



# Sternal Cable System

SYSTEM OVERVIEW

REINVENTING EXPECTATIONS

**INTRODUCTION ..... 1**

**FEATURES & BENEFITS ..... 2**

**SURGICAL HIGHLIGHTS ..... 2**

**MECHANICAL TESTING..... 3**

**IMPLANTS & INSTRUMENTATION ..... 4**

**INDICATIONS & WARNINGS ..... 5**

The A&E Medical Sternal Cable System is an improved alternative over traditional monofilament sternal wire used to close median sternotomies. This system consists of multi-strand stainless steel and titanium cable which is tensioned and secured using A&E Medical's unique Tensioner/Crimper instrument. The cable is smooth and flexible, making insertion and removal easy and intuitive. The tensioner assures adequate tension is applied, while the tension scale ensures each cable is tensioned to the same degree before crimping. Multiple "figure 8" constructs work as one unit to provide optimal stabilization.

### **Strong**

The A&E Medical Sternal Cable is approximately ten times stronger in fatigue strength than the standard sternal wire.

### **Consistent**

The tensioning system permits adjustment of the cable intra-operatively to a known value, allowing for consistency in pressure along the midline.

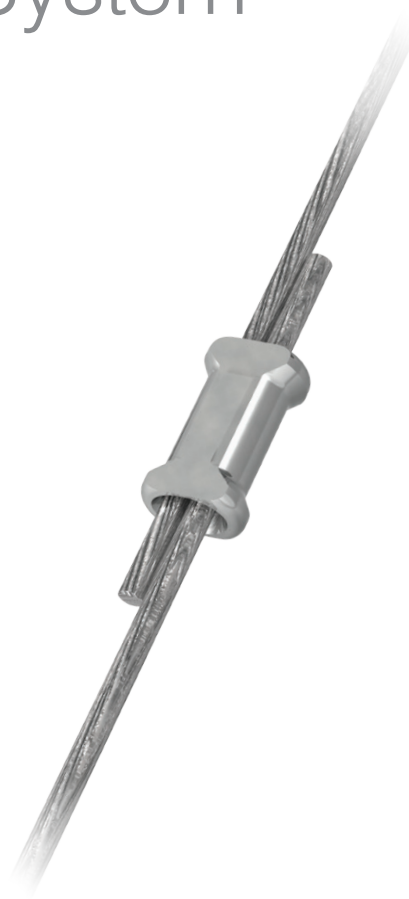
### **Flexible**

The sternal cable uniformly hugs the bone in a "figure 8" construct,\* thus decreasing the possibility of loosening, micro-motion, potential post-operative implant failure and related patient risk.

### **Reliable**

The strength of the sternal cable and its method of attachment, coupled with the ability to achieve consistency in tension, makes this system trusted by many surgeons. More than 200,000 sternal cables have been distributed worldwide.

# Sternal Cable System



### **Cable Design Features**

- Diameter: 1.1 mm SS, 1.3 mm Ti
- Unique multi-strand design eliminates the risk of kinking

### **Crimp Design Features**

- Crimps to secure tension and lock cables in position
- Low profile reduces tissue irritation
- Available in implantable Ti and SS

## REVISED HANDLE

with increased leverage, making it easier to squeeze and secure crimp

## INSTRUMENT DESIGN

reduces weight 35% and makes instrument easier to clean

## ERGONOMIC HANDLE

brings instrument to full tension

## SCALE

designed for full travel measurements

## LOCKING CHANNEL

eliminates need to thread cable

## SELF-CENTERING COUPLING

reduces surgical prep time

Spool Mechanism

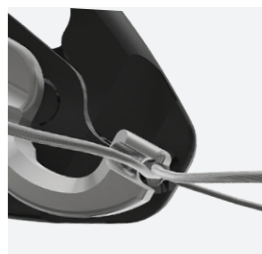
## OPTIMIZED CABLE GUIDES

prevent cable crossing

## SURGICAL HIGHLIGHTS



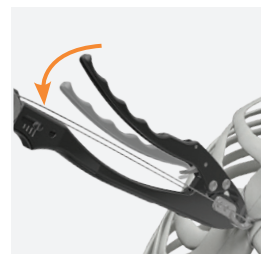
1 PASS NEEDLE



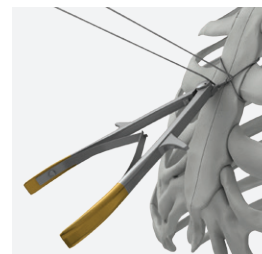
2 PASS CABLE



3 TENSION



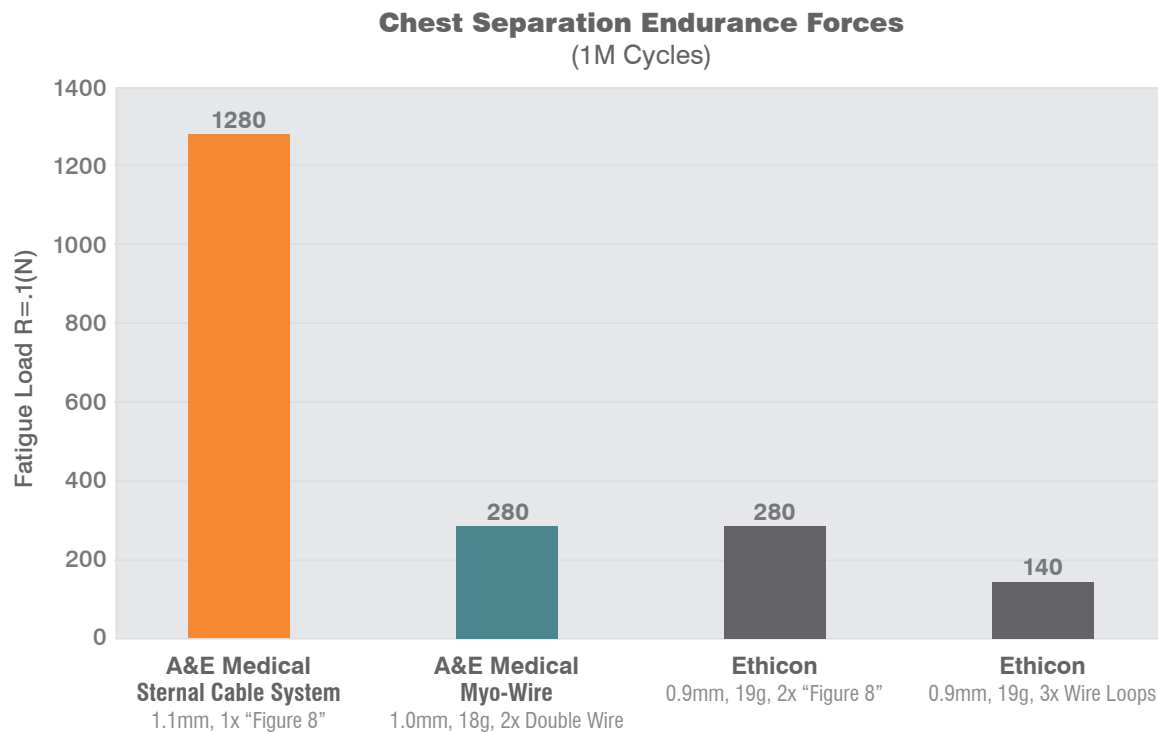
4 CRIMP



5 CUT

## Chest Separation Endurance Forces

The A&E Medical Sternal Cable System was subjected to extensive testing including Chest Separation Endurance Forces (below) where 6M breathing cycles/year is equal to 1M breathing cycles/8 week recovery period.







(Ref: Kostuik, JP Intervertebral Disk Replacement. In: Bridwell KH, Dewald RL eds. The Textbook of Spinal Surgery, 2nd ed. Philadelphia: Lippincott-Raven, 1997)

## Static Testing

The Cable "figure 8" construct also out performed #6 Wire in Static Testing using an MTS Bionix test stand and multiple wire configurations vs. a single A&E construct (below).

