







SP-CLHX

Anatomically Adapted Cementless Hip System

CE 0482

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

SP-CL HX

Anatomically Adapted Cementless Hip System

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Important Information

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 SP-CL system offers the CCD angles 126° and 135° as well as a 126° lateralized version. This combined with femoral heads with up to four head-neck lengths allows 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 (Abb. 1). Two factors are decisive:

1) Focal distance

Focal spot X-ray tube \longleftrightarrow Film cassette
A focal distance of 100 cm gives magnification of about 10%.

2) Object film distance

Femoral axis \longleftrightarrow Film cassette

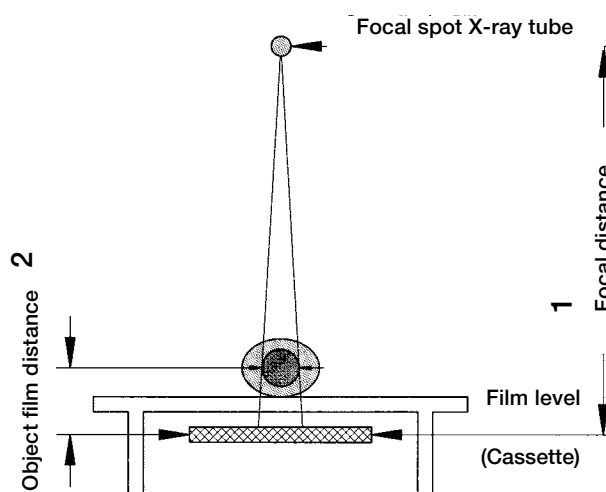


Fig. 1

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 $\div 1.1 = 54.5$ mm actual measurement. The same applies for other magnifications: e.g. at 15% magnification a 60 mm apparent measurement gives $60 \text{ mm} \div 1.15 = 52.2$ mm actual measurement.



Fig. 2

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.

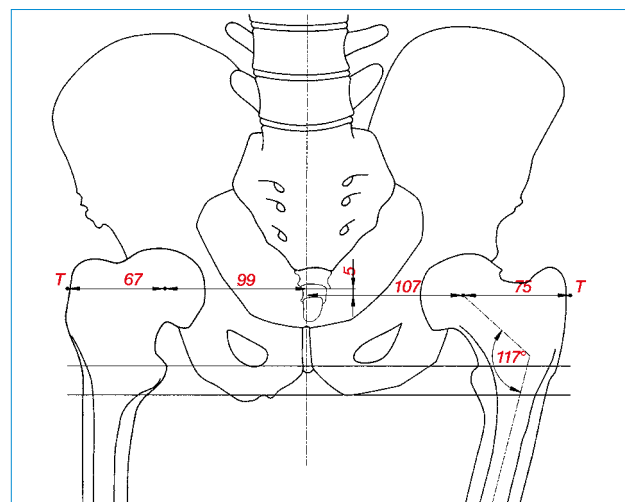


Fig. 3

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.

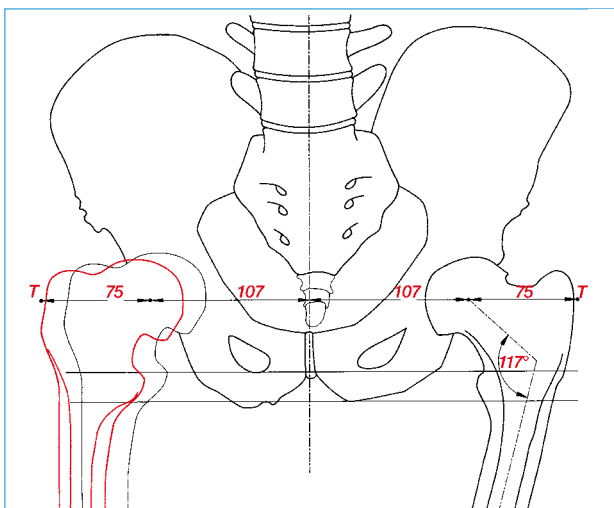


Fig. 4

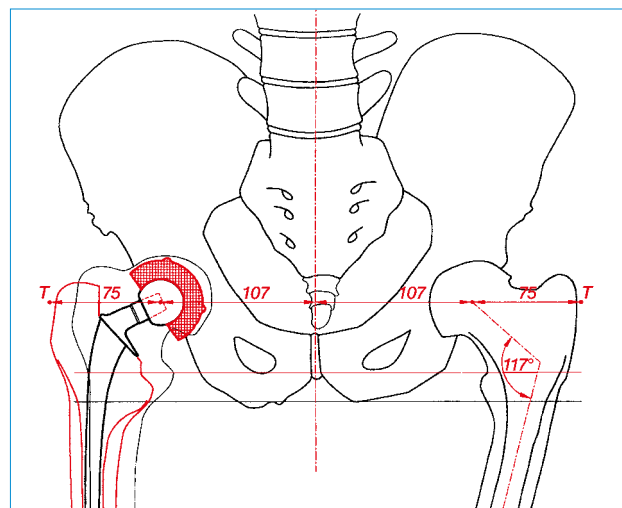


Fig. 5



Surgical Approaches

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

The following approaches are usual:

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

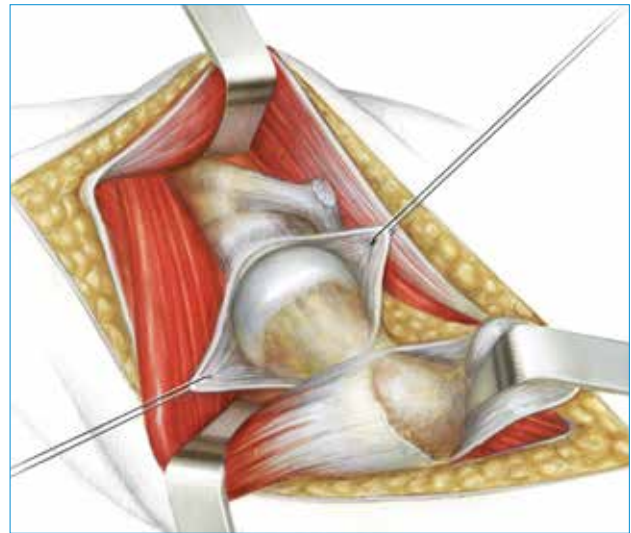


Fig. A: **Watson Jones**

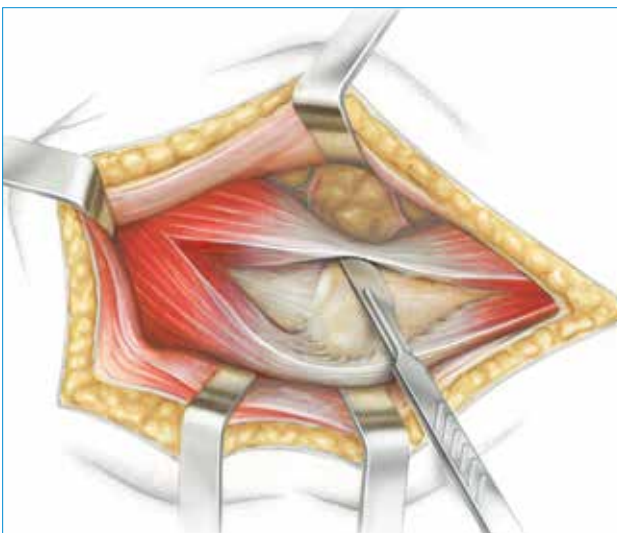


Fig. B: **Hardinge**

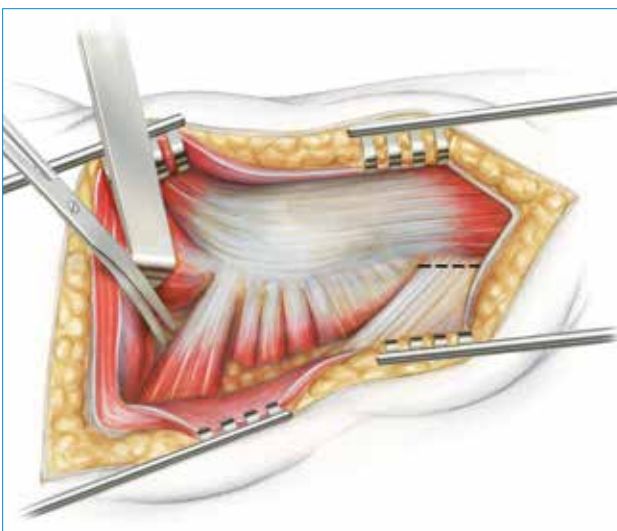
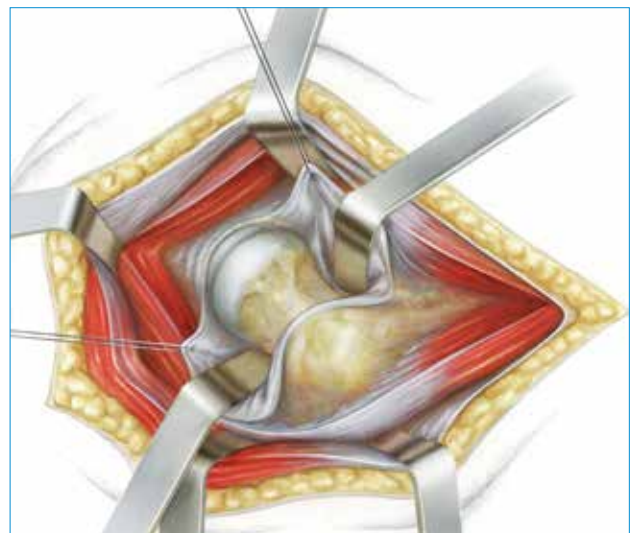
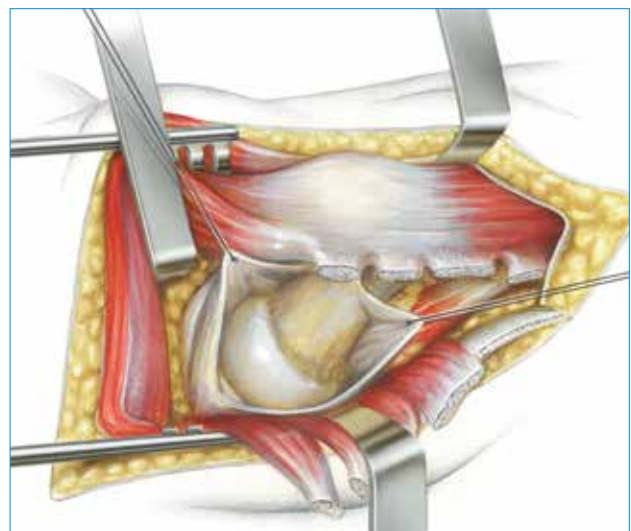


Fig. C: **Moore**



Surgical Technique



Fig. 1

Implantation of the acetabular cup

Avoid damaging the acetabular metal casing when implanting the cup prior to the implantation of the stem (Fig. 1).

Resection of the femoral neck

The hip is dislocated in the usual way. The standard osteotomy plane is normally at 45° to the axis of the femoral stem.

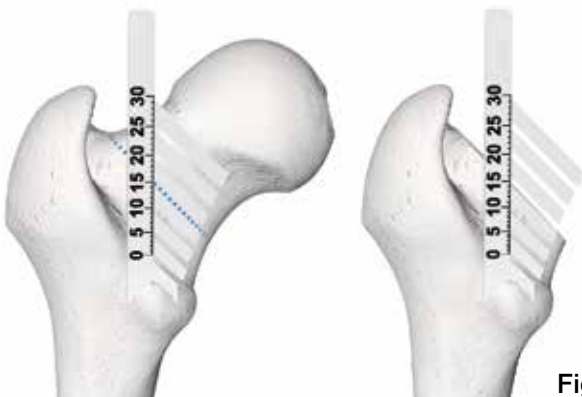


Fig. 2

For purposes of orientation the resection guide can be placed on the lesser trochanter parallel to the longitudinal axis of the femur (Fig. 2). Resection can then be carried out along the slit corresponding to the level selected in preoperative planning. The guide indicates both the level and the angle of resection. Care should be taken to ensure that resection is also carried out at 90° to the axis of the femoral neck in the a-p plane.



Fig. 3

A second vertical resection may be necessary in certain cases (Fig. 3). A compressor can also be used to check that the orientation of the resection plane is correct.

The acetabular cup is almost always prepared before the stem.

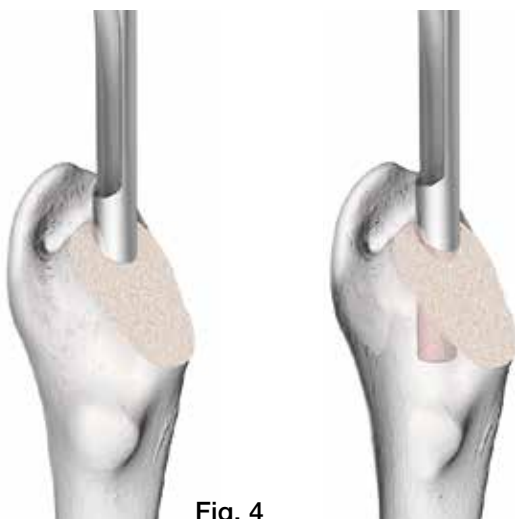


Fig. 4

Fig. 5

Preparation of the femur

The medullary cavity is opened with a gouge. This should be done as far laterally as possible to avoid varus positioning of the stem (Fig. 4 + 5). This also makes it easier to insert the compressor and drastically reduces the risk of fracturing the femoral shaft when driving in the prosthesis.



Fig. 6

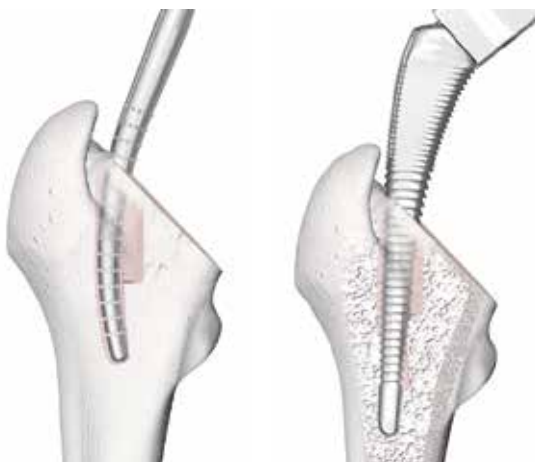


Fig. 7

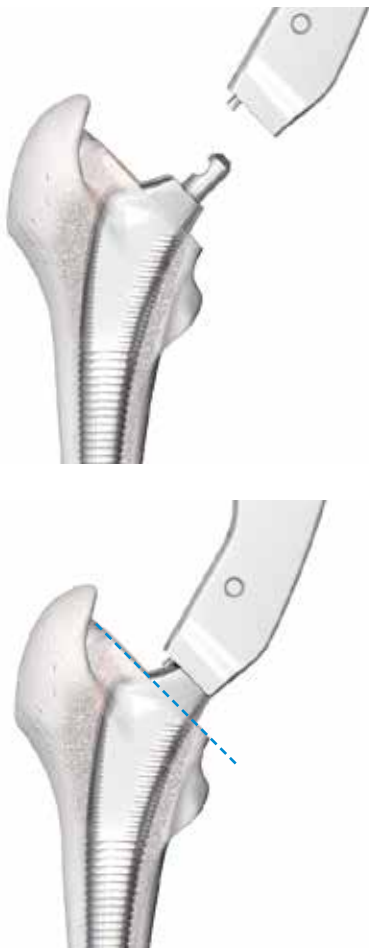


Fig. 8

The opening compressor can be used to prepare the cancellous bone in the lateral area of the great trochanter to prevent varus positioning of the compressor and the implant.

After the medullary cavity has been opened, it is prepared with the smallest compressor size. Attention should also be paid to the axial orientation during this process.

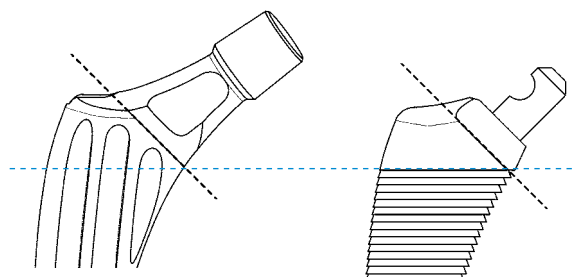
To fit the compressor, the lever on the handle is opened and the compressor is inserted with its medial side facing the lever. The lever is then closed again.

