# ORIGIN

Signature
ORTHOPAEDICS

# Table of Contents

# Introduction

The Signature Orthopaedics Origin Instrument system is an optimised instrument set for implantation of the Signature Orthopaedics cementless hip stem. The Origin instrument set features an adaptable broach handle that quick-connects to several instrument attachments to reduce the overall number of instruments and minimize the size and weight of the instrument tray.

## Indications

Signature Orthopaedics' hip replacement range is intended to replace a hip joint where bone stock is sufficient to support the implant. When a surgeon has selected prosthetic replacement as the preferred treatment, the devices are indicated for:

- Non-inflammatory degenerative joint disease including osteoarthritis or avascular necrosis
- Inflammatory joint disease including rheumatoid arthritis (excluding TSI stem)
- Correction of functional deformity including congenital hip dysplasia
- Traumatic injury involving the hip joint including traumatic arthritis or femoral head or neck fracture
- Failed previous hip surgery including internal fixation or joint fusion, reconstruction, hemiarthroplasty, surface replacement, or total replacement.

## Contraindications

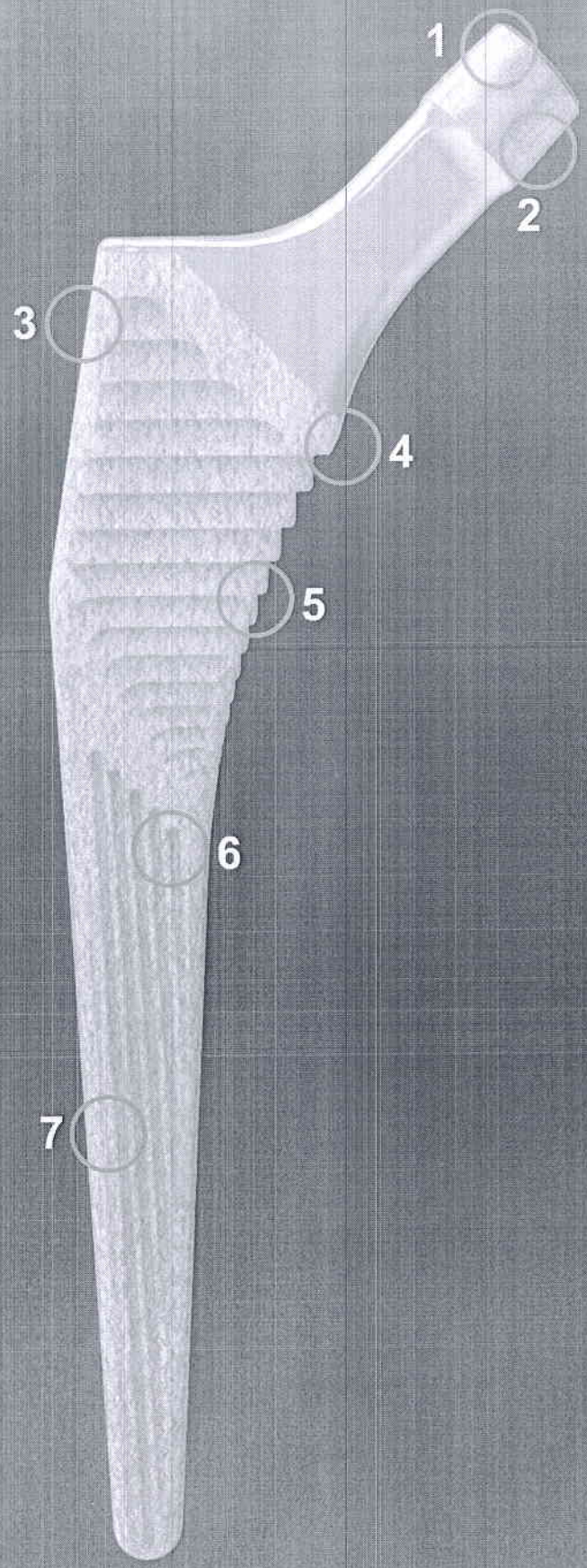
In general, prosthetic components require adequate bone support for correct fit and function. The use of prosthetic components is therefore contraindicated where any pathological condition may reduce the quantity and or strength of the bone which is supporting the prosthesis. Some contraindications are relative to the extent and severity of conditions and the benefits of prosthetic arthroplasty should be considered based on the patient's overall evaluation and the possibility of alternative treatment. Examples of such conditions include; osteoporosis, osteomalacia, osteogenesis imperfecta, or hypophosphatemia. Other contraindications include:

- Conditions limiting blood supply to the bone or joint.
- Systemic or local infection.
- Previous high dose radiotherapy.
- Psychological or neurological conditions which would restrict the patient's ability or compliance in restricting physical activity.
- Skeletal immaturity
- Conditions or activity which may place excessive load on the components such as; obesity, muscle, tendon & ligament deficiencies, multiple joint disabilities, and Charcot joints.

# Origin Stem Features

## Cementless Hip Stem

- Proven geometry, material and coating (Ti6Al4V with HA coating).
- Threaded proximal feature aids in positioning and removal.




**1. Multiple offsets**

**2. 12/14 Taper**

**3. Low-profile lateral shoulder,**
Enables easy insertion in reduced insertion techniques, including anterior approach.

**4. Collared, non-collared and Coxa Vara Versions**

**5. Step geometry**
Converts hoop stresses to compressive loads.

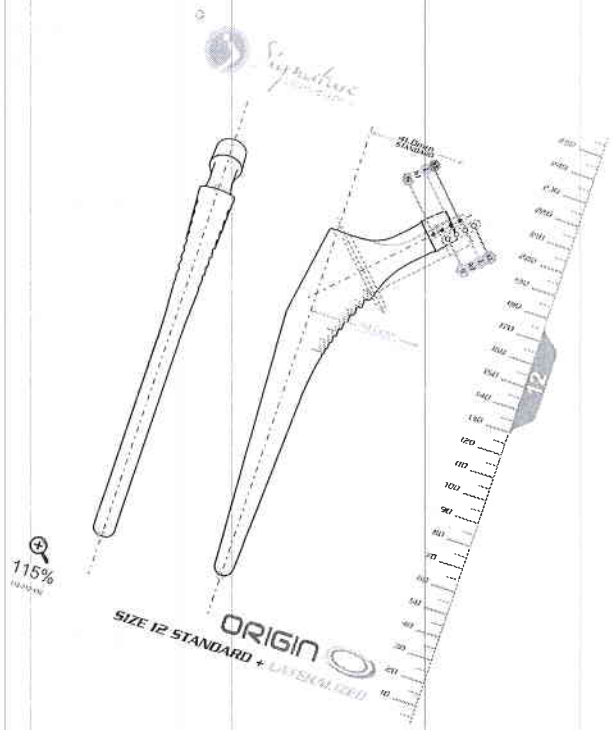
**6. Grooves**
Vertical and horizontal grooves provide rotational and axial stability.

**7. Hydroxyapatite Plasma Spray Coating**

- Thickness 120-190µm
- Tensile Strength >15 MPa
- Crystallinity ≥ 80%
- HA Content ≥ 70%

## Preoperative Planning

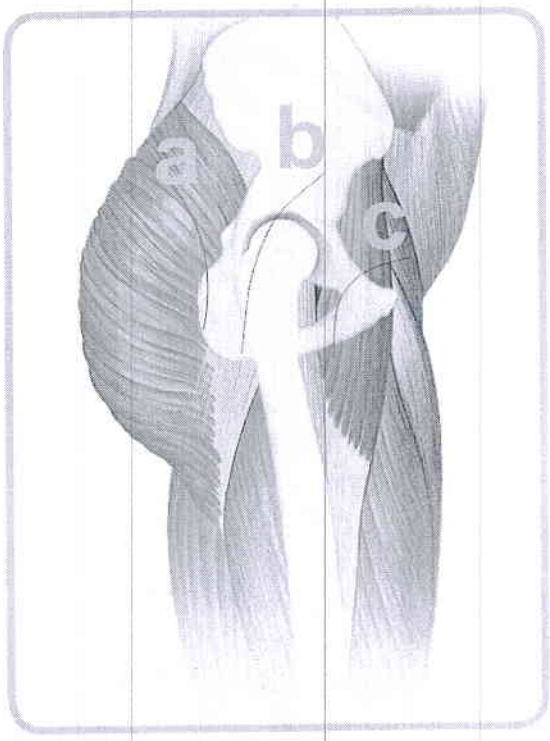
Origin X-Ray templates can be used over anterior/posterior and lateral radiographs to help determine the correct size to restore the patient's anatomy. Templates are 115% magnification.




## Preoperative Planning

The Logical cup can be used with any surgical approach that the surgeon selects.

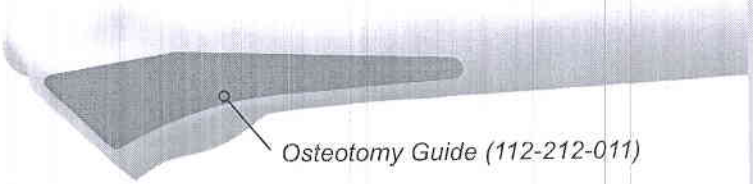
a. Posterior approach
b. Posterolateral/anterolateral approach
c. Anterior approach

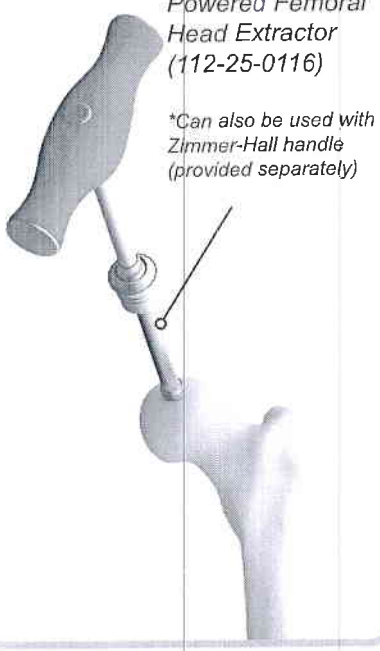



**Note:**
Prior to the following steps, complete all steps detailed in 111-12-0003 for the Logical acetabular cup implantation.

