

CoCr Metal femoral heads M30NW Metallic femoral heads



IMPORTANT:

AMPLITUDE, as a manufacturer recommends that all personnel responsible for handling and/or implanting the devices read and understand this document and the surgical technique before use.

The patient must be properly informed about the device and the information contained in the present instructions for use.

The medical devices presented in these instructions for use are not registered in all countries. Please contact your AMPLITUDE representative to find out if they are available.

1. DESCRIPTION AND USERS

This package contains an implantable medical device: a CoCr metal femoral head or a M30NW metallic femoral head. This prosthetic device is a component of hip prosthesis system. To form a hip prosthesis, all parts must be provided by AMPLITUDE. AMPLITUDE disclaims all responsibility if used with prosthetic components from other companies except specific authorised associations.

The selection of the appropriate implants must be made by using the recommendations of the surgical technique available upon request the instrumentation or/and by using the x-ray templates.

CoCr metal femoral heads are available in various diameters (22.2, 28, 32 and 36mm) and neck lengths (short, medium, long and extra-long neck) for **12/14 taper** femoral heads.

M30NW metallic femoral heads are available in various diameters (22.2, 28, and 32 mm) and neck lengths (short neck, medium neck, long neck, and extra-long neck) for **10/12** and **12/14 taper** femoral heads.

The implantation and removal of a joint prosthesis with its associated instrumentation must only be performed by a qualified surgeon. It requires knowledge of anatomy, biomechanics, and reconstructive surgery of the musculo-skeletal system. The surgeon must operate in accordance with the state of the art and the scientific progress in the knowledge of hip replacement surgery and the surgical technique.

These devices intended to be handled by scrub nurses, operating room staff and any participant of the supply chain from manufacturing to operating room. These devices are intended to be used in the sterile area of the operating room in healthcare facilities.

These devices are intended to be in contact with hip joint tissues, bones and fluids.

2. RECOMMENDATIONS ABOUT THE COMPONENTS ASSOCIATIONS

A total hip prosthesis consists of several components: a femoral stem, a femoral head and a cup with an acetabular liner. They should be fixed using the appropriate method, according to the instructions for use, the surgical techniques, and the specifications on the label.

When making the choice of components, the surgeon must have a complete understanding of the compatibility between the different components (size, type, material).

AMPLITUDE implants must be assembled using AMPLITUDE components as defined below and in the surgical techniques (see list below):

For CoCr metal femoral heads:

Device brand name	Surgical technique reference
SATURNE cup	TO.H.007
SATURNE II cup	TO.H.002
AUSTRAL cup	TO.H.015
E ² femoral stem	TO.H.011
EVOK femoral stem	TO.H.001
F.A.I.R. femoral stem	TO.H.003

For M30NW metallic femoral heads - 12/14 taper:

Device brand name	Surgical technique reference
SATURNE cup	TO.H.007
SATURNE II cup	TO.H.002
SPHERIC bipolar cup	TO.H.010
EVOK femoral stem	TO.H.001
F.A.I.R. femoral stem	TO.H.003

For M30NW metallic femoral heads - 10/12 taper:

Device brand name	Surgical technique reference
SATURNE acetabular cup (cementless / cemented)	TO.H.007
SATURNE II acetabular cup	TO.H.002
SPHERIC bipolar cup	TO.H.010
ACOR femoral stem	TO.H.006
INITIALE femoral stem	TO.H.009
OPTIMAL femoral stem	TO.H.012
Modular Neck Extraction Total Hip Arthroplasty	TO.H.023
INTEGRALE REVISION and GENERIC REVISION femoral stem	TO.H.013
INTEGRALE and GENERIC femoral stem	TO.H.005
STELLAR acetabular cup	TO.H.004

2.1 - Head/ femoral stem assembly:

All AMPLITUDE CoCr metal femoral heads - taper 12/14 are compatible with the following AMPLITUDE femoral stems **as long as they have a morse taper of the same type (12/14) and the same angle (5° 42' 30'')**:

- E² femoral stem (all sizes),
- EVOK femoral stem cemented and cementless version (all sizes),
- F.A.I.R. femoral stem (all sizes).

