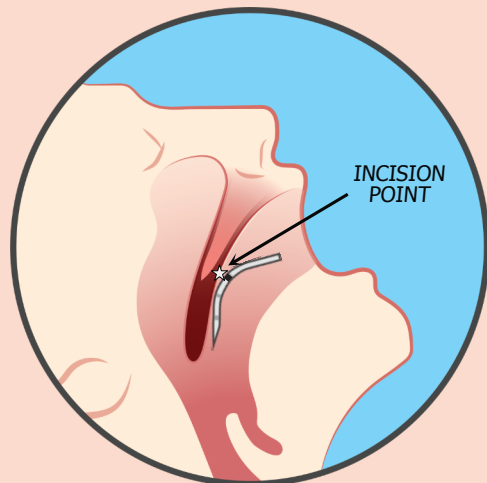
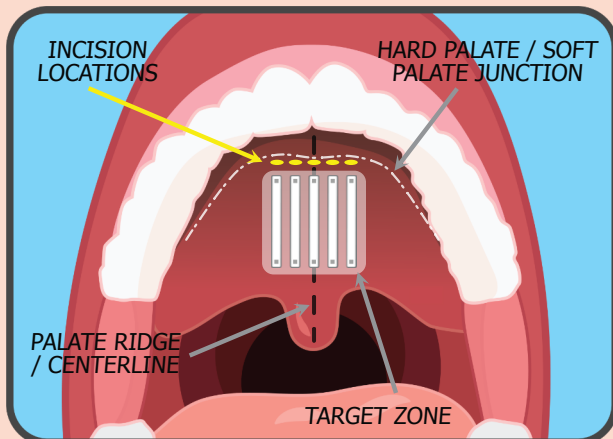
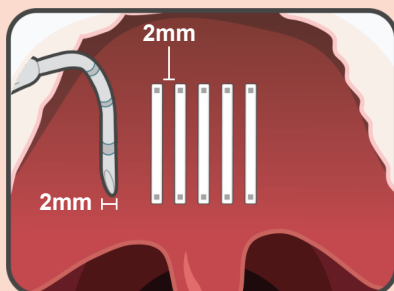


1. DETERMINE IMPLANT POSITIONING



Use the needle as a tool to visualize appropriate spacing of Implants and to ensure that the target zone of the soft palate tissue is long enough to accept Implants.



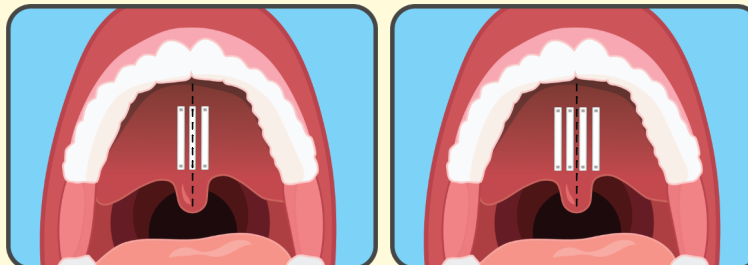
SERENE SLEEP PALATAL IMPLANT SYSTEM

THIS DOCUMENT SERVES AS A VISUAL AID FOR THE USAGE OF THE SERENE SLEEP PALATAL IMPLANT SYSTEM. REFER TO THE FULL INSTRUCTIONS FOR USE FOR FULL DOCUMENTATION INCLUDING WARNINGS, ETC.

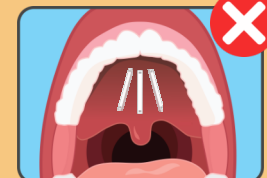
2. PLAN IMPLANT CONFIGURATION

Arrangement **MUST** be symmetric about the midline

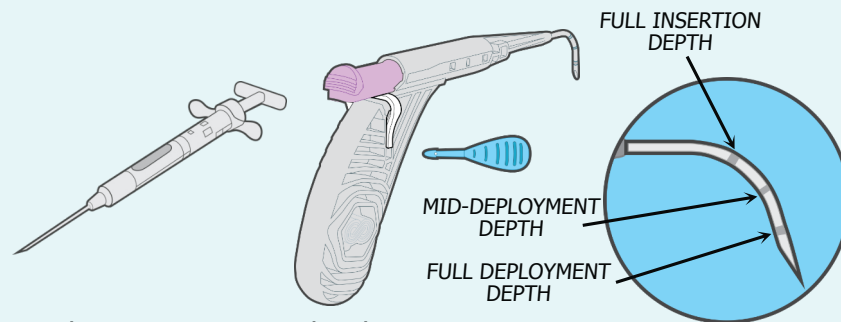
2 mm parallel spacing **MUST** be maintained



DO NOT position the Implants at an angle or space them more than 2 mm apart from each other.

