LINK®


# Standard P

## 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 P
## Cementless Hip Prosthesis Stems

## System Description

The cementless Standard P straight stem has a rectangular cross section with tapering profiles. In the proximal area it has ribs running longitudinally which level out towards the distal end. These extend into the trabecula of the femur and guarantee primary stability.

The stem has been constructed in such a way that unwanted twisting, varization and subsidence are avoided as far as possible.

The macro-roughness of the surface allows the stem to become well integrated into the bone giving optimal secondary stability.

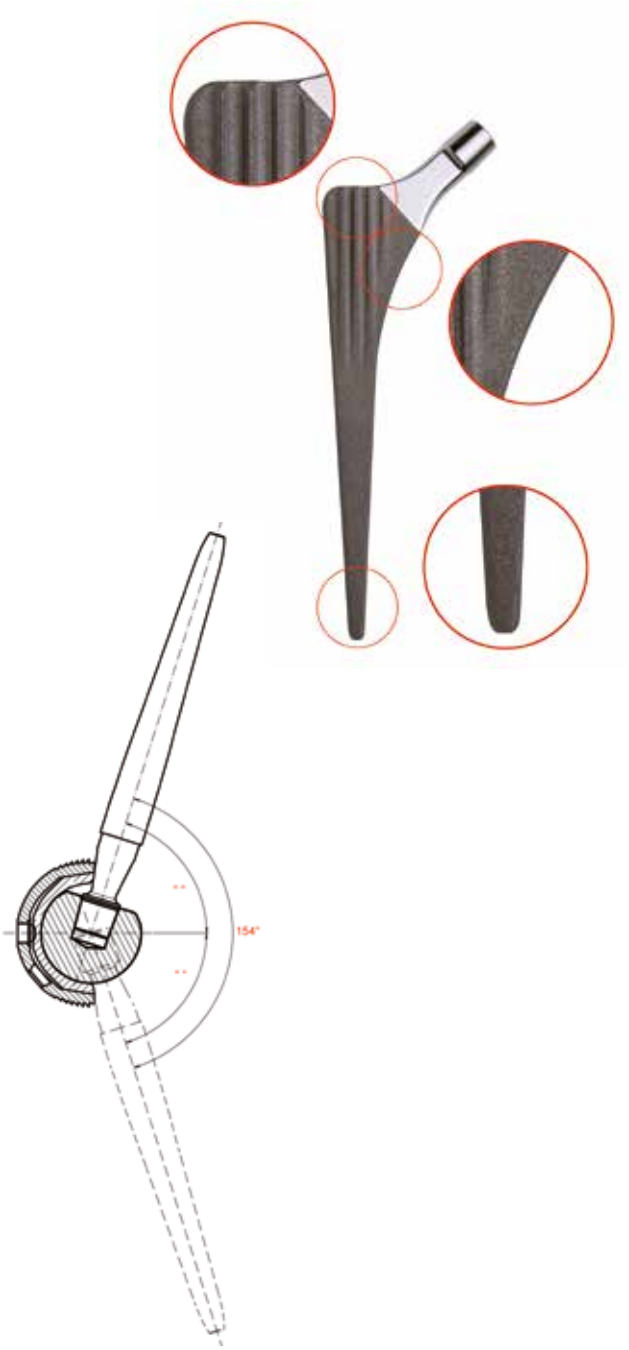
### Materials

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

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

### Kinematic Properties


Two different anatomical configurations are available: standard and lateralized.
This allows the surgeon to reconstruct different anatomical joint forms by shifting the stem axis from a “standard” position (reference offset 39.5-55.3 mm) to a “lateralized” position (offset +5 mm).




This option of enlarging the offset without changing the total length of the stem ensures optimal implant stability.

The broad medial curvature is rounded off so that the prosthesis gives a good anatomical fit in the area of the calcar femorale. The distal end is strongly tapered to prevent unwanted pressure peaks. The macro-roughness of the surface supports excellent biological fixation.

