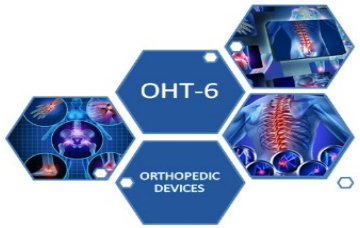


U.S. FOOD & DRUG ADMINISTRATION

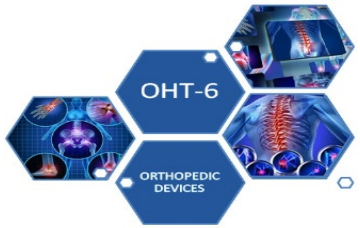
MEDICAL DEVICE STABILITY

Conducting Package Stability and Performance Validation for Terminally Sterilized Single-Use Medical Devices

— and —

Establishing Use-Life for Reusable Medical Devices

Steven Turtil, MS
Microbiology Reviewer, Extracolumnar Spinal Devices Team
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices

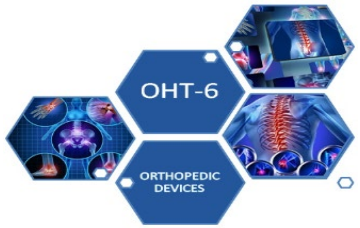


Regulatory Review

Class II – Moderate Risk Devices
Emphasis is on the 5 points in Section V.A of FDA's Sterile Devices Guidance, but comprehensive testing must be completed and will be reviewed in-depth upon inspection.

Class III – High Risk Devices
We comprehensively evaluate all test data upon submission.

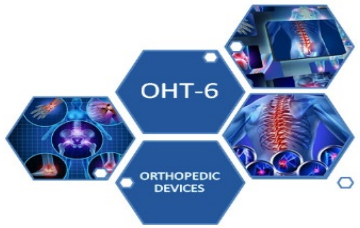
In both instances, all required testing must be completed and documented (and available for review) for each device type. What differs is WHEN it is reviewed. And even that may vary depending upon device type (e.g., existence of a "device specific guidance") or on an "as needed" basis.



OBJECTIVES:
MEDICAL DEVICE STABILITY

1. To understand packaging validation methods for terminally sterilized single-use medical devices:
   a. Package STABILITY – aging and shelf-life testing
   b. Package PERFORMANCE – distribution and integrity testing
2. To understand the use-life/reuse-life/service-life options for reusable medical devices, and how these are established

Product Stability and Performance are also evaluated



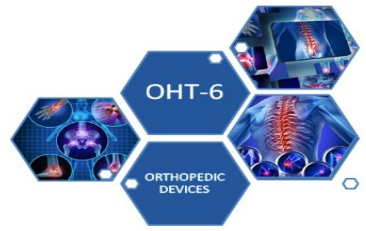
PACKAGING
STERILE BARRIER SYSTEMS

3.23
sterile barrier system — SBS
minimum package that minimizes the risk of ingress of microorganisms and allows aseptic presentation of the sterile contents at the point of use
[SOURCE: ISO 11139:2018, 3.272]

From a microbiology perspective, the sterile barrier system (SBS) should be designed to assure adequate sterilant penetration, as well as maintenance of sterility; from the point of sterilization during manufacture, to the time and place of medical device use.

- FDA recommends that package "**performance**" testing be designed and implemented to assure that the packaged product can withstand the rigors of real world, worst-case shipping and handling.
- FDA recommends that package "**stability**" testing be conducted to assure that the packaging will maintain product sterility for the duration of the stated expiration date.

FDA's 2016 Sterile Devices Guidance



Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile

Guidance for Industry and Food and Drug Administration Staff

Document issued on January 21, 2016.

The draft of this document was issued on December 12, 2008.

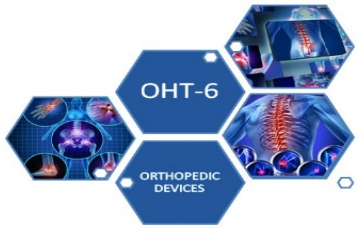
As of March 21, 2016, this document supersedes "Updated 510(k) Sterility Review Guidance K90-1" issued August 30, 2002.

This guidance has been updated March 16, 2016 to correct an inadvertent editorial change regarding reporting of endotoxin limits.

For questions about this document regarding CDRH-regulated devices, contact the Infection Control Devices Branch (INCB) at 301-796-5580.

For questions about this document regarding CBER-regulated devices, contact CBER's Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research



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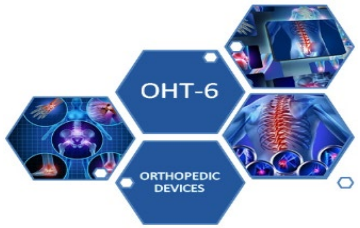


V. Sterilization Information for Devices Labeled Sterile

FDA

Sponsors should ensure the submission includes:

1. **Sterilization method description** per parts "a" to "f" (to include content such as chamber description, dose, residuals, as applicable)

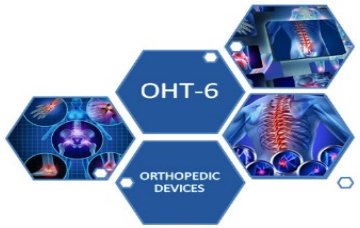
2. **Validation method**, and relevant standards, or a comprehensive description of the process and validation protocol.

3. **Sterility assurance level** (SAL) of 10^{-6} for devices labeled as sterile, 10^{-3} for devices that only contact intact skin.

4. **Pyrogenicity Claim**, if applicable:
   a description of the method, batch testing or sampling plan confirmation, the chosen testing limit and its justification, in endotoxin units/device.

5. A **description of the packaging** (sterile barrier system) and how it will maintain the device's sterility, and a **description of the package test methods**, but **not package test data**.*

* Some device submissions should provide packaging data (e.g., prefilled saline syringes). This depends on device type, so know your particular device types and review practices.



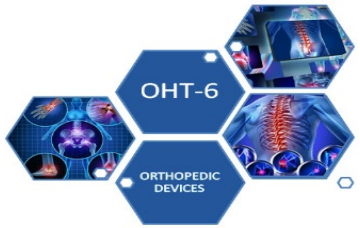
V. Sterilization Information for Devices Labeled Sterile

FDA

Sponsors should ensure the submission includes:

5. A description of the packaging (sterile barrier system) and how it will maintain the device's sterility, and a description of the package test methods, but not package test data.[13]

[13] FDA recommends that package test methods include simulated distribution and associated package integrity, as well as simulated (and/or real-time) aging and associated seal strength testing, to validate package integrity and shelf-life claims. Please refer to the current, FDA-recognized version of the AAMI/ANSI/ISO 11607-series of consensus standards.



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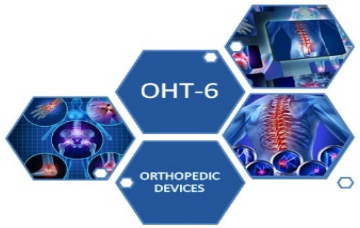


V. Sterilization Information for Devices Labeled Sterile

FDA

Sponsors should ensure the submission includes:

5. A description of the packaging (sterile barrier system) and how it will maintain the device's sterility, and the package test methods, but not package test data.

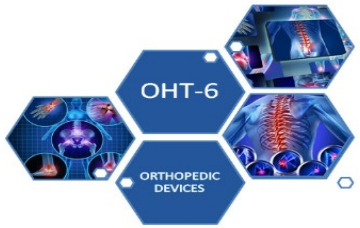
A simple summary of the testing design is sufficient:

- simulated shipping followed by package integrity testing

  and

- aging followed by seal strength testing.

Or a statement of conformity to the AAMI/ANSI/ISO 11607-series of consensus standards would suffice.



V. Sterilization Information for Devices Labeled Sterile

FDA

Sponsors should ensure the submission includes:

5. A description of the packaging (sterile barrier system) and how it will maintain the device's sterility, and the package test methods, but not package test data.

A more comprehensive response might look like:

PERFORMANCE:

Simulated distribution (e.g., ASTM D4169 "*Standard Practice for Performance Testing of Shipping Containers and Systems*")

followed by

Package integrity (e.g., ASTM F1929 "*Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration*")

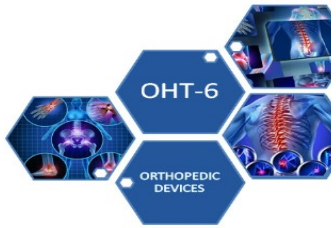
plus

STABILITY:

Simulated aging (ASTM F1980 "*Standard Guide for Accelerated Aging of Sterile Medical Device Packages*") or (and/or real-time) aging

followed by

Seal strength testing (e.g., ASTM F88 "*Standard Test Method for Seal Strength of Flexible Barrier Materials*")



DOUBLE STERILE BARRIER SYSTEM — EXAMPLE VALIDATION FLOWCHART

Rev. 5/23/2023

This is an ***example*** of a flowchart. It represents a ***hypothetical*** series of simulations and subsequent tests, intended to provide a high level of assurance that the packaging will demonstrate adequate stability, and the packaged product will be able to withstand real world, worst-case shipping and handling, without package failure or sterile barrier breach. The details of this test schedule may or may not be appropriate for other products, as test procedures should be developed on a case-by-case basis. In general, the Agency considers breach of the sterile barrier system to more likely be event related, than time related.

DRAFT

Manufacture and Package
150 + X packaged device samples and 300 + 2X data points

Sterilize 1 or 2X

Sterilize (2X option)

Sterilize (2X option)

Sealer Pilot Study – Peel Strength Test

X samples
(device may not be required).

Vary seal parameters: temperature, dwell time, pressure, etc., to establish optimum sealer settings.

STABILITY (Shelf Life)

3 Year Accelerated Aging
30 packaged devices
→ Peel Strength Test**
30 packages

3 Year Real-Time Aging Confirmatory
30 packaged devices
→ Peel Strength Test**
30 packages

PERFORMANCE (Integrity)

Shipping and Handling Simulation
e.g., per ASTM D4169
e.g., Distribution Cycle 13 / Assurance Level I
60 packaged devices

↓ Handling - per ASTM

↓ Vehicle Stacking - per ASTM

↓ Loose-Load Vibration - per ASTM

↓ Low Pressure - per ASTM

↓ Vehicle Vibration - per ASTM

↓ et cetera - per ASTM

↓ Validated Package Integrity Test**
e.g., Dye Penetration, ASTM F1929
60 packaged devices

Time "Zero" – Peel Strength Test**

30 samples
(device may not be required).

