Foreword

The long-sought dream of leadless cardiac pacing has finally been achieved thanks to on-going technology development.

Leadless pacemakers and subcutaneous/extravascular implantable cardioverter defibrillators (S-ICDs/EV-ICDs) mark a new era in cardiac pacing, allowing for a potentially significant reduction in device and lead-related complications.

Nevertheless, traditional transvenous pacing remains the most common method used to treat our patients. If on the one hand, the era of wireless cardiac pacing has begun, on the other hand, we are witnessing a rediscovery of a more physiological cardiac stimulation with the use of transvenous lead, that is permanent His bundle pacing.

Leads continue to be the Achilles' heel of transvenous cardiac pacing, and as long as transvenous cardiac pacing exists, we will have to deal with leads at implant, follow-up and extraction.

To maximize safety and efficacy and understand why possible failures and complications occur, implanters and physicians must be familiar with both the traditional and new cardiac implantable electronic devices (CIEDs).

This book is a must-read for anyone involved in the treatment of patients with CIEDs. It offers a complete overview of the historical milestones in cardiac pacing, defibrillation and cardiac resynchronization, and the important technological developments for the best treatment of our patients.

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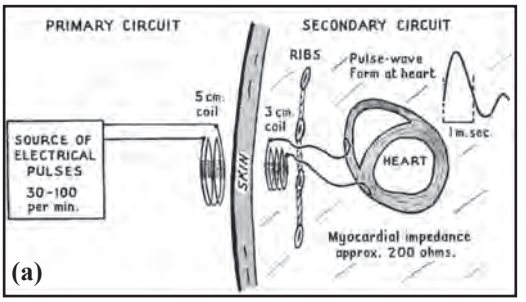
Dr. Leon Abrams at the University of Birmingham, Birmingham, United Kingdom, lead a group that invented another device (the Abrams-Lucas inductive coupled unit, made by *Lucas Industries*). The receiver consisted of a thousand turns of fine copper wire wound to form a ring and covered with silicone rubber (Figure 1.41 a/b). From this implanted coil, two wires were attached to the heart wall. Figure 1.42 a/b/c illustrates the concept.



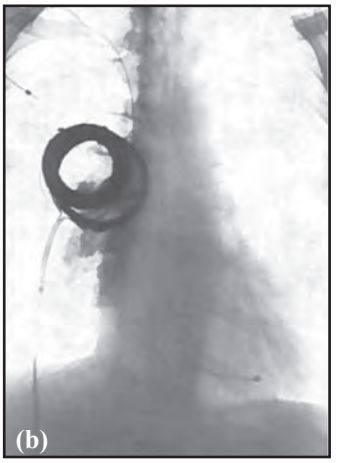


Figure 1.41. (a) Concept of Dr. Abrams' device, **(b)** chest X-ray showing external and internal coils (primary and secondary circuits). Courtesy *Dr. Michael Gammage, University of Birmingham, Birmingham, United Kingdom*.

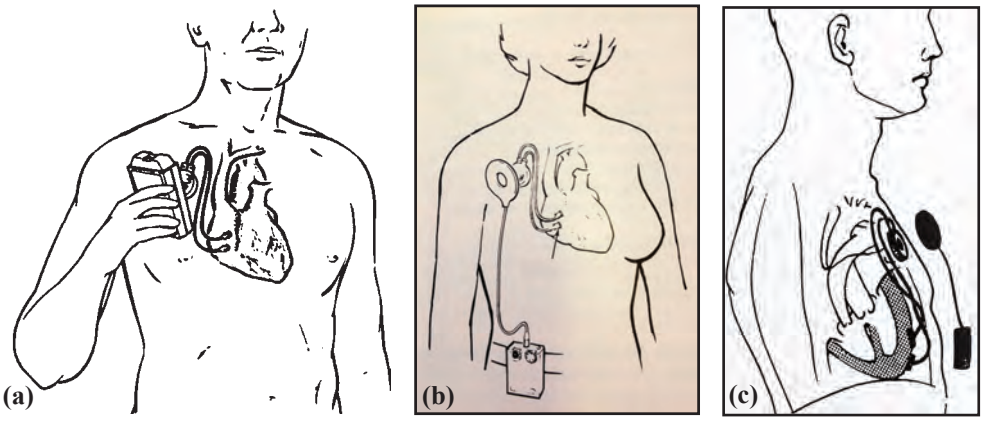


Figure 1.42. (a) (b) (c) Transmitter with external antenna and implanted receiver with electrodes affixed to heart muscle.

Fundamental problems involved in electromagnetic energy transport across tissue barriers triggered additional research. In 1963, Dr. Stoeckle et al. described a concept for cardiac pacing by direct inductive coupling between an external coil and a small pacemaker implanted on the ventricle. The implantable receiver module was made of resin covered by Silastic. Experiments were conducted using pin electrodes made of brass, stainless steel and platinum/iridium [*6*].

In 1965, electronic engineer Ignacio Escobar established a small pacemaker and lead factory in Medellín, Colombia. Devices were then built in Medellín and Bogota (Figure 1.43 a/b)

company, which acquired *Intec* in 1985. The device was given the trade name of automated implantable cardioverter defibrillator (AICD) (Figure 1.113 a/b). It was encased in titanium and weighed 250 gr. A sensing electrode was placed in the superior vena cava, and a rather large patch electrode was sutured over the apex of the heart.

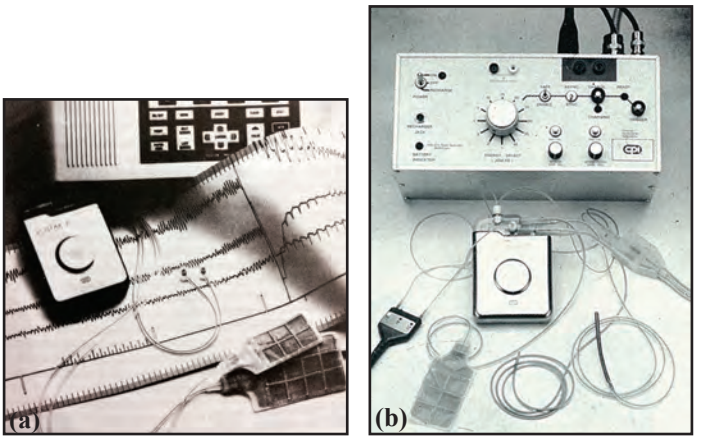


Figure 1.113. (a) (b) Automated implantable cardioverter defibrillator (AICD).

A sternotomy was required for implantation (Figure 1.114). The unit sensed ventricular fibrillation and stopped it with the application of an electrical shock of about 25 J directly over the heart. Epicardial patches and epimyocardial leads were used (Figure 115 a/b).

Figure 1.114. Sternotomy for implant of AICD (a large patch and 2 epicardial leads can be seen). The procedure was associated with surgical morbidity, postoperative hospital care requirement and hospital costs.

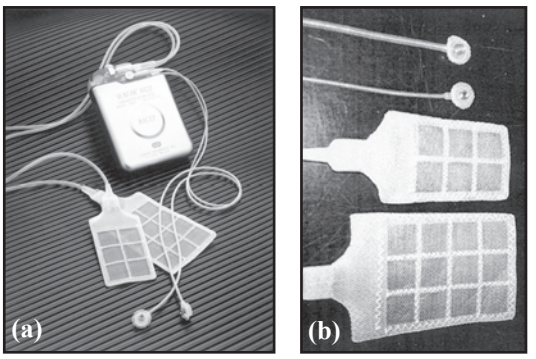


Figure 1.115. (a) Early ICD system, **(b)** epicardial patch electrodes used for defibrillation and epimyocardial screw-in leads for rate sensing.

have had enough time to contract before the ventricles do. From here, the impulse travels on to the right and left ventricles by way of the bundle of His, the right and left bundle branches and the conduction pathways. These specialized nerve fibers are located inside the muscular walls of the heart. The impulse is passed through the muscle cells of the ventricles causing them to contract and forcefully eject the blood contained within.

The following provides a brief chronological review of the discovery of the electrical system of the heart [1,2]:

- The Purkinje fibers
  In 1839, Jan Evangelista Purkinje (Figure 2.9) discovered the net of gray, flat and gelatinous fibers in the subendocardium of the heart.

Figure 2.9. Jan Evangelista Purkinje (1787–1869), Czech physiologist.

- The site of impulse formation
  Walter Gaskell (Figure 2.10), was one of the first to understand impulse formation and the peristaltic movement of heart muscle contraction. He observed that the impulse of the heart began in the sinus venosus, which had the most rhythmic ability, and then spread through the atrium downwards through the ventricle.

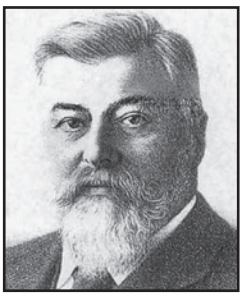


Figure 2.10. Walter Gaskell (1847–1914), physiologist at Cambridge University, United Kingdom. Among Gaskell's many contributions, his understanding of impulse formation and cardiac conduction in the early 80's is of special note.

- The connecting bundle between the atrium and the ventricle
  A conducting bundle between the atrium and the ventricle was found by Wilhelm His, Jr. (Figure 2.11) at the University of Leipzig. By examining different stages of embryological development, he discovered a connective tissue sheet which formed a bundle uniting the upper and lower cardiac chambers (1893).

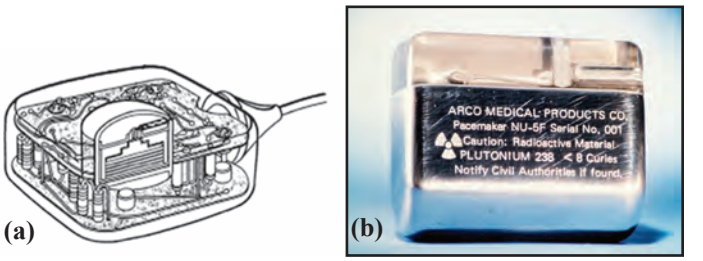


Figure 3.13. Nuclear-powered IPGs, **(a)** with a *Betacel* battery by *MC Donnell Douglas*, **(b)** manufactured by *Arco Medical Products Co.* (subsidiary of *Atlantic Richfield Company*, Leechburg, Pennsylvania, USA).

The generators had specific indicators marked on the case (words such as: "Nuclear", "Curies", the radiation symbol or the abbreviation "Pu-238"). Despite early encouraging results they went out of fashion mainly due to extensive regulatory paperwork and disposal of the energy source. Figure 3.14 a/b/c show nuclear-powered IPGs built by several manufacturers.

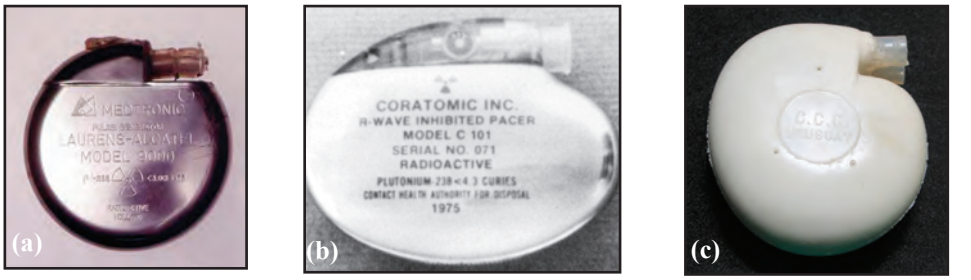


Figure 3.14. Nuclear-powered IPGs manufactured by **(a)** *Medtronic* and *Laurens-Alcatel*, **(b)** *Coratomic*, **(c)** *Centro de Construcción de Cardioestimuladores del Uruguay* (Courtesy *David Prutchi, PhD*.)

