

3D Printing Impact On Global Medical Supply Networks

McKinsey survey*

Companies fail to make strategic choices

Only 35% of the companies work with **competitive strategy** that is capable of beating the competition

Only 20% link their strategy to clear decisions about their **product portfolio** and allocation of **required resources (= SCM)**

Companies with an **effective strategy development** place a lot of value on the **macro trends (= scenario planning)**

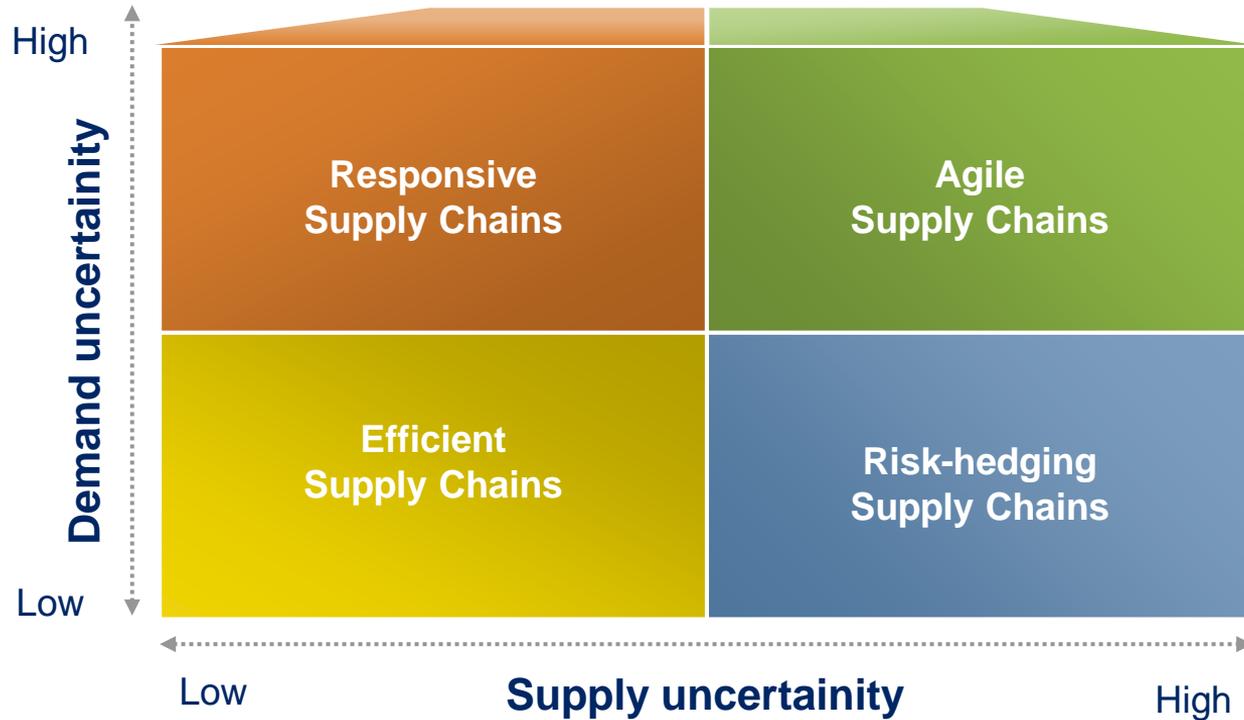
Strategic direction of healthy companies is **unclear to 25%** of the employees; almost 60% in unhealthy ones.

Many companies' strategies are below-par* !

**McKinsey survey among > 2,000 decision-makers (2016)*

Supply chain types

Supply and demand uncertainty



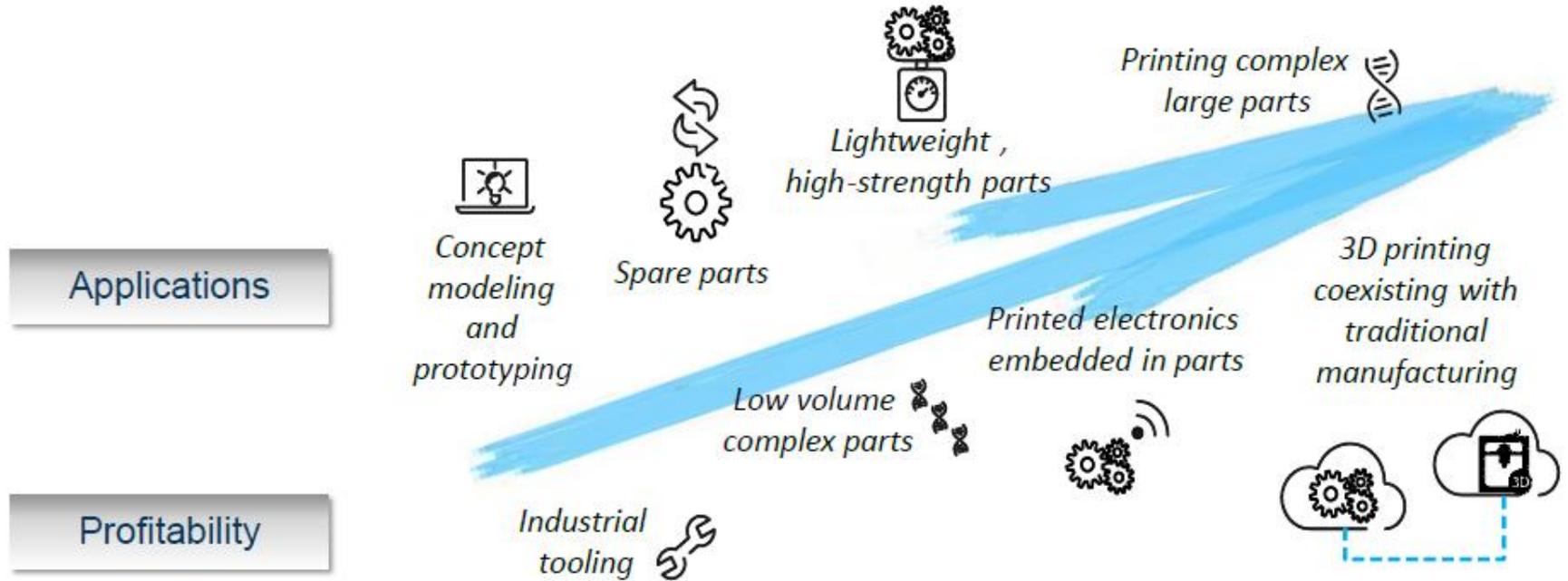


Strategic choice: 3D Printing



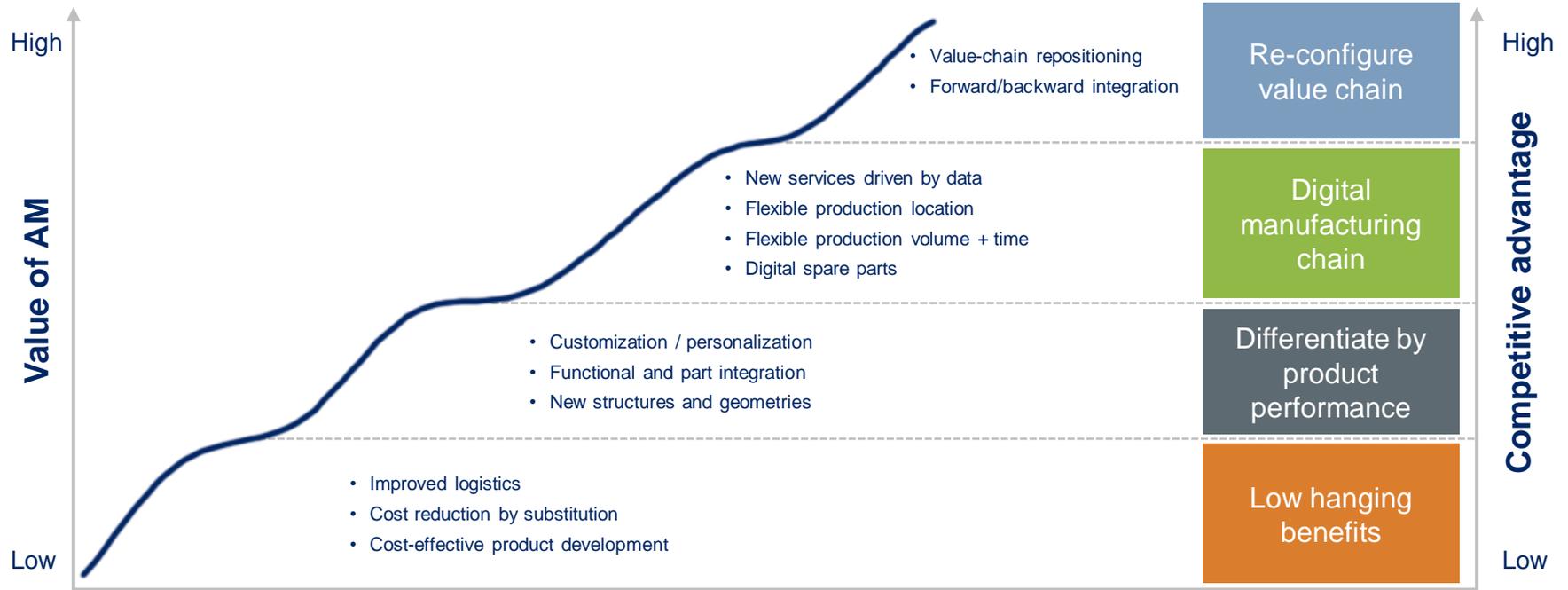
Why?

