

## NEEDLE-FREE DEVICES, TECHNOLOGIES AND GLOBAL MARKETS



HLC178A  
January 2015

Dr. Ritu Thakur Dangi  
*Project Analyst*

ISBN: 1-62296-016-5



**BCC Research**  
49 Walnut Park, Building 2  
Wellesley, MA 02481 USA  
866-285-7215 (toll-free within the USA),  
or (+1) 781-489-7301  
[www.bccresearch.com](http://www.bccresearch.com)  
[information@bccresearch.com](mailto:information@bccresearch.com)

**TABLE OF CONTENTS**

<b>TOPIC</b>	<b>PAGE NO.</b>
CHAPTER 1 INTRODUCTION	2
NEEDLE-FREE DEVICES	2
STUDY BACKGROUND	2
STUDY GOALS AND OBJECTIVES	3
INTENDED AUDIENCE	4
SCOPE OF THE REPORT	4
METHODOLOGY AND INFORMATION SOURCES	5
ANALYST'S CREDENTIALS	5
RELATED BCC RESEARCH REPORTS	5
BCC RESEARCH WEBSITE	6
DISCLAIMER	6
CHAPTER 2 SUMMARY	8
EXECUTIVE SUMMARY	8
<i>SUMMARY TABLE GLOBAL MARKET FOR NEEDLE-FREE TECHNOLOGIES, THROUGH 2019 (\$ MILLIONS)</i>	8
<i>SUMMARY FIGURE GLOBAL MARKET FOR NEEDLE-FREE TECHNOLOGIES, 2013-2019 (\$ MILLIONS)</i>	8
CHAPTER 3 DRUG DELIVERY DEVICES	12
STRUCTURE OF HUMAN SKIN	12
EPIDERMIS	12
DERMIS	12
HYPODERMIS	12
OVERVIEW OF DRUG DELIVERY SYSTEMS AND TECHNOLOGIES	13
CLASSIFICATION OF DRUG DELIVERY ACCORDING TO TECHNOLOGY	14
SUSTAINED RELEASE DRUG DELIVERY	14
PRODRUGS	14
IMPLANTS AND INTRAUTERINE DEVICES	15
TARGETED DRUG DELIVERY	15
POLYMERIC DRUG DELIVERY	15
CLASSIFICATION OF DRUG DELIVERY BY ROUTE OF ADMINISTRATION	16
ORAL DRUG DELIVERY	16
Proteins and Peptides	17
Enzyme Inhibitors	17
Mucoadhesives	17
Encapsulation Technologies	18
<i>TABLE 1 ADVANTAGES AND DISADVANTAGES OF ORAL DRUG DELIVERY</i>	18
<i>INJECTABLE OR PARENTERAL DRUG DELIVERY</i>	19
Needle/Syringe Injections	19
Safety Syringes/Needle-Free Injectors	19
<i>TABLE 2 ADVANTAGES AND DISADVANTAGES OF INJECTABLE DRUG DELIVERY</i>	20
PULMONARY DRUG DELIVERY	20
<i>TABLE 3 ADVANTAGES AND DISADVANTAGES OF PULMONARY DRUG DELIVERY</i>	21
NASAL DRUG DELIVERY	21
<i>TABLE 4 ADVANTAGES AND DISADVANTAGES OF NASAL DRUG DELIVERY</i>	21

<b>TOPIC</b>	<b>PAGE NO.</b>
ORAL MUCOSAL DRUG DELIVERY	22
<i>TABLE 5 ADVANTAGES AND DISADVANTAGES OF ORAL MUCOSAL DELIVERY</i>	22
RECTAL DRUG DELIVERY	22
<i>TABLE 6 ADVANTAGES AND DISADVANTAGES OF RECTAL DRUG DELIVERY</i>	23
OCULAR DRUG DELIVERY	23
<i>TABLE 7 ADVANTAGES AND DISADVANTAGES OF OCULAR DRUG DELIVERY</i>	23
TRANSDERMAL DRUG DELIVERY	24
Passive Methods	24
Active Methods	24
Combined Technologies	25
<i>TABLE 8 ADVANTAGES AND DISADVANTAGES OF TRANSDERMAL DRUG DELIVERY</i>	25
NEED FOR BETTER METHODS OF DRUG DELIVERY	25
AREAS OF ONGOING RESEARCH	26
CHAPTER 4 NEEDLE-FREE TECHNOLOGY AND DRUG DELIVERY DEVICES	29
NEEDLE-FREE DRUG DELIVERY DEVICES AND TYPES	29
HISTORY OF NEEDLE-FREE DEVICES	29
MARKET NEED FOR NEEDLE-FREE DEVICES	30
NEEDLE PHOBIA	31
Vasovagal	31
Associative	31
Resistive	31
Hyperalgesic	32
Vicarious	32
NEEDLESTICK INJURY	32
Overview of Needlestick Injury	32
Incidence of Needlestick Injuries	33
<i>TABLE 9 INCIDENCE OF NEEDLESTICK INJURIES BY GEOGRAPHY, 2013 (NO.)</i>	33
<i>FIGURE 1 INCIDENCE OF NEEDLESTICK INJURIES BY GEOGRAPHY, 2013 (% OF TOTAL)</i>	33
Causes of Sharps Injuries	34
Cost of Needlestick Injuries	34
Needlestick Injury Prevention	35
ADVANTAGES OF NEEDLE-FREE TECHNOLOGY	36
CHAPTER 5 NEEDLE-FREE DEVICE APPLICATIONS	38
APPLICATION OF NEEDLE-FREE DEVICES	38
<i>TABLE 10 GLOBAL NEEDLE-FREE TECHNOLOGIES MARKET BY SEGMENT, THROUGH 2019 (\$ MILLIONS)</i>	38
<i>FIGURE 2 GLOBAL NEEDLE-FREE TECHNOLOGIES MARKET BY SEGMENT, 2013-2019 (\$ MILLIONS)</i>	39
PAIN MANAGEMENT	40
Latest Developments in Needle-Free Pain Management	40
VACCINE DELIVERY	41
Latest Developments in Needle-Free Vaccine Delivery	42
Future Developments in Needle-Free Vaccine Delivery	42
INSULIN DELIVERY	42
Diabetes Overview	42

