LINK®

CombiCup System

Surgical Technique

CE 0482

Explanation of Pictograms			
	Manufacturer	REF	Article number
MAT	Material (number)	CE	Product meets the applicable requirements, which are regulated in the EU harmonization legislation for the affixing of the CE marking.

CombiCup System

CombiCup PF

- Titanium (Ti6Al4V) + porous pure titanium coating + HA coating
- Press-fit fixation
- Outer diameter 44 - 62 mm (2 mm steps)
- BIOLOX delta*, PE- and X-PE inserts, neutral
- Inserts with shoulder (PE and X-PE)
- 36 mm prosthesis heads from acetabular cup external diameter of 50 mm upwards
- Optional fixation screws
- Minimally-invasive instrument set (optional)

CombiCup SC

- Titanium (Ti6Al4V) + porous pure titanium coating + HA coating
- Screw-in fixation
- Outer diameter 44 - 62 mm (2 mm steps)
- BIOLOX delta*, PE- and X-PE inserts, neutral
- Inserts with shoulder (PE and X-PE)
- 36 mm prosthesis heads from acetabular cup external diameter of 50 mm upwards

*BIOLOX delta is made by CeramTec GmbH, Plochingen

History and Philosophy

The acetabular cup family on which the Combi-Cup system is based was developed in 1999 with Prof. Giacometti Ceroni from the Galeazzi Institute, Milan.

The aim of this development was to improve hip joint stability, reduce the risk of dislocation of hip replacements and optimize the friction properties of joint components.

According to Charnley, the loss of volume is less in small-diameter artificial joints made from metal-polyethylene and ceramic-polyethylene. This is because the area of contact between the femoral and acetabular components is smaller.

However, long-term use of small prostheses heads, can accelerate the wear and tear on polyethylene inserts. The smaller the surface of the ball, the more unfavourably the compression forces are distributed. This increases the penetration effect and the de-formation of the joint.

In addition, the diameter of the joint influences the range of motion significantly.

CombiCup PF and
CombiCup SC

A combination with a large diameter (e.g. 36 mm) offers significant advantages in terms of stability. With ceramic-ceramic couplings using this size, torques act upon the acetabular cup which correspond or fall below torques with 28 mm combinations. The joint is more stable and the risk of dislocation is lower because:

- with large diameters and the associated larger range of motion of the joint, the danger of impingement between the neck of the prosthesis and the edge of the acetabular cup is lower,
- with a larger radius the head of the prosthesis needs to move a greater distance in order to dislocate from the acetabular cup,
- the joint is more tolerant of slight angular mis-alignment of the cup than is the case with smaller diameters

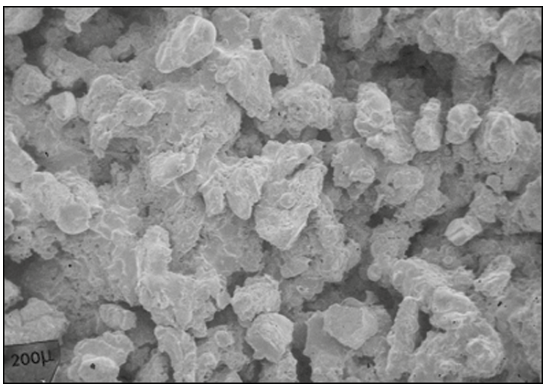
These factors were taken into consideration during development of the system which includes revised and improved versions of the two most common fixation methods (press-fit and screw-in cup). These changes have improved both surgical pro-cedure (better control of the position of the implant, easy introduction of acetabular cup inserts, increased primary stability, ergonomic instrument set) and clinical results (bone-preserving procedures, rapid integration).

The system also offers state-of-the-art technology with regard to construction (reworked taper between metal casing and insert) and materials (BIOLOX delta* ceramic and a modern crosslinked polyethylene material produced in a specific, validated manu-facturing process).

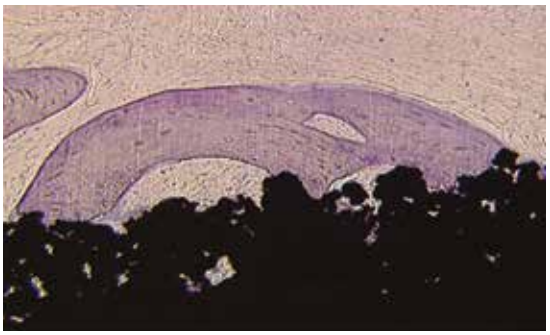
*BIOLOX delta is made by CeramTec GmbH, Plochingen

Materials

- CombiCup metal casings are made from a titanium alloy (Ti6Al4V).
- The surface in direct contact with the bone consists of a porous titanium layer measuring a minimum of 170 µm in thickness and an additional layer of hydroxyapatite measuring 60 µm in thickness.
- Inserts are available as BIOLOX delta* ceramic, PE and X-PE (crosslinked UHMWPE) versions. The PE and X-PE inserts bear a circular ring made from a titanium alloy (Ti6Al4V) to aid placement in the metal casing. They also feature a peg with a covering of titanium alloy (Ti6Al4V) to close the polar hole of the acetabular implant.
- Prosthesis heads are available in BIOLOX forte*, BIOLOX delta* and in CoCrMo alloy (LINK prosthesis head A, prosthesis head B). **BIOLOX inserts may only be used in combination with BIOLOX forte* or delta* prosthesis heads.**



Porous titanium layer

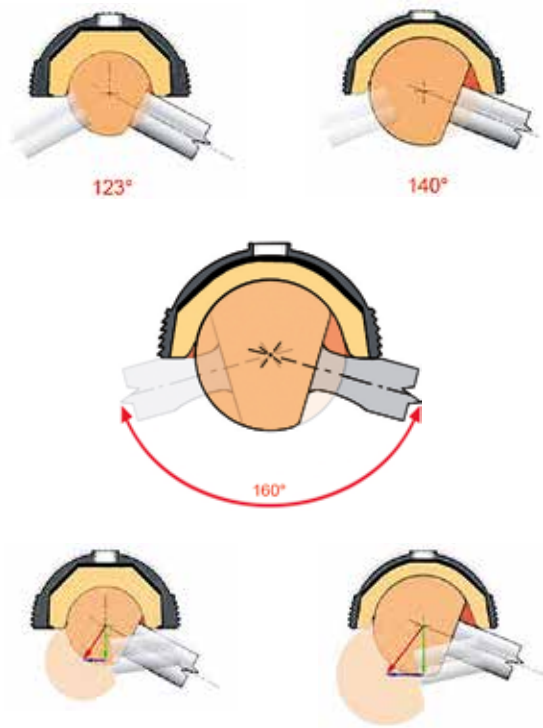

Growth of bone into the porous surface

Kinematic Properties

A head diameter of 36 mm, which is possible in the CombiCup system with acetabular cup sizes of 50 mm and over, allows the joint a range of motion of more than 140°. In a combination with 28 mm head diameter it is only 123°. The greater range of motion reduces the risk of accidental impingement between the neck of the prosthesis and the edge of the acetabular cup.

In the case of a combination of the CombiCup system metal casing and a LINK hip prosthesis stem with flattened neck section, the range of motion of the joint is almost 160° (combination with 36 mm head diameter).

With larger diameters, the prosthesis head must move a larger distance before it dislocates. The risk of dislocation in cases with inadequate soft tissue tension is therefore reduced.



*BIOLOX delta and BIOLOX forte are made by CeramTec GmbH, Plochingen

A loss of congruence and a reduction in the area of contact between head and insert can cause a leverage effect between the neck of the prosthesis and the cup. In this phenomenon, the load-bearing is concentrated on one point which causes the ceramic material to be at risk of damage. This risk is reduced in the new system.

The CombiCup system allows the use of larger component diameters and press-fit or screw-in cups. The system can be used in many different situations.
It is appropriate for primary hip replacement, treatment of dysplasia and for primary prosthesis revisions in which the choice of implant depends on the bone morphology and bone condition.

The CombiCup PF model has circular fixing grooves and features a diameter 2 mm larger than the corresponding acetabulum reamer. An optimum press-fit is obtained due to the mechanical tension between the acetabular cup implant and the acetabulum. Three pre-drilled holes with removable locking screws enable additional fixation in the cranial area by means of fixation screws.

