

Patient-Matched Implants (PMI)

DCMS User Guide

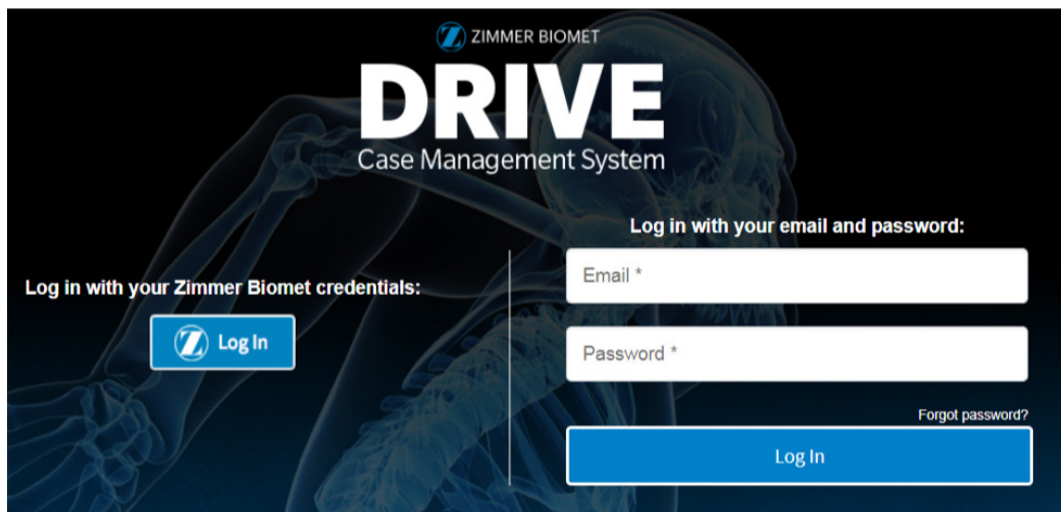
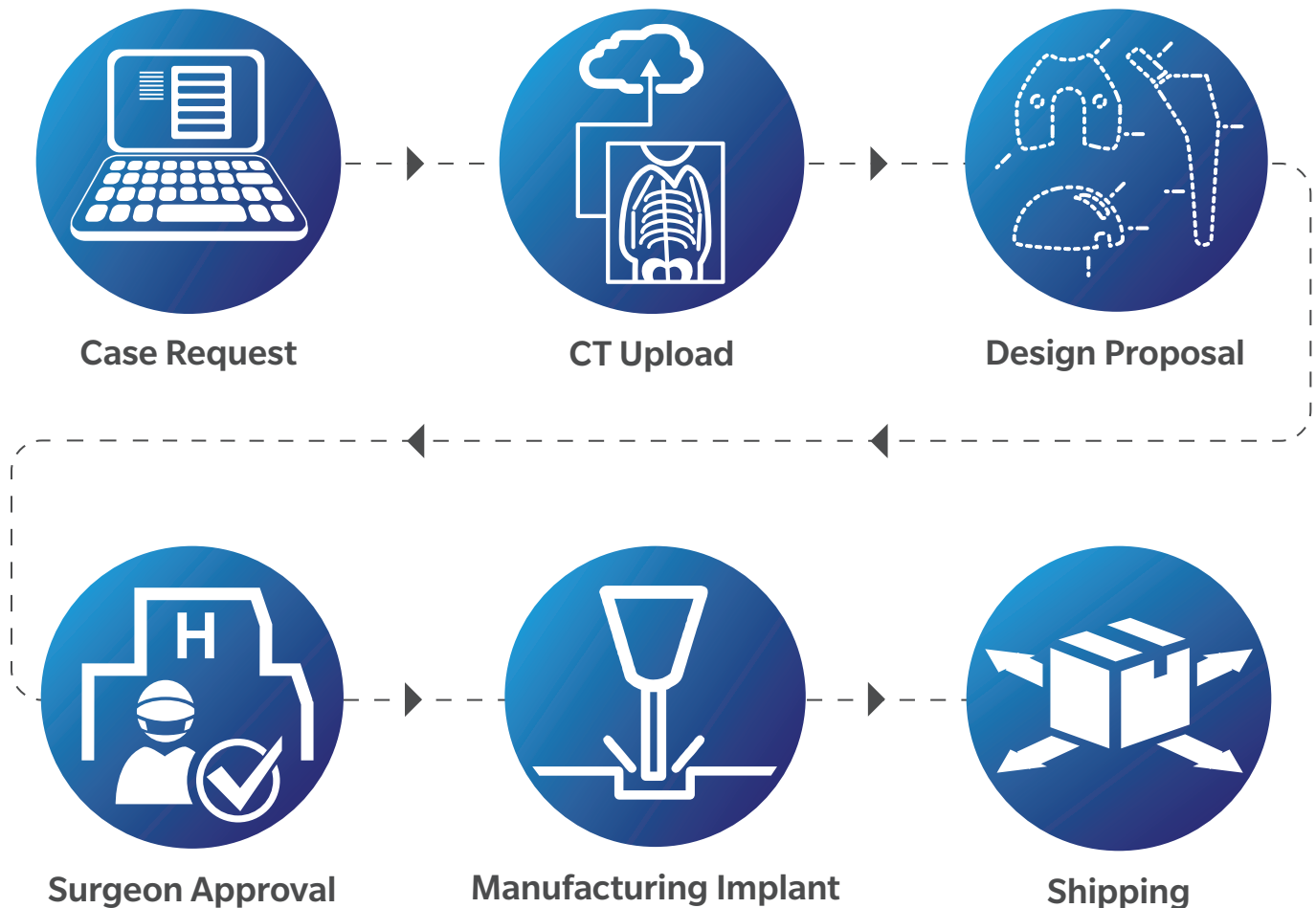


Table of Contents

Introduction	3
Summary	4
Surgeon & Sales Rep Registration Form	5
DCMS Registration Process	6
Logging on to DCMS	7
PMI & Custom Case Requirements	8
PMI & Custom Case Progression	9
Scheduling a PMI Case in DCMS	10–13
PMI Case List Search Options	14
PMI Surgeon “My Work” Case View – Surgeon Tasks	15
PMI DCMS Case Life Cycle	16
PMI DCMS Case Life Cycle – Image Association Review	17–18
PMI DCMS Case Life Cycle – Planning / Plan Review	19–22
PMI DCMS Case Life Cycle – Next Steps	23
PMI DCMS Case Life Cycle – Prescription Review	24
PMI DCMS Case Life Cycle – Shipping Ready	25
DCMS Action Key - Canceling a Case	26
PMI DCMS Resources Page and Contact Information	27

Introduction

This guide is intended as a reference to help sales representatives and surgeons understand the process of scheduling and managing PMI cases in the **DRIVE Case Management System (DCMS)**.



General PMI Questions

PMI Team

Call: +001 574-371-0558

email: pmirx@zimmerbiomet.com

Imaging Questions, Contact

Imaging Team

Call: +001 574-371-0557

email: pmi.imaging@zimmerbiomet.com

Image Upload Support

PACS Team

Call: +001 574-371-3710, Option #4

email: pacs@zimmerbiomet.com

Summary

PMI DCMS Process Overview



*Each uploaded plan is designed to be approved or rejected by the surgeon ONLY. This is not to be approved or rejected by any other individuals with access to the PMI case

Surgeon & Sales Rep Registration Form

The document below is required for surgeon registration/DCMS enrollment. Completed forms should be emailed to the PMI team at pmirx@zimmerbiomet.com.

