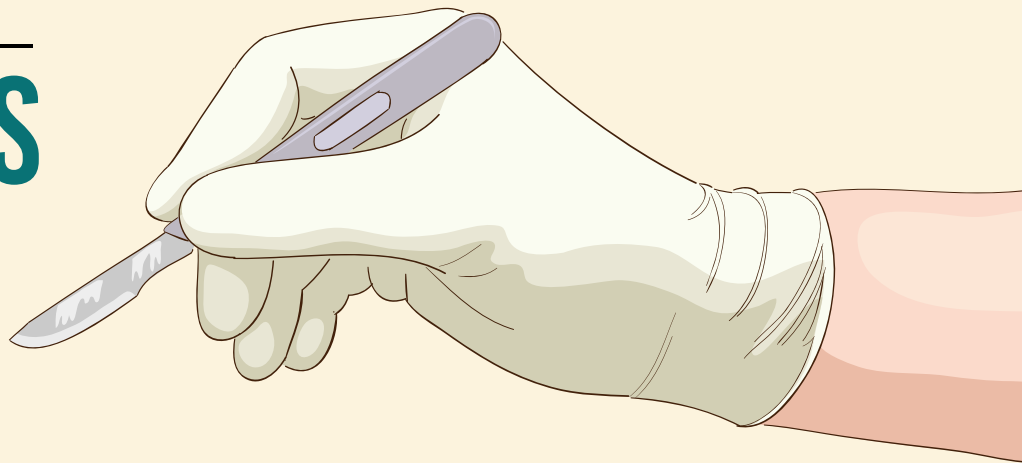


SURGEON'S MANUAL



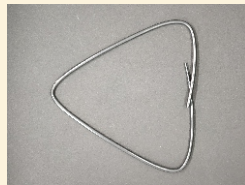
Contents



Aum Voice Prosthesis



Shushruth Inserter



Guide Wire



J Probe



TEP Brush



Scarf



Canvas Pouch



VR Fish Eyed Curved Trochar with Cannula (patent filed)

Compatibility Of The Device

The Aum Voice Prosthesis device is compatible



Radiation therapy



MRI, X-ray and radiation examination/therapy session



It has a radio-opaque tag

Device's Lifespan



Duration: On an average **6-12** months, requiring replacement



Reason: Wear and tear is due to the use and **biological colonization** of the

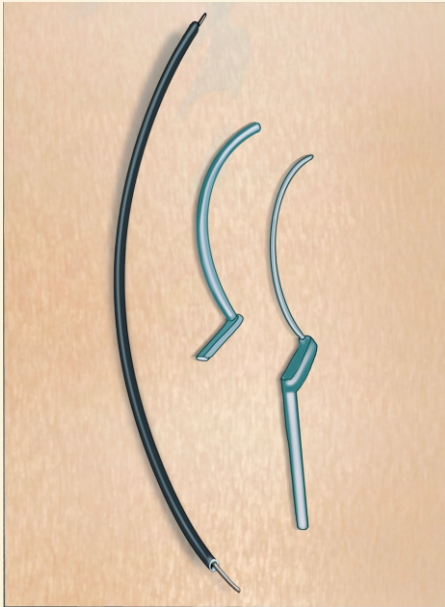
Instructions For Use

1 Primary Insertion/ Retrograde insertion (First Time)

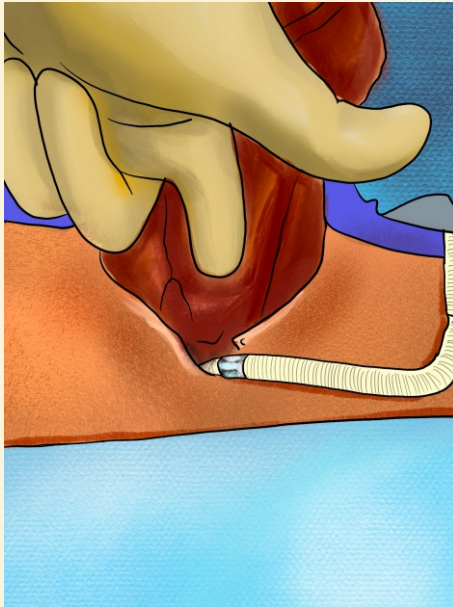
2 Antegrade Insertion (Replacement)

