Is there any precaution that should be taken near the expected device lifetime?

Continue with the regular post-operative monitoring with the surgeon and follow their recommendations.

What is the SCFE Screw made of?

The SCFE Screw is manufactured in medical grade Stainless-Steel (316L, ASTM 138). This is a biocompatible material made according to standards recognized by regulatory authorities. This is one of the most common Stainless-Steel grades used for implantable devices.

Is there any manufacturing residual that could pose a risk?

The SCFE Screw is meticulously decontaminated following a cleaning process validated according to medical industry standards that removes any manufacturing residue well below tolerable exposure values, thus maximizing safety.

Contact information in case of serious incident:

Any serious incident that occurs with the use of the FD Nail should be reported to Pega Medical and the Therapeutic Goods Administration (TGA) to the contact information below:

Pega Medical, Inc.

1111 Autoroute Chomedey
Laval, QC H7W 5J8 Canada
Email: feedback@pegamedical.com
Phone: 1-450-688-5144
Toll Free: 1-877-739-6358
Website: www.pegamedical.com

Therapeutic Goods Administration (TGA)

Email: iris@health.gov.au
Phone : 1800 809 361 (free call within Australia)

Users who are deaf or have a hearing or speech impairment can call through the National Relay Service:

- TTY or computer with modem users phone 1800 555 677 then ask for 1800 809 361
- Speak and listen (speech to speech relay) users phone 1800 555 727 then ask for 1800 809 361

For further information, visit TGA's website: https://www.tga.gov.au/medical-devices-ivd

Pega Medical™

SCFE SCREW FREE GLIDING SYSTEM™

Patient Information Leaflet

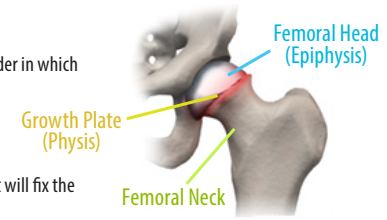
INTRODUCTION

This leaflet includes important information about the Free-Gliding SCFE Screw System (SCFE Screw). It will help you understand how the SCFE System works as well as the benefits and risks associated with this medical device.
Follow your surgeon's advice even if it differs from what is in this leaflet. If you need further information, your surgeon can answer any questions you may have, or you can contact us at: ***feedback@pegamedical.com***.

Please read this leaflet carefully and keep it in a safe place so that you may refer to it in the future if needed.

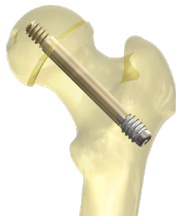
What is SCFE?

SCFE is an acronym for Slipped Capital Femoral Epiphysis. SCFE is a hip disorder in which the head of the femur slips off the neck of the bone at the growth plate.



What is the Free-Gliding SCFE Screw System?

The Free-Gliding SCFE Screw System is a self-extending two-part screw that will fix the Femoral Head and will elongate as normal growth of the bone occurs.



It includes the following model references:

Ø6.5mm Female Components	
CATALOG #	
SCF-T65-48S/50L	
SCF-T65-52S/54L	
SCF-T65-56S/58L	
SCF-F65-60S/62L	
SCF-F65-64S/66L	
SCF-F65-68S/70L	
SCF-F65-72S/74L	
SCF-F65-76S/78L	
SCF-F65-80S/82L	
SCF-F65-84S/86L	
SCF-F65-88S/90L	
SCF-F65-92S/94L	
SCF-F65-96S/98L	
SCF-F65-100S/102L	

Ø7.3mm Female Components	
CATALOG #	
SCF-T73-48S/50L	
SCF-T73-52S/54L	
SCF-T73-56S/58L	
SCF-F73-60S/62L	
SCF-F73-64S/66L	
SCF-F73-68S/70L	
SCF-F73-72S/74L	
SCF-F73-76S/78L	
SCF-F73-80S/82L	
SCF-F73-84S/86L	
SCF-F73-88S/90L	
SCF-F73-92S/94L	
SCF-F73-96S/98L	
SCF-F73-100S/102L	

Consumable Instruments	
DESCRIPTION	**CATALOG #**
5.0 mm Reamer (Entry)	SCF-CAR050
6.5 mm Reamer	SCF-CAR065
7.3 mm Reamer	SCF-CAR073

Consumable Instruments	
DESCRIPTION	**CATALOG #**
2.0 mm Guide Wire	SCF-GWR320
2.4 mm Guide Wire	SCF-GWR324
2.8 mm Guide Wire	SCF-GWR328
2.0 mm Guide Wire-CoCr	SCF-GWR320-CoCr
2.4 mm Guide Wire-CoCr	SCF-GWR324-CoCr

Ø6.5mm Male Components	
DESCRIPTION	**CATALOG #**
SHORT	SCF-M65-S
LONG	SCF-M65-L

Ø6.5mm Male Components	
DESCRIPTION	**CATALOG #**
MINI SHORT	SCF-M65-MS
MINI LONG	SCF-M65-ML

Ø7.3mm Male Components	
DESCRIPTION	**CATALOG #**
SHORT	SCF-M73-S
LONG	SCF-M73-L

Ø7.3mm Male Components	
DESCRIPTION	**CATALOG #**
MINI SHORT	SCF-M73-MS
MINI LONG	SCF-M73-ML

Caps	
DESCRIPTION	**CATALOG #**
Ø 6.5 mm	SCF-MC-065
Ø 7.3 mm	SCF-MC-073

What is it indicated for?

The SCFE Screw is a temporary implant used to:
• Stop or prevent Slipped Capital Femoral Epiphysis
• Fix femoral neck fractures.

Who is it indicated for?

All pediatric patients (less than or equal to 21 years old) with the exclusion of newborn and infants under 2 years of age.

Is there any special operating instructions for the use of the SCFE Screw?

The SCFE Screw does everything on its own, and will extend as you grow.

What is the intended performance of the SCFE Screw?

The SCFE Screw is used to fix the head of femur to the neck, stopping further slippage of the head of the femur. This prevents further damage to the hip, reducing the patient's pain.

The Free-Gliding SCFE Screw has been designed to prevent premature closure of the growth plate by allowing the normal growth of the neck of the femur instead of compressing. The SCFE Screw elongates as growth occurs keeping support of the femur's head and allowing the continuation of the growth without it sticking out of the femur bone. Thus, the SCFE Screw is placed deep into the bone and cannot be felt by patients after surgery.

In addition, by allowing the continuation of normal growth, the SCFE Screw also allows remodelling of the head neck junction back towards a normal alignment[1]. Moreover, the threads at the two extremities of the screw and the specially designed trilobe shape of the SCFE Screw components increase the fixation to the bone and blocks the rotation of the femoral head. Finally, the design of the SCFE Screw includes specific features to facilitate removal when your surgeon decides it is time.

Are there any possible undesirable side effects following the surgery?

The SCFE Screw surgical procedure, as any procedure to correct SCFE, may cause potential side effects including:
• Pain, discomfort, stiffness or abnormal sensations due to the presence of the device
• Metal sensibility and/or allergic reaction
• Nerve damage due to the surgical trauma
• Bone resorption due to stress shielding
• Postoperative bone fracture and pain
• Infection, both deep and superficial
• Unrecognized joint penetration, Chondrolysis
• Risk of growth disturbances
• Bone damage due to temporary or permanent loss of blood supply to the bone (Avascular Necrosis)

What kind of complications can occur from use of the SCFE Screw?

Although uncommon, some complications can occur such as:
• Non telescoping of the Screw,
• Migration of the implant,
• Inadequate healing, continued slippage at the growth plate

Are there any risks that could arise from the interaction of the SCFE Screw with other equipment and precautions to be taken?

The SCFE Screw has not been evaluated for safety and compatibility in the Magnetic Resonance environment. Speak to your surgeon about whether you can have MRI scans. You should inform the technicians performing the scan that you have an implant.

How long after surgery will it take to recover?

The length of the recovery period is determined by different factors such as severity of SCFE, the patient's weight and age and activity level. Each case is particular, and some patients will recover faster than others. In general, the patient will need crutches or a walker for up to about four weeks after surgery for stable SCFE and for at least six to eight weeks for unstable SCFE.

What kind of rehabilitation is needed after surgery?

Routine follow-up is recommended to avoid post-operative complications. Your doctor will instruct you to return for additional visits to monitor your progress. You should follow-up as proposed by your orthopaedic surgeon.
If you have any problems, you should see an orthopedic surgeon right away and inform him or her that you have an orthopedic implant.

What type of follow-up is needed after surgery?

The length of the recovery period is determined by many factors such as the extent of the surgery, the patient's age and activity level. Each case is particular, and some patients will recover faster than others. In general, the patient can start standing activities three to four weeks after surgery under the protection of an Ankle-Foot Orthoses (AFOs) or a Knee-Ankle-Foot Orthoses (KAFOs) braces.

Are there any symptoms that could indicate that the device is not properly functioning?

Please call your doctor if you develop any of the following symptoms:
• Pain, discomfort, or abnormal sensations due to the presence of the device
• Swelling, numbness, general weakness, or fever
• loss of function/range of motion
• Postoperative re-fracture or Inadequate healing
• Drainage continues from the site of your incision

What precautions should be taken if I experience any of the above symptoms?

• Consult your health care professional immediately.
• Use the prescribed medications to help minimize the risk of infection and inflammation.
• Do not engage in any strenuous activity until your doctor says it is okay to do so.
• Do not lift any heavy objects as this can cause undue stress on your implant.

How long will the SCFE implant last?

It depends on the age of the patient. In a very young patient, the SCFE Screw may have to be exchanged for a larger one due to bone growth or removed when complete healing or patient growth (growth plate closure) is attained. Otherwise, the SCFE Screw will only need to be replaced if complications arise. Else, it is recommended to remove or replace the SCFE Screw after 5 years of implantation to ensure good material stability.
Nevertheless, the final decision rests with the surgeon. Any decision to remove the device should take into consideration the potential risks of a secondary surgical procedure with your surgeon. Device removal should be followed by adequate postoperative management.

Is there anything that could affect the lifetime of the SCFE implant?

• Trauma, Infection, early weight bearing could shorten the device lifetime.
• Follow recommendations from your surgeon to limit physical activities, particularly those causing any type of mechanical stress on the femur. This is especially important during the postoperative or post implant removal healing period.
• Avoid any sudden change in position, strenuous activity, or falls.
• Proper post-operative care and regular follow up with healthcare professional and following instruction for use will contribute to lengthen the device lifetime.

[1] Morash, Kevin MD, et al. Femoral Neck Growth and Remodeling With Free-Gliding Screw Fixation of Slipped Capital Femoral Epiphysis, Journal of Pediatric Orthopaedics: April 2021 – Vol. 41.4 - p e309-e315