

ACS® UNI Fixed Bearing

Surgical Technique



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Note: The surgical technique described herein reflects the author's suggested treatment in straightforward interventions. It is ultimately the surgeon's decision which procedure is the most sensible and effective for the patient in question. The treatment described should be implemented according to the current state of the art. The instruments depicted and described with catalog numbers in the surgical technique refer to an example size. Other sizes and instrument variants can be found in the appendix to the surgical technique.

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ACS® UNI Fixed Bearing

The ACS® UNI FB is a unicompartmental knee system that maintains almost natural kinematics of the knee joint following full restoration of the joint line. The system is characterized by a flat polyethylene bearing which, like the body's natural kinematics, permits a low-friction rolling motion of the femur component.

The ACS® UNI femur component has a symmetric design and is available in 4 sizes. The femur component is made of CoCrMo in accordance with ISO 5832-4. For patients with a sensitivity to metal ions, the femur component is available in a TiN-coated variant. TiN is a ceramic coating with competitive advantages with respect to wear, resistance to erosion, and reduction of metal ion emission. The coating reduces the potential emission of allergy-inducing ions from the component to such a strong degree that the value lies below the detection limit. [1,2]

On the tibia side, an asymmetric component is implanted. The asymmetric design in a total of 7 sizes achieves optimal covering of the bone. The tibia components consist of im- platan®, a titanium alloy. A slide bearing made of polyeth- ylene is connected firmly with the tibia. It is symmetric and available in 6 heights (8-12 and 14 mm).

[1] Wisbey et al. Application of PVD TiN coating to Co-Cr-Mo based surgical implants. *Biomaterials* 1987, 11.

[2] Baumann A. Keramische Beschichtungen in der KTEP Standardlösung für Allergiker [Ceramic coatings in the KTEP standard solution for allergic persons]. *JATROS Orthopädie & Rheumatologie* 2001, 6:16-17



Pre-operative planning

Pre-operative planning and precise surgical techniques are mandatory to achieve optimal results. The instructions and the procedure given in the surgical technique for the system must be adhered to. Familiarity with the surgical technique recommended for this system and its careful application are essential to achieve the best possible outcome. Before surgery, the surgeon must conduct surgical planning in terms of the dimensions of the prosthetic model and the positioning of the implant components in the bone.

Implant templates are made available for this purpose:

Digital templates: Digital templates are included in the databases of common planning tools. If the desired templates are not included in the software, please request them from the planning tool supplier.

Radiographic templates: Alternatively, radiographic templates are available in various scale factors, which can be obtained from your local sales partner upon request.

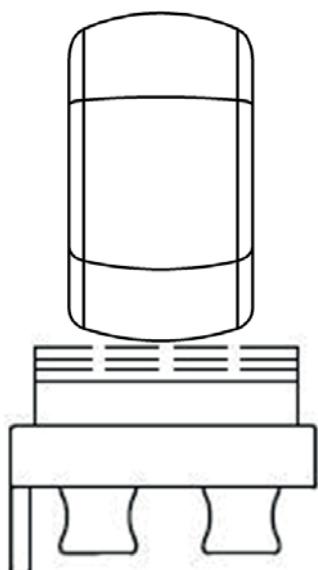
In addition, before surgery it must be ensured that:

- All necessary components are available. An adequate number of all necessary implant sizes should be available during surgery. It must be determined whether the implantation will be performed with or without cement.
- All instruments necessary are present for surgery. Implants may only be used with the corresponding instrument set of implantcast GmbH. The only exception to this are those instruments that are standardized for surgery.
- the correct surgical instrument sizes are used during surgery, in order to prevent damage to the implant.

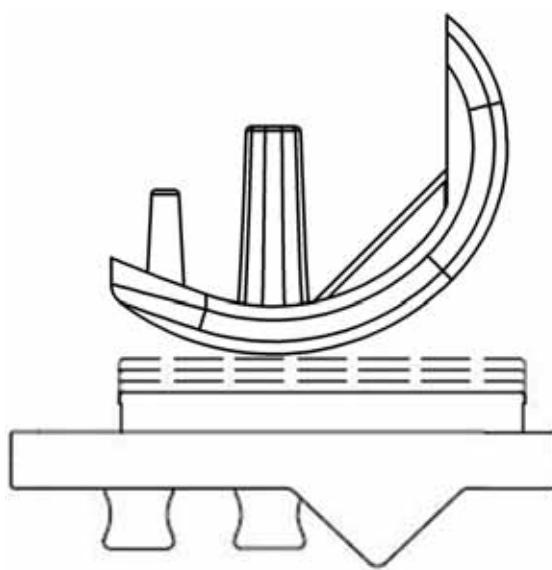
 Attention: Please note that in the case of sales on approval, the volume of implants and instruments may deviate from the information in the catalog annex of this surgical technique.

 Note: Further information can be found in the last section of this surgical technique or the instructions for use:

09300026GB ACS® Uni / PB Uni Knee System

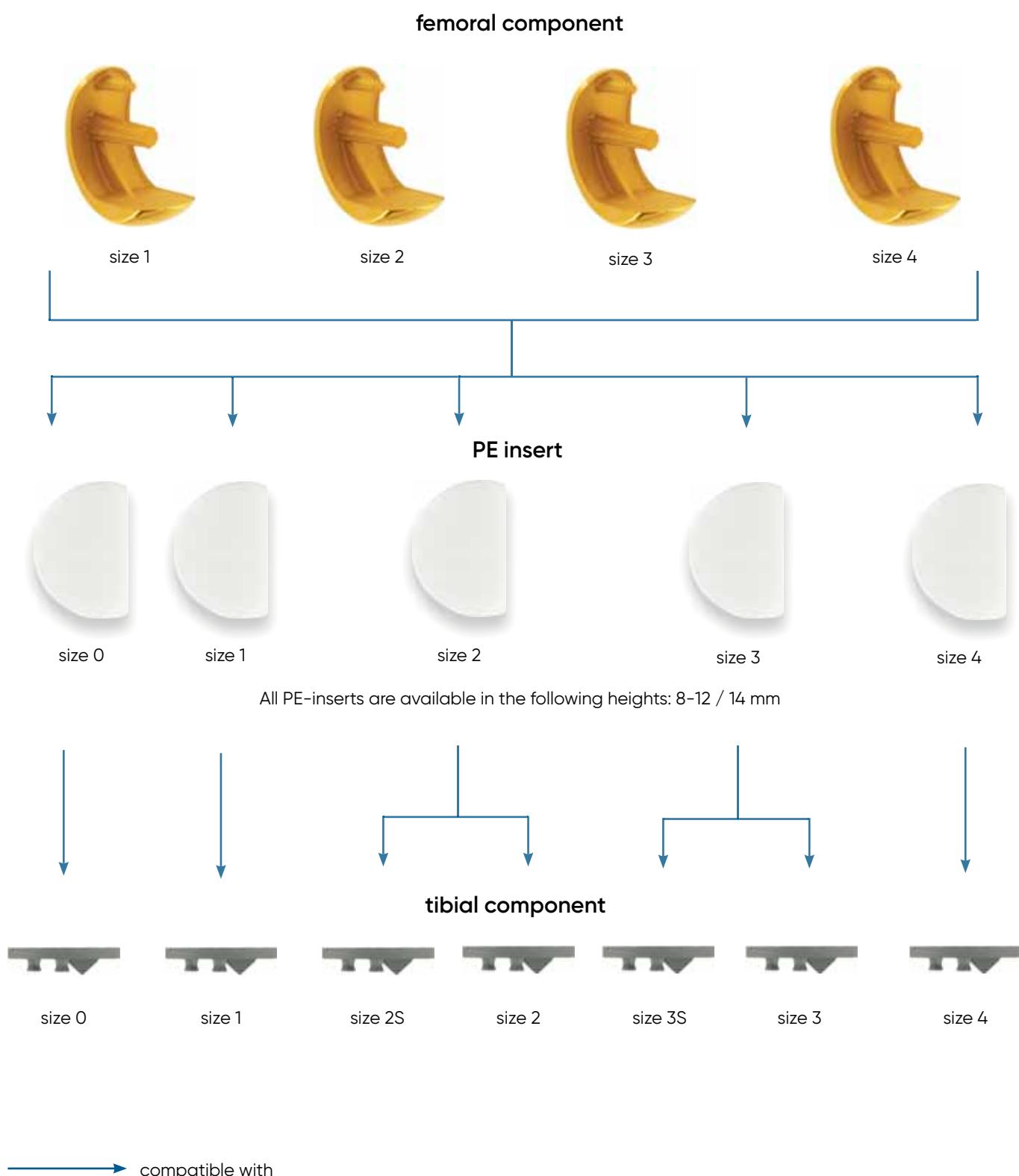


A/P view



M/L view

Compatibility Matrix



Surgical Technique

Surgical access

Flex the knee to 90° and perform a medial incision of the skin (Fig. 1). Less experienced surgeons are recommended to choose a larger access opening since this simplifies the operation.

