SuperCable™ *Iso-Elastic*™ Cerclage System

FAQs - Frequently Asked Questions

Is the *SuperCable*™ an approved medical device?

The *SuperCable*™ is approved for use in the United States, Canada, and European Union. FDA marketing clearance was granted under 510(k) number K030256.

Is there published data available on the *SuperCable*™?

Yes. Abstracts have been presented at the 2005 Orthopaedic Research Society (ORS) meeting in Washington DC, and at the 2005 International Society for Technology in Arthroplasty (ISTA) meeting in Kyoto, Japan.

What gives the *SuperCable*™ its unique properties?

A proprietary union of nylon and braided UHMWPE gives the cable a unique combination of strength, elasticity, and fatigue-resistance.

What about biocompatibility?

The cable materials are biocompatible and are qualified for long-term implantation in the body.

UHMWPE is slippery. Does the cable slide or migrate over time?

This phenomenon has been searched for on serial xrays and has not been found. A loose fibrous connective tissue tends to form around the cable after implantation in the body. This tissue likely keeps the cable from migrating. The tissue can be easily resected and then the cable is easily removed if necessary.

How easy is it to remove the cable after implantation?

Because the cable is biocompatible and engineered to be tissue-friendly, it does not require removal. However, if removal is necessary due to failure of other hardware, it can be accomplished easily by resecting any fibrous tissue that has formed around it.

How is the excess length of cable cut?

A scalpel can be used to easily cut the cable

Does the cable show up on x-rays?

The polymer cable is radio lucent, but the metal clasp does appear on xrays.

What are the approved indications for use?

- Repair of long bone fractures due to trauma or reconstruction
- Reattachment of the greater trochanter in total hip arthroplasty, surface replacement arthroplasty, or other procedures involving trochanteric osteotomy
- Sternotomy closure
- Sublaminar and intrafacet wiring of the spinal column.

Does the cable stay tight after extended periods of implantation?

Several cables have been removed during hardware (K-wire, bone plate, etc) removal after extended implantation in the body. None of the cables were loose at the time of removal.

What about polyethylene wear?

The cable has been fatigue-tested against a bone plate for 1 million cycles at 445 N (100 lbs) and exhibited no fraying, breakage, or gross damage.

Because cable tension is known to relax over time, the compressive stresses that lead to wear diminish over time.

In contrast to an UHMWPE total joint implant, only a small region of the cable experiences abrasive contact, limiting the amount of polyethylene that is available to be worn.

What about hydrolysis of nylon in the body?

Nylon is known to undergo hydrolysis in the presence of dilute acids and bases. The cable has been tested after 8 weeks of immersion in Ringer's solution. After soaking for 8 weeks, strength decreased by 6% and elongation to failure increased by 19%. The largest changes occurred after 1 week, and changes after 4 weeks were negligible. Changes due to immersion are not significant during the healing phase of bone.

What about viscoelastic (i.e. time-dependent) behavior of the polymer cable?

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

After a constant load of 445 N was fully applied to the cable, its length increased 2.5% after 5 days.

How do we summarize our experience with the cable thus far?

Strength of the *SuperCable* is comparable to that of traditional metal cerclage cable. The *SuperCable* maintained compression during the time period associated with primary bone healing and showed a substantially superior fatigue endurance limit than metal cerclage. The cable easily survived one million cycles of load, which is expected to be beyond the physiologic requirement for patients recovering from a bony fracture. The wear behavior of the cable was clearly superior to that of multifilament metal cerclage. After initial relaxation, the cable maintained compressive forces that are typical of the initial compression held by traditional metal cerclage wires. Cable creep was small and thought to be acceptable for fracture reduction and healing applications. Finally, early clinical results suggest that the cable is a safe and effective method for treatment of fractures.

What materials is the cable made from?

The polymer cable is made from a combination of nylon and ultra-high-molecular-weight polyethylene. The metal clasp is made from cobalt-chrome alloy, titanium alloy, or stainless steel.

What types of surgical applications has the cable been used in?

Peri-prosthetic fractures around femoral stem
Peri-prosthetic fractures around humeral stem
Transverse patella fracture
Greater trochanter avulsion
Non-union of the humerus
Non-union of the tibia
Traumatic fracture of the femur shaft
etc etc

Can the cable be used with allograft struts, metal plates, or metal grips from other manufacturers?

The cable can be used with allograft struts, metal plates, or grips as long as the cable is not pinched or placed in contact with sharp edges.

What is the Tensile Strength of the *Supercable*?

Tensile strength of the polymer cable is approximately 250 pounds. This strength compares favorably with cerclage wires and cables made from stainless steel, titanium alloy, or cobalt-chrome alloy (see table below). Data on metal cables were collected from published literature and promotional materials. Results for metal cerclage vary due to different cable configurations and testing regimes.

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

While tensile strength is comparable to that of metal cerclage, fatigue strength is a more clinically relevant measure of performance and effectiveness because fatigue loading is responsible for the majority of metal cerclage failures. Fatigue strength of the *SuperCable* is clearly superior to that of metal cerclage (see table below).

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