# Purpose and Scope

The purpose of this document is to outline the requirements for a Design Failure Modes, Effects, and Criticality Analysis (DFMEA) of the IPG Model 2408 and 2412 design. This analysis includes the torque wrench and port plug, which are included in the IPG package and also identified as separate accessory kit models 5500 & 5510, respectively. This analysis is focused on mechanical aspects of the IPG: a separate DFMEA was completed for electrical failure modes. The main objectives are to identify potential and known failures in normal and single fault conditions, to identify cause and effect of each condition and provide specific mitigations.

This DFMEA report will be re-assessed as appropriate, based on design changes and product performance (e.g., complaints, MDRs, and observations from the field).

# Reference Documents

FDA 21 CFR 803 Medical Device Reporting

EN ISO 14971:2012 Medical Devices – Application of risk management to medical devices

QAQP 0001 Document Control Procedure

QAQP 0047 FMEA Procedure

EESP 0071 24-Channel Implantable Pulse Generator Functional Specification

MESP 0113 24-Channel IPG Mechanical Functional Specification

EEFM 0022 IPG Electrical Design FMEA

# Definitions

Harm – Physical injury and/or damage to health or property.

Hazard – Potential source of harm.

Severity – The estimated consequence of the failure.

Risk – Probable rate of occurrence of a hazard causing harm and the degree of the severity of the harm.

Part Assembly Name - Name of assembly, part, or section of design documentation under evaluation

Function - Intended function of Part Assembly Name

Failure Mode – The way in which the function under evaluation fails.

Effect of Failure – The effect the failure mode has on the environment, next user, end user, process, etc. whichever is appropriate.

Cause of Failure – What conditions can bring about the failure mode. Sometimes a cause-of-cause is more easily identified or mitigated. In this case, cause-of-cause is identified and controlled.

Occurrence frequency – The probability that the given failure mode will occur.

Failure Detection – The probability that the problem will be detected prior to device use. Both detection during the manufacturing process and by the end user are considered.

Risk Priority Number (RPN) – Provides an indication of the relative priority of the failure mode. (RPN = occurrence\*severity\*detection)

Safety – Freedom from unacceptable risk or harm.

Malfunction – Failure of a device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in labeling. The intended performance refers to the intended use for which the device is labeled or marketed. (Reference 21 CFR 803.3(n).)

Serious injury – (1) injury or illness that is life threatening; (2) results in permanent impairment of body function or permanent damage to body structure, or (3) necessitates medical or surgical intervention to precluded permanent impairment of a body function or permanent damage to a body structure. (Reference 21 CFR 803.3(bb) (1).)

Project Engineer – The QIG Group employee responsible for overseeing an assigned project. This includes identifying all documents that are affected by the project and ensuring that required actions to those documents are accomplished.

# Responsibility

## Participants

Table 1 Participants

| **Name** | **Title** | **Primary Responsibility** |
| --- | --- | --- |
| Dan Kelsch | Design Engineering Manager | Project Engineer, Develop FMEA, Mechanical |
| Ben Cottrill | Project Lead | Project Lead, IPG System |
| Alex Smith | Design Engineering | Design Engineering |
| Jay Eiger | Design Engineering | Design Engineering |
| Bob Zenz | Quality Manager | Quality Engineering |
| Wes Omer | Process Engineer Manager | Process Development |
| Mike Labbe | Product Development Director | Development, IPG and Externals |
| Jeff Gagnon | Sales & Marketing Director | Marketing |
| Karen Bannick | Regulatory Consultant | Regulatory |
| Bernie Bosley | Risk Management Consultant | Risk Management & Quality |
| Lisa Jorgenson | Design Assurance Engineer | Design Assurance |
| Alison Julson | Process Engineer | Process Development |
| Gabe Routh | Process Engineer | Process Development |
| Dave Rakow | Process Engineer | Process Development |
| Carole Norris | Package Development Consultant | Packaging Development |
| Jeff Weisgarber | Program Manager | Project Engineer, Electrical |
| Rob Rubino | Battery Development Manager | Battery Development |
| Dave Dianetti | Product Development Engineer | Feedthrough Development |
| Jesse Geroy | Research & Development Manager | Accessory Development |

## Meetings

Table 2 Meetings

| **Date** | **Agenda** |
| --- | --- |
| 9/8/2010 | Kick-off Meeting, Review FMEA Procedure |
| 9/9/2010 | Start FMEA analysis to EESP 0071 |
| 9/30/2010 | Continue FMEA analysis to EESP 0071 |
| 10/7/2010 | Continue FMEA analysis to EESP 0071 |
| 10/11/2010 | Continue FMEA analysis to EESP 0071 |
| 10/21/2010 | Continue FMEA analysis to EESP 0071 |
| 10/28/2010 | Continue FMEA analysis to EESP 0071 |
| 11/4/2010 | Continue FMEA analysis to EESP 0071 |
| 11/11/2010 | Continue FMEA analysis to EESP 0071 |
| 11/18/2010 | Continue FMEA analysis to EESP 0071 |
| 12/9/2010 | Continue FMEA analysis to EESP 0071 |
| 12/14/2010 | Continue FMEA analysis to EESP 0071 |
| 06/29/2011 | Continue FMEA analysis to EESP 0071 |
| 07/20/2011 | Continue FMEA analysis to EESP 0071 |
| 07/28/2011 | Continue FMEA analysis to EESP 0071 |
| 08/10/2011 | Continue FMEA analysis to EESP 0071 |
| 08/10/2011 | Continue FMEA analysis to EESP 0071 (Lisa, Dan, Rob Rubino – discussion focused on battery) |
| 08/16/2011 | Continue FMEA analysis to EESP 0071 (Lisa, Dan, Jeff Weisgarber – discussion focused on Electrical Engineering FMEA) |
| 08/17/2011 | Continue FMEA analysis to EESP 0071 (Lisa, Dan, Dave Dianetti – discussion focused on feed through) |
| 8/31/2011 | Continue FMEA analysis to EESP 0071 (Lisa, Dave Rakow, Gabe Routh) |
| 9/14/2011 | Continue FMEA analysis to EESP 0071 (Lisa, Wes, Dave Rakow, Gabe Routh) |
| 9/22/2011 | Continue FMEA analysis to EESP 0071 |
| 10/18/2011 | Continue FMEA analysis to EESP 0071 |
| 10/27/2011 | Continue FMEA analysis to EESP 0071 |
| 11/08/2011 | Continue FMEA analysis to EESP 0071 |
| 11/14/2011 | Continue FMEA analysis to EESP 0071 |
| 11/18/2011 | Continue FMEA analysis to EESP 0071 |
| 11/29/2011 | Continue FMEA analysis to EESP 0071 |
| 12/13/11 | Continue FMEA analysis to EESP 0071 |
| 12/20/11 | Continue FMEA analysis to EESP 0071 |
| 01/04/2012 | Continue FMEA analysis to EESP 0071 (Lisa, Dan, Rob Rubino, Jeff Weisgarber – discussion focused on battery) |
| 01/06/2012 | Continue FMEA analysis to EESP 0071 (Lisa, Carole Norris, Alison Julson – discussion focused on packaging) |
| 01/12/2012 | Continue FMEA analysis to EESP 0071 (Lisa, Carole Norris, Alison Julson – discussion focused on packaging) |
| 01/18/2012 | Continue FMEA analysis to EESP 0071 (Lisa, Carole Norris, Alison Julson – discussion focused on packaging) |
| 01/24/2012 | Continue FMEA analysis to EESP 0071 (Lisa, Carole Norris, Alison Julson – discussion focused on packaging) |
| 01/30/2012 | Continue FMEA analysis to EESP 0071 (Lisa, Jeff Weisgarber – discussion focused on software-related detection methods) |
| 01/31/2012 | Continue FMEA analysis to EESP 0071 (Lisa, Dan, Alex, Wes, and Jesse Geroy– discussion focused on torque wrench & port plugs) |
| 02/14/2012 | Continue FMEA analysis to EESP 0071 |
| 02/21/2012 | Continue FMEA analysis to EESP 0071 (Lisa, Carole Norris, Alison Julson – discussion focused on packaging) |
| 02/23/2012 | Continue FMEA analysis to EESP 0071 (Lisa, Dan, Alex, Jeff Weisgarber – discussion focused on electrical) |
| 03/05/2012 | Continue FMEA analysis to EESP 0071 (Lisa, Dan, Alex, Jeff Weisgarber – discussion focused on electrical) |
| 05/15/2012 | Verify mitigations were implemented or planned |
| 09/18/2012 | Review open items, add analysis of epoxy, silicone dispersion, and silicone adhesive failure modes |
| 09/26/2012 | Review & update analysis of epoxy, silicone dispersion, and silicone adhesive failure modes (Lisa, Dave Rakow) |
| 09/28/2012 | Verify mitigation document reference numbers |
| 09/28/2012 | Verify packaging-related mitigation document reference numbers (Lisa, Carole Norris) |
| 10/02/2012 | Verify mitigation document reference numbers |
| 04/10/2013 | Assessed failure modes related to solvent attack. |
| 09/11/2013 | Assessed failure modes related to set screw thread binding (Dan, Alex) |
| 10/16/2013 | Added manufacturing reference documentation to mitigations (Lisa, Alison) |
| 10/24/2013 | Reviewed RPN rankings (Lisa, Dan, Alex) |
| 12/16/2013 | Reviewed mitigation references and updates |

# General Requirements

FMEA is documented in accordance with Document Control Procedure, QAQP 0001.