All AMPLITUDE M30NW metallic femoral heads - taper 12/14 are compatible with the following AMPLITUDE femoral stems **as long as they have a morse taper of the same type (12/14) and the same angle (5° 42' 30'')**:

- EVOK femoral stem cemented and cementless version (all sizes),
- F.A.I.R. femoral stem (all sizes).

All AMPLITUDE M30NW metallic femoral heads - taper 10/12 are compatible with all AMPLITUDE femoral stems, all variants, all sizes **as long as they have a Morse taper of the same type (10/12) and the same angle (5° 42' 30'')**:

- INTEGRALE femoral stem,
- GENERIC femoral stem,
- INTEGRALE revision femoral stem,

- GENERIC revision femoral stem,
- EXTREME reconstruction femoral stem (discontinued),
- INITIALE femoral stems (standard and dysplasia),
- INITIALE revision femoral stem,
- ACOR monobloc (cemented and cementless version) femoral stem (standard and lateralized version),
- OPTIMAL revision-reconstruction femoral stems with modular necks.

2.2 - Head/ modular neck assembly:

AMPLITUDE modular necks are designed to be assembled with modular femoral heads **as long as they have a morse taper of the same type (10/12 or 12/14) and the same angle (5° 42' 30'')**.

However, there are some incompatibilities between modular necks and femoral heads. These incompatibilities are described in the instructions for use that are provided with modular necks.

2.3 - The head/liner or head/acetabular component assembly must be done between a head and a liner (or acetabular component when used without metal-back) of same internal diameter.

Mixing sizes is not permitted (for instance: a 28 mm diameter head with a 32 mm inside diameter liner).

Note: The assembly of an extra-long neck head with a liner from the SATURNE / SATURNE II range is prohibited.

The assembly of a long neck head with a liner from the SATURNE / SATURNE II range increases the risk of wear of the liner and thus intra-prosthetic dislocation. Thus, this assembly is not recommended for patients younger than 75 years. For the same reasons, the assembly of a head with an extra-long neck with the SPHERIC cup is also to be avoided.

CoCr metal femoral head can be combined with either a polyethylene (PE) liner or a highly cross-linked polyethylene (XLPE) liner.

M30NW metallic femoral heads can be combined with a polyethylene (PE) liner.

AMPLITUDE CoCr metal femoral head are compatible with the following AMPLITUDE acetabular components (all sizes):

- AUSTRAL acetabular cup,
- SATURNE cemented acetabular cup,
- SATURNE cementless acetabular cup,
- SATURNE II acetabular cup.

AMPLITUDE M30NW metallic femoral heads (taper 10/12 and taper 12/14) are compatible with the following acetabular components (all sizes):

- SATURNE cementless acetabular cup,
- SATURNE cemented acetabular cup,
- SATURNE reconstruction acetabular cup (discontinued),
- SATURNE II acetabular cup,
- SPHERIC bipolar cup.

AMPLITUDE M30NW metallic femoral heads (taper 10/12) are compatible with the following acetabular components (all sizes):

- STELLAR (FREELINER) acetabular cup.

2.4 Associations with the instrumentation

AMPLITUDE CoCr metal femoral heads and M30NW metallic femoral heads must be implanted / removed using AMPLITUDE instrumentation specifically supplied for this purpose. AMPLITUDE instrumentation to remove medical devices is not available for all devices. In this case, the standard operating room instrumentation can be used.

AMPLITUDE CoCr metal femoral heads and M30NW metallic femoral heads can be implanted using

E.TO.I.L.E. orthopaedic extension table.

AMPLITUDE M30NW metallic femoral heads (taper 10/12) can also be implanted using AMPLIVISION navigation system and associated navigated instruments manufactured by AMPLITUDE.

Please consult dedicated IFUs provided with these devices for further information.

For all other combinations clinical performance has not been demonstrated.

3. COMPOSITION OF MEDICAL DEVICE

The constitutive materials of the femoral heads are:

Chrome Cobalt Alloy (CoCrMo) according to ISO 5832-12 standard.

The composition of the constitutive material used for CoCr metal femoral heads is detailed in the table below:

Element	Mass fraction %
Chromium (Cr)	26 to 30
Molybdenum (Mo)	5 to 7
Iron (Fe)	0.75 maximum
Manganese (Mn)	1 maximum
Silicon (Si)	1 maximum
Carbon (C)	0.14 maximum
Nickel (Ni)	1 maximum
Nitrogen (N)	0.25 maximum
Cobalt (Co)	Balance

Stainless steel alloy (M30NW) according to ISO 5832-9 standard.

