IRB 14-1571 – **Prospective Randomized Trial of Biologic Mesh versus Synthetic Mesh for the Repair of Complex Ventral Hernias**

Appendix 8

Date of Contact: _____/_____/_____

Timepoint: 6 months ☐ 1 year ☐ 2 years ☐

TELEPHONE CONTACT SCRIPT

Good Morning/Afternoon Mr./ Ms. _____

My name is _____ and I am calling on behalf of Dr. _____ to follow-up with you regarding your hernia operation on: Month: _____/ Year _____. The reason for my call is your participation on the study: " **Prospective Randomized Trial of Biologic Mesh versus Synthetic Mesh for the Repair of Complex Ventral Hernias**". It has been ___ months since your surgery I would like to know if you would have around 5-10 minutes to answer a few questions about your how you have been feeling from a hernia repair standpoint and also about your quality of life after your hernia repair.

- **If patient agrees, remind the subject that he is part of the trial and that their answers are being used for the study**
- **If patient says he cannot speak at the moment, ask when is a better time to call, or, give the option to call you back to your CCF office number.**
- **If patient denies to answer the questions or drop consent from participating in the study, please record it and inform the PI.**

Ask the following questions in order:

1. Mr./Ms _____, my first questions are:

Regarding your hernia operation...			Have you had additional surgery since your hernia operation? ☐Yes ☐No If yes, reason for abdominal surgery: ☐For hernia ☐For another reason
Do you feel your hernia has come back?	☐Yes	☐No	
Do you feel or see a bulge?	☐Yes	☐No	
Do you have physical pain or symptoms at the site?	☐Yes	☐No	

2. For the following statements, please let me know which of the options is the most appropriate for you:

	Strongly Disagree	Moderately Disagree	Slightly Disagree	Slightly Agree	Moderately Agree	Strongly Agree
1. My abdominal wall has a huge impact on my health	1	2	3	4	5	6
2. My abdominal wall causes me physical pain	1	2	3	4	5	6
3. My abdominal wall interferes when I perform strenuous activities, e.g. heavy lifting	1	2	3	4	5	6
4. My abdominal wall interferes when I perform moderate activities, e.g. bowling, bending over	1	2	3	4	5	6
5. My abdominal wall interferes when I walk or climb stairs	1	2	3	4	5	6
6. My abdominal wall interferes when I dress myself, take showers, and cook	1	2	3	4	5	6
7. My abdominal wall interferes with my sexual activity	1	2	3	4	5	6
8. I often stay at home because of my abdominal wall	1	2	3	4	5	6
9. I accomplish less at home because of my abdominal wall	1	2	3	4	5	6
10. I accomplish less at work because of my abdominal wall	1	2	3	4	5	6
11. My abdominal wall affects how I feel every day	1	2	3	4	5	6
12. I often feel blue because of my abdominal wall	1	2	3	4	5	6

For the HerQLes questions above, if patients do not perform any of the listed activities, mark as "1

Appendix 2

EQ-5D

Health Questionnaire

English version for the US

By placing a checkmark in one box in each group below, please indicate which statements best describe your own health state today.

Mobility

I have no problems in walking about ❑

I have some problems in walking about ❑

I am confined to bed ❑

Self-Care

I have no problems with self-care ❑

I have some problems washing or dressing myself ❑

I am unable to wash or dress myself ❑

Usual Activities *(e.g. work, study, housework, family or leisure activities)*

I have no problems with performing my usual activities ❑

I have some problems with performing my usual activities ❑

I am unable to perform my usual activities ❑

Pain/Discomfort

I have no pain or discomfort ❑

I have moderate pain or discomfort ❑

I have extreme pain or discomfort ❑

Anxiety/Depression

I am not anxious or depressed ❑

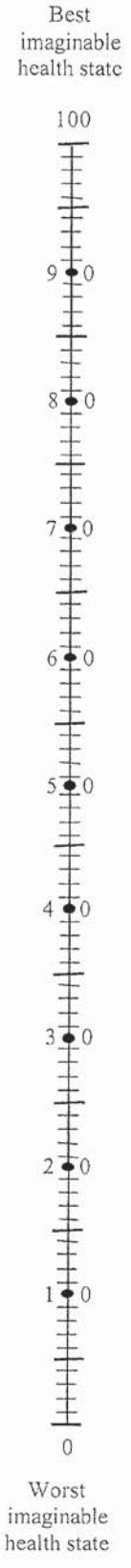
I am moderately anxious or depressed ❑

I am extremely anxious or depressed ❑

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Your own health state today



Appendix 3

Surgical Wound Classification

Wound Class	Definition	Examples	Reminders
Class I **Clean**	▶ Operative wound clean ▶ Non-traumatic, with no inflammation encountered ▶ No break in technique ▶ Respiratory, gastrointestinal and genitor-urinary tracts not entered ▶ Caesarean Section, elective, no pre-rupture of membranes or trial of labor	▶ Vascular Procedures ▶ Neurological procedures (inflamed II, infected III) ▶ Endocrine procedures ▶ Eye surgery (inflamed II, foreign body III, infected III) ▶ Orthopedic procedures (unless: trauma III, old wound IV, amputation II) ▶ Penile prosthesis ▶ Skin (mastectomy, lumpectomy, lesions, lipoma, cosmetic, I&D IV, old wounds III, inflamed III, infected IV) ▶ Exploratory Lap (no bowel involvement II) Miscellaneous procedures (lymph node excision/Bx unless inflamed III or infected IV, splenectomy, tenckhoff cath unless replacement II)	
Class II **Clean - contaminated**	▶ Operative wound clean-contaminated ▶ Non-traumatic wound with minor break in technique ▶ Gastrointestinal, respiratory or genitor-urinary tracts entered without significant spillage Includes: o Transection of appendix or cholecystic duct in the absence of infected bile or urine o Hysterectomy o Caesarean Section, emergency involving pre-rupture of membranes and / or trial of labor	▶ Thoracic procedures (except mediastinoscopy I, inflammation III, infected IV, foreign body III) ▶ GI procedures (including: laparoscopy, colonoscopy, gastroscopy) (gross spillage III, acute inflammation III, fresh accidental wound III) (itis III, Lithiasis II) ▶ GU procedures (infected III) ▶ Ear surgery (infected III) ▶ Nose/Oropharynx procedures (infected IV) ▶ GYN procedures (Oophorectomy I, inflamed III, infected IV)	▶ Any wound open for drainage II (except total hip / knee) ▶ Removing old implants (wires, pins, etc…) ▶ Re-operation at the same site
Class III **contaminated**	▶ Operative wound contaminated ▶ Fresh traumatic wound from clean source ▶ Operative wound with a major break in technique ▶ Gross spillage from the gastrointestinal tract ▶ Entrance into the genito-urinary or biliary tracts ▶ When infected urine or bile is present ▶ Incision encountering acute non-purulent inflammation.	▶ Inflammation ▶ Gross spillage ▶ Fresh accidental wound	▶ Foreign bodies in a wound (bullets, etc…)
Class IV **Dirty - infected**	▶ Operative wound dirty ▶ Traumatic wound from dirty source ▶ Traumatic wound with delayed treatment ▶ Fecal contamination ▶ Foreign body ▶ Retained devitalized tissue ▶ Operative wound w/ acute bacterial inflammation or perforated viscus ▶ Operative wound where clean tissue is transected to gain access to a collection of pus	▶ Infected ▶ I&D abscess ▶ Wound debridement	
Unclassified	▶ When unable to classify accurately an operative wound		▶ Communicable disease (aids, hepatitis, TB) is not classified the surgical wound is what is being classified

Surgical Site Infection (SSI) Event

Introduction: In 2002, in the United States, an estimated 14 million NHSN operative procedures were performed (CDC unpublished data). SSIs were the second most common healthcare-associated infection, accounting for 17% of all HAIs among hospitalized patients[1]. A similar rate was obtained from NHSN hospitals reporting data in 2006-2008 (16,147 SSI following 849,659 operative procedures) with an overall rate of 1.9%.[2]

While advances have been made in infection control practices, including improved operating room ventilation, sterilization methods, barriers, surgical technique, and availability of antimicrobial prophylaxis, SSIs remain a substantial cause of morbidity and mortality among hospitalized patients. In one study, among nearly 100,000 HAIs reported in one year, deaths were associated with SSIs in more than 8,000 cases.[3]

Surveillance of SSI with feedback of appropriate data to surgeons has been shown to be an important component of strategies to reduce SSI risk.[4,5,6,7] A successful surveillance program includes the use of epidemiologically-sound infection definitions and effective surveillance methods, stratification of SSI rates according to risk factors associated with SSI development, and data feedback.[5,6] Recommendations are outlined in the CDC's *Guideline for Prevention of Surgical Site Infection*, *1999*. [7]

Settings: Surveillance will occur with surgical patients in any inpatient/outpatient setting where the selected NHSN operative procedure(s) are performed.

Requirements: Select at least one NHSN operative procedure category (Table 1) and indicate this on the *Patient Safety Monthly Reporting Plan* (CDC 57.106). Collect numerator and denominator data on all procedures included in the selected procedure categories for at least one month.

The *International Classification of Diseases, 9th Revision Clinical Modifications* (ICD-9-CM) codes, which are defined by the ICD-9 Coordination and Maintenance Committee of the National Center for Health Statistics and the Centers for Medicare and Medicaid Services (CMS), are developed as a tool for classification of morbidity data. The preciseness of the data, as well as their wide use, allows their use in grouping surgery types for the purpose of determining SSI rates. ICD-9-CM codes are updated annually in October and NHSN operative procedure categories are subsequently updated and changes shared with NHSN users. Table 1: NHSN Operative Procedure Category Mappings to ICD-9-CM Codes below outlines operative procedures and their grouping into NHSN operative procedure categories according to ICD-9-CM codes. In addition, for certain NHSN operative procedure categories, Current Procedural Terminology (CPT) code mapping is provided. A general description of the types of operations contained in the NHSN operative procedure categories is also provided.

Table 1. NHSN Operative Procedure Category Mappings to ICD-9-CM Codes and CPT Codes

Legacy Code	Operative Procedure	Description	ICD-9-CM Codes / CPT Codes
AAA	Abdominal aortic aneurysm repair	Resection of abdominal aorta with anastomosis or replacement	38.34, 38.44, 38.64
AMP	Limb amputation	Total or partial amputation or disarticulation of the upper or lower limbs, including digits	84.00-84.19, 84.91
APPY	Appendix surgery	Operation of appendix (not incidental to another procedure)	47.01, 47.09, 47.2, 47.91, 47.92, 47.99
AVSD	Shunt for dialysis	Arteriovenostomy for renal dialysis	39.27, 39.42
BILI	Bile duct, liver or pancreatic surgery	Excision of bile ducts or operative procedures on the biliary tract, liver or pancreas (does not include operations only on gallbladder)	50.0, 50.12, 50.14, 50.21-50.23, 50.25, 50.26, 50.29, 50.3, 50.4, 50.61, 50.69, 51.31-51.37, 51.39, 51.41-51.43, 51.49, 51.51, 51.59, 51.61-51.63, 51.69, 51.71, 51.72, 51.79, 51.81-51.83, 51.89, 51.91-51.95, 51.99, 52.09, 52.12, 52.22, 52.3**,** 52.4, 52.51-52.53, 52.59-52.6, 52.7, 52.92, 52.95, 52.96, 52.99
BRST	Breast surgery	Excision of lesion or tissue of breast including radical, modified, or quadrant resection, lumpectomy, incisional biopsy, or mammoplasty	85.12, 85.20-85.23, 85.31-85.36, 85.41-85.48, 85.50, 85.53-85.55, 85.6, 85.70-85.76, 85.79, 85.93-85.96 19101, 19112, 19120, 19125, 19126, 19300, 19301, 19302, 19303, 19304, 19305, 19306, 19307, 19316, 19318, 19324, 19325, 19328, 19330, 19340, 19342, 19350, 19355, 19357, 19361, 19364, 19366, 19367, 19368, 19369, 19370, 19371, 19380

Legacy Code	Operative Procedure	Description	ICD-9-CM Codes / CPT Codes
CARD	Cardiac surgery	Procedures on the heart; includes valves or septum; does not include coronary artery bypass graft, surgery on vessels, heart transplantation, or pacemaker implantation	35.00-35.04, 35.06, 35.08, 35.10-35.14, 35.20-35.28, 35.31-35.35, 35.39, 35.42, 35.50, 35.51, 35.53, 35.54, 35.60-35.63, 35.70-35.73, 35.81-35.84, 35.91-35.95, 35.98-35.99, 37.10-37.12, 37.31-37.33, 37.35-37.37, 37.41, 37.49, 37.60*
CEA	Carotid endarterectomy	Endarterectomy on vessels of head and neck (includes carotid artery and jugular vein)	38.12
CBGB	Coronary artery bypass graft with **both** chest and donor site incisions	Chest procedure to perform direct revascularization of the heart; includes obtaining suitable vein from donor site for grafting	36.10-36.14, 36.19
CBGC	Coronary artery bypass graft with chest incision only	Chest procedure to perform direct vascularization of the heart using, for example the internal mammary (thoracic) artery	36.15-36.17, 36.2
CHOL	Gallbladder surgery	Cholecystectomy and cholecystotomy	51.03, 51.04, 51.13, 51.21-51.24 47480, 47562, 47563, 47564, 47600, 47605, 47610, 47612, 47620,
COLO	Colon surgery	Incision, resection, or anastomosis of the large intestine; includes large-to-small and small-to-large bowel anastomosis; does not include rectal operations	17.31-17.36, 17.39, 45.03, 45.26, 45.41, 45.49, 45.52, 45.71-45.76, 45.79, 45.81-45.83, 45.92-45.95, 46.03, 46.04, 46.10, 46.11, 46.13, 46.14, 46.43, 46.52, 46.75, 46.76, 46.94 44140, 44141, 44143, 44144, 44145, 44146, 44147, 44150, 44151, 44160, 44204, 44205, 44206, 44207, 44208, 44210
CRAN	Craniotomy	Excision repair, or exploration of the brain or meninges; does not include taps or punctures	01.12, 01.14, 01.20-01.25, 01.28, 01.29, 01.31, 01.32, 01.39, 01.41, 01.42, 01.51-01.53, 01.59, 02.11-02.14, 02.91-02.93, 07.51-07.54, 07.59, 07.61-07.65, 07.68, 07.69, 07.71, 07.72, 07.79, 38.01, 38.11, 38.31, 38.41, 38.51, 38.61, 38.81, 39.28

