

INTRODUCTION	xvi
STUDY GOALS AND OBJECTIVES.....	xvi
REASONS FOR DOING THE STUDY	xvi
SCOPE OF THE REPORT	xvi
METHODOLOGY	xvii
RELATED BCC STUDIES	xvii
ANALYST CREDENTIALS.....	xviii
BCC RESEARCH ONLINE SERVICES	xviii
DISCLAIMER	xviii
SUMMARY.....	xix
<i>SUMMARY TABLE ADVANCED ORTHOPEDIC TECHNOLOGY,</i>	
<i>IMPLANTS, AND REGENERATIVE PRODUCTS, THROUGH 2012 (\$</i>	
<i>MILLIONS)</i>	<i>xxi</i>
<i>SUMMARY FIGURE ADVANCED ORTHOPEDIC TECHNOLOGY,</i>	
<i>IMPLANTS AND REGENERATIVE PRODUCTS, THROUGH 2012 (\$</i>	
<i>MILLIONS)</i>	<i>xxi</i>
INDUSTRY OVERVIEW.....	1
HISTORY OF THE ORTHOPEDIC INDUSTRY	1
ADVANCED ORTHOPEDIC MARKET DEVELOPMENT	1
GOVERNMENT REGULATION OF DEVICES	1
Regulation, Cost and Classification of Devices by Region	2
Costs	2
<i>FIGURE 1 STANDARD SUBMISSION FEES AND EXPENDITURES</i>	
<i>FOR DEVICE APPROVALS PER COUNTRY (U.S. DOLLARS)</i>	3
United States (FDA).....	3
510(k) Exemptions	4
<i>TABLE 1 PARTS 862-892 OF 21 CFR</i>	5
Humanitarian Device Exemption (U.S.).....	6
Investigational Device Exemption (IDE)	6
Changes in FDA Advisor Roles	7
Canada (Health Canada).....	7
Europe (MDD).....	8
Europe (MDD) (Continued)	9
Japan.....	10
Australia	11
TREATMENT SETTINGS.....	12
Ambulatory Treatment Facilities	12
<i>TABLE 2 AMBULATORY VISITS ALL AGES, 1994 AND 2004</i>	12
<i>TABLE 3 AMBULATORY VISITS PER PERSON ALL AGES, 1994 AND</i>	
<i>2004</i>	13
Orthopedic Rehabilitation Facilities and Physical Therapy.....	13
ISSUES AFFECTING THE MARKET.....	13

Insurance and Reimbursement Issues	14
<i>TABLE 4 ANNUAL HEALTH EXPENDITURES AS A PERCENT OF GROSS DOMESTIC PRODUCT (GDP) BY COUNTRY, 2005 ESTIMATES (\$ THOUSANDS)</i>	15
<i>FIGURE 2 ANNUAL HEALTH EXPENDITURES AS A PERCENT OF GROSS DOMESTIC PRODUCT (GDP) BY COUNTRY, 2005 ESTIMATES (\$ THOUSANDS)</i>	16
Marketing and Advertising Issues and Trends.....	16
LEADING MANUFACTURERS' STRATEGIES	17
Manufacture, Distribution and Supply	17
<i>TABLE 5 ADVANCED ORTHOPEDIC MANUFACTURING AND SUPPLY FACILITIES</i>	18
Manufacture, Distribution ... (Continued)	19
Sales and Marketing	20
<i>TABLE 6 ADVANCED ORTHOPEDIC SALES, MARKETING AND ADMINISTRATIVE EXPENDITURES BY MANUFACTURER FOR FISCAL YEAR 2006 (\$ MILLIONS)</i>	21
<i>FIGURE 3 ADVANCED ORTHOPEDIC SALES, MARKETING AND ADMINISTRATIVE EXPENDITURES BY MANUFACTURER FOR FISCAL YEAR 2006 (\$ MILLIONS)</i>	22
Sales and Marketing (Continued).....	23
Medical Tourism Impact on the Orthopedic Market.....	24
<i>TABLE 7 HIP REPLACEMENT: WORLDWIDE COST VARIATIONS</i>	25
<i>FIGURE 4 HIP REPLACEMENT: WORLDWIDE COST VARIATIONS</i>	26
<i>TABLE 8 U.S. HEALTH INSURANCE COVERAGE BY AGE GROUP (%)</i>	27
<i>FIGURE 5 U.S. HEALTH INSURANCE COVERAGE BY AGE GROUP (%)</i>	27
<i>TABLE 9 WORLD HEALTH ORGANIZATION RANKING OF HEALTHCARE SYSTEMS, TOP 50</i>	28
WORLD DEMOGRAPHICS.....	29
<i>TABLE 10 ESTIMATED WORLD POPULATION BY AGE GROUP, 2005-2012 (MILLIONS)</i>	29
<i>FIGURE 6 ESTIMATED WORLD POPULATION BY AGE GROUP, 2005-2012 (MILLIONS)</i>	30
<i>TABLE 11 ESTIMATED WORLD POPULATION, BY REGION, 2005-2012 (MILLIONS)</i>	30
<i>FIGURE 7 ESTIMATED WORLD POPULATION BY REGION, THROUGH 2012 (MILLIONS)</i>	31
<i>TABLE 12 U.S. POPULATION ESTIMATES AND PROJECTIONS BY AGE GROUP FOR THE SPECIFIC YEARS, 1900-2050 (THOUSANDS)</i>	32
<i>FIGURE 8 U.S. POPULATION ESTIMATES AND PROJECTIONS BY AGE GROUP FOR THE SPECIFIC YEARS, 1900-2050 (THOUSANDS)</i>	32

