The Biomet, as the manufacturer of this device, does not practice medicine and does not recommend these or any other surgical techniques for use on a specific patient. The surgeon who performs any procedure is responsible for determining and utilizing the appropriate technique for such procedure for each individual patient. Biomet is not responsible for selection of the appropriate surgical technique to be utilized for an individual patient.


INTRODUCTION

The Biomet Medical Products (BMP™) Cable System provides a cost effective and simple method of trochanteric reattachment, fracture fixation, and cerclage cabling. Our system features cable implants based upon a clinically proven design concept and instrumentation that is a vast improvement over competitive cable systems. Our innovative cable plates offer both a technological and economic advantage that is exclusive to the BMP Cable System.

Cerclage Cable Vs. Monofilament Wire

The use of monofilament wire for cerclage wiring and trochanteric reattachment is a well established practice. Typically, a 1.0mm or 1.2mm monofilament stainless steel wire is used in conjunction with a wire twisting instrument. This practice is not without complications. Failure of monofilament wire can occur as a result of metal fatigue at the site of small surface defects or "notches" in the wire.

Testing has shown that a notch or scratch only .06mm or two thousandths of an inch deep in a 1.2mm wire can reduce its fatigue strength by 78%. Clinical results of monofilament wire used for reattachment of the greater trochanter show a loss of trochanteric position ranging from 2.7% to 19.4% and an incidence of wire breakage ranging from 17.2% to 26.5%.

Clearly the need for a cerclage material that is stronger and more durable than monofilament wire has been established. Multistrand cable, with its superior mechanical properties and versatility, has proven to be the solution.
Cable Implants

- Femur and Tibia Fractures: Fixation of spiral fractures in conjunction with I/M nailing techniques.
- Prophylactic Banding: In conjunction with press-fit total hip replacement.
- Stabilization of cortical onlay strut grafts
- Trochanteric Reattachment
- Humerus Fractures
- Patella Fractures
- Ankle Fractures
- Sternum Fixation after open chest surgery

Trochanteric Grip

Reattachment of the greater trochanter following osteotomy for total hip procedures or trochanteric advancement.

Cable Plates

- Fixation of femoral, tibial, or humeral fractures near the site of an intramedullary implant such as a fracture fixation nail or total joint prosthesis.
- Fixation of bone fractures where a combination of screws and cerclage cables would improve stabilization.
Cables
All cables are made with a 7 x 7 construction. Seven individual wires form a bundle and seven bundles are combined to form each cable. This construction was chosen to optimize a combination of cable strength and flexibility [Figure 1].

Cobalt Chrome (2.0mm and 1.6mm diameters) – The CoCr cables are for use in the vicinity of any CoCr or Titanium implant. The 2.0mm CoCr cable is also used in conjunction with the CoCr trochanteric grip.

Stainless Steel (2.0mm only) – The stainless steel cables are for use in the vicinity of any stainless steel implant and in conjunction with the BMP Cable Plate.

Either material can be used in applications where no implant is present. The CoCr cable implant has a breaking strength slightly greater than the stainless steel implant.

2.0mm diameter cables are the most commonly used size and are most appropriate for use on the femur where the highest loads can be seen.

1.6mm diameter cables are most commonly used when greater flexibility of the cable is required to bend around smaller diameter bones.

All cables are a generous 750mm in length to accommodate numerous applications [Figure 2].

Cable Sleeves
Three sleeves are available [Figure 3]:
- 2.0mm CoCr
- 1.6mm CoCr
- 2.0mm Stainless Steel

IMPORTANT: Sleeves are size and material specific. 2.0mm sleeves should only be used with 2.0mm cable of the same material. 1.6mm CoCr sleeves should only be used with 1.6mm CoCr cable!

Assembly
As the sleeve is crimped onto the cable, the sides of the sleeve are pressed in towards the cable, as shown in [Figure 5]. All cable sleeves must be installed with the correct side facing the surgeon to enable proper crimping of the sleeves. Notice that the side of the sleeve facing the surgeon must be wider than the side of the sleeve facing the bone. This wider side also has the etched information on it [Figures 4 & 5].

WARNING: Failure to install the sleeve with the wide side facing the surgeon could result in the inability to completely crimp the sleeve.

REMEMBER: WIDE SIDE UP / ETCHED SIDE UP
Trochanteric Grip

The BMP Trochanteric Grip is made of high strength cast cobalt chrome and is available in two sizes. Each Trochanteric Grip is used with a pair of the 2.0mm CoCr cables and does not require any additional cable sleeves (Figure 6).

Two Crimp Locations – Each cable is looped through one of the proximal or distal crimp locations. The crimping areas on the Trochanteric Grip can be compressed using the standard sleeve crimping tool.

Proximal Hooks – The proximal hooks reach over the top edge of the greater trochanter and resist the pull of the abductor forces.

