KINAMED®
INCORPORATED

SuperCable™ Iso-Elastic™ Cerclage System

SuperCable™ *Iso-Elastic*™ Cerclage System

What is it?

- **The worlds only polymer cerclage cabling system**
- **Cable is made with Nylon core and UHMWPe sheath (non-resorbable)**
- **Clasp is made from Ti 6Al/4V**
- **Cable diameter = 1.5mm x 2 strands**

SuperCable *Iso-Elastic* Cerclage System

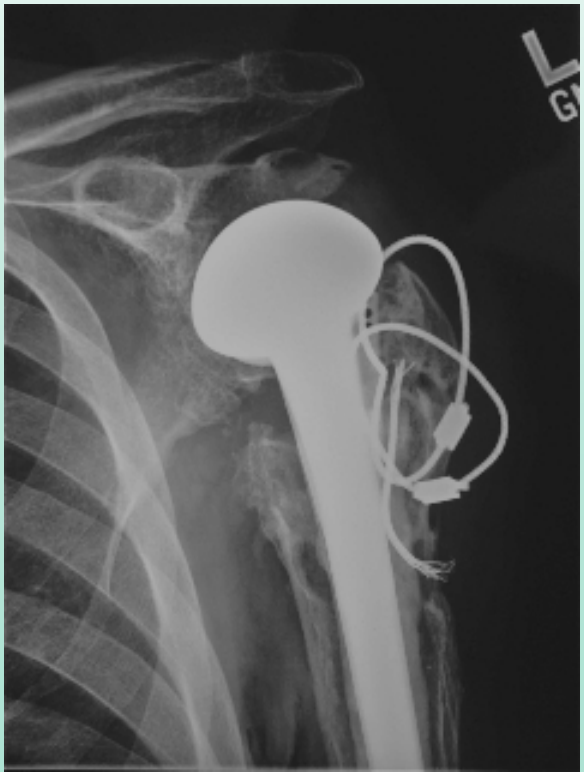
Why polymer instead of metal?

- **Metal cables have high rates of fatigue failure (Ritter – 32.5% breakage)**
- **Broken cables result in fixation loss and can be painful and can require additional surgery for removal.**

Features and Benefits

Why polymer instead of metal?

- **Failed metal cable migrating through the skin**

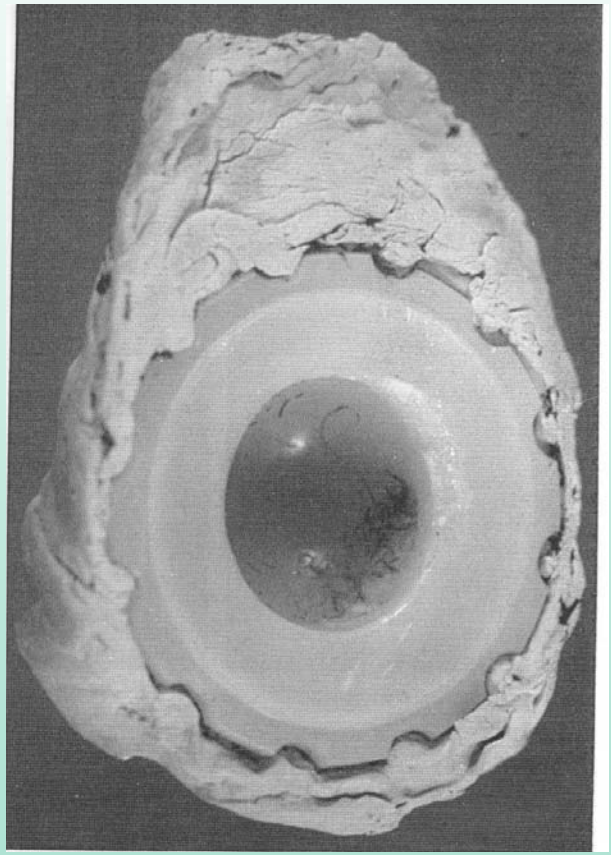


Photos and x-ray courtesy of Tom Norris, MD

San Francisco, CA

SuperCable *Iso-Elastic* Cerclage System

Why polymer instead of metal?



