

Cellbrick™ Knee

Infection Management Spacer



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Device Description

Cellbrick™ Knee Spacer –

The Cellbrick™ Knee Spacer is specifically designed to support infection management of periprosthetic joint infection (PJI) in two-stage revision total knee arthroplasty. This articulating design maintains the joint space, limb length, and ligament structure after implant removal, and preserves joint mobility which help to facilitate reimplantation during revision surgery.

Featuring a UHMWPE spacer core on both the femoral and tibial sides, the Cellbrick™ Knee Spacer is designed to provide enhanced biomechanical safety throughout its implantation period. The fenestrated design serves as an antibiotic cement carrier, without affecting antibiotic release. An optional intramedullary canal rod is available to provide extended infection management in either the femoral or tibial canal.

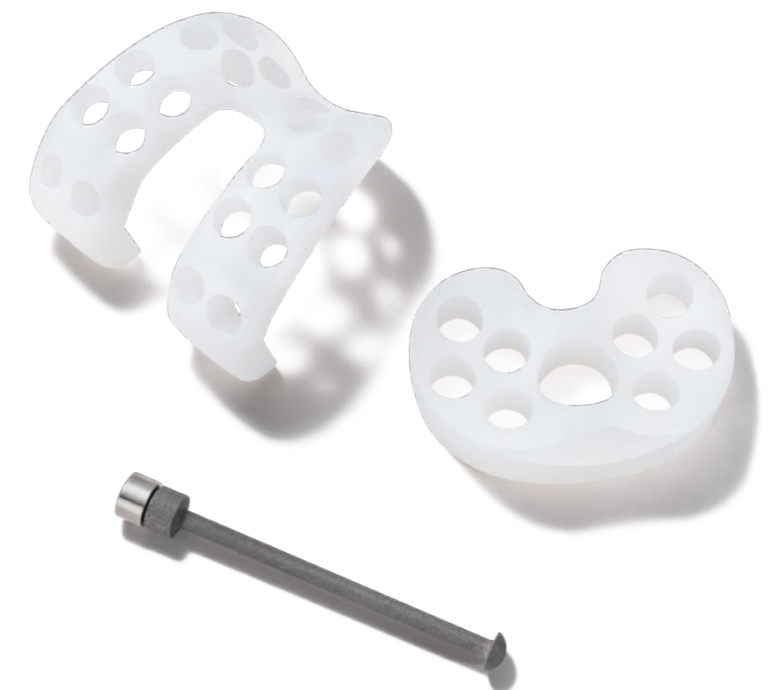
INDICATIONS

This product is indicated for temporary use (maximum of 180 days) as a total knee replacement (TKR) in skeletally mature patients undergoing a two-stage procedure due to a septic process.

This product is not intended for use for more than 180 days, at which time it must be explanted and a permanent device implanted or another appropriate treatment performed (e.g., resection arthroplasty, fusion, etc.). During the implantation period, patients have to use traditional mobility assist devices (e.g. crutches, walkers, canes) for daily activities.

With pre-clinical validations of antibiotic elution, tibial spacer fatigue test, and knee spacer wear test, only Palacos MV+G bone cement may be used for preparing the spacers.

