

CHAPTER ONE: INTRODUCTION.....	1
STUDY GOALS AND OBJECTIVES.....	1
REASONS FOR DOING THE STUDY	1
INTENDED AUDIENCE.....	1
SCOPE OF REPORT	1
METHODOLOGY AND INFORMATION SOURCES.....	2
ANALYST CREDENTIALS.....	3
RELATED BCC PUBLICATIONS	3
BCC ONLINE SERVICES.....	3
DISCLAIMER	3
 CHAPTER TWO: SUMMARY.....	 4
SUMMARY.....	4
SUMMARY (CONTINUED)	5
<i>SUMMARY TABLE U.S. MEDICAL MEMBRANE DEVICE MARKET,</i> <i>THROUGH 2016 (\$ MILLIONS)</i>	6
<i>SUMMARY FIGURE SALES AND PROJECTIONS FOR U.S. MEDICAL</i> <i>MEMBRANE DEVICES, 2000–2016 (\$ MILLIONS)</i>	6
 CHAPTER THREE: OVERVIEW	 7
<i>TABLE 1 MEDICAL MEMBRANE DEVICES</i>	8
 CHAPTER FOUR: INDUSTRY STRUCTURE	 9
MEMBRANE AND DEVICE MANUFACTURERS	9
OEM MANUFACTURER.....	9
OEM Membranes.....	10
<i>TABLE 2 MANUFACTURERS OF OEM MEMBRANES AND</i> <i>PRODUCTS</i>	10
<i>TABLE 2 (CONTINUED)</i>	11
<i>TABLE 2 (CONTINUED)</i>	12
OEM Devices.....	12
COMBINED MEMBRANE AND DEVICE MANUFACTURERS.....	12
HEALTHCARE PRODUCT OR MEDICAL TECHNOLOGY COMPANIES	12
DISTRIBUTION CHANNELS	13
UPSTREAM SUPPLIERS	13
PRODUCT DISTRIBUTION (MARKETING AND SALES)	14
<i>TABLE 3 DISTRIBUTION CHANNELS FOR MEDICAL MEMBRANE</i> <i>DEVICES</i>	14
<i>TABLE 3 (CONTINUED)</i>	15
CUSTOMERS	15
Healthcare Customers.....	15
Downstream Manufacturing Customers	16
Distributors or Partnership-Type Customers	16

Home User	16
INDUSTRY TRENDS	17
The Shifting of Traditional Business Models	17
The Expanding International Market and Continuing Growth in Legacy Markets	18
The Changing Definition of a Customer	18
Increasing Regulatory Scrutiny	18
510(k) Reform	19
Rising Cost Pressures	19
INDUSTRY PARTICIPANTS	20
<i>TABLE 4 MEDICAL MEMBRANE DEVICE MANUFACTURERS, PRODUCT TYPES AND SALES, 2010 (\$ MILLIONS)</i>	20
<i>TABLE 4 (CONTINUED)</i>	21
<i>TABLE 4 (CONTINUED)</i>	22
COMPANY PROFILES	22
3M	22
ABBOTT LABORATORIES	23
AETHLON MEDICAL	24
AGILENT TECHNOLOGIES	25
ALERE	25
Alere (Continued)	26
ASAHI KASEI KURARAY MEDICAL CO.	27
BAXTER INTERNATIONAL, INC.	28
BECTON, DICKINSON & CO.	28
B. BRAUN MEDICAL, INC.	29
CANTEL MEDICAL	30
ENZO BIOCHEM	31
EPS, INC.	31
ESCO TECHNOLOGIES	32
FENWAL, INC.	33
FRESENIUS GROUP	33
GAMBRO AB	34
GENBIO	35
GENERAL ELECTRIC CO.	36
W.L. GORE & ASSOCIATES	37
GVS GROUP	37
F. HOFFMAN-LA ROCHE	38
IMMUNETICS, INC.	39
JOHNSON & JOHNSON	39
KANEKA CORP.	40
KIMBERLY-CLARK	41
MEDOS MEDIZINTECHNIK	41
MEDTRONIC	42
EMD MILLIPORE	43

