Unit 3/44 McCauley St
Matraville NSW 2036

PROC-003

PROCEDURE
IMPROVEMENT OF SYSTEM/PRODUCT

Non-conformance
Corrective/Preventative/Improvement Action
Customer Feedback
Returned Goods
Clinical Complaint
Innovation Request

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

ATTACHMENTS
FORM-011 – Improvement of System/Product
FORM-021 – Returned Goods Report

Controlled copy only if stamped with Controlled Copy Stamp.
This revision supersedes all previous revisions.

1. INTRODUCTION

1.1 Purpose of Document

To set out the procedure for dealing with:

- non-conformance
- corrective/preventative or improvements
- customer feedback
- clinical complaints
- returned goods

1.2 Purpose of Procedure

To take action to correct problems and improve the company system and products.
To take action, if necessary, to correct errors and to prevent similar occurrences in the future.

1.3 Scope

This procedure covers six main areas:

a) Return of Goods (RGR), this is for returning goods that has been used in a clinical environment for analysis.

b) Innovation Requests (IR) - are when a suggestion is made for improvement of a product or a new product where it is not related to a complaint or safety issue. (The IR's purpose is to do research to determine if work & resources should be spent on an idea and if so transfer to a project etc. It is a method of documenting the incubation stage of R&D before design controls apply when it comes under project control.);

c) Clinical Complaints (CCR), for a report of an adverse outcome or if there is a prosthesis failure. If problem is related to clinical outcome, use PROC-001 Adverse Outcomes Procedure unless corrective, preventive action or report required;

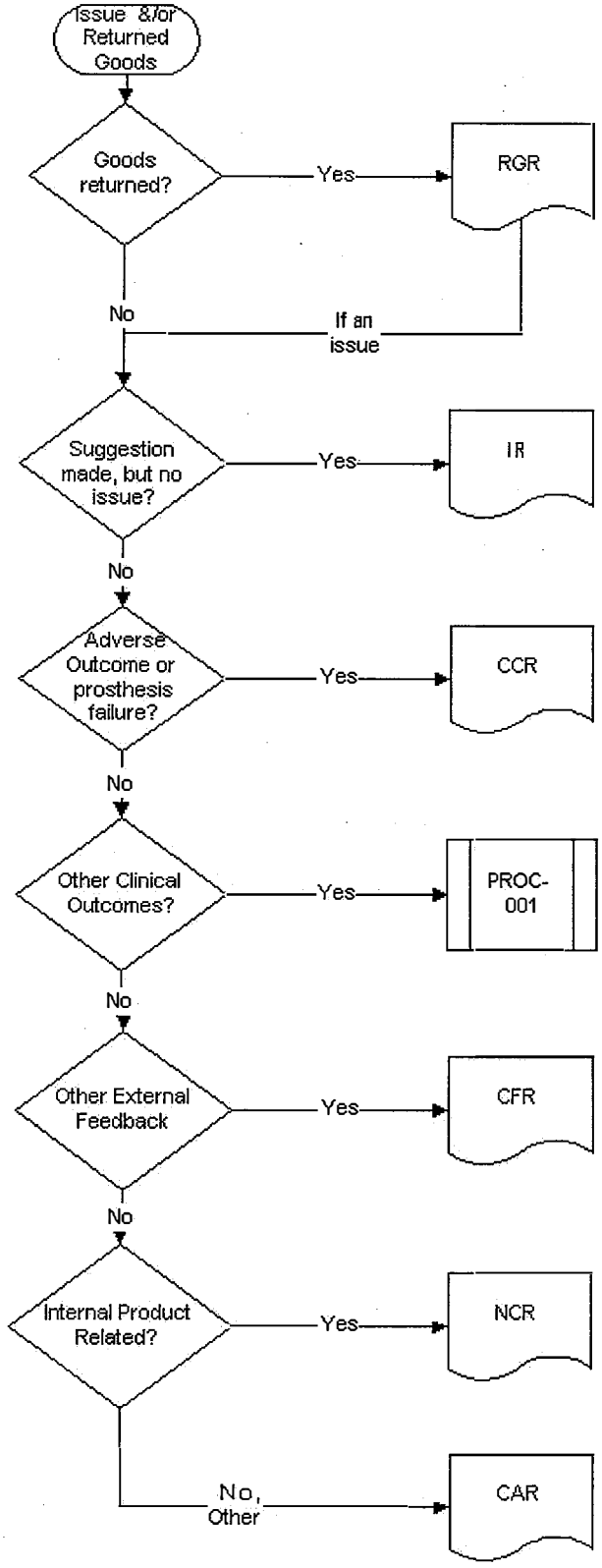
d) Customer Feedback Report (CFR) - Possible or potential problem has been found by a customer (including marketing, distributor or their customers), this includes any reported allegation, written or verbal, from customer of deficiencies related to the identity, quality, durability, reliability, safety or performance of a medical device that is not a clinical issue;

e) Non-conformance Report (NCR) - Possible or potential problems found with the product or the manufacturing process either observed within the company or by a subcontractor (often during inspection or testing) before the sale of the product;

f) Corrective/Preventative/Improvement Action Request (CAR) - Possible or potential problem found within the company system. Examples for CAR are the following:

- If a pattern of nonconformances is developing;
- If a weakness in the system is detected – at a quality review meeting or at any other time;
- If a non-conformance raises concerns about other product items (either completed or in-process) (normally done on same NCR);
- As the result of an internal audit, third party quality audit or a report from a regulatory authority.

See Flow chart for key in determining which type of process to use.


