



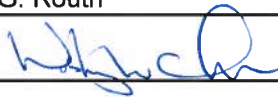
Greatbatch
Medical

SCS ALGOSTIM IPG PFMEA

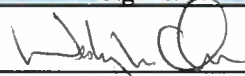



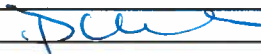
Document Number 1004467

Revision: B

REVISION HISTORY

Revision	Description	Approval	Date
A	Initial Release	G. Routh	2/16/2011
B	Updated Processes and Electrical Test		10-28-13


Plan Review Sign-Off

	Name (printed)	Signature	Date
Process Development	Wesley Omer		10-22-13
Design Assurance	Nick Heitz		22 OCT 13
Operations Quality	Eric Mulder		25 OCT 13
Value Stream/Manufacturing	Aaron Opbroek		10-24-13
Product Development	Dan Kelsch	SEE ATTACHMENT	
Regulatory	Doug Atkins		10-22-2013

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ATTACHMENT

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Regulatory	Doug Atkins		

Post Mitigations																		
ID	Function of Process Step	Failure Mode	Effect of Failure	Root Cause of Failure	Current Controls	Severity	Occurrence	Detection	RPN	Risk Region	Comments	Recommended Action	Action(s) Taken	Severity	Occurrence	Detection	RPN	Risk Region
10	ID Tag Attach	ID tag escapes from recess in cap battery holder	Physician inconvenience/dissatisfaction	not enough epoxy	MP, training, downstream handling	1	1	3	3	Acceptable								
20	1012549			epoxy not cured before movement	MP, training, downstream handling		1			3	Acceptable							
30			Premature device failure, explant, unintended revision surgery*	ID Tag not placed in the cavity securely	MP, training, downstream handling		1		3	Acceptable								
40				not enough epoxy	MP, training, downstream handling	3	1	3	9	Acceptable								
50				epoxy not cured before movement	MP, training, downstream handling		1		9	Acceptable								
60				ID Tag not placed in the cavity securely	MP, training, downstream handling		1		9	Acceptable								

SCS Algostim IPG - Stacker Sub Assembly

SCS Algostim IPG - Stacker Sub Assembly												Post Mitigations							
ID	Function of Process Step	Failure Mode	Effect of Failure	Root Cause of Failure	Current Controls	Severity	Occurrence	Detection	RPN	Risk Region	Comments	Recomm ended Action	Action (s) Taken	Severity	Occurrence	Detection	RPN	Risk Region	
10	Stacker Assy 1005202 Inspection and Set Screw Install 1010887	Incorrect part order	Stimulation compromised, unintended or intermittent stimulation	Assembly started with wrong part	Pictures in Work Instruction. Training, visual inspection	2	2	2	8	Acceptable									
20			High insertion force, unable to fully insert lead																
30		Part missing	High insertion force, unable to fully insert lead	manual loading of parts allows for operator to not load a part	Pictures in Work Instruction. Training, visual inspection	2	2	1	4	Acceptable									
40			Stimulation compromised, unintended or intermittent stimulation	assembly not secured prior to loading into header															
50		Parts not seated properly	High insertion force, unable to fully insert lead	manual loading of parts allows for parts to not be entirely seated	Pictures in Work Instruction. Training, visual inspection	2	2	2	8	Acceptable									
60				Part loaded in incorrect orientation															
70		silicone seal damage	High insertion force, unable to fully insert lead	handling/sharp tools	No sharp tools used, training, bore inspection	2	2	2	8	Acceptable									
80			Stimulation compromised, unintended or intermittent stimulation																
90		plastic stacker damage	Stimulation compromised, unintended or intermittent stimulation	tweezer technique	Training/Bore Inspection	2	2	2	8	Acceptable									
100			High insertion force, unable to fully insert lead																
110		Silicone on component	Potential Process Effect of Failure: > 80% First Pass Yield	contamination on fixture	Instruction in MP to clean	1	2	2	4	Acceptable									
120		Damaged component	Potential Process Effect of Failure: > 80% First Pass Yield	handling/use	In process inspection	1	2	2	4	Acceptable									
130		Displaced ball seal spring	Stimulation compromised, unintended or intermittent stimulation	Handling of parts during loading	Training/Bore Inspection/Fixture design	2	2	2	8	Acceptable									
140			High insertion force, unable to fully insert lead																
150		Crushed ball seal spring	Stimulation compromised, unintended or intermittent stimulation	Handling of parts during loading	Training/Fixture Design/bore inspection	2	3	2	12	Low									
160		Silicon Ingress - Med 6600	Electrical leakage	Incorrect amount	validated settings on EFD Dispenser	2	3	2	12	Low									