<b>TOPIC</b>	<b>PAGE NO.</b>
<i>FIGURE 3 DISTRIBUTION OF DIABETES TYPES GLOBALLY, 2013 (% OF TOTAL DIABETES)</i>	43
Epidemiology and Economic Burden	44
<i>TABLE 11 PREVALENCE OF DIABETES BY GEOGRAPHY, 2013 (\$ MILLIONS)</i>	44
<i>FIGURE 4 PREVALENCE OF DIABETES BY GEOGRAPHY, 2013` (% OF TOTAL)</i>	44
Traditional Insulin Delivery Systems	45
Needle-Free Insulin Delivery Systems	46
Insulin Jet Injectors	46
Inhalable Insulin Devices	47
Insulin Spray Systems	47
Insulin Micropump	47
Insulin Port	48
Transdermal Insulin Patches	48
Insulin Nanopump	48
<i>TABLE 12 COMPARISON BETWEEN PAINFUL AND PAINLESS NEEDLE-FREE INSULIN DRUG DELIVERY SYSTEMS</i>	49
Future Prospective for Needle-Free Insulin Delivery Systems	49
<b>PEDIATRIC DRUG DELIVERY</b>	50
Needle-Free Injectors	50
Low Workload Jet Injectors for Routine Immunizations	50
Multi-Channel Jet Injectors for Simultaneous Vaccine Delivery	50
Transdermal Methods and Microneedle Technologies for Various Drug Delivery Applications	50
<b>CHAPTER 6 NEEDLE-FREE INJECTORS</b>	52
<b>INTRODUCTION</b>	52
HISTORICAL BACKGROUND OF NEEDLE-FREE INJECTOR	52
CLINICAL NEED FOR NEEDLE-FREE INJECTORS	53
<b>NEEDLE-FREE INJECTOR TYPES</b>	53
<b>NEEDLE-FREE INJECTORS TYPES BY MEDICATION</b>	53
Liquid-Based Needle-Free Injectors	53
Powder-Based Needle-Free Injectors	54
Depot or Projectile Needle-Free injectors	55
<b>NEEDLE-FREE INJECTOR TYPES BY DRUG DELIVERY</b>	55
Intramuscular Injections	55
Subcutaneous Injections	55
Intradermal Injections	55
<b>NEEDLE-FREE INJECTOR TYPES BY SOURCE OF POWER</b>	55
Spring Powered	55
Compressed Gas Powered	55
<b>NEEDLE-FREE INJECTORS BY USAGE TYPE</b>	56
Single-Use Injectors	56
Disposable Injectors	56
Reusable Injectors	56
<b>COMPONENTS OF NEEDLE-FREE INJECTORS</b>	56
INJECTOR DEVICE AND DRUG RESERVOIR	56
NOZZLE	56
PRESSURE SOURCE	57

<b>TOPIC</b>	<b>PAGE NO.</b>
MECHANISM OF OPERATION	57
RAW MATERIALS AND KEY NEEDLE-FREE INJECTOR DESIGNS	57
RAW MATERIALS	57
KEY NEEDLE-FREE INJECTOR DESIGNS	58
Jet Injectors	58
Jet Injector Gun	58
Hypodermal Jet Injectors without a Needle	58
Low Workload Jet Injector	59
Multi-Channel Jet Injector	59
Biojector	59
Microjets	59
Intraject Technology	59
Mini-Ject Technology	60
Needle-Free, Auto and Pen Injectors	60
MadaJet	60
INJEX Needle-Free Injectors for Infiltration Anesthesia	60
NEEDLE-FREE INJECTOR APPLICATIONS	60
ADVANTAGES AND DISADVANTAGES OF NEEDLE-FREE INJECTORS	61
EFFICIENT DRUG DISTRIBUTION AND IMPROVED EFFICACY	61
GREATER PATIENT ACCEPTANCE AND COMPLIANCE	61
<i>TABLE 13 ADVANTAGES AND DISADVANTAGES OF NEEDLE-FREE INJECTORS</i>	61
SUPERIOR SAFETY	62
RELIABILITY AND REPEATABILITY	62
FASTER INJECTION TIME	62
ELIMINATES SHARPS WASTE	62
CLINICAL CHALLENGES AND UNMET NEEDS	63
FUTURE DEVELOPMENTS	63
CHAPTER 7 INHALER TECHNOLOGIES	65
PULMONARY DRUG DELIVERY	65
<i>TABLE 14 IDEAL CHARACTERISTICS OF THERAPEUTIC AEROSOLS</i>	65
<i>TABLE 15 ADVANTAGES AND DISADVANTAGES OF PULMONARY DRUG DELIVERY</i>	66
INHALER TECHNOLOGY	66
<i>TABLE 16 ADVANTAGES AND DISADVANTAGES OF INHALER TECHNOLOGIES</i>	66
HISTORICAL BACKGROUND	67
CLINICAL NEED FOR INHALER TECHNOLOGY	67
Epidemiology of Asthma	67
<i>TABLE 17 PREVALENCE OF ASTHMA BY GEOGRAPHY, 2013 (MILLIONS)</i>	68
<i>FIGURE 5 PREVALENCE OF ASTHMA BY GEOGRAPHY, 2013 (% OF TOTAL)</i>	68
Economic Burden of Asthma	69
TYPES OF INHALERS	69
MDI	69
<i>TABLE 18 ADVANTAGES AND DISADVANTAGES OF METERED DOSE INHALERS</i>	70
New Developments in MDI Technology	70
Advanced MDI and Use Enantiomer Preparations of Inhaled Drugs	70
Generic MDIs	70
Improved Patient Inhalation Coordination with Advanced MDI	70

