#### MED PACKED 2.0

Q&A Session // Industry Experts Answer Guest Questions



**Min Degruson** Associate Professor, Packaging at UW Stout



**Dan Burgess**Packaging Engineering
Fellow at Boston Scientific



Frank Jaskulke VP of Intelligence at Medical Alley Association



**Andrew Corson**Director of Manufacturing
Process Development at Gilero

#### **Table of Contents**

Page #	Question
3	The requirements for REACH and ROHS and traceability make recycling for medical devices nearly impossible; do you have any ideas to overcome these barriers?
4	If you have too many layers in your plastic, will that prevent your product from being breathable? Or how do you ensure your product has the correct circulation?
5	Doctors are always inquiring about 'green' options. The need is for rigid, steam-sterilizable, but most importantly bio-degradable materials. Any new info you can share that UW Stout may be researching at this point?
6	Do you see any customers specifying pull strength tolerances on snaps with tray and lid combinations?
7	What is your opinion of sterilization and transportation testing? Do you recommend separate or combined testing?
8	How do tray suppliers typically inspect for snap force on the line? For example, ensure it is consistent one part to another?
9	Can you comment on your experience or knowledge of the Tekni-Plex Tekni-MD PX Series for tray packaging?
10	What would you recommend for someone looking to increase the strength of their package without drastically increasing the price?
11	Do hospitals recycle packaging? And, do hospital purchasing groups consider environmental factors when making decisions?
12	What factors do you consider when selecting a plastic? Do you decide based on the unique product and its' geometry/mass?

THE REQUIREMENTS FOR REACH AND ROHS AND TRACEABIITY MAKE RECYLING FOR MEDICAL DEVICES NEARLY IMPOSSIBLE; DO YOU HAVE ANY IDEAS TO OVERCOME THESE BARRIERS?

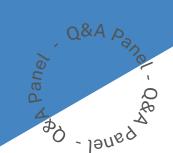




Answer

Sadly, no I do not – not for traceability and recycling. Right now I know there are challenges involved for the hospital facilities; although there are recycling technologies being introduced as I mentioned in my presentation, i.e. advanced chemical recycling encompassed with the mechanical. Hopefully the technology will advance along with solutions for other logistical challenges for the future of recycling.

IF YOU HAVE TOO MANY LAYERS IN YOUR PLASTIC, WILL THAT PREVENT YOUR PRODUCT FROM BEING BREATHABLE?
OR, HOW DO YOU ENSURE YOUR PRODUCT HAS THE CORRECT CIRCULATION?





Answer
For multilayer structures, generally we consider those non-breathable materials. But Tyvek with a coating, can be breathable.

**Min Degruson**Associate Professor, Packaging at UW Stout



I'll just add on what Min said. Yeah, definitely multilayer structure film typically isn't going to be breathable. But in a lot of medical device packaging, that (multilayer structure) is just one side or one half of the sterile barrier, if you will. Typically, the other side is going to be Tyvek or paper or something that is breathable, and in those cases really you are probably more focused on the surface area or the amount of breathable material that you have. And so, you may need to adjust that to get enough breathability.

And typically, the concern isn't necessarily whether or not you're able to sterilize the contents – because EO gas in experiments has shown that it can actually go through non-breathable films, because it can permeate that material because of the size of molecules, etc. Rather, it's about whether or not you can get that EO gas out so you don't have too high of residuals left on the device that would cause you to fail the regulatory and standards requirements related to residuals.

**Dan Burgess**Packaging Engineering Fellow at Boston Scientific

DOCTORS ARE ALWAYS INQUIRING ABOUT 'GREEN' OPTIONS. THE NEED IS FOR RIGID, STEAM-STERILIZABLE, BUT MOST IMPORTANTLY BIO-DEGRADABLE MATERIALS. ANY NEW INFO YOU CAN SHARE THAT UW STOUT MAY BE RESEARCHING AT THIS POINT?





Answer

Right now, in the plastic engineering lab, I do know that professors are researching bio-based and bio-degradable plastics. For myself, I am familiar with PHA and thermoformed starch-based plastics. Though, in this area, even for consumer and food packaging, there's an intense amount of research being done. But performance compatibly and cost for this type of material is where there is still work to be done.

### DO YOU SEE ANY CUSTOMERS SPECIFYING PULL STRENGTH TOLERANCES ON SNAPS WITH TRAY AND LID COMBINATIONS?





Answer

We do see them specify that frequently; I do see just as much, though, where they are specifying that as an outcome of the distribution testing. So, in the distribution testing you want to predefine your acceptance criteria; what makes a failure in the distribution testing? And, if one of those failures is that the part comes out of the snap, then clearly that is something you are looking at. You can look it as variable data as you mentioned, but you have to correlate that variable data back to an acceptance criteria that generally achieves a user requirement result of the part not coming out. You can either do it as a black box, or as variable data. So, the answer is yes.

Andrew Corson

Director of Manufacturing Process Development at Gilero

WHAT IS YOUR OPINION OF STERILIZATION AND TRANSPORTATION TESTING? DO YOU RECOMMEND SEPARATE OR COMBINED TESTING?





