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CREATEUR FABRICANT

Prius®

Surgical Technique

Evolutis
MOTION INSIDE

TABLE OF CONTENTS

PRIUS FEMORAL REVISION SYSTEM

The modular PRIUS revision and reconstruction system has been designed to facilitate proximal femur osteo-synthesis around a centro-medullary post which is constituted of the distal implant component.

The system is intra-operatively constructed around the diaphysis stem dependent on bone stock.

The surgeon can adapt the surgical protocol which is best adapted to the situation and can either implant the distal diaphysis component first before fixing the metaphysis component, or assemble both components on the table and implant them as one.

The choice between a straight distal stem component or a curved one (with optional distal screw fixation) will be determined by the length at which adequate distal bone fixation can be achieved.

Due to the modularity of the system and the possibility of associating a trochanteric hook, the indications for the PRIUS can go from intertrochanteric fractures with multiple fragments to more complex reconstructions which require fixation distal to the fracture site to facilitate synthesis of bone fragments and grafts, or the closure of a femorotomy.

The trochanteric hook is used in association with the femoral implants to which it can be secured.

Set of PRIUS templates

Diaphysis Calibration

After removal of the previous stem and careful cleaning of the femoral canal introduce the Ø10mm diaphysis reamer mounted on the T handle.

Note: apart from very narrow or blocked femoral canals this step is intended only for calibration of the medullary canal, not to ream it.
In reaming is required, prefer flexible and half-millimetre reamers, do not use straight rigid reamers to increase the intramedullar diameter.

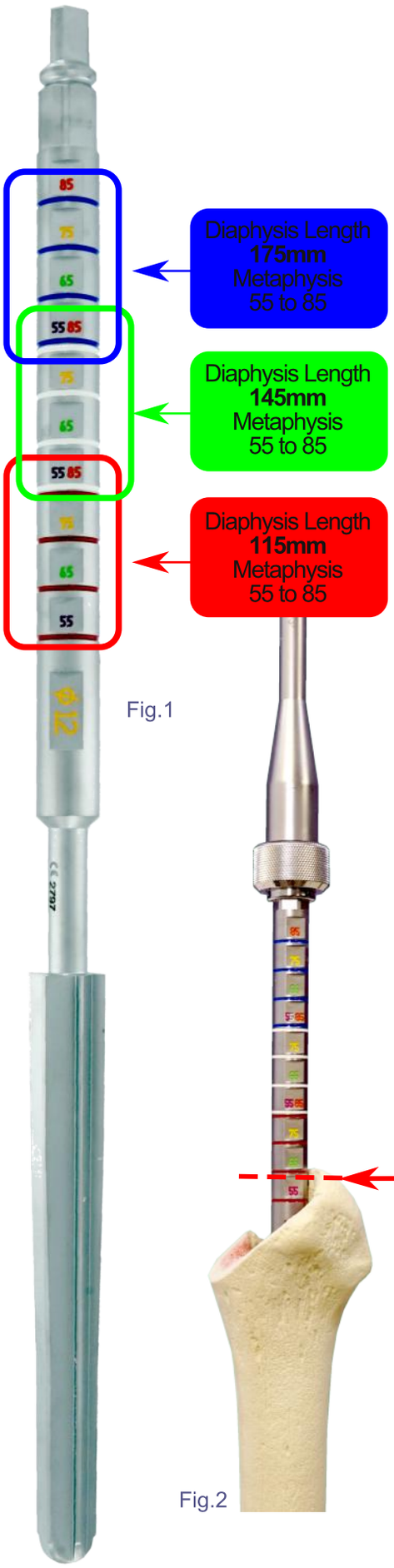
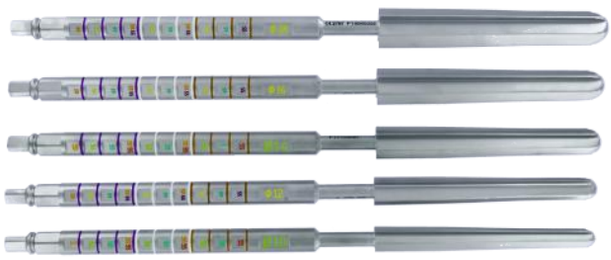
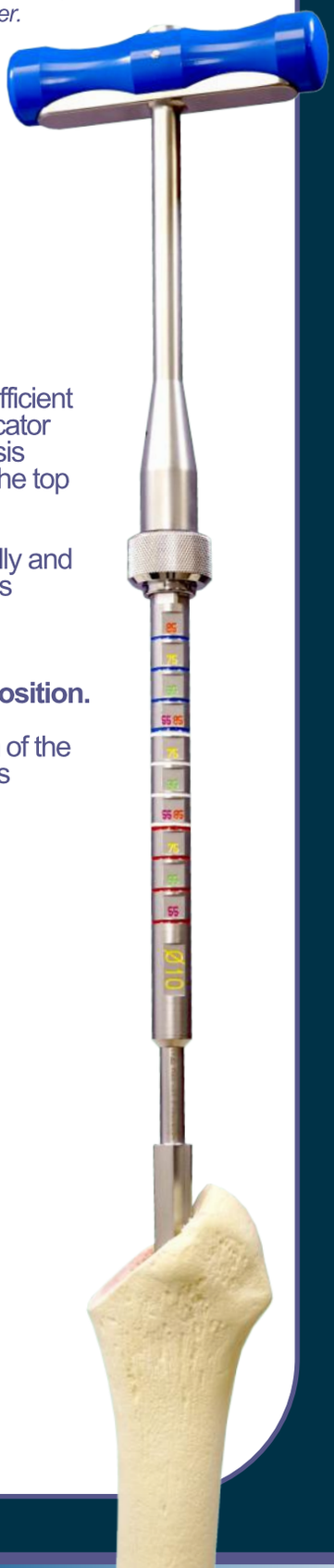


