

# U2™ Hip Stem

Femoral Hip System



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# Device Description

## **U2 Hip Stem –**

The U2 Hip Stem System is a cylindrical stem system used in primary hip arthroplasty. The stem options available under this system are Porous coated stem, HA coated stem and Cemented stem.

The U2 Hip Stem System adopts a Tri-wedge geometry for implant fixation. A unique matrix size distribution (available only in Porous coated stem and HA coated stem options) is available to provide optimal proximal and distal canal distributions for broader patient morphological conditions to achieve implant fit-and-fill. In addition, a cemented stem option that utilizes the same surgical instrumentation is also available as a backup solution when unexpected bone quality is identified.

- 14 available sizes in HA coated stem
- 13 available sizes in Porous coated stem
- 5 available sizes in Cemented stem
- Up to 12 head neck length selections

## **INDICATIONS**

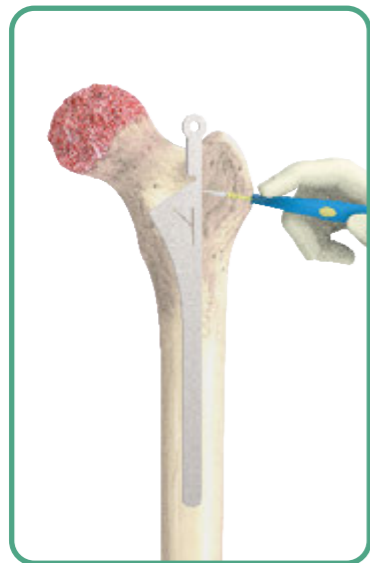
1. Non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia.
2. Inflammatory degenerative joint disease such as rheumatoid arthritis.
3. Correction of function deformity.
4. Revision procedures where other treatments or devices have failed.
5. Treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that is unmanageable using other techniques.

This device is a single use implant and intended for cementless use only except cemented stem which is designed for cemented use only.

*Please refer to the package inserts for important product information, including, but not limited to contraindications, warnings, precautions, and adverse effects.*



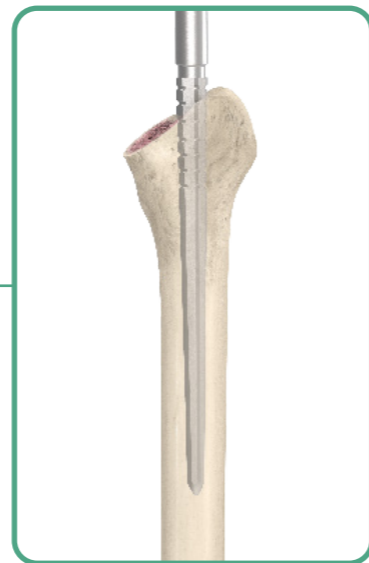
# Surgical Overview



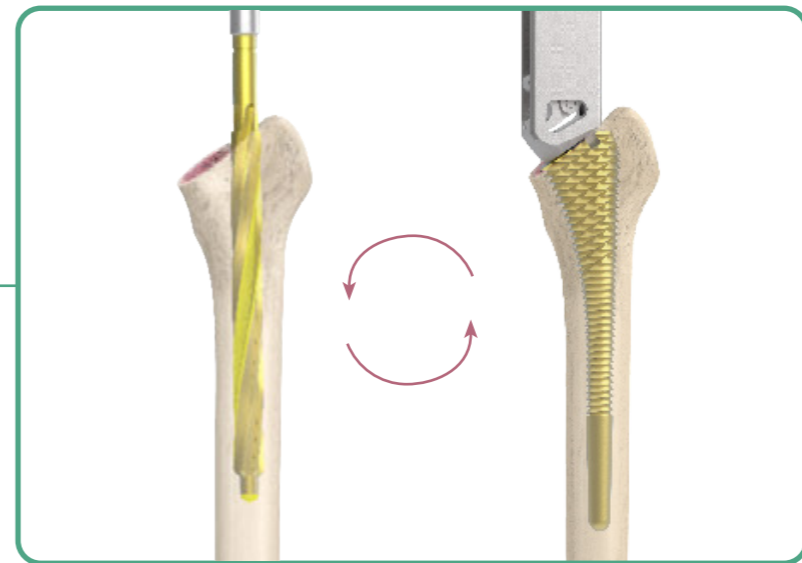
**A. Femoral Osteotomy**



**B. Femoral Canal Accessing**



**C. Canal Reaming**



**D. Canal Broaching and Reaming**



**E. Calcar Preparation (Optional)**



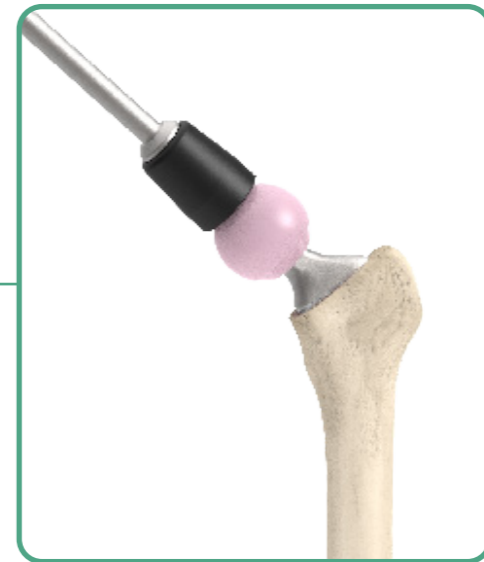
**F. Trial Reduction**



**G. Stem Insertion**



**H. Stem Impaction**



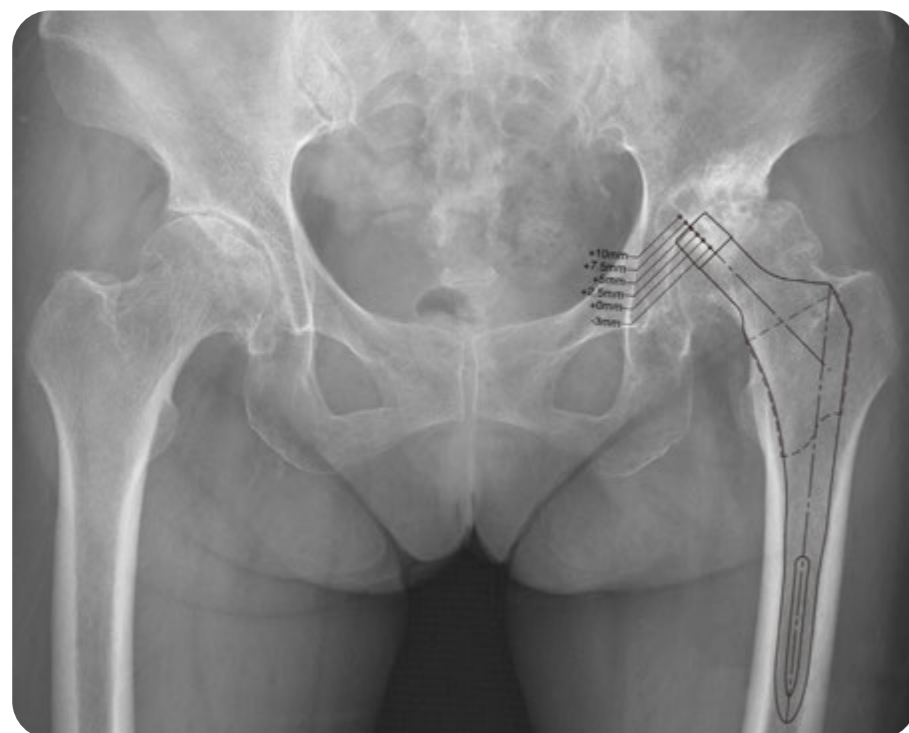
**I. Femoral Head Impaction**

# Preoperative Planning and Templating

Preoperative planning is essential for determining the optimal stem size, neck resection level and the appropriate neck length. Making an accurate femoral component selection begins with thorough radiographic evaluation of the affected femur, both the A/P view and lateral view. The A/P radiographic image should include bilateral hip joints to help evaluate the affected side. These radiographs provide an estimation of leg length discrepancy, femoral offset and center of rotation needed to reconstruct hip biomechanics.

