Healthpack 2015
SoTube®/SoSafe® Panel Discussion

March 5th 2015,
Norfolk
Why?
Are Medical devices packaging to be packaged forever in Pouches or Blisters?

Courtesy pictures Depuy Synthes a J&J division
HITCHCOCK

A good idea is a simple idea
a tube?
SoTube® & SoSafe®
patented technologies
SoTUBE® = A new packaging concept

Double Package
(internal + external)
with labels and shrink wrap foil
SoTUBE® = A concept

Double Package (internal + external) with labels and shrink wrap foil
SoTUBE® = A concept

Double Package (internal + external) with labels and shrink wrap foil

External stopper

Internal tube

External tube
SoTUBE® = A concept

Double Package (internal + external) with labels and shrink wrap foil

External stopper

Internal tube

External tube

Internal stopper + holder

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- SoTube Hold
- SoSafe Hold
- SoTube No Touch
SoTube
Hold

SoSafe
Hold

SoTube
NoTouch

Tilt to drop transfer

Pull to transfer

Unscrew to transfer
Customers’ choice

Which configuration?
Customers’ choice
SoTube vs SoSafe

OR Nurses
End users’ choice (Nurses)

« What method you think is best suited? »
Operating sterile nurses survey, 157 persons – May 2014.
French market (all surgeries)
Customers’ choice
SoTube vs SoSafe

Medical devices manufacturer
SoTube No touch
M. SCHMID Peter

SoSafe Hold
M. AUDIC Gilles
Discussion
Family
Product range
0

Family

Hands, foot, extremities implants, dental..

Osteosynthesis, Stent ..

Spine

Multiple implants, Spinal kit

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Family

- 4 sizes M / L /XL /XXL
- 1 option SoSAFE for each sizes
- 5 configurations

Osteosynthesis, stent ..
Spine
Multiple implants, Spinal kit
Hands, foot, extremity, dental..

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Gathering kit

Choice of medical devices needed
Picking from gathering boxes
Surgical KIT
Implants & Instruments in combox
Courtesy

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SoSTORE™ dispenser / FiFO management

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Sterilization
Is Sterile Really more expensive?

Workflow for reprocessed instruments, plates and screws

1. Instrument, implant and screw collection
2. Transport for reprocessing
3. Manual washing
4. Mechanical washing
5. Inspection
6. Tray assembly
7. Sterilization
8. Transport to storage or OR

Smith & nephew cost analysis vision non sterile versus sterile
Benefits/disadvantages
Space saving / 5

100 implants Before (with boxes)

100 implants After (with tubes)
| Benefit versus pouches / blisters choice | size, product visibility, easy opening and identification and the no touch aspects  
Support UDI |
<table>
<thead>
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<tbody>
<tr>
<td>Disadvantage</td>
<td>New delivery system and just because of the fact something that they know for decades (blisters and mainly pouches) are being replaced will lead to some push back but only until they get used to the tubes. I know a lot of examples on this, the healthcare customers like what they know and it takes time and learning to get them use to a new sterile packaging. But, once they get used, they will love it.</td>
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<tr>
<td>What could be improved ?</td>
<td>Slight modifications might be possible, but all of them would only be in the space of optimization</td>
</tr>
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| Benefit versus pouches / blister choice | • Easier handling of the implant versus pouches/blisters.  
• So-Safe, No touch concept.  
• Storage volume reduced (/5)  
• Shipping costs reduced due to lower volume  
• Handling and transportation form storage area to the surgery room simplified for the nurses  
• FIFO approach permitted thanks to storage system  
• Easy and fast device identification permitted thanks to the colored caps at the top of the tube  
• The replenishment and handling is “easy as a child”  
• 1st Surgery convinced |
<p>| Disadvantage | Due to small size labeling may be more complex to be read. At the really beginning before use, it may take some time to convince the end users of the benefits of this new solution. Human body doesn’t like changes. |
| What could be improved? | The implant holders may be optimized by the manufacturers to be able to propose a 100% no touch implant system. |</p>
<table>
<thead>
<tr>
<th>V.O.C voice of customers: who are they? nurse? surgeon</th>
<th>We have done a lot of VoC’s on tubes already, mainly with nurses but also with surgeons, they all love the tubes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Key technical challenges to your point of view</td>
<td>Key challenges will be to set up a new supply chain model with smart shipping and dispensing system for the tubes. From a technical aspect I do not see too many hurdles.</td>
</tr>
<tr>
<td>Specific challenges overcome in package development in your company</td>
<td>Speed to market  Smart Packaging solution are becoming the cutting edge in the market, with the packaging you can differentiate form competition  We have managed to change the awareness on importance of sterile packaging, moving from a “we just need a sterile solution” to “we need and attractive sterile solution that is user friendly, cost effective, easy to identify, small in size, etc.”</td>
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## SoSAFE Hold - Novastep choice

