Biotech Constraint Knee System

Surgical Technique

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"Movement is Life"

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Surgical Technique

In the event the Surgeon diagnoses the need for a constrained knee system, due to the patient's knee joint stability and other conditions, Biotech is able to provide the ideal constrained knee implant system solution, **the Biotech Constrained Knee System (BCK).**

Technical Procedure:

1. Selection and Implantation of the BCK Femoral Component

The resection of the femoral bone is to be conducted as per the **Biotech TRK Total Revision Knee (TRK)** Surgical Technique. The preparation of the Femoral bone, augmentations and stems are to be conducted as per the Biotech TRK Surgical Technique as well. The Biotech TRK System is provided along with this document.

The determination of the required size of the BCK Femoral component may be determined by utilizing the Trials provided in TRK Surgical Instrument Set.

The BCK Femoral Component is compatible with the modular accessories of the TRK System.

The BCK Femoral Component is provided in assembled form ready for implantation.

Once the Femoral Component size is determined, the corresponding BCK Femoral Component size is to be chosen and implanted on to the Patient's Femoral bone, the implantation of the BCK Femoral Component is to be conducted as per the TRK Surgical Technique.

The BCK Femoral Component comprises the following:

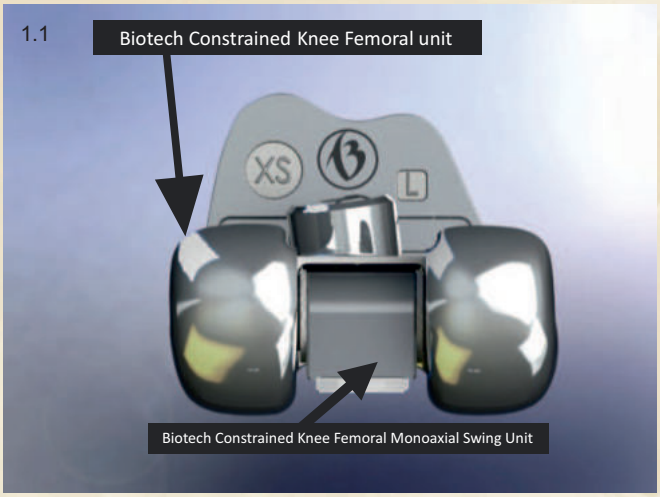
- BCK Femoral Unit
- BCK Femoral Mono-axial Swing Unit

The BCK Femoral Component is anatomical and is provided in 5 sizes for the Left and 5 Sizes for the Right Knee usage. The size rage is XS, S, M, L and XL.

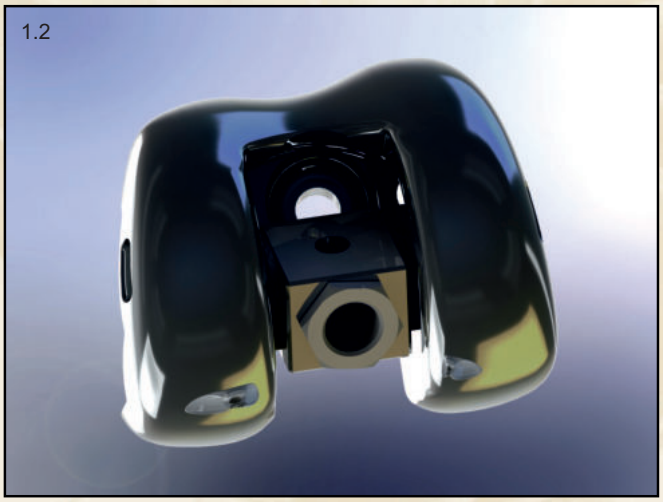
The BCK Femoral Unit and the BCK Femoral Mono-axial Swing Unit is NOT to be disassembled.

The BCK Femoral Component

Back View



Underside View



Side View

2. Selection and Assembly Of The BCK Tibial Tray

Once the BCK Femoral Component size has been ascertained, the surgeon may choose the required BCK Tibial Tray size. The BCK system allows the BCK Tibial Tray size to be on matching size to the BCK Femoral Component, or one size larger or one size smaller to the BCK Femoral Component, as may be required by the surgeon.

The preparation of the Tibial bone and determination of the Tibial Tray size is to be conducted as per the TRK Surgical Technique.

The BCK Tibial Tray is not anatomical and is provided in 5 sizes- XS, S, M, L, XL

The BCK Tibial Tray is compatible with the modular accessories used in the TRK system.

