

DRIVE

Case Management System

External User Manual Version 1.0

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1. Introduction

This document is intended to give the user a comprehensive overview of all the main functions and features of the DRIVE Case Management System and how to use them. This system is located at: www.drive.zimmerbiomet.com



Figure 1

2. DRIVE Overview

DRIVE Case Management System (DCMS) is a Zimmer Biomet Portal that will be the new location for case management of Materialise Personalized Guides for brands including:

- Persona® The Personalized Knee
- Vanguard® Knee
- NexGen® Complete Knee Solution
- Natural-Knee® System
- Oxford® Partial Knee
- Zimmer® Unicompartmental High Flex Knee*

DCMS is supported by all common web browsers (i.e. Google Chrome, Mozilla Firefox, Apple Safari, and Microsoft Internet Explorer v11). DCMS allows the Surgeon to access the surgical planner and approve cases, along with many other features. It combines the Signature™ Online Case Management and Zimmer Online Case Management Portals together, to provide one central location for internal and external Zimmer Biomet Personnel to access surgical cases.

Note: The many benefits of this web-based system include: global availability, no software installation required, and multiple user-interface capability including: PC, Mac, iPad, and tablet. Personal preferences (i.e. implants and instruments) are stored in the profile associated with the user's login.

* Not available in all countries.

2.1. Transfer Process and Credentialing

All Signature Online Management System (SOMS) and Zimmer Online Management System (ZOMS) users who have logged in at least once with credentials since January 2017 will be transferred to DCMS. There will be a onetime authentication process for each user upon registering. The authentication process will be necessary for every machine that the user logs on to. **Zimmer Biomet Sales Representatives will now be required to use Active Directory (AD) Accounts if they originally used an outside email address** (i.e. Gmail or Yahoo). All new users will need to reference Relationship HUB Documents for further registration instructions.

Relationships will be established based on current SOMS/ZOMS (i.e. Surgeon A linked to Sales Representative Team Member A).

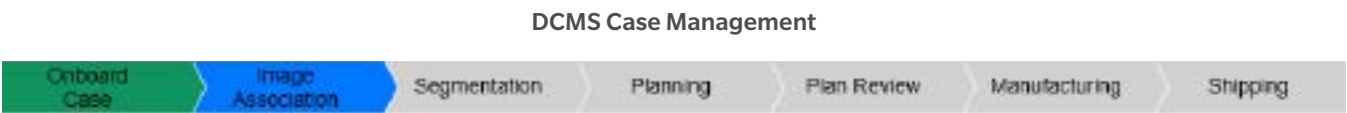


Figure 2

Note: Contact Customer Support at Personalized Solutions for any questions on scan sites, case questions, and how to use DCMS.

2.2. User Roles

Surgeons, Scan Technicians, and Patient Care Coordinators (PCCs) will have access to the DCMS Portal.

Materialise will be responsible for the “**Segmentation**,” “**Planning**,” “**Guide Design**,” “**Manufacturing**,” and “**Shipping**” (Figure 2).

Abbreviations

| | |
|-------------|--|
| DCMS | DRIVE Case Management System |
| CSR | Customer Support Representative |
| PCC | Patient Care Coordinator |
| NAM | North America |
| EMEA | Europe/Middle East/Africa |
| M3S | Materialise Medical Manufacturing System |
| APAC | Asia Pacific |
| PO | Purchase Order |
| MTLS | Materialise |
| SOMS | Signature Online Management System |
| ZOMS | Zimmer Online Management System |
| SCP | SurgiCase Planner |

2.2. User Roles (cont.)

Internal and External DCMS Authorization

| Surgeon | PCC | Scan Technician |
|--|---|--|
| <ul style="list-style-type: none">• Create Case• View Case• View Case List• Update Case• Update Case Cancel• Create Comment• View Comment• Create DICOM Study• View Plan• Update Plan Approve• Update Plan Save• Update Surgery Information• View Protected Health Information• Update Protected Health Information• Create Purchase Order-External• Update Purchase Order External• View Reports• View Logistics Information• View Shipping Information• Update Shipping Information | <ul style="list-style-type: none">• Create Case• View Case• View Case List• Update Case• Update Case Cancel• Create Comment• View Comment• Create DICOM Study• View Plan• Update Surgery Information• View Protected Health Information• Update Protected Health Information• Create Purchase Order-External• Update Purchase Order External• View Reports• View Logistics Information• View Shipping Information• Update Shipping Information | <ul style="list-style-type: none">• View Case• Create DICOM Study |

Figure 4

3. User Manual

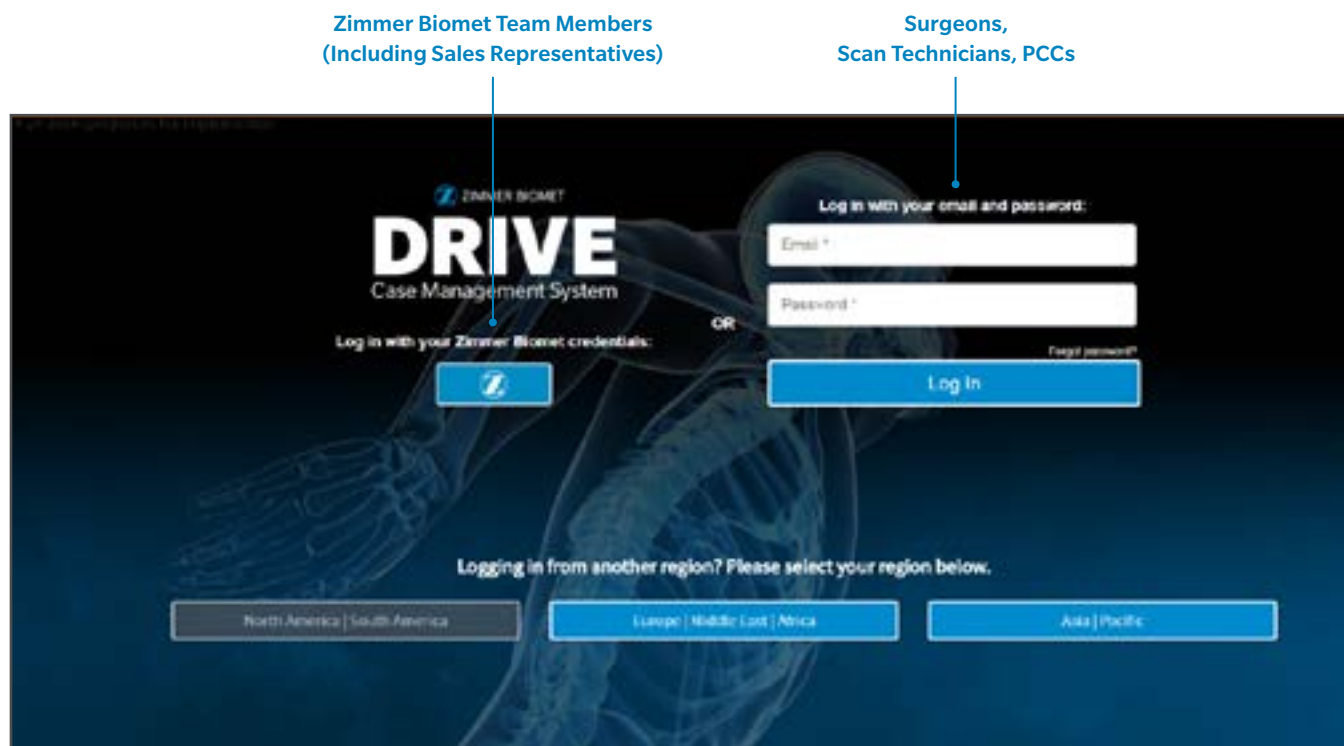


Figure 5

3.1. Logging On

Those who are non-Zimmer Biomet Personnel (i.e. Surgeons, Scan Technicians, and PCCs) will login with emails and passwords in the section located on the right side of the DRIVE Login Page (Figure 5).

Note: Corporate IT security and the industry best practice is to require two-factor authentication for accessing systems with confidential information (i.e. PHI – protected health information). You will need to:

- 1) Enter password
- 2) Get a verification code (text message)

Verification codes will expire after 10 minutes. If your code expires, you will need to request a new one. Select the “Back” button on the browser and re-login, and a new code will be sent.

Note: When traveling outside a user’s home region, the login will default to the geographic location where you are signing in from. The user will need to select a home region before logging in with credentials.

You should check the “Remember Me” box to avoid the two-step verification process every time you log in.

3.1. Logging On (cont.)

To access “Legal and Privacy Notices”:

- 1 Select “Legal & Privacy Notices” in the footer links (Figure 6).
- 2 Then, select the form or notice you would like.

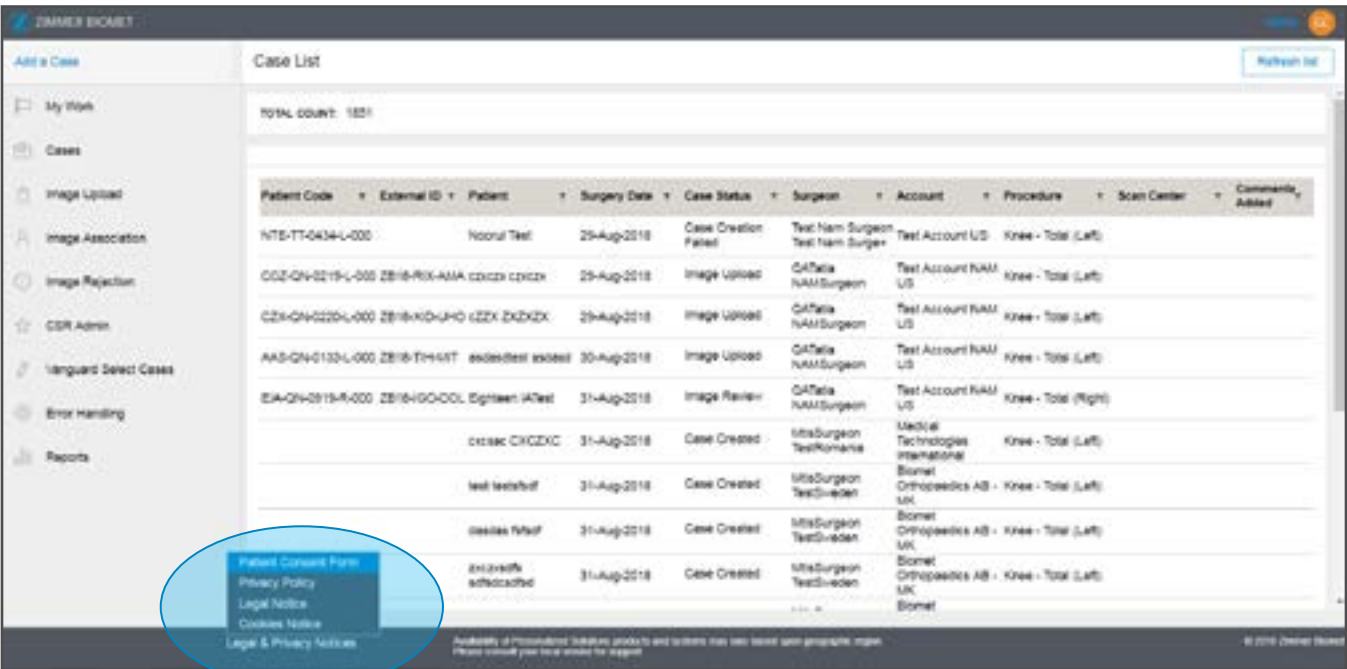


Figure 6

Legal & Privacy Notices

3.2. Creating a Case

DCMS Case Management



Figure 7

In Figure 7, green on the progress bar indicates a complete phase, blue indicates a current phase, and grey indicates a future phase to be completed.

