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The question: Cemented or uncemented?

The decision between a cemented and an uncemented hip stem is a choice that must be made by the surgeon. Based on the personal experience by the designing surgeon implanting over 6000 CLS stems, it was possible to carry out extensive research into the indications for this stem as well as its limitations. The results obtained with the CLS stem since 1984 are extremely encouraging. We are currently seeing a broadening of the range of indications in favour of uncemented stems, both in primary and revision surgery. Even though excellent results have been achieved, (even under critical conditions) it is still recommended that surgeons use a set of standard, reliable criteria to help make the decision between cemented and uncemented stems.
In 1985, an indication protocol was established that is based on the assessment of four clinical and radiological parameters in the patient investigated. Each parameter is given a point score. The final value obtained from the sum of the points establishes the indication and thus provides a valid guideline for the surgeon. The parameters are age, gender, severity of the osteoporosis and the anatomical characteristics of the femur.
Parameter No. 1: **Age**

As far as skeletal changes are concerned, it is generally known that age cannot be considered as a purely chronological parameter, but has to be assessed from a biological point of view. In simple terms, it can be said that for patients under the age of 50 years, a cementless stem is the routine solution, while after the age of 70 a cemented stem is generally preferred.

Points allocated:
- >70 years: 4 points
- 61–70 years: 2 points
- 51–60 years: 1 point
- <50 years: 0 points

Parameter No. 2: **Gender**

Due to the increasing osteoporosis resulting from the hormonal changes occurring during menopause, older women generally have poorer bone quality.

Points allocated:
- Women: 1 point
- Men: 0 points
Parameter No. 3: **Osteoporosis**

Severe osteoporosis represents a major disadvantage in regard to the primary stability of the implant or requires the use of an over-dimensioned stem with anchorage in the lower metaphyseal and diaphyseal region. This in turn has a negative effect on the blood supply to the bone. Radiological methods such as computer tomography and densitometry are available for the assessment of the severity of the osteoporosis. A suitable method for a conclusive assessment is the modified analysis of the trabeculae in the neck of the femur according to Singh – a process that is easy to carry out.

**Femoral-neck Index**

On the basis of these assessments, four degrees of severity of osteoporosis can be defined:

- **Severe (Singh 1–2):** 4 points
- **Moderate (Singh 3–4):** 2 points
- **Slight (Singh 5–6):** 1 point
- **Physiological (Singh 7):** 0 points

Parameter No. 4: The anatomy of the femur

**Morpho-cortical Index**
Experience shows that this index provides more information parameters. It comprises two variables, which do not always correlate with one another, in one single value:
- The morphology of the femur
- The thickness of the cortex

In regard to morphology, it is possible to differentiate between three categories of femur:
- Trumpet shape
- Cylinder shape
- Dysplastic femur

Because of its morphology, the trumpet-shaped femur provides the ideal conditions for an uncemented implant. The cylindrical femur requires an adequate cut in the subtrochanteric region and the removal of metaphyseal bone during the rasping process. The mechanically supportive cancellous bone and the cortex of the isthmus of the calcar, which forms the basis for the anchorage of the stem, have to be partly removed.

The morpho-cortical index (MCI), is defined on a standard x-ray picture. It is calculated from the correlation of the extracortical diameter of the femur, measured at the medial tip of the lesser trochanter to the intracortical diameter, measured 7 cm further in the distal direction.
The MCI is calculated using the following formula:

\[ \text{MCI} = \frac{\text{CD}}{\text{AB}} \]

**CD** = Distance between the outer boundaries of the lateral and the medial cortex. The measurement is made at the level of the tip of the trochanter, vertical to the axis of the femur.

**AB** = Diameter of the medullary cavity. The measurement is made 7 cm distal from the CD line, vertical to the axis of the femur.

The MCI in this absolute form can only be used if it was calculated in a standard x-ray picture with the legs in the normal 0 position and with rectilineal a-p irradiation.

The point-scores of the MCI:
- MCI ≤ 2.2: 4 points
- MCI > 2.3: 2 points
- MCI > 2.7: 1 point
- MCI ≥ 3.0: 0 points

**Final assessment:**
In cases where long-term cortisone therapy is envisioned, for example in rheumatoid arthritis, one point must be added as an additional risk factor.

