

# **OPERATIVE TECHNIQUE**







TEC-HYP01EN\_BR V02

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See Y-STRUT<sup>®</sup> instructions for use (NOT01-Y-STRUT)

This document has been produced with the contribution of orthopaedic surgeons and interventional radiologists recognized in several countries. It is the guide for Y-STRUT<sup>®</sup> users.

### Indications

Y-STRUT<sup>®</sup> is an implantable medical device indicated in the prevention of fracture of the proximal femur. It is constituted of two implants assembled in situ and combined with bone cement<sup>1</sup>. The implants are made of radio-transparent polymer PEEK.





Y-STRUT<sup>®</sup> is used in the two following indications:

In oncology, for percutaneous internal fixation for impending pathological fracture of proximal femur. Act of last resort (ultima ratio). Inclusion and non-inclusion criteria are defined in Y-STRUT<sup>®</sup> instructions for use NOT01-Y-STRUT.

In orthopaedics-traumatology, for contralateral percutaneous internal fixation of proximal femur, in patient with a low energy pertrochanteric fracture on the first side. Inclusion and non-inclusion criteria are defined in the Y-STRUT<sup>®</sup> instructions for use NOT01-Y-STRUT.

#### This document details the operative technique in the « oncology » indication.

Please refer to the TECHOP011 for the operative technique to implant Y-STRUT<sup>®</sup> in the «orthopaedics-traumatology» indication.

Y-STRUT<sup>®</sup> is inserted by means of a specific instrumentation. The material necessary to the procedure is detailed in the « References » part, at the end of this document.

#### In addition to the operative technique, please consult the instructions for use NOT01-Y-STRUT.

<sup>&</sup>lt;sup>1</sup> See instructions for use (NOT01-Y-STRUT)



## **Operative technique**

#### 1. Patient preparation and precautions

Y-STRUT<sup>®</sup> implantation requires anaesthesia. The anaesthetist will decide which type is most appropriate.

The patient is in **supine position** on an orthopaedic traction table or maintained by a scoop stretcher. The patient can also be in lateral position maintained by a scoop stretcher.

An imaging equipment will be used to control all the operating steps.

Y STRUT<sup>®</sup> is constituted of implant 1 and implant 2.

All instruments necessary to place implant 1 are identified with number "1". All instruments necessary to place implant 2 are identified with number "2".



#### This operative technique can only be performed by a trained practitioner.

Imaging control is required during the whole procedure to check the good progress of the operating steps and the good positioning of the device.

- Y Ensure that the imaging equipment is suitable to use with Y-STRUT® instrumentation (especially the instrumentation length).
- Y During the surgery, a facial and lateral imaging control of the proximal femur is required to ensure the good positioning of the device.

#### Before starting the procedure:

Ensure that the appropriate instrument kit and adequate quantity of implants sizes and accessories are available in the operating room.

Ensure that bone cement, compliant with the instructions for use NOT01-Y-STRUT, and its preparation and injection kit are available.

#### 2. Pilot assembly

Ref	Quantity	Name	Image
2000	1	Pilot	
2100	1	Black screw 1	<b>P</b>
2101	1	Screw 1	T
2102	2	Screw 2	<b>T T</b>
2011	1	Tube 1	

Before starting the procedure, the pilot, screws and tube 1 have to be assembled, depending on the side needing implantation.



Right side of the patient

Left side of the patient



#### *3.* The procedure

#### Positioning of the guide wire

In this step of the procedure, a surgical power tool with a clamping chuck of Ø 3mm is required.

Ref	Quantity	Name	Image
2300	1 (2 recommended)	Guide wire	

#### As precaution, it is recommended to have an extra guide wire available.

During the whole procedure, ensure that guide wires are not twisted or damaged. If so it is mandatory to use new guide wires.

Locate the greater trochanter by palpation to define the entry point of the guide wire. In the frontal and sagittal planes, the guide wire is centred in the femoral neck axis.



A skin incision of about 1 cm is made at the entry point of the guide wire.

The guide wire positioning is critical for the good progress of the procedure. It needs to be perfect before continuing with the surgery. At this stage, a lateral and antero-posterior (AP) imaging control is required.

**1.** Insert the guide wire by means of a surgical power tool. The guide wire needs to be positioned up to at least 5 mm from the cortex of the femoral head.

The guide wire may not stick out of the back of the power tool in order to avoid breaking because of vibration.

