LINK®

Vario-Cup 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.

Vario-Cup System

The Vario-Cup System

The Vario-Cup System consists of an UHMWPE component encased in an ultra-smooth polished EndoDur (CoCrMo) outer metal casing, for articulation in the bony acetabulum. It is to be used in conjunction with femoral components from the LINK Total Hip Systems.

The Vario-Cups are available in outer diameters ranging from 39 to 65 mm in 1 mm increments. Bipolar shells that are too small or too large lead to bone reactions due to inappropriate load transfer to the bony acetabulum. By choosing a component that fits correctly from the finely graduated range of prosthesis sizes, this complication can be avoided.

The Vario-Cups are available with inner diameters of 22, 28 and 32 mm. These are intended for use with LINK Prosthesis Heads with sizes of 22 mm, 28 mm and 32 mm respectively. (The outer diameters are 39 - 55 mm, 39 - 43 mm, 44 - 65 mm and 49 - 65 mm respectively.)

Vario-Cups are “self-centering” which provides for a functional view of their position in Post-op X-rays.

To prevent dislocation, an anti-luxation system has been developed. An UHMWPE Safety Ring is placed in a groove at the entrance of the polyethylene insert after assembly of Vario-Cup and femoral components.

CAUTION:
LINK prosthesis systems are manufactured to ensure precise intercompatibility so that appropriate components can be combined without incurring problems of function. They should not be used with hip components made by other manufacturers.

Features and Benefits:

- Main articulation between prosthesis head and polyethylene insert of Vario-Cup, reducing the movement between acetabulum and outer Vario-Cup surface
- Vario-Cup can be used in conjunction with femoral hip components of LINK Total Prosthesis Systems
- Vario-Cups are “self-centering”
- Can be combined with LINK Prosthesis Heads 22, 28 and 32 mm
- Surgeon has option to change intraoperatively to large head prosthesis
- Vario-Cup casings are made from EndoDur CoCrMo cast alloy

Preoperative Planning

Preoperative planning is conducive towards optimal surgical outcomes by ensuring the most appropriate implants are selected for the patient.
The key objectives involved are the correct positioning of the central rotational point of the hip, correct leg length and finally preservation or restoration of sufficient soft tissue tension by avoiding medialisation of the femur.

Achieving anatomically appropriate CCD or neck angle and head-neck length are of paramount importance. Hip stems with different CCD angles are offered by LINK as well as femoral heads with up to four head-neck lengths affording the surgeon great flexibility.

The choice of implant should ensure that the Vario-Cup, fills the acetabulum completely.

When these implants are used it is essential that there is no arthritis in the acetabulum and that no injuries are found during implantation.

Planning should ideally be based on two X-rays: an AP film of the pelvis and a mediolateral X-ray of the hip in question. When performing the pelvic X-ray it is important to ensure that:

1. Both femurs are shown in their entirety.

2. The femurs are straight and parallel and, if possible, internally rotated approximately 5° in that position.

3. Key landmarks needed for planning are visible: the inferior margins of the obturator foramen and of the acetabular teardrop.

When evaluating the X-rays, it is important to factor in any magnification incurred. Two factors are decisive (Fig.1):

1) Focal distance
Focal spot X-ray tube ⟷ x ⟷ Film cassette A focal distance of 100 cm gives magnification of about 10%.

2) Object film distance
Femoral axis ⟷ x ⟷ Film cassette

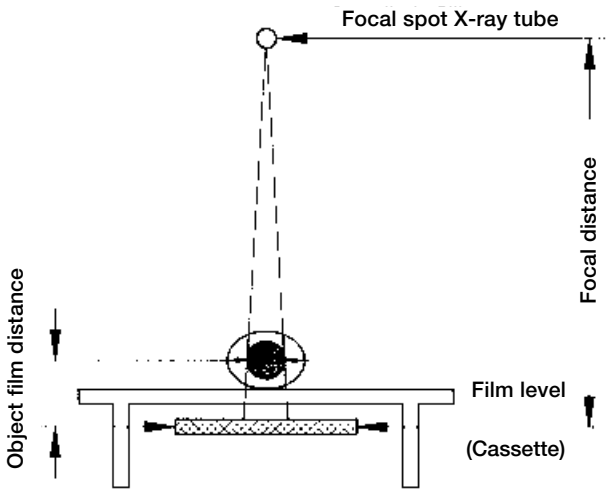


Fig. 1

Practical Steps

First, geometrical measurements are taken on the basis of the pelvic radiograph. This can be done on the X-ray directly (Fig. 2), but it is better to trace the skeletal contours onto tracing paper (Fig. 3).

A horizontal reference line is drawn along the inferior margins of the obturator foramen, followed by a vertical reference line along the sacral crest, ideally passing through the center of the pubic symphysis.

