



**for the treatment of
Obstructive Sleep Apnea**

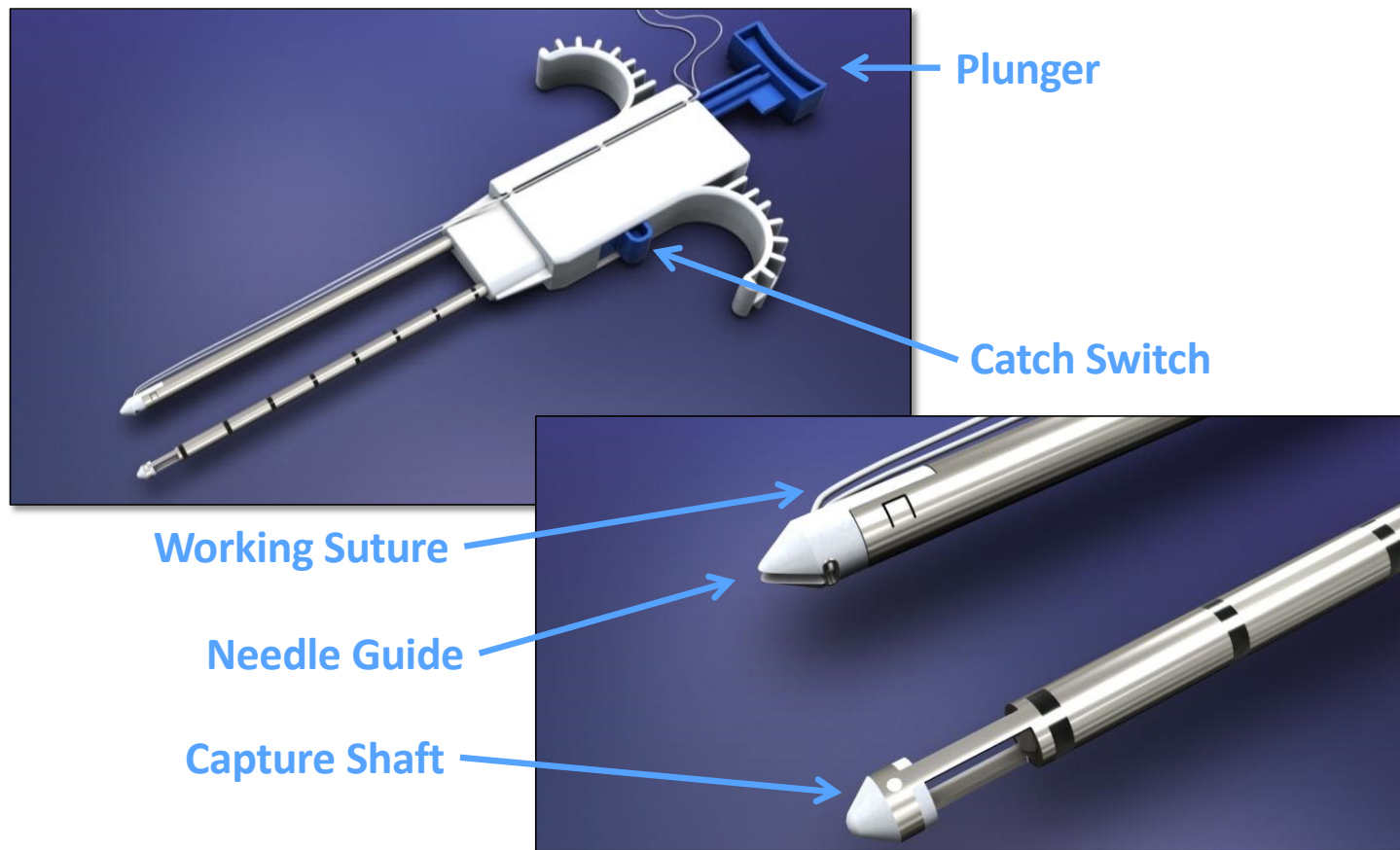


Physician Training Guide





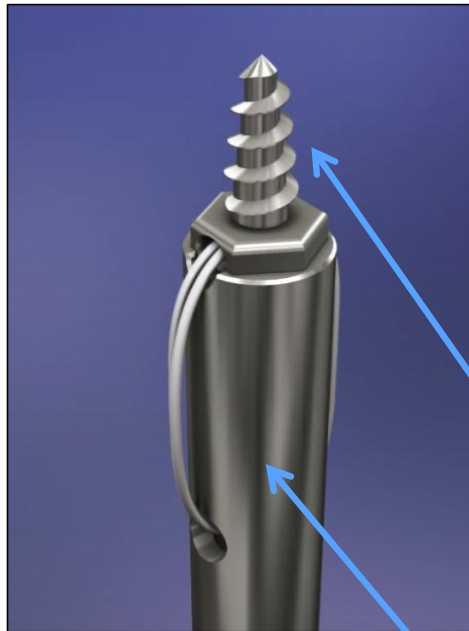
The Encore Suture Passer



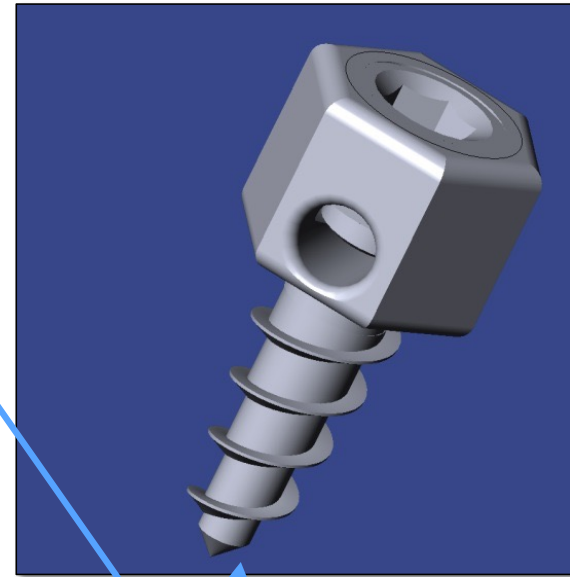
Encore Bone Anchor & Inserter



Inserter with
Bone Anchor
and Tether



Inserter Shaft



Bone Anchor

Threading Tool & Lock Tool



Threading Tool



Lock Tool



AIRLIFT® Hyoid Suspension Procedure - Animation



https://youtu.be/F_yornGArUQ



Hyoid Suspension Procedure Video



<https://vimeo.com/792410207/7892ae3573?fl=tl&fe=ec>



Hyoid Suspension Airway Effects



<https://vimeo.com/578093893>



Instructions for Use – LS0003

- For Hyoid Suspension and Tongue Suspension
- Refer to Instructions for Use (LS0003) for:
 - CONTRAINDICATIONS
 - WARNINGS
 - PRECAUTIONS
 - ADVERSE EFFECTS
 - STORAGE AND HANDLING



