# PORTLAND ORTHOPAEDICS PTY LTD
# MARGRON TOTAL HIP REPLACEMENT

**ABN 92 086 839 992**

**Unit 3, 44 McCauley Street**
**Matraville**
**NSW 2036**

# OPERATIONS MANUAL
# (QUALITY MANUAL)

This revision supersedes all previous revisions.

| Prepared by: | Date: | Position: |
|---|---|---|
| Approved by: | Date: | Position: CEO |

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## INTRODUCTION

### Purpose of Document

This document is an introduction to the company's policies and their implementation through standard operating procedures to meet requirements of Quality assurance standards EN46001/ISO13485.

### Background

The company was incorporated by Professor Ronald Sekel, an orthopaedic surgeon involved in joint replacement surgery for over twenty years.

Increased demand in recent years for hip joint replacements has resulted in the development of many different designs but to date no perfect prosthesis has yet been developed. For this reason the MARGRON Total Hip Replacement System has been designed. It is manufactured in Australia using known biomaterials, with a revolutionary new design to the stem.

Prosthesis with single screws have been designed in the past but have failed due to unscrewing after torque forces were applied across the hip with normal range of motion activities. The MARGRON hip uses double threading with differing speeds to immediately lock the prosthesis and prevent unscrewing as one thread works in opposition to the other. De-rotation cuts have been inserted in the threads and longitudinally in the prosthesis, to gain long-term locking with bone on-growth. A Hydroxyapatite coating has been applied to the upper half of the prosthesis to stimulate further bony on-growth and increased immediate and long-term fixation of the prosthesis.

Recurrent dislocation of contemporary hip replacements remain a problem and the MARGRON hip has been designed to reduce this incidence by being able to dial-up the optimum angle of insertion of the neck, once the stem has been inserted. This increased modularity should reduce the complication rate of dislocation and allow maximum range of movement of the hip joint.

The Margron system has been designed for flexibility. The male head taper allows the application of chrome cobalt or ceramic heads to be applied of varying lengths, so that the optimum overall leg length can be obtained during surgery. The MARGRON Hip Revision set offers extended surgical possibilities through the use stem, neck and extension modular components. These components suit the long osteotomies common in revision surgery and are a vital requirement in the "Total Hip" philosophy.

The goal throughout the design and production of the MARGRON prosthesis has been to provide a quality driven hip replacement of the highest standard. The MARGRON Total Hip Replacement System and TITE Tooling was recognised at the Australian Design Awards 1998 being awarded winner in the Engineering Design Category.

## COMPANY POLICY

Insert Company Policy

## ORGANISATION STRUCTURE & RESPONSIBILITIES

**Organisational Structure & Responsibilities**
The executive roles are:

1. CEO;
2. Chief Technical Officer;
3. Vice President Sales and Marketing;
4. Operations Manager;
5. Management Representative.
6. Production Manager (Vimek)
7. CEO (Portland Orthopaedics Inc in USA)
8. Authorised Representative (Europe)

The Chief Executive Officer: is ultimately responsible for all aspects of the research, development, manufacture and distribution of Portland Orthopaedics Pty Ltd products. The Chief Executive Officer has authority over all areas of Portland Orthopaedics Pty Ltd.

The Chief Technical Officer: is responsible for all aspects of the research, development and manufacture of Portland Orthopaedics Pty Ltd products.

The CEO and Chief Technical Officer are to be advised of all legal and regulatory affairs and matters involved with research and development, manufacturing, insurance and distribution. The CEO is to oversee the above both nationally and internationally.

Vice President Sales and Marketing: it is the responsibility of the Vice President Sales and Marketing to promote the distribution of and to advertise Portland Orthopaedics Pty Ltd's products in a highly ethical manner nationally and internationally. Distribution is to be carried out according to the regulatory affairs of each country in which the products are being marketed and distributed, and also according to the contractual, legally binding arrangements with Portland Orthopaedics Pty Ltd.

The Operations Manager is answerable to the CEO: It is the responsibility of the Operations Manager to keep notes of all meetings and to publish these within a seven day period. The Operations Manager is also responsible for the careful and accurate maintenance of all files and correspondence.