Once the completed forms are received, PMI will email invitations through DCMS to the concerned parties. Email invitations are sent directly from DCMS, therefore, we are unable to include other individuals on the invitation. Please contact PMI Customer Service with any questions. For users who are already registered, contact customer service to request adding the PMI assignment.

1. Registration Form

- Surgeon Information
- Sales Rep Information
- Distributor Information

2. Surgical Preferences (VRS, Triflange, CT Hip, Custom)

3. Scan Center NOT Required for PMI

Drive Case Management System (DCMS) Registration Form



PS Product: PSI/Signature™ Knee Guide ROSA® Knee **PMI**

Sales Representative Information and Association *REQUIRED*			
First Name	Last Name	Phone Number	E-mail Address
Sales Team		Distributor	
Distributor/Country (Shipping Address)			
Address		City	State/Province
Zip Code	Country	Surgeon(s) to Associate	

Surgeon Information and Association *REQUIRED*			Oxford® Knee Trained?	Yes	No
First Name	Last Name	E-mail Address			
Account/Hospital (Where surgery is performed)					
Address		City	State/Province		
Zip Code	Country	Phone Number	Sales Team/Rep		
Procedure					
Modality		Scan Center			

Scan Center Information *REQUIRED* (Not Required for PMI)			Is this site already approved?	Yes	No
Scan Center Name					
Address		City	State/Province		
Zip Code	Country	Phone Number	Modality		
Scanner Manufacturer		Model Name			
Field Strength (MRI)		Slices (CT)			
Does the scan center have a Full Length Board? (X-Ray)			How does the scan center take images? (X-Ray)		

DCMS Registration Process

The new user will be sent an invitation from DCMS, see figure 1. After clicking on the link embedded in the email, a new page will appear that prompts the user to create a password, see figure 2. After the password is submitted, the user will be prompted to acknowledge DCMS Terms and Conditions and Privacy Policy, see figure 3. Once acknowledged, the user will be notified that the registration was successful, see figure 4.



Figure 1

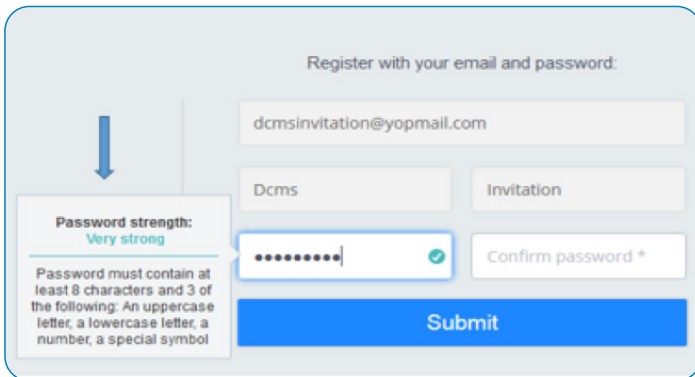


Figure 2

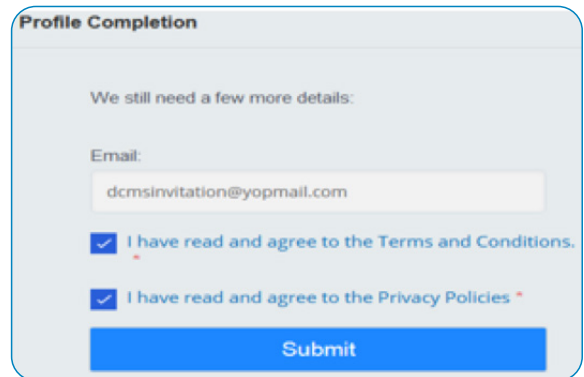


Figure 3

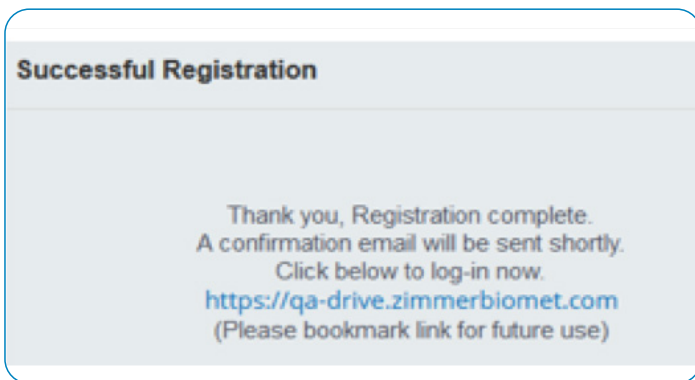


Figure 4

Logging Onto DCMS

DRIVE (DCMS) website url:

<https://drive.zimmerbiomet.com>

The screenshot shows the login interface for the DRIVE Case Management System. At the top, the Zimmer Biomet logo and the text 'DRIVE Case Management System' are visible. The page is divided into two main login sections. The left section, labeled '1', is for 'Zimmer Biomet credentials' and features a 'Log In' button with the Zimmer Biomet logo. The right section, labeled '2', is for 'email and password' login, containing fields for 'Email *' and 'Password *', a 'Forgot password?' link, and a 'Log In' button. A '3' callout points to the 'Forgot password?' link. Below these sections, a message asks users to 'select your region below'. Three region buttons are shown: 'North America | South America', 'Europe | Middle East | Africa' (labeled '4'), and 'Asia | Pacific'.

Sales Reps:

Log in with your ZB credentials

1

External Users:

Surgeons, PCC's and Scan Techs log in with credentials created when you accepted the invite.

2

Forgot password link for external users only.

3

Region should default appropriately.

4

PMI & Custom Case Requirements

Required Case Information

- Account/Hospital
- Sales Team/Rep
- Distributor/Country
- Case Type/Preference
- Preferred Shipping Address

Required Patient Information


- First and Last Name
- Date of Birth
- Gender
- Body Side
- Planned Surgery Date
- Indicated Use
- Special Instructions
- Patient Conditions

Please Note: For true custom cases, you will need to provide a basic device description to determine whether this falls under the customs scope (Example shown on pg. 12)

Patient-Matched Implants

Shoulder: Primary or Revision (VRS)


(Implant Example: Vault Reconstructive Shoulder System (VRS))
Start (see below)



Stop (see below)

Start: Above acromion process
Stop: 15 cm below top of humerus or 3 cm below existing implant
Slice Thickness and Spacing: 1.25 mm by 1.25 mm, 1.5 mm by 1.5 mm, 2.5 mm by 2.5 mm, or 3 mm by 3 mm is acceptable
Field of View: 25–30 cm FOV, depending on patient size. Needs to include entire scapula.
Algorithm: A standard or soft tissue algorithm, no bone enhancement
Note: Do not use metal artifact reduction (MAR/OMAR).