Preparation for Surgery

- Read product IFU
- General anesthesia (nasal intubation or LMA preferred)
- Antibiotics prophylaxis: Broad spectrum, prior to incision & one week post procedure
- Surgical drill (angled preferred): while a 1.75mm drill bit is provided in kit, a 1.5mm diameter drill bit may also be used
- Minimize or eliminate suture contact with patient skin by using ioban skin drape or placing sterile towels between suture & skin

Submental Access Site



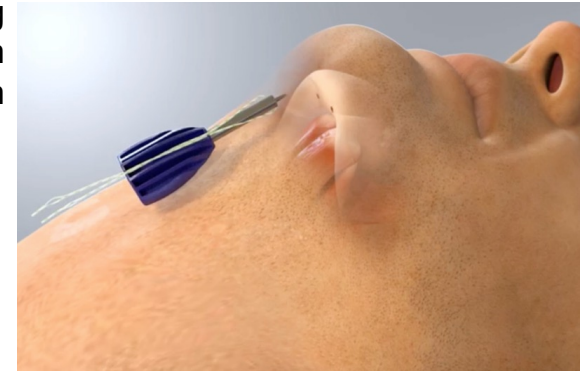
- A 2.0 cm incision is made to access the inferior border of the mandibular symphysis
- Alternatively, 2 incision approach (submental and anterior to hyoid bone) can be utilized to minimize dissection needed

Bone Screw Insertion

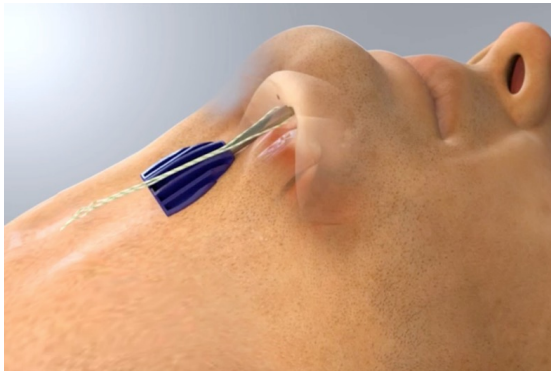
Pre-drill 1.5-1.75mm holes, ~1 cm lateral to midline on infero-posterior mandible



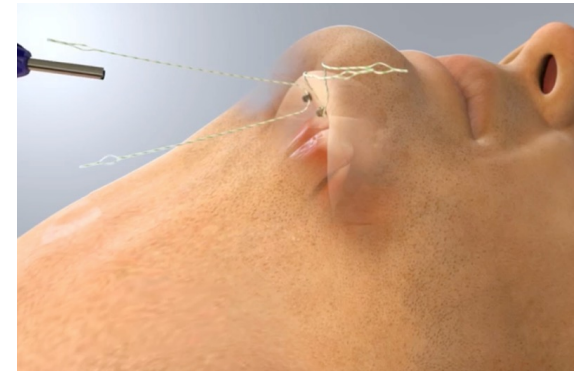
Hand insert, turning bone screw in clockwise direction



Ensure that through hole on Bone Screw is in A-P orientation

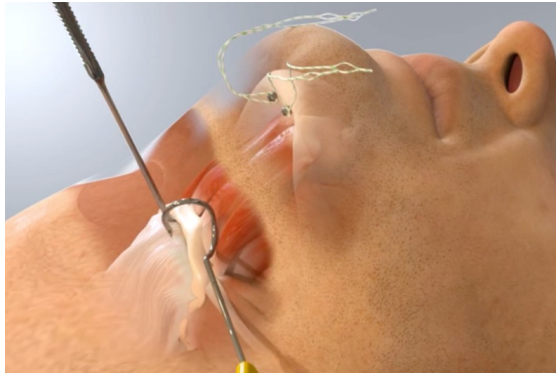


Place second Bone Screw on contralateral side

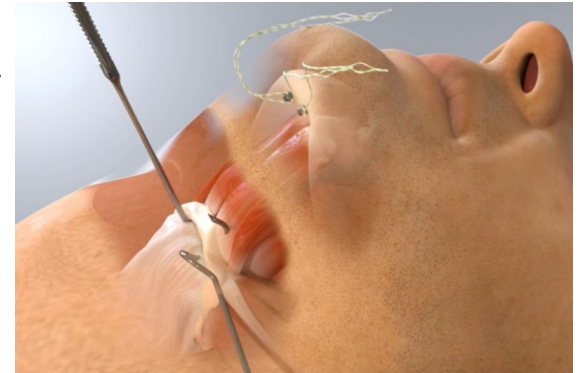


Suspension Line Pass Around Hyoid Bone

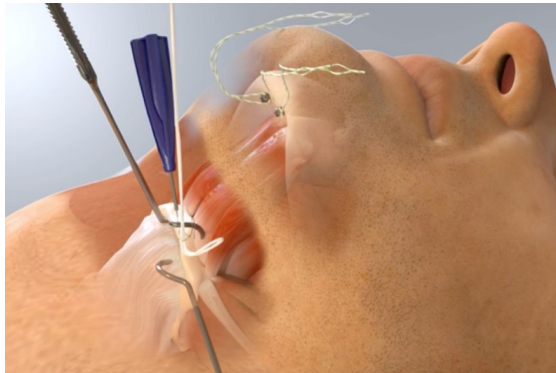
Drive Revolution
needle tip to the
posterior hyoid
surface



