1 REFERENCE DOCUMENTS

1.1 Internal

- Change Control (GP00-00019)
- First Article Inspections (QP00-00017)
- Biocompatibility Requirements (GP00-00074)
- CE Marking for Foreign Markets (RA00-00002)
- Hazard Analysis and Risk Assessment (GP00-00042)
- Process Validation Master Plan (GP00-00086)
- FGP00-00095p1 Design Review Approval Form
- FGP00-00095p2 Phase Two Deliverables Form
- FGP00-00095p3 Phase Three Deliverables Form
- FGP00-00095p4 Phase Four Deliverables Form
- FGP00-00095p5 Phase Five Deliverables Form
- FGP00-00095p6 Phase Six Deliverables Form

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1.2 External

- 21 CFR, US FDA Quality System Regulation, § 820.30
- US FDA, CDRH: Final – Design Control Inspectional Strategy, Eff. June 1, 1997
- ISO 9001/EN 46001 Design Controls
- Official Journal of European Communities, Council Directive 93/42/EEC (MDD)

2 DESIGN CONTROLS POLICY

All companies shall institute design control elements, from the initial concept to its final release for distribution, for any new or re-introduced medical device for which the Company has design responsibilities.

As any organization operates under the company's corporate quality system, the term 'The Company' used hereafter will imply requirements apply to any company unless otherwise stated.

2.1 Full Four Phase PDP's:

For products operating under technologies[1] or intended for clinical applications that are distinct in nature, or exceed the scope of a 510(k) currently owned by The Company, the requirements of the full four phase GP00-00095 will apply as necessary design controls.

2.2 Phase 5 PDP's:

This phase is for increased production or cavitation and minor design changes to products that don't exceed the scope of a 510(k) currently owned by The Company. Minor changes typically include material or color changes or other changes that do not affect the existing specification.

[1] Features, components, processes, or principles of operation

2.3 Phase 6 PDP's: Non-Proprietary Component Design / Design Changes / New Molds or Manufacturing Process PDP's:

This phase is for the design and manufacture of components commonly available in the medical industry and of a non-proprietary nature. If the Regulatory Assessment determines that a 510K is required, the four phase PDP should be used.

3 GENERAL DESCRIPTION

The method used to ensure adequacy of each control element is identified as a 'Product Development Protocol' (PDP). The PDP should be used for new products and for modifications to existing designs where the performance, manufacturing process, safety, or application is changing. Further, if the changes result in non-interchangeability between any components (from old to new configuration), the PDP should be instituted.[2]

This protocol helps to assure that performance requirements are based upon customer needs and the anticipated clinical usage of the product. The protocol is fundamental to the companies design controls, which assure that all issues relating to performance, safety, reliability and intended usage are addressed systematically.

4 MECHANICS OF A PDP

Although the protocol is generally divided into four phases (Concept / Specification; Prototype; Qualification; Validation), additional phases may be implemented for increased cavitation projects, foreign marketing requirements, or other needs as defined at the time of need. Product may be commercially distributed in its validated configuration for those instances where subsequent phases do not impact safety or efficacy of released product.

A design plan, including definition of why the project is being undertaken and an activity schedule, should be evident in the design history file. For each phase, 'deliverables' from all design activities must be completed and approved by a designated design approval group, *before the project can proceed.* The approved design approval group consists of a department heads from Manufacturing, Quality Assurance, Regulatory Affairs, R&D Engineering, Marketing, Sales, and a Medical Representative. Approval of a design phase, via a formal 'design review', constitutes authorization to proceed. This design review process also provides the opportunity for peer review into all aspects of the product and processes. (In the event that a project is discontinued based upon this review process, the reason for the decision and the senior management making the decision should be included in the history file.)

5 RESPONSIBILITIES

5.1 Team Representatives:

- Engineering R & D
- Marketing *(Mktg & Sales may represent clinical)*
- Quality Assurance / Quality Engineering
- Regulatory Affairs
- Tooling *(as needed)*

[2] Changes to existing designs may skip some of the PDP steps, provided the design approval group approves that the items not addressed are not applicable or are not affected by the change being made.

- Manufacturing / Assembly *(as needed)*
- Document Control
- Facility / Equipment Maintenance

Not all of these members will be at each meeting, but should be included on any meeting minutes and schedule changes in the event their area is impacted.