From these two lines, the center of rotation, difference in leg length, left/right femoral distance, distance between the left/right muscle T lever arms, etc. are defined and marked on the tracing paper.

This provides an overview and landmarks for orientation during surgery, e.g. transfer of dimensional reference to the bone. It must always be remembered that the measurements on the radiograph include a magnification effect that must be allowed for if the measurements are transferred to bone. If the magnification is 10%, measurements taken from the radiograph must be divided by 1.1. So, for example, 60 mm apparent ÷ 1.1 = 54.5 mm actual measurement. The same applies for other magnifications: e.g. at 15% magnification a 60 mm apparent measurement gives 60 mm ÷ 1.15 = 52.2 mm actual measurement.

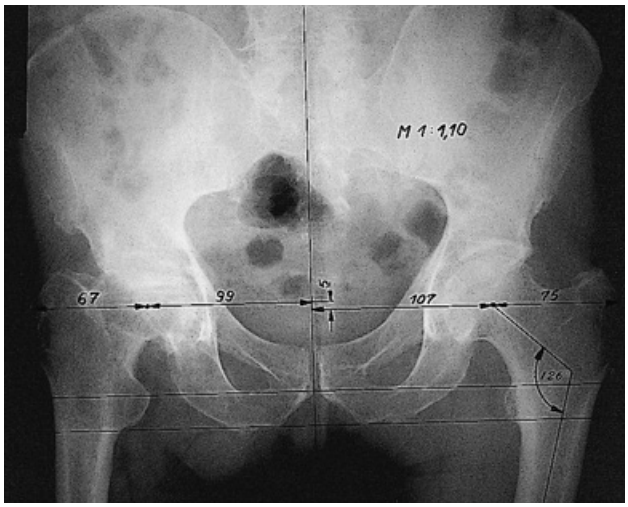


Fig. 2

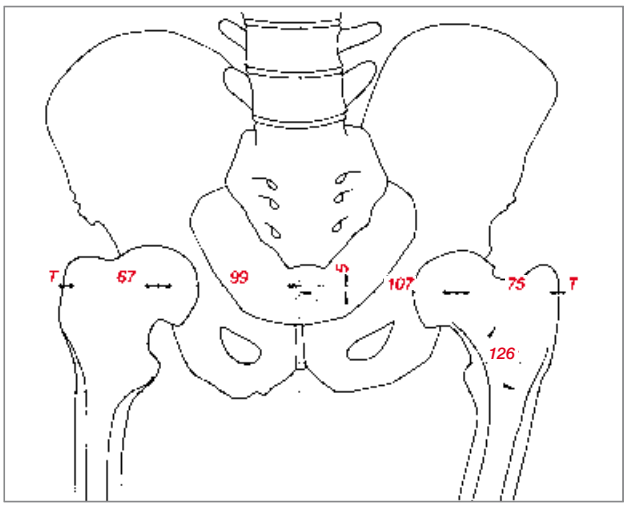


Fig. 3

Once the dimensions have been entered, the templates are used to select the best implant components for the particular case. The template is positioned on the radiograph such that the center of rotation coincides with the anatomical center of rotation as determined in the drawing.
The implant components selected should correct any anatomical insufficiencies derived from the measurements.

In addition to pelvic radiograph, the mediolateral radiograph is used to determine the stem shape and size of the femoral prosthesis as seen from the lateral view.

The planned result becomes clearer when the transparent sheet with the outlined skeletal contours, measurements, and sketched-in position of the acetabular cup is placed on top of the radiograph and adjusted so that the femur in the radiograph is in the desired outcome position in relation to the drawing of the pelvis. This position is then traced onto the tracing paper, preferably in a different color (Fig. 4).

The differences on the tracing paper, e.g. actual and planned positions of the femur, provide the visual overview required for surgical planning and precise selection of the implant components using the X-ray templates or, if necessary, for custom-design implants (Fig. 5).

Materials required:

1. Tracing paper
2. Transparent ruler, 1:1
3. Transparent protractor
4. Transparent radius/hole template
   Ø 24 to 58 mm, in 2 mm increments

INFORMATION:
Preoperative planning may be time-consuming but it provides intraoperative guidance and can enhance the final result.