<b>TOPIC</b>	<b>PAGE NO.</b>
Flow Gate Valve Technology in Spacers	71
Adaptive Aerosol Delivery Technology	71
Autohaler (Modified Form of pMDI)	71
<i>TABLE 19 ADVANTAGES AND DISADVANTAGES OF F STANDARD PRESS AND BREATHE METERED DOSE INHALERS</i>	71
DPI	71
New Developments in DPI Technology	72
Air Classifier Technology in Devices	72
Multiple Air Classifier Technology	72
Spiros Inhaler Technology	72
<i>TABLE 20 ADVANTAGES AND DISADVANTAGES OF DRY POWDER INHALERS</i>	73
MDI. vs DPI (Uniformity vs. Diversity)	73
<i>TABLE 21 COMPARISON OF INHALERS: MDI VS. DPI</i>	74
ADVANCES IN PULMONARY DRUG DELIVERY	74
Particle Engineering	74
Agglomerated Vesicle Technology	75
FUTURE DEVELOPMENTS	75
CHAPTER 8 TRANSDERMAL PATCH TECHNOLOGIES	77
TRANSDERMAL DRUG DELIVERY	77
<i>TABLE 22 PARAMETERS AFFECTING SELECTION OF DRUGS IN TRANSDERMAL DRUG DELIVERY SYSTEMS</i>	77
TRANSDERMAL PATCH TECHNOLOGY	77
<i>TABLE 23 IDEAL PROPERTIES OF TRANSDERMAL DRUG DELIVERY SYSTEMS</i>	78
CLINICAL NEED	79
HISTORICAL BACKGROUND	79
TYPES OF TRANSDERMAL PATCHES	79
Single-Layer Drug-in-Adhesive	79
Multilayer Drug-in-Adhesive	80
Reservoir	80
Matrix	80
Drug-in-Adhesive System	80
Matrix Dispersion System	80
Micro Reservoir System	81
Vapor Patch	81
<i>TABLE 24 ADVANTAGES AND DISADVANTAGES OF TRANSDERMAL PATCHES</i>	81
COMPONENTS OF A TRANSDERMAL PATCH	81
Polymer Matrix	82
Drug	82
Permeation Enhancers	82
Adhesive	82
Backing Laminates	82
Release Liner	82
Other Excipients	83
BENEFITS OF TRANSDERMAL PATCHES OVER OTHER DOSAGE FORMS	83
NEW INNOVATIONS IN TRANSDERMAL PATCHES	83
Dispenser for Transdermal Patches	83
Magnetophoresis Combined with Chemical Enhancers	83

<b>TOPIC</b>	<b>PAGE NO.</b>
LIMITATIONS OF TRANSDERMAL PATCHES	83
CLINICAL ISSUES OF TRANSDERMAL DELIVERY	83
FUTURE DEVELOPMENTS	84
CHAPTER 9 OTHER NOVEL NEEDLE TECHNOLOGIES	86
MICRONEEDLES	86
HISTORICAL BACKGROUND	86
TYPES OF MICRONEEDLES	86
Solid Microneedles	87
Fabrication of Solid Microneedles	87
Silicon Microneedles	87
Metal Microneedles	87
Polymer Microneedles	87
Ceramic Microneedles	87
Microneedle Rollers	88
Coated Microneedles	88
Dissolving Microneedles	88
Hollow Microneedles	88
APPLICATION OF MICRONEEDLES	88
Blood Glucose Measurements	88
Transdermal Drug Delivery	89
Immunobiologicals	89
Bioactive Macromolecules (Biopharmaceuticals)	89
Drug Delivery	89
Diagnosis	89
Cosmetic Products	89
ADVANTAGES AND DISADVANTAGES OF MICRONEEDLES	90
<i>TABLE 25 ADVANTAGES AND DISADVANTAGES OF MICRONEEDLES</i>	90
ADVANCES IN DRUG DELIVERY BY MICRONEEDLES	91
CURRENT AND FUTURE DEVELOPMENTS	91
PEN NEEDLES	91
CONSTRUCTION AND DESIGN OF PEN NEEDLES	92
<i>TABLE 26 ADVANTAGES AND DISADVANTAGES OF MICRONEEDLES</i>	92
CURRENT AND FUTURE DEVELOPMENTS	92
CHAPTER 10 NEEDLE-FREE DEVICE MARKET ASSESSMENT	94
DRUG DELIVERY DEVICES	94
GLOBAL NEEDLE-FREE TECHNOLOGIES MARKET	94
GLOBAL MARKET BY GEOGRAPHIC REGION	94
<i>TABLE 27 GLOBAL MARKET FOR NEEDLE-FREE TECHNOLOGIES BY REGION, THROUGH 2019 (\$ MILLIONS)</i>	94
<i>FIGURE 6 GLOBAL MARKET FOR NEEDLE-FREE TECHNOLOGIES BY REGION, 2013-2019 (\$ MILLIONS)</i>	95
GLOBAL MARKET BY SEGMENT	96
<i>TABLE 28 GLOBAL NEEDLE-FREE TECHNOLOGIES MARKET BY SEGMENT, THROUGH 2019 (\$ MILLIONS)</i>	96
<i>FIGURE 7 GLOBAL NEEDLE-FREE TECHNOLOGIES MARKET BY SEGMENT, 2013-2019 (\$ MILLIONS)</i>	96

