

Packaging Matters:

Understanding How Packaging Impacts Lifecycle Costs and the Journey of your Medical Device

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Framework for Evaluating Your Overall Lifecycle Costs



Lifecycle Framework Helps You Uncover Hidden Costs and Opportunities

Direct Packaging Costs & Considerations

- Device protection
- Sterile package integrity
- Device and user requirements

Hidden Costs & Untapped Opportunities

- Manufacturing: throughput and yield
- Pack-out: efficiency and ergonomics
- Sterilization: optimization and inventory management
- Distribution: transportation cost and packaging damage
- Product use: storage conditions and product opening



Look Beyond the Traditional Packaging Checklist for the Biggest Impact

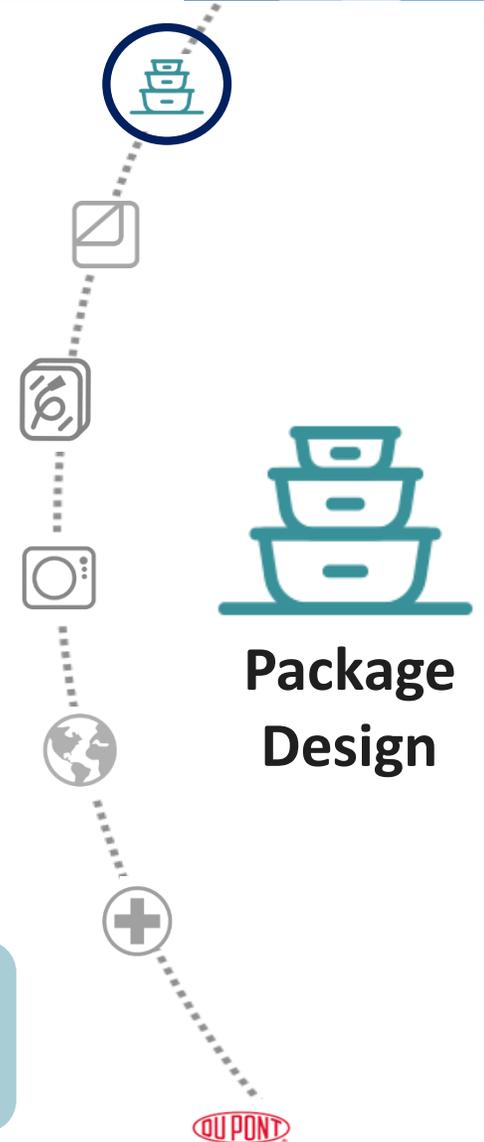
Traditional Package Design Checklist:

- ✓ Must pass distribution and package testing
- ✓ Meet regulatory requirements
- ✓ Material and design selection

Best practices:

- Include stakeholders across your organization to understand pain points
- Ask yourself how you can help solve other departments' problems
- Get out and observe

Its not just about picking a package and materials that can pass design validation. Evaluate your product's journey and select materials that reduce your overall product cost.



Several Manufacturing Metrics Could Be Impacted by Packaging

- Throughput and speed
- Yield and quality
- Machine downtime and changeover

Optimization of manufacturing operations will reduce your overall product costs.



Pack-out and Handling Phases Can Impact Many Cost Drivers

Efficiency

- Speed and loading time

Risk of returns or failures

- Handling
- Seal failures
- Material or substrate failures

Material failures that go unidentified in final pack-out could make it to your customer—resulting in returns or damaging your brand.



Packaging Decisions Affect Work in Progress Inventory During Sterilization

Gas sterilization

- Package expansion and headspace
- Cycle optimization and consolidation
- EO off-gassing time; hold time of finished inventory

Radiation sterilization

- Odor release post radiation sterilization

Other considerations

- Case and pallet size and configurations
- Ability to utilize multiple sterilization methods
- Novel sterilization processes

Analysis of the sterilization step can help you avoid several hidden costs including seal failures and high work in progress inventory.



Distribution

Shipping costs are related to overall package size

- Size reduction or increase units per box
- Number of pallets for internal shipment

Packaging materials are critical to product distribution

- Damage and product returns
- Field action and product recalls
- New and emerging market opportunities

Your products go through a lot, make sure they're protected. Package design decisions can allow you to drive costs out of secondary packaging and shipping without putting your device at risk.



