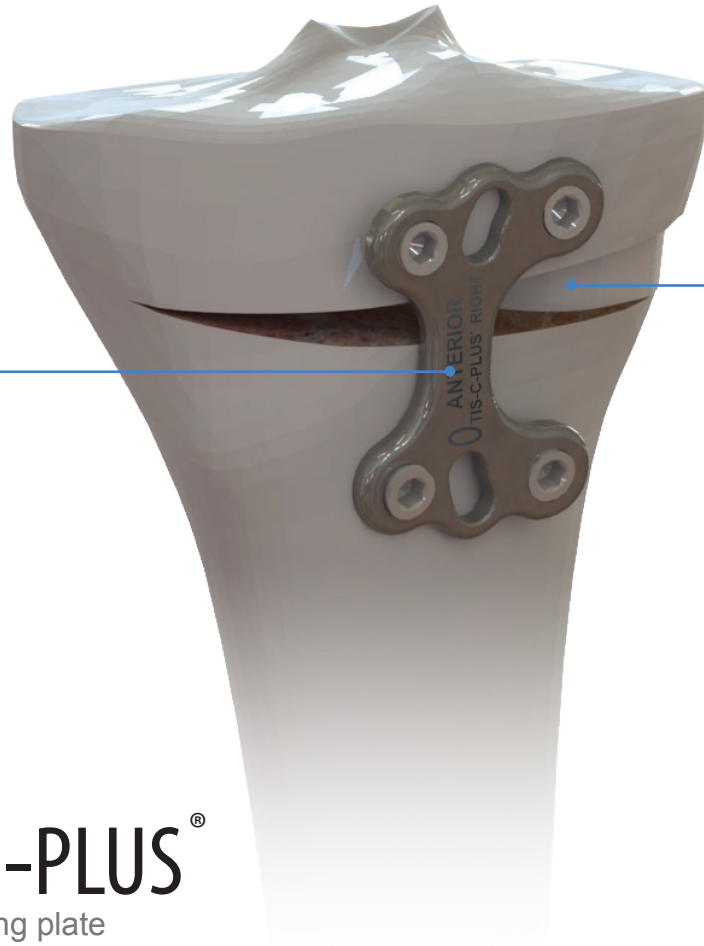


# Opening Wedge High Tibial Osteotomy

Complete system for minimally-invasive surgery



**OTIS**<sup>®</sup>  
100 %  $\beta$ -TCP  
Bioabsorbable wedge

**OTIS-C-PLUS**<sup>®</sup>  
Low profile locking plate



+ complete instrumentation set

## Bioabsorbable synthetic wedge

SBM, which boasts 20 years of experience in its field, was the first company (as early as 1996) to manufacture synthetic wedges for High Tibial Osteotomy (HTO) by metaphyseal addition <sup>2</sup>. Manufactured in Biosorb (100%  $\beta$  Tricalcium Phosphate), the OTIS<sup>®</sup> line of osteotomy wedges is designed to meet different porosity and size needs which makes it the most complete line of its kind available to this day.

### Adaptability

#### Anatomically shaped <sup>1-15</sup>

OTIS<sup>®</sup> implants, which combine a flat lower surface with an angulated upper surface, are designed to fit into the tibial osteotomy plane.

#### Several porosities

OTIS<sup>®</sup> implants have been adapted in terms of porosity to fit to any need 30% porosity for high mechanical resistance, 50% porosity for quick resorption.

#### Perfect precision

A complete set of 10 different wedge heights ranging from 6 to 15 mm in 1 mm increments, offering a precision of correction equal to 1°.

### Ensuring results

#### Bioactivity <sup>1-15</sup>

Biosorb closely resembles the mineral phase of bone, which enables a genuine chemical bond with the bone tissue without fibrous encapsulation nor inflammatory reaction.

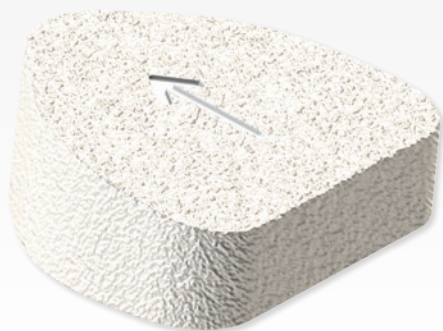
#### Osteointegration <sup>1-15</sup>

Complete control of the macroporosity guides bone cell penetration and improves bone graft integration with in the bone tissue.

#### Resorption <sup>1-15</sup>

OTIS<sup>®</sup> wedges are bioabsorbable: the implants are thus replaced by healthy new-formed bone once the cellular resorption process is complete.