- **Metal cables liberate metal particle debris**

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Fatigue Testing of Cerclage Stainless Steel Wire Fixation

Mathias P. G. Bostrom, *Stanley E. Asnis, Jens J. Ernberg, Timothy M. Wright, Virginia L. Giddings, †Wayne S. Berberian, and *Albert A. E. Missri

DISCUSSION

Although wire breakage is often viewed as an inconsequential radiographic finding, in reality it has been and remains a major problem in orthopaedic surgery. The estimated rates of breakage of monofilament wire used for reattachment of the greater trochanter during total hip arthroplasty vary from 17% to 32% (6). In addition to the problems of nonunion, delayed union, and loss of trochanteric position, these broken wires pose a significant threat of migrating into the joint resulting in significant third body wear (1,3,6). Sir John Charnley recog-

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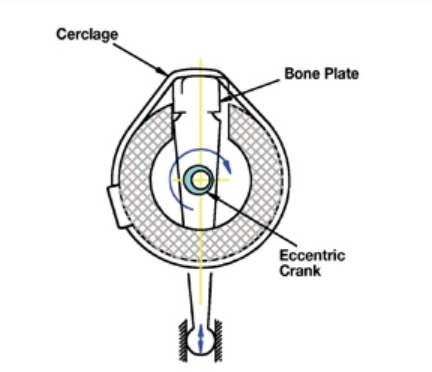
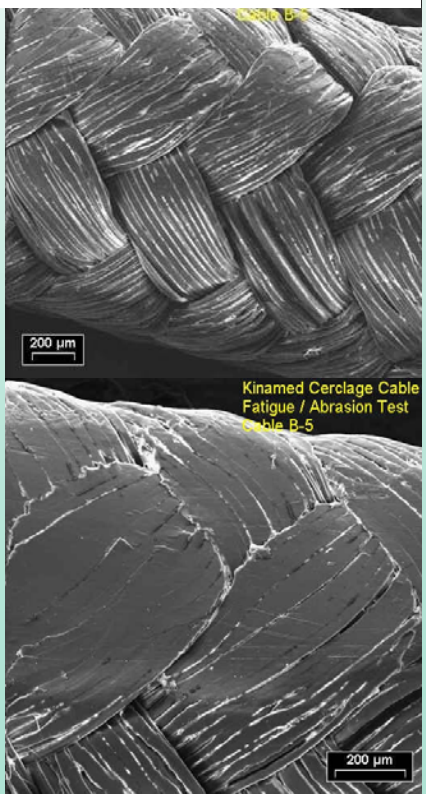


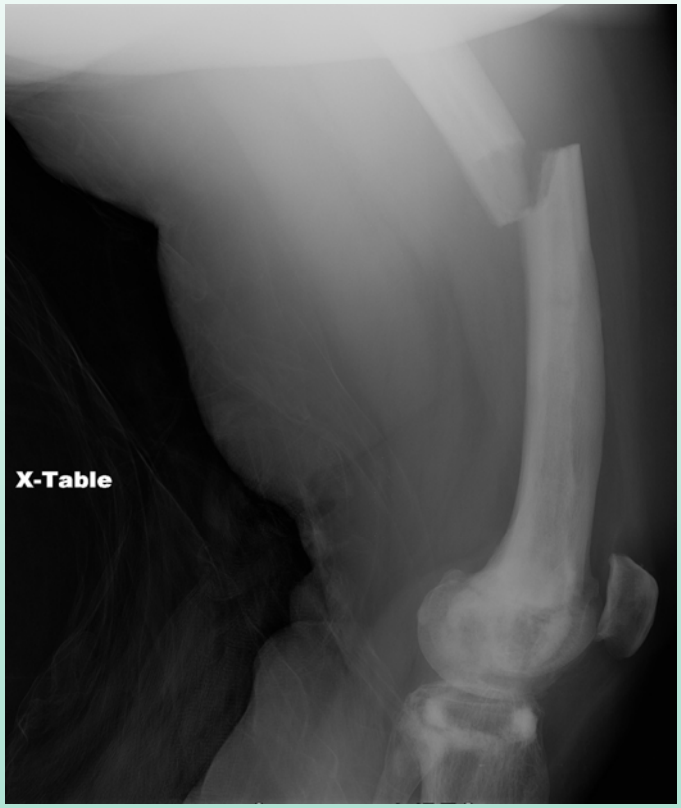


Why polymer instead of metal?

- **UHMWPe has superior fatigue strength and abrasion resistance as compared to metal cable**
- **Wear/Fatigue test described on brochure**
- **SuperCable provides a super tough, super durable cerclage system**

SuperCable *Iso-Elastic* Cerclage System

Why polymer instead of metal?