Maturity Life Cycle of Certain Parts



Why?

Total value becomes strategic

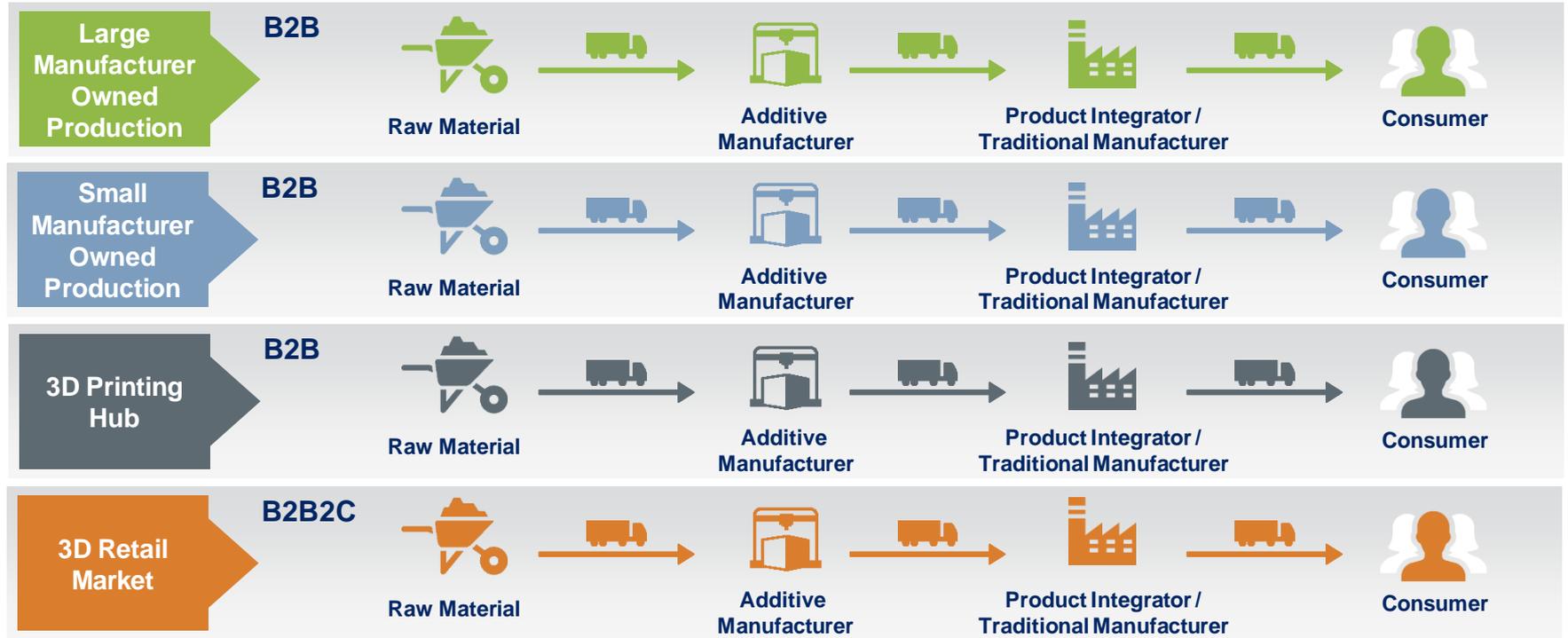




Future 3D Printing Distribution Network

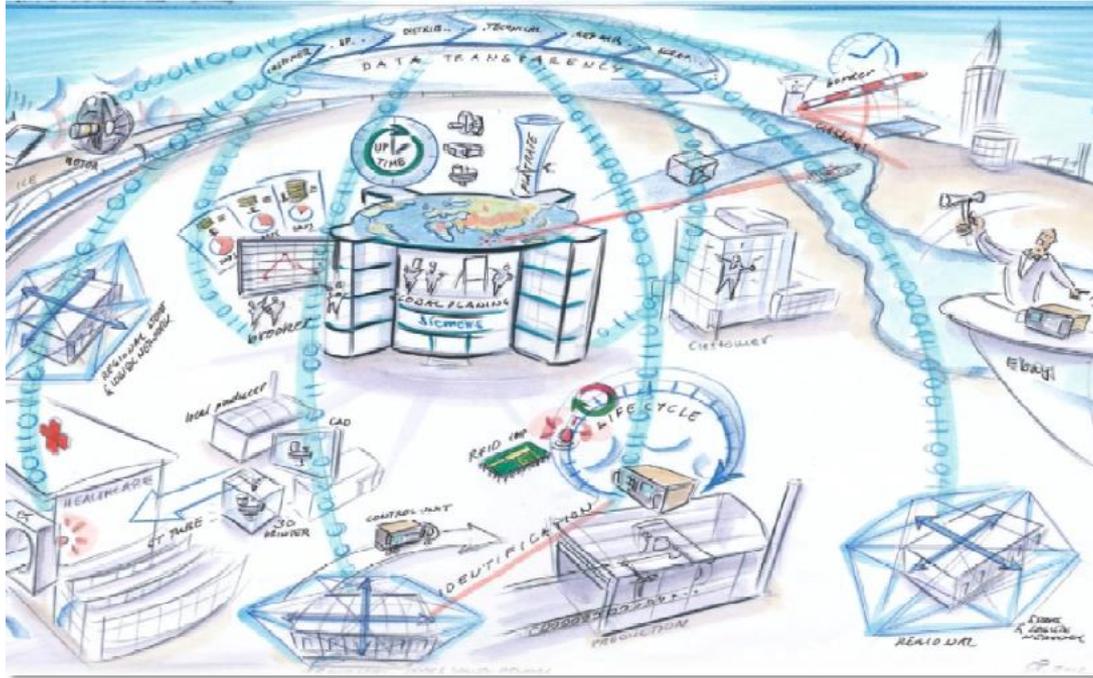
Execution models

What models do we see



Spare Parts Logistics

Many possibilities



1. 3rd party spare parts and grey markets
2. Additive manufacturing
3. New methods of IP protection
4. Battle for talents / new working profiles
5. Customer-centered spare parts logistics
6. Service – and performance-based contracts and financing
7. Global availability of spare parts
8. New obsolescence solutions
9. From push to pull spare parts supply chain
10. Flexible and selective logistics
11. Local strategies
12. Design to logistics
13. Alliances and collaboration in complex logistics networks
14. End2End data transparency over the spare parts lifetime
15. Automatic spare parts handling, identification and track & trace
16. Spare parts cloud
17. Green logistics
18. Recycling, return and repair logistics

3D Printing Will Change The Pharmaceutical World ! Because , Nowadays , Personalization Is Everything !

