Stryker’s titanium implants inspired by biology
Titanium nails have long been preferred for intramedullary nail fixation.* However, the use of titanium for other orthopaedic implants, especially in long bone plating, has become a much discussed topic in recent years. Titanium implants behave more like bone than stainless steel implants, offering a variety of advantages discussed in the following pages.

While orthopaedic implants are generally composed of either titanium or stainless steel, there are many differences in types of titanium - from grade 1 commercially pure titanium (CP-Ti) to grade 5 titanium alloy. There are also differences in the types of grade 5 titanium alloy, with Stryker utilizing the alloy Ti6Al4V for many years, including in the original Gamma and T2 nailing systems.

*Based on internal sales data.
Construct stiffness has been shown to directly correlate with secondary fracture healing.\textsuperscript{1,2} Titanium’s modulus of elasticity is closer to that of bone than stainless steel.\textsuperscript{3} Additionally, the design of the plate combined with the flexibility of titanium may allow the plate to more easily conform to the bone, allowing the surgeon to achieve a closer plate-bone fit.

Commercially pure titanium (CP-Ti) grade 2 and Ti6Al4V have a modulus of elasticity of 100-110 GPa and 100-130 GPa respectively, while 316L stainless steel has a Young’s modulus of 200 GPa.\textsuperscript{4} The greater elasticity of titanium allows for more implant flexibility which directly affects callus formation.\textsuperscript{1,3} Interfragmentary motion in the millimeter range is proven to induce bone healing that does not occur with less motion.\textsuperscript{5,6} In comminuted fractures treated with bridge plating, the fracture must heal with external callus formation.\textsuperscript{1}

In a study by Rodriguez et al, there were 36 nonunions (13.3\%) in a series of 271 supracondylar fractures across 3 level 1 urban centers.\textsuperscript{2,*} While the authors were unable to eliminate design as a factor, it is worth noting that of the 239 fractures treated with titanium plates, 9.6\% resulted in nonunions. Of the 32 fractures treated with stainless steel, 40.6\% resulted in nonunions.**

The authors were able to interpret that both plate design and material, combined, had an impact.

\textsuperscript{*}Study not specific to Stryker plating systems.
\textsuperscript{**}“Nonunion was defined as the need for a secondary surgical procedure to improve poor healing (ie, bone grafting, implant exchange, other).”
\textsuperscript{***} Based on a predictive algorithm for nonunion using maximum likelihood estimation in logistic regression. Limitations of the study included that it was retrospective and there was no consistency around defining nonunions.
**Titanium implants may provide a clearer CT image,** allowing you to more accurately answer important clinical questions

**Titanium implants** provide a clearer CT image than other common metals used for orthopaedic hardware, resulting in decreased image artifacts.\(^8,9\) Artifacts caused by metallic hardware may inhibit the ability to answer clinical questions.\(^8\)

Metal objects in the field of view during a CT scan may reduce the effect of x-rays. “When an image is reconstructed using this incomplete data, it leads to unnatural changes in appearance, known as artifacts, which are often observed as bright or dark streaks in the image.”\(^10\)

As shown in the pictures below, a study showed less artifact in titanium than stainless steel due to stainless steel’s higher fluoroscopic density.\(^8\)

Effect of metal composition on metal-related artifacts at multidetector CT. (a) Scout view of an ex vivo model of a pig femur with a 4.5-mm titanium alloy screw (arrow) and a 4.5-mm stainless steel screw (arrowhead). (b) CT image obtained through the short axis of the screws, with 140 kVp, 120 mAs, 0.6-mm collimation, and 1.0-mm reconstructed section thickness, shows more severe streak artifacts from the stainless steel screw than from the titanium alloy screw.\(^18\)

Effect of peak voltage on metal-related artifacts. A comparison of CT images obtained through the short axis of the screws in the pig femur model, with 140 kVp (c) and 80 kVp (d) and with other parameters the same (120 mAs, 0.6-mm collimation, and 1.0-mm reconstructed section thickness), shows a less obtrusive artifact on the image obtained with a higher peak voltage.\(^18\)
Titanium implants are well known for their excellent biocompatibility, resulting in a favorable tissue response. For those patients with a nickel allergy, estimated to affect 17% of women and 3% of men, titanium implants are preferred over stainless steel. Although not shown to correlate with clinical data, internal in vitro studies show a 20.7% reduction in bacterial colonization on anodized Ti6Al4V samples compared to stainless steel.

Titanium biocompatibility is defined by:

- Corrosion and surface reaction
- Healing in bone
- Interactions with proteins and cells
- Surface modification
Ease of removal in long bone plating

Titanium plating has come a long way from its initial introduction. Competitive, early generation titanium locking plates were impacted by screw stripping and cold-welding, making plate removal very difficult. Since the 2013 launch of AxSOS 3 Titanium, only 0.001% of cases have reported concerns with screw removal most often due to the overpowering of screws. During the development of AxSOS 3, the plates were implanted into sheep tibiae and extracted at 6 months and 12 months. This preclinical study demonstrated that all screws were extractable when following the surgical technique and manually tightening locking screws using a torque limiter.

Design features built into the AxSOS 3 screw/plate interface to allow for consistent screw insertion and removal

1. **Patented, round threaded screw head design** – instead of the typical sharp threaded design used in the shaft of screws, the rounded threads on the locking screw head make it easier to tighten and release the locking screw from the plate.

2. **Conically shaped screw head** – makes it easier for the screw to find its path to help ensure good axial alignment.

3. **One-threaded screw in a dual-threaded plate** – one thread path is clear.

4. **Type II anodization** – a surface treatment that partially melts the surface of the implant, changing the chemical composition, and resulting in up to a 17% increase in fatigue strength and a reduction in friction and wear.
References:


15. Data on file. As of March 18, 2016, USA only.


17. Data on file. Test report 300709CB1

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Trauma & Extremities

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