Legacy Code	Operative Procedure	Description	ICD-9-CM Codes / CPT Codes
CSEC	Cesarean section	Obstetrical delivery by Cesarean section	74.0, 74.1, 74.2, 74.4, 74.91, 74.99
FUSN	Spinal fusion	Immobilization of spinal column	81.00-81.08
FX	Open reduction of fracture	Open reduction of fracture or dislocation of long bones with or without internal or external fixation; does not include placement of joint prosthesis	79.21, 79.22, 79.25, 79.26, 79.31, 79.32, 79.35, 79.36, 79.51, 79.52, 79.55, 79.56 23615, 23616, 23630, 23670, 23680, 24515, 24516, 24538, 24545, 24546, 24575, 24579, 24586, 24587, 24635, 24665, 24666, 24685, 25337, 25515, 25525, 25526, 25545, 25574, 25575, 25607, 25608, 25609, 25652, 27236, 27244, 27245, 27248, 27254, 27269, 27283, 27506, 27507, 27511, 27513, 27514, 27535, 27536, 27540, 27758, 27759, 27766, 27769, 27784, 27792, 27814, 27822, 27826, 27827, 27828
GAST	Gastric surgery	Incision or excision of stomach; includes subtotal or total gastrectomy; does not include vagotomy and fundoplication	43.0, 43.42, 43.49, 43.5, 43.6, 43.7, 43.81, 43.82, 43.89, 43.91, 43.99, 44.15, 44.21, 44.29, 44.31, 44.38-44.42, 44.49, 44.5, 44.61-44.65, 44.68-44.69, 44.95-44.98
HER	Herniorrhaphy	Repair of inguinal, femoral, umbilical, or anterior abdominal wall hernia; does not include repair of diaphragmatic or hiatal hernia or hernias at other body sites	17.11-17.13, 17.21-17.24, 53.00-53.05, 53.10-53.17, 53.21, 53.29, 53.31, 53.39, 53.41-53.43, 53.49, 53.51, 53.59, 53.61-53.63, 53.69 49491, 49492, 49495, 49496, 49500, 49501, 49505, 49507, 49520, 49521, 49525, , 49550, 49553, 49555, 49557, 49560, 49561, 49565, 49566, 49568, 49570, 49572, 49580, 49582, 49585, 49587, 49590, 49650, 49651, 49652, 49653, 49654, 49655, 49656, 49657, 49659, 55540
HPRO	Hip prosthesis	Arthroplasty of hip	00.70-00.73, 00.85-00.87, 81.51-81.53 27125, 27130, 27132, 27134, 27137, 27138, 27236, 27299

Legacy Code	Operative Procedure	Description	ICD-9-CM Codes / CPT Codes
HTP	Heart transplant	Transplantation of heart	37.51-37.55
HYST	Abdominal hysterectomy; Includes that by laparoscope	Removal of uterus through abdominal wall; includes that by laparoscope	68.31, 68.39, 68.41, 68.49, 68.61, 68.69 58150, 58152, 58180, 58200, 58210, 58541, 58542, 58543, 58544, 58548, 58570, 58571, 58572, 58573, 58951, 58953, 58954, 58956
KPRO	Knee prosthesis	Arthroplasty of knee	00.80-00.84, 81.54, 81.55 27438, 27440, 27441, 27442, 27443, 27486, 27487
KTP	Kidney transplant	Transplantation of kidney	55.61, 55.69
LAM	Laminectomy	Exploration or decompression of spinal cord through excision or incision into vertebral structures	03.01, 03.02, 03.09, 80.50, 80.51, 80.53, 80.54†, 80.59, 84.60-84.69, 84.80-84.85
LTP	Liver transplant	Transplantation of liver	50.51, 50.59
NECK	Neck surgery	Major excision or incision of the larynx and radical neck dissection; does not include thyroid and parathyroid operations	30.1, 30.21, 30.22, 30.29, 30.3, 30.4, 31.45, 40.40-40.42
NEPH	Kidney surgery	Resection or manipulation of the kidney with or without removal of related structures	55.01, 55.02, 55.11, 55.12, 55.24, 55.31, 55.32, 55.34, 55.35, 55.39, 55.4, 55.51, 55.52, 55.54, 55.91
OVRY	Ovarian surgery	Operations on ovary and related structures	65.01, 65.09, 65.12, 65.13, 65.21-65.25, 65.29, 65.31, 65.39, 65.41, 65.49, 65.51-65.54, 65.61-65.64, 65.71-65.76, 65.79, 65.81, 65.89, 65.92-65.95, 65.99
PACE	Pacemaker surgery	Insertion, manipulation or replacement of pacemaker	00.50-00.54, 17.51, 17.52, 37.70-37.77, 37.79-37.83, 37.85-37.87, 37.89, 37.94-37.99
PRST	Prostate surgery	Suprapubic, retropubic, radical, or perineal excision of the prostate; does not include transurethral resection of the prostate	60.12, 60.3, 60.4, 60.5, 60.61, 60.62, 60.69

Legacy Code	Operative Procedure	Description	ICD-9-CM Codes / CPT Codes
PVBY	Peripheral vascular bypass surgery	Bypass operations on peripheral arteries	39.29
REC	Rectal surgery	Operations on rectum	48.25, 48.35, 48.40, 48.42, 48.43, 48.49-48.52, 48.59, 48.61-48.65, 48.69, 48.74
RFUSN	Refusion of spine	Refusion of spine	81.30-81.39
SB	Small bowel surgery	Incision or resection of the small intestine; does not include small-to-large bowel anastomosis	45.01, 45.02, 45.15, 45.31-45.34, 45.51, 45.61-45.63, 45.91, 46.01, 46.02, 46.20-46.24, 46.31, 46.39, 46.41, 46.51, 46.71-46.74, 46.93
SPLE	Spleen surgery	Resection or manipulation of spleen	41.2, 41.33, 41.41-41.43, 41.5, 41.93, 41.95, 41.99
THOR	Thoracic surgery	Noncardiac, nonvascular thoracic surgery; includes pneumonectomy and hiatal hernia repair or diaphragmatic hernia repair (except through abdominal approach)	32.09, 32.1, 32.20-32.23, 32.25, 32.26, 32.29, 32.30, 32.39, 32.41, 32.49, 32.50, 32.59, 32.6, 32.9, 33.0, 33.1, 33.20, 33.25, 33.28, 33.31-33.34, 33.39, 33.41-33.43, 33.48, 33.49, 33.98, 33.99, 34.01-34.03, 34.06, 34.1, 34.20, 34.26, 34.3, 34.4, 34.51, 34.52, 34.59, 34.6, 34.81-34.84, 34.89, 34.93, 34.99, 53.80-53.84
THYR	Thyroid and/or parathyroid surgery	Resection or manipulation of thyroid and/or parathyroid	06.02, 06.09, 06.12, 06.2, 06.31, 06.39, 06.4, 06.50-06.52, 06.6, 06.7, 06.81, 06.89, 06.91-06.95, 06.98, 06.99
VHYS	Vaginal hysterectomy; includes that by laparoscope	Removal of uterus through vagina; includes that by laparoscope	68.51, 68.59, 68.71, 68.79
VSHN	Ventricular shunt	Ventricular shunt operations, including revision and removal of shunt	02.21*, 02.22, 02.31-02.35, 02.39, 02.42, 02.43, 54.95^
XLAP	Abdominal surgery	Abdominal operations not involving the gastrointestinal tract or biliary system; includes diaphragmatic hernia repair through abdominal approach	53.71, 53.72, 53.75, 54.0, 54.11, 54.12, 54.19, 54.3, 54.4, 54.51, 54.59, 54.61, 54.63, 54.64, 54.71-54.75, 54.92, 54.93

*****NOTE: The procedure represented by this ICD-9-CM code can be performed in a number of ways. However, as for all surgeries, if, at the end of the procedure, the skin incision edges do not meet because of drains, wires, or other objects extruding through the incision, the incision is not considered primarily closed. Therefore, the procedure is not considered an NHSN operative procedure and any subsequent infection is not considered a procedure-associated infection (i.e., not an SSI or PPP).

†NOTE: If this procedure is performed percutaneously, it is not considered an NHSN operative procedure and should not be included in LAM denominator data.

^NOTE: Include only if this procedure involves ventricular shunt.

For a complete mapping of all ICD-9-CM codes to their assignment as an NHSN operative procedure category, a surgical procedure other than an NHSN operative procedure (OTH), or a non-operative procedure (NO), see ICD-9-CM Procedure Code Mapping to NHSN Operative Procedure Categories at http://www.cdc.gov/nhsn/library.html.

Definitions:

An NHSN operative procedure is a procedure

1) that is performed on a patient who is an NHSN inpatient or an NHSN outpatient; 2) takes place during an operation (defined as a single trip to the operating room (OR) where a surgeon makes at least one incision through the skin or mucous membrane, including laparoscopic approach, and closes the incision before the patient leaves the OR; and 3) that is included in Table 1.

*****NOTE: If the skin incision edges do not meet because of wires or devices or other objects extruding through the incision, the incision is not considered primarily closed and therefore the procedure is not considered an operation. Further, any subsequent infection is not considered a procedure-associated infection (i.e., not an SSI or PPP).

NHSN Inpatient: A patient whose date of admission to the healthcare facility and the date of discharge are different calendar days.

NHSN Outpatient: A patient whose date of admission to the healthcare facility and date of discharge are the same calendar day.

Operating Room (OR): A patient care area that met the Facilities Guidelines Institute's (FGI) or American Institute of Architects' (AIA) criteria for an operating room when it was constructed or renovated.[8] This may include an operating room, C-Section room, interventional radiology room, or a cardiac catheterization lab.

Implant: A nonhuman-derived object, material, or tissue that is placed in a patient during an operative procedure. Examples include: porcine or synthetic heart valves, mechanical heart, metal rods, mesh, sternal wires, screws, cements, internal staples, hemoclips, and other devices. Non-absorbable sutures are excluded because Infection Preventionists may not easily identify and/or differentiate the soluble nature of suture material used.

For surveillance purposes, this object is considered an implant until it or the area/structures contiguous with the implant are manipulated for diagnostic or therapeutic purposes. If infection develops after such manipulation, do not attribute it to the operation in which the implant was inserted; instead attribute it to the latter procedure. If the latter procedure is an NHSN operative procedure, subsequent infection can be considered SSI if it meets criteria. If the latter procedure is not an NHSN operative procedure, subsequent infection cannot be considered an SSI but may meet criteria for other HAI and be reported as such.

REPORTING INSTRUCTIONS:

- Some products are a combination of human- and nonhuman-derived materials, such as demineralized human bone matrix with porcine gel carrier. When placed in a patient during an operative procedure, indicate "Yes" for the Implant field.

A **superficial incisional SSI** must meet one of the following criteria:

Infection occurs within 30 days after the operative procedure
and
involves only skin and subcutaneous tissue of the incision
and
patient has at least one of the following:

a. purulent drainage from the superficial incision.
b. organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision.
c. at least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat, and superficial incision are deliberately opened by surgeon, and are culture-positive or not cultured. A culture-negative finding does not meet this criterion.
d. diagnosis of superficial incisional SSI by the surgeon or attending physician.

NOTE: There are two specific types of superficial incisional SSIs:

1. Superficial Incisional Primary (SIP) – a superficial incisional SSI that is identified in the primary incision in a patient that has had an operation with one or more incisions (e.g., C-section incision or chest incision for CBGB)
2. Superficial Incisional Secondary (SIS) – a superficial incisional SSI that is identified in the secondary incision in a patient that has had an operation with more than one incision (e.g., donor site [leg] incision for CBGB)

REPORTING INSTRUCTIONS:

- Do not report a stitch abscess (minimal inflammation and discharge confined to the points of suture penetration) as an infection.
- Do not report a localized stab wound infection as SSI. While it would be considered either a skin (SKIN) or soft tissue (ST) infection, depending on its depth, it is not reportable under this module.
- "Cellulitis", by itself, does not meet the criteria for Superficial Incisional SSI.

- If the incisional site infection involves or extends into the fascial and muscle layers, report as a deep-incisional SSI.
- Classify infection that involves both superficial and deep incision sites as deep incisional SSI.
- An infected circumcision site in newborns is classified as CIRC. Circumcision is not an NHSN operative procedure. CIRC is not reportable under this module.
- An infected burn wound is classified as BURN and is not reportable under this module

A **deep incisional SSI** must meet one of the following criteria:
Infection occurs within 30 days after the operative procedure if no implant is left in place or within one year if implant is in place and the infection appears to be related to the operative procedure
and
involves deep soft tissues (e.g., fascial and muscle layers) of the incision
and
patient has at least one of the following:

a. purulent drainage from the deep incision but not from the organ/space component of the surgical site
b. a deep incision spontaneously dehisces or is deliberately opened by a surgeon and is culture-positive or not cultured and the patient has at least one of the following signs or symptoms: fever (>38ºC), or localized pain or tenderness. A culture-negative finding does not meet this criterion.
c. an abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination
d. diagnosis of a deep incisional SSI by a surgeon or attending physician.

NOTE: There are two specific types of deep incisional SSIs:

1. Deep Incisional Primary (DIP) – a deep incisional SSI that is identified in a primary incision in a patient that has had an operation with one or more incisions (e.g., C-section incision or chest incision for CBGB)
2. Deep Incisional Secondary (DIS) – a deep incisional SSI that is identified in the secondary incision in a patient that has had an operation with more than one incision (e.g., donor site [leg] incision for CBGB)

REPORTING INSTRUCTIONS:

- Classify infection that involves both superficial and deep incision sites as deep incisional SSI.

An **organ/space SSI** involves any part of the body, excluding the skin incision, fascia, or muscle layers, that is opened or manipulated during the operative procedure. Specific sites are assigned to organ/space SSI to further identify the location of the infection. The table below lists the specific sites that must be used to differentiate organ/space SSI. An example is appendectomy with subsequent subdiaphragmatic abscess, which would be reported as an organ/space SSI at the intraabdominal specific site (SSI-IAB). Specific sites of organ/space (Table 2) have specific criteria which must be met in order to qualify as an NHSN event. These criteria are in addition to the general criteria for organ/space SSI and can be found in Chapter 17.

