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2525-15 Product Documentation

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1. REFERENCE

ISO 11607-1	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
ASTM D4169	Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM F2096	Standard Test Method for Detecting Gross Leaks in Porous Medical Packaging by Internal Pressurization (Bubble Test)
ASTM F1929	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ENG-WI-007	Operation of Vibration Table and Drop Test Equipment
ENG-RMF-045	Risk Analysis, Smoke Evacuation Accessories
ENG-DMR-012	DMR, Smoke Evacuation Pencil and Accessories
ASTM F1980-07	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
OPER-FRM-004	Inspection Form, Peel Pouch Burst Test

2. APPENDIX

Appendix I	Shipping Test Log Sheet
Appendix II	Print Legibility Log Sheet
Appendix III	Bubble Leak Test Log Sheet
Appendix IV	Dye Test Log Sheet
Appendix V	Seal Width Log Sheet
Appendix VI	Damage Inspection Log Sheet

3. SCOPE

This protocol pertains to the Zip Pen catalog numbers 2525-15 and 2525-15EC. The 2525-15 has a larger connector with slightly more mass, therefore the 2525-15 will be tested and is representative of both catalog numbers.

4. PURPOSE

The purpose of this protocol is to define the product ship testing requirements and package performance after ship testing. The protocol also verifies dimensional requirements for seal width, visual requirements for print clarity, and product damage. Successful completion of this testing provides confidence that the product will withstand the anticipated distribution environment and meet DMR requirements after distribution.

5. BACKGROUND

The Zip Pen 2525-15 and 2525-15EC are line extensions of the Zip Pen product line. This version has a 15 foot long cord and smoke evacuation tube. The product is assembled and packaged by an outside contractor overseas. The device is packaged in a 12.1" X 7.8" Nylon form-fill-seal pouch with Tyvek® lid stock. These packages are packed 20 per box, gamma sterilized, and shipped in Gaylord boxes from overseas to Megadyne where they are warehoused and then shipped in individual boxes to customers.

The Zip Pen 2525-10 has previously passed all verification tests and is currently on the market. The 2525-15 previously did not pass ship test. As a result of the previously failed ship test the package was redesigned. This protocol is specifically directed at testing the redesigned package.

6. DEFINITIONS AND ACRONYMS

DMR	Device Master Record

7. APPARATUS

7.1. Environmental Chamber

7.2. LAB AccuDrop 160

7.3. Martin Vibration Systems Vibration Table

7.4. Metal shim 0.06 in thick, approximately 2 in wide

7.5. Model F100-2600-3 Test-A-Pack Seal Strength Tester

7.6. Dye for Dye penetration test per ASTM F1929

7.7. Syringe with Needle for injecting Dye

7.8. Concentrated Impact Fixture ENG-DWG-768

8. RISK ASSESSMENT

8.1. A review of the Risk Analysis Document ENG-RMF-045 (Risk Analysis, Smoke Evacuation Accessories) identifies the risks associated with packaging. The highest severity rating is 10 attributable to compromised sterile barrier. The following is a list of failure modes, causes, mitigations and verifications.

Failure Mode	Cause	Mitigation	Verification
Cap falls off and electrode spears through package compromising sterile barrier	Lack of interference fit between electrode and cap	Product is in secondary bag inside of pouch. Pouch material is nylon and difficult to puncture	ASTM D4169 shipping test
Hole in package, sterile barrier broken	Ineffective packaging for this application	Material selection, Process control, labeling includes caution to discard package if pouch is damaged	ASTM D4169 shipping test
Hole in package, sterile barrier broken	Damaged during processing, wrong material thickness	Material selection, Process control, labeling includes caution to discard package if pouch is damaged	ASTM D4169 shipping test
Product damaged	Ineffective packaging for this application	Labeling includes caution to discard package if pouch is damaged	ASTM D4169 shipping test

9. EXPERIMENT DESIGN / SAMPLE SIZE JUSTIFICATION

9.1. Prior to the shipping test, all test products will be subjected to accelerated aging per ENG-PRT-049 to simulate 3 years. The aging temperature will be 55°C and the aging duration per the protocol is 111 days.

