LINK®

# Standard D

## Cementless Hip Prosthesis Stems

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. |

# Standard D
## Cementless Hip Prosthesis Stems

## System Description

The Standard D hip prosthesis stem is wedge-shaped with a rectangular cross section.
Primary stability is achieved by placing a straight stem with a double taper and rectangular cross section in the curved femoral canal and is aided by the large area of cortical contact.

The lateralized version allows individual reconstruction. Particular features of the Standard D hip prosthesis stem are its precision and the straightforward surgical procedure involved.

### Materials

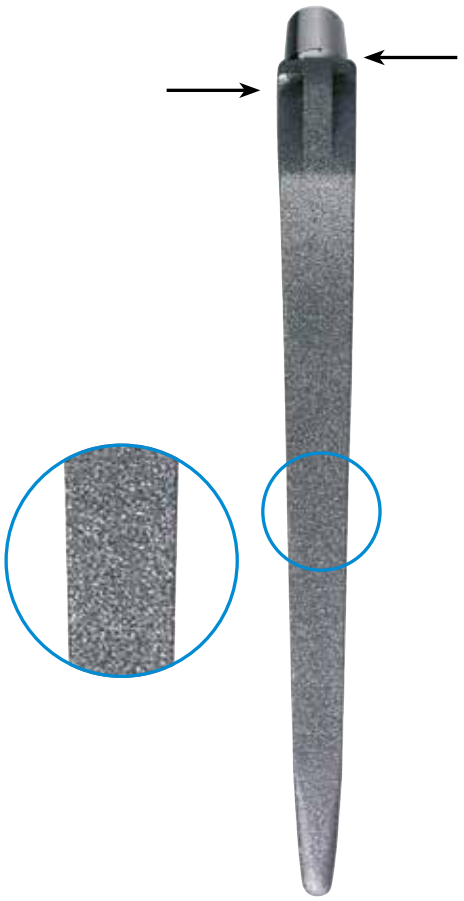
The stem is made from forged titanium alloy (Ti6Al4V).

The macro roughness of the surface is produced by blasting it with corundum particles. This gives a uniform surface structure with adequate roughness for good bone integration.


### Biomechanical properties

The CCD (caput collum diaphyseal) angle is 131° in the standard version and 124° in the lateralized version.
The lateralized version has a constant offset enlargement of 5 mm in all sizes, guaranteeing good joint stability without altering leg length. This version can be a good alternative, even with dysplastic bone conditions.

The straight stem with its double taper ensures good mechanical fixation over a wide area of contact. This allows the implant to be fixed at the required level. The rectangular cross section and the perforated lateroproximal projection on the trochanter reduces the risk of rotation.

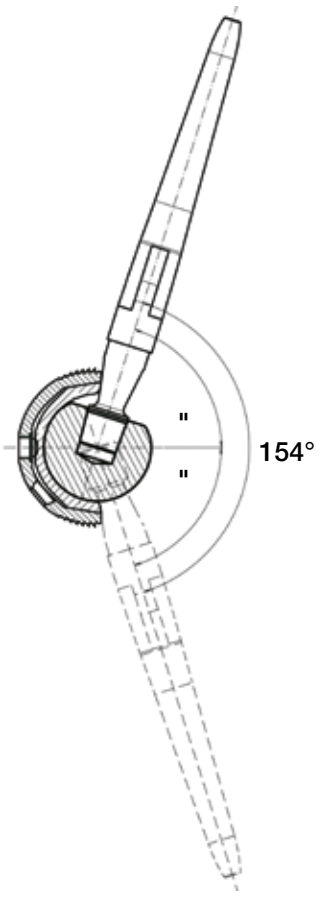


Forces are distributed over an extensive area of the cortical surface so that unintended force transmission reduced to a minimum.

The proximal medial area is rounded to ensure a good fit of the prosthesis in the calcar region. The distal tip is tapered and rounded to avoid unwanted pressure peaks. The profile in the sagittal plane is conical. This improves the support of the femoral curve and reduces the risk of subsidence.

The macro-roughness of the surface supports good biological fixation. The mechanical stability of the contact area is increased by the inclusion of indentations on the anterior and posterior sides of the metaphysis.

The polished surface of the neck reduces the risk of polyethylene particles being produced as a result of accidental contact with the acetabular component. The tapered neck, in combination with the short 12/14 taper, allows greaterrange of motion of over 150° (when combined with a head diameter of 36mm).




