Surgical Technique

Pyramid Hip Stem

Uncemented and cemented Hip Stem System

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1 Intended Use and Product Description

Intended use
The Pyramid Hip Stem system is intended as a femoral component in conjunction with other components for the primary partial or total replacement of the human hip joint.

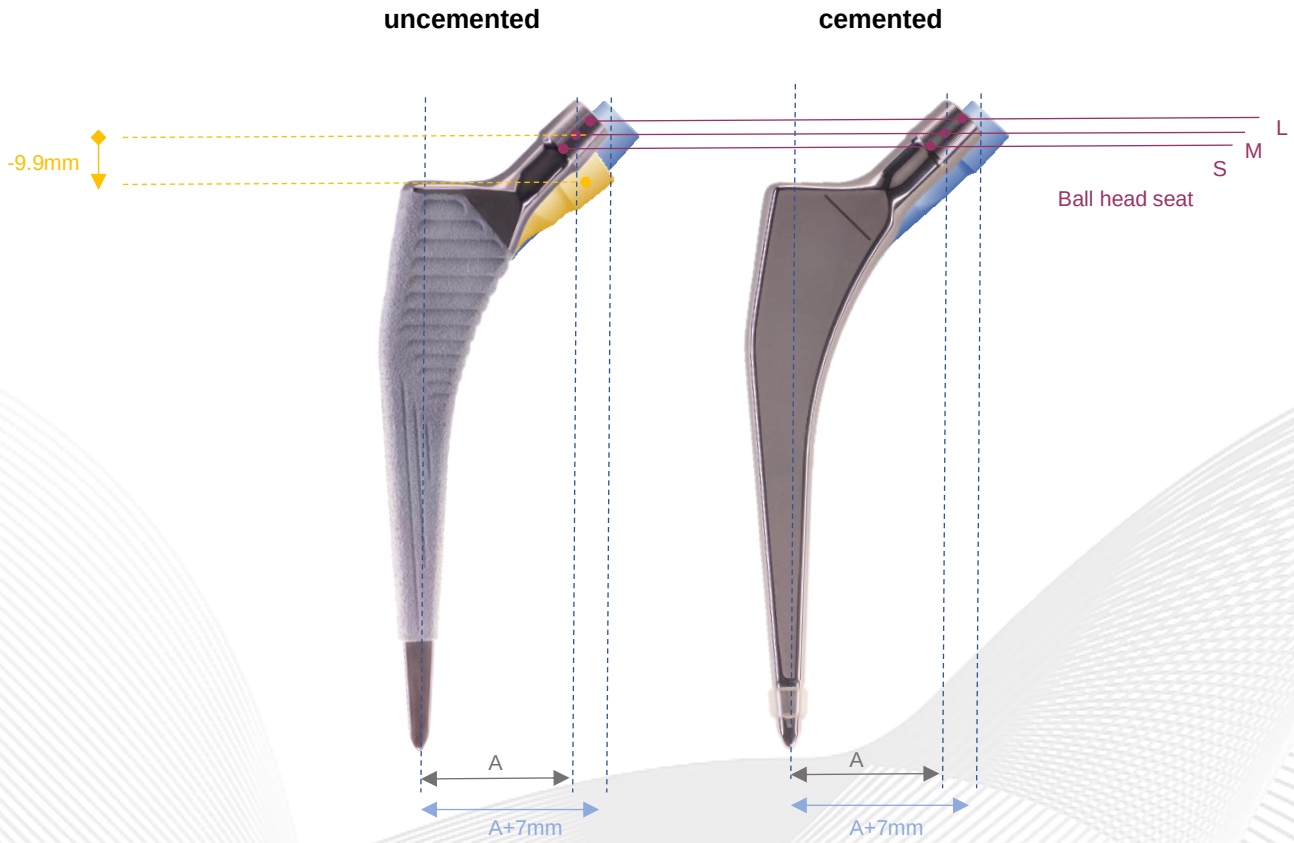
Uncemented Stem
The uncemented Pyramid hip stem is based on an implant concept that has led to good clinical results for over 20 years. The choice of material, the offset concept, range of sizes and the design of the surface for uncemented fixation in the proximal femur correspond to the latest state of the art.
For a biological fixation, the stem body of the uncemented version made of Ti6Al4V is provided with a high-roughness pure titanium plasma coating (TiVPS) and an additional thin layer of calcium phosphate. The underlying TiVPS coating supports a secure primary implant stability through its roughness and is the base for a long-term fixation. The top thin and soluble calcium phosphate layer supports the bone formation and thus the rapid osseointegration.

