Atesos medical AG, Schachenallee 29, CH-5000 Aarau

Surgical Technique Pyramid Hip Stem

Hip Stem System uncemented or cemented

Atesos medical AG
5000 Aarau
Switzerland

cemented **uncemented**

Edition: 04/17-EN

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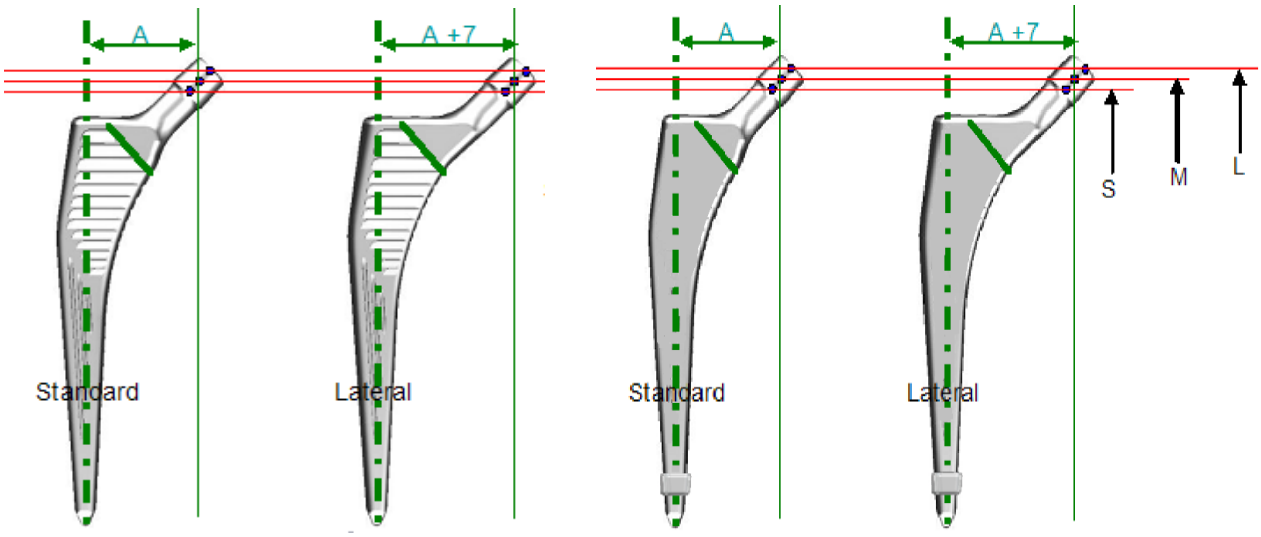
Product Description:

The PYRAMID Hip stem is based upon an implant concept that proves good clinical results for more than 20 years. The choice of material, offset concept, sizing system and the design of the surface for the **uncemented** fixation are in accordance with the latest state of the art. For fast and durable osseointegration the stem compound made of Ti6Al4V alloy is coated with a pure-titanium Plasma Coating (TiVPS) of high roughness and an additional thin Calcium Phosphate layer.

For the **cemented** version of the Pyramid hip stem a polished surface was consciously chosen because it shows better clinical results than rough surfaces. The basic material is provided with a high nitrogen content stainless steel according to ISO 5832-9.

The offset concept with constant CCD-angle (135°) for standard and lateralized stems allows the reconstruction of the joint mechanics without alteration of the leg length and the range of motion.
The Pyramid hip stem facilitates the use of mini incision or minimally invasive surgical techniques and is suitable for all established surgical approaches and a broad spectrum of femoral morphologies.
The sizing system comprises 12 standard and 11 lateral femoral stems each with a CCD angle of 135°. The lateralization is 7 mm for all sizes.
The Pyramid stem is suitable to be combined with all established cup models incl. systems with double mobility.

uncemented **cemented**



The instrumentation supports all established surgical interventions. In addition to the standard instruments there are instruments available with offset for MIS- interventions. In its design a special focus was set to easy and safe handling and to a wide variety of applications, including the “femur first” technique.

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Indications:

- Primary and secondary hip joint arthrosis.
- Fracture or avascular necrosis of the femoral head.
- Rheumatoide Arthritis in case of sufficient bone quality.

