



# Trocar Cannula Obturator

For Subcutaneous Implantation of a Hormone Pellet

Instructions for Use

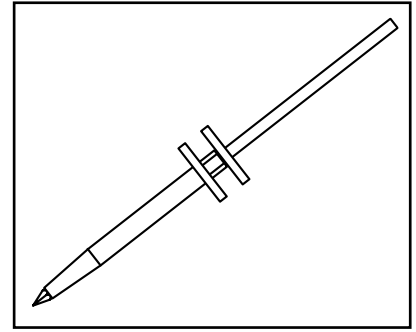


STERILE EO

CE 1639



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EC REP

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The following information should be read before using this device:

**Fig 1 - Trocar**

1. Bladeless Tip
2. Blunt End

**Fig 2 -Cannula**

3. Cannula
4. Hormone Pellet Feeder

**Fig 3 - Trocar (Obturator) and Cannula**

- Assembled Trocar and Cannula

**Indications:**

This device is used for the subcutaneous implantation of a Hormone Pellet.

**Users:**

Procedures should be performed only by physicians with adequate training and knowledge of these procedures. In addition, medical literature should be consulted regarding techniques, hazards, contraindications and complications prior to the undertaking of these procedures.

**Contraindications:**

See Hormone Pellet manufacturer's instructions for use.

**Recommended Use:**

*NB: Prior to commencing, have appropriate local anaesthesia and hormone implant available. All clinical practices to be undertaken on the advice of a medical professional.*

- Prepare the skin with antiseptic solution in accordance with standard medical practice.
- Cover area to be implanted with a surgical drape.
- Inject skin and appropriate subcutaneous area with local anaesthetic.
- Incise skin with scalpel.
- Insert disposable Trocar (Obturator) and Cannula (Fig 3) to appropriate depth and angle.
- Leaving Cannula (Fig 2) in position, remove Trocar and place Hormone Pellet (not supplied) down Cannula with sterile forceps.
- Push the Hormone Pellet fully down the cannula using the blunt end of the Trocar (Obturator) (Fig 1).

*NB: Incorrect placement of the Hormone Pellet may affect dissolution rate, refer to the Hormone Pellet manufacturer's instructions for use for the correct Hormone Pellet placement instructions.*

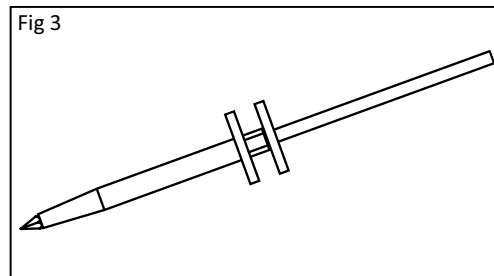
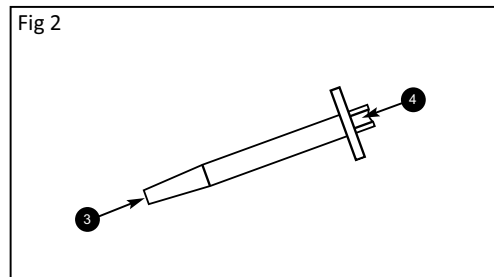
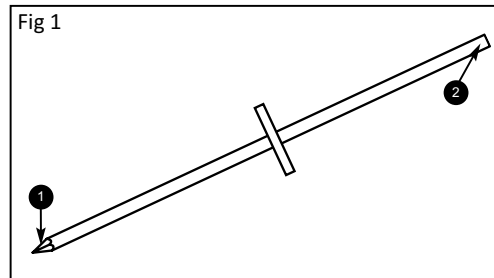
- Remove the Trocar (Obturator) and Cannula.
- Suture the wound and cut the suture with a disposable scalpel (this step is optional / suture not provided).
- Clean the wound with antiseptic and cotton wool balls and dry with gauze swabs before applying an appropriate dressing.
- Dispose of all items as single use into clinical waste and sharps bin.

**Cautions/Warnings:**

- The Femcare Trocar Cannula Obturator is for use only by experienced or trained Clinicians as a single use item.
- These instructions do not accommodate detailed surgical practices, which must be provided by a medical professional.
- Store in a cool dry place.
- This device is designed for Single Patient Use only and is not to be re-used or re-sterilised.
- Reuse of this sterile device poses a significant risk of cross contamination and sepsis and/or dependence on an unvalidated process. This device was not structurally designed or validated for reuse.
- Disposal: When used, dispose of according to accepted medical/clinical practice and local bylaws for products contaminated with bodily fluids and tissue.

**EU Notice:**

Any serious incident (as defined in EU MDR Ch. I, Article 2 (65)) that occurs in relation to this device should be reported to the manufacturer and the competent authority of the Member State where the incident occurs.



**Symbols and Graphics**



Product Code



Quantity



Lot Number



Date of Manufacture



Expiry Date



Medical Device



Refer to Instructions for Use



Single Use



Do not re-sterilize



Do not use if packaging is opened or damaged.



Device is not manufactured with natural rubber latex

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Sterilized using ethylene oxide



Manufacturer

Warranty and Liabilities:

[www.femcare.co.uk](http://www.femcare.co.uk)