Remove osteophytes to prepare the medial condyle.

Determination of femoral size

Once again, flex the knee joint to 90° and check the femur size, measured pre-operation, with the femoral sizing guide¹⁾ (Fig. 2).

Tibia preparation

OPTION 1: Referencing on the posterior condyles

Insert the 1-mm joint space feeler²⁾ for the corresponding femur size into the joint space (Fig. 3) and assess the ligament tension. If it is not satisfactory, use a thicker joint space feeler (2 mm, 3 mm) until sufficient ligament tension is achieved.

 Note: The required tibial resection height is measured from the condyle of the femur by the joint space feeler.



Fig. 1

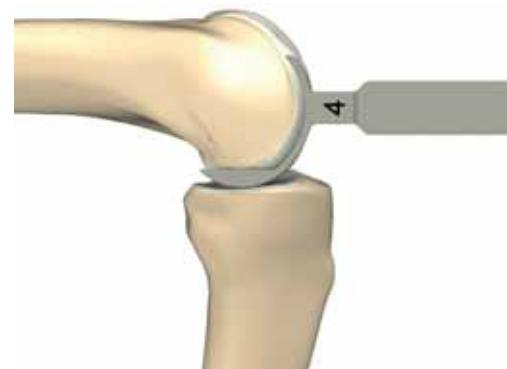


Fig. 2

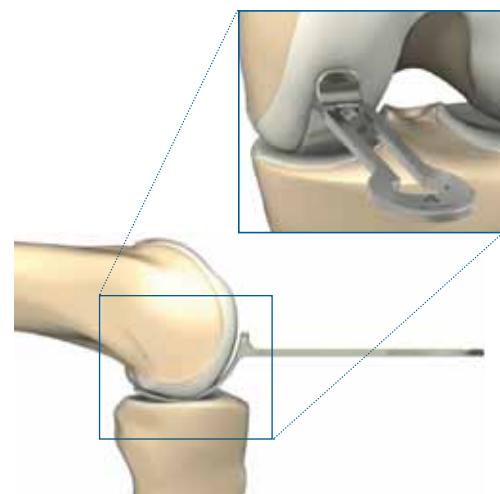


Fig. 3

¹⁾42160607: ACS® Uni femoral template; ²⁾42161760: ACS® Uni joint gap feeler

Connect the ankle clamp¹⁾, the tibia alignment rod²⁾ (1) and the tibia cutting block (4) (RL/LM³) or LL/RM⁴) with each other and attach everything to the tibia (Fig. 4).

Use the cutting block adapter⁵⁾ (2) and connect the joint space feeler⁶⁾ (3) with the tibia cutting block. The adapter can be used either for resection with the help of the slot ("slotted") or for an unguided ("unslotted") resection. Insert the adapter into the cutting block according to the desired resection style. The holes for the pin are labeled on the block (Fig. 5 and Fig. 6). The correct resection height is given by the adapter. Make sure that the joint space feeler wraps around the femoral condyle.

The tibial slope and axis are adjusted with the settings on the ankle clamp. The tibia alignment rod should pass over the medial third of the tuberositas tibiae. Adjust the medio-lateral position accordingly (5).

Orient the tibia alignment rod with the intramedullar axis of the tibia. When aligned in parallel, the cutting block generates a posterior slope of 5°. If a greater or lesser slope is required, make the corresponding setting on the ankle clamp (6).

Fix the tibia cutting block with two drill pins⁷⁾. Use the holes marked in Fig. 7. Remove the joint space feeler and the adapter and alignment instruments.

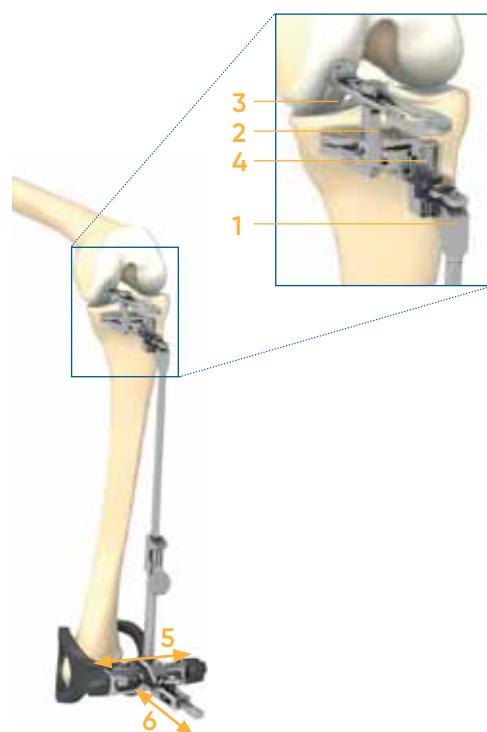


Fig. 4



Fig. 5

Fig. 6

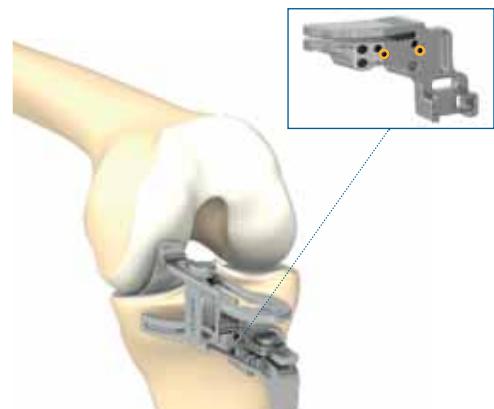


Fig. 7

¹42200930: ankle clamp; ²42210185: ACS® tibial alignment rod; ³42160370: tibial cutting block; ⁴42160371: tibial cutting block; ⁵42160372: Uni FB adapter for tibial resection; ⁶42161762: ACS® Uni joint gap feeler; ⁷77000121: drilling pin

OPTION 2: Referencing on the tibial plateau

Connect the ankle clamp¹⁾, the tibia alignment rod²⁾ (1) and the tibia cutting block (2) ("LM/RL"³ or "LL/RM"⁴) with each other and attach everything to the tibia (Fig. 8).

Connect the stylus⁵⁾ (3) with the tibia cutting block. Set the tibial resection height by turning the screw on the stylus. Adjust the stylus to the desired resection height (the minimum height from tibial plateau and PE is 8 mm) and use the tip to palpate for the deepest place on the destroyed side. Use the appropriate feeler tip based on the desired resection type ("slotted" or "non-slotted").

The tibial slope and axis are adjusted with the settings on the ankle clamp. The tibia alignment rod should pass over the medial third of the tuberositas tibiae. Adjust the medio-lateral position accordingly (4).

Orient the tibia alignment rod with the intramedullary axis of the tibia. When aligned in parallel, the cutting block generates a posterior slope of 5°. If a greater or lesser slope is required, make the corresponding setting on the ankle clamp (5).

The tibia cutting block can be aligned first and fixed with the long hole (Fig. 9). This makes it possible to recalibrate the height setting if needed without changing the M/L position of the cutting block.

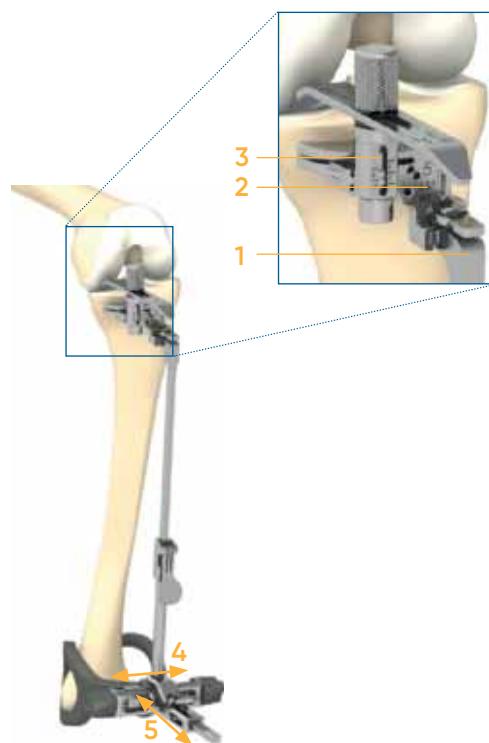


Fig. 8

Fix the tibia cutting block with two drill pins⁶⁾. Use the holes marked in Fig. 10. Remove the joint space feeler and the adapter and alignment instruments.