Cemented Stem
For the cemented version of the Pyramid hip stem a completely polished surface was chosen on intent, as this, shows better clinical long-term results than rough surfaces in combination with a cement bed around the stem. The base material is a high nitrogen version of ISO 5832-9 stainless steel.

The offset concept with the Standard (A) and Lateral (A+7mm) versions with a constant CCD angle (135°) allows the reconstruction of the joint mechanics without changes in leg length and range of motion.
With the CCD angle 125° version, situations with coxa vara can be reconstructed without lengthening the leg.

The stem geometry facilitates the use of mini-incision and minimally invasive surgical techniques and accommodates all common approaches and a wide range of femoral morphologies.
The range of sizes includes 12 standard and 11 lateral femoral stems, each with a CCD angle of 135°. The additional lateralization is 7 mm for all sizes. The range of stems with a 125° CCD angle includes 11 sizes with lateralization adapted to the stem size (see "Implant Component List" on page 13).

The Pyramid hip stem matches the Pyramid Hip Cup system: The ball heads correspond to the different Pyramid cup diameters and allow an optimal articulation. For more information on the acetabulum side, refer to the "Pyramid Hip Cup" surgical technique.



The set of instruments supports all common surgical approaches. In addition to the standard instruments, specific instruments with an offset for a MIS approach are available. When designing the instruments, special emphasis was put on easy and safe handling and universal applicability, including the "femur first technique".

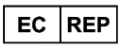
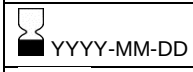
2 Indication

- Primary and secondary osteoarthritis of the hip
- Fracture or avascular necrosis of the femoral neck
- Rheumatoid arthritis in case of sufficient bone quality

3 Contraindication

- Major deformations and defects of the femur
- Radiographically manifest osteoporosis or osteomalcia
- Localized or generalized progressive tumour diseases
- Radiation-damaged bone bed
- Acute infections of the joint or its surroundings
- Persistent or potential infectious diseases with influence on the joint
- Severe muscle, nerve or vascular diseases that endangering the limb in question
- Pregnancy

4 Warnings & List of Symbols Used

	Manufacturer
	Medical Device
	European Authorized Representative
	Read Instructions for Use
	Expiry Date is reached after indicated date (Year – Month – Day)
	Do not use if package is damaged or seal is broken
	Sterilization in the final packaging by irradiation
	Sterilization in the final packaging by ethylene oxide gassing
	Double sterile barrier system
	Catalogue number / article order number
	Lot number
	Unique Device Identifier
	Do not re-sterilize
	Do not re-use
 cemented	Implant must be cemented
 non-cemented	Non-cemented / uncemented use

Ti-VPS / calcium phosphate coated implants must not be implanted with cement.
Read instructions for use before using the product.

5 Pre-operative Planning

Pre-operative planning is essential for component choice (both femoral and acetabular components) and for planning leg length and joint offset. The surgical technique and the X-ray templates provided (115%) or the digitally available templates support the planning procedure. Planning can help determine stem size in standard or lateral design and the ball head.
The height and angle of the neck resection should also be part of the planning. Standardized AP and lateral radiographs are important to ensure accurate planning. Adequate length of the femoral diaphysis should be visible on the radiographs.

6 Approaches

The range of implants and the associated instruments allow implantation via all common approaches, such as the lateral transgluteal approach according to Bauer, the antero-lateral approach according to Watson Jones, the dorsal approach and the anterior approach according to Smith Peterson, including the minimally invasive variants.

7 Instrument Handling

Note: Whether an uncemented or cemented solution is necessary, the preparation of the femur and use of the instruments is identical.

7.1 Patient Positioning and Approach

For the following procedure, a direct lateral approach was chosen as an example. During the procedure, the patient lies in a supine position.

