



Surgical Technique

Unas Short Stem

Uncemented Hip Implant System



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1 Intended Use and Product Description

1.1 Intended Use

The *Unas Short Stem* system, in combination with other components, is intended as a femoral component for primary partial or total replacement of the human hip joint.

1.2 Product Description

The *Unas Short Stem* is a classic *Short Stem* for reconstructing the function of the proximal femur with uncemented anchoring.

The *Short Stem* concept allows for a surgical technique that is gentle on soft tissue and preserves bone. The choice of material, offset concept, size range and surface design for **uncemented** anchoring correspond to the latest state of the art. For biological anchoring, the stem body made of Ti6Al4V is coated with a high-roughness pure titanium plasma layer (TiVPS) and an additional thin calcium phosphate layer. The roughness of the TiVPS coating supports secure primary implant anchoring and forms the basis for long-term stable fixation through osseointegration. The thin, soluble calcium phosphate coating on top supports bone formation and thus rapid osseointegration.

In order to better accommodate the different anatomical conditions of the hip joint, extensive X-ray analyses were used to develop a combination of *low* and *high* offset designs within the size system. This allows for an anatomically accurate, individual reconstruction of the joint mechanics, i.e. joint offset, center of rotation and leg length, while maintaining good primary stability of the *Stem*.

The stem geometry facilitates the use of minimal incisions and minimally invasive surgical techniques. It is suitable for all common approaches and a wide range of femoral morphologies. The stem geometry enables calcar-guided implantation, allowing the *Stem* to be used in surgical techniques ranging from total femoral neck resection to partial femoral neck preservation. This allows for individualisation of the femoral joint offset.

Preoperative planning is important for the safe and successful application and preselection of the product. This must always take into account the indications and contraindications. There are no restrictions with regard to ethnicity.

The size range includes 11 *high* and *low* offset femoral *Stems*. The additional lateralisation from *low* to *high* is five millimeters for sizes 1 to 5 and seven millimeters from size 6 onwards (Fig. 1).

The *Unas Short Stem* is suitable for combination with *Cup* models from the *Atesos medical* range or with other *Cup* models after testing.

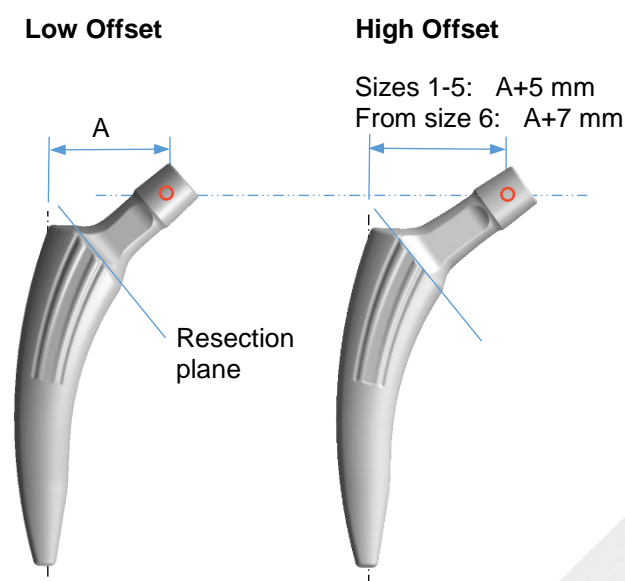


Fig. 1 Geometric parameters

The instrument set supports all common surgical approaches. In addition to the standard instruments, instruments in various offset variants are available for MIS approaches. When designing the instruments, particular emphasis was placed on simple and safe handling, as well as universal applicability, including the "femur first technique"

2 Indications







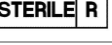







- Primary, secondary and post-traumatic hip joint arthrosis with sufficient bone quality for secure implant anchoring.
- Avascular necrosis of the femoral head with sufficient bone quality.
- Rheumatic diseases with sufficient bone quality
- Dysplasia coxarthrosis up to a CCD angle of approx. 145°

3 Contraindications

- Insufficient bone quality of the proximal femur
- Circulatory disorders in the femoral neck in cases of avascular necrosis (MRI examinations)
- Radiation-damaged bone bed
- Acute infections of the joint or its surroundings
- Lack of stability
- Medullary cavity unsuitable for stem geometry (possibly L. Dorr type C)
- Major deformities 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 Warnings & List of Symbols used

