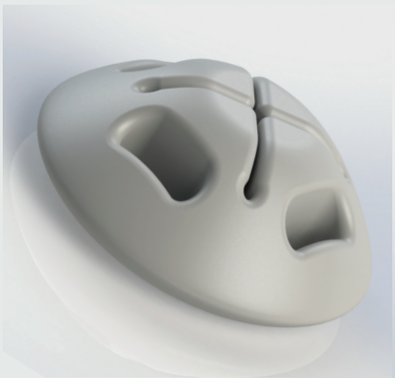
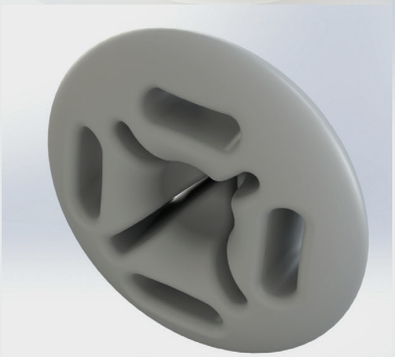
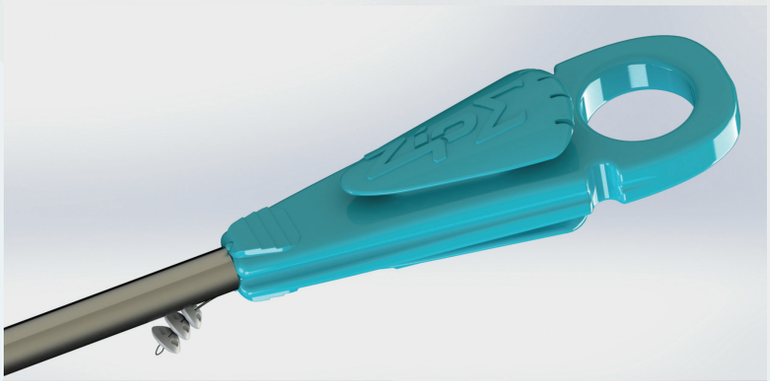
KNOTLESS TISSUE REPAIR AND ATTACHMENT

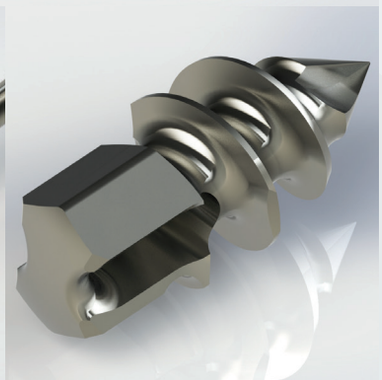
SURGICAL TECHNIQUE

Ziptek LLC









SUTURE CONFIGURATIONS

Single Series
Single Parallel
Double Parallel
Drop-Back-Series-Suture-Strand
Horizontal Mattress
Double Row

Ziptek's recommended suture configurations for the ZipE suture retention capture include; single parallel, double parallel, horizontal mattress, double row or a single series with a "drop back series suture strand" to the main screw or additional screw.

Ziptek cautions that surgeons should choose constructs that are best suited for tissue repair based upon tear size, configuration, tissue quality, likelihood of "rip-through", and strength.

If the surgeon chooses the Single Series configuration for primary fixation, the construct's capture's strength approaches that of a #2 braided polyester suture rather than a #2 UHMWPE braided suture. Ziptek recommends that the single series configuration be reserved for dog ears, or to supplement double row configurations, or other parallel suture configurations. If mandatory, the tendon sided suture retention capture's suture limb can be shuttled through the same screw for double bone fixation or brought through an additionally placed screw with a shuttle technique ("drop-back-series-suture-strand").

- The single series suture configurations approach the failure strength of a #2 braided polyester suture, and the surgeon should use surgical judgment as to when this is applicable.
- Single parallel suture configurations approach the failure strengths of a #2 braided UHMWPE suture.
- Double Parallel configurations approach the failure strengths of two #2 braided UHMWPE sutures.
- Adding a "drop-back-series- suture-strand" from one of the suture strands in parallel back to the screw further increases the failure strength.

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STEP 1

DRIVER PREPARATION
The driver has a hex head which covers the outer side of the screw. It has a sharp cutting edge. The device comes with up to two sutures and one doubled-nitinol suture shuttle wire. The sutures and wire are held in cleats on the driver handle, securing the screw to the tip of the driver shaft.

STEP 2

CANNULA INTRODUCTION
The driver with the self tapping screw are introduced into the cannula. A small hammer tap may be required to get the screw started.

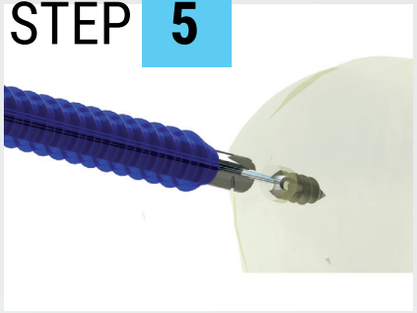
STEP 3

COUNTERBORE
The screw is screwed into the bone. Note that the outer edge of the driver hex is sharp and creates a counter bore and is removing bone greater than the width of the screw. It also countersinks the screw below the surface of the bone to a depth of 2.6 mm, allowing for placement of the suture capture flush with the bone.

STEP 4

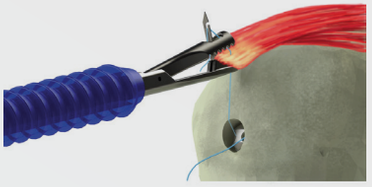
CLEAT RELEASE
This is an outside view of the handle, the sutures and the wire must be released from the cleats

STEP 5



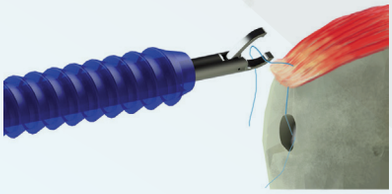
DRIVER RELEASE
Once released the driver is pulled directly back from the screw which is countersunk into the bone.

STEP 6



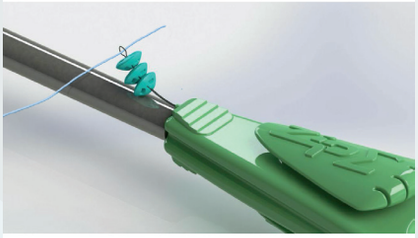
SUTURE PASSER
One strand is passed through the tendon with a standard suture passing instrument.

STEP 7



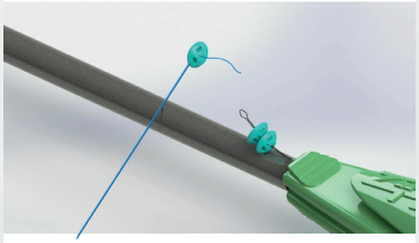
SUTURE RETRIEVER
The suture is retrieve with a grasper out through the same cannula

STEP 8



CAPTURE HOLSTER
This illustration shows one of the sutures being threaded through the wire loop of the capture holster.

STEP 9



CAPTURE LOADING
This step shows the capture sliding over the suture and disengaging itself from the capture holster.

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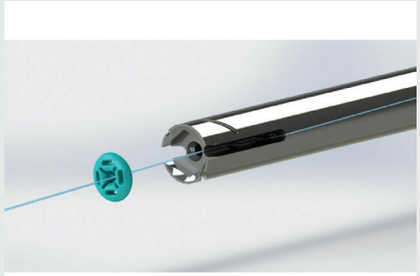
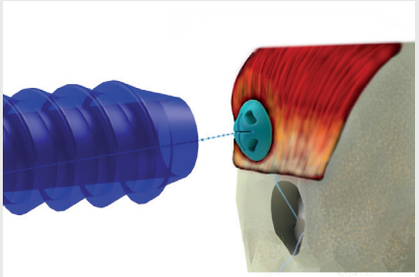
STEP 10



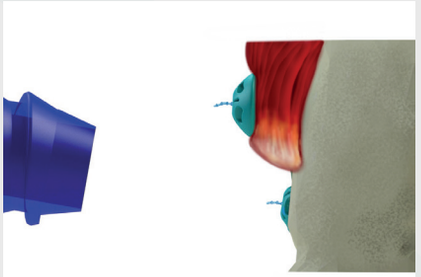
DRIVER LOADING-CAPTURE PUSHER
Following the driver engages the suture capture and pushes the capture down through the cannula. The driver should push the capture along the line of the suture strand as the edges of the driver are sharp and if angulated to the suture may cut it.

STEP 11



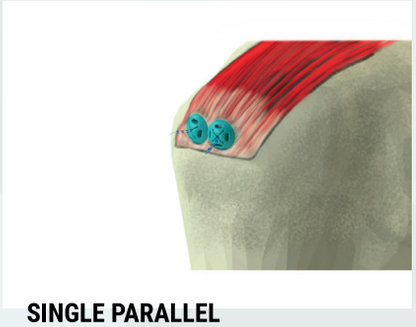
CAPTURE PUSHER AND TENSION OPPOSITE LIMB
The capture driver has pushed the capture on top of the tendon and there it remains seated. In order to achieve this, the opposite strand must be held firmly as nearly 6lbs of force is required to seat the suture capture.

STEP 12



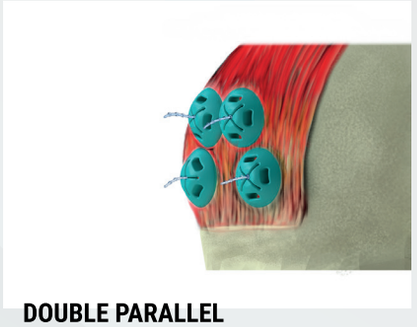
SINGLE SERIES
Take the suture strand that is remaining and place another capture. This capture can then be slid down over the screw head and be seated flush with the surface of the bone that was made from the counter-bore effect of the driver.

STEP 13



SINGLE PARALLEL
Rather than placing the capture down over the screw head, the second strand is passed through the tendon. The capture is loaded and the driver is used to run it down over the tendon.

STEP 14



DOUBLE PARALLEL
Steps 1-15, (as applicable) are repeated, with the second suture strand with the exception of step 13 and four captures are seated upon the tendon.

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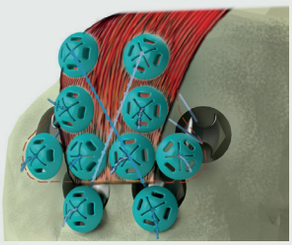
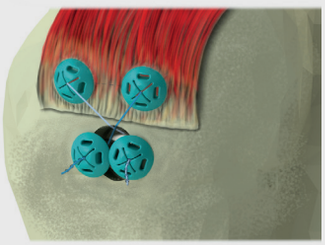
SUTURE SHUTTLE STEPS

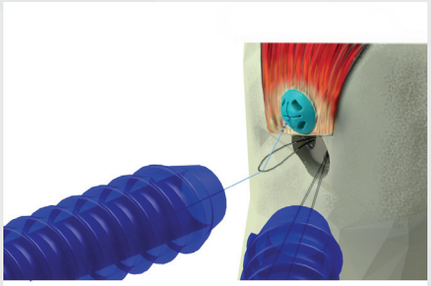
*Strands have already been passed through the tendon



Double Row

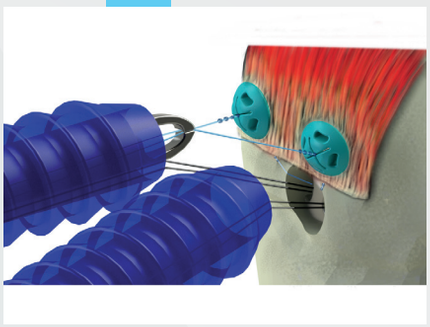


Horizontal Mattress



Drop-back-series-suture-strand

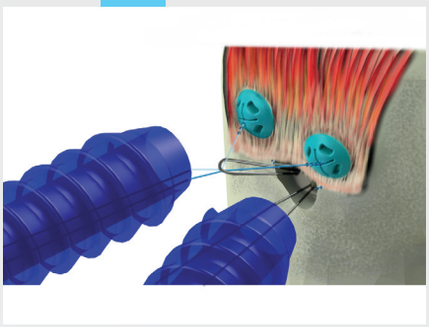
STEP A



DOUBLE SUTURE RETRIEVAL

Seating of the capture on top of the tendon.

STEP B



LOADING SUTURE SHUTTLE

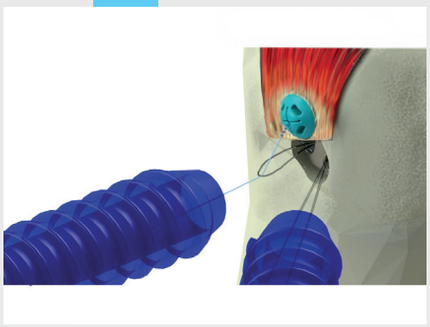
One or more suture strands are threaded through the wire loop. If two sutures are shuttled then there will be bone sided fixation x 2. If only one is shuttled, the second can be shuttled through an alternate screw.

The surgeon holds the end of the strand against itself after having been passed through the loop. The suture should be passed through the loop to a length that is needed to pass down through the screw and out through the cannula, roughly 8-10 inches.

The two ends of the wire are then pulled as the looped wired engages the suture strand being held in a loop by the surgeons fingers and the loop pulls the eight-ten inches forward and down the cannula. The surgeon does not let go, but follows with the looped strand under slight tension until the loop disappears into the cannula. The result being, the 8-10 inch tail of the suture strand will be brought down and shuttled through the screw and out through the same cannula.

The suture captures can be run down and placed directly over the screw on the bone side. The counter bore is made so one capture sits flush with the bone surface. If two sutures are shuttled, then the driver tip can create another countersink next to the first one and the second suture capture can rest there.

STEP C



ADDITIONAL SCREW POST

One suture can be passed through the initial screw using the suture wire shuttle from the same screw and the surgeon may choose to place a second screw with a wire suture shuttle and the second end of the suture strand can be shuttled through this additional screw. The surgeon may still use the suture in the second screw to create another single series, single parallel or double parallel configuration- see illustration.

Once the suture is retrieved a capture can be run down this suture strand and placed over the screwhead in the counterbore area. The driver tip should be utilized to create a second bore next to the screw head and following a second capture can be placed on the remaining suture strand and brought down and seated next to the first- both on the bone side's

*All cutting steps should leave behind at least two visible knots.

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KNOTLESS TISSUE REPAIR AND ATTACHMENT SOLUTION DEVICES

Description:
The ZipE® Knotless Tissue Repair and Attachment Solution Devices are implantable suture retention devices comprising of a button suture-capture, a bone anchor, and a beaded suture. The beaded suture constructed from ultra-high molecular weight polyethylene (UHMWPE) is passed through the button suture-capture and the bone anchor, thus creating a knotless soft tissue fixation device that locks against the bone when deployed.

Materials:
Beaded suture - Ultra high molecular weight polyethylene (UHMWPE)
Suture-capture - Poly-L-lactide/caprolactone copolymer, polycarbonate polyurethane
Bone anchor screw - Titanium, Poly(L-lactide-co-D,L-lactide)/ß-Tri-calcium phosphate

Indications:
ZipE® Knotless Tissue Repair and Attachment Solution Devices surgical suture-capture provides orthopedic surgeons with a knotless soft-tissue repair solution that allows tissue to be repaired without having to tie knots. This is especially useful during minimally invasive surgical procedures when using an arthroscope or endoscope. It is intended for fixation of tissue to bone by distributing suture tension over a greater surface area than traditional knots. [Suture Retention Device, 21 CFR 879.4930, Product Code KGS]

The ZipE® Knotless Tissue Repair and Attachment Solution Devices' Suture Anchor is intended for fixation of tissue to bone. This product is indicated for the following indications:

SHOULDER: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction

FOOT/ANKLE: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament Repair

KNEE: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis, ACL reconstruction, meniscal root repair and medial patellofemoral ligament repair

HAND/WRIST: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction

ELBOW: Biceps Tendon Reattachment, Tennis Elbow Repair, Ulnar or Radial Collateral Ligament Reconstruction

HIP: Labral and capsule repair.