Gender and Age	32
<i>TABLE 13 LIFE EXPECTANCY IN THE U.S. AT BIRTH AND PROJECTIONS BY SEX, 2002-2011 (AVERAGE NUMBER OF YEARS)</i>	33
<i>FIGURE 9 LIFE EXPECTANCY IN THE U.S. AT BIRTH AND PROJECTIONS, BY SEX, 2000-2011 (AVERAGE NUMBER OF YEARS)</i>	33
Incidence of Orthopedic Conditions	34
Osteoarthritis.....	34
Rheumatoid Arthritis	34
Ankylosing Spondylitis	35
Fibromyalgia	35
Gout	35
Scleroderma.....	35
Lupus.....	36
Bursitis and Tendonitis	36
Osteoporosis	36
Low Bone Mass	36
<i>TABLE 14 ESTIMATED* PREVALENCE/INCIDENCE OF CONDITIONS AFFECTING THE WORLDWIDE ORTHOPEDIC INDUSTRY</i>	37
<i>FIGURE 10 ESTIMATED* PREVALENCE/INCIDENCE OF CONDITIONS AFFECTING THE WORLDWIDE ORTHOPEDIC INDUSTRY (%)</i>	38
Orthopedic Procedure Volumes in the United States	38
<i>FIGURE 11 NUMBER OF U.S. HIP REPLACEMENT PROCEDURES, 2000-2006 (THOUSANDS)</i>	39
<i>FIGURE 12 NUMBER OF U.S. KNEE REPLACEMENT PROCEDURES, 2000-2006 (THOUSANDS)</i>	40
<i>FIGURE 13 NUMBER OF U.S. SPINAL FUSION PROCEDURES, 2000-2006 (THOUSANDS)</i>	40
<i>FIGURE 13 (CONTINUED)</i>	41
<i>FIGURE 14 NUMBER OF U.S. PHYSICIAN VISITS FOR ROTATOR CUFF PROBLEMS, 2000-2006 (MILLIONS)</i>	41
Rising Orthopedic Incidence and Evolving Lifestyle Trends	42
<i>TABLE 15 U.S. AGE-ADJUSTED PERCENT DISTRIBUTION OF BODY MASS INDEX (BMI) AMONG PERSONS 18 YEARS AND OVER BY SELECTED CHARACTERISTICS, 2003</i>	42
<i>FIGURE 15 OBESITY PERCENTAGES BY COUNTRY, 2005</i>	43
<i>TABLE 16 PERCENT OF SMOKERS IN THE U.S. POPULATION 18 AND OLDER BY AGE AND SEX, 2003 (%)</i>	44
<i>TABLE 17 PERCENT OF U.S. ADULTS ENGAGING IN LEISURE-TIME, TRANSPORTATION-RELATED AND HOUSEHOLD-</i>	

