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CREATEUR FABRICANT

Prius®

Surgical Technique

Evolutis
MOTION INSIDE

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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.

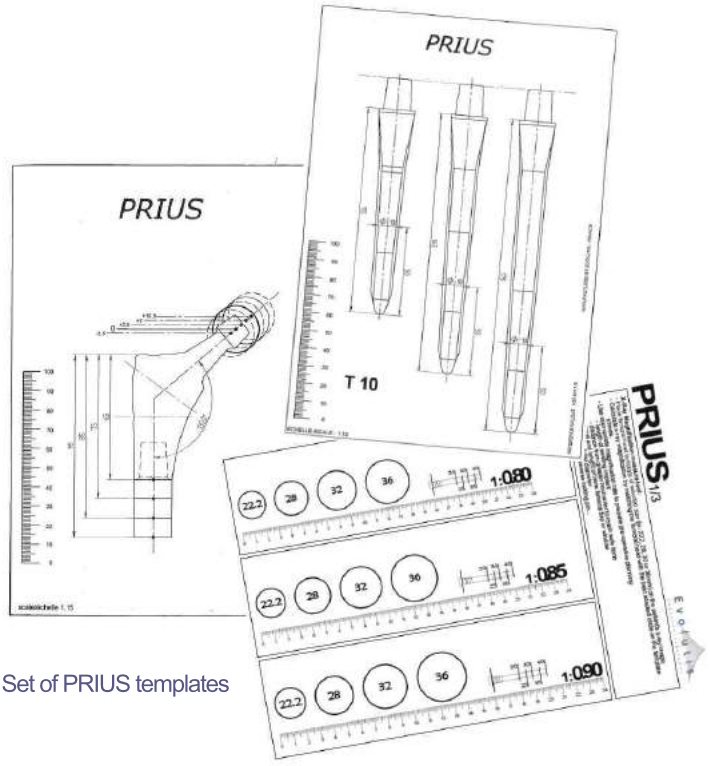
The system is intra-operatively constructed around the diaphysis stem dependent on bone stock.

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 an opening or femorotomy.

The trochanteric hook can be used alone or in association with the femoral implants to which it can be attached. Used alone it can be used for osteo-syntheis of a non-union of the greater trochanter.



Set of PRIUS templates

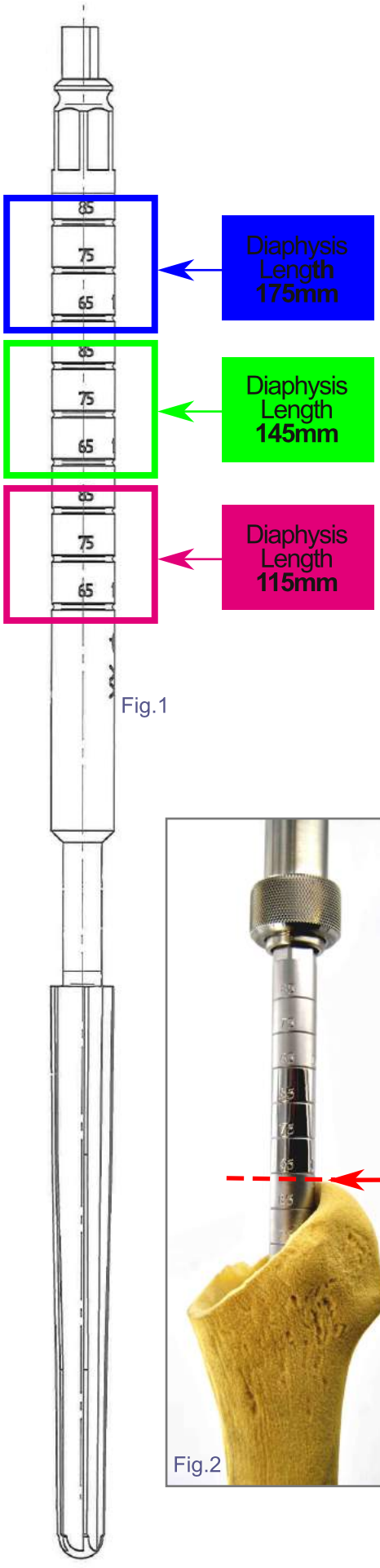


Fig.1

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.

