Title: Advisory Notice Procedure

1.0 Purpose

1.1. This procedure defines the system used to issue an Advisory Notice.

2.0 Responsibility

2.1. The Quality Assurance Department is responsible for this procedure.

3.0 Requirements

3.1. The narrative contained in **6.0 Method (Flowchart and/or Narrative)** defines the actions taken to issue an Advisory Notice.

4.0 Definitions

4.1. Advisory Notice – is a notice issued by the supplier, subsequent to delivery of the medical device, to provide supplemental information and/or to advise what action should be taken in the use of a medical device, the modification of a medical device, the return to the supplier of a medical device, and the destruction of a medical device for the purpose of corrective or preventive action and in compliance with national and regional regulatory requirements.

4.2. Adverse Event – occurs as a result of the failure of a medical device to perform or function as specified.

5.0 Records

5.1. Quality Assurance will handle the control of related records.

6.0 Method

6.1. When the potential for an Adverse Event exist **COMPANY** issues Advisory Notices to the end-user, via the distributor, when the use of the medical device changes, modification of the device is needed, or the return of the medical device is required.