Fig.1





Increase the sizes of the reamers incrementally, (Ø10mm to 18) with the AO T handle up until sufficient cortical contact is obtained. Use the reamer indicator marks which indicate the combination of diaphysis length and metaphysis size, when aligned with the top of the greater trochanter.

The last size reamer used should be stable axially and in rotation and allow for selection of a metaphysis component compatible with the geometry of the proximal femur and its bone stock.

Leave the last reamer in size in its blocked position.

Memorize the three values: diameter and length of the distal component, size (height) of the metaphysis component.

In this example:
Diaphysis length 115mm
+
Metaphysis 65mm

Fig.2

Steps for curved diaphysis components

In case of use of a curved stem, use a curved diaphysis rasp after the straight reamer.

The curved rasps must be introduced in line with the anterior femoral bow and not in rotation.

The T handle should be assembled on the diaphysis rasp PARALLEL to the curvature of the femur which allows for identification of its orientation inside the femur (fig 3).

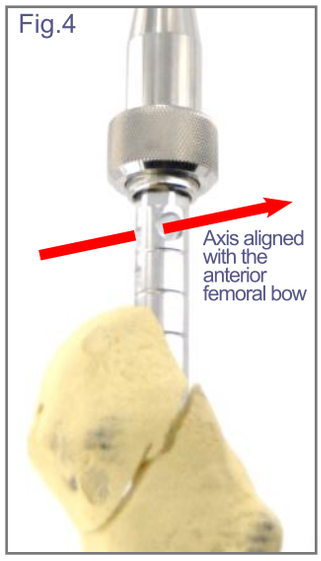
Another option is to introduce a screwdriver or cylindrical part into the hole in the proximal part of the rasp.
The axis is parallel to the rasp curve (fig 4).

- Mount the rasp Ø12 on the T handle
- Rasp the femur up until one of the metaphysis height indicator marks is aligned with the top of the greater trochanter
- Increase size incrementally until axial and rotational stability are achieved.
- Memorize the diameter of the last diaphysis rasp introduced.

Fig.3

Leave the last raspr in place in its blocking position.

Fig.4



The curved rasps are only available in length 205mm. For this reason they only show one set of 65, 75 and 85mm metaphysis size graduations

Preparation of the metaphysis

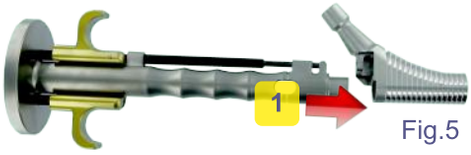


Fig.5

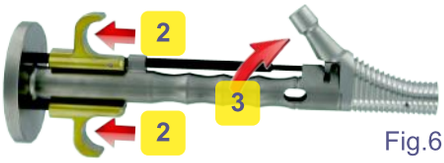


Fig.6

The metaphyseal preparation will be carried out with the diaphyseal reamer in place. The diaphyseal reamer guides the the metaphyseal rasp in the diaphyseal axis of the diaphys AND controls of the level of tintroduction of the rasp in accordance with the pre-operative templating or with the diaphyseal implant's blocking level.

Important notice: it is not a matter of incrementing the sizes of metaphyseal rasps. Only one proximal rasp will be used, corresponding to the height identified when introducing the diaphyseal reamer *(Fig.2 page 4)*.

Assembly of the rasp on the rasp-holder:
• Insert the rasp-holder in the proximal hole of the rasp ((1) Fig.5).
• Pull on the yellow triggers to open the locking mechanism ((2) Fig.6).
• Rotate the raaps-holder counter-clockwise, then release the triggers ((3) Fig.6).

Insert the metaphyseal rasp with the rasp-holder onto the reamer still in place in the femur (Fig.7).
Impact gradually until the height value of the rasp used is in line with the height mark in the rasp-holder window ((4) Fig.8).

