Surgical Technique

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BIRMINGHAM HIP◇

Dual Mobility Insert

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Nota Bene

The technique description herein is made available to the healthcare professional, to illustrate the authors, suggested treatment for the uncomplicated procedure. In the final analysis, the preferred treatment is that which addresses the needs of the specific patient.

Indications and Contraindications

Indications

The BIRMINGHAM HIP® Dual Mobility Insert is intended for use in BIRMINGHAM HIP Resurfacing (BHR®) System revision surgeries in cases where an acetabular cup is retained and the femoral component revised.

Contraindications

- Patients with infection or sepsis
- Patients who are skeletally immature
- Patients with any vascular insufficiency, muscular atrophy, or neuromuscular disease severe enough to compromise implant stability or postoperative recovery
- Patients with bone stock inadequate to support the device including:
  - Patients with severe osteopenia or patients with a family history of severe osteoporosis or severe osteopenia.

Please note

In cases of questionable bone stock, a DEXA scan may be necessary to assess bone stock status.

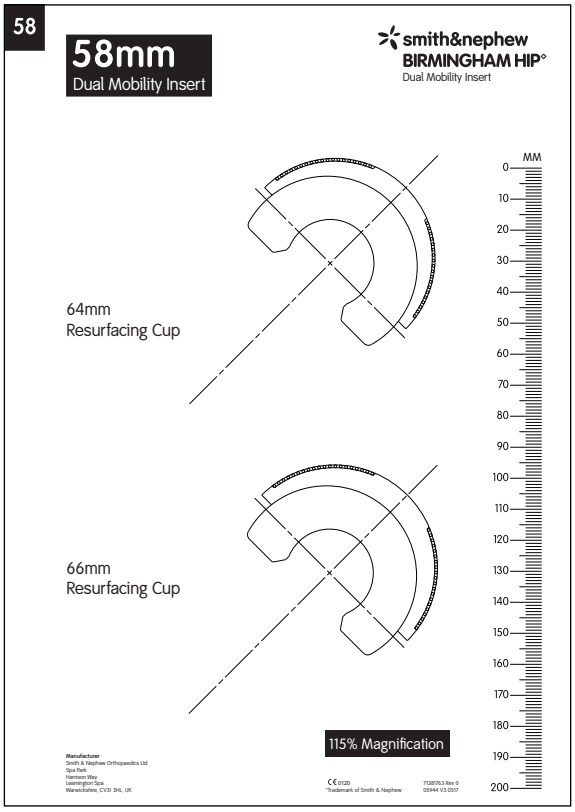
- Females in pregnancy due to the unknown effect on the fetus of metal ion release
- Patients with known moderate to severe renal insufficiency
- Patients who are immunosuppressed with diseases such as AIDS or persons receiving high doses of corticosteroids
- Patients who have a BMI greater than 40

Preoperative planning

Implant compatibility

Each insert is compatible with two standard acetabular cup sizes and one dysplasia cup size.

Femoral Head Size	BH Dual Mobility Insert Size	Compatible BHR Standard Cup Sizes		Compatible BHR Dysplasia Cup Sizes
22	38	44	46	46
	40	46	48	48
28	42	48	50	50
	44	50	52	52
	46	52	54	54
	48	54	56	56
	50	56	58	58
	52	58	60	60
	54	60	62	62
	56	62	64	64
	58	64	66	66



Please note

- The BIRMINGHAM HIP® (BH) Dual Mobility Insert is not recommended for use in a mal-positioned acetabular cup or where mal-positioning is a contributor to the cause of revision. It is not advised to use a BH Dual Mobility Insert in an acetabular cup with an inclination angle above 55° following supine X-Ray review due to the increased risk of edge loading or dislocation.
- The BHR® acetabular cup should be inspected intra-operatively for visible signs of damage. The BHR acetabular cup should be removed if there are any obvious signs of damage, deep scratches or corrosion.
- The fixation of the BHR acetabular cup should be inspected both pre and intra-operatively. If during preoperative radiographic assessment evidence of radiolucency, subsidence, migration, changes in angulation or osteolysis are present then the BHR acetabular cup should be removed. The BHR acetabular cup should also be removed if movement can be detected during intra-operative assessment of component stability.

Warning and Precautions

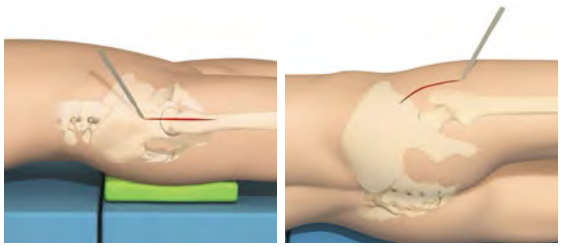
- Patients on medications (such as high-dose or chronic aminoglycoside treatment) or with comorbidities (such as diabetes) that increase the risk of future, significant renal impairment should be advised of the possibility of increase in systemic metal ion concentration. Preoperative and postoperative monitoring of renal function (such creatinine, GFR, BUN) will be necessary for these patients.
- Only physicians who are familiar with the implant components, instruments, procedure, clinical applications, adverse events, and risks associated with the BH Dual Mobility insert should use this device.

The more risk factors a patient has, the greater the risk of procedure failure requiring a revision of the hip.

Important note

Avoid stems having necks with a roughened surface finish and/or stems with extraction holes, openings, or abrupt surface transitions near the stem cone. Femoral heads with protruding collars (sizes 28 XL (+12) and 28 XXL (+16)) should also be avoided. These factors may significantly increase the risk of damaging the XLPE insert. 28 XL (+12) heads with a sleeve or 22L (+8) heads must not be used with the BH Dual Mobility Insert.

Positioning and access



The surgical procedure is performed with the patient in extended supine or lateral position.

Access to the operative site is based on previously recorded patient data or the preference of the operating surgeon.

Inserting the XLPE insert

The XLPE insert corresponding to the previous implanted BHR® head size (e.g. 50mm head = 50mm insert) is combined with the femoral head by using the insert ball head press (75017089).

Place the insert on the plastic holder and put the femoral head (OXINIUM®, ceramic or metal) on the hole of the insert. Push the top part of the instrument downwards until the femoral head and insert are enclosed.

Then turn the T-handle until the femoral head is completely locked together with the insert and can move freely.

Please note

A quiet hissing sound of escaping air is heard.

It is advisable to position the upper part of the instrument as low as possible.

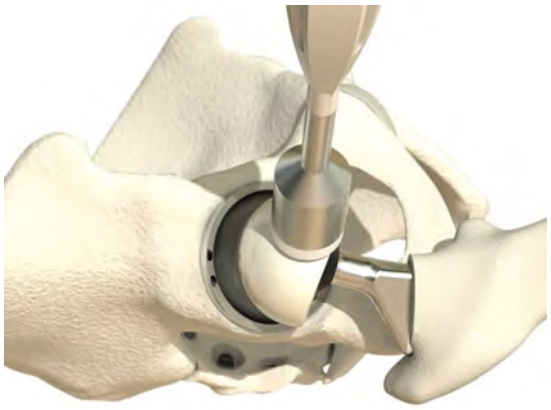
The following femoral head sizes can be used with the BH Dual Mobility Insert in combination with the corresponding insert:
22 S (+0mm), 22 M (+4mm)
28 XS (-3mm), 28 S (+0mm)
28 M (+4mm), 28 L (+8mm)

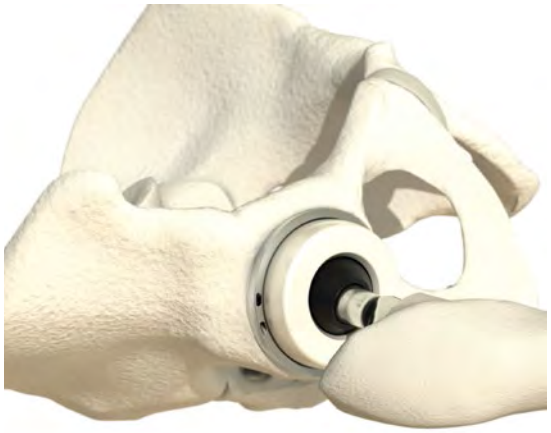
Please note

If required:

- You can use the Trial Insert and Global Femoral Trial head in the implanted BHR Cup.
- You must not use the Global Femoral Trial Heads or any other Femoral Trial Heads in combination with the definitive XLPE Insert.

Inserting the XLPE insert





Fit the XLPE insert/femoral head combination onto the stem cone manually and hammer in using the head impactor (71364009). Then insert the femoral head / insert into the cup.

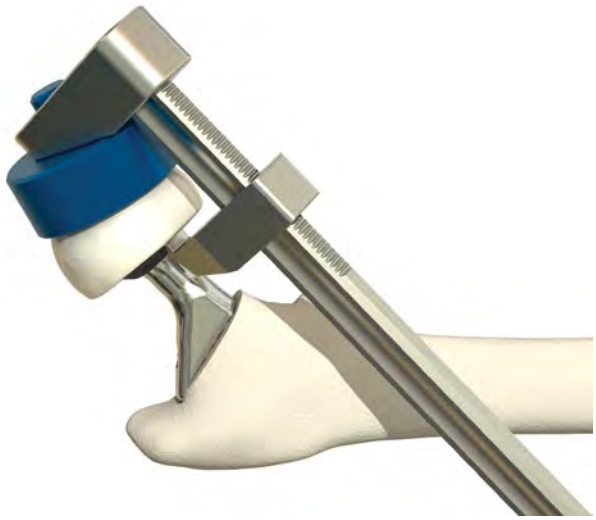
Important note

Ensure that no soft tissue affects the contact between the insert and the cup.

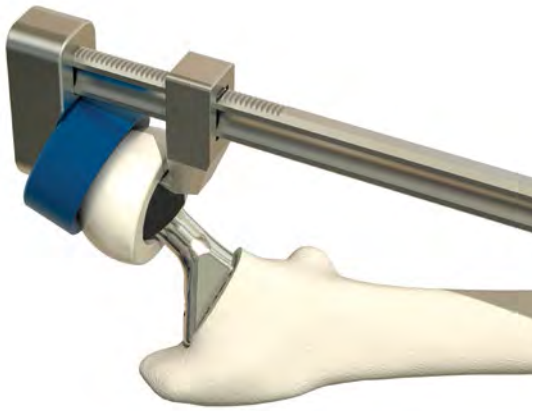
Avoid stems having necks with a roughened surface finish and/or stems with extraction holes, openings, or abrupt surface transitions near the stem cone.

Femoral heads with protruding collars (sizes 28 XL (+12) and 28 XXL (+16)) should also be avoided. These factors may significantly increase the risk of damaging the XLPE insert. 28 XL (+12) heads with a sleeve or 22L (+8) heads must not be used with the BH Dual Mobility Insert.

Removing an XLPE insert



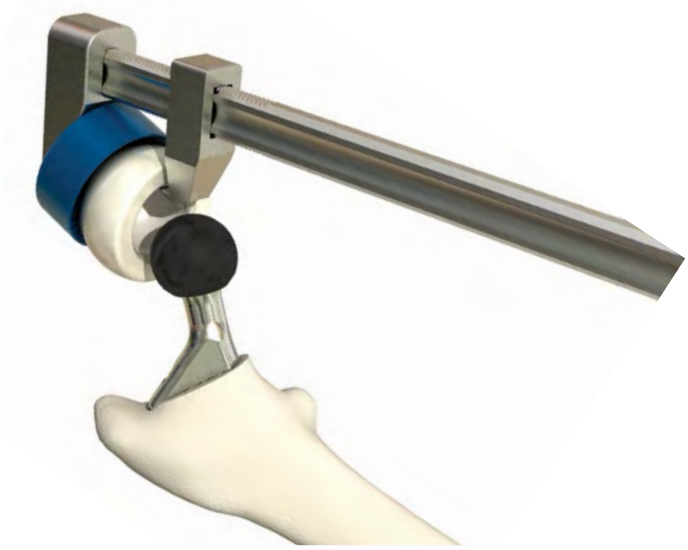
Fit the insert extractor over the XLPE insert.



Tighten ensuring the hook is secure under the insert and the femoral head is secure on the stem. Leaver the extractor upwards to remove the insert.

Please note

The insert extractor can be used with both monoblock and modular stems.



Post-operative Treatment

- Excessive physical activity levels, excessive patient weight, and trauma to the joint replacement may cause early failure of the implant.
- Loosening of components may increase production of wear particles and accelerate damage to the bone, making successful revision surgery more difficult.

Sterilization

Implants

- Implant components are supplied sterile to a Sterility Assurance Level (SAL) of 10-6. The BH Dual Mobility inserts are sterilised through ETO sterilisation.
- The BH Dual Mobility insert components are packaged in a triple peel pouch configuration to maintain sterility. The products have a seven (7) year sterile shelf-life where the sterile barrier is not broken.
- The product is not labeled “pyrogen free”.
- DO NOT RESTERILIZE implant components. Contact your local Smith & Nephew sales representative regarding procedures to return components to Smith & Nephew.

Instruments

Instruments used to implant the device system are supplied non-sterile and must be sterilized prior to use using one of the following validated, recommended methods:

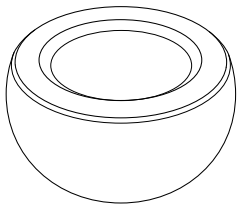
- **Dynamic Air Removal (Pre-vacuum) Steam Cycle**
  Exposure temperature: 132°C (270°F); Exposure time: 4 minutes
  Exposure temperature: 135°C (275°F); Exposure time: 3 minutes
  Minimum drying time: Wrapped devices - 15 minutes; Containerized devices - 30 minutes*
- **Gravity Displacement Steam Cycle**
  Exposure temperature: 132°C (270°F)
  Exposure time:
  – 15 minutes for instruments not in a containment device
  – 30 minutes* for devices in a containment device
  Minimum drying time: 30 minutes
- **Immediate Use Steam Sterilization (IUSS) or Flash Steam Cycle**
  Exposure temperature: 132°C (270°F)
  Exposure time: Dynamic air removal (pre-vacuum): 4 minutes

*This sterilization cycle is not considered by the United States Food and Drug Administration (US FDA) to be a standard sterilization cycle. Users should only use sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization containers) that have been cleared by the US FDA for the selected sterilization cycle specifications (time and temperature).

Implants

XLPE inserts

SAP no.	Insert Size (mm)	Femoral Head Size (mm)
74121638	38	22
74121640	40	22
74121642	42	28
74121644	44	28
74121646	46	28
74121648	48	28
74121650	50	28
74121652	52	28
74121654	54	28
74121656	56	28
74121658	58	28



Please note

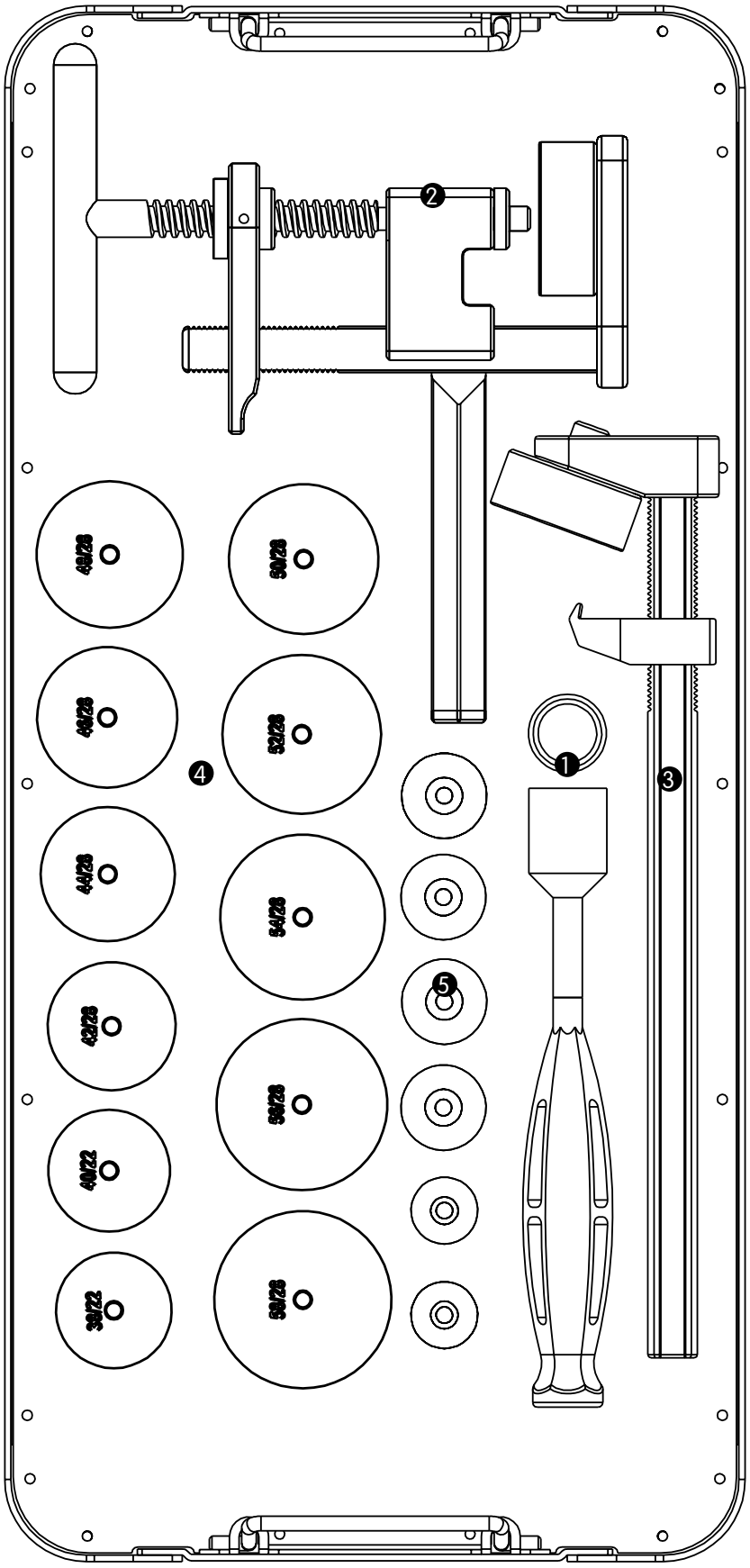
- 50mm BHR® head corresponds with 50mm insert. 38 and 40mm XLPE Inserts are only compatible with 22mm femoral heads.
- 28mm Femoral Heads are compatible with the remaining XLPE Insert range: 42mm – 58mm

Instrumentation

BH Dual Mobility Instrument Set

Case set SAP/Item no.90036100

	SAP no.	Description	Size	Ømm
	90036000	Tray		
❶	71364009	Femoral Head Impactor		
❷	75017089	Insert Ball Head Press		
❸	75017083	Insert Extractor		
❹	90036038	BH Dual Mobility Insert Trial	38	22
	90036040	BH Dual Mobility Insert Trial	40	22
	90036042	BH Dual Mobility Insert Trial	42	28
	90036044	BH Dual Mobility Insert Trial	44	28
	90036046	BH Dual Mobility Insert Trial	46	28
	90036048	BH Dual Mobility Insert Trial	48	28
	90036050	BH Dual Mobility Insert Trial	50	28
	90036052	BH Dual Mobility Insert Trial	52	28
	90036054	BH Dual Mobility Insert Trial	54	28
	90036056	BH Dual Mobility Insert Trial	56	28
	90036058	BH Dual Mobility Insert Trial	58	28
❺	75100839	Global Femoral Trial Head	S/+0	22
	75100840	Global Femoral Trial Head	M/+4	22
	75100843	Global Femoral Trial Head	XS/-3	28
	75100844	Global Femoral Trial Head	S/+0	28
	75100845	Global Femoral Trial Head	M/+4	28
	75100846	Global Femoral Trial Head	L/+8	28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Note

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