

Insight to Action

Liberty Mutual Insurance | Manufacturing

3-D Printing: New Dimensions in Risk

New Dimensions in Risk



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INSURANCE



OFFICIAL PROPERTY & CASUALTY INSURANCE PARTNER

3-D Printing in Action



Lightweight parts and products: cars, planes



Low-volume custom products: prosthetics



Biomaterials: human tissue



Food: packing molds, pizza, candy, potatoes



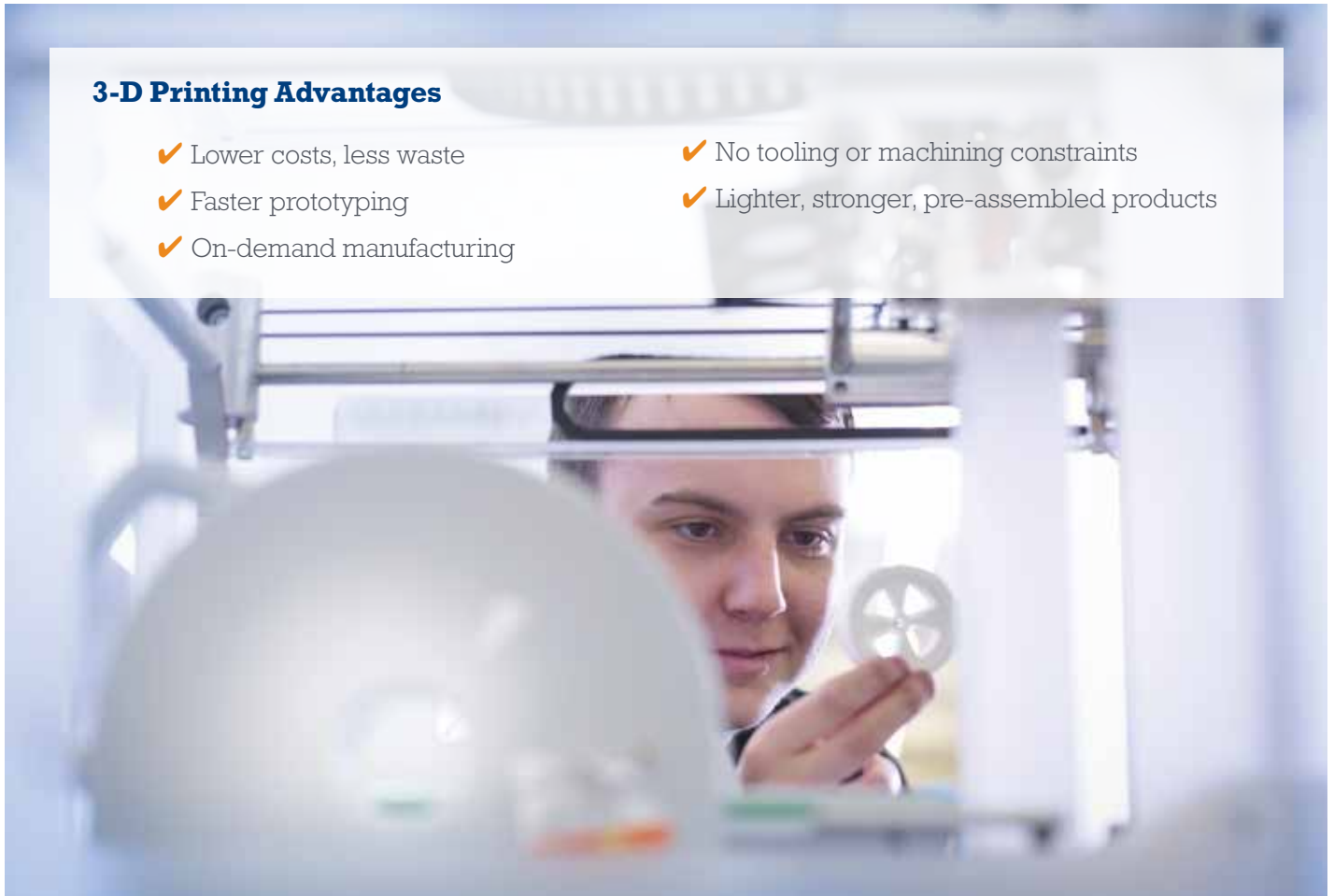
Architecture: 3-D models, prototypes

From grade school classrooms to major manufacturing facilities, 3-D printing has made quite an impression on the public's consciousness. Although the process, also known as additive manufacturing, has been around for decades, recent advancements have drastically improved the quality of printed objects while also lowering costs, a combination manufacturers are finding very attractive. Industries including aerospace, defense, automotive, and healthcare already use 3-D printing in everything from rapid prototyping to end-product manufacturing.

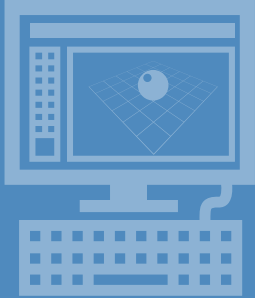
Whether your business is firmly entrenched in the 3-D printing revolution or you are considering adopting the technology to boost production and lower costs, we urge you to be aware of this rapidly growing phenomenon and how it's changing risk for manufacturers.

3-D Printing Advantages

- ✓ Lower costs, less waste
- ✓ Faster prototyping
- ✓ On-demand manufacturing
- ✓ No tooling or machining constraints
- ✓ Lighter, stronger, pre-assembled products



How 3-D Printing Works



1: A virtual design of the object is created in 3-D modeling software. If the process involves reproducing or modifying an existing object, the software can also import a scan of the physical object.



2: The software slices the final model into hundreds or thousands of horizontal layers of varying thickness.



3: The prepared file is uploaded to a 3-D printer, which creates, or “prints”, the object using successive layers of material until it produces a 3-D physical object.



Increased Production, Reduced Costs... Higher Risks?

Given 3-D printing's rapid evolution and acceptance, the risk landscape associated with the process is also changing quickly. As the range of 3-D-printed products includes tools, furniture, guns, makeup, and even food, it's not difficult to imagine some of the scenarios that will lead to claims. Similarly, in healthcare, 3-D printing is being used to develop products such as prosthetics, bone implants, and pacemakers. And in the not-too-distant future, research on combining 3-D printing technology with highly advanced materials will lead to printing human organs, implants made from biomaterials, and microscopic robots that fight cancer. Scientists have already begun printing veins and organs with living tissue. It won't take long before these and other innovative applications of the technology result in a very complex set of risks for manufacturers.

Insurance Exposures

Whenever a business shifts its operating model, it can also expect its exposures to change. Using 3-D printing to manufacture products could trigger a rise in claims stemming from worker and third-party injuries, property damage, intellectual property (IP) infringement, product liability, and cyber liability (design and data theft). The extent of any business's liability exposure will depend on what it produces and how it uses 3-D printing in its operations.

Product liability risk will undoubtedly increase along with the growth in 3-D-printed products. Product defects could be traced to several root causes:

- Defective digital design
- Defective or corrupted copies of digital designs
- Defective 3-D printers and materials
- Human error in implementing the digital design, or in using the 3-D printer and materials

Such flaws and problems could lead to slowly emerging and long-tail liabilities.

The nature of commerce will also change, since end users will be able to do much of their own manufacturing rather than buy from others. As the supply chain contracts with fewer suppliers and middlemen, liability will expand for those in the chain of commerce such as the product and printer manufacturers, software designer, feedstock supplier, distributor, and retailer.

The materials used by manufacturers present a greater potential loss exposure than the 3-D printer itself. When manufacturers using 3-D printing purchase raw materials from suppliers, they need to evaluate the materials just as carefully as they do in any manufacturing process. 3-D printing must undergo the usual rigorous testing found in traditional manufacturing to avoid a deterioration in product safety.

As 3-D printing blurs the line between manufacturer and end user, determining which party is responsible for how the end product is used, or for injury or damage to people and property resulting from the product's use, will grow more complex. Who among the entities that print and sell products, manufacturers of 3-D printers, and digital designers are ultimately responsible? Whether the manufacturers of 3-D printers and software should be responsible for product liability claims arising from 3-D printing errors will initially be established on a case-by-case basis.

Potential Exposures:

- Bodily injury
- Counterfeiting
- Cyber liability
- General liability
- Health hazards
- Intellectual property
- Physical damage
- Product liability
- Professional liability
- Workers compensation



Bodily Injury

As with traditionally manufactured products, many products manufactured by 3-D printing may be hazardous to users and bystanders if they malfunction. For example, some individuals have already used 3-D printing to produce handguns. A malfunctioning gun could explode in the hands of a user attempting to fire it, potentially leading to a claim against the manufacturer of the printer and others. The claim might allege the printer did not properly print the gun. There are other bodily injury scenarios, involving countless other products, that will result in user claims and coverage questions.



Professional Liability

Insurance for designers will become more critical than ever as their digital 3-D models are distributed and interpreted by a wide variety of printers of different configurations and calibrations. The boundaries between product designer and producer will also blur and require a review of the scope of professional liability coverage. As 3-D printing technology grows in the medical, construction, and engineering segments, we also foresee possible implications for medical malpractice and engineering E&O insurance.



Health Hazards

Readily available materials for 3-D printers may expose operators and property to hazardous chemicals. For example, many 3-D printers rely on heated thermoplastic extrusion and deposition, a process that produces significant aerosol emissions and harmful particles. Because traditional environmental pollution generally occurs outside, some courts have held that the pollution exclusion does not apply to indoor contamination; however, more courts are reaching the opposite conclusion.



Intellectual Property (IP)

Three-dimensional printing raises serious IP issues for designers and manufacturers of products, especially consumer products. Anyone could use 3-D printing to intentionally or unintentionally re-create an existing product design, manufacture the product, and then distribute it. In the 3-D printing realm, IP rights infringement may very well become the rule rather than the exception. If anyone can make any product, anyone can make products that infringe on trademarks, copyrights, and patents.



Counterfeiting

Manufacturers already struggle with counterfeit products; 3-D printing magnifies the risk because it can cut the time from development to a market-ready product to a few hours. Counterfeiting can now be as simple as scanning a product, making a computer model of it, and printing the product from that model. Counterfeiters can also sell designs for consumers to use to make the counterfeit product with their own 3-D printers.

Counterfeiting results in the original manufacturer losing money on its significant investment in design, manufacturing, and marketing. The more illegally copied products on the market, the higher the risk of defective products, which could result in bodily injury and property damage claims. Manufacturers could face litigation for products they didn't manufacture. The entity with the exclusive rights to a protected copyright, trademark, or patent might also be subject to significant legal liability and suffer damage to its reputation. The maker and seller of a 3-D-printed product needs to have permission to use the design and replicate products for profit.



Regulatory Implications

If 3-D printing enables the production of small-scale medical devices, then it's possible such work will take place outside a traditional factory subject to government regulation and inspection. FDA oversight of manufacturing intends to make medical products safer, but at present, the agency has provided only draft guidance to describe how 3-D printing should be used to create medical devices. Also, this guidance does not address how the FDA plans to regulate 3-D-printed devices.

In 3-D printing, consistency and quality of the final parts are major concerns. Currently, there's no way to ensure the safety and integrity of additive-manufactured products, even though organizations like ASTM (Additive Manufacturing Technology Standards) International are working to develop voluntary consensus standards. The technology however, is advancing much more quickly than the standards and regulations are being developed.

Mitigating the Risks with Insurance

Do we need a new quality assurance process?

Who's liable if the end user is injured?

What do our supplier contracts say about defective designs?

