Successful Packaging Design

Why we are here today

- To create better understanding of what makes a packaging design a success and how we can work together to create these designs right from device inception.

We will show how these successful designs can be created by

- **Examining** the current design process.
- **Identifying** how this process can be improved.
- **Demonstrating** examples of where the design process worked well to create medical packaging that fulfilled all aspects of its design brief.
The role of successful medical packaging is to deliver a clean, sterile, protected medical device to the point of use, and to allow aseptic presentation to the end patient.
Successful Packaging Design will deliver the sterile device to the end user whilst also helping to market & sell the final product through

- Functionality
- Successful Design
- Cost Control
- Innovation
- aesthetics
Functionality

- Correct packaging functionality will be achieved through full understanding of the packaging's end use.
- This is achieved by a detailed dialogue with the customer early in the design process to establish:
  - A clear understanding of the end user/ intended market.
  - This will then determine functionality requirements.
  - Unique requirements can also be taken into account.
Innovation

• Innovation is the creative element of design that can help make a packaging solution successful by setting your product apart in the marketplace.
• Detailed dialogue with customers early in the design process will allow more packaging innovation because we can fully understand your requirements and work on creative new solutions to existing issues.
Aesthetics

- Aesthetics will have a huge effect on overall packaging success as these will a large factor in selling the final product.
- Packaging aesthetics along with functionality will determine the practicality to the end user.
- The packaging aesthetics must create confidence that the medical device within has been delivered in sterile condition.
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Cost

• Successful packaging will fulfil all the previous criteria whilst also keeping the overall cost of the unit low without compromise to the quality of medical device delivered to market.
• Packaging costs should also be discussed early in the design process as this may have effect on type of packaging solution/material selected by Bemis.
• Packaging costs will be influenced by the overall device cost.
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All the groups below should be involved early in the design process to create the correct packaging solution for you.

- Customer
- R & D
- Product Engineering
- Sales
- Operations
- Materials
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Packaging should not be an “afterthought”. Packaging needs to be developed in parallel with the medical device. This complete understanding of the product allows our cross functional team to deliver the correct packaging solution which fulfils the criteria for successful packaging.
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Product Engineering Functions

- New Packaging Solutions
- Existing Packaging Solutions
- Specification Artwork Creation
- Customer Support Enquiries
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Specification Creation – Linear Tear Vent Pouch

The Design

ASTM Design Standards

End Product

<table>
<thead>
<tr>
<th>Specification Approval</th>
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<tbody>
<tr>
<td><strong>NAME</strong></td>
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<tr>
<td>Drawn By</td>
</tr>
<tr>
<td>Customer</td>
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</table>
Artwork Creation – Linear Tear Vent Pouch

End Product

The Design
Successful Packaging Design

Product Engineering/ R&D can play a central role due to our cross functional involvement as a department.

Customer Enquiries
Design Capabilities

Material Selection

Cross functional teams

Design Improvements
Either Product Engineering or R&D can act as a central contact point co-ordinating the activities within Bemis to get a new packaging solution for your product delivered.

A central point of contact within Bemis will help to drive the project because this individual will organise internal activities for the customer within Bemis.

The central point of contact can co-ordinate all cross functional departments within Bemis to express their concerns/opinions on the proposed design solution.
Packaging Design Failure Modes

Packaging designs that fail, often do at the latter stages of a project when a medical device’s design and packaging has been completed.

**Timeline** Packaging was an afterthought, Packaging for a medical device should be developed in parallel with the device (early design issues that could affect the integrity of the packaging can then be identified and designed out).

**Design** Poor design brief given to Product Engineering/R&D (Lack of information on sterilisation requirements, types of transport, intended final use of product). Product Engineering and R&D need the “full picture” to ensure we specify the best solution.
Suitability Packaging format requested by customer just may not match the demands of the medical device no matter how much development work is done to try and correct issue.

Material incorrect material selection used for the medical device (example- cheaper Pet/Pe films used with medical devices that have sharp edges which then fail transport testing, Polyamide based material would have been correct solution.)
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• The following slides show two examples of designs created by Bemis working together closely with our customers.
• Both of these products were developed from a clearly defined packaging brief which detailed all the life cycle requirements.