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SCS Algostim IPG - FT Side Sub Assembly

SCS Algostim IPG - FT Side Sub Assembly												Post Mitigations							
ID	Function of Process Step	Failure Mode	Effect of Failure	Root Cause of Failure	Current Controls	Severity	Occurrence	Detection	RPN	Risk Region	Comments	Recommend ed Action	Action(s) Taken	Severity	Occurrence	Detection	RPN	Risk Region	
10	L-Tab Welding 1010547	Low tensile <6lbs	Unable to control stimulation or communicate	Low power (Duration, Diode Current, Frequency)	Weld Program, Power Check, MP, Tensile Test	3	1	3	9	Acceptable									
20				Spot Size Too Small	Power Check, Qualified Equipment, Process Specific Equipment		1		9	Acceptable									
30				Spot Size too Big	Power Check, Qualified Equipment, Process Specific Equipment		1		9	Acceptable									
40				Parts not making intimate contact (Positioning of L-Tab to Can)	Qualified fixture, MP, Tensile Test		1		9	Acceptable									
50				Parts contaminated	IP, Print		2		18	Low									
60		Stimulation compromised, unintended or intermittent stimulation			Welded wrong location, alignment incorrect	MP, Header Attach		2		18	Low								
70					Insufficient cover gas	Weld Program, Calibrated Gas Controller, MP		2		18	Low								
80					Laser out of Focus	Weld Program, Power Check, MP, Tensile Test		1		9	Acceptable								
90					Dirty Cover Glass	Weld Program, Power Check, MP, Tensile Test		1		9	Acceptable								
100					Loose Spatter		Potential Process Effect of Failure: > 80% First Pass Yield	High Power (Duration, Diode Current, Frequency)	Weld Program, Power Check, MP, Tensile Test	1	1	2	2	Acceptable					
110		Welded wrong location, alignment incorrect	MP, Header Attach					1		2	Acceptable								
120		Parts contaminated	IP, Print					2		4	Acceptable								
130		Parts not making intimate contact (Positioning of L-Tab to Can)	Qualified fixture, MP, Tensile Test					1		2	Acceptable								
140		Fixture Damaged	Qualified fixture, MP, Tensile Test					1		2	Acceptable								
150	Excessive Spatter > .005		Potential Process Effect of Failure: > 80% First Pass Yield	Insufficient cover gas				Weld Program, Calibrated Gas Controller		2		4	Acceptable						
160				High Power (Duration, Diode Current, Frequency)	Weld Program, Power Check, MP	1	1	2	2	Acceptable									
170				Welded wrong location, alignment incorrect	MP, Header Attach		1		2	Acceptable									
180				Parts contaminated	IP, Print		2		4	Acceptable									
190				Parts not making intimate contact (Positioning of L-Tab to Can)	Qualified fixture, MP, Tensile Test		1		2	Acceptable									
200				Fixture Damaged	Qualified fixture, MP, Tensile Test		1		2	Acceptable									

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900	<p>Stimulation compromised, unintended or intermittent stimulation</p> <p>Premature device failure, explant, unintended revision surgery*</p> <p>Potential Process Effect of Failure: > 80% First Pass Yield</p> <p>Damaged - Cosmetic appearance of can</p>	Incorrect Power settings	MP, Recipe control, power check	1	4	Acceptable						
910		FT to enclosure FT slot tolerance stack up - Excessive Gap	MP, Tool Qual, Leak Check	2	8	Acceptable						
920		Contamination	IP, MP	2	8	Acceptable						
930		Improper Handling Technique (Dropped, Load, Unload, etc)	MP	1	2	1	2	Acceptable				

