STABILIZORTHO

SimpliFix
Surgical Technique

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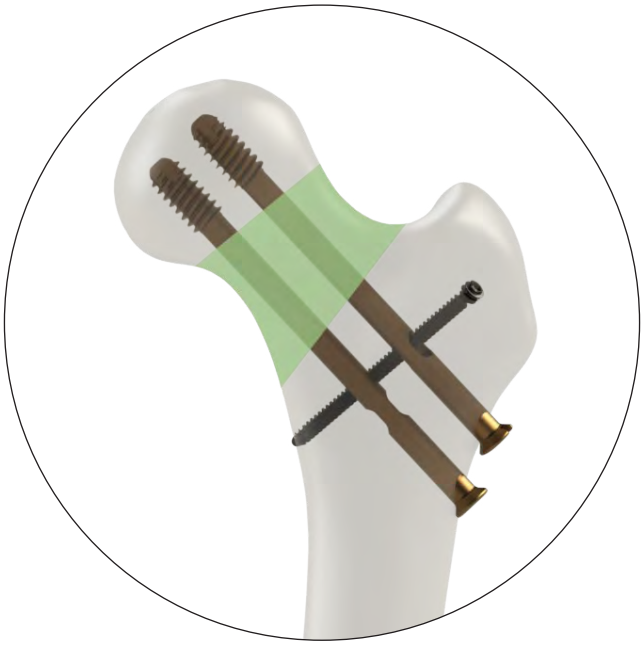
Introduction

Indications

The SimpliFix Hip System is intended for fracture fixation of large bones and large bone fragments such as femoral neck fractures, slipped capital femoral epiphyses and an adjunct to a dynamic hip screw DHS in basilar neck fractures.



Contraindications

- Intertrochanteric fractures (AO type 31-A3)
- Subtrochanteric fractures

Contraindications for the system are active or latent infection; sepsis; insufficient quantity or quality of bone/soft tissue; and material sensitivity. If sensitivity is suspected, tests must be performed prior to implantation to determine metal sensitivity. Patients who are unwilling or incapable of following postoperative care instructions are contraindicated for these devices. These devices are not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

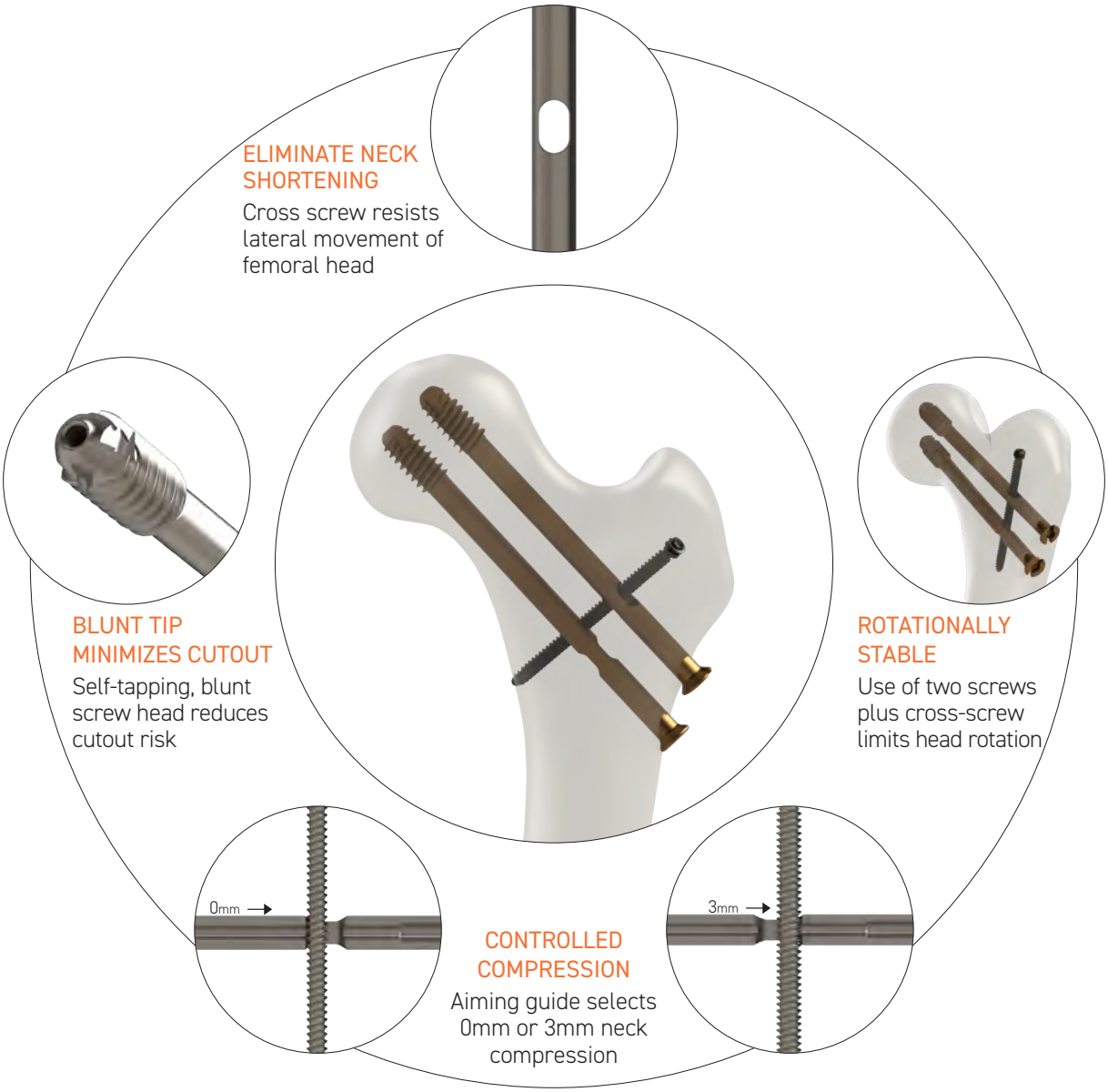
Adverse Effects

Possible adverse effects are pain, discomfort, or abnormal sensations and nerve or soft tissue damage due to the presence of an implant or due to surgical trauma. Fracture of the implant may occur due to excessive activity, prolonged loading upon the device, incomplete healing, or excessive force exerted on the implant during insertion. Implant migration and/or loosening may occur. Metal sensitivity or histological or allergic reaction resulting from implantation of a foreign material may occur.

Nerve or soft tissue damage, necrosis of bone or bone resorption, necrosis of the tissue or inadequate healing may result from the presence of an implant or due to surgical trauma.

SimpliFix Hip System

SimpliFix is a revolutionary fixation device for use with minimally displaced and non-displaced, intracapsular femoral neck fractures. This technology aims to reduce the incidence of complications that other devices and techniques have failed to address. Utilizing surgeon-controlled compression, the system aims to resist femoral neck shortening. Maintaining the patient's natural anatomy and preserving femoral neck length has been shown to improve postoperative pain and functional outcomes.[1-4] Using a novel cross-screw technique, SimpliFix minimizes rotation of the femoral head. Maintaining rotational stability is a critical factor in preventing displacement and subsequent femoral neck shortening.[5]



1. Felton J, et al. Femoral Neck Shortening After Hip Fracture Fixation Is Associated With Inferior Hip Function: Results From the FAITH Trial. J Orthop Trauma. 2019 Oct;33(10):487-496
2. Slobogean GP, et al. Femoral neck shortening in adult patients under the age of 55 years is associated with worse functional outcomes: analysis of the prospective multi- center study of hip fracture outcomes in China (SHOC). Injury. 2017;48:1837–1842
3. Zlowodzki M, et al. The effect of shortening and varus collapse of the femoral neck on function after fixation of intracapsular fracture of the hip: a multi-centre cohort study. J Bone Joint Surg Br. 2008;90:1487–1494
4. Weil YA, et al. Femoral neck shortening and varus collapse after navigated fixation of intracapsular femoral neck fractures. J Orthop Trauma. 2012;26:19–23
5. Li J, et al. Comparison of three different internal fixation implants in treatment of femoral neck fracture-a finite element analysis. J Orthop Surg Res. 2019 Mar 12;14(1):76

Surgical Procedure

Patient Position

The patient should be placed in the supine position.

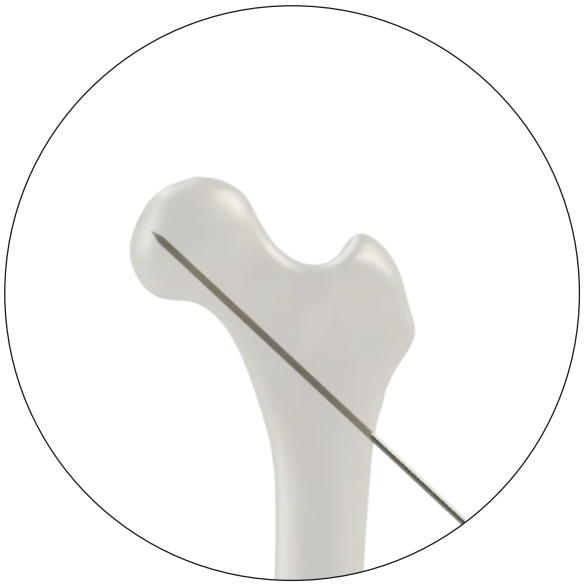
Fluoroscopic Assessment

Care should be taken to ensure flouroscopic visualization of the proximal femur in both AP and lateral views.

Exposure

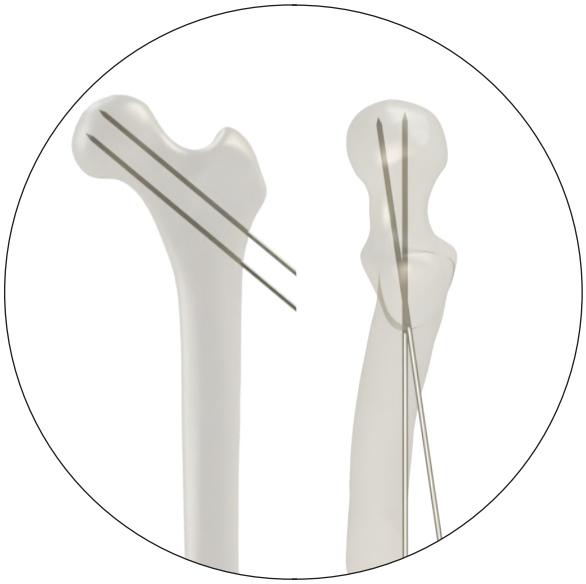
Approximately 2 - 3 cm below the greater trachanter, make a 3 - 4 cm long incision along the midline of the lateral femur. Dissect the subcutaneous soft tissue, splitting the fascia, as necessary, until exposed bone.

Surgical Technique



Insert Inferior ø2.4 Guidewire

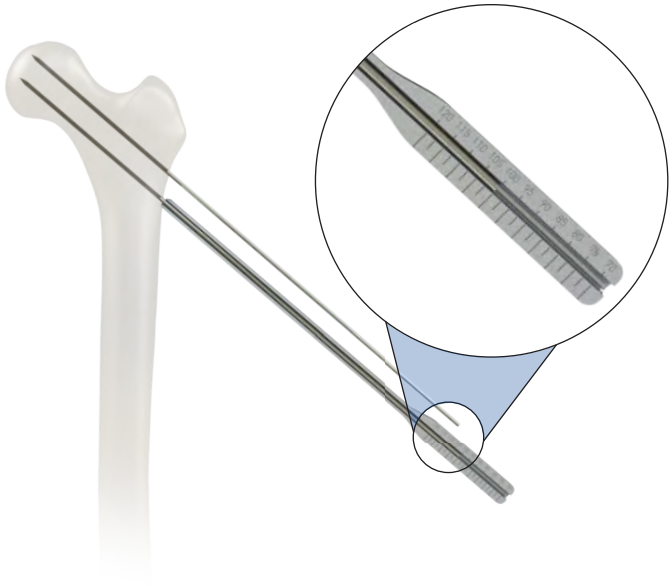
Insert first ø2.4 Guidewire (KWR.24.305) along the midline of the inferior calcar, advancing until 5mm below articular surface.



Insert Superior ø2.4 Guidewire

Insert second ø2.4 Guidewire (KWR.24.305) aiming to anterior/superior corner of femoral head. Advance wire until 5mm below articular surface.

Verify Guidewire Placement: Confirm the trajectory of both superior and inferior guidewires under fluoroscopy in both AP and lateral views before proceeding.



Measure Inferior Guidewire

Measure inferior guidewire using slide on Depth Gauge (DPGB.02). Advance depth gauge until seated on lateral cortical bone of femur. Measure exposed wire. Confirm desired SimpliFix (SFX) screw length.

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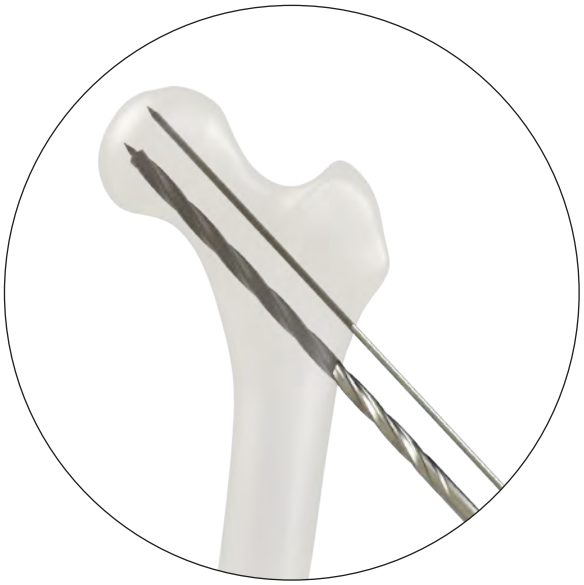
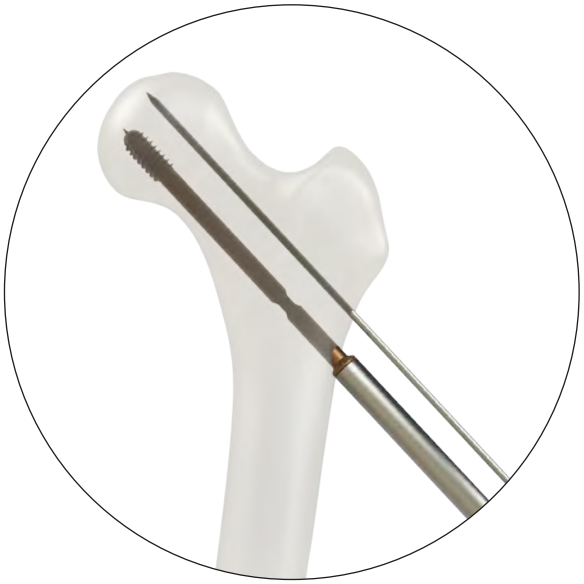


Overdrill Inferior Guidewire

Overdrill inferior guidewire using ø6.2 Cannulated Drill (DRBC.62.250). Advance drill proximal to tip of guidewire, maintaining purchase of wire in bone.