The composition of the constitutive material used for M30NW metallic femoral heads is detailed in the table below:

Element	Mass fraction %
Carbon (C)	0.08 maximum
Silicon (Si)	0.75 maximum
Manganese (Mn)	2.00 to 4.25
Nickel (Ni)	9.0 to 11.0
Chromium (Cr)	19.5 to 22.0
Molybdenum (Mo)	2.0 to 3.0
Niobium (Nb)	0.25 to 0.80
Sulfur (S)	0.01 maximum
Phosphorus (P)	0.025 maximum
Copper (Cu)	0.25 maximum
Nitrogen (N)	0.25 to 0.50
Iron (Fe)	Balance

AMPLITUDE CoCr metal femoral heads and M30NW metallic femoral heads are not made with natural rubber latex. No materials containing natural rubber latex are used during the manufacturing process.

Specific warnings related to some materials

CoCr metal femoral heads contain the following substance defined as carcinogenic, mutagenic or toxic to reproduction (CMR) 1B in a concentration of maximum 69% weight by weight.

Cobalt: Chemical Abstract Service unique identifier (CAS No): 7440-48-4.

For more information, please consult ECHA website: <https://echa.europa.eu/home>.

4. INTENDED USE AND PATIENT POPULATIONS

The M30NW metallic femoral heads are intended for being used as femoral components for replacement of

total or partial hip joint in order to reduce pain and restore hip function in comparison with preoperative status. The CoCr metal femoral heads are intended for being used as femoral components for total hip replacement in order to reduce pain and restore hip function in comparison with preoperative status.

A total or partial (option only possible with M30NW metallic femoral heads) hip arthroplasty can only be considered in case of severe joint pathology after failure of the conservative treatments.

The CoCr metal femoral heads and M30NW metallic femoral heads are intended to be implanted in patients with mature skeletal development and with adequate available bone stock (left to the surgeon's discretion) and whose health condition allows undergoing an orthopaedic surgery.

The choice of total or partial (option only possible with M30NW metallic femoral heads) hip arthroplasty for each patient is made by experienced surgeons.

5. INDICATIONS

Primary total hip arthroplasty is indicated in:

- Primitive and secondary hip osteoarthritis,
- Aseptic osteonecrosis,
- Rheumatoid arthritis/inflammatory diseases,
- Femur, hip and/or acetabulum fracture.
- Hip joint arthroplasty when other devices or treatments have failed.

M30NW metallic femoral heads are also suitable for revision hip arthroplasty and for joint reconstruction.

M30NW metallic femoral heads are also indicated in case of primary partial hip arthroplasty for the relief of pain and significant disability following femoral neck fracture.

CoCr metal femoral heads and M30NW metallic femoral heads must be used in combination with systems as approved by AMPLITUDE (see chapter 2).

6. PERFORMANCE CHARACTERISTICS AND CLINICAL BENEFITS

The expected clinical benefits of total hip prostheses using CoCr metal femoral heads and total/partial hip using M30NW metallic femoral heads are:

- Restoring hip joint functionality,
- Relieving pain.

Based on literature and national registry data, about 96% of primary total hip arthroplasty, 94% of partial hip arthroplasty and 84% of revision total hip arthroplasty implants continue to function at 10 years after surgery. However, patients' factors such as weight, bone quality, activity level and other medical condition and comorbidities may increase or decrease the expected lifetime of any implantable orthopaedic device.

7. CONTRAINDICATIONS

The main contraindications for total or partial (option only possible with M30NW metallic femoral heads) hip prostheses are:

- Pregnancy,
- Breastfeeding (only for CoCr metal femoral heads),
- Acute or chronic, local, or systemic infections which may affect the implant function,
- Severe mental, muscular, vascular, or neurological deficiencies affecting the limb in question,
- Destruction of bone or poor bone quality which may affect stability of the implant,
- Allergy to the implant materials.

Any underlying condition affecting the patient must be treated beforehand.

