METRIC®
BRINGING BONES TOGETHER™

Technical Documents
Table of Contents

Super Scaffold™
Intramedullary Fixation System (IFS)

Super Staple™
Nitinol Bone Implant System

METRIC
BRINGING BONES TOGETHER™

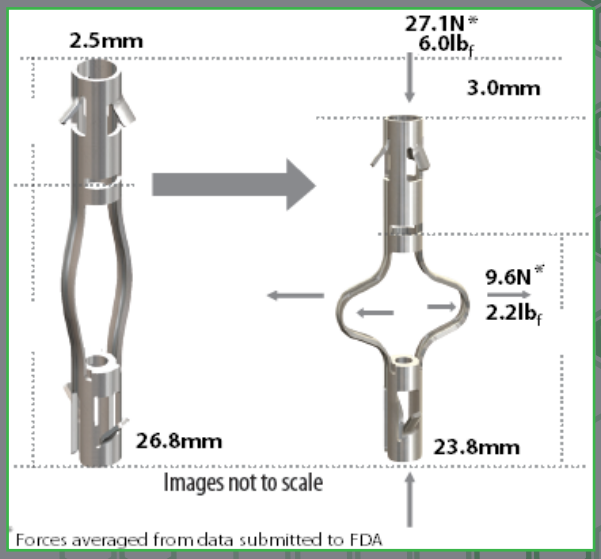
Super Scaffold™

Intramedullary Fixation Scaffold (IFS™) System

Unique Design

The Intramedullary Bone Fixation Scaffold (IFS™) for Inter-digital Fusion is a tubular fenestrated intramedullary bone fixation implant and ingrowth scaffold.

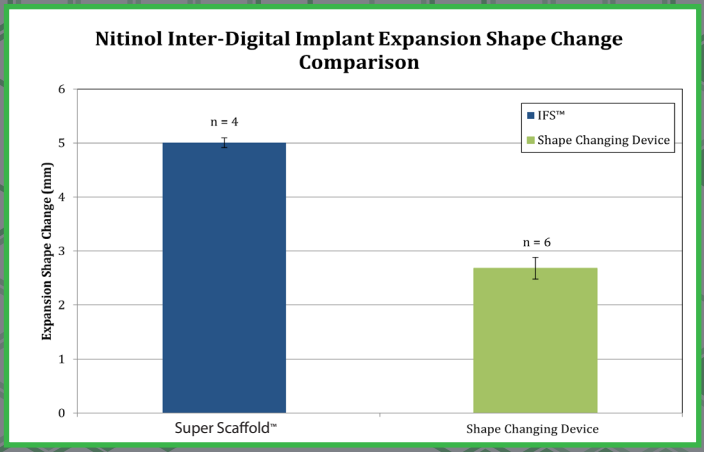
- Pairs of distal and proximal wings lock into bone and allow the IFS™ to be screwed in or out.
- Bulges expand to conform to the inner bone anatomy and shorten the IFS™
- IFS™ shortening pull bones together and compresses the fusion site while healing
- Hollow cylinder and fenestrations allow for bone ingrowth in the IFS™ and across the fusion site.

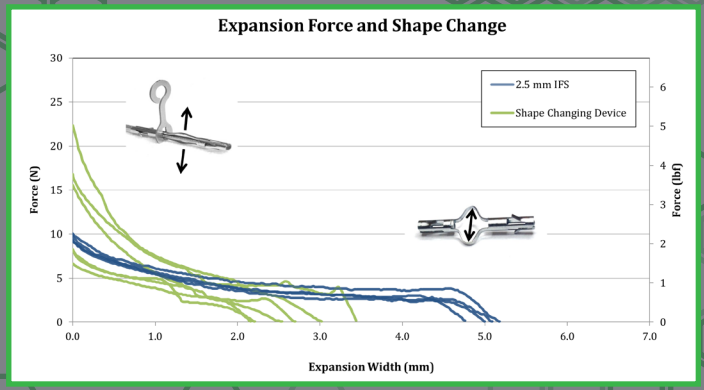


High Bone Fixation through Expansion Shape Change

Metric's IFS™ design exhibits 87% greater expansion shape change when compared to other shape changing hammertoe products on the market, providing superior fixation.