5.2 Team Leadership

A team, led by a designated project leader develops products. The leader is responsible for communicating to ancillary groups when deliverables require coordination outside of the team. The project leader then collects all deliverables and schedules a design review at the end of each developmental phase.

In the event there is a delay or a problem with a design activity, it is the responsibility of the person assigned to the corresponding deliverable to present the issues to the design team and to document the final decision for the history file.

5.3 Individual Team Members

The cross-functional Team Members as outlined in Section 4.1 shall be responsible for representing their respective areas of discipline, procuring the identified deliverables from these areas, and ensuring the deliverables reflect current status. If the deliverable is superseded by additional changes, an update should be forwarded to the Team Leader.

5.4 Maintaining Current Documentation

Team members providing input into the development of a product, and documenting those efforts, that this is an evolutionary process, should recognize it. As documents become obsolete for their intended purpose, updated records should be generated and forwarded to the team leader for retention in the design history file. This practice should continue until Phase 4 is approved in a formal design review. After which time, obsolete documents will be retained in individual history files for those documents along with the revised documents.

6 RECORDING OF DESIGN HISTORY

6.1 Design History File (DHF)

The DHF in its entirety provides evidence that adequate design controls were implemented during each phase of development. It may also be useful for establishing patent rights. The DHF shall be sectioned by phase, including a checklist for all deliverables from the particular phase, and signatures reflecting acceptance of the design review for that phase. (Signature pages with dated approvals may be combined onto a single page if preferred.)

Each DHF may be distinct in its required deliverables. For some, the deliverable may be a reference to an existing document and its corresponding revision. The examples given in this procedure are not intended to be all-inclusive, but represent the minimum routine deliverables. Checklists (itemizing deliverables) should be established based on the individual project. Any new deliverables require identification of the individual responsible for providing such. The deliverables from each phase of development shall form the *Design History File* (DHF) for the product. (Deliverables shall be dated.) <u>For every design phase, a complete checklist is required prior to calling a design review meeting.</u> If a revisional change to the PDP (GP00-00095) affects

a current phase in development, then it is incumbent for the team leader to incorporate the change into the current project PDP.

6.2 Delayed Deliverables

In the event that a deliverable is delayed until the next phase, the following information should be documented:

- Reason for the delay
- Person responsible for ensuring the deliverable is completed in the next phase
- An updated checklist for the next phase, reflecting the additional deliverable that is being delayed (may be handwritten and initialed)
- Brief explanation or justification as to why there is no adverse impact.

Signatures by the design approval group during design review indicate acceptance of the deliverables and/or justifications for that phase.

7 PHASE ONE → CONCEPT / SPECIFICATION

7.1 INTRODUCTION

Product development begins with a customer need. When this need is translated into an idea for a product, a developmental concept is established. This phase encompasses the requirements, which is also known as 'design input'.

7.2 DELIVERABLES

Reference FGP00-00095p1

7.2.1 Marketing Request (Responsibility: Marketing)

The concept is communicated to development engineering (R&D) in the form of a written request. The request should include: description of how the product would be used, clinical applications and environments of use, functional requirements, performance capabilities (operating characteristics and ranges, single use, etc.), information about any known competitive products, cosmetic features, complimentary or interfacing devices, delivery medications, sterility needs, pricing parameters, tentative annual forecast, and any additional design input that has been established.

7.2.2 Senior Management Authorization (Responsibility: Marketing)

To ensure adequate resources are allocated and Company priorities considered, written authorization from the senior management is required in order to begin development of a product. This should accompany the Marketing Request where feasible. No particular 'format' is required for this deliverable. Senior management is defined as the approval of three vice presidents or the CEO where applicable.

7.2.3 Performance Specification (Responsibility: Engineering R&D)

Based on the Marketing Request, this document describes the performance characteristics, the clinical applications (such as operating conditions, environments of use, capabilities, interfacing requirements to other products), safety, biocompatibility and sterilization [single and multiple] requirements. It should be specific, with performance requirements quantified where possible. These requirements shall be translated into measurable design outputs that can be used to

conduct design verification. It should also list applicable standards with which the device will comply.

This document should indicate the clinical rationale for the performance requirements identified. The specification should address all applicable US and European regulatory requirements (including the Medical Device Directive) for the device design.

