

User Guide

Surgeon



Protecting Patients, Supporting Innovation



Document control

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Beyond Compliance - Surgeon User Guide

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Welcome

This User Guide for Surgeons is a resource to help you to quickly understand the Beyond Compliance system.

This guide will:

- Show how to log on to the system
- Provide a step-by-step guide to inputting, editing and deleting data, if necessary
- Enable you to view your own data and that submitted by other authorized surgeons using the same registered implant
- Signpost where to get more help and information

Getting started

Beyond Compliance is only available to authorized surgeons who have been approved and trained by the manufacturer of specific implants. Within the system Lead Surgeons and Consultants-in-Charge can see all procedures in which they have been involved and can edit records, including adding patient consent, in either role.

Each account is set up by the Helpdesk who issue a User Name linked to an initial password that can only be used once.

If additional Data Entry accounts are required, please contact the Help Desk. Accounts must not be shared.

At first login, all users are asked to change this temporary password to a new one, which is confidential to them.

On receipt of your User Name and Temporary Password, go to the Beyond Compliance website www.beyondcompliance.org.uk.



Logging In

To log on to the Beyond Compliance system, go to www.beyondcompliance.org.uk and click on 'Secure Login' on the top right-hand side of the front page.



A login screen will appear with two tabs: Patient Consent and Help.



The 'Patient Consent' tab links to a one page document that can be downloaded, printed and signed by each patient for storage by the surgeon with the patient's clinical notes.

The Help tab has four dropdown options to choose the appropriate User Guide. User Guides are available for Surgeons, Data Entry staff, Expert Evaluators (or Rapporteurs) and Manufacturers.

If there are any problems with activating an account, Users should contact the Helpdesk using the details in the top-right corner. Within the secure environment, authorized users should call 0845 263 6376 or email: support@beyondcompliance.org.uk



Authorized users may enter their User Name and click on the screen). In this case a new password will be sent to the registered email address of the authorized user.

At first login, and whenever the service desk is required to reset your password, you will be asked to change the temporary password to a new one, which is confidential to you.



Once within the system, users may change their password at any time by clicking on your User Name in the top right-hand corner.

The password must consist of 8 to 20 characters, including at least one upper case, one lower case and one numeric character. The password expires every 90 days.

Users have 5 attempts to type in the correct User Name and Password combination before your account will be locked out. If this happens, please contact the Helpdesk to reset your account.

After you have changed your password, you will need to re-enter your User Name and your new password to login.

Following a successful login, you will be presented with the Main Screen that has five tabbed options: -

Procedures, Reports, Patient Consent, Messages and Help.





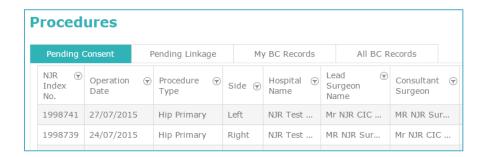
- 1. <u>Procedures:</u> provides access to information about the procedures that have used components registered with the Beyond Compliance service.
- Reports: provides access to confidential documents that have been provided either by designated Expert Advisory
 Panel members or by authorized staff of the manufacturer of the implant registered with the Beyond Compliance
 service.
- 3. Patient Consent: provides a link to download the Patient Consent form.
- 4. <u>Messages</u>: provides access to messages that have been broadcast to individual users or groups of users within Beyond Compliance. Messages may be personalized to individual users and include specific information.
- 5. Help: provides a link to the User Guides.

Viewing Records

There are four types of records:

- 1. Pending Consent
- 2. Pending Linkage
- 3. My BC Records
- 4. All BC Records

<u>Pending Consent</u> records provide information about procedures recorded in the National Joint Registry (NJR) in which an implant registered with Beyond Compliance (BC) has been used, but patient consent for Beyond Compliance has not yet been recorded, or Pre-Operative records prior to linkage with a procedure recorded within the NJR.



<u>Pending Linkage</u> records are records made prior to linkage with a procedure recorded within the NJR. Often, these records are made pre-operatively by the surgical team.