Note: User permissions are based on regional requirements. For example, only the Surgeon and PCC can create cases in EMEA.

Once logged into the portal, a Surgeon or PCC can create a patient case.

To create case, a Surgeon or PCC should:

- 1 Select “Add a Case” function (Figure 8).
- 2 Select “Personalized Solutions” and search for Surgeon’s name and region.
- 3 Check the ‘Surgeons List’ and select “Open” when Surgeon’s name appears (Figure 9).
- 4 Select the “Continue” button at the bottom right-hand corner when the complete to move onto the next step.

Note: If the Surgeon logs in, step 1 will read: “Patient”

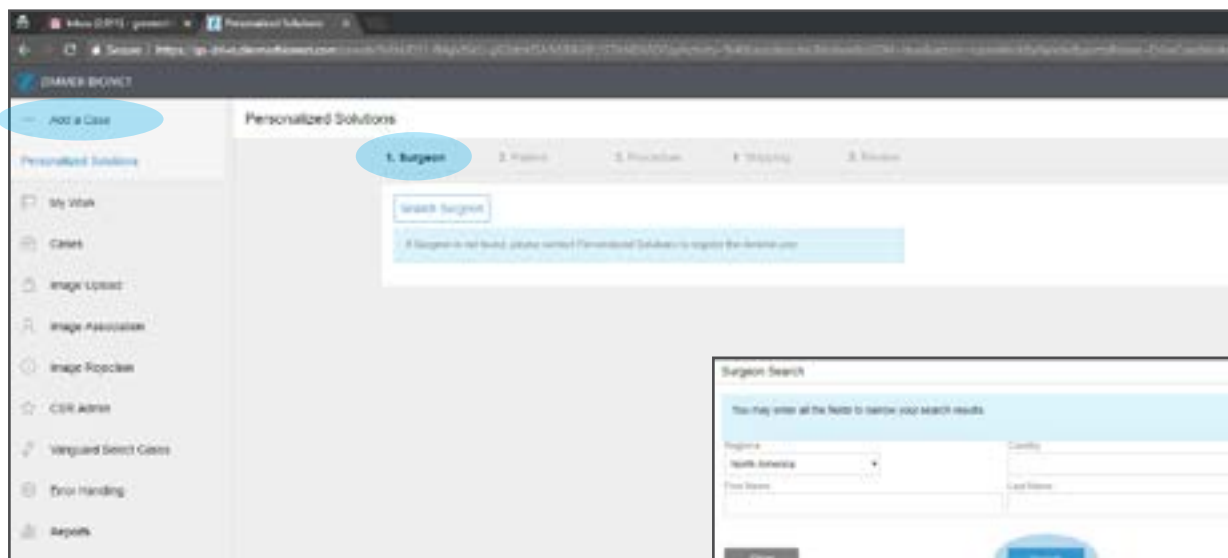


Figure 8



Figure 9

3.2. Creating a Case (cont.)

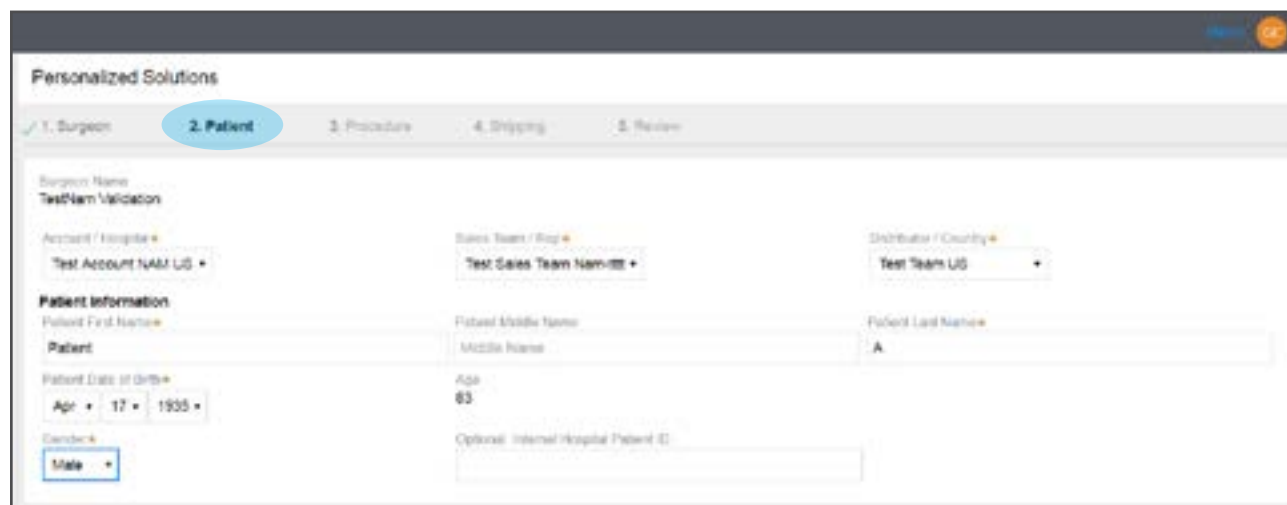
- 5 Fill out the patient information in step 2 (Figure 10). Then, select the “Account/ Hospital,” the “Sales Team/ Rep,” and the “Distributor/ Country” (indicated by *). Next, fill out the “Patient Information” section. The required fields in this section are as follows:

- Patient First Name
- Patient Last Name
- Patient Date of Birth
- Gender

The Patient Middle Name and Patient ID are optional fields.

When complete, select the “Continue” button at the bottom right-hand corner and move onto the next step.

To refer back to previous pages, select the “Back” button located at the bottom left-hand corner of each page.



The screenshot shows a web form titled "Personalized Solutions" with a progress bar at the top indicating five steps: 1. Surgeon, 2. Patient (highlighted), 3. Procedure, 4. Shipping, and 5. Review. The form is divided into sections. The "Surgeon Name" section includes a "TestName Validation" field and dropdowns for "Account / Hospital" (Test Account NAM US), "Sales Team / Rep" (Test Sales Team Nam000), and "Distributor / Country" (Test Team US). The "Patient Information" section includes fields for "Patient First Name" (Patient), "Patient Middle Name" (Middle Name), "Patient Last Name" (A), "Patient Date of Birth" (Apr 17 1935), and "Gender" (Male). There is also an "Optional: Internal Hospital Patient ID" field.

Figure 10

- 6 Fill out the procedure in step 3 (Figure 11). It is required to select:
- Body Side
 - Procedure
 - Surgery Date (Please note: a minimum of 20 business days is required for manufacturing)
 - Scan Center

After the “Body Side” is selected, the option to select “Bone Model” is available. Select either “MRI” or “CT” in order to select a Scan Center.

Note: By checking the “Bone Model” box, you indicate that you would like to receive a bone model with the patient case. If you order the Signature Vanguard Total Knee or Oxford Partial Knee, and you are located in a 100% bone model country (U.S., Australia, Israel, Canada, and New Zealand), then you will receive a bone model with the case, regardless if it was selected or not. Checking the “Vanguard Select (PSF)” indicates that you would like to receive a patient specific femur.

To refer back to previous pages, select the “Back” button located at the bottom left-hand corner of each page

When complete, select the “Continue” button at the bottom right-hand corner and move onto the next step.

3.2. Creating a Case (cont.)

Figure 11

- 7 In step 4, the default shipping address will appear as the distributorship address for the United States (NAM) and the country-specific locations for Canada (NAM), APAC, and EMEA (Figure 12). If you are located in US and would like to change the address, then you can do so at this time by overwriting on the following fields:

- Attention
- Name
- Country
- Street 1 (and possibly Street 2 and/or Street 3)
- State/Province
- City
- Zip Postal Code

Note: If you are located in Canada, APAC, or EMEA, this option is not available. It must go to the country-specific location address. In some countries, the shipping has been set to local Zimmer Biomet offices.

To refer back to previous pages, select the “Back” button located at the bottom left-hand corner of each page.

When complete, select the “Continue” button at the bottom right-hand corner and move onto the next step.

3.2. Creating a Case (cont.)

Personalized Solutions

✓ 1. Surgeon ✓ 2. Patient ✓ 3. Procedure **4. Shipping** 5. Review

Shipping Address

Address *

Test US Distributor

Name *

Test Team US

Country *

United States

Street *

332 E Bell Dr.

Street 2

Street 3

State/Province *

Indiana

City *

Warsaw

ZIP/Postal Code *

46082

Figure 12

8 In step 5, you can review the patient case (Figure 13). In this section, you can view the name of the Surgeon, Patient Information, and the Body Side Information. If you need to refer back to any of the previous pages, you can select the “Back” button located at the bottom left corner of each page.

Once the patient case is reviewed, select the “Continue” button at the bottom right-hand corner of the screen.

After a new patient case is created, anyone associated with the case will be emailed and notified.

Personalized Solutions

✓ 1. Surgeon ✓ 2. Patient ✓ 3. Procedure ✓ 4. Shipping **5. Review**

Surgeon Name

Test Nam Surgeon Test Nam Surgeon

Account / Hospital

Test Account US

Surgeon Team / Role

Test Sales Team NAM Demo

Distributor / Country

DEMO NAM US Distrib

Patient Full Name

Patient A

Patient Date of Birth

16-May-1936

Age

62

Gender

Male

Optional: Internal Hospital Patient ID

Body Side

Left

Procedure

Knee - Partial

Surgery Date

05-Apr-2019

Body Side Left

Figure 13

3.3. Image Upload Methods

CSRs will monitor the “Image Upload” function and will be notified when the image upload is past due. The Scan Center will be sent a three day advanced warning to upload the images, a one day warning, and an email one day after the images are uploaded. The Sales Representative will be copied on all three of the emails. The Surgeon will only be copied on the email in EMEA. The PCC will be copied on the post-upload email.

Three ways to get images to Zimmer Biomet Personalized Solutions:

- Direct Method (This is the preferred method by Zimmer Biomet)
- Mail in CD
- Web Uploader via Nuance Powershare

Direct Method can be uploaded via Laurel Bridge DICOM Router or via VPN. This is an already-in-place feature, and it is supported by Zimmer Biomet Personalized Solutions.

3.3.1. Setting Up the Direct Method

Initial steps include:

- 1 The Sales Representative contacts the targeted Scan Centers to start discussions and gathers contact information regarding the Scan Centers (i.e. name phone number, email, address, CT/MRI)
- 2 The Sales Representative contacts Personalized Solutions Customer Support Team at: personalizedsolutions@zimmerbiomet.com / 574-371-3710 and provides them the Scan Center Contact Information.

