

Health Canada approves Abbott's Absorb™ bioresorbable stent, the first fully dissolving heart stent

- Revolutionary device made of naturally dissolving material, similar to dissolving sutures
- Treats coronary artery disease like a metallic stent, but then disappears after the artery is healed, leaving no metal behind to restrict natural vessel motion
- More than 150,000 people in more than 100 countries have already been treated with this novel technology

MARKHAM, Ontario, July 14, 2016 /PRNewswire/ -- Abbott (NYSE: ABT) announced today that Health Canada has approved the company's Absorb bioresorbable heart stent, making the first-of-its-kind medical device commercially available to treat people in Canada with coronary artery disease.

Absorb is the only dissolving heart stent approved for the treatment of coronary artery disease, which ranks as the number one killer of Canadian men and women. Coronary artery disease is the most common type of heart disease, which affects an estimated 1.3 million Canadians and remains a leading cause of death worldwide despite decades of therapeutic advances.

While stents are traditionally made of metal, Abbott's Absorb stent is made of a naturally dissolving material, similar to dissolving sutures. Absorb disappears completely¹ in approximately three years, once it has done its job of keeping a clogged artery open and promoting healing of the treated artery segment. By contrast, metal stents are permanent implants that restrict vessel motion for the life of the person treated.

"The Absorb stent is a significant advance in the way that coronary artery disease can be treated," said Philippe L.-L'Allier, M.D., director, interventional cardiology, Montreal Heart Institute. "Its novel technology means that once the stent has dissolved, the treated artery can pulse and flex as demands on the heart change with everyday activities. It also means physicians can more easily offer their patients other treatment options if necessary in a patient's future."

With Health Canada's approval of the Absorb bioresorbable stent, Abbott plans to offer the innovative device to Canadian hospitals nationwide starting this summer.

Alberta resident, Cynthia Gibeau, 60, was treated with the Absorb bioresorbable heart stent three years ago through a special access program after she was diagnosed with blockages in her coronary arteries. "When I was told that I could receive a stent that would disappear once it had done its job, I felt so relieved," said Cynthia. "It's been three years since the procedure and I have great peace of mind knowing that the device opened the blockage, delivered its medicine and then dissolved, leaving behind an artery without a permanent metallic structure."

"Abbott's goal is to help people everywhere live better, fuller and healthier lives," said Deepak Nath, Ph.D., senior vice president, vascular, Abbott. "The Absorb bioresorbable stent treats coronary artery disease without committing people to a permanent metal implant—giving them peace of mind and helping them get back to their daily lives without the concern of having a permanent metallic implant. We're very excited to bring the promise of Absorb to patients in Canada."

In clinical studies conducted around the world, the Absorb bioresorbable stent demonstrated comparable short-term and mid-term outcomes to the leading metallic stent—Abbott's Xience™ drug eluting stent. At one year in a pre-specified group of approximately 2,000 U.S. patients in the pivotal ABSORB III randomized clinical trial, patients who received the dissolving Absorb stent experienced comparable rates of specific adverse events in the intended patient population (reference vessel diameter of ≥ 2.5 mm and ≤ 3.75 mm)—including heart disease-related death, heart attacks attributed to the stented artery and repeat procedures at the treated lesion (collectively termed target lesion failure)—as compared to patients who received the metallic Xience stent.

Abbott's Absorb stent, sold commercially as the Absorb GT1 Bioresorbable Vascular Scaffold (BVS) system, is now available in more than 100 countries, including Canada. The device was also recently approved for use in the United States. Absorb has been used to treat more than 150,000² people with coronary artery disease worldwide.

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¹ Absorb dissolves except for two pairs of tiny metallic markers that remain in the artery to enable a physician to see where the device was placed.

² Based on worldwide device utilization rate. Data on file at Abbott.

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