Medtronic designed a nuclear-powered generator in cooperation with *Alcatel*, a French company which manufactured the power source (Figure 3.15 a/b). First human implant of the device was performed by Dr. Paul Laurens and Dr. Armand Piwnica in 1972 at *Hôpital Broussais*, Paris, France.

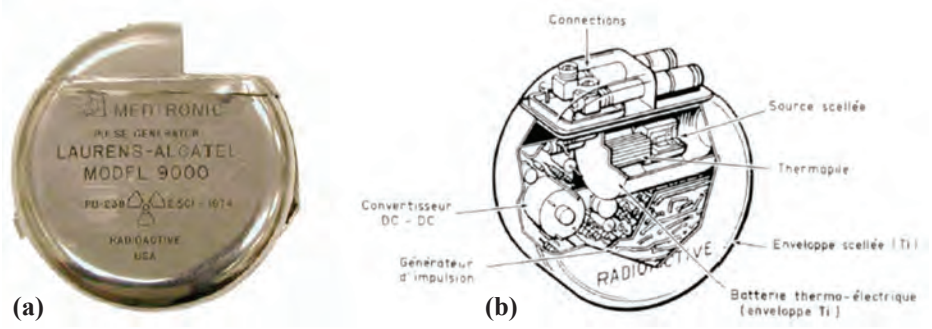


Figure 3.15. (a) Nuclear-powered pulse generator manufactured by *Medtronic* and *Laurens-Alcatel*, **(b)** illustration of construction and components.

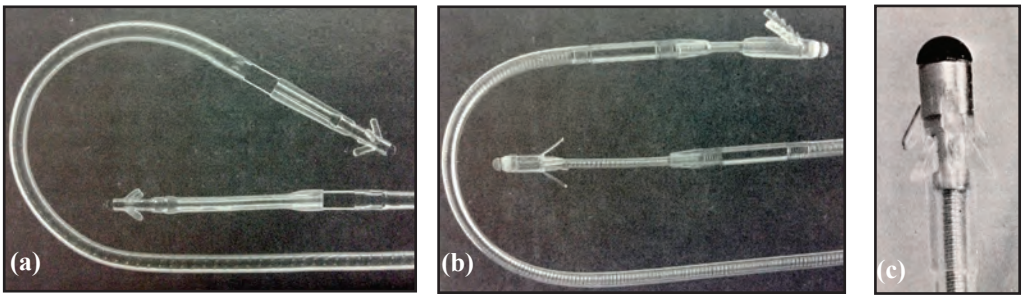
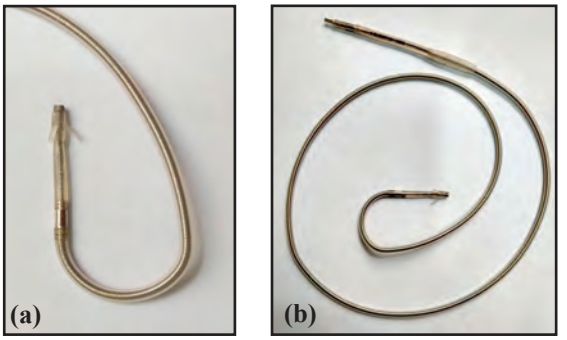


Figure 3.29. (a) (b) (c) Tines on passive fixation leads (courtesy *Dr. Harry Mond*, *The Royal Melbourne Hospital, Victoria, Australia*).

Figure 3.30. (a) (b) *Centro de Construcción de Cardioestimuladores del Uruguay* (CCC) J-lead and close-up of distal lead body. Courtesy *Dr. Diego Lupano, Instituto Nacional de Cirugía Cardíaca, Montevideo, Uruguay*.



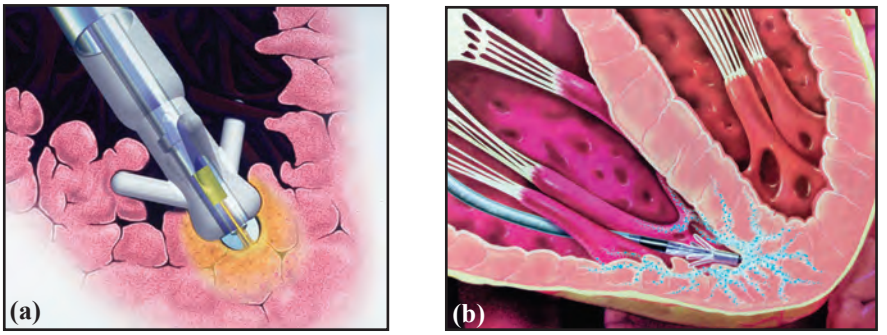
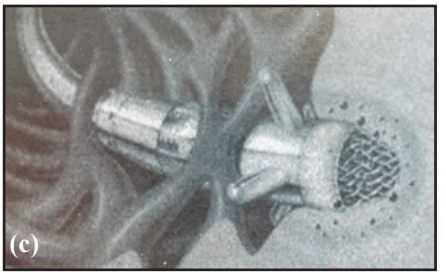


Figure 3.31. (a) (b) (c) Illustrations of passive fixation lead tip trapped in trabeculae. The tines provide acute passive fixation of the electrode to the wall of the heart during surgical placement.



Passive fixation leads are placed in locations that will naturally hold them in place. Straight leads are usually implanted in the RV apex and "J" leads are pre-shaped for positioning in the RAA (Figures 3.32-41).

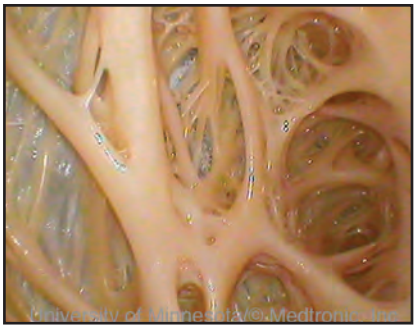
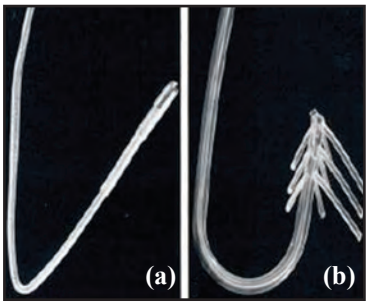


Figure 3.32. Pectinate muscles throughout the RAA. Very thin walls of the right atrium are visible and almost transparent to the outside of the heart. Courtesy *University of Minnesota and Medtronic*.

Figure 3.33. RAA showing pectinate muscles spanning the walls. Courtesy *University of Minnesota and Medtronic*.



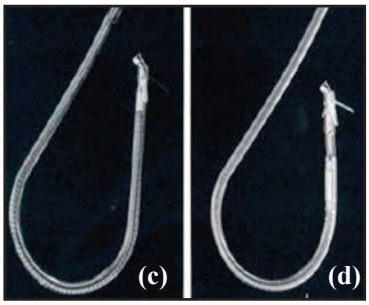
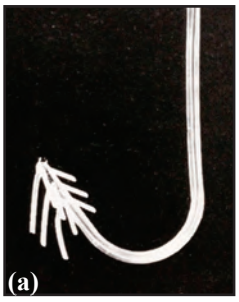
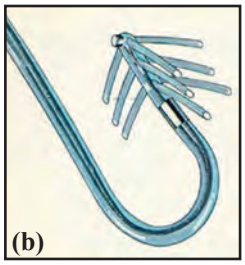


Figure 3.34. Early pre-shaped passive fixation leads: **(a)** *Siemens-Elema* with permanent bend, **(b)** *Medtronic* multi-tined "Christmas tree" with angled electrode so that the tines push it against the atrial appendage (the silicone rubber tines can be trimmed according to the requirements of the operators), **(c)** *Medtronic* polyurethane with small tines, **(d) (e)** *Medtronic* 6990U bipolar (the conductor forms the J memory loop).





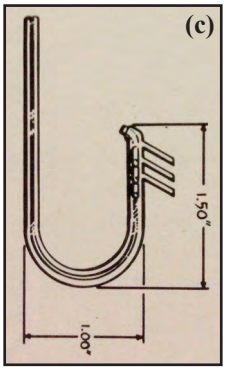


Figure 3.35. (a) (b) (c) Distal portions of *Medtronic* multi-tined lead.

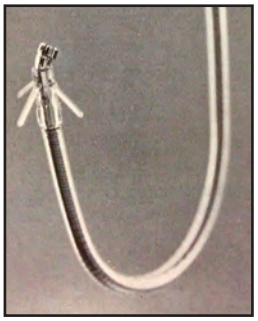
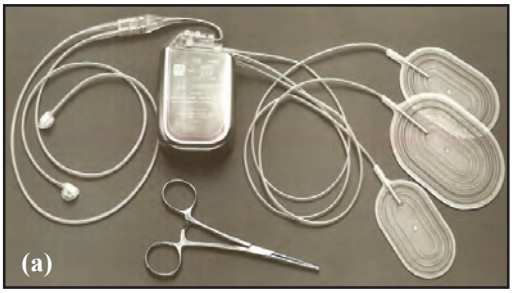


Figure 3.36. Distal end of *Medtronic* 6991U lead. Three polyurethane tines surround a canted platinum-iridium tip.



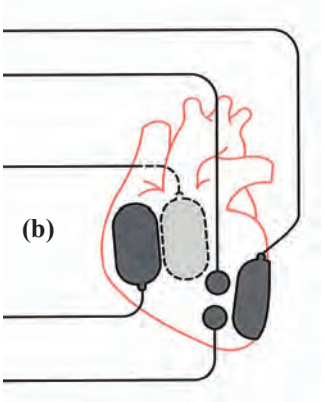
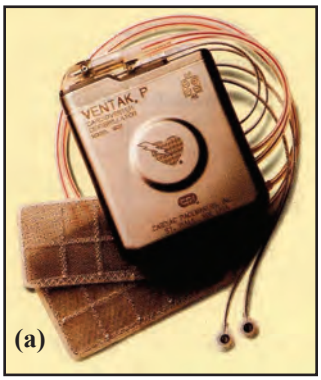
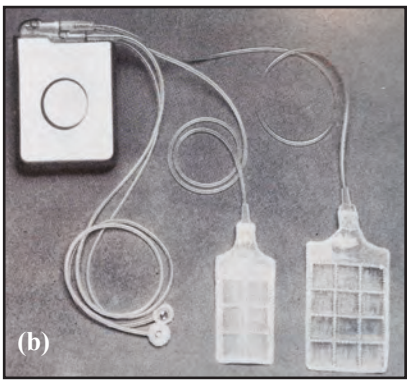


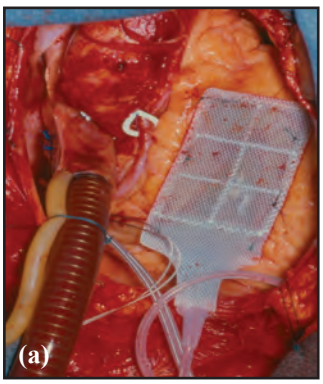
Figure 4.14. (a) PCD with three-patch leads (the 2 smaller electrodes shown on the left are the pacing electrodes adapted as a bifurcated bipolar system), **(b)** illustration of how the patch leads and the pacing electrodes were positioned.

Figure 4.15. (a) (b) ICD with a two-patch leads and two epimyocardial leads. Courtesy *Dr. Harry Mond, The Royal Melbourne Hospital, Victoria, Australia*.





