1. **Purpose**

The purpose of this document is to define the policies and procedures for identifying, mitigating, and managing risk throughout the organization. These policies and procedures include risk analysis, risk evaluation, risk control, evaluation of overall residual risk acceptability, risk management reports, and production and post-production information.

1. **Scope**

The risk management procedure applies to all distributable and new development products. Risk management principles may be applied to non-product specific applications such as project management.

1. **General**
   1. **Definitions**

* **Hazard –** potential source of physical injury or damage to the health of people, or damage to property or the environment.
* **Residual Risk –** Risk remaining after risk control measures have been taken.
* **Risk –** Combination of the probability of occurrence of hazard and the severity of that hazard.
* **Severity –** Measure of the possible consequences of a hazard
  1. **Responsibilities**

**Engineering –** Engineering is responsible for initiating and completing the risk management plan. Engineering is responsible for evaluating design and processing changes for potential impacts to the risk management plan.

**Quality –** Quality is responsible for the implementation and continued compliance to the risk management process.

**Management –** Management is responsible for approving the risk analysis and evaluation criteria. Management is responsible for approving the overall residual risk acceptability.

* 1. **Equipment and Materials –** N/A
  2. **Safety Precautions –** N/A
  3. **Training Requirements –** Engineering and Quality are required to be trained on this procedure and the training documented.
  4. **Record Management –** Risk management records shall be maintained in the Design History File (DHF) or associated development documentation.
  5. **Reference Documents and Materials**

**21 CFR 820** – FDA Quality System Regulations

**SOR/98-282** – Canadian Medical Device Regulations

**MDR 2017/745** – EU Medical Device Regulation

**MDD 93/42/EEC** – EU Medical Device Directive

**ISO 13485** – Medical Device Quality Management Systems

**ISO 14971** – Application of Risk Management to Medical Devices

**QP-0002** – Design Control Process

**QP-0011** – Customer Complaints and Advisory Notice Process

**QP-0012** – Corrective and Preventive Action (CAPA) Process

**QP-0021** – Medical Device Reporting and Recall Process

1. **Risk Management Process**

The company utilizes risk analysis, risk evaluation, risk control, and evaluation of residual risk acceptability to manage the risks associated with each medical device. The risk management process is initiated during new product development and maintained throughout the product life-cycle. Risk management planning is incorporated into the Design Control Process (QP-0002) and documented with the Design History File (DHF). The Failure Modes and Effects Analysis (FMEA) is the primary tool utilized for risk management.

* 1. **Risk Analysis**

The risk analysis shall include the following:

* A description and identification of the object of analysis
* Identification of the person(s) and organization completing the analysis
* The scope and date of the analysis
* The intended use and reasonably foreseeable misuses
* The characteristics that could affect the safety of the medical device

The analysis shall identify known and foreseeable sequences or combinations of events that can result in hazardous situations. For each hazard, the associated risk(s) shall be estimated using available information or data. The risk estimate includes a component of probability and a component of severity.

* 1. **Risk Evaluation**

For each identified hazard, the company shall determine if risk reduction activities are required based upon accepted criteria. The criteria utilized for this determination shall approved by management.

* 1. **Risk Control**

Risk determined to be unacceptable by the risk evaluation shall be mitigated by risk controls. The following risk control options shall be utilized in the priority listed:

* Inherent safety by design
* Protective measures in the medical device or in the manufacturing process
* Information for safety included in labeling

The implementation and effectiveness of control measures shall be verified and documented. Following implementation, the residual risk shall be re-analyzed and evaluated to determine if additional risk controls are required. The new controls shall be evaluated to ensure no new hazards are introduced by the control and determine any impact to the risk estimates of other hazards. All risks shall be reduced as far as possible.

* 1. **Risk / Benefit Analysis**

After completing all possible risk reduction, the company shall conduct a risk/benefit analysis of the residual risk. The company shall utilize data, literature, and expert opinion to determine if the medical benefits of the intended use outweigh the residual risk. The company shall only proceed if the medical benefit is determined to be great than the residual risk and the associated justification is documented.

* 1. **Evaluation of Overall Residual Risk Acceptability**

Following the completion of the risk analysis, evaluation, and control phases; the company shall determine if the overall residual risk posed by the medical device is acceptable versus the benefit provided by the medical device. For an overall residual risk that is judged acceptable, the company shall determine which information is necessary to include the in the associated labeling to disclose the overall residual risk.

* 1. **Risk Management Report**

Prior to the release for commercial distribution of the medical device, the company shall complete a review and documented approval of the risk management process. This review shall ensure:

* The risk management plan has been appropriately implemented
* The overall residual risk is acceptable
* Appropriate methods are in place to obtain relevant production and post-production information.
  1. **Production and Post-Production Information**

Production and Post-Production risk management shall be completed through the design control, CAPA, and customer complaint processes.

The risk management documentation shall be reviewed upon the following:

* New or revised standards impacting risk management
* Previously unrecognized hazards or hazardous situation are present
* The estimated risk(s) from a hazard are determined to be inaccurate
* The estimated benefits(s) from medical device are determined to be inaccurate
* Changes have been made that potentially impact risk management

1. **Revision History**

| **Rev #** | **Doc #** | **Effective Date** | **CHO** | **Description of Change** |
| --- | --- | --- | --- | --- |
| 01 | QP-0017 |  |  | Initial implementation of the Risk Management Process. |