9.2. Two cases of each catalog number will be subject to the ship test protocol. This sample size will allow for 40 packages of each size to be evaluated after the shipping cycle. Normally a sample size of 30 would be used but since the cases come in quantities of 20 the sample is increased.

Type	Test Type	Sterile Samples 2525-15
Shipping Test/Conditioning	Protocol	2 Cases (contain 40 total samples)
Lot Number Clear and Legible	Visual Inspection	40 ea.
Print Clear and Legible	Visual Inspection	40 ea.
Package Bubble Leak Test	Visual Inspection	40 ea.
Dye test	Visual Inspection	40 ea.
Burst Test	Measurement	40 ea.
Minimum Seal Width	Measurement	40 ea.
Product damage	Visual Inspection	40 ea.

9.3. The aerosol challenge test required by the ship test protocol ENG-PRT-049 will not be performed. The justification for this decision is as follows. Reviewing ISO 11607-1, the purpose of the aerosol challenge test is to evaluate the materials as a barrier against microbial ingress. This package uses materials that have documented evidence for meeting the requirements for aerosol challenge. The Nylon bottom web (PerfecForm 36615-MM from Perfecseal) has been tested by the manufacturer and certified to meet ISO 11607-1(2006) Part 1 Annex C. The Tyvek® top web material (Type 1073B from Dupont) has been tested by the manufacturer and certified to meet ISO 11607-1(2006). Documentation for these materials can be found in test report ENG-RPT-330. Therefore, the aerosol challenge test is not required.

9.4. After accelerated aging, and prior to evaluation, the samples will be subjected to a shipping and storage cycle. This cycle includes temperatures from -40°C to 55°C and humidity's from 15% to 95%. This temperature and humidity cycling is designed to run consecutively with the ASTM D4169 pre-conditioning.

9.5. A summary of the experimental design is as follows:

Accelerated aging
Shipping and storage cycle and preconditioning
Shipping test
Inspection for Print Clear and legible
Inspection for Lot Number clear and legible
Dye test
Bubble test
Burst test
Inspection for Minimum seal width
Damage Inspection

10. GENERAL REQUIREMENTS

10.1. Tests shall be performed under typical warehouse conditions. Typical warehouse conditions are:

Temperature: 23°C ±5°C
Relative Humidity: 50% ±35%

Note that these conditions are a wider range than is called out in ASTM D4169. This deviation from standards is considered acceptable because actual warehouse, transport and storage conditions will vary greatly from the range listed in the standard.

10.2. The ASTM D4169 standard requires the choice of an assurance level. For this test assurance level II will be used except where noted. This is the recommended starting level in the standard.

10.3. The test schedule for this test will follow Distribution Cycle 3. This cycle has seven elements performed in the following order; Pre-conditioning, Manual Handling, Vehicle Stacking, Vehicle Vibration, Loose Load Vibration, Concentrated Impact, and Manual Handling. This cycle is followed by evaluation of the product.