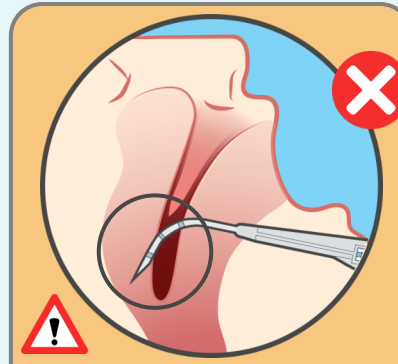


3. PREP & NEEDLE INSERTION

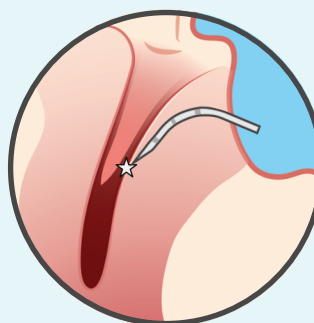


Sterilize tissue. Inject local anesthetic at each insertion site along the profile where each Implant will be placed.

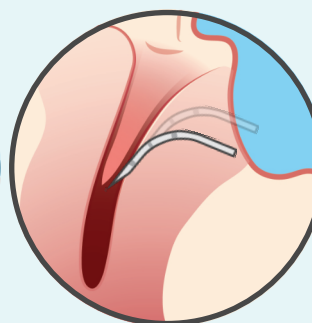
Remove needle cap. Remove blue pull tab. Identify the 3 markings on the Delivery Tool needle



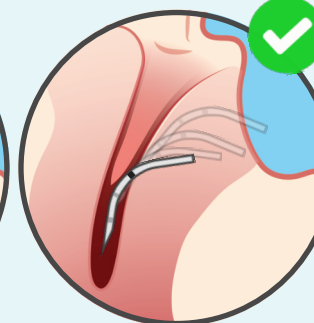
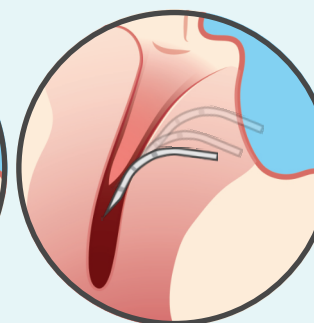
Ensure that the needle **DOES NOT** pierce/exit any portion of the tissue and become exposed.



Make incision and begin needle entry.

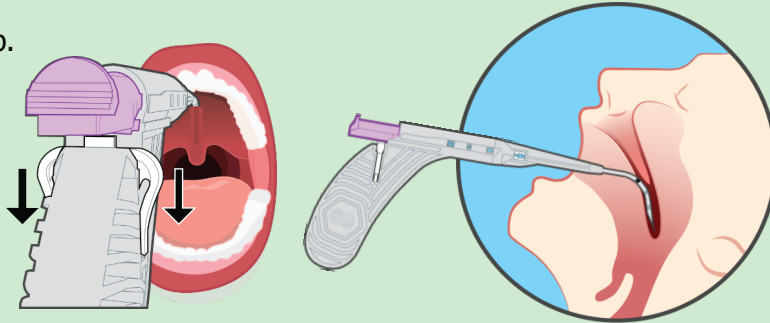


Allow hard palate boundary to guide needle trajectory. Advance in arcing motion to follow the profile of the soft palate at the mid-plane of the tissue, until the "full insertion depth marker" is barely visible.



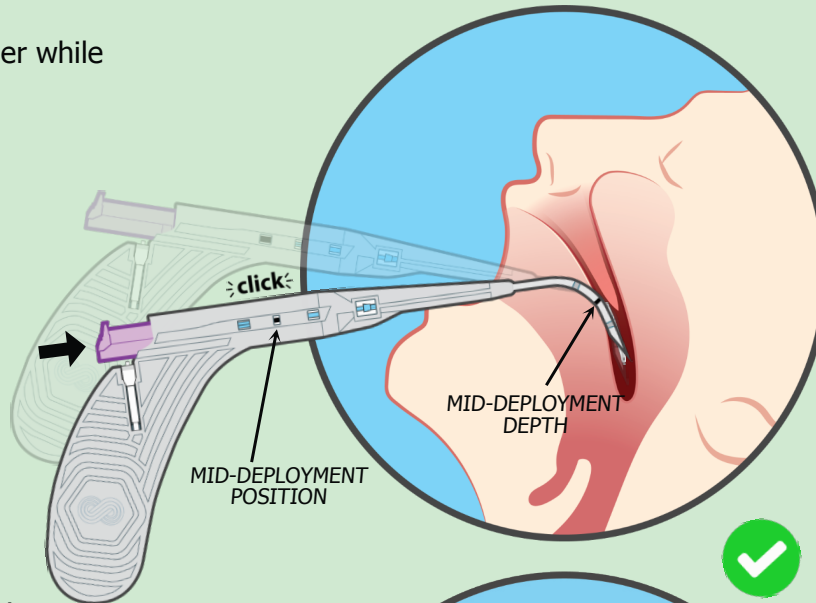
4. IMPLANT DEPLOYMENT

Disengage the Safety Clip.