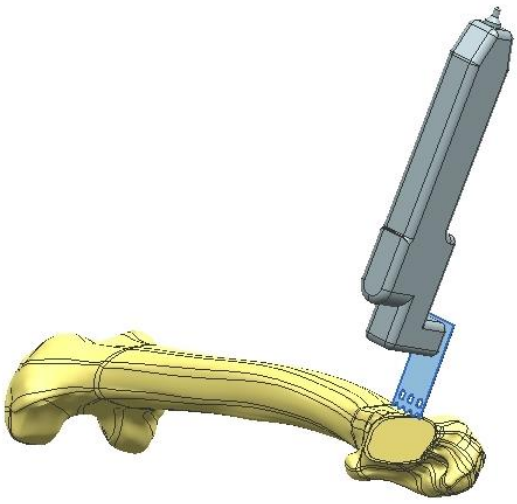


Fig. 1

7.2 Removal of femoral head

The osteotomy starts laterally at the trochanteric fossa (perpendicular to the axis of the neck) and ends medially about one finger's breadth above the lesser trochanter.
The level of neck resection should be adjusted in abnormal anatomy according to preoperative planning and appropriate intraoperative measurements (Fig. 1).
The osteotomy can be performed before or after dislocation of the femoral head.

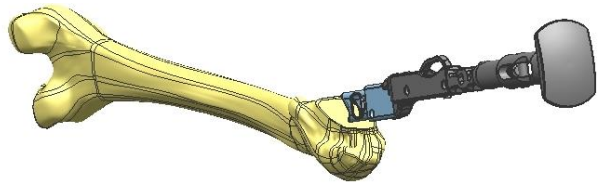
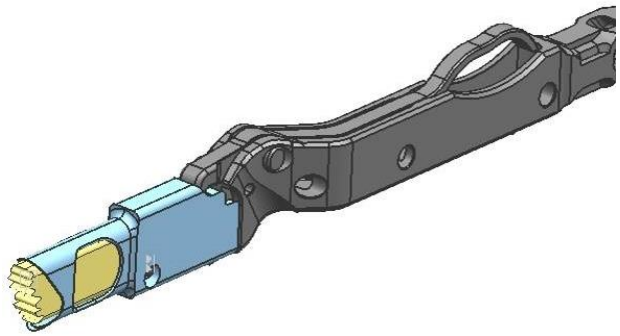


Fig. 2

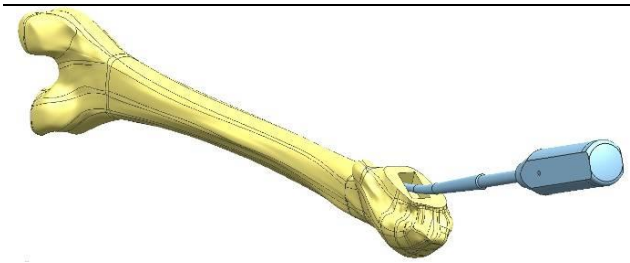
7.3 Preparation of the femur

The medullary canal is opened with the box chisel, which is attached to the rasp handle in combination with an impact handle (Fig. 2). The ante torsion required for the implant must be taken into account (10-15°). The opening is made as close as possible to the base of the greater trochanter to achieve good varus-valgus alignment of the stem.



Extracted bone material can be removed through the side window for later use (Fig. 3).

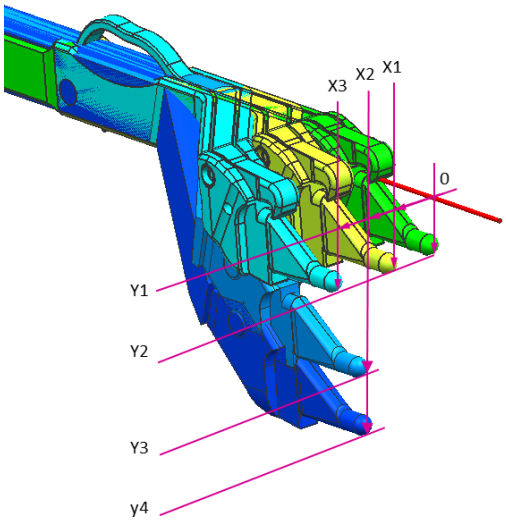
Fig. 3



The penetration broach is inserted into the medullary canal and the position of the medullary axis is located (Fig. 4).

If the penetration depth is insufficient, then the penetration broach must be advanced further by rotating it until the medullary canal is accessible.