The PS Picture, Archive and Communications System (PACS) Support Team Process includes:

- 1 Scan Center Contact Information are provided to PS PACS Support Team to initialize set up.
- 2 An initial introduction e-mail sent to the provided contact person outlining the two primary ways preferred to receive images (VPN or Laurel Bridge/Compass).
- 3 If the site is not comfortable with either of those options – a call is scheduled to discuss other secure ways to send the images that are compliant with local laws and regulations.
- 4 Once the connection is established, the test images are sent in for Customer Service to review.

3.3. Image Upload Methods (cont.)

3.3.2. Image Upload Steps within DCMS

If you are transferring images, indicate how you intend to transfer those images to Zimmer Biomet (Figure 14).

- Option 1:** Direct Method - Images are sent via Laurel Bridge or VPN.
- Option 2:** CD - Images are burnt on a disc and mailed to Personalized Solutions at:
Zimmer Biomet
Attention: Personalized Solutions, Building D
56 E Bell Drive
Warsaw, IN 46582 (send via UPS or FedEx).

Option 3: Web Uploader - User selects the “Nuance” button.

A CSR will need to associate the images once the images have been uploaded. This will be completed within 24 hours of the status changed to “Image Association.”

Upload Image

Due in 12 days ago

Please indicate the method by which images have been uploaded to Zimmer Biomet.

Option 1 : Direct Method
By selecting this option, you are indicating that images have already been sent directly to Zimmer Biomet via a VPN connection or Laurel Bridge

Option 2 : CD
By selecting this option, you are indicating that images have been mailed to Zimmer Biomet via CD. (Note: Not Available in EMEA)

Option 3 : Web Uploader
By selecting this option, you are indicating that images have been sent to Zimmer Biomet via the Nuance PowerShare web uploader. Click the below icon to access the web uploader



☐ Option 1 : Direct Method

☐ Option 2 : CD

☐ Option 3 : Web Uploader

Cancel

Submit

Figure 14

3.4. Case Lists

3.4.1. Menu Bar

The menu bar is located to the left-hand side of the screen (Figure 15). The work baskets within the menu bar are listed as:

- **My Work:** Requires the specific user logged in to take action
- **Cases:** Shows all of the active cases (some may require action, and others may not)
- **Image Upload:** All of the cases in the image upload status (a user will need to take action)
- **Reports:** How one accesses closed and cancelled cases

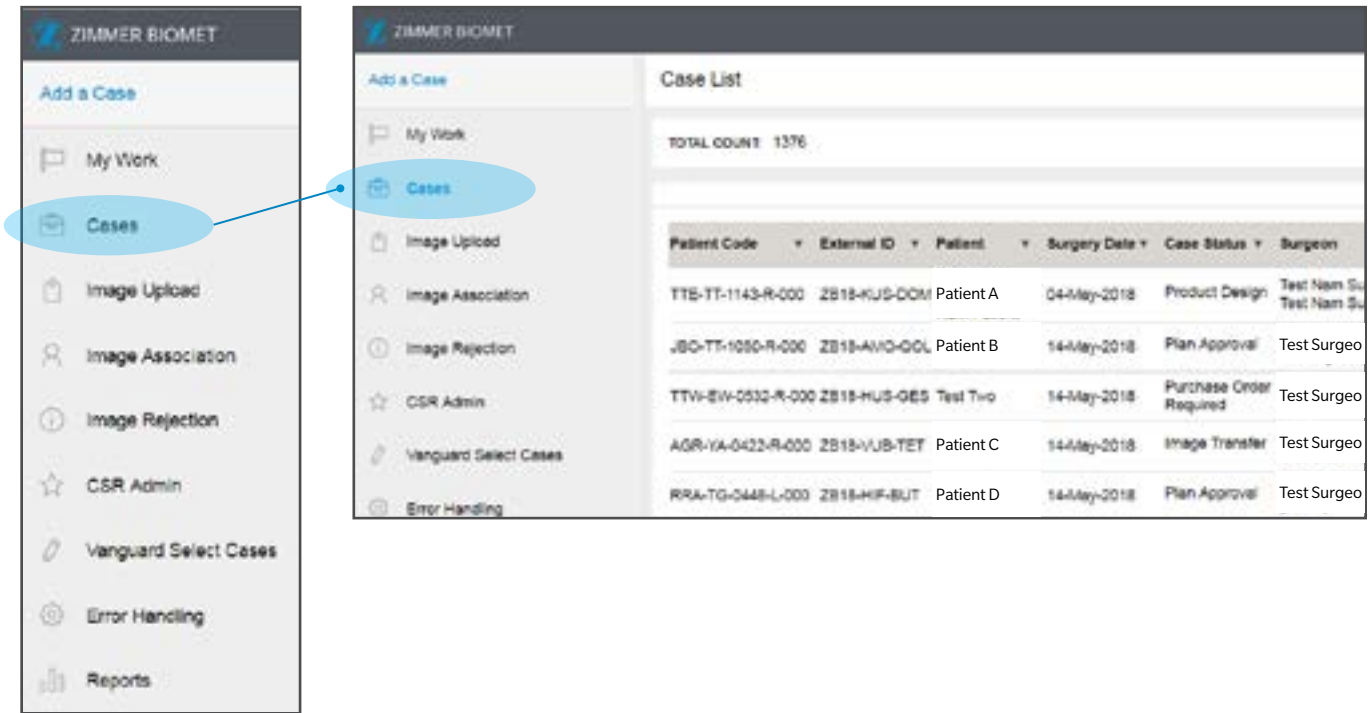


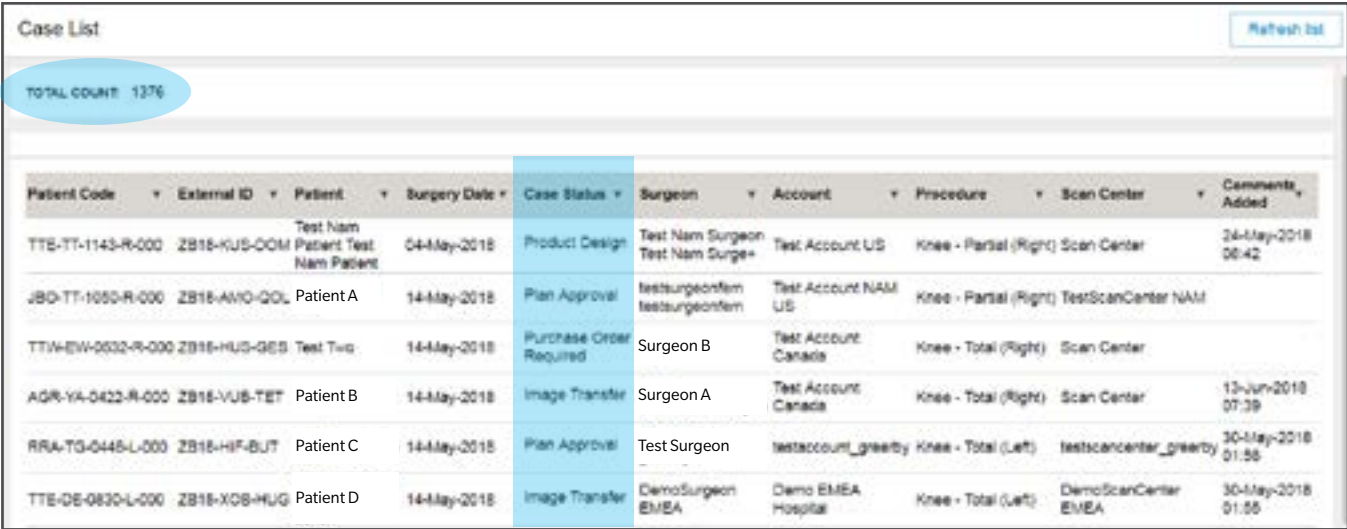
Figure 15

3.4. Case Lists (cont.)

3.4.2. Case Statuses

The Patient Code, External ID, the Name of the Patient, Surgery Date, Case Status, Surgeon, Account, Procedure, and Scan Center are all visible (Figure 16). You can select a patient’s information to pull up a case and view/edit the case details. You can also select any of the arrows next to the titles to make specific searches. See Figure 18 for location of arrows (indicated by the red box). As a Surgeon or PCC, you may select a patient’s information to pull up a case and view/edit the case details. Scan Technicians can only see the case lists. Refer to Figure 16 for all “Case Status” definitions.

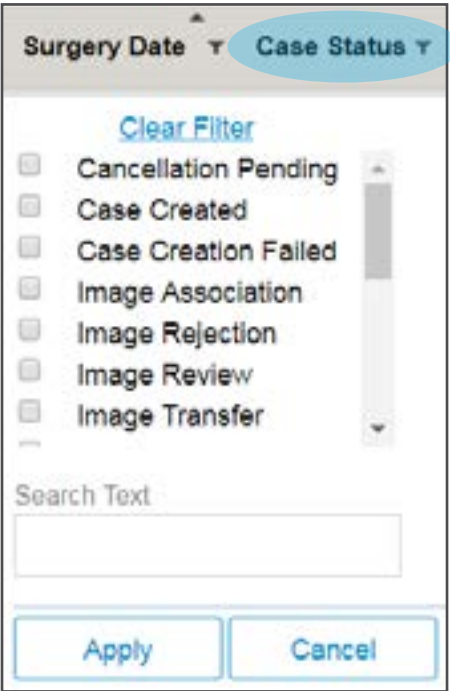
A total count for the number of cases in each work basket is located at the upper-left of corner of the page.



| Patient Code | External ID | Patient | Surgery Date | Case Status | Surgeon | Account | Procedure | Scan Center | Comments Added |
|-------------------|--------------|-----------------------------------|--------------|-------------------------|-----------------------------------|---------------------|------------------------|------------------------|-------------------|
| TTS-TT-1143-R-000 | ZB15-KUS-00M | Test Nam Patient Test Nam Patient | 04-May-2018 | Product Design | Test Nam Surgeon Test Nam Surgeon | Test Account US | Knee - Partial (Right) | Scan Center | 24-May-2018 00:42 |
| JBO-TT-1050-R-000 | ZB15-AVO-GOL | Patient A | 14-May-2018 | Plan Approval | testsurgeonfem testsurgeonfem | Test Account NAM US | Knee - Partial (Right) | TestScanCenter NAM | |
| TTW-EW-0032-R-000 | ZB15-HUS-GES | Test Two | 14-May-2018 | Purchase Order Required | Surgeon B | Test Account Canada | Knee - Total (Right) | Scan Center | |
| AGR-YA-0423-R-000 | ZB15-VUS-TET | Patient B | 14-May-2018 | Image Transfer | Surgeon A | Test Account Canada | Knee - Total (Right) | Scan Center | 13-Jun-2018 07:39 |
| RRR-TG-0445-L-000 | ZB15-HIF-BUT | Patient C | 14-May-2018 | Plan Approval | Test Surgeon | testaccount_greerby | Knee - Total (Left) | testscancenter_greerby | 30-May-2018 01:55 |
| TTE-DE-0830-L-000 | ZB15-XOS-HUG | Patient D | 14-May-2018 | Image Transfer | DemoSurgeon EMEA | Demo EMEA Hospital | Knee - Total (Left) | DemoScanCenter EMEA | 30-May-2018 01:55 |

Figure 16

As a Surgeon or PCC, you can select the arrow next to “Case Status” or any of the fields on the bar to filter through the cases for a specific case search (Figure 18). You can select any of the categories that pertain to your search, or you can type in key words into the “Search Text” box and select “Apply” (Figure 17).



