



# WHERE'S THE VALUE?

What's worth the effort?



#### MEDICAL DEVICE INNOVATION GROWTH

Going from old to new

- The old norm of medical device companies was to deliver value through manufacturing and selling their products.
- New, higher demands have increased exponentially in the past 5 years.
- Medical Device companies are now having to meet the demands with more innovative, effective, and low-cost devices.
- If they can find a new device that meets those needs, they are more likely to purchase it and use it then in the past.
- This puts the added pressure on Engineers with the ability to create such medical devices.



### REINVENTING

What to focus on

- There's a higher demand for more effective and smarter devices that pose less of a risk for the patient.
- There's also a higher demand for devices that can prevent as opposed to treat and cure certain conditions.
- The desire for a greater amount of condition specific data analysis is ever present.
- People prefer treatments they can mostly control and perform themselves, with less visits to their doctor necessary.

## REINVENTION SOLUTIONS

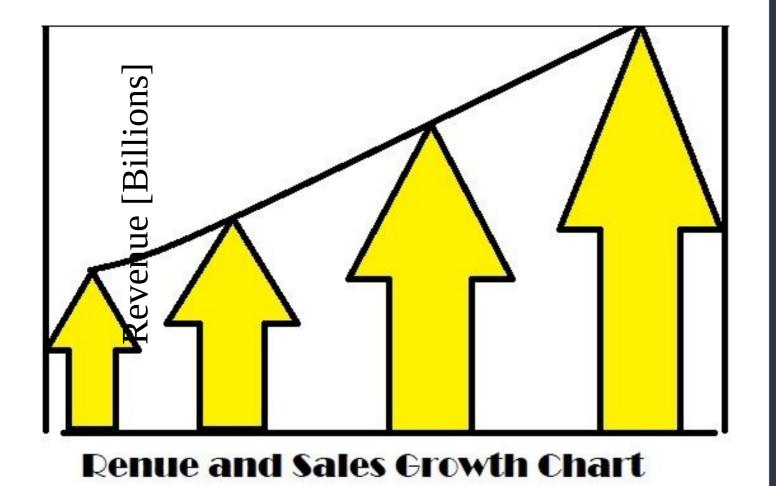
#### Bett er Connections

- Companies are using more and more electronic "smart" devices to help monitor their patients' bodies.
- The most preferred "smart" devices that patients like to use are called wearables.
- The less invasive the device, the more likely patients are willing to agree to it.
- Patients are more likely to stick with a treatment that they
  can perform on their own and doesn't require a lot of
  doctor's office visits.

#### Prioritizing Quality

- Patients want the treatments being used on them to be effective and low cost.
- Devices being provided to the patient for at home treatment need to be simple to use.
- If a device doesn't provide positive results within a limited time frame, patients might be disgruntled.
- Medical Device companies are partnering in order to assure that their devices are competitive and cutting edge.

#### Global Medical Device Forecast to 2030



2025

2020

2015

2030

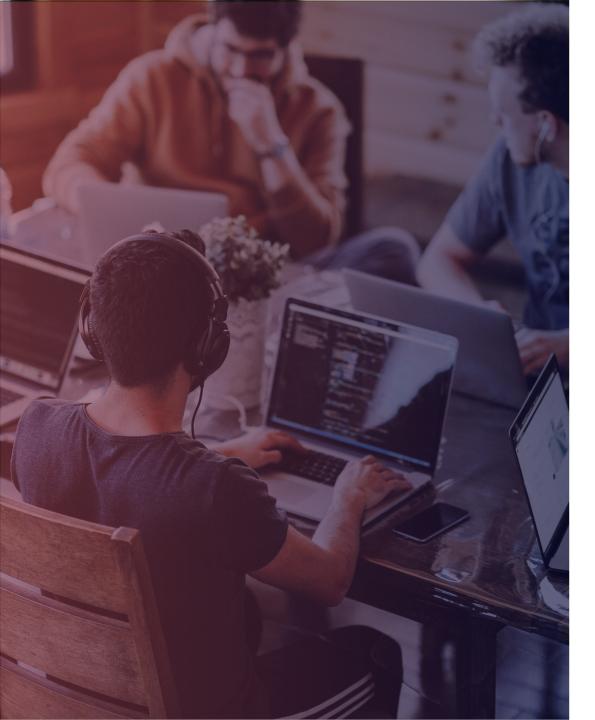
#### DEFINITE NEED

Billion Dollar Industry

- The global annual sales forecast for medical devices is expected to rise by over 5% per year, reaching \$800 billion by 2030.
- Purchasing responsibilities have already changed from clinical to economic buyers.
- Governments around the world are trying hard to decrease health care costs for patients, which increases demand for cheaper devices.