My BC Records provides the details of all patients treated by the Surgeon, where a BC product has been used, and patient consent for Beyond Compliance has been recorded by the responsible surgeon.



<u>All BC Records</u> provides the details of all patients treated by all surgeons, where a BC product has been used, and patient consent for Beyond Compliance has been recorded. Each surgeon can only see the full records for patients that they are responsible for and the general records of procedures involving the specific BC implant for which they are authorized.



The record lists are limited to ten records per page in order to make the details easy to read. Where there are more than ten records, the number of pages is displayed at the bottom of the screen on the **left-hand** side. A Refresh button is provided on the **right-hand** side at the bottom of the screen.

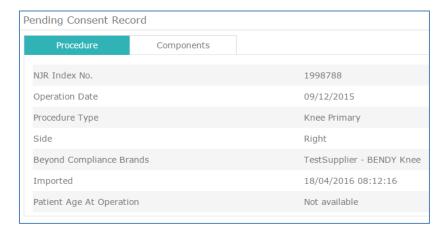




Viewing Details

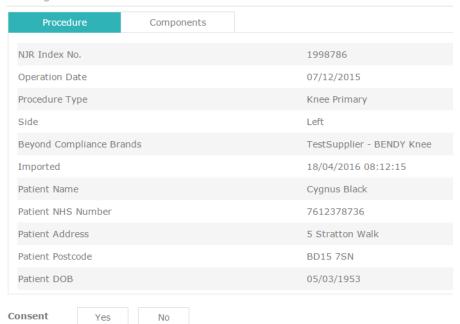
Select the procedure from the grid and click to open a new window that has two tabs: Procedure or Components

Most users will see the following general information about the procedure and strictly limited information about the patient:



Users who are responsible for the patient's care, e.g. Surgeons (who have conducted the said procedure) or their linked Data Entry staff, may see Patient Identifiable Data such as:

Pending Consent Record



All users may view details of Components, where available. The information covers:

- o Manufacturer
- o Brand
- o Description
- o Catalogue Number
- ODEP Rating
- Component Type
- o Implant Joint Type
- Composition
- Fixation Method





Sorting

Any list of Records can be sorted by any of the columns in ascending or descending order by clicking on the heading:

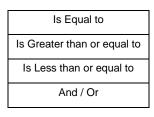
NJR Index No.	Lead Surgeon Name
Operation Date	Manufacturer
Procedure Type	Brand
Side	Updated By
Hospital Name	Updated On

Filtering

It is also possible to filter records within the columns.

a) For the column titled 'NJR Index No.' the pop-up box options are:

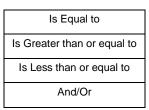




If two ranges /procedures are required, the operator "OR" should be selected.

b) For the columns titled 'Operation Date' and 'Updated On', the pop-up box options are similar to above with an additional Calendar option to select the date:







c) For the other columns, the pop-up box options are:



Where any text entered is used to search the column records

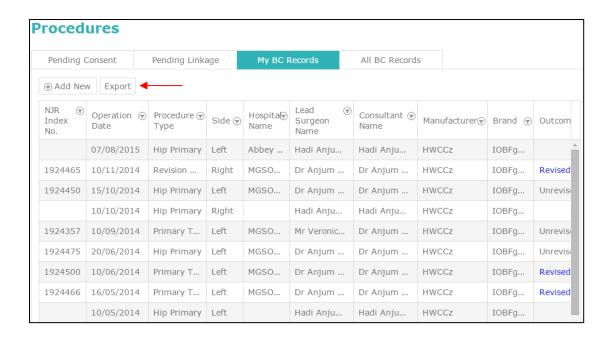
Exporting Summary Data

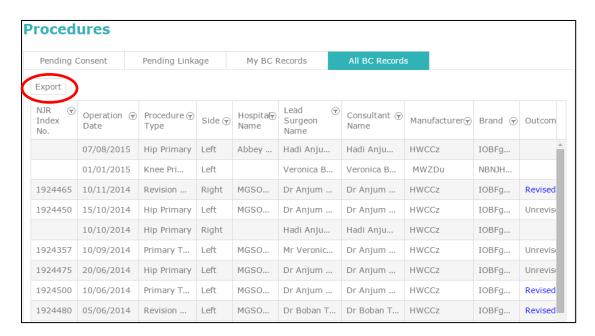
- When a user logs into Beyond Compliance, the system displays information based upon their specific security rights.
- Under PROCEDURES, each available tab will have an [Export] button.
- If the user clicks on the [Export] button, the data being displayed can be downloaded.
- Only the displayed on the grid can be downloaded.
- The download will include all records across all pages for the selected tab.
- If filters are applied, the system will only download the filtered records.
- Similarly, if sorting has been applied, the system will download the sorted records.
- The records are downloaded in .csv format.
- If no records are present, the [Export] button will be disabled.



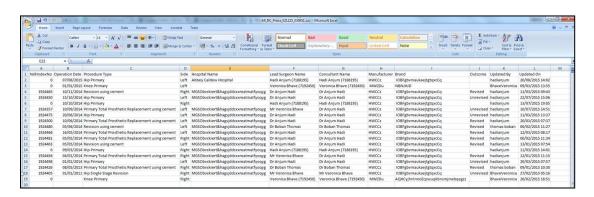








The downloaded file can then be opened for review and analysis on the local pc, for example:





Recording Patient Consent for Pending Records

Specific patient consent is required for Beyond Compliance.

A one-page document can be downloaded from the Beyond Compliance <u>website</u> which, when signed, should be stored with the patient's clinical notes.



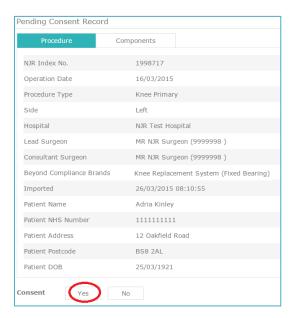
Beyond Compliance Service Patient Information Sheet and Consent Form

The manufacturer of your implant has chosen to include it in the **Beyond Compliance** Service, to provide an additional level of independent scrutiny of the performance of the implant.

"Beyond Compliance" is a service available to manufacturers of implantable medical devices to support the safe introduction of new or modified implants. The Service collects and reports information about patients receiving these

To start registering patients into the Beyond Compliance service, you will need to select a Procedure listed under the Pending Record tab for a patient linked to information imported from the National Joint Registry (NJR) or create a New/Pre-Operative record.

When a patient procedure is selected from the Pending Consent list, information about the Procedure and the Components used is shown together with two buttons (Patient Consent: Yes or No) at the bottom of the record. The Consent buttons are available when viewing information about the Procedure or the Components.





Click on the "Components" tab to view the list of components used in the selected procedure



When consent is set to "Yes", the record will be considered a Beyond Compliance record. It will be added to the Beyond Compliance database. The record will be removed from the 'Pending Records' tab and listed under the 'My BC Records' tab.

The Record will also be listed under the 'All BC Records' tab. However, the Patient Identifiable Data (PID) will only be shown to the authorized surgeon under the 'My BC Records' tab.

If Consent is set to "No", the basic information in the record will still be added to the database within Beyond Compliance but the Patient Identifiable Data (PID) will remain anonymised to all users.

NB. It is important to check that all the patient identifiable information is visible before changing the Patient Consent status in Beyond Compliance. It may take some time for the full record to become available after the initial NJR record is visible, as the patient information is cross-checked centrally for validity and accuracy by the National Joint Registry. If the user assumes that a record is that of a particular patient, before the full patient identification information is available, the user may later experience difficulties when trying to merge records or add extra information to the record in Beyond Compliance.

New/Pre-Operative Records

A facility to create a new/pre-operative patient record is provided so that a Surgeon or a Data Entry person can create a procedure on Beyond Compliance, in advance of the procedure or independently of the National Joint Registry (NJR).

In due course, if the procedure is recorded on the NJR, the record can be linked to the new/pre-operative record.

