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The Evolve stem is a highly polished, High Nitrogen Stainless Steel (ISO5832-9) dual tapered cemented stem. The design of the stem is based on the clinically successful principals of the "Exeter" design, that has been successfully utilised worldwide for over 40 years and one million implants.

The highly polished double taper design helps to create compressive radial loading, and reduce friction between cement and implant.

It has a 12/14 taper connection for easy adaption to multiple head and taper sleeve options. The collarless neck helps to facilitate intraoperative adjustments.

The stem is available in 5 sizes and 4 offsets, making a total of 10 unique stems, with a CCD angle 125° and 135° (Per 1pg summary).

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.

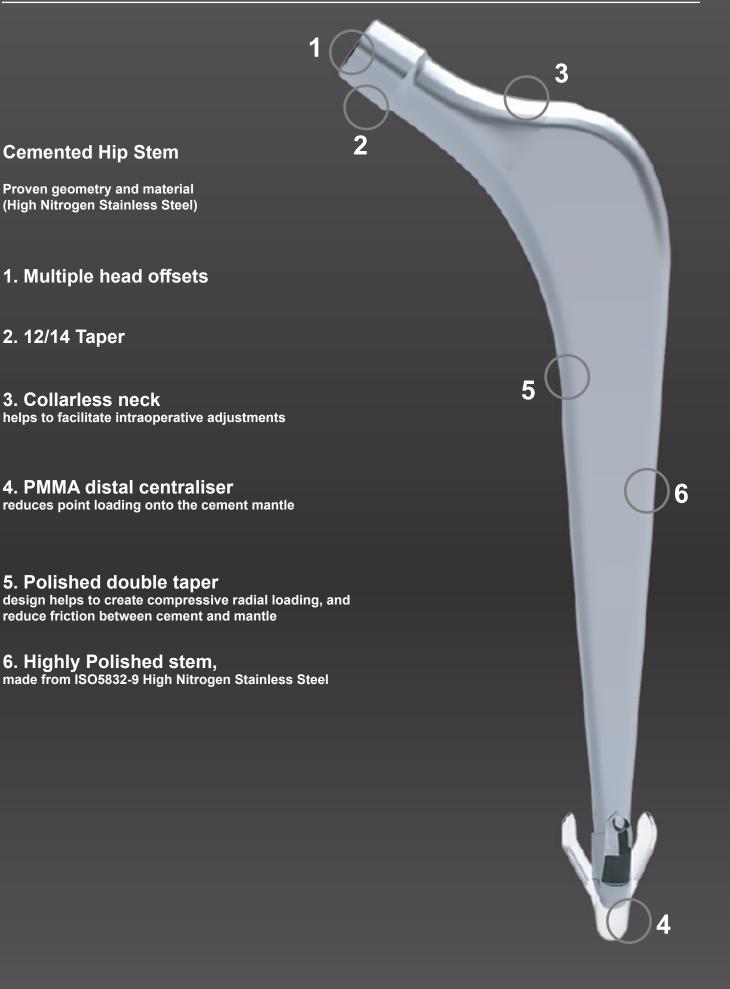
Contraindications

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.



Evolve Stem Features

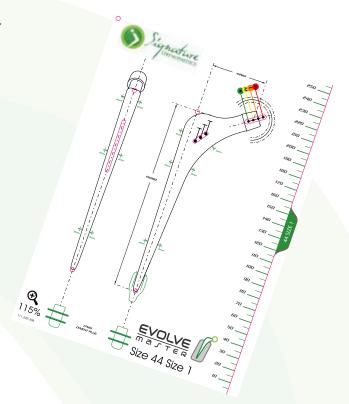


Steps 1-2 of 9



Preoperative Planning

Evolve 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.



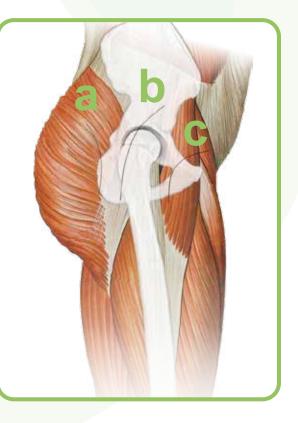


Preoperative Planning

The Evolve Stem can be used with any surgical approach that the surgeon selects.

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









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.