SLOWLY advance the slider while retracting needle.

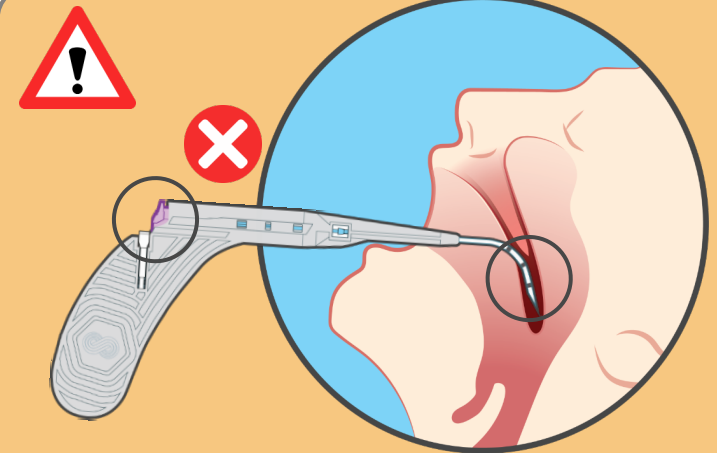
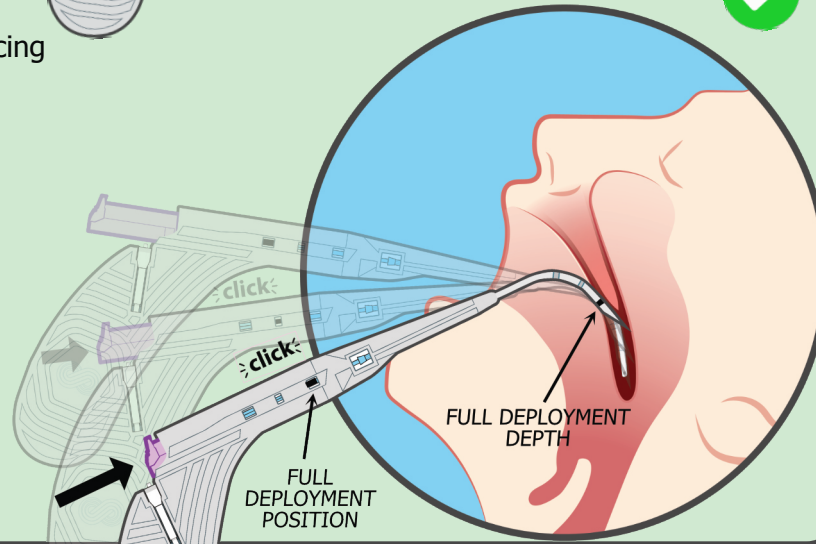
**Mid-Deployment
Depth Marker**
corresponds with
**Mid-Deployment
Position 'click'**



Continue **SLOWLY** advancing the slider while retracting needle.

**Full Deployment
Depth Marker**
corresponds with
**Full Deployment
Position 'click'**

Withdraw needle from tissue one Implant is fully deployed.



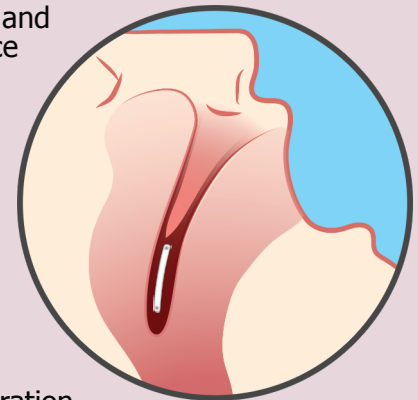
DO NOT depress the slider without also retracting the needle from the tissue in a coordinated fashion. This may lead to improper Implant positioning and subsequent Implant extrusion.

5. INSPECTION AND SUBSEQUENT IMPLANTS

Inspect the incision site and the dorsal (nasal) surface of the soft palate.

If the Implant is exposed or visible, it must be removed. Use forceps to gently remove the Implant from the tissue.

Repeat instructions to place subsequent implants following the planned implant configuration



DO NOT reposition the needle in the original penetration site or replace an extracted implant until the incision has healed

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INSTRUCTIONAL-071-01 PALATAL IMPLANT SYSTEM VISUAL IFU

