SCORE, SCORE Allergy Solution & SCORE II Total Knee Prostheses

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 **SCORE or SCORE Allergy Solution or SCORE II** range: a SCORE femoral component or a SCORE Allergy Solution femoral component or a SCORE II femoral component or a SCORE tibial baseplate or a SCORE Allergy Solution tibial baseplate or a SCORE tibial insert or a SCORE II tibial insert. This prosthetic device is a component of a total knee system. To form the SCORE or SCORE Allergy Solution or SCORE II total knee prostheses, all parts must be provided by AMPLITUDE. AMPLITUDE disclaims all responsibility if used with prosthetic components from other companies.

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

SCORE total knee prostheses consist of a SCORE femoral component, a SCORE tibial insert, a SCORE tibial baseplate and a patellar implant. The patellar implant may not be implanted during each surgery, depending on patient's condition.

SCORE Allergy Solution total knee prostheses consist of a SCORE Allergy Solution femoral component, a SCORE tibial insert, a SCORE Allergy Solution tibial baseplate and a patellar implant. The patellar implant may not be implanted during each surgery, depending on patient's condition.

SCORE II total knee prostheses consist of a SCORE II femoral component, a SCORE II tibial insert, a SCORE tibial baseplate and a patellar implant. The patellar implant may not be implanted during each surgery, depending on patient's condition.

SCORE femoral components are available in 7 sizes (1 to 7), for both right and left sides. They are available in cemented versions (orthopaedic cement) without coating and in cementless versions with hydroxyapatite (HA) coating in combination with a titanium undercoating on the areas in contact with bone.

SCORE Allergy Solution femoral components are available in 7 sizes (1 to 7), for both right and left sides. They are available only in cemented versions (orthopaedic cement).

SCORE II femoral components are available in 9 sizes (0 to 8), for both right and left sides. They are available in cemented versions (orthopaedic cement) without coating and in cementless versions with hydroxyapatite (HA) coating in combination with a titanium undercoating on the areas in contact with bone.

SCORE tibial inserts are available in 7 sizes (1 to 7) and 5 thicknesses (10, 12, 14, 16, 20 mm). They are symmetrical, and therefore, can be used for the right or left side. The indicated thickness on the label includes the thickness of the tibial baseplate.
SCORE II tibial inserts are available in 9 sizes (0 to 8) and 6 thicknesses (10, 11, 12, 14, 16, 20 mm). They are symmetrical, and therefore, can be used for the right or left side. The indicated thickness on the label includes the thickness of the tibial baseplate.

SCORE tibial baseplate models are available in 9 sizes (0 to 8). They are symmetrical, and therefore, can be used in the right or left side. They are available in cemented versions (orthopaedic cement) without coating, and in cementless version with hydroxyapatite coating (HA) associated with a titanium undercoating on the areas in contact with bone.

SCORE Allergy Solution tibial baseplate models are available in 7 sizes (1 to 7). They are symmetrical, and therefore, can be used in the right or left side. They are available only in cemented versions (orthopaedic cement).

SCORE and SCORE II total knee prostheses are intended to be implanted with or without orthopaedic cement. SCORE Allergy Solution total knee prosthesis is intended to be implanted only with orthopaedic cement. The description of the medical device affixed on the packaging specifies the fixation method.

The implantation and removal of a joint prosthesis using its associated instrumentation must be performed only 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, the surgical techniques, and the state of the art of knee surgery including modern cementing techniques. **SCORE, SCORE Allergy Solution and SCORE II total knee prostheses** are also intended to be used by scrub nurses, operating room staff and any participant of the supply chain from manufacturing to operating room.

SCORE, SCORE Allergy Solution and SCORE II total knee prostheses are intended to be used in the sterile area in operating room of healthcare facilities.

All knee prosthetic elements of **SCORE, SCORE Allergy Solution and SCORE II total knee prostheses** are intended to be in contact with the knee joint tissues, fluids and bones.

2. RECOMMENDATIONS ABOUT THE COMPONENTS ASSOCIATIONS

SCORE and SCORE Allergy Solution tibial baseplates may be associated with additional devices such as extension stems, offset adapters and/or tibial augments. These additional devices are available in various versions. 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, thickness, material).

AMPLITUDE implants must be assembled using AMPLITUDE components as defined below and in the following surgical techniques:

Medical device	Surgical techniques
SCORE/SCORE AS	TO.G.008, TO.G.009, TO.G.010, TO.G.019, TO.G.037, TO.G.038
SCORE II	TO.G.008, TO.G.009, TO.G.010, TO.G.013, TO.G.019, TO.G.037, TO.G.038, TO.G.12, TO.G.52

Compatibilities with the optional devices

Association of SCORE and SCORE II total knee prostheses with the optional devices (extension stems: lengths 75, 100, 150 and 200 mm and diameter 10, 12, 14 and 16 mm; offset adapters 2, 4 and 6 mm; and tibial augments) are indicated in the IFU supplied with these implants.

Association of SCORE Allergy Solution total knee prostheses with the optional devices (extension stems: lengths 75 and 100 mm and diameter 10 and 12 mm; and tibial augments) are indicated in the IFU supplied with these implants.

It is compulsory to use a cemented tibial baseplate when a tibial augment is associated with it.
In the absence of an association with an extension stem, the standard keel (supplied in the tibial baseplate packaging) must be mounted and locked on the tibial baseplate by the surgeon before implantation to avoid polyethylene particles migration in the femoral bone channel.

Compatible size associations between SCORE, SCORE Allergy Solution and SCORE II components

SCORE and SCORE Allergy Solution femoral components must only be used in association with SCORE tibial inserts. SCORE II femoral components must only be used in association with SCORE II tibial inserts.

SCORE II femoral components and tibial inserts are incompatible with SCORE tibial inserts and SCORE and SCORE Allergy Solution femoral components respectively.

SCORE tibial baseplate is intended to be used for SCORE, SCORE revision and SCORE II prostheses. **Sizes 0 and 8 are intended to be used with SCORE II components only.**

SCORE Allergy Solution tibial baseplate is intended to be used only for SCORE Allergy Solution prostheses**.**

Several associations are made possible between the different tibial implant sizes (insert and baseplate). **However, only femoral component and tibial bearing inserts of same size must be associated with one another.**

See **Table A** at the end of this IFU for compatible size associations between all SCORE II total knee prostheses components.

See **Table B** at the end of this IFU for compatible size associations between all SCORE and SCORE Allergy Solution total knee prostheses components.

→ **For details regarding the use of SCORE tibial baseplate with SCORE revision femoral components and inserts, please refer to the IFU supplied with these devices.**

Associations with patellar implants

SCORE, SCORE Allergy Solution and SCORE II femoral components are compatible with AMPLITUDE patellar implants. All information regarding compatibilities is detailed in the patellar implants specific IFU provided with these devices.
The validated associations and assembly compatibilities for SCORE, SCORE Allergy Solution and SCORE II prosthetic components are given at the end of this IFU. **Only the combinations in Tables A & B have been validated by AMPLITUDE, any other association is prohibited.**

Associations with the surgical instruments

SCORE, SCORE Allergy Solution and SCORE II total knee prostheses must be implanted / extracted using AMPLITUDE instrumentation specifically supplied for this purpose. AMPLITUDE instrumentation to extract medical devices is not available for all devices. In this case, the standard operating room instrumentation can be used.

SCORE, SCORE Allergy Solution and SCORE II total knee prostheses might also be implanted using AMPLIVISION navigation system manufactured by AMPLITUDE and associated instrumentation. They might also be implanted using i.M.A.G.E. patient-matched system manufactured by AMPLITUDE.
Please consult dedicated IFUs provided with these devices for further information.

3. COMPOSITION OF MEDICAL DEVICE

The constitutive materials of the SCORE, SCORE Allergy Solution, and SCORE II total knee prostheses components are:

- **For SCORE or SCORE Allergy Solution or SCORE II femoral component and SCORE or SCORE Allergy Solution tibial baseplate:**

*****Cobalt Chromium alloy (CoCrMo) according to ISO 5832-4 standard. The composition of the constitutive materials is detailed in the table below.

Element	Compositional limits % (m/m)
Chromium (Cr)	26.5 to 30.0
Molybdenum (Mo)	4.5 to 7.0
Nickel (Ni)	1.0 max.
Iron (Fe)	1.0 max.
Carbon (C)	0.35 max.
Manganese (Mn)	1.0 max.
Silicon (Si)	1.0 max.
Cobalt (Co)	Balance

For **SCORE Allergy Solution femoral component** and **tibial baseplate,** the constitutive materials include an additional Titanium nitride (TiN) coating that contains %Ti + %N = 100%.

*Only for cementless devices (HA/Ti coating): the composition of Hydroxyapatite coating is according to ISO 13779-2, ISO 13779-6 and ASTM F1185 standards and the composition of titanium undercoating is according to ISO 13179-1 standard. The composition of these materials is detailed in the table below.

	Element	Composition limits (mass fraction)
Titanium undercoating	Carbon (C)	≤ 0.10%
	Hydrogen (H)	≤ 0.30%
	Iron (Fe)	≤ 0.60%
	Nitrogen (N)	≤ 5.00%
	Oxygen (O)	≤ 10.00%
	Titanium (Ti)	Balance
Hydroxyapatite coating	Pentacalcium hydroxide tris(orthophosphate) ($Ca_5(PO_4)_3OH$)	100%

- **For SCORE and SCORE II tibial bearing insert:**

*Ultra-high molecular weight polyethylene (UHMWPE) according to ISO 5834-1 and ISO 5834-2 standards. The material is 100% homopolymer of ethylene (polyethylene) with possible traces of: Titanium (Ti), Aluminium (Al), Calcium (Ca) and Chlorine (Cl).

- **For standard keel:**

*Stainless steel (M30NW) according to ISO 5832-9 standard. The composition of the constitutive materials 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
Residuals	-
Each	0.1 maximum
Total	0.4 maximum

SCORE, SCORE Allergy Solution and SCORE II prostheses components 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
This medical device contains the following substance defined as carcinogenic, mutagenic or toxic to reproduction (CMR) 1B in a concentration of maximum 69% weight by weight for **SCORE, SCORE Allergy Solution and SCORE II** femoral components and maximum 62% weight by weight for **SCORE and SCORE Allergy Solution tibial baseplates**:
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

SCORE, SCORE Allergy Solution and SCORE II total knee prostheses are intended for the replacement of the total knee joint in order to reduce pain and restore knee function in comparison with pre-operative status. **SCORE, SCORE Allergy Solution and SCORE II total knee prostheses must be implanted preserving the integrity of the lateral ligaments and sacrificing anterior and posterior cruciate ligaments.**

A total knee arthroplasty can only be considered in case of severe joint pathology after failure of the conservative treatments. **SCORE, SCORE Allergy Solution and SCORE II total knee prostheses** are intended to be implanted in patients (male and female) with mature skeletal development, with adequate available bone stock (left to the surgeon's discretion) and whose health condition allows undergoing an orthopaedic surgery. The choice of total knee arthroplasty for each patient is made by experienced surgeons.

5. INDICATIONS

SCORE, SCORE Allergy Solution and SCORE II total knee prostheses are indicated for:
- Primary or secondary osteoarthritis.
- Osteonecrosis.
- Rheumatoid arthritis / inflammatory diseases.
- Revising an osteotomy.
- Revising total, unicompartmental or femoro-patellar prostheses.

SCORE, SCORE Allergy Solution and SCORE II total knee prostheses are indicated for partial or total revisions treatment of specific total knee prosthesis cases (remains at the discretion of the surgeon).

SCORE Allergy Solution total knee prosthesis is indicated in the above listed cases when the patient presents high risk of metal hypersensitivity.

6. PERFORMANCE CHARACTERISTICS AND CLINICAL BENEFITS

The expected clinical benefits of total knee prostheses are:
- Restoring knee joint functionality.
- Relieving pain.
- Improving range of motion as well as joint stability.

Based on literature and national registry data, about 95% of primary total knee implants and about 80% of revision total knee implants continue to function at 10 years after surgery for SCORE and SCORE II total knee prostheses.
Based on literature and national registry data, about 94% of total knee implants continue to function at 10 years after surgery for SCORE AS total knee prostheses.
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 an implantation surgery of **SCORE, SCORE Allergy Solution and SCORE II total knee prostheses** are:
- Pregnancy and breastfeeding.
- 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.
- Highly localized arthrosis requiring osteotomy or unicompartmental arthroplasty.
- Anatomic disorder (intraarticular misalignment, ligament laxity) requiring a constrained or hinge prosthesis.
- Allergy to the implant materials.

Any underlying condition affecting the patient must be treated beforehand.

8. PREREQUISITES, WARNINGS 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 infection and/or falls.
- Metabolic disorders that reduce the patient’s resistance or induce progressive bone deterioration.
- Local bone tumors.
- Severe bone deformities likely to affect the positioning or the stable implantation of the implants.
- Severe osteoporosis.
- Playing sports intensively.
- Playing risky sports or engaging in risky activities.
- Addictive behavior.

It is essential not to modify the components.

8.2 Perioperative precautions

Modular components must be assembled securely. During assembly, the surgeon must avoid repeated assembly and disassembly of standard keel or offset connector or extension stem on the tibial baseplate.

Before the implantation of any components, check the integrity of implant surface and make sure that it is free of any foreign object (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 surgical technique.
Before the implantation of tibial baseplate, check that the screwed components are properly assembled.

During the impaction of the different components of the knee prosthesis, it is necessary to handle all components and specifically the polished ones with the utmost care in order to avoid any scratches or impacts. 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 loosening and dislocation**.**

During the surgery the surgeon must always assess the need to replace the native patella.

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 knee prosthesis. It cannot be guaranteed that the patient will recover total range of motion and anatomical function of the knee after the total knee 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 **SCORE, SCORE Allergy Solution and SCORE II total knee prostheses** include (some are occasional (between 1 in 1,000 and 1 in 100 implantations) with the use of **SCORE[1], SCORE Allergy Solution[1] and SCORE II[2] total knee prostheses)**:
- Impact of the surgery on the patient's general condition.
- Wounding of an important artery in the lower limb (e.g. popliteal artery) or a nerve (the sciatic nerve in particular).
- Disruption or rupture of the extensor system (e.g. patellar or quadricipital tendons).
- Rupture of an extensor muscle, following a patellar fracture or ruptured tendon for instance.
- Infection.
- Prolonged stiffness[1,2].
- Knee instability.
- Pain[1].
- Patellar clunk syndrome[1].
- Allergy to the implant materials.
- Osteolysis.
- Adverse reactions of human tissues to wear debris and particles.
- Peri-prosthetic bone fracture[1].
- Dislocation of the component or the entire prosthesis.
- Loosening of the component or the entire prosthesis.
- Wearing of the bearing surfaces.
- Breakage of the component or the entire prosthesis.
- Migration of a component or the entire prosthesis.
- Impingement between the implant and the surrounding tissues.

Other events linked to the surgery or known in the state of the art can also occur:
- Cardio-vascular, thromboembolic disorders: superficial or deep vein thrombosis and fat or pulmonary embolism.
- Hematoma.
- Algoneurodistrophy.
- Heterotopic ossification.
- Pejorative bone remodeling.

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 1.5T or 3T.
- Maximum spatial gradient field of 38 T/m (=3,800 G/cm) for a 1.5T MRI system and 19 T/m (= 1900 G/cm) for a 3.0T MRI system.
- Normal operating mode only.
- Maximum MR system reported whole-body-averaged specific absorption rate (WB-SAR) of 2 W/kg for 15 minutes of scanning.

Heating:
Maximum measured temperature rise with 1.5T MRI is 8.6°C for 15mn of scanning with a WB-SAR measured by calorimetry of 3.27 W/kg (1.5-T/64MHz, GE Signa system, HDxt, software hd23.0_v02). For a 3T MRI, maximum heating is 9.9°C for 15mn of scanning with a measured WB-SAR of 2.39 W/kg (3.0-T/128MHz, GE Signa system, HDxt, software hd23.0_v02).
Amplitude recommends the following 45-minute scanning sequence:
- 5 imaging sessions
- Imaging session duration: 3 minutes
- Time between imaging sessions: 6 minutes.

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 artefact caused by the device extends at maximum 99 mm when imaged with a gradient echo pulse sequence and a 1.5T or 3T MRI system.

RF coils:
- Whole body transmit RF coils are authorized for any landmark.
- Head, torso and upper extremities local RF transmit coils are authorized.
- Lower extremities local RF transmit coils are prohibited.
- Receive-only coils are authorized for any landmark.

11. STORAGE / HANDLING / DISPOSAL

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

Implants must be handled with clean gloves to avoid soiling the surface to be cemented.

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 elements 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. The implant/explant must be destroyed in accordance with applicable regulations for handling of biological medical waste.

The use-by 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 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 SCORE, SCORE Allergy Solution and SCORE II total knee prostheses is available on the European database on medical devices (EUDAMED) website at the following address: https://ec.europa.eu/tools/eudamed.

The summary of safety and clinical performances is linked to the System BASIC UDI-DI of SCORE, SCORE Allergy Solution and SCORE II total knee prostheses. The summary of safety and clinical performances is available using the following code directly on EUDAMED website.

System BASIC UDI-DI of SCORE total knee prosthesis: 37010895SYSKN103066Q.
System BASIC UDI-DI of SCORE Allergy Solution total knee prosthesis: 37010895SYSKN103046L.
System BASIC UDI-DI of SCORE II total knee prosthesis: 370108955SYSKN10301AB.

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 knee 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 at the end of these IFU.
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

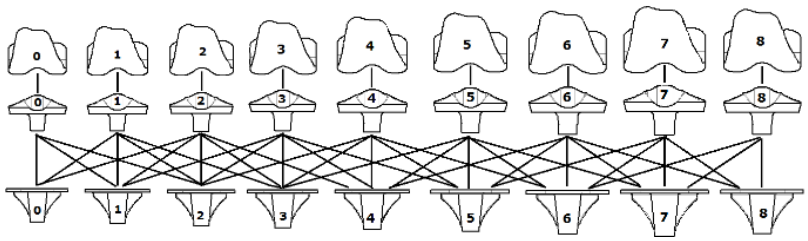
All the information strictly necessary for the surgeon to identify the device is located on the external package of the medical device.
Symbols are described at the end of these instructions for use.

Date CE marking first applied: 2002
The CE marking is only valid if it also appears on the packaging label.

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 OF MANUFACTURE AND COUNTRY OF MANUFACTURE (MADE IN FRANCE)
	MR CONDITIONAL
	KEEP AWAY FROM SUNLIGHT
	MEDICAL DEVICE
	UNIQUE DEVICE IDENTIFIER
	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.