Distal Spikes – The distal spikes are embedded in the lateral surface of the greater trochanter and provide rotational stability to the construct.

Connecting Bar – A single connecting bar, contoured to the curvature of the greater trochanter, maintains the structural integrity of the device.

Cable Plates*

Five lengths of cable plates are currently available and made of high strength 316L stainless steel (Figure 7). The 5mm plate thickness provides substantial support to the fracture site (Figure 8).

One Piece Construction – The BMP Cable Plate is the first to offer crimping sleeves machined as an integral part of the plate.

Cable Plates* – The BMP Cable Plate can be used in conjunction with only the 2.0mm stainless steel cable.

Compression Screw Holes – Each plate features screw holes designed to give the surgeon the option of creating compression across the fracture site. Screws are inserted eccentrically through the oval hole as far from the fracture as possible. This results in axial compression of the fracture.

The screw holes match up with the head of most standard 4.5mm stainless steel cortical bone screw designs and allow angulation of the screws in any direction. The center hole in each plate is “neutral” and does not create fracture compression.

Stainless Steel Cables –

NOTE: The BMP Cable Plate can be used in conjunction with only the 2.0mm stainless steel cable.

Cable Plate Templates

Five corresponding cable plate templates are available (Figure 9). The anodized aluminum templates are etched to indicate crimp and screw hole locations.
The installation process for any cable component tends to be a labor intensive process. Our instruments were designed with the goal of making this process as hassle free as possible. The instrumentation is designed to address the needs of the surgeon for a precise, reproducible, yet fast installation of the components. Several of these design features set our system apart from the competition.

**Tensioner Design Features**

1. **Self-Centering Cam Locks**:
   The cam lock bar on each tensioner is allowed to pivot about its center point (Figure 10). This means that the crimp sleeve can easily be centered between the guide pulleys by pivoting the cam lock bar with the surgeon’s free hand. Competitive tensioners tend to bind when the crimp sleeve touches a guide pulley.

2. **Narrow Guide Pulley Width**:
   The self-centering feature enables us to keep the width of the guide pulley assembly to a minimum (Figure 11). This allows easier access to the cable implants while tensioning in tight places.

**T-Handle Tensioner (#498007)**

The threaded T-handle design (Figure 11) enables the surgeon to tension the cable up to the actual breaking strength of the cable! This is the ultimate in tensioning capability. The surgeon tightens the cable by repeatedly turning the T-handle in a clockwise direction.

**Crimper (#498003)**

This single Crimper is all that is needed to precisely and repeatedly crimp all of the BMP Cable Sleeves, Trochanteric Grip crimp locations, and Cable Plate crimp locations (Figure 12).

- **20 to 1 mechanical advantage** means easy one-hand operation.
- **Ratchet Mechanism**: prevents “under crimping” of the sleeves by not allowing the crimper to release from the sleeve until a minimum crimping level is achieved by the surgeon.
- **Dead Stop Mechanism**: The crimper hits a dead stop inside the linkage which prevents the surgeon from “over crimping” the sleeves. Some competitive crimpers allow over crimping of the sleeves which could cause sleeve damage or notching of the cable. This could result in the loss of cable tension or early failure of the assembly.
- **These two features combine** to ensure that every cable sleeve is crimped precisely and consistently.
**Cable Passers**  
(Small #498009/  
Large #498008)  
Two sizes of Cable Passers are available to correspond with the diameter of bone that you are cabling. Each passer is a simple, one-piece construction with nothing to assemble or disassemble. Both passers work with all cable sizes [Figure 13].

**Cable Cutter**  
(#498010)  
The BMP Cable Cutter works on a principle of “offsetting circles” to effortlessly shear the cable, producing a cleanly cut, frayless end [Figure 14]. The design allows the surgeon to cut the cable much closer to the edge of the crimp sleeve than most competitive instruments [Figure 15]. Just a single cutter required to cut both 1.6mm and 2.0mm diameter cables.  
**CAUTION:** This cutter is designed to cut cables only. Do not attempt to cut pins or wires!

**Impactors**  
Two Trochanteric Grip Impactors are available to suit the surgeon’s preference.

**Standard**  
Trochanteric Grip Impactor (#498006)  
The Grip Impactor is used for simple impaction of the grip into the greater trochanter [Figure 16]. The plastic impact surface prevents damage to the implant and especially the crimp locations during impaction.

**Manipulator/Impactor**  
(#498011)  
The Manipulator/Impactor firmly clamps onto the Trochanteric Grip to aid in the positioning and insertion of the implant [Figure 17]. The device enables the surgeon to use the trochanteric grip hooks to pull the trochanteric fragment down into position against the abductor tension while tightening the cables.

