

Normal P axis, PR, rate & negative rhythm
P V_1 - .10 mV or more negative
Q/S in V_1 & V_2
QTc $>$ 470 ms
ANT/LAT/INF
 $ST-T$ negative ANTR, $ST > -.05$ mV
 $T > -.30$ mV, $ST > -.05$ mV

GlobalData »
MediPoint

**CARDIAC RHYTHM MANAGEMENT –
US ANALYSIS AND MARKET FORECASTS**

Executive Summary

Cardiac Rhythm Management Devices: Key Metrics in US	
Sick Sinus Syndrome Prevalence, 2012	0.3 million
Atrioventricular Block Prevalence, 2012	0.7 million
Ventricular Tachycardia Prevalence, 2012	1.8 million
Ventricular Fibrillation Prevalence, 2012	0.6 million
Cardiac Rhythm Management Market Revenue, 2012	
US	\$6.1bn
US Market Revenue by Device Type, 2012	
Pacemakers	\$2.1bn
Implantable Cardioverter-Defibrillators	\$2.6bn
Cardiac Resynchronization Therapy Pacemakers	\$73m
Cardiac Resynchronization Therapy Defibrillators	\$1.4bn
Events Affecting the CRM Market	
Approval of S-ICD (Boston Scientific) by US FDA	↑↑
Launch of Advisa MRI (Medtronic) in US	↑
Forecast US Revenue by Device Type, 2020	
Pacemakers	\$2.1bn
Implantable Cardioverter-Defibrillators	\$2.9bn
Cardiac Resynchronization Therapy Pacemakers	\$88m
Cardiac Resynchronization Therapy Defibrillators	\$1.9bn

Source: GlobalData.

Cardiac Rhythm Management Market to Experience Significant Expansion Through 2020

Revenue from the US cardiac rhythm management market, consisting of pacemaker (PM), implantable Cardioverter-defibrillator (ICD), cardiac resynchronization pacemaker (CRT-P) and cardiac resynchronization therapy defibrillator (CRT-D) devices, is forecast to increase at a compound annual growth rate of 2.7% from \$6.1 billion in 2012 to over \$7.5 billion by 2020. This growth will come as a result of increasing incidences of arrhythmia and heart failure, combined with rising market penetration of pacing and pulse generator technology. Programs supporting this type of therapy are increasingly desirable as the occurrence of cardiac dyssynchrony continues to rise; it is estimated roughly 1% of the population suffers from an irregular heartbeat, although pervasiveness rises to over 20% in elderly people. While tachycardia and bradycardia are the most common indications for treatment, heart failure, diabetes, and obesity can contribute to ongoing rhythm management concerns.

The extremely competitive CRM market is dominated by several key players, who must continue to innovate in the face of mounting pricing pressure and strict regulation as they battle to gain market share.

Executive Summary

New technologies being developed, including leadless pacemakers and energy harvesting generators, promise to heighten products sales and new account openings, while industry standards continue to develop in regards to remote home monitoring and rate-adaptive therapy. Ongoing studies investigating applicability and appropriateness of varying rhythm management modalities are expected to further clarify suitable device indications and therapy best-practices, while advances in diagnostics as well as adjunctive therapy will assure better patient outcomes and shorter hospital stays in future years.

Key Drivers during the Forecast Period

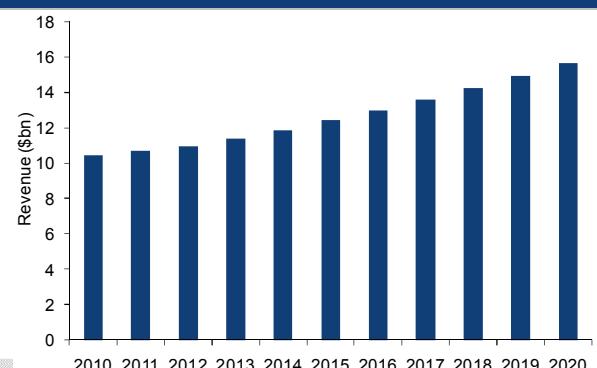
- Growing incidences of arrhythmia and heart failure
- Heightened adoption rates
- New advancements in leadless devices and energy harvesting technology
- Increased emphasis on early intervention and primary prevention
- Strong CRM program adoption in hospitals, resulting in new account openings

Key Barriers during the Forecast Period

- High-costing devices to hinder CRM adoption
- Lacking reimbursement expected to limit market expansion and hospital product offerings

- Intense CRM market competition with limited innovation on the horizon

Pacemaker, ICD, CRT-D, CRT-P Market, Global, Revenue, (\$bn), 2010–2020



Source: GlobalData.