Contraindications:

Larger deformations and defects of the femur. Radiographically apparent Osteoporosis or Osteomalacy. Progressive tumor diseases local as well as general, irradiation aggrieved bone substance, acute infection of the joint or its environment, passed or still impending infection disease with potential manifestation in the joint, severe muscular nerve or vessel diseases, that may affect the extremity, pregnancy.

Preoperative Planning:

The preoperative planning is essential for the pre selection of the implant components, for the femur as well as for the hip cup components and for the planning of the leg length and the joint offset. For the planning of the stem size standard or lateral and the ball- head x-ray templates are available as transparencies [1)] (115%) or as digital data. Level and orientation of the neck resection also should be part of the planning. To guarantee a precise planning standardized AP and lateral x-rays are important. On the x-rays an adequate length of femoral diaphysis should be visible.

1): There is a small difference of the neck length between head diameter 28 and 32/36 (0.5mm). On the x-ray templates (foil) this difference is not shown to keep it simple.

Incisions:

The implant range and the corresponding instrumentation permit the implantation through all established incisions, like the lateral transgluteal incision according to Bauer, the antero- lateral incision according to Watson Jones, the dorsal incision and the anterior incision according to Smith Peterson including the minimally invasive versions.

Warning Indications & Symbols:

	Manufacturer
	Read instruction for use
	Single use only!
JJJJ/MM	Expiration date year / month
	Do not use if the packaging is damaged or the seal is broken.
STERILE R	Sterilized by gamma radiation in the final packaging
non-cemented	Non-cemented use
25°C	To be exposed to maximum temperature < 25°C
REF	Order Number
LOT	Batch number manufacturer
	Do not re-sterilize

Do not implant Ti-VPS / calziumphosphat -coatet implants with cement.

Read instruction for use before using the product.

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Use of the instruments:

The use of the instruments for preparation of the femur is identical, independently from the later choice of the product (uncemented or cemented).

Position of the patient and incision

For the present instruction a direct lateral approach was selected. For the intervention the patient is positioned prostrate in supine position.

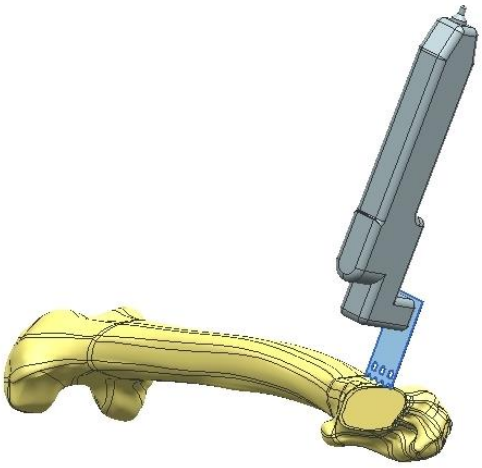

Fig. 1:

Removal of the femoral head

The Osteotomy starts lateral of the Fossa trochenterica (perpendicular to the neck axis) and ends medially approx. one finger breadth above the Trochanter Minor. In case of abnormal anatomy the level of the neck resection should be modified according to the preoperative planning and the corresponding intraoperative measurements (Fig. 1).
The osteotomy can be performed before or after the dislocation of the femoral head.

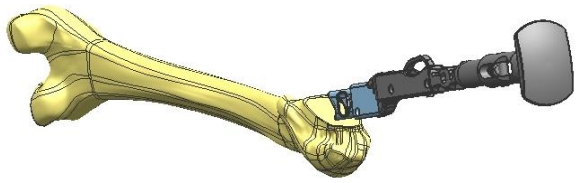

Fig. 2:

Preparation of the Femur

The femoral canal is opened with the box chisel which is connected as attachment to the rasp handle (Fig. 2). In doing so the necessary antetorsion angle for the implant should be respected (10-15°). The opening should be as close as possible to the basis of the Trochanter Major to achieve a good varus – valgus orientation of the stem.

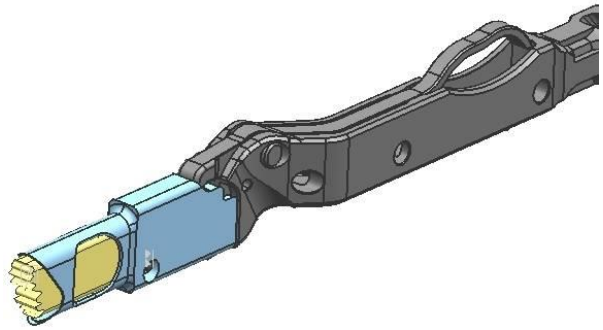

Fig. 3:

For further on use the extracted bone volume can be removed from the chisel through the lateral window (Fig. 3).

