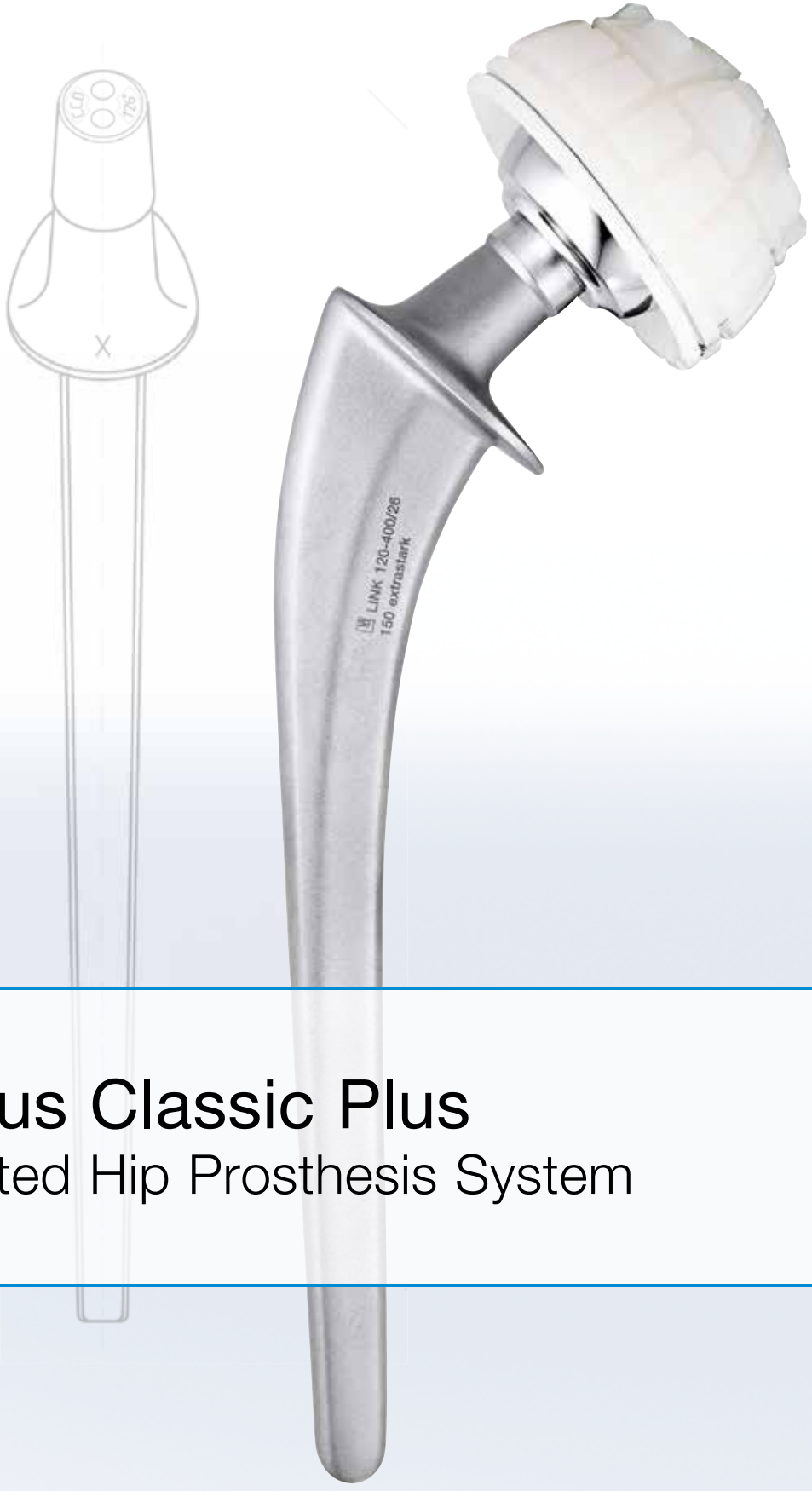
LINK®



Lubinus Classic Plus

Cemented Hip Prosthesis System

CE 0482

Explanation of Pictograms			
	Manufacturer	REF	Item number
MAT	Material number	CE	Product fullfills the esseitial requirements of the Medical Device Directive 93/42/EEC

Lubinus Classic Plus
Cemented Hip Prosthesis System

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. The Lubinus Classic Plus System offers one CCD angle 126° and femoral heads with up to four head-neck lengths affording the surgeon great flexibility.

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.

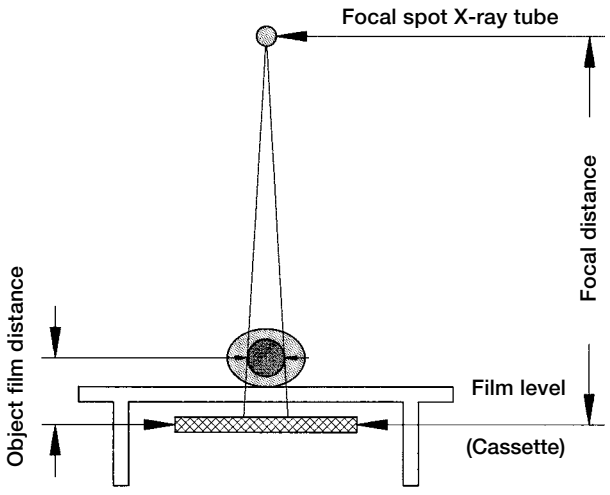
2. The femurs are straight and parallel and, if possible, internally rotated approximately 5° in that position.

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:

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



1

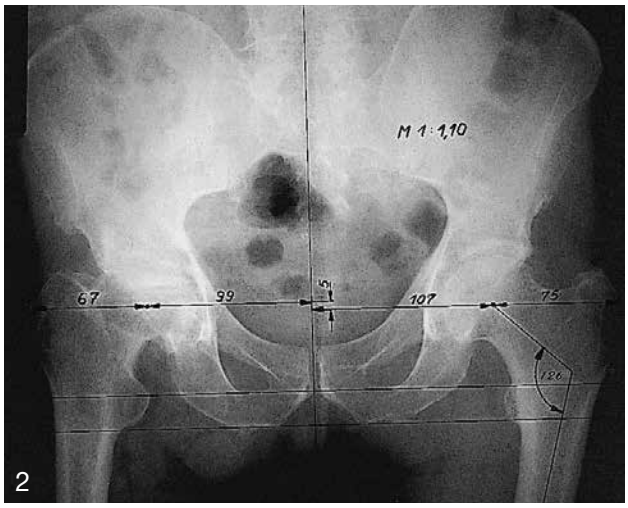
Practical Steps

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.