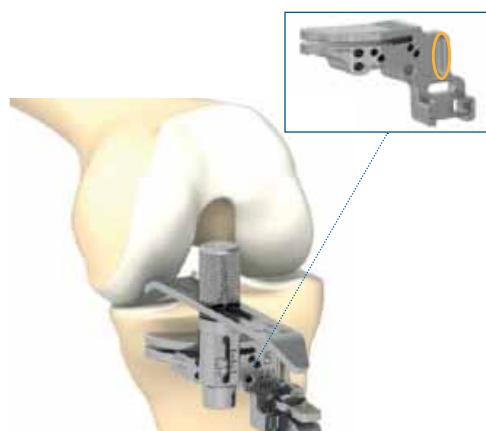


Fig. 9

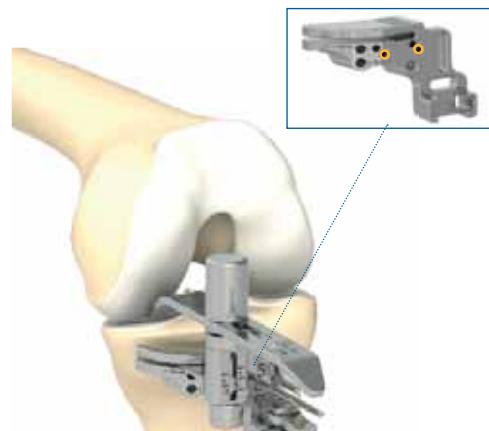


Fig. 10

¹42200930: ankle clamp; ²42210185: ACS® tibial alignment rod; ³42160370: tibial cutting block; ⁴42160371: tibial cutting block; ⁵42200402: tibial stylus 0-10; ⁶77000121: drilling pin

The resection height can be checked for verification purposes (Fig. 11).

If a correction to the resection height is required, the block can be relocated 2.5 mm distally via the pinholes.

 Note: The resection should only minimally undercut the defect area. In case of very pronounced defects, the resection plane can also lie above the defect area as long as there is sufficient surface for the tibia component to rest on.

If the position of the cutting block is satisfactory, the block can be secured with an additional oblique pin (Fig. 12).

To prevent an undercutting of the eminentia intercondylaris during the resection, an additional pin can be inserted for the slot-guided resection to serve as a stop (Fig. 13). There are 4 pin positions available. Select the pin position that lies at the most medial position but which does not cause any weakening of the eminentia intercondylaris.

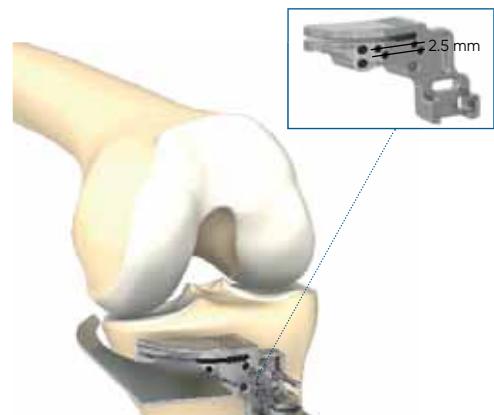


Fig. 11

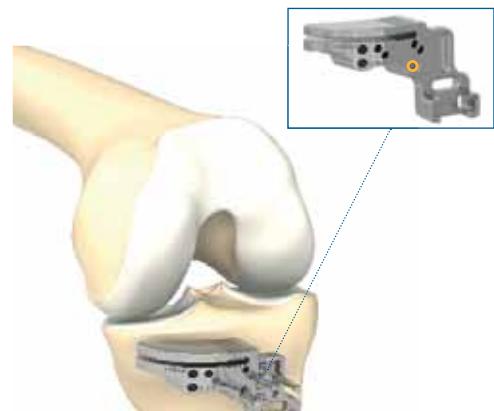


Fig. 12

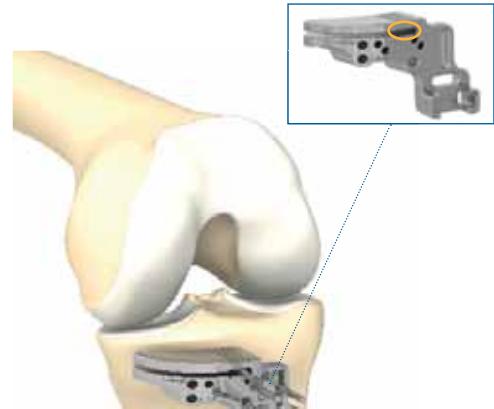


Fig. 13

First, use a jigsaw blade to perform the vertical resection (Fig. 14). Use the markings on the tibial resection guide for orientation in order to perform a vertical resection in the right angle. The eminentia intercondylaris and the base of the cruciate ligament should be retained during the resection.

During the cut, the saw must be constrained parallel to the "stop pin" in order to not weaken the tibial plateau and to avoid the risk of fracture.

 Note: Use a stable and sufficiently long jigsaw saw blade for the resection.

The horizontal resection can be performed with or without the help of the slot (depending on the previous alignment) (Fig. 15). Make sure to not undercut the eminentia intercondylaris and weaken it!

 Note: The jigsaw blade can be left in the bone during the horizontal resection as another way to protect the eminentia intercondylaris.

The two cuts should produce a clean L-resection (Fig. 16).

Now remove the pins and the tibial cutting block.

 Note: To check whether enough tibial bone was removed, the 8 mm joint space gauge can be inserted into the joint at this time. If the joint space is too tight for insertion, a follow-up resection is necessary.



Fig. 14



Fig. 15



Fig. 16

Femur preparation

Make a final measurement of the femur component size with the femoral size guide¹⁾. Flex the knee joint to 90° and make sure that the size guide rest against the posterior condyle such that the axis of the grip makes a 90° angle with the tibial axis. Size 4 is read from the upper edge of the instrument (Fig. 17). All other sizes are read from the slots underneath. Use methylene blue to mark the position of the previously measured femur component. The marking indicates the height of the femur component. Then extend the knee and check the position of the marking. It should still be visible over the anterior tibia edge.

OPTION 1: Intramedullary alignment

 Note: Use the femoral cutting blocks with **REF 4216-1701, -1702, -1703, -1704** for preparation with intramedullary alignment!

Bend the knee again.

Open up the medullary cavity with the 5-mm ic drill²⁾ (Fig. 18). The position should be approx. 1 cm anterior of the base of the PCL and 2–3 mm lateral of the medial wall of the intercondylar notch.

Make a mark in the middle of the defective femur condyle (Fig. 19). This marking will serve as a guide for aligning the femur component during the rest of the surgical procedure.

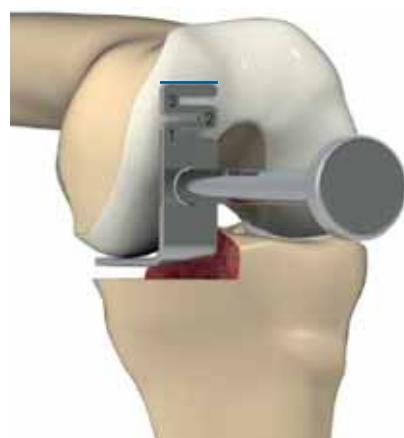


Fig. 17



Fig. 18



Fig. 19

¹⁾42160712: ACS® Uni femoral sizing guide; ²⁾42160715: ic-drill

The alignment of the femoral component is made in a 100° bend. Use the handle¹⁾ to insert the intramedullary alignment rod²⁾ into the medullary cavity (Fig. 20).

 Note: Allow the IM rod to protrude somewhat from the bone at first. This simplifies assembly of the IM adapter in the next step.

Slide the resection guide³⁾ in the corresponding size together with the gray resection joint space gauge⁴⁾ into the joint space (Fig. 21). Start with the gray joint space gauge that has "8" engraved on the running surface. Choose the height of the gray resection joint space gauge such that it lies flat on the tibial resection, while the femoral resection guide has contact with the distal and posterior bone.