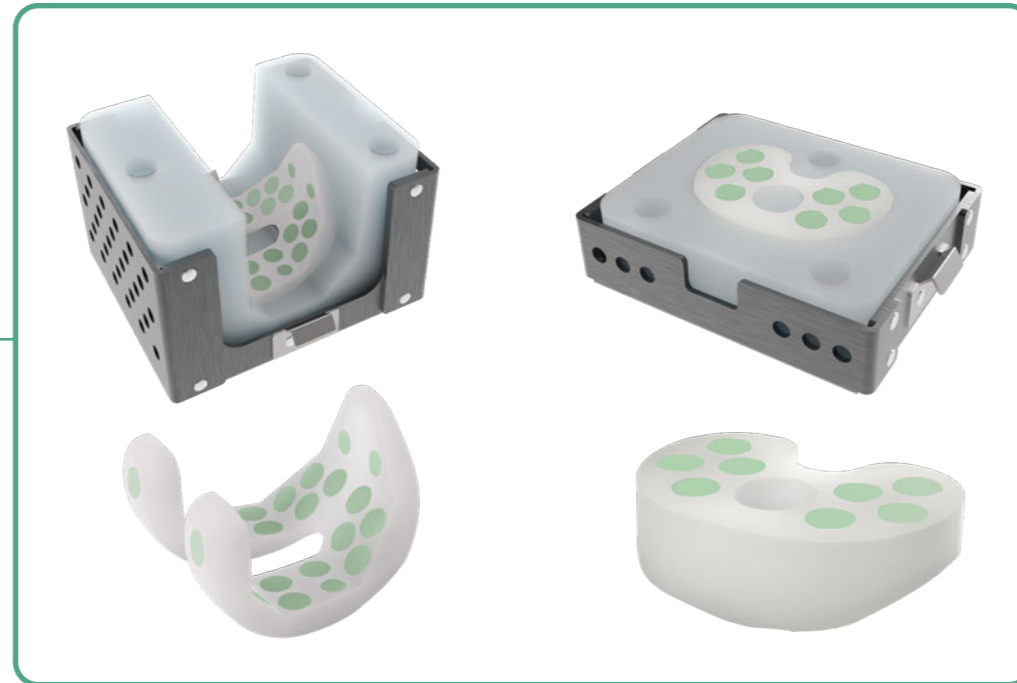
Please note, this Surgical Technique Guide is consistent with our validated labeling. It is not intended to substitute for each surgeon's individual medical judgement regarding patient care. It is intended to be a reference document to be utilized in supporting usage of United Orthopedics' Cellbrick™ Knee Spacer.