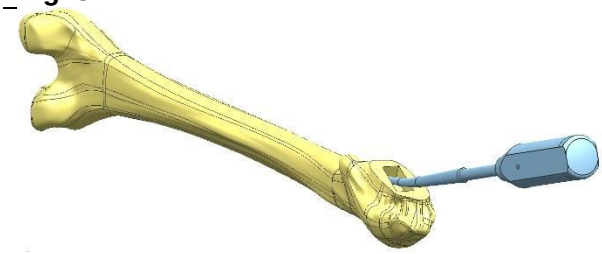

Fig. 4:

The penetration awl is inserted into the femoral canal and the orientation of the canal axis is located (Fig. 4).

If the penetration depth is insufficient, the awl should be further advanced until the canal is accessible.

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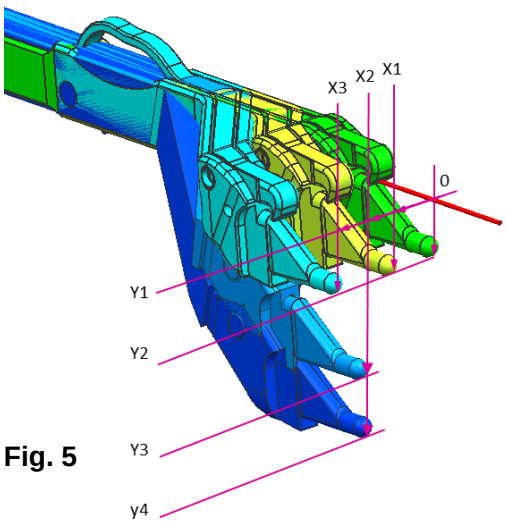

Fig. 5

The trial broaches are being used connected to the rasp handle. To address the specific surgical approach and / or the anatomy of the particular patient both straight rasp handles and rasp handles with different offsets for left and right application are available. (Fig. 5)

	Offset lateral (X mm)	Offset dorsal (Y mm)
Rasp handle straight	0	13
Rasp handle double offset 13/17 le + ri	13	17
Rasp handle double offset 30/17 le + ri	30	17
Rasp handle double offset 26/37 le + ri	26	37
Rasp handle double offset 26/52 le + ri	26	52

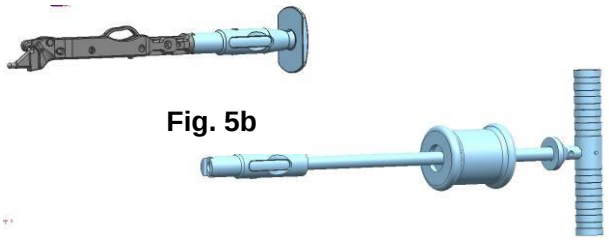

Fig. 5b

All rasp handles can be used in combination with the IMT power tool <<Woodpecker>> and with the punch handle or the Slap Hammer (Fig. 6).

Fig. 6:

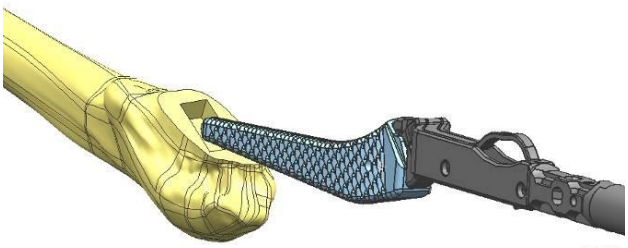

Fig. 7a:

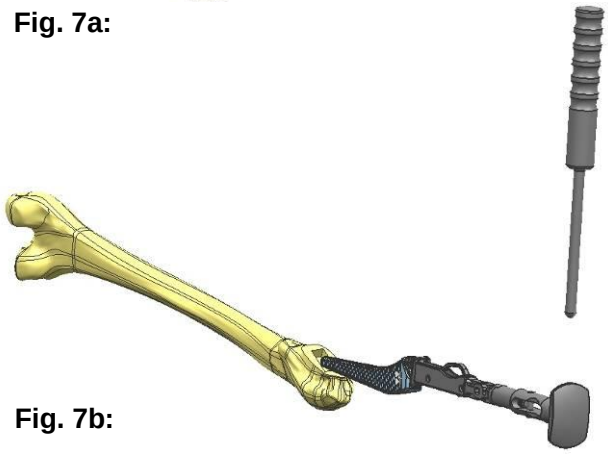

Fig. 7b:

Starting with the smallest trial broach («0») rasping is continuously performed using the following size of broach (Fig. 7a). Reference for the correct orientation of the broach is the axis of the diaphysis and the plain parallel to the dorsal femoral condyles, represented by the 90° flexed knee. The broaching continues until the actual broach sits stable in the canal at the correct level. During broaching the correct antetorsion should be monitored.

As aiming aid for the antetorsion serves the handle of the Woodpecker or the bar across the impaction handle (Fig. 7b), which is to put into the bore at the punch handle.

Remark:

During the stepwise rasping we recommend to guide the medial curvature of the broach along the medial Calcar femoris to achieve a good proximal fit of the shaft to the bone.

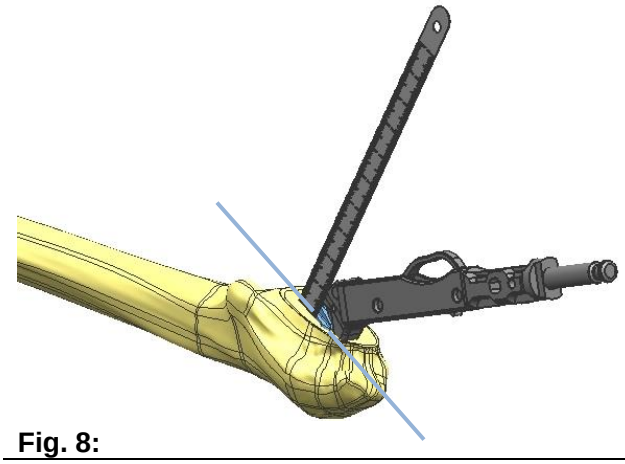

Fig. 8:

The limit of the Ti VPS / Calcium Phosphate coated area of the shaft correspond to the resection plain, which is labelled on the broach. (Fig. 8).

We recommend to advance the broach until the mark in order to cover the coated area completely by the femur. If there are problems in the process, consider the possibility of resect the femur.

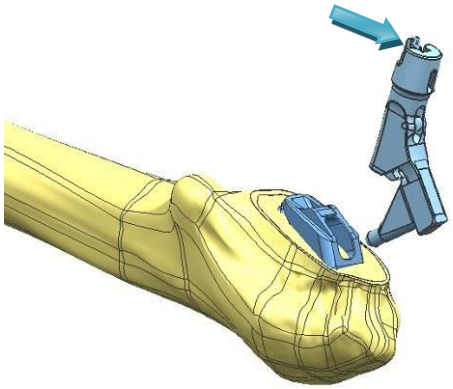

Fig. 9a:

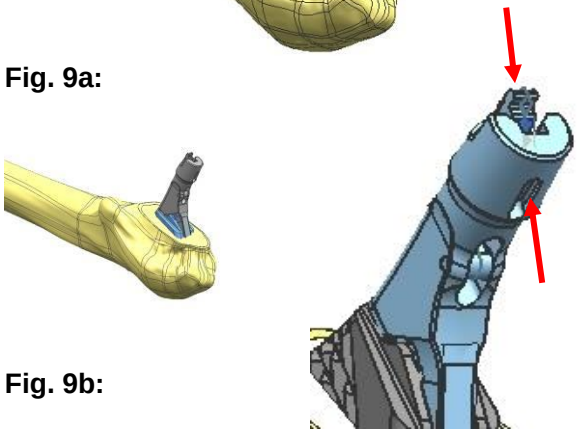

Fig. 9b:

Trial Reduction

If the correct position is given, disconnect the rasp handle and mount the trial neck module (standard or lateral) to the trial rasp (Fig. 9a and 9b).

The trial neck module can be mounted either by hand or with the help of a serrefine (e.g. 'Backhaus-Klemme'). Put in the ends of the forceps into the notches of the trial neck module (see arrows).