Loss of congruence, concentration of loading at a single point and risk of breaking

Acetabular Cup Reamer

2 mm press-fit

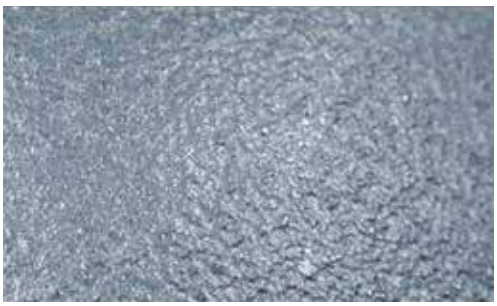
In order to ensure optimum bone in-growth, the surfaces of the CombiCup PF and CombiCup SC acetabular cups consists of a double coating: an external layer of hydroxyapatite, which favours the growth of bone into the second layer of porous titanium underneath.

The CombiCup SC variant has six screw threads to ensure optimum primary stability. These absorb the rotation force which occurs at the cup equator without interrupting the bone wall. The hemispherical construction of the cup gives excellent hold in the acetabulum so that the load is transmitted to the whole surface of the subchondral bone without there being overloading in the region of the screw thread. The bone is thus preserved. In comparison to the corresponding truncated cone-like profile, valuable osseous substance is retained.

The high congruence of the hemispherical Combi-Cup SC acetabular cup component with the bone wall, and the HA coated, porous titanium layer, favors integration into the bone even where bone quality is poor.

Ti6Al4V with HA Coating, magnified

CombiCup SC



Ti6Al4V with porous titanium coating, magnified

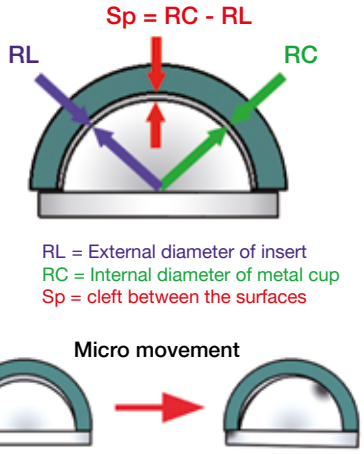
CombiCup PF

Product Properties

The CombiCup system provides three metal casing lines which can, in turn, be combined with numerous acetabular cup inserts manufactured from different materials and of different sizes. The connection between acetabular cup and metal casing is conical. This construction has proven valuable for the following reasons:
This construction has proven suitable because it allows continuous non-deforming contact of the surfaces involved.

Conical connection

In the case of hemispherical acetabular cup inserts, which are connected to the acetabular cup at the equator line by a locking mechanism, an unavoidable cleft is formed due to the different curve radii in this construction, which results in micro movement. This causes repeated friction contact between the surfaces which can lead to abrasion and release of polyethylene particles.



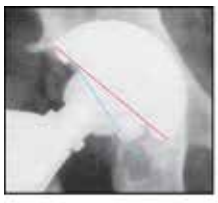
RL = External diameter of insert
RC = Internal diameter of metal cup
Sp = cleft between the surfaces

Hemispherical connection

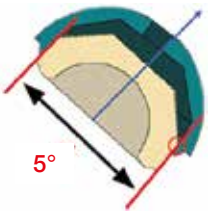
The CombiCup system, however, provides a newly-constructed insert to avoid this problem. All conical connections are usually considered difficult to disassemble. This applies particularly in the case of an angle of less than 10° (the angle of the “Euro cone” is 5°40‘) or under certain friction conditions.

In the past, ceramic inserts for acetabular cups were manufactured with this taper geometry. If there is a direct connection with the metal casing malposition can have negative consequences, such as chipping of the edge. This type of insert is frequently hard to remove in the case of revisions.

The CombiCup system inserts feature a taper with an angle of approximately 19°. This angle was chosen in order to facilitate insertion, reduce the risk of chipping of the edges of ceramic inserts and facilitate disassembly. The polyethylene inserts possess the same properties.



dislocated insert



5° connection angle: malposition and chipping of the edges

A stable and secure connection is therefore enabled, regardless of the material used for the acetabular cup insert.

UHMWPE inserts (PE and X-PE) are constructed in the following manner to make fixation easier:

The area of contact with the internal conical surface of the acetabular cup includes an elastic metal band, 0.7 mm in thickness, made from titanium alloy.

Both inside and outside, the band corresponds exactly to the conical shape of the acetabular insert. The lack of movement between the metal casing and the band on the one hand and between the band and acetabular insert on the other hand is due to conical fixation: the larger the axial load, the greater the stability of the connection.

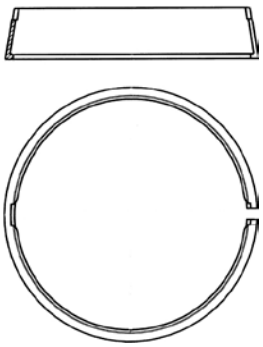
After insertion and axial alignment of the acetabular insert, the connection between the acetabular insert and the metal casing is extremely stable, even without axial loading. In order to guarantee a high level of safety, all acetabular inserts fulfil the minimum standards for ceramics imposed by CeramTec GmbH.

The system also offers two additional mechanisms for secure fixation of the acetabular inserts.

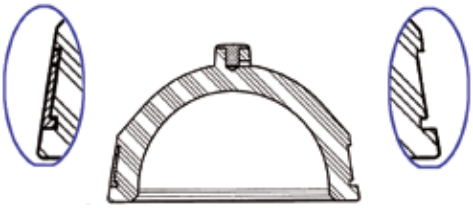
- The lower edge of the band engages with the external surfaces of the acetabular cup insert allowing insert and band to be removed together if necessary.
- On the conical surface of the insert there are two 180° opposing locking notches to avoid rotational movement between PE and titanium band.

Neutral acetabular cup insert

Acetabular cup insert with shoulder



Conical band made from titanium alloy



Locking notches for rotational stability

All polyethylene acetabular cup inserts are supplied with a small, polar peg which has a titanium cap. This peg has two functions:

- It serves as an insertion guide.
- It closes the polar hole in the acetabular cup to protect the inside of the cup against the entry of biological materials.

The polar end of the ceramic inserts have a ceramic peg deliberately designed without a titanium cap.

Polar-hole locking screws are not necessary in either type of cup.

The edge of the metal casing is polished to prevent possible abrasion due to accidental contact with the stem of the prosthesis.

In addition to the three pre-drilled screw holes, the CombiCup PF model has an additional inner polar recess, to allow fitting onto the impactor. This special recessing on the internal polar side ensures the secure fit of the instrument and enables free positioning of the metal casing in the acetabulum.

The CombiCup SC models also have a polar hole for the screwing-in instrument set. The floor of the polar side is recessed, as in the CombiCup PF version, allowing secure fitting and precise screwing in of the acetabular cup.

CombiCup SC acetabular cups must be screwed in carefully because of the indications involved. They feature two inspection holes, which provide a better view of the bone. Following verification that the fit is correct, these holes are closed again using the locking screws which were previously removed.

CombiCup PF metal casing

CombiCup SC metal casing

X-ray of CombiCup PF

Indications

The CombiCup System is indicated for use in total hip arthroplasty. CombiCup PF and CombiCup SC acetabular cups are intended to be used for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

- non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis
- hip dislocation using inserts with shoulder
- post-traumatic arthritis
- correction of functional deformity in case of acetabulum verticalization, anteversion and retroversion
- fractures of femoral neck.

Contraindications

Absolute contraindications include:

- Local or systemic infection
- Septicaemia
- Persistent acute or chronic osteomyelitis
- Confirmed nerve or muscle lesion compromising hip joint function

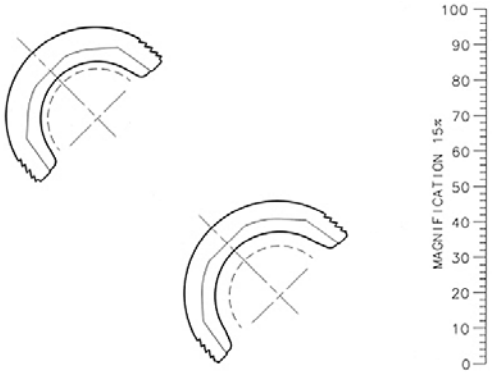
Relative contraindications include:

- Vascular or nerve disease affecting the concerned limb
- Poor bone stock (e.g. due to osteoporosis or extended previous revision surgery) compromising the stability of the implant
- Metabolic disorders which may impair fixation and stability of the implant
- Any concomitant disease and dependence that might affect the implanted prosthesis
- Metal hypersensitivity to implant materials

Sizes

Metal casings for the PF and SC series are available in 10 sizes, in increments of 2 mm. These can be combined with the corresponding acetabular cup insert sizes manufactured from different materials:

- Acetabular cup sizes 44, 46 and 48 mm can be combined with acetabular inserts in size S (small).
- Acetabular cup sizes 50 and 52 mm can be combined with acetabular inserts in size M (medium).
- Acetabular cup sizes 54, 56, 58, 60 and 62 mm can be combined with acetabular inserts in size L (large).