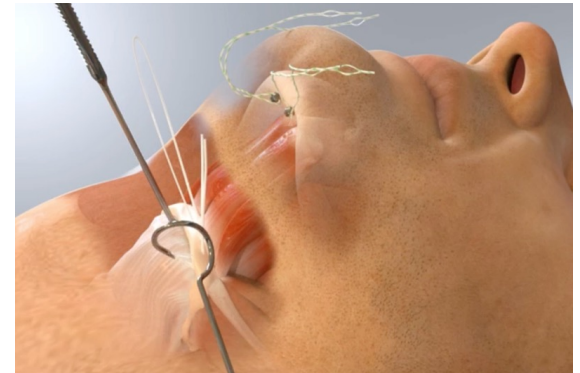
Rotate Revolution
tip around hyoid –
stay tight to the
hyoid to avoid
having needle tip
enter the
vallecula/airway



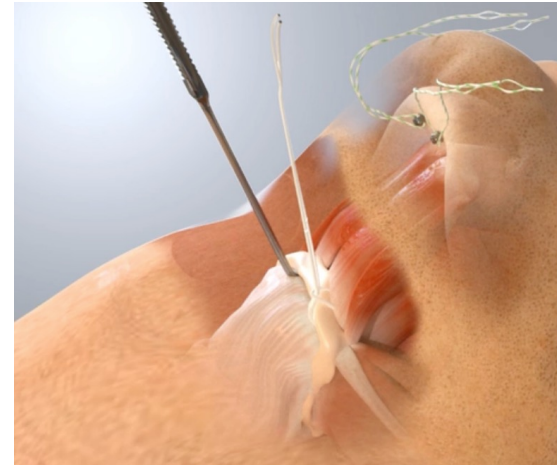
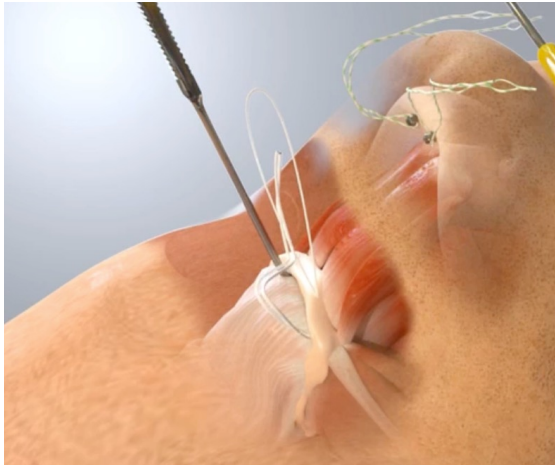
Use the Threading
Tool to pass folded
Suspension Line
through Revolution
eyelet



Reverse
Revolution rotation
around the hyoid
bone



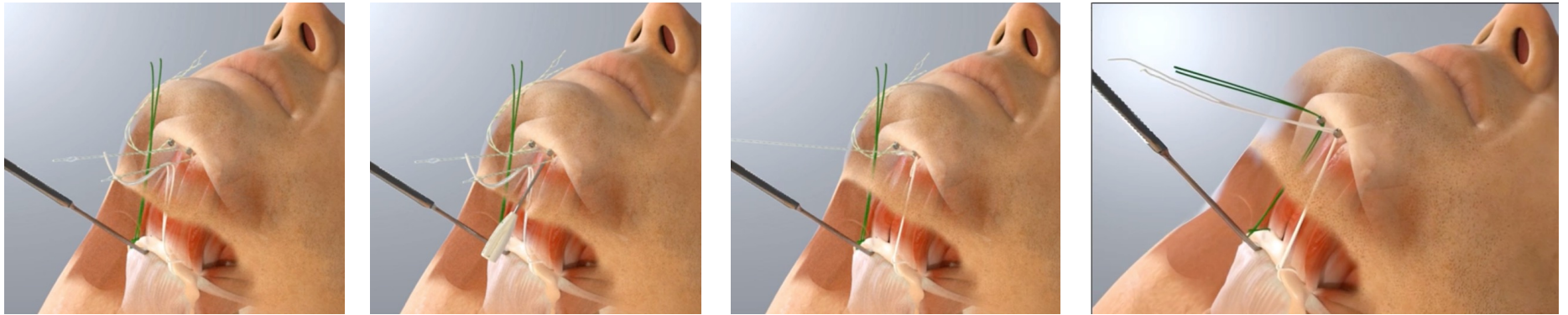
Secure Suspension Line Around Hyoid Bone



Thread Suspension Line tails through the folded Suspension Line loop as shown (creates girth hitch). Pull Suspension Line tails to tighten the loop around the hyoid bone. Repeat on contralateral side then bring sutures to chin incision via subplatysmal tunnel.



Thread Suspension Line Through Bone Screws



Using the pre-placed Threading Suture or the Threading Tool, loosen the Bone Anchor Set Screw until 2-3 threads are showing, then pull Suspension Line tails through the corresponding Bone Screw. Repeat for contralateral Suspension Line and Bone Screw.

Tension and Lock Suspension Lines



- Place the patient's head in a "normal pillow supine" position. If sutures are tensioned when neck is extended, then suture tension will likely be reduced when the head is in a normal sleeping position.
- Pull tension on each Suspension Line to suspend the hyoid bone and lock in place by tightening the lock screw with the Lock Tool as shown. Use of hex lock tool other than that provided in the kit may over-torque the set screw and damage the Suspension suture.
- Trim excess suture, ensuring that suture tails are kept away from incision.



Infection Prevention & Wound Closure

- Prior to closing incision site, the following steps should be followed to minimize infection risk:
 - Trim tails of suspension suture to 3-5 mm or tuck tails around back of anchors. Long suture tails in the wound side can potentially interfere with the healing process
 - Prior to closure, irrigate wound with anti-bacterial solution. Bacitracin and saline is one recommendation.
 - Close wound in layers.
 - A compression dressing used 3 days to one week will help to minimize swelling.
 - A drain can be used to further reduce fluid build up and risk of infection.





Post Op

- Patients may feel pain and experience some difficulty swallowing for 1-2 weeks. Extreme or intolerable pain should not occur. If this happens, consider reducing suspension line tension.