7.2.4 Regulatory Assessment (Responsibility: Regulatory Affairs)

This document describes the regulatory pathway for bringing the product to market. This should include the Company's position as to whether a submission to the US FDA is required; it should also include the device classifications in accordance with the US FDA and with the *Council Directive 93/42/EEC of 14 June 1993 Concerning Medical Devices, Annex IX.*

7.2.5 Design Review (Responsibility: Team Leader)

This is a documented review by technical and senior management. (Refer to the sample approval sheet in this document.) The approval group shall include reviewers not directly involved with the particular design development activity being reviewed. Approval is required prior to proceeding to the next development phase. The Concept, Prototype and Qualification phases shall include review by a "Medical Group" consisting of internal Sales and Marketing, and by field Product Specialists and/or external medical practitioners (if required).

8 PHASE TWO → PROTOTYPE

8.1 INTRODUCTION

In this phase, the concept is developed into a prototype, which can be used to verify that the design [output] should perform in such a manner that it meets design [input] requirements for intended use. Manufacturing processes are planned and analyzed for suitability and cost efficiency. A process flowchart may be drawn to describe the proposed manufacturing and inspection processes. Automation, or any long-term goals, should be identified for proper planning. Preliminary risk analyses will be conducted for potential hazards during normal and fault conditions.

8.2 DELIVERABLES

Reference FGP00-00095p2

8.2.1 Project Description and Schedule (Responsibility: Engineering R&D)

This is a summary of what will be required for the project. It should include a schedule showing the project deliverables and anticipated completion dates shall be developed and updated throughout the design development process. A blank PDP schedule form for use with Microsoft Project Software is located in f:\\pdp\pdp.mpp. (The summary and schedule would be the 'design plan'.)

8.2.2 Prototype Drawings Released (Responsibility: Engineering R&D)

Following formal design review, V-level feasibility drawings will be generated and released to allow for tool quotes and prototype fabrication.

8.2.3 Prototype Tooling (Responsibility: Engineering R&D, Technical Ops)

The tooling required in order to manufacture prototypes for evaluation shall be ordered based upon X-level drawings.

8.2.4 First Articles (Responsibility: Quality Assurance)

All prototype components manufactured from prototype tooling shall be dimensionally characterized/ inspected (First Article, dimensional evaluation) and documented.

8.2.5 Test Protocols & Reports (Responsibility: Validation Lab)

These documents, recorded as official test reports and protocols, should describe the test findings from tests conducted to evaluate design prototypes. Testing should include 'edge of failure' analysis and should be utilized to update reliability assessment.

8.2.6 Updated Performance Specification (Responsibility: Engineering R & D)

Based upon prototype testing results and other factors, revise the Performance Specification as appropriate.

8.2.7 Marketing Assessment of Prototype (Responsibility: Marketing)

This document describes the design acceptability from an [internal] Sales/Marketing perspective. It should identify any design features requiring change, and define the level of importance for the change.

8.2.8 Materials Biological Compatibility Testing (Responsibility: Quality Engineering)

Materials used in the product shall be tested as required for biological compatibility in accordance with the design input requirements. This testing shall be documented in a report and may be performed by an outside testing service per existing protocols. All fluid path materials must meet ISO 10993 and MDD requirements for biocompatibility.

8.2.9 Proposed Manufacturing Process Plan (Responsibility: Manufacturing and Engineering

This document describes the proposed methods for manufacturing the product. This document should describe anticipated capital expenditures for tooling, equipment, facilities, timeline and manpower.

8.2.10 Process Flow Chart (Responsibility: Manufacturing)

This document should depict the process sequence for assembly, inspection, quarantine staging, sterility, and warehousing.

8.2.11 Manufacturing Line and Facility Plan / Layout (Responsibility: Manufacturing)

This document depicts the proposed facility plan for the manufacturing line of the product, including a layout identifying workstations, stocking locations, and applicable utilities (electrical, air, water hook-ups, ventilation sites).

8.2.12 Product Labeling (Responsibility: Document Control)

Product labels and Directions-for-Use should be finalized and incorporated into the Change Control process for device master records. They should comply with EN 980 – Graphical symbols for use in the labeling of medical devices.