If the cortical bone of the femoral head is accidentally perforated, you have to make a cement plug. Please refer to the "cement injection" part to avoid leaking risks.

#### **Optional:**

Before the guide wire positioning, an 8-gauge trocar with a length of 15 cm can be used to define the implantation axis.

The trocar is centred into the femoral neck axis as described above. The mandrel is removed, the guide wire is inserted through the trocar, and then the trocar is removed.



Positioning of the pilot

Ref	Quantity	Name	Image
2021	1	Dilator 1	
Assemb	led pilot (See	upper)	
2031	1	Drill 1	

2. Insert dilator 1 onto the guide wire up to the bone.



- **3.** Insert the pilot onto dilator 1 up to the bone.
- Y The teeth of tube 1 will connect with the bone and have to remain in contact with the bone during the whole procedure (a).
  - The pilot has to be perfectly parallel to the femur (b).



Y

4. Remove dilator 1.



#### Drilling implant 1 location site

In this step of the procedure, a surgical power tool with a clamping chuck of Ø 6mm is required.

Ref	Quantity	Name	Image
2031	1	Drill 1	

Secure drill 1 onto the power tool.

Check the rotation direction of the drill.

**5.** Insert drill 1 over the guide wire through the pilot until it reaches the bone, then drill the location site for implant 1.



Y Imaging control of the drilling progression is required.

6. Stop drilling at about 10 mm from the cortex of the femoral head, positioning the drill between two marker lines (see n°7).



Y Check that the guide wire does not move during the drilling and does not pierce the cortical wall of the femoral head.

7. Read the implant 1 size in between the two marker lines of drill 1: 80-85-90-95-100 mm



8. Select the corresponding implant 1.

Example

Implant 1 : Size 80 mm

1 - 80

9. Remove drill 1. If the guide wire is driven out with when removing the drill, another guide wire must be used to maintain a good position.





## Y <u>DO NOT</u> insert implant 1 before drilling the implant 2 location site.

The template is used to allow drilling the implant 2 location site, imitating implant 1.

Ref	Quantity	Name	Image
2040	1	Template	

10. Manually insert the template over the guide wire through the pilot until the stop (a). Direct its handle

parallel to the pilot (b) orienting the symbol  $^{ imes}$  in the head / foot position of the patient.

Tighten screw 1 to secure the template position (c).



DO NOT USE a mallet to insert the template.

Check that tube 1 is still in contact with the bone.



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In this step of the procedure, a surgical power tool with a clamping chuck of Ø 6mm is required.

Ref	Quantity	Name	Image
2012	1	Tube 2	N
2300	1 (2 recommended)	Guide wire	
2022	1	Dilator 2	
2032	1	Drill 2	

**11.** Gather a guide wire, dilator 2 and tube 2, and insert them all together through the second entry of the pilot as shown below (1 cm between each instrument).



**12.** Check that the pilot is still parallel to the femur and that the guide wire is aimed at the femoral diaphysis.

**13.** Bring all instruments together up to the skin and orient the symbol  $\land$  on the handle of tube 2 to be in the correct head / foot position of the patient, so that the teeth in contact with the skin are parallel with it.



Make a small skin incision to allow tube 2 to enter.

**14.** Insert guide wire 2 up to the bone.





- **15.** Simultaneously push dilator 2 and tube 2 up to the bone.
- Y Ensure that dilator 2 is always ahead of tube 2 in order to protect the tissues from the teeth of the tube up to the bone.
- Y Ensure that the symbol  $\wedge$  on the handle is correctly oriented according to the head / foot position of the patient and so the teeth are parallel to the bone.



Ensure that the teeth of tubes 1 and 2 are in contact with the bone.

**16.** Lock the position of tube 2 by means of screw 2 on the top and the position of dilator 2 by means of lateral screw 2.



- **17.** Maintain the position by firmly holding the handle of the pilot and pushing toward the bone.
- Y Ensure that the pilot remains parallel to the femoral diaphysis: the entry point of the guide wire 2 is in the middle of the femoral shaft (AP imaging control).





Y Ensure that tubes 1 and 2 are positioned firmly in contact with the bone by profile imaging control.



Ensure that dilator 2 is in contact with the diaphysis.

Ensure that the handle of the template is parallel to the pilot.

Ensure that template is locked by means of screw 1.

<u>NOTE 1:</u> Dilator 2 and tube 2 allow the guide wire to remain rigid when going through the cortical diaphysis. <u>NOTE 2:</u> The good positioning of implants 1 and 2 is guaranteed when the teeth of tubes 1 and 2 are firmly pushed onto the bone.

