Online Supplemental Table 1. Study Endpoint Definitions

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| **Term** | **Study Endpoint Definition** |
| Death | Death that may be associated with either a procedure or device-related adverse event within 1 month after the operation |
| Hernia Recurrence | Loss of surgically acceptable hernia repair at the original treatment site |
| Hernia Recurrence requiring intervention | Repeat operation that may have been due to loss of surgically acceptable hernia repair at the original treatment site |
| Hernia mesh-related reinterventions | A second operation in the area of the hernia repaired initially to address complications that may have been caused by or associated with the mesh |
| Readmission | An unplanned hospitalization that may have been related to either the device or procedure with a length more than 24 hours in length |
| Reoperation | A device or procedure-related surgical or interventional procedure |
| Surgical Site Infection (SSI) CDC Definitionsa | Superficial Incisional SSI   * Infection occurs within 30 days after the operation; * Infection involves only the skin or subcutaneous tissue; and * At least 1 of the following:   + Purulent drainage (culture documentation not required);   + Organisms isolated from fluid/tissue of superficial incision;   + At least 1 sign of inflammation (e.g. pain or tenderness, induration, erythema, local warmth of the wound);   + Wound is deliberately opened by the surgeon; or   + Surgeon or attending physician declares the wound infected * Do not report the following conditions as SSIb:   + Stitch abscess (minimal inflammation and discharge confined to the points of suture penetration)   + Infection of an episiotomy or newborn circumcision site.   + Infected burn wound   + Incisional SSI that extends into the fascial and muscle layers (see deep incisional SSI)   **Deep Incisional SSI**   * Infection occurs within 30 days of operation or within 1 year if an implant is present; * Infection involves deep soft tissues (e.g. fascia and / or muscle) of the incision; and * At least 1 of the following:   + Purulent drainage from the deep incision but without organ/space involvement;   + Fascial dehiscence or fascia is deliberately separated by the surgeon due to signs of inflammation;   + Deep abscess is identified by direct examination, during reoperation, by histopathology, or radiologic examination; or   + Surgeon or attending declares deep incisional infection is present   **Organ/Space SSI**   * Infection occurs within 30 days of operation or within 1 year if an implant is present; * Infection involves anatomic structures not opened or manipulated by the operation; and * At least 1 of the following:   + Purulent drainage from a drain placed by a stab wound into the organ / space;   + Organisms isolated from organ/space by aseptic culturing technique;   + Identification of abscess in the organ/space by direct examination, during reoperation, by histopathological examination; or   + Diagnosis of organ/space SSI by surgeon or attending physician |
| Surgical Site Occurrence (SSO)c | Complications at the surgical site e.g., seroma, wound dehiscence or formation of enterocutaneous fistula |

Abbreviations: CDC=Centers for Disease Control; SSI=surgical site infection; SSO=surgical site occurrence a Report infection that involves both superficial and deep incision sites as deep incisional SSI; Report an organ/space SSI that drains through the incision as a deep incisional SSI. Horan TC, et al*. Am J Infect Control.* 1992t;20(5):271-274.

b Mangram AJ, et al. *Infect Control Hosp Epidemiol*. 1999;20(4):250-78.

c Breuing K, et al. *Surgery*. 2010;148(3):544-58.