Product Use

Package materials need to survive the product's clinical environment

- Storage and handling
- Unanticipated storage conditions

Packaging influences your user's experience

- Aseptic presentation
- Product opening and fiber tear

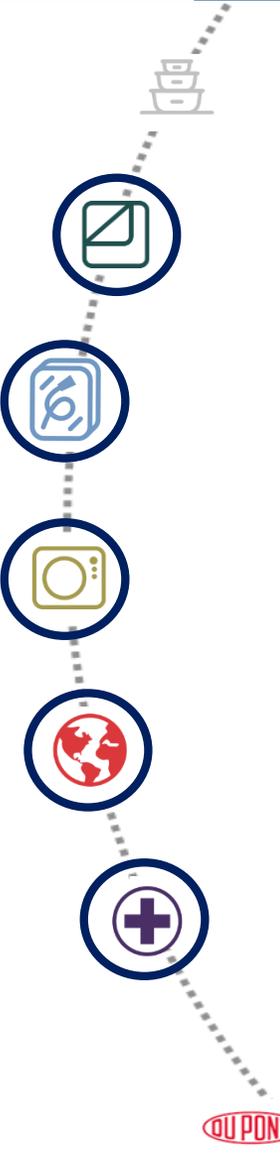
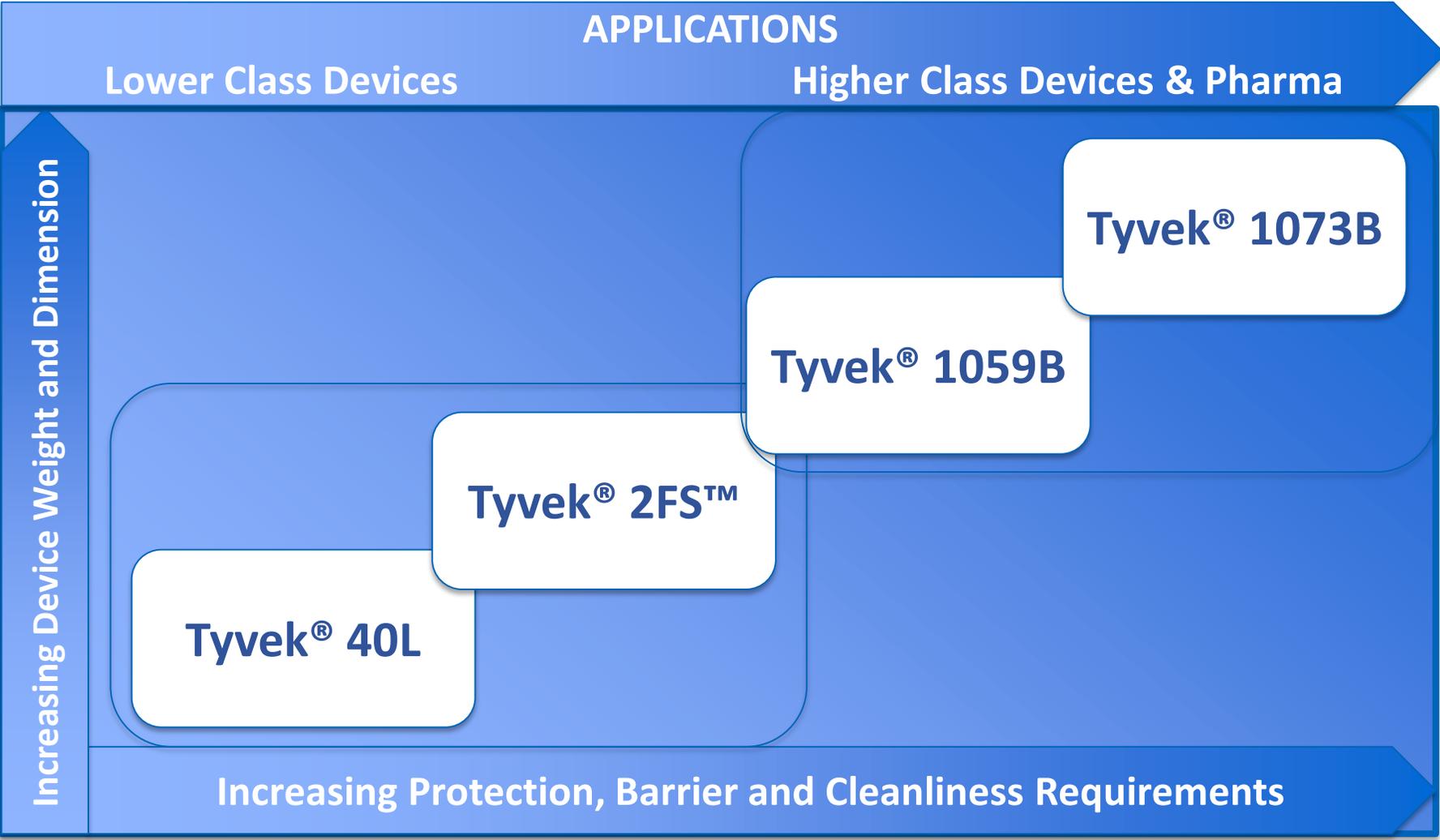
A product package that exhibits tears, seal failures or is hard to open is a product that will be avoided by your customers.