The polished surface of the tapered neck reduces the risk of polyethylene particles being formed as a result of accidental contact with the acetabular component. The neck is also tapered. The combination with the 12/14 taper thus gives a large range of motion of over 150° (in combination with a head diameter of 36 mm).

**Applications**

The Standard P hip prosthesis stem is a cementless 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.

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

### Preoperative planning

The stem size of the implant and the offset are determined using the appropriate templates (Fig. 1).

The templates are enlarged by a factor of 1 : 1.15. The size is determined from good quality AP and axial X-rays with adequate contrast. Each X-ray image should be large enough to allow an entire template to be laid on top.

The stem size and the level for resection of the femoral neck should be selected such that the tip of the greater trochanter is level with the center of the prosthesis head (Fig. 2).

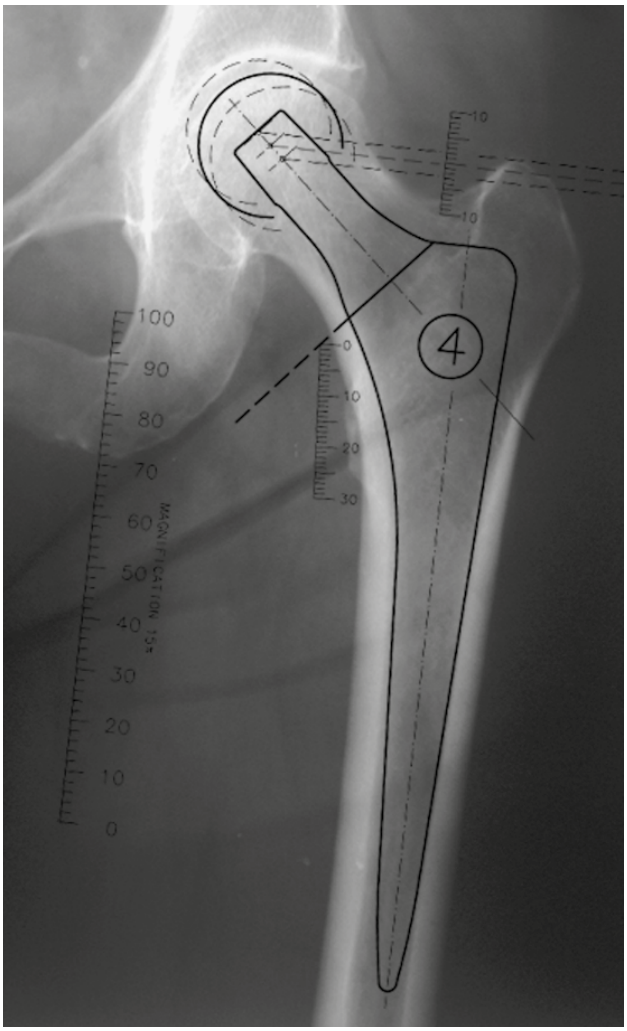



Fig. 1

**Note:**
**Preoperative planning gives an initial estimate but cannot conclusively determine the size of stem to be used. This is decided intraoperatively.**

