



# The “Right to Repair” is Wrong for Patients

*From consumer electronics to farm equipment to medical devices, the “right to repair” is in the news as policymakers across the country grapple with what the law should be. The manufacturing and repair of highly complex medical technologies and devices is rigorously regulated by FDA, the global gold standard for medical device safety and efficacy—and for good reason: patient safety is No. 1. Here’s why the “right to repair” complex medical devices is wrong for patients...*



## **Patient safety is paramount.**

- > Unlike medical device manufacturers, unauthorized 3rd-party servicers are not required to follow FDA regulations or report adverse events.
- > The service/repair of a complex device could be a life-or-death matter. OEMs and authorized 3rd-party servicers receive significant training and have extensive expertise for which providing a simple manual is no substitute.
- > 2018 STUDY: 4,300+ reports of adverse events—including 40 deaths, 294 serious injuries—from devices repaired, replaced, or maintained by 3rd-party servicers.



## **No credible evidence exists of systemic shortages or delays in equipment repair.**

- > There is no credible evidence of systemic shortages or delays in equipment repair. Any shortages are intermittent and largely driven by global supply issues that strain access to parts, no matter the servicer.

- > Device manufacturers regularly authorize 3rd-party servicers to repair medical devices. There are more than 21,000 companies currently servicing medical devices, according to FDA.



### **Authorized servicers help save patients' time and money.**

- > Improper servicing can result in increased delays in care.
- > In fact, manufacturers are often called in after a 3rd party has failed to repair a machine.
- > Some devices require 90+ custom-made tools for servicing.
- > Many replacement parts for medical devices are also very specialized and precise in design and function.
- > 3rd-party attempts to duplicate these parts can be disastrous: For some devices, modifications of less than a thousandth of an inch—either through ineffective repair or use of inappropriate replacement parts—can negatively affect device safety, resulting in serious patient injury or death.



### **Repair mandates are harmful to patients and the innovation they depend on.**

- > Patients rightly expect medical devices always to perform at a high level and not merely put back into “working order” by untrained, less-experienced servicers—or worse, not work at all due to substandard methods or parts.
- > Improper repair may also increase the risk of exposing patient health data to increased cybersecurity attacks.
- > Requiring manufacturers to turn over product keys and manuals effectively eviscerates intellectual property rights and undermines incentives to innovate.