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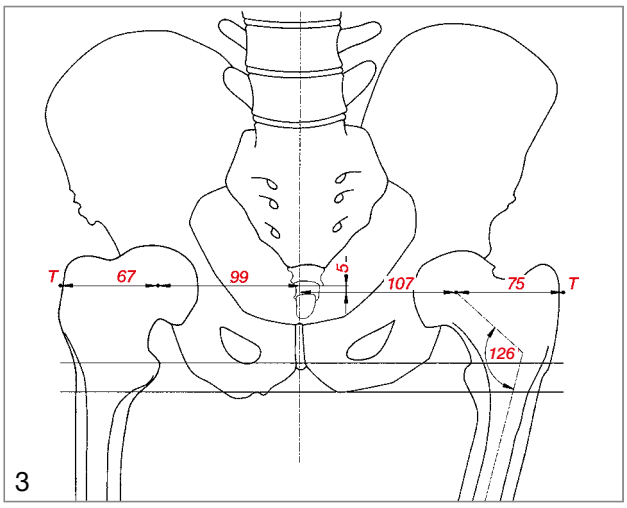


3

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.

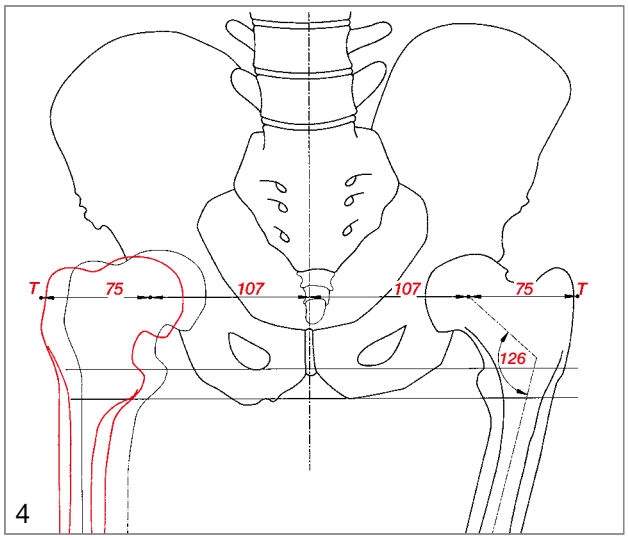
The planned result becomes clearer when the transparent sheet with the outlined skeletal contours, measurements, and sketched-in position of the acetabular cup is placed on top of the radiograph and adjusted so that the femur in the radiograph is in the desired outcome position in relation to the drawing 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

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



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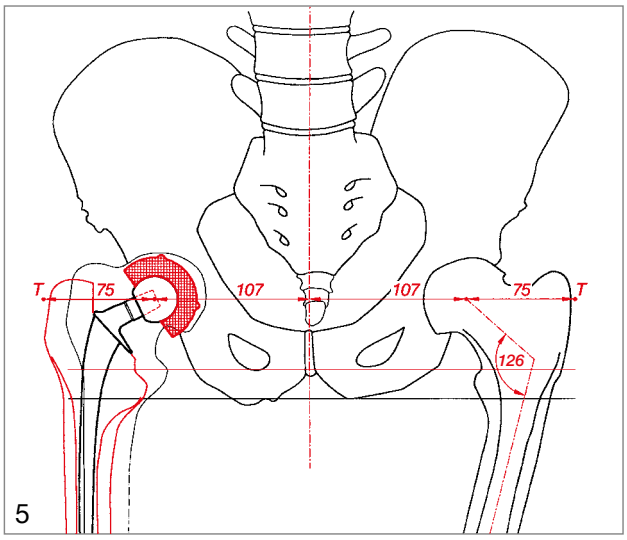

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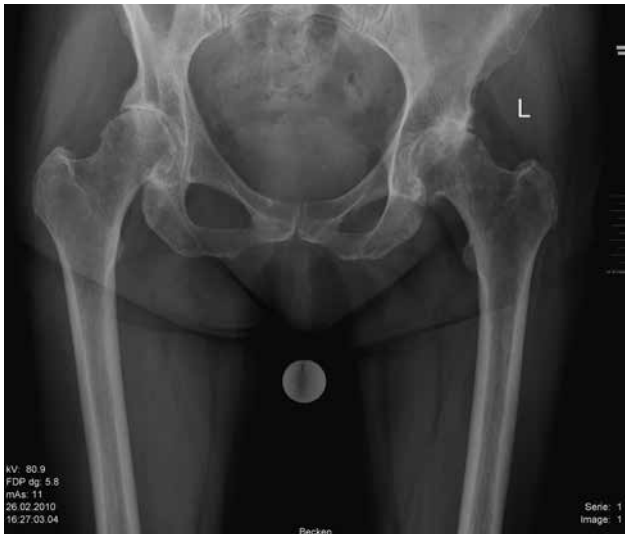
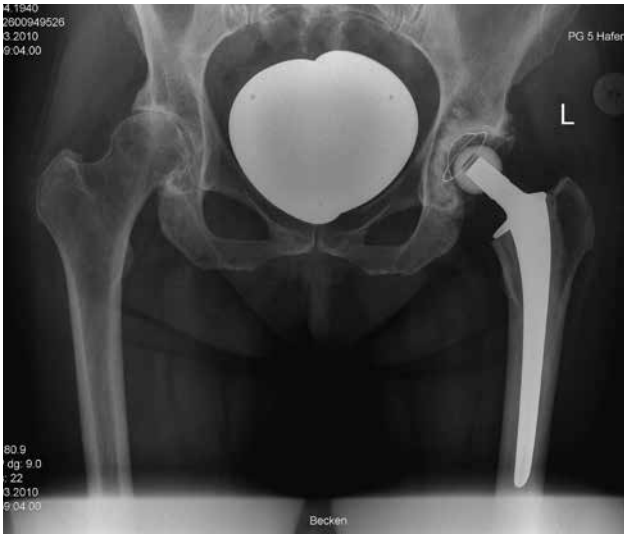
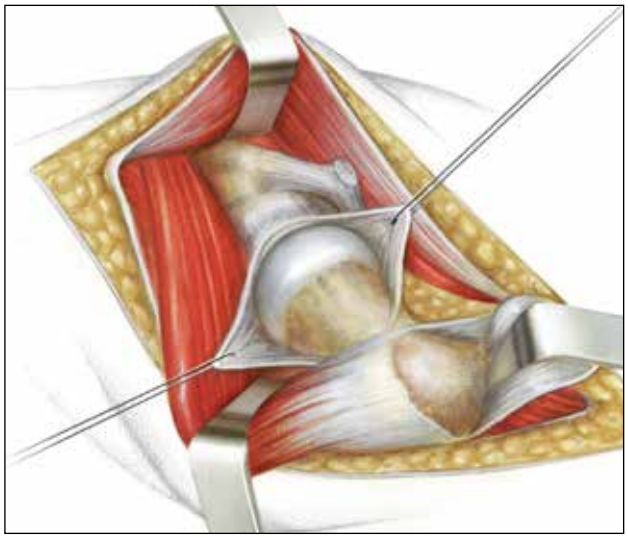