### Wide choice of corrections

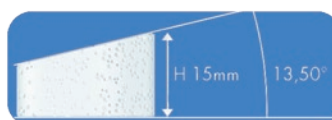
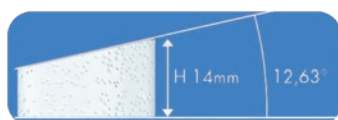
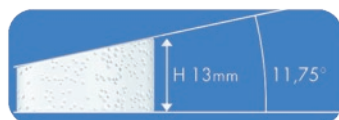
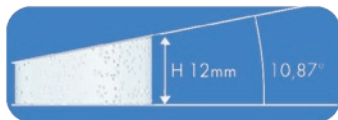
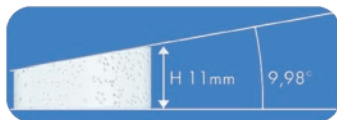
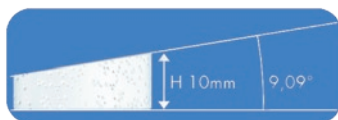
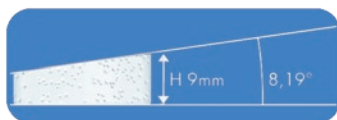
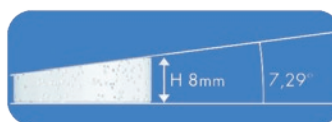
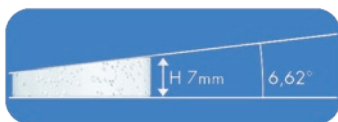
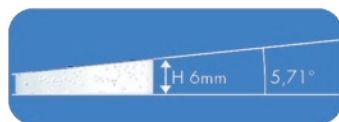


OTIS<sup>®</sup>

**30 % porosity**  
Mechanical strength  
(associated to a plate or staples)

OTIS 50<sup>®</sup>

**50 % porosity**  
Accelerated resorption  
(must be associated to a locking plate).



## Compressive locking plate

The OTIS-C-PLUS® plate is made of biocompatible stainless steel, it is anatomically shaped and low profile which makes it perfect for minimally-invasive surgical approaches. Its locking system ensures graft compression to guarantee optimal tibial stabilization as well as rapid weight-bearing.

### Safe and fast placement

#### Anatomically shaped

Specially designed for HTO stabilization, OTIS-C-PLUS® fits to the patient's anatomy and does not need to be pre-formed in most cases.

#### Resistant<sup>13-15</sup>

Biocompatible stainless steel plates are very resistant and can be easily removed (unlike titanium alloy plates).

#### Lockable

The twelve lengths of self-tapping locking screws are pre-oriented, which provides the ability to adapt the surgery (mono or bicortical anchorage) and to reduce surgical time.

### Quicker recovery

#### Compression

OTIS-C-PLUS® is a compression plate: graft compression promotes its absorption and provides stability.

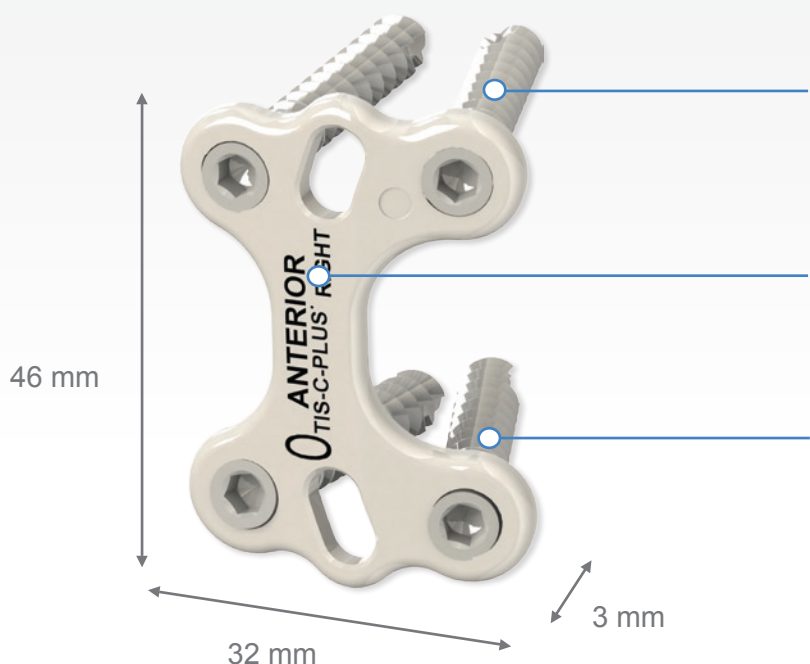
#### Almost immediate weight-bearing<sup>13-15</sup>

The rigidity of the plate is provided by its shape: the more rigid the osteosynthesis, the quicker weight-bearing can occur. Full weight-bearing is possible after 45 days.

