

**BKS®**  
**Difficult**  
**Primary**



**SURGICAL  
TECHNIQUE**



The following technique is a general guide for instrumentation of BKS® Difficult Primary. It is assumed that the surgeon is already familiar with the fundamentals of total knee replacement. Each patient represents an individual case that may require modification of the technique according to the surgeon's judgment.

Please see the Balanced Knee® System Instructions for Use (IFU) for intended uses, indications, device description, contraindications, precautions, warnings and potential risks.

U.S. Federal Law restricts this device to sale by or on the order of a physician.

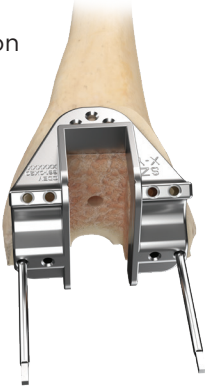


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# Surgical Technique Overview

1.  
Pin Revision  
Box Cut  
Guide



2.  
Place T-Block  
in Notch with  
Stylus



3.  
Pin and  
Ream



4.  
Position,  
then Pin  
Tibial Drill  
Guide



5.  
Ream  
through  
Drill Guide



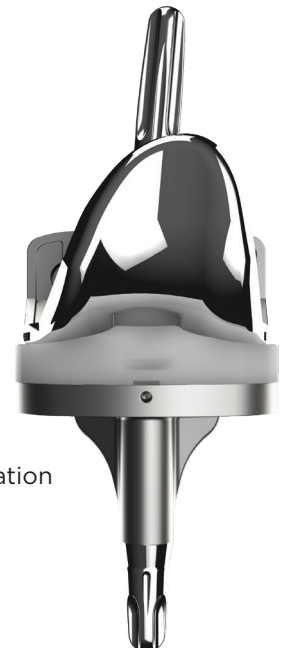
6.  
Trial Femoral  
Components



7.  
Trial Tibial  
Components



8.  
Final  
Implantation





# BKS® Difficult Primary System Overview

Ortho Development's BKS Difficult Primary instrumentation is used in conjunction with BKS® Primary Knee instrumentation to provide intraoperative flexibility when additional options for stability and constraint are desired.

## The Difficult Primary System includes:

- Revision Femoral Components, sizes 2-6
- Revision Sloped Tibial Trays, sizes 2-6
- Constrained (CK) inserts, 8mm-16mm
- Cemented Stems in ø12mm and ø14mm in 30mm and 50mm lengths
- 2mm Posterior Augments, sizes 2-6 (available on request)



## Surgical Technique

Perform all femoral and tibial preparation using primary instrumentation following either the Balanced Knee® System Surgical technique (351-1-10694) or the BKS TriMax® Surgical Technique (351-1-10748). If additional stability or constraint is desired, continue with the following steps.

### Femoral Preparation

Use the Revision Box Cut Guide to make the intracondylar box cut. The Revision Box Cut Guides come in two sizes, 1-5 and 6-7.

*Note: The Revision Box Cut Guide comes in size 6-7, the Difficult Primary system does not include size 7 femoral components. Size 7 modular femoral components are found in the BKS Revision system.*

Select the appropriate size Revision Box Cut Guide based upon the size previously used to make all primary cuts. Place the Revision Box Cut Guide flush on the anterior cortex and distal cut surface, and align the Revision Box Cut Guide mediolaterally on the distal femur. Pin the Revision Box Cut Guide to the femur using Fixation Pins in the desired pin holes (Figure 1). Use a reciprocating saw to create or deepen the notch. Remove the Fixation Pins and Revision Box Cut Guide from the distal femur.

*Note: The width of the intracondylar box cut is the same as the box cut for BKS® (all sizes), and BKS TriMax (sizes 4-7) PS femoral components, but the depth is different.*

Figure 1:  
Revision  
Box Cut  
Guide pinned  
into place

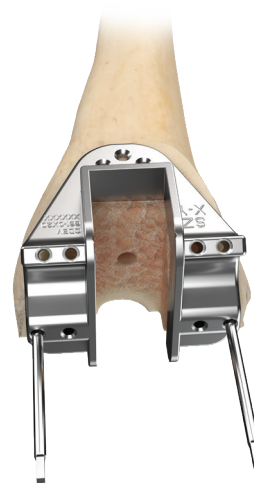


Figure 2:  
T-Block  
Reamer  
Guide Left



Figure 3:  
Adjust Stylus  
to Femoral  
Component  
Size



Figure 4:  
Stylus on  
Anterior  
Cortex



Select the 15mm or 17mm diameter 5° T-Block Reamer Guide. The reamer creates a 3mm cement mantle, 1.5mm circumferentially.

*Note: Cemented Stems are available in 2 diameters—12mm and 14mm; and in 2 lengths—30mm and 50mm. Use the ø15mm reamer for a ø12mm Cemented Stem or the ø17mm reamer for a ø14mm Cemented Stem.*

Place the selected T-Block Reamer Guide onto the distal femur. If performing surgery on the right leg, ensure that the T-Block Reamer Guide is oriented so that the “RIGHT” marking is present on the anterior surface. Similarly, if performing surgery on the left leg, ensure that the T-Block Reamer Guide is oriented so that the “LEFT” marking is present on the anterior surface (Figure 2). Adjust the Reamer Guide Stylus to the previously trialed femoral size (Figure 3). Place the Reamer Guide Stylus onto the T-Block Reamer Guide and ensure the stylus rests on the anterior cortex (Figure 4). This will set the A/P translation of the final Junction Box in a neutral position. Pin the T-Block Reamer Guide with two Fixation Pins in the desired holes and remove the Reamer Guide Stylus.

Select the ø15mm or ø17mm reamer. Insert the reamer into the T-Block Reamer Guide (Figure 5).

Ream until the desired depth mark, 30mm or 50mm, is flush with the T-Block Reamer Guide (Figure 6).

Once reaming is complete, remove the T-Block Reamer Guide and Fixation Pins.

Figure 5:  
Femoral  
Reamer

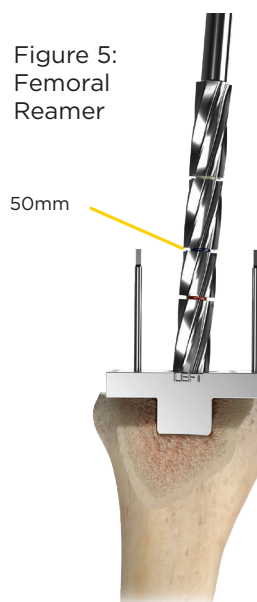


Figure 6:  
Ream to  
Depth Mark

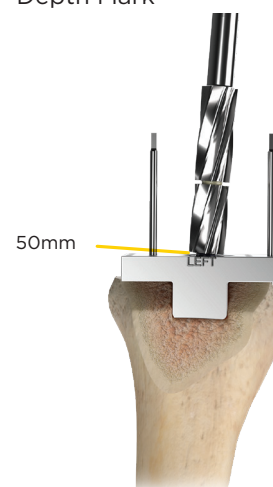


Figure 7:  
Tibial Drill  
Guide



Figure 8:  
Tibial  
Reamer

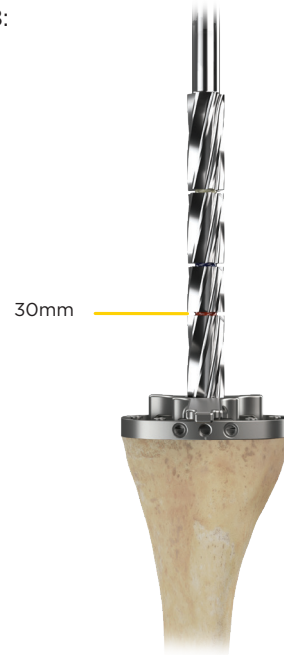
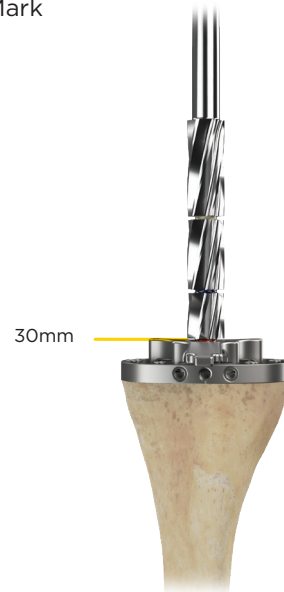


Figure 9:  
Ream to  
Depth Mark



## Tibial Preparation

Use the Revision Tibial Tray Trial based upon the size that was determined when the primary cuts were performed. Align the Revision Tibial Tray Trial with the rotational mark made during primary trial reduction.

*Note: The Difficult Primary Instrument Set contains only the Sloped Tibial Tray Trials. Sloped Tibial Tray Trials are designed to match the slope of the cut made. For Neutral Tibial Tray Trials that require a neutral cut and contain 5 degrees slope added on to the top, use the Neutral Tibial Tray Trials found in the BKS Revision Instrument Set.*

The Tibial Drill Guide comes in two sizes,  $\varnothing 15\text{mm}$  and  $\varnothing 17\text{mm}$ , to achieve a built-in 3mm cement mantle (1.5mm circumferentially).

*Note: Cemented Stems are available in 2 diameters—12mm and 14mm; and two lengths—30mm and 50mm. Use the  $\varnothing 15\text{mm}$  reamer for a  $\varnothing 12\text{mm}$  Cemented Stem or the  $\varnothing 17\text{mm}$  reamer for a  $\varnothing 14\text{mm}$  Cemented Stem.*

Attach the appropriate Tibial Drill Guide for the intended stem size to the Tibial Tray Trial by seating the two posterior pegs first, then seat the anterior pegs until the Drill Guide rests into place (Figure 7).

Insert the corresponding reamer for desired stem size into the Tibial Drill Guide (Figure 8). Ream until the desired depth mark, 30mm or 50mm, is flush with the Drill Guide (Figure 9).

*Note: The Cemented Reamers will ream to a depth 20mm beyond the distal tip of the stem on the tibial side only to allow for placement of a cement restrictor if desired. Cement restrictors are not sold by Ortho Development.*

### Femoral Trial Assembly

Assemble the selected Revision Femoral, Junction Box and Cemented Stem Trials by loosely threading the Cemented Stem Trial into Junction Box Trial one or two rotations. Do not tighten the threads yet. The Junction Box Trial markings must face laterally to align with the A/P markings on the lateral side of the Femoral Trial. This ensures proper use as the Junction Box Trial is right and left specific.

Slide the Junction Box Trial assembly onto the rails in the Femoral Trial. Set the Junction Box Trial markings to 0 (neutral), and hand-tighten the Stem Trial threads. Once the stem trial is tightened, the Junction Box will be locked into position (Figure 10).

### Tibial Trial Assembly

Assemble the selected Tibial Tray and Cemented Stem Trials by threading the Stem Trial into the Tibial Tray Trial (Figure 11).

### Trial Reduction

Place the Femoral Trial assembly onto the distal femur. With the Femoral Trial assembly in place, and the knee in flexion, insert the Tibial Tray Trial assembly onto the proximal tibia. Select a Tibial Insert Trial, a PS Trial from the primary instrumentation, or a CK Trial from the Difficult Primary instrumentation depending on the desired level of constraint, and place it onto the Tibial Tray Trial. Perform a full range of motion check, noting medial and lateral stability and overall A/P and M/L alignment of the Trials. Once the desired stability is achieved, proceed with final implantation.

*Note: The Modular Femoral Component and Tibial Tray sizes can mismatch by two sizes, up or down, for both CK and PS inserts. Consult the Instructions for Use for additional details.*

Figure 10:  
Femoral Trial  
Construct

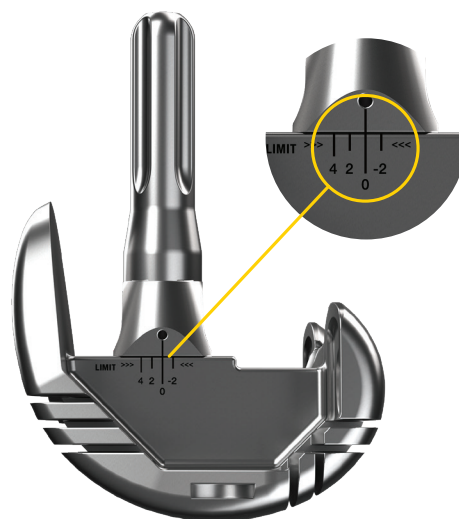


Figure 11:  
Tibial Trial  
Construct



## Final Implant Assembly

### Femoral

Select the final Femoral Component, Junction Box, and Cemented Stem that correspond to the last trial sizes used. Assemble the components by loosely threading the Cemented Stem into Junction Box one or two rotations. Do not tighten the threads yet. The Junction Box is right and left specific. Ensure the Junction Box markings face laterally to align with the A/P markings on the lateral side of the Femoral Component. Attach the Junction Box assembly to the Femoral Component by dropping and then sliding it into place. Set the Junction Box markings to 0 (neutral). Use the Stem Extension Wrench to tighten. Once the stem is tightened, the Junction Box will be locked into position (Figure 12).

### Tibial

Select the final Tibial Tray Component that corresponds to the last trial size used. Using the 5mm Hex Wrench, remove and discard the Tibial Tray Keel Cap from the Tibial Tray. Thread the selected Cemented Stem into the Tibial Tray. Use the Tibial Tray and Stem Extension Wrenches to tighten (Figure 13).

Figure 12:  
Final  
Femoral  
Construct



Figure 13:  
Final  
Tibial  
Construct



Figure 14:  
CK Insert



Figure 14a:  
CK Insert  
with pin  
impacted



Final  
construct



## Final Implantation

Thoroughly clean the entire surgical site with pulsatile lavage.

### Femoral

Place bone cement using preferred cementing technique. Place the assembled implant onto the femur. Use the Femoral Impactor and a mallet to securely seat the implant and pressurize the cement. Remove all excess cement.

### Tibial

Place bone cement using the preferred cementing technique. Place the assembled implant onto the tibia. Use the Tibial Impactor and a mallet to securely seat the implant and pressurize the cement. Remove all excess cement. Select PS or CK Tibial Insert for final step in implantation.

### PS Tibial Insert

Once the Femoral and Tibial Components have been implanted, and the bone cement has cured, reassess range of motion and joint stability. Inspect the Tibial Tray for any debris. Use caution to avoid scratching the tray. Place the PS Tibial Insert onto the Tibial Tray. Engage the posterior locking mechanism first. Attach the Tibial Insert Clamp by placing the peg of the clamp into the Tibial Tray. Squeeze the clamp, locking the Tibial Insert into place. The insert should seat easily with an audible snap. Inspect the insert to ensure it is fully seated.

### CK Tibial Insert

Inspect the Tibial Tray for any debris. Use caution to avoid scratching the tray. Engage the posterior locking mechanism first. Attach the Tibial Insert Clamp by placing the peg of the clamp into the Tibial Tray. Squeeze the clamp together, locking the Tibial Insert into place. The insert should seat easily with an audible snap. Inspect the insert to make sure it is fully seated. Impact the CK pin using the Pin Impactor until a noticeable hard stop is felt. When assembled correctly, the pin will no longer protrude out of the top of the insert post (Figure 14a).

### Closing the Wound Above

After taking the knee through the full range of motion and the desired result is achieved, the wound should be closed in a standard fashion.



# BKS Difficult Primary Implants

## FEMORAL COMPONENT

ITEM #	DESCRIPTION
561-1201	Modular Femoral Component Left Size 2
561-1202	Modular Femoral Component Right Size 2
561-1301	Modular Femoral Component Left Size 3
561-1302	Modular Femoral Component Right Size 3
561-1401	Modular Femoral Component Left Size 4
561-1402	Modular Femoral Component Right Size 4
561-1501	Modular Femoral Component Left Size 5
561-1502	Modular Femoral Component Right Size 5
561-1601	Modular Femoral Component Left Size 6
561-1602	Modular Femoral Component Right Size 6



## JUNCTION BOX

ITEM #	DESCRIPTION
561-5000	Femoral Junction Box 5°



## TIBIAL COMPONENT

ITEM #	DESCRIPTION
562-2200A	Modular Tibial Tray Sloped Size 2
562-2300A	Modular Tibial Tray Sloped Size 3
562-2400A	Modular Tibial Tray Sloped Size 4
562-2500A	Modular Tibial Tray Sloped Size 5
562-2600A	Modular Tibial Tray Sloped Size 6



