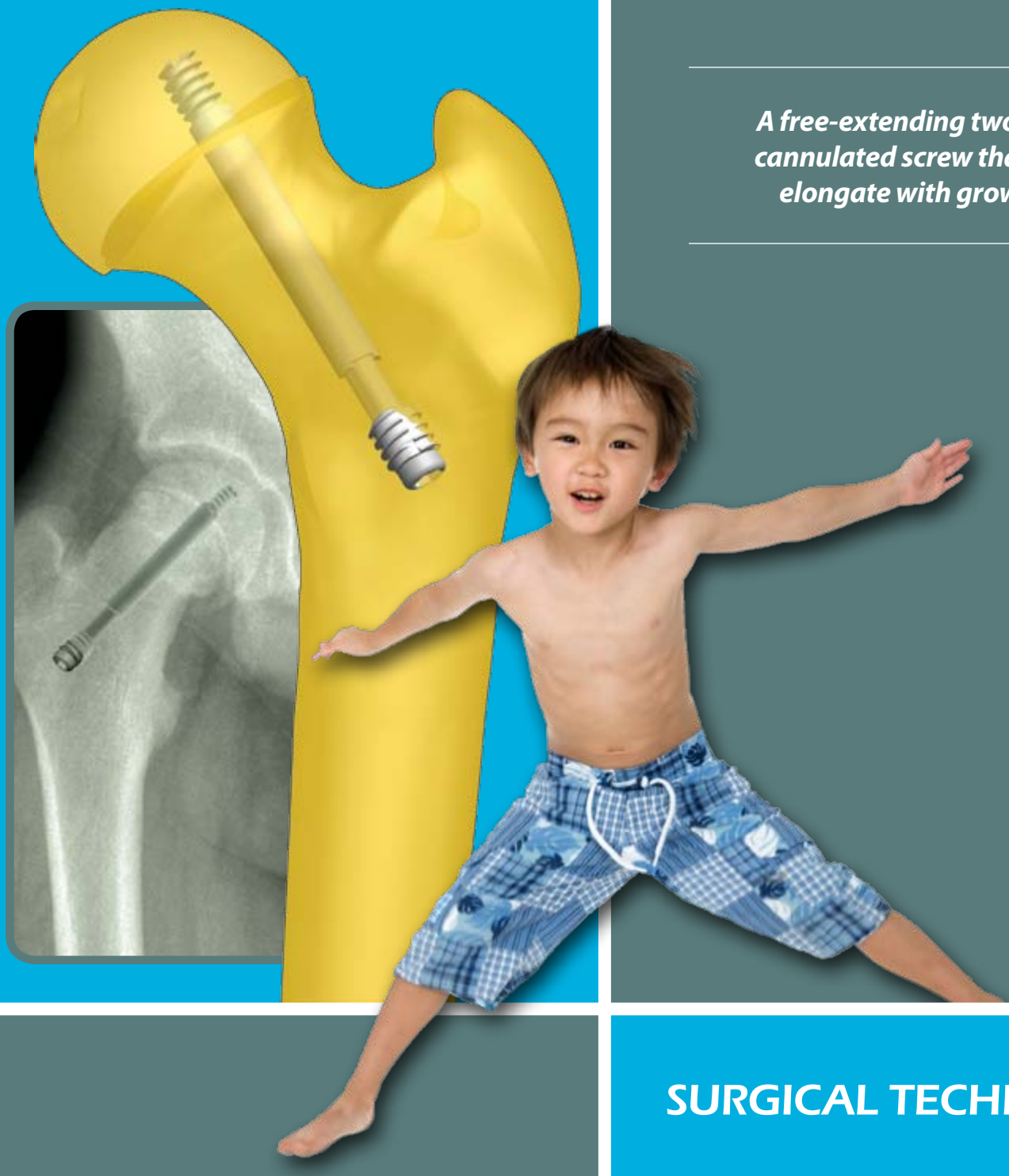
Pega Medical

SCFE SCREW

FREE GLIDING

by Pega Medical



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

SURGICAL TECHNIQUE

SCFE SCREW. FREE GLIDING by Pega Medical

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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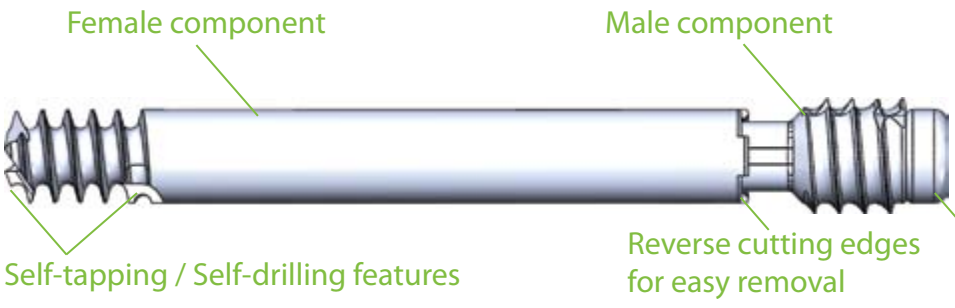
FG-ST-EN rev B