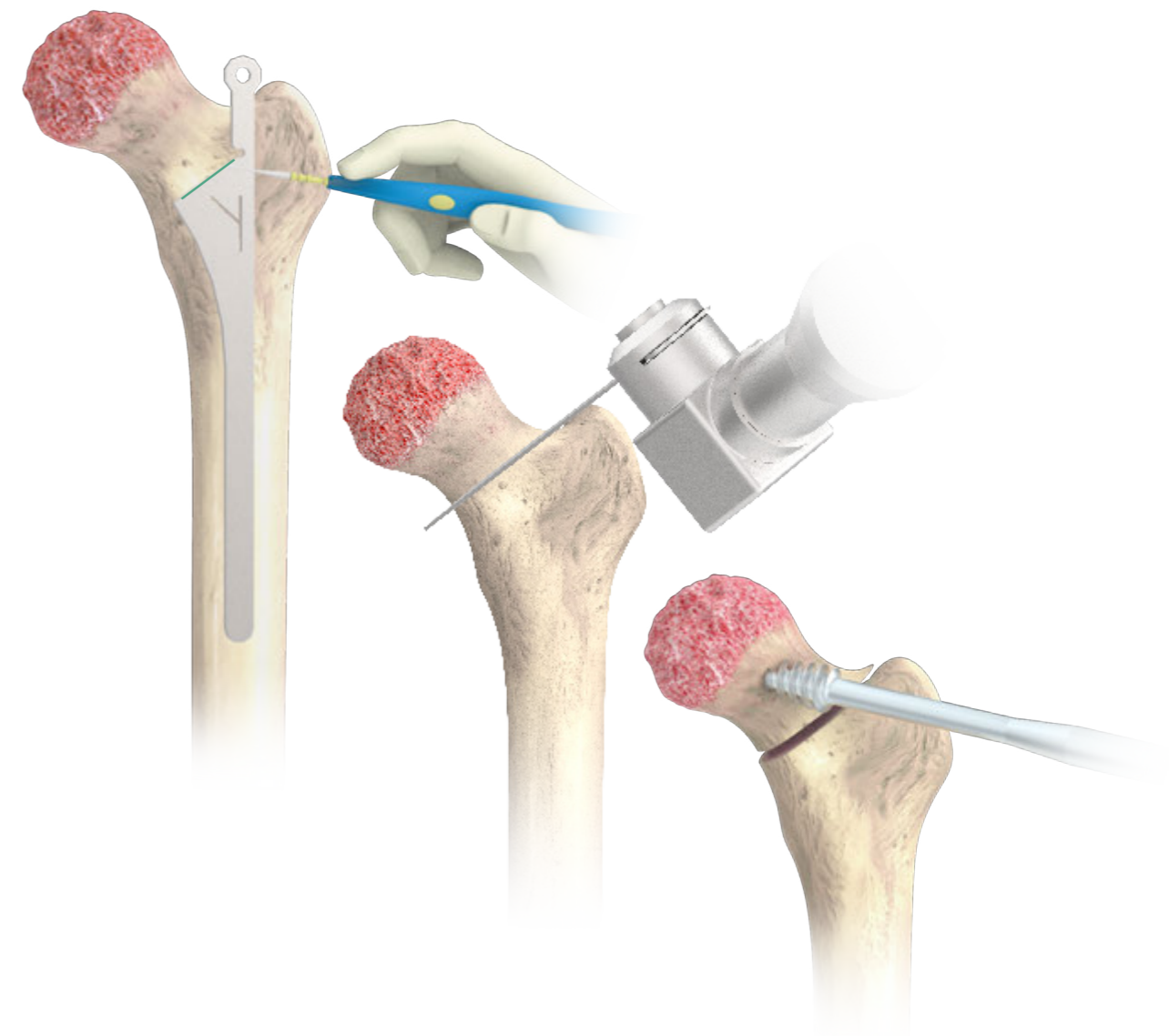
It is recommended to pre-operatively template the prosthesis size that best fits the metaphysis canal area and fills the diaphysis canal area. Templates show the neck length and offset for each of the head/ neck combinations (-3 to +10 mm, depending on head material and diameter).

The final determination of implant choice should take into account the acetabular cup position, cup size, and hip center.



## A. Femoral Osteotomy

During preoperative templating, determine the neck resection level by referencing the distance above the lesser trochanter (about 10-15 mm). Intra-operatively, align the **Neck Resection Guide** with the anatomical axis of the femoral canal. Mark the cut line using electrocautery, then complete the femoral neck resection with a power saw. Remove the femoral head with the **Femoral Head Extractor**.



Instruments



Neck Resection Guide



Femoral Head Extractor

# B. Femoral Canal Accessing

Utilize the **Femoral Cutting Chisel** for adequate lateral/ posterior piriformis fossa initial entry into femoral canal.



Instruments

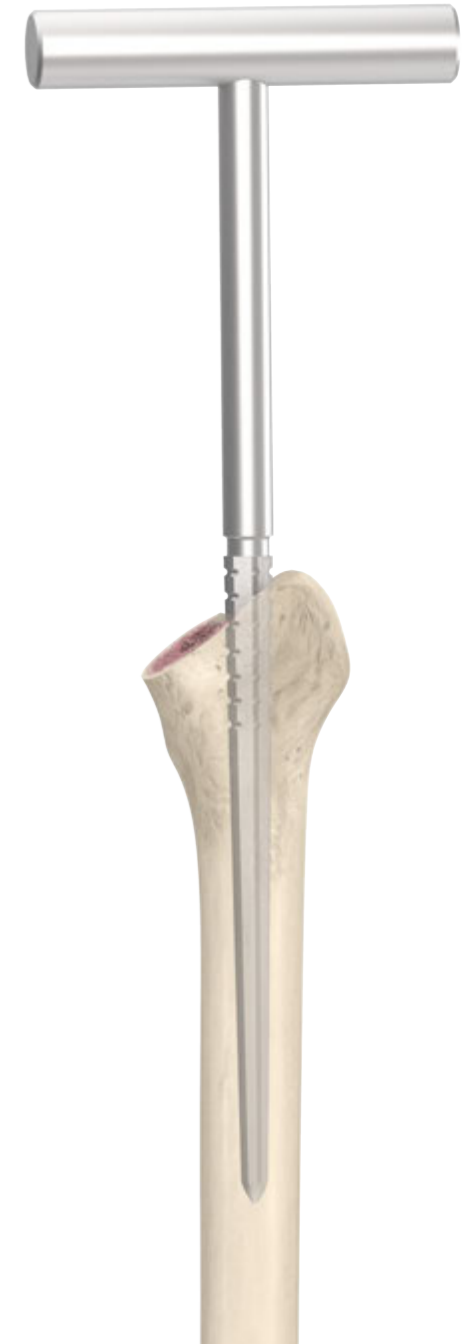


Femoral Cutting Chisel

# C. Canal Reaming

When the surgeon chooses the Porous coated stem and HA coated stem, it is recommended to utilize the "Ream-Broach-Ream" technique.