The anatomical form of the compressors means that the anteversion usually adjusts itself automatically when they are driven in. The femoral canal is prepared with compressor of increasing size until maximum stability is achieved. The process is complete as soon as the compressor is positioned in the femoral canal so that it is rotationally stable, central and aligned with the axis.

Note:

The compressor size is not necessarily the same as in preoperative planning, but can vary up to two sizes.

SP-CL stems are fixed in a bed of compacted cancellous bone. The compressors used ensure that the bone substance is compacted without removing it from the bone. When driving the compressors in and out, unintentional turning movements of the handle/compressor unit should be avoided to prevent damage to the implant bed.



Note:

The SP-CL compressors have a marking line a few millimeters below the handle attachment point. The height of this line on the compressor is exactly at the level of the transition between the modified surface and the blasted neck section of the SP-CL stem. The final prosthesis stem is driven in with reference to this line up to the corresponding position of the last compressor.

The position required for this component can thus be reproduced exactly.

Fig. 9



Fig. 10



Fig. 11



Fig. 12

Trial reduction

The acetabular component is usually implanted before the stem so that trial reduction is possible.

This is carried out with the final size of compressor in situ. The handle is removed and the trial neck segment selected in preoperative planning (CCD angle, type) is placed on the compressor. The different trial heads are then used to check for optimal offset and correct leg length and to test whether stability is adequate.

The range of movement is also checked to avoid impingement of bone and implant and rule out any instability.

The combination of the prosthetic head with the trial neck segments is not permissible.

When all checks have been made, the trial head and trial neck segments are removed by hand. The handle is then used to remove the compressor, which is still in situ, from the femoral canal.

Implanting the final stem

The stem to be used (size, CCD angle, type) has been determined by performing trial reduction. The appropriate implant is now removed from the sterile packaging and inserted manually as far into the medullary canal as possible. This helps to protect the prepared implant bed.

The tip of the impactor is placed in the lateral depression on the upper surface of the prosthesis. The design of the impactor ensures that any lateral forces occurring during implantation do not reach the stem (Fig. 12).



Fig. 13

Using steady hammer blows the stem is now carefully driven in until it reaches its final position. This is indicated when the transition line on the prosthesis is at the same height as that on the compressor last used (Figure 13).

Trial reduction can then be repeated. The selected trial head is placed on the implant and trial reduction is carried out.

The trial head is then removed again.



Fig. 14

Attaching the final prosthesis head

The taper of the stem is cleaned and dried thoroughly. This is particularly important with ceramic heads. The head is then attached by hand with axial pressure and a turning movement.

The head is hit lightly with the driver (Fig. 14 + 15).

Once the joint surfaces have been cleaned the joint is reduced with the final implant components.

The wound is closed in layers.



Fig. 15

Removing the components

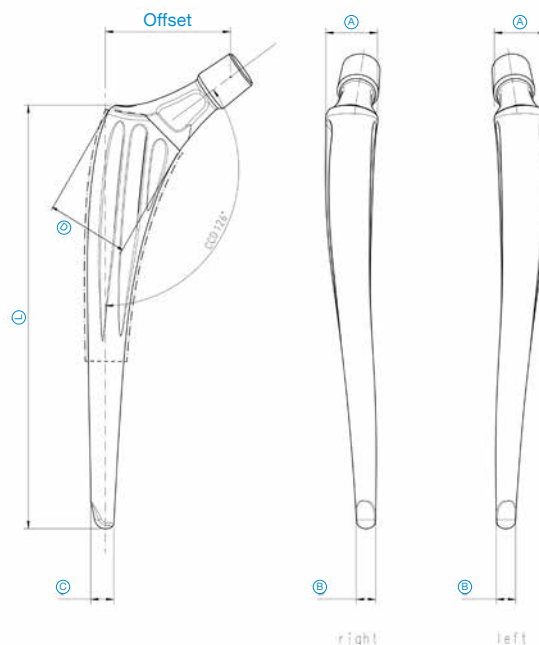
The different components can be removed if required. The prosthesis head can be removed separately in an

axial direction using a plunger/stem/rod which is placed at the base of the head.

The femoral component can be driven out with the extraction instrument (130-252/00), which is connected to the compressor handle with the adapter.

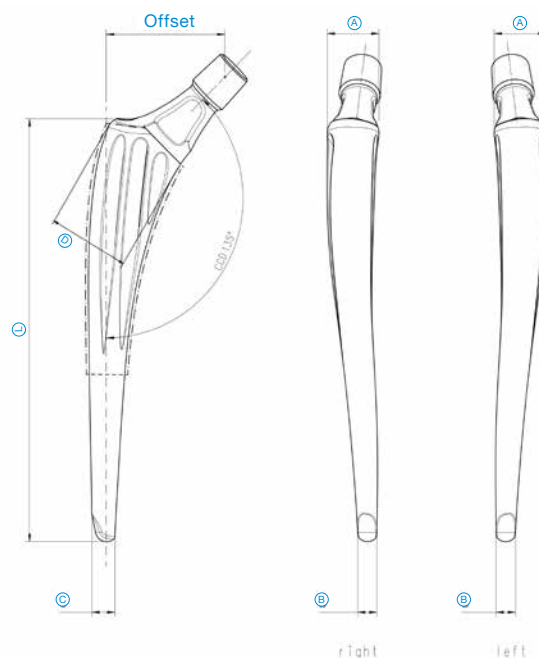
Note:

If a ceramic head has to be replaced with another ceramic head, only ceramic revision heads with a metal inner taper must be used.

SP-CL Hip Stem, standard, CCD 126°
MAT Tilastan-S (TiAl6V4), HX-coated


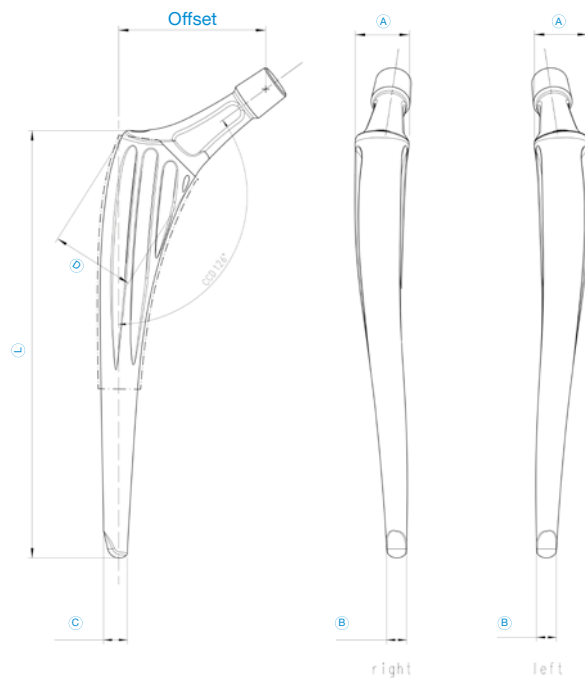
<div>REF</div> <div>RIGHT</div>	<div>REF</div> <div>LEFT</div>	Stem size	Offset mm	⌀ mm	Ⓐ mm	Ⓑ mm	Ⓒ mm	Ⓓ mm
177-200/26*	177-220/26*	1	34.7	115	14.4	5.4	6.4	22.5
177-201/26*	177-221/26*	2	36.1	120	15.0	5.6	6.7	23.4
177-202/26*	177-222/26*	3	37.4	125	15.5	5.8	6.9	24.3
177-203/26	177-223/26	4	38.8	130	16.1	6.0	7.2	25.2
177-204/26	177-224/26	5	40.2	135	16.7	6.2	7.4	26.1
177-205/26	177-225/26	6	41.6	140	17.3	6.5	7.7	27.0
177-206/26	177-226/26	7	43.0	145	17.8	6.7	7.9	27.9
177-207/26	177-227/26	8	44.4	150	18.4	6.9	8.2	28.8
177-208/26	177-228/26	9	45.8	155	19.0	7.1	8.4	29.7
177-209/26	177-229/26	10	47.2	160	19.6	7.3	8.7	30.6
177-210/26	177-230/26	11	48.6	165	20.1	7.5	8.9	31.5
177-211/26	177-231/26	12	49.6	165	20.7	7.8	9.2	32.2
177-212/26	177-232/26	13	50.5	165	21.3	8.0	9.5	33.2
177-213/26	177-233/26	14	51.5	165	21.8	8.2	9.7	34.0
177-214/26	177-234/26	15	52.5	165	22.4	8.5	10.0	34.8
177-215/26	177-235/26	16	53.5	165	23.0	8.7	10.3	35.6
177-241/26	177-251/26	18	53.5	165	24.2	9.1	10.8	37.2
177-243/26	177-253/26	20	53.5	165	25.4	9.6	11.3	38.8
177-245/26	177-255/26	22	53.5	165	26.5	10.0	11.9	40.4