<b>TOPIC</b>	<b>PAGE NO.</b>
<i>FIGURE 8 NEEDLE-FREE DRUG DELIVERY TECHNOLOGY MARKET BY SEGMENT, 2013 (% OF TOTAL MARKET)</i>	97
GLOBAL MARKET BY APPLICATION	98
<i>TABLE 29 GLOBAL NEEDLE-FREE TECHNOLOGY MARKET BY APPLICATION, THROUGH 2019 (\$ MILLIONS)</i>	98
<i>FIGURE 9 NEEDLE-FREE TECHNOLOGY MARKET BY APPLICATION, 2013 (% OF TOTAL MARKET)</i>	99
MARKET GROWTH DRIVERS AND RESTRAINTS	99
Growth Drivers	99
Increase in Disease Population Worldwide.	99
Needle Phobia and Increasing Awareness about the Risk of Needlestick Injuries	99
Increasing Demand for Painless Drug Delivery Technologies	100
Growing Demand for Minimally Invasive Delivery Methods	100
Demand for More Sophisticated Delivery Systems for Effective Treatment	100
Growing Demand for Drug-Device Combinations	100
Limitations of Oral Drug Delivery	100
Limitations of Hypodermic Needles	101
Growing Demand for Needle-Free Technologies for Chronic Pain Management	101
Increasing Awareness about the Safety and Efficacy of Drug Delivery Technologies	101
Rising Prevalence of Diabetes	101
Increasing Awareness about Pediatric Vaccinations	101
Increasing Use of Needle-Free Injections in Anesthesia Delivery	102
Booming Global Vaccine Market	102
Mass Immunization Programs	102
Cost-Efficient Drug Delivery	102
Growth of Biologics and Entry of Biosimilars in Leading Pharmaceutical Markets	102
Development of Home-Care and Self-Medication Devices	103
Growing Market for Injectable Medications	103
Growing Market for Injectable HGH	103
Growth Restraints	103
High Cost of Needle-Free Technology	103
Increasing Regulatory Scrutiny and Inefficient Manufacturing Processes	103
Downward Pricing Pressure, Increasing Material Cost and Inefficient Manufacturing Processes	103
Increasing Competition and Decreasing Profit Margins	104
Increasing Research and Development Cost	104
Shorter Product Life Cycles	104
Risks and Complications	104
COMPETITIVE LANDSCAPE	104
<i>TABLE 30 GLOBAL NEEDLE-FREE DEVICE MARKET REVENUE SHARES, 2013 (\$ MILLIONS/%)</i>	105
<i>FIGURE 10 GLOBAL NEEDLE-FREE DEVICE MARKET LEADERS, 2013 (% OF TOTAL MARKET)</i>	105



<b>TOPIC</b>	<b>PAGE NO.</b>
CHAPTER 11 MARKET STRATEGY	108
NEEDLE-FREE DEVICES MARKET STRATEGY	108
KEY STRATEGIC EVENTS DURING THE LAST FEW YEARS	108
<i>TABLE 31 NEEDLE-FREE DEVICE MARKET, KEY MERGERS/ACQUISITIONS</i>	109
Key Mergers and Acquisitions	109
OPKO Health's Acquisition of Inspiro Medical	109
Endo International's Acquisition of Zogenix' DosePro Migraine Therapy Business	110
North Coast Medical's Acquisition of ActivaTek	110
Teva Pharmaceutical's Acquisition of NuPathe	110
Teva Pharmaceutical's Acquisition of MicroDose Therapeutx	110
Becton Dickinson's Acquisition of Safety Syringes	111
Medical Marketing Berlin/Paketeria AG's Acquisition of INJEX Pharma	111
Key Product and Technology Developments	111
NxStage Announces FDA Clearance of a Single Needle Technology	111
Vaxxas' Nanopatch Garners WHO Support for Polio Vaccine Delivery	111
FDA Approves Use of bioCSL's Afluria Influenza Vaccine with PharmaJet Needle-Free Injector	112
Bioject Inc. Expands its Global Distribution Network	112
Glide Pharma Completed the Successful Proof-of-Concept Study with Octreotide	112
Crossject Launched Bioequivalence Clinical Study with Zeneo (Methotrexate)	112
Bioject Enters Into Agreement with Fondaco	113
Antares Pharma's Otrexup Injection Approved by the FDA	113
Zogenix Received FDA Approval for 4 mg Sumavel DosePro (Sumatriptan Injection)	113
3M Co. Licensed Fentanyl Transdermal Patch Technology to Stada Arzneimittel	113
Adamis Pharmaceuticals Acquired Dry Powder Inhaler Technology from 3M Co.	113
Bioject Medical Technologies Featured on Bloomberg International	113
PharmaJet's Stratis Needle-Free Injector Achieved WHO PQS Certification	114
Glide Pharma Completed Design Optimization Agreement with Nypro Healthcare	114
Antares Pharma Obtained U.S. Patent for Vibex Technology	114
Zogenix Signs Co-promotion Deal for Needle-Free Migraine Treatment	114
INJEX Pharma Received FDA Clearance for the INJEX 30	114
Medical International Technology Gains Chinese SFDA Certification for Med-Jet	114
Bioject Medical Technologies to Supply ID Pens	115
Zogenix and Durect Signed Development and License Agreement	115