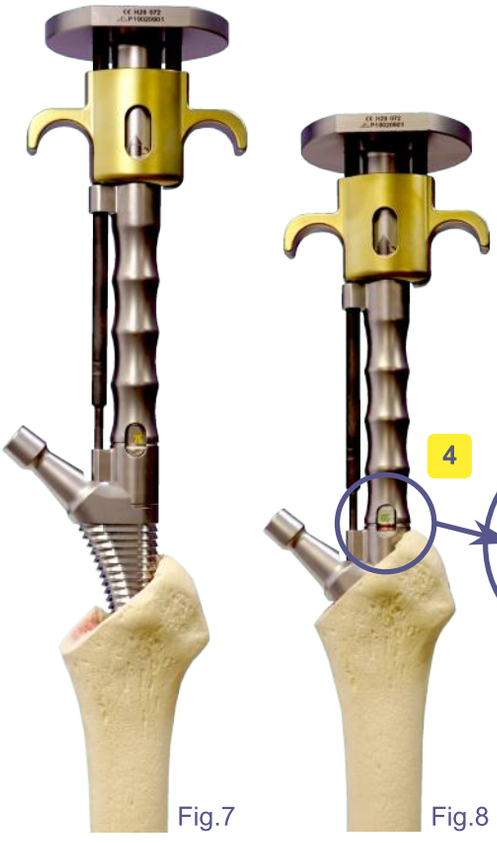


Fig.7

Fig.8

Remove the metaphyseal rasp and rasp-holder.
Re-engage the T-handle on the reamer and remove.

** : available only on special request*

Fig.9

Metaphysis-Diaphysis junction preparation

The cone shaped reamer allows to smooth over the junction between the metaphysis reamer (Ø20mm) and the diaphysis reamer.
It becomes especially necessary when diaphysis reamer preparation is less than or equal to Ø14.

Assemble the cone reamer on the T handle or power tool.

Ream the diaphysis up until the depth indicator chosen in the previous steps (fig 9):
- Distal mark = metaphysis size 55mm
- Lower middle mark = metaphysis size 65mm
- Higher middle mark = metaphysis size 75mm
- Proximal mark = metaphysis size 85mm

Assembly of the metaphysis on the diaphysis stem

Assemble together the diaphysis of the chosen length and diameter with the metaphysis height (fig 10) as determined by the sizing steps.

Assembly is undertaken on the operating table.

1 - Introduce the morse taper of the diaphysis stem into the metaphysis component

2 - If necessary (curved diaphysis) adjust the anteversion of the metaphysis using the marks on the metaphysis component (-15°, 0°, +15°) (fig 11)

3 - Impact the metaphysis and Introduce the locking screw (3.5mm hex screwdriver) through the metaphysis component and screw it into the diaphysis stem

- Screw down firmly

The metaphysis-diaphysis locking screw and the cap screw are packed separately but are is the same box as the metaphysis component.

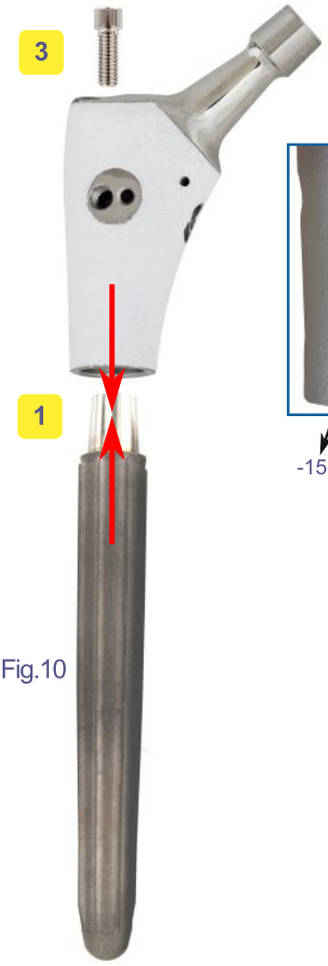


Fig.10

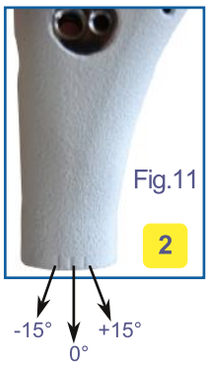


Fig.11

IMPLANTATION IN TWO STAGES

Implantation of the assembled stem

Screw the slap hammer onto the metaphysis component.

Introduce the assembled implant into the femur and progressively impact it taking care of the anteversion position and up until its final position (fig 12).

Remove the slap hammer and block off the thread with the cap screw provided.

End cap screw for the metaphysis thread hole

Fig.12

IMPLANTATION IN 2 STAGES

Fig.14

Fig.15

Fig.13

Implantation of a definitive stem without distal screws

This stage follows on from the common stages (pages 4 to 6).
This paragraph concerns the 2 stage operative protocol of the PRIUS modular implant:

*-Implantation of a s**traight or curved diaphysis component** first*
-Implantation of the metaphysis component in a second stage

Assemble the diaphysis of the chosen length and diameter as determined by the sizing steps onto the combined impactor (fig 13).

Place the diaphysis stem into the femur and impact it (fig 14).

When using a curved stem be careful to place the stem in the correct anatomic anterior femoral bow.

Impact the diaphysis stem with a hammer up until the proximal indicator mark is aligned with the greater trochanter as selected previously (fig 15).

Following steps for implantation of a definitive stem without distal screws: go directly to page 13.

Distal fixation augmented with tranverse screw–pins

This stage follows on from the common stages (page 4 to 6).

This paragraph concerns the 2 stage operative protocol of the PRIUS modular implant with additional distal fixation of the diaphysis component by screw-pins.

- *Implantation of a curved diaphysis component first*
- *Implantation of the metaphysis component in a second stage*

Additional distal fixation with screw-pins is only possible using curved diaphysis components.