	Manufacturer
	Medical Device
	European Authorised Representative
	Follow the Instructions for Use
 YYYY-MM-DD	The Product can be used until Year/Month/Day
	Do not use if the Packaging is damaged or the Seal has been broken
	Sterilisation in the final Packaging by Irradiation
	Double Sterilisation Barrier System
	Catalogue Number / Item Order Number
	Batch Designation
	Unique Device Identifier
	Do not re-sterilise
	Do not reuse
 Non-cemented	Cement- free use



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

5 Preoperative Planning

Preoperative planning is essential for the preselection of femoral and acetabular components and for planning leg length, center of rotation and joint offset. X-ray templates are available in transparent form ⁽¹⁾ (115%) or in digital form. The corresponding software is commercially available from relevant, qualified suppliers. Standardised AP and axial X-rays are important for ensuring precise planning.

During planning, the *Stem* should be positioned along the Calcar geometry with lateral metaphyseal support to achieve the best possible primary stability.

To reconstruct the joint geometry, the implant can be positioned along the calcar arc, 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 influence the size selection and implant position and are also part of the planning process.

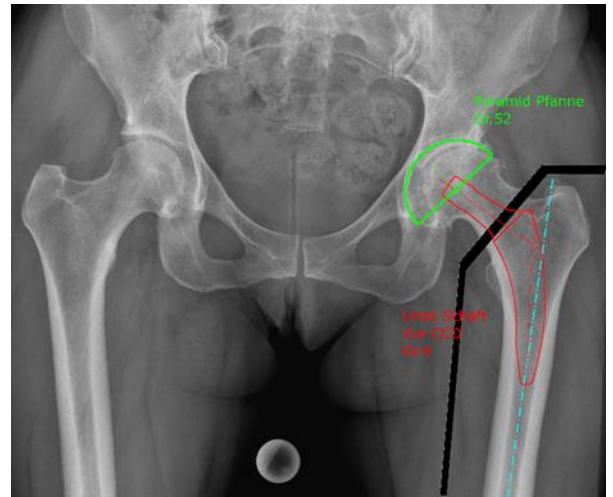


Fig. 2 Planning principles

6 Access

The implant range 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 according to Kocher-Langenbeck and the anterior approach according to Smith Peterson, including the minimally invasive variants.

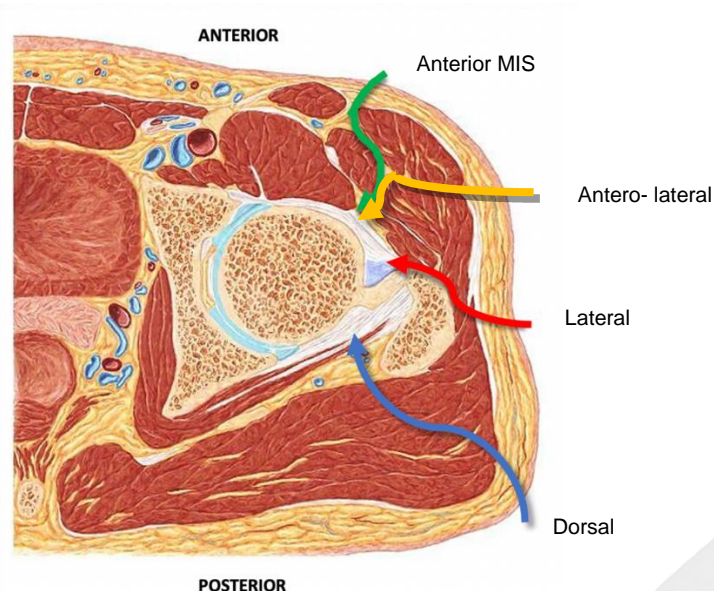


Fig. 3 Different types of access

7 Use of the Instruments

The instruments are used in the same way to prepare the femur, regardless of whether a *low* offset or *high* offset model is subsequently selected. Intraoperative X-ray control of the instrument and implant positions is strongly recommended to ensure correct reconstruction of the joint.

7.1 Patient Position and Approach

For the purposes of this description, a direct lateral approach has been chosen as an example. During the procedure, the patient lies in a supine position with the legs extended.