0–4 points: **cementless stem**

5 points: **questionable indication**

≥ 6 points: **cemented stem**
Conclusion: There is a broad indication for uncemented anchorage.

The uncemented stem in general and the CLS stem in particular have definitively proven their worth. In comparison with the cemented stem, the uncemented solution is far more bone conserving. This becomes an important factor if revision surgery is necessary.

The insertion of the uncemented stem is less invasive and takes the biomechanics of the femur into account. The bone and the prosthesis combine to form a unit. As a result, the blood supply and vitality of the bone are maintained.

In principle, the uncemented stem is preferably used in younger patients. It is, however, not contraindicated in the elderly – especially for patients in poor general health. It can be implanted more rapidly and there is no thermal damage to the tissue due to the cement.

The use of a cemented stem is nevertheless justified in elderly patients for a number of reasons: The life expectancy of the patient is often shorter than the average survival time of a cemented stem. In the presence of poor bone quality, the cement allows unproblematic correction of defective manipulations. With cementing, faster restoration of the ability to walk is also to be expected, since – at least within certain limits – it does not involve the reparative phase, which in the case of the cementless stem leads to the definitive anchorage of the bone. Finally, the economic factor plays a role that is not to be underestimated.

It can generally be said that if one adheres to the classical indications – while still allowing the possibility of further indications in the future – good and very good results can be obtained. In this respect, the use of the MCI is of fundamental importance because it follows the basic biomechanical ideas used in the design of the CLS prosthesis. It has been proven that the CLS can be readily combined with the trumpet shaped femur. In contrast, with a cylindrical medullary cavity, it is normally necessary to use a more invasive prosthesis, which has an unfavourable bone-prosthesis interaction.

Comparison has shown that the MCI, like the cortical index (CI) after Gruen are good indicators for the quality of the bone. There seems to be a connection both between the CI and the MCI and between the MCI and the measurement of the mineral content of the bone by the Dexa method.
The indications for the CLS cup  
Bone quality as the deciding factor

The indications for this acetabular cup are rather varied. The CLS expansion cup is indicated in practically all forms of idiopathic coxarthrosis, ischaemic necrosis, rheumatoid arthritis and – with very good results – in protrusive forms. It is also suitable in replacement implantations following arthrodesis and after fractures of the acetabulum.

With an adequate surgical technique, the expansion cup can also be used for revisions in cases with major defects of the floor of the acetabulum; for primary implantations in cases with moderate osteoporosis; and for slightly dysplastic hips.

Insufficient peripheral anchorage constitutes a contraindication for the CLS cup.

In order to achieve an adequate press-fit in the region of the equator; adequate peripheral anchorage is essential. The absence of a rim segment of the acetabulum constitutes a contraindication. If the defect involves \( \frac{1}{4} \) of the rim of the acetabulum or more, then the contraindication is absolute, whereas a defect involving less than \( \frac{1}{6} \) of the circumference is well compensated and does not require any special precautions. The CLS cup can also be used in cases with a defect of the rim of the acetabulum of more than \( \frac{1}{6} \) and less than \( \frac{1}{4} \). In these cases, special attention has to be paid to the flanges. All six flanges must be supported by bone.

Due to the biomechanics of the pelvis, when changing from the sitting to the standing position, peak loading is exerted in the postero-superior quadrant. In the presence of inadequate bone structure, this zone has to be treated with special care. In the latter case, the lack of support at the rim of the acetabulum must not involve more than \( \frac{1}{6} \) of the circumference.
Within the framework of the preoperative planning, the stem size, the optimal anchorage of the stem in the medullary cavity and the correct position of the acetabular and femoral components are determined in order to ensure equal leg length.