Range of motion in combination with a head diameter of 36mm.

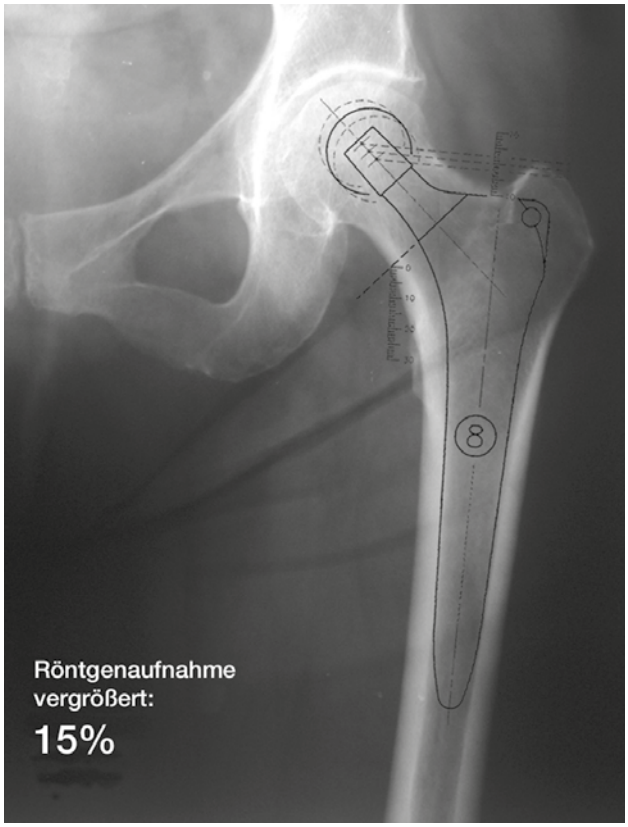



Fig. 5

### Preoperative Planning

For optimal results the operation should be planned in advance using the appropriate templates. The templates are enlarged by a factor of 1 : 1.15.

Good quality AP and axial X-rays with adequate contrast are used to assess the size of implant required. Each X-ray should be large enough to allow the whole template to be laid on top (Fig. 5)

**Note:**
**Preoperative planning gives an initial estimate but cannot conclusively determine the size of stem to be used. The final decision must be made intraoperatively.**

### Assessing stem size

1) Place the horizontal line running through the center of the “MEDIUM” head on the template over the center of the anatomical femoral head. If the anatomical head is very deformed place the horizontal line at the level of the tip of the greater trochanter. In this position the template shows the level for cutting of the femoral neck.

2) Choose the size of stem whose outline on the template coincides with the inner side of the cortex on the X-ray.

3) When these criteria are fulfilled, check in the axial plane whether the stem fits the femoral bow.

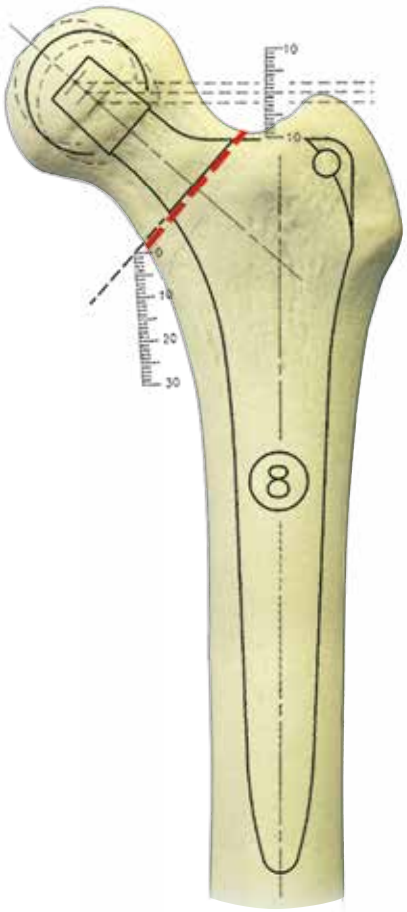


Fig. 6

4) On the template read off the distance between the lesser trochanter and the resection plane. This value is measured with a centimeter rule during the operation. It should be emphasised that the middle part of the stem is fixed in the diaphysis. Support on the medial wall of the femur is therefore not absolutely essential. Efforts to achieve such support during preoperative planning can cause subsidence of the prosthesis stems.