*A physical CD-Rom must be mailed to Zimmer Biomet PMI department.
Processing of CT data and/or X-rays by Zimmer Biomet is not to be construed as supplying a medical diagnosis. This service merely represents another step in facilitating diagnosis by the physician user. Zimmer Biomet shall not be liable or responsible for any physician-supplied services, such as diagnosis or treatment. Zimmer Biomet makes no representations or warranties as to the accuracy or completeness of this service nor does Zimmer Biomet represent or warrant that this service is fit for any particular application or purpose.



8

PMI & Custom Case Progression

1. Contact PMI Department

- Register surgeon in DCMS
- Submit case request via the DCMS

2. CT Image Reconstruction

- Sales Representative will submit Patient's CT Scans to the PMI Imaging Team who will review and segment the images (please reference PMI CT Protocol)

3. Implant Proposal

- The assigned Engineer will collaborate with the surgeon to create a design matched to the Patient's anatomy and upload it to DCMS

4. Surgeon Approval

- Once surgeon is satisfied with the finalized design proposal, they will give final sign off for production
- Timeline is case-by-case dependent on surgeon feedback (rejection/approval of design)

5. Manufacturing Implant

- After approval and receipt of the surgeon's prescription, the final implant is manufactured and shipped to you

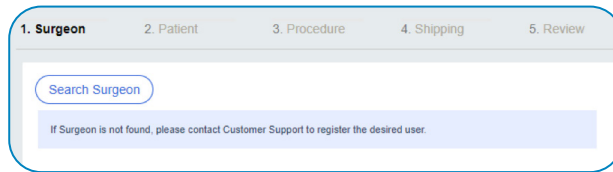
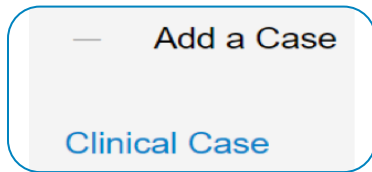
6. Shipping/Procedure

- Implant is received and surgeon is ready for surgery; instructions for use and surgical technique included if applicable

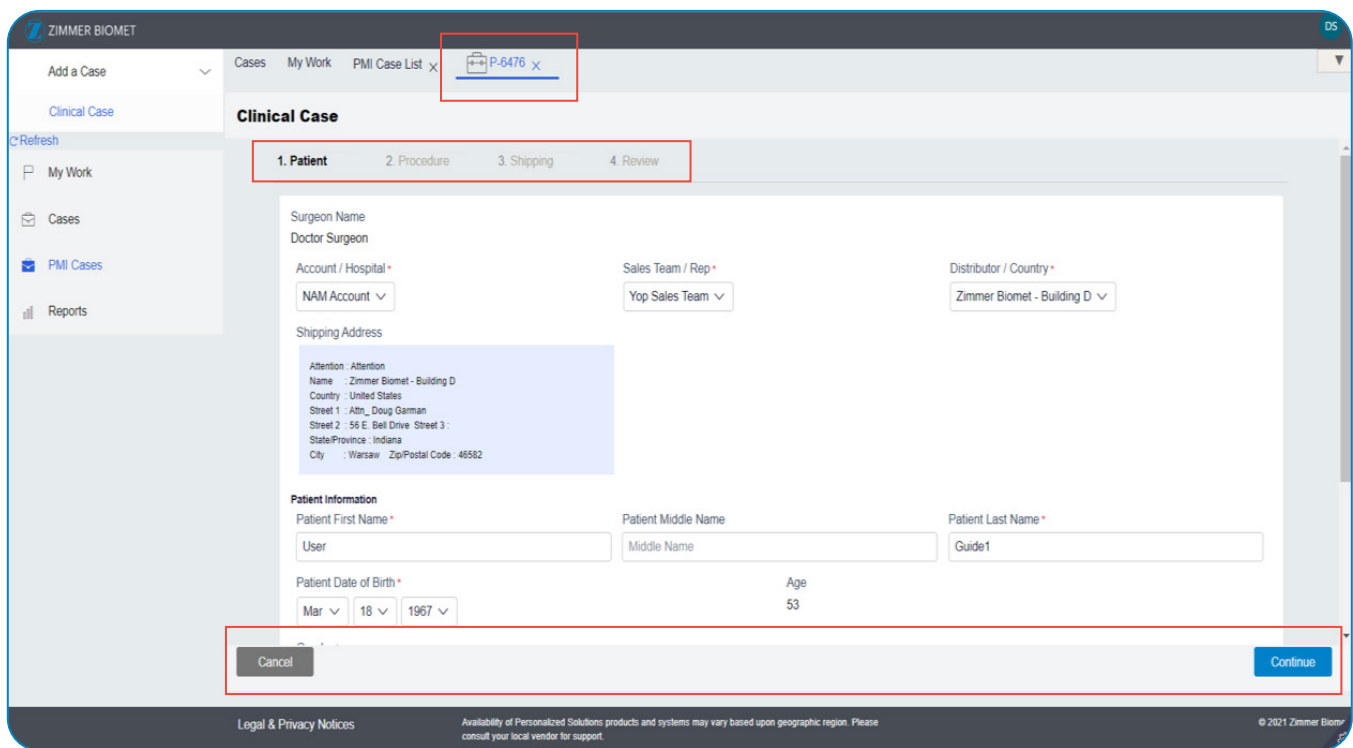
Please Note: Custom case times will vary from the cleared devices. Once a case has been submitted, the assigned engineer can communicate a more definitive timeline.

Scheduling a PMI Case in DCMS

1. Once in DCMS, click on “Add a Case,” then click “Clinical Case”. User will then select and / or search for surgeon Name; a surgeon’s own name will auto populate and they can immediately begin entering the case information. Click Continue.













2. Select the appropriate information required for Patient, Procedure and Shipping to then Review all information is accurate before confirming the case submission (Steps included on next pages)




Scheduling a PMI Case in DCMS (continued)


4. **Procedure:** Select the PMI Cleared or Custom Implant Product Family Preference (If preference isn't shown, click "Add new preference" shown beneath the displayed options. Select a Body Side. Enter the Planned Surgery Date.* Click Continue. (**Contact PMI CSR if desired PMI Technology Assignment is not available for selection.**)

Product Preference

Anatomy	Technology	Modality	Procedure	Family	
Shoulder	PMI	CT	NA	VRS	Select  
Shoulder	PMI	CT	NA	Custom	Select  
Hip	PMI	CT	NA	Triflange	Select  
Hip	PMI	CT	NA	Custom	Select  
Hip	PMI	CT	NA	CT Hip	Select  

 Add new preference

Body Side*
Left

Planned Surgery Date (Left Side)*
-- -- -- 

Scan Center
Select.. ← **Please Note:** Scan center selection is not required for PMI cases

Optional: Hospital PO Number

*Please list preferred surgery date. Actual surgery date to be determined once design is approved.

Scheduling a PMI Case in DCMS (continued)

5. **Supplemental:** Answer the patient history questions. Select an “Indicated Use”; Enter any Special Instructions; Select the “Patient Conditions”. Click Continue.

