



### Competitive features of MEDEX 641:

- Available in clear and tints
- Tough and durable
- Lower forming temperatures
- Clean trimming
- Precise gauge control
- Easily sterilized via ETO or Gamma ETO
- Non-hygroscopic
- FDA, USP Class VI compliant
- Food contact (21 CFR 177.1640) approved
- Seals with traditional lid stock
- No topical release coatings

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### Out of the Gate and Into the Market:

## As Early Stage-Gate End Product, MEDEX 641 Sets Standard for Disciplined Development

#### Responding to a Market Need

Medical device manufacturers, like virtually all other industries, have become extremely focused on cost reduction and drive this initiative down through their suppliers. The packaging suppliers know that their raw materials, such as plastic sheet, are the single largest element of their cost, and thus, the greatest area of cost focus. Because of this there's always been a desire to find lower cost material alternatives, with emphasis on performance properties comparable to the industry standard: PETG (Polyethylene Terephthalate Glycol-modified). While PVC, polystyrene, acrylics and other resins are used in medical packaging, PETG has remained the dominant material in the industry.

MEDEX® 641 was developed as a lower cost, clear medical packaging alternative to traditional medical packaging plastics, including PETG. The end result of disciplined innovation, MEDEX 641 has achieved a significant difference in total cost compared to other sheet materials.

#### Better Price for Equal Quality

Exhaustive research was conducted to develop a new material that delivered the processing and performance features demanded by packaging design professionals and thermoforming experts alike. Naturally, the medical packing industry will not compromise on packaging integrity and the ability to sterilize and hold a shelf life. They

simply want to have alternatives in terms of lower total cost. The goal was to find a packaging alternative that offered a better price point for the same level of quality.

"There was no point in introducing a product that would be more expensive and compromise on other factors that were needed as industry standards. A 'me, too' result would add no incremental value. We kept the focus on what could we do differently," said Josh Gray, President of GOEX Corporation.

The medical packaging market gained that elusive alternative when MEDEX 641 emerged from the GOEX Stage-Gate development process. MEDEX 641 extruded sheet material was developed specifically for rigid medical and pharmaceutical packaging applications. GOEX, along with medical device packaging customer, Prent Thermoforming, kept focused and on track by use of continuous checkpoints and validation.

#### An Alternative for Packaging Applications

MEDEX 641 is a proprietary resin blend that GOEX extrudes, and it is available as a clear or medical blue-tint material, essential in the medical packaging market for quick content visibility. MEDEX 641 thermoforms easily and trims exceptionally well. MEDEX 641 resin has attributes that contribute to easy formed-part separation or de-nesting without needing topical release agents like silicone.

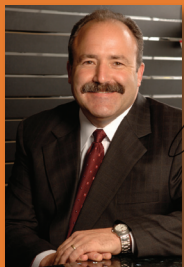
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**Disciplined Development Leads  
to Smart Innovation**

*GOEX isn't your typical extruder. We're not bound by any particular resin when it comes to solving a problem. We choose the best resin, and if we don't currently extrude it, we'll evaluate what it takes to add it.*

*We especially love the stubborn problems, but trial and error are archaic ways to solve them. Yet, that's how the plastics industry often operates. Our experience is that a reactive approach doesn't work well. Instead, GOEX brings discipline to development to leverage resources most efficiently. We have transitioned from "yes, we can," to "yes, we could, but should we?"*

*GOEX uses a six-step Stage-Gate process as the foundation of disciplined product development. We've applied this approach to about 20 projects over the past four years, with MEDEX being the first. You'll learn more about both the product and our collaboration efforts in this issue of Sheetline. We'll look at the process from the perspective of a customer, Prent Thermoforming. Above all, we'll focus on what disciplined development means for you.*

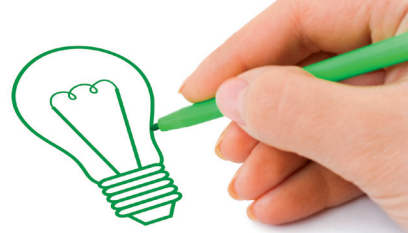


Sincerely,

Joshua D. Gray  
President & CEO,  
GOEX Corporation

## Considering Printing on Plastic? Prepare with These Tips

by: Bob Waddell, Vice President – Sales



Is your business new to printing plastics, or perhaps you're still at the evaluation stage regarding plastic printing? If so, when you prepare by identifying and understanding the challenges you can expect, your entry into plastics printing will be much smoother.

GOEX Corporation has been extruding rigid plastic sheet and roll stock products for more than 25 years, and we can share valuable lessons we've learned about printing on this durable, versatile material. More than one customer has benefitted from our experience! Why not you?

### Tip #1: Consider the Material

It all starts with having the right material for the right job. Proper material selection is key, because the wrong material will stop you in your tracks. As printers already know, not all papers perform equally, and it's the same with plastics. Not all plastics are even suited for print applications either. Make sure you're working with a material that has some chance of success.