PRIUS distal stems can receive up to 3 locking screw-pins.
A minimum of 2 is recommended.

Fig.16

Assemble the diaphysis stem of the length and diameter chosen during the calibration stage (page 5) onto the targeting jig corresponding to the operated side (fig 16).

Introduce the assembly screw into the proximal jig, then screw the stem firmly onto the jig (fig 17) with the T handle screwdriver (Hex.8).

Fig.17

Outside of the patient undertake a trial alignment of the guide sleeves and drills to check overall alignment (fig 18).

If necessary, loosen the locking nut holding the stem onto the jig to improve the alignment of the sleeves and drill, and then lock down the assembly again.

Remove the 2 drills, 2 drill sleeves and 2 outer guide sleeves.

Fig.18

IMPLANTATION IN TWO STAGES

Fig.19

Introduce the diaphysis stem into the femur using the jig frame (fig 19).

Should the implantation require impacting, screw the combined impactor onto the top of the jig and gently impact (fig 20).

Impact the stem until good primary fixation is achieved and embedded up to one of the greater trochanter alignment marks selected during the calibration phase (fig 21).

Fig.20

Fig.21

Fig.22

Place one of the outer guide sleeves into the jig in the most proximal position (fig 22).

A skin incision and muscle dissection is undertaken to facilitate the introduction of the sleeve up until cortical bone contact.

Introduce the drill guide sleeve into the outer sleeve (fig 23).

Place the Ø4mm drill on a power tool, place it in the drill guide and drill until contact of the second cortex (fig 24).

Remove the power tool from the drill bit, and leave the drill in place for stability whilst preparing the second screw hole (fig 25).

Repeat with a second drill in a distal hole
- Outer guide sleeve
- Drill guide sleeve
- Bi cortical drilling

Remove the 2nd drill bit whilst leaving in place both guide sleeves (fig 26).

Introduce the screw length gauger through the drill sleeve and measure the length of the screw-pin required (fig 27).


Fig.23


Fig.24


Fig.25


Fig.26


Fig.27

IMPLANTATION IN TWO STAGES

Fig.28

Screw pins are available in 5mm increments.
If measurement is between 2 sizes choose the longer length.

Remove the measuring gauge and the drill sleeve (fig 28).


Fig.29

Screw the thread on the head of the screw-pin into the holder (fig 29).

Introduce the screwdriver through the holder which is hollow, into the screw head, and slide the assembly through the outer sleeve left in situ (fig 30).

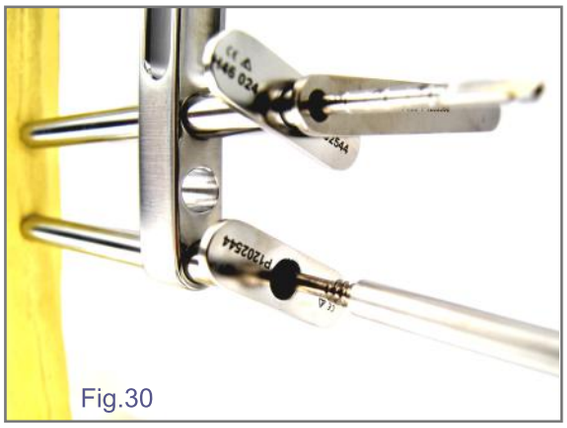


Fig.30

Screw the screw-pin into the bone going through the distal stem up until firm contact (fig 31).

Unscrew the holder from the screw head whilst holding onto the screwdriver, finish screwing.

Remove the screwdriver.

Repeat these steps for the proximal tranverse screw-pin.

Remove the jig from the distal stem.

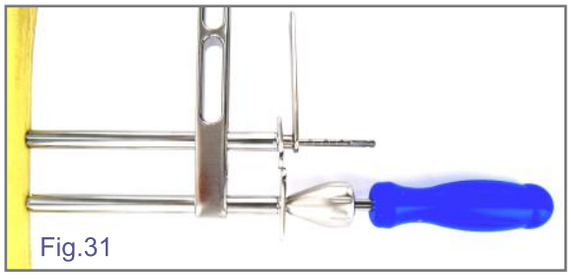


Fig.31

Trials

Once that the PRIUS diaphysis stem is firmly anchored in the femoral canal (fig 32), metaphysis trials can be undertaken to confirm the height of the metaphysis component to be used and the best anteversion.


Fig.32

Clean and dry the diaphysis morse taper.

Select the metaphysis component adapted to the calibration steps (Fig.2 page 4).

Place the metaphysis trial over the diaphysis morse taper (fig 33).

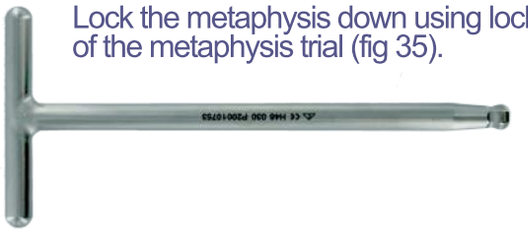
Turn it to the best anteversion position.


Fig.33


Fig.34


Fig.35

Lock the metaphysis down using locking screw which is part of the metaphysis trial (fig 35).



Trial using trial heads (fig 36).

