



UNICOMPARTMENTAL KNEE
SYSTEM

summary

01

General presentation

- p.3 - p.4

02

List of reference

- p.5 - p.9 -

03

Technical information

- p.10 - p.22 -

04

Identification

- p.24 - p.36

01 General presentation

- ▷ The product presented hereafter is a class III sterile medical device according to Annex VIII Chapter III rule 8 of the 2017/745 (EU) Medical Devices Regulation.
- ▷ This primary unicompartmental 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 cemented or cementless femoral component that replaces the distal extremity of the femur,
 - the tibial tray for fixed bearing insert with peg and optional fixation screw
 - the tibial fixed bearing insert ensures the link between the tibia and the femur.
- ▷ **Or of two parts :**
 - the cemented femoral component,
 - the all polyethylene tibial component.
- ▷ This system allows, with 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. 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,
 - The implant allows a 8 rake,
 - The femoral component anchorage is made thanks to two parallel pegs. They present a 70° angle
 - 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.

- The surface in contact with the bearing insert is polished.
- The tray presents a system that locks the fixed bearing insert.

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,
- 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 tibial tray

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 fixed bearing insert

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

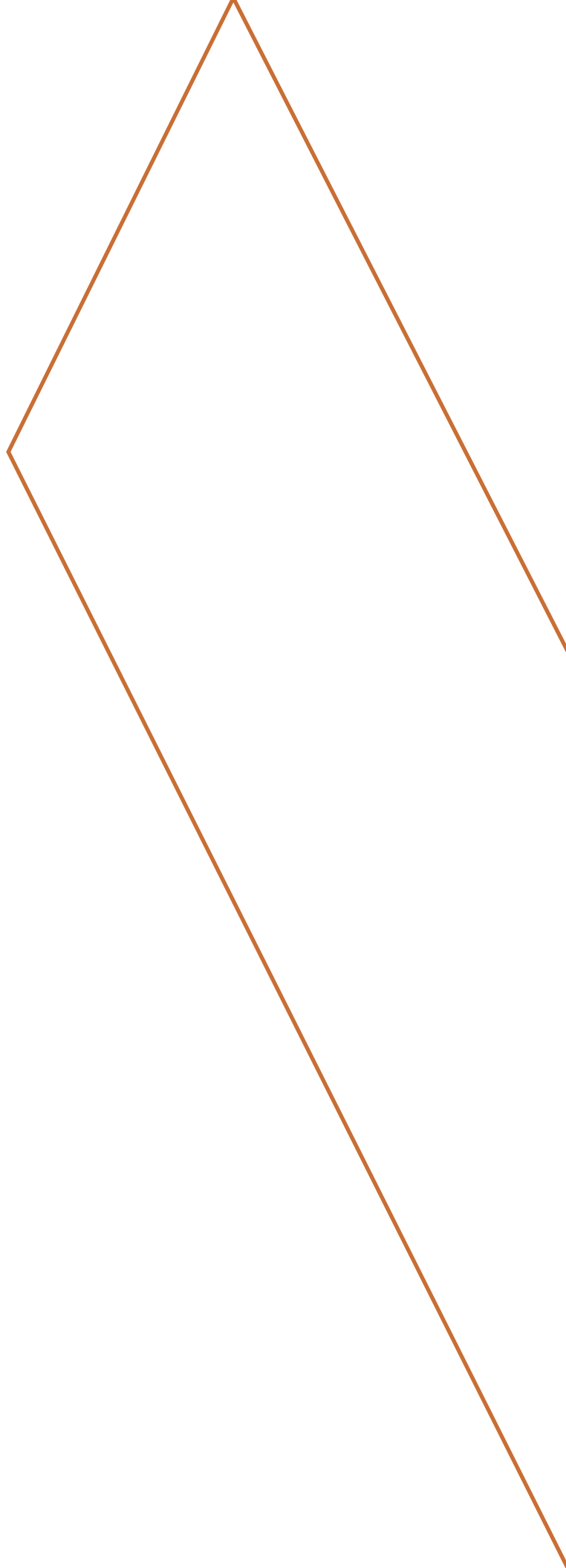
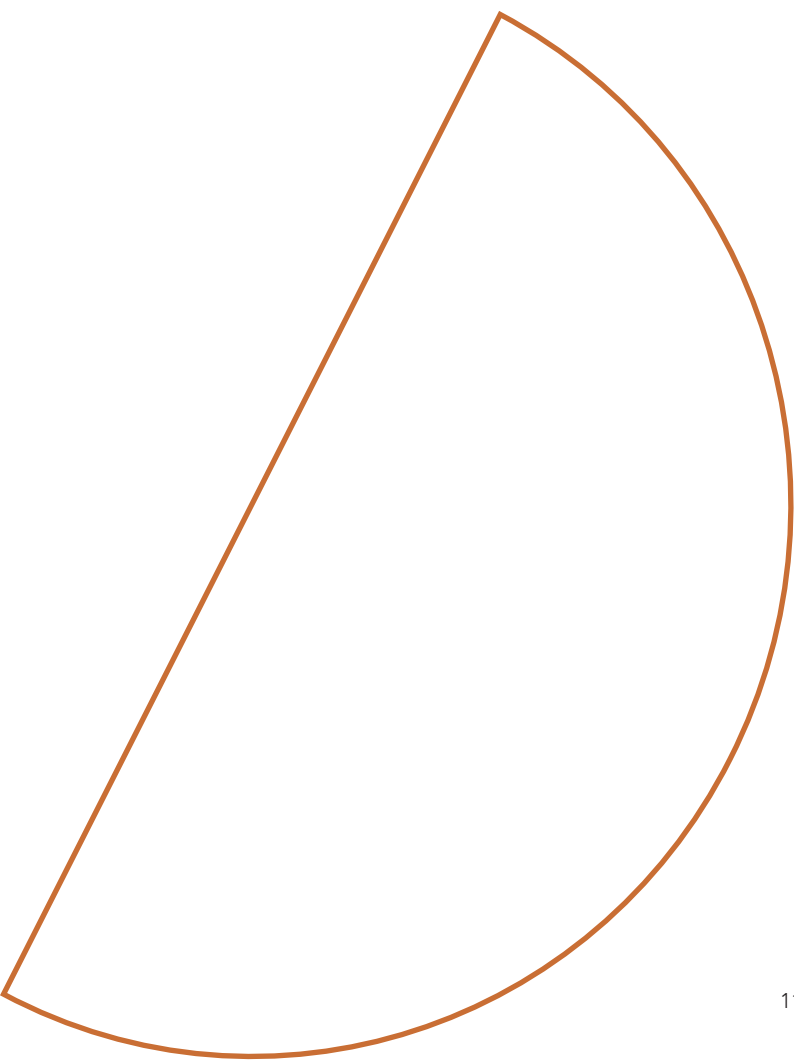
*Check availability in your country