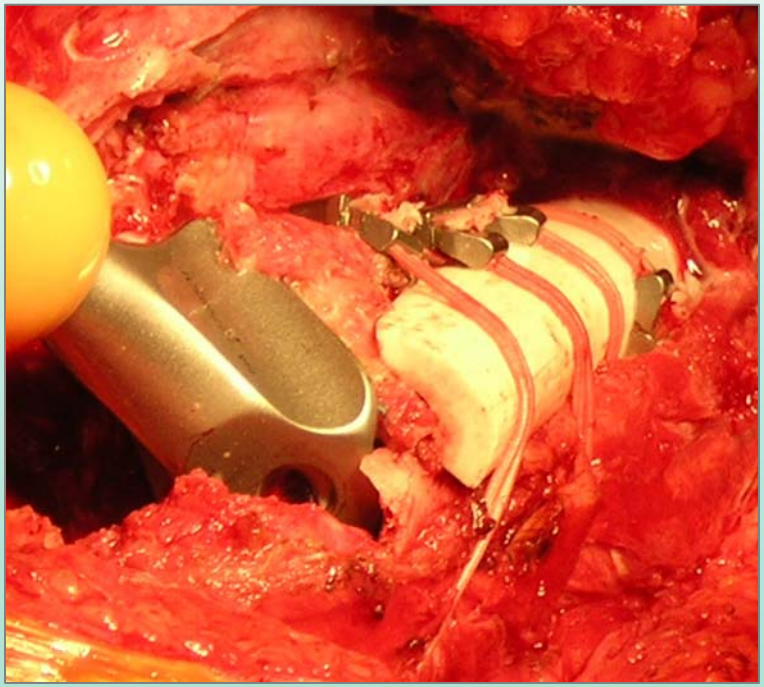


"Iso-Elastic™"

- **SuperCable has engineered elasticity**
- **Elasticity provides dynamic compression across construct offering the possibility of improved healing**

SuperCable *Iso-Elastic* Cerclage System

Why polymer instead of metal?



"Iso-Elastic™"

- **Metal cables dig into bone**
- **Metal cables then become lose and micromotion ensues**
- **SuperCable can compensate due to elastic energy stored**

Features and Benefits

Other Features:

Each cable provides two strands instead of one

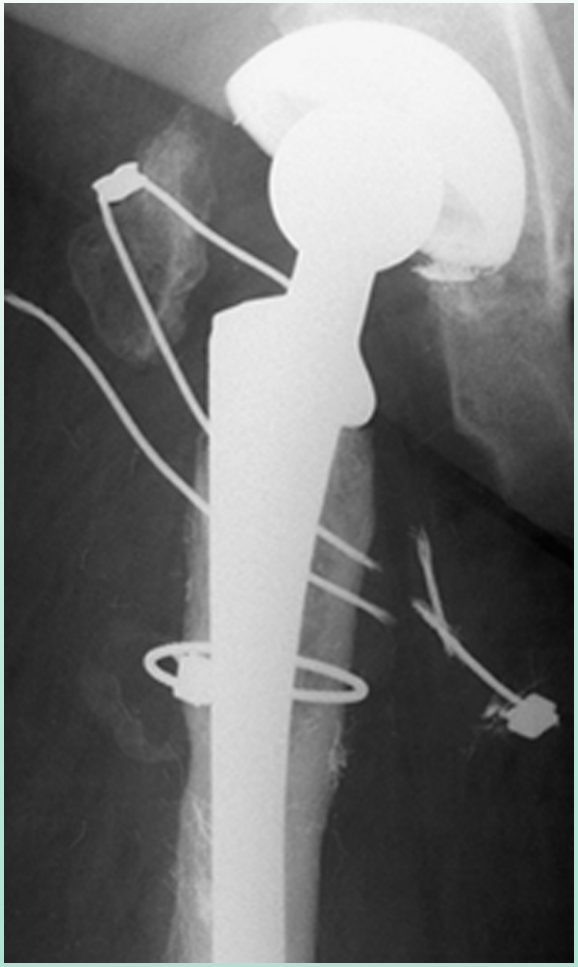
- **Spreads the compressive load over twice the area**
- **This “snowshoe” effect may reduce the bone cutting or grooving often seen with metal**

Features and Benefits

Why polymer instead of metal?