Reduce the articulation to undertake the usual mobility and stability testing.

Remove the trial metaphysis component having memorised its position and also the trial head and its length

- Unscrew the locking screw
- Re-assemble the Rasp-holder onto the metaphysis trial
- Remove the metaphysis trial from the distal stem.

Unlike the definitive metaphysis component, the trial component does not lock onto the diaphysis morse taper. Its' removal should be easy, not damage the taper and not affect the distal fixation.


Fig.36

Fig.37

Fig.38

Fig.39

Fig.40

End cap screw for the metaphysis thread hole

Implantation of the definitive metaphysis component

Screw the definitive metaphysis component onto the combined impactor (fig 37).

Clean and dry the diaphysis morse taper in situ.

Position the metaphysis on the morse taper of the diaphysis, reproducing the desired anteversion (fig 38).

Impact the metaphysis component onto the diaphysis stem taking care not to over impact the stem.

Screw into place the locking screw (fig 39).

Screw into place the end cap screw on the metaphysis (fig 40).

Femoral head trials

Place a trial head on the definitive metaphysis morse taper cone (fig 41).

Reduce the articulation with the head pusher- reducer.

Undertake tests to ensure
- Articular stability
- Limb length
- Cam effects
- Range of motion and mobility

Select the definitive head of the most appropriate size.

Fig.41

Definitive head implantation

Place the definitive head by hand on the clean dry morse taper.

If a ceramic head is being used twist it by 90° to ensure optimum centring on the morse taper.

Impact using the cup impactor tip (H03 037) assembled on the combined impactor (H28 040) (fig 42).

Reduce the articulation.

Re-test stability and mobility.

Fig.42

Disassembly between metaphysis and final diaphysis

When performing intra-bone ablation, check that the metaphysis is no longer attached to the bone before starting the extraction step.
First remove theend cap screw (Fig.43), then the locking screw between the metaphysis and the diaphysis (Fig.44).

Fig.43

Fig.44

Adjust the disassembly tool (H28 024) to the dimension of the metaphysis using the screw-stop.

Adjust the T-handle in the disassembly tool.
Confirm the screw-stop is aligned with the mark of the same length as the metaphysis in place.
Example in fig.45: adjustment for an 85mm metaphysis.

Fig.45

Insert the disassembly tool into the hole of the metaphysis and engage the screw-stop in the thread of the proximal hole of the metaphysis (Fig.46).
Detach the metaphysis off the diaphysis by continuing to screw the screw-stop with the T-handle (Fig.47).

Remove the metaphysis.

Fig.46

Fig.47

IMPLANTATION OF THE TROCHANTERIC HOOK

The trochanterian hook, in addition to the implantation of a Prius revision stem, allows the osteosynthesis of the bone fragments following a per-trochanteric fracture, to stabilize a femoral flap -or a window- induced by the femoral approach, or to maintain a trochanteric bone fragment or segmental grafts in a stable and solid way.
The Trochanteric hook may also be indicated as a result of a post-operative fracture or secondary pseudarthrosis of the greater trochanter when a Prius implant is already in place.
The implantation technique is facilitated by a rigid and simple proximal jig.

Note: the anterior and posterior sides of the PRIUS metaphysis have uncoated circular zones with 2 holes. These zones are there for fixing the proximal jig of the trochanteric hooks.

Trochanteric hook associated to the PRIUS stem

Fig.48

Positioning of the proximal jig

The proximal jig is fixed directly onto PRIUS metaphysis component in situ.

For the posterior approach do not close or fill the posterior metaphysis bone area with graft before having fixed the hook to the implant.

Fix the jig onto the metaphysis component, either left or right (fig 48).

Note: Should a short hook be used with an anterior approach, use the left guide for the right side and vice versa.

Fig.49

Fig.50

Use of the screws for fixing the hook to the metaphysis component

Position the hook and bone fragments in place, holding them firm with bone holding forceps.

Put into place the 2 drill guides by going through the soft tissues up until contact with the hook.

Drill the proximal hole using the stop drill Ø6mm, and leave the drill in place.

Drill the distal hole using the second drill, remove the guide and drill (fig 49).
Remove the drill and drill guide.

Place the outer guide in the distal hole, and measure the screw length necessary.
There are 3 lengths, 40, 55 and 70mm.
Mount the fixation screw on the holder and place it through the guide.
Screw the distal screw into place (fig 50).

Remove the proximal stop drill.

Replace the drill guide by the outer guide.

Measure the screw length necessary.

Mount the fixation screw on the holder and place it through the guide.

Screw the proximal screw into place (fig 51).

Remove the screwdriver, guide and proximal jig (fig 52).

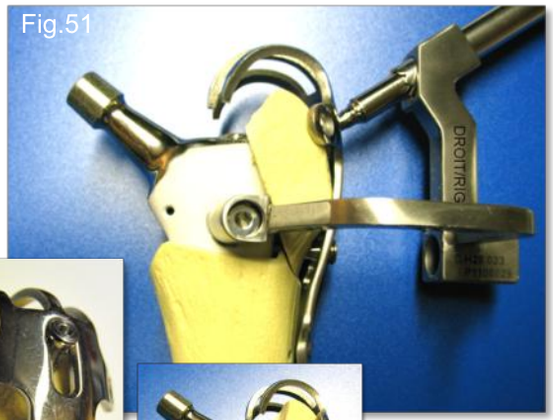


Fig.51



Fig.52

Bone fragment osteosynthesis

Bone fragments and graft can be fixed and held into place using the trochanteric hook.
The flanges on the proximal and distal part allow for fragment fixation with Ø4.5mm cortical bone screws.

