Surgical Technique

Unas Short Stem

Uncemented Hip Stem System

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Contents

1 Intended Use and Product Description

Intended Use
The Unas short stem system, in conjunction with other components, is intended as a femoral component for the primary partial or total replacement of the human hip joint.

Product Description
The Unas short stem is a classic short stem for the reconstruction of the function of the proximal femur with uncemented fixation, in accordance with the indications and contraindications.
The short stem concept allows for a soft-tissue-sparing and a bone-saving surgical technique.
The material selection, concept of offset, 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 short stem body (fixation section) 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.

In order to cover different anatomical conditions, combinations of high and low offset versions for the individual sizes were developed in extensive X-ray analysis.
With these two implementations per size, the individual reconstruction of the joint mechanics, e.g. join offset, centre of rotation and leg length, can be achieved with a high degree of approximation, while at the same time providing good primary stability of the stem implantation.

The stem geometry facilitates the use of mini-incision and minimally invasive surgical procedures and is suitable for all common approaches and a wide range of femoral morphologies.
It enables calcar-guided implantation, whereby the stem can be used from femoral neck resection to partially preserving surgical techniques. Thus an individualization of the femoral joint-offset becomes possible.
Preoperative planning, taking into account the indications and contraindications, is important for the safe and successful application and the pre-selection of the product. There are no restrictions regarding races and ethnical groups.

The range of sizes includes 11 low offset and high offset femoral stems. The additional lateralization low to high is 5 millimetres for the sizes 1 to 5 and seven millimetres from size 6 (Fig.1).

The Unas short stem can be combined with acetabular models from the Atesos range or with others acetabular models after testing.

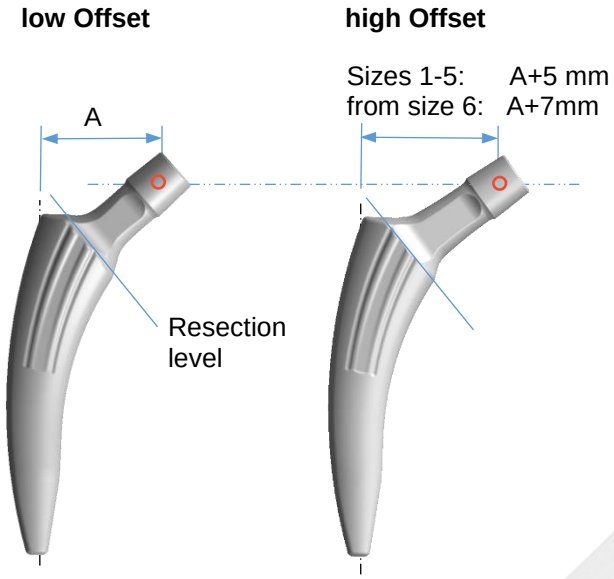


Fig. a: Geometry indicators

The set of instruments supports all common surgical approaches. In addition to the standard instruments, MIS instruments are offered in various offset variants for minimally invasive approaches. When designing the instruments, special emphasis was placed on easy and safe handling and universal applicability, including the "femur first technique".

2 Indications

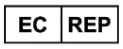
- Primary, secondary and post-traumatic hip arthrosis with sufficient bone quality for secure implant anchorage.
- Avascular necrosis of the femoral head with adequate bone quality.
- Rheumatic diseases with sufficient bone quality
- Dysplasia coxarthrosis up to a CCD angle of approx. 145°

3 Contraindications

- Poor bone quality of the proximal femur
- Circulatory disorders in the femoral neck in the case of avascular necrosis (MRI examinations)
- Bone bed damaged by radiation
- Acute infections of the joint or its surroundings
- Lack of stability
- Marrow cavity unsuitable for the shaft geometry (possibly L. Dorr type C)
- Larger deformations and defects of the femur
- Femoral neck angle (CCD angle) < 120° or >145°

For further and detailed information on indications and contraindications, see the package insert.

