

Bioabsorbable Stents: A Breakthrough Solution On Hold

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The Challenge of Treating Coronary Artery Disease

In order to treat coronary artery blockages, around 600,000 people each year in the United States have metal coronary stents placed into their chests.¹ Coronary artery disease the most common disease in the country and accounts for the most deaths per year.²

One of the problems with metal stents is that they stay in patients forever; even though the stent is generally not needed after its purpose is served. Their presence can inhibit certain treatments, as well as scans and surgeries, in the future. And, they may negatively impact the natural flow of blood, leading to other complications, such as blood clots.

FDA Approval for the First Bioabsorbable Stent

In 2016, the first bioabsorbable stent, made by Abbott Vascular, was approved in the United States.³ It was named the Absorb GT1 bioresorbable vascular scaffold (BVS). Made of a naturally dissolving polymer, the stent can widen a clogged artery for a period of two years; after which time the stent dissolves and effectively disappears through absorption into the body. The concept is similar to that of dissolvable sutures. In their late 2016 YouTube video on Bioabsorbable Stents, Cleveland Clinic noted that experts at that time had estimated a market potential for these stents up to \$2 billion within six years.⁴

Challenges for the Product

Over the course of its first year following FDA approval, the Absorb BVS was severely hindered by the results of several trials that raised questions about the theoretical advantages of the stent. Some even showed evidence of risks and complications attributable to the Absorb BVS.⁵ As a result, the FDA initiated its own investigation related to the concerns arising from the trials.⁶

¹ *Bioabsorbable Stents: Top 10 Medical Innovations 2017*. Cleveland Clinic Channel. YouTube. October 26, 2016. Accessed on November 30, 2017. Available at:

<https://www.youtube.com/watch?v=pDdis6zfeUo&feature=youtu.be>

² *Ibid.*

³ *FDA approves first absorbable stent for coronary artery disease*. FDA News Release. U.S. Food and Drug Administration. July 5, 2016. Accessed on November 30, 2017. Available at:

<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm509805.htm>

⁴ *Bioabsorbable Stents*, *op. cit.*

⁵ Husten, Larry. *More Bad News For The Once Promising Bioresorbable Stent*. Cardio Brief. March 31, 2017.

Accessed on November 30, 2017. Available at: <http://www.cardiobrief.org/2017/03/31/more-bad-news-for-the-once-promising-bioresorbable-stent/>

⁶ *Ibid.*

By the time September 2017 rolled around – little more than a year since the FDA’s approval of the Absorb BVS – Abbott Vascular announced that it will end commercial sales of the product. The company cited low demand for the Absorb BVS as the reason for its discontinuation.⁷

But, the company also stated that they “[W]ill continue work on a next generation bioabsorbable device.” Abbott Vascular’s spokesperson, Jonathan Hamilton, added that “[f]irst-generation products often go through iterations as experience is gained using them. Absorb is a highly innovative ground-breaking device, and we're incorporating learnings into a second-generation product.”⁸

Bioabsorbable Polymers and Patient Care Going Forward

Though perhaps not in its current form, the bioabsorbable stent, constitutes an exciting opportunity. Both for patients and for companies such as Abbott Vascular. Whether or not Abbott Vascular will be at the forefront for the next generation of these products is hard to tell. But, the utilization of bioabsorbable polymers for medical devices will likely represent a key area of opportunity going forward.

Bioabsorbable stents constitute one example of a bioabsorbable tissue scaffold. Other applications for bioabsorbable polymers in patient treatment include sutures, screws and pins, and drug delivery systems.

The company Zeus, Inc., which produces the Absorv®-branded bioabsorbable products, lists a number of areas of application, including orthopedic applications and even tissue engineering.⁹

⁷ Fornell, Dave. Abbott Will End Sales of Absorb Bioresorbable Stent. Diagnostic and Interventional Cardiology. September 8, 2017. Accessed on November 30, 2017. Available at: <https://www.dicardiology.com/article/abbott-will-end-sales-absorb-bioresorbable-stent>

⁸ *Ibid.*

⁹ *Absorv – Bioabsorbable Extrusions.* Zeus, Inc. Website. Accessed on November 30, 2017. Available at <https://www.zeusinc.com/products/biomaterials/absorv-bioabsorbable-extrusions>