

TECHNOLOGY DRIVEN INNOVATION:

EMERGING TRENDS IN MEDICAL DEVICE MANUFACTURING



EWI[®]

We Manufacture Innovation

THE GLOBAL MEDICAL DEVICE MARKET

The \$350 billion global market⁽¹⁾ is expected to grow at a compound annual growth rate of 4.9% from 2015-2020.



To continue a trajectory of steady growth, the global medical device industry must adapt to the dynamic changes disrupting the



healthcare landscape. An aging population, a push for more personalized treatment, and the increasing availability of healthcare are some of the factors driving new markets and an expanding consumer base. In addition, regulatory scrutiny and federal initiatives like the medical device excise tax have levied extra pressure on R&D budgets.

Rapid changes in the industry require manufacturers to accelerate the design and production of innovative devices.

To deliver reliable devices that provide the diagnostic, monitoring, and therapeutic capabilities that the market demands, companies must use new materials and advanced manufacturing technologies.

Doing so enables companies to capitalize on current trends and secure a return on their R&D investments.



7 TRENDS IMPACTING MEDICAL DEVICE MANUFACTURERS:

- Wearable health monitoring devices
- Technology fusion
- Miniaturization of implantable devices
- Improved quality inspection
- Aging global population
- Growth of emerging markets
- Slow regulatory approval processes



WEARABLE HEALTH MONITORING DEVICES

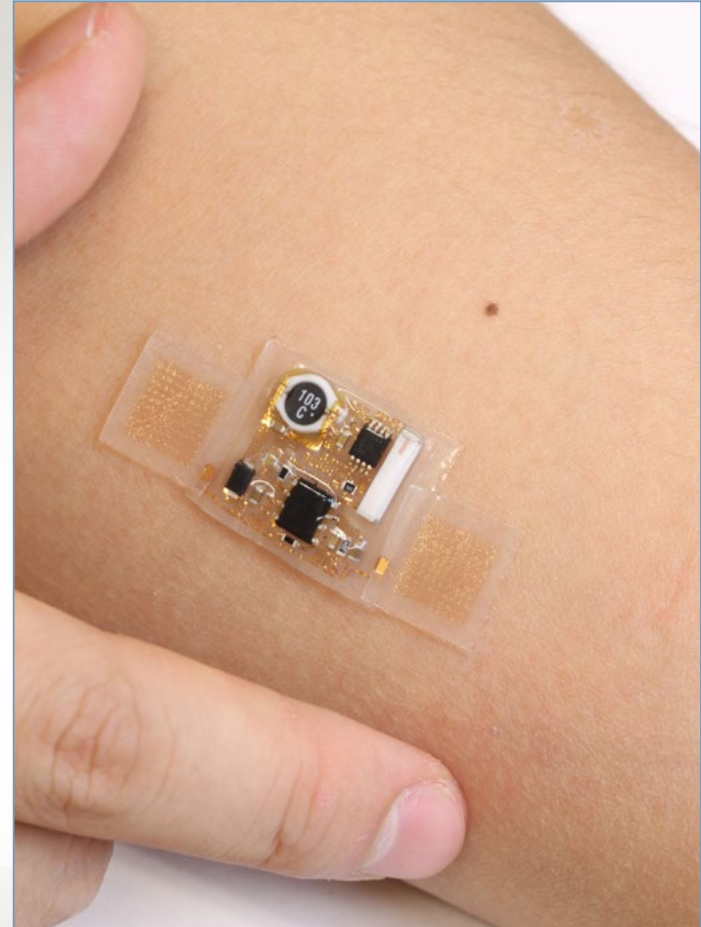
As the market for personal health care management devices continues to expand, there is growing demand by patients, acting as “healthcare consumers,” for wearable devices to play a more active role in their own healthcare. This demand results in device requirements that provide increased affordability, portability, and ease-of-use for “patient-consumers.”

CHALLENGE:

Designing wearable health monitoring devices that are unobtrusive, easy to use, and have accurate sensing capabilities

Relevant Technologies:

- Microjoining technologies
- Flexible circuit joining
- Polymer materials joining
- Small-scale battery manufacturing processes



TECHNOLOGY FUSION

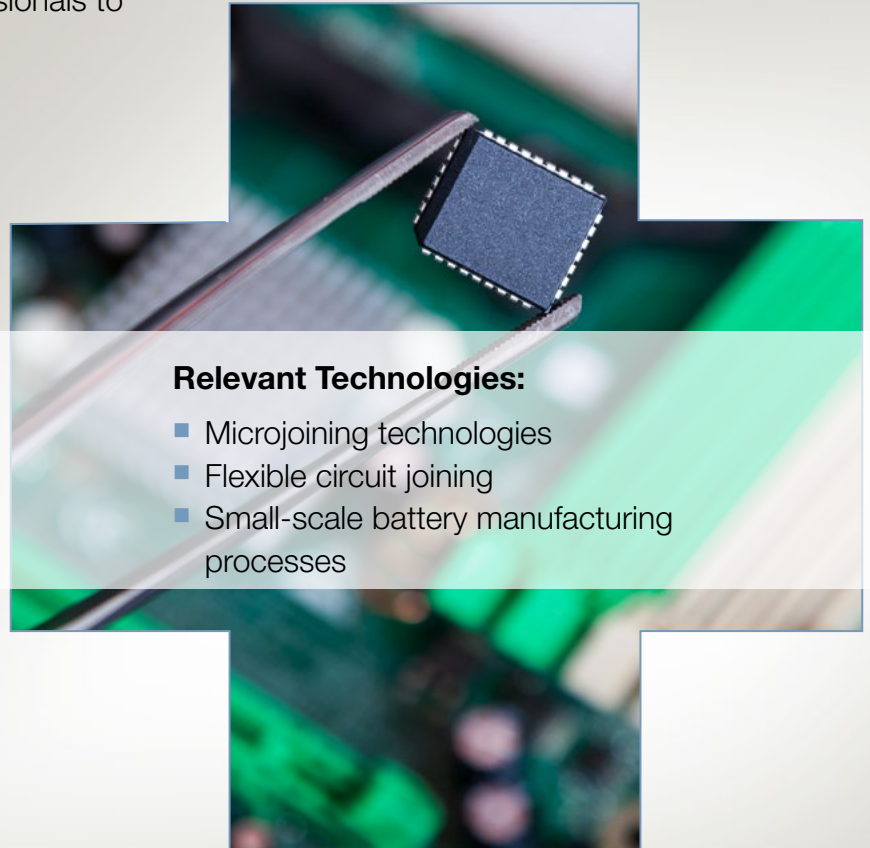
Smart devices capable of sending and receiving real-time information allow users to stay on top of their personal health, as well as enable health care professionals to keep track of critical patient information.

CHALLENGE:

Incorporating small-scale electronic circuits, sensors, and batteries into easy-to-wear monitoring devices

Relevant Technologies:

- Microjoining technologies
- Flexible circuit joining
- Small-scale battery manufacturing processes



