# Surgical Technique

# *Unisyn*™ Hip System

Shalby Advanced Technologies, Inc.
Restoring Mobility, Improving Lives.

## *INDICATIONS AND USAGE*

Significantly impaired joints resulting from rheumatoid, osteo, and post-traumatic arthritis.

Revision of failed femoral head replacement, hip arthroplasty or other hip procedures.

A. Proximal femoral fractures.

B. Avascular necrosis of the femoral head.

C. Non-union of proximal femoral neck fractures.

D. Other indications such as congenital dysplasia, arthrodesis conversion, coxa magna, coxa plana, coxa vara, coxa valga, developmental conditions, metabolic and tumorous conditions, osteomalacia, pseudarthrosis conversion, and structural abnormalities.

UNISYN™ assemblies with roughened and plasma coated bodies are intended for cemented or uncemented use.

UNISYN™ assemblies with plasma/HA or HA coated bodies are intended for uncemented use only.

Described By Pioneering Surgeon: Charles E. Bryant, M.D.

# *UniSyn*™ Hip System

## *Surgical Technique*

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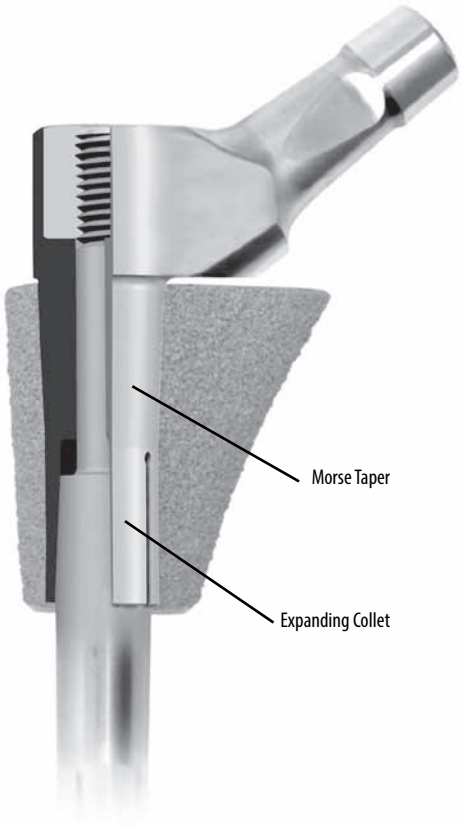


## Introduction

The UniSyn Hip System is designed with flexibility in mind. The complete interchangeability of components allows for independent adjustment of each anatomic variable. It also simplifies surgery by providing more surgical options and a logical, stepwise technique.

At the core of the UniSyn System is its patented connection technology. The technology combines two established connections, a Morse Taper and an Expanding Collet. These two connections act in concert to stabilize the neck against applied loads and are the key to providing a wide range of component sizes with a single connection geometry.
***Sixteen*** different ***Neck*** sizes for unmatched restoration of ***leg length***, ***lateral offset***, and ***anteversion***. Four vertical lengths with four lateral options for each, covering primary hips to calcar revision cases.


***Twenty One*** different ***Proximal Bodies***. Titanium plasma sprayed Bodies have six different cone diameters with multiple medial projections for each size. Double tapering medial projections with a natural medial arc provide better proximal fit than conventional modular bodies.

***Stems*** in each millimeter diameter from ***10 to 20mm***.

***Straight Stem*** lengths from ***130 to 210mm***.
***Bowed Stem*** lengths in ***210, 260, and 310mm***.
Custom Stems available upon request.

*NOTE: Please read the UniSyn Hip System Instructions for Use (IFU) accompanying UniSyn products prior to implanting this device in a clinical setting.*

Neck Resection Guide

## Neck Resection

Resection level is determined by properly aligning the ***Neck Resection Guide*** and fixing it with the ***Pin*** at the femoral head center.

The first cut is made perpendicular to the axis of the femur, laterally towards the intertrochanteric line.

The second cut is then made parallel to the intertrochanteric line proximally to the top of the femoral neck. Care should be taken not to extend the cuts past each other as the notch may create a stress riser. A rongeur may be used to radius the corner if a notch is formed.

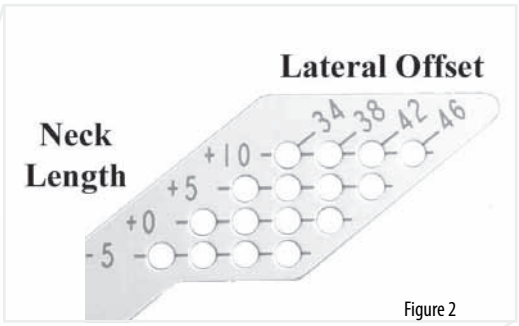


Figure 2

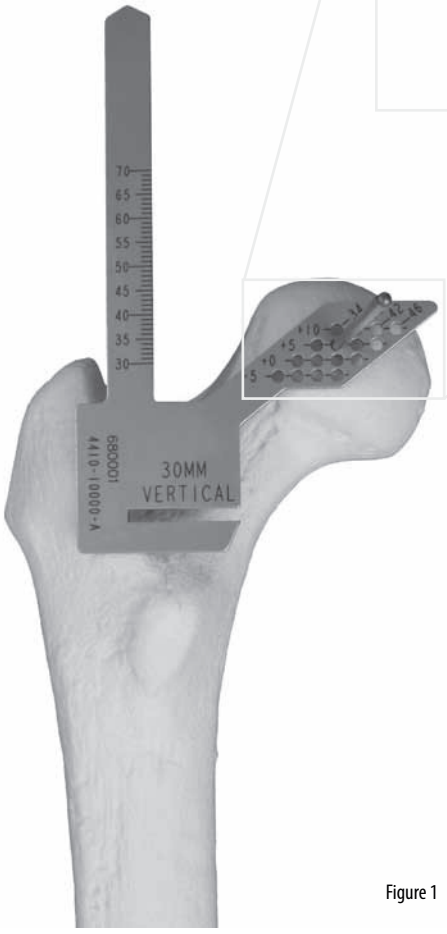


Figure 1

Figure 3

# Femoral Canal Preparation

## Exposing the Femoral Canal

The medial aspect of the greater trochanter is removed with the ***Circular Osteotome***. (Figure 4)

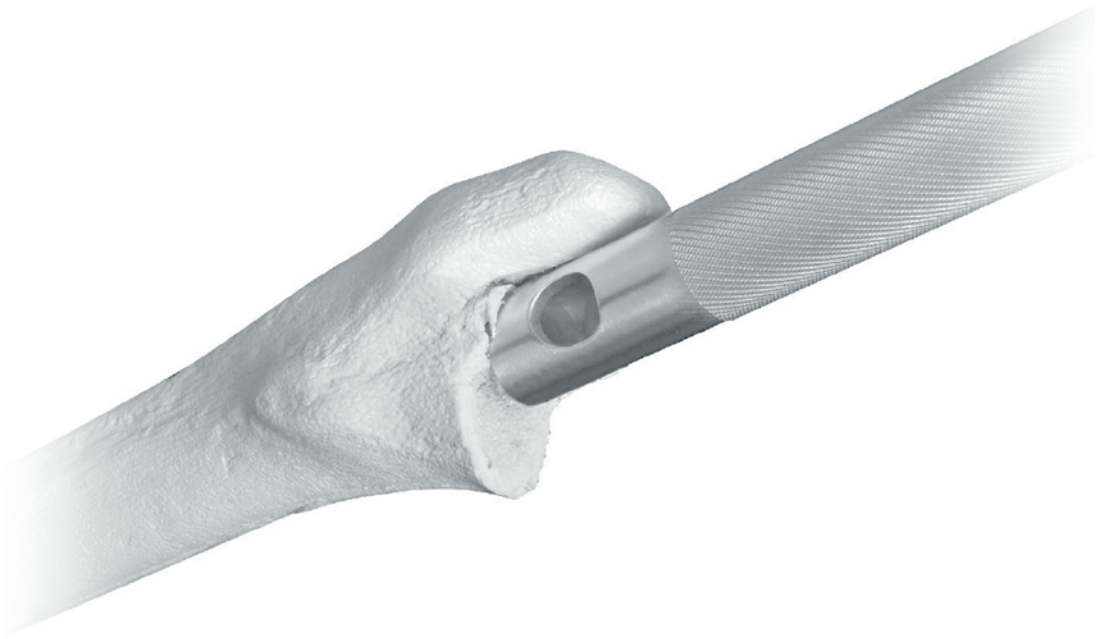

Figure 4

The intramedullary canal is entered with the ***Starter Drill*** using the ***T-handle***. (Figure 5)

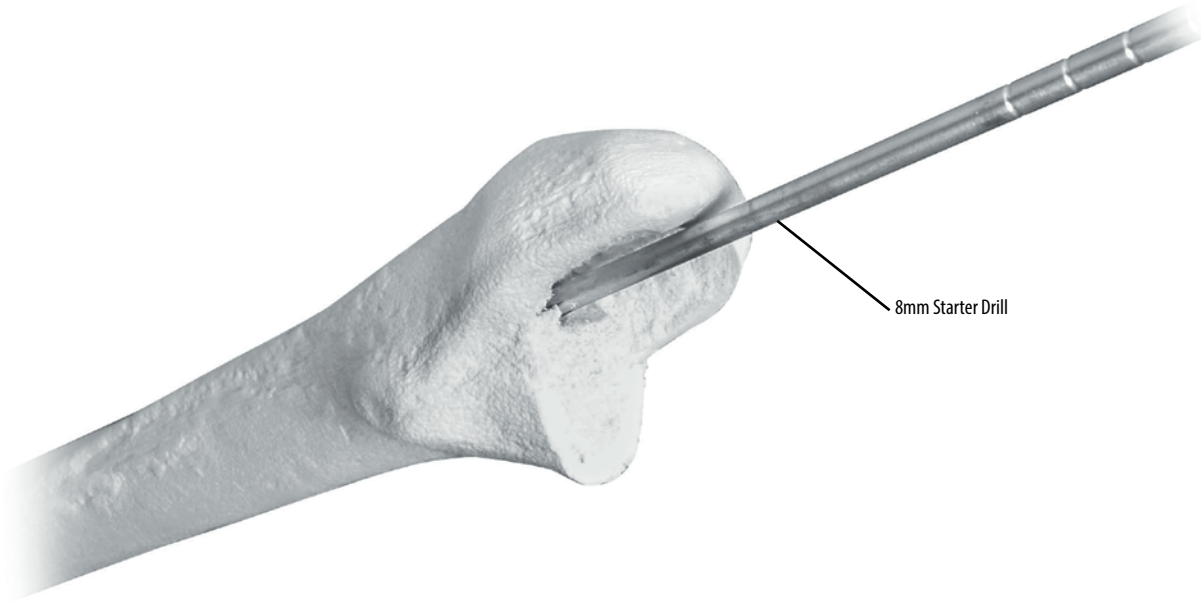


Figure 5

Circular Osteotome

Starter Drill

T-handle

Straight Reamer
(8.5mm)

Straight Reamer
(20.5mm)

## Distal Reaming

The distal canal is sequentially reamed until uniform cortical contact is established.

Each ***Straight Reamer*** is marked with two wide grooves. The first wide grove indicates the appropriate depth for the standard length stem of that diameter. The second wide groove indicates the appropriate depth for the extended length stem of that diameter. Advance the reamer until the appropriate wide groove is even with the resection level.

Implants are available in 1mm increments from 10mm to 20mm in diameter. See Fig. 9 for length options.

*NOTE: To avoid varus positioning of the Implant, it is important to push the Straight Reamer laterally into the greater trochanter.*

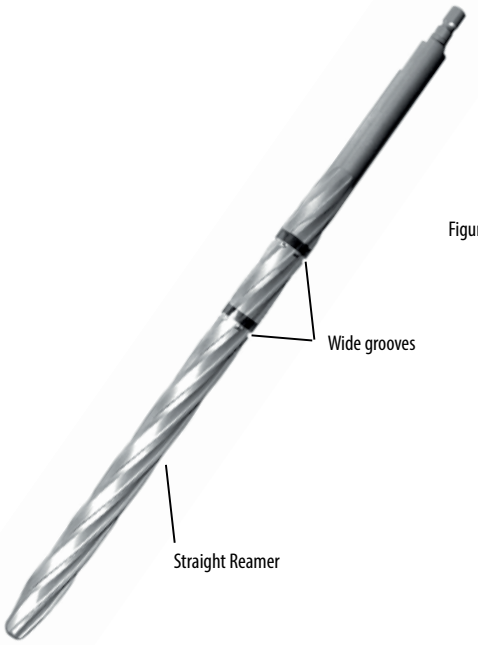


Figure 6

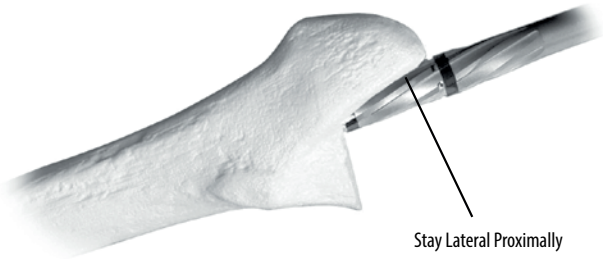


Figure 7

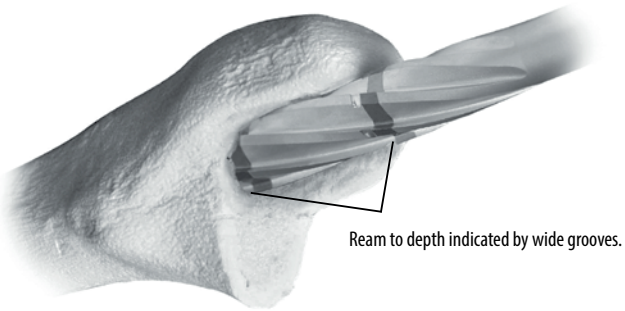


Figure 8

| Standard Stem Dimensions | | | Stem Diameters (mm) | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 |
| Stem Lengths (mm) | Straight | 130 | 10 x 130 | 11 x 130 | 12 x 130 | | | | | | | | |
| | | 140 | | | | 13 x 140 | 14 x 140 | | | | | | |
| | | 150 | | | | | | 15 x 150 | 16 x 150 | | | | |
| | | 160 | | | | | | | | 17 x 160 | 18 x 160 | | |
| | | 170 | 10 x 170 | 11 x 170 | 12 x 170 | | | | | | | 19 x 170 | 20 x 170 |
| | | 180 | | | | 13 x 180 | 14 x 180 | | | | | | |
| | | 190 | | | | | | 15 x 190 | 16 x 190 | | | | |
| | | 200 | | | | | | | | 17 x 200 | 18 x 200 | | |
| | | 210 | | | | | | | | | | 19 x 210 | 20 x 210 |
| | Bowed | 210 | | | 12 x 210 | 13 x 210 | 14 x 210 | 15 x 210 | 16 x 210 | 17 x 210 | 18 x 210 | 19 x 210 | 20 x 210 |
| | | 260 | | | 12 x 260 | 13 x 260 | 14 x 260 | 15 x 260 | 16 x 260 | 17 x 260 | 18 x 260 | 19 x 260 | 20 x 260 |
| | | 310 | | | 12 x 310 | 13 x 310 | 14 x 310 | 15 x 310 | 16 x 310 | 17 x 310 | 18 x 310 | 19 x 310 | 20 x 310 |

Figure 9

## 18mm Cone Reaming

Figure 10

The ***18mm Cone Reamer*** may be used as an option to initially open the proximal femoral metaphysis. Insert it until the groove is at the resection level.

