

**PROBUPHINE® REMS PROGRAM**  
**CRITERIA FOR PROCEDURAL COMPETENCY:**  
**INSERTION**

**Trainees must demonstrate competency in performing the following techniques.**

<b>1</b>	Identify insertion site (8-10 cm) above medial epicondyle of the humerus
<b>2</b>	Clean the insertion site with alcohol prep.
<b>3</b>	Mark insertion site with a marker (2.5 – 3.0 mm) and mark the tracks for each implant with by drawing 4 lines with each line 4 cm in length and distributed 4-6 mm apart.
<b>4</b>	Put on sterile gloves.
<b>5</b>	Use aseptic technique to place sterile equipment and implants in sterile field.
<b>6</b>	Clean incision sites with ChloroPrep using gentle repeated back and forth strokes for 30 seconds
<b>7</b>	Apply sterile drape.
<b>8</b>	Anesthetize insertion area.
<b>9</b>	Check that the Obturator and cannula are functioning properly.
<b>10</b>	After determining anesthesia is adequate and effective, lift skin with forcep, make a 2.5 – 3.0 mm shallow opening with scalpel.
<b>11</b>	Insert cannula into the opening (not to exceed 20 degree angle) with bevel-up stop marking facing upwards until the proximal line is no longer visible under the opening.
<b>12</b>	Insert one implant into cannula and re-insert the obturator and advance obturator until the marking reaches the bevel-up stop marking on cannula.
<b>13</b>	Hold obturator fixed in place, retract cannula along obturator, and lock obturator.
<b>14</b>	Stabilize the implant with finger while retracting the applicator to distal marking.
<b>15</b>	Redirect applicator to the next channel marking and repeat steps 11-13.
<b>16</b>	Verify presence of each implant by palpation.
<b>17</b>	Clean incision site and apply liquid adhesive and steri-strips.
<b>18</b>	Place small adhesive bandage over the insertion site.
<b>19</b>	Apply pressure bandage with sterile gauze.
<b>20</b>	Complete patient Identification Card and Chart Label.
<b>21</b>	Discuss and provide patient a copy of wound care sheet and medication guide.

**MAXIMUM INCISION LENGTH REQUIRED IS 3 mm**

3mm

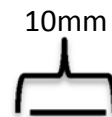


**PROBUPHINE® REMS PROGRAM**  
**CRITERIA FOR PROCEDURAL COMPETENCY:**  
**REMOVAL**

**Trainees must demonstrate competency in performing the following techniques.**

<b>1</b>	Reconfirm location of implants by palpation. IF ALL FOUR IMPLANTS CAN NOT BE PALPATED, DO NOT ATTEMPT TO REMOVE. REQUEST ULTRASOUND OR MRI.
<b>2</b>	Clean removal site properly with alcohol prep.
<b>3</b>	Mark location of the implants and mark location of incision site parallel to the axis of the arm between second and third implant.
<b>4</b>	Put on sterile gloves. Use aseptic technique to place sterile equipment in sterile field.
<b>5</b>	Use aseptic technique to place sterile equipment in sterile field.
<b>6</b>	Clean removal site with ChloroPrep using gentle repeated back and forth strokes for 30 seconds
<b>7</b>	Apply sterile drape.
<b>8</b>	Anesthetize incision site and subcutaneous space below implants.
<b>9</b>	Confirm anesthesia is adequate and make a 7 – 10 mm incision parallel to the axis of the arm between 2 <sup>nd</sup> and 3 <sup>rd</sup> implants.
<b>10</b>	Pick up skin edge with a toothed forceps and separate the tissue above and below the first visualized implant. Grasp the center of implant with X-plant clamp and apply gentle traction.
<b>11</b>	Remove implant.
<b>12</b>	If necessary, use the scalpel to shave away adhered tissue.
<b>13</b>	After removal of each implant confirm entire implant is removed by measuring 26 mm in total length.
<b>14</b>	Repeat steps 10 – 13 until all implants are removed.
<b>15</b>	Close the incision with sutures.
<b>16</b>	Place an adhesive bandage over the incision and wrap arm with pressure dressing.
<b>17</b>	Dispose of all implants in keeping with regulations governing disposal of biohazardous waste.
<b>18</b>	Counsel patient on proper wound care and provide wound care sheet.

**MAXIMUM INCISION LENGTH REQUIRED IS 10 mm**



**EACH IMPLANT REMOVED IMPLANT SHOULD BE 26 mm**