Surgery Date **Case Status**

Clear Filter

- ☐ Cancellation Pending
- ☐ Case Created
- ☐ Case Creation Failed
- ☐ Image Association
- ☐ Image Rejection
- ☐ Image Review
- ☐ Image Transfer

Search Text

Apply Cancel

Figure 17

3.4. Case Lists (cont.)

3.4.2. Case Statuses (cont.)

| External Case Status | Description |
|------------------------|---|
| Case Created | Case has been added to the system |
| Image Upload | Images need to be uploaded for the case |
| In Process | Images have been uploaded and case in In Progress with Materialise |
| e-Manufacturing | The case has moved to 3D Reconstruction and Planning in M3S |
| Plan Pending Signature | <p>The plan has been approved in SurgiCase Planner and requires Surgeon electronic signature to finalize the approval</p> <p><i>Note: If case status changes to e-Manufacturing after the signature has been entered, it means that the PO still needs to be entered before the case can proceed.</i></p> |
| Manufacturing | The case is in the Design & Manufacturing stage in M3S |
| Shipped | Manufacturing has completed and the case has been shipped |
| Closed | The case has been shipped and delivered and is closed |
| Cancellation Pending | The case is awaiting confirmation from Materialise that the case can be cancelled |
| Cancelled | The case has been cancelled |

Figure 18

3.5. Editing a Case

Limited patient case information can be changed up until manufacturing (Figure 19). To edit a case:

- 1 Select “Cases” function, select case for edit, and then select the “Actions” drop down menu in the top right corner.
- 2 Select “Edit Case Details” in the drop down menu.
- 3 Then, edit or cancel the case. Editable information depends on your position within the case approval process.

There are multiple fields displayed. As a Surgeon or PCC, you can:

- Enter the Purchase Order (PO)
- Change the Account
- Enter the Patient ID
- Change the Procedure and Surgery Dates
- Change the Bone Model

“Actions”
drop down menu

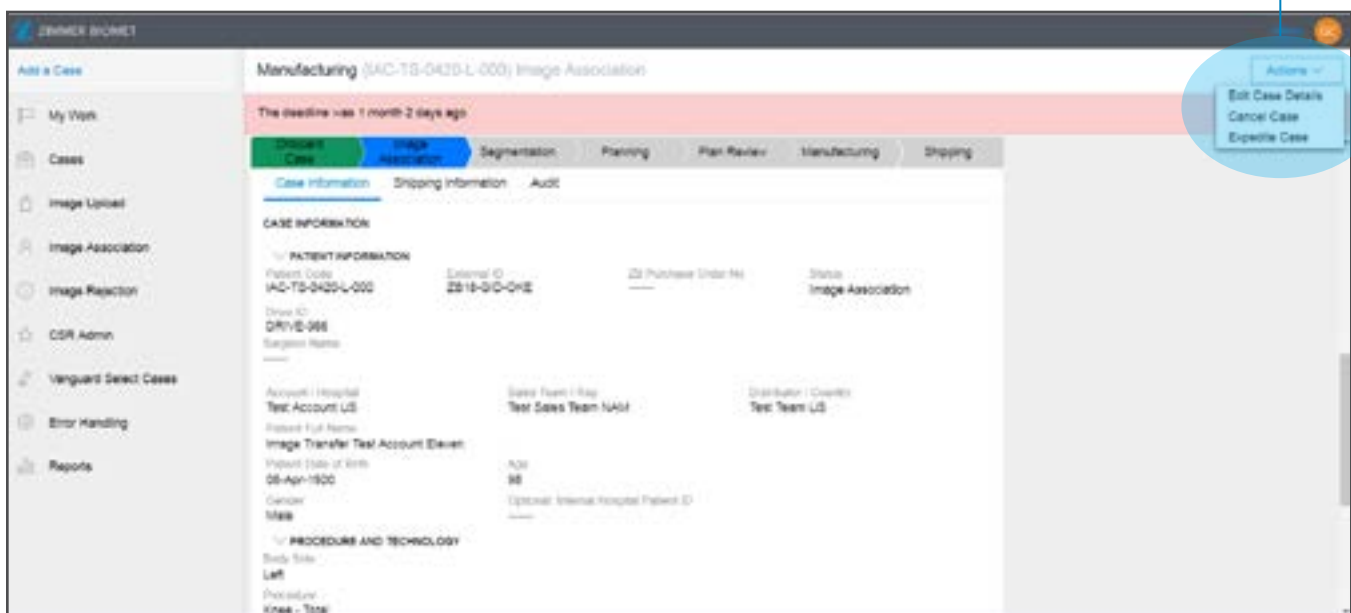


Figure 19

3.5. Editing a Case (cont.)

3.5.1 Entering a Purchase Order

The Purchase Order (PO) Number is required to manufacture the surgery guides (Figure 20). If a plan is approved without a PO, the case will not progress until the PO is provided. A Zimmer Biomet Customer Support Team Member may contact the Sales Representative to obtain the correct PO number if PO has not been entered in a timely manner.

Figure 20

3.5.2. Changing the Surgery Date

As a Surgeon or PCC, you can edit the surgery date by selecting the fields under “Surgery Date” (Figure 21). The surgery date availability date is agreed upon via system logic with Zimmer Biomet and Materialise. A warning will be displayed if the surgery date is not feasible.

If images are uploaded after the due date, the Surgeon will be sent an automated email notifying them that the surgery date was rescheduled to the earliest next available date. The Sales Representative will be copied on this email.

Figure 21

3.5. Editing a Case (cont.)

3.5.3. Changing the Procedure

The procedure type can be edited, and it is located under “Procedure” (Figure 22). As a Surgeon, you can change the procedure type up until the plan is approved.

Note: Changing a procedure in DCMS will be limited once the case has been created; but it can be changed in the SurgiCase® Planner until the plan has been approved. Once a plan is approved, the procedure cannot be changed.

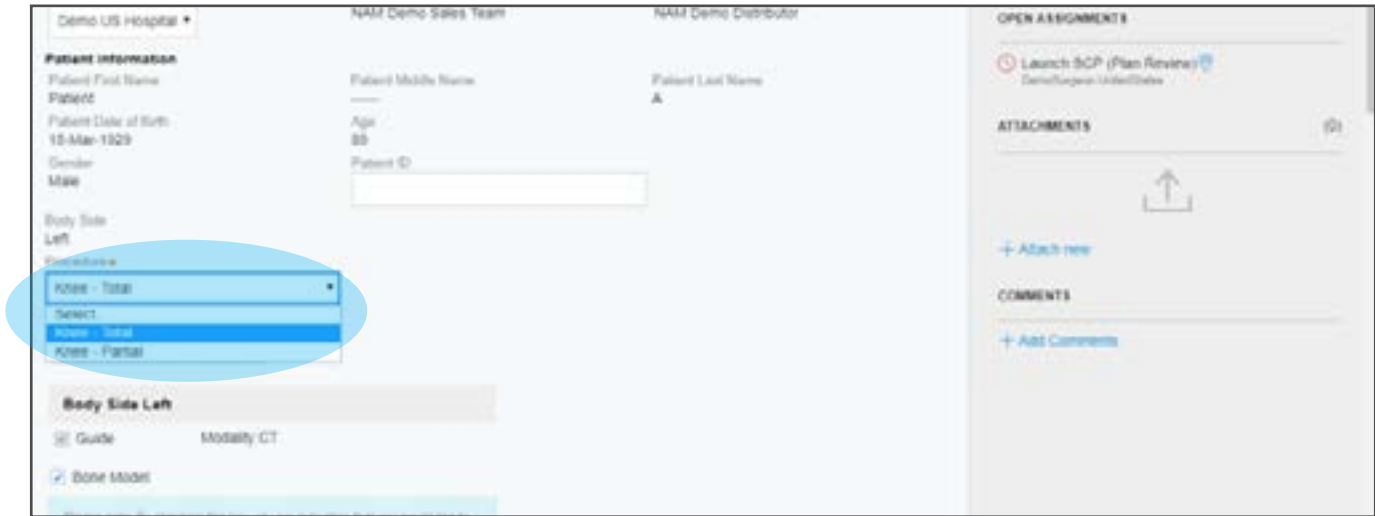


Figure 23

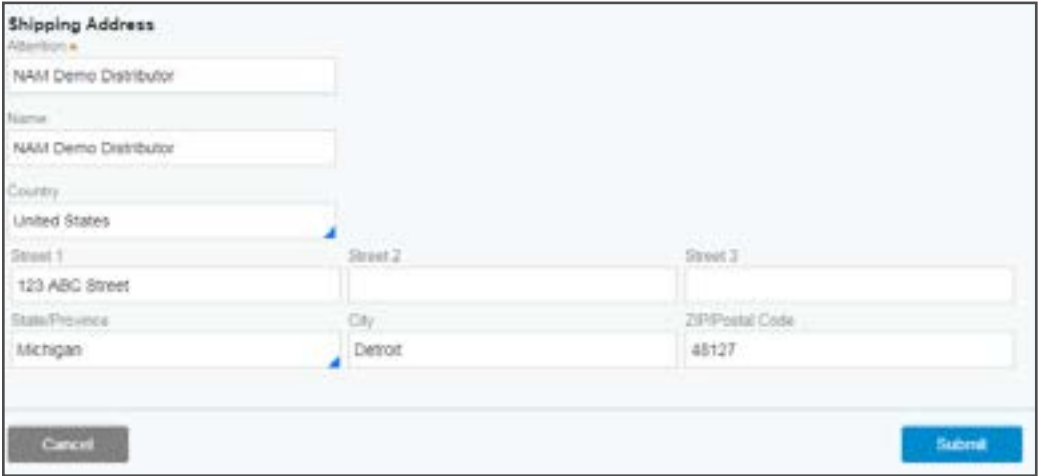
Note: This includes changes for surgical procedures, not surgical preferences (i.e. cut blocks). To change Surgeon preferences, access SurgiCase Planner within the planner software.

3.5. Editing a Case (cont.)

3.5.4. Viewing/Changing Shipping Information

By design, shipping addresses will default to the distributorship address for the United States (NAM) and the country’s specific location for EMEA and APAC (Figure 23). Due to logistical optimization, this cannot be changed for Canada (NAM), EMEA, or APAC. If you are located in the United States, you can change the shipping address in the “Edit Case Details” function up until manufacturing.

Sales Representatives will be sent an email once the product has shipped, and PCCs will be copied on that email. The shipping tracking number will be a hyperlink within the email.



The screenshot shows a web form titled "Shipping Address". It contains several input fields for address information. The "Attention" field is set to "NAM Demo Distributor". The "Name" field is also set to "NAM Demo Distributor". The "Country" dropdown menu is set to "United States". The "Street 1" field contains "123 ABC Street". The "Street 2" field is empty. The "Street 3" field is empty. The "State/Province" dropdown menu is set to "Michigan". The "City" field contains "Detroit". The "ZIP/Postal Code" field contains "48127". At the bottom of the form, there are two buttons: "Cancel" and "Submit".