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. Note the three sizes; Diameter and length of the distal component, size (height) of the metaphysis component.

Fig.2

In this example:

Diaphysis length 145mm

+

Metaphysis 65mm

Steps for curved diaphysis components

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

The rasps being curved, must be introduced in line the 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.

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

Fig.3

Fig.4

Fig.5

Stop the metaphysis reaming when distal stem length indicator is flush with the top of the diaphysis reamer

Fig.6

Metaphysis preparation

Assemble the metaphysis reamer onto the T handle.

With the diaphysis reamer left in place, introduce the metaphysis reamer over the diaphysis reamer and manually ream the metaphysis-diaphysis junction area (fig 5).

If necessary power tool reaming can be done to adapt the inner bone diameter to the metaphysis component with care to preserve sufficient cortical bone.

Note: this stage allows to confirm the height of the metaphysis component which was already determined in the preceding steps of planning and diaphysis reaming.

Stop the metaphysis-diaphysis junction reaming when the summit of the diaphysis reamer is aligned with the height indicator corresponding to the diaphysis stem previously determined during diaphysis calibration (indicator aligned with the summit of the greater trochanter) (fig 6).
Remove both metaphysis and diaphysis reamers.

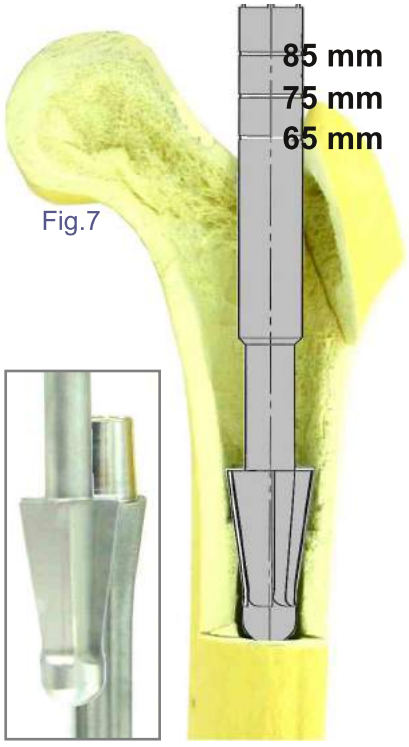


Fig.7

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 7):

- Distal mark = metaphysis size 65mm
- 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 8) 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 9)

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.

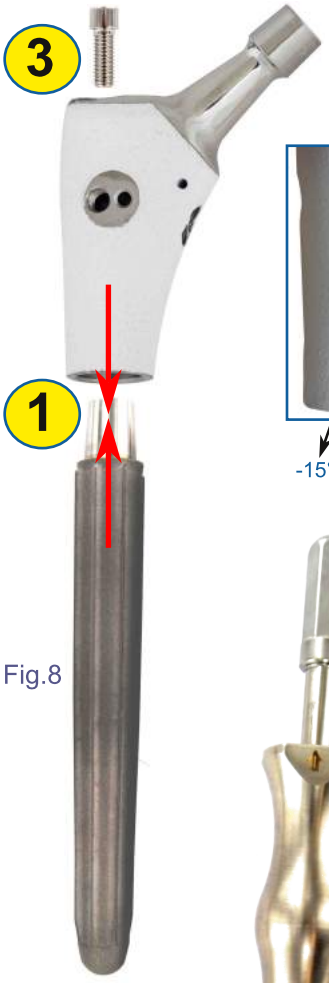


Fig.8

Fig.9

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 10).

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

Cap screw to block of thread hole

Fig.10

Implantation of a definitive stem without distal screws

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

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

Fig.12

Fig.11

Assemble the diaphysis of the chosen length and diameter as determined by the sizing steps onto the combined impactor (fig 11).

Place the diaphysis stem into the femur and impact it (fig 12).

