



UNICOMPARTMENTAL KNEE
SYSTEM

summary

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01 General presentation

- ▷ The product presented hereafter is a class III sterile medical device according to the first article of the Directive 2005/50/CE modifying the annex IX of the Directive 93/42/CEE.
- ▷ This primary unicompartamental knee system is composed of several implants intended to replace the internal or external femoro tibial areas of the knee.
- ▷ **It is composed of three parts :**
 - the femoral component that replaces the distal extremity of the femur,
 - the tibial tray for fixed bearing insert,
 - the tibial fixed bearing insert ensures the link between the tibia and the femur.
- ▷ **Or of two parts :**
 - the femoral component,
 - the all polyethylene tibial component.
- ▷ This system allows, with the same femoral component and the same instruments to choose between a full polyethylene tibial component or a metal-back tibial tray for fixed bearing insert.
- ▷ **Femoral component :**
 - The Cobalt Chromium alloy (CoCrMo) implant is symmetric with a slim inferior edge that avoid conflicts with the patella. It is available both in cemented and without cement (Titanium spray HAP) versions and exists in 7 sizes,
 - The implant drawing presents two radii of curvature, a constant radius from stretching to bending, and a second radius, smaller allowing a better bending,
 - The implant allows a 8 rake,
 - The femoral component anchorage is made thanks to two parallel pegs. They present a 70° angle that reduces the ejection forces,
 - Minimal femoral cuts in the bone (6 mm) in order to preserve the bone,
 - Sterilization by gamma irradiation.

01 General presentation

Tibial tray with peg for fixed bearing insert :

- The implant is in Cobalt Chromium alloy (CoCrMo) and is available in cementless version with Titanium spray and HA coating.
- The implant is asymmetric: Right Medial / Left Lateral and Left Medial / Right Lateral and is available in 7 sizes with an homothetic progression,
- The primary stability is ensured by a « press fit » effect obtained by the titanium spray, and by an anteriorised peg.
- The sterilization is realized by gamma irradiation.

This peg incorporates a hole for an optional fixation screw. With or without the use of the fixation screw, an obturator cap in PEEK fills the hole in order to limit any deformation of the fixed bearing insert,

- The surface in contact with the bearing insert is polished to limit a back side wear out.
- The tray presents a system that locks the fixed bearing insert in order to avoid micro movements.

01 General presentation

Fixed tibial bearing insert :

- The insert is flat, symmetric and available in 7 sizes and 4 thicknesses presenting a millimetric evolution (9, 10, 11, 12 mm),
- The insert presents an original clipping system on the baseplate that avoid micro movements,
- The insert is made of machined Ultra High Molecular Weight Polyethylene (UHMWPE),
- The sterilization is realized by vacuum gamma irradiation.

All polyethylene tibial component with stabilization keel :

- The component is flat, symmetric and available in 7 sizes and 5 thicknesses presenting a millimetric evolution (8, 9, 10, 11, 12 mm),
- The primary stability is ensured both by a stabilization keel and by a particular surface aspect (reversed relief),
- The implant is designed to be cemented,
- The implant is made of machined Ultra High Molecular Weight Polyethylene (UHMWPE),
- The sterilization is realized by vacuum gamma irradiation.

Instrumentations :

Instrumentations are available in conventional and patient-matched computer assisted versions. These ergonomic systems are accurate and repeatable.

02

List of reference*

UNI SCORE Femoral component

UNI SCORE femoral component - HA coated - cementless	References
UNI SCORE femoral component - HA coated - cementless Size 1	1-0202201
UNI SCORE femoral component - HA coated - cementless Size 2	1-0202202
UNI SCORE femoral component - HA coated - cementless Size 3	1-0202203
UNI SCORE femoral component - HA coated - cementless Size 4	1-0202204
UNI SCORE femoral component - HA coated - cementless Size 5	1-0202205
UNI SCORE femoral component - HA coated - cementless Size 6	1-0202206
UNI SCORE femoral component - HA coated - cementless Size 7	1-0202207

UNI SCORE femoral component - cemented	References
UNI SCORE femoral component - cemented - Size 1	1-0202301
UNI SCORE femoral component - cemented - Size 2	1-0202302
UNI SCORE femoral component - cemented - Size 3	1-0202303
UNI SCORE femoral component - cemented - Size 4	1-0202304
UNI SCORE femoral component - cemented - Size 5	1-0202305
UNI SCORE femoral component - cemented - Size 6	1-0202306
UNI SCORE femoral component - cemented - Size 7	1-0202307

02

List of reference*

UNI SCORE Fixed bearing insert

UNI SCORE tibial tray with peg for fixed bearing insert - HA coated - cementless	References
UNI SCORE tibial tray for fixed bearing insert HA coated cementless Size 1 RM/LL	1-0205701
UNI SCORE tibial tray for fixed bearing insert HA coated cementless Size 2 RM/LL	1-0205702
UNI SCORE tibial tray for fixed bearing insert HA coated cementless Size 3 RM/LL	1-0205703
UNI SCORE tibial tray for fixed bearing insert HA coated cementless Size 4 RM/LL	1-0205704
UNI SCORE tibial tray for fixed bearing insert HA coated cementless Size 5 RM/LL	1-0205705
UNI SCORE tibial tray for fixed bearing insert HA coated cementless Size 6 RM/LL	1-0205706
UNI SCORE tibial tray for fixed bearing insert HA coated cementless Size 7 RM/LL	1-0205707

UNI SCORE tibial tray with peg for fixed bearing insert - HA coated - cementless	References
UNI SCORE tibial tray for fixed bearing insert HA coated cementless Size 1 LM/RL	1-0205801
UNI SCORE tibial tray for fixed bearing insert HA coated cementless Size 2 LM/RL	1-0205802
UNI SCORE tibial tray for fixed bearing insert HA coated cementless Size 3 LM/RL	1-0205803
UNI SCORE tibial tray for fixed bearing insert HA coated cementless Size 4 LM/RL	1-0205804
UNI SCORE tibial tray for fixed bearing insert HA coated cementless Size 5 LM/RL	1-0205805
UNI SCORE tibial tray for fixed bearing insert HA coated cementless Size 6 LM/RL	1-0205806
UNI SCORE tibial tray for fixed bearing insert HA coated cementless Size 7 LM/RL	1-0205807

*Check availability in your country

02

List of reference*

UNI SCORE Tibial tray

UNI SCORE tibial fixed bearing insert	References
UNI SCORE tibial fixed bearing insert Size 1 Thickness 9	1-0202621
UNI SCORE tibial fixed bearing insert Size 1 Thickness 10	1-0202631
UNI SCORE tibial fixed bearing insert Size 1 Thickness 11	1-0202641
UNI SCORE tibial fixed bearing insert Size 1 Thickness 12	1-0202651
UNI SCORE tibial fixed bearing insert Size 2 Thickness 9	1-0202622
UNI SCORE tibial fixed bearing insert Size 2 Thickness 10	1-0202632
UNI SCORE tibial fixed bearing insert Size 2 Thickness 11	1-0202642
UNI SCORE tibial fixed bearing insert Size 2 Thickness 12	1-0202652
UNI SCORE tibial fixed bearing insert Size 3 Thickness 9	1-0202623
UNI SCORE tibial fixed bearing insert Size 3 Thickness 10	1-0202633
UNI SCORE tibial fixed bearing insert Size 3 Thickness 11	1-0202643
UNI SCORE tibial fixed bearing insert Size 3 Thickness 12	1-0202653
UNI SCORE tibial fixed bearing insert Size 4 Thickness 9	1-0202624
UNI SCORE tibial fixed bearing insert Size 4 Thickness 10	1-0202634
UNI SCORE tibial fixed bearing insert Size 4 Thickness 11	1-0202644
UNI SCORE tibial fixed bearing insert Size 4 Thickness 12	1-0202654
UNI SCORE tibial fixed bearing insert Size 5 Thickness 9	1-0202625
UNI SCORE tibial fixed bearing insert Size 5 Thickness 10	1-0202635
UNI SCORE tibial fixed bearing insert Size 5 Thickness 11	1-0202645
UNI SCORE tibial fixed bearing insert Size 5 Thickness 12	1-0202655
UNI SCORE tibial fixed bearing insert Size 6 Thickness 9	1-0202626
UNI SCORE tibial fixed bearing insert Size 6 Thickness 10	1-0202636
UNI SCORE tibial fixed bearing insert Size 6 Thickness 11	1-0202646
UNI SCORE tibial fixed bearing insert Size 6 Thickness 12	1-0202656
UNI SCORE tibial fixed bearing insert Size 7 Thickness 9	1-0202627
UNI SCORE tibial fixed bearing insert Size 7 Thickness 10	1-0202637
UNI SCORE tibial fixed bearing insert Size 7 Thickness 11	1-0202647
UNI SCORE tibial fixed bearing insert Size 7 Thickness 12	1-0202657