7.2 Resection of the Femoral Head

The osteotomy of the femoral neck is based on the preoperative planning and should be performed perpendicular to the neck axis. The osteotomy can be performed before or after dislocation of the femoral head.

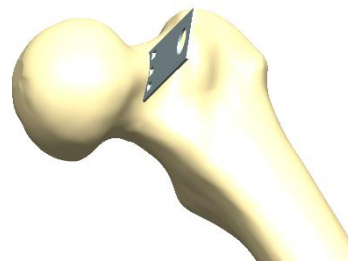


Fig. 4 Resection of the femoral head

7.3 Opening of the Medullary Cavity

The medullary cavity is opened with the *Punch* in such a way that a calcar-guided implant position is achieved. As a rule, the entry point is slightly dorsal to the midline of the resection.

If a small size (size 1 or size 2) is planned, the *Punch* may not be used in order to avoid removing too much cancellous bone.

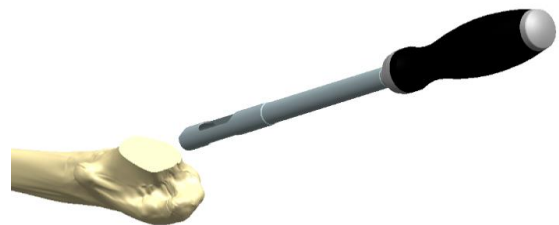


Fig. 5 Opening of medullary cavity by using the *Punch*

7.4 Preparation of the Femur

The medullary cavity is prepared using the *Penetration broach* along the medial calcar contour to establish the position of the medullary axis.

If the penetration depth is insufficient, the *Penetration broach* must be advanced deeper by turning it until the medullary canal is accessible. Care must be taken not to pierce the metaphyseal cortex (*via falsa*)



Fig. 6 Preparing the medullary cavity by using the *Penetration broach*

The *Rasps* are used in conjunction with the *Rasp handles*. Straight or offset *Rasp handles* with different offsets are available in left and right versions to suit the chosen surgical approach. The *Rasp handle Double Offset 26/37 10°* version is primarily recommended for the implantation of the Unas system.

All *Rasp handles* can be used together with the IMT "Woodpecker" drive unit, the *Impact handle*, or the *Slide hammer*.

Starting with the smallest *Rasp*, rasping is continued step by step, using the next larger *Rasp*. The reference point for the correct anteversion alignment of the *Rasp* is the axis of the diaphysis and the plane running parallel to the dorsal femoral condyles, represented by the knee bent at 90°.

The rasping process is carried out in accordance with the curved stem geometry along the Calcar geometry and is continued until the selected *Rasp* is positioned stably at the correct height. During rasping, care must be taken to maintain the anteversion.

Note: Unas *Rasps* are very sharp and create a precise implant bed, not primarily by compacting, but by sharp cutting. Therefore, very strong hammer blows are not usually necessary to achieve the desired high primary stability.

The marked resection level (**A**) of the *Rasp* corresponds to the upper limit of the anchoring area.

The engraved mark (**B**) on the *Rasp* corresponds to a raised position of the stem by +2 mm. Depending on the bone conditions (soft bone), a deep shaft position can be prevented.



Fig. 7 Straight *Rasp handle* and two offset *Rasp handle* configurations

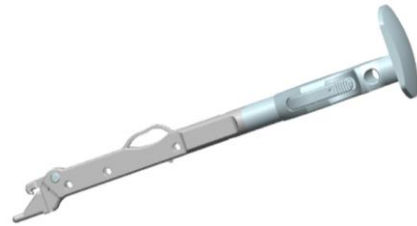


Fig. 8 *Rasp handle* mounted on *Impact handle*

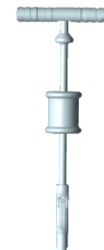


Fig. 9 *Slide hammer*

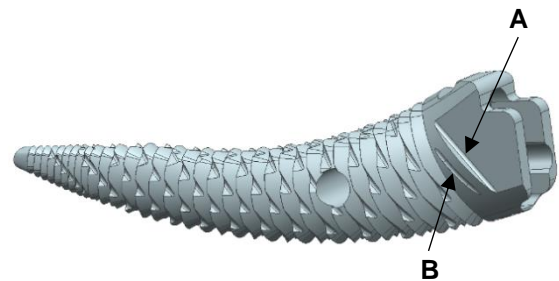


Fig. 10 **A:** Upper limit of anchoring area, **B:** Mark corresponds to a +2 mm raised position used in poor bone quality to prevent excessive subsidence of the stem

7.5 Insertion of the Ball Head

The plastic protective cover can now be removed from the stem cone.

