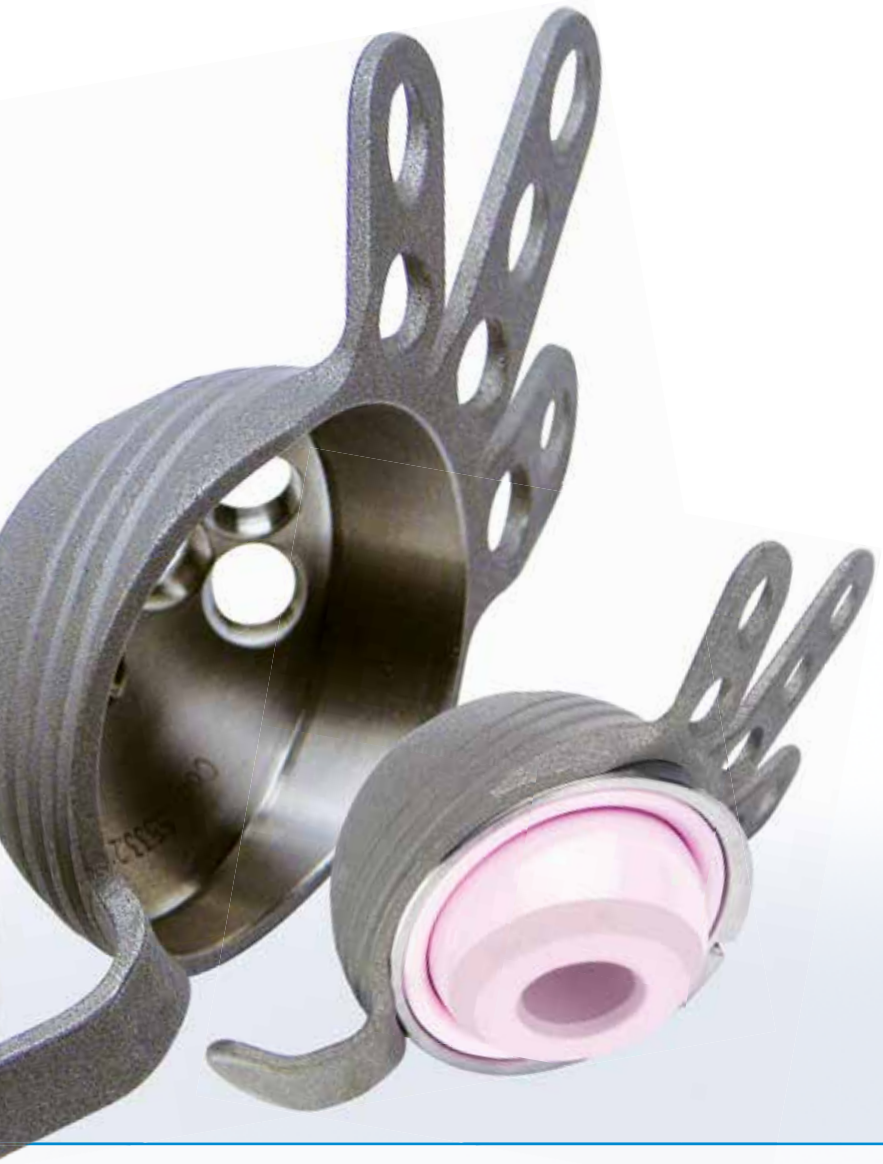
LINK®



CombiCup R

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 R

CombiCup R

- Titanium with porous surface
- Stable fixation by means of fixation screws inside the acetabular cup
- Lugs which can be adapted to the patient's anatomy for secure locking and additional screw fixation
- For CombiCup ceramic (BIOLOX delta*), PE- and X-PE inserts
- Optional PE- and X-PE inserts with shoulder for increased security
- Neutral, lateralizing and angled augments for anatomic reconstructions
- Realistic size range from 50 - 66 mm in diameter (5 sizes)

Metal Casings

CombiCup R

MAT Ti + PoroTi

REF	Outer Ø mm	For inserts
182-020/50	50	large
182-020/54	54	large
182-020/58	58	large
182-020/62	62	large
182-020/66	66	large

Inserts and Augments for CombiCup R Metal Casings

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 canopy approximately 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

*BIOLOX delta is made by CeramTec GmbH, Plochingen

Augments

MAT Ti6Al4V

REF	Angle	Size	For insert	Lateralization mm
182-110/01	0°	large	medium	0
182-110/02	0°	large	medium	+ 5
182-110/10	10°	large	medium	0
182-110/15	10°	large	medium	+ 5
182-110/20	20°	large	medium	0
182-110/25	20°	large	medium	+ 5

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

Fixation Screws for CombiCup

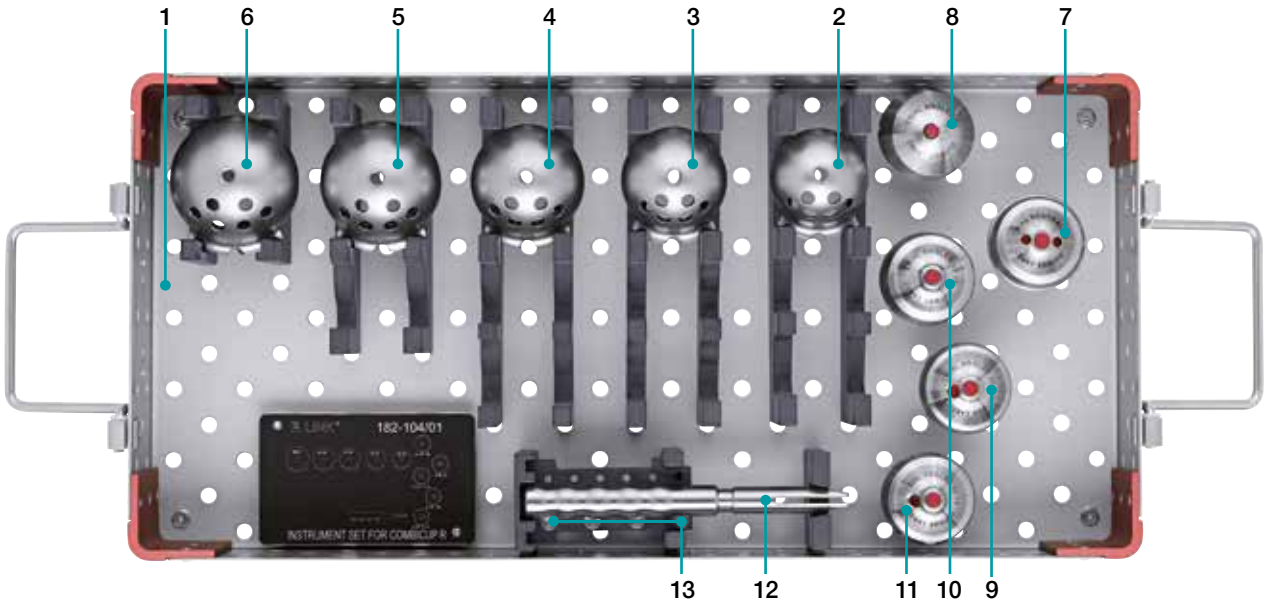
Fixation screws

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

*BIOLOX delta is made by CeramTec GmbH, Plochingen

Additional Instrument Set for CombiCup R

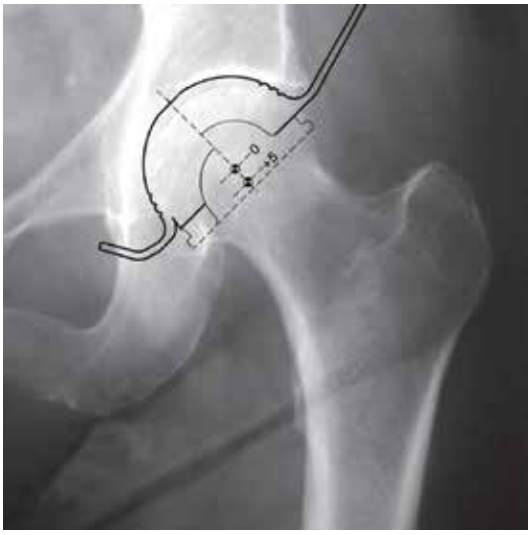


REF	Additional instrument set for CombiCup R
182-104/01	**Instrument set,** complete

1	182-110/04	**Sterilizing case**	
	REF	**Trial cups** Ø mm	
2	182-140/50	50	
3	182-140/54	54	
4	182-140/58	58	
5	182-140/62	62	
6	182-140/66	66	
	REF	**Trial augments, Size: large** Angle	Lateralization mm
7	182-135/72	0°	+ 5
8	182-136/73	10°	0
9	182-136/74	20°	0
10	182-136/75	10°	+ 5
11	182-136/76	20°	+ 5
12	182-131/21	**Handle for winglets modeling**	
13	182-131/22	**Fixation screw for trial augments,** Qty. 4	

Note: This is an additional instrument set for Combi Cup R. The basic CombiCup instrument set (REF 182-101/01), the CombiCup PF additional instrument set (REF 182-102/01) and the instrument set for CombiCup fixation screws (REF 182-105/01) are also required. See CombiCup surgical technique.

Preoperative Planning



For optimum results, preoperative planning should always be carried out with the corresponding X-ray template, which depicts a 15 % enlargement of the profile of the acetabular cup component.

The templates show the center of rotation of the femoral head with an augment without lateralization (0 mm) and with lateralization (+5 mm).

CombiCup R

Reamer with cross-bar coupling **Fig. 1**

Reamer shaft

Reaming of the Acetabulum
Using your preferred surgical technique, expose the acetabulum so that its interior is easily visible during reaming. If an implant is already in place, remove it. Remove any osteophytes and expose the edge of the acetabular cup so that you can assess the anatomy and possible defects. It is important to have a good view of the lower edge of the acetabulum so that you can position the caudal hook of the CombiCup R correctly. Prepare the acetabulum with the Combi-Cup acetabulum reamers.

Select a reamer with the appropriate diameter (Fig. 1). Begin with a reamer whose diameter is smaller than the cup diameter that was selected using the X-ray templates.

Fig. 2

Fig. 3

Fitting the Acetabulum Reamer

1) Attach the reamer to the divider bars of the cross-bar coupling.

2) Push the locking sleeve on the shaft downwards and twist the reamer counterclockwise one quarter of a turn (Fig. 2).

3) Allow the locking sleeve to click into place (Fig. 3).

Fig. 4

Dismounting of the Reamer

To remove the reamer, push the locking sleeve down. Turn the reamer counterclockwise and remove from the shaft.

Insert the reamer into the acetabulum so that its stem has approximately 45° inclination and 15° anteversion (Fig. 4). Ream in a clockwise direction.

Note: These angles correspond to the ideal alignment of the acetabular cup. If the acetabular cup anatomy is altered, 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.

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

Universal handle

Impactor

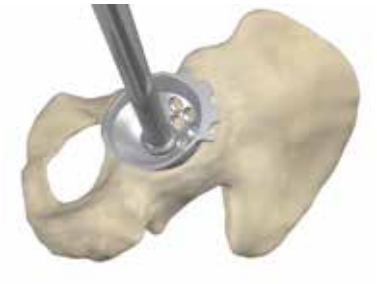


Fig. 5

Trial Acetabular Cup and Implantation
The required size is determined with the aid of the trial acetabular cups, which are screwed onto the universal handle (Fig. 5). The position of the lugs of the final metal casing can be verified with the help of the trial acetabular cups.

A metal casing of the same size as the reamer last used is subsequently implanted.

The nominal diameter of the metal casing to be implanted is the same as that of the last reamer 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 is to be implanted. This diameter is stated on the product packaging and on the metal casing.

Remove the corresponding metal casing from the sterile packaging.

Fig. 6

Shape the cranial lugs of the CombiCup with the modeling instrument in such a way that they fit the anatomy of the ilium (Fig. 6). Handle the lugs with care here to avoid damage (for example repeated bending to and from can damage the material‘s structure). Adapt the caudal hook in the same manner (Fig. 7).

