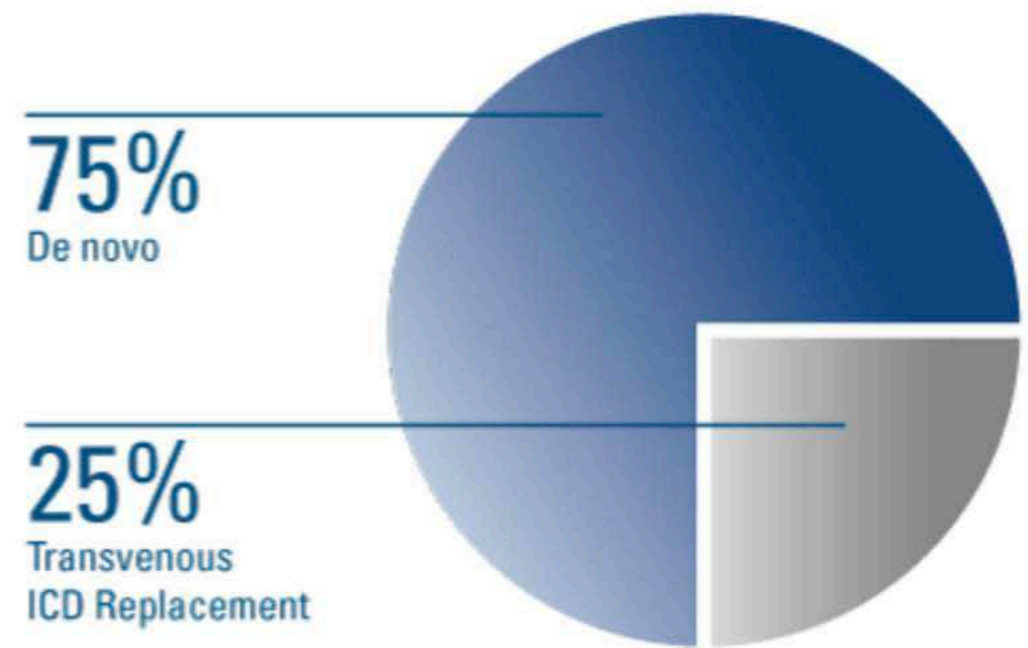


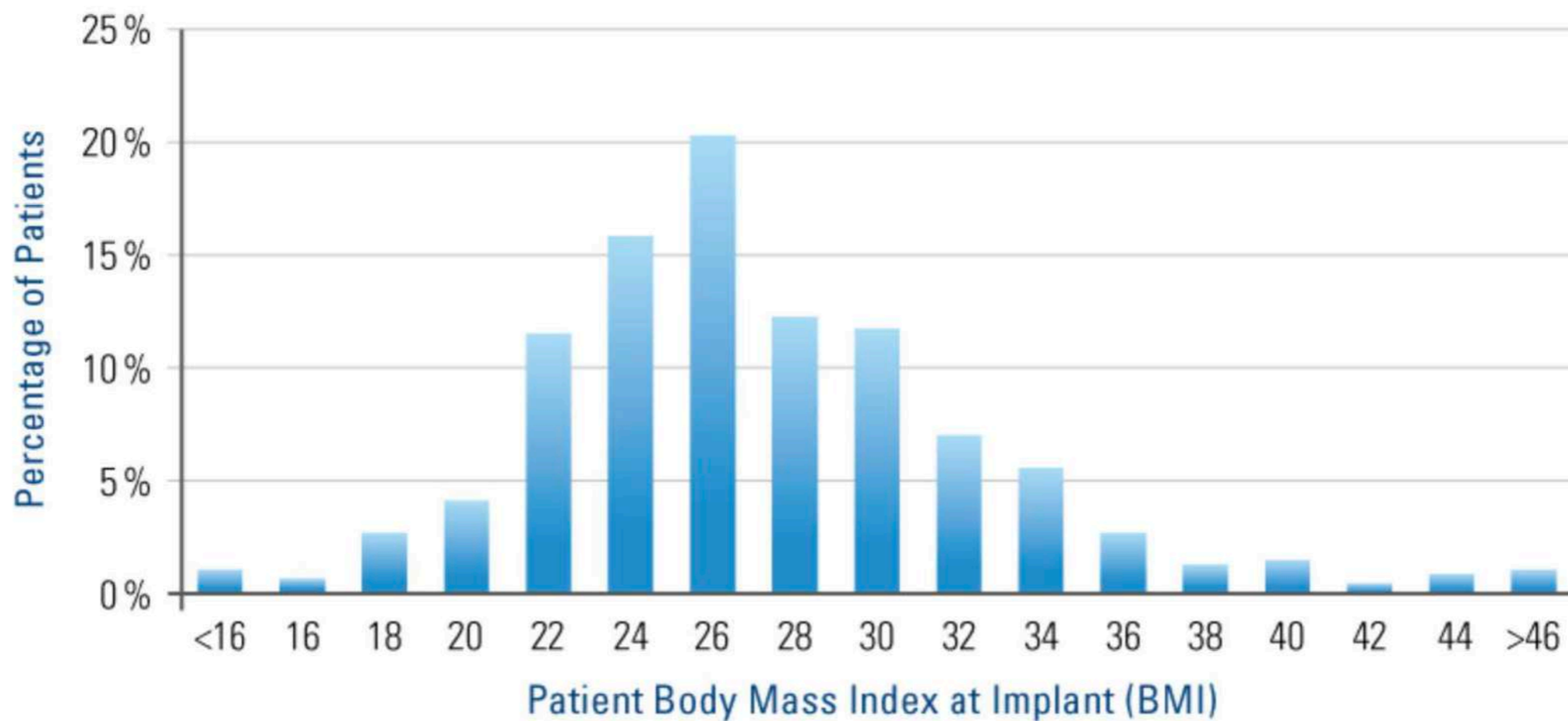