Surgical Overview



A. Size Selection



C. Spacer Preparation



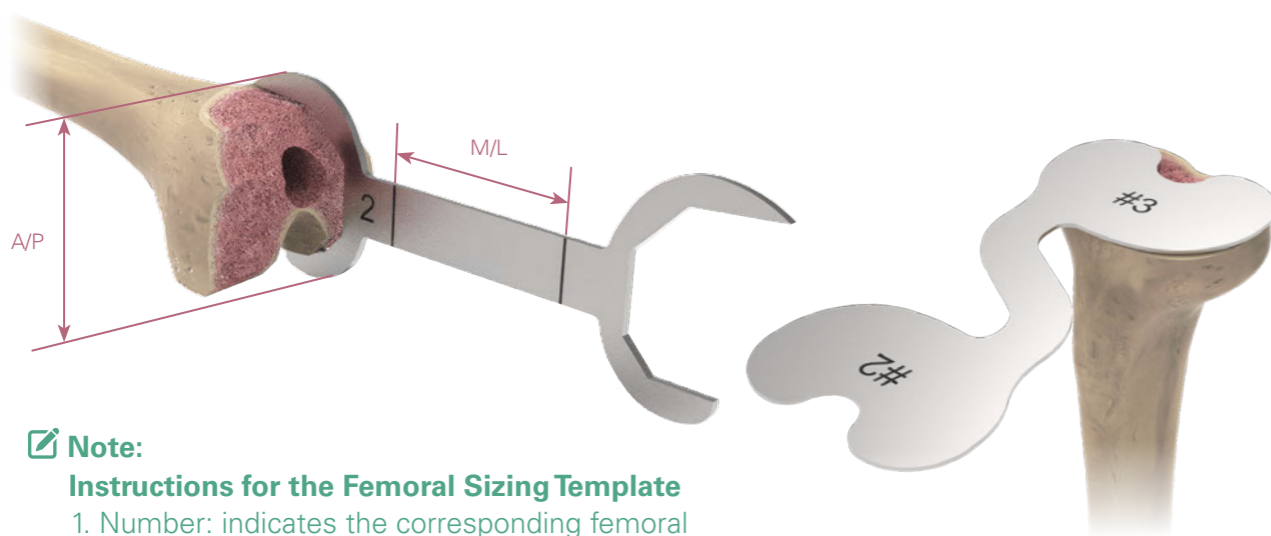
B. (Optional) Canal Rod Preparation



D. Spacer Implantation

A. Bone Preparation & Size Selection

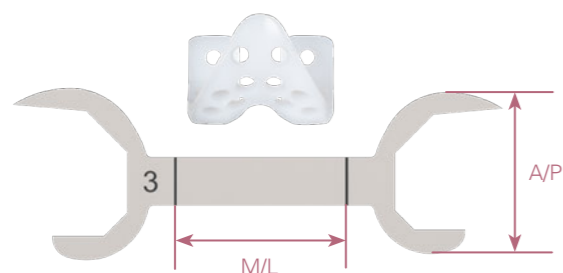
Remove previously implanted components, residual bone cement, and clean the infected joint. Utilize the **Tibial Sizing Template** and **Femoral Spacer Sizing Template** to determine the size of the spacer components by referencing the residual bone or the size of the previous implants.



Note:

Instructions for the Femoral Sizing Template

1. Number: indicates the corresponding femoral spacer size in A/P dimension.
2. Solid lines: define the boundary of the corresponding spacer size in M/L direction.

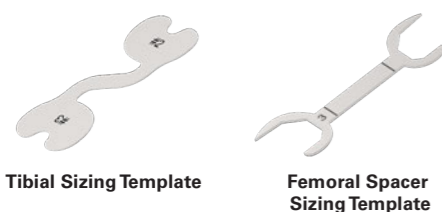


Femoral Spacer Sizing Template



Tibial Sizing Template

Instruments



Tibial Sizing Template

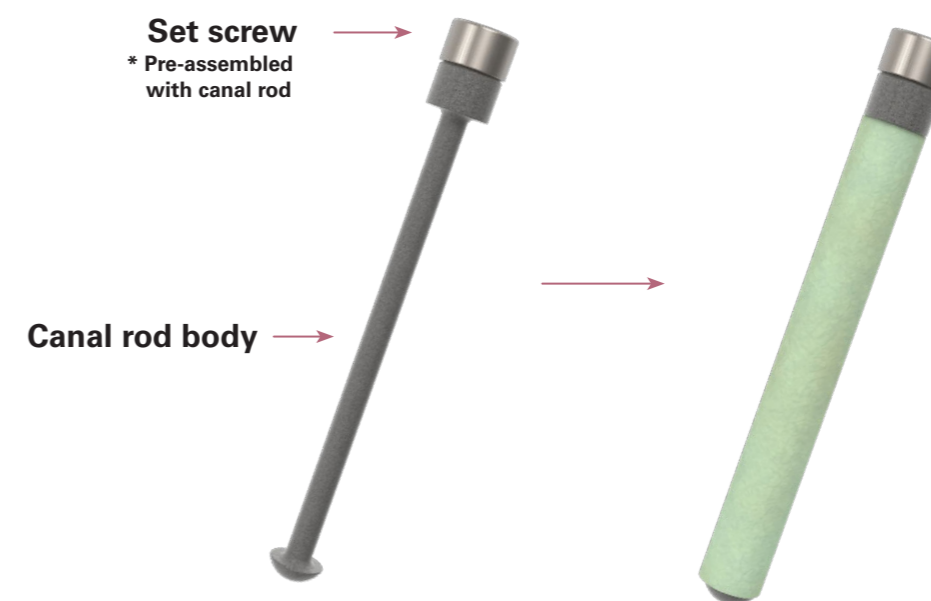
Femoral Spacer Sizing Template

B. (Optional) Canal Rod Preparation

If deep infection management is required, properly wrap the antibiotic cement around the shaft of the canal rod, and leave the head region of canal rod uncovered. Place the canal rod in a stable, appropriate position until the cement has fully cured.

Note:

The canal rod can be prepared at the same time as, or after, spacer implantation.