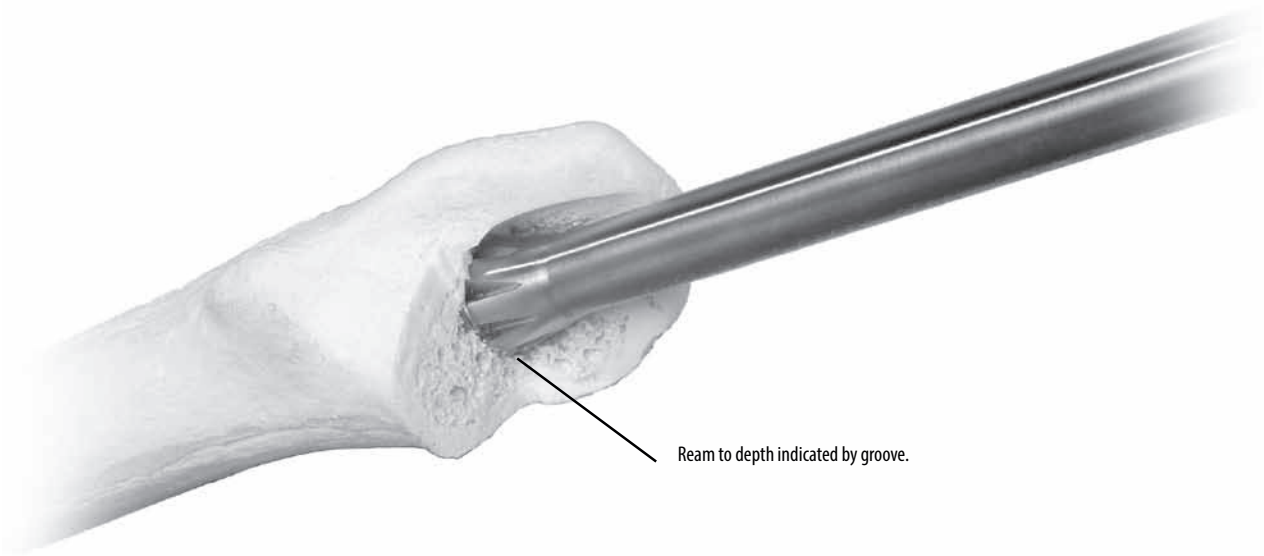


Figure 11

Cone Reamer

Distal Pilot

Cone Reamer

# Proximal Cone Preparation

## Cone Reamer Assembly

Select the ***Distal Pilot*** corresponding to the diameter of the final Straight Reamer used.

Figure 12

Retract the sleeve on the ***Cone Reamer*** and insert the ***Distal Pilot***.

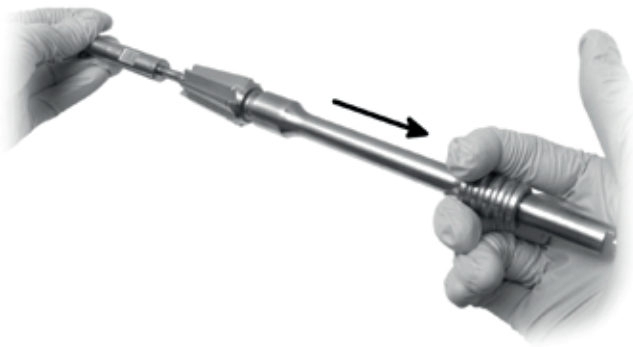

Figure 13

After allowing the outer sleeve of the ***Cone Reamer*** to spring back, turning the ***Distal Pilot*** 1/4 of a turn in either direction will lock the Distal Pilot in the Cone Reamer.

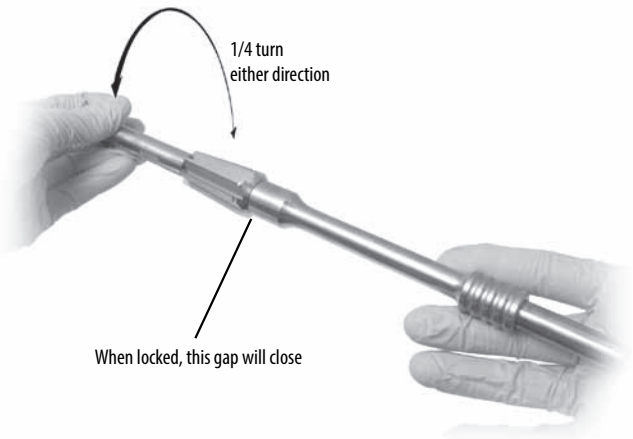


Figure 14

Cone Reamer

## Cone Reaming

***Cone Reamer*** sizes are 20mm, 22mm, 24mm, 26mm, 28mm, 30mm, and 32mm*. This references the diameter at the proximal end of the cone reamer. Available Proximal Bodies are listed below.

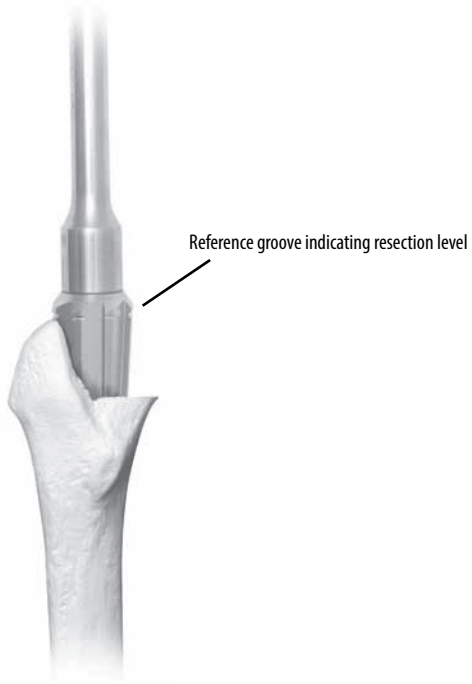


Figure 15

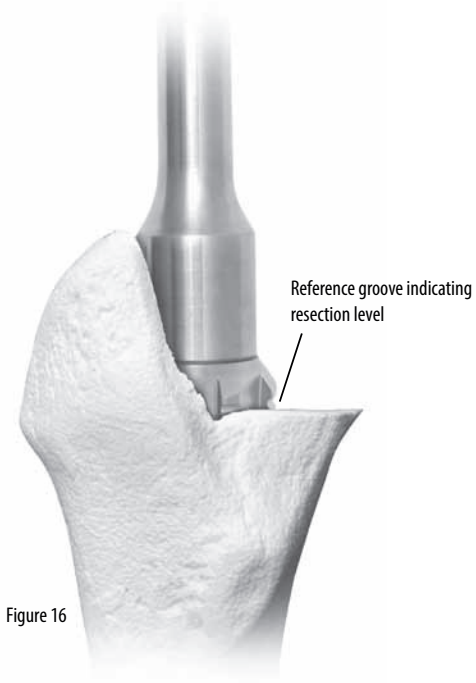


Figure 16

The ***Cone Reamer*** should be inserted until the groove in the reamer is at the resection level. This level corresponds with the top of the Implant Proximal Body.

The cone diameter should be increased until contact is established with both the anterior and posterior endosteal walls.

| Available Proximal Bodies | | | Medial Projection (mm) | | | | |
|---|---|---|---|---|---|---|---|
| | Superior | Inferior | 22 | 26 | 30 | 34 | 38 |
| Cone Diameter (mm) | **32*** | 26 | | | 32 x 30* | 32 x 34* | 32 x 38* |
| | **30** | 24 | | 30 x 26* | 30 x 30 | 30 x 34 | 30 x 38 |
| | **28** | 22 | | 28 x 26 | 28 x 30 | 28 x 34 | |
| | **26** | 21 | 26 x 22 | 26 x 26 | 26 x 30 | 26 x 34 | |
| | **24** | 19 | 24 x 22 | 24 x 26 | 24 x 30 | 24 x 34 | |
| | **22** | 18 | 22 x 22 | 22 x 26 | 22 x 30 | | |

Figure 17

*** Available by special order**


Distal Pilot


Medial Broach


Broach Handle

# Medial Preparation - Broaching Method

## Assembly

The same diameter ***Distal Pilot*** used for cone reaming is used for medial broaching. The cone diameter of the ***Medial Broach*** should correspond to the final Cone Reamer used. It is recommended to begin with the Broach that has the smallest medial projection for a given cone diameter.

