



Critical considerations for the design of a safe, performing and compliant medical package

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Learning points

- Basic functions of a package
- Peel pouches, headerbags, thermoformed blisters – what needs to be considered?
- Temperature and pressure variations during transport
- Product families

Basic Functions of a Medical Package

- Product protection
 - Microbial barrier
 - Physical protection from damage
- Compatibility with the sterilization method
- Maintenance of sterility and integrity until use
- Easy opening and aseptic presentation
- Identification of the product (printing, labeling)



1. Peel Pouches

Design tips

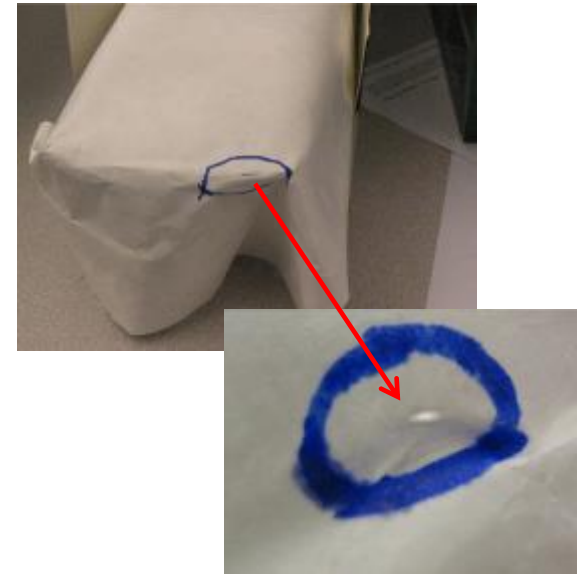
- Allow ample room between chevron tip and edge of pouch



1. Peel Pouches – cont'd

Folding should be avoided

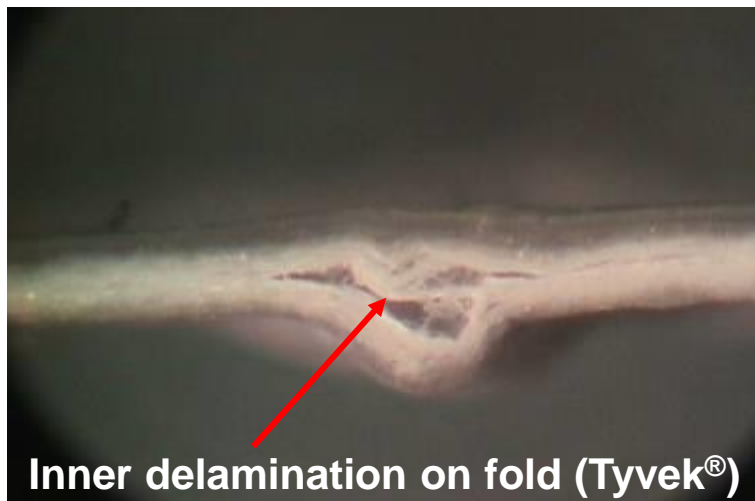
- Can form abrasion points with the carton
- Scuffing can cause holes in the package – made of Paper, Nylon, Tyvek[®],...



1. Peel Pouches – cont'd

Folding can cause a sheet inner delamination (Tyvek®) or even material break (cellulosic material)

- Inner delamination can lead to false positives during integrity testing
- Microbial barrier is not compromised with Tyvek®
- Be careful with other porous materials!

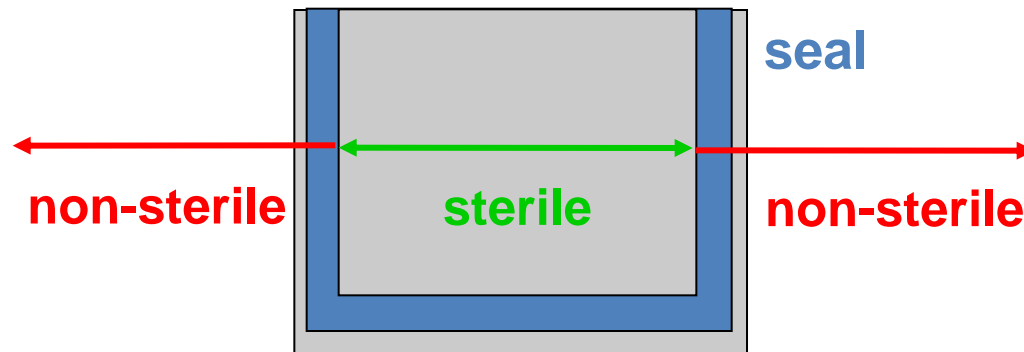


2. Header bags



Design tips

- Design the opening large enough to allow the product to be aseptically presented.
- Association of periOperative Registered Nurses (AORN)...
 - ... Considers the inner edge of the heat seal as the line separating sterile from non-sterile