8.2.13 Packaging Design Finalization (Responsibility: Quality Assurance, Marketing, Document Control)

The proposed packaging for the product should be finalized and documented in product drawing(s).

8.2.14 Targeted Product Cost Estimate (Responsibility: Marketing)

This document describes the targeted product cost, selling price, anticipated margin, and marketing strategy (including plans to distribute domestically and/or internationally).

8.2.15 Risk Management Summary (Responsibility: Quality Assurance)

A Risk Management Summary shall be initiated. It should focus on potential hazards created by user/patient/application related issues.

8.2.16 Design FMEA (Responsibility: Quality Assurance)

A Design FMEA should also be initiated during the prototype phase. The Design FMEA should outline possible product failures and identify any testing that may be appropriate. These documents should be continually updated as new hazards or failure modes are identified.

Reference GP00-00042. Note: This risk analysis should be reviewed during the qualification and validation phases for additional risks imposed as a result of the manufacturing process.

8.2.17 Regulatory Submission (Responsibility: Regulatory Affairs)

Any necessary regulatory submission shall be written and sent to the required governmental bodies. If no submission is required, a letter to the file shall be written to explain the rationale for not filing. The regulatory assessment provided in phase one may be sufficient.

8.2.18 Design Review (Responsibility: Engineering R&D)

A design review meeting can be called only after the phase II checklist is completed.

9 PHASE THREE → QUALIFICATION

9.1 INTRODUCTION

In this phase, the prototype design is tested to verify that the product (also called the design output) meets input requirements, even under challenged conditions. The product shall be manufactured from tooling intended for use in fabricating sellable product. The tooling and equipment used to fabricate the product shall be documented and qualified. Manufacturing, maintenance, and Quality Assurance procedures shall be generated and approved.

9.2 DELIVERABLES

Reference FGP00-00095p3

9.2.1 Product Drawings Release (Responsibility: Engineering R&D, Document Control)

Following formal design review from Phase II, X-level (prototype) drawings are revised to reflect a 'Y' status (denoting pre-production). These are released on a Change Order for use in obtaining tool quotes and prototype fabrication.

9.2.2 Tooling Drawings (Responsibility: Engineering R&D, Technical Ops)

Tooling drawings shall be produced for production equipment.

9.2.3 Production Tooling P.O. (Responsibility: Engineering R&D, Technical Ops)

Tooling and equipment required for the manufacture of the product should be ordered according to tooling drawings and/or OEM #.

9.2.4 Manufacturing Procedures (Responsibility: Engineering R&D, Manufacturing)

Step-by-step manufacturing processes shall be finalized and documented.

9.2.5 Inspection Procedures (Responsibility: Quality Assurance)

The inspection process, methods and sampling plans shall be documented in procedures. (The risk analysis should be reviewed when establishing adequate sampling and methods.)

9.2.6 Training Documentation (Responsibility: All as required)

Training of personnel in the activities described in the Manufacturing and Quality Inspection Procedures shall be performed and documented.

9.2.7 First Articles (Responsibility: Quality Assurance)

Mold tooling shall be First Article inspected to drawing specifications. Components manufactured from production tooling shall be First Article inspected.

9.2.8 Maintenance Procedures (Responsibility: Technical Ops)

The maintenance requirements, frequencies and methods shall be documented in procedures.

9.2.9 Equipment Maintenance (Responsibility: Technical Ops, QA)

Any equipment utilized for the manufacture or inspection of product shall be identified, specified to the extent necessary to maintain consistency and, if applicable, undergo an installation qualification test to assure the equipment functions properly. This qualification should include verification that the output meets specifications. Software validation (as required) shall be performed.

9.2.10 Design Qualification Testing (Responsibility: Validation Lab)

Consists of testing, documenting that the product design, manufactured using production tooling and conditions, meets the input requirements of the Product Performance Specification. This test shall be documented in Test Protocols and Test Reports and should include challenging the product under worst case clinical conditions where feasible.

9.2.11 Packaging Qualification (Responsibility: Validation Lab)

Packaging is part of the product design. Therefore, product development should include testing to ensure that the package provides a sterile barrier for the product and can withstand anticipated conditions during storage, transit, and necessary handling, without damaging the product. This testing shall be documented in a Test Protocol (PV) and Test Reports (SE). Additional packaging samples will be built and aging initiated for a 6-Yr Sterile Barrier Qualification to be completed prior to Phase VI CE Marketability. Packaging should comply with EN 868-1 – Packaging Materials for Sterilization.

