Pega Medical

SCFE SCREW FREE GLIDING SYSTEM™

A free-extending two part cannulated screw that will elongate with growth.

SURGICAL TECHNIQUE

SCFE SCREW FREE GLIDING SYSTEM™

The Free-Gliding SCFE Screw System, *designed to treat the most common hip problem in growing children, SLIPPED CAPITAL FEMORAL EPIPHYSIS (SCFE), continues the tradition of Pega Medical's family of innovative pediatric devices. This screw is intended to prevent or stop further slippage of the capito-femoral physis, in children with open growth plates. Medial and lateral threaded fixations, connected through a trilobe free-extending shaft provide stability. The Free-Gliding SCFE Screw System allows for physiological remodeling of the femoral head in order to maintain optimal neck/shaft ratio and biomechanical function.*

The Free-Gliding SCFE Screw System

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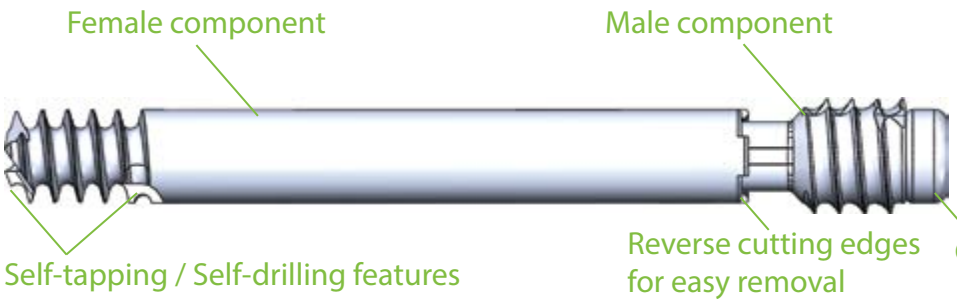
FG-ST-EN rev F

The Free-Gliding SCFE Screw is a free-extending cannulated screw designed specifically for the treatment of SCFE and neck fractures in skeletally immature patients. The implant assembly includes a Male component (which is attached to the lateral cortex), a Female component (which anchors the femoral head) and a Cap. The telescopic design will elongate with growth thus eliminating the need for a protruding screw position at the lateral cortex or pin advancement revision surgery. Moreover, the implant's design avoids compression of the growth plate while providing rotational stability. The device is inserted as simply as a standard threaded screw.



Surgical Planning

The following described procedure is applicable to all intended uses of The Free-Gliding SCFE Screw System. The surgical technique should be performed under image intensification (C-arm) using a radiolucent or fracture table.

DIAMETER CONSIDERATIONS

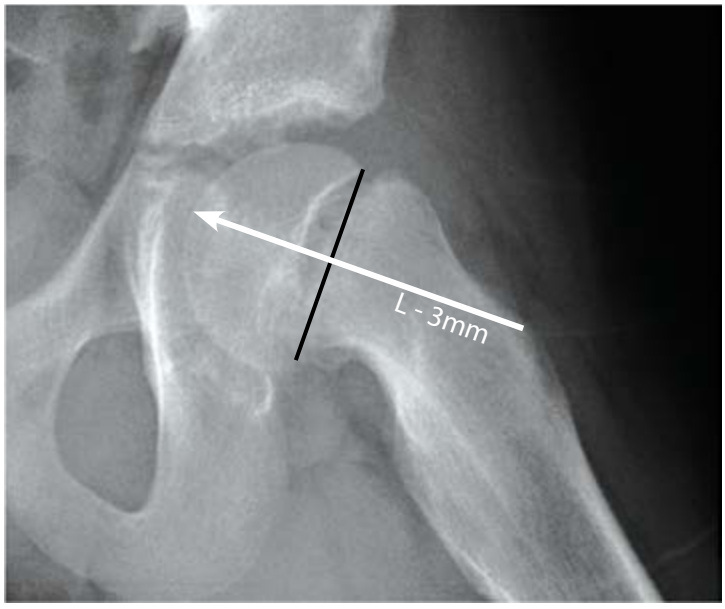
Selection of the screw diameter is based on the femoral neck diameter. Available diameters are 6.5mm and 7.3mm.

