Breast Implant Registry: Data Collection Form v2.0

All the mandatory **(M)** data items are on the first two pages

Patient Demographics (M)			
NHS, CHI or H&C number (M if known)		**Date of Birth (M)** (dd/mm/yyyy)	- - / - - / - - - -

If NHS, CHI or H&C number is not known, this section is **(M)**

First Name			**Surname**		
Gender	Female		Not known		**Postcode**
	Male		Not specified		- - - - - - -

Is this patient a medical tourist?	Yes		No	
If yes, Country of Residence? (M)				

Operation – (M)											
Operating hospital name/site code (M)											
GMC Number Responsible Consultant (M)											
GMC Number of Operating Surgeon (M) If different to above											
Operation Date (M) (dd/mm/yyyy)	- - / - - / - - - -										
ASA Grade	1		2		3		4		5		

Category of Operation (M)					
Augmentation ☐	Replacement/ exchange of implants ☐	Explant ☐	Reconstruction immediate ☐	Reconstruction delayed ☐	Exchange of expander to implant ☐
Laterality (M)					
Same procedure on each ☐	Left only ☐	Right only ☐	Different procedure on each ☐		

Device - M for everything except explant	**Left**	**Right**
Manufacturer (M)		
Serial number (M)		
Unique Device Identifier (UDI) DI (M) 14 digits after (01) in barcode		
Catalogue ref number (M if UDI not known)		
Lot number (M if UDI not known)		
Left implant label sticker	Right implant label sticker	

Breast Implant Registry: Data Collection Form v2.0

All the mandatory **(M)** data items are on the first two pages

Mesh - M for everything except explant	**Left**	**Right**
Was a mesh/dermal sheet used? (M)	Yes / No	Yes / No
Manufacturer (M if mesh/dermal sheet used)		
Serial number (M)		
Unique Device Identifier (UDI) DI (M) 14 digits after (01) in barcode		
Catalogue ref number (M if UDI not known)		
Lot number (M if UDI not known)		
Left mesh/dermal sheet label sticker	Right mesh/dermal sheet label sticker	

Revision Procedure - M for replacement/exchange of implants and explant. Available for exchange of expander	**Left**		**Right**	
Reason for Revision (M) (complete complications section)	☐ Complication	patient ☐ preference	☐ Complication	patient ☐ preference
Original implant inserted overseas?	Yes / No / Unknown		Yes / No / Unknown	
Manufacturer of explanted device				
Serial number of explanted device				
Date of original implant, if known (dd/mm/yyyy)	- - / - - / - - - -		- - / - - / - - - -	
Capsulectomy	Full / Partial / None		Full / Partial / None	

Complications / Operative findings – available for all categories of operation except augmentation and reconstruction		**Left**	**Right**
Silicone extravasation found	Intracapsular		
	Extracapsular		
	Distant		
	None		
Device rupture / deflation	Yes reason for revision		
	Yes found incidentally		
	No		
Capsular contracture	Yes reason for revision		
	No		
Skin scarring problems	Yes reason for revision		
	No		

All the mandatory **(M)** data items are on the first two pages

Device malposition	Yes reason for revision		
	Yes found incidentally		
	No		
Deep wound infection	Yes reason for revision		
	No		
Seroma / Haematoma	Yes reason for revision		
	Yes found incidentally		
	No		
Anaplastic Large Cell Lymphoma (ALCL)	Yes reason for revision		
	Yes found incidentally		
	No		
Double capsule	Yes reason for revision		
	Yes found incidentally		
	No		
Extrusion / dehiscence	Yes reason for revision		
	No		

Surgery Details – available for all categories of operation		**Left**	**Right**
Plane	Sub-glandular/fascial		
	Sub-pectoral/dual plane		
	Sub-flap		
	Pre-pectoral		
Concurrent mastopexy		Yes / No	Yes / No
Flap cover (not available for augmentation)	Dermal		
	Free		
	Pedicled		
	None		

Infection Control – available for all categories of operation except explant	
Peri-operative antibiotics (including pre-op, intra-op or post-op)	Yes / No
Antibiotic dipping solution used?	Yes / No
Antiseptic rinse used?	Yes / No
Surgical gloves changed for implant insertion?	Yes / No
Sleeve/funnel (Keller funnel) used?	Yes / No
Nipple guards used?	Yes / No
Drains used?	Yes / No
Impregnated substance inserted? (e.g. Collatamp)	Yes / No
Incisional negative pressure wound therapy (NPWT) device used?	Yes / No