

## COMPLICATIONS ASSOCIATED WITH INTRATHECAL DRUG INFUSION

It is important to inform patients of the potential for serious complications associated with intrathecal drug infusion, including the use of the SynchroMed<sup>®</sup> and IsoMed<sup>®</sup> implantable infusion pumps. The informed-consent discussion should include disclosure of the symptoms listed in the table shown below, especially neurological deficits and dysfunctions that have been reported. This discussion should be documented in the medical record. It is recommended that all patients have an updated, signed informed consent in their medical record, including patients who have been using the pump. An updated informed-consent conversation should be held at the earliest practical time.

### Suggested Informed-Consent Language

*Formation of an inflammatory mass (granuloma) at or near the tip of intrathecal catheters has been reported with the intrathecal infusion of opioids, baclofen, pharmacy-compounded drugs, and other pharmacological admixtures—particularly when administered in relatively high doses and/or high concentration. The reported incidence is as high as 3 percent. Some cases occur within six months, while others occur as long as 10 or more years after starting opioid therapy. Granuloma formation has been associated with a wide range of doses and concentrations of opioids, and no dose and/or concentration can be considered completely free of risk. The risk appears to be cumulative over time and increases with higher concentrations. Individual patient susceptibility to inflammatory mass cannot be predicted.*

*The table below summarizes the frequency of symptoms reported from October 1990 through September 2007. The most frequently reported symptoms are:*

- *decreased therapeutic response/inadequate pain relief (reported in 33.5 percent of patients),*
- *pain (reported in 32.6 percent of patients), and*
- *neurological deficit/dysfunction (reported in 17.4 percent of patients).*

### Summary of Symptoms Reported for Cases of Inflammatory Mass

Symptoms	Number of Reports of Symptom	Percent of cases with Symptom (n = 448)
Decreased therapeutic response/inadequate pain relief	150	33.5%
<b>Pain</b>	146	32.6%
<b>Neurological deficit/dysfunction</b>	78	17.4%
Unknown (reports did not provide the patient's condition)	74	16.5%
<b>Paralysis/paraplegia/paresis</b>	67	15.0%
Weakness/muscle weakness	62	13.8%
Numbness	43	9.6%
<b>Incontinence</b>	32	7.1%
<b>Ambulation difficulties</b>	12	2.7%
<b>Urinary retention</b>	8	1.8%
Tingling	8	1.8%
Headache	7	1.6%
Muscle spasm(s)	7	1.6%
Burning sensation	6	1.3%
Other (each reported in less than 1% of cases)	68	15.2%

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*Material in this Risk Management Alert was adapted from information contained in Medtronic's January 2008 letter to the health care community.*