

Contents

Foreword, xiv

Introduction, xv

1 Historical Milestones, 1

Electrical stimulation, 1

Cardiac pacing, 5

Cardiac defibrillation, 36

Cardiac resynchronization therapy (CRT), 51

2 Cardiovascular System, Cardiac Rhythm and Disorders, 57

The heart, 57

Cardiac function, 59

Electrical conduction system, 60

Heartbeat anatomy, 63

Heart rhythm disorders, 65

Bradycardia, 66

Tachycardia, 67

Heart failure, 68

3 Pacing Leads, 75

Description of an implantable pacemaker system, 75

Evolution of pacemaker technology, 76

Construction and components, 84

Polarity, 91

Lead stiffness, 95

Single-pass VDD lead, 96

Biatrial pacing lead, 100

Length and diameter, 100

4 Tachy Leads, 103

Description of an implantable cardioverter defibrillator system, 103

Evolution of technology - ICDs and leads, 106

Construction and components, 115

Polarity, 127

Shocking circuits, 128

Coil electrode, 131

Single-pass VDD ICD lead, 134

5 CRT Leads and Delivery Systems, 137

Description of an implantable biventricular pacing system, 137

Construction, components and programming options, 140

- Delivery systems, 144
- Lead fixation mechanisms, 148
- Over-the-wire (OTW), 154
- Endocardial cardiac resynchronization therapy (eCRT), 156

6 Epimyocardial Leads, 159

- The early days, 159
- Construction and components, 168
- Clinical applications, 171
- Special tools required for implants, 175

7 Temporary Pacing Leads, 179

- Epicardial, 182
- Transvenous, 184
- Transthoracic, 186
- Transesophageal, 186
- Transcutaneous, 187

8 Electrode, 189

- Fixation mechanisms - the early days, 189
- Passive fixation mechanisms, 190
- Active fixation mechanisms, 193
- Materials and designs, 198
- Electrode-myocardium interface, 205
- Anti-inflammatory drugs, 209

9 Conductor, 217

- Materials, 218
- Design and definition, 221
- Failure mechanisms, 224

10 Insulation, 231

- History of insulation materials, 232
- Silicone, 233
- Polyurethane, 234
- Fluoroethylene polymers, 238
- Copolymers, 239
- SI Polyimide, 240
- Degradation of insulation materials, 240
 - Abrasion, 241
 - Crush, 243
 - Creep, 244
 - Elongation, 245

11 Connector, 247

- The early days, 249

- The need for standardization, the IS-1 connector, 254
- Connectors for high power leads and the DF-1 standard, 257
- Four-pole connector standards, the IS-4 and the DF-4, 258
- Adaptors, 260
- 12 Stylet and Guide Wire, 263**
 - Stylet, 263
 - Three-dimensional curve stylet, 265
 - Stylet guide, 266
 - Locking stylet, 267
 - Guide wire, 267
 - Hybrid guide wire, 268
- 13 Suture Sleeve, 271**
 - Design and clinical implications, 272
- 14 Accessories, 275**
 - Analyzer cable interface tool, 275
 - Connector plug, 275
 - Fixation tool, 276
 - Guide wire steering handle, 278
 - Lead pin cap, 278
 - Medical adhesive kit, 279
 - Vein lifter, 280
- 15 Lumenless Lead and Delivery System, 281**
 - Lead and delivery system, 281
 - The driving force for change, 283
 - Definitions of pacing sites, 283
 - Definitions of alternative pacing sites, 284
 - His bundle pacing, 285
- 16 Fluorovisibility, 291**
 - Equipment, 291
 - Views and interpretations, 292
- 17 Lead Performance, 297**
 - Classification of medical devices and regulatory pathways, 297
 - Class I medical devices, 297
 - Class II medical devices, 298
 - Class III medical devices, 298
 - Concept of reliability, 299
 - Reliability and performance, 300
 - Tracking and monitoring, 301
 - Bench testing guidance, 303
 - Complications, 305

Recall, 305
Manufacturer and user facility device experiences (MAUDE) database, 307

18 Lead Extraction, 309

Indications for transvenous lead extraction, 310
 Infection, 310
 Chronic pain, 311
 Thrombosis or venous stenosis, 311
 Functional leads, 312
 Non-functional leads, 313
Fibrous encapsulation, 314
Elements and technical considerations prior to lead extraction, 317
Description of tools and techniques of extraction, 320
 Traction, 320
 Weighted traction, 320
 Intravascular counter-traction, 321
 Locking stylet, 321
 Retriever tool, 322
 Laser-assisted extraction, 323
 Mechanical dilator sheath set, 324
 Extraction tools and techniques for lumenless lead, 326

19 Lessons Learned, 329

Abandoned leads, 329
Calcification and encapsulation, 330
Contact allergy, 332
Dextrocardia, 333
Electrocautery effect on lead insulation material, 333
Endocarditis with lead infections, 335
Erosion and infection, 337
Incomplete contact between lead connector pin and device header, 341
Lead dislodgement, 341
Leads related cardiac perforation, 343
Pacemaker-induced superior vena cava syndrome, 346
Pericardial effusion, 347
Persistent left superior vena cava, 348
Phrenic nerve stimulation in CRT, 349
Subclavian vein obstruction, 350
Tricuspid valve regurgitation, 351
Twiddler's syndrome, 351

20 Manufacturers – Background, Acquisitions and Mergers, 359

21 Guidelines for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices, 365

Classification of recommendations, 365
Levels of evidence, 366

- 22 Magnetic Resonance Imaging (MRI), 367**
Basic concept and description of MRI equipment, 368
Patient safety and system classification, 369
State of technology, 371
Future, 373
- 23 Sensors Integrated in Pacing Leads, 375**
Cardiac pressure sensor, 376
Mixed venous oxygen saturation sensor, 377
Central venous blood temperature sensor, 378
Minute ventilation sensor, 379
Cardiac muscle vibrations sensor, 381
Left atrial pressure sensor, 381
- 24 Forces, Flexing and Other Implant Dynamics Leads Experience In Vivo, 383**
Interaction of factors, 383
Design and material considerations, 384
Lead mechanics and patient anatomy, 385
Classification of in vivo environments, 389
 Pocket, skeleto-muscular region and venous entry point, 389
 Vascular and intracardiac, 395
 Electrode-tissue interface, 396
 Coronary sinus, 401
 Subcutaneous / extravascular, 402
 Epicardial / Epimyocardial, 404
- 25 Leadless Pacing, 407**
Review of concept, 407
Reasoning for leadless pacing, 408
Current state of technology, 409
- Glossary, 413**
- Suggested Readings, 443**
- Index, 447**