PORTLAND ORTHOPAEDICS PTY LTD
MARGRON TOTAL HIP REPLACEMENT

Unit 3, 44 McCauley Street
MATRAVILLE NSW 2036

PROCEDURE
DOCUMENT & RECORD CONTROL

This revision supersedes all previous revisions.

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

The following ATTACHMENTS form part of this Document.
Nil

Controlled copy only if stamped with Controlled Copy Stamp and issued with copy number

1. INTRODUCTION

1.1 Purpose of Document

To define and control the process of Controlling Documents & Records

1.2 Purpose of Procedure

To control the processing of documents both active and inactive (records).

1.3 Scope

Does not include used or superseded documents that have become records.

1.4 Other Documents Referred To

External Reference:
Nil

Internal References:

PROC-002 Procedure Document Change
PROC-005 Procedure – Purchasing, Receiving, Stock Control of Product & Dispersal
PROC-011 Procedure Research & Development
PROC-015 Procedure Project Control

REG-001 Register – Internal Documents
REG-004 Register - Standards
REG-012 Register - Products
REG-015 Register - Product (Device) Master Files
REG-017 Register - Bibliography
REG-020 Register Design History File
REG-021 Register Laboratory (Red) Books.

1.5 Definitions

Nil

1.6 General Responsibility / Authority

The responsibility for the procedure is with the Management Representative, who has the authority to delegate responsibility to other people to carry out the work. Where this Authority has already been delegated, it is noted is Responsibilities.

1.7 Structure

Documents and records are broken up into the following groups:

- System Documents
  e.g. Quality manual, procedures and system forms etc used in running the company.
- Design History Documents & Records
  e.g. Risk Analysis, Verification & Validation records and project history.
- Product (Device) Master Records
  e.g. Specification, drawings and regulatory files.
- Product Manufacturing Master Records
  e.g. Operation detail drawings, work instructions etc
- Process documents and records
  e.g. Machine Training Syllabus, Calibration, and Maintenance etc and common production processes that are not specific to a single product
- Product (Device) History Records
  e.g. Manufacturing order records
- External Documents
  e.g. Customer Specifications & drawings, standards, regulations, papers etc
- Software
  e.g. programs, data files etc for machines or computers.

2. PROCEDURE - SYSTEM DOCUMENTS

Purpose

System documents are those documents related to the running of the company. This comprises:

Operations Manual (including policies);
Procedures;
Registers;
System Forms.

Product related documents are part of Design History Record, Product Master Record and Product History Record treated later.

2.1 Operations or Quality Manual

Company Policy is set out in the Operations Manual. Where a procedure exists relating to a policy implementation, this should be referenced. Where a Procedure does not exist, the manual should be used as guidance.

As with all documents, the preparation, generation, distribution and alteration of manual is the responsibility of the CEO of Portland Orthopaedics Pty Ltd.

Control of the manual will follow 2.5 'Controlled Document Control'.

The Site Information File is now superseded. It is stored behind the operations Manual.

2.2 Procedures

Procedures are the implementation of policy. They supply instructions on how processes are to be carried out.

Control of the procedures will follow 2.5 'Controlled Document Control'.

2.3 Registers

Registers are listings of documents & records to improve control and to make it easier to carry out work.

As all authorisations already appear on the documents or records, this authorising signature is considered as authorising the updating of the registers. Full trace back to the original document is available at any time. Procedure PROC-002 Procedure Document Change is not applicable in updating the registers.

The structure of registers is to be set out in the originating procedure with this procedure specifying the method of control. Registers will not have a revision number but shall have a print date. There shall be only one master copy of a register with signatures held. Do not follow 2.5 'Controlled Document Control'.

If possible, an electronic copy will be held as back up. Wherever possible, the computer file used to print the document should be retained on the server in Portland/Quality Control directory that is back up (see Software).

2.4 System Forms

Forms are an aid in collecting information.

Control of the procedures will follow 2.5 'Controlled Document Control' except for the following:
Change control authorising signatures do not appear on the form so they do not cause confusion with other signatures that are to appear on the forms;

2.5 Controlled Document Control

Document Identification and Format

Each document conforms to the format containing:

Name of organisation – Portland Orthopaedics Pty Limited
Document title
Document ID
Revision number or date
Location of document on computer, including path & file name
Page x of y

Document ID & Registration

Each system document will have a unique Document ID (to make it easy to identify & locate) and will be registered in REG-001 Register Internal Documents.