Fig. 4

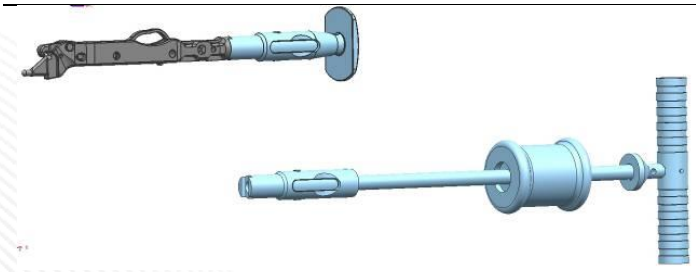


The Pyramid rasps are attached to the rasp handles. Straight rasp handles with different offsets are available in left and right versions to adapt to the selected surgical approach and/or the anatomy of the respective patient.

(Fig. 5).

	Lateral offset (X mm)	Dorsal offset (Y mm)
Rasp handle straight	0	13
Rasp handle double offset 13/17 left + right	13	17
Rasp handle double offset 30/17 left + right	30	17
Rasp handle double offset 26/37 left + right	26	37
Rasp handle double offset 26/52 left + right	26	52

Fig. 5



All rasp handles can be used together with the IMT «Woodpecker» drive unit or the impact handle and slide hammer (Fig. 6).

Fig. 6

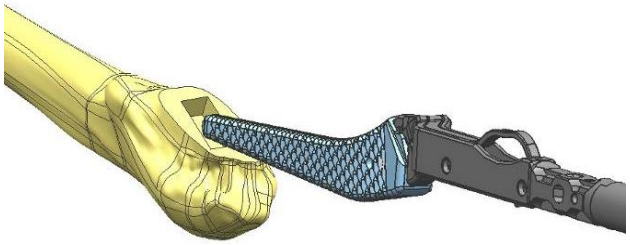


Fig. 7a

Fig. 7b

Beginning with the smallest rasp («0»), rasp and increase the diameter by using the next larger rasp successively (Fig. 7a).

The reference for the correct alignment of the rasp is the axis of the diaphysis and the plane running parallel to the dorsal femoral condyles, represented by the 90° flexed knee. The rasping process is continued until the selected rasp is in a stable position at the correct height. During rasping, attention must be paid to maintaining ante torsion.

For orientation, the rasp machine or the rod of the stem impactor can be used as targeting aid for the ante torsion. Insert the rod of the stem impactor into the hole of the impact handle (Fig. 7b).

Notice:
We recommend guiding the medial curve of the rasp along the calcar femoris as far as possible during the gradual rasping in order to achieve a good proximal form fit of the stem.

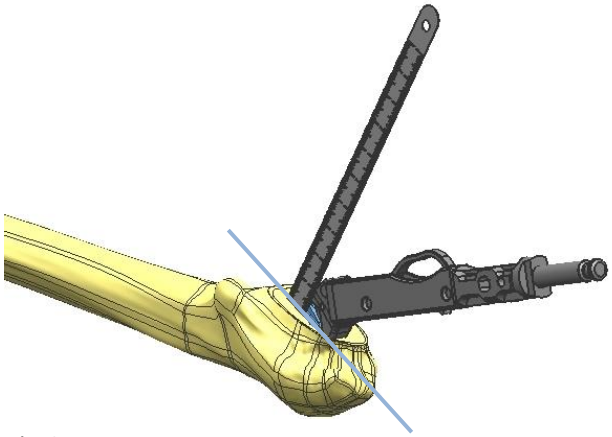


Fig. 8

The Ti-VPS / calcium phosphate coated area of the stem corresponds to the resection level marked on the rasp (Fig. 8).

We recommend inserting the rasp up to the mark if possible, so that the coated area of the stem is completely covered by the femur. If problems arise, a possible further resection should be considered.

