

**AN (NI) 2002/10**

**DATE: 4 November 2002**

**For Attention and Action by:  
Chief Executive of each HSS Trust  
General Manager/Chief Executive of each HSS Board  
Chief Executive of each Agency**



**HEALTH ESTATES  
ESTATE POLICY**

**NORTHERN  
IRELAND  
ADVERSE  
INCIDENT  
CENTRE**

**TITLE:**

**SYNCHROMED® IMPLANTABLE DRUG PUMP:  
RISK OF MEDICATION ERRORS DUE TO  
INACCURATE LISTING OF INTRATHECAL  
DRUGS.**

**MANUFACTURER/SUPPLIER**

Medtronic Inc.

**PROBLEM**

- Distribution of inaccurate intrathecal drug information for the SynchroMed® implantable infusion pump.
- Potential for inappropriate intrathecal drug administration to patients.

**DISTRIBUTION**

This notice should be brought to the attention of all who need to know or be aware of it, including those listed below, in accordance with local procedures. This will include:

- Liaison Officers for onward distribution to all clinicians involved in administering drugs via an implantable pump, in particular-
- Oncologists
- Neurologists and Neurological Surgeons
- Anaesthetists
- Clinicians involved with Pain Clinics
- Nursing staff in Pain Clinics
- Pharmacists
- Oncology and Palliative Care Nurses
- Directors of Nursing
- Risk Managers
- Health & Safety Officers/Advisors
- Private Clinics
- Hospices

Boards/Trusts should ensure that if appropriate, this information is passed to all persons having the responsibility for the premises registered under "THE REGISTERED HOMES (NI) ORDER 1992.

**IMMEDIATE ACTION**

- Remove the Medtronic Educational Brief: Drug Formulation SynchroMed® Infusion System (ref. September 2002 / 02.03) from circulation.
- Always check the medicinal product information to confirm the approved route(s) of administration before use.
- Be aware that not all drugs, or formulation additives, are compatible with the pump. If in doubt, check the compatibility of specific medicinal products with Medtronic.

**ADVISE**

**NOTICE**

## BACKGROUND

The SynchroMed® system comprises a programmable implantable drug pump and catheter, to facilitate infusion of medicinal products to specific target sites, either intermittently or continuously at clinician programmed rates. Current applications for the SynchroMed® pump are pain management, chemical cancer treatments, and management of severe spasticity.

In September 2002, Medtronic issued Educational Brief: Drug Formulation SynchroMed® Infusion System (ref. September 2002 / 02.03) to UK hospitals. This advised of potential compatibility problems between some medicines and the SynchroMed® drug pump. The warning was based on a series of non-UK incidents where the use of inappropriate preparations had resulted in pump malfunction. The "Brief" contained inaccurate information in that a list of pump compatible medicines was stated as being approved for intrathecal use.

Some of the medicines quoted in the "Educational Brief (02.03)" are **NOT** approved in the UK for intrathecal administration. One product (a vinca alkaloid which can be fatal if given by this route) is **specifically contra-indicated for intrathecal use**.

Furthermore, the inclusion of certain additives with medicines that would otherwise be compatible with the pump, can result in damage to the pump. This may compromise the effective performance of the pump and hence patient safety.

Examples of additives likely to cause problems are sodium metabisulphite, ethanol if comprising 10% or more of the final solution and additives inducing a pH outside of the range 4 to 8. This list is not exhaustive. For pump compatibility advice on specific formulations, please consult with your Medtronic representative.

In light of the inaccurate information provided within the September 2002 Educational Brief (02.03), Medtronic have now revised their advice and the amended version is appended to this document.

