The Primary Advantage

A Mixed Approach To Superior Trend Detection
Topics Covered in 2016

Clinical Lab Services  Molecular POC Tests  Long Term Care
Hospital Infections  Genomic Editing  Inherited Diseases Tests
Bandages&Dressings  Medical Device Markets  Personalized Medicine
Autoimmune Testing  Flu Vaccines  Electrophoresis
Cardiac Markers  Targeted Proteomics  Ultrasound
Immuoassays  Lung Cancer Gene Therapy  qPCR
Biologics  Mexico Testing Markets  CTC Tests
PICCs  Medical Beds  Transdermal Patches
X-Ray Markets  Negative Pressure  Biological Dressings
Protein Arrays  MicroRNA  Wheelchairs
Syringe Infusion  DTC Genomic Testing  Electromodulation
DNA Microarray  Cholesterol Testing  Neuronal Markers
IVD in India  Flu Testing  Liquid Biopsy
Insulin Pumps  DTC Genomic Testing  Kinase Inhibitors
Implantable Pumps  Flu Testing  Prenatal Tests
Liquid Biopsy  Implanted Pumps  Wheelchairs
Kinase Inhibitors  Biopharmaceutical Media  HPV Testing
Prenatal Tests  Telemonitors  in situ hybridization
Wheelchairs  Home Care Services  PSA Testing
HPV Testing  Electromodulation  ...And OTHER MARKETS
NGS Sample Prep  Sequencing  China Device Markets
regularly consulted by major media for market sizes, estimates, and commentary
Methodology

- **Exhaustive Research**: 2 to 6 month undertakings, including a review of company financials, medical journals, trade publications.

- **Primary**: Interviews with industry executives, experts, and end-users to test assumptions and discover trends.

- **Educated Analysis**: From an experienced analyst with a track record of analyzing markets, who can interpret developments in the industry.
Primary is Key

• **Exhaustive Research:** 2 to 6 month undertakings, including a review of company financials, medical journals, trade publications

• **Primary:** interviews with industry executives, experts, and end-users test assumptions and discover trends

• **Educated Analysis:** from an experienced analyst with a track record of analyzing markets, who can interpret developments in the industry
Base Device Research Round

Census Bureau for population demographics – life expectancy, aging, birthrates, etc.

FDA Medical Device Approval List, Clinicaltrials.gov

CMS for New Devices Formulary Approvals

USPTO search

Visit Trade Shows, Read Trade journals

Company 10K/Qs for relevant revenue information, concerns, forward looking statements
Base Primary Device Research Round

Average 30-50% Response

Interviewer is Independent

Interviewer is an Expert

Follow Up With Previous Interviewees
A Mix of Primary Sources

• **Big Manufacturers** - industry leaders for growth

• **Small Company** - new and unique product information and trends

• **Government** - one more piece of the puzzle that is critical to formulating the market

• **End User** *MOST IMPORTANT* Nurses, MDs, techs and hospital materials management
Secondary Info Can Be Inaccurate

Market Share Claims

Use of Most Favorable Syndicated Research for Market Share

Local and Smaller Co. Underreported

Companies Let Underperforming Divisions results go “dark”
Healthcare Market Experts

Unique Discoveries

Niche Segment Disclosure

Private companies are behind the wall

Up and Coming Competitors

Unique Trend Discovery – EMR money is from consulting, Infusion nurse popularity of midline insertion catheters, Amount of respiratory device usage for a patient’s stay, prices of products, etc.
Identifying Trends/Shifts in Medical Devices

SLA Pharmaceutical and Health Technologies Division Spring Meeting 2016
Devices are becoming much more important to our business, but it is difficult and time consuming to compile competitive information on devices in our space.

Senior Competitive Intelligence Manager, Big Pharma Corp.
Meddevicetracker with Medtech Insight Reports

A medtech intelligence tool for saving time and resources in understanding medical device and diagnostic markets that compete with or complement your drug or device.
Question: How do I find out what devices are in the pipeline that could compete with our drug candidate?