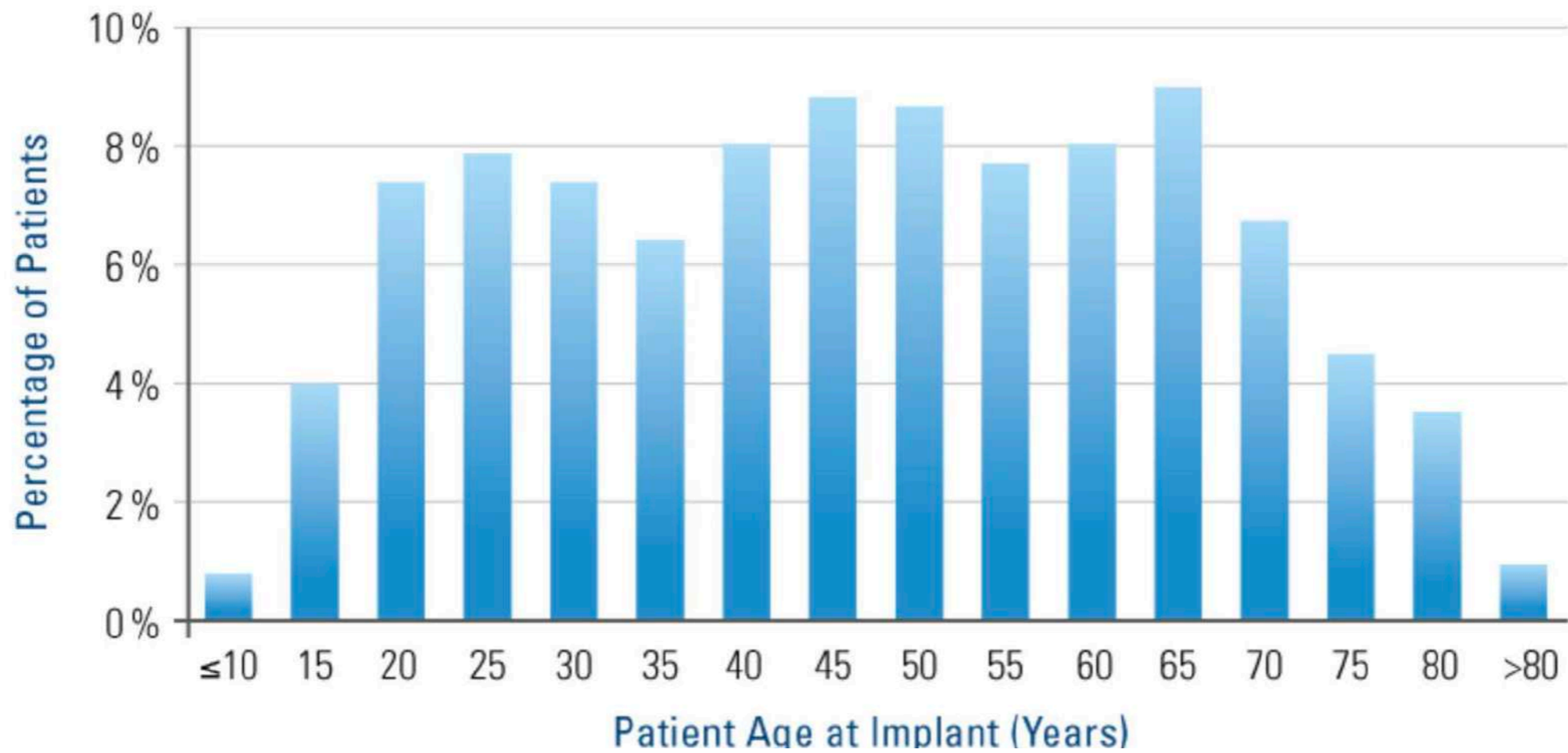
Ventricular Tachycardia