Figure 23

3.5. Editing a Case (cont.)

3.5.5 Adding/Viewing Comments and Attachments

To add a comment, as a Surgeon or PCC:

- 1 Select “Add/View Comments” button located at the lower right-hand corner (Figure 24).
- 2 Type their public or private comments into the text box (Figure 25).
- 3 Select “Post” on the left-hand side.

To view a comment, as a Surgeon or PCC:

- 1 Select “Add/View Comments” button located at the lower right-hand corner (Figure 24).
- 2 View comments located at the bottom of the screen (Figure 25)

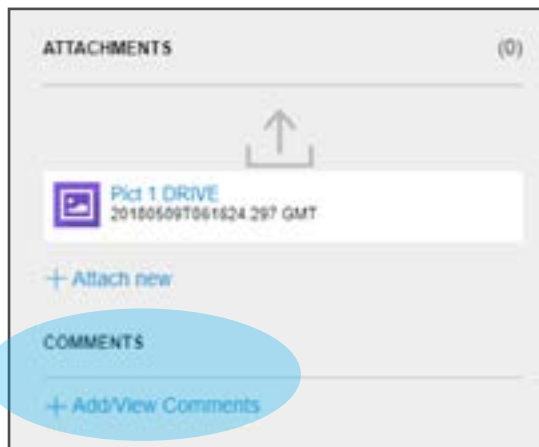


Figure 24

Note: Private comments are for internal communications between the Zimmer Biomet Team and Materialise Customer Support. Public comments are communications for anyone who has access to the case. The comments section will automatically default to private comments (Figure 25).

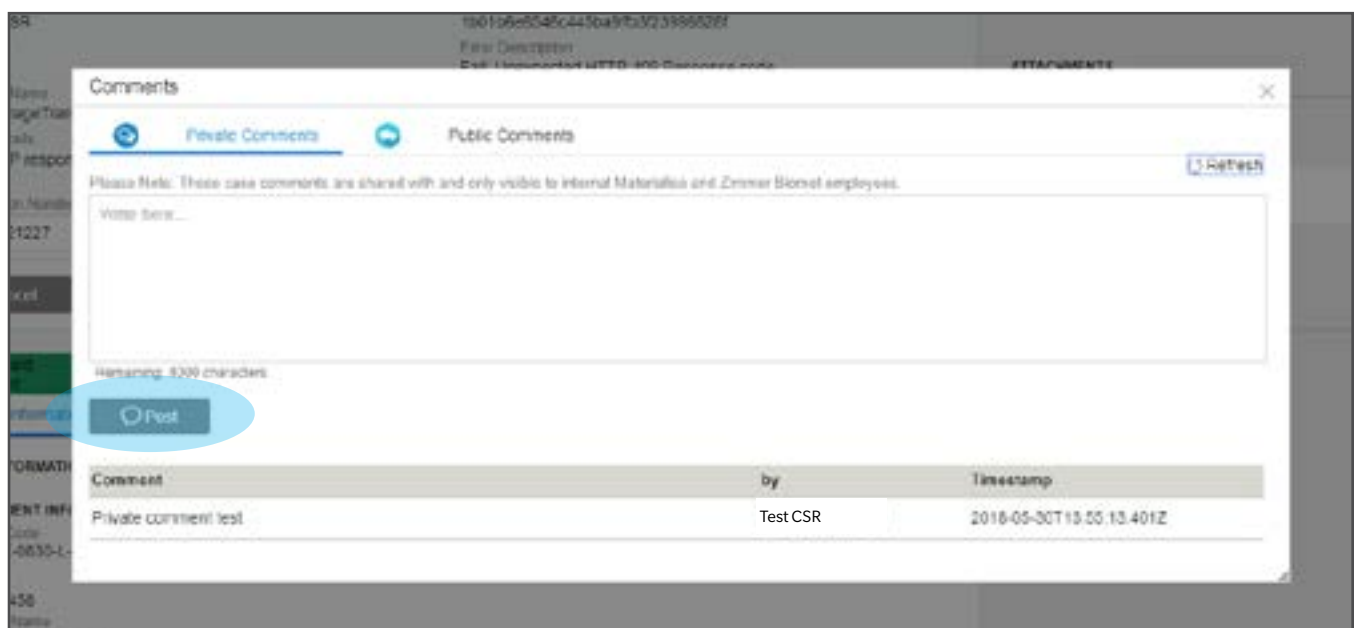


Figure 25

3.5. Editing a Case (cont.)

3.5.5 Adding/Viewing Comments and Attachments (cont.)

To add attachments to a case, as a Surgeon or PCC:

- 1 Select the “Attach new” button located in the lower right-hand corner (Figure 26).
- 2 Select either “File from device” or “URL” to attach file.



Figure 26

- 3 For “File from device” option: either select “Select file(s)” or drag the file to “Drag and drop files here” (Figure 27).

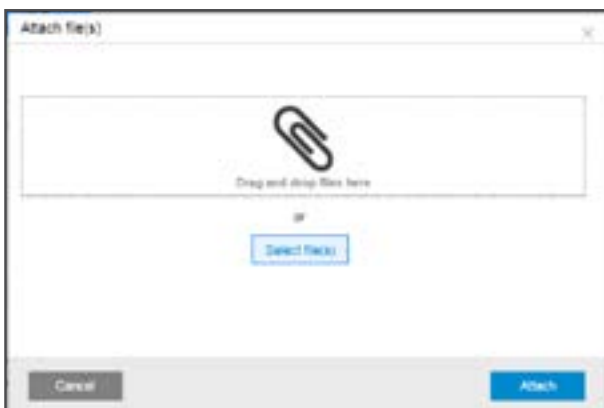


Figure 27

- 4 For “URL” option: type in a subject under “Subject” and type in a URL under “URL” (Figure 28) and select “Submit.” Both fields are required.



Figure 28

3.6. Cancelling Cases

As a Surgeon or PCC, you have the ability to cancel a case and will select “Cancel Case” from the drop down menu on the right side of the screen, if you wish to cancel a case (Figure 29).

When a cancelled case is in the “Image Upload” phase, the Scan Technician will be notified. The Sales Representative, Surgeon, and PCC will be copied on the email. A case may be cancelled up until manufacturing.

To cancel a case:

- 1 Select **required** reason for cancellation from the drop down menu (Figure 30).
- 2 Select “Submit.”
- 3 MTLS will be notified that a request for cancellation has been submitted. MTLS will be responsible for accepting or rejecting the request for cancellation. The case will remain open until MTLS has accepted the cancellation.

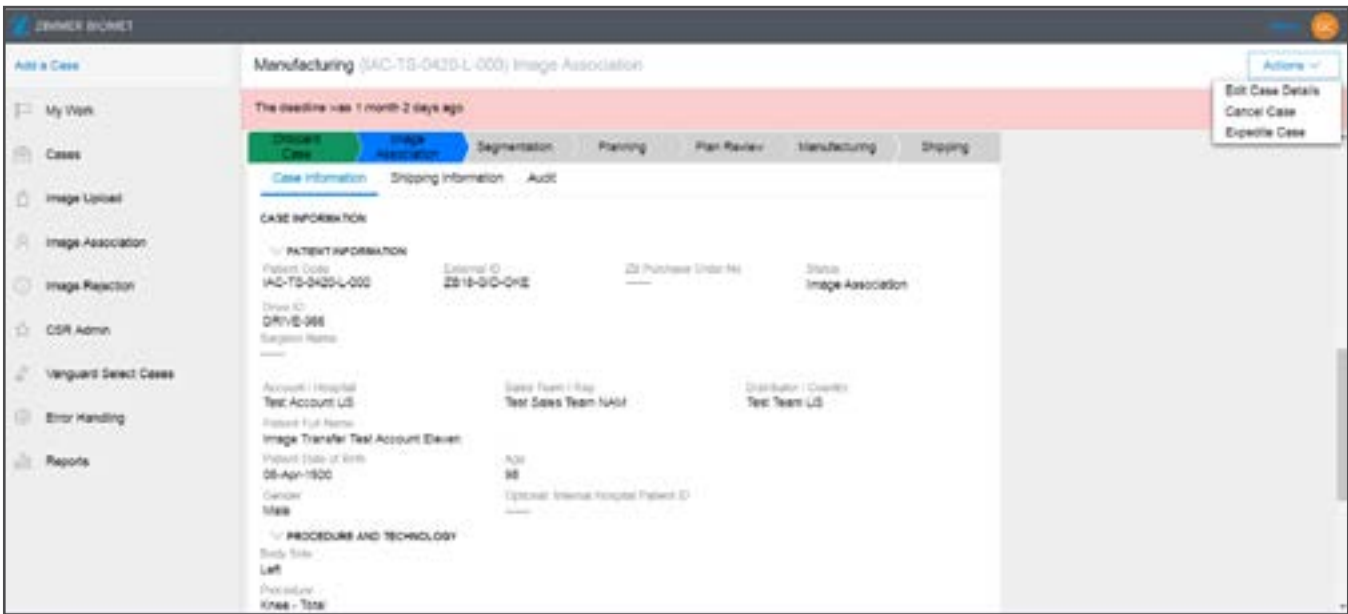


Figure 29

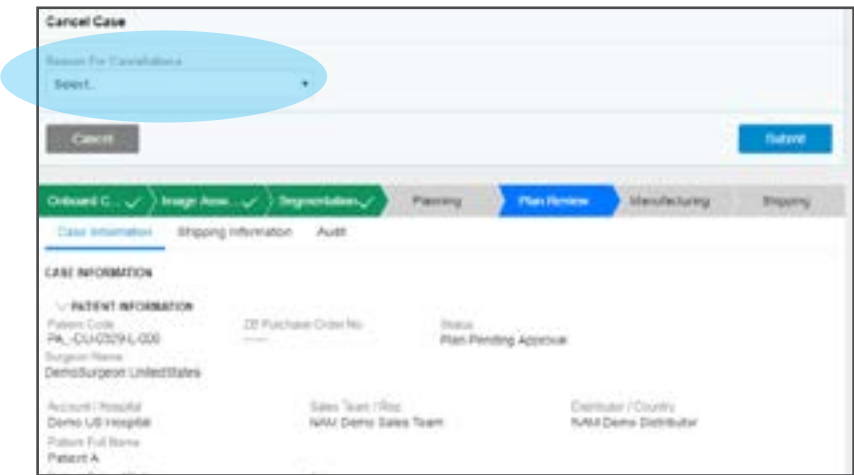


Figure 30

3.7. Approving a Case

3.7.1. Launch Web Planner

The Web Planner (e.g. SurgiCase Planner) can be launched when it is time to view the patient case plans (Figure 31). The Surgeon and PCC will have access to the SurgiCase Planner.