The BCK Tibial Tray is provided with a BCK Tibial Insert Fixation Screw within the same package.

The BCK Tibial Tray could be combined with the following accessories of the TRK system:

- Modular Rocket Component
- Modular Stem Components
- Tibial Augmentation (TAB)
- Sleeve
- Offset

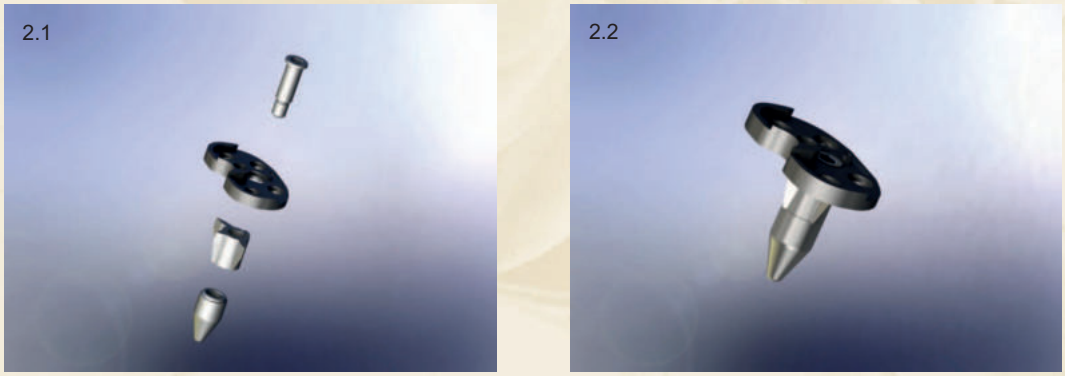


Illustration: Modular Rocket Component on the BCK Tibial Tray

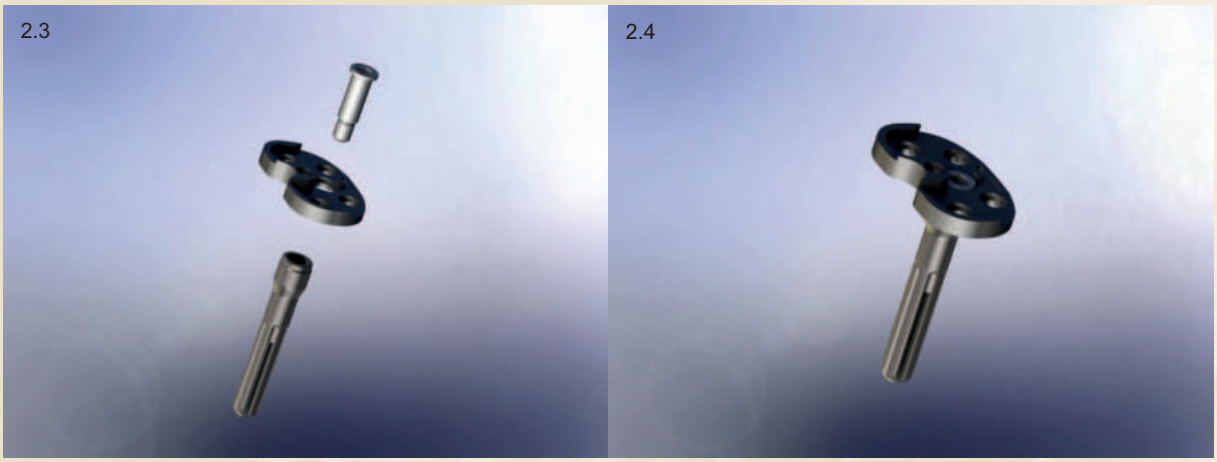


Illustration: Modular Shaft Component on the BCK Tibial Tray

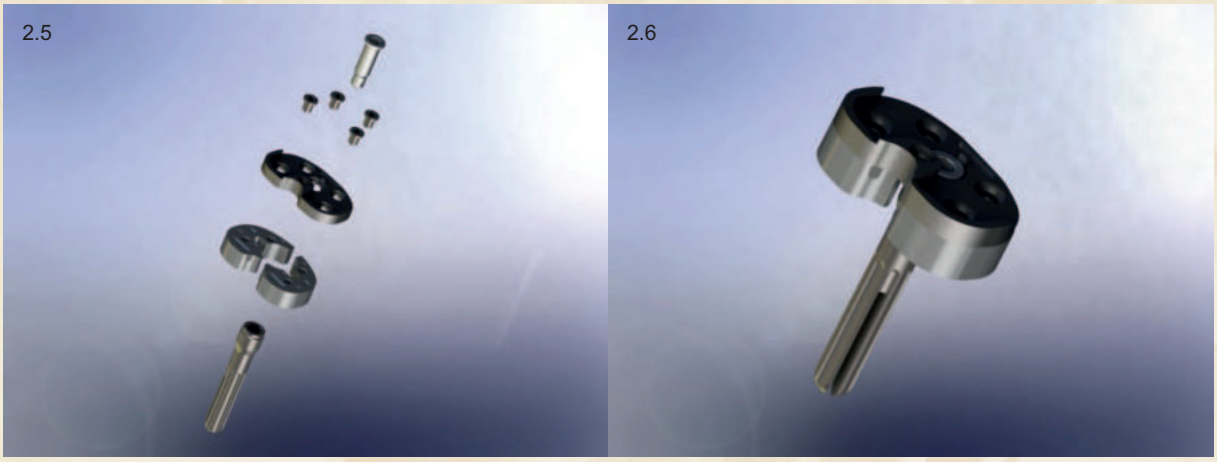


Illustration: Modular Augmentation on the BCK Tibial Tray

Illustration: Modular Shaft combined with the Modular Sleeve Component on the BCK Tibial Tray

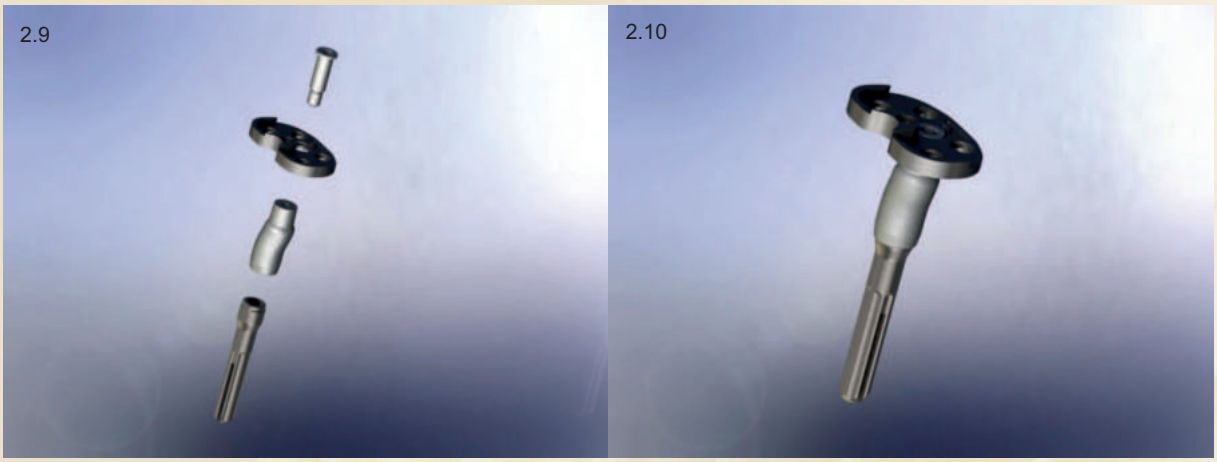


Illustration: Modular Shaft combined with the Modular Offset Component on the BCK Tibial Tray

3. Selecting the appropriate size BCK Tibial Insert

The corresponding size of the BCK Tibial Insert is to be chosen to match the size of the chosen BCK Tibial Tray.

Example:
A BCK Tibial Tray size M would use a BCK Tibial Insert size M.

Selecting the appropriate size of Tibial Insert Thickness

Once the size of the BCK Tibial Insert is chosen as given above, the surgeon would decide the required thickness of the BCK Tibial Insert. For each size of Tibial Insert, Biotech provides four standard thickness sizes -10mm 12mm 15mm 18mm. On special request Biotech may produce and supply additional thickness sizes.

Determining the required thickness of the BCK Tibial Insert is to be conducted as per the TRK Surgical Technique and utilizing the Trial Tibial Inserts provided in the TRK System's Instrument set.