**18.** Use the surgical power tool to drill wire 2 into femur until it reaches guide wire 1. Remove the power tool.



**19.** Unlock the lateral screw 2 and remove dilator 2.



**20.** Place drill 2 onto the power tool and insert it over guide wire 2 through tube 2.

Now drill the location site for implant 2.

Y Ensure that guide wire 1 firmly remains in its position during this step of the procedure to avoid guide wire 2 to move forward.

Check the drilling progression with imaging control.

When drill 2 reaches the guide wire 1, you can feel it vibrate. Stop the drilling.



**21.** Pull back the first guide wire enough to allow drill 2 to cross the path of the first channel. Unlock screw 1 that maintains the template to help with the drilling.



**22.** Finish drilling the location site for implant 2 through the template. When drill 2 stops against the template, the drilling is completed.

When drill 2 reaches template 1, the drilling must URGENTLY be stopped.



Ensure that tube 2 remains nicely against the bone and read the implant 2 size in between the two marker lines of drill 2: 55-60-65-70-75 mm



#### 23. Examples of readings:



Reading in between 2 lines: directly choose the size (in this case 70).

**24.** Select the corresponding implant 2.

Example

Implant 2: Size 70 mm



Reading on the line: prefer the smaller size (in this case 70).



#### Assembling implants on implant-holder (gripper + positioner)

Ref	Quantity	Name	Image
201-100 201-85 201-95 201-80 201-90	1	Implant 1	
202-80 202-65 202-75 202-60 202-70 202-55	1	Implant 2	
2051	1	Gripper 1	
2052	1	Gripper 2	
2061	1	Positioner 1	
2062	1	Positioner 2	<b>}</b> >

#### Assembling implant 1 on implant-holder 1

Insert gripper 1 into positioner 1.

Insert implant 1 you selected earlier into positioner 1 according to the symbol (a) until the two are in contact (b).



b.



Hold implant 1 and positioner 1 in one hand while pushing and screwing the gripper clockwise. As soon as you feel resistance, the screwing is complete.

Y Do not screw the gripper excessively in order not to damage the implant made of polymer.



Y Ensure that the implant is lined up with the implant-holder and that there is no space in between them. If not, start again.

#### Assembling implant 2 on implant-holder 2

Reproduce the same procedure to assemble implant 2 onto implant-holder 2.



#### Positioning the implants

**25.** Pull back drill 2 and guide wire 2 to allow the template removal. At this stage the power tool can be removed to facilitate the following steps.



**26.** Put guide wire 1 back into place, fully pressed down.



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**27.** Remove the template by hand and carefully maintain guide wire 1 fully pressed down.



**28.** Insert implant 1 by means of implant-holder 1 over guide wire 1, up to the stop of the pilot. Implant 1 is radio transparent, yet it includes visualizing markers made of tantalum at its distal end. The marker has to be on the head side, over the guide wire.



A second marker, below the guide wire, indicates the connection with implant 2.

Respect the symbol orientation  $\bigwedge$  and position the handle of the implant-holder parallel to the pilot. Lock screw 1.



**29.** Remove guide wire 1.





**30.** Put guide wire 2 back into place, fully pressed down through implant 1.



**31.** Completely remove drill 2 and carefully maintain guide wire 2 into place (if the guide wire is driven out when removing the drill, a new guide wire must be used to maintain it in good position.)



**32.** Insert implant 2 by means of implant-holder 2 over guide wire 2, until it neatly locks into implant 1. Ensure that guide wire 2 is not moving forward.

Implant 2 must go through implant 1.

Y



**33.** To correctly finish the positioning of implant 2 respect the symbol orientation  $^{\land}$  and position the handle of implant-holder 2 parallel to the pilot. Lock lateral screw 2.



#### Y <u>DO NOT USE</u> a mallet to insert the implants.

<u>NOTE</u>: If you feel a resistance to fully insert implant 2, unlock screw 1 to free implant 1. When the 2 implants are fully inserted, lock screws 1 and 2.

#### Control of implants positioning

#### **34.** Imaging control

Control of implant positioning is done via imaging, by means of the tantalum markers which allow visualization of the implants.



Y If the two markers connect to form a V shape, the two implants are correctly inserted and locked together.

