# KAREY FEMORAL STEMS



## 1. MEDICAL DEVICE TYPE

According to Directive 93/42/CE, it is classified as class III because it is a long term, implantable, surgical invasive medical device.

## 2. GENERAL PRODUCT DESCRIPTION. DESIGN RATIONALE

The KAREY stem for primary surgery has two models: Cemented and Hydroxyapatite Coated.


The main difference between these models is the machining of the side walls. In the case of the KAREY stem cemented in nitrogen steel (Karey-CN), these are not machined since the aim is to achieve a fairly uniform geometry, especially joining the anteroposterior faces with the mediolateral ones to reduce tensions in the interface, since these are the main cause of prosthetic loosening and movement, especially if at a stress concentration point in the stem-cement interface there is a sharp or not very rounded edge of the stem that will cause the cement to fail due to its lower tensile modulus.

In the case of the stem coated with Hydroxyapatite, due to the fact that its primary fixation must be by Press-Fit, thanks to the adjustment provided by its triple-wedge geometry, it has a staggered wedge-like machining of lateral faces, which Provides a better fit on the proximal femur. In addition, the finish is rougher than the cemented one so that osseointegration is done on a larger surface and increases its quality.

The design characteristics have been studied with the aim of providing the correct and necessary stability for the perfect work of the prosthesis thanks to the trapezoidal frustoconical section, which varies longitudinally. This section prevents the stem from progressively “sinking” due to the body weight applied once implanted (subsidence), while providing longitudinal support along the femoral canal. This adjustment will not only prevent subsidence, but will also prevent the prosthesis from pitching.

The perfect fit of the bone-cement / bone-stem coating interfaces makes calcar support unnecessary, however, if additional insurance is required due to the patient's own bone conditions, the non-cemented stem also has a version with support collar on calcar. On the other hand, stability to rotation is achieved, not only with its trapezoidal section, but it is also improved thanks to the distal grooves made, which prevent the stem from rotating once fixed.

The KAREY prosthesis will have a progressive decrease in size towards the bottom, since it has thus been shown that this is a good load transmission system since a property of the cone is that when it is adjusted it becomes firmer and each time it moves the cone, a higher load is required to move it again.

The KAREY-CN stem, when adjusted, generates wedge-shaped stresses within the cement, which are dissipated by sliding and subsequent relaxation on the cement interface. As this takes place, the load regime changes to radial compression. There is an associated reduction in shear, at interfaces and within the cement (if any).

In the KAREY-HA, the structural characteristics of grooves, ribs, rough surfaces or surface coatings, as is the case of the stem with Hydroxyapatite, prevent this method of load

transmission and result in a shear force, which is transmitted directly to the interface. The force exerted by a tapered stem, such as this one, on the bone is a combination of compression and shear friction. The resulting compression of these two vectors depends on the surface finish of the stem and the triple wedge.

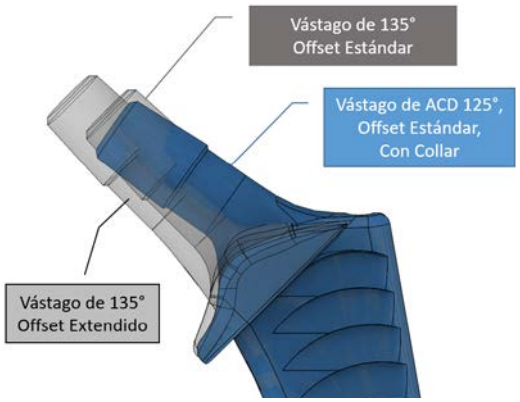
The essence of this KAREY stem is the use of the triple-taper concept to protect the biological interface from shear while producing a radial compressive load.

Another of the differentiating characteristics of the KAREY stem is its wide range of sizes. The stem comes with Standard and Extended Offsets (abbreviated as SO and HO respectively, according to the acronym in English Standard Offset and High Offset), which provides better adaptability to the anatomical conditions of each patient when positioning the center of rotation of the femoral head. In addition, it is possible to choose between a neck-diaphyseal angle of 135º or 125º depending on the pre-operative planning. The distribution of metaphyseal sizes has been extended, with Sizes T6 to T16, for extremely small (dysplastic cases) or large metaphyses.

## 2.1 Main features. Design attributes.

- The KAREY stem has two alternatives for its fixation: CEMENTED (KAREY-CN) and NON-CEMENTED (Plasma-coated Hydroxyapatite 130 µm thick, KAREY-HA).
- KAREY product variants provide different Offsets (SO / HO), CCD angles of 125º and 135º, as well as options with or without non-cemented stem collar.

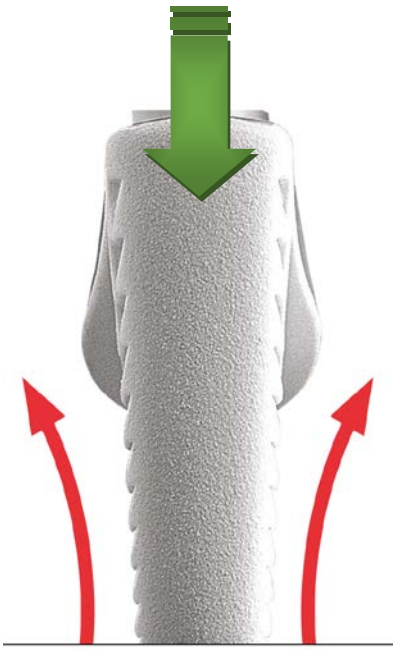
  *Note: To know all the available combinations, we will have to refer to the Surgical Technique of the corresponding stem.




- The KAREY-CN stem will be a cemented stem, so it will be designed with the aim of combining in a stem those morphological characteristics that could provide a more stable

behavior against rotational stresses that can cause the implant to fail due to loosening or failure of the cement.

- The KAREY-CN Stem is intelligently designed: in its proximal or metaphyseal area, it has a progressive trapezoidal geometry. Optionally, it is supplied with a distal centralizer (for sizes 11 and up), compatible with the latest generation cementation techniques (vacuum pressurization, cement restrictor and centralizer), which allows a uniform layer of cement to be obtained on the entire surface. stem envelope.
- The KAREY-CN will have a gloss polished external surface, without a support collar on the calcar. It is generally recognized that this type of stem reduces the risk of loosening. In the proximal part it will have a connection for the introducer-impactor instrument.
- The KAREY-HA stem will be a non-cemented stem, so it will be designed with the aim of combining in a stem those morphological characteristics that could provide more stable behavior and promote a greater stem-bone mass interface, to achieve a greater distribution of loads on the new bone generated from osseointegration.
- The KAREY-HA Stem is intelligently designed: in its proximal or metaphyseal area, it has the same basal geometry as the reference “Corail” stem, except for the machining of the lateral faces. In the KAREY-HA stem, the idea of wedges that favor primary fixation and thus be able to guarantee better osseointegration has prevailed.



- The KAREY-HA will have a rough external surface mainly due to the Hydroxyapatite plasma projection processes. Optionally, as already mentioned, it will have a support collar on the calcar. It is generally recognized that this type of stem reduces the risk of loosening. Analogous to the cemented version, the HA stem has, in the proximal part, a connection for the introducer-impactor instrument.
- In addition, of the two fixation models that can be given for the KAREY hip stem, there will also be the option of a stem for revision surgeries. The essential and differentiating characteristics are similar to the primary implantation stems (although under review, it is only available in a 135º CCD angle,

without a centralizer), however, it has a longer stem and Calcar support in all cases. In this type of revision surgery, support is necessary because it can cause significant trauma in the extraction area of the previously implanted primary stem, which can reduce the quantity / quality of bone support.

## 3. LIFESPAN:

The lifespan of this stem is estimated between 10 and 15 years, depending on the interaction of several factors; some are the responsibility of the manufacturer, others such as the implantation technique, are the responsibility of the surgeon directing the operation, and some others are related to the patient, such as the biological and physiological response of the implant, the medical condition of the patient, the behavior of the same with regard to their weight gain, carrying heavy loads and adopting a high level of daily physical activity, as indicated in point 4 of the ISO 21534 standard.

"Patients receiving hip joint replacement implants should be aware that the longevity of the implant may depend on the patient's weight and activity level."

However, the end of the useful life of an implanted prosthesis deserves a specific treatment for each patient and, therefore, it will be the specialist doctor who determines that the prosthesis does not satisfactorily fulfill the function for which it was implanted at the time.

## 4. PRODUCT RANGE. VARIANTS.

CEMENTLESS KAREY-HA STEM

| CEMENTLESS KAREY-HA STEM, STANDARD OFFSET 135º<br>BASIC UDI CODE: 84352258IMP10402022U | | |
|---|---|---|
| CODE | DENOMINATION | ARTICLE DESCRIPTION |
| F0400008E | **KAREY-HA 135 SO 8** | *CEMENTLESS KAREY-HA FEMORAL STEM, Collarless, 135º Standard Offset, Taper 12/14, Ti6Al4V ELI + HA, Sterile Size 8* |
| F0400009E | **KAREY-HA 135 SO 9** | *CEMENTLESS KAREY-HA FEMORAL STEM, Collarless, 135º Standard Offset, Taper 12/14, Ti6Al4V ELI + HA, Sterile Size 9* |
| F0400010E | **KAREY-HA 135 SO 10** | *CEMENTLESS KAREY-HA FEMORAL STEM, Collarless, 135º Standard Offset, Taper 12/14, Ti6Al4V ELI + HA, Sterile Size 10* |
| F0400011E | **KAREY-HA 135 SO 11** | *CEMENTLESS KAREY-HA FEMORAL STEM, Collarless, 135º Standard Offset, Taper 12/14, Ti6Al4V ELI + HA, Sterile Size 11* |
| F0400012E | **KAREY-HA 135 SO 12** | *CEMENTLESS KAREY-HA FEMORAL STEM, Collarless, 135º Standard Offset, Taper 12/14, Ti6Al4V ELI + HA, Sterile Size 12* |
| F0400013E | **KAREY-HA 135 SO 13** | *CEMENTLESS KAREY-HA FEMORAL STEM, Collarless, 135º Standard Offset, Taper 12/14, Ti6Al4V ELI + HA, Sterile Size 13* |
| F0400014E | **KAREY-HA 135 SO 14** | *CEMENTLESS KAREY-HA FEMORAL STEM, Collarless, 135º Standard Offset, Taper 12/14, Ti6Al4V ELI + HA, Sterile Size 14* |
| F0400015E | **KAREY-HA 135 SO 15** | *CEMENTLESS KAREY-HA FEMORAL STEM, Collarless, 135º Standard Offset, Taper 12/14, Ti6Al4V ELI + HA, Sterile Size 15* |
| F0400016E | **KAREY-HA 135 SO 16** | *CEMENTLESS KAREY-HA FEMORAL STEM, Collarless, 135º Standard Offset, Taper 12/14, Ti6Al4V ELI + HA, Sterile Size 16* |