Use the **T-Handle Stem Reamer** manually to enlarge the medullary canal. While inserting the stem reamer, be sure that the grip handle is perpendicular to the canal.



Instruments



T-Handle Stem Reamer

# D. Canal Broaching and Reaming

## Porous coated stem and HA coated stem

Slightly enlarge the canal by using the **U2 Stem Reamer**.

Attach the smallest **U2 Broach** to the **Broach Handle** and sequentially enlarge the canal until the ideal proximal press-fit size is achieved. If there is any interference while broaching.

Once the proximal size is determined, employ the **U2 Stem Reamer** and ream the canal to the most advantageous diameter that corresponds with the desired proximal size. Reaming range should not be in excess of the cortical bone contact.

U2 Broach Sizing Chart

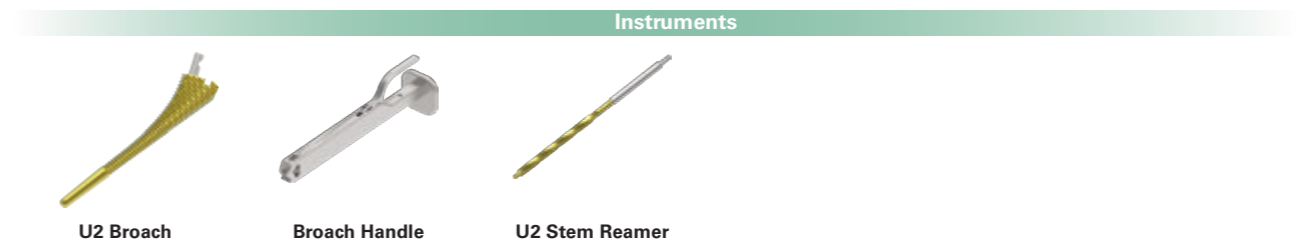
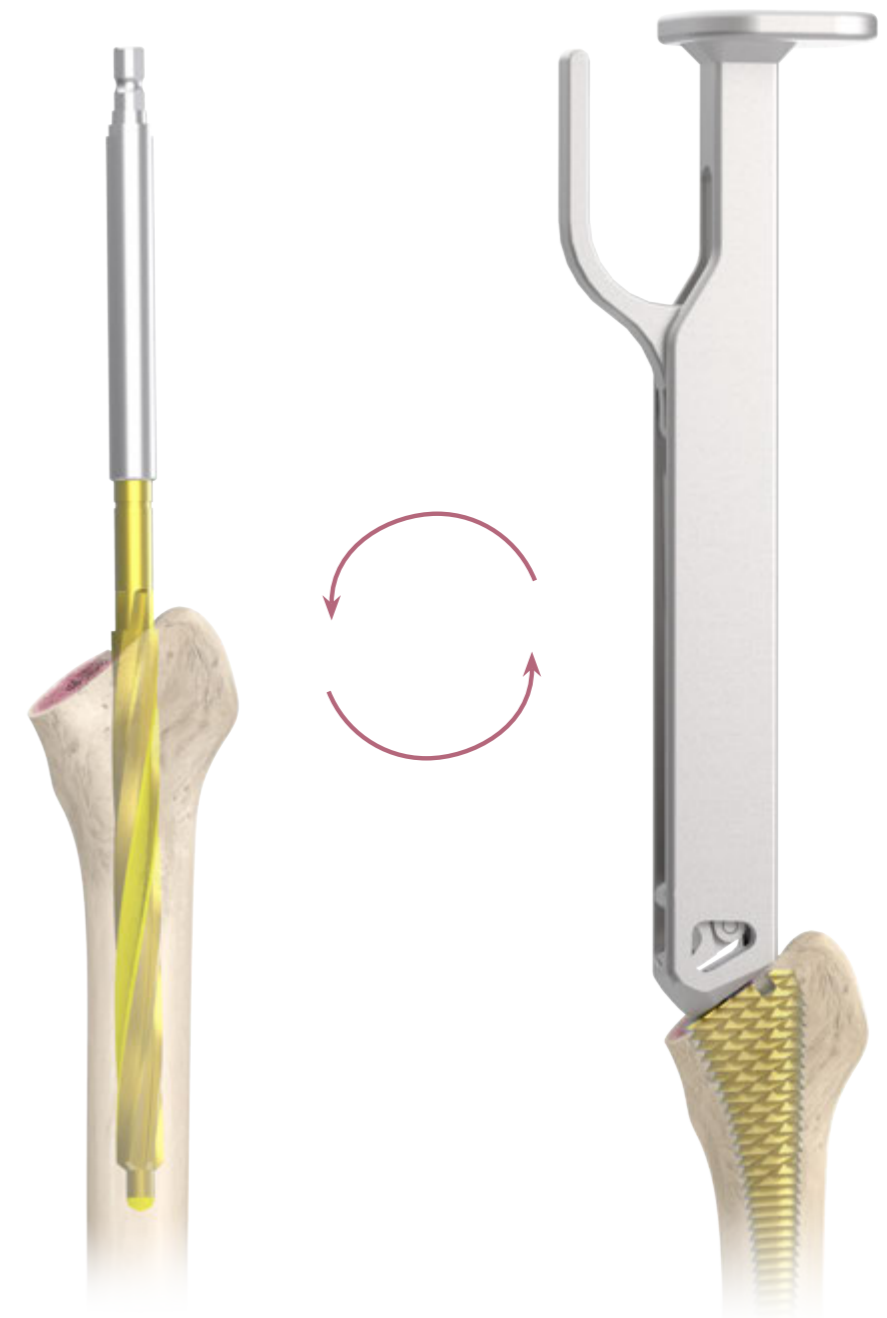
| Size | Distal Diameter(mm) |
|------|---------------------|
| # 0  | Ø 8                 |
| # 1  | Ø 9                 |
| # 2  | Ø 10                |
| # 3  | Ø 10                |
| # 4  | Ø 11                |
| # 5  | Ø 12                |
| # 6  | Ø 13                |
| # 7  | Ø 15                |

## Cemented stem

If the Cemented Stem is chosen, "Ream-Broach-Ream" technique would not be necessary. After the femoral canal has been opened, connect the **U2 Stem Reamer** to the power device and create appropriate distal implant diameter. Sequential femoral reaming begins with the smallest reamer and gradually enlarge in 1 mm increments. Reaming should continue until cortical bone contact is achieved and desired diameter is met.