From 1982 until late 1991, the standard implantable system entailed the use of epicardial patches that had to be positioned and sutured around the heart. The electrical discharge was delivered through these patches. All implantable units were manufactured by *Cardiac Pacemakers, Inc*. (*CPI*). During the 1980s the *CPI* system consisted of semi rigid patches of a titanium mesh embedded in a clear plastic square design (Figure 4.16 a/b).



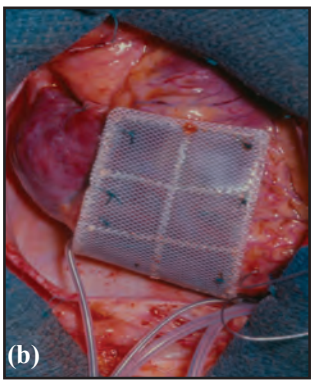


Figure 4.16. (a) *CPI* patch system sutured on the heart, **(b)** close-up of the patch showing the titanium mesh. Courtesy *Dr. Ernesto Molina, University of Minnesota, Minneapolis, Minnesota, USA*.

Sensing and high power cables are commonly covered by layers of extruded ETFE or surrounded by PTFE tubings serving as redudant insulation and protection. Some multilumen ICD lead bodies incorporate circular or oval empty lumens (sometimes called "crush" or "wonder lumen") to unload the main insulation from mechanical stresses induced by compression, bending and torsion. Figures 4.58-60 illustrate the evolution of multilumen lead body design and the different construction patterns among the major manufacturers.

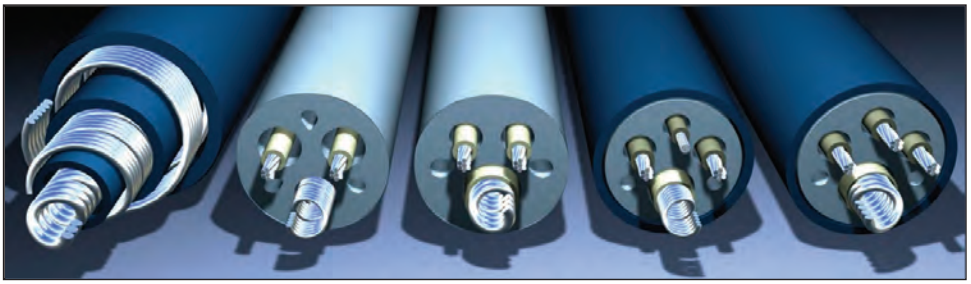


Figure 4.58. Evolution of *Medtronic* HV lead design (coaxial on the left and multilumen for the other 4 cross sections).

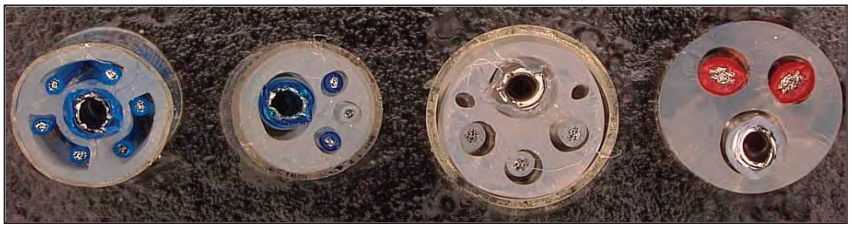


Figure 4.59. Cross sections of multilumen designs. From left to right: Durata 7 Fr (*Abbott/St. Jude Medical*), Fidelis 7 Fr and Sprint Quattro 9 Fr (*Medtronic*) and Reliance 9 Fr (*Boston Scientific*). Used with permission from *St. Jude Medical, CRDM*.

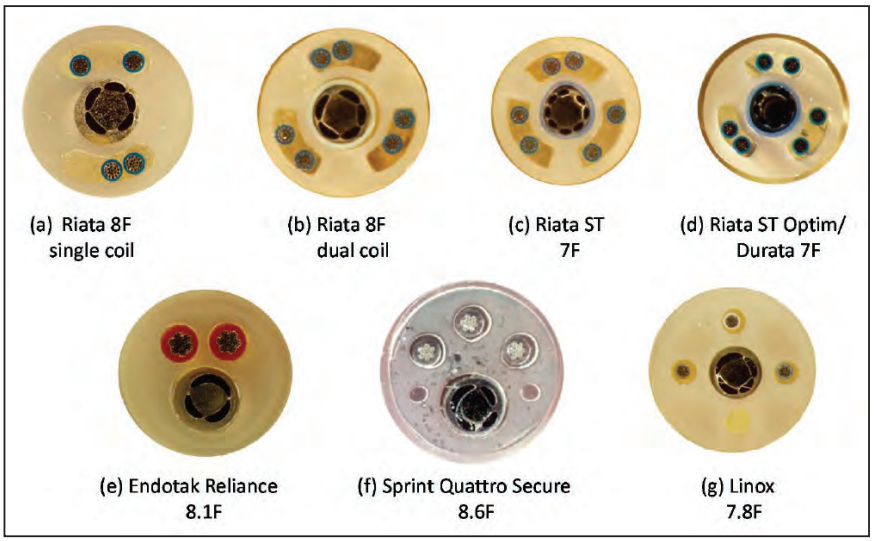


Figure 4.60. Cross sections of multilumen designs (to scale). Courtesy *Dr. Ernest Lau, Department of Cardiology, Royal Victoria Hospital, Belfast, United Kingdom*.

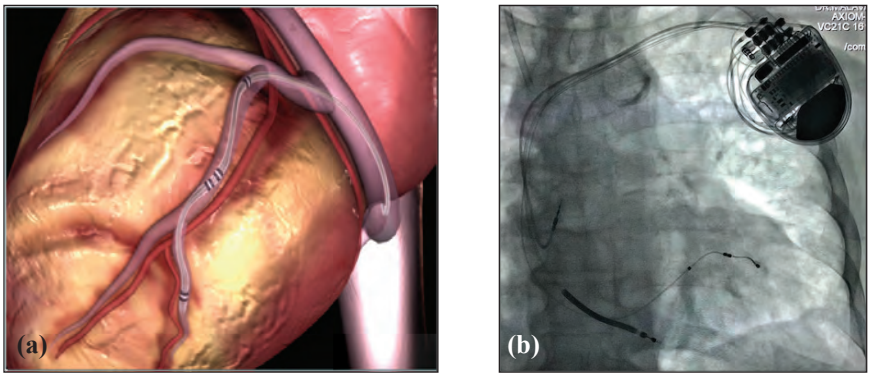


Figure 5.34. (a) Illustration and close-up of Attain™ Performa™ LV lead within a cardiac vein, **(b)** chest X-ray with a CRT-D, the LV lead is an Attain™ Performa™ (Courtesy *Dr. Federico Malavassi, Hospital Clínica Bíblica, San Jose, Costa Rica*).

"S" shaped curve (Figures 5.35-36)

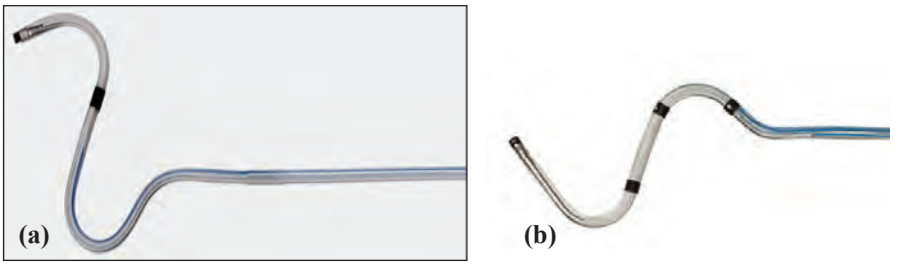


Figure 5.35. (a) Quicksite™ LV lead (the distal pre-shaped "S" curve is aimed at pressing against the wall of the vein to provide a means of fixation), **(b)** Quartet® 4 electrode LV lead (used with permission from *Abbott/St. Jude Medical*, CRDM).

Figure 5.36. (a) (b) Attain™ Performa™ with short spacing between the 2 center electrodes (aimed at reducing the incidence of phrenic nerve stimulation).

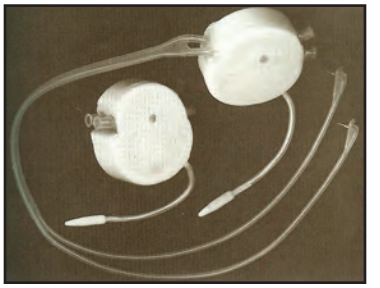


Figure 6.8. Early *Chardack-Greatbatch/Medtronic* pulse generator with *Chardack/Medtronic* myocardial electrode.

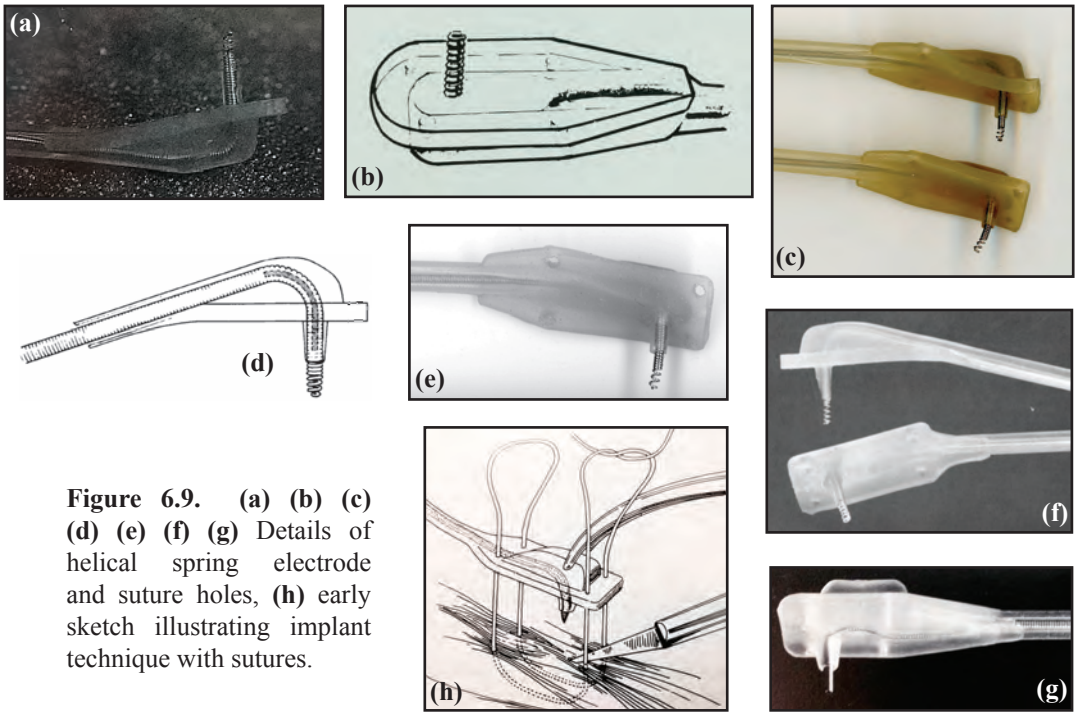


Figure 6.9. (a) (b) (c) (d) (e) (f) (g) Details of helical spring electrode and suture holes, **(h)** early sketch illustrating implant technique with sutures.

