Appendix H

Serious Adverse Event (SAE)
Report Form

SOUTH AFRICAN SURGICAL OUTCOMES STUDY 2

Protocol Number:_____

Site Name:_____

Pt ID:_____

Date Participant Reported/Date of Site Awareness:

__ __ / __ __ __ / __ __ __ __
d d m m m y y y y

1. SAE Event Term (Diagnosis, ex: Stroke, Myocardial Infarction).
2. SAE onset date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___
   d d m m m y y y y
3. SAE stop date: ___ ___ / ___ ___ ___ / ___ ___ ___ ___
   d d m m m y y y y
4. Location of SAE:_____
5. Was this an unexpected adverse event? ☐Yes ☐No
6. Brief description of participant with no personal identifiers:

   Sex: ☐F ☐M Age: _____

   Diagnosis for study participation:_____

   _____
7. Brief description of the nature of the SAE (attach description if more space is needed):

   _____

   _____
8. Category of the SAE:

   ☐ Date of death ___/_____/_____ (dd/mmm/yyyy)
   ☐ Life threatening
   ☐ Hospitalization – initial or prolonged
   ☐ Disability/incapacity
   ☐ Congenital anomaly/birth defect
   ☐ Required intervention to prevent permanent impairment
   ☐ Other:_____

9. Intervention type:

   ☐ Medication or nutritional supplement (specify):_____

   ☐ Device (specify):_____

   ☐ Surgery (specify):_____

   ☐ Behavioral/lifestyle (specify):_____

10. Relationship of event to intervention:

    ☐ Unrelated (clearly not related to the intervention)

    ☐ Possible (may be related to the intervention)

    ☐ Definite (clearly related to the intervention)

11. Was study intervention discontinued due to event? ☐Yes ☐No

12. What medications or other steps were taken to treat the SAE?

    _____

13. List any relevant tests, laboratory data, and history, including preexisting medical conditions.

    _____

14. Was this event a study related endpoint?

15. Type of report:

    ☐ Initial

    ☐ Followup

    ☐ Final

Signature of principal investigator: Date: