

# Design and scale shaped liquid tight bags without the risks.

## Polyolefins can deliver the performance you need.

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LiquaLoc Flexibles

Who says a soft, flexible, liquid tight medical bag with shapes and fitments must be made of PVC? Actually, many packaging experts out there today will tell you that. The truth is, it's outdated thinking. With the right handling capabilities and expertise, polyolefins can deliver all the performance of PVC without any health risks.



### Expanded performance characteristics, broader applications for custom shaped bags

Unsupported Polyolefins (e.g., polyethylene and polypropylene) now meet broad application performance characteristics requiring custom blends and/or coextruded structures that can be converted into custom shaped bags.

	PVC	POLYOLEFINS
ABILITY TO WORK WITH SHAPES	✓	✓
FITMENT MATERIALS	✓	✓
TRANSPARENCY	✓	✓
COST-EFFECTIVENESS	✓	✓
CHEMICALLY STABLE	✓	✓
EASY TO PROCESS	✓	✓
LONG SHELF LIFE	✓	✓
CONVENIENCE OF USE	✓	✓
EASY STERILIZATION	✓	✓
SOFT, FLEXIBLE, AND QUIET	✓	✓
<b>NON-CONTROVERSIAL IN MEDICAL USE</b>		✓

So, why design new or switch from what's working so well already? **Take a look at that last point.** There is considerable (and growing) controversy about the use of PVCs in medical applications. Want to secure your global market share as new regulations are put in place? **Polyolefins are your choice.**

So, why haven't companies already jumped on the polyolefin bandwagon for shaped liquid tight bags? There are three hurdles that first must be overcome:

1. **Designing shaped bags with unsupported films**
2. **Getting the right seal with shaped bags**
3. **Scaling manufacturing of unsupported polyolefin designs**



### Unlocking the potential of polyolefin constructions

Traditionally, the problem with using polyolefins was that manufacturers needed to create multi-layer laminations to consistently support the films on the production lines. Laminations are stiff, noisy, and often lack the softness needed for the application. In addition, the adhesives used in laminations have migratory issues.

Many manufacturers can construct polyolefin prototypes, but it becomes much more challenging to work with unsupported films if the design requires something other than a traditional three-side-seal rectangular bag.

### The right seal unlocks your opportunities for shapes

Thermal bonding is the preferred method to seal two or more layers together. RF welding and ultrasonic can be used, however are difficult to execute and are slower processes.

There are two ways of achieving a permanent seal with thermal bonding — impulse and heated platen. Impulse heat sealing is limited to a square or rectangle. A heated platen seal offers the design flexibility of unlimited shapes and seal sizes. The temperature is controlled using closed-loop temperature controllers and thermocouples.

The advantage of the heated platen seal is its ability to offer heat seals with unlimited geometries.

### The right die design will unlock scalability!

Designers often will create a bag design that meets the customer's goals and expectations during the prototyping stage, however is not yet in a configuration that lends itself to being both efficiently and effectively manufactured in a production sense. How can you scale?

The key to manufacturing bags in polyolefin films is the die design and process. The die must be engineered in a way that maximizes the heat seal strength and manufacturability. This includes:

- Transferring a near melted web through a process without stretching/distortion.
- Planning for any shrinkage in the material due to die temperatures.
- Protecting the material from sticking to heat seal dies.

The design of the geometry must also consider the internal force or pressure that the liquid tight medical fluid may see during the filling, shipping, or use of the bag. Additionally, there are proprietary techniques that allow for the bag material to be **sealed and cut at the same time**, therefore ensuring a liquid tight seal without fail.

### Finding the right partner to deliver your custom-shaped polyolefin liquid tight medical fluid bag

Now that you know polyolefins can deliver outstanding performance without the associated risks, there are a few questions you should ask of any potential manufacturer before embarking on developing your next revolutionary idea.

- Can they achieve a good seal with fittings/tubes and an unsupported polyolefin construction? Before someone says they can, ask how they plan to seal it.
- Do they have the technology to create custom heat seal dies that will accommodate your design in scale? Most anyone can make a prototype — the proof comes in the manufacturability at scale.
- Can they offer a liquid tight guarantee? Remember, it's your brand and product reputation resting on the performance of your solution.

There's tremendous opportunity out there for the use of polyolefins in the design of custom-shaped liquid tight medical fluid bags. All it takes is your imagination and a manufacturing partner with the expertise to execute your outside-the-rectangle thinking.

# Design and scale shaped liquid tight bags without PVC.

## Part II Why Change Now?

In Part I, we addressed how Polyolefins can deliver the performance you need in a bag versus PVC. In Part II we address urgency – is this a change that makes a positive impact for the company, employees, patient or stockholders? In other words, “why now” is the most common reservation – fair enough. We did some additional research to provide the support, we believe, to build a business case packed with urgency, and more importantly a packaging alternative that has little to no design or size limitations.