To access this option, a Surgeon or Data Entry person will log-in and be shown the Procedures screen. By clicking on 'Procedures' and the 'My BC Records' tab, an 'Add New' option becomes available located on the top left hand corner of the 'My BC Records' grid.

Clicking on '(+) Add New' opens a new window containing 'Procedure Record' form for entering the details Data can be entered in the following fields:

- Patient Consent*
- Patient NHS Number
- Patient Name
- Patient Date of Birth
- Patient Post Code
- Patient Email Address
- Hospital
- Operation Date
- Lead Surgeon*



- Side*
- Brand*
- Manufacturer*
- Joint*
- Procedure Type*

Mandatory fields are marked with an asterisk.

Duplicate data is prevented by requiring the combination of NHS number (if available), Joint, Operation date (when provided) and Side to be unique.

The Form has 'Save' and 'Cancel' buttons and a 'X' button for Closing in top right-hand corner.

A validation error message will be shown on attempting to 'Save' if data for mandatory fields is missing. On 'Save' if all mandatory requirements are met the message 'Record Saved Successfully' will be shown. After saving the procedure, the details will be visible under the 'My BC Records' and 'All BC Records' tabs.

On 'Cancel', if any changes have been made, then the User will be asked for a confirmation. After confirmation, or if no changes are made, 'Cancel' will discard the changes.

Manually created procedures can only be edited or deleted until linked to a NJR procedure.

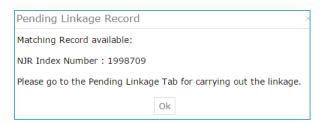
The 'Delete' facility is only available to lead Surgeons linked to the manually created BC procedure. Manually created BC procedure can only be deleted if there are no patient records or questionnaires attached. On 'Delete', the User will be asked for a confirmation that will result in deleting the entire manually created procedure from BC database.

Pending Linkage

NJR procedures that use implant components, which are registered with Beyond Compliance, are updated overnight.

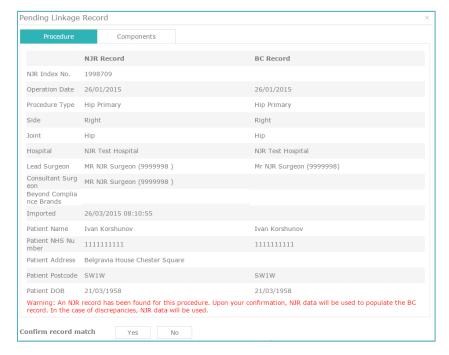
Each night, new NJR records are checked for potential merging with existing records within Beyond Compliance that match on the basis of the Patient NHS Number, Joint, Side, Operation Date and having a blank NJR Index Number.

When a potential match is found, the record is displayed under the 'Pending Linkage' rather than the 'Pending Consent' tab. In addition, if the existing record under 'My BC records' is viewed, a pop-up window notifies the user that there is a potential match:





When the user views the record under the 'Pending Linkage' tab, a pop-up window displays the two matching records side-by-side:



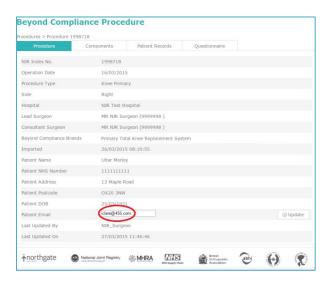
Only the surgeons who are responsible for the procedure or their authorized data entry user may view the complete record and complete the linkage.

If the user confirms the record match, this record will now be displayed under 'My BC Records' and will no longer appear under the 'Pending Linkage' tab. All duplicate data for the manually-created procedure will be overridden by data from NJR procedure.

Any additional information such as clinical attachments, submitted questionnaires or patient email address will be retained.

My BC Records

When Patient Consent for a Pending Procedure is set to "Yes" by the Surgeon, that record becomes a BC record and will be listed under this tab. As an option, an authorized Surgeon or linked Data Entry person may capture an email address for a patient who has given consent for their data to be held in the Beyond Compliance service.





The email address may be used for any future communications directly to the patient. The same email address (linked by NHS number) will be used for all implant procedures against the same patient. However, the email address does not have to be unique – i.e. the same email address can be used for multiple patients (for example, a mother or a father might use a son's or a daughter's email address).

Only authorized Surgeons and linked Data Entry staff can capture a patient's email address. This facility is not available to Manufacturers, Rapporteurs/Evaluators or Administrators as Patient Identifiable Data is not displayed to these User Types.

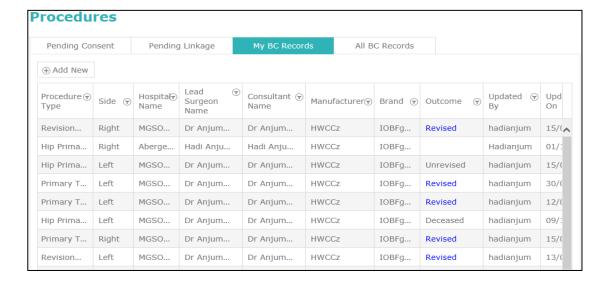
The email address can only be captured under 'My BC Records' and 'All BC Records' under the Procedures menu option.

When an authorized User (the surgeon who performs the procedure or a linked data entry person) clicks on a complete procedure under the 'Pending Consent' tab, and updates the Consent to 'Yes', the User is taken to 'My BC Records' tab which will allow the email address to be updated.

To save, click on the 'Update' button and the system will store the email address.

This facility will only be available for records that are otherwise complete. It will not be provided for pending procedures and for anonymous procedures. The text field will have a maximum size of 100 characters. If the email validation check finds an error, a failure message will be displayed.

As consent has been given by the patient, the surgeon is now able to see the OUTCOME status of the implant.



The OUTCOME status may be Revised, Unrevised or Deceased. A blank display may occur if essential data is missing in the original NJR records, such as the patient's NHS number, the SIDE on which the procedure was undertaken or the NJR Index Number is not available. It may also occur if the NJR record has not been recorded as completed.



If the OUTCOME status is 'Revised', the text becomes highlighted and, when selected, will open a screen displaying details of the revision procedure.

Procedure	Components	Patient Records	Questionnaire	
NJR Index No.		1924470		
Operation Date		13/10/2014		
Procedure Type		Knee Single Stage Revision		
Side		Right		
Survival Time Of The Implant		1.5 years		
Beyond Compliance Brands		MWZDu - AQHCyjhnlmioEcpwuqkbnsmjmxbqegzz		
Imported		16/06/2015 08:10:53		
Patient Age At Operation		23		

Survival Time of the Implant field value is calculated using the formula

Survival Time of the Implant = (Date of Death - Date of Operation)

The Implant Survival Time will be displayed in years to one decimal place. For example, if the Date of Death is 10th December 2015 and the Date of Operation is 6th August 2013 then the system will calculate and display the Survival Time of the Implant as "2.3 years".

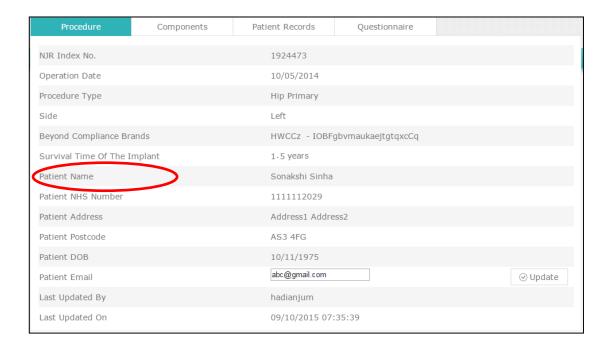
If a patient (who has received an implant registered with Beyond Compliance that has not been revised) dies, the system will update the registered Outcome for that patient to show the status as 'Deceased',

If the implant had already been revised before the patient died, the system will continue to show the Outcome as 'Revised',

Outcomes are only shown when patients have been recorded as giving consent to share data within Beyond Compliance,

When a user clicks on the Outcome (Deceased), the system will also display the Procedure details screen with a field entitled "Survival Time of the Implant",

Users responsible for the patient, e.g. Surgeons (who have conducted the said procedure) or linked Data Entry user, can view the survival time of the implant field and patient identifiable data





Other users can only view survival time of the implant field.

Only the surgeon (and linked Data Entry User) will be able to see the My BC Records tab which displays Patient Identifiable Data; anonymised data is visible to other users, under the All BC Records tab.

For revision procedures, the details of the surgeon and hospital will only be visible if the Consultant in Charge is the same for the primary and revision procedure.

For all records within My BC Records, two further tabs are available, where the Surgeon can add events to Patient Records or add Questionnaires, where applicable:



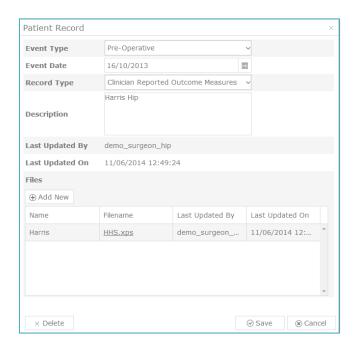
Adding New Information

Patient Records

Additional events can also be edited and deleted, if necessary. The authorized surgeon is in control of adding, updating and amending these additional records. Within the Patient Record, each item is called an element.

Authorized Surgeons and linked Data Entry Users can add new information elements to Patient Records in Beyond Compliance by clicking on the 'Add New' button that now becomes available:

When the Add New is clicked, the following screen will display





This is where you can upload additional information elements about the selected patient.

The tablebelow explains the type of information that you can record and which elements of the information are mandatory.

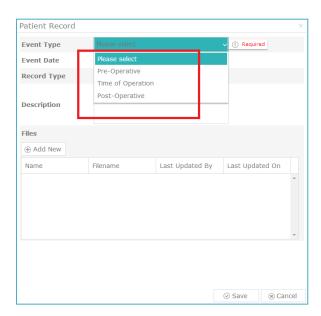
Please Note. No Patient identifiable information should be recorded in this section.

Although this section is only available to authorized users, Patient Identifiable Data is privileged information and should only be disclosed to the healthcare professional who has obtained patient consent and is responsible for their clinical care.

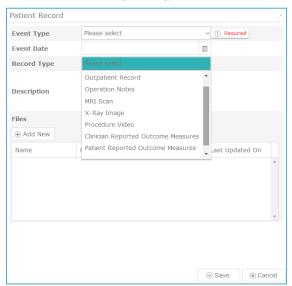
Other authorized users within Beyond Compliance, such as Advisory Board members, may view this uploaded data.

We recommend that during the process of documents de-identification the patient's First Name, Last Name, Date of Birth, Postcode and the NHS number should be removed. However, it is acceptable to retain the Hospital ID and / or the unique NJR number. Either or both numbers may be used in the file name.

There are three types of events:



There are eight records types, which are available for any event type:





Event Type

- Pre-Operative
- Time of Operation
- Post-Operative

Event Date (choose from the calendar or type in)

Record Type

- Outpatient Record
- Operation Notes
- MRI Scan
- X-Ray Image
- Procedure Video
- Clinical Reported Outcome Measures
- Patient Reported Outcome Measure
- Other when selected, another text box is displayed so that the type can be specified Patient Name (Optional)

Description (maximum length 4000 characters)

Files (the section for uploading new files)

Name (the name of the file as you would like it to appear in the list)

Filename (you can select a file from your device by clicking on the Select button)

'This file contains no patient identifiable data' tick box (self-explanatory)

When new information is added it will be shown in the following way

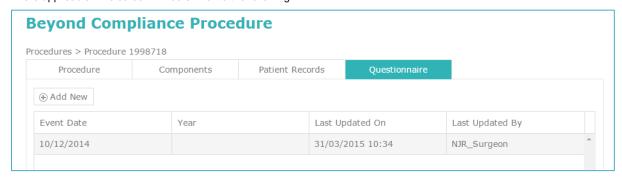


The records can be sorted by any of the columns (except the Attachment Count column) in ascending or descending order by clicking on the heading. Please note that only a single level sort is currently available (i.e. the records can be sorted by any single field at a time).



