



PROBUPHINE® REMS PROGRAM CRITERIA FOR PROCEDURAL COMPETENCY: INSERTION

INSERTION

Trainees must demonstrate competency in performing the following techniques.

	Identify insertion site (8-10 cm) above medial epicondyle of the humerus
2	Clean the insertion site with alcohol prep.
3	Mark insertion site with a surgical marker (2.5 – 3mm) and mark the tracks for each implant by drawing 4 lines with each line 4 cm in length and distributed 4-6 mm apart.
4	Put on sterile gloves.
5	Use aseptic technique to place sterile equipment and implants in sterile field.
6	Check applicator function by removing the obturator from the cannula and relocking it.
7	Clean insertion site with antiseptic solution (e.g., chlorhexidine) using gentle repeated back and forth strokes for 30 seconds.
8	Apply sterile drape.
9	Anesthetize insertion area.
1	After determining anesthesia is adequate and effective, make a shallow incision that is 2.5 – 3mm in length with a scalpel, lift skin with forceps.
1	Insert the tip of the applicator, with the bevel-up stop marking on the cannula facing upwards, into the opening (not to exceed a 20 degree angle) until the proximal marking on the cannula just disappears into the incision.
1	Unlock the obturator and remove the obturator. Then insert one implant into cannula and re-insert the obturator and advance obturator until the obturator stop marking reaches the bevel-up stop marking on cannula.
1	Hold obturator fixed in place, retract cannula along obturator, and lock obturator.
1	Stabilize the implant with finger while retracting the applicator (cannula and obturator) to distal marking.
1	Redirect applicator to the next channel marking and repeat steps 11-13 until all four implants have been inserted. Remove the applicator completely from the incision.
1	Verify presence of each implant by palpation.
1	Clean incision site and apply liquid adhesive and steri-strips.
1	Place small adhesive bandage over the insertion site.
1	Apply pressure bandage with sterile gauze.
LL	







PROBUPHINE REMS PROGRAM CRITERIA FOR PROCEDURAL COMPETENCY: REMOVAL

REMOVAL

Trainees must demonstrate competency in performing the following techniques.

1	Reconfirm location of implants by palpation. IF ALL FOUR IMPLANTS CAN NOT BE PALPATED, DO NOT
	ATTEMPT TO REMOVE. REQUEST ULTRASOUND OR MRI.
2	Clean removal site properly with alcohol prep.
3	Using a surgical marker, mark location of the implants and mark location of incision site (7-10 mm)
	parallel to the axis of the arm between second and third implant.
4	Put on sterile gloves.
5	Use aseptic technique to place sterile equipment in sterile field.
6	Clean removal site with an antiseptic solution (e.g., chlorhexidine) using gentle repeated back and
	forth strokes for 30 seconds
7	Apply sterile drape.
8	Anesthetize incision site and subcutaneous space below implants (which helps to lift implants
	toward the skin, facilitating removal of the implants).
9	Confirm anesthesia is adequate and make a 7-10 mm incision parallel to the axis of the arm between
	2 nd and 3 rd implants, along the marked tracks from step 3 above.
10	Pick up skin edge with a toothed forceps and separate the tissue above and below the first visualized
	implant. If necessary, use the scalpel to shave away adhered tissue.
11	Grasp the center of implant with X-plant clamp and apply gentle traction.
12	Remove implant.
13	After removal of each implant, confirm entire implant is removed
	by measuring 26 mm in total length, before proceeding to removal of the next implant.
14	Repeat steps 10 – 13 until all implants are removed.
15	Close the incision with sutures.
16	Place an adhesive bandage over the incision and wrap arm with pressure dressing.
17	Dispose of all implants in keeping with regulations governing disposal of biohazardous waste.

MAXIMUM INCISION LENGTH REQUIRED IS 10 mm

EACH IMPLANT REMOVED SHOULD BE 26 mm



