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Access the Best Medtech Analysts in the Business

As an Informa Pharma Intelligence product subscriber, you will receive 24/7 access to our expert journalists and analysts who cover all aspects of the pharmaceutical and medtech markets , including: R&D, clinical trials, market access, policy and regulation, financing and licensing.

If you have a question about any of our news stories, analysis or data, or about any market or business issues that you face, ask our global team who will respond within 48 hours.

We invite you to meet our Medtech team...

Medtech Analysts

Amanda Maxwell

European Regulatory Affairs Editor

Primary specialisms: Diagnostics, Medical Devices, European Policy and Regulation, Pricing and Reimbursement

Biography: Amanda reports and provides analysis on developments in medical technology regulatory affairs, with a focus on the current and future EU regulations for medical device, IVDs and device/drug combination products

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Ashley Yeo

Healthcare Editor (medtech)

Primary specialisms: Diagnostics, Market Access, Policy and Regulation, Pricing and Reimbursement

Biography: Ashley delivers content that gives insight into current and future trends in the global medtech industry, and what players need to do, and with whom, to keep ahead of the game in this fast-evolving and highly competitive sector

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Elizabeth Orr

Senior Reporter

Primary specialisms: Diagnostics, Medical Devices, Policy, Regulation, and Legal

Biography: Elizabeth reports on the medical device and diagnostics industry. She focuses on legal issues such as enforcement and intellectual property, but also covers device policy and regulation in the US and abroad

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Gayle Grimes

Market Analyst

Primary specialisms: Commercial Strategy, Market Access, Medical Devices, Orthopedics and Surgical Procedures

Biography: Gayle is a market analyst covering the medical device industry. She writes reports that provide sales forecasts and market analysis for various segments of the medical device industry, including neurology, orthopedics, spine, and women's health

Pharma Intelligence Products: Meddevicetracker Reports

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Medtech Analysts *continued*

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Biography: Marion covers the in-depth Market Intelligence features, highlighting industry trends, the competitive landscape and emerging technologies with key insights from leading experts

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Reed Miller
Deputy Editor

Primary specialisms: Diagnostics, Medical Devices and Cardiology

Biography: Reed focuses on new technology development, especially the conduct and regulation of clinical trials of cardiovascular devices, and commercial developments ranging from new start-ups to large established conglomerates

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Shawn M. Schmitt
Executive Editor

Primary specialisms: Manufacturing Quality Assurance, Medical Devices, Policy and Regulation

Biography: Shawn reports on medical device regulation, quality control, compliance, enforcement and post-market issues

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Sue Darcey
Senior Reporter

Primary specialisms: Diagnostics, Market Access, Medical Devices, Pricing and Reimbursement

Biography: Sue's coverage of the medical device and diagnostics industry includes monitoring medical device post-market performance and safety, US federal legislation, US Medicare and Medicaid Services device reimbursement strategies, and new genomic diagnostics and laboratory tests

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Medtech Analysts *continued*

Ferdous Al-Faruque
Senior Reporter

Primary specialisms: Commercial Strategy, Diagnostics, Market Access, Medical Devices, Policy and Regulation, Pricing and Rembursement

Biography: Ferdous specializes in new medical device technologies such as mobile health, combination products, unique device identifiers, and issues surrounding interoperability and cybersecurity. He is also our resident podcast expert, and has brought listeners the voices of top FDA officials as well as industry leaders

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Catherine Longworth
Reporter

Primary specialisms: Commercial Strategy, Diagnostics, Market Access, Medical Devices

Biography: Catherine writes breaking news, features and analysis on commercial and R&D developments in the medical device industry, with a focus on Europe and Asia, and conducts exclusive interviews with the sector's biggest companies and experts, and innovative start-ups

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Chrystal Larsen
Lead Market Analyst

Primary specialisms: Medical Devices, Pain Modulation and Hearing Loss

Biography: Chrystal provides timely business intelligence & analysis covering the medical device industry, writing market & technology reports focused on the following areas: diabetes management, neuromodulation, obesity/minimally invasive weight loss devices, ophthalmic surgery, patient monitoring, and other topics

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Medtech Analysts *continued*

Carrie Neptune

Lead Market Analyst

Primary specialisms: Infectious Diseases, Respiratory

Biography: Carrie researches, writes, and publishes market intelligence reports in the areas of wound management, respiratory care, infection control, pain management, and drug delivery. Carrie uses extensive primary/secondary research and proprietary algorithms to formulate reliable market forecasts, and provides a comprehensive view of existing market size, products, competitors, and trends.