CombiCup PF

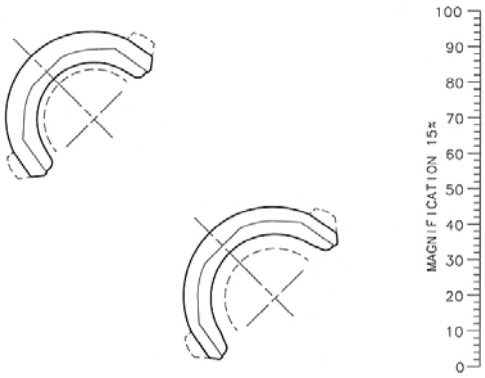
Inserts:

- PE (UHMWPE)
  Size S (small), Size M (medium), Size L (large)
  for prosthesis heads with a diameter of 28 mm

- X-PE (crosslinked UHMWPE),
  Size S (small) – for prosthesis heads with a diameter of 28 mm

  Size M (medium) – for prosthesis heads with a diameter of 28 or 32 mm

  Size L (large) – for prosthesis heads with a diameter of 28, 32 or 36 mm



CombiCup SC

PE and X-PE inserts are available in neutral form and with anti-luxation shoulder (shoulder height 7 mm).

- BIOLOX delta*,
  Size S (small) for prosthesis heads with a diameter of 32 mm
  Size M (medium) for prosthesis heads with a diameter of 36 mm
  Size L (large) for prosthesis heads with a diameter of 36 mm or 40 mm

* BIOLOX delta is made by CeramTec GmbH, Plochingen

Metal Casings

CombiCup PF

MAT Ti6Al4V + PoroTi + HA

REF	Outer Ø mm	For insert
182-001/44	44	small
182-001/46	46	small
182-001/48	48	small
182-001/50	50	medium
182-001/52	52	medium
182-001/54	54	large
182-001/56	56	large
182-001/58	58	large
182-001/60	60	large
182-001/62	62	large

CombiCup SC

MAT Ti6Al4V + PoroTi + HA

REF	Outer Ø mm	For insert
182-010/44	44	small
182-010/46	46	small
182-010/48	48	small
182-010/50	50	medium
182-010/52	52	medium
182-010/54	54	large
182-010/56	56	large
182-010/58	58	large
182-010/60	60	large
182-010/62	62	large

Inserts for CombiCup Acetabular Cup Components

Ceramic inserts

MAT BIOLOX delta*

REF	Inner Ø mm	Insert size
182-150/02	32	small
182-150/03	36	medium
182-150/04	36	large
182-150/05	40	large

Neutral X-PE inserts

MAT crosslinked UHMWPE + Ti6Al4V

REF	Inner Ø mm	Insert size
182-151/01	28	small
182-151/02	28	medium
182-151/03	32	medium
182-151/04	28	large
182-151/05	32	large
182-151/06	36	large

X-PE inserts with shoulder

MAT crosslinked UHMWPE + Ti6Al4V
Shoulder height 7 mm

REF	Inner Ø mm	Insert size
182-152/01	28	small
182-152/02	28	medium
182-152/03	32	medium
182-152/04	28	large
182-152/05	32	large
182-152/06	36	large

Note: CombiCup PE and X-PE acetabular cup inserts may be combined with LINK prosthesis heads type A and type B. CombiCup BIOLOX delta* inserts may only be used in combination with prosthesis heads Type A (BIOLOX forte* or delta*). They may not be combined with metal heads or components supplied by other manufacturers.

*BIOLOX forte and BIOLOX delta are made by CeramTec GmbH, Plochingen

Fixation Screws for CombiCup

Fixation screws

MAT Ti6Al4V

REF	Ø mm	Length mm
180-657/20	6.5	20
180-657/25	6.5	25
180-657/30	6.5	30
180-657/35	6.5	35
180-657/40	6.5	40
180-657/45	6.5	45
180-657/50	6.5	50
180-657/55	6.5	55
180-657/60	6.5	60

