Wagner Cone Prosthesis® Hip Stem

Surgical Technique

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Description

The Wagner Cone Prosthesis Hip Stems are circular, fluted grit blasted stems made from a titanium alloy: Protasul®-64WF (Ti-6Al-4V).

The Wagner Cone Prosthesis Hip Stems have to be used in combination with arthroplasty components approved by Zimmer Biomet orthopedic companies (see https://labeling.zimmerbiomet.com). A THA construct consisting of a Wagner stem, a ball head and a cup is used in the treatment of degenerative disease of the hip.

The Wagner Cone Prosthesis Hip Stems are intended for single use only and are provided sterile. The Wagner Cone Prosthesis Hip Stems are for press-fit fixation only.

Intended Purpose

The Wagner Cone Prosthesis Hip Stems are intended to reduce pain and improve hip function through cementless fixation of total hip arthroplasty (THA) in the femur of patients with an adequate bone stock to support the components.

Indications and Contraindications

Indications

The Wagner Cone Prosthesis Hip Stem intended for use in total hip arthroplasty for:

- Non-inflammatory degenerative joint disease (NIDJD), e.g. avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g. rheumatoid arthritis.
- Failed previous surgery (not THA) where pain, deformity, or dysfunction persists.

Contraindications

- 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
- Local bone tumors and/or cysts.
- Pregnancy.

For more information please refer to IFU D011500330

Table of Contents

Introduction

The Wagner Cone Prosthesis Stem is designed for uncemented fixation in bone conditions at the proximal end of the femur and for congenital dysplasia of the hip (CDH) cases.

The surface of the prosthesis is rough blasted which, together with the longitudinal ribs, is designed to support bony apposition over a large area.

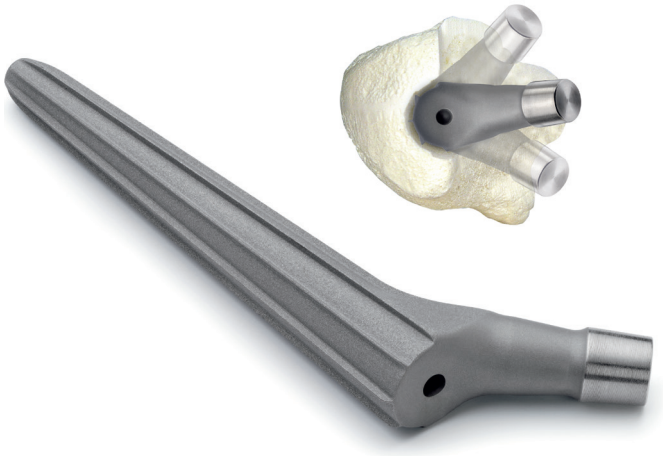
The circular tapered stem is not subject to any rotation force during insertion, i.e. the angle of antetorsion can be determined by the surgeon. The stem has 8 longitudinal ribs. The relatively sharp ridges of the ribs cut into the bone, thus allowing for optimal rotational stability. This feature is also designed to address thigh pain associated with some uncemented prosthetic systems.

In order to achieve a broad-based support of the prosthesis in the region of the calcar, the medial rib is inserted distally to this area into the convex support surface. The ribs on the lateral part start from the tip of the shoulder in order to ensure the greatest possible area of contact in the trochanter, which is intended to support rotational stability and improve osseointegration.

The Wagner Cone Prosthesis Stem is available in different CCD angles, 125° and 135°. This provides a range of offset options, supporting adjustment of the center of rotation, the CCD angle and the leg length.

Both CCD angle versions are available in 12 diameters (size 13–24 mm) to fit the individual width of the medullary canal.

The Wagner Cone Prosthesis Hip Stem is designed for cylindrical proximal femoral bone that could fracture when conventional flared stems are used. The Wagner Cone Prosthesis Stem is also designed for deformities of the femur where fixation of conventional stems is problematic. The Wagner Cone Prosthesis Hip Stem is intended for long-term uncemented fixation of total hip arthroplasty.



Instrumentation

The core instruments are reamers which are used for the careful preparation of the medullary canal as well as modular trial stems used for determining the most adapted Wagner Cone Prosthesis Stem version and the best-suited size of implant.

