

Surgical Technique Pyramid Hip Cup

Uncemented Hip Cup System

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Surgical Technique Pyramid Hip Cup

Product description:

The Pyramid acetabular system allows for excellent primary stability without excessive seating forces due to the unique unidirectional macrostructure surface. The metal shell is made of a Ti6Al4V alloy and has a constant press fit ratio between reaming and oversize for all diameters and is flattened in the pole –region.

The Pyramid Cup is offered in 2 different coated types: a double coated version, made of a Ti-Plasma sprayed coating of thickness 0.2mm and a thin layer CaP of thickness 20µm which serves for accelerated osseointegration and is fully absorbed.

The single coated version is covered with this CaP layer only, underneath there is a macro structure* overlaid by a roughness of approx.. 6-8 µm produced by grit blasting.

Only the double coated version is delivered in sizes 46-68 (70) in a type with optional cancellous bone screw fixation and for revision cases. When delivered, the screw holes are closed.

The threaded hole in the pole is sealed by a screw after implantation.

* Patent pending

Chart 1a+1b display the disposable articulating inlays.

Ceramic inlays for the head sizes 28, 32, 36 mm are available. The ceramic system provides the largest head diameter for the given shell--used. Standard Polyethylene inlays are available for the head sizes 28mm (shell 42-48 mm) and 32 mm (shell 50-62 mm). Inlays made of x-linked Polyethylene are offered for the largest possible head diameter (28 – 32 – 36 mm) for respective shell size. From cup size 50, head size 32 or 36 can be chosen.

Primary shell (w.out screw holes)	articulating inlays		
	Polyethylene	x-linked Pe	Ceramic*
42 - 44	28	28	28
46 - 48	28	32	32
50 - 52	32	32 36	36
54 - 56	32	32 36	36
58 - 62	32	32 36	36

Chart 1a: Head diameters and inlays for primary shell

Revision shell (3-holes)	articulating inlays		
	Polyethylene	x-linked Pe	Ceramic*
46 - 50	28	32	32
52 - 56	32	32 36	36
58 - 60	32	32 36	36
62 – 68 (70)	32	32 36	36

Chart 1b: Head diameters and inlays for revision shell

* BioloX Delta-Inserts, Manufacturer CeramTec GmbH Medical Products Division or ELECC@plus -Inserts, Manufacturer HiPer MEDICAL AG

The **instrumentation** is adaptable to any surgical approach. In addition to standard tools offset instruments for MIS incisions are offered. Its design focuses on easy and safe handling and universal use, including the femur first technique.

Indications:

Standard Press-fit Cup without additional screw holes: Primary and secondary arthritis of the hip, fracture or avascular necrosis of the femoral neck, rheumatoid arthritis in case of sufficient bone quality.

Press-fit Cup with optional additional screw fixation: Primary situations in case of reduced bone quality, revision situations with moderate proximal or central bone-defect were the ventral and dorsal acetabular wall is still present (Paprosky 2a).

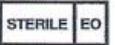
Contraindications:

Extensive deformations and defects of the acetabulum, radiographic manifest osteoporosis or osteomalacia, progressive tumour diseases local and generalized, radiation compromised bone stock, acute infection of the joint or the environment, persistent or potential infectious diseases with influence on the joint; muscular nerve or vessel disease which may threaten the extremity, pregnancy.

Surgical incisions:

The implant system and the associated instruments permit the implantation by all established incisions like the lateral transgluteal incision according to Bauer, the antero- lateral incision according to Watson Jones, the posterior 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.
	Sterilized by gamma radiation in the final packaging
	Sterilized by EO in the final packaging
 non-cemented	Non-cemented use
 25°C	To be exposed to maximum temperature < 25°C (information on packaging obligatory)
	Order Number
	Batch number manufacturer
	Do not re-sterilize

Read instruction for use before using the product.

Preoperative Planning:

The surgery should be planned by means of the information in the surgical technique and by means of the attached x-ray templates (115%) or the digitally supplied templates. Planning can assist in determining the size and orientation of the cup together with leg length and joint offset.

Use of the instruments:

For implantation of the Pyramid hip- cup all established incisions can be used. For minimally invasive incisions curved instruments or instruments with offsets are available.

Approach to the hip- joint and preparation of the Acetabulum for preparation of the bony bed for the hip cup. All figures in this description are referenced to a lateral approach in a supine position.

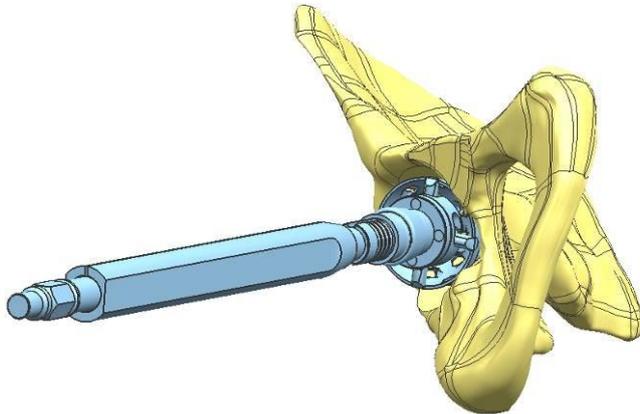


Fig. 1a:

Reaming of the Acetabulum using the hemispherical reamer and the straight (Fig. 1a) or offset shaft (Fig. 1b) until the correct size, corresponding to the planning or the intraoperative situation is reached.