**Positioning the patient**

**Note:**
**Fig. 7 shows the normal position for posterolateral surgical access. All the following steps also apply for the supine position and all other surgical access routes.**

The patient lies on the side.

Posterolateral access (Fig. 7).
Open the fascia lata and resect the external rotator muscles. Then make an incision in the joint capsule. Dislocate the femoral head in a dorsal direction so that it lies free.

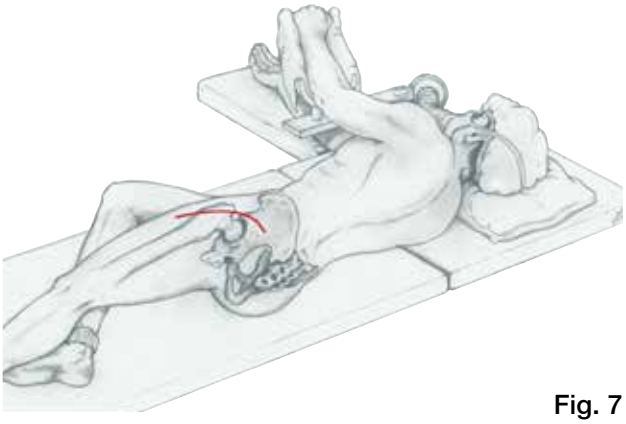


**Fig. 7**

**Resection of the femoral neck**

After dislocating the femur use a centimeter rule to establish the resection level previously determined from the X-ray. When the resection level has been decided, resect the femoral neck with an oscillating saw (Fig. 8).

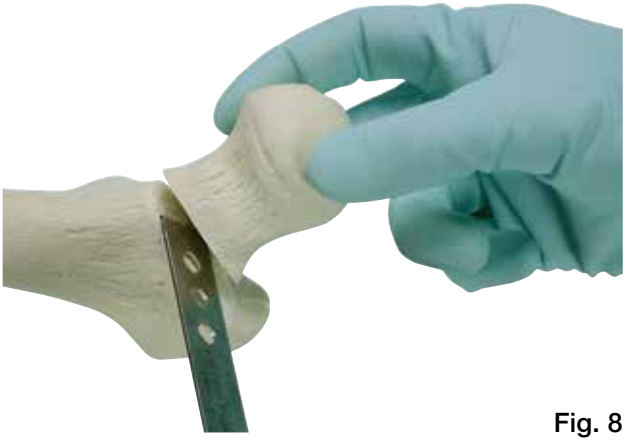


**Fig. 8**

Box chisel Fig. 9

**Correct resection makes rasping and trial reduction easier. However, resection of the femoral neck at a different level does not compromise the stability of the implant because, as described, this is not dependent on proximal medial support.**

**Note:**
**After resection of the femoral neck, the surgical technique described here requires preparation of the acetabular cup.**

Fig. 10

### Preparation of the medullary cavity

Open the femoral shaft with the box chisel (Fig. 9-10). The osteotomy must accord with the anteversion decided previously and must be sufficiently lateral to prevent incorrect (varus) insertion of the rasp stem.

Rasp stem Fig. 11

### Rasping the medullary cavity

The medullary cavity is prepared for the Standard D prosthesis stem using modular rasps (Fig. 10) of increasing size which are locked onto the rasp handle (Fig. 12).

Rasp handle Fig. 12

Fig. 13

Open the lever and push the rasp attachment into the socket of the handle. Then close the lever (Fig. 13).

Fig. 14

Always start with the smallest rasp and always continue with the next size up (Fig. 14). When the teeth of the rasp are completely immersed in the medullary cavity do not drive the rasp in further (Fig. 15).

Fig. 15

Fig. 16

When the optimal rasp size is reached (which is usually, though not always, the same as was anticipated in preoperative planning), remove the handle and leave the rasp in place (Fig. 16-17). Place the required trial neck segment (standard or lateralized) on the rasp (Fig. 18).