"Time 0" data is baseline data and represents real packaged product immediately after manufacture.

DRAFT

STRESSES OF SHIPPING AND HANDLING*

For standards such as ASTM D4169, Assurance Level and Distribution Cycle should be identified and justified.

This defines Dropping, Vibration, Stacking, and Temperature extremes, etc.

Test packages should include device or simulated device (i.e., similar mass and geometry) and should be tested against all the rigors of the real-world shipping environments.

NOTES on STABILITY:

NOTE 1. This hypothetical test is intended to support a 3-year shelf life claim. The Agency typically approves product based on accelerated aging and expects submission of confirmatory real time test data, when available.

NOTE 2. This is designed to address package stability and not product stability.

GENERAL NOTES:

NOTE 1. If packaging is comprised of a double sterile barrier system, both internal and external packaging systems should be tested.

NOTE 2. Visual inspection should also be incorporated into the overall validation design.

* See applicable FDA recognized consensus standards, available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.
Examples: ISO 11607: Packaging for terminally sterilized medical devices, Parts 1 and 2; ASTM D4169 Performance Testing of Shipping Containers and Systems; ASTM F1980 (Accelerated Aging); ASTM F1929 (Dye Penetration Test); ASTM F88 (Seal Strength); ASTM F1886 (Visual Inspection).

** All test methods should be validated, use statistically significant sample sizes (95% Confidence and 95% Reliability is recommended), and include a predetermined, scientifically justified test endpoint.

PACKAGING

INTERNATIONAL STANDARD **ISO 11607-1**

Second edition
2019-02

Packaging for terminally sterilized medical devices —

Part 1:
Requirements for materials, sterile barrier systems and packaging systems

Emballages des dispositifs médicaux stérilisés au stade terminal —

Partie 1: Exigences relatives aux matériaux, aux systèmes de barrière stérile et aux systèmes d'emballage

Reference number
ISO 11607-1:2019(E)

INTERNATIONAL STANDARD **ISO 11607-2**

Second edition
2019-02

Packaging for terminally sterilized medical devices —

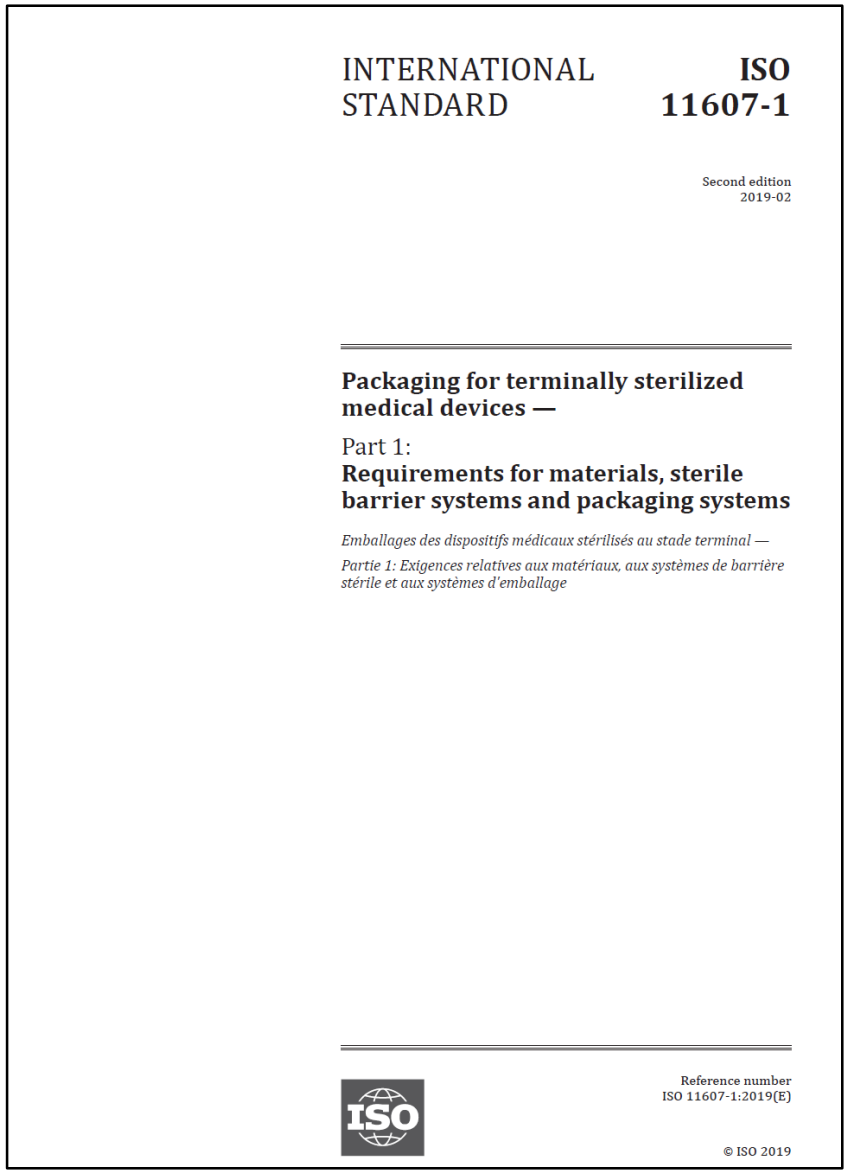
Part 2:
Validation requirements for forming, sealing and assembly processes

Emballages des dispositifs médicaux stérilisés au stade terminal —

Partie 2: Exigences de validation pour les procédés de formage, scellage et assemblage

Reference number
ISO 11607-2:2019(E)

PACKAGING



INTERNATIONAL STANDARD **ISO 11607-1**

Second edition
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Packaging for terminally sterilized medical devices —

Part 1:
Requirements for materials, sterile barrier systems and packaging systems

Emballages des dispositifs médicaux stérilisés au stade terminal —
Partie 1: Exigences relatives aux matériaux, aux systèmes de barrière stérile et aux systèmes d'emballage

Reference number
ISO 11607-1:2019(E)

© ISO 2019

1 Scope

This document specifies requirements and test methods for materials, preformed sterile barrier systems, sterile barrier systems and packaging systems that are intended to maintain sterility of terminally sterilized medical devices until the point of use.

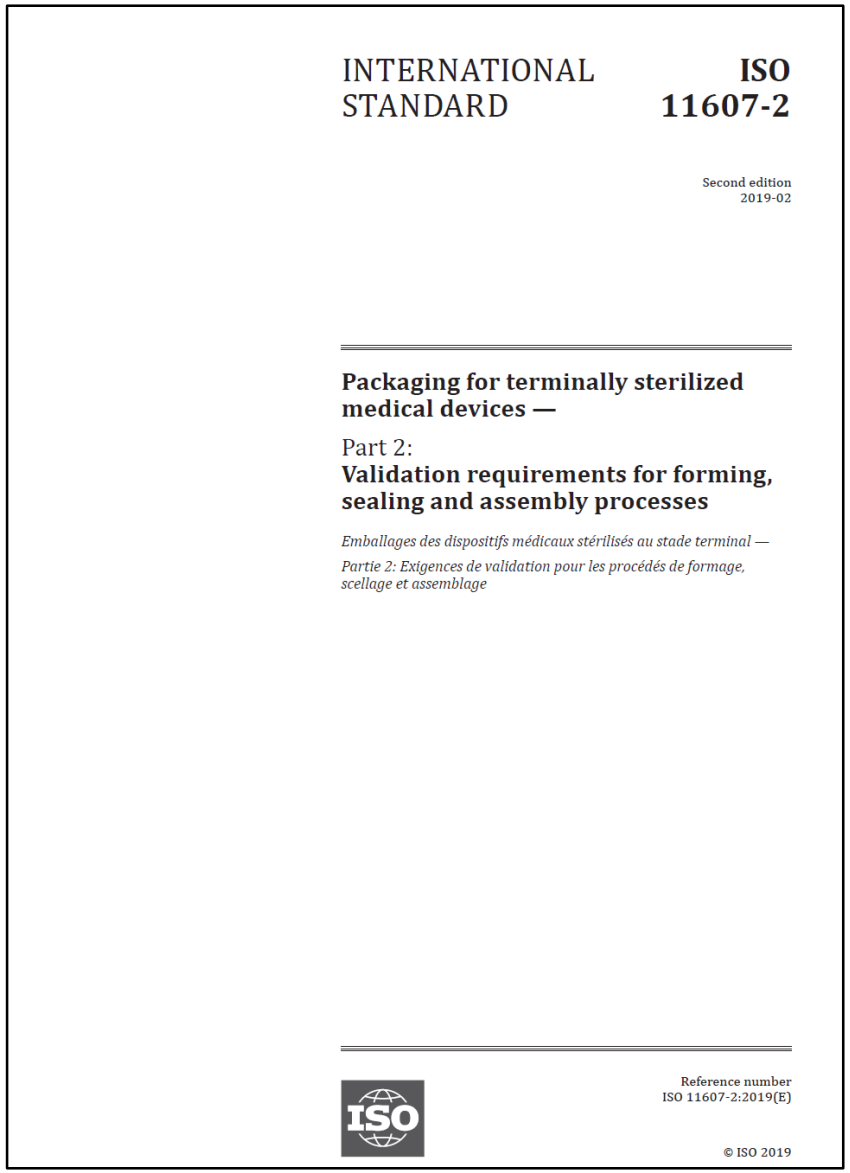
It is applicable to industry, to health care facilities, and to wherever medical devices are placed in sterile barrier systems and sterilized.

It does not cover all requirements for sterile barrier systems and packaging systems for medical devices that are manufactured aseptically. Additional requirements can be necessary for drug/device combinations.

It does not describe a quality assurance system for control of all stages of manufacture.

It does not apply to packaging materials and/or systems used to contain a contaminated medical device during transportation of the item to the site of reprocessing or disposal.

PACKAGING



INTERNATIONAL STANDARD **ISO 11607-2**

Second edition
2019-02

Packaging for terminally sterilized medical devices —

Part 2:
Validation requirements for forming, sealing and assembly processes

Emballages des dispositifs médicaux stérilisés au stade terminal —
Partie 2: Exigences de validation pour les procédés de formage, scellage et assemblage

Reference number
ISO 11607-2:2019(E)

1 Scope

This document specifies requirements for the development and validation of processes for packaging medical devices that are terminally sterilized. These processes include forming, sealing and assembly of preformed sterile barrier systems, sterile barrier systems and packaging systems.

It is applicable to industry, to health care facilities, and to wherever medical devices are packaged and sterilized.

It does not cover all requirements for packaging medical devices that are manufactured aseptically. Additional requirements can be necessary for drug/device combinations.