## Femoral Neck Resection

The osteotomy guide should be used in conjunction with preoperative planning, to determine the level of the femoral neck resection. This can be performed in multiple steps, depending on surgeon preference.



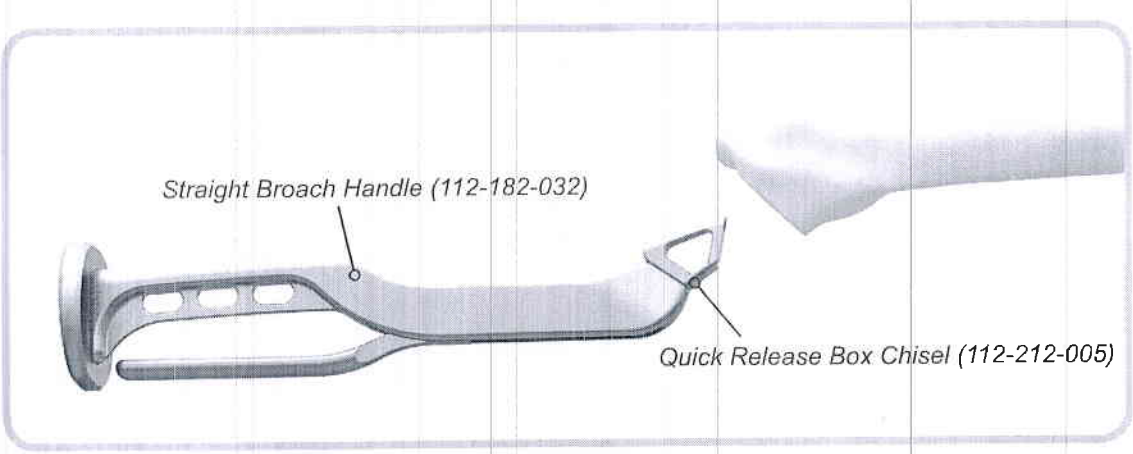
*Powered Femoral Head Extractor (112-25-0116)*

**Can also be used with Zimmer-Hall handle (provided separately)*

**Optional technique:**
The femoral head extractor may be used with the T-handle or under power to aid in the removal of the resected head, especially during an anterior approach technique.

## Femoral Preparation

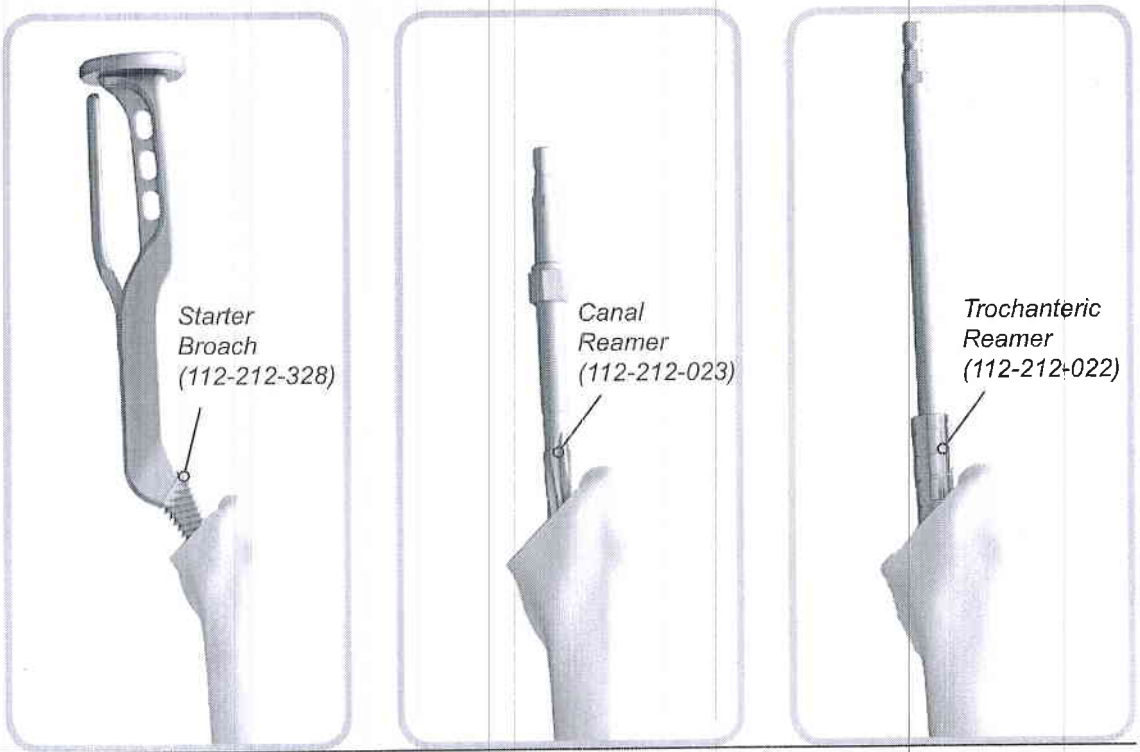
Enter the femoral canal as laterally as possible with the Box Osteotome to initiate access to the medullary canal. The Canal Reamer may be used as needed to open the natural axis of the femoral canal for broach preparation.




**Optional technique:**

While the Origin system is intended to be a broach-only system, the Origin instrument tray contains instruments for optional use to ensure proper axial alignment along the femoral canal and to induce lateral bias where needed:

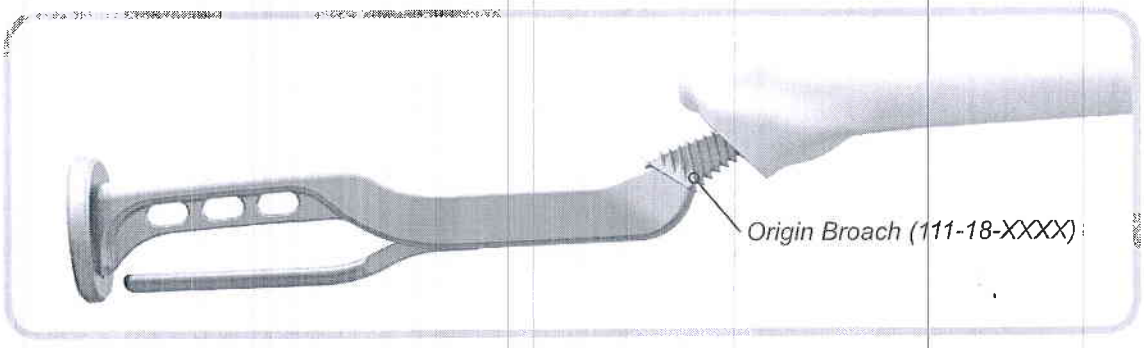
a. Starter broach induces lateral bias by rasping beneath the greater trochanter
b. Canal reamer creates a guide hole for the distal end of the trochanteric reamer
c. Trochanteric reamer removes trochanteric bone tissue laterally to ensure neutral alignment with the femoral axis during broaching



5

## Compaction Broaching

The broach should run parallel to the posterior cortex following the natural anatomy of the femur. Begin with the smallest broach and increase the size of the broach sequentially until longitudinal and rotational stability is achieved: broaching should then be stopped. Careful preoperative planning is key to help selection of the final broach size. The version will be determined be the natural version of the femur.

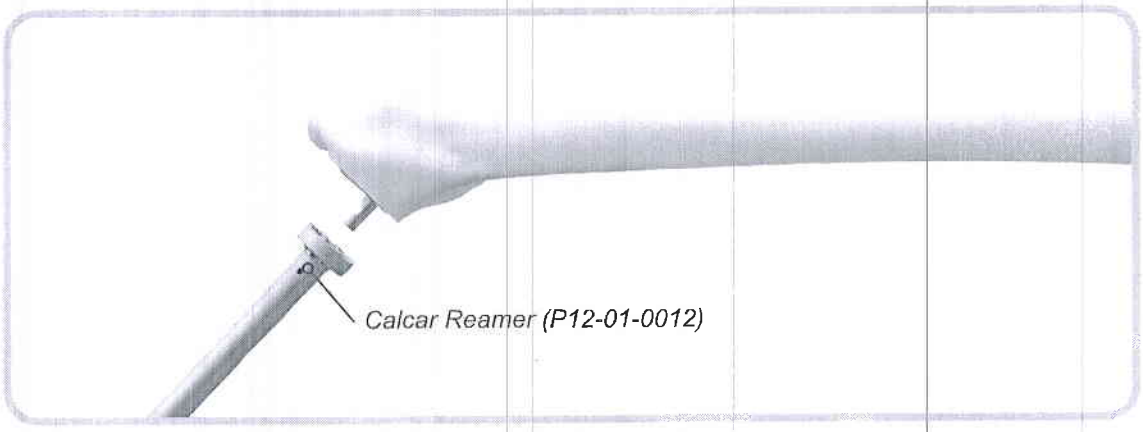



**Note:**
Refer to **Appendix: Compaction Broaching Techniques and Tips** for detail on the theory of compaction broaching, why this technique is used for Origin stems, and how to form a bed of compacted bone that will maximize the longevity and stability of Origin stems in many bone types.

