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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

1. Sales Rep completes and submits Registration Form to PMI Customer Service Rep (CSR)
2. PMI CSR invites surgeon to join DCMS via email
3. Surgeon activates DCMS account through email invitation and password creation
4. Sales Rep or surgeon adds PMI case in DCMS
5. Sales Rep or Hospital submits CT Scans/Disks via upload or to PMI shipping address
6. Case is moved into Image Association to receive a Case ID and image review
7. Images are then reviewed and segmented by the Imaging Team before moving into planning
8. Assigned Engineer creates and uploads plan proposal for review by the surgeon*
9. Surgeon will be given the option to Accept / Reject the plan
10. Once approval is received, Engineer can advance the case in DCMS to begin manufacturing
11. PMI implant is manufactured and shipped to designated location for surgery

*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
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

Sales Reps:
Log in with your ZB credentials

External Users:
Surgeons, PCC’s and Scan Techs log in with credentials created when you accepted the invite.

Forgot password link for external users only.

Region should default appropriately.
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)
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.)

*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.
Scheduling a PMI Case in DCMS (continued)

6. **Shipping**: Confirm the Shipping Address.

   ![Shipping Address Form]

   ![Continue Button]

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

   ![Review Form]

   ![Continue Button]
**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.
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

Action Required: Sales Rep, PCC, or surgeon will submit the case request in DRIVE
Action Required: If images are Not-to-Protocol, image review by surgeon will be required.
No action from Sales Rep
NO Action Required

NO Action Required
Action Required: Once the Engineer uploads the proposal, the surgeon will review and signoff on the uploaded plan in DRIVE (DCMS).
Action Required: POs should be requested before manufacturing.
Prior to shipping, the surgeon will signoff on the Final Design Notice.
Action Required: (OUS) PO REQUIRED TO SHIP

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:

<table>
<thead>
<tr>
<th>PACs Contact Information:</th>
<th>Mailing Address:</th>
</tr>
</thead>
<tbody>
<tr>
<td><a href="mailto:pacs@zimmerbiomet.com">pacs@zimmerbiomet.com</a></td>
<td>Attn: PMI Imaging Group</td>
</tr>
<tr>
<td>574-371-3710</td>
<td>Zimmer Biomet</td>
</tr>
<tr>
<td></td>
<td>228 E. Bell Dr – Bldg B.</td>
</tr>
<tr>
<td></td>
<td>Warsaw, IN 46582</td>
</tr>
</tbody>
</table>

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:
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 on-boarded.

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

<table>
<thead>
<tr>
<th>Patient Code</th>
<th>Case ID</th>
<th>Patient</th>
<th>Planned Surgery Date</th>
<th>Case Status</th>
<th>Surgeon</th>
<th>Account</th>
<th>Procedure</th>
<th>Plan Approved Deadline</th>
</tr>
</thead>
<tbody>
<tr>
<td>PMI-204</td>
<td>Phil Tes</td>
<td>28-Jul-2021</td>
<td>In Process</td>
<td>Doctor Surgeon</td>
<td>N/A Account</td>
<td>NA</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td>PMI-185</td>
<td>Ima Hurin</td>
<td>15-May-2021</td>
<td>Plan Pending Approval</td>
<td>Doctor Surgeon</td>
<td>N/A Account</td>
<td>NA</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td>MS0645640D21D0</td>
<td>SOS-1273</td>
<td>12-May-2021</td>
<td>Plan Pending Approval</td>
<td>Doctor Surgeon</td>
<td>N/A Account</td>
<td>TSA/anatomic</td>
<td>28-Apr-2021</td>
<td></td>
</tr>
</tbody>
</table>

---

**Cases**

<table>
<thead>
<tr>
<th>Case ID</th>
<th>Status</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>PMI-185</td>
<td>Plan Pending Approval</td>
<td>Comprehensive VRS Glenoid with F.A.S.T. guides assembled (sterile)</td>
</tr>
</tbody>
</table>

Accept/Reject Plan

- **Patient Name:** Ima Hurin
- **Physician Name:** Doctor Surgeon
- **Today’s Date:** 02-Jun-2021
- **Side:** Left
- **Engineer Name:** Kristen
- **Patient ID:** Ima1

The devices below will be provided by PMI:

- **Part Numbers:**
  - 110027734: Comprehensive VRS Glenoid with F.A.S.T. guides assembled (sterile)
  - 110031378: Comprehensive VRS Mini Taper Adaptor (sterile)
  - 110019066: Comprehensive VRS bone and implant model (non-sterile, but can be sterilized)
  - 110031178: Comprehensive VRS bone and implant model (non-sterile, but can be sterilized)

- **Materials:**
  - Ti-6Al-4V
  - Porous Coll

**Note:** VRS implant and models expire 6 months after date of manufacture.
Plan review example continued below:

<table>
<thead>
<tr>
<th>() Plan Pending Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implant Image:</td>
</tr>
</tbody>
</table>

All other implants and instruments must be arranged & provided by distributorship including but not limited to:
- 6.5mm Central Screws and 4 7.5mm Peripheral Screws
- Comprehensive VR8 Implant set 110030090 L (US-350) or 999101 (US) or 651Y (Japan)
- 11028045 - VR8 2.7mm 4" drill bits QTY 2
- Comprehensive Reverse and Comprehensive Reverse Mini Instrument Set
- Comprehensive Reverse Implants

Additional Comments:

**Technique(s):**

VR8 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 VR8 may not fit as designed. Please consider a two stage to remove the glenoid component before the design of the VR8.
- 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
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.
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.

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):
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.

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:
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 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: ____________________________

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.
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).
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

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