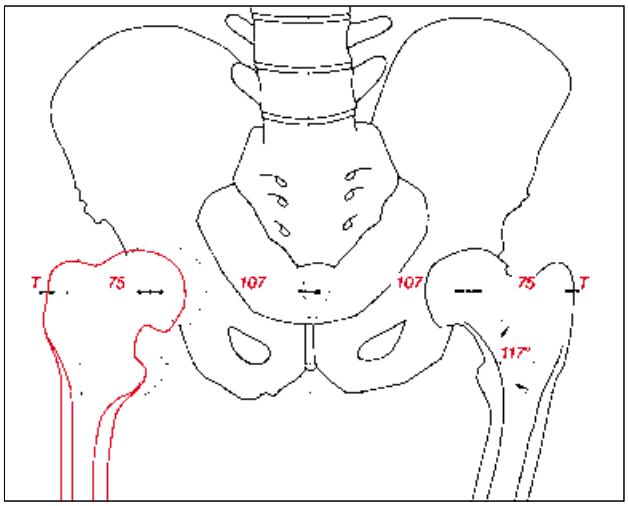


Fig. 4

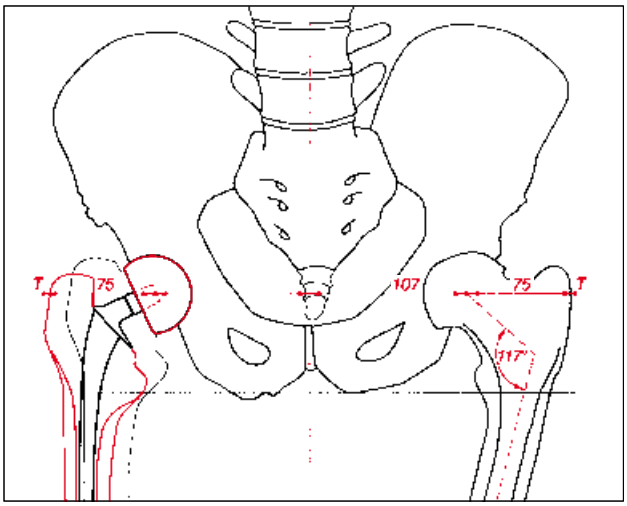


Fig. 5

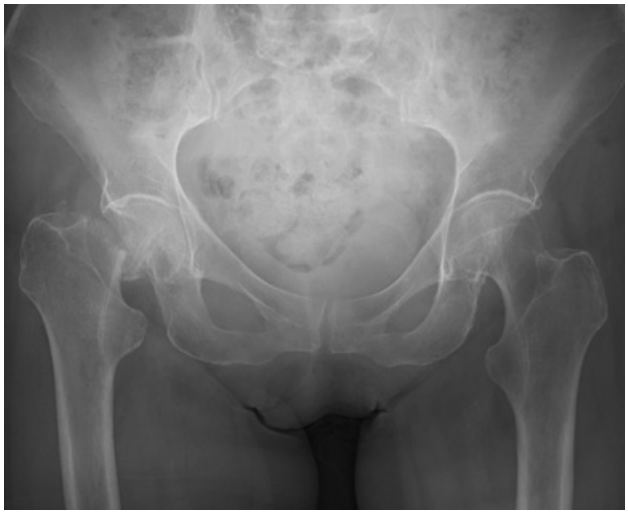


Fig. 6

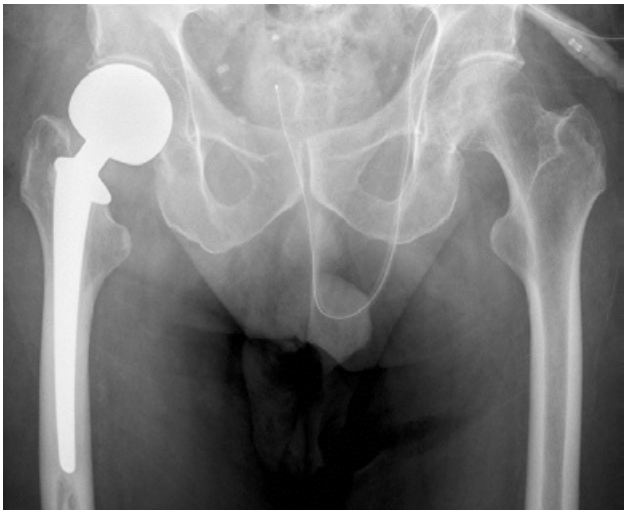


Fig. 7

Instructions for use of the Vario-Cup System

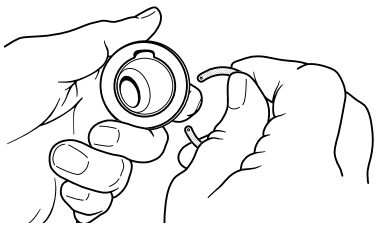


Fig. 8

Place the Vario-Cups onto the prosthesis head outside the patients body.

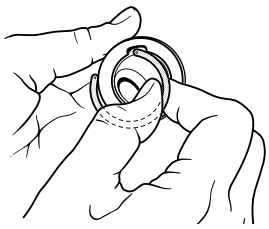


Fig. 9

Insert one end of the flexible Safety Ring into the groove just inside the entrance of the polyethylene insert.

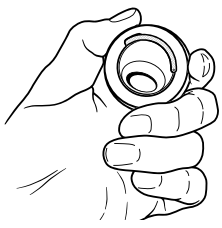


Fig. 10

Feed in the rest of the flexible Safety Ring so that it is completely seated in the groove.