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Richard Faint

Head of Medtech

Primary specialisms: CNS, Cardiovascular, Immunology and Inflammation, Infectious Diseases, Metabolic, Neurology, Oncology, Psychiatry, Respiratory

Biography: Richard is Head of Content, leading the medical device and diagnostics, and consumer health teams, who together bring diverse clinical, commercial, and regulatory experience to deliver clear and innovative business solutions to clients.

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Meddevicetracker Ask the Analyst Examples

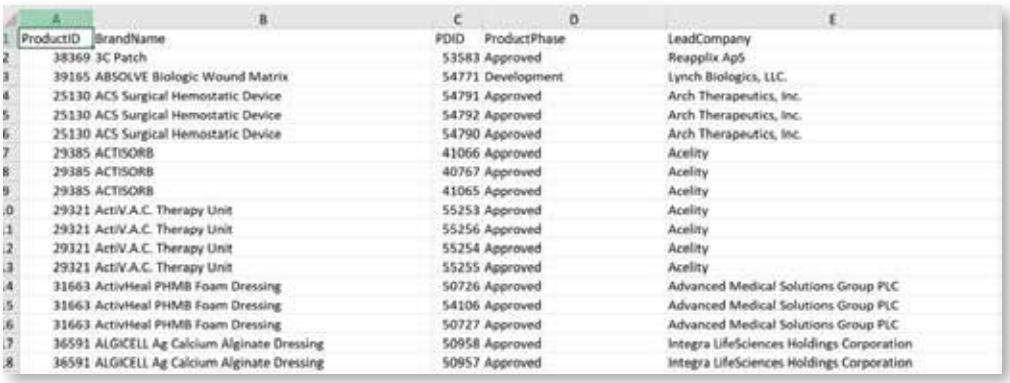
Question
Can you direct me to where I can find reports and market insights around wound healing?

Answer
Thank you for your request in regard to reports and market insights around wound healing. I've included links to the relevant reports below. The last few reports are a little bit older, but I included them to provide a sense of historical trends and as a reference point.

Wound Care: Tissue-Engineered Skin Replacements and Active Wound Repair Modulators
Wound Care: Advanced Dressings and Closure Products
Advanced Wound Care Products Market- December 2016
U.S. Markets for Advanced Wound Care Products- August 2015
U.S. Markets for Skin Replacements and Substitutes and Active Wound Repair- February 2013
U.S. Markets for Wound Dressings and Wound Cleansing/Debridement Products- November 2012
U.S. Markets for Current and Emerging Wound Closure Technologies- October 2012

I've also compiled a list of all wound healing products that are covered within Meddevicetracker, included in the attached Excel document. Products that are used to facilitate wound healing are located under several different indications (Wound Healing, Burn Injury, Diabetic Foot and Other Ulcers, Chronic Pressure Ulcers, and Chronic Venous Ulcers). The first tab is a product search across all of these indications whereas the following tabs are product searches for each specific indication broken out. Please let me know if there is anything else I can do to assist!

(See image for excel: "Wound Healing Products ATA" below)