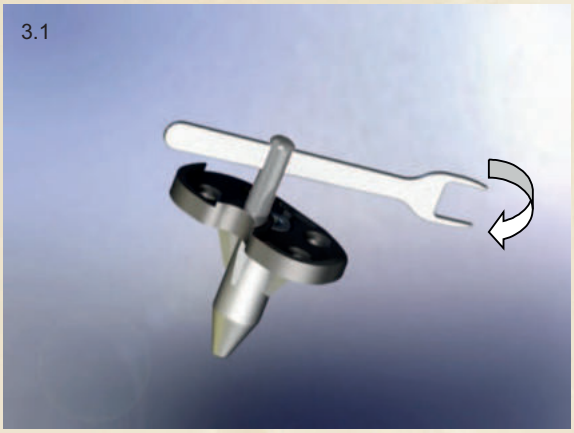
The BCK Tibial Insert is provided with the following, within the same package:

1. Insert Stem of appropriate length

2. An extra Polyethylene Hex Bolt.
   This extra Polyethylene Hex Bolt is to be used in case of a BCK System Revision surgery or dismantling of the BCK Femoral Component from the BCK Tibial Tray during a Primary surgery, as described in point 6 below in this Surgical Technique.

Both components (BCK Tibial Insert and Insert Stem) are clearly size marked.

The BCK Tibial Insert Stem is to be fastened soundly to the BCK Tibial Tray by insertion to the corresponding-matching threaded hole in the BCK Tibial Tray, the provided wrench with the BCK System is to be used for this purpose.

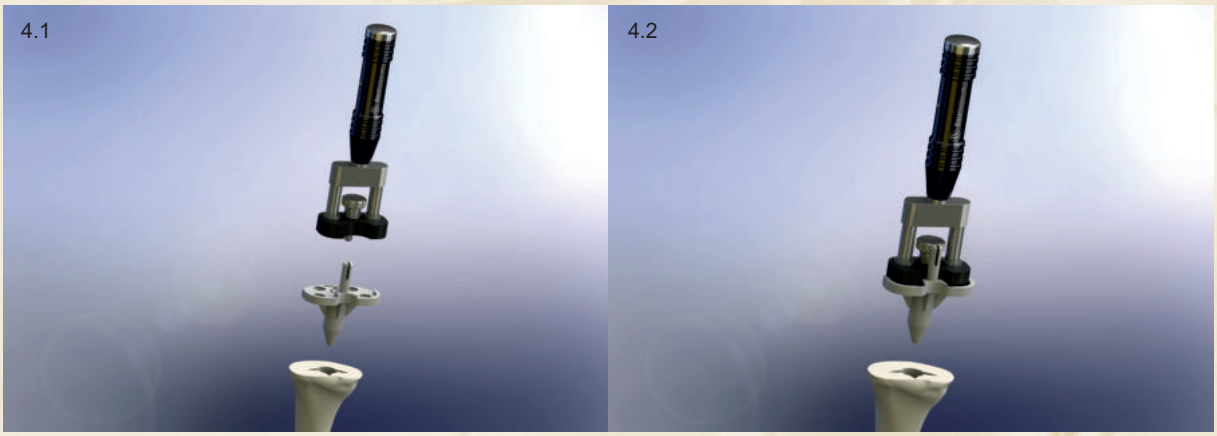


During Assembly

Post assembly

4.Implantation of the Fully Assembled BCK Tibial Tray to the Patient's Tibial Bone and Subsequent Installation of the BCK Tibial Insert.

The now fully assembled BCK Tibial Tray is to be attached to the BCK Tibial Inserter Instrument provided with the BCK System.



Fully assembled BCK Tibial Tray attached to the BCK Tibial Inserter Instrument

Once the Tibial Tray in attached to the BCK Tibial Inserter Instrument, the surgeon is to implant the BCK Tibial Tray onto the Patient's Tibial bone utilizing the BCK Tibial Inserter Instrument. The implantation of the BCK Tibial Tray is to be conducted as per the TRK Surgical Technique.

BCK Tibial Tray being implanted on to the Tibial bone utilizing the BCK Tibial Inserter Instrument

Fully assembled BCK Tibial Tray post implantation on the Tibial Bone

Installation of the BCK Tibial Insert on to the BCK Tibial Tray.

The Selected BCK Tibial Insert is to be slide on to the BCK Tibial Tray.

Pre assembly

Pre assembly

The BCK Tibial Insert Fixation Screw provided with the BCK Tibial Tray is to be inserted and fastened to the BCK Tibial Tray, utilizing the screwdriver provided in the TRK instrument set.