4 Warning Symbols

	Manufacturer
	Medical Device
	European Authorized Representative
	Read instruction for use
 YYYY-MM-DD	Expiration date year / month / day
	Do not use if the packaging is damaged or the seal is broken.
	Sterilized by gamma radiation in the final packaging
	Double Sterile Barrier System
	Catalogue Number / Article Order Number
	Batch Number Manufacturer
	Unique Device Identifier
	Do not re-sterilize
	Single use only!
 non-cemented	Non-cemented use

Do not implant Ti-VPS / calcium phosphate -coated implants with cement.
Read instruction for use before using the product.

5 Preoperative Planning

Preoperative planning is essential for component preselection, both femoral and acetabular components, and for planning leg length, centre of rotation and joint offset. In order to plan the stem size in low and high offset implementations and the femoral head, x-rays templates are available as transparencies [1)] (115%) or in digital form. The corresponding software is provided by relevant, qualified suppliers.
To ensure accurate planning, standardized AP and axial radiographs are important.

During planning, the stem should be positioned along the calcar geometry with a lateral metaphyseal support for the best possible primary stability.

To reconstruct the joint geometry, the implant can be positioned along the calcar arch, always ensuring good lateral support. The largest possible implant should always be planned. If the implant is too small, there is a risk of early implant migration.

The plane and angle of the neck resection affect the size choice and implant position and are also part of the planning.

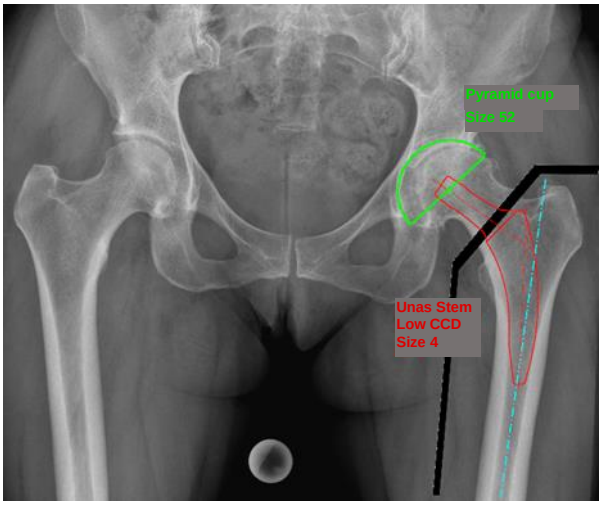


Fig. b: Planning basics for Unas Short Stem

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 in accordance with Watson Jones, the dorsal approach according to Kocher Langenbeck and the interior approach as stated by Smith Peterson, including the minimally invasive variants.

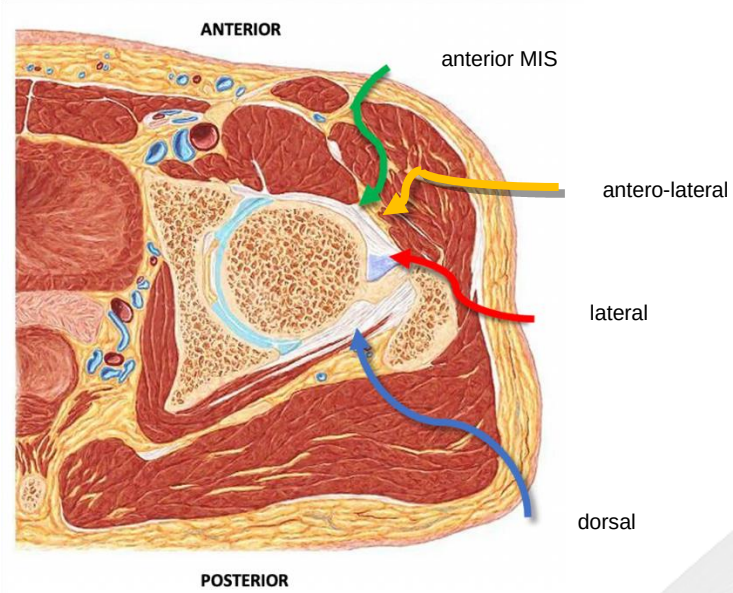


Fig. c: Different kinds of approaches

7 Application of Instruments

The use of the instruments for preparing the proximal femur is identical, regardless of whether the low offset or high offset model is selected later. To ensure the correct reconstruction of the joint, an intraoperative X-ray control of the instrument and implant positions is strongly recommended.

7.1 Patient Positioning and Approach

For the described steps below, a direct lateral approach was chosen as an example. During the procedure, the patient is in a supine position.

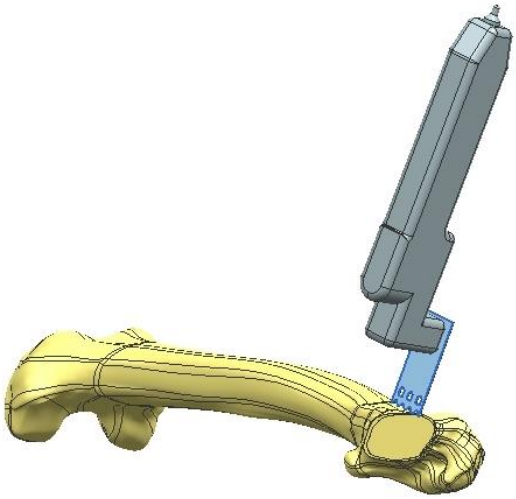


Fig. 1:

7.2 Removal of femoral head

The osteotomy of the femoral neck depends on the preoperative planning and should be perpendicular to the axis of the neck (Fig. 1).
The osteotomy can be performed before or after dislocation of the femoral head.

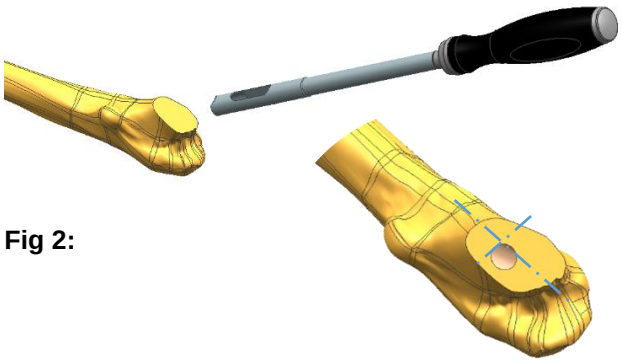


Fig 2:

7.3 Opening of the medullary canal

The medullary canal is opened with the punch (Fig. 2) so that a calcar-guided implant position is achieved. The entry point is usually slightly dorsal to the midplane of the resection.
If a small size (size 1 or size 2) is planned, the punch may not be used in order not to remove too much cancellous bone.

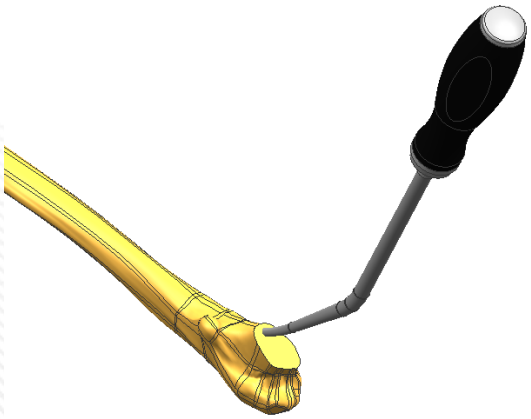


Fig. 3:

7.4 Preparation of the femur

The medullary canal is opened with the reamer close to the medial calcar contour and the position of the medullary canal axis is located (Fig. 3).

If the depth of penetration is insufficient, then the awl must be advanced further by rotating it until the medullary canal is accessible. Care must be taken, not to penetrate the metaphyseal cortex (via falsa).