Note:

1. The assembly of the **Tibial IM Rod** and **Handle** can be used to preserve the intramedullary pathway for canal rod insertion.
2. For the exact processing time, please refer to the instructions for use of the bone cement.

Instruments

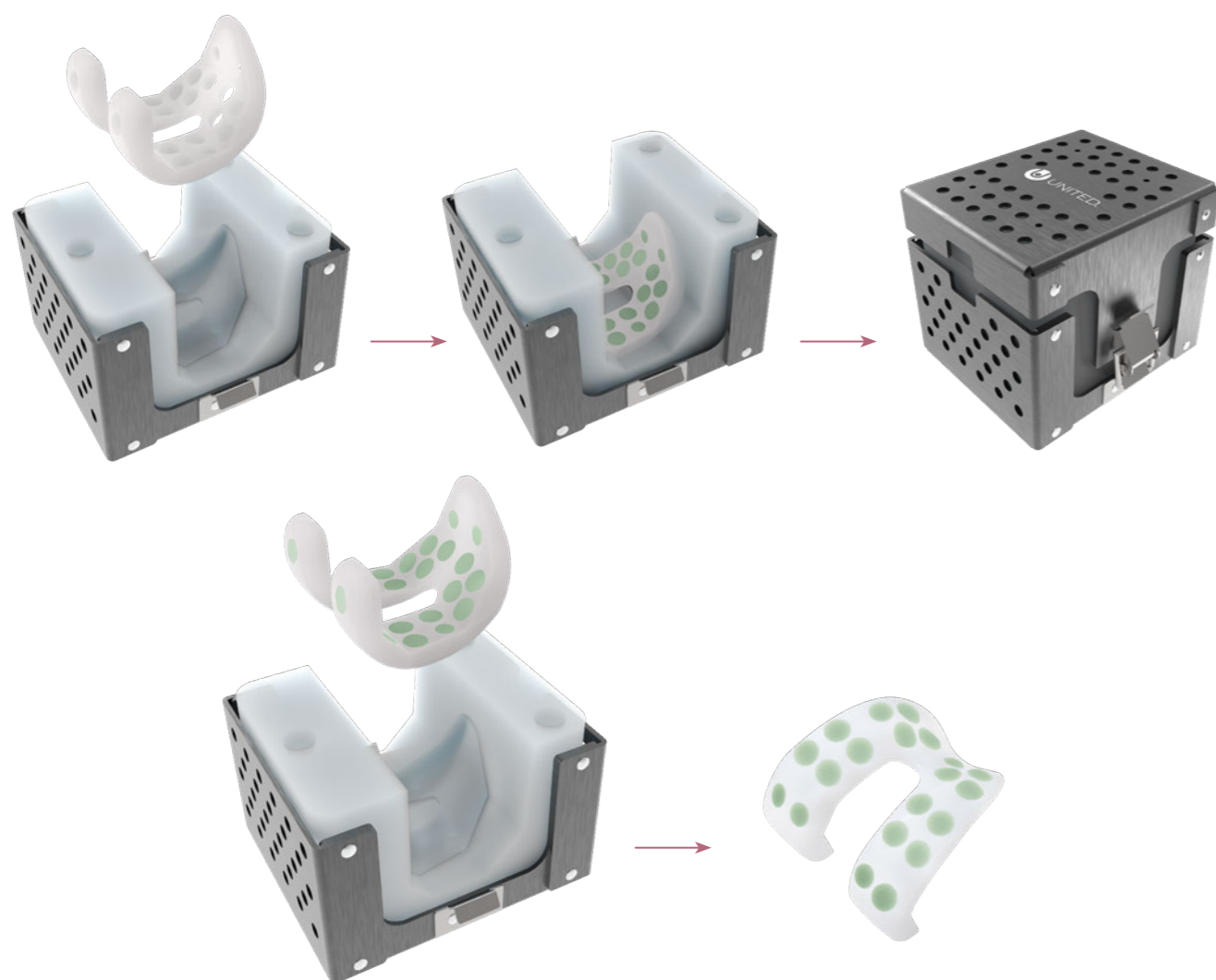


IM Rod Handle

Tibial IM Rod

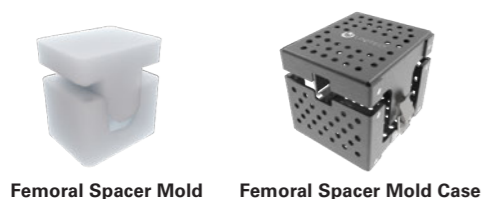
C.Spacer Preparation

Insert the femoral and tibial spacers respectively into the **Femoral** and **Tibial Spacer Mold**, and apply the antibiotic cement into the holes of the spacer. Remove the excess bone cement. Close the upper and lower **Spacer Mold**, and then put them into the correct **Spacer Mold Case**.



Note: For the exact processing time, please refer to the instructions for use of the bone cement.