REG-001 will contain the Document ID/No., Document Title, Issue, Date, Status and Location.

New Documents

New system documents (not product) will only be formally introduced after a successful trial period. During this trial period, feedback regarding documents will be considered. Criticisms can be made directly on the documents and must be dated and signed, and the reasons for criticisms fully explained. The trial period shall last as long as the responsible author determines is reasonable.

The release of new documents is under the same control as Document alteration.

Document Alteration

Amendments may only be performed by authorised personnel after receiving written authority from the Chief Technology Director or the CEO. Minor Documentation corrections can then be made on the existing Master document, then dated and signed. The same changes must then be made on all other existing documents.

The introduction of new document versions will be recorded in the Document Register REG-001 with the current revision, date & status.

Refer to procedure PROC-002 Procedure Document Change.

Updated documents such as forms or manuals will incorporate these changes and be identified as a new version

Document Issuing

Each time a new Document is issued as a controlled copy, it shall be a copy of the master with the authorising signatures (a print out from the computer without signatures is not a controlled copy), it is to be stamped with the controlled copy stamp in red, given a designated copy # and a record of the copy location kept with the master.

Copy control of forms will only be applicable to copy masters (used to make copies), which will not be stamped with the controlled copy stamp but marked with yellow highlighter, which will not appear when form is copied.

All obsolete copies of documents (refer to listing location with master copy) are to be retrieved, destroyed or defaced as "SUPERSEDED" or "CANCELLED" on front page if being kept for record purposes. The master copy (defaced) must be kept for archiving and placed behind the new Master.

System Document storage

Masters are held at Portland Orthopaedics Pty Ltd at all times, and held in a secure fireproof cabinet when not in use.

Wherever possible, the computer file used to print the document should be retained on the server in Portland/Quality Control directory that is back up.

3. PROCEDURE - DESIGN HISTORY DOCUMENTS & RECORD

3.1 Design History Documents & Records Types

Design History Documents & Records are retained in several types of documents:

- Program Documents
- Project Files
- Device Master Record (DMR)
- Design History File (DHF)
- Lab Books

3.2 Program Documents

Where a family of products is being developed, this is carried out as a program. This program will have confidential files including program plan and budgets, which will determine the projects required for product (and product line) development and include business risk analysis. Refer to PROC-011 Procedure Research & Development for details.

There are also two technical documents referenced and updated during development:

- REQS Requirements Specification &
- RSKS Product Risk Analysis.

These are registered documents in REG-001 Register - Internal Documents with issue levels as they will be regularly updated during development. These are not controlled documents required DCN and controlled copies. They are required to be signed.

3.3 Project Files

Project Files contain:

- Project Administration Documents – Project Authority, Project Plans
- Project History – History summary, correspondence, drafts

Refer to PROC-015 Procedure Project Control for the process.

3.4 Device Master Record

These are part of the output of a design comprising specifications drawings etc. Refer to Section 4 for details.

3.5 Design History File (DHF)

The Design History Files contains the documents from project output that show compliance with requirements that are not Device Master Records e.g. verification & validation reports.

These documents are to be registered in REG-020 Register Design History File The format is DHF-xx-yyy where xx is the program letters & yyy is the next consecutive number in the register. The register also contains:

- Document Title;
- Source column to enter the project number (e.g. PR XY 123) in which the report was generated; and
- Previous Ref. column to enter any previous ref number on the document.

The documents are filed in DHF number order.
Due to the importance of these documents, it is vital that these are stored in a fire proof safe and they are not to be left out overnight.

3.6 Lab Books (Red Book)

The purpose of the 'Red Book' is to document the activities of those employees directly involved in the creation of intellectual property. These records may assist in future possible legal action. The book should be completed in sufficient detail so as to build a picture of the activities undertaken. This includes all telephone calls and a brief as to the contents of the discussion, all meetings and a brief as to the meetings members, contents, major discussions and decisions made. All major achievements and steps in the creation of projects and the related intellectual property should similarly be noted.

No pages should be removed or left blank. No information should be erased or whited out. A line through text to be removed is sufficient. This is a legal document and should be treated as one. All red books are to be signed for and returned when complete.