At the start of the preoperative planning, three lines are drawn on the X-ray picture: The tangent of the two ischia forms the base line. A second line is drawn through the floors of the two acetabulae, and a third between the lesser trochanters. On the side that is not to be operated on, the center of rotation of the joint is determined. Then the distances between the joint, baseline and «teardrop» are drawn. In addition, the longitudinal axis of the pelvis is also drawn.
The planning steps, with an example of unilateral coxarthrosis

**Determination of the size and position of the cup**
The center of rotation of the joint to be operated on is determined by transposing the two lines that have been drawn on the opposite side. The cup template is then placed on the side that is to be operated on. The position of the acetabular components is determined by the outline of the cup, the center of rotation that was determined, the level of the «teardrop» and the required abduction angle of 40° – 45°.

**Drawing in of pelvis and cup**
The tracing paper is placed on the x-ray picture and the template. The longitudinal edge must run parallel to the vertical axis of the pelvis. The pelvis and the cup are drawn in and then the tracing paper removed from the x-ray.

**Determination of the size and position of the stem**
The stem template is placed on the femur so that the stem fits into the medullary space displaying the correct type of anchorage. The size of the stem must be selected so that at least ¾ of the proximal ribbed structure is anchored in the cancellous bone. Ideally, one of the three T lines touches the tip of the greater trochanter.
**Height of the pelvis**

The femoral template is to be left in place. The drawing of the pelvis is placed with the acetabular components made in Step 2 on the x-ray picture. If lengthening of a leg is necessary, the drawing of the pelvis lies higher than the pelvis on the x-ray picture, by the difference in the length to be corrected. In the case of planned shortening of a leg, the drawing must be correspondingly lower by the distance to be corrected. Stem size and length of neck must be selected so that the differences correspond to the measurements that are to be corrected.

**Final result**

The outlines of the femur and the cortex and the selected implant/ball-head combination are drawn on the transparent paper. The distance between the proximal end of the stem section and the lesser trochanter is measured and entered. The line from the shoulder of the prosthesis to the greater trochanter is extended and measured. The line between the tip of the greater trochanter and the center of rotation is drawn in.
Case study

preoperative a-p

postoperative
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Surgical Technique
Based on the suggestion by the designing surgeon

1 Positioning of the patient:
Placement in the lateral position*
The patient is positioned on the operating table with one pressure pad on the pubic bone and one on the sacrum. In subsequent positioning, it is important that the pelvis is not lowered, either sideways or in the caudal direction, and that it is fixed securely. The leg on the opposite side is bent 45° at the hip and 90° at the knee, which helps to stabilize the position of the patient.

* Different surgical approaches are possible. The following describes the author’s recommended approach, however any other approach can be used.
2 Surgical approach to the hip: Incision
The posterolateral approach is recommended. The joint is bent at an angle between 30° and 40°. A rectilinear incision is made to the tip of the greater trochanter and is then continued for about 6 cm on the diaphysis. After transection of the subcutis, the Fascia lata is exposed.

3 The approach to the deeper layers
The Fascia lata is incised and dissociated of the fibers of the Gluteus maximus muscle, and the Charnley wound retractor is placed directly on the Fascia.

In this way, the plane of the external rotator muscles and the tendon attachment of the Gluteus maximus muscle are exposed on the Linea aspera of the femur. The tendon attachment is partly released in order to relax the soft parts. This favours the displacement of the femur in the ventral direction and also its internal rotation.
4 Transection of the external rotator muscles and dislocation of the hip
After inserting a bent Hohmann retractor under the Gluteus medius muscle, the tendon of the M. piriformis is located and transected, as are some of the tendons of the external rotator muscles. The joint capsule is then opened from the dorsocranial direction. With a combined flexion, adduction and internal rotation movement, the head of the femur can now be dislocated from the acetabulum.

5 Osteotomy of the neck of the femur
The lesser trochanter serves as reference point for the osteotomy plane on the neck of the femur, which was already included in the preoperative planning. The level of the osteotomy is influenced by the anteverision of the neck of the femur: the greater the anteverision, the lower the level of the osteotomy. Normally, it proves an advantage to retain 1 to 1.5 cm of the neck of the femur. This creates a sheath into which the proximal, ribbed part of the stem can fit.
The next step is the osteotomy with the reciprocating saw. Starting from the medial mark, the upper edge of the neck of the femur is reached at the point where it rises from the mass of the trochanter. It may be necessary to continue the osteotomy with a cut continued further upwards, parallel to the axis of the femur.
6 Exposure of the acetabulum

After the leg has been moved back into the neutral position, the anterior and lower Hohmann levers are applied. The anterior lever, on the upper front rim of the acetabulum below the 2 o’clock position, immediately under the tendon of the Rectus femoris muscle, moves the femur in the ventral direction and allows a broad view into the acetabulum.

