



### INSERTION AND REMOVAL PROCEDURES

Viadur® is supplied in a box containing one sterile Viadur® implant in a sealed vial, one Viadur® sterile implanter, and one sterile Viadur® Kit. The Viadur® Kit is designed to provide a sterile field and supplies to facilitate the insertion and/or subsequent removal of the implant.

In addition to the Viadur® Kit, sterile gloves are required for the insertion procedure and subsequent removal of the implant.

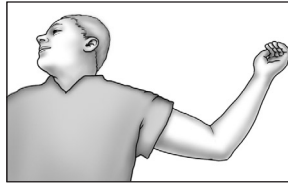
#### INSERTION PROCEDURE

Under aseptic conditions, an implanter is used to place the implant under the skin.

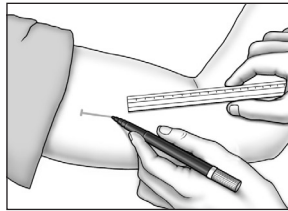
The implant is inserted using the procedure outlined below.

#### IDENTIFYING THE INSERTION SITE

1. Have the patient lie on his back on the examination table, with his left arm (if the patient is left-handed, the right arm) flexed at the elbow and externally rotated so that his hand is out to his side.



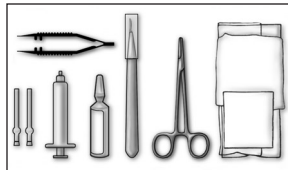
Using a pen and ruler, mark a site on the inner, upper arm approximately 8-10 cm above the elbow crease in the groove between the biceps and triceps muscles. Make sure that the site is unaffected by movement of the muscles.



#### PREPARING THE STERILE FIELD

1. To establish a sterile field, carefully open the sterile Viadur® Kit. The sterile kit contains:

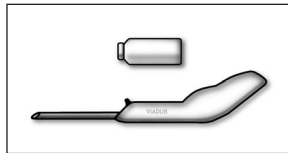
- 1 scalpel
- 1 forceps
- 1 syringe
- 1 package povidone-iodine swabs
- 1 package wound closure strips
- 1-22 Ga x 1.5" needle
- 1-25 Ga x 1.5" needle
- 1 ampule Lidocaine Hydrochloride USP 2%, 10 mL
- 6 gauze sponges
- 2 alcohol prep pads
- 1 package skin protectant
- 1 bandage
- 1 fenestrated drape
- 1 marking pen
- 1 ruler
- 1 mosquito clamp



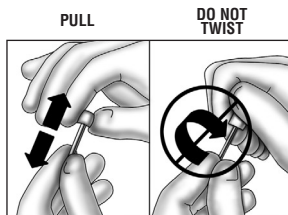
2. The implant tray contains:

- 1 sealed vial, which contains the Viadur® implant
- 1 sterile implanter

To open the vial, remove the metal band from the bottle and pull up the stopper. Carefully drop the implant from the bottle onto the sterile field. Then, carefully drop the implanter onto the sterile field.

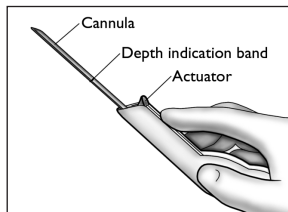


Using sterile technique, remove the protective cap from the implant by pulling the cap straight off. **DO NOT TWIST CAP OFF AS IT MAY UNSCREW THE DIFFUSION MODERATOR. CAUSE ITS REMOVAL, OR OTHERWISE DAMAGE THE IMPLANT. SHOULD DAMAGE OCCUR, DO NOT INSERT THE IMPLANT AS PRODUCT FUNCTION CAN BE IMPAIRED.**

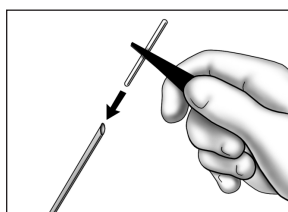


#### LOADING THE IMPLANTER

1. The implanter is packaged in the correct configuration for implant loading and insertion. Make sure the cannula is fully extended as shown, and the actuator is in its most forward position.