The ***Distal Pilot*** is inserted into the ***Medial Broach*** until it clicks into place.

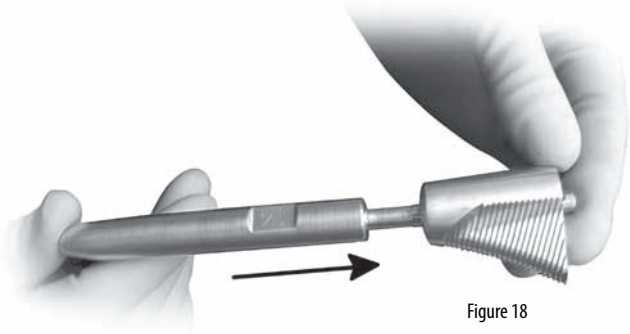
Figure 18


Figure 19

The ***Distal Pilot*** and ***Medial Broach*** are then attached to the ***Broach Handle***.

Using the Trigger on the ***Broach Handle***, the Locking Pin is retracted. When the ***Medial Broach*** is fully inserted onto the Broach Handle, the Trigger is released locking the Broach and the ***Distal Pilot*** to the Broach Handle.

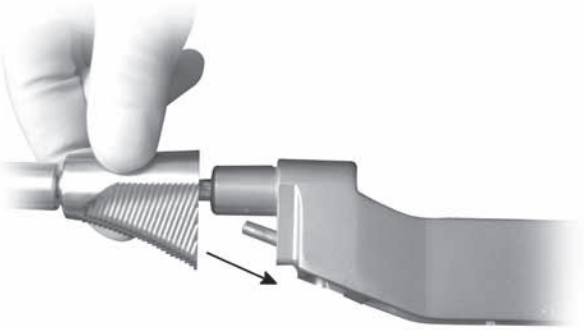
Figure 20

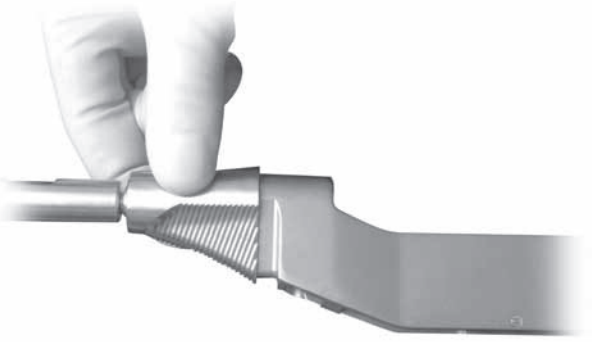
Figure 21

## Broaching

Medial Broach

The ***Medial Broach*** is introduced into the femur. (figure 22)

Figure 22

The Broach only has teeth on the medial side. The smooth anterior, posterior and lateral surfaces fit into the cavity created by the Cone Reamer. (figure 23)

Once the Medial Broach with the smaller medial projection has been fully inserted to the resection level (figure 24) the next larger Broach is inserted to optimize fit in the medial endosteum. (figure 25)

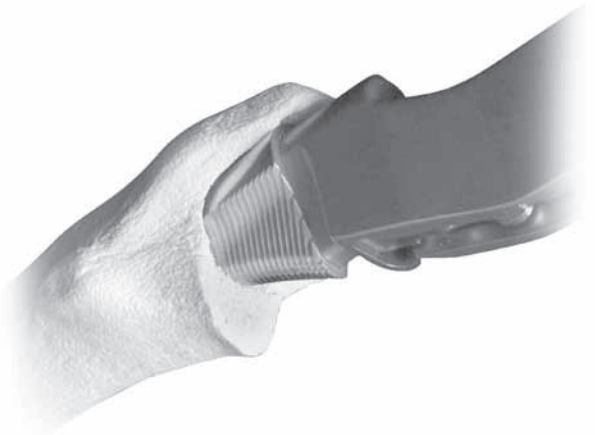

Figure 23

Once broaching is completed, leave the final Broach in place. This will serve as a platform for establishing the size and position of the Neck component. Continue on to page 15.

*NOTE: Bone has been removed by the cone reamer. Although the broach is relieved in this area, the conical portion of the implant will fill the gap.*

Figure 24

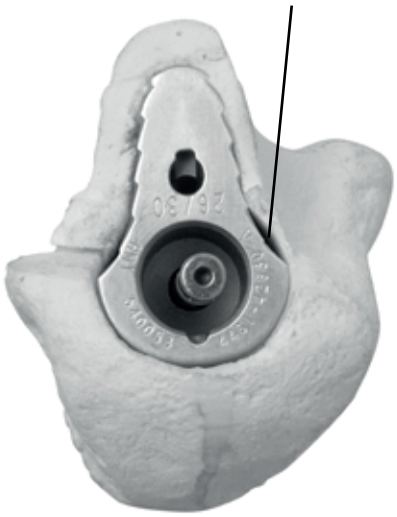

Figure 25

Taper Neck Trial

Taper Neck Positioner

Version Rod

# Setting Version

## Neck Connector Assembly

To attach the ***Taper Neck Trial*** onto the ***Taper Neck Positioner***, align the positioner tab with the slot on the Taper Neck Trial.

Align and insert the tapered neck of the Trial into the seated Broach. Align the tapered neck with the large Broach hole and the stabalizing rod into the smaller Broach hole.

## Adjustment

Insert the ***Version Rod*** into the side of the knob on the ***Taper Neck Positioner***.

When the version rod is set parallel to the tibia, the position of the broach in the femoral canal, in degrees, is noted by the position of the marked tab on the goniometer dial. Set the desired amount of version by rotating the rod the desired number of degrees to the operated side. The reading on the dial will then reflect an equal change in degrees, and the position of the taper neck trial (right or left) in relation to the broach. (Fig. 29).

The ***Version Rod*** indicates the total amount of anteversion.

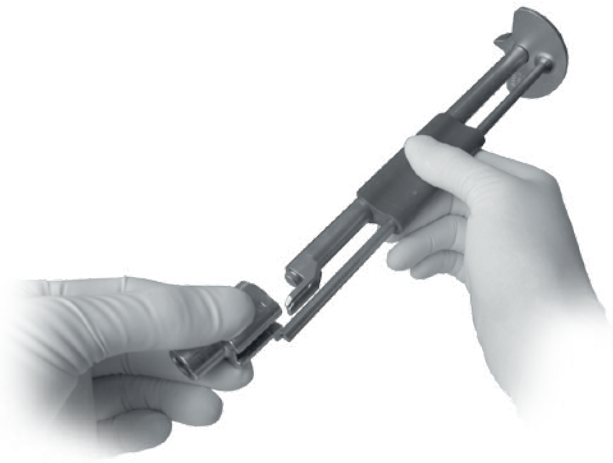

Figure 26

Figure 27

Figure 28


Figure 29

Figure 30

## Adjustment

To secure the desired version, use a mallet to lightly tap the positioner and lock the tapered neck into the Broach.

The ***Taper Neck Positioner*** is then removed for Trial Neck selection.