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<th>V.O.C voice of customers: who are they? nurse? surgeon</th>
<th>Surgeons are satisfied about the tube system but they are not the main actor in the process of using this solution. Nurses are really excited about this solution because it really makes their life easier for reasons cited in benefits. Distributors are also very excited because they optimize their shipment and storage conditions, but also implement a FIFO approach that permits them to save money! Caps system is so intuitive that it makes a perfect Poka-Yoke to prevent the end user from any reference mix up!</th>
</tr>
</thead>
<tbody>
<tr>
<td>Key technical challenges to your point of view</td>
<td>No key technical challenges, just optimization.</td>
</tr>
<tr>
<td>Specific challenges overcome in package development in your company</td>
<td>Implement new sizes / shapes if needed based on this concept.</td>
</tr>
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</table>
Validation
FDA expectations

SoTube concept is class I medical devices
However FDA considers sterile barrier packages
  to be at the equivalent regulatory classification
  as the medical device it is withholding.

*For example, if a medical device is considered to be class II, then its sterile packaging will
  be evaluated under class II requirements*
SoTUBE® = Typical validation chart
VPR500.04 : validation N°1

**ROUTINE PROCESS**
- SoTUBE Injection
- IMPLANTS cleaning
- IMPLANTS packaging in SoTUBE

**VALIDATION**
- SoTUBE Injection
- IMPLANTS cleaning
- IMPLANTS packaging in SoTUBE

**STERILISATION**

**TRANSPORT**
- Transport SIMULATION

**STORAGE**

**AGING Study**
- Real
  - T_1 year
  - T_5 years
  - T_10 years
- Accelerated
  - T_1 year
  - T_5 years
  - T_10 years

**Bioburden**
- Average Bioburden
- Average bioburden

**COT / HCT analysis**

**LAL measurement**

**SoTube integrity**
- Microbiological sealing test
- Liquid sealing test
- Sterility test

**Biocompatibility**

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Sealing ?
Sealing

Gas sealing > liquid sealing > bacteria sealing > solid sealing

- Gas sealing: closure efficiency versus gas
- Liquid sealing: closure efficiency versus liquid
- Bacteria sealing: closure efficiency versus bacteria

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Leak definition

- All packaging are leaking... criteria definition

1. Smallest leaks only allow gas flow
2. Larger leaks may also allow liquid flow
3. Largest leaks may also allow microbial ingress

Selenium products are considered in this area
SEALING technology

• Sealing = Closure
  
  • On pouches / on Blister = heat sealing
  • On Tubes = compressed integrated gasket sealing + conical/conical
  The sealing zone on the tubes/stopper concept is obtained by interaction of a stopper on the (non continuous) threaded tube and by:
  1. deforming a section “integrated gasket” of the stopper on the tube to achieve sealing
  2. achieving assembling “conical on conical”

• Sealing criteria

  ✓ Sealing Zone 6 mm minimum (EN 868-5)
  ✓ On all tubes sizes
  ✓ On all configurations
Sealing

CONICAL/CONICAL

STOPPER

TUBES

8mm Zone d’étanchéité Sealing zone
SEALING

INTEGRATED GASKET

SEALING AREA

Tubes not yet closed
SEALING

INTEGRATED GASKET

SEALING AREA

Tubes not yet closed

Screwing
SEALING

INTEGRATED GASKET + CONICAL/CONICAL

Tubes not yet closed

Tubes closed

SEALING AREA

TUBES

STOPPER

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Thank you