Fig. 7

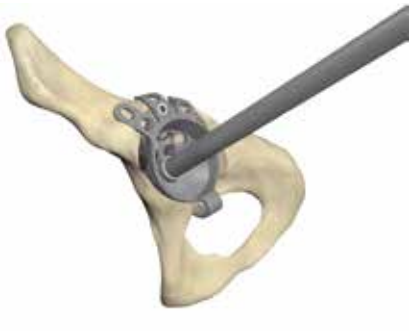


Fig. 8

Connect the metal casing to the universal handle or the acetabular cup impactor in the instrument set. Hold the instrument still and drive in the acetabular cup component firmly with a hammer. Ensure that the caudal hook is positioned in the foramen obturatum as intended (Fig. 8).

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. Detach the impactor and check the contact between the metal casing and the acetabulum through the pre-drilled holes.
If necessary, mount the impactor again and drive the metal casing further in.

Then screw in the fixation screws through the pre-drilled holes in the metal casing.

CombiCup fixation screw

Fig. 9

Insertion of Fixation Screws
Use only CombiCup screws (Fig. 9). Other screws are not permitted.
All the holes in the lugs can be used provided that there is sufficient bone to anchor the screws.

Fig. 10

The instrument set includes one short and one long drill bit for drilling holes 15 mm and 30 mm deep respectively (Fig 10). The appropriate drill bit is used with the flexible shaft and drill guide (Fig. 11).

Fig. 11

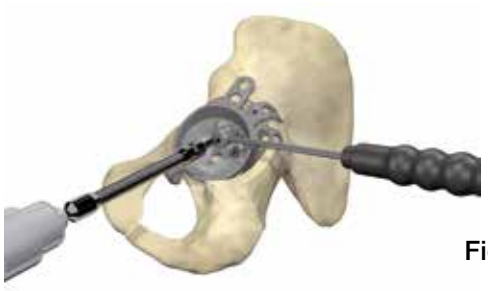


Fig. 12

Insert the drill guide in the direction dictated by the selected hole and drill into the bone (Fig. 12).

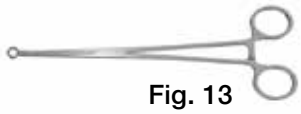


Fig. 13

Hold the screw below the head with the holding forceps (Fig. 13), position it and screw it in using either the rigid screwdriver or the jointed screwdriver (Fig. 14). Once the screw takes hold, remove the forceps and complete the screwing process.

Note: We ask surgeons to pay particular attention when implanting CombiCup R cups with Combi-Cup R augments (REF 182-110/xx).
The bone screws must be screwed in fully during the operation so that they do not protrude, in order to guarantee a complete conical coupling between the augment and the acetabular cup.

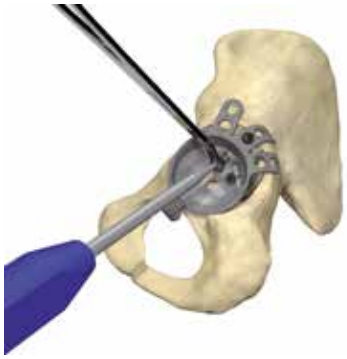


Fig. 14

After inserting the screws into the metal casing, fix the cranial lugs in the same manner. It is recommended that the pre-drilled holes closest to the acetabular cup be used first, then the remaining holes.

Fig. 15

Insertion of Trial Augments
If augments are being used, the trial augments can be inserted now (Fig. 15).

Augments are used to reconstruct center of rotation, covering and anteversion.

Fig. 16a

The trial augment is fixed in the required position and, where necessary, fixed into the metal casing with the trial screws in the instrument set (see also page 11, section “Notes for inserting augments”).

When inserting the augment, first place the polar screw in the augment and hold it with the screwdriver. Then insert the augment and align it by centering the screw in the pre-drilled hole (Fig. 16a + 16b).

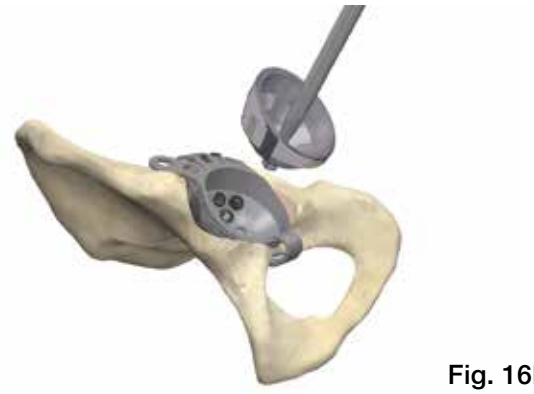


Fig. 16b

Notes for Inserting Augments:

No trial component is required for the neutral augment with no angling or lateralization, as one of the large trial inserts with the appropriate head size can be used. The final neutral augment with no angling or lateralization possesses a single hole for the polar pin of the ceramic or polyethylene insert. No retaining screw is necessary for the final component.