#### Limited scars<sup>13-15</sup>

The plate is low-profile (30% shorter than standard osteosynthesis, only 3 mm thick), which makes it perfect for a genuine minimally-invasive surgical approach.

### An optimized design



#### Proximal screws

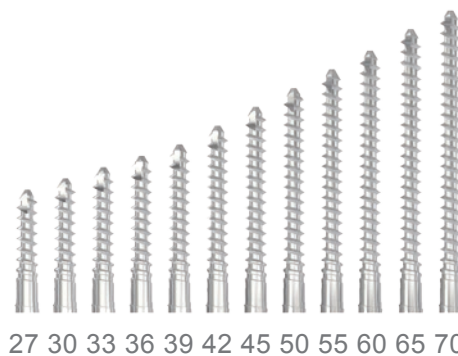
Perpendicular to the plate

#### Central fold

Anatomically shaped  
Avoids twisting the plate

#### Distal screws oriented downwards

Ensure compression



Twelve lengths of  $\varnothing$  6.5 mm self-tapping screws, without counter nuts (length in mm)

# OTIS-C-PLUS®

## Surgical technique

Two models of OTIS-C-PLUS® plates are available: right and left knee. To ensure proper positioning of the wedge and the plate, it is important to adhere to the following procedure (right knee in this example).

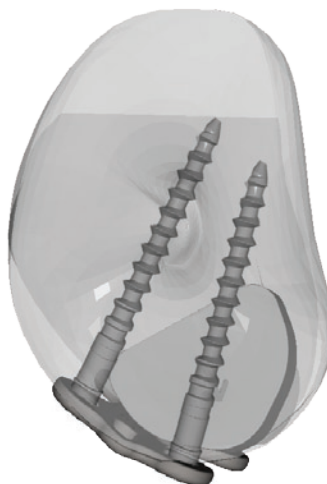
CAUTION: Do not insert the screws through the wedge to prevent graft damage.



Watch the video



Posterior view



Transverse view

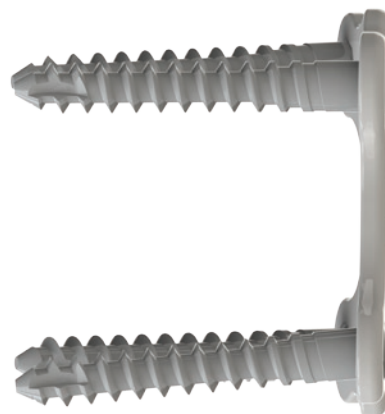


Plate - Side view

## OTIS-C-PLUS® plates



Right knee



Left knee

- T Temporary screws
- 1 First screw
- 2 Second screw
- 3 Third screw
- 4 Fourth screw

## Planning

Pre-operative confirmation of the correction required can be done in various ways:

- Hernigou's trigonometric chart (Rev. Chir. Orthop., 1992, 78, 258-283).
- The method using a cord allows for visualization of the lateral to medial mechanical axis.
- A protractor is used to measure the angle per-operatively.

## Step 1



### Medial metaphyseal incision

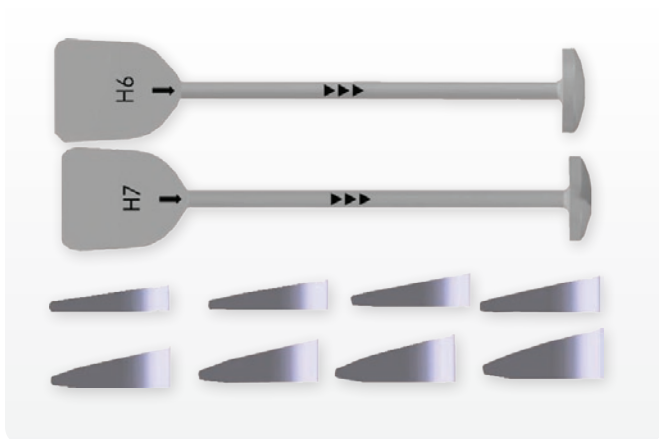
The medial metaphyseal incision has three reference points: the medial border of the tibial metaphysis, the posterior border of the patellar ligament, and the joint line.

The incision is short, 5 to 6 cm, longitudinal and equidistant from the patellar ligament and the posterior border of the tibia, just under the joint line. After incision through the subcutaneous tissue, the medial border of the patellar ligament and the deep tissue under the ligaments are dissected.

The internal fibroligamentous plane is incised longitudinally and progressively lifted from the tibial metaphyseal surface to allow the rugine to slide behind the medial border, and a right angle retractor to be inserted to protect the popliteal fossa.

