stryker®

MITCH TRH™ System

Modular Head Operative Technique

Manufactured by:

FINSBURY ORTHOPAEDICS

Pending Approval

Introduction

The MITCH TRH™ System is an evolutionary design, comprising of traditional resurfacing components, developed by Stryker ® Orthopaedics, in conjunction with an experienced development group at Finsbury Orthopaedics Limited. The System includes a range of large diameter modular head components which articulate with the resurfacing cup component and are impacted onto a Stryker® femoral stem with a V40™ taper to form a primary total hip arthroplasty. The Modular Head component ensures the surgeon has an option for the revision of the resurfacing femoral component and the opportunity to tailor his implant choice following an intra-operative assessment of the proximal femoral bone quality and the requirement for the restoration of joint biomechanics.

Indications

The Modular Head component of the MITCH TRH™ System can be utilised in conjunction with a Stryker® femoral stem with a V40™ taper as a revision option for the MITCH TRH™ System traditional resurfacing component.

It is also indicated for use as the femoral component of a primary alternate bearing when combined with a Stryker® femoral stem with a V40™ taper in patients who have chronic pain and limited mobility as a result of degenerative changes secondary to osteoarthritis, post traumatic arthritis, rheumatoid arthritis and avascular necrosis.

Please refer to Appendix 1, page 17 for the list of Stryker stems that are compatible with the MITCH TRH V40™ Modular Heads.

The indication for use of joint replacement prostheses include:

- Painful and disabled joint resulting from osteoarthritis, rheumatoid arthritis where one or more compartments are involved,
- Failure of previous joint replacement procedure,
- Correction of varus, valgus, or post traumatic deformity.
- Correction or revision of unsuccessful osteotomy or arthrodesis.

Patient selection factors which should be considered include:

- The need to obtain pain relief and improve mobility,
- The ability and willingness of the patient to follow instructions
- A good nutritional state of the patient,
- The patient must have reached full skeletal maturity.

Contraindications

Absolute contraindications include: infection and sepsis.

Relative contraindications include:

- Osteoporosis,
- Metabolic disorder, or a condition of marked bone loss which could impair bone formation,
- Vascular insufficiency, muscular atrophy, or neuromuscular disease,
- Uncooperative patient,
- Distant foci of infection (which may cause hematogenous spread to the implant site.
- Incompetent or deficient soft tissue surrounding the joint,
- The possibility of pregnancy when using metal on metal articulation
- Moderate to severe renal insufficiencyt

Pre-Operative Planning

For implants, x-ray templates and trial components are provided and should be used for verification of the definitive size of component.

1. Sizing

Using the templates provided, assess the X-ray to approximate the most suitable cup size and position.

The head offset can be adjusted by moving the Head/Cup template in relation to the stem template to overlay in one of 4 offset positions, -4, +0, +4 and +8.

Surgical Exposure

As a guide, the chosen surgical approach should provide sufficient exposure to ensure visualisation of the exposed femoral neck with minimal soft tissue trauma during the procedure and allow the precise positioning of the definitive implants using the instrumentation supplied

1.

Implantation of MITCH TRH™ System modular head can be achieved through a variety of surgical approaches.

All Standard approaches that provide adequate access for Total Hip Replacement are acceptable.

This document illustrates the patient lying in a lateral decubitus position on the contra-lateral side.

The Cup Alignment device assumes that the pelvis is in this true lateral orientation and well supported.

Acetabular Preparation

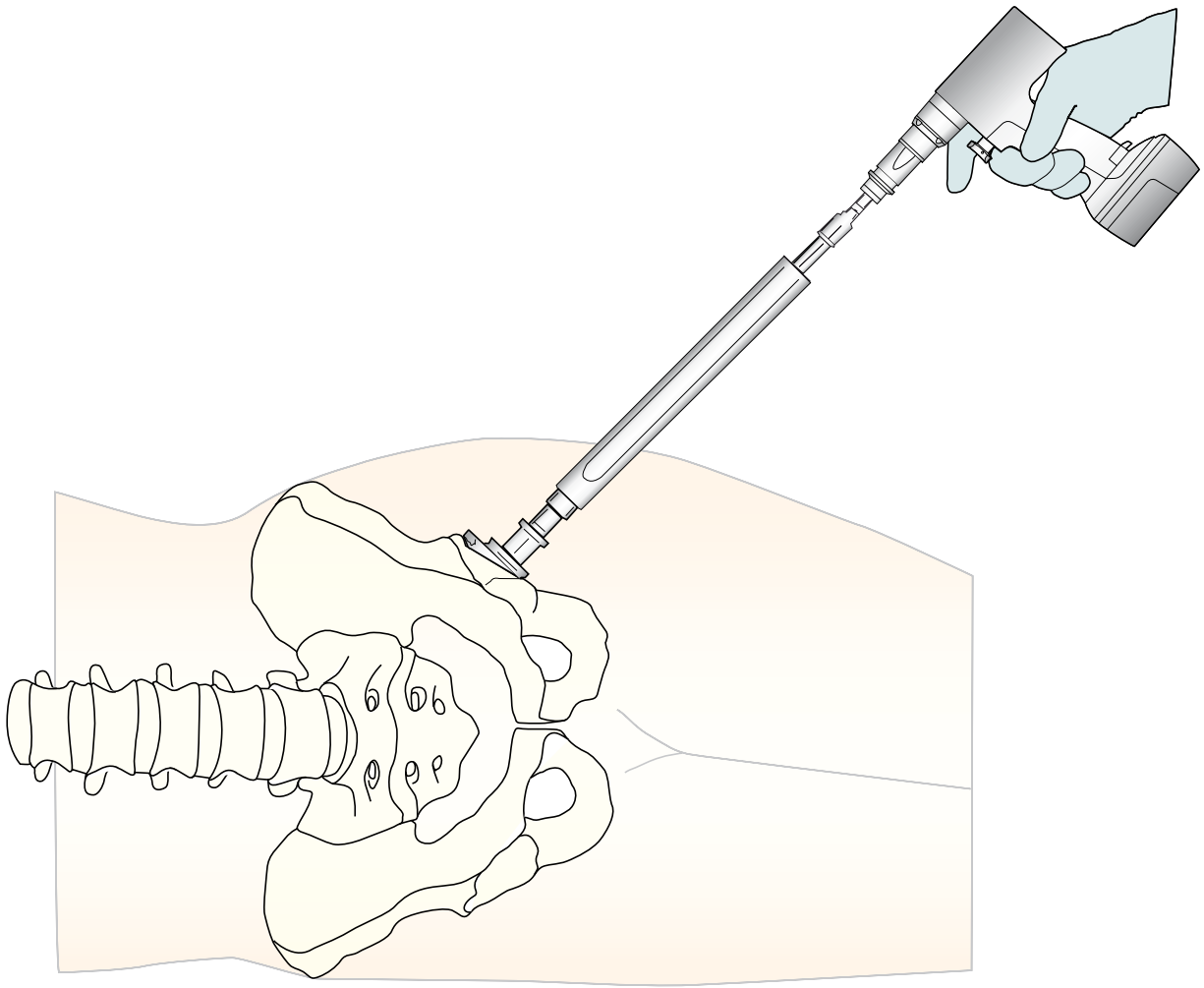
The goal of acetabular preparation is to create a hemispherical cavity which ensures a uniformity of implant-bone contact, a sufficient interference fit for initial stability and the positioning of the acetabular implant at the anatomical centre of rotation.