Issue &/or Returned Goods
Goods returned?
Yes
RGR
No
If an issue
Suggestion made, but no issue?
Yes
IR
No
Adverse Outcome or prosthesis failure?
Yes
CCR
No
Other Clinical Outcomes?
Yes
PROC-001
No
Other External Feedback
Yes
CFR
No
Internal Product Related?
Yes
NCR
No, Other
CAR

1.4 References

Internal References:

FORM-011 Form – Improvement of System/Product
FORM-021 Form - Returned Goods Report

PROC-001 Procedure Adverse Outcome
PROC-004 Procedure - Recall
PROC-006 Procedure - Reviewing Quality System
PROC-015 Procedure - Project Control
PROC-019 Procedure - Risk Management of medical devices

REG-002 Register – Improvement of System/Product
REG-019 Register – Returned Goods (RGR)
REG-023 Register – Customer Feedback (CFR)
REG-024 Register – Non-conformances (NCR)
REG-025 Register – Corrective /Preventive Action Requests (CAR)
REG-026 Register – Innovation Requests (IR)
REG-027 Register – Clinical Complaint

1.5 Responsibility/Authority

The CTO is responsible for documenting, investigating and collating problems, complaints and returned products. The CTO or CEO has the authority to delegate work to others.

1.6 Definitions

CEO: Chief Executive Officer
CTO: Chief Technical Officer
Anyone: can be any employee of the company or a related company familiar with this procedure unless indicated.

CAR: Corrective Action Request
CCR: Clinical Complaint Report
CFR: Customer Feedback Report
IR: Innovation Requests
NCR: Non-conformance Report
RGR: Returned Goods Report

Nonconformance: The failure of an action, a material or a job to meet the requirements of the quality system or its specified requirements.
Disposition: To decide on and implement a course of action to resolve a non-conformance (dispose of a non-conformance in ISO 9000 terminology).

Concession/Permit: i.e. a variation from specification. A concession occurs after the process has occurred whereas a permit is a planned variation. This often occurs after a concession to correct a situation.
Complaint means any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution. (21 CFR 820.3 Definitions)

MDR: Medical Device Reporting. The USA MDR regulation provides a mechanism for the Food and Drug Administration (FDA) and manufacturers to identify and monitor significant adverse events involving medical devices. The goals are to detect and correct problems in a timely manner.
Vigilance: Vigilance programs are a range of activities undertaken by the TGA and the manufacturer or sponsor after any party becomes aware of:

- adverse events,
- malfunctions,
- results of testing, or
- other information,

about medical devices supplied in Australia. Similar programs apply to Europe.

1.7 Background

This procedure & forms was created by combining Portland procedure PROC-003 with Vimek procedures P1301 & P1401, these two procedures becoming obsolete. This was done to reduce the chance of mis-communication, becoming lost ('falling between the cracks') and duplicating of work (i.e. 2 reports with neither having the full story).

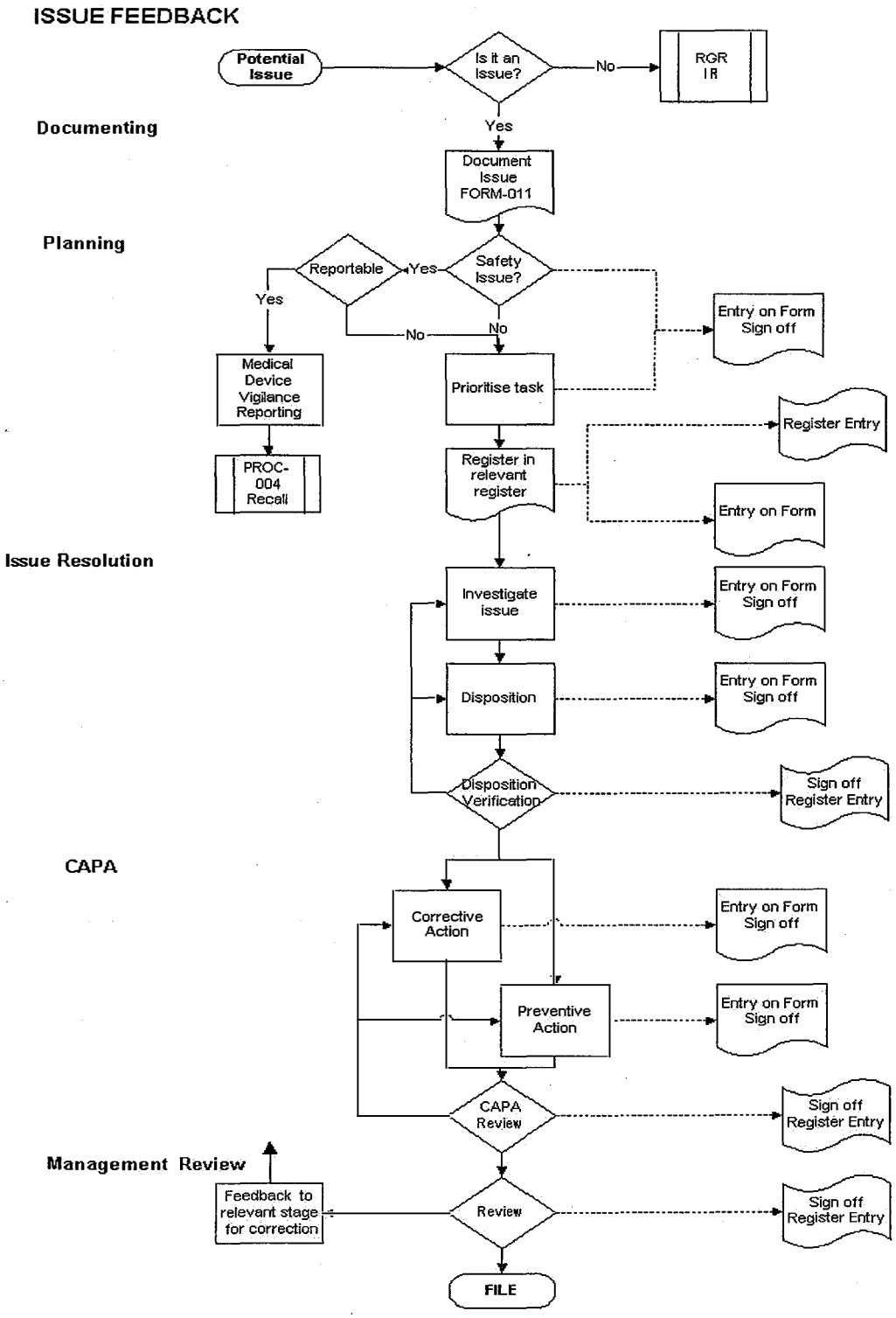
The old registers were modified as below

