CAREPATHrx™
Specialty Pharmacy & Infusion Solutions

ACCESSING AND REFILLING SYNCHROMED INFUSION SYSTEMS

Section: Nursing
Compliance: ACHC Infusion Pharmacy
ACHC Standards: N/A
URAC Standards: N/A
TJC Standards: N/A
Policy ID: NUR011
Effective: 1/1/21
Reviewed: 5/1/21, 5/1/22, 11/15/24
Revised: 11/15/2024
Approved by: Kathleen Patrick, President, 1/1/21, 5/1/21, 5/1/22, 11/15/24

I. POLICY SCOPE

A. The Medtronic Synchromed Infusion System is an implantable drug delivery system used to treat pain, spasticity, and cancer, in long-term infusion therapy via any route of infusion to a specific site.

B. Accessing and refilling Synchromed pumps will be accomplished by those nurses who have been oriented/in-serviced in the proper techniques included but not limited to accessing procedure, filling the pump with medication and programming the internal pump using the proper equipment.

II. NURSING OVERVIEW:

A. Pocket fill is the improper injection of drug into the subcutaneous tissue, which includes the pump pocket.

1. Observe the patient for any signs or symptoms that could indicate a pocket fill or any other drug-related event.

2. Pocket fill may occur if the refill needle is not inserted through the refill port septum until it has reached the metal bottom of the refill port, or if the needle is moved from the correct position during the refill procedure.

3. Pocket fill can result in significant tissue damage or a loss of or change in symptom control, drug withdrawal symptoms, or a clinically significant or fatal underdose or overdose.

B. Nurse Clinician to maintain Antiseptic Non-Touch Technique (ANTT) throughout procedure.

C. To observe residual volume deficits, compare the actual residual volume with the expected residual volume.

D. Nurse to be supervised during Synchromed Infusion System refilling until able to independently maintain ANTT, complete pump fill procedure, assess pump status, troubleshoot pump and assess for pocket fill.

E. The complete Synchromed Infusion System consists of three major components:

1. The programmable implanted pump
2. The attached delivery catheter
3. An external programmer and tablet

F. The Synchromed pump has three internal chambers:

1. The battery module
2. The drug reservoir chamber with bellows
3. The electronics module

G. An internal peristaltic pump pumps the drug out of the reservoir. This pump is controlled by microprocessor-based electronics

H. The Synchromed pump is a programmable, lithium battery powered device that stores and delivers medication according to instruction received from the programmer. The expected life of the battery is five to seven years, depending on the rate of infusion.

I. The drug reservoir capacity varies in each pump.

1. The Synchromed II can have either a 20 ml or 40 ml medication reservoir volume. With a fluid volume of less than 2ml in the reservoir, the pump output may decrease significantly (more than 15%) with a concomitant loss of drug effects.
2. Refer to pump manual for reservoir capacity.

J. To assure proper output, the pump should be refilled before the reservoir volume reaches 2ml.

K. The drug reservoir is emptied and refilled by percutaneous injection with a non-coring needle through the self-sealing silicone septum in the raised fill port located in the center of the pump.

L. The Synchromed implantable catheter body is constructed of radiopaque material attached to the Synchromed pump.

M. The catheter tip may be intrathecal, epidural, intravascular, or intra-arterial.

N. The location of the catheter tip should be ascertained if available prior to acceptance for home care, since care of the catheter and anticipated drug effects will differ, depending on catheter tip placement. The model number of the catheter should also be requested and ascertained if available (operative report) to verify volume of the internal catheter.

O. The Synchromed Catheter Access System is a side port providing a transcutaneous entry point, via syringe, to the implanted catheter for direct infusion and/or diagnostic purposes. Blood withdrawal through this access port is <u>not</u> recommended. This port DOES NOT contain filtration components.

NOTE: This access port provides a direct bolus into the catheter. Care MUST be taken to avoid accessing this port rather than the reservoir septum.

P. The communicator (wand)is a hand-held wand powered by the tablet it is connected to. The wand transmits to the Tablet by Bluetooth. The programming head transmits to and receives data from the implanted pump via radio waves (telemetry). The tablet creates a report of relevant data. The data is downloaded, then uploaded to the patient's electronic medical record (EMR).