Does the patient currently have any existing implants (i.e. is this request associated with a planned revision)? *

Yes No

In association with this request, will or has any Zimmer Biomet product been revised? *

Yes No Unknown

In association with this request, is there reason to believe that a Zimmer Biomet product did NOT perform to expectation? *

Yes No Unknown

Has the Zimmer Biomet Product Experience Group previously been notified? *

Yes No N/A

product.experience@zimmerbiomet.com) Applicable only if "Yes" or "Unknown" was answered to either questions above, if this document is the initial communication with the product experience group, then select "No"

Indicated Use *

Select.. ▾

Special Instructions

Format ▾ **B** *I* U

Provide any additional information related to this request or patient condition.

Select Patient Conditions

Oncology

Allergy

Anatomic Abnormality

Infection

Bone Loss/ Erosion

Bone/ Joint Disease

Component Placement

Component Migration/ Loosening

Component Wear/ Fracture/ Other Issues

Component Dislocation/ Subluxation

Trauma Or Fracture/ Periprosthetic Fracture

Other

Back **Continue**

Scheduling a PMI Case in DCMS (continued)

6. Shipping: Confirm the Shipping Address.

Shipping Address

Attention *

Name *

Country *

Phone Email

Street 1 * Street 2 Street 3

State/Province * City * ZIP/Postal Code *

7. Review: After reviewing all details, click Create to generate the case.

✓ 1. Surgeon ✓ 2. Patient ✓ 3. Procedure ✓ 4. Supplemental ✓ 5. Shipping **6. Review**

Review

Surgeon Name
Doctor Surgeon

Account / Hospital Sales Team / Rep Distributor / Country
NAM Account Yop Sales Team Zimmer Biomet - Building D

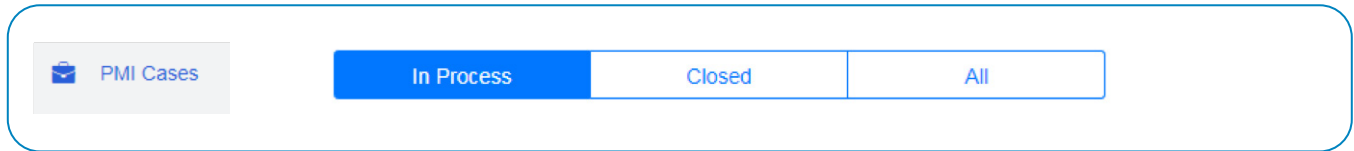
Patient Full Name
DEMO PMI

Patient Date of Birth Age
16-May-1937 84

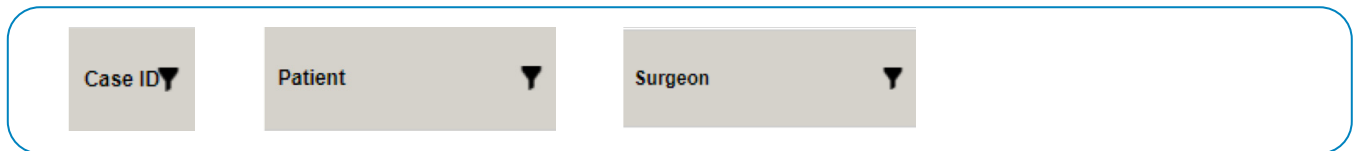
Gender
Male

PMI Case List Search Options

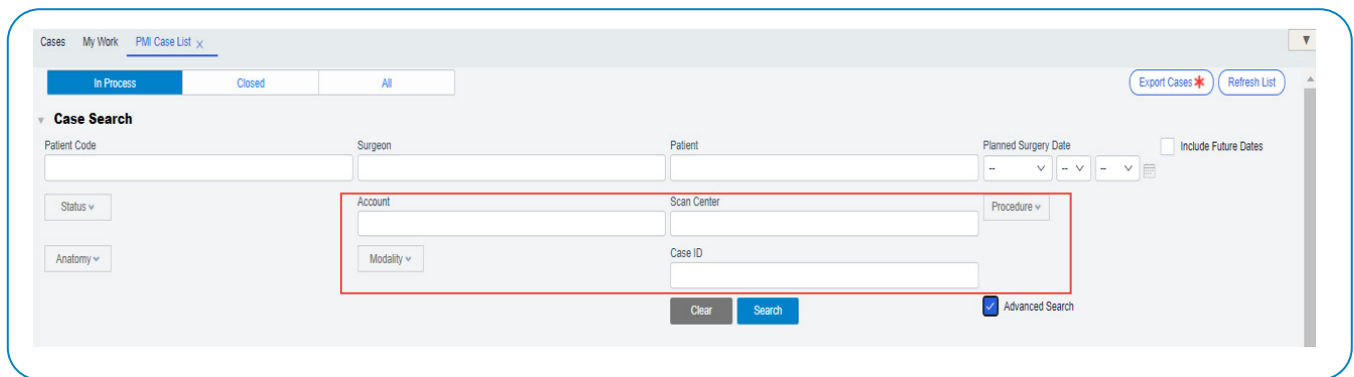
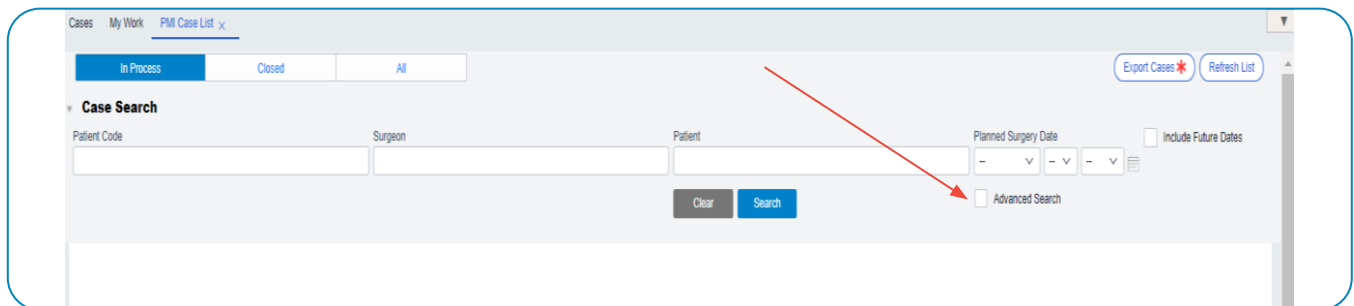
Once a case is added, the PMI Cases list provides multiple search options for locating available cases. The case list defaults to active cases, but the user has the ability to select and search “Closed” and / or “All” cases. The color Blue indicates the active search option.



The case list banner is set up like an excel spread sheet with columns and corresponding filters that can be found to the right of the searchable column header.



PMI DCMS case list also provides for a more advanced search. This feature can be utilized by selecting the Advanced Search box.



PMI surgeon “My Work” Case View – Surgeon Tasks

While in DRIVE, surgeons and other users will be able to filter the case search for easier access.

- DRIVE will automatically open to the “My Work” Section for surgeons when a task has been assigned to the surgeon

When conducting a general case search, PMI Case List must be selected to view/search PMI Cases.