This manoeuvre is facilitated by the partial transection of the tendon of the Gluteus minimus muscle and of the fasciculus of fibers, which strengthens the capsule, above, and fuses with the Gluteus medius muscle.

The lower wound retractor, which is applied under the Pulvinar acetabuli, corresponds to the upper edge of the Foramen obturatum. It smoothes the remaining joint capsule and facilitates its removal. This provides an optimal view of the rim of the acetabulum.
7 Preparation of the acetabulum and determination of the center of rotation

The correct positioning of the center of rotation creates the necessary conditions for restoring the hip's «physiological» function. However, with the altered anatomical characteristics associated with the different pathological conditions the position of the cup prosthesis always remains a challenge. With the reaming of the acetabulum, depending on the available bone, it is possible to optimize the position of the center of rotation.

The center of rotation is established in the course of the preoperative planning. The measurement of the planned countersink must be reproduced in the patient as accurately as possible.

Starting from the reference point in the floor of the acetabulum, the Fossa acetabuli is notched in the center of the acetabulum, using the smallest reamer or, better, the gouge. At the same time, part of the subchondral bone, corresponding to the planned countersink, is removed. Normalization of the acetabulum (or geometrical rounding, with disappearance of the reference point on the roof of the acetabulum) is achieved by using reamers of increasing diameter until the planned measurement is reached.
8 Peripheral anchorage of the expansion cup

Fixation by means of expansion was developed on the basis of a precursor of the original Press-Fit system, the principal feature being the peripheral anchorage obtained through a push button effect. This idea was combined with the modern Press-Fit concept and optimized in the expansion cup:

1) On the one hand, it is a true press-fit, because the anchorage cusps of the cup are slightly over-dimensioned, compared with the reamed acetabulum.

2) On the other, the peripheral anchorage is accentuated by the position of the anchorage cusps along the circumference as well as by the mechanism of the expansion: as the cup is relaxed and expands when releasing the insertion instrument, the load is shifted from the area of the pole to the equator of the cup.

The reaming must be sufficiently deep to allow complete fixation of all three rows of cusps. The fixation by three rows of fixation cusp is optimal, although clinical experience shows that fixation of only the first two rows of cusps is required.

Possible bone cysts in the area of the acetabular rim are filled with bone chips produced by the deep reaming. Care must also be taken to ensure that no eccentricity is created through the final work with the reamer. It is therefore advisable to carry out the final reaming work by hand, in addition, it is recommended to align the axis of the reamer according to the assumed definitive orientation of the cup.
9 Positioning of the acetabular cup

Only after the creation of a regular hemisphere can the cup be inserted. If during the reaming, the lamina has been reached, the floor of the acetabulum is lined with bone chips produced by the reaming.

The size labeling on the CLS titanium shells corresponds to the size labeling of the reamers. It is now compressed with the appropriate cup-positioning instrument until the individual segments are in contact with one another at the equator. This is how the desired under-dimensioning is obtained, in order to be able to place the implant in the acetabulum without driving it in.

Using the handle of the instrument, the optimal position, with an abduction angle of 45° and 15°–20° anteversion, can easily be obtained. Before relaxing the positioning instrument, the definitive position can be checked with a special orienting instrument. By turning the locking sleeve, while firmly holding the handle, the compression on the shell is released. The pressure decreases and by expanding the cup achieves a firm fit. By turning the chuck through 30°, the hooks of the compression forceps disengage from the petals of the cup and release them.

**Important:**

In order to retain the strength of the cup, it should not remain under compression for longer than 1 minute. It is advisable to anchor the implant in the acetabulum, using the cup-positioning instrument, immediately after compression. The titanium CLS shell may only be compressed twice.
10 Expansion of the CLS shell

The positioning of the shell and the possible distance behind the shell from the acetabulum must be checked: a space of a few millimeters is within the acceptable range, and the acetabulum may be filled in with reamed-out cancellous bone to fill any void behind the cup. If any osteophytes are pushing against the implant, it is advisable to remove them before the final expansion is carried out.