## STEM EXTENSION

ITEM #	DESCRIPTION
565-1203	Cemented Stem Extension Ø12mm x 30mm
565-1205	Cemented Stem Extension Ø12mm x 50mm
565-1403	Cemented Stem Extension Ø14mm x 30mm
565-1405	Cemented Stem Extension Ø14mm x 50mm





**TIBIAL INSERT**

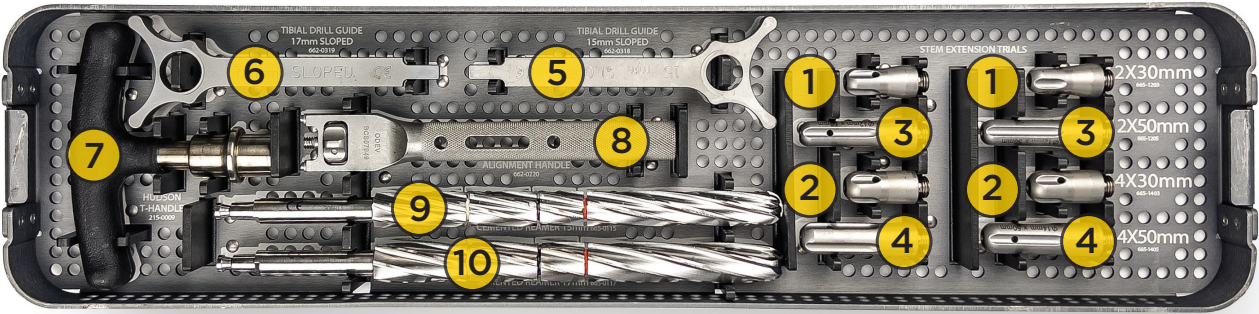
ITEM #	DESCRIPTION
563-2208	BKSR Constrained Tibial Insert Sz 2 8mm
563-2210	BKSR Constrained Tibial Insert Sz 2 10mm
563-2212	BKSR Constrained Tibial Insert Sz 2 12mm
563-2214	BKSR Constrained Tibial Insert Sz 2 14mm
563-2216	BKSR Constrained Tibial Insert Sz 2 16mm
563-2308	BKSR Constrained Tibial Insert Sz 3 8mm
563-2310	BKSR Constrained Tibial Insert Sz 3 10mm
563-2312	BKSR Constrained Tibial Insert Sz 3 12mm
563-2314	BKSR Constrained Tibial Insert Sz 3 14mm
563-2316	BKSR Constrained Tibial Insert Sz 3 16mm
563-2408	BKSR Constrained Tibial Insert Sz 4 8mm
563-2410	BKSR Constrained Tibial Insert Sz 4 10mm
563-2412	BKSR Constrained Tibial Insert Sz 4 12mm
563-2414	BKSR Constrained Tibial Insert Sz 4 14mm
563-2416	BKSR Constrained Tibial Insert Sz 4 16mm
563-2508	BKSR Constrained Tibial Insert Sz 5 8mm
563-2510	BKSR Constrained Tibial Insert Sz 5 10mm
563-2512	BKSR Constrained Tibial Insert Sz 5 12mm
563-2514	BKSR Constrained Tibial Insert Sz 5 14mm
563-2516	BKSR Constrained Tibial Insert Sz 5 16mm
563-2608	BKSR Constrained Tibial Insert Sz 6 8mm
563-2610	BKSR Constrained Tibial Insert Sz 6 10mm
563-2612	BKSR Constrained Tibial Insert Sz 6 12mm
563-2614	BKSR Constrained Tibial Insert Sz 6 14mm
563-2616	BKSR Constrained Tibial Insert Sz 6 16mm



