E² Femoral stem

IMPORTANT:
AMPLITUDE, as a manufacturer, recommends that all staff people responsible for handling, decontaminating, sterilizing and/or implanting the devices read and understand the Instructions For Use (IFU) 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 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 from the E² range. This prosthetic device is a component of a total hip prosthesis system. To form a total 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 and trial implants supplied with the instrumentation or/and by using the x-ray templates.

E² femoral stems are available in 4 offsets (35.5, 37.5, 44 and 50 mm), with 1, 4, 5 and 3 sizes respectively. **E² femoral stems** are intended to be implanted with cement only. The description of the medical device affixed on the packaging, specifies the fixing method.

The implantation and removal of a joint prosthesis with its associated instruments 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 current information, scientific progress in the knowledge of hip replacement surgery, the surgical technique and the state of the art of hip replacement including modern cementing techniques.

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

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

2. RECOMMENDATIONS ABOUT THE COMPONENTS ASSOCIATIONS

The total hip prosthesis consists of several components: the femoral stem and the femoral head with either the acetabular cup with a liner or a bipolar cup. Some of these components may be associated with additional devices such as cement restrictor, distal centralizer, base hole cover or large head fixation screws. These additional devices are available in various sizes/lengths. 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 their choice, the surgeon must have a complete understanding of the compatibility between the different components (size, type, material).

AMPLITUDE implants must be assembled using components as defined below and in the surgical technique (TO.H.011).

2.1 Associations with femoral heads

E² femoral stems are all to be used with a modular head. All 12/14 femoral heads manufactured by AMPLITUDE are compatible with a femoral stem as long as head/neck taper compatibility (Morse taper of the same type and the same angle) and indications are respected.
The validated associations and assembly incompatibilities of the E² femoral stems with femoral heads are given in Table A at the end of these instructions for use. **Only the combinations in Table A have been validated by AMPLITUDE, any other association is prohibited.**

2.2 Associations with distal centralizer

The E² stem may be used with a distal centralizer.

2.3 Associations with acetabular cups

The list of cups for which AMPLITUDE has ensured compatibility with the stem is: SATURNE and SATURNE II, AUSTRAL, C².

For any other stem/cup combination, please contact an AMPLITUDE representative.

2.5 Associations with the surgical instruments

E² femoral stems 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.

Please consult dedicated IFUs provided with the other devices for further information.
For all other combinations clinical performance has not been demonstrated.

3. COMPOSITION OF MEDICAL DEVICE

The constitutive material of the E² femoral stems is:

Stainless steel alloy (M30NW) according to ISO 5832-9 standard.
The composition of the constitutive material used for E² femoral stems 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
Sulphur (S)	0.01 maximum
Phosphorus (P)	0.025 maximum
Copper (Cu)	0.25 maximum
Nitrogen (N)	0.25 to 0.50
Iron (Fe)	Balance

The E² femoral stems are not made with natural rubber latex. No material containing natural rubber latex is used during the manufacturing process.

4. INTENDED USE AND PATIENT POPULATIONS

E² femoral stem is intended for being used as femoral component for replacement of the total hip joint in order to reduce pain and restore hip function in comparison with preoperative status.

A total hip arthroplasty can only be considered in case of severe joint pathology after failure of the conservative treatments. The E² femoral stems are intended to be implanted in patients:
- with mature skeletal development,
- with adequate available bone stock (left to the surgeon's discretion),
- whose health condition allows undergoing an orthopaedic surgery.

The choice of total hip arthroplasty for each patient is made by experienced surgeons.

5. INDICATIONS

E² femoral stems are indicated in case of primary total hip arthroplasty for the relief of pain and significant disability following:
- Primitive and secondary hip osteoarthritis,
- Aseptic osteonecrosis,
- Rheumatoid arthritis/inflammatory diseases,
- Femur, hip and/or acetabulum fractures.

E² femoral stems must be used in combination with systems as approved by AMPLITUDE (see chapter 2).

6. PERFORMANCE CHARACTERISTICS AND CLINICAL BENEFITS

The expected clinical benefits following a primary total hip arthroplasty with E² femoral stems are:
- Restoring hip joint functionality,
- Relieving pain.

Based on literature and national registry data, about 96% of primary total hip 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 hip replacement are:
- Pregnancy.
- Acute or chronic, local or systemic infections which may affect the implant function.
- Severe mental, muscular, neurological or vascular 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. Avoid repeated assembly and disassembly of the femoral head.

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, position, assemble and impact implants according to the surgical techniques.
During the impaction of the different components of the hip prosthesis, it is necessary to handle all components and specifically the polished ones 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 acetabular cup, stem neck, femoral head … 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.**

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 or 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.

8.4 MRI

The risks associated with a passive implant placed in a magnetic resonance (MR) environment have been evaluated and include heating, implant migration and image artefacts at or near the implant site. Non-clinical testing has demonstrated that AMPLITUDE implant systems are MR conditional (for further details please see paragraph 10 of the IFU).

Warnings and precautions are given to users. 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 hip prosthesis. Patients should be advised to consult their surgeon in case of doubt about the following side effects and especially in case of noise during movement.

It cannot be guaranteed that the patient will recover total range of motion and anatomic function of the hip after the total hip arthroplasty.
The most recurrent potential residual risks/side effects and potential complications usually encountered with the use of the prosthesis and/or its implantation are summarized here after.
Risks with an undesirable effect on the patient can be classified as rare (<1 in 1,000 implantations) :
- Periprosthetic bone fracture.
- Impingement between the implant and the surrounding tissues.
- Neurovascular disorders.
- Wear of bearing surfaces.
- Lower-limb length discrepancy.
- 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.
- Bone dissolved over time (Osteolysis).
- Impingement between the femoral neck and the acetabular cup.
- Migration or loosening of a component or the entire prosthesis.
- Pain.
- Bone Cement Implantation Syndrome (BSIS).

or occasional (between 1 in 100 and 1 in 1,000 cases):
- Infection.
- Dislocation of the component or the entire prosthesis.
- Breakage of the component or the entire prosthesis.

Other events linked to the surgery or current knowledge can also occur:
- Hematoma.
- Heterotopic ossification.
- Cardiovascular thromboembolic disorders: fat or pulmonary embolism, superficial or deep vein thrombosis.
- Pejorative bone remodeling.
- Squeaking during movement.
- Mechanical noise / grinding in the prosthetic joint.

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:
Maximum measured temperature rise with 3T MRI is 5.7°C 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).

Image Artifacts:
MR image quality may be compromised around the position of the implant. Therefore, optimization of MR imaging parameters to compensate for the presence of this implant may be necessary.
The image artefact caused by the device extends at maximum 118.5 mm when imaged with a gradient echo pulse sequence at 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 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 symbol indicates the packaging which maintains the sterile condition of a device. The prosthetic device contained inside this packaging is considered as sterile. 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 an explanted 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 of biological medical waste.

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. In case of a fracture of a component, there is a risk of injury caused by sharp edges of ceramic or metal fragments during a revision.

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

12. STERILIZATION

This medical device is delivered sterile **in a double packaging barrier system** after sterilization using gamma irradiation with a 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 PERFORMANCES

The Summary of Safety and Clinical Performances is intended to provide public access to an updated summary of the main safety and clinical performance aspects of the device.
This summary the E² femoral stems 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 performances is linked to the BASIC UDI-DI of the E² femoral stems, a unique identification code that was attributed to the device. The summary of safety and clinical performances is available using this code directly on EUDAMED website.

BASIC UDI-DI of the E² femoral stems: 370108951030109TI08P.

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 hip prosthesis system. The implant card needs to be completed with a traceability label for each device in the implanted hip 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 the implant card are printed onto the implant card.
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: 2021.
The CE marking is only valid if it also appears on the packaging label.