1. Acetabular Exposure

Excise the labrum and remove osteophytes to visualise the entire acetabular rim.
Clear soft tissue and cartilage to reveal the true floor of the acetabulum.
A clear and unrestricted view should be achieved.

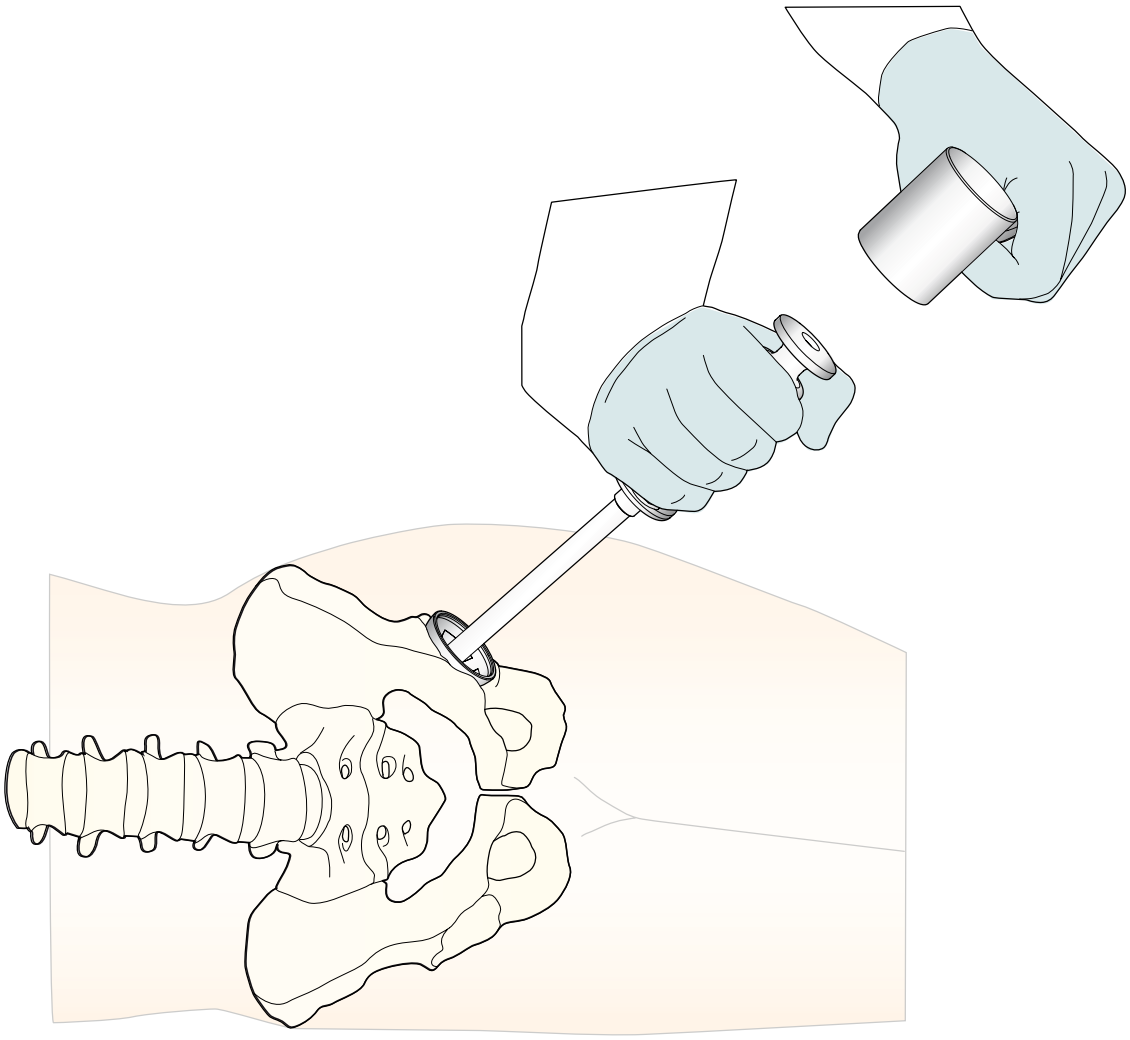
2. Acetabular Reaming

Check which cup size corresponds with the head size assessment. The nominal diameter of the definitive implant will determine the nominal diameter of the final acetabular reamer.
Reaming should commence with a reamer with a nominal size of 6 to 8 mm smaller than the nominal diameter of the definitive implant and progress sequentially until the reamed hemisphere is approximately 1mm smaller than the nominal diameter of the definitive implant.
In denser, sclerotic acetabulae, reaming nominally size for size may be appropriate and in larger less dense acetabulae reaming nominally more than 1 mm smaller may be appropriate.
Note: It is advisable to ream deeper than the hemisphere, so the larger hemispherical cup engages fully up to the acetabular rim. Insufficient depth is highlighted by a tendency for the Cup Trial to 'jump out' when moved and should be rectified by further reaming.