Old	became	New
Portland REG-002 NCR, CFR & CFR		Obsolete
Portland REG-019 RGR		Portland/Vimek RGR - REG-019
Vimek CFR/RGR		Portland/Vimek CFR – REG-023
Vimek NCR		Portland/Vimek NCR – REG-024
Vimek CAR		Portland/Vimek CAR – REG-025

The old records were left in the old registers, as this was how they were cross-referenced.
New reports were numbered as a continuation of previous numbers to retain a continuous record.

2. PROCEDURE –ISSUE FEEDBACK - CCR, CFR, NCR & CAR

Flowchart



2.1 Recognising an Issue

Responsibility: Anyone

Task

Possible Issues

A potential problem does not have to be proven for it to be reported as an issue. See Scope for possible types of issues.

These issues can occur anywhere, from design, purchasing, manufacturing processes (i.e. inspection etc), distribution, post–marketing vigilance, audits, regulatory authority or a report outside the company (e.g. journals, newspapers, magazines etc).

Examples of issues:

- Non-conformance of product;
- Non-conformance or weakness of system or documentation;
- results of an internal audit, third party quality audit or a report from a regulatory authority;
- pattern of non-conformances developing;
- report from a customer, or other sources.

Not Issues

If any product is returned i.e. external to company, it is to be considered as possibly contaminated & as non-conforming product and so marked & isolated. Special attention may need to be given to decontamination, see section 3 - Procedure Returned Goods – RGR for controlling returned goods. This is not applicable to internal non-conforming goods.

If there is no report of a problem or complaint but a suggestion for product innovation or improvement, go to PROC-015 section 3 Innovation Request.

Documentation

Nil

2.2 Documenting Problem

Responsibility: Anyone

Task

Enter on FORM-011 - Improvement of System/Product.

Fill out 'Description and comments' describing problems with any relevant information. If it is related to a product (e.g. non-conformity) enter part type (or range), batch number(s), serial number(s) etc. Record any history or documents. Attach any relevant documents. If action has been taken to reduce problem, it should be recorded. If in the event of being notified of a product failure, request a

full history of the patient (patient name is not required), surgeon, date of operation and the product (serial # or lot #), if available.

Determine if person reporting the problem requires feedback and note.

Sign and date section

If the problem could cause harm to people, this should be highlighted and brought to CTO attention immediately.

If there is non-conforming product, Items that fail inspection are segregated and tagged with a red label and identified with the lot number and a written description on masking tape or tag of the nature of the non-conformance and its report number then placed in quarantine.

Documentation

Entry in Description on FORM-011.

Tag on product

2.3 Initial Assessment & Registering

Responsibility: Safety related – CTO & CEO
Not safety related – CEO

Task

Safety Assessment

A person, designated by CEO or CTO, on receiving a form, should assess, as soon as possible, if any harm did or can occur to a person. Refer to Appendix B "Medical Device Vigilance Reporting". There are limits on reporting as short as 5 days with penalties for defaulting.
If an adverse reaction or complication has occurred or could occur, the CTO or his representative will endeavour to contact the treating doctor directly by telephone, fax or letter, whichever is the most appropriate and the complication or adverse reaction will be discussed and appropriate action then taken. See APPENDIX B, MEDICAL DEVICE VIGILANCE REPORTING for definitions for when cases need reporting, time limits for report and report forms to be used.

Registering

The purpose of the register is to keep an easy reference record of the reports and to easily verify the status of the reports.

Determine the type of report. Refer to section Scope for definitions of each type. Register the report/request registered with next number in appropriate Register entering other data if available.
Types are:

CCR	-	Clinical Complaint Report	REG-027
CFR	-	Customer Feedback Report	REG-023

NCR	-	Non-Conformance Report	REG-024
CAR	-	Corrective/preventative/improvement Action Request	REG-025

Record the type & number on the form.

Prioritising

Determine priority and person delegated to action the next stages. Refer to appendix B for further details on Medical Device Vigilance reporting. Time frames are limited.

In the event of a catastrophic or serious fault in the prosthesis (Clinical Complaint), Portland will notify each of the treating doctors by telephone, fax or letter, whichever is the most appropriate, recommending appropriate action to be taken, e.g. recall of all patients immediately and will follow PROC-004 Recall.

Documentation

Entry on FORM-011 in Initial Assessment
Entry into appropriate register
Entry on identification tag of number in register if product involved

2.4 Investigation/Evaluation

Responsibility: Person designated by CTO or CEO

Task

Investigate the problem to determine the cause and record the results. If it is a prosthesis failure, a request will be made that information be made available to Portland Orthopaedics Ltd as soon as possible on the cause of the prosthesis failure. If the prosthesis has been retrieved from the patient, then Portland Orthopaedics Pty will request that it be returned for analysis (see also returned product in Section 3).