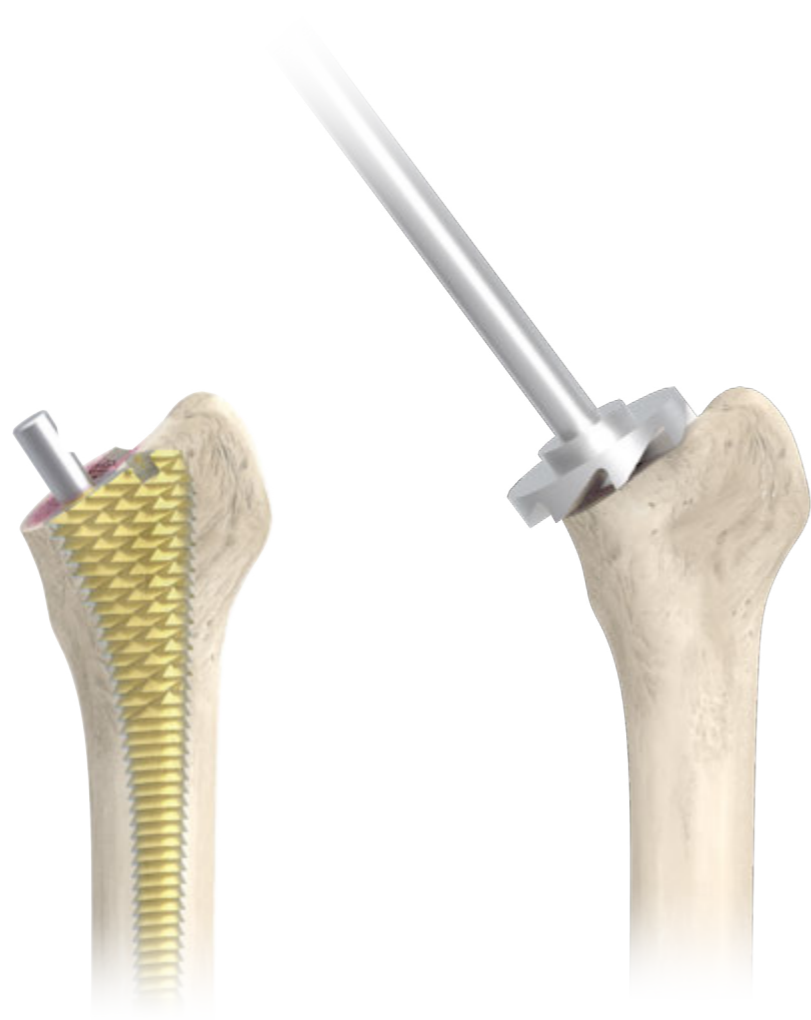
Once the canal is reamed, begin with the broach of the smallest size until the size leaves an approximately 2-4 mm of distance from the stop point of the broach to the medial wall of the femur shaft.

# D. Canal Broaching and Reaming

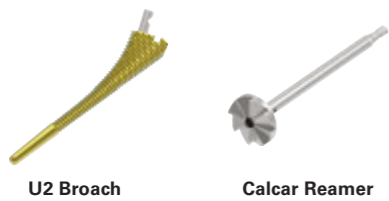


## E. Calcar Preparation (Optional)

For cemented implants, after the final broach is seated, place the **Calcar Reamer** over the broach trunnion and plane the femoral neck until it reaches the appropriate surface with the collar of the Cemented stem.



Instruments



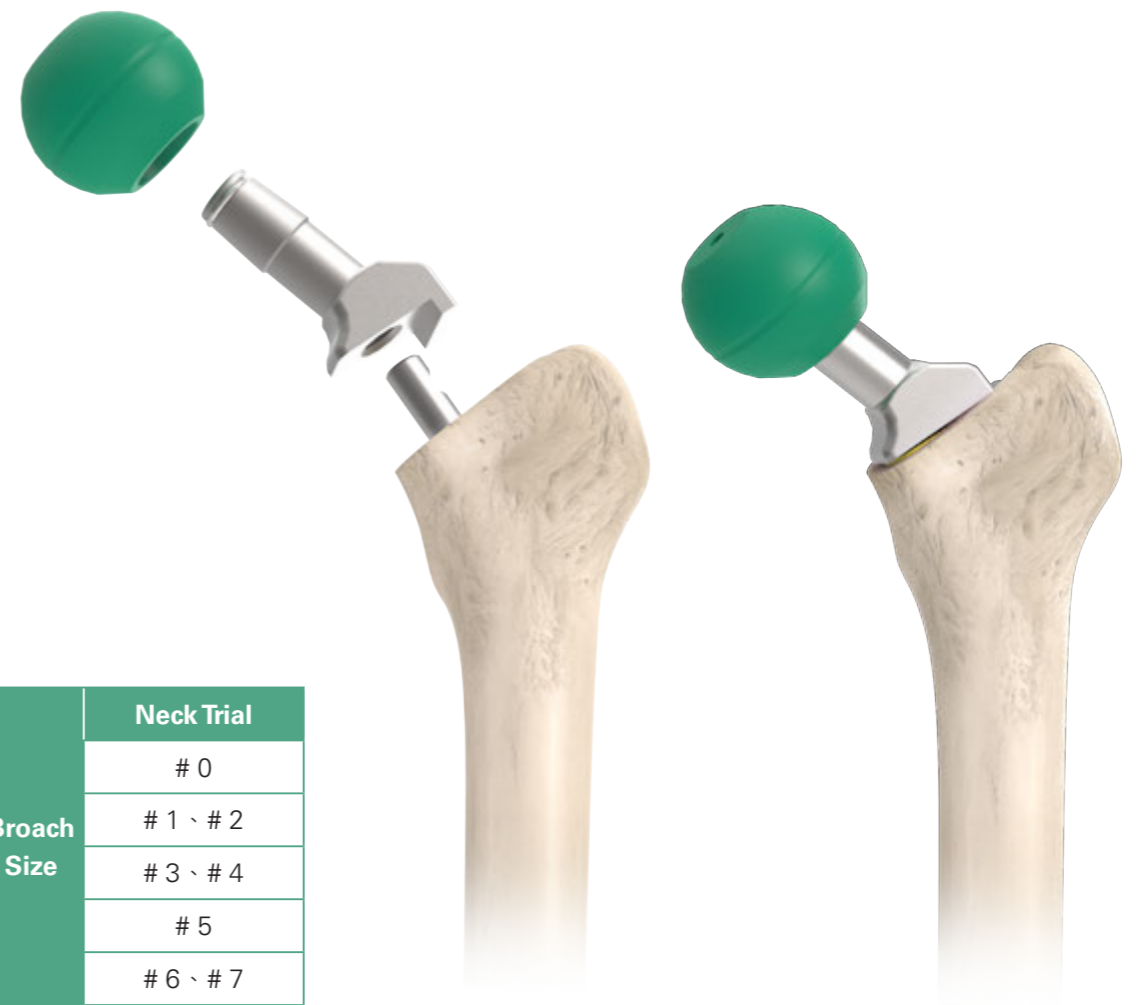
U2 Broach

Calcar Reamer

## F. Trial Reduction

Assemble the corresponding size of **Neck Trial** onto the broach.

Perform the trial reduction using the **Femoral Head Trial** with the desired diameter and neck length.



| Broach Size | Neck Trial |
|-------------|------------|
|             | # 0        |
|             | # 1 、 # 2  |
|             | # 3 、 # 4  |
|             | # 5        |
|             | # 6 、 # 7  |

Instruments



U2 Broach

Neck Trial

Femoral Head Trial

## G. Stem Insertion

After trial reduction, remove the broach and introduce the stem by using the **Quick Connect Holder**. Use the holder to firmly attach the stem via the insertion hole on the stem shoulder.

Gently tap the holder to achieve initial stem implantation into the medullary canal.

**⚠ Caution:**  
The **Quick Connect Holder** is designed to position the implant, not for final impaction. Please **impact gently**.



Instruments



U2 Quick Connect Holder

## H. Stem Impaction

Use **Stem Impactors** to further advance the stem into the canal. The prosthesis should be seated until the most proximal portion of the coating surface is in line with the neck resection level.