An **organ/space SSI** must meet one of the following criteria:
Infection occurs within 30 days after the operative procedure if no implant is left in place or within one year if implant is in place and the infection appears to be related to the operative procedure
and
infection involves any part of the body, excluding the skin incision, fascia, or muscle layers, that is opened or manipulated during the operative procedure
and
patient has at least one of the following:

a. purulent drainage from a drain that is placed through a stab wound into the organ/space
b. organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space
c. an abscess or other evidence of infection involving the organ/space that is found on direct examination, during reoperation, or by histopathologic or radiologic examination
d. diagnosis of an organ/space SSI by a surgeon or attending physician.

REPORTING INSTRUCTIONS:

- Occasionally an organ/space infection drains through the incision and is considered a complication of the incision. Therefore, classify it as a deep incisional SSI.
- Report mediastinitis following cardiac surgery that is accompanied by osteomyelitis as SSI-MED rather than SSI-BONE.
- If meningitis (MEN) and a brain abscess (IC) are present together after operation, report as SSI-IC.
- Report CSF shunt infection as SSI-MEN if it occurs ≤ 1 year of placement; if later or after manipulation/access, it is considered CNS-MEN and is not reportable under this manual.
- Report spinal abscess with meningitis as SSI-MEN following spinal surgery.
- Episiotomy is not considered an operative procedure in NHSN.

Table 2. Specific sites of an organ/space SSI. Criteria for these sites can be found in the NHSN Help System (must be logged in to NHSN) or Chapter 17.

Code	Site	Code	Site
BONE	Osteomyelitis	JNT	Joint or bursa
BRST	Breast abscess or mastitis	LUNG	Other infections of the respiratory tract
CARD	Myocarditis or pericarditis	MED	Mediastinitis
DISC	Disc space	MEN	Meningitis or ventriculitis
EAR	Ear, mastoid	ORAL	Oral cavity (mouth, tongue, or gums)
EMET	Endometritis	OREP	Other infections of the male or female reproductive tract
ENDO	Endocarditis	OUTI	Other infections of the urinary tract
EYE	Eye, other than conjunctivitis	SA	Spinal abscess without meningitis
GIT	GI tract	SINU	Sinusitis
HEP	Hepatitis	UR	Upper respiratory tract
IAB	Intraabdominal, not specified	VASC	Arterial or venous infection

Code	Site	Code	Site
	else-where		
IC	Intracranial, brain abscess or dura	VCUF	Vaginal cuff

Numerator Data: All patients having any of the procedures included in the selected NHSN operative procedure category(s) are monitored for signs of SSI. The *Surgical Site Infection (SSI)* form (CDC 57.120) is completed for each such patient found to have an SSI. If no SSI events are identified during the surveillance month, check the Report No Events field in the Missing PA Events tab of the Incomplete/Missing List.

NOTES:

1. If a patient has several NHSN operative procedures prior to an infection, report the operative procedure code of the operation that was performed most closely in time prior to the infection date, unless there is evidence that the infection is associated with a different operation.
2. If a procedure from more than one NHSN operative procedure category was done through a single incision, attempt to determine the procedure that is thought to be associated with the infection. If it is not clear (as is often the case when the infection is a superficial incisional SSI), or if the infection site being reported is not an SSI, use the NHSN Principal Operative Procedure Category Selection Lists (Table 3) to select which operative procedure to report.

Table 3. NHSN Principal Operative Procedure Category Selection Lists

The following lists are derived from Table 1, NHSN Operative Procedure Categories. The operative procedures with the highest risk of surgical site infection are listed before those with a lower risk.		
Priority	**Code**	**Abdominal Operations**
1	SB	Small bowel surgery
2	KTP	Kidney transplant
3	LTP	Liver transplant
4	BILI	Bile duct, liver or pancreatic surgery
5	REC	Rectal surgery
6	COLO	Colon surgery
7	GAST	Gastric surgery
8	CSEC	Cesarean section
9	SPLE	Spleen surgery
10	APPY	Appendix surgery
11	HYST	Abdominal hysterectomy
12	VHYS	Vaginal Hysterectomy
13	OVRY	Ovarian surgery
14	HER	Herniorrhaphy
15	CHOL	Gall bladder surgery
16	AAA	Abdominal aortic aneurysm repair
17	NEPH	Kidney surgery
18	XLAP	Laparotomy

The following lists are derived from Table 1, NHSN Operative Procedure Categories. The operative procedures with the highest risk of surgical site infection are listed before those with a lower risk.		
Priority	**Code**	**Thoracic Operations**
1	HTP	Heart transplant
2	CBGB	Coronary artery bypass graft with donor incision(s)
3	CBGC	Coronary artery bypass graft, chest incision only
4	CARD	Cardiac surgery
5	THOR	Thoracic surgery
Priority	**Code**	**Neurosurgical (Spine) Operations**
1	RFUSN	Refusion of spine
2	FUSN	Spinal fusion
3	LAM	Laminectomy
Priority	**Code**	**Neurosurgical (Brain) Operations**
1	VSHN	Ventricular shunt
2	CRAN	Craniotomy
Priority	**Code**	**Neck Operations**
1	NECK	Neck surgery
2	THYR	Thyroid and or parathyroid surgery

The *Instructions for Completion of Surgical Site Infection* form (Tables of Instructions, Tables 12 and 2a) includes brief instructions for collection and entry of each data element on the form. The SSI form includes patient demographic information and information about the operative procedure, including the date and type of procedure. Information about the SSI includes the date of SSI, specific criteria met for identifying the SSI, when the SSI was detected, whether the patient developed a secondary bloodstream infection, whether the patient died, and the organisms isolated from cultures and the organisms' antimicrobial susceptibilities.

Denominator Data: For all patients having any of the procedures included in the NHSN Operative Procedure category(s) selected for surveillance during the month, complete the *Denominator for Procedure* form (CDC 57.121). The data are collected individually for each operative procedure performed during the month specified on the *Patient Safety Monthly Surveillance Plan* (CDC 57.106). The *Instructions for Completion of Denominator for Procedure* form (Tables of Instructions, Table 13) includes brief instructions for collection and entry of each data element on the form.

NOTES:

1. If procedures in more than one NHSN operative procedure category are performed during the same trip to the OR even if performed through the same incision, a Denominator for Procedure (CDC 57.121) record is reported for <u>each</u> NHSN operative procedure category being monitored.

For example, if a CARD and CBGC are done through the same incision, a *Denominator for Procedure* record is reported for each.

EXCEPTION: If a patient has both a CBGC and CBGB during the same trip to the OR, report only as a CBGB. Only report as a CBGC when there is a chest incision only. CBGB and CBGC are never reported for the same patient for the same trip to the OR. For bilateral operative procedures see #4 below.

2. If procedures of different ICD-9-CM codes from the same NHSN Operative Procedure Category are performed through the same incision, record only one procedure for that category. For example, a facility is performing surveillance for both CBGB and CARD procedures. A patient undergoes an aortocoronary bypass of one coronary vessel (36.11, CBGB) and the replacement of both the mitral and tricuspid valves (35.23 and 35.27, both CARD) during the same trip to the OR. You would complete a *Denominator for Procedure* record for the CBGB and another one for the CARD because ICD-9-CM codes 35.23 and 35.27 fall in the same operative procedure category (CARD).
3. If more than one NHSN operative procedure category is performed through the same incision, record the combined duration of all procedures, which is the time from skin incision to primary closure.
4. For bilateral operative procedures (e.g., KPRO), two separate Denominator for Procedure (CDC 57.121) records are completed. To document the duration of the procedure, indicate the incision time to closure time for each procedure separately or, alternatively, take the total time for both procedures and split it evenly between the two.
5. Laparoscopic hernia repairs are considered one procedure, regardless of the number of hernias that are repaired in that trip to the OR. In most cases there will be only one incision time documented for this procedure. If more than one time is documented, total the durations.. Open [i.e., non-laparoscopic] hernia repairs are reported as one procedure for each hernia repaired via a separate incision, i.e., if two incisions are made to repair two defects, then two procedures will be reported. It is anticipated that separate incision times will be recorded for these procedures. If not, take the total time for both procedures and split it evenly between the two.
6. Following laparoscopic surgeries, if more than one of the incisions should become infected, only report as a single SSI.
7. If a patient goes to the OR more than once during the same admission and another procedure is performed through the same incision within 24 hours of the original operative incision, report only one procedure on the *Denominator for Procedure* (CDC 57.121) form combining the durations for both procedures. For example, a patient has a CBGB lasting 4 hours. He returns to the OR six hours later to correct a bleeding vessel. The surgeon reopens the initial incision, makes the repairs, and recloses in 1.5 hours. Record the operative procedure as one CBGB and the duration of operation as 5 hour 30 minutes. If the wound class has changed, report the higher wound class. If the ASA class has changed, report the higher ASA class.
8. Do not include in the procedural denominators, procedures during which the patient expired in the operating theatre.

Data Analyses: The SIR is calculated by dividing the number of observed infections by the number of expected infections. The number of expected infections, in the context of statistical prediction, is calculated using SSI probabilities estimated from multivariate logistic regression models constructed from NHSN data during a baseline time period to represent a standard population[2]

NOTE: The SIR will be calculated only if the number of expected HAIs (numExp) is ≥ 1.

While the SSI SIR can be calculated for single procedure categories, and for specific surgeons, the measure also allows you to summarize your data across multiple procedure categories, while adjusting for differences in the estimated probability of infection among the patients included across the procedure categories. For example, you will be able to obtain one SSI SIR adjusting for all procedures reported. Alternatively, you can obtain one SSI SIR for all colon surgeries (COLO) only within your facility.

SSI rates per 100 operative procedures are calculated by dividing the number of SSIs by the number of specific operative procedures and multiplying the results by 100. SSI will be included in the numerator of a rate based on the date of procedure, not the date of event. Rate calculations can be performed separately for the different types of operative procedures and stratified by the basic risk index. SSI rate calculation options are available in the advanced analysis feature of the NHSN application.

- Basic SSI Risk Index. The index used in NHSN assigns surgical patients into categories based on the presence of three major risk factors:

  1. Operation lasting more than the duration cut point hours, where the duration cut point is the approximate 75th percentile of the duration of surgery in minutes for the operative procedure.
  2. Contaminated (Class 3) or Dirty/infected (Class 4) wound class.
  3. ASA classification of 3, 4, or 5.

  The patient's SSI risk category is simply the number of these factors present at the time of the operation.

---

[1]Klevens RM, Edwards JR, et al. Estimating health care-associated infections and deaths in U.S. hospitals, 2002. Public Health Reports 2007;122:160-166.

[2] Yi M, Edwards JR, et al. Improving risk-adjusted measures of surgical site information for the National Healthcare Safety Network. Infect Control Hosp Epidemiol 2011; 32(10):970-986.

[3]Emori TG, Gaynes RP. An overview of healthcare-associated infections, including the role of the microbiology laboratory. Clin Microbiol Rev 1993;6(4):428-42.

[4] Condon RE, Schulte WJ, Malangoni MA, Anderson-Teschendorf MJ. Effectiveness of a surgical wound surveillance program. Arch Surg 1983;118:303-7.

[5] Society for Healthcare Epidemiology of America, Association for Professionals in Infection Control and Epidemiology, Centers for Disease Control and Prevention, Surgical Infection Society. Consensus paper on the surveillance of surgical wound infections. Infect Control Hosp Epidemiol 1992;13(10):599-605.

[6]Haley RW, Culver DH, White JW, Morgan WM, Emori TG, Munn VP. The efficacy of infection surveillance and control programs in preventing healthcare-associated infections in US hospitals. Am J Epidemiol 1985;121:182-205.

[7]Centers for Disease Control and Prevention. Guideline for prevention of surgical site infection,1999. Infect Control Hosp Epidemiol, 1999;20(4):247-278.

[8] Facilities Guidelines Institute. Guidelines for design and construction of health care facilities. American Society for Healthcare Engineering; Chicago IL; 2010.

Appendix 5. Definitions and Treatment Plans for Surgical Site Occurrences

Surgical Site Occurrence (SSO): a complication or adverse event occurring at a surgical site; includes, but is not limited to, superficial, deep incisional, and organ/space surgical site infections

Surgical Site Occurrence Requiring Procedural Intervention (SSOPI): a complication or adverse event occurring at a surgical site that is managed or treated with an invasive procedure

Surgical Site Occurrences Types and Consensus Treatment Plans:

SSO Type	**Definition**	**Consensus Treatment Plan**
wound cellulitis	inflammation of subcutaneous loose connective tissue, as evidenced by erythema, swelling, warmth, and/or tenderness	1. complete 10-day course of oral antibiotics: Clindamycin 300 mg PO TID OR Doxycycline 100 mg PO BID PLUS Cephalexin 500 mg PO QID OR Amoxicillin 500 mg PO TID OR TMP/SMX 1-2 double-strength tabs PO BID PLUS Amoxicillin 500 mg PO TID 2. reassess wound
non-healing incisional wound	skin and/or subcutaneous tissue of an incisional wound that do not heal within 90 days of procedure, without signs or symptoms of infection; fascia remains intact	dress wound at least daily with ¼" packing tape if < 2 cm^2 or saline-soaked wet-to-dry gauze if ≥ 2 cm^2 or negative pressure therapy until healed

wound dehiscence/fascial disruption	opening or disruption of fascia along the suture lines of a surgical site within 90 days of procedure	1. reoperation for surgical debridement and fascial closure; 2. dressing of skin and subcutaneous tissue with negative pressure therapy or at least daily dressings with saline-soaked wet-to-dry gauze until healed; 3. mesh does not require removal
skin or soft tissue ischemia	local ischemia to the skin or soft tissue	watchful waiting to determine if skin or soft tissue ischemia progresses to skin or soft tissue necrosis
skin or soft tissue necrosis	pathologic death of the skin or soft tissue	allow skin or soft-tissue necrosis to demarcate, followed by sharp debridement
wound serous drainage	drainage of serum from the surgical site wound or drain	dress wound at least daily with ¼" packing tape if < 2 cm^2 or saline-soaked wet-to-dry gauze if ≥ 2 cm^2 until healed, Culture effluent
wound purulent drainage	drainage of pus from the surgical site wound or drain; surgical site infection	(See superficial, deep incisional, or organ/space surgical site infection corresponding to location)
chronic sinus drainage	a fistulous tract and/or cavity with drainage of fluid that persists beyond 90 days of procedure	1. dress wound at least daily with ¼" packing tape if < 2 cm^2 or saline-soaked wet-to-dry gauze if ≥ 2 cm^2 until 90 postoperative days 2. after 90 postoperative days, locally explore wound, debride unincorporated material, and dress wound at least daily with ¼" packing tape if