* on request, not part of the standard set configuration

SP-CL Hip Stem, standard, CCD 135°
MAT Tilastan-S (TiAl6V4), HX-coated


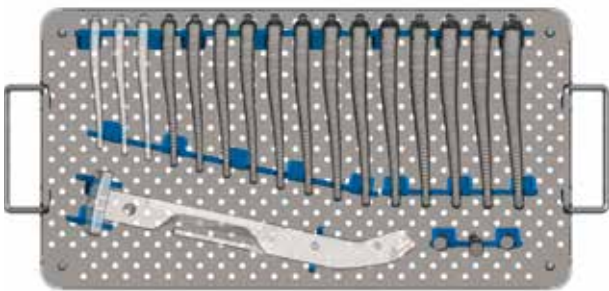
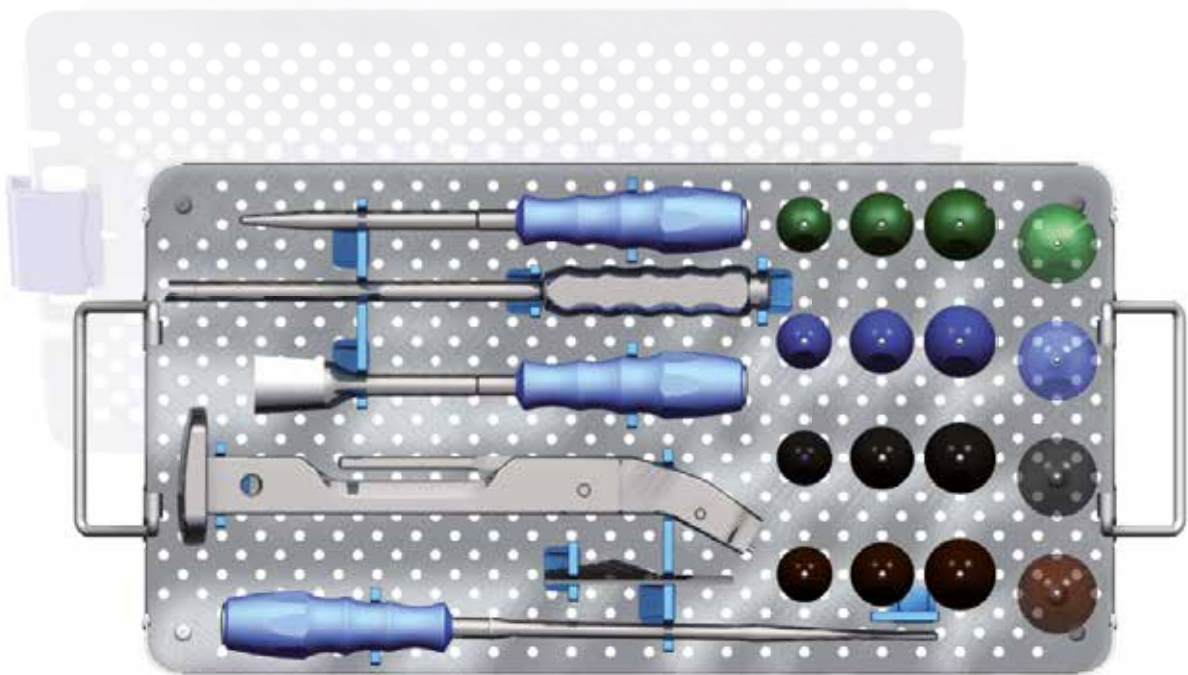
REF RIGHT	REF LEFT	Stem size	Offset mm	L mm	A mm	B mm	C mm	D mm
177-400/35*	177-420/35*	1	33.2	115	14.4	5.4	6.4	22.5
177-401/35*	177-421/35*	2	34.5	120	15.0	5.6	6.7	23.4
177-402/35*	177-422/35*	3	35.7	125	15.5	5.8	6.9	24.3
177-403/35	177-423/35	4	37.0	130	16.1	6.0	7.2	25.2
177-404/35	177-424/35	5	38.3	135	16.7	6.2	7.4	26.1
177-405/35	177-425/35	6	39.6	140	17.3	6.5	7.7	27.0
177-406/35	177-426/35	7	40.9	145	17.8	6.7	7.9	27.9
177-407/35	177-427/35	8	42.1	150	18.4	6.9	8.2	28.8
177-408/35	177-428/35	9	43.4	155	19.0	7.1	8.4	29.7
177-409/35	177-429/35	10	44.7	160	19.6	7.3	8.7	30.6
177-410/35	177-430/35	11	46.0	165	20.1	7.5	8.9	31.5
177-411/35	177-431/35	12	46.8	165	20.7	7.8	9.2	32.2
177-412/35	177-432/35	13	47.7	165	21.3	8.0	9.5	33.2
177-413/35	177-433/35	14	48.6	165	21.8	8.2	9.7	34.0
177-414/35	177-434/35	15	49.6	165	22.4	8.5	10.0	34.8
177-415/35	177-435/35	16	50.3	165	23.0	8.7	10.3	35.6
177-441/35	177-451/35	18	50.3	165	24.2	9.1	10.8	37.2
177-443/35	177-453/35	20	50.3	165	25.4	9.6	11.3	38.8
177-445/35	177-455/35	22	50.3	165	26.5	10.0	11.9	40.4

* on request, not part of the standard set configuration

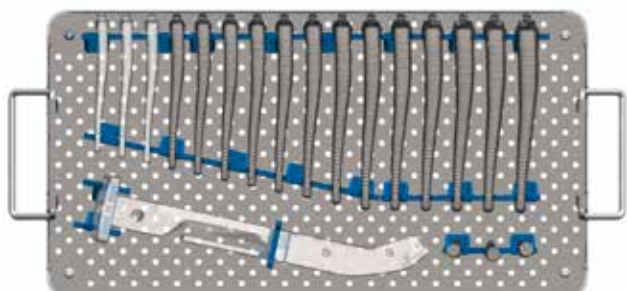
SP-CL Hip Stem, lateralized, CCD 126°
MAT Tilastan-S (TiAl6V4), HX-coated


<div>REF</div> <div>RIGHT</div>	<div>REF</div> <div>LEFT</div>	Stem size	Offset mm	Ⓕ mm	Ⓐ mm	Ⓑ mm	Ⓒ mm	Ⓓ mm
177-603/26	177-623/26	4	45.3	130	16.1	6.0	7.2	25.2
177-604/26	177-624/26	5	46.7	135	16.7	6.2	7.4	26.1
177-605/26	177-625/26	6	48.1	140	17.3	6.5	7.7	27.0
177-606/26	177-626/26	7	49.5	145	17.8	6.7	7.9	27.9
177-607/26	177-627/26	8	50.8	150	18.4	6.9	8.2	28.8
177-608/26	177-628/26	9	52.2	155	19.0	7.1	8.4	29.7
177-609/26	177-629/26	10	53.6	160	19.6	7.3	8.7	30.6
177-610/26	177-630/26	11	55.0	165	20.1	7.5	8.9	31.5
177-611/26	177-631/26	12	56.0	165	20.7	7.8	9.2	32.2
177-612/26	177-632/26	13	57.0	165	21.3	8.0	9.5	33.2
177-613/26	177-633/26	14	58.0	165	21.8	8.2	9.7	34.0
177-614/26	177-634/26	15	59.0	165	22.4	8.5	10.0	34.8
177-615/26	177-635/26	16	60.0	165	23.0	8.7	10.3	35.6
177-641/26	177-651/26	18	60.0	165	24.2	9.1	10.8	37.2
177-643/26	177-653/26	20	60.0	165	25.4	9.6	11.3	38.8
177-645/26	177-655/26	22	60.0	165	26.5	10.0	11.9	40.4