Contraindications
1. Infection.
2. Patient conditions including blood supply limitations, and insufficient quantity or quality of bone or soft tissue.
3. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
4. Foreign body sensitivity. Where material sensitivity is suspected, testing should be completed prior to implantation of the device.

ZIPTEK, LLC
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FDA-6600-1 REV.1 03/03/2015

PATENTS

ROTATOR CUFF DEVICE
#6013083

ROTATOR CUFF METHOD
#6206886

TISSUE REPAIR SYSTEM
#6,491,714 B1

TISSUE ATTACHMENT SCREW
#8,814,904 B2

LOCKING SUTURE RETENTION DEVICE
#8,845,686

ZipE® SUTURE BUTTON/CAPTURE
US APPLICATION- #13/664,717

ZipE® SUTURE CAPTURE METHOD
-DRIVER-MOLD
PCT 2014 #14/22973- WIPO-PATENTABLE

ZipE® SCREW-DRIVER-MOLD
US APPLICATION- #14203846

ZipE® SCREW-DRIVER-MOLD
US DESIGN APPLICATION- #29484538

EUROPEAN APPLICATION
#11 837011.3

MEXICAN APPLICATION
#MX/A/2013/004662

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WARNINGS

ZipE® Knotless Tissue Repair and Attachment Solution Devices products, provide the surgeon with a means of aid in the management of soft tissue to bone reattachment procedures. While these devices are generally successful in attaining these goals, they cannot be expected to replace normal healthy bone or withstand the stress placed upon the device by full or partial weight bearing or load bearing, particularly in the presence of nonunion, delayed union, or incomplete healing. Therefore, it is important that immobilization (use of external support, walking aids, braces, etc.) of the treatment site be maintained until healing has occurred. Surgical implants are subject to repeated stresses in use, which can result in fracture or damage to the implant. Factors such as the patient's weight, activity level, and adherence to weight bearing or load bearing instructions have an effect on the service life of the implant. The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of the implant, but also must be aware of the mechanical and metallurgical aspects of the surgical implants.

1. Correct selection of the implant is extremely important. The potential for success in soft tissue to bone fixation is increased by the selection of the proper type of implant. While proper selection can help minimize risks, neither the device nor grafts, when used, are designed to withstand the unsupported stress of full weight bearing, load bearing or excessive activity.

2. The implants can loosen or be damaged and the graft can fail when subjected to increased loading associated with nonunion or delayed union. If healing is delayed, or does not occur, the implant or the procedure may fail. Loads produced by weight bearing and activity levels may dictate the longevity of the implant.

3. Inadequate fixation at the time of surgery can increase the risk of loosening and migration of the device or tissue supported by the device. Sufficient bone quantity and quality are important to adequate fixation and success of the procedure. Bone quality must be assessed at the time of surgery. Adequate fixation in diseased bone may be more difficult. Patients with poor quality bone, such as osteoporotic bone, are at greater risk of device loosening and procedure failure.

4. Implant materials are subject to corrosion. Implanting metals and alloys subjects them to constant changing environments of salts, acids, and alkalis that can cause corrosion. Putting dissimilar metals and alloys in contact with each other can accelerate the corrosion process that may enhance fracture of implants. Every effort should be made to use compatible metals and alloys when marrying them to a common goal, i.e., screws and plates.

5. Care is to be taken to insure adequate soft tissue fixation at the time of surgery. Failure to achieve adequate fixation or improper positioning or placement of the device can contribute to a subsequent undesirable result.

6. The use of appropriate immobilization and postoperative management is indicated as part of the treatment until healing has occurred.

7. Correct handling of implants is extremely important. Do not modify implants. Do not notch or bend implants. Notches or scratches put in the implant during the course of surgery may contribute to breakage. Intraoperative fracture of screws can occur if excessive force (torque) is applied while seating bone screws.

