Surgical Technique

Pyramid Hip Cup

Uncemented Hip Cup System

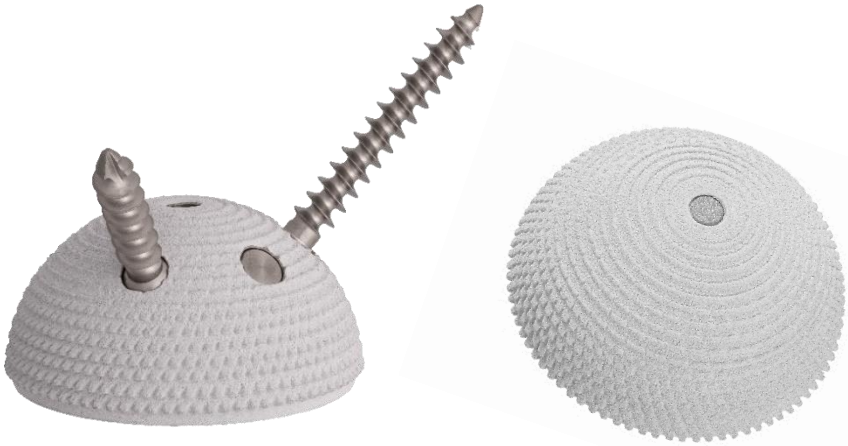


Table of Contents

1 Intended Use and Product Description

1.1 Intended Use

The *Pyramid Hip Cup System*, in combination with other components, is intended as an acetabular component for replacing the human hip socket with uncemented fixation.

1.2 Pyramid press- fit Hip Shells

The *Pyramid Hip Shell* has good seating behaviour and excellent primary stability due to its unidirectional macrostructure. The *Shell* is made of a Ti6Al4V alloy, has a constant oversize relative to the nominal diameter (= milling diameter) for all sizes and is flattened at the pole.
The *Pyramid Hip shell* has a double coating consisting of a Ti plasma layer approx. 0.2 mm thick and a thin CaP layer approx. 20 µm thick. The latter serves to accelerate osseointegration and is completely resorbed.
The shells are available in sizes 42-62 mm (primary cup) and 42-68 mm (revision shell, variant with optional screw anchoring). The screw holes are closed upon delivery.
The threaded hole in the pole is hermetically sealed with a screw after implantation (the same for all shell types).

1.3 Articulation Inserts

Ceramic inserts are available for ball head sizes of 28 mm, 32 mm and 36 mm, whereby the largest possible head diameter is always used for the respective shell diameter. Articulation inserts made of highly cross-linked polyethylene (x-linked PE) are available in diameters of 28 mm, 32 mm and 36 mm, based on the largest possible head diameter in each case. From shell size 50 mm upwards, you can choose between head sizes of 32 mm and 36 mm.

	Inserts					
Primary Shell (without screw holes)	x-linked PE			Ceramic		
42 - 44	28			28		
46 - 48		32			32	
50 - 52		32	36			36
54 - 56		32	36			36
58 - 62		32	36			36

Table 1: *Ball head* diameter and *inserts primary shells*

	Inserts				
Revision Shell (3 screw holes)	x-linked PE			Ceramic	
46 - 50		32			32	
52 - 56		32	36			36
58 - 60		32	36			36
62 – 68 (70)		32	36			36

Table 2: Ball head diameter and *inserts* for *revision shells*

All instruments are implant-specific, are delivered non-sterile and are medical devices for sterile reprocessing (502.C006). The instruments support all common surgical approaches. In addition to standard instruments, specific instruments for MIS approaches are also available. During the design process, particular emphasis was placed on simple and safe handling and universal applicability, including the *femur first technique*.

2 Indication

Standard press-fit cup without additional screw hole:

- Primary and secondary hip joint arthrosis
- Fracture or avascular necrosis of the femoral head
- Rheumatoid arthritis with sufficient bone quality

Press-fit cup with optional additional screw fixation (3 holes):

- Primary situations with poor bone quality
- Revision situations with moderate proximal and/or central bone defect, in which the ventral and dorsal acetabular walls are preserved (Paprosky 2a)

3 Contraindication

- Major deformities and defects of the acetabulum
- Osteoporosis or osteomalacia
- Progressive tumour diseases, localised or generalised
- Radiation-damaged bone bed
- Acute infections of the joint or its surroundings
- Suffered and continuing threat of infectious disease with possible joint manifestation
- Severe muscle, nerve or vascular diseases that endanger the limb in question
- Pregnancy

