

Avenir® Hip System

Surgical Technique



Avenir Müller Cemented Hip Stem Description

The Avenir Müller Cemented Hip Stem is a straight, double-tapered, highly-polished stem made from Protasul®-S30 stainless steel material. All Avenir Müller Cemented Hip Stems are intended to articulate with specified ball heads through the 12/14 taper and have to be used in combination with hemi or total hip arthroplasty (THA) components approved by Zimmer Biomet orthopedic companies (see <https://labeling.zimmerbiomet.com>). A THA construct consisting of a stem, a ball head and a cup is used for the treatment of degenerative diseases or trauma of the hip. The Avenir Müller Cemented Hip Stems are intended for single use only and are provided sterile. Avenir Müller Cemented Hip Stems are for cemented use only.

Intended Purpose

The Avenir Müller Cemented Hip Stems are intended to reduce pain and improve hip function through cemented fixation of hemi or total hip arthroplasty (THA) for primary procedures in the femur of patients with an adequate bone stock to support the component.

Indications and Contraindications

Indications

The product is intended for total or hemi hip arthroplasty with cemented applications for rehabilitating hips damaged as a result of:

- Noninflammatory degenerative joint disease (NIDJD), e.g. avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g. rheumatoid arthritis.
- Acute traumatic fracture of the femoral head or neck.
- Failed previous hip surgery (not THA) where pain, deformity, or dysfunction persists.
- Optional use in revision: in some medical conditions (e.g. early revision when healthy and good bone stock exists), the surgeon may opt to use primary implants in a revision procedure.

Contraindications

- Acute, chronic, local, or systemic infections.
- Severe muscular, neural, or vascular diseases that endanger the limbs involved.
- Lack of bony structures proximal or distal to the joint, so that good anchorage of the implant is unlikely or impossible.
- Total or partial absence of the muscular or ligamentous apparatus.
- Any concomitant diseases that can jeopardize the functioning and the success of the implant.
- Allergy to the implanted material, especially to metal (e.g. stainless steel).
- Local bone tumors and/or cysts.
- Pregnancy.

For more information please refer to IFU D011500297

Avenir Müller Uncemented Hip Stem Description

The Avenir Müller Uncemented Hip Stem is an uncemented straight stem, made from titanium alloy (Protasul®-64WF) with a macrosurface structure and coated with Hydroxyapatite. All Avenir Müller Uncemented Hip Stems are intended to articulate with specified ball heads through the 12/14 taper and have to be used in combination with total hip arthroplasty (THA) components approved by Zimmer Biomet orthopedic companies (see <http://labeling.zimmerbiomet.com>). A THA construct consisting of a stem, a ball head and a cup is used for the treatment of degenerative diseases or trauma of the hip. During total hip arthroplasty, the stems may be combined with constrained or semi-constrained acetabular systems. The Avenir Müller Uncemented Hip Stems are intended for single use only and are provided sterile.

Intended Purpose

The Avenir Müller Uncemented Hip Stems are intended to reduce pain and improve hip function through cementless fixation of total hip arthroplasty in the femur of patients with an adequate bone stock to support the component.

Indications and Contraindications

Indications

The Avenir Müller Uncemented Hip Stems are intended for use in total hip arthroplasty for:

- Noninflammatory degenerative joint disease (NIDJD), e.g. avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g. rheumatoid arthritis.
- Acute traumatic fracture of the femoral head or neck.

Contraindications

- Acute, chronic, local, or systemic infections.
- Severe muscular, neural, or vascular diseases that endanger the limbs involved.
- Lack of bony structures proximal or distal to the joint, so that good anchorage of the implant is unlikely or impossible.
- Total or partial absence of the muscular or ligamentous apparatus.
- Any concomitant diseases that can jeopardize the functioning and the success of the implant.
- Allergy to the implanted material.
- Local bone tumors and/or cysts.
- Pregnancy.

For more information please refer to IFU D011500294

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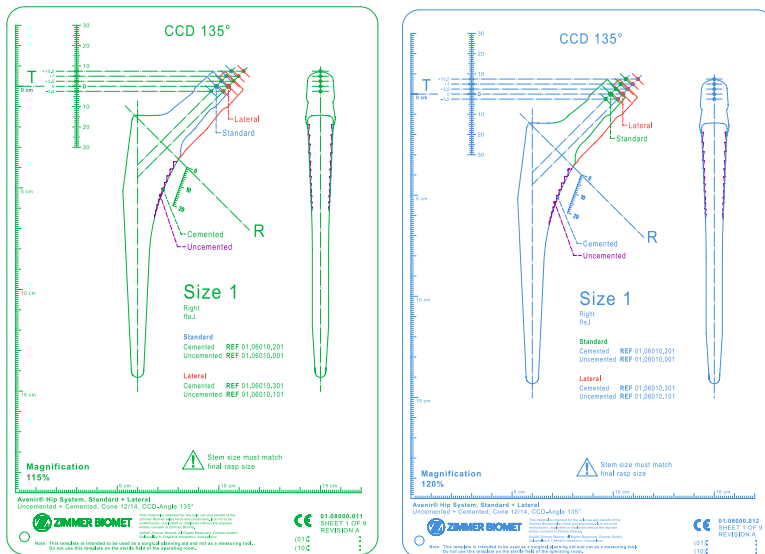