<i>RELATED PHYSICAL ACTIVITY¹ BY SELECTED CHARACTERISTICS, 2003 (%)</i>	45
Comparison of Bone Mineral Density Levels	45
Comparison of Bone Mineral ... (Continued).....	46
TECHNOLOGY	47
INTRODUCTION	47
WORLD PATENT TRENDS.....	47
<i>TABLE 18 ADVANCED ORTHOPEDIC PATENTS FILED WORLDWIDE BY YEAR, 1992-2006</i>	48
<i>FIGURE 16 ADVANCED ORTHOPEDIC PATENTS FILED WORLDWIDE BY YEAR, 1992-2006</i>	48
PATENT TRENDS BY COUNTRY	48
<i>TABLE 19 WORLDWIDE ADVANCED ORTHOPEDIC PATENTS BY COUNTRY THROUGH 2006</i>	49
<i>FIGURE 17 WORLDWIDE ADVANCED ORTHOPEDIC PATENTS BY COUNTRY THROUGH 2006 (%)</i>	49
PATENT TRENDS BY ASSIGNEE.....	50
<i>TABLE 20 ADVANCED ORTHOPEDIC PATENT INFORMATION FOR LEADING COMPANIES</i>	50
<i>TABLE 20 (CONTINUED)</i>	51
<i>TABLE 20 (CONTINUED)</i>	52
<i>TABLE 20 (CONTINUED)</i>	53
<i>TABLE 20 (CONTINUED)</i>	54
<i>TABLE 20 (CONTINUED)</i>	55
<i>TABLE 20 (CONTINUED)</i>	56
<i>FIGURE 18 ADVANCED ORTHOPEDIC PATENTS HELD BY LEADING COMPANIES</i>	57
Patent Trends by Assignee (Continued).....	58
Patent Trends by Assignee (Continued)	59
EMERGING TECHNOLOGY AREAS	60
Nanotechnology and Microprocessors.....	60
Digital X-rays.....	61
Bone Density Improvements.....	61
High-resolution Cartilage Imaging.....	61
Stem Cells	62
Government Limitations	62
Embryonic Stem Cells	63
Adult Stem Cells.....	63
New Stem Cell Findings	63
Bone Technology and Stem Cells	64
Synthetic Bone Grafting Technology	64
Bone Modeling for Osteoporotic Spinal Fracture Testing	64
Advanced Mechanical Implant Creation	64
CURRENT TECHNOLOGY USES.....	65

Bone Growth Stimulators	65
TENS Units.....	65
LED Therapy	65
Light-emitting Diodes with Infrared Lasers	66
Thermal Imaging	67
BONE REPAIR AND REGENERATIVE PRODUCTS	68
Bone Grafts	68
<i>TABLE 21 BONE GRAFT PRODUCTS AND MATERIALS</i>	<i>69</i>
Procedures Using Bone Grafts	70
PRODUCT DESCRIPTIONS	70
Allografts/autografts.....	70
<i>TABLE 22 BONE ALLOGRAFT/AUTOGRAFT PRODUCTS AND</i>	
<i> COMPETITORS.....</i>	<i>71</i>
Allografts/Autografts (Continued).....	72
Bone Growth Stimulators	73
<i>TABLE 23 BONE GROWTH STIMULATOR PRODUCTS AND</i>	
<i> COMPETITORS.....</i>	<i>73</i>
Bone Growth Stimulators (Continued)	74
Bone Growth Stimulators (Continued)	75
Synthetic Bone Replacements.....	76
<i>TABLE 24 SYNTHETIC BONE REPLACEMENT PRODUCTS AND</i>	
<i> COMPETITORS.....</i>	<i>76</i>
Synthetic Bone Replacements (Continued)	77
Synthetic Bone Replacements (Continued)	78
NEW PRODUCT DEVELOPMENTS.....	79
MARKET ANALYSIS	79
Markets by Product Type	79
Markets by Product Type (Continued).....	80
<i>TABLE 25 GLOBAL BONE REPAIR AND REGENERATIVE PRODUCTS</i>	
<i> MARKET FORECAST, THROUGH 2012 (\$ MILLIONS).....</i>	<i>81</i>
<i>FIGURE 19 GLOBAL BONE REPAIR AND REGENERATIVE PRODUCTS</i>	
<i> MARKET FORECAST 2005-2012 (\$ MILLIONS)</i>	<i>82</i>
MARKETS BY WORLD REGION	82
<i>TABLE 26 REVENUE DISTRIBUTION FOR BONE REPAIR AND</i>	
<i> REGENERATIVE PRODUCTS BY WORLD REGION, 2006</i>	<i>83</i>
<i>FIGURE 20 REVENUE DISTRIBUTION FOR BONE REPAIR AND</i>	
<i> REGENERATIVE PRODUCTS BY WORLD REGION, 2006 (%).....</i>	<i>84</i>
Leading Suppliers and Participants	84
Leading Suppliers and ... (Continued).....	85
<i>TABLE 27 SUMMARY OF BONE REPAIR AND REGENERATIVE</i>	
<i> PRODUCTS BY COMPETITOR REVENUES, 2006 (\$ MILLIONS).....</i>	<i>86</i>
<i>FIGURE 21 SUMMARY OF BONE REPAIR AND REGENERATIVE</i>	
<i> PRODUCTS BY COMPETITOR REVENUES, 2006 (%).....</i>	<i>86</i>