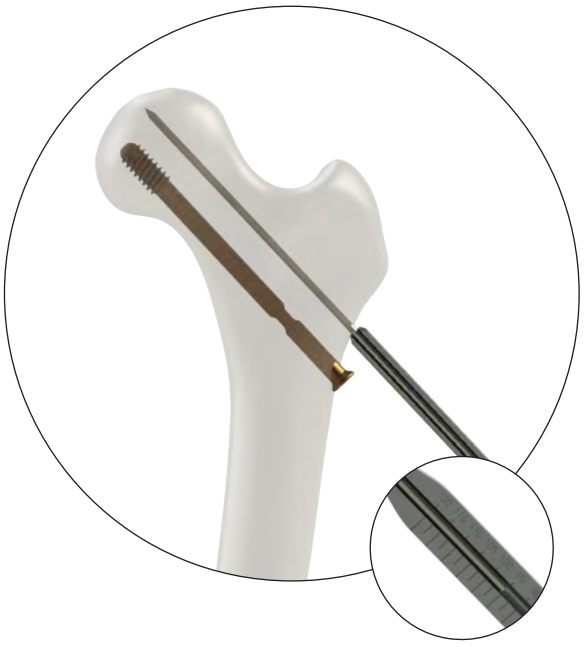
Drive / Seat Inferior SimpliFix Screw

Over the guidewire, insert the appropriate length SimpliFix screw (SFX.82.XXX) using the SFX Power Driver (DRV.S8.135). The surgeon may elect to drive the SFX screw on power or use the (Black) Cannulated Paddle Handle (DVHC.00).

Note: Do not fully seat the SFX screw on power.

Note: Use paddle handle to fully seat SFX screw to cortical bone of femur.

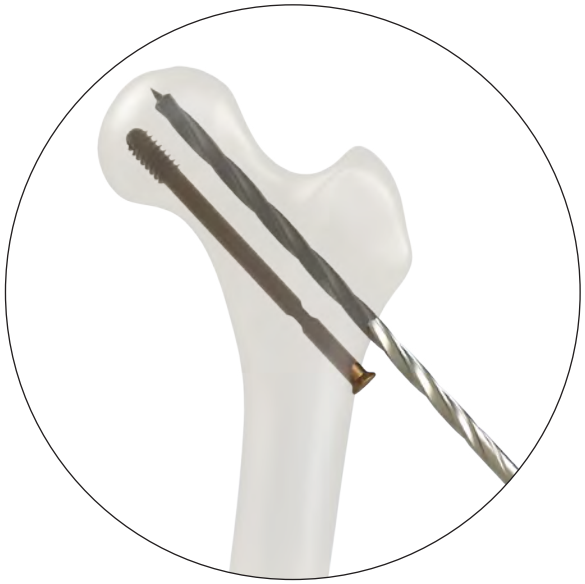
Remove Inferior Guidewire: Once SFX screw is fully seated, remove inferior guidewire before proceeding.



Measure Superior Guidewire

Measure superior guidewire using slide on Depth Gauge (DPGB.02). Advance depth gauge until seated on lateral cortical bone of femur. Measure exposed wire. Confirm desired SimpliFix (SFX) screw length.

Surgical Technique



Overdrill Superior Guidewire

Overdrill superior guidewire using ø6.2 Cannulated Drill (DRBC.62.250). Advance drill proximal to tip of guidewire, maintaining purchase of wire in bone.

Assemble T-handle / Secure Cross Screw

Insert SFX Retaining Bolt (DVHC.IC) into SFX T-handle (DVHC.01) until positive click is perceived. Securely attach the appropriate length SFX screw (SFX.82.XXX) to the SFX T-handle using the retaining bolt.

Note: Care should be taken to ensure T-handle fins are correctly seated in mating slots of SFX screw.

Drive / Seat Superior SimpliFix Screw

Insert SFX screw and T-handle over guidewire. Fully seat SFX screw to cortical bone of femur, paying attention to the rotation of T-handle for placement of Cross Screw (SCS.37.XXX).

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Confirm T-handle / Cross Screw Position

Care should be taken to ensure that the rotational position of the T-handle and SFX clearance hole will allow for unobstructed passage of the cross screw. This should be confirmed on both AP and lateral views.

Note: The surgeon may elect to advance or reverse the SFX screw to accommodate cross screw placement.

Remove Superior Guidewire: Once SFX screw is fully seated, remove superior guidewire before proceeding.

Assemble / Install Targeting Arm

Assemble Targeting Arm (STA.00) and Targeting Arm Thumb Screw (STA.TS.00). Securely attach targeting arm to T-handle using thumb screw. Confirm rotational position of T-handle / targeting arm assembly.

Note: The surgeon may elect to rotationally affix the targeting arm by placing a ø2.4 Guidewire (KWR.24.305) through the guidewire clearance hole on the targeting arm.