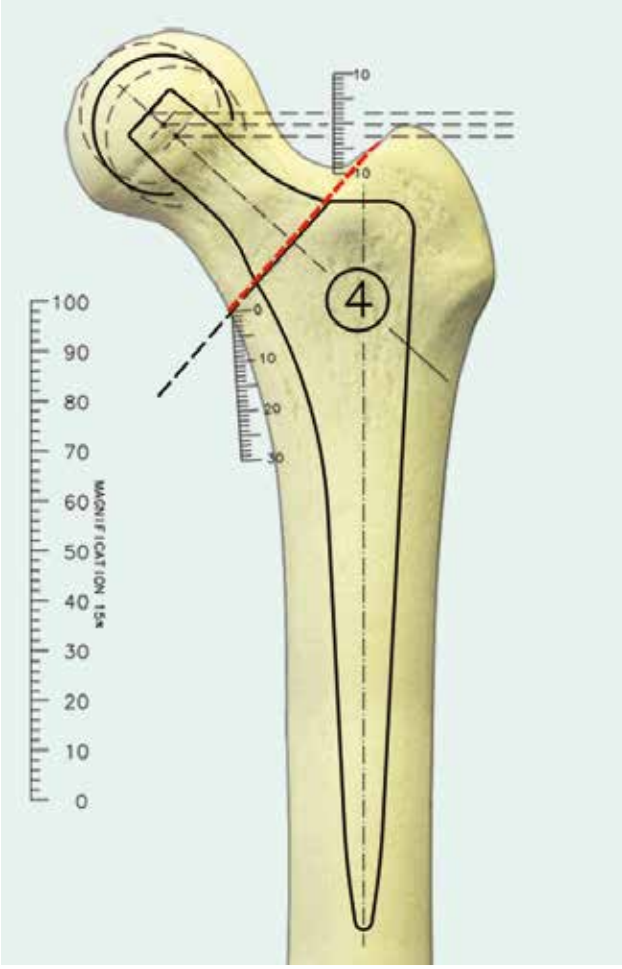



Fig. 2

## Positioning the patient

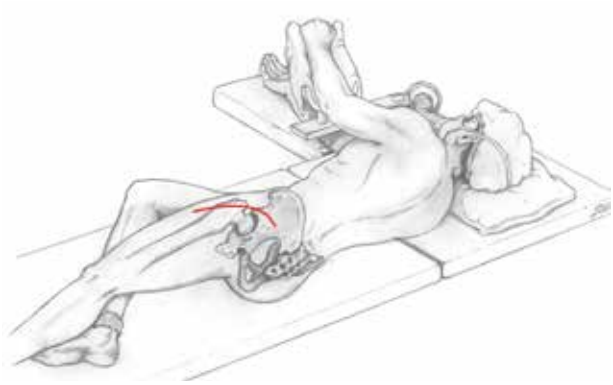


Fig. 3

**Note:**
**Fig. 3 shows the usual 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 his/her side.

Make a posterolateral incision (Fig. 3).

After opening of the fascia lata and resection of the external rotator muscles, make an incision in the joint capsule. Dislocate the femoral head in a dorsal direction so that it lies free.

## Resection of the femoral neck

Fig. 4

After dislocation the femoral head is resected with an oscillating saw (Fig. 4).

The stability of the implant does not depend on the medioproximal support. As a result, resection at an unplanned level does not damage the stability.

**Note:**
**After resection of the femoral neck, the acetabulum is usually prepared.**

## Opening the medullary cavity

Fig. 5

Using the box chisel, open the medullary cavity in such a way that the required anteversion is produced (Fig. 5).

## Preparation of the medullary cavity

Fig. 6

Use the Standard P rasp stems to prepare the implant bed.

Fig. 7

Open the lever on the rasp handle (Fig. 6 + 7) and place the neck of the rasp in the socket on the handle.

Fig. 8

Then close the lever again (Fig. 8).

Fig. 9

Starting with the smallest rasp prepare the medullary cavity with increasing sizes until the required depth is reached (Fig. 9). This is usually, though not always, the depth envisaged during preoperative planning. Leave the last rasp in place and remove the rasp handle.

## Trial reduction

Fig. 10

The acetabular cup is usually implanted before the stem. Trial reduction can then be carried out.

Fig. 11

Two trial neck sections (standard and lateralized) are available so that sufficient tension, appropriate leg length and physiology can be recreated (Fig. 10-11). Attach the selected trial neck section to the rasp still in the femur.

Fig. 12

Fig. 13

Push the trial head (Ø 28 mm; S, M, L) onto the trial neck until it locks (Fig.12-13). Carry out trial reduction (Fig. 14).