Surgical Approaches

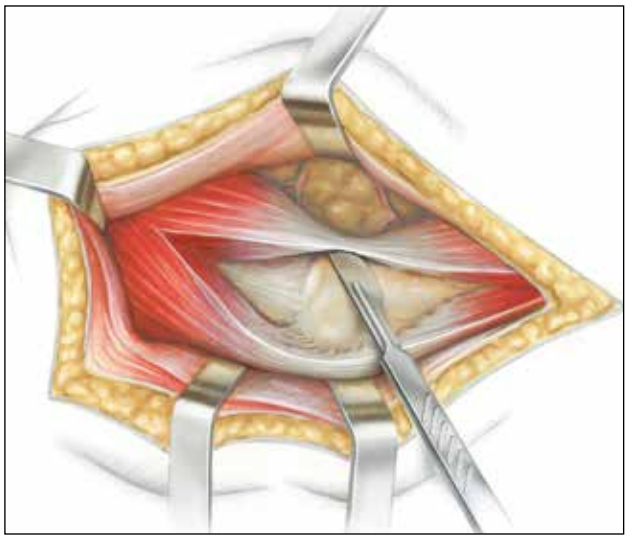


(A) **Watson Jones**

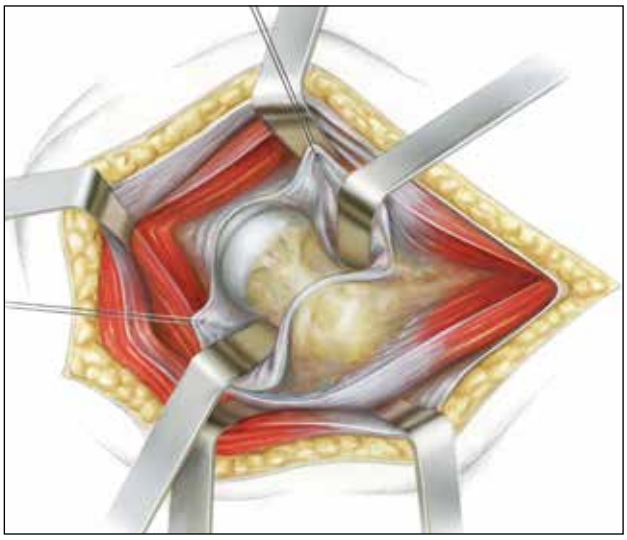
The choice depends on the surgeon's experience and his/her decision based on the individual situation.

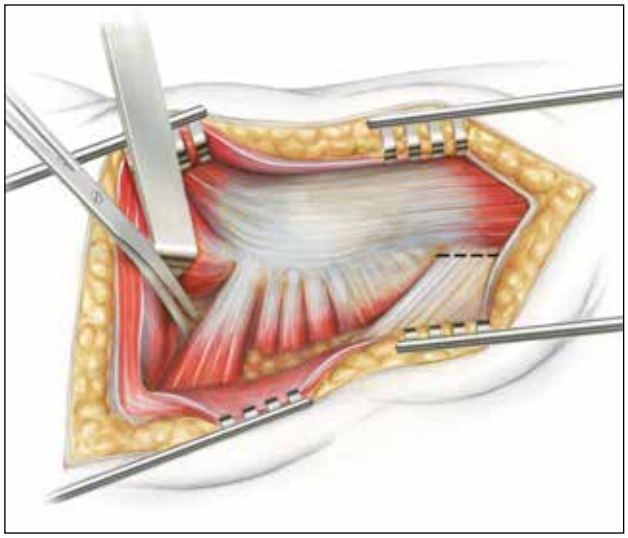
The following approaches are usual:

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

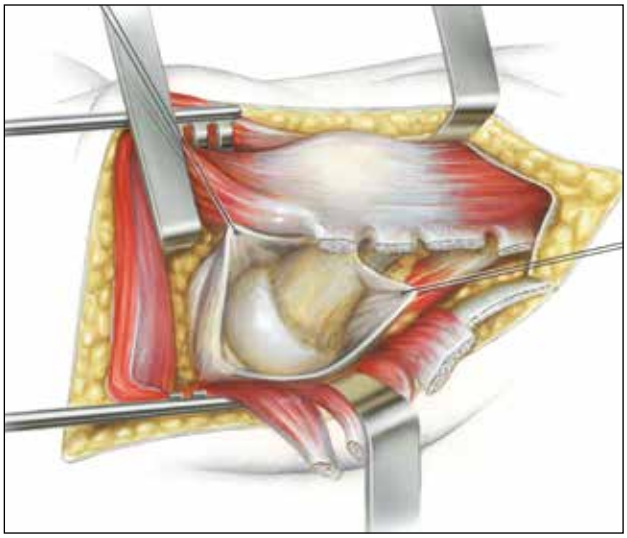


(B) **Hardinge**





(C) **Moore**



Surgical Technique

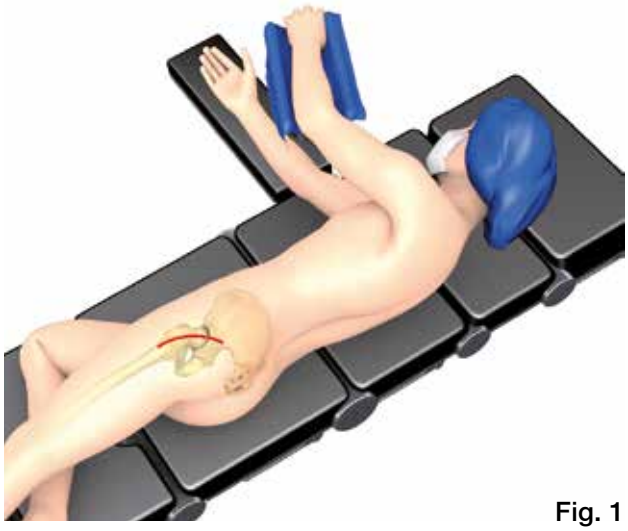


Fig. 1

Patient positioning

Note:
Fig. 1 shows the usual position for posterolateral surgical approach.