- Easily view a competitive landscape of devices/diagnostics by indication
- Sort by most recent event, product name, company, product type, or development phase
- Quickly learn which product candidates are major players
Question: How do I keep track of products I need to follow?

- Track upcoming milestones for products of interest
- Stay up-to-date on product events related to trials, regulatory filings/approvals, reimbursement, partnering, and product launches

**dermaPACE for Diabetic Foot Ulcers**

<table>
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<th>Lead Company:</th>
<th>SANUWAVE Health, Inc. (SNWV)</th>
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**Update Mar 24, 2016: Date Range Delayed (Apr 1, 2016 - Jun 30, 2016)**
SANUWAVE announced that it has submitted a Pre-Submission package to FDA and expects to meet face-to-face with the FDA review team in late-April or early-May 2016. The goal of this meeting is to work interactively with FDA to bring dermaPACE to market in the most expeditious possible manner. The Company anticipates a final product submission to FDA in Q2 2016.

**Source:** Press Release Mar 24, 2016

**Update Dec 15, 2015: New Information (Jan 1, 2016 - Apr 30, 2016)**
SANUWAVE said it is working on a Pre-Submission package to be presented to FDA in January, 2016. In this Pre-Submission package, the Company will discuss the positive results of the combined studies and will present SANUWAVE’s submission strategy. A meeting with FDA is expected in Q1 2016 to finalize the submission strategy, with full submission for FDA approval to follow shortly thereafter.

**Source:** Press Release Dec 15, 2015

**Update Oct 8, 2015: Date Range Refined (Jan 1, 2016 - Mar 31, 2016)**
The Company has just begun an in-depth analysis of the trial results. The PMA submission is expected to be sent to FDA in early Q1 2016.

**Source:** Investor Presentation Nov 13, 2015 (SNWV)
Press Release Oct 8, 2015
Question: Where can I find clinical trial information for devices?

- Quickly access clinical trial details for devices, such as inclusion/exclusion criteria, associated events, upcoming milestones, and trial results

Libra IPG for Major Depressive Disorder (MDD)
Question: How do I generate a report with all pain products in later development stages that recently engaged in partnering activity?

- Search across the entire database for products, historical events, and upcoming milestones, using multiple search criteria
- Choose your output based on your workflow needs; on screen or excel

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<td>✓ Coronary Artery</td>
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<td>✓ Heart Ventricles</td>
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<td>✓ Partnership - Acquisition Closed</td>
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<td>✓ Partnership - Cancellation (Emerging Markets)</td>
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<td></td>
<td>✓ Partnership - Distribution Agreement</td>
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Question: How do I understand the market potential for a particular device in a particular market?

- Locate 5-year market forecasts, market share breakdowns
- Dive deeper into a competitive analysis and discussion of product benefits and distinguishing factors

### Exhibit 2-9: 2014, Patch-Based Pain Management Products Market, Share by Supplier

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<tr>
<th>Company</th>
<th>Estimated Sales</th>
<th>Estimated Market Share</th>
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<tbody>
<tr>
<td>Endo Pharmaceuticals</td>
<td>$855.1M</td>
<td>36.7%</td>
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<tr>
<td>Sandoz/Novartis</td>
<td>377.5</td>
<td>16.2%</td>
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<tr>
<td>Mylan Technologies/Mylan</td>
<td>344.8</td>
<td>14.8%</td>
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<tr>
<td>Allergan</td>
<td>274.9</td>
<td>11.8%</td>
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<tr>
<td>Janssen Pharmaceuticals/Johnson &amp; Johnson</td>
<td>188.7</td>
<td>8.1%</td>
</tr>
<tr>
<td>Others</td>
<td>289.0</td>
<td>12.4%</td>
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</table>
| Total                          | $2,330.0M       | 100.0%                 

