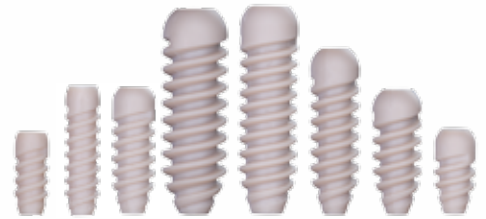


G-FORCE™

Tenodesis System

SURGICAL TECHNIQUE



Design Surgeons:

Gregory C. Berlet, MD

Hodges Davis, MD

Carroll Jones, MD



Contents

Chapter 1	3 Introduction
	Product Information
Chapter 2	4 Surgical Technique
	8 Additional Information
	Instrument Tray
	Ordering Information

G-FORCE™ Tenodesis System

Surgical Technique as described by Gregory C. Berlet, MD; Hodges Davis, MD; and Carroll Jones, MD

Proper surgical procedures and techniques are the responsibility of the medical professional. The following guidelines are furnished for information purposes only as techniques used by the design surgeons. Each surgeon must evaluate the appropriateness of the procedures based on his or her personal medical training and experience. Prior to use of the system, the surgeon should refer to the product package insert for complete warnings, precautions, indications, contraindications and adverse effects. Package inserts are also available by contacting Wright Medical Technology, Inc.

In the US there are approximately 120,000 foot and ankle procedures performed annually requiring the attachment of soft-tissue to bone. With nearly as many ACL reconstructions and over twice as many rotator cuff repairs performed each year, the clinical need for effective soft-tissue fixation is extensive. The G-FORCE™ Tenodesis System provides 35% higher pull-out strength* than a leading tenodesis screw, intra-operative tendon tensioning via a novel Suture Loop Guide Rod, a radiolucent PEEK-OPTIMA® screw material, and a non-catastrophic mode of screw failure.

*Under simulated clinical conditions. WMT data on file: ER08-0098.

Product Information

G-FORCE™ Tenodesis Screws are indicated for use in soft-tissue reattachment procedures in the shoulder, foot/ankle, knee, elbow and wrist/hand where the sizes offered are patient appropriate. Tenodesis screw sizes are as follows:



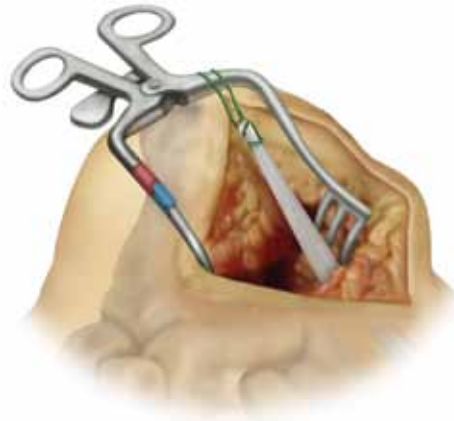
The implants are provided single-packed sterile, while the Suture Loop Guide Rods are provided single-packed non-sterile for convenient kit replenishment.

Tendon Attachment Surgical Technique

1) USE PREFERRED TECHNIQUE TO EXPOSE TENDON OF INTEREST.

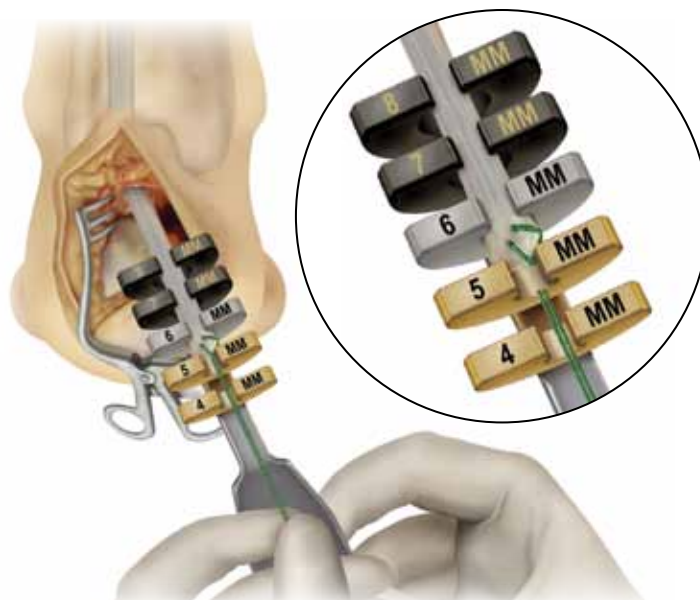
If tendon transfer is being performed, detach as needed. If an avulsed tendon is being re-attached, locate detached tendon end.