LENGTH CONSIDERATIONS

The implant's placement should be 3mm short of the subchondral bone to avoid insertion into the joint. Direct measurement of the length of the screw assembly is done with the *Depth Gage* over the *Guide Wire* prior to reaming.

⚠ **To assure continued normal growth, the entire threaded portion of the female component must be past the growth plate and within the epiphysis in both the AP and Lateral views.**

Screw components are selected from Table 1.



Once the diameter is selected, Male and Female components are combined to obtain the desired final screw length.

Table 1: Screw Selection Guide

	Ø 6.5			Ø 7.3		
	SCREW LENGTH	MALE COMPONENT	FEMALE COMPONENT	SCREW LENGTH	MALE COMPONENT	FEMALE COMPONENT
MINI	48	SCF-M65-**MS**	SCF-**T**65-48S/50L	48	SCF-M73-**MS**	SCF-**T**73-48S/50L
	50	SCF-M65-**ML**		50	SCF-M73-**ML**	
	52	SCF-M65-**MS**	SCF-**T**65-52S/54L	52	SCF-M73-**MS**	SCF-**T**73-52S/54L
	54	SCF-M65-**ML**		54	SCF-M73-**ML**	
	56	SCF-M65-**MS**	SCF-**T**65-56S/58L	56	SCF-M73-**MS**	SCF-**T**73-56S/58L
	58	SCF-M65-**ML**		58	SCF-M73-**ML**	
STANDARD	60	SCF-M65-**S**	SCF-F65-60S/62L	60	SCF-M73-**S**	SCF-F73-60S/62L
	62	SCF-M65-**L**		62	SCF-M73-**L**	
	64	SCF-M65-**S**	SCF-F65-64S/66L	64	SCF-M73-**S**	SCF-F73-64S/66L
	66	SCF-M65-**L**		66	SCF-M73-**L**	
	68	SCF-M65-**S**	SCF-F65-68S/70L	68	SCF-M73-**S**	SCF-F73-68S/70L
	70	SCF-M65-**L**		70	SCF-M73-**L**	
	72	SCF-M65-**S**	SCF-F65-72S/74L	72	SCF-M73-**S**	SCF-F73-72S/74L
	74	SCF-M65-**L**		74	SCF-M73-**L**	
	76	SCF-M65-**S**	SCF-F65-76S/78L	76	SCF-M73-**S**	SCF-F73-76S/78L
	78	SCF-M65-**L**		78	SCF-M73-**L**	
	80	SCF-M65-**S**	SCF-F65-80S/82L	80	SCF-M73-**S**	SCF-F73-80S/82L
	82	SCF-M65-**L**		82	SCF-M73-**L**	
	84	SCF-M65-**S**	SCF-F65-84S/86L	84	SCF-M73-**S**	SCF-F73-84S/86L
	86	SCF-M65-**L**		86	SCF-M73-**L**	
	88	SCF-M65-**S**	SCF-F65-88S/90L	88	SCF-M73-**S**	SCF-F73-88S/90L
	90	SCF-M65-**L**		90	SCF-M73-**L**	
	92	SCF-M65-**S**	SCF-F65-92S/94L	92	SCF-M73-**S**	SCF-F73-92S/94L
	94	SCF-M65-**L**		94	SCF-M73-**L**	
	96	SCF-M65-**S**	SCF-F65-96S/98L	96	SCF-M73-**S**	SCF-F73-96S/98L
	98	SCF-M65-**L**		98	SCF-M73-**L**	
	100	SCF-M65-**S**	SCF-F65-100S/102L	100	SCF-M73-**S**	SCF-F73-100S/102L
	102	SCF-M65-**L**		102	SCF-M73-**L**	

Assembled screw length can be validated using the Slide Ruler (SCF-SRL-100).

Surgical Technique

Step 1

ENTRY POINT

The entry point must be at or above the level of the lesser trochanter. It should also be anterolateral, as opposed to the lateral entry point used in the fixation of fractures around the hip. Screws should be directed from anterolateral to posteromedial. Care should be taken to remain in the center of the capital epiphysis. Posterosuperior placement in the epiphysis should be avoided at all costs to prevent damage to the lateral epiphyseal vessels.