# Procedure

1. Review the various possible hazards. These include energy hazards, biological hazards and hazards resulting from functional failure, maintenance and aging. These lists are intended to provide an aide-mémoire in identifying possible failure modes.
   1. Energy hazards include electricity, heat, mechanical force, ionizing radiation, non-ionizing radiation, electromagnetic fields, moving parts, suspended masses, patient support device failure, pressure vessel rupture, acoustic pressure, vibration, and magnetic fields.
   2. Biological hazards include bio-contamination, bio-incompatibility, incorrect formulation, toxicity, allergenicity, mutagenicity, teratogenicity, carcinogenicity, infection, pyrogenicity, inability to maintain hygienic safety, and degradation.
   3. Environmental hazards include electromagnetic interference, inadequate supply of power or coolant, restriction of cooling, likelihood of operation outside prescribed environmental conditions, incompatibility with other devices, accidental mechanical damage, and contamination due to waste production and / or device disposal.
   4. Incorrect output of energy or substances hazards include electricity, radiation, volume, pressure, supply of medical gases, and supply of anesthetic agents.
   5. Hazards related to the use of the device include inadequate labeling, inadequate operating instructions, inadequate specification of accessories, inadequate specification of pre-use checks, over complicated operating instructions, unavailable or separated operating instructions, use by unskilled/untrained personnel, reasonably foreseeable misuse, insufficient warning of side effects, inadequate warning of hazards likely with re-use of single-use devices, incorrect measurement and other metrological aspects, incorrect diagnosis, erroneous data transfer, misrepresentation of results, incompatibility with consumables/accessories/other devices.
   6. Inappropriate, inadequate, or over-complicated user interface hazards include mistakes and judgment errors, lapses and cognitive recall errors, slips and blunders (mental or physical), violation or abbreviation of instructions, complex or confusing control system, ambiguous or unclear device state, ambiguous or unclear presentation or settings, measurements, or other information, misrepresentation of results, insufficient visibility, audibility, or tactility, poor mapping of controls to action, poor mapping of displayed information to actual state, and controversial modes or mappings as compared to existing equipment.
   7. Hazards arising from functional failure, maintenance and aging include inadequacy of performance characteristics for the intended use, lack of or inadequate specification for maintenance, inadequate maintenance, and lack of adequate determination of end of device life, loss of mechanical integrity, inadequate packaging, improper use/reuse, and deterioration of function.
2. Part Identification – Identify the assembly or component being analyzed.
3. Part Function – Describe the part function in relationship to the device, assembly, or therapy.
4. Failure Mode – Describe each possible failure mode. No judgment is to be made on the likelihood of failure only on how it could fail. A review of past design FMEAs, quality history, warranty data, durability data, and reliability problems on comparable components are a recommended starting point.
5. Effect of Failure – Describe the effect of the failure mode. What does the user or system experience as a result of the failure mode just listed?
6. Cause of Failure – Analyze what conditions can bring about the failure mode.
7. Estimate the occurrence frequency – Estimate the probability that the given failure mode will occur using a ranking scale of 1 to 5, where 1 indicates a low probability of occurrence whereas a 5 means a near certainty of occurrence as shown in Table 4. Probability in Table 4 means the statistical proportion outside the specification limits.
8. Severity – Evaluate the severity or estimated consequence of the failure on a scale of 1 to 5, where 1 means a minor nuisance whereas a 5 indicates a severe, total failure. See Table 5.
9. Failure Detection – Estimate the probability that the problem will be detected prior to device use – either during the manufacturing process or by the user. A low number indicates that detection is likely to occur; in contrast, a high number indicates that the detection is less likely to occur prior to device use. See Table 7.
10. Calculation of Risk Priority Number (RPN) – The RPN index is calculated by multiplying the rankings of occurrence, severity, and detection. The RPN index obtained provides an indication of the relative priority of the failure mode. This FMEA uses the template version (QAQP 0047, revision 1.10) that was active when the FMEA was started. One of the updates implemented in revision 1.11 was to list both an initial RPN & final RPN. This FMEA does not list the initial RPN for each failure mode, since the RPN values were updated as mitigations were identified and implemented.
11. Evaluate all RPNs relative to each other.
12. Identify mitigation action to reduce risk for relatively high RPNs or observed trends.
    1. Risk reduction strategies include but are not limited to: specification changes, design changes, manufacturing process changes, increased testing in design phase, increased testing in manufacturing process, and changes to product labeling.
    2. For product/projects in the design phase, corrective/preventive action identified through the risk management process may be managed through the design controls process (i.e. do not need to be managed through the CAPA process).
    3. For risk mitigation measures that require changes to the design, or additional features or specifications for the product, a review of the Design Input Specifications will be conducted to ensure that appropriate updates are made as necessary to reflect these changes. This will ensure that these mitigation measures are tracked through the design process and included in design verification or validation testing.
13. Mitigation action to address the cause of the failure mode. It should be considered for RPNs determined to be unacceptable. Rationale for RPN number used as a “cut-off” or other approach for defining “unacceptable” risk level should be in the FMEA report. (Number may vary for each FMEA.)
14. After completion of risk mitigation measures, risk should be reevaluated. Repeated risk mitigation and risk re-evaluation shall occur until residual risk has been determined to be acceptable or benefits of the product are deemed to outweigh residual risks.

# Sample Size Guidance

The following is for guidance on sample sizes to be used in design verification testing (DVT). Sample size may vary for a given device depending on what functions is being tested. Sample sizes are justified in the applicable test plan and justifications must be statistically valid. RPNs resulting from FMEA are one form of justification for sample size

Table 3 Sample Size Guidance

|  |  |  |
| --- | --- | --- |
| RPN | Comment | Attribute Sample Size Guidance |
| 65 - 125 | There is a reasonable potential for harm from device use. Sample sizes less than 59 require risk justification | ≥ 59 |
| 28 - 64 | Potential for harm due to failure is not remote. Sample sizes less than 22 require risk justification | ≥ 22 |
| 9 - 27 | Failure modes show early in process and/or rarely emerge in clinical use | 5 - 22 |
| 1 - 8 | Failure modes unlikely to lead to harm | 0 - 5 |

Note: Above sample size guidance is in relation to attribute data only. Other statistical methods may be employed to determine sample size when variables data are available.

# Ranking Criteria

## Occurrence

Table 4 Occurrence Ranking Criteria

| **Criteria** | **Estimated Probability in device-months (Note 1)** | **Estimated Probability in 1-year use** | **Ranking** |
| --- | --- | --- | --- |
| Remote probability or occurrence | x ≤ 1/12,000,000 | x ≤ 1/1,000,000 | 1 |
| Low probability or occurrence | 1/12,000,000 ≤ x < 1/1,200,000 | 1/1,000,000 ≤ x <1/100,000 | 2 |
| Moderate probability of occurrence | 1/1,200,000 ≤ x < 1/12,000 | 1/100,000 ≤ x <1/1,000 | 3 |
| High probability or occurrence | 1/12,000 ≤ x < 1/12 | 1/1,000 ≤ x <1 | 4 |
| Very High probability or occurrence | 1/12 ≤ x | 1 ≤ x | 5 |

Note 1: Occurrence is the rate of failure of the failure cause with the stated mitigation in place (if there is one). Occurrence is categorized in device-months. This number can also be used as total failure rate by multiplying it by the expected life. For example, it the failure rate is 0.01 and the expected service life is 12 months, then the total failure rate is 0.12 (12 \* 0.01)

## Severity

Table 5 Severity Ranking Criteria

| **Criteria** | **Ranking** |
| --- | --- |
| No or minor affect to device operation or performance; impact may not be noticed by user. No affect to patient or operator safety. Device faults in a manner that presents a nuisance or inconvenience to user but does not result in loss of functionality and does not affect patient or user safety. | 1 |
| Device faults (loss of some functionality, but not device failure) partially or intermittently, in a safe manner. Device faults consistently, in a safe manner performance. | 2 |
| Device fails (inoperable) in safe manner. Serious injury to patient and/or operator unlikely. | 3 |
| Device faults fails in manner that may be unsafe. Serious injury to patient and/or operator likely. Intervention required to prevent non-serious or non-permanent injury. | 4 |
| Device fails in unsafe manner. Death or serious injury or permanent injury to patient and/or operator or intervention required to prevent serious injury or death. | 5 |

Table 6 Specific Failure Effects As Determined By FMEA

| Failure Effect | Severity Ranking |
| --- | --- |
| Excessive heat – severe (above 42C)\* | 4 |
| Unable to control stimulation or communicate | 3 |
| Erosion\* | 3 |
| Infection\* | 3 |
| Bioincompatible\* | 3 |
| Unable to recharge | 3 |
| Tissue damage, irritation | 3 |
| Unintended effect\* | 3 |
| Contributes to latent lead failure | 3 |
| Revision difficulty, unable to remove lead from IPG | 3 |
| Premature device failure, explant, unintended revision surgery\* | 3 |
| Device failure not requiring surgery (reprogram) | 2 |
| Electrical leakage | 2 |
| Stimulation compromised, unintended or intermittent stimulation | 2 |
| No stimulation output (Under stimulation\*) | 2 |
| Stimulation on wrong channel or to can | 2 |
| Product damage/sterility compromised | 2 |
| Decreased battery life | 2 |
| Instructions/labeling not available, adulterated product | 2 |
| High insertion force, unable to fully insert lead | 2 |
| Excess recharge time or increased recharge frequency | 2 |
| Poor diagnostics | 2 |
| Implant difficulty, unable to assemble system, unable to implant | 1-2 |
| Physician inconvenience/dissatisfaction | 1 |

\* These effects are expressed in terms of patient hazard. See EEEX 0071 SCS Hazard Summary for definition.

## Detection

Table 7 Detection Ranking Criteria

| **Criteria** | **Ranking** |
| --- | --- |
| Remote likelihood that product would be used without detecting this failure condition, since it is easily detectable in manufacturing or by user. | 1 |
| Low likelihood that product would be used without detecting this failure condition, since it is easily detectable in manufacturing or by user | 2 |
| Moderate likelihood that product would be used without detecting failure condition, since the failure effect is more subtle in nature or is intermittent. | 3 |
| High likelihood for use of product without detecting failure condition, defect not readily detectable. | 4 |
| Very High likelihood that failure condition will not be detected prior to failure during use. Failure is Undetectable through inspection or testing or latent failure mode | 5 |

Table Risk Priority Number (RPN) Summary of RPN >27

| **RPN** | **S** | **D** | **O** | **Failure Mode** | **Summary** |
| --- | --- | --- | --- | --- | --- |
| 30 | 3 | 5 | 2 | Latent fine leak in metal | Failure modes have been assessed & mitigated. Residual risk has been reduced to as low as reasonably practicable. |
| 30 | 3 | 5 | 2 | Premature failure of components post implant |
| 30 | 3 | 5 | 2 | Latent gross / fine leak within FT assembly |
| 30 | 3 | 5 | 2 | Unable to insert torque wrench |
| 30 | 3 | 5 | 2 | Insufficient strain relief |
| 30 | 3 | 5 | 2 | Battery does not provide power latently |
| 30 | 3 | 5 | 2 | Battery fails to recharge latently |
| 30 | 3 | 5 | 2 | Corrosion |
| 30 | 3 | 5 | 2 | Lead has been secured too loosely |