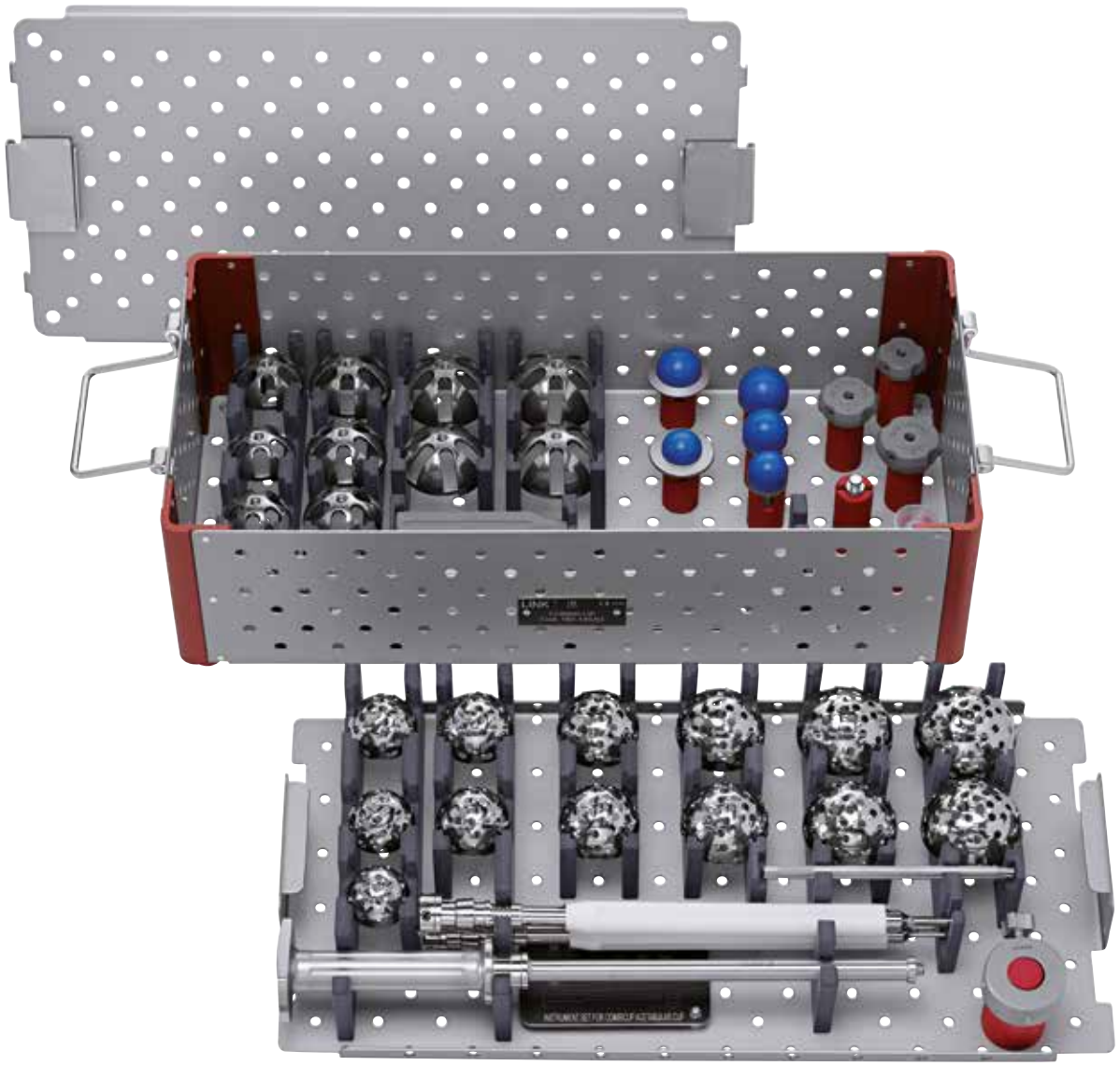
Fixation screw

Additional Instrument Set for Fixation Screws

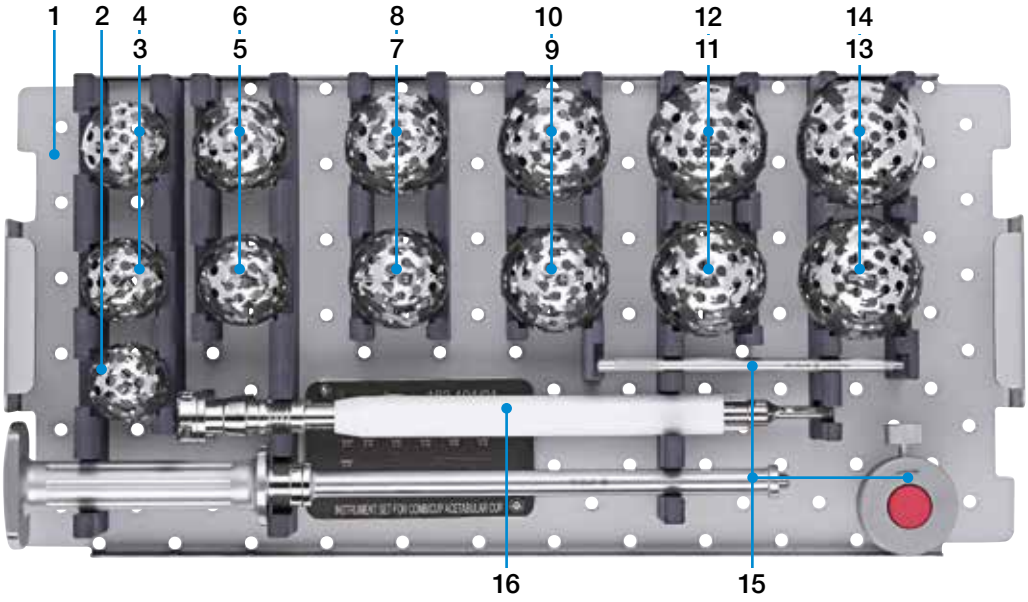
REF	Additional instrument set for fixation screws
182-105/01	Complete set

1	182-138/24	**Instrument bag** (not illustrated)
2	182-138/30	**Flexible drill shaft,** Qty. 2
3	182-138/02	**Drill, long,** Ø 4.5 mm
4	182-138/03	**Drill, short,** Ø 4.5 mm
5	182-138/31	**Screwdriver,** jointed, 3.5 mm hex width
6	182-131/16	**Screwdriver,** straight, 3.5 mm hex width
7	182-138/32	**Drill guide,** for drill Ø 4.5 mm
8	182-138/23	**Forceps for holding screws**

Basic Instrument Set for CombiCup



REF	Basic instrument set for CombiCup, complete
182-101/01	Complete Set



1	182-110/11	**Sterilizing container**			
		Acetabulum reamer with crossed-bar coupling			
	REF	Ø mm		REF	Ø mm
2	131-170/42	42	**9**	131-170/56	56
3	131-170/44	44	**10**	131-170/58	58
4	131-170/46	46	**11**	131-170/60	60
5	131-170/48	48	**12**	131-170/62	62
6	131-170/50	50	**13**	131-170/64	64
7	131-170/52	52	**14**	131-170/66	66
8	131-170/54	54			
15	182-131/08	**Impactor with 2 alignment rods and positioning guide**			
16	131-171E*	**Shaft with handle** for acetabular reamer, fittings optional, Qty. 2			

***How to order:** 131-171E = with Jacobs Chuck Fitting

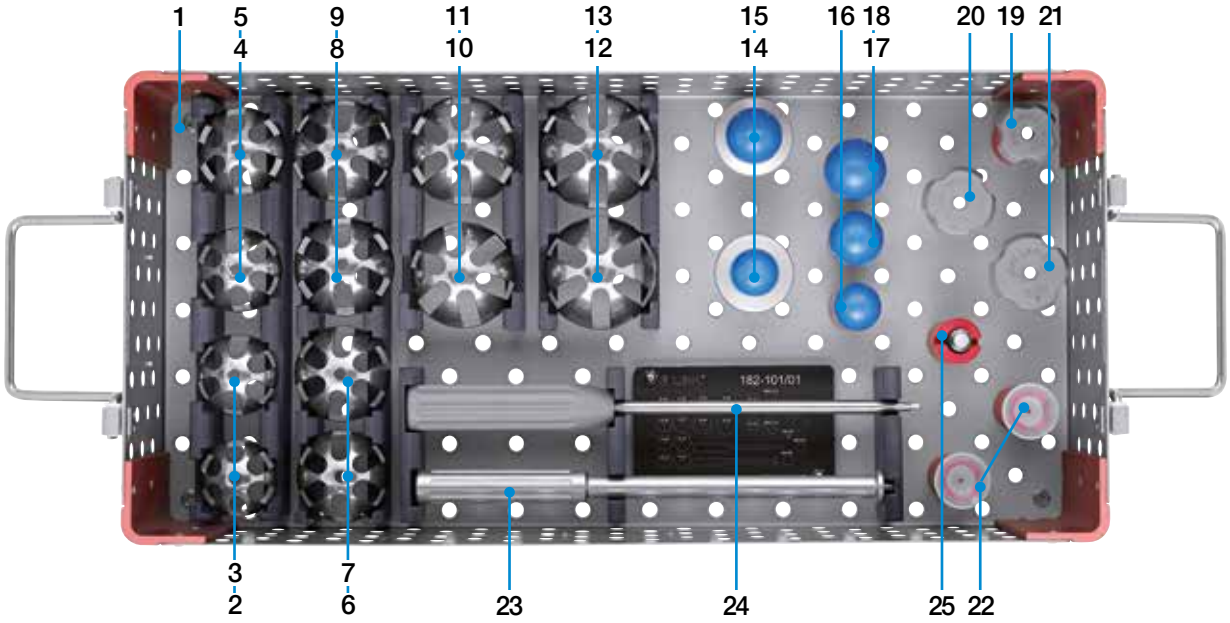
B
Hudson

C
Harris

D
AO

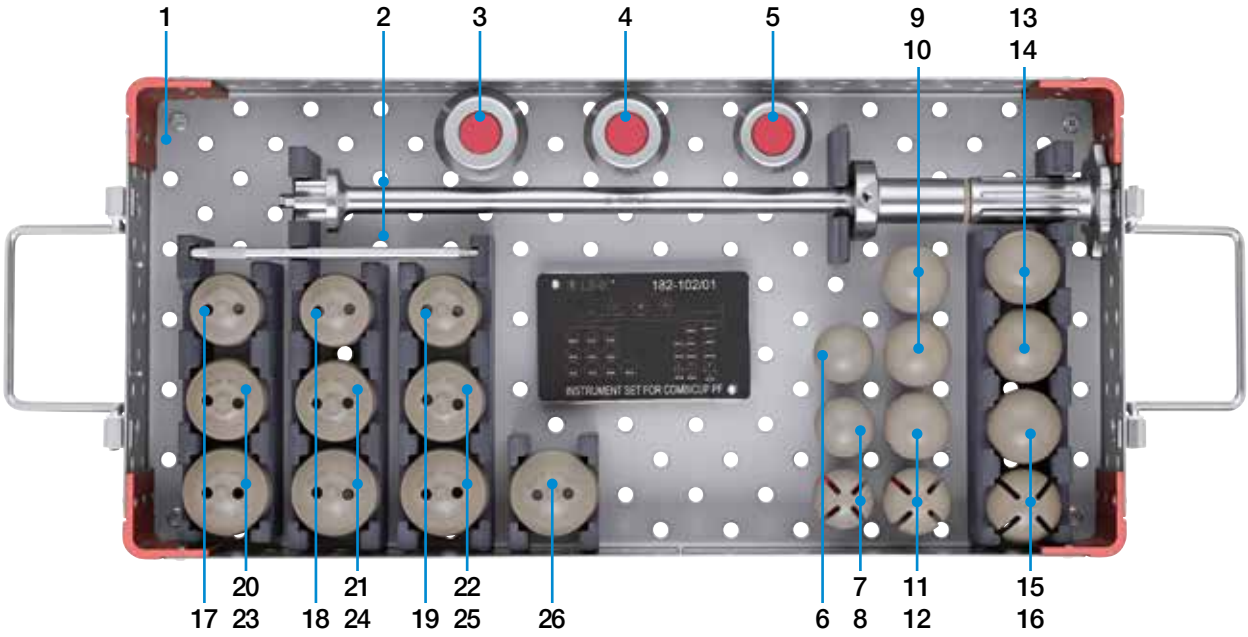
E
Jacobs Chuck

H
Zimmer



1	182-110/11	**Sterilizing container**			
		Trial acetabular cups			
	REF	Ø mm		REF	Ø mm
2	182-135/44	44	8	182-135/56	56
3	182-135/46	46	9	182-135/58	58
4	182-135/48	48	10	182-135/60	60
5	182-135/50	50	11	182-135/62	62
6	182-135/52	52	12	182-135/64	64
7	182-135/54	54	13	182-135/66	66
14	182-131/28	**Impactor for cemented acetabular cups,** Ø 28 mm			
15	182-131/32	**Impactor for cemented acetabular cups,** Ø 32 mm			
16	182-135/28	**Impactor for acetabular cup insert,** Ø 28 mm			
17	182-135/32	**Impactor for acetabular cup insert,** Ø 32 mm			
18	182-135/36	**Impactor for acetabular cup insert,** Ø 36 mm			
19	182-137/32	**Ceramic insert positioner handle, small** (Ø 32 mm)			
20	182-137/36	**Ceramic insert positioner handle, medium** (Ø 36 mm)			
21	182-137/40	**Ceramic insert positioner handle, large** (Ø 40 mm)			
22	182-137/01	**Ceramic insert positioner,** Qty. 2			
23	182-131/05	**Universal handle**			
24	182-131/06	**Screwdriver,** rigid, 3.5 mm hex width			
25	182-137/11	**Adapter for insert positioner**			