Instrument set for LINK **SP-CL** Hip Stems



Compressors, right

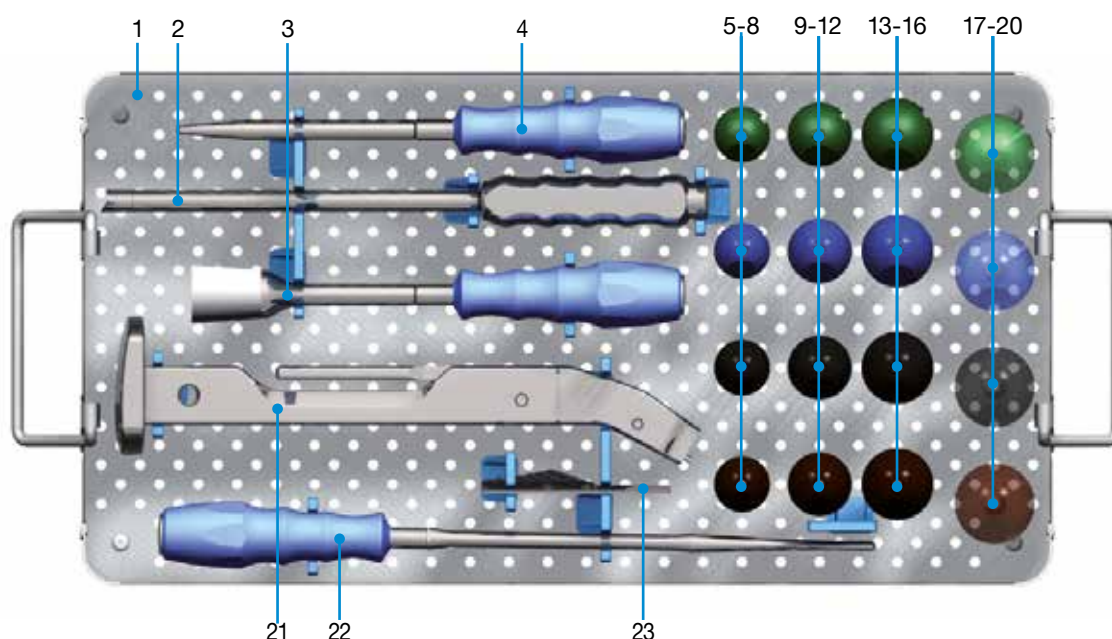


Compressors, left



Compressors, extra large sizes, right and left

REF	Instrument Set, complete
175-110/00	Instrument set Instruments, complete
175-120/00	Instrument set Compressors, right, complete
175-130/00	Instrument set Compressors, left, complete
175-140/00	Instrument set Compressors, right and left, complete, extra large sizes

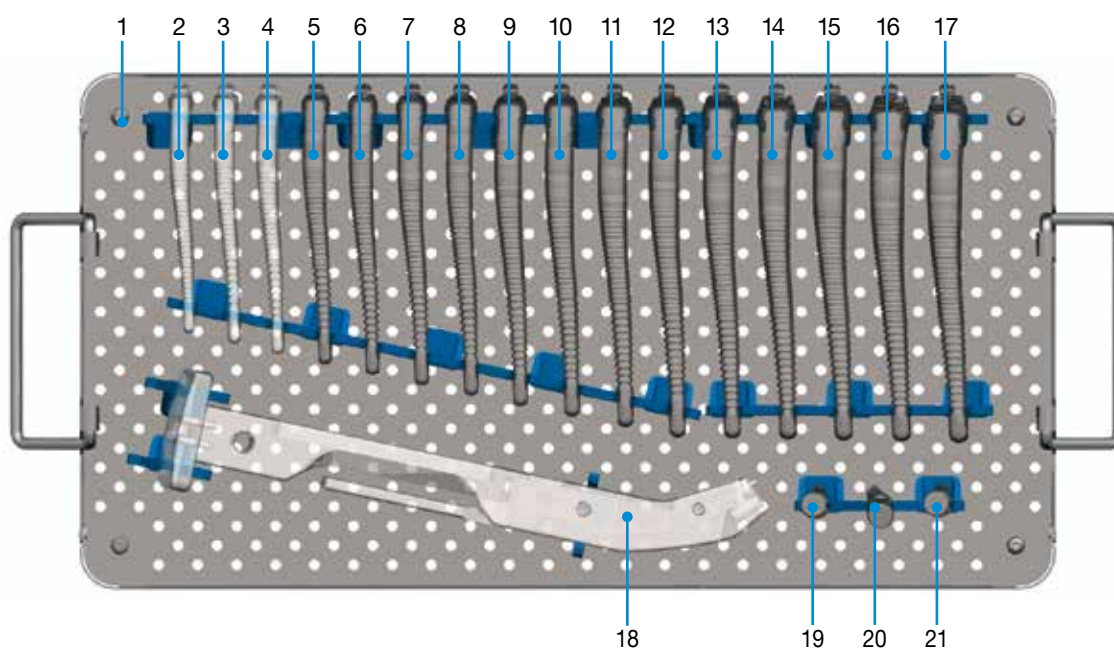
175-110/00 Instrument set, complete


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

* on request, not part of the standard set configuration

175-120/00 Instrument set, Compressors, RIGHT, complete

175-130/00 Instrument set, Compressors, LEFT, complete (NOT ILLUSTRATED)