# Design FMEA

| **IPG Model**  **2808/2412** | **Function** | **Failure Mode** | **Failure Effect (S)** | **Detection Method (D)** | **Cause of Cause (O)** | **Failure Cause (O)** | **S** | **D** | **O** | **RPN** | **Mitigation Action** | **Mfg** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Can (Enclosure)** | Maintain hermetic environment for internal electronics | Immediate gross or fine leak at seam | Gross leak: moisture, shorting, heat, biocompatibility failure, corrosion, revision surgery  Fine Leak: moisture, shorting,  corrosion , revision surgery | Hermetic seal test | weld process outside control parameters | bad shield weld | 3 | 1 | 2 | 6 | DVT for helium leak (MERE 0440) |  |
|  |  |  |  |  |  |  |  |  |  |  | Hermetic seal test in production (1010778) | **X** |
|  |  |  |  |  | poor fit between right and left shield |  | 3 | 1 | 2 | 6 | Hermetic seal test in production (1010778) | **X** |
|  |  |  |  |  |  |  |  |  |  |  | Right and Left shield half trim specification for edge surface coplanarity ,edge width, and right half circumference dimensions match left half (1210-001451, 1210-001450) |  |
|  |  |  |  |  | material impurities | brittle intermetallics, etc. | 3 | 1 | 1 | 3 | Metal purity requirement (1210-001451, 1210-001450) |  |
| Hermetic seal test in production (1010778) | **X** |
|  |  | immediate gross or fine leak in metal | Gross leak: moisture, shorting, heat, biocompatibility failure, corrosion, revision surgery  Fine Leak: moisture, shorting,  corrosion, revision surgery | Hermetic seal test | overstress in forming/stamping process | crack in metal or metal too thin | 3 | 1 | 1 | 3 | Hermetic seal test in production (1010778) | **X** |
|  |  |  |  |  |  |  |  |  |  |  | Specify titanium properties: grade, grain structure thickness, alloy on lower end of aluminum content favoring higher vanadium (1210-001451, 1210-001450) |  |
|  |  | immediate gross or fine leak at FT | Gross leak: moisture, shorting, heat, biocompatibility failure, corrosion  Fine Leak: moisture, shorting,  corrosion | Hermetic seal test | gap or space between FT and shield edge (x, y axis) | bad FT weld | 3 | 1 | 1 | 3 | Hermetic seal test in production (1010778) | **X** |
| FT-to- shield overlap drawing requirement (1210-001814, 1210-001815, 1210-001451, 1210-001450) |  |
| FT envelope dimensions controlled fit with shield half dimension (1210-001814, 1210-001815, 1210-001451, 1210-001450) |  |
|  |  |  |  |  | inadequate weld penetration | bad FT weld | 3 | 1 | 1 | 3 | FT material thickness dimension (1210-001814, 1210-001815) |  |
| Hermetic seal test in production (1010778) | **X** |
|  |  |  |  |  |  |  |  |  |  |  | Can material thickness dimension (1210-001451, 1210-001450) |  |
|  |  |
|  |  |  |  |  | gap or space between FT and shield surface (flatness) | bad FT weld | 3 | 1 | 1 | 3 | Close contact FT to can (1210-001451, 1210-001450, 1210-001814, 1210-001815) |  |
| FT flat in shield parallel to cut edge drawing requirement (1210-001814, 1210-001815) |  |
| Hermetic seal test in production (1010778) | **X** |
|  |  | Latent fine leak in metal | Premature device failure, revision surgery | Device fully or partially inoperable | stress during stamping process | corrosion stress cracking | 3 | 5 | 2 | 30 | Production weld process validation, cover gas(1005214) | **X** |
|  |  |  |  |  |  |  |  |  |  |  | Specify corrosion resistant material (titanium) (1210-001451, 1210-001450) |  |
|  |  |  |  |  |  |  |  |  |  |  | Weld seam discoloration requirement (1010554) | **X** |
|  |  |  |  |  |  |  |  |  |  |  | Heated die stamping process (tools A15714D1, A15916D1 | **X** |
|  |  |  |  | Device fully or partially inoperable | stress during stamping process | corrosion stress cracking | 4 | 5 | 1 | 20 | Material selection of known corrosion-resistant material (1210-001451, 1210-001450) |  |
|  |  | Latent gross leak | Premature device failure, heat, bioincompatibility |  | condensation induced corrosion on battery pin | Battery outgas or venting | 4 | 5 | 1 | 20 | Battery fluid exposure test report (RDE 11-597) |  |
|  |  |  |  |  | battery short (internal or external) |  | 4 | 5 | 1 | 20 | Battery output fused on circuit board (1320-000050, 1330-000050) |  |
|  |  |  |  |  |  |  |  |  |  |  | Greatbatch battery group DVT for outgas or vent (Reports ER 10-202 & RER 2010-0201) |  |
|  | Mechanical protection of electronics | Premature failure of components post implant | Premature device failure, revision surgery | Device fully or partially inoperable | external pressure (static or cycled) | excessive shield flex | 3 | 5 | 2 | 30 | Internal structures (1210-001691, 1210-001679, 1210-001496) |  |
|  |  |  |  |  |  |  |  |  |  |  | DVT for cyclic force (MERE 0440) |  |
|  |  |  |  |  |  |  |  |  |  |  | DVT for static force (MERE 0440) |  |
|  |  |  |  |  |  |  |  |  |  |  | Titanium material thickness requirement (1210-001451, 1210-001450) |  |
|  | biocompatible | incompatible | Tissue irritation, inflammation, explant | Material certs |  | Incompatible materials | 3 | 3 | 1 | 9 | Titanium material required (1210-001451, 1210-001450) |  |
|  |  |  |  |  |  |  |  |  |  |  | Biocompatibility report (MERE 0573) |  |
|  |  |  |  |  |  |  |  |  |  |  | Receiving checks material certs (17QWI-0021) | **X** |
|  |  |  |  | visual inspection |  | contamination | 3 | 3 | 1 | 9 | Manufacturing cleaning step & covered by protective tape during processing (1010786 & 1007000) | **X** |
|  |  |  |  |  |  |  |  |  |  |  | Visual inspection (1007803) | **X** |
| **Feed-through** | Maintain hermetic environment for internal electronics | immediate gross / fine leak within FT assembly | Gross leak: moisture, shorting, heat, biocompatibility failure, corrosion  Fine Leak: moisture, shorting,  corrosion | Leak test | stress during welding | crack in  ceramic | 3 | 1 | 3 | 9 | 100% leak test as device assembly (1010778) | **X** |
|  |  |  |  |  |  |  |  |  |  |  | Visual inspection (1010548) | **X** |
|  |  |  |  |  |  | braze joint failure | 3 | 1 | 1 | 3 | 100% leak test as FT component (10-9 atm leak rate, 1210-001814, 1210-001815) | **X** |
|  |  |  |  |  |  |  |  |  |  |  | 100% leak test as device assembly (1010778) | **X** |
|  | Maintain hermetic environment for internal electronics | latent gross / fine leak within FT assembly | Gross leak: moisture, shorting, heat, biocompatibility failure, corrosion  Fine Leak: moisture, shorting,  corrosion |  | applied stress from handling or use | crack in  ceramic | 3 | 5 | 2 | 30 | DVT mechanical stress followed by leak test (MERE 0440) |  |
|  | filters electrical noise | filter goes open | Unintended effect due to emi shielding lost | electrical test | excessive heat at flex finger solder joint compromises epoxy bond | filter loses electrical contact | 3 | 2 | 1 | 6 | Epoxy cure temperature is higher than temperature exposure during soldering (1013185, SPA-101) |  |
|  |  |  |  |  |  |  |  |  |  |  | 100% electrical test in manufacturing - measures capacitance (EEPR 0181, EEPR 0182) | **X** |
|  | conducts stim signal | conductor opens | no stim output | electrical test |  | pin breaks | 2 | 1 | 1 | 2 | Ductile pin material, rugged to bending (1210-001814, 1210-001815) |  |
|  |  |  |  |  |  |  |  |  |  |  | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182) | **X** |
|  |  | intermittent conductor opens | intermittent stim output | electrical test |  | pin breaks | 2 | 3 | 1 | 6 | Ductile pin material, rugged to bending (1210-001814, 1210-001815) |  |
|  |  |  |  |  |  |  |  |  |  |  | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182) | **X** |
| **Header**  **lead frame** | conduct current signal | No transfer of electrical current from FT to header contact | No Stim output | Electrical test | FT to lead frame weld failure | break in conduction path | 2 | 3 | 3 | 18 | Nail head on FT for larger weld surface (1210-001814, 1210-001815) |  |
|  |  |  |  |  |  |  |  |  |  |  | Strain relief on lead frame at FT side (1210-001534 - 001538) |  |
|  |  |  |  |  |  |  |  |  |  |  | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182) | **X** |
|  |  |  |  |  | lead frame misaligned on FT side (small contact area) |  | 2 | 2 | 3 | 12 | Hook design on lead frame FT end (1210-001534 - 001538) |  |
|  |  |  |  |  |  |  |  |  |  |  | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182) | **X** |
|  |  |  |  |  | lead frame misaligned on contact side (small contact area) |  | 2 | 3 | 3 | 18 | Flat surface on contact block (1210-000414) |  |
|  |  |  |  |  |  |  |  |  |  |  | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182) | **X** |
|  |  |  |  |  | contact to lead frame weld failure |  | 2 | 1 | 3 | 6 | Flat surface on contact block (1210-000414) |  |
|  |  |  |  |  |  |  |  |  |  |  | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182) | **X** |
|  |  |  |  |  | material incompatible with contact block |  | 2 | 2 | 1 | 4 | Material selection (1210-001534 - 001538) |  |
|  |  |  |  |  |  |  |  |  |  |  | Material cert (1210-001534 - 001538) |  |
|  |  |  |  |  |  |  |  |  |  |  | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182) | **X** |
|  |  |  |  | Device fully or partially inoperable, patient may detect & turn off stim with subsequent impedance measurement | flex fatigue |  | 2 | 5 | 2 | 20 | Strain relief on lead frame at FT side (1210-001534 - 001538) |  |
|  |  |  |  |  |  |  |  |  |  |  | Motion restrained by adhesive backfill and encased in header shell (1006560) |  |
|  |  |  |  |  |  |  |  |  |  |  | DVT for header fatigue testing (MERE 0440) |  |
|  |  |  |  |  | tensile stress |  | 2 | 5 | 1 | 10 | Strain relief at FT side (1210-001534 - 001538) |  |
|  |  | Transfer of electrical current from FT to wrong or several header contacts | Unintended stim | Electrical test |  | misaligned FT side | 2 | 1 | 3 | 6 | Hook design on lead frame FT end to hold in place (1210-001534 - 001538) |  |
|  |  |  |  |  |  | misaligned contact side | 2 | 1 | 3 | 6 | Frame strip (Note: is removed after assembly) (1210-001534 - 001538) |  |
|  |  |  |  |  | moved by operator during manufacture before silicone adhesive add | adjacent lead frames contact each other | 2 | 2 | 3 | 12 | Backfill between frames requirement (MEEX 0099 space between conductive elements) |  |
|  |  |  |  |  |  |  |  |  |  |  | 100% electrical test for shorted outputs in manufacturing (EEPR 0181, EEPR 0182) | **X** |
|  |  |  |  |  | lead frames bent |  | 2 | 2 | 3 | 12 | Frame strip (Note: is removed after assembly) (1210-001534 - 001538) |  |
| **Antenna** | transmit and receive communication signal | doesn’t transmit or receive | Unable to control stim or communicate | Electrical test | feedthrough to antenna weld failure | antenna path open | 3 | 1 | 3 | 9 | Nail head on FT (1210-001814, 1210-001815) |  |
|  |  |  |  |  |  |  |  |  |  |  | Strain relief design on antenna conductor at FT (1210-001499) |  |
|  |  |  |  |  |  |  |  |  |  |  | Magnet off capability (EESP 0071 F5926) |  |
|  |  |  |  |  |  |  |  |  |  |  | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182) | **X** |
|  |  |  |  |  | misaligned |  | 3 | 1 | 3 | 9 | Hook design on antenna conductor at FT (1210-001499) |  |
|  |  |  |  |  |  |  |  |  |  |  | Magnet off capability (EESP 0071 F5926) |  |
|  |  |  |  |  |  |  |  |  |  |  | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182) | **X** |
|  |  |  |  |  | flex fatigue |  | 3 | 5 | 1 | 15 | Strain relief design on antenna conductor at FT (1210-001499) |  |
|  |  |  |  | Device fully or partially inoperable |  |  |  |  |  |  | Motion restrained by adhesive back fill and encased in header shell (1006560) |  |
|  |  |  |  |  |  |  |  |  |  |  | Magnet off capability (EESP 0071 F5926) |  |
|  |  |  |  |  |  |  |  |  |  |  | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182) | **X** |
|  |  |  |  |  | tensile stress |  | 3 | 5 | 1 | 15 | Strain relief design on antenna conductor at FT (1210-001499) |  |
|  |  |  |  |  |  |  |  |  |  |  | Magnet off capability (EESP 0071 F5926) |  |
|  |  |  |  |  |  |  |  |  |  |  | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182) | **X** |
|  |  |  |  | Electrical test | Loop terminals touching near FTs | antenna path shorted | 3 | 1 | 1 | 3 | Header shell designed for 2 separate channels for antenna leads (1211-000500, 1211-000499) |  |
|  |  |  |  |  |  |  |  |  |  |  | Magnet off capability (EESP 0071 F5926) |  |
|  |  |  |  |  |  |  |  |  |  |  | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182) | **X** |
| **Stackers** | maintain spacing between connector contacts | connector contacts not aligned with lead contacts | stim compromised | Visual inspection, detected at subsequent process |  | poor fit, space between stackers | 2 | 1 | 2 | 4 | Interlock feature on stackers, seal, contact, end cap drawing dimensions (1210-000414, 1210-001525, 1210-001448, 1210-001521, 1210-001508, 1210-001519) |  |
|  |  |  |  |  |  |  |  |  |  |  | Visual inspection (1010887) | **X** |
|  | maintain electrical insulation | electrical leakage | stim compromised | clinician programmer diagnostic Impedance measurement |  | stacker - seal interface not touching | 2 | 5 | 2 | 20 | Seal under compression (1005202) |  |
|  |  |  |  |  |  |  |  |  |  |  | DVT for leakage (MERE 0440) |  |
|  |  |  |  |  | solvent attack | cracking | 2 | 5 | 1 | 10 | DVT for leakage (MERE 0440) |  |