3 Antegrade Insertion in Narrow Stoma (Replacement)

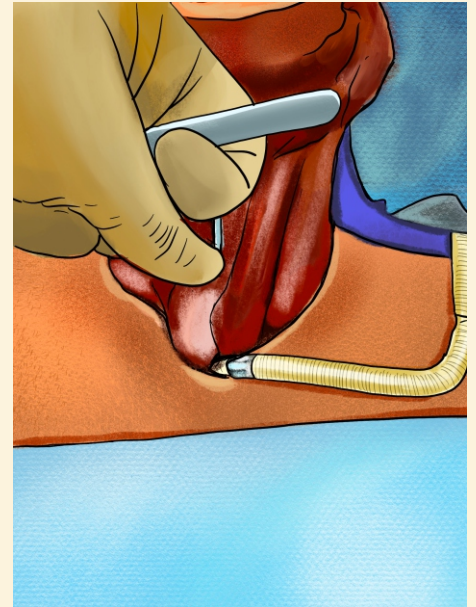
1. Primary Insertion/Retrograde Insertion Steps



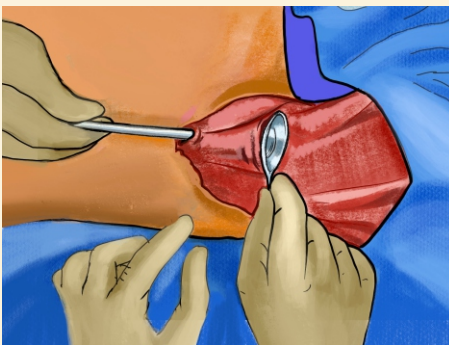
STEP 1 - Instruments required for puncture and placement of prosthesis.



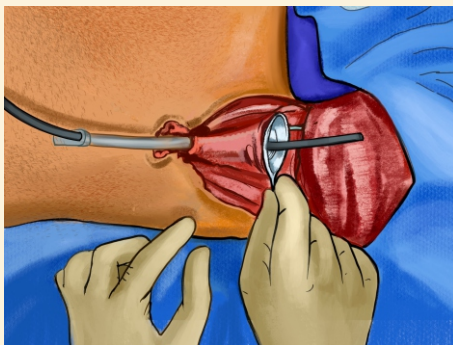
STEP 2 - After laryngectomy, identify the party wall.



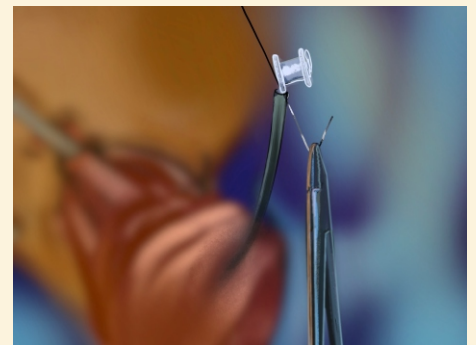
STEP 3 - Do a cricopharyngeal myotomy such that the gloved finger is just about visible.



STEP 4 - Place the proctoscope/ rigid esophagoscope (for secondary insertion) in the neopharynx and puncture the party wall with the c-knife as depicted to make the puncture.



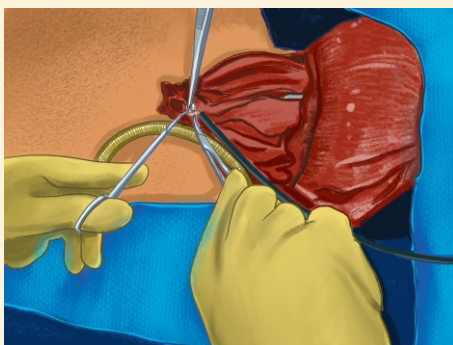
STEP 5 - Withdraw the knife leaving in position the outer sheath. Pass the guide wire through the



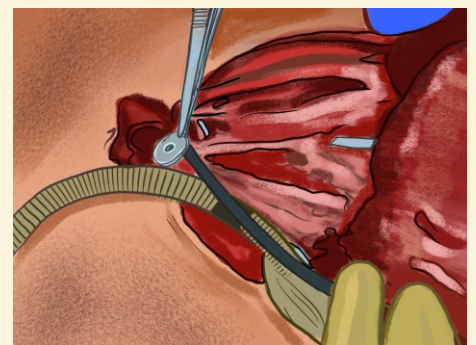
STEP 6 - Secure the voice prosthesis to the head end of the guidewire and remove the



STEP 7 - Pull the guide wire caudally to draw the prosthesis into the puncture.



