

Page No.	Text of New Surgical Technique Bold font = added to ST	Text of Old Surgical Technique <i>Bold Italicized font = text removed from ST</i>
	<p>component system utilizes a <i>Metasul</i> bearing, which is a forged CoCr on forged CoCr metal/ metal articulation. This is a proven low wear, low-friction articulation, which has been implanted in over 350,000 patients since 1988. No other metal/metal bearing has such a long and successful track record.</p> <p>This experience forms the basis of the latest generation of metal/metal articulations, the <i>Metasul</i> LDH large diameter head.</p> <p>Preservation of Bone Stock The <i>Durom</i> acetabular component has been designed to allow maximum preservation of bone stock. The 4mm wall thickness of the acetabular component is as low as practically possible to resist deformation (CoCr is a stiffer material than titanium material) under load while allowing a low clearance (diametrical mismatch) of the articulation. The cup subtends an angle of 165°, which is similar to the natural acetabulum. These features facilitate significant preservation of acetabular bone stock.</p> <p>[diagrams added]</p>	<p>This experience forms the basis of the latest generation of metal-on-metal articulations, the <i>Metasul</i> large-diameter head system.</p> <p><i>The Durom Acetabular Component, which mates with the <i>Metasul</i> LDH large diameter head, was designed to preserve bone stock and optimize range of motion. The wall thickness of the acetabular component is reduced to a strict minimum, and the cup sustains an angle of 165 degrees, comparable to that of the natural acetabulum.</i></p>
3	<p>Durable Fixation The <i>Durom</i> acetabular component has been designed to be press fit. It is a truncated hemisphere which derives initial fixation from a built-in 1–2mm press fit produced by under-reaming (Fig. 1). In addition, the presence of circumferential equatorial fins which lock into the acetabular rim result in an extra 1mm press fit at the rim only (Fig. 2).</p> <p>The surface coating of the <i>Durom</i> acetabular component is vacuum plasma sprayed pure titanium (<i>Porolock</i>® Surface Ti-VPS). This process, carefully controlled, allows a very high adhesive strength between the cobalt chrome substrate and the <i>Porolock</i> Ti-VPS coating, minimizing the potential risk of titanium particle generation. Titanium vacuum plasma sprayed coatings have been associated with reliable bone on-growth allowing durable secondary fixation.</p> <p>The circumferential fins, high surface roughness, and initial 2mm press fit allow initial implant stability while the <i>Porolock</i> plasma sprayed material promotes reliable scratch fit.</p> <p>Joint Stability Range of motion varies from 144° to 168° based upon the determined size of the acetabular component and the mating large diameter head. Range of motion is essential in total hip replacements to obtain unrestricted walking and optimized functioning of the hip, while reducing the potential risks of</p>	<p>The <i>Porolock</i>™ Tt VPS surface coating of the <i>Durom</i> acetabular component is pure titanium deposited using vacuum plasma spray technology. This process, carefully controlled, allows a very high adhesive strength between the cobalt chrome substrate and the <i>Porolock</i>Ti-VPS coating, minimizing the potential risk of titanium particle generation.</p> <p>The circumferential fins, high surface roughness, and initial 2mm pressfit allow initial implant stability while the <i>Porolock</i> plasma sprayed material promotes reliable scratch fit.</p> <p>Range of motion varies from 144° to 168° based upon the determined size of the acetabular component and the mating large diameter head. Range of motion is essential in total hip replacements in order to obtain unrestricted walking and optimized functioning of the hip, while reducing the potential risks of prosthetic impingement. The <i>Metasul</i> LDH large diameter heads are available from 38 to 60</p>

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	prosthetic impingement. The <i>Metasul LDH</i> large diameter heads are available from 38 to 60mm and must be used in combination with the <i>Durom</i> acetabular component.	mm and must be used in combination with the <i>Durom</i> acetabular component.