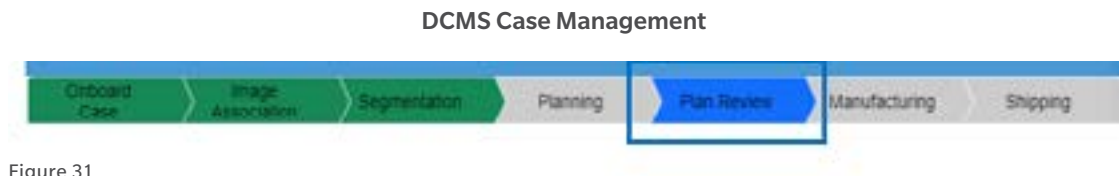


Figure 31

- 1 Select “My Work” (Figure 32).

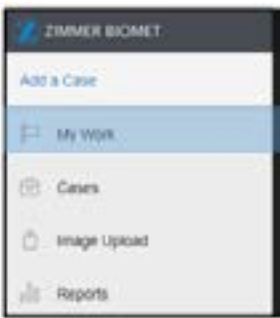


Figure 32

Select chosen patient information line (Figure 33).

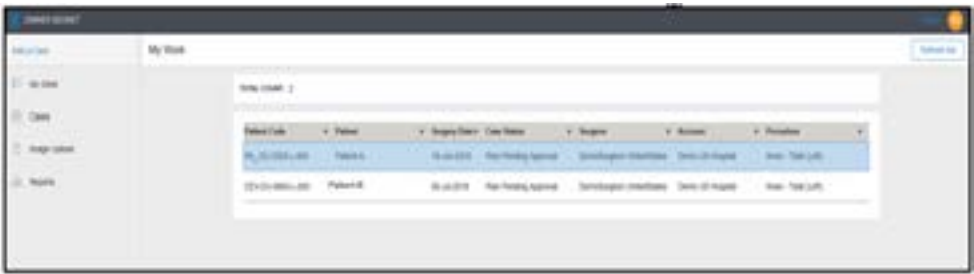


Figure 33

- 2 Select “Actions” > “Review Plan” (Figure 34).



Figure 34

3.7. Approving a Case (cont.)

3.7.1. Launch Web Planner (cont.)

- 3 Select “Click Here to Launch Web Planner” to launch the SurgiCase Planner (Figure 35).

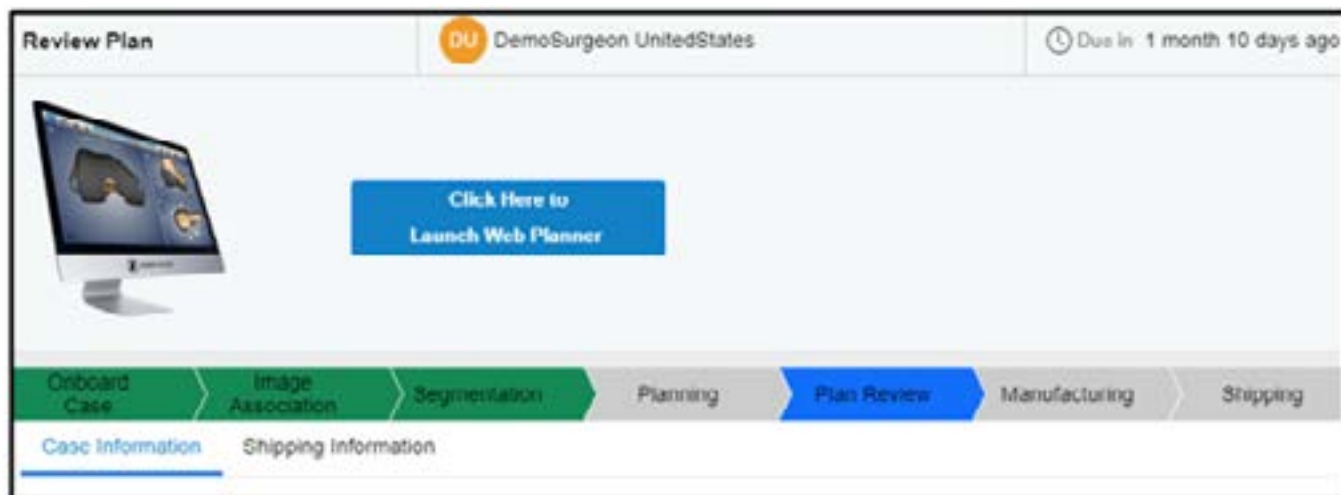


Figure 35

3.7.2. How to Approve a Case

Only a Surgeon has the ability to approve a case. Please note: due to IT, Compliance, and Regulatory requirements, all cases must be approved by a Surgeon regardless of the legacy system, **the default approval option is no longer available.**

The Surgeon will be sent an email notification when a case is ready for approval and requires an e-signature. The Sales Representative and PCC will be copied on these emails. Another email will be sent to the Surgeon if the case approval needed to be re-evaluated and is ready for the Surgeon to approve again. The Sales Representative and PCC will also be copied on this email.

3.7. Approving a Case (cont.)

3.7.2. How to Approve a Case (cont.)

Please see SurgiCase Planner Manual for detailed instructions. If you are a Surgeon:

- 1 Within the SurgiCase Planner, apply modifications, then select “Approve Plan” (Figure 36).

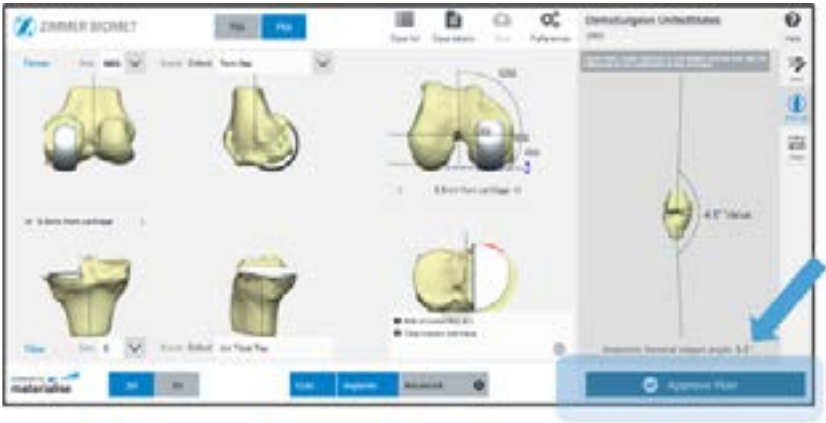


Figure 36

Once you have selected “Approve Plan,” a warning will appear on the screen if you need to look over the plan again (Figure 37).



Figure 37

Once you select “Approve,” you will be routed to the screen below.

Note: It is very important that you allow the screen to load and does not exit out of the page, so that you can be taken to the next phase of approval (Figure 38).



Figure 38

3.7. Approving a Case (cont.)

3.7.2. How to Approve a Case (cont.)

- 2 You will be taken back to “Case Details” (Figure 39).



Figure 39

- 3 You will select “Actions” > “Capture Signature” (Figure 40).



Figure 40

- 4 You will enter password, and select “Submit Signature” button. Your email address will be pre-populated (Figure 41).

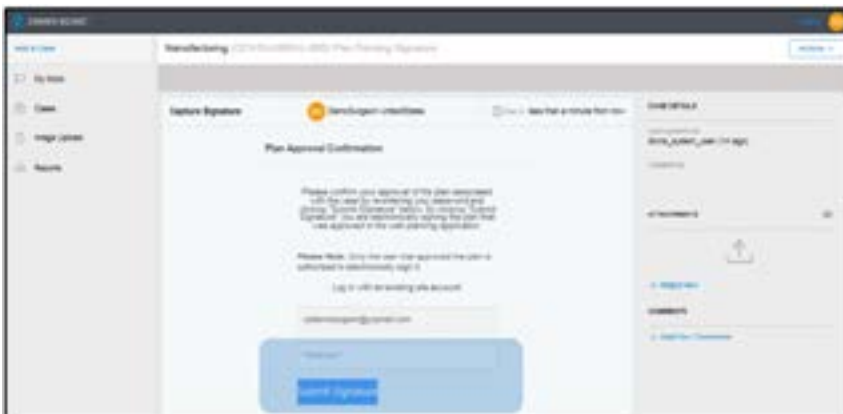


Figure 41

3.7. Approving a Case (cont.)

3.7.2. How to Approve a Case (cont.)

Once you select the “Submit Signature” button, you will be taken back to patient’s information page. You will need to submit a captured signature, which is located at the top of the page (Figure 42).

The image shows a web-based interface for capturing a signature. At the top, there is a header bar with three sections: 'Capture Signature' on the left, a user profile section in the middle showing a yellow circular icon with 'DU' and the text 'DemoSurgeon UnitedStates', and a clock icon on the right with the text 'Due in less than a minute from now'. Below the header is a large, empty rectangular area for capturing the signature. At the bottom of the modal, there are two buttons: a grey 'Cancel' button on the left and a blue 'Submit' button on the right.

Figure 42

Note: You must enter your password to approve a case due to FDA CFR part 11 electronic signature requirements. If you select approve, but do not enter a password, the CASE IS NOT APPROVED, and you will receive an email notifying you that the case is awaiting an electronic signature. You will receive a notification an hour after you do not finish the approval process.

3.7. Approving a Case (cont.)

3.7.3. Surgeon PDF

The Surgeon and PCC can access the Surgeon PDF via DCMS. The Surgeon PDF is located under attachments on the right-hand side of the screen (Figure 43). Surgeon PDFs will now show any changes made to the case.

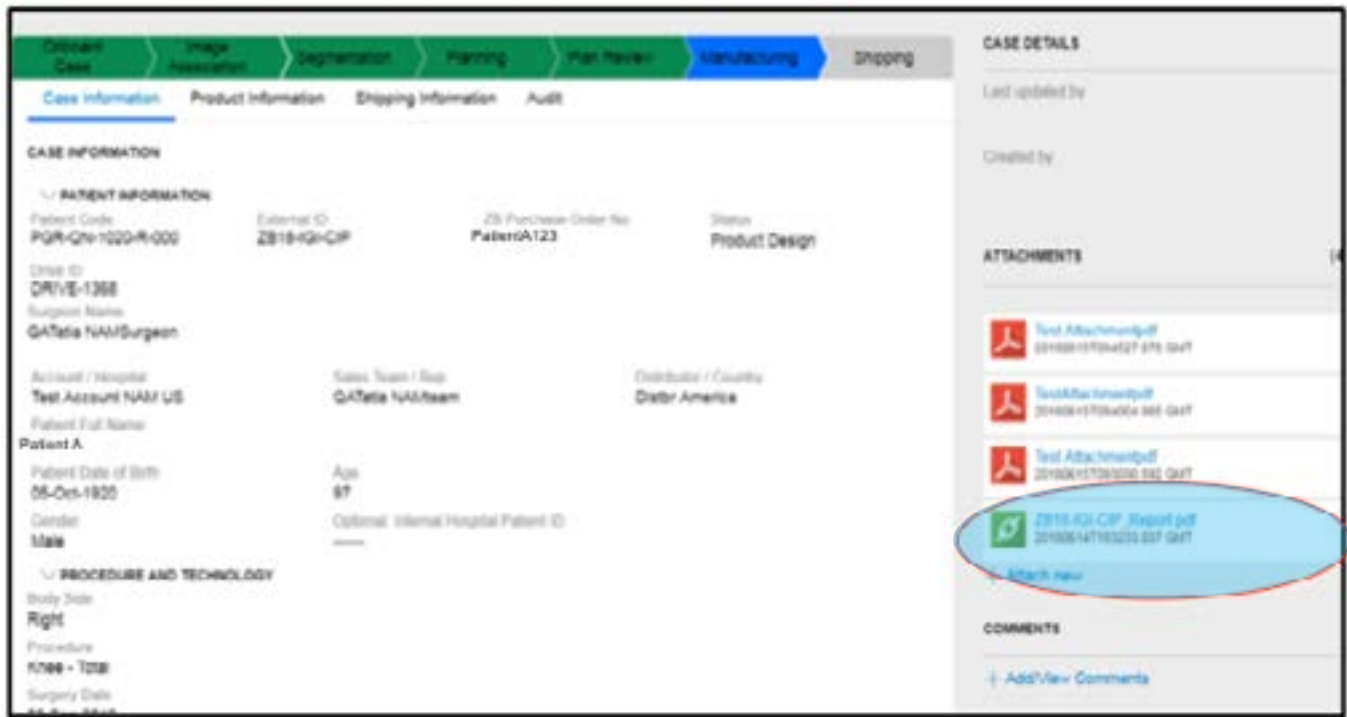


Figure 43

3.7. Approving a Case (cont.)

3.7.3. Surgeon PDF (cont.)

An example of the new Surgeon PDF format is featured below (Figures 44 and 45).