8. PREREQUISITES, WARNING AND PRECAUTIONS

8.1 Preoperative precautions

Patients must be informed about the factors that could compromise the success of the surgery and in particular:

- Overweight,
- Case history detailing infections and/or falls,
- Metabolic disorders that reduce the patient resistance or induce progressive bone deterioration,
- Local bone tumours,
- Severe bone deformities likely to affect the position or the stable implantation of the implants,
- Severe osteoporosis,
- Playing sports intensively,
- Playing risky sports or engaging in risky activities,
- Addictive behaviour.

It is essential not to modify the components.

8.2 Perioperative precautions

Modular components must be assembled securely. Component which has already been placed on a prosthesis stem and then removed must not be placed on the stem again.

Before the implantation of mechanically assembled components make sure that it is free of any foreign objects (bone chips, cement, tissue, various debris...). These may be the cause of abnormal wear of the joint surfaces. Use dedicated instruments to handle, assemble and position implants according to surgical techniques.

During the impaction of the different components of the prosthesis, it is necessary to handle the polished components with the utmost care in order to avoid any scratch or impact.

In case of surgical revisions, the state of the prosthetic components already in place (like stem neck or acetabular component etc.) must be assessed. Deteriorations such as scratches may have an impact on the functionality and/or stability of the prosthesis. **Damaged components must be replaced.**

In the case of revision surgery for M30NW metallic femoral heads, the remaining femoral head must be removed using a suitable instrument to avoid damage to the stem taper. After removal, the remaining stem taper must be inspected.

The surgeon must ensure that the different components are properly implanted, that they are functioning well together and that they are stable **at each stage and before closing the incision**.as this can lead to a potential risk of squeaking and/or grinding, loosening and dislocation.

8.3 Postoperative precautions

It is important for the patient to notify the surgeon of any event likely to compromise the good integration of the implant. Furthermore, the patient must undergo regular post-operative follow-ups to allow the detection of possible signs of deterioration of the prosthesis function. Likewise, any noise coming from the replaced joint must be reported by patients to their surgeon, even if the patient does not notice a decline in performance.

AMPLITUDE disclaims any responsibility in case of incorrect use of this medical device.

9. RESIDUAL RISKS AND SIDE EFFECTS

AMPLITUDE recommends that the surgeon informs the patient about all side effects of total/partial hip prosthesis. Patients should be advised to consult their surgeon in case of doubt about the following side effects. It cannot be guaranteed that the patient will recover total range of motion and anatomic function of the hip after the total or partial hip arthroplasty.

The most recurrent potential residual risks / side effects and potential complications usually encountered as rare (<1 in 1,000 implantations) with the use of CoCr metal femoral heads and M30NW metallic femoral heads include. Some are occasional (< 1 in 100 implantations) with the use of CoCr¹ metal femoral heads:

- Allergy to the implant materials,
- Adverse reactions of human tissues to wear debris and particles,
- Impact of the surgery on the patient's general condition,
- Periprosthetic bone fracture¹,
- Impingement between the implant and the surrounding tissues,
- Dislocation of component or the entire prosthesis¹,
- Impingement between the femoral neck and the acetabular cup,
- Lower limb-length discrepancy,
- Pain,
- Infection¹,
- Migration of a component or the entire prosthesis
- Loosening of a component or the entire prosthesis¹,
- Breakage of the component or the entire prosthesis,
- Wear of the bearing surfaces,
- Osteolysis,

Other events linked to the surgery or known in the state of the art can also occur:

- Hematoma,
- Heterotopic ossification,
- Pejorative bone remodelling around the prosthesis.
- Neurovascular disorders.
- Cardio-vascular, thromboembolic disorders: fat or pulmonary embolism, superficial or deep vein thrombosis.

Reporting side effects/serious incidents:

Serious incidents in relation to the device shall be reported to the manufacturer and the competent authority of the country in which the incident occurred.

10. MRI SAFETY INFORMATION



Security in magnetic resonance environment (MRI):

Nonclinical standardized testing demonstrated that the devices are compatible with MRI when used with the configurations specified below:

- Static magnetic field of 3T,
- Maximum spatial gradient field of 1,500 Gauss/cm,
- Normal operation mode only,
- Maximum MR system reported whole-body-averaged specific absorption rate (WB-SAR) of 2 W/kg for 15 minutes of scanning.