### Exhibit 3-1: 2015, Selected Inhalation Therapy Agents

<table>
<thead>
<tr>
<th>Therapy Type</th>
<th>Agent(s)</th>
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<tbody>
<tr>
<td>Allergy-Blocking Agents</td>
<td>Cromoglycate</td>
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<tr>
<td>Mast Cell Stabilizers</td>
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<tr>
<td>Anti-Inflammatory Agents</td>
<td></td>
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<tr>
<td>Corticosteroids</td>
<td>Beclomethasone&lt;br&gt;Budesonide&lt;br&gt;Dexamethasone&lt;br&gt;Flunisolide&lt;br&gt;Fluticasone&lt;br&gt;Triamcinolone</td>
</tr>
<tr>
<td>NSAIDs</td>
<td>Cromolyn sodium&lt;br&gt;Nedocromil sodium</td>
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<tr>
<td>Bronchodilators</td>
<td>Ipratropium bromide</td>
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<tr>
<td>Anticholinergics</td>
<td>Albuterol&lt;br&gt;Bilobarol&lt;br&gt;Pirbuterol&lt;br&gt;Proterogol&lt;br&gt;Salmeterol&lt;br&gt;Terbutaline</td>
</tr>
<tr>
<td>Beta Antagonists</td>
<td>Albuterol&lt;br&gt;Bilobarol&lt;br&gt;Pirbuterol&lt;br&gt;Proterogol&lt;br&gt;Salmeterol&lt;br&gt;Terbutaline</td>
</tr>
<tr>
<td>Methylxanthines</td>
<td>Dipyridamole&lt;br&gt;Oxtriphylline&lt;br&gt;Theophylline</td>
</tr>
</tbody>
</table>
Content Coverage

• Current coverage areas:
  • Cardiovascular
  • Neurology/Central Nervous System
  • Psychiatry
  • Autoimmune/Wound Care

• Planned expansion in 2016:
  • Drug Delivery Technology
  • Orthopedics
  • Women’s Health
Scope

- Product Scope:
  - Class II, III, HDE, De Novo, LDT, companion diagnostic
  - U.S., Europe, Japan, selected emerging markets

- Company profiles include:
  - Company locations, subsidiaries, acquisitions, and earnings and ticker information if public.

- Product coverage includes:
  - Development history, trial information, agency interactions, filings and approvals (particularly 510(k) and PMA), advisory panel meetings, various types of trial data, reimbursements, patents, financial offerings, and various other development milestones.

- Specialization in ‘real-time’ event tracking
  - The most up-to-date developments where users can be kept informed through customized email alerts.

- Widest breadth and most transparent coverage of catalysts
  - Map out future milestones that will impact a product’s development.

- Market Analysis
  - Overall market trends, 5-year market forecasts, Procedure volumes analysis, Emerging technologies
Thank you!

Questions? Interested in a full product demo?

Contact Jocelyn August for more information:

Jocelyn.august@informa.com

(858) 200-2372

Or

Visit www.meddevicetracker.com
Medical Devices: Insights from clinical trials, literature, and patents

DPHT Spring Meeting 2016 - Orlando, Florida

Matt Eberle, Product Specialist, matt.eberle@bizint.com

April 5, 2016
Why Not Drug Pipeline Databases?

Drug Pipeline databases cover drugs:
- “Drug and cell-based products are tracked across all therapeutic areas and throughout the entire development process, from discovery to launch.”
- “51,000+ drug monographs”
- “over 60,000 highly detailed and fully searchable drug profiles”

A handful of related records in pipeline sources
- Can give the appearance of coverage
- Focus still on the drug - drug delivery/formulation/diagnostic
A device is not a drug

Everolimus

Alternative Names: Absorb; Affinitor; Affinitor Dispersible; Afinitor; Afinitor Disperz; Certican; Epitrop BVS; Promus; Promus Element; Promus Premier; RAD; RAD-001; SDZ RAD; Synergy; Votubia; Xience nano; Xience Prime; Xience V; Xience Xpedition; Zortress

Latest Information Update: 04 Mar 2016

At a glance

Originator: Novartis; Univers
Developer: Abbott Laboratory; Boston Scientific; Hannover Medicine; Novartis Collaboration; Sanofi; Texas M. D. And
Class: Antineoplastics; ...