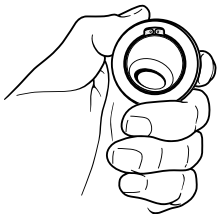


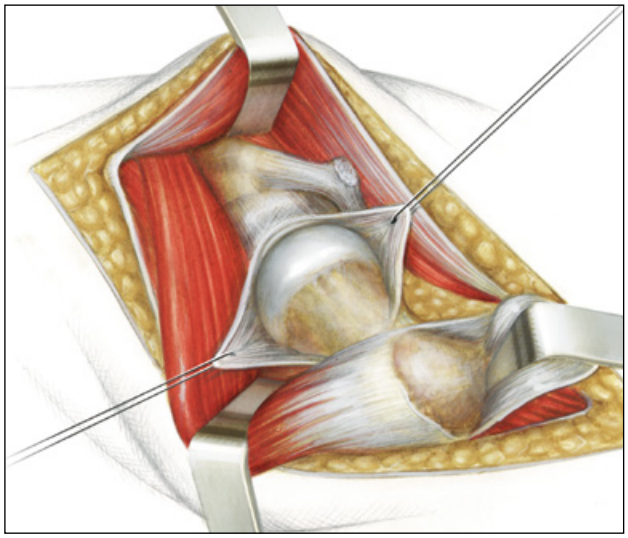
Fig. 11

Inserting the Safety Ring reduces the entrance diameter of the insert and thus prevents dislocation.

The Safety Ring can be removed easily with the help of an angled hook. If the holes in the ends of the ring are not visible, use the hook to rotate the ring in the socket until the holes appear in the recessed window. Then insert the hook in one of the holes and extract the ring.

Fig. 12

Surgical Approaches

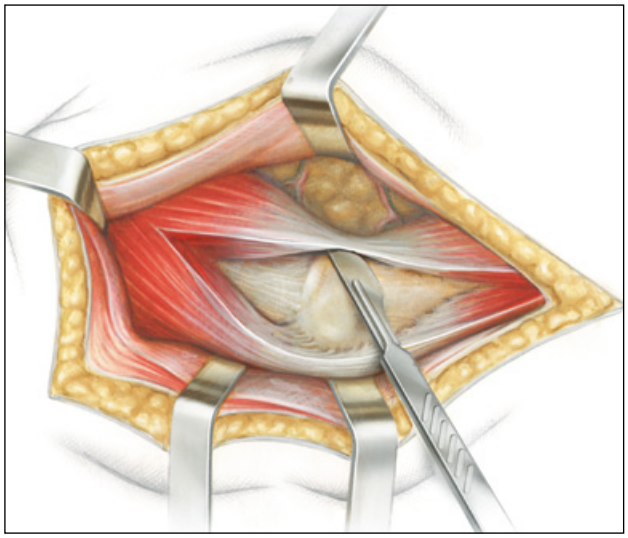


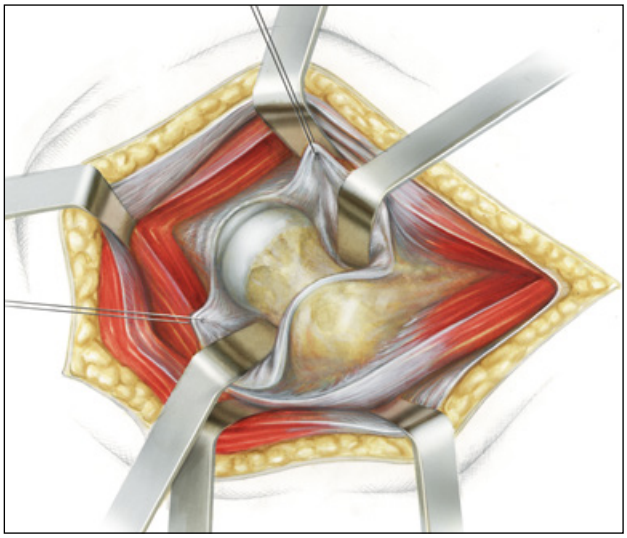
(A) **Watson Jones**

The Vario-Cup System can be implanted using any of the standard approaches depending on the surgeon's experience.*

The following approaches are usual:

- antero-lateral **– Watson Jones** (A)
- direct lateral **– Hardinge** (B)