	REF	Version	Size
1	175-121/00	Compressor tray, RIGHT, empty	
2	175-200/01*	right	1
3	175-200/02*	right	2
4	175-200/03*	right	3
5	175-200/04	right	4
6	175-200/05	right	5
7	175-200/06	right	6
8	175-200/07	right	7
9	175-200/08	right	8
10	175-200/09	right	9
11	175-200/10	right	10
12	175-200/11	right	11
13	175-200/12	right	12
14	175-200/13	right	13
15	175-200/14	right	14
16	175-200/15	right	15
17	175-200/16	right	16
18	130-394/02*	Single angled Handle for compressors, right	

	REF	Version	Size
	175-131/00	Compressor tray, LEFT, empty	
	175-201/01*	left	1
	175-201/02*	left	2
	175-201/03*	left	3
	175-201/04	left	4
	175-201/05	left	5
	175-201/06	left	6
	175-201/07	left	7
	175-201/08	left	8
	175-201/09	left	9
	175-201/10	left	10
	175-201/11	left	11
	175-201/12	left	12
	175-201/13	left	13
	175-201/14	left	14
	175-201/15	left	15
	175-201/16	left	16
	130-394/03*	Single angled Handle for compressors, left	

* on request, not part of the standard set configuration

Neck segment for fitting to compressor with taper 12/14 mm

	REF	Description	Type	CCD	Version	for compressor- & stem size
19	175-195/26	Neck segment	std.	126°	right	1 - 16
20	175-197/26	Neck segment	lat.	126°	right	4 - 16
21	175-195/35	Neck segment	std.	135°	right	1 - 16
	175-196/26	Neck segment	std.	126°	left	1 - 16
	175-198/26	Neck segment	lat.	126°	left	4 - 16
	175-196/35	Neck segment	std.	135°	left	1 - 16



175-140/00 Instrument set, Compressors, complete, extra large sizes, right and left



	REF	Version	Size
1	175-141/00	Compressor tray, empty	
2	175-201/18	left	18
3	175-201/20	left	20
4	175-201/22	left	22
5	175-200/22	right	22
6	175-200/20	right	20
7	175-200/18	right	18

130-394/01 Universal Handle for rasp stems and compressors

130-394/02 Universal Handle for rasp stems and compressors, angled, right

130-394/03 Universal Handle for rasp stems and compressors, angled, left



Coupling of the compressor



Fig. 1

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



Fig. 2

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



Fig. 3

To disengage open the handle again (arrow) (Fig. 3).

The handle for compressors can then be detached from the compressor.

Additional Instruments

(not included in instrument set)



179-122 Insertion Forceps, lockable



179-122/01 Exchangeable Taper Cap
for Insertion Forceps 179-122


130-252/00 Instrument set for extraction
(not illustrated)

Instructions for Cleaning and Maintenance

Specific instructions for instruments are available on request: E-mail customer@linkhh.de

X-ray Templates

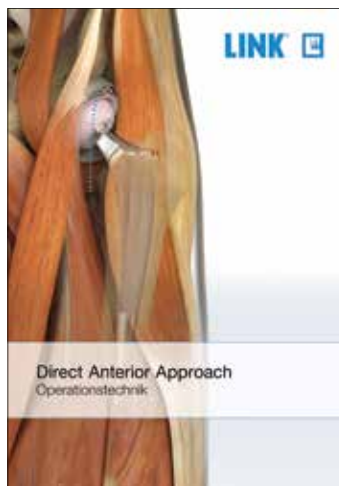
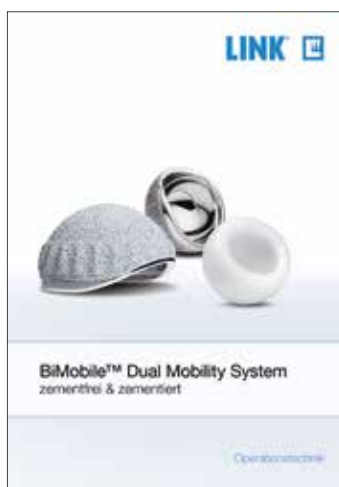
for SP-CL Hip Prosthesis Stems, cementless

Stem  Ti6Al4V, HX Coating, taper 12/14 mm, sizes 1-16, set with 16 sheets

REF	CCD angle	Actual size
175-801/02	126°	110%
175-801/04	135°	110%
175-801/03	126° lateralized	110%

Additional Information

Catalogs on request: E-mail customer@linkhh.de



www.sp-cl.com



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

Specified Indications and Contraindications: SP-CL cementless Hip Prosthesis System (all types)
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
Poor general state of health
Acute and chronic infections, local and systemic, insofar as they compromise the successful implantation of a THA
Allergies to (implant) materials
Distinctive muscular-, nerve-, vascular or other diseases which put the affected limb at risk
Insufficient/inadequate bone mass- or quality which prevents a stable anchorage of the prosthesis

The stems are indicated for cementless use only.

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.

The SP-CL hip prosthesis stem can only be combined with prosthesis heads that do not exceed +10,5 mm additional neck length.

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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The Surgical Technique described has been written to the best of our knowledge and belief, but it does not relieve the surgeon of his/her responsibility to duly consider the particularities of each individual case.

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