## CEMENTLESS KAREY-HA STEM, HIGH OFFSET 135º

**BASIC UDI CODE: *84352258IMP10402022U***

| CODE | DENOMINATION | ARTICLE DESCRIPTION |
|---|---|---|
| F0401009E | KAREY-HA 135 HO 9 | *Ti6Al4V ELI KAREY-HA Femoral Stem + Hidroxiapatite (HA), Cementless, Collarless, 135º High Offset, Taper 12/14, Sterile, Size 9* |
| F0401010E | KAREY-HA 135 HO 10 | *Ti6Al4V ELI KAREY-HA Femoral Stem + Hidroxiapatite (HA), Cementless, Collarless, 135º High Offset, Taper 12/14, Sterile, Size 10* |
| F0401011E | KAREY-HA 135 HO 11 | *Ti6Al4V ELI KAREY-HA Femoral Stem + Hidroxiapatite (HA), Cementless, Collarless, 135º High Offset, Taper 12/14, Sterile, Size 11* |
| F0401012E | KAREY-HA 135 HO 12 | *Ti6Al4V ELI KAREY-HA Femoral Stem + Hidroxiapatite (HA), Cementless, Collarless, 135º High Offset, Taper 12/14, Sterile, Size 12* |
| F0401013E | KAREY-HA 135 HO 13 | *Ti6Al4V ELI KAREY-HA Femoral Stem + Hidroxiapatite (HA), Cementless, Collarless, 135º High Offset, Taper 12/14, Sterile, Size 13* |
| F0401014E | KAREY-HA 135 HO 14 | *Ti6Al4V ELI KAREY-HA Femoral Stem + Hidroxiapatite (HA), Cementless, Collarless, 135º High Offset, Taper 12/14, Sterile, Size 14* |
| F0401015E | KAREY-HA 135 HO 15 | *Ti6Al4V ELI KAREY-HA Femoral Stem + Hidroxiapatite (HA), Cementless, Collarless, 135º High Offset, Taper 12/14, Sterile, Size 15* |
| F0401016E | KAREY-HA 135 HO 16 | *Ti6Al4V ELI KAREY-HA Femoral Stem + Hidroxiapatite (HA), Cementless, Collarless, 135º High Offset, Taper 12/14, Sterile, Size 16* |

## CEMENTLESS KAREY-HA STEM, COLLARED, STANDARD OFFSET 135º

**BASIC UDI CODE: *84352258IMP10402012S***

| CODE | DENOMINATION | ARTICLE DESCRIPTION |
|---|---|---|
| F0400108E | KAREY-HA 135 SO COLLAR 8 | *Ti6Al4V ELI KAREY-HA Femoral Stem + Hidroxiapatite (HA), Cementless, Collared, 135º Standard Offset, Taper 12/14, Sterile, Size 8* |
| F0400109E | KAREY-HA 135 SO COLLAR 9 | *Ti6Al4V ELI KAREY-HA Femoral Stem + Hidroxiapatite (HA), Cementless, Collared, 135º Standard Offset, Taper 12/14, Sterile, Size 9* |
| F0400110E | KAREY-HA 135 SO COLLAR 10 | *Ti6Al4V ELI KAREY-HA Femoral Stem + Hidroxiapatite (HA), Cementless, Collared, 135º Standard Offset, Taper 12/14, Sterile, Size 10* |
| F0400111E | KAREY-HA 135 SO COLLAR 11 | *Ti6Al4V ELI KAREY-HA Femoral Stem + Hidroxiapatite (HA), Cementless, Collared, 135º Standard Offset, Taper 12/14, Sterile, Size 11* |
| F0400112E | KAREY-HA135 SO COLLAR 12 | *Ti6Al4V ELI KAREY-HA Femoral Stem + Hidroxiapatite (HA), Cementless, Collared, 135º Standard Offset, Taper 12/14, Sterile, Size 12* |
| F0400113E | KAREY-HA 135 SO COLLAR 13 | *Ti6Al4V ELI KAREY-HA Femoral Stem + Hidroxiapatite (HA), Cementless, Collared, 135º Standard Offset, Taper 12/14, Sterile, Size 13* |
| F0400114E | KAREY-HA 135 SO COLLAR 14 | *Ti6Al4V ELI KAREY-HA Femoral Stem + Hidroxiapatite (HA), Cementless, Collared, 135º Standard Offset, Taper 12/14, Sterile, Size 14* |
| F0400115E | KAREY-HA 135 SO COLLAR 15 | *Ti6Al4V ELI KAREY-HA Femoral Stem + Hidroxiapatite (HA), Cementless, Collared, 135º Standard Offset, Taper 12/14, Sterile, Size 15* |
| F0400116E | KAREY-HA 135 SO COLLAR 16 | *Ti6Al4V ELI KAREY-HA Femoral Stem + Hidroxiapatite (HA), Cementless, Collared, 135º Standard Offset, Taper 12/14, Sterile, Size 16* |

## CEMENTLESS KAREY-HA STEM, COLLARED, HIGH OFFSET 135º

**BASIC UDI CODE: *84352258IMP10402012S***

| CODE | DENOMINATION | ARTICLE DESCRIPTION |
|---|---|---|
| F0401109E | KAREY-HA 135 HO COLLAR 9 | *Ti6Al4V ELI KAREY-HA Femoral Stem + Hidroxiapatite (HA), Cementless, Collared, 135º High Offset, Taper 12/14, Sterile, Size 9* |
| F0401110E | KAREY-HA 135 HO COLLAR 10 | *Ti6Al4V ELI KAREY-HA Femoral Stem + Hidroxiapatite (HA), Cementless, Collared, 135º High Offset, Taper 12/14, Sterile, Size 10* |
| F0401111E | KAREY-HA 135 HO COLLAR 11 | *Ti6Al4V ELI KAREY-HA Femoral Stem + Hidroxiapatite (HA), Cementless, Collared, 135º High Offset, Taper 12/14, Sterile, Size 11* |
| F0401112E | KAREY-HA 135 HO COLLAR 12 | *Ti6Al4V ELI KAREY-HA Femoral Stem + Hidroxiapatite (HA), Cementless, Collared, 135º High Offset, Taper 12/14, Sterile, Size 12* |
| F0401113E | KAREY-HA 135 HO COLLAR 13 | *Ti6Al4V ELI KAREY-HA Femoral Stem + Hidroxiapatite (HA), Cementless, Collared, 135º High Offset, Taper 12/14, Sterile, Size 13* |
| F0401114E | KAREY-HA 135 HO COLLAR 14 | *Ti6Al4V ELI KAREY-HA Femoral Stem + Hidroxiapatite (HA), Cementless, Collared, 135º High Offset, Taper 12/14, Sterile, Size 14* |
| F0401115E | KAREY-HA 135 HO COLLAR 15 | *Ti6Al4V ELI KAREY-HA Femoral Stem + Hidroxiapatite (HA), Cementless, Collared, 135º High Offset, Taper 12/14, Sterile, Size 15* |

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| F0401116E | KAREY-HA 135 HO COLLAR 16 | *Ti6Al4V ELI KAREY-HA Femoral Stem + Hidroxiapatite (HA), Cementless, Collared, 135º High Offset, Taper 12/14, Sterile, Size 16* |

## CEMENTLESS KAREY-HA STEM, COXA VARA (125º), STANDARD OFFSET

**BASIC UDI CODE: *84352258IMP10402022U***

| CODE | DENOMINATION | ARTICLE DESCRIPTION |
|---|---|---|
| F0410009E | KAREY-HA 125 SO 9 | *Ti6Al4V ELI KAREY-HA Coxa Vara Femoral Stem + Hidroxiapatite (HA), Cementless, Collarless, 125º Standard Offset, Taper 12/14, Sterile, Size 9* |
| F0410010E | KAREY-HA 125 SO 10 | *Ti6Al4V ELI KAREY-HA Coxa Vara Femoral Stem + Hidroxiapatite (HA), Cementless, Collarless, 125º Standard Offset, Taper 12/14, Sterile, Size 10* |

## CEMENTLESS KAREY-HA STEM, COXA VARA (125º), COLLARED, STANDARD OFFSET

**BASIC UDI CODE: *84352258IMP104020125***

| CODE | DENOMINATION | ARTICLE DESCRIPTION |
|---|---|---|
| F0410109E | KAREY-HA 125 SO COLLAR 9 | *Ti6Al4V ELI KAREY-HA Coxa Vara Femoral Stem + Hidroxiapatite (HA), Cementless, Collared, 125º Standard Offset, Taper 12/14, Sterile, Size 9* |
| F0410110E | KAREY-HA 125 SO COLLAR 10 | *Ti6Al4V ELI KAREY-HA Coxa Vara Femoral Stem + Hidroxiapatite (HA), Cementless, Collared, 125º Standard Offset, Taper 12/14, Sterile, Size 10* |
| F0410111E | KAREY-HA 125 SO COLLAR 11 | *Ti6Al4V ELI KAREY-HA Coxa Vara Femoral Stem + Hidroxiapatite (HA), Cementless, Collared, 125º Standard Offset, Taper 12/14, Sterile, Size 11* |
| F0410112E | KAREY-HA 125 SO COLLAR 12 | *Ti6Al4V ELI KAREY-HA Coxa Vara Femoral Stem + Hidroxiapatite (HA), Cementless, Collared, 125º Standard Offset, Taper 12/14, Sterile, Size 12* |
| F0410113E | KAREY-HA 125 SO COLLAR 13 | *Ti6Al4V ELI KAREY-HA Coxa Vara Femoral Stem + Hidroxiapatite (HA), Cementless, Collared, 125º Standard Offset, Taper 12/14, Sterile, Size 13* |
| F0410114E | KAREY-HA 125 SO COLLAR 14 | *Ti6Al4V ELI KAREY-HA Coxa Vara Femoral Stem + Hidroxiapatite (HA), Cementless, Collared, 125º Standard Offset, Taper 12/14, Sterile, Size 14* |
| F0410115E | KAREY-HA 125 SO COLLAR 15 | *Ti6Al4V ELI KAREY-HA Coxa Vara Femoral Stem + Hidroxiapatite (HA), Cementless, Collared, 125º Standard Offset, Taper 12/14, Sterile, Size 15* |
| F0410116E | KAREY-HA 125 SO COLLAR 16 | *Ti6Al4V ELI KAREY-HA Coxa Vara Femoral Stem + Hidroxiapatite (HA), Cementless, Collared, 125º Standard Offset, Taper 12/14, Sterile, Size 16* |

## CEMENTLESS KAREY-HA STEM, COXA VARA (125º), COLLARED, HIGH OFFSET

**BASIC UDI CODE: *84352258IMP104020125***

| CODE | DENOMINATION | ARTICLE DESCRIPTION |
|---|---|---|
| F0411109E | KAREY-HA 125 HO COLLAR 9 | *Ti6Al4V ELI KAREY-HA Coxa Vara Femoral Stem + Hidroxiapatite (HA), Cementless, Collared, 125º High Offset, Taper 12/14, Sterile, Size 9* |
| F0411110E | KAREY-HA 125 HO COLLAR 10 | *Ti6Al4V ELI KAREY-HA Coxa Vara Femoral Stem + Hidroxiapatite (HA), Cementless, Collared, 125º High Offset, Taper 12/14, Sterile, Size 10* |
| F0411111E | KAREY-HA 125 HO COLLAR 11 | *Ti6Al4V ELI KAREY-HA Coxa Vara Femoral Stem + Hidroxiapatite (HA), Cementless, Collared, 125º High Offset, Taper 12/14, Sterile, Size 11* |
| F0411112E | KAREY-HA 125 HO COLLAR HO 12 | *Ti6Al4V ELI KAREY-HA Coxa Vara Femoral Stem + Hidroxiapatite (HA), Cementless, Collared, 125º High Offset, Taper 12/14, Sterile, Size 12* |
| F0411113E | KAREY-HA 125 HO COLLAR 13 | *Ti6Al4V ELI KAREY-HA Coxa Vara Femoral Stem + Hidroxiapatite (HA), Cementless, Collared, 125º High Offset, Taper 12/14, Sterile, Size 13* |
| F0411114E | KAREY-HA 125 HO COLLAR 14 | *Ti6Al4V ELI KAREY-HA Coxa Vara Femoral Stem + Hidroxiapatite (HA), Cementless, Collared, 125º High Offset, Taper 12/14, Sterile, Size 14* |
| F0411115E | KAREY-HA 125 HO COLLAR 15 | *Ti6Al4V ELI KAREY-HA Coxa Vara Femoral Stem + Hidroxiapatite (HA), Cementless, Collared, 125º High Offset, Taper 12/14, Sterile, Size 15* |