<b>TOPIC</b>	<b>PAGE NO.</b>
CHAPTER 12 MARKETED AND PIPELINE PRODUCTS	117
KEY MARKETED PRODUCTS	117
NEEDLE-FREE INJECTORS	117
Antares Pharma	117
Medi-Jector Vision Needle-Free Injector	117
Vibex Pressure Assisted Auto Injection System	117
Pen Injector	118
Otrexup	118
Bioject Medical Technologies	118
Biojector 2000 Needle-Free Injection System	118
Vitajet Insulin Delivery System	119
Cool.click Needle-Free Injection System	119
Serojet Needle-Free Injection System	119
Zetajet Auto-Disable Needle-Free Delivery System	119
Endo International	120
Sumavel DosePro Needle-Free Delivery System	120
Activa Brand Products Inc.	120
Advantajet	120
D'Antonio Consultants International	120
Lectrajjet Disposable Syringe Jet Injector System	120
National Medical Products	120
J-Tip Needle-Free System	120
Medical International Technologies	121
Med-Jet Needle-Free System	121
PenJet Corp.	121
PenJet Needle-Free System	121
Pharmajet	122
Stratis Needle-Free System	122
Valeritas	122
Mini-Ject Needle-Free System	122
h-Patch	122
Micro-Trans	122
Akra Dermojet	123
Dermojet HR	123
Dermojet Polymedical with Interchangeable Injection Tips	123
Automatic Dermojet	123
Felton International	123
HSI-500 Needle-Free Injector	123
INJEX Pharma	124
INJEX 30 Multiple Application Needle-Free Device	124
Jet Syringe/Rojex Disposable, Single-Use Devices	124
INJEX 50 Needle-Free Injection	124
Keystone Industries	124
Syrijet Mark II	124
Glide Pharma	124
Glide SDI Drug Delivery System	124
The Medical House PLC (Subsidiary of Consort Medical)	125

<b>TOPIC</b>	<b>PAGE NO.</b>
mhi-500 Novel Needle-free Insulin Delivery System	125
Spring-Powered SQ-PEN	125
Bespak Drug Delivery Solutions	125
Shreya Life Sciences	125
Recojet Needle-Free Insulin Delivery Device	125
Merck Serono	126
SeroJet	126
Pfizer	126
PowderMed	126
Key Device Approvals by the FDA	126
<i>TABLE 32 NEEDLE-FREE INJECTORS: KEY DEVICE APPROVALS BY THE FDA, 2005-2014</i>	126
<b>INHALERS</b>	127
Short-Acting Bronchodilators	127
Corticosteroids	127
Combination Drugs	128
Key Marketed MDI Devices	128
<i>TABLE 33 KEY METERED DOSE INHALERS ON THE MARKET</i>	128
<b>TRANSDERMAL PATCH</b>	129
<i>TABLE 34 TRANSDERMAL PATCH: KEY MARKETED DEVICES</i>	129
<b>OTHER NOVEL NEEDLE TECHNOLOGIES</b>	130
<i>TABLE 35 "OTHER" NOVEL NEEDLE TECHNOLOGY-BASED DEVICES ON THE MARKET</i>	131
<b>KEY PIPELINE PRODUCTS</b>	132
<b>NEEDLE-FREE INJECTORS</b>	132
Antares Pharma	132
Vibex MTX	132
Vibex QS (QuickShot)	132
Bioject Medical Technologies	132
ID Pen Injector	132
Iject Needle-Free Injection	133
Jupiter Jet	133
Zogenix	133
Relday	133
Pulse NeedleFree Systems	133
Needle-Free Systems	133
Echo Therapeutics	133
Prelude SkinPrep System	133
American Medical Systems	134
JetTouch Needle-Free Injection System	134
Crossject Medical Technology	134
Zeneo Disposable, Prefilled, Needle-Free, Automatic Injection System	134
<i>TABLE 36 KEY NEEDLE-FREE DEVICES IN THE PIPELINE</i>	134
<b>METERED DOSE INHALERS</b>	135
Teva Pharmaceutical	135
Albuterol HFA MDI	135
Beclomethasone Dipropionate MDI	135

<b>TOPIC</b>	<b>PAGE NO.</b>
Sunovion	135
Levalbuterol HFA MDI	135
Solvay Pharmaceuticals and Nektar Therapeutics	135
Dronabinol MDI	135
GlaxoSmithKline	136
FP/SLM HFA MDI 50/25 mcg	136
<i>TABLE 37 KEY METERED DOSE INHALERS IN THE PIPELINE</i>	136
TRANSDERMAL PATCHES	136
Amnio Technology	136
PalinGen (Amniotic Membrane Patch)	136
ICURE Pharmaceutical Inc.	137
Donepezil Patch	137
Formoterol Patch	137
Oxybutynin Patch	137
Merz Pharmaceuticals GmbH	137
Overnight Intensive Patch	137
Mundipharma Research Ltd.	137
Buprenorphine Patch (Extended Release)	137
Tyndall National Institute	137
ImmuPatch	137
<i>TABLE 38 KEY TRANSDERMAL PATCHES IN THE PIPELINE</i>	138
OTHER NOVEL TECHNOLOGIES	139
Seagull Technology	139
SonoEye	139
CHAPTER 13 REGULATORY STRUCTURE	141
REGIONAL REGULATORY STRUCTURES	141
UNITED STATES	141
EUROPEAN UNION	143
<i>TABLE 39 DIFFERENCES IN REGULATORY APPROVAL IN THE U.S. VS. EUROPE</i>	145
JAPAN	145
OTHER ASIA	146
China	146
Hong Kong	147
Korea	147
Taiwan	147
India	147
FDA TECHNICAL CONSIDERATIONS	148
FDA RECALLS AND SAFETY ALERTS	149
OCCUPATIONAL HEALTH AND SAFETY LAWS	149
UNITED STATES	149
Needlestick Safety and Prevention Act/Blood-Borne Pathogens Standard	149
EUROPEAN UNION	150
CHAPTER 14 PRICING AND REIMBURSEMENT	152
REGIONAL REIMBURSEMENT STRUCTURES	152
UNITED STATES	152