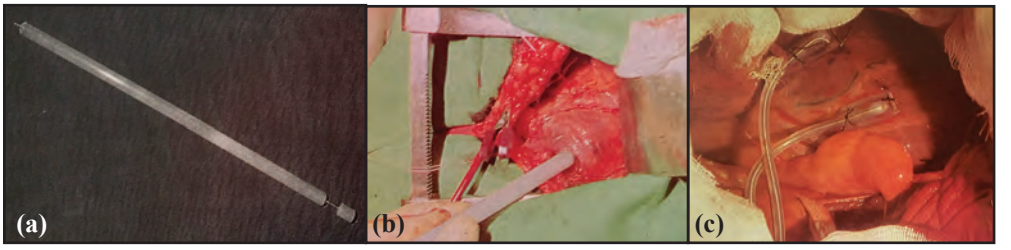


Figure 6.10. (a) (b) Tool designed to test pacing thresholds prior to suturing the electrodes, **(c)** epimyocardial electrodes in final position (courtesy *Dr. Héctor Mazzetti, Hospital Juan A. Fernández, Buenos Aires, Argentina*).

Epicardial

Epicardial temporary pacemaker systems are used almost exclusively in patients undergoing cardiac surgery. The leads (also known as heart wires) are placed on the right atrium, right ventricle, or both to restore the conduction system of the ailing heart (Figures 7.7-8). Atrial leads are placed where the muscle is the thickest (the area of the atrium toward the right atrial appendage is thin and may be easily torn by sutures). Ventricular leads are implanted in the surface of the anterior wall of the right ventricle. Leads are removed 3-7 days post-implant by gently pulling out the wire.

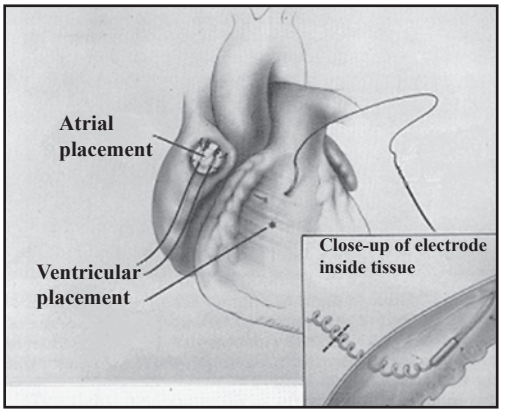


Figure 7.7. The leads are usually Teflon-coated, unipolar or bipolar stainless steel wires (also called heart wires) that are attached to the myocardium and brought out through the chest wall.

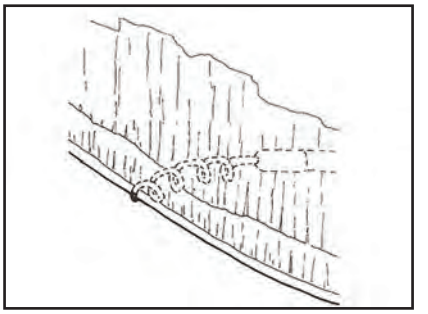


Figure 7.8. Close-up of electrode and fixation coil inside the heart tissue.

Typical constructions include a thin curved myocardial needle to minimize trauma during heart wire insertion, one or two electrodes if the construction is either unipolar or bipolar, an insulated conductive wire and a small chest needle (Figures 7.9-11).

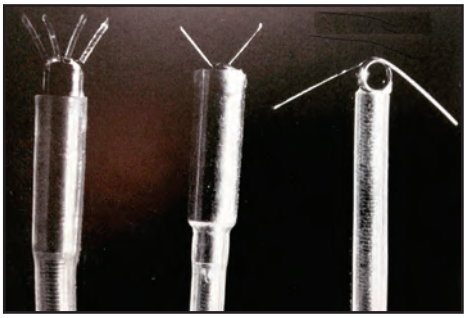


Figure 8.15. Early concepts of active fixation mechanisms.

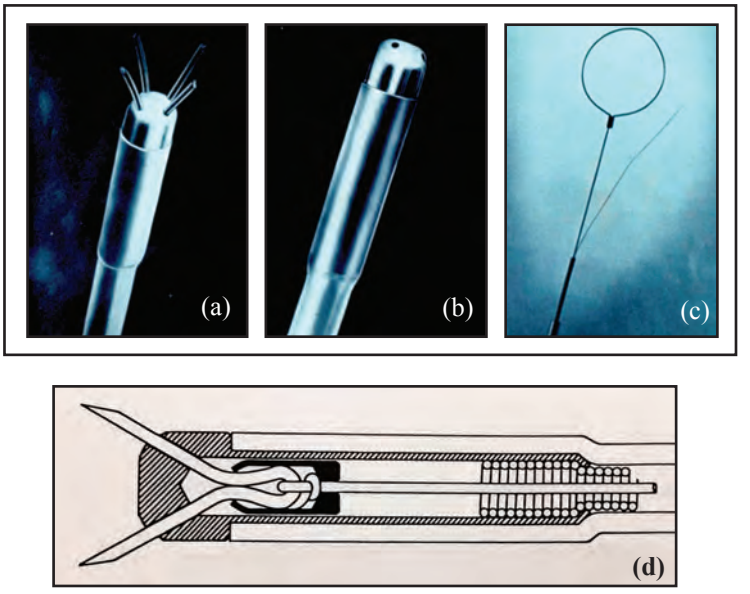
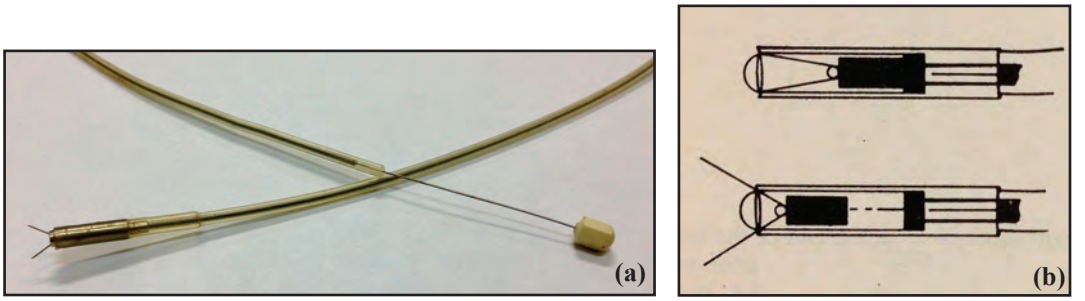


Figure 8.16. (a) (b) (c) (d) *Vitatron* "MIP 2000" electrode concept with 4 nylon spikes (developed by *G. Schmidt*). The lead is inserted with prongs retracted, once positioned the prongs are ejected into the myocardium; a stiff cord controls the spikes extension and retraction (courtesy *Dr. Harry Mond, The Royal Melbourne Hospital, Victoria, Australia*).



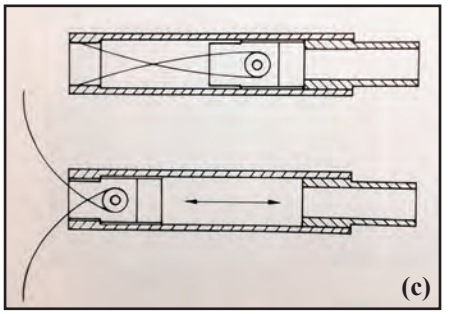
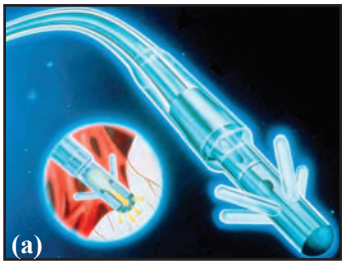
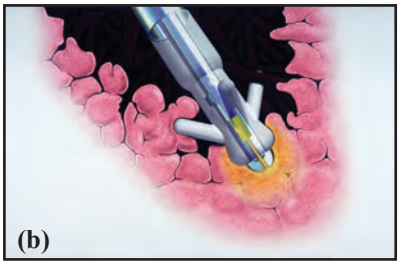


Figure 8.17. (a) Electrode concept with 2 spikes (*Biotronik* IE-65-I), a central wire controlled the spikes deployment, **(b) (c)** illustrations of spikes retracted and extended. Courtesy *Dr. Juan Carlos Pachon, Instituto Dante Pazzaneze de Cardiologia, São Paulo, SP, Brazil*.





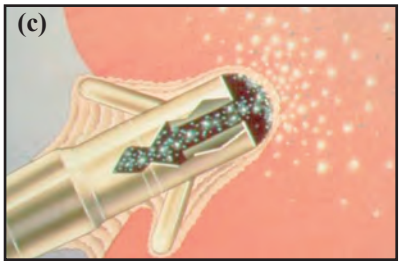
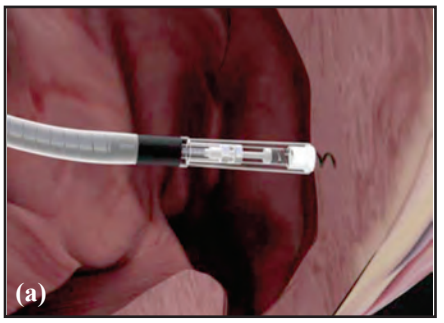


Figure 8.63. (a) (b) (c) Steroid-eluting electrodes. Behind the porous tip surface is a silicone rubber plug filled with an inflammation suppressing steroid. The secretion of the drug through the tip surface decreases inflammation and resulting encapsulation. It increases the electrode's pacing efficiency and efficacy, and the sensing sensitivity. **(d)** the white to creamy white steroid plug is visible in the center of the electrode tip.



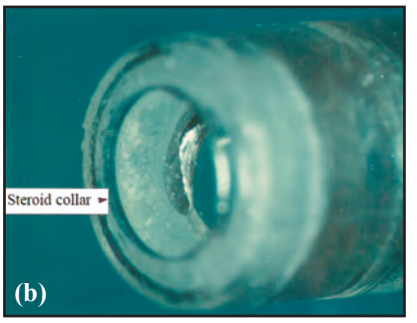


Figure 8.64. (a) (b) Steroid-eluting collar surrounding the helix electrode. Prior to steroid elution, active fixation leads would typically have higher pacing thresholds than passive leads at implantation, and this threshold would decline rapidly within the first 15-30 minutes following implantation. This was felt to be related to acute injury as the screw was advanced into the myocardium. With the advent of steroid-eluting leads these rises in stimulation thresholds are markedly reduced or essentially eliminated.

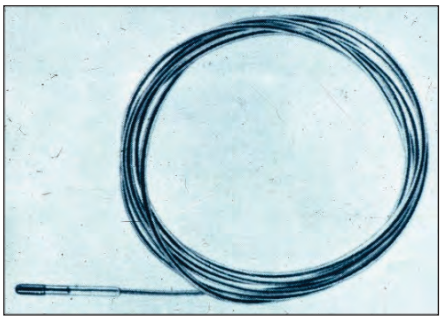


Figure 9.4. *Elema-Schönander* unipolar lead EM 588 (courtesy *Dr. Harry Mond, The Royal Melbourne Hospital, Victoria, Australia*).

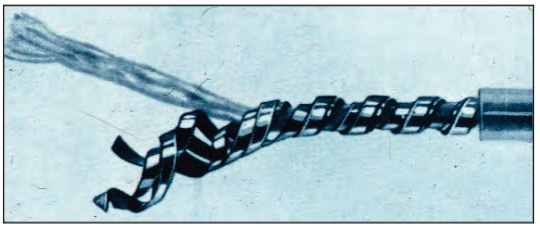


Figure 9.5. Conductor made of stainless steel bands (courtesy *Dr. Harry Mond, The Royal Melbourne Hospital, Victoria, Australia*).

Other conductors were made with the drawn brazed strand (DBS) technique (nickel alloy wires drawn together with heated silver). The DBS construction consists of six stainless steel strands surrounded by a low resistance silver conductor in the middle, between the strands and on the outer surface (Figures 9.6-7). The polyurethane-insulated leads were found with serious insulation failures caused by internal oxidation from the DBS (corrosion of the DBS) and this type of conductor is no longer used in combination with polyurethane.