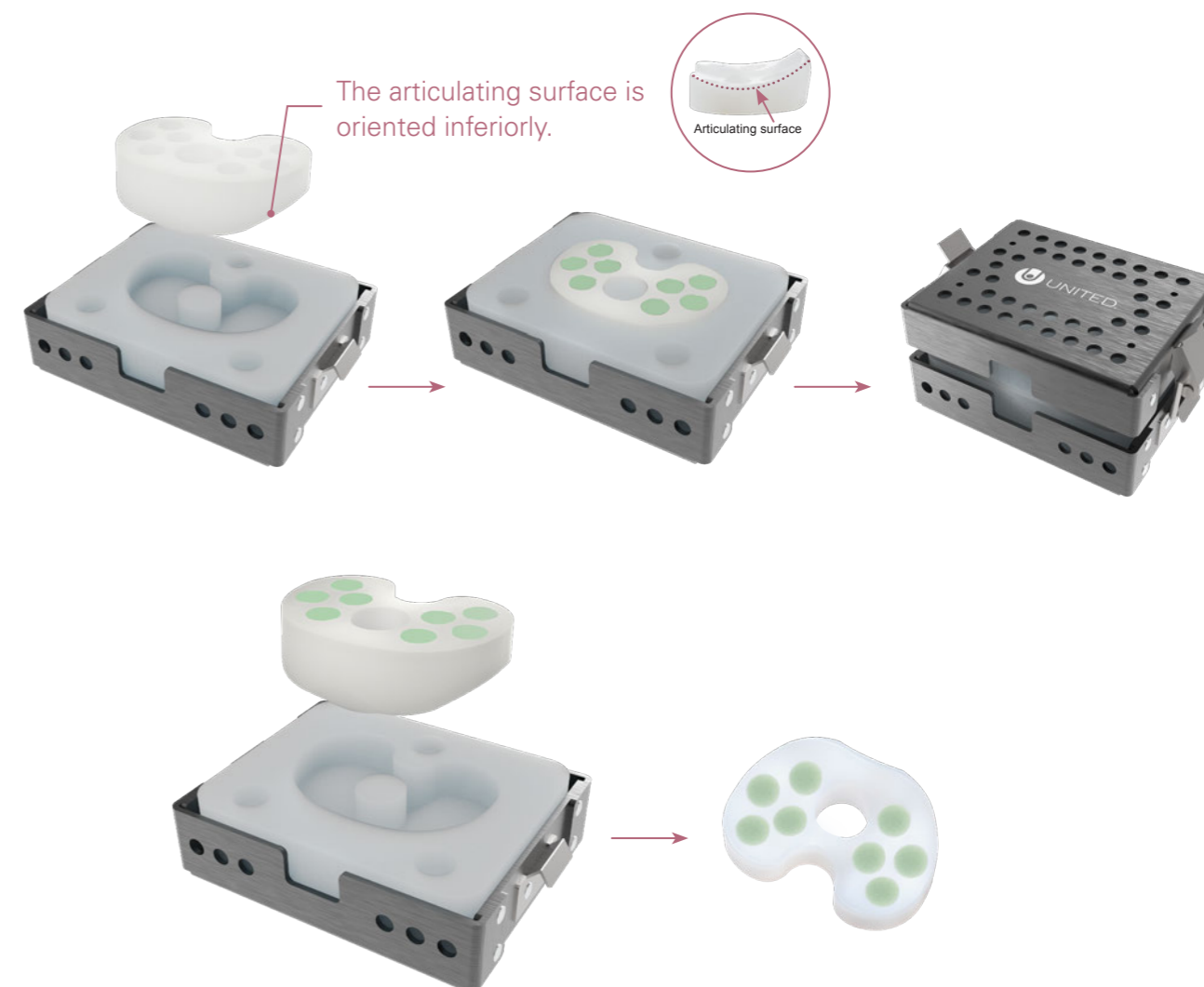
Instruments



Femoral Spacer Mold Femoral Spacer Mold Case

C.Spacer Preparation

After cement has cured, open the **Spacer Mold Case** and **Spacer Mold**, remove the spacer from the **Spacer Mold**. Trim the redundant cement with a rongeur if necessary.



Note: Ensure that the articulating surface is smooth before implantation (i.e., cement plugs do not protrude from the fenestrations after molding).

Instruments



Tibial Spacer Mold Tibial Spacer Mold Case

D. Spacer Implantation

Apply antibiotic cement to the implant-bone interface of the spacer, as well as to the distal femur and tibial plateau. Then position the spacer onto the bone in the appropriate orientation. If deep infection management is required, insert the cement-wrapped canal rod into the femoral or tibial canal to an appropriate depth.

Move the leg through flexion and extension to ensure the tibial spacer aligns properly with the femoral spacer before the cement cures. Thoroughly examine the femoral and tibial spacers, and remove any excess cement.



Note:

1. Ensure that the head of the canal rod does not protrude excessively from the spacer, as this may interfere with spacer articulation.
2. When positioning the canal rod, ensure that the set screw is not positioned below the resected bone surface.

Appendix: Removal of Canal Rod

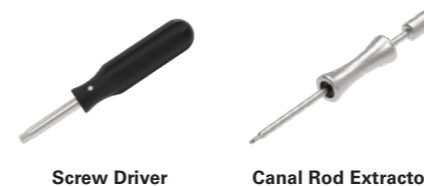
After removal of the femoral or tibial spacer, use the **Screw Driver** to remove the set screw and expose the internal thread on the head of the canal rod. Secure the **Canal Rod Extractor** to the head of canal rod, and apply reverse impaction to remove the canal rod from femoral or tibial canal.

Femoral canal rod removal

Tibial canal rod removal



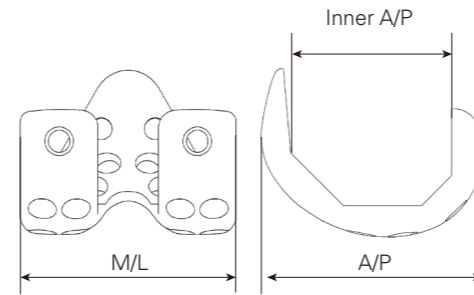
Instruments



Screw Driver

Canal Rod Extractor

Order Information

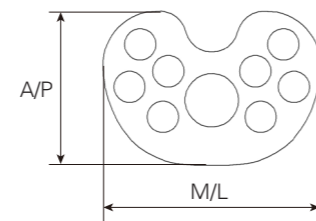


Femoral Spacer

Size	Catalog number	
UHMWPE*	#2	2106-1020
	#3	2106-1030
	#4	2106-1040
	#5	2106-1050

Size	M/L	Inner A/P	A/P
#2	60	42.9	60
#3	64	46.6	64
#4	68	50.3	68
#5	72	54	72

Unit: mm



Tibial Spacer

Size	Catalog number	
UHMWPE*	#2	2206-1020
	#3	2206-1030
	#4	2206-1040
	#5	2206-1050