<b>TOPIC</b>	<b>PAGE NO.</b>
Healthcare Common Procedure Coding System Code	153
<i>TABLE 40 HCPCS 2014 CODE A4210: NEEDLE-FREE INJECTION DEVICE, EACH</i>	154
Insurance and Reimbursement	154
EUROPE	155
JAPAN	156
OTHER ASIA	156
MEDICAL DEVICE PRICING TRENDS	156
CHAPTER 15 CONCLUSIONS AND OUTLOOK FOR NEEDLE-FREE DEVICES	159
MAJOR MARKET INFLUENCES	159
SOCIAL FACTORS	159
TECHNOLOGICAL DEVELOPMENTS	159
Breath-Actuated Metered-Dose Inhalers	160
Novel Formulation Approaches and Technologies for Transdermal Patches	160
Innovations to Create Autoinjector Syringes to Prevent Unnecessary Contamination	160
Laser-Powered Needle-Free Injections	160
Other Advanced Transdermal Drug Delivery Technologies	161
Next-Generation Needle-Free Drug Injector	161
Next-Generation Stamp-Sized Nanopatch	161
DEMOGRAPHIC AND ECONOMIC TRENDS	161
Increasing Aging Population	162
<i>TABLE 41 ESTIMATED WORLD POPULATION AND ANNUAL GROWTH BY SELECTED AGE GROUP AND SELECTED YEARS, THROUGH 2030 (MILLIONS)</i>	162
<i>FIGURE 11 ESTIMATED WORLD POPULATION BY SELECTED AGE GROUP AND SELECTED YEARS, 2000-2030 (\$ MILLIONS)</i>	162
<i>TABLE 42 WORLD POPULATION BY SELECTED GEOGRAPHIC REGION, THROUGH 2030 (MILLIONS)</i>	163
<i>FIGURE 12 WORLD POPULATION BY SELECTED COUNTRY, 2000-2030 (\$ MILLIONS)</i>	163
U.S. Demographics	164
<i>TABLE 43 U.S. POPULATION ESTIMATES AND PROJECTIONS BY AGE GROUP, THROUGH 2030 (MILLIONS)</i>	164
<i>FIGURE 13 U.S. POPULATION ESTIMATES AND PROJECTIONS BY AGE GROUP, 2000-2030 (MILLIONS)</i>	165
U.S. Gender, Age and Life Expectancy	165
<i>TABLE 44 ESTIMATES OF ANTICIPATED U.S. LIFE EXPECTANCY AT BIRTH AND PROJECTIONS BY GENDER, 2005-2020 (YEARS)</i>	166
<i>FIGURE 14 ESTIMATES OF ANTICIPATED U.S. LIFE EXPECTANCY AT BIRTH AND PROJECTIONS BY GENDER, 2005-2020 (YEARS)</i>	166
European Demographics	166
<i>TABLE 45 EUROPEAN POPULATION ESTIMATES AND PROJECTIONS BY AGE GROUP, THROUGH 2030 (MILLIONS)</i>	167
<i>FIGURE 15 EUROPEAN POPULATION ESTIMATES AND PROJECTIONS BY AGE GROUP, 2000-2030 (MILLIONS)</i>	167
Japanese Demographics	167
<i>TABLE 46 JAPANESE POPULATION ESTIMATES AND PROJECTIONS BY AGE GROUP, THROUGH 2030 (MILLIONS)</i>	168
<i>FIGURE 16 JAPANESE POPULATION ESTIMATES AND PROJECTIONS BY AGE GROUP, 2000-2030 (MILLIONS)</i>	168

<b>TOPIC</b>	<b>PAGE NO.</b>
Increasing Prevalence of Diabetes	168
<i>TABLE 47 GLOBAL DIABETES PREVALENCE, 2013 AND 2030</i>	169
Income Growth in Developing Markets	169
<i>TABLE 48 PROJECTED TRENDS IN PER CAPITA REAL GDP GROWTH BY REGION, 2012-2015 (ANNUAL AVERAGE PERCENTAGE CHANGE)</i>	169
CHANGING STRUCTURE OF THE HEALTHCARE INDUSTRY	170
Development of Home-Care and Self Medication Devices	170
Developments in Health Insurance and Reimbursement	170
FUTURE OUTLOOK	170
CHAPTER 16 APPENDIX A: ABBREVIATION(S)	174
CHAPTER 17 APPENDIX B: VENDOR PROFILES	177
ACTIVA BRAND PRODUCTS INC.	177
AKRA DERMOJET	177
ALKERMES PLC	178
ALZA CORP.	178
AMNIO TECHNOLOGY LLC.	179
ANTARES PHARMA INC.	179
ARADIGM CORP.	180
ASTELLAS PHARMA INC.	181
ASTRAZENECA PLC	181
BATTELLE	182
BESPAK EUROPE LTD.	182
BIOJECT MEDICAL TECHNOLOGIES	183
BRISTOL-MYERS SQUIBB	184
CAMBRIDGE CONSULTANTS LTD.	184
CLEARSIDE BIOMEDICAL INC.	185
CORIUM INTERNATIONAL INC.	185
COVIDIEN	186
CROSSJECT	186
CYDEX PHARMACEUTICALS INC.	187
D'ANTONIO CONSULTANTS INTERNATIONAL	187
DR. REDDY'S LABORATORIES LTD.	187
DUOJECT MEDICAL SYSTEMS INC.	188
DURECT CORP.	188
ECHO THERAPEUTICS	189
ELI LILLY & CO.	190
ENDO INTERNATIONAL	190
EUROJET MEDICAL INC.	191
FERNDALE PHARMA GROUP INC.	191
FERRING PHARMACEUTICALS INC.	192
GERRESHEIMER AG	192
GLAXOSMITHKLINE PLC	192
GLIDE PHARMACEUTICALS TECHNOLOGIES LTD.	193
HASELMEIER GMBH	194
INJEX PHARMA AG	194
INTERCELL AG	195