Then connect the IM adapter⁵⁾ with the IM rod²⁾ and the femoral resection guide³⁾ (Fig. 22). Make sure that the IM adapter is inserted in the medial hole of the femoral resection guide! When connecting the three instruments, insert the IM rod into the medullary cavity until the stop is reached.

Align the femoral resection guide with the femur condyle. Make sure that the joint space gauge does not contact the sagittal edge and that the resection guide rests correctly against the joint space gauge.

 Note: The marking previously made on the condyle can now be used as an additional orienting mark when aligning. It should be visible through the two drill holes on the resection guide.

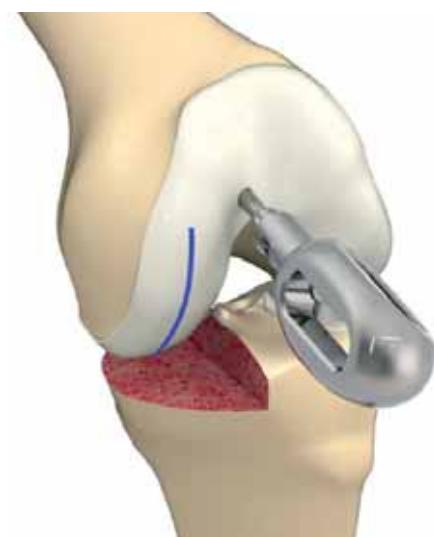


Fig. 20

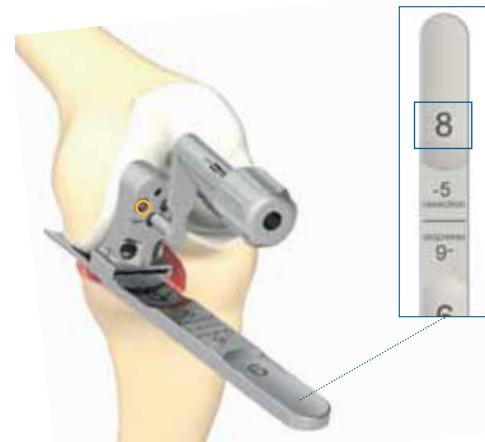


Fig. 21

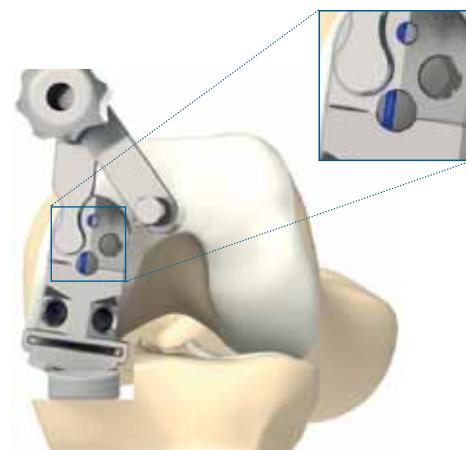


Fig. 22

¹⁾42160714: ACS® Uni handle for intramedullary alignment rod; ²⁾42160713: ACS® Uni intramedullary alignment rod; ³⁾42161704: ACS® Uni femoral resection guide anatomic; ⁴⁾42160383: Uni FB joint gap check resection; ⁵⁾42161709: ACS® Uni IM adapter

First fix the femoral resection guide with the 6-mm drill¹⁾ through the larger (lower) of the two drill holes (Fig. 23). Insert the drill into the bone until it reaches the stop. After that, the drill remains in the bone.

Then insert the longer 3-mm ic drill²⁾ into the smaller (upper) drill hole (Fig. 24). Leave the drills in the bone to fix the instrumentation and for stability during the resection. The handle can be removed if necessary (size 3 and 4).

 Note: The drills can be tensioned in the machine with the ic adapter³⁾. This allows for a quick release if the drills need to be left in the bone.

Remove the joint space gauge. The IM adapter can also be removed if needed. The IM rod initially remains in the bone. Resect the posterior condyle with the help of the slot (Fig. 25).

 Note: It is recommended to use the narrow ic saw blade of width 13 mm and thickness 1.37 mm.

Then remove all instruments.



Fig. 23



Fig. 24



Fig. 25

¹⁾42160625: ic-drill; ²⁾42160226: ic-drill; ³⁾42230022: ic-adapter

Option 2: Extramedullary alignment

 Note: Use the femoral cutting blocks with **REF 4216-0701, -0702, -0703, -0704** for preparation with extramedullary alignment!

Flex the knee joint to 90–100°.

Make a mark in the middle of the defective femur condyle (Fig. 26). This marking will serve as a guide for aligning the femur component during the rest of the surgical procedure.

For stabilization, first insert the gray joint space gauge¹⁾ with the side marked with an "8" into the bending space. Using the handle²⁾, set the femoral resection guide³⁾ of the size found earlier between the joint space gauge and the femoral condyle and push it into the joint space until the resection guide contacts the distal condyle (Fig. 27).

If an excessively tight joint space makes it impossible to insert the tibial resection guide, another resection must be made to the tibia. For this, use the tibial alignment guide again together with the tibial resection guide.

On the other hand, if the joint space is so large that the femoral resection guide has too much play when inserted, use a joint space gauge of a larger height.

Use the extramedullary femoral alignment guide⁴⁾ and insert it onto the femoral resection guide in the marked holes (Fig. 28) according to the side being operated on ("RL/LM" or "LL/RM"). Guide the external alignment rod⁵⁾ through the femoral alignment guide and set the correct valgus angle.

Note the following points for the alignment:

- The femur resection guide has both distal as well as posterior contact to the femur.
- The central holes on the femur resection guide should be as centered as possible on the femur condyle (blue mark).
- The extramedullary alignment rod points to the femur head.



Fig. 26



Fig. 27

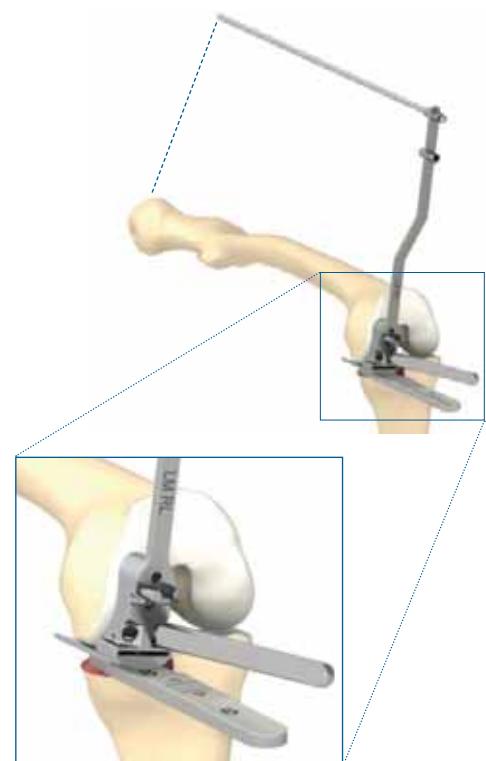


Fig. 28

¹⁾42160383: Uni FB joint gap check resection; ²⁾42160710: ACS® Uni handle for femoral resection guide; ³⁾42160704: ACS® Uni femoral resection guide; ⁴⁾42160711: ACS® Uni femoral alignment guide extramedullary; ⁵⁾42230035: external alignment rod

First fix the femoral resection guide with the 6-mm drill¹⁾ through the larger of the two drill holes (Fig. 29). Insert the drill into the bone until it reaches the stop. After that, the drill remains in the bone.

Then insert the longer 3-mm ic drill²⁾ (Fig. 30). Leave the drills in the bone to fix the instrumentation and for stability during the resection. The handle can be removed if necessary (size 3 and 4).

 Note: The drills can be tensioned in the machine with the ic adapter³⁾. This allows for a quick release if the drills need to be left in the bone.

After fixating the femoral resection guide, the joint space gauge can be removed and the posterior femur condyle resected (Fig. 31). Perform the resection through the slot guide on the resection guide.

 Note: It is recommended to use the narrow saw blade of width 13 mm and thickness 1.37 mm.

Then remove the femoral resection guide, the alignment guide and both drills.