Step 2

INSERTION OF THE GUIDE WIRE

Under image intensification, insert the *Guide Wire* through the *Tissue Protector* and the *Guide Wire Sleeve* into the epiphysis. The *Guide Wire* should end 3mm short of the subchondral bone.

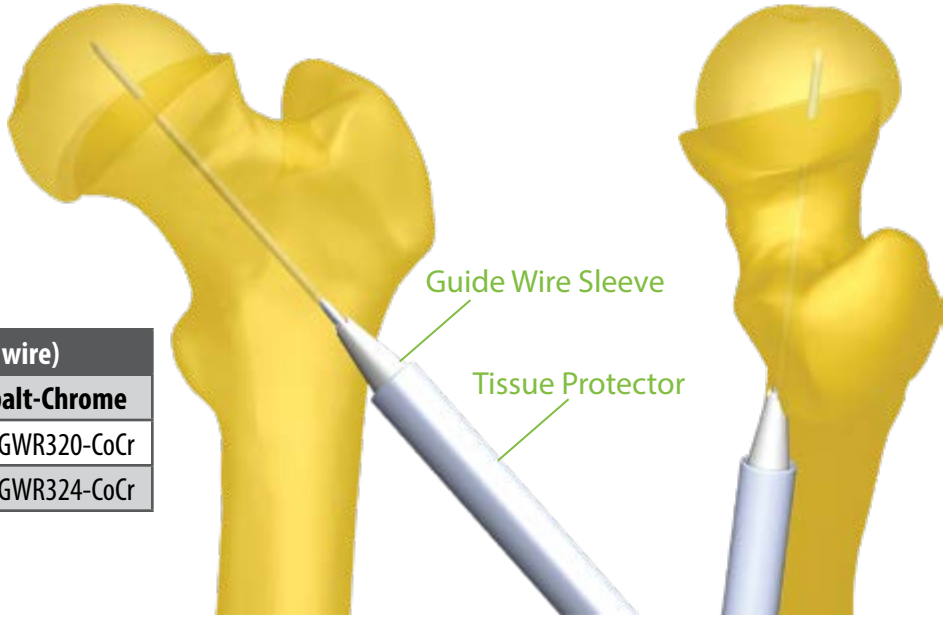
Validate the position of the *Guide Wire* under C-arm visualization in both AP and Lateral views prior to reaming.

The Guide Wire Sleeve or reamer should be used to protect the Guide Wire during manipulations.

2.0 and 2.4mm Cobalt-Chrome Guide Wires and a 2.8mm stainless steel Guide Wire are available for additional stiffness. See Table below.

Please note that the use of the 2.8mm Guide Wire for entry reaming requires the exchange of the wire prior to screw insertion.

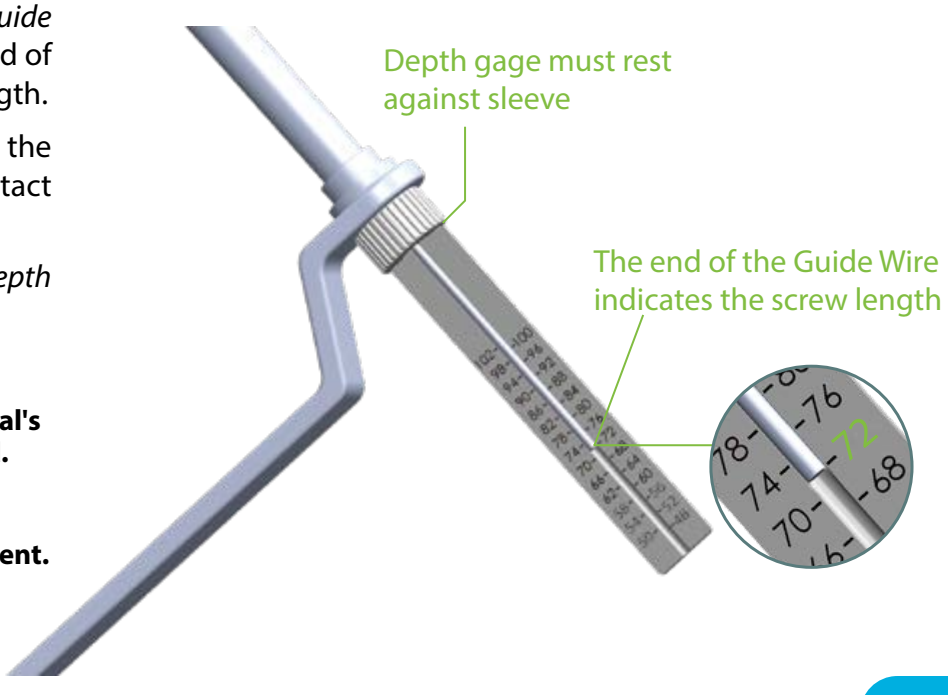
Screw Size	Guide Wire Diameter	Catalog # (single wire)	
		Stainless steel	Cobalt-Chrome
6.5	2.0 mm	SCF-GWR320	SCF-GWR320-CoCr
7.3	2.4 mm	SCF-GWR324	SCF-GWR324-CoCr