6

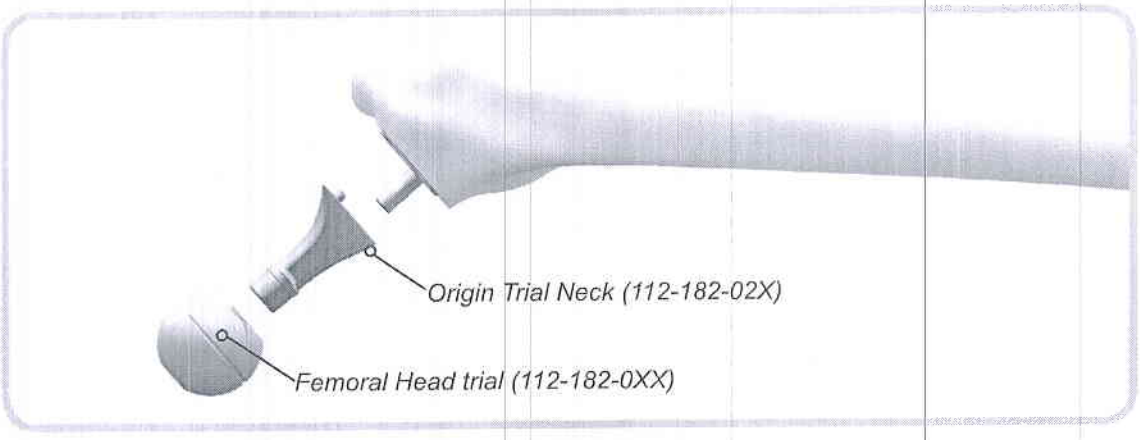
## Calcar Reaming

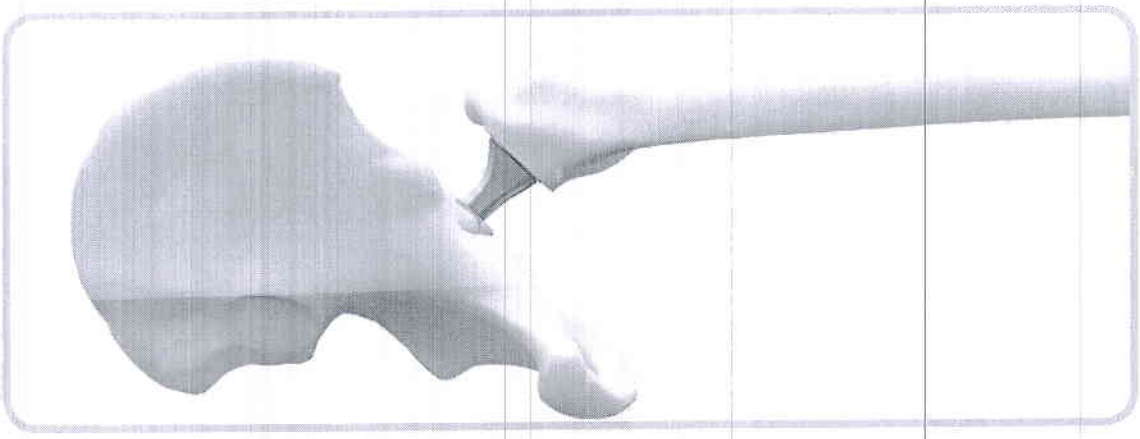
With the broach in situ, use the Calcar Reamer to achieve a flat resection surface. Slide the reamer over the broach quick connect fitting to maintain the resection angle. Carefully advance the reamer towards the broach face and into the resected edge of the femur until it bottoms out against the broach face.



## Trial Reduction

With the final broach still in situ, attach the appropriate trial neck and trial head. Reduce the hip and assess what adjustments, if any, are required to provide stability through a full range of motion. Remove the trial head, trial neck and final broach. DO NOT irrigate or dry the femoral canal. This will help to preserve the compacted cancellous bone quality and encourage biological fixation of the stem.

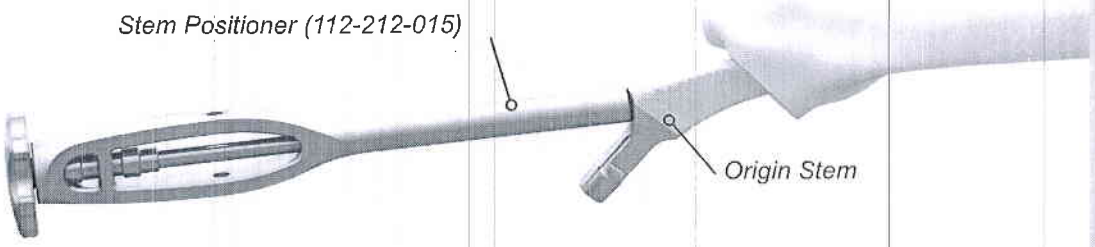


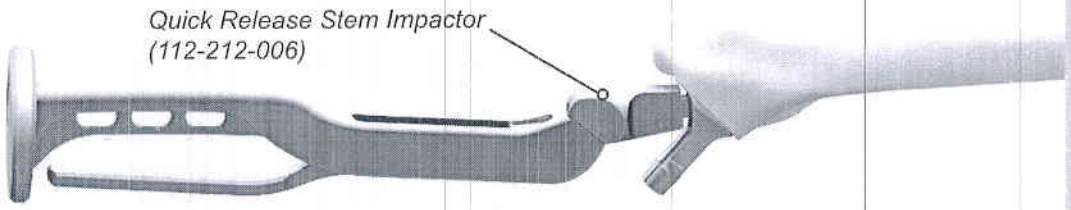



**Instrument identification:**
Trial heads are colour coded based on offset. Refer to Origin Implants Sizing Guide in this surgical technique for more details.

## Femoral Component Insertion

When implanting the definitive stem (same size as final broach) in the femoral canal, ensure that it is directed in by hand. This will help avoid changing the version as a precautionary measure. There should be no more than 15-20mm between the resection line and the top of the HA coating on the stem. If the stem does not readily go down this far, the surgeon should broach again. Once the stem is placed, lightly tap the stem impactor to fully seat. DO NOT over-impact as this may lead to splitting of the femur.



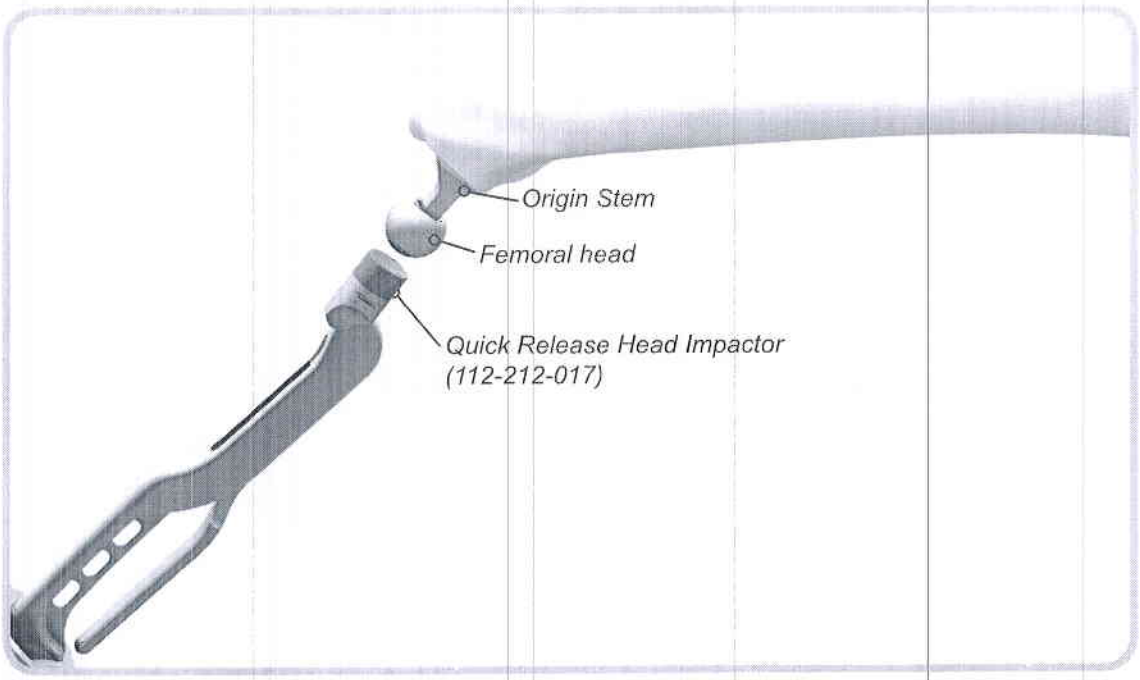

### Instrument operation:

To connect the Origin stem to the stem positioner, first slide the inner shaft of the positioner through the outer shaft, spinning the strikeplate so the inner shaft threads in and falls through. Turn the threaded tip of the inner shaft into the female threads on the Origin stem until a snug hold is achieved to prevent damage to the threads.

9

## Femoral Head Impaction

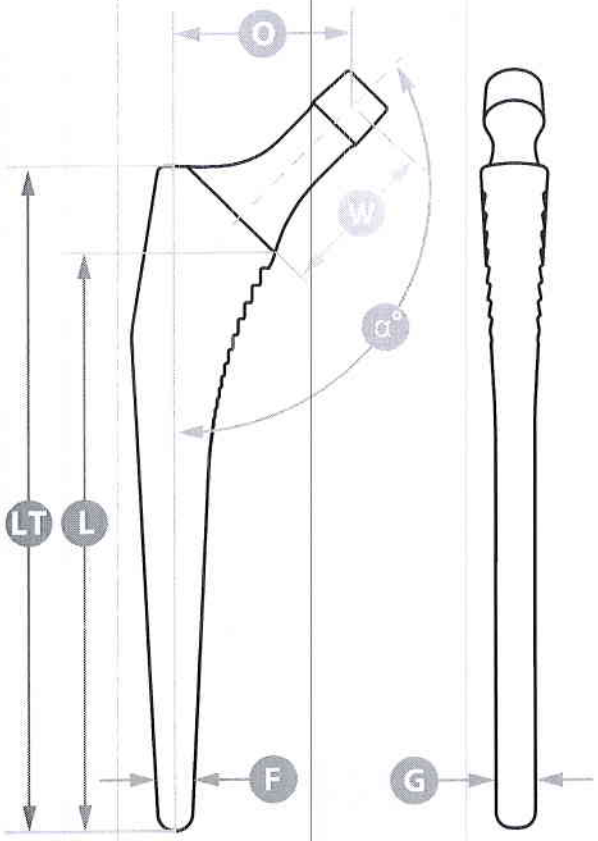
A final trial reduction is carried out to confirm joint stability and range of motion. Clean and dry the stem taper to remove any particulate matter or debris. Place the femoral head onto the taper and lightly tap it using the head impactor. Ensure that bearing surfaces are clean and finally reduce the hip.