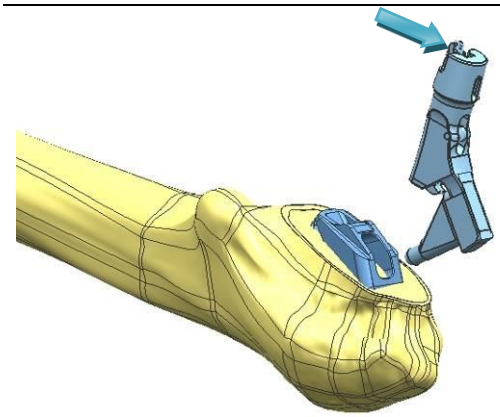


Fig. 9a

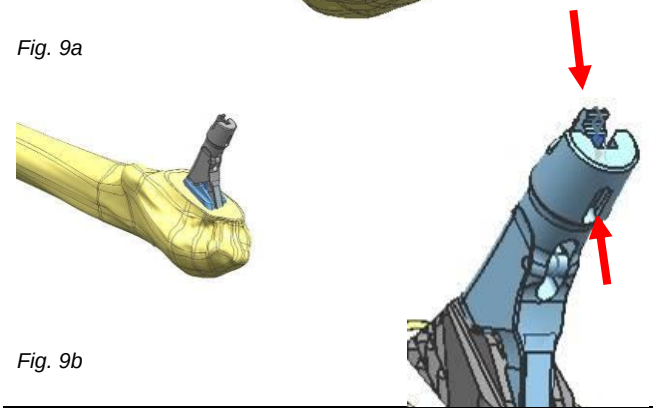


Fig. 9b

7.4 Trial reduction

When the appropriate rasp is properly seated, remove the rasp handle and place the neck trial (standard, lateral or CCD125) onto the rasp (Fig. 9a and b).

The neck trial can be inserted and removed either by hand or with a clamp (e.g. 'Backhaus clamp'). The pointed ends of the clamp are inserted into the two openings on the cone of the neck trial (see arrows).

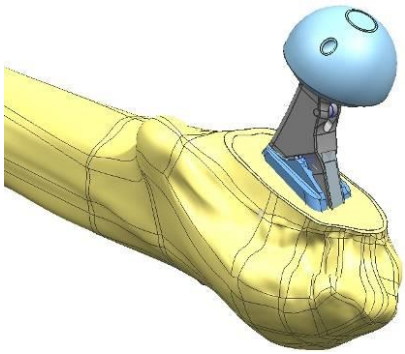


Fig. 10a

Place a trial head corresponding to the planned acetabular cup on the neck trial (Fig. 10a).
Joint reduction is performed to determine leg length, joint stability, and range of motion.

The trial reduction can be supported with the stem impactor incl. head repositioning device for the ball head (see analogue to Fig. 13a + b).

Note:
The head neck lengths S and L with a diameter of 32 and 36 mm are each 0.5 mm shorter resp. longer than the diameter of 28 mm (S:-0.5 mm / S+0.5 mm).

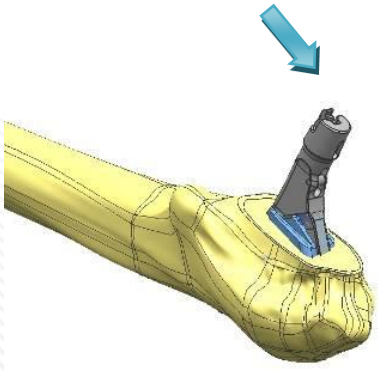


Fig. 10b

Remove trial head and neck trial (Fig. 10b).

A clamp can be used to operate the release lever to disassemble the neck trial.

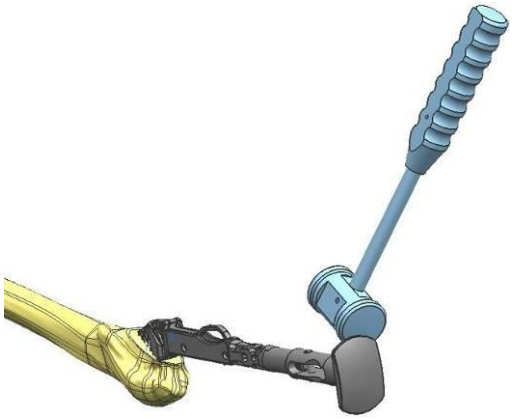


Fig. 11

Remove the rasp by reconnecting the rasp handle to the impact handle and striking against the plate of the impact handle (Fig. 11) or against an inserted rod (as shown in Fig. 7b).

Alternatively, the IMT "Woodpecker" drive unit can be used.