Building a business case often falls as an undesirable task, but never-the-less a requirement for almost anything that will disrupt the status quo. We get it, so we’re keeping it easy and breaking the process into 3 different categories:

### 1. PVC Health Risks

Let’s start with a baseline understanding of what has made PVC so controversial that companies across the globe, along with several countries, have banned it from being used to produce any healthcare packaging:

**All sources site DEHP as a chemical agent used to manufacture flexible PVC:**

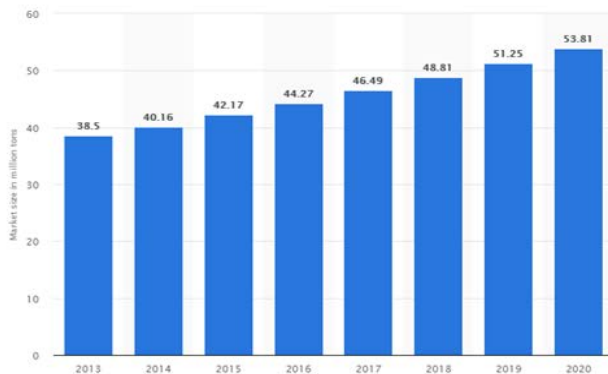
“Medical devices such as blood bags, IV bags and tubing are made of PVC (polyvinyl chloride) which contains a chemical agent called DEHP. This agent softens the rigid PVC material and reports from medical journals *suggested that phthalates in general, including DEHP, might be chemicals that mimic human hormones which can cause damage to the male reproductive tract leading to decreased fertility.*”

According to the US Library of Medicine and National Institute of Health other PVC chemical agent health concerns, include:

- Airborne or touching PVC often includes exposure to phthalates (DEHP) and **chlorine**.
- When receiving biological fluids such as nutrients, blood or blood components that have been stored in PVC containers, patients may be exposed to plasticizers via the **intravenous route**.
- Phthalates, dioxins, and BPA are suspected to be **endocrine disruptors**.
- Manufacturing, burning, or landfilling PVC releases **dioxins**.
- Exposure to PVC can impact drinking water through **Vinyl Chloride**

The toxic exposure risks may seem to make this a black and white issue. Oddly, demand of PVC is projected to grow, but so does the exposure to these risks as evidenced below:

**Polyvinyl chloride (PVC) market size worldwide from 2013 to 2020 (in million tons)**



**DESCRIPTION** SOURCE MORE INFORMATION

This statistic shows the market size of polyvinyl chloride (or PVC for short, and also known as polychlorethene) worldwide in 2013 and 2014, with forecasted figures for 2015 to 2020. It is forecasted that the global market size of PVC will be some 53.81 million tons in 2020.

Data visualized by + a b l e o u  
About this statistic

© Statista 2019 Show source

What’s not clear from the chart above, is how much of the growth rate is driven by unregulated countries, along with rigid PVC which is used primarily to manufacture primarily construction piping. Regardless, it’s an accepted, and some would state, a natural behavior to avoid change at all costs – the operational disruptions alone justify the resistance and usually support the continued standardized practices. *Until they don’t.*

**A Growing Consensus – Creates a Trend Line of Doubt**

For more than 4 decades several credible “watchdog” organizations have been tracking, testing, and monitoring the adverse effects of PVC’s material chemical agent make-up. Below are just a few of the alarming citations:

- **American Medical Association (AMA)** - adverse effects of DEHP to male infants which have been documented included:
  - Respiratory distress
  - Pathological changes to lung tissue that resembles hyaline membrane disease
  - Historical damage to the testes
  - Testicular and epididymal atrophy and agenesis
- **EU-Commission** has asked a scientific committee to investigate Intravenous Exposure via PVC Containers.
- The **Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)** “there is a reason for some concern for premature born male neonates for which the DEHP exposure may be transiently above the dose inducing reproductive toxicity in animal studies.” A few other patient groups besides neonates may also be at risk, i.e. “the male fetus and male infant of pregnant women or lactating women, respectively, in hemodialysis”
- The **EPA has concerns** regarding phthalates’ toxicity and the evidence of pervasive human and environmental exposure to it. A number of studies have revealed a link between phthalate exposure and human health.
- **The American Public Health Association** has established prior policy regarding children’s environmental health and healthy schools, chlorinated chemicals, persistent organic pollutants, chemicals policy, prevention of dioxin generated by health care facilities through use of polyvinyl chloride (PVC), and reducing the rising rates of asthma in children.
- **The U.S. FDA, the Swedish Chemicals Inspectorate, the Japanese Ministry of Health and a Health Canada expert panel** have warned certain patients — particularly sick infants — are at risk of harm from phthalate-containing vinyl medical devices

**2. Litigation and Settlement Risks**

There’s a natural resistance by companies of all sizes to make significant operational changes, so it’s not surprising that packaging change(s), are rarely made without some very good reasons. Assuming the material attributes meet necessary specifications, the next consideration is gaining and understanding of how the current or new product(s) could impact the company at large. Frequently, the best early indicators are the actions taken by other manufacturers or facilities. Below is a small sampling of companies that have developed policies to reduce or phase out PVC:

Products	Companies Phasing Out PVC
Consumer Products & Packaging	Adidas, Asics, Nike, Puma
Food Packaging	Dean Milk Chug Brand (food packaging), Eagle, Brand Cremora (food packaging), Federated Groups (food packaging)
Health Care	Abbott Laboratories, Baxter International, B. Braun, Catholic Healthcare West (IV Bags), Consorta, Kaiser Permanente, Tenet Healthcare Corporation
Retailers	Bed, Bath, & Beyond, Best Buy, H&M, IKEA, JCPenney’s, Kmart, Sears, Target, Wal-Mart

\*For more information regarding those medical device and fluid companies that are actively replacing PVC: [Healthy Building Network](#) or [Chemical Watch](#)



Adding to the enterprises that have made this significant decision, several significantly sized Healthcare facilities with locations throughout the US and globally have begun the same process:

- **Karolinska Hospital** documents eight-year PVC phase-out project
- **Kaiser Permanente** PVC and DEHP in neonatal intensive care units
- **Miller Children's Hospital** Attaining 100% DEHP elimination in iv bags
- **Lucille Packard NICU** Makes major strides to remove DEHP and saves \$200,000 by switching to custom-made DEHP-free iv product
- **Evergreen Hospital NICU** DEHP- and PVC-free
- Six months after FDA warnings about DEHP, **John Muir Medical Center** is proudly DEHP-free

**When Does Price Become Too Steep?**

The **companies cited** above don't enter into radical decision making to change a manufacturing process or product(s) based on subjective opinion, but rather several data points are taken into consideration including the health and well-being of patients and employees, quality control and assurance standards, litigation risks and public trust, to name only a few.



**WARNING: This product contains, and can expose you to, DEHP, a phthalate chemical known to the State of California to cause birth defects and other reproductive harm. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).**

Adoption and/or material elimination trends are early indicators that provide an economic pulse and a financial tolerance test which is often driven by law suits, litigation, and ultimately settlements which speak louder than any other state.

\*For more information regarding active litigation or settlements, please refer to the following sources: [Chicago Tribune](#), [CBS News](#), [California.Gov](#)

**3. Polyolefins as a Viable Alternative to PVC**

As previously noted, Kaiser Permanente, the nation's largest nonprofit health plan provider, didn't make this decision lightly to phase out PVC, but rather through a committee specifically charged as a watchdog over neonatal patient care – this team applied a risk-management process to define a clear process that initiates clinical trials to seek out alternatives. And the good news is, there is an alternative that meets and exceeds expectations – Custom Liquid Tight medical fluid bags and Components (Polyolefin) manufactured by Vonco Products.

A Polyolefin such as Low Density Polyethylene (LDPE) is inherently very flexible without the use of any plasticizers. It is chemically inert and deemed to be non-hazardous. The use of a virgin LDPE guarantees the content is free of any recycled materials that could place questions on the additional content of unknown materials in the blend.

For more information on Polyolefins as an alternative, see [Novachem.com](http://Novachem.com)



**Custom Shaped Bag**



**Custom Multi-Compartment Bag**



**Custom Fitment Pouches**



**Now for the Proof**

First, let’s outline healthcare packaging mandates:

- Ability to work with shapes
- Fitment materials
- Transparency
- Cost-effectiveness
- Chemically stable
- Easy to process
- Long shelf life
- Convenience of use
- Easy sterilization
- Soft, flexible, and quiet

It’s been a long-held belief, PVC is the only material that meets these standards – fortunately, this a myth whose time has come to yield to Vonco’s medical fluid bags, which also meet and even exceed all of these standards. That certainly supports part of the business case, but there’s so much more –when considering the greater level of functionality and ease of use because of the patented approach to designing and quickly manufacturing the medical fluid bag solutions (see part 1 Design and scale shaped liquid tight bags without the risks).

Vonco’s liquid tight, medical fluid bags eliminates the inherent chemical risks found in PVC. As a result, you can now significantly reduce or eliminate the line item allocated towards litigation and settlement. While you’re converting this cost to \$0, you may also be able to lower your liability insurance premium. We’ll call that an added-value benefit.

**Next, Account for the Risks**

Healthcare facilities and manufacturers have a low risk tolerance – and for good reason. The strict FDA guidelines is what makes the US healthcare industry the best in the world.

**Time to Deliver**

Many may take the leap in assuming the time to deliver is going to exceed that of the PVC product inventory – fortunately, Vonco is a US based company, and time to deliver will meet or even reduce the manufacturing and distribution time-line.

**Ability to Customize**

**Polyolefins can deliver the performance you need** to develop and scale medical fluid bags with shapes, tubing and connections that remain liquid tight. With the right handling capabilities and expertise, polyolefins can deliver all the performance of PVC without any of its associated risks. There’s a tremendous opportunity out there for the use of polyolefins in the design of custom-shaped liquid tight, medical fluid bags. All it takes is your imagination and a manufacturing partner with the expertise to execute your outside-the-rectangle thinking. And that’s what you’ll get with Vonco.

**Quick Comparison Table:**

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