The level and orientation of neck resection are not critical for the Evolve Hip stem because it has no features that would affect the position of the osteotomy.

However, there should be adequate proximal support for the stem, guidance for which is given by the three markings on the femoral prosthesis. It is advised that the neck osteotomy is not made so low as to leave all three markings proud of the cement mantle.



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.



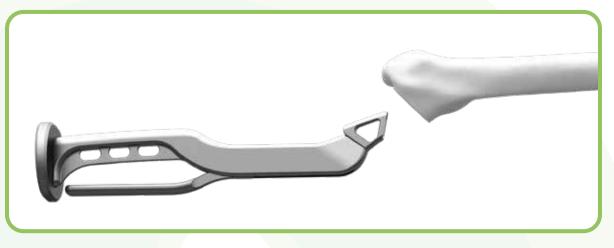




Femoral Preparation

A rectangular box chisel is used to cut a slot in the proximal neck and trochanteric region. The chisel should be as lateral as possible against the transition to the greater trochanter to create a slot to accommodate the prosthesis in a neutral position.

The slot may be extended laterally by notching the cortex of the trochanter using a rongeur or small rasp.



Optional technique:

While the Evolve 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 cana and to induce lateral bias where

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 trochanteris reamer

femoral axis during broaching







Femoral Broaching

Prepare the femoral canal by first using rasp size 1, and progress to the next larger size rasp. To ensure proper rasp height and subsequent implant height, calibration marks are located on the connector piece, which reference the height of the final implant. The first contact with the cortex usually occurs at the distal end of the rasp.

Progress will become more difficult with each progressive impaction and the pitch of the impactor will change from low to high once cortical bone is engaged.

The next larger size rasp is usually the final size as preoperatively templated. The final rasp should be seated to the resection line and there should be no visible movement of the broach when the slaphammer is rotated. The final implant size will directly correspond to the final rasp size.



Note:

If excess force is required to introduce a broach to the correct level then the surgeon should either drop down a broach size or, if this is not possible, the canal may be enlarged with the taper pin reamer, taking care not to compromise the layer of trabecular bone. A calcar planer may be used if the broach is countersunk.



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. The three holes on the broach correspond to circular markings on the stem, that later help seat the stem to the same position as the broach.





Instrument identification:

Trial heads are colour coded based on offset. Refer to Evolve Implants Sizing Guide in this surgical technique for more details.

Optional Instrument:

Optional trial necks available. Trial different offsets with same broach body in place.

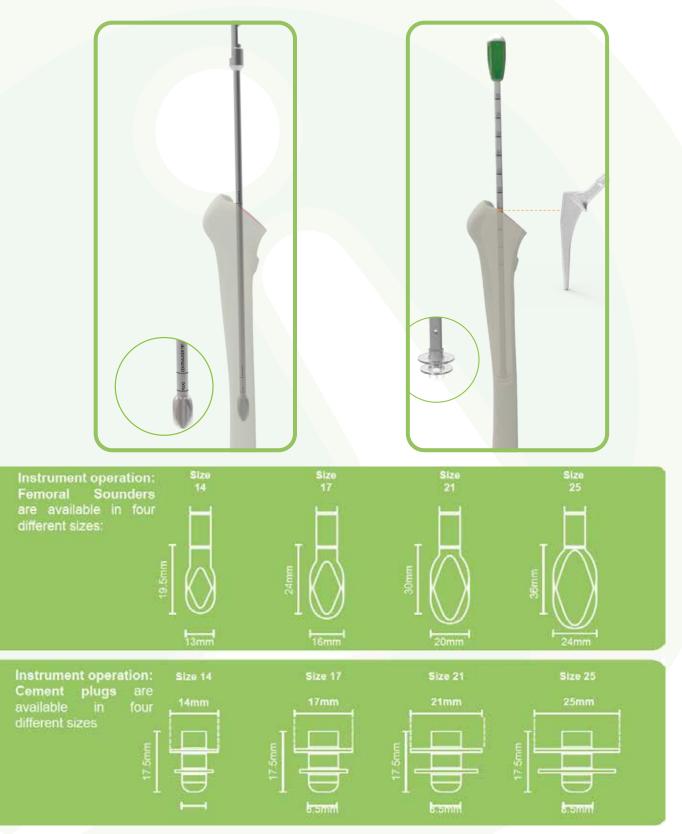






Additional Femoral Preparation

Size and insert the appropriate cement plug to create a firm seal distally. Wash the prepared bone cavity with pulse lavage and dry before injecting the cement. The depth of the plug can be gauged off the marking on the femoral sounder and plug inserter, to be measured in line with the tip of the greater trochanter







