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## Care Bundle Approach to Minimizing Infection Rates after Neurosurgical Implants for Neuromodulation: A Single Surgeon Experience

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### Abstract

**Introduction:** Implant-related infections carry a high morbidity. Infectious rates for neuromodulation implants range from 1–9% for DBS, 0–10% for SCS systems, and 3–15% for IT pump systems. Meanwhile, studies on care bundles report infection rate reduction to 1.0% for SCS, and 0.3% for cardiac implants. Herein, we evaluate the effectiveness of an infection prevention bundle (IPB) in minimizing infections after surgeries for neuromodulation implants.

**Methods:** An IPB focused on pre-operative checklists, screening questionnaires, MRSA/MSSA decolonization, weight-based antibiotic prophylaxis, strict draping and surgical techniques, and wound care education; was implemented in our Functional Neurosurgery division in April 2015. We retrospectively reviewed all surgeries for implantation or replacement of SCS, DBS, and IT pump system components from March 2013 to October 2017. Subjects were divided into pre-IPB and post-IPB groups. All cases were performed by a single surgeon. Each surgical site was considered a unique surgical case. Infection rates were calculated for pre-IPB and post-IPB groups.

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**Results:** A total of 688 patients underwent 1,161 unique surgical cases (222 DBS electrodes, 419 IPG, 203 SCS, 317 IT pumps) during the study period. There were 546 pre-IPB and 615 post-IPB surgical cases. Pre-IPB infection rates were: 0%, 1.3%, and 8.7% for SCS, DBS, and IT pumps, respectively. Post-IPB infection rates were: 0%, 0.3%, and 1.8% for SCS, DBS, and IT pumps, respectively.

**Conclusions:** Implementation of a standardized IPB approach reduced the number of infections for all studied neuromodulation implants. This approach can be adopted within any specialty to potentially decrease the incidence of implant-related infections.

### Keywords

Bundle; checklists; deep brain stimulation (DBS); intrathecal (IT) pumps; spinal cord stimulation (SCS); surgical implant; surgical site infection (SSI)

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### Introduction:

Implant-related infections carry a high morbidity. Common complications associated with implant-related surgeries include hemorrhage, infection, and hardware failure. Infectious rates for neuromodulation implants range from 1–9% for DBS,<sup>1–8</sup> 0–10% for SCS systems,<sup>9, 10</sup> and 3–15% for IT pump systems.<sup>11–13</sup> Meanwhile, studies on care bundles report reduction in infection rates for SCS from 10.4% to 1.0%,<sup>9</sup> and rates as low as 0.3% for cardiac implants.<sup>14–16</sup>

Given the implications associated with implant-related infections, such as requirement for further surgical revisions, possible hardware removal with exacerbation of the underlying disorder, and increased healthcare costs; the standardization of infection prevention strategies should be a top priority of quality improvement initiatives within a Functional Neurosurgery practice.<sup>1</sup> Furthermore, the implementation of best practices to minimize implant-related infections is necessary to help ensure cost-effectiveness and continued access to these therapies. In this study, we sought to evaluate the effectiveness of implementing a custom infection prevention bundle (IPB) in minimizing infections after surgeries for implantation of neuromodulation devices.

### Methods:

#### Study Location:

Froedtert Memorial Lutheran Hospital (FMLH) in Milwaukee, Wisconsin, an academic medical center with 804 inpatient beds.

#### Study Design:

To evaluate the effectiveness of an infection prevention bundle (IPB) instituted in April 2015, we performed a retrospective chart review of adult patients who underwent surgery/ surgeries for implantation or replacement of SCS, DBS, and IT drug delivery system components at FMLH during the period of March 2013 to October 2017. The subjects were divided into two groups: the pre-intervention or pre-IPB group, and the post-intervention or post-IPB group. (Figure 1)

Data collection was focused on demographics (sex, age at time of surgery), length of follow up, risk factors, surgeries for implantation, revision, and/or removal of hardware, indications for surgery, incidence of infections, and the infectious agent(s) identified.

To control for practice-related variabilities, all cases reviewed were performed by a single surgeon (P.P., senior author). Each surgical site was counted as a unique surgical case. Infection rates were calculated for all initial implantation surgeries and all subsequent revision/replacement surgeries before and after implementation of the IPB. The global incidence of post-operative surgical site infection (SSI) when using a 90-day versus a 1-year infection surveillance period was evaluated. Only patients with a minimum follow-up of 12 months were included in subgroup and risk factor comparisons.