To limit the risk of partition of the lateral tibial plateau, the opening can be achieved with Lambotte osteotomies.

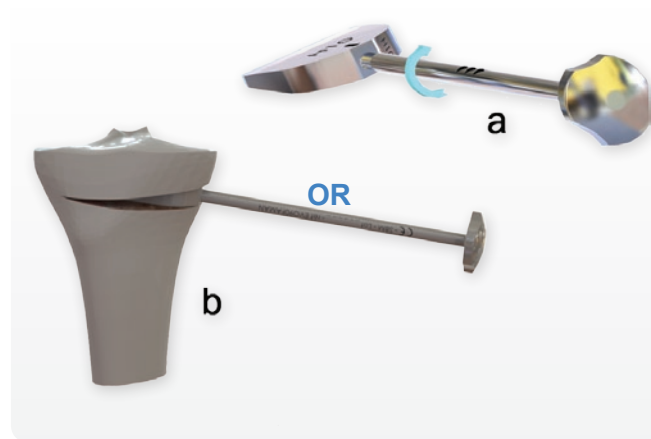
## Step 2



### Trial implant selection

The instrumentation set offers a range of 10 metallic trial implants with heights from 6 to 15 mm corresponding to the definitive implants.

## Step 3



### Implant from H 8 to 15 mm: (a)

Directly screw the handle on the trial implant.

### Implant H 6 or H 7: (b)

Grab the one-piece trial implant and insert it directly up to the osteotomy incision.

#### Step 4



#### Impaction

Impact the metallic trial implant within the osteotomy incision, until it is level with the postero-medial cortical bone.

Control the correction obtained by fluoroscopy.

#### Step 5



#### Retrieval

Retrieve the metallic implant by using the slotted hammer.

#### Step 6



#### Wedge positioning

Replace the metallic trial implant by the definitive implant. Carefully position the graft by hand in the osteotomy incision (e.g. using a gauze), an arrow located on the top surface helps position the implant properly.

*Note: if the edges of the implant are damaged during impaction, this will not affect the mechanical strength of the implant.*

#### Step 7



#### Impaction

The instrumentation set provides you with an impactor and its adapted tip specially designed to adjust the implant in the osteotomy incision.

Screw the polyoxymethylene (POM) tip on the impactor handle: the POM is polymer that acts as a shock absorber thus reducing the risk of fracture during final implant positioning.

## Step 8

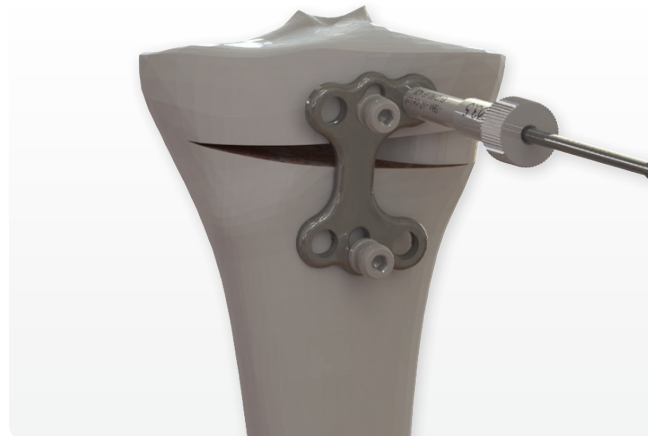


### Temporary screws

If needed, pre-form the plate by using the plate twister (screw in the drill guides to avoid thread damage).

Place the OTIS-C-PLUS® plate and drill with the Ø 3 mm lock drill through the holes meant for the temporary screws, then screw in the temporary screws.

## Step 9



### Posterior epiphyseal orifice (hole n° 1)

Twelve lengths are available: from 27 to 70 mm with increments of 3 to 5 mm for optimal adaptation.

Drill through the Ø 3,5 mm guide with the Ø 3,5 mm drill to the appropriate length then withdraw the guide.

## Step 10



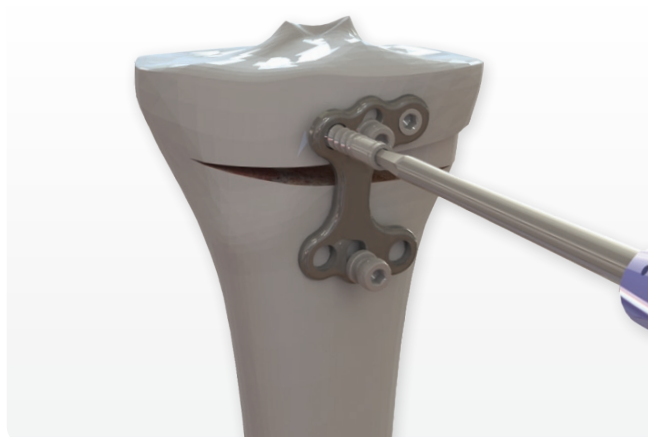
### 1<sup>st</sup> screw (hole n°1)

Use the countersink bit to ease the insertion of the screw.