Additional Instrument Set for CombiCup PF



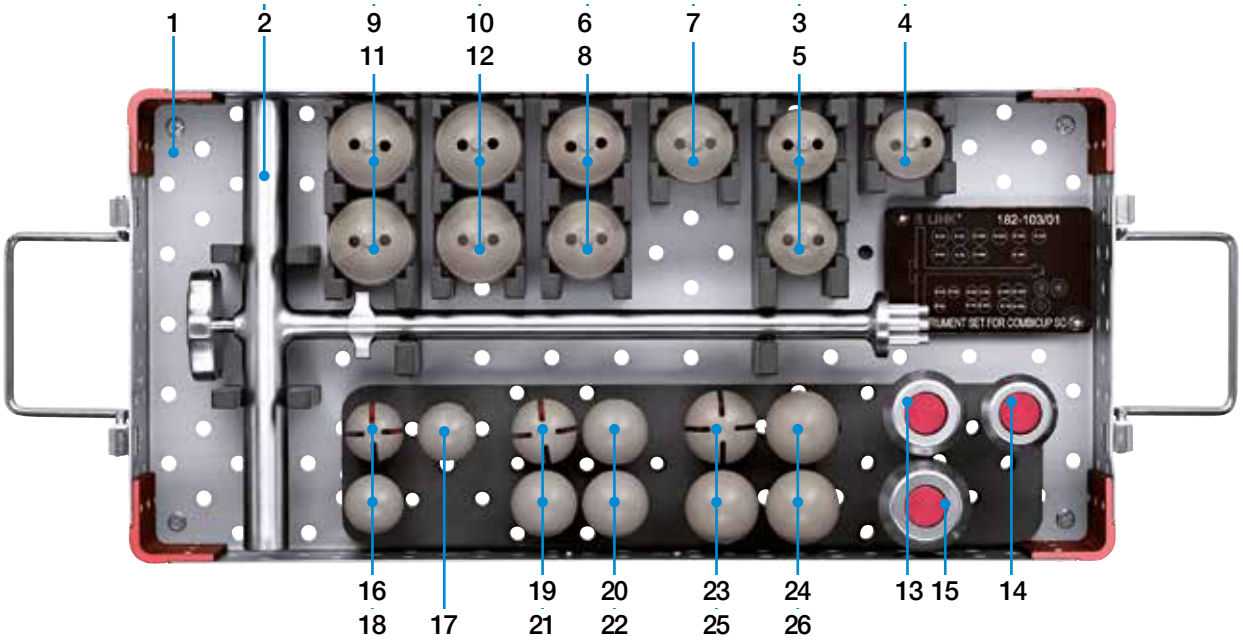
REF	Additional instrument set for CombiCup PF
182-102/01	Complete set

1	182-110/05	**Sterilizing container**					
2	182-131/11	**Impactor (including 2 alignment rods, threaded)**					
3	182-131/25	**Adapter, small**					
4	182-131/26	**Adapter, medium**					
5	182-131/27	**Adapter, large**					
		Trial heads, taper 12/14 mm					
	REF	Ø mm	Size		REF	Ø mm	Size
6	182-132/01	32	short	12	182-136/04	36	extra long
7	182-132/02	32	medium	13	182-140/01	40	short
8	182-132/03	32	long	14	182-140/02	40	medium
9	182-136/01	36	short	15	182-140/03	40	long
10	182-136/02	36	medium	16	182-140/04	40	extra long
11	182-136/03	36	long				
		Trial inserts					
	REF	Ø mm	Size		REF	Ø mm	Size
17	182-132/28	28	small	22	182-133/36	36	medium
18	182-132/32	32	small	23	182-134/28	28	large
19	182-132/36	36	small	24	182-134/32	32	large
20	182-133/28	28	medium	25	182-134/36	36	large
21	182-133/32	32	medium	26	182-134/40	40	large

Optional Instruments for CombiCup PF (not illustrated)

REF	Optional instrument set for CombiCup PF
182-131/41	**MIT-H cup impactor for CombiCup PF**
182-131/45	**Adapter, small (MI)**
182-131/46	**Adapter, medium (MI)**
182-131/47	**Adapter, large (MI)**
182-135/41	**Adapter for trial cups (MI)**
182-131/50	**Screwdriver,** 5.0 mm hex width

Additional Instrument Set for CombiCup SC



REF	Additional instrument set for CombiCup SC
182-103/01	Complete set

1	182-110/23	**Sterilizing container**						
2	182-131/34	**Wrench for CombiCup SC**						
		Trial inserts						
	REF	Ø mm	Size		REF	Ø mm	Size	
3	182-132/28	28	small	**8**	182-133/36	36	medium	
4	182-132/32	32	small	**9**	182-134/28	28	large	
5	182-132/36	36	small	**10**	182-134/32	32	large	
6	182-133/28	28	medium	**11**	182-134/36	36	large	
7	182-133/32	32	medium	**12**	182-134/40	40	large	
13	182-131/25	**Adapter, small**						
14	182-131/26	**Adapter, medium**						
15	182-131/27	**Adapter, large**						
		Trial heads, taper 12/14 mm						
	REF	Ø mm	Size		REF	Ø mm	Size	
16	182-132/01	32	short	**22**	182-136/04	36	extra long	
17	182-132/02	32	medium	**23**	182-140/01	40	short	
18	182-132/03	32	long	**24**	182-140/02	40	medium	
19	182-136/01	36	short	**25**	182-140/03	40	long	
20	182-136/02	36	medium	**26**	182-140/04	40	extra long	
21	182-136/03	36	long					

CombiCup PF

Reamer with crossed-bar coupling

Reaming of the Acetabulum

Using your preferred surgical technique, expose the acetabulum and remove any osteophytes and soft tissue in the acetabular cup area. If bone defects are found after the acetabulum has been exposed, a bone transplant can be inserted if necessary, prior to reaming.

1 A reamer of the appropriate diameter is chosen for reaming (Fig. 1). The work should be commenced using a reamer whose diameter is smaller than the acetabular cup diameter determined using the X-ray templates.

Reamer shaft

2 **Fitting the acetabulum reamer onto the reamer shaft** (Fig. 2):

1) Attach the reamer to the bars of the crossed-bar coupling.
2) Push the locking device on the shaft downwards and twist the reamer counterclockwise one quarter of a turn (Fig. 3).
3) Click the locking device into place (Fig. 4).

3

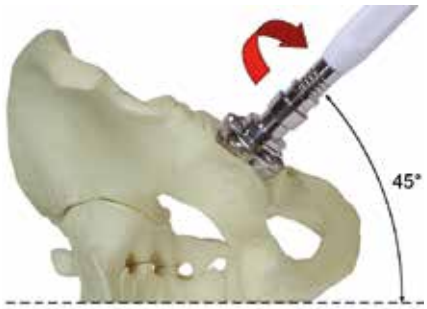
Dismantling of the Reamer

To remove the reamer from the reamer shaft, push the locking device down. Turn the reamer clockwise and remove it from the shaft.

The reamer is usually inserted into the acetabulum at approximately 45° inclination and 15° anteversion (Fig. 5). The bone is reamed in a clockwise direction.

4

Note: These angles correspond to the ideal alignment of the acetabular cup. If the acetabular cup anatomy is altered or if there is a risk of dislocation, it may be necessary to ream out the acetabulum at a different angle in which case the above values no longer apply. We recommend that the ideal angle is nevertheless maintained as far as possible when reaming.