STEP 8 - Using the forceps bring in a part of the tracheal flange of the prosthesis into the puncture site. Using the modified ball probe, in a sweeping movement bring out the entire tracheal flange and safety limb out.



STEP 9 - Prosthesis secured in position

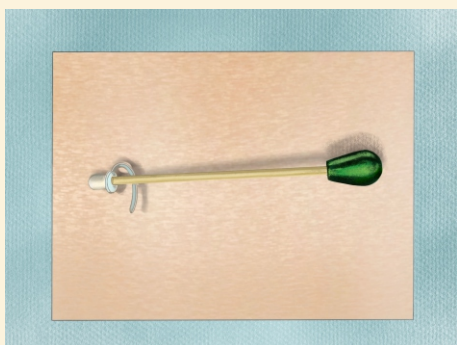
2. Antegrade Insertion (Replacement)



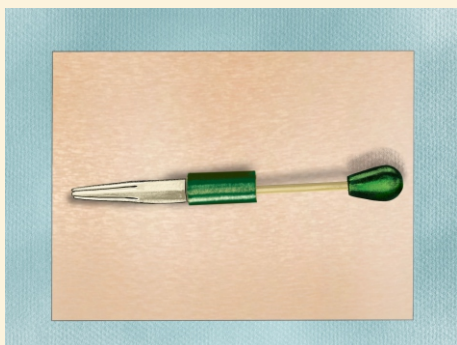
STEP 1 - Components required for replacement.



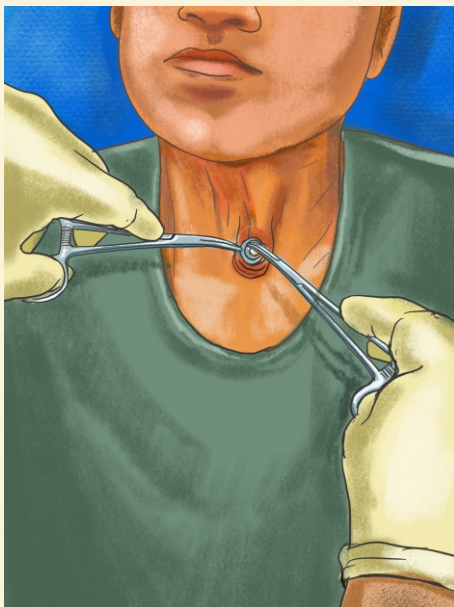
STEP 2 - Fold the esophageal end and squeeze it into the capsule.



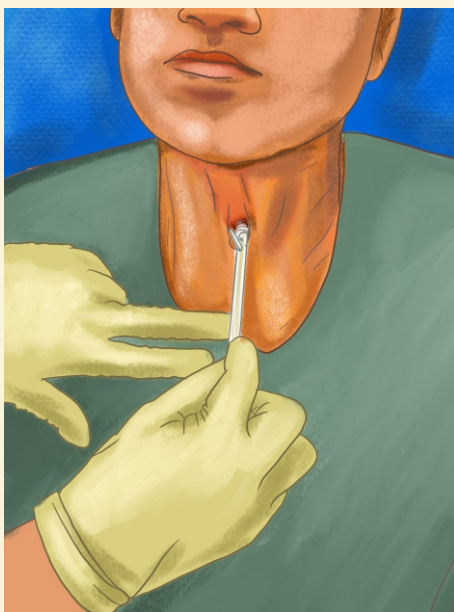
STEP 3 - Ensure the Voice Prosthesis is properly positioned onto the Shushruta Inserter and secure in place by passing the safety limb into the secure locks.



STEP 4 - Recheck if the prosthesis is securely placed.



STEP 5 - Using two mosquito forceps pull out the old TEP gently and suction the puncture



STEP 6 - Insert the loaded TEP into the puncture.

STEP 7 - Ask the patient to swallow saliva. Hold the inserter in place till the capsule is completely dissolved, confirmed by whitish liquid coming from around the prosthesis.

Remove the safety limb from the secure lock and hold it with a mosquito.

Gently withdraw the Shushruta Inserter leaving the TEP in place.

Cut the safety limb and rotate the prosthesis such that the cut safety limb faces downwards.

Offer the patient a glass of water and ask to consume it. Look for TEP leak.