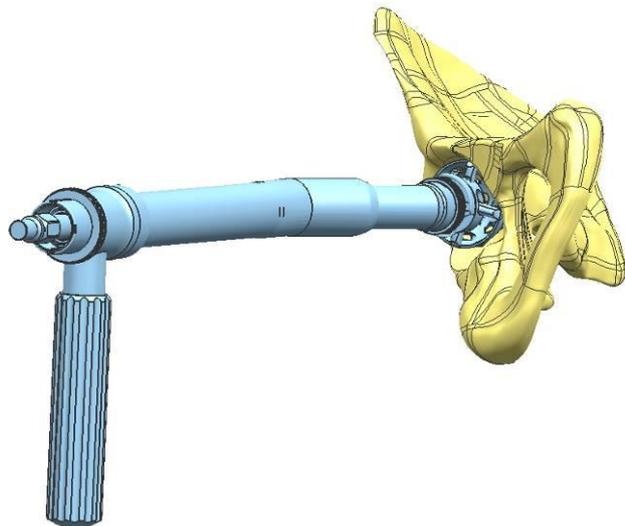


Fig. 1b:

The reamer serves in this step to check the shape and the coverage of the bony bed. It should be reamed until reaching subcortical bone while respecting the anatomical centre of the Acetabulum.

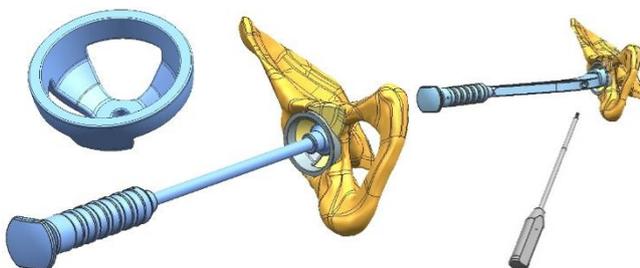


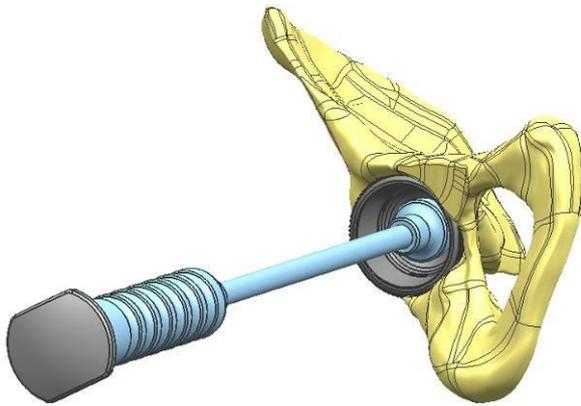
Fig. 1c

Seating instrument shell straight and MIS

Test of the bony bed:

Optionally, there are trial shells with flattened pol and a slight equatorial oversize available. In ideal situation concerning the bony bed, the trial shells will be seated with a slight pressfit.

Trial shells will be seated with the seating instrument for shells (straight or MIS version possible).



Positioning of the cup in the bony bed using the straight (Fig. 2a) or the curved impactor (Fig. 2b). Impaction of the cup down to the planned seating depth. Maximum inclination: 45°

The straight impactor must be tightened firmly and should not be turned in left direction during impaction because of danger to damage the thread of the pole.

Shells with additional option for screw fixation show an extra marking line to indicate 'superior'.

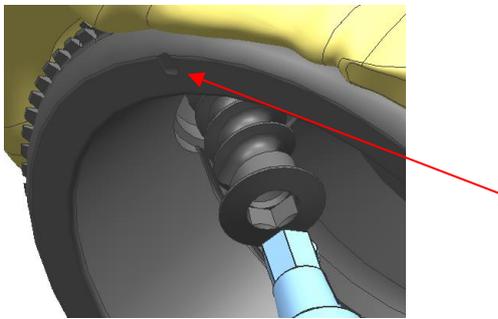
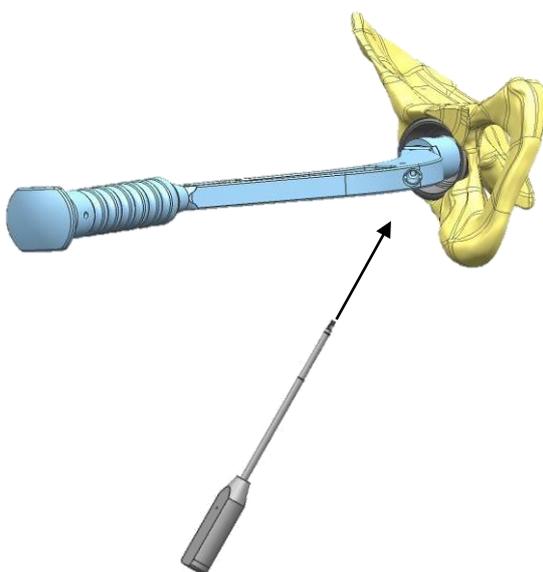