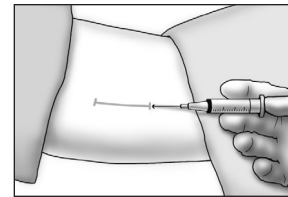


2. Using sterile forceps, slide the implant into the end of the cannula and push until it stops. When properly loaded, the implant should not protrude more than 1 mm past the bottom of the beveled edge.

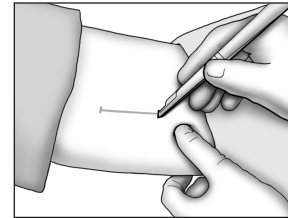


#### INSERTING THE IMPLANT

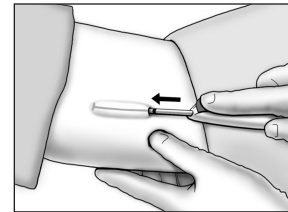
1. Using aseptic technique, cleanse the insertion site, then drape the patient's arm. After determining the absence of known allergies to the anesthetic agent, infiltrate the site with lidocaine. Advance the needle to infiltrate the intended 5 cm track for the implant insertion.



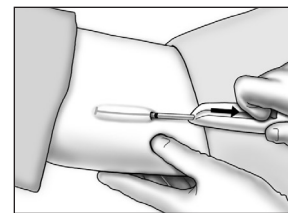
2. Determine that anesthesia is adequate. Make an incision of approximately 5 mm with the scalpel, just through the dermis.



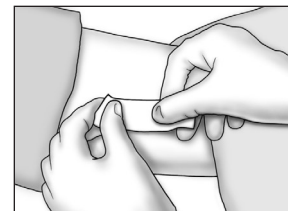
3. Grasp the handle of the implanter and extend the index finger to rest on the back of the actuator as shown. Insert the cannula tip into the incision with the bevel up and advance it subcutaneously along the intended track. To ensure subcutaneous placement, the Viadur® implanter should visibly raise the skin at all times during insertion. The implanter should not enter muscle tissue, but be well within the subcutaneous space. Advance the implanter to the depth indicator on the cannula, which indicates the recommended insertion length.



4. Holding the implanter handle in position, use the index finger to slide the actuator slowly back until it stops. (This retracts the actuator cannula into the handle, leaving the implant beneath the skin.) Do not pull back on the implanter handle while sliding the actuator back, as this may lead to incorrect positioning of the implant and subsequent extrusion. Withdraw the implanter from the incision. Release of the implant can be checked by palpation. It is important to keep the implanter steady and not to push the implant into the tissue. After placement, sterile gauze may be used to apply pressure briefly to the insertion site to ensure hemostasis.



5. Cleanse the insertion area. Press the edges of the incision together, and tightly close the incision with one or two surgical closure strips. Cover with an adhesive bandage. Observe the patient for a few minutes for signs of bleeding from the incision before he is discharged. Instruct the patient to keep the area clean and dry for 24 hours, and to avoid heavy lifting and strenuous physical activity for 48 hours. The surgical closure strip can be removed as soon as the incision has healed, ie, normally in 3 days.



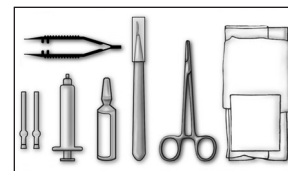
#### REMOVAL PROCEDURE

Viadur® must be removed following 12 months of therapy.

The position of the patient and the sterile technique are the same as for insertion.

To remove Viadur® use the Viadur® Kit or the following sterile items:

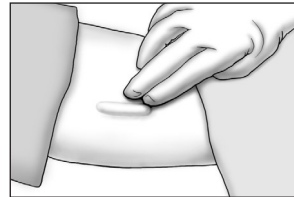
- 1 scalpel
- 1 forceps
- 1 syringe
- 1 package povidone-iodine swabs
- 1 package wound closure strips
- 1-22 Ga x 1.5" needle
- 1-25 Ga x 1.5" needle
- 1 ampule Lidocaine Hydrochloride USP 2%, 10 mL
- 6 gauze sponges
- 2 alcohol prep pads
- 1 package skin protectant
- 1 bandage
- 1 fenestrated drape
- 1 marking pen
- 1 ruler
- 1 mosquito clamp



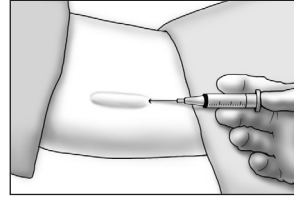
#### PREPARING THE SITE

1. Inspect the site, palpating the location of the implant. Mark the position of the implant with marking pen. Cleanse with povidone-iodine swab. Drape the area with a fenestrated drape.

Suggestion:  
If unable to locate by palpation, radiological imaging may be helpful.

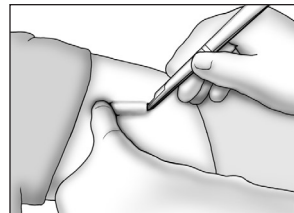


2. After determining the absence of known allergies to the anesthetic agent, apply a small amount of local anesthetic under the end of the implant nearest the original incision site. Then advance the needle to infiltrate the tissue along the track.

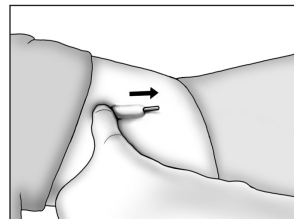


#### REMOVING THE IMPLANT

1. Determine that anesthesia is adequate. Apply pressure to one end of the implant to elevate the other end. Make an incision of approximately 5 mm at the elevated end of the implant. Do not make a large incision.



Continue to apply pressure to the end of the implant to encourage expulsion. Push the implant gently towards the incision with the fingers. When the tip is visible or near the incision, grasp it with a clamp and remove.



2. If necessary, cut through any fibrous encapsulation with the scalpel to free the implant.
3. Properly dispose of removed implant immediately, before opening the vial containing the new implant.

If inserting a new Viadur®, return to section describing INSERTION PROCEDURE.

The new Viadur® implant may be placed through the same incision site. Alternatively, the contralateral arm may be used.

4. Cleanse insertion site area. Apply pressure to each end of the incision to close the wound. Apply one or two surgical closure strips to close the wound tightly, and cover with an adhesive bandage. Observe the patient for a few minutes for signs of bleeding from the incision before he is discharged. Instruct the patient to keep the area clean and dry for 24 hours, and to avoid strenuous physical activity for 48 hours.

#### HOW SUPPLIED

Viadur® is supplied in a box containing 2 inner package trays. One tray contains a sterile Viadur® implant in a sealed vial and a sterile Viadur® implanter. The other tray constitutes a sterile Viadur® Kit, which includes: 1 scalpel, 1 forceps, 1 syringe, povidone-iodine swabs, 1 package wound closure strips, 1-22 Ga x 1.5" needle, 1-25 Ga x 1.5" needle, 1 ampule lidocaine HCl USP 2% (10 mL), 6 gauze sponges, 2 alcohol prep pads, 1 package skin protectant, 1 bandage, 1 fenestrated drape, 1 marking pen, 1 ruler, and 1 mosquito clamp. A physician insert, patient information, and insertion and removal instructions are also provided in the box.

(NDC 0026-9711-01)

Rx Only.

Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F). [See USP Controlled Room Temperature]

For more information call 1-800-288-8371 or visit [www.VIADUR.com](http://www.VIADUR.com).

#### REFERENCES

1. Sennello LT et al. Single-dose pharmacokinetics of leuprolide in humans following intravenous and subcutaneous administration. *J Pharm Sci* 1986; 75(2):158-160.
2. MacLeod TL et al. Anaphylactic reaction to synthetic luteinizing hormone-releasing hormone. *Fertil Steril* 1987; 48(3):500-502.



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