11. ACCELERATED AGING

11.1. Perform accelerated aging to simulate 3 years of shelf life per ASTM F1980-07 (2011).

11.1.1. For reaction doubling rate $Q_{10} = 2.0$.

11.1.2. Aging temperature $T_{AA} = 55°C$.

11.1.3. Ambient temperature $T_{RT} = 22°C$.

11.1.4. Using the factors above, aging to simulate 3 years of shelf life requires 111 days in the aging chamber.

11.2. Record the equipment model and calibration information for the environmental chamber.

11.3. Record the start and completion date for the accelerated aging on a log sheet.

12. SHIPPING AND STORAGE CYCLE AND PRECONDITIONING

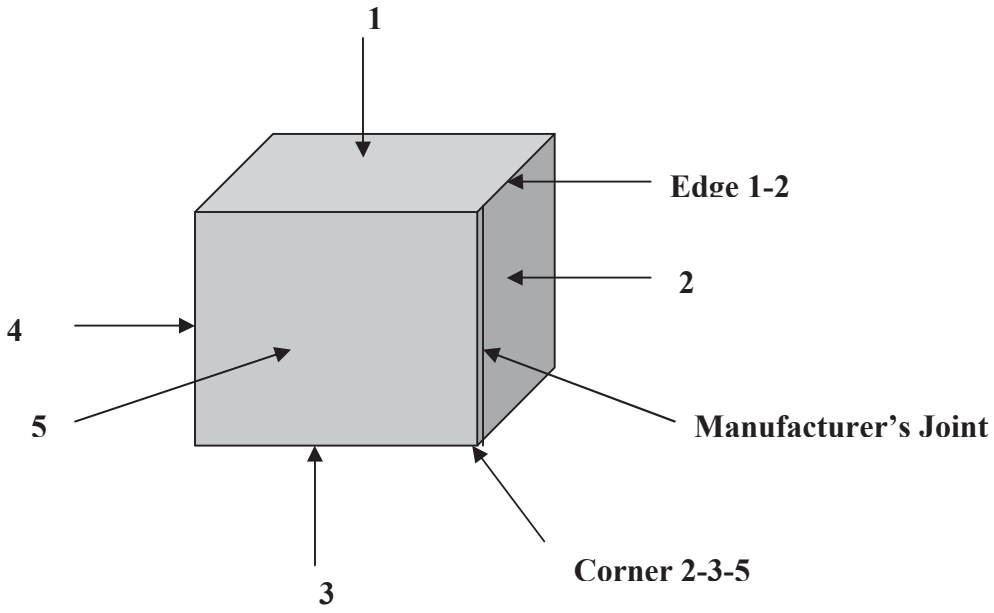
12.1. After aging, follow the Pre-Conditioning temperature and humidity schedule listed below.

CONDITIONS	DURATION
Transition from ambient to -40°C	Based on Chamber Capability
Hold -40°C no humidity control	4 hours
Transition from -40°C to 55°C	Set time to 0:00 and set the standard deviation to 1°C

Transition from 55°C to 55°C and 95%RH	Set time to 0:00 and set the standard deviation to 1°C and 2% RH
Hold 55°C and 95%RH	4 hours
Transition from 55°C and 95% RH to 55°C and 15% RH	Set time to 0:00 and set the standard deviation to 1°C and 2% RH
Hold 55°C and 15%RH	4 hours
Transition from 55°C and 15% RH to 23°C and 50%RH	Set time to 0:00 and set the standard deviation to 1°C and 2% RH
Hold 23°C and 50%RH	72 hours

13. SHIPPING TEST

13.1. Following the conditioning, using a permanent marker, identify the faces of the shipping boxes according to the following diagram.



13.2. Record the gross weight (Wt.) of the shipper box containing product in pounds.

13.3. Record the Catalog number of the product.

13.4. Record the Lot Number of the product.

13.5. Perform the Manual Handling test (drop test) as follows.

13.5.1. The required drop height from ASTM D4169 paragraph 10.2.3 using assurance level II is 15 inches for packages from 0 to 20 pounds. Package weight is approximately 14.5 pounds.

13.5.2. Set the height on the LAB AccuDrop 160 to 15 inches. Drop the test package in the following sequence.

Drop Sequence	Drop Height	Orientation	Specific face, edge or corner
1	15 in.	Top	Face 1
2	15 in.	Edge	Edge 5-3
3	15 in.	Edge	Edge 6-3
4	15 in.	Corner	Corner 2-3-5
5	15 in.	Corner	Corner 4-3-6
6	15 in.	Bottom	Face 3

13.5.3. Record package drops on the data sheet in Appendix I.

13.6. Perform the vehicle stacking test. For the vehicle stacking test, use ASTM D4169 paragraph 11.3 for warehouse stacking made up of identical shipping units. For this test, the parameters for assurance level III will be applied. The justification for this adjustment is that the Zip Pen unit boxes will be shipped from the supplier in large Gaylord boxes. The Gaylord box carries a portion of the load when they are stacked for overseas shipment. The maximum stack is three boxes high (10.6 inches per box) in each of two Gaylord's, therefore a height of 63.6 inches will be used in the formula. The formula for the weight of the compression is as follows:

$$L = M \times Jx((H-h)/h)xF$$

Where the mass M =14.5 lbs., J = 1 lbf/lb, H=63.6 inches, and h= 10.6 inches and F = 3.0, a factor to account for the combined effect of the individual factors taken from paragraph 11.2 of ASTM D4169. Record information in Appendix I.

Catalog Number	Carton Weight (lbs.)	Stack Height (ft.)	Compression (lbs.)
2525-15	14.5	5.3	217.5

Note that the carton weight listed above is estimated from prototypes. If the actual carton weight varies from this value the compression weight needs to be adjusted.

13.6.1. Place *Face 3* of the shipper box on the ground.

13.6.2. Place a wood board on top of the shipper box, such that the shipper box is centered underneath the board. The wood board must extend a minimum of two inches on all sides of the box.

13.6.3. Place the test load (determined above) on the center of the wood board.

13.6.4. Allow the weight to remain on the wood board for a minimum of 3 seconds.

13.6.5. Inspect the package for damage. Record observed shipper box damage, if applicable.

13.7. Following the compression test perform the Vehicle Vibration test, record information in Appendix I.

13.7.1. Place the shipper box containing packaged product on the vibration table so that *Face 3* rests on the platform.

13.7.2. Start the vibration system beginning at the lowest frequency.

13.7.3. Slowly increase the frequency of the vibration until the shipper box begins to momentarily leave the surface of the platform.

13.7.4. Check the frequency using the shim.

13.7.4.1. Swipe the shim under the shipping box along the longest side from one end to the other. The shim should be able to travel on the long side of the box from one end of the box to the other.

13.7.4.2. At this frequency the movement of the shim will be continuous movement. If the shim does not travel uninterrupted, increase the frequency of the vibration table.

13.7.5. Leave the box on the vibration table for a period of 10 minutes.

13.7.6. After 10 minutes of Vehicle Vibration, reduce the frequency for the Loose Load vibration.

13.7.7. Check the frequency using the shim.

13.7.7.1. Swipe the shim under the shipping box along the longest side from one end to the other. The shim should be able to travel on the long side of the box from one end of the box to the other but with an interrupted motion.

13.7.8. Leave the box on the vibration table for a period of 40 minutes.

13.8. Following the vibration tests, perform the Concentrated Impact test per ASTM D6344.

13.8.1. The impact test will be done on faces 1, 2 and 3 from the figure in 11.1 Use the impact equipment identified in ENG-DWG-768.

13.8.2. The impact energy applied to each face will be 4.0 ft-lbf. This energy is applied by dropping the cylinder of mass 1.5 lbf. from a height of 32 inches.

13.8.3. Record the impact test on the data sheet in Appendix I.

13.9. Following the vibration test, perform the second package handling (drop test). Follow the sequence listed below. Make all of the drops from 15 inches except the final drop which is from 30 inches.

Drop Sequence	Drop Height	Orientation	Specific face, edge or corner
1	15 in.	Edge	Edge 4-6
2	15 in.	Face	Face 4
3	15 in.	Face	Face 6
4	15 in.	Corner	Corner 2-1-5
5	15 in.	Edge	Edge 2-1

6	30 in.	Bottom	Face 3

13.10. Following the shipping tests, evaluate the product as follows:

13.11. Inspect the exterior of each box and note any damage. Record pass/fail results in Appendix I.

13.12. If there is damage to the shipping boxes, take pictures for the test report.

14. INSPECTION FOR PRINT CLEAR AND LEGIBLE

14.1. Remove the pouches one at a time from the shipping container. Number each package with a unique identifier. Visually inspect each pouch for clarity of print. Record pass/fail results in Appendix II.

14.2. Visual inspections of the pouch are to be performed using no magnification, under normal, diffused (indirect) fluorescent lighting, at a distance of 16 - 18 inches, with a maximum of 5-second time limit for visual inspection.

15. INSPECTION FOR LOT NUMBER CLEAR AND LEGIBLE

15.1. Using the same product from step 14 above, inspect the lot number to insure that it matches the box lot number and the C of C Lot number.

15.2. Visually inspect each pouch one at a time for clarity of print of the lot number and expiration date. Record pass/fail results in Appendix II.

15.3. Visual inspections of the lot number are to be performed using no magnification, under normal, diffused (indirect) fluorescent lighting, at a distance of 16 - 18 inches, with a maximum of 5-second time limit for visual inspection.

16. DYE TEST

16.1. Perform the dye test per ASTM F1929.

16.2. Pierce the pouch with a needle attached to the syringe and inject the dye. Rotate the package so that the dye runs around the seal.

16.3. Observe the seals for areas of seal release. Mark any seal release areas with a marker.

16.4. Record the results on the Dye test data sheet in appendix IV.

17. BUBBLE LEAK TEST

17.1. Perform the bubble leak test per ASTM F2096 in a sink or plastic tub or sink that is deep enough to submerge the entire pouch.

17.2. Test the pouches one at a time. Insert the needle from the pump in the same pierced hole that was used for the dye test. It is acceptable to reinforce the puncture area with a piece of clear tape. Submerge the pouch under water. Pump the pouch up and look for bubbles. Record pass/fail results in Appendix III.

17.3. If bubbles are observed, circle the area with a marker and set the pouch aside for evaluation by Engineering.

18. BURST TEST

18.1. Cover the needle puncture area from the Dye test and Bubble Leak test with clear tape. Perform the burst test on the same samples that were dye and bubble tested.

18.2. Perform standard burst test on the Model F100-2600-3 Test-A-Pack Seal Strength Tester.

18.3. Record the burst test values on form OPER-FRM-004. The minimum burst value for these packages is 19 in. H_2O.

19. MINIMUM SEAL WIDTH

19.1. Open each pouch completely removing the Tyvek lid. Remove the bag containing the Zip Pen. Transfer the test sample number from the pouch to the bag and set aside. Visually inspect the seal area of the Nylon pouch for the narrowest portion of the seal. Using a scale marked in .01" increments, measure the seal width, record the value and which side it was taken from. The sample size for this measurement is 40 samples. Record data on the form in Appendix V.

20. PRODUCT DAMAGE INSPECTION

20.1. Open each bag one at a time and remove the Zip Pen.

20.2. Visually inspect the Zip Pen, Electrode Holster and Bag for damage. Damage includes cracks, rub marks, bent electrodes and holes in the unit bag. Also inspect for particulate in the bag and on the product.

20.3. Record pass/fail results in Appendix VI. If a product is considered to fail, describe the failure in the comments on the log sheet.

20.4. Visual inspections for product damage are to be performed using 10X magnification under the microscope lighting, with a maximum of 30 second time limit for visual inspection.

21. ACCEPTANCE CRITERIA

21.1. Shipping Test

21.1.1. Each box shall remain intact and not break open during the test. Indentations on edges or corners are acceptable.

21.2. Print Clear and Legible

21.2.1. The printing of each pouch shall be clear and legible with no smears or missing print.

21.3. Lot Number

21.3.1. The correct Lot number shall be printed on each pouch. The printing shall be clear and legible with no smears or missing print.

21.4. Dye test

21.4.1. The primary reason for the dye test is to make the seal edge more visible and to insure there are no breaches in the seal. There shall be no breaches in the seal.

21.5. Package Bubble Leak Test

21.5.1. There shall be no tears, holes or open seals in any pouch that compromise sterility after the ship test exposure.

21.6. Burst Test

21.6.1. The minimum allowable burst value is 19 in. H_2O. All package burst test values shall be above this limit.

21.7. Minimum Seal Width

21.7.1. The minimum seal width is 0.20” All seals shall meet or exceed this dimension.

21.8. Product Damage

21.8.1. There shall be no damage to the Zip Pen, Electrode, Holster or bag of the Zip Pen on any of the samples.

APPENDIX I

Shipping Test Log Sheet

Preconditioning:

Start Date: _____ Chamber Number:_____

Completion Date: _____ Last Calibration:_____

Signature/Date: _____ Calibration due:_____

Drop Test:

Catalog _____ Lot # _____ Weight _____

Drop Sequence	Drop Height	Orientation	Specific face, edge or corner	Initials/Date
1	15 in.	Top	Face 1	
2	15 in.	Edge	Edge 5-3	
3	15 in.	Edge	Edge 6-3	
4	15 in.	Corner	Corner 2-3-5	
5	15 in.	Corner	Corner 4-3-6	
6	15 in.	Bottom	Face 3	

Comments: _____

Signature: _____ Date: _____

Compression Test:

Catalog _____ Pounds Force _____

Comments: _____

Signature: _____ Date: _____

Appendix I Continued
Shipping Test Log Sheet

Vibration:

High Frequency, 10 minutes, Initials_____ Low frequency 40 minutes, Initials _____

Completion Date: _____

Signature: _____ Date: _____

Concentrated Impact Test 1.5 lbf mass dropped from 32 inches

Face 1 Initials_____ Face 2 Initials _____Face 3 Initials_____

Completion Date: _____

Second Drop Test:
Catalog_____Weight _____ Drop Height: _____

Drop Sequence	Drop Height	Orientation	Specific face, edge or corner	Initials/Date
1	15 in.	Edge	Edge 4-6	
2	15 in.	Face	Face 4	
3	15 in.	Face	Face 6	
4	15 in.	Corner	Corner 2-1-5	
5	15 in.	Edge	Edge 2-1	
6	30 in.	Bottom	Face 3	

Comments: _____

Signature: _____ Date: _____

Appendix II
Print Legibility Log Sheet

Inspect the product per the protocol and enter the number of units that pass or fail in the box below.

Catalog #	Pass	Fail
Pouch Print		
Lot Number Print		

Comments:_____

_____

_____

Inspected by: Date completed

Appendix III
Bubble Leak Test Log Sheet

Catalog #_____ Lot # _____

Sample	Pass	Fail	Comment
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			

Sample	Pass	Fail	Comment
21			
22			
23			
24			
25			
26			
27			
28			
29			
30			
31			
32			
33			
34			
35			
36			
37			
38			
39			
40			

Signature: _____ Date: _____

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Appendix IV
Dye Penetration Test Log Sheet

Catalog #_____ Lot # _____

Sample	Pass	Fail	Comment
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			

Sample	Pass	Fail	Comment
21			
22			
23			
24			
25			
26			
27			
28			
29			
30			
31			
32			
33			
34			
35			
36			
37			
38			
39			
40			

Signature: _____ Date: _____

Appendix V
Seal Width Log Sheet

Catalog #_____ Lot #: _____

Sample	Cavity	Front	Back	Right	Left
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					
21					
22					
23					
24					
25					
26					
27					
28					
29					
30					
31					
32					
33					
34					
35					
36					
37					
38					
39					
40					

Appendix VI
Product Damage Inspection Log Sheet

Inspect the product for damage per the protocol and enter the number of units that pass or fail in the box below. Inspect the Zip Pen, Electrode, Holster and Bag for damage. Damage includes cracks, rub marks, bent electrodes and holes in the unit bag. Also inspect for particulate in the bag and on the product.

Catalog #	Pass	Fail
Damage		

Comments:_____

_____

_____

Inspected by: Date completed