Figure 1

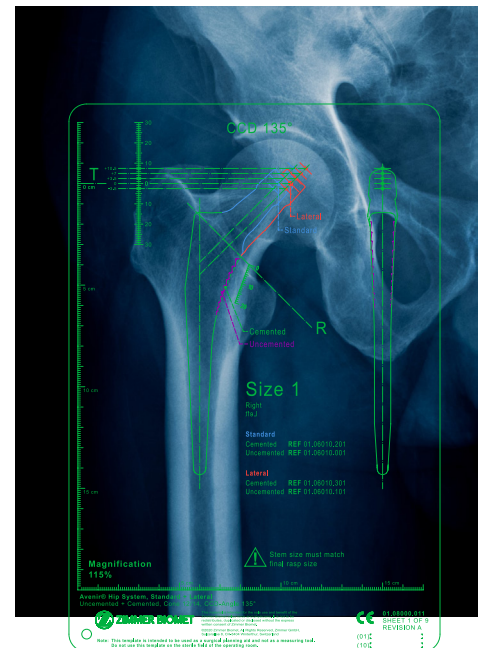


Figure 2

Pre-operative Planning

The objectives of pre-operative planning are to define:

- Pre-operative leg length
- Acetabular component size and position
- Femoral component size
- Femoral offset and center of rotation

The Avenir Hip System provides X-ray templates with 115% and 120% magnification (Figure 1).

It is recommended to use a radiographic marker to assess the X-ray magnification and select the appropriate template.

It is recommended that templates are positioned over the AP X-rays to best decide the correct implant size and center of rotation (Figure 2).

Digital Pre-operative Planning

The Avenir Hip System 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 with aiming at best deciding the correct implant size and center of rotation.

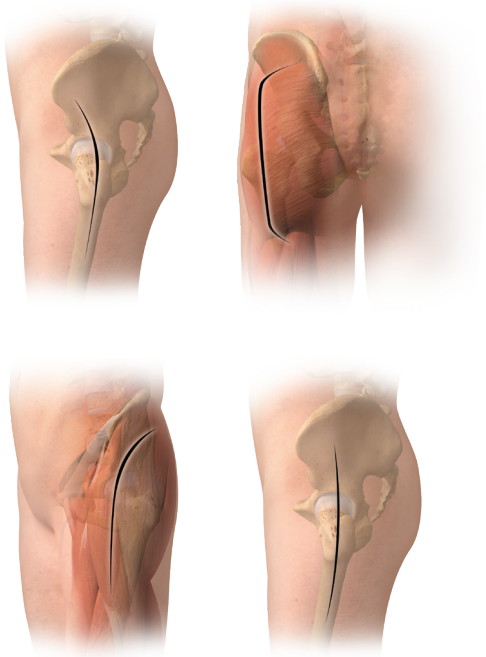


Figure 3



Figure 4

Patient Positioning/Surgical Exposure

The Avenir femoral component can be implanted using any of the standard approaches for total hip replacement (Figure 3).

This surgical technique may be adapted to the surgeon's specific approach.

The aim of the approach selected is to provide optimal visualization of both the acetabulum and proximal femur in order to help reproduce the normal hip anatomy and aiming to restore the physiologic center of rotation.

Femoral Neck Resection

Once the femoral head is dislocated, cut the femoral neck according to the preoperative plan, using marks between the greater and the lesser trochanter (Figure 4).



Figure 5



Figure 6

Femoral Canal Opening

Carefully prepare the medial section of the greater trochanter with the boxed chisel (Figure 5).

Open the medullary cavity using the T-handle awl. Position the awl close to the tip of the greater trochanter in order to avoid varus positioning (Figure 6).



Figure 7



Figure 8

Femoral Canal Preparation

Start the femoral preparation with the smallest rasp considering appropriate anteversion (Figure 7).

Progress with sequentially larger rasps until reaching the pre-operatively templated implant size.

Zimmer Biomet offers different handle designs for different approaches. Choose the appropriate one according to the selected surgical approach.

Once complete stability is achieved with the final rasp, remove the handle from the rasp (Figure 8).

ⓘ **Note:** When using a line-to-line broaching technique, the final rasp size should match the final implant size for both cementless and cemented versions.