For CCR reports, a record of each attempt to obtain information, and the nature of the response is to be made (FDA). At least one request for information should be made in writing. Refer to appendix B for further details on Medical Device Vigilance reporting and MDR Event files. Time frames are limited.

If the investigation determines that the activities of a subcontractor, vendor or customer contributed to the complaint, then they are to be informed and relevant information shall be exchanged.

Review the results to determine if a report to regulatory authorities needs to be made.

Sign off and date.

Documentation

Entry in Investigation/Evaluation on FORM-011

2.5 Disposition

Responsibility: Person designated by CTO

Task

If immediate problem has already been corrected or reduced, describe what has been done. This could be done before full investigation, e.g. quarantine product. If only partially corrected describe what has been done.

The problem is reviewed and disposition determined and documented. This includes the control of movements, storage, subsequent processing and notifying other functions that may be affected.

If the problem (not a product) requires immediate action before a change to the system can occur, then the actions should be recorded as a series of instructions. It can be on an attached sheet as a PERMIT (see Section 5) still requiring the same level of approval as the original document.

For non-conforming product, refer to section 5.1 for disposition options. The Production Manager records how the problem is to be dealt with in the 'Disposition' section of the report and records the report ID (e.g. NCR number) into the 'Notes' column of the operations control sheet [F021]. This is to include generation of rework instructions.

Have action authorised by a manager.

Documentation

Entry in Disposition section of form

Any attachments (Permits, work instruction etc)

2.6 Disposition & Feedback Completed

Responsibility: Person designated by CTO

Task

Checking

When work in Disposition has been completed it is signed off. This can be done before or after corrective/preventative action, whichever comes first.

If this includes rework, check verification entries in the operations control sheet for satisfaction of final inspection requirements. If final inspection has passed OK, then close out the Disposition. If there are still problems with the rework, resubmit it to the Manager Production for further disposition under the same NCR and update the NCR accordingly.

For an NCR with a close out of disposition, file a copy of the NCR (with any operations control sheet and rework drawing(s)/work instructions) with its manufacturing order. The original NCR with a copy of the attachments remains open until corrective action is completed.

Feedback

Where feedback is required to the originator of the report, contact the person and obtain a response if satisfied. Record the results (attach e-mails etc).

Sign off

Sign off section.

Entry Disposition Close Out date in register.

Documentation
Sign off Disposition Closed
Entry in Register

2.7 Other Corrective Action Recommended/Taken

Responsibility: Person designated by CTO or CEO

Task

Record exactly what Corrective action has been done in box.

Corrective action is to be taken to eliminate the causes of an existing non-conformity, defect of other undesirable situation in order to prevent recurrence.

Analysis should also be made to determine if any other products could have a similar problem. This includes whether any action needs to be addressed to earlier production, production of similar kinds of components or after delivery or use has started.

If finished product could be defective, action (appropriate to the effects, or potential effect, of the nonconformity) taken may include:

- withholding product available for sale
- withdrawal of product (where therapeutic goods removed from supply or use for reasons not related to their quality, safety or efficacy),
- recovery (therapeutic goods removed from sale or supply by the sponsor that have not left their direct control).
- giving advice to customers; this may take the form of checks to be carried out before use, providing additional guidance on the use of the product or for the replacement of certain products. This could be in the form of a safety alert (advice about a specific situation where a therapeutic good, while meeting all specifications and therapeutic indications, might present an unreasonable risk of substantial harm if certain specified precautions are not observed.

Safety alerts are intended only to provide information on the safe use of therapeutic goods.), or a product notification (precautionary information about a therapeutic good, when it is unlikely to involve significant adverse health consequences), (Copies of safety alerts should be forwarded to the Australian Recall Coordinator for distribution to the relevant health authorities for their information.)

- in extreme cases, the recall of products or issuing a hazard alert where regulatory authorities have to be informed see PROC-004. A hazard alert means issuing precautionary information about an implanted device where it has been proven that there is no stock to be recalled and all affected devices are already implanted. Hazard alerts only relate to implantable medical devices. The appropriate action to be taken, particularly where patient safety may be a consideration should be discussed with the Australian Recall Coordinator.

Show how the system should be changed or corrected (eg training etc) to prevent the problem from recurring.

If no further action is being taken then it should be so stated with reasons.

Have action (or no action) authorised by Manager before implementing.

Documentation

Entry on Form-011

2.8 Preventative Action Recommended/Taken

Responsibility: Person designated by CTO or CEO

Task

Record exactly what preventive action has been done in the box.
Preventive action is to be taken to eliminate the cause of a potential non-conformity, defect, or other undesirable situation in order to prevent occurrence. This is to be done using the information from this problem and any other sources of information (concessions, audit reports etc), determine action required to eliminate the causes of potential nonconformities in order to prevent their occurrence. *This review should include work instructions, drawings & sampling methods if this could have affected the non-conformance.*

Statistical techniques should be reviewed in the light of nonconforming product, quality audit results, feedback information or other appropriate considerations.

If no further action is being taken then it should be so stated with reasons.

Have action (or no action) authorised by Manager before implementing.

Documentation

Entry on Form-011

2.9 Outcome Verification and Close Out

Responsibility: Person designated by CTO

Task

This section is to be signed off after all the above items have been completed and any comments added (eg references to any other documents) with copies any relevant documents attached as a method of verification. If it is related to a customer feedback or preventive action, verify that the actions have been carried out. Verification may include carrying out an audit to ensure the changes have been effective.

Check the required records have been kept, especially for CCR that the MDR event file records are available per Appendix B.