Latest Press Releases
Latest Event Transcripts
Broker Research Reports
Development Profile
Literature Review
Development Status
Chemical Structures
Drug Names
Sales and Forecasts
Clinical Trials
Deals and Patents
SWOT Analysis
Change History
Sources

SNAPSHOT

Drug Name: everolimus

Other Drug Names: Afinitor; Afinitor Disperz; Apinito; Certican; RAD-001; RAD-001A; RAD001C; SDZ-RAD; Votubia; Zortress; everolimus

Originator Company: Novartis AG
Active Companies: Novartis AG
Inactive Companies: 
Highest Phase: Launched
Active Indications: Acute lymphoblastic leukemia; Advanced solid tumor; Angiomyolipoma; Astrocytoma; Bladder cancer; B-cell tumor; Colorectal tumor; Cutaneous T-cell lymphoma; Diffuse large B-cell lymphoma; Epilepsy; Esophageal tumor; Glioma; Head and neck tumor; Heart transplant rejection; Kidney transplant rejection; Liver transplant rejection; Lung transplant rejection; Macroglobulinemia; Medullary thyroid cancer; Metastatic breast cancer; Metastatic renal cancer; Neuroendocrine tumor; Neurofibromatosis type I; Non-Hodgkin lymphoma; Non-small-cell lung cancer; Pancreatic endocrine tumor; Renal cell carcinoma; Solid tumor; Stomach tumor; Thyroid tumor; Transplant rejection; Uveal melanoma

Inactive Indications: Acute myelogenous leukemia; Age related macular degeneration; Autosomal dominant polycystic kidney disease; Endometrioid carcinoma; Fallopian tube cancer; Gastrointestinal stromal tumor; Genetic disorder; Hematological neoplasm; Hepatocellular carcinoma; Herpesvirus type 8 infection; Hodgkin's disease; Hormone refractory prostate cancer; Inflammatory bowel disease; Lymphoma; Mantle cell lymphoma; Melanoma; Meningioma; Mesothelioma; Multiple myeloma; Ovary tumor; Pancreas tumor; Peritoneal tumor; Pulmonary fibrosis; Renal insufficiency; Rheumatoid arthritis; Sarcoma; Small-cell lung cancer; Tuberculosis; Uterine cancer; Uveitis

Target-based Actions: mTOR inhibitor; mTOR complex 1 inhibitor
No Drug Pipeline, No Problem

Clinical Trials
- What is the mix of trials by phase and status?
- Which companies have clinical stage programs?

Literature
- Who are the key opinion leaders?
- What are the new developments?

Patents
- What are the key companies?
- What novel technologies are they developing?
Bioresorbable stents represent a breakthrough technology promising to enhance the outcomes of patients treated by percutaneous intervention (1). The benefits of bioresorbable stents are intuitive. Indeed, all else being equal, most physicians and patients would agree that a stent that disappears after its useful function is served would be a preferable device to a permanent metallic implant. Moreover, as suggested by recent ABSORB stent may receive approval from the Food and Drug Administration by the end of 2016. An important requirement for any technology should be demonstration of superiority versus contemporary metallic initial phase after implantation (2). This non, an essential condition, for their adoption as testing potential late benefit. Unless you are nearing Medicare age, you will not remember the exhilaration created by the introduction of the neointimal hyperplasia that line the inside of the stent wall. In contrast, the bioresorbable stent allows tissue to grow into the pores and infiltrate the stent. However, just as any technology, bioresorbable stents have challenges that must be overcome. A research team in Korea has developed new innovations for bioresorbable stents by adding a host of biosensors that can track and store data, deliver drugs, and communicate with healthcare providers. This new technology is expected to overcome some of the complications associated with current technology.
Which Clinical Trials sources...