The surgeon is free to choose the surgical approach on the basis of his/her experience and judgment, and according to the specific situation.

The following illustrations show the visualization with a posterior approach and with the patient in the lateral position.

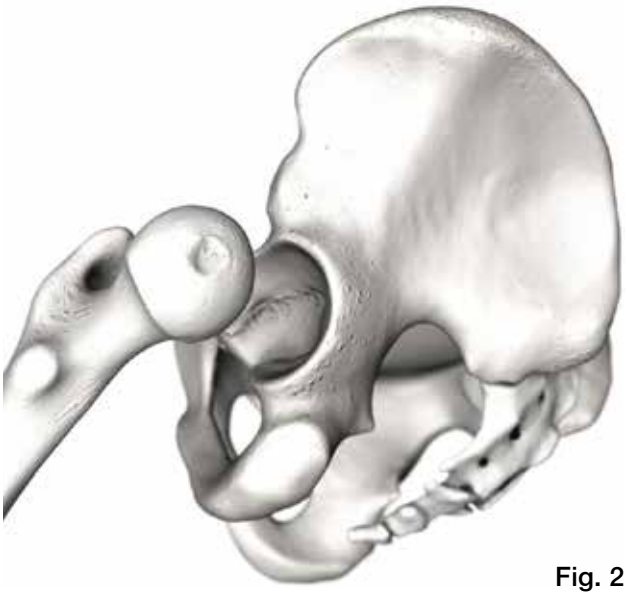


Fig. 2

Introduction/Basic principle

The hip is dislocated in the usual way (Fig. 2) and the femoral neck is osteotomized. This is usually done at a 45° angle. An osteotomy gauge can be used.

Tip: It is advisable to initially resect up to 2 mm less than preoperatively planned in order to correct the resection, if necessary, with better visualization after removal of the femoral head.

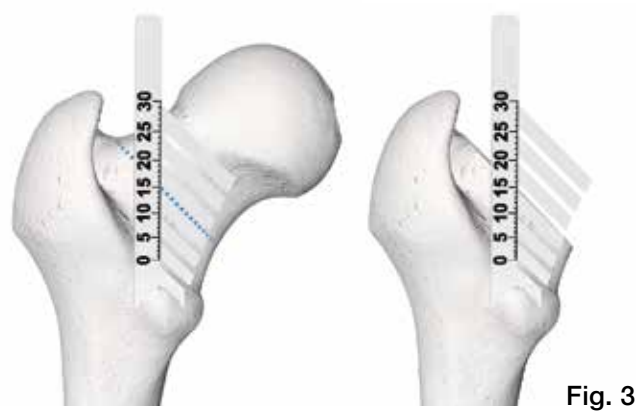


Fig. 3

Osteotomy of the femoral neck

For orientation, the osteotomy gauge can be placed on the lesser trochanter and aligned parallel to the longitudinal axis of the femur (Fig. 3). The osteotomy can now be performed in the slot on the gauge that corresponds to the preoperatively planned level. Both the level and the inclination of the osteotomy are given by the gauge. It must be ensured that the osteotomy is performed at 90° to the axis of the femoral neck, also in a-p orientation.

Fig. 4

In certain cases, a second vertical resection may be required (Fig. 4). The correct orientation of the resection plane can also be checked by means of a rasp. As a general rule, the acetabulum is prepared first, prior to preparation of the femoral neck.

Fig. 5

Opening the medullary canal

The medullary canal is opened with a gauge (Fig. 5). This is done as laterally as possible in order to avoid varus positioning of the stem.
Furthermore, this facilitates introduction of the rasp, and also reduces the risk of femoral shaft fracture when the prosthesis is driven in.

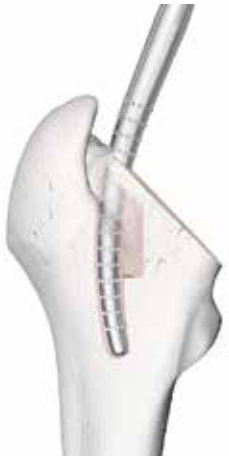


Fig. 6

The opening rasp can be used additionally to prepare the cancellous bone in the lateral area of the great trochanter in order to prevent varus positioning of the rasp and the implant (Fig. 6).

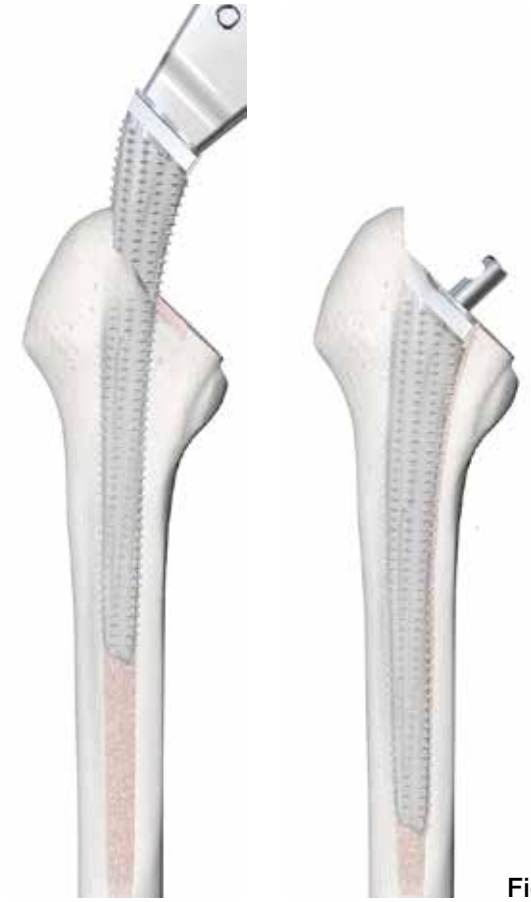


Fig. 7

Clamping in the handle

To insert the rasp, open the lever of the handle and insert the compressor with its medial side pointing toward the lever. Then the lever is closed again to fix the rasp.