		< 2 cm^2 or saline-soaked wet-to-dry gauze if ≥ 2 cm^2 until healed
localized stab wound infection	a localized infection and/or inflammation restricted to the site of a transfascial fixation suture	1. locally explore stab wound 2. dress wound at least daily with ¼" packing tape until healed 3. complete 10-day course of oral antibiotics: Clindamycin 300 mg PO TID OR Doxycycline 100 mg PO BID <u>PLUS</u> Cephalexin 500 mg PO QID OR Amoxicillin 500 mg PO TID OR TMP/SMX 1-2 double-strength tabs PO BID <u>PLUS</u> Amoxicillin 500 mg PO TID 4. reassess wound 5. If localized stab wound infection persists beyond 30 postoperative days, open wound, remove offending transabdominal fixation suture, and dress wound at least daily with ¼" packing tape if < 2 cm^2 or saline-soaked wet-to-dry gauze if ≥ 2 cm^2 until healed
stitch abscess	a localized superficial	1. locally explore wound

	collection of pus and/or inflammation restricted to the skin and subcutaneous tissue around a suture, with confirmed presence of suture in wound	and remove offending suture 2. dress wound at least daily with ¼" packing tape until healed
seroma	a localized collection of serum within a tissue or space	asymptomatic seroma: watchful waiting; symptomatic seroma: percutaneous drainage of fluid with or without drain placement, cultures obtained.
infected seroma	a localized collection of serum within a tissue or space that has become infected and has converted to an abscess; surgical site infection	(See superficial, deep incisional, or organ/space surgical site infection corresponding to location)
hematoma	a localized collection of extravasated blood within a tissue or space	1. evaluate for active bleeding and need to immediately establish hemostasis; 2. evaluate blood counts for possible need for transfusion of blood products as per clinical standard of care; 3. asymptomatic hematoma: watchful waiting of fluid collection symptomatic hematoma: percutaneous drainage of fluid collection with or without drain placement, If hemodynamically unstable, might require return to OR for surgical control.
infected hematoma	a localized collection of	(See superficial, deep

	extravasated blood within a tissue or space that has become infected and has converted to an abscess; surgical site infection	incisional, or organ/space surgical site infection corresponding to location)
exposed biologic mesh	an implanted biologic scaffold (xenograft) that has become exposed to the extracorporeal space	1. dressing of skin and subcutaneous tissue with negative pressure therapy or at least daily with saline-soaked wet-to-dry gauze until healed; 2. mesh does not require removal 3. may consider split thickness skin graft when granulation bed is present
exposed synthetic mesh	an implanted synthetic material scaffold that has become exposed to the extracorporeal space	1. dressing of skin and subcutaneous tissue with negative pressure therapy or at least daily with saline-soaked wet-to-dry gauze until healed; mesh does not require removal 2. may consider split thickness skin graft when granulation bed is present
contaminated biologic mesh	pathogen presence on a biologic scaffold (autograft, allograft, or xenograft) without signs or symptoms of local or systemic inflammation of the host; pathogen presence confirmed by culture-positive fluid around mesh	1. contamination source control with: percutaneous drainage with or without drain placement OR operative drainage with irrigation or pulse lavage; 2. mesh does not require removal

contaminated synthetic mesh	pathogen presence on a synthetic material scaffold without signs or symptoms of local or systemic inflammation of the host; pathogen presence confirmed by culture-positive fluid around mesh	1. contamination source control with: percutaneous drainage with or without drain placement OR operative drainage with irrigation or pulse lavage; 2. mesh does not require removal
infected biologic mesh	pathogen presence on a biologic scaffold (autograft, allograft, or xenograft) with signs or symptoms of local or systemic inflammation of the host; pathogen presence confirmed by culture-positive fluid around mesh; surgical site infection	1. intravenous or oral antibiotics as determined by culture results and evidence-based standard of care 2. infectious source control with: percutaneous drainage with or without drain placement OR operative drainage with irrigation or pulse lavage; 3. mesh does not necessarily require removal. Remove mesh if not incorporated into surrounding soft tissue bed, or if signs or symptoms of local or systemic infection newly develop, persist, or worsen. 4. if mesh is removed, a subsequent operative procedure to repair abdominal wall defect

		with mesh reinforcement may be needed
infected synthetic mesh	pathogen presence on a synthetic material scaffold with signs or symptoms of local or systemic inflammation of the host; pathogen presence confirmed by culture-positive fluid around mesh; surgical site infection	1. intravenous or oral antibiotics as determined by culture results and evidence-based standard of care 2. infectious source control with: percutaneous drainage with or without drain placement OR operative drainage with irrigation or pulse lavage; 3. mesh does not necessarily require removal. Remove mesh if not incorporated into surrounding soft tissue bed, or if signs or symptoms of local or systemic infection newly develop, persist, or worsen. 4. if mesh is removed, a subsequent operative procedure to repair abdominal wall defect with mesh reinforcement may be needed
mucocutaneous anastomosis disruption	opening or disruption in a surgically-created communication between the enteric mucosa and cutaneous soft tissue	1. if signs or symptoms of local or systemic inflammation or infection, intravenous antibiotic treatment with broad-spectrum coverage of enteric

		organisms, as per evidence-based standard of care 2. reoperation for wound exploration, irrigation, and stoma revision; 3. If mesh not exposed to enteric contents, mesh does not require removal. 4. If mesh is not incorporated into surrounding soft tissue bed when exposed to enteric contents, remove mesh. 5. If mesh is incorporated into surrounding soft tissue bed when exposed to enteric contents, attempt to salvage mesh. If signs or symptoms of local or systemic infection newly develop, persist, or worsen, remove mesh. 6. If mesh is removed, a subsequent operative procedure to repair abdominal wall defect with mesh reinforcement may be needed.
enterocutaneous fistula	a pathologic tract or cavernous communication between the enteric viscera and cutaneous soft tissue	1. intravenous antibiotic treatment with broad-spectrum coverage of enteric organisms, as per evidence-based standard of care 2. reoperation for wound exploration, irrigation, and correction of underlying problem; 3. If mesh not exposed to

		enteric contents, mesh does not require removal. 4. If mesh is not incorporated into surrounding soft tissue bed when exposed to enteric contents, remove mesh. 5. If mesh is incorporated into surrounding soft tissue bed when exposed to enteric contents, attempt to salvage mesh. If signs or symptoms of local or systemic infection newly develop, persist, or worsen, remove mesh. 6. If mesh is removed, a subsequent operative procedure to repair abdominal wall defect with mesh reinforcement may be needed.
enteric serosal tear	a superficial injury to the serous layer of the enteric viscera	1. repair serosal injury with vicryl sutures; 2. mesh does not require removal
enterotomy	a full-thickness incision into or injury to the enteric viscera	1. intravenous antibiotic treatment with broad-spectrum coverage of enteric organisms, as per evidence-based standard of care 2. If enterotomy occurs and is recognized during index operative procedure, repair enterotomy with two layers of suture or resect and reanastomose bowel.

		3. If mesh is not exposed to enteric contents, proceed with mesh placement and/or mesh does not require removal. 4. If recognition of enterotomy is delayed until after the index operative procedure, and reoperation through midline incision necessary for re-exploration, irrigation, and correction of the underlying problem, mesh will require removal. 5. If mesh is removed, a subsequent operative procedure to repair abdominal wall defect with mesh reinforcement may be needed.
enteric ischemia	local anemia to enteric tissue due to compromise or disruption of the blood supply	1. intravenous antibiotic treatment with broad-spectrum coverage of enteric organisms, as per evidence-based standard of care 2. Address underlying cause of enteric ischemia; 3. Resect non-viable portions of the gastrointestinal tract as necessary; 4. Mesh does not require removal. 5. If enteric ischemia occurs after index operative procedure, and reoperation is

		necessary, mesh may be removed if obstructive to reoperation through midline incision. 6. If mesh is removed, a subsequent operative procedure to repair abdominal wall defect with mesh reinforcement may be needed.
enteric necrosis	pathologic death of the enteric tissue	1. intravenous antibiotic treatment with broad-spectrum coverage of enteric organisms, as per evidence-based standard of care 2. Address underlying cause of enteric necrosis; 3. Reoperation to resect necrotic portions of the gastrointestinal tract; 4. If mesh not exposed to enteric contents, mesh does not require removal. 5. If mesh is not incorporated into surrounding soft tissue bed when exposed to enteric contents, remove mesh. 6. If mesh is incorporated into surrounding soft tissue bed when exposed to enteric contents, attempt to salvage mesh. If signs or symptoms of local or systemic infection newly develop, persist, or worsen, remove

		mesh. 7. If mesh is removed, a subsequent operative procedure to repair abdominal wall defect with mesh reinforcement may be needed.
enteric leak	pathologic drainage of enteric contents into surrounding tissue or space	1. intravenous antibiotic treatment with broad-spectrum coverage of enteric organisms, as per evidence-based standard of care 2. possible percutaneous drainage if well-contained leak OR reoperation for wound exploration, irrigation, and correction of underlying problem; 3. If mesh not exposed to enteric contents, mesh does not require removal. 4. If mesh is not incorporated into surrounding soft tissue bed when exposed to enteric contents, remove mesh. 5. If mesh is incorporated into surrounding soft tissue bed when exposed to enteric contents, attempt to salvage mesh. If signs or symptoms of local or systemic infection newly develop, persist, or worsen, remove mesh. 6. If mesh is removed, a subsequent operative

		procedure to repair abdominal wall defect with mesh reinforcement may be needed.
superficial surgical site infection	(see CDC definition; Appendix 4)	1. intravenous or oral antibiotics as determined by culture results and evidence-based standard of care 2. infectious source control: open, debride, and irrigate or pulse lavage wound 3. dress wound at least daily with ¼" packing tape if < 2 cm^2 or saline-soaked wet-to-dry gauze if ≥ 2 cm^2 or negative pressure dressing until healed 4. mesh does not necessarily require removal. Remove mesh if not incorporated into surrounding soft tissue bed, or if signs or symptoms of local or systemic infection newly develop, persist, or worsen. 5. if mesh is removed, a subsequent operative procedure to repair abdominal wall defect with mesh reinforcement may be needed
deep incisional surgical site infection	(see CDC definition; Appendix 4)	1. intravenous or oral antibiotics as determined by culture results and evidence-based standard of care

		2. infectious source control: percutaneous drainage with or without drain placement OR operative drainage, debridement, and irrigation or pulse lavage; 3. if operative management, dress wound at least daily with ¼" packing tape if < 2 cm^2 or saline-soaked wet-to-dry gauze if ≥ 2 cm^2 or negative pressure therapy until healed 5. mesh does not necessarily require removal. Remove mesh if not incorporated into surrounding soft tissue bed, or if signs or symptoms of local or systemic infection newly develop, persist, or worsen. 6. if mesh is removed, a subsequent operative procedure to repair abdominal wall defect with mesh reinforcement may be needed
organ/space surgical site infection	(see CDC definition; Appendix 4)	1. intravenous or oral antibiotics as determined by culture results and evidence-based standard of care 2. infectious source control: percutaneous drainage

		with or without drain placement if well-contained infection/abscess OR operative drainage, debridement, irrigation or pulse lavage, and address underlying source of infection; 4. if operative management, dress wound at least daily with ¼" packing tape if < 2 cm^2 or saline-soaked wet-to-dry gauze if ≥ 2 cm^2 or negative pressure therapy until healed 5. mesh does not necessarily require removal. Remove mesh if not incorporated into surrounding soft tissue bed, or if signs or symptoms of local or systemic infection newly develop, persist, or worsen. 6. if mesh is removed, subsequent operative procedure to repair abdominal wall defect with mesh reinforcement may be needed
unanticipated surgical site occurrence	surgical site occurrence not defined here	Communicate to all multi-site co-investigators within 24 hours of occurrence, and determine consensus management or treatment plan.

Cleveland Clinic
Consent to Participate in a Research Study

Study Title: **A PROSPECTIVE RANDOMIZED TRIAL OF BIOLOGIC MESH VERSUS SYNTHETIC MESH FOR THE REPAIR OF COMPLEX VENTRAL HERNIAS**

Principal Investigator: Michael Rosen, MD. (216) 445-3441

Carefully review this consent document. The purpose of a consent document is to provide you with information to help you decide whether you wish to participate in research. Your decision is completely voluntary and will not affect your medical care if you choose not to participate. It is important for you to ask questions and understand the research risks, benefits and alternatives.

Please note:

- **You are being asked to participate in a research study**
- **Carefully consider the risks, benefits and alternatives of the research**
- **Your decision to participate is completely voluntary**

Your doctor may be an investigator in this research study, and as a research investigator, is interested in both your welfare and in the conduct of the research study. Before entering this study or at any time during this research, you may ask for a second opinion about your care from another doctor who is not involved with the research study. You are not under any obligation to participate in any research project offered by your doctor.

1. INFORMATION ON THE RESEARCH

Why Are You Being Asked To Take Part In This Research?

You are being asked to participate in a clinical research study because you are scheduled to undergo a repair of your abdominal hernia with a reinforcement material (mesh) as part of your needed medical care.

Why Is This Study Being Done?

The purpose of this research study is to compare open abdominal incisional hernia repair using either a biologic reinforcement material (made from pig tissue)or a synthetic reinforcement material (made from plastic materials) to provide some support during wound healing at the site of your hernia defect where your tissue is weakened. Using materials to reinforce tissue defects is standard of care and both the synthetic mesh SoftMesh™ (CR Bard, Murray Hill, NJ) and the biologic mesh Strattice™ (Lifecell, Branchburg NJ) are some of the many standard mesh materials that are used. You may have a complicated history of hernia and it is known before your surgery that you have a contaminated wound. The use of biologic and synthetic mesh in contaminated fields is considered experimental. Your planned open abdominal incisional hernia repair can be repaired with either reinforcement material. The study will also evaluate early and

long-term recovery effects of both materials in the quality of life and the rate of hernia recurrence as well as the occurrence of complications.

You are being offered the opportunity to take part in this research because you have been diagnosed with a complex ventral incisional hernia (the skin, muscle and tissue layers of the abdomen are weak and bulge or tear and an organ has pushed through the weakened area to form a balloon-like sac). Your surgeon has decided to repair your hernia with a reinforcement material (mesh). This surgery will be an "open" surgical procedure and reinforcing your tissue with material is necessary for your type of hernia repair.

