

TRUMATCH®

Personalized Solutions

Step-by-Step User Guide

Step-by-Step Guide for Planning and Tracking Customized Patient Plans and Instruments for Total Knee Arthroplasty



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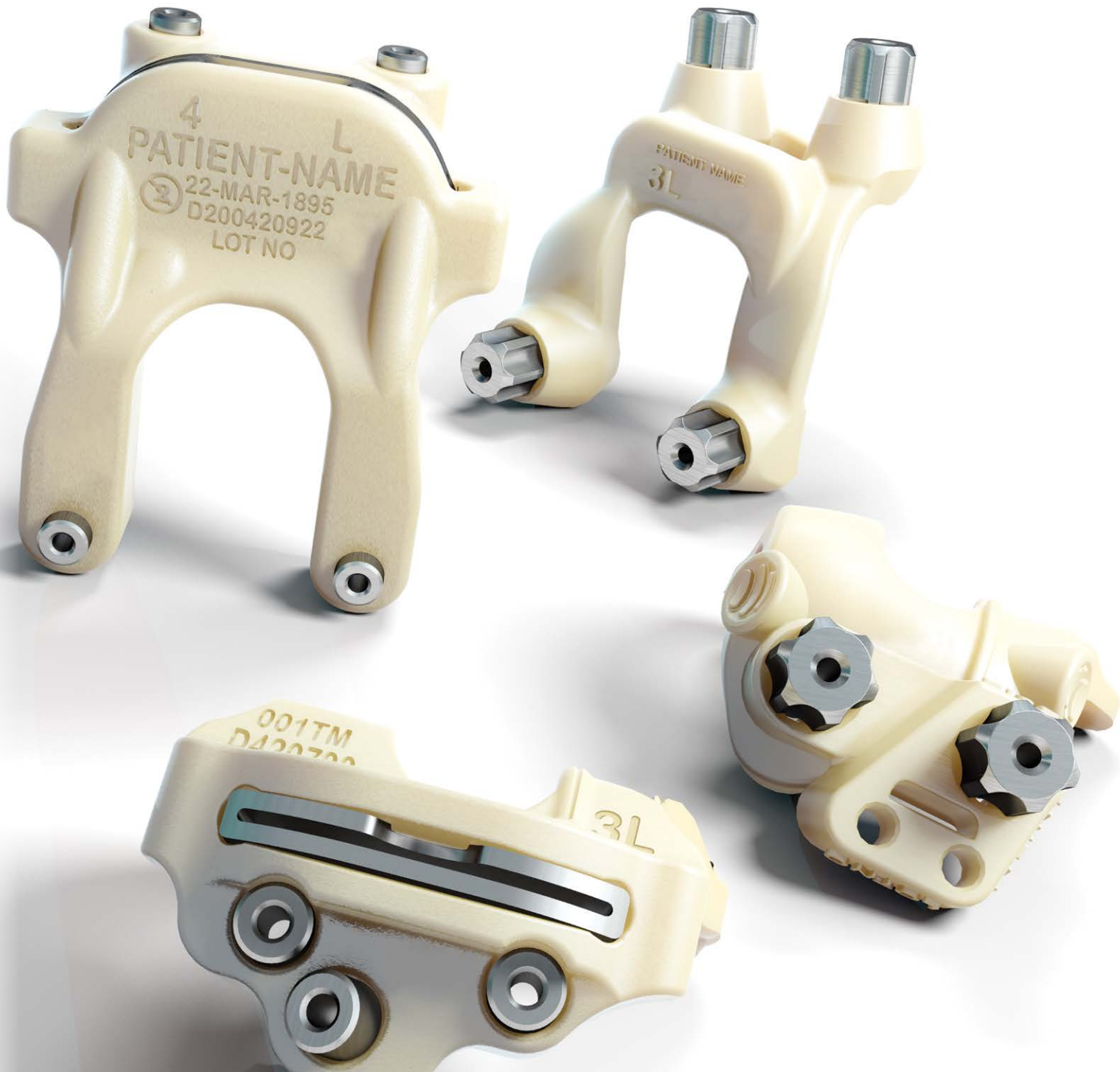
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TRUMATCH® Personalized Solutions Introduction



This User Guide has been created to aid in the management of the TRUMATCH® Personalized Solutions customer account and ordering process.