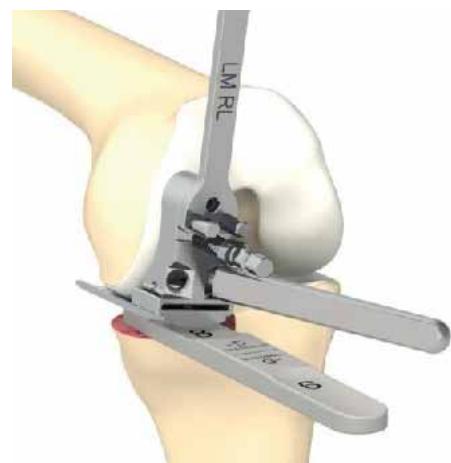


Fig. 29



Fig. 30



Fig. 31

¹⁾42160625: ic-drill; ²⁾42160226: ic-drill; ³⁾42230022: ic-adapter

Femur preparation, continued

Place the femoral reamer guide of size 0¹⁾ with the thicker peg into the prepared (lower) peg hole (see Fig. 32). Make sure that the femur reamer guide penetrates the bone until the stop is reached.

! Attention: Do not insert the femoral reamer guide into the anterior hole!

Start with the reamer of the correct size²⁾ (same size as femur) to ablate bone material (Fig. 33). Cut cautiously until the reamer reaches the stop. Enough cartilage and bone should be removed such that subchondral bone is exposed.

≡ Note: Make sure that the reamer is rotating before it makes contact with bone. In addition, the reamer should not be tilted or leave the specified reaming surface.

Remove the femur reamer guide using the pin extractor³⁾. Leave the bone residue built up under the femur reamer guide. It will serve as a reference for later follow-up reaming.

Place the correctly sized trial femur component⁴⁾ on the bone (Fig. 34).

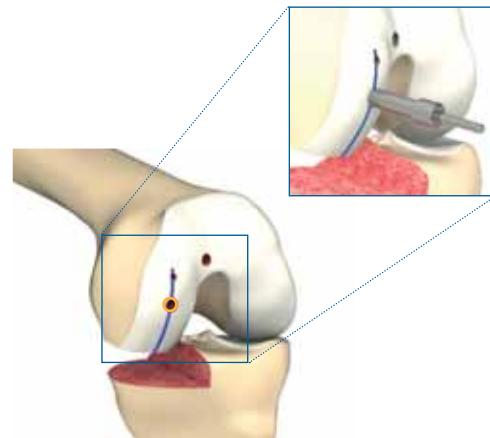


Fig. 32

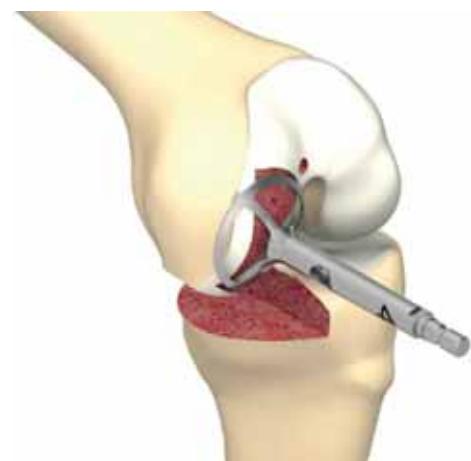


Fig. 33

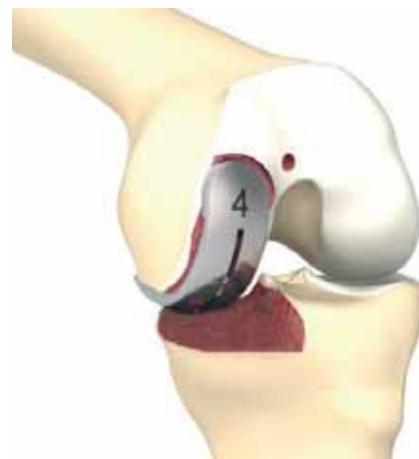


Fig. 34

¹⁾42160340: ACS® Uni SG femoral reaming guide; ²⁾42160334: ACS® Uni SG femoral reamer; ³⁾75120800: pin extractor; ⁴⁾42160354: ACS® Uni SG trial femoral component

Place the white joint space gauge¹⁾ of the desired height in the joint space (Fig. 35). Check whether the selected height produces sufficient stability in bending. If not, use a thicker joint space gauge.

Make a note of the thickness of the joint space gauge that produces stability in the bending space.

Remove the white joint space gauge and bring the knee into extension. Insert the gray resection joint space gauge²⁾ into the extension space (Fig. 36). If the most recently used white joint space gauge was engraved with "8", then start with the gray resection joint space gauge that also has "8" engraved on the running surface.

Make a note of the joint space gauge that produced stability in the extension space.

The difference between the bending space (white joint space gauge) and the extension space (gray resection joint space gauge) indicates how much more femoral reaming is necessary.

Example: If there is a bending space of "8" and an extension space of "-5 resection", then use the "3" reamer guide to make the follow-up cut (Fig. 37).

8 (joint space gauge) - 5 (resection joint space gauge) = 3

Remove the trial femur component (Fig. 38). There is a special extractor available.



Fig. 35



Fig. 36

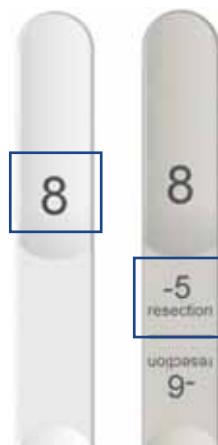


Fig. 37

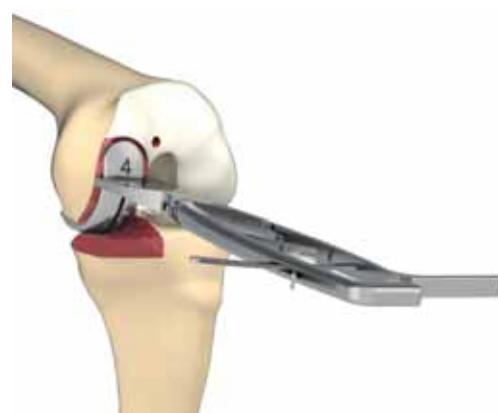


Fig. 38

¹42160380: Uni FB joint gap check; ²42160383: Uni FB joint gap check resection

Insert the reamer guide¹⁾ of the size calculated previously into the bone (Fig. 39). Again, make sure that the femur reamer guide penetrates the bone until the stop is reached.

 Note: Make sure that the protruding bone around the reamer guide is intact, as this will be the reference height for the reaming process.

Repeat the reaming process (Fig. 40) with the femur reamer²⁾ of the correct size (same size as the femur). Gently press down on the reamer until it reaches the stop.

 Note: Always make sure that the reamer is rotating before it makes contact with bone. In addition, the reamer should not be tilted or leave the specified reaming surface.

Remove the reamer guide with the pin extractor³⁾ and clean the prepared surface (Fig. 41):

- Remove the posterior protruding bone (A)
- Remove the protruding bone around the peg hole (B)

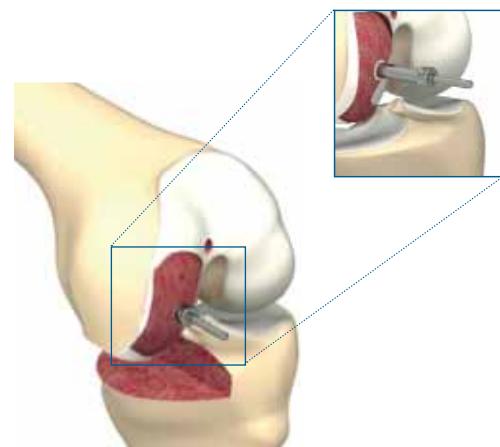


Fig. 39

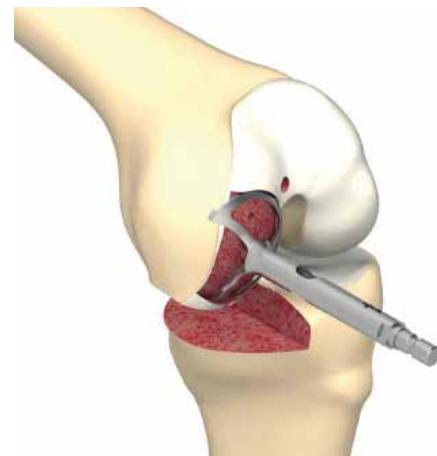


Fig. 40

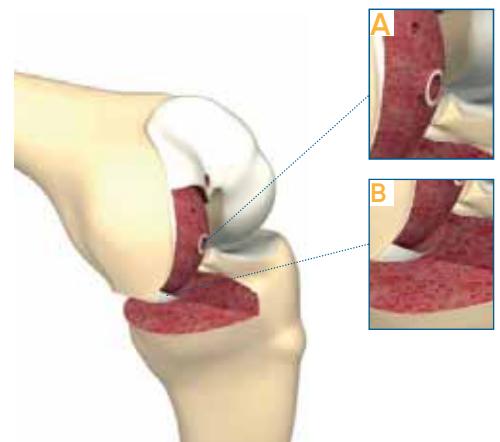


Fig. 41

¹42160342: ACS® Uni SG femoral reaming guide; ²42160334: ACS® Uni SG femoral reamer; ³75120800: pin extractor

Trial reduction

Use the Uni FB trial tibia component¹⁾ to measure the size of the tibial implant (Fig. 42). The tibia base plate should have full cortical support without protruding over the edge.