4 Warnings & List of Symbols

	Manufacturer
	Medical Device
	European Authorized Representative
	Read Instruction for Use
 JJJJ-MM-DD	Expiration Date Year-Month-Day
	Do not use if the Packaging is damaged or the Seal is broken
	Sterilization in the final Packaging by Gamma Radiation
	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 resterilize
	Do not reuse
 non-cemented	Non-cemented / uncemented use

Do not implant Ti-VPS / calcium phosphate -coated implants with cement

Read instructions for use before using the product

5 Preoperative Planning

The surgery should be planned based on the information in the surgical technique and the supplied X-ray templates (115%) or the digitally available templates. Planning can facilitate the determination of the size and orientation of the cup together with the leg length and offset of the joint.

6 Access

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

7 Use of the Instruments

The situation shown here is a lateral approach for implantation of the *Pyramid Hip Cup*. For other types of access and minimally invasive approaches, corresponding instruments with curved recesses or specific lateral offset are available.
Cup sizes and the corresponding cups with press-fit oversize have the same size designation.

7.1 Reaming

Fig. 1 *Straight Reamer* with hemispherical *Reamer*

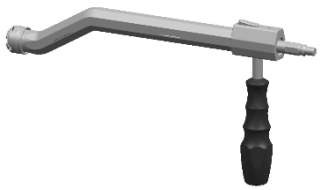


Fig. 2 *MIS Offset Reamer*

Initiation of reaming using 2 - 4 sizes smaller than the planned final *Reamer* size.
Reconstruction or correction of the anatomical acetabular center according to the preoperative plan.

Reaming is performed in 2 mm increments using a *Straight Reamer* (Fig. 1) or *MIS Offset Reamer* (Fig. 2) until the subchondral cortical bone is reached.

Predominantly vascular bone → Osseointegration

Bony coverage with preservation of the acetabular rim

- High primary stability
- Reliable osseointegration

7.2 Test of Bony Support (optional)

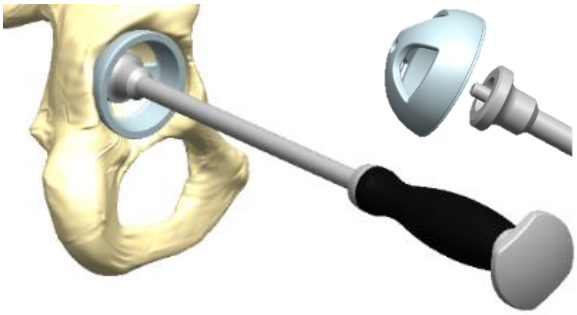


Fig. 3 *Trial shell* mounted on *Shell impactor*

Determination of the final acetabular shell size using the *Trial shell*. The *Trial shell* achieves a light press-fit (approximately 50%) within the reamed acetabulum.

Screw the *Trial shell* onto the *Shell impactor* and lightly impact it.
Verify correct seating (light press-fit):

- Bony coverage with correct orientation
- Circumferential contact with the bony bed
- Decision regarding optional screw fixation

If seating is insufficient and adequate bony support is present, prepare the next larger or subsequent size as required.

7.3 Implantation of the Hip Shell

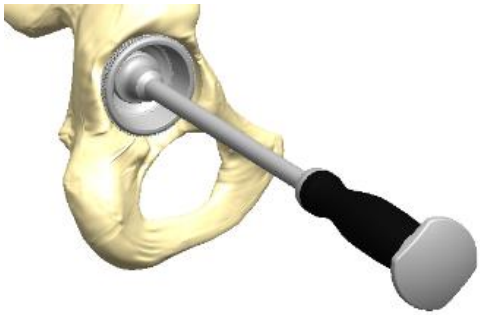


Fig. 4 Placement of *Hip shell* with *Shell impactor*

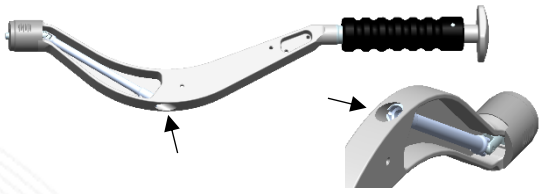


Fig. 5 The *Hip shell* is assembled and disassembled on the curved *Shell impactor* by using a hex *Screwdriver. Firmly operate screw of the curved Shell impactor at the arrow-marked location*

Attach the *Hip shell* to either the straight or curved *Shell impactor* (Fig. 4).
Implant the *Hip shell* at approximately 45° of inclination (35°- 50°) and approximately 10° of anteversion.