Insertion of the Fixation Screw

5. Combining the assembled and implanted BCK Tibial Tray to the implanted BCK Femoral Component

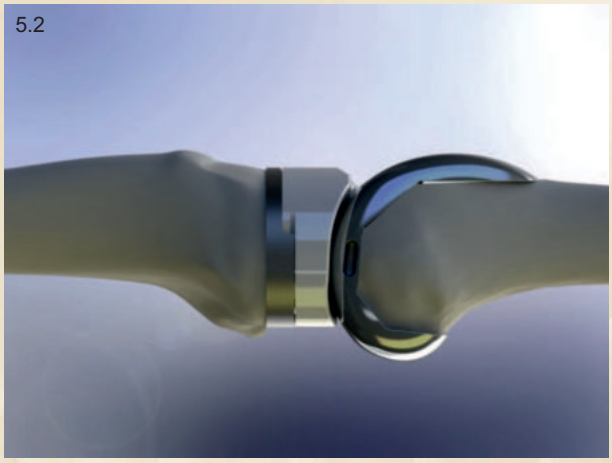
Prior to the combining of the fully assembled and implanted BCK Tibial Tray to the BCK Femoral Component, it should be ensured that both BCK Tibial Tray and the BCK Femoral Components are fully bonded to the Tibial and Femoral bones respectively.

The BCK Tibial Insert Stem is to be positioned at the entrance of the BCK Femoral Mono-axial Swing Unit, keeping the Knee Joint in a flexed position, as depicted in the image below.

The BCK Tibial Insert Stem positioned at the entrance of the BCK Femoral Mono-axial Swing Unit

A surgical assistant is to firmly hold in place the Femoral section of the patients Leg, whilst the surgeon is to hold the Tibial section of the patient's leg.

Subsequently the surgeon is to move the patient's Knee joint from the flexed position to a fully extended position. Whilst moving the Knee Joint from the flexed position to the extended position the surgeon is to apply pressure compressing the Tibial Bone towards the Femoral Bone, ensure that during the extension maneuver the BCK Insert Stem would enter the BCK Femoral Mono-axial Swing Unit's entrance and lock the BCK Insert Stem within the BCK Mono-axial Swing Unit.



The Knee joint in a fully extended position

Once the Knee Joint has been moved from the flexed position to the extended position, the BCK Tibial Insert Stem would be locked into the BCK Mono-axial Swing Unit.

Warning

Once the above procedure is completed the removal of the locked Tibial Insert Stem from the BCK Mono-axial Swing Unit is a sensitive and time consuming procedure. Hence we propose that the surgeon ensure all sizing and Trials are properly conducted to avoid the requirement of the removal of the locked Tibial Insert Stem from the BCK Mono-axial Swing Unit.

The Combined BCK Tibial Tray and Femoral Component

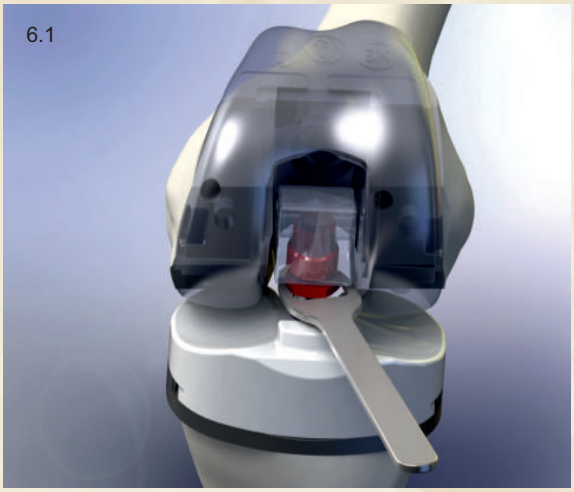
6.Biotech Constrained Knee System Revision or Dismantling

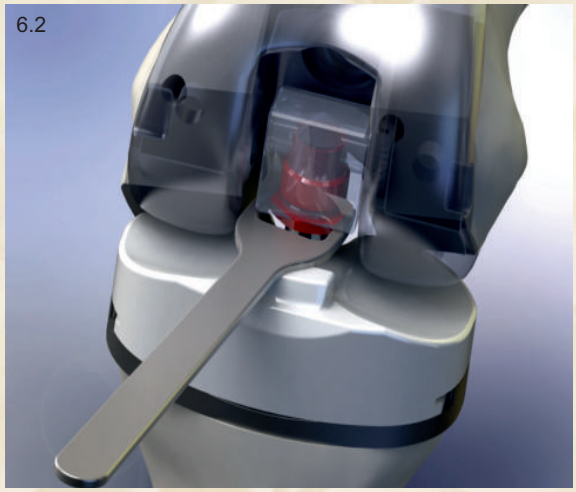
In the event of a BCK Revision surgery or the surgeon requires to dismantle the BCK during a Primary surgery, the following procedure is to be followed. It should be noted that this is a sensitive and time consuming procedure.