02

List of reference*

UNI SCORE All-poly component

UNI SCORE all-poly component	References
UNI SCORE all poly tibial component Size 1 Thickness 8	1-0202811
UNI SCORE all poly tibial component Size 1 Thickness 9	1-0202821
UNI SCORE all poly tibial component Size 1 Thickness 10	1-0202831
UNI SCORE all poly tibial component Size 1 Thickness 11	1-0202841
UNI SCORE all poly tibial component Size 1 Thickness 12	1-0202851
UNI SCORE all poly tibial component Size 2 Thickness 8	1-0202812
UNI SCORE all poly tibial component Size 2 Thickness 9	1-0202822
UNI SCORE all poly tibial component Size 2 Thickness 10	1-0202832
UNI SCORE all poly tibial component Size 2 Thickness 11	1-0202842
UNI SCORE all poly tibial component Size 2 Thickness 12	1-0202852
UNI SCORE all poly tibial component Size 3 Thickness 8	1-0202813
UNI SCORE all poly tibial component Size 3 Thickness 9	1-0202823
UNI SCORE all poly tibial component Size 3 Thickness 10	1-0202833
UNI SCORE all poly tibial component Size 3 Thickness 11	1-0202843
UNI SCORE all poly tibial component Size 3 Thickness 12	1-0202853
UNI SCORE all poly tibial component Size 4 Thickness 8	1-0202814
UNI SCORE all poly tibial component Size 4 Thickness 9	1-0202824
UNI SCORE all poly tibial component Size 4 Thickness 10	1-0202834
UNI SCORE all poly tibial component Size 4 Thickness 11	1-0202844
UNI SCORE all poly tibial component Size 4 Thickness 12	1-0202854
UNI SCORE all poly tibial component Size 5 Thickness 8	1-0202815
UNI SCORE all poly tibial component Size 5 Thickness 9	1-0202825
UNI SCORE all poly tibial component Size 5 Thickness 10	1-0202835
UNI SCORE all poly tibial component Size 5 Thickness 11	1-0202845
UNI SCORE all poly tibial component Size 5 Thickness 12	1-0202855
UNI SCORE all poly tibial component Size 6 Thickness 8	1-0202816
UNI SCORE all poly tibial component Size 6 Thickness 9	1-0202826
UNI SCORE all poly tibial component Size 6 Thickness 10	1-0202836
UNI SCORE all poly tibial component Size 6 Thickness 11	1-0202846
UNI SCORE all poly tibial component Size 6 Thickness 12	1-0202856
UNI SCORE all poly tibial component Size 7 Thickness 8	1-0202817
UNI SCORE all poly tibial component Size 7 Thickness 9	1-0202827
UNI SCORE all poly tibial component Size 7 Thickness 10	1-0202837
UNI SCORE all poly tibial component Size 7 Thickness 11	1-0202847
UNI SCORE all poly tibial component Size 7 Thickness 12	1-0202857