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| F0411116E | **KAREY-HA 125 HO COLLAR 16** | *Ti6Al4V ELI KAREY-HA Coxa Vara Femoral Stem + Hidroxiapatite (HA), Cementless, Collared, 125º High Offset, Taper 12/14, Sterile, Size 16* |

| CEMENTLESS KAREY-HA STEM, STANDARD OFFSET 135º<br>BASIC UDI CODE: *84352258IMP10402022U* | | |
|---|---|---|
| CODE | DENOMINATION | ARTICLE DESCRIPTION |
| F0400006E | **KAREY-HA 135 SO 6** | *Ti6Al4V ELI KAREY-HA Femoral Stem + Hidroxiapatite (HA), Cementless, Collarless, 135º Standard Offset, Taper 12/14, Sterile, Size 6* |

CEMENTED KAREY-CN HIGH NITROGEN STAINLESS STEEL

| CEMENTED KAREY-CN, STANDARD OFFSET<br>*BASIC UDI CODE: 84352258IMP104020532* | | |
|---|---|---|
| CODE | DENOMINATION | ARTICLE DESCRIPTION |
| **F0420008E** | KAREY-CN 135 SO 8 | *High Nitrogen Stainless Steel KAREY-C Femoral Stem* (M30NW ISO 5832-9), *Cemented, Collarless, 135°, Standard Offset, Taper 12/14, Sterile, Size 8* |
| **F0420009E** | KAREY-CN 135 SO 9 | *High Nitrogen Stainless Steel KAREY-C Femoral Stem* (M30NW ISO 5832-9), *Cemented, Collarless, 135°, Standard Offset, Taper 12/14, Sterile, Size 9* |
| **F0420010E** | KAREY-CN 135 SO 10 | *High Nitrogen Stainless Steel KAREY-C Femoral Stem* (M30NW ISO 5832-9), *Cemented, Collarless, 135°, Standard Offset, Taper 12/14, Sterile, Size 10* |
| **F0420011E** | KAREY-CN 135 SO 11 | *High Nitrogen Stainless Steel KAREY-C Femoral Stem* (M30NW ISO 5832-9), *Cemented, Collarless, 135°, Standard Offset, Taper 12/14, Sterile, Size 11* |
| **F0420012E** | KAREY-CN 135 SO 12 | *High Nitrogen Stainless Steel KAREY-C Femoral Stem* (M30NW ISO 5832-9), *Cemented, Collarless, 135°, Standard Offset, Taper 12/14, Sterile, Size 12* |
| **F0420013E** | KAREY-CN 135 SO 13 | *High Nitrogen Stainless Steel KAREY-C Femoral Stem* (M30NW ISO 5832-9), *Cemented, Collarless, 135°, Standard Offset, Taper 12/14, Sterile, Size 13* |
| **F0420014E** | KAREY-CN 135 SO 14 | *High Nitrogen Stainless Steel KAREY-C Femoral Stem* (M30NW ISO 5832-9), *Cemented, Collarless, 135°, Standard Offset,, Taper 12/14, Sterile, Size 14* |
| **F0420015E** | KAREY-CN 135 SO 15 | *High Nitrogen Stainless Steel KAREY-C Femoral Stem* (M30NW ISO 5832-9), *Cemented, Collarless, 135°, Standard Offset, Taper 12/14, Sterile, Size 15* |
| **F0420016E** | KAREY-CN 135 SO 16 | *High Nitrogen Stainless Steel KAREY-C Femoral Stem* (M30NW ISO 5832-9), *Cemented, Collarless, 135°, Standard Offset, Taper 12/14, Sterile, Size 16* |

# CEMENTED KAREY-CN, HIGH OFFSET

## *BASIC UDI CODE: 84352258IMP104020532*

| CODE | DENOMINATION | ARTICLE DESCRIPTION |
|---|---|---|
| **F0421009E** | KAREY-CN 135 HO 9 | *High Nitrogen Stainless Steel KAREY-C Femoral Stem (M30NW ISO 5832-9), Cemented, Collarless, 135°, High Offset, Taper 12/14, Sterile, Size 9* |
| **F0421010E** | KAREY-CN 135 HO 10 | *High Nitrogen Stainless Steel KAREY-C Femoral Stem (M30NW ISO 5832-9), Cemented, Collarless, 135°, High Offset, Taper 12/14, Sterile, Size 10* |
| **F0421011E** | KAREY-CN 135 HO 11 | *High Nitrogen Stainless Steel KAREY-C Femoral Stem (M30NW ISO 5832-9), Cemented, Collarless, 135°, High Offset, Taper 12/14, Sterile, Size 11* |
| **F0421012E** | KAREY-CN 135 HO 12 | *High Nitrogen Stainless Steel KAREY-C Femoral Stem (M30NW ISO 5832-9), Cemented, Collarless, 135°, High Offset, Taper 12/14, Sterile, Size 12* |
| **F0421013E** | KAREY-CN 135 HO 13 | *High Nitrogen Stainless Steel KAREY-C Femoral Stem (M30NW ISO 5832-9), Cemented, Collarless, 135°, High Offset, Taper 12/14, Sterile, Size 13* |
| **F0421014E** | KAREY-CN 135 HO 14 | *High Nitrogen Stainless Steel KAREY-C Femoral Stem (M30NW ISO 5832-9), Cemented, Collarless, 135°, High Offset, Taper 12/14, Sterile, Size 14* |
| **F0421015E** | KAREY-CN 135 HO 15 | *High Nitrogen Stainless Steel KAREY-C Femoral Stem (M30NW ISO 5832-9), Cemented, Collarless, 135°, High Offset, Taper 12/14, Sterile, Size 15* |
| **F0421016E** | KAREY-CN 135 HO 16 | *High Nitrogen Stainless Steel KAREY-C Femoral Stem (M30NW ISO 5832-9), Cemented, Collarless, 135°, High Offset, Taper 12/14, Sterile, Size 16* |