Fig. 17

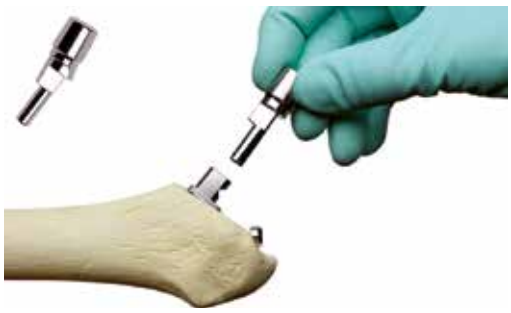


Fig. 18

**Trial neck segment, lateralized**

**Trial neck segment**

Trial head
Fig. 19

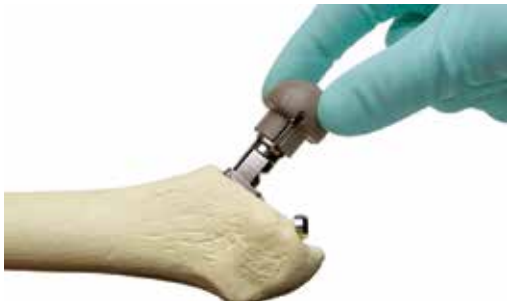


Fig. 20

### Trial reduction

It is assumed that the acetabular component has already been implanted. Place the trial head on the trial neck and perform trial reduction (Fig. 19-20).

Fig. 21

Fig. 22

If the implant seems too short remove the rasp and continue preparation with a larger rasp (the next size up). In some cases the next size of rasp may not submerge up to the resection level and may protrude further. This does not cause problems with the stability of the stem and makes it possible to correct the height. Reduce again. After deciding the length of the final head remove first the trial head and trial neck and then the rasp (Fig. 21-24).

**Note:**
**The instrument set contains trial heads (diameter 28 mm) in lengths S, M and L.**

Fig. 23

Fig. 24

Standard D hip prosthesis stem Fig. 25

### Inserting the stem

Take a Standard D hip prosthesis stem of the same size as the last rasp and remove it from the sterile packaging. Screw the positioner/extractor into the proximal threaded hole in the stem (Fig. 25-26).

Fig. 26

Fig. 27

Drive the stem in up to the depth that you determined earlier with the rasp (Fig. 27-28).

Fig. 28

Fig. 29

Remove the cap protecting the taper (Fig. 29).

Trial head
Fig. 30

**Final trial reduction**

Place the required trial head on the taper of the stem (Fig. 30-31) and reduce so that the prosthesis head articulates with the acetabular cup component already implanted.

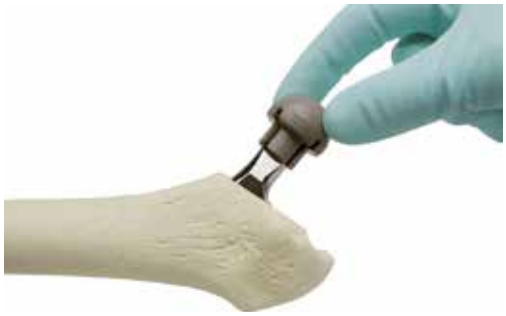


Fig. 31

Determine the length of prosthesis head required (S, M or L) depending on the soft tissue tension (Fig. 32).

Then remove the trial head.

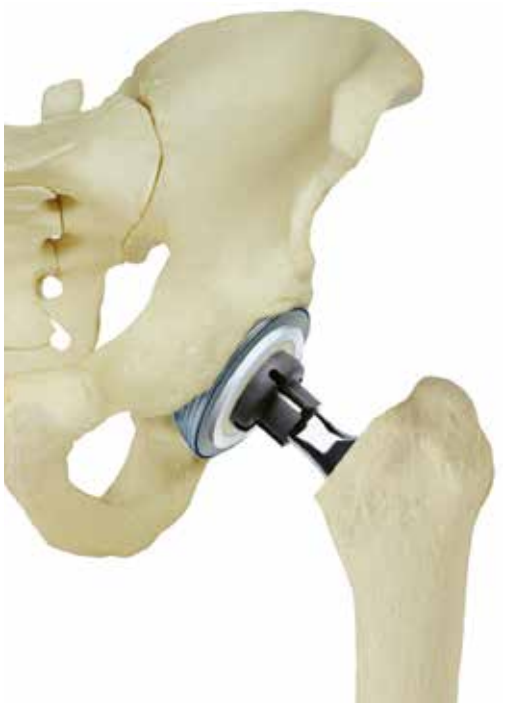


Fig. 32

Fig. 33

Fig. 34

Fig. 35

**Impactor for hip prosthesis heads**
(not included)

Fig. 36

**Attaching the final prosthesis head**

Take the appropriate head (material, diameter, length) and remove it from the sterile packaging.