# NEW MEDICAL TECHNOLOGY REQUIREMENTS

Clinical	Regulatory Approval	Manufacturing	Distribution	Marketing
Increased Prevention	Proof of existence for patents filing	Smart contracts with CROs, CMOs, etc	Digital tracking and traceability	Smart patient health profile
Patient Enrollment	Verification-smart contracts	Manufacturing process control	Counterfeit protection	Connected ecosystem
E-Consent	Records management	Payment transactions across supply chains	Inventory management systems	Secure medical device data
Trial Documentation	Methods & Results	Regulatory compliance requirements	Effective & efficient targeted recalls	Preventative device maintenance
Data Sharing	IP registration and exchange	Enhanced safety measure evidence	Payment transactions across supply chain	Healthcoin and health insurance

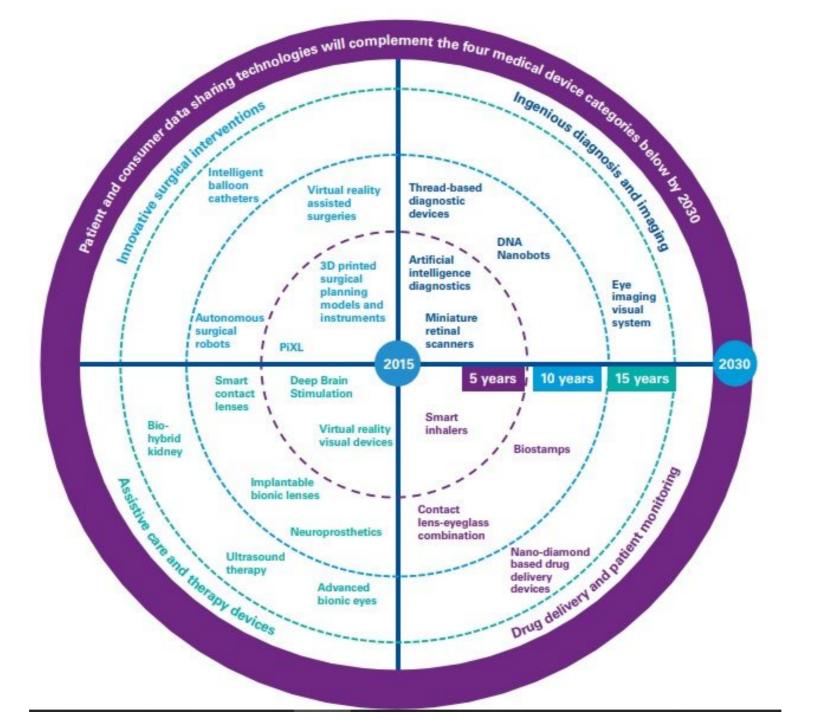


### INNOVATION DEMAND

Major Areas of Need

- Innovative Surgical Interventions.
  - There's a high demand for more autonomous surgical robots
  - This type of technology has FDA approval since 2015 and is already being used across the US
- · Ingenious diagnosis and imaging.
  - The utilization of DNA, nanobots, and AI to speed up diagnosis
  - Accurate image recognition and analysis is largely needed
- Improved drug delivery and patient monitoring.
  - Communicating reminders for patients
  - Sending necessary data to the physicians overseeing the care given
- Better Assistive Care and Monitoring
  - Bioengineered organs are already being used, but there's room for improvement
  - A big issue is ensuring the body accepts the foreign object and little to no infection occurs

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## **More Futuristic Medical Technologies**

- Mixed reality opens new ways for medical education
  - Augmented, virtual and mixed reality are all technologies opening new worlds for the human senses.
  - While the difference between these technologies might seem arbitrary at first, it greatly determines how they can be used in healthcare
- Brain-computer interfaces bring hope for the paralyzed
  - There's still a lot of research to be done in the area of brain-computer interfaces (BCI)
  - Brain implants today are where laser eye surgery was decades ago
- Might we all end up being recreational Cyborgs?
  - There are already many examples of real-life cyborgs
  - The cyborg-craze will eventually start with people who implant devices and technologies in their bodies just to seem cooler.
- 3D printing everything from pills to biomedically engineered body parts
  - In 2015, the FDA approved the use of 3D printers to create pills in mass quantities
  - The 3D printer can print dermic, hypodermic, and epidermic skin cells.
  - The Bioprinting Organ Process is quickly becoming the future of the medical industry.

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# 3D Printed Body Parts Examples

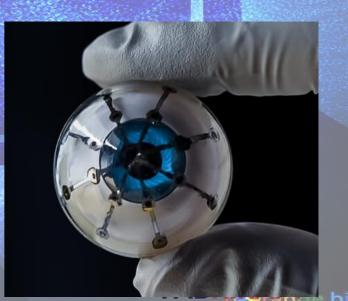












## 10 BEST CAD SOFTWARE FOR 3D PRINTING

- Blender
- BricsCAD Shape
- DesignSpark Mechanical
- SketchUp
- FreeCAD

- Fusion 360
- Meshmixer
- OnShape Free
- SelfCAD
- Sketchup Free
- Tinkercad

#### **3D Printer Costs and Varieties**



\$2,854 with payment plans available at www.cyberhypesales.com



\$149 Used at www.ebay.com



# **BIONIC LIMBS**

- In recent decades, the overwhelming focus of research into and development of new artificial hands has been on perfecting different types of grasps.
- Many of the most expensive hands on the market differentiate themselves by the number and variety of selectable prehensile grips.

