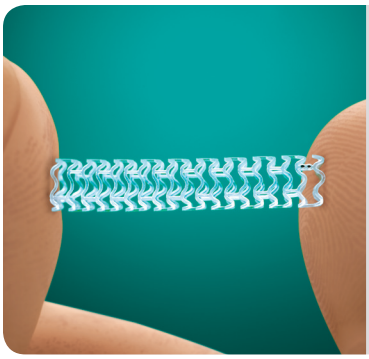
About Absorb™



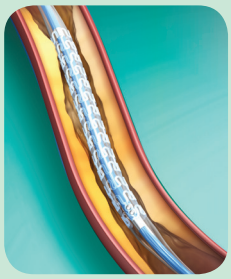
The Absorb dissolving heart stent is the first and only device of its kind – a drug eluting coronary stent that dissolves, completely and naturally, in the body over time. Absorb treats coronary artery disease like a metallic stent, propping the diseased vessel open to restore[1] blood flow, but then disappears after the artery is healed, leaving no metal behind to restrict natural vessel motion.

- While stents are traditionally made of metal, Abbott's Absorb stent is made of a naturally dissolvable material called polylactide, similar to dissolving stitches. Absorb disappears completely in approximately 3 years, once it has done its job of keeping a clogged artery open and promoting healing of the artery. By contrast, metal stents are permanent implants.
- Absorb represents a major advance in the interventional treatment of coronary artery disease—the next significant innovation in a chain of revolutionary treatments for heart disease starting with balloon angioplasty in the 1970s, bare-metal stents in the 1980s, and drug eluting stents in the 2000s.
- In clinical studies conducted around the world, Absorb has demonstrated comparable outcomes to the leading metallic stent—Abbott's XIENCE drug eluting stent. At one year in ABSORB III, a 2,000-patient company-sponsored U.S. clinical trial, patients who received Absorb experienced comparable rates of specific adverse events—including heart disease-related death and heart attacks and repeat procedures related to the stented artery (collectively termed target lesion failure)—as compared to patients who received the metallic XIENCE stent.
- Absorb has been used to treat more than 150,000 people and is available in more than 100 countries worldwide. It received European regulatory approval in 2010 and approval from the U.S. Food and Drug Administration in 2016.

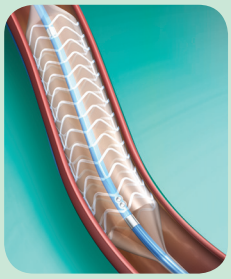
What is Coronary Artery Disease?

Heart disease is the leading cause of death for men and women around the world, and coronary artery disease is the most common type of heart disease[3,4] Coronary artery disease occurs when arteries that supply blood to the heart become narrowed or blocked due to plaque buildup (fatty deposits), leading to chest pain (angina) and increasing the risk of a heart attack.

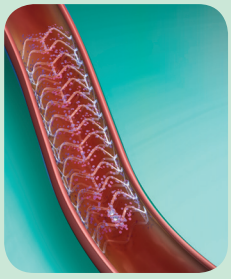
How Absorb Works



Absorb is placed into the artery on a balloon at the end of a thin flexible tube.

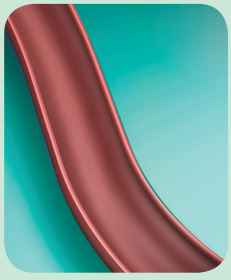


Absorb is expanded by inflating the balloon, pushing the plaque against the artery wall to enable greater blood flow.



The balloon is removed, leaving Absorb to slowly release medication to the diseased area.

With blood flow restored[1], Absorb begins dissolving.



Over time Absorb dissolves into the blood vessel.[2]

[1] Absorb improves coronary luminal diameter, restores blood flow and enables movement of the treated vessel. Source: Absorb GT1 IFU.
[2] 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.
[3] The top 10 causes of death, World Health Organization. Updated May 2014 Available at: http://www.who.int/mediacentre/factsheets/fs310/en/index.html
[4] What Is Coronary Heart Disease? National Heart, Lung and Blood Institute. Updated Oct. 23, 2015 Available at: http://www.nhlbi.nih.gov/health/health-topics/topics/cad/

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For U.S. media, see Important Safety Information on the following page.

INDICATIONS
The Absorb GT1 Bioresorbable Vascular Scaffold (BVS) is a temporary scaffold that will fully resorb over time and is indicated for improving coronary luminal diameter in patients with ischemic heart disease due to *de novo* native coronary artery lesions (length ≤ 24 mm) with a reference vessel diameter of ≥ 2.5 mm and ≤ 3.75 mm.

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Absorb GT1™

Rx ONLY

Bioresorbable Vascular Scaffold System

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CONTRAINDICATIONS

The Absorb GT1 BVS System is contraindicated for use in:

- Patients who cannot tolerate, including allergy or hypersensitivity to, procedural anticoagulation or the post-procedural antiplatelet regimen.
- Patients with hypersensitivity or contraindication to everolimus or structurally-related compounds, or known hypersensitivity to scaffold components (poly(L-lactide), poly(D,L-lactide), platinum) or with contrast sensitivity.