- **No sharp cable ends to irritate patient tissue**
- **May require revision surgery for cable removal**

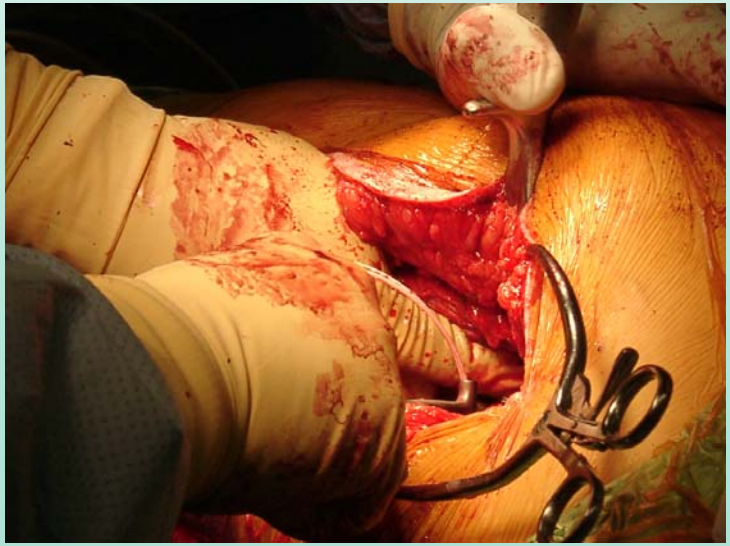
Features and Benefits



Why polymer instead of metal?

- **No sharp cable ends to cut surgeons gloves**
- **Can be dangerous for surgeon finding and removing broken cables**

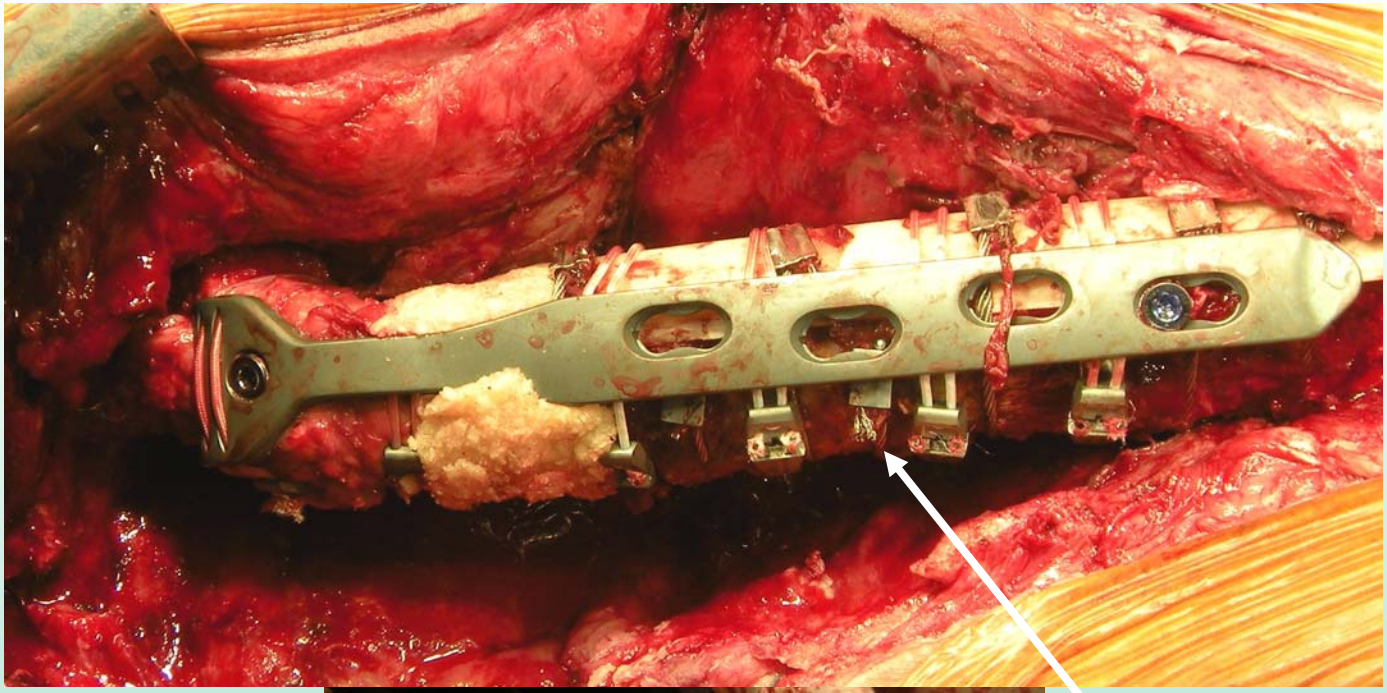
Features and Benefits



Why polymer instead of metal?