Preparation of the medullary canal

Once the medullary canal has been opened, preparation begins using the smallest rasp the axial orientation into consideration.
The intended anteverison has to be taken into account already when the smallest rasp is inserted (as a rule, 15°). When inserting the rasp, the surgeon must ensure correct axial alignment.
With increasing sizes of the rasps, the femoral canal is prepared until maximum stability with the largest possible diameter is achieved. The process is complete as soon as the rasp is positioned centrally in the femoral canal, rotationally stable and axially aligned. The handle is then removed and the rasp is left in situ (Fig. 7).

The rasp stems are approximately the same size as the prosthesis.
In order to create a cement coating with an approx. 2-3 mm wall thickness, the next smallest prosthesis stem must be used (e.g. last rasp stem large = prosthesis stem medium)

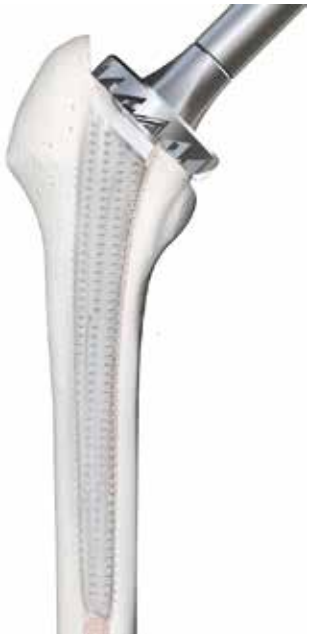


Fig. 8

Final Reaming of Resection Area

A Calcar Reamer is used for final precise reaming of the resected end of the femur, guided by the rasp neck.

Creation of Flat Surface

The Calcar Reamer is now used to create a flat surface on the proximal femur at the correct angle for the collar (Fig. 8).

Attention:
To prevent the Reamer from being damaged it must always be pushed as far as possible onto the neck of the Rasp before starting to ream.

Fig. 9

Trial Reduction

Usually, the acetabular cup is implanted before the stem component so that trial reduction can now be done.

Fig. 10

The trial reduction is done with the final rasp left in situ. The handle is removed for this purpose, and the trial neck segment previously determined in the preoperative planning (right/ left, CCD angle) is attached. Various trial heads are used to check for optimal offset, correct leg length and adequate stability. The range of movement is also checked in order to exclude any impingement of bone or implant with the acetabular cup, and to prevent any instability (Fig. 9-10).

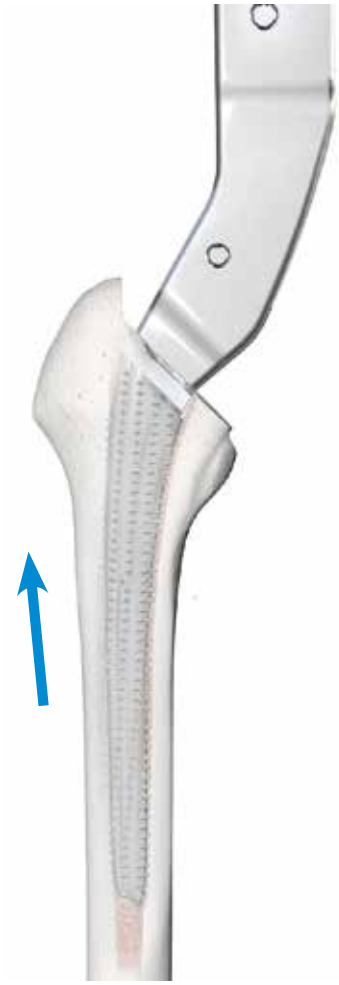


Fig. 11

Removal of the trial components and rasp

Finally, the trial head and neck segment are removed. The compressor is removed from the femoral canal using the rasp handle (Fig.11).

Fig. 12

Fig. 13

Cementing technique

After removing the rasp, the femoral canal is rinsed thoroughly. Jet lavage is recommended for this purpose.
The femoral canal is then sealed distal to the planned prosthesis tip by means of a cement restrictor.

The cement is mixed under vacuum and then inserted into the femoral canal using an applicator syringe with nozzle. Application begins distally. The canal is filled with cement retrogradely and uniformly by slowly pulling out the nozzle while the cement is being applied (Fig. 12-13).
Then the cement is compressed in the femoral canal for approx. 30 seconds, for which a cement compressor should be used.

Tip: Before filling the femoral canal, check the viscosity of the cement by touching the cement on the tip of the applicator syringe with your finger, while wearing clean gloves. When the cement adheres well to the glove and draws out long, heavy threads, this is the best time to apply the cement.

Fig. 14

Placing the final stem

The prosthesis stem to be used (size, CCD angle) was determined by means of the trial reduction performed previously. The corresponding implant is now removed from the sterile packaging and introduced into the medullary canal as far as possible, either manually or with the inserting forceps. This must be done with care so as to avoid damage to the implant bed (Fig. 14).

Fig. 15

Final positioning of the stem

The impactor is used to press the stem manually into its final position. While the cement is setting, the prosthesis stem is pressed firmly into the cement bed. In this phase, the rounded tip of the impactor is located movably in the hemispherical recess on the lateral collar of the prosthesis so that movements by the surgeon cannot be transmitted to the stem (Fig. 15).

Fig. 16

Final trial reduction with Trial Head

Another trial reduction can then be performed by placing the selected trial head onto the implant. Finally, the trial head is removed again (Fig. 16).