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

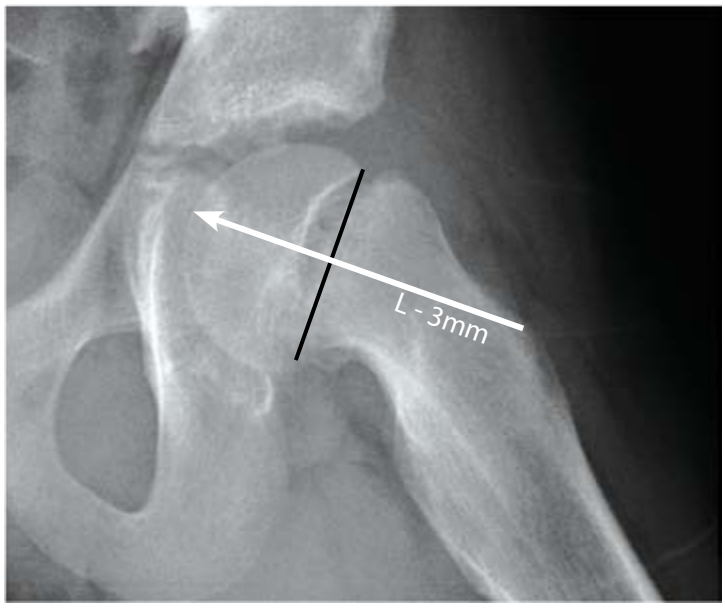
Selection of the screw diameter is based on the femoral neck diameter. Available diameters are 6.5mm and 7.3mm.

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, a Male component, short (S) or long (L), is combined with one of the 11 Female components to obtain the desired final screw length.

Table 1: Screw Selection Guide

Ø 6.5		
SCREW LENGTH	MALE COMPONENT	FEMALE COMPONENT
60	SCF-M65-**S**	SCF-F65-60S/62L
62	SCF-M65-**L**	
64	SCF-M65-**S**	SCF-F65-64S/66L
66	SCF-M65-**L**	
68	SCF-M65-**S**	SCF-F65-68S/70L
70	SCF-M65-**L**	
72	SCF-M65-**S**	SCF-F65-72S/74L
74	SCF-M65-**L**	
76	SCF-M65-**S**	SCF-F65-76S/78L
78	SCF-M65-**L**	
80	SCF-M65-**S**	SCF-F65-80S/82L
82	SCF-M65-**L**	
84	SCF-M65-**S**	SCF-F65-84S/86L
86	SCF-M65-**L**	
88	SCF-M65-**S**	SCF-F65-88S/90L
90	SCF-M65-**L**	
92	SCF-M65-**S**	SCF-F65-92S/94L
94	SCF-M65-**L**	
96	SCF-M65-**S**	SCF-F65-96S/98L
98	SCF-M65-**L**	
100	SCF-M65-**S**	SCF-F65-100S/102L
102	SCF-M65-**L**	

Ø 7.3		
SCREW LENGTH	MALE COMPONENT	FEMALE COMPONENT
60	SCF-M73-**S**	SCF-F73-60S/62L
62	SCF-M73-**L**	
64	SCF-M73-**S**	SCF-F73-64S/66L
66	SCF-M73-**L**	
68	SCF-M73-**S**	SCF-F73-68S/70L
70	SCF-M73-**L**	
72	SCF-M73-**S**	SCF-F73-72S/74L
74	SCF-M73-**L**	
76	SCF-M73-**S**	SCF-F73-76S/78L
78	SCF-M73-**L**	
80	SCF-M73-**S**	SCF-F73-80S/82L
82	SCF-M73-**L**	
84	SCF-M73-**S**	SCF-F73-84S/86L
86	SCF-M73-**L**	
88	SCF-M73-**S**	SCF-F73-88S/90L
90	SCF-M73-**L**	
92	SCF-M73-**S**	SCF-F73-92S/94L
94	SCF-M73-**L**	
96	SCF-M73-**S**	SCF-F73-96S/98L
98	SCF-M73-**L**	
100	SCF-M73-**S**	SCF-F73-100S/102L
102	SCF-M73-**L**	