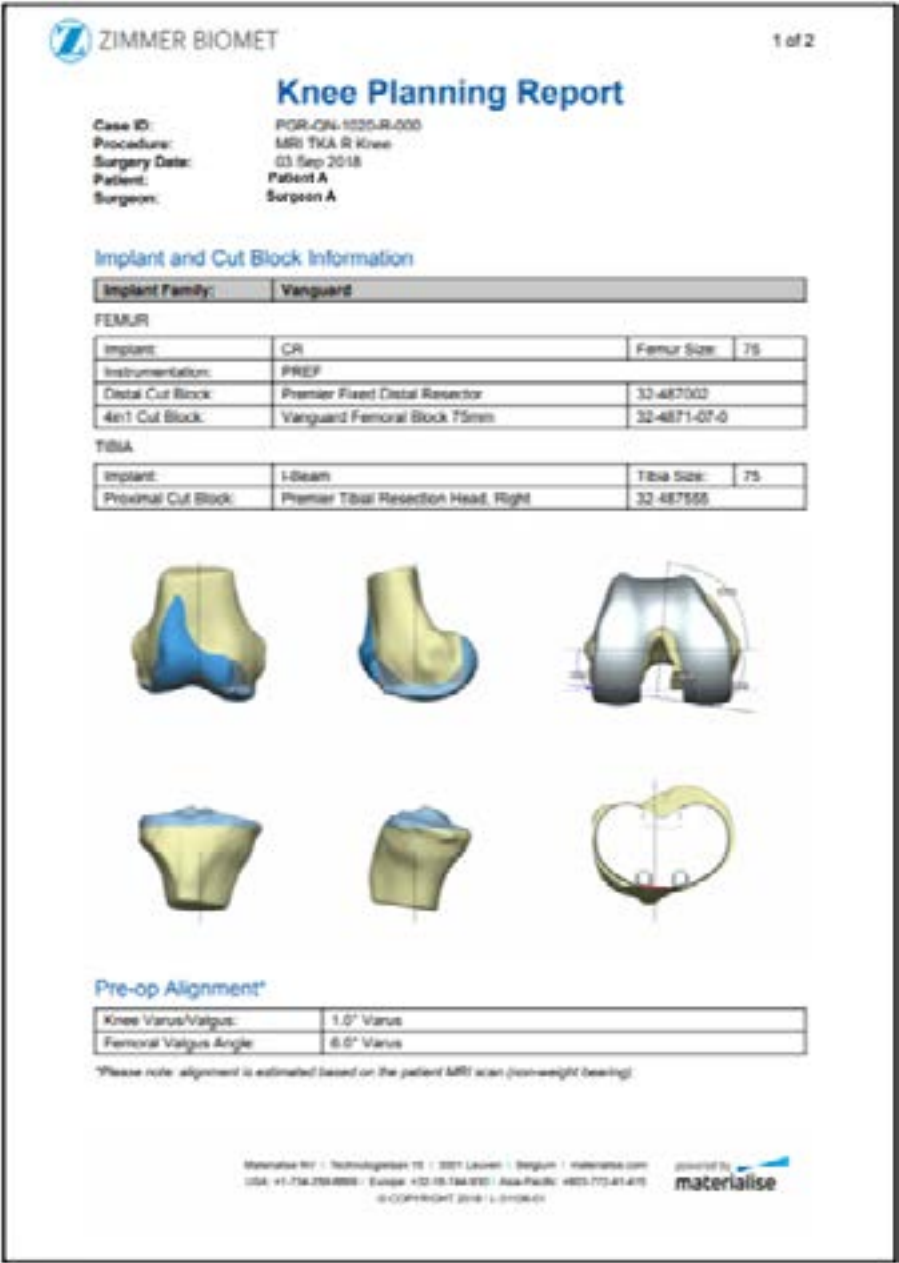


Figure 44

3.7. Approving a Case (cont.)

3.7.3. Surgeon PDF (cont.)

An example of the new Surgeon PDF format is featured below (Figures 44 and 45).

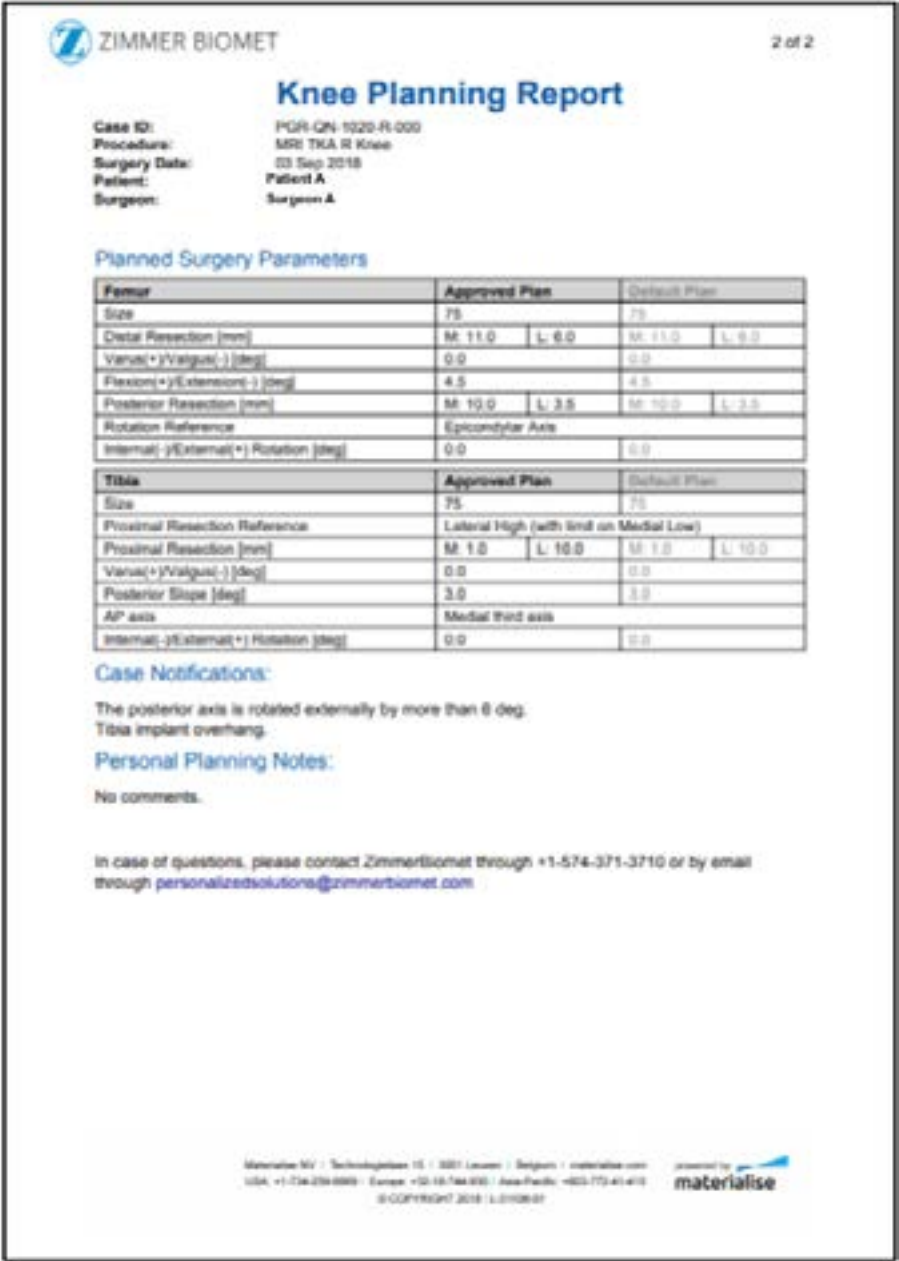


Figure 45

3.7. Approving a Case (cont.)

3.7.4. Post Approval

Surgeons and PCCs can select the “Cases” function and select a case. This will provide the case details that have been updated to include the product information. The “Product Information” tab is present on the case but only gets populated with data once the Surgeon approves the case, and it is in product design (Figure 46).

Note: The Surgeon can navigate to case information, product information, shipping information, and audit (case history).

Onboard CaseImage AssociationExceptionSegmentationPlanningPlan ReviewManufacturingShipping

Case InformationProduct InformationShipping InformationAudit

Implants

Implant Brand

Implant Construct Guide

Femoral Implant Size

80

Tibial Implant Size

87

Technology & Instrumentation

Guide Type

Pin Position

Femoral Resection Block Distal

:

Lot Number

ZB18ZUXROJ

Expiration Date

2018-09-23T00:00:00

Part Number

42-422567

Femoral Resection Block 4in1

:

Tibial Resection Block

RD-140512 : Microplasty Tibial Resection Head, Right

Figure 46

3.8. Shipping Information

As a Surgeon or PCC, you can locate shipping information under the “Shipping Information” tab (Figure 47). This tab can be found once a case is in the “Shipping” phase. There will not be a tracking number until items have been shipped.

The screenshot shows the 'Shipping Information' tab selected in the DRIVE Case Management System. The top navigation bar includes tabs for Onboard Case, Image Association, Exception, Segmentation, Planning, Plan Review, Manufacturing, and Shipping. Below this, a sub-navigation bar shows Case Information, Product Information, Shipping Information (highlighted), and Audit. The main content area is titled 'SHIPPING INFORMATION' and contains the following fields:

| Shipping Address | | |
|----------------------------------|-----------------|--------------------------|
| Attention Test US Distributor | | |
| Name Test Team US | | |
| Country United States | | |
| Street 1 123 Demo Lane | Street 2 --- | Street 3 --- |
| State/Province Indiana | City Warsaw | ZIP/Postal Code 46582 |
| Tracking Number | | |

Figure 47

3.9 Reports: Closed Cases

As a Surgeon or PCC, you can access closed cases by:

- 1 Selecting “Reports” (Figure 48).
- 2 Selecting “All Reports.”
- 3 Selecting “Closed Cases Volume.”

