

# ADVANCEMENTS IN THE TREATMENT OF HEART DISEASE

Before the late 1970s, open heart surgery was the only option for treating patients with persistent symptoms of coronary artery disease, the most common form of heart disease. Patients now have less invasive options involving the insertion of devices through a small incision in the groin or wrist to the blocked vessel in the heart. These devices have significantly advanced over time.

## 1977

### BALLOON ANGIOPLASTY

Inflatable balloon inserted into the blocked vessel in the heart to push the plaque against the vessel wall and restore blood flow.



## 1988

### BARE METAL STENT

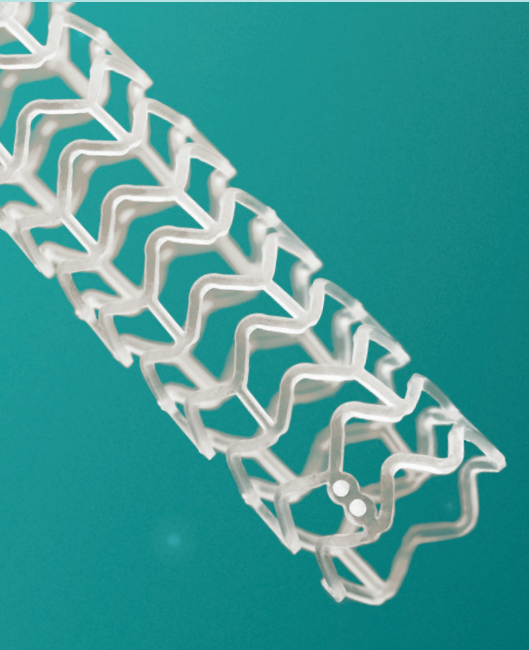
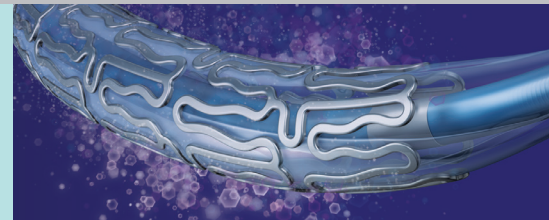
Metallic mesh tube implanted into the vessel after balloon angioplasty to restore blood flow to the heart and to keep the vessel open over time.



## 2001

### DRUG ELUTING STENT

Metallic mesh tube coated with medication to prevent re-narrowing of the blood vessel where the stent is placed.



## TODAY

### DISSOLVING STENT — ABBOTT'S ABSORB™

Absorb is the first fully dissolving device of its kind - a drug eluting coronary stent that dissolves, completely and naturally, in the body over time. Made of a naturally dissolving material (similar to dissolving stitches), the device disappears in approximately 3 years, once it has done its job of keeping a clogged artery open and promoting healing of the artery.<sup>1,2</sup>

Developed by Abbott, the global healthcare company.

<sup>1</sup> 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.

<sup>2</sup> Preliminary evidence suggests that natural vessel function is possible and may improve long term outcomes. Source: Serruys PW et al. ABSORB Cohort B 5-Year. TCT 2015

For media use only.

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  $\leq$  24 mm) with a reference vessel diameter of  $\geq$  2.5 mm and  $\leq$  3.75 mm.

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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  $\leq$  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  $\geq$  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  $\geq$  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 poly(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.

## Abbott Vascular

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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](http://www.abbottvascular.com/ifu) for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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