Protecting your client or your business from the risks associated with 3-D printing starts with assessing your risk management profile. Consult with your insurer and:

- Discuss security controls and how copyrights are researched and carefully examined for reproducing products and designs they do not own.
- Discuss equipment, processes, employee training, design sources, and materials, as well as the intended and potential end uses.
- Discuss QA, safety testing, and hazard controls for 3-D printing activities. What are the risks at each stage, from manufacturing to testing, distribution, and end use? Review the risks associated with the quality of the raw materials being used and potential new combinations of materials that may not have an established track record.
- Conduct a risk assessment with the final product before replication so that defects are eliminated. Make sure that this review considers how materials are selected and fabricated.
- Conduct a supply chain review. Understand the complexities of traceability with regard to the designs, raw materials, components, and parties responsible for manufacturing defects.
- How is proprietary information secured? How are people with access to IP authorized and managed? Make sure there are methods in place to screen employees in these positions.
- What are the local, state, and national regulatory risks?
- Get advice from your carrier and consult your legal counsel about ways to limit liability. Do you have strong contractual relationships? As a vendor or buyer in the supply chain, have you negotiated disclaimers, non-liability clauses, or caps to limit liability?
- Make sure the 3-D printer and surrounding space is equipped with properly designed ventilation and air filtration systems that remove hazardous fumes and particulates away from the operator and out of the room.



A Partner to Help Reduce the Length, Width, and Depth of Risk

Three-dimensional printing is here to stay and so are its risks. At this point in its evolution, it would be presumptuous for anyone to say they have all the answers — after all, the questions are still emerging. However, Liberty Mutual underwriters, risk control consultants, and claims teams are experienced in and extremely knowledgeable about manufacturing. We approach this new area as we do any other: by meticulously examining the potential exposures, researching the legal implications, and creating processes and controls that businesses can implement to protect themselves against costly new claims.

You know our well-earned reputation as a leading insurer for the manufacturing industry and a superior provider of workers compensation and liability insurance. The people, technology, and sophisticated solutions we've put in place to achieve this position will continue to support brokers and manufacturers as 3-D printing takes over more and more of the workload.



Contributing Editors

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Liberty Mutual

As solution-driven underwriters with specialty expertise, Liberty Mutual Insurance delivers integrated products and services tailored to your business. We understand the exposures unique to industrial equipment and machinery manufacturers and can help protect even the most complex risks. By partnering with Liberty Mutual Insurance, you'll receive a customized solution by underwriters located in regional offices who have deep industry expertise.

Resources:

How Stuff Works (How 3-D Printing Works)

<http://computer.howstuffworks.com/3-d-printing.htm>

Property Casualty 360°: Printer Risk, Now in 3D!

<http://www.propertycasualty360.com/2013/11/19/printer-risk-now-in-3d>

Risk & Insurance: 3D Printing Offers New Risk Challenges

<http://www.riskandinsurance.com/3d-printing-offers-new-risk-challenges/>

Insurance Journal: The New Age of Technology: 3D Printing

<http://www.insurancejournal.com/magazines/features/2013/05/06/290460.htm>

Claims Management: Thorns of 3D Printing

<http://claims-management.theclm.org/home/article/Thorns-of-3D-Printing>

CSC: 3D Printing and the Future of Manufacturing

http://www.csc.com/innovation/insights/92142-3d_printing_and_the_future_of_manufacturing

Kennedys: 3-D printed products, product liability and insurance implications

<http://www.kennedyslaw.com/article/3dprintedproducts/>

CII: 3D printing: what lines of insurance does it impact?

<http://www.cii.co.uk/knowledge/claims/articles/3d-printing-what-lines-of-insurance-does-it-impact/32196>

ASTM International

<https://www.astm.org/>

The Legal Intelligencer: 3-D Printing Set to Disrupt Products Liability Law

<http://www.thelegalintelligencer.com/id=1202758456545/3D-Printing-Set-to-Disrupt-Products-Liability-Law>

Talk to your Liberty Mutual Insurance account executive or representative today to find out how we can help reduce risk in all its dimensions.

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