SCS Algostim IPG - Lid Side Sub Assembly

SCS Algostim IPG - Lid Side Sub Assembly										Post Mitigations									
ID	Function of Process Step	Failure Mode	Effect of Failure	Root Cause of Failure	Current Controls	Severity	Occurrence	Detection	RPN	Risk Region	Comments	Recommened Action	Action(s) Taken	Severity	Occurrence	Detection	RPN	Risk Region	
10	L-Tab Welding 1010549	Low tensile <8lbs	Unable to control stimulation or communicate	Low power (Duration, Diaode Current, Frequency)	Weld Program, Power Check, MP, Tensile Test	3	1	3	9	Acceptable									
20				Incorrect Spot Size	Power Check, Qualified Equipment		1			9	Acceptable								
30				Parts not making intimate contact (Positioning of L-Tab to Can)	Qualified fixture, MP, Tensile Test		1			9	Acceptable								
40				Parts contaminated	IP, Print		2			18	Low								
50				Welded wrong location, alignment incorrect	MP, Header Attach		2			18	Low								
60			Stimulation compromised, unintended or intermittent stimulation	Insufficient cover gas	Weld Program, Calibrated Gas Controller		2		18	Low									
70				Laser out of Focus	Weld Program, Power Check, MP, Tensile Test		1		9	Acceptable									
80				Dirty Cover Glass	Weld Program, Power Check, MP, Tensile Test, PM		1		9	Acceptable									
90		Loose Spatter	Potential Process Effect of Failure: > 80% First Pass Yield	High Power (Duration, Diaode Current, Frequency)	Weld Program, Power Check, MP, Tensile Test	1	1	2	2	Acceptable									
100	Welded wrong location, alignment incorrect			MP, Header Attach		1			2	Acceptable									
110	Parts contaminated			IP, Print		2			4	Acceptable									
120	Parts not making intimate contact (Positioning of L-Tab to Can)			Qualified fixture, MP, Tensile Test		1			2	Acceptable									
130	Fixture Damaged			Qualified fixture, MP, Tensile Test		1			2	Acceptable									
140				Insufficient cover gas	Weld Program, Calibrated Gas Controller		2		4	Acceptable									
150	Excessive Spatter > .005		Potential Process Effect of Failure: > 80% First Pass Yield	High Power (Duration, Diaode Current, Frequency)	Weld Program, Power Check, MP	1	1	2	2	Acceptable									
160				Welded wrong location, alignment incorrect	MP, Header Attach		1			2	Acceptable								
170				Parts contaminated	IP, Print		2			4	Acceptable								
180				Parts not making intimate contact (Positioning of L-Tab to Can)	Qualified fixture, MP, Tensile Test		1			2	Acceptable								
190				Fixture Damaged	Qualified fixture, MP, Tensile Test		1			2	Acceptable								
200				Insufficient cover gas	Weld Program, Calibrated Gas Controller		2		4	Acceptable									
210	Damaged L-Tab		Tissue damage, irritation	Parts Loaded Incorrectly	MP, Header Attach	3	2	1	6	Acceptable									
220				Fixture Damaged	MP, Header Attach		1			3	Acceptable								
230				Parts Loaded Incorrectly	MP, Header Attach		1			5	Acceptable								
240				L-Tab Welded Upside Down and/or Backwards	Potential Process Effect of Failure: Multiple Line Failures (catastrophic failure of the equipment or process)	Fixture Damaged	MP, Header Attach		1		5	Acceptable							

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780		Excess recharge time or increased recharge frequency	MP, Visual Inspection, Tool Qual	1	4	Acceptable							
790		Unable to control stimulation or communicate	MP, Visual Inspection, Tool Qual	1	4	Acceptable							
800		Unable to recharge	MP, Visual Inspection, Tool Qual	1	4	Acceptable							

SCS Algostim IPG - Header Stacker Sub Assembly

Post Mitigations																		
ID	Function of Process Step	Failure Mode	Effect of Failure	Root Cause of Failure	Current Controls	Severity	Occurrence	Detection	RPN	Risk Region	Comments	Recommended Action	Action(s) Taken	Severity	Occurrence	Detection	RPN	Risk Region
10	Attach Septum to Header	Strain relief protruding at an angle	Potential Process Effect of Failure: > 80% First Pass Yield	strain relief not seated properly (Tooling controlled)	MP, Training, Inspection	2	2	2	8	Acceptable								Acceptable
20	1011489	Septum protruding unevenly	Potential Process Effect of Failure: > 80% First Pass Yield	Septum not placed correctly	MP, Training, Inspection	1	2	2	4	Acceptable								Acceptable
30	IPG/ Header and Stacker Assembly	Damaged septum	Revision difficulty, unable to remove lead from IPG	Handling	MP, Training, Inspection	3	2	2	12	Low								Low
40			Implant difficulty, unable to assemble system, unable to implant				2		12	Low								Low
50	1007762	Bubbles	Stimulation compromised, unintended or intermittent stimulation	Incorrect amount of material and location of material	MP, Training, Inspection	3	3	2	18	Low								Low
60			Infection*	bubbles not removed before cure.	MP, Training, Inspection		3		18	Low								Low
70				strain relief not placed correctly			2		12	Low								Low
80		Stacker assy placed upside down	Potential Process Effect of Failure: > 80% First Pass Yield	loaded incorrectly	MP, Training, Inspection	1	2	1	2	Acceptable								Acceptable
90		Not pressed down (uneven)	Potential Process Effect of Failure: > 80% First Pass Yield	Fixturing issue	MP, Training, Inspection	1	2	2	4	Acceptable								Acceptable
100				assembly technique	MP, Training, Inspection		2		4	Acceptable								Acceptable
110		Contact blocks go out of alignment	Potential Process Effect of Failure: > 80% First Pass Yield	No tension while loading	MP, Training, Inspection	1	2	1	2	Acceptable								Acceptable
120		Si on contact blocks	Potential Process Effect of Failure: > 80% First Pass Yield	Too much silicone	MP, Training, Inspection	1	3	2	6	Acceptable								Acceptable
130				handling	MP, Training, Inspection		3		6	Acceptable								Acceptable
140				Operator technique	MP, Training, Inspection		3		6	Acceptable								Acceptable
150		Battery life reduced (Due to above 60 C cure)	Premature device failure, explant, unintended revision surgery*	Temp Too High	MP, Training, Inspection, IQ	3	2	2	12	Low								Low
160			Decreased battery life							Acceptable								Acceptable

SCS Algostim IPG - Final Assembly

SCS Algostim IPG - Final Assembly										Post Mitigations								
ID	Function of Process Step	Failure Mode	Effect of Failure	Root Cause of Failure	Current Controls	Severity	Occurrence	Detection	RPN	Risk Region	Comments	Recommended Action	Action(s) Taken	Severity	Occurrence	Detection	RPN	Risk Region
10	1A Board level test	Amplitudes incorrect	Simulation compromised, unintended or intermittent stimulation	Operator technique, incorrect info loaded	MP, Training, Equipment Qual	2	3	2	12	Low								
20	1009906	Frequencies incorrect	Premature device failure, explant, unintended revision surgery*	Operator technique, incorrect info loaded	MP, Training, Equipment Qual	3	3	2	18	Low								
30		RF tuning incorrect	Premature device failure, explant, unintended revision surgery*	Operator technique, incorrect info loaded	MP, Training, Equipment Qual	3	3	2	18	Low								
40		Fuel gauge calibration incorrect	Unable to recharge	Operator technique, incorrect info loaded	MP, Training, Equipment Qual	3	3	2	18	Low								
50		Charge control error	Premature device failure, explant, unintended revision surgery*	Operator technique, incorrect info loaded	MP, Training, Equipment Qual	3	3	2	18	Low								
60		Current draw measurement error	Premature device failure, explant, unintended revision surgery*	Operator technique, incorrect info loaded	MP, Training, Equipment Qual	3	3	2	18	Low								
70		Temperature sense test error	Excessive heat – severe (above 42C)*	Operator technique, incorrect info loaded	MP, Training, Equipment Qual	4	3	2	24	Low								
80	1B Board level test	Outputs are not correct	Premature device failure, explant, unintended revision surgery*	Operator technique, incorrect info loaded	MP, Training, Equipment Qual	3	3	1	9	Acceptable								
90	1009906	Telemetry non-functional	Premature device failure, explant, unintended revision surgery*	Operator technique, incorrect info loaded	MP, Training, Equipment Qual	3	3	1	9	Acceptable								
100		Corrupted memory and/or product code	Premature device failure, explant, unintended revision surgery*	Operator technique, incorrect info loaded	MP, Training, Equipment Qual	3	3	1	9	Acceptable								
110		Fuel gauge/charging non-functional	Premature device failure, explant, unintended revision surgery*	Operator technique, incorrect info loaded	MP, Training, Equipment Qual	3	3	1	9	Acceptable								
120	IPG Laser Marking	Wrong Information / Incorrect artwork	Potential Process Effect of Failure: > 80% First Pass Yield	Program Modified	Operational Monitoring Mode - controls blocks that can be edited	1	2	2	4	Acceptable								
130	1010786			Incorrect Info Loaded	compare against screen shots in MP		2		4	Acceptable								
140				Loaded Wrong Program	compare against screen shots in MP		3		6	Acceptable								
150		Too Dark / Rough Feel to Mark	Potential Process Effect of Failure: > 80% First Pass Yield	Incorrect Settings (Laser Power)	marking program, Operational Monitoring mode, PM	1	3	3	9	Acceptable								
160				Program Modified	Operational Monitoring Mode - controls blocks that can be edited		1		3	Acceptable								
170				Wrong Laser Focal Plane	shelf and fixtures to control z-height of part		3		9	Acceptable								
180				Surface Finish of Can (Color and texture)	bead blasting prior to laser mark		3		9	Acceptable								
190				Can Contaminated	clean prior to laser mark with 99% IPA		3		9	Acceptable								
200		Too Light	Potential Process Effect of Failure: > 80% First Pass Yield	Incorrect Settings (Laser Power)	marking program, Operational Monitoring mode, PM	1	3	2	6	Acceptable								
210				Program Modified	Operational Monitoring Mode - controls blocks that can be edited		1		2	Acceptable								
220				Wrong Laser Focal Plane	shelf and fixtures to control z-height of part		3		6	Acceptable								

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1010	Simulation compromised, unintended or intermittent stimulation	Parts not making intimate contact (Positioning of weld tab to Can)	Qualified fixture, MP, Final electrical Test	2	12	Low
1020		Parts contaminated	IP, Print, Final Electrical Test	2	12	Low
1030		Welded wrong location, alignment incorrect	MP, Final Electrical Test	1	6	Acceptable
1040	Excess recharge time or increased recharge frequency	Insufficient cover gas	Weld Program, Calibrated Gas Controller	1	6	Acceptable
1050		Laser out of Focus	Weld Program, Final Electrical Test	1	6	Acceptable
1060		Dirty Cover Glass	MP, PM, Power Check, Final Electrical Test	2	12	Low
1070		Beam Alignment	PM, Power Check, Final Electrical Test	1	6	Acceptable
1080	Excessive Spatter > 005	Unable to control stimulation or communicate	High Power (Duration, Diaode Current, Frequency)	4	1	2
1090		Unable to recharge	Welded wrong location, alignment incorrect	1	8	Acceptable
1100	Simulation compromised, unintended or intermittent stimulation	Parts contaminated	IP, Print, Final Electrical Test	2	16	Low
1110	Excess recharge time or increased recharge frequency	Parts not making intimate contact (Positioning of ball tab to Can)	Tool Qual, MP, Final electrical Test	2	16	Low
1120	Excessive heat – severe (above 42C)*	Fixture Damaged	Tool Qual, MP	1	8	Acceptable
1130		Insufficient cover gas	Weld Program, Calibrated Gas Controller	1	8	Acceptable
1140	Potential Process Effect of Failure: > 80% First Pass Yield	Parts Loaded Incorrectly	MP, Visual Inspection	1	2	Acceptable
1150		Handling	Tool Qual, MP	3	6	Acceptable
1160		Fixture Damaged	Tool Qual, MP	1	2	Acceptable
1170		Insufficient cover gas	Weld Program, Calibrated Gas Controller	1	2	Acceptable
1180	Potential Process Effect of Failure: > 80% First Pass Yield	High Power (Duration, Diaode Current, Frequency)	Daily Power Check, Final Electrical test, Visual Inspection	1	2	Acceptable
1190		Parts contaminated	IP, Print, Final Electrical Test	2	4	Acceptable
1200		Low power (Duration, Diaode Current, Frequency)	Daily Power Check, Final Electrical test, Visual Inspection	1	2	Acceptable
1210		Incorrect Alignment	MP, Visual Inspection, Final Electrical Test	1	2	Acceptable
1220	Bad Weld - Alignment	Wrong Weld Program	MP, Visual Inspection, Final Electrical Test	3	1	2
1230	Bad Weld - Blown Weld	Incorrect Power settings	Recipe Control, MP	1	2	Acceptable
1240	Simulation compromised, unintended or intermittent stimulation	Contamination	Recipe Control, MP, Final electrical Test	6	Acceptable	Acceptable
1250	Excess recharge time or increased recharge frequency		IP, Print, Final Electrical Test	4	Acceptable	Acceptable
1260						

