Pick the Right Packaging System for Your Orthopedic Device

Wendy Mach, Canyon Labs

Sponsored by

Millstone

OMTEC

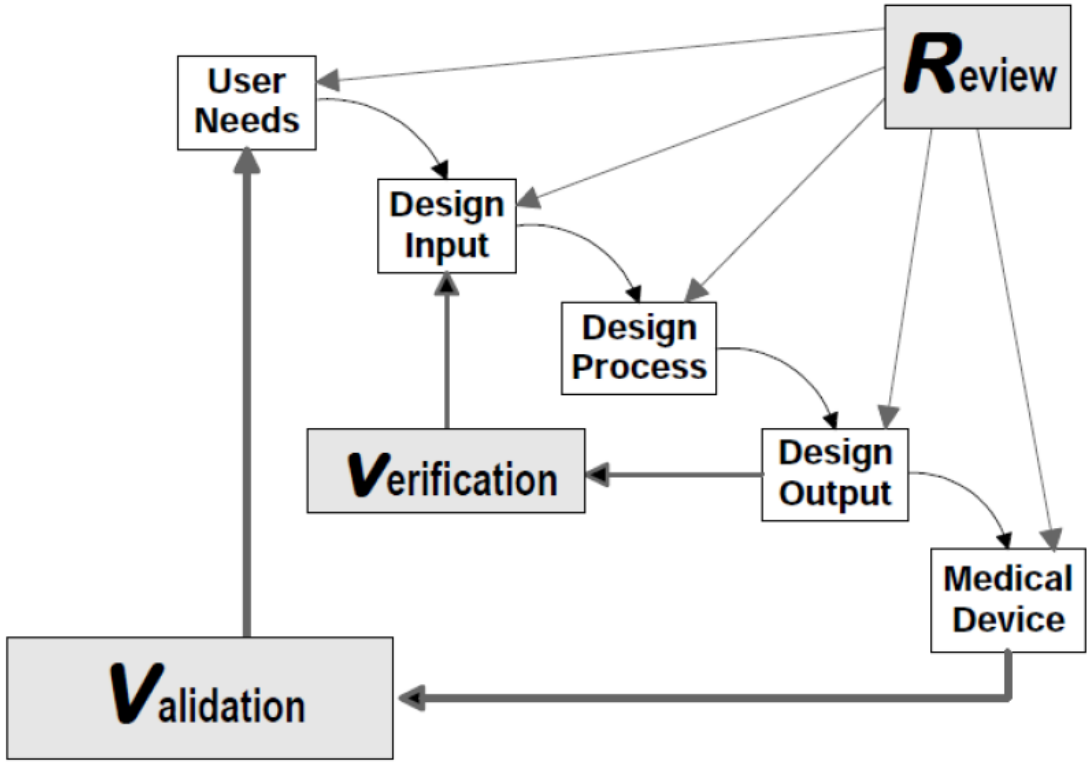
Agenda

- Design Input
- Design Output
- Design Review
- Design Verification
- Design Validation
- Packaging Failures

Packaging – it's all about Design

FDA CFR 21.8.820

Design controls are in place to require manufacturers of medical devices to maintain procedures to control the design of the device to ensure that specified design requirements are met.



Reference: Design Control Guidance for Medical Device Manufacturers, FDA Center for Devices and Radiological Health

FDA

OMTEC

Design Input

820.3(f) “Design input means the physical and performance requirements of a device that are used as a basis for device design.”

Understand your user needs - voice of the customer

- Package designs must be easy to open and intuitive. Systems should be transparent, allowing for quick recognition.
- Visual cues and good thermoformed designs that will both protect and display items in a manner that supports the surgical team.
- Shippers must ensure outer package integrity and durability.

Listen for competitor complaints

Design Input - Device protection

Consider implant geometry, weight, sharp edges, coatings, surface protection

Design Input - Device Protection

Packaging - protects the device and maintains the sterile barrier to the point of use.

Packaging also enables medical staff to clearly identify parts and confirm no punctures or abrasion damage occurred during transport. Some configurations must support multiple cycles without degradation.