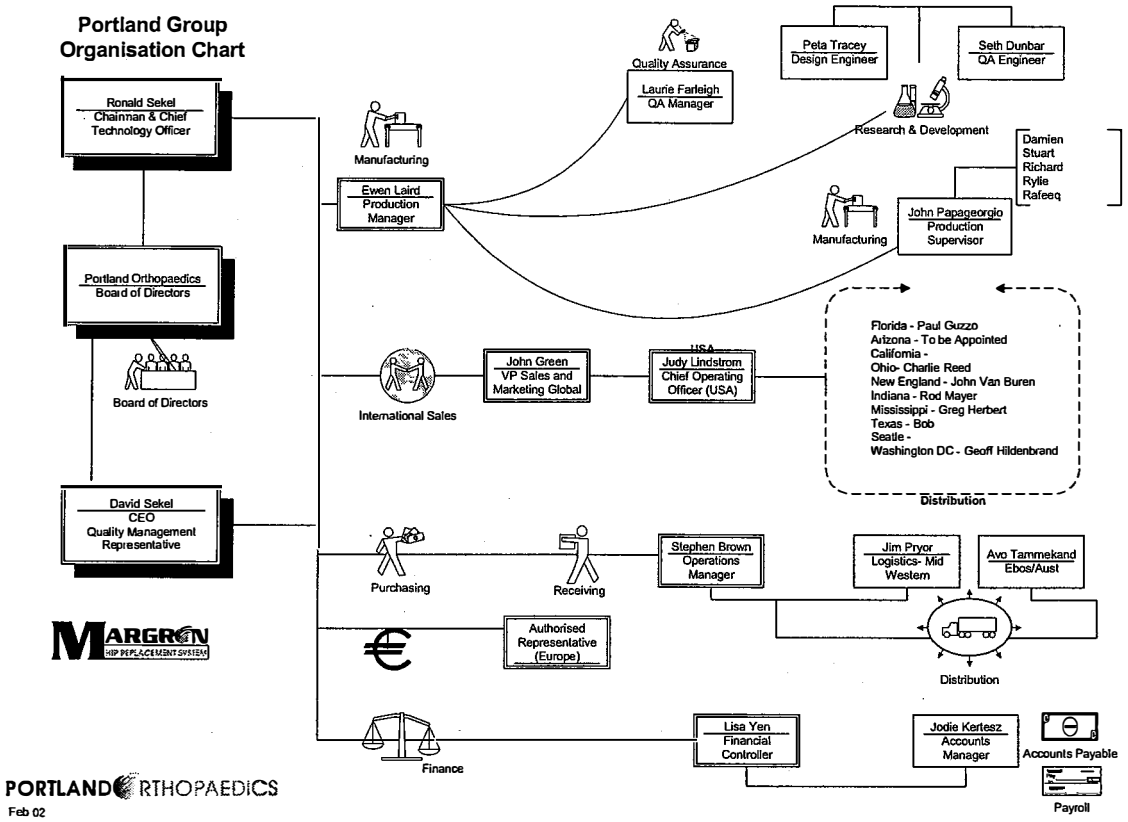
Management Representative: It is the responsibility of the Management Representative, irrespective of other responsibilities, to ensure that the quality system is established, implemented and maintained. He will also report on the performance of the systems as a basis for improvement and liaise with external parties on masters relating to the quality system. The management representative shall also be responsible for undertaking audits of the quality system, its records and the keeping of records of the same.

Production Manager (Vimek) is responsible for planning, developing production methods and manufacture of product.

Chief Operating Officer (Portland Orthopedics Inc in USA) is responsible for operations USA.

Authorised Representative (Europe) is responsible for regulatory requirements for Europe. Refer to PROC-014 –Procedure AUTHORISED REPRESENTATIVE (EUROPE) for responsibilities and processes.

Refer also to procedure PROC-008 " Procedure Training & Job Description" and REG-008 "Register – Authorised Personnel" for other personnel.




## Responsibility & Authority Delegation

When delegation occurs, the delegation usually involves delegation of authority (for another individual to do the delegated task) but not of the responsibility.

## Regulatory Responsibilities

### Policy

Management shall be responsible for meeting regulatory responsibilities. This is particularly applicable for medical device products. These responsibilities vary with the country where the device is sold although most countries are harmonising to the guidelines of the Global Harmonization Task Force.

