Encore Tongue Suspension System: Procedure Guide

Guide for anesthesia and implantation according to Sam Mickelson, MD, Atlanta, GA (USA)

Ancillary Equipment
The Encore System Bone Screw requires a 1.5 mm pre-drilled pilot hole in the inferior aspect of the mandible. A hand drill or power drill with a 1.5 mm twist drill bit (preferably with a 6-8 mm stop) is necessary to create the pilot hole.

Anesthesia and Pre-op Medication
The Encore procedure is typically performed under general anesthesia, but may be performed with local anesthesia and sedation.

General anesthesia: Nasal or oral intubation or a laryngeal mask airway (LMA) can be used. Using an LMA may allow for easier reduction of sedation during the final tensioning step to insure overtensioning is not done.

Local anesthesia: This technique offers safety benefits and allows for the airway to be observed without interference from an endotracheal tube; however, patients may not tolerate the oral access required for suture passing.

Patients should receive antibiotic prophylaxis and steroids prior to the skin incision.

Prep, Incision and dissection
The scrub nurse should have extra gloves available so the surgeon may palpate the tongue with one hand and then change to sterile gloves to work with the neck incision.

Patients should be positioned supine, with neck extended, using a shoulder roll and their head on a donut. The sniffing position will aid in exposure of the posterior aspect of the mandible. Mark the midline of the tongue with a skin marker either before or after induction of anesthesia. Inject lidocaine with epinephrine into the planned incision site and down to the periostium of the mandible. If performing the procedure under local anesthesia, use a long needle to anesthetize the base of the tongue and the submental region down to the upper aspect of the hyoid bone and spray the oral cavity with a topical anesthetic. Consider placement of a silk suture on the mid-tongue dorsum to protrude the tongue, as necessary, and maintain a midline position.

Use your preferred prep solution on the neck from the lower lip to the sternum. Drape with sterile towels inferiorly, laterally and superiorly above the upper lip. Place a folded towel over the chin to allow access to the oral cavity. Perform a 2-3 cm horizontal incision in the submental crease and incise down to and through the periostium on the postero-inferior aspect of the mandible. Clear the periostium from the portion of the mandible where the bone screws will be inserted (See figure 1). Obtain hemostasis with electrocautery.

Fig. 1: Incision Site
**Bone Screw Insertion**

Using the drill, create one or two (if two suspension loops are to be placed) pilot holes 5-6 mm deep using suction and irrigation. If using one suture loop, the hole will be in the midline and if using two, they should be 3-5 mm off midline. Positioning the holes at the posterior aspect will minimize the potential for the patient to feel the bone screws after the procedure. Using the inserter with pre-loaded bone screw, insert the bone screws into the pilot holes until the head of the bone screw comes in contact with the bone. The dark lines on the inserter should be in an A-P orientation to insure that the bone screw has its through-hole aligned properly. After insertion, simply pull back on the inserter to release the bone screw. The white suture can be removed by loosening the lock screw 1-2 turns (See figure 2).

**Suspension Line Implantation: Location and Orientation**

The suture passer is used to place a “working suture” loop deep within the tongue at the desired suspension location. Vertical or horizontal loops can be made. The two most common configurations are stacked midline horizontal loops (one loop inferior just above the hyoid bone and one superior at the region of the circumvallate papilla) or stacked mid-line vertical loops. To form the first loop, insert the suture passer in the desired orientation (vertical or horizontal) through the incision and, while palpating the base of tongue with the free hand, direct the tips of the suture passer to the desired loop position. The tips of the suture passer are blunt, so there is a natural tendency for it to stop against the tough mucosa at the base of the tongue. The suture passer should dissect easily through the genioglossus. If resistance is felt, a small incision into the genioglossus muscle can be made. Once the suture passer is in its most posterior position, create the loop by pressing on the needle plunger completely, in one smooth motion, until a “click” is heard and the suture capture knob on the suture passer has moved to its distal position (See figure 3). The click indicates that the needle has been fully advanced and the suture capturing mechanism has been triggered. Gently remove the suture passer being careful to not pull the working suture completely out of the tongue (See figure 4). To release the working suture from the suture passer, pull back on the suture capture knob until it locks in its proximal position. To exchange the working suture for the suspension line, place approximately 5 cm of the suspension line through the looped end of the working suture and pull the working suture to track the suspension line through the tongue (See figure 5). **NOTE: To minimize the risk of contaminating the wound/device with oral bacteria, be sure to re-glove the hand used for palpating the tongue before re-accessing the surgical site or handling the Encore.**
Place a hemostat on the ends of the suspension line. To create the second suspension loop, reload the suture passer and repeat (See figure 6). At this point in the procedure, it may be desirable to evaluate the loop orientation and location by advancing the tongue with the suspension loops while observing the airway with a scope or palpating with your finger to determine the effect on the airway.

