







LINK Prosthesis Heads

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. |

LINK Prosthesis Heads

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Important Information

System Description

The LINK Prosthesis Heads A

for total hip prostheses are small ceramic balls that are placed onto the hip stem. Due to the conical design of the 12/14 taper, the heads sit firmly on the stem and require no additional fixation.

LINK Prosthesis Heads A come in four diameters (28mm, 32mm, 36mm and 40mm) and four neck lengths, ranging from -4mm to +8mm. Detailed correlation can be seen in table below.

LINK Prosthesis Heads A come in two different materials that result in different colours:

- ISO 6474-2 ZTA Zirconoxid reinforced Aluminiumoxid Ceramic LINK CeraDur (White)
- ISO 6474-2 ZTA Zirconoxid reinforced Aluminiumoxid Ceramic BIOLOX delta (Pink)

The LINK Prosthesis Heads B

for total hip prostheses are small metal balls that are placed onto the hip stem. Due to the conical design of the 12/14 or 14/16 taper, the heads sit firmly on the stem and require no additional fixation.

LINK Prosthesis Heads B come in several diameters (22mm, 24mm, 26mm, 28mm, 32mm and 36mm) and neck lengths ranging from -4mm to +10.5mm.

Prosthesis Heads

Prosthesis Heads A

MAT LINK CeraDur - Ceramic
Taper 12/14 mm



| REF | Head-Ø mm | Neck length | Neck length mm |
|------------|-----------|-------------|----------------|
| 198-791/01 | 28 | short | -3.5 |
| 198-791/02 | 28 | medium | 0 |
| 198-791/03 | 28 | long | +3.5 |
| 198-792/01 | 32 | short | -4 |
| 198-792/02 | 32 | medium | 0 |
| 198-792/03 | 32 | long | +4 |
| 198-792/04 | 32 | extra long | +7 |
| 198-793/01 | 36 | short | -4 |
| 198-793/02 | 36 | medium | 0 |
| 198-793/03 | 36 | long | +4 |
| 198-793/04 | 36 | extra long | +8 |
| 198-794/01 | 40 | short | -4 |
| 198-794/02 | 40 | medium | 0 |
| 198-794/03 | 40 | long | +4 |
| 198-794/04 | 40 | extra long | +8 |

Note:

Ceramic Inserts out of LINK CeraDur must only be combined with LINK CeraDur Prosthesis Heads.

Prosthesis Heads A

MAT BIOLOX delta* - Ceramic
Taper 12/14 mm



| REF | Head-Ø mm | Neck length | Neck length mm |
|------------|-----------|-------------|----------------|
| 128-791/01 | 28 | short | -3.5 |
| 128-791/02 | 28 | medium | 0 |
| 128-791/03 | 28 | long | +3.5 |
| 128-792/01 | 32 | short | -4 |
| 128-792/02 | 32 | medium | 0 |
| 128-792/03 | 32 | long | +4 |
| 128-792/04 | 32 | extra long | +7 |
| 128-793/01 | 36 | short | -4 |
| 128-793/02 | 36 | medium | 0 |
| 128-793/03 | 36 | long | +4 |
| 128-793/04 | 36 | extra long | +8 |
| 128-794/01 | 40 | short | -4 |
| 128-794/02 | 40 | medium | 0 |
| 128-794/03 | 40 | long | +4 |
| 128-794/04 | 40 | extra long | +8 |

* BIOLOX delta is a product made by CeramTec GmbH, Plochingen, Germany

Prosthesis Heads

Prosthesis Heads B

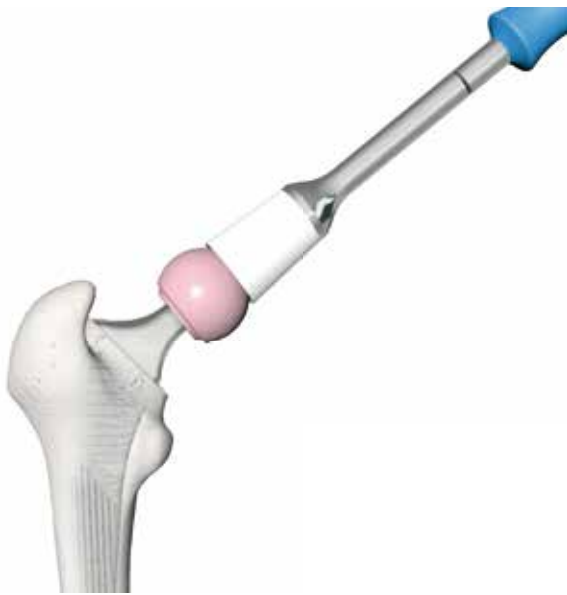
MAT CoCrMo alloy

Taper 12/14 mm



| REF | Head-Ø mm | Neck length | Neck length mm |
|----------------------------|-----------|------------------|----------------|
| 198-822/01 | 22 | short | -3.5 |
| 198-822/02 | 22 | medium | 0 |
| 198-824/01 | 24 | short | -3.5 |
| 198-824/02 | 24 | medium | 0 |
| 198-826/01 | 26 | short | -3.5 |
| 198-826/02 | 26 | medium | 0 |
| 198-826/03 | 26 | long | +3.5 |
| 198-828/01 | 28 | short | -3.5 |
| 198-828/02 | 28 | medium | 0 |
| 198-828/03 | 28 | long | +3.5 |
| 198-828/04 | 28 | extra long | +7 |
| 198-828/05 | 28 | extra extra long | +10.5 |
| 198-832/01 | 32 | short | -4 |
| 198-832/02 | 32 | medium | 0 |
| 198-832/03 | 32 | long | +4 |
| 198-832/04 | 32 | extra long | +8.5 |
| 198-836/01 | 36 | short | -4 |
| 198-836/02 | 36 | medium | 0 |
| 198-836/03 | 36 | long | +4 |
| 198-836/04 | 36 | extra long | +8 |

Surgical Technique



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 (**175-360**) is used to gently tap the prosthesis head into position.