For our major markets, refer to the regulations of:

| | |
|---|---|
| Australia | TGA |
| USA | FDA |
| Europe | MDD 93/42/EEC (Medical Device Directive) |

These regulations, which are to be met during the design and development stage and manufacture, have the following major areas depending on risk classification and risk analysis of the device:

- Control of design, manufacture & distribution (e.g. Quality System);
- Safety of device & approval before marketing (e.g. Listing, 510k);
- Monitoring product problems, reporting & recalls (e.g. IRIS, MDR, Vigilance systems);
- Representation in marketed area (e.g. sponsor, Authorized Representative).
- Documentation of the methods of addressing the regulatory requirements (MDD, 510k etc) are to be contained in regulatory files including references to additional information. These files should include the classification of the device, conformity assessment route chosen, compliance with the essential requirements, principles or guidances, clinical investigations, technical documentation, labelling, CE marking, vigilance system and the authorised person.

### Implementation

Control of design, manufacture & distribution - refer to this manual;
Safety of device & approval before marketing – refer to PROC-011;
Monitoring product problems, reporting & recalls – refer to PROC-001, PROC-003 & PROC-004;
Representation in marketed area (e.g. sponsor, Authorized Representative) – refer to PROC-014.
Documentation addressing the regulatory requirements (MDD, 510k etc) are to be contained in regulatory files RF-XXX stored in fireproof safe, e.g.:
Margron Hip Implants USA (510k) see RF-002,
Margron Hip Implants Europe (MDD) see RF-005,
Margron Hip Instruments & Trials Europe (MDD) see RF-004.

These files contain the classification of the device, conformity assessment route chosen, compliance with the essential requirements, principles or guidances, labelling and the authorised person. References are made to the clinical investigations, technical documentation and vigilance system (see above). These referenced documents are registered & controlled under the Document & Record Control Procedure, e.g. Risk Analysis - RSK family, Technical, Verification, Validation Documents – SPEC, DHF.

## MANAGEMENT REVIEW

### Policy

Senior management will regularly review and keep relevant and current the company's quality system to ensure it's continuing suitability, adequacy and effectiveness. This includes any aspects of the company's operations that could impact on quality, including the need for changes to the organisation's quality management system, quality policy and quality objectives. The reviews shall be recorded.

### Implementation

Refer to PROC-006 Reviewing the Quality System.

## SYSTEM STRUCTURE

### Policy

A system shall be maintained and documented as a means of ensuring that our products conform to specified requirements. A manual outlining the document structure, making reference to the system procedures, shall be maintained to effect this policy.

### Implementation

Documents and records are broken up into the following groups:

- System Documents (Manual, Procedures, Registers & System Forms)
- Design History Documents & Records (Requirements, Risk Analysis, Verifications etc.)
- Product (Device) Master Records (Specifications, Drawings etc.)
- Product (Device) History Records
- External Documents (Standards, Regulations & Guidances)
- Software

For details on the documents and records, refer to PROC-010 Procedure Document & Record Control.

This manual has references to procedures included in Implementation.

## PLANNING & RESOURCES

### Policy

All systems, products and projects being developed will be planned. This includes:

- defining requirements (with clarification of standards of acceptability), identification and acquisition or development (i.e. any measurement requirement involving capability that exceeds the known state of art) of any controls, processes, equipment (including inspection and test equipment), fixtures, resources and skills that may be needed to achieve the required quality;
- ensuring the compatibility of the design, the production process, installation, servicing, inspection and test techniques (with updating procedures as necessary);
- identification of suitable verification at appropriate stages in the realisation of the product;
- identification and preparation of records.

From time to time the CEO will review the existing and likely additional resources of the company. That review will include future resources for personnel (trained or otherwise), management, work performances and verification of duties through internal quality audits and performance reviews and shall be evidenced through organisational charts and staff annual performance results.

### Implementation

Refer to PROC-011 Procedure Research & Development.

## CONTRACT REVIEW

### Policy

Other than when specifically set out in a procedure (eg Proc 005) all contracts and agreements shall be received and reviewed by the respective responsible manager for that area. Once the responsible manager has reviewed the agreement (oral or written) and when they are satisfied with the contents and terms, they shall present that agreement together with a memorandum as to the circumstances surrounding the agreement and a report as to the ability of the company and the third party to cope with the terms, to the CEO for review and or approval.

The CEO, together with the responsible manager, may elect to forward the agreement to Portland's lawyers for review and or comments and negotiations.

The CEO will also review the company's ability to meet the resources required in the agreement before binding the company.

The CEO shall be solely responsible for binding the company in any agreement and no other person has the authority to do so unless the CEO specifically delegates such authority in writing and the authority shall be only for that purpose.