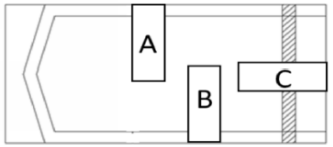
PACKAGING - Terminology

aseptic presentation
transfer of sterile contents from its sterile barrier system using conditions and procedures that minimize the risk of microbial contamination

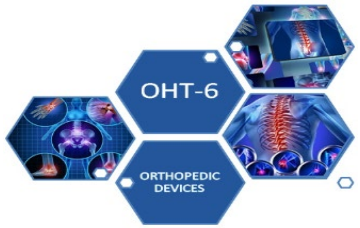
microbial barrier
property of a sterile barrier system to minimize the risk of ingress of microorganisms

packaging system
combination of a sterile barrier system and protective packaging

preformed sterile barrier system
sterile barrier system (3.23) that is supplied partially assembled for filling and final closure or sealing
EXAMPLE Pouches, bags and open *reusable containers* (3.17).



protective packaging
configuration of materials designed to prevent damage to the sterile barrier system and its contents from the time of their assembly until the point of use



PACKAGING - Terminology

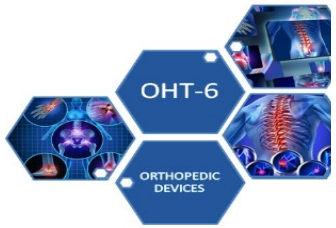
process parameter
specified value for a *process variable* (3.16)
Note 1 to entry: The specification for a process includes the process parameters and their tolerances.

seal integrity
<packaging> characteristics of a seal to minimize the ingress of microorganisms

seal strength
mechanical capacity of the seal to withstand force

sterile barrier system
SBS
minimum package that minimizes the risk of ingress of microorganisms and allows aseptic presentation of the sterile contents at the point of use

terminal sterilization
process whereby a product is sterilized within its sterile barrier system



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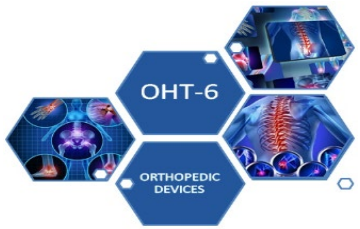


B.1 General

The following documents contain provisions that may be used to demonstrate conformity with provisions of this document. When using test methods and procedures listed in Table B.1, it is important to note the date of issue of these documents. Specific requirements for the use of test methods are found in 4.4.

The criteria for inclusion of test methods and procedures given in Table B.1 are that they shall be nominated for inclusion and commercially available from a standards development organization, trade association or national standards body. Consequently, the Bibliography contains additional test methods that were published in the literature. This annex is not intended to be all-inclusive and the development of new test methods is known to be underway at the time of publication.

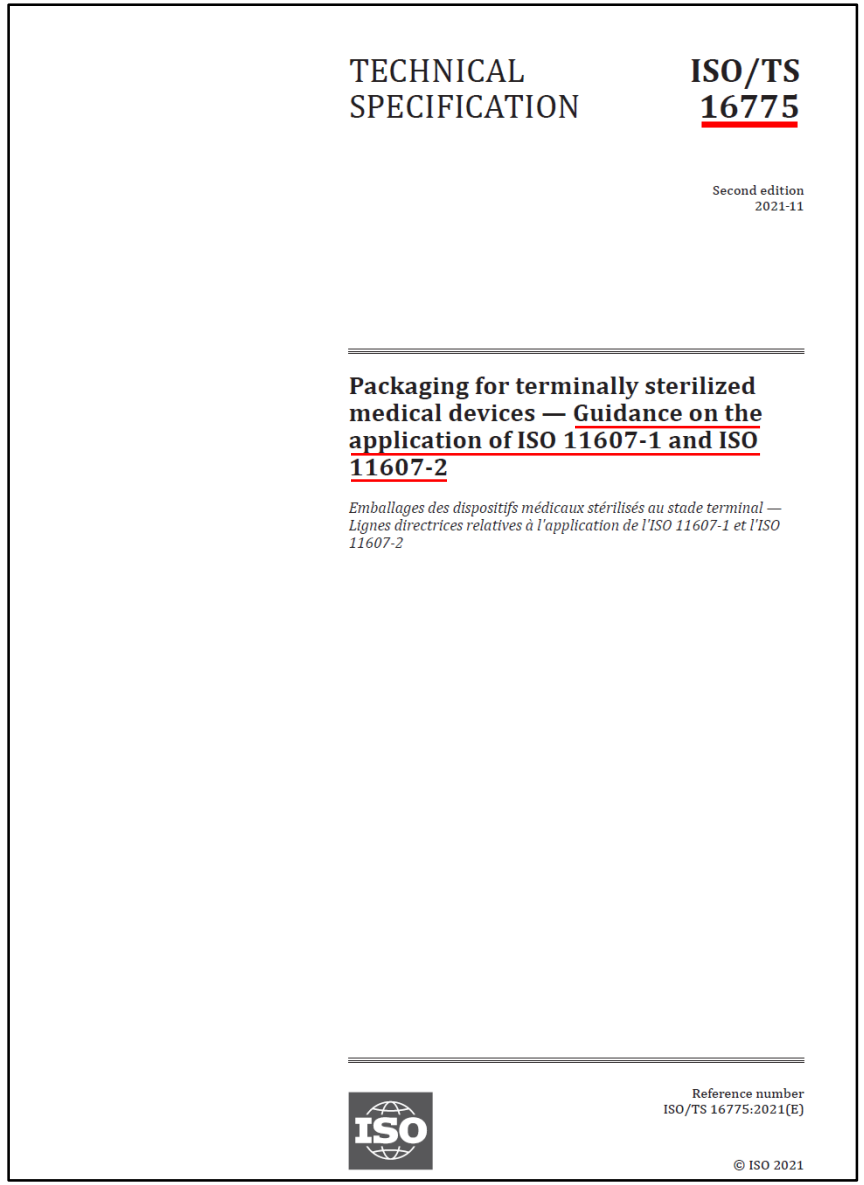
B.2 Packaging materials and preformed sterile barrier systems

Table B.1—Test methods and their status

Attribute/ Characteristics	Reference	Title of reference	Test method has statement of precision and/or bias, repeatability and reproducibility	Test method only has statement of precision and/or bias	Guidance, Standard Practice
Accelerated aging	ASTM F1980	Standard guide for accelerated aging of sterile barrier systems for medical devices	NA[a]	NA	Yes
	EN 868–8	Packaging for terminally sterilized medical devices—Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 — Requirements and test methods	NA	NA	Yes
Air permeance	ISO 5636-3	Paper and board—Determination of air permeance (medium range)—Part 3: Bendtsen method	No	No	NA
	ISO 5636-5	Paper and board—Determination of air permeance and air resistance (medium range)—Part 5: Gurley method	No	No	NA
	JIS P-8117	Paper and board—Determination of air permeance and air resistance (medium range)—Gurley method	Yes	—	NA

Test method only has statement of precision and/or bias	Guidance, Standard Practice
—	NA
Yes	NA
—	NA
—	NA
No	NA
No	NA
No	NA
—	NA
—	NA
—	NA
NA	Yes
NA	Yes
—	NA
—	NA
—	NA
—	NA
—	NA

ISO 16775 – PACKAGING – GUIDANCE ON 11607



TECHNICAL SPECIFICATION

ISO/TS 16775

Second edition
2021-11

Packaging for terminally sterilized medical devices — Guidance on the application of ISO 11607-1 and ISO 11607-2

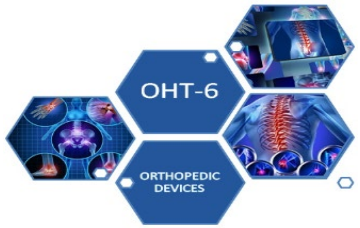
Emballages des dispositifs médicaux stérilisés au stade terminal — Lignes directrices relatives à l'application de l'ISO 11607-1 et l'ISO 11607-2

Reference number
ISO/TS 16775:2021(E)

PACKAGING

Contents

PACKAGING



V. Sterilization Information for Devices Labeled Sterile

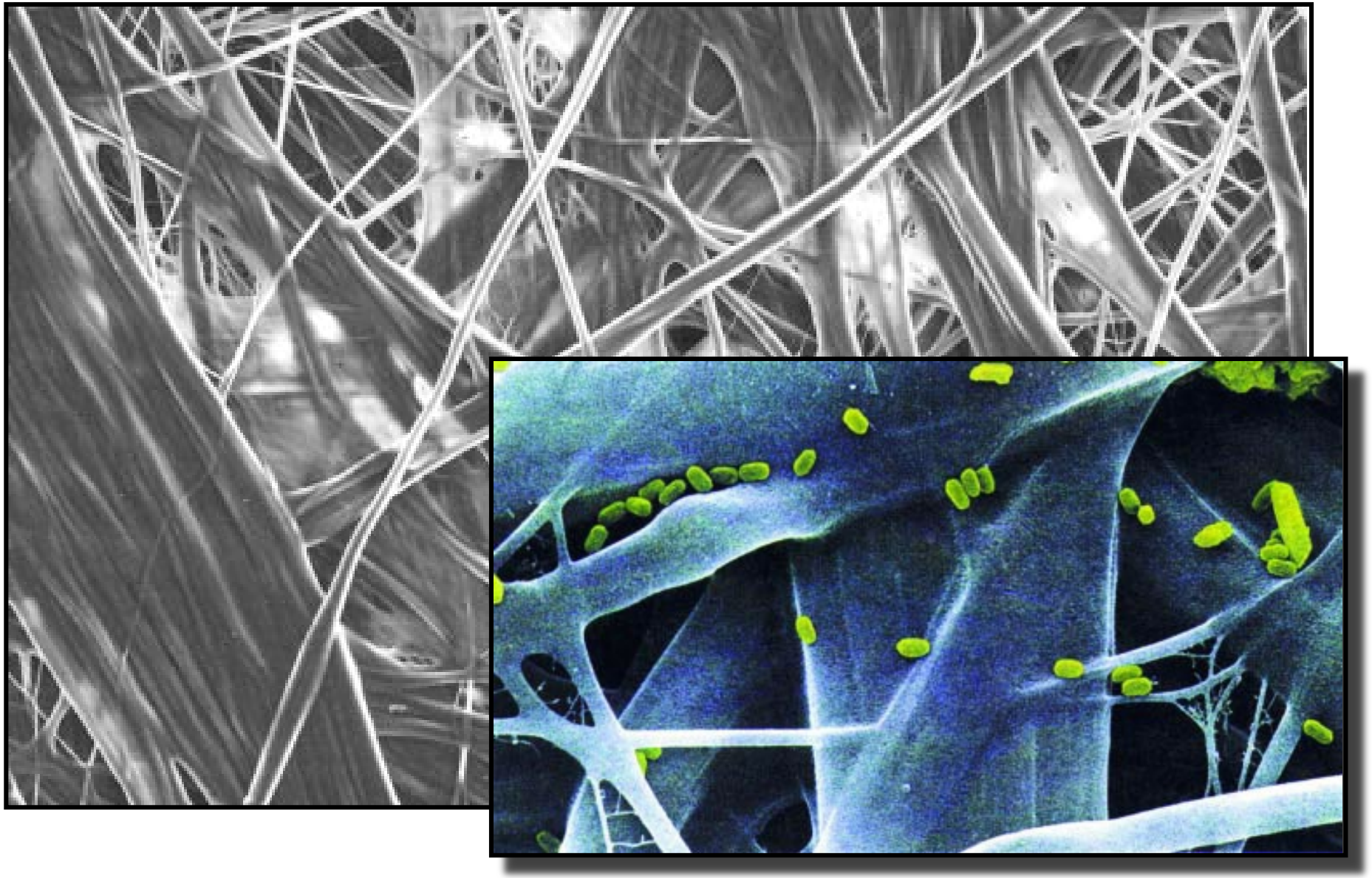
Sponsors should ensure the submission includes:

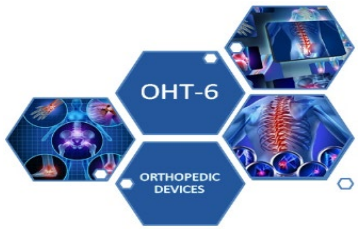
5. **A description of the packaging (sterile barrier system) and how it will maintain the device's sterility, and the package test methods, but not package test data.**

   Examples - Package Materials and Compatibility.
   Allows for sterilant penetration & sterility maintenance.

   - **EO: Breathable materials –**
     - **Tyvek/Mylar combination, or Tyvek/PETG tray**
   - **Steam: must allow steam penetration**
     - **Paper/plastic (possibly, *for low temps*, Tyvek/film).**
   - **Radiation: can be non-breathable.**
     - **foil, Mylar, film**
   - **Dry Heat: Varies - must allow for transfer of heat.**

PACKAGING MATERIALS – EXAMPLE





PACKAGIN PLES

Miscellaneous P and 1059B Trans

Property	Comparable Test Method	Units	Current Type	1059B Transition Protocol Typical Value
Microbial Barrier	ASTM F1608 ASTM F2638	LRV % pMax		>4 <0.5
Bendtsen Air Permeability	ISO 5636-3	mL/min		557
Moisture Vapor Transmission Rate	TAPPI T523[1]	$g/m^2/24$ hr		>1600
Hydrostatic Head	AATCC TM 127 EN 20811[2]	cm H_2O		157
Tensile Strength, MD	ASTM D5035[3] EN ISO 1924-2[3]	N/2.54 cm		190
Tensile Strength, CD	ASTM D5035[3] EN ISO 1924-2[3]	N/2.54 cm		185
Elongation, MD	ASTM D5035[3] EN ISO 1924-2[3]	%		19
Elongation, CD	ASTM D5035[3] EN ISO 1924-2[3]	%		23
Elmendorf Tear, MD	ASTM D1424 EN 21974	N		3.0
Elmendorf Tear, CD	ASTM D1424 EN 21974	N		3.8
Mullen Burst	ASTM D774 ISO 2758	kPa		1034
Spencer Puncture	ASTM D3420[4]	J/m^2		7746
Opacity	TAPPI T425 ISO 2471[5]	%		92
Thickness (Individual)*	ASTM D1777[6] EN 20534[7] EN ISO 534	µm		178

NOTES: 1073B and 1059B Transition Protocol typical values repres
Values will be refreshed, as necessary, upon data collection from a
based on roll averages, except for thickness (individual), with samp
pooled individual data points from multiple rolls. Miscellaneous pr
drift. Customers must conduct their own tests to ensure suitability
Any downstream operations, such as coatings applied by sterile pa
*Thickness variability target is equal to, or less than, incumbent pr
MD = machine direction; CD = cross direction; LRV = log reduction

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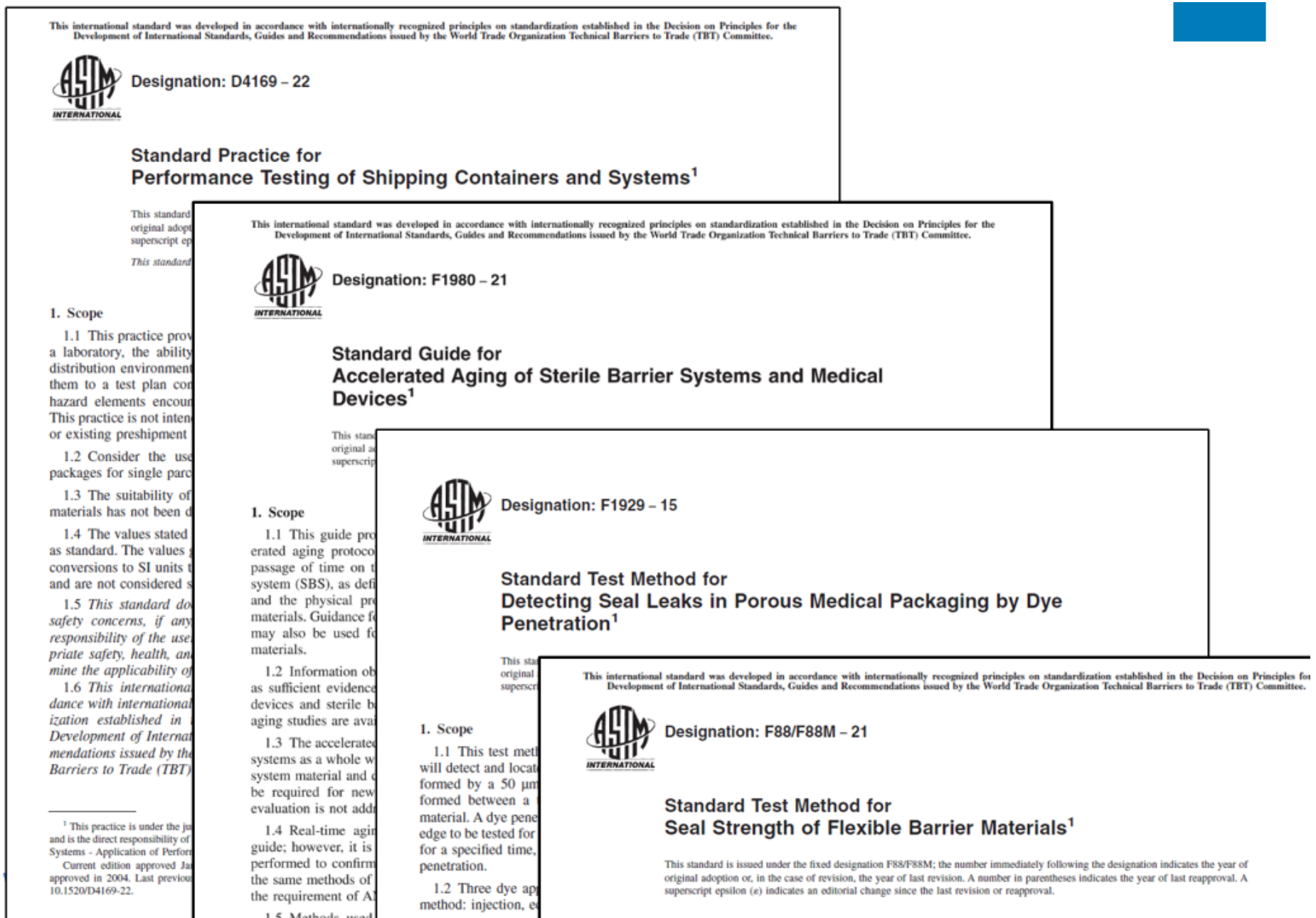
Spencer Puncture	ASTM D3420[4]	J/m^2

DUPONT
vek.

% RH.
ain.
auge length.
8-mm) probe.
king standards, area and illumination.
ter presser foot.
4.5 psi (100 kPa).

connection with this information.
ED, INCLUDING WITHOUT LIMITATIONS,

PACKAGING – SIMULATIONS AND TESTING



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Designation: D4169 – 22

Standard Practice for
Performance Testing of Shipping Containers and Systems[1]

1. Scope

This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.

Designation: F1980 – 21

Standard Guide for
Accelerated Aging of Sterile Barrier Systems and Medical Devices[1]

1. Scope

Designation: F1929 – 15

Standard Test Method for
Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration[1]

1. Scope

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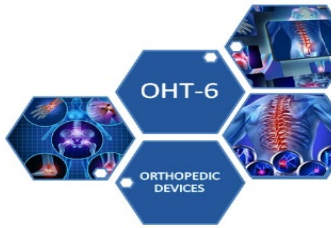
Designation: F88/F88M – 21

Standard Test Method for
Seal Strength of Flexible Barrier Materials[1]

This standard is issued under the fixed designation F88/F88M; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.



DOUBLE STERILE BARRIER SYSTEM — EXAMPLE VALIDATION FLOWCHART

Rev. 5/23/2023

This is an ***example*** of a flowchart. It represents a ***hypothetical*** series of simulations and subsequent tests, intended to provide a high level of assurance that the packaging will demonstrate adequate stability, and the packaged product will be able to withstand real world, worst-case shipping and handling, without package failure or sterile barrier breach. The details of this test schedule may or may not be appropriate for other products, as test procedures should be developed on a case-by-case basis. In general, the Agency considers breach of the sterile barrier system to more likely be event related, than time related.

DRAFT

Manufacture and Package
150 + X packaged device samples and 300 + 2X data points

Sterilize 1 or 2X

Sterilize (2X option)

Sterilize (2X option)

Sealer Pilot Study – Peel Strength Test

X samples
(device may not be required).

Vary seal parameters: temperature, dwell time, pressure, etc., to establish optimum sealer settings.

