

PORLAND ORTHOPAEDICS PTY LTD MARGRON TOTAL HIP REPLACEMENT

**Unit 3
44 McCauley St
MATRAVILLE NSW 2036**

PROCEDURE ADVERSE OUTCOMES

This revision supersedes all previous revisions.

Prepared by:	Date:	Position:
Approved by:	Date:	Position:

The following ATTACHMENTS form part of this document.

FORM-001 Adverse Outcome Form
FORM-004 Adverse Outcome Inspection Log

Controlled copy only if stamped with Controlled Copy Stamp.

1. INTRODUCTION

1.1 Purpose of Document

To identify and regulate the steps to be taken for monitoring and recording results in the Adverse Outcome Review and Investigation Program.

1.2 Purpose of procedure

Adverse Outcome Review and Investigation Program is to collect information to improve the product. It requires careful monitoring of any complications or adverse reactions, which occur during and after implantation of the prosthesis and including instrumentation.

1.3 Scope

All results and feedback on patients relating to the implanting of Margron products.

1.4 References

Internal References

PROC-003 Improvement of systems /product.

PROC-004 Recall.

PROC-014 Authorised Representative.

FORM-001 Adverse Outcome Form

FORM-004 Adverse Outcome Inspection Log

FORM-020 Margron Total Hip Replacement Protocol Log

REG-013 Adverse Outcome Register

External References

TGA 'Medical Device Incident Report' form from

http://www.tga.gov.au/docs/doc/forms/iris_mdir01.doc.

FDA Form 3500A (<http://www.fda.gov/medwatch/safety/3500a.pdf>).

FDA abbreviated instructions on Form 3500A at <http://www.fda.gov/cdrh/abrevins.pdf>

FDA Form 3417

1.5 Responsibility

The responsibility and authority for this procedure is with the CTO or CEO who have the authority to delegate responsibility to others to do the work.

1.6 Definitions

Portland - means Portland Orthopaedics Pty Limited

CTO – means Chief Technology Officer

CEO – means Chief Executive Officer

AOR – means Adverse Outcome Report, a completed Adverse Outcome Form (e.g. FORM-001)

CAR- means Corrective Action Request, the main document of PROC-003 Procedure Improvement of System/Product.

2. PROCEDURE SETTING UP CENTRES

2.1 Multi-centre Trials

A multi-centre trial has been organised to test the prosthesis performance in patients. It is the responsibility of the treating doctor who is participating in the trial and who implants the prosthesis to monitor the patients over a given period.

2.2 Selection of Centres

Responsibility

CTO &/or CEO

Task

All examination centres will be selected on the condition that the treating doctors agree to monitor the patients.

Portland has contracted with Portland Orthopaedics (Aust) Pty Ltd (was EBOS Pty Ltd) to distribute the Margron Total Hip Replacement in Australia. During the distribution period, the distributor and its representatives are responsible contractually to collect information from the treating doctors, and at three-monthly intervals report back to Portland on the progress of the multi-centre clinical trial.

For elsewhere in the world, the treating Doctor is responsible for completing the forms provided by Portland (FORM-020 Margron Total Hip Replacement Protocol Log) for purposes of regular assessment of the patient, and the treating doctor is responsible for returning the completed documentation to Portland at the specified intervals for a minimum of five years. It is also up to the distributor under contract to collect the information from doctors on completion.

Documents or Records to be Produced

Distributor Contract

2.3 Adverse Reaction Reporting

Responsibility

Participating Surgeon

Task

In the event of an adverse reaction or complication occurring, whether directly or even remotely connected to the hip replacement, then the treating doctor, whether participating in the multi-centre clinical trial of the Margron hip replacement or not, shall complete the Adverse Reaction document (included in FORM-020 Margron Total Hip Replacement Protocol Log) and forward it immediately to Portland.