The Manipulator/Impactor also clamps onto the crimp sleeves of the cable plate. This aids the surgeon when positioning the plate on the bone, reducing the bone fragments, and installing cables or screws.

**Instrument Cases**  
(#592038)  
The #592038 case accommodates two of the T-Handle Tensioners and all other cable instruments [Figure 18]. The case will accommodate either the impactor or the manipulator/impactor but not both simultaneously.

**Cable Cutter**  
(#498010)  
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1. **Passing the Cable**

Hook one of the two Cable Passers around the bone (#498008 or #498009). Next feed the cable into the hole nearest the handle of the Passer until the cable completely surrounds the bone. Remove the Cable Passer while leaving the cable in place (Figure 20).

2. **Sleeve Positioning**

Insert each end of the cable through the holes in the sleeve from opposite directions.

*It is imperative that the narrow side of the sleeve be against the bone and the wider, etched side face the surgeon* (Figure 20). *This positioning enables the crimper to properly engage the sleeve.* (Figure 21 & Figure 22)

3. **Cable Tensioning**

Option B. T-Handle Tensioner (#498007) (Figure 23). Prepare the tensioner for operation by first positioning the cam lock mechanism down near the guide pulleys by turning the T-Handle counterclockwise.

Next, hook each end of the cable around the guide wheels and back through the automatic cam locks.

Pull on each cable end to remove any slack.
Turning the T-Handle clockwise will now move the cam lock mechanism toward the handle automatically locking the cable and applying equal tension to the cables [Figure 24].

**TIP:** It is now easy to center the crimp sleeve between the guide wheels by simply pivoting the cam lock bar. This is a major advantage over the competition!

Tension can be released from the cable at any time by turning the T-Handle counterclockwise.

4. **Crimping the Sleeve**

After reaching the desired cable tension, the Crimper (#498003) is used to crimp the sleeve. Place the crimper jaw over the sleeve and squeeze the handles together [Figure 25].

The ratchet mechanism in the crimper, prevents under crimping of the sleeve by precisely controlling the amount of sleeve deformation. The handles must reach a designated position before they will release from the crimp sleeve ensuring a minimum crimp. This ratchet mechanism is a safety feature pioneered by the BMP Cable System. A dead stop built into the crimper will also prevent the surgeon from over crimping the sleeve which could cause cable notching or sleeve damage.

As the sleeve is crimped onto the Cable, the sides of the sleeve are pressed in toward the cable. All cable sleeves must be installed with the correct side facing the surgeon to enable proper crimping. The side of the sleeve facing the surgeon must be wider than the side of the sleeve facing the bone. This wider side also has the etched information on it.

After the sleeve has been crimped, the surgeon should remove the tension from the cable by turning the T-Handle counter clockwise, automatically releasing the cable. The tensioner is now removed.

5. **Cutting the Cable**

The cable is easily cut by passing each cable end through the hole in the Cable Cutter (#498010) and squeezing together the handles [Figure 26]. The "offsetting circles" concept design ensures a clean cut without fraying of the cable ends.

Each cable should be cut as close to the crimp sleeve as possible.
Osteotomy of the greater trochanter is often performed for technically difficult reconstructions of the proximal femur; revision, and sometimes primary total hip replacement. It can also be used during trochanteric advancement procedures such as a sliding trochanteric osteotomy. The BMP trochanteric grip offers the surgeon a proven and effective means to stabilize the trochanteric bone fragment and thus aid in the bony union.

Several patterns of cable routings have been used by surgeons to resist the abductor forces and securely reattach the greater trochanter. Some of these options are shown at right:

- Trochanteric Grip with cables routed around a cemented stem (Figure 27).
- Trochanteric Grip with cables routed through the anterior and posterior cortices lateral to the stem (Figure 28).
- Trochanteric Grip with cables routed medially through the lesser trochanter, femoral neck, or allograft (Figure 29).

Although many options are available, the goal for each is the same.

The osteotomy surfaces are very rough and cancellous in nature. The goal of all the techniques is to provide compressive forces between these rough surfaces and thereby increase the frictional resistance to the superior shearing forces. This increases the strength and rigidity of the fixation. By routing the cables in a proximal lateral to distal medial direction, part of the abductor muscle forces are also counteracted by the tension in the cables.

Surgical indications will dictate which cable routing is most appropriate for each specific case. The following surgical technique will focus on the steps taken to reduce the greater trochanter and secure the trochanteric grip into place. It is independent of the method of cable routing chosen. The Cable Passers (#498008 and #498009) can be utilized to facilitate the passing of the cables around the femur.
1. **Reducing the Trochanteric Fragment**

Reduction is facilitated by holding the femur in a slightly flexed, internally rotated, and abducted position. The trochanteric fragment can then be reduced by pulling it into the desired position using standard bone reduction forceps or a common bone hook. The trochanteric grip mounted onto the Manipulator/Impactor (Figure 30) can also be used to reduce the trochanteric fragment.