All Lab Books are to be registered and signed for in REG-021 Register Laboratory (Red) Books with person's name, volume number and date. This information is also to appear on the book.

When returned for filing i.e. filled or ceasing employment, again the registered is to be dated & signed as received by filing person (as designated by CEO) and date entered on book.

4. PROCEDURE – PRODUCT (DEVICE) MASTER RECORD

The Product Master Record is all the routine documentation required to manufacture product. This is often called a Device Master Record (DMR) when the product is a medical device.

The structure is as follows:
Product register
Device Master File
Specifications, Drawings, Work Instructions, Protocols etc

4.1 Product Register

Product Register REG-012 contains:

- Catalogue (Part) Number
- Product Name (Description)
- Product (Device) Master File
- Other information to determine the status of the product

4.2 Product (Device) Master Files

The Product (Device) Master File for each type of product contains a listing and location of:

- Product specifications,
- Drawings,
- Work instructions,
- Protocols,
- Standards etc

required for the manufacture of the product.

This file is updated as per PROC-002 Procedure Document Change.
The records are stored in REG-015 Register - Product (Device) Master Files.

4.3 Specifications, Drawings, Work Instructions, Protocols etc

These are usually the Design Output documentation in the development of a product that become part of the Product (Device) Master record.

These documents will be under the same controls as system documents per 2.5 Controlled Document Control

Where possible, electronic versions of the documents should be stored on the computer server for back up in case of the destruction of the original. This electronic copy is not to be used as a master copy as it is not signed as approved.

5. PROCEDURE – PRODUCT (DEVICE) HISTORY RECORD

Product (Device) History Record contains the documents or references to the:

- Purchase Order
- Confirmation of Order
- Manufacturing Documents or Certificate of Conformance referring to them
- Delivery Note
- Receiving Note (to be developed)
- Distribution & Traceability via computer Sales program

The process is documented in PROC-005 Procedure – Purchasing, Receiving, Stock Control of Product and Dispersal.

6. EXTERNAL DOCUMENTS

6.1 Controlling Standards, Regulatory

All standards documents are contained in the Standards File held in the bookshelves or at our subscription with IHS on the Internet.

For our hardcopy standards, a register of standards is held in REG-004. Behind the register are copies of the standards

To access our standards at "specselect":

1. go to http://specselect.ihs.com.au
2. username:Portland, password :portland2002
3. use search to find standard (click "search for standards", "search your standards")
4. select standard
5. click on standard name to view

IHS keeps these standards up to date as part of the service.

To purchase a standard available from IHS:

1. go to http://specselect.ihs.com.au
2. username:Portland, password :portland2002
3. use search to find standard (click "search for standards", "search all available standards")
4. select standard
5. contact IHS (1800 062 299) and request quote (for specselect price)
6. send quote to David with explanation and justification of purchase
7. CEO will either OK request (and forward to Stephen to enter purchase order, as well as requestor with confirmation who contacts IHS with OK for purchase) or reject and reply to requestor with reason.
8. IHS will add document to our subscription

If the standard is not offered by IHS, then follow normal purchasing procedure after determining a source.

Regulatory Documents either have to be purchased or available from the Internet. Where this document is to be kept for future reference, then it can be stored with the standards using the hardcopy system. It is the responsibility of the user to check that the stored copy is the latest version.

6.2 Controlling Customer Supplied Documents

At present, the only customer supplied documents are controlled under distribution system PROC-005 Procedure – Purchasing, Receiving, Stock Control of Product and Dispersal.

6.3 Controlling External Documents that can be referenced (Bibliography)

These are documents like papers, reports etc. that are published (and do not change unlike standards, regulations or customer documents) that are likely to be reference during development etc by multiple projects.

Note: If the document is limited to one project, it can be filed in the project with a project document number.

These documents are to be recorded in the bibliography register REG-017 and given a reference number BIB-xxxx. The register will also contain a list of keywords (topics) related to the document to help searches.

These documents are stored in register order in folders on shelves (lowest level security & storage as they are replaceable from external sources). These documents should not be destroyed, as they can be part of the Design History Record.

6.4 Controlling External that will not to be referenced

This group contains documents that generally have a limited life and are generally replaced by later editions e.g.:

- Newsletters, magazines, newspapers etc
- Marketing literature etc

These documents are not registered or referenced in any way. If a document is to be reference, then the document or a copy must be transferred to the bibliography section or to a project & given a project document number.