Step 3

MEASUREMENT OF THE SCREW LENGTH

- Slide the tapered end of the *Depth Gage* into the *Guide Wire Sleeve* over the *Guide Wire*. Read the measurement at the end of the *Guide Wire* to obtain the screw length.
- For accurate measurement, the tip of the *Guide Wire Sleeve* should be in contact with the cortex.
- Remove the *Guide Wire Sleeve* and *Depth Gage* after measurement.



⚠ **For acurate measurement Pega Medical's *Guide Wire* (L = 330 mm) must be used.**

⚠ **If purchase in the cortex is a concern, subtract 2 mm from length measurement.**

Step 4

ENTRY REAMING

Entry Reaming can be done using a 5.0 Reamer (SCF-CAR050). The use of the entry reamer is advisable for instances of hard bone or very oblique entry point.

Screw Size	Reamer
ø 6.5	SCF-CAR065
ø 7.3	SCF-CAR073

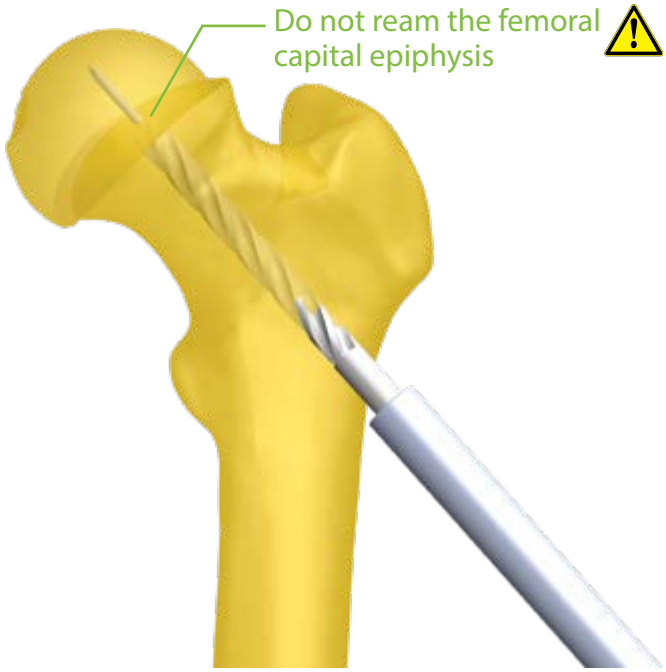
FINAL REAMING

Select the cannulated *Reamer* according to the diameter of the screw selected at Step 1.

- **Reaming should be done under C-arm visualization to prevent advancement of the *Guide Wire* into the joint space.**
- **Do not force the *Reamer* when drilling becomes difficult. Partially retract the *Reamer*, when required, in order to clean out debris.**

Insert the *Reamer* through the *Tissue Protector* and over the *Guide Wire* to avoid damaging the surrounding tissues. Advance the *Reamer* with steady and moderate pressure to begin reaming the screw canal. **Ream up to but not through the growth plate.**

The threaded tip of the *Guide Wire* (distal 10mm) **must remain unreamed** to allow screw purchase and to maintain *Guide Wire* fixation. The screw is self-tapping and self-reaming in order to advance with ease into the epiphysis.



