

Esteem II SP Battery Replacement Surgical Procedure Guidelines

Eric M. Kraus, M.D., M.S., F.A.C.S.
v 2.0 (30Oct14)

1. Audiologist to document depleted SP and need for battery replacement – measure remaining SP voltage
 - a. Arrange date, time, and place for replacement
 - b. Confirm procedure and FCE availability with Envoy Medical
 - c. Copy SP programming data sheet – supply to FCE attending the procedure
 - i. FCE – use updated SP data sheet to program new SP for implantation
 - ii. FCE – day of procedure, link patient’s personal programmer to new SP
2. Examine patient and provide informed consent & preoperative instructions
 - a. Consider preop nasal swab to r/o MRSA carrier state; preop Vancomycin + Cephalosporin prophylaxis
 - i. If MRSA positive by PCR, begin nasal mupirocin cream or ointment in both nostrils for 7 days prior to procedure
 - ii. Consider chlorhexidine bath the morning of the procedure
 - iii. Want to decrease probability of both methicillin susceptible (MSSA) and methicillin resistant (MRSA) staphylococcal aureus carrier state
 - b. Preop x-ray: advised for new surgeons, determine lead position. Pre-op x-ray optional for experienced Esteem surgeons.
 - c. Incision design – evaluate/assess and discuss with patient
 - i. Standard post-auricular “Lazy S” or “Lazy L” is postauricular skin is not thin and contracted tightly around proximal leads (shrink wrapped skin)
 1. May proceed with Local MAC anesthesia
 - ii. Inverted temporo-parietal “U” flap with capsular flap for shrink wrapped skin condition.
 1. Notify anesthesia team of conversion to general LMA/ET anesthesia.
3. Contact Envoy Medical: arrange for FCE to be present
 - a. Meter, coupler, fresh meter battery
 - b. Alligator clip cables (2)
 - c. Personal Programmer
 - d. Check stock de-ionized water at center
 - e. Forms to be signed & submitted
 - f. Pre-program replacement SP with patient’s SP settings & link PP to new SP
 - g. Center should have all necessary Esteem equipment on site to perform complete explantation and reimplantation of device in situation in which leads may be injured or cut during battery replacement
4. Sedate patient: IV Local MAC anesthesia with Versed, Alfenta, O2, etc. or employ general anesthesia as indicated.
5. Time Out:
 - a. document patient & date of birth
 - b. side of procedure (surgeon should mark preoperatively)
 - c. proposed procedure

- d. patient medication allergies
 - e. preop antibiotics/medications to be given in OR
 - f. diabetic status
 - g. other patient issues such as pacemaker status
 - h. availability of surgical instruments/equipment, availability of Esteem computers/meters/supplies/etc.
 - i. confirm only bipolar cautery being used during procedure
 - j. intended discharge disposition
 - k. new SP status: new SP programmed by FCE with updated settings and turned "on"; new SP linked with patient's personal programmer
6. Intraoperative patient prep:
- a. Clip hair & cleanse skin with alcohol
 - b. drape out area with #1000 drape
 - c. stockinet cap application
 - d. supplemental O₂ by anesthesia, monitor VS & LOC/comfort, etc.
7. Cleanse skin with alcohol again & draw limited incision
- a. Use previous postauricular incision, palpate leads and mark position of leads at header block exit if postauricular skin is thick and not contracted tightly down around proximal leads
 - b. Extend incision superiorly around SP to facilitate SP removal from pocket
 - c. Coordinate with anesthesia
 - i. Have anesthesia administer Alfenta IV, wait 1.5 minutes and begin infiltration of local anesthetic
 - ii. Infiltrate with 1% xylocaine with 1:100,000 epinephrine (8-10 ml)
 - iii. Be mindful not to inject leads with local anesthesia or puncture/lacerate leads with needle
 - d. Prep and drape, use Ioban barrier
 - e. Steri-strip auricle anteriorly to protect auricle (2 ½" steri-strips crossed to retract auricle anteriorly work very well and are gentle)
 - f. When using temporo-parietal scalp flap (Inverted "U")
 - i. Clip temporo-parietal hair
 - ii. Draw out inverted "U" incision, being careful to curve in the inferior incision toward the auricle but not narrow the inferior base of the flap excessively
 - iii. Have scrub tech have 4-5 #15 blades available on Mayo to facilitate flap elevation and elevation of "capsular flap"
 - iv. Elevate flap in stages, bipolar for hemostasis
 - v. Incise sharply around perimeter of SP with #15 blade to raise capsular flap with main skin flap. Later, dissect capsular flap from main flap sharply, maintaining anterior base. The capsular flap will be rolled and used to cover the proximal leads at the end of the procedure.
8. Use OR microscope to enhance tissue contrast & digital palpation to protect leads during dissection
- a. Begin incision **superiorly** and continue in stages working inferiorly, identify SP as soon as possible and dissect to header block, staying as close to

possible to the SP. Use the SP as your guide. Be careful and vigilant when approaching the header block.