- Most people who use a prosthetic limb are unilateral amputees—people with amputations that affect only one side of the body—and they virtually always use their dominant "fleshy" hand for delicate tasks such as picking up a cup.
- The common clinical evaluations to determine the success of a prosthetic are based on using only the prosthetic, without the help of other body parts.

# **BIONIC LIMB ISSUES**

• This metaphorical race to the moon is a mission that has forgotten its original concern: helping disabled people acquire and use the tools they want.

• There are inexpensive, accessible, low-tech prosthetics that are available right now and that need investments in innovation to further bring down costs and

improve functionality.

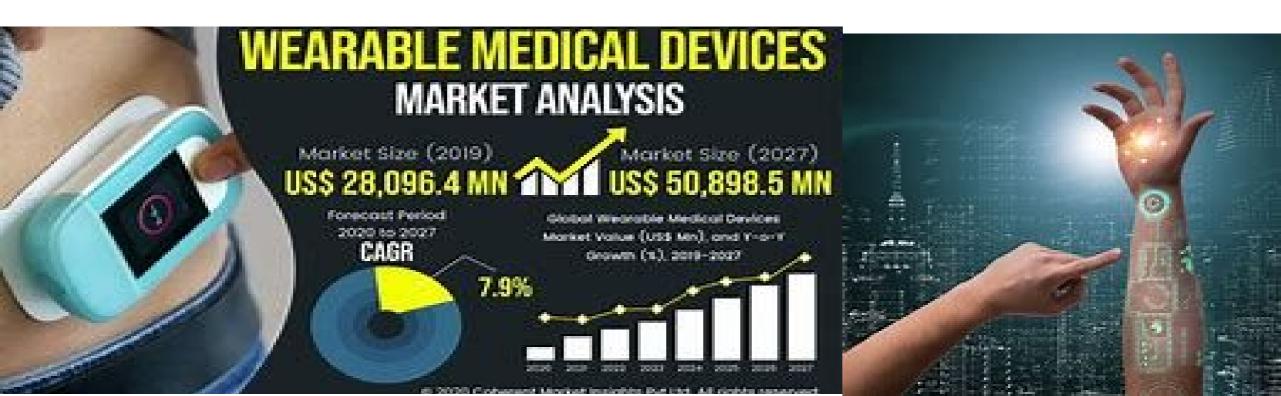
 The vast majority of prosthetics R&D remains focused on refining the grasping modes of expensive, hightech bionic hands.

- Currently, the devices require frequent professional support to change grip patterns and have costly repair processes
- Ideally, the device should be easily fixable by the user.



#### WEARABLE DEVICES

- While the earliest versions of wearables were marketed to consumers in the form of fitness trackers, the most exciting and life-changing wearables now are medical devices worn on the body as an accessory, patch or tattoo, or implanted inside the body.
- Wearable can already provide doctors with the following data blood pressure, oxygen saturation level, heart rate, and a myriad of other physiological data.
- Remote patient monitoring (RPM), which increased nearly 40% between 2020-2021 and almost 572% between 2019-2021, has multiple applications.
- There are many areas that these types of devices can be used and improved.



#### **Solutions to Get Ahead**

- Connecting Businesses to Consumers Better
  - Hospitals and Clinics need to find better ways to communicate with their patients.
  - Patients want to be able to provide their Doctors with the data necessary to improve their afflictions.
- Connecting Businesses to Businesses Better
  - Businesses that are willing to collaborate with other Businesses will be at a significant advantage.
  - Medical Device Companies that are open to sharing their ideas and working with cutting edge tech are more likely to succeed.
- Maximizing the Company's Profit
  - By creating devices that increase the customization of each patient's care
  - By creating patents that are more affordable and still able to accomplish effective results



## THE THREE R'S



#### Reconfigure



## STEPS TO CREATING A MEDICAL DEVICE

- 1. Carefully evaluate the current cutting-edge devices already available to the public
- 2. Find an area that has a high demand for new technologies, i.e. the medical industry
- 3. Make sure you understand the engineering knowledge necessary to make the changes that haven't already been made.
- 4. Spend as much time as you need to make sure you've designed a safe, effective, low-cost Device
- 5. Find a way to test the design and confirm it meets all the goals you set out to achieve
- 6. Eventually, make sure to investigate getting a patent for your device, many law firms exist to help with this step.



# References

"Medical Devices 2030" by Roger van den Heuvel, Chris Stirling Anuj Kapadia, and Jia Zhou of KPMG Global Strategy Group Other Various Online Sources