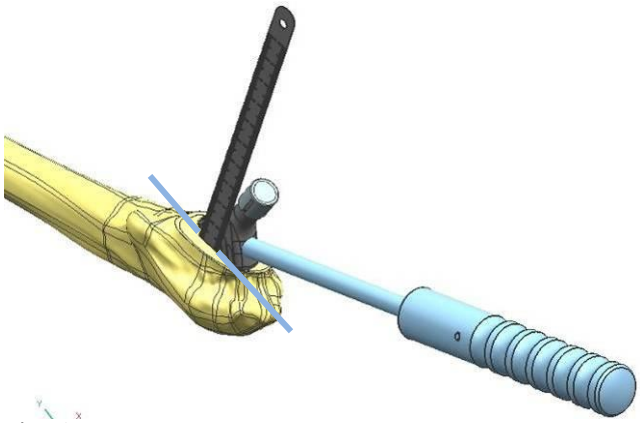


Fig. 12a

Fig. 12b

7.5 Uncemented Stem

The femoral component is inserted by hand. We recommend not removing the protective plastic sleeve on the cone until the stem is in its final position, just prior to attaching the ball head.

Positioning is done with the help of the stem impactor (Fig. 12a). Adjust the intensity of the hammer blows to the bone quality during the positioning process.
Stop the implantation process as soon as a change in tone and a permanent position confirm the firm seat. Check the embedment depth of the stem analogously to Fig. 8.

Note:
The *stem size 0 standard* is 1 mm less lateralized than the corresponding neck trial.
The edge of the coating corresponds to the marking on the rasp and marks the required insertion depth of the stem.

If the stem needs to be removed, use the extraction screw (Fig. 12b).

Rasp size	Stem size
X	**X**
When using the **same** sizing, a minimum 1mm thick cement mantle should be used. The **centralizer** supports cementing.	
X	**X+1**
If the stem **size is one size larger** than the rasp size (line-to-line implantation), **remove the centralizer** and only use a very **thin cement mantle**.	

7.6 Cemented Stem

The sizing of the cemented stems is corresponds with the X-ray planning and the surgical technique. When using a size similar to the last rasp size used, the overall cement mantle is at least 1mm thick.

If the stem is to be implanted 'line-to-line', one stem size larger than the last rasp applied must be used and the centralizer removed prior to implantation (done with a light tap on the centralizer, which can then be easily removed). For rasp size 0 only 'line-to-line' implantation is possible.

We generally recommend using the same stem size as the last rasp size used, as this results in a cement mantle that is at least 1mm thick.

The femoral component is inserted by hand.

We recommend not removing the protective plastic sleeve on the cone until the stem is in its final position, just prior to attaching the ball head.

We recommend using a low viscosity cement using a current cementing technique. See the cement supplier's manufacturer's instructions for details. The choice of cement is the responsibility of the surgeon.

Note:
The *stem size 0 standard* is 1 mm less lateralized than the corresponding neck trial.
The neck diameters of the cemented stems are slightly larger than the neck trials. This results in a slightly better range of motion when repositioning. However, the deviation is a maximum of 4°.

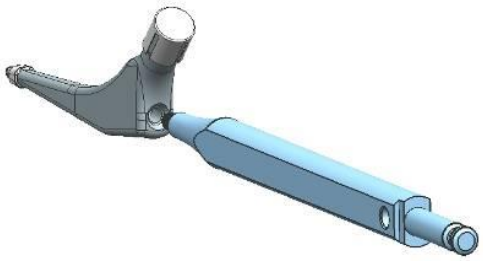


Fig. 12c

If the stem needs to be removed, use the extraction screw (Fig. 12c).

Warning: Always insert the thread of the extraction screw fully into the cavity of the stem in order to prevent any deformation on the instrument.

7.7 Insertion of the ball head

Fig. 13a

Fig. 13b

Remove the plastic protective sleeve from the stem cone.

Before positioning the ball head, carefully clean the stem cone with water and dry it by hand if necessary. Attach the ball head by hand and fasten it with a slight turning movement.

Carefully hammer onto the ball head with the aid of the stem impactor and screwed-on head repositioning device (Fig. 13a+b). Reduce and manipulate the joint to check functionality with regard to range of motion and stability in positions at risk of dislocation in internal and external rotation. Check the achieved leg length again.

Note:
Simply putting on the ball head is not enough; carefully lock it with controlled hammer blows. Ceramic heads must never be hammered on with a metal instrument.