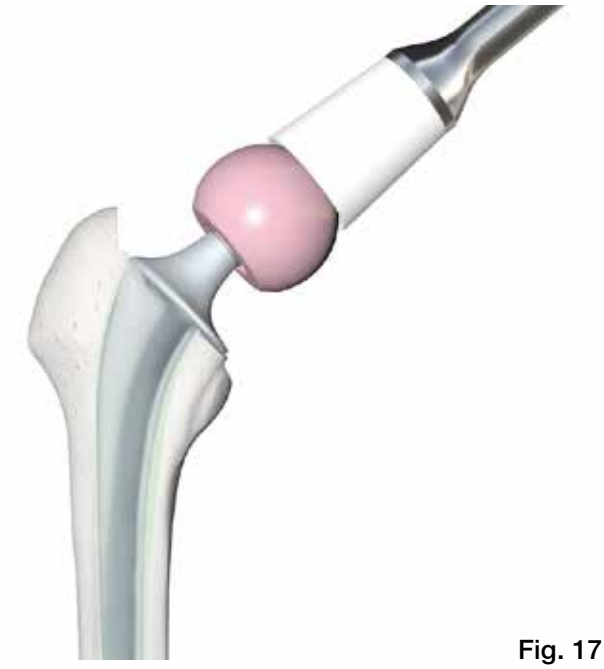


Fig. 17

Attaching the prosthesis head

The taper of the stem is carefully cleaned and dried. This is particularly important with ceramic heads. Then the head is attached by hand with a rotational movement, applying axial pressure. To finish, the acetabular head driver is used to gently tap the prosthesis head into position (Fig. 17).

Attention:
To prevent damage to the surface of the Prosthesis Head the plastic impact surface of the driver has to be clean and undamaged. If this part of the driver becomes damaged it must be replaced before the driver can be used again.

Fig. 18

Lubinus Classic Plus Hip Prosthesis Stem in situ

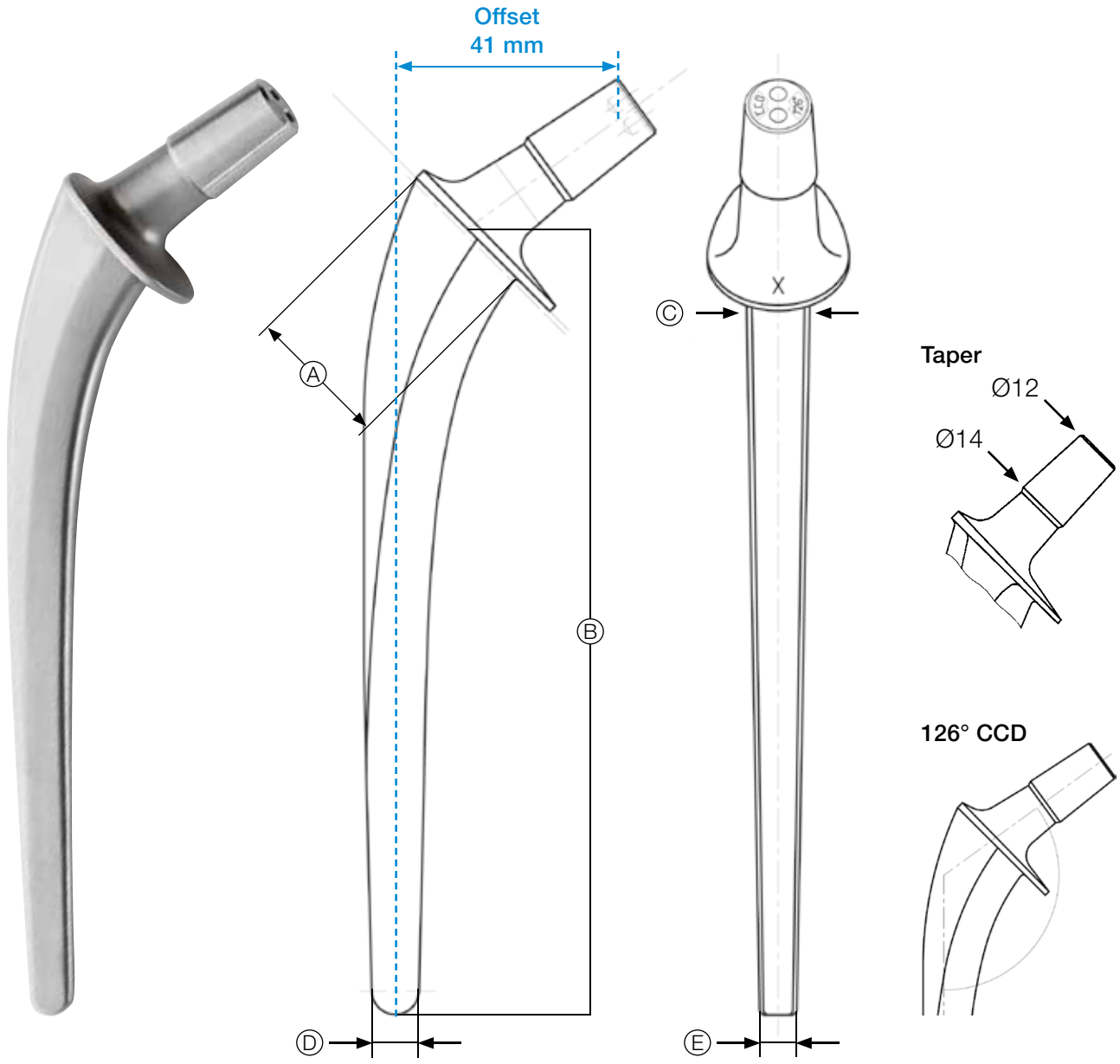
After cleaning the joint surfaces, the joint is reduced (Fig. 18).