3. Cup Trialing

Correct assessment of reamed size can only be made with the MITCH TRH™ System Cup Trials, which have a slightly smaller diameter than the definitive implants.
Screw the chosen Cup Trial Handle fully into the selected Cup Trial, position in the acetabulum and impact.
Check that full bone contact is achieved around the trial edge.
Assess the fit of the cup trial by releasing the Cup Trial Handle to see if it holds in the acetabulum.
There must be a firm enough fit to ensure the trial implant is difficult, but not impossible, to re-orientate when the trial is fully seated in the reamed acetabular cavity.
Remove the trial.

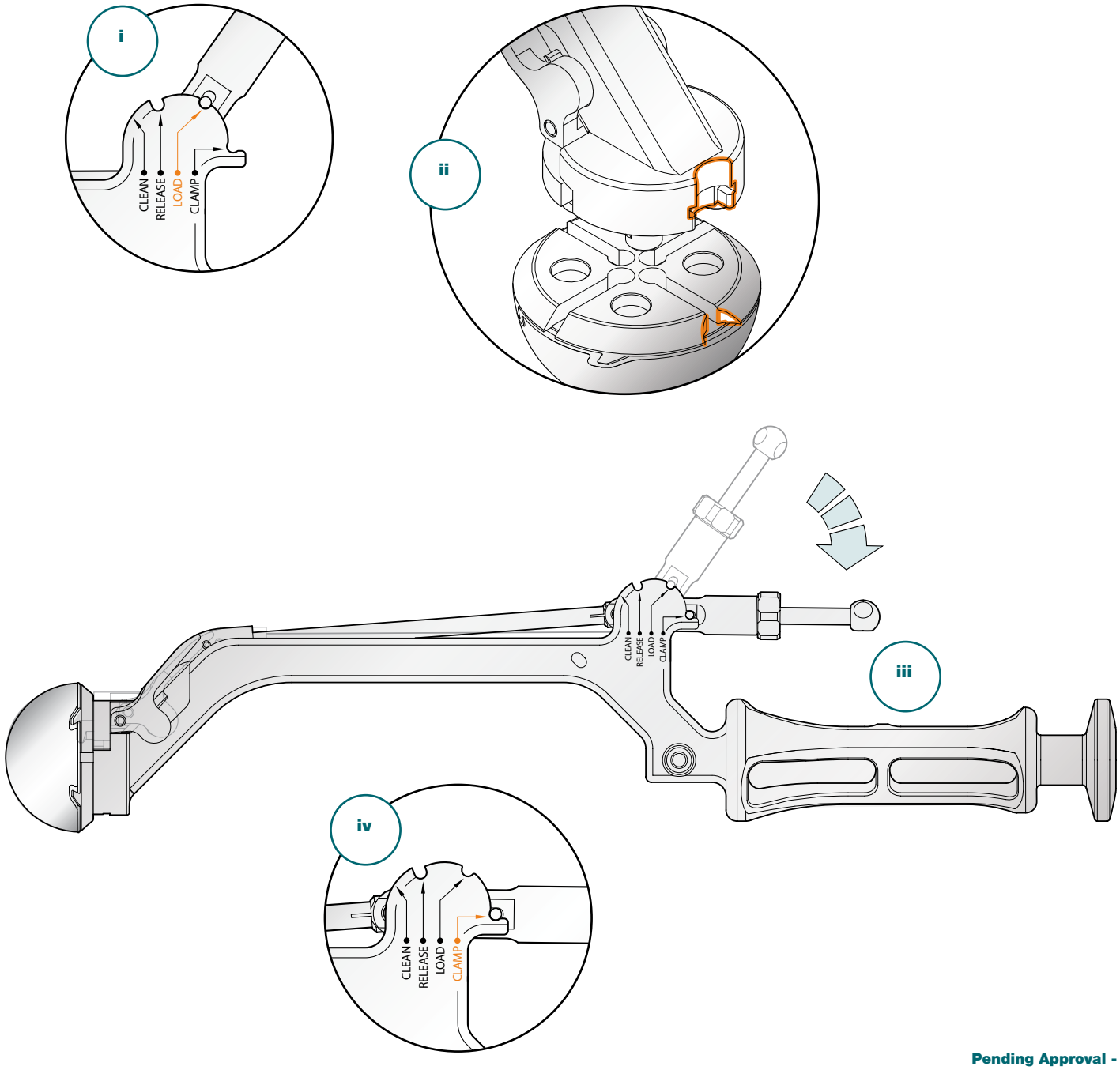


Acetabular Implantation

The optimal acetabular component is the size that partners the optimal femoral component whilst demonstrating a uniformity of implant-bone contact, a sufficient interference fit to ensure initial, biological and mechanical fixation which is positioned at the anatomical centre of rotation.