Where agreements are oral, the memo to the CEO will form the company's records as to the terms of the agreement.

### Implementation

The majority of contracts are part of Purchasing and Sales (Distribution) PROC-005 Procedure, Receiving, Stock Control and Dispersal. Other contracts are under senior management control.

## DOCUMENTATION AND RECORDS

### Documentation Policy

Portland Orthopaedics Pty Ltd requires that all documents used in the workplace be subject to a strict policy by which there is control over the creation, storage, alteration, distribution and printing.

The object of this policy is to enhance the quality of data collection and communication, minimise the risk of errors in record-keeping, ensure procedural consistency, allow the tracing to source of all information pertaining to the manufacture and distribution of components, and finally to provide for auditing of the system. The design and contents of these SOPs are to be based on EN 46002:1997/ EN ISO9002 for the manufacture of medical devices.

### Implementation

Refer to PROC-010 Procedure Document & Record Control
and PROC-002 Procedure Document Change

### Records Control Policy

Records shall be controlled so that they remain good condition, are retrievable (the ease to depend on records importance and its probability it will need to be retrieved) and retained for a minimum of regulatory period. For technical records relating to implants, this minimum is shelf life plus lifetime in the patient. Particular emphasis is placed on traceability back through production and to usage via lot/serial numbers.

The policy is also applicable to records stored in computer or as software.

### Implementation

Refer to PROC-010 Procedure Document & Record Control

## DESIGN (R&D)

### Policy

Portland will develop products from concept and rough designs to final product e.g. the Margron Total Hip Replacement.

This will be carried out in controlled stages with documentation.
This includes the following minimum requirements:

- Design Input is formally documented.
- Design and Development Planning where the process is formally planned.
- Design Review is performed at the conclusion of each stage of development to ensure that the design stage output meets the design stage input requirements.
- Design Verification methods include testing, demonstration and documentation review.
- Design Validation is performed at the conclusion of the design process to ensure that the product conforms to the defined user requirements. Validation is performed on the final design under defined operating conditions reflecting clinical use. Validation also includes clinical evaluation either by literature review or clinical trials. The conduct and outcomes of all clinical evaluations are formally recorded and documented.
- Design Output is documented in final design specifications, drawings etc (Product Master Record). and data/reports which support the design with calculations, analysis etc. Design out is to be checked and approved before release for production.
- Design Changes are to be subjected to the same processes as above.

The necessary inputs and activity are to be well documented by way of minutes of meetings and communicative letters held on file.

Requirements relating to necessary statutory and regulatory inputs are to be fully dealt with in consultation with various consultants.

Technical interfaces between the various agencies are to be co-ordinated by the CTO.

The development activity to achieve initial manufacturing and clinical trials is to be conceptualised and co-ordinated by the CTO.

Specifications and Engineering Drawings are to be produced. All final documents pertaining to design output are to be reviewed and then verified by the Chief Technical Officer. After making necessary modifications to meet all specified requirements they are to be released for manufacture under the signature and authorisation of the Chief Technical Officer.

Where statistical techniques are identified for establishing, controlling and verifying process capability and product characteristics, there shall be established and maintained procedures or work instructions to implement and control the application of the statistical techniques identified (see also Statistical Techniques later).

### Implementation

Refer to PROC-011 Procedure Research & Development.

Refer to PROC-010 Procedure Document & Record Control for Device Master Record.

## PURCHASING

### Policy

Product and other supplies and services within the quality system are to be purchased under controlled conditions. This includes:

- Obtaining product & services from controlled (approved) sources;
- Clear data on product or service to be purchased;
- Checking the product when received;
- Maintaining records showing traceability of product back to inputs (materials etc).

The sources of product & services shall be evaluated to a level depending on risk to the product. This includes design, verification and manufacturing (see Manufacturing).

Purchasing data is kept on the computer in the Exchequer program with reference to specifications etc.

Each product will be inspected when received for correct documentation and external labelling (the product itself generally cannot be inspected as it is sterile). Any product rejected should be clearly marked and isolated.

Purchasing records are to include the purchase order number, the subcontractor's reference as well as the product and its serial numbers.

Where product is to be checked before receiving at the subcontractors premises, the purchase order documents shall specify verification arrangements and method of product release.

Similarly, where specified in the contract, a customer or his representative shall be afforded the right to verify at the subcontractor's premises and our premises that the product conforms to specified requirements. This shall not absolve Portland of the responsibility to provide acceptable product nor preclude subsequent rejection.