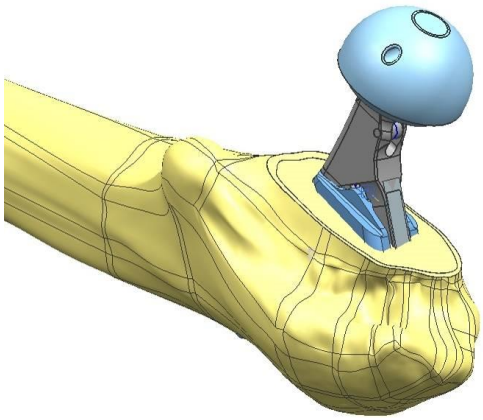

Fig. 11a:

Mounting of a trial head onto the Trial neck module corresponding to the planned cup insert (Fig. 11a). Repositioning the joint for the determination of the leg length, the joint stability and the range of motion. The trial reduction can be supported by the impactor for the ball head (Fig. 14).

Remark:
In relation to the diameter 28 mm the head- neck length of the diameter 32 and 36 mm heads are by 0.5 mm shorter resp. longer (S: - 0.5 mm; L: +0.5 mm).

Press to release

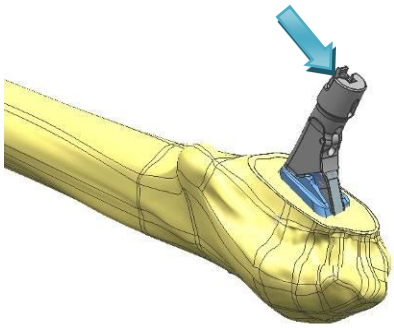

Fig. 11b:

Remove the Trial Head and the trial neck module (Fig. 11b). There can be used a serrefine to release the lever.

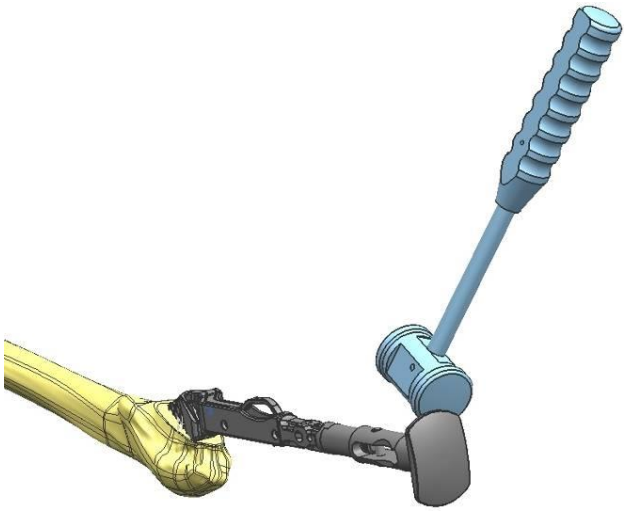

Fig. 12:

Removal of the trial rasp by again connecting the rasp handle to the impaction handle and rejecting the assembly by hammering against the impaction plate (Fig. 12) or against a bar across the impaction handle (stem impactor Fig. 7b). Alternatively the IMT Power tool „Woodpecker“ can be used.

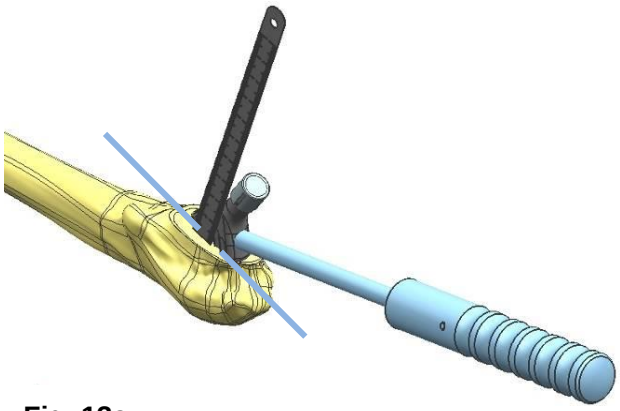

Fig. 13a:

Fig. 13b:

Uncemented stem

The positioning of the stem is done by hand. We recommend leaving the plastic protection cover for the cone in place until the stem is in its final position and the ball head can be applied.
The seating is done with the stem impactor (Fig. 13a). For seating of the stem the intensity of the hammer blows should be adapted to the bone quality.
Stop with the seating as soon as a change in sound and the steady position of the stem confirm the stable fit. Check the position of the stem according to Fig. 8.