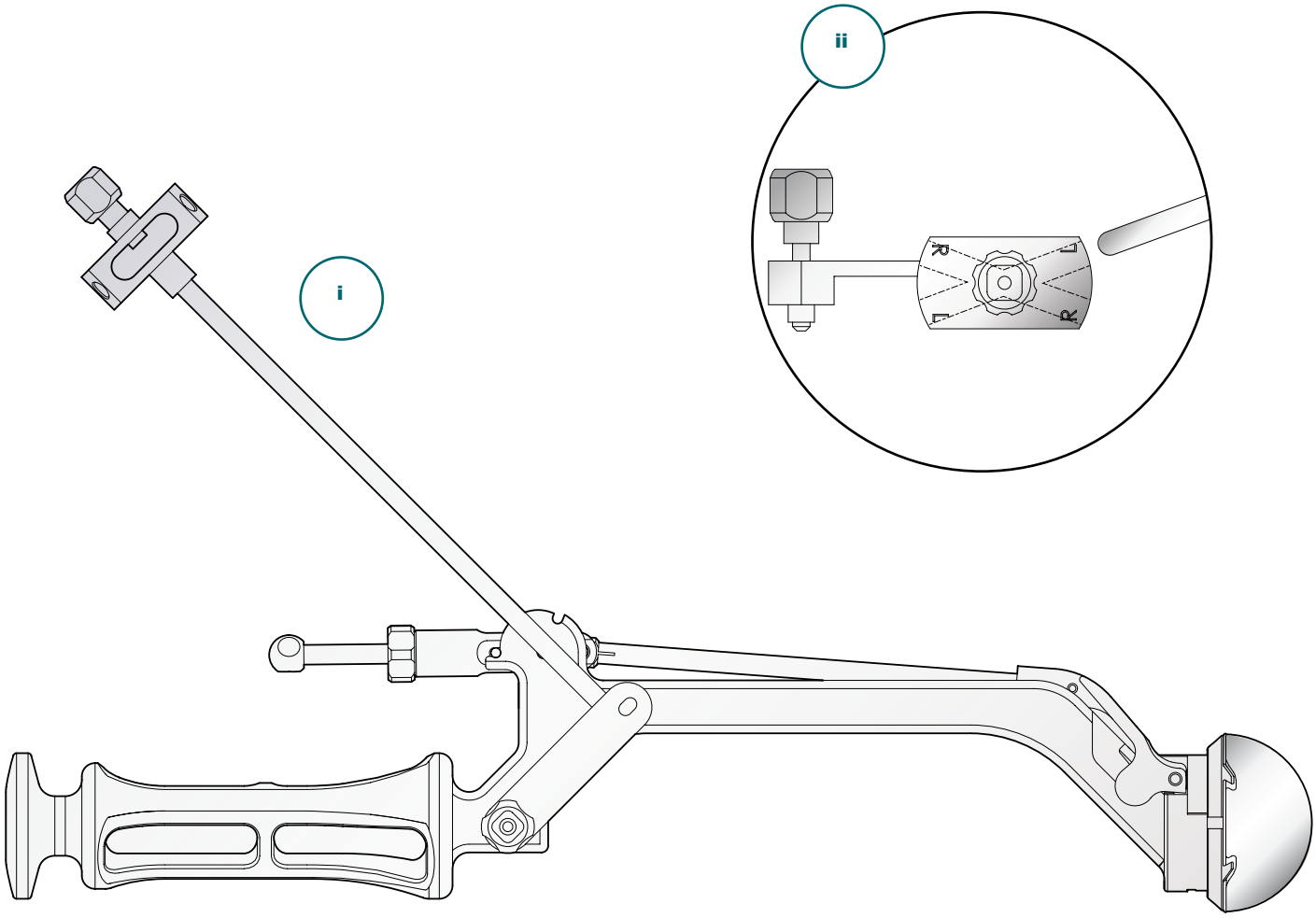
1. Prepare Implant

Set the Cup Introducer lever to 'LOAD' position (i). Locate the Cup Introducer into the Cup Impaction Plate ensuring all 4 pins engage fully. A notch on the Introducer should align with 1 of 2 corresponding notches on the Impaction Plate to give the correct instrument / implant alignment (ii). Shift the lever towards the handle until it snaps positively into the 'CLAMP' position (iii), (iv).



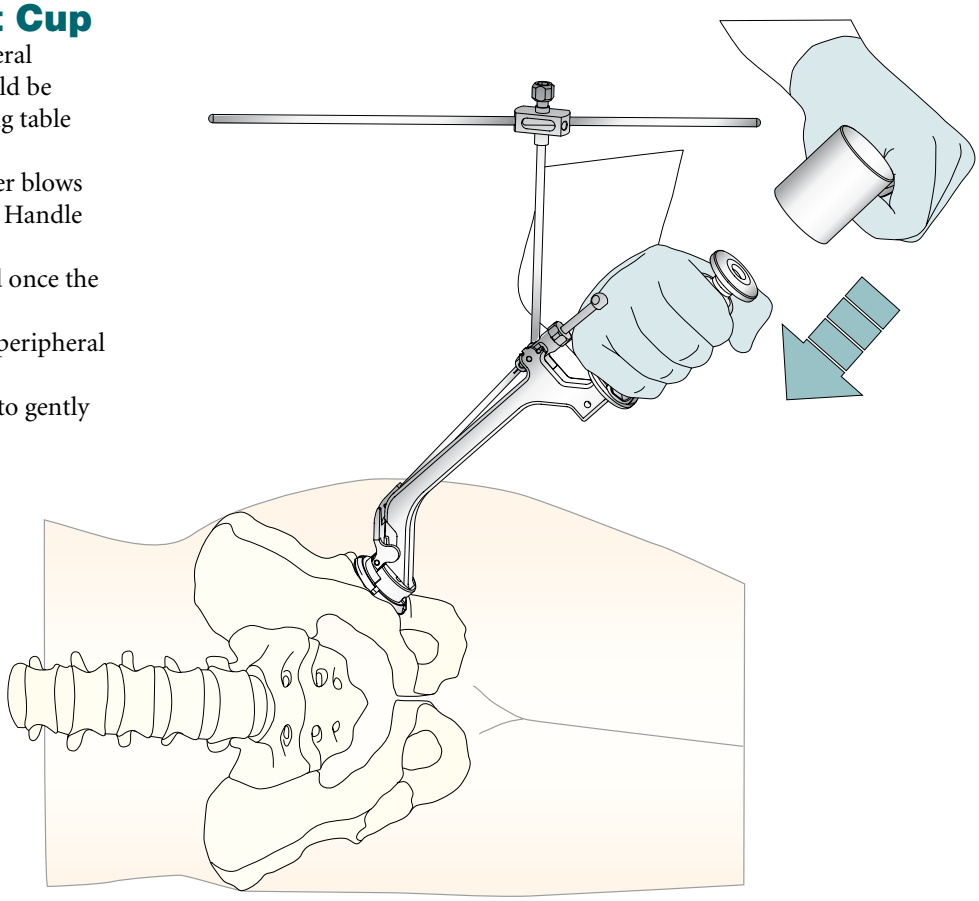
3. Cup Alignment

An optional Cup Alignment Guide can be attached to the Cup Introducer Handle to help guide the cup. The instrument is set at guide position of 45 degrees abduction and 20 degrees anteversion (i).
Insert the Cup Alignment Guide in the correct recess for either a left or right hip as indicated by the laser marking on the alignment guide (ii).