Measure the thread length using the depth gauge. Insert a screw with a length equal to or immediately less than the measured length.

In order to lock the plate, screw until part of the screw comes level with the plate (see side view of the plate - page 4).

## Step 11



### 2<sup>nd</sup> screw (hole n°2)

Drill through the Ø 3.5 mm drill guide using the Ø 3.5 mm drill. Use the countersink bit to ease the insertion of the screw.

Measure the thread length using the depth gauge. Insert a screw with a length equal to or immediately less than the measured length.

In order to lock the plate, screw until part of the screw comes level with the plate.

Screw the drill Ø 4.5 mm guide on hole n°3 for the third screw.

## Step 12



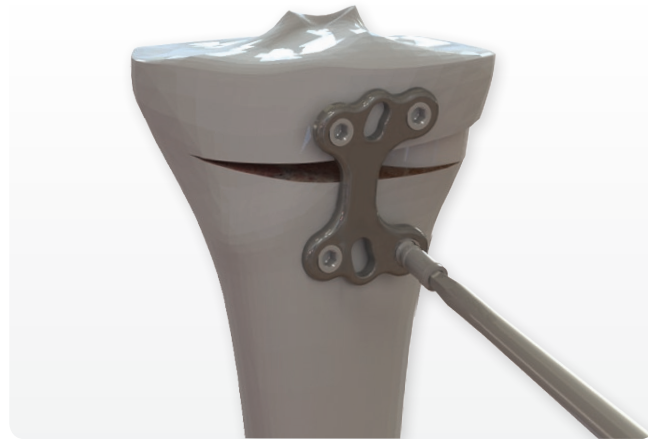
### 3<sup>rd</sup> screw (hole n°3)

Drill through the drill guide with Ø 4.5 mm drill bit. Then use the countersink bit to ease the insertion of the screw.

Measure the thread length using the depth gauge. Insert a screw with a length equal to or immediately less than the measured length.

In order to lock the plate, screw until part of the screw comes level with the plate.

## Step 13



### 4<sup>th</sup> screw (hole n°4)

Remove the temporary screws with the screwdriver.

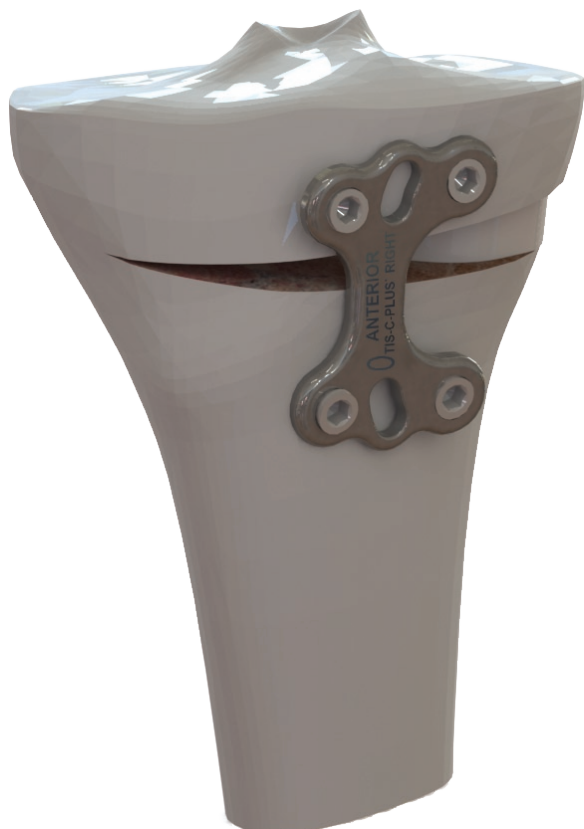
Drill through the drill guide with the Ø 4.5 mm drill bit. Use the countersink bit to ease the insertion of the screw.

Measure the thread length using the depth gauge. Insert a screw with a length equal to or immediately less than the measured length.

In order to lock the plate, screw until part of the screw comes level with the plate.

Double-check that each screw is properly locked in.

## OTIS-C-PLUS® placement



### Follow-up

When a locking plate such as the OTIS-C-PLUS® plate is used, early weight-bearing is possible with the help of two crutches for a period of 6 weeks. Hospitalization lasts 3 to 4 days, weight-bearing is allowed after approximately 45 days. Thigh/knee splints offer an undeniable analgesic effect.