The stems were mechanically tested according to ISO 7206-4,-6 and -8 in combination with ball heads up to a maximum neck length XXL. The use of longer neck lengths is the responsibility of the surgeon.

If an implanted stem is retained during a revision, only ceramic revision heads with a titanium sleeve or metal ball heads may be used. If the ceramic ball head has previously fractured, only **ceramic** revision heads with a titanium sleeve may be used.

7.8 Wound Closure

The following steps correspond to the standard procedure of hip joint surgery. Before the joint is repositioned and the wound is closed, the operating area must be thoroughly cleaned of foreign body particles, bone cement, bone chips or other debris.
Possibly insertion of drains.

8 Post-op treatment

8.1 Uncemented Stem

Depending on the age and state of health of the patient, the movement therapy can be started either on the day of the operation or on the following day and the operated leg can be fully loaded. However, partial loading using forearm supporting crutches for up to 6 weeks may also be necessary.

For the first 48 hours, the use of a suitable position with slight abduction is recommended.

Administration of antibiotics and thrombosis prophylaxis according to local guidelines or at the discretion of the surgeon.

Recommended follow-up intervals: postoperatively, 3-6 months, then annually

8.2 Cemented Stem

Depending on the healing of the wound, patients can get up early after the operation with assistance and usually put full weight on the operated leg or only put weight on it partially during the first few weeks. Walking training is done with forearm crutches.

For the first 48 hours, the use of a suitable position with slight abduction is recommended.

Administration of antibiotics and thrombosis prophylaxis according to local guidelines or at the discretion of the surgeon.

Recommended follow-up intervals: postoperatively, 3-6 months, then annually

9 Disassembly, cleaning, assembly and sterilization of instruments

All instruments in the system must be sterilized with superheated steam. Reprocessing and steam sterilization must be carried out in accordance with the requirements of the applicable standards (EN ISO 17664). For more information on instrument disinfection, cleaning and sterilization, see the “Reprocessing of reusable instruments” brochure provided as part of the Atesos product documentation.

If there is evidence of TSE contamination, a pre-vacuum steam sterilization cycle should be performed with an exposure time of 18 minutes at 134°C (273°F).

All instruments of the Pyramid Hip Stem System are to be disinfected, cleaned and sterilized without further disassembly.

Important instructions:

Disposal information:
Before disposing of instruments and implant components that have been in contact with patients, they must be disinfected and sterilized. The disposal takes place according to material-specific aspects, according to the specifications of the institution.

Duty to report:
All users are obliged to report serious incidents related to the product to the responsible authorities.

10 Implant Components List

Pyramid Hip Stem, uncemented

Features

- Standard and lateral options available
- CCD-angle 135°
- Cone 12/14

Material

- Core: Ti-6Al-4V: ISO 5832-3
- Coating: Ti-VPS, calcium phosphate

Standard **Lateral**

Art. No. Standard	Art. No. Lateral	Size
310001	-	0
310002	310014	1
310003	310015	2
310004	310016	3
310005	310017	4
310006	310018	5
310007	310019	6
310008	310020	7
310009	310021	8
310010	310022	9
310011	310023	10
310012	310024	11

Pyramid Hip Stem, cemented

Features

- Standard and lateral options available
- CCD-angle 135°
- Cone 12/14

Material

- Core: Stainless Steel Polished: ISO 5832-9
- Centralizer: PMMA

Standard **Lateral**

Art. No. Standard	Art. No. Lateral	Size
350000	-	1
350001	350013	2
350002	350014	3
350003	350015	4
350004	350016	5
350005	350017	6
350006	350018	7
350007	350019	8
350008	350020	9
350009	350021	10
350010	350022	11
350011	350023	12

Pyramid Hip Stem, uncemented CCD125

Features

- CCD-angle 125°
- Cone 12/14

Material

- Core: Ti-6Al-4V: ISO 5832-3
- Coating: Ti-VPS, calcium phosphate

Standard	Art. No. Standard	Size
	310101	1
	310102	2
	310103	3
	310104	4
	310105	5
	310106	6
	310107	7
	310108	8
	310109	9
	310110	10
	310111	11

Ball heads

Ceramics ELEC® plus

outer Ø	Size	Comments
28	S	No Atesos product
28	M	No Atesos product
28	L	No Atesos product