NOVOSCI	44
NXSTAGE MEDICAL	45
OMNIFLO.....	46
PALL CORP.....	46
QUIDEL CORP.	47
RESPONSE BIOMEDICAL.....	48
SARTORIUS STEDIM BIOTECH.....	49
SERIM RESEARCH CORP.	49
SIEMENS HEALTHCARE DIAGNOSTICS, INC.....	50
SORIN GROUP	51
SPECTRAL DIAGNOSTICS, INC.....	52
TERUMO MEDICAL CORP.	53
THERMO FISHER SCIENTIFIC.....	54
TORAY INDUSTRIES, INC.	55
TRENDS IN DEVICE MANUFACTURE	55
MARKET BARRIERS.....	56
REGULATION OF THE MEDICAL DEVICE INDUSTRY	56
Legal Liability.....	57
HEALTHCARE SYSTEM CONSIDERATIONS.....	58
<i>TABLE 5 HEALTHCARE SPENDING AS A PERCENTAGE OF GROSS</i>	
<i>DOMESTIC PRODUCT, 1950–2016 (% OF GDP).....</i>	<i>59</i>
<i>FIGURE 1 HEALTHCARE SPENDING AS A PERCENTAGE OF GROSS</i>	
<i>DOMESTIC PRODUCT, 1950–2016 (%).....</i>	<i>59</i>
WHERE THE MONEY GOES	60
Hospital Care.....	60
Physician and Clinical Services	60
Prescription Drug Spending.....	61
Other Spending.....	61
<i>TABLE 6 NATIONAL HEALTH EXPENDITURES BY TYPE, 2010 AND</i>	
<i>2016 (\$ BILLIONS, %).....</i>	<i>62</i>
<i>FIGURE 2 NATIONAL HEALTH EXPENDITURES BY SERVICE, 2010</i>	
<i>AND 2016 (\$ BILLIONS).....</i>	<i>63</i>
WHY COSTS ARE RISING?.....	63
Why Costs are Rising? (Continued)	64
ACCESS TO CARE	65
<i>TABLE 7 HEALTHCARE COVERAGE IN THE U.S. BY TYPE, 2010 (%)</i>	<i>66</i>
<i>FIGURE 3 HEALTHCARE COVERAGE IN THE U.S. BY TYPE, 2010 (%)</i>	<i>66</i>
MANAGED CARE.....	67
Capitation-Type Reimbursement.....	68
Consolidation and Commercialization.....	68
HOW MANAGED CARE AFFECTS THE MEDICAL DEVICE	
MARKET	69
VERTICAL INTEGRATION OF PRODUCT AND CARE	
MARKETS.....	70

Vertical Integration of ... (Continued).....	71
RECENT LEGISLATION.....	72
MEDICAL DEVICE USER FEE AND MODERNIZATION ACT OF 2002	72
THE PATIENT PROTECTION AND AFFORDABLE CARE ACT.....	73
How ACA Affects Medical Device Manufacturers.....	74
How ACA ... (Continued).....	75
CHAPTER FIVE: MEDICAL MEMBRANE DEVICE TECHNOLOGY.....	76
MEMBRANE MANUFACTURING	76
POLYMERS	76
<i>TABLE 8 APPROPRIATE POLYMERS FOR MEDICAL MEMBRANES</i>	76
Medical Use Criteria for Polymers	77
MANUFACTURING TECHNIQUES.....	78
<i>TABLE 9 MEMBRANE MANUFACTURING METHODS</i>	79
MEMBRANE STRUCTURES.....	80
<i>TABLE 10 MEMBRANE MORPHOLOGIES AND PROPERTIES</i>	80
MEMBRANE GEOMETRIES.....	81
<i>TABLE 11 HOLLOW FIBER AND FLAT SHEET MEMBRANES AND DEVICES</i>	81
<i>TABLE 11 (CONTINUED)</i>	82
TECHNICAL PARAMETERS OF MEDICAL MEMBRANE DEVICES.....	83
<i>TABLE 12 TECHNICAL PARAMETERS OF MEDICAL MEMBRANE DEVICES</i>	84
<i>TABLE 12 (CONTINUED)</i>	85
DEVICE MANUFACTURING.....	85
DEVICE MANUFACTURING (CONTINUED)	86
PRICING	87
<i>TABLE 13 AVERAGE PRICES FOR MEDICAL MEMBRANE DEVICES (\$)</i>	88
COMPETITIVE TECHNOLOGIES	88
<i>TABLE 14 MEDICAL MEMBRANE DEVICES AND COMPETING TECHNOLOGIES</i>	89
CHAPTER SIX: PATENT SURVEY	90
BY APPLICATION	90
<i>TABLE 15 PATENTS BY APPLICATION, NUMBER, AND PERCENTAGE, OCTOBER 1, 2005, TO SEPTEMBER 30, 2011 (NUMBER/%)</i>	91
<i>FIGURE 4 PATENTS BY APPLICATION, NUMBER, AND PERCENTAGE (OCTOBER 1, 2005, TO SEPTEMBER 30, 2011)</i>	91
<i>FIGURE 4 (CONTINUED)</i>	92
BY COMPANY	92
BY COMPANY (CONTINUED).....	93