#### Y If not:

- Ensure that the handles of the implant-holders are parallel to the pilot.
- Ensure that the symbols are correctly oriented according to the patient's position head / foot.
- Ensure that implant-holder 1 is well positioned up to the stop onto the pilot.
- Ensure that implant 2 is fully pressed down.

#### **35.** Manual test (OPTIONAL)

To ensure that implant 2 is locked into implant 1, gently twist implant-holder 1. You must feel resistance as implant 2 prevents implant 1 rotation.

To ensure that implant 2 is correctly inserted and oriented, fully insert guide wire 1 into implant 1 and gently twist the implant-holder 2. You must feel resistance. Implant 2 is correctly inserted.

**36.** Lock screw 1 and the lateral screw 2, then remove guide wire 1.



#### Hyprevention provides the catheter necessary to inject the cement.

A minimum of 20cc of cement with the corresponding injection material is required separately, in compliance with the instructions for use NOT01-Y-STRUT.

Ref	Quantity	Name	Image
2311	1 (2 recommended)	Catheter	]q=

One unique catheter is used to fill both implants.

Y In case of perforation of the cortex of the femoral head during the procedure, refer to the instructions at the end of the paragraph BEFORE starting the cement injection.

Cement injection is performed in 3 steps: 1) fill distal part of implant 1, 2) fill implant 2 and 3) fill proximal part of implant 1.



- Y Inject the needed quantity of cement to fix the implants (depending on the implant size) and to fill the tumour in oncology indication.
- Y <u>DO NOT</u> inject cement to close to the implants' holders.
- **37.** Prepare the cement.

**Y** Respect the manufacturer's instructions to prepare the cement.

In the case where 2 doses of cement are used, <u>DO NOT</u> mix 2 different cements.

**38.** Slightly pull back the guide wire 2, positioning the tip between the tantalum marker and the entry point of the implant 2 (the presence of the guide wire 2 avoid the reflux of cement into the soft tissues).



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**39.** Remove the mandrel of catheter, connect the injection system of the cement to the standard luer-lock connection of the catheter and fill it with cement.

Y It is important to prefill the catheter with cement outside of the implant / instruments to prevent air from coming in.

Before performing the cement injection, ensure that guide wire 2 remains still in the implant 2 and ensure that there is enough room in the implant 1 for the catheter to go into. The guide wire 2 keeps the cement from entering the implant 2 while filling the implant 1.

**40.** Insert catheter into implant-holder 1 up to the distal marker of implant 1 (femoral head).



- **41.** Progressively inject the cement into implant 1 starting from the distal end.
  - Use the landmarks on catheter to check the filling of implant 1.
  - During the injection, ensure that the cement is going through the perforations of the implant and that it is distributed homogeneously.
- **42.** Progressively pull back the catheter up to the connection of implant 1 and 2.



**43.** When the cement has reached the implants connection. The catheter remains at the connection site. Progressively pull back, step by step, the guide wire 2 from the implant holder 2 while continuing the cement injection in order that it is spread through the implant 2.



- Inject the needed quantity of cement to fix the implants (depending on the implant size) and to fill the tumour.
- **44.** Stop the injection when reaching the last lateral hole of implant 2 to avoid the extra bone cement leakage. The presence of the guide wire 2 allows to avoid the cement reflux in the soft tissues.
  - Implant-holder 2 must not get into contact with the cement in order not to get fixed to the implant.
- **45.** Finish the cement injection into implant 1 by stepping back little by little the catheter from implants connection up to proximal part of implant 1. At this stage, the injection system can be removed and the injection can be finished with the mandrel.



- Y Implant-holder 1 must not get into contact with the cement in order not to get fixed to the implant.
- Y If the tumour cannot be filled by the cement injection through the implant, it is possible to fill it via a separate trocar.

#### Instructions in case of perforation

In case of perforating the cortex of the femoral head with guide wire 1, you have to make a cement plug using a dose of cement and an extra catheter.

- Prepare a dose of cement.
- With a catheter, inject a small quantity of cement to make a plug at the end of implant 1, WITHOUT leaking outside of the cortex.
- Wait the time recommended by the manufacturer for the cement polymerization to allow the plug formation.
- Now you can inject the cement into the implants as described from steps 38 to 45 above.

## Y In this case, a new dose of cement and new catheters are required to inject the cement into the implants.



#### 4. Instruments removal

Disassemble the implant-holder starting with instruments 2 and then instruments 1.

#### **PRECAUTION: SCREWS 1** and 2 must be LOCKED onto the implants-holders.

**46.** Unscrew gripper 2 (round handle) while holding positioner 2 in position (T shape handle). Remove gripper 2 when it is fully unscrewed.