ZIMMER BIOMET

OS

Add a Case > Cases **My Work**

Refresh

My Work

Cases

PMI Cases

Reports

TOTAL COUNT: 7

Patient Code	Case ID	Patient	Planned Surgery Date	Case Status	Surgeon	Account	Procedure	Plan Approval Deadline
FMT-DS-1258-L-AB8	M3S-1439	First Mtls	29-Sep-2020	Plan Pending Signature	Doctor Surgeon	NAM Account		07-Sep-2020
	PMI-91	PMI Cleared	29-Dec-2020	Plan Pending Approval	Doctor Surgeon	NAM Account		29-Dec-2020
STE032L64DS20UO	SOS-787	SOS Test	26-Jan-2021	Plan Pending Approval	Doctor Surgeon	NAM Account		29-Dec-2020
KON-DS-0120-L-1B0	M3S-2028	Kevin PPK Guide 111720 One Test	26-Jan-2021	Plan Pending Approval	Doctor Surgeon	NAM Account		07-Jan-2021
TSO16EL49DS20UO	SOS-865	test SOSGuide	26-Jan-2021	Plan Pending Approval	Doctor Surgeon	NAM Account		11-Jan-2021
	PMI-146	DCMS Guide	10-Apr-2021	Plan Pending Approval	Doctor Surgeon	NAM Account	NA	—
KTW-DS-0120-L-9EA	M3S-2029	Kevin 11172020 Two PPK Guide	02-Feb-2021	Plan Pending Approval	Doctor Surgeon	NAM Account		14-Jan-2021

Legal & Privacy Notices

Availability of Personalized Solutions products and systems may vary based upon geographic region. Please consult your local vendor for support.

© 2021 Zimmer Biomet

My Work

Refresh list

Patient Code	Case ID	Patient	Planned Surgery Date	Case Status	Surgeon	Account	Procedure	Plan Approval Deadline
FMT-DS-1258-L-AB8	M3S-1439	First Mtls	29-Sep-2020	Plan Pending Signature	Doctor Surgeon	NAM Account		07-Sep-2020
	PMI-91	PMI Cleared	29-Dec-2020	Plan Pending Approval	Doctor Surgeon	NAM Account		29-Dec-2020
TSO16EL49DS20UO	SOS-865	test SOSGuide	26-Jan-2021	Plan Pending Approval	Doctor Surgeon	NAM Account		11-Jan-2021
KON-DS-0120-L-1B0	M3S-2028	Kevin PPK Guide 111720 One Test	26-Jan-2021	Plan Pending Approval	Doctor Surgeon	NAM Account		07-Jan-2021
STE032L64DS20UO	SOS-787	SOS Test	26-Jan-2021	Plan Pending Approval	Doctor Surgeon	NAM Account		29-Dec-2020
	PMI-146	DCMS Guide	10-Apr-2021	Plan Pending Approval	Doctor Surgeon	NAM Account	NA	—
	PMI-156	Create Custom	08-Jul-2021	In Process	Doctor Surgeon	NAM Account	NA	—
KTW-DS-0120-L-9EA	M3S-2029	Kevin 11172020 Two PPK Guide	02-Feb-2021	Plan Pending Approval	Doctor Surgeon	NAM Account		14-Jan-2021

PMI DCMS Case Life Cycle

PMI case status is shown on the Progress Banners below:

- White banner with green lettering = Phase Complete
- White banner with black lettering = Phase in Process
- Grey banner with black lettering = Phase Incomplete/Not Started

Figure 1 PMI Cleared and Custom Case Progress Banner



Figure 2 PMI Progress Banner/Action/Case Status

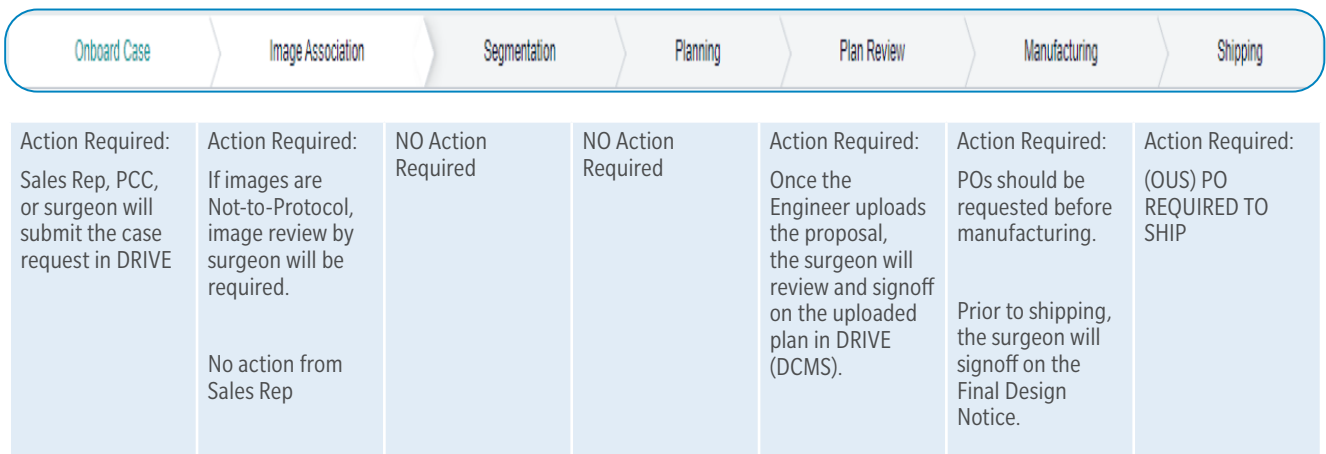


Figure 3 Fully Completed Green PMI Progress Banner/Action/Case Status



PMI DCMS Case Life Cycle – Image Association Review

Please contact the PACs Team (include PMI in the email subject line) for image upload support.

Please Note: the PMI Imaging Team must be notified of all uploads so they know which system to check:

PACs Contact Information:	Mailing Address:
pacs@zimmerbiomet.com	Attn: PMI Imaging Group
574-371-3710	Zimmer Biomet
	228 E. Bell Dr – Bldg B.
	Warsaw, IN 46582

If the CT images are **Not-to-Protocol**, the Imaging team will provide an explanation for this and the surgeon will now see the case show up in their **“My Work”** section (pg. 14) for review and signoff before the case can move to the Segmentation phase. The surgeon’s view of this is shown below:

Cases My Work x PMI-156 x

(0) In Process

Review Not-to-Protocol Images

If you wish to continue to process the case with the images that do not meet the standard protocol, please enter the details below and select 'Accept'. If you prefer to upload new images that that will meet the standard protocol, please enter details below and select 'Reject'. Upon selecting 'Reject', the case will remain in the Image Review status and new images can be uploaded

ZIMMER BIOMET

25-02-2021

Dear Dr. Doctor Surgeon ,

The Zimmer Biomet PMI® IMAGING DEPARTMENT has received a (CT modality) scan for patient Create Custom (). Upon review of the scan data it was noted that the item(s) below do not follow our recommended scanning protocol. In order to proceed with reconstructing this data for your specialty device request, we require confirmation acknowledging your desire to proceed with the scan data provided. Alternatively, you can elect to order a new scan.

Item(s) that do not follow the recommended PMI scan protocol.
Please review the Not-to-Protocol images.

If you wish to proceed with the existing scan, please confirm your authorization to continue case processing by providing your signature.