Update the relevant register (see section 2.3) with Close out date.

Documentation

Entry on Form-011

Entry in Register

2.10 Management Reviewing

Responsibility: QA Manager

Task

This document should be reviewed by the CTO or CEO so that management will remain up to date with any problems and changes. An analysis will also be done to detect trends. This will allow an overall picture so that any other improvements can be made.

Update the relevant register (see section 2.3) with Review date.

Documentation

Sign off CEO or CTO

Entry in Register

2.11 Filing

Responsibility: Person designated by CTO

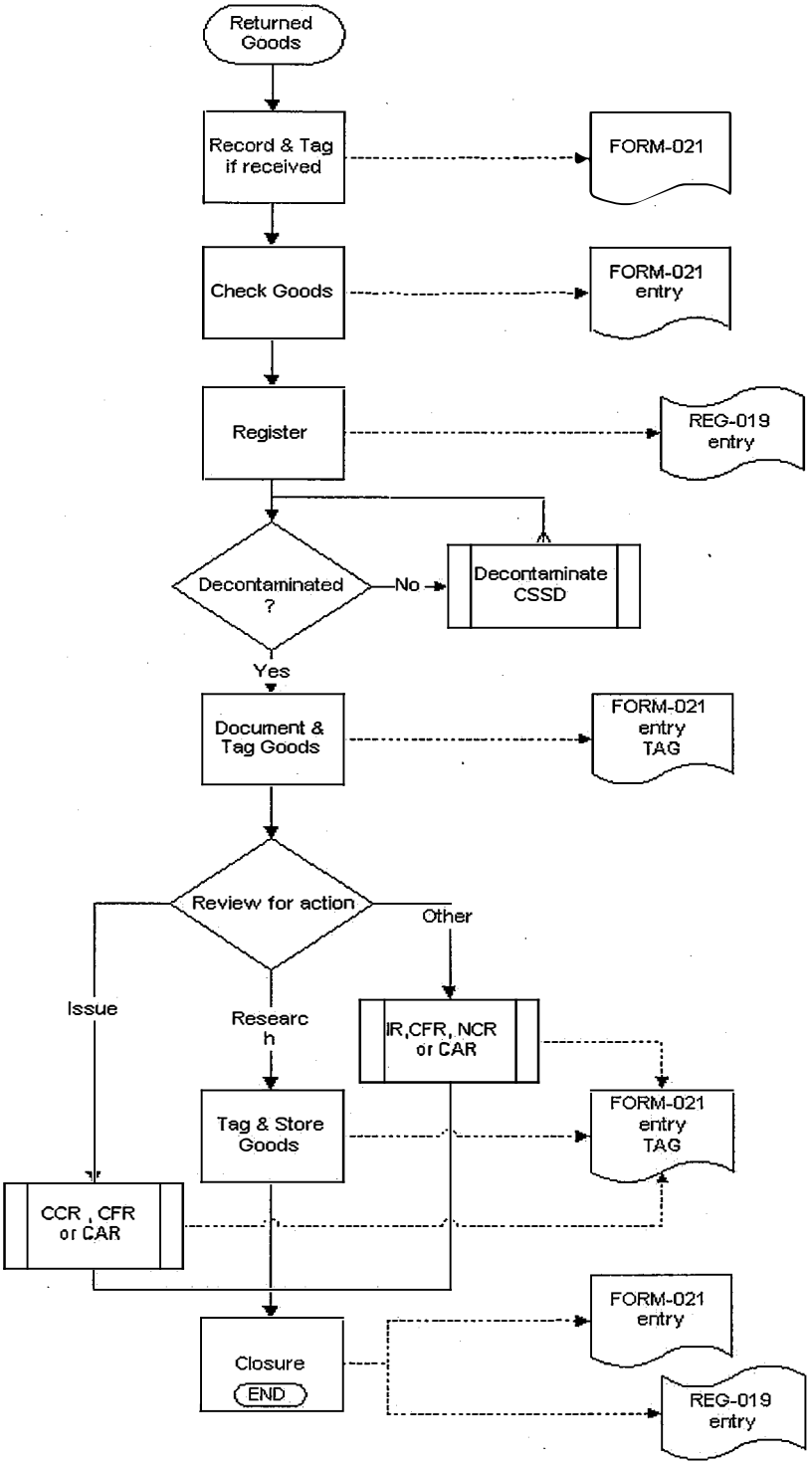
Task

File completed document in relevant register file (see section 2.3).

Documentation
Nil

3. PROCEDURE – RETURNED GOODS - RGR

Flowchart



Warning

All returned implants will be considered contaminated until determined shown otherwise. The packaging should not be opened by personnel not trained in handling this type of product.

3.1 Recording Returned Goods

Responsibility: Sender or not completed, the Receiver

Task

Any returned goods (except goods being transferred between stores per PROC) are to be recorded on 'Return Goods Report' [FORM-021] by completing Part 1. The 'GOODS' section must be completed for traceability.
Attach any customer documents supplied e.g. Sterilization/disinfection documentation from surgeon or CSSD of hospital.

Documentation

Completed Part 1 of Form 021
If possible, copy of Sterilization/disinfection documentation (attached to the product)

3.2 Checking & Registering

Responsibility: Person designated by CTO or CEO

Task

Checking

When goods are received, identify and record the goods part number and Serial or Lot Numbers. Check & note condition of the goods.

All returned goods will be considered non-conforming product and marked to distinguish them from other conforming products.

Registering

Register the details in the Returned Goods register REG-019 and add register number to the form and returned goods.

Decontamination Status

If medical devices are returned from use in or with a patient,
check package is sealed and clearly identified;
check items for contamination and whether the have been decontaminated (including Class 1 Instruments). They should be decontaminated.