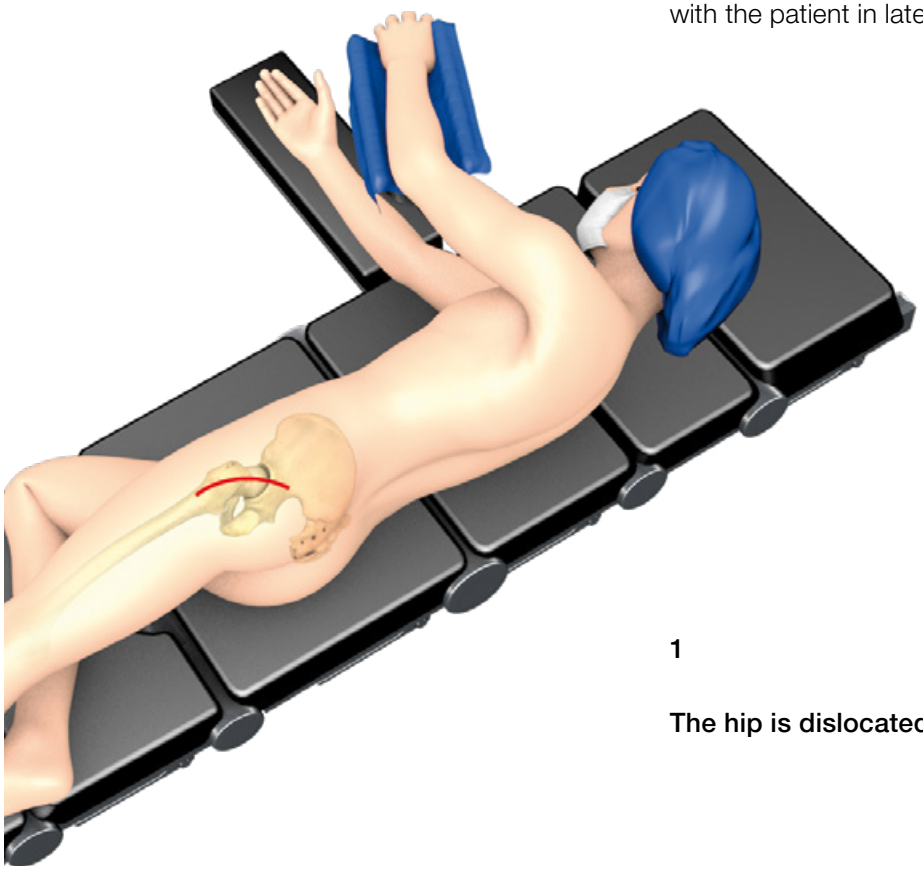


(B) **Hardinge**

* Postero-lateral approach is associated with an increased dislocation risk in hemi-arthroplasty. (Fullam et al., 2019)

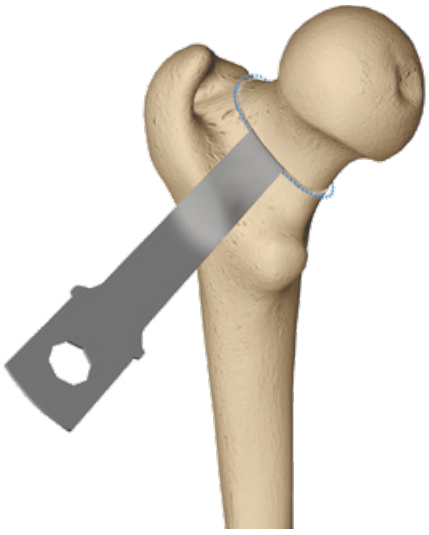
Surgical Technique

The following pictures show a posterior approach with the patient in lateral position.



1

The hip is dislocated the usual way.



2

Resection of femoral head

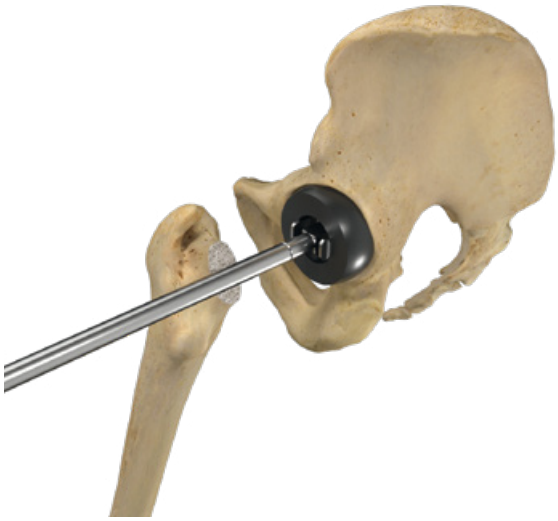
Resection of the femoral head according to the LINK femoral stem system.

3

Implantation

Exposure of the acetabulum after femoral head resection.

> **INFORMATION:**
> **Surgical techniques for the different prosthesis stems are described in detail in separate catalogs for each individual system (see p. 15, Additional Prosthesis Systems)**



4

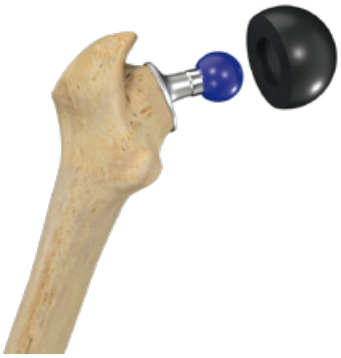
Determination of implant size

The Trial Cup is attached to the handle and inserted into the acetabulum to determine the size of the implant.