Q. The Medtronic Synchromed Refill Kit is used to access the reservoir fill port and refill all the Medtronic Synchromed pumps. This kit contains components designed especially for the Synchromed Infusion systems

R. Refer to Pump Manual for additional details.

S. A toll-free technical support service is available 24 hours a day for clinicians managing Synchromed Infusion Implants. Telephone Customer Service at 1-800-328-0810.

T. Drug Stability varies by pump and drug type in the Synchromed. Refer to manufacture manual for drug stability in other pumps.

U. Precautions:

1. The Synchromed Refill Kit shall be used during all pump refill procedures
2. Firmly tighten all connections to prevent leaks
3. Do not exceed a refill rate of 18 ml/minute when filling the pump reservoir
4. When refilling the pump with a vesicant drug, care must be taken to prevent spillage or leakage of the drug into adjacent tissue
5. When local or systemic infection is suspected, use extreme caution when emptying and/or refilling the pump reservoir
6. All components of the refill kit are sterile. Should sterility of the refill kit be in question, discard and use a new kit

V. The physician's order will contain:

1. Catheter tip location
2. Name of drug
3. Drug concentration and volume
4. Drug infusion rate
5. Flushing instructions, if applicable

III. PROCEDURE

A. Supplies:

1. Model 8500 Synchromed Refill Kit including:

   a. Empty 20ml syringe
   b. (2) 22 gauge straight non-coring needles
   c. Extension tubing with clamp
   d. Fenestrated barrier
   e. Template
   f. Bacterial filter (note needed for pharmacy compounded drugs)
   g. 0.22-micron filter

2. Gauze pads
3. Povidone-iodine swabs (3)
4. Prefilled 20 ml syringe containing the MAXIMUM amount of the prescribed drug (pump specific) plus 2 ml for priming the filter
5. Sterile gloves
6. Adhesive bandage (optional)

7. Mask
8. Sharps Container

B. STEP BY STEP PROCEDURE

1. Explain procedure and purpose to the patient or caregiver

2. Clean and disinfect work area using an appropriate disinfectant.

3. Perform hand hygiene (refer to *Infection Control Policy*: **Hand Hygiene**) and don gloves.

4. Gather supplies on a clean, disinfected, aseptic field.

5. Don gloves

6. Check label of medication for name, drug name, dose frequency and expiration date. Confirm product matches provider order

7. Inspect the package to verify it has not been damaged. Use ANTT throughout the procedure to prevent contamination of the pump's reservoir, fluid pathway, and device pocket

8. Prepare the Medtronic Synchromed Programmer for use. Refer to the technical manual or programming guide provided with the programmer for programming instructions

9. Complete telemetry reading of the Synchromed pump (current pump status) with the Communicator (follow manufacturer's instructions). Interrogate the pump and documenting pump model number, reservoir capacity and reservoir volume.

10. Gather supplies as listed previously.

11. Prepare patient to fill the pump, by placing patient in a flat position with pump exposed. If pump is difficult to palpate, place the patient on his side with the pump location side facing upwards.

12. Perform telemetry to check current pump status to determine the volume of fluid remaining in the drug reservoir.

13. Wash hands. Open refill kit and glove packages. Don sterile gloves.

14. Prepare the injection site by cleansing area with Povidone-iodine swabs using a circular motion from center of pump site to outside. Repeat this step with the remaining two swabs. Allow to dry.

15. Place fenestrated drape, exposing pump site.

16. Assemble an extension tubing set, with non-coring needle, and empty 20 ml syringe.

17. Confirm patency of extension and needle by expelling air from syringe through system. Close the clamp on the extension after confirmation.

18. Locate the center of the Synchromed pump

19. Palpate the pump edges then place the template over the pump, aligning edges of the template with the edges of the pump, and the template cut out access with the port access (if used).

20. Insert the non-coring needle perpendicular to the surface of the pump into the pump's septum until the needle touches the needle stop. Do not use excessive force. The titanium needle stop under the septum will damage the needle tip if excess force is used.