Biventricular Therapy on the Rise as Devices Approved

Newly developed biventricular CRT-P and CRT-D devices are expected to undergo significant market adoption in the coming years as physician adoption increases, additional patient outcomes are published, and average selling price declines. Furthermore, as more centers develop their CRT offerings, hospitals will be looking to implement new programs for advanced CRM, to enable their physicians to begin implanting the devices.

Despite higher prices when compared with single-chamber pacemakers, dual-chamber and biventricular CRT-P products have experienced notable rises in procedure volumes, driving growth in total sale revenue from these market segments.

Executive Summary

Currently, dual-chamber devices account for the largest segment of the CRM market, although CRT is experiencing adoption rates similar to what dual-chamber devices did several years ago.

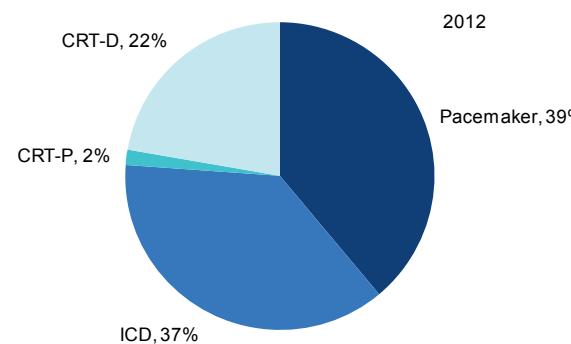
Given improved efficacy, better outcomes and physician partiality, these next-generation devices have seen significant adoption in the US market.

Significant Growth in Target Population

The population requiring CRM therapy continues to grow, due to increasing prevalence of serious risk factors, including obesity, diabetes, hypertension, and congestive heart failure. According to a 2013 briefing published by the World Health Organization, over 1 billion people suffer from hypertension worldwide, which is a major cause of congestive heart failure, a condition common in over 25 million people (WHO, 2013). Similarly, the International Diabetes Federation states an estimated 285 million people had diabetes in 2010, which is predicted to increase to 438 million by 2030 (International Diabetes Federation, 2013). Additionally, the global obesity population is increasing at a rapid, uncontrolled rate. Lifestyle factors, including tobacco, alcohol and caffeine intake, can also greatly increase the risk of arrhythmias.

With limited pharmacotherapy to treat dyssynchrony, CRM devices are expected to remain the go-to option for patients with rhythm management concerns.

Pacemaker, ICD, CRT-D, CRT-P Market Breakdown (%), Global, 2012



Source: GlobalData.

Primary Prevention on the Rise

Traditionally, the majority of implantable Cardioverter-defibrillators implanted have been implanted for secondary prevention indications; however, this is slowly changing. As mature markets undergo a paradigm shift in treatment, the percentage of primary prevention cases continues to rise; nearly 70% of ICDs implanted in the US in 2012 were for primary prevention indications. As treatment schedules evolve, CRM companies will have an ever-growing opportunity to sell their products for primary prevention indications.

Device Innovation Expected to Drive Sales

While advancements in device algorithms and rate-adaptive programming, as well as reductions in size and weight, have all distinguished various brands on the market to date, these technological advancements offer limited patient outcome improvements from brand to brand.

Executive Summary

However, the introduction of remote home monitoring promises to dramatically change treatment. Home monitoring telemetry will decrease the number of patient hospital visits, a particularly attractive feature for customers living in remote regions far from access to healthcare. Furthermore, advances in leadless and energy harvesting technology are expected to be revolutionary to the CRM industry, especially in the US. Through eliminating the need for lead replacement and, especially, generator battery replacement, manufacturers hope to boost device sales in younger and more remote populations, who are reluctant to receive a new device that requires substitution every seven to 12 years.