Instruments

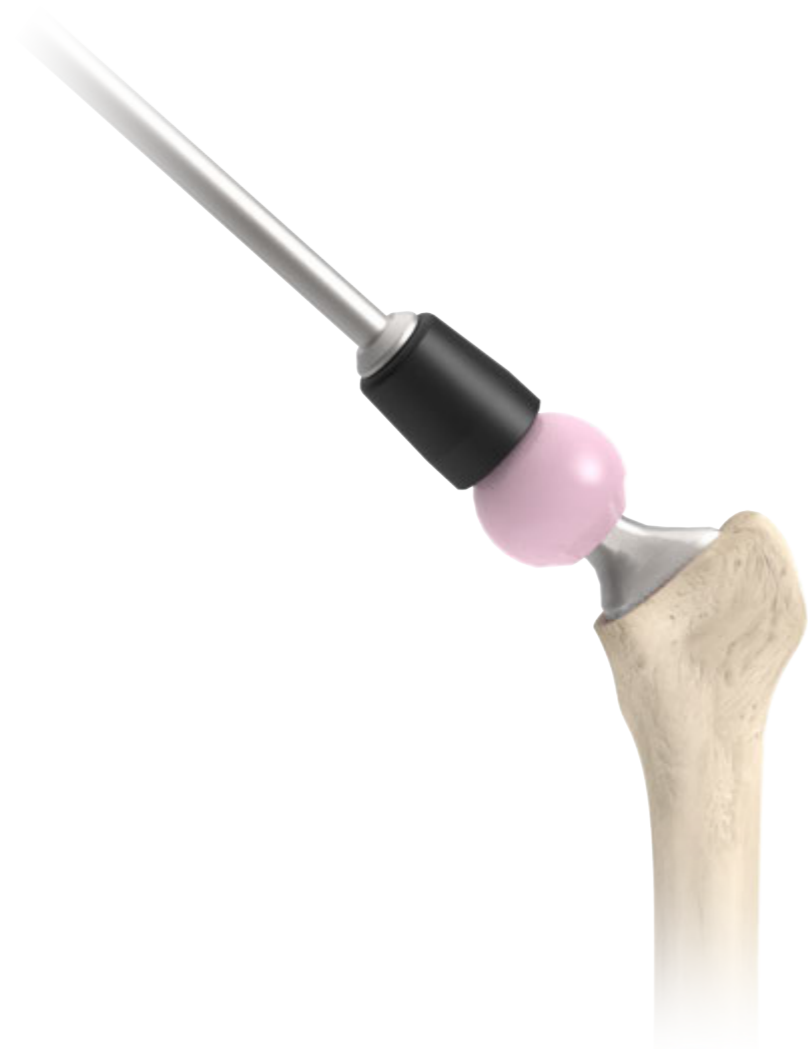


Stem Impactor

# I. Femoral Head Impaction

Perform a final trial reduction to confirm stability and leg length by using the **Femoral Head Trials**. After the appropriate femoral head size has been determined, place it onto the cleaned and dried trunnion by hand.

Connect the **Femoral Head Impactor** and **Universal Handle** and moderately impact the femoral head until it is firmly seated.



Instruments



Femoral Head Trial



Femoral Head Impactor



Universal Handle

# Appendix

## Cement Restrictor Insertion (Cemented Stem Only)

Select the appropriate Cement Restrictor according to the final reamer size. Assemble the **Full PE Cement Restrictor Inserter** and the Cement Restrictor. Insert the assembly into the canal to the designated depth (read the mark on the shaft of inserter).

After the restrictor is located, dry the femoral canal by passing a swab down the canal. Remaining debris can also be removed during this procedure. The bone cement can then be introduced in low viscosity state. Cement can be injected in a retrograde fashion to gradually fill the canal.



Instruments



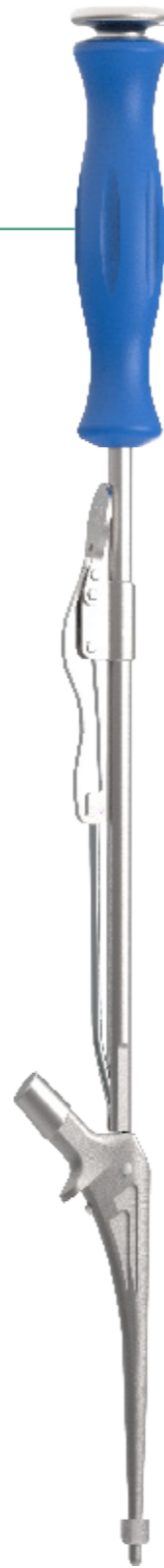
Full PE Cement Restrictor Inserter

# Appendix

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## Cement Stem Insertion (Cemented Stem Only)

Use the **Quick Connect Holder** to hold the U2 cemented stem, and press the stem into the femoral canal until the adequate depth is reached (the collar reaches to the resection surface). Remove the excessive cement. Hold the stem until the cement is polymerized, and disengage the **Quick Connect Holder**.



Instruments



U2 Quick Connect Holder

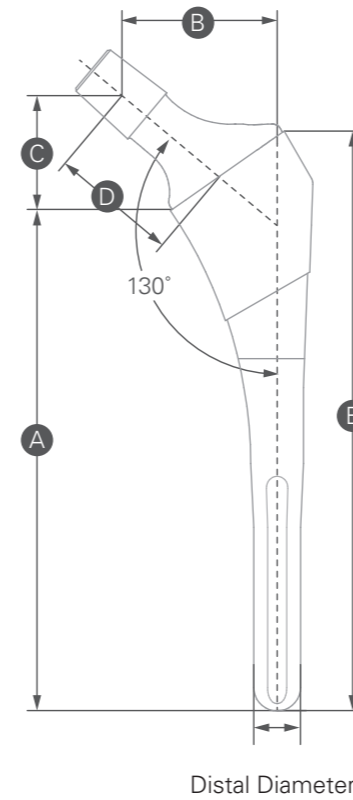
# Order Information

Made with Titanium (Ti6Al4V) Alloy and Titanium Plasma Spray with Hydroxyapatite Coating.

**U2 Matrix HA Stem**



| Catalog Number | Description  |
|----------------|--------------|
| 1104 - 1001    | # 0, Ø 8 mm  |
| 1104 - 1012    | # 1, Ø 9 mm  |
| 1104 - 1023    | # 2, Ø 10 mm |
| 1104 - 1024    | # 2, Ø 11 mm |
| 1104 - 1033    | # 3, Ø 10 mm |
| 1104 - 1034    | # 3, Ø 11 mm |
| 1104 - 1035    | # 3, Ø 12 mm |
| 1104 - 1044    | # 4, Ø 11 mm |
| 1104 - 1045    | # 4, Ø 12 mm |
| 1104 - 1055    | # 5, Ø 12 mm |
| 1104 - 1056    | # 5, Ø 13 mm |
| 1104 - 1066    | # 6, Ø 13 mm |
| 1104 - 1067    | # 6, Ø 14 mm |
| 1104 - 1078    | # 7, Ø 15 mm |



| Size | Distal Diameter | A<br>Medial Length | B<br>Offset | C<br>Vertical Height | D<br>Neck Length | E<br>Lateral Length |
|------|-----------------|--------------------|-------------|----------------------|------------------|---------------------|
| #0   | 8               | 106                | 30          | 22.7                 | 27               | 120                 |
| #1   | 9               | 110                | 35          | 24.2                 | 30               | 126                 |
| #2   | 10              | 115                | 36          | 24.3                 | 30               | 132                 |
| #3   | 10              | 113                | 39          | 28.2                 | 34               | 132                 |
| #2   | 11              | 121                | 36          | 24.3                 | 30               | 138                 |
| #3   | 11              | 119                | 39          | 28.2                 | 34               | 138                 |
| #4   | 11              | 118                | 39          | 29.3                 | 34               | 138                 |
| #3   | 12              | 126                | 39          | 28.2                 | 34               | 145                 |
| #4   | 12              | 125                | 39          | 29.3                 | 34               | 145                 |
| #5   | 12              | 124                | 43          | 33.2                 | 38               | 145                 |
| #5   | 13              | 131                | 43          | 33.2                 | 38               | 152                 |
| #6   | 13              | 129                | 45          | 36.6                 | 41               | 152                 |
| #6   | 14              | 135                | 45          | 36.6                 | 41               | 158                 |
| #7   | 15              | 142                | 45          | 37.5                 | 41               | 166                 |