The neutral augment (with no angling) with +5 mm lateralization has a single polar hole, in which a fixation screw is inserted (in both trial and final components).

The augment with 10° angling and without lateralization has a polar pin instead of the retaining screw (in both trial and final components). The available hole accommodates the polar pin of the ceramic or polyethylene insert.

The augment with 10° angling and +5 mm lateralization has a single polar hole in which a fixation screw is inserted (in both trial and final components).

Fig. 17

The augments with 20°angling (neutral and with lateralization) have two holes. The figure shows the trial augment positioned in the metal casing and the pre-drilled hole to accommodate the fixation screw for the trial and the final augment. This pre-drilled hole is opposite the reference notch (in Fig. 17 the hole for the retaining screw is marked in red).

Both trial and final augments are positioned manually without fixing screws.

The position of the angled trial augment can be varied by turning it inside the metal casing, in order to correct the anteversion/covering of the implant. The notch in the final and trial augments makes it easier to find the same position for the final implant.

To alter the position of the augment slacken the screw (if used) slightly and loosen the augment by giving it a soft tap on the edge. Then retighten the screw (if used).

Fig. 18

Trial Reduction
The acetabular cup component is normally implanted before the femoral stem. As soon as the acetabulum component has been inserted, all contact between the cup components and the shaft of the femur should be avoided once the acetabulum component is in place.

It is therefore recommended that the trial insert of the corresponding size be placed in the metal casing (or in the trial augment, where present, Fig. 18).

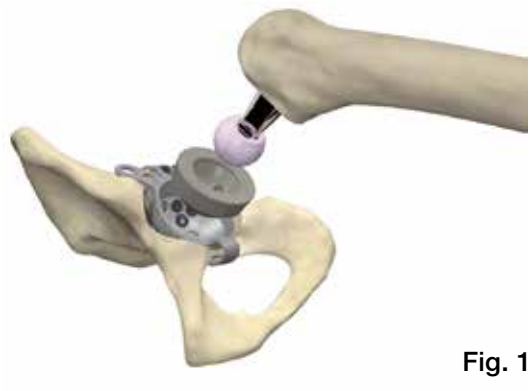


Fig. 19

After positioning the corresponding trial head, trial reduction is carried out. In the event of incorrect alignment of the metal casing and femoral component (danger of impingement or dislocation), the augment can be moved in order to change the center of rotation, anteversion and covering.

Use electrocautery to make a mark on the bone at the estimated dislocation point. This serves as an orientation aid for the PE-/X-PE insert with shoulder or the angled augment.

Insertion of the final Augment
If ceramic components are being used an augment must be inserted. Augments may also be used for all polyethylene inserts if modification of the center of rotation, covering or anteversion is desired.

Prior to insertion of the augment, clean the inside of the metal casing carefully and check that no surrounding soft tissue hinders insertion of the augment. The insertion procedure is the same as that for fitting trial augments. The augments can be turned in the metal casing before fixation, in order to correct anteversion/covering of the implant.

Fig. 20

Fig. 21

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 marking in the middle of the raised edge enables precise alignment to the required position (Fig. 21).

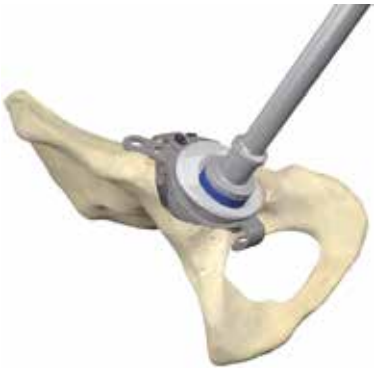


Fig. 22

Insertion of Polyethylene Inserts (PE and X-PE)
Note: Polyethylene inserts are supplied with a polar pin with a titanium cap. A polar locking screw is therefore unnecessary.