Answer

Typically we are going to sterilize units whether we send them through distribution simulation or we put them into aging. And the reason for that is because no matter what, the product is going to get sterilized before it goes to the customer. That's a normal part of the manufacturing process – it's not going to leave your building without seeing that. Now, when it comes to sterilization testing – we don't do sterilization testing per say. We do validate sterilization cycles and we do testing on the packaging side to prove we maintain sterile barrier integrity; so I'm not quite sure where the sterilization testing portion of the question came from.

**Dan Burgess**Packaging Engineering Fellow at Boston Scientific

HOW DO TRAY SUPPLIERS TYPICALLY INSPECT FOR SNAP FORCE ON THE LINE? FOR EXAMPLE, ENSURE IT IS CONSISTENT ONE PART TO ANOTHER?



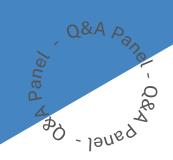


Answer

We don't have as many trays with snaps, but if I were approaching that scenario I would look for a known object. Maybe there is a gold master standard and a test that would apply that force and that snap in a manner that you could read it back. So using a tensile test machine, and a test method validation that shows it is consistent for different users. That's how I would approach putting that as a specification.

**Andrew Corson** *Director of Manufacturing Process Development at Gilero* 

## CAN YOU COMMENT ON YOUR EXPERIENCE OR KNOWLEDGE OF THE TEKNI-PLEX TEKNI-MD PX SERIES FOR TRAY PACKAGING?

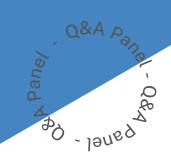




Answer

Yes, it has great trimability and formability, and excellent impact strength. So, it is a great option to be used for a thermoformed tray.

# WHAT WOULD YOU RECOMMEND FOR SOMEONE LOOKING TO INCREASE THE STRENGTH OF THEIR PACKAGE WITHOUT DRASTICALLY INCREASING THE PRICE?





Answer

That's an interesting question. Depending on the material combination, you may be able to adjust your seal strength by making process changes. The cost there is just the additional development work related to your process. From a web strength standpoint, you are kind of stuck with what you have unless you want to switch to a different web material. But, there are a lot of different materials that are similar in price but offer different properties. So maybe the question or the focus should be more on the particular hazard you are concerned about. Say for example you are worried about puncture; you can pick a material or material combination that has nylon in it, which will give you better puncture resistance, at a cost that is similar to what you are already using. But maybe your current design has better flex-crack resistance – so there are trade-offs you may have to make to get the specific protection you need, without drastically impacting cost.





Yeah I would agree with Dan. Really, what is the area of strength you are looking for – the web or the seal strength? Work with your suppliers to evaluate your material options and any new information available.





Another thing to look at, too, that sometimes we forget about is: what are we doing from a testing standpoint? Are we over testing? Maybe you need to look at your test methods, your distribution simulation or whatever conditioning and hazards you're applying during the development process and say – are we over doing it here? Because a lot of the methods that talk about distribution simulation, give you choices. You can pick different levels of hazards to apply. Maybe you're picking something that is too high for your supply chain, and isn't really representative of what your product is going to see. So that might be a free thing you can do (to analyze the strength your packaging requires).

**Dan Burgess**Packaging Engineering Fellow at Boston Scientific

DO HOSPITALS RECYCLE PACKAGING? AND, DO HOSPITAL PURCHASING GROUPS CONSIDER ENVIRONMENTAL FACTORS WHEN MAKING DECISIONS?





Answer

I am glad people are asking about recycling! That means people care. Definitely, hospitals are working on it. You know there is a great group, Healthcare Recycling Consult, working with several hospitals trying to establish a recycling program and then see how it works for them. So right now, hospitals care because the general public cares. But education is really needed to be out there for hospitals to be able to do so. There's a lot of hesitance still, including for the recycler (not just hospitals). [Recycler's] worry when it comes from the hospital, that there may be hazards in the material to be concerned about. So it's not just the hospital's concern about recycling; it's the recycler and us, the packaging engineers, and our designs. The trend is there, but there is a lot of work that needs to be done. Education, definitely, needs to be done. Just like many years ago when we were trying to educate the general public on recycling, now hospitals need the education.

# WHAT FACTORS DO YOU CONSIDER WHEN SELECTING A PLASTIC? DO YOU DECIDE BASED ON THE UNIQUE PRODUCT AND ITS' GEOMETRY/MASS?





Answer
Yes, all of the above.

**Min Degruson** Associate Professor, Packaging at UW Stout



Definitely; the mass, shape of the contents, and the type of the hazards of the contents present to whatever materials you choose should be considerations. But not only that I guess, but also the webs of what range of seal strengths that can be created with your material combinations. Some material combinations can only get so high of a seal strength. So, in some cases, if you have heavy contents, I think as Min talked about in her presentation, you may not even want to use a flexible [material]. You may look at that [product] and say this thing is a pound or two pounds - it's pretty heavy, so maybe we should just look at a tray. Going with a flexible, we'll probably have a tough time finding something that will maintain its integrity and not fail when exposed to distribution hazards.





Yeah, it's very true. I think Andrew in his presentation mentioned some stats about this; when you think about the medical device packaging itself, you're choosing different types of plastics and you're also choosing formats. It could be a pouch, rigid tray, thermoform seal (semi-rigid), and all those different factors play into that selection. It's not just the type of plastics, or just the type of formats. It's a pretty complex decision.