### **Eligibility Criteria:**

Inclusion criteria: Males and females older than 18 years of age who underwent elective surgery for implantation or replacement of SCS system components, DBS system components, or IT drug delivery systems at FMLH by a single functional surgeon (P.P., senior author) within the study period of March 2013 to October 2017 and who had a minimum follow-up of 3 months were included.

Exclusion criteria: Patients younger than 18 years of age. Patients who underwent implant placement or replacement surgeries outside of FMLH, by a surgeon other than P.P., and/or outside of the study period of March 2013 to October 2017. Subjects with less than 3 months of follow-up time were not included in the data collection.

### **Determination of Surgical Site Infection:**

The diagnosis of deep surgical site infection followed the guidelines by the Center for Disease Control and Prevention (CDC)<sup>17</sup> and included infections occurring within 30 or 90 days after the operative procedure (note: our infection surveillance is extended to a minimum of 1 year given the presence of implantable devices), involving deep soft tissues of the incision (e.g. fascial and muscle layers), and at least one of the following:

- a. Purulent drainage from deep incision.
- b. A deep incision that spontaneously dehisces, or a deep incision deliberately opened/aspirated by a surgeon and organism is identified by a culture or non-culture based microbiologic testing method which is performed for purposes of clinical diagnosis or treatment; or culture or non-culture based microbiologic testing method is not performed AND at least one of the following signs or symptoms: fever ( $>38^{\circ}\text{C}$ ), localized pain or tenderness. A culture or non-culture based test that has a negative finding does not meet this criterion.
- c. An abscess or other evidence of infection involving the deep incision that is detected on gross anatomical or histopathologic exam, or imaging test.

Only deep surgical site infections requiring surgery for wound debridement/washout and/or hardware removal were considered in this study. Our infection surveillance extends to a minimum of 1 year given the presence of implantable devices.

**Ethical Review/Approval:**

The study was performed in the context of quality improvement without experimental practices or the need for patient's identifiable information, therefore it was granted exempt status from our institutional review board.

**Infection Prevention Bundle (IPB):**

The IPB implemented in April 2015 consisted of the following items:

1. Pre-operative counseling and questionnaire: patient counseling and preparation instructions, screening questions for signs of infection and presence of open or non-healing wounds.
2. Pre-operative check list:
  - a. Nurse call with reminder of pre-operative instructions 2 days prior to surgery.
  - b. Nasal MRSA/MSSA decolonization: Twice daily application of 2% mupirocin ointment to bilateral nares with final application on the morning of surgery.
  - c. Body decolonization: Cleansing with 2% chlorhexidine gluconate cloths the evening before surgery and the morning of surgery.
3. Pre-operative weight-based antibiotics within 60 minutes of incision
4. Strict draping and surgical techniques (see Operating room practice section and Figures 2, 3)
5. Weight-based post-operative antibiotics for 24hr for patients staying overnight vs one dose for outpatients.
6. Post-operative wound care education to patient and family.

**Operating Room Practice:**

A single functional neurosurgeon (P.P., senior author) performed every case either by himself or with assistance from a single neurosurgical resident. Both surgeon and assistants wore non-paper gowns and double gloves for every case. Exterior gloves were changed after draping for all stage I DBS (electrode placement) procedures. There was no restriction on the number of people allowed in the room at a given time, the frequency of door openings, or the frequency of scrub technician turnover.

DBS surgeries were performed in a staged fashion. Stage I DBS surgeries (electrode implantation) were performed under monitored anesthesia care (MAC) and local anesthesia. Microelectrode recording (MER) was utilized in all Stage I DBS surgeries. Stage II DBS (IPG insertion and connection) were performed under general anesthesia. DBS IPG replacements were performed under MAC and local anesthesia. SCS paddle and battery implantations were performed under MAC and local anesthesia. Initial IT pump system implantations and revisions were performed under general anesthesia. Routine IT pump replacements were performed under MAC and local anesthesia.

Local hair is removed with electric clippers immediately before surgery. Standard surgical site skin preparation is performed by an operating room nurse using a chlorhexidine/alcohol-based solution. Additional skin cleansing with povidone-iodine is performed for all Stage I DBS cases prior to stereotactic headframe pin placement and prior to local anesthetic infiltration to the proposed scalp incision. This is followed by a final skin preparation with a chlorhexidine/alcohol-based solution prior to draping.