**Note:** If the suture pass fails to make a working suture loop, ensure that there is no torque or twisting forces on the suture passer while attempting to make the suture pass. Twisting or torquing can cause the shafts of the suture passer to become misaligned.

**Suspension Line Threading**
To thread the suspension line through the bone screw, first insure that the lock screw has been un-screwed until 2-3 threads are exposed to allow enough room for the suspension line within the bone screw. Then, insert the threading tool through the bone screw in an anterior to posterior direction (See figure 7). Hemostats may be helpful to spread the wires of the threading tool once it has been threaded through the bone screw. Thread 1-2 cm of both ends of the suspension line through the threading tool and pull in an anterior direction to pull the tails of the suspension line through the bone screw.
Suspension Line Tension Adjustment and Locking
The amount of advancement or tension applied to the suspension line during the implantation procedure will depend on the patients particular needs and the number of suspension loops placed. In general, the greater the tension applied to the suspension line, the greater the discomfort, and altered speech and swallowing the patient will experience. The amount of initial advancement reported has ranged from 2 mm to 20 mm. Advancement in the range of 2 mm to 7 mm is generally very well tolerated. To advance and lock the suspension line, pull the desired amount and while maintaining the advancement, tighten the lock screw with the lock tool until it is “finger tight”. When placing two suspension sutures, be sure to record the position of each suture line and which screw they are attached to.

Wound Closure and Recovery
Due to the palpation of the tongue during this procedure, it is possible to contaminate the surgical site with oral bacteria. Therefore, the wound should be copiously irrigated with bacitracin (or other antibacterial agent) and saline and hemostasis verified. Leave .5 cm of excess suspension line anterior to the screws. In the event the patient requires tension to be reduced, ensure there is sufficient suture line to do so. Place the extra suspension line medially between the screws. Use standard closure techniques to close the wound in layers. A sterile pressure dressing is applied on completion of the surgery.

Recovery from the implantation procedure depends on how the patient tolerates the degree of advancement applied to the suspension lines. In the recovery room, it is important to ensure that the patient is able to drink, has adequate pain control and does not have any significant edema or signs of hematoma prior to discharge.

Notes
If necessary, postoperative pain may be treated with oxycodone, hydrocodone, acetaminophen, ibuprofen, ketolorac or tramadol as needed until the pain subsides.

Antibiotic prophylaxis is recommended for 24-48 hours, using an appropriate broad spectrum antibiotic.

To reduce potential edema, patients may be treated with a short course of steroids, and instructed to sleep with head of bed elevated. If using CPAP or an oral appliance pre-operatively, consider continued use until procedure efficacy can be documented.

Clinical experience indicates that some patients may need suspension line tension adjustment if symptoms do not improve or if there is chronic discomfort. Tension titration has been performed up to 4 months after the initial implantation procedure under local anesthesia and is generally very well tolerated.

Disclaimer: This procedure guide does not replace the instructions for use for the Encore System and any drugs listed. The Instructions-for-Use provided in the product packaging are mandatory and have to be followed stringently. It is the responsibility of the user to perform the Encore Procedure according to the Instructions-for-Use.