2) USE SUTURE OF CHOICE TO WHIPSTITCH TENDON END.



3) TIGHTLY PULL THE TENDON THROUGH THE RINGS OF THE TENDON SCALE TO GAUGE TENDON SIZE.

Holding the suture with one hand, tightly pull the tendon through the rings of the Tendon Scale. The tendon size will be the size of the last ring the tendon fits through, completely filling inner diameter. For example, if the tendon fits through and fills the size 6 ring but does not fit through the size 5 ring, the tendon is sized 6mm.



4) IT IS SUGGESTED THAT THE DRILL AND SCREW SIZE SHOULD EACH BE ONE SIZE LARGER THAN THE TENDON SIZE.

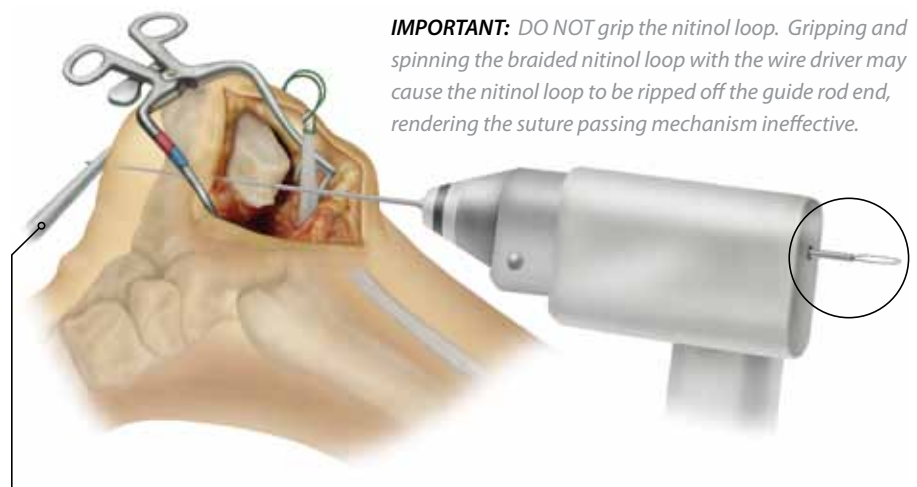
However, it is up to the surgeon to determine which technique is appropriate for each patient. Using the previous example, if the tendon is sized 6mm, a 7mm reamer and screw should be selected. Note the color-coding on the Tendon Scale. If the tendon is a size 6, locate the ring one size larger – in this case the 7mm ring – which is black. For reaming you will now use the black tissue protector tube, black 7mm reamer, and the black driver for the 7mm screw.

NOTE: Screw sizing with the G-FORCE™ System may vary from other tenodesis screw systems. In hard bone an attempt to achieve greater interference by inserting an 8mm screw into a 7mm hole for a 6mm tendon, for example, can make the resulting fit too tight. This can make removal of the driver difficult, can bend the driver tip upon removal, and/or can fracture the bone surrounding the hole.

NOTE: In especially soft bone, line-to-line sizing for a greater interference fit may be desired.

5) INSERT THE SUTURE LOOP GUIDE ROD INTO AND THROUGH THE BONE IN THE DESIRED TENDON ATTACHMENT LOCATION.

The guide rod has a braided nitinol loop designed to help pass the suture for tendon tensioning. Leave this loop exposed out the back of the wire driver.

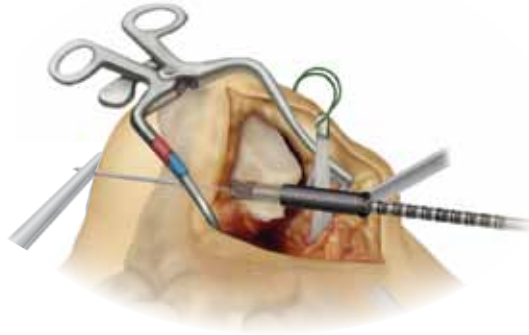


IMPORTANT: DO NOT grip the nitinol loop. Gripping and spinning the braided nitinol loop with the wire driver may cause the nitinol loop to be ripped off the guide rod end, rendering the suture passing mechanism ineffective.

HINT: Clamp the now-exposed sharp rod end to avoid pulling the rod out of the bone as the wire driver is removed, and to hold in place while reaming the bone hole. Remove the wire driver.

6) REAM BONE HOLE.