Kind Regards,
Doctor Surgeon
PMI® IMAGING DEPARTMENT
pmi.imaging@zimmerbiomet.com

Approval is required to proceed with provided scan	
Physician (Printed):	Doctor Surgeon
Physician (Signature):	

Accept/Reject Accept Reject

PMI DCMS Case Life Cycle – Image Association Review (Cont.)

If the surgeon **approves** the Not-to-Protocol images, the Imaging Team will progress the case to the Segmentation phase and will **NOT** require new scans. If the surgeon **rejects** the Not-to-Protocol images, new scans will be required to move forward.

Please Note: Cases scheduled as Imageless will be automatically advanced to Planning when case is onboarded.

Preview of Acceptance and Rejection Screens for Not-to-Protocol images:

The screenshot shows a web interface for Plan Approval Confirmation. At the top, there are two radio buttons: "Accept" (selected and highlighted with a red box) and "Reject". Below this is the section "Plan Approval Confirmation" with a paragraph of instructions: "Please confirm your approval of the form associated with the case by re-entering your password and clicking 'Submit Signature' below. By clicking 'Submit Signature' you are electronically signing the form." A "Please Note" states: "Only the user that approved the plan is authorized to electronically sign it." There is a "Log in with an existing site account:" section with a text input field containing "doctornam@yopmail.com" and a "Password *" input field. A blue "Submit Signature" button is located below the password field. A "Forgot password?" link is positioned below the "Submit Signature" button. At the bottom of the form, there is an "Accept/Reject" section with two radio buttons: "Accept" and "Reject" (selected and highlighted with a red box). Below this is a "Enter Comments *" section with a rich text editor toolbar containing options for Font, Size, Bulleted List, Numbered List, Bold, Italic, Underline, Link, Unlink, Undo, and Redo. The editor area is empty. At the bottom left is a "Cancel" button and at the bottom right is a "Submit" button.

PMI DCMS Case Life Cycle – Planning/Plan Review

Once a plan has been uploaded for surgeon review, the surgeon will first identify the proper case in DRIVE to complete the task. After opening the case through the “My Work” section, it will open to the review of the plan as shown below:

My Work Refresh list

TOTAL COUNT: 3

Patient Code	Case ID	Patient	Planned Surgery Date	Case Status	Surgeon	Account	Procedure	Plan Approval Deadline
	PMI-254	PMI Tes	28-Jul-2021	In Process	Doctor Surgeon	NAM Account	NA	—
	PMI-153	Ima Hurtin	15-May-2021	Plan Pending Approval	Doctor Surgeon	NAM Account	NA	—
MSO645L64DS21UO	SOS-1273	manual sos	12-May-2021	Plan Pending Approval	Doctor Surgeon	NAM Account	TSA/Anatomic	28-Apr-2021

Cases My Work x PMI Case List x **PMI-153** x

() Plan Pending Approval

Accept/Reject Plan DS

Patient Name: Ima Hurtin Physician Name: Doctor Surgeon Rev: A

Today's Date: 02-Jun-2021 Side: Left Case Number: —

Engineer Name: Kristen Patient ID: Ima1

The devices below will be provided by PMI:

Part Numbers:	Part Description:	Materials:
110027734	Comprehensive VRS Glenoid with F.A.S.T. guides assembled (sterile)	Ti-6Al-4V and Porous Coat
110031378	Comprehensive VRS Mini Taper Adaptor (sterile)	Ti-6Al-4V
110019066	Comprehensive VRS bone and implant model (non-sterile, but can be sterilized)	Polyamide
110031178	Guide, bone model, and implant model (non-sterile, but can be sterilized)	

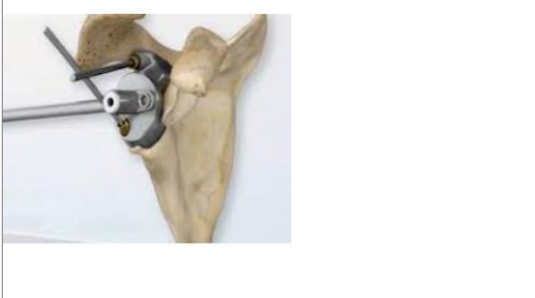
Note: VRS Implant and models expire 6 months after date of manufacture

PMI DCMS Case Life Cycle – Planning/Plan Review (Cont.)

Plan review example continued below:

Plan Pending Approval

Implant Image:



All other implants and instruments must be arranged & provided by distributorship including but not limited to:

- 6.5mm Central Screws and 4.75mm Peripheral Screws
- Comprehensive VRS loaner set 110030060 L (US-SMS) or 999101 (US) or 651Y (Japan)
- 110028045 - VRS 2.7mm 4" drill bits QTY: 2
- Comprehensive Reverse and Comprehensive Reverse Mini Instrument Set
- Comprehensive Reverse Implants

Additional Comments:

Technique(s):

VRS Surg Tech

Warning(s):

- *If there is anything currently in the glenoid that could cause discrepancies during CT reconstruction or additional bone loss during removal, the VRS may not fit as designed. Please consider a two stage to remove the glenoid component before the design of the VRS.*
- *Patient anatomy may change over time. It is the operating physician's responsibility to determine if the implant is suitable for the patient. It is recommended that if more than 6 months have passed between the original CT scan used for implant design and the surgery, an additional CT scan be conducted to confirm the anatomy.*

I have reviewed the surgical technique and acknowledge any and all indications/contraindications/warnings above. I acknowledge that the device design was the result of engineering requirements and physician input, and all features are necessary for treatment of the patient by result of the collaborative design process.

Physician Signature	
---------------------	--

Accept/Reject

Accept Plan Reject Plan

PMI DCMS Case Life Cycle – Planning/Plan Review (Cont.)


PLEASE NOTE: If the case is accessed through the PMI Case List instead of the “My Work” section, the surgeon will need to access the “+Add Attachments” section on the right-hand side of the screen to review the plan before accepting or rejecting the proposal.

() Plan Pending Approval

Accept/Reject Plan DS

Accept/Reject Accept Plan Reject Plan


Attachments Refresh



0469.3-GLBL-en Comprehensive Vault Reconstruction System Sur




Attachments X

Attach a File here...



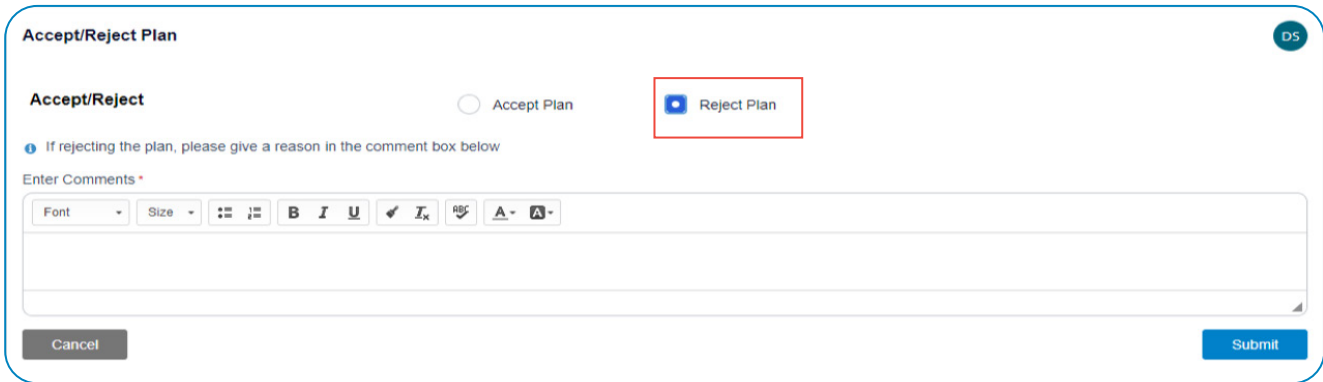
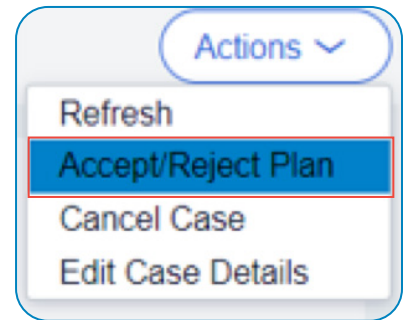
Drag and drop files here