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

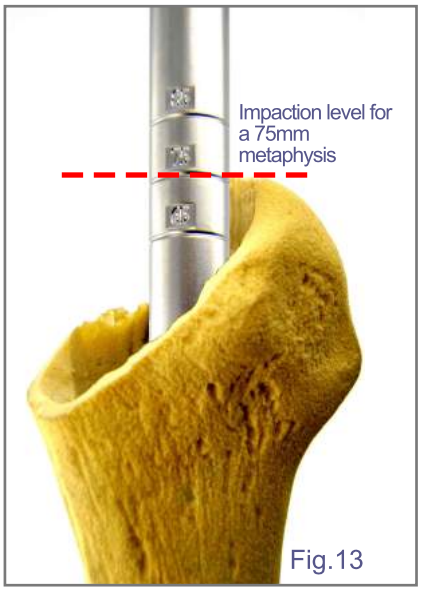


Fig.13

Impact the diaphysis stem with a hammer up until the proximal indicator mark is aligned with the greater trochanter as selected previously (fig 13).

Distal fixation augmented with tranverse screw–pins

This stage follows on from the common stages (page 5).

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.23

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 24).

Screw the stem firmly onto the jig (fig 24).

Fig.24

Outside of the patient undertake a trial alignment of the guide sleeves and drills to check overall alignment (fig 25).

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.25

IMPLANTATION IN TWO STAGES


Fig.26

Introduce the diaphysis stem into the femur using the jig frame (fig 26).

Should the implantation require impacting, screw the combined impactor onto the top of the jig and gently impact (fig 27).

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 28).


Fig.27


Fig.28


Fig.29

Place one of the outer guide sleeves into the jig in the most proximal position (fig 29).

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 30).

Place the Ø4mm drill on a power tool, place it in the drill guide and drill until contact of the second cortex (fig 31).

Remove the power tool from the drill bit, and leave the drill in place for stability whilst preparing the second screw hole (fig 32).

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 33).

Introduce the screw length measurer through the drill sleeve and measure the length of the screw-pin required (fig 34).


Fig.30


Fig.31


Fig.32


Fig.33


Fig.34

IMPLANTATION IN TWO STAGES


Fig.35

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

Remove the measuring device and the drill sleeve (fig 35).


Fig.36

Screw the thread on the head of the screw-pin into the holder (fig 36).

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 37).

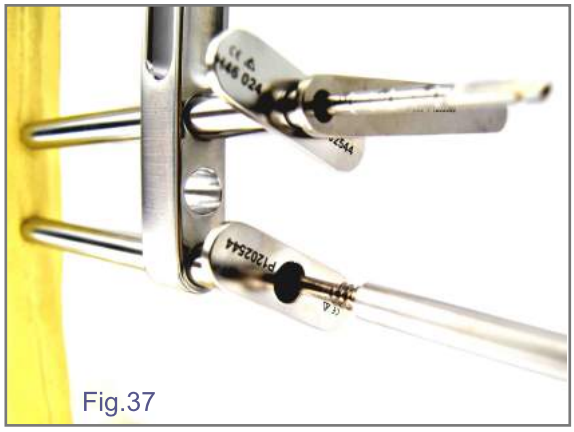


Fig.37

Screw the screw-pin into the bone going through the distal stem up until firm contact (fig 38).

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.

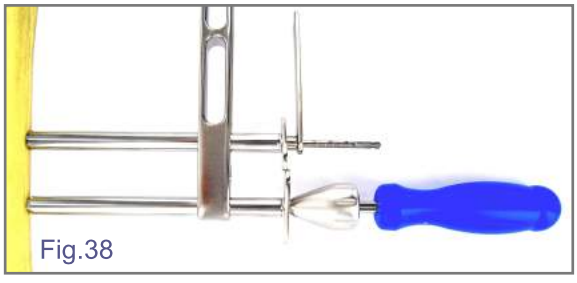


Fig.38

Trials

Once that the PRIUS diaphysis stem is firmly anchored in the femoral canal (fig 14), metaphysis trials can be undertaken to confirm the height of the metaphysis component to be used and the best anteversion.


Fig.14

Clean and dry the diaphysis morse taper.

Select the metaphysis component adapted to the calibration steps (page 5).