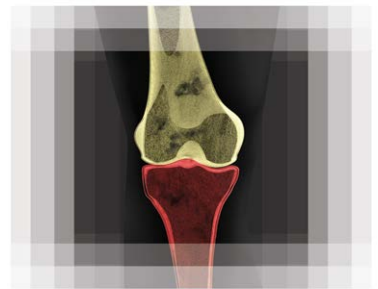
This step-by-step guide will illustrate how to activate a surgeon account, review the surgeon profile, approve TRUMATCH Personalized Solutions patient proposals, and track case status.



Process Overview

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.

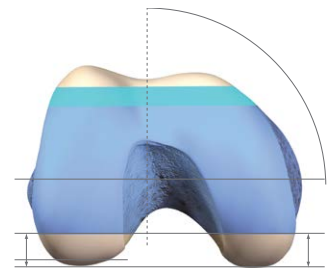


2 Image Processing and Patient Proposal

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 request, if necessary, any revisions and approve the Patient Proposal.

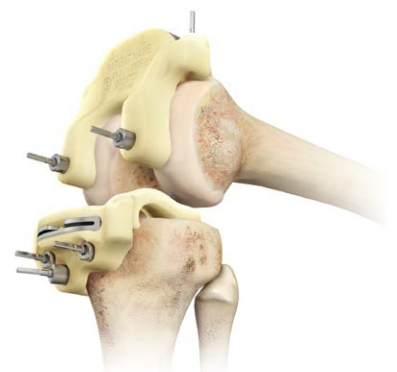


4 Instrument Preparation

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.

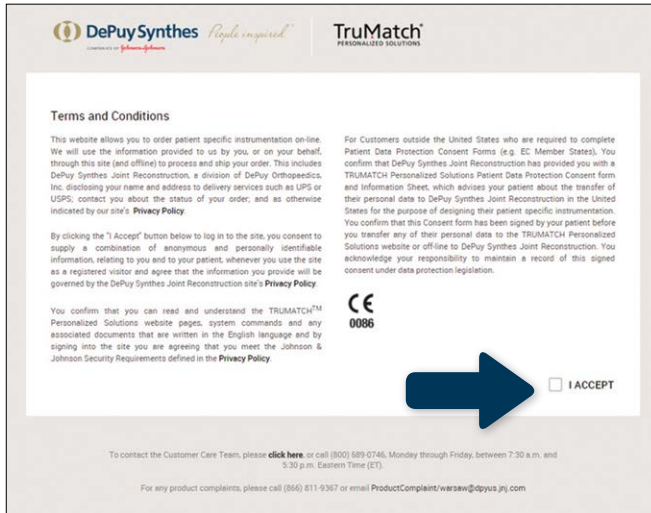


Account Setup Overview

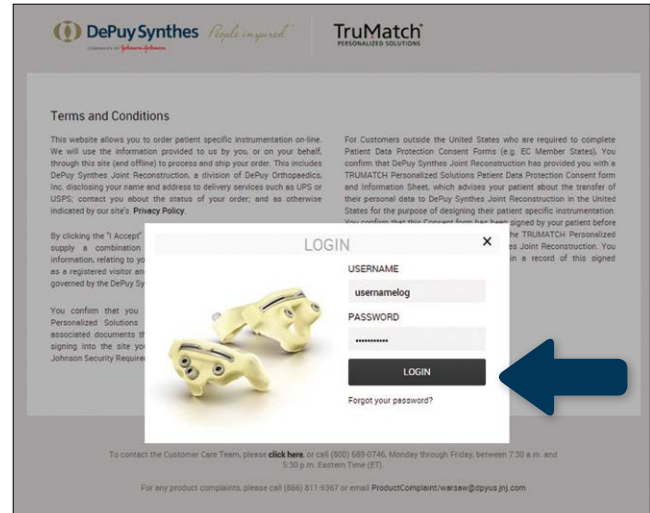
Accessing the TRUMATCH Personalized Solutions Customer Portal

TruMatchSolutions.com

Utilizing the username and password provided by the TRUMATCH Personalized Solutions Case Coordination Team, log in to the TRUMATCH Personalized Solutions portal at trumatchsolutions.com



Read Terms and Conditions and then check the "I ACCEPT" box



Enter your LOGIN credentials and click "LOGIN"