Linear Tear Vent Pouch

DES Pouch
Linear Tear Vent Pouch
Linear Tear Vent Pouch

Pouch Front

Pouch Rear
Customer Design Requirements
1. Functionality – Sterilisation with less Tyvek area.
2. Innovation – Linear tear of film required when opening.
3. Aesthetics – Improve current artwork appearance
Manufactured on Patch-bag machine.
M/C Footprint: 13m long x 2m wide approx.
Speed: 10-23 CPM (Depending on Draw length)
Patches added to Vent Pouch by:
First punching hole through film
Second station seals patch to film
 Successful Packaging Design

Patches added to Vent Pouch by:
First punching hole through film
Second station seals patch to film
Successful Packaging Design

Please play Video

Video is for visual representation only.
Successful Packaging Design

Please play Video

Video is for visual representation only.
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1. Vent holes punched
2. Patch added over hole
3. 2nd web joins on top of bottom
4. Pouch seals formed
5. Tear nicks/ hang hole added
6. Final pouch
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**Design Features**

- **Tear-nick Opening Feature**
- **New Artwork** – Including directions for opening.
- **EtO Sterilisation vent**
- **Hang-hole**
- **Narrow seals (5mm) to maximise internal pouch space.**
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Design Features

Material Linear Tear Functionality

[Images of Bemis Healthcare Packaging products with text on them]

- Linear Tear Vented Pouch
- 100μm (4 mil) White LDPE Film with Tyvek® Vent
- Available with hang hole feature
- EO and radiation sterilizable
- Customizable options provided

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Design Appraisal

1. Functionality – Sterilisation with less Tyvek® area
   Achieved – Sterilisation performance equal to previous pouch with less Tyvek®

2. Innovation – Linear tear of film required when opening
   Achieved – As evident from previous slide, easy opening

3. Aesthetics – Improve current artwork appearance
   Achieved – Artwork improved with the addition of opening directions

   Achieved – Overall Pouch unit cost reduced by use of less Tyvek®
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Our vent technology machine is 900mm wide and has the capability of applying 8x60mm vents simultaneously over 8x30mm poly punch holes, depending on customer requirements for breathability and sterilisation.

Our Vent technology machine now also has the ability of applying 4x152mm vents to bags which have higher requirements for breathability and sterilisation.

The number of vents per bag is customer specified and dependant on their sterilisation cycle and validation requirements.
Design Variations

20 patch vent (60mm)

4 patch vent (60mm)

2 vent pouch (152mm)

Vent layouts matched to individual customer requirements
## Design Information 60mm

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<th>2-Up Orientation</th>
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<tr>
<td>Top Seal Width: 5mm*</td>
<td>Top Seal Width: 5mm*</td>
<td></td>
</tr>
<tr>
<td>Hang hole: 6mm*</td>
<td>Hang hole: 6mm*</td>
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</tbody>
</table>

*As per product specification

Minimum distance between rows of patches is determined by bag design or draw length. The draw length determines the process throughput speed.
## Design Information 152mm

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<tr>
<td>Max Web Width OD</td>
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<td>Max Width OD: 450mm</td>
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<tr>
<td>Max No of Vents</td>
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<td>Leg Seal Width</td>
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<td>Leg Seal Width: 3mm*</td>
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<tr>
<td>Top Seal Width</td>
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</tr>
<tr>
<td>Hang hole</td>
<td>6mm*</td>
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*As per product specification

Minimum distance between rows of patches is determined by bag design or draw length. The draw length determines the process throughput speed.
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Design Information

Mono Films – Patch Bag (1 step process)
- 100um Linear Tear Film
- 89um Low Slip LLDPE
- 75um white peel seal film
*Note: Patch must seal to the outer layer of mono film*

Laminates – Roll Stock (2 step process required to produce pouch/bags)
- 12um/50um PET/PE Weld and Peel Films
- 12um/70um PET/PE Weld and Peel Films
- 12um/30um PET/PE Weld
Note: Patch must seal to the inner sealing layer of laminate film.
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Design Considerations

What size is the bag? i.e. External dimensions
What seal widths does the customer require?
How many patches?
Position of the patches?
Size of Patches?
What materials?
If Linear Tear, what orientation does it need to be in?
Opening Feature details and position?
Print required
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DES Pouch
A drug-eluting stent (DES) is a peripheral or coronary stent (a scaffold) placed into narrowed, diseased peripheral or coronary arteries that slowly releases a drug to block cell proliferation.