MINIATURIZATION OF IMPLANTABLE DEVICES

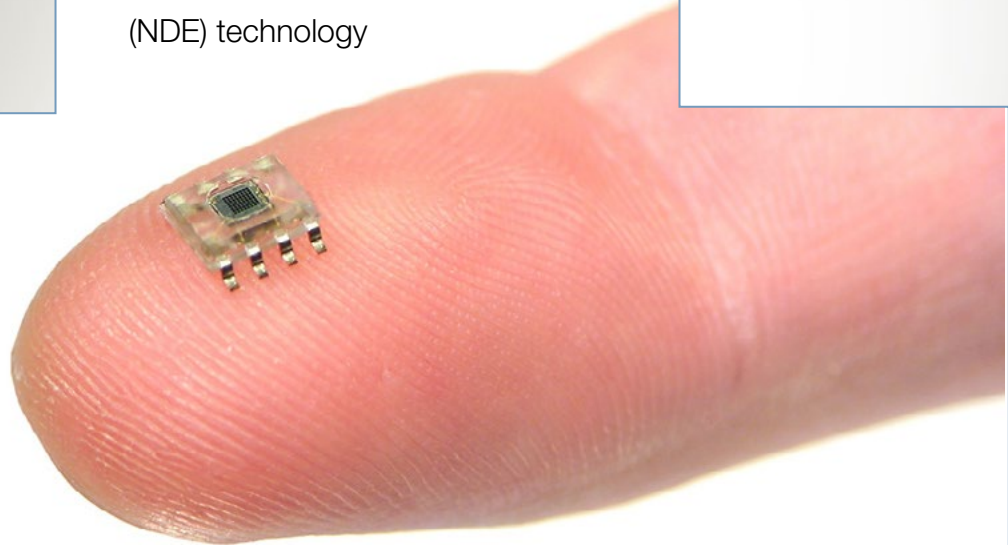
To reduce invasiveness, implantable devices are undergoing miniaturization. Because many of these devices require power, manufacturers must design increasingly smaller batteries.

CHALLENGE:

Retaining all the functionality of implantable cardiac and neurological monitoring devices but at a scale that allows the device to be less invasive

Relevant Technologies:

- Small-scale battery manufacturing processes
- Micro-scale nondestructive evaluation (NDE) technology



IMPROVED QUALITY INSPECTION

As medical devices become smaller, more complex, and harder to inspect, reliable quality testing methods become more important.

CHALLENGE:

Developing accurate quality assurance processes that are cost effective

Relevant Technologies:

- Flexible automation
- Micro-scale NDE technology

AGING GLOBAL POPULATION

With global life expectancy rising, there is increasing demand for medical devices from an aging population looking to maintain active lifestyles. These “baby boomers” are likely to need treatment for orthopedic procedures. Healthcare providers are seeking to reduce the overall expense of care associated with chronic diseases by reducing costly hospitalizations that often accompany treatment of long-term chronic diseases.

CHALLENGES:

1. Providing less expensive, custom-designed orthopedic implants that provide access to quality-of-life extending therapies
2. Designing less invasive chronic disease monitoring devices that provide better care and fewer hospitalizations



Relevant Technologies:

- Flexible automation
- Additive manufacturing of biocompatible materials

GROWTH OF EMERGING MARKETS

Emerging markets represent an important area of growth for medical devices. Addressing these low-to-mid tier markets requires lower cost, simpler devices to keep production costs down.

CHALLENGE:

Designing and manufacturing a new class of medical diagnostic and therapeutic devices that enable low-cost health care to third world countries

Relevant Technologies:

- Microjoining technologies
- Flexible automation
- Dissimilar materials joining



SLOW REGULATORY APPROVAL PROCESSES

Companies must be able to respond quickly to new FDA regulation and legislation events that are common in the medical device industry—particularly as devices continue to increase in complexity.

CHALLENGE:

Designing robust manufacturing processes that lead to higher quality products



CASE STUDY:

Installing Micro-Sensors for an Implantable Device

A medical device start-up approached EWI with the need to attach micro-sized titanium sensor pads to a small-diameter platinum wire for a neuro-modulation device. EWI developed a unique process to solve this challenge:



- Using a vapor deposition chamber, a 10- μm thin titanium film was deposited onto a sacrificial glass substrate
- A parallel-gap micro-resistance welding system was then used to weld the 75- μm platinum wire to the thin titanium film.
- The heat delivered to the titanium thin film during the weld process welded the platinum wire to the titanium as desired, and also delaminated the titanium film from the underlying sacrificial glass substrate, leaving only the small titanium pad.
- This process gave the medical device client the fundamental manufacturing technology essential for growth and success of the company.

ABOUT EWI

EWI has a long tradition of providing materials joining, fabrication, and allied manufacturing technologies to companies in the medical device industry. Our expert engineering teams apply innovative technologies to help medical manufacturers gain a competitive advantage by accelerating their product design and speed-to-market cycles.

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