The IFS™ bone locking force is 9.6N or 2.2lbf.





Data submitted to FDA for 510(k)

A02-007-01 (IR)

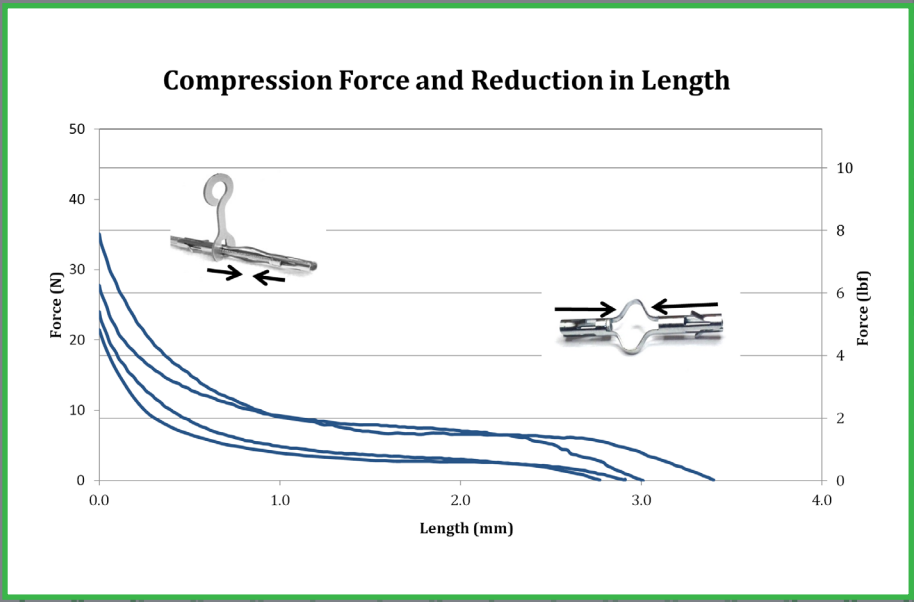
METRIC
BRINGING BONES TOGETHER™

Super Scaffold™

Intramedullary Fixation Scaffold (IFS™) System

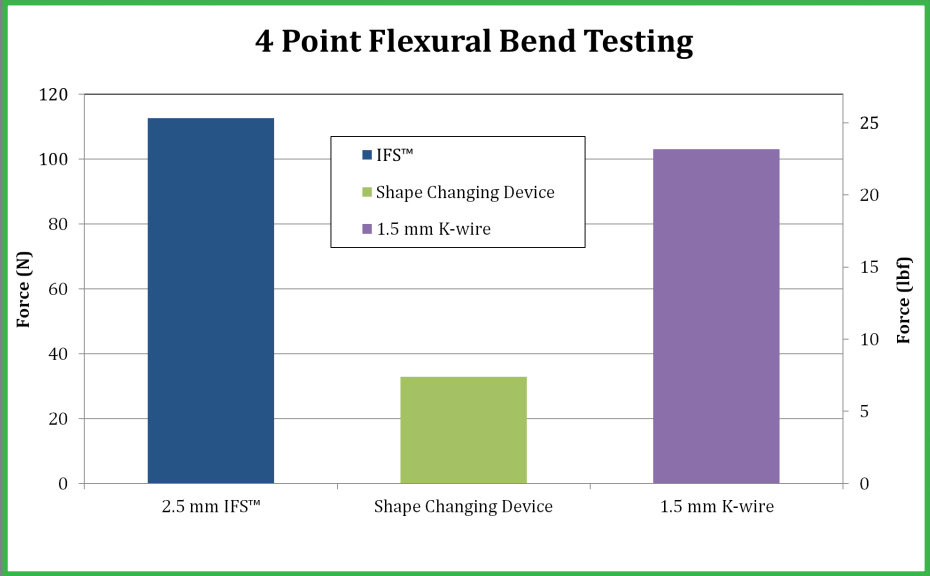
Continuous Compression

The IFS™ contracting bulge design provides high bone compression force over a wide range of shape change (average 27.1N (6.0 lbf) over 3mm), continuously pulling bones together and compressing the healing interface.



High Strength

The tubular design of the IFS™ exhibits greater bending forces than competitor's shape changing device and K-wires.



Data submitted to FDA for 510(k)

A02-007-01 (IR)

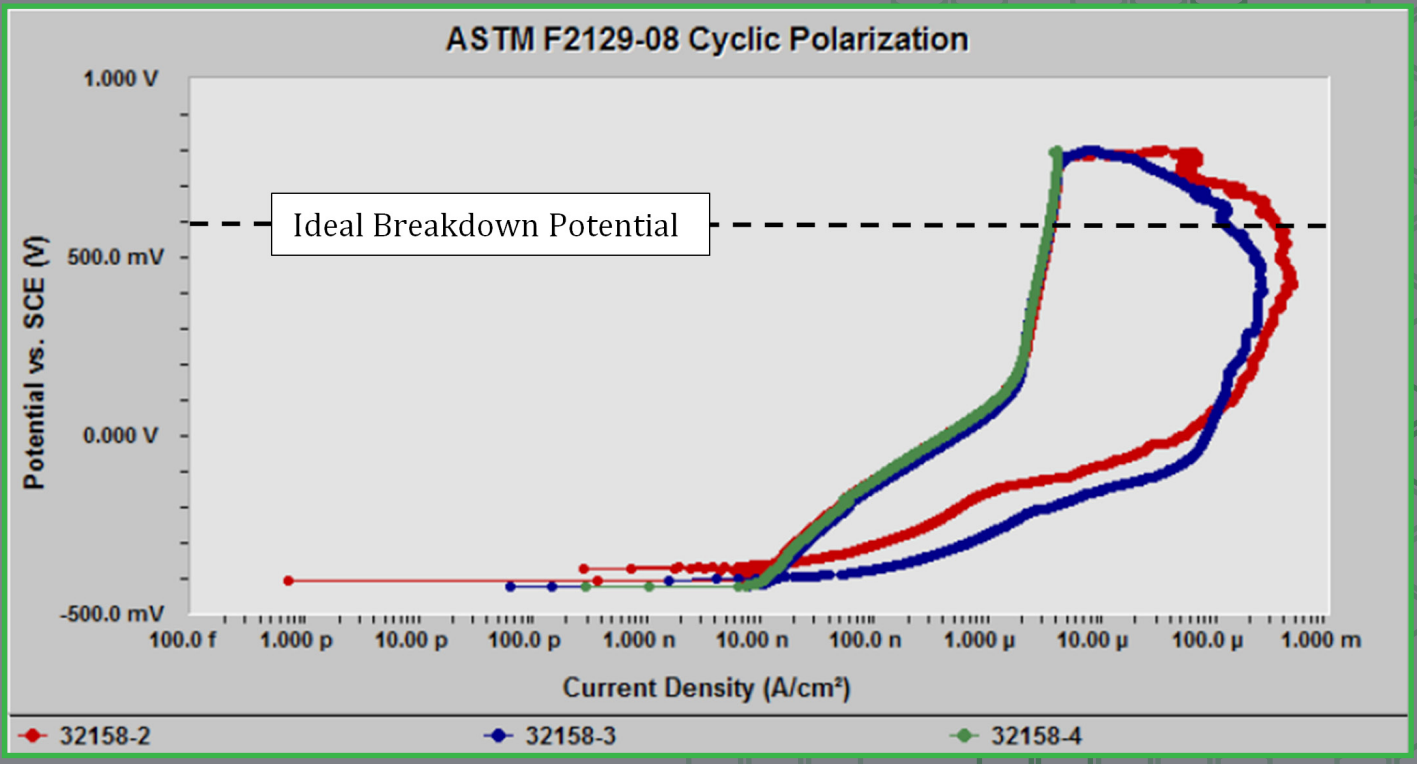
METRIC
BRINGING BONES TOGETHER™

Super Scaffold™

Intramedullary Fixation Scaffold (IFS™) System

Biocompatibility

Higher corrosion resistance and biocompatability are enhanced through the formation of a titanium rich oxide surface on the implant, thus minimizing nickel ion release. All IFS™ implants tested had a breakdown potential *exceeding* the "ideal" breakdown of 600mV[1].



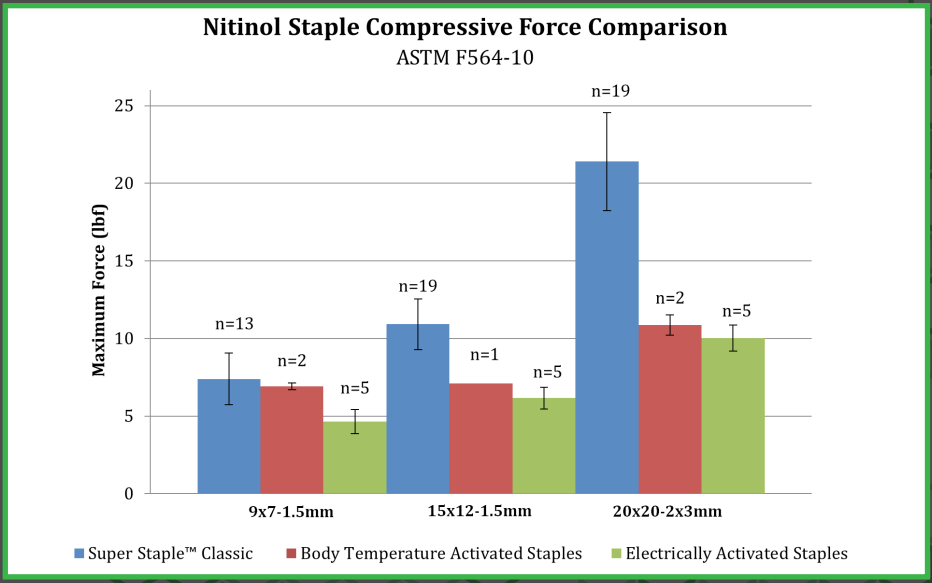
1. Rosenbloom and Corbett, Proceedings of the International Conference on Shape Memory and Superelastic Technologies, May, 2006.

METRIC
BRINGING BONES TOGETHER™

Super Staple™
Nitinol Bone Fixation System

High Strength

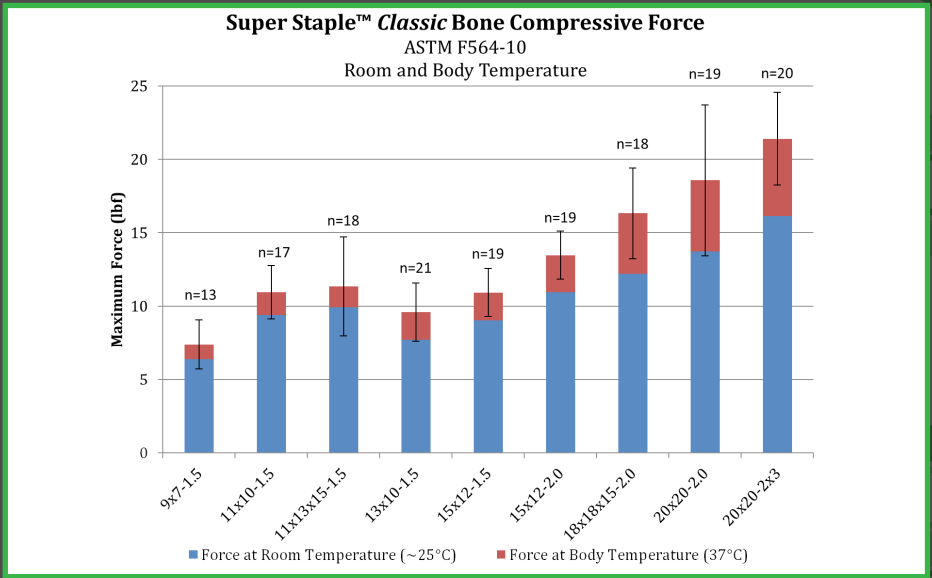
Metric's Super Staple™ Classic exhibits 7-113% greater compressive force than body temperature and electrically activated nitinol bone staples.



Instantaneous Compression Operatively

Metric's Super Staple™ Classic exerts high instantaneous compressive forces that increase 14 to 35% at body temperature.

Force Created at room temperature (blue) and additional force exerted with body heating (red).