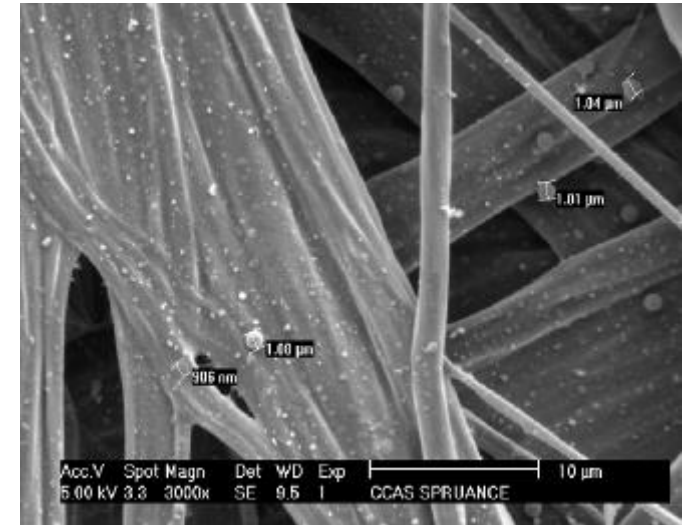
3. Thermoformed blisters

A faulty lidding can cause **delamination** or **tear** during opening:

Risk:

Compromized Aseptic Presentation

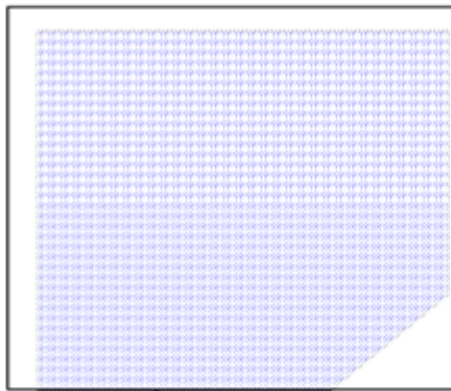
→ **Contaminated Device**



3. Thermoformed blisters

– Triggers of delamination and tear

1. Misplacement of the porous lid or cut through blister seal

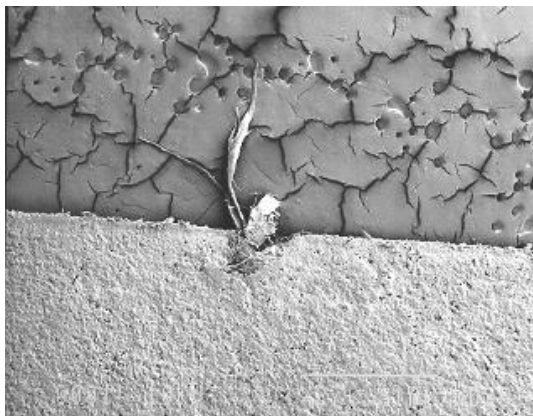


Possible Fiber Tear

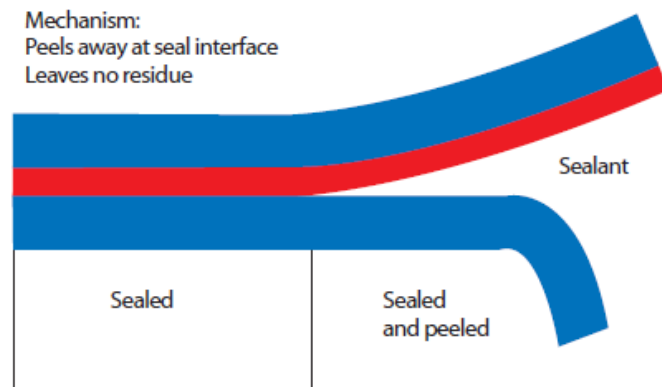
2. Oversealing / Transparentization



3. Ragged edge caused by faulty knives

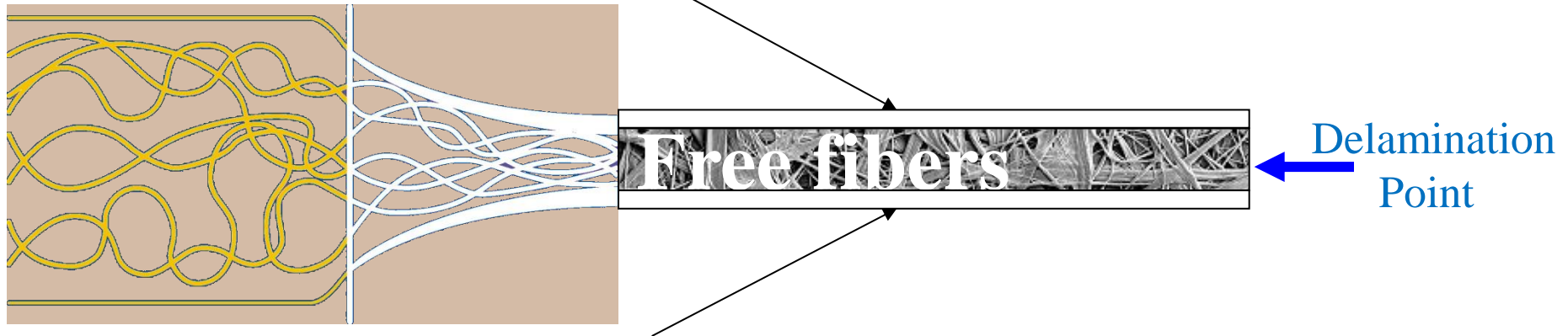


