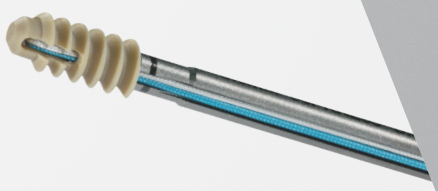
GRAVITY™

PEEK-OPTIMA® Suture Anchor



SURGICAL TECHNIQUE

WRIGHT™

FOCUSED EXCELLENCE

GRAVITY™

PEEK-OPTIMA® Suture Anchor

SURGICAL TECHNIQUE

Contents

Proper surgical procedures and techniques are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. 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 the manufacturer. Contact information can be found on the back of this surgical technique and the package insert is available on the website listed.

Please contact your local Wright representative for product availability.

chapter 1

Introduction

Description

GRAVITY™ PEEK-OPTIMA® Suture Anchors are designed to provide optimal stability, while utilizing a radiolucent material, PEEK-OPTIMA®. All anchors feature an internal square drive and suture eyelet, allowing for pre-loaded suture(s) that is protected during insertion. GRAVITY™ PEEK-OPTIMA® Suture Anchors are available in 2.7, 3.5, and 5.5mm diameters. GRAVITY™ PEEK-OPTIMA® Suture Anchors may be used to address a variety of soft tissue applications that span the forefoot, midfoot, and hindfoot.

System Benefits

- Force Fiber® suture is prepared from ultra-high molecular weight polyethylene (UHMWPE) to be strong, durable and lubricious
- Fully-threaded PEEK-OPTIMA® anchor design increases pull-out strength
- No silicone is added during the manufacturing of Force Fiber®
- Suture organization helps save time and streamlines the procedure
- Pre-loaded anchor design eliminates the need for intraoperatively threading suture through the anchor eyelet or needle, reducing the number of procedural steps
- Sterile, single packed implant and instrumentation streamlines the procedure
- Force Fiber® suture's coreless braid configuration enhances handling characteristics

* Force Fiber® is a registered trademark of Teleflex, Inc.

** Data on file at Teleflex

Indications

GRAVITY™ PEEK-OPTIMA® Suture Anchors are indicated for use:

- In the repair of shoulder instability, secondary to Bankart lesion, rotator cuff tear, slap lesion, acromioclavicular separation, biceps tenodesis, deltoid tear separation, or capsular shift or capsulolabral reconstruction.
- In the repair of elbow instability, secondary to biceps tendon detachment, tennis elbow, or tear. Separation or tear of the ulnar collateral ligament, or radial collateral ligament.
- In the repair of hand/wrist instability, secondary to tear or separation of the scapholunate ligament, ulnar collateral ligament, or radial collateral ligament.
- In the repair of knee instability, secondary to tear or separation of the medial collateral ligament, lateral collateral ligament, patellar tendon, or posterior oblique ligament, or secondary to iliotibial band Tenodesis.
- In the repair of foot/ankle instability, secondary to tear or separation of the Achilles tendon, lateral stabilization tendons/ligaments, medial stabilization tendons/ligaments, midfoot tendons/ligaments, or metatarsal tendons/ligaments, tendon transfers, tendon reattachments, and ligament reconstructions of the midfoot, forefoot, and hindfoot procedures associated with flatfoot reconstruction, hindfoot deformity, midfoot reconstruction, lateral/medial ankle reconstruction or instability, Hallux Valgus or Varus, and MTP instability including:
    - Achilles reattachment/reconstruction
    - Flexor Digitorum Longus transfer
    - Flexor Hallucis Longus transfer
    - Extensor Hallucis Longus transfer
    - Brostrom procedures
    - Peroneal tendon relocation
    - Capsule repair
    - Deltoid reconstruction / reattachment
    - Plantar plate repair
    - Spring ligament repair

Surgical Technique

chapter 2

GRAVITY™ PEEK-OPTIMA® Suture Anchor Size Assessment

The GRAVITY™ PEEK-OPTIMA® Suture Anchor features multiple anchor diameters and suture options. **| Tabel 1** The surgeon's final decision on anchor size and suture should be based on the procedure's requirement of the device, the degree of soft-tissue tension desired, and the patient's anatomy.

Table 1: Suture Anchor Sizing Matrix

Part Number	Instr. Set	Color Coding	Suture Size Type*	Suture Quantity	Anchor Diameter	Anchor Length	Drill Diameter	Drill Depth	Tap Diameter	Tap Depth
86PK2027	86IN2027	Orange	2-0 FORCE FIBER®	1	2.7mm	7.6mm	2.2mm	11.6mm	2.7mm	10.5mm
86PKN035	86IN0035	Grey	0 FORCE FIBER®	2	3.5mm	9.6mm	2.5mm	14.0mm	3.5mm	12.9mm
86PKN255	86IN0255	Red	2 FORCE FIBER®	2	5.5mm	12.7mm	3.9mm	18.4mm	5.5mm	17.0mm

*Suture length = 24in for all three anchors.