# BKS Difficult Primary Instrument Trays

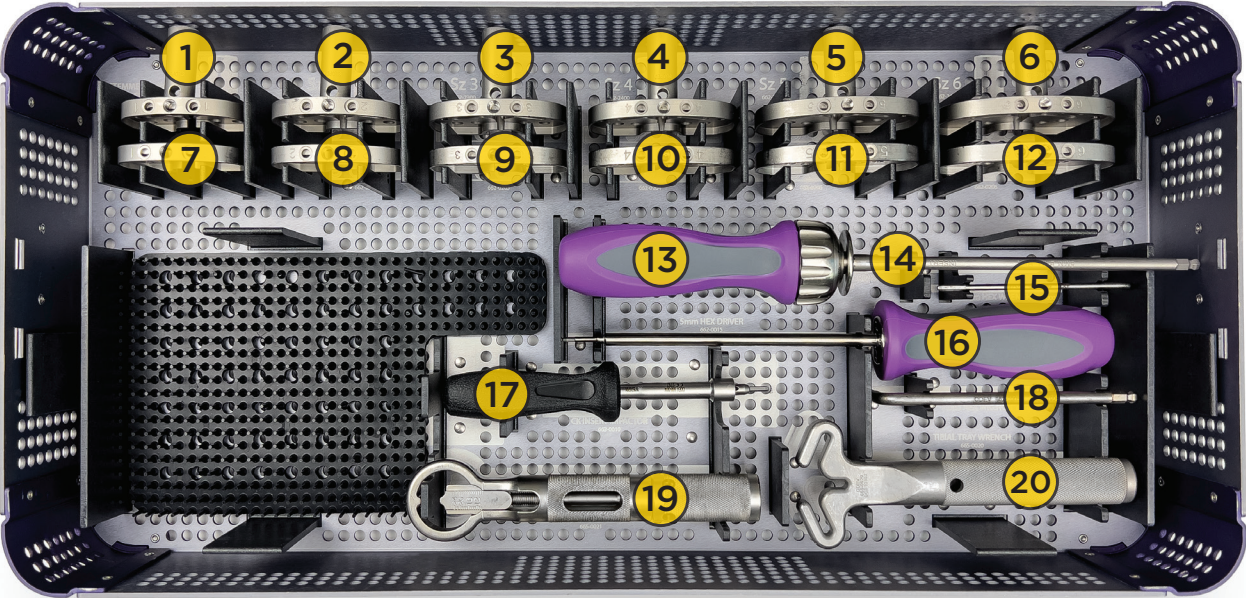
## 661-9020 BKS DIFFICULT PRIMARY TIBIA

NUMBER	ITEM #	DESCRIPTION	QTY
1	665-1203	Stem Extension Trial 12x30mm	2
2	665-1403	Stem Extension Trial 14x30mm	2
3	665-1205	Stem Extension Trial 12x50mm	2
4	665-1405	Stem Extension Trial 14x50mm	2
5	662-0318	Tib Drill Guide Ø15mm Sloped	1
6	662-0319	Tib Drill Guide Ø17mm Sloped	1
7	215-0009	Hudson Large Female T-Handle	1
8	662-0220	Alignment Handle	1
9	665-0115	Cemented Reamer Ø15mm	1
10	665-0117	Cemented Reamer Ø17mm	1



661-9020 BKS DIFFICULT PRIMARY TIBIA

NUMBER	ITEM #	DESCRIPTION	QTY
1	662-2100	Stemmed Tray Trial Sloped Sz1	1
2	662-2200	Stemmed Tray Trial Sloped Sz2	1
3	662-2300	Stemmed Tray Trial Sloped Sz3	1
4	662-2400	Stemmed Tray Trial Sloped Sz4	1
5	662-2500	Stemmed Tray Trial Sloped Sz5	1
6	662-2600	Stemmed Tray Trial Sloped Sz6	1
7	662-0201	Tibial Tray Sizer Trial Sz 1	1
8	662-0202	Tibial Tray Sizer Trial Sz 2	1
9	662-0203	Tibial Tray Sizer Trial Sz 3	1
10	662-0204	Tibial Tray Sizer Trial Sz 4	1
11	662-0205	Tibial Tray Sizer Trial Sz 5	1
12	662-0206	Tibial Tray Sizer Trial Sz 6	1
13	852-0001C	Ratchet Handle Straight	1
14	662-0016	5mm Ball End Hex Driver	1
15	667-0001A	2.5mm Hex Wrench	1
16	667-0003A	2.5mm Hex Torque Limiting Driver	1
17	668-0014	2.5mm Posterior Augment Hex Driver	1
18	662-0005A	5mm Hex Wrench	1
19	665-0021	Stem Extension Wrench	1
20	665-0020	Tibial Tray Wrench	1