S-ICD System Indication

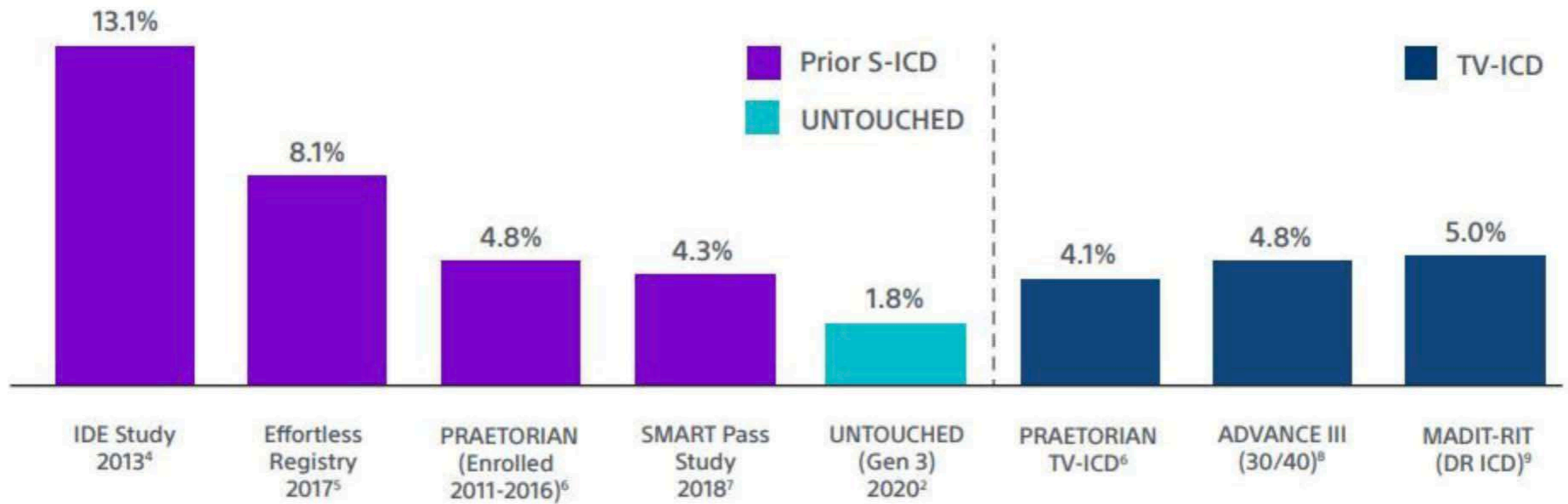


S-ICD System Implants





INAPPROPRIATE SHOCK RATE



S-ICD Conversion Rates

UNTOUCHED²

N = 1,111
(Enrolled 2015 - 2018)



PAS 1 Year⁹

N = 1,637
(Enrolled 2013 - 2015)



EFFORTLESS 3 Year⁴

N = 985
(Enrolled 2009 - 2013)



IDE³

N = 321
(Enrolled 2009)