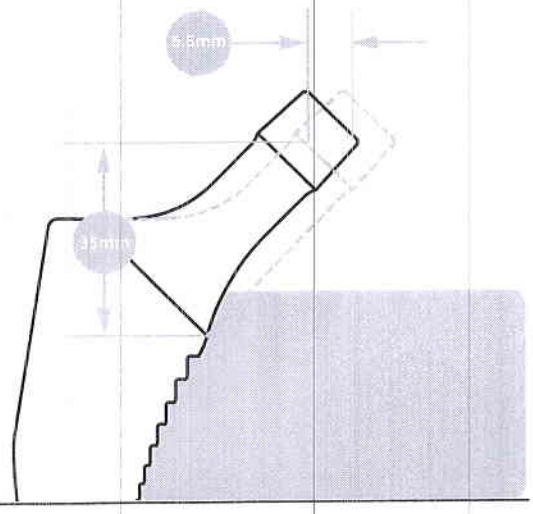
# Origin Implant Sizing Guide



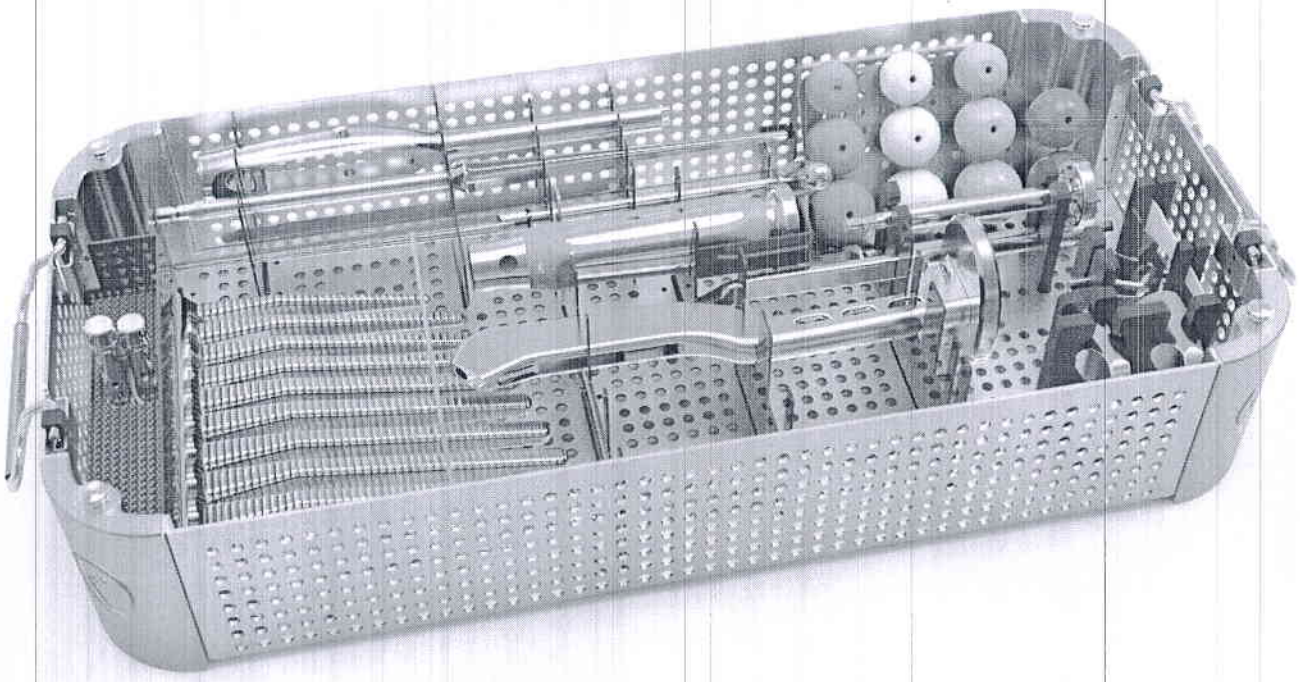
| SIZE | OFFSET | LT | L | W | O | α° | F | G |
|---|---|---|---|---|---|---|---|---|
| 8 | Standard Offset | 116 | 94 | 38.2 | 38.2 | 135 | 6.3 | 7.9 |
| | Standard Offset Collared | 116 | 94 | 38.2 | 38.2 | 135 | 6.3 | 7.9 |
| 9 | Standard Offset | 131 | 109 | 40.1 | 38.6 | 135 | 6.3 | 8.1 |
| | High Offset | 131 | 109 | 41.1 | 43.5 | 135 | 6.3 | 8.1 |
| | Standard Offset Collared | 131 | 109 | 38.5 | 38.6 | 135 | 6.3 | 8.1 |
| | Cox Vara | 131 | 109 | 40.3 | 45.5 | 125 | 6.3 | 8.1 |
| 10 | Standard Offset | 141 | 119 | 40.1 | 39.5 | 135 | 6.6 | 8.5 |
| | High Offset | 141 | 119 | 42.0 | 46.5 | 135 | 6.6 | 8.5 |
| | Standard Offset Collared | 141 | 119 | 38.5 | 39.5 | 135 | 6.6 | 8.5 |
| | Cox Vara | 141 | 119 | 40.3 | 46.5 | 125 | 6.6 | 8.5 |
| 11 | Standard Offset | 146 | 124 | 40.1 | 40.0 | 135 | 7.5 | 9.0 |
| | High Offset | 146 | 124 | 42.0 | 47.0 | 135 | 7.5 | 9.0 |
| | Standard Offset Collared | 146 | 124 | 38.5 | 40.0 | 135 | 7.5 | 9.0 |
| | Cox Vara | 146 | 124 | 40.3 | 47.0 | 125 | 7.5 | 9.0 |
| 12 | Standard Offset | 151 | 129 | 40.1 | 41.0 | 135 | 8.4 | 9.5 |
| | High Offset | 151 | 129 | 42.0 | 48.0 | 135 | 8.4 | 9.5 |
| | Standard Offset Collared | 151 | 129 | 38.5 | 41.0 | 135 | 8.4 | 9.5 |
| | Cox Vara | 151 | 129 | 40.3 | 48.0 | 125 | 8.4 | 9.5 |
| 13 | Standard Offset | 156 | 134 | 40.1 | 41.5 | 135 | 9.3 | 9.8 |
| | High Offset | 156 | 134 | 42.0 | 48.5 | 135 | 9.3 | 9.8 |
| | Standard Offset Collared | 156 | 134 | 38.5 | 41.5 | 135 | 9.3 | 9.8 |
| | Cox Vara | 156 | 134 | 40.3 | 48.5 | 125 | 9.3 | 9.8 |
| 14 | Standard Offset | 161 | 139 | 40.1 | 42.0 | 135 | 10.0 | 10.0 |
| | High Offset | 161 | 139 | 42.0 | 49.0 | 135 | 10.0 | 10.0 |
| | Standard Offset Collared | 161 | 139 | 38.5 | 42.0 | 135 | 10.0 | 10.0 |
| | Cox Vara | 161 | 139 | 40.3 | 49.0 | 125 | 10.0 | 10.0 |
| 15 | Standard Offset | 166 | 144 | 40.1 | 43.0 | 135 | 10.8 | 10.0 |
| | High Offset | 166 | 144 | 42.0 | 50.0 | 135 | 10.8 | 10.0 |
| | Standard Offset Collared | 166 | 144 | 38.5 | 43.0 | 135 | 10.8 | 10.0 |
| | Cox Vara | 166 | 144 | 40.3 | 50.0 | 125 | 10.8 | 10.0 |
| 16 | Standard Offset | 171 | 149 | 40.1 | 43.5 | 135 | 11.8 | 10.3 |
| | High Offset | 171 | 149 | 42.0 | 50.5 | 135 | 11.8 | 10.3 |
| | Standard Offset Collared | 171 | 149 | 38.5 | 43.5 | 135 | 11.8 | 10.3 |
| | Cox Vara | 171 | 149 | 40.3 | 50.5 | 125 | 11.8 | 10.3 |
| 18 | Standard Offset | 181 | 159 | 40.1 | 44.5 | 135 | 13.4 | 11.0 |
| | High Offset | 181 | 159 | 42.0 | 52.0 | 135 | 13.4 | 11.0 |
| | Standard Offset Collared | 181 | 159 | 38.5 | 44.5 | 135 | 13.4 | 11.0 |
| | Cox Vara | 181 | 159 | 40.3 | 52.5 | 125 | 13.4 | 11.0 |




| | | Ø28 | Ø32 | Ø36 | Ø40 |
|---|---|---|---|---|---|
| S | CrCo | -3.5 111-152-011 | -4.0 111-152-021 | -4.0 111-152-031 | -4.0 111-152-041 |
| | Ceramic | 111-152-611 | 111-152-621 | 111-152-631 | 111-152-641 |
| M | CrCo | +0.0 111-152-012 | +0.0 111-152-022 | +0.0 111-152-032 | +0.0 111-152-042 |
| | Ceramic | 111-152-612 | 111-152-622 | 111-152-632 | 111-152-642 |
| L | CrCo | +4.0 111-152-013 | +4.0 111-152-023 | +4.0 111-152-033 | +4.0 111-152-043 |
| | Ceramic | 111-152-613 | 111-152-623 | 111-152-633 | 111-152-643 |
| XL | CrCo | +8.0 111-152-024 | +8.0 111-152-034 | +8.0 111-152-044 | |
| | Ceramic | 111-152-624 | 111-152-634 | 111-152-644 | |