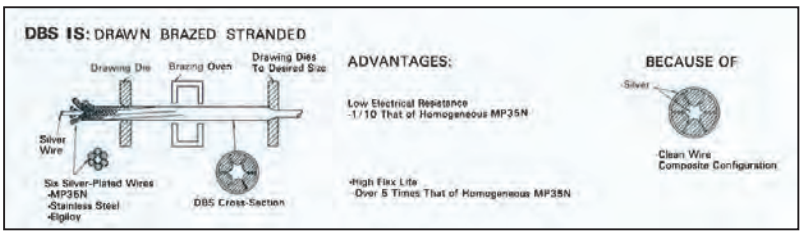


Figure 9.6. Illustration of DBS processing.

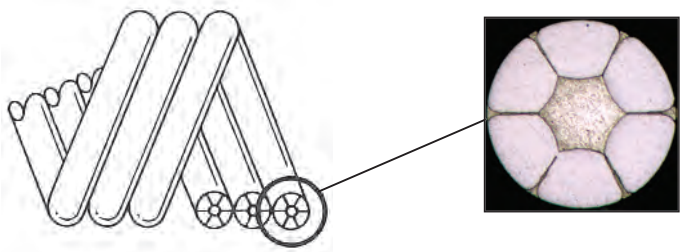


Figure 9.7. Cross-section of DBS composite wire. The silver occupies the central core and the spaces between the nickel alloy wires (silver also forms a thin coating around the wires).

The tinsel wire (Figure 9.8) was another early form of electrical conductor. Tinsel wire was made by flattening the conductor material into a ribbon and then spirally wrapping one or more conductors around a strong fabric core which provided high tensile strength. The core could be damaged by high temperature which made it

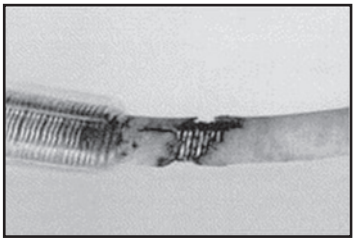


Figure 10.5. Crazing of lead surface and breakdown of the outer insulation (failure likely started as ESC).

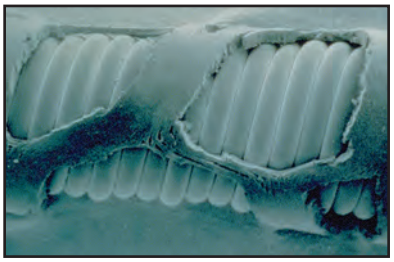


Figure 10.6. Electron microscope picture of extreme ESC.

ESC is known to lead to a micro-cracked surface (Figure 10.7) or even cracked bulk material (this allows for collagenous tissue ingrowth which represents a strong bond between the implant and the surrounding tissue). The propensity of lead insulation to crack depends upon the polymer's molecular morphology (in turn, dependent upon extrusion processes, annealing, etc.), the amount of antioxidant present (dependent upon extraction, morphology, and/or consumption during annealing processes), and insulation configuration (thicker tubing will be less strained by a given stress).

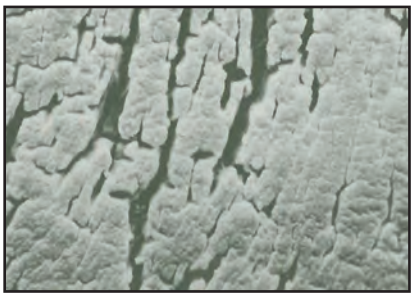


Figure 10.7. Close-up of surface micro-cracking

Crazing is another term to describe polymer degradation. It can be described as the formation of voids with fibers stretching across the voids (Figure 10.8). As the craze grows, some of the fibers break and a crack is formed. The crack can then grow and progress across the polymer, leading to rupture/failure.

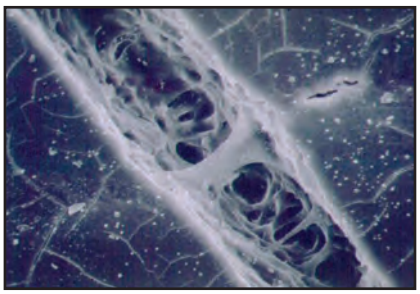
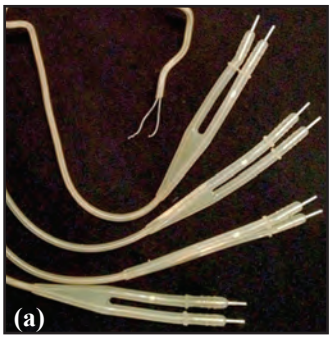


Figure 10.8. Formation of fibers stretching across a void. Crazing is dependent of the molecular weight of the polymer.

Leads are subjected to large amount of stress and must be mechanically designed to avoid fracture. Stress concentrates at any abrupt change in diameter or at any abrupt



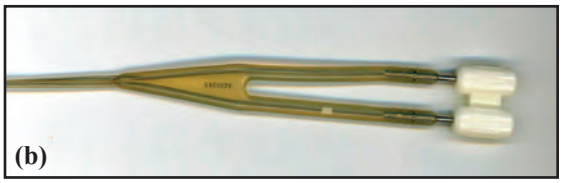


Figure 11.18. (a) (b) Bifurcated lead connector designs

Figure 11.19. *ELA* Stimulith (l'*Électronique Appliquée*, *Montrouge, France*) design. Courtesy *Dr. Cristina Tentori*, *Hospital Juan A. Fernández*, *Buenos Aires, Argentina*).

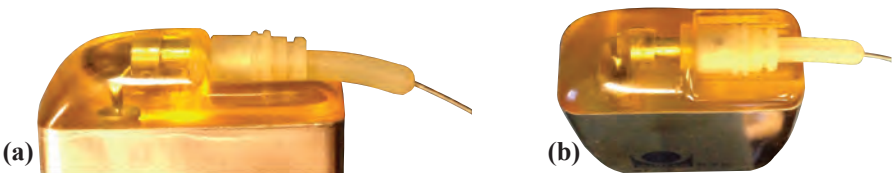


Figure 11.20. (a) (b) *Biotec* connector (*Biotec* Biomedical Technologies of Bologna, Italy). Courtesy *Dr. IWP Obel, Milpark Hospital, Johannesburg, South Africa*.

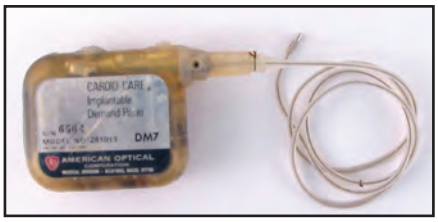
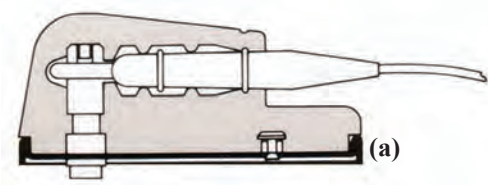


Figure 11.21. *American Optical Corporation* pacemaker and lead (Bedford, Massachusetts, USA).



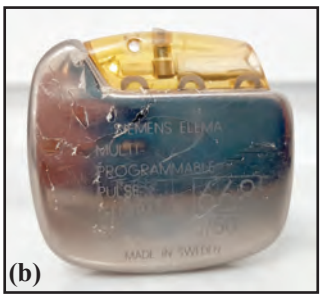


Figure 11.22. (a) Illustration of an early connector module. **(b)** Siemens Elema pacemaker, courtesy *Dr. Prof. Andrzej Przybylski, University of Rzeszow, Rzeszow, Poland*.

Eventually, two similar unipolar connector designs were developed: a "*Medtronic* 5 mm" and a "*Cordis* 6 mm" designs. Figure 11.23 a/b/c/d shows both connectors and figure 11.24 illustrates the connection into the device module.

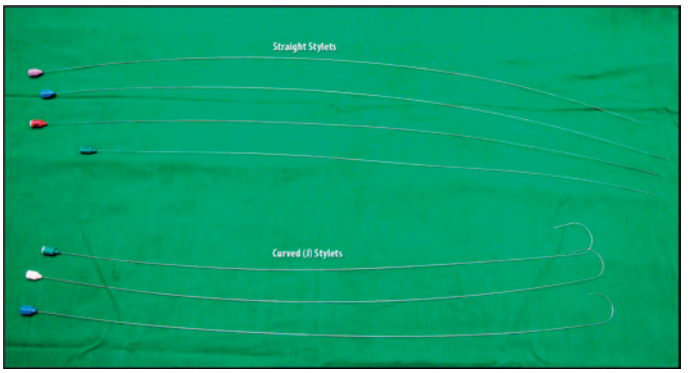


Figure 12.2. Display of straight and curved (J) stylets. Courtesy *St. Jude Medical, Inc*.

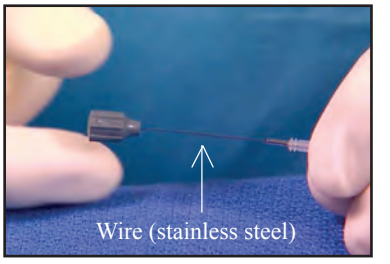


Figure 12.3. Stylet inserted in lead.

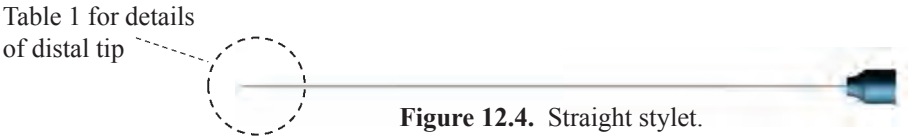


Figure 12.4. Straight stylet.

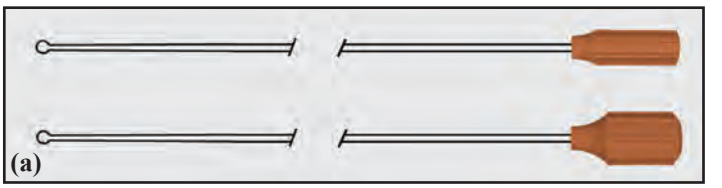


Figure 12.5. (a) (b) "J" and straight stylets with different tip designs and knobs.

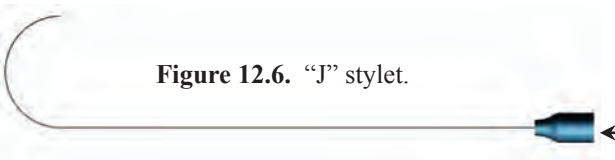
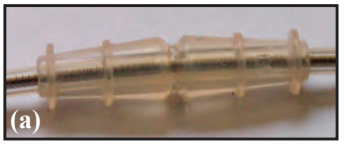


Figure 12.6. "J" stylet.

Knob (usually marked with wire length and diameter)

Design and clinical implications

Some suture sleeves include a single groove (Figure 13.3 a/b), multiple grooves (to give implanting physicians more choices when anchoring the lead) and tabs (Figures 13.4-7). Securing at implantation is an important step to prevent lead dislodgement. The sutures used must be fastened firmly but, given the relative fragility of lead insulation, must not be allowed to compromise the lead structure or integrity.



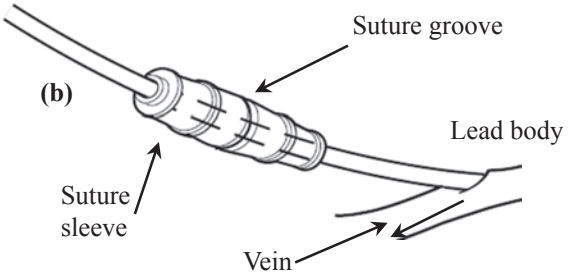


Figure 13.3. (a) Single groove sleeve and **(b)** illustration of the sleeve around lead body.

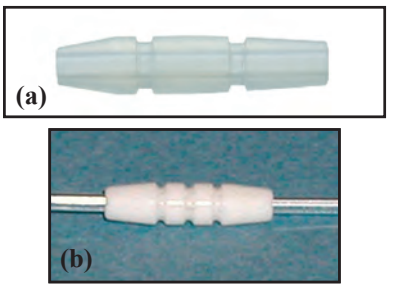


Figure 13.4. (a) (b) Ligature sleeves with multiple grooves.

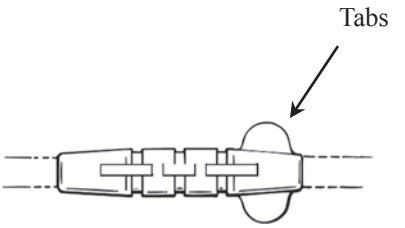
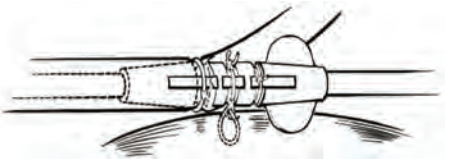
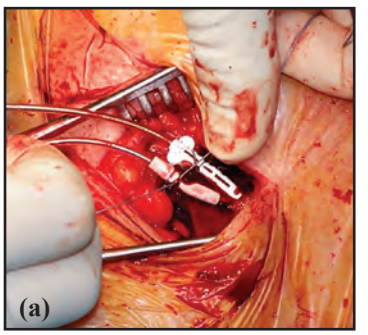


Figure 13.5. The tabs are provided to minimize the possibility of the sleeve entering the vein.

Figure 13.6. Suture sleeve secured to the lead and fascia using three grooves.





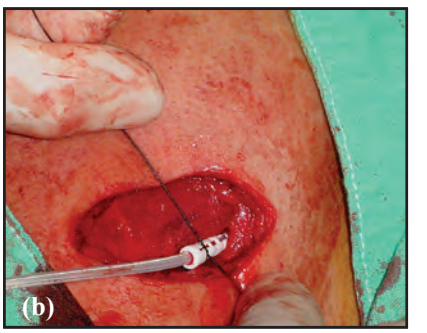
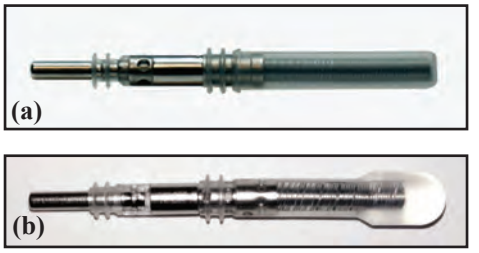


Figure 13.7. (a) (b) Ligature sleeves secured around lead bodies.



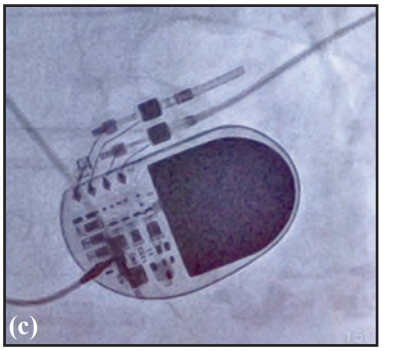
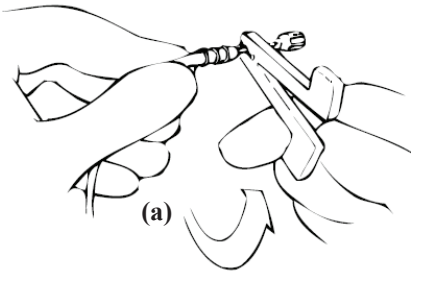


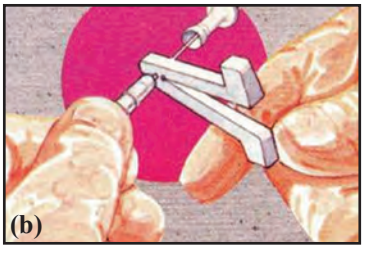
Figure 14.3. (a) (b) IS-1 connector pin plugs, **(c)** X-ray of an IPG with plugged atrial port (courtesy *Carlos Lugo, CCDS, Peñuelas, Puerto Rico*).

Figure 14.4. IS4/DF4 plug can be indicated for a patient with an implantable pacemaker/defibrillator that has an unused IS4/DF4 receptacle. Courtesy *Oscor*.

Fixation tool

Also known as pinch-on tool or helix extension tool (Figures 14.5-8), it is used to extend (clockwise rotation) and retract (counterclockwise rotation) the helix of an active fixation lead.





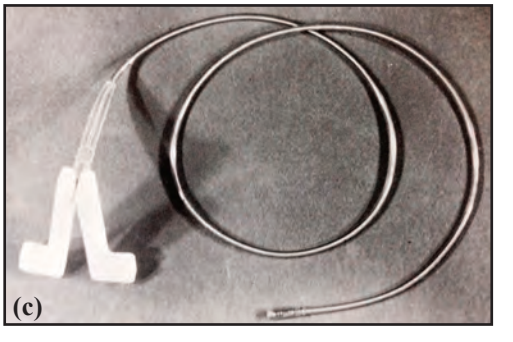


Figure 14.5. (a) (b) Clockwise rotation of pinch-on tool to extend helix of an active fixation lead, **(c)** tool attached to the connector pin of an active fixation lead.

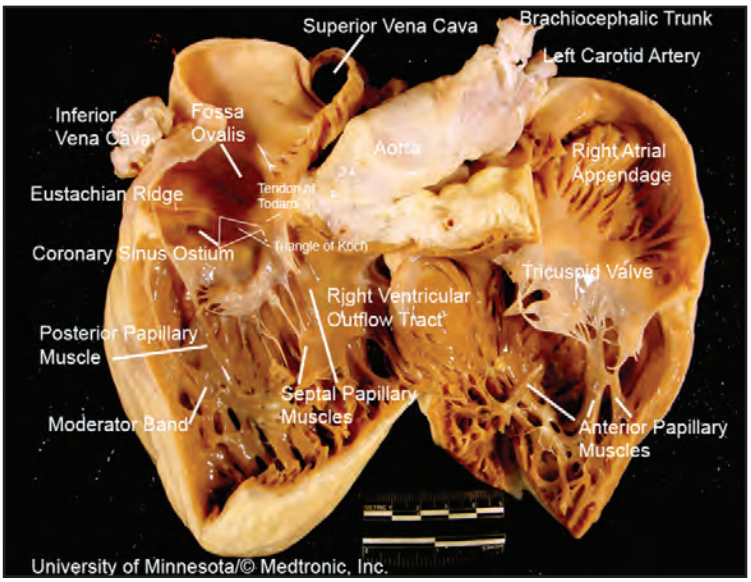


Figure 15.11. The triangle of Koch can be seen enclosed by the septal leaflet of the tricuspid valve, the coronary sinus, and the membranous part of the interatrial septum. Courtesy *University of Minnesota and Medtronic*.

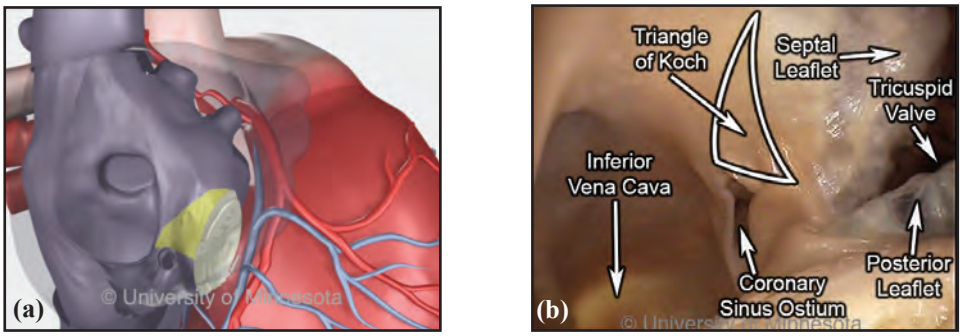


Figure 15.12. **(a)** Triangle of Koch (in yellow), **(b)** triangle of Koch (canine right atrium) where the AV node and the bundle of His reside subendocardially. Courtesy *University of Minnesota and Medtronic*.

The His bundle extends inferiorly and leftward from the AV node, directly past the posterior and inferior margins of the membranous interventricular septum and remains undivided for a few millimeters (Figures 15.13-14).

The little protrusions in the back of the vertebrae are called processes and are what makes the views looks bumpy when the view is rotated. For example, an RAO projection would show the processes on left side of the image and smooth body on right, while an LAO projection would reveal the smooth body on left side of spine image and the processes on the right (Figure 16.8)

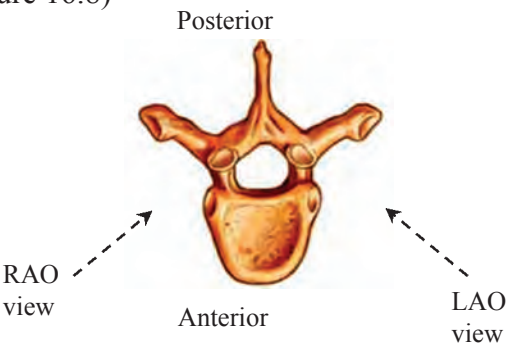


Figure 16.8. Axial (overhead) view of a thoracic vertebrae. The protrusions appear on the left when viewing in RAO and on the right in LAO.

Visual quality can vary widely among different fluoroscopy units and techniques. Plastics and less dense materials are not visible in fluoroscopy. Denser metals, such as platinum, are more easily viewed. The distal portion of a passive fixation lead is shown under normal fluoroscopic conditions in Figures 16.9.

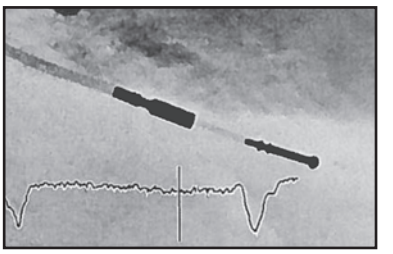


Figure 16.9. X-ray view of a bipolar passive fixation. Courtesy *Dr. Makoali Makotoko, Mediclinic Heart Hospital, Pretoria, South Africa.*

When active fixation leads are implanted, fluoroscopy is used to verify helix electrode extension and/or retraction. Figures 16.10-14 illustrate views and interpretations (which vary among manufacturers). Image magnifier is helpful to visualize the details.

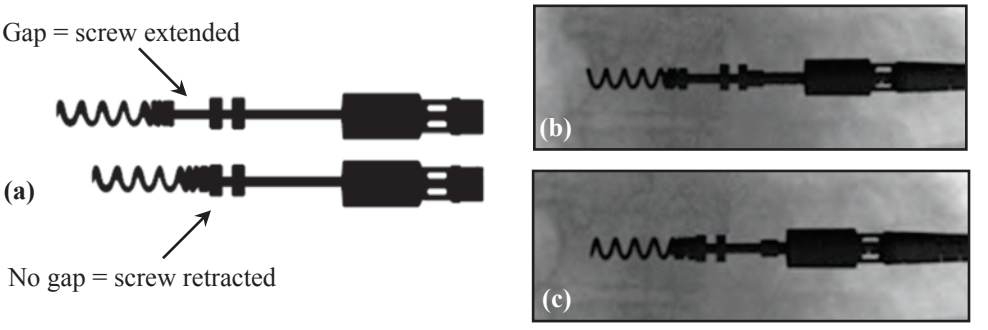


Figure 16.10. (a) (b) (c) X-ray views of helix extension and retraction mechanism.