Place the metaphysis trial over the diaphysis morse taper (fig 15).

Turn it to the best anteversion position.

Lock the metaphysis down using locking screw which is part of the metaphysis trial (fig 16).


Fig.15


Fig.16

Trial using trial heads (fig 17).

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
- Screw the slap hammer onto the metaphysis trial
- Disconnect and remove the metaphysis trial from the distal stem (fig 18).

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.17


Fig.18

Fig.19

Fig.20

Fig.21

End cap screw for the metaphysis thread hole

Fig.22

Implantation of the definitive metaphysis component

Screw the definitive metaphysis component onto the combined impactor (fig 19).

Clean and dry the diaphysis morse taper in situ.

Position the metaphysis on the morse taper of the diaphysis, reproducing the desired anteversion (fig 20).

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

Screw into place the locking screw (fig 21).

Screw into place the end cap screw on the metaphysis (fig 22).

Trials

Place a trial head on the definitive metaphysis morse taper cone (fig 39).

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.39

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 head pusher (fig 40).

Reduce the articulation.

Re-test stability and mobility.

Fig.40

IMPLANTATION OF THE TROCHANTERIC HOOK

The trochanteric hook allows for stable synthesis of the fragments resulting from an intra-trochanteric fracture, to re-attach a femorotomy opening due to the surgical approach, to re-unite a trochanteric fragment, or to stabilise graft.
The simple targeting jig facilitates its positioning.

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.

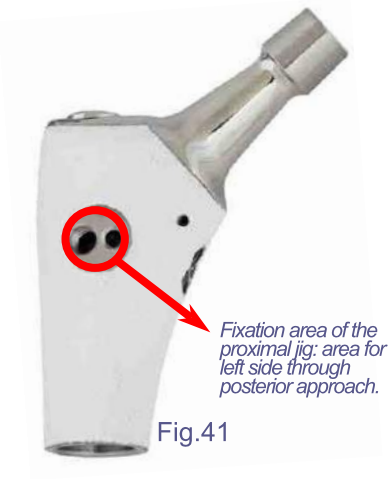


Fig.41

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 41).

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

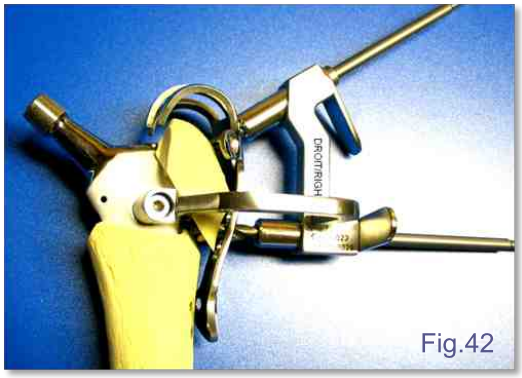


Fig.42

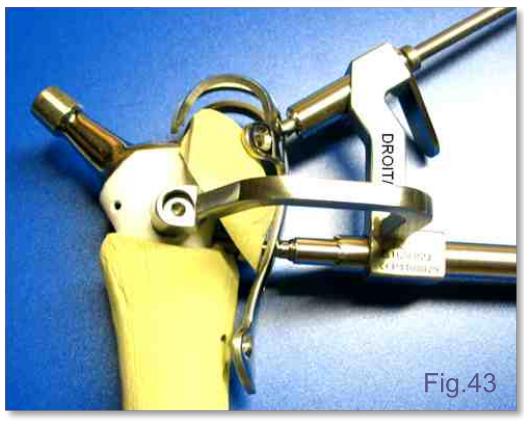


Fig.43

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 42).
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 43).

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 44).

Remove the screwdriver, guide and proximal jig (fig 45).

Fig.44


Fig.45

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 either cortical or cancellous bone screws.

Place the fragment into position with bone holding forceps.

Drill through it using a Ø3,2mm drill (fig 46).

Measure the screw length using a measurer (fig 47).

Drill firmly into place the screw of appropriate selected length (fig 48).