Sterile draping is performed by the attending neurosurgeon with or without assistance from a resident or a scrub technician. Two layers of iodophore-impregnated incise drapes are utilized in all Stage I DBS cases (Figure 2). Paper drapes and iodophore-impregnated incise drapes are used to achieve water tight closures in all DBS IPG, SCS, and IT pump placement, and replacement cases (Figure 3). Sterile draping of the C-arm fluoroscopy machine is performed by the scrub technician.

All implants remain closed in their package until immediately needed and are soaked in vancomycin solution (1mg/mL) prior to implantation. All pump implants are anchored using 2–0 silk sutures while the rest of the implants are anchored with 2–0 Vicryl sutures. Wound irrigation with saline is carried out with a bulb syringe prior to wound closure. Wound closures are performed following anatomical layers using 0-Vicryl for fascial layers, 2–0 Vicryl for the intermediate subcutaneous layers, an inverted layer of 3–0 Vicryl for the more superficial subcutaneous layers, and a running 4–0 Vicryl subcuticular suture with Dermabond for the final skin closure. All wounds are dressed with Telfa non-adherent dressing (Covidien Medtronic) and Tegaderm transparent film dressing (3M United States) for 24–48hr.

### **Statistical Analysis:**

Data analysis focused on calculation of infection rates with mean  $\pm$  standard deviation, and group comparisons via student's *t* test and the rate ratio test.<sup>18</sup> The Wilson score interval for calculating the binomial proportion confidence limits. Data analysis was performed using statistical software R3.3.1.

### **Results:**

#### **Population:**

A total of 688 patients (460 males/224 females;  $50 \pm 17$  years old) underwent a total of 1,161 unique site surgeries during the study period. This included 222 DBS electrode surgeries (199 initial, 8 replacements, 15 revisions), 419 IPG surgeries (185 initial, 209 replacements, 25 revisions), 203 SCS surgeries (174 initial, 17 replacements, 12 revisions), and 317 IT pump system surgeries (192 initial, 105 replacements, 20 revisions). Of these, 546 occurred before the implementation of the IPB (pre-IPB) and 615 occurred after the implementation of the IPB (post-IPB). Tables 1–3, Figure 1.

#### **Post-operative follow-up:**

The mean follow-up time was 32 months (24–53months) in the pre-IPB group and 20 months (12–31months) in the post-IPB group. In patients with IT pump delivery systems for

intractable cancer-related pain, follow-up was limited due to cancer-related deaths (9 out of 12 in the pre-IPB group and 1 of 2 in the post-IPB group). As such, follow-up in this subgroup ranged from 4–36 months in the pre-IPB group and 3–15 months in the post-IPB group.

#### **Incidence of infection and infection surveillance periods:**

The overall infection rate for all surgical case types (i.e. SCS + DBS+ IT pumps) was 2.9% in the pre-IPB group and 0.2% in the post-IPB group when considering infections occurring within 90 days from surgery and 3.1% in the pre-IPB group and 0.7% in the post-IPB group when considering infections occurring within 1 year from surgery. Table 2. The average time from surgery to surgical site infection (SSI) was 1.3 months in the pre-IPB and 4.2 months in the post-IPB group. Table 4.

When using a 90-day infection surveillance period, the incidence of infection in the pre-IPB group was: 0%, 1%, 8.7% for SCS, DBS (Stage I + II), and IT pump cases, respectively. In contrast, post-IPB infection rates were: 0% 0%, 0.6% for SCS, DBS (Stage I + II), and IT pump cases, respectively. When using a 1-year infection surveillance period, the incidence of infection in the pre-IPB group was: 0%, 1.3%, and 8.7% for SCS, DBS (Stage I + II), and IT pump cases, respectively. In contrast, post-IPB infection rates were: 0%, 0.3%, and 1.8% for SCS, DBS (Stage I + II), and IT pump cases, respectively. Table 2.

#### **Surgical site infection-causative organisms:**

Under the 1-year infection surveillance period, the infectious agents identified included: *Staphylococcus aureus* (3), *Staphylococcus epidermidis* (4), *Escherichia coli* (2), *Enterobacter aerogenes* (1), *Corynebacterium jeikeium* (1), and *Morganella morganii* (1), and *Pseudomonas aeruginosa* (3), *Propionibacterium granulosum* (1). Table 4.