9.2.12 Sterility Validation (Responsibility: Quality Assurance)

In accordance with PV00-00001, testing is conducted to ensure that the dosage is appropriate for this product, and that all sterilization controls are in place. Manufacturing should forward ten samples, individually bagged, from each of the three lots used for validation to Regulatory Affairs for coordination of lab testing. The sterilization process used for sterile product shall be validated and documented in a test report. Testing may be performed by an outside testing service. Sterility Validation must meet requirements of EN552-Sterilization of Medical Devices – Validation and Routine Control of Sterilization by Irradiation, EN556 – Sterilization of Medical Devices Sterility Assurance Level for Medical Devices Labeled “Sterile”, and ISO11137 – Sterilization of Health Care Products – Requirements for validation and Routine Control – Radiation Sterilization.

9.2.13 Identify and Qualify Key Suppliers (Responsibility: Engineering R&D, Quality Assurance)

Suppliers of key product components or services shall be identified and qualified. This qualification shall be documented in accordance with the companies purchasing data requirements.

9.2.14 Bill of Materials / Work Orders (Responsibility: Document Control)

The BOM and Work Order documentation to manufacture the product shall be developed, reviewed, approved and released.

9.2.15 Device Master Record (Responsibility: Document Control)

The Device Master Record document shall be developed for this product.

9.2.16 Hazard Analysis (Responsibility: Quality Assurance)

In accordance with GP00-00042, the risk-to-medical benefit shall be established. It will be written in the form of a Special Evaluation (SE). It will include the updated Risk Management Summary and Design FMEA initiated during Phase 2. It will also include a Process FMEA. It should now take into account all internal processes as well as user-related and inherent product risks. (This should include review of preproduction documents and processes, prototype and design qualification testing.)

9.2.17 Process Validation Master Plan (Responsibility: Manufacturing)

The process validation master plan is the overall plan that identifies the key elements that will be required for process validation. This should be performed per GP00-00086.

9.2.18 Design Review (Responsibility: Engineering R & D)

10 PHASE FOUR - VALIDATION / DESIGN TRANSFER

10.1 INTRODUCTION

In this phase, the manufacturing process is validated to demonstrate that product made under normal production conditions consistently meets design specifications, and that product remains equivalent to the design qualification product. Product built in this phase of the development cycle is potentially sellable. A Change Order releasing this product, with any remaining Device Master Records, is required.

10.2 DELIVERABLES

Reference FGP00-00095p4

10.2.1 Process Validation (Responsibility: Validation Lab)

Testing is conducted to determine the capability of the manufacturing process when run under normal production conditions for producing a product, which meets the performance requirements of the Performance Specification in a statistically significant manner with a representative sample plan. Testing shall be documented in a protocol and test report. This report should include justifications for design inputs that are static and have been previously verified by design qualifications.

10.2.2 Market Acceptance Trial Plan (Responsibility: Marketing / Sales)

Documented trial at a limited number of sites / accounts to assess market acceptance. THIS IS NOT A REQUIREMENT FOR EACH PROJECT.

10.2.3 Verification of Complete Design History File (Responsibility: Engineering R&D)

This is a requirement for product release. All deliverables, as defined on the project schedule or other suitable organization tool, should be referenced for crosschecking. The history file should include accurate reflection of the design activities required to complete the project with distributable product. All blanks on the checklists developed for each design phase (see samples in this procedure) must be filled in. This must be completed prior to the Design Review.

10.2.4 Design Review (Responsibility: Team Leader)

The Design Approval Group shall conduct a formal review of the Process Validation Test results. Approval is required in order to close validation phase and release product for distribution.

11 PHASE FIVE – INCREASED PRODUCTION / CAVITATION / MINOR DESIGN CHANGES

11.1 INTRODUCTION

This phase of deliverables may be subsequent to release of finished product to original configuration. Refer to the design plan for this phase for definition of purpose for this project. The deliverables below are intended to identify post-release phases of product/process

improvements while maintaining a state of quality control and documenting design development efforts.