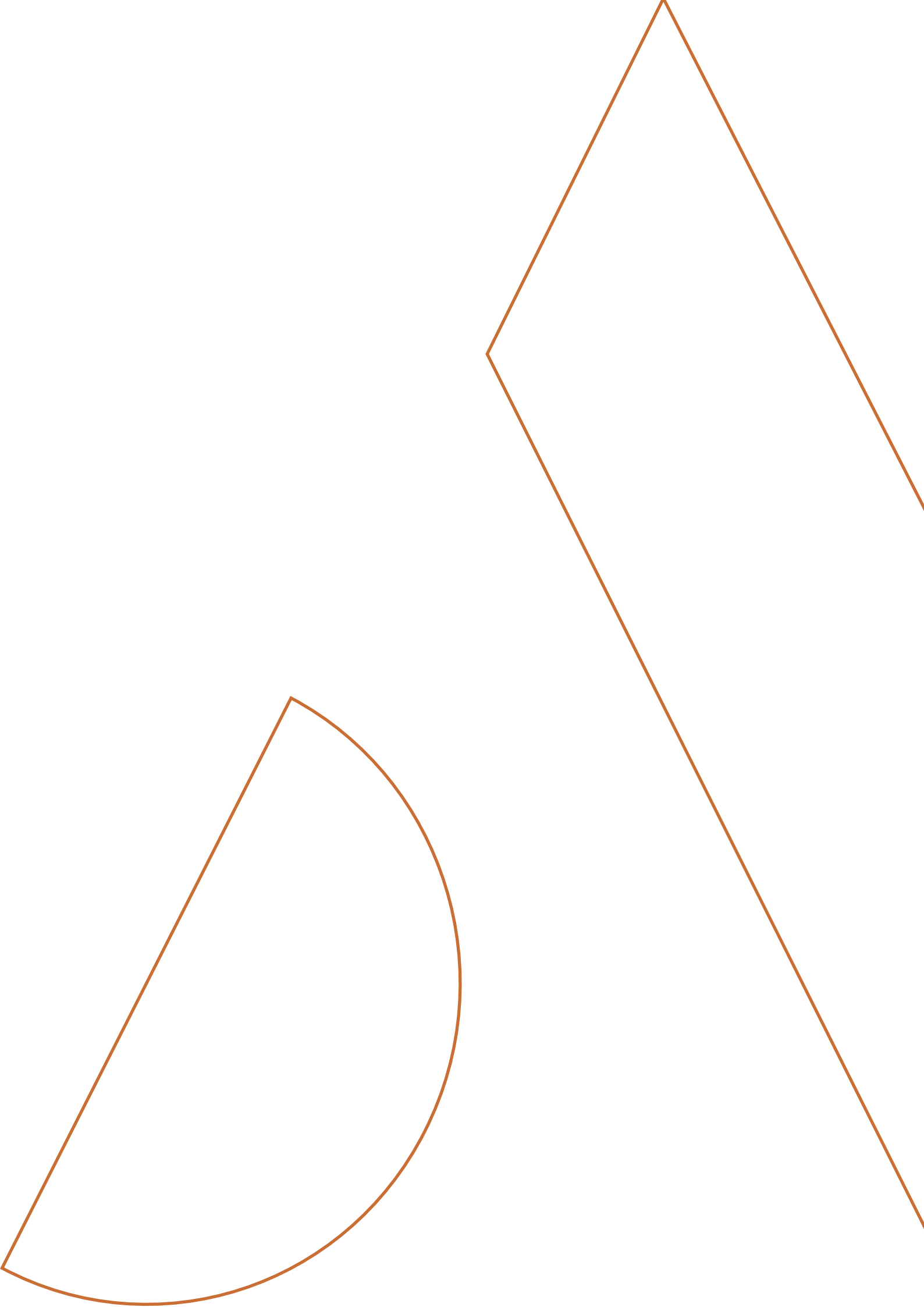
*Check availability in your country

02

List of reference*

Fixation screw

Cancellous bone screw	Reference
Fixation screw diameter 6.5 Lg. 16mm	1-0101616
Fixation screw diameter 6.5 Lg. 20mm	1-0101620
Fixation screw diameter 6.5 Lg. 25mm	1-0101625
Fixation screw diameter 6.5 Lg. 30mm	1-0101630
Fixation screw diameter 6.5 Lg. 35mm	1-0101635
Fixation screw diameter 6.5 Lg. 40mm	1-0101640
Fixation screw diameter 6.5 Lg. 45mm	1-0101645