- b. Digitally palpate for curled leads prior to making any cuts.
 - c. Use sharp #15 scalpel and sharp, pointed scissors for dissection (have several #15 blades available on the instrument set, change frequently due to dense fibrosis)
 - d. Stay close to SP and dissect toward header block, use self retaining retractor
 - e. Identify header block and dissect Sensor and Driver leads
 - i. Use scissors and McCabe facial nerve dissector to remove fibrotic sheath from leads. Treat the leads the way you treat the facial nerve during a parotidectomy dissection.
 - ii. Use great care during dissection to avoid lead injury
 - iii. Dissect leads for 1 cm distally along each braided lead
 - f. In case of injured lead – each lead has three layers
 - i. Isolate lead injury site
 - ii. Dry site with 4x4 gauze sponges and place sponges medial to lead
 - iii. Inspect lead with microscope
 1. If only outer insulation is cut and wires are intact, proceed as below.
 2. If wire is cut, terminate case and reschedule patient for explantation and reimplantation (should have informed patient of this possibility during informed consent session). (Could proceed with explant and reimplant depending on patient's specific condition/preparation/etc., OR time available, Esteem equipment availability and ability to convert to general anesthesia.)
 - iv. Intraoperative lead repair (salvage):
 1. After drying leads, reapproximate cut lead insulation
 2. Support lead with dry gauze or instrument wipe
 3. Apply Dermabond cyanoacrylate around leads
 4. Permit Dermabond to cure completely
 5. Apply second layer of Dermabond and permit layer to cure
 6. Proceed as below
 7. Have FCE test leads and system once new SP has been connected
 - g. Obtain hemostasis with bipolar cautery
 - h. Frequent irrigation with cold bacitracin saline highly recommended
 - i. Release SP from pocket with Freer elevator
 - j. Remove SP from pocket, without tension, using a Kocher clamp, read off old serial number to FCE
9. Detach leads from SP
- a. Inspect SP for ingress of fluid, etc. prior to detaching leads
 - b. Connect leads to cables and perform capacitance testing, feedback testing, etc.
 - c. Change gloves

10. Clean leads with de-ionized water and instrument wipes x 2
 - a. Read off Serial number of Sensor and Driver to FCE for documentation
 - b. Roll lead between thumb and index finger with wipe to meticulously remove all particles and blood
 - c. Permit lead to untwist and return to relaxed position
 - d. Insert lead fully into proper header slot (slots are marked on SP) i.e. insert Sensor lead into Sensor slot, Driver lead into Driver slot
 - e. Remove blue Teflon tapes
 - f. Inspect SP for full insertion of leads through distal slot contact
 - g. Take digital photograph of SP, both sides, if available
 - h. If under Local MAC anesthesia, patient will often report immediate return of hearing in the ear
11. Insert Personal Programmer into sterile sleeve
 - a. Check to make sure that SP is "On". Have FCE test patient.
 - b. Increase and decrease volume to confirm SP function
 - c. Turn off SP
12. Obtain hemostasis with bipolar cautery
13. Irrigate SP pocket liberally with bacitracin saline solution.
14. Gently rotate SP into pocket so as not to stretch or pull on the leads
15. Proceed with two layer, water-tight closure
 - a. 3-0 chromic for subcutaneous layer
 - b. 5-0 non-absorbable skin layer, avoid injuring leads during closure (may use subcuticular closure as individual preference – recommend subcuticular 3-0 or 4-0 Vicryl®, followed by Dermabond®)
 - c. Apply antibiotic ointment if skin sutures used
 - d. Turn SP "On". Use patient's standard settings (i.e. A-3, etc.)
 - e. Place patient's hearing aid in contralateral ear, if available
 - f. Apply Glasscock mastoid dressing loosely
 - g. Transfer patient to PACU for monitoring and recovery
16. Complete and sign Envoy Medical paperwork for FCE
17. FCE will return depleted SP to Envoy Medical
18. Make arrangements for patients to return to the office/clinic for updated programming of the new SP. Usually, it is preferable to perform the programming and evaluation at the 7-10 day postoperative period when the patient is fully awake/alert and not under the influence of anesthetics/narcotics, etc.
19. Supply patient with written postoperative instructions, necessary prescriptions for postoperative antibiotics/analgesics/ointments/etc., and date/time of return visit.
20. Follow-up with surgeon and audiologist as needed.