OrthoPilot[®]

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Aesculap Orthopaedics



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The OrthoPilot System assists in the precise implantation of knee and hip prostheses.¹ Integration in the surgical workflow as well as minimal prolongation of operation time were essential criteria in the development of the OrthoPilot system.² At the same time, we focused on a navigation system that is non-traumatic for the patient. From the beginning, a method was developed that eliminates use of CTs and MRIs and the X-ray exposure or the expenses that these entail and extends surgery time as minimally as possible.

Indications for Use:

The OrthoPilot Next Generation Navigation Platform is a system for computer-aided navigation of surgical instruments. Its purpose is to position endoprosthesis in arthroplasty in the patient. It aids the surgeon in accurately positioning the cutting guides, drills and reamers for total endoprosthesis replacement surgery and provides intraoperative measurements of bone alignment. It indicates angles and positions for implant placement.

For more information about indications and contraindications, please refer to the Instructions for Use posted on www.aesculapimplantsystems.com.

- CT Scan not required
- Ergonomic instruments precisely aligned to the surgery
- User-friendly navigational flow integrates itself easily into the operation
- Intraoperative documentation with OrthoPilot
- Numerous studies confirm better alignment using navigation^{3,4,5,6}
- Routinely used in over 600 hospitals
- Over 300 OrthoPilot publications worldwide^{7,8}

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Table of Contents

1.	Instrument Overview6
2.	Preoperative Planning Using Radiographic Images9
3.	Preparation of the Patient10
4.	OrthoPilot Setup and Transmitter Position
	4.1 OrthoPilot Positioning 11
	4.2 Femoral Transmitter
	4.3 Tibial Transmitter12
	4.4 Camera Adjustment13
5.	Entering Patient-Related Information14
6.	Palpation of the Femoral Reference Points15
	6.1 Recording the Knee Center15
	6.2 Recording the Posterior Medial Condyle15
7.	Palpation of the Tibial Reference Points16
	7.1 Determination of Tibia Center16
	7.2 Reference for the Cutting Height Indicator16
8.	Ankle Joint Palpations17
	8.1 Medial and Lateral Malleolus17
	8.2 Anterior Ankle Joint Point17
9.	Registration of the Hip Joint Center18
10.	Registration of the Knee Joint Center19
11.	Compression in Flexion, Representation of Mechanical Leg Axis
	11.1 Compression in Flexion20
	11.2 Representation of the Mechanical Leg Axis
12.	Resection of the Tibia Plateau and Reassessing the Tibial Resection
	12.1 Resection of the Tibia Plateau21
	12.2 Reassessing the Tibial Resection
13.	Condyle Recording23
14.	Measuring the Joint Gap in Flexion and Extension24
	14.1 Measuring of the Joint Gap in Flexion24
	14.2 Measuring the Joint Gap in Extension24
15.	Femoral Planning25

16.	Distal Femur Resection, Control and Rotational Orientation26
	16.1 Distal Femur Resection26
	16.2 Reassessing the Distal Resection27
	16.3 Positioning of the 2-in-1 Saw Guide28
17.	Mechanical Axis
18.	Workflow Options
	18.1 Tibia First with Soft Tissue Management
	18.2 Tibia Cut Only
	18.3 Tibia Cut Only with Loadline30
19.	Software and Consumeables
	19.1 Software OrthoPilot UKA
	19.2 Consumeable Passive Marker Spheres
20.	Instrument Set Overview OrthoPilot® UKA
21.	Schematic Program Flow UKA 3.0
	21.1 Schematic Program Flow Tibia First with Soft Tissue Management34
	21.2 Schematic Program Flow Tibia Cut Only35
	21.3 Schematic Program Flow Tibia Cut Only with Loadline

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Tibial Sawing Guides		Tibia Cut Control Plate univation® X	univation Spreader with Spreading Forceps	
100 AD		A.B.		
Left-medial	NM584R	Tibia cut control plate NP893R	univation spreader	NP894R
Right-medial	NM585R		Spreading forceps	NP609R
2-in-1 Saw Guides, Left and Right Medial (RM)	Medial (LM)	univation X Spacer, Navigated	Passive Transmitters	+
2-in-1 saw guide F1 LM	NM006R	univation X spacer, navigated NM473R	Yellow	FS633
2-in-1 saw guide F2, F3, F	4 NM008R		Blue	FS634
LM			Red	FS635
2-in-1 saw guide F1 RM	NM007R			
2-in-1 saw guide F2, F3, F	4 NM009R			