<b>TOPIC</b>	<b>PAGE NO.</b>
JCR PHARMACEUTICALS CO. LTD.	195
KEYSTONE INDUSTRIES	195
LINEAGE THERAPEUTICS INC.	196
LOHMANN THERAPIE-SYSTEME AG	196
MALLINCKRODT PLC	196
MEDICAL INTERNATIONAL TECHNOLOGIES	197
MEDI-PATCH CLINIC	197
MERCK SERONO S.A.	197
MINNESOTA RUBBER & PLASTICS	198
MPI RESEARCH	198
MYLAN INC.	198
NANOPASS TECHNOLOGIES LTD.	199
NATIONAL MEDICAL PRODUCTS INC.	199
NEKTAR THERAPEUTICS	200
NOVARTIS	200
NOVEN PHARMACEUTICALS	201
NOVO NORDISK A/S	201
NYPRO INC.	202
OWEN MUMFORD LTD.	202
PACIRA PHARMACEUTICALS INC.	203
PATHEON	203
PENJET CORP.	204
PFIZER INC.	204
PHARMAJET INC.	204
PSIVIDA CORP.	205
PULSE NEEDLE-FREE SYSTEMS INC.	205
QLT INC.	206
<i>RETRACTABLE TECHNOLOGIES INC.</i>	206
SANOFI-PASTEUR	206
SHL GROUP AB	207
TAKEDA	208
TAPEMARK	208
TEAM CONSULTING LTD.	209
TEVA PHARMACEUTICALS INDUSTRIES LTD.	209
THERAJET INC.	211
TRANSPHARMA MEDICAL LTD.	211
VALERITAS INC.	211
VAXXAS PTY LTD.	212
YPSOMED HOLDING AG	213
ZOGENIX	213
CHAPTER 18 APPENDIX C: INDUSTRY AND PROFESSIONAL ORGANIZATIONS	216
AMERICAN ASSOCIATION FOR RESPIRATORY CARE	216
ASSOCIATION OF NEEDLE-FREE INJECTION MANUFACTURERS	216
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH	216
CENTERS FOR MEDICARE & MEDICAID SERVICES	217
DEPARTMENT OF HEALTH AND HUMAN SERVICES	217

<b>TOPIC</b>	<b>PAGE NO.</b>
EUDAMED	217
FOOD AND DRUG ADMINISTRATION	218
IFPMA	218
INTERNATIONAL DIABETES FEDERATION	218
INTERNATIONAL ASSOCIATION FOR THE STUDY OF OBESITY	219
ISIPS	219
NATIONAL CENTER FOR BIOTECHNOLOGY INFORMATION	219
NATIONAL INSTITUTE ON AGING	220
OECD	220
OPTICAL SOCIETY	220
PATH	220
PMDA	221
USAMRIID	221
WORLD HEALTH ORGANIZATION	222



**LIST OF TABLES**

<b>TABLE HEADING</b>	<b>PAGE NO.</b>
SUMMARY TABLE GLOBAL MARKET FOR NEEDLE-FREE TECHNOLOGIES, THROUGH 2019 (\$ MILLIONS)	8
TABLE 1 ADVANTAGES AND DISADVANTAGES OF ORAL DRUG DELIVERY	18
TABLE 2 ADVANTAGES AND DISADVANTAGES OF INJECTABLE DRUG DELIVERY	20
TABLE 3 ADVANTAGES AND DISADVANTAGES OF PULMONARY DRUG DELIVERY	21
TABLE 4 ADVANTAGES AND DISADVANTAGES OF NASAL DRUG DELIVERY	21
TABLE 5 ADVANTAGES AND DISADVANTAGES OF ORAL MUCOSAL DELIVERY	22
TABLE 6 ADVANTAGES AND DISADVANTAGES OF RECTAL DRUG DELIVERY	23
TABLE 7 ADVANTAGES AND DISADVANTAGES OF OCULAR DRUG DELIVERY	23
TABLE 8 ADVANTAGES AND DISADVANTAGES OF TRANSDERMAL DRUG DELIVERY	25
TABLE 9 INCIDENCE OF NEEDLESTICK INJURIES BY GEOGRAPHY, 2013 (NO.)	33
TABLE 10 GLOBAL NEEDLE-FREE TECHNOLOGIES MARKET BY SEGMENT, THROUGH 2019 (\$ MILLIONS)	38
TABLE 11 PREVALENCE OF DIABETES BY GEOGRAPHY, 2013 (\$ MILLIONS)	44
TABLE 12 COMPARISON BETWEEN PAINFUL AND PAINLESS NEEDLE-FREE INSULIN DRUG DELIVERY SYSTEMS	49
TABLE 13 ADVANTAGES AND DISADVANTAGES OF NEEDLE-FREE INJECTORS	61
TABLE 14 IDEAL CHARACTERISTICS OF THERAPEUTIC AEROSOLS	65
TABLE 15 ADVANTAGES AND DISADVANTAGES OF PULMONARY DRUG DELIVERY	66
TABLE 16 ADVANTAGES AND DISADVANTAGES OF INHALER TECHNOLOGIES	66
TABLE 17 PREVALENCE OF ASTHMA BY GEOGRAPHY, 2013 (MILLIONS)	68
TABLE 18 ADVANTAGES AND DISADVANTAGES OF METERED DOSE INHALERS	70
TABLE 19 ADVANTAGES AND DISADVANTAGES OF F STANDARD PRESS AND BREATHE METERED DOSE INHALERS	71
TABLE 20 ADVANTAGES AND DISADVANTAGES OF DRY POWDER INHALERS	73
TABLE 21 COMPARISON OF INHALERS: MDI VS. DPI	74
TABLE 22 PARAMETERS AFFECTING SELECTION OF DRUGS IN TRANSDERMAL DRUG DELIVERY SYSTEMS	77
TABLE 23 IDEAL PROPERTIES OF TRANSDERMAL DRUG DELIVERY SYSTEMS	78
TABLE 24 ADVANTAGES AND DISADVANTAGES OF TRANSDERMAL PATCHES	81
TABLE 25 ADVANTAGES AND DISADVANTAGES OF MICRONEEDLES	90
TABLE 26 ADVANTAGES AND DISADVANTAGES OF MICRONEEDLES	92
TABLE 27 GLOBAL MARKET FOR NEEDLE-FREE TECHNOLOGIES BY REGION, THROUGH 2019 (\$ MILLIONS)	94
TABLE 28 GLOBAL NEEDLE-FREE TECHNOLOGIES MARKET BY SEGMENT, THROUGH 2019 (\$ MILLIONS)	96
TABLE 29 GLOBAL NEEDLE-FREE TECHNOLOGY MARKET BY APPLICATION, THROUGH 2019 (\$ MILLIONS)	98
TABLE 30 GLOBAL NEEDLE-FREE DEVICE MARKET REVENUE SHARES, 2013 (\$ MILLIONS/%)	105
TABLE 31 NEEDLE-FREE DEVICE MARKET, KEY MERGERS/ACQUISITIONS	109
TABLE 32 NEEDLE-FREE INJECTORS: KEY DEVICE APPROVALS BY THE FDA, 2005-2014	126
TABLE 33 KEY METERED DOSE INHALERS ON THE MARKET	128
TABLE 34 TRANSDERMAL PATCH: KEY MARKETED DEVICES	129
TABLE 35 "OTHER" NOVEL NEEDLE TECHNOLOGY-BASED DEVICES ON THE MARKET	131
TABLE 36 KEY NEEDLE-FREE DEVICES IN THE PIPELINE	134
TABLE 37 KEY METERED DOSE INHALERS IN THE PIPELINE	136

<b>TABLE HEADING</b>	<b>PAGE NO.</b>
TABLE 38 KEY TRANSDERMAL PATCHES IN THE PIPELINE	138
TABLE 39 DIFFERENCES IN REGULATORY APPROVAL IN THE U.S. VS. EUROPE	145
TABLE 40 HCPCS 2014 CODE A4210: NEEDLE-FREE INJECTION DEVICE, EACH	154
TABLE 41 ESTIMATED WORLD POPULATION AND ANNUAL GROWTH BY SELECTED AGE GROUP AND SELECTED YEARS, THROUGH 2030 (MILLIONS)	162
TABLE 42 WORLD POPULATION BY SELECTED GEOGRAPHIC REGION, THROUGH 2030 (MILLIONS)	163
TABLE 43 U.S. POPULATION ESTIMATES AND PROJECTIONS BY AGE GROUP, THROUGH 2030 (MILLIONS)	164
TABLE 44 ESTIMATES OF ANTICIPATED U.S. LIFE EXPECTANCY AT BIRTH AND PROJECTIONS BY GENDER, 2005-2020 (YEARS)	166
TABLE 45 EUROPEAN POPULATION ESTIMATES AND PROJECTIONS BY AGE GROUP, THROUGH 2030 (MILLIONS)	167
TABLE 46 JAPANESE POPULATION ESTIMATES AND PROJECTIONS BY AGE GROUP, THROUGH 2030 (MILLIONS)	168
TABLE 47 GLOBAL DIABETES PREVALENCE, 2013 AND 2030	169
TABLE 48 PROJECTED TRENDS IN PER CAPITA REAL GDP GROWTH BY REGION, 2012-2015 (ANNUAL AVERAGE PERCENTAGE CHANGE)	169

**LIST OF FIGURES**

<b>FIGURE TITLE</b>	<b>PAGE NO.</b>
SUMMARY FIGURE GLOBAL MARKET FOR NEEDLE-FREE TECHNOLOGIES, 2013-2019 (\$ MILLIONS)	8
FIGURE 1 INCIDENCE OF NEEDLESTICK INJURIES BY GEOGRAPHY, 2013` (% OF TOTAL)	33
FIGURE 2 GLOBAL NEEDLE-FREE TECHNOLOGIES MARKET BY SEGMENT, 2013-2019 (\$ MILLIONS)	39
FIGURE 3 DISTRIBUTION OF DIABETES TYPES GLOBALLY, 2013 (% OF TOTAL DIABETES)	43
FIGURE 4 PREVALENCE OF DIABETES BY GEOGRAPHY, 2013` (% OF TOTAL)	44
FIGURE 5 PREVALENCE OF ASTHMA BY GEOGRAPHY, 2013 (% OF TOTAL)	68
FIGURE 6 GLOBAL MARKET FOR NEEDLE-FREE TECHNOLOGIES BY REGION, 2013-2019 (\$ MILLIONS)	95
FIGURE 7 GLOBAL NEEDLE-FREE TECHNOLOGIES MARKET BY SEGMENT, 2013-2019 (\$ MILLIONS)	96
FIGURE 8 NEEDLE-FREE DRUG DELIVERY TECHNOLOGY MARKET BY SEGMENT, 2013 (% OF TOTAL MARKET)	97
FIGURE 9 NEEDLE-FREE TECHNOLOGY MARKET BY APPLICATION, 2013 (% OF TOTAL MARKET)	99
FIGURE 10 GLOBAL NEEDLE-FREE DEVICE MARKET LEADERS, 2013 (% OF TOTAL MARKET)	105
FIGURE 11 ESTIMATED WORLD POPULATION BY SELECTED AGE GROUP AND SELECTED YEARS, 2000-2030 (\$ MILLIONS)	162
FIGURE 12 WORLD POPULATION BY SELECTED COUNTRY, 2000-2030 (\$ MILLIONS)	163
FIGURE 13 U.S. POPULATION ESTIMATES AND PROJECTIONS BY AGE GROUP, 2000-2030 (MILLIONS)	165
FIGURE 14 ESTIMATES OF ANTICIPATED U.S. LIFE EXPECTANCY AT BIRTH AND PROJECTIONS BY GENDER, 2005-2020 (YEARS)	166
FIGURE 15 EUROPEAN POPULATION ESTIMATES AND PROJECTIONS BY AGE GROUP, 2000-2030 (MILLIONS)	167
FIGURE 16 JAPANESE POPULATION ESTIMATES AND PROJECTIONS BY AGE GROUP, 2000-2030 (MILLIONS)	168