4	<p>Overview of Implant Sizing The actual diameter of the <i>Durom</i> acetabular component is 2mm greater than its labeled size. For example, a size 54 cup measures 56mm on the outer diameter at the coated area. This results in a 2mm press fit when reaming to 54mm and implanting a size 54 <i>Durom</i> Cup. Trials are line to line and do not feature any press fit (Fig. 3). [...]</p> <p>The inner diameter of a <i>Durom</i> acetabular component mates with a corresponding <i>Metasul LDH</i> large diameter head. A letter code confirms the appropriate combination. For example, a 54/N <i>Durom</i> Cup must be used with a 48/N <i>Metasul LDH</i> large diameter head. The <i>Metasul LDH</i> large diameter heads may be used with a wide range of Zimmer hip stems.</p> <p>Important information regarding Metasul Metal Pairings Cup systems intended for <i>Metasul</i> pairings may only be paired with the corresponding <i>Metasul</i> ball heads provided for this purpose. The operating surgeon must always make sure that the chosen cup and ball head match each other in accordance with this requirement. <i>Metasul</i> femoral heads are designated with a groove in the area of the taper, which is evident on the x-rays.</p>	<p>Range of Implants A <i>Durom</i> acetabular component is combined with a <i>Metasul LDH</i> large diameter head 6mm smaller. A letter code confirms the appropriate combination, for example: a 54/N <i>Durom</i> acetabular component must be used with a 48/N <i>Metasul LDH</i> large diameter head. The <i>Durom</i> acetabular component has been designed to be implanted without cement. The <i>Metasul LDH</i> large diameter heads may be used with a wide range of Zimmer hip stems. The actual equatorial diameter of an acetabular component is greater than its nominal diameter by 2mm. For example a 54N acetabular component has an actual outer diameter of 56mm. <i>If the last reamer used Is 54mm, the 54mm trial implant will be used (the trial implant is line to line with the reamer), and the stated size of the acetabular implant Is 54/N. As a result, there is a press-fit of 2 mm.</i></p>
6	<p>Patient Selection The <i>Metasul LDH</i> large diameter head when used in conjunction with a <i>Durom</i> acetabular component may be used for a wide variety of indications and is most appropriate for patients with good bone quality and adequate acetabular bone stock.</p> <p>Indications for Use</p> <ul style="list-style-type: none"> • Patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis. • Those patients with failed previous surgery where pain, deformity, or dysfunction persists. • Revision of previously failed hip arthroplasty. Total hip replacements may be considered for younger patients if any unequivocal indication outweighs the risk associated with the age of the patient and modified demands regarding activity and hip joint loading are assured. This includes severely crippled patients with multiple joint involvement, for whom an immediate need of hip mobility leads to an expectation of significant improvement in the quality of their lives. 	<p>[From ST found in the original 510K: <i>“The Durom acetabular component without cement may be used for a wide variety of indications. For example it is adapted for primary and secondary coxarthroses, subject to a slightly deformed or complete acetabulum. All the cases for which the quality of the acetabulum bone is insufficient to guarantee primary stability are contraindicated.”</i>]</p>

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	<p>Contraindications</p> <ul style="list-style-type: none"> • Patient’s physical conditions that would eliminate or tend to eliminate adequate implant support or prevent the use of an appropriately sized implant, e.g., previous surgery, insufficient quality or quantity of bone resulting from conditions such as cancer or congenital dislocation, metabolic bone disease of the upper femur or pelvis, femoral osteotomy revision, girdlestone revision, osteoporosis, osteomyelitis, neuromuscular compromise or vascular deficiency in the affected limb in sufficient degree to render the procedure unjustifiable (e.g., absence of musculoligamentous supporting structures, joint neuropathy) or other conditions that may lead to inadequate skeletal fixation. • Active infection of the hip, old or remote infection. This may be an absolute or relative contraindication. • Allergy to the implanted material, above all to metal (e.g., cobalt, chromium, nickel, etc.). • Local bone tumors and/or cysts. • Pregnancy. • Kidney insufficiency: In spite of the fact that there is no currently known causal relationship with increased serum cobalt and serum chromium levels, it is not possible to exclude completely any impairments of health due to low long-term additional loading. In the presence of chronic kidney insufficiency, however, a <i>Metasul</i> metal/metal pair should not be used or should only be used subject to close monitoring of progress (serum cobalt, serum chromium, serum creatine, BUN, echocardiography) in order to avoid increased serum cobalt and serum chromium levels and after carefully weighing the therapeutic benefits against the risks. 	