A 510(k) is a premarketing submission made to the FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device that is not subject to premarket approval (PMA).

Concepts of reliability

Reliability is the likelihood that a product will meet customers' expectations by performing its intended function within specified tolerances, under stated conditions, for a given period.

Reliability engineers often describe the lifetime of a population of products using a graphical representation called the bathtub curve (Figure 17.2). The bathtub shape is characteristic of the failure rate curve of many well-designed products and components including the human body. The curve consists of three periods and associated types of failure:

- Burn-in period or infant mortality: large and rapidly decreasing number of new component failures. Failures during infant mortality are caused by material defects, design mistakes, errors in assembly, etc.
- Normal life: constant failure rate. Normal life failures are normally considered to be random cases of "stress exceeding strength."
- Wear-out period: post-expected product life with increasing number of failures over time. Wear-out is a fact of life due to fatigue.

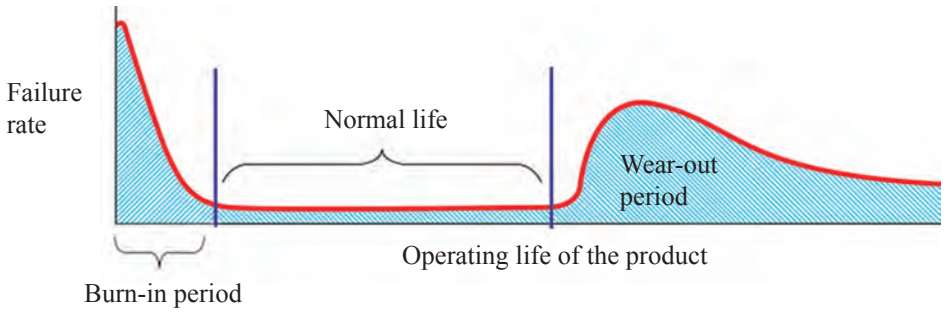


Figure 17.2. Bathtub curve (failure rate versus time).

The bathtub curve does not depict the failure rate of a single item but describes the relative failure rate of an entire population of products over time. Some individual units will fail relatively early, most will last until wear-out, and some will fail during the relatively long period typically called normal life. The actual time periods for these three characteristic failure distributions can vary greatly. Infant mortality does not mean that a product will fail within, for example, 30 days or any other defined

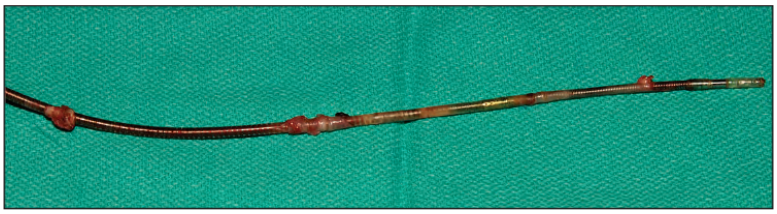
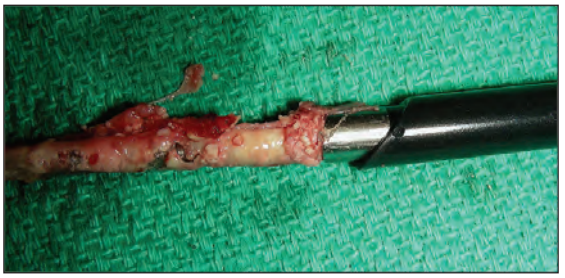


Figure 18.5. Fibrous encapsulation around lead body (courtesy *Dr. Bruce Wilkoff, Cleveland Clinic, Cleveland, Ohio, USA*).

Figure 18.6. (a) (b) Fibrous encapsulation around lead body (courtesy *Dr. Bruce Wilkoff, Cleveland Clinic, Cleveland, Ohio, USA*).

Figure 18.7. Fibrous encapsulation around lead body (courtesy *Dr. Bruce Wilkoff, Cleveland Clinic, Cleveland, Ohio, USA*).



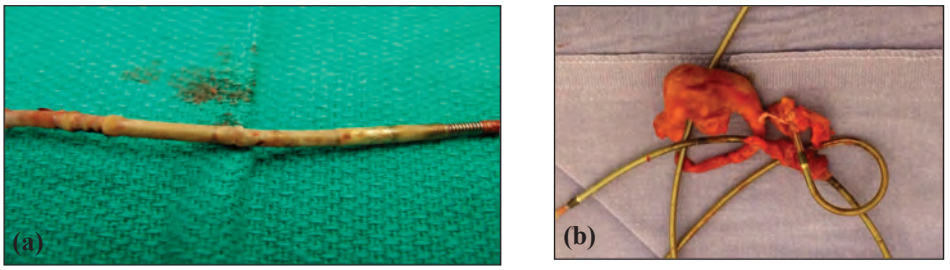


Figure 18.8. (a) Encapsulating tissue accumulated around a lead body. Courtesy *Dr. John Burgess* and *Dr. John Rothschild, Libin Cardiovascular Institute of Alberta, Calgary, Alberta, Canada*. **(b)** Tissue encapsulation around atrial and ventricular leads.

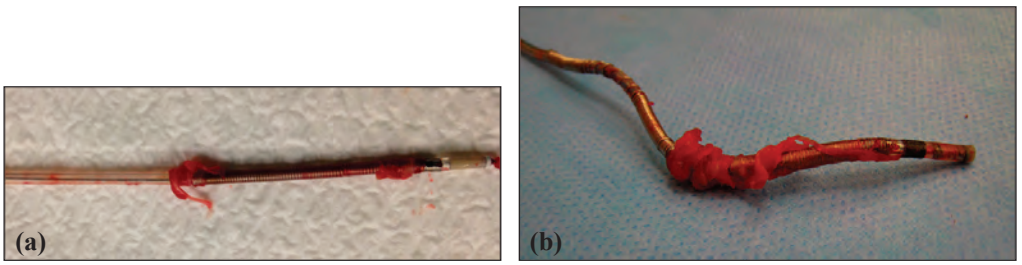


Figure 18.9. (a) (b) Encapsulating tissue accumulated at the distal end of a lead. Courtesy *Dr. Francisco Perez, Hospital San Lucas, Ponce, Puerto Rico*.

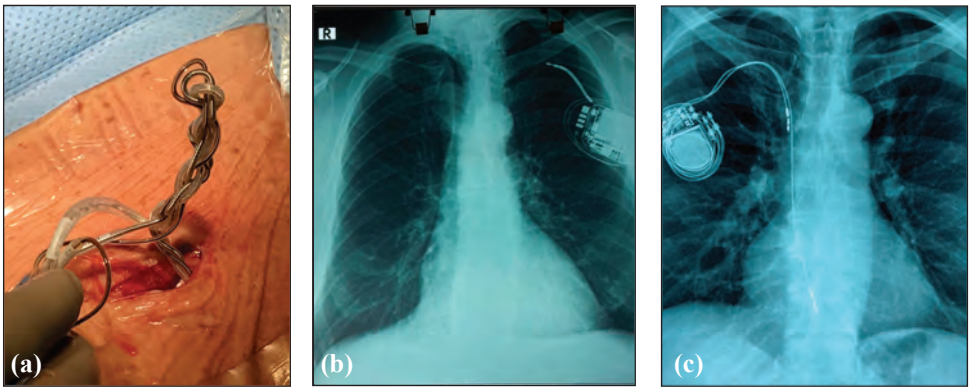


Figure 19.60. (a) (b) (c) Twiddler's syndromes. Note: (a) Courtesy *Dr. Mevan Wijetunga, Altru Health System, Grand Forks, North Dakota, USA*, and *Anthony Miller, Grand Forks, North Dakota, USA*, (b) (c) courtesy *Dr. Federico Malavassi*, *Hospital Clínica Bíblica, San José, Costa Rica*.

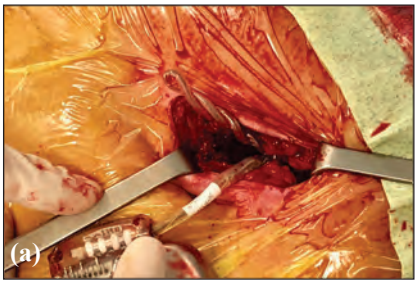
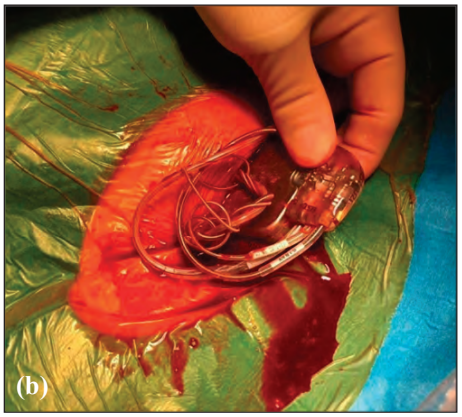


Figure 19.61. (a) (b) Twisted lead body of a high voltage lead. (a) is Courtesy *Dr. Federico Migliore*, *Hospital Università di Padova*, *Padova, Italia.*



Bayliss suggested that the twisting and retraction of the lead was proportional to the force making the device turn around its longitudinal axis. Subsequent reports described a variation in which the lead appeared retracted up to the pocket without evidence of torsion and neatly wrapped around the generator. A third observation is attributed to the progressive movement of the lead in relation to the motion of the arm. The "ratchet" effect is explained by the anchoring sleeve allowing the lead to move in direction of the device but acting as a brake avoiding its return in direction of the heart (since the mechanism does not involve manipulation of the device, it is not considered as a Twiddler). Finally, a fourth variant describes the "reverse Twiddler", in this situation the lead moves in direction of the heart; it is manifested with excess of lead body (with and without twist) inside the heart. Figures 19.62-63 illustrate the observations.

Elestim-Cardio
Moscow, Russia
http://www.elestim-cardio.ru

- Founded by Valentin Mojarov in 1997.

Integer
Plano, Texas, USA
http://www.integer.com

- *Greatbatch* acquired *Centro de Construcción de Cardioestimuladores* (*CCC*) in 2014. *CCC* had been founded by Dr. Orestes in 1969.
- *Greatbach* acquired *Lake Region Medical* in 2015.
- The merge of *Greatbatch, Lake Region Medical and Electrochem* formed *Integer Holdings Corporation* in 2016.

Lepu Medical Electronic Technology
Changping District, Beijing, China
http://www.lepumedical.com

- Founded in 1986.
- *Lepu Medical* acquired *Qinming* Medical in 2010.

Medico
Rubano, Padova, Italy
http://www.medicoweb.com

- Founded in 1973.

Medived
Bangalore, India
http://www.medived.com

- Founded by Dinesh Puri.

Levels of evidence

Evidence supporting recommendations is ranked as level A if the data is derived from multiple randomized clinical trials involving a large number of individuals. Evidence is ranked as level B when data se derived from a limited number of trials involving comparatively small numbers of patients or from well-designed data analysis of nonrandomized studies or observational data registries. Evidence is ranked as level C when consensus of expert opinion is the primary source of recommendation.

Level A	Data derived from multiple randomized clinical trials or meta-analyses. Multiple populations evaluated.
Level B	Data derived from a single randomized trial or nonrandomized studies. Limited populations evaluated.
Level C	Only consensus opinion of experts, case studies, or standard of care. Very limited populations evaluated.