Assemble Cross Screw Sleeve / Drill Guide / Trocar

Insert Trocar (XXX) into Drill Guide (STA.DRG.37.140). Insert trocar / drill guide assembly into Screw Sheath (STA. CSS.37.135).

Surgical Technique

Select Fracture Dynamizaton / No Dynamization

Determine whether the 0mm or 3mm position for the cross screw will be used.

Insert Cross Screw Assembly into Targeting Arm

Insert cross screw assembly into the desired targeting arm position (0mm or 3mm). Confirm position of assembly. Lower assembly to skin, confirming desired entry point. Using scalpel, make stab incision at entry point. By hand, advance assembly until firmly seated on bone. Turn screw sheath clockwise or counterclockwise until firmly locked in place. Remove trocar.

Note: Once the trocar is removed, prior to locking, the assembly may be gently tapped with mallet to ensure seating on bone.

Note: Position of assembly should be confirmed via fluoroscopy prior to pre-drilling.

Pre-Drill Cross Screw Hole

Insert ø2.7 Drill (DRB.27.270) into drill guide until seated on bone. Drill bi-cortical.

Note: Prior to removing drill, anticipated cross screw position can be confirmed by inserting a ø2.4 guidewire, by hand, through the clearance hole at the back of the targeting arm. Either tactile resistance and/or an audible tap can confirm that the drill has passed through the SFX screw.

Surgical Technique

Confirm Cross Screw Length

Screw length can be determined using the calibrated markings on the ø2.7 Drill (DRB.27.270) when used in conjunction with the screw sleeve.

Note: The screw sleeve must be seated on bone to ensure an accurate bi-corical screw length measurement.

Insert Cross Screw

Using the T8 Driver (DRV.T8.165), insert the appropriate length Cross Screw (SCS.37.XXX) through the screw sleeve. The surgeon may elect to drive the cross screw on power or use the (Black) Cannulated Paddle Handle (DVHC.00).

Note: Do not fully seat the cross screw on power.

Note: Use paddle handle to fully seat the cross screw into cortical bone of femur.

Note: Cross screw position can be confirmed by inserting a ø2.4 guidewire, by hand, through the clearance hole at the back of the targeting arm. Either tactile resistance and/or an audible tap can confirm that the cross screw has passed through the SFX screw.

Note: Once passage of cross screw through SFX screw is confirmed, the screw sleeve may be slightly retracted to confirm full seating of cross screw via fluoroscopy.

Remove Screw Sleeve and Targeting Arm

Withdraw screw sleeve from targeting arm.
Turn targeting arm thumb screw counterclockwise to release targeting arm from T-handle.

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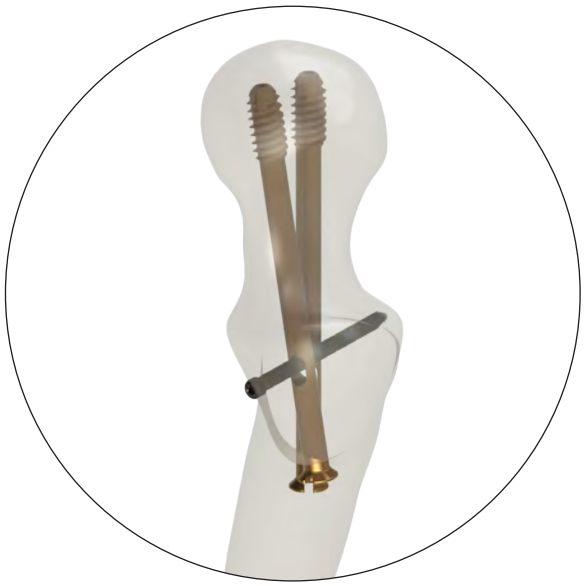
Remove T-handle

Turn SFX retaining bolt counterclockwise to release T-handle from SFX screw.

Final Verification

Evaluate the repair construct under fluoroscopy in AP and lateral views, assessing the reduction and confirming proper positioning of implants.