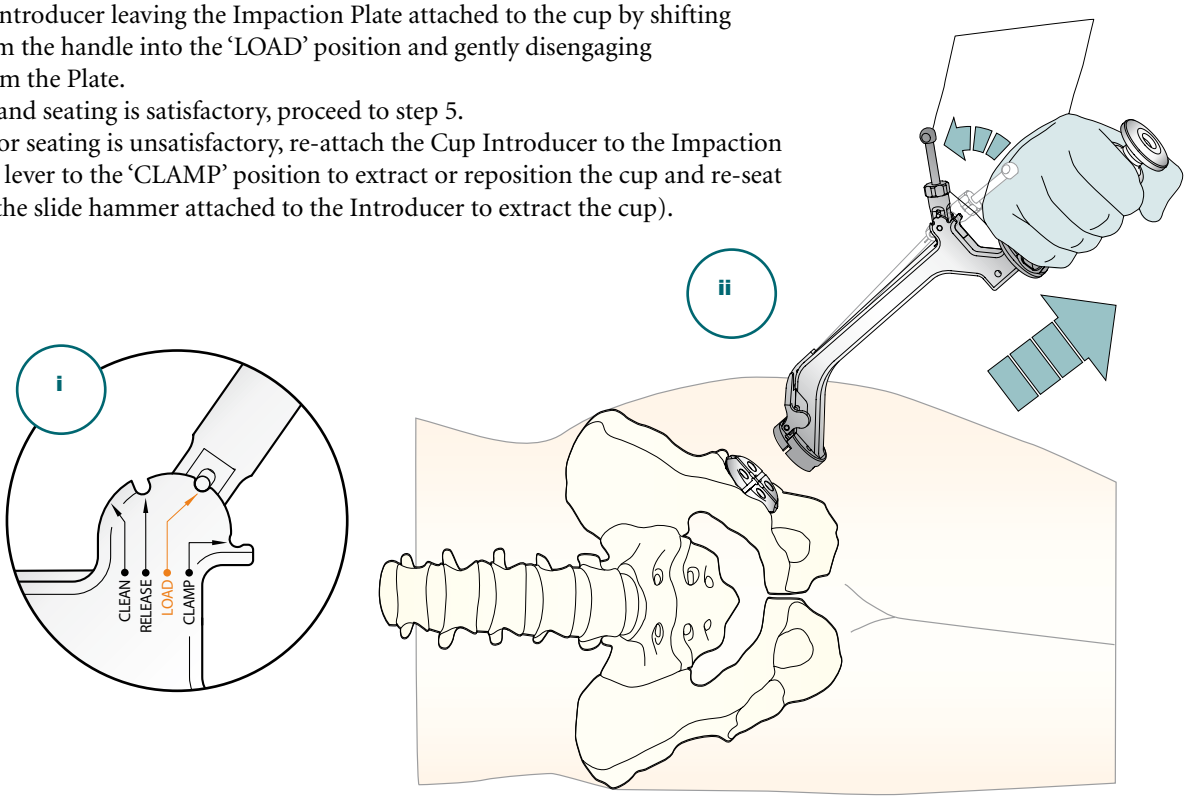
3. Position and Impact Cup

With the pelvis orientated in the true lateral position, the Cup Alignment Guide should be horizontal. Pelvic flexion on the operating table has to be accounted for.
Impact the Cup with several firm hammer blows on the strike plate of the Cup Introducer Handle until it is fully seated.
A change in impact note should be heard once the Cup is fully seated.
This can be confirmed by observing full peripheral cup/bone contact at the acetabular rim.
Test the firmness of the cup fit by trying to gently rock the pelvis with the Cup Introducer.
In case the cup has been loosened by testing, repeat the hammer blows.