STABILITY (Shelf Life)

3 Year Accelerated Aging
30 packaged devices
→ Peel Strength Test**
30 packages

3 Year Real-Time Aging Confirmatory
30 packaged devices
→ Peel Strength Test**
30 packages

PERFORMANCE (Integrity)

Shipping and Handling Simulation
e.g., per ASTM D4169
e.g., Distribution Cycle 13 / Assurance Level I
60 packaged devices

↓ Handling - per ASTM

↓ Vehicle Stacking - per ASTM

↓ Loose-Load Vibration - per ASTM

↓ Low Pressure - per ASTM

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↓ et cetera - per ASTM

↓ Validated Package Integrity Test**
e.g., Dye Penetration, ASTM F1929
60 packaged devices

Time "Zero" – Peel Strength Test**

30 samples
(device may not be required).

"Time 0" data is baseline data and represents real packaged product immediately after manufacture.

DRAFT

STRESSES OF SHIPPING AND HANDLING*

For standards such as ASTM D4169, Assurance Level and Distribution Cycle should be identified and justified.

This defines Dropping, Vibration, Stacking, and Temperature extremes, etc.

Test packages should include device or simulated device (i.e., similar mass and geometry) and should be tested against all the rigors of the real-world shipping environments.

NOTES on STABILITY:

NOTE 1. This hypothetical test is intended to support a 3-year shelf life claim. The Agency typically approves product based on accelerated aging and expects submission of confirmatory real time test data, when available.

NOTE 2. This is designed to address package stability and not product stability.

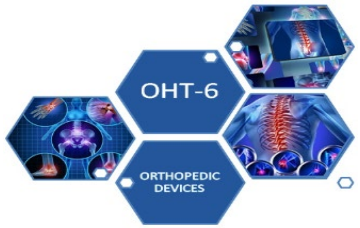
GENERAL NOTES:

NOTE 1. If packaging is comprised of a double sterile barrier system, both internal and external packaging systems should be tested.

NOTE 2. Visual inspection should also be incorporated into the overall validation design.

* See applicable FDA recognized consensus standards, available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.
Examples: ISO 11607: Packaging for terminally sterilized medical devices, Parts 1 and 2; ASTM D4169 Performance Testing of Shipping Containers and Systems; ASTM F1980 (Accelerated Aging); ASTM F1929 (Dye Penetration Test); ASTM F88 (Seal Strength); ASTM F1886 (Visual Inspection).

** All test methods should be validated, use statistically significant sample sizes (95% Confidence and 95% Reliability is recommended), and include a predetermined, scientifically justified test endpoint.



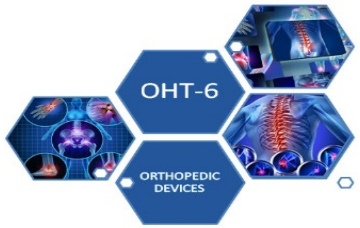
PACKAGING and ACCELERATED AGING

- ASTM F1980-21: “Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices”

- “SHELF LIFE OF MEDICAL DEVICES” - FDA 1991, Guidance Document https://www.fda.gov/regulatory-information/search-fda-guidance-documents/shelf-life-medical-devices

- “General Aging Theory and Simplified Protocol for Accelerated Aging of Medical Devices” - https://www.mddionline.com/design-engineering/general-aging-theory-and-simplified-protocol-accelerated-aging-medical-devices

- ASTM F1980: Accelerated Aging Time and Temperature - https://www.youtube.com/watch?v=0H-ePF0KxLs



PACKAGING and ACCELERATED AGING

FDA

Shelf Life of Medical Devices - FDA Guidance

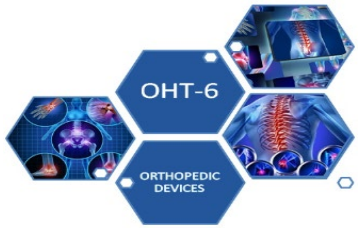
As a rule of thumb, every 10°C increase for the tested temperature above normal storage temperature will enhance the expiration date by a factor of two.

- https://www.fda.gov/regulatory-information/search-fda-guidance-documents/shelf-life-medical-devices

Accelerated Aging Testing

The Arrhenius equation indicates that a +10°C increase in temperature doubles the rate (known as a Q_{10} factor of 2) of chemical reaction. This is the most popular and conservative method of calculating Accelerated Aging.

- https://www.westpak.com/industry-solutions/medical-device/accelerated-aging/



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"Accelerated studies, combined with basic stability information on the components, drug products, and container-closure system, may be used to support tentative expiration dates provided full shelf life studies are not available and are being conducted."

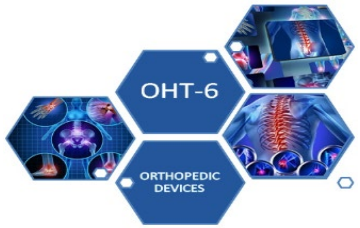
Procedure for Testing Shelf Life

A written procedure for establishing and monitoring shelf life of medical devices should include the following:

5. Accelerated Aging Parameters, including information that validates the accelerated system. The results need to be supported by real time testing of shelf life samples to confirm the tentative shelf life data collected from the accelerated tests.

ISO 11607-1

8.3.3 Stability testing, using accelerated aging protocols, shall be regarded as sufficient evidence for claimed expiry dates until data from real-time aging studies are available.



LIMITATIONS – Temperature and Materials

ASTM F1980: Standard for Accelerated Aging of Sterile Barrier Systems and Medical Devices

What is the best temperature to use for an ASTM F1980 test?

The ASTM F1980 standard suggests using an accelerated aging temperature below 60°C. Aging your product at a greater temperature provides the **advantage** of a faster simulation of the aging interval, but this comes with **risks** for particular products and packaging materials. Medical devices are often engineered with delicate materials that may drastically change when exposed to temperatures exceeding +60°C.

- https://www.westpak.com/test-standards/astm-f1980/#:~:text=What%20is%20the%20best%20temperature,temperature%20below%2060%C2%B0C.

In general, all materials have different Q_{10} factors; but most of those used in packaging have a $Q_{10} = 2$.

ACCELERATED AGING

General Aging Theory and Simplified Protocol for Accelerated Aging of Medical Devices

Karl J. Hemmerich
https://www.mddionline.com/design-engineering/general-aging-theory-and-simplified-protocol-accelerated-aging-medical-devices

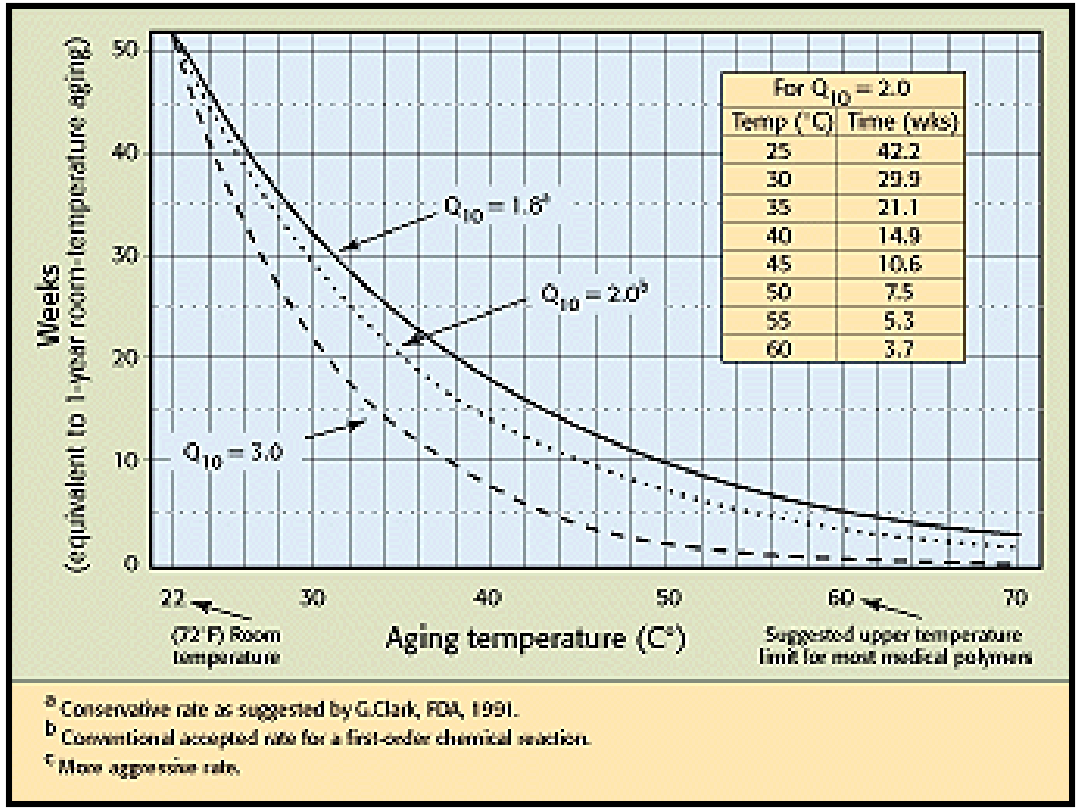
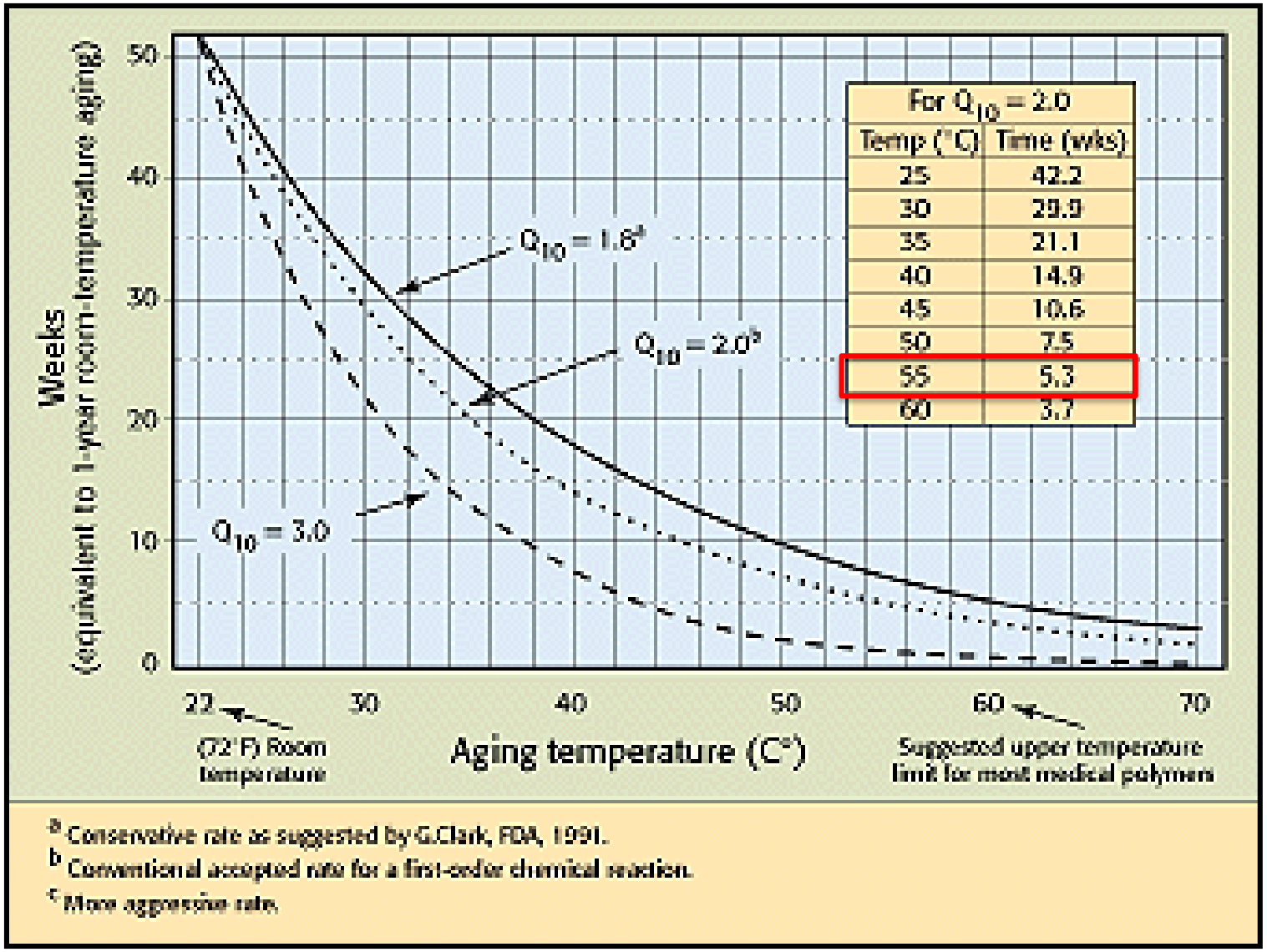
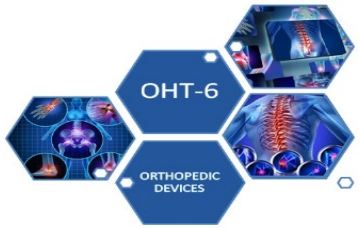


