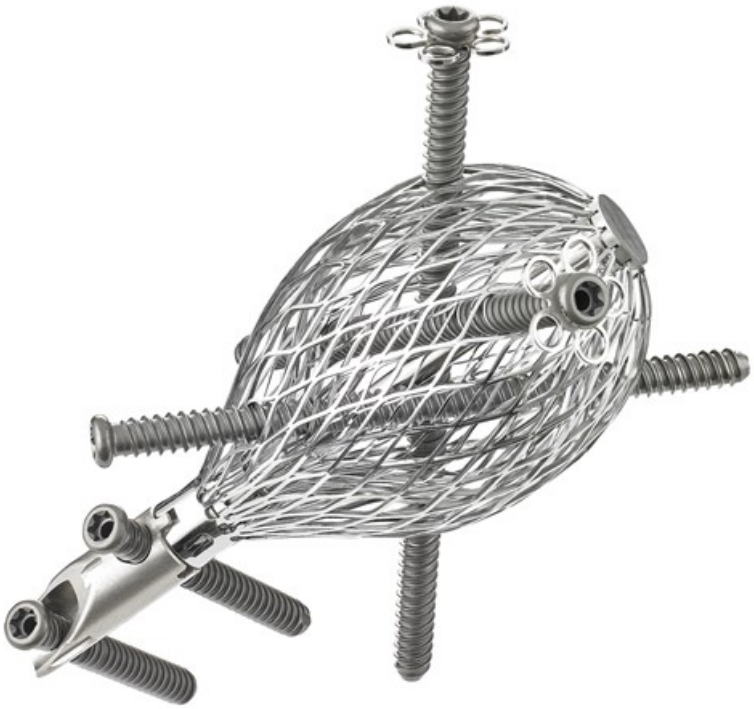
Categories (**highlight category**):

Biologics	(*biology of bone, inflammatory signals, science of arthritis)*
Company News	(*corporate mergers, fund raises, executive hires or fires, plant openings or closings, sales news)*
Extremities	*(products or procedures for elbows, shoulders, hands and wrists, foot and ankles, product awards)*
Large Joints	*(products or procedures for hips or knees, product awards)*
Legal & Regulatory	(*FDA news, lawsuits)*
People in the News	*(surgeon or doctor news, retiring, hiring, awards, deaths, milestones for ortho community)*
Reimbursement	(*Medicare or other payer news)*
Spine	(*products or procedures for back pain, spine surgery, product awards)*
Sports Medicine	(*products or procedures to treat sports related injuries, product awards)*
Trauma	(*products or procedures for fracture and soft tissue repair resulting from a traumatic injury)*

Key Words: FDA, Food and Drug Administration, metal implants, Nitinol, NEST, Conventus, Actipore PLFX, Biorthex, Stryker, Tritanium, lumbar cages, Ti6AL4V, Office of Science and Engineering Laboratories, OSEL:



Caption: The Conventus Proximal Humerus Fracture Management System, an orthopedic device made from Nitinol; Source:
https://www.conventusortho.com/products/ph-cage/

Title: FDA Proposes New Testing For Orthopedic Implants Made With Nitinol

The Food and Drug Administration (FDA) announced April 18 that it is proposing new guidelines for pre-market testing of Nitinol, a titanium-nickel alloy widely used in medical implants.

As far as FDA has said, nothing has been found to be wrong with devices made from this metal. Then why this action?

The April 18 draft guidelines are the first of what may be several planned new guidelines for testing metal implants under a broad new regulatory initiative which FDA Commissioner Scott Gottlieb and Jeff Shuren, M.D., director of FDA's Center for Devices and Radiological Health announced on March 15. Their intent is to require more and deeper pre-market tests of all the newer materials going into implants. It's part of FDA's plan for addressing how to regulate new devices made with new materials but which use predicates made from older materials when seeking 510(k) clearances.