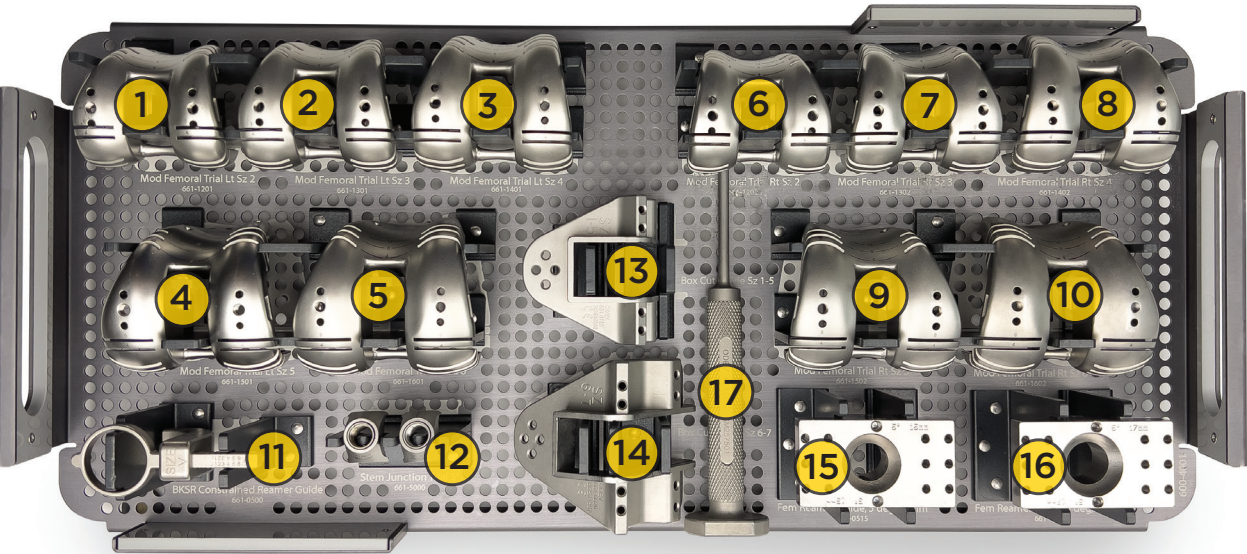




# BKS Difficult Primary Instrument Trays

661-9021 BKS DIFFICULT PRIMARY FEMUR

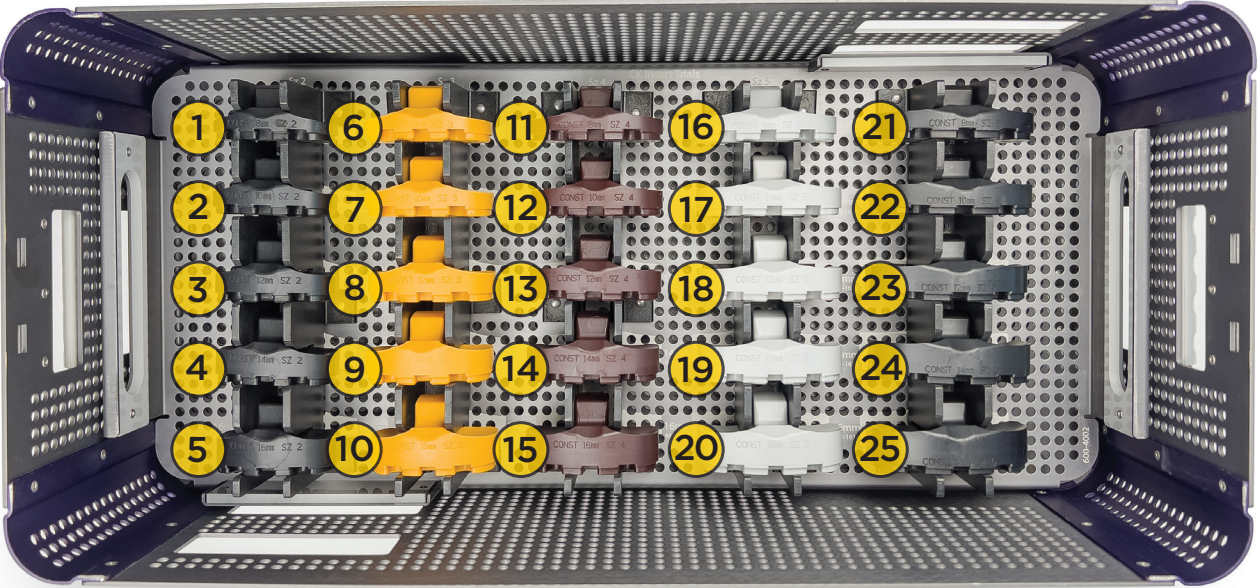
NUMBER	ITEM #	DESCRIPTION	QTY
1	661-1201	Mod Femoral Trial Lt Sz 2	1
2	661-1301	Mod Femoral Trial Lt Sz 3	1
3	661-1401	Mod Femoral Trial Lt Sz 4	1
4	661-1501	Mod Femoral Trial Lt Sz 5	1
5	661-1601	Mod Femoral Trial Lt Sz 6	1
6	661-1202	Mod Femoral Trial Rt Sz 2	1
7	661-1302	Mod Femoral Trial Rt Sz 3	1
8	661-1402	Mod Femoral Trial Rt Sz 4	1
9	661-1502	Mod Femoral Trial Rt Sz 5	1
10	661-1602	Mod Femoral Trial Rt Sz 6	1
11	661-0500	BKSR Constrained Reamer Guide	1
12	661-5000	Stem Junction Trial 5°	2
13	661-0120	Box Cut Guide Sz 1-5	1
14	661-0620	Box Cut Guide Sz 6-7	1
15	661-0515	Fem Reamer Guide, 5 deg, 15mm	1
16	661-0517	Fem Reamer Guide, 5 deg, 17mm	1
17	663-0007	CK Insert Pin Impactor	1



661-9021 BKS DIFFICULT PRIMARY FEMUR

NUMBER	ITEM #	DESCRIPTION	QTY
1	663-1208	CK Insert Trial Sz 2 8mm	1
2	663-1210	CK Insert Trial Sz 2 10mm	1
3	663-1212	CK Insert Trial Sz 2 12mm	1
4	663-1214	CK Insert Trial Sz 2 14mm	1
5	663-1216	CK Insert Trial Sz 2 16mm	1
6	663-1308	CK Insert Trial Sz 3 8mm	1
7	663-1310	CK Insert Trial Sz 3 10mm	1
8	663-1312	CK Insert Trial Sz 3 12mm	1
