Perspectives On A Question of Safety

How has news questioning the safety of medical devices misled the public about testing protocols?

Greg McKnight
Director of Engineering, Accutek Testing Laboratory

Any device failure is an unfortunate event. The patient experiences that failure first hand, and the device manufacturer suffers too. It’s easy for the media to run stories on such events, often with limited information outside of the event itself. The public is rarely informed of the massive resources and efforts expended toward ensuring devices are as safe and effective as possible.

In fact, there are hundreds of test methods developed specifically to verify that medical devices are safe and effective. But even though test methods are developed and implemented with good intent, the scope of the test cannot always cover real world circumstances, usually unbeknownst to the manufacturers and test engineers. It is only after a failure is realized and test methods scrutinized that shortcomings are discovered.

Fortunately, test methods such as ISO and ASTM are governed by well qualified groups of professionals, comprised of individuals working in academia, test labs, device manufacturers, government institutions, and other related parties. Their purpose is to ensure the integrity and relevance of test methods based upon R&D efforts and, most importantly, real world requirements, to maximize the safety and effectiveness for medical device recipients. The public is usually unaware of these mechanisms and resources working on their behalf.

Dan Walsh
Life Sciences Industry Specialist, PA Consulting Group

A recent article about medical device testing in Newsday asserts: “Many widely used medical devices have never been tested for safety and manufacturers are only required to file paperwork and pay a small fee.” While such hyperbole makes for good press, articles like this are misleading and inaccurate.

In reality, the “paperwork” includes the entire device development documentation, running to thousands of pages of testing. Developers test materials’ compatibility with human tissue, test the function and malfunction of the device to mitigate failures. The “small fee” is not small and is necessitated by funding cuts over the last decade in Congressional budgets for the FDA.

The FDA Quality System Requirements (21 CFR 820) outline a rigorous design control and validation process. Clinical trials are mandatory for any Class III device and most companies conduct testing of Class II devices. In addition, the FDA and international regulators issue specific guidance for high-risk devices like artificial joints, coronary stents, in-dwelling catheters, pacer/defibrillators, and very extensive requirements for inhalers, patient monitors, infant incubators, prosthetic limbs, and wheelchairs. No device gets cleared for sale without satisfying the regulators that they have addressed these requirements.

Dawn Lissy
President, Empirical Testing Corp.

I’m not sure it has. The current regimen of premarket medical device testing, in accordance with both FDA and international regulations, is perhaps the most rigorous in the history of medicine. Yet gaps will, and perhaps

will always, remain in the testing that can be done in a non-clinical setting. The challenges lie frequently in the ability to replicate the clinical scenario to which a medical device will be subjected and in capturing the variety of scenarios that may be faced, both in on and off-label use of a device. With thousands of medical device approvals issued by the FDA every year, inevitably these limitations will become evident among a few devices and thus, the focus of media introspection.

Does the public demand accountability and pursuit of optimal testing and validation procedures? Absolutely, and improvement and innovations in methods, protocols, and standards are rapidly progressing. But especially when failures in preclinical testing and evaluation are highlighted, the demand for and contributions of the device testing field both increase and are recognized as a result. This won't change.

Todd Konieczny
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Anytime the safety of a medical device is questioned, it is natural for consumers to be concerned about the impact of the news on their personal well-being. While mainstream news media and industry trade publications certainly cover many aspects of medical device safety, they do not always delve as deeply into the industry's testing protocols, which are an essential piece in the process. It is critical for medical device manufacturers and consumers to be aware of the stringent protocols medical devices must adhere to before they can be sold or used domestically or globally.

Medical devices must demonstrate compliance with electrical safety standards. This mandatory process helps ensure devices do not pose any fire, shock, or overall safety hazards to the patient or anyone that comes in contact with the product. All OSHA-recognized Nationally Recognized Testing Laboratories (NRTL), like Intertek, test medical devices to the same mandatory national or international standards. These third party testing partners are especially well versed in the safety requirements for medical devices, because oftentimes, they participate in standards development committees along with other industry leaders and medical device manufacturers.

Despite today's world of continuing technological advances and the constantly changing regulatory environment, safety has always been the primary focus of the medical industry. Manufacturers and consumers can rest assured, knowing the safety of their medical devices has been well evaluated and certified before use.