#### **Initial implantations versus replacement surgeries:**

Infection rates for initial implantations were: 0% for SCS systems (N=80); 1.1% for DBS for electrodes (N=93), 2.2% for IPGs (N=89); and 5.7% for IT pump systems (N=88) in the pre-IPB group, and 0% for SCS systems (N=94); 0% for DBS electrodes (N=106), 1% for IPGs (N=96); and 1.9% for IT pump systems (N=104) in the post-IPB group (see Table 3, Figure 1).

Infection rates for replacement surgeries were: 0% for SCS systems (N=9); 25% DBS electrodes (N=4), 0% IPGs (N=88); and 15.4% for IT pump system components (N=52) in the pre-IPB group, and 0% for SCS systems (N=8); 0% for DBS electrodes (N=4), 0% for IPGs (N=121); and 1.9% IT pump system components (N=53) in the post-IPB group (see Table 3, Figure 1).

#### **Risk Factors:**

There was no significant difference in sex distribution or age between the groups. Diagnoses or indications for surgery included movement disorders (e.g. Parkinson's disease, essential tremor, dystonia), spasticity (secondary to cerebral palsy, spinal cord injury, stroke, and multiple sclerosis), and intractable cancer-related pain.

Three patients in the pre-IPB DBS group (3 of 188) required wound debridement and hardware removal from four distinct surgical sites. One of these patients suffered an infection after having multiple surgeries for revision, removal, and replacement of a malfunctioning thalamic electrode within a period of 1 month. Given the low incidence of infection in the DBS group, it was not possible to assess the contribution of risk factors (e.g. diagnosis, comorbidities, etc.). Similarly, there were no infections in the SCS group and therefore contribution of risk factors to incidence of infection was not necessary.

The incidence of infection was highest for the IT pump system groups with a total of 13 surgical site infections (8 of 93 patients) in the pre-IPB group and 3 surgical site infections (2 of 100 patients) in the post-IPB group. This difference was significant when comparing between pre-IPB and post-IPB IT pump system cases per unique surgical site ( $p=0.012$ ) but not when comparing by number of patients ( $p=0.086$ ). Obesity ( $BMI >30\text{kg/m}^2$ ) and a history of previous hardware-related surgical site infection were associated with a higher incidence of infection in both the pre-IPB and post-IPB groups, but this did not reach statistical significance ( $p=0.65$  and  $0.72$ , respectively). Other risk factors associated with a higher incidence of infections include neurogenic bowel/bladder, cerebral palsy, and history of quadriplegia/quadruparesis, although similarly these did not reach statistical significance. Table 5.

## Discussion:

Infection rates were lower for both pre-IPB and post-IPB groups when using the new 90-day infection surveillance period recommended by the CDC NHSN<sup>17</sup> compared to the previous recommendation of a 1 year surveillance for procedures involving implants.<sup>19</sup> Consistent with a recent report by Abode-Iyamah et al. 2018,<sup>20</sup> our findings suggest that using the shorter infection surveillance period of 90 days may underestimate the incidence of implant-related infections and ultimately lead to loss of opportunities in the identification of risk factors and interventions to prevent or mitigate these infections.

There were no infections in the SCS group in either the pre-IPB or post-IPB periods. This may be related to the fact that several of the items included in the IPB were already being employed in this group prior to April 2015. For the staged DBS cases, only one infection occurred after implementation of the IPB such that the overall infection rate decreased from 1.3% (4/298) to 0.3% (1/343) after its application ( $p=0.293$ ). The infection rate for the IT pump system group decreased from 8.7% to 1.8% after implementation of the IPB ( $p=0.012$ ).

There was a higher incidence of infections in the IT pump system replacement group (15.4%,  $N=52$ ) compared to initial placements (5.7%,  $N=88$ ) in the pre-IPB study period. This higher incidence of infection for implant replacements is consistent with various reports.<sup>2, 5, 6</sup> There was also a higher incidence of infections for electrode replacement surgeries (25%,  $N=4$ ) compared to initial placements (1.1%,  $N=93$ ) in the pre-IPB study period, although this large difference is likely related to the small number of electrode replacement surgeries (Figure 1, Table 3). It is also important to note that the one patient who suffered an infection after electrode replacement surgery had undergone multiple







of a standardized IPB reduced the number of infections after implantation and replacement of DBS system components, SCS system components, and IT drug delivery systems. This is a simple approach that can be easily customized and adopted within any branch of Neurosurgery and across specialties to potentially decrease the incidence of implant-related infections and improve patient outcomes. This work will add to the growing literature on risk factors for infectious complications and infection prevention strategies as applied to neuromodulation therapies with implanted neurological devices. This is of special relevance since implementation of best practices to minimize implant-related infections is necessary to help ensure cost-effectiveness and continued access to these therapies.