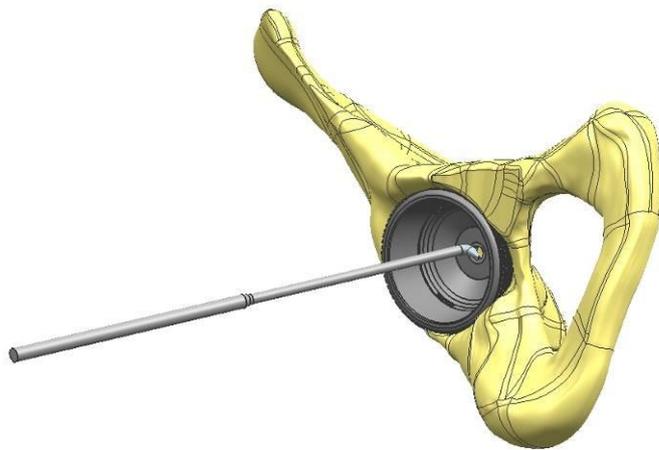
Fig. 2a:



In case of the curved impactor the cup is mounted and released with help of the Hexagon Screwdriver.

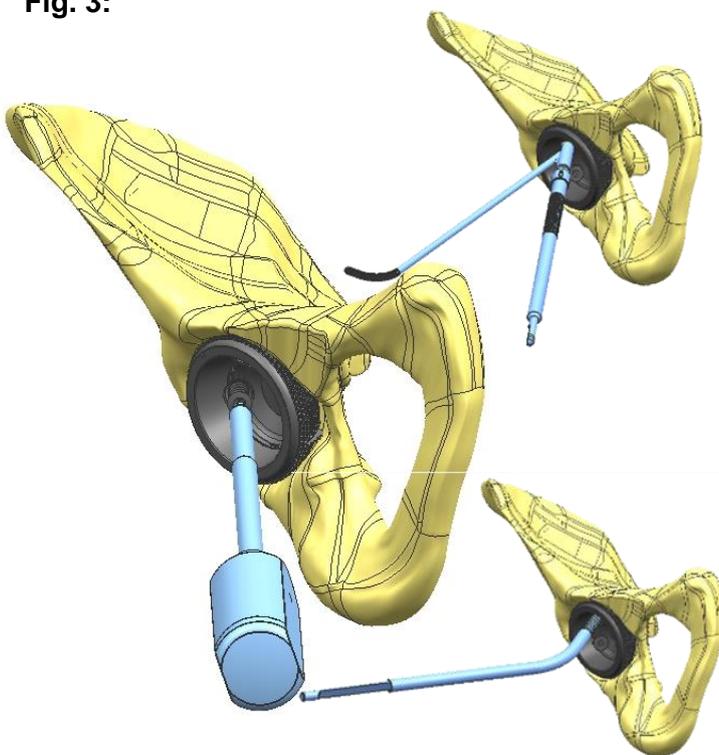
To prepare, the cup can be screwed to the curved impactor while pushing ahead and slowing the cardan shaft with your finger. Afterwards tighten firmly with the Hexagon Screwdriver.

Fig. 2b:



The seating depth can be checked by the palpating hook across the pole- hole (Fig. 3). For correct seating depth the space between cup and bone- surface should not be more than 1-2 mm.

Fig. 3:



3-hole Shell: The insertion of a 3-hole shell is done exactly in the same way as the primary cups (pay attention to the rotational position).

If additional cancellous bone screws shall be used, first the firmly screwed in closing screws have to be removed. Use the Hexagon Screwdriver SW 3.5 mm (or the cardan version). Take care that the closing screws do not fall into the wound because they are very small.

Please dispose them appropriately.

After drilling and before seating the cancellous bone screws, drill depth can be checked. Check if Orientation and seating position (<15° fully seated) of the screws are correct to prevent contact with inlays.

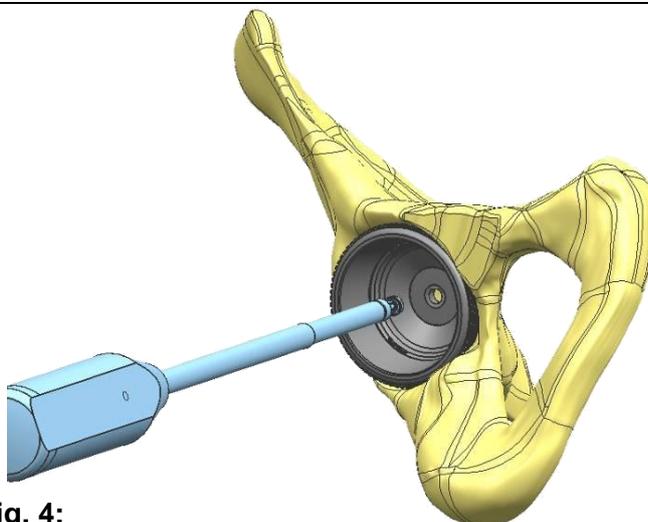


Fig. 4:

Closing of the pole hole (Fig. 4) with the pole screw. The Hexagon Screwdriver snaps firmly into the pole screw and can be turned into the shell under visual inspection.

ATTENTION: Tightening of the pole screw with small force only, max. 4Nm ! (to compare: this corresponds approximately to 60-80% of maximum possible force). Please look after the pole screw to be tightened flat-seating with the bottom of the cup (if necessary use the palpation hook to control).



Selection of the cup inlay corresponding to the size of the cup shell and the selected head size. The connector corresponding to the chosen head size (28 – 32 – 36 mm) is mounted to the Inlay seating instrument “Octopus” and is gently tightened.

There are special connectors for hooded inlays. The instrument is used with both hands (Fig. 5a).

Alternatively the connectors can be mounted on the seating instrument for shells. Therefore, a special adapter has to be mounted in between. If the connector for attachment Octopus cannot be released manually, use the strong side of the palpating hook to unscrew.

The trial or the final inlay is connected to the seating instrument by pulling the vacuum pump (Fig. 5a).

Attention: with the alternative method, final and trial inlays are only slightly firm and tend to loose from the connectors earlier!

Positioning of the inlay by gentle rotation around the long axis followed by impaction until the assembly position is reached (Fig. 5b). The instrument is separated from the inlay by turning the impaction plate.

Fig. 5a:

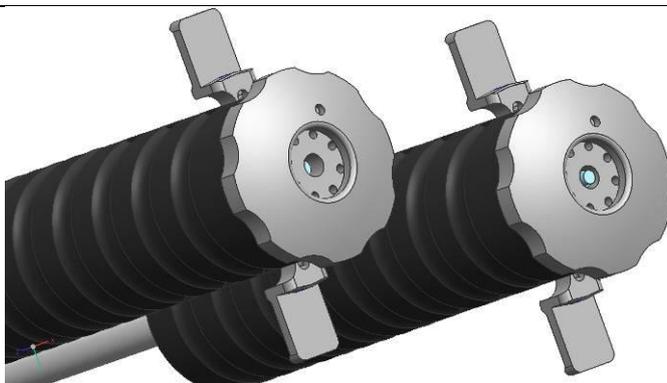


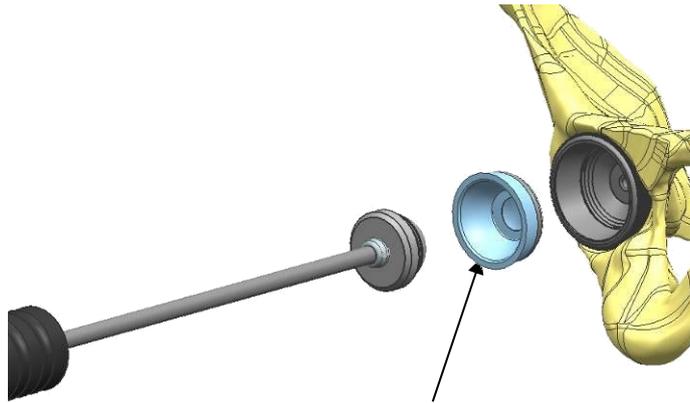
Fig. 5b:

The amount of the holding force is indicated with the central pin of the impaction plate and is generally around 50N (5 kg).

The holding force is correct if the central pin is totally countersunk into the impaction plate. The holding force is not correct if the central pin is flush with the countersunk plane or sticking out of the impaction plate. In this case the following points must be checked:

- Is the connector corresponding to the chosen head size firmly tightened?
- Is the connector correctly seated in the shell?

Repeat the procedur according to Fig. 5a.



Test of joint function:

The correct joint-function can be checked with the trial inserts (Fig. 5c).

Trial inserts are available both in standard or hooded design.

Trial inserts have to be chosen according to shell size and corresponding to the chosen head size.

Trial inserts can be removed with the help of the palpating hook (chamfer -> see fig. 5c) or with the seating instrument 'Octopus'.

Fig. 5c:

Chamfer to be removed
by the palpation hook

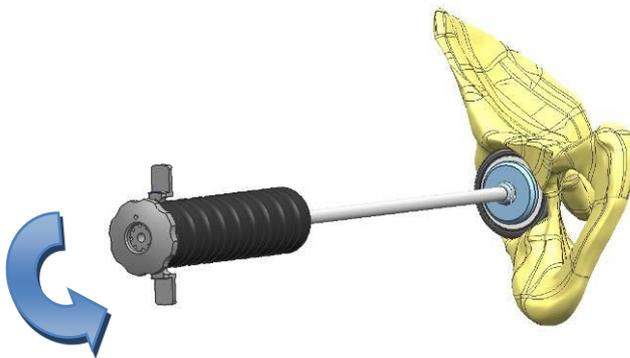


Fig. 5d:

Implantation of the inlay:

Remove carefully all tissue, bone or blood rests out of the implanted shell.

Positioning of the inlay with careful rotation along the centre line and impaction to the assembly position.

Turning of the impactation plate releases the instrument from the inlay (Fig. 5d)

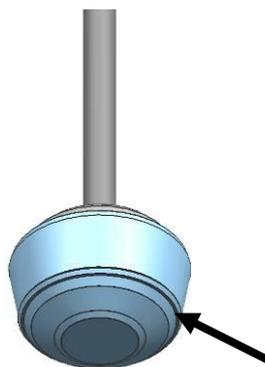


Fig. 5e:

PE-inlays made of standard material differ from highly cross linked PE-inlays in a circular turned groove (Fig. 5e).

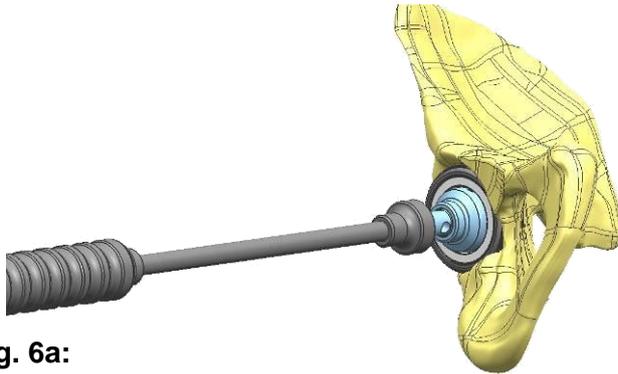


Fig. 6a:

Firm seating of the final inlay with the connector for trial ball heads and a trial ball head size L (corresponding the chosen inlay size), combined with the straight or curved shell impactor (Fig. 6a). It is important to make sure that the inlay is used for the corresponding size of head.

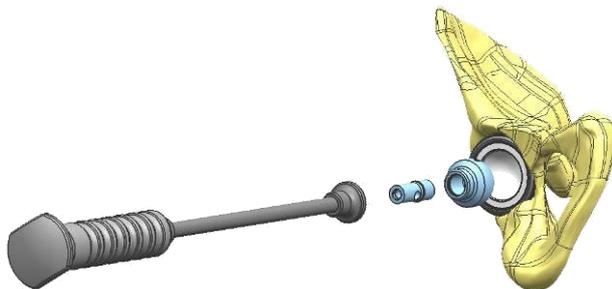


Fig. 6b:

If the connector for trial ball heads cannot be released manually, use the strong side of the palpating hook to unscrew.

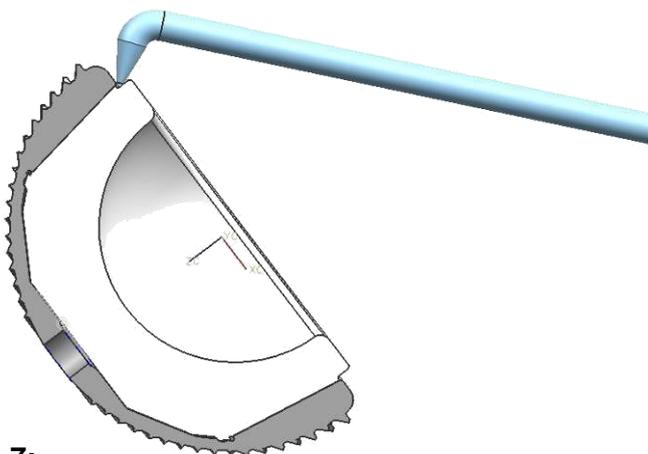


Fig. 7:

Crosscheck the correct position of the inlay in the shell using the palpation hook. In the correct position the outer rim of the polyethylene inlay overlaps the rim of the shell. ¹⁾ (Fig 7).

If a ceramic inlay is used both rims are in one plain.

1): 1 – 2mm

The following steps conform to the standard procedure of a hip joint replacement. Before the definitive repositioning of the joint and the wound closure the surgical site must be irrigated copiously to remove particles, bone cement, bone chips or other tissue fragments.

After treatment:

Depending on the age and health condition of the patient one can start on the day of surgery or the day after with physical therapy.

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

Medication with antibiotics and thrombosis prophylaxis should be followed according to the guidelines and according to the judgement of the physician.

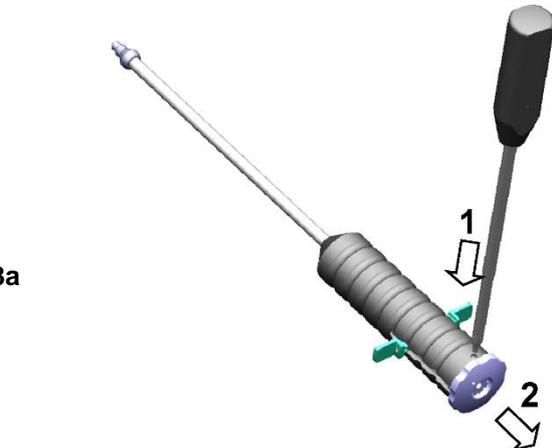
Recommended follow-up intervals are postoperative, 6 month, then annually.

Disassembly; Cleaning, Assembly and Sterilisation of Instruments:

All instrument components are sterilized by steam sterilization. Procedures following valid standards should be used for the cleaning and sterilization of reusable instruments. Further information is attached to the product package insert and is available in the brochure “preparation of reusable instruments”.

Additional details for assembly and disassembly for non-self-explaining instruments:

Fig. 8a



The **seating instrument for inlays Octopus** should be separated for cleaning and assembled according to the following description:

The inlay specific adapters are detachable from the instrument for cleaning and sterilization by a screw thread.

The piston mechanism has to be pushed down totally. After pushing the pushbutton (1) on the side of the instrument with the torque screwdriver, the impactor plate (2) can be removed from the grip handle (Fig. 8a). The piston mechanism can be pulled out of the grip handle (3). The instrument will be disinfected, cleaned and sterilized in these 3 separate parts.

Before assembly, the piston closure should be visually checked for damage. We recommend adding a suitable lubricant to the red sealing and the black sliding ring after cleaning but before sterilizing. The piston mechanism should be pushed into the grip handle until the stop is reached. The impactor plate should be pressed on the grip handle and positioned by turning. The impactor plate will be arrested by the pushbutton which snaps in the grip handle.

The instrument is usable for surgery after combination with the chosen inlay adapter.

Fig. 8b

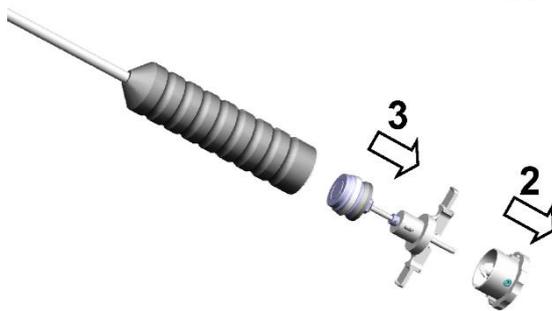


Fig. 9



MIS shell impactor in usable and assembled state.

The instrument is sterilized in this state.

Fig. 10



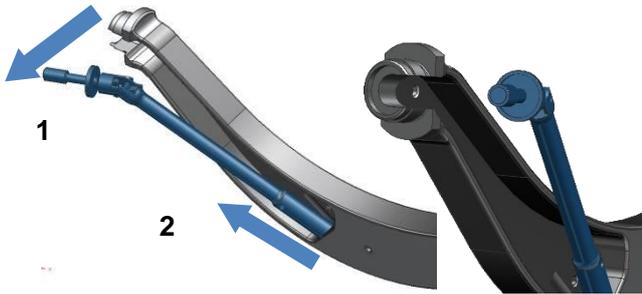
Disassembling:

Pull apart instrument and adapter.

Assembling:

Insert adapter until latching; the thread has to be visible. Consider correct rotation position of the adapter.

Fig. 11



Disassembling: Pull apart the cardan shaft laterally first (1), then from the upper guidance (2).

Assembling: Insert the cardan shaft first into the upper (2) and then into the lower guidance (1).

Fig. 12



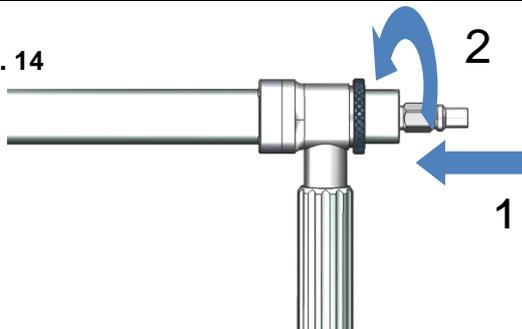
MIS shell impactor in disassembled state. The instrument is cleaned in this state.

Fig. 13



Offset **MIS reamer shaft** (*Chana reamer*) in usable and assembled state.

Fig. 14



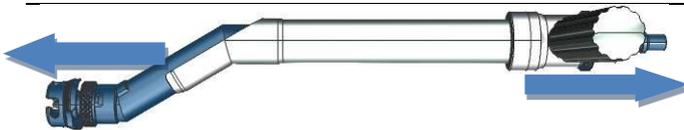
Disassembling:

Push the fixing nut with the knurled ring (1) and turn in clockwise direction (2).

Assembling:

Push the fixing nut with the knurled ring (1) and turn in anticlockwise direction (2).

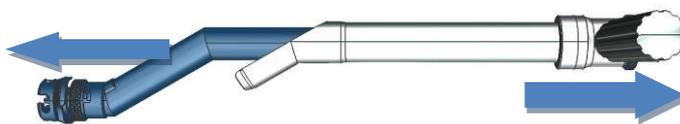
Fig. 15a



Disassembling:

Pull apart the inner and the outer tube. (Fig. 15a and 15b)

Fig. 15b



Assembling:

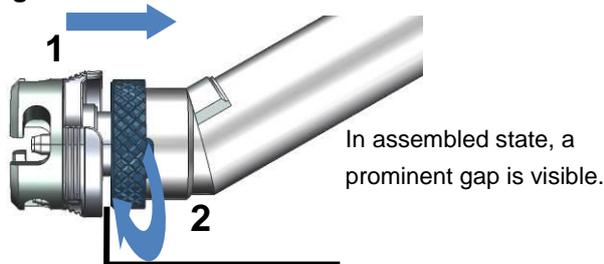
Press together the inner and the outer tube.

Fig. 16



Disassembly of outer and inner tube.

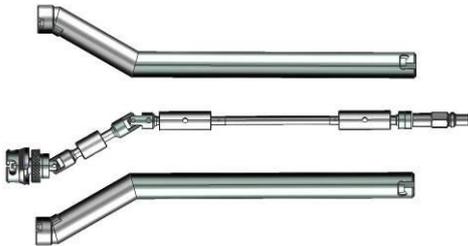
Fig. 17



Disassembling: Push the locking ring in direction of the reamer shaft body (1) and turn in clockwise direction (2) (Fig. 17)

Assembling: Push the locking ring in direction of the reamer shaft body (1) and turn in counter clockwise direction.

Fig. 18



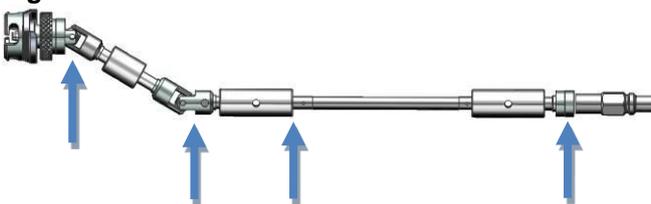
Disassembling:

Fold apart the inner tube parts and take away the cardan shaft.

Assembling:

Put in the cardan shaft and put together the inner tube parts.

Fig. 19



Clean all hinges and plastic guidances before placing into the machine.



Fig. 20

Straight reamer shaft in usable and assembled state.

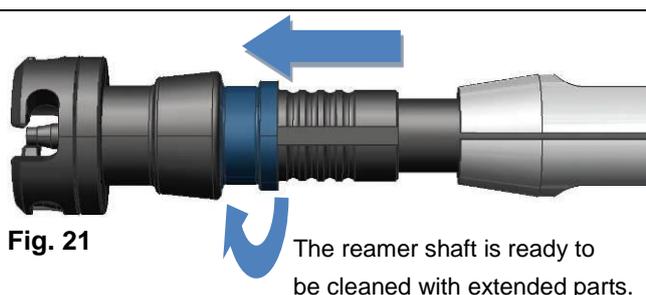


Fig. 21

Disassembling:

Push the locking nut in direction of the end of the coupling (1) and turn in clockwise direction while pushing (2).

Assembling:

Push the locking nut in direction of the end of the coupling (1) and turn in counter clockwise direction until the nut is **engaged** (2).

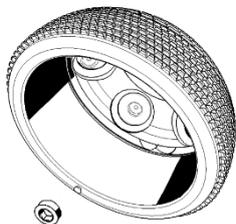
List of Implant Components:

Pyramid Hip shell incl. Pole screw:



Double coated	Single coated	Size
321061	321021	42 / D
321062	321022	44 / D
321063	321023	46 / E
321064	321024	48 / E
321065	321025	50 / F
321066	321026	52 / F
321067	321027	54 / G
321068	321028	56 / G
321069	321029	58 / H
321070	321030	60 / H
321071	321031	62 / H

Pyramid Revision Cup (3-holes) incl. Polscrew:



Revision (3-holes) Cup

Double coated	Size
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)

Remarks: In case of a 3-holes Cup, only the colour or corresponding letter is indicating the correct inlay size.

Cancellous bone screws:



Art.no	Length	Name:
000-290-25	25mm	Cancellous bone screw \varnothing 6.5 x 25mm
000-290-30	30mm	Cancellous bone screw \varnothing 6.5 x 30mm
000-290-35	35mm	Cancellous bone screw \varnothing 6.5 x 35mm
000-290-40	40mm	Cancellous bone screw \varnothing 6.5 x 40mm
000-290-45	45mm	Cancellous bone screw \varnothing 6.5 x 45mm

(other lengths on request)

Pyramid PE Insert Standard & Hooded:

	<u>Ref. No.</u>	<u>Size</u>	<u>Remarks</u>
	331001	28 / D	
	331002	28 / E	
	331003	32 / F	
	331004	32 / G	
	331005	32 / H	
	331006	28 / D	
	331007	28 / E	
	331008	32 / F	
	331009	32 / G	
	331010	32 / H	

Pyramid PE x-link Insert Standard & Hooded:

	<u>Ref. No.</u>	<u>Size</u>	<u>Remarks</u>
	332001	28 / D	
	332002	32 / E	
	332011	32 / F	
	332012	32 / G	
	332013	32 / H	
	332003	36 / F	
	332004	36 / G	
	332005	36 / H	
	332006	28 / D	
	332007	32 / E	
	332014	32 / F	
	332015	32 / G	
	332016	32 / H	
	332008	36 / F	
332009	36 / G		
332010	36 / H		

Ceramic Inserts (Manufacturer CeramTec GmbH Medical Products Division : Material Biolox Delta® OR HIPER Medical AG, Oberkrämer: Material ELEC®plus)

	<u>Ref. No.</u> Ceramtec)	<u>Ref. No.</u> (Hiper)	<u>Cup size / Ball head-ø</u>	<u>Remarks</u>
	XLW 18-Insert 28/35G 38.49.7188.515.20	ELEC®plus Insert 28/35-18 120000	28 / D	<p>No combination of products from CERAMTEC and HIPER is allowed at any time!</p>
	XLW 18-Insert 32/39G 38.49.7188.525.20	ELEC®plus Insert 32/39-18 120210	32 / E	
	XLW 18-Insert 36/44G 38.49.7188.545.20	ELEC®plus Insert 36/44-18 120380	36 / F	
	XLW 18-Insert 36/48G 38.49.7188.555.20	ELEC®plus Insert 36/48-18 120400	36 / G	
	XLW 18-Insert 36/52G 38.49.7188.565.20	ELEC®plus Insert 36/52-18 120420	36 / H	

Overview: Shells and Inserts



<u>Insert</u>	<u>PE</u>	<u>x-link</u>	<u>Ceramic</u>
D	 D/28	 D/28	 D/28
E	E/28	E/32	E/32
F	F/32	F/32 F/36	F/36
G	G/32	G/32 G/36	G/36
H	H/32	H/32 H/36	H/36

www.atesos.ch
Lit.Nr.: 501.E002-B1 / Ed. 03/16

Pyramid Cup + Insert

<u>Primary Cup</u>	<u>Revision Cup</u> (3 holes)
 42 44 46 48 50 52 54 56 58 60 62 64 66 68	 46 48 50 52 54 56 58 60 62 64 66 68 (70)

