

# User Guide

*Manufacturer*



*Protecting Patients, Supporting Innovation*

## Document control

### Change control table:

Version	Description	Release date	Reason for change	Reviewer
2.6	Manufacturer User Guide	7/5/2015	Review, Update & New Functionality (U41 - Linking NJR & BYC Procedures)	Alan Needham / Olga Taylor
2.6.1	Manufacturer User Guide	23/6/2015	Change of legal company name	Alan Needham/Olga Taylor
2.7	Manufacturer User Guide	6/10/2015	New functionality (U21 Outcomes & U48 Access for Lead Surgeon & Consultant in Charge) + additional guidance	Alan Needham/Olga Taylor
3.0	Manufacturer User Guide	21 <sup>st</sup> April 2016	New Features	Alan Needham/Olga Taylor

## Beyond Compliance - Manufacturer User Guide

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### Welcome

This User Guide for Manufacturers is a resource to help you 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 the data submitted by authorized surgeons using registered implants
- Signpost where to get more help and information

Further information regarding the process may be found on the Beyond Compliance website

<http://www.beyondcompliance.org.uk/>

### Getting started

Beyond Compliance is only available to authorized staff within Manufacturers who have registered specific implants for evaluation purposes.

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

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](http://www.beyondcompliance.org.uk).

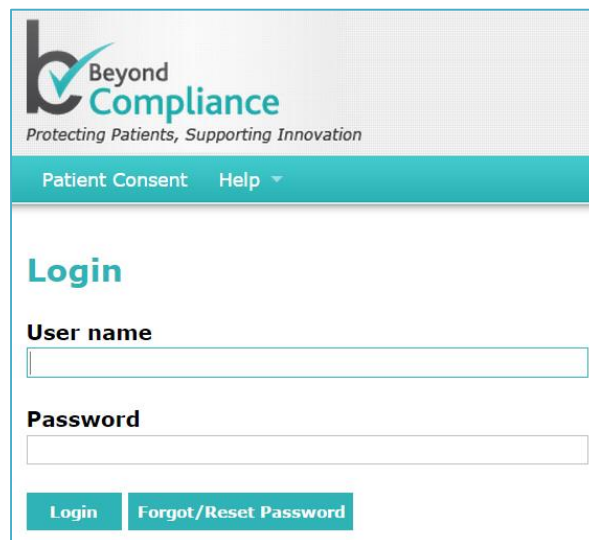
If additional accounts are required, please contact the Helpdesk. Accounts must not be shared.

## Logging In


To log on to the Beyond Compliance system, go to [www.beyondcompliance.org.uk](http://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 experiencing 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](mailto:support@beyondcompliance.org.uk)

Authorized users may enter their User Name and click on the  button (shown above on the Home 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. Procedures: provides access to information about the procedures that have used components registered with the Beyond Compliance service.
2. 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. Messages: 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 three types of records:

1. Pending Consent
2. Pending Linkage
3. All BC Records

Pending Consent 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.

Procedures						
Pending Consent		Pending Linkage		All BC Records		
NJR Index No.	Operation Date	Procedure Type	Side	Hospital Name	Lead Surgeon Name	
1998717	16/03/2015	Knee Primary	Left	NJR Test H...	MR NJR Surge...	
1998709	26/01/2015	Hip Primary	Right	NJR Test H...	MR NJR Surge...	

### Surgeon authorization status

- When a Rapporteur/Evaluator logs in to the system they can see all procedures, for the relevant implant to which they are assigned, that have been used by any surgeons who are registered within the Beyond Compliance system,
- However, surgeons may use an implant for which, within Beyond Compliance, they have not been authorized specifically,
- Rapporteur/Evaluators can view all the procedures, including those procedures where the surgeon has not been specifically authorized for the implant. The system will highlight any procedure where the surgeon has used a branded component (that is registered with Beyond Compliance) for which the surgeon is not specifically authorized on Beyond Compliance
- This is important because, surgeons can only view procedures within Beyond Compliance (BC) for which they are specifically authorized by the manufacturer, following training and BC registration.
- Highlighting is shown only where the Consultant-in-Charge is unauthorized to use the implant and this feature does not apply to Lead Surgeons.

Procedures

Pending Consent

Pending Linkage

All BC Records

Export

NJR Index No.	Operation Date	Procedure Type	Side	Hospital Name	Lead Surgeon Name	Consultant Surgeon	Manufacturer	Brand
1998793	14/12/2015	Hip Primary	Right	NJR Test ...	Consultant ...	Mr NJR CIC ...	TestSupplier	FLEXI H
1998783	12/12/2015	Knee Primary	Right	NJR Test ...	Consultant ...	Mr NJR CIC ...	TestSupplier	BENDY H
1998789	10/12/2015	Hip Primary	Right	NJR Test ...	Mr NJR CIC ...	Consultant ...	TestSupplier	FLEXI H
1998788	09/12/2015	Knee Primary	Right	NJR Test ...	MR NJR Surg..	Consultant ...	TestSupplier	BENDY H
1998787	08/12/2015	Knee Primary	Left	NJR Test ...	Consultant ...	Mr NJR CIC ...	TestSupplier	BENDY H
1998786	07/12/2015	Knee Primary	Left	NJR Test ...	MR NJR Surg..	Mr NJR CIC ...	TestSupplier	BENDY H
1998785	06/12/2015	Knee Primary	Right	NJR Test ...	Consultant ...	MR NJR Surg..	TestSupplier	BENDY H
1998784	05/12/2015	Knee Primary	Left	NJR Test ...	Mr NJR CIC ...	MR NJR Surg..	TestSupplier	BENDY H
1998782	15/11/2015	Hip Primary	Right	NJR Test ...	MR NJR Surg..	Mr NJR CIC ...	TestSupplier	FLEXI H

1 - 10 of 15 items

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

Procedures						
Pending Consent		Pending Linkage		All BC Records		
NJR Index No.	Operation Date	Procedure Type	Side	Hospital Name	Lead Surgeon Name	

All BC Records 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.

Procedures

Pending Consent		Pending Linkage		All BC Records						
NJR Index No.	Operation Date	Procedure Type	Side	Hospital Name	Lead Surgeon Name	Consultant Name	Manufacturer	Brand	Outcom	
1998751	17/08/20...	Knee Pri...	Right	NJR Te...	MR NJR Su...	Consultant ...	TestSupplier	BENDY...	Unrevisi	
	16/08/20...	Knee Pri...	Left	NJR Te...	CIC Surgeo...	CIC Surgeo...	TestSupplier	BENDY...		
1998749	15/08/20...	Primary T...	Right	NJR Te...	MR NJR Su...	Consultant ...	TestSupplier	FLEXI ...	Revised	
	14/08/20...	Hip Primary	Left	NJR Te...	Consultant ...	Consultant ...	TestSupplier	FLEXI ...		
1998772	04/02/20...	Knee Pri...	Right	NJR Te...	Mr NJR CIC...	MR NJR Su...	TestSupplier	BENDY...	Unrevisi	
1998746	07/01/20...	Knee Pri...	Right	NJR Te...	Mr NJR CIC...	Consultant ...	TestSupplier	BENDY...	Unrevisi	
	N/A	Hip Primary	Right	NJR Te...	NJR Surgeo...	NJR Surgeo...	TestSupplier	FLEXI ...		
	N/A	Hip Primary	Left	NJR Te...	CIC Surgeo...	CIC Surgeo...	TestSupplier	FLEXI ...		

Number of pages

1

2

3

1 - 8 of 8 items

Refresh button

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:

Pending Consent Record	
Procedure	Components
NJR Index No.	1998788
Operation Date	09/12/2015
Procedure Type	Knee Primary
Side	Right
Beyond Compliance Brands	TestSupplier - BENDY Knee
Imported	18/04/2016 08:12:16
Patient Age At Operation	Not available

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	
Procedure	Components
NJR Index No.	1998786
Operation Date	07/12/2015
Procedure Type	Knee Primary
Side	Left
Beyond Compliance Brands	TestSupplier - BENDY Knee
Imported	18/04/2016 08:12:15
Patient Name	Cygnus Black
Patient NHS Number	7612378736
Patient Address	5 Stratton Walk
Patient Postcode	BD15 7SN
Patient DOB	05/03/1953
<b>Consent</b> <input type="button" value="Yes"/> <input type="button" value="No"/>	

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

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

Beyond Compliance Procedure								
Procedures > Procedure 1924492								
Procedure	Components	Patient Records	Questionnaire					
Manufacturer	Brand	Description	Cat. No.	ODEP Rating	Component Type	Implant Joint Type	Composition	Fixation Method
MWZDu	MWENia	FRMAN MOD HIP STEM 10MM	623421R	3A	Hinged/Linked	Knee		Cemented

### 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:




Show items with value that:

Is equal to 

And 



Is equal to 


Filter Clear



Is Equal to
Is Greater than or equal to
Is Less than or equal to
And/Or


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:



Show items with value that:

Is equal to 


And 

Is equal to 


 


Filter Clear

Is Equal to
Is Greater than or equal to
Is Less than or equal to
And / Or

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

Show items with value that:

Contains 



Filter Clear

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.

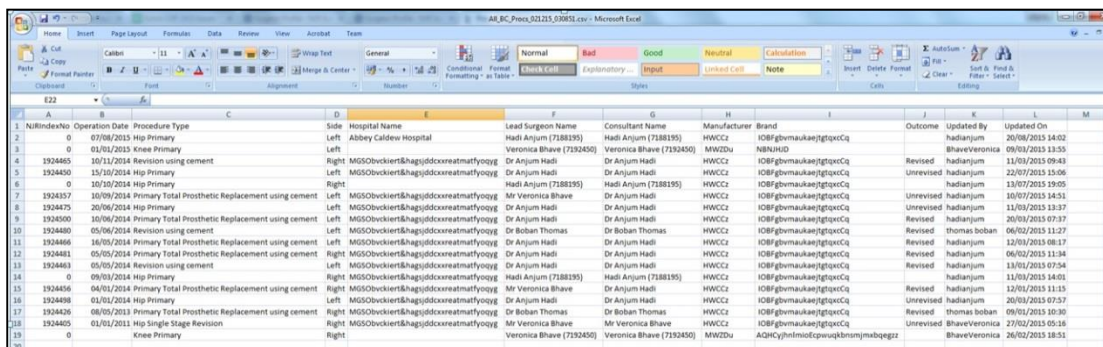
- The download will include all records across all pages for the selected tab.
- If filters are applied, the system will only download the filtered records.
- Similarly, if sorting has been applied, the system will download the sorted records.
- The records are downloaded in .csv format.
- If no records are present, the [Export] button will be disabled.

Pending Consent		Pending Linkage		All BC Records				
<div>Export</div>								
<div>▼</div> Operation Date	<div>▼</div> Procedure Type	<div>▼</div> Side	<div>▼</div> Hospital Name	<div>▼</div> Lead Surgeon Name	<div>▼</div> Consultant Surgeon	Manufacturer	Brand	<div>▼</div>
'83 12/12/2015	Knee Primary	Right	NJR Test H...	Consultant S...	Mr NJR CIC S...	TestSupplier	BENDY Knee	
'88 09/12/2015	Knee Primary	Right	NJR Test H...	MR NJR Surg...	Consultant S...	TestSupplier	BENDY Knee	

Pending Consent		Pending Linkage		All BC Records				
Export								
NJR Index No.	Operation Date	Procedure Type	Side	Hospital Name	Lead Surgeon Name	Consultant Name	Manufacturer	Brand
1998791	12/12/2015	Hip Primary	Right	NJR Test H...	Consultant S...	MR NJR Surg...	TestSupplier	FLEXI HI
1998790	11/12/2015	Hip Primary	Left	NJR Test H...	Mr NJR CIC S...	MR NJR Surg...	TestSupplier	FLEXI HI

Pending Consent		Pending Linkage		All BC Records					
Export									
NJR Index No. 	Operation Date 	Procedure Type 	Side 	Hospital Name 	Lead Surgeon Name 	Consultant Name 	Manufacturer 	Brand 	Outcome 
1998778	05/04/2015	Knee Sing...	Right	NJR Tes...	MR NJR Sur...	MR NJR Sur...	TestSupplier	BENDY ...	Unrevis
1998772	04/02/2015	Knee Prim...	Right	NJR Tes...	Mr NJR CIC...	MR NJR Sur...	TestSupplier	BENDY ...	Unrevis
1998763	03/05/2014	Knee Prim...	Left	NJR Tes...	MR NJR Sur...	Consultant ...	TestSupplier	BENDY ...	Unrevis

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

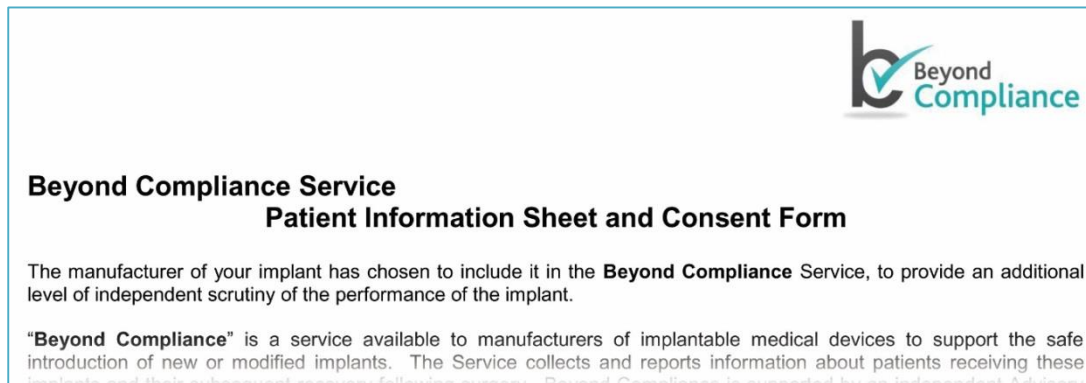


NJR Index No.	Operation Date	Procedure Type	Side	Hospital Name	Lead Surgeon Name	Consultant Name	Manufacturer	Brand	Outcome	Updated By	Updated On
1998778	05/04/2015	Knee Sing...	Right	NJR Tes...	MR NJR Sur...	MR NJR Sur...	TestSupplier	BENDY ...	Unrevis	hadianj	10/07/2015 14:51
1998772	04/02/2015	Knee Prim...	Right	NJR Tes...	Mr NJR CIC...	MR NJR Sur...	TestSupplier	BENDY ...	Unrevis	hadianj	11/03/2015 13:37
1998763	03/05/2014	Knee Prim...	Left	NJR Tes...	MR NJR Sur...	Consultant ...	TestSupplier	BENDY ...	Unrevis	hadianj	26/02/2015 18:51

## 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 [website](#) which, when signed, should be stored by the surgeon 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.

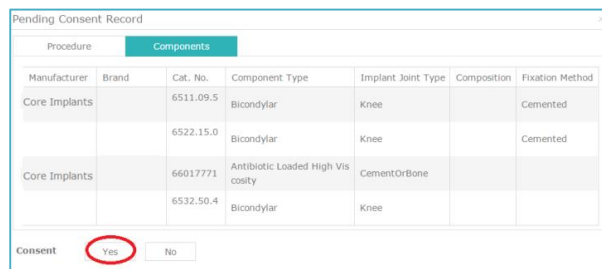
**"Beyond Compliance"** is a service available to manufacturers of implantable medical devices to support the safe introduction of new or modified implants. The Service collects and reports information about patients receiving these implants and their subsequent recovery following surgery. Beyond Compliance is supported by an independent Advisory

To start registering patients into the Beyond Compliance service, authorized surgeons 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.

As Patient Identifiable Data can be viewed, these Consent screens are only available to the authorized surgeons responsible for the patient's clinical care or their delegated Data Entry users. 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.

Pending Consent Record	
Procedure	Components
NJR Index No.	1998717
Operation Date	16/03/2015
Procedure Type	Knee Primary
Side	Left
Hospital	NJR Test Hospital
Lead Surgeon	MR NJR Surgeon (9999998 )
Consultant Surgeon	MR NJR Surgeon (9999998 )
Beyond Compliance Brands	Knee Replacement System (Fixed Bearing)
Imported	26/03/2015 08:10:55
Patient Name	Adria Kinley
Patient NHS Number	1111111111
Patient Address	12 Oakfield Road
Patient Postcode	BS8 2AL
Patient DOB	25/03/1921
<b>Consent</b> <input checked="" type="radio"/> Yes <input type="radio"/> No	

The Consent buttons are available when viewing information about the Procedure or the Components.



Pending Consent Record						
Procedure		Components				
Manufacturer	Brand	Cat. No.	Component Type	Implant Joint Type	Composition	Fixation Method
Core Implants		6511.09.5	Bicondylar	Knee		Cemented
		6522.15.0	Bicondylar	Knee		Cemented
Core Implants		66017771	Antibiotic Loaded High Vis cosity	CementOrBone		
		6532.50.4	Bicondylar	Knee		

Consent ☒ Yes ☐ No

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 for the responsible surgeon. However, the Patient Identifiable Data will only be shown to the authorized surgeon under the 'My BC Records' tab.

The Record will also be listed under the 'All BC Records' tab without Patient Identifiable Data where it can be seen by authorized Manufacturer users.

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.

### 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.

After saving the procedure, the details will be visible under the 'My BC Records' and 'All BC Records' tabs.

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.

## Pending Linkage

Records for 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:

Pending Linkage Record

Matching Record available:

NJR Index Number : 1998709

Please go to the Pending Linkage Tab for carrying out the linkage.

Ok

When an authorized Surgeon or linked Data Entry user views the record under the 'Pending Linkage' tab, a pop-up window displays the two matching records side-by-side:

Pending Linkage Record

Procedure	Components
<b>NJR Record</b>	<b>BC Record</b>
NJR Index No.	1998709
Operation Date	26/01/2015
Procedure Type	Hip Primary
Side	Right
Joint	Hip
Hospital	NJR Test Hospital
Lead Surgeon	MR NJR Surgeon (9999998 )
Consultant Surgeon	MR NJR Surgeon (9999998 )
Beyond Compliance Brands	
Imported	26/03/2015 08:10:55
Patient Name	Ivan Korshunov
Patient NHS Number	111111111
Patient Address	Belgravia House Chester Square
Patient Postcode	SW1W
Patient DOB	21/03/1958
Warning: An NJR record has been found for this procedure. Upon your confirmation, NJR data will be used to populate the BC record. In the case of discrepancies, NJR data will be used.	
Confirm record match	<div>Yes</div> <div>No</div>

Only authorized surgeons who are responsible for the procedure or their linked data entry user may view the complete record (including Patient Identifiable Data) and merge the records.

If the user confirms the record match, this record will now be displayed under 'My BC Records' and 'All BC Records'.

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.

## All BC Records

When a Pending Procedure consent is set to "Yes" each record is 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.

As consent has been given by the patient, the OUTCOME status of the implant is displayed.

Procedures

Pending Consent	Pending Linkage	My BC Records	All BC Records						
<div><div><div>⊕ Add New</div></div></div>									
Procedure Type	Side	Hospital Name	Lead Surgeon Name	Consultant Name	Manufacturer	Brand	Outcome	Updated By	Updated On
Revision...	Right	MGSO...	Dr Anjum...	Dr Anjum...	HWCCz	IOBFg...	Revised	hadianjum	15/0...
Hip Prima...	Right	Aberge...	Hadi Anju...	Hadi Anju...	HWCCz	IOBFg...		Hadianjum	01/0...
Hip Prima...	Left	MGSO...	Dr Anjum...	Dr Anjum...	HWCCz	IOBFg...	Unrevised	hadianjum	15/0...
Primary T...	Left	MGSO...	Dr Anjum...	Dr Anjum...	HWCCz	IOBFg...	Revised	hadianjum	30/0...
Primary T...	Left	MGSO...	Dr Anjum...	Dr Anjum...	HWCCz	IOBFg...	Revised	hadianjum	12/0...
Hip Prima...	Left	MGSO...	Dr Anjum...	Dr Anjum...	HWCCz	IOBFg...	Deceased	hadianjum	09/0...
Primary T...	Right	MGSO...	Dr Anjum...	Dr Anjum...	HWCCz	IOBFg...	Revised	hadianjum	15/0...
Revision...	Left	MGSO...	Dr Anjum...	Dr Anjum...	HWCCz	IOBFg...	Revised	hadianjum	13/0...

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 - AQHCyjhnlmioEcpwuqkbnsmjmx bqegzz		
Imported	16/06/2015 08:10:53		
Patient Age At Operation	23		

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

$$\text{Survival Time of the Implant} = (\text{Date of Death} - \text{Date of Operation})$$

- 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",

Beyond Compliance Procedure			
Procedures > Procedure 1998749			
Procedure	Components	Patient Records	Questionnaire
NJR Index No.	1998749		
Operation Date	15/08/2015		
Procedure Type	Primary Total Prosthetic Replacement not classifie		
Side	Right		
Beyond Compliance Brands	TestSupplier - FLEXI Hip		
Survival Time Of The Implant	0.1 Years		
Imported	20/04/2016 08:12:13		
Patient Age At Operation	45		

Only users who are directly responsible for the patient, e.g. surgeons (who have conducted the procedure) or their linked Data Entry user, can view patient identifiable data

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

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.

Within All BC Records, two further tabs are available:

## Beyond Compliance Procedure

Procedures > Procedure 1998718

Procedure	Components	Patient Records	Questionnaire			
<div><div><div><div></div></div><div>Add New</div></div></div>						
Event Type	Event Date	Description	Record Type	Last Updated By	Last Updated On	Attachments Count

Manufacturers can view any extra information added to Patient Records or Questionnaires by authorized surgeons.

These additional items (called elements) must not contain any Patient Identifiable Information (PID) which is privileged information and should only be disclosed to a healthcare professional who has obtained patient consent and is responsible for the patient's clinical care.

Other authorized users within Beyond Compliance, such as Manufacturers, may view this uploaded data.

We recommend that during the process of document 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.

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

Beyond Compliance Procedure

Procedures > Procedure 1998703

Procedure	Components	Patient Records	Questionnaire			
<div><div><div><div></div></div><div>Add New</div></div></div>						
Event Type	Event Date	Description	Record Type	Last Updated By	Last Updated On	Attachments Count
Pre-Operative	03/03/2014	Dummy	X-Ray Image	TestSurgeon3	04/03/2014 1...	1
Pre-Operative	27/02/2014	The Beyond C...	MRI Scan	TestSurgeon3	26/02/2014 0...	0
Pre-Operative	23/02/2014	Test data for ...	Outpatient Re...	TestSurgeon3	23/02/2014 0...	1
Post-Operative	13/02/2014	Oxford Hip Sc...	Patient Report...	TestSurgeon3	17/02/2014 1...	1
Time of Opera...	13/12/2013	X-RAY	X-Ray Image	TestSurgeon3	13/02/2014 1...	1
Pre-Operative	30/11/2013	PROMs	Patient Report...	TestSurgeon3	08/11/2013 1...	2

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).



The fields and options are: (all fields are mandatory):

#### 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 it appears in the list)

**Filename** (uploaded file from a local device by clicking on the Select button)

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

#### 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:

### Beyond Compliance Procedure

Procedures > Procedure 1998718

Procedure	Components	Patient Records	Questionnaire
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⊕ Add New

Event Date	Year	Last Updated On	Last Updated By
10/12/2014		31/03/2015 10:34	NJR_Surgeon

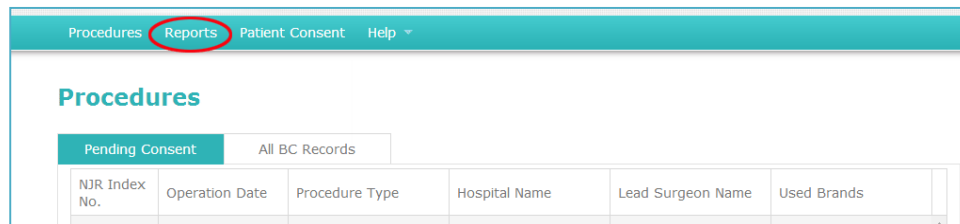
The records can be viewed by clicking on the relevant record which will open in a pop-up window.

## Reports

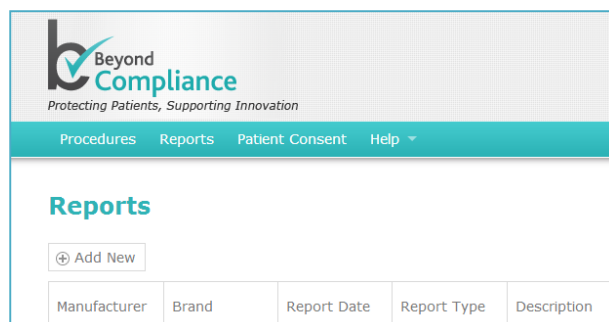
Authorized Manufacturers and Rapporteurs/Evaluators are able to upload confidential document reports and images for associated implant brands that provide additional, useful information for Beyond Compliance brands.

There is no limit on the size of file that can be uploaded

When a Manufacturer logs in they are 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 who is logged in, together with an '(+) Add New' button will be displayed.



The grid 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.

If no records are available, there will be a message 'No items to display' on the lower right-hand side of the grid.

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

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

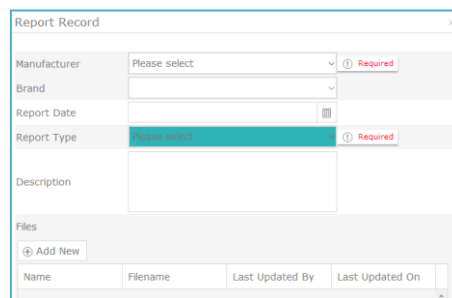
Please note that surgeons are only authorized to view those reports for the BC implant to which they are linked. Data Entry staff are not able to view these additional reports.

## Uploading Reports

Clicking on '(+) Add New' opens a window (entitled 'Report Record') with a form to complete the details of the report (document or image) to be uploaded. If not required, click the 'X' icon to close the window.

The following information must be provided about the new document/image to be uploaded: Manufacturer, Brand, Report Type and Name:

- Manufacturer, Brand and Report Type are to be selected from a drop-down menu of options
- The 'Report Types' are 'Initial', 'On-going', 'Final' and 'Other'
- If the 'Report Type' is 'Other' the User must provide a short description of the 'Report Type'
- A 'Report Name' must also be provided by the User.



When a User has entered the mandatory data into the 'Report Record' pop-up form, this information can be saved without uploading a file. For example, this option helps when a file is not yet available but will be provided in due course.

To upload a file once the mandatory information has been provided, click on the '(+) Add New' button (within the pop-up window) which now becomes enabled:

- A new pop-up window will be displayed that allows the User to browse their local machine and to select a single file to upload at a time
- Although multiple files can be uploaded for a report, each file must be uploaded separately so that the User enters a File description
- After entering Name description, a file may be selected to upload
- The User must confirm that the selected file contains "no patient identifiable data"
- The system will then complete the details regarding 'Last updated by', 'Last updated on', the 'FileName' selected and calculate the number of attachments
- If the "Cancel" button is clicked, the file upload pop up will close and the selected file will not be associated with the Report
- The system only allows a unique combination of Manufacturer, Brand, Report type and actual file name
- If the User clicks the 'X' icon on the File pop up, then a confirmation message is displayed so that User can confirm cancellation
- If the cancellation is confirmed, by clicking on the "Yes" button, then any data entered and file selected is not associated with the Report Record
- If the cancellation is not confirmed, by clicking on the "No" button, then the message is closed and any previously entered data and/or selected files are displayed
- If User enters Name, selects a file, selects checkbox and clicks the "OK" button then the selected file is displayed in the Files list for selected Report Record
- The User should repeat the above process to add more files to the Report Record
- A scroll bar is enabled if number of files exceeds the maximum space available so that the User can view all files for the Report Record.

Note: Although the file names are displayed in the File list they have not been uploaded into Beyond Compliance until the User clicks “Save” button for Report Record.

When the User clicks the “Save” button then:

- If mandatory fields are completed with valid data, then any data entered is saved
- Report Record is saved with specified details
- Selected files are saved and linked with the brand record
- Current User is stored for Last Updated By for Report detail and/or applicable File(s)
- Current System Date Time is stored for Last Updated On for Report detail and/or applicable File(s)
- Display Report details tab updated with new report details
- List is displayed in current User’s last used sort order or as default if not sorted prior to adding the Report Record.

Pagination controls are displayed when the Report Records list has more than 10 records. When the list spans several pages, the system will show the number of items displayed and the total number available (e.g. 1 – 10 of 28 items).

### Editing Report Records

If the User selects a Report Record from the list then the system will:

- Display the Report details pop up for selected Report Record
- Display the previously-entered data for selected Report Record
- Allow all fields to be edited so that the User can:
  - add one or more files to the Report Record
  - edit the Name description, select a file and confirm the selected file contains no patient identifiable data
  - delete an existing file for the selected Report
- Only change the record when the User clicks the “Save” button for Report Details.

### Delete Report Record

The “Delete” button allows Users to remove any Report Records from a selected Report.

Only the user who has created the record should be able to delete the report record. Other users who have permission to edit a record should just edit the file attachment from the record. Any other fields should be locked down.

If a User selects a single item from the list, the Report Records pop up is displayed and a “Delete” button is available so that the selected Report Record can be deleted.

When the User clicks the “Delete” button then:

- a confirmation message is displayed asking the User to confirm that the selected Report Record can be deleted
- on clicking “No” the message is closed and Report Record is not deleted
- on clicking the “Yes” button then:
  - The message is closed
  - Report Record is deleted from the list, including all details and any files that have been uploaded
  - The screen is refreshed to display the updated Report details.

## 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.

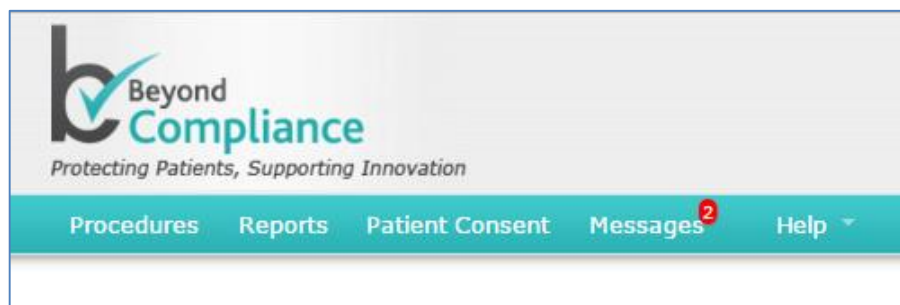
Where the message has specific information relating to a particular implant, separate messages will be sent for each implant.

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:

Procedures Reports Patient Consent Messages Help		
Messages		
Subject	Message Date Time	Message Body
Implant Information Update	06/01/2016 21:23:11	The Implant used for knee procedures will be updated...
Manufacturer on Implant is...	05/01/2016 23:43:48	The information given by the manufacturer for the imp...
1 2 3 4 5 1 - 10 of 41 items		

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](mailto:support@beyondcompliance.org.uk)