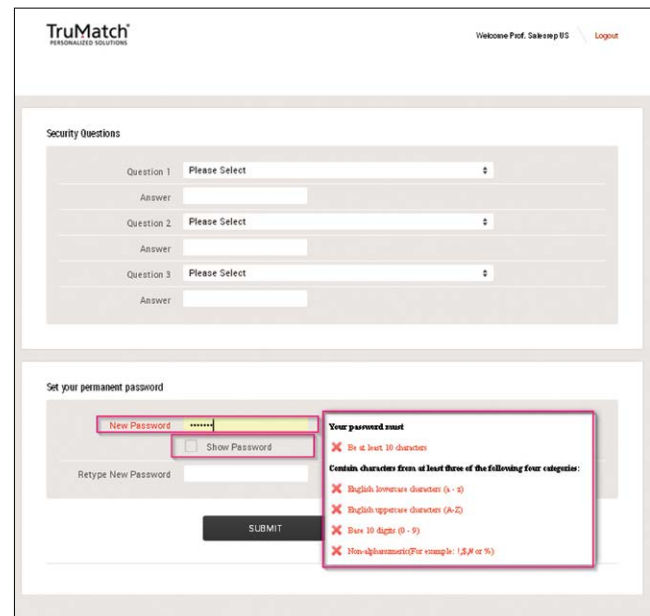
Managing Passwords

Please take appropriate security precautions when using the Web Portal.

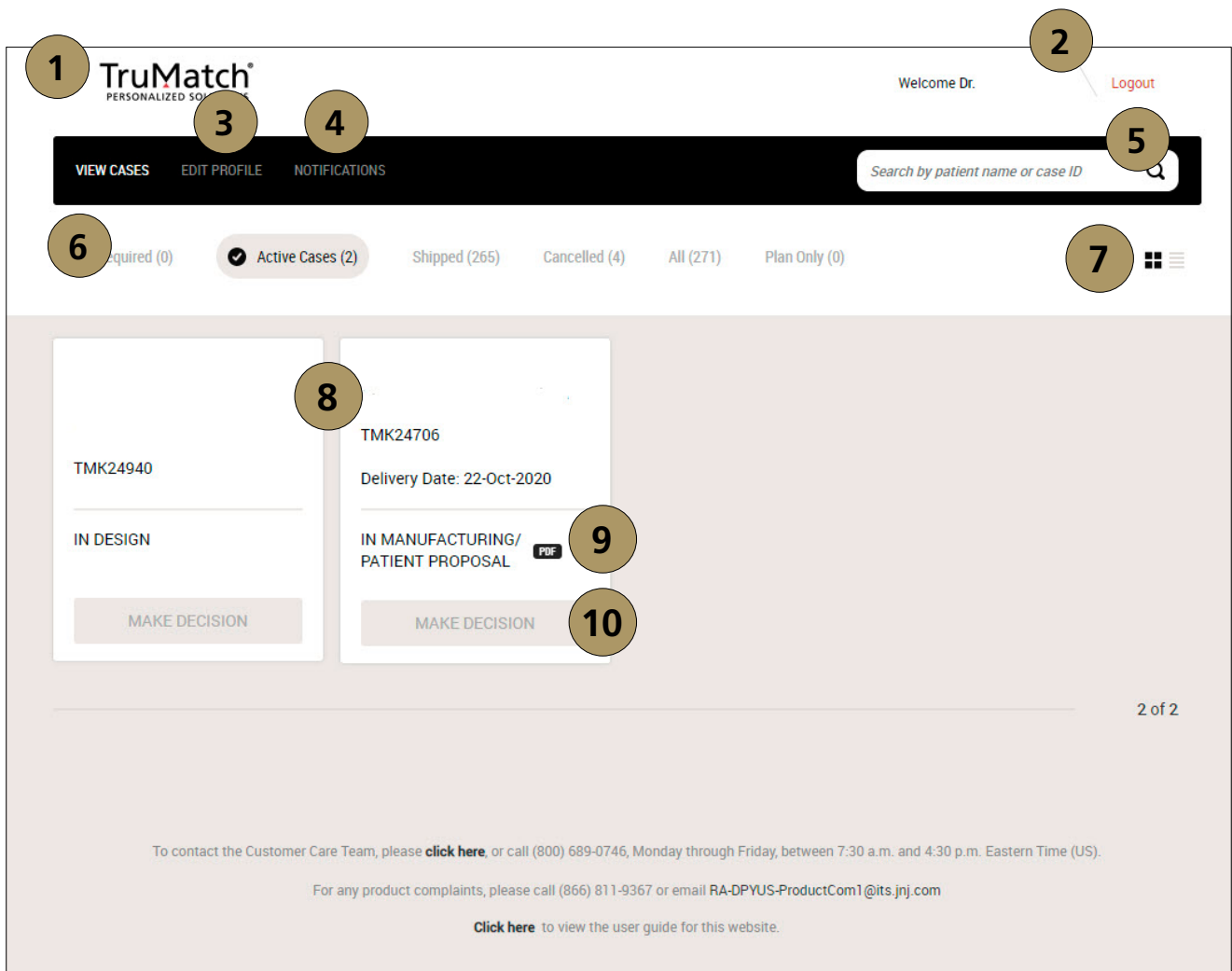
Please log out and close your web browser once you have finished your session.