Data submitted to FDA for 510(k)

A01-011-01 (IR)

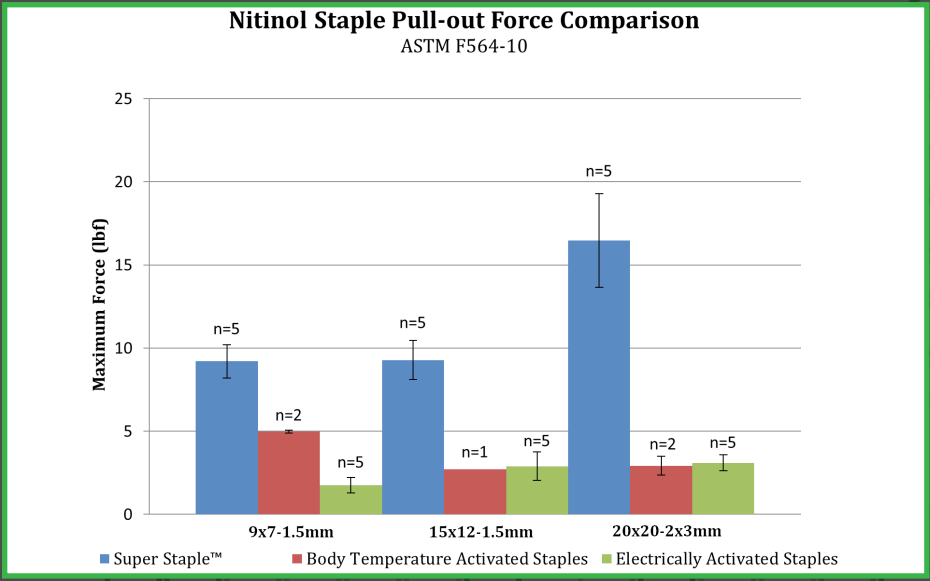
METRIC
BRINGING BONES TOGETHER™

Super Staple™

Nitinol Bone Fixation System

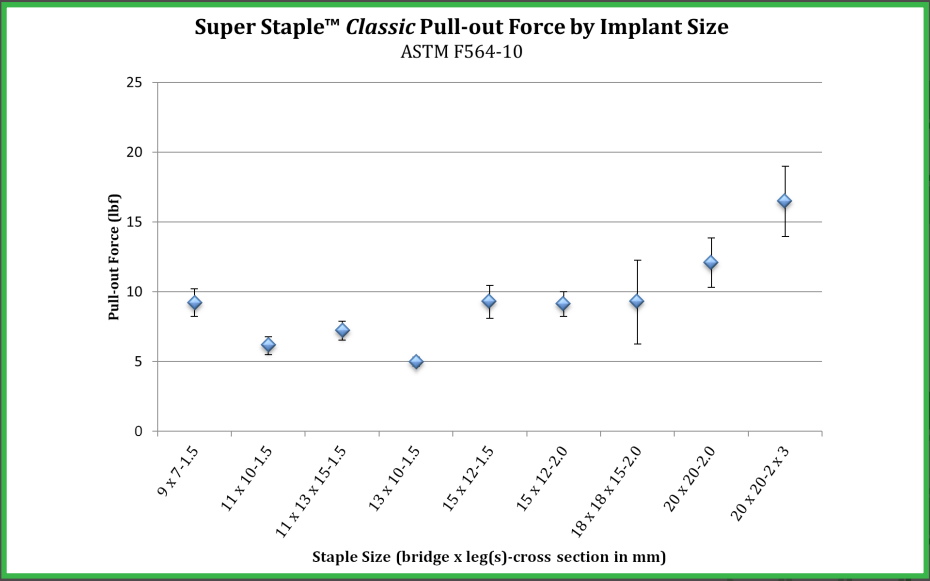
High Pull-Out Strength

Metric's Super Staple™ Classic has two to six times (2x-6x) higher pull-out force than body temperature activated or electrically activated nitinol staples.



Pull-Out Force Increases with Size

Metric's Super Staple™ Classic has high pull-out forces that increase with implant size.