Before positioning the *Ball head*, the stem cone should be carefully cleaned and dried. The *Ball head* is attached manually and mounted with a slight twisting motion.

The *Ball head* can be carefully hammered into place by connecting the *Stem impactor* with the *Head repositioning device*.

The joint should now be repositioned and manipulated to check its functionality in terms of range of motion and stability. The achieved leg length is checked again.

Note: Simply placing the *Ball head* is insufficient, it must be carefully tapped into position. *Ceramic Ball heads* must never be impacted using a metal instrument.

The *Stems* have been mechanically tested in accordance with ISO 72064 and -6 in combination with *Ball heads* with a maximum neck length according to size XXL. The use of longer neck lengths is the responsibility of the surgeon.

If a fixed *Stem* is retained during revision, only ceramic *Revision Ball heads* with titanium sleeves or metal *Ball heads* may be used. If the ceramic *Ball head* has previously broken, only **ceramic** *Revision Ball heads* with titanium sleeves may be used.

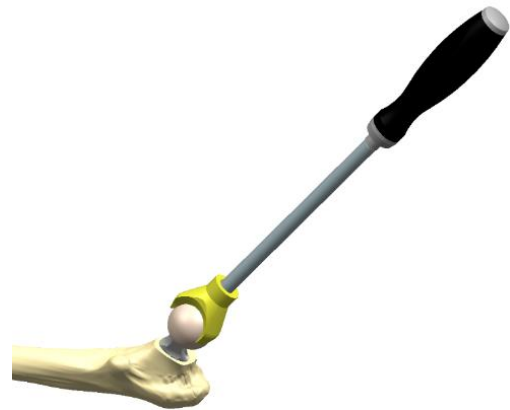


Fig. 11 Head repositioning device mounted on the Stem impactor for seating the Ball head using a Hammer

7.6 Wound Closure

The following steps correspond to the standard procedure for hip joint surgery and are at the discretion of the treating surgeon. Before repositioning the joint and closing the wound, the surgical area must be thoroughly cleaned of foreign particles, bone chips or other tissue debris. It may be advisable to insert a drain.

8 Follow- up Treatment

Depending on the patient's age and state of health, movement therapy can be started either on the day of the operation or the following day, and the operated leg can be fully weight-bearing. However, partial weight-bearing with forearm crutches may be necessary for up to 6 weeks.

For the first 48 hours, it is recommended that the leg be positioned in slight abduction.

Antibiotics and thrombosis prophylaxis are administered in accordance with local guidelines or at the discretion of the treating surgeon.

The recommended follow-up intervals are 3 and 6 months after surgery, then annually.

9 Disassembly, Cleaning, Assembly and Sterilisation of Instruments

All instruments in the system must be sterilised with hot steam. Reprocessing and steam sterilisation must be carried out in accordance with the conditions of the applicable standards (EN ISO 17664-1). Further information on the disinfection, cleaning and sterilisation of instruments can be found in the brochure *Reprocessing of reusable instruments*, which is provided as part of the *Atesos medical* product documentation.

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

All instruments of the *Unas Short Stem* system are disinfected, cleaned and sterilised 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. Disposal is carried out according to material-specific criteria, in accordance with the institution's guidelines.

Reporting Obligation:

All users are obliged to report serious incidents in connection with the product to the competent authorities.