4. Non-adapted peel system

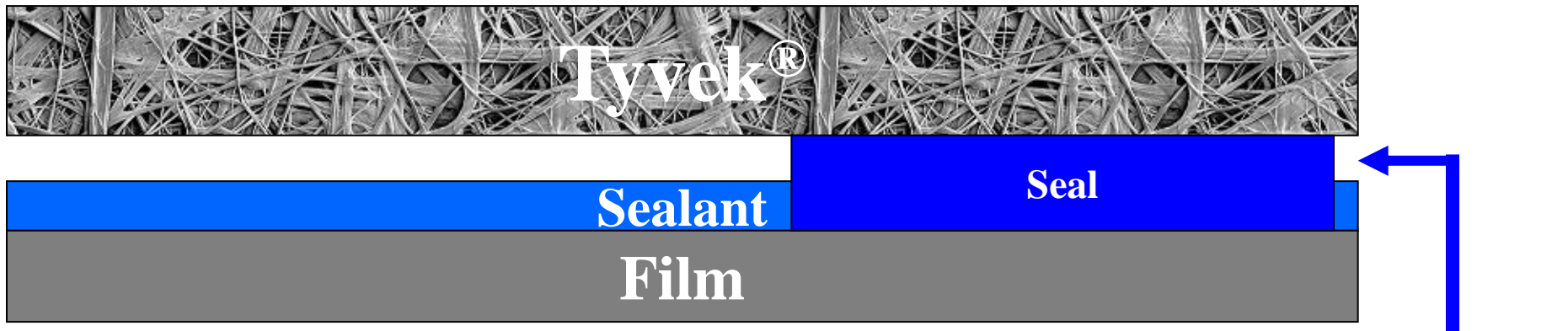


3. Thermoformed blisters - Preformed

3-Layer TYVEK® STRUCTURE



Solution: Unsealed gap



**Unsealed gap
> 0,5 mm**

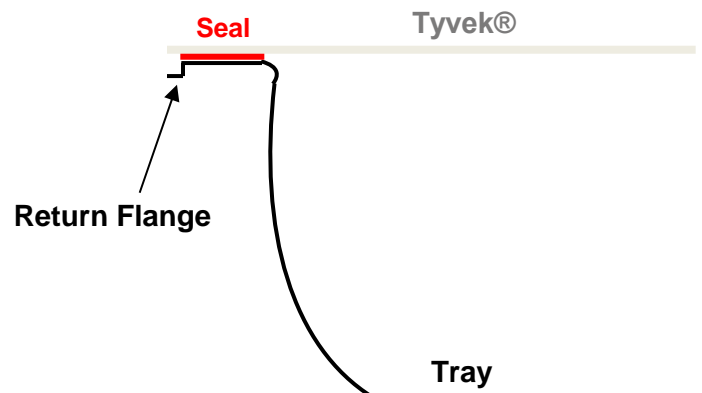


3. Thermoformed blisters - Preformed

Solution 2: Blister geometry



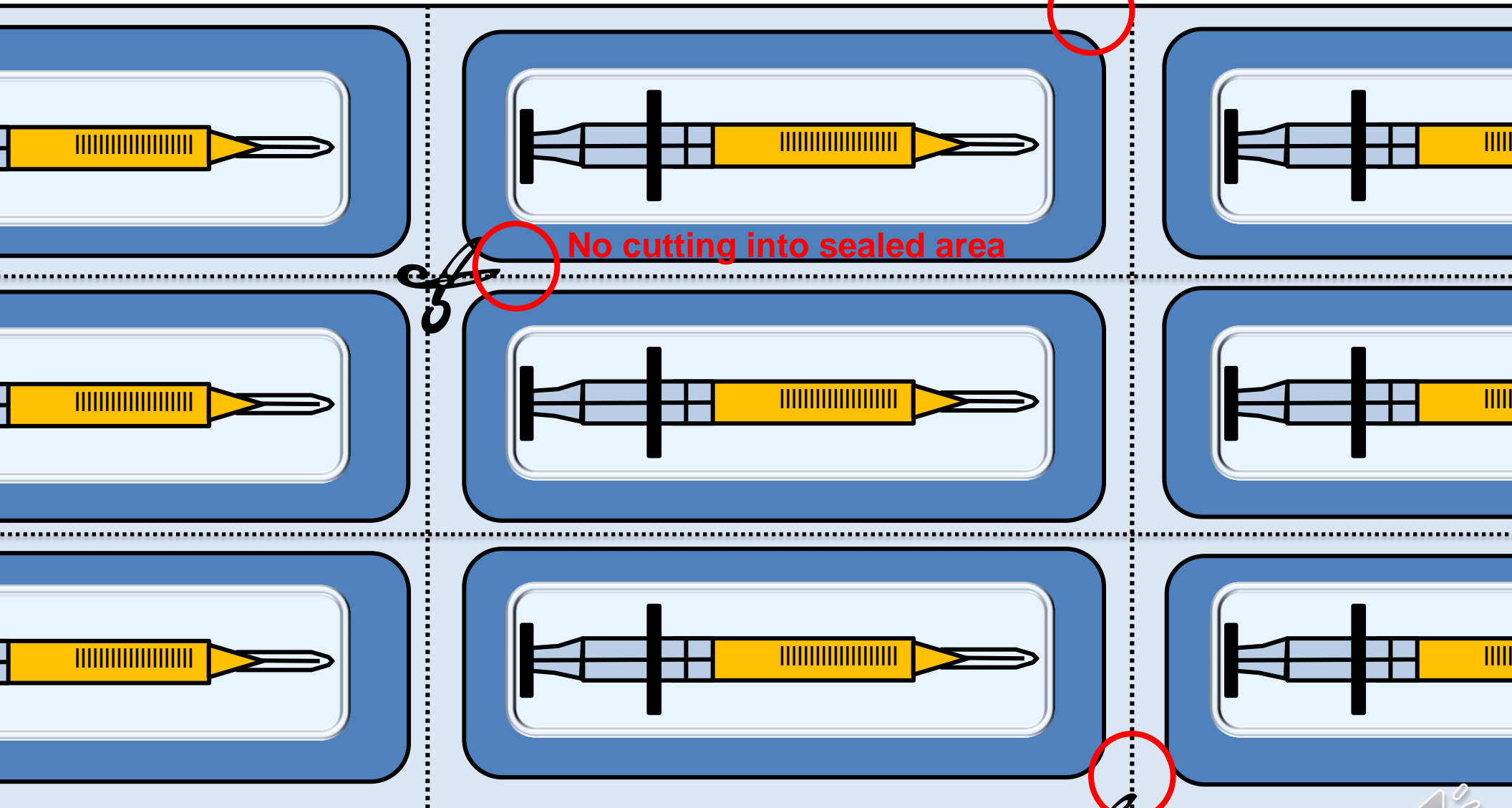
- Eliminates lid placement issues
- Condition: Sufficient size of the lid