Newsletters, magazines, newspapers etc are to be stored in folders on shelves (lowest level security & storage).

Marketing literature etc collected as part of a project is to be kept in files (divided into clearly marked group e.g. company name) in project program drawer (low level security & storage).

Destruction of these documents is at the discretion of project leader, CEO or CTO. They do not have a minimum life, as they are not referenced.

7. SOFTWARE

No software is used in the products, only as tools in making the product that is inspected afterwards (under subcontractor Vimek Quality System) or as tools for producing documents & records.

The printouts are the documents or records. The files retained are for convenience in producing new documents. If these files are destroyed, it does not affect the system except as a delay in producing new items. However, every precaution should be taken to maintain an up to date backup of all documents and records (see below).

If this status changes, the senior management must be informed and the procedures changed.

Access to all documents is protected by a security password known only to the individual executive staff and the CEO.

7.1 Controlling master program software

Master program software installation and upgrade diskettes are retained in safe storage in the office. In case of fire, replacement software can be obtained for new computers either from master copies if saved or purchased. (Making backup copies can be either difficult or illegal).

7.2 Controlling & backing up general software data

The control of software data is at the discretion of the operator e.g. files used to generate procedures, drawings, work instructions, OCS etc. The preferred programs for generating documents are Microsoft Word, Microsoft Excel and Enterprise Exchequer. The storage of these files is at the discretion of the CEO on the file server.

Perform a minimum of weekly backups to disk, tape or cartridge with three sets in rotation. Record backup set number and date on backup disk or tape. If possible, at least one back up disc/tape should be stored off-site in rotation.

The CEO shall be responsible for the files on a computer be reviewed for backup, documentation deletion or wiping when:

An employee's employment is terminated
Computers are replaced
As other appropriate circumstances occur.

8. ARCHIVING

Documents and records are stored as set out in the relevant section of the procedures. Where storage location is unclear, refer to Appendix A.

Archiving is the removal of documents from the main filing system, (because it is unlikely the documents will be referred to in the future) and placing in storage until destruction.

8.1 Preparing for Archiving

Paper records to be archived are to be packed in a container (archive box, plastic bag etc) and clearly mark with

- the description of the records (including date range or control number range etc) and
- year records can be destroyed. Archiving period is 20 years which is life of product + 5 years or as specified by customer., as the implanted prostheses are expected to have a survivorship of 75% at fifteen years.

NOTE: Software records should be archived using a method available under the then current technology, however if the storage medium available has a limited life below 20 year period, the record should be transferred to paper or some other arrangement should be made. (At present, all required records have master copy as the paper copy with software copy as a tool.)

8.2 Archive storage

Paper records are maintained safely in orderly dry files in designated storage shelves. Only the CEO or a delegated officer will grant access to archived documents.

8.3 Destruction of records

At the end of the life of the record, (year recorded that record can be destroyed), the record can be destroyed at the discretion of a manager.

9. DOCUMENT AND RECORD SECURITY

All documents and records will be controlled under 3 security levels:

1. General
2. Restricted
3. Highly Confidential

A general folder colour scheme is to be used to easily identify security level of records. This will not be applicable to old records but only to future records.

Refer to Appendix A for security level for various types of documents and records.

9.1 Level 1 General Security Controls

Unrestricted internal use but restricted (Confidential) for external use.
For sending copy outside in any form requires authorization from CEO or CTO.

Colour: BLUE or GREEN – Projects, Nonconformance Reports, Customer Feedback Reports, Corrective Action Requests etc

ORANGE - Logistics

BEIGE or BLACK - Other

9.2 Level 2 Restricted Security Controls

Documents or records at this level are not to be removed from storage location; they can be viewed while remaining in storage area. Copying is restricted, authorization required by CEO or CTO.
For sending a copy outside in any form requires authorization from CEO or CTO.

These documents and records are to filed away when not in use and the cabinets/cupboards to be locked at night.

Colour: PINK or YELLOW – Master Documents or Records

9.3 Level 3 Highly Confidential Security Controls

These documents and records are limited (both internal and external) to who can see, cannot be copied or removed except on the authority of the CEO or CTO.

These documents and records are not to be left lying around on desks etc but must be locked away when not in use.

Disposal: When disposing of records, the records must be shredded or in some other manner made unreadable.