10 List of Implant Components

10.1 Unas Short Stem, uncemented

Features	Material
<ul style="list-style-type: none"> > Low and high offset variants available > Cone 12/14 	<ul style="list-style-type: none"> > Core: Ti-6Al-4V: ISO 5832-3 > Coating: TiVPS, calcium phosphate




Low Offset	High Offset		Low Offset	High Offset	
		Size	Item No.	Item 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

Ceramic Ball heads

Material:

- > Zirconium oxide reinforced aluminium oxide ceramic (ISO 6474-2)

Ceramic ELEC® plus	Outer Ø	Size	Item No.
	28	S	110230
	28	M	110240
	28	L	110250
	32	S	110260
	32	M	110270
	32	L	110280
	32	XL	110291
	36	S	110300
	36	M	110310
	36	L	110320
	36	XL	110330


(Manufacturer: HiPer Medical AG, Oberkrämer, Germany)

Note: XXL Ball heads are available for all materials upon request.

Metal Ball heads

Material:

- > CoCrMo (ISO 5832-12)


	Outer Ø	Size	Item No.
	22	M	177.02.22
	22	L	177.03.22
	28	S	188.01.28
	28	M	188.02.28
	28	L	188.03.28
	28	XL	188.04.28
	32	S	189.01.32
32	M	189.02.32	
32	L	189.03.32	
32	XL	189.04.32	

(Manufacturer: Stemcup Medical Products AG, Zurich, Switzerland)

10.3 Revision Ball Heads (with titanium sleeve)

Material

- > Zirconium oxide reinforced aluminium oxide ceramic (ISO 6474-2)
- > Titanium sleeve (ISO 5832-3)


	Outer Ø	Size	Item No.
	28	S	160000
	28	M	160010
	28	L	160020
	28	XL	160030
	32	S	160040
	32	M	160050
	32	L	160060
	32	XL	160070
	36	S	160080
	36	M	160090
	36	L	160100
	36	XL	160110

(Manufacturer: HiPer Medical AG, Oberkrämer, Germany)

10.4 Bipolar Heads

Material:

- > CoCrMo (ISO 5832-12)
- > UHMW-PE (ISO 5834-2)

	Outer Ø	Inner Ø	Item No.
	42	22	138.22.42
	44	28	138.28.44
	46	28	138.28.46
	48	28	138.28.48
	50	28	138.28.50
	52	28	138.28.52
	54	28	138.28.54
	56	28	138.28.56
	58	28	138.28.58
	60	28	138.28.60
	62	28	138.28.62

(Manufacturer: Stemcup Medical Products AG, Zurich, Switzerland)

Note: For *Bipolar heads*, see separate surgical technique from Stemcup Medical Products AG at URL: <https://stemcup.ch>



11 List of Instruments

Item No.	Description
800152	Penetration Broach
800154	Straight Rasp Handle
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	Ruler
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 450 g 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 if only Stem Set is available, without San Set, 2): Optional

12 Basic UDI-DIs

Basic UDI-DI	Intended Use
764106428INST-01KM	Comparative instruments for determining implant size and checking positioning and joint stability.
764106428INSTSTEM-IR-084V	Reusable surgical instruments for preparing the bone bed by cutting, drilling, sawing, scraping, shaving, clamping, stapling or similar.
764106428INST-05KV	Instrument for inserting/setting and/or removing orthopaedic hip implants and manipulation instruments
764106428STEMUNAS-04HS	Femoral component for primary partial or total replacement of the human hip joint
764106428INST-06KX	Instrument for force transmission during insertion/placement and/or removal of implants and manipulation instruments
764106428INST-02KP	Products for the methodical organisation, storage, transport, use and reprocessing of other medical devices
Basic UDI-DI Third-Party Products	Product Group
425043607	Ceramic Ball Heads
0764012143meballheadsD7	Metal Ball Heads
0764012143bipolarLS	Bipolar Ball Heads
<i>Note: Ceramic ball heads, metal ball heads, revision heads and bipolar heads are purchased from third parties and are subject to approval by the respective manufacturer.</i>	

13 Contact



Atesos medical AG
Schachenallee 29
5000 Aarau
Switzerland

Email: info@atesos.ch
URL: <https://atesos.ch>
Tel: +41 (0)62 823 15 15
Fax: +41 (0)62 823 26 94



hestomed GmbH
Am Eichenwald 13
09356 St. Egidien
Germany

Email: info@hestomed.de
URL: <https://hestomed.de>
Tel: +49 6298 3753 100
Fax: +49 37204 638-21

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Subject to change without notice. For the currently valid surgical technique, please consult the Atesos medical AG website at URL or QR code:
<https://atesos.ch>