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### List of Abbreviations

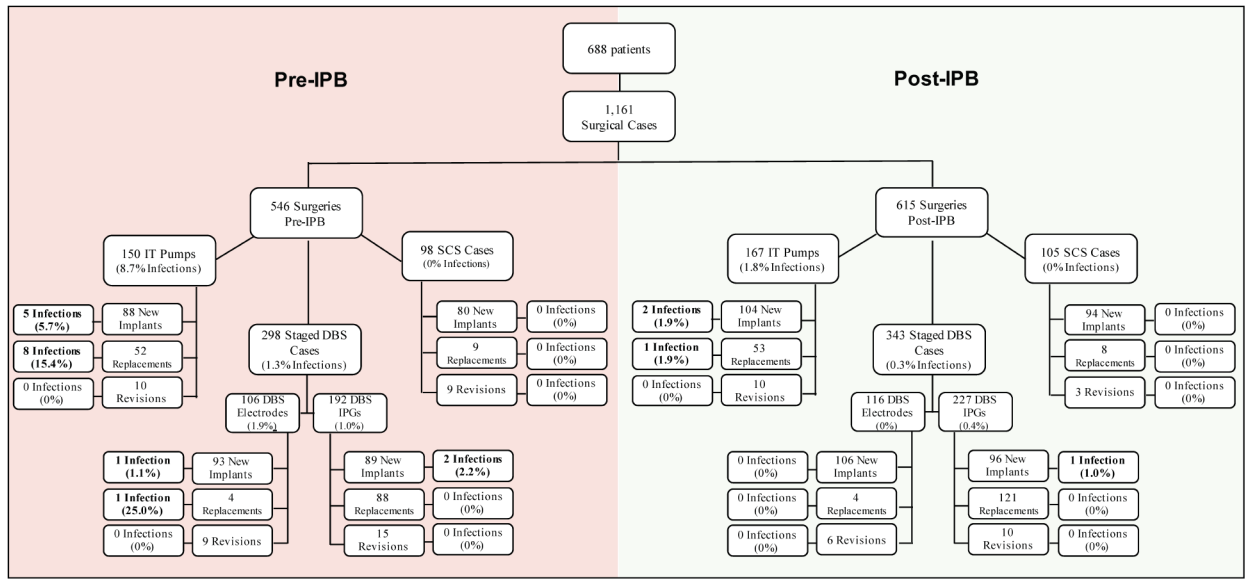
<b>CDC</b>	Centers for Disease Control and Prevention
<b>DBS</b>	Deep brain stimulation
<b>FMLH</b>	Froedtert Memorial Lutheran Hospital
<b>hr</b>	Hour
<b>IPG</b>	Implantable pulse generator
<b>IPB</b>	Infection prevention bundle
<b>IT</b>	Intrathecal
<b>IV</b>	Intravenous
<b>MRSA</b>	Methicillin-resistant <i>Staphylococcus aureus</i>
<b>MSSA</b>	Methicillin-sensitive <i>Staphylococcus aureus</i>
<b>MER</b>	Microelectrode recording
<b>MAC</b>	Monitored anesthesia care
<b>NHSN</b>	National Healthcare Safety Network
<b>SCS</b>	Spinal cord stimulation
<b>SSI</b>	Surgical site infection