By turning the expansion cone in the counterclockwise direction, the screw canal can be correctly filled without applying force. Then, maximum expansion is achieved by turning in the clockwise direction, while keeping the knob on the handle pressed. By turning in the counterclockwise direction, the instrument can be removed.

It can be clearly seen how the cusps that are pressed into the surrounding bone ensuring a high level of primary stability.
11 Fixation of the insert

Before the insert is placed, it must be checked as to whether marginal osteophytes in the acetabulum and possible remains of the capsule can interfere with the correct positioning of the insert. The Sulene™ insert is mounted on the setting instrument and in this way can be correctly positioned in the cup.

By turning in a counter clockwise direction, the thread takes purchase and by turning in the opposite direction, the insert is then screwed in as far as possible manually.

The setting instrument is then withdrawn and the insert is finally screwed-in using the wrench and the insertion instrument. Finally, the parallel positioning and the contact between the rim of the acetabular insert and the metal shell must be checked.

After careful rinsing, the cup is protected with a gauze swab and the Hohmann retractor removed. Now the stem component can be implanted.
12 The CLS stem and the press-fit principle

With the CLS stem, the primary stability is obtained through the press-fit principle. The precondition for the functioning of this principle is the way in which the two components oppose one another. In order to guarantee the stability of the interaction between them, the opposing surfaces of the bone and the prosthesis must be highly congruent, which is only possible with a linear design. The CLS stem, with its three-dimensional conical shape, is pressed into the tough-elastic implant space in the corticocancellous bone of the metaphysis, which has been prepared with slightly smaller dimensions. For this reason, the author has carefully developed a rasp system that makes the surgical procedure reproducible.

The conical shape of the stem guarantees remarkable primary stability and ensures that this stability is maintained thanks to the self-stabilizing properties of the implant. In addition, the structure of the bone surrounding the prosthesis shows that the conical shape of the implant favours a largely proximal transfer of stress.

For implantation of the CLS 145° Classic and CLS 135° stems, the same instruments and the same surgical technique are used. The rasp has a neck angle of 145°. Therefore, with the implantation of a CLS 135° stem, the eccentric test-head should be used. The following comparative table provides an overview of the neck-lengths and the offsets. The top face of the morse taper cannot be used as a reference plane to determine the position of the stem.

<table>
<thead>
<tr>
<th>Size</th>
<th>CLS 145°</th>
<th>CLS 135°</th>
<th>Difference</th>
<th>Difference in length (x)</th>
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<td>51.9 mm</td>
<td>4.1 mm</td>
<td>5.7 mm</td>
</tr>
</tbody>
</table>
13 Preparation of the medullary cavity of the femur

The leg is turned inwards, by internal rotation of up to 90°, which is combined with bending and adduction of the hip. The lower leg is bent at 90° to the thigh. This provides a spatial reference point, in order to be able to establish the anteversion of the femoral component of the prosthesis and its position parallel to the cortex.

In order to facilitate the exposure of the mass of the trochanter, a Hohmann retractor is placed under the lesser trochanter as a lever, taking care to ensure that the iliopsoas tendon is not injured. A second lever is placed at the tip of the greater trochanter in order to move the muscle to the side of the diaphysis and to expose the remaining lateral portion of the neck of the femur. This has to be removed for the correct alignment of the stem.

The remaining portion of the neck of the femur and a small part of the greater trochanter can be removed with the instrument provided for this purpose or directly with the saw.
14 Use of the awl and rasps in preparation of the space for the prosthesis in the femur

The proximal notches on the awl mark the height of the shoulder of the implant. The awl has to be inserted laterally and slightly dorsal. The attachment of the M. piriformis provides a reference point for this. As a rule, this corresponds to the point at which, in the preoperative planning, the tangent of the endosteal edge of the outer cortex meets the greater trochanter. It provides an accurate, measurable conception of the obstacle to the prosthesis.

