

**Notice Information: Medical Devices - Warning
12 March 2004**

Part 1. Product Information

- a) Title:
- b) Product Name/Type:
- c) Reference:
- d) Manufacturer/Supplier:

Part 2. Target Audience

- a) Target Audience:

Part 3. Problem/Issue

- a) Problem/Issue:

Part 4. Background Information

a) Background Information:

It has been brought to the attention of the Irish Medicines Board (IMB) that Cervical Halo traction devices, even those labelled as MRI compatible can cause imaging problems or patient discomfort when worn during an MRI scan. The problem has not been seen to occur with all patients. Halo traction components manufactured from titanium, aluminium or carbon composite materials are non-ferrous and may be labelled as MRI compatible. However these materials are conductors of electricity and as a result it is theoretically possible for current induction to take place through a patient / device during scanning. To date the problem has been reported from two Irish hospitals. The manufacturer has been unable to identify a definitive cause to the problems experienced in these hospitals. The distributor for the device in Ireland has written to all Irish customers advising them of the potential problem. To address the MRI safety issue Jerome Medical have decided, as a precautionary measure, to remove the "MRI Compatible" label from the all new devices manufactured. Jerome Medical also hope to have a new product manufactured from ceramic and glass available for use in three months. This product will be labelled MRI Compatible. In the meantime, multiple factors that could contribute to imaging problems or patient discomfort include:

The configuration / location of the device within the MRI. A concentration of metal componentry or metal parts located close to the device core can cause arcing. The use of non MRI compatible components within the orthopaedic device e.g. nuts / bolts / washers. The re-use of single use device components, which are no longer safe for use in a MRI. Cervical halo units are sold as single use devices. Change to the MRI strength. Newer MRI device can be more powerful than those used previously and therefore may no longer function within the recommended limits of the orthopaedic device. The above list of causes does not only relate to Cervical Halo Traction devices but are also applicable to other similar orthopaedic fixation devices.

Part 5. Action to be taken

a) Action to be taken:

Ensure that all devices that are sold as single use devices are only use once Ensure that MRI compatible devices are configured and positioned in the MRI so as to ensure that they are not too close to the MRI core and that metal components are not criss-crossing or concentrated in one area Ensure that the use of all MRI compatible devices are reviewed when any changes are made to the MRI strength to ensure that they still remain compatible Ensure that patients screening forms are completed for all patients. (see form attached checklist) Report any indications of problems to the IMB

Part 6. Enquiries

- a) All enquiries should be made to:

All adverse incidents relating to a Medical Device should be reported to the: Medical Devices Department Irish Medicines Board Earlsfort Centre Earlsfort Terrace Dublin 2 If you have any enquiries, you may contact the Medical Devices Department at: Telephone: +353-1-6764971 Fax: +353-1-6767836 Email: vigilance@imb.ie Website: www.imb.ie Enquiries to the manufacturer should be addressed to: Jerome Medical 305 Harper Drive Moorestown NJ 08057 3239 USA Telephone: +1-856-234-8603 Fax: +1-856-722-5487 APPENDIX 01 Although MR is safe for most patients, for certain subjects, MRI may pose unnecessary risk. Most contraindications that would rule out a subject involve metallic foreign bodies, however, there are several other concerns of which investigators should be aware. If any question exists regarding a subject's MR compatibility the subject must not be scanned. *Conditions that Would Rule Out a Subject* Cardiac pacemaker Surgical aneurysm clips Neurostimulator Implanted pumps Metal fragments in body / eyes Nitroglycerin patch (rule out if subject cannot remove patch; foil may heat up) Coloured contact lenses should not be worn in scanner Certain cochlear implants Weight >285 (also consider shoulder and chest size; the diameter of the magnet bore is 55cm). *Conditions that Might Rule Out a Subject* Ear implants (most are OK, certain cochlear implants are not) Stents, metal rods, plates or screws in body or mouth Injury to eyes involving metal (subject must have X-ray exam to rule out fragments) Previous surgery (if metal left in body) IUD (most are OK, except Copper-7) Hearing aid (should be removed before scanning) Dentures (should be removed before scanning) History of vestibular or inner ear abnormality such as Meniere's Disease Prosthetic heart valve (most are plastic now) Pregnancy Breast feeding (rule out if using Gadolinium) Braces (causes severe frontal artifact; rule out for EPI) Tattoos or permanent eyeliner (if ink contains metallic specks) *Other Screening Considerations* Claustrophobia Physical discomfort (body size, back or neck pain, etc.) Movement disorders (i.e. ticks, restless legs, etc., that may cause movement artifact) Vision / Hearing problems Problems using response devices *Things Not to Bring or Wear in the Scanner* ANYTHING in your pockets Metal jewellery (including face and body piercing items) Watches Hair holders Eyeglasses Metal on clothing (i.e. metal buttons, snaps or trimming, under wire bras, belt buckles) Eye shadow (many contain metallic specks that can heat up) Coloured contact lenses (remind subject to bring a case to store contacts in during scanning) SN2004(02): Cervical Halo Traction Apparatus

Part 7. Keywords

- a) Keywords:

Cervical Halo Traction Apparatus