TRUMATCH®
Personalized Solutions
3.0 System Step-by-Step User Guide

Step-by-Step Guide for Planning and Tracking Customized Patient Instruments for Total Knee Arthroplasty
# Table of Contents

## PROCESS OVERVIEW

## ACCOUNT SETUP OVERVIEW
- Accessing the TRUMATCH Personalized Solutions Customer Portal  
  - Managing Passwords

## WEB PORTAL OVERVIEW

## PATIENT IMAGING PROCESS OVERVIEW
- CT Center Assignment
- CT Center Protocol
- Passing CT Study

## PATIENT PROPOSAL OVERVIEW
- Case Creation
- Patient Consent
- Patient Proposal Review

## TRUMATCH 3.0 NEW CODE LISTINGS

## IMAGING CENTER AND CASE SUPPORT
This User Guide has been created to aid in the management of the TRUMATCH® Personalized Solutions customer account and ordering process.

This step-by-step guide will illustrate how to activate a surgeon account, review the surgeon profile, approve TRUMATCH Personalized Solutions patient proposals, and track case status.
1. **Patient Imaging**

Following an assessment and recommendation from the surgeon, the TRUMATCH Personalized Solutions process begins with acquiring a CT image of the leg, from hip to ankle, per a defined TRUMATCH Personalized Solutions scanning protocol. The image acquisition will be conducted at a certified imaging center and will then be electronically forwarded to the TRUMATCH Personalized Solutions team. The TRUMATCH Personalized Solutions team will confirm the quality of the image and proceed to developing the Patient Proposal.

2. **Image Processing and Patient Proposal**

Utilizing proprietary software, the TRUMATCH Personalized Solutions design team will create a three-dimensional model of the whole leg, utilizing the surgeon’s surgical preferences to create a personalized Patient Proposal. The Patient Proposal will include information such as distal femoral and proximal tibial resection levels, varus/valgus alignment, femoral rotation, femoral and tibial sizing, and tibial slope.

3. **Patient Proposal Approval**

An email will alert the surgeon when the case-specific Patient Proposal is ready for his/her comment and approval. The surgeon is then able to visit a password-protected area of the TRUMATCH Personalized Solutions website to make, if necessary, any revisions and approve the Patient Proposal.

4. **Instrument Preparation**

Once the surgeon approves the details of the Patient Proposal, preparation of the personalized patient-specific instruments takes place within the dedicated manufacturing centers. Individual patient name and data are etched on each instrument to confirm identification in the Operating Room (OR). Stainless steel guides within the resection guides are designed to reduce particle generation during bone resection.

5. **Delivery and Surgery**

The TRUMATCH Personalized Solutions resection guides are delivered sterile. The guides are delivered on or prior to the stated delivery date communicated following completion of the TRUMATCH Personalized Solutions Patient Proposal approval. Surgery can take place any time thereafter up to 180 days from the date of manufacturing.
Read Terms and Conditions and then check the "I ACCEPT" box

Enter your LOGIN credentials and click "LOGIN"

Managing Passwords

Please take appropriate security precautions when using the Web Portal.

Please log out and close your web browser once you have finished your session.

- Create a strong password.
  - The password should be at least 10 characters long.
  - The password cannot be one of the previous 10 passwords used.
  - The password must contain characters from at least three of the following four categories:
    1. English uppercase characters (A-Z)
    2. English lowercase characters (a-z)
    3. Base 10 digits (0-9)
    4. Non-alphanumeric symbols
       (For example: !, $, #, %)

- Do not share your password.
- Change your password periodically.
- Use only trusted and secured devices to access the Web Portal.

In the event of any cybersecurity concerns about the TRUMATCH Personalized Solutions Web Portal, please visit productsecurity.jnj.com.
1. Landing page displays all ACTIVE CASES requiring surgeon ACTION

2. Click LOGOUT when you have completed the session

3. Click EDIT PROFILE to edit Surgical Preferences
   NOTE: Implant and Guide Type changes must be requested through the TRUMATCH Customer Care Team

4. Click NOTIFICATIONS to edit email notification preferences

5. Search for cases by PATIENT NAME or CASE NUMBER

6. Select one of the TABS to search by CASE STATUS

7. Choose preferred view: BLOCK VIEW or LIST VIEW

8. Click Patient Name to view PATIENT INFORMATION and CASE DETAILS

9. Click PDF to view PATIENT PROPOSAL

10. Click MAKE DECISION to APPROVE, REDesign AND RESUBMIT, APPROVE WITH CHANGE, or CANCEL THIS CASE

11. PENDING IMAGE identifies that an image has failed protocol and requires resubmission

12. Tap on the 🔍 to reveal reason for image failure
CT Center Assignment

During registration, a validated imaging center will be assigned to each user profile based on location or preference. For questions related to the CT Center Validation Process, contact the TRUMATCH Personalized Solutions Case Coordination Team.