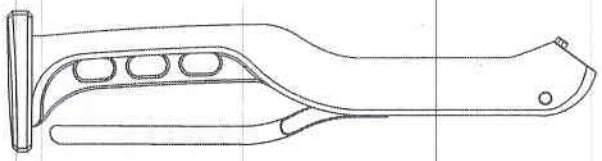
# Origin Instrument



# Standard Origin Instruments

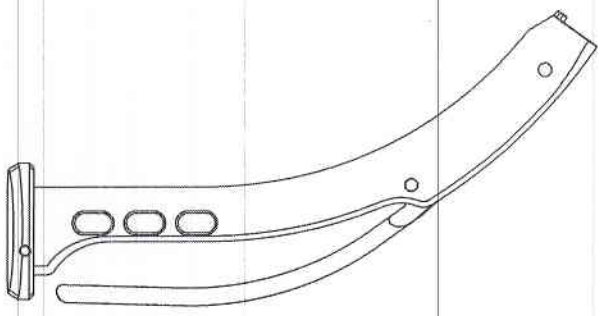
**Straight Broach Handle**

112-182-032



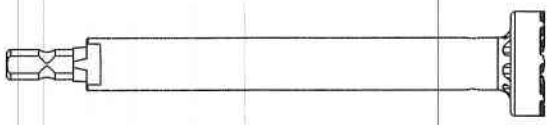
**Curved Broach Handle**

112-182-001



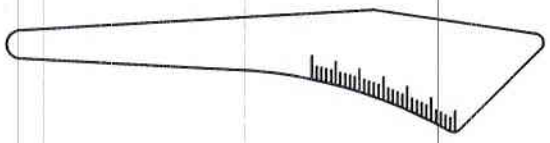
**Calcar Reamer**

P12-01-0012



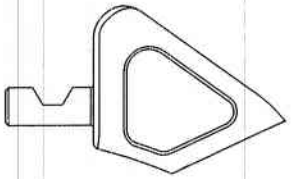
**Osteotomy Guide**

112-212-011



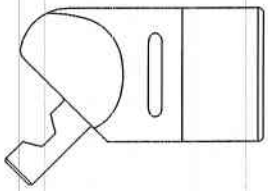
**Quick Release Box Chisel**

112-212-005



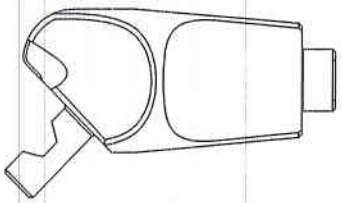
**Quick Release Head Impactor**

112-212-017



**Quick Release Stem Impactor**

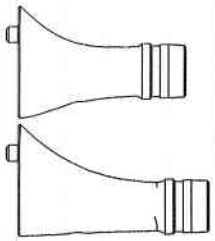
112-212-006

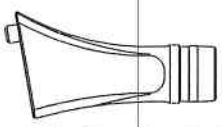


# Standard Origin Instruments

**Origin Trial Neck**

| | |
|---|---|
| 112-182-020 | Standard Offset |
| 112-182-021 | High Offset |
| 112-182-022 | Coxa Vara |

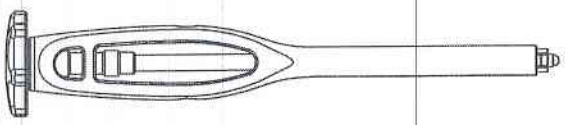




'Blue Coxa Vara Trial Neck'

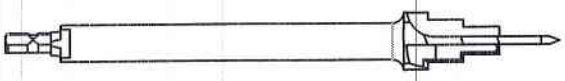
**Stem Positioner**

| | |
|---|---|
| 112-212-015 | Assembly |
| 112-212-021 | Inner |



**Stepped Entry Reamer**

112-162-001

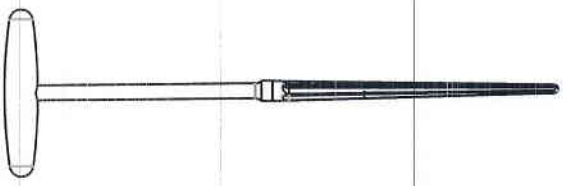


**IM Drill**

112-182-087

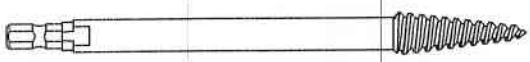
**Tapered Pin Reamer**

112-182-013



**Femoral Head Extractor**

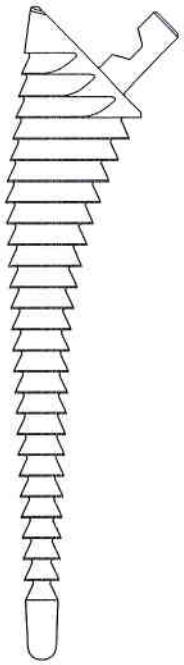
112-182-117



# Origin Instruments

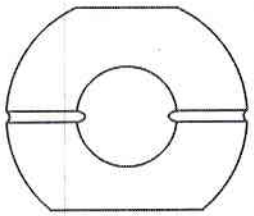
### Origin Broaches

| | |
|---|---|
| 111-18-0809 | Size 8 |
| 111-18-0909 | Size 9 |
| 111-18-1009 | Size 10 |
| 111-18-1109 | Size 11 |
| 111-18-1209 | Size 12 |
| 111-18-1309 | Size 13 |
| 111-18-1409 | Size 14 |
| 111-18-1509 | Size 15 |
| 111-18-1609 | Size 16 |
| 111-18-1809 | Size 18 |



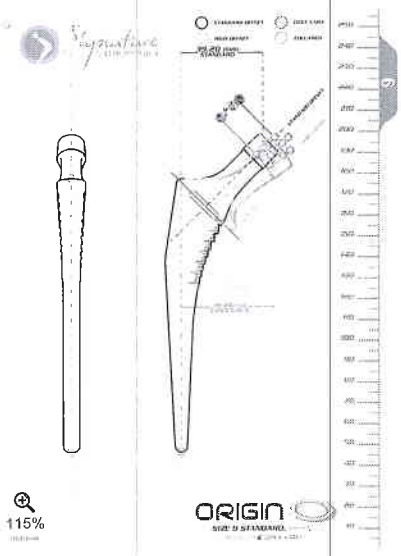
### Trial Femoral Heads

| | |
|---|---|
| 111-182-040 | Ø28mm -3.5mm Green |
| 111-182-041 | Ø28mm 0.0mm Yellow |
| 111-182-042 | Ø28mm +4.0mm Orange |
| 111-182-017 | Ø32mm -3.5mm Green |
| 111-182-018 | Ø32mm 0.0mm Yellow |
| 111-182-019 | Ø32mm +4.0mm Orange |
| 111-182-020 | Ø32mm +8.0mm Red |
| 111-182-021 | Ø36mm -3.5mm Green |
| 111-182-022 | Ø36mm 0.0mm Yellow |
| 111-182-023 | Ø36mm +4.0mm Orange |
| 111-182-024 | Ø36mm +8.0mm Red |
| 111-182-043 | Ø40mm -3.5mm Green |
| 111-182-044 | Ø40mm 0.0mm Yellow |
| 111-182-045 | Ø40mm +4.0mm Orange |
| 111-182-046 | Ø40mm +8.0mm Red |



### Origin Preoperative Templates

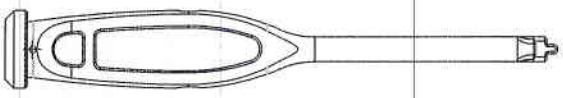
| | |
|---|---|
| 112-212-108 | Size 8 Template |
| 112-212-109 | Size 9 Template |
| 112-212-110 | Size 10 Template |
| 112-212-111 | Size 11 Template |
| 112-212-112 | Size 12 Template |
| 112-212-113 | Size 13 Template |
| 112-212-114 | Size 14 Template |
| 112-212-115 | Size 15 Template |
| 112-212-116 | Size 16 Template |
| 112-212-118 | Size 18 Template |