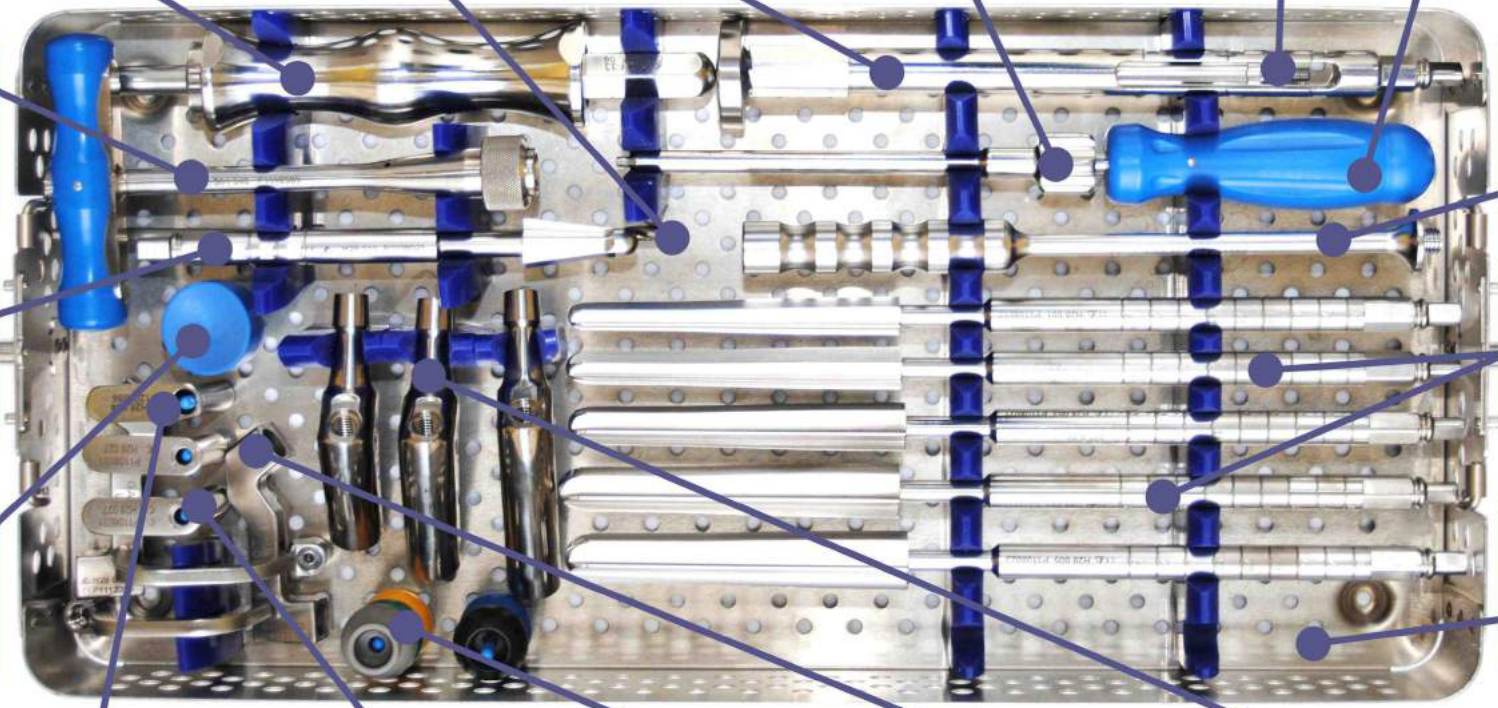

Fig.46


Fig.47


Fig.48

Instrumentation SNAPSHOT

Ref : H28 9100 — PRIUS Basic set / *Base*



H01 033
M10 Slap Hammer
Extracteur à Masselotte M10

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

H28 018
Metaphyseal Reamer
Alésoir Métaphysaire

S01 011
Holding sleeve for screw
Préhenseur pour vis

H28 040
Combined impactor
Impacteur combiné

S01 009
H3.5 Hex screwdriver
Tournevis hexagonal H3.5

S01 042
T handle with AO connect.
Poignée en T AO grand modèle

H28 010
Junction reamer
Alésoir Raccord

H03 037
Cup impactor tip
Embout poussoir de cupule

H03 036
M10 Impactor Handle
Manche Impacteur M10

H28 001 to/à H28 005
Ø10 to 18mm
Intramedullar reamer
Alésoir intramédullaire Ø10 à18mm