CT Center Protocol

Each validated imaging center is provided with the CT Center User Guide. This protocol is designed to optimize the scan settings to capture the bony geometry of an affected knee. Included in this protocol is the Scanning Checklist, the Scanning Procedure, and the Scan Parameters.

Passing CT Study

Each CT study provided to the TRUMATCH Personalized Solutions Acquisition Team must pass the TRUMATCH Personalized Solutions Knee Scanning Protocol before a patient proposal can be generated. A scanning procedure (CT Center User Guide) is provided to each CT Center to be used as a guide to ensure a CT Study meets the criteria for a passing scan.

The protocol will allow DePuy Synthes to accurately create a 3-D model of the patient’s bone and use it to design a patient-specific knee instrument.

### Scanning Procedure Checklist

- 5mm thick spacing in hip and ankle (Figure 1)
- 0.5 to 0.8mm thin spacing in knee (Figure 1)
- Thick & thin slices can overlap, but cannot have gaps
- 25cm (or less) FOV is consistent throughout scan
- Soft tissue recon filter
- Femoral head and talus are included
- Axial images
- DICOM header contains the following:
  - Patient Name
  - Patient Date of Birth
  - Patient Gender
  - Ordering Physician
  - Institution Name (Name of CT Imaging Center)
  - Side Affected (Left or Right)
- No metal present within 8cm of joint (see Figure 2)
- If metal is present in contralateral knee, it is flexed away from joint line (see Figure 3)

### Scan Parameters

<table>
<thead>
<tr>
<th>Contrast</th>
<th>Area</th>
<th>FOV</th>
<th>Centers</th>
<th>Spacing/Thickness</th>
<th>Pitch</th>
<th>kV</th>
<th>Recon Filter</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>Specified Leg</td>
<td>25 cm Max</td>
<td>Constant</td>
<td>Equal see values in Figure 1</td>
<td>1:01</td>
<td>120-140</td>
<td>Soft Tissue</td>
</tr>
</tbody>
</table>

*Figure 1*

![Figure 1](image1.png)

**Knee Scanning Protocol**

DePuy Orthopaedics, Inc. | 755 Orthopaedics Drive | Warsaw, Indiana 46582 | T: (800) 689-0746

This protocol will allow DePuy Synthes to accurately create a 3-D model of the patient’s bone and use it to design a patient-specific knee instrument.
Case Creation

Utilizing proprietary software, the TRUMATCH Personalized Solutions design team will create a three-dimensional model of the whole leg, utilizing the surgeon’s surgical preferences to create a personalized Patient Proposal. Once the proposal is ready for review, a Case Coordinator will alert the surgeon to visit the portal and make, if necessary, any revisions and approve.

Patient Consent

Following confirmation of patient information, the surgeon will be prompted to acknowledge whether the patient has or has not provided consent for the collection of their data for analytical, developmental, and research purposes.

Consent for research is not a requirement and it’s to the discretion of the patient if he/she chooses to do so. The surgeon is responsible for maintaining evidence of consent and it must be made available to TRUMATCH upon request. Copies of the consent forms can be found by visiting TRUMATCH at depuysynthes.com or by going to https://www.depuysynthes.com/hcp/knee/products/qs/TRUMATCH-Personalized-Solutions#tab3.

Patient Proposal Review

To review and make a decision for a TRUMATCH Personalized Solutions PATIENT PROPOSAL, click on the PDF button (number 9 of the Web Portal User Guide, page 6).

Once the PATIENT PROPOSAL has been reviewed, the surgeon must choose 1 of 4 options by clicking “MAKE DECISION.”