CARTILAGE AND OTHER SOFT TISSUE REPAIR AND REGENERATIVE PRODUCTS	87
Product Descriptions	88
Fixation Systems and Other Specialized Devices	88
<i>TABLE 28 FIXATION SYSTEMS AND OTHER SPECIALIZED DEVICES AND MARKETERS</i>	88
<i>TABLE 28 (CONTINUED)</i>	89
Fixation Systems and ... (Continued)	90
Biologics and Biomaterials	91
<i>TABLE 29 CARTILAGE AND SOFT TISSUE BIOLOGICS AND BIOMATERIALS SEGMENT</i>	91
New Product Developments	92
MARKET ANALYSIS	93
Markets by Product Type	94
<i>TABLE 30 CARTILAGE AND OTHER SOFT TISSUE REPAIR AND REGENERATIVE PRODUCTS MARKET, THROUGH 2012 (\$ MILLIONS)</i>	95
<i>FIGURE 22 CARTILAGE AND OTHER SOFT TISSUE REPAIR AND REGENERATIVE PRODUCTS MARKET, 2005-2012 (\$ MILLIONS)</i>	96
Markets by World Region	96
<i>TABLE 31 WORLDWIDE DISTRIBUTION OF REVENUES FROM CARTILAGE AND OTHER SOFT TISSUE REPAIR AND REGENERATIVE PRODUCTS BY REGION, 2006 (%)</i>	97
<i>FIGURE 23 WORLDWIDE DISTRIBUTION OF REVENUES FROM CARTILAGE AND OTHER SOFT TISSUE REPAIR AND REGENERATIVE PRODUCTS BY REGION, 2006 (%)</i>	97
Leading Suppliers and Participants	98
<i>TABLE 32 SUMMARY OF CARTILAGE AND OTHER SOFT TISSUE REPAIR AND REGENERATIVE PRODUCTS BY COMPETITOR REVENUES, 2006 (\$ MILLIONS)</i>	99
<i>FIGURE 24 SUMMARY OF CARTILAGE AND OTHER SOFT TISSUE REPAIR AND REGENERATIVE PRODUCTS BY COMPETITOR REVENUES, 2006 (%)</i>	100
JOINT REPLACEMENTS, IMPLANTS AND REGENERATIVE PRODUCTS.....	100
Joint Replacements, Implants ... (Continued)	101
Joint Replacements, Implants ... (Continued)	102
Product Description	103
Hip Replacements	103
<i>TABLE 33 HIP REPLACEMENT PRODUCTS AND COMPETITORS</i>	103
<i>TABLE 33 (CONTINUED)</i>	104
<i>TABLE 33 (CONTINUED)</i>	105
Hip Replacements.(continued)	106
Hip Replacements.(continued)	107

Hip Replacements.(continued).....	108
Knee Replacements.....	109
<i>TABLE 34 KNEE REPLACEMENT PRODUCTS AND COMPETITORS.....</i>	<i>109</i>
<i>TABLE 34 (CONTINUED).....</i>	<i>110</i>
Knee Replacements (Continued)	111
Knee Replacements (Continued)	112
Spine Replacements	113
<i>TABLE 35 SPINE REPLACEMENT PRODUCTS AND COMPETITORS.....</i>	<i>113</i>
<i>TABLE 35 (CONTINUED).....</i>	<i>114</i>
<i>TABLE 35 (CONTINUED).....</i>	<i>115</i>
Spine Replacements (Continued).....	116
Spine Replacements (Continued).....	117
Other Extremity Replacements and Joint Products	118
<i>TABLE 36 OTHER EXTREMITY REPLACEMENTS, JOINT</i> <i>PRODUCTS AND COMPETITORS.....</i>	<i>118</i>
<i>TABLE 36 (CONTINUED).....</i>	<i>119</i>
Other Extremity ... (Continued).....	120
Biological Joint Products and Other Related Devices	121
<i>TABLE 37 BIOLOGICAL JOINT PRODUCTS AND OTHER RELATED</i> <i>DEVICES.....</i>	<i>122</i>
Biological Joint ... (Continued)	123
New Product Developments	124
MARKET ANALYSIS	124
Markets by Product Type	125
Markets by Product ... (Continued).....	126
<i>TABLE 38 GLOBAL JOINT REPLACEMENT, IMPLANT AND</i> <i>REGENERATIVE PRODUCT MARKET FORECASTS, THROUGH</i> <i>2012 (\$ MILLIONS).....</i>	<i>127</i>
<i>FIGURE 25 GLOBAL JOINT REPLACEMENT, IMPLANT AND</i> <i>REGENERATIVE PRODUCT MARKET FORECASTS, THROUGH</i> <i>2012 (\$ MILLIONS).....</i>	<i>127</i>
Markets by World Regions	128
<i>TABLE 39 WORLDWIDE REVENUE DISTRIBUTION FOR JOINT</i> <i>REPLACEMENTS, IMPLANTS AND REGENERATIVE PRODUCTS,</i> <i>2006 (%).....</i>	<i>128</i>
<i>FIGURE 26 WORLDWIDE REVENUE DISTRIBUTION FOR JOINT</i> <i>REPLACEMENTS, IMPLANTS AND REGENERATIVE PRODUCTS,</i> <i>2006 (%).....</i>	<i>129</i>
LEADING SUPPLIERS AND PARTICIPANTS	129
Leading Suppliers ... (Continued).....	130
<i>TABLE 40 SUMMARY OF JOINT REPLACEMENTS, IMPLANTS AND</i> <i>REGENERATIVE PRODUCTS BY COMPETITOR REVENUES, 2006</i> <i>(\$ MILLIONS).....</i>	<i>131</i>

<i>FIGURE 27 SUMMARY OF JOINT REPLACEMENTS, IMPLANTS AND REGENERATIVE PRODUCTS BY COMPETITOR REVENUES, 2006 (%)</i>	131
MARKET SUMMARY.....	132
<i>TABLE 41 GLOBAL MARKET FOR ADVANCED ORTHOPEDICS BY PRODUCT SEGMENT, THROUGH 2012 (\$ MILLIONS)</i>	133
<i>FIGURE 28 GLOBAL MARKET FOR ADVANCED ORTHOPEDICS BY PRODUCT SEGMENT, THROUGH 2012 (\$ MILLIONS)</i>	133
GEOGRAPHIC MARKET ANALYSIS.....	134
<i>TABLE 42 WORLDWIDE ADVANCED ORTHOPEDIC PRODUCT REVENUE DISTRIBUTION, BY REGION, 2006 (\$ BILLIONS)</i>	134
<i>FIGURE 29 WORLDWIDE ADVANCED ORTHOPEDIC PRODUCT REVENUE DISTRIBUTION BY REGION, 2006 (%)</i>	135
INDUSTRY PARTICIPANTS BY TYPE.....	135
<i>TABLE 43 ADVANCED ORTHOPEDIC TECHNOLOGY INDUSTRY PARTICIPANTS BY TYPE, 2006-2007</i>	136
COMPANY PROFILES.....	137
INTRODUCTION.....	137
AESCULAP (B BRAUN).....	137
ARTHREX, INC.....	138
ARTHROCARE CORP.....	138
BIOMET, INC.....	139
DEPUY, INC.....	140
ENCORE MEDICAL CORP.....	141
EXACTECH, INC.....	141
GENZYME BIOSURGERY.....	142
ISOTIS ORTHOBIOLOGICS, INC.....	142
CONMED LINVATEC.....	143
MEDTRONIC SOFAMOR DANEK.....	144
OSTEOTECH, INC.....	144
SMITH & NEPHEW, PLC.....	145
STRYKER CORP.....	146
SYNTHES, INC.....	146
WRIGHT MEDICAL TECHNOLOGY, INC.....	147
ZIMMER HOLDINGS, INC.....	147
Zimmer Holdings, Inc. (Continued).....	148
APPENDIX: LEADING PRODUCT MANUFACTURERS.....	149
APPENDIX: LEADING PRODUCT MANUFACTURERS.....	149
LEADING PRODUCT MANUFACTURERS (CONTINUED).....	150
LEADING PRODUCT MANUFACTURERS (CONTINUED).....	151
LEADING PRODUCT MANUFACTURERS (CONTINUED).....	152
LEADING PRODUCT MANUFACTURERS (CONTINUED).....	153
LEADING PRODUCT MANUFACTURERS (CONTINUED).....	154

LEADING PRODUCT MANUFACTURERS (CONTINUED)..... 155