|  | assure contacts share same centerline | contacts out of alignment | high insertion force, can’t fully insert lead  electrical leakage | Visual inspection, detected at subsequent process |  | poor fit, space between stackers | 2 | 1 | 2 | 4 | Interlock feature on stackers (1210-001525, 1210-001448) |  |
|  |  |  |  |  |  |  |  |  |  |  | Bore inspection (1007700) | **X** |
|  |  |  |  |  |  |  |  |  |  |  | Process (stacker alignment pin in production 1005202) | **X** |
|  |  |  |  |  | solvent attack | cracking | 2 | 5 | 1 | 10 | DVT for leakage (MERE 0440) |  |
|  | orients contacts for welding to lead frame | not oriented | stim compromised | Visual inspection, detected at subsequent process |  | contact in stacker wrong way | 2 | 1 | 1 | 2 | Alignment feature on stacker one-way fit design between contact and stacker (1210-000414, 1210-001525, 1210-001448) |  |
|  |  |  |  |  |  |  |  |  |  |  | Visual inspection (1010887) | **X** |
|  |  | weld failure | stim compromised | visual & electrical test |  | stacker leg feature too long which prevents contact between contact block & lead frame | 2 | 2 | 1 | 4 | Drawing dimensions (1210-001525, 1210-001448) |  |
|  |  |  |  |  |  |  |  |  |  |  | Visual of weld (1005413, 1005414) | **X** |
|  |  |  |  |  |  |  |  |  |  |  | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182) |  |
|  | keep backfill out of bore | backfill ingress | high insertion force  electrical leakage  electrical contact interference | visual bore inspection |  | poor fit, space between stackers | 2 | 2 | 2 | 8 | Interlock feature on stackers (1210-001525, 1210-001448) |  |
|  |  |  |  |  |  |  |  |  |  |  | Visual inspection (1007700) | **X** |
|  |  |  |  |  |  |  |  |  |  |  | Automated stacker groove fill process (1005202) | **X** |
|  |  |  |  |  | solvent attack | cracking | 2 | 2 | 1 | 4 | Visual inspection (1007700) |  |
| **Silicone dispersion** | Prevent backfill ingress between contact block & stacker | backfill ingress | high insertion force  electrical leakage  electrical contact interference | visual bore inspection |  | material selected that allows ingress | 2 | 2 | 3 | 12 | Bore inspection (1007700) | **X** |
|  |  |  |  |  |  |  |  |  |  |  | DVT lead insertion (MERE 0440) |  |
| **End cap** | positions end of lead to register contacts | connector contacts not aligned with lead contacts | stim compromised | visual inspection, subsequent process steps |  | end cap assembled backwards or not aligned with stacker | 2 | 1 | 1 | 2 | One-way fit design between end cap, contact and stacker (1210-000414, 1210-001508, 1210-001519, 1210-001525, 1210-001448) |  |
|  |  |  |  |  |  |  |  |  |  |  | Visual inspection (1005202) | **X** |
|  |  |  |  |  |  | Design does not allow full insertion | 2 | 1 | 1 | 2 | Diameter & hole depth dimensions (1210-001508, 1210-001519) |  |
|  | visual marker for full lead insertion | can’t see lead | Re-seat lead, difficulty inserting lead, unlikely to cause lead damage | visual inspection, subsequent process steps |  | bubbles in silicone backfill or surface roughness | 1 | 1 | 1 | 1 | DVT for visual confirmation (MERE 0440) |  |
|  |  |  |  |  |  |  |  |  |  |  | 100% visual for bubbles (1007762, 1007803) | **x** |
|  |  |  |  |  |  | opaque/yellow | 1 | 2 | 2 | 4 | Material is dried before molding (1005326  1005582) | **x** |
|  | aligns stacker set | stacker set not aligned with connector | high insertion force | visual inspection, subsequent process steps |  | not assembled correctly | 2 | 1 | 1 | 2 | One-way fit design between end cap and stacker (1210-001508, 1210-001519, 1210-001525, 1210-001448) |  |
|  |  |  |  |  |  |  |  |  |  |  | Visual inspection (1005202) | **X** |
| **Connector contact block** | Contact with lead | High impedance or open at contact interface | stim compromised | 100% electrical test |  | Poor contact | 2 | 1 | 2 | 4 | DVT for motion testing (MERE 0440) |  |
|  |  |  |  |  |  |  |  |  |  |  | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182) | **X** |
|  |  |  |  |  |  | Corrode | 2 | 1 | 1 | 2 | Spring Platinum material requirement (1211-000414) |  |
|  |  |  |  |  |  |  |  |  |  |  | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182) | **X** |
|  |  | does not accept lead | Excess insertion force | Visual inspection |  | Inner spring not seated or otherwise interferes | 2 | 1 | 3 | 6 | DVT for insertion force (MERE 0440) |  |
|  |  |  |  |  |  |  |  |  |  |  | Bore inspection (1007700) | **X** |
|  | Contact with lead frame | Open circuit on that channel | stim compromised | 100% electrical test |  | material incompatible with lead frame | 2 | 1 | 1 | 2 | Material selection of like materials (1210-000414, 1210-001534 - 001538) |  |
|  |  |  |  |  |  |  |  |  |  |  | Material cert (1003484) |  |
|  |  |  |  |  |  | Inadequate weld surface area | 2 | 1 | 1 | 2 | Weld process validation (1005214) | **x** |
|  |  |  |  |  |  |  |  |  |  |  | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182) | **X** |
| **Setscrew block & setscrew** | retain lead | does not retain lead | stim compromised | physician observes torque wrench does not click |  | setscrew strips | 2 | 3 | 3 | 18 | Torque –limiting wrench – torque specification requirement (1005444) |  |
|  |  |  |  |  |  |  |  |  |  |  | Labeling to ensure torque wrench clicks (0300-000021, 0300-000022, 0300-000036) |  |
|  |  |  |  |  |  | low friction force | 2 | 3 | 3 | 18 | Cup tip design –setscrew (friction resists backing out) (1210-001809) |  |
|  |  |  |  |  |  | setscrew not tight enough | 2 | 3 | 3 | 18 | Torque wrench provided with IPG (1007791) |  |
|  |  |  |  | Device fully or partially inoperable |  | setscrew cross threaded – occurs at implant | 2 | 4 | 3 | 24 | Labeling – turn torque wrench clockwise (0300-000021, 0300-000022, 0300-000036) |  |
|  |  | damages lead contact ring | Implanted lead replacement | Physician observes at revision |  | deforms ring, excessive point force | 3 | 5 | 1 | 15 | Torque –limiting wrench – torque specification requirement (1005444) |  |
|  |  |  |  |  |  |  |  |  |  |  | Labeling to require use with torque wrench packaged with product (0300-000021, 0300-000022, 0300-000036) |  |
|  |  |  |  |  |  |  |  |  |  |  | DVT for lead damage (MERE 0440) |  |
|  |  |  |  |  |  |  |  |  |  |  | High strength MP35N lead setscrew ring material (1003821) |  |
|  |  |  |  |  |  |  |  |  |  |  | Setscrew designed with cup tip (not pointed) (1003471) |  |
|  | align with stacker set | block not aligned with stacker set | Unable to insert lead | Visual inspection, subsequent process steps |  | compression of strain relief by setscrew block moves setscrew block out of alignment with stacker set | 2 | 1 | 1 | 2 | Interlocks w/stacker (1210-001525, 1210-001448, 1210-001512, 1210-001517) |  |
|  |  |  |  |  |  |  |  |  |  |  | Visual inspection (1005202) | **X** |
|  | Keep setscrew actively captured | setscrew fall in bore | Unable to insert lead | Physician observes at implant |  | Vibration during shipment | 2 | 1 | 1 | 2 | Screw is designed too long to fall in (1210-001809) |  |
|  |  |  |  |  |  |  |  |  |  |  | DVT for vibration & setscrew retention (MERE 0440) |  |
|  |  |  |  |  |  |  |  |  |  |  | Setscrew block not threaded all the way (1210-001512, 1210-001517) |  |
| Counterbore in the septum (1210-001819, 1210-001820) |  |
|  |  | setscrew fall out | Unable to secure lead | Physician observes at implant |  | Vibration during shipment | 2 | 1 | 2 | 4 | Septum designed to keep screw in block (1210-001819, 1210-001820) |  |
|  | Allow setscrew to tighten | Setscrew will not tighten | Unable to secure lead | Physician observes lead still loose after tightening setscrew |  | Binding of screw threads, wear debris | 2 | 3 | 3 | 18 | Thread class 2A specified on setscrew to allow wear debris some clearance (1210-001809) |  |
|  |  |  |  |  |  |  |  |  |  |  | DVT for lead insertion & withdrawal (MERE 0440) |  |
| **Strain relief** | relieve strain on lead | insufficient strain relief | latent lead failures | Device fully or partially inoperable, patient may detect & turn off stim with subsequent impedance measurement |  | stress concentration point | 3 | 5 | 1 | 15 | DVT flex test (lead connector flex test MERE 0189) |  |
|  | compress stackers | loss of stacker compression | electrical leakage / unintended stim, high insertion force | Device fully or partially inoperable, clinician programmer diagnostic Impedance measurement |  | strain relief or header material compression set | 2 | 5 | 2 | 20 |  |  |
| Backfilled header (1006560) |  |
|  |  |  |  |  |  |  |  |  |  |  | Durometer set to 50A, requirement added for post-cure (1210-001675, 1210-001549) |  |
|  | Seal bore from backfill | Backfill leaks in | High insertion force, electrical fail, seal fail, fail to insert | Borescope inspection |  | Improper fit | 2 | 1 | 2 | 4 | Compressed seal (1007762) |  |
|  |  |  |  |  |  |  |  |  |  |  | 100% borescope inspection (1007700) | **X** |
| **Septum** | retain setscrew in position outside of bore | setscrew blocks lead entry | can’t insert lead w/o backing screw out | Physician observes at implant |  | setscrew migrates into bore | 1 | 1 | 4 | 4 | Interference fit between setscrew threads and septum (1210-001819, 1210-001820, 1210-001809) | **X** |
|  |  |  |  |  |  |  |  |  |  |  | DVT vibration (MERE 0440) |  |
|  | keeps setscrew clean | Unable to insert torque wrench | can’t replace IPG on revision (force explant of lead along with IPG) | Physician observes at revision |  | tissue encapsulation or other biological material interfering | 3 | 5 | 2 | 30 | Tight seal fit (compression fit of 2 halves) (1210-001819, 1210-001820) |  |
|  | retains setscrew in header assembly | setscrew falls out | cannot assemble system | Physician observes at implant |  | setscrew backs completely out | 1 | 1 | 2 | 2 | Movement resisted by interference fit between setscrew threads and septum 1210-001819, 1210-001820, 1210-001809) |  |
| Torque wrench ‘click’ (1005444) |  |
|  | allows access to set screw | can’t access setscrew | cannot assemble system | Physician observes at implant or revision |  | seal ‘heals’, to halves seal together | 1 | 3 | 1 | 3 | 2-piece molded design (1210-001819, 1210-001820) |  |
|  | seal setscrew threads from backfill | backfill leaks into threads | difficulty retaining lead | Physician observes at implant |  | Improper fit / installation | 2 | 2 | 3 | 12 | Process step to insert setscrew & back out (1007762) | **X** |
|  |  |  |  |  |  |  |  |  |  |  | Septum design feature to block backfill (1210-001819, 1210-001820) |  |
|  |  |  |  |  |  |  |  |  |  |  | Use silicone adhesive between header & septum (1011489) | **X** |
| **Header shell** | compress stacker | does not maintain dimensional integrity over time | electrical leakage / unintended stim | Device fully or partially inoperable, clinician programmer diagnostic Impedance measurement |  | header material compression set | 2 | 5 | 1 | 10 | Accelerated aging test (MERE 0478) |  |
|  |  |  |  |  |  |  |  |  |  |  | Changed material from polyurethane to polysulfone material (1211-000500, 1211-000499) |  |
|  |  |  |  |  | solvent attack | header cracks | 2 | 5 | 2 | 20 | Anneal header (1211-000499, 1211-000500) | **X** |
|  | align stackers | loss of stacker alignment | high insertion force | Physician observes at revision |  | header material compression set | 2 | 5 | 1 | 10 | Interlocking stacker design (1210-001525, 1210-001448, 1210-001508, 1210-001519) |  |
|  |  |  |  |  |  |  |  |  |  |  | Accelerated aging test (MERE 0478) |  |
|  |  |  |  |  |  |  |  |  |  |  | Changed material from polyurethane to polysulfone material (1211-000500, 1211-000499) |  |
|  | relieve strain on lead, provides minimum bend radius | insufficient strain relief | latent lead failures | Device fully or partially inoperable, patient may detect & turn off stim with subsequent impedance measurement |  | stress concentration point | 3 | 5 | 2 | 30 | Lead DVT flex test (MERE 0189) |  |
|  | mechanical protection | internal parts damaged | stim output compromised | Device fully or partially inoperable, patient may detect & turn off stim with subsequent impedance measurement |  | force applied to header is transferred to internal header components | 2 | 5 | 2 | 20 | Header material is rigid (1211-000500, 1211-000499) |  |
|  |  |  |  |  |  |  |  |  |  |  | Header anchored to can (1211-000430, 1211-000435) |  |
|  | form to hold backfill | does not retain backfill between can and header | stim output compromised | Visual inspection of header backfill |  | silicone adhesive leaks out | 2 | 1 | 2 | 4 | DVT for leakage of backfill into bore (MERE 0440) |  |
|  |  |  |  |  |  |  |  |  |  |  | Visual inspection (1007762, 1007803) | **X** |
|  | anchors IPG | IPG migrates or flips | explant, recharge inefficiency | Physician observes increased charging time or diminished RF communication | Excessive force on suture hole | suture holes break | 3 | 4 | 1 | 12 | Minimum material between suture hole and edge requirement (1211-000500, 1211-000499) |  |
|  |  |  |  |  |  |  |  |  |  |  | DVT suture pull strength (MERE 0440) |  |
|  |  |  |  |  | solvent attack |  | 3 | 4 | 2 | 24 | Anneal header (1211-000499, 1211-000500) |  |