Clinical Evidence



Hyo-mandibular Suspension Efficacy Standalone

- Standalone AIRLIFT along with necessary nasal procedures (n=19)
- 43% mean AHI reduction
- 42% with AHI < 10
- 47% Surgical success per Sher criteria

Table 1 Description of patients undergoing hyoid myotomy and suspension.

Patient variable	
Female, No. (%)	6 (29)
Male, No. (%)	15 (71)
Mean age, y (range)	55.3 (31–76)
Mean BMI (range)	29.2 (22.8–43.4)
Mild apnea (AHI <15 events/h), No. (%)	2 (11)
Moderate apnea (AHI 16–30 events/h), No. (%)	4 (21)
Severe apnea (AHI >30 events/h), No. (%)	13 (68)
Complications, No. (%)	0 (0)

Table 2 Outcomes before and after hyoid myotomy and suspension (n = 19).

Outcome variable	Pre	Post	P value
BMI, mean (SD)	29.2 (5.7)	28.9 (6.1)	0.172
AHI, mean (SD)	39.7 (21.2)	22.6 (22.7)	<0.01
Lowest O ₂ saturation, mean (SD)	82.2 (9.9)	86.6 (6.2)	<0.01
Epworth Sleepiness Scale, mean (SD)	8.2 (4.4)	8.3 (5.2)	0.904
Surgical success (>50% reduction in AHI and postoperative AHI <20 events/h), No. (%)	9/19 (47.4)	—	—
Final AHI <10 events/h, No. (%)	8/19 (42.1)	—	—



Hyo-mandibular Suspension with UPPP Efficacy

- Multi-level AIRLIFT along with modified UPPP (n=39), multicenter
- 69% mean AHI reduction; 74% median AHI reduction
- 77% Surgical Success per Sher criteria (30/39)

Table 1. Baseline Patient Demographics.

Patient variable	
Age (mean $\pm$ St dev)	57.0 $\pm$ 11.9
Gender (male/female)	(27/12)
BMI (mean $\pm$ St dev)	32.2 $\pm$ 7.13
AHI > 30, (number [%])	32 (82%)

Abbreviations: AHI, apnea hypopnea index; BMI, body mass index.

Table 3. Pre- and Postoperative AHI Results Resulting From Hyomandibular Suspension With UPPP.^a

Parameter [average $\pm$ St dev]	Pre	Post	P
AHI [average $\pm$ St dev]	49.9 $\pm$ 25.6	15.4 $\pm$ 14.9	<.001
Mild OSA (%)	0 (0.0)	29 (74.4)	
Moderate OSA (%)	7 (16.9)	5 (12.8)	
Severe OSA (%)	32 (82.1)	5 (12.8)	

Abbreviations: AHI, apnea hypopnea index; Ave., average; OSA, obstructive sleep apnea; St dev, standard deviation; UPPP, uvulopalatopharyngoplasty.

^aN = 39.

Van Tassel et al. ENT Journal 2021. <https://journals.sagepub.com/doi/abs/10.1177/01455613211001132>

Hyo-mandibular Suspension with UPPP Efficacy

- All patients saw some reduction of AHI
- BMI has little effect on outcomes

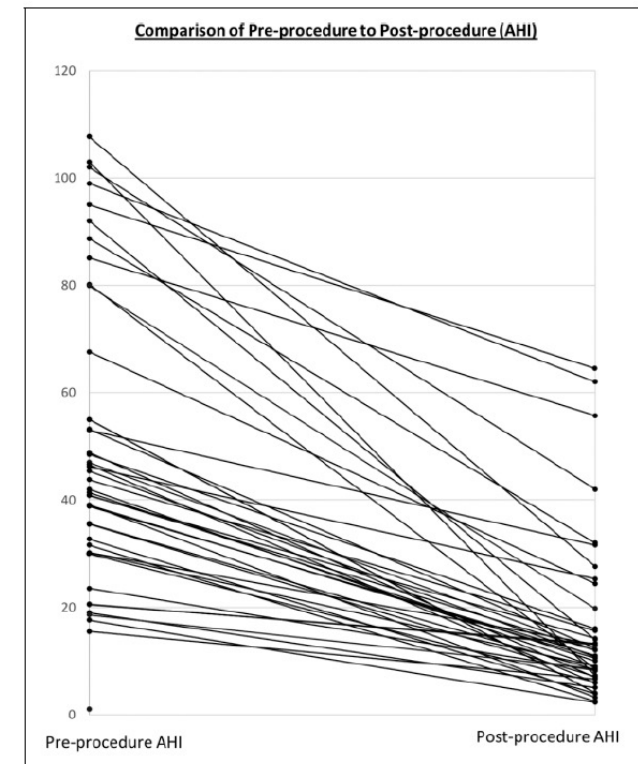
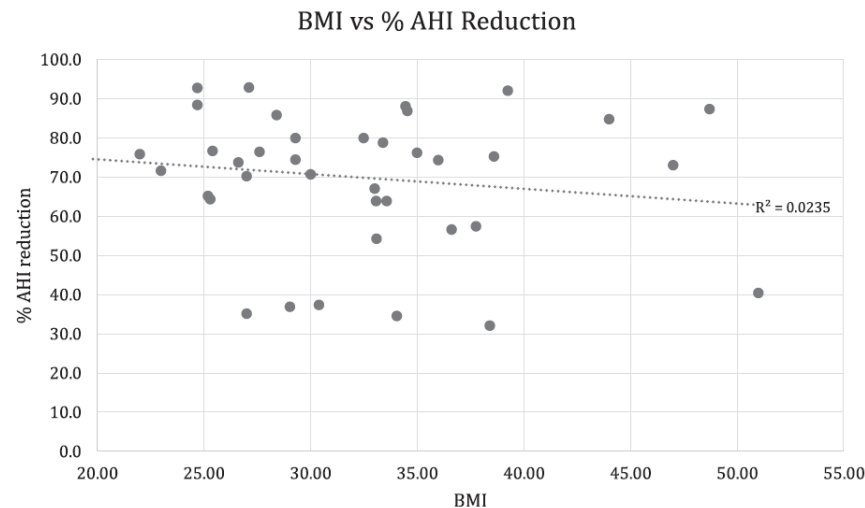


Figure 3. Individual preoperative and postoperative AHI outcomes (AHI = apnea hypopnea index, events/hour).