11.2 DELIVERABLES

Reference FGP00-00095p5

11.2.1 Process Validation (Responsibility: Validation Lab)

Testing is conducted to determine the capability of the manufacturing process when run under normal production conditions for producing a product, which meets the performance requirements of the Performance Specification in a statistically significant manner with a representative sample plan. Testing shall be documented in a protocol and test report. This report should include justifications for design inputs that are static and have been previously verified by design qualifications.

11.2.2 Design Plan & Schedule (Responsibility: Technical Ops.)

A design plan, including definition of why the project is being undertaken and an activity schedule, should be evident in the design history file.

11.2.3 Tooling Drawings (Responsibility: Engineering R&D, Technical Ops)

Tooling drawings shall be produced for production equipment.

11.2.4 Documented Process Changes (Responsibility: Engineering R&D, Technical Ops)

Should include but not be limited to changes to process documents such as work orders.

11.2.5 Updated Procedures (Responsibility: Manufacturing)

Should include but not be limited to changes to assembly and test procedures.

11.2.6 Documentation of Training (Responsibility: As needed)

When changes to procedures are made, documentation of training must be included.

11.2.7 Revised Hazard Analysis (Responsibility: Quality Assurance)

An assessment of the Hazard Analysis must occur and an update must be made if applicable.

11.2.8 Regulatory Assessment (Responsibility: Regulatory Affairs)

This document describes the regulatory pathway for bringing the product to market. This should include the Company's position as to whether a submission to the US FDA is required; it should also include the device classifications in accordance with the US FDA and with the *Council Directive 93/42/EEC of 14 June 1993 Concerning Medical Devices, Annex IX.*

11.2.9 Design Review (Responsibility: Team Leader)

The Design Approval Group shall conduct a formal review of the Process Validation Test results. Approval is required in order to close validation phase and release product for distribution.

12 PHASE 6 - Non-Proprietary Component Design / Design Changes / New Molds or Manufacturing Process

12.1 INTRODUCTION

This design control is for the manufacture of components commonly available in the medical industry and of a non-proprietary nature. If the Regulatory Assessment determines that a 510K is required, the four phase PDP should be used. Refer to the design plan for this phase for definition of purpose for this project. The deliverables below are intended to identify post-release phases of product/process improvements while maintaining a state of quality control and documenting design development efforts.

12.2 DELIVERABLES

12.2.1 Design Plan & Schedule (Responsibility: Technical Opps)

A design plan, including definition of why the project is being undertaken and an activity schedule, should be evident in the design history file.

12.2.2 Regulatory Assessment (Responsibility: Regulatory Affairs)

This document describes the regulatory pathway for bringing the product to market. This should include the Company's position as to whether a submission to the US FDA is required; it should also include the device classifications in accordance with the US FDA and with the *Council Directive 93/42/EEC of 14 June 1993 Concerning Medical Devices, Annex IX.*

12.2.3 Product Drawings (Responsibility: Technical Opps)

Product drawings are complete and released in QUMAS.

12.2.4 Manufacturing Processes (Responsibility: Technical Opps)

Step-by-step manufacturing processes shall be finalized and documented.

12.2.5 Design FMEA (Responsibility: Quality Assurance)

The Design FMEA should outline possible product failures and identify any testing that may be appropriate. These documents should be continually updated as new hazards or failure modes are identified.

12.2.6 Materials Biological Compatibility Testing (Responsibility: Quality Engineering)

Materials used in the product shall be tested as required for biological compatibility in accordance with the design input requirements. This testing shall be documented in a report and may be performed by an outside testing service per existing protocols. All fluid path materials must meet ISO 10993 and MDD requirements for biocompatibility.

12.2.7 Approved Vendor Status (Responsibility: Quality Engineering)

Suppliers of key product components or services shall be identified and qualified. This qualification shall be documented in accordance with The Companies purchasing data requirements.

12.2.8 Regulatory Assessment (Responsibility: Regulatory Affairs)

This document describes the regulatory pathway for bringing the product to market. This should include the Company's position as to whether a submission to the US FDA is required; it should also include the device classifications in accordance with the US FDA and with the *Council Directive 93/42/EEC of 14 June 1993 Concerning Medical Devices, Annex IX.*

12.2.9 Design Review (Responsibility: Team Leader)

The Design Approval Group shall conduct a formal review of the Process Validation Test results. Approval is required in order to close validation phase and release product for distribution.