*NOTE: Once Trial Neck selecion is completed, the Taper Neck Trial can be removed using the Taper Neck Dissassessmebly tool. If necessary, a slap hammer can be threaded into the Taper Neck Trial for removal.*

Figure 31

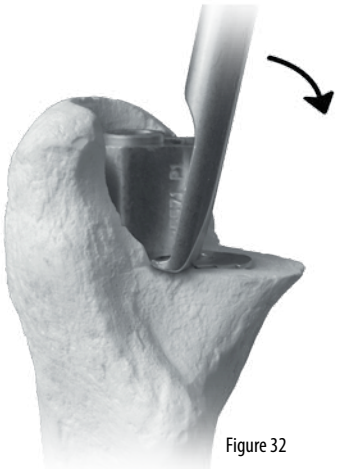

Figure 32

Taper Neck Positioner

Neck Trial

## Neck Selection

During ***Neck Trial*** selection, the lateral offset, vertical length, and anteversion can be adjusted independently. To adjust the offset and/or length, a set of 16 different Trials is provided. Standard sizes can be found in Fig. 33 below.

| Neck Options | | Offset* | | | |
|---|---|---|---|---|---|
| | | 34mm | 38mm | 42mm | 46mm |
| Length* | 30mm | 30 x 34 | 30 x 38 | 30 x 42 | 30 x 46 |
| | 36mm | 36 x 34 | 36 x 38 | 36 x 42 | 36 x 46 |
| | 45mm | 45 x 34 | 45 x 38 | 45 x 42 | 45 x 46 |
| | 55mm | 55 x 34 | 55 x 38 | 55 x 42 | 55 x 46 |

** Offset = distance from the stem center line to center of +0 head.*
** Length = distance from the top of the proximal body to center of +0 head.*

34mm offset

Figure 34

38mm offset

Figure 35

42mm offset

Figure 36

46mm offset

Figure 37


Figure 38

## Implant Assembly

Loosely assemble the ***Neck/Body Implants*** and clip the ***Version Guide*** around the base of the neck.

Set the version on the bottom of the ***Version Guide*** to duplicate that of the Version Adjustment Tool. Use the peak of the medial spout to align with the desired marking. A slight squeeze of the Body against the Neck will set them in place.

Figure 39

Insert the ***Assembly Knob*** through the ***Neck/Body Implants*** (Fig. 40).

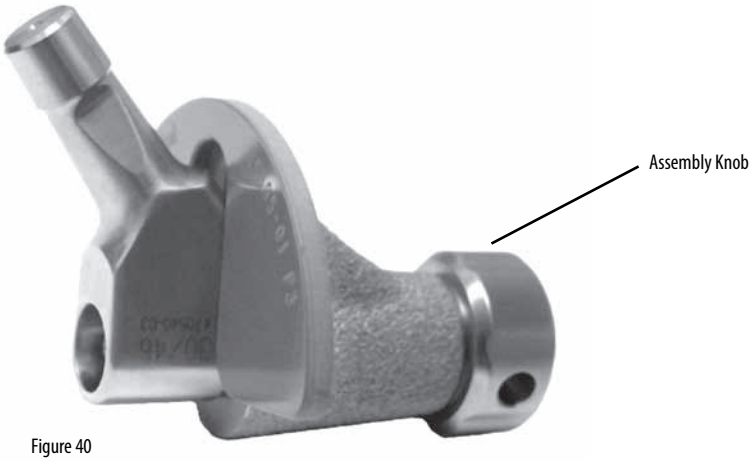


Figure 40

Version Guide

Assembly Knob


Implant Assembly Tool

## Neck/Body

With the handle fully open, insert the ***Implant Assembly Tool*** into the countersink of the ***Neck Implant***. Completely screw the ***Assembly Knob*** into the Assembly Tool.

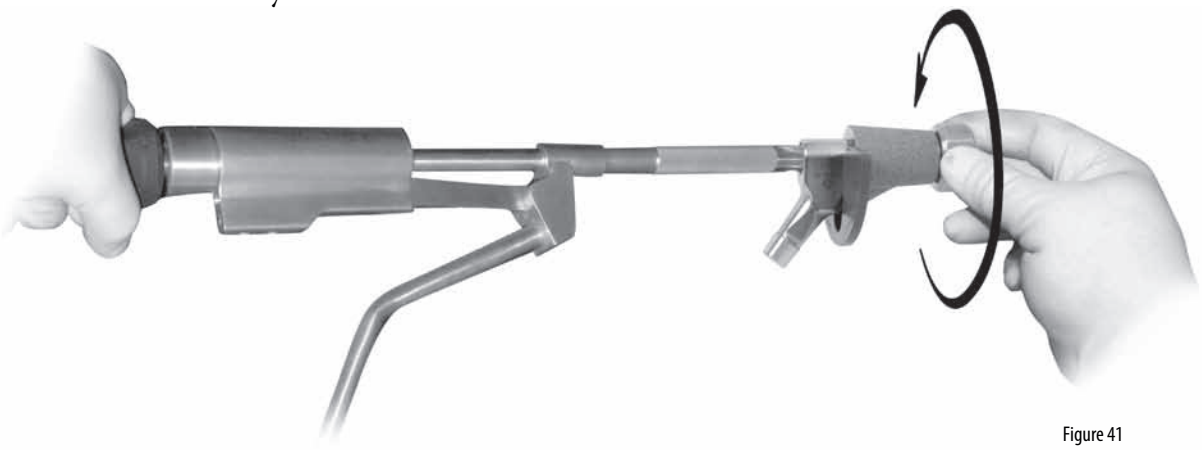

Figure 41

Push the outer button down to reset the calibrated compression indicator (Fig. 42).

Close the handles of the ***Implant Assembly Tool*** until the indicator button pops up.

*NOTE: This indicates a force of 1500 lbs has been applied to lock the Neck/Body Taper Connection.*

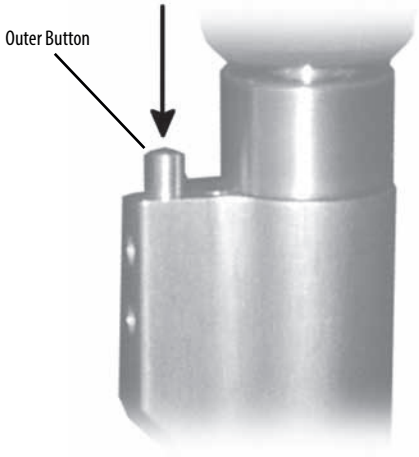


Figure 42

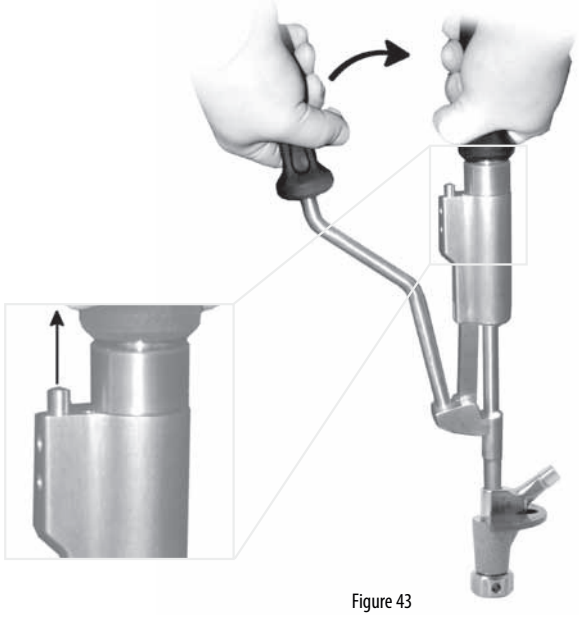

Figure 43



Figure 44

## Stem

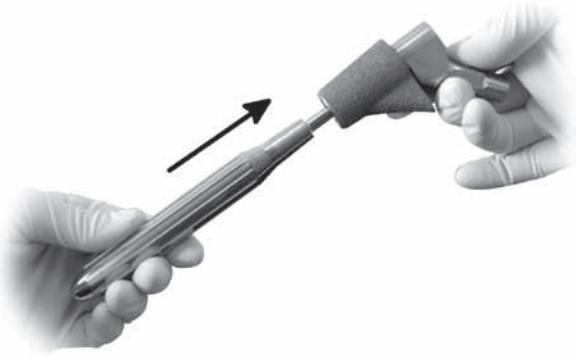

Figure 45

The ***Stem Implant*** is passed through the ***Neck/ Body Assembly***.

Figure 46

Thread the ***Implant Insertion/Disassembly Driver*** onto the ***Stem Implant***. This will firmly hold the Stem while allowing the Neck/Body to rotate freely.