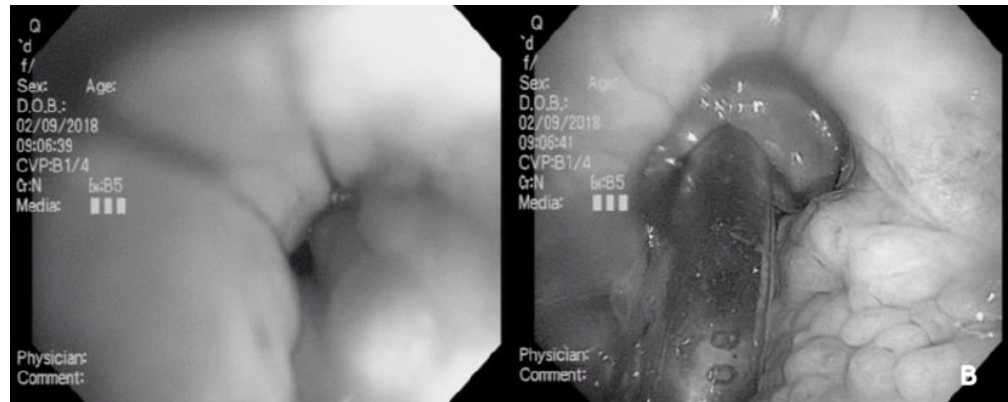
Hyo-mandibular Suspension with UPPP Efficacy

- Even patients without “surgical success” had 49% AHI reduction

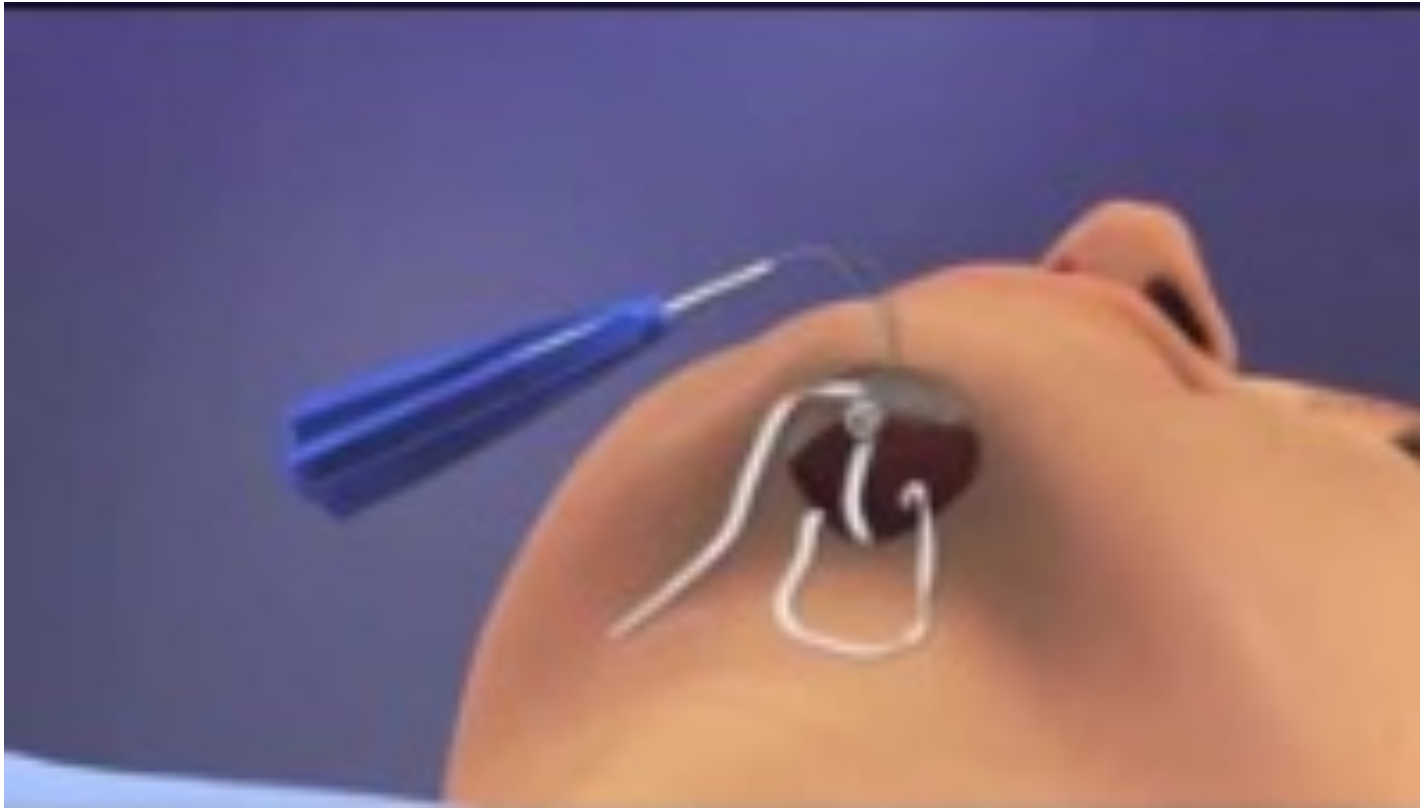
Table 4. Surgical Success Comparison.

Parameter (average $\pm$ St dev)	Surgical success (n [%])		P
	Yes, 30 (76.9%)	No, 9 (23.1%)	
BMI	31.4 $\pm$ 7.2	34.7 $\pm$ 7.0	.247
Age	57.2 $\pm$ 12.2	55.2 $\pm$ 12.0	.629
Baseline AHI	43.6 $\pm$ 20.2	70.8 $\pm$ 32.9	.004
Follow-up AHI	9.2 $\pm$ 4.3	36.0 $\pm$ 19.9	
Ave. AHI Improvement	79%	49%	

Abbreviations: AHI, apnea hypopnea index; Ave., average; BMI, body mass index; St dev, standard deviation.