Include Medical Devices

- ClinicalTrials.gov
- Thomson Reuters Cortellis Clinical Trials Intelligence - “includes over 190,000 global trials, covering drugs, biologics, *medical devices* and biomarkers.”
- Adis Clinical Trials Intelligence
Clinical Trials

- What is the mix of trials by phase and status?
- Which companies have clinical stage programs?
# Combine and Integrate Trial Records

<table>
<thead>
<tr>
<th>Trial Title</th>
<th>Acronym</th>
<th>Database</th>
<th>Phase</th>
<th>Overall Status</th>
<th>Start Date</th>
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<tbody>
<tr>
<td>Absorb Bioresorbable Scaffold vs. Drug Coated Balloon for Treatment Of In-Stent-Restenosis</td>
<td>AbsorbISR</td>
<td>101.1 NCT</td>
<td>Phase 3</td>
<td>Recruiting</td>
<td>March 2015</td>
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<td>BIOTRONIK - A Prospective Randomized Multicenter Study to Assess the Safety and Effectiveness of the Orsiro SiroLimus Eluting Coronary Stent System in the Treatment Of Subjects With up to Three De Novo or Restenotic Coronary Artery Lesions - V</td>
<td>BIOFLOW-V</td>
<td>102.1 NCT</td>
<td>Phase 3</td>
<td>Recruiting</td>
<td>May 2015</td>
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<td>Performance of Bioresorbable Scaffold in Primary Percutaneous Intervention of ST Elevation Myocardial Infarct (BVS in STEMI)</td>
<td>BVS in STEMI</td>
<td>103.1 NCT</td>
<td>Phase 3</td>
<td>Recruiting</td>
<td>August 2014</td>
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Trial Phase

Bioresorbable stent trials by phase

- Phase I: 16
- Phase I/II: 3
- Phase II: 19
- Phase II/III: 11
- Phase III: 34
- Phase IV: 87
- Phase not specified: 93
Trial Status

Bioresorbable stents trials by status

- Planned, 29
- Open, Recruiting, 82
- Active, Not Recruiting, 57
- Completed, 83
- Terminated, 9
- Other, 3

Legend:
- Planned
- Open, Recruiting
- Active, Not Recruiting
- Completed
- Terminated
- Other
Trial Trends - Company by Trial Start

Bioresorbable stent trials by start date

- Abbott Vascular
- Amaranth Medical Inc.
- AstraZeneca
- Biosensors International
- BIOTRONIK
- Boston Scientific Corp
- Cardiovascular Research Foundation Korea
- Deutsches Herzzentrum Muenchen
- Elixir Medical Corporation
- JW Medical Systems Ltd
- Lepu Medical Technology (Beijing) Co., Ltd
- Meril Life Sciences Pvt. Ltd
- Micell Technologies
- OrbusNeich
- REVA Medical, Inc.
- Sahajanand Medical Technologies Pvt. Ltd.
- Seung-Jung Park
- Shanghai MicroPort Medical (Group) Co., Ltd
- SINO Medical Sciences Technology
- Terumo
Which Literature sources...

Biomedical databases

- MEDLINE®
- Embase®
- BIOSIS Previews®
Literature

- Who are the key opinion leaders?
- What are the new developments?
Look for Key Opinion Leaders

Bioresorbable stents top authors

<table>
<thead>
<tr>
<th>Author</th>
<th>Score</th>
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<tr>
<td>Serruys, Patrick W.</td>
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<td>Onuma, Yoshinobu</td>
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<td>Geuns, Robert Jan Van Garcia, Hector Manuel Garcia</td>
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<td>Whitbourn, Robert</td>
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<td>McClean, Dougal</td>
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Identify new developments

New chemical names last 5 years

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<th>Year</th>
<th>Biodegradable Plastics</th>
<th>calcium silicate</th>
<th>ceramic</th>
<th>diethyl fumarate</th>
<th>ferro-manganese alloy</th>
<th>gellan</th>
<th>gold</th>
<th>magnesium ion</th>
<th>molybdenum</th>
<th>Nanocapsules</th>
<th>nitroglycerin</th>
<th>oxide</th>
<th>poly(ethylene glycol)diacrylate</th>
<th>poly-N-isopropylacrylamide</th>
<th>Silicon Dioxide</th>
<th>silver</th>
<th>titanium dioxide</th>
<th>zinc</th>
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Review the associated literature