Once the stem type (offset) and the final head have been selected, remove the trial head and neck section. Then remove the rasp with the appropriate rasp handle.

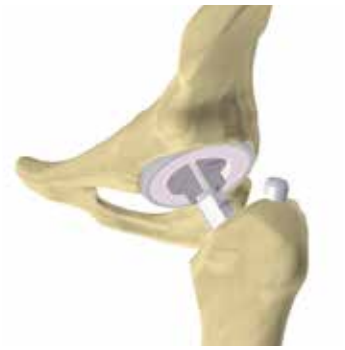


Fig. 14

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

### Inserting the stem

Fig. 15

Remove the Standard P prosthesis stem of the required size and type (standard or lateralized) from the sterile packaging.


Fig. 16

Fit the impactor into the socket on the shoulder of the stem (Fig. 15) and screw the long inner rod into the prosthesis stem with the T-shaped handle (Fig.16).

Fig. 17

Remove the T-shaped handle and insert the stem into the medullary canal (Fig. 17).

Fig. 18

Fig. 19

Drive it in up to the required depth with the impactor (Fig. 18 + 19) and a hammer.


Fig. 20

Remove the impactor by releasing the inner rod with the T-shaped handle (Fig. 19 and 20).

Fig. 21

Remove the cap protecting the taper (Fig. 21).

### Final trial reduction

Fig. 22

The trial heads can now be used to re-determine the correct head length for the prosthesis (Fig. 22). Reduce the joint and determine the ideal length for the prosthesis head, taking soft tissue tension and range of motion into account (Fig. 23).

Then remove the trial head.

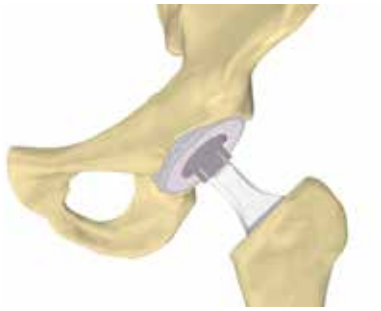


Fig. 23

### Attaching the final prosthesis head

Fig. 24

Remove the appropriate head (material, diameter, length) from the sterile packaging.
Clean and dry the taper of the stem thoroughly. This is essential, particularly with ceramic heads. Mount the head manually using axial pressure and a turning motion (Fig. 24).

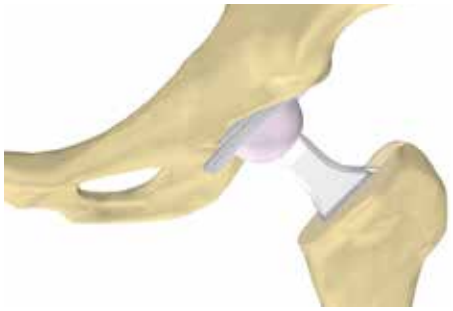


Fig. 25

Reduce the joint once the joint surfaces are absolutely clean (Fig. 25).

### Removing the components

Fig. 26

Fig. 27

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

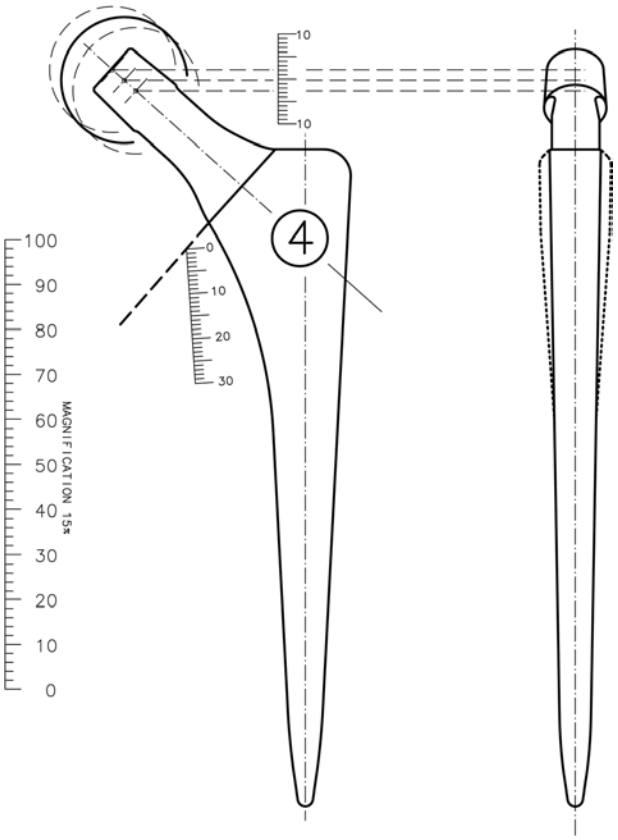
**Caution:**
**If a ceramic head has to be replaced with another ceramic head, only ceramic revision heads (with a metal inner taper) should be used.**