<table>
<thead>
<tr>
<th>OPTION 1</th>
<th>OPTION 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>APPROVE</td>
<td>APPROVE WITH CHANGES</td>
</tr>
<tr>
<td>A date of delivery will be confirmed and TRUMATCH Personalized Solutions Guide manufacture will commence.</td>
<td>A new proposal will be created with requested changes. A date of delivery will be confirmed and TRUMATCH Personalized Solutions Guide manufacture will commence. NOTE: additional review/approval will not be required by the surgeon.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>OPTION 3</th>
<th>OPTION 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>REDESIGN AND RESUBMIT</td>
<td>CANCEL THIS CASE</td>
</tr>
<tr>
<td>A new proposal will be created with requested changes and the revised proposal will be submitted to the surgeon for review and approval.</td>
<td>Patient information will remain on your TRUMATCH Personalized Solutions Web Portal with a status of CANCELLED.</td>
</tr>
</tbody>
</table>
**Step 1:**

Review patient details and then Click **CONFIRM PATIENT INFORMATION**

**Step 2:**

Review and Click **YES or NO**

Review patient consent form and select corresponding acknowledgment

**Step 3:**

After proposal review, make your decision (i.e., choose one of the following OPTIONS: 1 - APPROVE, 2 - APPROVE WITH CHANGES, 3 - REDESIGN AND RESUBMIT, 4 - CANCEL THIS CASE).

If decision is OPTION 2 - APPROVE WITH CHANGES or OPTION 3 - REDESIGN AND RESUBMIT, use drop-down boxes to select and identify REQUIRED CHANGES and then press APPROVED. Additional requests, for example Implant and Guide Type changes, can be made in the COMMENTS/INSTRUCTIONS area.

**Step 4:**

After making your decision and completion of any required changes, confirmation is required. Enter your TRUMATCH Personalized Solutions Web Portal password into the pop-up window to complete the case approval process.
Use with Intuition ™ Instruments:

Dear Dr. Test Surgeon,

Please review the following patient proposal. Using the TRUMATCH ™ Personalized Solutions Surgeon Portal, click the "Make Decision" button on your case listing to select the appropriate status. Please contact TRUMATCH ™ Personalized Solutions support if you have any questions or need further information.

Phone: 1-800-689-0746 Email: trumatchsupport@its.jnj.com

Patient Information:

- Patient Name: Test Patient
- Gender: F
- DOB: 1951-07-03
- Affected Side: R
- Profile: Varus
- Reference Case #: 04971
- Date: 2018-07-09

Case Information:

- Femoral Instrument Type: Resection Guide
- Tibial Instrument Type: Resection Guide
- Implant System: ATTUNE Knee
- Instrument System: Intuition
- Femoral Component: Sz 6N CR R
- Tibial Component: Sz 5 CR
- Femoral Sizing Reference: Anterior Down
- External Rotation Reference: 3° from Posterior Condyles
- Distal Femoral Resection: 9.0 mm from the Most Distal Condyle
- Proximal Tibial Resection: 8.0 mm from the High Plateau
- Posterior Tibial Slope: 7° (Match between 0 and 7°)
- Cartilage loss estimates: 8%(M) 0%(L)
- Image Type: CT

Notes/Comments:

- Proposal Version: 1

Upon Your Approval, DePuy Synthes Companies Will Manufacture the TRUMATCH ™ Personalized Solutions Guides. An email will be received notifying the surgeon once the Patient Proposal is ready for review and approval. Surgeon review and approval is required before manufacturing can commence.

The patient proposal can be accessed in 2 ways: either via the hyperlink embedded in the notification email or via the “View Cases” area of the TRUMATCH Personalized Solutions Web Portal. The Patient Proposal can be viewed electronically by clicking on the “Patient Proposal” hyperlink for the relevant patient.
Displays full leg A/P mechanical axis

The anatomical axis value is shown for reference purposes only (all resections are planned perpendicular to the mechanical axis)

Displays the planned combined, distal femoral, and proximal tibial bone resections using the surgeon preferences (mm)

Combined Bone Resections

<table>
<thead>
<tr>
<th>Side</th>
<th>Ext</th>
<th>Flex</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lateral</td>
<td>14.1</td>
<td>16.5</td>
</tr>
<tr>
<td>Medial</td>
<td>12.1</td>
<td>13.0</td>
</tr>
</tbody>
</table>

Implant Thickness (with 6mm PE)

<table>
<thead>
<tr>
<th>Side</th>
<th>Ext</th>
<th>Flex</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lateral</td>
<td>19.1</td>
<td>18.1</td>
</tr>
</tbody>
</table>

Cartilage offset value and bone thickness (mm)

Orientation Indicators

S - Superior
I - Inferior
M - Medial
L - Lateral
A - Anterior
P - Posterior

Title describing the specific information displayed on each page

Alignment

Full Femoral Mechanical Axis

Full Tibial Mechanical Axis

Identifer of anterior cortex point used to size the femoral component

Quick reference information appears on each page

Displays implant construct thickness (femur + polyethylene insert + tibial components)

