INSTRUCTIONS FOR USE
COBALT CHROMIUM FEMORAL HEAD

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1. Product name and description

This box contains a modular femoral head. It is a component of a total hip prosthesis used when replacing the natural hip joint.
This range is compromised of the following parts:

Name	References
CoCr 5°42 FEMORAL HEAD ø 22.2 / -2 / 12-14 – SHORT NECK	P0206C22
CoCr 5°42 FEMORAL HEAD ø 22.2 / 0 / 12-14 – AVERAGE NECK	P0206M22
CoCr 5°42 FEMORAL HEAD ø 22.2 / +2 / 12-14 – LONG NECK	P0206L22
CoCr 5°42 FEMORAL HEAD ø 28 / -5 / 12-14 – EXTRA SHORT NECK	P0206028
CoCr 5°42 FEMORAL HEAD ø 28 / -3.5 / 12-14 – SHORT NECK	P0206C28
CoCr 5°42 FEMORAL HEAD ø 28 / 0 / 12-14 – AVERAGE NECK	P0206M28
CoCr 5°42 FEMORAL HEAD ø 28 / +3.5 / 12-14 – LONG NECK	P0206L28
CoCr 5°42 FEMORAL HEAD ø 28 / +7 / 12-14 - EXTRA LONG NECK	P0206E28
CoCr 5°42 FEMORAL HEAD ø 28 / +10.5 / 12-14 - XXL NECK	P0206228
CoCr 5°42 FEMORAL HEAD ø 32 / -6 / 12-14 – EXTRA SHORT NECK	P0206032
CoCr 5°42 FEMORAL HEAD ø 32 / -4 / 12-14 – SHORT NECK	P0206C32
CoCr 5°42 FEMORAL HEAD ø 32 / 0 / 12-14 – AVERAGE NECK	P0206M32
CoCr 5°42 FEMORAL HEAD ø 32 / +4 / 12-14 – LONG NECK	P0206L32
CoCr 5°42 FEMORAL HEAD ø 32 / +8 / 12-14 – EXTRA LONG NECK	P0206E32
CoCr 5°42 FEMORAL HEAD ø 32 / +12 / 12-14 – XXL NECK	P0206232

2. Materials used for the implant

Name	Material	Standards
P0206xxx CoCr HEAD	Low carbon-content cobalt chromium	NF ISO 5832-12: 2007

3. Choice of implants

Femoral heads must be used with a femoral stem that has a 12/14 at 5°42 neck (SpD2=12.6) and a polyethylene/metal friction torque acetabular cup.

4. Indications

- Use for total hip arthroplasty with polyethylene/metal friction torque.

5. Expected performance

For the performance of this medical device, please see the performance of the femoral or cotyloid implant with which it will be used.

6. Contraindications

- Combination with a metal or ceramic insert.
- Allergy to any of the components of the implant.

7. Factors likely to compromise implant success and device performance

- Significant deformations, congenital dislocation
- Ligament instability or serious and untreatable muscle contractures
- Patient history of infections or repeated falls

8. Adverse effect

- In all cases of joint replacement, asymptomatic localized progressive bone resorption (osteolysis) may be noted around prosthetic components as a result of foreign body reactions triggered by particles. These particles are generated by the interaction between the various components, as well as between the components and bone, mainly through mechanisms of wear, adhesion and fatigue. Other particles may also be produced by the wearing of another body. Osteolysis may lead to successive complications requiring the removal and replacement of prosthetic components.
- Although rare, cases of metal intolerance following insertion of prosthetic joints have been observed. In rare cases, implantation of foreign material in tissues may result in histological reactions involving the formation of macrophages and fibroblasts.
- Dislocation or subluxation of prosthetic components due to improper positioning and/or migration of components can occur. Muscle and fibrous tissue laxity can also contribute to these conditions.
- Prosthetic components can come loose or migrate following trauma.

9. Shelf life and sterility

Implants are supplied sterile and packaged individually in double wrapping. Sterilization is carried out by exposure to a minimum dose of 25 kGy of gamma irradiation.
The expiration date is printed on the label. Do not use implants after the expiration date.