The reader should note that theses recommendations represent a succinct summary of the more extensive evidence base, critical evaluation, supporting text, tables, figures, and references that are included in the full-text guidelines:

2012 ACCF/AHA/HRS Focused Update Incorporated Into the ACCF/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities

A Report of the American College of Cardiology Foundation/American Heart Association
Task Force on Practice Guidelines and the Heart Rhythm Society

Developed in Collaboration With the American Association for Thoracic Surgery and Society of Thoracic Surgeons

Full guidelines report and published executive summary are available on the following web sites:

http://www.acc.org
http://www.americanheart.org

- Movement of the device.
- Programming changes.
- Asynchronous pacing.
- Activation of tachyarrhythmia therapies.
- Inhibition of pacing output.
- Induced lead currents that could lead to cardiac stimulation.

Heating of the lead tip can result in tissue damage. The area of endocardium and myocardium close to the tip of the electrode has a potential risk of thermal injury (Figure 22.5) which may result in deterioration of pacing thresholds and/or atrial or ventricular perforation.

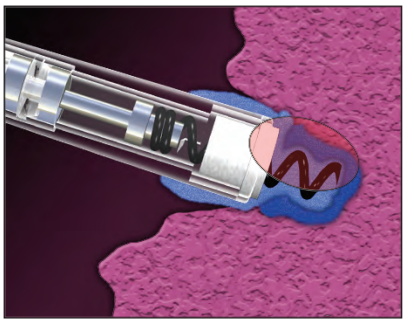


Figure 22.5. Illustration of a helix screwed into the cardiac tissue and scar tissue forms as part the normal healing process. Extreme RF power levels can produce high lead tip heating and increase in pacing capture threshold.

In 2006, a new classification system for implants and ancillary clinical devices has been developed by the ASTM (American Society for Testing and Materials) and is now the standard supported by the US Food and Drug Administration (FDA):

- MR Safe

Device or implant is completely non-magnetic, non-electrically conductive, and non-RF reactive, eliminating all of the primary potential threats during an MRI procedure.

- MR Conditional

A device or implant that may contain magnetic, electrically conductive or RF-reactive components that is safe for operations in proximity to the MRI; provided the conditions for safe operation are defined and observed.

- MR Unsafe

For objects that are significantly ferromagnetic. There is a direct threat to persons and equipment within the magnet room.

pacemaker shield and a separate auxiliary passive lead implanted subcutaneously in the chest (Figures 23.7-8). A constant current pulse train was sent from the tip of the auxiliary lead to the pulse generator casing with chest wall movement altering the dipole distance. The implantation of the separate auxiliary lead was not difficult but added time to the operation and patient discomfort both during and after the procedure (complications included skin erosion and dislodgement).

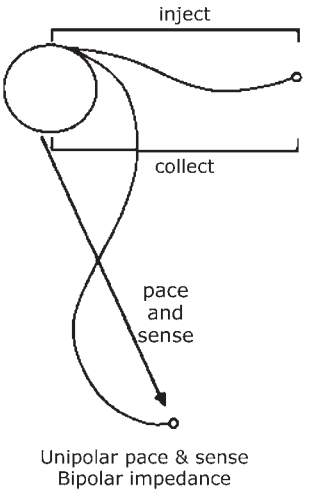
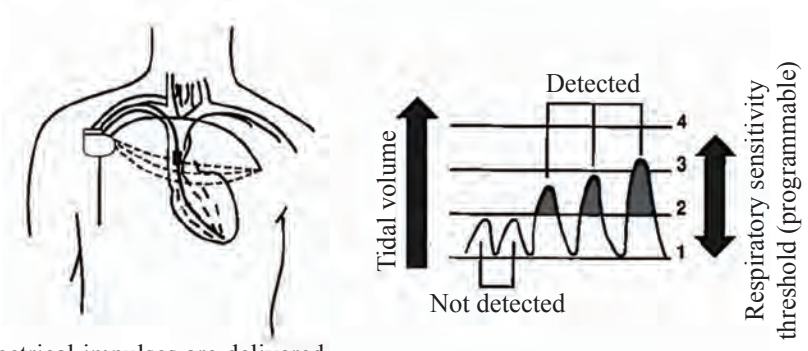


Figure 23.7. The Biorate pacemakers (RDP3 and MB-1 from *Biotec*) sensed the respiratory rate using an auxiliary electrode placed about 8 to 10 cm from the pacemaker shield. Impedance was measured with a bipolar electrode system with the pacemaker acting as the active electrode and the tip of the auxiliary lead as the passive electrode. The depth of respiration considered as a breathing rate was determined by a programmable respiratory level, and the detected respiratory rate was converted to a change in pacing rate by a slope of rate response.



Electrical impulses are delivered between the auxiliary lead and the IPG can

Figure 23.8. Impedance of the thoracic cavity changes as each breath is drawn. Impedance changes are tracked, rate response begins when the tidal volume of each breath exceeds the programmed sensitivity level.

In 1988, Mond et al. reported successful measurement of transthoracic impedance in rate responsive pacemakers to provide an estimate of minute ventilation [*9*]. As the demand for oxygen increases, the breathing becomes more rapid and deeper. The change in volume and rate of breathing causes a change in the impedance across the chest cavity as the lungs fill and empty.

(0) Medial border of the pectoralis minor
(1) Cephaloaxillary vein junction
(2) Pectoralis major fixation
(3) Axillosubclavian vein entry
(4) Base of the lung apex
(5) Aorta wrap
(6) Superior vena cava origin
(7) Right atrium
(8) Tricuspid valve

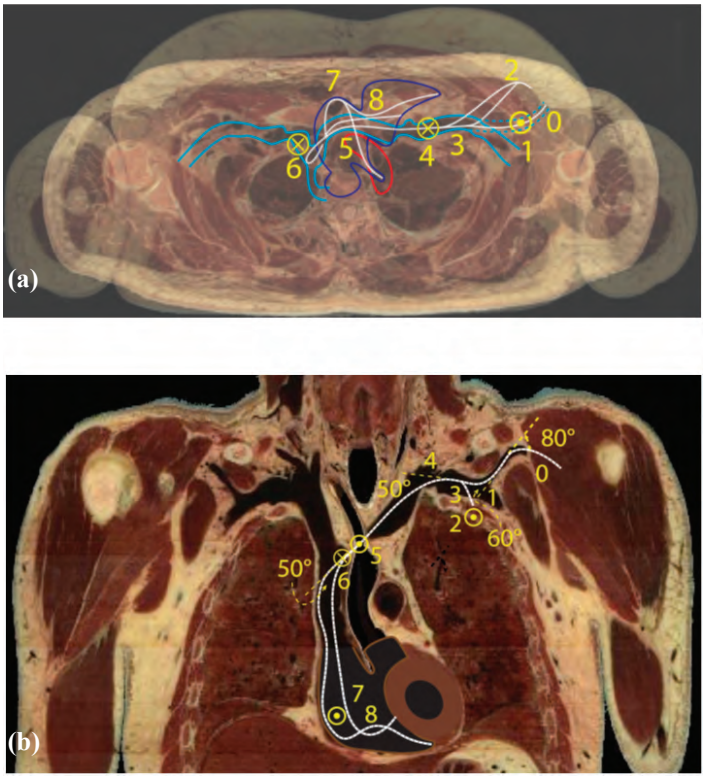
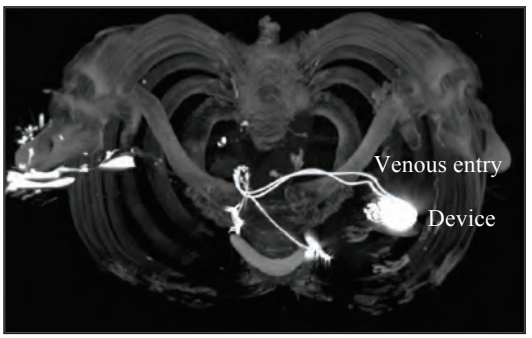


Figure 24.2. Lead course based on anatomy. **(a)** Superimposed transverse sections at the axilosubclavian-brachiocephalic vein and the midventricular cavity levels, **(b)** coronal section at the midaxillary lines A circle with a dot inside points out of the plane; a circle with a cross inside points out into the plane. Sections of the thorax based on the Visible Human Project. Courtesy *Dr. Ernest Lau, Department of Cardiology, Royal Victoria Hospital, Belfast, United Kingdom*.

Figure 24.3. The course of a lead depends on patient anatomy, implantation technique and lead construction/structure.



Along with the chemical and cellular environment around the implant, the body also exerts mechanical loads (forces) upon leads by interactions or juxtaposition with bones, muscles, and organs (Figure 24.4). The mechanical loads to which a lead is exposed can be classified by their directions and periodicity. Axial loads are applied along the axis of the lead (bending, tension or compression), transverse loads are applied across the axis of the lead (shear or crush) and torsional loads are applied around the axis (rotation or twisting).

- Failure of components (conductor fracture, insulation breakdown).
- Lead dislodgement (cardiac perforation, loss of capture/sensing).

Concerns about device failure and longevity, issues regarding pocket infection or hematomas caused by device implants, risks associated with lead failure (fracture, dislodgement, extraction, insulation failure) and patients' quality of life (mobility, life style) have been driving the development of leadless pacing.

Current state of technology

Years ago, the technology was not available to implant a device directly into the heart without the loss of important functionality such as battery life. With the miniaturization of circuits, improvement of battery technology, enhancement of endocardial fixation and delivery systems, the leadless pacing concept has become a reality with the Nanostim leadless pacemaker (*Abbott*) and the Micra™ transcatheter pacing system (*Medtronic*) as illustrated in Figure 25.3 and Table 1.

Figure 25.3. Micra™ transcatheter pacing system (TPS) and Nanostim leadless cardiac pacemaker (LCP).

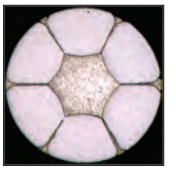
Table 1

Leadless Pacemakers	Nanostim LCP	Micra TPS
		
Dimensions, mm	42.0 x 5.99	25.9 x 6.7
Volume, cc	1	0.8
Weight, g	2	2
Sheath Size, Fr	21 OD/ 18 ID	27 OD/ 23 ID
Fixation Mechanism	Helix	4 Nitinol Tines

The leadless pacemakers are fully self-contained, miniaturized devices designed to provide patients with bradycardia an advanced pacing technology via minimally invasive approach. No surgical pocket is required, and the device is cosmetically invisible to the patient after implant.

Dislodgment
Radiographic, microdislodgment, electrical or electrocardiographic evidence of electrode displacement from the original implant site or electrode displacement that adversely affects pacing and/or lead performance.

Drawn brazed strand (DBS)
A conductor made of several small wires stranded around a core of a softer, highly conductive material such as silver.



Drug-eluting lead
A lead that provides time-released delivery of a drug (typically a corticosteroid) to the tissue adjacent to the electrode. The drug minimizes the acute trauma caused by the tip and thus improves the pacing threshold.

Dual-chamber device
A device with dual-chamber pacing capability, that is, the ability to pace DDD or DDDR mode.

Dyssynchrony
Activation of different parts of the heart improperly synchronized.

Ejection fraction (EF)
Indicator of the efficiency of ventricular pumping, contractility and heart function.

Elective replacement indicator
The point at which it is recommended to replace a device because the battery energy is low.

Electrocardiogram (ECG or EKG)
Graphic representation of the electrical activity of the heart, as recorded by surface electrodes.

Electrocautery
Burning of tissue using heat conduction from a metal probe.

Electrode
Portion of a pacing lead that acts as a long-term interface between the lead and the heart tissue.

Electrode-tissue interface
Area of complex interaction between the pacing lead electrode and the heart tissue.