Surgical Technique

Step 1

ENTRY POINT

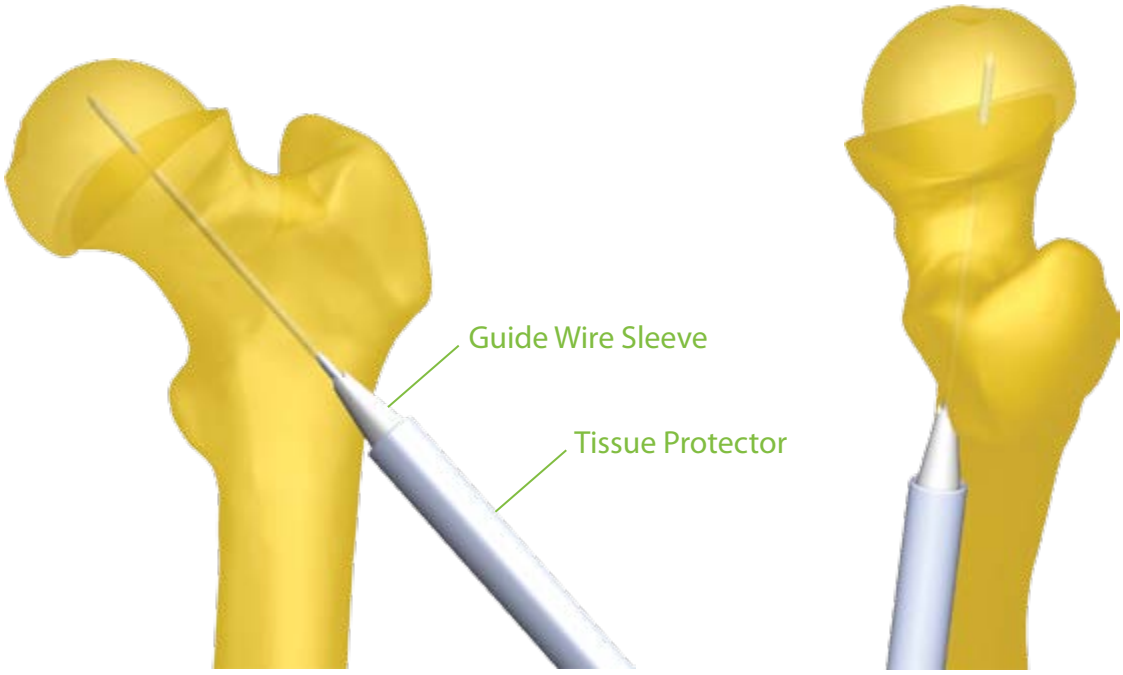
The entry point must be at or above the level of the lesser trochanter. It should also be anterolateral, as opposed to the lateral entry point used in the fixation of fractures around the hip. Screws should be directed from anterolateral to posteromedial. Care should be taken to remain in the center 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.

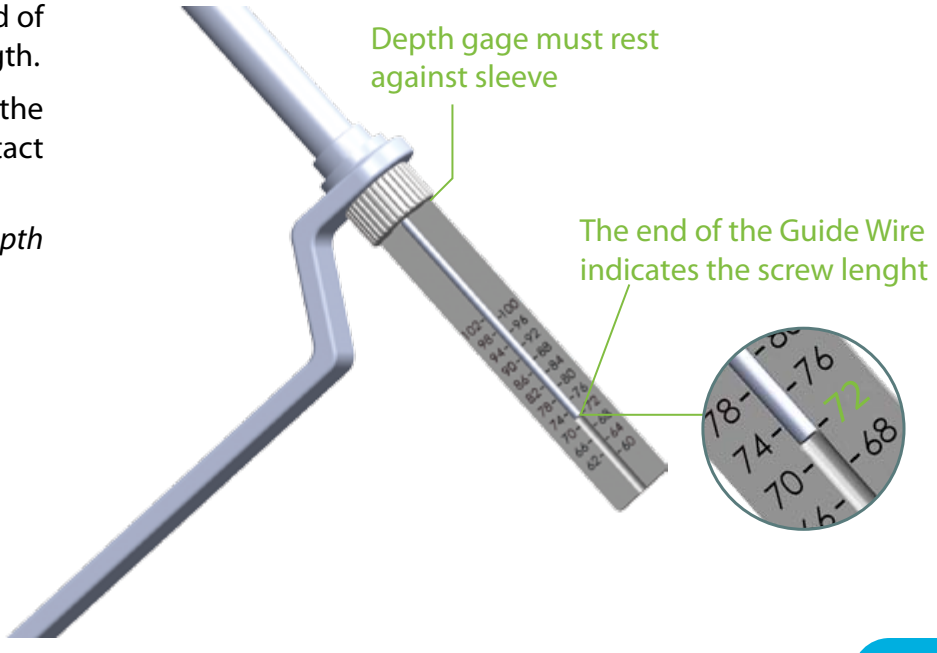
Validate the position of the *Guide Wire* under C-arm visualization in AP and Lateral views prior to reaming.