The surgeon also has the option of “advancing” the greater trochanter at this time. This is done by replacing the trochanteric fragment in a more distal position to tighten the abductor muscles and increase the abductor lever arm.

2. **Introducing the Trochanteric Grip**

The Trochanteric Grip implant can be securely attached to the Manipulator/Impactor (#498011) by tightening the knob (Figure 31). This assembly then becomes an excellent instrument to hook the proximal edge of the trochanteric fragment and aid in the positioning of the fragment on the femur.

The cables are most easily routed through the Trochanteric Grip prior to positioning the grip onto the bone. The proximal hooks of the Trochanteric Grip are positioned through the abductor muscle insertions and over the proximal edge of the trochanteric fragment. **NOTE:** The proximal hooks must pass through the abductor muscle insertions as close to the bone as possible. The excess cable slack should be taken up by hand as the implant is moved into position.

3. **Initial Seating of the Trochanteric Grip**

The grip is then embedded into the trochanteric fragment by impacting lightly on the Manipulator/Impactor (Figure 32). The plastic surface of the instrument prevents damage to the implant. The goal is to engage the distal spikes into the trochanteric fragment and thus provide rotational stability to the construction.

4. **Cable Tensioning and Final Positioning**

Two Cable Tensioners should be used simultaneously to tension both the proximal and distal cables (Figure 33). The Cable Tensioners are installed on the cables and the cables are secured into the cam lock mechanism of the tensioner. Pull on each cable end to remove any slack. The cam lock bar can be pivoted to center the trochanteric grip between the guide pulleys. Turn the T-handle clockwise to tension the cable. If the surgeon still requires the Manipulator/Impactor in place, a tensioner should be positioned on either side of the handle as shown.
An assistant can now handle the tensioner as the surgeon manipulates the trochanteric fragment into its final position. This can be accomplished with a variety of instruments including the Manipulator/Impactor or a common bone hook passed over the top of the greater trochanter. While the desired position is being maintained, the cables can be tightened by using the tensioners and secure the Trochanteric Grip in place. The Manipulator/Impactor may be removed if the desired stabilization is achieved.

5. Final Seating and Cable Tensioning

Verify that the proximal hooks have properly engaged in the proximal edge of the trochanter. Sometimes hard bone can prevent firm engagement of the hooks. The grip is now fully seated with an Impactor (#498006 or #498011) (Figure 34). The impacting should always be in a distal direction to prevent the trochanteric fragment from slipping proximally during impaction.

The cables are now fully tensioned and any slack created by the Impactor is eliminated.

The firm fixation of the trochanter can be verified by manipulation of the femur while palpating and visually inspecting for any movement between the trochanteric fragment and the femur. If the position or fixation of the trochanter is not satisfactory, repeat the tensioning and final seating process.

6. Crimping of the Trochanteric Grip to the Cables

The Trochanteric Grip can now be crimped using the Crimper (#498003) (Figure 35). **NOTE: No cable sleeves are required!** The crimping section of the trochanteric grip acts as the crimping sleeve. The area can be crimped twice to utilize the entire width of the crimp area for maximum holding power.

7. Cutting the Cable Ends

The free ends of the cable can now be easily cut by passing each end through the hole in the Cable Cutter (#498010) (Figure 36) and squeezing together the handles. Each cable should be cut as close to the trochanteric grip as possible.
MECHANICAL TESTING

Testing was performed with the objective of proving that the strength of the BMP Cable System was equivalent, or superior, to that of a competitive device. The ultimate strength of the cable as well as the cable/sleeve assembly was determined for both the BMP and Cobalt Chrome Control Group Components.

Cable Tensile Test:

Cable Avg. Breaking Tension
Biomet 2.0mm CoCr: 602lb.
Control Components 2.0mm CoCr: 583lb.

Cable/Sleeve Assembly Loop Test:

Avg. load until slipping Cable/Sleeve of cable within the sleeve
Biomet: 2.0mm CoCr: 584lb.
Control Group: 2.0mm CoCr: 505lb.
### Stainless Steel Cable and Sleeves

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*Not required for use of cable plate*

### 316 L Stainless Steel Cable Plates

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### Stainless Steel 4.5mm Cortical Screws

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<td>1.6mm dia. x 750mm cable and 1.6mm sleeve</td>
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### Cobalt Chrome Implants

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### Stainless Steel 4.5mm Cortical Screws

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### Cylinder 4.5mm Cortical Screws

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<td>Cable Passer – Lrg</td>
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<td>Cable Cutter</td>
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<td>498011</td>
<td>Trochanteric Grip Manipulator/Impactor</td>
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<td>592638</td>
<td>Sterilization Case</td>
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