H28 9000
Tray for straight stem PRIUS
Panier PRIUS tiges droites

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

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

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

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

H28 041 to/à H28 045
Trial metaphysys H65, H75, H85 & H95
Métaphyses d'essai H65, H75, H85 et H95

Dec 2015 / Ref: BI_PRIUS SNP H28

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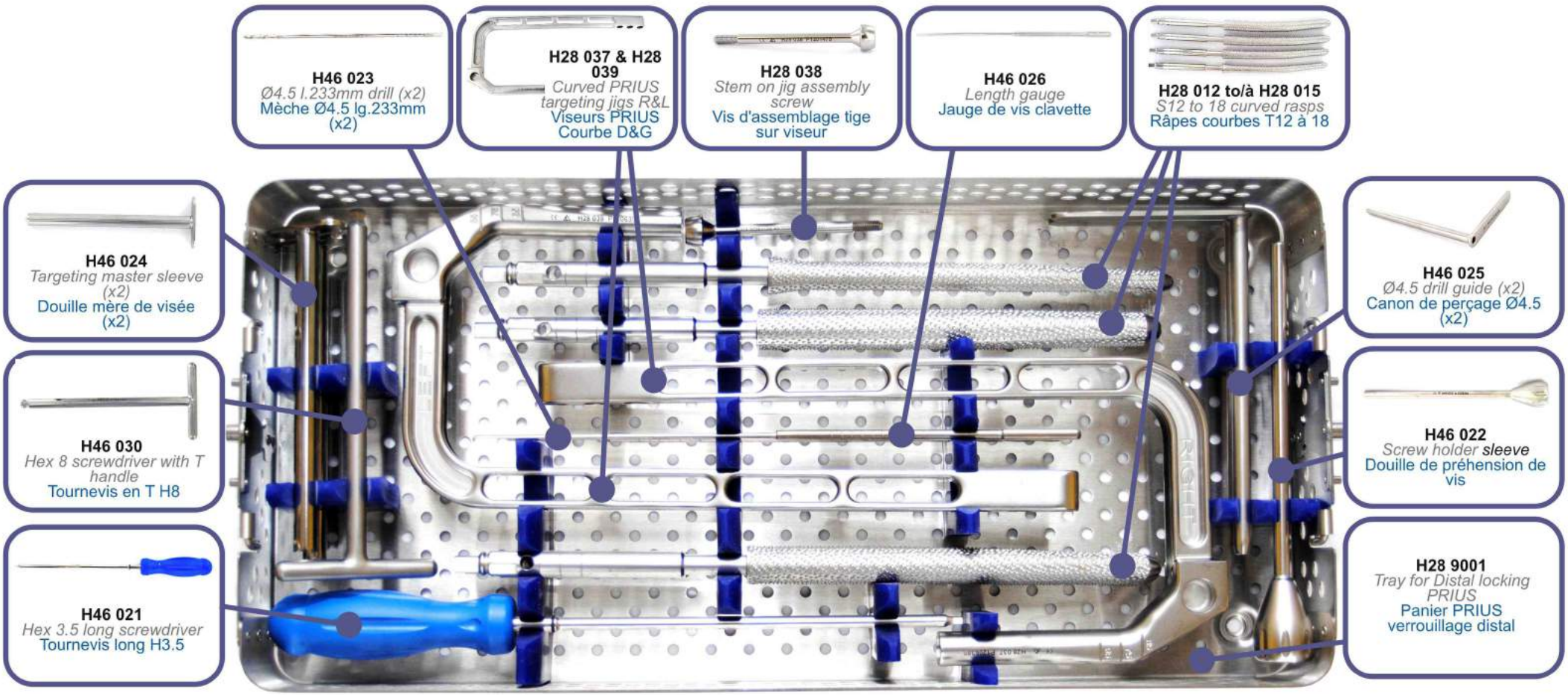
Instrumentation SNAPSHOT