Unit: mm

# Order Information

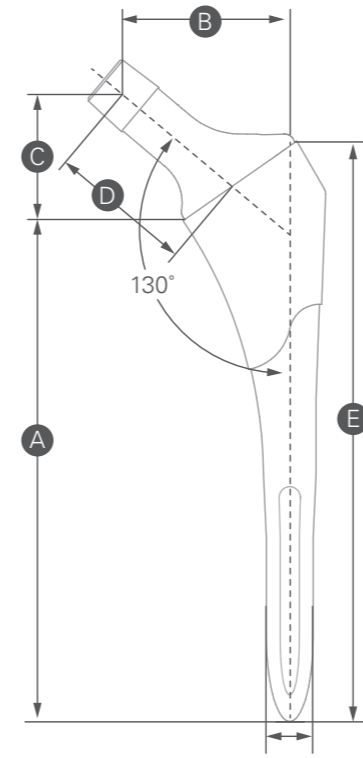
| Catalog Number | Description |
|----------------|-------------|
|----------------|-------------|

Made with Titanium (Ti6Al4V) Alloy and Sintered Titanium Bead.

**U2 Matrix Porous Stem**



|             |              |
|-------------|--------------|
| 1104 - 3212 | # 1, Ø 9 mm  |
| 1104 - 3223 | # 2, Ø 10 mm |
| 1104 - 3224 | # 2, Ø 11 mm |
| 1104 - 3233 | # 3, Ø 10 mm |
| 1104 - 3234 | # 3, Ø 11 mm |
| 1104 - 3235 | # 3, Ø 12 mm |
| 1104 - 3244 | # 4, Ø 11 mm |
| 1104 - 3245 | # 4, Ø 12 mm |
| 1104 - 3255 | # 5, Ø 12 mm |
| 1104 - 3256 | # 5, Ø 13 mm |
| 1104 - 3266 | # 6, Ø 13 mm |
| 1104 - 3267 | # 6, Ø 14 mm |
| 1104 - 3278 | # 7, Ø 15 mm |



Distal Diameter

| Size | Distal Diameter | A<br>Medial Length | B<br>Offset | C<br>Vertical Height | D<br>Neck Length | E<br>Lateral Length |
|------|-----------------|--------------------|-------------|----------------------|------------------|---------------------|
| #1   | 9               | 110                | 35          | 24.2                 | 30               | 126                 |
| #2   | 10              | 115                | 36          | 24.3                 | 30               | 132                 |
| #3   | 10              | 113                | 39          | 28.2                 | 34               | 132                 |
| #2   | 11              | 121                | 36          | 24.3                 | 30               | 138                 |
| #3   | 11              | 119                | 39          | 28.2                 | 34               | 138                 |
| #4   | 11              | 118                | 39          | 29.3                 | 34               | 138                 |
| #3   | 12              | 126                | 39          | 28.2                 | 34               | 145                 |
| #4   | 12              | 125                | 39          | 29.3                 | 34               | 145                 |
| #5   | 12              | 124                | 43          | 33.2                 | 38               | 145                 |
| #5   | 13              | 131                | 43          | 33.2                 | 38               | 152                 |
| #6   | 13              | 129                | 45          | 36.6                 | 41               | 152                 |
| #6   | 14              | 135                | 45          | 36.6                 | 41               | 158                 |
| #7   | 15              | 142                | 45          | 37.5                 | 41               | 166                 |

Unit: mm

# Order Information

| Catalog Number | Description |
|----------------|-------------|
|----------------|-------------|

Made with Cobalt Chromium Molybdenum (CoCrMo) Alloy.

### U2 Cemented Stem



|             |              |
|-------------|--------------|
| 1104 - 5223 | # 2, Ø 10 mm |
| 1104 - 5234 | # 3, Ø 11 mm |
| 1104 - 5245 | # 4, Ø 12 mm |
| 1104 - 5256 | # 5, Ø 13 mm |
| 1104 - 5267 | # 6, Ø 14 mm |

### Centralizer



| Catalog Number | Size | Canal Size (mm) |
|----------------|------|-----------------|
|----------------|------|-----------------|

Made with Ultra High Molecular Weight Polyethylene (UHMWPE).

### Cement Restrictor

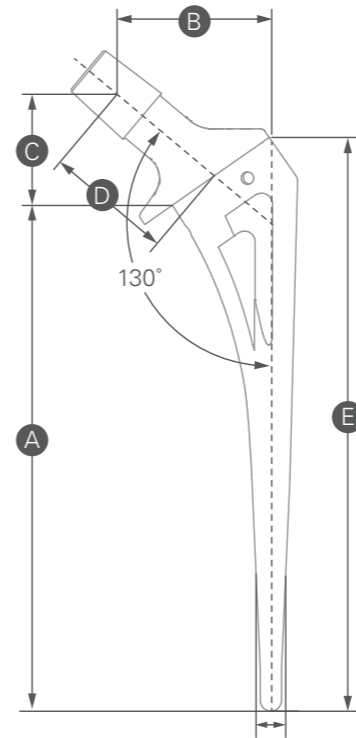


|             |      |    |
|-------------|------|----|
| 1905 - 7007 | # 7  | 7  |
| 1905 - 7008 | # 8  | 8  |
| 1905 - 7009 | # 9  | 9  |
| 1905 - 7010 | # 10 | 10 |
| 1905 - 7011 | # 11 | 11 |
| 1905 - 7012 | # 12 | 12 |
| 1905 - 7013 | # 13 | 13 |
| 1905 - 7014 | # 14 | 14 |
| 1905 - 7015 | # 15 | 15 |
| 1905 - 7016 | # 16 | 16 |

### Cement Restrictor, I-Type



|             |      |         |
|-------------|------|---------|
| 1907 - 1008 | # 8  | 8 - 9   |
| 1907 - 1010 | # 10 | 10 - 11 |
| 1907 - 1012 | # 12 | 12 - 13 |
| 1907 - 1014 | # 14 | 14 - 15 |
| 1907 - 1016 | # 16 | 16 - 17 |
| 1907 - 1018 | # 18 | 18 - 19 |



Distal Diameter

| Size | Distal Diameter | A Medial Length | B Offset | C Vertical Height | D Neck Length | E Lateral Length |
|------|-----------------|-----------------|----------|-------------------|---------------|------------------|
| #2   | 10              | 110             | 36       | 23.7              | 30            | 126              |
| #3   | 11              | 115             | 39       | 27.3              | 34            | 132              |
| #4   | 12              | 120             | 39       | 28.4              | 34            | 138              |
| #5   | 13              | 125             | 43       | 32.4              | 38            | 144              |
| #6   | 14              | 130             | 45       | 35.7              | 41            | 151              |

Unit: mm

# Femoral Head

 Special Order Items

| Catalog Number | Description (mm) |
|----------------|------------------|
|----------------|------------------|

Made with Cobalt Chromium Molybdenum (CoCrMo) Alloy.