RM

2-in-1 saw guide F5 RM

2-in-1 saw guide F5 LM

NM011R

NM010R

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1. Instrument Ov	verview (contin	ued)		
Distal Saw Guide				
Distal saw guide	NM540R			

2. Preoperative Planning Using Radiographic Images



Preoperative X-Ray Planning

With the aid of the univation X-ray templates, the size of the femoral component and the anatomical tibial slope on the X-Ray is defined preoperatively. Therefore, quality X-rays are needed. Observe all notes in the respective surgical technique, brochure, instruction for use and package inserts.

In addition, the mechanical medial proximal tibia angle (mMPTA) must be measured with maximum precision from the X-ray. Ideally, a whole leg image in standing position should be used. This data must be entered into the OrthoPilot system in the surgical data screen.

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Positioning and sterile draping of the patient is carried out according to the standard procedures which are also applied in the conventional technique. Aesculap recommends using a leg holder, which facilitates leg control during the various phases of the surgery.

In order to record the register points and carry out all the necessary bone cuts, it is necessary to change the leg position several times. The leg holder enables the knee position to be changed between full extension and full flexion.

TIP

To facilitate mobilization of the quadriceps, bring the knee to 100° flexion prior to activating the tourniquet. If a pad is used, make sure that it does not hinder full circulation of the hip joint which is required for registering the femoral head center.

4. OrthoPilot Setup and Transmitter Position



4.1 OrthoPilot Positioning

When positioning the OrthoPilot, ensure that the physician has an unobstructed view of the screen at all times. Unit or camera can be positioned either on the opposite side of the leg to be operated on (contralateral) or on the same side (ipsilateral). In many cases, it has proven beneficial to position the camera at shoulder height on the opposite side of the patient and align at approx. 45° to the operating field.

TIP

Aim the laser pointer inside the handle of the camera at the knee joint to be operated on while the leg is in approximately 90° flexion. The camera alignment can be adjusted at any stage of the operation except during determination of the hip center.



4.2 Femoral Transmitter

In general: the transmitter should be positioned so that it is visible to the camera during the entire surgery. The femur transmitter must be fixed on the femur with the aid of 4.5 mm cortical screws and the rigid body (RB) (NP619R) at about 10 cm proximal to the joint line. The bicortical screw is pre-drilled by using a 3.2 mm drill (NP615R) through the drill sleeve (NP616R). Then, the length of the necessary bicortical screw is determined with the help of the measuring instrument (NP281R) by hooking on the opposite cortical and reading on the dial. The rigid body (NP619R) is pushed forward – optionally through the tissue protection sleeve (NQ941R) - and brought into contact with the bone. Then, one of the bicortical screws (NP620R -NP625R) is introduced first mechanically, but the last turns are performed with the help of a manual screwdriver. The transmitter adapter should point to the femoral head of the hip, inclined towards the camera. It is recommended to test the secure fit.

Note: The tip of the pointer with a length of about 10 cm can serve as a guide for the distance to the joint.

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4. OrthoPilot Setup and Transmitter Position (continued)



4.3 Tibial Transmitter

Through a separate, approximately 1 cm long incision, about 10 cm distal to the joint line, a RB (NP619R) is fixed to the tibia after preparation of the soft tissue and predrilling with the 3.2 mm drill (NP615R) through the drill sleeve (NP616R) and after determining the length of the bicortical screw with the measuring instrument (NP281R). The last turns of the screw are performed with a manual screwdriver. Attach the passive transmitter (FS635) marked in red to the femoral rigid body (RB) adapter. Attach the passive transmitter (FS634) marked in blue to the tibial rigid body (RB) adapter. Attach the yellow passive transmitter (FS633) to the respective instruments required at each stage.

