Contents

Acknowledgements .................................................................................................................. xiii
Preface .................................................................................................................................. xiv

SECTION I
GUIDELINES AND RECOMMENDATIONS FOR MR SAFETY

Bioeffects of Static Magnetic Fields ...................................................................................... 2
Bioeffects of Gradient Magnetic Fields .................................................................................. 8
Bioeffects of Radiofrequency Fields ...................................................................................... 11
Acoustic Noise and MR Procedures ....................................................................................... 17
Body Piercing Jewelry ........................................................................................................... 25
Claustrophobia, Anxiety, and Emotional Distress in the MR Environment ......................... 27
Epicardial Pacing Leads and Intracardiac Pacing Leads ......................................................... 35
Extremity MR System ............................................................................................................ 38
Guidelines for the Management of the Post-Operative Patient Referred for a Magnetic Resonance Procedure ..................................................................................................... 42
Guidelines for Screening Patients for MR Procedures and Individuals for the MR Environment .................................................................................................................................. 45
Guidelines to Prevent Excessive Heating and Burns Associated with Magnetic Resonance Procedures ...................................................................................................................... 58
Infection Control in the MRI Environment .............................................................................. 64
Magnetic Resonance Imaging: Information for Patients ......................................................... 68
Metallic Foreign Bodies and Screening .................................................................................... 73
Metallic Orbital Foreign Bodies and Screening ....................................................................... 75
Monitoring Patients in the MR Environment .......................................................................... 78
Bone Fusion Stimulator/Spinal Fusion Stimulator ........................................... 199
Bravo pH Monitoring System ........................................................................... 206
Breast Tissue Expanders and Implants ............................................................. 207
Cardiac Pacemakers and Implantable Cardioverter Defibrillators ..................... 210
Cardiac Pacemaker: Accent MRI Pacemaker System ........................................ 223
Cardiac Pacemaker: Advisa DR MRI SureScan Pacing System ......................... 225
Cardiac Pacemaker: Ensura DR MRI SureScan Pacing System ......................... 228
Cardiac Pacemaker: EnRhythm MRI SureScan Pacing System ......................... 231
Cardiac Pacemakers: ProMRI Pacing Systems .................................................. 234
Cardiac Pacemaker: Revo MRI SureScan Pacing System ................................... 235
Cardiovascular Catheters and Accessories ...................................................... 237
Carotid Artery Vascular Clamps ...................................................................... 241
Celsius Control System or Temperature Modulation Therapy ......................... 242
Cerebrospinal Fluid (CSF) Shunt Valves and Accessories ............................... 247
Cochlear Implants ......................................................................................... 258
Coils, Stents, Filters, and Grafts ...................................................................... 266
Cranial Flap Fixation Clamps and Similar Devices .......................................... 272
Dental Implants, Devices, and Materials ......................................................... 274
Diaphragms .................................................................................................... 275
Dressings Containing Silver and MRI Procedures ........................................... 276
Dressing Containing Silver and MRI: Aquacel AG .......................................... 280
ECG Electrodes .............................................................................................. 281
EmpowerMR Contrast Injection System ......................................................... 282
Epidural Pump, ambIT Epidural Pump .............................................................. 283
Essure Device ........................................................................................................... 284
External Fixation Devices ..................................................................................... 285
Foley Catheters With and Without Temperature Sensors ............................... 287
FREEHAND System,
   Implantable Functional Neurostimulator ...................................................... 293
Glaucoma Drainage Implants (Shunt Tubes) ...................................................... 295
Guidewires ........................................................................................................... 297
Halo Vests and Cervical Fixation Devices ......................................................... 299
Hearing Aids and Other Hearing Systems ......................................................... 305
Heart Valve Prostheses and Annuloplasty Rings .............................................. 306
Hemostatic Clips, Other Clips, Fasteners, and Staples ................................. 309
InSound XT Series and Lyric Hearing Device ................................................... 313
Insulin Pumps ...................................................................................................... 314
Intrauterine Contraceptive Devices and Other Devices ............................... 317
IsoMed Implantable Constant-Flow Infusion Pump ....................................... 319
Licox CC1.P1, Oxygen and Temperature Probe,
   Brain Tissue Oxygen Monitoring System ................................................... 322
Magnetically-Activated Implants and Devices ................................................. 326
Medivanee Nasogastric Sump Tube with YSI Series 400
   Temperature Sensor ......................................................................................... 328
Miscellaneous Implants and Devices ............................................................... 330
Neurostimulation Systems: General Information ........................................... 332
Neurostimulation Systems: Deep Brain Stimulation ....................................... 337
Neurostimulation System: Enterra Therapy,
   Gastric Electrical Stimulation (GES) ............................................................. 346
Neurostimulation System: InterStim Therapy -
   Sacral Nerve Stimulation (SNS) for Urinary Control .................................. 347
Neurostimulation Systems: Spinal Cord Stimulation
   St. Jude Medical ................................................................................................. 349
Neurostimulation Systems: Spinal Cord Stimulation
   Medtronic, Inc. ................................................................................................. 350
Neurostimulation System: Vagus Nerve Stimulation ..................................... 359
Ocular Implants, Lens Implants, and Devices ................................................. 360
<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orthopedic Implants, Materials, and Devices</td>
<td>362</td>
</tr>
<tr>
<td>Otologic Implants</td>
<td>365</td>
</tr>
<tr>
<td>Oxygen Tanks and Gas Cylinders</td>
<td>369</td>
</tr>
<tr>
<td>Palatal System Implant Assembly</td>
<td>371</td>
</tr>
<tr>
<td>Pellets and Bullets</td>
<td>375</td>
</tr>
<tr>
<td>Penile Implants</td>
<td>377</td>
</tr>
<tr>
<td>Pessaries</td>
<td>378</td>
</tr>
<tr>
<td>PillCam Capsule Endoscopy Device</td>
<td>379</td>
</tr>
<tr>
<td>RF BION Microstimulator</td>
<td>380</td>
</tr>
<tr>
<td>Reveal Plus Insertable Loop Recorder</td>
<td>385</td>
</tr>
<tr>
<td>Reveal DX 9528 and Reveal XT 9529 Insertable Cardiac Monitors</td>
<td>387</td>
</tr>
<tr>
<td>St. Jude Medical (SJM) Confirm, Implantable Cardiac Monitor</td>
<td>388</td>
</tr>
<tr>
<td>SAM Sling</td>
<td>390</td>
</tr>
<tr>
<td>Scleral Buckle (Scleral Buckling Procedure)</td>
<td>391</td>
</tr>
<tr>
<td>Sleuth Implantable ECG Monitoring System</td>
<td>392</td>
</tr>
<tr>
<td>Surgical Instruments and Devices</td>
<td>394</td>
</tr>
<tr>
<td>Sutures</td>
<td>396</td>
</tr>
<tr>
<td>TheraSeed Radioactive Seed Implant</td>
<td>407</td>
</tr>
<tr>
<td>Transdermal Medication Patches</td>
<td>408</td>
</tr>
<tr>
<td>Vascular Access Ports, Infusion Pumps, and Catheters</td>
<td>412</td>
</tr>
<tr>
<td>VeriChip Microtransponder</td>
<td>414</td>
</tr>
<tr>
<td>VOCARE Bladder System, Implantable Functional Neuromuscular Stimulator</td>
<td>415</td>
</tr>
</tbody>
</table>
The List: Information and Terminology ............................................. 418