32	S	No Atesos product
32	M	No Atesos product
32	L	No Atesos product

36	S	No Atesos product
36	M	No Atesos product
36	L	No Atesos product

(Manufacturer: HiPer Medical AG, Oberkrämer, Germany)

Note:
XL and XXL ball head sizes for all materials available upon request

Metal ball heads

outer Ø	Size	Comments
28	S	No Atesos product
28	M	No Atesos product
28	L	No Atesos product
32	S	No Atesos product
32	M	No Atesos product
32	L	No Atesos product

Revision head (with titanium sleeve)

outer Ø	Size	Comments
28	S	No Atesos product
28	M	No Atesos product
28	L	No Atesos product
32	S	No Atesos product
32	M	No Atesos product
32	L	No Atesos product
36	S	No Atesos product
36	M	No Atesos product
36	L	No Atesos product

Bipolar heads

outer Ø	Size	Comments
42		No Atesos product
44		No Atesos product
46		No Atesos product
48		No Atesos product
50		No Atesos product
52		No Atesos product
54		No Atesos product
56		No Atesos product
58		No Atesos product
60		No Atesos product
62		No Atesos product

Note: For bipolar heads see separate surgical technique

11 Instrument List

Item-Number	Description/Size	Remarks
800151	Box chisel	
800152	Penetration broach	
800153	Pilot rasp	
800154	Rasp handle straight	
800155	Rasp handle double offset 13/17 left	
800156	Rasp handle double offset 13/17 right	
800157	Impact handle	
800158	Pyramid rasp size 0	
800159	Pyramid rasp size 1	
800160	Pyramid rasp size 2	
800161	Pyramid rasp size 3	
800162	Pyramid rasp size 4	
800163	Pyramid rasp size 5	
800164	Pyramid rasp size 6	
800165	Pyramid rasp size 7	
800166	Pyramid rasp size 8	
800167	Pyramid rasp size 9	
800168	Pyramid rasp size 10	
800169	Pyramid rasp size 11	
800171 I/II	Stem impactor (I/II)	
800171 II/II	Head repositioning device (II/II)	
800172	Extraction screw	
800174	Ruler	
800175	Pyramid neck trial standard 0-11	
800176	Pyramid neck trial lateral 1-11	
800178	Rasp handle double offset 30/17 left [2)]	
800179	Rasp handle double offset 30/17 right [2)]	
800182	Rasp handle straight DAA [2)]	
800183	Rasp handle double offset 37/26 left [2)]	
800184	Rasp handle double offset 37/26 right [2)]	
800185	Rasp handle double offset 52/26 left [2)]	
800186	Rasp handle double offset 52/26 right [2)]	
800187	Rasp handle double offset 37/26-10° left	
800188	Rasp handle double offset 37/26-10° right	
800189	Punch	
800201	Trial Head ø28 S	
800202	Trial Head ø28 M	
800203	Trial Head ø28 L	
800204	Trial Head ø28 XL	
800205	Trial Head ø28 XXL	
800206	Trial Head ø32 S	
800207	Trial Head ø32 M	
800208	Trial Head ø32 L	
800209	Trial Head ø32 XL	
800210	Trial Head ø36 XXL	
800211	Trial Head ø36 S	
800212	Trial Head ø36 M	
800213	Trial Head ø36 L	
800214	Trial Head ø36 XL	
800215	Trial Head ø36 XXL	
800103	Hammer 450g [1)]	

800226	Slide hammer [2)]
800247	Pyramid neck trial CCD125 1-3
800248	Pyramid neck trial CCD125 4-7
800249	Pyramid neck trial CCD125 8-11

1) Optional, if there is only a socket set, without a socket set

2) Optional

12 Basic UDI-DIs

Basic UDI-DI	Produktgruppe
764106428STEMUNCEM-02HB	Class III Products uncemented hip stem
764106428STEMCEM-03B2	Class III Products cemented hip stem
764106428INSSTEM-IIA-09MJ	Class IIa Products femoral side
764106428INSTSTEM-IR-084V	Class Ir Products femoral side
764106428INSTCUP-IR-07GB	Class Ir Products acetabular side*

Note: Items marked "Not an Atesos product" are bought in and are subject to the approval of the relevant manufacturer.

*Only hammer affected

13 Contact

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Ed. 07/2023
We reserve the right to make changes, consult the Atesos medical website for the currently valid surgical technique.