WARNINGS

- **For single use only**. Do not resterilize or reuse. Note the product "Use by" date on the package.
- Careful assessment of the target lesion reference vessel diameter and selection of the appropriate scaffold diameter relative to the target lesion reference vessel diameter are required to minimize potential damage to the scaffold during post-dilatation and to ensure adequate scaffold apposition and an appropriate post-implantation minimum lumen diameter.
- **In small vessels (visually assessed reference vessel diameter ≤ 2.75 mm), on-line QCA or intravascular imaging with intravascular ultrasound or optical coherence tomography is strongly recommended to accurately measure and confirm appropriate vessel sizing (reference vessel diameter ≥ 2.5 mm). (See Section 8.1.6 – Implantation of Absorb in Small Coronary Arteries (Post Hoc Analysis))**
- If quantitative imaging determines a vessel size < 2.5 mm, do not implant the Absorb GT1 BVS. Implantation of the device in vessels < 2.5 mm may lead to an increased risk of adverse events such as myocardial infarction and scaffold thrombosis.
- Adequate lesion preparation prior to scaffold implantation is required to ensure safe delivery of the scaffold across the target lesion. It is not recommended to treat patients having a lesion that prevents complete inflation of an angioplasty balloon. It is strongly recommended to achieve a residual stenosis between 20% and 40% after pre-dilatation to enable successful delivery and full expansion of the scaffold.
- Ensure the scaffold is not post-dilated beyond the allowable expansion limits (**see Absorb GT1 IFU Section 12.7 - Clinician Use Information, Further Expansion of the Deployed Scaffold**).
- Antiplatelet therapy should be administered post-procedure (**see Absorb GT1 IFU Section 9.1 - Patient Selection and Treatment, Individualization of Treatment**).
- This product should not be used in patients who are not likely to comply with the recommended antiplatelet therapy.
- Judicious selection of patients is necessary, since the use of this device carries the associated risk of scaffold thrombosis, vascular complications, and / or bleeding events.

PRECAUTIONS

- Implantation of the scaffold should be performed **only** by physicians who have received appropriate training.
- **Do not exceed the Rated Burst Pressure (RBP) as indicated on the product label.**
- Post-dilatation is strongly recommended for optimal scaffold apposition. When performed, post-dilatation should be at high pressure (> 16 atm) with a noncompliant balloon.
- Care must be taken to properly size the scaffold to ensure that the scaffold is in full contact with the arterial wall upon deflation of the balloon. All efforts should be made to ensure that the scaffold is not under dilated. **Refer to Absorb GT1 IFU Section 12.7 - Clinical Use Information, Further Expansion of the Deployed Scaffold**.
- Balloon dilatation of any cells of a deployed Absorb GT1 BVS may cause scaffold damage. **Avoid scaffolding across any side branches ≥ 2.0 mm in diameter**. Placement of a scaffold has the potential to compromise side branch patency.
- It is not recommended to treat patients having a lesion with excessive tortuosity proximal to or within the lesion.
- Non-clinical testing has demonstrated the Absorb GT1 BVS is MR Conditional. A patient with this device can be safely scanned in all MR environments 3T or less.
- The safety and effectiveness of the Absorb GT1 BVS have not been established for subject populations with the following characteristics:
  - Coronary artery reference vessel diameters < 2.5 mm or > 3.75 mm • Lesion lengths > 24 mm • Lesions located in arterial or saphenous vein grafts • Lesions located in unprotected left main artery • Ostial lesions • Lesions located at a bifurcation • Previously stented lesions • Moderate to severe calcification • Chronic total occlusion or poor flow (< TIMI 1) distal to the identified lesions • Three-vessel disease • Unresolved thrombus at the lesion site or anywhere in the vessel to be treated • Excessive tortuosity proximal to or within the lesion • Recent acute myocardial infarction (AMI)

POTENTIAL ADVERSE EVENTS

Adverse events that may be associated with PCI, treatment procedures and the use of a coronary scaffold in native coronary arteries include the following, but are not limited to:

- Allergic reaction or hypersensitivity to latex, contrast agent, anesthesia, device materials (platinum, or polymer [poly(L-lactide) (PLLA), polymer pol(D,L-lactide) (PDLLA)]), and drug reactions to everolimus, anticoagulation, or antiplatelet drugs, Vascular access complications which may require transfusion or vessel repair, including: Catheter site reactions, Bleeding (ecchymosis, oozing, hematoma, hemorrhage, retroperitoneal hemorrhage), Arteriovenous fistula, pseudoaneurysm, aneurysm, dissection, perforation / rupture, Embolism (air, tissue, plaque, thrombotic material or device), Peripheral nerve injury, Peripheral ischemia, Coronary artery complications which may require additional intervention, including: Total occlusion or abrupt closure, Arteriovenous fistula, pseudoaneurysm, aneurysm, dissection, perforation / rupture, Tissue prolapse / plaque shift, Embolism (air, tissue, plaque, thrombotic material or device), Coronary or scaffold thrombosis (acute, subacute, late, very late), Stenosis or restenosis, Pericardial complications which may require additional intervention, including: Cardiac tamponade, Pericardial effusion, Pericarditis, Cardiac arrhythmias (including conduction disorders, atrial and ventricular arrhythmias), Cardiac ischemic conditions (including myocardial ischemia, myocardial infarction [including acute], coronary artery spasm and unstable or stable angina pectoris), Stroke / Cerebrovascular accident (CVA) and Transient Ischemic Attack (TIA), System organ failures: Cardio-respiratory arrest, Cardiac failure, Cardiopulmonary failure (including pulmonary edema), Renal insufficiency / failure, Shock, Blood cell disorders (including Heparin Induced Thrombocytopenia [HIT]), Hypotension / hypertension, Infection, Nausea and vomiting, Palpitations, dizziness, and syncope, Chest pain, Fever, Pain, Death.

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CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use inside the product carton (when available) or at www.abbottvascular.com/ifu for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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