- 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: !, \$, # or %)
- 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.



Web Portal Overview



NOTE: the names seen in this example are fictionalized for privacy purposes.

- 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
- 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

Patient Imaging Process Overview

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.



PERSONALIZED SOLUTIONS

Knee Scanning Protocol

DePuy Orthopaedics, Inc. | 700 Orthopaedic 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

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)

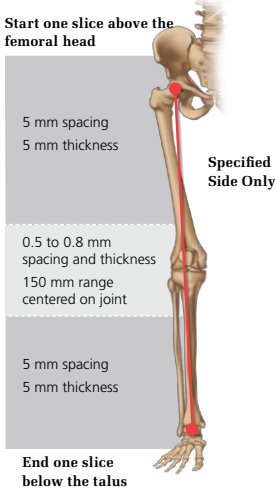


Figure 1

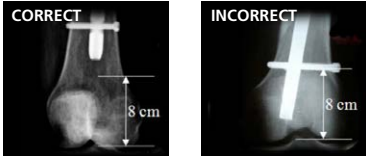


Figure 2

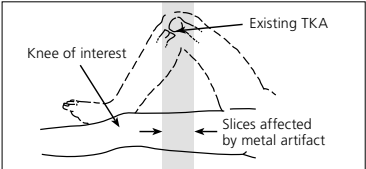


Figure 3

Scan Parameters

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

Patient Proposal Overview

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, an email notification 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 jnmedicaldevices.com or by going to <https://www.jnjmedicaldevices.com/en-US/product/trumatchr-personalized-solutions>.

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."

OPTION 1

APPROVE

A date of delivery will be confirmed and TRUMATCH Personalized Solutions Guide manufacture will commence.

OPTION 2

APPROVE WITH CHANGES

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.

OPTION 3

REDESIGN AND RESUBMIT

A new proposal will be created with requested changes and the revised proposal will be submitted to the surgeon for review and approval.

OPTION 4

CANCEL THIS CASE

Patient information will remain on your TRUMATCH Personalized Solutions Web Portal with a status of CANCELED.

Step 1:

Field	Current Value	Change To
Implant System	ATTUNE™ Knee System	
Guide Type	Resection Guide	Please Select
Removal Component Type	CR	Please Select

Review patient details and then Click CONFIRM PATIENT INFORMATION

Review and Click HERE

Step 2:

Confirm patient information

The patient has provided Consent (US Form / International Form) for use of patient images and aggregate data by the manufacturer for internal analytical, development, and research purposes

Yes
 No

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.

Field	Current Value	Change To
Implant System	ATTUNE™ Knee System	
Guide Type	Resection Guide	Please Select
Removal Component Type	CR	Please Select

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.

Patient Proposal Overview

Patient Proposal Review


The Patient Proposal contains detailed information that will be used to 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.

Dear Dr. Revra DePuy,
 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: 800-689-0746, 574-372-7129 Email: TruMatchSupport@its.jnj.com

Use with Intuition™ Instruments:



**ATTUNE® Knee System
 INTUITION™
 Instruments or
 SIGMA® High
 Performance
 Instruments will be
 shown based on your
 Implant Selection**

<u>Patient Information:</u>		<u>Case Information:</u>	
Patient Name:	Revra DePuy	Femoral Instrument Type:	Plan Only
Gender:	M	Tibial Instrument Type:	Plan Only
DOB:	1860-03-22	Implant System:	ATTUNE Knee
Affected Side:	L	Instrument System:	Intuition
Profile:	Varus	Femoral Component:	Sz 5 CR L
Reference Case #:	TMK00001	Tibial Component:	Sz 4 CR
Date:	2020-02-10	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:	9.0 mm from the High Condyle
		Posterior Tibial Slope:	5°
		Image Type:	CT