			Excessive heat – severe (above 42C)*	Damaged Assembly	Weld Program, Power Check, MP	4	4	16	Low						
2620			Electrical leakage												
2630			Potential Process Effect of Failure: > 80% First Pass Yield	Damaged - Cosmetic	MP	4	4	16	Low						
2640			Potential Process Effect of Failure: > 80% First Pass Yield	Operator technique		1	3	9	Acceptable						
2650	Surface Finishing/Blasting		Potential Process Effect of Failure: > 80% First Pass Yield	Operator technique		1	3	9	Acceptable						
2660	1007659		Potential Process Effect of Failure: > 80% First Pass Yield	Handling		1	1	4	Acceptable						
2670			Potential Process Effect of Failure: > 80% First Pass Yield	Handling		1	1	4	Acceptable						
2680			Potential Process Effect of Failure: > 80% First Pass Yield	Handling		1	1	2	Acceptable						
2690	Laser Marking		Potential Process Effect of Failure: > 80% First Pass Yield	Someone modified Program		1	2	4	Acceptable						
2700	1010786		Potential Process Effect of Failure: > 80% First Pass Yield	Loaded Wrong Program			3	6	Acceptable						
2710			Potential Process Effect of Failure: > 80% First Pass Yield	Incorrect Settings (Laser Power, Speed, Freq)		1	3	9	Acceptable						
2720				Wrong Laser Focal Plane			3	9	Acceptable						
2730				Surface Finish of Can (Color and texture)			3	9	Acceptable						
2740				Can Contaminated			3	9	Acceptable						
2750			Potential Process Effect of Failure: > 80% First Pass Yield	Incorrect Settings (Laser Power, Speed, Freq)		1	3	6	Acceptable						
2760				Wrong Laser Focal Plane			3	6	Acceptable						
2770				Surface Finish of Can (Color and texture)			3	6	Acceptable						
2780				Cover Glass Dirty			3	6	Acceptable						
2790				Can Contaminated			3	6	Acceptable						
2800			Potential Process Effect of Failure: > 80% First Pass Yield	Handling		1	3	6	Acceptable						
2810			Potential Process Effect of Failure: > 80% First Pass Yield	Can not loaded correctly		1	3	9	Acceptable						
2820				Fixturing loaded or setup incorrectly			3	9	Acceptable						
2830			Potential Process Effect of Failure: > 80% First Pass Yield	Incorrect Settings (Laser Power, Speed, Freq)		1	3	6	Acceptable						
2840				Wrong Laser Focal Plane			3	6	Acceptable						
2850				Surface Finish of Can (Color and texture)			3	6	Acceptable						
2860				Can Contaminated			3	6	Acceptable						

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4200	Device damaged	Potential Process Effect of Failure: 60% - 80% First Pass Yield	Operator technique, incorrect info loaded	MP, Training, Equipment Qual	2	3	2	12	Low										
4210	Label Generation																		
1013815																			
4220	Sterile Packaging	Physician inconvenience/dissatisfaction	inner and retainer tray assembly not completely sealed in outer tray	MP	2	2	2	8	Acceptable										
4230	1007791	Product damage/sterility compromised																	
4240	Final Pack	Physician inconvenience/dissatisfaction	incorrect temp, time, or pressure	MP, PM/Calibration	2	3	2	12	Low										
4250	1007792	Product damage/sterility compromised	FM on outer tray	blow off prior to use, visual inspection and can rework		2	2	8	Acceptable										
4260		Product damage/sterility compromised	narrow gasket width	sealing nest TO, PM	3	2	2	12	Low										
4270		Product damage/sterility compromised	incorrect temp, time, or pressure	MP, PM/Calibration		3	2	18	Low										
4280		Physician inconvenience/dissatisfaction	loaded incorrectly	MP, knobs on tray to indicate where "open here" labels should be	1	3	3	9	Acceptable										
4290		Potential Process Effect of Failure: > 80% First Pass Yield	loaded incorrectly	MP, single sided adhesive on lid - therefore won't create seal	1	1	1	1	Acceptable										
4300		Physician inconvenience/dissatisfaction	loaded backwards causing poor seal	MP, 3x8 model will not fit correctly	1	3	2	6	Acceptable										
4310		Instructions/labeling not available, adulterated product	ineffective label application	MP	2	2	2	8	Acceptable										
4320		Instructions/labeling not available, adulterated product	FM on label adhesive	MP, cleanroom practices		2	2	8	Acceptable										
4330		Instructions/labeling not available, adulterated product	Ink not dry prior to handling	Laser printing labels?	2	1	1	2	Acceptable										
4340		Instructions/labeling not available, adulterated product	Printer malfunction	visual inspection		3	2	12	Low										
4350		Instructions/labeling not available, adulterated product	Corrupt File	MP, QC check	3	3	2	18	Low										
4360		Physician inconvenience/dissatisfaction	missed step in loading contents	MP, QC check	1	3	2	6	Acceptable										
4370		Instructions/labeling not available, adulterated product	handling	MP, QC check	2	3	3	18	Low										

Reference 1013323 Label Generation PFMEA