

Harmonised classification, data uploads and quality / validation methods

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Agreed Classification

NEC

What is a registry device classification system?

- Structured data capture system categorising implants by design characteristics
- Categorisation of implants consistent to support outcome analysis
- More granular than GMDN and other classification systems which registries have found to not be sufficient to support outcome analysis for a variety of purposes, e.g. PMS reporting services for MedTech and outlier analysis.
- Benefits to industry include supporting MedTech SOTA requirements (comparing similar devices)

The Challenge



Agreed Classification – Hip Sample

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Hip Acetabular Component Type Examples

Joint type	Class Component (sub group)	Class Attribute	Class Value
Hip	H1.1 Acetabular Component	Type *	Modular
Hip	H1.1 Acetabular Component		Monobloc
Hip	H1.1 Acetabular Component		Surface Replacement Cup
Hip	H1.1 Acetabular Component		Preassembled
Hip	H1.1 Acetabular Component		Prefixed
Hip	H1.1 Acetabular Component		Reconstruction Shell
Hip	H1.1 Acetabular Component		Dual Mobility



Agreed Classification – Hip Sample

Hip Femoral Component Type Examples

Joint type	Class Component (sub group)	Class Attribute	Class Value
Hip	H1.5 Femoral Component	Type *	Monobloc
Hip	H1.5 Femoral Component		Modular Head Stem (Standard)
Hip	H1.5 Femoral Component		Femoral Stem with Modular Neck
Hip	H1.5 Femoral Component		Femoral Stem Proximal Section Inc. Femoral Neck
Hip	H1.5 Femoral Component		Femoral Stem Proximal Section Exc. Femoral neck
Hip	H1.5 Femoral Component		Femoral Neck Prosthesis
Hip	H1.5 Femoral Component		Metaphyseal (short stem) Prosthesis
Hip	H1.5 Femoral Component		Metaphyseal (short stem) Prosthesis with Modular Neck
Hip	H1.5 Femoral Component		Tumour Prosthesis



Agreed Classification – Knee Sample

Knee Femoral Component Type Examples:

Joint type	Class Component (sub group)	Class Attribute	Class Value
Knee	K1.1 Femoral Component	Type*	Total (inc bicondylar)
Knee	K1.1 Femoral Component		Unicondylar
Knee	K1.1 Femoral Component		Bi- Compartmental
Knee	K1.1 Femoral Component		Patellofemoral



Agreed Classification – Knee Sample

Knee Tibial Tray Component Types Example

Joint type	Class Component (sub group)	Class Attribute	Class Value
Knee	K1.2 Tibial Tray Including Monobloc	Type *	Total - Modular
Knee	K1.2 Tibial Tray Including Monobloc		Total - Monobloc
Knee	K1.2 Tibial Tray Including Monobloc		Total - Preassembled
Knee	K1.2 Tibial Tray Including Monobloc		Total - Prefixed
Knee	K1.2 Tibial Tray Including Monobloc		Unicondylar - Modular
Knee	K1.2 Tibial Tray Including Monobloc		Unicondylar - Monobloc
Knee	K1.2 Tibial Tray Including Monobloc		Unicondylar - Preassembled
Knee	K1.2 Tibial Tray Including Monobloc		Unicondylar - Prefixed



Agreed Classification – Knee Constraint

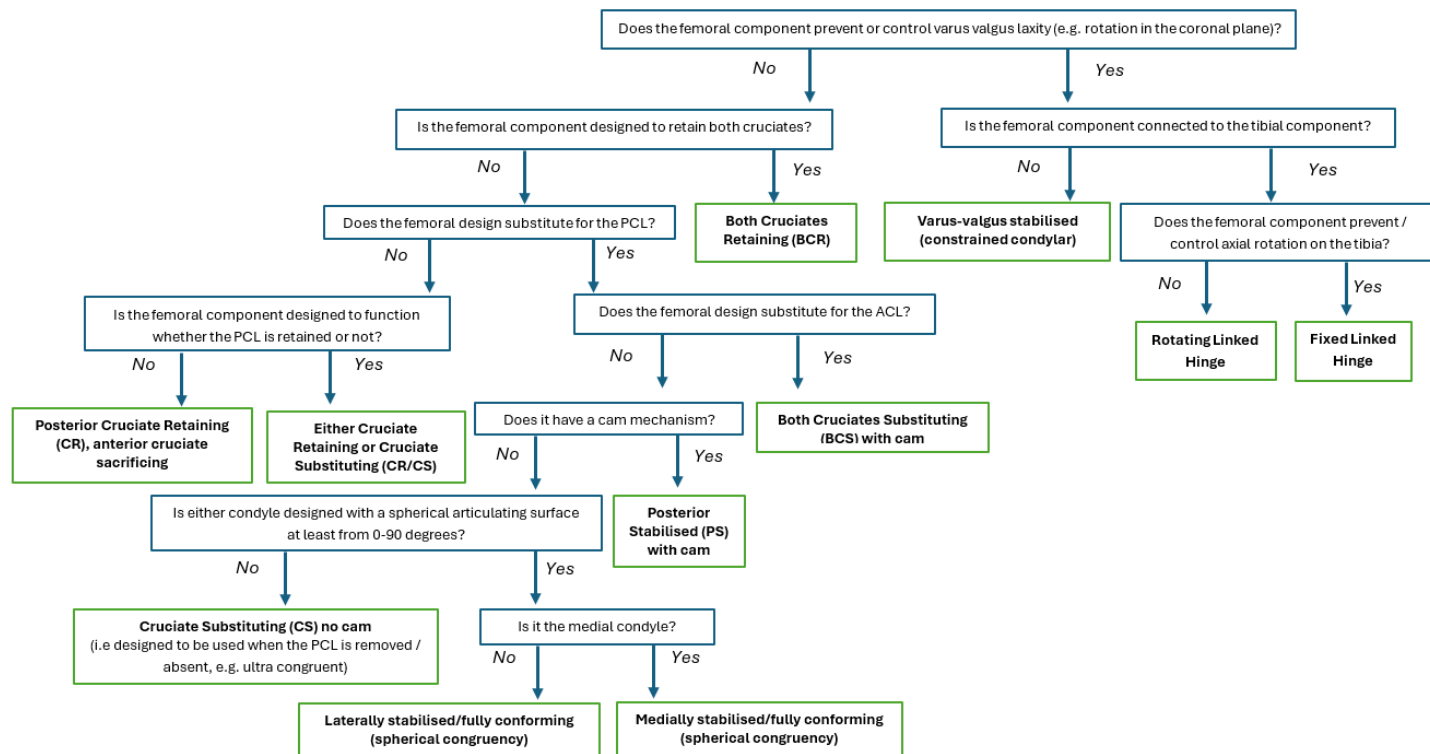
Joint type	Class Component (sub group)	Class Attribute	Class Value
Knee	K1.3 Tibial Insert	Stability	Both Cruciates Retaining (BCR)
Knee	K1.3 Tibial Insert		Posterior Cruciate Retaining (CR), anterior cruciate sacrificing
Knee	K1.3 Tibial Insert		Cruciate Substituting (CS) no post
Knee	K1.3 Tibial Insert		Either Cruciate Retaining or Cruciate Substituting (CR/CS)
Knee	K1.3 Tibial Insert		Posterior Stabilised (PS) with post
Knee	K1.3 Tibial Insert		Both Cruciates Substituting (BCS) with post
Knee	K1.3 Tibial Insert		Medially stabilised/fully conforming (spherical congruency)
Knee	K1.3 Tibial Insert		Laterally stabilised/fully conforming (spherical congruency)
Knee	K1.3 Tibial Insert		Varus-valgus stabilised (constrained condylar)
Knee	K1.3 Tibial Insert		Rotating linked hinge
Knee	K1.3 Tibial Insert		Fixed linked hinge
Knee	K1.3 Tibial Insert		Other/other description
Knee	K1.3 Tibial Insert	Type of insert mobility	Fixed
Knee	K1.3 Tibial Insert		Rotating
Knee	K1.3 Tibial Insert		Translating
Knee	K1.3 Tibial Insert		Translating and rotating

Additional Lower-Level Data Captured - Examples

- **Device Material:** CoCr, Ti, SS, Ceramics
- **Fixation:** Cemented, Cementless
- **Size:** Articulating Diameter (28mm, 30mm, 32mm, 34mm, 36mm, etc)
- **Side:** Right, Left, Universal, RM/RL, LL/LM, Lateral, Medial, etc
- **Coatings:** HA, Calcium Phosphate, Ti, etc
- **Polyethylene Modifications:** XL, Heat Treated, Vitamin Antioxidant
- **Stem Design:** Collared, Uncollared
- **Texture:** Rough, Smooth, Porous, etc

Agreed Classification – Knee Constraint Decision Tree



Stability Decision Tree



Data Uploads


NEC

About NJR – Implant Classification / Data Collection Demo






Component Database

NJR Connect - Data Services

**National
Joint Registry**

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Welcome to
NJR Connect - Data Services

-  Monitor your outcomes
-  Download reports
-  Update your profile

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[Sign in](#)

Further information: [User Guide](#)
Helpdesk: +44 (0)845 345 9991
v6.8.0.5

Enabled by
NEC

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Suppliers can view all their products recorded in the registry.

g.uk/DataEntry_SandPit/secure/frm National Joint Registry

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Component Maintenance Search

Catalogue No Group Manufacturer Reset
Description Sub Group Distributor Search
GTIN Number

New
Copy
Historic

Manufacturer	Group	Catalogue Number	GTIN	Component Description	Sub Group	On the market	Status
Corin	Hip	000Test		Test database cup	Acetabular Component	Yes	Edit
Corin	Hip	010.4242	123r	Alpha Lock Plus Acetabular Cup Cementless 42mm diameter	Acetabular Component	Yes	Edit
Corin	Hip	010.4244	123y	Alpha Lock Plus Acetabular Cup Cementless 44mm diameter	Acetabular Component	Yes	Edit
Corin	Hip	010.4246	45l	Alpha Lock Plus Acetabular Cup Cementless 46mm diameter	Acetabular Component	Yes	Edit
Corin	Hip	010.4246_test		Alpha Lock Plus Acetabular Cup Cementless 50mm diameter	Acetabular Component	Yes	Edit
Corin	Hip	010.4248		Alpha Lock Plus Acetabular Cup Cementless 48mm diameter	Acetabular		Edit
Corin	Hip	010.4248_lm		test	Acetabular		Edit
Corin	Hip	010.4250		Alpha Lock Plus Acetabular Cup Cementless 50mm diameter	Acetabular		Edit
Corin	Hip	010.4252		Alpha Lock Plus Acetabular Cup Cementless 52mm diameter	Acetabular		Edit
Corin	Hip	010.4254		Alpha Lock Plus Acetabular Cup Cementless 54mm diameter	Acetabular Component	Yes	Edit

Click the Edit link (on the right) to edit this component.

Status key:
Red Cross – does not contain enough information to allocate component to a procedure.
Amber tick - meets the minimum requirements to allocate this component to a procedure.
Green tick - This component is fully completed.

1 - 10 of 4458 items

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About NJR – Implant Classification / Data Collection Demo

Search a suppliers product library by cat no, product type, group, description , GTIN etc.

Component Maintenance Search

Catalogue No Group Manufacturer Reset
 Description Sub Group Distributor Search
 GTIN Number

Manufacturer	Group	Catalogue Number	GTIN	Component Description	Sub Group	On the market	Status	
Corin	Hip	010.6042		CeraFit Acetabular Cup Cementless 42mm diameter	Acetabular Component	Yes	✓	Edit
Corin	Hip	010.6044		CeraFit Acetabular Cup Cementless 44mm diameter	Acetabular Component	Yes	✓	Edit
Corin	Hip	010.6046		CeraFit Acetabular Cup Cementless 46mm diameter	Acetabular Component	Yes	✓	Edit
Corin	Hip	010.6048		CeraFit Acetabular Cup Cementless 48mm diameter	Acetabular Component	Yes	✓	Edit
Corin	Hip	010.6050		CeraFit Acetabular Cup Cementless 50mm diameter	Acetabular Component	Yes	✓	Edit
Corin	Hip	010.6052		CeraFit Acetabular Cup Cementless 52mm diameter	Acetabular Component	Yes	✓	Edit
Corin	Hip	010.6054		CeraFit Acetabular Cup Cementless 54mm diameter	Acetabular Component	Yes	✓	Edit
Corin	Hip	010.6056		CeraFit Acetabular Cup Cementless 56mm diameter	Acetabular Component	Yes	✓	Edit
Corin	Hip	010.6058		CeraFit Acetabular Cup Cementless 58mm diameter	Acetabular Component	Yes	✓	Edit
Corin	Hip	010.6060		CeraFit Acetabular Cup Cementless 60mm diameter	Acetabular Component	Yes	✓	Edit
Corin	Hip	010.6062		CeraFit Acetabular Cup Cementless 62mm diameter	Acetabular Component	Yes	✓	Edit
Corin	Hip	010.6064		CeraFit Acetabular Cup Cementless 64mm diameter	Acetabular Component	Yes	✓	Edit
Corin	Hip	010.6066		CeraFit Acetabular Cup Cementless 66mm diameter	Acetabular Component	Yes	✓	Edit

Lines per Page 1 - 13 of 13 items

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Browser address bar: http://www.njrclinicianfeedback.org.uk/DataEntry_SandPit/secure/frm

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Component Maintenance Search

Catalogue No:
 Description:
 GTIN Number:

Group:
 Sub Group:

Manufacturer:
 Distributor:

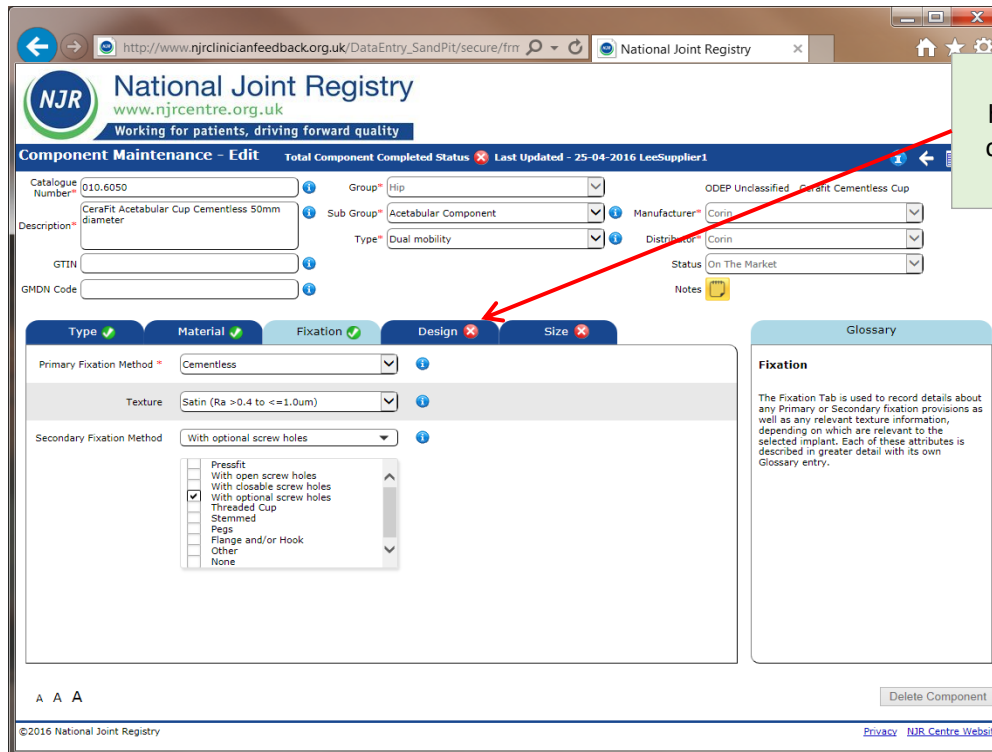
Manufacturer	Group	Catalogue Number	GTIN	Component Description	Sub Group	On the market	Status	
Corin	Hip	010.6042		CeraFit Acetabular Cup Cementless 42mm diameter	Acetabular Component	Yes		Edit
Corin	Hip	010.6044		CeraFit Acetabular Cup Cementless 44mm diameter	Acetabular Component	Yes		Edit
Corin	Hip	010.6046		CeraFit Acetabular Cup Cementless 46mm diameter	Acetabular Component	Yes		Edit
Corin	Hip	010.6048		CeraFit Acetabular Cup Cementless 48mm diameter	Acetabular Component	Yes		Edit
Corin	Hip	010.6050		CeraFit Acetabular Cup Cementless 50mm diameter	Acetabular Component	Yes		Edit
Corin	Hip	010.6052		CeraFit Acetabular Cup Cementless 52mm diameter	Acetabular Component	Yes		Edit
Corin	Hip	010.6054		CeraFit Acetabular Cup Cementless 54mm diameter	Acetabular Component	Yes		Edit
Corin	Hip	010.6056		CeraFit Acetabular Cup Cementless 56mm diameter	Acetabular Component	Yes		Edit
Corin	Hip	010.6058		CeraFit Acetabular Cup Cementless 58mm diameter	Acetabular Component	Yes		Edit
Corin	Hip	010.6060		CeraFit Acetabular Cup Cementless 60mm diameter	Acetabular Component	Yes		Edit
Corin	Hip	010.6062		CeraFit Acetabular Cup Cementless 62mm diameter	Acetabular Component	Yes		Edit
Corin	Hip	010.6064		CeraFit Acetabular Cup Cementless 64mm diameter	Acetabular Component	Yes		Edit
Corin	Hip	010.6066		CeraFit Acetabular Cup Cementless 66mm diameter	Acetabular Component	Yes		Edit

Lines per Page: 1 - 13 of 13 items

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Edit an existing component to update missing data fields.

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Component Maintenance - Edit Total Component Completed Status ✗ Last Updated - 25-04-2016 LeeSupplier1

Catalogue Number ✗ 010.6050 i Group ✓ Hip ODEP Unclassified - Corin Cementless Cup

Description i CeraFit Acetabular Cup Cementless 50mm diameter i Sub Group ✓ Acetabular Component i Manufacturer ✓ Corin

GTIN i Type ✓ Dual mobility i Distributor ✓ Corin

GMDN Code i Status ✓ On The Market

Notes 📝

Fixation

Primary Fixation Method ✓ Cementless i

Texture i Satin (Ra >0.4 to <=1.0um)

Secondary Fixation Method i With optional screw holes

- ☐ Pressfit
- ☐ With open screw holes
- ☐ With closable screw holes
- ☒ With optional screw holes
- ☐ Threaded Cup
- ☐ Stenomed
- ☐ Pegs
- ☐ Flange and/or Hook
- ☐ Other
- ☐ None

A A A

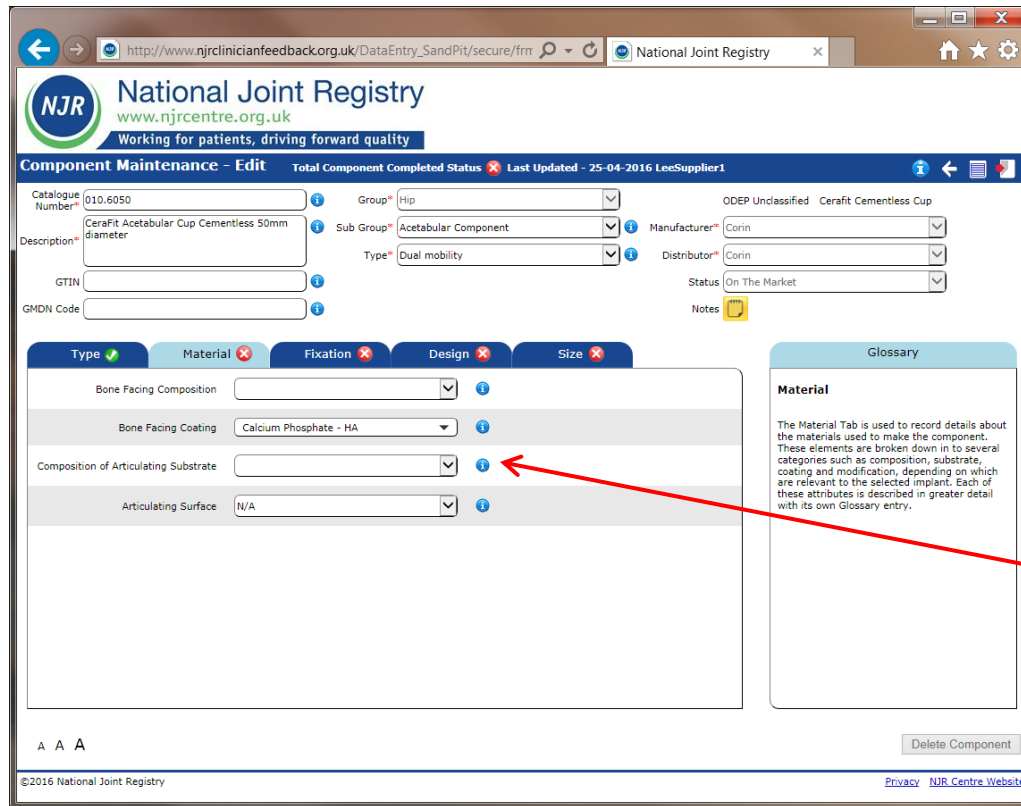
Delete Component

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Tabs per category highlights where data is complete (green tick) or missing (red cross).

About NJR – Implant Classification / Data Collection Demo

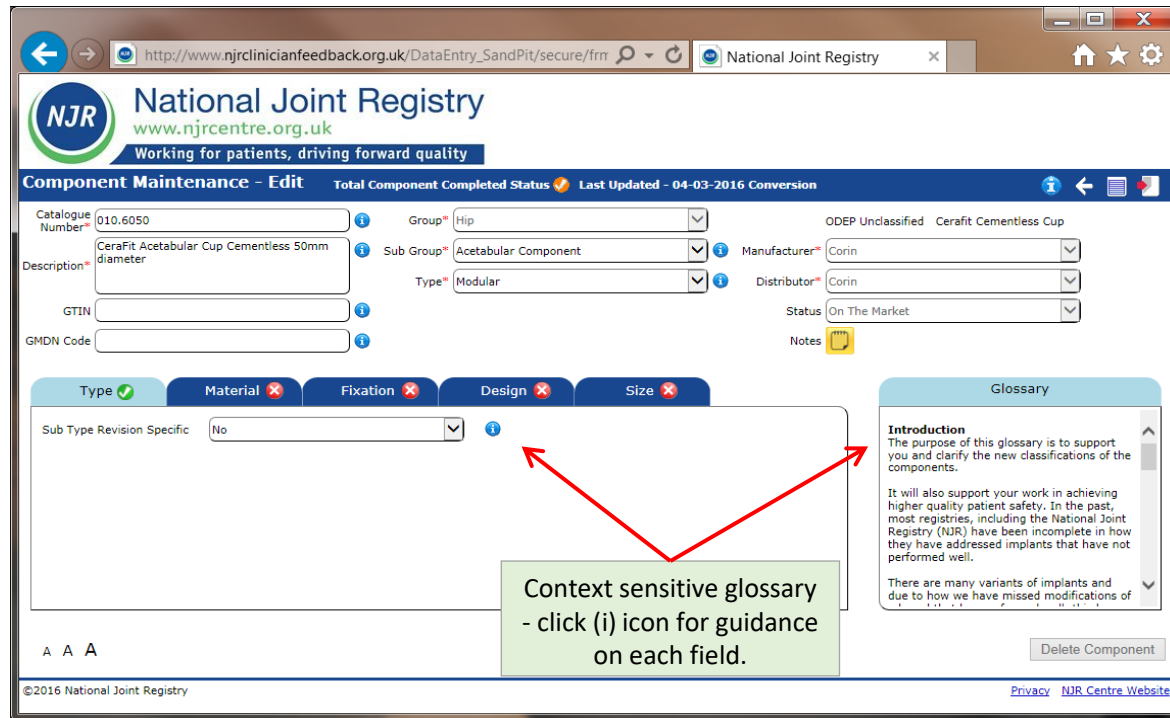


The screenshot shows the 'Component Maintenance - Edit' form in the NJR system. The form is divided into several sections:

- Header:** NJR National Joint Registry logo and website address (www.njrcentre.org.uk).
- Component Maintenance - Edit:** A section with a title bar showing 'Total Component Completed Status' and 'Last Updated - 25-04-2016 LeeSupplier1'.
- Form Fields:**
 - Catalogue Number:** 010.6050
 - Description:** CeraFit Acetabular Cup Cementless 50mm diameter
 - GTIN:** (empty)
 - GMDN Code:** (empty)
 - Group:** Hip
 - Sub Group:** Acetabular Component
 - Type:** Dual mobility
 - Manufacturer:** Corin
 - Distributor:** Corin
 - Status:** On The Market
 - ODEP Unclassified:** CeraFit Cementless Cup
 - Notes:** (empty)
- Material Tab:** A tab labeled 'Material' with a red 'X' icon. It contains a table with the following rows:
 - Bone Facing Composition:** (dropdown menu)
 - Bone Facing Coating:** Calcium Phosphate - HA
 - Composition of Articulating Substrate:** (dropdown menu)
 - Articulating Surface:** N/A
- Glossary:** A section titled 'Material' explaining that the Material Tab is used to record details about the materials used to make the component. It states: 'These elements are broken down in to several categories such as composition, substrate, coating and modification, depending on which are relevant to the selected implant. Each of these attributes is described in greater detail with its own Glossary entry.'
- Footer:** ©2016 National Joint Registry, Privacy, NJR Centre Website, and a 'Delete Component' button.

The fields that appear depend upon the implant group, sub group and type (business rules).

About NJR – Implant Classification / Data Collection Demo



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Component Maintenance - Edit Total Component Completed Status Last Updated - 04-03-2016 Conversion

Catalogue Number: 010.6050 Group: Hip ODEP Unclassified Cerafit Cementless Cup

Description: CeraFit Acetabular Cup Cementless 50mm diameter Sub Group: Acetabular Component Manufacturer: Corin

GTIN: Type: Modular Distributor: Corin

GMDN Code: Status: On The Market

Notes:

Type Material Fixation Design Size

Sub Type Revision Specific: No

Context sensitive glossary
- click (i) icon for guidance on each field.

Glossary

Introduction
The purpose of this glossary is to support you and clarify the new classifications of the components.

It will also support your work in achieving higher quality patient safety. In the past, most registries, including the National Joint Registry (NJR) have been incomplete in how they have addressed implants that have not performed well.

There are many variants of implants and due to how we have missed modifications of


Delete Component

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About NJR – Implant Classification / Data Collection Demo

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Component Maintenance - Edit Total Component Completed Status  Last Updated - 25-04-2016 LeeSupplier1

Catalogue Number: 010.6050 Group: Hip ODEP Unclassified Cerafit Cementless Cup
Description: CeraFit Acetabular Cup Cementless 50mm diameter Sub Group: Acetabular Component Manufacturer: Corin
GTIN: 1234 Type: Dual mobility Distributor: Corin
GMDN Code: 1234 Status: On The Market

Type  **Material**  **Fixation**  **Design** 

Articulation Diameter: 34.50
External Diameter: 44mm

All fields now complete.
Overall Status updated to green tick.

The Size Tab contains additional attributes to describe the various dimensions of the Component, depending on which are relevant to the selected implant. Each of these attributes is described in greater detail with its own Glossary entry.

Delete Component

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About NJR – Implant Classification / Data Collection Demo

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Apply updates in bulk by exporting data into a reloadable spreadsheet.

← → http://www.njrclinicianfeedback.org.uk/DataEntry_SandPit/secure/frm National Joint Registry

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Component Maintenance Search

Catalogue No: Group: Manufacturer: Reset

Description: Sub Group: Distributor: Search

GTIN Number:

Manufacturer	Group	Catalogue Number	GTIN	Component Description	Sub Group	On the market	Status
Corin	Hip	010.6042		CeraFit Acetabular Cup Cementless 42mm diameter	Acetabular Component	Yes	Edit
Corin	Hip	010.6044		CeraFit Acetabular Cup Cementless 44mm diameter	Acetabular Component	Yes	Edit
Corin	Hip	010.6046		CeraFit Acetabular Cup Cementless 46mm diameter	Acetabular Component	Yes	Edit
Corin	Hip	010.6048		CeraFit Acetabular Cup Cementless 48mm diameter	Acetabular Component	Yes	Edit
Corin	Hip	010.6050	1234	CeraFit Acetabular Cup Cementless 50mm diameter	Acetabular Component	Yes	Edit
Corin	Hip	010.6050_b	1234b	CeraFit Acetabular Cup Cementless 50.4mm diameter	Acetabular Component	Yes	Edit
Corin	Hip	010.6052		CeraFit Acetabular Cup Cementless 52mm diameter	Acetabular Component	Yes	Edit
Corin	Hip	010.6054		CeraFit Acetabular Cup Cementless 54mm diameter	Acetabular Component	Yes	Edit
Corin	Hip	010.6056		CeraFit Acetabular Cup Cementless 56mm diameter	Acetabular Component	Yes	Edit
Corin	Hip	010.6058		CeraFit Acetabular Cup Cementless 58mm diameter	Acetabular Component	Yes	Edit
Corin	Hip	010.6060		CeraFit Acetabular Cup Cementless 60mm diameter	Acetabular Component	Yes	Edit
Corin	Hip	010.6062		CeraFit Acetabular Cup Cementless 62mm diameter	Acetabular Component	Yes	Edit
Corin	Hip	010.6064		CeraFit Acetabular Cup Cementless 64mm diameter	Acetabular Component	Yes	Edit
Corin	Hip	010.6066		CeraFit Acetabular Cup Cementless 66mm diameter	Acetabular Component	Yes	Edit

Lines per Page: 1 - 14 of 14 items

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http://www.njrclinicianfeedback.org.uk/DataEntry_SandPit/secure/frmComponent...

About NJR – Implant Classification / Data Collection Demo

The spreadsheets are joint specific and capture the same fields as the system. Add or amend data within the sheet to reload and apply updates in bulk.

SHOULDERS S0.4						Core Component Details <i>Shared Architecture</i>		Type
Key						MDS		MDS
Upd. Flag	Catalogue No.	Overall Status	On Mkt	GTIN	Sub Brand	Sub-Group <i>Other columns dependent on this - shown by sub-chapter short ref. (shown in red text)</i>		Type
Yes	04207.103		TRUE	00889024274655	Anatomical Shoulder	Anatomical Shoulder Fix Humeral fracture stem size 10-130mm	S1.1Humeral Stem (Diaphysis) Components	S1.1Modular
	04207.103		TRUE	00889024275036	Anatomical Shoulder	Anatomical Shoulder Humeral Stem cemented 14-200	S1.1Humeral Stem (Diaphysis) Components	S1.1Modular
			TRUE	00889024275102	Anatomical Shoulder	Anatomical Shoulder Humeral Stem cemented 16-200	S1.1Humeral Stem (Diaphysis) Components	S1.1Modular
			TRUE	00889024275119	Anatomical Shoulder	Anatomical Shoulder Humeral Stem cemented 18-200	S1.1Humeral Stem (Diaphysis) Components	S1.1Modular
			TRUE	00889024274815	Anatomical Shoulder	Anatomical Shoulder Humeral Stem cemented 16-120	S1.1Humeral Stem (Diaphysis) Components	S1.1Modular
			TRUE	00889024274822	Anatomical Shoulder	Anatomical Shoulder Humeral Stem cemented 18-120	S1.1Humeral Stem (Diaphysis) Components	S1.1Modular
			TRUE	00889024275058	Anatomical Shoulder	Anatomical Shoulder Humeral Stem cemented 7-130	S1.1Humeral Stem (Diaphysis) Components	S1.1Modular
			TRUE	00889024275065	Anatomical Shoulder	Anatomical Shoulder Humeral Stem cemented 9-200	S1.1Humeral Stem (Diaphysis) Components	S1.1Modular

Update Yes or Leave Blank
Select "Yes" if you wish to reflect any changes in NJR

A numbering key in the column headers illustrates which fields are applicable for each component.

Hover text within spreadsheet. Provides guidance on each field.

Data Quality Checks & Methods

NEC

Import / export spreadsheet validation

- Spreadsheet locked for editing structure
- Use of drop-down menus containing approved values for consistent data structure. Limited free text
- Hover text provides guidance on questions asked
- Spreadsheet validated and imported only by dedicated NJR staff
- Loaded in Test environments
- Import routine validation – business rules
- Import error logs available highlighting fields completed incorrectly

SHOULDERS		Key				Core Component Details				Type	
SR#		MDS				Shared Architecture				MDS	

Data Quality – Data Entry System

- As the NJR collects data on implantable medical devices it allows for improved data quality.
- Sophisticated validation rules have been integrated into the hospital data entry system to ensure hospital users add a minimum number of components. This improves the quality of data submitted.

Example: Primary TKR Using Cement. Unicondylar implants not accepted for a total knee replacement, vice versa.

<input type="checkbox"/> The component validation advice must be addressed before this surgery record can be completed. If the advice is incorrect in this case, please tick this box.
Component Combination Validation Comments
Please include a Bone Substitute and Cement - Bone cement component to complete the full set of components required
Please include a Femoral group component to complete the full set of components required
Please include TibialTrayIncludingMonobloc - Total modular to complete the full set of components required
Check with the operating surgeon that the patient procedure and implants used are correct. If correct, contact your NJR Regional Co-ordinator.

- Rules can be shared with other registries adopting the same device classification, e.g. RIAP

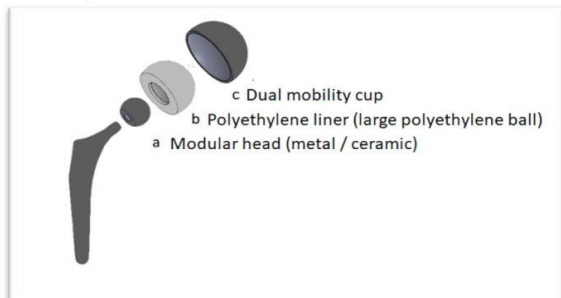
Data Quality System Business Rule Checks – Dual Mobility Example

- NJR enables complete construct checks at the point data is entered by hospitals based on patient procedure types selected
- Example: Patient Procedure = Dual Mobility THR (two main constructs)
- Data Entry system understands which devices make up each construct to support data completeness

❖ Design 1, monobloc dual mobility includes:

- Dual mobility cup (inc. articulating surface);
- Dual mobility polyethylene liner (large polyethylene ball); and
- Modular head (metal or ceramic).

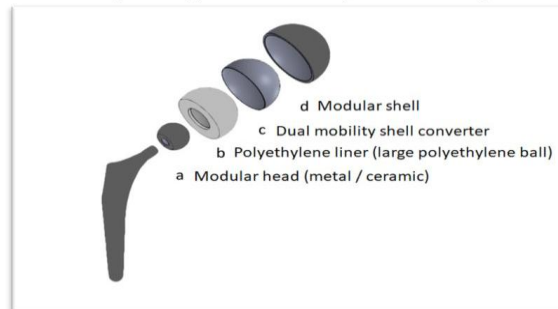
Figure 1. Type 1 dual mobility construct design



❖ Design 2, modular dual mobility includes:

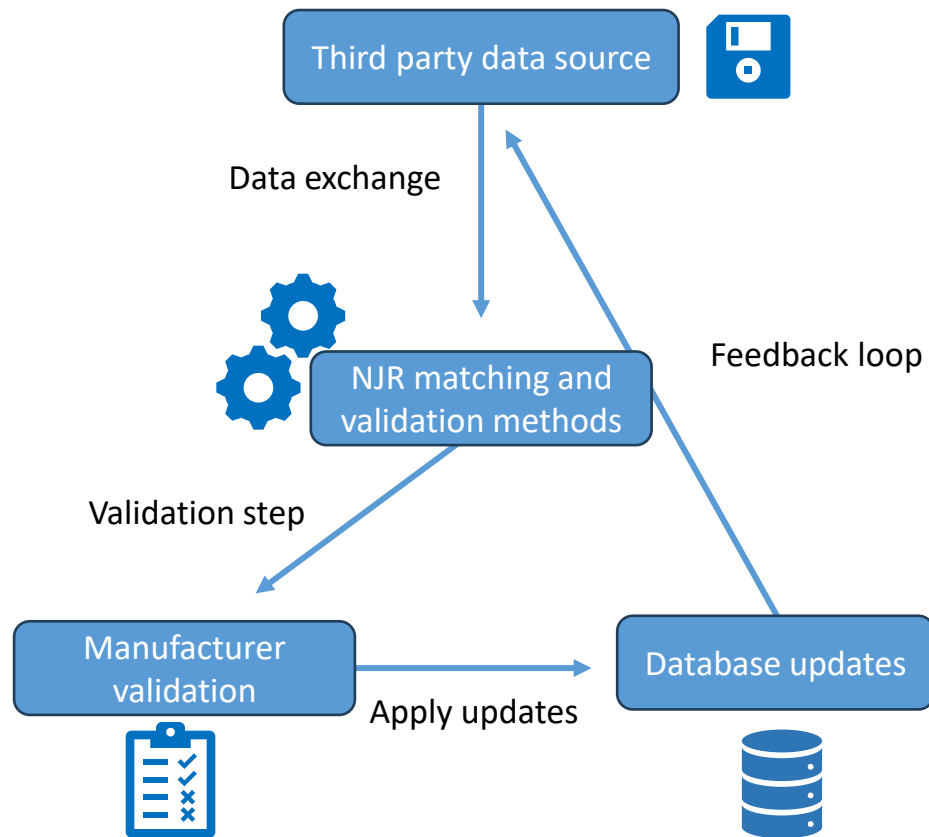
- Modular shell (standard);
- Dual mobility converter;
- Dual mobility polyethylene liner (large polyethylene ball); and
- Modular head (metal or ceramic).

Figure 2. Type 2 dual mobility construct design



Implant Data Quality Checks – Comparisons To Other Registries

- NJR has developed algorithms to support data quality cross referencing to determine if common devices in different territories are classified the same
- Exercise supports filling data gaps, identifying conflicting information for resolution and has avoided duplicate entry by manufacturers
- Fuzzy matching techniques and other methods applied to determine if different terms for the same values match, for example Cobalt Chrome (CoCr) and Cobalt Chrome Alloy
- NJR has undertaken this exercise on implant data from both the EPRD and IPL v1
- A future routine data quality audit process could be set up to run this frequently and apply updates to synchronise databases.



Thank you

Contact Details

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