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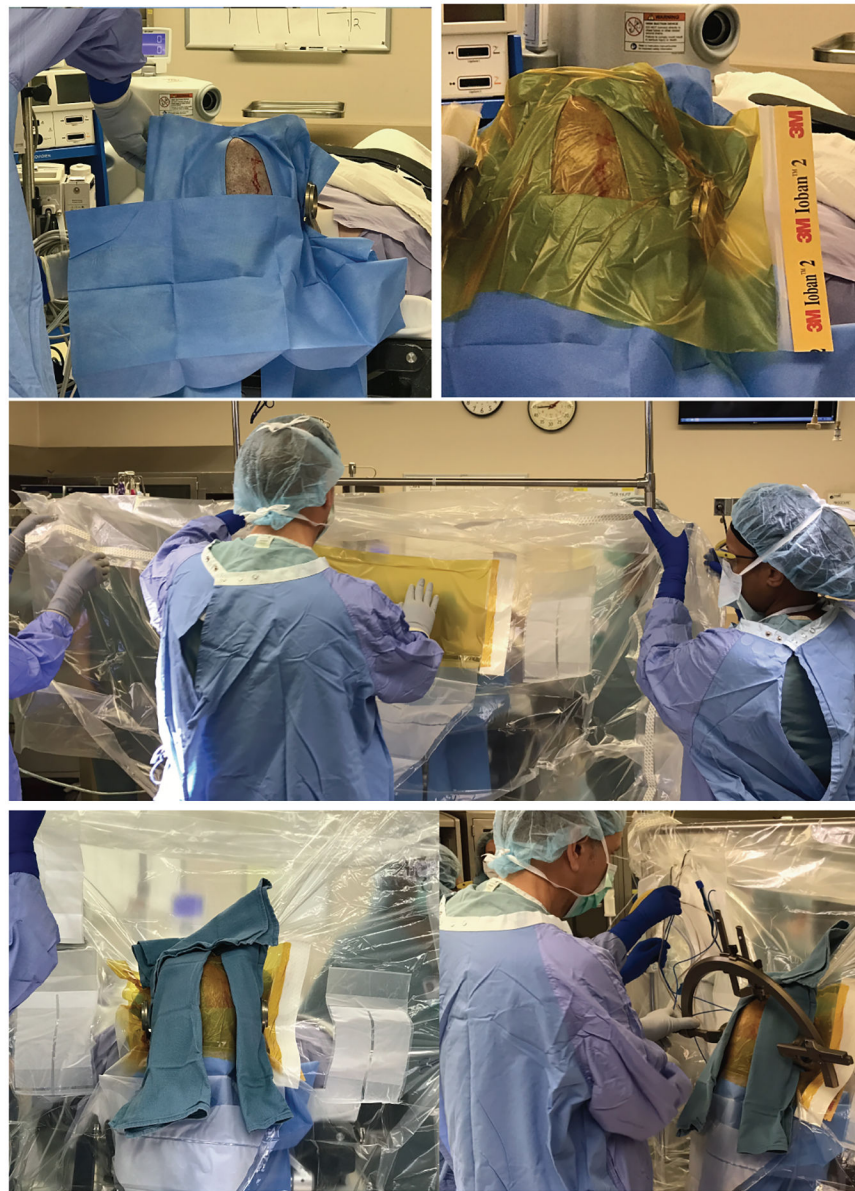
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**Figure 1.** Surgical cases and implant-related infections with 1-year post-operative surveillance



**Figure 2.** Draping technique for DBS Stage I surgeries. Top: After a standard skin prep with chlorhexidine/alcohol-based solution, sterile paper drapes are placed surrounding the incision and these are covered by antimicrobial incise drapes. Middle: A second layer of antimicrobial incise drape is first placed over the previously draped incision and the lateral flanks are then tied around IV poles on either side to separate the surgical field from the non-sterile patient field. Bottom: Cuts are made on the incise drape to allow the z-bars through to allow connection to the arc (outer gloves are changed after this step). Exposed non-sterile areas are then covered with sterile towels. Finally, the frame arc is attached and set to pre-determined coordinates.





**Figure 3.** Draping technique for DBS IPG replacement surgeries. Left: A mayo tray is placed above the patient's head with enough height to ensure patient comfort. After a standard skin prep with a chlorhexidine/alcohol-based solution, sterile paper drapes are attached to the top of the mayo tray and then around the patient's incision without leaving gaps. Right: Antimicrobial incise drapes are placed over the paper drapes creating a water-tight closure. Surgical field drapes are then placed in standard fashion.

**Table 1.**

Baseline patient characteristics for pre-IPB and post-IPB groups with 1-year post operative surveillance

Surgery Group	Characteristic	Pre-IPB Group		Post-IPB Group	
		All Patients	Infected Patients	All Patients	Infected Patients
<b>DBS Systems</b>	No. of patients, (%)	188 (100%)	3 (1.6%)	198 (100%)	1 (0.5%)
	Average Age in years	69 ± 16	75 ± 5	68 ± 15	64
	Sex (Male:Female)	139:49	3:0	153:45	1:0
<b>SCS systems</b>	No. of patients, (%)	51 (100%)	0 (0%)	58 (100%)	0 (0%)
	Average Age in years	60 ± 25	N/A	66 ± 12	N/A
	Sex (Male:Female)	29:22	0:0	32:26	0:0
<b>IT pump systems</b>	No. of patients, (%)	93 (100%)	8 (8.6%)	100 (100%)	2 (2.0%)
	Average Age in years	46 ± 16	39 ± 15	47 ± 14	44 ± 18
	Sex (Male:Female)	58:35	4:4	64:36	0:2