03 Technical information

UNI SCORE femoral component - HA coated - cementless

Manufacturer

AMPLITUDE, 11 Cours Jacques OFFENBACH,
Zone MOZART 2, 26000 VALENCE, France

Presence of latex in the product's composition: None

Material:

Chrome Cobalt alloy Implantable according to standard ISO 5832-4
Titanium + Hydroxyapatite (HA) coating according to ISO 13179-1, ISO 13179-2, ISO 13179-6 and
ASTM F1185 standards

Manufacturing process:

Casting
Inspection
Polishing
Engraving
Inspection
Passivation
Cleaning
Sand blasting and Titanium + Hydroxyapatite (HAP) coating
Cleaning
Internal label printing
Inspection
Final cleaning
Packaging and labelling
Packing
Sterilization by gamma irradiation with a minimum dose of 25 kGy
Release

CE Mark:

Notified Body: BSI Group The Netherlands B.V (CE2797)
Date EC marking first applied: 2007

03 Technical information

UNI SCORE femoral component - cemented

Manufacturer

AMPLITUDE, 11 Cours Jacques OFFENBACH
ZA MOZART 2, 26000 VALENCE, France.

Presence of latex in the product's composition: None

Material:

Chrome Cobalt alloy Implantable according to standard ISO 5832-4

Manufacturing process:

Casting
Inspection
Polishing
Engraving
Inspection
Passivation
Cleaning
Internal label printing
Inspection
Final cleaning
Packaging and labelling
Packing
Sterilization by gamma irradiation with a minimum dose of 25 kGy
Release

CE Mark:

Notified Body: BSI Group The Netherlands B.V (CE2797)
Date EC marking first applied: 2007

03 Technical information

Uni SCORE tibial tray with peg for fixed bearing insert – HA coated – cementless

Manufacturer

AMPLITUDE, 11 Cours Jacques OFFENBACH
ZA MOZART 2, 26000 VALENCE, France.

Presence of latex in the product's composition: None

Material :

Chrome Cobalt alloy Implantable according to standard ISO 5832-12

PEEK implantable according to standard ASTM F2026 (UNI SCORE tibial tray with peg for fixed bearing insert)

Titanium + Hydroxyapatite (HA) coating according to ISO 13179-1, ISO 13179-2, ISO 13179-6 and ASTM F1185 standards

Manufacturing process:

Machining

Polishing

Engraving

Inspection

Passivation

Sand blasted and Titanium + Hydroxyapatite (HAP) coating

Cleaning

Gathering

Inspection

Final cleaning

Packaging

Sterilisation by gamma irradiation with a minimum dose of 25 kGy

Release

CE Mark:

Notified Body: BSI Group The Netherlands B.V (CE2797)

Date EC marking first applied: 2014

03 Technical information

UNI SCORE tibial fixed bearing insert

Manufacturer

AMPLITUDE, 11 Cours Jacques OFFENBACH
ZA MOZART 2, 26000 VALENCE, France.

Presence of latex in the product's composition: None

Material:

Ultra High Molecular Weight Polyethylene (UHMWPE) Implantable according to ISO 5834-1 and ISO 5834-2 standards

Manufacturing process:

Machining
Engraving
Inspection
Internal label printing
Cleaning
Packaging clean room
Boxing
Packing
Sterilisation by gamma irradiation with a minimum dose of 25 kGy
Release

CE Mark:

Notified Body: BSI Group The Netherlands B.V (CE2797)
Date EC marking first applied: 2007

03 Technical information

UNI SCORE all-polyethylene tibial component

Manufacturer

AMPLITUDE, 11 Cours Jacques OFFENBACH
ZA MOZART 2, 26000 VALENCE, France.