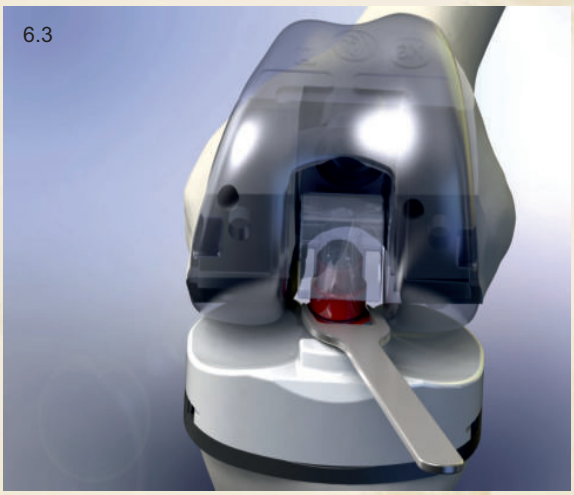
Revision or Dismantling Step 1

As a first step the Mono-axial Swing Unit's **White color Polyethylene Hexagon shaped bolt (Polyethylene Hex Bolt)** located between the BCK Femoral Component and the BCK Tibial Insert is to be unscrewed.

The Polyethylene Hex Bolt is located at the point where the BCK Tibial Insert Stem enters the BCK Femoral Mono-axial Swing Unit. The wrench provided with the BCK system is to be used for this purpose. Once the Polyethylene Hex Bolt is fully unscrewed, it would dis-attach from the BCK Mono-axial Swing Unit along with the BCK Tibial Insert Stem. This would leave the BCK Tibial Insert Stem dis-attached from the BCK Femoral Mono-axial Swing unit. As depicted in the images below.







Unscrewing of the Polyethylene Hex Bolt from the Mono-axial Swing Unit.

Please note that the Polyethylene Hex Bolt of the Mono-axial Swing Unit in reality is White in color, however it is depicted in Red Color in the images for ease of reference.

Revision or Dismantling Step 2

The BCK Tibial Insert Stem is to be unscrewed from the BCK Tibial Tray using the wrench provided with the BCK system.

Warning

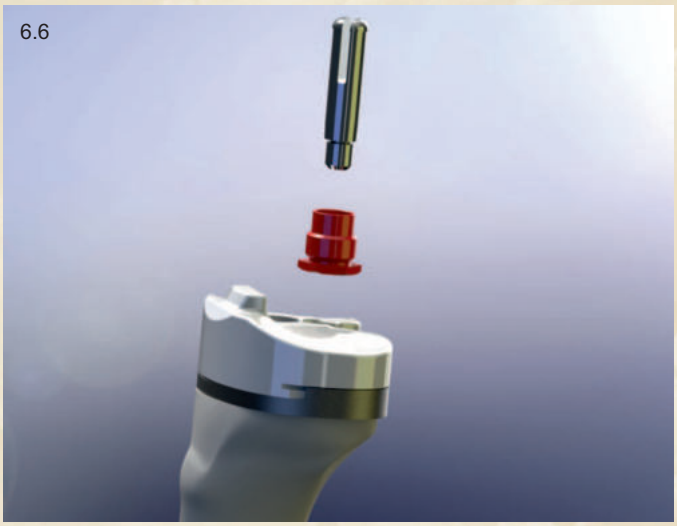
Once the BCK Tibial Insert Stem is unscrewed from the BCK Tibial Tray, the Insert Stem is NOT to be re-used. A NEW BCK Insert with Stem is to be used subsequently on re-assembly.

Once the Polyethylene Hex Bolt is removed from the BCK Femoral Mono-axial Swing Unit, the Polyethylene Hex Bolt is NOT to be re-used. A NEW Polyethylene Hex Bolt is to be used on re-assembly. An extra Polyethylene Hex Bolt is provided with each BCK Tibial Insert and included in the same package for this purpose.

