ST. JUDE MEDICAL **Cardiovascular and Ablation Technologies Division**	Document No. 90152516 Ver. A DHF No: N/A Document Type: Shelf Life / Accelerated Aging Protocol __ Report X Product: N/A Page: 1 of 10
Document Name: Packaging Accelerated Aging Shelf Life Report for SBS systems using the Tyvek/Poly pouch material	

1.0 PURPOSE

The purpose of this testing was to verify the stability, after 3 years accelerated aging, of all Sterile Barrier Systems (SBS) assembled by or for St. Jude Medical Irvine using pouch materials consisting of DuPont® Mangar 92 GA PET/ .002LDPE, U/C 1073B Tyvek. All SJM Irvine pouch part numbers using the same sealing methodology and materials of construction can be addressed by this report with appropriate assessments/ rationale.

2.0 SCOPE

The scope of this report is to specify the tests, test parameters, sample sizes and rationale used to determine the shelf life stability for SBS and the materials that make up those systems and verify their ability to maintain integrity and strength over time using accelerated aging principals.

3.0 APPLICABLE DOCUMENTS

3.1 Applicable Documents

Document Number	Title	Version
90082940	Design FMEA, Cables Family	A
90002587	Design Verification WI	G

3.2 Reference Documents

Document Number	Title	Version
ISO 11607-1:2006	Packaging for Terminally Sterilized Medical Devices: Part 1	Standard
ISO 11607-2:2006	Packaging for Terminally Sterilized Medical Devices: Part 2	Standard
ASTM International F1886-09	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection	Standard
ASTM International F2096-11	Standard Test Method for Detecting Gross Leaks in Porous Medical Packaging by Internal Pressurization	Standard
ASTM International F88M-09	Standard Test Method for Seal Strength of Flexible Barrier Materials	Standard
ASTM International	Standard Guide for Accelerated Aging of Sterile Medical Device Packages	Standard

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Document Number	Title	Version
F1980		
QA-610	IR QM Ethylene Oxide Sterilization Process, Standard Operating Procedure	H
QA-611	EO Sterile Validation Process, Standard Operating Procedure	F
QA-612	Sterile Prod Release Routine Processing, Standard Operating Procedure	K
250013	SJM AF Irvine Process Instruction, Packaging EP Catheters and Cables	AH
90002706	WI, Shelf Life – Aging	F

4.0 RESPONSIBILITIES

Responsibility	Task
Packaging Engineering	• Test, create and release report.

5.0 DEFINITIONS

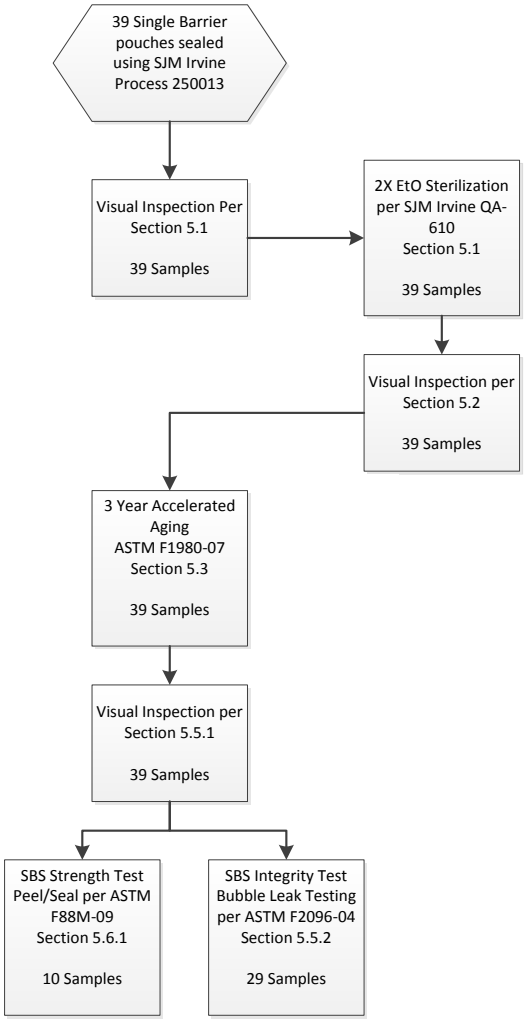
Definitions specific to this document are shown in the following table:

Term	Definition
N/A	N/A.

6.0 FLOW CHART

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7.0 TEST REQUIREMENTS

7.1 Test Materials

Part Number	Quantity	Description
160465	39	Pouch- DuPont® Mangar 92 GA PET/ .002 LDPE, U/C 1073B Tyvek
161304	39	Shelf Carton

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7.2 Samples

A total of 39 pouches were sealed per the SJM AF Irvine sealing process. All 39 pouches underwent a visual inspection and testing. Testing of the 39 samples was as follows:

Test	Sample Size
Peel / Seal Testing	10
Bubble Leak Testing	29

These 39 samples were cartoned in the applicable carton for the device and accelerated aged in this configuration. Table 1 of Design Verification WI 90002587 designates that for a medium risk classification 10 samples were required for variable distributions and 29 samples were required for attribute distributions. The flow chart on the following page describes the order of testing and quantities needed for each phase of testing.

8.0 RESULTS AND ANALYSIS

8.1 Sterilization

Samples were 2x EtO sterilized to simulate maximum sterilization conditions per SJM Irvine, processes #QA-610, QA-611, QA-612. A total of 39 sealed pouches were sent for sterilization and follow up testing.

8.2 Visual Inspection – ASTM F1886-09

Test Method
A total of 39 packages were used for the visual inspection after sterilization and before accelerated aging.

Procedure
The pouch was inspected visually for channels in the seal. This inspection was completed by inspecting the entire sealed area of the package for completeness and uniformity.

Pass/Fail Criteria
Seals shall not contain any visual anomalies which indicate a breach or open path across the entire width of the seal.

Results
All 39 packages did not exhibit any visual anomalies during visual inspection. The data sheet(s) for this inspection can be found in Appendix A.

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8.3 Accelerated Aging – ASTM F1980-07

Samples of the pouches were aged for 3 year equivalency. A total of 39 pouches were used for the 3 year accelerated aging phase testing. Calculations for accelerated aging are based on ASTM F1980-07, Standard Guide for Accelerated Aging of Sterile Medical Device Packages.

Equation 1:	$AFF = Q_{10}[(T_{AA} - T_{RT})/10]$
Equation 2:	AAT = Desired RT / AAF

Where:
T_{AA}: accelerated aging temperature (◦C)
T_{RT}: estimated storage temperature (◦C)
Q_{10}: aging factor
AAF: accelerated aging factor
AAT: accelerated aging time

Assumptions used for this testing:

Accelerated aging temperature: T_{AA}= 50◦C (122◦F)
Storage conditions: T_{RT}= 20◦C (68◦F)
Aging Factor: Q_{10} = 2
Desired real time aging: RT = 3 year (1095 days + 31 days for YYYY/MM format) (1126 days)

Using equation 1 and calculating for AAF: AAF = $2^3 = 8$
Using equation 2 and calculating for AAT: AAT = 1126 days / 8 = 140.75 ≈ 141 days.

Procedure
In an environmental chamber, the pouch was exposed to the following conditions:

141 days at 50°C ± 3◦C ≤ 20% relative humidity

The above cycle provided the equivalent of 3 years of aging. This cycle was performed one time to simulate 3 years of real time aging.

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NOTE: During the accelerated aging performed at a SJM approved test facility (DDL, Inc.), there was a malfunction in the accelerated aging chamber causing the chamber to shut off for a period of 17 hours. The time (17 hours) was added to the end of the cycle in accordance with ASTM F1980. The applicable standard was followed and thus the malfunction did not impact the results of this testing. The malfunction and time added at the end of the cycle is documented in the DDL report located in Appendix E.

St. Jude Medical product instructions for use requires the product be stored in a cool, dark, dry place. The Q10 aging factor is based on the assumption that the chemical reactions involved in the deterioration of material follows the Arrhenius reaction rate function. The Arrhenius function states that for every 10 rise in temperature, an approximate two times increase in the chemical reaction rate results. The accelerated aging temperature chosen for this process was large enough to benefit in efficiency from raising the aging temperate, but not so high that the product/ packaging will distort.

8.4 SBS Post Aging Analysis

It is necessary and required to do at least one strength test and one integrity test when evaluating the SBS samples. The visual integrity was performed first. Since there were not any visual anomalies, a second integrity test was not necessary.

8.5 SBS Integrity Tests

These tests were used to measure the effects of processing, sterilization/aeration and aging on the integrity of the SBS seal. The data was recorded as a pass/fail criteria.

8.5.1 Visual Inspection – ASTM F1886-09

Test Method
A total of 39 packages were used for the visual inspection after sterilization and accelerated aging.

Procedure
The pouch was inspected visually for channels in the seal. This inspection was completed by inspecting the entire sealed area of the package for completeness and uniformity.

Pass/Fail Criteria
Seals shall not contain any visual anomalies which indicate a breach or open path across the entire width of the seal.

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Results
All 39 packages did not exhibit any visual anomalies during visual inspection. The data sheet(s) for this inspection can be found in Appendix B.