Amplitude does not recommend the use of a 1.5T MRI machine.

Heating:

For M30NW metallic femoral heads taper 10-12

Maximum measured temperature rise with 3T MRI is 5.7°C for 15mn of scanning with a WB-SAR measured by calorimetry of 2.06 W/kg (3.0-T/128MHz, GE Discovery MR750w system, software DV25.0_1549b).

For CoCr metal femoral heads and M30NW metallic femoral heads taper 12-14

Maximum measured temperature rise with 3T MRI is 9.2°C for 15mn of scanning with a WB-SAR measured by calorimetry of 4.7 W/kg (3.0-T/128MHz, GE Discovery MR750w system, software DV25.0_1549b).

Image Artifacts:

MR image quality may be compromised around the area of the implant. Therefore, optimization of MR imaging parameters to compensate for the presence of this implant may be necessary.

The image artifact caused by the device extends at maximum 118.5 mm when imaged with a gradient echo pulse sequence and a 3T MRI system.

11. STORAGE/HANDLING/DISPOSAL

Store the device in standard hospital environmental conditions unless specific requirements are defined and described on the product label.

The medical device delivered in this packaging is for **single use only**.

The prosthetic device contained inside this packaging is considered as sterile. A symbol indicates the packaging which maintains the sterile condition of the device. The integrity of the packaging must be checked before opening in order to detect any damage that may impact the integrity of the implant and its sterility.

A component with any kind of damage must not be used but has to be discarded instead. This also applies, for example, to a component which has been dropped. Only unused and undamaged components taken from the original packaging immediately prior to assembly must be used.

If the packaging has been damaged or if the packaging has been opened without the device having been implanted during surgery, do not use the device for subsequent surgery as its performance or sterility may be altered, involving patient safety.

Never use a damaged or reuse a removed implant as this could expose the patient to serious risks of infection or implant failure. Following ablation, carefully handle an explant as this could expose the user to risks of infection and/or cut. The implant must be destroyed in accordance with applicable regulations for handling biological medical waste

The expiry date of the device is shown on the outer packaging. This date must be checked before opening the packaging.

12. STERILIZATION

These medical devices are delivered sterile in a **double packaging barrier system** with a sterilization using gamma irradiation with minimum dose of 25 kGy.

If an accidental de-sterilization occurs, the medical device must be returned to AMPLITUDE.

13. SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

The Summary of Safety and Clinical Performance is intended to provide public access to an updated summary of the main safety and clinical performance aspects of the device.

This summary for **CoCr metal femoral head or M30NW metallic femoral heads** is available on the European Database on Medical Device (EUDAMED) website at the following address https://ec.europa.eu/tools/eudamed_

The summary of safety and clinical performance is linked to the BASIC UDI-DI of **CoCr metal femoral head or M30NW metallic femoral heads**. The summary of safety and clinical performance is available using this code directly on EUDAMED website.

BASIC UDI-DI of **CoCr metal femoral head**: 370108951030402PE07D.

BASIC UDI-DI of **M30NW metallic femoral heads taper 10/12 and 12/14**: 370108951030406PE089.

14. INFORMATION TO BE PROVIDED TO THE PATIENT

Some information presented in these instructions for use and additional documents need to be supplied to the patient.

Implant card:

An implant card is provided in the packaging of at least one of the components of the joint prosthesis system. The implant card needs to be completed with a traceability label for each device in the implanted joint prosthesis. The implant card provides information allowing the identification of the device, including the device name, the lot number, the UDI, the device model, as well as the name, the address and the website of the manufacturer. The website gives access to patient leaflets. Instructions to fill in the implant card are printed at the end of these instructions for use.

Once completed, the implant card is to be given to the patient.

Patient leaflet:

Information to be provided to the patient with an implantable device are available on the manufacturer's website <https://implantcard.amplitude-ortho.com> thanks to online and downloadable patient leaflets. Patients need their completed implant cards to access to these documents.

The following information are presented in patient leaflets with a wording adapted to lay people, they are also displayed into these instructions for use as:

- Warnings, and precautions:

- Contraindications and preoperative precautions in chapters 7 & 8.1,
- Residual risks and side effects in chapter 9,
- Measures to be taken with regard to reciprocal interference with MRI environment in chapter 10.