What do Physicians Think?

While CRM therapy has been around for many years, a majority of patients don't fully understand the treatment, or are unaware of their own dyssynchrony. Increases in patient awareness as well as physician diagnosis are expected to drive CRM sales.

"[Patients] are not aware that there is a device that can prevent sudden cardiac death, and they don't know to ask for [therapy]."

Key Opinion Leader

While advancements in treatment guidelines and industry best-practices have provided greater clarity in regards to appropriateness of treatment, gaps remain in the understanding of arrhythmia, and there is significant room for procedural improvement as well as international guideline development.

"The guidelines as envisioned are tremendously important and have a great use and a great purpose. However, the implementation [of] these guidelines is confused by competing other documents."

Key Opinion Leader

While advancements in CRM therapy have provided improved patient outcomes, this evolution has been in parallel with developments in adjunctive therapy, which continues to progress as well and greatly affects patient outcomes.

"Although there are a lot of achievements within the CRM field, the advantages in the adjunctive therapy go hand-in-hand."

Key Opinion Leader

While improvements in programming and rate-adaptive algorithms have driven device sales and established physician preferences to an extent, the introduction of leadless technology and energy harvesting devices is expected to be far more impactful, and will mark the next revolution for CRM products.

Executive Summary

“Energy harvesting is very interesting. If physicians don’t have to replace the generator, that is perfect.”

Key Opinion Leader

While many companies are striving to completely eliminate device leads, other advances in lead technology have done the opposite. In particular, multi-electrode ventricular leads are increasingly common in company pipelines, and many believe that these next-generation products will provide significant improvements in patient treatment.

“In the future, we are looking at multi-electrode LV leads, and I’m pretty enthusiastic about those multi-polar leads, as I think this is probably one of the future trends.”

Key Opinion Leader

SAMPLE

Table of Contents

1 Table of Contents

1	Table of Contents	7
1.1	List of Tables	14
1.2	List of Figures	19
2	Introduction	20
2.1	Catalyst	20
2.2	Related Reports	21
2.3	Upcoming Related Reports	21
3	Disease Overview	22
3.1	Anatomy and Physiology	22
3.1.1	Risk Factors	23
3.1.2	Etiology	25
3.2	Pathophysiology	26
3.2.1	Cardiac Arrhythmias	26
3.3	Clinical Presentation	32
3.3.1	Symptoms	32
3.4	Diagnosis	33
3.4.1	Blood and Urine Diagnostic Procedures	33
3.4.2	Electrocardiography-Based Diagnostic Procedures	34
3.4.3	Computerized Tomographic Angiography	35
3.4.4	Electrophysiological Testing	35
3.4.5	Electromechanical Wave Imaging	35
3.4.6	Echocardiography	36
3.4.7	Tilt-Table Testing	36
3.4.8	Diagnostic and Electrophysiological Studies	36
3.4.9	New York Heart Association Scale	36
3.4.10	American College of Cardiology Scale	37

Table of Contents

3.4.11 Level of Evidence	37
3.5 Epidemiology	38
3.5.1 Prevalence.....	38
4 Industry Overview.....	41
4.1 Overview.....	41
4.2 Clinical Outcomes.....	41
4.2.1 Pacemakers.....	41
4.2.2 ICDs	49
4.2.3 CRT-Ps.....	56
4.2.4 CRT-Ds	57
4.3 Procedure Trends	58
4.3.1 Cost and Appropriateness Still a Concern with Dual-Chamber Devices.....	58
4.3.2 Cardiac Resynchronization Therapy Increasingly Popular Around the World.....	60
4.3.3 Device Reuse Programs to Transform Currently Wasted Resource.....	61
4.3.4 Hospital Market Growth	62
4.4 Market Access	62
4.4.1 US	62
4.4.2 Reimbursement Trends	64
4.5 Regulatory Issues/Recalls.....	67
4.5.1 Medtronic Pacemakers Recalled over Failure Risk, 2009	67
4.5.2 St. Jude Riata ICD Leads Recalled, 2011.....	68
4.6 Mergers and Acquisitions.....	68
4.6.1 Boston Scientific Acquires C.R. Bard's Electrophysiology Business.....	68
4.6.2 Sorin Group Closes Further Investment and Option-to-Buy in Enopace Biomedical	68
4.7 Key Partnerships.....	69
4.7.1 Leti Forms Partnership with Sorin, TIMA, Cedrat Technologies, Tronics and EASII IC ...	69
4.7.2 St. Jude Medical to Invest in Nanostim	69