Remarks:
Stem size 0 Standard has 1 mm less lateralisation as the corresponding trial neck module.
The rim of the coating corresponds to the mark on the trial rasp and indicates the necessary seating depth of the stem.
If the stem has to be removed this can be done with the Extraction shaft (Fig. 13b).

Broach size. **X** -> Stem size **X**

- ➔ At least 1mm thick cement mantle
- ➔ Centralizer

Broach size. **X** -> Stem size **X+1**

- ➔ ‚line-to-line' -> thinner cement mantle
- ➔ Centralizer to be removed

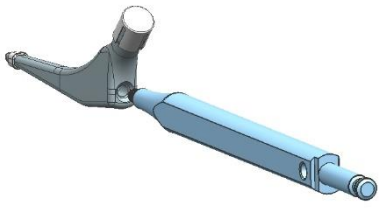

Fig. 13c:

Cemented stem

The size designation of the cemented stems is already adapted to the X-ray planning and the surgical technique. When using an analog size according to the last used broach, this results in an overall cement mantle of at least 1 mm thickness.
If the stem shall be implanted ‚line-to-line' it is required to use a size larger than the previous used broach and the centralizer shall be removed before implantation (done with a light knock at the centralizer, which can then be easily removed). For the broach size 0, only a ‚line-to-line' implantation is possible.
We generally recommend the same stem size as the last used broach, because in this way a cement mantle of at least 1 mm thickness will result.

The positioning of the stem is done by hand. We recommend leaving the plastic protection cover for the cone in place until the stem is in its final position and the ball head can be applied.

We recommend the use of low viscosity cement by using a cementation technique of the third generation. For details, please see the cement manufacturer's specifications. The choice of the cement is the surgeon's own responsibility.

Remarks:
Stem size 0 Standard has 1 mm less lateralisation as the corresponding trial neck module.
The neck diameters of the cemented stems are slightly increased compared to the corresponding neck modules. This results in a slightly better range of motion when using the trial necks. The deviation is however a maximum of 4 °.

If the stem has to be removed this can be done with the Extraction shaft (Fig. 13c).

Fig. 14a:

Fig. 14b:

Mounting of the ball head

Remove the protection cover from the cone.

Before positioning of the ball head if necessary clean the stem cone thoroughly by hand with water and wipe it dry. Position the ball head by hand and affix it by gentle twisting.

Impact the ball head carefully with the ball head impactor (Fig. 14 a+b). Repositioning of the joint and manipulation to check the joint function in terms of range of motion, stability in the luxation sensitive positions in internal and external rotation. Repeated review of the achieved leg length.

Remark:
It is insufficient to just position the ball head without firm seating by impaction. Ceramic Heads must not be impacted by a metal instrument.

The stems have been mechanically tested according to ISO 7206-4, -6 and -8 in combination with ball heads up to the lengthiest neck length XXL It is in the responsibility of the surgeon, if a larger neck length is being used.

If a good integrated stem will be kept in case of a revision surgery, only ceramic ball heads with inner titanium sleeves or metal heads are accepted

Wound closure:
The following steps correspond to the standard procedure of a hip joint surgery. Before repositioning of the joint and the closure of the incision the surgical field should be cleaned thoroughly from particles, bone cement, bone chips or other tissue particle.

After treatment uncemented shaft
Depending on the age and health condition of the patient one can start on the day of surgery or the day after with movement therapy and the treated leg can be put on full weight bearing.

For the first 48 hours the use of suitable bedding in gentle abduction is recommended. The use of a crutch can be useful during the first days, but is not mandatory.

The medication with antibiotics and thrombosis prophylaxis should be done according to the guide- lines and according to the judgement of the physician.

Recommended follow-up intervals are postoperative, 3-6 months, then annually.

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After treatment cemented shaft

Depending on the wound healing, patients can get up either the same day or the day after surgery under supervision and the treated leg can be put on full weight bearing. It is possible that the walking exercise must be done with crutches up to 6 weeks.

For the first 48 hours the use of suitable bedding in gentle abduction is recommended.