|  | Connect to IPG can | gap in connection | electrical leakage, infection | Visual inspection of header backfill |  | header slot interference with l-tabs | 3 | 2 | 2 | 12 | Visual indication during process if not seated (1005238) | **X** |
|  |  |  |  |  |  |  |  |  |  |  | Visual inspection (1007762, 1007803) | **X** |
|  |  | sharp edge between header & can | tissue irritation, catch on physician’s glove | visual inspection |  | flash on part edge | 3 | 2 | 3 | 18 | Visual inspection (1005875, 1005872) | **X** |
|  |  |  |  |  |  |  |  |  |  |  | DVT report (MERE 0440) |  |
|  |  |  |  |  |  | inadequate gap filling | 3 | 2 | 3 | 18 | Visual inspection (1008609) | **X** |
|  |  |  |  |  |  |  |  |  |  |  | DVT report (MERE 0440) |  |
| **Seals** | Electrical insulation between contacts | No insulation | Unintended stim | Device fully or partially inoperable, clinician programmer diagnostic impedance measurement |  | Seal damage / contamination | 2 | 4 | 3 | 24 | DVT for leakage (MERE 0440) |  |
|  |  |  |  |  |  |  |  |  |  |  | Transparent stacker material (1210-001525, 1210-001448) |  |
|  |  |  |  |  |  |  |  |  |  |  | 100% borescope inspection (1007700) | **X** |
|  | Flexible , allow lead to pass | High insertion force | Damage lead, unable to insert | Physician observes at implant, borescope inspection |  | ID too small | 2 | 2 | 2 | 8 | ID specified (1210-001521) |  |
|  |  |  |  |  |  |  |  |  |  |  | DVT insertion force (MERE 0440) |  |
|  |  |  |  |  |  | flash | 2 | 2 | 2 | 8 | Limited flash drawing requirement (1210-001521) |  |
|  |  |  |  |  |  | Foreign material | 2 | 2 | 1 | 4 | Controlled build environment (42054) | **X** |
|  |  |  |  |  |  |  |  |  |  |  | Clean part requirements (1210-001521) |  |
|  |  |  |  |  |  | Incorrect material selection | 2 | 4 | 2 | 16 | DVT insertion force (MERE 0440) |  |
|  |  |  |  |  |  |  |  |  |  |  | Material cert (1210-001521) |  |
| **Silicone Backfill** | Electromechanical Seal between conductors | short between conductors | stim output compromised | visual inspection |  | bubbles | 2 | 3 | 3 | 18 | DVT for insulation resistance 10-day soak (MERE 0440) |  |
| 100 % bubble inspection (1006560, 1007803) | **X** |
|  |  |  |  |  |  | under fill | 2 | 2 | 2 | 8 | Space between conductors specified (MEEX 0099) |  |
|  |  |  |  |  |  |  |  |  |  |  | DVT for insulation resistance 10-day soak (MERE 0440) |  |
|  |  |  |  |  |  |  |  |  |  |  | Visual inspection (1007762, 1007803) | **X** |
|  |  |  |  |  |  | delamination | 2 | 3 | 3 | 18 | DVT for insulation resistance 10-day soak (MERE 0440) |  |
| Visual inspection (1007762, 1007803) | **X** |
|  | Electromechanical seal to external environment | short to external environment or can | Unintended stim | visual inspection |  | bubbles | 2 | 3 | 3 | 18 | DVT for insulation resistance 10-day soak (MERE 0440) |  |
|  |  |  |  |  |  |  |  |  |  |  | Bubble inspection (1006560, 1007803) | **X** |
|  |  |  |  |  |  | under fill | 2 | 2 | 2 | 8 | Space between conductors specified (MEEX 0099) |  |
|  |  |  |  |  |  |  |  |  |  |  | DVT for insulation resistance 10-day soak (MERE 0440) |  |
|  |  |  |  |  |  |  |  |  |  |  | Visual inspection (1007762, 1007803) | **X** |
|  |  |  |  |  |  | delamination | 2 | 3 | 3 | 18 | DVT for insulation resistance 10-day soak (MERE 0440) |  |
|  |  |  |  |  |  |  |  |  |  |  | Visual inspection (1007762, 1007803) | **X** |
|  | Secures parts in place | in wrong place | stim output compromised, high lead insertion force | electrical test |  | Lead frame move during backfill operation | 2 | 2 | 2 | 8 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182) | **X** |
|  |  |  |  |  |  |  |  |  |  |  | Visual inspection (1007762, 1007803) | **X** |
|  |  | move over time | stim output compromised, high lead insertion force | Device fully or partially inoperable, patient may detect & turn off stim with subsequent impedance measurement |  | material not strong enough to retain parts in position | 2 | 4 | 2 | 16 | Material certification required (1210-001690) |  |
|  | Allows visualization of lead tip | cannot see lead tip when inserted | lead not fully inserted -stim output compromised, unintended stim | Device fully or partially inoperable, may be detected at implant if one or more contacts is not connected | contamination | cloudy, bubbles | 2 | 2 | 2 | 8 | Specify clear adhesive (1210-001690) |  |
|  | Provides smooth top edge | internal sharp edges exposed | tissue irritation, erosion | visual inspection for sharp edges |  | under fill exposing internal edges of components or connector | 3 | 2 | 2 | 12 | DVT for smooth edges (MERE 0440) |  |
|  |  |  |  |  |  |  |  |  |  |  | Visual inspection (1007762, 1007803) | **X** |
|  | eliminate small spaces | small spaces in IPG not filled (for microbes to hide) | infection | visual inspection |  | under fill exposing internal edges of components or connector | 3 | 3 | 2 | 18 | DVT for smooth edges (MERE 0440) |  |
|  |  |  |  |  |  |  |  |  |  |  | Visual inspection (1007762, 1007803) | **X** |
|  |  |  |  |  |  | bubbles | 3 | 3 | 2 | 18 | DVT for insulation resistance 10-day soak (MERE 0440) |  |
|  |  |  |  |  |  |  |  |  |  |  | Visual inspection (1007762, 1007803) | **X** |
|  | Protect lead frames | Allows external damage | unintended stimulation | Device partially inoperable, patient may detect & turn off stim with subsequent impedance measurement |  | Scalpel cut or other sharp object | 2 | 5 | 2 | 20 | IFU includes statement about handling IPG & potential damage from sharp instruments (0300-000020) |  |
| **Silicone adhesive** | Adheres septum to header, to hold in place & prevent backfill ingress | backfill ingress seals septum halves together | Unable to implant, prevents physician from inserting torque wrench | visual inspection |  | excessive amount of material applied | 2 | 3 | 3 | 18 | visual inspection (1007762, 1007803, 1011489) | **X** |
|  | Adheres septum to header to hold in place & prevent backfill ingress | backfill ingress to back of header | tissue irritation due to uneven surface | visual inspection |  | excessive amount of material applied | 3 | 2 | 2 | 12 | visual inspection (1007762, 1007803, 1011489) | **X** |
| **Epoxy** | Bond header to enclosure | Header separates from enclosure | unintended stimulation, Lose MICS, possible revision | visual inspection | Poor surface preparation | Inadequate bond strength | 3 | 3 | 2 | 18 | Application of primer to prepare bond surface (1005238) |  |
|  |  |  |  |  | Poor mixing |  | 3 | 2 | 1 | 6 | Specify using frozen pre-mixed epoxy (1210-001689) |  |
|  |  |  |  |  | Improper material selection |  | 3 | 2 | 1 | 6 | DVT for header bend, pull, push (MERE 0440) |  |
| **Anchor pin & L-tab** | align header in place during epoxy cure | header misaligned | potential tissue irritation | visual inspection, & subsequent process | bad weld | ‘L’ tab separates from can | 3 | 1 | 2 | 6 | L-tab weld process validation (1005214) | **X** |
|  |  |  |  |  |  |  |  |  |  |  | Specify sufficient material (1210-001500) |  |
|  |  |  |  |  |  |  |  |  |  |  | DVT for connector pull strength (MERE 0440) |  |
|  |  |  |  |  |  |  |  |  |  |  | Visual inspection (1005238, 1007803) | **X** |
|  |  |  |  |  |  |  |  |  |  |  | Epoxy bond provides joining strength at interface and reduces movement (1008609) |  |
|  |  |  |  |  |  | fail to insert pin | 3 | 1 | 2 | 6 | Visual inspection (1005238, 1007803) | **X** |
|  |  |  |  |  |  |  |  |  |  |  | Design utilizes a visual, flush, hard stop, when pin is inserted fully and correctly (1211-000500, 1211-000499, 1210-001523) |  |
|  |  |  |  |  |  | Out of alignment (right-left) | 3 | 1 | 2 | 6 | Pins will not insert if out of alignment this direction (1005238) |  |
|  |  |  |  |  |  |  |  |  |  |  | Visual inspection (1005238, 1007803) | **X** |
|  |  |  |  |  |  | Out of alignment (front back) | 3 | 1 | 2 | 6 | Connector will not fit on to ‘L’ tabs if out of alignment in this direction (1005238) |  |
|  |  |  |  |  |  |  |  |  |  |  | Visual inspection (1005238, 1007803) | **X** |
|  |  |  |  |  |  | Out of alignment (up down) | 3 | 1 | 1 | 3 | Built into l-tab (1210-001500) |  |
|  |  |  |  |  |  |  |  |  |  |  | Visual inspection (1005238, 1007803) | **X** |
| **Charge coil** | Pick up inductive charge | No energy pickup | Stimulation eventually stops | Charge at final electrical test | Broken wire | Coil open | 3 | 1 | 2 | 6 | DVT for drop & vibration (MERE 0440) |  |
|  |  |  |  |  |  |  |  |  |  |  | Manual states to charge prior to implant (0300-000021, 0300-000022) |  |
|  |  |  |  |  | Wire connection to block breaks |  | 3 | 1 | 3 | 9 | DVT for drop & vibration (MERE 0440) |  |
|  |  |  |  |  |  |  |  |  |  |  | Strain relief between wound coil and PCB (1010552) |  |
|  |  | Does not pick up sufficient energy | Excessive recharge time | Charge at final electrical test | Compromised insulation | Coil short to can, other windings, or other components | 2 | 3 | 2 | 12 | DVT for drop & vibration (MERE 0440) |  |
| Added 1-mil parylene coating (1010235) |  |
| **Weld band** | Protects charge coil from weld splatter | Allows heat/splatter through | Damage coil, will not charge or excessive charge time | Device fully or partially inoperable, charge controller indicates error to patient |  | Falls off or moves up or down at or prior to seam weld | 3 | 2 | 3 | 18 | Laser weld band-to-can all the way around before weld operation (1010550) |  |
|  |  |  |  |  |  |  |  |  |  |  | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182) | **X** |
| **Rigid flex board** | Provides electrical connection between PCB & FT | Open circuit prior to use | Device output failure, loss of communication, or loss of recharge capability | patient may detect & turn off stim with subsequent impedance measurement | Flex fatigue | conductor fracture | 3 | 1 | 1 | 3 | Flat wide design (1320-000050) |  |
|  |  |  |  |  |  |  |  |  |  |  | DVT vibration (MERE 0440) |  |
|  |  | Intermittent or latent open | Device output failure, loss of communication, or loss of recharge capability | Device partially inoperable, patient may detect & turn off stim with subsequent impedance measurement | Flex fatigue | conductor fracture | 3 | 4 | 2 | 24 | Flat wide design, 2nd moment of area in flex axis (1010233) |  |
|  |  |  |  |  |  |  |  |  |  |  | DVT vibration (MERE 0440) |  |
|  |  | Short to can | Unintended stim | patient may detect & turn off stim with subsequent impedance measurement |  | Fractured flex member straightens out, then touches can | 2 | 1 | 1 | 2 | Polyimide overlay on both sides of ‘flex member’ (1320-000050) |  |
|  |  |  |  |  |  |  |  |  |  |  | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182) | **x** |
|  |  |  |  |  |  |  |  |  |  |  | Recharge coil insulated (1010235) |  |
| **Battery** | Provide power to circuit board | Does not provide power initially | Device output failure, loss of communication, or loss of recharge capability | 100% electrical test | Inadequate weld process | Weld failure | 3 | 1 | 2 | 6 | Weld process validation for pull strength (EEPR 0181, EEPR 0182) | **x** |
| Pull strength design requirement (1005467) |  |
| 100% electrical test in manufacturing (EEPR 0181, EEPR 0182) | **X** |
| Charge level adjustment prior to shipping (EESP 0071) |  |
| Manual states to fully charge prior to implant (0300-000021, 0300-000022) |  |
|  |  |  |  |  | Shock & vibration |  | 3 | 3 | 2 | 18 | DVT for shock & vibration (MERE 0440) |  |
| 100% electrical test in manufacturing (EEPR 0181, EEPR 0182) | **X** |
| Manual states to fully charge prior to implant (0300-000021, 0300-000022) |  |
|  |  |  |  |  | Incompatible weld material |  |  |  |  |  | Material specification for inter-connect ribbon & block (1210-001445) |  |
|  |  |  |  |  |  |  | 3 | 1 | 1 | 3 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182) | **X** |
|  |  |  |  |  | Incorrect component material | Battery tab failure | 3 | 1 | 2 | 6 | DVT for shock & vibration (MERE 0440) |  |
|  |  |  |  |  |  |  |  |  |  |  | Manual states to fully charge device prior to implant (0300-000021, 0300-000022) |  |
|  |  |  |  |  |  |  |  |  |  |  | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182) | **X** |
|  |  |  |  |  |  |  |  |  |  |  | Material specified on drawing (1210-001539) |  |
|  |  | Does not provide power latently | Device output failure, loss of communication, or loss of recharge capability | Device fully or partially inoperable, hardware shutdown | Inadequate weld process | Weld failure ribbon to board, ribbon to battery | 3 | 5 | 2 | 30 | Weld process validation for pull strength (Report 2010-0596 Ni Lead to Negative Pin weld, Report 2010-0871 Ni Lead to Moly pin weld) | **X** |
| Pull strength design requirement (1211-000436) |  |
|  |  |  |  |  | Shock & vibration |  | 3 | 5 | 2 | 30 | DVT for shock & vibration (MERE 0440) |  |
|  |  |  |  |  | Incompatible weld material |  | 3 | 5 | 1 | 15 | Material specification for inter-connect ribbon & block (1210-001539) |  |
|  |  |  |  |  | Corrosion | Latent disconnect from the board | 3 | 5 | 1 | 15 | Hermetic design with inert atmosphere (1005239) |  |
| 100% leak test (1010778) | **X** |
|  |  |  |  |  | Cycle fatigue cracking |  | 3 | 5 | 1 | 15 | DVT vibration test (MERE 0440) |  |
| Design of nickel strip (1210-001539) |  |
| Battery & board mounted on common chassis (1211-000436) |  |
|  |  |  |  |  | Battery tab failure -incorrect material |  | 3 | 5 | 1 | 15 | DVT for shock & vibration (MERE 0440) |  |