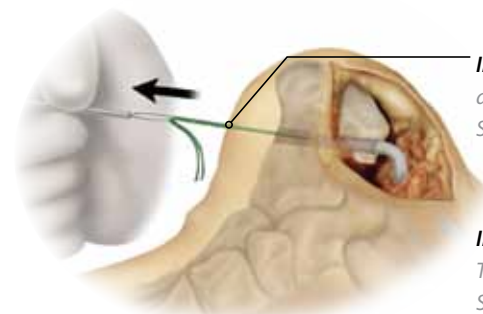
Place the tissue protector over the Suture Loop Guide Rod prior to drilling the bone hole. Next, place the appropriately sized cannulated reamer over the Suture Loop Guide Rod and through the tissue protector, reaming a pilot hole in the bone for the implant and tendon. If a through-hole technique is preferred, ream completely through the bone. If a blind-hole technique is preferred, hole depth can be measured off of the tissue protector and laser marks on the reamer shaft. Note: Tissue protector must be in complete contact with bone for accurate depth reference. In the current example a 7mm screw has been selected. Use the black 7mm cannulated reamer and black tissue protector insert. Since the 7mm screw only comes in a 25mm length, drill down 25mm, with depth measured off the laser marks on reamer as read from the top of the tissue protector. Be sure to ream deep enough – in this case at least 25mm – to ensure the screw head will not sit proud to the cortical bone surface when fully inserted. Remove the reamer. If a blind-hole technique is being used, measuring the tendon length and marking should be done at this time by ensuring tendon length is sufficient to fill the depth of the reamed hole.



7) PASS THE ENDS OF THE WHIPSTITCHED SUTURE THROUGH THE NITINOL SUTURE LOOP OF THE GUIDE ROD.



8) USE THE SUTURE LOOP GUIDE ROD TO PULL THE SUTURE THROUGH THE BONE HOLE.

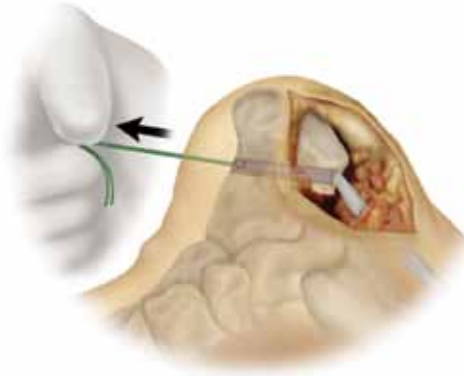


IMPORTANT: Make stab incision in soft-tissue at Guide Rod exit point to prevent suture and Suture Loop from getting caught in soft-tissue.

IMPORTANT: DO NOT USE WIRE DRIVER TO PASS GUIDE ROD. Pass the rod by hand. Spinning the rod once suture has been threaded will bind suture and may rip Suture Loop.

9) MANUALLY TENSION THE TENDON.

Pull the suture to manually achieve optimal tension of the tendon.



NOTE: If using the blind-hole technique, ensure tendon length does not prevent proper tensioning. If tendon is too long, cut to appropriate length, re-whipstitch tendon end, pass suture through bone hole, and tension as needed.

10) INSERT SCREW.

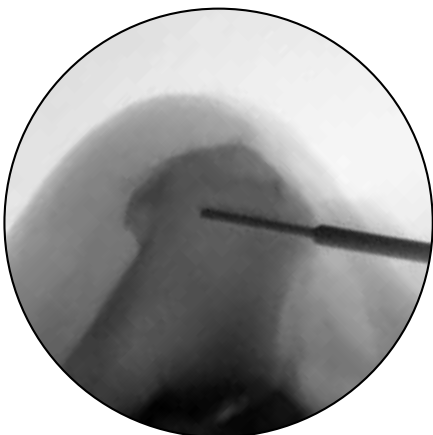
Load the appropriately sized G-FORCE™ Tenodesis screw onto its respective driver. In this example, the black driver is used for the 7mm screw, as shown. Locate the pilot hole using the protruding tip of the driver, and insert the G-FORCE™ Tenodesis screw into the hole to the desired depth using the ratcheting driver handle. It is recommended that the spherical G-FORCE™ Tenodesis screw head be placed flush with the bone's cortical surface. When the screw is completely inserted, remove the driver.



NOTE: If the driver seems to be stuck in the screw, reverse the screw approximately 1/8 of a turn to loosen the driver tip from the screw.