**47.** Unlock the two screws 2 and partially remove positioner 2. While holding the pilot, ensure that implant 2 remains in position (markers control).

If implant 2 has moved back, push it again into its location by pressing gripper 2.



Totally remove positioner 2 and tube 2.

**48.** Unscrew gripper 1 (round handle) while holding positioner 1 in position (T shape handle). Remove gripper 2 when it is fully unscrewed.





**49.** Remove simultaneously positioner 1 and the pilot.



Y Ensure by imaging control that the implants are well positioned and there are no cement residues remaining in the tissues.

#### 5. Suture of incisions

Suture the incisions.

## Instruments cleaning

At the end of the procedure all instruments must be completely disassembled, as presented in the list of instruments.

Check that the instruments were not damaged during the procedure. It is imperative to remove an instrument that was damaged as it could injure the patient or compromise the procedure during the next intervention.

Y Carefully ensure that the teeth of tubes 1 and 2 are not twisted or broken.

 $\mathbf{Y}$ Ensure that there is no cement residue on/in the instruments.

igY Ensure that the cutting parts of drill 1 and 2 remain sharp.

Y Ensure that the screw threads are not damaged.

Each instrument or part of it will be cleaned individually.

The damaged instruments have to be replaced before performing a new procedure.

For instruments cleaning and sterilization, see the instructions for use NOT01-Y-STRUT.



## **Revision procedure**

A revision procedure needs to be performed EXCLUSIVELY by an orthopaedic surgeon in an operating room.

Y Precaution: Before removing the implant, an alternative device needs to be chosen and available in the operating room.

Ref	Quantity	Name	Image
2200	1	Trephine	

The instrumentation kit includes a trephine to entirely remove Y-STRUT®.

During the revision procedure, implant 2 is removed first, and then implant 1.



- Incise the skin at the previous scar made for implant 2 and dissect up to the bone.
- Locate the extremity of implant 2 by palpation.
- With imaging control locate the implant 2 axis by means of a guide wire.

## If the entry points of the implants 1 and 2 are not found by palpation, the revision procedure has to be done by open surgery.

- Secure the trephine onto the power tool.
- Drill implant 2 with the trephine over its entire length (a).
- Remove the trephine.
- Remove implant 2 with pliers.
- Repeat the same procedure to remove implant 1 (b).

After material removal, an alternative device will be placed.

Y Contact Hyprevention for any questions regarding the revision procedure and choice of replacement device.





## References

Implant 1						
Ref	Length (mm)	Material	Diameter (mm)	Image		
201-100	100		9			
201-95	95					
201-90	90	PEEK 9		9		
201-85	85			Length		
201-80	80					

	Implant 2						
	Ref	Length (mm)	Material	Diameter (mm)	Image		
	202-80	80		8			
	202-75	75					
Ī	202-70	70	חרבע				
Ī	202-65	65	PEEN				
Ī	202-60	60			Length		
	202-55	55					

Sterile and single-use accessories provided by Hyprevention								
	Ref	Quantity	Name	Image				
	2300	2	Guide wire					
	2311	1	Catheter	Jame				

Container Y-STRUT <sup>®</sup> Hyprevention								
	Ref	Quantity	Name	Image				
	2400	1	Container	REF: 2400 cc				

## Instruments Kit Y-STRUT<sup>®</sup> Hyprevention

Ref	Quantity	Name	Image
2000	1	Pilot	
2100	1	Black screw 1	T
2101	1	Screw 1	
2102	2	Screw 2	
2011	1	Tube 1	
2012	1	Tube 2	N
2021	1	Dilator 1	
2022	1	Dilator 2	
2031	1	Drill 1	
2032	1	Drill 2	
2040	1	Template	
2051	1	Gripper 1	
2052	1	Gripper 2	
2061	1	Positioner 1	
2062	1	Positioner 2	
2200	1	Trephine	

All instruments and accessories are in stainless steel, except for the pilot which is in aluminium.

#### Additional material necessary for the procedure not provided

- Surgical power tool with a clamping chuck of Ø3 mm to insert the guide wires and of Ø 6mm to insert the drills.
- Cement (See the instructions for use NOT01-Y-STRUT to choose the cement).
- Material to prepare and inject the cement.

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To get the instructions for use (NOT01-Y-STRUT), refer to the information on the product's label or contact Hyprevention, see details below:

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