# CEMENTED KAREY-CN, STANDARD OFFSET

## & CEMENTATION CENTRALIZER

## *BASIC UDI CODE: 84352258IMP10402042Y*

| CODE | DENOMINATION | ARTICLE DESCRIPTION |
|---|---|---|
| **F0420511E** | KAREY-CN 135 SO 11 + CENTRALIZER Ø10 | *High Nitrogen Stainless Steel KAREY-C Femoral Stem* (M30NW ISO 5832-9), *Cemented, Collarless, 135°, Standard Offset, Taper 12/14, Sterile, Size 11 with Ø10 Centralizer* |

| | | |
|---|---|---|
| **F0420512E** | KAREY-CN 135 SO 12 + CENTRALIZER Ø10 | *High Nitrogen Stainless Steel KAREY-C Femoral Stem* (M30NW ISO 5832-9), *Cemented, Collarless, 135°, Standard Offset, Taper 12/14, Sterile, Size 12 with Ø10 Centralizer* |
| **F0420513E** | KAREY-CN 135 SO 13 + CENTRALIZER Ø10 | *High Nitrogen Stainless Steel KAREY-C Femoral Stem* (M30NW ISO 5832-9), *Cemented, Collarless, 135°, Standard Offset, Taper 12/14, Sterile, Size 13 with Ø10 Centralizer* |
| **F0420514E** | KAREY-CN 135 SO 14 + CENTRALIZER Ø12 | *High Nitrogen Stainless Steel KAREY-C Femoral Stem* (M30NW ISO 5832-9), *Cemented, Collarless, 135°, Standard Offset, Taper 12/14, Sterile, Size 14 with Ø12 Centralizer* |
| **F0420515E** | KAREY-CN 135 SO 15 + CENTRALIZER Ø12 | *High Nitrogen Stainless Steel KAREY-C Femoral Stem* (M30NW ISO 5832-9), *Cemented, Collarless, 135°, Standard Offset, Taper 12/14, Sterile, Size 15 with Ø12 Centralizer* |
| **F0420516E** | KAREY-CN 135 SO 16 + CENTRALIZER Ø12 | *High Nitrogen Stainless Steel KAREY-C Femoral Stem* (M30NW ISO 5832-9), *Cemented, Collarless, 135°, Standard Offset, Taper 12/14, Sterile, Size 16 with Ø12 Centralizer* |

## CEMENTED KAREY-CN, HIGH OFFSET

## & CEMENTATION CENTRALIZER

***BASIC UDI CODE: 84352258IMP10402042Y***

| CODE | DENOMINATION | ARTICLE DESCRIPTION |
|---|---|---|
| **F0421511E** | KAREY-CN 135 HO 11 + CENTRALIZER Ø10 | *High Nitrogen Stainless Steel KAREY-C Femoral Stem (M30NW ISO 5832-9), Cemented, Collarless, 135°, High Offset, Taper 12/14, Sterile, Size 11 with Ø10 Centralizer* |
| **F0421512E** | KAREY-CN 135 HO 12 + CENTRALIZER Ø10 | *High Nitrogen Stainless Steel KAREY-C Femoral Stem (M30NW ISO 5832-9), Cemented, Collarless, 135°, High Offset, Taper 12/14, Sterile, Size 12 with Ø10 Centralizer* |
| **F0421513E** | KAREY-CN 135 HO 13 + CENTRALIZER Ø10 | *High Nitrogen Stainless Steel KAREY-C Femoral Stem (M30NW ISO 5832-9), Cemented, Collarless, 135°, High Offset, Taper 12/14, Sterile, Size 13 with Ø10 Centralizer* |
| **F0421514E** | KAREY-CN 135 HO 14 + CENTRALIZER Ø12 | *High Nitrogen Stainless Steel KAREY-C Femoral Stem (M30NW ISO 5832-9), Cemented, Collarless, 135°, High Offset, Taper 12/14, Sterile, Size 14 with Ø12 Centralizer* |

| | | |
|---|---|---|
| **F0421515E** | KAREY-CN 135 HO 15 + CENTRALIZER Ø12 | *High Nitrogen Stainless Steel KAREY-C Femoral Stem (M30NW ISO 5832-9), Cemented, Collarless, 135°, High Offset, Taper 12/14, Sterile, Size 15 with Ø12 Centralizer* |
| **F0421516E** | KAREY-CN 135 HO 16 + CENTRALIZER Ø12 | *High Nitrogen Stainless Steel KAREY-C Femoral Stem (M30NW ISO 5832-9), Cemented, Collarless, 135°, High Offset, Taper 12/14, Sterile, Size 16 with Ø12 Centralizer* |

* Note: In the KAREY-CN stem versions WITH CENTRALIZER, a Cementing Centralizer will ALWAYS be pre-assembled in the distal hole of the stem, both integrated in the same container.