### Tip #2: Consult Your Supplier

The first place to go for advice is your plastic sheet supplier – like GOEX, for example. Ask for suggestions based on their experience. You are responsible for the final product use and performance to your customer. Why not make an informed choice on what materials are typically used? A knowledgeable supplier should be able to help. GOEX's extensive product offering can start you in the right direction.

### Tip #3: Handle with Care

GOEX produces sheet materials in a controlled process environment, where overall cleanliness, facility temperature, and moisture control contribute to production of quality sheets. However, once that material is shipped to you, following these guidelines ensures you can process the material with optimum performance as intended by the manufacturer.

- ✓ Keep the material at or near room temperature. This is strongly recommended to avoid sheet warping from temperature and humidity extremes. A 65°F-85°F environment is best.
- ✓ If transport or other external conditions are extremely hot or cold, allow up to 72 hours for core sheets to adjust to printing room temperature and humidity.
- ✓ Avoid stacking skids of material whenever possible.
- ✓ Use fork extensions when moving skids longer than 48". Our skids are strong, but improper handling can cause a skid to flex too much and damage the plastic sheets.
- ✓ Always inspect the outer stretch film for any punctures or tears when receiving and before unwrapping the material. Accidental handling damage by the freight carrier or in receiving can result in expensive and time-consuming problems if damaged material is later run through your press.
- ✓ Cut banding and remove the GOEX outside stretch wrap, but keep the inner film wrap on until just prior to printing. This helps keep the sheet as clean as when we produced it for you.
- ✓ If you have ordered Corona Treatment sheet, you are advised to print within 30-45 days to achieve the optimum benefit of the treatment.

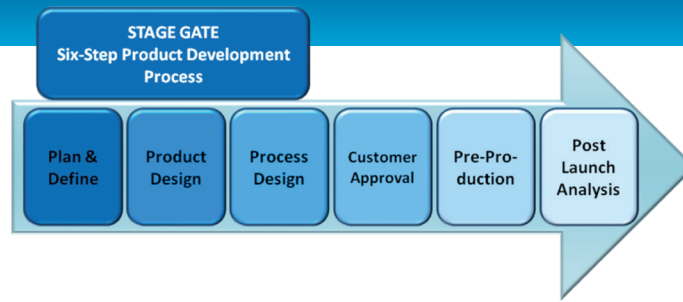
### Tip #4: Investigate the Ink

Ink selection works just like material selections. Don't be lulled into thinking that one ink is right for every plastic substrate. Your ink suppliers can be valuable resources, and the good ones welcome any opportunity to help. If needed, many will make some form of ink system modification based on the chosen printing substrates and the printing methods used. GOEX is willing to work with ink suppliers on your behalf, thereby assuring the best print outcome possible.

### Tip #5: Contact Goex for Answers

We are always ready to help our customers and their clients learn about the advantages and challenges of working with substrates. Don't guess. Be sure!

# Setting the Stage for Collaboration



## Through the Starting Gate

It's a common occurrence; a customer organization asks GOEX for a product for a particular need. "At that point, we're all at a fork in the road. GOEX can rush to develop a product based on few facts and lots of assumptions that may be wrong. Or we can load the request into Stage-Gate and evaluate it in terms of market value, volume and timing, and see if there is a legitimate business case to proceed. Our response is we would be glad to consider it, and here's what we need to start Gate One," explained Bob Waddell, Vice President - Sales.

## An Inclusive Approach

Stage-Gate provides a grounded framework to scope a project, including all people, departments and systems that might be affected. It starts with a comprehensive, cross-sectional evaluation that gets everyone looking internally and externally at things like processes, market position and product value. As many disciplines as necessary get involved: sales, manufacturing, engineering, polymer science and more.

By including all relevant points of a customer's organization, Stage-Gate avoids solving one problem only to create a new one for another department, like fixing a printing issue, but negatively impacting secondary functions like cutting, embossing or costing.

## No Opinions. Only Facts


Sometimes the development process begins with an inquiry through Sales. Other times GOEX identifies a need in the market and does all the input work. If it's a joint project, customers actively participate, or else the request won't get out of the gate. The customer will be heavily involved and committed through the entire process.

Instead of trusting opinions to guide development, customers internally assess the need and then verbalize and document it. "We ask them to analyze their needs and requirements and communicate in a format we can have confidence in and reference. We check back if the initial requirements aren't clear. For instance, if they ask for a weatherable material for an outdoor application, is the need for one year or ten years?" said Waddell. "There has to be direction and cooperation with the customer. If we don't get information back when we seek answers, we conclude there is too much unknown risk to proceed with development."

## Collaboration and Commitment


GOEX doesn't have all the in-house processes to match those that customers have, and some testing methods are unique to customers' operations. "When GOEX submits materials for the customer, they have to commit to running them and giving timely feedback. Recognizing they have time, energy and resources established in their organizations that are confidential, we respect that. We don't have to know that level of that detail; we just have to know they are committed to evaluating," Waddell explained.