This prevents fibrosis that, together with clots, could otherwise block the stented artery, a process called restenosis.
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Advantages of Drug Eluting Stents:

• Last longer than alternative therapies.
• Result in less procedures for the patients.
• Fewer operations means lower healthcare costs.
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- Combination Device
- Drug coating to prevent in-stent restenosis
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• Traditionally a DES is packed in two separate pouches.

• One pouch to allow ethylene oxide sterilisation (EtO) and the other to provide oxygen, moisture and light barrier during storage.

• Bemis Healthcare Packaging developed a unique one pouch system.
Customer Package Requirements:

- EtO Sterilization ✓
- Complete Oxygen & Moisture Barrier ✓
- Single Pack Solution ✓
- Discreet Desiccant Capability ✓
- Nitrogen Flush Capability ✓
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- Tyvek®/PE/Tyvek® insert sealed inside a foil pouch to make two pockets: one to hold the DES and the other to hold a scavenger.
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- Oxygen, moisture and light barrier.

![Diagram showing packaging layers: BOPA, white PE, Foil, PE, EZPeel ® with 25μ aluminium foil providing barrier]
• Oxygen, moisture and light barrier.

25μ BOPA provides strength and toughness.
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- Oxygen, moisture and light barrier.

BOPA
white PE
Foil
PE
EZPeel®

50μ EZPeel® provides hermetic sealing and easy opening.
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- Oxygen, moisture and light barrier.

![Diagram showing layers of packaging materials: BOPA, white PE, Foil, PE, EZPeel®. Primary materials are bonded together using PE.]
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ETO

Gas flushed

Scavenger

DES
Successful Packaging Design

First seal ETO sterilisation. Second seal gas flush.
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- Seal Permeability
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• Easy Opening
• White Transfer
Successful Packaging Design

• Primary function is the manufacture of multi-chambered pouches for combination devices

• Class 7 cleanroom

• Equipment Features Include:
  • State of the art control platform
  • Integrated web cleaning systems
  • Integrated web inspection system
  • Online material thickness sensors

• DES Pack Range:
  • Small (180mm x 250mm)
  • Medium (245mm x 310mm)
  • Large (265mm x 370mm)
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• Unique combination pouch development; excellent in applications that require high moisture and barrier properties whilst permitting EtO sterilisation.

• Superior puncture resistance offering additional protection for your product during shipping and storage.

• Bemis Healthcare Packaging is the preferred and trusted packaging partner to the world’s leading providers of Drug Eluting Stents.
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Successful Design Guidance

- Engage Bemis early in the medical device development process
- Gather Package design information from multiple sources
- Prototype your package solution
- Performance test your prototype design with device or simulated device
- Evaluate package integrity and medical device performance
  Iterate as required to eliminate high severity hazards and minimise to low hazards
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• Information from customers to Bemis that will aid the design of successful packaging.
• Complete picture on product (Size, Artwork if required, final use, means of transport, type of sterilisation & applicable legislation/registered bodies).
• Specific requirements
• Packing information
• If the above information is supplied early in the design of packaging for a new product, We can use cross functional co-ordination to create the best solution in regards to materials, production & innovation.
Principles for good packaging design

Design

• Define the requirements of a packaging system early in the product development process.
• This sets the stage for long-term success.
• Identifying possible packaging system failures and addressing them during the design phase greatly increases the chance of successful packaging validation and patient safety.
Size

- One of the crucial design phases and most common cause of packaging failure, this is the result of improperly sized packaging elements in relation to the device.
- Packaging size and format needs to take account of how the product will act during packing & transport to end customer (Movement etc.).
- Product needs to fit snugly in outer packaging format to prevent potential damage & loss of sterile barrier rendering the final product useless.
Testing

- Packaging testing should be addressed from the very start of the design process. This will help to quickly identify unforeseen deficiencies in the design.
- Packaging testing/evaluation can be performed in-house at Bemis as well during the design process to try and “engineer” out design issues.
- Establishing a testing protocol prior to testing complete with clearly understood Pass/fail Criteria is paramount to identify problem areas in the packaging design.
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Final Thoughts

In the competitive landscape of the current medical device marketplace, almost as important as the medical device is the package it arrives in. Successful packaging design today has evolved from an afterthought to an integral part of the device’s user experience.

The packaging system must maintain the sterile barrier system, protect the device while in transit and use, and successfully communicate the device’s maker’s branding and value proposition. When this process is considered early with great intent and purpose, mistakes can be avoided, costs can be saved, and the ideal packaging system can be created.
Thank You!

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