Inventory List

Implants

SimpliFix Cannulated Screws

ø8.3mm, 16mm Thread Length
Titanium, Individually Sterile Packed

SKU	Length
SFX.83.070	70mm
SFX.83.075	75mm
SFX.83.080	80mm
SFX.83.085	85mm
SFX.83.090	90mm
SFX.83.095	95mm
SFX.83.100	100mm
SFX.83.105	105mm
SFX.83.110	110mm
SFX.83.115	115mm
SFX.83.120	120mm

SimpliFix Headless Cross Screws

ø3.7mm, Fully Threaded
Titanium, Individually Sterile Packed

SKU	Length
SCS.37.045	45mm
SCS.37.050	50mm
SCS.37.055	55mm
SCS.37.060	60mm
SCS.37.065	65mm
SCS.37.070	70mm
SCS.37.075	75mm
SCS.37.080	80mm
SCS.37.085	85mm
SCS.37.090	90mm

Consumables

Guidewire

ø2.4mm, Drill Tip
Sterile Packed (2 per box)

SKU	Length
KWRD.24.305	305mm

ø2.4mm, Trocar Tip
Sterile Packed (2 per box)

SKU	Length
KWR.24.305	305mm

Cannulated Drill

ø6.2mm, Cannulated
Individually Sterile Packed

SKU	Length
DRBC.62.250	250mm

Calibrated Drill

ø2.7mm
Individually Sterile Packed

SKU	Length
DRB.27.270	270mm

Instruments

SKU	Description
DPGB.02	Slide On Depth Gauge
DRV.S8.153	SimpliFix Power Driver, Cannulated, AO Connect (consumable)
DRV.T8.165	T8 Driver, AO Connect (consumable)
DRV.T8.195	T8 Driver, Calibrated, AO Connect (consumable)
DVHC.00	Paddle Handle, Cannulated, AO Connect
DVHC.01	SFX T-Handle Driver, Cannulated
DVHC.IC	SFX Retaining Bolt, Cannulated (consumable)
OBT.24.425	Obturator, ø2.4
STA.00	Targeting Arm
STA.TS.00	Targeting Arm, Thumb Screw
STA.CSS.37.135	Targerting Arm, Screw Sleeve
STA.DRG.37.140	Targerting Arm, ø2.7 Drill Guide
STA.TRO.140	Targerting Arm, Trocar

Miscellaneous

Important

This document does not include all the information necessary for selection and use of a device. Please see full labeling for all necessary information.

Sterile Packed Items

The following items are ETO sterile packed.

SKU	Description	Qty (per Pkg)
SFX.87.XXX	SimplFix Cannulated Screw, Titanium 6Al-4V ELI ø8.3mm, 16mm Thread, Various Lengths	1
SCS.37.XXX	SimplFix Headless Cross Screw, Titanium 6Al-4V ELI ø3.7mm, Fully Threaded, Various Lengths	1
KWR.24.305	Guidewire, Trocar Tip ø2.4mm, 305mm	2
DRBC.62.250	Drill, Cannulated ø6.2mm, 250mm	1
DRB.27.270	Drill, Calibrated ø2.7mm, 270mm	1

Warning and Precautions

- Implants must never be reused. Previous stresses may have created imperfections that can potentially lead to device failure. Protect implant against scratching or nicking. Such stress concentration can lead to failure.
- All instruments are subject to repeated stresses. Instruments should be inspected prior to use to assess functionality. Scratches or dents can result in breakage. Dullness of cutting edges can result in poor functionality. Damaged instruments should be replaced to prevent potential patient injury. Many instruments are intended for use with a specific implant system. It is essential that the surgeon and staff understand the appropriate technique for the instruments and associated implants.
- Disassemble and thoroughly clean all instruments per Cleaning Instructions.
- Use fluoroscopy to prevent unintentional penetration of vital organs.
- Do NOT permanently implant guidewires. Use guidewires for provisional fixation only.
- Do NOT reuse disposable instruments.
- The SimpliFix Hip System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of SimpliFix Hip System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result ininjury or device malfunction.

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SFX.83 TNQ-REV 2