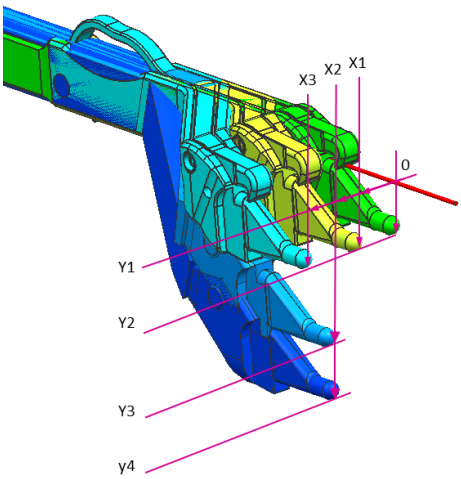


Fig. 4

The manipulation rasps are attached to the rasp handles. Straight or 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. The double offset 26/37 10° version is primarily recommended for the implantation of Unas.

(Fig. 4).

	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
Rasp handle double offset 26/37 10° le +ri	26	37

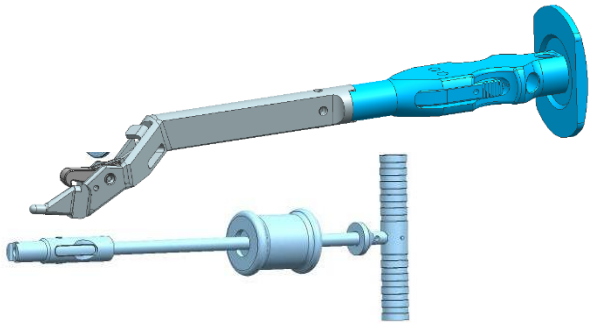


Fig. 5:

All rasp handles can be used together with the IMT «Woodpecker» rasp machine, impact handle and hammer or slide hammer (Fig. 5).

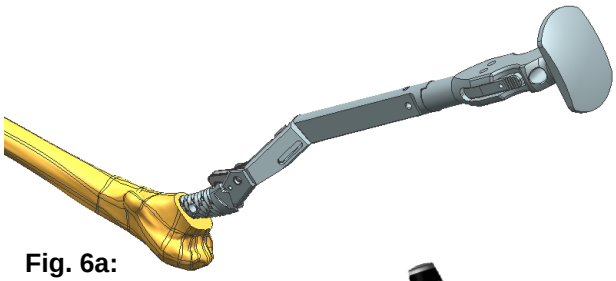


Fig. 6a:

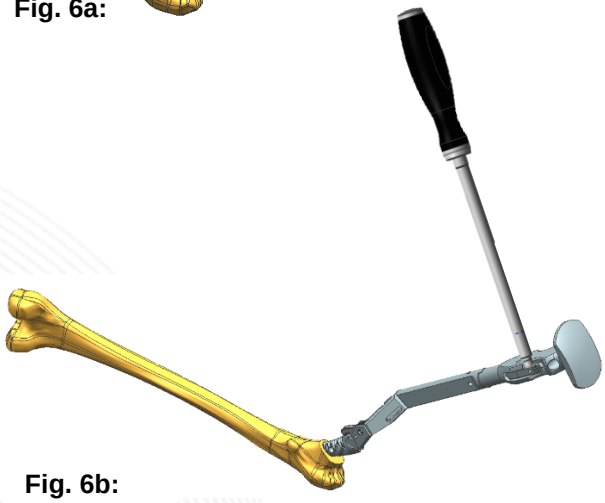


Fig. 6b:

Beginning with the smallest rasp, rasping is continued step by step with a subsequent larger size (Fig. 6a). Reference for the correct ante-version 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 orientation of the rasp machine or the rod of the femoral stem impactor, which is pushed into the hole on the impact handle (Fig. 6b), serves as a targeting aid for the ante-torsion.

The rasping process is carried out along the calcar geometry according to the arched shape of the stem implant and 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.

Note:
Unas rasps are sharp-cutting rasps, which do not primarily produce a precise implant bed by compacting, but by sharp cutting. Therefore very strong hammer blows are **not** necessary to achieve the desired high primary stability.