- Expected lifetime & necessary follow-up:

- Performance characteristics and clinical benefits of the device in chapter 6,
- Postoperative precautions, including necessary follow-up in chapter 8.3,

- Safe use of the device by the patient & materials:

- Quantitative and qualitative data about implanted materials in chapter 3,
- Postoperative precautions in chapter 8.3.

15. MEANING OF SYMBOLS

All the information strictly necessary for the surgeon to identify the device is located on the external package of the medical device.

Symbols are described at the end of these instructions for use.

Date CE marking first applied:

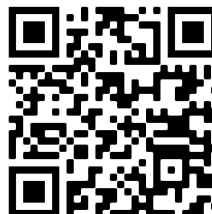
M30NW metallic femoral heads – taper 10/12: **1999**

M30NW metallic femoral heads – taper 12/14: **2009**

CoCr metal femoral heads: **2020**

The CE marking is only valid if it also appears on the packaging label.

<u>SYMBOL</u>	<u>MEANING</u>
	DO NOT RE-USE
	DO NOT RESTERILIZE
	USE BY DATE
	BATCH CODE
	STERILIZED USING IRRADIATION
	CONSULT INSTRUCTIONS FOR USE OR CONSULT ELECTRONIC INSTRUCTIONS FOR USE
	CAUTION
	CATALOG NUMBER
	DO NOT USE IF PACKAGE IS DAMAGED AND CONSULT INSTRUCTIONS FOR USE
	KEEP DRY
	MANUFACTURER
	DATE OF MANUFACTURE AND COUNTRY OF MANUFACTURE (MADE IN FRANCE)
	MR CONDITIONAL
	KEEP AWAY FROM SUNLIGHT
	MEDICAL DEVICE
	UNIQUE DEVICE IDENTIFIER
	DO NOT CONTAINS OR NO PRESENCE OF NATURAL RUBBER LATEX
	PRESCRIPTION ONLY
	QUANTITY
	DOUBLE STERILE BARRIER SYSTEM - check the instructions for use for what to do if the sterile packaging is damaged or unintentionally opened before use
 XXX	CONTAINS HAZARDOUS SUBSTANCES (Indicates a medical device that contains substances that can be carcinogenic, mutagenic, reprotoxic (CMR) or substances with endocrine disrupting properties) XXX : refers to the hazardous substance being present in the device described by its symbol in the periodic table of elements.

REF: NO145 (indG)**NO145-G / 2026-09-29****AMPLITUDE**

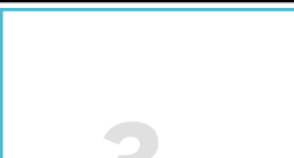
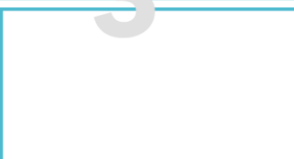
11 cours Jacques Offenbach - ZA Mozart 2

26000 VALENCE – FRANCE

Tél : +33 (0)4.75.41.87.41 / Fax : +33 (0)4.75.41.87.42



   	 	
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 	 	PATIENT'S IMPLANTS CARD* CARTE IMPLANTS POUR LE PATIENT HIP IMPLANTS** - IMPLANTS DE HANCHE  https://implantcard.amplitude-ortho.com amplitude AMPLITUDE 11 cours Jacques Offenbach, Zone d'Activités Mozart 2 26000 VALENCE - FRANCE IMPLANTCARD-HIP-05
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   	 	IMPLANT CARD* - CARTE IMPLANT HIP IMPLANTS** - IMPLANTS DE HANCHE  https://implantcard.amplitude-ortho.com amplitude 11 cours Jacques Offenbach, Zone d'Activités Mozart 2 26000 VALENCE - FRANCE IMPLANTCARD-HIP-2IMD-03
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- (1) (EN) Please fill in information according to the logos signification below
- (2) (EN) Check the operated side (left/right)
- (3) (EN) Stick the device labels in the frames delimited for this purpose (in blue)
- (4) (EN) Stick here multilingual labels according to the need

	(EN) Patient Name
	(EN) Healthcare institution
	(EN) Surgery date