Geometry

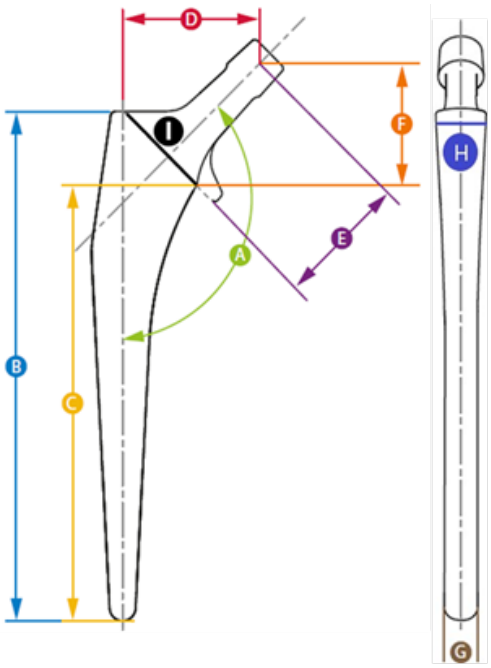


Figure 3. 1. Dimensions primary KAREY stem.

| KAREY - HA SO 135° | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Reference | Size | Neck Shaft Angle (A) | Stem Length (B) | Stem Length (C) | Offset (D) | Neck Length (E) | Neck Height (F) | Distal Width (G) | Proximal Width (H) | Osteotomy Line (I) |
| F0400006E | 6 | 135° | 110 | 93 | 30.8 | 33.45 | 30.2 | 8.75 | 14.27 | 23.65 |
| F0400008E | 8 | 135° | 114.5 | 93.3 | 38.4 | 38.63 | 35.91 | 6.9 | 13.1 | 30 |
| F0400009E | 9 | 135° | 130 | 109.45 | 38.27 | 37.68 | 35.53 | 8.07 | 13.2 | 28.8 |
| F0400010E | 10 | 135° | 140 | 118.92 | 39.15 | 38.32 | 36.07 | 9.01 | 13.7 | 29.16 |
| F0400011E | 11 | 135° | 145 | 123.43 | 39.9 | 38.8 | 36.52 | 9.65 | 14.3 | 29.6 |
| F0400012E | 12 | 135° | 150.03 | 128.01 | 41.21 | 40.14 | 37.57 | 10.02 | 15 | 30.21 |
| F0400013E | 13 | 135° | 155.26 | 132.81 | 42.41 | 41.4 | 38.53 | 9.91 | 15.36 | 30.7 |
| F0400014E | 14 | 135° | 160 | 138.17 | 42.72 | 41.35 | 38.57 | 9.82 | 15.78 | 31.13 |
| F0400015E | 15 | 135° | 165.05 | 142.09 | 43.62 | 41.71 | 38.86 | 9.95 | 16.2 | 31.25 |
| F0400016E | 16 | 135° | 170 | 146.13 | 43.94 | 42.53 | 39.64 | 10 | 16.73 | 32.57 |

| KAREY - HA HO 135° | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Reference | Size | Neck Shaft Angle (A) | Stem Length (B) | Stem Length (C) | Offset (D) | Neck Length (E) | Neck Height (F) | Width (G) | Proximal Width (H) | Osteotomy Line (I) |
| F0401009E | 9 | 135° | 130 | 109.45 | 45 | 43.5 | 37.04 | 8.07 | 13.2 | 28.8 |
| F0401010E | 10 | 135° | 140 | 118.92 | 46 | 44.5 | 37.97 | 9.01 | 13.7 | 29.16 |
| F0401011E | 11 | 135° | 145 | 123.43 | 47 | 45.5 | 38.89 | 9.65 | 14.3 | 29.6 |
| F0401012E | 12 | 135° | 150.03 | 128.01 | 48 | 46 | 39.07 | 10.02 | 15 | 30.21 |
| F0401013E | 13 | 135° | 155.26 | 132.81 | 49.5 | 47 | 39.36 | 9.91 | 15.36 | 30.7 |
| F0401014E | 14 | 135° | 160 | 138.17 | 50 | 48 | 40.7 | 9.82 | 15.78 | 31.13 |
| F0401015E | 15 | 135° | 165.05 | 142.09 | 50.5 | 48.5 | 39.97 | 9.95 | 16.2 | 31.25 |
| F0401016E | 16 | 135° | 170 | 146.13 | 51 | 49 | 42.22 | 10 | 16.73 | 32.57 |

| KAREY - HA SO 125° COLLAR | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Reference | Size | Neck Shaft Angle (A) | Stem Length (B) | Stem Length (C) | Offset (D) | Offset Extendido (D) HO | Neck Length (E) | Neck Height (F) | Distal Width (G) | Proximal Width (H) | Osteotomy Line (I) |
| F0410109E | 9 | 125° | 130.0 | 109.5 | 39 | 45 | 35.54 | 31.02 | 8.07 | 13.2 | 34.8 |
| F0410110E | 10 | 125° | 140.0 | 118.9 | 39.5 | 46 | 36.56 | 32.45 | 9.01 | 13.7 | 35.16 |
| F0410111E | 11 | 125° | 145.0 | 123.4 | 40 | 47 | 37.57 | 33.87 | 9.65 | 14.3 | 35.6 |
| F0410112E | 12 | 125° | 150.0 | 128.0 | 40.5 | 47.5 | 38.04 | 34.54 | 10.02 | 15 | 37.3 |
| F0410113E | 13 | 125° | 155.3 | 132.8 | 41 | 48 | 38.59 | 35.13 | 9.91 | 15.36 | 38 |
| F0410114E | 14 | 125° | 160.0 | 138.2 | 41.5 | 49.5 | 39.09 | 35.77 | 9.82 | 15.78 | 38.46 |
| F0410115E | 15 | 125° | 165.1 | 142.1 | 42 | 50 | 39.6 | 36.13 | 9.95 | 16.2 | 38.66 |
| F0410116E | 16 | 125° | 170.0 | 146.1 | 43 | 51 | 40.11 | 36.79 | 10 | 16.73 | 42.23 |