Reamers

The Wagner Cone Prosthesis Stem, with its circular cross-section, can be an option for slender configurations of the proximal femur, as well as for cases involving pathologic morphology. When these conditions are present, an important focus should be placed on the preparation of the medullary canal in the most bone preserving manner. The use of reamers allows the surgeon to prepare the medullary canal with care and precision, even in cases of poor bone quality of the proximal femur where the use of rasps is not an ideal option.

Modular Trial Stems

Trial stems are used to determine the exact positioning and correct size of the final implant. The trial stems of the Wagner Cone Prosthesis Implant are modular, with one distal part for each size and two different proximal parts, 125° and 135°, per size. This allows flexibility during trial reduction. The proximal part can be exchanged in situ leaving the distal part in the bone to avoid damage to the bone.

Please note that the distal parts of the trial stems have only four ribs (instead of eight, as on the implants) to facilitate the extraction of the trial stem and to avoid unnecessary damage to the bone during the trial procedure. The trial stem may be inserted as far as the intended anchoring depth of the implant to assess accurately the tension of the soft tissue, range of motion and degree of antetorsion.

Trial Stem

Reamer

Pre-operative Planning

Digital templates are available through various digital template providers.

When using digital templating for a primary THR, it is necessary to use a magnification marker with a known dimension. This is required to calculate the correct magnification.

As soon as the correct magnification has been determined, the system can be used to best decide the correct implant size and centre of rotation.

The pre-operative planning follows standard procedures. A good quality X-ray template is essential. The first step in planning consists in selecting suitable implants for the acetabulum and the femur using the X-ray templates on the original X-ray films.

When selecting the size of the Wagner Cone Prosthesis Stem it is important that the configuration of the femur allows close contact between the middle third of the prosthetic stem and the cortex, and not just that the tip of the stem fits tightly in the medullary cavity.

Selection of the correct stem diameter is particularly important. **The most common mistake is choosing a stem diameter that is too small. Such a decision can result in secondary subsidence of the prosthesis**. The outline on the template corresponds exactly to the dimensions of the implant.

In choosing the diameter, it must be remembered that reaming with the reamer removes a thin layer of bone and that the sharp longitudinal ribs cut slightly into the bone during insertion. **The outline of the prosthetic stem on the planning template must therefore overlap the inner outline of the cortex in the region of the middle third of the stem by 1 mm on each side.**

Furthermore, the most adapted version of the Wagner Cone Prosthesis Stem (125° or 135°) to best restore the offset, the center of rotation and the CCD angle is selected.

Planning drawing

On the outline drawing of the pelvis, the position of the cup implant with the center of rotation is first sketched and the current and desired position of the tip of the trochanter is marked in order to check the leg length.

Using the X-ray template, the outline of the selected Wagner Cone Prosthesis Stem is then transferred to the planning sketch and the line of resection is also drawn from the template. The planning sketch is now laid on the X-ray film and the outline of the femur is transferred carefully. The tip of the greater trochanter on the X-ray is at the level of the previously made marking for the desired trochanter position.

Finally, the distance between the cone of the stem and the proximal limit of the lesser trochanter is measured. In reconstructing deformed hip joints, further marking points can be given and their distances measured. All longitudinal measurements must be made according to the scale on the template as this takes into account the degree of magnification of the X-ray. All measurements should be entered on the planning sketch so that they can be referred to during the operation.

Surgical Approach

The Wagner Cone Prosthesis Hip Stem can be implanted with different operative approaches. The individual steps shown in this Surgical Technique are for the conventional posterior access with the patient in a lateral position, as it is particularly suitable for the Wagner Cone Prosthesis Hip Stem, being a straight stem and introduced in the axis of the medullary cavity. With the posterior approach, when the hip and knee are flexed, the way to the medullary cavity is free without the need for temporary removal of the greater trochanter and without the instrument exerting pressure on the muscles.

With the lateral, transgluteal and anterior approaches, retraction of the muscles is more difficult. Moreover, with the posterior approach, the incision is smaller and there is less blood loss with the patient in the lateral position. This appears particularly apparent in obese patients.

The incision or resection of the posterior joint capsule is a critical issue in the posterior approach. Posterior dislocation of the prosthesis can occur more readily during the healing phase, if the cup and/or the stem are placed in insufficient anteversion. Trial reduction and use of trial stems is recommended prior to definitive implantation.