## ENQUIRIES

Enquiries to the manufacturer should be addressed to:

Mark Bennett  
Medtronic Ltd  
Suite One, Sherbourne House, Croxley Business Centre, Watford WD18 8WW, Tel:  
01923-212213, Fax: 01923-241004

Enquires to the NIAIC should quote the reference number AN (NI) 2002/10 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC), Health Estates, Estate Policy  
Directorate, Stoney Road, Dundonald, Belfast BT16 1US  
Tel: 02890 523714, Fax: 02890 523900, Email: [brian.godfrey@dhsspsni.gov.uk](mailto:brian.godfrey@dhsspsni.gov.uk)



Brian Godfrey  
NIAIC Manager

### HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in Safety Notice SN (NI) 2002/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at [www.dhsspsni.gov.uk/niaic](http://www.dhsspsni.gov.uk/niaic)

*Health Estates is an Executive Agency of the Department of Health, Social Services and Public Safety  
Aisíneacht Feidhmeannach don Roinn Sláinte, Serbhísi Sóisialta agus Sábháilteacht Phoiblí*



HEALTH ESTATES

ESTATE POLICY

**NORTHERN  
IRELAND  
ADVERSE  
INCIDENT  
CENTRE**

**ADVICE**

**NOTICE**


**EDUCATIONAL BRIEF**
**Revised October 2002 / 02.03a**
*(Destroy previous version September  
2002/02.03)*
*Tools for Safe Patient Management*
**Revised DRUG FORMULATION  
SYNCHROMED® Infusion System**

Model 8616/8617/8618 SynchroMed  
Implantable Pump  
Model 8626/8627 SynchroMed EL Implantable  
Pump  
10 mL and 18mL Pumps

**Purpose and Immediate Action**

Following the identification of ambiguities in Medtronic's Educational Brief marked 2002/02.03, Medtronic wishes to advise of the immediate withdrawal of the 2002/02.03 brief, which should now be withdrawn from circulation and destroyed. This document replaces the 2002/02.03 brief and provides important information about medicinal products that may compromise the safe and effective performance of the SynchroMed® Infusion System.

**Explanation of the Issue**

Seemingly similar products may contain preservatives, antimicrobials or antioxidants, or exhibit chemical properties that are not compatible with the SynchroMed Infusion System. This could result in the cessation of pump function, potentially reducing or interrupting therapy efficacy, thus jeopardizing patient safety.

**Preservatives (Antimicrobials and Antioxidants) and Other Excipients**

Some medicinal products may contain antimicrobials and/or antioxidants. These additives may alter the material properties of the SynchroMed Infusion System components; therefore any medicinal product prescribed for administration via the SynchroMed Infusion System must be preservative-free.<sup>1</sup> The following list identifies additives which are known to adversely affect the SynchroMed Infusion System. The list provides examples and is not all-inclusive.

- Acetate/acetic acid buffer
- Ethanol comprising 10% or more of the solution
- 1% sodium metabisulfite
- Additives lowering pH below 4.0

**pH**

Extreme pH conditions, outside of the ranges of 4-8, could interfere with the safe and reliable performance of the SynchroMed Infusion System. Some medicinal products may exhibit unexpected and adverse pH-dependent interactions with pump materials.<sup>2</sup>

**Known Incompatible Drugs**

Medtronic has identified the following main actives as being incompatible with the materials used in the SynchroMed Infusion System:

- Dopamine
- Mitomycin C
- Cyclosporin A
- Apomorphine
- Meperidine
- Octreotide, pH 4.11

- Interleukin II, with 25 mg Human Serum Albumin (HSA)/mL

Medicinal products containing these drugs must never be prescribed for delivery using the SynchroMed Infusion System; they will damage the internal drug path inside the SynchroMed Implantable infusion pump. Please note that this is not an all-inclusive list of potentially incompatible drugs.

## Recommendations

As you prescribe medications for administration using the SynchroMed Infusion System, always check the following:

- It is important that you refer to the appropriate medicinal product information for a complete list of indications, contraindications, warnings, precautions, and dosage and administration information.
- Ensure that the medicinal product is preservative-free, does not contain more than 10% ethanol is within pH range 4-8.
- If you have questions about other excipients, contact Medtronic as indicated below.
- Finally, consult the SynchroMed implantable infusion pump Technical Manual for stability durations of the main actives in the pump reservoir.

## For Assistance

Contact your Medtronic representative.

## References

1. Gianino J, et al. Intrathecal Drug Therapy for Spasticity and Pain. Practical Patient Management. New York: Springer-Verlag, 1996.

2. Bennett G, Deer T, DuPen S, Rauck R, Yaksh TL Hassenbusch SJ. Future directions in the management of pain by intraspinal drug delivery. *J Pain Symptom Manage* 2000;20:S44-S50.



**Medtronic**  
*When Life Depends on Medical Technology*

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