Sustainability – interest in recyclable materials, bulk packaging, environmental concerns

Design Input - Sterilization Modality

- Understand how the mode of sterilization affects both product and packaging will drive material selection
- Not all materials are compatible with all forms of sterilization
  - Ethylene oxide
  - Radiation
  - Steam
  - Novel
- AAMI TIR17:2017(R)2020 Compatibility of materials subject to sterilization

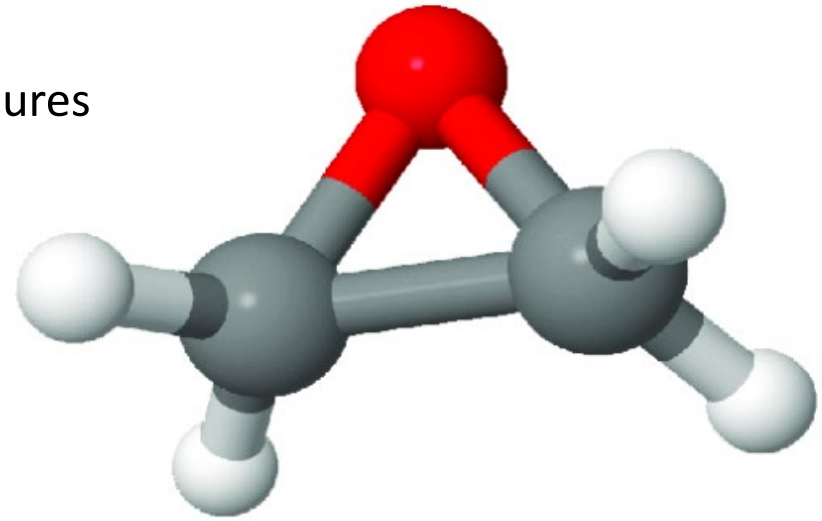
Design Input - Sterilization Modality

Ethylene Oxide

Gas-based sterilization processes require a gas pathway to reach and sterilize all surfaces.

Packaging design considerations include:

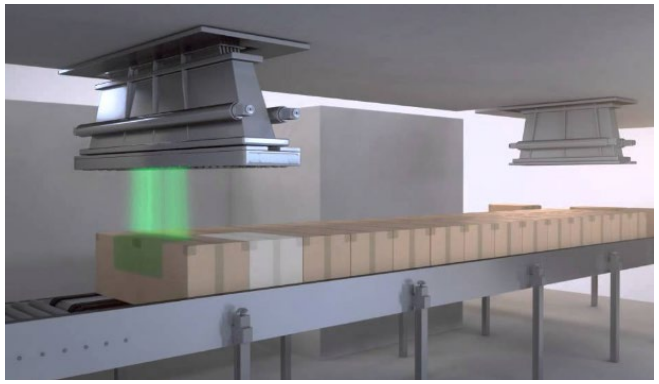
- highly permeable to gas and water vapor (gas in gas out)
- Resistant to pressure changes including deep vacuum and high pressures
- Highly compatible with temperatures (ambient to 63°C)
- Low absorption to EO



Design Input - Sterilization Modality

Radiation (gamma, e-beam, x-ray)

Some materials degrade or change during certain sterilization processes.



Packaging design considerations include:

- Polymers – need additives to stabilize
- Focus on evenly distributing mass
- Inks used in labeling of products and/or packaging can contain metals and should be included in any evaluation regarding induced radioactivity.

Design Input - Sterilization Modality

Moist Heat

Suitability is dependent on the heat sensitivity of the materials

Rigid Packaging for liquids - needs to allow for heat transfer without loss of product, impact on dosage and stability.

Flexible Packaging – design for air removal, pressure changes and exposure to moist heat.

Beware of the thermal glass transition point (T_g)

Silicone holders keep delicate instruments in place during sterilization, preventing damage. The vented silicone holders allow sterilant to access the entire instrument, reducing the risk of contaminants entering the OR.

Design Input - Biocompatibility

Consider the interaction between product and packaging to minimize the potential for an adverse biological response

- Nature of contact
- Type of contact
- Frequency and duration of contact
- Materials

Design Input - Distribution Process

Understand the logistics of your packaging and device experience

- Maritime
- Road and Truck
- Air
- Rail

Design Output

820.3(g)

“Design output means the results of a design effort at each design phase and at the end of the total design effort. The finished design output is the basis for the device master record. The total finished design output consists of the device, its packaging and labeling, and the device master record.”

Design Output

Comprised of (at minimum)

- Manufacturing drawings and procedures
- Product and Packaging Specifications
  - ASTM Test Methods - Minimum peel force
  - Critical Quality attributes
- Include acceptance criteria
- Appropriate for purchasing

Comprehensive documentation associated with the design of the device and packaging system to ensure it meets the high level of safety, quality and functionality.

Design Verification

820.3(aa)

“Verification means confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.”

The basis of verification is a three-pronged approach involving tests, inspections, and analyses

- Package integrity tests.
- Biocompatibility testing of materials.
- Bioburden testing of products to be sterilized.

Design Review

820.3(h)

“Design review means a documented, comprehensive, systematic examination of a design to evaluate the adequacy of the design requirements, to evaluate the capability of the design to meet these requirements, and to identify problems. “

Design Validation

820.3(z)

“Validation means confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled”

FDA

Packaging design and validation studies can take several months to complete, so it is essential to plan for the timing early in the design phase.