<table>
<thead>
<tr>
<th>Title</th>
<th>Author</th>
<th>Source</th>
<th>Publication Date</th>
<th>Chemical names last 5 yrs</th>
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<tr>
<td>Strength reliability and in vitro degradation of three-dimensional powder printed strontium-substituted magnesium phosphate scaffolds</td>
<td>Meiningher, Susanne Mandal, Sourav Kumar, Alok Groll, Jürgen Basu, Ekramjit Gbureck, Uwe</td>
<td>Acta Biomaterialia (Feb 1, 2016), vol. 31, p. 401-411.</td>
<td>2016-02-01</td>
<td>magnesium ion</td>
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<td>Biodegradable Stent Platforms: Are We Heading in the Right Direction?</td>
<td>Lavi, Shahar DAvivik, Vladimir</td>
<td>Canadian Journal of Cardiology (Aug 1, 2015), vol. 31, no. 8, p. 957-959.</td>
<td>2015-08-01</td>
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<td>Effectiveness of Biodegradable Magnesium Alloy Stents in Coronary Artery and Femoral Artery</td>
<td>Yue, Yuman Wang, Lili Yang, Nuo Huang, Jinglin Lei, Licheng Ye, Huiming Ren, Lihui Yang, Shixiang</td>
<td>Journal of Interventional Cardiology (Aug 1, 2015), vol. 28, no. 4, p. 358-364.</td>
<td>2015-08-01</td>
<td>aluminum zinc</td>
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</tbody>
</table>
Which Patent sources...

- Thomson Reuters Cortellis
- PatBase
- LifeQuest
Patents

- What are the key companies?
- What novel technologies are they developing?
Trends - competitors by priority year

Biosorbable patents - company by priority year

1989  1991  1993  1995  1997  1999  2001  2003  2005  2007  2009  2011  2013  2015

Abbott Laboratories
Atrium Medical Corp
Bzewada Biomedical LLC
Biotronik VI Patent AG
Boston Scientific Ltd
Conor Medsystems Inc
Cook Group Inc
Cordis Corp
Cytori Therapeutics Inc
DePuy Mitek Inc
Edwards Lifesciences Corp
Ethicon Inc
Gunze Ltd
KCI Licensing Inc
Med Institute
Medtronic Inc
Medtronic Vascular Inc
Micell Technologies Inc
OrbusNeich Medical Inc
Rutgers University
Scimed Life Systems Inc
Smith & Nephew Inc
Terumo Corp
Tufts University
Classification codes unique to top assignees
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<th>Original Assignee</th>
<th>Priority Date</th>
<th>IPCs unique among top assignees</th>
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<tr>
<td>1. THIN STRUT STENT FROM BIOABSORBABLE POLYMER WITH HIGH FATIGUE AND RADIAL STRENGTH AND METHOD TO MANUFACTURE THEREOF</td>
<td>1.1 Patbase</td>
<td>MERIL LIFE SCIENCES PVT LTD</td>
<td>2014-07-07</td>
<td>B21D39</td>
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<td>2. The short pulse laser machining which is improved using the light absorbing agent for manufacturing the medical device like the stent of the polymer</td>
<td>2.1 CORTP, 2.2 Patbase</td>
<td>Abbott Cardiovascular Systems Inc.</td>
<td>2013-03-13</td>
<td>B23K35</td>
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<td>3. Laser cut intraluminal medical devices</td>
<td>3.1 CORTP, 3.2 Patbase</td>
<td>Cordis Corporation</td>
<td>2005-12-15</td>
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<td>4. Micro-structured and nano-structured surfaces on biodegradable polymers</td>
<td>4.1 LIFEq</td>
<td>NANYANG TECHNOLOGICAL UNIVERSITY</td>
<td>2005-07-06</td>
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<td>5. BIOMIMETIC SCAFFOLDS</td>
<td>5.1 Patbase, 6.2 LIFEq</td>
<td>HASHI CRAIG, HUANG NGAN FONG, KURPINSKI KYLE, LI SONG, PATEL SHYAM, UNIV CALIFORNIA</td>
<td>2006-01-27</td>
<td>B27N3</td>
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