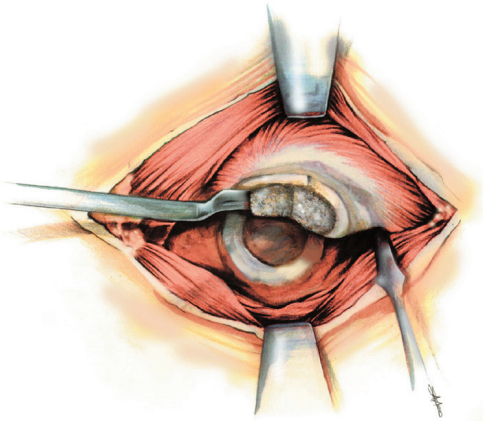


Figure 1

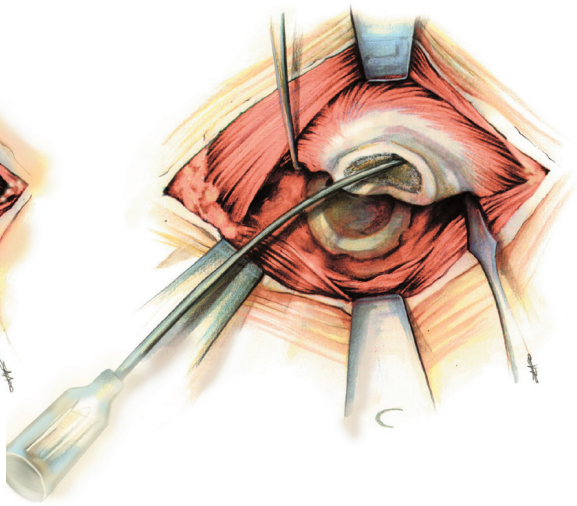


Figure 2

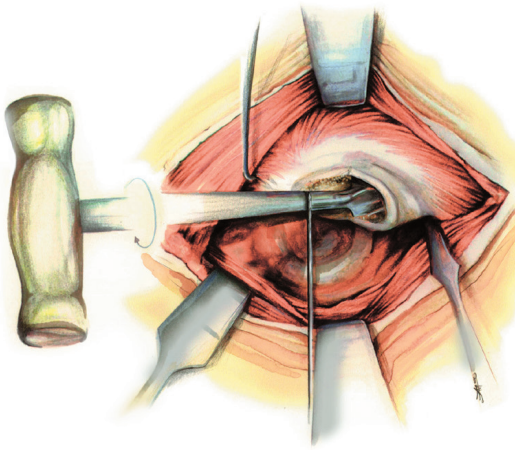


Figure 3

Preparation of the Femoral Canal

Open the medullary cavity with a hollow chisel. At the same time, taking into account the planned antetorsion of 10–15°, the trochanter is grooved inside so that the reamer and prosthesis are not subsequently diverted in a varus direction. Resect the cancellous bone sparingly to allow enough room for the reamer.

Widen the femoral medullary cavity is widened conically with the reamers in the longitudinal direction of the femur until noticeable resistance is felt. Check the depth of penetration of the reamer with a Kirschner wire which is placed on the tip of the greater trochanter.

Note: Reaming can be performed under power (operating at ream speed). However, at a minimum, the final reamer size should be driven manually.

Figure 4

Figure 5

Figure 6

Trial Reduction with the Trial Stem

To assess leg length, abductor muscle tension and joint stability, perform a trial range of motion using a trial stem. To assemble the trial prosthesis, three components are used: 1) the trial stem distal part (01.00569.113/124), the trial stem proximal part (01.00569.213/224 or 01.00569.313/324), and 3) the screw for trial stems (01.00569.001) (Figures 4 and 5). The diameter of the distal part of the trial stem corresponds to the last used reamer. The proximal part of the trial stem is selected according to the CCD angle defined in the pre-operative planning, the size is chosen corresponding to the last used reamer.

It is recommended to assemble the trial stem outside of the body using the screwdriver, and to insert it as a monobloc. Insert the trial stem in the femur until it is properly seated (Figure 6).

When there is severe preexisting antetorsion, make sure that the prosthesis is placed in the corrected position so that the neck of the prosthesis is not sitting on the rim of the cortex of the femoral neck. If necessary, some bone must be removed with a fine chisel until there is a sufficient gap between the neck of the prosthesis and the bone.

Select the trial head size as templated and seat it onto the trial taper.

Figure 7

Figure 8

Figure 9

Figure 10

Trial Reduction with the Trial Stem (cont.)