Size	M/L	A/P
#2	66	46.5
#3	69	49
#4	72	51.5
#5	76	54.5

Unit: mm



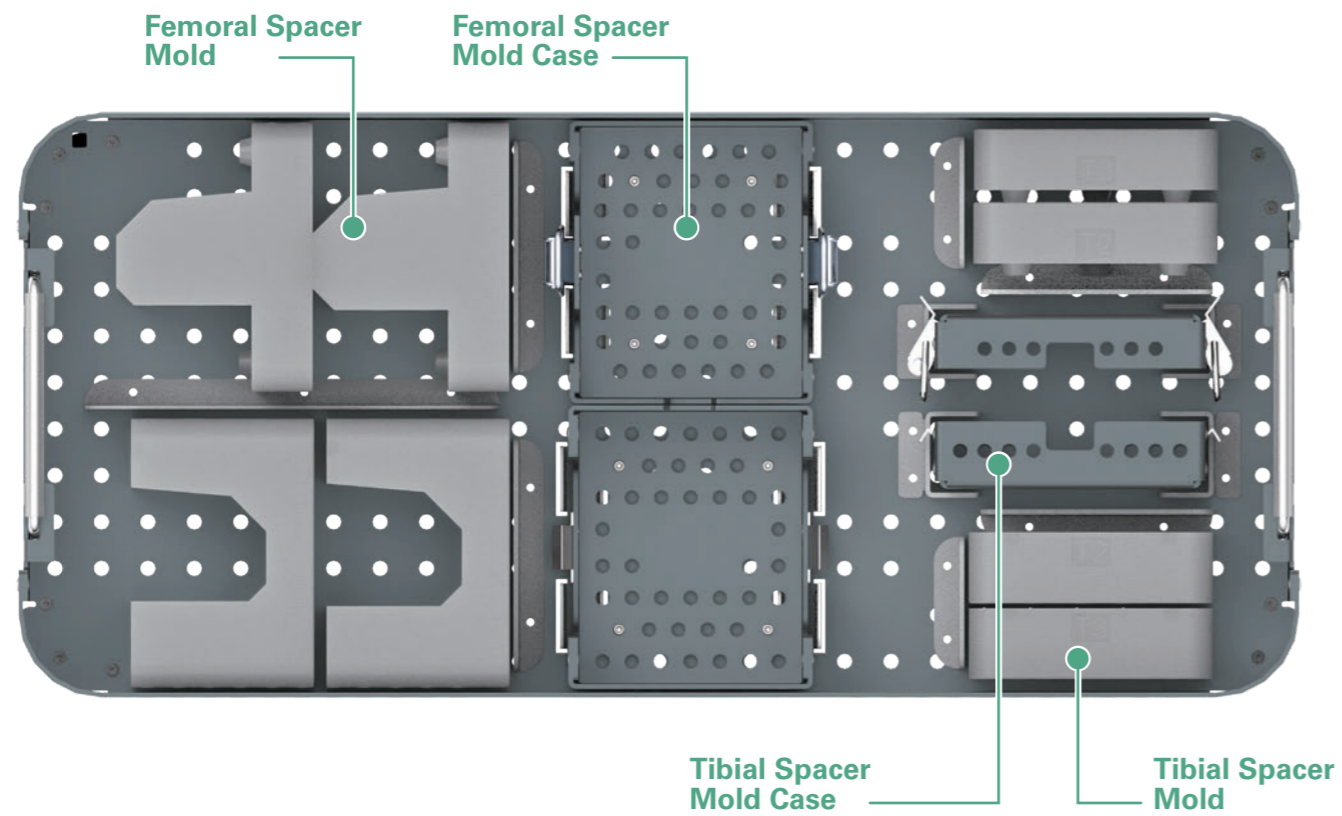
Ø4 x 80 mm	
Ti-6Al-4V*	2706-1009

Canal Rod

*UHMWPE is an abbreviation for ultra-high molecular weight polyethylene.
*Ti-6Al-4V is an abbreviation for Titanium-6 Aluminum-4 Vanadium.