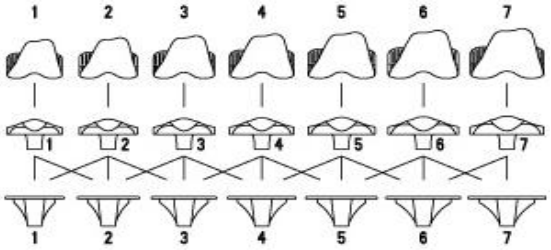
A. Compatible size associations between SCORE II components

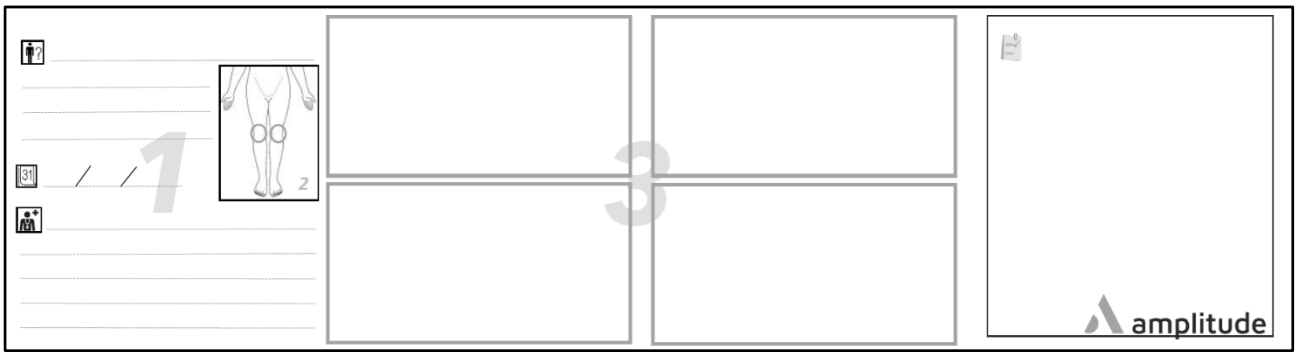
Note: Mixing femoral components and tibial inserts SCORE, SCORE II and SCORE revision is forbidden.

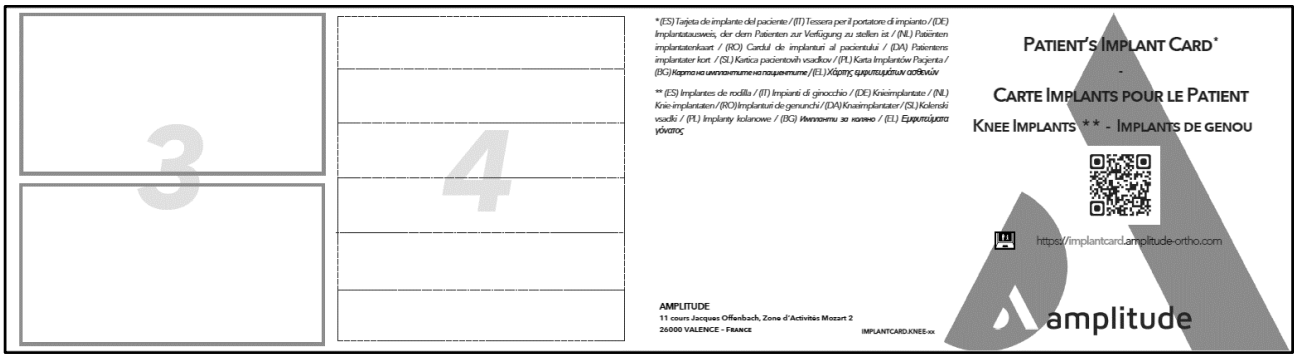


B. Compatible size associations between SCORE and SCORE Allergy Solution components

Note: Mixing femoral components and tibial inserts SCORE, SCORE II and SCORE revision is forbidden.







(1) Please fill in information according to the logos signification below
(2) Check the operated side (left/right)
(3) Stick the device labels in the frames delimited for this purpose (in blue)
(4) Stick here multilingual labels according the need

	Patient Name
	Healthcare institution
	Surgery Date

REF: NO222 (indB)

https://eIFU.amplitude-ortho.com

NO222-B 2024-08-13

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