LINK Prosthesis heads with 12/14 taper can be combined with all LINK Hip stems with 12/14 taper and LINK heads with 14/16 taper can be combined with all LINK Hip stems with 14/16 taper.

Except stated otherwise. Please refer to the implant specific surgical technique.

Note:

Instruments that are required for implanting Prosthesis Heads are part of the LINK hip systems instrument sets and are listed in the respective catalogues.

Accessories

Instructions for Cleaning and Maintenance

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

Literature

Prosthesis Heads A, Ceramic

Do Ceramic Femoral Heads Reduce Taper Fretting Corrosion in Hip Arthroplasty? A Retrieval Study by S. M. Kurtz PhD, S. B. Kocagöz BSc, Josa A. Hanzlik MSc, R. J. Underwood PhD, J. L. Gilbert PhD, D. W. MacDonald MSc, G-C. Lee MDD, M. A. Mont MDe, M. J. Kraay MD, G. R. Klein MD, J. Parvizi MD, C. M. Rimnac PhD

Corrosion in modular total hip replacements: An analysis of the head-neck and stem-sleeve taper connections. by S. Munir, BE, MBIomedEa,*, Michael B. Cross, MDa,b, Christina Esposito, PhDa, Anna Sokolovaa, and William L. Walter, MBBS, FRACS, FAOrthA, PhDa

The Lancet, 'Failure rates of stemmed metal-on-metal hip replacements: analysis of data from the National Joint Registry of England and Wales'

[http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(12\)60353-5/abstract](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(12)60353-5/abstract)

http://www.altimed.by/en/products/hips/heads/biolox_delta_head/

<https://www.ceramtec.com/ceramic-materials/biolox/wear-osteolysis/>

<https://www.ceramtec.com/ceramic-materials/biolox/biocompatibility/>

<https://www.ceramtec.com/ceramic-materials/biolox/wear-osteolysis/>

Tribology of total hip arthroplasty prostheses, What an orthopaedic surgeon should know

Claude B. Rieker (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5367615/>)

Parvizi J. The influence of head material on polyethylene wear. Presented at the 13th EFORT Congress 2012. May 23-25. Berlin

Prosthesis Heads B, CoCrMo

Design Dossier W. LINK – DOC 08614 und 08725

Design Dossier W. LINK – DOC 08614 und 08725

Long, M., & Rack, H. (1998). Titanium alloys in total joint replacement—a materials science perspective. *Biomaterials*, 19(18), 1621-1639

Biomaterial test showed enhanced antimicrobial efficacy (against staphylococcus aureus) comparing titanium alloy and tantalum: Eurofins BioPharma, Product Testing Munich GmbH; Department of Microbiology, Behringstrasse 6/8, 82152, PlaneggMünchen, Germany; www.eurofins.com/pharma-services, Microbiology, Munich@eurofins.com (DOC-10461)



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

Indications / Contraindications

| LINK Prosthesis Heads A, Ceramic |
|---|
| Indications |
| Total primary hip endoprosthesis surgery in combination with prosthesis stems and cup or Bipolar Heads |
| Revision hip surgery (= endoprosthesis removal) using new prosthesis stems and cup |
| Revision hip surgery (= endoprosthesis removal) with cup left in situ without damage or permissible damage of the cup and liner, or when cup liner is exchanged |
| Contraindications |
| Revision hip surgery (=endoprosthesis removal) with the stem left in situ, when the taper of the stem is damaged |

| LINK Prosthesis Heads B, Metal (CoCrMo) |
|---|
| Indications |
| Total primary hip endoprosthesis surgery in combination with prosthesis stems and cup or Bipolar Heads |
| Revision hip surgery (= endoprosthesis removal) using new prosthesis stems and cup |
| Revision hip surgery (= endoprosthesis removal) with cup left in situ without damage or permissible damage of the cup and liner, or when cup liner is exchanged |
| Contraindications |
| Revision hip surgery (=endoprosthesis removal) with the stem left in situ, when the taper of the stem is damaged |
| Revision (=endoprosthesis removal) of a ceramic head, it has to be replaced with a revision ceramic head (with a metal inner taper) |

Note

A technical compatibility between all LINK heads with 12/14 taper and all LINK hip stems with 12/14 taper, as well as 14/16 heads and stems, is given. Valid head neck extensions are defined in the stem specific surgical technique. However, in certain revision cases a further extension might be clinically indicated and can be seen as the best treatment option for the patient. This has to be carefully evaluated by the surgeon, considering the patient's clinical condition and the level of physical activity before performing a hip replacement.

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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