- No sharp cable ends to cut surgeons gloves
- Sharp cable ends can be dangerous during placement
- Exposes surgeon and patient to increased infection risk

Features and Benefits



Sharp frayed end of previously placed metal cable

Features and Benefits

Great Instrumentation

- Simple, quick and easy to use
- Cable tensioner is also the cable locking device

Features and Benefits

Great Instrumentation

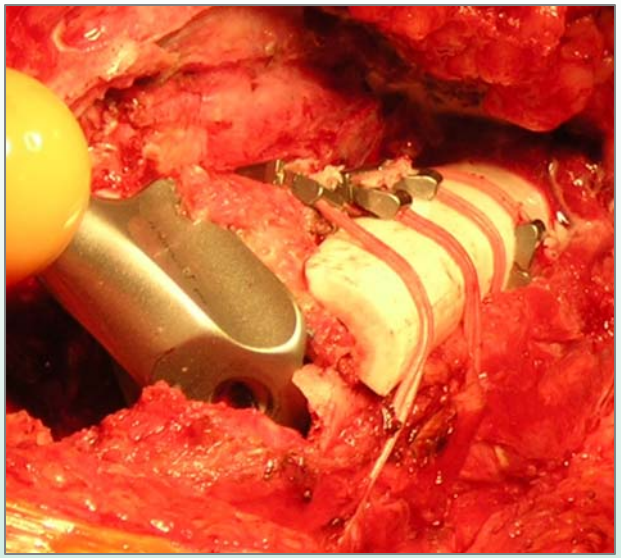
- Cables can easily be retightened after locking
- Faster, simpler system eliminates cumbersome tension retaining devices

SuperCable *Iso-Elastic* Cerclage System

Indications:

- Fixation of fractures and osteotomies in long bones

Typical Uses



- Revision THR – trochanteric osteotomy
- Revision THR – femoral osteotomy
- Revision THR – onlay grafting
- Revision SR – onlay grafting
- Periprosthetic fractures (hip, shoulder, knee)
- Olecrenon fracture
- Patella fracture

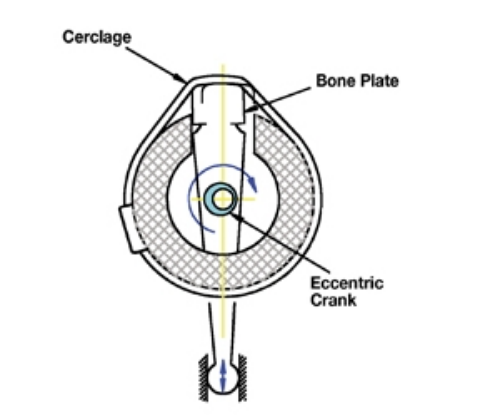
Selling Strategies

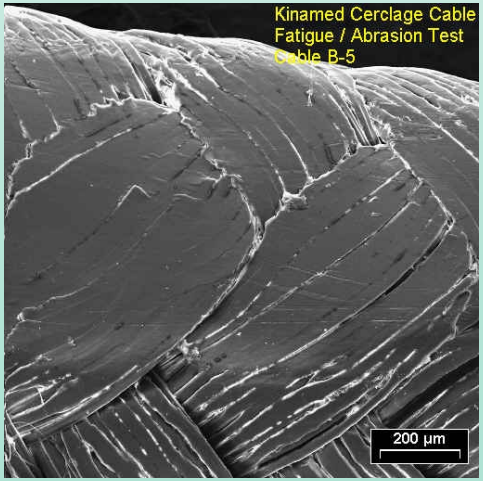
Evaluation surgery tips

- Perform a quick “sawbones” demo with surgeon before the case so he/she understands details of instrument usage!
- Teach proper orientation of cable passer
- Teach proper orientation of cable clasp
- Allow surgeon to use tensioning instrument to tighten and lock a cable on a sawbones

Frequently Asked Questions

Won't the UHMWPe sheath result in poly wear debris?





- **No, the gel-spun poly sheath is extremely resistant to wear as shown by testing to 1 million cycles over metal plate**
- **In this extreme test there is very little loss of poly as compared to the volumes lost in total joint implants**

SuperCable *Iso-Elastic* Cerclage System

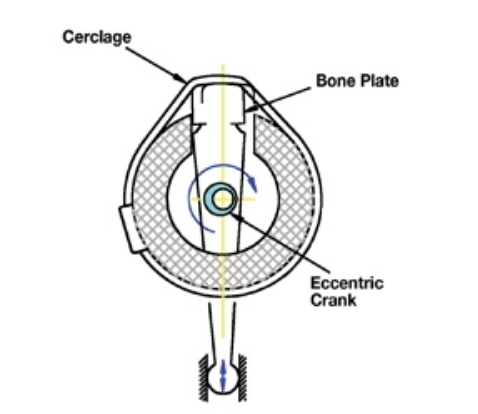
Why polymer instead of metal?