7	<p>Preoperative Planning</p> <p>Templates of the <i>Durom</i> acetabular component are available for preoperative planning. They are available in 120% magnification for conventional radiographs.</p> <p>Magnification is greater in heavier patients and less in thinner patients. It is necessary to combine these templates with that of the stem used by making the centers of rotation correspond. The final size of the prosthesis is determined during the surgical procedure.</p> <p>With the <i>Durom</i> acetabular component templates, it is possible to determine the most important parameters for planning the procedure:</p> <ul style="list-style-type: none"> • the physiological center of rotation (from the opposite side) • the ideal position of the acetabular component, in particular its depth, as well as its inclination angles • the approximate size of the implant 	<p>Templates of the <i>Durom</i> acetabular component are available for preoperative planning. They are available in 120% magnification for conventional radiographs <i>and 100% magnification for digital x-rays</i> (Fig.1 (a & 1b)).</p> <p>Magnification is greater in <i>obese</i> patients and less in thinner patients. It is necessary to combine these templates with that of the stem used by making the centers of rotation correspond. The final size of the prosthesis is determined during the surgical procedure.</p> <p>With the <i>Durom</i> acetabular component templates, it is possible to observe <i>several key criteria</i> when planning the procedure:</p> <ul style="list-style-type: none"> • the physiological center of rotation (from the apposite side) • <i>the ideal position and depth of the acetabular component as well as its inclination, which should be between 40 and 45° depending upon specific patient anatomy</i>

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	<p>Note: Because the risk of dislocation of the <i>Metasul LDH</i> large diameter head is much lower than lesser diameter articulations (e.g., 28 and 32mm), the acetabular component can be positioned to better fit the acetabulum to an extent from the conventional orientation to maximize bony support and fixation. Placement will generally fall within 40°-50° abduction angle and 10°-20° anteversion angle.</p>	<ul style="list-style-type: none"> • the approximate size of the implant
8	<p>1. Acetabular Preparation The acetabular labrum is completely excised, and any large peripheral osteophytes are removed. The stump of the ligamentum teres is excised, and the true floor of the acetabulum is identified. Technique Tip: It is important to excise soft tissue to visualize the entire rim of the acetabulum. This will help when using trial cups to assess the depth reamed. It will also reduce the likelihood of soft tissue entrapment which may prevent the cup from seating during cup insertion.</p> <p>[diagrams added]</p> <p>2. Reaming <i>Note: This technique demonstrates the use of 180° hemispherical reamers to prepare the acetabulum. If using reamers other than 180° hemispherical reamers, visual cues to assess reaming should be adjusted (Fig. 4). Sequential reaming is carried out with hemispherical acetabular reamers. It is important to ream to a spherical socket. Hold the reamer steady and apply pressure in the same direction that the prosthesis will be implanted. Orbital reaming should not be utilized. Start with a reamer 2 sizes smaller than the templated implant size or if a small reamer is used to create a center of ream, care should be taken not to over medialize.</i></p> <p>One should not over-deepen the acetabulum. The reamers subtend an angle of 180° whereas the acetabular components and trials subtend an angle of 165°. This means that the acetabular trials are nominally 2.3–3.8mm shallower than the corresponding reamer, depending on diameter (Fig. 5). Consequently, the acetabulum should only be deepened until the edge of the hemispherical reamer is almost flush with the true bony rim of the acetabulum. The socket will then be deep enough to fully insert the corresponding <i>Durom</i> acetabular component taking into account the 2mm diametrical (1mm radial) oversizing of the implant compared to the reamer.</p> <p>Note: Actual reaming depth should only be assessed using the trials and not the reamers.</p>	<p>Surgical Technique <i>Surgeon preference will dictate the choice of surgical approach used to implant the Durom Acetabular Component.” [In the original 510(k) version, this section is introduced with the sentence, “Every approach of hip articulation and prosthetic hip replacement is usable for positioning the Durom hip components. It will be chosen according to the surgeon's preferences.”]</i></p> <p>Acetabular preparation The acetabular labrum is excised and significant peripheral osteophytes are removed. The stump of the ligamentum teres is excised and the true floor of the acetabulum identified.</p> <p>Reaming <i>Sequential reaming is carried out with the hemispherical acetabular reamers (Fig. 2). The Durom acetabular component has a truncated hemisphere of 165°. It is, therefore, not necessary to over deepen the acetabulum. Assuming that a near hemispherical cavity has been created and adequate cancellous bone has been exposed, reaming is stopped. In case of sclerotic acetabular bone, a 1 mm press-fit should allow the acetabular component to seat properly with sufficient primary stability.</i></p> <p>Note: During the acetabular preparation, one must be particularly careful in order to prevent excessive reaming of the bone and to maintain a hemispherical cavity (Fig. 3).</p>