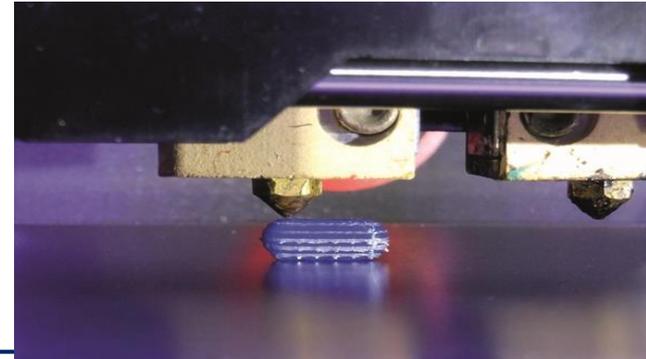
1. Democratizing Pharmaceuticals By Personalized Medicine & Drug Dosing

“Currently it is impossible to have a tablet on the market to suit every size of child. This is why we use liquid medicines for children,” he says.
The popular belief that children will not or should not swallow pills is false, Tomlin adds. “Studies show that most four-year-olds would actually rather take tablets. Personalized 3D Printed medications may serve particular well for patients who respond to same drugs in different ways.”

Allowing a MD or Pharmacist to use each patient’s individual information like :
Age, Race , Gender – to produce their optimal medication dose and treat multiple Ailments at once.

2. Unique Dosage Forms

Inkjet-based 3D printing technology to create limitless dosage forms.



3D Printing Will Change The Pharmaceutical World ! Because , Nowadays , Personalization Is Everything !

3. More Complex Drug Release Profiles

Drug release profiles explain how drug is broken down when taken by the patient. Designing & printing drugs firsthand makes it easier to understand their release Profiles, and study variations of separate ingredients.

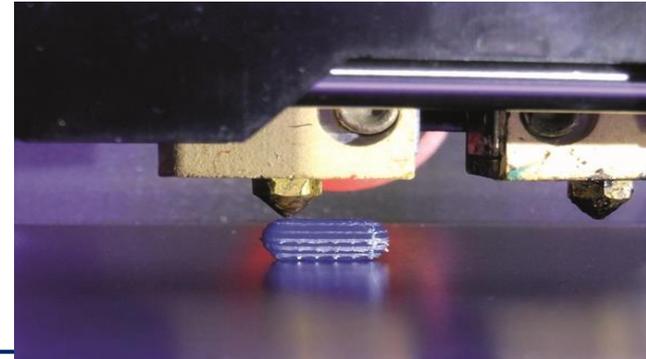
4. Printing Living Organs & Tissues.

We are probably less than 20 years away from printing a 3D heart , liver or kidney. But we are already in a position where we can print Human skin & flat structures.

5. R&D Enhancement By Rapid Prototyping & Safer Drugs Testing.

6. Getting More Affordable To Improve Lives

Low-cost prosthetics, printed locally by 3D desktops (Maker-bot for example)
At BOP countries (Bottom Of Pyramid).



Potential Challenges In 3D Printing Pharmaceuticals

1. Product Liability Risk

- Parties across the manufacturing spectrum could be liable for the fallout.
- This might also include the printer manufacturer, the software designer, the material suppliers and the product manufacturer.
- There is no litigation in this area yet, and therefore no precedent – so it's unclear which parties will be most susceptible to product liability claims.
- Pharmaceutical companies venturing into 3D printing should develop a strategy for licensing their blueprints to ensure they're financially and legally protected.
- The first conversations should include their lawyers and insurance brokers.

2. Cyber Risk

3. Regulations

- “Garage Biology” still requires comprehensive regulations and compatibility.

4. The Safety and Efficiency of 3D Printers

5. Patents / The Impact On IP

- Mass reproduction of 3D printed drugs and products is a growing concern for IP owners.
- The commercialization of 3D printing will lead to a large number of small-scale manufacturers and this will make policing IP increasingly complex.
- Most branded drugs are patented so manufacturers can recover the billions of dollars invested in R&D during drug development.
- After 20 years these patents expire and – in a process overseen by the FDA - generic drug makers can clone the medicine.
- However, empowering individual pharmacies and smaller entities to clone drugs through 3D printing jeopardizes this patent protection.
- The chemical compounds that make up drugs can potentially be reverse engineered and cloned very quickly without expensive manufacturing.
- 3D printing also increases the threat of counterfeit medicines.
- Printers are much more vulnerable to hackers than traditional manufacturing processes, and the incredibly short production time magnifies this risk.