Ref : H28 9101
PRIUS Distal Locking set / *Verrouillage distal*



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

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

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

H46 026
Length gauge
Jauge de vis clavette

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

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

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

H46 021
Hex 3.5 long screwdriver
Tournevis long H3.5

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

H46 022
Screw holder sleeve
Douille de préhension de vis

H28 9001
Tray for Distal locking PRIUS
Panier PRIUS verrouillage distal

Dec 2015 / Ref: BI_PRIUS SNP H28

Instrumentation Sets

PRIUS Instrumentation de base *Base Instrumentation Set* H28 9100

Ref	Description	Q	Ref	Description	Q
H28 9000	Panier Base *Base Tray*	1	H28 010	Raccord alésoir *Junction Reamer*	1
H01 033	Masselotte M10 *Sliding Hammer*	1	H28 018	Alesoir metaphysaire *Metaphyseal reamer*	1
H02 2280	Tête d'essai Ø28 -3.5mm *Trial head*	1	H28 022	Viseur proximal gauche *Left proximal frame*	1
H02 2281	Tête d'essai Ø28 +0mm *Trial head*	1	H28 023	Viseur proximal droit *Right proximal frame*	1
H02 2282	Tête d'essai Ø28 +3.5mm *Trial head*	1	H28 025	Forêt à butée Ø6mm *Abutment drill*	2
H02 2283	Tête d'essai Ø28 +7mm *Trial head*	1	H28 027	Douille de perçage Ø6.2mm *Sleeve for drill*	2
H02 2284	Tête d'essai Ø28 +10.5mm *Trial head*	1	H28 040	Impacteur combiné *Combined impactor*	1
H03 036	Manche impacteur M10 *Impaction shaft*	1	H28 041	Methaphyse d'essai H65 *Trial Metaphysis*	1
H03 037	Embout pousse-cupule *Cup pusher tip*	1	H28 042	Methaphyse d'essai H75 *Trial Metaphysis*	1
H28 001	Alésoir Ø10 *Reamer*	1	H28 043	Methaphyse d'essai H85 *Trial Metaphysis*	1
H28 002	Alésoir Ø12 *Reamer*	1	H28 044	Douille pour préhenseur *Sleeve for screw holder*	1
H28 003	Alésoir Ø14 *Reamer*	1	S01 009	Tournevis H3.5 *Screwdriver*	1
H28 004	Alésoir Ø16 *Reamer*	1	S01 011	Préhenseur de vis *Screw holder*	1
H28 005	Alésoir Ø18 *Reamer*	1	S01 042	Poignée en T *T handle*	1
H28 006	Alésoir Ø20 *Reamer*	1			

PRIUS Instrumentation Quilles Courbes *Curved Keel Instrumentation Set* H28 9101

Ref	Description	Q	Ref	Description	Q
H28 9001	Panier Quilles Courbes *Curved Keel Tray*	1	H28 039	Viseur gauche *Left drilling jig*	1
H28 012	Râpe courbe T12 *Curved rasp*	1	H46 021	Tournevis long Ø3,5 Long *Screwdriver*	1
H28 013	Râpe courbe T14 *Curved rasp*	1	H46 022	Douille pour préhenseur *Sleeve for screw holder*	1
H28 014	Râpe courbe T16 *Curved rasp*	1	H46 023	Mèche de perçage Ø4,5 *Screw drill*	2
H28 015	Râpe courbe T18 *Curved rasp*	1	H46 024	Douille mère *Main sleeve*	2
H28 016	Râpe courbe T20 *Curved rasp*	2	H46 025	Douille de perçage Ø4.5mm *Sleeve for drill*	2
H28 037	Viseur droit *Right drilling jig*	1	H46 026	Mesureur de vis *Depth gauge*	1
H28 038	Vis d'assemblage *Assembly screw*	1	H46 030	Tournevis en T Ø8 *T screwdriver*	1

Instrumentation H28 9100

Instrumentation H28 9101

Prius®

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 for use included in the packaging of the implant, as well as the surgical technique manual initially delivered with the instrument set, or available for download on the www.evolutisfrance.com website.

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Designed and Manufactured in France

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