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.



Step 4

REAMING

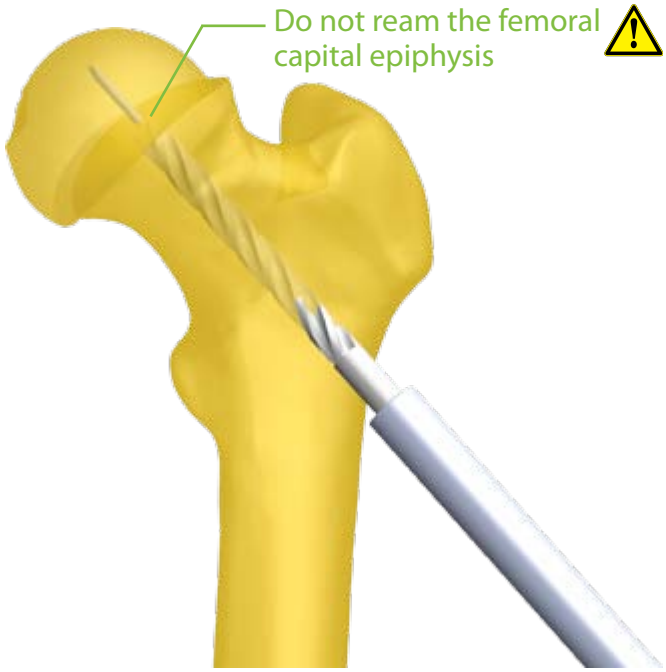
Select the cannulated *Reamer* according to the diameter of the screw selected at Step 1.

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

- **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.



Step 5

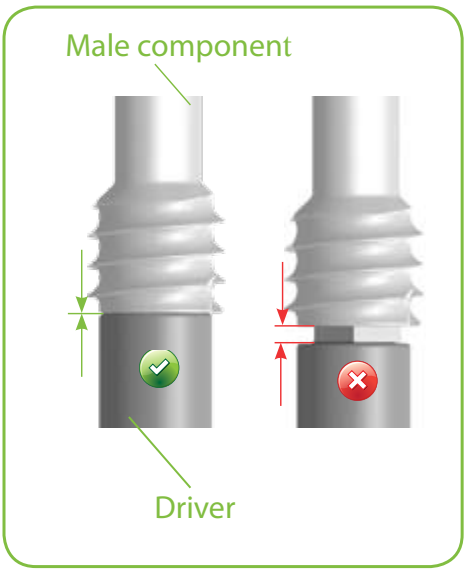
SCREW INSERTION

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.

Driver must correspond to implant size

Screw Size	Driver
ø 6.5	SCF-MLD265
ø 7.3	SCF-MLD273



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.**

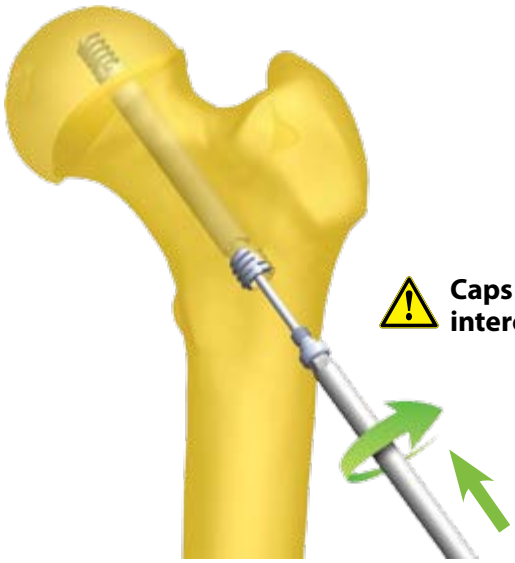
Do not impact the driver at insertion.