Place the PE trial insert²⁾ in the trial tibia component and then place the femur trial component³⁾ on the bone once again. Perform the trial reduction (Fig. 43).

The trial tibia component does not yet need to be fixed at this point in time.

If the knee joint is too unstable through its range of motion, place a higher PE trial insert into the trial tibia component. The PE trial inserts are available in the heights 8, 9, 10, 11, 12 and 14 mm.

Then affix the trial tibia component to the bone. For this, use two small fixation pins⁴⁾ that are inserted through the two anterior holes (Fig. 44). After fixation, check the seating of the trial component.

 Note: It is recommended to first pre-drill the pin holes with a drill pin. Due to the position of the pin holes, posterior lifting of the trial tibia component may occur.



Fig. 42

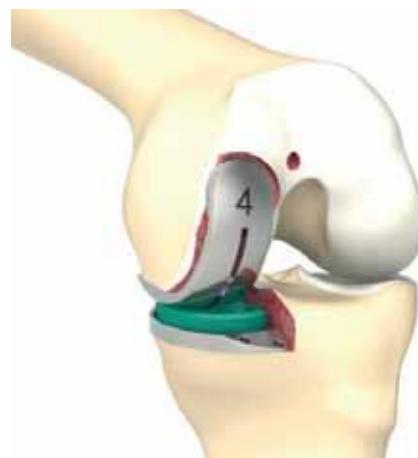


Fig. 43

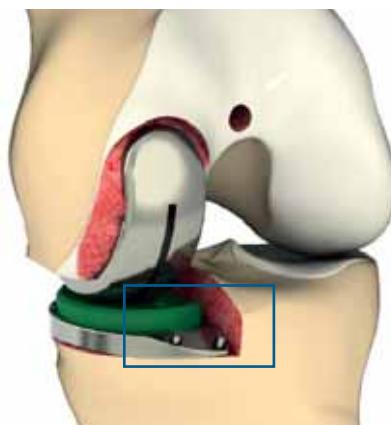


Fig. 44

¹⁾40120023: Uni FB tibial trial component; ²⁾40120308: Uni FB tibial trial insert; ³⁾42160354: ACS® Uni SG trial femoral component; ⁴⁾42160519: fixation pin with stop

Tibial end preparation

Remove the trialfemur component (Fig. 45).

Use the Uni FB fin chisel¹⁾ to prepare the tibial fin (Fig. 46). Exercise extreme caution during preparation in order to minimize the risk of a tibial fracture.

Prepare the tibial pegs using the peg drill²⁾ (Fig. 47).

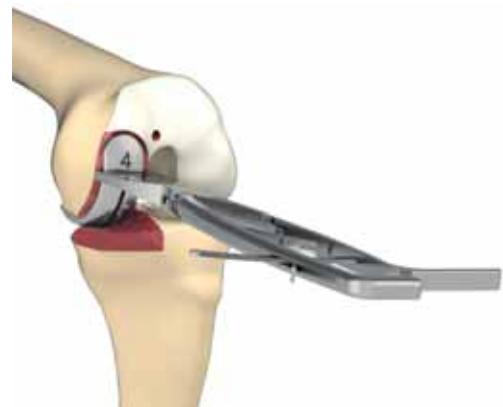


Fig. 45



Fig. 46



Fig. 47

¹⁾42160361: Uni FB fin chisel; ²⁾42160362: Uni FB peg drill

Femoral end preparation

Place the trial femur component on the bone again. The trial tibia component can be removed.

The femoral fin is prepared through the slot in the trial femur component (Fig. 48). Connect the fin punch¹⁾ of the correct size with the handle²⁾. Tap the fin punch in until it reaches a stop.

Then remove the femoral trial component.

If desired, the Ø 6 mm peg hole can be further compacted with the help of the punch³⁾ (Fig. 49).

Prepare small holes in the femur with the 2.5-mm drill⁴⁾ (Fig. 50). These will later take up cement during the implant process and thus increase the stability of the implant.

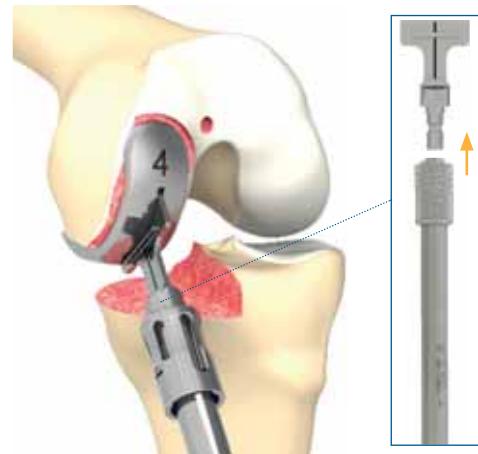


Fig. 48



Fig. 49

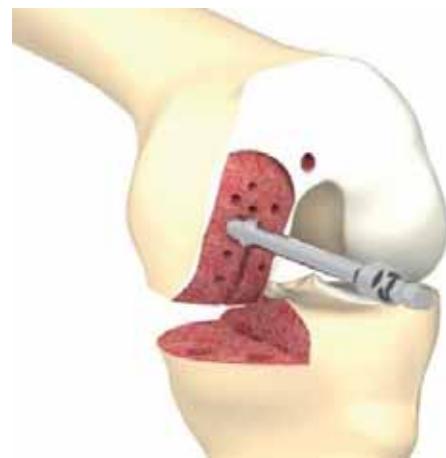


Fig. 50

¹⁾42160527: ACS® Uni femoral fin punch; ²⁾42210047: handle for tibial trial cone with fins; ³⁾42160505: ACS® Uni punch for femoral stem; ⁴⁾42240135: drill with stop

Implantation

Begin implanting the tibia component. For this, use the ic impactor¹⁾ and the tibia impactor adapter²⁾ (Fig. 51). Connect the two instruments by placing the impactor plate on the impactor and rotating it by 90°.

Now use the ic impactor with the PE impactor adapter³⁾. Tap the PE insert of the size and height determined previously into the tibia (Fig. 52). Check the correct seating of the PE in the tibia.

Then implant the femur component using the femur impactor⁴⁾ (Fig. 53).

 Note: In doing so, make sure that only a small amount of cement is applied in the posterior region of the femur component, since it will no longer be possible to dorsally remove excess bone cement afterwards.

 Note: The components must be immobilized while the cement hardens.



Fig. 51

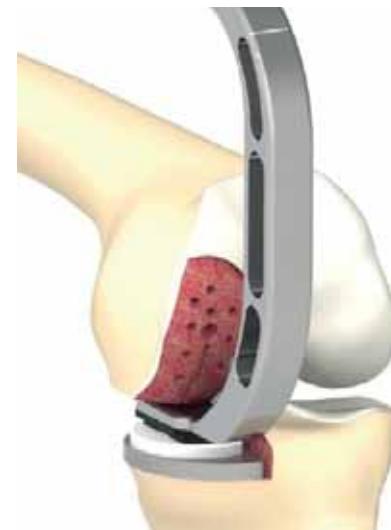


Fig. 52

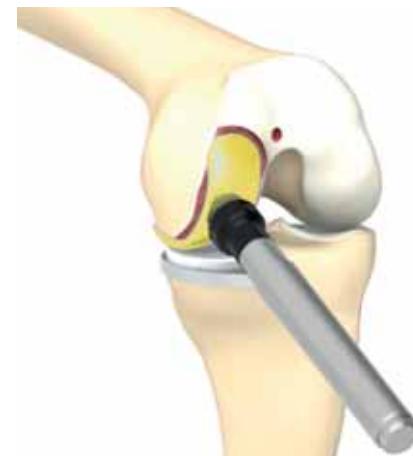


Fig. 53

¹⁾42160522: ic-impactor; ²⁾40110034: PB Uni tibial impaction adapter; ³⁾40110035: PB Uni PE impaction adapter; ⁴⁾42160506: ACS® Uni femoral impactor

This completes the implantation (Fig. 54 and Fig. 55).