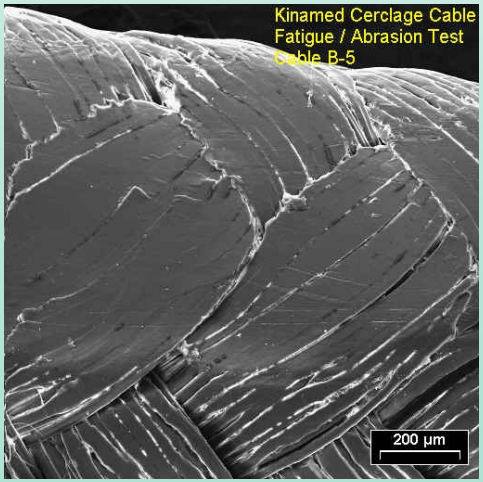
- **SuperCable can be placed over metal implants**

(sharp edges are to be avoided)

Frequently Asked Questions

How does the strength of SuperCable compare to metal cable systems?





- **Strength can be measured in two ways:**
  - **tensile strength (single max load) and**
  - **fatigue strength (repetitive load)**

- **Breakage in cabling systems are generally caused by fatigue failure not tensile failures!**

Frequently Asked Questions

How does the strength of SuperCable compare to metal cable systems

- The chart below compares fatigue strength (cycles to failure) of SuperCable to that of metal cables and wires
- The figures for metal cerclage systems were taken from the literature and those from SuperCable from in-house testing described here and on the brochure
- All metal systems started seeing failure at 100,000 cycles while SuperCable saw none at 1 million cycles with higher loading!

Cerclage Type	Cyclic Load	Cycles to Failure
SuperCable	100 pounds	No failures at 1 million cycles
Stainless steel wire	35 – 80 pounds	100,000 cycles
Titanium alloy cable	20 – 50 pounds	100,000 – 1 million cycles
Cobalt-chrome alloy cable	20 – 50 pounds	100,000 – 1 million cycles

Frequently Asked Questions

How does the strength of SuperCable compare to metal cable systems

Cerclage Type	Tensile Strength
SuperCable	~250 pounds
Stainless steel wire	70 – 150 pounds
Titanium alloy cable	250 – 460 pounds
Cobalt-chrome alloy cable	300 – 700 pounds

- **For the record, the chart alongside compares tensile strength of SuperCable to metal cables and wires**
- **Remember though – it is not tensile failures that are a problem - fatigue failure causes breakage of metal cerclage!**

Frequently Asked Questions

How much bone compression is applied at the “low” and “high” marks on the tensioning knob?

- **“Low” mark = approximately 80 lbs. (360N) of compressive force**
- **“High” mark = approximately 120 lbs. (530N) of compressive force**

Frequently Asked Questions

How do I determine if I should tension to "low" vs. "high" when applying the cable

- **"Low" may be appropriate for patients that have compromised bone strength (osteopenia, etc.)**
- **"High" may be appropriate for large bones in high load areas in patients with good bone strength**
- **In all cases the surgeon should exercise his/her clinical judgment when tensioning the cable**

Frequently Asked Questions

I can see where the “Iso-Elastic” stored energy in the SuperCable may provide greatly improved fixation and stability but could there be too much energy stored leading to bone necrosis?

- **This has not been seen in the clinical follow-up we have collected (see Clinical Data PP)**
- **The SuperCable also relaxes and loses a portion of its compressive load over time**

Frequently Asked Questions

Tell me more about this cable relaxation – won't this result in loss of fixation?

- **No, compressive force remains despite some cable relaxation**
- **This is in marked contrast to a non-elastic metal cable that can loose all compressive force as soon as the cable grooves into the bone!**

Frequently Asked Questions

How quickly does this relaxation occur?

- **Relaxation tests show that initial cable tension decreases by approximately 40% after 8 weeks of static loading.**
- **The majority of loss occurs after the first day and only 1% of the total loss occurs during the final 30 days of the test.**
- **Steady-state tension is reached and maintained after a relatively short period of time.**