4. OrthoPilot Setup and Transmitter Position (continued)



4.4 Camera Adjustment

The field of view of the camera is shown on the screen as a cylindrical volume. The transmitters within the field of view of the camera are displayed in this cylinder capacity as colored balls (corresponding to the color coding), with their respective identification letters:

- Transmitter on the femur: Red ball with identification letter "F"
- Transmitter on the instrument: Yellow ball with identification letter "P"
- Transmitter on the tibia: Blue ball with identification letter "T"

When all three transmitters are at an appropriate distance from the camera, the camera's field of view is bordered in green on the screen. The distance from the camera to the transmitters is given in meters.

TIP

When aligning the camera, take into consideration that the leg is extended, abducted or adducted during the operation. The camera must be set up so that it can register the transmitters in every position. The OR staff can readjust the camera to improve the visibility of the transmitters at any time during surgery, except during the step "Registration of the hip joint center". **Option:** The screen for positioning the camera can be accessed at any time via the user-toolbox-menu in the upper right corner of the screen (default). As an option during the software installation, the camera adjustment screen can be set to always occur after the patient data screens in order to enforce the adjustment.

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Passive

6. Palpation of the Femoral Reference Points



6.1 Recording the Knee Center

An approximate knee center point is palpated with the tip of the pointer distally in the center of the trochlea. Here, the pointer (FS604) is connected with the yellow transmitter (FS633) (passive).

TIP

To facilitate palpation of the point, it is recommend to place the leg in a flexed position. A point can be registered that is in the middle of the trochlea at the border to the notch.



6.2 Recording the Posterior Medial Condyle

The tip of the pointer is placed in the middle of the posterior medial condyle. The point selected is the one lying furthest posterior, (i.e. the one with the greatest distance from the anterior femoral cortex).

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7.1 Determination of Tibia Center

In this step, the center of the anterior edge of the anterior cruciate ligament has been recorded. In the case of degenerative changes, the following point is found:

- In the middle of the medial-lateral diametral line of the tibial head,
- At the transition from the first to the second third of the anterior/posterior diametral line of the tibia head, measured from the anterior edge.



7.2 Reference for the Cutting Height Indicator

In this step, the reference point for the cutting height indicator is recorded. It is recommended to use significant landmarks for palpation, for example, the deepest point of the defect or the surface of the joint. In a later step, the positioning of the tibial saw guide, the cutting height is shown in relation to this palpation.



8. Ankle Joint Palpations



8.1 Medial and Lateral Malleolus

The pointer is placed at the center of the medial malleolus, and the respective point is recorded using the right pedal. The recording on the lateral side is made in the same manner.

8.2 Anterior Ankle Joint Point

For the recording, the pointer is placed at the anterior edge of the distal tibia as close as possible to the ankle joint gap. The following step is displayed: "Anterior ankle". This palpation point should lie on the central tibial axis immediately adjoining the ankle joint center. It should be palpated there (as indicated by the white point). The screen display helps the surgeon to find the anterior ankle point by a percentage display having its origin in the palpation of the medial malleolus. A green "safe zone" is displayed around 49% +/- 5%.

TIP

The second metatarsus/second ray or the extensor hallucis longis tendon can be used as a reference during this step. The percentage indicator serves as a plausibility check. If the anterior point (second ray) lies outside the green security area, it is advisable to repeat the palpation of the malleoli.







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9. Registration of the Hip Joint Center



The start screen for registration of the hip joint center is displayed. Only when the leg is not moving, an upward pointing arrow appears and the data entry can start with the movement of the femur in the 12 o'clock direction.

TIP

The circular movement which is described can be performed in a clockwise or counterclockwise direction.

The femur is moved so that the white circle, like the hands on a clock, is moving over the fields arranged in a large circle. As soon as sufficient measurement data for determining the femoral hip center has been registered, the program automatically moves to the next step.

In the case of a twitchy or too large movement, the messages "Incorrect data" or "Too wide movement" may appear and the movement must be repeated.

TIP

- Ensure the femur transmitter is visible during the entire cycle of the movement.
- Ensure unrestricted freedom of circular movement (no obstruction by holding and fixing equipment.)
- Avoid transmitting force from the femur to the pelvis.
- Avoid any pelvic movement (responsibility of the surgeon; if this cannot be avoided, alternative determination of hip center, achieved via long press of right footswitch, can be performed. This would require an additional RB fixed to the iliac crest.)
- Avoid of a hip flexion angle > 45°.