All CombiCup system inserts are fixed into the metal casings/augments with a Morse taper. Before implanting the final cup insert, carefully clean the inside of the metal casing (or the augment) and check that no surrounding soft tissue hinders insertion. Polyethylene inserts (Fig. 20) can also be fitted without using an insert positioner.
Grasp inserts at the edge with thumb and index finger. The index finger is on the concave side.

Push the neutral insert with a slight twisting motion toward the base of the acetabular cup.
Press the insert in carefully using the index finger. Check the correct position of the insert by feeling round the entire edge. The edge of the neutral insert must not protrude over the edge of the metal casing.

In the case of inserts with a shoulder, particular care must be taken to ensure correct positioning. Do not hold the insert at the projection (shoulder) and press into the metal casing, as this can lead to malposition. For insertion hold the insert at the neutral end between the thumb and index finger. Press the insert into the metal casing using the index finger. Ensure that the neutral edge of the insert does not protrude over the edge of the metal casing by feeling round the entire edge.

Screw the inserter-positioner onto the impactor and drive the insert lightly in an axial direction (Fig. 22).

If the insert jams in the oblique position, it must be removed, which can be carried out by lightly hitting the edge of the metal casing with the handle of a suitable instrument. The vibration makes the insert spring out.
To remove the polyethylene insert, screw a self-tapping cancellous bone screw into it.

After thorough cleaning of the articular surfaces, the joint can then finally be reduced. An error in the positioning of the metal casing can be corrected using special polyethylene inserts with shoulders (anti-luxation edge).

Fig. 23

Fig. 24

Fig. 25

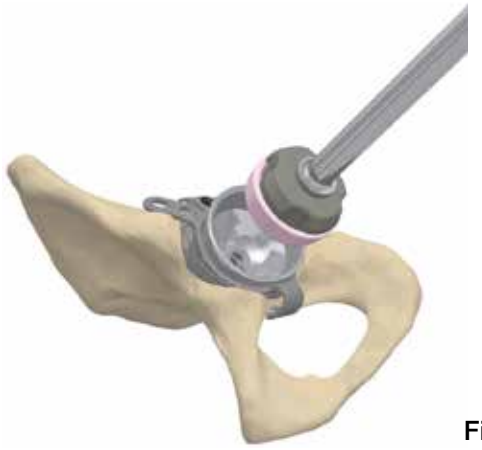


Fig. 26

Fig. 27

Implantation of ceramic inserts
A direct combination of metal casings and ceramic inserts without augments is not permitted.

Ceramic inserts must not be introduced directly into the metal casing. **An augment must be used.**
Before placing the insert, clean the inside of the augment carefully and check that surrounding soft tissue does not hinder hinder the procedure.
Implant the insert (Fig. 23) using the special insert positioner. The insert positioner consists of an elastic suction cup and a plastic handle. Choose the handle size appropriate for the size of the insert (small, medium, large).

Connect the positioner with the universal handle (Fig. 24) and mount the ceramic insert on the suction cup (Fig. 25). Then implant the insert (Fig. 26).

Note: Ceramic inserts are supplied with a polar pin. A polar locking screw is therefore not required. For further information on handling CombiCup inserts refer to the CombiCup surgical technique.

Check that the insert is correctly seated by feeling round the entire edge (Fig. 27). The edge of the insert must not protrude over the edge of the metal casing. The insert can otherwise become damaged.
If the insert jams in the oblique position, it must be removed, which can be carried out by lightly hitting the edge of the metal casing using the handle of a suitable instrument. The vibration causes the insert to spring out.

Caution! Do not reintroduce the removed ceramic insert 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 insert can be used. Use of a ceramic prosthesis head is strongly recommended.
It may be necessary to replace the femoral implant, so that a ceramic prosthesis head can be used. Then proceed as described.

X-ray Templates

REF	X-ray templates for CombiCup R
182-201/01	**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

For more information please register for our LINK Media Library (linkorthopaedics.com)

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

CombiCup R cups with Augments are indicated also in:

- revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure
- clinical management problem where arthrodesis or alternative reconstruction techniques are less likely to achieve satisfactory results
- where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum

The CombiCup system is intended for cementless use.

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

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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