Tongue Suspension Procedure - Animation



<https://www.youtube.com/watch?v=KjdNa4lnPXA&t=2s>



Preparation for Surgery

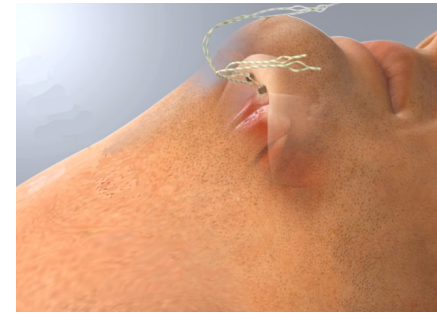
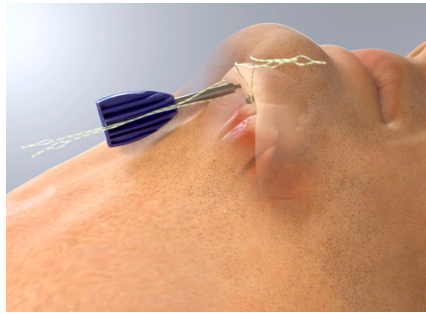
- Read product IFU
- General anesthesia (nasal intubation or LMA preferred)
- Antibiotics prophylaxis: Broad spectrum, prior to incision & one week post procedure
- Surgical drill (angled preferred): while a 1.75mm drill bit is provided in kit, a 1.5mm diameter drill bit may also be used
- Minimize or eliminate suture contact with patient skin by using ioban skin drape or placing sterile towels between suture & skin

Sub-mental Access Site



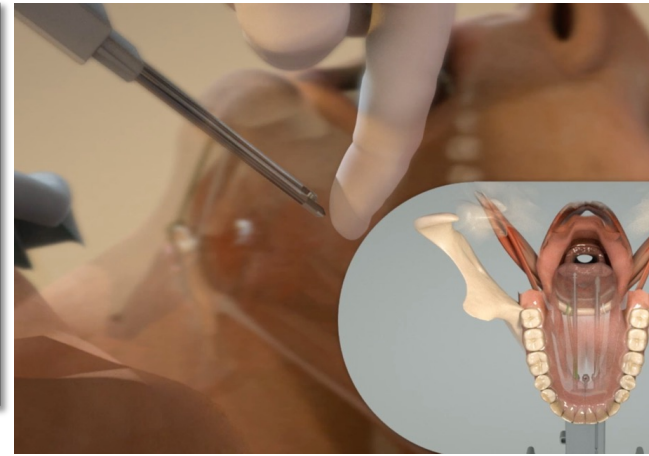
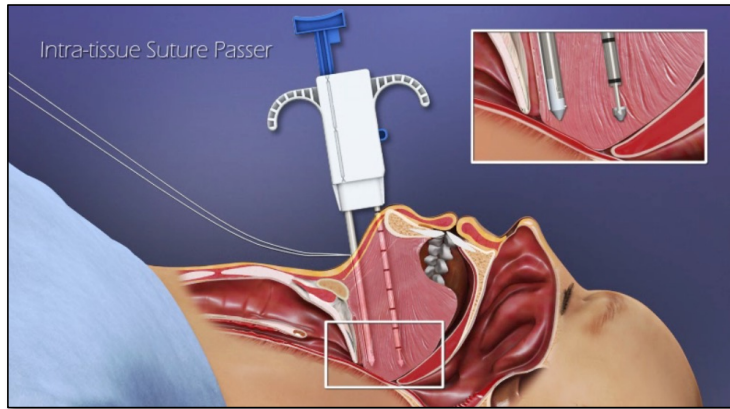
- Through a 2 - 3 cm submental incision, dissect to the inferior mandible.

Placing the Bone Anchor(s)



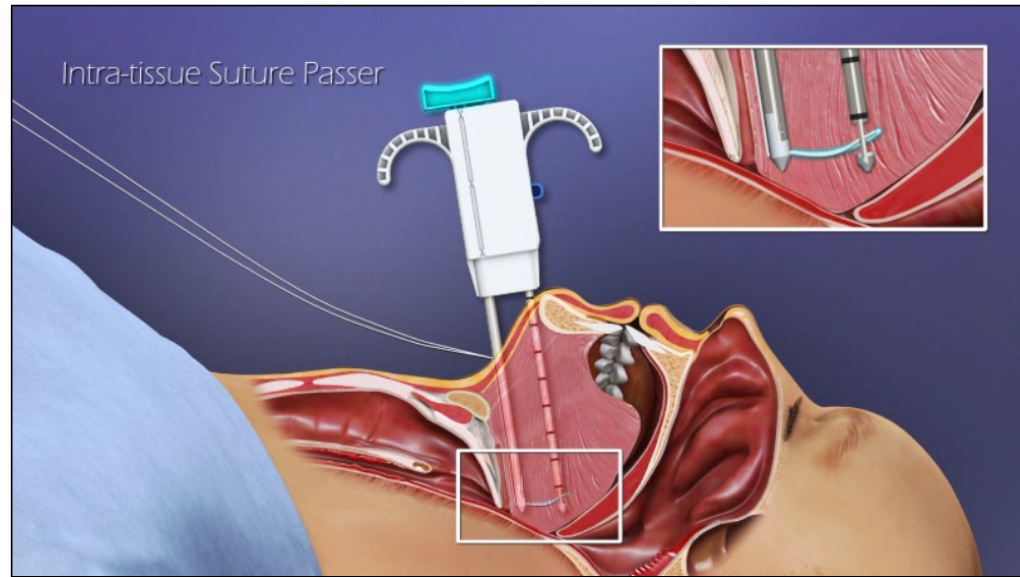
- Predrill two 1.5 – 1.7 mm dia. pilot holes approximately 1 cm lateral of midline
- Insert Bone Anchors into pre-drilled holes.
- Ensure that through hole on bone anchors is in A-P orientation.
- Tag the looped tether line ends away from the incision

Positioning the Suture Passer



- Choose horizontal, vertical, or other orientation
- First loop typically placed in inferior position to stabilize hypopharynx
- Digital palpation used to confirm positioning and depth
- REMEMBER TO DOUBLE GLOVE AND TO REMOVE GLOVE ON PALPATING HAND AFTER SUTURE PASS