5

Trial reduction

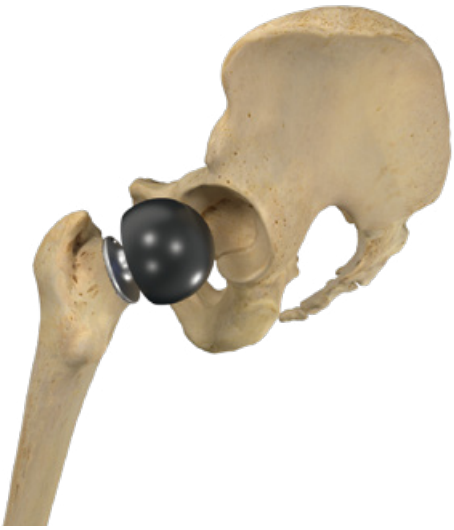
It is possible to do a trial reduction of the hip with the Trial Cup. This can either be done with the Femoral Rasp and trial neck or the final implant. For this the Trial Cup is removed out of the acetabular cup.



The Trial Head Ø 28 mm with the required neck length is attached to the neck of the stem.

After the Trial Cup is positioned on the Trial Head the joint is reduced.

CAUTION:
Please notice that the Vario-Cups with Ø 39 to 43 mm are only compatible with Ø 22 mm prosthesis heads!
The trial cups for the trial reduction are only compatible with Ø 28 mm trial heads. The trial reduction is used to check the stability of the joint and determine the neck length. Therefore the trial head diameter is not decisive!



After reduction of the joint, the leg length, joint stability and range of motion are checked.

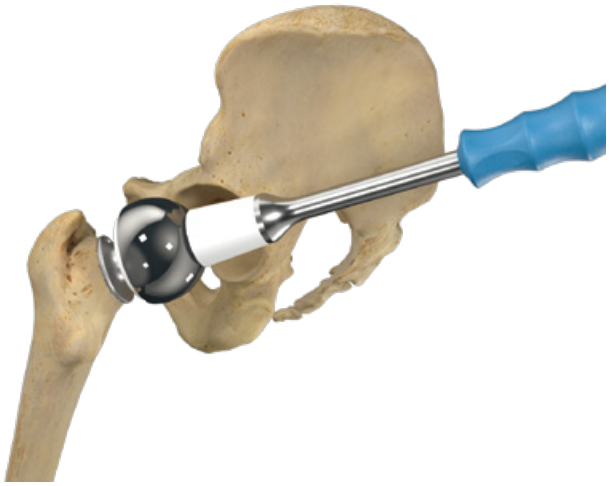
CAUTION:
The trial reduction is not as stable as the reduction with the final implant, due to the measurements of the inner diameter of the Trial Cup.

The Trial Head and Cup are removed.

6

Preparation of the Implant

The Vario-Cup and the Prosthesis Head are assembled outside the patient. For this follow the description on page 06.



7

Positioning of the Prosthesis Head together with the Vario-Cup

Place the construction of the femoral head and the Vario-Cup on the carefully cleaned taper of the stem and fix it with a light tap on the Head Impactor (e.g. 175-360). Thereafter the final reduction is performed.

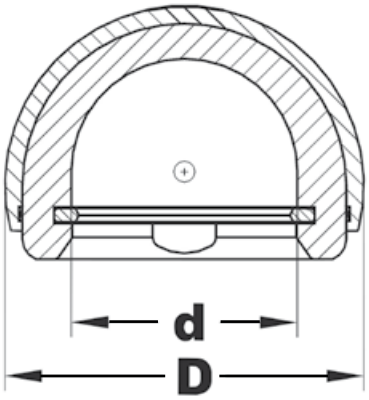
8

The Vario-Cup System in situ.

Permanent implant components in situ.
The wound is closed in layers.