Lubinus Classic Plus Hip Prosthesis Stems

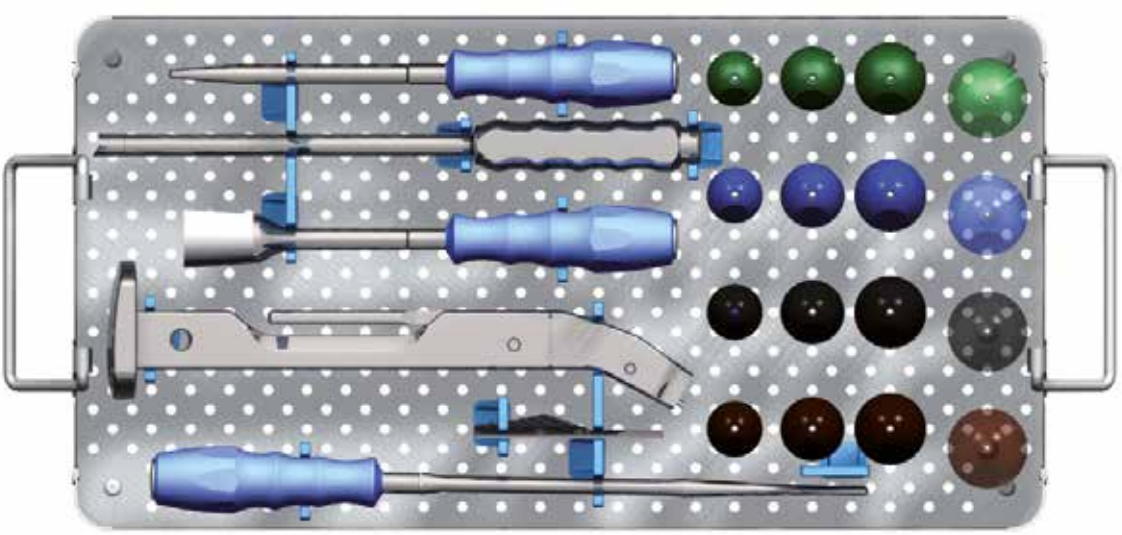
MAT: EndoDur

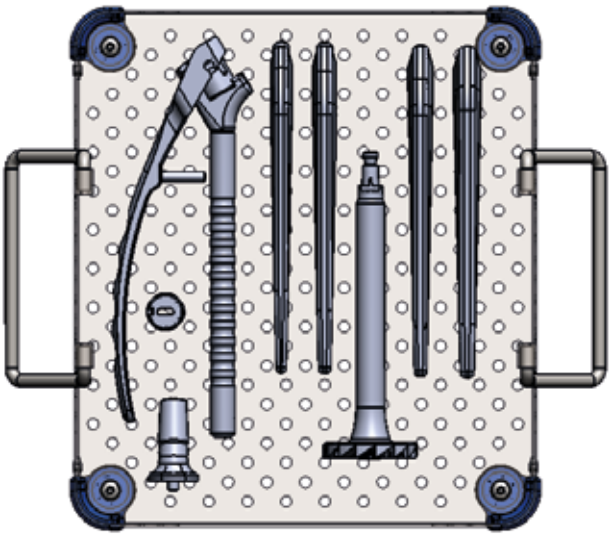
REF	Stem width	Ⓐ	Ⓑ	Ⓒ	Ⓓ	Ⓔ
120-415/26	narrow	23.0	150.0	10.5	7.0	5.0
120-410/26	medium	25.0	150.0	11.5	8.0	6.0
120-405/26	large	27.0	150.0	12.5	9.0	7.0
120-400/26	x-large	30.0	150.0	13.5	10.0	8.0

All dimensions in mm



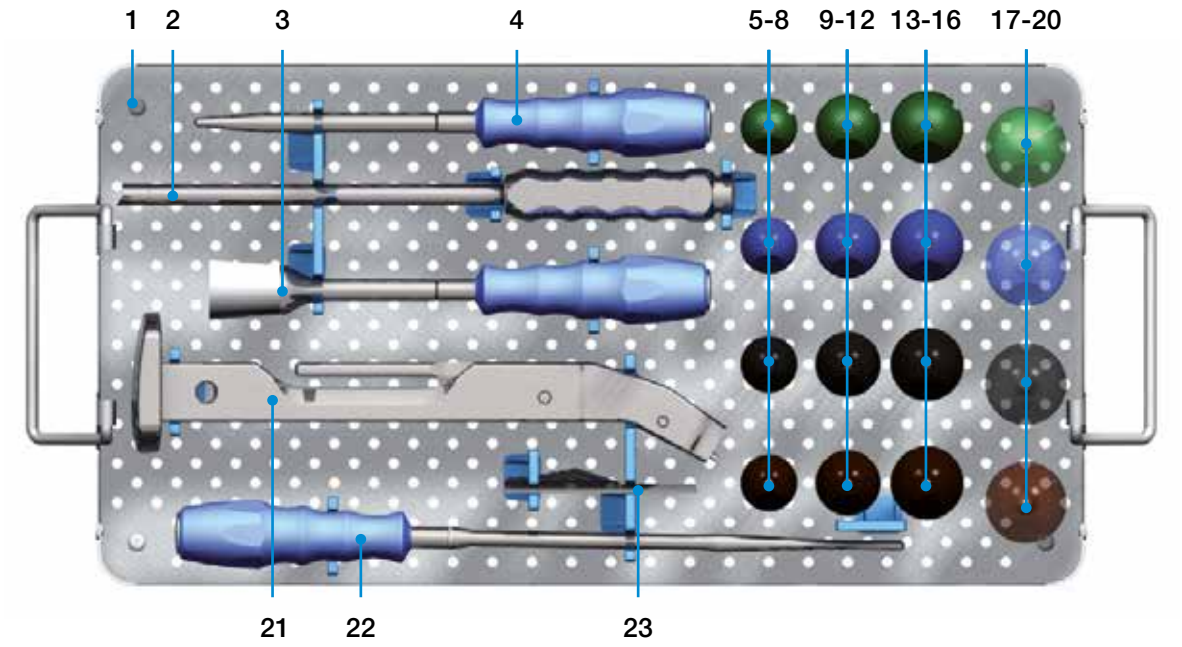
Instrument Set for Lubinus Classic Plus Hip Prosthesis Stems





REF	Instrument Set for Lubinus Classic Plus Hip Prosthesis Stems
175-110/00	**Basic Instruments,** complete
131-801/61	**Instrument Set Rasps,** complete

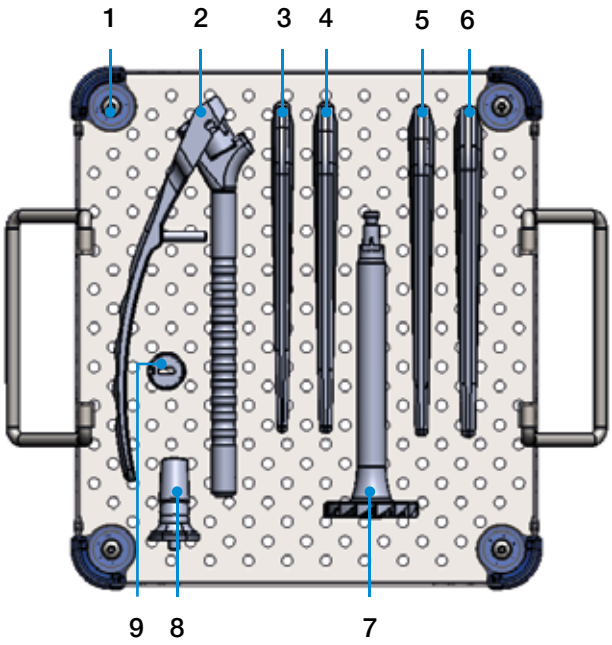
175-110/00 **Basic Instruments**, complete