A separate standard operative consent will be provided relative to your surgery or if applicable other conditions being treated. This is standard of care. You will receive a reinforcement material even if you decide not to participate in the study. You will receive standard postoperative care which includes your length of stay in the hospital and postoperative follow-up visits.

How Many People Will Take Part In The Study?
About 253 people will take part in this study at approximately 5 hospitals and medical facilities in the US. Approximately 103 people will take part at Cleveland Clinic.

There is a possibility that the investigators may become aware of new findings that may affect your willingness to continue participation. You will be informed of these new findings so that you may choose to continue or discontinue your voluntary participation.

What Is Involved In The Study?
If you agree to be in this study, you will be asked to sign this consent form. You will have the following tests and procedures to make sure that you can participate:

You will be evaluated preoperatively at a screening visit to ensure that you qualify to participate in the study. If you choose to participate in the study, information on your activities and quality of life experience will also be collected and documented on questionnaires before surgery. These short questionnaires will take approximately 15 minutes to complete. The study staff will also collect additional personal and medical information including your age, gender, height, and weight, surgical history, preoperative symptoms and information relating to your current hernia.

Your active participation in this study will last for 24 months and will involve one preoperative evaluation visit, one operative procedure visit, and 4 follow up visits.

Visit 1: Screening

If you agree to participate by signing the informed consent, you will have Screening assessments completed. At this study visit, the doctor will ask about your past medical and surgical history and any medications you are taking and you will have a brief physical examination. An

abdominal pelvic CT scan (a picture of your abdomen) will be obtained preoperatively in all patients based on our standard approach and your physician will review these and any test results that are used to diagnose your hernia. If you qualify for study participation, you will be asked to join the study. If you choose to participate in the study, the study staff will collect additional information such as your gender, age, height, weight, your medical and surgical history, and information relating to your current hernia. You will be asked to fill out and complete two brief survey questionnaires that ask about your activities and how your hernia impacts what you can do. The questionnaires will take approximately 15 minutes to complete. Prior to surgery photos may also be taken of your abdominal hernia. Your face will not be photographed and no identifying information will be attached to the photo.

You will receive routine pre-operative care, which will vary depending upon any additional procedures that may be performed during your hernia repair. This may include lab work, a special diet, and bowel cleansing. This routine care is not part of the study.

Randomization

If you participate in this study, you will be assigned to a study group by chance using a process similar to the flip of a coin. This process is called randomization. This means that half of the people in this study will have their hernia repaired with the standard biological mesh, Strattice™. The other half of the people in the study will have their hernia repaired with a synthetic mesh, SoftMesh™. Neither you nor the study staff will select the group to which you will be assigned. However, this information can be obtained if you have a medical emergency.

Visit 2: Day of Surgery

On the day that your hernia is repaired, you will be randomized to receive either the biological reinforcement mesh or the synthetic mesh if you meet the inclusion criteria of the study. This surgical mesh will be used to support the tissue around the area of your hernia repair. Your surgery will be performed in the usual open manner. As part of standard of care drains may be placed around the mesh. As part of the study your doctor will collect information about your hernia or your surgery such as the size of your hernia, how long the surgery took, how much blood you lost during the surgery, antibiotics and IV fluids that are given, and where and how many drains were placed.

Visit 3: Post Surgery Care

You will have a physical evaluation every day as part of your routine post-operative care while you are in the hospital**.** The nature and severity of any wound event and all medical and surgical interventions, including re-operations will be collected. During your hospital stay after your hernia is repaired, information about your stay will be collected such as the return of your bowel function, the length of your stay, and medications you have received.

Follow Up

You will be given instructions to return to the physician's clinic to be examined by the study doctor at 4 weeks, 6 months, 1 year, and 2 years following your surgery. Depending on your doctor's discretion, some of these follow-up visits may be completed using the Cleveland Clinic virtual video visit which is a medically secure platform that is similar to Skype or FaceTime. You will have your abdominal wound evaluated and examined for general health and hernia reoccurrence. You will be asked about any medications you are taking and about any problems you may have had with your hernia repair. Information about any procedures that may be performed during this time will be collected. You will be asked to complete the same surveys that you filled out prior to surgery at each of these visits. You will be informed which mesh you received at your 24 month follow up visit.

If at any time throughout the study period a hernia recurrence is suspected clinically, then an abdominal CT scan will be performed to objectively evaluate the repair as standard of care dictates. All additional procedures, interventions, and adverse events will be collected throughout the final visit at 24 months. The entire length of your active participation in this study will be approximately 24 months after your hernia is repaired.

How Long Will You Be In The Study?

Your participation in this study will last a maximum of 24 months after your hernia is repaired. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, it is important you talk with your doctor first.

2. RISKS AND DISCOMFORTS

What Are The Risks Of The Study?

In this study, you will receive routine medical care. As with any routine surgical procedure, there are some risks that are associated and they will be discussed in a separate surgical consent form as applicable. You may experience some pain, bleeding, and discomfort, however this is with any surgical operation. Common occurrences following hernia repair include seroma (accumulation of fluid) or hematoma (blood) around the hernia repair, inflammation, opening of the wound, or infection, and hernia recurrence. You may also experience additional therapies or treatments, including the removal of the reinforcement material (mesh) to treat any of these events. The possible side effects and complications of your surgery relate to the procedure itself and will have nothing to do with data collection. In regards to the surveys you will complete for the study, some of the questions may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it and go to the next question.

Participation in this study may involve risks that are currently unforeseeable due to the nature of this research. However, if any new risks become known in the future, you will be informed of them.

Risks of Drawing Blood and Blood Testing:
Risks associated with drawing blood may include momentary discomfort and/or bruising (small red discoloration) in the area of the IV catheter or blood draw sites. Infection, excess bleeding, clotting, or fainting due to a temporary lowering of blood pressure are also possible, although unlikely.

Unforeseen Risks:
In addition to the risks listed above, there may be some unknown or infrequent and unforeseeable risks associated with the use of this material. You or your legally authorized representative will be informed as soon as possible if new information becomes available that may affect your willingness to continue participation in this study.

Finally, there is the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential, however, this cannot be guaranteed.

3. BENEFITS

Are There Benefits To Taking Part In The Study?
There will be no direct benefit to you by your participation in this research study. Your study participation will help us better understand the usefulness of synthetic versus biologic meshes in a contaminated hernia repair.

4. COSTS

Are there any costs to you if you participate in this study?
You and/or your insurance provider will be responsible for all costs related to your routine medical care, that is, care you would have received whether or not you were part of this study. You may wish to contact your insurance representative to discuss costs further before making your decision about participating in the study.

5. COMPENSATION

You will not be paid for participation in this study.

6. RESEARCH RELATED INJURY

What will happen if you are injured as a result of taking part in the research?

In the event you are injured as a result of participation in this research, medical care is available to you. The costs of such medical care will be billed to you or your insurance company. There

are no plans to provide compensation for lost wages, direct or indirect losses. The Cleveland Clinic will not voluntarily provide compensation for research related injury. You are not waiving any legal rights by signing this form. Further information about research related injury is available by contacting the Institutional Review Board at 216-444-2924.

7. PRIVACY AND CONFIDENTIALITY

What will happen to your information that is collected for this research?
Cleveland Clinic has rules and procedures to protect information about you. Federal and State laws also protect your privacy.

The research team working on the study will collect information about you. This includes your health information, data collected for this research study and personal identifying information including your name, address, date of birth and other identifying information. The Sponsor will use this study information for research, the stated purpose of the study, and may also use it for submissions related to market approval.

Generally, only people on the research team will know your identity and that you are in the research study. However, sometimes other people at Cleveland Clinic may see or give out your information. These include people who review research studies including the Institutional Review Board and Research Compliance, their staff, lawyers, or other Cleveland Clinic staff. If you agree, your personal physician may be informed of your participation in the study.

People outside Cleveland Clinic may need to see your information for this study. Examples include government groups (such as the Food and Drug Administration), safety monitors, other hospitals in the study and the sponsor of the research and their agents. Cleveland Clinic will do our best to ensure your information is kept confidential and that only the health information which is minimally required to conduct the study is used or disclosed to people outside Cleveland Clinic; however, people outside Cleveland Clinic who receive your information may not be covered by this promise.

You do not have to give this permission to use and give out your information; however you will not be able to participate in this research study without providing this permission by signing this consent form. The use and disclosure of your information has no expiration date.

You may cancel your permission to use and disclose your information at any time by notifying the Principal Investigator in writing**,** Michael Rosen MD. 9500 Euclid Avenue Cleveland, Ohio 44195. If you do cancel your permission to use and disclose your information, your participation in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in the study.

8. RESULTS

What will happen to the results of this study?
A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

If the results of this study are published, your identity will remain confidential.

9. QUESTIONS

Who do you call if you have any questions or problems?
If you have any questions, concerns or complaints about the research, or develop a research-related problem, contact Michael Rosen, MD at 216-445-3441 during regular business hours of 8am-5pm or you may contact the study coordinator at 216-445-3851. After hours please call the clinic operator at 216-444-2000 or 800-223-2273 and ask for the General Surgery Resident on call. If you have questions about your rights as a research subject, you should contact the Institutional Review Board at (216) 444-2924.

In the event of an emergency, dial 911 immediately. If you require emergency care, be sure to tell the emergency care provider about your participation in this study. Contact the study doctor or study staff as soon as possible.

10. VOLUNTARY PARTICIPATION

What are your rights as a research participant?
Taking part in this study is voluntary. You will be told of any new, relevant information from the research that may affect your health, welfare, or willingness to continue in this study. You may choose not to take part or may leave the study at any time. Withdrawing from the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to withdraw from the study you should discuss with your study doctor your decision to ensure a safe withdrawal.

You may refuse to be in or remove yourself from the study at any time without providing a reason and this will not affect the standard of care you receive. To withdraw from the study, tell the investigator you no longer want to participate by contacting Michael Rosen, MD at 216- 445-3441.

If you choose to withdraw from the study, you will be followed based on standard of care at your institution. The investigator or the Sponsor can remove you from the study without your approval. Possible reasons could be if participation appears to be medically harmful to you, if it is discovered that you do not meet eligibility requirements, or if the study is cancelled.

If you are removed from the study or if you decide to stop before completing the study, you may be asked (for your own safety) to undergo final study assessments, examinations, and laboratory tests.

11. SIGNATURES

Statement of Participant

I have read and have had verbally explained to me the above information and have had all my questions answered to my satisfaction. I understand that my participation is voluntary and that I may stop my participation in the study at any time. Signing this form does not waive any of my legal rights. I understand that a signed copy of this consent will be provided to me. By signing below, I agree to take part in this research study.

_____
Printed name of Participant

_____ _____
Participant Signature Date

Statement of Person Conducting Informed Consent Discussion

I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this research study.

_____
Printed name of person obtaining consent

_____ _____
Signature of person obtaining consent Date

Appendix 7

Patient Initials | | | | Subject number | | | | Site | /

CASE REPORT FORM

A Prospective Randomized Trial of Biologic Mesh versus Synthetic Mesh for the Repair of Complex Ventral Hernias.

Principal Investigator: _____
CRF Version Number: 01/14/2013.05

.

Completed by: _____
Signature Date

Physicians Signature _____
Date

Patient Initials | | | | Subject number | | | | Site | /

VISIT 1 (SCREENING) **INCLUSION CRITERIA**

Date of Assessment: __ __ / __ __ / __ __ __ __

(M M/ DD / YYYY)

The following criteria MUST be answered YES for participant to be included in the trial (except where NA is appropriate):		**Yes**	**No**
1.	The subject is ≥ 21 years of age	☐	☐
2.	Scheduled to undergo a planned open single staged reconstruction of a contaminated abdominal wall defect	☐	☐
3.	Ability to undergo general anesthesia	☐	☐
4.	Is willing and able to give informed consent	☐	☐
5.	Is this a clean-contaminated (Class 2) or contaminated (Class 3) case per Surgical Site Infection Risk Guidelines?	☐	☐
6.	Has an estimated parastomal hernia or midline defect size of ≥9 cm^2 by physical /or radiological exam.	☐	☐
7.	Can achieve midline fascial closure?	☐	☐
8.	Is subject willing to return for scheduled and required study visits?	☐	☐
If any of the above criteria is answered NO, the participant is NOT eligible for the trial and must not be included in the study. Please list reason(s) for ineligibility for screen failure on Participant Eligibility Review page.			

Completed by: _____
Signature Date

Physicians Signature _____
Date

Patient Initials ☐☐☐ **Subject number** ☐☐☐ **Site** ☐

VISIT 1 (SCREENING) **EXCLUSION CRITERIA**

Date of Assessment: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)

The following criteria MUST be answered NO for the participant to be included in the trial:		**Yes**	**No**
1.	Patients have a defect that the surgeon cannot achieve primary fascial apposition and requires a bridge of mesh.	☐	☐
2.	Is the patients BMI over 45?	☐	☐
3.	Is the patient Pregnant?	☐	☐
4.	Will undergo a laparoscopic hernia repair.	☐	☐
5.	Do they have a class 1 or 4 wound per Surgical Site Infection Risk Guidelines?	☐	☐
6.	Are they on immunosuppressant>10 mg of prednisone/day?	☐	☐
7.	Do they have a collagen vascular disorder?	☐	☐
8.	Is patient having a prior mesh removed due to a current active mesh infection? (A synthetic mesh that is not incorporated is exposed or has a chronic draining sinus with clear pus around the material. Does not include synthetic mesh incorporated in abdominal wall and not infected)	☐	☐
9.	Does the patient have Ascites?	☐	☐
10.	Are they in end stage renal (on hemodialysis) or pre-existing liver disease (Hepatitis B and C or Total Bilirubin >3.0)?	☐	☐
11.	Is the patient malnourished as defined by serum albumin<2.0?	☐	☐
12.	Do they have a smoking history within 1 month of surgery?	☐	☐
13	Does the patient have an objection to the implantation of porcine products?	☐	☐
14.	Is the subject participating in another clinical study?	☐	☐
If any of the above criteria is answered YES, the participant is NOT eligible for the trial and must not be included in the study. Please list reason(s) for ineligibility for screen failure on Participant Eligibility Review page.			