<i>TABLE 16 PATENTS, BY COMPANY, NUMBER, AND PERCENTAGE (OCTOBER 1, 2005, TO SEPTEMBER 30, 2011)</i>	94
<i>TABLE 16 (CONTINUED)</i>	95
CHAPTER SEVEN: HEMODIALYZERS	96
MARKET SIZE AND GROWTH	96
MARKET SIZE AND GROWTH (CONTINUED)	97
MARKET SIZE AND GROWTH (CONTINUED)	98
<i>TABLE 17 SALES AND PROJECTIONS FOR HEMODIALYZERS, THROUGH 2016 (\$ MILLIONS)</i>	99
<i>FIGURE 5 SALES AND PROJECTIONS FOR HEMODIALYZERS, 2000–2016 (\$ MILLIONS)</i>	99
HISTORY	100
OVERVIEW	100
DIALYZERS	101
DIALYZER SPECIFICATIONS.....	101
<i>TABLE 18 PRIMARY DIALYZER TYPES AND REPRESENTATIVE PRODUCTS</i>	102
MODES OF HEMODIALYSIS	103
MEASURING DIALYZER PERFORMANCE.....	103
DIALYZER REUSE.....	104
Reuse vs. Single Use.....	104
MEDICARE AND ESRD.....	105
Bundled Payment	106
COMPETITIVE TECHNOLOGIES.....	106
COMPANIES ACTIVE IN THE DIALYZER INDUSTRY	107
MARKET SHARE, HEMODIALYZERS	107
<i>TABLE 19 U.S. MARKET SHARE, HEMODIALYZER MANUFACTURERS, 2011 (%)</i>	107
<i>FIGURE 6 U.S. MARKET SHARE, HEMODIALYZER MANUFACTURERS, 2011 (%)</i>	108
CHAPTER EIGHT: BLOOD OXYGENATORS	109
MARKET SIZE AND GROWTH	109
MARKET SIZE AND GROWTH (CONTINUED)	110
<i>TABLE 20 SALES AND PROJECTIONS FOR BLOOD OXYGENATORS, THROUGH 2016 (\$ MILLIONS)</i>	111
<i>FIGURE 7 SALES AND PROJECTIONS FOR BLOOD OXYGENATORS, 2000–2016 (\$ MILLIONS)</i>	111
HISTORY	112
OVERVIEW	112
BLOOD OXYGENATORS.....	112
OXYGENATOR SPECIFICATIONS	113
COMPETITIVE TECHNOLOGIES.....	113
COMPANIES ACTIVE IN THE BLOOD OXYGENATOR MARKET	114

TABLE 21 MEMBRANE OXYGENATOR MANUFACTURERS AND PRODUCTS.....	114
MARKET SHARE, BLOOD OXYGENATORS.....	114
TABLE 22 MARKET SHARE: BLOOD OXYGENATOR MANUFACTURERS, 2011 (%).....	115
FIGURE 8 MARKET SHARE, BLOOD OXYGENATOR MANUFACTURERS, 2011 (%).....	115
CHAPTER NINE: IV FILTERS	116
MARKET SIZE AND GROWTH	116
MARKET SIZE AND GROWTH (CONTINUED)	117
TABLE 23 SALES AND PROJECTIONS FOR IV FILTERS, THROUGH 2016 (\$ MILLIONS).....	118
FIGURE 9 SALES AND PROJECTIONS FOR IV FILTERS, 2000–2016 (\$ MILLIONS).....	118
HISTORY	119
OVERVIEW.....	119
ENDOTOXIN REMOVAL.....	120
NUTRIENT ADMIXTURE FILTRATION	120
IN-LINE BLOOD COMPONENT FILTRATION.....	121
EMULSION DRUGS.....	121
TABLE 24 DRUGS FOR WHICH FILTRATION IS RECOMMENDED DURING ADMINISTRATION (MICRONS).....	122
INFANT IV THERAPY	122
COMPANIES ACTIVE IN THE IV FILTER MARKET	123
TABLE 25 MANUFACTURERS OF IV FILTERS AND PRODUCTS.....	123
CHAPTER TEN: DIAGNOSTIC DEVICES	124
MARKET SIZE AND GROWTH	124
MARKET SIZE AND GROWTH (CONTINUED)	125
MARKET SIZE AND GROWTH (CONTINUED)	126
TABLE 26 SALES AND PROJECTIONS FOR DIAGNOSTIC DEVICES, 2000–2016 (\$ MILLIONS).....	127
FIGURE 10 SALES AND PROJECTIONS FOR DIAGNOSTIC DEVICES, 2000–2016 (\$ MILLIONS).....	127
HISTORY	127
OVERVIEW.....	128
CLINICAL DIAGNOSTICS	128
POINT-OF-CARE TESTING	128
TABLE 27 CONDITIONS DETECTED WITH IN VITRO DIAGNOSTICS.....	129
HOME TESTING	130
TYPES OF ASSAYS.....	131
Challenges in Assay Design	131
TECHNOLOGY.....	132
AUTOMATION.....	133