Radiological integration of the OTIS® implant starts as early as the sixth month on both surfaces; the border between the metaphyseal bone and the implant becomes indistinct and the graft loses its geometric appearance.



## Clinical examples

Opening Wedge High Tibial Osteotomy, right knee.

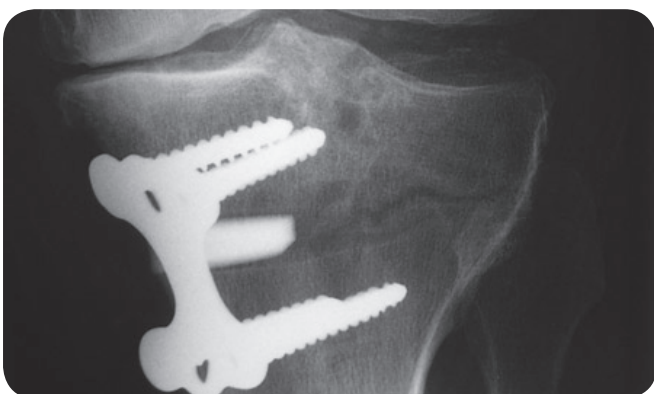
*Courtesy of Doctor Jean-Claude PANISSET, Clinique des cèdres, Grenoble, France.*



Post-operative, front view

Opening Wedge High Tibial Osteotomy, left knee.

*Courtesy of Professor Dominique SARAGAGLIA, CHU Sud Grenoble, France.*

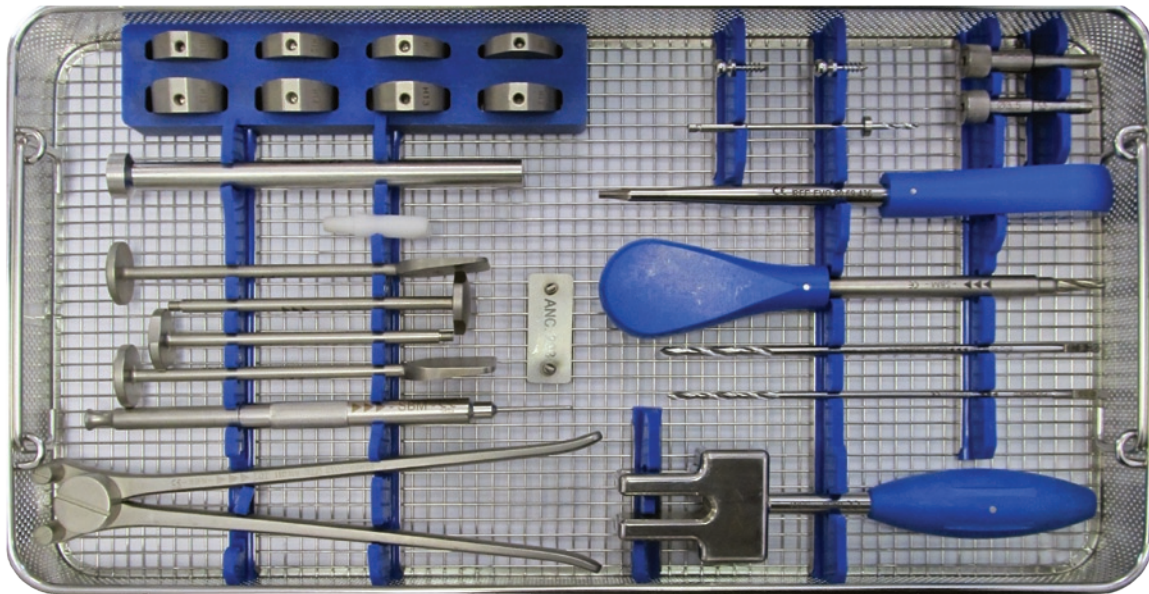


Post-operative, front view



Post-operative, side view

# Instrumentation



## Instruments



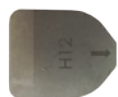
Drill guides Ø 3.5 and Ø 4.5 mm



Drill for temporary screw Ø 3 mm



L 195 mm drills Ø 3.5 and Ø 4.5 mm



OTIS metallic trial implants  
Heights 8, 9, 10, 11, 12, 13, 14, 15 mm



Handle for OTIS metallic trial implants (x2)



OTIS one-piece metallic trial implant  
Heights 6 and 7 mm



Round headed temporary screw (x2)



Countersink bit



Depth gauge



Impactor (body and tip)