It is recommended to check the positioning of the implants with an X-ray image.



Fig. 54



Fig. 55

Implants

ACS® UNI femoral component cemented

Material: *implavit®*; CoCrMo acc. to ISO 5832-4

Coating: *TiN-coating*

article number	size
42060001	1
42060002	2
42060003	3
42060004	4



ACS® UNI femoral component cementless

Material: *implavit®*; CoCrMo acc. to ISO 5832-4

Coating: *TiN-coating / implaFix®; cpti-coating*

article number	size
42061001	1
42061002	2
42061003	3
42061004	4



Uni FB tibial component

Material: *implatan®*; TiAl₆V₄ acc. to ISO 5832-3

article number	size	side
40100010*	0	ll/rm
40100011	1	ll/rm
40100012	2	ll/rm
40100013	3	ll/rm
40100014	4	ll/rm
40100016*	2S	ll/rm
40100017*	3S	ll/rm
40100020*	0	lm/rl
40100021	1	lm/rl
40100022	2	lm/rl
40100023	3	lm/rl
40100024	4	lm/rl
40100026*	2S	lm/rl
40100027*	3S	lm/rl



* Not included in loan set and have to be ordered separately.

Uni FB PE insert implacross® EMaterial: *implacross® E*; crosslinked UHMW-PE with Vitamin E

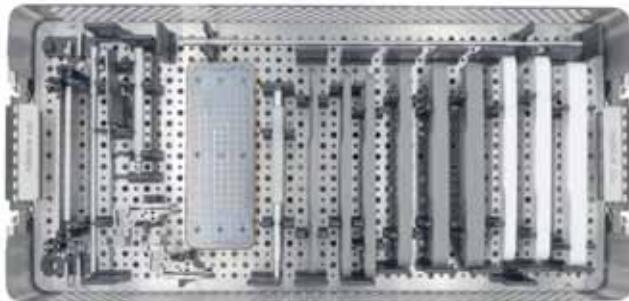
article number	size	height
40101108	1	8 mm
40101109	1	9 mm
40101110	1	10 mm
40101111	1	11 mm
40101112	1	12 mm
40101114	1	14 mm
40101208	2	8 mm
40101209	2	9 mm
40101210	2	10 mm
40101211	2	11 mm
40101212	2	12 mm
40101214	2	14 mm
40101308	3	8 mm
40101309	3	9 mm
40101310	3	10 mm
40101311	3	11 mm
40101312	3	12 mm
40101314	3	14 mm
40101408	4	8 mm
40101409	4	9 mm
40101410	4	10 mm
40101411	4	11 mm
40101412	4	12 mm
40101414	4	14 mm
40102008	0	8 mm
40102009	0	9 mm
40102010	0	10 mm
40102011	0	11 mm
40102012	0	12 mm
40102014	0	14 mm



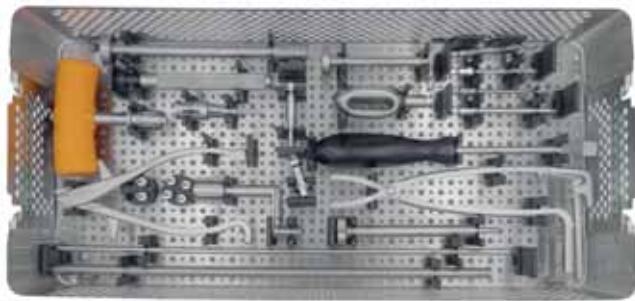
Container

ACS® Uni FB femoral basic container

42160692



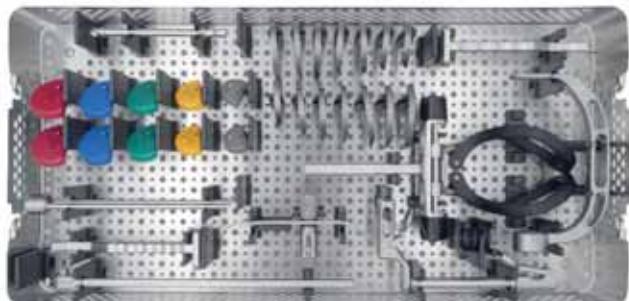
upper tray



lower tray

ACS® Uni FB tibial container

42160691



ACS® Uni FB trial PE container

42160695



ACS® Uni FB femoral sz. 1+2 container

42160693



ACS® Uni FB femoral sz. 3+4 container

42160694



ACS® Uni femur additional container

42160685



Attention: Instruments are delivered non-sterile. The relevant information on processing must be observed.

Instruments

ACS® Uni FB femoral basic container

42160692

drilling pin

article number	length	diameter	quantity
77000121	77 mm	2.5 mm	4
77000122	97 mm	2.5 mm	2

fixation pin with stop

article number	length	diameter	quantity
42160519	45 mm	2.5 mm	2

Uni FB joint gap check

article number	height
42160380	8/9 mm
42160381	10/11 mm
42160382	12/14 mm

Uni FB joint gap check resection

article number	height
42160383	-3/-4 mm
42160384	-5/-6 mm
42160385	-7/-8 mm
42160386	-9/-10 mm
42160387	-11/-12 mm
42160388	-13/-14 mm

tibial cutting block

article number	side
42160370	rl/rm
42160371	ll/rm

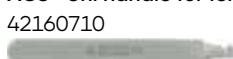


ACS® Uni femoral template

article number	size
42160606	1/2
42160607	3/4



ACS® Uni handle for femoral resection guide



resection check

42230009



Pin inserter

article number	diameter
77000108	2.5 mm



ACS® Uni intramedullary alignment rod

article number	length	diameter
42160713	300 mm	5 mm
42161708	150 mm	5 mm

ic-T-handle Zimmer-Jakobs

42230023



ACS® Uni femoral impactor

42160506



ACS® Uni femoral trial extractor

42160520



Chisel angled

42160605



ACS® Uni femoral sizing guide

42160712



ACS® Uni handle for intramedullary alignment rod

42160714



ACS® Uni IM adapter

42161709



ic-pin-adapter

42200421



handle for tibial trial cone with fins

42210047



ic-adapter

42230022



external alignment rod

article number	length	diameter
42230035	400 mm	6 mm

drill with stop
article number 42240135 diameter 2.5 mm

pin extractor
75120800

Uni FB adapter for tibial resection
42160372



ACS® Uni punch for femoral stem
42160505



ic-drill
article number 42160226 diameter 3 mm
42160625 6 mm
42160715 5 mm



ACS® Uni SG femoral reaming guide
article number length
42160340 0 mm
42160341 1 mm
42160342 2 mm
42160343 3 mm
42160344 4 mm
42160345 5 mm



ACS® Uni FB tibial container
42160691

handle for trial component
40110029



PB Uni tibial impaction adapter
40110034



PB Uni PE impaction adapter
40110035



Uni FB tibial trial component

article number	size	side
40120010	0	ll/rm
40120011	1	ll/rm
40120012	2	ll/rm
40120013	3	ll/rm
40120014	4	ll/rm
40120015	2s	ll/rm
40120016	3s	ll/rm
40120020	0	rl/lm
40120021	1	rl/lm
40120022	2	rl/lm
40120023	3	rl/lm
40120024	4	rl/lm
40120025	2s	rl/lm
40120026	3s	rl/lm



Uni FB tibial trial insert

article number	size	height
40120108	1	8 mm
40120109	1	9 mm
40120208	2	8 mm
40120209	2	9 mm
40120308	3	8 mm
40120309	3	9 mm
40120408	4	8 mm
40120409	4	9 mm
40120908	0	8 mm
40120909	0	9 mm