10. Registration of the Knee Joint Center



In this program step, the movement of the transmitter at the femur is tracked in relation to the transmitter at the tibia, and the center of the knee joint is determined. The message "knee center" is displayed on the screen. By pressing the right pedal, determination of the knee joint center is started. Flexion and extension movements are next carried out with the leg. For this, the leg should be grasped with one hand under the heel.

In order to coordinate the actual movement with the display on the screen, it is recommended to start the movement with the knee in approximately 90° flexed position. Rotation of the tibia is not mandatory. Nevertheless, rotation at 90° flexion may be carried out to increase accuracy as soon as two arrows are displayed on the screen. Solid arrows indicate that the data was recorded. As soon as sufficient measurement data has been recorded, the software automatically moves on to the next program step. If the maximum range of movement was repeatedly covered (even without inward or outward rotation), the next step can optionally be advanced by the user pressing the right pedal.

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11. Compression in Flexion, Representation of Mechanical Leg Axis



11.1 Compression in Flexion

In this step, be sure to bring the posterior condyles of the femur in contact with the tibial plateau at 90° of flexion using light pressure. This is required to ensure a transformation of the palpated points for a more precise calculation of the mechanical axis.



11.2 Representation of the Mechanical Leg Axis

In the following step, the registered axis location/position is displayed in coronal and in sagittal view. The axis location/ position is displayed dynamically while the relationship between the mechanical tibial axis and the mechanical femoral axis is calculated on a step by step basis. The system thus enables dynamic goniometry of the knee joint, including specification of the current axis deviation or flexion position within the scope of movement.

TIP

This step can be used as a feasibility check of the abnormal axis position in various flexion positions of the leg and also permits preliminary conclusions to be drawn regarding the ligament situation by applying varus and valgus stress.

12. Resection of the Tibia Plateau and Reassessing the Tibial Resection



12.1 Resection of the Tibia Plateau

Depending on which leg is being operated on, attach the tibial cutting block to the corresponding transmitter. The exact resection height in relation to the palpated reference point of the tibia (program step "Reference for the medial cutting height indicator") can be determined on a proximal or distal basis through the movement of the cutting block. The tibial cutting block can be navigated on the basis of the desired varus/valgus and slope value in relation to the mechanical axis. The tibial cutting guide is initially fixed from the anterior side using two headless screw pins. The cutting guide can now still be relocated via the available pin holes in 1 mm steps if this is required.

The block is finally fixed at the desired set resection height, slope and varus/valgus alignment using an additional headed screw pin brought in obliquely. Resection can now be performed.



TIP

In order to avoid contamination of the marker spheres on the transmitters, it is advisable to either remove the transmitters or to cover them appropriately until resection has been completed.

In many cases it is beneficial to first adjust the anterior/ posterior slope and the cutting height and then correct the varus/valgus around the initially placed pin in order to get closer to the desired position.

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12. Resection of the Tibia Plateau and Reassessing the Tibial Resection (continued)



12.2 Reassessing the Tibial Resection

The tibia control plate (NP893R) with attached transmitter serves for reassessing and recording the tibial resection. The actual orientation and position of the resection surface to the mechanical axis with respect to the varus/valgus angle and the tibial slope is displayed on the screen. The data recorded here using the right pedal is used for further calculations, and it is therefore imperative to record this value afresh if resection of the tibia is repeated.

13. Condyle Recording



The distal and posterior condyle is recorded with the help of the orientation block (NP894R) which must be in contact with both the distal as well as the posterior condyle (two-point contact). The alignment in the sagittal plane is displayed on the right half of the screen. The data capture should take place when the block is located in the sagittal plane perpendicular to the mechanical femur axis (i.e. the display on the screen has a slope of about 0°).

TIP

Two-point contact is essential. Based on that calculation and display of, for example the gap values in extension and flexion, is performed.



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14. Measuring the Joint Gap in Flexion and Extension



14.1 Measuring of the Joint Gap in Flexion

The measurement of the joint gap is usually performed with the spacers (available in different thicknesses). As an option, the univation[®] spreader and spreading forceps can be used.