Femoral Cementing

Cement is introduced from a distal to proximal fashion and as the canal fills distally the cement gun nozzle is gradually withdrawn until the canal is completely filled with cement. Apply cement under pressure by sealing the proximal femur whilst continuing to inject the cement. When the canal is full, the gun is withdrawn and the femoral seal is placed over the nozzle of the gun. The cement in the nozzle is pushed back until it is level with the seal and then the nozzle is cut short at the point at which it emerges through the seal. Maintain pressure until the cement is ready for the stem to be inserted.





The cement in the nozzle is pushed back until it is level with the seal and then the nozzle is cut short at the point at which it emerges through the seal.

Stem Implantation:

Attach the distal centraliser to the end of the stem. Steadily insert the stem down the middle of the femur, making sure version and alignment are correct. Insert the stem to the depth as measured off the rasp during trial reduction. During stem insertion maintain cement pressure by stopping the cement from extruding out the top of the femur. Do not leave all three depth markings proud of the osteotomy line as this would risk leaving inadequate proximal support for the implant. Once in place, maintain the stem position and continue to pressurise the cement proximally by using a proximal collar seal.

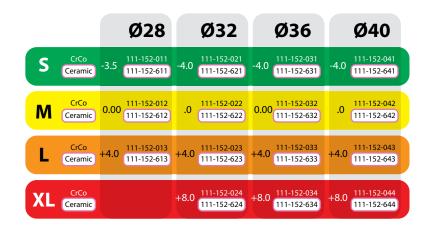


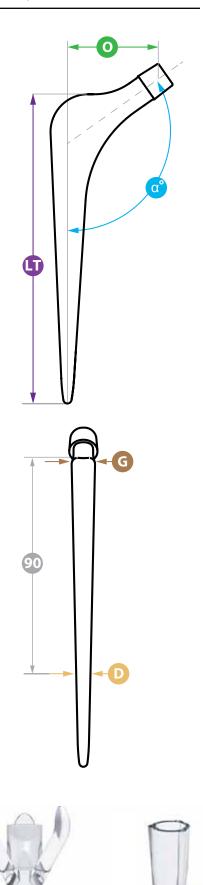




Evolve Masters					
P/N	Size	LT	0	a°	G
111-242-351	35.5 Size 1	127	35.5	125	10.9
111-242-370	37.5 Size 0	150	37.5	125	10.4
111-242-371	37.5 Size 1	150	37.5	125	10.9
111-242-372	37.5 Size 2	150	37.5	125	11.4
111-242-373	37.5 Size 3	150	37.5	125	11.9
111-242-440	44 Size 0	150	44	125	10.4
111-242-441	44 Size 1	150	44	125	11.0
111-242-442	44 Size 2	150	44	125	11.4
111-242-443	44 Size 3	150	44	125	11.9
111-242-444	44 Size 4	150	44	125	12.6
111-242-501	50 Size 1	150	50	125	10.9
111-242-502	50 Size 2	150	50	125	11.4
111-242-503	50 Size 3	150	50	125	11.9
111-242-504	50 Size 4	150	50	125	12.6

Evolve					
111-162-133	SO Size 1	116	37.5	130	11.0
111-162-142	HO Size 1	116	40.5	125	11.0
111-162-240	SO Size 2	125	39.5	130	11.0
111-162-244	HO Size 2	125	44	125	11.0
111-162-342	SO Size 3	134	41.5	130	11.0
111-162-364	HO Size 3	134	46	125	11.0
111-162-444	SO Size 4	143	43.5	130	11.5
111-162-448	HO Size 4	143	48	125	11.5
111-162-546	SO Size 5	151	45.5	130	12.0
111-162-550	HO Size 5	151	50	125	12.0