The stem can be removed with the slap hammer from the instrument set. This is screwed onto the impactor (Fig. 26-27).

## Standard P Hip Prosthesis Stems

Microporous surface structure, cementless

MAT Ti6Al4V, taper 12/14 mm




The stems are available in two different forms:

- Standard (CCD angle 132°) and lateralized (CCD angle 128°, offset +5 mm)
- Each of these forms is available in 11 sizes, increasing in steps
- The system thus allows optimal anatomical fitting of the prosthesis and makes it possible to recreate the properties of the whole joint with good functional results

Standard P stem

**Standard P hip prosthesis stems, standard**
MAT Ti6Al4V, microporous
Taper 12/14, CCD angle 132°

| REF | Size |
|---|---|
| 163-001 | 1 |
| 163-002 | 2 |
| 163-003 | 3 |
| 163-004 | 4 |
| 163-005 | 5 |
| 163-006 | 6 |
| 163-007 | 7 |
| 163-008 | 8 |
| 163-009 | 9 |
| 163-010 | 10 |
| 163-011 | 11 |

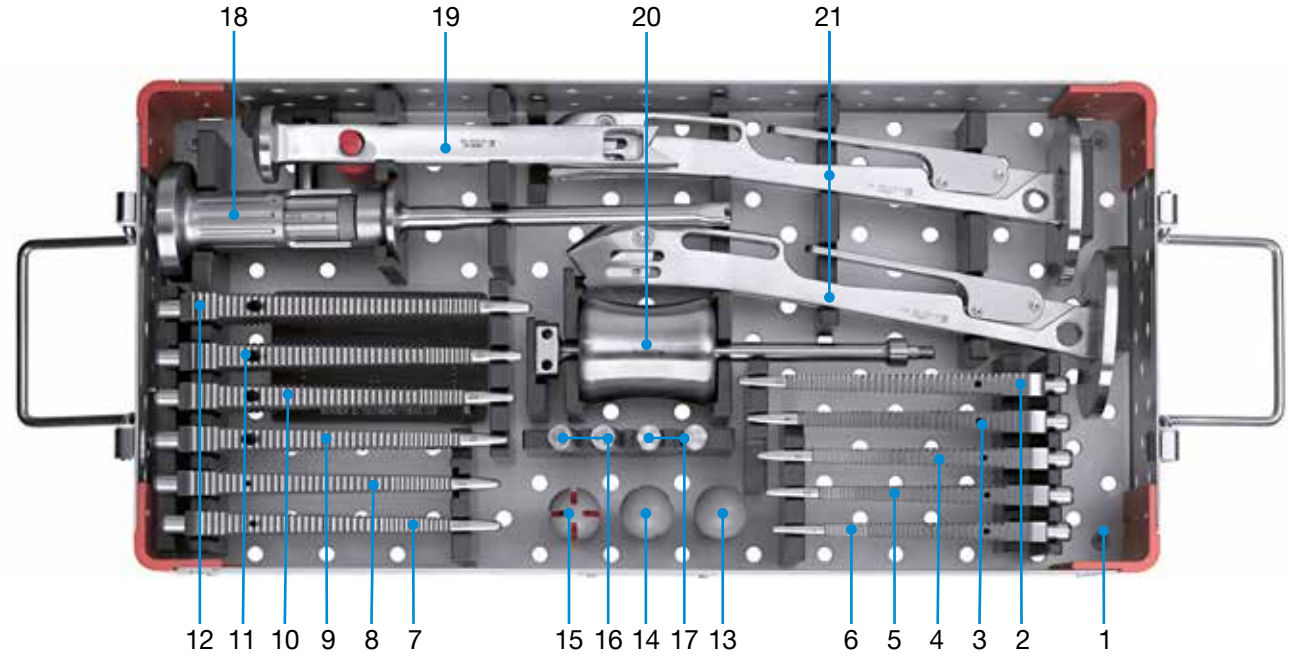
Standard P stem, lateralized

**Standard P hip prosthesis stem, lateralized**
MAT Ti6Al4V, microporous
Taper 12/14, CCD angle 128°

| REF | Size, lateralized + 5 mm |
|---|---|
| 163-021 | 1 |
| 163-022 | 2 |
| 163-023 | 3 |
| 163-024 | 4 |
| 163-025 | 5 |
| 163-026 | 6 |
| 163-027 | 7 |
| 163-028 | 8 |
| 163-029 | 9 |
| 163-030 | 10 |
| 163-031 | 11 |

## Instrument Set - Standard P, modified

**163-100/11 Instrument Set - Standard P Hip Prosthesis Stems**
**163-101/11 Container, sterilizable, only**




| | REF | Description | Qty |
|---|---|---|---|
| 1 | 163-101/11 | **Container**, sterilizable, only | 1 |