8. Do not use excessive force when inserting suture anchors. Excessive force (e.g., long, hard hammer blows) may cause fracture or bending of the device. Prior to insertion of the implant, predrill, awl, or tap.

9. DO NOT USE if there is a loss of sterility of the device.

10. Discard and DO NOT USE opened or damaged devices, and use only devices that are package in unopened or undamaged containers.

11. Ensure contact of tissue to bone when implanting. DO NOT OVERTIGHTEN the screw. Structural damage to the tissue and implant may occur if the screw is overtightened.

12. Adequately instruct the patient. Postoperative care is important. The patient's ability and willingness to follow instructions is one of the most important aspects of successful fracture management. Patients effected with senility, mental illness, alcoholism, and drug abuse may be at a higher risk of device or procedure failure. These patients may ignore instructions and activity restrictions. The patient is to be instructed in the use of external supports, walking aids, and braces that are intended to immobilize the fracture site and limit weight bearing or load bearing. The patient is to be made fully aware and warned that the device does not replace normal healthy bone, and that the device can break, bend or be damaged as a result of stress, activity, load bearing, or weight bearing. The patient is to be made aware and warned of general surgical risks, possible adverse effects, and to follow the instructions of the treating physician. The patient is to be advised of the need for regular postoperative follow-up examinations as long as the device remains implanted.

13. The ZipE® Knotless Tissue Repair and Attachment Solution Devices' Suture-captures are used with a size #2 UHMWPE suture or one of equivalent or greater strength, unless otherwise indicated.

POSSIBLE ADVERSE EFFECTS

1. Nonunion or delayed union of tissue, which may lead to breakage of the implant.
2. Bending or fracture of the implant.
3. Loosening or migration of the implant.
4. Metal sensitivity, or allergic reaction to a foreign body.
5. Pain, discomfort, or abnormal sensation due to the presence of the device.
6. Nerve damage due to surgical trauma.
7. Necrosis of bone or tissue.
8. Inadequate healing.
9. Intraoperative or postoperative bone fracture and/or postoperative pain
10. Loose Body

PACKAGING, STORAGE AND LABELING

ZIPTEK, LLC products should only be accepted if the factory packaging and labeling arrive intact. Products must be stored in the original unopened packaging, away from moisture and should not be used after the expiration date.

STERILITY

The device is supplied sterile. Do not resterilize. Check the package label for the sterilization method.

CAUTION:

Federal Law (USA) restricts to sale by or on the order of a physician.

AUTHORIZED REPRESENTATIVE: Ziptek, LLC 1250 S. Tamiami Trail Suite 303 Sarasota, FL 34239 US

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ORDERING INFORMATION

KNOTLESS TISSUE REPAIR AND ATTACHMENT SOLUTION DEVICES

MATERIAL CODES

PRODUCT #	DESCRIPTION
A6-6550-S	ZIPE 6.5 MM POLYCARBONATE/URETHANE CAPTURE, 5.0 MM TITANIUM SCREW
A6-6545-S	ZIPE 6.5 MM POLYCARBONATE/URETHANE CAPTURE, 4.5 MM TITANIUM SCREW
* RA6-6550-S	ZIPE 6.5 MM PLA/CAPROLACTONE CAPTURE, 5.0 MM PLDLA/BTCP PLUG
* B71-S-4	CAPTURE HOLSTER WITH 4 PCS OF POLYCARBONATE/URETHANE CAPTURES
* RB71-S-4	CAPTURE HOLSTER WITH 4 PCS OF PLA/CAPROLACTONE CAPTURES
* C3-0236-UPE	36” #2 USP UHMWPE KNOTTED SUTURE
* C4-2040-NI	40" NITINOL WIRE SUTURE SHUTTLE
* C2-50155-TI	25.0 MM TITANIUM SCREW - QTY. 2
* C2-45155-TI	24.5 MM TITANIUM SCREW - QTY. 2
* RC2-50155-PLT-2	5.0 MM PLDLA/BTCP PLUG - QTY.2

*Check on Availability

1250 S. Tamiami Trail Suite 303 Sarasota, FL 34239 US

PRO-4400-7-1

http://www.ziptekglobal.com/