OMTEC

Design Validation - Packaging

Transportation/distribution testing

Extended time in transit on inland transportation movements exposes the packaging to temperature fluctuations that increase risks.

Ocean transportation increases risks through container placement on the vessel, sunlight exposure, container insulation, and dwell time on the dock—all introducing additional packaging stressors.

Design Validation - Packaging

Transportation/distribution testing

Packages are subjected to a series of inputs including drop/shock, vibration, compression, altitude, temperature, and humidity.

Important to consider the range of temperatures that the packaging will be exposed to as part of the transportation process.

Design Validation - Packaging

Baseline testing

The samples are subjected to strength, integrity, and microbial barrier testing to determine if there are breaches in the sterile barrier.

Strength tests include seal peel and/or burst.

Integrity tests include visual inspection, bubble emission, or dye migration.

Microbial barrier tests include either whole package aerosol challenge, ASTM F1608, ASTM F2638, or the Gurley permeability test.

Design Validation - Packaging

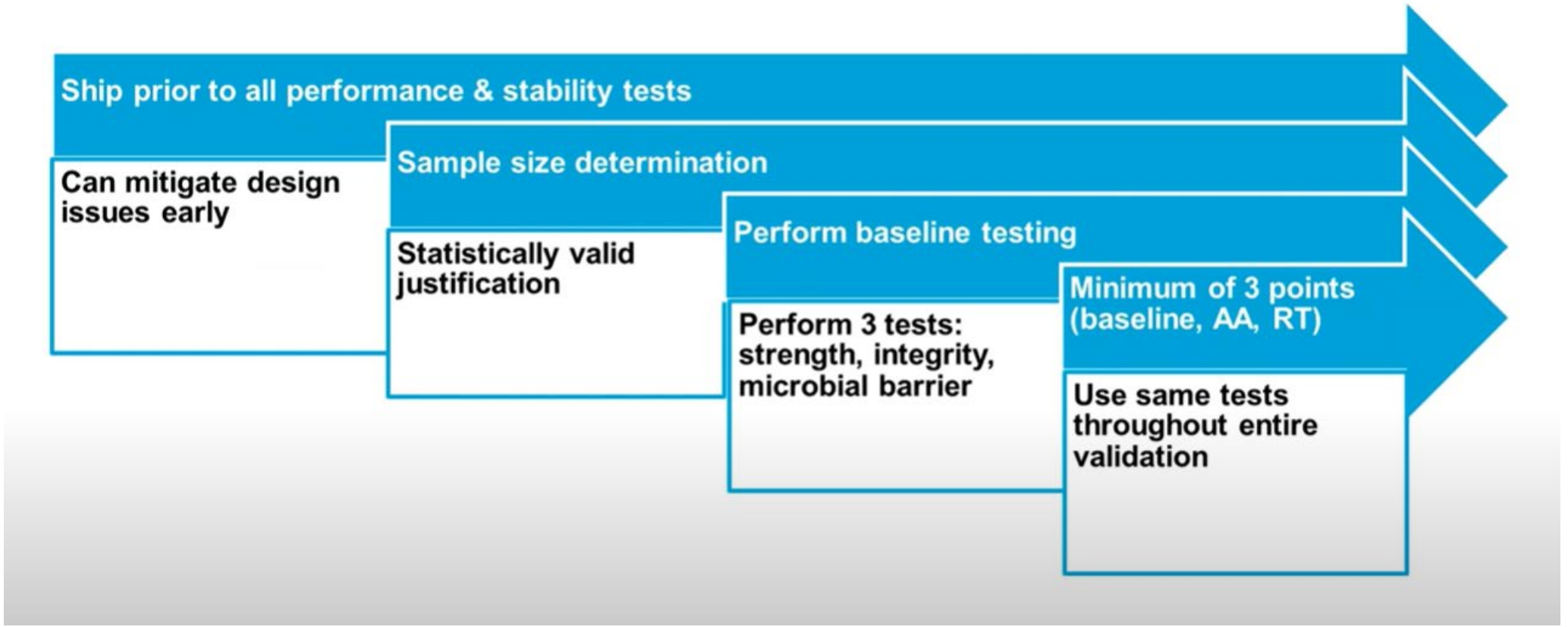
Shelf-life Validation Establishment

Real-time aging is required by ISO 11607.

Accelerated Aging (optional) - The most common temperature to use for accelerated aging is 55ºC, which simulates one year of real time in 46 days. It is possible to go to market with accelerated aging data, but real-time aging needs to be started concurrently and validate the results of accelerated aging studies.

After each time point, repeat baseline test methods to demonstrate continued Integrity acceptance.

Design Validation - Packaging



Design Validation – Packaging Failures

Packaging failure is just as critical as a device failure when looking at the timeline for a new product launch.

