

Paper Ballot
Absorb GT1 Bioresorbable Vascular Scaffold System

The sponsor has proposed the following Indications for Use:

“The Absorb GT1 Bioresorbable Vascular Scaffold is indicated for improving coronary luminal diameter in patients with ischemic heart disease due to de novo native coronary artery lesions (length \leq 24 millimeters) with a reference vessel diameter of \geq 2.5 millimeters and \leq 3.75 millimeters.”

The following questions relate to the approvability of the Absorb GT1 Bioresorbable Vascular Scaffold System. Please answer them based on your expertise, the information you reviewed in preparation for this meeting, and the information presented at the panel meeting.

Panelist Name: _____

Please place an “X” next to your vote for each question.

Voting Question 1:

Is there reasonable assurance that the Absorb GT1 Bioresorbable Vascular Scaffold System is safe for use in patients who meet the criteria specified in the proposed indication?

YES _____

NO _____

ABSTAIN _____

Voting Question 2:

Is there reasonable assurance that the Absorb GT1 Bioresorbable Vascular Scaffold System is effective for use in patients who meet the criteria specified in the proposed indication?

YES _____

NO _____

ABSTAIN _____

Voting Question 3:

Do the benefits of the Absorb GT1 Bioresorbable Vascular Scaffold System outweigh the risks for use in patients who meet the criteria specified in the proposed indication?

YES _____

NO _____

ABSTAIN _____