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	<p>Technique Tip: In hard bone it is advisable to use reamers in 1mm increments when approaching the definitive acetabular size.</p>	
9	<p>3. The Use of the Acetabular Trial Implant</p> <p>The accuracy of reaming and the optimal position of the implant are assessed using an acetabular trial the same size as the last used even numbered reamer. The acetabular trials are not used to test stability. They are “line to line” with the same-sized reamer and should seat within the prepared acetabulum. The diameter of the corresponding definitive acetabular component is 2mm greater than the trial cup, generating the press-fit. The trial cup should be placed parallel to the anatomical bony rim of the acetabulum following the anterior and posterior walls. Anteversion and inclination angles are noted for final implantation of the acetabular component.</p> <p>Note: It is important to trim any rim osteophytes to within 2–4mm of the true rim, as they can block the full insertion of the definitive implant.</p> <p>Following the trimming of rim osteophytes it should be possible to reinsert the acetabular trial in the desired position with gentle tapping. If there is still resistance to fully seating and removing the acetabular trial, this indicates that the rim is too tight and that it will be difficult to insert the corresponding acetabular component.</p> <p>Note: If the acetabulum is small or the bone is sclerotic, re-reaming using a 1mm larger reamer is appropriate, resulting in a nominal overall 1mm press-fit. The amount of press fit used should be determined at time of surgery and based upon bone quality.</p> <p>Alternatively, “focal reaming” of the tight spots of the acetabular rim can be used: the trial cup is fully inserted and then rocked to determine the pivot points where the rim is over-tight. These are usually the areas of sclerotic bone adjacent to the anterior-inferior iliac spine and the ischium (Fig. 6). The tight spots are relieved by gently placing a small diameter reamer (e.g., 46mm) against the sclerotic bone, removing just ½ to 1mm of bone locally (Fig. 7). Attention: Care must be taken not to remove excess bone when focal reaming.</p> <p>At the completion of acetabular preparation, reassess with the trial cup. At this time, it should be possible to fully seat the trial in the desired orientation with light taps of the mallet. There should be 1–2mm of peripheral bone protruding (anterior and posterior walls) for engagement</p>	<p><i>Positioning of the trial acetabular implant</i></p> <p>The accuracy of the reaming is checked using an acetabular trial of the same size as the last reamer used (Fig. 4). <i>Any remaining protruding rim osteophytes are removed and acetabular cysts grafted appropriately.</i></p> <p><i>The acetabular trials have the same dimensions as the reamers.</i> They are not used to test stability. The trials are used to evaluate the quality of acetabular preparation. The nominal size of the <i>Durom</i> acetabular component is the same as the acetabular trial: e.g. a 54mm acetabular trial component will be used with implant size 54/N. The outer diameter of the implanted acetabular component is larger than the acetabular trial allowing for a 2mm press fit</p>

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	<p>of the equatorial fins of the implant.</p> <p>Note: The acetabular implant is 1mm taller than its corresponding trial.</p> <p>Technique Tip: When final press fit and cup position are determined with the trial cup, it is important to note landmarks of cup depth, abduction angle and anteversion. At this point it is helpful to leave the trial cup in final position until the <i>Durom</i> acetabular component impaction is imminent for a visual reference to cup placement.</p>	
10	<p>Acetabular Implantation</p> <p>1. Mounting the Acetabular Component The definitive acetabular component is placed on the disposable cup holder, which is provided with the packaging (Fig. 8). The appropriately sized cup inserter is then mounted on to the acetabular component. The threaded rod is tightened securely with the tightening bar and the inserter cap is then screwed onto the cup introducer handle (Fig. 9).</p> <p>2. Insertion of the Acetabular Component Any remaining soft tissue which may prevent the acetabular component from seating during insertion should be excised.</p> <p>The acetabular component is impacted into the prepared acetabulum using a heavy mallet. As much of the circumferential equatorial fins as possible should engage in the bony rim to ensure primary stability.</p> <p>Because the risk of dislocation of <i>Metasul LDH</i> large diameter head is much lower than traditional diameter articulations, the acetabular component can be positioned to better fit the acetabulum to an extent from the conventional orientation to maximize bony support and fixation. Placement will generally fall within 40°–50° abduction angle and 10°–20° anteversion angle.</p> <p>It is important to note that the CoCr is a stiffer material than titanium, and more force may be required to fully seat the acetabular component during final cup impaction.