Plate twister



Slotted hammer



Hexagonal screwdriver Ø 3.5 mm

## Ordering information

### OTIS® osteotomy wedges

Codes	Designation	Pack.
P822365222	OTIS implant - height 6 mm	1
P822365224	OTIS implant - height 7 mm	1
P822365226	OTIS implant - height 8 mm	1
P822365228	OTIS implant - height 9 mm	1
P822365230	OTIS implant - height 10 mm	1
P822365232	OTIS implant - height 11 mm	1
P822365234	OTIS implant - height 12 mm	1
P822365236	OTIS implant - height 13 mm	1
P822365238	OTIS implant - height 14 mm	1
P822365240	OTIS implant - height 15 mm	1

### OTIS® 50 osteotomy wedges

Codes	Designation	Pack.
P822667222	OTIS 50 implant - height 6 mm	1
P822667224	OTIS 50 implant - height 7 mm	1
P822667226	OTIS 50 implant - height 8 mm	1
P822667228	OTIS 50 implant - height 9 mm	1
P822667230	OTIS 50 implant - height 10 mm	1
P822667232	OTIS 50 implant - height 11 mm	1
P822667234	OTIS 50 implant - height 12 mm	1
P822667236	OTIS 50 implant - height 13 mm	1
P822667238	OTIS 50 implant - height 14 mm	1
P822667240	OTIS 50 implant - height 15 mm	1

### OTIS-C-PLUS® plates and screws

Codes	Designation	Packaging
EVO9067522	OTIS-C-PLUS right plate	1
EVO9067722	OTIS-C-PLUS left plate	1
EVO9066027	OTIS screw - length 27 mm	1
EVO9066030	OTIS screw - length 30 mm	1
EVO9066033	OTIS screw - length 33 mm	1
EVO9066036	OTIS screw - length 36 mm	1
EVO9066039	OTIS screw - length 39 mm	1
EVO9066042	OTIS screw - length 42 mm	1
EVO9066045	OTIS screw - length 45 mm	1
EVO9066050	OTIS screw - length 50 mm	1
EVO9066055	OTIS screw - length 55 mm	1
EVO9066060	OTIS screw - length 60 mm	1
EVO9066065	OTIS screw - length 65 mm	1
EVO9066070	OTIS screw - length 70 mm	1

### Complete instrumentation for High Tibial Osteotomy

Codes	Designation	In the basket
EVO9035100	OTIS-C ø 3 mm drill for temporary screw	1
EVO9069A45	OTIS-C ø 3,5 mm round-headed temporary screw	2
EVO9069622	OTIS-C plate twister	1
EVO9069428	OTIS-C ø 3,5 mm drill guide	1
EVO9069430	OTIS-C ø 4,5 mm drill guide	1
EVO9069432	OTIS-C ø 3,5 mm drill - length 195 mm	1
EVO9069434	OTIS-C ø 4,5 mm drill - length 195 mm	1
EVO9040203	OTIS-C ø 3,5 mm hexagonal screwdriver	1
EVO9069436	OTIS-C countersink bit	1
EVO9069438	OTIS-C depth gauge	1
EVO9069444	OTIS impactor body	1
EVO9069446	OTIS impactor tip	1
EVO90FAH06	OTIS one-piece metallic trial implant - height 6 mm	1
EVO90FAH07	OTIS one-piece metallic trial implant - height 7 mm	1
EVO90FAH08	OTIS metallic trial implant - height 8 mm	1
EVO90FAH09	OTIS metallic trial implant - height 9 mm	1
EVO90FAH10	OTIS metallic trial implant - height 10 mm	1
EVO90FAH11	OTIS metallic trial implant - height 11 mm	1
EVO90FAH12	OTIS metallic trial implant - height 12 mm	1
EVO90FAH13	OTIS metallic trial implant - height 13 mm	1
EVO90FAH14	OTIS metallic trial implant - height 14 mm	1
EVO90FAH15	OTIS metallic trial implant - height 15 mm	1
EVO90FAMAN	Handles for OTIS metallic trial implants	2
EVO90FAMAR	Slotted hammer for OTIS metallic trial implants	1
EVO90FA700	OTIS-C-PLUS stainless steel basket with silicone holders	1
<b>EVO90FA800</b>	<b>OTIS-C-PLUS complete instrumentation set</b>	

### Extraction kit for OTIS plate and screws

Codes	Designation	Packaging
EVO9069439	Screwdriver for OTIS screws extraction	1
EVO9069T65	Trephine for OTIS screw extraction	1

## Bibliography

<sup>1</sup> Synthèse et caractérisation de biomatériaux à base de Phosphates de Calcium,  
CLEMENT D.

Thèse de Doctorat, INP Toulouse, 1990.

<sup>2</sup> Biocompatibilité, stabilité mécanique et dégradation des compacts de Phosphate Tricalcique : Etude d'une série continue de 16 cas entre 2 et 4 ans de recul,

BONNEVIALLE P., CLEMENT D., CHALAL B., MANSAT M.  
Réunion annuelle du GESTO, Toulouse, 1997.

