TKA smart application software Columbus® and Vega System®

Contents
1. Safe handling ........................................... 2
2. Product description .................................... 3
2.1 Intended use ........................................... 3
2.2 Indications and contraindications ..................... 3
3. Application ............................................. 4
4. System components .................................... 4
4.1 Components required for operation .................... 4
4.1 Columbus® ............................................. 5
4.1 Vega System® .......................................... 5
4.2 Installing and starting the software .................... 5
4.3 Operating principle of the OrthoPilot® software module ........................................... 5
5. Working with the OrthoPilot® application software .......................................... 6
5.1 Special instruments for OrthoPilot® application ........................................... 6
5.2 Options ................................................. 6
5.3 Safety and functionality ................................ 7
5.4 Safe operation - plausibility checks .................... 7
5.5 Entering the patient data ................................ 8
5.6 Data acquisition ........................................ 8
5.7 Kinematic data acquisition ................................ 8
5.8 Locating the hip center without iliac transmitter ........................................... 9
5.9 Locating the hip center with iliac transmitter ........................................... 9
5.10 Registration of anatomical landmarks ................. 10
5.11 Plausibility checks ..................................... 11
5.12 Navigated bone preparation ......................... 11
5.13 Quitting the software .................................. 12
6. Record .................................................. 12
7. Information about the licenses used .................... 12
7.1 Info ................................................... 12
8. Technical Service ....................................... 13
9. Distributor in the US/Contact in Canada for product information and complaints .......... 13

1. Safe handling

CAUTION

Federal law restricts this device to sale by or on order of a physician!

These instructions for use must be kept available and accessible for all OR staff and all other users!

WARNING

When using the OrthoPilot® navigation system as an aid for implanting knee endoprostheses, all devices, the basic system, and the implants and instruments may only be used and applied as described in the respective instructions for use and product information documents.

To ensure safe application of the OrthoPilot® software module, users must familiarize themselves with the instructions for use and all product information documents prior to using the system.

The OrthoPilot® navigation system may be used only by qualified surgeons who are experienced in the manual operating technique and have received comprehensive training by Aesculap technicians or surgeons experienced in using the navigation system!
Please refer to the following product information documents in particular:

<table>
<thead>
<tr>
<th>Designation</th>
<th>Art. no.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Instructions for use OrthoPilot® system FS100</td>
<td>TA010004</td>
</tr>
<tr>
<td>Instructions for use OrthoPilot® system FS101....FS106</td>
<td>TA012658</td>
</tr>
<tr>
<td>Quick Guide for OrthoPilot® system FS104/FS106</td>
<td>TA012653</td>
</tr>
<tr>
<td>Instructions for use OrthoPilot® operating system, operation, software</td>
<td>TA012659</td>
</tr>
<tr>
<td>(FS101/FS102)</td>
<td></td>
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<tr>
<td>Instructions for use OrthoPilot® FS100/FS010 - operating system, operation</td>
<td>TA012821</td>
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<tr>
<td>software</td>
<td></td>
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<tr>
<td>Operating technique, product information OrthoPilot® TKA smart</td>
<td>O42802</td>
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<tr>
<td>Manual operating technique, product information Columbus®</td>
<td>DOC620</td>
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<td>Manual operating technique, product information Columbus® MIOS</td>
<td>DOC620</td>
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<tr>
<td>Manual operating technique, product information Vega System®</td>
<td>O43302</td>
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2. **Product description**

2.1 Intended use

Application software FS228 is a software module for the computer-aided navigation of surgical instruments, the aim of which is to achieve optimal positioning of knee endoprostheses in the patient's joint. The patient data required for this procedure are registered intraoperatively, making preoperative CT scans unnecessary. Two (optionally three) active or passive infrared transmitters applied on the patient provide the link between the patient and the computer. The transmitters are located by an infrared camera connected to the computer. The instruments are also fitted with infrared transmitters to allow the spatial correlation between the instruments and the transmitter locations on the bone to be established by the computer.

2.2 Indications and contraindications

The system can be used in all cases where an arthroplasty of a knee is surgically indicated. Contraindications for these prostheses are listed in the documentation enclosed with the respective implants. The presence of excessive damage to the joint can make the determination of the joint center from kinematic data unreliable. If this is the case, the software automatically selects joint centers that are calculated redundantly from points scanned with sufficient precision. As this procedure cannot be carried out on the hip, the system can be used in such cases only if the operation-side hip joint is sufficiently mobile.
4. System components

4.1 Components required for operation

<table>
<thead>
<tr>
<th>Designation</th>
<th>Art. no.</th>
</tr>
</thead>
<tbody>
<tr>
<td>OrthoPilot® system</td>
<td>FS100/FS101</td>
</tr>
<tr>
<td>Passive transmitters</td>
<td>FS633, FS634 and FS635</td>
</tr>
<tr>
<td>Active transmitters</td>
<td>FS601</td>
</tr>
<tr>
<td>OrthoPilot® single-use passive markers</td>
<td>FS616 or FS617</td>
</tr>
<tr>
<td>For use with active transmitters: TIU module or SCU module</td>
<td>FS100/FS101</td>
</tr>
<tr>
<td>For use of ultrasonic devices for intraoperative imaging: Ultrasound module</td>
<td>FS101 only</td>
</tr>
</tbody>
</table>

Note
For further details and information regarding OrthoPilot® Basic system FS100, see TA010004; for OrthoPilot® Basic system FS101, see TA012658. Also refer to the “OrthoPilot® operating system, operation, software” instructions for use (TA012659/TA012821) prior to putting the product into operation.

3. Application

The software application described in this document is intended exclusively for use with the following implant systems:
- Columbus®
- Vega System®

Further information regarding the use of the respective system components can be found in the appropriate instructions for use and product information documents.
4.3 Operating principle of the OrthoPilot® software module

The OrthoPilot® software module FS228 for orthopedic applications in knee arthroplasty allows precise guidance for the application of drill holes and bone cuts and for the implantation of endoprostheses. The given, patient-specific anatomical–geometrical elements, such as leg axes and pelvis position, which provide the basis for the alignment of the bone-preparation cuts and of the endoprostheses, are determined by the computer by means of kinematic and palpation data registered intraoperatively. The operating surgeon records the relevant anatomical structures by palpating them with a pointer. This allows a precise computation of the bone preparation steps, the implant bed, and the implant position and, consequently, precise, computer-controlled positioning of the navigated instruments.

CAUTION

OrthoPilot® software module FS228 has been designed for exclusive use with the appropriate instrument system or endoprosthesis system, respectively. All components mentioned in this document have been harmonized in such a way that they provide for the user a complete system for bone preparation and/or prosthesis implantation.

4.2 Installing and starting the software

Note
For further details regarding the installation and start-up of the software, as well as other system technical information, see the “OrthoPilot® operating system, operation, software” instructions for use TA012659/TA012821.
TKA smart application software Columbus® and Vega System®

5. Working with the OrthoPilot® application software

The following is an outline of the essential steps and critical points for successful data acquisition. The subsequent, necessary bone preparation steps are also performed with the help of the application software. These steps are largely identical to the steps required for a manual TKA operation.

The complete, intraoperative workflow for the navigated operation is described in detail in product information brochure no. DOC620, "Operating technique OrthoPilot® TKA – Total Knee Arthroplasty”.

5.1 Special instruments for OrthoPilot® application

The special instruments are fitted with adapters for infrared transmitters. Navigation technology allows instrument positioning with millimeter and angle-degree precision. Therefore, the OrthoPilot® navigation system is equipped with extremely precise adjusting mechanisms for the resection depth, the frontal and sagittal angles, and the rotation. As OrthoPilot® is calibrated only for use with these special instruments, only Aesculap instruments may be used with the system. The special instruments are subject to the relevant guidelines and regulations for cleaning and sterilization of autoclavable instruments. Further information in this regard can be found in the appropriate instructions for use of the implants, instruments, and devices.

5.2 Options

User error!

➢ Any settings may be changed only by Aesculap software specialists.

WARNING

➢ To ensure safe use of OrthoPilot® TKA application software, always follow Operating Manual DOC620.

