

A Q&A on SafetyFix, the 1st Bone Screw Created with Easy Removal in Mind

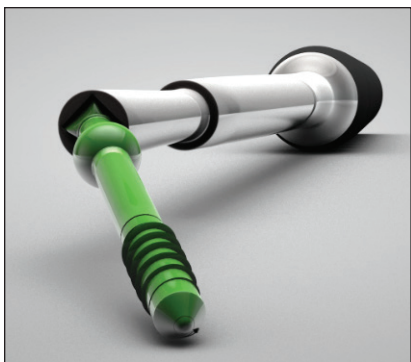
By SafetyFix USA Product Specialists: **Michael Horwitz, DPM, FACFAS; Vincent Staschiak, DPM, FACFAS; Stephen Barrett, DPM, MBA FAENS; Jim Kilman; Joe Tortorici**

SafetyFix Medical Technologies, located in St. Louis Missouri, is responsible for the design and marketing of the first bone screw created with ease of removal in mind and cleared by the FDA. In-house sales manager, Jim Kilman, is available anytime to answer questions about this groundbreaking implant.



Q: How is this implant in terms of implantability and ease of use?

A: Oftentimes a doctor will start with one or two screws, which lets them perceive that engagement of the distal cortex is strong and that the screws are easy to use. The screws are self-tapping, non-cannulated and use a .062 pilot hole drilled with a k-wire. Very simple.



Q: Is there any special training needed to use this product?

A: If you are used to using surgical hardware, this is no different. We have videos that demonstrate best practices

that are easy to view online. Some exciting news is that we will soon have our cannulated product hit the market.

Patients do not like the idea of having metal left in their body.

Q: When do you expect to have your cannulated product?

A: Before the end of this year. Lots of doctors are inquiring about our cannulated product. We, of course, have many doctors who are finding ways to use the

screws for conventional distal osteotomies, but what is extremely exciting is the enthusiasm within the international MIS and small incision community. We feel that these screws will allow for stable fixation of MIS and small incision procedures like akin osteotomy's and lesser metatarsal procedures in unique ways. We are working with leaders in this area and are in the process of creating videos that will demonstrate new techniques for fixation where often fixation was not used.

Q: What is been the biggest pushback from doctors when it comes to using removable bone screws?

After patients report to other patients how easy the process was, practices gain referrals.

A: Without a doubt, the question we get the most is "Does the screw irritate the skin?". My answer is usually twofold. First, trust the FDA. That's a loaded question because the FDA approved metal on metal implants and quite a few products that have not served patients well. But the FDA cleared this product because of the overwhelming amount of predicative data that they'd already collected from other hardware devices and buried K wires. Secondly, know that we have done our research! Many hundreds of procedures performed in many different ways have given us the confidence to create a product that has been engineered with these variables in mind. For instance, the head of the screw is beveled. In a viscous environment like the body, this means that the coefficient of friction is very low and that neurovascular structures and tendons can coexist well with this head shape. And I will add that new doctor users should trust themselves. After using one or two screws the experience should speak for itself.



Q: What is patient acceptance like?

SafetyFix (continued)

A: It's been proven over and over that patients do not like the idea of having metal left in their body. When the Swiss came out with AO fixation, they recommended removal in



all cases and there was good reason for this. Later on, doctors became more complacent and selectively chose to remove hardware based on many considerations such as irritation, allergy etc. One look at our website and the overwhelming number of articles that point to the direct biomechanical and biochemical effects of metal in the body, and any patient is easily persuaded that it is better if the metal is removed as long as it is not contraindicated to the patient. A particular textbook entitled "Degradation of Implant Materials" and edited by Noam Elias, an Israeli corrosion lab expert, has dedicated 18 chapters to both the macroscopic and microscopic absorption of metal and the effects it potentially could have on the body. Patients are becoming aware of the metallic hip metalosis problems that are all over the Internet today. They're looking for better methods and safe alternatives. Patient acceptance is extremely high. Doctors who are using our brochures have no problems with acceptance. And after patients report to other patients how easy the process was, practices gain referrals.

Q: Just how easy is the removal process?

A: 30 seconds after prep. It's that simple. An experienced surgeon can utilize incisions as small as 3 mm, stretch the incision with the hemostat to accommodate the driver, and remove a screw in 30 seconds without entering deep soft tissues or getting near the bone.

Q: How do I go about getting a set?

A: Contact our home office and ask for Jim Kilman. He has been instrumental in setting up both hospitals and surgery centers. Loaner sets

can be sent and consignment orders processed for regular users.

Call 314-880-0750, visit www.safetyfixmedical.com, or click here for more information.