3. Antegrade Insertion in Narrow Stoma (Replacement)



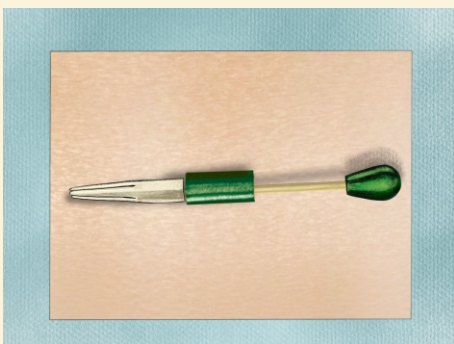
STEP 1 - Components required for replacement.



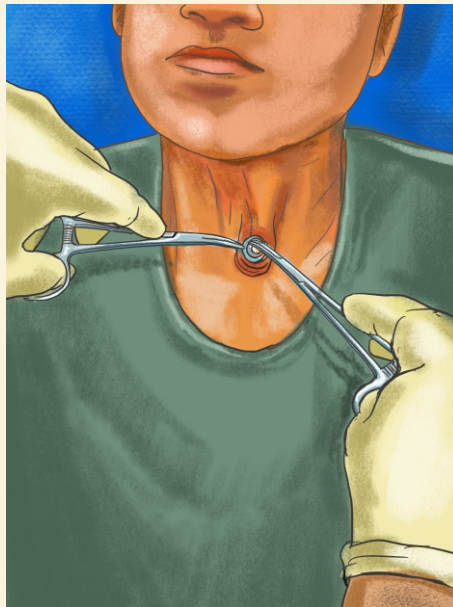
STEP 2 - Fold the esophageal end and squeeze it into the capsule.



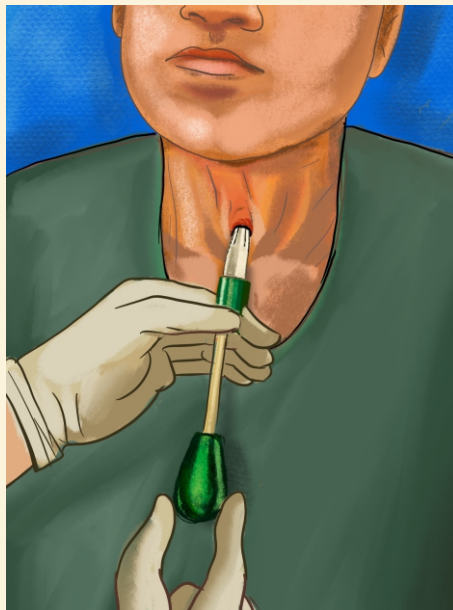
STEP 4 - Recheck if the prosthesis is securely placed.



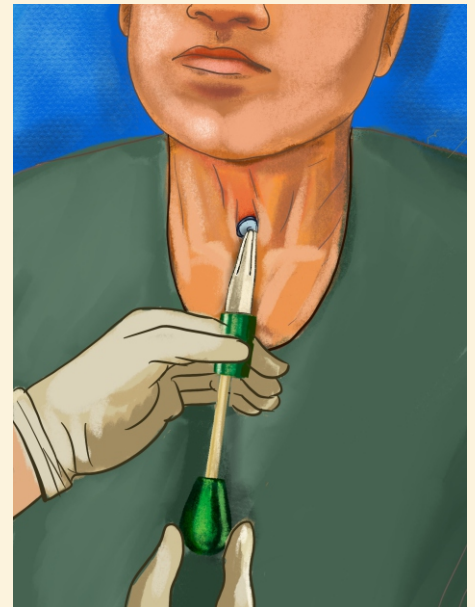
STEP 3 - Ensure the Voice Prosthesis is properly positioned onto the Shushruta Inserter and secure in place by passing the safety limb into the secure locks. Attach the beak, place by passing the safety limb



STEP 5 - Using two mosquito forceps pull out the old TEP gently and suction the puncture



STEP 6 - Insert the beak and the inserter into the puncture.



STEP 7 - Push the plunger inwards to place the prosthesis into the puncture.

STEP 8 - Ask the patient to swallow saliva. Hold the inserter in place till the capsule is completely dissolved, confirmed by whitish liquid coming from around the prosthesis.

Remove the safety limb from the secure lock and hold it with a mosquito. Gently withdraw the Shushruta Inserter leaving the TEP in place.

Cut the safety limb and rotate the prosthesis such that the cut safety limb faces downwards.

Offer the patient a glass of water and ask to consume it. Look for TEP leak.