WIRE EXCHANGE (ONLY IF 2.8 WIRE WAS USED)

Using the Reamer as a guide, remove the 2.8mm Guide Wire and replace with the wire corresponding to the selected screw size. See Table from Step 2.

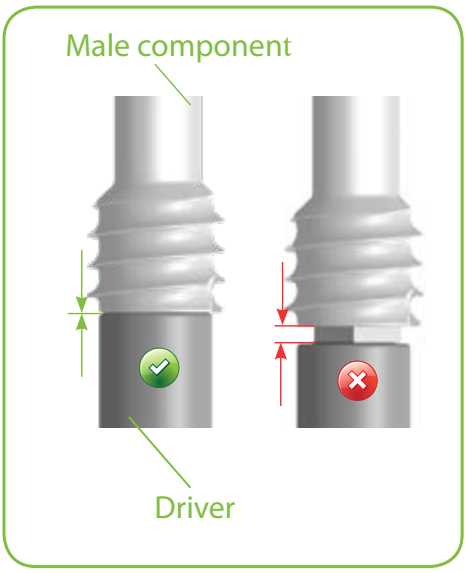
Step 5

SCREW INSERTION

5.1 LOADING OF THE MALE COMPONENT

Using the *Driver* (corresponding to the implant size), turn the locking knob until the Male component is fully engaged onto the *Driver*. There should be no space between the screw head and the *Driver* when properly assembled.

If the *Driver Handle*, Thread Shaft and Knob are not assembled please refer to page 8 for Driver assembly instructions.



Driver must correspond to implant size

Screw Size	Driver
ø 6.5	SCF-MLD265 / SCF-MLD365
ø 7.3	SCF-MLD273 / SCF-MLD373

5.2. LOADING OF THE FEMALE COMPONENT

To complete the screw assembly, simply slide the Female component onto the Male component up to the collar of the Male component.

5.3. INSERTION OF THE ASSEMBLED SCREW

The assembled screw is inserted into the reamed canal over the *Guide Wire* as would be a standard one-piece screw. This action simultaneously engages the thread of the Female into the epiphysis of the femoral head and the thread of the Male into the lateral cortex. **Take care not to let the Male distract from the Female during insertion.**

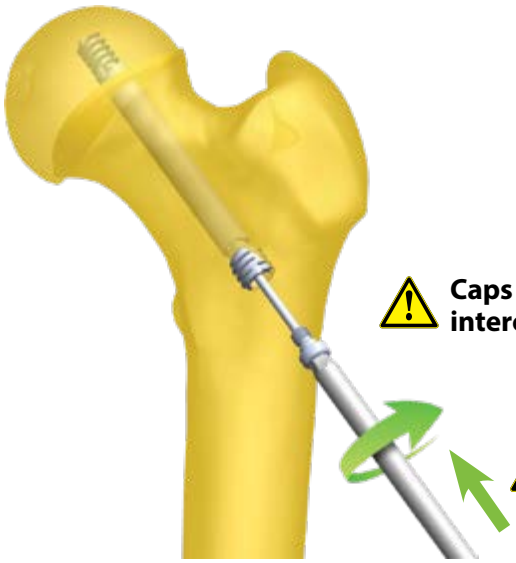
Do not impact the Driver at insertion.

Once the desired position of the screw is achieved, remove the *Driver* by unscrewing the locking knob (counterclockwise rotation). At this point, the range of motion must be checked (using the "approach and withdrawal" technique) under C-arm visualization to assure the screw does not exit the femoral head on any view. Contrast can be injected through the screw's cannulation to ensure no joint penetration.