1	175-111/00	**Tray,** empty
2	175-380	**Gouge**
3	175-360	**Impactor for Prosthesis Heads** with exchangeable plastic head, 280 mm
4	130-622	**Impactor**
5	175-928/11	**Plastic Trial Head 28 S**
6	175-928/12	**Plastic Trial Head 28 M**
7	175-928/13	**Plastic Trial Head 28 L**
8	175-928/14	**Plastic Trial Head 28 XL**
9	175-932/11	**Plastic Trial Head 32 S**
10	175-932/12	**Plastic Trial Head 32 M**
11	175-932/13	**Plastic Trial Head 32 L**
12	175-932/14	**Plastic Trial Head 32 XL**
13	175-936/11	**Plastic Trial Head 36 S**
14	175-936/12	**Plastic Trial Head 36 M**
15	175-936/13	**Plastic Trial Head 36 L**
16	175-936/14	**Plastic Trial Head 36 XL**
17	175-940/11*	**Plastic Trial Head 40 S**
18	175-940/12*	**Plastic Trial Head 40 M**
19	175-940/13*	**Plastic Trial Head 40 L**
20	175-940/14*	**Plastic Trial Head 40 XL**
21	130-394/01	**Handle for Compressors** with quick coupling stems
22	175-390	**Compressor to start,** curved
23	175-310/05	**Resection Guide,** 72 mm

* on request, not part of the standard set configuration

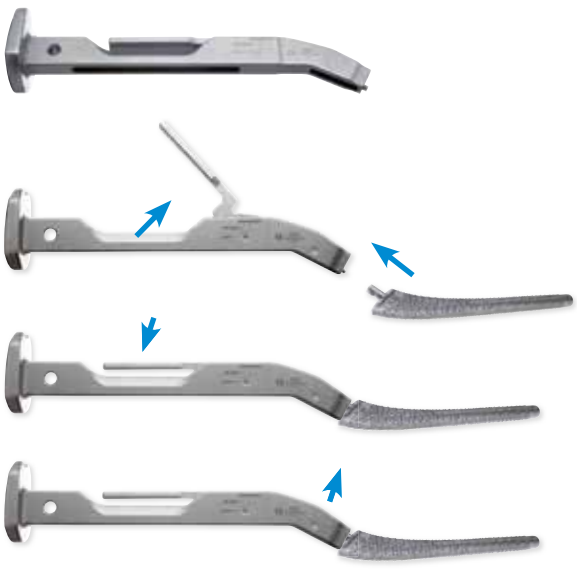
131-801/61 **Instrument Set Rasps**, complete



1	131-804/01	**Tray,** empty
2	131-830/03	**Inserting Forceps** with exchangeable plastic sleeve, 200 mm
		Rasp Stems, 150 mm
		Size
3	131-825/61	narrow
4	131-820/61	medium
5	131-815/61	large
6	131-810/61	extra large
		Calcar Reamer for plane-parallel resection
7	130-407/02B	Ø 40 mm, Hudson Fitting or
	130-407/02D	Ø 40 mm, AO Fitting*
8	131-829/01	**Trial Neck Segment**
9	131-830/04	**Exchangable Taper Cap,** for Inserting Forceps 131-830/03

* fitting optional

Coupling of the rasp



1
To couple rasp and handle, the catch is retracted fully (arrow, left). Then, the rasp fitting is inserted into the mount on the front of the handle (arrow, right, Fig. 1).

2
To secure the connection between rasp and handle, the catch is pushed forwards (arrow) (Fig. 2).

3
To disengage open the handle (arrow) (Fig. 3).
The handle can then be detached from the rasp.

Additional Instruments

(not included in instrument set)

130-165 **Mallet**
Ø 30 mm, 270 mm, 600 gram

130-165/01 **Replacement Head**
for Mallet 130-165

130-394/02 **Universal Handle**
for Rasp Stems and compressors, angled, right

130-394/03 **Universal Handle**
for Rasp Stems and compressors, angled, left (not illustrated)

130-610 **Cement Packer**
Ø 10 mm, 300 mm

131-250/23 **T-handle**
for inserter 131-250/26

05-2002/03 **N21 standard container**
575 × 275 × 130 mm

05-1002/03 **H21 half container**
275 x 275 x 130 mm

Bone Plug Packer

to insert Bone Plugs into the medullary cavity, 400 mm

REF	Ø mm
unthreaded	
131-200	8.0
131-202	10.0
131-204	12.0
131-206	14.0
131-208	16.0
131-210	18.0
threaded	
131-220	8.0
131-222	10.0
131-224	12.0
131-226	14.0
131-228	16.0
131-230	18.0

Length 383 mm

Length 400 mm

131-250/26 **Inserter for Medullary Plug,** graduated, 355 mm, Qty. 2

Intramedullary Plug

MAT: UHMWPE

REF	Ø mm
109-130/12	12.0
109-130/13	13.0
109-130/14	14.0
109-130/15	15.0
109-130/16	16.0
109-130/17	17.0
109-130/18	18.0
109-130/19	19.0
109-130/20	20.0

Trial Heads

REF	Size	Ø mm	Neck length mm
132-924/01	short	24	-3.5
132-924/02	medium	24	0

Accessories

X-ray Templates for Lubinus Classic Plus Hip Prosthesis Stems
CCD angle 126°, head Ø 28 + 32 mm, (with neutral head-neck length), 110% actual size, set of 4 sheets

REF	X-ray templates
131-836/26	**Lubinus Classic Plus Hip Prosthesis Stems**

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)

Indicated indications and contraindications: **Lubinus Classic Plus Hip Prosthesis 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
Primary and secondary osteoarthritis
Rheumatoid arthritis
Correction of functional deformities
Avascular necrosis
Femoral neck fractures
Revision after implant loosening dependent on bone mass and quality
Contraindications
Acute and chronic infections, local and systemic insofar as they compromise the successful implantation of a total hip prosthesis (preoperative microbiological analysis recommended)
Allergies to (implant) materials
Insufficient / inadequate bone mass- or quality, which prevents a stable anchorage of the prosthesis

Please note:
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.

Please note:
LINK Lubinus Classic Plus Hip Stems can be combined with prostheses heads up to +4mm additional neck length.

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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