Table of Contents

4.7.3 Sorin Group Signs Supply Agreement for Boston Scientific Corporation Lotus Valve System	71
4.8 Economic Impact	71
4.8.1 Cost-Effectiveness of Pacemakers	71
4.8.2 Cost-Effectiveness of ICDs	72
4.8.3 Cost-Effectiveness of Cardiac Resynchronization Therapy	72
4.9 Market Drivers.....	73
4.9.1 Rapidly Increasing Patient Populations Suitable for Device Implantation to Drive Sales ..	73
4.9.2 Technological Advances and New Products in Pipeline to Drive Sales	76
4.9.3 Evolving Indications for Cardiac Rhythm Management Therapy	81
4.9.4 Imaging Guided Placement of Leads	84
4.9.5 Cost-Saving Benefits of Remote Home Monitoring	85
4.9.6 Increased Primary Prevention Procedures.....	87
4.9.7 Increases in Implantation from Positive Clinical Trials.....	88
4.9.8 Antibacterial Envelopes to Reduce Rates of Complication and Increase Device Safety..	89
4.9.9 Strong Portfolio of Pipeline Products from Key Players to Drive Future Growth of the Market	89
4.9.10 Leadless Technology Eliminates Lead-Related Complications	90
4.9.11 Diagnostic Rate Improvements Expected to Drive CRM Device Sales.....	91
4.9.12 Increased Device Implantation in Pediatrics.....	91
4.10 Market Barriers	92
4.10.1 US Healthcare Reform May Impact US CRM Market Growth Adversely	93
4.10.2 Increased Emphasis on Value-Based Payment Programs through Medicare and Cost-Effectiveness Research to Cause Competitive Pricing Pressure.....	93
4.10.3 Innovative and Next-Generation Drug Therapy May Pose a Challenge to CRM Devices in the Future	94
4.10.4 Slow Adoption of Remote Patient Monitoring Could Restrain Market Growth.....	94
4.10.5 Inconsistencies between Various Guidelines Affects Treatment	95
4.10.6 Inappropriate Shock Rates May Thwart Potential CRM Patients.....	96

Table of Contents

4.10.7 Patient Education to Increase Awareness and Device Adoption	96
4.10.8 Declining Average Selling Prices to Adversely Affect CRM Product Revenues	97
5 Competitive Assessment	98
5.1 Overview.....	98
5.2 Regional Market Share	98
5.2.1 Pacemaker and CRT-P Market Company Share in the US	98
5.2.2 ICD and CRT-D Market Company Share in the US.....	100
6 Unmet Needs	101
6.1 Overview.....	101
6.2 Leads and Electrode Development	101
6.2.1 MRI-Compatible Generators and Leads.....	102
6.2.2 Single-Lead Systems with Atrial Diagnostics	104
6.3 Power-Supplying Batteries.....	104
6.4 Energy-Harvesting Batteries	105
6.5 Rates of Infection	106
7 Pipeline Products	107
7.1 Overview.....	107
7.2 Pipeline Products by Phase in Development.....	107
7.3 Pacemaker and CRT-P Product Profiles	108
7.3.1 Aortic Pacemaker (Hadasit Medical Research Services & Development Ltd.)	108
7.3.2 Cardiac Energy Harvesting Pacemaker (University of Michigan)	109
7.3.3 Endurance Microgenerator (Endurance Rhythm).....	109
7.3.4 Implantable Dual-Chamber Pacemaker (MicroPort Scientific).....	110
7.3.5 Unconditional MRI-Compatible Implantable Pacemaker (Kenergy, Inc.)	110
7.3.6 Tissue-Engineered Autonomous Pacemaker (Duke University).....	111
7.3.7 Wireless Cardiac Stimulation Device (EBR Systems, Inc.).....	111
7.4 ICD and CRT-D Product Profiles.....	112

Table of Contents

7.4.1	Atrial Defibrillator (SmartWave Medical Ltd.).....	112
7.4.2	CardiaLen (CardiaLen, Inc.).....	112
7.4.3	Chronicle (Medtronic)	113
7.5	Clinical Trials to Watch.....	114
7.5.1	Overview	114
7.5.2	SELECT-LV Trial of WiCS-LV System (EBR Systems, Inc.)	114
7.5.3	MultiPoint Pacing Clinical Trial of Quadra Assura CRT-D (Medtronic)	116
7.5.4	MADIT-ASIA Trial with Invive CRT-P (Boston Scientific).....	117
7.5.5	MultiPoint Pacing IDE Study of Promote Quadra (St. Jude Medical).....	119
7.5.6	Post Approval Study of S-ICD System (Boston Scientific).....	120
7.5.7	ProMRI Study of the Evia/Entovis Pacemaker System.....	122
7.5.8	MIRACLE EF Clinical Study of Consulta CRT-P (Medtronic)	124
8	Current and Future Players	127
8.1	Overview.....	127
8.2	Trends in Corporate Strategy	127
8.3	Biotronik.....	128
8.3.1	Overview	128
8.3.2	Portfolio Evaluation.....	130
8.3.3	Commercial Positioning	140
8.3.4	Company SWOT Analysis	141
8.4	Boston Scientific	141
8.4.1	Overview	141
8.4.2	Portfolio Evaluation.....	143
8.4.3	Commercial Positioning	152
8.4.4	Company SWOT Analysis	153
8.5	Impulse Dynamics.....	153
8.5.1	Overview	153

Table of Contents

8.5.2	Portfolio Evaluation.....	153
8.5.3	Commercial Positioning	154
8.5.4	Company SWOT Analysis	154
8.6	Medtronic.....	155
8.6.1	Overview	155
8.6.2	Portfolio Evaluation.....	157
8.6.3	Marketed Products.....	159
8.6.4	Additional Products.....	167
8.6.5	Commercial Positioning	169
8.6.6	Company SWOT Analysis	171
8.7	Sorin Group	171
8.7.1	Overview	171
8.7.2	Portfolio Evaluation.....	173
8.7.3	Marketed Products.....	174
8.7.4	Commercial Positioning	175
8.7.5	Company SWOT Analysis	176
8.8	St. Jude Medical	176
8.8.1	Overview	176
8.8.2	Portfolio Evaluation.....	177
8.8.3	Marketed Products.....	179
8.8.4	Commercial Positioning	192
8.8.5	Company SWOT Analysis	193
9	Market Outlooks and Forecasts.....	194
9.1	Market Outlooks and Forecasts by Geography	194
9.1.1	US	194
10	Appendix	203
10.1	Bibliography	203

Table of Contents

10.2 Abbreviations	216
10.3 Report Methodology.....	221
10.3.1 Overview	221
10.3.2 Coverage.....	221
10.3.3 Secondary Research	221
10.3.4 Forecasting Methodology.....	222
10.3.5 Primary Research – Key Opinion Leader Interviews	223
10.3.6 Expert Panel Validation.....	224
10.4 Physicians and Specialists Included in this Study	225
10.5 About the Authors	227
10.5.1 Analysts.....	227
10.5.2 Global Head of Healthcare.....	228
10.6 About MediPoint.....	229
10.7 About GlobalData.....	229
10.8 Disclaimer.....	229

SAMPLE

Table of Contents

1.1 List of Tables

Table 1: New York Heart Association Scale	37
Table 2: American College of Cardiology Scale.....	37
Table 3: Level of Evidence.....	38
Table 4: Prevalent Cases of Congestive Heart Failure, US, Ages \geq 45 Years, Men and Women (n), 2012–2019.....	40
Table 5: Pacemaker Implantation Classification Guideline.....	43
Table 6: Patient Post-Operative Condition with ICD Implantation, 2012.....	50
Table 7: Level of Evidence Guidelines	54
Table 8: CRT-P versus Conventional Pacemakers, Sales Volume Comparison, US, 2012	60
Table 9: CRT-D versus Conventional ICD Products, Sales Volume Comparison, US, 2012.....	60
Table 10: Healthcare Expenditure by Payer (%) and Healthcare Expenditure per Capita (\$), US, 2011	64
Table 11: Medicare Standardized Payment Rates for Hospitals for Pacemaker/CRT-P Implantation	65
Table 12: Medicare Standardized Payment Rates for Hospitals for Pacemaker/CRT-P Replacement.....	66
Table 13: Medicare Standardized Payment Rates for Hospitals for ICD/CRT-D Implantation.....	66
Table 14: Medicare Standardized Payment Rates for Hospitals for ICD/CRT-D Replacement	67
Table 15: Percentage of Population Aged 65 Years and Older, US, 2005–2015.....	74
Table 16: Percentage of Smoking Population by Country (%), US, 2010	74
Table 17: Percentage of Overweight and Obese Population (Aged 15 Years and Above), US, 2012	75
Table 18: Diabetes Prevalence Rates by Region (%), 20–79 Years, North America, 2007 & 2010.....	75
Table 19: Technological Innovations, Cardiac Rhythm Management Devices.....	77
Table 20: Benefits of Quadripolar Lead Technology.....	79
Table 21: Updated Cardiac Resynchronization Therapy Guidelines	80
Table 22: Barriers in Access to Quality Healthcare Leading to Disparities in CRM Treatment.....	92
Table 23: Average Selling Price (\$) Comparison, US, 2012.....	97

Table of Contents

Table 24: Pacemaker and CRT-P Market, US, Revenue (\$) and Company Share (%), 2012.....	99
Table 25: ICD and CRT-D Market, US, Revenue (\$) and Company Share (%), 2012	100
Table 26: Product Profile – Aortic Pacemaker	108
Table 27: Product Profile – Cardiac Energy Harvesting Pacemaker	109
Table 28: Product Profile – Endurance Microgenerator	109
Table 29: Product Profile – MicroPort Pacemaker	110
Table 30: Product Profile – Kenergy Pacemaker	110
Table 31: Product Profile – Tissue-Engineered Autonomous Pacemaker	111
Table 32: Product Profile – Wireless Cardiac Stimulation Device	111
Table 33: Product Profile – Atrial Defibrillator.....	112
Table 34: Product Profile – CardiaLen	112
Table 35: Product Profile – Chronicle.....	113
Table 36: Clinical Trial for WiCS-LV System	114
Table 37: Clinical Trial for Quadra Assura CRT-D	116
Table 38: Clinical Trial for Invive CRT-P.....	117
Table 39: MultiPoint Pacing IDE Study for Promote Quadra	119
Table 40: Post Approval Study of S-ICD System.....	120
Table 41: ProMRI Study of the Evia/Entovis Pacemaker System.....	122
Table 42: MIRACLE EF Clinical Study of Consulta CRT-P	124
Table 43: Company Profile – Biotronik.....	130
Table 44: Product Profile – Cylos 990	133
Table 45: Product Profile – Effecta.....	134
Table 46: Product Profile – Evia/Entovis	135
Table 47: Product Profile – Estella	136

Table of Contents

Table 48: Product Profile – Stratos	137
Table 49: Product Profile – Ilesto 7	137
Table 50: Product Profile – Lumax	140
Table 51: Biotronik SWOT Analysis, 2012.....	141
Table 52: Company Profile – Boston Scientific.....	142
Table 53: Product Profile – Advantio.....	145
Table 54: Product Profile – Altrua	146
Table 55: Product Profile – Cognis.....	147
Table 56: Product Profile – Energen	148
Table 57: Product Profile – Incepta	148
Table 58: Product Profile – Ingenio	149
Table 59: Product Profile – Invive	150
Table 60: Product Profile – Punctua.....	151
Table 61: Product Profile – S-ICD System 2.0.....	151
Table 62: Product Profile – Teligen	152
Table 63: Boston Scientific SWOT Analysis, 2012	153
Table 64: Company Profile – Impulse Dynamics	153
Table 65: Product Profile – Optimizer IVs.....	154
Table 66: Impulse Dynamics SWOT Analysis, 2012.....	154
Table 67: Company Profile – Medtronic	156
Table 68: Product Profile – Advisa	159
Table 69: Product Profile – Adapta	160
Table 70: Product Profile – Brava/Viva.....	161
Table 71: Product Profile – Consulta.....	162

Table of Contents

Table 72: Product Profile – EnPulse	162
Table 73: Product Profile – EnRhythm	163
Table 74: Product Profile – Ensura MRI	163
Table 75: Product Profile – Evera	164
Table 76: Product Profile – Protecta	164
Table 77: Product Profile – Secura	165
Table 78: Product Profile – Syncra.....	166
Table 79: Product Profile – Revo	166
Table 80: Product Profile – Concerto	167
Table 81: Product Profile – EnTrust	168
Table 82: Product Profile – Maximo II	168
Table 83: Medtronic SWOT Analysis, 2012.....	171
Table 84: Company Profile – Sorin Group.....	173
Table 85: Product Profile – Esprit.....	174
Table 86: Product Profile – Paradym.....	174
Table 87: Product Profile – Reply 2000.....	175
Table 88: Sorin Group SWOT Analysis, 2012	176
Table 89: Company Profile – St. Jude Medical.....	177
Table 90: Product Profile – Accent.....	180
Table 91: Product Profile – Accent MRI	181
Table 92: Product Profile – Anthem	182
Table 93: Product Profile – Allure Quadra	183
Table 94: Product Profile – AnalyST Accel	183
Table 95: Product Profile – Assurity	184

Table of Contents

Table 96: Product Profile – Current Accel	184
Table 97: Product Profile – Current Plus	185
Table 98: Product Profile – Ellipse	185
Table 99: Product Profile – Endurity.....	186
Table 100: Product Profile – Fortify Assura.....	186
Table 101: Product Profile – Fortify.....	187
Table 102: Product Profile – Microny	187
Table 103: Product Profile – Leadless Pacemaker	188
Table 104: Product Profile – Promote Plus.....	189
Table 105: Product Profile – Quadra Assura	190
Table 106: Product Profile – Unify Assura.....	190
Table 107: Product Profile – Unify Quadra.....	191
Table 108: Product Profile – Unify.....	191
Table 109: Product Profile – Zephyr.....	192
Table 110: St. Jude Medical SWOT Analysis, 2012	193
Table 111: US Cardiac Rhythm Management Device Implantation.....	195
Table 112: Implantable Cardioverter-Defibrillators Patient Clinical History Breakdown (%), US, 2012.....	198
Table 113: Implanting Physician Training Status (%), US, 2012	199
Table 114: Pacemakers and Cardiac Resynchronization Therapy Pacemakers, US, Revenue (\$m), 2010–2020	201
Table 115: Implantable Cardioverter-Defibrillators and Cardiac Resynchronization Therapy Defibrillators Market, US, Revenue (\$m), 2010–2020	202

Table of Contents

1.2 List of Figures

Figure 1: Types of Arrhythmia	26
Figure 2: Generic Pacemaker Code	43
Figure 3: Guide for Pacemaker Implantation	44
Figure 4: Patient and General Population Preferences for CRM Device Reuse, US	61
Figure 5: Evaluating Effectiveness of Remote Home Monitoring	86
Figure 6: Pacemaker and CRT-P Market, US, Company Share (%), 2012	98
Figure 7: ICD and CRT-D Market, US, Company Share (%), 2012	100
Figure 8: CRM Pipeline Products by Phase in Development	107
Figure 9: Cardiac Resynchronization Therapy Implantation, US, by Age (%), 2011	197
Figure 10: Cardiac Rhythm Management Implantation by Sex (%), US, 2012	198
Figure 11: Pacemaker Implantation by Payer, US, 2012	199
Figure 12: Pacemaker Implantation by Hospital Size, US, 2012	200
Figure 13: Pacemakers and Cardiac Resynchronization Therapy Pacemakers, US, Revenue (\$m), 2010–2020	201
Figure 14: Implantable Cardioverter-Defibrillators and Cardiac Resynchronization Therapy Defibrillators Market, US, Revenue (\$m), 2010–2020	202

© GlobalData. This report is a licensed product and is not to be copied, reproduced, shared or resold in any form.

Introduction

2 Introduction

Cardiac rhythm management (CRM) comprises any method of treatment aimed at regulating the heart's rhythm, including medication, medical devices, and occasionally surgery. There can be a number of reasons why CRM is needed, all of which generally involve malfunctions of the heart's electrical system, and are related to cardiac dyssynchrony. While medication can be effective in mild to moderate cases, patients with more severe conditions must turn to device use or surgical intervention in order to receive the therapy they require. Over the years, CRM device treatment has become less invasive, and significant advances in pacing and pulse generator technology have enabled effective long-term device therapy with limited complications.

There are a number of devices that are utilized for CRM, and depending on the patient's arrhythmia, they may receive a pacemaker (PM), implantable cardioverter-defibrillator (ICD), cardiac resynchronization therapy pacemaker (CRT-P) or cardiac resynchronization therapy defibrillator (CRT-D). CRM device implementation depends on the patient's current status and how the physician expects their dysrhythmia to progress, although other concerns in regards to pricing, reimbursement, and complication rates all have an effect on the decision to implant as well, especially in emerging markets where patient awareness is lacking and healthcare budgets are limited.

2.1 Catalyst

The CRM industry continues to experience meaningful growth through improved device therapy, adoption in remote regions, increased patient awareness, and updates in national and international guidelines. Companies are increasingly looking to provide tiered product offerings to target larger patient populations with differing reimbursement options. While 15 years ago CRM products were not programmable, most current devices have 200 parameters, which can be reprogrammed non-invasively using telemetry, and result in substantial performance differences between the various brands of CRM products. Despite innovation and new product launches, many customers are genuinely happy with the performance and features of current devices, and as a result, the CRM market continues to be troubled by a challenging pricing environment that does not reward innovation. Companies now must figure out how to add value in different ways, principally related to device cost effectiveness.

Introduction

The CRT-P and CRT-D markets in the US have experienced significant growth in recent years despite relatively static pacemaker and ICD sales. With competition tight between just a few major players, added emphasis will be put on affordability, technology innovation, and distribution networks in the coming years.

- Next-generation CRT products have experienced significant adoption in recent years
- Pipeline technologies including leadless generators and energy harvesting devices will drive future device sales
- Remote home monitoring telemetry is expected to increase CRM device adoption, especially in remote areas
- The industry shift from single-chamber to dual-chamber ICDs will drive additional revenue
- Pricing headwinds, especially in developing countries, will steadily reduce the average selling price of CRM products
- New distribution channels globally will strengthen market access for US-based companies

2.2 Related Reports

- MediPoint: Cardiac Assist Devices Global Analysis and Market Forecasts GDME0175MAR / Published March 2013
- MediPoint: Transcatheter Aortic Valve Replacement Global Analysis and Market Forecasts GDME0165MAR / Published November 2012

2.3 Upcoming Related Reports

- MediPoint: EP Ablation Global Analysis and Market Forecasts / To be published February 2014

Appendix

10.6 About MediPoint

MediPoint is the flagship product for GlobalData's Medical team. Each MediPoint report is built from the ground-up by our team of healthcare analysts in the US and UK. Each report includes input from experienced physicians and leading Key Opinion Leaders (KOLs). Running throughout each report in the series, "What Do Physicians Think" quotes provide a unique insight into how healthcare professionals are reacting to events within the industry, and what their responses could mean for industry strategists.

10.7 About GlobalData

GlobalData is a leading global provider of business intelligence in the Healthcare industry. GlobalData provides its clients with up-to-date information and analysis on the latest developments in medical device research, disease analysis, and clinical research and development. Our integrated business intelligence solutions include a range of interactive online databases, analytical tools, reports and forecasts. Our analysis is supported by a 24/7 client support and analyst team. GlobalData has offices in New York, Boston, London, India and Singapore.

10.8 Disclaimer

All Rights Reserved.

No part of this publication may be reproduced, stored in a retrieval system or transmitted in any form by any means, electronic, mechanical, photocopying, recording or otherwise without the prior permission of the publisher, GlobalData.