Both spacer and/or distractor must lie flat on the tibial resection surface in order to ensure precise measurement. Recording of the data is performed by pressing the right pedal.



14.2 Measuring the Joint Gap in Extension

The measurement of the joint gap in extension is performed the same way as in flexion (see above) and by using either the available spacers or the univation spreader and spreading forceps.

Both spacer and/or distractor must lie flat on the tibial resection surface in order to ensure precise measurement. Recording of the data is performed by pressing the right pedal.





15. Femoral Planning



- 1. At this point, the femur size is chosen (stage: "Entering patient-related information"), here size 3
- Total height of tibial components (metal plate + PE-Inlay), here 7 mm
- 3 Remaining extension gap, here of 0 mm in green (yellow values signify negative gaps and distension of the soft tissue)
- Remaining flexion gap, here of 1 mm in green (yellow values signify negative gaps and distension of the soft tissue)
- 5. Enlargement or reduction of amount of distal femur resection in relation to the implant thickness, here a reduction of 1 mm (indicated by the minus sign and white number). This signifies less cut and slight distalization of the implant.
- 6. Enlargement of amount of posterior resection in relation to the implant thickness, here of 0 mm (indicated by white number)
- 7. Recyle bin:

With a long press on the left pedal, the recycle bin can be activated. All actively modified values are reset to the initial values calculated by the software again.

8. White arrow pointing to the left: With a short press on the left pedal, the previous step can be reached.

- 9 White arrow pointing to the right: With a short press on the right pedal, the next step can be reached.
- Crosshairs: With a long press on the right pedal, the "virtual pointer" can be reinitialized, if the visibility is poor.

The following three situations can occur:

- Extension gap = flexion gap: no change of resections necessary
- Extension gap > flexion gap:
 - A. The extension gap is adapted to the flexion gap and, therefore, the distal resection decreased.
 - B. The flexion gap is adapted to the extension gap and, therefore, the posterior resection increased.
- Extension gap < flexion gap: The extension gap is adapted to the flexion gap and, therefore, the distal resection increased.

TIP

A reduction/decrease of the posterior resection is not foreseen.

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16. Distal Femur Resection, Control and Rotational Orientation



16.1 Distal Femur Resection

The distal femur saw guide is connected to the navigated univation[®] X spacer by following the step that was chosen in the femoral planning and pushing it forward until contact with the distal condyle is reached. Here, e.g. on step -1, indicated by the wording "Distal offset -1" in gray color in the center of the screen.

The navigated spacer with correctly placed distal saw guide is placed on the tibia resection, with the leg in extension. The distal saw guide must be in contact with the distal condyle.

Now the saw guide can be navigated to the preferred varus/valgus and slope orientation and then fixed with two headless screwpins. After that, the resection can be performed.

TIP

Please ensure, as indicated on the screen, that the spacer is in contact with the distal condyle before fixation.





16. Distal Femur Resection, Control and Rotational Orientation (continued)



16.2 Reassessing the Distal Resection

For the reassessment of the distal resection, the necessary 2-in-1 saw guide is determined by the previously ("femoral planning") defined step of the navigated univation X spacer and slide on the spacer. Here, e.g. step 0, indicated by the wording "Posterior offset 0" in gray color in the center of the screen.

With the leg flexed, the spacer is set on top of the tibia resection, and the 2-in-1 saw guide is brought in contact with the distal resection. On the screen, the measured varus/valgus as well as slope value is indicated.

TIP

If, for example, the tibial resection has been performed in 5° posterior slope, the distal femur cut would be parallel in 5° extension accordingly.

Fig. 28a

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16. Distal Femur Resection, Control and Rotational Orientation (continued)



16.3 Positioning of the 2-in-1 Saw Guide

Depending on femur size and treated condyle, connect the 2-in-1 saw guide to the navigated univation[®] X spacer. The step-position of the spacer for the correct connection with the saw guide is displayed as a value in gray color in the center of the screen. This is according to the previously defined value for that in the femoral planning.

During the orientation, the navigated univation X spacer must be in contact with the posterior condyle. The varus/ valgus as well as slope-value that are determined by the distal resection are shown for repeated control. The saw guide is fixed with two headed pins (the upper one 30 mm, the lower one 50 mm long) in the desired rotational position.