After the medullary space has been prepared in this way, the awl is inserted deep, for centering of the canal, taking care to ensure that it is pressed in the direction of the greater trochanter. The aim is to follow the predetermined line towards the lateral cortex, parallel to the axis of the femur and to avoid a varus deformity.

The bed for the stem is now prepared, using rasps of increasing size, until the highest possible degree of stability is obtained. The preoperatively measured distance between the proximal shoulder of the prosthesis and the trochanter major, serve as orientation.
The desired stability is based on the concept of a press fit in the cortex and cancellous bone. This is why the rasps have smooth zones for compression of the cancellous bone and cutting zones for rasping of parts of the cortex.*

After the surgeon has established the size of the prosthesis during the planning, the definite size is determined by progressive, stepwise rasping, starting with 3 to 4 smaller rasp sizes. In this way, using the increasing dimensions, the cancellous bone is compressed. Where necessary, the cortex has to be reamed. The rasps are inserted, with small, precise hammer blows, and then withdrawn.

The final, definitive reaming must be carried out only with the rasp planned for this. The last rasp should be operated manually.

* The rasp is designed to lead to a defined smaller dimension in relation to the internal morphology of the femur. Generally, it is underdimensioned in the proximal portion of the rasp – that is, the portion with which cancellous bone is to be compressed.

In the middle portion of the rasp, corresponding to the subtrochanteric zone – that is, where a point of contact with the cortex is desired, there is complete congruency. At the distal end, the rasp is of a slightly smaller dimension, in order to prevent stress peaks on the end of the prosthesis. The design of the cutting tool is aimed at meeting these requirements.
15 Alignment of the stem

With the first rasp, care must be taken to ensure a correct anteversion (10–15°). This can be monitored by means of the handle of the rasp. The neck of the femur may display a pathological anteversion, which the surgeon has to take into account and possibly rectify. This can be done, for example, by a lower osteotomy of the neck of the femur or by controlled splitting. According to the safety-margin concept, the sum of the anteversion of the femur and the anteversion of the acetabulum must be 25 ± 7°. One should, however, try to keep the angle between the two components of the prosthesis as close as possible to the physiological angle.

The reference parameter for the correct alignment of the rasp is the plane running through the axis of the diaphysis and parallel to the condyles of the femur. Keeping the angle of the bend of the lower leg at 90°, vertical to the floor, the rasp is turned 15° downwards. The ideal angle, which is formed from the lower leg and the long bar of the rasp, can be checked visually.
16 Insertion of the stem
After removal of the rasp, a prosthesis of the appropriate size is inserted and driven in until it is completely stable. In this process, it is important to proceed with the necessary light touch. This is learned with experience. It should be remembered that because of the wedge mechanism, an excessive load may be exerted that can bear on the trochanter to the point that it might cause a fracture.

It is important to adjust the force of the hammer blows, according to the quality of the bone and to stop the hammer blows immediately if you hear a change in the sound of the blows, from dull (cancellous bone) to sharp (cortex).

17 Assembly of the modular head and repositioning
After insertion of the prosthesis, the definitive neck of the prosthesis is established on the basis of the measurements laid down in the preoperative planning and by trial repositioning using trial heads.

The last step in the assembly is the fitting of the previously defined head onto the stem of the prosthesis. After thoroughly cleaning the cone, the head of the prosthesis is placed with a slight turning movement and fixed with one blow of the hammer.

After the repositioning, the surgeon checks the range of motion and stability of the joint. This should be checked with both internal and external rotation.

With the placing of drains and suturing of the different layers, the operation is now complete.
Femoral Stems for Total Hip Arthroplasty

A femoral stem component is used in conjunction with a femoral head component for replacement of the proximal femur in cases:

- A femoral stem component is used in conjunction with a femoral head component for replacement of the proximal femur in total hip arthroplasty. Femoral stems are available in different designs, materials, sizes, neck lengths and taper sizes. A taper is incorporated in the design of the stem to interlock it with the femoral head.

1.1 Indications/Contraindications for Use

Indications and contraindications for the use of these components may be relative or absolute and must be carefully weighed against the patient's entire evaluation and the possibility for possible alternative procedures. Patient selection should be largely dependent on patient's age, general health, conditions of available bone stock, prior surgery and anticipated further surgeries. Prosthetic replacement is generally only indicated for patients who have reached skeletal maturity.