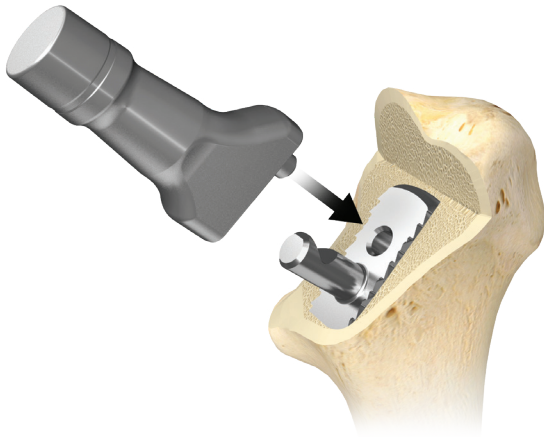


Figure 9



Figure 10

Trial Reduction

With the final rasp in place, select the appropriate provisional neck (standard or lateral) and connect it onto the rasp (Figure 9).

Once the provisional neck is in place, select the correct provisional head size and position it on the provisional neck (Figure 10). Perform a trial reduction using the head impactor. Repeat the procedure with different head offsets until reaching joint stability, soft tissue tension and desired leg length.

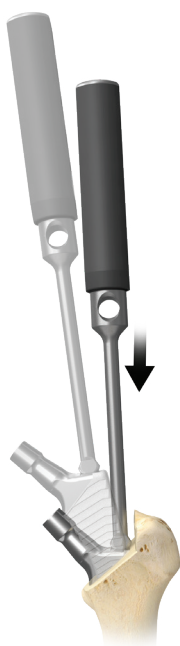


Figure 11

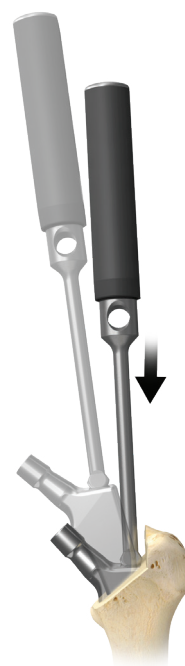


Figure 12

Femoral Implant Insertion

When implanting a cementless or cemented stem, the definitive implant must correspond to the last rasp used. Insert the femoral component into the femoral canal using the stem inserter (Figure 11 and 12).

Cementless Stem Insertion

Drive the stem into the femur using the impactor until the edge of the hydroxyapatite coating corresponds to the insertion depth of the rasp.

Special attention on the anteversion is necessary during the first few centimeters of insertion, as subsequently the implant positions itself in the femoral bed.

Cemented Stem Insertion

When using a cemented stem, clean and dry the femoral shaft using a high-pressure pulse lavage system in order to remove blood, fat and debris from the cancellous surface of the canal. Insert an appropriate distal femoral plug.

Deliver the cement in the clean and dry femoral shaft in a retrograde fashion.

Apply the proximal seal and pressurize the cement to improve the interlock of the bone-cement interface. Insert the stem inside the cement until the laser etched osteotomy line is aligned with the resection plane, maintaining pressure on the stem through the inserter handle until the cement is polymerized.

For cementing guidance, please refer to Zimmer Biomet's Modern Cementing Technique for Hip Arthroplasty (brochure 1913).

Note: When using a line-to-line broaching technique, the final rasp size should match the final implant size for both cementless and cemented versions.



Figure 13



Figure 14

Head Impaction

If desired, a further trial reduction can be completed after implantation of the definitive femoral stem (Figure 13).

Once again, the range of motion, joint stability and leg length can be assessed.

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

Seat the 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).



Figure 15

Postoperative Treatment

The postoperative treatment depends upon the patient. **The surgeon should inform the patient of postoperative restrictions, the acceptable level of physical activity that can be performed and how their lifestyle may be impacted.**

Implant Removal

Should an Avenir stem require removal, only the specific extraction instrument should be used.

Connect the extractor to the final implant through the threaded hole and pull the stem out of the femoral canal by using the slide hammer.

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Check for country product clearances and reference product specific Instructions for Use.

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For ordering information refer to the following documents:

- 0885 - OUS Ordering Information leaflet
- 0885 - US Ordering Information leaflet

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.



CE mark on a surgical technique is not valid unless there is a CE mark on the product label.

Product with this system are under the design control of various legal manufacturers. Refer to the product labeling of each device for the legal manufacturer.



Legal Manufacturer

Zimmer Switzerland
Manufacturing GmbH
Sulzerallee 8,
8404 Winterthur, Switzerland
Telephone +41/ (0) 58 854 80 00
Fax +41/ (0) 52 244 86 70

Zimmer, Inc.
1800 West Center St.
Warsaw, Indiana 46581-0708
USA
Telephone 574-267-6131

www.zimmerbiomet.com