21. Open clamp on extension tubing

22. Withdraw the fluid from the reservoir by gently creating negative pressure by pulling the syringe plunger back. Empty the reservoir completely, i.e., until air bubbles are present in the extension tubing. The amount withdrawn should be approximately equal to the previously noted reservoir volume from the current pump status.

23. Approximately 0.5ml of fluid will remain in the extension tubing and should be clear and colorless. Sterile abscesses are common after initial pump placement; care should be taken to assess aspirated fluid to ensure it is not cloudy or colored due to an abscess.

    Note: If local or systemic sepsis is suspected, the residual fluid may be cultured

24. Close the clamp and remove 20 ml syringe

25. Attach the 0.22-micron filter to the syringe containing the prescribed fluid. Purge all air from the filter and expel any excess drug until the actual reservoir volume is remaining in the syringe

26. Attach the syringe with filter to the extension tubing set attached to the non-coring needle accessing the pump reservoir.

27. Open the clamp and slowly (maximum 18 ml/minute) inject the fluid into the reservoir. Do not force the injection

    CAUTION: Excessive pressure caused by an overfilled reservoir or too rapid fill rate may cause damage to the pump or affect infusion accuracy. During injection, periodically withdraw and observe a portion of the drug to confirm it has the expected appearance, indicating that the needle continues to be properly positioned.

28. When the filling is completed, close the clamp on the extension tubing and carefully remove the needle from the pump septum

29. Apply pressure to needle site with 4x4 gauze pad for one minute to assure no bleeding

30. Remove cleansing agent from skin using alcohol

31. Apply adhesive bandage, if desired

32. Program the appropriate new parameters, e.g., reservoir volume, prescription, etc. and perform telemetry to update the pump.
    Note: If bolus infusion is started, wait until it is completed before performing any other telemetry. Telemetry during this infusion mode will stop and cancel the bolus. Refill procedure may be done before programming pump with new parameters

33. Download the pump report and then upload it to the patient's EMR.

34. Discard used and unused needles from the refill kit into the sharp's container. Discard all other components of refill kit in an appropriate container

35. The nurse stays with the patient for 30-60 minutes post Synchromed fill to monitor patient for side effects, including changes in pain perception, new or worsening side effects, and fever. Assess for clinical signs of drug overdose (pocket fill) with dizziness, sedation, euphoria, anxiety, or increased pain or spasticity.

C. PATIENT EDUCATION:

1. Actions and potential side effects of the drug

2. Who to call in the event of an emergency

3. The patient should carry an identification card and wear a Medical Alert bracelet. Additionally, the patient should inform their physicians and dentist

4. The patient should be taught the meaning of the alarms, and who to contact if the alarm should beep

5. The patient must be aware of the importance of his/her availability for pump refills and must inform the nurse if travel is planned, to schedule appropriately

6. Redness, swelling, or pain near the pump or a fever should be reported to the physician

7. Activities in which a blow to the pump could occur should be avoided by the patient (i.e., contact sports)

8. If the patient plans diathermy treatments, or to use a sauna or hot tub, the physician must be contacted. Extreme heat can alter the flow of the medication

9. Scuba diving is not advised

10. High current industrial equipment, transmitting towers and antennas should be avoided

11. The patient should be aware that they may not feel the effects of changes in infusion rates for 24 - 48 hours, if the flow rate is very low

12. Airport metal detectors may be set off by the pump. The patient should carry a physician's letter if travel is planned

13. Inform patients of the importance of notifying radiology of presence of Medtronic Synchromed pumps before scheduling an MRI, and the importance of referencing the MRI guidelines for Medtronic Implantable Infusion Systems. The Medtronic MRI guidelines can be found at: https://mriquestions.com/uploads/3/4/5/7/34572113/synchromed_ii_mri_m005186c_a_001_view.pdf

D. DOCUMENTATION to include:

1. Pump data report placed in the patient's EMR.
2. Patient education

3. Procedure performed
4. Patient tolerance
5. Appearance of pump site
6. Dose and amount of medication/solution used for pump refill
7. Amount of residual medication noted
8. Follow-up plan

IV. REFERENCES:

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