Update to the March 2014 Communication on Overinfusion
Recommendations and Guidelines

Recommendations (Developed in collaboration with clinical experts):

- Medtronic does not recommend prophylactic removal of SynchroMed II pumps.
- To minimize the risk of overinfusion, use the approved/indicated drug formulations for the SynchroMed II pump. The use of nonindicated drug formulations (such as admixtures, compounded drugs and unapproved drug concentrations) increases the likelihood of overinfusion.
- Educate patients, caregivers and family members to recognize the signs and symptoms associated with intrathecal drug therapy overdose, underdose or withdrawal.
- At every refill visit, question and examine the patient for signs and symptoms of overdose, underdose or withdrawal.
- Follow the refill instructions in the approved labeling so that any volume discrepancy can be detected based on the amount of medication withdrawn (expected) prior to refilling with new solution. (See Important Guidelines below).
- At every refill visit record the actual and expected reservoir volume.
- Review prior refill data to identify any changes in volume discrepancy over time. If there are increases in volume discrepancy over time (volume withdrawn from the pump is less than expected) or if there is a volume discrepancy of more than 2 mL:
  - Evaluate for other potential causes of volume discrepancy, for example: inaccurate volume measurements, incomplete pump aspiration, incorrect volume entry into clinician programmer at refills, unrecognized partial pocket fill, or aspiration of pump medication by patient or caregiver.
  - Evaluate for factors that may increase the likelihood of overinfusion. These factors include: nonindicated drug formulations, overfilling of the pump reservoir, operation of the pump with no fluid in the reservoir, catheter occlusion, and pump stops or motor stalls lasting more than 48 hours.
  - If overinfusion is suspected, consider scheduling an interim pump reservoir volume check prior to the next scheduled refill. Evaluate and question the patient for symptoms consistent with overinfusion. If after the interim check, overinfusion continues to be of concern, clinically monitor the patient and consider pump replacement.
  - Reducing the dose and/or concentration is not a recommended mitigation for overinfusion due to the identified failure modalities.
  - To stop delivery of drug from a pump suspected of overinfusion, program a “therapy stop,” which sets the pump to minimum rate, and aspirate any remaining drug from the reservoir to avoid continued drug delivery.

Important Guidelines:
Always follow pump refill instructions per the device labeling. The following steps should be conducted during each pump refill procedure to allow detection of an overinfusing pump:

- Aspirate all fluid from the reservoir until air bubbles no longer appear in the syringe, and record as the amount withdrawn.
- Compare the amount withdrawn from the pump reservoir with the expected volume displayed by the pump programmer. The amount withdrawn should approximately equal the expected volume.
- Determine fill volume (fill with no more than the labeled reservoir volume, 20 or 40 mL).
- Accurately measure the volume to be instilled.
- If you are unsure whether drug was injected correctly into the pump, completely aspirate the pump to verify that the entire injected volume of drug has been removed.
- Ensure that the refill date is chosen sufficiently in advance of the low reservoir alarm date so the drug reservoir of an overinfusing pump is not prematurely depleted.

Inform Medtronic Neuromodulation Technical Services if overinfusion is suspected. Please return any explanted products to Medtronic for mechanical and functional analysis. To minimize changes in the pump condition after explant, pumps that are suspected of overinfusion should be returned with fluid in the reservoir, set to a minimum infusion rate, and returned using the designated returned product mailer. Your local Medtronic representative can assist you in return of product.