Figure 1. Accelerated aging of polymers (time versus temperature), showing the time (in weeks) equivalent to 1 year of room-temperature aging when a polymer is heat-aged at a selected temperature (°C).

ACCELERATED AGING





ARRHENIUS EQUATION

Accelerated Aging Time = Desired Real Time divided by the Accelerated Aging Factor

$$365\ \text{Days} \ / \ \text{AAF} = Q_{10}^{[(T_{AA} - T_{RT})/10]}$$

AAF – Accelerated Aging Factor
Q_{10} – Factor depending on material type
T_{AA} – Accelerated Aging Temperature
T_{RT} – Storage Temperature

$$365\ \text{Days} / 2^{[(T_{AA} - T_{RT})/10]}$$

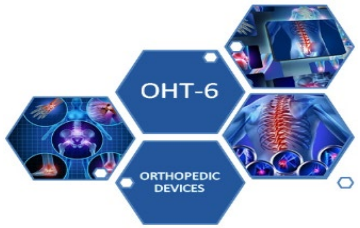
$$365\ \text{Days} / 2^{[(55°C - 23°C)/10]}$$

$$365\ \text{Days} / 2^{[(32°C)/10]}$$

$$365\ \text{Days} / 2^{[3.2]}$$

$$365\ \text{Days} / 9.19$$

39.72 Days Accelerated = 1 Year Real Time



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$$365\ \text{Days} / 2^{[(T_{AA} - T_{RT})/10]}$$

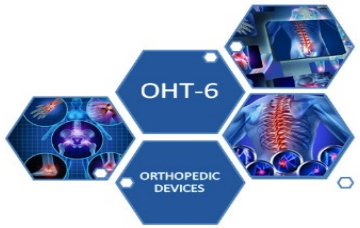
$$365\ \text{Days} / 2^{[(50°C - 23°C)/10]}$$

$$365\ \text{Days} / 2^{[(27°C)/10]}$$

$$365\ \text{Days} / 2^{[2.7]}$$

$$365\ \text{Days} / 6.5$$

56.15 Days Accelerated = 1 Year Real Time



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T_{RT} – Storage Temperature

$$365\ \text{Days} / 2^{[(T_{AA} - T_{RT})/10]}$$

$$365\ \text{Days} / 2^{[(60°C - 23°C)/10]}$$

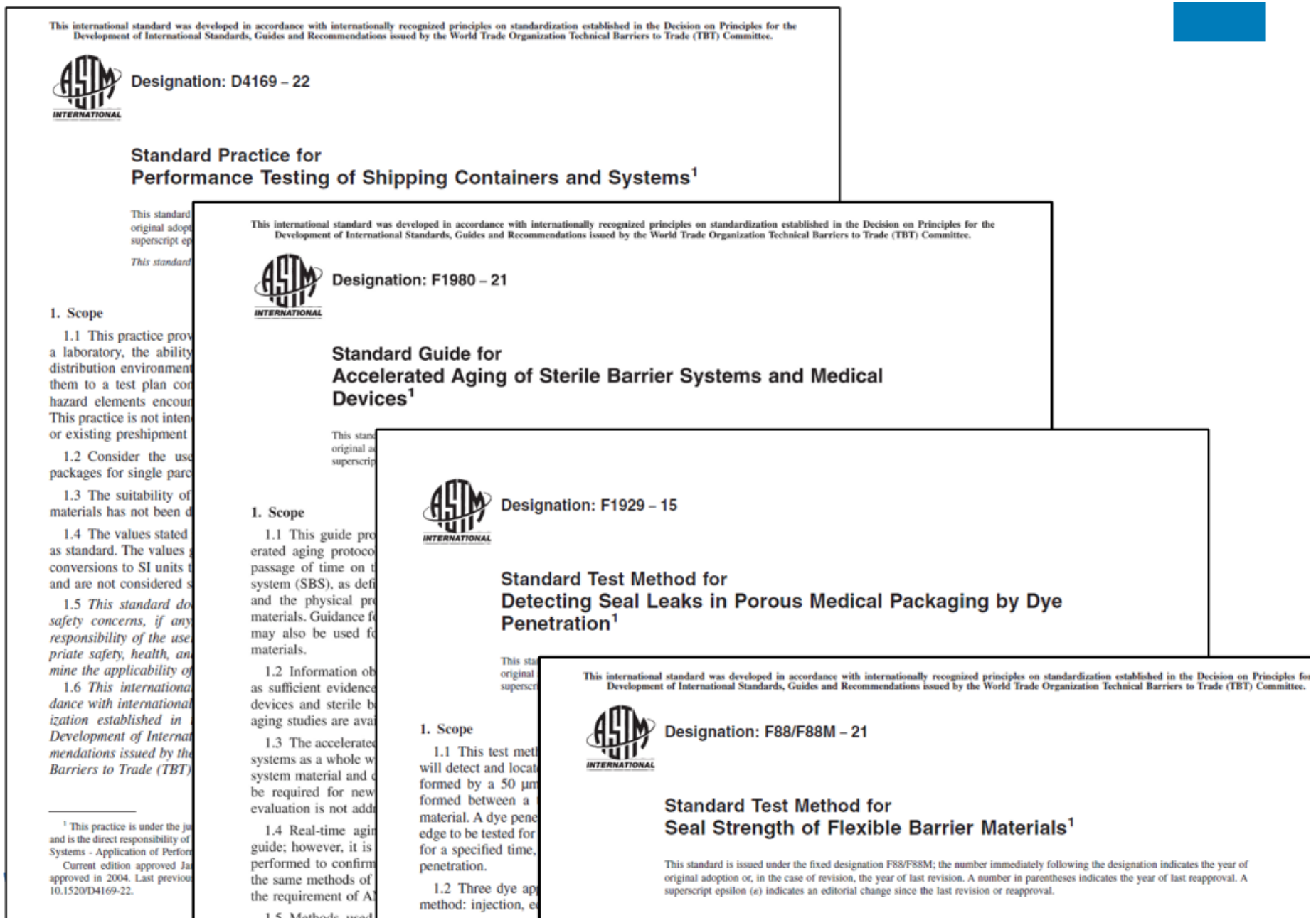
$$365\ \text{Days} / 2^{[(37°C)/10]}$$

$$365\ \text{Days} / 2^{[3.7]}$$

$$365\ \text{Days} / 12.99$$

28.1 Days Accelerated = 1 Year Real Time

PACKAGING



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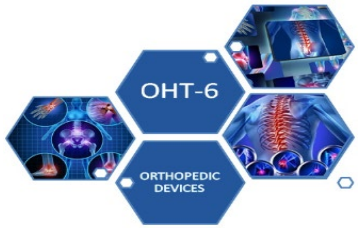
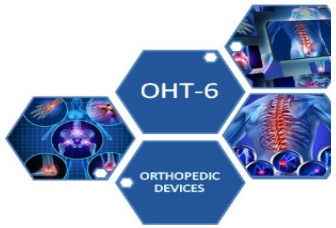


SEAL STRENGTH - ACCEPTANCE CRITERION

This should be scientifically justified:

- **There is no single standardized acceptance criterion.**
- **A common minimum value is 1 lb/inch, and values should be above this, but . . .**
  - **Too strong is problematic**
  - **Too weak is problematic**
- **Values below 1 lb/inch may be acceptable for smaller, lighter mass devices, if scientifically justified.**



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Rev. 5/23/2023

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DRAFT

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Sterilize (2X option)

Sterilize (2X option)

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e.g., per ASTM D4169
e.g., Distribution Cycle 13 / Assurance Level I
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For standards such as ASTM D4169, Assurance Level and Distribution Cycle should be identified and justified.

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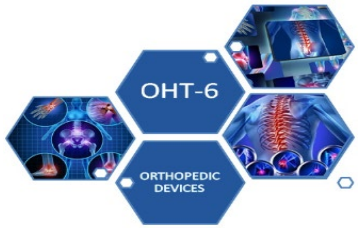

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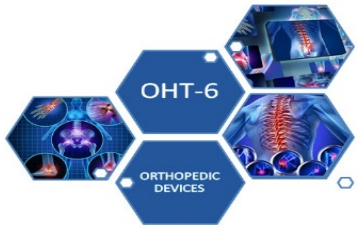
Procedure for Testing Shelf Life

A written procedure for establishing and monitoring shelf life of medical devices should include the following:

5. Accelerated Aging Parameters, including information that validates the accelerated system. The results need to be supported by real time testing of shelf life samples to confirm the tentative shelf life data collected from the accelerated tests.