Completed by: _____
Signature Date

Physicians Signature_____
Date

Patient Initials ☐☐☐ **Subject number** ☐☐☐ **Site** ☐

VISIT 1 (SCREENING) **DEMOGRAPHIC DATA**

Date of Assessment: __ __ / __ __ / __ __ __ __
(MM/ DD / YYYY)

Participant Informed Consent:	
Date participant signed written consent form: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY)	**Does the patient meet inclusion/exclusion criteria?** **Yes**_____ **No**_____
Name of person obtaining informed consent: _____	

Demographic Data:				
Date of Birth: __ __ / __ __ / __ __ __ __ (MM / DD / YYYY) **Age:** _____**yrs**				
Ethnicity:				
Caucasian	Caucasian, not of Hispanic origin ☐	Hispanic ☐	American Indian or Alaskan Native ☐	
Black	African American ☐			
Asian/Pacific Islander	Asian/Pacific Islander ☐			
Other:	Specify:_____ _____			
Sex:	☐ Male ☐ Female			
Allergies: ☐ PCN List others: _____				

Completed by: _____
Signature Date

Physicians Signature_____
Date

Patient Initials ☐☐☐ **Subject number** ☐☐☐ **Site** ☐

VISIT 1 (SCREENING) **MEDICAL HISTORY**

Date of Assessment: __ __ / __ __ / __ __ __ __

(MM / DD / YYYY)

Has the patient had any relevant medical history?	☐ **No** ☐ **Yes,** Complete below		
Condition / illness	**Start date** (MM/DD/YYYY)	**Stop date** (MM/DD/YYYY)	**Or tick if ongoing at Screening Visit?**
	___/___/___	___/___/___	☐
	___/___/___	___/___/___	☐
	___/___/___	___/___/___	☐
	___/___/___	___/___/___	☐
	___/___/___	___/___/___	☐
	___/___/___	___/___/___	☐
	___/___/___	___/___/___	☐
	___/___/___	___/___/___	☐
	___/___/___	___/___/___	☐
	___/___/___	___/___/___	☐
	___/___/___	___/___/___	☐
	___/___/___	___/___/___	☐
	___/___/___	___/___/___	☐

Completed by: _____
Signature Date

Physicians Signature _____
Date

Patient Initials | | | | **Subject number** | | | | **Site** |

VISIT 1 (SCREENING) **SURGICAL HISTORY**

Date of Assessment: __ __ / __ __ / __ __ __ __

(MM / DD / YYYY)

Surgery	Date	Approach
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		
11.		
12.		
13.		
14.		

Diagnostic testing performed: Date: ____/_____/_____

☐ CT ☐ MRI ☐ Other (state) _____

Results:

_____
_____
_____
_____
_____

Completed by: _____
Signature Date

Physicians Signature_____
Date

Patient Initials ☐☐☐ Subject number ☐☐☐ Site ☐

VISIT 1 (SCREENING) **PHYSICAL EXAM**

Date of Assessment: __ __ / __ __ / __ __ __ __

(MM / DD / YYYY)

Was Physical Examination performed? ☐ **No** ☐ **Yes, Complete below**				
System	***Abnormal**	**Normal**	**Not done**	***If noted ABNORMAL, please provide brief description and comment if clinically significant or not (CS/NCS)**
General Appearance	☐	☐	☐	
Skin	☐	☐	☐	
Eyes, Ears, Nose & Throat	☐	☐	☐	
Head, Neck & Thyroid	☐	☐	☐	
Heart	☐	☐	☐	
Lungs	☐	☐	☐	
Chest (including breasts)	☐	☐	☐	
Abdomen	☐	☐	☐	
Extremities	☐	☐	☐	
Genitalia	☐	☐	☐	
Anorectal	☐	☐	☐	
Lymph Nodes	☐	☐	☐	
Muscular-Skeletal	☐	☐	☐	
Neurological	☐	☐	☐	
Others	☐	☐	☐	

Estimated Defect Size Width: _____ cm (>9cm) Length: _____ cm

Completed by: _____

Signature Date

Physicians Signature _____

Date

Patient Initials | | | | Subject number | | | | Site | |

Baseline VISIT 1 (SCREENING) **WOUND CLASSIFICATION**

Date of Assessment: __ __ / __ __ / __ __ __ __

(MM / DD / YYYY)

TABLE 1

Surgical Field/Wound Characterization	Description
Type 1 (Clean) **(Subject - not included in study)**	An uninfected operative wound in which no inflammation is encountered and the respiratory, alimentary, genital or uninfected urinary tracts are not entered. In addition, clean wounds are primarily closed and, if necessary, drained with closed drainage. Operative incisional wounds that follow nonpenetrating (blunt) trauma should be included in this category if they meet the criteria.
Type 2 (Clean-contaminated)	A operative wound in which the respiratory, alimentary, genital*, or urinary tracts are entered under controlled conditions and without unusual contamination. Specifically, operations involving the biliary tract, appendix, vagina, and oropharynx are included in this category, provided no evidence of infection or major break in technique is encountered. *Includes female and male reproductive tracts.
Type 3 (Contaminated)	A surgical field with any of the following: ➢ major breaks in sterile technique ➢ open, fresh, accidental wounds ➢ gross spillage from the gastrointestinal tract incisions with acute, nonpurulent inflammation
Type 4 (Dirty) **(Subject - not included in study)**	Includes old traumatic wounds with retained devitalized tissue and those that involve existing clinical infection or perforated viscera

INCLUDED IN STUDY: Type 2 (Clean-contaminated) and Type 3 (Contaminated), characterized wounds WILL BE INCLUDED in the study.

EXCLUDED FROM STUDY: Type 1 (Clean) and Type 4 (Dirty), characterized wounds will NOT be included in the study.

Check one

- O **Type 1 (Clean)**
- O **Type 2 (Clean-Contaminated)**
- O **Type 3 (Contaminated)**
- O **Type 4 (Dirty)**

Completed by: _____

Signature Date

Physicians Signature _____

Date

Patient Initials ☐☐☐ Subject number ☐☐☐ Site ☐

Baseline VISIT 1 (SCREENING) **VITAL SIGNS**

Date of Assessment: __ __ / __ __ / __ __ __ __

(MM / DD / YYYY)

Were Vital Signs performed?	☐ **No** ☐ **Yes,** Complete below
Blood Pressure : ____ ___ ___ / ___ ___ mmHg	**Oral Temperature:** ___ __. ___ **°C** **°F**
Pulse: ____ ___ ___ beats/min	**Respirations:** _____/min
Weight: _____(lbs) or _____ kg	**Height:** _____ inches or _____cm
BMI: _____**kg/m2**	

Risk Factors:

☐ Obesity ☐ Hypertension (requiring medication) ☐ Hyperlipidemia
☐ Smoker (active within 3 months of surgery) ☐ Ascites ☐ Dialysis (date) ___/___/_____
☐ Diabetes Mellitus (indicate): ☐ non-insulin therapy ☐ insulin ☐ diet controlled
☐ Prior Mesh Infection ☐ CHF ☐ Prior MI (date): __/__/____
☐ Previous cardiac surgery (date) __/__/____ ☐ Previous radiotherapy (date) ____/____/____
☐ PVD ☐ Stroke/CVA ☐ TIA ☐ HIV
☐ Cancer (date and type) __/__/____ _____
☐ COPD (indicate): ☐ chronic bronchitis ☐ emphysema
☐ Dyspnea (indicate): ☐ upon moderate exertion ☐ at rest
Serum Albumin (if known): ___.___(g/dl) **(Ref 3.4 to 5.0 g/dl)**

☐ Primary incisional hernia ☐ Recurrent ventral/incisional hernia
# of times previously repaired (exclude now) _____ ☐ Stoma present ☐ Urologic ☐ GI fistula
Location of hernia: _____ History of AW wound infection (date) __/__/____
☐ Non-healing open abdominal wound Started: ___/___/____
☐ Corticosteroid treatment ≤ 10mg/day (reason) _____
☐ Previously treated for MRSA (location and date) _____

Questionnaires completed: _____EQ-5D _____ HerQLes

Were photos completed: ☐Yes ☐ No If not why:_____

Comment: _____

Completed by: _____
Signature Date

Physicians Signature_____
Date

Patient Initials		Subject number		Site	

VISIT 1 (SCREENING) **SMOKING STATUS**

Date of Assessment: __ __ / __ __ / __ __ __ __
(MM / DD / YYYY)

Has the participant ever smoked? ☐No ☐Yes, Complete below		
☐	**Current Smoker**	**Participant's average daily use:** - Number of cigarettes : ___ ___ Packs: _____ - Number of cigars : ____ ___ - Number of pipes : ___ ___ **Smoked for ___ ___ years**
☐	**Former smoker**	**Smoked for ___ ___ years** **Date when smoking ceased: __ __ / __ __ / __ __ __ __** (MM / DD / YYYY) **When smoking, participant's average daily use:** - Number of cigarettes : ___ ___ Packs: _____ - Number of cigars : ____ ___ - Number of pipes : ___ ___

Completed by: _____
Signature Date

Physicians Signature_____
Date

Patient Initials				Subject number				Site	

VISIT 1 (SCREENING) **PARTICIPANT ELIGIBILITY REVIEW**

End of Screening Visit Checklist:			
		Yes	**No**
1.	**Does the participant satisfy the inclusion and exclusion criteria to date?**	☐	☐
2.	**Have all Screening Visit procedures been completed?**	☐	☐
3.	**Have the Medical History and Concomitant Medication pages been completed?**	☐	☐
4.	**Is the participant still willing to proceed in the trial?**	☐	☐

Participant's eligibility Investigator Sign-Off:	
Is the participant eligible to take part in the Clinical Trial? **PI's Signature**: _____ **Date** : __ __ / __ __ / __ __ __ __ (MM / DD / YYYY) **PI's Name:** _____	☐ Yes ☐ No, Please give reason for screen failure below
Reason(s) for screen failure:	
1.	
2.	
3.	

Completed by: _____
Signature Date

Physicians Signature_____
Date

Patient Initials | | | | Subject number | | | | Site | |

Study Procedure: SURGERY

Date of Procedure: __ __ /__ __/__ __ __ __ Surgeon: _____

Preoperative Regimen:

Was bowel prep performed? _____ Yes _____ No
Agent:_____

Were preoperative antibiotics given? Yes/No Type/Dose: _____

Time started: ___:___Time discontinued: ___:___ Was this within 60 min prior to incision?
Yes_____ No_____

Skin preparation: (check all that apply)
☐ Chlorhexadine ☐ Duraprep
☐ Iodine impregnated skin barrier ☐Steri drape

Does patient have stoma: Yes _____ No _____ Was it oversewn: Yes _____ No _____

Patient temperature: **___ __. ___ °C °F**

ASA score: _____ Epidural catheter: _Yes ____ _No _____

In the OR:

Procedure Start Time: _____ End Time: _____= Total: _____/min

Abdomen entered via: ☐ Midline laparotomy ☐ Transverse incision
☐ Laparotomy at lateral edge of graft if bowel were covered w/split skin graft
☐ Other (state) _____

Status of skin coverage over defect:
☐ Type I: Intact/stable skin ☐ Type II: Unstable/absent skin

Adhesions: ☐ No adhesions ☐ Yes-adhesiolysis required
- Abdominal wall to ☐ omentum ☐ colon
- Mesh (if present) to ☐ ileum ☐ colon
- Other (state) _____ to _____

Completed by: _____
Signature Date

Physicians Signature_____
Date

Patient Initials ☐☐☐ Subject number ☐☐☐ Site ☐

STUDY PROCEDURE: SURGERY

Acceptable Concomitant Procedures:

☐ Bowel resection ☐ GI fistula repair ☐ Adhesiolysis

☐ Cholecystectomy ☐ Appendectomy ☐ Panniculectomy closure

☐ Diverting ostomy/or ostomy reversal ☐ Gynecological procedure (hysterectomy)

☐ Urological procedures ☐ Cystectomy ☐ Creation of stoma

☐ Removal of non infected mesh Type: _____

☐ Iatrogenic injury: _____

☐ Other _____

Unacceptable Concomitant Procedures:

Are you removing mesh that is not incorporated and actively infected ☐ Yes ☐ No

Hernia/Wound Characterization:

Time: _____am/pm

Check one

- O **Type 1 (Clean)**
- O **Type 2 (Clean-Contaminated)**
- O **Type 3 (Contaminated)**
- O **Type 4 (Dirty)**

Does patient still meet inclusion criteria: Yes_____ No _____ (if no, check below)

☐ Hernia defect <9 cm when measured intraoperatively
☐ Is Type 4 wound class ☐ Mesh cannot be placed in retro-rectus position
☐ Requires bridging to achieve repair/fascia cannot be closed

Completed by: _____
Signature Date

Physicians Signature_____
Date

Patient Initials ☐☐☐ Subject number ☐☐☐ Site ☐

STUDY PROCEDURE: SURGERY

Size of defect (cm) (≥ 9cm) width _____cm Size of defect length_____ cm

Incisional hernia location: ☐ Upper midline/ epigastric ☐ Central/umbilical
☐ Upper quadrant/hypochondriac R /L ☐ Central /Lumbar R /L
☐ Lower midline/hypogastric/pubic ☐ Lower quadrant/iliac R/L

Abdominal Wall Reconstruction:

Muscle Release Performed

Midline fascia reapproximated Yes ☐ No ☐
Posterior rectus sheath separated from rectus abdominus muscle Yes ☐ No ☐
Transversus abdominis muscle released Yes ☐ No ☐

External oblique release: Yes ☐ No ☐

Endoscopic release Yes _____ No ____
Open release Yes _____ No ____
_____Perforator sparing release Yes _____ No ____
Bilateral Release Yes _____ No ____

Outcome of muscle release:

Posterior sheath reapproximated in midline Yes ____ No ____
Vicryl mesh utilized to close posterior sheath Yes ____ No ____

Were intraoperative cultures obtained? Yes ____ No ____
Site: _____ Time: ____:_____
Results:
_____
_____
Antimicrobial sensitivity to:
_____
_____
Was pulse lavage antibiotic irrigation (3 liter bag with Gentamycin (240mg), Ancef (3gm), and Bacitracin (500mg) completed: Yes _____No____
Only pulse lavage Yes ____ No_____

Completed by: _____
Signature Date

Physicians Signature_____
Date

Patient Initials ☐☐☐ Subject number ☐☐☐ Site ☐

STUDY PROCEDURE: SURGERY

Patient Randomized to (check one):

- O Strattice mesh (biologic)
- O Soft Tissue Mesh (synthetic) Randomization Envelope Number _____

Mesh placed:

- O Retro-Rectus Mesh Size: W_____ cm L_____ cm
- O Intra-Peritoneal
- O Extra-Peritoneal Lot # _____
- O Other: _____ Expiration Date: _____

Overlap of midline fascial closure:
☐ 5cm overlap on all sides or ☐ ____ cm overlap

Suture/ fixation of the device (and size): ☐ PDS ____ ☐ Maxon ____
Number of stitches/sutures _____

Midline fascia closed: Yes ☐ No ☐
Midline fascial closure suture: ☐ Maxon _____ ☐ PDS _____
Suturing method: ☐ Interrupted ☐ Running ☐ Other (state) _____

Any Adverse Events/Complications: Yes/No (If yes fill out adverse event form)

Completed by: _____
Signature Date

Physicians Signature_____
Date

Patient Initials | | | | Subject number | | | | Site | |

STUDY PROCEDURE: SURGERY

Date of Procedure: ___ ___/ __ __/ ___ ___ ___ ___

Estimated Blood Loss: _____ cc

Blood transfusion required Yes _____ No_____

Drain(s) placed: Number of drains: _____

Location:	Position (circle one):			
#1_____	Right	Center	Left	N/A
#2 _____	Right	Center	Left	N/A
#3 _____	Right	Center	Left	N/A
# 4 _____	Right	Center	Left	N/A

Body Temperature on arrival to recovery: **___ __. __ °C °F**

Intraoperative fluids administered: (see concomitant medication log)

Comments:

_____
_____
_____
_____
_____
_____

Completed by: _____
Signature Date

Physicians Signature_____
Date

Patient Initials ☐☐☐ Subject number ☐☐☐ Site ☐

Study visit # Discharge

Date of Visit: __/__/____ (MM / DD / YYYY) **Date of Discharge:** __/__/____ (MM / DD / YYYY)

Date of Admission: _____Hospital Length of Stay: _____days (OR to discharge)

Visit Checklist:

		Yes	No
1.	**Have there been any new Adverse Events?** (If yes, please record on Adverse Events Form)	☐	☐
2.	**Have there been any changes in Concomitant Medications?** (If yes, please record in Concomitant Medications Log)	☐	☐

Date first started passing gas: ___/___/____
Date of first bowel movement: ___/___/_____

Did patient have an NG tube placed? Yes ____ No_____
Date removed: ____/____/____

Have dressings been removed from the incision? Yes_____ No_____
Were antibiotics discontinued within 24hours of surgery? Yes _____ No _____-
If no why? _____
Were antibiotics restarted? Yes ___ No ___ Name: _____Duration:_____

(If antibiotics restarted please fill out separate infections disease adverse event form)

DRAINS

Drain	Amount drainage (ml)	Hours of drainage	Drain Character	Date of Removal
1				
2				
3				
4				

Completed by: _____
Signature Date

Physicians Signature_____
Date

Patient Initials ☐☐☐ Subject number ☐☐☐ Site ☐

Study visit # post op

Date of Visit:	__ __ / __ __ / __ __ __ __ (MM / DD / YYYY)	☐ **2week** ☐ **6 week** ☐ **6 month** ☐**12month** ☐ **24 month** ☐ **Other**_____

Evaluation of Inflammatory Response

Patient temperature: ___ __. ___ **°C** **°F**
Fever? ☐Yes ☐ No

Incision Line:

Is the incision line:

Closed? ☐ Yes ☐ No
Necrotic? ☐ Yes ☐ No
Draining? ☐ Yes ☐ No

Localized pain or tenderness? ☐ Yes ☐ No
Any fluctuance? ☐ Yes ☐ No
Erythema? ☐ Yes ☐ No

Has the wound dehisced? ☐ Yes ☐ No

Is there a hematoma? ☐ Yes ☐ No

If yes, ☐ Mild ☐ Moderate ☐ Severe

Was it aspirated? ☐ No ☐ Yes, Volume: _____ mls

Is there a seroma? ☐ Yes ☐ No

If yes, ☐ Self Limiting, requiring no intervention

☐ Aspirated Volume: _____ mls

Completed by: _____
Signature Date

Physicians Signature_____
Date

Patient Initials ☐☐☐ Subject number ☐☐☐ Site ☐☐☐☐☐☐☐☐☐☐

Study visit # post op

Date of Visit:	__ __ / __ __ / __ __ __ __ (MM / DD / YYYY)	☐ **2week** ☐ **6 week** ☐ **6 month** ☐**12month** ☐ **24 month** ☐ **Other**_____

Is there a wound infection? ☐ Yes ☐ No
(If yes, fill out an Infectious Disease Form)

Has the prior wound infection resolved? ☐ Yes ☐ No ☐ N/A

Were cultures obtained today or since the last visit? ☐ Yes ☐ No
Date: ___/___/____
Results:_____
_____
_____

Have antibiotics been started? ☐ Yes ☐ No ☐ N/A
(If yes, fill out on concomitant medication and Infectious Disease forms)

Bulge at site? ☐ Yes ☐ No
Palpable defect? ☐ Yes ☐ No

Was a CT Scan performed? ☐ Yes ☐ No Date: ___/___/____

Is there evidence of recurrent hernia? ☐ Yes ☐ No

If yes, size of defect width _____cm length_____ cm

Comment:_____
_____
_____
_____

Completed by: _____
Signature Date

Physicians Signature_____
Date

Patient Initials | | | | Subject number | | | | Site | |

Study visit # post op

Date of Visit:	__ __ / __ __ / __ __ __ __ (MM / DD / YYYY)	☐ 2week ☐ 6 week ☐ 6 month ☐12month ☐ 24 month ☐ Other_____

DRAINS

Drain	Amount drainage(ml)	Hours of drainage	Drain Character	Date of Removal
1				
2				
3				
4				

		Yes	No
1.	**Have there been any new Adverse Events?** (If yes, please record on Adverse Events Form)	☐	☐
2.	**Was this a Serious Adverse Event?** (please complete on SAE/UADE form)	☐	☐
3.	**Have there been any changes in Concomitant Medications?** (If yes, please record in Concomitant Medications Log)	☐	☐
4.	**Did patient complete the EQ-5D and HerQles questionnaires?**	☐	☐

☐ **Additional Surgery required-(Form A completed and attached)**

Have any wound related procedures been performed? Yes _____ No_____

If yes, please describe

Procedure	Description	Date Performed	Done to treat AE?

Completed by: _____

Signature Date

Physicians Signature_____

Date

Patient Initials ☐☐☐ Subject number ☐☐☐ Site ☐

Post operative Infectious Disease Form

☐ At discharge ☐ 2 week ☐ 6 week ☐ 6 month ☐ 12 month ☐ 24 month ☐ Other (state)_____

Check the box that applies:

☐ **Wound-Cellulitis**
An acute, diffuse infection of the skin and soft tissues

☐ Has an abrupt onset of redness, swelling, pain, or heat and pain in the infected area.
☐ Antibiotic started Duration: _____ Type: _____

☐ **Superficial incisional SSI**
Infection within 30 days after OR procedure AND involves only skin and subcutaneous tissue AND patient has at least ONE of the following: (check all that apply)

☐ a. Purulent drainage from superficial incision.
☐ b. Organism isolated from an aseptically obtained culture of fluid or tissue from the superficial incision.
☐ c. superficial incision was deliberately opened by a surgeon and is culture positive or not cultured and has at least one of the following signs or symptoms: pain or tenderness; localized swelling, redness, or heat. A culture negative finding does not meet this criterion.
☐ d. Diagnosis of superficial incisional SSI by the surgeon or attending physician.

NOTE:
a. Do NOT report stitch abscess (minimal inflammation and discharge confined to suture penetration site) as an infection
b. Do NOT report a localized stab wound or pin site infection as SSI.
c. "Cellulitis" by itself does NOT meet criteria for superficial incisional SSI
d. If infection extends into the fascial and muscle layers report as a deep incisional SSI.

Completed by: _____
Signature Date

Physicians Signature_____
Date

Patient Initials ☐☐☐ Subject number ☐☐☐ Site ☐

Post operative Infectious Disease Form-page 2

☐ At discharge ☐ 2 week ☐ 6 week ☐ 6 month ☐ 2 week ☐ 6 week ☐ 6 month ☐ 12 month ☐ 24 month ☐ Other (state)_____

☐ Deep Incisional SSI

Infection occurs within 30 or 90 days after the operative procedure AND involves deep soft tissues (e.g. fascial and muscles layers) of the incision AND patient has at least ONE of the following: (check all that apply)

- ☐ a. Purulent drainage from the deep incision.
- ☐ b. a deep incision spontaneously dehisces or is deliberately opened by a surgeon and is culture-positive or not cultured and the patient has at least one of the following signs or symptoms: fever (>38 C), or localized pain or tenderness. A culture-negative finding does not meet this criterion.
- ☐ c. an abscess or other evidence of infection involving the deep incision is found on direct examination during invasive procedure, or by histopathologic examination or imaging test..
- ☐ d. diagnosis of a deep incisional SSI by a surgeon or attending physician.

NOTE: Classify incisions that have both a superficial and deep incision as deep incisional SSI.

☐ Organ space SSI

Infection occurs within 30or 90 days after the operative procedure AND infection involves any part of the body, excluding the skin incision, fascia or muscle layers that is opened or manipulated during the operative procedure, AND patient has at least ONE of the following: (check all that apply)

- ☐ a. Purulent drainage from a drain that is placed into the organ/space
- ☐ b. organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space
- ☐ c. an abscess or other evidence of infection involving the organ/space that is found on direct examination, during invasive procedure, or by histopathologic examination or imaging testing.
- ☐ d. diagnosis of an organ/space SSI by a surgeon or attending physician and meets at least one criterion for a specific organ/space infection site as listed in NHSN.

Completed by: _____
Signature Date

Physicians Signature_____
Date

Patient Initials ☐☐☐ Subject number ☐☐☐ Site _____

Adverse Events
(One adverse event per form)

Date of Adverse Event: ____ / ____/ _____ (mm/dd/yyyy)
Date Adverse Event Reported: ____/_____/_____ (mm/dd/yyyy)
Resolved Date: _____/_____/_____ (mm/dd/yyyy)

Description of Adverse Event:

☐ Bleeding ☐ Infection- Site: _____ Type: _____

☐ Hematoma ☐ Bowel obstruction ☐ Ileus ☐ Fistula

☐ Wound dehiscence ☐ Flap necrosis ☐ Seroma ☐ Hernia recurrence

☐ Other (specify): _____

Was this adverse event thought to be related to procedure?

☐ (0) Definitely ☐ (1) Probably ☐ (4) Not assessable

☐ (2) Possibly ☐ (3) Not related

Was this adverse event thought to be related to device?

☐ (0) Definitely ☐ (1) Probably ☐ (4) Not assessable

☐ (2) Possibly ☐ (3) Not related

Intensity:

☐ (0) Mild ☐ (1) Moderate ☐ (2) Severe

Action Taken:

☐ None ☐ Surgical _____

☐ Interventional ☐ Medical

Other: _____

Was this Serious? ☐ Yes ☐ No

Outcome:

☐ (0) Resolved with no sequelae

☐ (1) Resolved with sequelae (specify): _____

☐ (2) Ongoing

☐ (3) Expired

☐ (4) Unknown

Completed by: _____
Signature Date

Physicians Signature_____
Date

Patient Initials ☐☐☐ Subject number ☐☐☐ Site ☐

ADDITIONAL SURGERY- FORM A

Date of Additional Surgery (mm/dd/yyyy): ___ ___/ __ __/ ___ ___ ___ ___
(Please notify Dr. Michael Rosen if additional surgery required)

Investigator/Surgeon: _____

Reason for Additional Surgery:

☐ Diagnostic ☐ Recurrent hernia

☐ Complication (note: also complete an adverse event form)

☐ Other (state)_____

Operative Procedure Performed:

☐ Debridement ☐ Hernia repair ☐ Mesh replaced (name of device)

_____

☐ Previous mesh removed (state reason) _____

☐ Other (state)_____

Gross Observations:

Mesh appearance:

☐ Normal ☐ Not visible ☐ Signs of Infection (fill out IDF form)

☐ Other (describe)

_____

_____

Tissue appearance at the device site:

☐ Normal ☐ Inflamed ☐ Other (describe) _____

☐ No Adhesions ☐ Yes-adhesiolysis required - (location)

_____

_____

Completed by: _____
Signature Date

Physicians Signature_____
Date

Patient Initials | | | | Subject number | | | | Site | |

TRIAL COMPLETION

Did participant complete the trial?	☐ **Yes,** Please provide **date of last visit**: __ __ / __ __ __ / 2 0 __ __ (MM / DD / YYYY) ☐ **No,** Please provide **date of withdrawal** and complete below: __ __ / __ __ __ / 2 0 __ __ (MM / DD / YYYY)

Early Withdrawal: please tick most appropriate reason for participant not completing the trial:

☐ **Adverse Events related:** please state related AE: _____

☐ **Participant's decision, specify: _____**

☐ **Investigator's decision, specify: _____**

☐ **Sponsor's decision**

☐ **Lost to follow up**

☐ **Other, specify: _____**

Completed by: _____
Signature Date

Physicians Signature_____
Date

Patient Initials | | | | **Subject number** | | | | **Site** | | Page _____of_____

ADVERSE EVENTS LOG

AE No	Event Name (Please give Diagnosis if known)	Start date (MM/DD/YYYY)	Stop date (MM/DD/YYYY)	Serious? If serious, please completed a JBRU SAE form	Con-comitant Medication given	Severity 0 - Mild 1- Mode-rate 2 - Severe	Relationship to Study device 0 - Definitely 1 - Probably 2 - Possibly 3 - Not related 4 - Not assessable	Relationship to Study procedure 0 - Definitely 1 - Probably 2 - Possibly 3 - Not related 4 - Not assessable	Outcome 0 – Resolved no sequelae 1- Resolved with sequelae 2 – Ongoing 3- Expired 4-Unknown
1		___/___/___	___/___/___	☐ No ☐ Yes	☐ No ☐ Yes				
2		___/___/___	___/___/___	☐ No ☐ Yes	☐ No ☐ Yes				
3		___/___/___	___/___/___	☐ No ☐ Yes	☐ No ☐ Yes				
4		___/___/___	___/___/___	☐ No ☐ Yes	☐ No ☐ Yes				
5		___/___/___	___/___/___	☐ No ☐ Yes	☐ No ☐ Yes				
6		___/___/___	___/___/___	☐ No ☐ Yes	☐ No ☐ Yes				