**U2 Femoral Head**



|             |        |       |
|-------------|--------|-------|
| 1206 - 1122 | * Ø 22 | + 0   |
| 1206 - 1322 | * Ø 22 | + 3   |
| 1206 - 1522 | * Ø 22 | + 6   |
| 1206 - 1722 | * Ø 22 | + 9   |
| 1206 - 1026 | Ø 26   | - 2   |
| 1206 - 1126 | Ø 26   | + 0   |
| 1206 - 1326 | Ø 26   | + 3   |
| 1206 - 1526 | Ø 26   | + 6   |
| 1206 - 1726 | Ø 26   | + 9   |
| 1206 - 1028 | Ø 28   | - 3   |
| 1206 - 1128 | Ø 28   | + 0   |
| 1206 - 1228 | Ø 28   | + 2.5 |
| 1206 - 1428 | Ø 28   | + 5   |
| 1206 - 1628 | Ø 28   | + 7.5 |
| 1206 - 1828 | Ø 28   | + 10  |
| 1206 - 1032 | Ø 32   | - 3   |
| 1206 - 1132 | Ø 32   | + 0   |
| 1206 - 1232 | Ø 32   | + 2.5 |
| 1206 - 1432 | Ø 32   | + 5   |
| 1206 - 1632 | Ø 32   | + 7.5 |
| 1206 - 1832 | Ø 32   | + 10  |
| 1206 - 1036 | Ø 36   | - 3   |
| 1206 - 1136 | Ø 36   | + 0   |
| 1206 - 1236 | Ø 36   | + 2.5 |
| 1206 - 1436 | Ø 36   | + 5   |
| 1206 - 1636 | Ø 36   | + 7.5 |
| 1206 - 1836 | Ø 36   | + 10  |

\* The actual spherical diameter of a 22 mm metal head is 22.2 mm.

# Femoral Head

| Catalog Number | Description (mm) |
|----------------|------------------|
|----------------|------------------|

**BIOLOX® delta  
Ceramic Head**



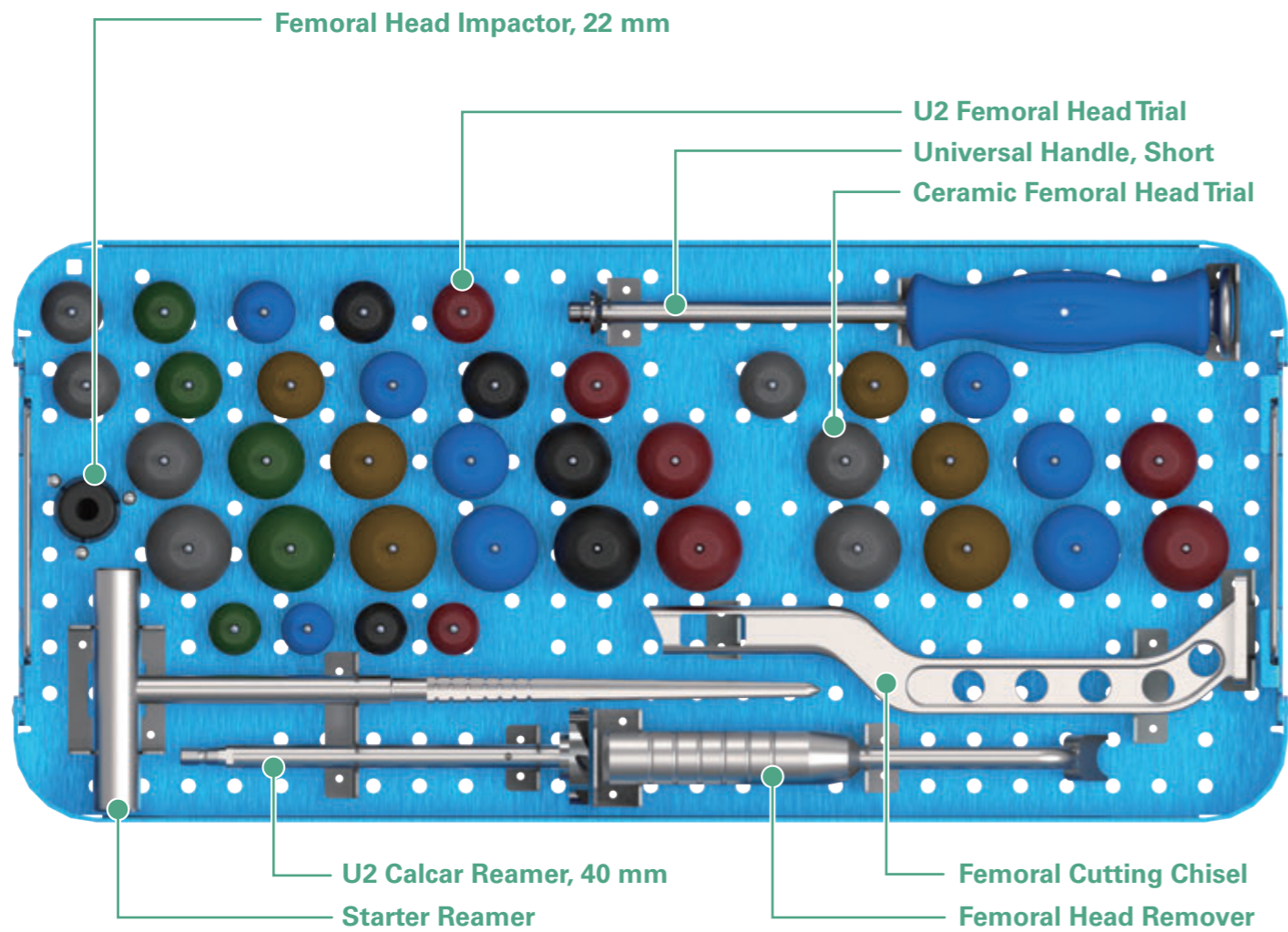
|             |        |    |       |
|-------------|--------|----|-------|
| 1203 - 5022 | * Ø 22 | S  | + 1   |
| 1203 - 5222 | * Ø 22 | M  | + 3   |
| 1203 - 5422 | * Ø 22 | L  | + 5   |
| 1203 - 5028 | Ø 28   | S  | - 2.5 |
| 1203 - 5228 | Ø 28   | M  | + 1   |
| 1203 - 5428 | Ø 28   | L  | + 4   |
| 1203 - 5032 | Ø 32   | S  | - 3   |
| 1203 - 5232 | Ø 32   | M  | + 1   |
| 1203 - 5432 | Ø 32   | L  | + 5   |
| 1203 - 5632 | Ø 32   | XL | + 8   |
| 1203 - 5036 | Ø 36   | S  | - 3   |
| 1203 - 5236 | Ø 36   | M  | + 1   |
| 1203 - 5436 | Ø 36   | L  | + 5   |
| 1203 - 5636 | Ø 36   | XL | + 9   |
| 1203 - 5040 | Ø 40   | S  | - 3   |
| 1203 - 5240 | Ø 40   | M  | + 1   |
| 1203 - 5440 | Ø 40   | L  | + 5   |
| 1203 - 5640 | Ø 40   | XL | + 9   |

\* The actual spherical diameter of a 22 mm metal head is 22.2 mm.