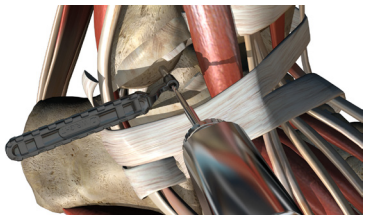


Figure 1A

Anchor Positioning

The GRAVITY™ PEEK-OPTIMA® Suture Anchors require bone preparation using a pre-drill and tap which accompany the anchor in a separate sterile packaged instrument set. Utilizing the drill guide (Figure 1A), place the drill at the desired angle and drill a pilot hole under power until a "hard stop" is reached, when the shoulder of the drill contacts the drill guide, indicating the appropriate depth is achieved. (Figure 1B & 1C)

NOTE: In poor density bone, the surgeon may wish to only use a pre-drill and not tap.

CAUTION: Be sure not to toggle the drill back and forth, as this will enlarge the prepared hole and potentially cause the anchor to be unstable.

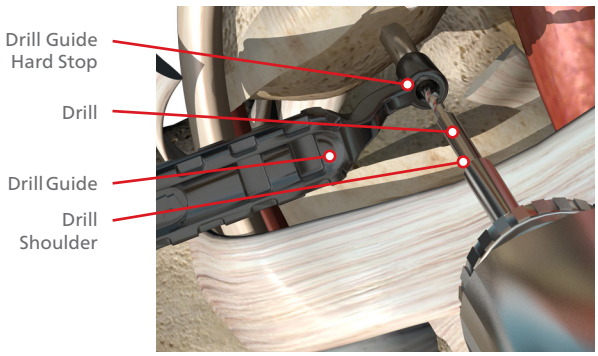


Figure 1B

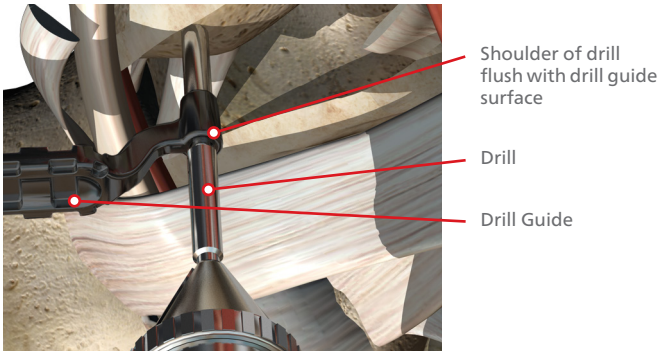


Figure 1C

Place the tap into the pilot hole (Figure 2A) and rotate clockwise until the last thread on the tap is flush with the bone surface. (Figure 2B)

CAUTION: Be sure not to toggle the tap back and forth while inserting, as this will enlarge the prepared hole and could cause the anchor to be unstable.

Back the tap out of the hole by turning counter clockwise until the tap is fully extracted from the bone.

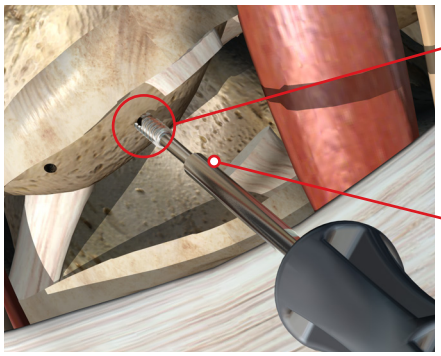


Figure 2A

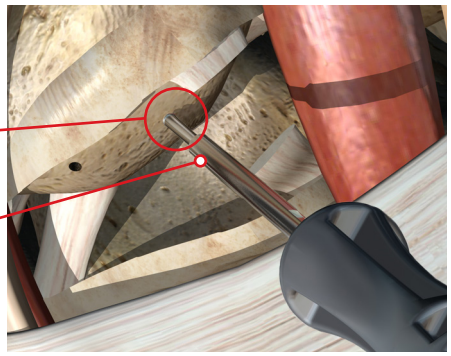


Figure 2B

Anchor Seating

Place the tip of the anchor into the pilot hole while maintaining slight pressure and rotate the handle clockwise to advance the anchor into the bone. (Figure 3)

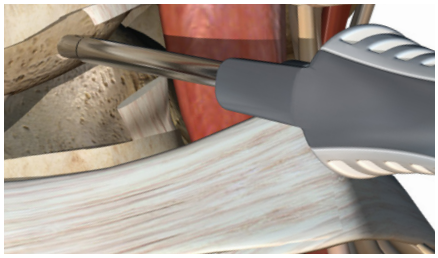


Figure 3

Advance the anchor until the optimal depth has been reached. A driver shaft depth marker is located approximately 1MM above the anchor and may be used as a reference.