9	663-1314	CK Insert Trial Sz 3 14mm	1
10	663-1316	CK Insert Trial Sz 3 16mm	1
11	663-1408	CK Insert Trial Sz 4 8mm	1
12	663-1410	CK Insert Trial Sz 4 10mm	1
13	663-1412	CK Insert Trial Sz 4 12mm	1

NUMBER	ITEM #	DESCRIPTION	QTY
14	663-1414	CK Insert Trial Sz 4 14mm	1
15	663-1416	CK Insert Trial Sz 4 16mm	1
16	663-1508	CK Insert Trial Sz 5 8mm	1
17	663-1510	CK Insert Trial Sz 5 10mm	1
18	663-1512	CK Insert Trial Sz 5 12mm	1
19	663-1514	CK Insert Trial Sz 5 14mm	1
20	663-1516	CK Insert Trial Sz 5 16mm	1
21	663-1608	CK Insert Trial Sz 6 8mm	1
22	663-1610	CK Insert Trial Sz 6 10mm	1
23	663-1612	CK Insert Trial Sz 6 12mm	1
24	663-1614	CK Insert Trial Sz 6 14mm	1
25	663-1616	CK Insert Trial Sz 6 16mm	1











Ortho Development® Corporation designs, manufactures, and distributes orthopedic implants and related surgical instrumentation—with a specialty focus on hip and knee joint replacement, trauma fracture repair and spinal fixation. ODEV was founded in 1994 and is located at the base of the Wasatch Mountains in the Salt Lake City suburb of Draper, Utah. The company has established distribution throughout the United States, Japan, and other select international markets.



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