A. Indications

1. Patient conditions of noninflammatory degenerative joint disease (NJD) D), e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD) D), e.g., rheumatoid arthritis.

2. Those patients with failed previous surgery where pain, deformity, or dysfunction persists.

3. Revision of previously failed hip arthroplasty.

Total hip replacements may be considered for younger patients if any unequivocal indication outweighs the risks 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.

B. Contraindications

1. 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.

2. Active infection of the hip, old or remote infection. This may be an absolute or relative contraindication. Every effort should be undertaken to rule out preoperative infection in a patient with suspicious symptoms, such as a history of, or when there are signs of, local infection, abscesses, fever, increased blood sedimentation rate, evidence of rapid joint destruction or bone resorption.

3. Other conditions that will place excessive demands on the joint:

- Charcot's joints
- Muscle deficiencies
- Multiple joint disabilities
- Refusal to modify postoperative physical activities
- Obesity.

4. Conditions that tend to impose severe loading on the affected extremity include, but are not limited to, the following:

- Obesity
- Heavy labor
- Active sports
- History of falls
- General neurological abnormalities or neurological conditions including mental conditions (e.g., mental illness, senility, drug use, alcoholism) that tend to pre-empt the patient's ability or willingness to follow the surgeon's postoperative instructions.

5. Physical conditions that tend to adversely affect the stable fixation of the implants include, but are not limited to, the following:

- Marked osteoporosis, osteomalacia
- Systemic and metabolic disorders leading to progressive deterioration of bone, (e.g., cortisone therapies, immunosuppressive therapies)
- History of general or local infectious disease
- Tumors and/or cysts of the supporting bone structure
- Suspected allergic reactions to implant materials
- Other joint disability (i.e., knees or ankles)
- Severe deformity leading to impaired anchorage or improper positioning of implants.
1. The preoperative planning and surgical technique for implantation of the femoral stem represent principles that are basic to sound surgical management in total hip replacement. Thorough familiarity with the surgical technique is essential. The use of certain surgical instruments is suggested in the performance of this surgery. Review of the use and handling of these instruments is important. Bent or damaged instruments may lead to improper implant position and result in implant failure. A surgical technique brochure fully describing the procedure is available from Sulzer Orthopedics.

2. When total hip replacement is being considered, particularly for the young and the active patient, the surgeon should discuss all aspects of the surgery and the implant with the patient before surgery. The discussion should include the limitations of joint reconstruction, limitations particular to the patient, the possible consequences resulting from these limitations and, therefore, the necessity of following the doctor's preoperative instructions.

3. Allergies and other reactions to implant materials, although rare, should be considered and ruled out preoperatively.

4. X-ray templates should be used to estimate implant sizes, placement and joint alignment. An adequate inventory of implant sizes as well as the corresponding instruments should be available at the time of surgery, including sizes larger and smaller than those expected to be used. Extra implant components are recommended.

5. It is forbidden to re-use a femoral stem that has previously been implanted in the body of the patient. It is also forbidden to re-use a femoral stem that has previously come into contact with the body fluid or tissue of another person.

6. The use of polymethylmethacrylate (PMMA) bone cement is securing, supporting and stabilizing devices intended for cemented fixation in bone, but it neither replaces the support function of sound bone nor eliminates the need for additional support during healing. In using cement for implant fixation, care should be taken to ensure complete cement support on all parts of the device embedded in the bone cement to help prevent possible stress concentrations that may lead to failure.

7. The safety and effectiveness of the use of this device in bilateral applications have not been established.

B. Intraoperative

1. The correct selection of the implant is extremely important. Selection of the implant refers to the appropriate type and size for each patient with consideration of the anatomical and biomechanical factors involved. Such factors include patient age, activity level, weight, bone and muscle conditions.

2. Prior to closure, the surgical site should be thoroughly cleansed of bone chips, ectopic bone, bone cement, etc. Foreign particles at the metal/plastic articular interface may cause excessive wear and/or friction. Ectopic bone and/or bone spurs may lead to dislocation or painful and restricted motion. Range of motion should be thoroughly checked for early contact or instability.