Presence of latex in the product's composition: None

Material:

Ultra High Molecular Weight Polyethylene (UHMW PE) Implantable according to ISO 5834-1 and ISO 5834-2 standards

Manufacturing process:

Machining
Engraving
Inspection
Internal label printing
Cleaning
Packaging clean room
Boxing
Packing
Sterilisation by gamma irradiation with a minimum dose of 25 kGy
Release

CE Mark:

Notified Body: BSI Group The Netherlands B.V (CE2797)
Date EC marking first applied: 2009

03 Technical information

Fixation screw Ø 6,5

Manufacturer

AMPLITUDE, 11 Cours Jacques OFFENBACH
ZA MOZART 2, 26000 VALENCE, France.

Presence of latex in the product's composition: None

Material:

Titanium alloy (Ti6Al4V) Implantable according to standard ISO 5832-3

Manufacturing process:

Machining
Microbead blasting
Anodised
Engraving
Cleaning
Packaging and labelling
Sterilisation by gamma irradiation with a minimum dose of 25 kGy
Release

CE Mark:

Notified Body: BSI Group The Netherlands B.V (CE2797)
Date EC marking first applied: 1999

04 Technical information

UNI SCORE femoral component - HA coated - cementless

Implant engraving








non-contractual pictures

Information :

- Manufacturer Logo
- Batch number
- Implant size
- C = CoCrMo

Label

		UNI SCORE femoral component <i>Composant fémoral UNI SCORE</i>		Size / Taille 1	
		HA coated - cementless <i>HAP - sans ciment</i>		UNI SCORE femoral component <i>Composant fémoral UNI SCORE</i>	
REF 1-0202201 LOT 123456 2028-05-01 2023-06-05 QTY 1		UNI SCORE femoral component <i>Composant fémoral UNI SCORE</i>		REF 1-0202201 LOT 123456 2028-05-01	
		UNI SCORE femoral component <i>Composant fémoral UNI SCORE</i>			
UDI (01)03701089510684(17)280501(11)230605(10)123456				CoCrMo HATi coating eifu.amplitude-ortho.com	



non-contractual pictures

Packaging

Paper Box :

Dimensions : 120 x 95 x 36

Couleur : Nil / 88

Packaging :

Double blister.

04 Product identification

UNI SCORE femoral component - cemented

Implant engraving



non-contractual pictures

Information :

- Manufacturer Logo
- Batch number
- Implant size
- C = CoCrMo

Label

		UNI SCORE femoral component <i>Composant fémoral UNI SCORE</i>		Size / Taille 1
 CoCrMo		Cemented <i>A cimentier</i>		Size / Taille 1
REF 1-0202301	LOT 123456	2028-05-01	2023-06-05	QTY 1
 UDI (01)03701089510752(17)280501(11)230805(10)123456		UNI SCORE femoral component Composant fémoral UNI SCORE		Cemented A cimentier
AMPLITUDE - 11 cours Jacques Offenbach - ZA Mozart 2 - 28000 VALENCE - FRANCE		REF 1-0202301 LOT 123456 2028-05-01		J08F eifu.amplitude-ortho.com



non-contractual pictures

Packaging

Paper Box :

Dimensions : 120 x 95 x 36

Couleur : Blue / 132

Packaging :

Double blister.

04 Technical information

Uni SCORE tibial tray with peg for fixed bearing insert – HA coated – cementless

Implant engraving


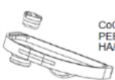





non-contractual pictures

Information :

- Manufacturer Logo
- Batch number
- Implant size
- C = CoCrMo

Label

		UNI SCORE tibial tray for fixed bearing insert <i>Embase tibiale UNI SCORE pour insert fixe</i> HA coated - cementless <i>HAP - sans ciment</i>		Size / Taille 1 RM/LL / IND/EXG	
 <p>CoCrMo PEEK HA/Ti coating</p>				Size / Taille 1 RM/LL / IND/EXG	
REF 1-0205701	LOT 123456	 2028-05-01	 2023-06-05	QTY 1	REF 1-0205701 LOT 123456 
UDI (01)03701089510684(17)280501(11)230605(10)123456					
AMPLITUDE - 11 cours Jacques Offenbach - ZA Mozart 2 - 26000 VALENCE - FRANCE					



non-contractual pictures

Packaging

Paper Box :

Dimensions : 120 x 95 x 36

Couleur : Dark Green / 354C

Packaging :

Double blister.