Uni FB fin chisel

article number	side
42160360	right
42160361	left



Uni FB peg drill



ic-impactor

42160522



tibial stylus 0-10

42200402



ankle clamp

42200930



ACS® tibial alignment rod

article number	angle
42210185	5°



**ACS® Uni FB trial PE container**

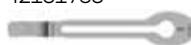
42160695

Uni FB tibial trial insert

article number	size	height
40120110	1	10 mm
40120111	1	11 mm
40120112	1	12 mm
40120114	1	14 mm
40120210	2	10 mm
40120211	2	11 mm
40120212	2	12 mm
40120214	2	14 mm
40120310	3	10 mm
40120311	3	11 mm
40120312	3	12 mm
40120314	3	14 mm
40120410	4	10 mm
40120411	4	11 mm
40120412	4	12 mm
40120414	4	14 mm
40120910	0	10 mm
40120911	0	11 mm
40120912	0	12 mm
40120914	0	14 mm

**ACS® Uni joint gap feeler**

article number	size	height
42161751	1	1 mm
42161752	1	2 mm
42161753	1	3 mm
42161754	2	1 mm
42161755	2	2 mm
42161756	2	3 mm

**ACS® Uni FB femoral sz. 1+2 container**

42160693

ACS® Uni SG femoral reamer

article number	size
42160331	1
42160332	2

**ACS® Uni SG trial femoral component**

article number	size
42160351	1
42160352	2

**ACS® Uni femoral fin punch**

article number	size
42160524	1
42160525	2

**ACS® Uni femoral resection guide anatomic**

article number	size
42161701	1
42161702	2

**ACS® Uni femoral fin punch**

article number	size
42160526	3
42160527	4

**ACS® Uni femoral resection guide anatomic**

article number	size
42161703	3
42161704	4

**ACS® Uni joint gap feeler**

article number	size	height
42161757	3	1 mm
42161758	3	2 mm
42161759	3	3 mm
42161760	4	1 mm
42161761	4	2 mm
42161762	4	3 mm





ACS® Uni femur additional container

42160685

ACS® Uni femoral resection guide

article number	size
42160701	1
42160702	2
42160703	3
42160704	4



ACS® Uni femoral alignment guide extramedullary

42160711



Instructions for use

Intended Purpose and Product Description

The ACS® UNI Knee System is a unicompartmental knee system. It is intended to replace the bearing surface of only one femoral condyle and the corresponding tibial condyle of the knee during primary or revision-related knee replacement surgery.

The ACS® UNI femoral component is a femoral component for cemented or non-cemented anchorage; it is intended for use in resurfacing a femoral condyle.

The Uni FB tibial component is a fixed-bearing tibial component for cemented anchorage; it is intended for use in resurfacing a tibial condyle.

The Uni FB PE-insert is a tibial fixed-bearing insert intended for articulation with a femoral component.

Pre-Operative Instructions

A pre-operative planning is mandatory for optimal results. Before surgery, a surgical planning with regard to the dimensions of the prosthetic model and the positioning of the implant components in the bone has to be carried out by the surgeon.

For this purpose, x-ray templates of the implants are available:

Digital templates: Digital templates are included in the databases of the common planning systems. For missing templates, please contact the provider of the planning software and request these templates.

Radiographic templates: Alternatively, radiographic templates are available in various scale factors, which can be obtained from your local representative.

The surgeon must ensure that:

- all needed components are available. A sufficiently large range of implant sizes should be available for each operation. It must be determined whether the implantation should be done cemented or cementless.
- all instruments necessary will be present for surgery and that they match the implants being used. Only instruments designed for use with the implant system by implantcast GmbH may be used. An exception are exclusively the standardized instruments used during surgery.
- the correct sized instruments are used during surgery to prevent damage to the implants.

Operative Instructions

Before use, the implant must be checked to ensure that the product reference number, lot number and size correspond with the data on the labelling (REF, LOT and size).

Use appropriate aseptic technique when removing the implant from the packaging. The user is taking full responsibility for this. Implants should be implanted immediately after removal from the original packaging.

The surfaces of the implants are extremely sensitive. Implants must not come into contact with objects that could damage the surfaces. Before implantation, the implant must be visually inspected by the user for possible damage. Damaged implants must not be used.

The implant must not be modified in any way! Modifications to the implant may lead to impairment of its function and early failure of the prosthesis. In case of changes or manipulation, the regulatory responsibility is transferred to the person changing or manipulating the components and the manufacturer is no longer liable for the product.

When bone cement is used, the instruction for use of the respective cement manufacturer should be followed.

Bone cement must not come or remain in contact with the articulating surfaces of the implant during or after the surgery. Bone cement residues that could dislodge over time and get between the articulation surfaces must be removed. Bone cement fragments and residues may lead to increased wear and damage of the implant

components.

In cementless applications, a firm fixation of the implant at the time of surgery is essential for the success of the implantation. The cementless components are seated in the bone by pressfit which requires to perform precise surgery and the use of the instruments provided for this purpose.

Prior to wound closure, the surgical area including the articulation surfaces of the implant must be thoroughly cleaned to remove any foreign bodies such as bone splinters, bone cement residues and any remaining fragments of a previously revised component or instrument.

It is also recommended to take an intraoperative X-ray image and examine it for remaining particles and remove them before wound closure.

Post-Operative Instructions

Post-operative patient care, patient instructions and warnings from the attending surgeon are of the utmost importance.

The use of an external support of the operated extremity to promote healing is recommended for a limited period.

Active and passive movements of the operated extremity should be monitored.

The post-operative regime should be aimed at the prevention of overloading of the operated extremity and stimulation of the healing process.

Regular monitoring of the position and condition of the prosthetic components and the surrounding bone is recommended.

Indications and target group

The decision for joint replacement should be based on careful evaluation. The indication for this type of surgery should only be made when all other conservative or surgical alternatives are less promising than artificial joint replacement.

Risk of postoperative complications can be limited by careful evaluation of the individual anatomical and load conditions, the condition of the soft tissues, and the condition of the bone bed for the implants.

Treatment with the ACS® Uni Knee System is generally only indicated for patients with mature skeletons.

The necessary preoperative examinations should be performed by the attending medical doctor before intervention. The examinations depend on the patient's medical history.

In consideration of these principles, the following indications apply for the ACS® Uni Knee System:

- unicompartmental joint failure with considerable functional impairment when other therapeutic measures have no greater promise of success,
- postoperative conditions following prior surgeries with or without use of implants,
- non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis,
- post-traumatic osteoarthritis,
- treatment of fractures that cannot be treated using other surgical techniques, and
- rheumatoid arthritis.

ATTENTION: It is also imperative that:

- the ligamentous apparatus is intact (lig. CA and CP as well as collateral ligaments),
- the joint cartilage and the meniscal cartilage of the opposing compartment are intact, and
- no major dislocations or flexion contractures are present.

the target group is patients that meet the indications given in these instructions for use and for whom the insert of the ACS® Uni Knee System is a suitable therapy option. The attending doctor will decide whether the product is suitable for the individual patient, and which

implant is to be used. This decision depends on several factors, such as the patient's age and weight, bone quality, shape of the bone and deformation of the joint.

Contraindications

The durability of an implant can be limited by biological, material, and biomechanical factors. Therefore, a careful examination of the indications is recommended in overweight patients, in patients with very high joint loads due to high physical activity, and in patients who are younger than 60 years of age.

The ACS® Uni Knee System is contraindicated in the following cases:

- allergy to one of the implant materials (The label on the secondary packaging of the respective component indicated the materials used. It is strongly recommended that an allergy test be performed.),
- current infections,
- physiological or anatomical conditions which preclude or are not expected to maintain an adequate bony support of the implant, or which do not allow the implantation of a sufficiently large prosthesis,
- bone tumors in the implant anchorage area,
- untreated vascular diseases of the affected extremity,
- metabolic disorders that may impair bone formation. In case of insufficient quantity and quality of bone stock, an alternative prosthetic treatment allowing for sufficient bony anchorage should be considered.
- severe axis deviation, and
- ligament instability.

Risk factors

The following risk factors can interfere with the success of the ACS® Uni Knee System:

- excessive strain on the joint due to strenuous manual labor and/ or unsuitable physical activities,
- severe deformities that interfere with the anchorage or with the exact positioning or function of the implant,
- therapies that degrade bone quality,
- muscular insufficiency,
- neuromuscular diseases in the affected extremity,
- conditions which interfere with the patient's ability or willingness to follow the physician's instructions, especially during the healing phase,
- obesity,
- nicotine and/or drug abuse,
- alcoholism,
- prior surgeries on the affected extremity,
- diabetes, and
- psoriasis.

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