| 2 | 163-111/01 | **Rasp stem**, Size 1 | 1 |
| 3 | 163-111/02 | **Rasp stem**, Size 2 | 1 |
| 4 | 163-111/03 | **Rasp stem**, Size 3 | 1 |
| 5 | 163-111/04 | **Rasp stem**, Size 4 | 1 |
| 6 | 163-111/05 | **Rasp stem**, Size 5 | 1 |
| 7 | 163-111/06 | **Rasp stem**, Size 6 | 1 |
| 8 | 163-111/07 | **Rasp stem**, Size 7 | 1 |
| 9 | 163-111/08 | **Rasp stem**, Size 8 | 1 |
| 10 | 163-111/09 | **Rasp stem**, Size 9 | 1 |
| 11 | 163-111/10 | **Rasp stem**, Size 10 | 1 |
| 12 | 163-111/11 | **Rasp stem**, Size 11 | 1 |
| 13 | 162-428/01 | **Plastic trial head**, Ø 28 mm L | 1 |
| 14 | 162-428/02 | **Plastic trial head**, Ø 28 mm M | 1 |
| 15 | 162-428/03 | **Plastic trial head**, Ø 28 mm S | 1 |
| 16 | 163-102/01 | **Trial neck segment** for prosthesis head | 2 |
| 17 | 163-102/02 | **Trial neck segment** for prosthesis head | 2 |
| 18 | 162-401/11 | **Stem impactor and extractor** for prosthesis stem | 1 |
| 19 | 162-403/01 | **Box chisel** | 1 |
| 20 | 162-401/21 | **Slaphammer** | 1 |
| 21 | 162-412/01 | **Rasp handle** for attachement to rasp | 2 |

## X-ray Templates

| REF | X-ray templates |
|---|---|
| | for Standard P hip prosthesis stem, cementless<br>MAT Ti6Al4V, microporous, taper 12/14, 115% natural size,<br>Set of 11 sheets |
| 163-200/01 | **Standard P Hip Prosthesis Stem, standard** |
| 163-200/02 | **Standard P Hip Prosthesis Stem, lateralized** |

## Indications - Contraindications

**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!**

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