3. Thermoformed blisters – Form-Fill-Seal

Solution: Customized sealing tool

Keep edge unsealed



No cutting into sealed area

No cutting into sealed area

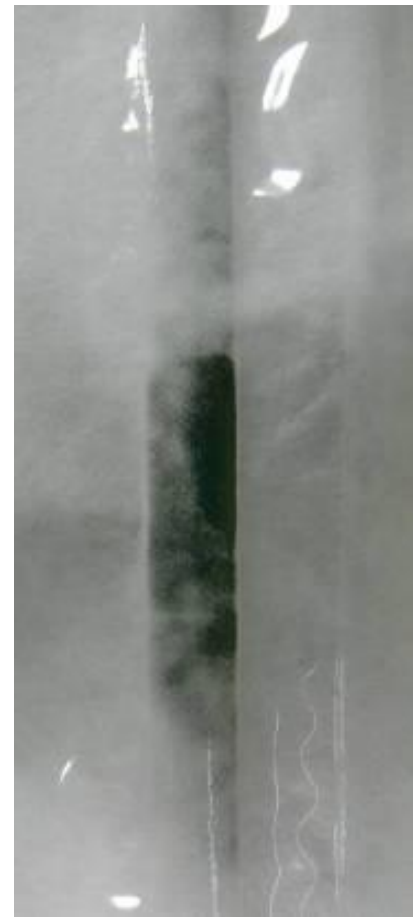
Oversealing and transparentization

Note:

- To be avoided for **peelable** seals
- Not visible when using paper
- Transparentization is a result of melting Tyvek®

How to avoid:

- Reduce sealing energy transfer (e.g. Temp., Time, Pressure)
- Add Teflon® sheet to the heat seal platen
- Check for “hot spots” on the tool (e.g. pressure-/ thermo-sensitive paper)
- Check durometer/stiffness of rubber matting material (shore 70 for Tyvek®, riffled pattern)



Temperature and pressure variations during transport

- Results in pressure differences inside package vs. outside package - non breathable materials can't adjust to changes in air pressure
- An excessive pressure can damage the packaging



Product families

– one investment to optimize working effort

One proven packaging configuration for different devices,
using

the same reliable and best performing materials,
has many benefits:

- Less machine downtime and start up time necessary
- Less process waste
- Less validation and re-validation effort
- Easier process control



→ **Higher productivity and lower costs**

Conclusion

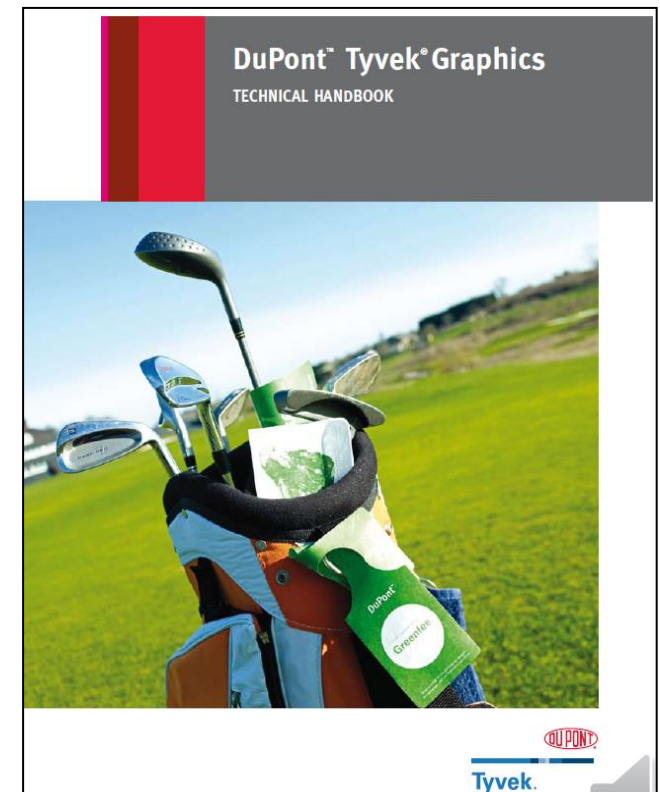
A good packaging solution, well thought through, properly tested and validated, will minimize your risks and will provide you PEACE OF MIND for many years!



Technical documentation – DuPont™ Tyvek®

- DuPont™ Technical Reference Guide for Medical and Pharmaceutical Packaging
- Dupont™ Tyvek® Compliance to ISO 11607-1:2006
- DuPont™ Tyvek® Graphics Technical Handbook

www.MedicalPackaging.DuPont.com



DuPont Medical Packaging

More Information . . .

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THANK YOU FOR YOUR INTEREST!

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