DO NOT RESTERILIZE IMPLANTS

The performance of the device cannot be guaranteed if implants are re-sterilised (as plastic parts can become distorted or change structurally during the sterilisation process, and surfaces can become damaged; moreover, the efficacy of the decontamination method and integrity of the coating cannot be guaranteed).

10. Specific instructions for use

- Packaging must not show signs that could indicate a defect in the sterility and/or integrity of the medical device.
- Never use damaged or explanted implants. If reused, the implant's long-term performances in terms of restoring function and mobility cannot be guaranteed. In addition, the use of an explant could contaminate the patient.
- When handling implants in the operating room, all necessary precautions must be taken to reduce risk of damaging the implants (scratches, etc.).
- For the Morse Taper to operate correctly, the male and female parts of the conical assembly must not be soiled.
- The implantation must be performed by an orthopedic surgeon experienced in lower limb surgery.
- Use the instrumentation designed by the manufacturer for inserting the related femoral stem.
- Do not use items from this prosthetic system with items from other systems and/or other manufacturers, other than those listed in Point 11.
- 22,2mm heads P0206C22, P0206M22 et P0206L22 are not compatible and must not be used with following Zimmer cup and liner:
  - Müller® and Brunswick cups
  - Alpha liner (associed with Allofit® cups)
  - Trilogy® liners 20deg Elevated (associed with Trilogy and Trabecular Metal™ Modular cups)
- The possible effects of a magnetic resonance imaging environment on this device have not been determined. This product has not been subjected to heating or migration tests in a magnetic resonance imaging environment.
- Soiled implants must be handled as biological waste.

11. Compatible medical devices

- Any Biomet femoral stem with a taper that meets the following specifications:
  - 5°42' taper angle
  - SpD2 = 12.6
- Polyethylene/metal friction torque Biomet Group acetabular cups with the correct diameter and their related instrumentation.
- Zimmer cups (except exclusion on point 10) :
  - Continuum®
  - Trilogy
  - Allofit®
  - Allofit IT
  - Trabecular Metal Modular
  - Müller
- Instrumentation for Biomet Group stems with a taper that meets the abovementioned specifications.

12. Storage

Products should be stored in their original packaging

13. Additional instructions for the surgeon

The surgeon should be aware that the anatomic, chemical and physical characteristics of living tissue limit the possibilities in the form and choice of material. Consequently, it should be noted that, like bone that no longer carries out its functions, prosthetics have their limits.
Proper implantation of the femoral head is essential for successful arthroplasty and long-lasting results.
Regular roentgenographic tests must be carried out to avoid future serious complications.

14. Patient information

Accepted practices in postoperative care are important. Failure of the patient to follow postoperative care instructions involving rehabilitation can compromise the success of the procedure. The patient is to be advised of the limitation of the reconstruction and the need for protection of the implants from full load bearing until adequate fixation and healing have occurred.

Excessive, unusual and/or awkward movement and/or activity, trauma, excessive weight, and obesity have been implicated with premature failure of certain implants by loosening, fracture, dislocation, subluxation and/or wear. Loosening of the implants can result in increased production of wear particles, as well as accelerate damage to bone making successful revision surgery more difficult.

The patient is to be made aware and warned in advance of general surgical risks, possible adverse effects as listed, and to follow the instructions of the treating physician, including follow-up visits. The patient must be

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The patient is to be made aware and warned in advance of general surgical risks, possible adverse effects as listed, and to follow the instructions of the treating physician, including follow-up visits. The patient must be warned that the device does not replace normal healthy bone, and that the implant can break or be damaged as a result of excessive load bearing or trauma. The patient must be warned to inform any other medical practitioner who may treat him in the future of the presence of the implant.

Wear and corrosion of the metal components can cause an "adverse local tissue reaction (ALTR)" or an "adverse reaction to metal debris (ARMD)", which can damage the surrounding bone and soft tissues. The debris can cause soft tissue necrosis and may affect the results of revision surgery.

	**Warning, see the instruction leaflet**
	**Do not reuse**
LOT	**Batch code**
REF	**Catalogue reference**
	**Use by**
STERILE R	**Sterilized by irradiation**

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