List of Instruments:

Ref. No.	Name / Size	Remarks
	Acetabulum Reamer Size 40	No Atesos product
	Acetabulum Reamer Size 41 ²⁾	No Atesos product
	Acetabulum Reamer Size 42	No Atesos product
	Acetabulum Reamer Size 43 ²⁾	No Atesos product
	Acetabulum Reamer Size 44	No Atesos product
	Acetabulum Reamer Size 45 ²⁾	No Atesos product
	Acetabulum Reamer Size 46	No Atesos product
	Acetabulum Reamer Size 47 ²⁾	No Atesos product
	Acetabulum Reamer Size 48	No Atesos product
	Acetabulum Reamer Size 49 ²⁾	No Atesos product
	Acetabulum Reamer Size 50	No Atesos product
	Acetabulum Reamer Size 51 ²⁾	No Atesos product
	Acetabulum Reamer Size 52	No Atesos product
	Acetabulum Reamer Size 53 ²⁾	No Atesos product
	Acetabulum Reamer Size 54	No Atesos product
	Acetabulum Reamer Size 55 ²⁾	No Atesos product
	Acetabulum Reamer Size 56	No Atesos product
	Acetabulum Reamer Size 57 ²⁾	No Atesos product
	Acetabulum Reamer Size 58	No Atesos product
	Acetabulum Reamer Size 59 ²⁾	No Atesos product
	Acetabulum Reamer Size 60	No Atesos product
	Acetabulum Reamer Size 61 ²⁾	No Atesos product
	Acetabulum Reamer Size 62	No Atesos product
	Acetabulum Reamer Size 63 ²⁾	No Atesos product
	Acetabulum Reamer Size 64 ²⁾	No Atesos product
	Acetabulum Reamer Size 65 ²⁾	No Atesos product
	Acetabulum Reamer Size 66 ²⁾	No Atesos product
	Acetabulum Reamer Size 67 ²⁾	No Atesos product
	Acetabulum Reamer Size 68 ²⁾	No Atesos product
	Acetabulum Reamer Size 69 ²⁾	No Atesos product
	Acetabulum Reamer Size 70 ²⁾	No Atesos product
	Reaming shaft straight/standard with AO Connector	No Atesos product
800191	Protection sleeve for reaming shaft straight/standard	
	Reaming shaft MIS with AO Connector ³⁾	No Atesos product
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 42-44 / 28 ²⁾	
800062	Trial insert 46-48 / 32 ²⁾	

800063	Trial insert 50-52 / 36 ²⁾	
800064	Trial insert 54-56 / 36 ²⁾	
800065	Trial insert 58-62 / 36 ²⁾	
800105	Trial insert 46-48 / 28 ²⁾	
800106	Trial insert 50-52 / 32 ²⁾	
800107	Trial insert 54-56 / 32 ²⁾	
800108	Trial insert 58-62 / 32 ²⁾	
800109	Trial insert hooded 42-44 / 28 ²⁾	
800110	Trial insert hooded 46-48 / 32 ²⁾	
800111	Trial insert hooded 50-52 / 36 ²⁾	
800112	Trial insert hooded 54-56 / 36 ²⁾	
800113	Trial insert hooded 58-62 / 36 ²⁾	
800114	Trial insert hooded 46-48 / 28 ²⁾	
800115	Trial insert hooded 50-52 / 32 ²⁾	
800116	Trial insert hooded 54-56 / 32 ²⁾	
800117	Trial insert hooded 58-62 / 32 ²⁾	
800086	Inlay Seating instrument 'Octopus'	
800087	Connector 28 Seating Instr. 'Octopus'	
800088	Connector 32 Seating Instr. 'Octopus'	
800089	Connector 36 Seating Instr. 'Octopus'	
800090	Connector 28 hooded Seating Instr. 'Octopus'	
800091	Connector 32 hooded Seating Instr. 'Octopus'	
800092	Connector 36 hooded Seating Instr. 'Octopus'	
800093	Connector for attachment Octopus ²⁾	
800097	Seating instrument shell MIS ³⁾	
800098	Cardan shaft ³⁾	
800099	Connector to shell ³⁾	
800102	Seating instrument shell straight	
800103	Hammer 450g	
800218	Hexagon Screwdriver SW 3.5 mm	
800232	Hexagon Cardan Screwdriver SW 3.5 mm ²⁾	
800223	Palpation hook	
800229	Connector for trial ball heads ¹⁾	
800233	T-handle AO-coupling	
800203	Trial ball head ø28 L ¹⁾	
800208	Trial ball head ø32 L ¹⁾	
800213	Trial ball head ø36 L ¹⁾	
	Flexi-Bit drill ø3.2mm, length 30mm	No Atesos product
	Flexi-Bit drill ø3.2mm, length 60mm	No Atesos product
	Flexi-Bit drill ø4.5mm, length 30mm	No Atesos product
	Flexi-Bit drill ø4.5mm, length 60mm	No Atesos product
	Flexi-Bit shaft, length 180mm	No Atesos product
	Screw holding forceps	No Atesos product
	Drilling jig ø3.2mm	No Atesos product
	Screw holding forceps curved (2 pcs.)	No Atesos product

¹⁾ Optional, if cup set only is available (without stem set)

²⁾ Optional

³⁾ Optional for MIS application

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