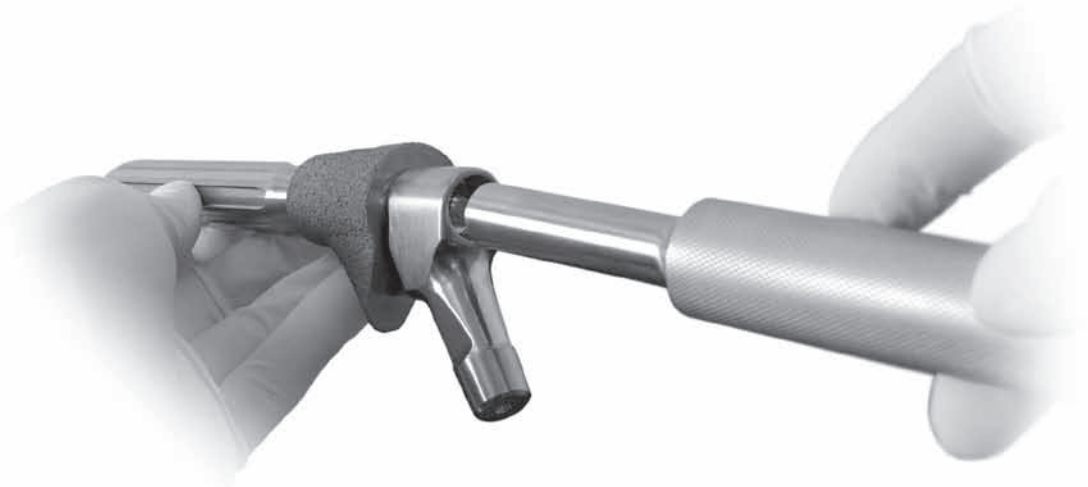

Figure 47

Implant Insertion/ Disassembly Driver

Insertion/Disassembly Driver

Rotate the ***Stem Implant*** to position slot in the desired orientation prior to engaging flutes in the distal canal.

Impact the ***Stem Implant*** with the ***Implant Insertion/Disassembly Driver***. The stem will be driven slightly ahead of the ***Neck/Body Assembly***, allowing the assembly to rotate freely about the stem and settle in the prepared position (Fig. 49).* Remove the Implant Insertion/Disassembly Driver by unscrewing it from the threaded stem.

The ***Implant Insertion/Disassembly Driver*** should be easily removed. However, if it does become jammed, the cap at the end can be loosened, relieving any pressure that might be causing resistance.

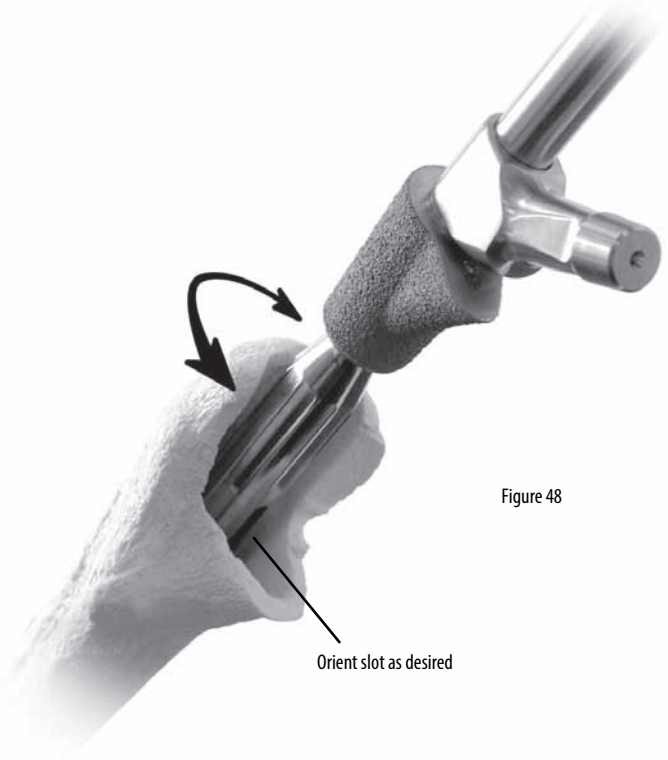


Figure 48

Figure 49

** NOTE: The UniSyn Hip System was designed for uncemented use, however, if it is necessary to cement a UniSyn Hip we recommend the addition of cement to appropriately stabilize the chosen implant.*

Figure 50

## Final Assembly

A threaded ***Extension*** and ***Extension Sleeve*** are provided to simplify attachment of the ***Implant Assembly Tool***.

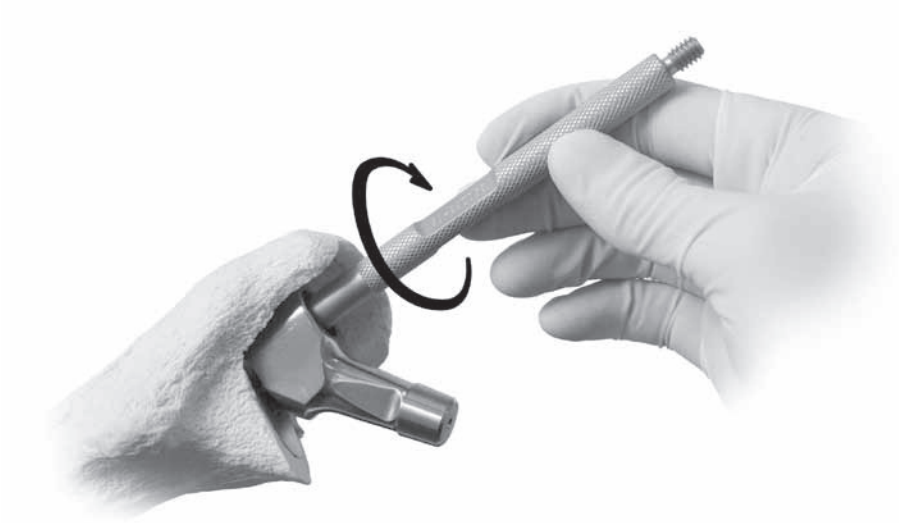

Figure 51

Hand thread the female end of the ***Extension*** fully onto the exposed threaded end of the ***Stem Implant***. This should thread easily by hand.

**CAUTION: Do Not Cross Thread!**
*** If necessary for removal use combo wrench (Figure 61)**

Figure 52

Slide the ***Extension Sleeve*** over the threaded ***Extension*** with the narrow end fitting into the countersink of the ***Neck Implant***.

Extension
and Extension Sleeve

Insertion/Disassembly
Driver

Combination Wrench

Implant Assembly Tool

Insertion/Disassembly Driver

Extension and Extension Sleeve

With the handle ***open***, thread the ***Implant Assembly Tool*** onto the threaded ***Extension***. Continue threading to fully draw the ***Stem Implant*** up into the ***Neck/Body Assembly***. (Figure 53)

Push the outer button down to reset the calibrated compression indicator. (Figure 54)

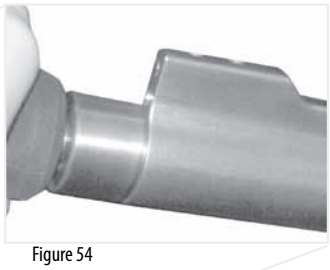

Figure 54

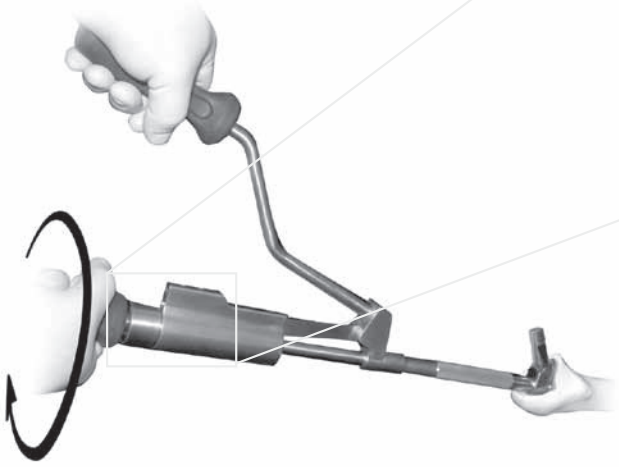

Figure 53

Compress the two handles of the ***Implant Assembly Tool*** together to engage the taper of the ***Stem Implant*** with the ***Neck/Body Assembly***. (Figure 55)