The preferred method of decontamination is cleaning followed by sterilization (CSSD). If this is not feasible because it would cause destruction of evidence, then high-level disinfection is required. This is to be discussed with Dr Ron Sekel (CTO) to determine if required otherwise per CSSD protocol.

If they are not decontaminated, they are to be sent for decontamination to Dr Ron Sekel at St George Private Hospital at Kogarah NSW per standard CSSD protocols or high-level disinfection as specified by Dr Ron Sekel.
The product is to return with sterilization documentation ("The Green Form" or equivalent e.g. sterilisation tags, indicator bags etc) or equivalent for high level disinfection.

Tagging

Mark RGR number, description of product or part number contamination status on the packaging or attached to the product. Attach a copy of Sterilization/disinfection documentation.

Documentation
Completed part of Part 2 of Form 021

3.3 Feeding Back Results and Closure

Responsibility: Person designated by CTO / CEO

Task

Review the form, to determine action.

If there is a problem, a CCR is raised referencing the customer feedback and is processed (see earlier in this procedure) as quickly as possible.
If a CCR is not raised, the reason shall be recorded, e.g. for research purposes only.
If customer needs feedback e.g. a complaint (noted at time of receipt), this is transferred to the CCR.

NOTE: If there is a problem, the problem should be evaluated as soon as possible to determine if any harm can occur to a person. Refer to Appendix B Medical Device Vigilance Reporting for criteria and process. There are limits on reporting as short as 5 days with penalties for defaulting.

If goods were returned for research purposes, mark "For future analysis" and decontamination status (should already be noted) on the goods packaging (sealed) then store for analysis. This storage area shall be in an area away from finished or "in process" medical devices so that no cross contamination or mix can occur. Analysis of these explanted goods to be carried by subcontractors or people (competent in analysis & handling) when required as determined by the CTO/CEO.

If for 'Other' reason, determine future action on individual basis and raise relevant documentation (CAR, NCR, CFR, IR). Transfer or store the goods.

Closure

Check action has been completed including any CAR are closed and note closing date. Sign off RGR.

Note in 'Register Returned Goods' REG-019, the result type e.g. CAR, date of closure.

Documentation

Completed FORM 021
Entry REG-019
Possible CAR.

4 VARIATIONS ON DOCUMENTED PROCESSES – DISPOSITION OPTIONS, CONCESSIONS, PERMITS, REWORK AND CUSTOMER REQUEST AUTHORITY

4.1 Non-Conforming Product Disposition Options

The available options for goods that fail inwards inspection are to:

- Accept them in consultation with the vendor / subcontractor /customer with or without rectification (i.e. a concession);
- Return them to the vendor / subcontractor /customer (leave them on the truck or have the vendor / subcontractor / customer collect them or have them sent back).

The available options for work that fails other inspection are:

- Rework/repair until specification is met (i.e. Permit);
- Accept without rectification (i.e. a Concession);
- Reject & scrap or regrade for alternative application.

These options are actioned as below:

a) If accepting with concession (Concession) or reworking (Permit), then document. This form can be used as a CONCESSION to allow deviations from specifications or procedures/work instructions. The justification for a concession is to be documented. A non-conforming medical device can be accepted by concession only if regulatory requirements are met. Concessions of products for customers are to have written acceptance from the customer if appropriate. The form can also be used as a Permit to allow future deviations or rework (for this problem only) of specifications or procedures/work instructions. If either a Concession or a Permit is done then this document should record as a minimum product type and batches and/or serial numbers. It shall always have a limit either in time, quantity or lots. An open Concession or Permit is not allowed. This would be a change.

b) Before rework/repair/regrade authorisation, a determination of any adverse effect of the rework upon the product shall be made and documented. Any product for rework/repair/regrade shall be clearly identified as to its status so that it cannot be confused with conforming product or re-enter the production system without its rework instructions (PERMIT). Any rework shall be documented in a work instruction that has undergone the same authorization and approval as the original work instruction.

c) Any product for scrap shall be clearly identified as to its status so that it cannot be confused with conforming product or re-enter the production system and that it is disposed of safely

4.2 Concessions or Permits

Responsibility: Manager requesting Concession or Permit.

Task

If a Concession/Permit (i.e. a change from specification either better or worse) is being used, then *regulatory requirements still have to be met. The Concession/Permit has to be authorized by CEO or CTO. Where applicable, also by the Customer.*

For traceability (in case of problems,) the following should be recorded:
Items that are being concessed'
Quantity, Lot No's, & S/No's (whichever is applicable),
Specification being concessed,
Identity of the person authorizing the concession.
A concession has to be always limited in Period, Quantity, Lots etc, as an open-ended concession/permit is a change. Traceability is required as experience has shown that more than one Concession/Permit (when thought to have no problems), has later been found to require correction and the parts needed to be traced.

If the Concession/Permit needs an extension, this also needs to be approved with Lots No.'s etc recorded either on a new NCR or the original NCR. This is required again for control and traceability.

A previous concession is a reason for not accepting another concession, as the problem was not corrected. If the Concession/Permit needs an extension, this also needs to be approved with Lots No.'s etc recorded either on a new NCR or the original NCR. This is again for control and traceability.

For any rework, see Reworking below

Documentation
Entry on feedback report (NCR, CAR, CFR)

4.3 Reworking

Responsibility: Manager Production, Authorised Tradesperson

Task

For rework items, the rework shall be documented in a work instruction that has undergone the same authorization and approval procedure as the original instruction. This can be done by photocopy the relevant drawing(s) and over stamp with the 'Rework' rubber stamp [F026] and note (can be by hand) on the drawing any modifications to inspection, measurement and test requirements. This shall include repeating any measurements that may be affected by the rework. This shall undergo the same authorization and approval as the original work instruction.