IPB = Infection prevention bundle

DBS = deep brain stimulation

IPG = implantable pulse generator

IT = intrathecal

SCS = spinal cord stimulator



**Table 2.** Implant-related infections with 90-day versus 1-year post-operative surveillance protocol

Surgical Cases	Pre-IPB		Post-IPB		Pre-IPB		Post-IPB	
	No. Patients	Infections (%)	No. Patients	Infections (%)	Unique Surgical Cases	Infections (%)	Unique Surgical Cases	Infections (%)
All Case Types								
90-day surveillance	332	11 (3.3%)	356	1 (0.3%)	546	16 (2.9%)	615	1 (0.2%)
1-year surveillance		15 (4.5%)		3 (0.8%)		17 (3.1%)		4 (0.7%)
All DBS Cases								
90-day surveillance	188	2 (1.1%)	198	0 (0%)	298	3 (1.0%)	343	0 (0%)
1-year surveillance		3 (1.6%)		1 (0.5%)		4 (1.3%)		1 (0.3%)
Electro de Cases								
90-day surveillance	76	2 (2.6%)	72	0 (0%)	106	2 (1.9%)	116	0 (0%)
1-year surveillance		2 (2.6%)		0 (0%)		2 (1.9%)		0 (0%)
DBS IPG Cases								
90-day surveillance	112	1 (0.9%)	126	0 (0%)	192	1 (0.5%)	227	0 (0%)
1-year surveillance		2 (1.8%)		1 (0.8%)		2 (1.0%)		1 (0.4%)
All SCS Cases								
90-day surveillance	51	0 (0%)	58	0 (0%)	98	0 (0%)	105	0 (0%)
1-year surveillance		0 (0%)		0 (0%)		0 (0%)		0 (0%)
All IT Pump Cases								
90-day surveillance	93	8 (8.6%)	100	1 (1.0%)	150	13 (8.7%)	167	1 (0.6%)
1-year surveillance		8 (8.6%)		2 (2.0%)		13 (8.7%)		3 (1.8%)

IPB = Infection prevention bundle

DBS = deep brain stimulation

IPG = implantable pulse generator

SCS = spinal cord stimulator

IT = intrathecal

All case types = SCS+DBS+IT pumps

**Table 3.** Incidence of implant-related infections per surgical case type with 1-year post operative surveillance

Surgical Cases	Pre-IPB		Post-IPB		Pre-IPB		Post-IPB	
	No. Patients	Infections (%)	No. Patients	Infections (%)	Unique Surgical Cases	Infections (%)	Unique Surgical Cases	Infections (%)
All DBS Cases	188	3 (1.6%)	198	1 (0.5%)	298	4 (1.3%)	343	1 (0.3%)
Electrode Cases	76	2 (2.6%)	72	0 (0%)	106	2 (1.9%)	116	0 (0%)
New implants	67	1 (1.5%)	70	0 (0%)	93	1 (1.1%)	106	0 (0%)
Replacements	4	1 (25%)	4	0 (0%)	4	1 (25%)	4	0 (0%)
Revisions	8	0 (0%)	5	0 (0%)	9	0 (0%)	6	0 (0%)
DBS IPG Cases	112	2 (1.8%)	126	1 (0.8%)	192	2 (1.0%)	227	1 (0.4%)
New implants	54	2 (3.7%)	63	1 (1.6%)	89	2 (2.2%)	96	1 (1.0%)
Replacements	53	0 (0%)	68	0 (0%)	88	0 (0%)	121	0 (0%)
Revisions	12	0 (0%)	7	0 (0%)	15	0 (0%)	10	0 (0%)
All SCS Cases	51	0 (0%)	58	0 (0%)	98	0 (0%)	105	0 (0%)
New implants	40	0 (0%)	47	0 (0%)	80	0 (0%)	94	0 (0%)
Replacements	9	0 (0%)	8	0 (0%)	9	0 (0%)	8	0 (0%)
Revisions	9	0 (0%)	3	0 (0%)	9	0 (0%)	3	0 (0%)
All IT Pump Cases	93	8 (8.6%)	100	2 (2.0%)	150	13 (8.7%)	167	3 (1.8%)
New implants	44	3 (6.8%)	52	1 (1.9%)	88	5 (5.7%)	104	2 (1.9%)
Replacements	52	5 (9.6%)	53	1 (1.9%)	52	8 (15.4%)	53	1 (1.9%)
Revisions	10	0 (0%)	10	0 (0%)	10	0 (0%)	10	0 (0%)