I have reviewed the AEs on this log and have assessed them for seriousness, causality, severity and outcome and confirm that, to the best of my knowledge, it accurately reflects the study information obtained for this participant

PI signature _____ _____ **Date:**_____ ☐ **Please check box if this is the last page used**

Completed by: _____

Name Signature Date

Patient Initials | | | | Subject number | | | | Site | |

Page _____of______

ADVERSE EVENTS LOG (CONTINUATION PAGE)

AE No	Event Name (Please give Diagnosis if known)	Start date (MM/DD/YYYY)	Stop date (MM/DD/YYYY)	Serious? If serious, please completed a JBRU SAE form	Concomitant Medication given	Severity 0 - Mild 1- Moderate 2 - Severe	Outcome 0 - Resolved 1- Resolved with sequelea 2 - Not resolved	Relationship to Study procedure 0 - Definitely 1 - Probably 2 - Possibly 3 - Unlikely 4 - Not related 5 - Not assessable
__		____/____/____	____/_____/____	☐ No ☐ Yes	☐ No ☐ Yes			
__		____/_____/____	____/_____/____	☐ No ☐ Yes	☐ No ☐ Yes			
__		____/_____/____	____/_____/____	☐ No ☐ Yes	☐ No ☐ Yes			
__		____/_____/____	____/_____/____	☐ No ☐ Yes	☐ No ☐ Yes			
__		____/_____/____	____/_____/____	☐ No ☐ Yes	☐ No ☐ Yes			
__		____/_____/____	____/_____/____	☐ No ☐ Yes	☐ No ☐ Yes			

I have reviewed the AEs on this log and have assessed them for seriousness, causality, severity and outcome and confirm that, to the best of my knowledge, it accurately reflects the study information obtained for this participant

PI signature_______________________________ **Date:**_________________________ ☐ **Please check box if this is the last page used**

Completed by: ____

Name Signature Date

Patient Initials | | | | Subject number | | | | Site | | Page _____of_____

CONCOMITANT MEDICATIONS LOG

Has the participant used any Concomitant Medications? ☐ **No** ☐ **Yes,** Complete below

CM No.	Medication name (Record <specify Generic or Brand> name)	Start date (MM/DD/YYYY)	Stop date (MM/DD/YYYY)	Or tick if ongoing at end of study?	Reason for use (Enter related AE diagnosis, or other reasons for use, e.g. Prophylaxis)	Dose (Units)	Route	Frequency
1.		___/___/___	___/___/___	☐				
2.		___/___/___	___/___/___	☐				
3.		___/___/___	___/___/___	☐				
4.		___/___/___	___/___/___	☐				
5.		___/___/___	___/___/___	☐				
6.		___/___/___	___/___/___	☐				
7.		___/___/___	___/___/___	☐				

I have reviewed the this log and confirm that, to the best of my knowledge, it accurately reflects the study information obtained for this participant

PI signature_____ **Date:**_____ ☐ **Please check box if this is the last page used**

Completed by: _____

Name Signature Date

Patient Initials | | | | Subject number | | | | Site | | Page _____of_____

CONCOMITANT MEDICATIONS LOG (CONTINUATION PAGE)

CM No.	Medication name (Record Generic name)	Start date (MM/DD/YYYY)	Stop date (MM/DD/YYYY)	Or tick if ongoing at end of study?	Reason for use (Enter related AE diagnosis, or other reasons for use, e.g. Prophylaxis)	Dose (Units)	Route	Frequency
__.		___/____/____	___/____/____	☐				
__.		___/____/____	___/____/____	☐				
__.		___/____/____	___/____/____	☐				
__.		___/____/____	___/____/____	☐				
__.		___/____/____	___/____/____	☐				
__.		___/____/____	___/____/____	☐				
__.		___/____/____	___/____/____	☐				
__.		___/____/____	___/____/____	☐				

I have reviewed the this log and confirm that, to the best of my knowledge, it accurately reflects the study information obtained for this participant

PI signature_____ **Date:**_____ ☐ **Please check box if this is the last page used**

Completed by: _____
Name Signature Date

Patient Initials | | | | Subject number | | | | Site | |

Page

PRINICIPAL INVESTIGATOR'S SIGN OFF

Principal Investigator's Signature Statement:	
I have reviewed this CRF and confirm that, to the best of my knowledge, it accurately reflects the study information obtained for this participant. All entries were made either by myself or by a person under my supervision who has signed the Delegation and Signature Log.	
Principal Investigator's Signature: _____ **Principal Investigator's Name:** _____	**Date of Signature**: __ __/ __ __ / __ __ __ __ (MM / DD / YYYY)

MONITORING PLAN

Table of Contents

Abbreviations

AE	Adverse Event
CRF	Case Report Form
FDA	Food and Drug Administration
GCP	Good Clinical Practice
ICF	Informed Consent Form
ICH-GCP	International Conference on Harmonization -Good Clinical Practice
IEC	Independent Ethics Committee
IRB	Institutional Review Board
PI	Principal Investigator
SAE	Serious Adverse Event
SD	Source Documents
UADE	Unanticipated Adverse Device Effect

1.0 Introduction

This Monitoring Plan should be used as a guide while monitoring at an investigational site. The following is a list of the minimum criteria and does not replace an understanding of, or adherence to, the requirements contained in the approved protocol, any possible amendment(s) or numbered memo(s). The monitoring group will abide by the Code of Federal Regulations, International Conference on Harmonization-Good Clinical Practice (ICH-GCP) and any applicable local regulations, as well as the Sponsor's Standard Operating Procedures (SOP) for monitoring the trial. In the event of a conflict between this document and a SOP, this document supersedes the SOP.

2.0 Project Identification

- ***Project Description:*** A Prospective Randomized Trial of Biologic Mesh versus Synthetic Mesh for the Repair of Complex Ventral Hernias.
- ***Study Population:*** Patients undergoing open ventral hernia repair for clean-contaminated and contaminated abdominal wall hernias
- ***Study Arms:*** Davol Bard Soft Mesh vs. Lifecell Strattice Mesh
- ***Total Number of Subjects:*** 250 (100 at Cleveland Clinic)
- ***Follow-Up Time Points:*** 1 Month, 6 Months, 12 Months, and 24 Months
- ***Duration of Subject Follow Up:*** 24 Months
- ***Planned Number of Sites to be Monitored:*** 4
- ***Sponsor-Investigator:*** Michael Rosen, MD

3.0 Initiation Visit

Please note that remote monitoring is to be used for non-Cleveland Clinic sites. Thus, the word "visit" will be used in this document to describe both an in-person monitoring visit and a remote monitoring session. The tasks to be completed remain the same.

After a site has received regulatory approval and the site agreement is signed and executable, an initiation visit may be scheduled with the site. The major goal of such a visit is to verify that personnel at the clinical site understand their obligations during the clinical trial, as required by federal regulations and ICH-GCP as well as study plans and procedures. This may include, but not be limited by, discussions related to PI and Coordinator responsibilities during the conduct of the trial, inclusion/exclusion criteria, definitions of AE/SAE/UADE, AE/SAE/UADE reporting procedures, regulatory obligations, appropriate use of investigational products and their accountability, the informed consent process, and CRF completion instructions. A tour of the facility may also be requested to ensure it is adequate to conduct the study. This may include, but not be limited to, the emergency department, study drug/device storage area, monitoring areas; CRF and study supply storage areas.

4.0 Frequency of Monitoring

The first regular monitoring at Cleveland Clinic is to occur within 90 days of the first enrolled subject. The primary goal of the clinical monitoring is to assure the study is conducted in compliance with ICH-GCP, ensure subject safety, and validate clinical data against source documents. SDV will be performed on the third randomized subject. Site monitoring should be arranged to suit the schedules of the monitor and site staff. Confirmation by email will outline the date, time and expectations of the monitoring. It will also include but not be limited to information pertaining to the visit i.e., CRFs to be completed for monitoring, SDs to be available for review, outstanding items from the previous visit, if applicable, to be addressed, etc.

For other study sites that were active prior to the study transition to Cleveland Clinic, the first visit is to occur within 180 days, or upon enrollment of the next "tenth" subject, e.g., subject 10, 20, 30…)

Subsequent visits will occur for each 10 subjects enrolled.

Additional monitoring could be triggered by sponsor request, unexpected enrollment rates, unacceptable number of queries and/or protocol violations.

5.0 Monitoring Activities

- Review of all original signed ICFs for completeness and accuracy, including review of the version signed.
- Source verify key sections of selected CRFs.
- Verify compliance with current regulations and GCP guidelines.
- Review all inclusion and exclusion criteria, SAEs/UADEs and endpoints for each 10^{th} subject.
- Verify protocol compliance and note any issues for follow-up with the site.
- Verify appropriate subjects are enrolled in the study at the expected accrual rate.
- Verify appropriate drug/device accountability; drug/device storage and handling including review of the drug/device accountability forms.
- Verify acceptability of facilities and equipment.
- Review the Signature and Delegation Logs, Subject Identification Logs, Enrollment Logs and Screening Logs.
- Verify that any new staff have been appropriately trained and have signed a Training Log.
- Facilitate data query resolution.
- Verify timely reporting and follow up of AEs, SAEs, UADEs, and any protocol deviations/violations.
- Verify submission of any SAE/UADE to Sponsor, Institutional Review Board, FDA and/or any other applicable authority as required by the policies and regulations of the various groups
- Review of site regulatory files and IRB communication.
- Review to verify that blind was maintained

6.0 Contacts and Documentation

The site staff should be contacted by email every three months to ascertain any problems at the site and to check their study status. These contacts should be documented and emails should be forwarded to the Sponsor's study coordinator for filing.

7.0 Case Report Form Completion

Only site staff listed on the Signature and Delegation Log are authorized to enter data or make corrections to the database. Only physicians listed on the FDA Investigator Agreement and Site Delegation Log are allowed to sign paper CRFs/DCFs. CRFs must be completed and submitted within one week of the study visit. Sites using their electronic medical records as source may elect to forego paper CRFs, directly transcribing from the EMR to the RedCap database.

CRF review will include review for legibility, completeness and consistency with source documents. CRFs should be completed on all subjects that have been randomized. Ancillary CRF pages will only be completed and submitted if applicable, otherwise they will remain blank and will not be submitted.

8.0 Source Document Verification

SDV is the process of comparing data recorded in the database to the data contained in the SD. Source documents may include but not be limited to subject medical history, current hospitalization examinations, chart notes, lab reports, x-rays and ECGs. **Please note for subjects selected for SDV, monitors must verify that all data on the CRF is backed up by source documentation at the site in accordance to the monitor plan.** The subject's record will be screened for relevant data that is not captured in the CRF (e.g. verifying that no AE/SAE/UADEs and /or other endpoints are missed). For this study SDV will occur during monitoring and will be completed as follows:

Verification of the following for each 10th subject enrolled*:*

- Informed Consent
- SAEs/UADEs
- Inclusion/Exclusion criteria
- Key Data Elements (see attached blank CRFs with key fields highlighted)

In the process of verifying the CRF data, the monitor compares that data with the medical records, lab reports, and other source records.

Where routine office medical records or other study data are directly recorded in a computer system, the site must provide a signed and dated hard copy or electronic scanned copy for use as source documentation. This copy must be retained at the study site.

CRFs forwarded for remote monitoring purposes may be de-identified, although the monitor may ask that relevant dates not be obscured. The subject ID number should be written on each page, to aid in identification.

An excessive number of CRF discrepancies at the site will prompt review of three subjects in addition to those planned.

9.0 CRF Retrieval

Subject records will be requested as needed by the monitor prior to monitoring. Certified copies—or scans thereof—of source documents are to be provided to the monitor for review.

The preferred method of transmission is secure email, but any HIPAA-compliant means of transfer is permissible, as determined by site policies and procedures.

10.0 Informed Consent Form Process

- Verify that the appropriate IRB or Independent Ethics Committee (IEC) has approved the Informed Consent document in use.
- Verify that the appropriate, approved Informed Consent document as approved by the IRB/IEC was signed and dated by the subject or legal representative and by the investigator or his/her designee prior to any study procedure being performed.

- Verify all original signed ICFs are filed at the study site and that they are available for review.
- Verify that all subjects consented, have received a copy of the ICF.
- Verify that the informed consent process is documented in the source records.

11.0 Inclusion/Exclusion Criteria

- Verify that all subjects are eligible to participate in the trial based on the protocol's inclusion and exclusion criteria.
- Randomization date, time and assigned number will be confirmed for all subjects.

12.0 Regulatory Document Binder

- The monitor will verify that any staff changes are reflected on a new Investigator Agreement and on the Signature and Delegation log, and are submitted to the site's IRB/EC.
- The monitor will verify any changes or amendments to the protocol and/or to the informed consent and any AE/SAE/UADE are reported to the IRB/EC, as appropriate.
- The monitor will verify that the site submits required study progress reports to the IRB/EC, and must make sure that IRB/EC approval for the site's participation in the study is current.
- The monitor will verify that all training documents for site personnel have been updated.
- At the end of the study, the monitor will verify that the site submits a final report to their IRB/EC.

13.0 Device Accountability

The monitor will perform accountability of the trial devices at each monitoring visit. The monitor will verify that correct study device was administered by reviewing the accountability log, operative notes, and study randomization table.

14.0 Randomization

The monitor will review randomization procedures in conjunction with device accountability, as described above.

15.0 Return and Destruction

In the event that study device(s), once removed from their packaging, cannot be used, the sites will destroy study them according to standard procedures. The destruction records will be reviewed during each monitoring.

16.0 Monitoring Visit Reports

A final visit report outlining details of the visit, deficiencies or outstanding issues will be sent to the site within ten business days of the visit.

17.0 Termination Visit Activities

A termination visit should occur within 90 business days after completion of all study-related activity. A confirmation letter outlining the termination visit activities will be sent to the site to be visited 30 days prior to the visit.

If no subjects were enrolled at the site, the termination visit may be completed by telephone and/or email.

The monitor will perform the following tasks during the termination visit:

- Verify the IRB/EC/IEC is informed of study closure in writing. *This may occur subsequent to the monitoring, depending on site procedures.*
- Facilitate the resolution of outstanding Data Clarification Forms (DCFs)
- Perform final device accountability
- Review the Regulatory Document Binder and ensure that all necessary regulatory documents are in the sponsor's possession.
- Verify proper return/disposal of study supplies
- Review record retention and regulatory responsibilities with the Investigator and study staff