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K 965251; Medtronic PS Medical AlgoLine Intraspinal Catheter

SUMMARY OF SAFETY AND EFFECTIVENESS PROBLEMS ASSOCIATED WITH INTRASPINAL CATHETERS (ADVERSE EFFECTS) System

The adverse effects associated with the use of the AlgoLine Intraspinal Catheter System may include, but may not be limited to, the following.

Catheter Complications

Change in catheter performance, due to kinking, disconnection, leakage, breakage, complete or partial occlusion, dislodgement or migration, or fibrosis or hygroma, which can result in:

- delivery of drug into the subcutaneous tissue,
- drug withdrawal symptoms,
- return of underlying symptoms,
- free-floating catheter in the cerebrospinal fluid (CSF),
- underinfusion of the drug,
- CSF leak leading to spinal headache, CSF subcutaneous collection, or rare CNS pressure-related problems,
- damage to the spinal cord, or
- surgical replacement / revision of the catheter.

Drug Complications

- Local and systemic drug toxicity and related side effects
- Complications due to use of untested drugs with the system
- Complications due to using drugs not in accordance with the drug labeling

Procedural (Surgical) Complications

- Lumbar puncture-type headache
- CSF leak leading to spinal headache, CSF subcutaneous collection, or rare CNS pressure-related problems
- Radiculitis
- Arachnoiditis
- Bleeding
- Damage to the spinal cord
- Meningitis
- Spinal headache
- Medical complications
- Complications from anesthesia
- Damage to the catheter due to improper handling

Other

- Allergic or immune system response to the implanted materials
- Body rejection phenomena
- Complications due to the interaction of the catheter with unusual physiological variations in patients
- Surgical replacement of the catheter due to complications
- Complications due to other intervening acts

PRODUCT COMPLAINT HISTORY

Approximately 5,000 AlgoLine intraspinal catheters of various models and designs have been distributed worldwide. As of January 15, 1997, the complaint history consists of a total of nine complaints involving 12 catheters reported. These complaints have included:

- (3 ea) Catheter fracture
- (3 ea) Catheter leakage
- (2 ea) Strain relief missing from package (involving 5 packages)
- (1 ea) Tuohy needle broke during use

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