</p> <p>Attention: It is critical that the fins fully engage in the anterior and posterior walls, not only to maximize primary stability but also to reduce the risk of psoas tendon irritation anteriorly. On occasion, particularly in cases of developmental hip dysplasia, the rim of the implant will be exposed in the postero-superior quadrant of the acetabulum. This is acceptable (Fig. 10).</p> <p>3. Final Impaction of the Acetabular Component</p>	<p><i>Impaction of the acetabular component</i> <i>The definitive acetabular component is attached to the appropriate cup inserter and the threaded rod is tightened securely with the large tightening bar. The impactor head is then screwed on to the cup-coupling handle. The acetabular component is impacted into the prepared acetabulum in approximately 10 to 15° of anteversion and a 45° of inclination or abduction (Fig. 5).</i></p> <p>Final impaction of the acetabular component When the acetabular component is fully seated, (Fig. 6) the cup inserter is removed</p>

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	<p>When the acetabular component is seated and stable, the cup inserter is removed by unscrewing the inserter cap and loosening the threaded rod with the tightening bar. The appropriately sized final cup impactor should be used to complete the insertion of the acetabular component. The key to final implant placement is to engage as much of the equatorial fins as possible and to fully seat the cup to the level previously identified using the trial (Fig. 11).</p> <p>Note: Only the cup impactor should be used for final impaction of the acetabular component.</p> <p>Warning: The <i>Durom</i> acetabular component should not be adjusted in the acetabulum after impaction. Moving the cup will dislodge the circumferential equatorial fins, disrupt the prepared bed of the acetabulum, and will make it difficult to re-engage the fins in the rim of the acetabulum. This can compromise fixation of the cup.</p> <p>Fig. 8 <i>Durom</i> cup and disposable cup holder. Fig. 9 Mounting the acetabular component.</p>	<p>by unscrewing the <i>impactor head</i> and loosening the threaded rod (Fig. 7a & 7b).</p> <p><i>If necessary, the appropriately sized cup impactor can be used to complete the insertion of the acetabular component.</i></p>
11	<p>Use of the Trial Head Use of the Trial Head with its Head Adaptor</p> <p>The femoral trial head corresponding to the inner diameter of the <i>Durom</i> acetabular component is selected and the appropriately sized trial head adapter is placed into the femoral head. The femoral head with trial adapter is mounted onto the femoral stem, ensuring that the latter is fully seated on the femoral stem taper (Fig. 12).</p> <p>The hip is then reduced. The length of the neck, the ligament tension and the range of motion are checked. If the results are not acceptable, the same procedure must be repeated with different sizes of head adapters. Following reduction, the circumference of the acetabular component is checked to make sure there is no entrapment of soft tissue.</p>	<p><i>Assembly of the Metasul LDH large diameter head and adapter</i> Use of the trial head and adapter</p> <p><i>Assemble the appropriately sized trial head adapter on the femoral stem, ensuring it is sitting flush on the taper. The femoral head trial corresponding to the inner diameter of the <i>Durom</i> acetabular component is then attached to the adapter (Fig. 8).</i></p> <p><i>The hip is reduced and neck length, ligament tension and range of motion are checked. If the results are insufficient, the same procedure must be repeated with different sizes of head adapters.</i></p>
14	<p>Final Reduction When using the posterior approach, the acetabular component is exposed by retraction of the posterior capsular flap. Reduce the <i>Metasul LDH</i> large diameter head with the femoral pusher while applying longitudinal traction and external rotation of the leg (Fig. 21). It is important to ensure that the femoral head does not make contact with the edge of the acetabular component, as this could result in scratching of the femoral head (Fig. 22).</p>	

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	<p>Note: If a cemented stem is used, the femoral head should be cleaned with pulsed lavage and wet swabs.</p> <p>Following reduction, the circumference of the acetabular component is checked to make sure there is no entrapment of soft tissue. The hip is then checked for range of movement, impingement, stability, and leg length.</p>	
21	<p>1 Crowninshield RD, Maloney WJ, Wentz DH, Humphrey SM, Blanchard CR. Biomechanics of large femoral heads what they do and don't do. Clin Orthop Rel Res. 2004; 429:102-107.</p> <p>2 Grübl A, Marker M, Brodner W, Giurra A, Heinze G, Meisinger V, Zehetgruber H, Kotz R. Long-term follow-up of metal-on-metal total hip replacement. J Orthop Res. July 2007.</p> <p>3 Rieker CB, Schön R, Köttig P, Development and validation of a second-generation metal-on-metal bearing. J. Arthrop. 2004; Vol 19 No. 8 & Suppl. 3; p 5-11.</p> <p>4 Data on file at Zimmer.</p>	<p><i>Tipper JL Firkins, PJ. Ingham E., Fisher J. Stone MH, Farrar, Quantitative analysis of the wear and wear debris from low and high carbon content cobalt chrome alloys used in metal on metal total hip replacements, Journal of Materials Science: Materials in Medicine 10 (1999) 353-362.</i></p>