|  |  |  |  |  |  |  |  |  |  |  | Material specified (1210-001539) |  |
|  |  |  |  |  | Intermetallics |  | 3 | 5 | 1 | 15 | Report summarizing assessment of intermetallics at battery/ribbon weld (RER 2012-0871) |  |
|  |  | Provides power intermittently | Intermittent device output failure, loss of communication, or loss of recharge capability | Device fully or partially inoperable, hardware shutdown | Inadequate weld process | Weld failure ribbon to board, ribbon to battery | 3 | 4 | 2 | 24 | Weld process validation for pull strength (1005214) | **X** |
| Pull strength design requirement (1211-000436) |  |
|  |  |  |  |  | Shock & vibration |  | 3 | 4 | 2 | 24 | DVT for shock & vibration (MERE 0440) |  |
|  |  |  |  |  | Incompatible weld material |  | 3 | 4 | 1 | 12 | Material specification for inter-connect ribbon & block (1210-001539) |  |
|  |  |  |  |  | Corrosion | Intermittent disconnect from the board | 3 | 4 | 1 | 12 | Hermetic design with inert atmosphere (1211-000436) |  |
|  |  |
| 100% leak test (1010778) | **X** |
|  |  |  |  |  | Cycle fatigue cracking |  | 3 | 4 | 1 | 12 | DVT vibration test (MERE 0440) |  |
| Design of nickel strip (1210-001539) |  |
| Battery & board mounted on common chassis (1211-000436) |  |
|  |  |  |  |  | Battery tab failure -incorrect material |  | 3 | 4 | 1 | 12 | DVT for shock & vibration (MERE 0440) |  |
|  |  |  |  |  | Intermetallics |  | 3 | 4 | 1 | 12 | Report summarizing assessment of intermetallics at battery/ribbon weld (RER 2012-0871) |  |
|  | maintain hermetic battery seal | Battery hermetic seal fails | Device output failure, loss of communication, or loss of recharge capability | Device fully or partially inoperable | Hermetic IPG can seal failure | Wet short resulting in moly pin corrosion | 3 | 5 | 1 | 15 | Battery reliability evaluation report with shock and hermetic seal test (RER-2010-0950) |  |
| 100% battery production seal testing (1B9514, 1CP-02-C01) | **X** |
| Battery fluid exposure test report (RDE 11-597) |  |
|  | rechargeable | Fails to recharge initially | Device output failure, loss of communication, or loss of recharge capability | 100% electrical test | Mechanical vibration/shock | Conductive path broken | 3 | 1 | 2 | 6 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182) | **X** |
| DVT shock/vibration (MERE 0440) |  |
|  |  |  |  |  |  |  |  |  |  |  | Battery reliability evaluation report with shock and hermetic seal test (RER-2010-0950) |  |
|  |  | Fails to recharge latently | Device output failure, loss of communication, or loss of recharge capability | Device fully or partially inoperable, charge controller indicates error to patient | Mechanical vibration/shock | Conductive path broken | 3 | 5 | 2 | 30 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182) | **X** |
| Battery reliability evaluation report with shock and hermetic seal test (RER-2010-0950) |  |
|  |  |  |  |  |  |  |  |  |  |  | IPG DVT shock/vibration, shield flex (MERE 0440) |  |
|  |  |  |  |  | Weld failure | Electrolyte leaking | 3 | 5 | 1 | 15 | Weld process qualification (RER 10-0336, RER 10-0335) | **X** |
| Production sampling (1PI-19-C02-S03-K) | **X** |
|  |  |  |  |  | Glass seal failure |  | 3 | 5 | 1 | 15 | Glass seal process validated (RER 2010-0318) | **X** |
| 100% helium leak test (1010778) | **X** |
|  | Maintain capacity | High discharge rate latently | Heating | Device fully or partially inoperable, | Dry interconnect short cathode to case | Short | 4 | 5 | 1 | 20 | Cathode battery terminal encased by plastic box (1210-001539) |  |
|  |  |  |  |  |  |  |  |  |  |  | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182) | **X** |
|  |  |  |  |  |  |  |  |  |  |  | Evaluation testing demonstrated limited temperature rise & duration (MERE 0331 Battery Short Circuit Testing Report) |  |
|  |  |  |  | Device fully or partially inoperable, | Dry interconnect short anode to cathode |  | 4 | 5 | 1 | 20 | Large separation distance between anode & cathode (1210-001539) |  |
|  |  |  |  |  |  |  |  |  |  |  | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182) | **X** |
|  |  |  |  |  |  |  |  |  |  |  | Evaluation testing demonstrated limited temperature rise & duration (MERE 0331 Battery Short Circuit Testing Report) |  |
|  |  |  |  | Fuse opens circuit | Circuit board short |  | 4 | 5 | 1 | 20 | Fuse on PC board near battery connection (1320-000050, 1330-000050) |  |
|  |  |  |  | Device fully or partially inoperable, | Internal battery short |  | 4 | 5 | 1 | 20 | Tri-layer separator with shutdown function (1B9497, 90338) |  |
| 100% production voltage stability testing (1PI-31-C01) | **X** |
| Insulation design effectiveness tested (RER 2010-0950) |  |
|  |  | Slightly higher than normal discharge rate | Increased recharge frequency | Patient notices increased recharge frequency |  | Wet short | 2 | 5 | 1 | 10 | Characterization testing for current draw (RDE 12-535 M2993) |  |
|  |  |  |  |  |  |  |  |  |  |  | 100% hermetic seal test-process (1B9514, 1CP-02-C01) | **X** |
|  |  | Lost capacity over time | Decreased battery life | Patient notices increased recharge frequency |  | Drain to zero volts too frequently | 2 | 5 | 1 | 10 | Deep discharge tolerant battery (EESP 0071 FRS 0873) |  |
| Low battery storage mode (EESP 0071 F2850) |  |
| **Base battery holder** | aligns battery to board | does not align battery | Device output failure, loss of communication, or loss of recharge capability | Device fully or partially inoperable | Vibration ,impact, or pressure | component fractures | 3 | 5 | 1 | 15 | Battery connection strain relief (1210-001539, 1010551) |  |
|  |  |  |  |  |  |  |  |  |  |  | Component fills enclosure space (1210-001496) |  |
|  |  |  |  |  |  |  |  |  |  |  | Use non-brittle material (1210-001496) |  |
|  |  |  |  |  |  |  |  |  |  |  | DVT includes vibration, load, and impact tests (MERE 0440) |  |
| **Cap battery holder** | aligns battery to the enclosure | does not align battery to enclosure | Device output failure, loss of communication, or loss of recharge capability | Device fully or partially inoperable | Vibration ,impact, or pressure | component fractures | 3 | 5 | 1 | 15 | Battery connection strain relief (1210-001539, 1010551) |  |
|  |  |  |  |  |  |  |  |  |  |  | Component fills enclosure space (1210-001679) |  |
|  |  |  |  |  |  |  |  |  |  |  | Use non-brittle material(1210-001679) |  |
|  |  |  |  |  |  |  |  |  |  |  | DVT includes vibration, load, and impact tests (MERE 0440) |  |
| **Front side frame** | spaces PCB away from enclosure | allows components to touch enclosure | Device output failure, loss of communication, or loss of recharge capability | Device fully or partially inoperable | Vibration ,impact, or pressure | component fractures | 3 | 5 | 1 | 15 | Use non-brittle material (1210-001691) |  |
|  |  |  |  |  |  |  |  |  |  |  | DVT includes vibration, load, and impact tests (MERE 0440) |  |
| **Dessicant** | absorbs excess moisture | corrosion | Device output failure, loss of communication, or loss of recharge capability | Device fully or partially inoperable |  | excess surface moisture | 3 | 5 | 2 | 30 | 100% hermetic seal test (1010778) | **X** |
|  |  |  |  |  |  |  |  |  |  |  | Manufacturing drying procedure (1010495) | **X** |
| **Battery Insulator** | Electrical insulates battery from board | Short battery to board | Device output failure, loss of communication, or loss of recharge capability | Visual inspection | Handling during manufacturing | Perforation in insulation | 3 | 1 | 2 | 6 | Manufacturing steps require minimal handling (1010895) | **X** |
|  |  |  |  | Visual inspection | Contaminated adhesive | Insulator detached | 3 | 2 | 1 | 6 | Manufacturing step to place insulator right after backing removed (1010895) | **X** |
|  |  |  |  | Visual inspection | Mishandling during manufacturing |  | 3 | 2 | 2 | 12 | Manufacturing steps require minimal handling (1010895) | **X** |
|  |  |  |  |  |  |  |  |  |  |  | Design requirement for no unbonded edged (1211-000436) |  |
| **Graphite Sheets** | Distribute heat along can surface | Local hot spots on exterior of can | Tissue heating during recharge | 100% electrical test, local temperature monitored during charge | Contaminated adhesive | Detached from can | 4 | 2 | 2 | 16 | Manufacturing step to place insulator right after backing removed (1010895) | **X** |
| 100% thermistor electrical test in manufacturing (EEPR 0181, EEPR 0182) | **X** |
|  |  |  |  | 100% electrical test , local temperature monitored during charge | Mishandling during manufacturing |  | 4 | 2 | 2 | 16 | Manufacturing procedure uses fixture and vacuum to conform sheet to can half (1010895) | **X** |
|  |  |  |  |  |  |  |  |  |  |  | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182) | **X** |
|  |  |  |  | 100% electrical test , local temperature monitored during charge | Mishandling during manufacturing | Excessive perforation of graphite layer | 4 | 2 | 2 | 16 | Manufacturing procedure uses fixture and vacuum to conform sheet to can half (1010895 | **X** |
|  |  |  |  |  |  |  |  |  |  |  | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182) | **X** |
|  |  |  |  | 100% electrical test , local temperature monitored during charge | Component defect |  | 4 | 1 | 2 | 8 | Design drawing states no perforations (1210-001452, 1210-001453) |  |
|  |  |  |  |  |  |  |  |  |  |  | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182) | **X** |
|  |  |  | Extended recharge time | 100% electrical test , local temperature monitored during charge | Contaminated adhesive | Detached from can | 2 | 5 | 1 | 10 | Manufacturing step to place insulator right after backing removed (1010895) | **X** |
|  |  |  |  |  |  |  |  |  |  |  | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182) | **X** |
|  |  |  |  | 100% electrical test , local temperature monitored during charge | Mishandling during manufacturing |  | 2 | 5 | 1 | 10 | Manufacturing procedure uses fixture and vacuum to conform sheet to can half (1010895 | **X** |
|  |  |  |  |  |  |  |  |  |  |  | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182) | **X** |
|  |  |  |  | 100% electrical test , local temperature monitored during charge | Mishandling during manufacturing | Excessive perforation of graphite layer | 2 | 5 | 1 | 10 | Manufacturing procedure uses fixture and vacuum to conform sheet to can half (1010895 | **X** |
|  |  |  |  |  |  |  |  |  |  |  | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182) | **X** |
|  |  |  |  | 100% electrical test , local temperature monitored during charge | Component defect |  | 2 | 5 | 1 | 10 | Design drawing states no perforations (1210-001452, 1210-001453) |  |
|  |  |  |  |  |  |  |  |  |  |  | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182) | **X** |
|  | Electrically insulate can from active internal parts | Short battery to can | Connects enclosure channel to ground, Device output failure, loss of communication, or loss of recharge capability | Electrical testing | Mishandling during manufacturing | Perforation of insulating layer | 3 | 2 | 1 | 6 | Manufacturing procedure uses fixture and vacuum to conform sheet to can half (1010895 | **X** |
| 100% Electrical test in manufacturing (EEPR 0181, EEPR 0182) | **X** |
|  |  |  |  |  | Component defect |  | 3 | 2 | 1 | 6 | Design drawing states no perforations (1210-001452, 1210-001453) |  |
| Visual inspection of component (1010244, 1010251) | **X** |
|  |  | Short PCB assembly to can | Device output failure, loss of communication, or loss of recharge capability | Electrical testing | Mishandling during manufacturing | Perforation of insulating layer | 3 | 2 | 1 | 6 | Manufacturing procedure uses fixture and vacuum to conform sheet to can half (1010895 | **X** |
| 100% Electrical test in manufacturing (EEPR 0181, EEPR 0182) | **X** |
|  |  |  |  |  | Component defect |  | 3 | 2 | 1 | 6 | Design drawing states no perforations (1210-001452, 1210-001453) |  |
|  |  |  |  |  |  |  |  |  |  |  | 100% Electrical test in manufacturing(EEPR 0181, EEPR 0182) | **X** |
| **ID Tag** | Provides device identification under x-ray | Short PCB assembly | Premature device failure | Device fully or partially inoperable | Misassembled | ID tag escapes from recess in cap battery holder | 3 | 5 | 1 | 15 | Trap fit cap battery holder (1210-001679) |  |
| Manufacturing procedure (1012549) | **X** |
|  |  |
|  |  |  |  |  | Mechanically shocked |  | 3 | 5 | 1 | 15 | Trap fit cap battery holder (1210-001679) |  |
| DVT after mechanical shock (MERE 0440) |  |
| Epoxy between ID tag and cap battery holder (1012549) | **x** |
|  |  | Unable to read ID | Physician inconvenience - Difficult to identify implanted device | x-ray | Misassembled | ID tag escapes from recess in cap battery holder | 1 | 5 | 1 | 5 | Trap fit cap battery holder (1210-001679) |  |
| Manufacturing procedure (1012549) | **X** |
|  |  |  |  |  |  |  |  |  |  |  | X-ray silhouette of IPG shape is recognizable (1211-000430, 1211-000435) |  |
|  |  |  |  |  | Mechanically shocked |  | 1 | 5 | 1 | 5 | Trap fit cap battery holder (1210-001679) |  |
| DVT after mechanical shock (MERE 0440) |  |
|  |  |  |  |  |  |  |  |  |  |  | Epoxy between ID tag and cap battery holder (1012549) | **x** |
|  |  |  |  |  |  |  |  |  |  |  | X-ray silhouette of IPG shape is recognizable (1211-000430, 1211-000435) |  |
| **Thermistor** | Monitor temperature of enclosure during charging | Unable to accurately monitor temperature | potential tissue heating above 41C | Electrical test | poor solder joint | failed connection to PCB | 4 | 1 | 3 | 12 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182) | **X** |
|  |  |  |  |  |  |  |  |  |  |  | Check thermistor function prior to charging (SWSP 0112 # 527) |  |
|  |  |  |  |  | vibration/shock |  | 4 | 2 | 3 | 24 | DVT for shock & vibration (MERE 0440) |  |
|  |  |  |  |  |  |  |  |  |  |  | Check thermistor function prior to charging (SWSP 0112 # 527) |  |
|  |  |  |  |  | broken wire |  | 4 | 1 | 3 | 12 | 100% electrical test, in manufacturing (EEPR 0181, EEPR 0182) | **X** |
|  |  |  |  |  |  |  |  |  |  |  | Check thermistor function prior to charging (SWSP 0112 # 527) |  |
|  |  |  | poor diagnostics, small offset between can and thermistor temperature | Electrical test | potting issues | poor thermal connection to can | 2 | 3 | 3 | 18 | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182) | **X** |
|  |  |  | Unintended effect - biased current to thermistor delivered to can | IPG firmware thermistor diagnostic detects | compromised insulation | short in thermistor to can | 3 | 5 | 1 | 15 | DVT for shock & vibration (MERE 0440) |  |
|  |  |  |  |  |  |  |  |  |  |  | IPG firmware thermistor diagnostic (SWSP 0112) |  |
|  |  |  |  |  |  |  |  |  |  |  | 100% electrical test in manufacturing (EEPR 0181, EEPR 0182) | **X** |
| **Torque Wrench** | Tighten setscrews to secure lead | Lead secured too loosely | stim output compromised/unintended stim | Supplier testing | defective wrench | clicks at torque too low | 3 | 2 | 1 | 6 | Wrench specification requirement, tested 100% at supplier (1005444) |  |
|  |  |  |  | Device fully or partially inoperable | overuse of wrench |  | 3 | 5 | 2 | 30 | Labeled as single use (0300-000021, 0300-000022, 0300-000036, 1210-001897) |  |
|  |  |  |  | manufacturing process | FM/debris in threaded region | wrench clicks prior to engaging lead | 3 | 2 | 2 | 12 | Manufacturing process for loading the screw (1010887) | **X** |
|  |  | Lead secured too tightly | lead damage/ stim output compromised/unintended stim | Supplier testing | defective wrench | clicks at torque too high | 3 | 2 | 1 | 6 | Wrench specification requirement, tested 100% at supplier (1005444) |  |
| **Port Plug** | Fill open bore | debris in bore | unable to insert lead at revision, infection | fluoro |  | falls out | 3 | 5 | 1 | 15 | Manuals states to use torque wrench to secure port plug (0300-000021, 0300-000022, 0300-000036, 1210) |  |
|  |  |  |  | fluoro | screw overtightened | port plug breaks | 3 | 5 | 1 | 15 | Manuals state to use torque wrench to secure port plug (0300-000021, 0300-000022, 0300-000036, 1210) |  |
|  |  |  |  |  |  |  |  |  |  |  | Specified elastic material (1005705) |  |
|  |  | unable to remove at revision | unable to insert lead at revision | visual during revision |  | plug shape deforms | 2 | 5 | 1 | 10 | Manuals state to use torque wrench to secure port plug (0300-000021, 0300-000022, 0300-000036, 1210) |  |
|  |  |  |  |  |  |  |  |  |  |  | Specified elastic material (1005705) |  |
| **Inner tray & Retainer** | Contain parts | Parts move | Physical damage to IPG or contents, can’t implant | Visual |  | Poor fit - parts | 2 | 2 | 2 | 8 | Package design to secure parts from motion (1005730, 1005731) |  |
|  |  |  |  |  |  |  |  |  |  |  | Packaging design validation –vibration & drop (MERE 0223) |  |
|  |  |  |  |  |  | retainer too loose | 2 | 2 | 2 | 8 | Package design to secure parts from motion (1005730, 1005731) |  |
|  |  |  |  |  |  |  |  |  |  |  | Packaging design validation vibration & drop (MERE 0223) |  |
|  |  |  | Component moves & damages sterile barrier, can’t implant | Visual |  | Poor fit - parts | 2 | 2 | 2 | 8 | Package design to secure parts from motion (1005730, 1005731) |  |
|  |  |  |  |  |  |  |  |  |  |  | Packaging design validation vibration & drop (MERE 0223) |  |
|  |  |  |  |  |  | retainer too loose | 2 | 2 | 2 | 8 | Package design to secure parts from motion (1005730, 1005731) |  |
|  |  |  |  |  |  |  |  |  |  |  | Packaging design validation vibration & drop (MERE 0223) |  |
|  | Removable from outer tray without exposure to non-sterile handling | Stuck in outer tray | Physician inconvenience - Difficult to remove inner tray from outer tray | Visual |  | Interference fit | 1 | 3 | 2 | 6 | Dimensional specification (1005729, 1005730) |  |
|  |  |  |  |  |  | Sticky (same materials ‘stick’) | 1 | 3 | 2 | 6 | Material selection (1005729, 1005730) |  |
|  |  | Retainer adhered to outer lid | possible exposure to contaminants, can’t implant | Visual |  | Incorrect position of inner assembly into outer tray | 2 | 3 | 2 | 12 | Design requirement for tray alignment (1007791) |  |
|  |  |  |  |  | lid creep during sterilization | oversealing | 2 | 3 | 4 | 24 | Sterilization orientation specified in sterilization process (M100448) |  |
|  |  |  |  |  |  |  |  |  |  |  | Final pack visual inspection (1007792) | **X** |
|  |  |  |  |  | sealing parameters |  | 2 | 2 | 2 | 8 | Sealing process validation (1005214) | **X** |
|  | Controlled removal of parts | Difficult to remove IPG from cavity | Physician dissatisfaction | Visual |  | Interference fit | 1 | 1 | 2 | 2 | Design requirement for finger pick-outs (1005730) |  |
|  |  | Difficult to remove torque wrench from cavity | Physician dissatisfaction | Visual |  | limited cavity space | 1 | 1 | 1 | 1 | Design requirement for finger pick-outs (1005730) |  |
|  |  | Difficult to remove port plug pouch from cavity | Physician dissatisfaction | Visual |  | limited cavity space | 1 | 1 | 3 | 3 | Design requirement for port plug cavity (1005730) |  |
| **Outer tray & Lid** | Maintain sterility | Cannot sterilize | Infection | visual inspection of sterile pack |  | Not permeable | 3 | 2 | 1 | 6 | Sterilization validation (QARE 0539) | **X** |
|  |  |  |  |  |  |  |  |  |  |  | Material selection (Tyvek) (1007259) |  |
|  |  |  |  |  |  |  |  |  |  |  | Sterile pack configuration used during sterilization (MESP 0093) |  |
|  |  | Does not maintain sterility | Infection | seal visual inspection |  | Seal failure | 3 | 2 | 2 | 12 | Peel width & strength design requirement (MESP 0093) |  |
|  |  |  |  |  |  |  |  |  |  |  | Seal process validation (1005214) | **X** |
|  |  |  |  |  |  |  |  |  |  |  | Shelf life testing (MERE 0391) |  |
|  |  |  |  |  |  |  |  |  |  |  | Seal visual inspection (1007791) | **X** |
|  |  |  |  | Observed prior to implant | product weight and orientation | Premature seal separation (seal creep) due to retainer impacting seal during handling | 3 | 2 | 4 | 24 | Packaging validation testing (MERE 0223) |  |
|  |  |  |  | Sterile & final pack visual inspection | Abrasion | Tyvek Material failure | 3 | 3 | 1 | 9 | Packaging validation testing (MERE 0223) |  |
|  |  |  |  | Sterile & final pack visual inspection | incoming component defect |  | 3 | 2 | 1 | 6 | Sterile & final pack visual inspection (1007791, 1007792) | **X** |
|  |  |  |  |  |  |  |  |  |  |  | Receiving inspection (1005729, 1006695) | **X** |
|  |  |  |  |  |  |  |  |  |  |  | Design requirement for minimum tray thickness (1005729) |  |
|  |  |  |  | Observed prior to implant | Damage during distribution | Tray material failure | 3 | 3 | 1 | 9 | Packaging validation testing (MERE 0223) |  |
|  |  |  |  | Sterile & final pack visual inspection | incoming component defect |  | 3 | 2 | 1 | 6 | Sterile & final pack visual inspection (1007791, 1007792) | **X** |
|  |  |  |  |  |  |  |  |  |  |  | Receiving inspection (1005729, 1006695) | **X** |
|  |  |  |  |  |  |  |  |  |  |  | Design requirement for minimum tray thickness (1005729) |  |
|  | Easy to open with gloved hands | Difficult to open | possible exposure to contaminants, can’t implant | Visual | Excessive adhesion | High peel force | 2 | 3 | 2 | 12 | Adhesive width and material requirement (MESP 0093, 1007259) |  |
|  |  |  |  |  |  |  |  |  |  |  | Visual inspection of seal (1007791) | **X** |
|  |  |  |  | Visual |  | Difficult to hold and peel back | 2 | 3 | 2 | 12 | Design requirement for finger holds (1005730) |  |
| **Labeling** | Identify contents | Label falls off | Adulterated product, Cannot identify / trace product, can’t implant product | Visual |  | Poor label stock adhesion | 2 | 2 | 2 | 8 | Packaging validation for label durability in drop, humidity, and temp cycle (MERE 0223) |  |
|  |  |  |  |  |  |  |  |  |  |  | Final pack visual inspection (1007792) | **X** |
|  |  |  |  |  |  | Mishandling of label prior to and during placement | 2 | 2 | 3 | 12 | Final pack visual inspection (1007792) | **X** |
|  |  | Damage to labels | Adulterated product, Cannot identify / trace product, can’t implant product | Visual |  | Damage during shipment or handling | 2 | 2 | 2 | 8 | Design requirement for label stock thickness (1005905) |  |
|  |  |  |  |  |  |  |  |  |  |  | Packaging validation testing (MERE 0223) |  |
|  |  | Smears | Adulterated product, Cannot identify / trace product, can’t implant product | Visual |  | Non durable ink | 2 | 3 | 2 | 12 | Packaging design validation for label & ink durability in drop, humidity, and temp cycle (MERE 0223) |  |
|  |  | Incorrect content | Adulterated product, Cannot identify / trace product, can’t implant product | Visual |  | Permanent information incorrect | 2 | 3 | 2 | 12 | Label validation (QAPR 0134) |  |
|  |  |  |  |  |  | Variable information incorrect | 2 | 3 | 2 | 12 | Label Process validation (1013324) | **X** |
|  |  |  |  |  |  |  |  |  |  |  | Label validation (QAPR 0134) |  |
|  |  |  |  |  |  |  |  |  |  |  | Final pack visual inspection (1007792) | **X** |
| **Shelf box** | Protect & Contain contents | Damage to sterile barrier system | Sterility compromised, cannot implant | Visual |  | Contents loose | 2 | 2 | 2 | 8 | Design requirement for carton design & dimensions (1007632) |  |
|  |  |  |  |  |  |  |  |  |  |  | Packaging validation testing with vibration, loose load (MERE 0223) |  |
|  |  |  |  |  |  | Carton not durable | 2 | 2 | 2 | 8 | Design requirement for carton design (1007632) |  |
|  |  |  |  |  |  |  |  |  |  |  | Packaging validation testing (MERE 0223) |  |
|  |  |  |  |  |  | Manuals too thick | 2 | 2 | 2 | 8 | Manual fit within carton (1007632) |  |
|  |  |  |  |  |  |  |  |  |  |  | Weight of manuals tested is documented in packaging validation report (MERE 0223) |  |
|  |  |  | damage to product | Visual |  | Contents loose | 2 | 2 | 1 | 4 | Design requirement for carton design & dimensions (1007632) |  |
|  |  |  |  |  |  |  |  |  |  |  | Packaging validation testing with vibration, loose load (MERE 0223) |  |
|  |  |  |  |  |  | Carton not durable | 2 | 2 | 1 | 4 | Design requirement for carton design (1007632) |  |
|  |  |  |  |  |  |  |  |  |  |  | Packaging validation testing (MERE 0223) |  |
|  |  |  |  |  |  | Manuals too thick | 2 | 2 | 1 | 4 | Manual fit within carton (1007632) |  |
|  |  |  |  |  |  |  |  |  |  |  | Weight of manuals tested is documented in packaging validation report (MERE 0223) |  |
|  |  | Damage to Literature | Physician inconvenience | Visual |  | Carton not durable | 1 | 2 | 2 | 4 | Design requirement for carton design (1007632) |  |
|  |  | Loss of literature | Instructions or patient labeling not available, unable to implant | Visual |  | Carton not durable | 2 | 1 | 1 | 2 | Design requirement for carton design & sealable bag (1007632, 1007753) |  |
|  |  |  |  |  |  |  |  |  |  |  | Tear label (1003300) |  |
|  | Facilitates battery charging | Prolonged battery charging | Implant difficulty - device not fully charged at time of implant | Physician observes with clinician programmer |  | Improper alignment of IPG in package | 2 | 2 | 3 | 12 | Design requirement for carton design (1007632) |  |
|  |  |  |  |  |  |  |  |  |  |  | Design requirement for IPG alignment within package (EESP 0071) |  |
|  |  |  |  |  |  | Too much space between device and charging head | 2 | 2 | 2 | 8 | Design requirement for carton design (1007632) |  |
|  |  |  |  |  |  |  |  |  |  |  | Design requirement for IPG alignment within package (EESP 0071) |  |
| **Port Plug Pouch** | Contain port plug | Difficult to open pouch | Physician inconvenience, loss/drop port plugs | Visual |  | High separation force of pouch seal | 2 | 2 | 2 | 8 | Design requirement for supplier’s pouch seal (1007110) |  |
|  |  |  |  |  |  | Difficult to remove tape | 2 | 2 | 2 | 8 | Design selection of tape material (84036) |  |
| **Tear Label** | Tamper evident | Integrity suspect | Physician inconvenience | Visual |  | Open package before use for charging | 1 | 2 | 2 | 4 | Carton design facilitates recharging without opening carton (EESP 0071) |  |
|  |  |  |  |  |  | Damage during distribution | 1 | 2 | 3 | 6 | Design requirement for tear label material and dimensions (1003300) |  |
|  |  |  |  |  |  |  |  |  |  |  | Packaging validation testing (MERE 0223) |  |
|  | Seal carton | Loss of literature | Instructions or patient labeling not available, unable to implant | Visual |  | Damage during distribution | 2 | 2 | 1 | 4 | Design requirement for tear label material and dimensions (1003300) |  |
|  |  |  |  |  |  |  |  |  |  |  | Packaging validation testing (MERE 0223) |  |

Note 1: Line items identified by “X” in the Mfg. column are mitigation actions related to Manufacturing and/or Process FMEA.

# Revision History

|  |  |  |  |
| --- | --- | --- | --- |
| **Revision Level** | **Revision Description** | **ECN**  **No#** | **Effective Date** |
| 1.1 | Initial FMEA against IPG specification EESP 0071 rev 1.2. This revision is an interim analysis, which will be updated to address the open items listed in section 8. | 1436 | 04/18/12 |
| 1.2 | Added analysis of epoxy, silicone dispersion, and silicone adhesive failure modes. Added reference documents to mitigation actions where applicable. This revision is an interim analysis, which will be updated to address the open items listed in section 8. | 1557 | 10/12/12 |
| 1.3 | Added failure modes related to solvent attack. Updated formatting of section 8 Ranking Criteria. Updated septum and setscrew part numbers. Added mitigation for adding epoxy between ID tag and cap battery holder. This revision is an interim analysis, which will be updated to address the open items listed in section 9. | 1754 | 05/02/13 |
| 1.4 | Added additional function, failure mode, and mitigation related to the setscrew binding in the setscrew block via debris in threads or galling. | 1961 | 10/04/13 |
| 1.5 | Added reference documents to mitigation actions where applicable. Updated mitigation items with additional details. Added Table 6 RPN Summary. Removed EE FMEA references. Addressed open items listed in section 9. | 2156 | 12/30/13 |