For assembly and disassembly of the *Hip shell* on the curved *Shell impactor* (Fig. 5), firmly operate the screw.

With the *Hip shell* correctly aligned, gently impact it with the *Hammer* to seat and fix it within the bony bed.
Once correctly oriented and fixed, the orientation of *the Hip shell* can no longer be adjusted; complete removal of the *Hip shell* is then required.

In case of good bone quality and insufficient seating depth, use the 900 g *Hammer* to achieve the final position.

Caution: Ensure the *Shell impactor* is securely screwed on. During implantation, do not allow counterclockwise rotation, as this may lead to loosening of the screw connection or damage to the pole thread.

7.4 Setting Depth & Locking Screws

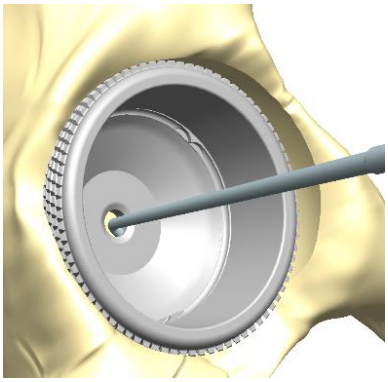


Fig. 6 Checking setting depth of *Hip shell* by using the *Palpation hook*

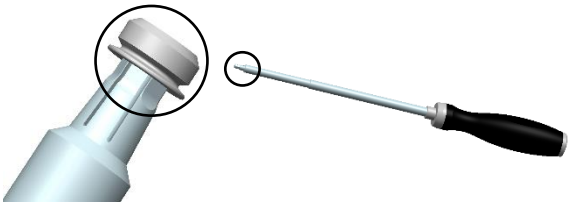


Fig. 7 Locking screw can be secured on the tip of the hex or cardan *Screwdriver* by a click- system for smooth insertion

Check the insertion depth using the *Palpation hook*. There should be no more than 1-2 mm of free space between the shell pole and the bone surface.

If necessary, use the *900 g Hammer* to insert the *Hip shell* deeper.

The *Pole screw* is "clicked" onto the *Screwdriver* to prevent loss and tightened by hand. The *Pole screw* head must be flush with the base of the *Hip shell*.

7.5 Implantation of the 3- Hole Hip Shell

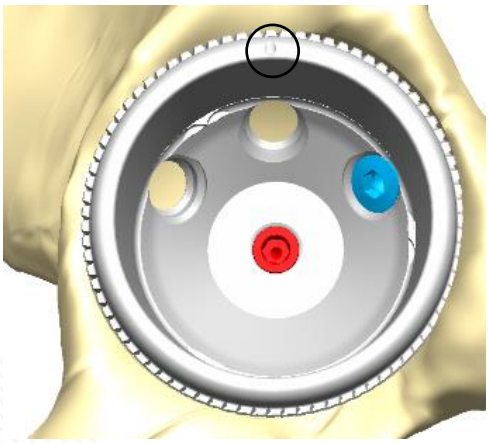


Fig. 8 Black Circle: Cranial marking for correct placement of the *3- Hole Hip shell*. Red: Pole screw; Blue: *Cancellous bone screw*

The *3- Hole Hip shell* allows for anchoring using additional *Cancellous bone screws* in cases of insufficient primary stability and poor bone conditions.

The *3- Hole Hip shell* is implanted in the same way as the standard version (7.3, 7.4)

During implantation, pay attention to the "**cranial marking**."

Remove *Locking screws* before implantation.

7.6 Placement of Cancellous Bone Screws

Fig. 9 *Drilling guide*

Fig. 10 *Screw measuring device*

Pre-drill the screw channel using a *Drilling guide* and *Flexible drilling shaft*.

Determine the length of the *Cancellous bone screws* using the *Screw measuring device*.

The maximum axial deflection of the *Cancellous bone screws* should not exceed 15°.

Sink the *Cancellous bone screws* so that the screw heads are placed at <15° to the shell axis and do not touch the articulation.

Secure the *Pole screw* using light manual force.