REF: NO180 (indC)
https://eIFU.amplitude-ortho.com

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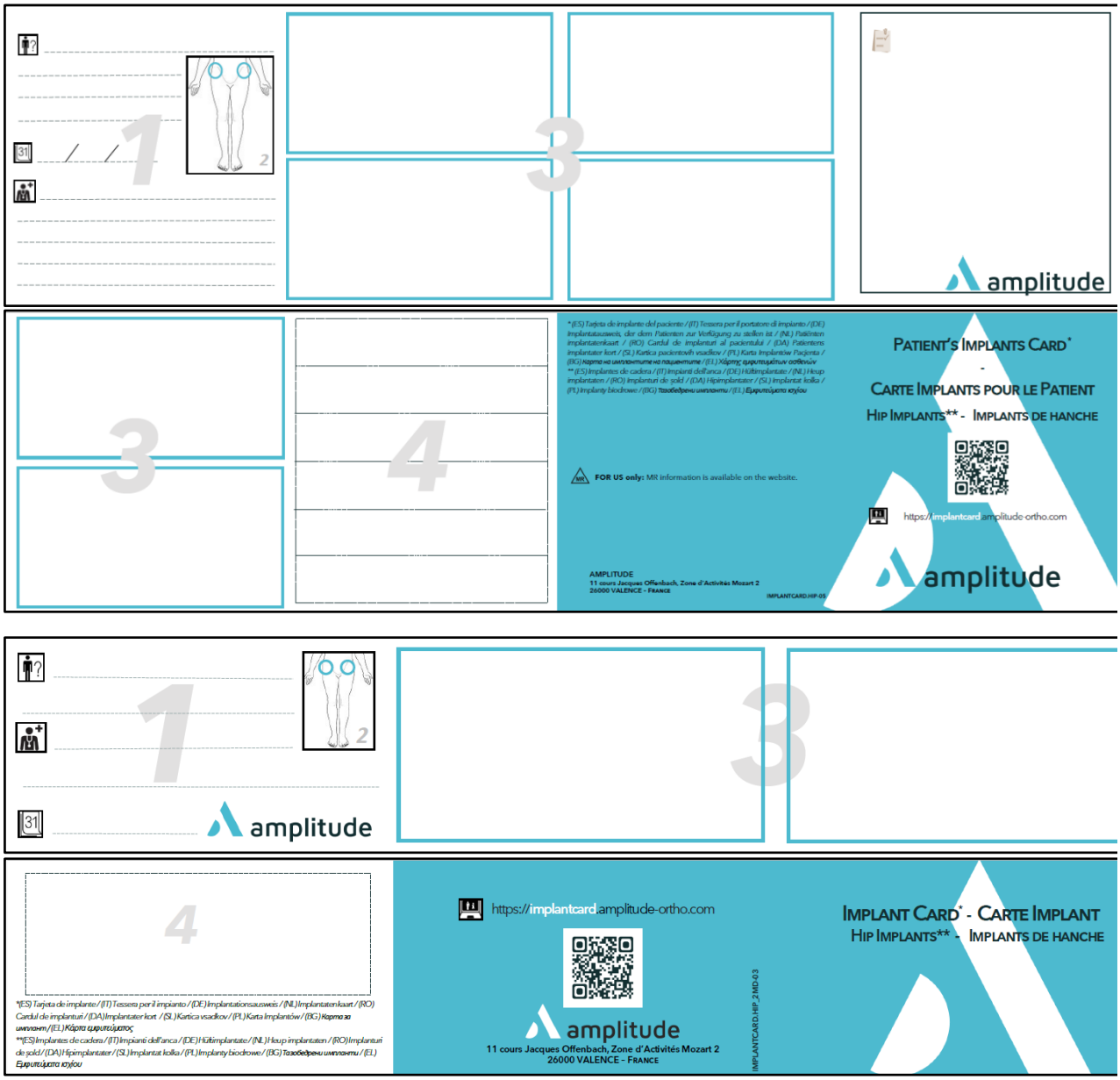
CE 2797

SYMBOL	MEANING
	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 AND COUNTRY OF MANUFACTURE (MADE IN FRANCE)
	MR CONDITIONAL
	KEEP AWAY FROM SUNLIGHT
	DO NOT CONTAIN OR NO PRESENCE OF NATURAL RUBBER LATEX
	PRESCRIPTION ONLY
	QUANTITY IN THE PACKAGE
	MEDICAL DEVICE
	UNIQUE DEVICE IDENTIFIER
	DOUBLE STERILE BARRIER SYSTEM - CHECK THE INSTRUCTIONS FOR USE FOR WHAT TO DO IF THE STERILE PACKAGING IS DAMAGED OR UNINTENTIONALLY OPENED BEFORE USE

A - Femoral component pairings	Metal femoral head M30NW (12/14 taper)	Ceramic femoral head BIOLOX® Delta (12/14 taper)	Sleeve and BIOLOX® Delta Ceramic revision femoral head (12/14 taper)	CoCr metal femoral head (12/14 taper)
E² femoral stem	✓	✓	✗	✓

✓ : **Compatible** pairing ✗ : **Incompatible** pairing



(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