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 the 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

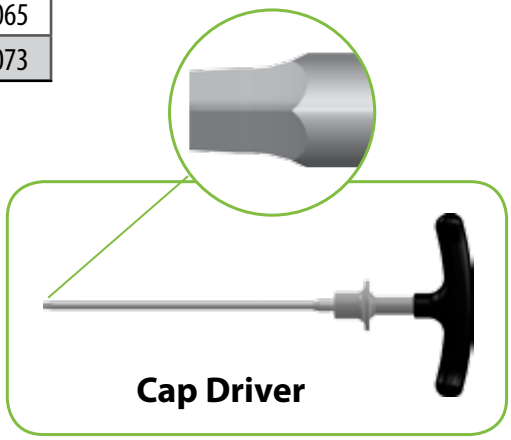
INSERTION OF THE CANNULATED CAP

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 interchangable



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

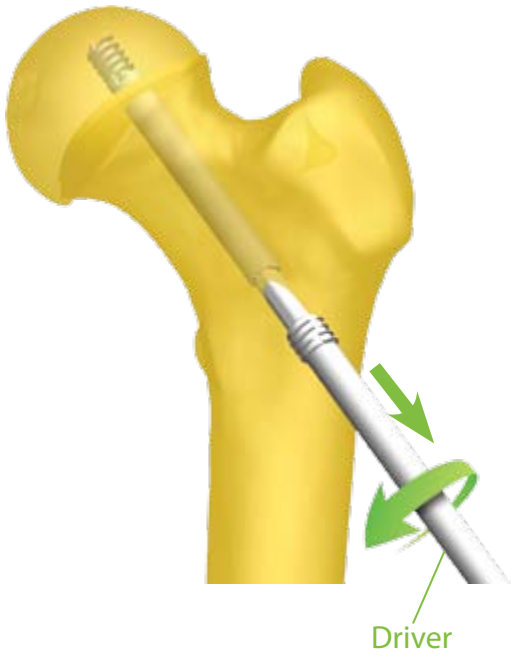
CAP REMOVAL

Use the *Cap Driver* to remove the Cap.

MALE COMPONENT REMOVAL

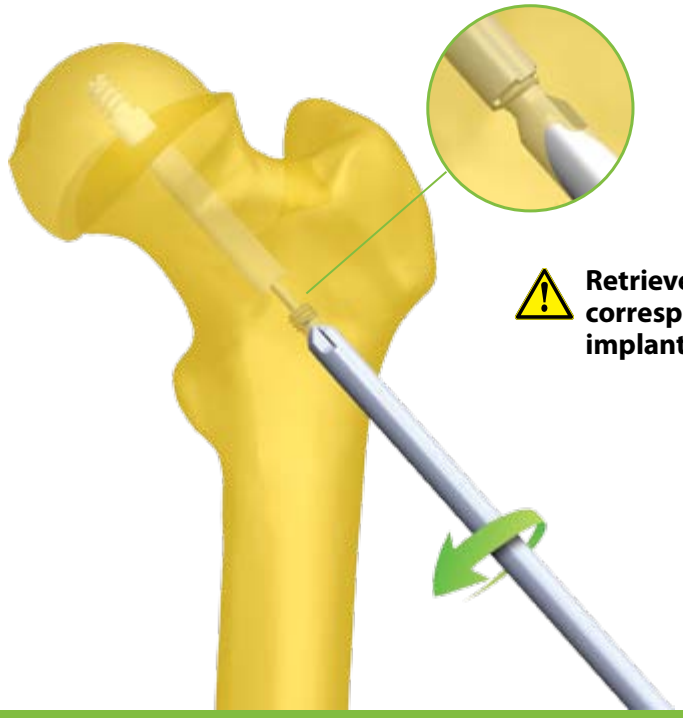
Engage the *Driver* into the Male component (as per step 5.1) by turning the locking knob clockwise. Remove the male component via a **counterclockwise rotation** of the handle.

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



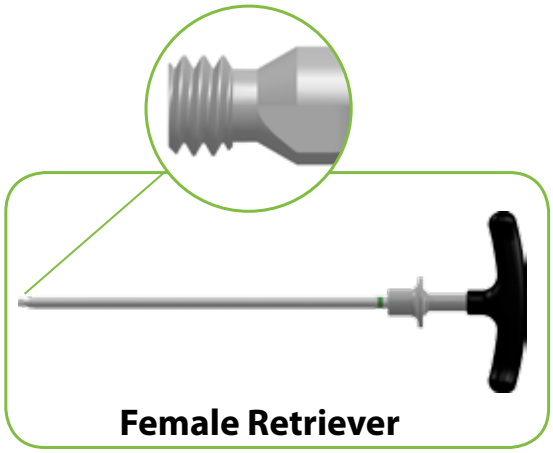
FEMALE COMPONENT REMOVAL

Engage the *Female Retriever* (corresponding to the implant size) 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.

Notes

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