<sup>3</sup> Utilisation du Phosphate Tricalcique dans les OTV par addition interne,

LASCAR T., FAVARD L., BURDIN P., TRAORE O.  
30ème réunion de la S.O.O., Pont l'Abbé, 1997.

<sup>4</sup> Intérêt du Phosphate Tricalcique  $\beta$  en chirurgie orthopédique et traumatologique : à propos de 56 cas,

GALOIS L., MAINARD D. et collab.

Congrès de la S.O.F.C.O.T., Paris, Novembre 1998.

<sup>5</sup> Comblement des pertes de substance osseuse par le Phosphate Tricalcique  $\beta$  en traumatologie,

GALOIS L., MAINARD D., COHEN P., PFEFFER F., TRAVERSARI R., DELAGOUTTE J-P  
Ann. Chir., 125, 972-981, 2000.

<sup>6</sup> 23 cas d'utilisation du Phosphate Tricalcique pour le comblement des pertes de substance osseuse au pied,

GALOIS L., MAINARD D., COHEN P., DELAGOUTTE J-P.

Med. Chir. Pied, 17, 44-53, 2001.

<sup>7</sup> Ostéotomie tibiale de valgisation par addition médiale d'un coin de phosphate tricalcique,

BONNEVIALLE P., ABID A., MANSAT P., VERHAEGHE L., CLEMENT D., MANSAT M.

Revue de chirurgie orthopédique, 88, 486-492, 2002.

<sup>8</sup>  $\beta$ -Tricalcium Phosphate ceramic as a bone substitute in orthopaedic surgery,

GALOIS L., MAINARD D., DELAGOUTTE J-P.

International Orthopaedics (SICOT), 26, 109-115, 2002.

<sup>9</sup> L'ostéotomie de valgisation assistée par ordinateur dans le genu varum arthrosique : résultats radiologiques d'une étude cas-témoin de 56 cas,

SARAGAGLIA D., PRADEL P., PICARD F.

e-mémoires de l'Académie Nationale de Chirurgie, 3(2) :21-25, 2004.

<sup>10</sup> Valgisation tibiale par ouverture médiale utilisant un coin de céramique de phosphate tricalcique. A propos de 70 cas revus avec un recul moyen de 18 mois,

DEHOUX E., MADI K., FOURATI E., MENSA C., SEGAL P.

Mémoire, Revue de chirurgie orthopédique, 91, 143-148, 2005.

<sup>11</sup> Computer-assisted high tibial and double-level osetomies for genu varum deformity,

SARAGAGLIA D., ROBERTS J., RUBENS-DUVAL B.

Techniques in Knee Surgery, 5(4) :212-217, 2006.

<sup>12</sup> Resorbability of rigid beta-tricalcium phosphate wedges in open-wedge high tibial osteotomy. A retrospective radiological study,

KRAAL T., MULLENDER M., DE BRUINE J.H.D., REINHARD R., DE GAST A., KUIK D.J., VAN ROYEN B.J.

The Knee, 15, 201-205, 2008.

<sup>13</sup> Outcome of opening wedge high tibial osteotomy augmented with a Biosorb wedge and fixed with a plate and screws in 124 patients with a mean of ten years follow-up,

SARAGAGLIA D., BLAYSAT M., INMAN D., MERCIER N.

Int Orthop. 2010. DOI 10.1007

<sup>14</sup> Results of forty two computer-assisted double level osteotomies for severe genu varum deformity

SARAGAGLIA D., BLAYSAT M., MERCIER N., GRIMALDI M.

Int Orthop. (2012) 36:999-1003

<sup>15</sup> Gonarthrose femoro-tibiale sur genu varum : place de l'ostéotomie tibiale par addition médiale d'un coin de phosphate tricalcique. L'expérience du service à propos de 80 cas

BELBACHIR B., SERHANE L., AZZOUC S., LAZIB N., BENBRAHIM N., CHAABANA S., TALBI Y., HAMOULHADJ M., MOUSSAOUI F., MERABET S., OUAHMED A.

Revue algérienne de chirurgie orthopédique, n°1 2012.



**SBM SAS**

CE  
0459



Carefully read the instructions for use that comes with the medical device or labeling provided to medical professionals. OTIS: class III device. OTIS-C-PLUS: class IIb device.  
Document not legally binding - Can be modified without prior notice.  
Manufactured by SBM © 2013 Ref: MGOTPBREN - v5.0114

ZI du Monge  
65100 LOURDES  
FRANCE  
Phone: (+33) 5 62 42 32 12  
Fax: (+33) 5 62 42 32 52  
www.sbm-france.com