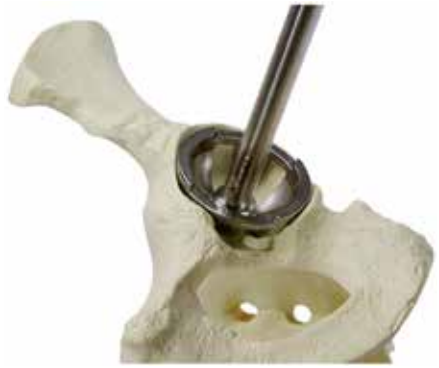
5 Proceed in stages with reamers in increasing diameters until the subchondral bone is exposed.

Universal handle

Impactor

6

Trial and inserting of Acetabular Cups
Following preparation of the acetabulum area, the trial cup is screwed onto the impactor or the universal handle and inserted into the acetabulum (Fig. 6 and 7). The size of the trial cup corresponds to the size of the reamer last used.
In minimally invasive procedures the trial cup can also be inserted with the adapter for trial cups (MI) which is available as an option.



7

Each trial acetabular cup is of the same diameter as the corresponding reamer, so that the correct position can be verified. The wide openings enable the surgeon to check whether the trial cup is sitting evenly across the base of the acetabulum.

Alignment rods

Impactor for CombiCup PF

8

The nominal diameter of the metal casing to be implanted is the same as that of the reamer last used. If, for example, a reamer with a diameter of 54 mm (actual diameter) was used, an acetabular cup with a nominal diameter of 54 mm must be implanted. This diameter is stated on the product packaging and on the acetabular component. The actual diameter of the acetabular cup in this example is 56 mm to generate a stable press-fit.

The impactor for CombiCup PF (Fig. 8) is used for introducing and inserting the metal casing. The instrument is combined with one of the three modular adapters in sizes S, M and L, corresponding to the inner size of the acetabular cup, which ensure optimum distribution of the impact load on the acetabular component (Fig. 9).

An MIT-H cup impactor (curved) is available as an option for minimally invasive techniques. It is to be used in combination with special adapters in the sizes S (small MI), M (medium MI) and L (large MI).

Adapter for acetabular cup impactor CombiCup PF

9

10

Select the adapter which corresponds to the inner size of the metal casing (the size is stated on the packaging and the internal surface of the acetabular components) and attach it to the appropriate end of the impactor (Fig. 10).

11

If fitted correctly, the adapter is fixed to the flange magnetically. Attach the metal casing to the impactor (Fig. 11).
Make sure the screw holes of the cup are positioned on the side of the impactor marked with “Cup holes on this side“ (item no. 182-131/11)

12

13

Find the intended locking position by turning the metal casing against the impactor so that the cup audibly clicks into place and the edge of the acetabular cup lies flush with the adapter. The clicking into place indicates that both impactor pins are seated in the pole of the acetabular cup. The correct position is also indicated on the handle of the impactor (Fig. 12–13).

14

Hold the metal casing in your hand and connect the impactor to the metal casing by turning the handle clockwise (Fig. 14).
When the optional MIT-H impactor is used, the metal casing is fixed by turning the handle on the side (Cardan shaft).

15

The mechanism by which metal casing and impactor are coupled and the use of an adapter for fixation make it impossible to drop the acetabular cup component during implantation (Fig. 15).

Furthermore, the adapter makes it easier to re-attach the metal casing in case the implant needs to be repositioned or removed.

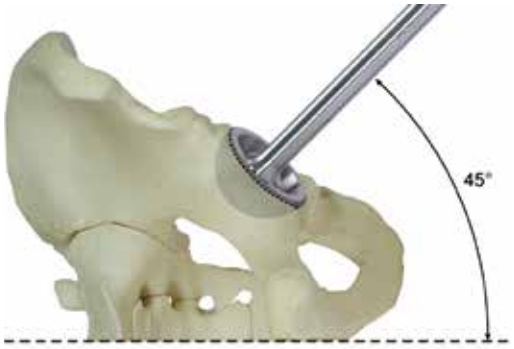


Fig. 16

The metal casing is usually positioned in the acetabulum at approximately 45° inclination (Fig. 16).

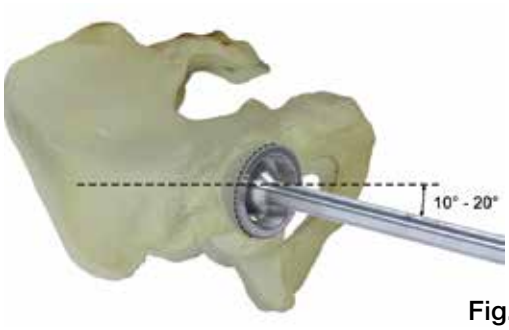


Fig. 17

Note: When introducing a ceramic insert, the inclination angle should not be greater than 45° (approximately 40° is recommended). In addition, the anteversion angle should lie between 10° and 20° in order to reduce the risk of impingement (Fig. 17).

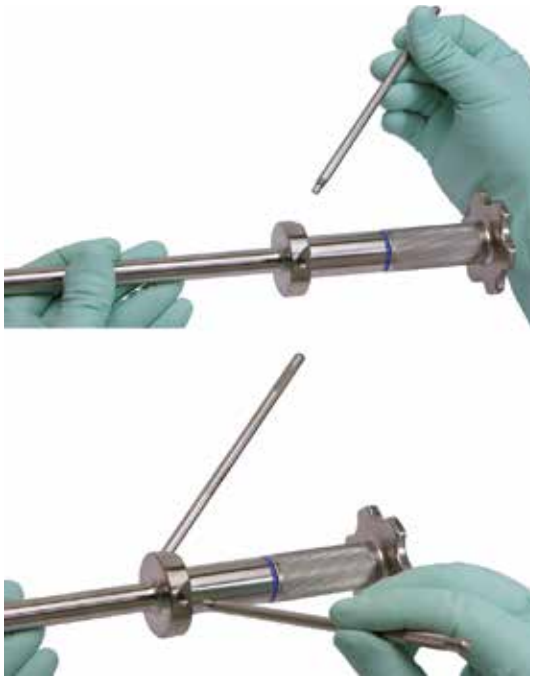
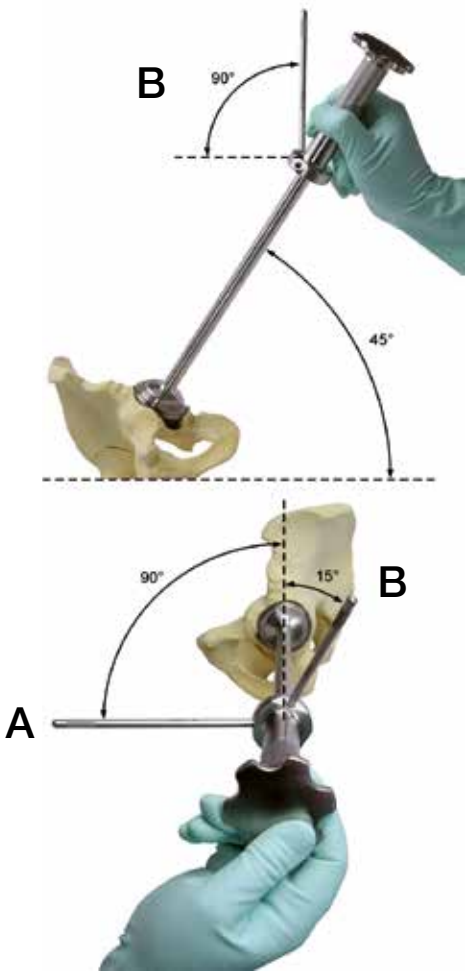


Fig. 18

Incorrect alignment can lead to damage of the ceramic insert in the event of partial dislocation of the prosthesis head. The stem of the hip prosthesis must therefore also be inserted with correct anteversion. If the metal casing is to be fixed with screws it should be aligned with the screw holes (containing the appropriate locking screws) facing in a craniolateral direction.

The instruments in the basic instrument set allow precise positioning of the acetabular cup component, regardless of the positioning of the patient and the surgical access. For correct alignment of the metal casing, screw the alignment rods into the corresponding locator holes in the impactor (Fig. 18).



19

If the patient is lying on his/her side on the operating table, alignment rod (A) should be horizontal and alignment rod (B) should be perpendicular to the operating table. In this position, the inclination of the acetabular component is 45° and the anteversion is 15° (Fig. 19).

Hold the impactor steady and drive the metal casing into the acetabulum with a sufficiently heavy mallet. Test the primary stability by carefully moving the impactor in a lever motion in different planes.

Release the impactor from the metal casing by unscrewing and check the contact between the metal casing and the acetabulum through the polar and cranial holes (remove one or more of the coverings). Reattach the impactor and hit it again if required.

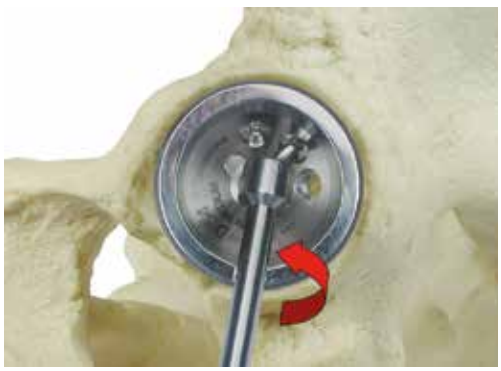
If removed, now re-attach the coverings.

If the acetabular cup component is not sufficiently stable the acetabulum should be reamed further with a reamer one size larger, independently of screw fixation. In this case, the corresponding larger metal casing is to be used.

Screwdriver, jointed

20

The metal casing may also be fixed with fixation screws if required (the screw holes must be in the craniolateral side). Remove the required number of locking screws (Fig. 21) using the jointed screwdriver (Fig. 20).



21

22

Fixation using Fixation Screws
In the event that fixation is carried out using fixation screws, only CombiCup screws should be used (Fig. 22). Other screws may lead to problems when introducing the insert into the metal casing.

Short drill Flexible shaft

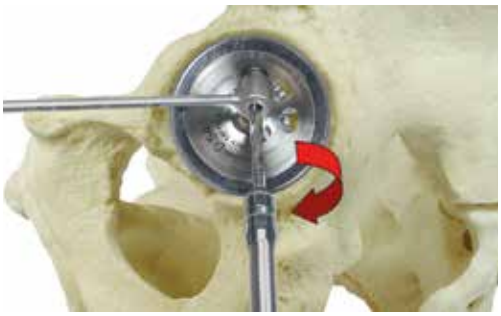
Long drill Flexible shaft

23

Drill guide

24

Two drill bits are available, one long and one short, to drill holes 15 mm and 30 mm in depth respectively (Fig 23). Use the required drill bit (Fig. 23) with the flexible shaft and the drill guide (Fig. 24-25). Insert the drill guide into the chosen screw hole in the direction indicated and drill into the bone (Fig. 25).



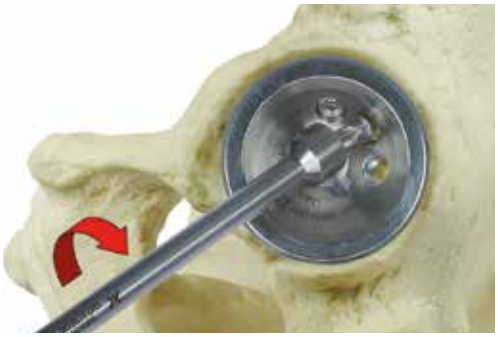
25

Holding forceps for screws

26

Hold the screw under the head with the holding forceps (Fig. 26) and screw it into the bone using the rigid or jointed screwdriver (Fig. 27).

27



28

Once the screw takes hold, remove the forceps and complete the screwing process (Fig. 28). The head of the screw must not protrude from the internal surface of the metal casing, otherwise the acetabular cup insert cannot be positioned correctly. Proceed in the same manner for other holes, as required. A maximum of three screws can be inserted.

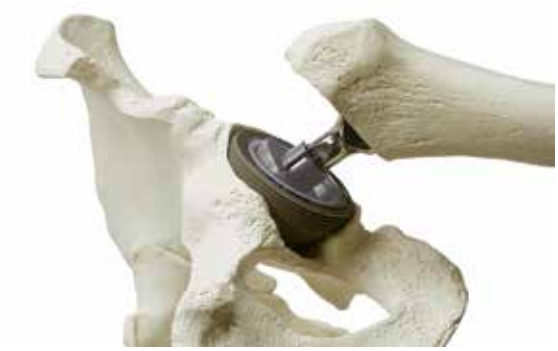
Trial insert **29**

Trial head **30**

Trial Reduction
The acetabular cup component is usually implanted before the stem. As soon as the acetabular component has been inserted, any contact between the acetabular component and the femoral stem should be avoided. It is therefore recommended that the trial insert (Fig. 29, which is also used for trial reduction) or a compress be placed in the metal casing. Trial reduction is carried out after preparation of the stem components. The instrument sets for CombiCup PF and CombiCup SC cups contain trial heads measuring 32, 36 and 40 mm (Fig. 30).

In the event that ideal alignment of the metal casing and femoral component is not possible (because there is a risk of impingement or dislocation), ceramic inserts should not be used. In this case, a polyethylene insert with shoulder (anti-luxation) should be selected.

31 Apply marking to the bone at the estimated dislocation point by means of electrocautery. This serves as an aid to orient the PE insert with shoulder.



32

Introduction of the final Acetabular Cup Insert
The required size (small, medium or large) is noted on the product label and also on the inside of the metal casing. Before introducing the final acetabular cup insert, clean the inside of the metal casing carefully and check that no surrounding soft tissue hinders introduction of the insert.

All CombiCup inserts are fixed using a taper. This does not require a clicking device or similar on the external edge of the metal casing. The insert can therefore be introduced in any position.

33

34

35

36

Implantation of ceramic inserts
Prior to introduction of the insert, clean the inside of the metal casing carefully and check that surrounding soft tissue does not hinder introduction of the insert.

Implant the insert (Fig. 33) using the special insert positioner. The insert positioner consists of an suction cup which is to be combined with the appropriate plastic handle. Choose the handle size according to the size of the insert (small, medium/large, large (40 mm head diameter)).

Connect the positioner with the universal handle (Fig. 34) and mount the ceramic insert on the suction cup (Fig. 35). Then implant the insert.

Note: Ceramic inserts are supplied with a polar peg. A polar locking screw is therefore not required (see page 09).

Check the correct position of the insert by feeling round the entire edge (Fig. 36). The edge of the insert must not protrude over the edge of the metal casing. The insert may otherwise be damaged.
If the insert jams in the wrong position, it can be removed by gently tapping the edge of the metal casing with the handle of a suitable instrument. The insert will spring out due to the vibration.

Caution! Do not reintroduce this ceramic insert after removing it and do not introduce a new ceramic insert into a metal casing that has already held a ceramic insert. In this case, only a polyethylene (PE/X-PE) insert can be used. A ceramic prosthesis head must then be used.
The femoral implant must also be replaced in this case so that a ceramic prosthesis head can be used. Ceramic revision heads with a metal lining (BIOLOX Option*) are also available on request as an alternative.
Then proceed as described.

*BIOLOX Option is made by CeramTec GmbH, Plochingen

37

Implantation of UHMWPE Inserts (PE and X-PE), Fig. 37

Note: Polyethylene inserts are supplied with a polar peg with a titanium cap. A polar locking screw is therefore not required (see page 09).

Polyethylene inserts can also be introduced without the use of a positioning instrument. When introducing inserts in this manner, hold the insert carefully between the thumb and index finger. The index finger is on the concave side.

Press the insert carefully into the metal casing using the index finger.

As with the ceramic insert, check the correct position of the insert in the acetabular cup component.
If removal of the insert is neccessary, a self-tapping cancellous bone screw can be screwed into the polyethylene insert.

Note: In the case of inserts with shoulder, the correct alignment of the anti-luxation edge at the previously marked position must be checked prior to final fixation of the insert. A line marked in the middle of the front surface of the raised edge enables precise alignment to the required position (Fig. 37).

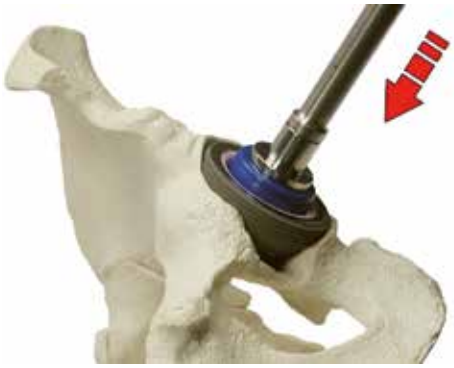
Impactor for acetabular cup inserts **38**

To achieve a stable connection, screw the appropriate impactor for acetabular cup inserts (Fig. 38) onto the universal handle or the impactor (Fig. 39–40).

Universal handle **39**

Impactor

40

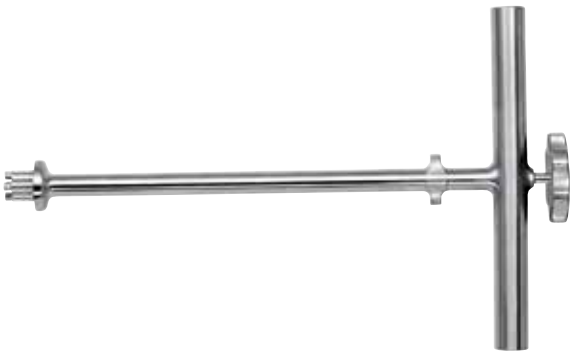


41

Drive the insert in an axial direction by hitting gently (Fig. 41). The connection is ultimately stabilised by the forces exerted when the joint bears weight.

Following thorough cleaning of the articular surfaces, the joint is finally reduced.

CombiCup SC



Wrench for CombiCup SC 1

The acetabulum is prepared in the same manner as has been described for the CombiCup PF metal casing.

As is usual in the case of screw-in acetabular cups, the outside edge can be slightly enlarged when reaming the acetabulum to facilitate later screwing in of the acetabular cup.

With this type of acetabular cup, actual and nominal diameters are the same. The diameter of the acetabular cup to be implanted is therefore always identical to the diameter of the reamer last used.
If, for example, a reamer with a diameter of 54 mm was used last, an acetabular cup component with a diameter of 54 mm must be implanted. This diameter is stated on the product packaging and on the acetabular component. In this case, overlaying of the bone site is not required.

Additional fixing with fixation screws is not intended.

Inserting of Metal Casing
Insert the wrench for CombiCup SC (Fig. 1) into the metal casing in such a way that the 4 adapter pins click into the recesses in the base of the metal casing (Fig. 2).

2

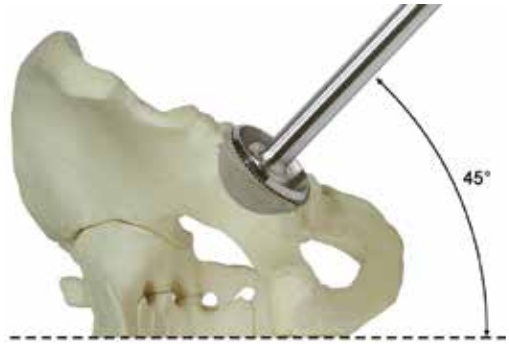
Fix the acetabular cup component (Fig. 4) by turning the screw on the handle (Fig. 3).

3

4

Insert the acetabular cup component into the acetabulum and screw in under pressure in a clockwise direction,until it sits as flush as possible with the edge of the acetabulum (Fig. 5).

5



Positioning of Acetabular Cup Components
The metal casing is usually placed in the acetabulum at approximately 45° inclination (Fig. 6).

6

7

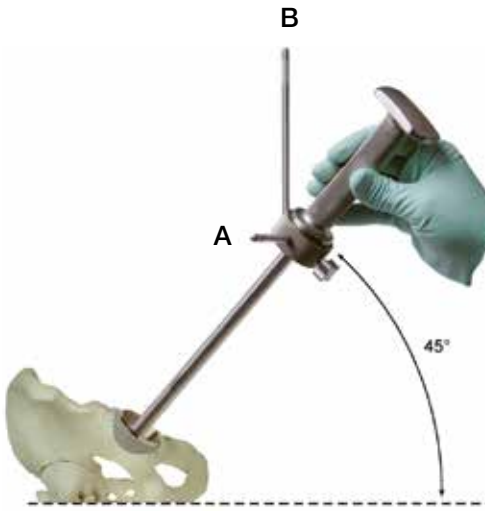
Note: When introducing a ceramic insert, the inclination angle should not be greater than 45° (approximately 40° is recommended). In addition, the anteversion angle should lie between 10° and 20° to reduce the risk of impingement (Fig. 7).

Incorrect alignment can lead to damage of the ceramic insert in the event of partial dislocation of the prosthesis head. The stem of the hip prosthesis must therefore also be implanted with correct anteversion.

Impactor with alignment rods and positioning guide

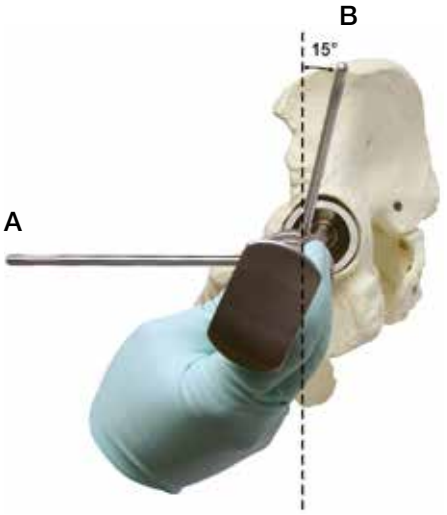
8

After the wrench for CombiCup SC has been removed, screw the handle of the impactor into the metal casing. Then attach the positioning guide and screw both alignment rods into the locator holes (Fig. 8).
Before attaching the impactor to the cup, slide the metal ring of the positioning guide onto the receptacle at the impactor‘s handle.



9

If the patient is lying on his/her side on the operating table, alignment rod (A) should be horizontal and alignment rod (B) should be perpendicular to the operating table. In this position, the inclination of the acetabular cup component is 45° and the anteversion is 15° (Fig. 9–10).



10

The metal casing should be seated deep enough in the acetabulum. Test the primary stability by carefully moving the impactor in a lever motion in different planes.

Remove the impactor and look through the inspection holes to check the contact between the cup component and the acetabulum. Close the holes again after checking.
Attach the wrench for CombiCup SC again and screw in the metal casing further if required. In the event of insufficient primary stability of the acetabular cup component, the acetabulum should be reamed further with a reamer one size larger. In this case, the corresponding larger metal casing is to be used.

11

For detaching the cup wrench from the acetabular cup component, screw the locking screw of the cup wrench counter-clockwise to detach the acetabular cup component (Fig. 11).

Neutral insert

Trial Reduction and Introduction of the final Acetabular Cup Insert
Prior to introduction of the final acetabular cup insert, clean the inside of the acetabular cup carefully and check that no surrounding soft tissue hinders introduction of the insert.

Insert with shoulder

All CombiCup inserts are fixed using a taper. This requires no clicking device or similar on the external edge of the metal casing.
The insert can therefore be introduced in any rotational position.

The trial and introduction of the final insert is described in the corresponding sections of the technique for the CombiCup PF.

X-ray Templates

REF	X-ray templates for CombiCup PF
182-110/07	**Metal casings** 115% actual size, 1 set of 2 sheets

REF	X-ray templates for CombiCup SC
182-110/08	**Metal casings** 115% actual size, 1 set of 2 sheets

Instructions for Cleaning and Maintenance

Specific instructions for instruments are available on request from customer@linkhh.de

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L. Costa
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Lisboa, Portugal - 4/7 June 2005

From Small to Big Diameters: Advantages, Opportunities and Solutions.
F. Benazzo - G. Rinaldi - F. Ravasi - P. Dalla Pria
7° E.F.O.R.T. European Congress 2005 -
Lisboa, Portugal - 4/7 June 2005

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Important Information

Please note the following regarding the use of our implants:

1. **Choosing the right implant is very important.**
   The size and shape of the human bone determines the size and shape of the implant and also limits the load capacity. Implants are not designed to withstand unlimited physical stress. Demands should not exceed normal functional loads.

2. **Correct handling of the implant is very important.**
   Under no circumstances should the shape of a finished implant be altered, as this shortens its life span. Our implants must not be combined with implants from other manufacturers. The instruments indicated in the Surgical Technique must be used to ensure safe implantation of the components.

3. **Implants must not be reused.**
   Implants are supplied sterile and are intended for single use only. Used implants must not be used again.

4. **After-treatment is also very important.**
   The patient must be informed of the limitations of the implant. The load capacity of an implant cannot compare with that of healthy bone!

5. **Unless otherwise indicated, implants are supplied in sterile packaging.**
   Note the following conditions for storage of packaged implants:
- Avoid extreme or sudden changes in temperature.
- Sterile implants in their original, intact protective packaging may be stored in permanent buildings up until the “Use by” date indicated on the packaging.
- They must not be exposed to frost, dampness or direct sunlight, or mechanical damage.
- Implants may be stored in their original packaging for up to 5 years after the date of manufacture. The “Use by” date is indicated on the product label.
- Do not use an implant if the packaging is damaged.

6. **Traceability is important.**
   Please use the documentation stickers provided to ensure traceability.

7. **Further information** on the material composition is available on request from the manufacturer.

Follow the instructions for use!

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