Vario-Cups, self-centering

MAT
EndoDur (CoCrMo alloy)
and UHMWPE

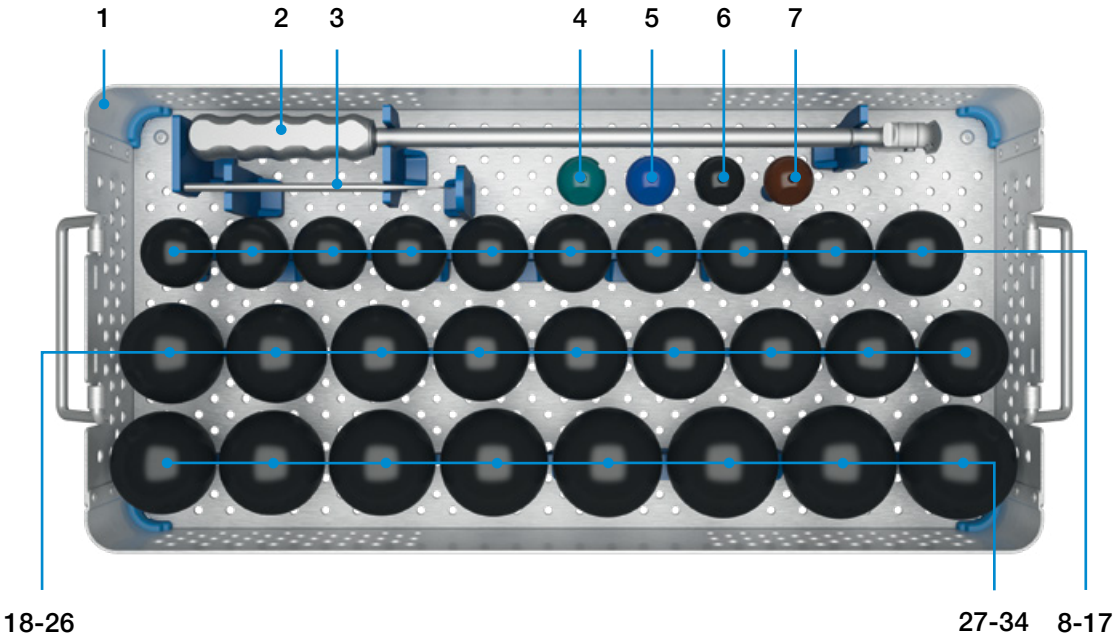


Inner Ø (d)			Outer Ø (D)
22 mm	28 mm	32 mm	mm
REF	REF	REF	
99-0055/39			39
99-0055/40			40
99-0055/41			41
99-0055/42			42
99-0055/43			43
99-0055/44	107-220/44		44
99-0055/45	107-220/45		45
99-0055/46	107-220/46		46
99-0055/47	107-220/47		47
99-0055/48	107-220/48		48
99-0055/49	107-220/49	107-230/49	49
99-0055/50	107-220/50	107-230/50	50
99-0055/51	107-220/51	107-230/51	51
99-0055/52	107-220/52	107-230/52	52
99-0055/53	107-220/53	107-230/53	53
99-0055/54	107-220/54	107-230/54	54
99-0055/55	107-220/55	107-230/55	55
	107-220/56	107-230/56	56
	107-220/57	107-230/57	57
	107-220/58	107-230/58	58
	107-220/59	107-230/59	59
	107-220/60	107-230/60	60
	107-220/61	107-230/61	61
	107-220/62	107-230/62	62
	107-220/63	107-230/63	63
	107-220/64	107-230/64	64
	107-220/65	107-230/65	65

Safety Ring for Vario-Cups
MAT UHMWPE, height 2 mm

REF	Head Ø mm
107-200/22	22
107-200/28	28
107-200/32	32

130-799/16 Instrument Set for Vario-Cup System



1	130-799/15	**Instrument Tray,** empty			
2	130-820/01	**Handle for Cup Trial,** Inner-Ø 28 mm			
3	130-819	**Hook for applying or removing Safety Ring,** 145 mm			
4	132-928/01	**Plastic Trial Head,** PPH, green, Ø 28 mm, Taper 12/14 mm, Neck L = S / -3,5 mm			
5	132-928/02	**Plastic Trial Head,** PPH, blue, Ø 28 mm, Taper 12/14 mm, Neck L = M / 0 mm			
6	132-928/03	**Plastic Trial Head,** PPH, black, Ø 28 mm, Taper 12/14 mm, Neck L = L / +3,5 mm			
7	132-928/04*	**Plastic Trial Head,** PPH, brown, Ø 28 mm, Taper 12/14 mm, Neck L = XL / +10,5 mm			
		Trial Cups for Vario-Cup System, Inner-Ø 28 mm			
8	99-0220/39	Outer-Ø 39 mm	22	99-0220/53	Outer-Ø 53 mm
9	99-0220/40	Outer-Ø 40 mm	23	99-0220/54	Outer-Ø 54 mm
10	99-0220/41	Outer-Ø 41 mm	24	99-0220/55	Outer-Ø 55 mm
11	99-0220/42	Outer-Ø 42 mm	25	99-0220/56	Outer-Ø 56 mm
12	99-0220/43	Outer-Ø 43 mm	26	99-0220/57	Outer-Ø 57 mm
13	99-0220/44	Outer-Ø 44 mm	27	99-0220/58	Outer-Ø 58 mm
14	99-0220/45	Outer-Ø 45 mm	28	99-0220/59	Outer-Ø 59 mm
15	99-0220/46	Outer-Ø 46 mm	29	99-0220/60	Outer-Ø 60 mm
16	99-0220/47	Outer-Ø 47 mm	30	99-0220/61	Outer-Ø 61 mm
17	99-0220/48	Outer-Ø 48 mm	31	99-0220/62	Outer-Ø 62 mm
18	99-0220/49	Outer-Ø 49 mm	32	99-0220/63	Outer-Ø 63 mm
19	99-0220/50	Outer-Ø 50 mm	33	99-0220/64	Outer-Ø 64 mm
20	99-0220/51	Outer-Ø 51 mm	34	99-0220/65	Outer-Ø 65 mm
21	99-0220/52	Outer-Ø 52 mm			