7.7 Testing Joint Function (optional)

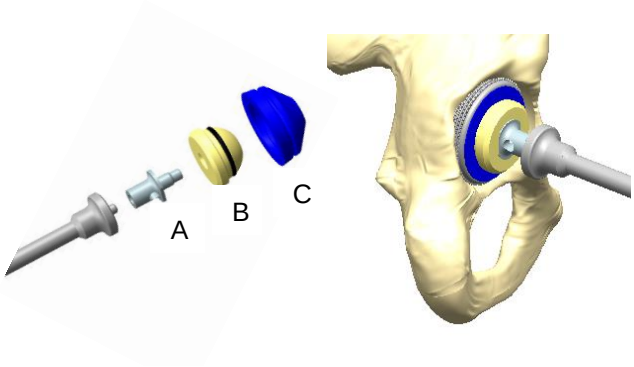


Fig. 11 Instructions for assembling the instruments for *Trial shell* insertion

Before definitively inserting the *Insert*, joint function should be tested using a *Trial shell*. In cases of dislocation tendency *Hooded articulation inserts* are available.

Instruments

- *Shell impactor* straight or MIS
- *Coupling adapter* (A)
- *Attachment for Insert* (B)
- *Trial Shell* (C)
- *Hammer*

Mount the *Coupling adapter* on the *Shell impactor*. Then choose, according to the *Trial shell* size, the fitting *Attachment for insert.*

Place *Trial shell* in the *Hip shell an tap it into place with the Hammer.*

7.8 Insert Implantation

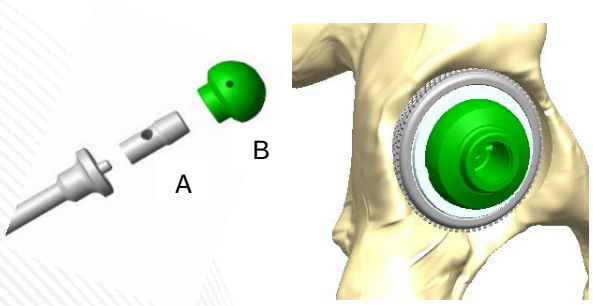


Fig. 12 Instructions for assembling the instruments for Insert insertion

Two types of *Inserts* are available: Polyethylene I*nserts* hooded and without a hood, as well as ceramic *Inserts*.

First prepare the instruments according to 7.7 then place the *Insert* in the *Hip shell*. Once the end position is reached, loosen and remove the *Shell impactor* by turning the impact plate.

To fix the Insert in place following instruments are needed:

- *Shell impactor*
- *Connector for trial heads* (A)
- *Trial head* (B)
- *Hammer*

Choose the *Trial head* corresponding to the size of the *Insert*. Place the *Trial head* in the I*nsert* and tap it in place with the *Hammer*.

7.9 Verify Insert Placement

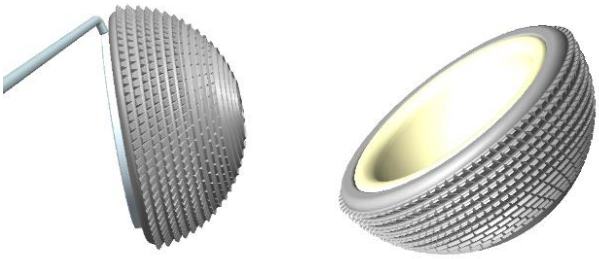


Fig. 13 Left: Polyethylene Insert. Right: Ceramic Insert

Polyethylene *Inlays* are fixed in the *Hip shell* via a form fit (snap lip).
When correctly positioned, the edge protrudes by approximately 1.5 mm. This prevents metal-on-metal contact in the event of stem-cup impingement.

The ceramic *Insert* is flush with the *Hip shell* edge.

7.10 Special Features

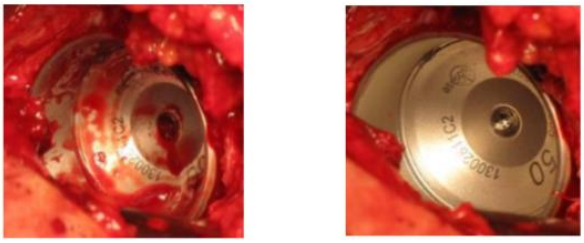


Fig. 14 Left: Blood residues in Hip shell, Insert must not be inserted. Right: Dry and clean hip shell, ready for Insert insertion

Polyethylene *Inserts* fit into the *Hip shell* without any gaps to achieve maximum durability.