Evolve Instrument Trays

Primary Evolve Instrument Tray





Evolve Instruments

Straight Broach Handle

112-182-112

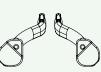
Straight Broach Handle

112-182-050

Short Broach Handle 112-25-0146

Dual Offset Broach Handle

112-25-0044 112-25-0045



Curved Broach Handle

112-182-001

Curved Broach Handle

112-182-166

Calcar Reamer

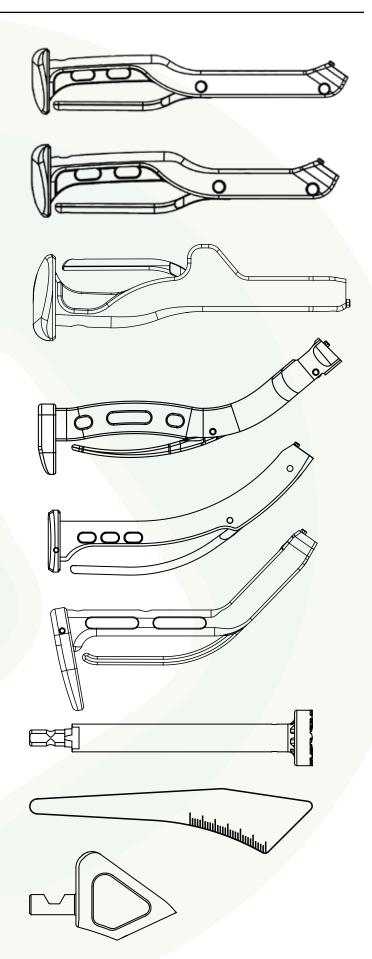
P12-01-0012

Osteotomy Guide

112-182-014

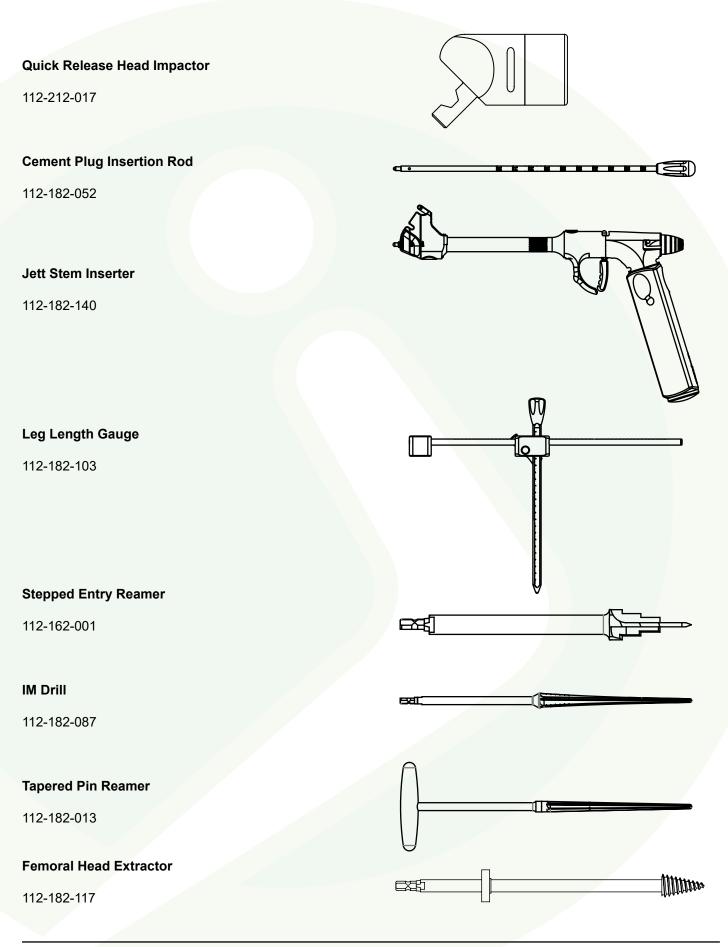
Quick Release Box Chisel

112-212-005





Evolve Instruments





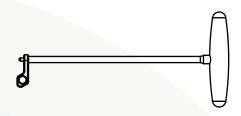
Evolve Instruments

Stem Pusher

112-182-106

Standard Trial Neck

111-242-150



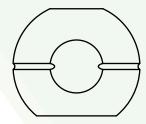


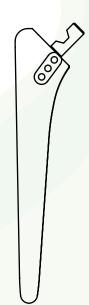
Trial Femoral Heads

111-182-040	Ø28mm -3.5mm Green
111-182-041	Ø28mm 0.0mm Yellow
111-182-042	Ø28mm +3.5mm Orange
111-182-017	Ø32mm -4.0mm 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 -4.0mm 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 -4.0mm Green
111-182-044	Ø40mm 0.0mm Yellow
111-182-045	Ø40mm +4.0mm Orange
111-182-046	Ø40mm +8.0mm Red

Evolve Master Broaches

111-241-351	35.5mm Size 1
111-241-370	37.5mm Size 0
111-241-371	37.5mm Size 1
111-241-372	37.5mm Size 2
111-241-373	37.5mm Size 3
111-241-440	44.0mm Size 0
111-241-441	44.0mm Size 1
111-241-442	44.0mm Size 2
111-241-443	44.0mm Size 3
111-241-444	44.0mm Size 4
111-241-501	50.0mm Size 1
111-241-502	50.0mm Size 2
111-241-503	50.0mm Size 3
111-241-504	50.0mm Size 4





Evolve Optional Instruments

Reacher Trial Necks

111-242-151(44mm offset to 50mm)111-242-152(37.5mm offset to 44mm)111-242-153(37.5mm offset to 50mm)	
Large Tapered Pin Reamer 112-182-144	
Extra Large Tapered Pin Reamer 112-182-148	
Canal Reamer 112-212-023	
Trochanteric Canal Reamer	

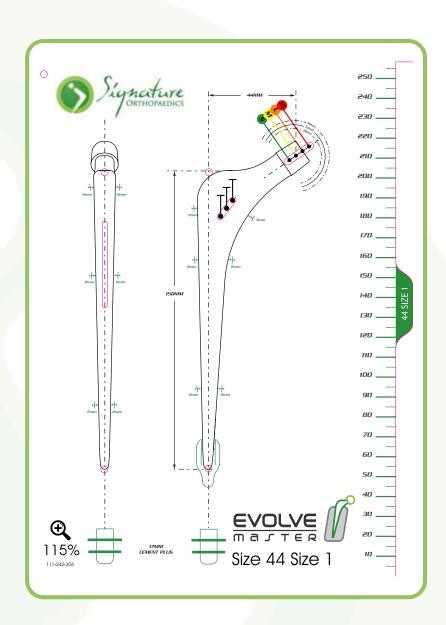
112-212-022



Evolve Preoperative Templates

Evolve Templates

111-242-300	35.5mm Size 1
111-242-301	37.5mm Size 0
111-242-302	37.5mm Size 1
111-242-303	35.5mm Size 2
111-242-304	37.5mm Size 3
111-242-305	44.0mm Size 0
111-242-306	44.0mm Size 1
111-242-307	44.0mm Size 2
111-242-308	44.0mm Size 3
111-242-309	44.4mm Size 4
111-242-310	50.0mm Size 1
111-242-311	50.0mm Size 2
111-242-312	50.0mm Size 3
111-242-313	50.0mm Size 4





Evolve Master Implants

111-242-351	35.5mm Size 1
111-242-370	37.5mm Size 0
111-242-371	37.5mm Size 1
111-242-372	35.5mm Size 2
111-242-373	37.5mm Size 3
111-242-440	44.0mm Size 0
111-242-441	44.0mm Size 1
111-242-442	44.0mm Size 2
111-242-443	44.0mm Size 3
111-242-444	44.4mm Size 4
111-242-501	50.0mm Size 1
111-242-502	50.0mm Size 2
111-242-503	50.0mm Size 3
111-242-504	50.0mm Size 4

Evolve Stems

111-162-133	Size 1 Standard Offset
111-162-142	Size 1 High Offset
111-162-240	Size 2 Standard Offset
111-162-244	Size 2 High Offset
111-162-342	Size 3 Standard Offset
111-162-364	Size 3 High Offset
111-162-444	Size 4 Standard Offset
111-162-448	Size 4 High Offset
111-162-546	Size 5 Standard Offset
111-162-550	Size 5 High Offset

Wide

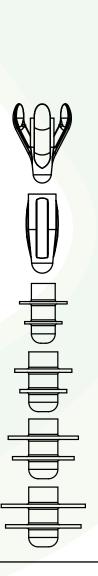
Distal Centraliser

111-162-002

111-162-003 Narrow

Cement Plug

112-182-150	14mm
112-182-151	17mm
112-182-152	21mm
112-182-153	25mm







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



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