Prior to authorization and approval, a determination of any adverse effect of the rework upon product shall be made and documented.

The red tag and rework instructions shall travel with the rework items until items are verified as correct.

The 'Rework' job is subject to all of the inspection and test requirements of its operation control sheet as for any other manufacturing order [P1002, P1003] with the same sign off.

Completion of the rework is recorded in the 'Notes' column of the lot's original operations control sheet.

Documentation

Photocopied drawings with authorised 'Rework' rubber stamp imprint [F026] and modified inspection, measuring and test requirements (if any)

Authorised entry in 'Notes' against rework process(es) in the operations control sheet [F021]

4.4 Customer Request Authority

Responsibility: Manager

Task

The Customer Request Authority [F001] is used where the request could have an impact on the quality of the product.

The request is placed in "Permit".

The action to be taken is placed in Disposition and should be signed by a customer's representative and a copy given to customer.

A copy is placed with the affected Manufacturing orders.

Documentation

Completed document

4.5 Inwards Urgent Release Authorisation

See PROC-018 for details

APPENDIX A

RECORD OF CHANGES

Issue No.	DATE	RECORDED AMENDMENT	DCN #
1	3/11/00	Release	0001
2	11/10/02	Sec. 1.6 Added CTO responsible for documenting, interpreting and collating problems, complaints and returned products. Change other responsibilities to align. Sec 1.7 Definitions added Sec 2.4 Added note to determine if regulatory reporting required. Sec 2.7 Added separate sub sections for corrective & preventive action Sec. 2.7: Add note on reviewing statistical techniques Added new section 3 'Procedure Returned Goods' and references elsewhere. Added REG-019 & FORM-021 as required elsewhere. Sec 2.9 Analysis to be done. CTO to sign off review. Added extra notes on non-conformances to sec's 2.2, 2.5 Added references to PROC-001 Adverse Outcome and regulatory vigilance requirements sec 2.2, 2.4	0055
3	8/12/03	Moved attachments to front page Section 3 rewritten to include more information on decontaminating. Investigation and later parts removed and become part of CAR which already includes them.	0096
4		Addition of requirements from Vimek procedure P1301 & P1401 to unify the procedures & introduce REG-023, REG-024 & REG-025. Addition of Clinical Complaint Report for easier analysis & REG-027. Modification of section 2.3 to included checking of safety (from PROC-001) and prioritising as well as registering. Sections 2.7 & 2.8 Separated Corrective & Preventive Action adding more details. Added section 4 VARIATIONS ON DOCUMENTED PROCESSES including information from Vimek procedures. Added Appendix B Medical Device Vigilance Reporting Added Appendix C Register formats Added flowcharts Obsolete REG-002 Reg- Improvement of System/Product	

APPENDIX B MEDICAL DEVICE VIGILANCE REPORTING

For Australia:

Any event that meets three basic reporting criteria, even if it does not involve a patient or user, should be reported to the TGA:

1. An adverse event has occurred.
2. The manufacturer's medical device is associated with the event.
3. The event led to death or serious injury, or might lead to death or serious injury if it were to occur again.

An "adverse event" is defined as an event that led to a death, or led to a serious injury to a patient, user or other person.

Serious injury (also known as serious deterioration in state of health) is:

- a life threatening illness or injury,
- a permanent impairment of a body function, (The term "permanent" means irreversible impairment or damage to a body structure or function. The term excludes minor impairment or damage.)
- permanent damage to a body structure, or
- a condition necessitating medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure. (In this context, medical intervention is not in itself a serious injury. It is the reason that motivated the medical intervention that should be used to assess whether an event should be reported.)

1. An adverse event has occurred

In this instance the manufacturer or sponsor becomes aware of information about an adverse event that is associated with the device they manufacture or supply. This also includes situations where testing performed on the device, examination of the information supplied with the device or any scientific information indicates some factor that could lead or has led to an event.

2. The manufacturer's medical device is associated with the event

In assessing the link between the device and the event, the sponsor should take into account:

- the opinion, based on available information, from a health care professional;
- information concerning previous, similar events;
- other information held by the sponsor.

This judgement may be difficult when there are multiple devices and drugs involved. In complex situations, it should be assumed that the device was associated with the event.

3. The event led to death or serious injury, or might lead to death or serious injury if it were to occur again.

These factors are:

- a death of a patient, user or other person.

- a serious injury of a patient, user or other person.
  (The interpretation of the term "serious" is not easy, and should be made in consultation with a medical practitioner when appropriate.)
- where no death or serious injury had occurred but the event might lead to the death or serious injury of a patient, user or other person if the event recurs. These types of events are also known as "near incidents".

There are also reporting exemption rules, see TGA's Australian Medical Devices Guidelines, Guidance Document Number 11, "Postmarket Activities" for further details (copy is in Standards Folder & on the TGA internet website) for further details.

Examples of reportable adverse events
1. The premature revision of an orthopaedic implant due to loosening or fracture but is not reportable if:

- An orthopaedic surgeon implants a hip joint and warns against sports-related use. Patient chooses to go water skiing and subsequently requires premature revision.
- The early revision of an orthopaedic implant due to loosening caused by the patient developing osteoporosis.

2. After delivery of an orthopaedic implant, errors were discovered in heat treatment records raising questions about the effectiveness of the implant's materials that would create a risk to public health.