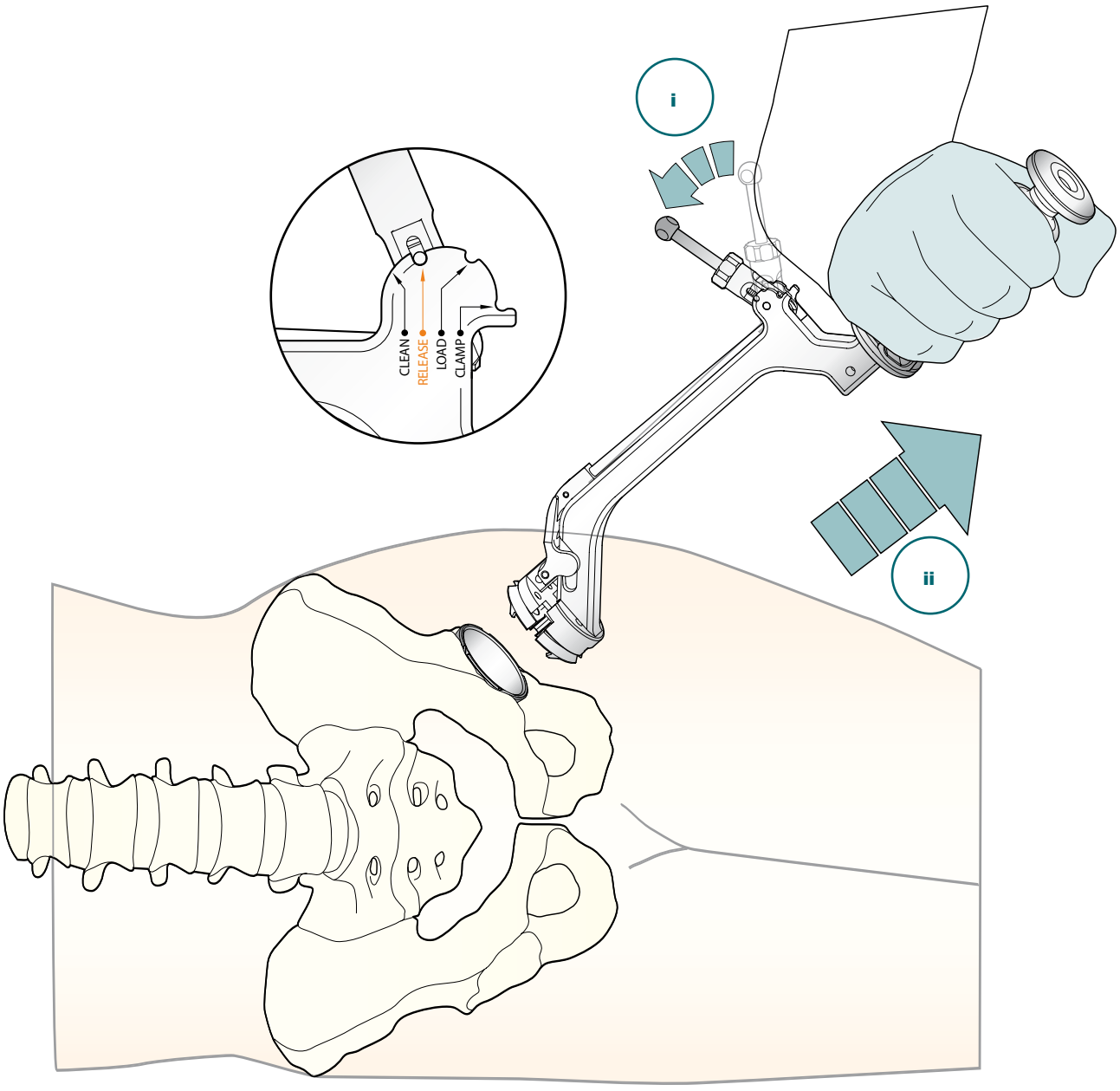
4. Assess Cup Orientation

Remove the Cup Introducer leaving the Impaction Plate attached to the cup by shifting the lever away from the handle into the 'LOAD' position and gently disengaging the Introducer from the Plate.
If the orientation and seating is satisfactory, proceed to step 5.
If the orientation or seating is unsatisfactory, re-attach the Cup Introducer to the Impaction Plate and shift the lever to the 'CLAMP' position to extract or reposition the cup and re-seat it (optionally use the slide hammer attached to the Introducer to extract the cup).



5. Remove the Impaction Plate

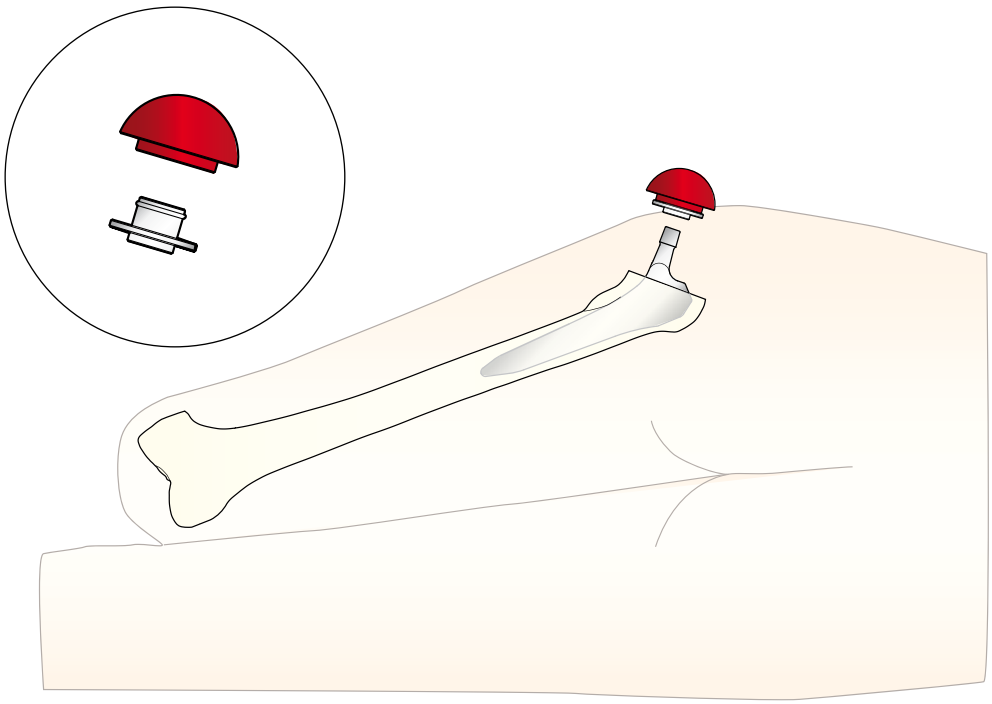
Ensure the lever on the Introducer is in the 'LOAD' position.
Re-attach the Introducer with a notch corresponding to the notch on the impaction Plate.
Shift the lever to the 'RELEASE' position (i) and remove the Introducer with the plate attached (ii).



Modular Head Impaction

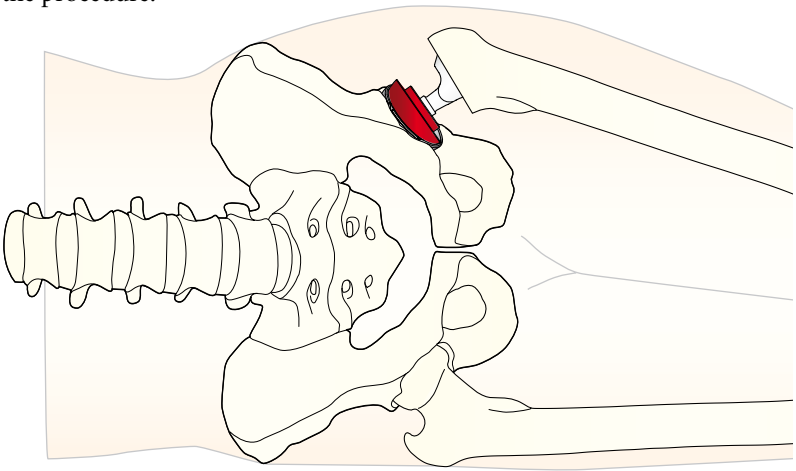
1. Assemble the Head Trial Components

Follow the appropriate Stryker V40™ Stem Operative Technique. Then with the appropriate Stryker V40™ Trial Stem, Rasp or Broach in position, select the Modular Head Trial matching the nominal diameter of the acetabular component and insert one of the four available Head Trial Offset Collars (-4, +0, +4 or +8mm). For full details of the V40™ stem insertion please refer
to the appropriate operative technique.



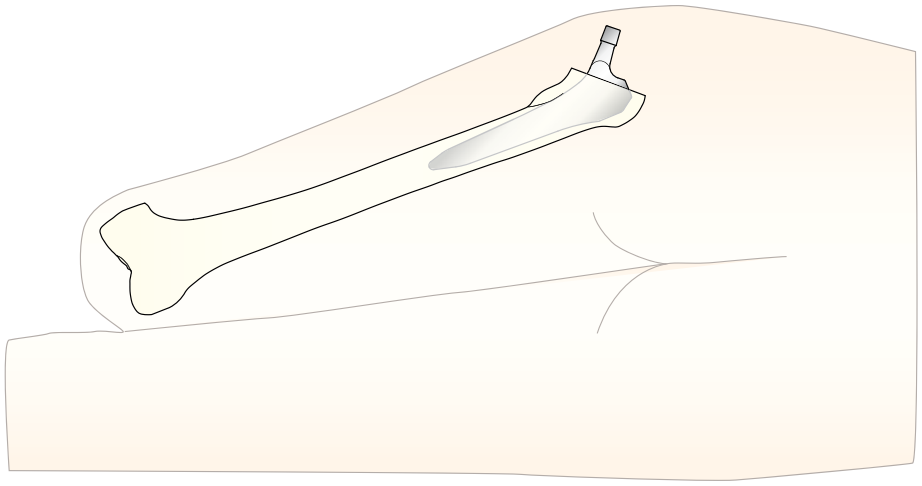
2. Trial Reduction

Flush the entire joint with saline, and wash and inspect the polished surfaces.
Place the Head Trial/Head Trial Offset collar assembly on the Trial Stem and reduce the hip.
Reduce the hip taking great care to reduce the components cleanly without scraping the head on the cup rim.
A retractor can be used to hold the hip capsule away from the acetabulum.
Perform a full check to ensure that there is no entrapment of soft tissues, and that the range of movement and stability is satisfactory.
Change the Head Offset Collar if required and repeat the procedure.



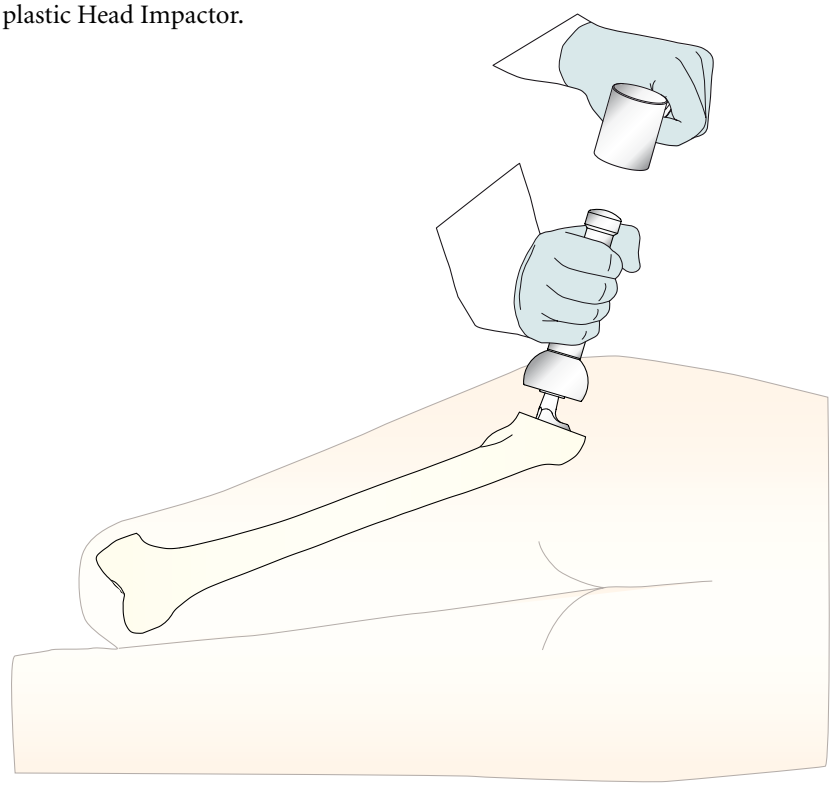
3. Implant the Definitive Stem

Remove all trial components and implant the definitive stem implant (see appropriate Stryker® stem with V40™ taper operative technique).



4. Impact Modular Head

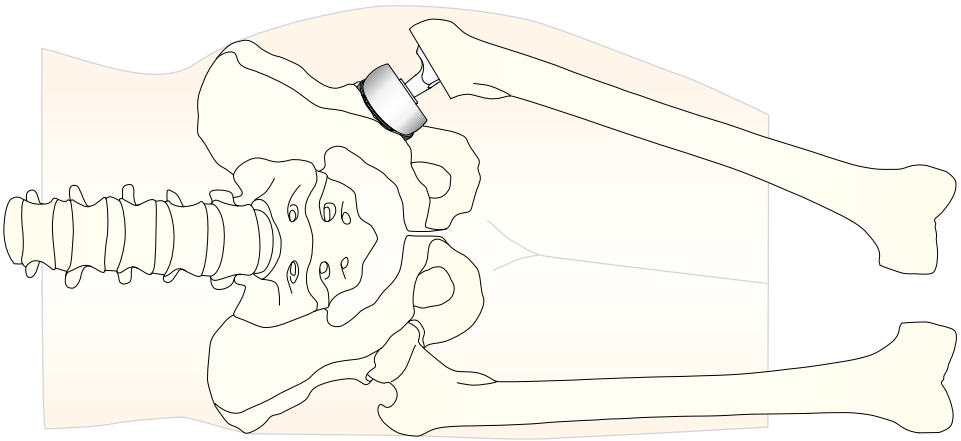
Select the correct size Modular Head matching the nominal diameter of the acetabular component with a neck offset matching the chosen Neck Length Collar.
Clean the stem taper and assemble the head, turning slightly to ensure correct alignment.
Impact the head with several light blows, using the plastic Head Impactor.