Note: If closed cases cannot be seen, then disable the pop-up blocker.

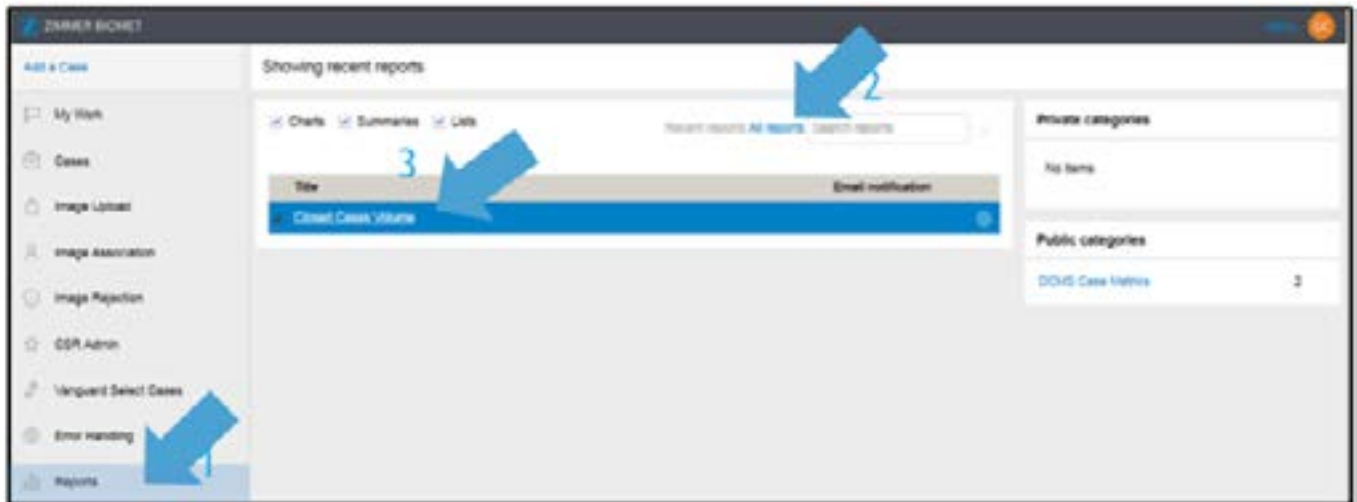


Figure 48

3.9 Reports: Closed Cases (cont.)

Once you select “Closed Cases Volume,” it will open in a new window, and you will:

- 1 Select date range, and select “Apply Filters” (Figure 49) (cases can only be filtered for a month at a time).
OR
- 2 Select the “Knee” line.



Figure 49

Note: When selecting the “Knee” line, closed cases will appear.

A list of cases for date range selected will be displayed. You can do one of the following:

- 1 Select “Actions” to export closed case reports to PDF or Excel (Figure 50).



Figure 50

3.9 Reports: Closed Cases (cont.)

- 2 Select a single case, and a report will open in DCMS (Figure 51).

Note: The DCMS Case Screen is behind the report pop-up. You will need to minimize the report or select the browser window

Onboard Case

Image Association

Segmentation

Planning

Plan Review

Manufacturing

Shipping

Case Information

Product Information

Shipping Information

Audit

CASE INFORMATION

▼ PATIENT INFORMATION

Patient Code

TET-DS-1030-R-000

Surgeon Name

Duplicate Surgeon2

Account / Hospital

Test Account US

Patient Full Name

Test 0005ETE ETE

Patient Date of Birth

13-Oct-1930

Gender

Female

ZB Purchase Order No

132132

Sales Team / Rep

NAM Demo Sales Team

Age

87

Optional: Internal Hospital Patient ID

Status

Closed

Distributor / Country

NAM Demo Distributor

Drive ID

DRIVE-1047

Figure 51

4. Troubleshooting

The Personalized Solutions Email Address is: personalizedsolutions@zimmerbiomet.com.

Q I'm getting an error when entering the verification code during login.

A Verification codes will expire after 10 minutes. If your code expires, you will need to request a new one. Select the "Back" button on the browser and re-login, and a new code will be sent.

Q I'm seeing the following error when trying to log into DCMS in Internet Explorer 11 (Figure 52):

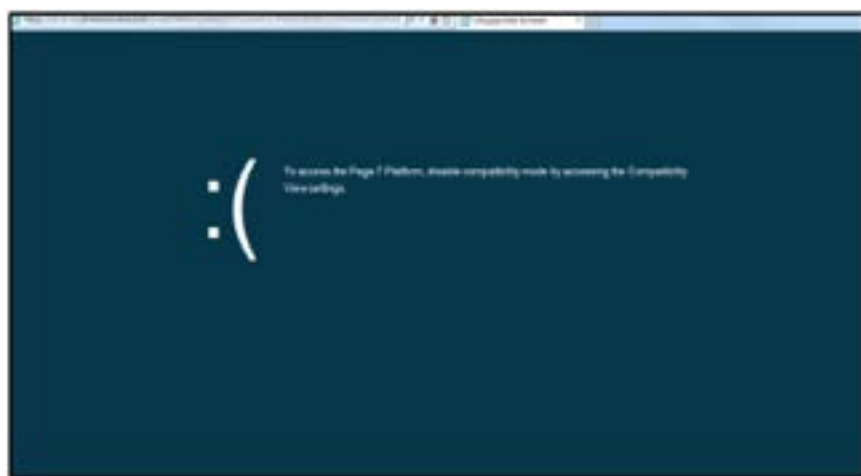


Figure 52

A This is an issue with the IE11 browser, in order to fix this issue, please see the below steps:

1. Select the "Gear" icon in the browser and then "Compatibility View Settings" (Figure 53).



Figure 53

4. Troubleshooting (cont.)

2. Ensure that there are no websites listed in the “Websites you’ve added to Compatibility View” section (Figure 54).

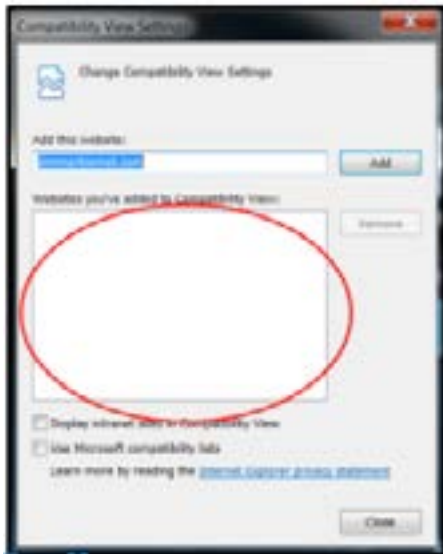


Figure 54

3. Ensure that the “Display intranet sites in Compatibility View” box is unselected (Figure 55).
4. Select “Close.”
5. Close the browser, reopen it, and try logging into DCMS again.



Figure 55

4. Troubleshooting (cont.)

Q I'm not getting logged into DCMS when using Internet Explorer 11 and logging in as a Zimmer Biomet user with my corporate account.

A This is an issue with the IE11 browser. In order to fix this issue, please do the following:

1. Select the "Gear" icon in the browser, and then select "Compatibility Settings" (Figure 56).



Figure 56

2. Ensure that there are no websites listed in the "Websites you've added to Compatibility View" section (Figure 57).
3. Ensure that the "Display intranet sites in Compatibility View" is unselected (Figure 58).
4. Select "Close."
5. Close the browser, reopen it, and try logging into DCMS again.



Figure 57



Figure 58

4. Troubleshooting (cont.)

Q I'm seeing an error page after successfully logging in instead of the "Case List" in DCMS.

A Make sure that you're using a compatible browser (Chrome, Safari, FireFox, IE11).
Edge is compatible with DCMS but not compatible with SurgiCase Planner.

Q The SurgiCase Planner isn't launching from DCMS.

A Make sure that you're using a compatible browser (Chrome, Safari, FireFox, IE11) and device (desktop or iPad/tablet).

8. FAQs

Q What email address will be used?

A As a Surgeon, Scan Technician, or Administrator, you will use what is currently in SOMS and ZOMS.

Q What devices will DCMS and SurgiCase work on?

A DCMS is compatible with desktop, tablets (including iPads) and mobile phones.
The SurgiCase Planner is compatible with desktops and iPads.

Q How do I create a case?

A See section 3.2. Creating a Case

Q How does a Surgeon approve a case?

A There is a 2-step process that the Surgeon must go through. First, the Surgeon selects 'Approve,' and then enters a password. See section 3.7.2. How to Approve a Case

Q How do I manage image uploads?

A The preferred method is Direct Method via Laurel Bridge or VPN.
See section 3.3.2. Image Upload Steps within DCMS

Q How do I add a scan site?

A Contact Personalized Solutions, where CSR will gather information. A test scan will be required for new sites. If it is already an existing scan site, CSR should go into Relationship HUB to set up.

Q How do I add a new user?

A Contact Personalized Solutions, CSR should go into Relationship HUB to set up.

Q Can I change a surgery date?

A Yes, see section 3.5.2. Changing the Surgery Date.

5. FAQs (cont.)

Q How do I check on the status of a case?

A Select “Cases” on the left-hand side of the screen to view all cases, and filter by case status (Figure 59).



Figure 59

Q We are having issues uploading images. How can we troubleshoot this?

A If you are using VPN or Laurel Bridge, contact Personalized Solutions Team. If you are using NUANCE, Powershare call: 1-866-809-4746 for technical support.

Q Can I track my case (shipping)?

A You can track shipping on the DCMS Screen or through email. Sales Representatives will receive an email notification, which includes the tracking number, a Hyperlink to FedEx/UPS, the Procedure type, the name of the Surgeon, and the date of the surgery. All of this information can be found under the “Shipping” tab (Figure 60). You must go to “Shipping.”



Figure 60

5. FAQs (cont.)

Q How do I upload or create a test scan for MRI/CT?

- A** Send images to Personalized Solutions via Direct Method, CD, or Web Uploader. Communicate that test images have been sent by emailing Personalized Solutions at: (574) 371- 3710 or personalizedsolutions.zimmerbiomet.com.

Q As a Signature user, why do I have to approve my plans now?

- A** To meet the IT, Compliance, and Regulatory requirements, all cases must be approved by a Surgeon regardless of the legacy system and process that they used.

Q How to get historical case information (pdfs, planning, etc.) from the former SOMs and ZOMs site once they shut down?

- A** Please contact Personalized Solutions Customer Support with Case ID, Surgeon Name, and/or Surgery Date at: (574) 371- 3710 or personalizedsolutions@zimmerbiomet.com.

Q How to get case historical information (pdfs, planning, etc.) from DCMS?

- A** This information can be obtained from the Case List and Case Reports. You can go back one year with DCMS.

Q How frequently do you have to change your password?

- A** You need to change your password every 180 days.

Other Issues?

If encountering other issues, please include the following information when reporting the problem to help the team identify root causes and troubleshoot:

- Browser
- Device (i.e. desktop, tablet, etc.)
- Geographic location
- Network from where the application was being accessed (Hospital, Zimmer Biomet facility, etc.)
- Steps to reproduce the problem
- Screenshots



Please visit PS.ZimmerBiomet.com for additional information.

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