After that, the posterior resection and the oblique resection are performed.

TIP

Please ensure, as indicated on the screen, that the spacer is in contact with the posterior condyle while fixing the guide.



17. Mechanical Axis



The mechanical axis achieved postoperatively (varus/valgus angle), as well as the maximum possible extension of the leg, can now be checked using trial implants, and at the end using the final implant. A documented result of the operation is provided, which can be attached to the patient file if desired.



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18. Workflow Options

18.1 Tibia First with Soft Tissue Management

The tibia first workflow with soft tissue management is the one presented in all previous chapters.

18.2 Tibia Cut Only

The tibia cut only workflow contains the palpations performed according to Chapters 8 and 9, as well as the option to navigate and reassess the tibia resection in relation to the tibial mechanical axis according to Chapter 13. No rigid body is needed on the femur, no palpations are performed on the femur side and there is no information about the overall mechanical axis/load line.

18.3 Tibia Cut Only with Loadline

Within this workflow-option, the user can derive additional information about the overall mechanical axis compared to the above described (Chapter 19.2) by placing an additional rigid body on the femur. Additional recordings are necessary according to Chapters 7, 10, 11 and 12 in order to get additional information on the overall mechanical axis. Measurement of gaps, femoral planning, as well as navigation of femoral cuts, are omitted.

19. Software and Consumeables

19.1 Software OrthoPilot UKA

19.2 Disposable Passive Marker Spheres

Software Module		Marker Spheres	
OrthoPilot UKA	FS234	NDI single-use passive markers (3 x 4 pcs.)	FS616
		CAP single-use passive markers (3 x 4 pcs.)	FS618SU

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20. Instrument Set Overview OrthoPilot[®] UKA



ST0626 - UKA Navigation Instrument Set Tray 1 of 2									
Index	Qty.	Item No.	Description	Index	Qty.	Item No.	Description		
Α	1	FS604	OrthoPilot Active Pointer 0°	G	1	NP893R	univation® Tibia Check Plate		
В	1	FS633	OrthoPilot Passive Rigid Body, Yellow	Н	1	NM473R	univation X Spacer, Navigated		
С	1	FS634	OrthoPilot Passive Rigid Body, Blue	I	1	NP894R	univation Femur Orienter		
D	1	FS635	OrthoPilot Passive Rigid Body, Red	J	1	NQ940R	MIOS [®] T-handle		
E	1	NP281R	OrthoPilot Screw Length Measuring Gauge	K	1	NQ941R	MIOS Soft Tissue Protection Sleeve		
F	1	NS423R	IQ Screwdriver SW 3.5	L	1	NM1090R	univation X Storage Navigation Instruments		



ST06	ST0626 – UKA Navigation Instrument Set Tray 2 of 2								
Index	Qty.	Item No.	Description	Index	Qty.	Item No.	Description		
А	1	NP616R	OrthoPilot Drill Guide D 3.2 mm L 100 mm	F	2	NP622R	OrthoPilot Bicortical RB-Fixation Screw 40 mm		
В	3	NP619R	OrthoPilot Rigid Body Adapter	G	2	NP623R	OrthoPilot Bicortical RB-Fixation Screw 45 mm		
С	1	NP618R	OrthoPilot Screwdriver on Motor RB-Screw F.	Н	2	NP624R	OrthoPilot Bicortical RB-Fixation Screw 50 mm		
D	2	NP620R	OrthoPilot Bicortical RB-Fixation Screw 30 mm		2	NP625R	OrthoPilot Bicortical RB-Fixation Screw 55 mm		
E	2	NP621R	OrthoPilot Bicortical RB-Fixation Screw 35 mm	J	1	NP615R	OrthoPilot Drill D 3.2 mm 160/80 mm		

21. Schematic Program Flow UKA 3.0

21.1 Schematic Program Flow Tibia First with Soft Tissue Management



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21. Schematic Program Flow UKA 3.0 (continued)



21. Schematic Program Flow UKA 3.0 (continued)

21.2 Schematic Program Flow Tibia Cut Only





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21. Schematic Program Flow UKA 3.0 (continued)

21.3 Schematic Program Flow Tibia Cut Only with Loadline



Notes

OrthoPilot[®]

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Notes

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