Place the fragment into position with bone holding forceps.

Drill through it using a Ø3,2mm drill (fig 53).

Measure the screw length using a measurer (fig 54).

Drill firmly into place the screw of appropriate selected length (fig 55).


Fig.53

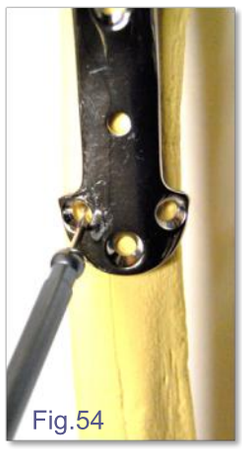


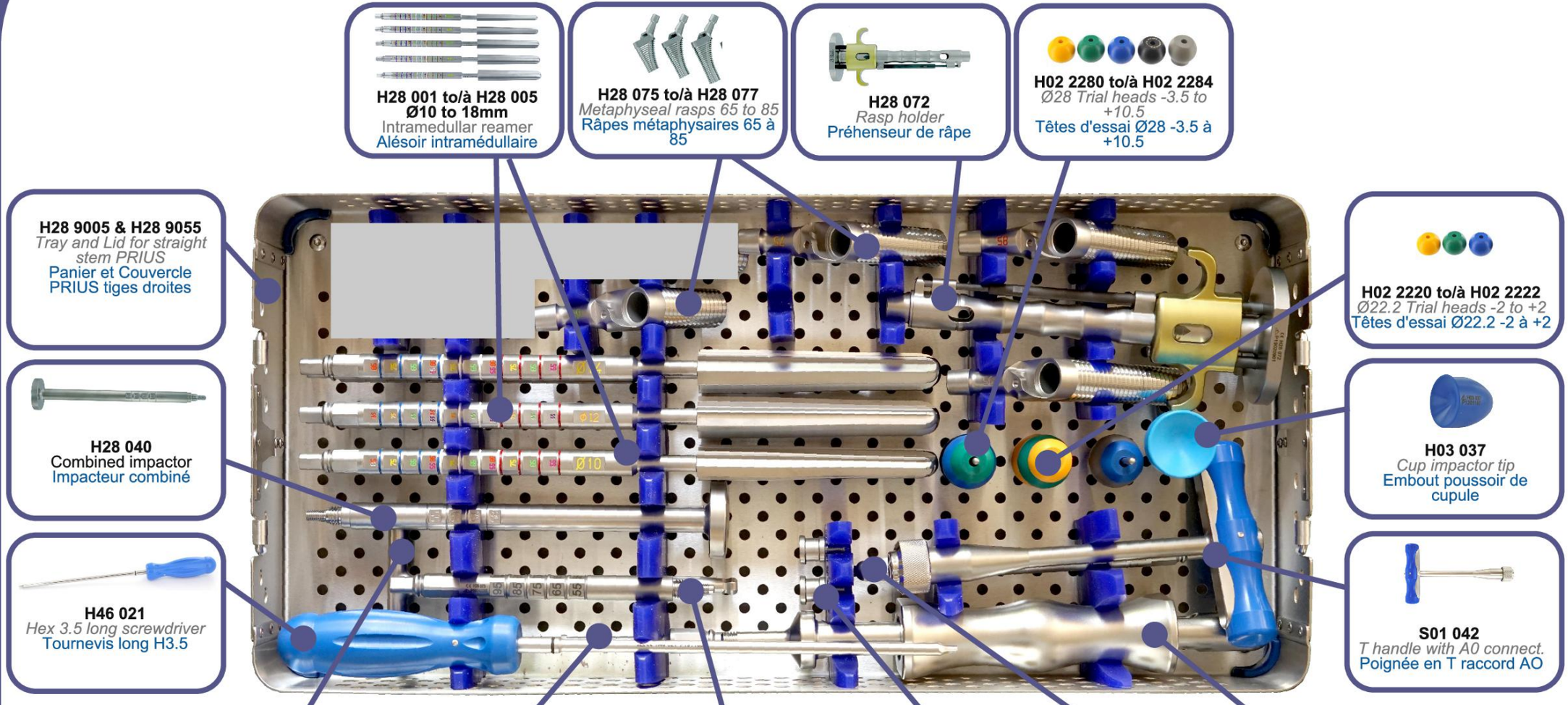
Fig.54


Fig.55

Instrumentation SNAPSHOT

Ref : H28 9105

PRIUS Basic set / *Base*



H28 001 to/à H28 005
Ø10 to 18mm
Intramedullar reamer
Alésoir intramédullaire

H28 075 to/à H28 077
Metaphyseal rasps 65 to 85
Râpes métaphysaires 65 à 85

H28 072
Rasp holder
Préhenseur de râpe

H02 2280 to/à H02 2284
Ø28 Trial heads -3.5 to +10.5
Têtes d'essai Ø28 -3.5 à +10.5