Notes/Comments:

Communication between TRUMATCH Personalized Solutions Designer and Surgeon: e.g., *Changes to surgeon positioning preference settings to avoid anterior femoral notching*

Displays the proposal's Revision or Version

Proposal Version: 1

CONFIDENTIAL

UPON YOUR APPROVAL, DEPUY SYNTHES COMPANIES WILL MANUFACTURE THE TRUMATCH™ PERSONALIZED SOLUTIONS INSTRUMENTATION OR ACCESSORIES BASED UPON THE INFORMATION SUPPLIED BY YOU. DEPUY SYNTHES COMPANIES HAS NOT VALIDATED OR VERIFIED AND WILL NOT VERIFY OR VALIDATE THE CORRECTNESS OR APPLICABILITY OF THE INFORMATION SUPPLIED BY YOU AND DEPUY SYNTHES COMPANIES THEREFORE MAKES NO, AND EXPRESSLY DISCLAIMS ANY, EXPRESS OR IMPLIED WARRANTY OF ANY KIND RELATED TO ANY TRUMATCH PERSONALIZED SOLUTIONS, INSTRUMENTATION, TEMPLATES OR ACCESSORIES, INCLUDING WITHOUT LIMITATION ANY WARRANTY THAT SUCH INSTRUMENTATION, TEMPLATES OR ACCESSORIES ARE FIT AND SUFFICIENT FOR THE PURPOSE INTENDED.

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

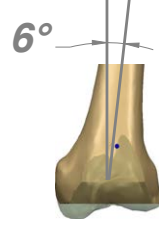
Title describing the specific information displayed on each page

Alignment

Displays full leg A/P mechanical axis

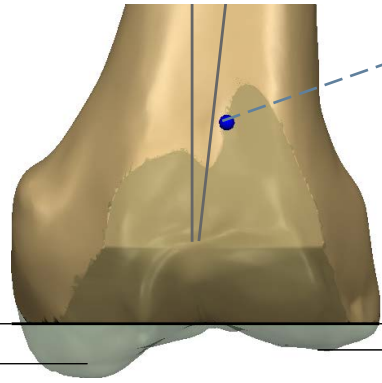


The anatomical axis value is shown for reference purposes only



S

Identifier of anterior cortex point used to size the femoral component



Cartilage offset value and bone thickness (mm)

Total condylar resection (mm)

M

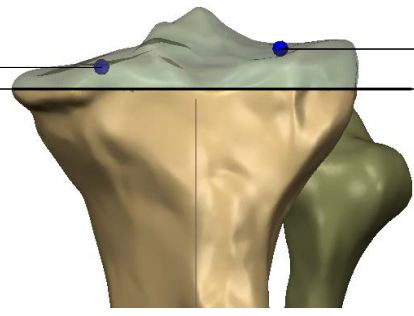
Displays the planned combined, distal femoral, and proximal tibial bone resections using the surgeon preferences (mm)



4.9
 Medial
 (0.0 Cartilage
 +4.9 Bone)

9.0
 Lateral
 (0.0 Cartilage
 +9.0 Bone)

L



Combined Bone Resections

Medial	Lateral
13.9 EXT	14.9 EXT
15.7 FLEX	17.5 FLEX

Implant Thickness
 (with 6mm PE)
19.1 EXT
18.1 FLEX

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ATTUNE Knee
 Fem. Size: 5 L
 Tib. Size: 4 L
 TMK00001
 Page 2 of 5

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)

