

Pagelopolus Endocrinology

Standard Operating Procedure (SOP): Estradiol Pellet Implantation

Document type: Clinical SOP Version date: 2026-02-26 Applies to: Licensed clinicians trained in minor sterile subcutaneous implantation procedures

1. Purpose and Scope

This SOP standardizes estradiol pellet implantation workflow, documentation, and safety escalation in outpatient settings. It adapts a published pellet insertion sequence to Pagelopolus Endocrinology workflow and anchors each section to medical references. [R1][R2][R3]

2. Clinical Governance Requirements

- 1 Procedure is performed only by trained, credentialed clinicians with documented competency in sterile minor procedures. [R2][R10]
- 2 Patient must complete informed consent for hormone therapy and procedure-specific consent before implantation. [R5][R10]
- 3 If compounded pellets are used, include a separate compounded-product acknowledgment. [R6][R7]

3. Pre-Procedure Clinical Assessment

- 1 Confirm indication, goals of care, alternatives, and expected treatment timeline. [R5]
- 2 Counsel on fertility implications and options before treatment when relevant. [R5]
- 3 Review thromboembolic and cardiovascular risk; consider route adjustments for higher VTE risk profiles. [R5]
- 4 Review current medications with specific attention to anticoagulants, antiplatelets, and NSAIDs and follow clinic bleeding-risk policy. [R2][R11]
- 5 Confirm no active skin infection at intended insertion site. [R2][R4]
- 6 Verify allergies to local anesthetics, antiseptics, adhesives, and tape. [R2][R3]
- 7 Verify baseline and interval laboratory monitoring plan per hormone protocol. [R5]

4. Day-of-Procedure Time-Out and Setup

- 1 Perform formal time-out: two patient identifiers, planned procedure, site, pellet product/strength/quantity, allergies, and signed consent status. [R10]
- 2 Position patient to safely expose upper gluteal/flank implantation zone while preserving privacy draping. [R1]
- 3 Perform hand hygiene and maintain aseptic field setup. [R2]
- 4 Use sterile draping and place procedural kit for ergonomic one-direction workflow. [R1][R2]
- 5 Disinfect vial stoppers with alcohol before medication access. [R3]

5. Site Preparation and Local Anesthesia

- 1 Prep skin with clinic-approved antiseptic; allow adequate drying time before incision. [R4][R2]
- 2 Prepare local anesthetic per protocol (lidocaine with or without epinephrine). [R1]
- 3 Buffer with sodium bicarbonate when used by protocol to reduce infiltration discomfort. Evidence supports pain reduction in many settings but is mixed across studies. [R8][R9]
- 4 Create a dermal wheal and infiltrate planned subcutaneous tract before incision. [R1]

6. Implantation Procedure (Adapted Step Sequence)

- 1 Use a #11 blade to create a small transverse skin incision at prepared site. [R1]
- 2 Advance sterile cannula/trocar through subcutaneous plane, parallel to skin, avoiding deep tissue trajectory. [R1]
- 3 Remove sharp trocar while maintaining cannula position. [R1]
- 4 Load prescribed estradiol pellet(s) into cannula with sterile forceps. [R1]
- 5 Use blunt trocar to advance pellets past cannula tip while stabilizing tract. [R1]
- 6 Withdraw cannula and blunt trocar; apply direct pressure for hemostasis. [R1][R2]
- 7 Clean surrounding skin, apply Steri-Strips or paper tape closure, then apply sterile dressing. [R1][R2]

7. Immediate Post-Procedure Instructions

- 1 Instruct patient to limit vigorous lower-body/gluteal activity for 48 hours. [R1]
- 2 Remove outer gauze and shower next day unless clinician specifies otherwise. [R1]
- 3 Remove skin strips in 5-7 days if intact healing. [R1]
- 4 Provide return precautions for worsening erythema, swelling, drainage, fever, escalating pain, or suspected extrusion. [R1][R11][R12][R13]
- 5 Provide 24/7 contact pathway for urgent complications. [R2]

8. Documentation Requirements (Same Day)

- 1 Procedure note must include:
 - Implant site and laterality
 - Pellet product, strength, quantity
 - Lot number and expiration
 - Local anesthetic type and volume
 - Sterile prep agent
 - Immediate tolerance and observed complications [R1][R2][R11]
- 1 Record aftercare instructions provided and patient understanding verified. [R2]

9. Follow-Up and Monitoring

- 1 Schedule wound and symptom follow-up per clinic policy (typically early post-procedure contact plus hormone follow-up visits). [R2][R5]
- 2 Continue endocrine monitoring schedule and dose adjustment framework per hormone protocol. [R5]
- 3 Report serious adverse events through standard internal QA and FDA MedWatch pathways when applicable. [R7]

10. Complication Response Framework

- 1 Bleeding or hematoma: pressure, reassessment, and re-evaluation of antithrombotic exposure. [R2][R11]
- 2 Suspected infection: assess for cellulitis/abscess and treat per local antimicrobial policy. [R2][R11]
- 3 Pellet extrusion: assess wound status, infection signs, and timing of any re-implantation only after clinical reassessment. [R11][R12][R13]
- 4 Vasovagal symptoms: position safely, monitor vitals, observe to stability. [R2]
- 5 Acute medication reaction: activate emergency response protocol. [R2]

11. Inference Note (Transparency)

Evidence directly specific to estradiol pellet insertion technique is limited. This SOP therefore combines:

- 1 A dedicated pellet insertion procedural source for step sequence and field setup. [R1]
- 2 General infection-control and safe-injection standards for sterile execution. [R2][R3][R4]
- 3 Pellet implant adverse-event literature and pellet label safety data (largely testosterone pellet literature) to inform complication surveillance. [R11][R12][R13]

References

- [R1] Trocar Supplies. Hormone Pellet Therapy and Insertion Procedure. <https://trocarsupplies.com/pages/insertion-procedure>
- [R2] CDC. Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings. <https://www.cdc.gov/infection-control/hcp/core-practices/index.html>
- [R3] CDC. Injection Safety. <https://www.cdc.gov/injection-safety/about/index.html>
- [R4] WHO. Global Guidelines for the Prevention of Surgical Site Infection (pre-op skin prep recommendations). <https://www.ncbi.nlm.nih.gov/books/NBK401132/>
- [R5] Coleman E, et al. Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. Int J Transgend Health. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9553112/>
- [R6] Endocrine Society Position Statement. Compounded Bioidentical Hormone Therapy. <https://www.endocrine.org/advocacy/position-statements/compounded-bioidentical-hormone-therapy>
- [R7] FDA. Menopause and Hormones: Common Questions (compounded hormones are not FDA approved). <https://www.fda.gov/consumers/womens-health-topics/menopause>

- [R8] Cepeda MS, et al. Adjusting the pH of lidocaine for reducing pain on injection. Cochrane Database Syst Rev. <https://pubmed.ncbi.nlm.nih.gov/12917913/>
- [R9] Bartfield JM, et al. Buffered versus plain lidocaine for local anesthesia in wound management. Ann Emerg Med. <https://pubmed.ncbi.nlm.nih.gov/8381259/>
- [R10] WHO. WHO Surgical Safety Checklist. <https://www.ncbi.nlm.nih.gov/books/NBK44249/>
- [R11] DailyMed. TESTOPEL (testosterone pellets) label (implant site infection, bruising, fibrosis, bleeding, pellet extrusion). <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=81310d87-0fd2-43d2-b493-629694e5e594>
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- [R13] Kelleher S, et al. Extrusion of testosterone pellets: a randomized controlled clinical study. Clin Endocrinol (Oxf). <https://pubmed.ncbi.nlm.nih.gov/11788644/>