IPB = Infection prevention bundle

DBS = deep brain stimulation

IPG = implantable pulse generator

SCS = spinal cord stimulator

IT = intrathecal

**Table 4.**

Characteristics of infected patients in pre-IPB and post-IPB groups

Study Period	Subject	Sex	Age	Implant Type	Infected Surgical site(s)	Time to SSI (months)	Organism(s)
Pre-IPB	P1	F	48	ITP	Lumbar wound	1.0	<i>Pseudomonas aeruginosa</i>
Pre-IPB	P2	M	42	ITP	IT catheter, pump	0.5	<i>Pseudomonas aeruginosa</i> , <i>Staphylococcus epidermidis</i>
Pre-IPB	P3	F	30	ITP	Lumbar wound	0.5	No growth at explant
Pre-IPB	P3	F	30	ITP	IT catheter, pump	1.1	No growth at explant
Pre-IPB	P4	F	60	ITP	IT catheter, pump	1.3	<i>Enterobacter aerogenes</i>
Pre-IPB	P5	M	66	ITP	IT catheter, pump	0.3	<i>Escherichia coli</i>
Pre-IPB	P6	F	25	ITP	IT catheter, pump	0.4	<i>Escherichia coli</i>
Pre-IPB	P7	M	37	ITP	IT pump	2.1	<i>Staphylococcus epidermidis</i>
Pre-IPB	P8	M	24	ITP	IT pump	1.5	No growth at explant
Pre-IPB	D1A	M	73	DBS	Electrode, IPG	0.9	MRSA
Pre-IPB	D2A	M	81	DBS	Electrode	0.2	<i>Morganella morganii</i>
Pre-IPB	D3B	M	72	DBS	IPG	5.7	<i>Staphylococcus aureus</i> , <i>Corynebacterium jeikeium</i>
Post-IPB	P9	F	57	ITP	IT catheter, pump	4.9	<i>Pseudomonas aeruginosa</i>
Post-IPB	P10	F	31	ITP	IT pump	2.9	No growth at explant
Post-IPB	D4B	M	64	DBS	IPG	4.7	<i>Staphylococcus epidermidis</i> , <i>Propionibacterium granulosum</i> , <i>Klebsiella oxytoca</i>

MRSA = Methicillin-resistant staphylococcus aureus

SSI = Surgical site infection

Time in red = time greater than 90 days or 3 months

**Table 5.**

Baseline demographics, risk factors, and incidence of SSI with 1-year surveillance protocol for patients with IT pump systems

Characteristic	Pre-IPB Group		Post-IPB Group	
	All Patients	Infected Patients	All Patients	Infected Patients
No. of patients, (%)	93 (100%)	8 (8.6%)	100 (100%)	2 (2.0%)
Average Age in years	46 ± 16	39 ± 15	47 ± 14	44 ± 18
Sex (Male:Female)	58:35	4:4	64:36	0:2
Characteristic	Total Patients	Infected Patients, (%)	Total Patients	Infected Patients, (%)
Previous Implant revision (non-infectious)	2	0 (0%)	8	0 (0%)
Previous implant-related SSI	1	<b>1 (100%)</b>	4	<b>1 (25%)</b>
Obesity (BMI > 30kg/m <sup>2</sup> )	22	<b>4 (18.2%)</b>	15	<b>1 (6.7%)</b>
Diabetes	4	0 (0%)	9	0 (0%)
Paraplegia	29	<b>2 (6.9%)</b>	31	1 (3.2%)
Quadriplegia/Quadriparesis	51	<b>5 (9.8%)</b>	67	1 (1.5%)
Neurogenic bowel/bladder	66	<b>8 (12.1%)</b>	66	2 (3.0%)
Spinal Cord Injury	32	2 (6.3%)	44	0 (0%)
Cerebral Palsy	24	<b>4 (16.7%)</b>	24	1 (4.2%)
Demyelinating disorder	19	1 (5.3%)	26	1 (3.8%)
History of stroke, ICH	13	1 (7.7%)	14	0 (0%)
Cancer	16	1 (6.3%)	5	0 (0%)
Statin use	12	0 (0%)	19	0 (0%)

BMI = body mass index

IPB = infection prevention bundle

ICH = intracerebral hemorrhage

IT = intrathecal

SSI = surgical site infection

No. = number