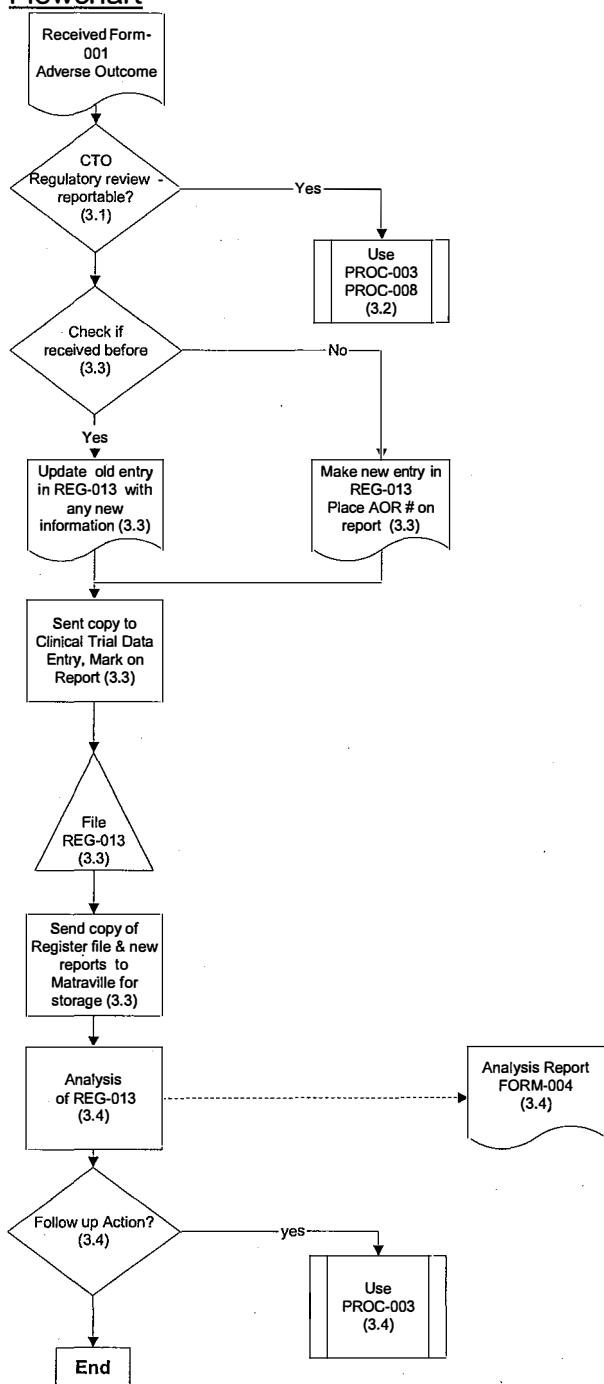
It is the responsibility of the treating doctor participating in the multi-centre clinical trial to follow the patients at the correct intervals and report back to Portland via

the prosthesis distributors, Authorised Representative in Europe (PROC-014) or directly to Portland elsewhere. The report can be made on Adverse Outcome form (FORM-001 [AO Form] or Form M in Margron Total Hip Replacement Program Protocol Log FORM-020).

Documents or Records to be Produced
Possible Report

3. PROCEDURE ADVERSE OUTCOME REPORTING & ACTION

Flowchart



3.1 Report Assessment

Responsibility

CTO

Task

An Adverse Reaction form, on being received at the office of Portland, will be immediately forwarded to the CTO.

The CTO, on receiving an Adverse Reaction form will assess the seriousness of the report (see 3.2 below for determining when reporting is required). On receipt of information of an adverse reaction or complication, the CTO or his representative will endeavour to contact the treating doctor directly by telephone, fax or letter, whichever is the most appropriate. The complication or adverse reaction will be discussed and appropriate action then taken.

Complications and adverse reactions will be of two types:

1. Those due to accidental misadventure, eg. post-operative pneumonia, a fall while mobilising, causing a fracture, etc.
2. Those directly due to the prosthesis insertion or post-operative function of the prosthesis, e.g. fracture of the femur during insertion, loosening of the prosthesis, dissociation of the neck from the stem components, etc.

Documents or Records to be Produced

Entry into Adverse Outcome Summary

3.2 Regulatory Reporting

Responsibility

CTO

Task

For Australia, all deaths, serious illness or serious injuries arising from or attributable in some way to the use or application of a device, as soon as possible after becoming aware of the incident are to be reported on 'Medical Device Incident Report' form obtainable from

http://www.tga.gov.au/docs/doc/forms/iris_mdir01.doc. This includes deficiencies in labelling, instructions or packaging, defective components, performance failures, poor construction or design.

For USA, a report is required when a manufacturer becomes aware of information that reasonably suggests that one of their marketed devices has or may have caused or contributed to a death, serious injury, or has malfunctioned, and that the device or a similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if malfunction were to recur.

This will be reported on Form FDA 3500A

(<http://www.fda.gov/medwatch/safety/3500a.pdf> with abbreviated instructions in <http://www.fda.gov/cdrh/abrevins.pdf>). This report must be submitted to FDA within 30 calendar days. A "5-day report" to FDA is required with 5 work days after:

(1) becoming aware that a reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to public health; or
(2) becoming aware of an MDR reportable event from which FDA has made a written request for submission of a 5-day report involving a particular type of medical device or type of event.

NOTE: Manufacturer must submit a baseline report (accompanying the corresponding Form 3500A) when an event involving the device model or device family is reported for the first time. Use FDA Form 3417 (it provides basic device identification information).

For Europe,

There are two kinds of reportable incidents:

Adverse Incident – an incident that caused the death or serious deterioration in the health of a patient, user or other person,

Near Incident – an incident that might have caused the death or serious deterioration in the health of a patient, user or other person.

Refer to Appendix A for further guidance.

Maximum time for reporting:

Adverse Incident 10 days

Near Incident 30 days

Reports on incidents should be made to the Competent Authority in the country of the occurrence of the incident.

In the event of a catastrophic or serious fault in the prosthesis, Portland will notify each of the treating doctors by telephone, fax or letter, whichever is the most appropriate, recommending appropriate action to be taken, eg. recall of all patients immediately and will follow PROC-003 – Improvement of system/product and PROC-004 Recall.

Documents or Records to be Produced

Possible Report to regulatory authority

3.3 Recording and Filing

Responsibility

CTO or CTO Authorised person

Task

Checking & Recording

After checking the report is not a repeat or a follow up report on a previous report, the Adverse Outcome report (FORM-001) shall be entered into the Adverse Outcome Summary (REG-013) and given the next AOR number. The AOR Number shall also be recorded on the Adverse Outcome Report.

If the report is a repeat (use REG-013 to identify by Surgeon, Patient ID & date), add the new information to the previous entry in Adverse Outcome Summary (REG-013) & note this OAR Number on the report.

Clinical Trial Analysis Recording

A copy of the report is faxed to the Orthowave Data Entry person for inclusion in the clinical trial reporting system if applicable. Note on the report is information has been sent.

Filing

The Adverse Reaction report will be filed as a hard copy in AOR number order in REG-013.

The Adverse Reaction Collection file has been made up in two sections:

- Section 1. Where the Adverse Reaction form is immediately placed on being received by Portland.
- Section 2. The second section where the Adverse Reaction form is signed by CTO or his representative and then placed in the signed-off section, confirming that the Adverse Reaction form has been perused by CTO or his representative.

Backup Storage

Send copy of Register REG-013 (e-mail) with copy of new reports (fax) to Matraville for duplicate records.

Documents or Records to be Produced

Entries on Report

Entries into REG-013

Data Entry in Orthowave

3.4 Analysis & Follow Up

Responsibility

CTO

Task

At six-monthly intervals the CTO or his representative will review the Adverse Outcome Summary (REG-013) and relevant Adverse Outcome Forms (FORM-001), to detect trends and then sign off and date the Adverse Outcome Inspection Log (FORM-004) that he has reviewed the Adverse Reaction file and has taken appropriate action. The Adverse Outcome Summary (REG-013) is in a spreadsheet format allowing a copy to be made and sort, filtering etc to help with analysis.

In the event of a trend developing, Portland will take appropriate action, by following PROC-003 – Improvement of system/product.

Documents or Records to be Produced

Adverse Outcome Summary entry

Adverse Outcome Inspection Log

Possible CAR

APPENDIX A

Further Guidance on Reportable Incidents for Europe

(Reference British MDA 'Guidance on the Medical Devices Vigilance System for CE Marked Joint Replacement Implants')

Revisions carried out primarily because of infection or misalignment/malpositioning during implantation are not generally considered to be malfunction or deterioration of the implant and are not therefore usually considered to be reportable under the Vigilance System. Misalignment/malpositioning are however reportable if they are considered to have occurred as a direct consequence of the design of the implant or of the design of the instrumentation intended to be used in conjunction with the implant.

Revisions carried out because of mechanical failure of the implant (however long it has been implanted) are considered to be a malfunction unless there is clear evidence that the main cause of failure was not implant related. Examples of such cases include:

- Inappropriate implant selection;
- Misalignment/malpositioning during implantation;
- Failure of the cement bed in cemented implants.

Revisions carried out primarily because of aseptic loosening within the expected life of the device (as specified in the information supplied with the implant by the manufacturer) are also considered to be a malfunction or deterioration of the implant and are also reportable. Where the expected life of the implant is not specified, revisions carried out because of aseptic loosening within 10 years of primary implantation should be reported.

In some cases, the reason for revision may not be well defined or may involve a number of aetiological factors. Under these circumstances, the incident should be reported.

APPENDIX B

Format of REG-013 Adverse Outcome Summary

This register will have the following fields:

AOR#
Notification Date
Patient ID
Surgeon
Complication
Action Taken
Outcome

APPENDIX C

RECORD OF CHANGES

Issue No.	RECORDED AMENDMENT	DATE	DCN #
1	Release	22/4/98	None
2	Completely rewritten and includes regulatory reporting.	7/8/02	0048
3	Section 3.2 for Europe, changed reporting to country of incident. Added reference to PROC-014 Authorised Representative in section 2.3	8/10/02	0054
4	Moved attachments to front page Updated regulatory web site references Portland Orthopaedics (Aust) Pty Ltd was EBOS Pty Ltd Section 3.3 added Clinical Trial Analysis Recording & Back up Storage and more detail on Checking & recording. Change format to include responsibility & Documentation FORM –002 deleted & added REG-013 Adverse Outcome Summary		