Reduction And Closure

1. Reduction

Flush out the entire joint with saline, cleaning and inspecting the polished articulating surfaces.
Reduce the hip, taking great care to avoid scraping the head along the cup rim.
Finally re-assess range of motion, stability and leg length.

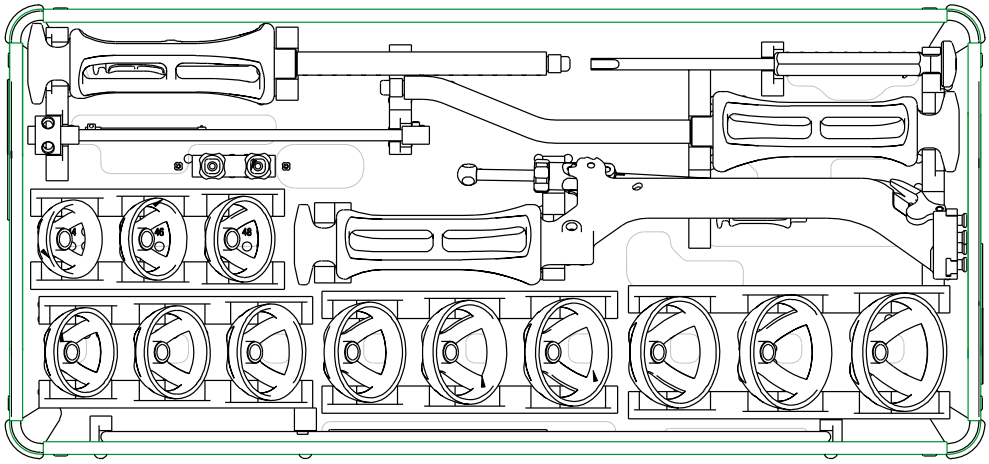


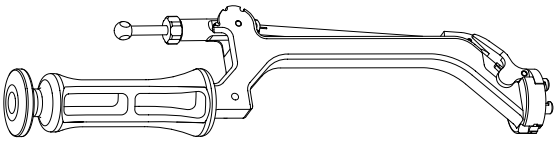
2. Close Wound

Follow the preferred procedure to re-attach muscular structures
and suture the fat layers and skin, inserting a drain if required.

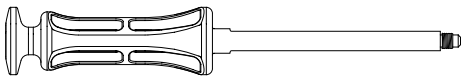
Instrumentation

Acetabular Preparation Set

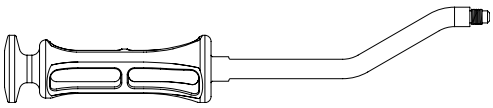




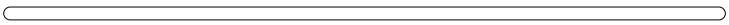
RAI99890040
Acetabular Cup Impactor



RAI99890029
Straight Cup Trial Handle

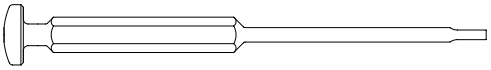


RAI99890030
Curved Cup Trial Handle



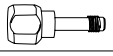
RAI99890031
Cup Alignment Rod

RAI99890032
Cup Alignment Aerial



RAI99890033
Punch

RAI99890034
Screw

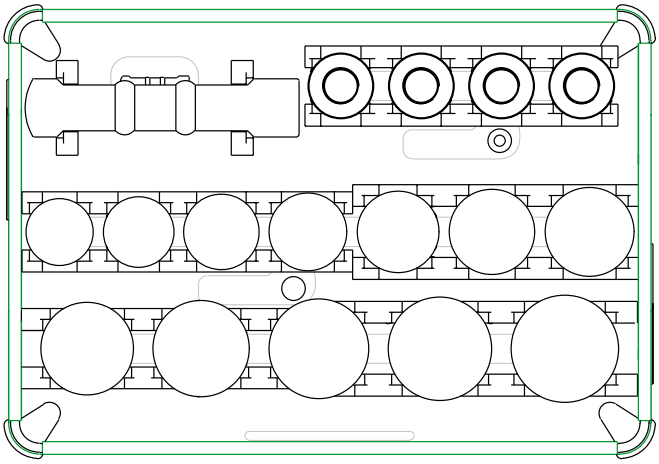


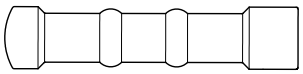
RAI99890035
Dog Screw

RAI99899044 - RAI99899066
Acetabular Cup Trial

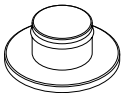
Instrumentation

Modular Head Set

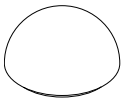




MHI99890057
Head Impactor



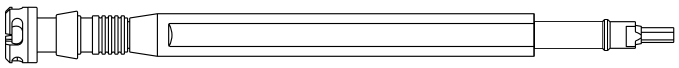
MHI99890058 - MHI99890061
Head Trial Offset Collar



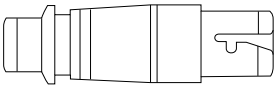
MHI99899738 - MHI99899760
Modular Head Trial

Instrumentation
Acetabular Reamers

21020438-21020466
Cutting Edge Reamer



21020410
Reamer Handle



4103235000
Power Tool Adapter

Appendix 1

Stryker® V40™ femoral stems approved for use with MITCH TRH™ System modular heads as manufactured by Finsbury Orthopaedics.

Stryker® V40™ Femoral Stem	Material
ABG II Accolade TMZF Meridian TMZF Citation TMZF Restoration DLS Restoration DPM Restoration T3 Restoration PS Super Securfit HA Symax Hipstar	Titanium Alloy
Accolade C Meridian PA Meridian ST Citation AT Reliance PF Reliance CM Definition PM ABG II Cemented	CoCr
Exeter Dedicace Legend V40™	Orthinox (Stainless Steel)

Notes

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Solely for use by Health Care Professionals

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Literature Number: **MITOT02EN**

MITOT02EN

MTX/GS 09/06

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