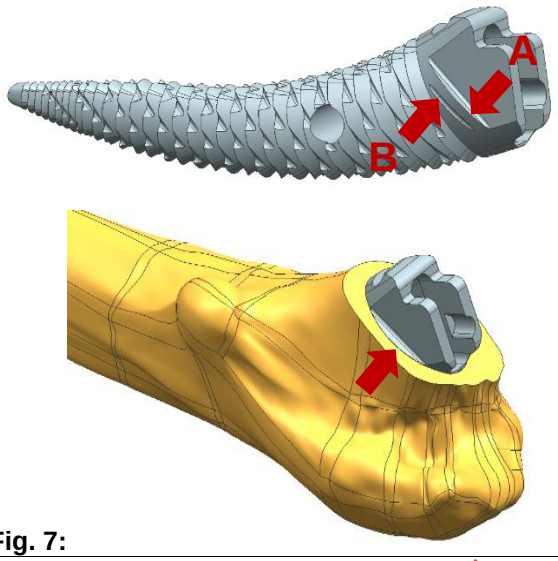


Fig. 7:

The marked resection level (**A**) of the rasp corresponds to the upper limit of the anchorage area (coated area of the shaft, see Fig. 8a).

The engraved mark (**B**) on the rasp corresponds to a raised position of the stem by +2mm.
Depending on the bone condition (i.e. soft bone), a raised position of the stem may be preferable in order to counteract a post-op resintering of the implant.

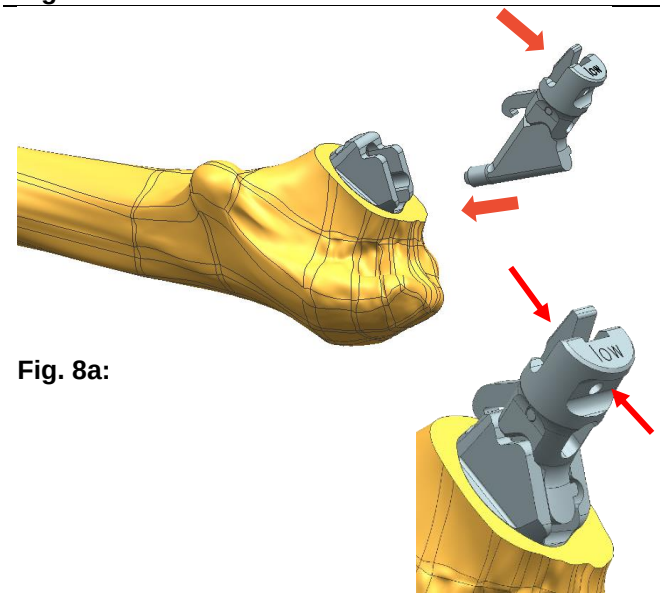


Fig. 8a:

Fig.8c

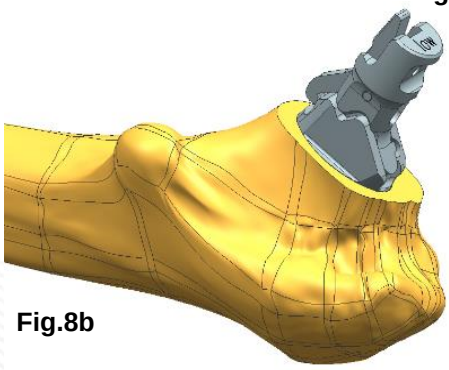


Fig.8b

7.5 Trial positioning and joint reduction

When the rasp is correctly seated, the rasp handle is removed and the Unas trial neck module (low or high) of the corresponding size is placed on the rasp (Fig. 8a and b).

The neck module can be attached 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 module (Fig. 8c).

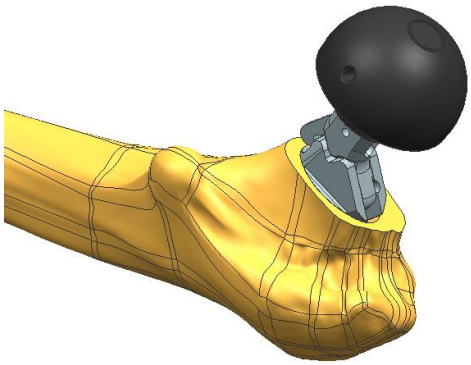


Fig. 9a:

Place a trial head corresponding to the planned socket inlay on the trial neck module (Fig. 9a).

Reposition the joint to determine leg length, joint stability, and range of motion. Repositioning can be supported with the stem impactor (Fig. 12a) in combination with the screwed-on head repositioning device.

Note:
The recess for the trial neck in the trial head in sizes S and L with a diameter of 32 and 36 mm are each 0.5 mm shorter or longer than the diameter of 28 mm (S:-0.5 mm / S+0.5 mm).

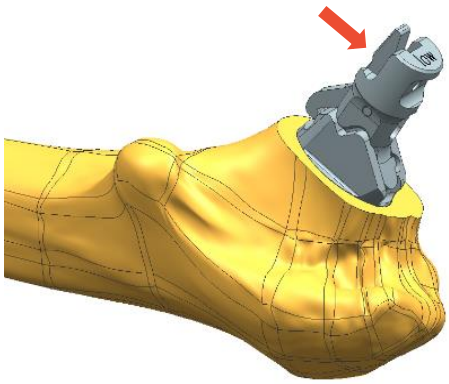


Fig. 9b:

Remove trial head and trial neck module (Fig. 9b). A clamp can be used to operate the release lever to disassemble the neck module.

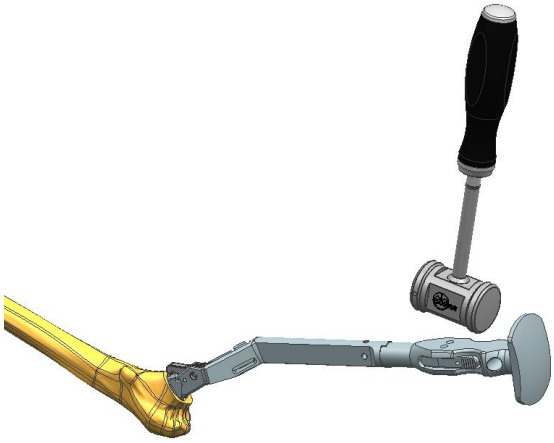


Fig. 10:

Remove the rasp by reconnecting the rasp handle to the impact handle and knocking it against the impact plate of the impact handle (Fig. 10) or against an inserted rod (from stem impactor, see acc. To Fig. 6b).

Alternatively, the IMT "Woodpecker" rasp machine can be used.

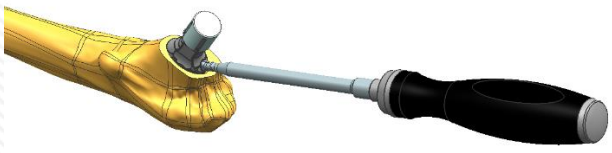


Fig. 11a:

7.6 Stem implantation

The femoral component is inserted by hand.

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

Setting is done with the help of the stem impactor (Fig. 11a). During the setting process, the rotational orientation of the stem can be checked by visual control of the alignment of the impactor tip in the oval shaped recess of the implant.

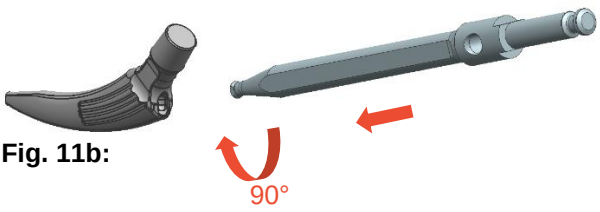


Fig. 11b:

Adjust the intensity of the hammer blows to the bone quality during the setting process.

Stop the setting process as soon as a change of sound and a permanent position confirm the firm seat. Check the embedment depth of the stem analogously to Fig. 7.

Hint:
The rim of the coating corresponds to the marking (A) on the trial rasp and marks the required insertion depth of the stem. In case of a desired elevated seat (equal to description at Fig. 7) the rim of the coating may be proud to the resection level.

If the stem has to be removed, use the retraction instrument (Fig. 11b). For extraction twist the extractor by 90° to lock it in the implant recess.

7.7 Insertion of ball head

Fig. 12a:

Remove the plastic protective sleeve from the stem neck.

Before positioning the ball head, carefully clean the stem neck with water and dry it by hand if necessary.

Mount the ball head by hand and fasten it with a slight turning movement.

Carefully hammer in the ball head with the stem impactor incl. screwed-on head repositioning device (Fig. 12a+b).

Reposition and manipulate the joint to check functionality with regard to range of motion and stability in the positions at risk of dislocation in internal and external rotation. Check the achieved leg length again.

Fig. 12b:

Note:
Simply putting on the ball head is not enough: controlled hammer blows are necessary.
Ceramic heads must never be hammered in with a metal instrument.

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

If a fixed 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 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 an insertion of a drain is necessary.

8 Post-op Treatment

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 support 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 may be necessary.

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

9 Disassembly, Cleaning, Assembly and Sterilisation of Instruments

All instruments in the system are to be sterilised with superheated steam. Reprocessing and steam sterilization must be carried out in accordance with the conditions of the applicable standards (EN ISO 17664).

For more information on instrument disinfection, cleaning and sterilisation, 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 sterilisation cycle should be performed with an exposure time of 18 minutes at 134°C (273°F). All instruments of the Unas short stem system are disinfected, cleaned and sterilized without further disassembly.

Important information

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

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

10 Articles

10.1 Stems

Unas Short Stem, uncemented

Characteristics

- Low and high offset option available
- Cone 12/14

Material

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

low offset

high offset

Size	low offset Art.No.	high offset Art.No.	Difference
1	310201	310221	+5 mm
2	310202	310222	+5 mm
3	310203	310223	+5 mm
4	310204	310224	+5 mm
5	310205	310225	+5 mm
6	310206	310226	+7 mm
7	310207	310227	+7 mm
8	310208	310228	+7 mm
9	310209	310229	+7 mm
10	310210	310230	+7 mm
11	310211	310231	+7 mm

10.2 Ball Heads

Ceramics ELEC® plus

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

Ø outer	Size	Notes
32	S	No Atesos product
32	M	No Atesos product
32	L	No Atesos product

Ø outer	Size	Notes
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 available upon request with all materials

Metal Ball Heads

Ø outer	Size	Notes
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 Heads

Ø outer	Size	Notes
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

10.3 Instruments

Art.No.	Description
800152	Penetration broach
800154	Rasp handle straight
800155	Rasp handle double offset 13/17 left
800156	Rasp handle double offset 13/17 right
800157	Impact Handle
800171 II/II	Head repositioning device
800174	Scale
800178	Rasp handle double offset 30/17 left[2)]
800179	Rasp handle double offset 30/17 right[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[2)]
800188	Rasp handle double offset 37/26-10° right[2)]
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 ø32 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)]
800251	Unas Rasp Size 1
800252	Unas Rasp Size 2
800253	Unas Rasp Size 3
800254	Unas Rasp Size 4
800255	Unas Rasp Size 5
800256	Unas Rasp Size 6
800257	Unas Rasp Size 7
800258	Unas Rasp Size 8
800259	Unas Rasp Size 9
800260	Unas Rasp Size 10
800261	Unas Rasp Size 11
800262	Unas Trial Neck 1-5 low offset
800263	Unas Trial Neck 1-5 high offset
800264	Unas Trial Neck ≥6 low offset
800265	Unas Trial Neck ≥6 high offset
800266	Guided Stem Impactor
800267	Retraction Instrument Stem

1): Optional, in case only stem set at hand without cup set 2): Optional

11 Basic UDI-DIs

Basic UDI-DI	Product group
764106428STEMUNAS-04HS	Class III Products Femoral Side
764106428INSUNAS-IIA-10J9	Class IIa Products Femoral Side
764106428INSTSTEM-IR-084V	Class Ir Products Femoral Side

12 Contact

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