| KAREY - C SO 135° COLLARLESS | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Reference | Size | Neck Shaft Angle (A) | Stem Length (B) | Stem Length (C) | Offset (D) | Neck Length (E) | Neck Height (F) | Distal Width (G) | Proximal Width (H) | Osteotomy Line (I) |
| F0420008E | 8 | 135° | 114.48 | 94.02 | 37.97 | 38.31 | 34.91 | 5.41 | 11.53 | 25.64 |
| F0420009E | 9 | 135° | 130.26 | 108.3 | 37.97 | 38.96 | 36.38 | 6.55 | 11.71 | 26.81 |
| F0420010E | 10 | 135° | 140 | 117.6 | 38.87 | 39.54 | 37.05 | 7.5 | 12.19 | 27.46 |
| F0420011E | 11 | 135° | 144.95 | 121.5 | 39.61 | 40.57 | 37.89 | 8.13 | 12.82 | 27.88 |
| F0420012E | 12 | 135° | 150 | 125.9 | 40.92 | 41.87 | 39.19 | 8.5 | 13.48 | 28.44 |
| F0420013E | 13 | 135° | 155.26 | 130.4 | 42.12 | 42.9 | 40.11 | 8.4 | 13.87 | 28.95 |
| F0420014E | 14 | 135° | 160 | 134 | 42.44 | 42.81 | 40.74 | 8.3 | 14.25 | 29.27 |
| F0420015E | 15 | 135° | 165 | 138.7 | 42.98 | 43.42 | 41.13 | 8.42 | 14.69 | 29.75 |
| F0420016E | 16 | 135° | 170 | 144.1 | 44.13 | 43.6 | 41.15 | 8.47 | 15.19 | 31.36 |

| KAREY - C HO 135° COLLARLESS | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Reference | Size | Neck Shaft Angle (A) | Stem Length (B) | Stem Length (C) | Offset (D) | Neck Length (E) | Neck Height (F) | Distal Width (G) | Proximal Width (H) | Osteotomy Line (I) |
| F0421009E | 9 | 135° | 150.35 | 108.3 | 45 | 39.36 | 35.23 | 6.55 | 11.71 | 26.81 |
| F0421010E | 10 | 135° | 160.53 | 117.6 | 46 | 39.94 | 36.09 | 7.5 | 12.19 | 27.46 |
| F0421011E | 11 | 135° | 165.33 | 121.5 | 47 | 40.97 | 36.78 | 8.13 | 12.82 | 27.88 |
| F0421012E | 12 | 135° | 169.8 | 125.9 | 48 | 42.27 | 36.87 | 8.5 | 13.48 | 28.44 |
| F0421013E | 13 | 135° | 175.57 | 130.4 | 49.5 | 43.3 | 37.81 | 8.4 | 13.87 | 28.95 |
| F0421014E | 14 | 135° | 179.96 | 134 | 50 | 43.21 | 38.37 | 8.3 | 14.25 | 29.27 |
| F0421015E | 15 | 135° | 185.01 | 138.7 | 50.5 | 43.82 | 38.84 | 8.42 | 14.69 | 29.75 |
| F0421016E | 16 | 135° | 191.34 | 144.1 | 51 | 44 | 40.19 | 8.47 | 15.19 | 31.36 |

## *Dimensions.*

• The KAREY Stem will be manufactured with a variable Offset by size and neck variant (SO and HO), for its primary models, as described in the tables above.

• The KAREY Stem will have a 12/14 Cone for assembly with the femoral head.

• The KAREY Stem will be manufactured with a Cervical-diaphyseal Angle of 135º and 125º.

• KAREY-HA has a range with a collar. KAREY-CN, has a version with a centralizer, from Size 11 and above.

• Long monobloc revision stems are available, to consult their characteristics we will have to refer to the technical sheet of the KAREY REVISION stem.

5. STERILIZATION:

The sterilization of these products is carried out by Gamma Radiation with controlled dosimetry, thus complying with this Essential Requirement regarding infection and microbial contamination, as well as with all the harmonized regulations in this regard.

6. PACKAGING

The Packaging System, formed by a Preformed Sterile Barrier System and a Protective Packaging, of this terminally sterilized medical device, satisfies the following points:

1. Provide physical protection and maintain the integrity of the sterile barrier system.

2. Allows sterilization and is compatible with the indicated sterilization process.

3. Maintains sterility until the point of use or until the expiration date.

4. Proper assembly of the Packaging System.

5. Allows aseptic presentation.

6. Provides an adequate microbial barrier.

7. Its compatibility with the labeling system.

8. Its Labeling facilitates the identification of the product, its traceability, manufacturing material.

9. The materials used in the packaging do not contain or release toxic products.

7. MANUFACTURING MATERIALS

CEMENTLESS KAREY-HA STEM

- *Ti6Al4V titanium alloy:*

It is the "grade 5" titanium alloy, the most widely used in the medical field (it contains aluminum and vanadium according to its composition: [Ti6Al4V]. Aluminum increases the

transformation temperature between the alpha and beta phases. Vanadium decreases that temperature.In addition, it has high tenacity.

As approximate and characteristic mechanical values of this material we can give the following values:

It has a tensile strength of 845-896 MPa, an elastic limit of 775-830 MPa, a ductility of 10%, a hardness of 33 HRB, very good weldability and an electrical resistivity of 1.67 (μΩm). Its application is common wherever high mechanical resistance and high temperatures of use and lightness of material are required. This Material is considered Acceptable for the manufacture of Implants by the UNE-EN ISO 21534 standard, Annex A.

CEMENTED KAREY-CN STEM

- *High Nitrogen Stainless Steel M30NW*

Nitrogenated Stainless Steel M30NW (AISI 316 LVM; Alloy 21Cr-10Ni-3Mn-2.5Mo), a biocompatible material that, thanks to its high mechanical-chemical resistance, has been successfully used for years in the manufacture of this type of implant, being one of the one of the most widely used materials considered to be biocompatible and long-term implantable to date, so its functionality is sufficiently supported by a huge number of clinical cases of a very diverse category.

It is an alloy with low carbon content and high nitrogen content that meets the technical specifications detailed in standards ASTM F 1586-95 and ISO 5832-9.