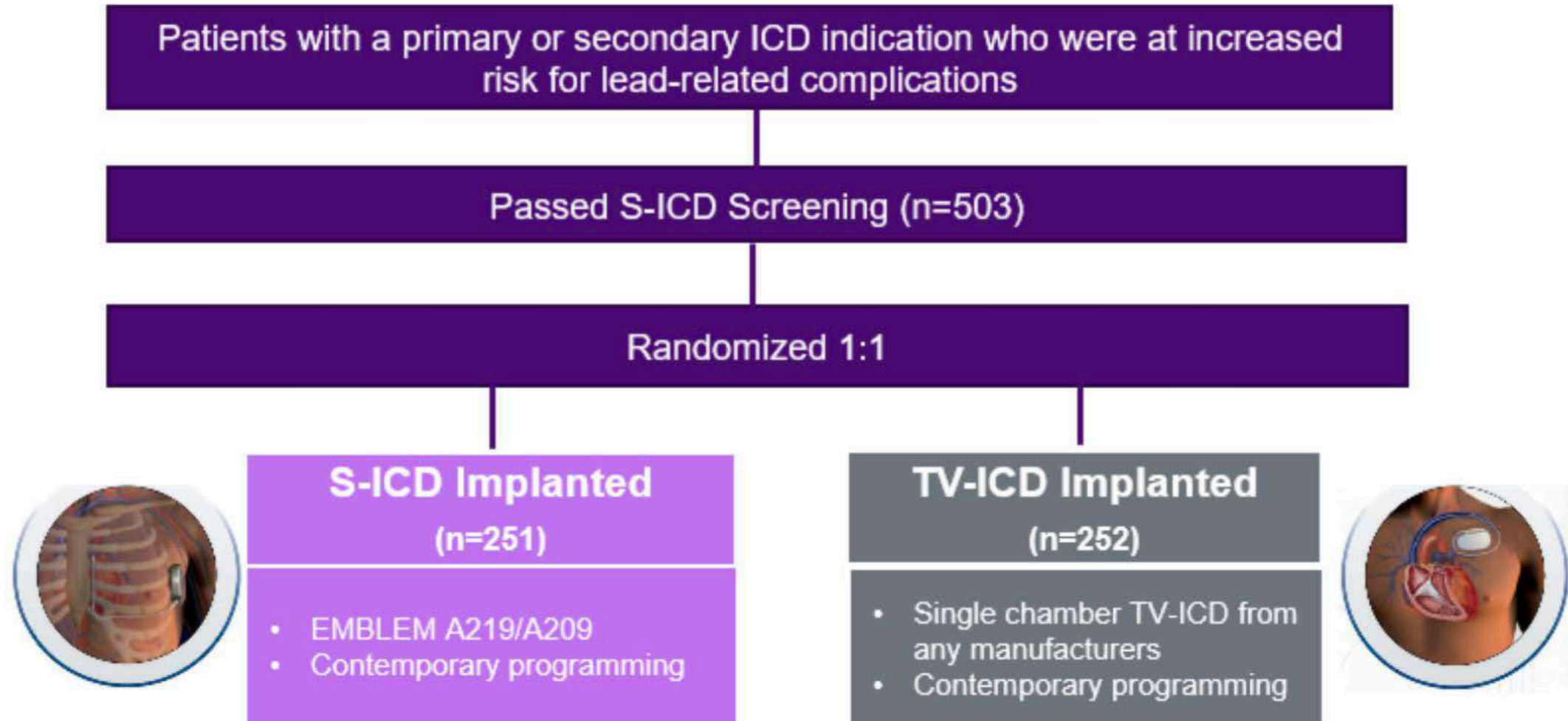
■ First Shock ■ Final Shock



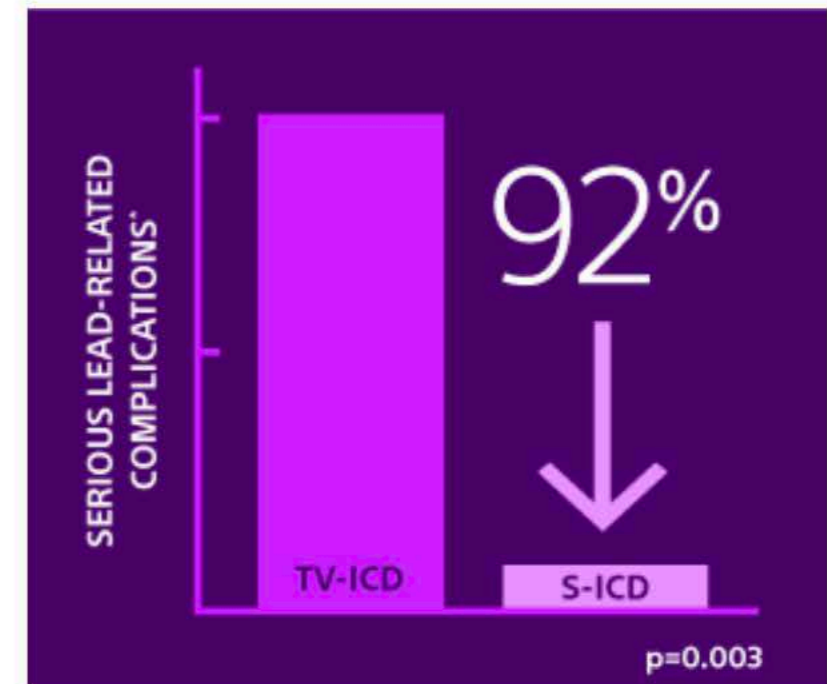
0
SYSTEMIC
INFECTIONS²

ATLAS Randomized Controlled Trial: S-ICD Superior to TV-ICD

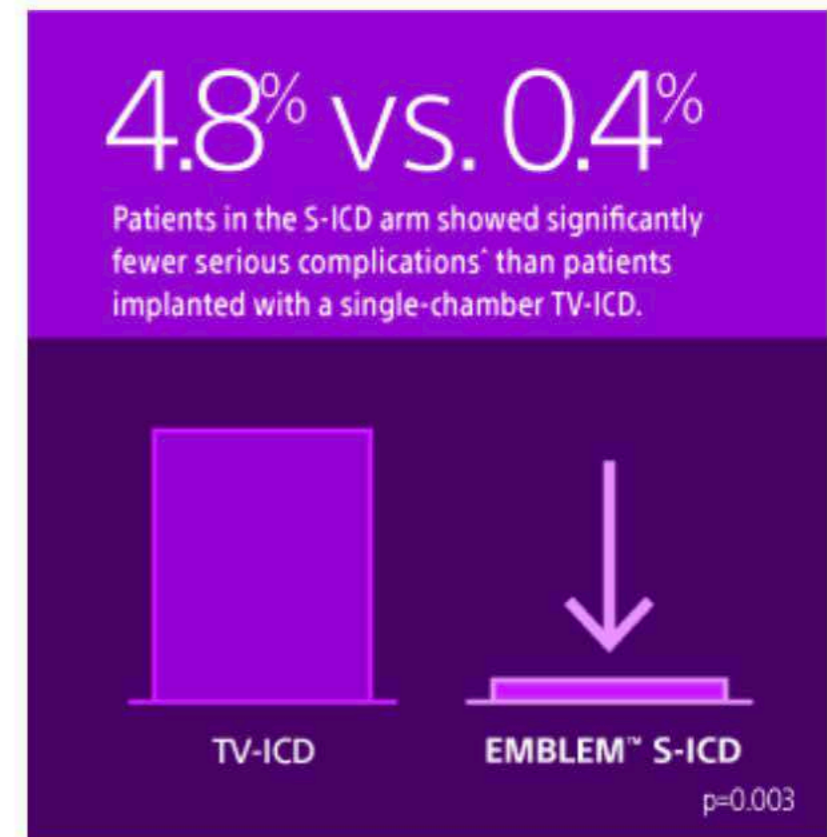
Enrollment and Randomization Protocol



The ATLAS trial met its **primary superiority endpoint** demonstrating a highly significant 92% reduction in serious lead-related complications* at six months for the EMBLEM™ S-ICD compared to any manufacturer's single chamber TV-ICD devices. $p=0.003$ ¹



Serious lead-related complication* occurred in **12 times** as many patients in the single chamber TV-ICD arm (4.8%) at six months compared to 1 patient (0.4%) in the S-ICD arm.¹



Future upgrade pathway with the Modular CRM (mCRM™) System*

Should patients currently implanted with an EMBLEM S-ICD device develop a need for intracardiac ATP and/or bradycardia pacing, an upgrade pathway will be available once the EMPOWER Leadless Pacemaker (LP)* and mCRM system receive FDA approval.