* On request
** Please notice that the final implants are only compatible with Ø 22 mm prosthesis heads!

Accessories

X-ray Templates for Vario-Cup System
110% actual size, set of 4 sheets

REF	X-ray templates
130-915/02	**Vario-Cups**

Instructions for Cleaning and Maintenance

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

Literature

- Frisch, W., Kaiser, N.
  Die Vario-Kopf Prothese. Erfahrungsbericht über die Versorgung medialer Schenkelhalsfrakturen beim alten Menschen mit dem alleinigen Hüftkopfersatz.; Chir. Praxis 42.85-91 (1990)

- Fullam, J., Theodosi, P.G., Charity, J. et al.
  A scoping review comparing two common surgical approaches to the hip for hemiarthroplasty. BMC Surg 19, 32 (2019).

- Niebuhr, H., Nahrstedt, U., Brüning, M., Rückert, K.
  Die Vario-Kopf Endoprothese in der Behandlung der Schenkelhals- und schenkelhalsnahen Fraktur. Unfallchirurgie, Sonderdruck 17:146-151 (1991)

- Leonardsson Q, Garellick G, Karrholm J, Akesson K, Rogmark C.
  Changes in implant choice and surgical technique for hemiarthroplasty. 21,346 procedures from the Swedish Hip Arthroplasty Register 2005-2009.; Acta Orthop. 2012;83(1): 7-13

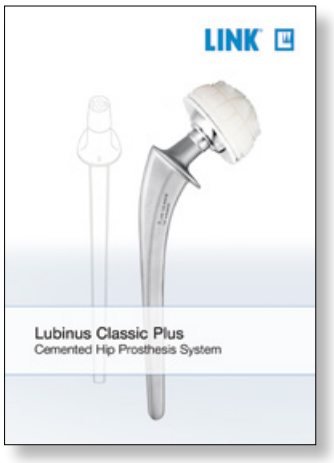
- Leonardsson O, Karrholm J, Akesson K, Garellick G, Rogmark C.
  Higher risk of reoperation for bipolar and uncemented hemiarthroplasty.; Acta Orthop. 2012;83(5): 459-66

- Kanto K, Sihvonen R, Eskelinen A, Laitinen M.
  Uni- and bipolar hemiarthroplasty with a modern cemented femoral component provides elderly patients with displaced femoral neck fractures with equal functional outcome and survivorship at medium-term follow-up. Arch Orthop Trauma Surg. 2014; 134(9): 1251-9

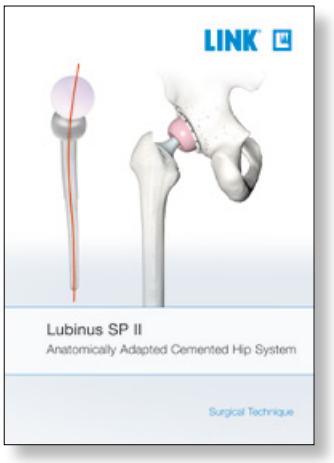
- Swedish Hip Arthroplasty Register, Annual Report 2017; www.shpr.se

Additional Prosthesis Systems

The **Vario-Cup System** can be combined with other LINK Hip Prosthesis Systems:



LINK Lubinus Classic Plus



LINK Lubinus SP II

LINK Ribbed System
(not illustrated)

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

Vario-Cup System
General Indications
Mobility-limiting diseases, fractures or defects of the hip joint or proximal femur which cannot be treated by conservative or osteosynthetic procedures
Indications
Femoral neck fractures
Revision surgeries
Contraindications
Acute and chronic infections, local and systemic insofar as they compromise the successful hemi-arthroplasty (preoperative microbiological analysis recommended)
Allergies to (implant) materials
Insufficient / inadequate bone mass- or quality, which prevents a stable anchorage of the prosthesis
Acetabular injuries (e.g. fractures)
Acetabular arthritis

INFORMATION:
These indications/contraindications refer to standard cases. The ultimate decision on whether or not an implant is suitable for a patient must be made by the surgeon based on his/her individual analysis and his/her experience.

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!

Waldemar Link GmbH & Co. KG, Hamburg

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