The outer button will pop up when the proper amount of force is applied to fully engage the taper of the ***Stem Implant*** in the ***Neck/Body Assembly***. This also expands the cylindrical collet of the Neck Implant, further securing it within the Body Implant. (Figure 56)

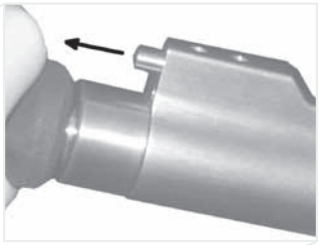

Figure 56

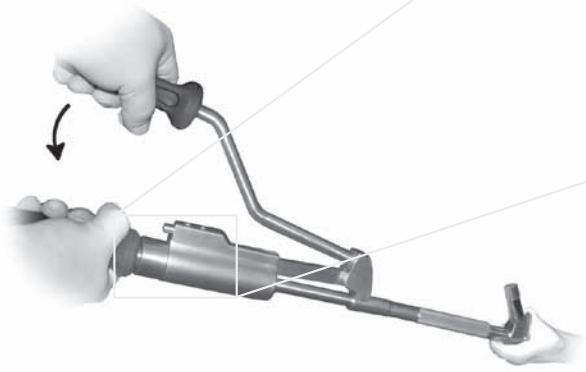

Figure 55

Figure 57

Insert the ***Locking Nut*** into the ***Polyethylene Holder***.

Figure 58

Thread the ***Locking Nut*** onto the ***Stem Implant***.

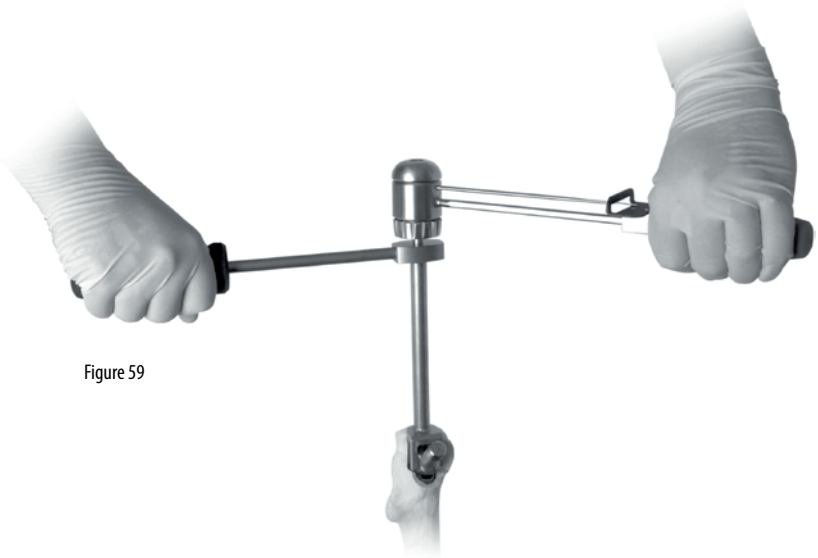

Figure 59

Assemble the ***Socket/Neck Stabilizer***, ***Stabilizer Handle***, and ***Torque Wrench*** as shown (Fig. 59). Use the Stabilizer Handle to minimize rotational force on the Neck Implant while turning the Torque Wrench until the pointer reaches the "120" mark (Fig. 60).

Figure 60

Neck Stabilizer

Stabilizer Handle


Combination Wrench


Neck Stabilizer


Insertion/Disassembly Driver

# Implant Disassembly/Removal

## Locking Nut Removal

The first step in removing or disassembling the implant is to remove the ***Locking Nut***. Use the ***Combination Wrench*** (Fig. 61) on the ***Socket / Neck Stabilizer*** to remove the Locking Nut. Use the ***Stabilizer Handle*** to minimize rotational force on the ***Neck Implant*** while turning.

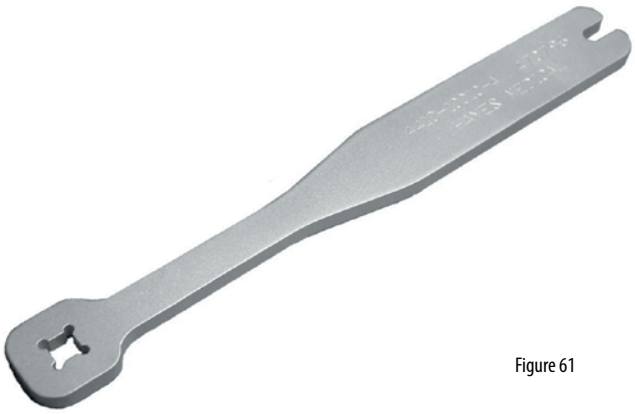
Figure 61

## Distal Stem Disengagement

*The taper of the* ***Stem Implant*** *must be disengaged before the* ***Neck/Body Implants*** *can be separated.* Thread the ***Implant Insertion/ Disassembly Driver*** onto the Stem Implant and impact to disengage the taper of the Stem Implant from the ***Neck/Body Assembly***.

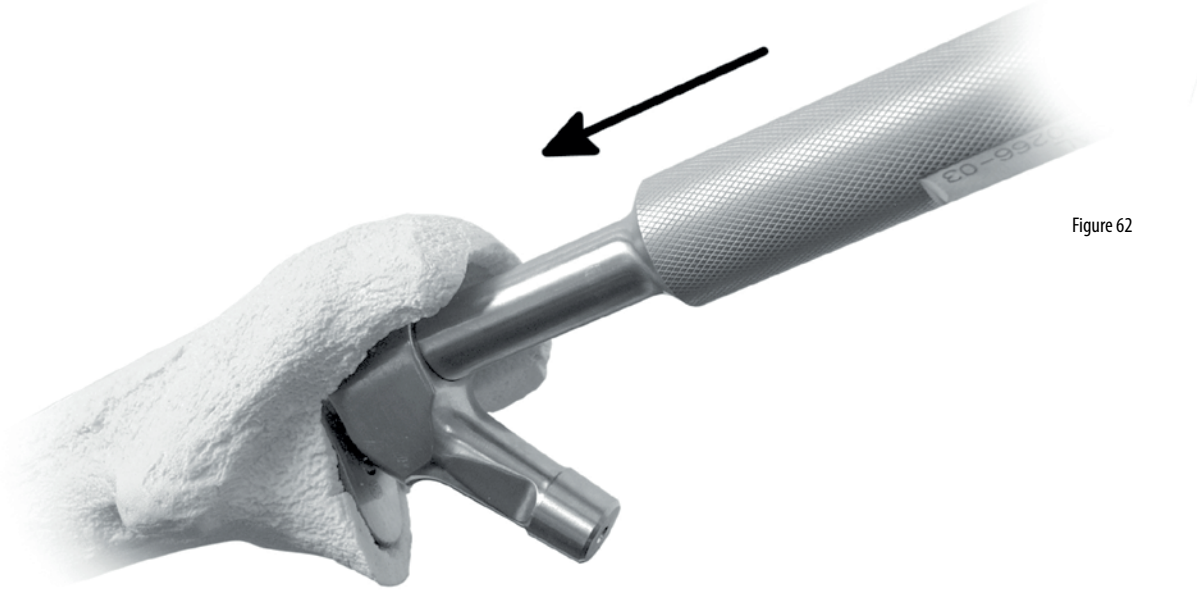
Figure 62

## Body/Neck Disassembly


Disassembly Key

Place the ***Disassembly Key*** in the space between the ***Neck*** and ***Body*** Implants. Direct the wedge to avoid impingement on the Neck taper joining the Body Implant. Place a retractor on the opposite side of the neck to protect the soft tissue. *Do <u>not</u> impact the key into the Neck Taper!*


Figure 63

Once the taper is disengaged, the ***Neck Implant*** can be repositioned or removed by hand.