Quick reference information appears on each page

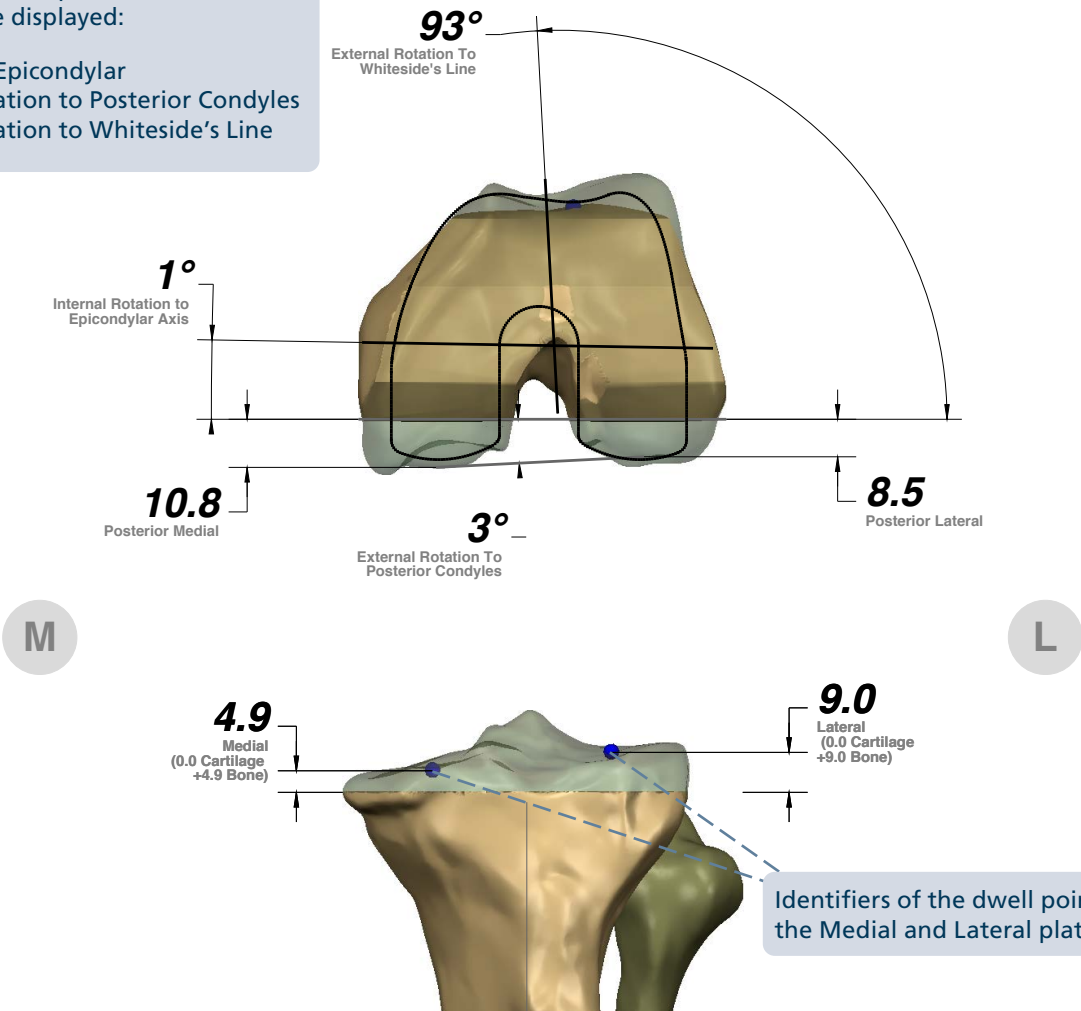
Patient Proposal Overview

Patient Proposal Review

Flexion

Three femoral component rotational references are displayed:

- Rotation to Epicondylar
- External rotation to Posterior Condyles
- External rotation to Whiteside's Line



Combined Bone Resections	
Medial	Lateral
13.9 EXT	14.9 EXT
15.7 FLEX	17.5 FLEX

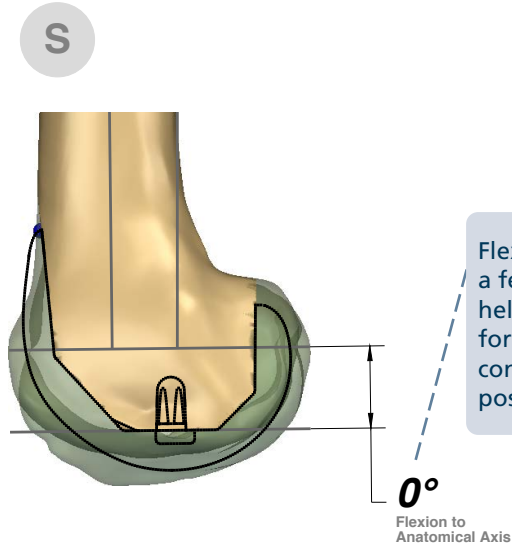
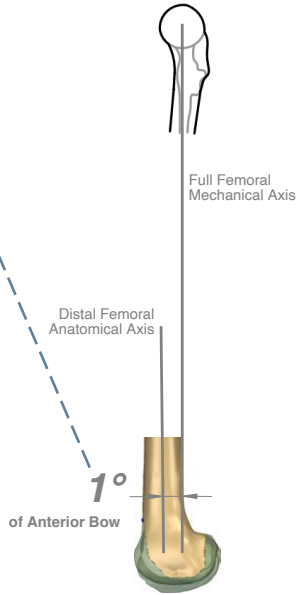
Implant Thickness (with 6mm PE)
19.1 EXT
18.1 FLEX