### Implementation

Refer PROC-005 Purchasing, Receiving, Stock Control of Product and Dispersal.

Refer to PROC-009 Assessing Vendors and Subcontractors.

## MANUFACTURING

### Policy

The manufacturing process is generally subcontracted. To demonstrate control of processes, the sub-contractors involved in the manufacturing of the prosthesis are to be individually reviewed for GMP. Depending on the risk to the quality of the product, the subcontractors are to be accredited for GMP (e.g. EN46002, ISO 9002) for high risk and at least be reviewed for medium risk situations where testing of received product / process can occur.

Products are to be manufactured by approved sub-contractors to specifications and drawings e.g. SPEC-002 Specification Manufacture – Implants.

Traceability documents and release orders are to be involved at each stage of manufacture. Records of all stages are to be kept either by Portland or the approved subcontractor and be available for inspection.

At present there are no customer-supplied products, if this situation develops, senior management should be informed so that procedures and process control can be introduced.

As manufacturing is subcontracted and all Portland inspection is visual, there is no in-process inspection or inspection, measuring or test equipment. If this situation changes, senior management should be informed so that procedures and process control can be introduced

### Implementation

Refer to PROC-010 for Product Master File and Product History Record and REG-015 for Product (Device) Master Files.

Refer to PROC-009 Assessing Vendors and Subcontractors.

## PRODUCT IDENTIFICATION, TRACEABILITY, INSPECTION AND STOCK CONTROL

### Policy

Portland Orthopaedics Pty Ltd will uniquely identify each product type (marked on product) and keep a permanent record of each individually numbered implant from receiving to including its individual distribution in a record computer file.

Each finished, clearly labelled and packaged implant component will be stored in a cupboard at Portland Orthopaedics Pty Ltd until either purchased by a contracted distributor or transferred to another store overseas controlled by Portland.

Inspections (including final inspection at dispersal) shall be recorded and stored.

### Implementation

Product Identification
Refer to REG-012 Product Register

Receiving Stock, Traceability & Stock control
Refer PROC-005 Purchasing, Receiving, Stock Control of Product and Dispersal.

## PROCEDURE FOR PROSTHESIS DISPERSAL

### Policy

The distributor will usually be contacted by the user and made aware of the decision to purchase the product.

A contracted or related distributor, surgeon or hospital wishing to purchase and use the products, are required to maintain records of the distribution of medical devices and to ensure that such records are available for inspection. Portland shall also maintain records of distribution of medical devices.

The purchaser will be advised on the availability and forwarded instruments for insertion of the prosthesis, as well as a full range of the prosthesis. At the end of the medical procedure, the instruments and prostheses not used will be returned and the purchaser billed accordingly. The distributor will check instrument sets to note that they have been fully returned. The prosthesis will be checked back into stock where necessary.

The used components, which were not returned will be individually entered into the computer log by their individual numbers, including the name of the patient, surgeon or distributor, serial number and Lot (Batch) number of each individual item of prosthesis used.

An Adverse Outcome Form is available for the purpose of reporting any problems with the prosthesis. Regulatory Authorities consider Adverse Incident Reporting, Vigilance, Complaints etc to be important and enforceable. Feedback of this nature is essential for an ongoing review of the prosthesis.

### Implementation

Implant Distribution and Invoicing
Refer PROC-005 Purchasing, Receiving, Stock Control of Product and Dispersal.
PROC-001 Adverse Outcome

## STORAGE, HANDLING, PACKAGING, PRESERVATION & TRANSPORT

### Policy

Storage, handling, packaging and transport are to be processed in a systematic way to ensure that mix-ups, damage, deterioration, contamination or other adverse effects to product do not occur.

Where possible, the packaging of the product should be included in the design manufacture of the product to ensure that sterile medical device is

- presented in a container which maintains the sterility of the device, is
- capable of being presented in an aseptic manner, and
- clearly reveals that it has been opened.

Where a product has special preservation requirement, it shall be included in procedures otherwise product will rotate on FIFO (i.e. product Serial Number).

### Implementation

Refer to PROC-012 Procedure Storage, Handling & Transport and
PROC-005 Procedure Purchasing, Stock Control of Product and Dispersal

## PRODUCT FEEDBACK (Vigilance System, Customer Feedback and Nonconformances)

Portland Orthopaedics Pty Ltd realises its ongoing responsibility to patients who may have received a defective prosthesis. The likelihood of adverse events can be minimised through preventive actions including reporting, investigation and follow up of failures that could have led to adverse events.