The List .......................................................................................... 427

Aneurysm Clips ............................................................................. 427
Biopsy Needles, Markers, and Devices ........................................ 449
Breast Tissue Expanders and Implants ........................................ 455
Cardiac Pacemakers, ICDs, and Cardiac Monitors ....................... 457
Cardiovascular Catheters and Accessories ................................. 459
Carotid Artery Vascular Clamps .................................................. 462
Cerebrospinal Fluid (CSF) Shunt Valves and Accessories .......... 463
Coils, Stents, Filters, and Grafts .................................................... 469
Dental Implants, Devices, and Materials ..................................... 497
ECG Electrodes ............................................................................ 498
Foley Catheters With and Without Temperature Sensors ............ 500
Halo Vests and Cervical Fixation Devices .................................... 501
Heart Valve Prostheses and Annuloplasty Rings ......................... 503
Hemostatic Clips, Other Clips, Fasteners, and Staples ................. 519
Miscellaneous ............................................................................. 525
Ocular Implant, Lens Implants, and Devices ............................... 563
Orthopedic Implants, Materials, and Devices ............................. 568
Otologic and Cochlear Implants .................................................. 583
Patent Ductus Arteriosus (PDA),
Atrial Septal Defect (ASD),
Ventricular Septal Defect (VSD) Occluders,
and Patent Foramen Ovale (PFO) Closure Devices .................. 596
Pellets and Bullets ...................................................................... 599
Penile Implants ............................................................................ 601
Pessaries ...................................................................................... 603
Sutures ........................................................................................ 605
Vascular Access Ports, Infusion Pumps, and Catheters ................ 606

The List: References ........................................................................ 617

Appendix I: Guidance for Industry and FDA Staff. Criteria for
Significant Risk Investigations of Magnetic Resonance
Diagnostic Devices. Food and Drug Administration,
Center for Devices and Radiological Health ............................... 625

Appendix II: Websites for MRI Safety, Bioeffects,
and Patient Management .............................................................. 630