\*BIOLOX® is a registered trademark of the CeramTec Group, Germany

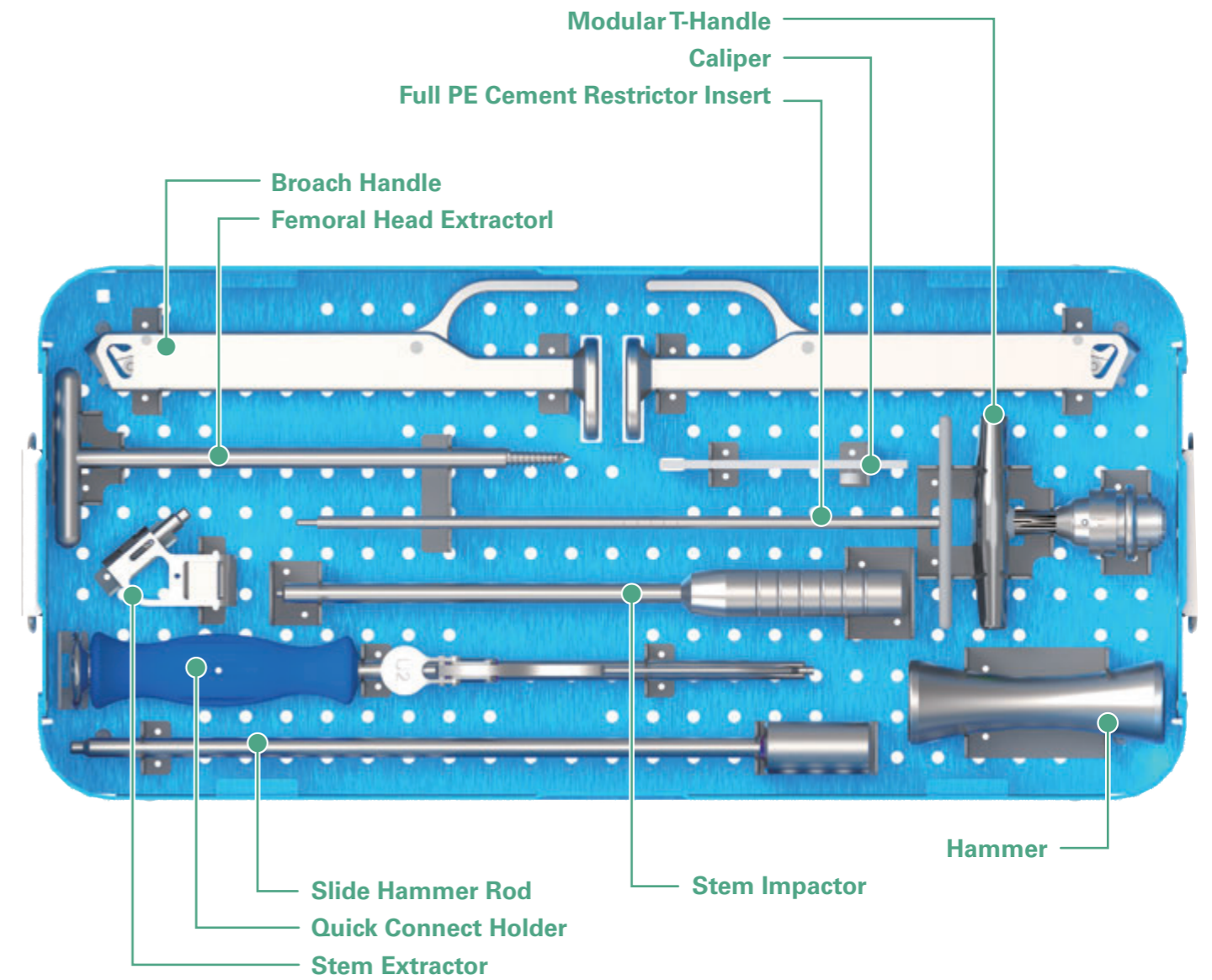
# Instrument Tray Guide

## U2 Hip Basic – Upper Tray



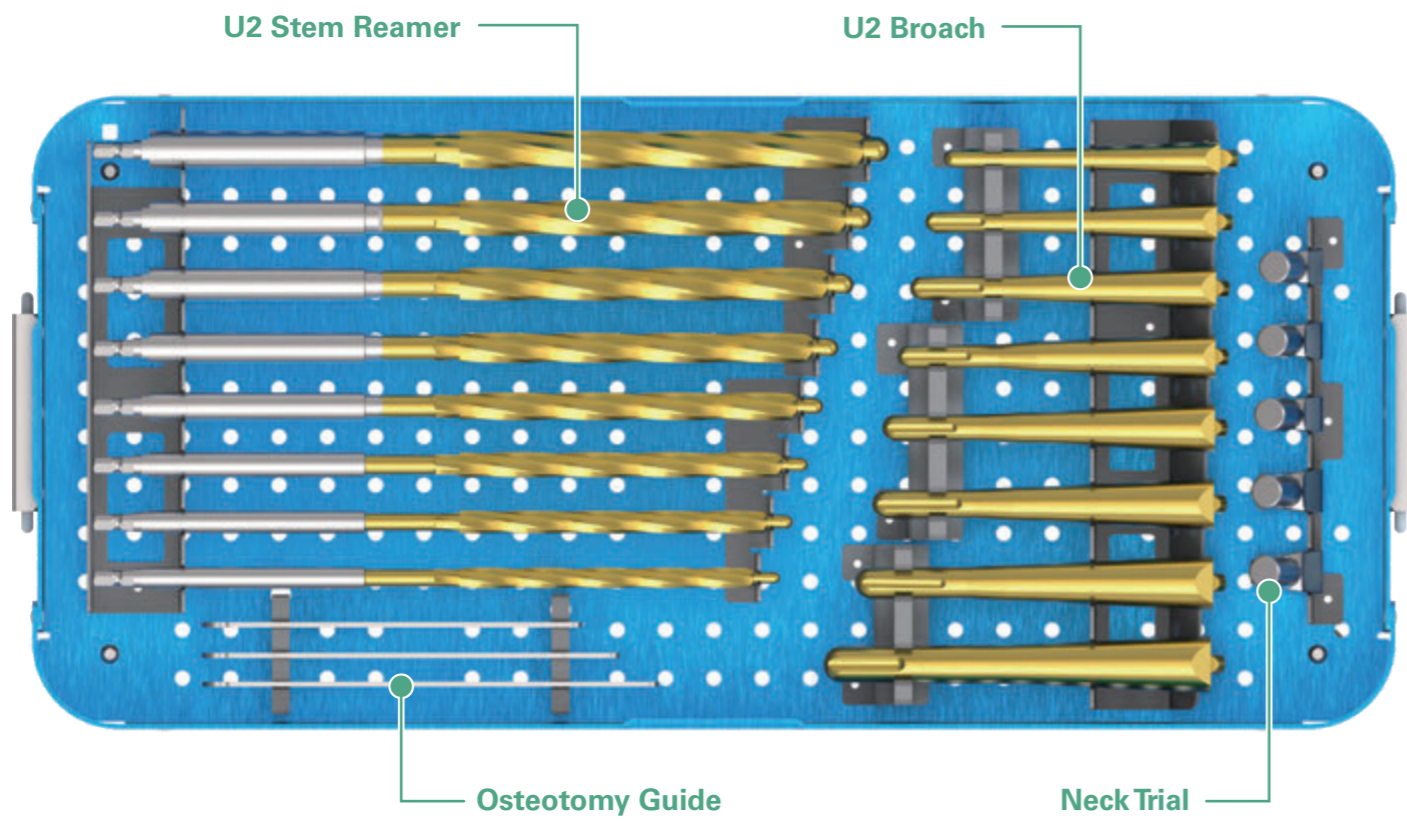
# Instrument Tray Guide

## U2 Hip Basic – Lower Tray



# Instrument Tray Guide

## U2 Hip Stem Case



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