02

List of reference*

Fixation screw

Fixation screw	Reference
Fixation screw diameter 6.5 mm Lg. 16mm	1-0101616
Fixation screw diameter 6.5 mm Lg. 20mm	1-0101620
Fixation screw diameter 6.5 mm Lg. 25mm	1-0101625
Fixation screw diameter 6.5 mm Lg. 30mm	1-0101630
Fixation screw diameter 6.5 mm Lg. 35mm	1-0101635
Fixation screw diameter 6.5 mm Lg. 40mm	1-0101640
Fixation screw diameter 6.5 mm 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: 2007

03 Technical information

Fixation screw Ø 6,5 mm

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	
UDI (01)03701089510684(17)280501(11)230605(10)123456				REF 1-0202201 LOT 123456 2028-05-01	
AMPLITUDE - 11 cours Jacques Offenbach - ZA Mozart 2 - 26000 VALENCE - FRANCE		eifu.amplitude-ortho.com		J-12	



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 Composant fémoral UNI SCORE		Size / Taille 1
CoCrMo		Cemented A cimentier		Size / Taille 1
REF 1-0202301	LOT 123456	2028-05-01	2023-06-05	QTY 1
		UDI (01)03701089510752(17)280501(11)230605(10)123456		
AMPLITUDE - 11 cours Jacques Offenbach - ZA Mozart 2 - 28000 VALENCE - FRANCE				



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	
 CoCrMo PEEK HATI coating				Size / Taille 1 RM/LL / IND/EXG	
REF 1-0205701	LOT 123456	2028-05-01	2023-06-05	QTY 1	
UNI SCORE tibial tray for fixed bearing insert / Embase tibiale UNI SCORE pour insert fixe HA coated - cementless / HAP - sans ciment					
REF 1-0205701 LOT 123456 2028-05-01					
UDI (01)03701089510684(17)280501(11)230605(10)123456					
AMPLITUDE - 11 cours Jacques Offenbach - ZA Mozart 2 - 26000 VALENCE - FRANCE					
STERILE R RX only MD Co MR CE 2797 eifu.amplitude-ortho.com					



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

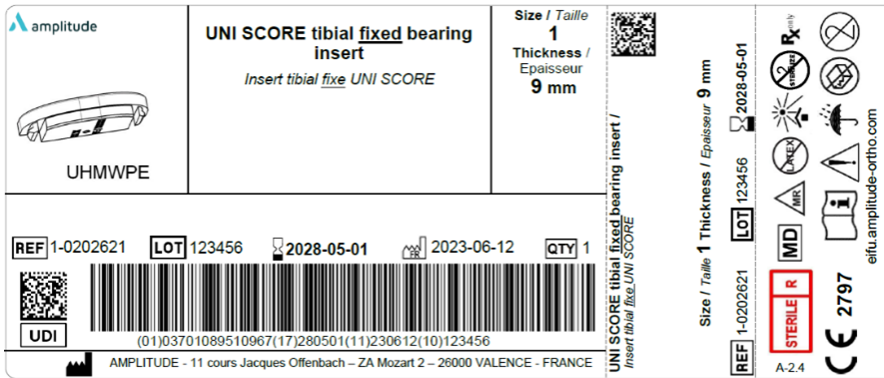


non-contractual pictures

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		



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 mm

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.