Completing the Suture Pass



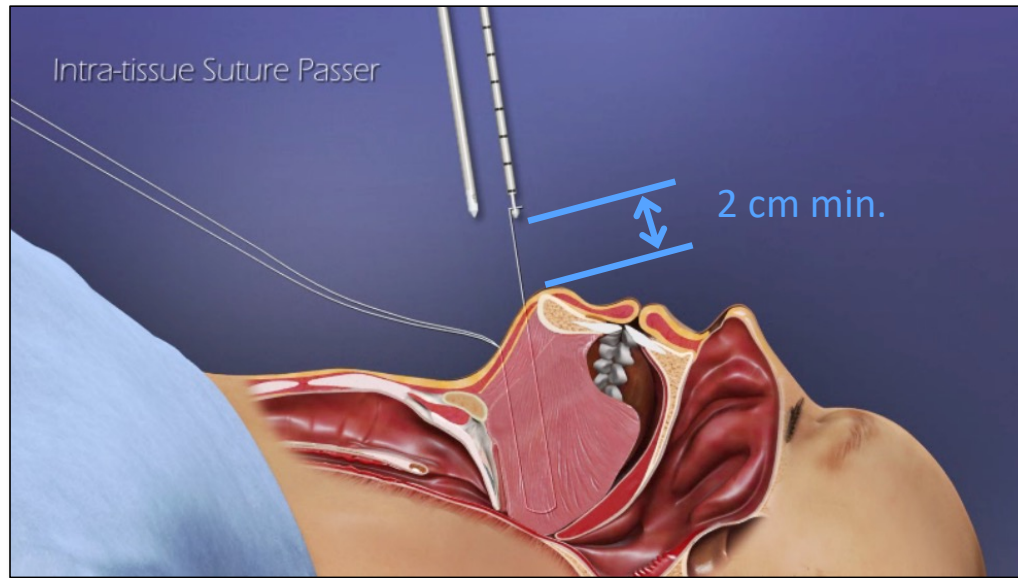
- Suture pass made while minimizing the “twisting” force applied to the Suture Passer
- Release palpation to avoid interfering with needle trajectory
- Completely depress the Plunger without stopping until Catch Switch activates
- Completely release the Plunger before withdrawing passer



Completing a Successful Suture Pass

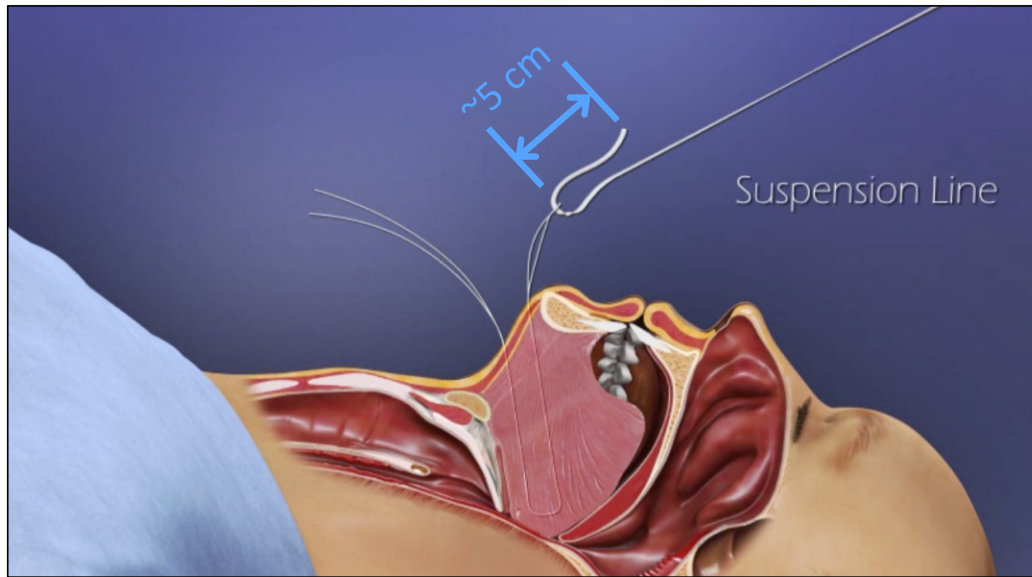
- Ensure that the tails of the Working Suture are not constrained when attempting suture pass
- Minimize amount of “twisting” force or torque applied to the Suture Passer when depressing the Plunger
- Release palpation to avoid interfering with the Needle trajectory
- Completely depress Plunger with fluid motion until Catch Switch is activated
- Completely release Plunger before withdrawing the Suture Passer
- Ensure that the Working Suture has been properly reloaded prior to inserting the Suture Passer into the incision

Withdrawing the Suture Passer



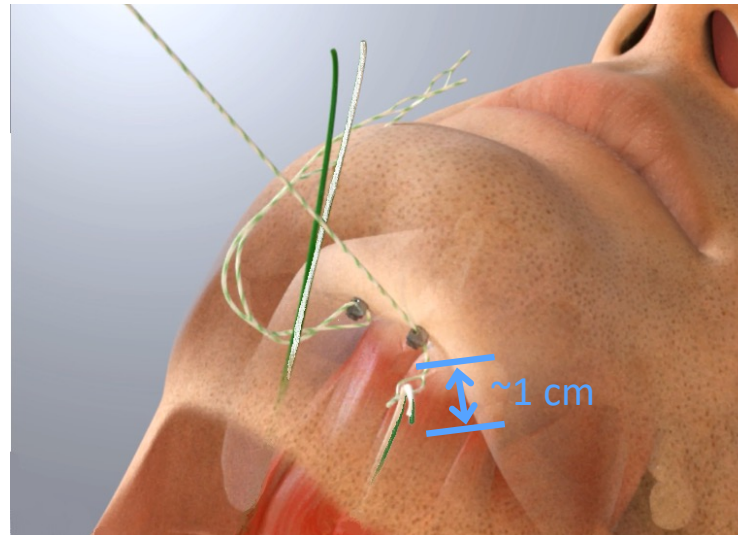
- Withdraw the Suture Passer straight back far enough to leave at least a 2 cm loop of suture
- Pull back on the Catch Switch to release suture from the Suture Passer

Suspension Line Exchange



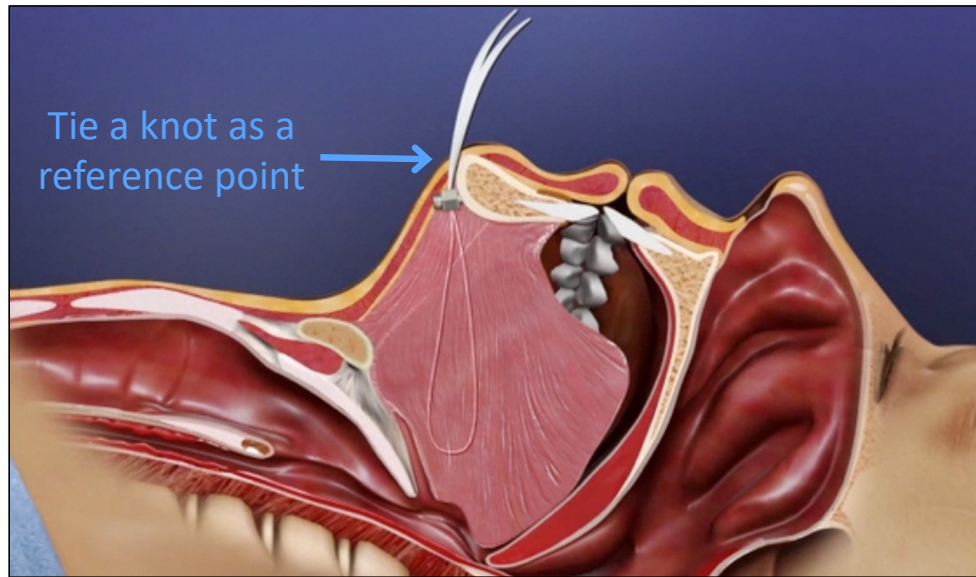
- Thread approximately 5 cm of the Suspension Line through the Working Suture loop and pull through tongue
- Center the Suspension Line
- Perform test “tug” on line to evaluate effect on tongue base. If result is insufficient, consider a new pass to reposition or reorient the Suspension Line
- Repeat suture pass technique for second superior loop

Threading the Suspension Line through the Bone Anchor



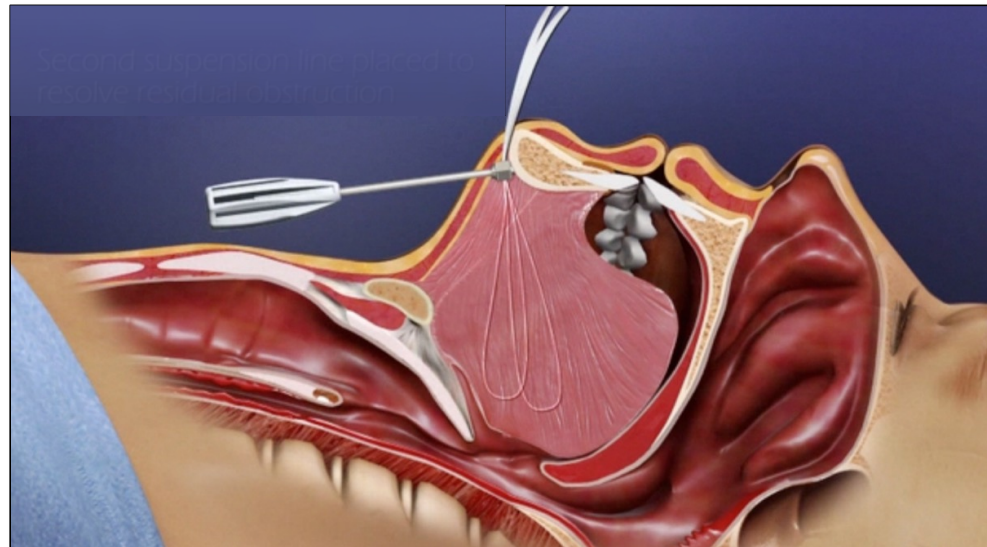
- Thread Suspension Line through the Bone Anchor using the pre-loaded Threading Suture or Threading Tool
 - ~1cm of the Suspension Line through Threading Suture loop or Tool loop
 - Both tails of the Suspension Line should be threaded simultaneously
- Ensure there is adequate slack on suspension loop side before threading

Optional: Set Advancement Marker



- OPTIONAL: With loop in neutral position, tie a surgeons knot in the tails to set neutral reference point

Suspension Line Advancement and Locking



- Use a pharyngoscopy or other visualization technique to adjust tension on the Suspension Line until the desired airway is achieved
- Use the Lock Tool to lock each Suspension Line in place by tightening Lock Screw finger tight. Use of hex lock tool other than that provided in the kit may over-torque the set screw and damage the working suture.
- Confirm there is a patent airway after locking the Suspension Lines. If possible, have patient swallow or talk to ensure the Suspension Lines are not over-tensioned.
 - Advancing too aggressively can increase patient discomfort and post-operative pain.



Tension Adjustment Decision Making

- Initial Advancement Titration
 - Suspension Line implanted with 'slack' taken up
 - Utilize DISE/direct visualization to set advancement or confirm after 8-10 mm of advancement.
 - Measure/record amount advanced for each loop. 8-10 mm is typical advancement
- Subsequent advancement modification
 - If clinically warranted at 30 days
 - Performed under local anesthesia or possibly with DISE
 - Document amount of final advancement

Infection Prevention & Wound Closure

- **During procedure:** Double gloving and/or providing some bacterial barrier to the oral cavity during palpation is necessary to prevent contamination of the implant and/or surgical site.
- **Prior to closing incision site,** the following steps should be followed to minimize infection risk:
 - Trim tails of suspension suture to 3-5 mm or tuck tails around back of anchors. Long suture tails in the wound side can potentially interfere with the healing process.
 - Prior to closure, irrigate wound with anti-bacterial solution. Bacitracin and saline is one recommendation.
 - Close wound in layers.
 - A compression dressing used 3 days to one week will help to minimize swelling.
 - A drain can be used to further reduce fluid build up and risk of infection.





Post Op

- Patients may feel pain and experience some difficulty swallowing for 1-2 weeks. Extreme or intolerable pain should not occur. If this happens, consider reducing suspension loop tension.