Suture Deployment

All anchors are loaded with Force Fiber® sutures which pass through the anchor, up the driver shaft, and are stored inside the suture cartridge. Upon final seating of the anchor, release the suture cartridge by pulling back on the cartridge's driver shaft clasp and disengaging it from the driver shaft. (Figure 4) When the suture cartridge is fully disengaged from the handle, gently pull back on the driver handle to release the driver tip from the suture anchor. Set aside the driver handle and maintain possession of the suture cartridge. (Figure 5)

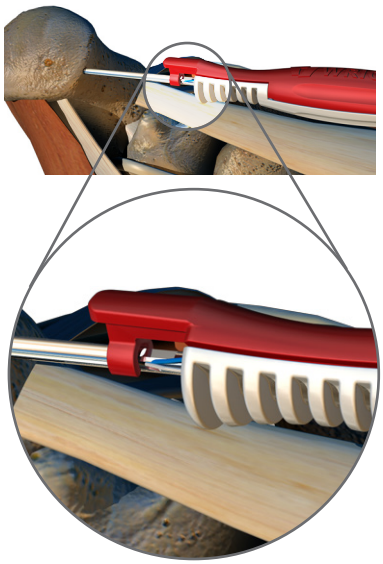


Figure 4

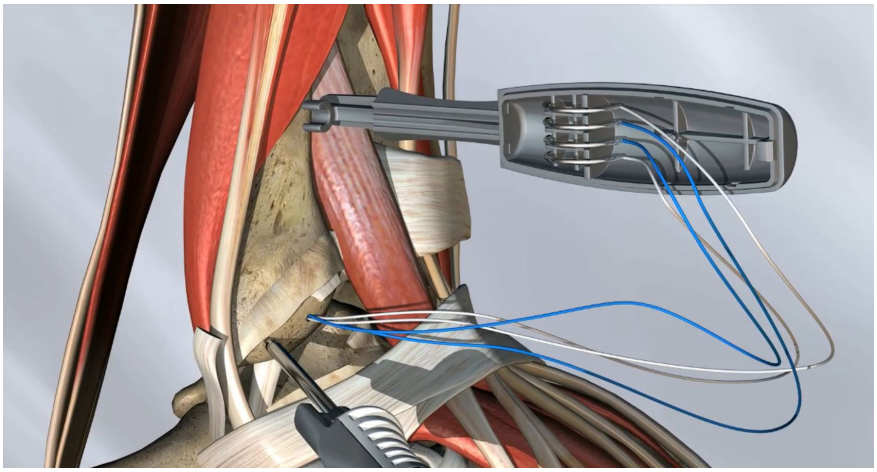


Figure 5

Soft-tissue Fixation

Using a needle driver, hemostat, or forceps, remove each needle from the cartridge and drive them through the desired soft-tissue, tensioning the tissue as needed. Secure the soft-tissue to the bone by tying knots with the suture. It may be helpful to use the suture cartridge to organize the needles and suture during soft-tissue fixation.

Explant Information

The implant can be removed if needed. To re-engage the anchor, utilize the handle and driver shaft of the appropriate size driver (see sizing chart). Insert the driver tip into the anchor and rotate the handle counterclockwise to remove the implant.

Note: If the removal of the implant is required due to revision or failure of the device, the surgeon should contact the manufacturer using the contact information located on the back cover of this surgical technique to receive instructions for returning the explanted device to the manufacturer for investigation.

Postoperative Care

Postoperative care is the responsibility of the medical professional and determined based on the procedure performed.

Ordering Information

Ordering Information*	
Part Number	Description
86PK2027	PEEK-OPTIMA® ANCHOR 2.7MM (Implant Only)
86PKN035	PEEK-OPTIMA® ANCHOR 3.5MM (Implant Only)
86PKN255	PEEK-OPTIMA® ANCHOR 5.5MM (Implant Only)
86IN2027	2.7mm Instrument Set (Instruments Only)
86IN0035	3.5mm Instrument Set (Instruments Only)
86IN0255	5.5mm Instrument Set (Instruments Only)

* For each case scheduled, every anchor diameter should include a corresponding instrument diameter

WRIGHT
FOCUSED EXCELLENCE

1023 Cherry Road
Memphis, TN 38117
800 238 7117
901 867 9971
www.wright.com

56 Kingston Road
Staines-upon-Thames
Surrey TW18 4NL
United Kingdom
+44 (0)845 833 4435

161 Rue Lavoisier
38330 Montbonnot Saint Martin
France
+33 (0)4 76 61 35 00

015694A_14-Jun-2017