8.5.2 Bubble Leak Test - ASTM F2096-11

Test Method
29 pouches were used for bubble leak testing after undergoing accelerated aging as well as a visual inspection test.

Procedure
The pouch was inflated underwater to a predetermined pressure. The package was then observed for a steady stream of air bubbles indicating a failure area. The test pressure is to be established and should be based on the test method for porous material packaging.

Pass/ Fail Criteria
There shall not be the presence of bubbles in the impermeable structure or seals which would indicate a breach in the materials.

Results
All 29 pouches did not show the presence of bubbles during the test. Thus showing the pouch maintains its sterile barrier. The data sheet(s) for this testing can be found in Appendix C.

8.6 SBS Strength Test

8.6.1 Seal Strength Test - ASTM F88M-09

This test was used to measure the effects of processing, sterilization/aeration and aging on the strength of the SBS seal. The data obtained is not used as pass/fail criteria but rather to measure any trends or shifts in the values as a result of the aging stresses when compared to sterilized and unsterilized non-aged control samples. Trends which indicate a significant lowering of the strength characteristics as compared to the control samples would indicate that a particular SBS configuration or material combination might not be desirable.

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Test Method
A total of 10 pouches were used for the post accelerated aging seal strength testing. Packages for seal strength testing came from the samples that underwent accelerated aging and visual inspection.

Procedure
The separation rate at which the two plies of material were separated is 12 inches per minute. Refer to ASTM F88 for details on how the sample tail can be handled. The test was performed with the unsupported method. The following figure 1.2 describes where the samples were taken from the pouches.

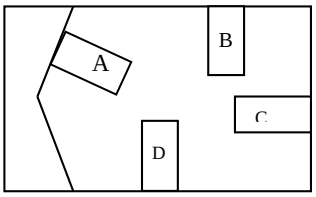


Figure 1.2

Pass/Fail Criteria
Upon peeling vendor seals (A,B,D) there shall not be any fiber shredding, splitting, or tearing such that “the utility of the medical device is impaired”. It is the intent that the manufactures seal (C) is to be strong, potentially non-peel-able, seal.

The peel strength values will not be less than 1.0 lbf for the manufacturing seal.

Results
All 40 samples taken from the 10 pouches had seal strengths ≥1.0 lbf. Thus passing our requirements, and showing evidence of a strong, non peelable seal. The data sheet(s) for this testing can be found in Appendix D.

Following the execution of protocol 90134993, it was identified that the protocol’s acceptance criteria for peel strength (1.0 lbf) did not match the product requirement (1.5 lbf) as defined by document 90082869 CATD Cable Family Product Requirement Ver B and applicable Irvine product specification documents.

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An assessment was completed by a cross-functional team and the team determined that aligning the product requirement for all products in the cable family as defined in Section 1.0 of PRD 90082869 was necessary. Currently, cables from the Minnetonka SJM facility are produced with a pouch seal strength specification of 1.0 lbf whereas cables from the Irvine SJM facility are produced with a pouch seal strength specification of 1.5 lbf. Per the cable family DFMEA 90082940, the potential harm associated with loss of sterile barrier (the pouch seal failure mode) is infection, with an overall risk classification of medium. The 1.0 lbf minimum pouch seal strength and mitigation of associated risks have been shown effective through design verification. As demonstrated by the documents listed in the Pouch Seal Strength section of 90125589 Cable Family DV Master Plan and the test result presented in this report, all current cable family products meet a 1.0 lbf specification.

This product requirement change shall be pursued along all regulatory paths. Upon approval, the cable family PRD 90082869 and the applicable Irvine product specification documents shall be updated to reflect the aligned cable family pouch seal strength product requirement of 1.0 lbf. As an additional control measure, Irvine in-process controls for pouch seal strength will remain with a set-up peel strength test with a minimum 1.5 lbf minimum requirement.

9.0 VERSION CHANGES and IMPACT ASSESMENT

There are no changes in version between the protocol 90134993 and this report 90152516.

10.0 CONCLUSION

This report documents that the stability, after 3 years of accelerated aging of the DuPont® Mangar 92 GA PET/ .002LDPE, U/C 1073B successfully maintained its Sterile Barrier System and is acceptable for use. Therefore, all current/future SJM Irvine pouch part numbers using the same sealing methodology and materials of construction are acceptable for use upon assessment and rationale.

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11.0 APPENDIX

Appendix A: Data Sheets for Visual Inspection (Section 5.2)
Appendix B: Data Sheets for Visual Inspection (Section 5.5.1)
Appendix C: Data Sheets for Bubble Leak Testing (Section 5.5.2)
Appendix D: Data Sheet for Peel/Seal Testing (Section 5.6.1)
Appendix E: Final Report, DDL, Inc.

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