or

Type	Attachment	User	Timestamp
Public	 0807.2-GLBL-en PMI Protocol	Kristen Bellinger	2/11/2021 9:01 PM
Public	 0469.3-GLBL-en Comprehensive Vault Reconstruction System Sur	Kristen Bellinger	2/11/2021 9:01 PM
Public	 _ProtocolOverride_20210211T195332.099.pdf	Doctor Surgeon	2/11/2021 7:53 PM

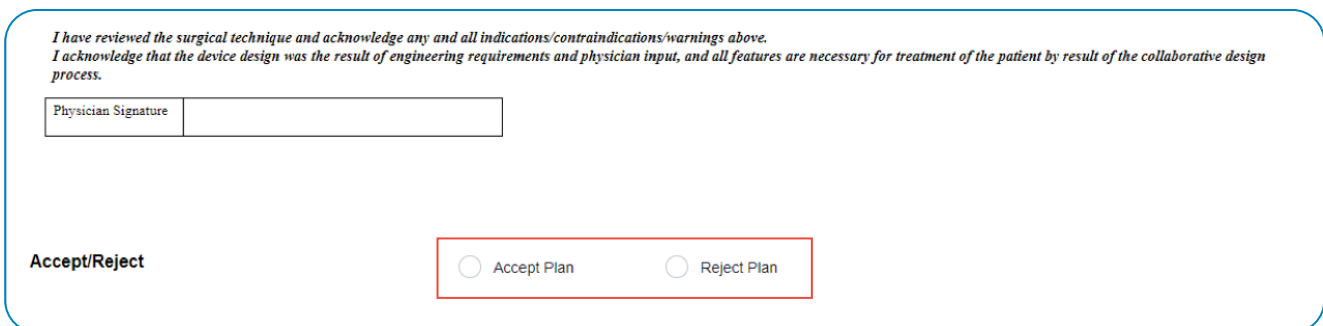
PMI DCMS Case Life Cycle – Planning/Plan Review (Cont.)

For **true custom cases**, it will be required to Accept/Reject the proposal without e-signature signoff until the manufacturing stage of the case where the surgeon will complete this action. If the surgeon chooses to reject the proposal for any reason, they will be prompted to add comments for justification of rejection and the Assigned Engineer will make the necessary changes or edits for a new proposal.



The "Accept/Reject Plan" dialog box features a title bar with "Accept/Reject Plan" and a "DS" icon. Below the title, there are two radio buttons: "Accept Plan" (unselected) and "Reject Plan" (selected and highlighted with a red border). A message states: "If rejecting the plan, please give a reason in the comment box below". Below this is a text area labeled "Enter Comments" with a rich text editor toolbar containing options for font, size, bold, italic, underline, strikethrough, link, and unlink. At the bottom, there are "Cancel" and "Submit" buttons.

For **cleared PMI cases**, the surgeon will be asked to signoff electronically on the proposal for acceptance or provide justification for rejection as previously shown. This signoff will look exactly like the electronic signature required for Not-to-Protocol image review (see p. 18):



This section contains a signature line with the text: "I have reviewed the surgical technique and acknowledge any and all indications/contraindications/warnings above. I acknowledge that the device design was the result of engineering requirements and physician input, and all features are necessary for treatment of the patient by result of the collaborative design process." Below this is a "Physician Signature" label and an empty text box. At the bottom, there are two radio buttons: "Accept Plan" (unselected) and "Reject Plan" (unselected and highlighted with a red border).

PMI DCMS Case Life Cycle – Next Steps

Once the plan has been approved and moved into manufacturing, **at this time the Final Design Notice and Screw Map (If Applicable) will be added to the case.**

() Plan Approved

Onboard Case > Image Association > Segmentation > Planning > Plan Review > Manufacturing > Shipping

Information **Audit**

History

Page 1 of 2

Time	Description	Performed by
2/26/21 2:08 PM	Status Changed from 'Plan Approval' to 'Plan Approved'	Doctor Surgeon
2/26/21 2:08 PM	Status changed to Open-PlanApproved.	Doctor Surgeon
2/26/21 2:08 PM	Accept/Reject Plan completed	Doctor Surgeon

For true custom cases, once the assigned engineer has progressed the case to manufacturing, the surgeon will then have to review and signoff on the Final Design Notice of the device as shown in the next images:

() Manufacturing

PRESCRIBING INFORMATION

PHYSICIAN INFORMATION(completed by Requesting Physician or Dentist):

Name of Practice: Doctor Surgeon

Practice Address: Street

City: Warsaw State: Indiana Zip Code: 46354

PMI DCMS Case Life Cycle – Prescription Review

True custom case surgeon review of prescription continued. **The surgeon must fill out the prescribing details and this section cannot be left blank:**

Provide Prescribing Details (Include unique pathology or physiological condition and why product is needed?):

1. I have received, and reviewed the Final Design Notification and Overall Risk-Benefit Analysis and hereby prescribe this Specialty Device for the above named patient.
 Yes No
2. Will the requested device be created or modified in order to comply with your order?
 Yes No
3. Is the requested device generally available in the United States in finished form through labeling or advertising by the manufacturer, importer, or distributor for commercial distribution?
 Yes No
4. Is the requested device designed to treat a unique pathology or physiological condition that no other device is domestically available to treat? (Consider the entire U.S. marketplace and other manufacturers)
 Yes No
5. Is the requested product: i) intended to meet your special needs in the course of your professional practice or ii) intended for use by an individual patient named in your order?
 Yes No
6. Is the requested device for the purpose of treating a sufficiently rare condition such that conducting clinical investigations on such device would be impractical?
 Yes No

To the best of my knowledge I have accurately responded to the above questions and I wish to pursue a Specialty Device request to meet the specific needs of my patient.