## Reduces Wasted Time and Flawed Effort

"The project may begin under false assumptions, or the initial thinking turns out to be flawed. There's nothing wrong with that. The problem comes from building on such shaky foundations. We can develop for an application, but at the end of the day, if it doesn't meet the economic model, what's the point? Everyone has limited resources. With Stage-Gate, there is less likelihood of wasting time and money. It's smart business to keep moving things forward to either completion or to termination, if realistically, that's the best decision," declared Waddell. 

## What Stage-Gate Means

A Stage-Gate Process is a conceptual and operational roadmap for moving a new-product project from idea to launch. Stage-Gate divides the effort into distinct stages separated by management decision gates. The cross-functional team must successfully complete a prescribed set of related tasks in each stage prior to obtaining management approval to proceed to the next stage of development.

The Stage-Gate® Product Innovation process is the result of the world's most comprehensive research into understanding what determines product/project success and failure. Pioneered and developed by Dr. Robert G. Cooper, it is a widely implemented and trusted innovation process. 






MEDEX 641 performs in many of the same ways as other medical packaging materials. Typical applications so far include:

- Device packaging
- Lids
- Trays
- Mounting cards

GOEX offers a comprehensive report on MEDEX 641 covering key areas of product performance, including Coefficient of Friction, Lid Stock Sealing, Compliance Information, Recycling and Biocompatibility/Cytotoxicity. Packaging experts must still conduct their own validation testing for any intended application, since other specific internal or proprietary processing methods could affect test results.

#### Greater Yield, Lower Density and Higher Recyclability

MEDEX 641 can be approximately 20 percent less dense than alternatives like PETG, XT polymer, polycarbonate and PVC. This difference translates into more formed parts per pound of plastic converted, and can account for significant cost advantages, along with environmental benefits.

MEDEX 641 is a thermoplastic styrenic alloy that is completely recyclable into any styrenic waste stream. Because the density is considerably less than many other medical packaging materials, this translates into less material (by weight) to dispose of or recycle. 

## Who We Help: GOEX Customer Spotlight

### Prent Focuses on Medical Device Packaging Market

The medical packaging industry is not always an “off the shelf” business. Products often require packaging based on specific needs, and Prent has carved out a market solving customers’ unique problems.

“Prent is a 100 percent custom house; everything is customer-specific with no common products across clients,” explained Jeff Adeo, Prent Vice President of North American Operations/Lean Six Sigma.

Most major medical device makers use Prent packaging products, and Prent designs and develops many of these from GOEX resins. “GOEX is more a technical engineered material company, which makes them unique, and they have more specialized materials. GOEX has more options than any of our other suppliers,” said Adeo.

He continued, “When a medical packaging product is being developed, the material choice is determined by things like the marketing or sterilization method required. Some customers may want a clear material; another just wants cheaper and doesn’t care if it’s a clear package.”

#### Strict Cleanliness Standards

Prent’s U.S. customer base is over 96 percent medical, so cleanliness is extremely important. “If we’re inheriting loose or embedded particulate in sheets, our processes aren’t set up to find and eliminate those. We need very clean

product coming in the door, and that means partnering with a clean establishment that meets these standards,” explained Dave Henry, Prent Director of Quality Assurance.

#### Creating a More Affordable Alternative

Several years ago, in a bold move to help its customers reduce packaging costs, Prent, in conjunction with GOEX Corporation, embarked on aggressive research and development to provide a new medical grade material that would be more cost effective and meet the demands of the medical thermoform packaging market.

Prent and their customers are under continuous pricing pressure. Beyond simply improving productivity and efficiency, the market also needed a more affordable, clear material than currently existed for medical packaging applications.

Features were to be aligned with what medical packaging materials typically offer, and Prent’s targets for cost and quality set the direction. MEDEX® 641 would be created as an alternative to “legacy” packaging materials like XT (acrylic), Polycarbonate, PETG and PVC.

#### Testing Is Extensive and Ongoing

Evaluation is one of longest parts of the process when it comes to medical packaging. Some applications take 6 to 12 months and longer to fully test. Rigorous FDA requirements and other testing protocols for medical device packaging include shock and vibration, drop testing and response to different sterilization, humidity, aging and heat conditions.


After GOEX did preliminary testing of flat sheets, Prent thermoformed dimensional samples. Later, the Prent customer base got involved in further testing of specific applications, sealing and sterilization.

Ultimately, every packaging customer must test their own designs, because no single material will work for every medical packaging application.

#### Project Management Keeps Effort Focused

It costs a lot to bring out new materials, so companies want to make the best effort up front to ensure a good investment. The Stage-Gate system helped keep the MEDEX project grounded in practicality.

“Project management keeps us on task and with this discipline, we come out with products that meet the upfront input. Disciplined development ensures we’re hearing the voice of the customer,” said Pete Goral, GOEX Vice President - Quality Systems.

Going into the project, Prent’s goals were to reduce packaging costs for the medical device industry, while also shrinking the environmental footprint of the packaging. Emerging from the project, MEDEX 641 has hit its targets, while achieving cost advantages of up to 20 percent compared to PETG. Prent has gained an exciting, affordable option for helping customers create the best solutions for many packaging needs. 

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**Production Notes**  
Stock: GOEX CAROM 45 PVC  
Press: Komori 640+L Double Coater and UV