TRIAL ID: | Initials: F M L | Site ID: _____

UNIVERSITY OF BIRMINGHAM

BCTU Birmingham Clinical Trials Unit


# IN - THEATRE FORM

ONLY TO BE COMPLETED BY AN OPERATING SURGEON OR SOMEONE WHO WAS PART OF THE INDEX OPERATION.

**Please complete this form immediately after the patient has had surgery.**

## PART A - Intra-operative Details

Did the patient have surgery? ◯ No ◯ Yes

If No, please specify why not:

_____

_____

_____

If the patient did **not** undergo surgery please go to PART C.

Date of surgery: *e.g. 31-JAN-2017* D D - M M M - Y Y Y Y

If the date of surgery is not the date of randomisation, please explain why:

_____

_____

Lead Operating Surgeon: _____

Organ(s) or structures operated upon: *(Please tick No or Yes to all)*

| | | |
|---|---|---|
| Oesophagus/ Stomach /Duodenum | ◯ No | ◯ Yes |
| Small Bowel | ◯ No | ◯ Yes |
| Colon/ Rectum | ◯ No | ◯ Yes |
| Gall Bladder/ Biliary System/ Liver | ◯ No | ◯ Yes |
| Kidney/ Ureter/ Bladder/ Urethra | ◯ No | ◯ Yes |
| Gynaecological Structures | ◯ No | ◯ Yes |
| Endocrine System | ◯ No | ◯ Yes |
| Major Vascular Structures | ◯ No | ◯ Yes |
| Other | ◯ No | ◯ Yes |

If Other, please specify: _____

Up to 60 minutes prior to incision, were prophylactic antibiotics given? *(Please tick one)* ◯ No ◯ Yes

If Yes, please give generic name(s) of prophylactic antibiotics in the spaces provided.

_____

_____

Was the WHO surgical safety checklist used? *(Please tick one)* ◯ No ◯ Yes

Hair removal at site of wound? *(Please tick one)*

◯ No hair at site of wound ◯ In theatre (Electric) ◯ In theatre (Razor/ Blade) ◯ Before theatre arrival ◯ Not done

Length of incision: *(To the nearest cm)* __ __ cm

Total operation duration: __ __ __ Minutes

What was the surgical approach? *(Please tick one)*

◯ Open (Midline) ◯ Open (Non-Midline) ◯ Laparoscopic assisted ◯ Laparoscopic converted to open

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Actual intra-operative contamination level? *(Definitions provided on Randomisation CRF)* *(Please tick one)*
◯ Clean ◯ Clean - Contaminated ◯ Contaminated ◯ Dirty

Was a wound/ incision wash performed? *(Please tick one)* ◯ No ◯ Yes

If Yes, please state: *(Tick all that apply)* ◯ Saline/ Water ◯ Betadine ◯ Other

Is a stoma present? *(Please tick one)*
◯ No
◯ Yes (pre-existing)
◯ Yes (formed during this operation)

Was an incise drape used? *(Please tick one)*
◯ No
◯ Yes (Ioban-impregnated)
◯ Yes (non-impregnated)

How was the skin closed? *(Tick all that apply)*
◯ Continuous sutures
◯ Interrupted sutures
◯ Staples
◯ Skin left open *(Patient to remain in ROSSINI 2)*
◯ Other (If Other, please specify _____)

Were triclosan impregnated sutures used? *(Please tick one)* ◯ No ◯ Yes

Was a wound edge protection device used? *(Please tick one)* ◯ No ◯ Yes

What skin preparation was used? *(Please tick No or Yes to all)*

| | | |
|---|---|---|
| 0.5% Alcoholic Chlorhexidine | ◯ No | ◯ Yes |
| 2% Alcoholic Chlorhexidine | ◯ No | ◯ Yes |
| Alcoholic Povidone Iodine | ◯ No | ◯ Yes |
| Aqueous Chlorhexidine | ◯ No | ◯ Yes |
| Aqueous Povidone Iodine | ◯ No | ◯ Yes |
| Other (If Yes, please specify: _____) | ◯ No | ◯ Yes |

Was a Gentamicin-impregnated sponge (Collatamp) placed in the wound at the end of the operation? *(Please tick one)* ◯ No ◯ Yes

Was intra-operative temperature monitoring used? *(Please tick one)* ◯ No ◯ Yes

What was the estimated blood loss? *(Please tick one)* ◯ <100ml ◯ 100 - 500ml ◯ 501 - 1000ml ◯ >1000ml

Was an 'on-table' blood transfusion required? *(Please tick one)* ◯ No ◯ Yes

Was the patient on inotropes at the end of the operation? *(Please tick one)* ◯ No ◯ Yes

Were catheters left in place for local anaesthetic infiltration? *(Please tick one)* ◯ No ◯ Yes

Is the patient going to continue antibiotics post-operatively? *(Please tick one)* ◯ No ◯ Yes

Grade of operating surgeon: *(Please tick one)* ◯ Consultant ◯ Registrar level ◯ SHO ◯ ANP

Grade of surgeon administering intervention(s): *(Please tick one)* ◯ Consultant ◯ Registrar level ◯ SHO ◯ ANP

Grade of surgeon closing fascia: *(Please tick one)* ◯ Consultant ◯ Registrar level ◯ SHO ◯ ANP

Grade of surgeon closing skin: *(Please tick one)* ◯ Consultant ◯ Registrar level ◯ SHO ◯ ANP

## PART B - Intra-operative Serious Adverse Event Reporting

Intra-operative adverse skin event:

| | | |
|---|---|---|
| Allergic Reaction | ◯ No | ◯ Yes |
| Skin Reaction | ◯ No | ◯ Yes |
| Fire/ Combustion | ◯ No | ◯ Yes |

If Yes, a SAE form must be completed.

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## PART C - Intervention received

Which trial intervention(s) did the patient **RECEIVE?** *(Please tick No or Yes to all)*

DACC DRESSING ◯ No ◯ Yes

GLOVES AND INSTRUMENTS (immediately before fascial closure) ◯ No ◯ Yes

Was this the same as the patient's randomised allocation? *(If No, please complete a Protocol Non-Compliance Form)* ◯ No ◯ Yes

If No, please specify why not:

_____

_____

_____

ROSSINI 2 allows for more than one intervention to be used on a patient if needed, therefore please state how many of each intervention(s) were used? *If none were used, please state 0.*

DACC DRESSING ☐

## Intra-operative details completed by:

Full Name: *(PRINT NAME)* _____

Signature: _____

Position: _____

Date: *e.g. 31-JAN-2017* D D - M M M - Y Y Y Y

Thank you for completing this CRF. You are now required to transcribe this information onto REDCap (https://bctu-redcap.bham.ac.uk/). This CRF can be used as Source Documentation and filed in the patient's records.