Clean and dry the taper of the stem thoroughly. This is essential, particularly with ceramic heads. Mount the head by hand using axial pressure and a turning motion (Fig. 33-34).

Impact the head lightly if necessary (Fig. 35-36) using the plastic impactor (available on request).

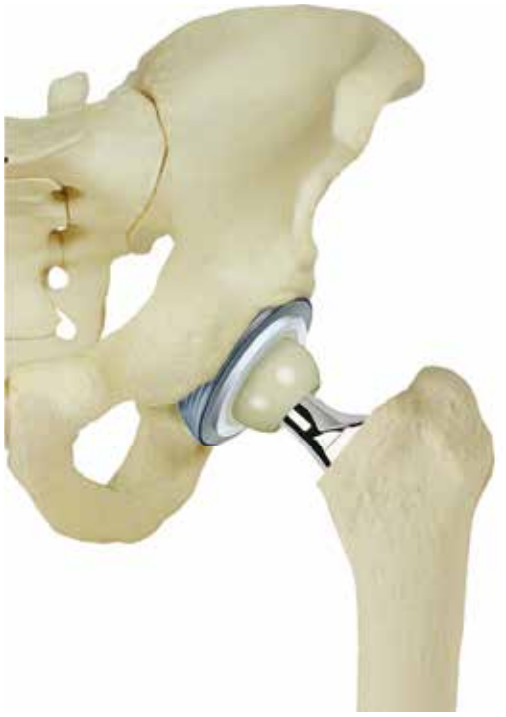


Fig. 37

Clean the joint surfaces thoroughly and then finally reduce the joint (Fig. 37).

Driver / extractor

Fig. 38

**Removing the components**

The various prosthesis components can be removed if necessary.
The prosthesis head can be removed in an axial direction using a rod which is placed at the base of the head.

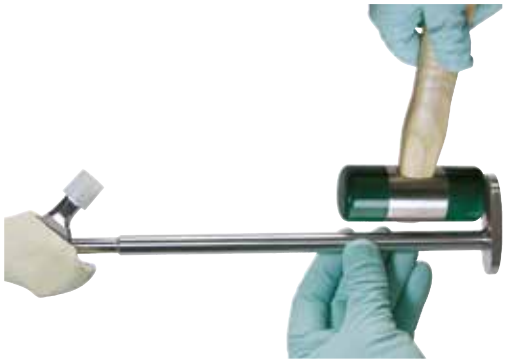


Fig. 39

**Caution:**
**If a ceramic head has to be replaced with another ceramic head, only ceramic revision heads (with a metal inner taper) should be used.**

The stem can be removed with the appropriate stem remover (Fig. 38-39) when removed intraoperatively.

Fig. 40

**Cleaning the instruments**

Holes allow the cleaning solution to drain off (Fig. 40).

Fig. 41

The rasps (Fig. 41) and all other instruments should be cleaned as described in the relevant instructions for cleaning and care.