Step 6

INSERTION OF THE CANNULATED CAP

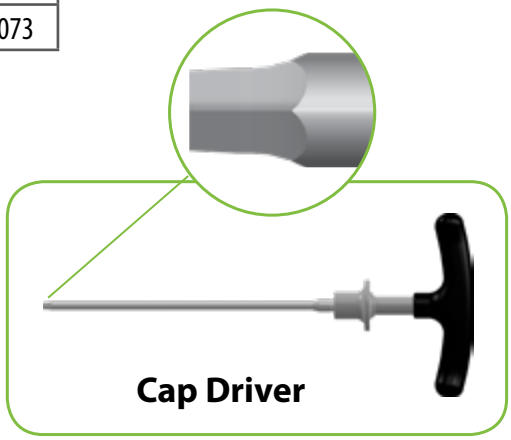
Using the cannulated *Cap Driver* insert the appropriate Cap into the Male component. Drive the Cap until it is fully engaged within the Male component. The Cap will prevent bone ongrowth and facilitate removal. The *Guide Wire* can now be removed.



Screw Size	Cap
ø 6.5	SCF-MC-065
ø 7.3	SCF-MC-073

Caps are not interchangeable

Do not overtighten since this may lead to inadvertent screw advancement.



Retrieval of screw

GUIDE WIRE INSERTION

Under C-arm visualization, insert the *Guide Wire* through the implant's cannulation. The *Guide Wire* will facilitate guidance of the retrieval instruments.

In the event of bone on-growth onto the Cap, a rongeur or reamer can be used to remove the excess bone

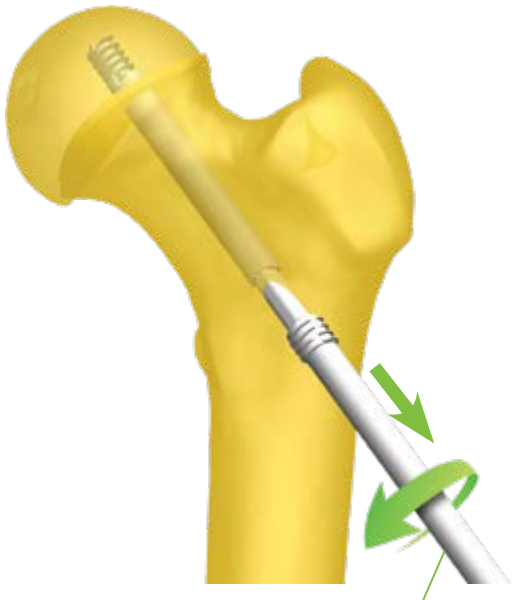
CAP REMOVAL

Use the *Cap Driver* to remove the Cap.

MALE COMPONENT REMOVAL

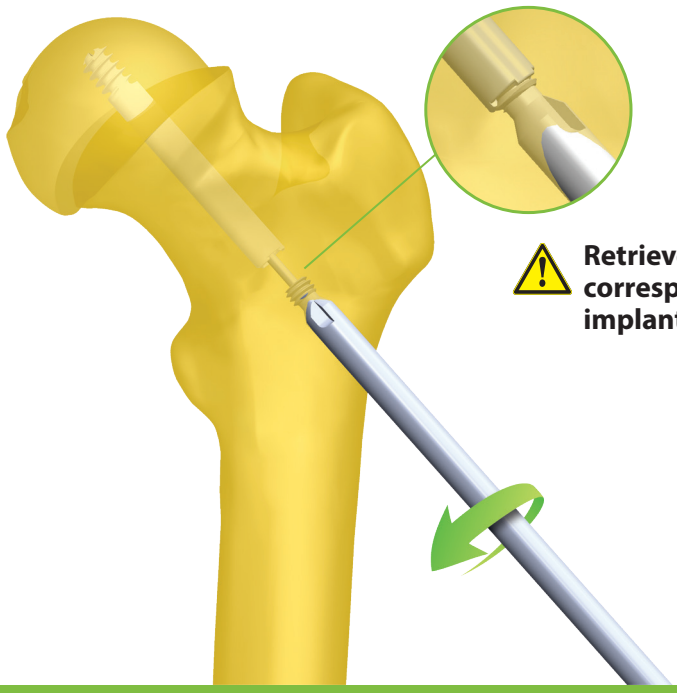
Engage the *Driver* into the Male component (as per step 5.1) by turning the locking knob clockwise. Remove the male component via a **counterclockwise rotation** of the handle.