Data submitted to FDA for 510(k)

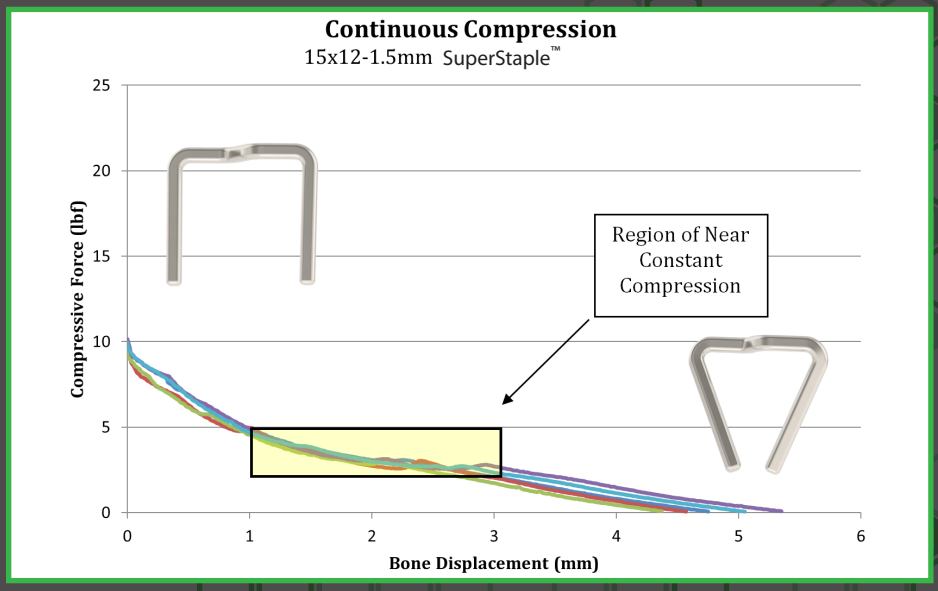
A01-011-01 (IR)

METRIC®
BRINGING BONES TOGETHER™

Super Staple™
Nitinol Bone Fixation System

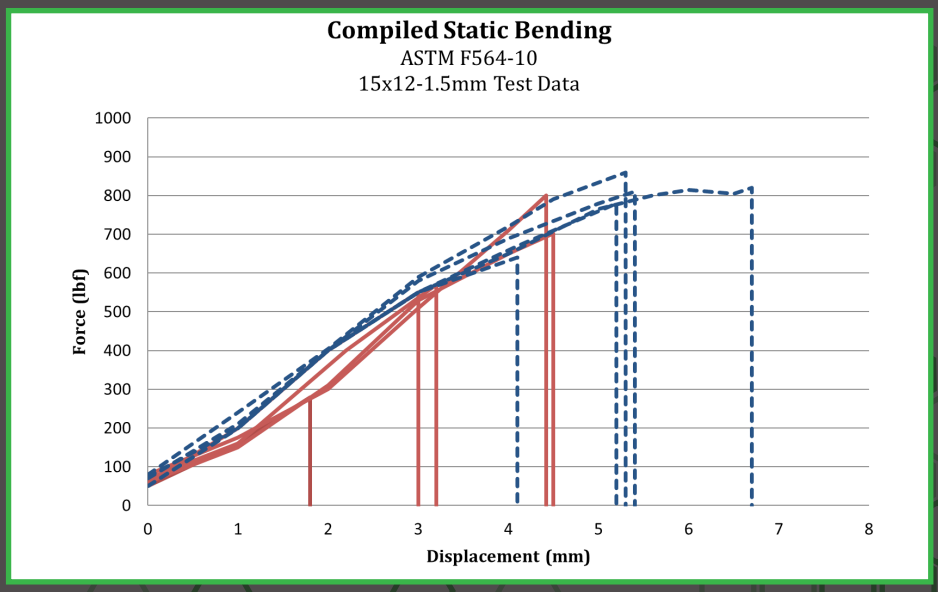
Uniform Compressive Forces with Shape Change

Metric's Super Staple™ Classic contracting bridge and converging leg design exerts uniform and near constant compressive force over a wide range of shape change.



High Failure Force

Metric's Super Staple™ Classic (blue ▬) is stiffer, has more shape change and fails at a higher force than electrically activated (red ▬) nitinol staples.