The OrthoPilot® software can be adapted to individual users’ requirements in various ways:

• Use of active IR transmitters only
• Using passive IR transmitters only
• Activating/deactivating acoustic messages
• If the range of motion or the mobility of the hip is restricted, the alternative method for registering the hip center must be applied (using a reference basis on the iliac crest).
• Second reference point for the resection depth on the tibia head
• Palpation of the epicondyles as reference for the rotation of the femoral component
5.3 Safety and functionality

The precision of the values displayed during the operation primarily depends on the quality of the landmarks registered kinematically or through palpation. Optimal data acquisition requires adequate knowledge of the anatomical conditions.

The bone structures displayed on the screen are not based on diagnostic imaging procedures carried out on the patient undergoing the surgical procedure. Consequently, the display does not represent the bone structure of the individual patient; it only serves as a visual aid for intuitive user guidance.

5.4 Safe operation – plausibility checks

As with every technical device, OrthoPilot® is subject to possible malfunctions due to technical faults or user errors. However, since interventions performed with the OrthoPilot® navigation system can be aborted at any time and continued manually with standard instruments, such malfunctions do not pose an additional risk to the patient, provided they are discovered in good time. Therefore it is important, particularly during the early stages of using OrthoPilot®, to continuously check the plausibility of the steps suggested by the system. Should there arise any doubts as to whether the system is functioning correctly, the test procedure must be repeated (if possible), or the intervention must be continued by non-navigated surgery using the conventional operating technique.

In case of technical problems during the surgical intervention, e.g. if the program suddenly shuts down, the anatomical geometry (e.g. axis relations) can be re-registered by restarting the application software. If the axis situation is re-registered after the restart, its plausibility with regard to the radiological picture (e.g. image of the entire leg under load in a standing position) must be checked again.
5.5 Entering the patient data

When entering the patient data, take care to select the appropriate camera position and side corresponding to the actual operating side. Failure to do so will result in incorrect computations by the application software.

5.6 Data acquisition

Data are registered through three different, basic methods:
- Kinematic data registration
- Registration of palpated anatomical landmarks
- Registration of preoperative data via keyboard input

All kinematic measurements and palpations must be carried out with the best possible precision. Also, other data used as input for the OrthoPilot® system must be determined with maximum precision.

5.7 Kinematic data acquisition

Kinematic data are registered for determining the joint centers (hip and knee).

CAUTION
Generally, each step of the program sequence should be confirmed as soon as the respective measurement result is displayed on screen and is found to match the user's intentions. The values displayed at the time of confirmation are saved to the log file and used for further calculations. Erroneous data confirmation or incorrect data input can result in miscalculations and, consequently, incorrect positioning of burr holes, incisions, and implants.

CAUTION
If transmitters are moved too rapidly, the camera may be unable to track the transmitters, causing the traffic light symbol to signal red. This can happen in all steps in which the transmitters are moved through a relatively large area.
5.8 Locating the hip center without iliac transmitter

This method of kinematic data registration is most sensitive in terms of data precision, because only one reference transmitter on the femur is used. In this way, additional trauma to the patient, caused by a second reference transmitter on the iliac crest, is avoided. Normally, the message “Data inadequate” is displayed if the quality of the registered data is not good enough. Otherwise, the program automatically moves to the next program step as soon as sufficient data have been measured and recorded.

![CAUTION]

As the registration of the hip center in this way is the only registration using only the position and alignment of one navigation reference basis relative to the position of the POLARIS camera (avoiding a reference basis on the iliac crest), it is extremely important that the camera position relative to the operating table does not change during data registration. (In all other steps, the relative position of two reference bases is used for data registration. This makes those results independent of camera movements.)

5.9 Locating the hip center with iliac transmitter

Fixating a transmitter on the iliac crest is indicated in cases where the user prefers safe and precise determination of the hip center by means of two reference transmitters. This method should be applied if the necessary immobilization of the pelvis and, consequently, the precise determination of the location of the hip head center cannot be ensured otherwise.