(https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm633602.htm)

Nitinol, an alloy of titanium and nickel, is used in orthopedics for "internal fixation by the use of fixatives, compression bone stables used in osteotomy and fracture fixation, rods for the correction of scoliosis, shape memory expansion staples used in cervical surgery, staples in small bone surgery, and fixation systems for suturing tissue in minimal invasive surgery," according to the article Biomechanical Properties of Nitinol Staples: Effects of Troughing, Effective Leg Length, and 2-Staple Constructs in The Journal of Hand Surgery, October 18, 2018.

(https://www.sciencedirect.com/science/article/pii/S0363502317319056).

At least one lumbar cage is made from Nitinol, the Actipore™ PLFx from a Canadian company, Biorthex, which says it's made from a "biologically and biomechanically compatible porous Nitinol material" which "has an elasticity almost identical to cancellous bone that results in load sharing. The isotropic interconnected porous structure of the device promotes rapid tissue ingrowth in conjunction with bone cell survival."

(http://www.biorthex.com/plifx.html)

There may be other Nitinol lumbar cages on the market. The original patents for Stryker's Tritanium were for a titanium-nickel alloy, according to an early trademark filing, but modern Tritanium lumbar cages use the titanium-aluminum-vanadium alloy Ti6Al4V. Knowledgeable sources tell us that all porous titanium implants will probably eventually be subject to additional testing requirements.

Also, the Conventus three-dimensional fracture management cage systems are made with Nitinol.

(https://www.conventusortho.com/)

Why is Nitinol the first metal under the new initiative?

Gottlieb's and Shuren's April 18 statement said, "Devices made with Nitinol provide many important benefits to patients, but we need to be able to assess whether, among other things, there are any health risks when the material comes into contact with various parts of the body for extended periods of time. To ensure that the benefits patients receive from these devices outweigh any risks resulting from their use, the FDA needs to receive the right information as part of the premarket review process."

However, they didn't say why they chose Nitinol to be the first metal subjected to new proposed testing guidelines. Their March 15 statement says FDA has seen that some patients have powerful allergic or inflammatory reactions to metal implants, but they didn't point to any actual horror stories. One possibility is that Nitinol has been widely used in cardiovascular stents, which would raise the stakes considerably if the metal in a device were a problem.

The April 18 proposed guidelines are detailed in a 17-page paper, "Technical Considerations for Non-Clinical Assessment of Medical Devices containing Nitinol - Draft Guidance for Industry and Food and Drug Administration Staff." Questions about the document can be directed to the Division of Applied Mechanics at (301) 796-2501, or Matthew Di Prima, Ph.D. at (301) 796-2507 or by email matthew.diprima@fda.hhs.gov .

(https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM636179.pdf)

The guidelines propose new requirements for mechanical stress testing, computational stress/strain analysis, corrosion testing (including pitting, nickel ion release and galvanic corrosion) and biocompatibility, as well as new labeling to warn surgeons that:

"Persons with allergic reactions to these metals may suffer an allergic reaction to this implant. Prior to implantation, patients should be counseled on the materials contained in the device, as well as potential for allergy/hypersensitivity to these materials."

FDA has a lab of its own to test metal implants; makes progress on NEST

"We also have our own team of FDA scientists and engineers conducting research to better understand device materials in our Center for Devices and Radiological Health's (CDRH) Office of Science and Engineering Laboratories (OSEL)," Gottlieb and Shuren said in the March 15 announcement.

"We are also working to fully implement the National Evaluation System for health Technology (NEST – see "510(k) Overhaul Gaining Momentum at FDA," Orthopedics This Week, December 17, 2018) that will link and synthesize data from different sources including clinical registries, electronic health records and medical billing claims; this will help improve the quality of real-world evidence that will empower the FDA to more quickly identify, communicate and act on new or increased medical device safety concerns," they said.

By combining data from all these sources, NEST is intended to be a faster and more thorough reporting system for medical device problems than the current Manufacturer and User Facility Device Experience (MAUDE) database. — *WVD*