To ensure that polyethylene *Inserts* are securely mounted in the *Hip shell*, no tissue remnants or fluid should remain in the *Hip shell*. The *Hip shell* should be cleaned and dried prior to mounting.

8 Follow- up Treatment

Depending on the patient's age and health status, movement therapy can be started either on the day of surgery or the following day. Full weight-bearing on the operated leg is permitted.

For the first 48 hours, the use of an appropriate positioning with slight abduction is recommended. The use of forearm crutches may be helpful during the first few days but is not strictly required.

Administration of antibiotics and thrombosis prophylaxis should follow the guidelines or the surgeon's discretion.

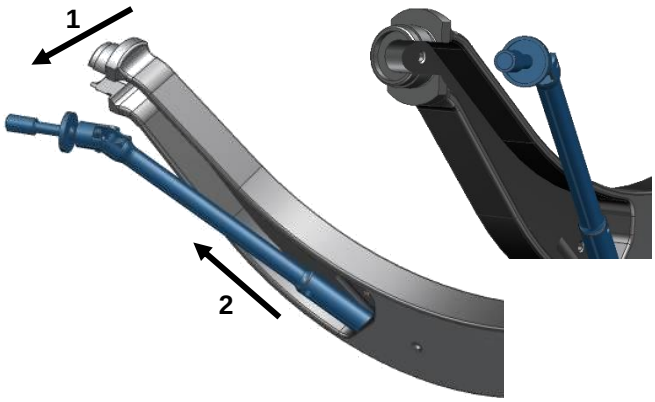
Recommended follow-up intervals: Immediately postoperatively, 6 months postoperatively and then annually.

9 Disassembly, Cleaning, Assebly and Sterilization of Instruments

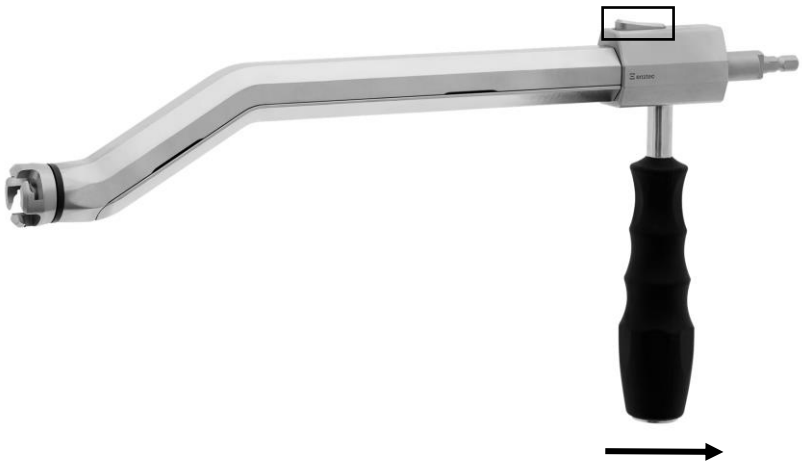
Sterilize all instruments of the system with superheated steam. When cleaning and sterilizing reusable instruments, validated procedures and systems that comply with the applicable standards must be applied. For more information, see the instruction for use of the associated implant product and the brochure "Processing of reusable instruments".

Additional details on disassembly and assembly of non-self-explanatory instruments:

MIS Shell Impactor

	The **MIS shell impactor** in a ready-to-use, assembled condition. Sterilize the instrument while it is assembled in this way. Disassemble the instrument for cleaning: › *Shell impactor MIS* › *Cardan shaft M6* › *Shell adapter*
	**Disassembly:** Pull the instrument and *Shell adapter* apart.
	Assembly: Slide the sleeve onto the shaft until it clicks into place and the thread becomes visible. Ensure that the sleeve is correctly aligned rotationally.
	**Disassembly:** Pull out the *Cardan shaft* first sideways (1), then out of the upper guide (2).
	Assembly: Insert *Cardan shaft* into upper guide (2), then insert into lower guide (1).
	*MIS Shell impactor* in dismantled condition with *Cardan shaft* and *Shell adapter.* Clean the instrument in this condition.

MIS Offset Reamer



To disassemble the *Offset reamer*, press the button located above the plastic handle. The handle body can then be slid off the shaft in the direction of the arrow. The upper part of the shaft housing can now be moved and removed until the arrow markings on the instrument are aligned.

