PANEL QUESTIONS

REPEL-CV
Bioresorbable Adhesion Barrier

1

Question #1 – Safety

- Please provide your interpretation of the safety data collected in the REPEL-CV study.

2

Question #2 – Effectiveness

- Please provide your clinical and/or statistical interpretation of the results of the primary effectiveness endpoint analysis in the study population. Please provide your evaluation of the clinical benefit of the device.

3

Question #3 – Secondary Endpoints

- Please provide your clinical and/or statistical interpretation of the secondary effectiveness data.

4

Question #4a – Labeling

- Please discuss whether the data provided can be used to extrapolate the proposed Indications for Use from pediatric to adult patients who may or may not have a planned re-operation.

5

Question #4b – Labeling

- Please discuss whether the proposed labeling accurately informs physicians as to how to use this device and if the device can be indicated for placement between pericardial surfaces.

6

Question #4c – Labeling

- Please discuss if the data obtained from experience with Ventricular Assist Device patients is applicable to patients with other types of prosthetic devices.

7

Question #4d – Labeling

- Please discuss whether there are any other issues of safety or effectiveness not adequately covered in the proposed labeling.

8

Question #5a – Post-Approval Study

- Please discuss the appropriateness of mediastinitis as the primary endpoint versus a composite primary endpoint.

9

Question #5b – Post-Approval Study

- Please discuss whether a 4% non-inferiority margin is clinically significant and an acceptable margin of difference.

10

Question #5c – Post-Approval Study

- Please comment on the appropriateness of the length of follow-up to evaluate long-term safety.

11