Note: It is normal for the Female component to rotate while the Male component is being removed.



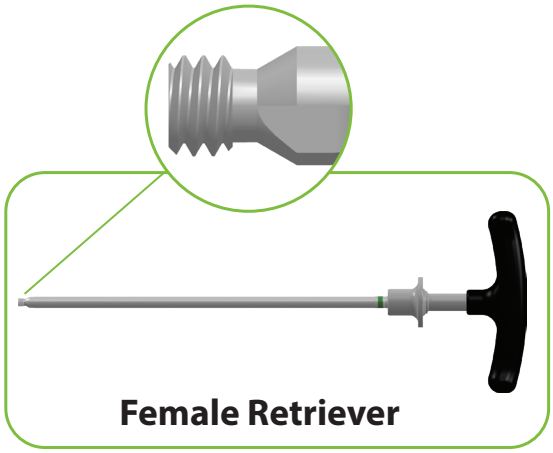
FEMALE COMPONENT REMOVAL

Slide the *Female Retriever* (over the *Guide Wire* and thread) into the Female component using a **counterclockwise rotation**. Rotate while applying traction to remove the implant component. If insertion of the *Female Retriever* is difficult, **reaming up to the female component might be required prior to removal**.



Retriever must correspond to implant size

Screw Size	Female Retriever	Reamer
ø 6.5	SCF-FER065	SCF-CAR065
ø 7.3	SCF-FER073	SCF-CAR073



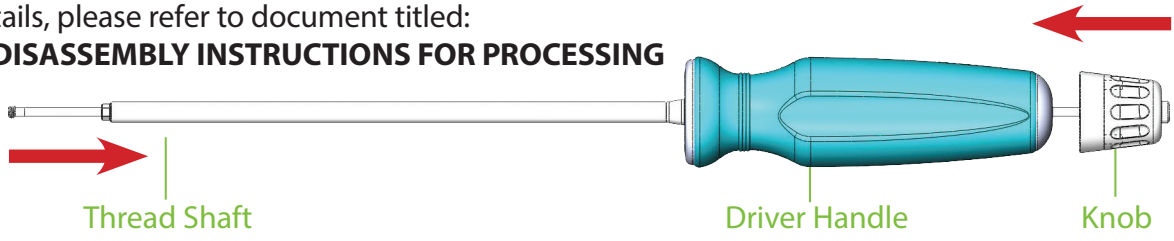
Female Retriever

Additional Recommendations

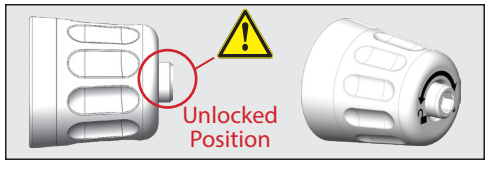
Prophylactic pinning of the contralateral hip is recommended in many cases: noncompliant patients, endocrinopathy or renal disease, patients under 10 years of age or with open triradiate cartilage, children with syndromes, etc. The Modified Oxford Bone scoring system and posterior sloping angle may help identify the patients requiring prophylactic treatment.

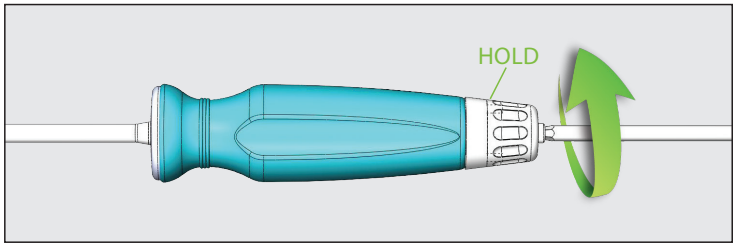
Driver Assembly

For more details, please refer to document titled:
ASSEMBLY/DISASSEMBLY INSTRUCTIONS FOR PROCESSING



If required, use the *Cap Driver* to unlock the Knob with a counterclockwise rotation.





Use the *Cap Driver* and T-handle to screw the Knob onto the Thread Shaft.

Pega Medical

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