Construct	Peak Load (N) Average	Peak Load (N) Stand. Dev.
Wire #6 (1x Fig. 8)	791.4	15
Wire #6 (3x Loops)	1302.3	96
Wire #6 (2x Fig. 8)	1988.2	254
Single Cable (Fig. 8)	3687.9	1989

### STAINLESS STEEL OFFERINGS

Part Number	Description	Package Configuration	
400-689	Cutting Edge Needle with SS Cable	5 packs with 4 Cables per pack	
400-690	Cutting Edge Needle with SS Cable	5 packs with 3 Cables per pack	
400-727	Cutting Edge Needle with SS Cable	5 packs with 1 Cable per pack	
400-425	Tapered Cutting Needle with SS Cable	5 packs with 4 Cables per pack	
400-427	Tapered Cutting Needle with SS Cable	5 packs with 1 Cable per pack	
400-411	Reverse Cutting Needle with SS Cable	5 packs with 4 Cables per pack	
400-890	Reverse Cutting Needle with SS Cable	5 packs with 3 Cables per pack	
400-413	Reverse Cutting Needle with SS Cable	5 packs with 1 Cable per pack	
402-618	Tapered Blunt Needle with SS Cable	5 packs with 4 Cables per pack	
402-522	Tapered Blunt Needle with SS Cable	5 packs with 1 Cable per pack	
402-523	3 Tapered Blunt and 1 Cutting Edge Needle with SS Cable	5 packs with 4 Cables per pack	
401-020	3 Tapered Cutting and 1 Reverse Cutting Needle with SS Cable	5 packs with 4 Cables per pack	
400-401	SS Crimps	1 pack containing 2 Crimps	

### TITANIUM OFFERINGS

Part Number	Description	Set Configuration
401-096	Cutting Edge Needle with Ti Cable	1 pack with 4 Cables per pack
408-722	Tapered Blunt Needle with Ti Cable	1 pack with 4 Cables per pack
408-719	Tapered Cutting Needle with Ti Cable	1 pack with 4 Cables per pack
408-720	3 Tapered Blunt and 1 Cutting Edge Needle	1 pack with 4 Cables per pack
408-721	Reverse Cutting Needle with Ti Cable	1 pack with 4 Cables per pack
408-723	Ti Crimps	1 pack containing 2 Crimps

### INSTRUMENTATION

Part Number	Description	Set Configuration	
400-410	Cable Cutter	1 per set	
407-714	Crimper/Tensioner	2 per set	
431-762	Sterilization Tray	1 per set	

## IMPLANTS

### INDICATIONS

- Cardiovascular sternal closure

### CONTRAINDICATIONS

Contraindications may include, but are not limited to:

- Presence of documented infection;
- Patient metal allergy or intolerance;
- Presence of severe osteopenia and/or osteoporosis, rapid bone absorption, metabolic bone disease, cancer, tumor, or tumor-like condition of the bone;
- Inadequate tissue coverage of implant site;
- Interference with other critical anatomical structures;
- Undiagnosed infection, end stage malignant disease, or other unexplained disease;
- Severely comminuted fractures;
- Any patient unwilling to follow postoperative instructions; and
- Any situation not defined by Indications.

### WARNINGS AND PRECAUTIONS

- WARNING: Do not intermix implants with different metallic alloy types.
- WARNING: Do not use if packaging is damaged/opened prior to use.
- CAUTION: Operating surgeon should have a good understanding of the cable system, surgical technique, and biomechanical principles of cable fixation.
- CAUTION: Federal law (USA) restricts the use of this device on the order of a physician only.
- IMPORTANT: Avoid over tensioning cables as they may break/fray.
- IMPORTANT: Cables may cut through soft bone that is not protected and immobilized.

This system has not been evaluated for safety and compatibility in the MR environment. This system has not been tested for heating or migration in the MR environment.

## INSTRUMENTS

### INTENDED USE

Sternal surgical instruments are for use only with A&E Sternal Cable System implants.

### WARNINGS AND PRECAUTIONS

1. Avoid over tensioning the cable construct.
2. Saline is corrosive to stainless steel and should not be used.
3. High pH level detergents may cause pitting and tarnishing of the instruments.



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