Unscrewing of the BCK Tibial Insert Stem from the BCK Tibial Tray.

Revision or Dismantling Step 3

Once the BCK Tibial Insert Stem is unscrewed from the BCK Tibial Tray the Polyethylene Hex Bolt is to be removed from the BCK Tibial Insert Stem.



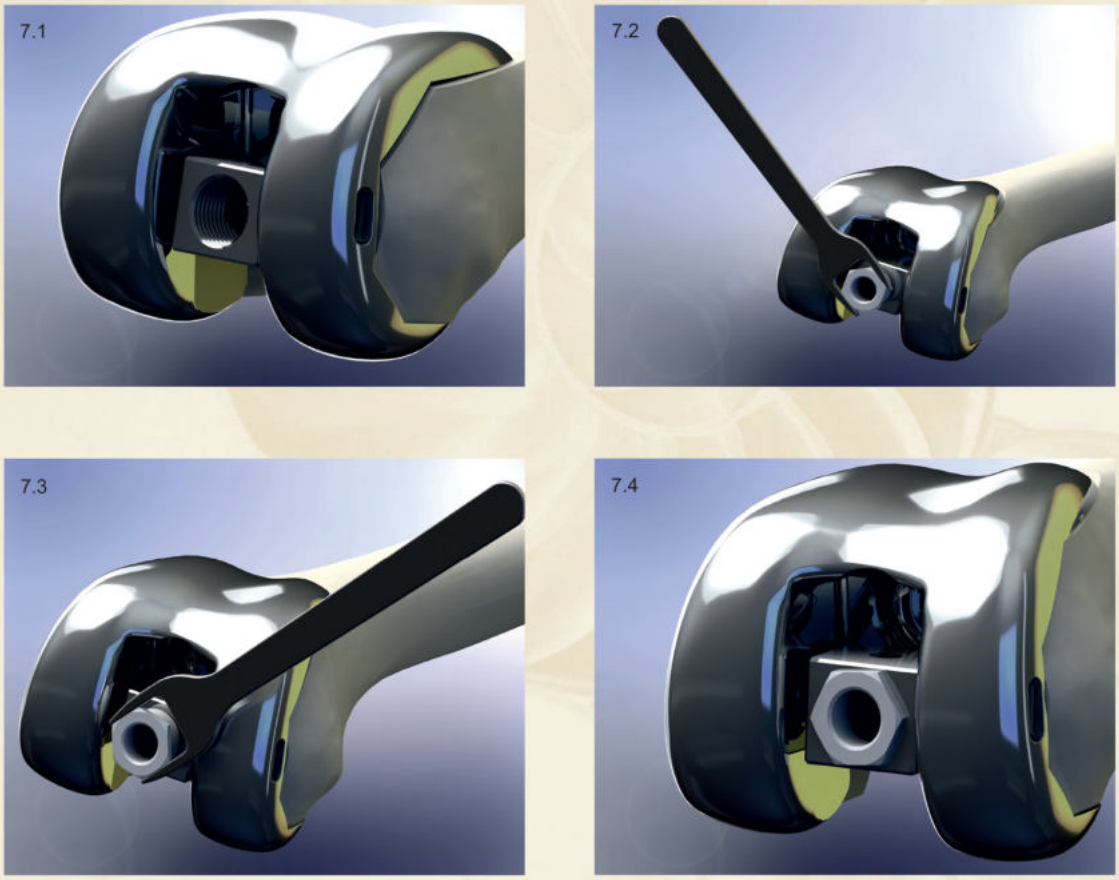
The Polyethylene Hex Bolt being removed from the BCK Tibial Inset Stem

7. Re-combining the BCK Tibial Tray to the BCK Femoral Component

Once the surgeon is ready to re-attach the BCK Tibial Tray to the BCK Femoral Component, the surgeon is to follow the following procedure;

Attach a new Polyethylene Hex Bolt back into the BCK Femoral Mono-axial Swing Unit. An extra Polyethylene Hex Bolt is provided for this requirement with each BCK Tibial Insert and included in the same package.

The new Polyethylene Hex Bolt is to be first inserted and fastened by hand, and subsequently tightened utilizing the provided wrench.



The New Polyethylene Hex Bolt being attached to the BCK Femoral Mono-axial Swing Unit.

Subsequently the surgeon is to choose a **new** BCK Tibial Insert with Stem, and repeat the procedure from point 3 of this Surgical Technique given above.

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