Where to start:

Visual Inspection – identify gross failures such as holes, tears or abrasions

Microscopic Inspection – helps to identify if a failure was internal or externally created

Polymeric analysis – determines whether the materials changed during the manufacturing or sterilization process.

Risk analysis tools – Fishbone, failure mode effectiveness analysis, flow diagrams, in-process reviews, etc., can be used to determine actions, conditions, or effects that occurred during the process

Suppliers – was there a change?

Conclusion

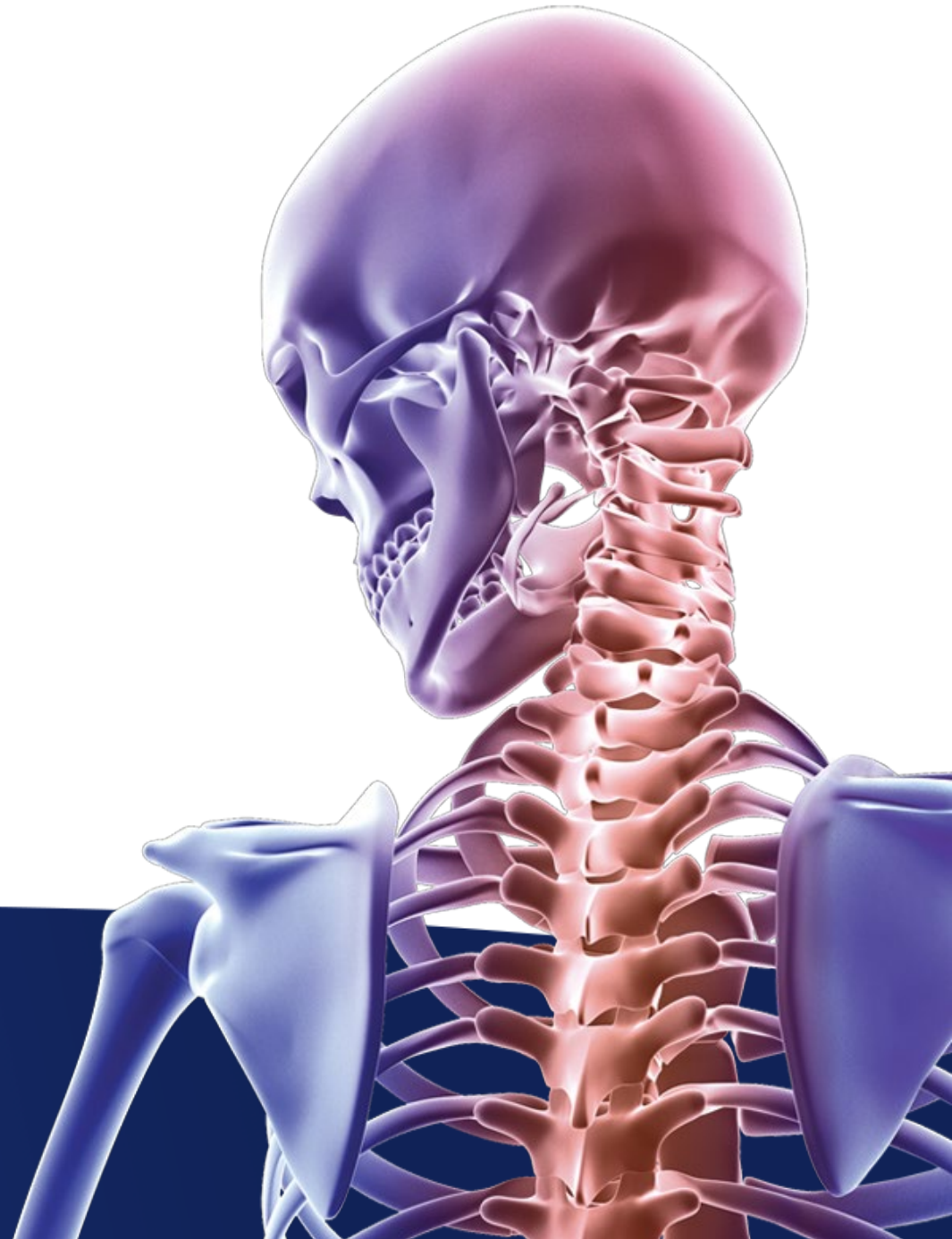
Orthopedic and medical device manufacturers are constantly looking for means to make all aspects of design, development, and production faster, safer, and less expensive.

The advantages of understanding design and material impacts on packaging early in the process is essential, especially when it comes to speed to market

Thank You

Wendy Mach
Senior Director, Technical Services
wmach@canyonlabs.com

OMTEC



THANK YOU

Learn more about OMTEC
at OMTECexpo.com

OMTEC®