H28 9005 & H28 9055
Tray and Lid for straight stem PRIUS
Panier et Couvercle PRIUS tiges droites

H28 040
Combined impactor
Impacteur combiné

H46 021
Hex 3.5 long screwdriver
Tournevis long H3.5

H02 2220 to/à H02 2222
Ø22.2 Trial heads -2 to +2
Têtes d'essai Ø22.2 -2 à +2

H03 037
Cup impactor tip
Embout poussoir de cupule

S01 042
T handle with A0 connect.
Poignée en T raccord AO

H46 030
Hex 8 screwdriver with T handle
Tournevis en T H8

H28 084
Metaphysis extractor
Extracteur de métaphyse

H28 073
Guide for metaphyseal rasps
Guide râpes métaphysaires

H28 086
Assembly screw for metaph/diaph
Vis assemblage metaph/diaph

H28 010
Junction reamer
Alésoir Raccord

H01 033
M10 Slap Hammer
Extracteur à Masselotte M10

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Instrumentation SNAPSHOT

Ref : H28 9106
PRIUS Distal Locking set / *Verrouillage distal*

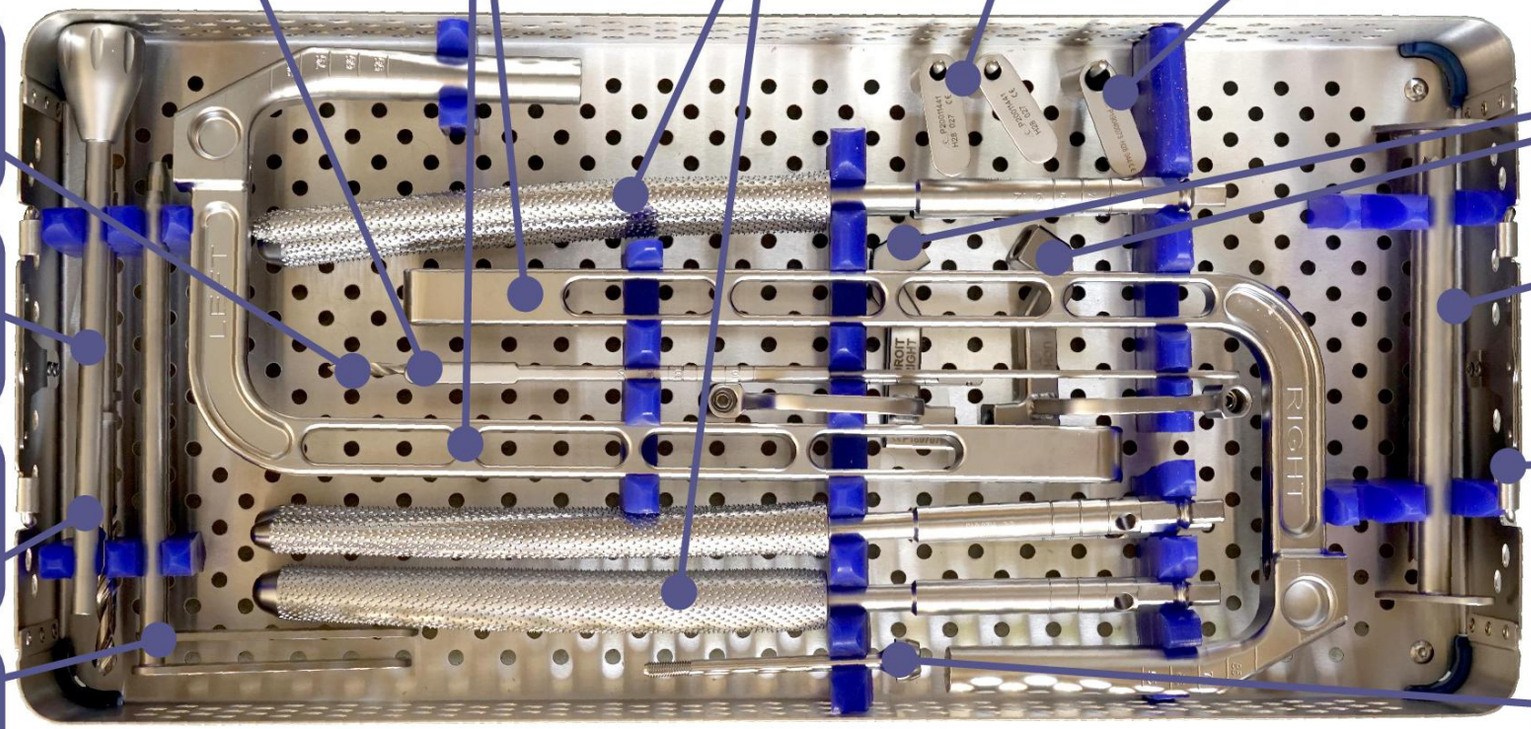
H46 026
Length gauge
Jauge de vis clavette