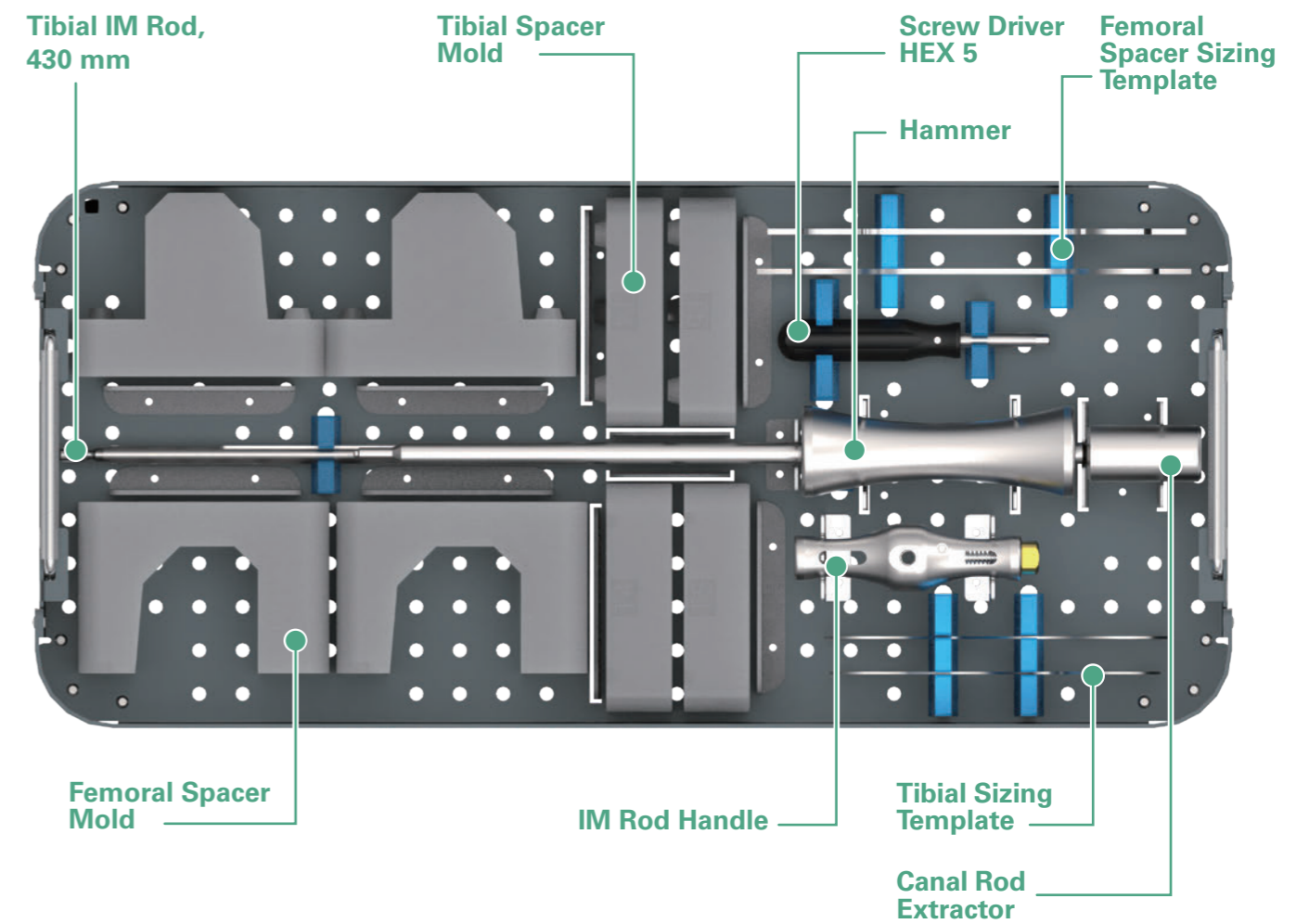
Instrument Tray Guide

Cellbrick Knee Spacer Tray, #1



Instrument Tray Guide

Cellbrick Knee Spacer Tray, #2



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