All adverse events should be reported and recorded on the Adverse Outcome System (vigilance system). Information for other sources should also be recorded on a Customer Feedback System.

A decision is made by the CEO or CTO to determine if the incident caused or might have caused the death or serious deterioration in the health of a patient, user or other person. If this does occur, then it is a reportable incident to the various regulatory authorities. There are strict limits for the reporting time (5 days for some cases in USA) with penalties if not done. The process is then carried out with various regulatory authorities. A recall may be required.

If it does not require reporting or does not involve an adverse outcome, the feedback information will still be investigated via Customer Feedback Report (CFR) and immediate action taken if required to correct the situation. Investigation will also determine if:

a) other product is also affected and corrective action taken to correct problem; and
b) the future problem can be corrected with preventive action.

The records for Adverse Outcome and Customer Feedback are to be analysed to find trends that indicate improvements that can be made in product or processes.

NOTE: Regulatory Authorities consider Adverse Incident Reporting, Vigilance, Complaints, Recalls etc systems to be important and are to be conducted in compliance with the applicable regulations.

Non-conforming product are to be identified, isolated and documented. These are to be investigating to determine disposition and determine corrective action to prevent problem recurring and preventive action to determine it similar problems can occur with other product and prevent them from occurring.

### Implementation

If the event is related to clinical outcome, follow procedure "Adverse Outcome" PROC-001.

Refer to Procedure PROC-003 Procedure Improvement of System/Product.

## RECALL

At any stage, as a result of investigation of compliant or an anecdotal reference by concerned persons regarding the safety of the prosthesis to the patient or implanting team, a series of measures to recall the product will be made operational.

These measures consist of looking up the distribution data to identify the location of prosthesis, contacting the hospital/surgeon and asking them to return the unused prostheses. The returned prostheses will be kept in another area to prevent inadvertent mix-up with existing stocks. These prostheses will then be inspected by qualified personnel to find the cause of the defect/deficiencies, who will then prepare a report to be reviewed by a competent authority. Corrective actions will then be taken and concerned people, including the customers, will be notified.

In case the prosthesis has already been implanted, the treating physician will be advised to monitor the progress of the said patient closely. In the eventuality of that hip requiring revision surgery, wherein the stem and/or neck would be extracted, a return of the retrieved prosthesis would be sought.

### Implementation

Refer to Procedure PROC-004 Recall.

## SYSTEM IMPROVEMENT AND AUDITING

### Policy

Portland Orthopaedics Pty Limited will continue to improve the effective design and efficient implementation of all its Management Systems.

To achieve this, all systems, procedures and activities that form part of the quality system will be regularly reviewed and audited.

Portland Orthopaedics Pty Limited will ensure that internal quality audits are planned and conducted for all elements of the standard to verify compliance with the standard, compatibility of operations, and the effectiveness of the quality system so as to improve the business system.

The system can also be improved by raising a CAR (Corrective Action Request) and this request is to be investigated, if immediate actions are required, they are to be recorded and implemented and corrective or preventive action to be implemented to prevent future problems.

### Implementation

Refer to PROC-003 Procedure Improvement of System/Product

Refer to PROC-007 Audit

## TRAINING

### Policy

Portland Orthopaedics Pty Limited recognises that to staff the business efficiently, personnel must be suitably trained and must be able to work in their position to a high standard of quality and productivity.

This is achieved by determining the necessary competencies required for each person performing work, and by providing training or taking other actions to satisfy all needs, to ensure that personnel are aware of the relevance and importance of their activities.

The Company also evaluates the effectiveness of these actions and maintains appropriate records of Education, Training, Skills and Experience.

### Implementation

This is achieved via the processes of "Employment of New People" & "Staff Training". "Ceasing Employment" is to minimise disruption that can occur when personnel leave the company. See Training & Job Description Procedure – PROC-008.

## SERVICING

### Policy

Whilst servicing is not required for implanted devices intended for single use, periodic servicing or maintenance may be required for other products that repeatedly used (e.g. Instrument sets) to ensure they remain suitable for their intended purpose.

### Implementation

Refer to PROC-012 Procedure Servicing.