3. The largest cross-section component that allows for adequate bone support to be maintained is recommended. Failure to use the optimum size may result in loosening, bending, cracking, or fracture of the component, bone, or cement if cement used.

4. Stem and cup positioning and neck length are of critical importance. Subluxation, dislocation, and/or fracture of components may result due to muscle looseness and/or malpositioning of components.

C. Postoperative

Postoperative care is important. The patient should be instructed on the limitations of this device and should be cautioned regarding the load-bearing, range of motion, and activity levels permissible. Early load-bearing should be carefully controlled. A prosthesis passport/patient card must be made out for the patients.

1. Early postoperative care should be carefully structured to maintain range of motion, and to prevent dislocation or thromboembolism.

2. Postoperative therapies, patient handling, (e.g., changing dressings, placing on bedpans, etc.) and patient activities should be structured to prevent excessive loading of the operative hip. Surgical procedure chosen, patient's age and/or bone quality may necessitate extending the period of limited weight bearing.

3. Periodic X-rays are recommended for close comparison with immediate postoperative X-rays to detect long-term evidence or progressive changes in implant position or loosening, or evidence of bending, cracking of component or cement, and/or disassembly of components.

4. The patient should be encouraged to promptly report any unusual changes in the operative extremity to his physician.

2.1 Adverse Events

The potential adverse effects occurring with any total hip replacement may commonly include:

1. Changing position of the prosthesis (bending, fracture and/or disassembly of components or cement) with or without loosening or clinical symptoms.

2. Perforation, fissure of the acetabulum, femur or trochanter, and/or trochanter avulsion.

3. Subluxation, dislocation, decreased range of motion, and shortening or lengthening of the extremity.

4. Fractures of the femur resulting from stress, bone defects resulting from earlier surgical procedures, deformity and/or osteoporosis.

5. Ectopic ossification.

6. Early or late infection.

7. Cardiovascular disorders, including damage to blood vessels (lilac obturator, and femoral arteries), wound hematomas, venous thrombosis, pulmonary embolism, and myocardial infarction.
8. Temporary or permanent neuropathies involving the femoral, sciatic, peroneal or obturator nerves.
9. Pulmonary disorders including pneumonia and atelectasis.
10. Aggravated conditions in other joints or back due to intra-operative trauma, leg length discrepancy, femoral medialization, or muscular deficiencies.
11. Excessive wear of the acetabular component from damage to mating wear surfaces or debris particles.
12. Tissue reactions and allergies to corrosion or wear products and cement particles.
13. Urological complications, especially urinary retention and infection.
15. Possible detachment of coatings could be associated with increased debris.
16. Other complications associated with general surgery, drugs, or ancillary devices used, blood, etc.
17. Pain

2.2 Sterilization
Implants have been sterilized by a minimum of 25 KGy (2.5 Mrad) of gamma irradiation.

2.3 Cleaning and Resterilization
Contact with substances containing chlorine, phosphorus, fluorine or detergents containing fats must be avoided. Metal components can be resterilized, provided they have not come into contact with body fluid, bone, etc., and have not previously been implanted. Sulzer Orthopedics recommends that all such implants be returned to the manufacturer for appropriate cleaning or resterilization.

3. Storage and Handling
- Examine all protective implant packing for possible damage prior to product use as this could impair the sterility. If the packaging bears a product sterility expiry date, the date must be observed. If the expiry date for sterility has passed, the implants must be returned to the manufacturer.
- Implants must be stored unopened in the original packing.
- Protective devices must not be removed until immediately before use.
- Implants that can no longer be used may be returned to the manufacturer for proper disposal free of charge.
- Any additional warnings (e.g. adhesive warning labels on the packaging) are to be observed.

4. Pictograms
![Symbol for Follow the Instructions for Use](image)
![Symbol for Not to be re-used](image)
![Symbol for To be used by... (Year, Month)](image)
![Symbol for Contents packed without sterilization](image)
![Symbol for Sterile and Sterilization by Radiation](image)

5. Trademarks
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