If the trial reduction does not yield the desired result it can be repeated as often as necessary by using the following possible options to better restore the anatomy:

- Use of different lengths of trial heads.
- Exchange and replacement of the proximal part of the trial stem in situ by the other version of the proximal part (either 125° or 135°). Replace the proximal part by first loosening and removing the screw. The proximal part can then be removed with the extractor for the proximal parts and be replaced with the other version of proximal part (Figures 7 and 8).
- Changing the antetorsion by rotating the proximal part only. This can be done in situ by loosening the screw and turning the proximal part until the desired antetorsion is reached.
- Proceeding with the next diameter reamer after removing the trial stem and repeating the trial step with the appropriately sized trial stem.

The trial stem can be removed both as a monobloc assembly by using the extractor on the extractor hole (Figure 9) and in two steps, first removing the proximal part with the extractor for proximal parts and then the distal part with the extractor for distal parts (Figure 10).

Figure 11

Figure 12

Insertion of the Stem

Insert the prosthesis of the appropriate size by hand until resistance can be felt (Figure 11).

Use the impactor to ensure final seating of the Wagner Cone Prosthesis Femoral Stem using hammer taps. Insert the spike of the impactor into the impacting hole, in the shoulder of the prosthesis, so that the fork-shaped flange surrounds the neck of the prosthesis (Figure 12). With this instrument, rotate the prosthesis into the desired antetorsion and impact into its definitive position with a few moderate mallet strikes. The stability of the fixation can be assessed as follows: at first the prosthesis penetrates somewhat deeper into the medullary cavity with each mallet strike until the required stability is reached and the prosthesis does not move any further continuing mallet strikes. At the same time, the sound of the mallet strike changes. Finally, check the depth of femoral stem penetration according to the pre-operative plan with the use of a tape measure.

Note: When there is a preexisting antetorsion make sure, that the neck of the prosthesis is not sitting on the rim of the cortex of the femoral neck. If necessary, some bone must be removed with a fine chisel, until there is a gap of approximately 3mm in width and 10 mm in depth between the neck of the prosthesis and the bone.

Figure 13

Figure 14

Final Trial Reduction

For the final trial reduction, seat a trial head on the stem taper (Figure 13). Reduce the hip and examine by moving the leg in all directions, especially in flexion and internal rotation. Soft tissue tension is checked with longitudinal traction on the extended leg. If necessary, re-implant the prosthesis with an adjusted angle of antetorsion and repeat trial reduction.

After redislocation, fill the intermediate spaces remaining between the prosthesis and the bone tightly with the chips of cancellous bone which were obtained during the dissection. With a very narrow femur, ensure that the medial surface of the prosthetic neck does not lie on the cortex at the site of osteotomy of the femoral neck. If this is the case, the cortex must be removed with a fine chisel, until there is a gap of approximately 3mm in width and 10mm between prosthesis and bone.

Head Impaction

Once the provisional head is removed, carefully clean and dry the taper of the stem.

Seat the selected Femoral Head using the appropriate plastic impactor and mallet (minimum suggested weight: 0.5 kg) on the pole of the Femoral Head with a minimum of three strikes and ensure full seating on the stem taper. The impact direction should not be more than 20 degrees from the neck axis, otherwise the impact force may have reduced effect in connecting the taper (Figure 14).

Upon reducing the joint, the function of the hip is assessed.

The short external rotators are refixed. The redon drain is inserted and the appropriate closure technique is performed.

Note: Always check that the neck taper and female taper of the femoral head are clean and dry before impaction. Also, do not impact the femoral head onto the taper before driving the prosthesis down the femoral canal as the femoral head may loosen during impaction of the implant.

Post-operative Treatment

The post-operative treatment of patients with a Wagner Cone Prosthesis Hip Stem is determined by the surgical technique, patient bone quality, patient activity level, fit of the implant and the surgeon's judgment.

Note: Accepted practices of post-operative care should be followed. The patient must be informed and made aware of the limitations of total joint reconstruction and the necessity of limiting weight and physical activity to protect the femoral stem from unnecessary stresses. In patients where proximal support was not achievable, additional risk may be present.

Implant Removal

In case of a revision surgery the stem can be extracted by using the extractor instruments for Wagner Cone Hip Stem.

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For ordering information refer to 0623.

For Instructions for Care, Cleaning, Maintenance and Sterilization Manual refer to 3455.

For disassembly instructions (where applicable) refer to 1258 Disassembly Manual.

If damage or wear detected on instruments, please consult the Reusable Instrument Lifespan Manual 1219.

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