# Optional Origin Instruments

**Stem Positioner UniBody**

112-212-026



**Canal Reamer**

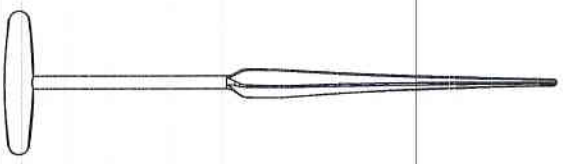
112-212-023

**Trochanteric Canal Reamer**

112-212-022

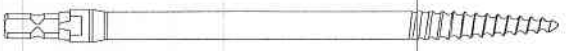
**XL Tapered Pin Reamer**

112-182-148



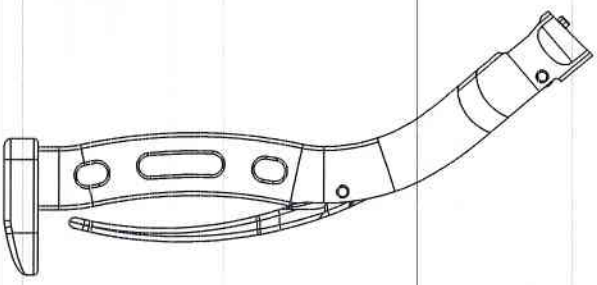
**Powered Femoral Head Extractor**

112-25-0116



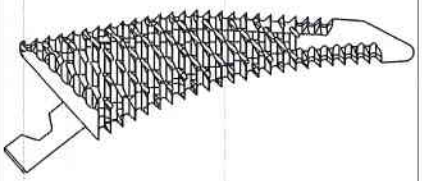
**Curved Broach Handle**

112-25-0044



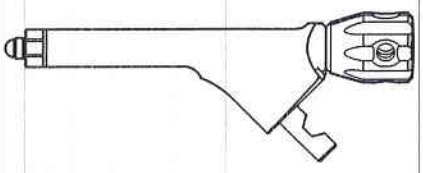
**Starter Broach**

112-212-328



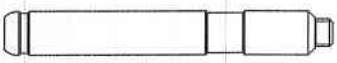
**Quick Release Stem Inserter**

112-212-323



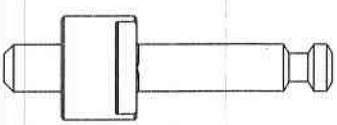
**Anteversion Grip**

112-182-034



**Broach Handle Power Adaptor**

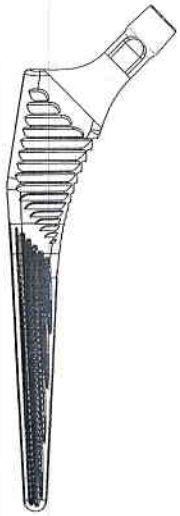
112-212-018



# Origin Implants

## Origin Standard Offset Stem

| | |
|---|---|
| 111-18-0800 | Size 8 |
| 111-18-0900 | Size 9 |
| 111-18-1000 | Size 10 |
| 111-18-1100 | Size 11 |
| 111-18-1200 | Size 12 |
| 111-18-1300 | Size 13 |
| 111-18-1400 | Size 14 |
| 111-18-1500 | Size 15 |
| 111-18-1600 | Size 16 |
| 111-18-1800 | Size 18 |

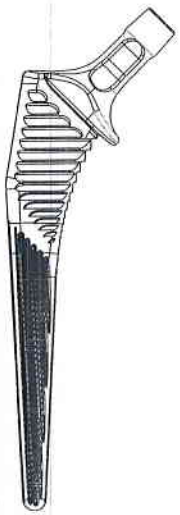


## Origin High Offset Stem

| | |
|---|---|
| 111-18-0901 | Size 9 |
| 111-18-1001 | Size 10 |
| 111-18-1101 | Size 11 |
| 111-18-1201 | Size 12 |
| 111-18-1301 | Size 13 |
| 111-18-1401 | Size 14 |
| 111-18-1501 | Size 15 |
| 111-18-1601 | Size 16 |
| 111-18-1801 | Size 18 |

## Origin Standard Offset Collared Stem

| | |
|---|---|
| 111-18-0902 | Size 9 |
| 111-18-1002 | Size 10 |
| 111-18-1102 | Size 11 |
| 111-18-1202 | Size 12 |
| 111-18-1302 | Size 13 |
| 111-18-1402 | Size 14 |
| 111-18-1502 | Size 15 |
| 111-18-1602 | Size 16 |
| 111-18-1802 | Size 18 |



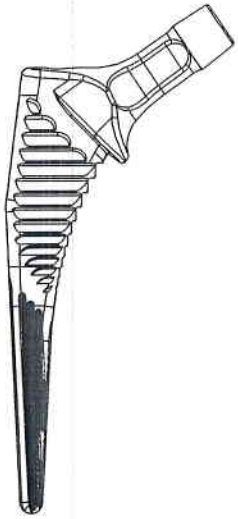
## Origin High Offset Collared

| | |
|---|---|
| 111-18-0903 | Size 9 |
| 111-18-1003 | Size 10 |
| 111-18-1103 | Size 11 |
| 111-18-1203 | Size 12 |
| 111-18-1303 | Size 13 |
| 111-18-1403 | Size 14 |
| 111-18-1503 | Size 15 |
| 111-18-1603 | Size 16 |
| 111-18-1803 | Size 18 |

# Origin Implants

## Origin Coxa Vara Stem

| | |
|---|---|
| 111-18-0904 | Size 9 |
| 111-18-1004 | Size 10 |
| 111-18-1104 | Size 11 |
| 111-18-1204 | Size 12 |
| 111-18-1304 | Size 13 |
| 111-18-1404 | Size 14 |
| 111-18-1504 | Size 15 |
| 111-18-1604 | Size 16 |
| 111-18-1804 | Size 18 |



## Femoral Heads

| | |
|---|---|
| 111-152-011 | Ø28mm -3.5mm CrCo |
| 111-152-012 | Ø28mm 0.0mm CrCo |
| 111-152-013 | Ø28mm +4.0mm CrCo |
| 111-152-021 | Ø32mm -3.5mm CrCo |
| 111-152-022 | Ø32mm 0.0mm CrCo |
| 111-152-023 | Ø32mm +4.0mm CrCo |
| 111-152-024 | Ø32mm +8.0mm CrCo |
| 111-152-031 | Ø36mm -3.5mm CrCo |
| 111-152-032 | Ø36mm 0.0mm CrCo |
| 111-152-033 | Ø36mm +4.0mm CrCo |
| 111-152-034 | Ø36mm +8.0mm CrCo |
| 111-152-041 | Ø40mm -3.5mm CrCo |
| 111-152-042 | Ø40mm 0.0mm CrCo |
| 111-152-043 | Ø40mm +4.0mm CrCo |
| 111-152-044 | Ø40mm +8.0mm CrCo |
| | |
| 111-152-611 | Ø28mm -3.5mm Ceramic |
| 111-152-612 | Ø28mm 0.0mm Ceramic |
| 111-152-613 | Ø28mm +4.0mm Ceramic |
| 111-152-621 | Ø32mm -3.5mm Ceramic |
| 111-152-622 | Ø32mm 0.0mm Ceramic |
| 111-152-623 | Ø32mm +4.0mm Ceramic |
| 111-152-624 | Ø32mm +8.0mm Ceramic |
| 111-152-631 | Ø36mm -3.5mm Ceramic |
| 111-152-632 | Ø36mm 0.0mm Ceramic |
| 111-152-633 | Ø36mm +4.0mm Ceramic |
| 111-152-634 | Ø36mm +8.0mm Ceramic |
| 111-152-641 | Ø40mm -3.5mm Ceramic |
| 111-152-642 | Ø40mm 0.0mm Ceramic |
| 111-152-643 | Ø40mm +4.0mm Ceramic |
| 111-152-644 | Ø40mm +8.0mm Ceramic |

# Appendix: Compaction Broaching Techniques and Tips

Successful long-term fixation of the Origin cementless hip stem relies on a "sheath" of compacted trabecular bone formed by the compaction broaching system. A successful procedure is equally dependent on the instruments provided in the tray as well as the surgeon's technique and understanding of the underluing mechanism.

The trabecular sheath is a cavity of dense cancellous bone that is formed line-to-line with the corresponding implant size. By design, the contact stress between compacted trabecular bone and implant is highly controlled down the length of the stem. According to Wolff's Law, this dense sheath and the traceculae that support it will strengthen over time in response to applied loads until the stiffness of the sheath closely matches the stiffness of the implant stem. A continuous stiffness gradient at the implant-bone interface minimizes stress shielding and micromotion.

It is important to select an appropriate stem size (and final broach size) to prevent any direct contact between the implant and the true cortical walls. Maintaining axial alignment with the canal from the first broach will make this determination easier. Instruments are included in the Origin case to aid in lateralization where needed. A change in pitch during impaction of the broach is often the first sign of an appropriate amount of compaction. Check for axial stability before checking for rotational stability as this can deform the trabecular sheath.

It is better to stop broaching when stability is achieved with a slightly countersunk broach than to attempt to force as oversized broach into the canal. The HA line on the implant stem will sit below the resection line but the stem will achieve exceptional stability. Consider a longer neck or higher head offset.

Managing Different Femoral Canal Geometries

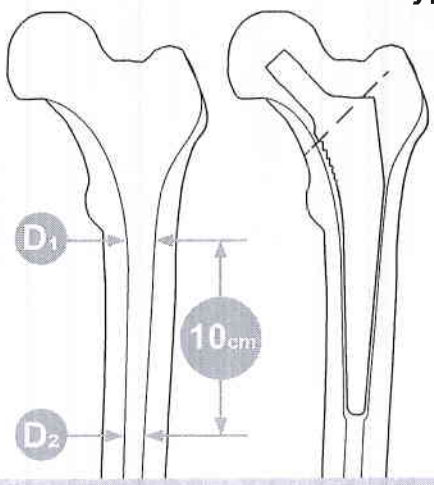
The Dorr femur type system classifies femurs based on a ratio that relates to the geometry of the femoral canal:

$$R = D_2/D_1$$

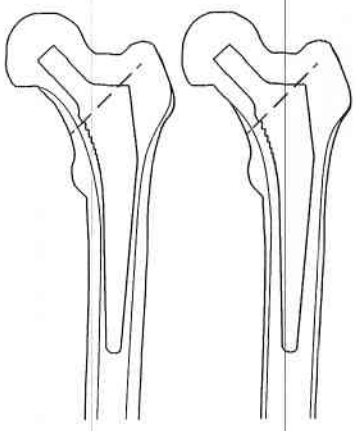
see figures at the bottom left

An R-value less than ~0.5 implies a very fluted canal that will more likely bind distally if the canal is not over-reamed. Preoperative templating is especially important for this reason. Refer to the Origin Implant Sizing guide in this technique to help decide what size reamer to use. The three types are as follows.

**Type A** **R < 0.5**
**Type B** **R = 0.5 to 0.9**
**Type C** **R > 0.9**




**Type A**
Reaming the femoral canal to the distal tip of the definitive stem ensures good compaction of the metaphyseal cancellous bone and prevents binding against the cortical wall, which can lead to stress shielding and an unseated stem.



**Types B & C**
The Origin broaches preserve the natural anatomy of the femoral canal. Rotational and axial stability and a change in pitch indicate an appropriate amount of compaction broaching.

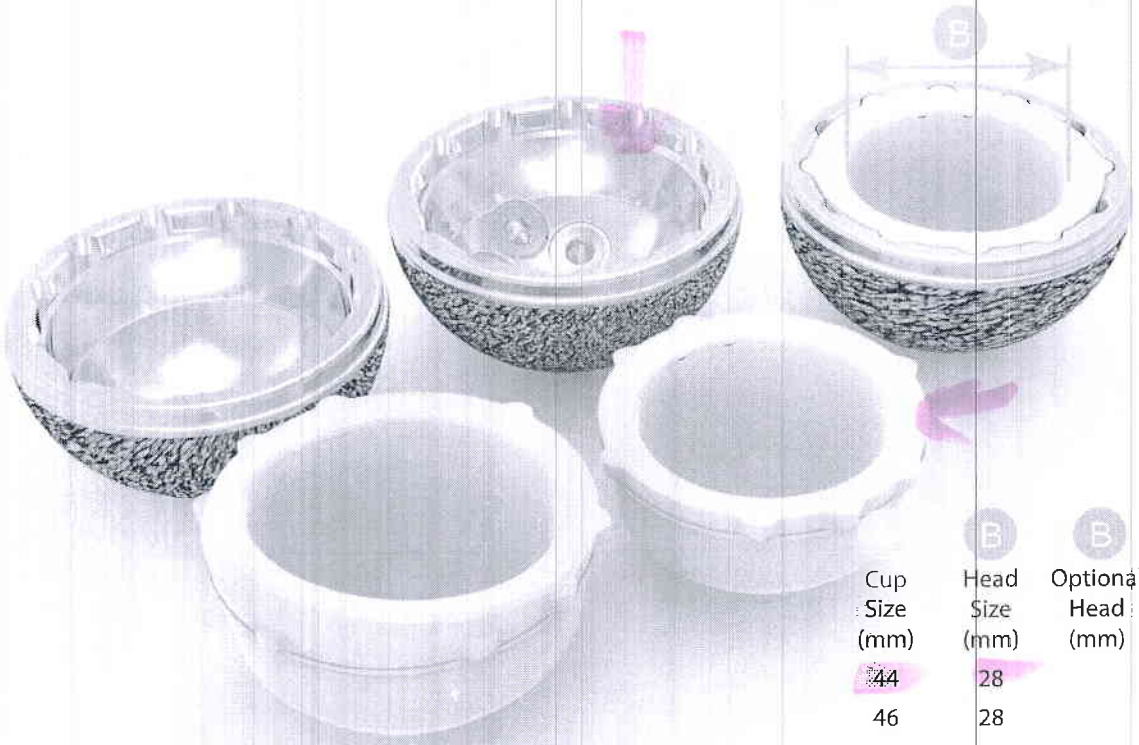
AUSTRALIAN MADE

Signature Orthopaedics
7 Sirius Rd
Lane Cove West, Sydney, 2066
NSW, Australia

Signature ORTHOPAEDICS

CE 0086

# LOGICAL G Ha SERIES CUP



| Cup Size (mm) | Head Size (mm) | Optional Head (mm) | Optional Head (mm) |
|---|---|---|---|
| 44 | 28 | | |
| 46 | 28 | | |
| 48 | 32 | | |
| 50 | 32 | | |
| 52 | 32 | 36 | |
| 54 | 32 | 36 | |
| 56 | 32 | 36 | 40 |
| 58 | 32 | 36 | 40 |
| 60 | 32 | 36 | 40 |
| 62 | 32 | 36 | 40 |
| 64 | 32 | 36 | 40 |

## Cup Liner

- Clinically proven geometry and material (GUR1020 compression moulded bar stock).
- Available with 10 / 20° hood, or without hood.
- UHMWPE bar stock is cross-linked at 7.5MRads and then remelted. The product is subsequently machined from remelted bar stock and sterilised with ETO.

## Cup

- Clinically proven geometry and material (TiAl4V)
- Clinically proven porous coating spayed with Ha
- Cup available with standard 3-hole and no hole options

## HA Coating

- Crystallinity - 68.2%
- HA content - 98.3%
- Ca/P ratio - 1.67
- Density - 99%
- Porosity - <5%
- Pull out strength - 35MPa
  (on Ti6Al4V)

## Porous Coating

- Tensile Strength > 60MPa
  Shear Strength > 30MPa
- Porosity 55-65% and pore size 250-300 microns.

Tender Committee
Orthopaedic Implants Tender
MOLDAVIA

The 3rd of May 2019

*Subject : Hip Prosthesis / Range of Femoral Heads / Additional information*

Dear Committee members,

In addition to my previous letter dated current April 25th I am pleased to give you hereunder some more information about femoral heads on the market.

Our standard range of CoCr femoral head offers the diameters 28, 32, 36 and 40 with 4 different lengths of neck usually classified as S, M, L and XL. This range is an international standard to cover the requirements of hip arthroplasty and complies with the norms on the market. The entire range is CE marked and also FDA approved.

To allow a wide range of combinations between components of hip prosthesis and then allow a perfect reconstruction of anatomy, the femoral heads could be used with standard stems and lateralized stems.

In addition to this, Signature Orthopaedics propose beyond the standard XLPE liners an entire range of lateralized XLPE liners that could be use in specific cases where surgeon may need this option to restore perfectly the anatomy of patients.

All those products are CE approved and available on demand on a routine basis.

In unlikely case of patient demanding a custom head, like I wrote in my previous letter, Signature Orthopaedics is in position to propose and produce custom head based on surgeon specific. In this case the component could be propose as a custom implant which do no required the CE mark. This is a usual situation for us as we do a lot of custom implants for example for tumor cases; In such situation as Signature Orthopaedics is ISO13485 and complies with the 93/42/EEC annex 2 directive we have agreement to produce custom implants.

With my Best Regards

Olivier PERNOIS

Signature Orthopaedics France

Director

**Tender Committee**
Orthopaedic Implants Tender
MOLDAVIA

The 25th of April 2019

*Subject : Hip Prosthesis / Range of Femoral Heads*

Dear Committee members,

By the present letter I hereby confirm that in addition to the standard range of metallic femoral heads (made of CoCr), SIGNATURE ORTHOPAEDICS is in position to offer custom heads with other neck length (offsets) to be used with the ARIA stem.

This will be produced in case of special request for specific case received from the user.

The 4 offsets introduced in our leaflet are the main standard used worldwide.

With my Best Regards

Olivier PERNOIS

Signature Orthopaedics France

Director

SIGNATURE ORTHOPAEDICS France SAS
Espace d'Entreprises - L'Arobase
2 Rue Georges Charpak
81100 CASTRES - France
T : +33(0)5 63 73 51 83 - F : +33(0)5 63 73 51 84
RCS CASTRES 815 115 696
N° TVA FR 89 815 115 696

Signature ORTHOPAEDICS

# EC DECLARATION OF CONFORMITY

We

**Manufacturer:** Signature Orthopaedics Europe Limited
**Address:** Unit A, IDA Business & Technology Park
Garrycastle, Athlone
N37 DY26 Co. Westmeath
Ireland

hereby declare under our sole responsibility that the following products

**Product:** Femoral Stems and Heads (refer attached list)
**Scope:** All production lots

being Class III medical devices according to Commission Directive 2005/50/EC, are placed on the European Market in accordance with the legislation of the United Kingdom transposing the MDD 93/42/EEC as amended by 2007/47/EC, Annex II.

The following harmonised standards have been applied:

| | |
|---|---|
| ISO 13485:2016 | Medical Device – Quality Management System – Requirements for Regulatory Purposes |

| **Notified Body:** | **4 Digit Notified Body Number:** |
|---|---|
| TÜV SÜD<br>Munich, Germany | 0123 |

| | |
|---|---|
| **Full Quality Assurance Procedures Certificate:** | G1 003228 0001 European conformity assessment certificate under Annex II.3 of the Directive 93/42/EEC on Medical Devices |
| **Design Examination Certificate:** | G7 003228 0007 European conformity assessment certificate under Annex II.4 of the Directive 93/42/EEC on Medical Devices |

This Declaration of Conformity is valid until repealed or superseded.

**Authorised Signatory:**
**Signature**

Olivier PERNOIS
**Name, Position**

10 May 2019
**Date**

*Attachment: List of Products*

| Part Number | Device |
|---|---|
| 111-152-014 | Signature -Head 28mm, CoCr size XL |
| 111-152-015 | Signature -Head 28mm, CoCr size XXL |
| 111-152-025 | Signature -Head 32mm, CoCr size XXL |

Unit A, IDA Business & Technology Park, Athlone, N37 DY26, Ireland
p +353 0 906400539 www.SignatureOrtho.com.au

TÜV SÜD Product Service • Octagon House • Concorde Way • Segensworth North • Fareham • PO15 5RL • UK

Product Service

Choose certainty.
Add value.

To Whom it may concern

Signature Orthopaedics had an ISO 13485:2016 audit booked in November 2018. Due to unforeseen circumstances out of our control, the audit did not go ahead, and the next available audit time has been booked for March 2019.

Two minor NCs were identified in the previous audit in August 2018, and a CAP has been accepted.

There are no concerns regarding the robustness of Signature orthopaedics quality system.