The medication with antibiotics and thrombosis prophylaxis should be done according to the guidelines and according to the judgement of the physician.

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

Disassembly; Cleaning, Assembly and Sterilisation of Instruments:

All instrument components are sterilised by vapour sterilisation. Procedures and installations according valid standards should be used for cleaning and sterilisation of reusable instruments. Further information is attached to the products package leaflet and is available by the brochure “preparation of reusable instruments”.

All instruments of the Pyramid hip stem system are disinfected, cleaned and sterilized without further disassembly.

List of implant components:

PYRAMID Hip Stem uncemented: Standard and Lateral
CCD 135°
Material Ti-6Al-4V: ISO 5832.3 / Ti VPS /
Calcium Phosphate coated
cone 12/14

standard

lateral

standard Ref.No.	lateral Ref.No.	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

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PYRAMID Hip Stem cemented: Standard and Lateral
CCD 135°
Material Stainless Steel polished: ISO 5832-9
Cone 12/14 / Centralizer PMMA

standard

lateral

standard Ref.No.	lateral Ref.No.	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

Ball heads:

Ceramic ELEC®

	28	32	36
S	319000	319003	319006
M	319001	319004	319007
L	319002	319005	319008

Ceramic ELEC® plus

	28	32	36
S	110230	110260	110300
M	110240	110270	110310
L	110250	110280	110320

Metal CoCrMo

	28	32
S	030-2800	030-3200
M	030-2801	030-3201
L	030-2802	030-3202

On request:

- XL and XXL ball heads
- Revision ball heads (with titanium sleeve)

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Bipolarhead*

Art.Nr.	Grösse
151-042	42
151-044	44
151-046	46
151-048	48
151-050	50
151-052	52
151-054	54
151-056	56
151-058	58
151-060	60
151-062	62

*see separate surgical technique

List of instruments:

Ref. No	Name	Remarks
800151	box chisel	
800152	penetration broach	
800154	Straight rasp handle	
800155	Rasp handle double offset 13/17 left	
800156	Rasp handle double offset 13/17 right	
800157	Impaction handle (impaction mushroom)	
800158	Pyramid broach size 0	
800159	Pyramid broach size 1	
800160	Pyramid broach size 2	
800161	Pyramid broach size 3	
800162	Pyramid broach size 4	
800163	Pyramid broach size 5	
800164	Pyramid broach size 6	
800165	Pyramid broach size 7	
800166	Pyramid broach size 8	
800167	Pyramid broach size 9	
800168	Pyramid broach size 10	
800169	Pyramid broach size 11	
800171	Stem impactor	
800172	Extraction shaft M6	
800174	Scale	
800175	Pyramid neck module STD, size 1…11	
800176	Pyramid neck module LAT, size 0…11	
800178	Raspelgriff Doppeloffset 30/17 links [2)]	
800179	Raspelgriff Doppeloffset 30/17 rechts [2)]	
800180	Raspelgriff Doppeloffset Monoblock 45/30 links [2)]	
800181	Raspelgriff Doppeloffset Monoblock 45/30 rechts [2)]	
800182	Raspelgriff gerade DAA [2)]	
800183	Raspelgriff Doppeloffset 37/26 links [2)]	
800184	Raspelgriff Doppeloffset 37/26 rechts [2)]	
800185	Raspelgriff Doppeloffset 52/26 links [2)]	
800186	Raspelgriff Doppeloffset 52/26 rechts [2)]	
800200	Ball head impactor	
800201	Trial ball head ø28 S	
800202	Trial ball head ø28 M	
800203	Trial ball head ø28 L	

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800204	Trial ball head ø28 XL
800205	Trial ball head ø28 XXL
800206	Trial ball head ø32 S
800207	Trial ball head ø32 M
800208	Trial ball head ø32 L
800209	Trial ball head ø32 XL
800210	Trial ball head ø32 XXL
800211	Trial ball head ø36 S
800212	Trial ball head ø36 M
800213	Trial ball head ø36 L
800214	Trial ball head ø36 XL
800215	Trial ball head ø36 XXL
800103	Hammer 450 gr.[1)]
800226	Slap Hammer [2)]

1): Optional, if stem set only is available (without cup set) 2): Optional *) removed from assortment

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This edition is subject to alterations, for actual valid surgical technique see webpage Atesos medical.