Figure 64


Slap Hammer

## Stem and/or Body Extraction

*NOTE: Stems which are 14mm in diameter and larger will not pass through the **Body Implant**.*

Fully thread the ***Slap Hammer*** onto the ***Stem Implant***. Distracting the stem will impart a distraction force on the ***Body Implant*** as well.

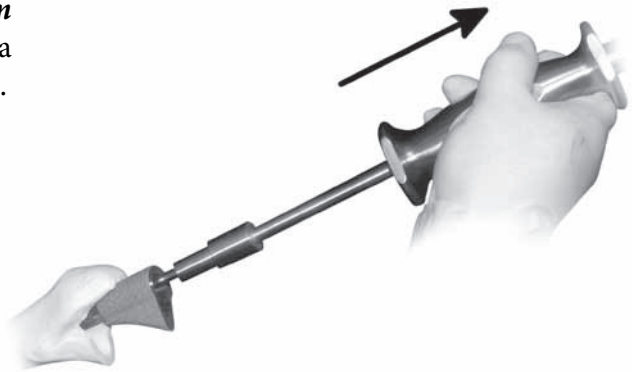

Figure 65

*NOTE: Stems which are 13mm in diameter or smaller will pass through the **Body Implant**.*

Fully thread the ***Slap Hammer*** onto the ***Stem Implant***. Distracting the Stem will remove the stem through the ***Body Implant***.

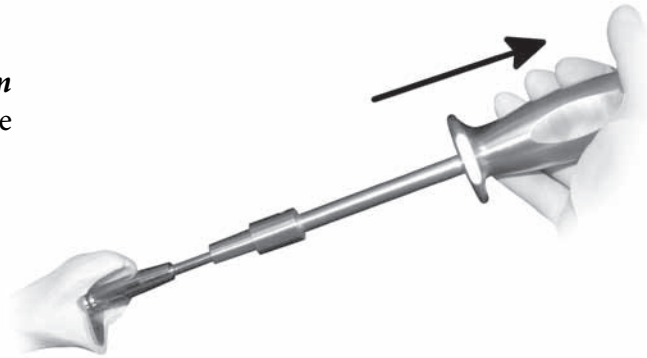

Figure 66

The Body Extractor provides a lip which can be inserted through the ***Body Implant*** and hooked on its distal edge. This can be threaded onto the Slap Hammer and used to remove the Body Implant.

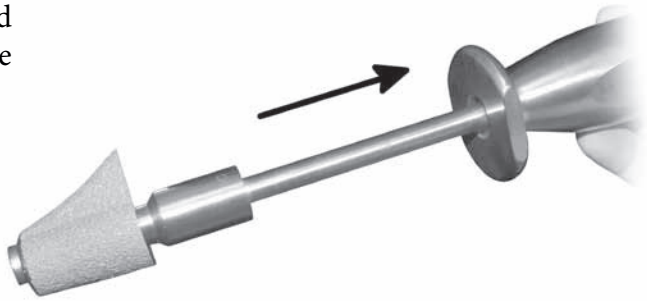

Figure 67

# UniSyn Plus Femoral Canal Preparation

## Distal Reaming for UniSyn Plus

The distal canal is sequentially reamed until uniform cortical contact is established.
Each Straight Reamer is marked with 2 wide laser marks and 2 thin laser marks. The wide laser marks indicate the appropriate depth for the standard length stem of that diameter. The first wide laser mark indicates the appropriate depth for the standard length stem of that diameter. The second wide laser mark indicates the appropriate depth for the extended length stem of that diameter. Advance the reamer until the appropriate wide laser mark is even with the resection level.

Choose the appropriate diameter reamer based upon which UniSyn Plus stem is to be used. For example, if a size 13 Plus is to be used a size 14 reamer is chosen; if a size 13 Plus 1 is to be used a size 15 reamer is chosen. (Note: a reamer one size larger than the stem is used for Plus stems; a reamer 2 sizes larger than the stem is used for Plus 1 stems.)

The thin laser marks indicate the appropriate depth for the oversized portion of the UniSyn Plus stem. The distal thin laser mark indicates the appropriate depth for the standard length UniSyn Plus stem. The more proximal laser mark indicates the appropriate depth for the extended length UniSyn Plus stem. Advance the reamer until the appropriate thin laser mark is even with the resection level.

Figure 68

# Classic Neck Positioner Technique - Setting Version

## Neck Connector Assembly

Figure 68

Figure 69

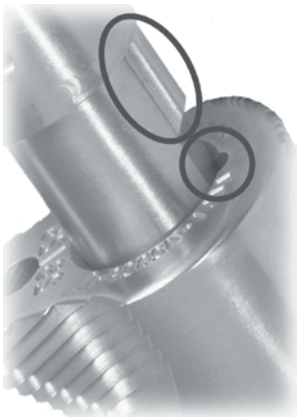

Figure 70

Insert the ***Version Adjustment Tool*** into the top of the ***Neck Positioner***. Make sure to align the tab on the Adjustment Tool with the notch on the Positioner as shown in Fig. 68.

Insert the ***Neck Positioner*** into the ***Medial Broach*** and align the tab on the lower portion of the Positioner with the slot in the lateral side of the broach hole as shown in Fig. 69.

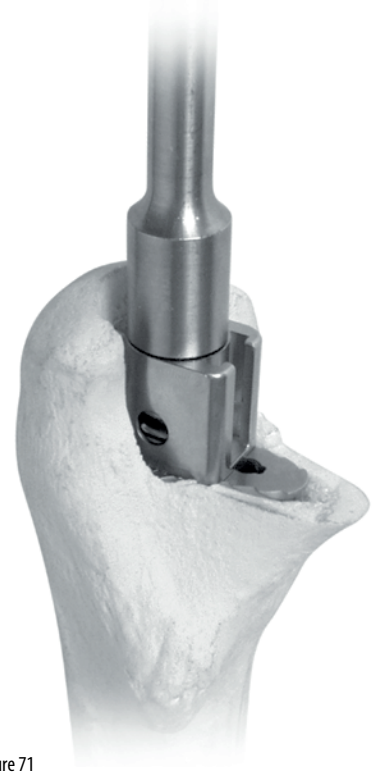

Figure 71

Be sure to fully seat the ***Neck Positioner***.

# Classic Neck Positioner Technique - Setting Version

## Adjustment

Adjust the version of the ***Neck Positioner*** by pushing down on the ***Version Adjustment Tool*** and rotating it.

Figure 72


Figure 73

Insert the **Version Rod** into the side of the knob on the **Version Adjustment Tool**.

It may be useful to set the ***Version Rod*** parallel with the tibia and note the version of the proximal femur as indicated by the ***Medial Broach*** (Fig. 72). Set the desired amount of anteversion by rotating the Positioner toward the operative side marking (Left or Right.)

The ***Version Rod*** can then be set to indicate the total amount of version desired.

If the ***Neck Positioner*** does not return to the locked position, slightly turn the ***Version Adjustment Tool*** and the Positioner will snap into place. Note the orientation as it will be needed later in the Neck/Body assembly step.

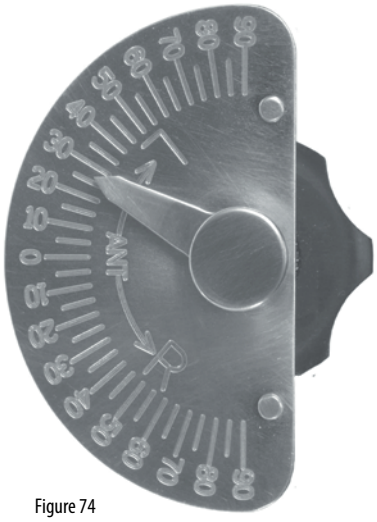


Figure 74

Figure 75

*NOTE: The version indicator scale references the version between the Neck Positioner and the Medial Broach, not the version between the posterior femoral condyles and the Neck Positioner.*

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