6. Simulation of Shipping and Handling Stresses Plan, including vibration tests, temperature extremes challenge, actual shipping and intentionally mishandling the device to determine the affect of unusual circumstances.



PACKAGING – Draft Deficiency – Part 1

FDA recommends that package "performance" testing (shipping simulation followed by package integrity testing) and package "stability" testing (aging (real-time or accelerated aging followed by real-time) followed by seal strength testing), both be performed to demonstrate adequate functionality of the package design, as well as shelf life claims (please refer to an FDA-recognized standard such as the ANSI/AAMI/ISO 11607-series "*Packaging for terminally sterilized medical devices*" for additional information).

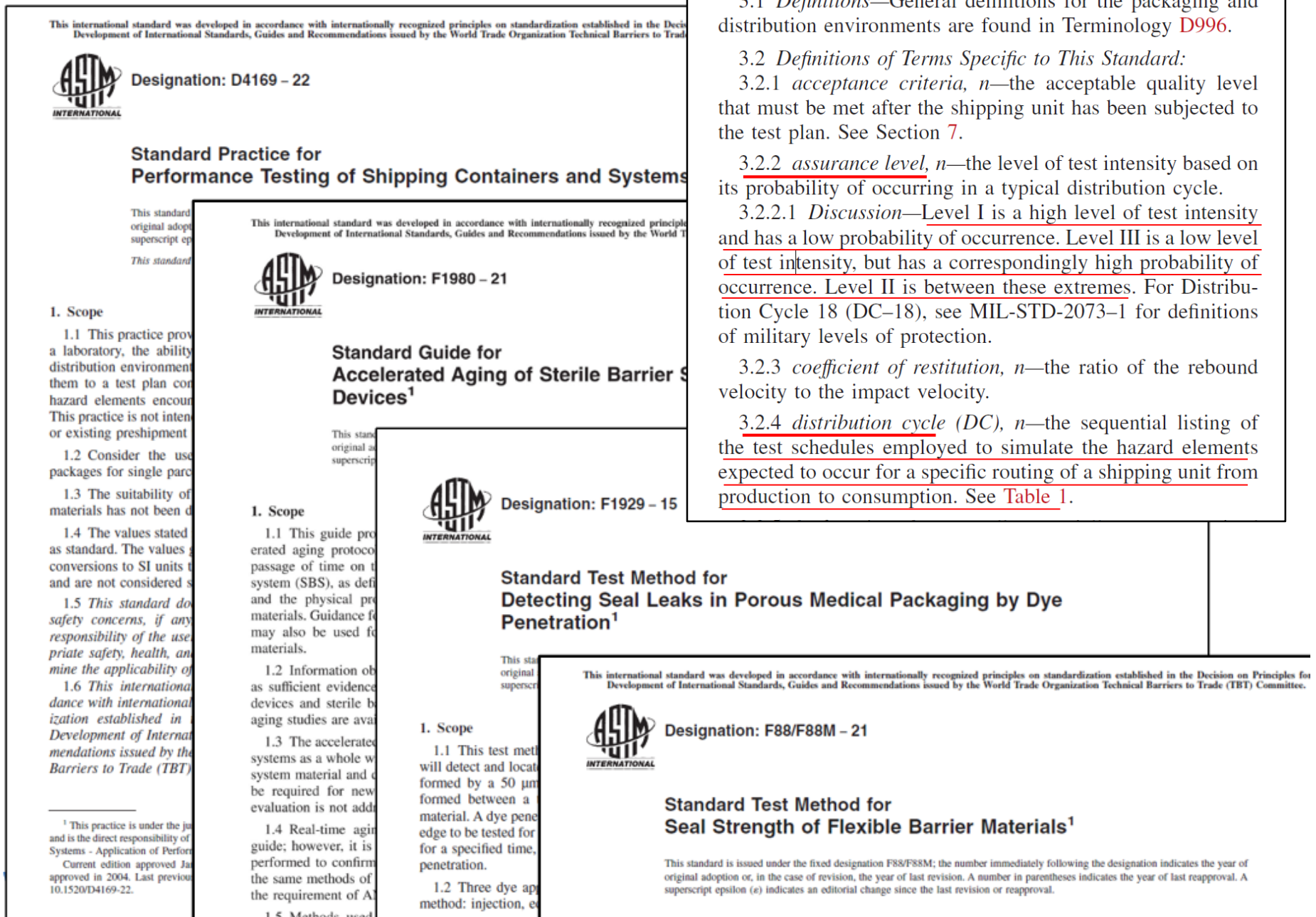
In general, FDA recommends:

- That package performance validation activities include conducting simulated shipping of packages followed by package integrity testing (e.g., dye penetration), and that package stability validation include aging of packages (real-time aging, or accelerated aging followed by confirmatory real-time aging) followed by seal strength testing. Furthermore, it is recommended that data from baseline (time "0") testing on un-aged packages, as well as accelerated aging calculations, be documented in your records.

  The Agency recommends the use of FDA-recognized consensus standards to simulate worst-case, real world shipping conditions by establishing a routing schedule and rigor of simulation (such as ASTM D4169, "*Standard Practice for Performance Testing of Shipping Containers and Systems*" and the associated Distribution Cycles and Assurance Levels defined within it), followed by package integrity testing.

  Note: a searchable database of FDA-recognized consensus standards is available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

PACKAGI



Designation: D4169 – 22

Standard Practice for
Performance Testing of Shipping Containers and Systems

1. Scope

Designation: F1980 – 21

Standard Guide for
Accelerated Aging of Sterile Barrier S
Devices[1]

1. Scope

Designation: F1929 – 15

Standard Test Method for
Detecting Seal Leaks in Porous Medical Packaging by Dye
Penetration[1]

1. Scope

Designation: F88/F88M – 21

Standard Test Method for
Seal Strength of Flexible Barrier Materials[1]

This standard is issued under the fixed designation F88/F88M; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

3. Terminology

3.1 *Definitions*—General definitions for the packaging and distribution environments are found in Terminology D996.

3.2 *Definitions of Terms Specific to This Standard:*

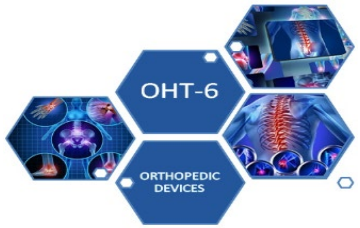
3.2.1 *acceptance criteria, n*—the acceptable quality level that must be met after the shipping unit has been subjected to the test plan. See Section 7.

3.2.2 *assurance level, n*—the level of test intensity based on its probability of occurring in a typical distribution cycle.

3.2.2.1 *Discussion*—Level I is a high level of test intensity and has a low probability of occurrence. Level III is a low level of test intensity, but has a correspondingly high probability of occurrence. Level II is between these extremes. For Distribution Cycle 18 (DC–18), see MIL-STD-2073–1 for definitions of military levels of protection.

3.2.3 *coefficient of restitution, n*—the ratio of the rebound velocity to the impact velocity.

3.2.4 *distribution cycle (DC), n*—the sequential listing of the test schedules employed to simulate the hazard elements expected to occur for a specific routing of a shipping unit from production to consumption. See Table 1.



PACKAGING – Draft Deficiency – Part 2

- That actual product or simulated product (that accurately mimics the device's mass and surface geometry) be included in packages that undergo performance testing. (In some instances, and if justified, it may be possible for package stability testing to be adequately designed and implemented without the inclusion of product (real or simulated) in the packaging.)
- That the number of samples used in package performance and package stability testing be large enough to provide for statistically significant analysis with a high degree of reliability; in particular, 95% confidence and 95% reliability is recommended. Accordingly, a minimum sample size of 60 is recommended for "attribute data" generated from performance tests such as dye penetration, and a minimum sample size of 30 is recommended for "variable data" generated from stability tests such as seal strength. The Agency further recommends that a full set of data be generated for both inner and outer sterile barriers for double sterile barrier systems.

SIMULATED SHIPPING AND HANDLING

D4169 – 22

TABLE 1 Distribution Cycles

DC	Distribution Cycle	Performance Test Schedule Sequence (see Section 9 for Test Schedule definition)						
		First	Second	Third	Fourth	Fifth	Sixth	Seventh
1	General Cycle—undefined distribution system							
2	Specially defined distribution system, user specified (see Appendix X2)							
3	Single package without pallet or skid, LTL motor freight							
4	Single package with pallet or skid, LTL motor freight							
5	Motor freight, TL, not unitized							
6	Motor freight, TL, or LTL—unitized							
7	Rail only, bulk loaded							

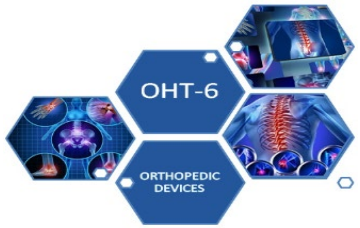
SIMULATED SHIPPING AND HANDLING

D4169 – 22

TABLE 1 Distribution Cycles

DC	Distribution Cycle	Performance Test Schedule Sequence (see Section 9 for Test Schedule definition)						
		First	Second	Third	Fourth	Fifth	Sixth	Seventh
13	Air (intercity) and motor freight (local, single package up to 150 lb (61.8 kg). Consider using Practice D7386 for single parcel carrier shipments.	Schedule A Handling	Schedule C Vehicle Stacking	Schedule F Loose-Load Vibration				

Other DC13 details omitted …



PACKAGING – Draft Deficiency – Part 3

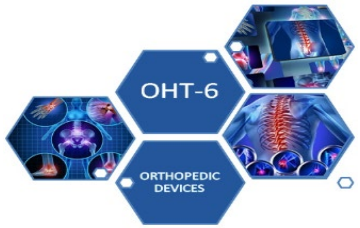
You have provided a description of your proposed packaging that is designed to allow sterilant penetration; however, it is unclear whether or not the packaging has been adequately validated to maintain sterility when subjected to the rigors of real-world shipping and handling, or to maintain sterility after aging.

a. Please clarify the proposed shelf life claim/expiration date for the subject device, based on your validation activities.

b. Please identify all standards used during the validation of your current packaging design.

c. [OPTION 1 – less rigorous, for 510(k)s]
Please provide a summary of your package performance and package stability validation activities. This should indicate simulation and testing chronology, simulation methods (e.g., shipping, aging), test methods (e.g., dye penetration, seal strength), and confirmation that both inner and outer seals were tested, if your packaging consists of a double sterile barrier design.