NONINVASIVE SAMPLING.....	134
COMPETITIVE TECHNOLOGIES	134
<i>TABLE 28 ALTERNATIVE METHODS OF IN VITRO TESTING</i>	<i>135</i>
<i>TABLE 29 MEMBRANE APPLICATIONS IN MOLECULAR</i> <i>DIAGNOSTICS</i>	<i>136</i>
COMPANIES ACTIVE IN THE DIAGNOSTIC DEVICE MARKET	136
<i>TABLE 30 MANUFACTURERS OF DIAGNOSTIC DEVICES AND</i> <i>PRODUCT TYPES</i>	<i>137</i>
MARKET SHARE, DIAGNOSTIC DEVICES.....	137
<i>TABLE 31 MARKET SHARE: DIAGNOSTIC DEVICE</i> <i>MANUFACTURERS, 2011 (%)</i>	<i>138</i>
<i>FIGURE 11 MARKET SHARE: DIAGNOSTIC DEVICE</i> <i>MANUFACTURERS, 2011 (%)</i>	<i>138</i>
CHAPTER ELEVEN: BLOOD MICROFILTERS	139
MARKET SIZE AND GROWTH	139
MARKET SIZE AND GROWTH (CONTINUED).....	140
<i>TABLE 32 SALES AND PROJECTIONS FOR BLOOD MICROFILTERS,</i> <i>2000–2016 (\$ MILLIONS)</i>	<i>141</i>
<i>FIGURE 12 SALES AND PROJECTIONS FOR BLOOD</i> <i>MICROFILTERS, 2000–2016 (\$ MILLIONS)</i>	<i>141</i>
HISTORY	141
OVERVIEW.....	142
OVERVIEW (CONTINUED)	143
<i>TABLE 33 THERAPEUTIC APHERESIS OUTCOMES AND</i> <i>GUIDELINES</i>	<i>144</i>
<i>TABLE 33 (CONTINUED)</i>	<i>145</i>
TECHNOLOGY.....	146
<i>TABLE 34 COMPARISON OF BLOOD FRACTIONATION</i> <i>TECHNOLOGY</i>	<i>147</i>
TRENDS AND TECHNICAL DEVELOPMENTS.....	147
<i>TABLE 35 DEVELOPMENTS IN THERAPEUTIC APHERESIS</i>	<i>148</i>
<i>TABLE 36 POTENTIAL APPLICATIONS OF THERAPEUTIC</i> <i>APHERESIS</i>	<i>149</i>
COMPANIES ACTIVE IN THE BLOOD MICROFILTER MARKET	149
<i>TABLE 37 MAJOR MANUFACTURERS OF BLOOD MICROFILTERS</i> <i>AND PRODUCTS</i>	<i>150</i>
MARKET SHARE OF BLOOD MICROFILTERS	150
<i>TABLE 38 MARKET SHARE, BLOOD MICROFILTERS, 2011 (%)</i>	<i>150</i>
CHAPTER TWELVE: THE MEDICAL MEMBRANE DEVICE MARKET	
ABROAD.....	151
THE MEDICAL MEMBRANE DEVICE MARKET ABROAD.....	151
THE MEDICAL MEMBRANE ... (CONTINUED)	152

APPENDIX PATENT SURVEY.....	153
<i>TABLE 39 PATENT SURVEY (OCTOBER 1, 2006, TO SEPTEMBER 30, 2010)</i>	153
<i>TABLE 39 (CONTINUED)</i>	154
<i>TABLE 39 (CONTINUED)</i>	155
<i>TABLE 39 (CONTINUED)</i>	156
<i>TABLE 39 (CONTINUED)</i>	157
<i>TABLE 39 (CONTINUED)</i>	158
<i>TABLE 39 (CONTINUED)</i>	159
<i>TABLE 39 (CONTINUED)</i>	160
<i>TABLE 39 (CONTINUED)</i>	161
<i>TABLE 39 (CONTINUED)</i>	162
<i>TABLE 39 (CONTINUED)</i>	163
<i>TABLE 39 (CONTINUED)</i>	164
<i>TABLE 39 (CONTINUED)</i>	165
<i>TABLE 39 (CONTINUED)</i>	166
<i>TABLE 39 (CONTINUED)</i>	167
<i>TABLE 39 (CONTINUED)</i>	168
<i>TABLE 39 (CONTINUED)</i>	169
<i>TABLE 39 (CONTINUED)</i>	170
<i>TABLE 39 (CONTINUED)</i>	171
<i>TABLE 39 (CONTINUED)</i>	172
<i>TABLE 39 (CONTINUED)</i>	173
<i>TABLE 39 (CONTINUED)</i>	174
<i>TABLE 39 (CONTINUED)</i>	175
<i>TABLE 39 (CONTINUED)</i>	176