NOTE: Potential joint laxity or tightness can be assessed when this information is used in conjunction with the Combined Bone Sections information (mm)

Displays full leg A/P mechanical axis

Displays the planned combined, distal femoral, and proximal tibial bone resections using the surgeon preferences (mm)

Cartilage offset value and bone thickness (mm)

Orientation Indicators

S - Superior
I - Inferior
M - Medial
L - Lateral
A - Anterior
P - Posterior

Title describing the specific information displayed on each page

Full Femoral Mechanical Axis

Identifer of anterior cortex point used to size the femoral component

Quick reference information appears on each page

Displays implant construct thickness (femur + polyethylene insert + tibial components)

NOTE: Potential joint laxity or tightness can be assessed when this information is used in conjunction with the Combined Bone Sections information (mm)
Three femoral component rotational references are displayed:
- Rotation to Epicondylar
- External rotation to Posterior Condyles
- External rotation to Whiteside’s Line

Identifiers of the dwell points in the Medial and Lateral plateaus

Combined Bone Resections
<table>
<thead>
<tr>
<th>Lateral</th>
<th>Medial</th>
</tr>
</thead>
<tbody>
<tr>
<td>14.1 EXT</td>
<td>12.1 EXT</td>
</tr>
<tr>
<td>16.5 FLEX</td>
<td>13.0 FLEX</td>
</tr>
</tbody>
</table>

Implant Thickness (with 6mm PE)
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<tr>
<th>Lateral</th>
<th>Medial</th>
</tr>
</thead>
<tbody>
<tr>
<td>19.1 EXT</td>
<td>18.1 FLEX</td>
</tr>
</tbody>
</table>
Femoral Sizing and Lateral Alignment

**Angle between distal femur (anatomical) and the full femur (mechanical) axes**

- **3° of Anterior Bow**
- **0° Flexion to Anatomical Axis**

**Femoral Sizing and Lateral Alignment**

- **Full Femoral Mechanical Axis**
- **Distal Femoral Anatomical Axis**

**Flexion may be added to a femoral component to help achieve the best fit for a patient while considering anterior and posterior resections.**

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**Surgeon’s preference for tibial slope**

- **7° Posterior Slope**
- **7° Natural Slope**

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**CONFIDENTIAL**

ATTUNE Knee
Fem. Size: 6N R
Tib. Size: 5 R
04971
Page 4 of 5
Wall Chart - Summary

Sz 6N CR

PLF 8.5

PMF 9.9

DLF 6.1

DMF 9.0

LT 8.0

MT 3.1

Sz 5

Total bone resection (mm)
NOTE: if measuring actual bone cuts intraoperatively, be aware that saw blade thickness may affect remnant thickness by up to 2 mm

Tibial resection thickness (MT and LT) is measured from the lowest point on the middle third of the respective tibial plateau.

Displays tibial resection profile

Displays tibial rotation and component coverage

References the medial 1/3 of the tibial tubercle
NOTE: Reference line is also replicated on the tibial guide to facilitate guide positioning
### TRUMATCH® 3.0 Personalized Solutions Code Listings

<table>
<thead>
<tr>
<th>Femoral/Tibia Cut or Pin</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>Part #</td>
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<tr>
<td>420578</td>
<td>TRUMATCH CT PIN GUIDE KIT L</td>
</tr>
<tr>
<td>420579</td>
<td>TRUMATCH CT PIN GUIDE KIT R</td>
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<tr>
<td>420580</td>
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<tr>
<td>420581</td>
<td>TRUMATCH CT PIN GUIDE FEM R</td>
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<td>TRUMATCH CT PIN GUIDE TIBIAL L</td>
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<tr>
<td>420583</td>
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<tr>
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<td>420920</td>
<td>TRUMATCH CT CUT GUIDE TIBIAL R</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Femoral Cut Guide/Tibia Pin Guide</th>
<th>Description</th>
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<tbody>
<tr>
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<td>TRUMATCH CT FEM CUT TIB PIN L</td>
</tr>
<tr>
<td>420907</td>
<td>TRUMATCH CT FEM CUT TIB PIN R</td>
</tr>
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</table>

### Imaging Center and Case Support

For questions regarding a TRUMATCH Personalized Solutions Case or for Imaging Support, please contact a TRUMATCH Case Coordinator at the following:

TRUMATCH Coordinator
1-800-689-0746
trumatchesupport@its.jnj.com

Office hours are M-F, 7:30-4:30 p.m. EST.
The TRUMATCH Solutions Website was tested with Internet Explorer 11 and Chrome 60 web browsers.