Regards

Paul Jenkins

Operations Manager MHS UK
TUV SUD Product Service
Office: +44 (0)1727 837490
Mobile: +44 (0)7740 235 874

Email address: Paul.Jenkins@tuv-sud.co.uk
www.tuv-sud.co.uk

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

# Certificate

## No. Q1N 002842 0003 Rev. 00

**Holder of Certificate:** **Signature Orthopaedics Pty Ltd**
7 Sirius Road
Lane Cove West NSW 2066
AUSTRALIA

**Certification Mark:**

tuv-sud.com/ps-cert

**Scope of Certificate:** Design, development and manufacture of cemented and cementless knee and hip systems, bone cement delivery systems, trial implants, spinal implants, osteosynthesis implants, non-resorbable soft tissue fixation implants, radiopaque markers, and related instrumentation including reusable, single use sterile, measuring and those connected to active and non-active medical devices.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

**Report No.:** 75941211

**Valid from:** 2018-07-20
**Valid until:** 2019-02-28

**Date,** 2018-07-20

I. Preuß

Stefan Preiß

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT


TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

# Certificate

## No. Q1N 002842 0003 Rev. 00

**Applied Standard(s):**

EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems
Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012
Upgrade required until 2019-03-31

**Facility(ies):**

Signature Orthopaedics Pty Ltd
7 Sirius Road, Lane Cove West NSW 2066, AUSTRALIA

Signature Orthopaedics Europe Limited
Unit A, IDA Business & Technology Park, Garrycastle, Athlone,
N37 DY26 Co. Westmeath, IRELAND

-/-


TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

# EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

**No. G1 003228 0001 Rev. 00**

**Manufacturer:**

**Signature Orthopaedics Europe Limited**
Unit A
IDA Business & Technology Park
Garrycastle
Athlone
N37 DY26 Co. Westmeath
IRELAND

**Facility(ies):**

Signature Orthopaedics Europe Limited
Unit A, IDA Business & Technology Park, Garrycastle, Athlone,
N37 DY26 Co. Westmeath, IRELAND

**Product Category(ies):**

**Cemented and cementless knee and hip systems, bone cement delivery system, trials implants, spinal implants,osteosynthesis implants, non-resorbable soft tissue fixation implants, radio opaque markers, and related instrumentation including reusable, single use sterile, non active measuring used during implantation surgery and those connected to active and non-active medical devices.**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

**Report No.:** 75941211_CN_EC

**Valid from:** 2018-08-06
**Valid until:** 2020-02-18

**Date,** 2018-08-06

Stefan Preiß


TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

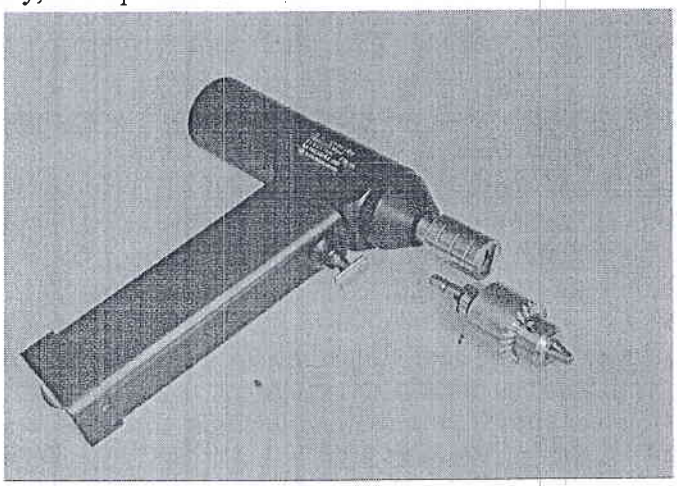
**Wuhu Ruijin Medical Instrument & Devices Co.,Ltd**
Add:33rd, East Wanchun Road, Jiujiang District,Wuhu City,Anhui Province,China.
Website:www.whruijin.com
Email:wendy@whruijin.cn
Tel:+86-553-5905318 FAX: +86-553-5223846
Fax:+86-0553-5223846

# Medical Electric hip joint drill

Thank you for using our products,we are honored that we can provide good service for your noble work. Before using medical electric drill and saw,please kindly reading the operating manual carefully.

## I: Application and Feature:

Medical Electric drill & saw is one of power tools which used in orthopedic operation.Gradually replaced traditional industrial drill and saw,it can be autoclavable up 135°C high temprature and 1.6Mpa high pressure.can be killed some of bacteria and verses which fumigating can not.it also shorten the sterilization, Just under High temperature and high pressure,just 20 minutes,win the valuable time for the patient.the device is optional,and its good looks,small size,light weight,no wires,easy to carry,safe operation.



Picture 1

## II: Composition:

| |
|---|
| 1: One Mainframe |
| 2: One charger |
| 3: One battery |
| 4: One drill chuck |
| 5: One sterilizing channel |
| 6: One aluminum alloy box |

## III: Model Explanation:

| Model | Composition |
|---|---|
| RJ-JZ-I | Handpiece, charger, battery, drill chuck, sterilizing channel, one aluminum alloy box |

## IV: Main Technical Data:

| | | |
|---|---|---|
| Hand Piece | Working Voltage | 14.4V |
| | Output Power | ≥20W |
| | Unit rise in temprature | ≤25℃ |
| Charger | Input Voltage | AC 220V，50Hz |
| | Output Power | 14.4V，900mA |
| | Input Power | 30VA |
| Battery | Voltage | 14.4V |
| | Charging time | About 3 hours |

## V: Technical Data of acetabulum burnishing drill:

| | |
|---|---|
| Non-load speed | ≥300r/min |
| Non-load noise | ≤63dB（A） |
| Diameter run-out | ≤0.5mm |

WUHU RUIJIN MEDICAL INSTRUMENT & DEVICE CO., LTD
ADD: 33RD, Wanchun Road, Wuhu Economic District, Wuhu, Anhui Province, China.
PC: 241000 TEL: 86-553-5905318 FAX: 86-553-5223845 WEBSITE: www.whruijin.com/en

# Medical Electric Oscillating saw

## Application and Feature:

Medical electric swing saw(Picture 1)is used for joint Surgery. Medical Electric Swing saw have been Gradually replaced the Traditional Industrial Drill and saw which only can be fumigating. It can be autoclavable by high temperature and 1.6Mpa High Pressure, can be killed some of bacteria and verses which fumigating can not.it also shorten the sterilization. Just under High temperature and high pressure,just 20 minutes,win the valuable time for the patient.the device is optional,and its good looks, small size, light weight, no wires, easy to carry, safe operation.

Picture 1

## Composition:

The surgical power tool is composed of handpiece, charger, battery. The shell is hermetic. The charger is not used for medical instrument.

WUHU RUIJIN MEDICAL INSTRUMENT & DEVICE CO., LTD
ADD: 33RD, Wanchun Road, Wuhu Economic District, Wuhu, Anhui Province, China.
PC: 241000 TEL: 86-553-5905318 FAX: 86-553-5223845 WEBSITE: www.whruijin.com/en

**Main Technical Feature:**

| | | |
|---|---|---|
| Hand Piece | Working Voltage | 14.4V |
| | Output Power | ≥20W |
| | Unit rise in temperature | ≤25℃ |
| Charger | Input Power | AC 220V，50Hz |
| | Output Power | 14.4V，700mA |
| | Input Power | 30VA |
| Battery | Voltage | 14.4V |
| | Charging time | About 3 hours |

**Technical Data:**

| | |
|---|---|
| Non-load rotating Frequency | ≥16000r/min |
| **Non-load noise** | ≤90dB（A） |

**Products Classification:**

Medical electric saw drill's classification is based on shocking protection, the motor belongs to inner power B type device, charger belongs to II – B type common device; the device can not be used in flammable anaesthesia air & air mix or oxygen mix air.

**Marking introduction:** ⚠ Working condition: Start up from cold status, run 1 minute with load condition, then stop working, after the instrument become cold, then work again.

**Marking Introduction:** ⧈:Class II type instrument; : B type Instrument

**Mark:** **L:** foreward **R:** reversal

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

# CERTIFICATE

No. Q2N 16 06 95446 001

**Holder of Certificate:** Wuhu Ruijin Medical Instrument & Device Co., Ltd.
No 33, Wanchun Road
Economic and Technological Development Zone
241000 Wuhu City, Anhui Province
PEOPLE'S REPUBLIC OF CHINA

**Facility(ies):** Wuhu Rujin Medical Instrument & Device Co., Ltd
No 33, Wanchun Road, Economic and Technological Development Zone, 241000 Wuhu City, Anhui Province, PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**

**Scope of Certificate:** Production and Distribution of
Medical Electric Saw Drill,
Medical Electric Drill,
Medical Electric Saw,
Saw Blade,
Drill Bit,
Autoclavable Box,
Flexible Reamer

**Applied Standard(s):** EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

**Report No.:** SH16104901

**Valid from:** 2016-11-08

**Valid until:** 2019-11-07

**Date,** 2016-11-08

Stefan Pavlik

Page 1 of 1

DAkkS

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

# EC Certificate

## Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

**No. G2 16 06 95446 002**

**Manufacturer:** Wuhu Ruijin Medical Instrument & Device Co., Ltd.
No.33, Wanchun Road
Economic and Technological Development Zone
241000 Wuhu City, Anhui Province
PEOPLE'S REPUBLIC OF CHINA

**EC-Representative:** **Wellkang Ltd**
Suite B, 29 Harley Stree:
LONDON
W1G 9QR
UNITED KINGDOM

**Product Category(ies):** **Medical Electric Saw Drill,**
**Medical Electric Drill,**
**Medical Electric Saw**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: SH16104901

Valid from: 2016-11-08
Valid until: 2021-11-07

Date, 2016-11-08

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123