Questionnaires

For some implants, pre-formatted questionnaires have been uploaded to the system for completion. Where this is the case, the 'Questionnaire' tab will be active (rather than greyed-out) and data that has been entered can be viewed, edited or added to, where applicable. The screen will be similar to the following:



The records can be viewed by clicking on the relevant record which will open in a pop-up window.

All BC Records

When a Pending Procedure consent is set to "Yes" by the Surgeon, each record is listed under the 'My BC Records' tab. It also becomes listed under the 'All BC Records' tab but with no Patient Identifiable Information (i.e. each record is anonymous in this area).

'All BC Records' include all Beyond Compliance records where procedures have been performed by any authorized surgeon who has used one or more Beyond Compliance components in the procedure.

All authorized surgeons and designated expert advisory panel evaluators linked to a specific BC implant can view anonymous records and any attachments. Attachments can be downloaded as a read-only file but only be edited, updated or deleted by the surgeon responsible for the procedure.



Editing a Record

To edit a record, a responsible surgeon may click anywhere on the relevant line, wherever the mouse pointer turns into a hand, which indicates a hyperlink.

Deleting a Record

Only the surgeon, who is responsible for the patient, can delete items within a patient record. These items are the attachments (i.e. X-rays, etc.) that have been uploaded by the responsible surgeon.



Reports

Surgeons are able to view reports that provide additional, useful information about Beyond Compliance brands with which they are associated. Reports or images about specific brands can be uploaded by associated Manufacturers or Evaluators (Rapporteurs).

When a Surgeon logs in they will be shown the Main screen with four tabbed options. The menu option 'Reports' is displayed next to the Procedures menu option.



On clicking the 'Reports' menu, a grid showing the list of reports for the brand and manufacturer, linked with the Surgeon who is logged-in, will be displayed.



The list may be sorted by the following columns: Manufacturer, Brand Name, Report Date, Report Type, Description, Last Updated by, and Last Updated on. This is done by clicking on any column heading.

Selecting an entry in the grid opens the record and displays the report details inside a modal window.

The report details and the corresponding file details cannot be modified. To download the read-only file to the computer, click on the file name and save to the system.

Please note that surgeons are only authorized to view those reports for the BC implant to which they are linked. Data Entry staff are not able to view these additional reports.



Messages

The system administrator may send broadcast messages to individual users or groups of users within Beyond Compliance,

Messages may be personalized to include specific information, such as number of procedures for an implant and the number of cases where patient consent has been recorded.

Where the message has specific information relating to a particular implant, separate messages will be sent for each implant.

Messages will be in read-only mode, cannot be edited and replies cannot be sent.

Hyperlinks within any message will redirect the user to the corresponding external link.

Users may delete any message, which removes the item from their message grid.

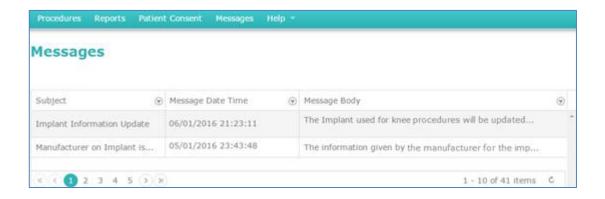
After log-in, users will note "Messages" option on the menu bar with a bubble displaying the number of unread messages.



If the user reads the messages the notification will decrement and when no unread messages remain the bubble will not be displayed.

When the user clicks on the Messages option on the menu bar, the system will display a grid with all messages received.

The grid will display Subject, Message Date Time and Message Body:



The messages may be filtered / sorted by Subject, Time or First line of message text.

Further Information

Please contact the service desk on 0845 263 6376 or email: support@beyondcompliance.org.uk