04 Technical information

UNI SCORE tibial fixed bearing insert

Implant engraving

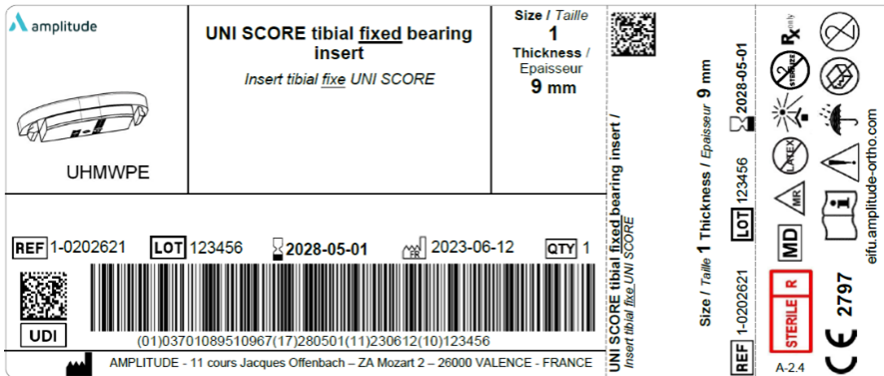


non-contractual pictures

Information :

- Manufacturer Logo
- Batch number
- Height and Implant size
- PE

Label



non-contractual pictures

Packaging

Paper Box :

Dimensions : 113x79x30

Couleur : Crimson / 68

Packaging :

Double 100/BON/PE/COEX bag.

04 Product identification

UNI SCORE all-polyethylene tibial component

Implant engraving







non-contractual pictures

Information :

- Manufacturer Logo
- Batch number
- Height and Implant size
- PE

Label

  UHMWPE	UNI SCORE all-poly tibial component Implant tibial tout PE UNI SCORE Cemented A cimenter	Size / Taille 1 Thickness / Epaisseur 8 mm	 UNI SCORE all-poly tibial component / Implant tibial tout PE UNI SCORE Cemented / A cimenter Size / Taille 1 Thickness / Epaisseur 8 mm REF 1-0202811 LOT 123456 2028-05-01 REF 1-0202811 LOT 123456 2028-05-01 MD STERILE R CE 2797 A-24 eifu.amplitude-ortho.com
	REF 1-0202811 LOT 123456 2028-05-01 2023-06-12 QTY 1  UDI (01)03701089511520(17)280501(11)230612(10)123456 AMPLITUDE - 11 cours Jacques Offenbach - ZA Mozart 2 - 26000 VALENCE - FRANCE	REF 1-0202811 LOT 123456 2028-05-01 REF 1-0202811 LOT 123456 2028-05-01 MD STERILE R CE 2797 A-24 eifu.amplitude-ortho.com	



non-contractual pictures

Packaging

Paper Box :

Dimensions : 113x79x30

Couleur : Pink / 52

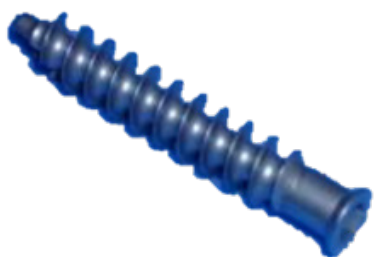
Packaging :

Double 100/BON/PE/COEX bag.

04 Product identification

Fixation screw Ø 6,5

Implant engraving



non-contractual pictures

Information :

- Manufacturer Logo
- Batch number
- Implant size
- Titanium alloy (Ti6Al4V)

Label



non-contractual pictures

Packaging

Paper Box :

Dimensions : 113 x 79 x 30

Couleur : White / 40

Packaging :

Double PA/PE bag.