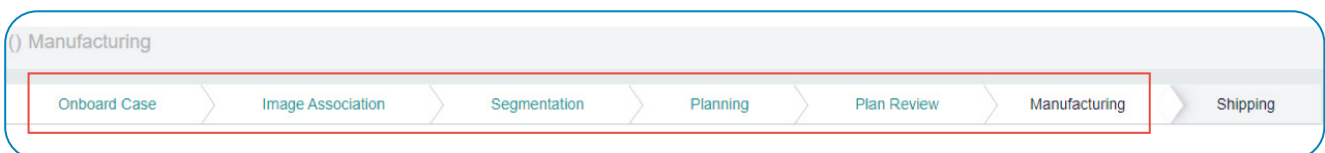
In the event that any of the implant(s) and/or instrument(s) listed above for this specific case/patient are not used, U.S. FDA regulations and Zimmer Biomet require that unused Zimmer or Biomet Products shall be properly destroyed by the Hospital and not used for any patient other than that named above.

By signing below, I agree that I acknowledge any and all risks associated with the device(s) requested and any Zimmer or Biomet product will be disposed of as specified above.
Signature/date required.

Physician Signature:	
----------------------	--

Accept Reject

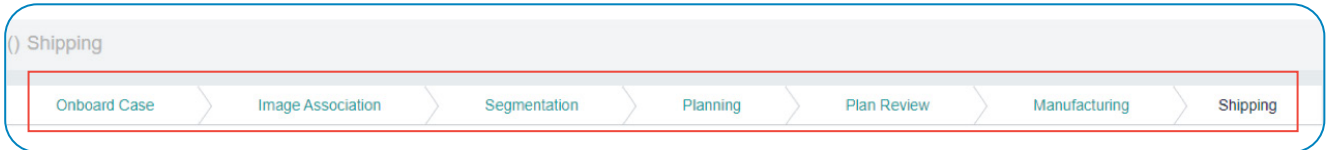
Once the prescription has been approved, the progress banner will be displayed as follows:



PMI DCMS Case Life Cycle – Shipping Ready

Once manufacturing is complete, the device is ready to ship to the provided shipping address.

All DCMS users connected to the case will see the progress banner displaying all of the phases highlighted in white with green lettering to demonstrate the case is complete:



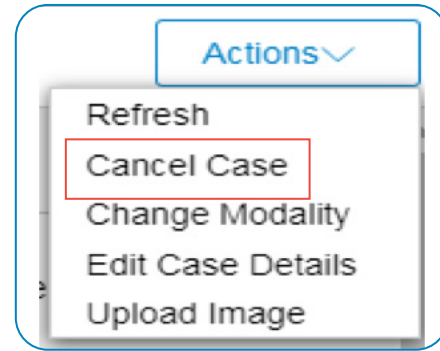
After a case has moved to Shipping, it will still show up in the PMI case list as “Closed” for access to case details and the audit trail for reference.

In Process Closed All									
⚠	▼ Patient Code	▼ External ID	▼ Case ID	▼ Patient	▼ Planned Surgery Date	▼ Case status	▼ Surgeon	▼ Account	▼ Procedure
			PMI-155	VRS PMI	01-Apr-2021	Awaiting Images	Doctor Surgeon	NAM Account	NA
			PMI-146	DCMS Guide	10-Apr-2021	Manufacturing	Doctor Surgeon	NAM Account	NA
			PMI-147	Test Test	17-Apr-2021	In Process	Doctor Surgeon	NAM Account	NA
			PMI-153	Ima Hurtin	15-May-2021	e-Manufacturing	Doctor Surgeon	NAM Account	NA
	US-TestCase		PMI-154	test patient	14-Jun-2021	e-Manufacturing	Doctor Surgeon	NAM Account	NA
			PMI-156	Create Custom	08-Jul-2021	Shipping	Doctor Surgeon	NAM Account	NA

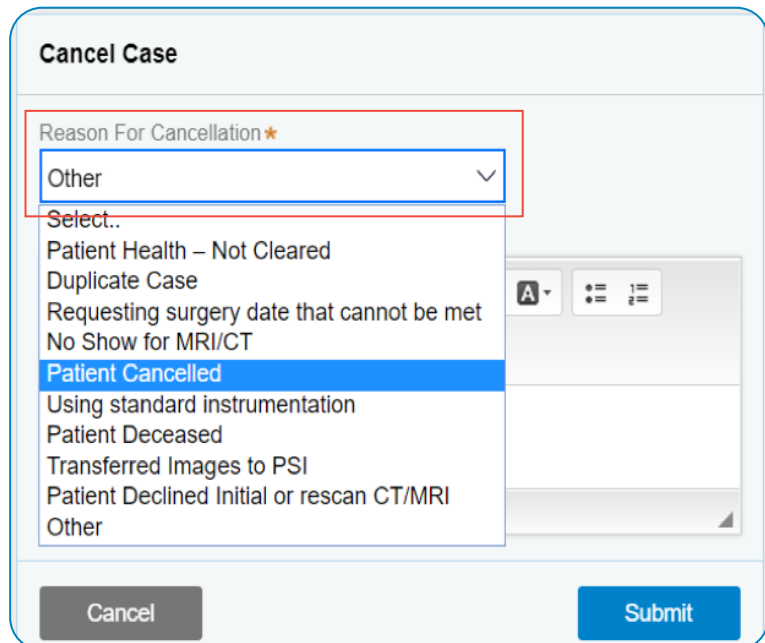
DCMS Actions Key - Canceling Case

How to cancel a case in DRIVE:

- Open the case.
- Click “Actions” (top right of case page).
- Select “Cancel Case” from the menu.
- Select the Reason For Cancellation from the dropdown.
- Click “Submit” to cancel the case.



PLEASE NOTE: Once a case has been canceled it cannot be reactivated. A new request must be submitted (Contact PMI Customer Service for assistance).

A screenshot of the 'Cancel Case' form in the DRIVE interface. The form has a title 'Cancel Case' and a field for 'Reason For Cancellation *'. The dropdown menu for this field is open, showing a list of reasons: 'Other', 'Select..', 'Patient Health – Not Cleared', 'Duplicate Case', 'Requesting surgery date that cannot be met', 'No Show for MRI/CT', 'Patient Cancelled', 'Using standard instrumentation', 'Patient Deceased', 'Transferred Images to PSI', 'Patient Declined Initial or rescan CT/MRI', and 'Other'. The 'Patient Cancelled' option is highlighted with a blue bar. Below the dropdown, there are two buttons: 'Cancel' and 'Submit'.

PMI DCMS Resource Page and Contact Information

The PMI DCMS Resource Page is coming soon! For any and all DCMS inquiries or issues, please contact PMI Customer Service.

General PMI Questions

PMI Team

Call: 574-371-0558

Email: pmirx@zimmerbiomet.com

Imaging Questions

Imaging Team

Call: 574-371-0557

Email: Pmi.imaging@zimmerbiomet.com

Image Upload Support

PACS Team

Call: 574-371-3710, Option #4

Email: pacs@zimmerbiomet.com

This material is intended for health care professionals. Distribution to any other recipient is prohibited.

For indications, contraindications, warnings, precautions, potential adverse effects and patient counseling information, see the package insert or contact your local representative; visit www.zimmerbiomet.com for additional product information.

All content herein is protected by copyright, trademarks and other intellectual property rights, as applicable, owned by or licensed to Zimmer Biomet or its affiliates unless otherwise indicated, and must not be redistributed, duplicated or disclosed, in whole or in part, without the express written consent of Zimmer Biomet.

©2021 Zimmer Biomet.



3626.1-GLBL-en-Issue Date-2021-11-02