The mCRM system is designed to provide upgrade pathways regardless if the EMBLEM S-ICD or EMPOWER LP is implanted first, providing physicians flexibility to tailor therapy to the individual patient's needs.²



EMBLEM S-ICD

The only extrathoracic implantable defibrillator that provides protection from both sudden cardiac death and the risks and complications associated with transvenous leads.

- Eliminates potential for vascular injury, transvenous lead insertion complications, lead-associated tricuspid regurgitation, mechanically induced pro-arrhythmia, and transvenous lead failure and associated extraction risk
- Reduces risk of systemic infection
- Preserves the vasculature
- Remains outside the ribcage, never touching the heart



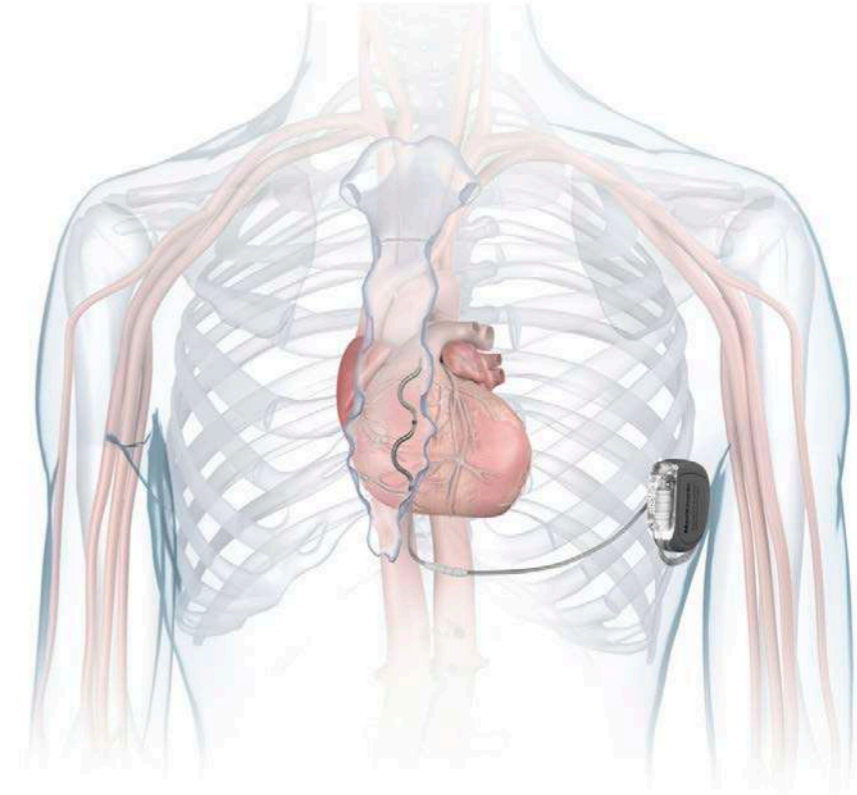
EMPOWER LP*

The EMPOWER LP is designed to be paired with S-ICD to provide pacing or ATP therapies at the time they are needed.

- ATP when commanded by a paired S-ICD
- Delivery system with inner extendable shaft
- 20.7 F delivery catheter
- Dedicated retrieval catheter
- Rate response via accelerometer
- > 10 Year average longevity expected when used primarily for ATP therapy as part of an mCRM System

OCT 23, 2023

Medtronic receives FDA approval for extravascular defibrillator to treat abnormal heart rhythms, sudden cardiac arrest



MDT-Aurora-EV-ICD-illustration-in-chest-high-res

Medtronic Aurora EV-ICD™ system

- Anti-tachycardia Pacing (ATP), to terminate ventricular arrhythmias (rapid and/or chaotic activity of the heart that can lead to SCA) using low-energy pacing pulses, potentially avoiding a defibrillation shock.
- Pause Prevention Pacing, to provide back-up pacing for brief, intermittent, heartbeat pauses.
- 40 Joule Defibrillation Energy, to deliver life-saving shocks in a device the size of transvenous ICDs (33 cc)
- Medtronic exclusive PhysioCurve™ design, to increase patient comfort and implant acceptance.
- 11.7-year projected longevity, to reduce device replacement procedures during a patient's lifetime.



THANK YOU
FOR YOUR
ATTENTION.

Dr. Farid Aliyev