H28 037 & H28 039
Curved PRIUS targeting jigs R&L
Viseurs PRIUS Courbe D&G

H28 012 to/à H28 015
S12 to 18 curved rasps
Râpes courbes T12 à 18

H28 027
Ø6.2 Drilling sleeve
Douille de perçage Ø6.2

H28 044
Guide sleeve for screw holder
Douille de guidage pour préhenseur de vis



H46 023
Ø4.5 l.233mm drill (x2)
Mèche Ø4.5 lg.233mm (x2)

H46 022
Screw holder sleeve
Douille de préhension de vis

H28 025
Ø6 Stop drill (x2)
Mèche Ø6 avec butée (x2)

H46 025
Ø4.5 drill guide (x2)
Canon de perçage Ø4.5 (x2)

H28 022 & H28 023
L & R Proximal targeting jigs
Viseurs proximaux D & G

H46 024
Targeting master sleeve (x2)
Douille mère de visée (x2)

H28 9006 & H28 9056
Tray and Lid for Distal locking PRIUS
Panier et couvercle PRIUS verrouillage distal

H28 038
Stem on jig assembly screw
Vis d'assemblage tige sur viseur

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REFERENCES

Metaphysis (incl. Screw) / Métaphyse (vis incluse)

Length / Longueur		
65mm	75mm	85mm
H27 M065	H27 M075	H27 M085

Diaphyseal stem / Tige diaphysaire

Ø	Length / Longueur			
	Straight/ Droite	Straight/ Droite	Straight/ Droite	Straight/ Droite
	115mm	145mm	175mm	205mm
Ø10mm	H27 S10115	H27 S10145	H27 S10175	-
Ø12mm	H27 S12115	H27 S12145	H27 S12175	H27 C12205
Ø14mm	H27 S14115	H27 S14145	H27 S14175	H27 C14205
Ø16mm	H27 S16115	H27 S16145	H27 S16175	H27 C16205
Ø18mm	H27 S18115	H27 S18145	H27 S18175	H27 C18205

Tranverse locking screw / Vis clavette

Ø	Length / Longueur			
	25mm	30mm	35mm	40mm
Ø6mm/Ø4.5mm	H15 SC6025	H15 SC6030	H15 SC6035	H15 SC6040

Trochanteric hook-plate / Crochet-Plaque

Length / Longueur				
100mm	130mm	200mm	240mm	280mm
T37 012	T37 010	T37 011	T37 013	T37 014

Attachment screw for hook-plate / Vis de solidarisation pour crochet

Length / Longueur		
40mm	55mm	70mm
H27 040	H27 055	H27 070

Ø4.5mm Cortical screw / Vis corticale Ø4.5mm

Length / Longueur					
25mm	30mm	35mm	40mm	45mm	50mm
T43 HA4525	T43 HA4530	T43 HA4535	T43 HA4540	T43 HA4545	T43 HA4550

Instrument set / Instrumentation Ancillaire

Base instrument set / Instrumentation de base	H28 9105
Distal locking complement / Complément de verrouillage	H28 9106
Straight trial stems / Diaphyses droites d'essai	H28 9102
Curved trial stems / Diaphyses courbes d'essai	H28 9103

Femoral Heads Têtes fémorales

Diameter / Diamètre	Length / Longueur	Stainless steel / Acier Inox	Cobalt-Chromium / Chrome-Cobalt	Composite Ceramic / Céramique Composite
Ø22	-2.0mm	H11 1220	H10 1220	-
	+0mm	H11 1221	H10 1221	-
	+2.0mm	H11 1222	H10 1222	-
Ø28	-7mm	H11 1279	H10 1279	-
	-3.5mm	H11 1280	H10 1280	H14 C1280
	+0mm	H11 1281	H10 1281	H14 C1281
	+3.5mm	H11 1282	H10 1282	H14 C1282
	+7mm	H11 1283	H10 1283	-
Ø32	-4mm	H11 1320	H10 1320	H14 C1320
	+0mm	H11 1321	H10 1321	H14 C1321
	+4mm	H11 1322	H10 1322	H14 C1322
	+8mm	H11 1323	H10 1323	H14 C1323
Ø36	-4mm	-	H10 1360	H14 C1360
	+0mm	-	H10 1361	H14 C1361
	+4mm	-	H10 1362	H14 C1362
	+8mm	-	H10 1363	H14 C1363

Important Notice:
The PRIUS® femoral revision implants belong to the class III implantable medical device classification.
The PRIUS® femoral revision implants are indicated in total hip revision procedures (THR) for the femoral component.
The surgeon is required to read the instructions S12 0302 for use included in the packaging of the implant or available for download on the www.evolutisfrance.com website, as well as the surgical technique manual H28 451 initially delivered with the instrument set or equally available for download on the www.evolutisfrance.com website.

Instrument set content may be subject to modifications and/or adapted to the customer's needs. Consequently the above item list is for indication purposes only. For an accurate list of the instrument set that has been delivered to your hospital, please refer to the delivery bill.

Gamma ray sterilised.

Material: *metaphysis, diaphysis, metaphysis screw, tranverse locking screw and attachment screw: titanium alloy TA6V according ISO 5832-3, with dual coating porous titanium and hydroxyapatite coating on metaphysis parts*
Hook-Plate and cortex screw: Stainless Steel 316L according ISO 5832-1

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