Reporting Time Limits

Reports of issues that represent a serious public health threat or concern, where there is imminent risk of death, serious injury, or serious illness and may require prompt remedial action, must be submitted within 48 hours. (regulation 5.7(1)(a) of the *Therapeutic Goods (Medical Devices) Regulations 2002*). The 48-hour timeframe is reserved for major issues where new evidence suggests that the risk profile of a device is not acceptable.

If the event resulted in a serious injury or a death, the sponsor must submit a manufacturer's report of the adverse event no later than 10 calendar days from the date of becoming aware of the event. (regulation 5.7(1)(b) of the *Therapeutic Goods (Medical Devices) Regulations 2002*)
If the event is a reportable "near adverse event", or the event did not result in death or serious injury, the sponsor must submit a manufacturer's report of the adverse event no later than 30 calendar days from the date of becoming aware of the event. (regulation 5.7(1)(c) of the *Therapeutic Goods (Medical Devices) Regulations 2002*). A "near adverse event" is defined as an event that might have led to a death or serious injury. For an event to be defined as a near adverse event, it is sufficient that:

- an event associated with the device happened;
- if the event occurred again, it might lead to death or serious injury or;

- testing or examination of the device or the information supplied with the device, or scientific literature, indicated some factor which could lead to a death or serious injury.

Reporting

The event is to be reported on 'Medical Device Incident Report' form obtainable from http://www.tga.gov.au/docs/doc/forms/iris_mdir01.doc.

Refer to TGA's Australian Medical Devices Guidelines, Guidance Document Number 11, "Postmarket Activities" for further details (copy is in Standards Folder & on the TGA internet website) for "Details to be included in a report".

The report is to be sent to the address in TGA's Australian Medical Devices Guidelines, Guidance Document Number 11, "Postmarket Activities" for further details (copy is in Standards Folder & on the TGA internet site), "Address for submission of Advers Events and other reports".

Note: If we gain access to the medical device suspected to be involved in an event, and the initial assessment, or cleaning or decontamination process, will involve altering the device in a way which may affect subsequent analysis, the manufacturer should, through the sponsor, inform the TGA before proceeding.

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.

Serious injury/(Serious illness) [§803.3(aa)(1)] is an injury or illness that:
• is life threatening, even if temporary in nature;
• results in permanent impairment of a body function or permanent damage to a body structure; or
• necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.
A malfunction [§803.3(m)] is a failure of the device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling for the device. Malfunctions are **not** reportable if they are not likely to result in a death, serious injury or other significant adverse event experience.

Reporting Time Limits

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.

Other reports must be submitted to FDA within 30 calendar days.

Reporting

Reports 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).

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

All MDR reports should be sent to:

Food and Drug Administration
Center for Devices and Radiological Health
Medical Device Reporting
PO Box 3002
Rockville, MD 20847-3002

To ensure the proper processing of all reports, the outside of the envelope shall be labeled in a specific manner. Refer to http://www.fda.gov/cdrh/manual/mdrman.pdf for details

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 below 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.

Examples of 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.

MDR EVENT FILES [Requirement of FDA regulation §803.18(b)(1)]

Although the following is required by USA FDA, it is also good practice for other regulatory authorities.

We must maintain complete MDR files in either written or electronic form. They must identify them prominently as "MDR Files" so they can be found easily. Manufacturers' MDR files will be maintained as part of their CCR Clinical complaint file required under the Quality System (QS) regulation (§820.198). An MDR report submitted to FDA is not considered in compliance with the MDR regulation unless the manufacturer evaluated the event in accordance with the QS regulation, regarding investigation of a possible device failure [See sections 820.198(c), (d) and (e)]. There must be a record of this investigation documented in the complaint file. Manufacturers are to maintain records related to an event (whether reportable or not) for two years from the date of the event or a period equivalent to the expected life of the device, whichever is longer. MDR files may incorporate references to other information sources such as medical records, patient files, and engineering reports.

MDR files must contain:

- information related to the event, including all documentation of deliberations and decision making processes used to decide whether the event was or was **not** reportable; and

- the original or a copy of the initial record complaint/event. This record should include the available information needed to complete the Form 3500A. The record may be a documented telephone call, a letter or facsimile, a service report, documents related to a lawsuit, a voluntary Form 3500 received from a health care professional or consumer, or a mandatory Form 3500A received from a user facility and/or a distributor,
- copies of any records documenting the firm's attempts to follow-up and obtain missing or additional information about the event. When the manufacturer cannot obtain information, they must write an explanation of these events for inclusion in the file. In addition, there must be an explanation of why any missing information, required by the MDR regulation, was not obtained and submitted.
- copies of any test reports, laboratory reports, service records and reports, and records of investigations.
- copies of all documentation involving the final assessment of the event, any deliberation and/or decision making processes used to determine whether an MDR report was or was not needed. When applicable, the final assessment should indicate what action (if any) the firm took to assure that the cause of the event is corrected or otherwise mitigated.
- copies of all 3500As submitted to FDA, when applicable. This includes a copy of any 3500As received from user facilities and distributors.
- documents verifying that the event has been evaluated in accordance with the applicable requirements of 21 CFR 820.198.
- references to any other relevant documents or information used during assessment.

Manufacturers must permit any authorized FDA employee or any other regulatory auditor (e.g. TGA) to access, copy, and verify the records in the MDR files.

APPENDIX C REGISTER FORMATS

CCR, CFR, NCR, CAR Register Format

The register will have provision for:

- Report number;
- Description;
- Lot/Po No.;
- Date raised;
- Disposition Closed;
- Date Closed;
- Review.

REG-019 Returned Goods Register (RGR) Format

The register will have provision for:

- RGR Report number
- Source
- Brief Details/Description
- Date raised
- Result type
- Date Closed
- Review