Putting the Framework in a Real World Setting

DuPont Medical Packaging



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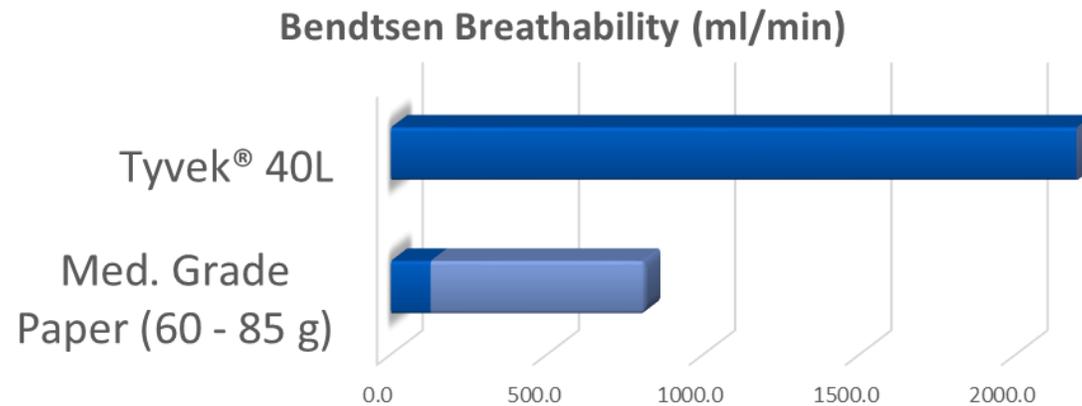
Setting the Stage: Focus on Porosity

The “required” goals of breathable packaging:

- ✓ Sterilize a pre-packaged device
- ✓ Provide and maintain a microbial barrier
- ✓ Allow for any off-gassing required

Can we ask more of breathable packaging?

- Pack-out
- Sterilization
- Distribution

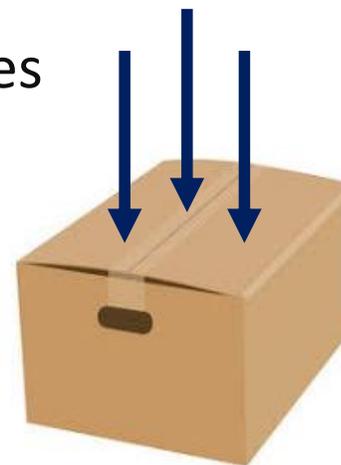


Scenario 1: Blown Seals During Pack-Out

Scene: The quality manager of your division is talking to you about intermittent customer complaints for seal failures when opening up shipments at their facility. Originally thought to be a random occurrence, there seems to be a trend occurring.

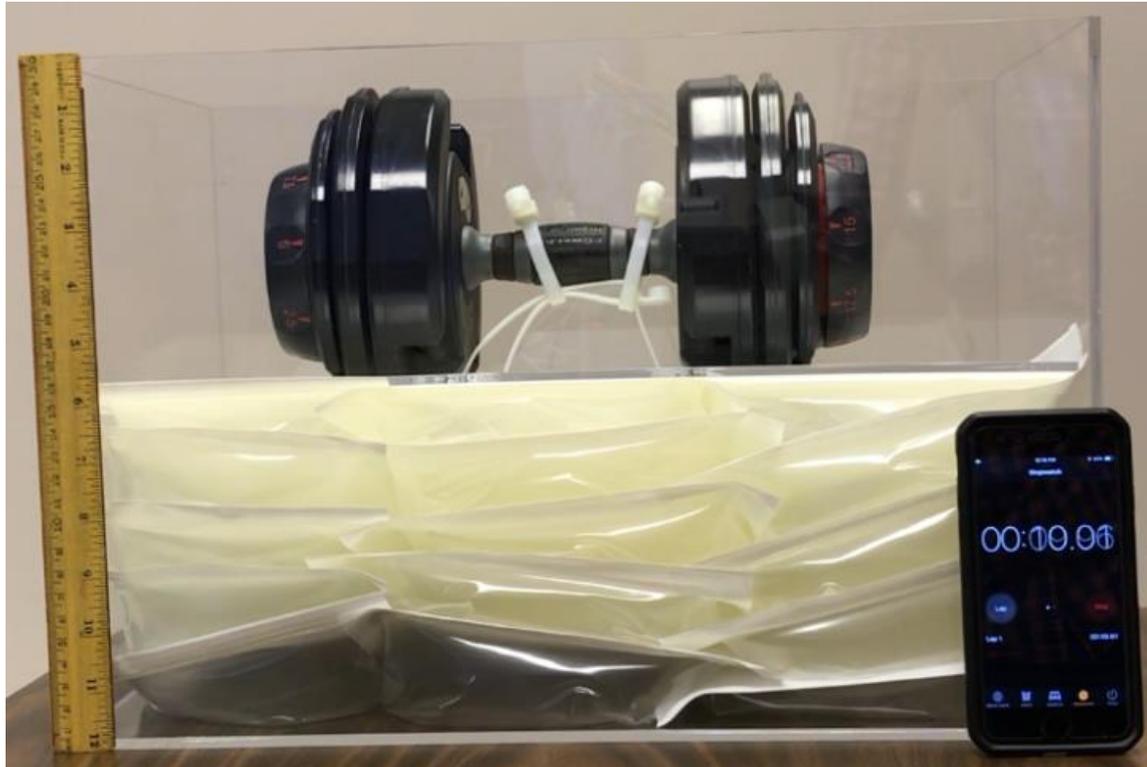
What to look for:

- How are operators grabbing finished packages
- Is entrained air limiting your pack-out rate
- Are operators using force to close packed boxes
- Are packages bursting during transport



Scenario 1: Blown Out Seals

Paper Blisters
10 seconds



Tyvek® 40L Blisters
10 seconds

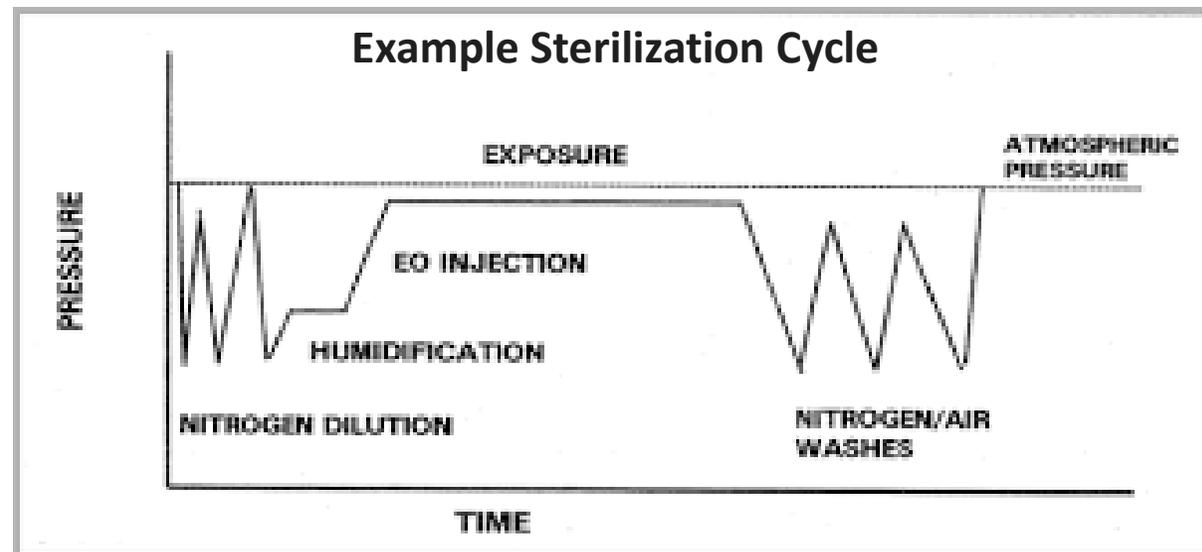


Scenario 2: Sterilization Costs Are Too High

Scene: You overhear your sterilization group discussing the need to reduce sterilization costs. When attempting to design optimized sterilization cycles they uncover quality issues due to seal failures.

What to look for:

- Special cycles due to package material limitations
- Are packages bursting during cycles
- Overall package and sterilization load
- Are you sterilizing empty space
- Long hold times for off-gassing



Scenario 2: Sterilization Costs Are Too High



How much head space are you sterilizing?

- Packaging material requirement
- Cycle requirement

Advantages directly tied to pack-out:

- Higher density of devices per box
- Ability to decrease size of secondary packaging

What about the sterilization process itself?

Scenario 2: Sterilization Costs Are Too High



Tyvek® 40L Blister at -1 Atm



Paper Blister at -1 Atm

What happens to your packages during sterilization?

- Packages with low breathability expand rapidly under vacuum
- Seals and packaging materials are stressed

Advantages directly tied to breathability:

- Smaller package expansion = reduced seal stress
- Reduced required headspace = more packages/box

Is your package ready for the future?

- Novel sterilization methods:
 - Intense pressure changes
 - High humidity
 - Can react with different materials

Scenario 3: Distribution Cost Change

Scene: Your company has an initiative to move manufacturing and you are now shipping over a further distance. The cost associated with shipping this further distance is eating into the site relocation savings.

What to Look For:

- Headspace in your secondary packaging
- Number and size of pallets used
- Types of transportation (air, sea, land)
- Increase in package damage (physical and environmental)
- Shorten lifecycle steps prior to transport



Framework for Evaluating Your Overall Lifecycle Costs