Data submitted to FDA for 510(k)

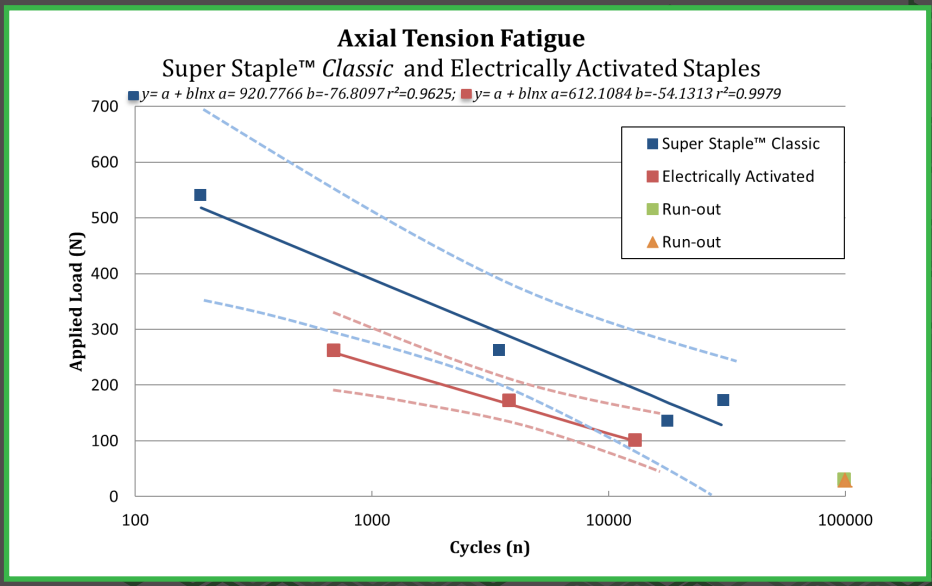
A01-011-01 (IR)

METRIC
BRINGING BONES TOGETHER™

Super Staple™
Nitinol Bone Fixation System

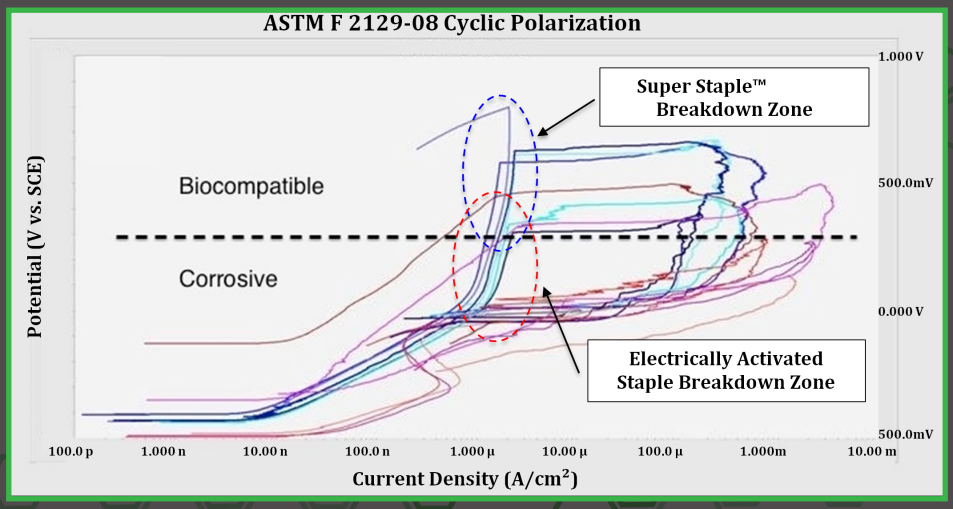
High Resistance to Cyclic Loading Failures

Metric's Super Staple™ Classic (blue ▬) on the average withstood 87% more cyclic force (99 lbf) at 10,000 cycles than the electrically activated (red ▬) staples as illustrated in the fatigue testing curves shown.



Biocompatibility

Metric's Super Staple™ Classic (6 blue hue curves) biocompatibility is enhanced and nickel ion release is impeded through the use of a titanium rich oxide formed on the implant which provides higher corrosion resistance than tested electrically activated (5 red hue curves) nitinol staples. All six Super Staple™ Classic implants tested were biocompatible having a breakdown potential over 300 millivolts. Only two of the five electrically activated nitinol staples tested were over the 300 millivolts threshold for biocompatibility.



Data submitted to FDA for 510(k)

A01-011-01 (IR)