## STATISTICAL TECHNIQUES

### Policy

The use of statistical methods can be beneficial in a wide range of circumstances, including data collection and analysis. They assist in deciding what data to obtain, and in making the best use of the data, to gain a better understanding of customer requirements and expectations. Statistical methods may be useful in product, service, process design, process control, nonconformity avoidance, problem analysis, risk determination, finding root causes, establishing product and process limits, forecasting, verification, and measurement or assessment of quality characteristics.

Statistical methods that may be beneficial for these purposes include:

- graphical methods (histograms, sequence charts, scatter plots, Pareto diagrams, cause and effect diagrams, etc) that help to diagnose problems and suggest appropriate computational approaches to further statistical diagnosis;
- statistical control charts for monitoring and controlling production and measurement processes for all types of product (hardware, software, processed materials, and services);
- design of experiments for determining which candidate variables have significant influence on process and product performance, and for quantifying the effects;

- regression analysis, which provides a quantitative model for the behaviour of a process or a product when the conditions of process operation or product design are changed;
- analysis of variance (separating the total observed variability) leading to variance component estimates useful for designing sample structures for control charts and for product characterisation and release; the magnitudes of the variance components are also a basis for prioritizing quality improvement efforts;
- methods of sampling and acceptance;
- sampling of products between production sectors;
- statistical methods for inspection and testing.

The documentation resulting from the application of statistical methods can be an effective means of demonstrating conformance to requirements for quality, and can be used as a form of quality records.

The number of items sampled from any batch should be based upon an established statistical rationale, the past history of the source of supply, and the quantity needed for analysis and retention.

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

**Implementation**

Refer to PROC-003 Improvement of System/Product

## EMAIL AND INTERNET USE

Employees typically send and receive personal email from the work place in the same manner that they use telephones for personal use. Unlike most telephone calls, email data is stored electronically and can be monitored by either employers or by co-workers or external sources, and may be subject to discovery should litigation ensue.

All employees should realise, both at Portland Orthopaedics Pty Ltd and Vimek Pty Ltd, that all systems and all data contained therein are owned by the business and are intended for business use only and that personal use is not permitted, and abuse of this system will result in disciplinary action.

The email system is not to be used for outside business ventures, to advance personal, political or religious causes, or to violate any state or federal laws, including laws relating to discrimination and harassment, copyright and trade mark infringement, trade secret protections and pornography.

No emails shall contain derogatory information about individuals or the competition. The internet shall not be used to receive information of the above nature.

All e-mails to use standardise signature.

## PROCEDURE IN THE EVENT OF A FIRE OR OTHER CATASTROPHE

In the event of a fire or other catastrophe, an endeavour will be made to remove the data cartridge backup from the contents of the secure cabinet, providing safety permits.

APPENDIX A

**Record of Changes**

| Rev | Recorded Amendment | DCN# | Date | Raised by |
|---|---|---|---|---|
| 1 | Release of document | - | 21/4/98 | F Stephan |
| 2 | Conversion to Word format and updated | - | 11/2/99 | A Tattam |
| 3 | Removal of product specification and updated | - | 15/6/00 | D Corbin |
| 4 | Update for Exchequer, New Premises & CEO | 14 | 27/8/01 | S Brown |
| 5 | Add Audit, Training and Review Procedures and inclusion of Management Representative. | 17 | 13/9/01 | S Brown |
| 6 | Add reference to PROC-008 & REG-008 to Organisational Structure.<br>Removed implementation of document policy and replaced with reference to PROC-010 & PROC-002.<br>Add reference to PROC-011 & PROC-010 to Design.<br>Add reference to PROC-010 & REG-015 to Manufacturing.<br>Add reference to PROC-003 to System Improvement, Auditing & management Review (modified title). | 28 | 2/04/02 | S Brown |
| 7 | Manual rewritten to include added policies & references to procedures including 'Responsibilities& Authority Delegation', Purchasing', 'Storage, handling, packaging, preservation & transportation' and 'Servicing'. | 0043 | 17/7/02 | L Farleigh |
| 8 | Added reference to EN46001 / ISO13485 in Introduction.<br>Regulatory Responsibilities section added.<br>Added reference to PROC-014 for responsibilities & processes for Authorised representative.<br>Added reference to non-conformances and customer feedback to 'Product Feedback'.<br>Statistical techniques section added. | 0052 | 8/10/02 | L Farleigh |
| 9 | Added extra sentences to Regulatory Responsibilities describing how to document and then find these documents about meeting regulatory responsibilities. | 0062 | 20/11/02 | L Farleigh |