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
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| 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.