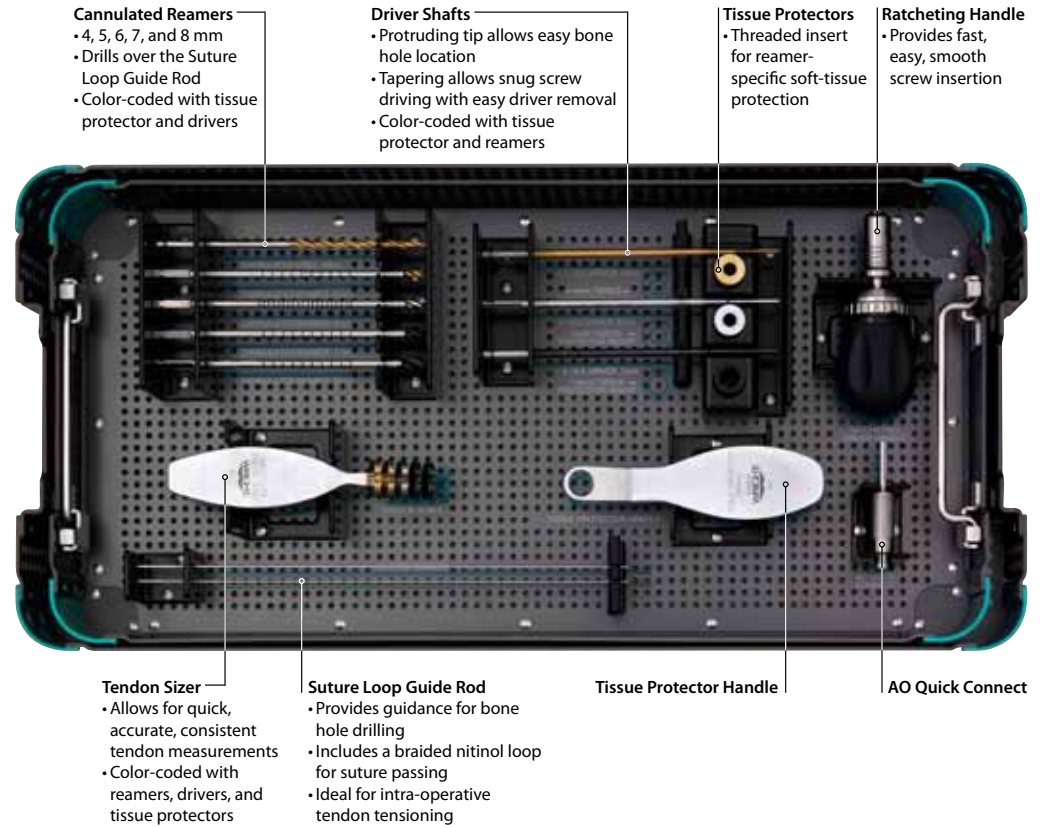
11) MANUALLY FLEX THE JOINT TO ENSURE THE TENSION OF THE TENDON IS APPROPRIATE UNDER NORMAL RANGE OF MOTION.

Under X-ray check the location of the screw if desired. Since the PEEK-OPTIMA® screw is radiolucent, the driver must be inserted while taking the image, as shown. If tendon tension is appropriate, proceed to close soft-tissue. If tension is not appropriate, insert driver into G-FORCE™ Tenodesis screw, remove screw, and manually adjust tension as needed.



G-FORCE™ Tenodesis System

Instrument Tray



Ordering Information

Implant (l x w)	Catalog No.	Implant (l x w)	Catalog No.		Catalog No.
4 mm x 10 mm	86PS0410	6 mm x 15 mm	86PS0615	Instrument Kit	86PSKIT1
4 mm x 15 mm	86PS0415	6 mm x 20 mm	86PS0620		
5 mm x 10 mm	86PS0510	7 mm x 25 mm	86PS0725	Consumable	Catalog No.
5 mm x 15 mm	86PS0515	8 mm x 25 mm	86PS0825	Suture Loop Guide Rod	86PS1000



Wright Medical Technology, Inc.

5677 Airline Road
Arlington, TN USA 38002
901.867.9971 phone
800.238.7188 toll-free
www.wmt.com

Wright Medical EMEA

Krijgsman 11
1186 DM Amstelveen
The Netherlands
011.31.20.545.0100 phone
www.wmt-emea.com

PEEK-OPTIMA® is a registered trademark of Invivo.
™Trademarks and ®Registered marks of Wright Medical Technology, Inc.
©2010 Wright Medical Technology, Inc. All Rights Reserved.

SK 681-1108R11.10