For further details on disassembly and cleaning of the offset reamer shaft, please refer to the manufacturer's instructions from Enztec Limited: 11805-00 at URL.

https://www.enztec.com/orthopaedic-instruments/hip-products/offset-reamer-driver/

Straight Reamer

To disassemble the *Straight reamer*, press the button at the end of the plastic shaft downward. The plastic shaft can then be slid in the direction of the arrow.

For further details on disassembly and cleaning of the straight reamer shaft, please refer to the manufacturer's instructions from Enztec Limited: 11896-00 at URL.

https://www.enztec.com/orthopaedic-instruments/hip-products/straight-reamer-driver/

10 List of Implants

Pyramid Hip Shell	Item No.	Size
incl. Pole Screw	321061	42 / D
	321062	44 / D
	321063	46 / E
	321064	48 / E
	321065	50 / F
	321066	52 / F
	321067	54 / G
	321068	56 / G
	321069	58 / H
	321070	60 / H
	321071	62 / H

Pyramid Revision Hip Shell (3- Hole)	Item No.	Size
incl. Pole Screw	321081	42 / D (on request)
	321082	44 / D (on request)
	321083	46 / E
	321084	48 / E
	321085	50 / E
	321086	52 / F
	321087	54 / F
	321088	56 / F
	321089	58 / G
	321090	60 / G
	321091	62 / H
	321092	64 / H
	321093	66 / H
	321094	68 / H
	321095	*70 / H (on request)*

› Note: For the selection of the appropriate *Insert*, only the colour or letter code is valid for the *3-Hole Shells*.

Cancellous Screws	Item No.	Description
	300.65.20-S	Cancellous Screws 6.5x20 mm STERILE
	300.65.25-S	Cancellous Screws 6.5x25 mm STERILE
	300.65.30-S	Cancellous Screws 6.5x30 mm STERILE
	300.65.35-S	Cancellous Screws 6.5x35 mm STERILE
	300.65.40-S	Cancellous Screws 6.5x40 mm STERILE

Pyramid PE x-link Insert	Item No.	Size
Standard	332001	28 / D
	332002	32 / E
	332011	32 / F
	332012	32 / G
	332013	32 / H
	332003	36 / F
	332004	36 / G
	332005	36 / H

Hooded	Item No.	Size
	332006	28 / D
	332007	32 / E
	332014	32 / F
	332015	32 / G
	332016	32 / H
	332008	36 / F
	332009	36 / G
	332010	36 / H

Ceramics Inserts	Item No.	Description	Size
	120000	ELEC®plus-Insert 28/35-18	28 / D
	120210	ELEC®plus-Insert 32/39-18	32 / E
	120380	ELEC®plus-Inset 36/44-18	36 / F
	120400	ELEC®plus-Insert 36/48-18	36 / G
	120420	ELEC®plus-Insert 36/52-18	36 / H

(Manufacturer: HiPer Medical AG, Oberkrämer, Germany. Material: ELEC®plus)

11 List of Instruments

Item No.	Description/Size
800032	Trial Shell Size 42 [2)]
800033	Trial Shell Size 44 [2)]
800034	Trial Shell Size 46 [2)]
800035	Trial Shell Size 48 [2)]
800036	Trial Shell Size 50 [2)]
800037	Trial Shell Size 52 [2)]
800038	Trial Shell Size 54 [2)]
800039	Trial Shell Size 56 [2)]
800040	Trial Shell Size 58 [2)]
800041	Trial Shell Size 60 [2)]
800042	Trial Shell Size 62 [2)]
800043	Trial Shell Size 64 [2)]
800044	Trial Shell Size 66 [2)]
800028	Trial Shell Size 68 [2)]
800029	Trial Shell Size 70 [2)]
800061	Trial Insert Size 42-44 / 28 [2)]
800062	Trial Insert Size 46-48 / 32 [2)]
800063	Trial Insert Size 50-52 / 36 [2)]
800064	Trial Insert Size 54-56 / 36 [2)]
800065	Trial Insert Size 58-62 / 36 [2)]
800087	Trial Insert Size 42-44 / 28 [2)]
800088	Trial Insert Size 46-48 / 32 [2)]
800089	Trial Insert Size 50-52 / 36 [2)]
800090	Attachment 28 for Hooded Insert
800091	Attachment 32 for Hooded Insert
800092	Attachment 36 for Hooded Insert
800093	Coupling Adapter
800097	MIS Shell Impactor[3)]
800098	Cardan Shaft[3)]
800099	Shell Adapter [3)]
800102	Shell Impactor, straight
800103	Hammer 450g
800135	Hammer 900g
800106	Trial Insert Size 50-52 / 32 [2)]
800107	Trial Insert Size 54-56 / 32 [2)]
800108	Trial Insert Size 58-62 / 32 [2)]
800203	Trial Head ø28 L [1)]
800208	Trial Head ø32 L [1)]
800213	Trial Head ø36 L [1)]
800218	Hexagon Screwdriver SW3.5mm
800223	Palpation Hook
800228	Aiming Device
800229	Connector for Trial Heads[1)]
800232	Hexagon Cardan Screwdriver SW3.5mm[2)]
800233	T-Handle AO- Coupling
T17797	Acetabulum Reamer Size 40
T17799	Acetabulum Reamer Size 42
T17801	Acetabulum Reamer Size 44
T17803	Acetabulum Reamer Size 46