FDA's Guidance for Additive and 3D Printed Medical Device Manufacturers

So far, more than 100 3D printed medical devices have undergone FDA premarket review.

- The FDA is evaluating submissions for new 3D printed medical devices to determine safety and effectiveness.
- The draft guidance provides manufacturers with recommendations for device design, manufacturing, and testing considerations when developing 3D printed devices.
- The type of premarket submission required for a device is still determined by its regulatory classification.

This draft guidance is broadly organized into two topic areas:

- Design and Manufacturing Considerations.
- Device Testing Considerations.

Next steps :

- Determining which existing US laws and regulations apply to additive manufacturing
- Developing a transparent policy to oversee 3D printing processes
- Reviewing regulatory issues pertaining to bio-printing of biological and tissue-based products

First 3D-printed drug approved by FDA

by Hope King @lisahopeking

🕒 August 4, 2015: 11:58 AM ET

👍 Recommend 1.6K



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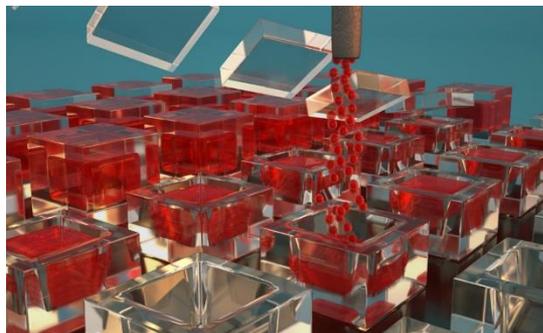
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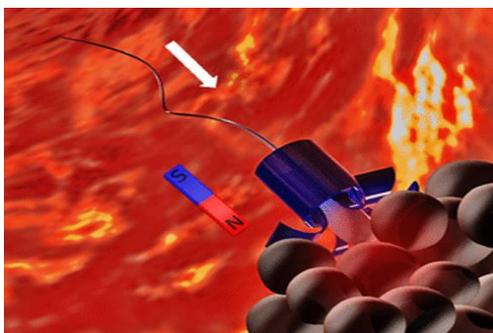
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Medical 3D Printing Breakthroughs in 2017

3D Printed Vaccines



3D Printed Spermboats



3D Printed Silicone Heart



3D Printed Lenses to Prevent Photosensitive Epileptic Seizures



Tuberculosis Diagnostic Device



Patient-Specific Liver Models



The World's First Selective-Dose Pharmaceutical Grade Medicinal Plants Inhaler

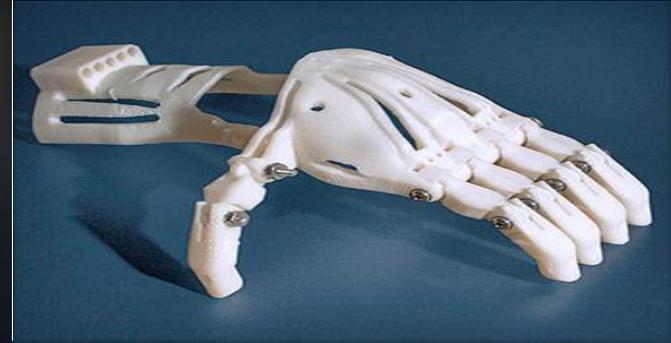
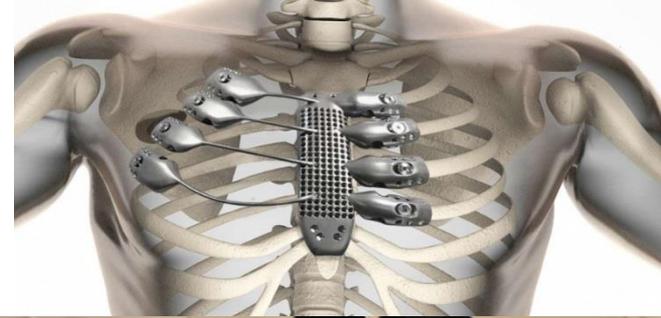


“ We finally may have a delivery system for medical cannabis that is effective, stable, safe and easy to use. ”

— Journal of Pain & Palliative Care Pharmacotherapy -
Reviewer



Additional Examples For 3D Printing Impact Medical Devices & Healthcare





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