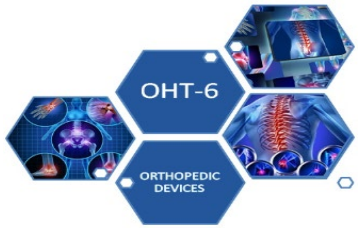
d. [OPTION 2 – more rigorous, for PMAs]
Please provide a summary flowchart documenting your package performance and package stability validation activities. This should indicate simulation and testing chronology, number of sterilization exposure cycles (if applicable), simulation methods (e.g., shipping, aging), test methods (e.g., dye penetration, seal strength), sample sizes and summary results, aging periods, identification of seal types tested (inner and outer, if double sterile barrier design), an indication as to which packages contained actual devices (or simulated devices of similar mass and geometry), and an indication as to which testing is yet to be completed.



PACKAGING – Draft Deficiency – Part 4

Additionally, please provide comprehensive package performance and package stability test protocols (including predetermined acceptance criteria), and all currently available test reports and test data.

Establishing that the packaging performance has been adequately validated will help ensure that the SBS will maintain product sterility during shipping and prior to use, minimize the risk of patient infection, and thereby reduce the risk to patient health.



REUSABLE DEVICES

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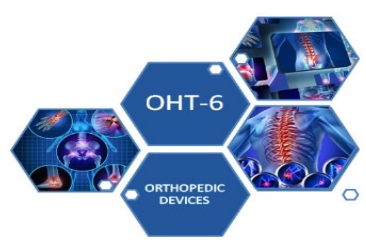
REUSE-LIFE (SERVICE-LIFE)

REUSABLE DEVICE — REUSE-LIFE (SERVICE-LIFE)



Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling

Guidance for Industry and Food and Drug Administration Staff

Document issued on: March 17, 2015

Appendix E of this guidance was updated on June 9, 2017.

This document supersedes: "Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance" issued April 1996.

The draft of this document was issued on May 2, 2011.

For questions regarding devices regulated by the Center for Devices and Radiological Health, contact the Infection Control Devices Branch (INCB) at (301) 796-5580. For questions regarding devices regulated by the Center for Biologics Evaluation and Research (CBER), contact the Office of Communication, Outreach and Development at 800-835-4709 or 240-402-7800.

FDA U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

REUSABLE DEVICE — REUSE-LIFE (SERVICE-LIFE)

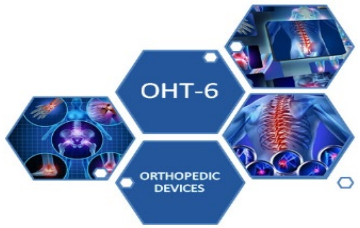
Contains Nonbinding Recommendations

Table of Contents

Criterion 5. Reprocessing instructions should be comprehensive.

Comprehensive instructions enable the user to understand precisely how to implement the entire reprocessing procedure safely and effectively. There may be several acceptable formats for instructions.

To ensure the reprocessing instructions are comprehensive, they should include all of the elements below. If any element is not applicable to your device, then you should state this in your premarket submission and provide a justification.



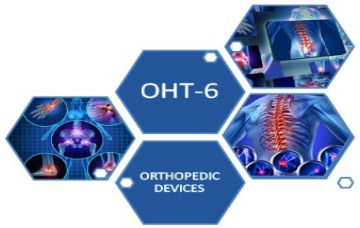
REUSABLE DEVICE — REUSE-LIFE (SERVICE-LIFE)

FDA

5. L. Reuse-Life

The labeling should either

1) inform the user how many times the device can be reused, based on testing; or



REUSABLE DEVICE — REUSE-LIFE (SERVICE-LIFE)

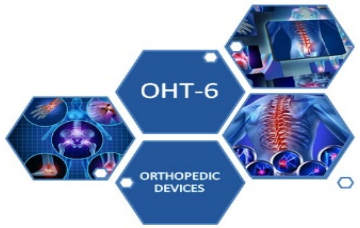
FDA

5. L. Reuse-Life

The labeling should either

1) inform the user how many times the device can be reused, based on testing; or

2) provide the user with a mechanism or method to ascertain whether the device has exceeded its use-life. In the latter case, the labeling should identify a method to establish that the device is still within performance specifications, as well as instructions for appropriate disposal of devices that fail. For example:



REUSABLE DEVICE — REUSE-LIFE (SERVICE-LIFE)

FDA

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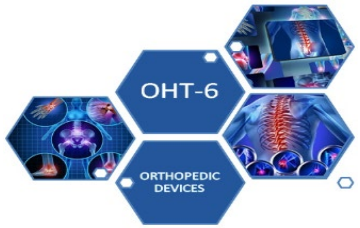
   - labeling that refers to a device design feature, such as a built-in, automatic pre-check function;



REUSABLE DEVICE — REUSE-LIFE (SERVICE-LIFE)

FDA

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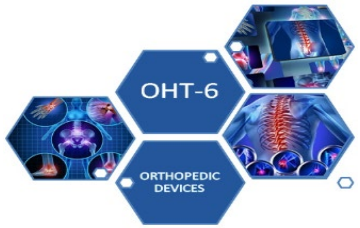
   - labeling that refers to a device design feature, such as a built-in, automatic pre-check function;
   - labeling that identifies a performance test that should be passed prior to reuse;



REUSABLE DEVICE — REUSE-LIFE (SERVICE-LIFE)

FDA

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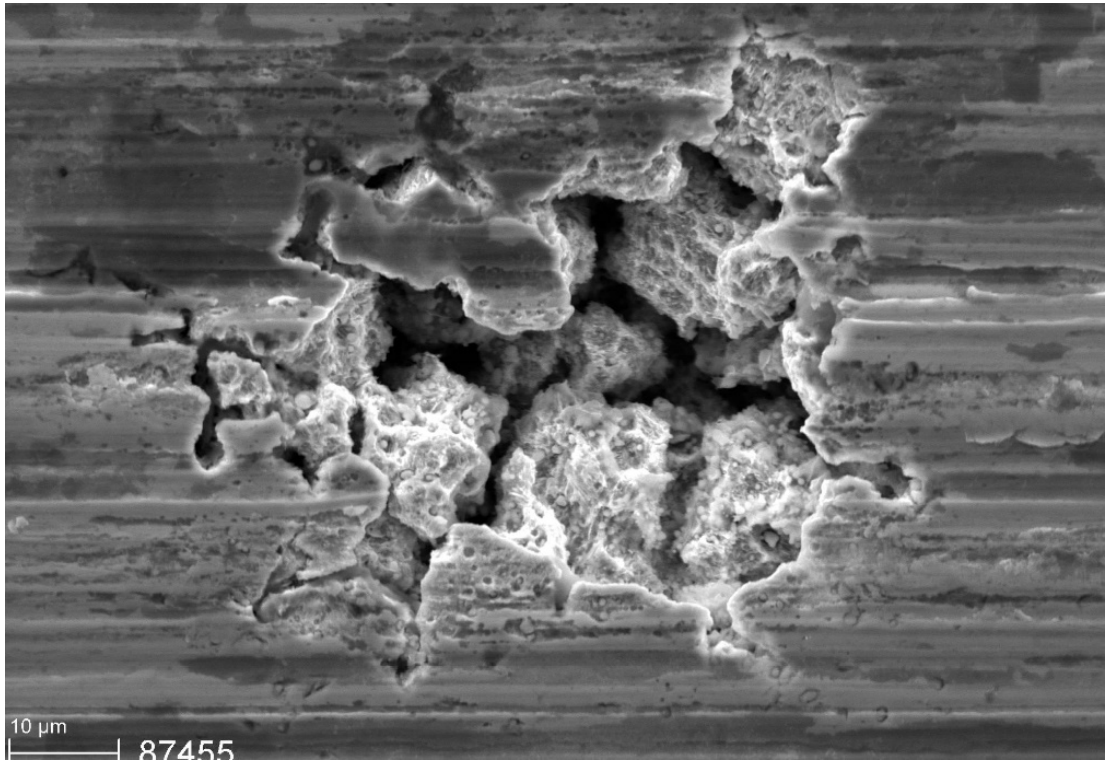
2) provide the user with a mechanism or method to ascertain whether the device has exceeded its use-life. In the latter case, the labeling should identify a method to establish that the device is still within performance specifications, as well as instructions for appropriate disposal of devices that fail. For example:

   - labeling that refers to a device design feature, such as a built-in, automatic pre-check function;
   - labeling that identifies a performance test that should be passed prior to reuse;
   - labeling that recommends visual inspection along with acceptance or failure criteria (e.g., unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals).

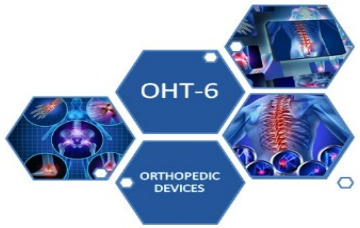
REUSABLE DEVICE — REUSE-LIFE (SERVICE-LIFE)

5. L. Reuse-Life



"*Investigating Surgical Instrument Damage: How to ensure your investment is protected©,*"
Dr. Matthias Tschoerner, IAHCSMM 2021 Annual Conference, Columbus, OH.

- labeling that recommends visual inspection along with acceptance or failure criteria (e.g., unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals).



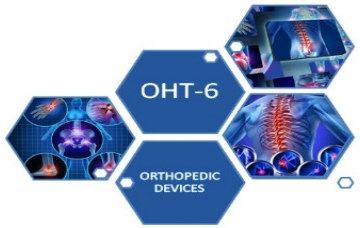
REUSABLE DEVICE — REUSE-LIFE (SERVICE-LIFE)

FDA

5. L. Reuse-Life

Whichever method is chosen, labeling should recommend how to evaluate deterioration in difficult to see areas of complex devices, especially those with lumens (e.g., leak testing).

Reuse-life may also be addressed by validating the number of times the product can be reprocessed and reused and providing this specification in the labeling. If the reuse-life of a device is limited to a specific number of use/reprocessing cycles, the labeling should also describe a specific tracking method for the number of reuse cycles. It may be appropriate for labeling to remind the user that the specific number of reuse cycles is dependent on full compliance with the directions for use of the device.



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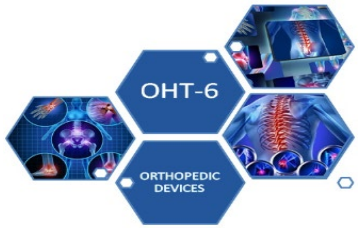

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THANK YOU!