	A	B	C	D	E
1	ProductID	BrandName	PDID	ProductPhase	LeadCompany
2	38369	3C Patch	53583	Approved	Reapplix ApS
3	39165	ABSOLVE Biologic Wound Matrix	54771	Development	Lynch Biologics, LLC.
4	25130	ACS Surgical Hemostatic Device	54791	Approved	Arch Therapeutics, Inc.
5	25130	ACS Surgical Hemostatic Device	54792	Approved	Arch Therapeutics, Inc.
6	25130	ACS Surgical Hemostatic Device	54790	Approved	Arch Therapeutics, Inc.
7	29385	ACTISORB	41066	Approved	Acelity
8	29385	ACTISORB	40767	Approved	Acelity
9	29385	ACTISORB	41065	Approved	Acelity
10	29321	ActiV.A.C. Therapy Unit	55253	Approved	Acelity
11	29321	ActiV.A.C. Therapy Unit	55256	Approved	Acelity
12	29321	ActiV.A.C. Therapy Unit	55254	Approved	Acelity
13	29321	ActiV.A.C. Therapy Unit	55255	Approved	Acelity
14	31663	ActivHeal PHMB Foam Dressing	50726	Approved	Advanced Medical Solutions Group PLC
15	31663	ActivHeal PHMB Foam Dressing	54106	Approved	Advanced Medical Solutions Group PLC
16	31663	ActivHeal PHMB Foam Dressing	50727	Approved	Advanced Medical Solutions Group PLC
17	36591	ALGICELL Ag Calcium Alginate Dressing	50958	Approved	Integra LifeSciences Holdings Corporation
18	36591	ALGICELL Ag Calcium Alginate Dressing	50957	Approved	Integra LifeSciences Holdings Corporation

Meddevicetracker Ask the Analyst Examples *continued*

Question

I would like the analyst to look into the remodlin pump for pulmonary hypertension and answer the following questions

1. Process to implant the pump?
2. Is this surgical implant like Duopa or more minor?
3. How long does the injection to refill the pump take? Please confirm that you can do this for me and the timeline. https://www.prnewswire.com/news-releases/united-therapeutics-announces-fda-approval-of-the-implantable-system-for-remodulin-300688819.html

Answer

We have received your request for information regarding the Remodulin pump. Please see the responses provided below: Meddevicetracker Product Profile: https://www.meddevicetracker.com/ProductReport.cfm?ProductID=7404

1. *Process to implant the pump?*
   The process to implant the pump is outlined in Medtronic's Technical Manual, beginning on Page 62.2.

2. *Is this surgical implant like Duopa or more minor?*
   - *While the pumps and implantation processes are similar, the Remodulin System implantation is a more minor procedure as the catheter is inserted into the vasculature using a subclavian approach, whereas the Duopa catheter is inserted into the jejunum.*
   - *The suggested catheter implantation locations for the Remodulin System can be seen on Page 79 of the Technical Manual.*
   - *A broad overview of the location of the Duopa pump can be viewed here.*

3. *How long does the injection to refill the pump take?*
   A breakdown of the flow rate, refill time, and device longevity can be found in the Technical Manual, beginning on Page 14.

Question

I would like to know where I can find the list of documents needed to registration of IVD in countries out of EU.

Answer

This is a broad question, so we will try to provide a completely comprehensive response. We have put together a table outlining IVD regulation facts, with links, for more than 50 countries around the world. That table is attached, and below the table are updates for select countries, as of March 2018.

(See document attached – Global IVD Regulation Information).

Medtech Insight also has a global medtech guidance document tracker that keeps tabs on documents issued by regulators from around the world, including those addressing IVD registration, this can be found here: https://medtech.pharmaintelligence.informa.com/datasets/guidances

Meddevicetracker Ask the Analyst Examples *continued*

Question
Hello, can you please provide follow up information regarding BTG Emphysema Treatment device? I am specifically interested in knowing whether there has been any response from the FDA to the company i.e. action letters, request for more information etc.

Answer
To your question regarding post-panel meeting follow up on BTG/PneumRX's Elevair Endobrochial Coil System: BTG was sent a "not-approvable" letter by FDA last month for the device. A statement from the company is pasted below. The letter is not public and the company is not providing further information about next steps. A not-approvable letter is technically not a full rejection, and it should include information from FDA about what may be necessary, including new data, new analyses or other actions, to make the device approvable. It would be up to the company to determine whether requested actions are feasible and to engage with FDA about possible solutions

Statement from BTG:

BTG receives not-approvable letter from the US FDA for ELEVAIR™
09 August 2018

BTG plc (LSE: BTG), the global specialist healthcare company, today announces that PneumRx® has received confirmation from the US Food and Drug Administration (FDA) that the Premarket Approval (PMA) application for its ELEVAIR™ Endobronchial Coil System for the treatment of people with severe emphysema is not approvable. This follows the FDA Advisory Panel's recommendation in June 2018 not to approve ELEVAIR™.
BTG is reviewing options and will provide an update in due course.