## Standard D Hip Prosthesis Stems

Microporous surface structure, cementless
MAT Ti6Al4V, taper 12/14

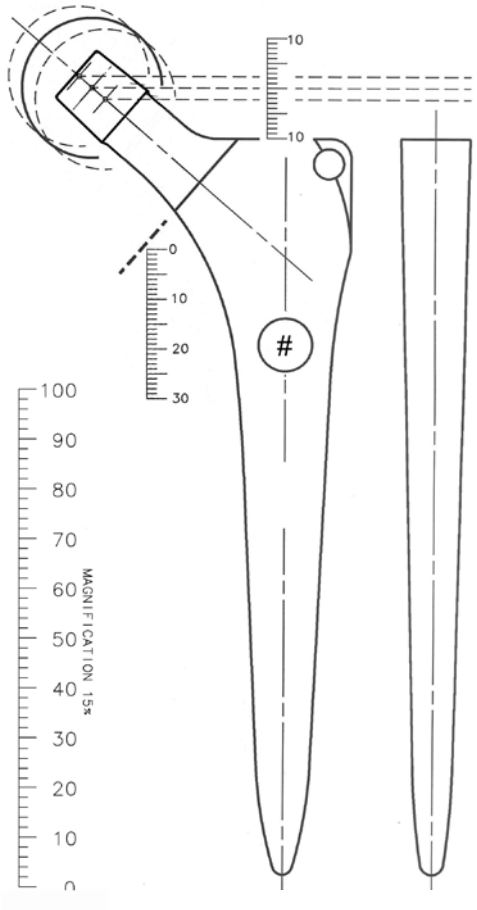



**Fig. 3**
Standard version

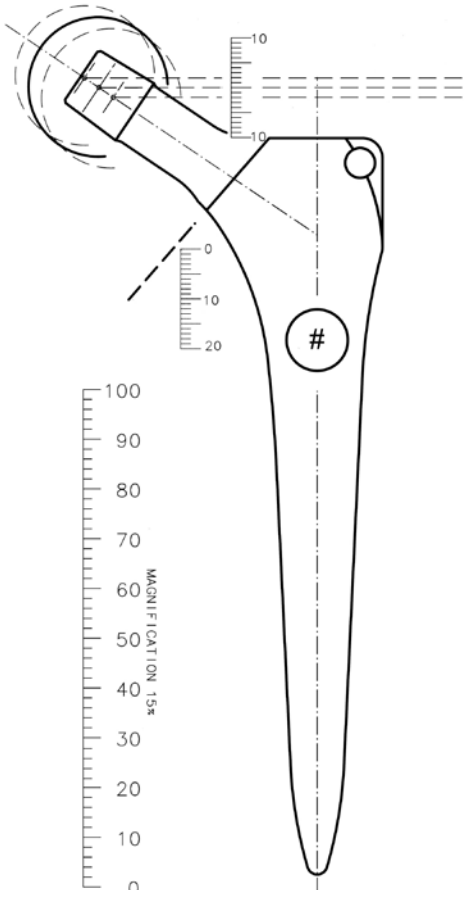



**Fig. 4**
Lateralized version

- Standard D stems are available in two versions: standard and lateralized. Each of these versions is available in 14 sizes.
- CCD angle of 131° in standard version (Fig. 3)
- CCD angle of 124°, offset +5mm, in lateralized version (Fig. 4)
- The system thus allows optimal anatomical fitting of the prosthesis and makes it possible to recreate balanced joint properties / joint equilibrium with good functional results.


**Standard D hip prosthesis stems, standard**

MAT Ti6Al4V, taper 12/14, CCD angle 131°

| REF | Size |
|---|---|
| 164-001 | 01 |
| 164-002 | 0 |
| 164-003 | 1 |
| 164-004 | 2 |
| 164-005 | 3 |
| 164-006 | 4 |
| 164-007 | 5 |
| 164-008 | 6 |
| 164-009 | 7 |
| 164-010 | 8 |
| 164-011* | 9 |
| 164-012* | 10 |
| 164-013* | 11 |
| 164-014* | 12 |

* on request

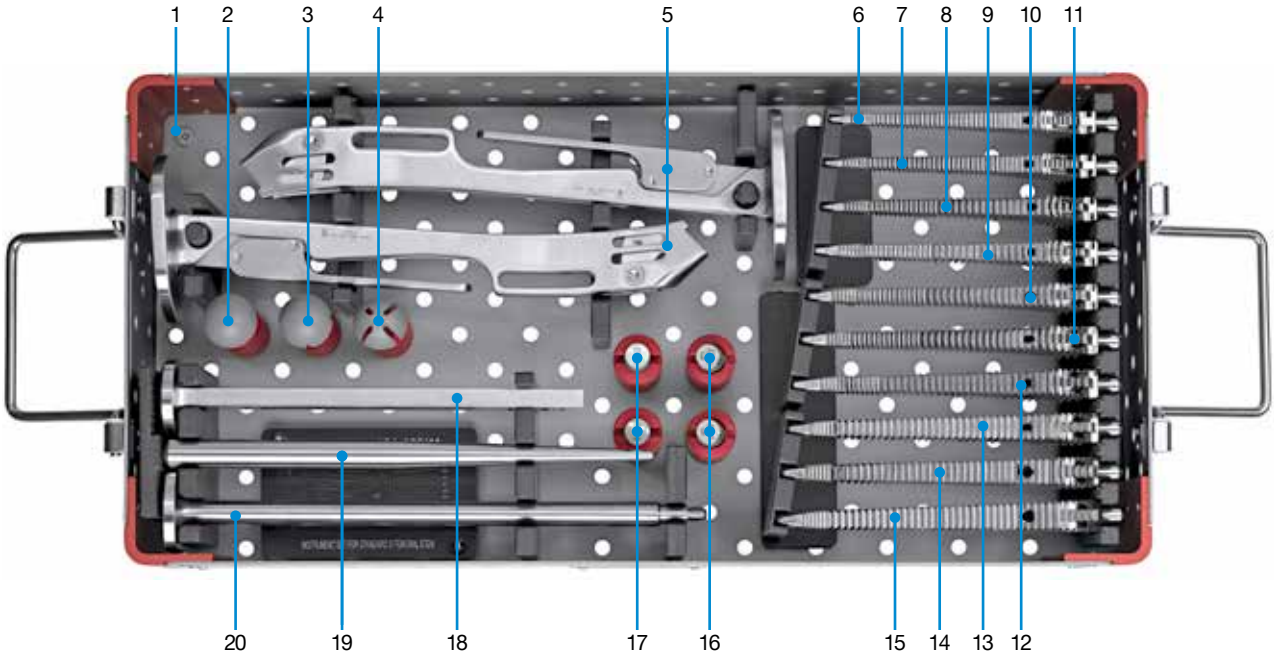

**Standard D hip prosthesis stems, lateralized**

MAT Ti6Al4V, taper 12/14, CCD angle 124°

| REF | Size |
|---|---|
| 164-021 | 01 |
| 164-022 | 0 |
| 164-023 | 1 |
| 164-024 | 2 |
| 164-025 | 3 |
| 164-026 | 4 |
| 164-027 | 5 |
| 164-028 | 6 |
| 164-029 | 7 |
| 164-030 | 8 |
| 164-031* | 9 |
| 164-032* | 10 |
| 164-033* | 11 |
| 164-034* | 12 |

* on request

## 164-100/11 Instrument Set – Standard D Hip Prosthesis Stems




| | REF | Description | Qty |
|---|---|---|---|
| 1 | 164-101/11 | **Container, sterilizable, only** | 1 |
| 2 | 162-428/01 | **Plastic trial head,** Ø 28mm S | 1 |
| 3 | 162-428/02 | **Plastic trial head,** Ø 28mm M | 1 |
| 4 | 162-428/03 | **Plastic trial head,** Ø 28mm L | 1 |
| 5 | 162-412/01 | **Rasp handle** for attachment to rasp | 2 |
| 6 | 164-111/01 | **Rasp stem**, Size 01 | 1 |
| 7 | 164-112/00 | **Rasp stem**, Size 00 | 1 |
| 8 | 164-112/01 | **Rasp stem**, Size 1 | 1 |
| 9 | 164-112/02 | **Rasp stem**, Size 2 | 1 |
| 10 | 164-112/03 | **Rasp stem**, Size 3 | 1 |
| 11 | 164-112/04 | **Rasp stem**, Size 4 | 1 |
| 12 | 164-112/05 | **Rasp stem**, Size 5 | 1 |
| 13 | 164-112/06 | **Rasp stem**, Size 6 | 1 |
| 14 | 164-112/07 | **Rasp stem**, Size 7 | 1 |
| 15 | 164-112/08 | **Rasp stem**, Size 8 | 1 |
| 16 | 164-102/01 | **Trial neck segment** for trial head | 2 |
| 17 | 164-102/02 | **Trial neck segment** for trial head | 2 |
| 18 | 162-403/01 | **Box chisel** | 1 |
| 19 | 162-401/01 | **Stem extractor** for prosthesis stem | 1 |
| 20 | 162-101/01 | **Driver-extractor** for prosthesis stem | 1 |
| | Optional on request | | |
| | 164-112/09 | **Rasp stem**, Size 9 | |
| | 164-112/10 | **Rasp stem**, Size 10 | |
| | 164-112/11 | **Rasp stem**, Size 11 | |
| | 164-112/12 | **Rasp stem**, Size 12 | |

## X-ray Templates

| REF | X-ray templates |
|---|---|
| | for Standard D hip prosthesis stem, cementless, taper 12/14, 115% natural size, set of 14 sheets |
| 164-200/01 | **Standard D hip prosthesis stem, standard** |
| 164-200/02 | **Standard D hip prosthesis stem, lateralized** |

## Indications

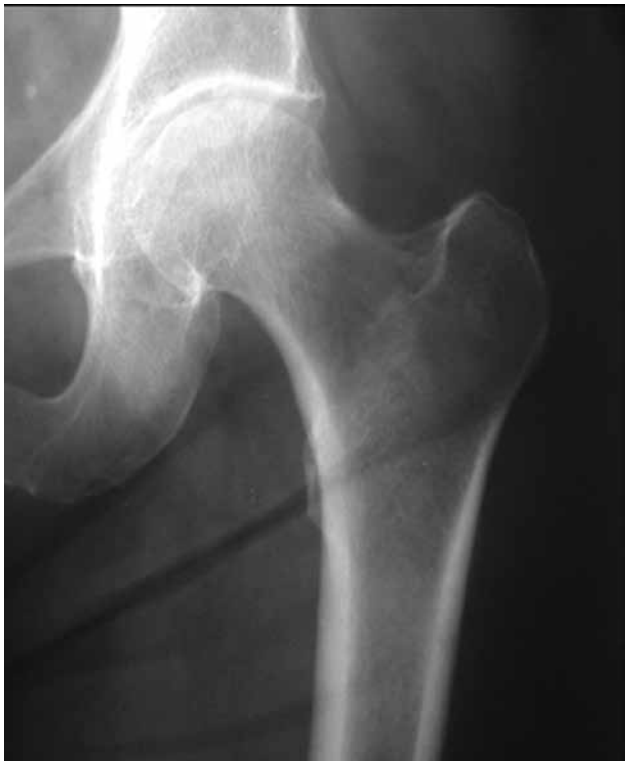


**Fig. 1**

Non-cemented implant for biological fixation as a total or partial hip prosthesis. Primary stability is provided by the wedge-shaped longitudinal profile with a rectangular cross-section.

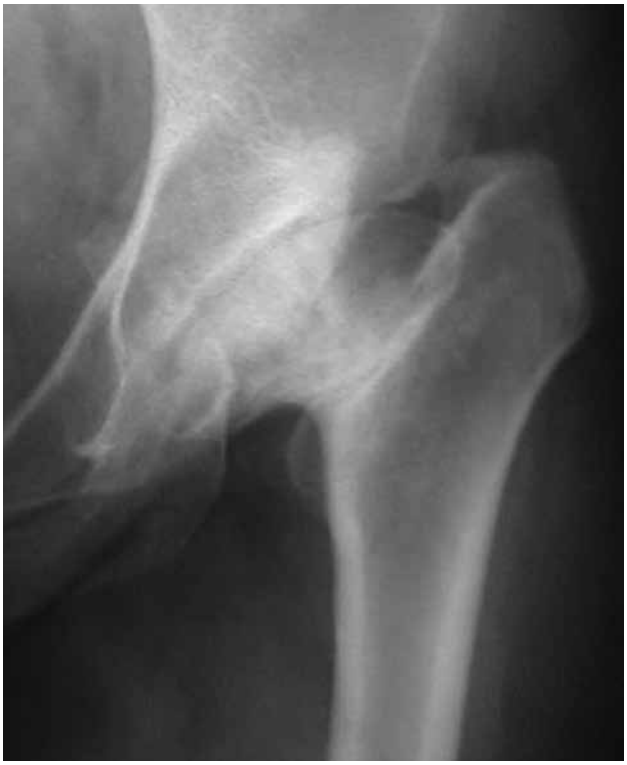


**Fig. 2**

Even where the bone anatomy is abnormal, this system is excellent for primary treatment of common hip disorders (e.g. hip dysplasia, see Fig. 2) or for secondary treatment (after trauma or osteotomy) as long as the bone quality is adequate.

**Indications**
Monolithic cementless stems are indicated for use in partial or total hip arthroplasty and they are intended for press-fit (uncemented) use. When used in total hip arthroplasty, monolithic cementless stems are intended for use with modular heads and compatible acetabular cups. When used in partial hip arthroplasty, they are intended for use with femoral heads intended for partial hip arthroplasty or bipolar heads.

Hip arthroplasty is intended for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

- Non-inflammatory degenerative joint disease including osteoarthritis, avascular necrosis and dysplasia;
- Rheumatoid arthritits;
- Treatment of femoral head and neck fractures.

**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 diseases affecting the concerned limb;
- Poor bone stock (for example 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!**

**Waldemar Link GmbH & Co. KG, Hamburg**

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