The pelvis tends to move inadvertently in the following cases:
- Restricted range of movement of the hip
- Adiposity of the patient
- Inconvenient position of a tourniquet
- Patients with peridural or spinal anesthesia without adequate immobilization
5.10 Registration of anatomical landmarks

To obtain correct data, minimal force should be applied when using the pointer. Do not bend the pointer. Any use of bent instruments will result in incorrect computation of angles, distances and implant size.

- Check the pointer for proper functioning according to the specifications given in TA012659/TA012821.

Especially at the early stages of operating with OrthoPilot®, inaccurate palpation of the points can result in incorrect measurements/data (e.g. femur size). Therefore, always perform plausibility checks of suggested dimensions. If in doubt, compare the electronic data with mechanical measurements obtained with the knee® instruments.

The calculation of the knee center uses both palpation and kinematic data. In this way the joint center is located with optimum precision. However, if large discrepancies between the two data sets are found, the software uses the joint center determined by palpation. Therefore, the palpations must be carried out with particular care.
5.11 Plausibility checks

Data registration must be accompanied by plausibility checks of the recorded anatomy. The displayed angle between the femoral joint line (tangential to the distal femoral condyles) and the mechanical femur axis must be compared with the preoperative planning data. Any discrepancies found in this comparison may make it necessary to delete data already registered and repeat the steps “Locating the hip center” and “Medial and lateral dorsal condyles”.

Once the data registration is complete, the overall leg axis angles must be checked for plausibility. If any discrepancies are found in this check, the surgeon may have to delete data already registered and repeat the steps “Locating the hip center”, “Medial and lateral dorsal condyle”, “Anterior corticalis point”, “Medial and lateral malleolus” and “Anterior central point”.

Should such discrepancies persist, the iliac reference point or the manual technique may have to be used instead.

Should the medial and the lateral sides have become confused during palpation of the landmarks, or if the registered data are absolutely incorrect anatomically, a warning message indicating that the palpation data are incompatible appears before the “Mechanical leg axis” is displayed. This means that all data already registered must be deleted and registered again. This is done by moving back through the program sequence by pressing the left foot switch. As the foot switch is kept pressed for a while, the respective data are deleted and can be registered again.

5.12 Navigated bone preparation

Note
Further steps and the complete, intraoperative workflow for the navigated operation are described in detail in product information brochure no. DOC620, “Operating technique OrthoPilot® TKA - Total Knee Arthroplasty”. 
5.13 Quitting the software

Note
For further details and information on the OrthoPilot® operating system, operation, software, see TA012659/TA012821.

6. Record

Note
See instructions for use “OrthoPilot® operating system, operation, software” TA012659/TA012821.

7. Information about the licenses used

LGPL
This product uses Qt framework version 4.6.2 under the license of LGPL version 2.1. Qt is protected by copyright© 2009 Nokia Corporation and/or its subsidiaries. Contact: Nokia Corporation (qt-info@nokia.com)

Apache
This product includes software developed by Apache Software Foundation (http://www.apache.org/). This is authorized by license for Apache version 2.0. Parts of this software are based on software copyright© 1999, IBM Corporation; see
http://www.ibm.com

Touch-It Virtual Keyboard
This product uses the Touch-It Virtual Keyboard® developed by Chessware SA and is protected by copyright© (http://www.chessware.ch/virtualkeyboard/).
We agree to the license terms of the above mentioned software products. For more information, please contact your national B. Braun/Aesculap agency.

7.1 Info
For more information, choose the Info button (i button) in the top right section of the screen, see Fig. 1, while the application is running.

Fig. 1
8. Technical Service

For service, maintenance or repairs, please contact your national B. Braun/Aesculap representatives. Modifications carried out on medical technical equipment may result in loss of guarantee/warranty rights and forfeiture of applicable licenses.

Service addresses
Aesculap Implant Systems LLC
Attn. Aesculap Technical Services
615 Lambert Pointe Drive
Hazelwood, MO 63042
Aesculap Repair Hotline
Phone: +1 800 214-3392
Fax: +1 314 865-4420
Other service addresses can be obtained from the address indicated above.

9. Distributor in the US/Contact in Canada for product information and complaints

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Center Valley, PA 18034
USA