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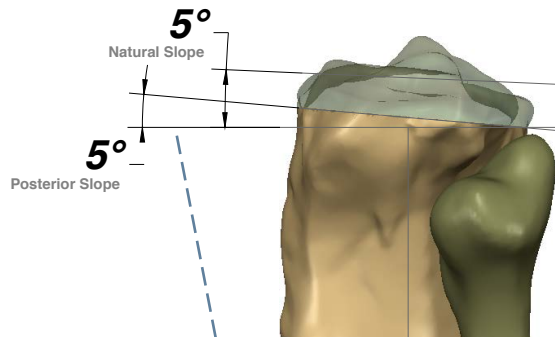
ATTUNE Knee
Fem. Size: 5 L
Tib. Size: 4 L
TMK00001
Page 3 of 5

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

Femoral Sizing and Lateral Alignment



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



Surgeon's preference for tibial slope

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ATTUNE Knee
Fem. Size: 5 L
Tib. Size: 4 L
TMK00001
Page 4 of 5

Patient Proposal Overview

Patient Proposal Review

Wall Chart - Summary

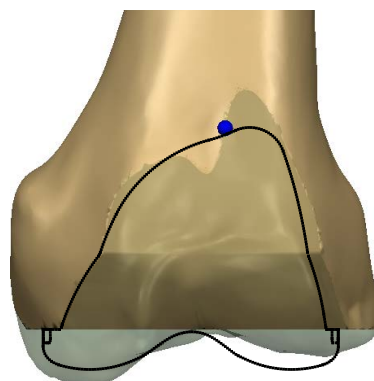
Sz 5 CR

PMF
10.8

PLF
8.5

DMF
9.0

DLF
5.9



Displays tibial resection profile

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

Displays tibial rotation and component coverage

MT
4.9

LT
9.0

Sz 4

References the medial 1/3 of the tibial tubercle

NOTE: Reference line is also replicated on the tibial guide to facilitate guide positioning

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

TRUMATCH® Personalized Solutions Product Code

Femoral/Tibia Cut or Pin	
Part #	Description
420578	TRUMATCH CT PIN GUIDE KIT L
420579	TRUMATCH CT PIN GUIDE KIT R
420580	TRUMATCH CT PIN GUIDE FEM L
420581	TRUMATCH CT PIN GUIDE FEM R
420582	TRUMATCH CT PIN GUIDE TIBIAL L
420583	TRUMATCH CT PIN GUIDE TIBIAL R
420915	TRUMATCH CT CUT GUIDE KIT L
420916	TRUMATCH CT CUT GUIDE KIT R
420917	TRUMATCH CT CUT GUIDE FEM L
420918	TRUMATCH CT CUT GUIDE FEM R
420919	TRUMATCH CT CUT GUIDE TIBIAL L
420920	TRUMATCH CT CUT GUIDE TIBIAL R

Femoral Cut Guide/Tibia Pin Guide	
Part #	Description
420906	TRUMATCH CT FEM CUT TIB PIN L
420907	TRUMATCH CT FEM CUT TIB PIN R

Plan-Only Option	
Part #	Description
431001	TRUMATCH CT PLAN ONLY

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
trumatchsupport@its.jnj.com

Office hours are M–F, 7:00 am–7:00 pm EST

Please refer to the indications for use for a complete list of indications, contraindications, warnings and precautions.



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700 Orthopaedic Drive
Warsaw, IN 46582
USA
Tel: +1 (800) 366-8143
Fax: +1 (800) 669-2530

DePuy Ireland UC
Loughbeg, Ringaskiddy
Co. Cork
Ireland
Tel: +353 2149 14 000
Fax: +353 2149 14 199

jnjmedicaldevices.com