T17805	Acetabulum Reamer Size 48
T17807	Acetabulum Reamer Size 50
T17809	Acetabulum Reamer Size 52
T17811	Acetabulum Reamer Size 54
T17813	Acetabulum Reamer Size 56
T17815	Acetabulum Reamer Size 58
T17817	Acetabulum Reamer Size 60
T17819	Acetabulum Reamer Size 62
T17821	Acetabulum Reamer Size 64 [2)]
T17823	Acetabulum Reamer Size 66 [2)]
T17825	Acetabulum Reamer Size 68 [2)]
T17827	Acetabulum Reamer Size 70 [2)]

4250-7090	Reamer MIS (with AO Cuppling)[3)]
4250-7070	Offset Reamer Hudson Cuppling [3)]
4250-7050	Offset Reamer Zimmer Cuppling [3)]
4250-7310	Reamer Straight Zimmer Cuppling
4250-7320	Reamer Straight Hudson Cuppling
4250-7330	Reamer Straight AO cuppling
800125	Flexible drilling Shaft Ø 3,2 Length 135 mm
44050/032	Flexi-Bit Drill Ø 3.2, Length 40 mm
44060/032	Flexi-Bit Drill Ø 3.2, Length 60 mm
44070/032	Flexi-Bit Drill Ø 3.2, Length 60 mm
800136	Screw holding Forceps
800137	Drill Guide ø3.2mm
800138	Screw Measurement Device, curved 2- parts

1) Optional, if only Pyramid Cup System present without Stem System, 2) Optional, 3) Optional for MIS application

Note: Acetabulum reamers are also available in odd sizes on request.

12 Overview: Shell and Inserts

Primary Shell	3- Hole hell (Revision)	Insert	x-link PE	Ceramics
				
42 44	42 44	D	D / 28	D / 28
46 48	46 48 50	E	E / 32	E /32
50 52	52 54 56	F	F / 32 F/ 36	F / 36
54 56	58 60	G	G / 32 G / 36	G / 36
58 60 62	62 64 66 68 (70)	H	H /32 H / 36	H / 36

13 Basic UDI-Dis

Basic UDI-DI	Product group
764106428PRESSFITCUP-01A3	Acetabular component for replacement of the human hip socket with uncemented anchoring
764106428INST-02KP	Products for the methodical organisation, storage, transport, use and preparation of other medical devices
764106428INST-06KX	Instrument for transmitting force during the insertion/placement and/or removal of implants and manipulation instruments
764106428INST-01KM	Comparative instruments for determining implant size and checking positioning and joint stability.
764106428INST-05KV	Instrument for inserting/setting and/or removing orthopaedic hip implants and manipulation instruments

14 Contact

Legal Manufacturer:

Atesos medical AG
Schachenallee 29
5000 Aarau, Switzerland

E-mail: info@atesos.ch
https://atesos.ch/en
Tel : +41 (0)62 823 15 15
Fax: +41 (0)62 823 26 94

European Authorized Representative:

EU REP

hestomed GmbH
Am Eichenwald 13
09356 St. Egidien, Germany

CE 1250

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We reserve the right to make changes. Consult the Atesos medical website for the currently valid surgical technique via URL https://atesos.ch/en or the following QR code: