PORTLAND ORTHOPAEDICS PTY LTD
MARGRON TOTAL HIP REPLACEMENT

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PROCEDURE
RECALL

This revision supersedes all previous revisions.

Prepared by:	**Date:**	**Position:** QA Manager
Approved by:	**Date:**	**Position:** CEO

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1. INTRODUCTION

1.1 Purpose of Document

To set out the procedure for dealing with the issuing of advisory notices and product recalls.

1.2 Purpose of Procedure

To warn users of our product of potential problems and to correct or remove product from distribution, if there is a problem that involve a "risk to health" with the product, in a timely manner.

1.3 Scope

This procedure covers the process of recalling a product after it has been decided to recall that product.

This can occur if required by a regulatory authority (e.g. TGA in Australia, FDA in USA and Notified Bodies in Europe amongst other authorities) issuing a notice (e.g. a cease distribution and notification order).

The company can also decide to carry out a recall, corrections or removals. The initial stages of determining if a problem requires a recall etc is done in procedure PROC-003 PROCEDURE IMPROVEMENT OF SYSTEM/PRODUCT.

1.4 References

Internal References:

PROC-001 PROCEDURE ADVERSE OUTCOME
PROC-003 PROCEDURE IMPROVEMENT OF SYSTEM/PRODUCT

External References:

TGA Uniform Recall Procedure for Therapeutic Goods 2001 ed.
Copy obtainable from http://www.health.gov.au/tga.

US Regulations 21 CFR Ch. 1 PART 7, Enforcement Policy
Copy obtainable from http://www.fda.gov/cdrh

US Regulations 21 CFR Ch. 1 PART 806, Medical Devices; Reports of Corrections and Removals.
Copy obtainable from http://www.fda.gov/cdrh

US Regulations 21 CFR Ch. 1 PART 810, Medical Devices Recall Authority.
Copy obtainable from http://www.fda.gov/cdrh

FDA Medical Device Recalls (Corrections & Removals

Copy obtainable from http:www.fda.gov/cdrh/devadvice/51.html

MDA (UK) Guidance on the Recall of Medical Devices

1.5 Responsibility/Authority

The responsibility and authority for the procedure is with the CTO (Chief Technology Officer) who has the authority to delegate responsibility to other people to carry out the work. If the CTO is not available, the CEO (Chief Executive Officer) will deputise. If both are to be absent, a person is to be nominated during period of absence to implement the procedure if necessary.

1.6 Regulatory Precedence

Where a regulatory requirement contradicts a default requirement of the procedure, the regulatory requirement shall take precedence e.g. if a regulator requires a failed prosthesis for analysis, then it should be sent instead of going to our laboratory for analysis.

1.7 Media Management

Responsibility for communications with press and authorisations to make statements to the media shall be the responsibility of the CEO or CTO. No person should make any statement to the press or any written acknowledgement or statement without the written authority of the CEO or CTO.

If time permits, the CEO/CTO should have all proposed statements signed off by the company's attorneys/solicitors prior to publishing.

All enquiries made by the press or media should be referred to the CEO or CTO who may appoint or engage a media consultant if time permits.

2. PROCEDURE

2.1 Recall Alert & Sources & Decision

The alert for a recall would normally occur either via PROC-001 PROCEDURE ADVERSE OUTCOME, PROC-003 PROCEDURE IMPROVEMENT OF SYSTEM/PRODUCT (where a problem has been found through a nonconformance, a corrective action or customer feedback) or notification from regulatory authority. Customer feedback includes any other external source including distributors and regulatory authorities (e.g. notification).

The CTO & CEO should be made aware of the problem. The CTO or CEO will then decide if an advisory notice or recall situation exists.

2.2 Immediate Actions (Assessment of problem)

The Managing Director will immediately:

(i) Notify people in following areas:
Quality Assurance
Warehousing & Distribution
Marketing & Sales
Manufacturing
Legal

(ii) Determine if a team is required to co-ordinate the recall with a Recall Co-ordinator appointed.

(iii) Collate and evaluate all information immediately available and determine the extent of the hazard.

(iv) Determine if an immediate stop is to be placed on distribution of product and if so inform distributors.

(v) Continue to investigate into the nature, extent, cause and remedy of the problem.
This would include:

- Production information on the lot,
- Any problem reports on the production lot,
- Any other product that may have been processed at the same time including their catalogue No.'s, Serial No.'s and Lot No.'s. e.g. packing, sterilizing.
- Similar reports on the product & other products.

(vi) Determine distribution of possible recall items including Cat. No.'s, Description, Lot No.'s, S/No.'s and location. This should be available in the distribution records that are kept.
From Serial Number Register, the Lot number can be determined.

From The Lot Number, the Manufacturing Order can found with the manufacturing History. This will determine other devices made in the same Lot.

If the problem occurred in a subcontracted process, determine PO number from MO record and obtain copy of PO. This will determine if any other Lots were affected. With this information, the distribution of product can be found the Exchequer records or paper distribution records.

(vii) Any information required by regulators

Australia - TGA, refer to Uniform Recall Procedure for Therapeutic Goods, Section E, Information Required for Assessment of Recall.
USA – FDA, refer to Medical Device Recalls (Corrections & Removals
GB – MDA, refer to 'Guidance on the Recall of Medical Devices ' section 6.

2.3 Time Limited Actions (Notification of recall)

Report to various national authorities if required (often with time limits).

Australia – 2 days
Where the recall is safety-related, (i.e. there is risk of injury or harm to patients), then inform the Federal Minister responsible for consumer affairs within 2 days of taking recall action. Refer to "Uniform Recall Procedure for Therapeutic Goods", section M.

USA - 10 days
A written report shall be submitted to FDA within 10 working days of any correction or removal of a device as set out in 21 CFR 806.10. This reference also includes what to report.

GB – per "Initial Incident Report"
Refer to MDA Guidance on the Recall of Medical Devices, Appendix F & section 5.

2.4 As Soon As Possible Actions (Plan)

Identify scope of affected product (range of lot/serial numbers and current disposition of affected product.

Produce Plan for method of recall. This may entail slightly different plans for Australia (with TGA), USA (with FDA) and GB (with MDA). This would also include:

- Liaise with Australian co-ordinator to assess classification, level & strategy. Refer to "Uniform Recall Procedure for Therapeutic Goods", section F.
- Liaise with USA FDA on hearings, recall classification & recall strategy. If notified FDA Recall, refer 21 CFR Ch. 1, Parts 7.41, 7.42. & 810
  If internal Correction or Removal, refer 21 CFR 21 Ch. 1 Part 806.
- Liaise with MDA.
- Method of informing distributors and customers.

- Requirements for storage, isolation or disposal of affected stock.

Develop Recall Letters & Media releases. Refer for guidance to:
"Uniform Recall Procedure for Therapeutic Goods", section G.
MDA Guidance on the Recall of Medical Devices, section 7.
This should provide:

- The description of the device and Cat. No.;
- The serial numbers or other identification (e.g. lot numbers);
- The reason for the issue of the notice/recall;
- Advice of possible hazards and consequent action to be taken.

Institute a log of events and keep records of returned product (tracking) with disposition.

2.5 Implement Recall Plan

Implement Plan by communicating both internal (warehouse/production) and external (distributors / hospitals / clinicians) with clear tracking of product.

2.6 Post Recall (Formal advice and negotiations / communications with regulators)

Communication with regulators will continue.

Australia
At 2 & 6 weeks, supply TGA with interim report on recall. Refer to "Uniform Recall Procedure for Therapeutic Goods", section H.
On completion of the recall;
Report to TGA the preventive action to be implemented to stop problem recurring.

USA
Submit recall status report to FDA as determined by FDA. Refer 21 CFR Ch1 7.53.
For termination of recall with FDA, the method for making a request for termination and FDA requirements can found in 21 CFR Ch. 1, Part 810.17. FDA will notify the company when it considers the recall terminated.

GB
MDA will agree appropriate milestones with the manufacturer or authorised representative for the provision of recall status reports, including a final report. Refer to MDA Guidance on the Recall of Medical Devices, section 11.

2.7 Follow up Action (Auditing & Corrective Action)

Check effectiveness of the recall by reconciling the amount of product received and auditing. Note: Records of the recall can be audited by Australian Consumer Affairs & TGA.

Where a recall was initiated following a report from a party outside Australia, a report may be requested with an outline of the results of investigations and a summary of the recall.

Where corrections and removals are not required to be reported to FDA, records must still be maintained as set out in 21 CFR 806.20. These records may be viewed by FDA.

Action is to be taken to prevent a recurrence of the problem which gave rise to the recall. These details will likely be required by the regulator(s).

2.8 Filing

A full record of the recall is to be retained and become part of the traceability record. It is most likely to be audited during next regular audit by TGA and FDA if an audit was not performed earlier.

APPENDIX A

RECORD OF CHANGES

Issue No.	DATE	RECORDED AMENDMENT	DCN #
1	4/2/01	Release	0007
2		Update for Uniform Recall Procedure for Therapeutic Goods (TGA) for changes in section letters that occurred in 2001 ed.. Modified section 1.5 to update and show deputies. Add section 1.6 Regulatory Precedence Add section 1.7' Media Management'. Restructured & title procedure to make clearer and indicate variations between countries. Updated procedures for reference for Great Britain. Section 2.2 added more information on traceability information. Section 2.4 Added more information on recall letters. Section 2.7 Added reconciling, auditing & corrective action.	