Colour: RED – all Highly Confidential Files.

10. DESTRUCTION OF DOCUMENTS & RECORDS

Responsibility

This is applicable to all Portland Group staff and applies to both internal and external documents.

Purpose

Portland produces many documents that contain sensitive information. This may take the form of wage records, pricing information, forecasting projections, financial documents, technical drawings and technical specifications. This information is vital to the organisation and should be guarded. Competitors will find this information useful in improving their competitive advantage over us. For this reason these types of documents should be treated with care and disposed of correctly.

Information that requires shredding includes:

- Company financial information
- Number of units sold or expected to be sold
- Personal details and files
- Wages and salary information
- Drawings and specifications (draft or final)

Do not underestimate the importance of protecting information. Competitors have been known to undertake 'dumpster diving', attempting to find information that will assist them.

Task

An archive box is located on level 1 and level 2 of the Matraville complex that is labelled 'documents for shredding'. Once a week this box will be shredded. If a document is internally sensitive (information such as wages and financial documents), these should not be placed in the shredding box, rather the onus is on the staff member to shred the documents themselves.

NOTE: The master copy of quality records must be kept for the archiving period, see archiving.

Documents

None

APPENDIX A Filing System and Security Levels

Filing Section	PORTLAND FILING SYSTEM Sections	Folders	Storage Type	Security Document	Security Copy	Auditable
QA System	by Doc Type	by Document #	Fireproof	2	1	Yes
Accounts/Finance	by Doc Type	by Alphabetical	Shelf/Cabinet	3	3	No
Administration, Sales & Marketing		by Alphabetical	Cabinet	3	3	No
Legal			Fireproof	3	3	No
Patents,	by Patent	by Country	Cabinet	3	3	No
Trademarks	by Trademark	by Country	Cabinet	3	3	No
Regulatory Affairs						
General	by Product Range	by Country	Cabinet	1	1	Yes
Submission Files	by File No.		Fireproof	2	1	
Design History Record						
Design History File Documents	by Product Range	by Number	Fireproof	1	1	Yes
Program Management Files	by Product Range		Cabinet	2	2	Yes
Project Files	by Product Range	by Number	Cabinet	1	1	Yes
Lab Book (Red Book)	By Person	by Volume	Cabinet	1	1	Yes
Device Master Record						
Manufacturing Specification, Drawings	by Doc Type	by Document #	Fireproof	2	2, 1	Yes
Device History Record	by Product Range	by Cert of Conformance	Shelf	2	-	Yes
Manufacturing	by Process	By company	Cabinet	2	-	Yes
Traceability Record - Old	by Product	by S/No.	Cabinet	2	-	Yes
Traceability Record - Current	by S/No. or Lot No.		Computer	2	-	Yes

PORTLAND FILING SYSTEM

Filing Section	Sections	Folders	Storage Type	Security Document	Security Copy	Auditable
External Documents						
Standards	by Doc Type	by Alpha/date	Shelf	1	1	Yes
Regulations	by Doc Type	by Alpha/date	Shelf	1	1	Yes
Bibliography	By Register No.		Shelf	1	1	Yes
Newsletters, magazines etc	by Doc Type	by Alpha/date	Shelf	1	1	Yes
Marketing literature	by Product Range	by Alpha/date	Shelf	1	1	Yes

RECORD OF CHANGES

Issue No.	RECORDED AMENDMENT	DATE	DCN #
1	Release	26/3/02	26
2	In Section 2.1, changed responsibility to CEO. Section 2.3 added paragraph about keeping computer copies of registers where possible. Section 2.5 'Controlled Document Control' made clearer the retrieval of documents especially forms and use of trial documents not applicable to product documentation. Section 4.3 added para on electronic storage of documents. Section 6.1 changed to include electronic copies of standards. Section 7, noted NC programs under Vimek control. Added section 9, 'Document and Record Security'. Added Security columns to Appendix A.	25/6/02	0039
3	Added sections 6.3 (bibliography) 6.4 (magazines etc) to controlling external documents.	6/8/02	0047
4	Section 1.7 Added examples Section 2.5 Re-titled & made clearer Section 3 Completely rewritten with extra information including REQS, RSK, DHF & Lab books. Section 9 Change folder colours Added Section 10 Destruction of Documents etc. Appendix A Updated for DHF Other minor changes, typo's etc		