Women are eligible if:

- They are undergoing delivery by lower segment Caesarean section through a transverse abdominal incision, irrespective of fever in labour, gestational age or whether they have a multiple pregnancy.

Women are NOT eligible if:

- There is a clear indication for a particular surgical technique or material to be used that prevents any of the allocated interventions being used, e.g. for a woman with a previous vertical abdominal incision it maybe considered inappropriate to do a transverse abdominal incision for this caesarean section. However, if a transverse incision is going to be performed the woman is eligible.

- They have had more than one previous caesarean section.

- They have already been recruited into the trial during a previous pregnancy.

Woman’s name: 

Ward:
Procedure for recruiting a woman

On admission: Check eligibility and discuss study with woman and family (if present)

Obtain signed or marked consent

At Study Entry: Complete the At Study Entry page of the Data Collection Booklet. You will be asked for this information over the telephone

Telephone the Regional Trial Office (RTO) for an allocation number

Open the envelope corresponding to the number that has been given over the telephone and take out the Allocation Form

Complete the allocation details on the At Study Entry page of the Data Collection Booklet. Fax the completed page to the RTO

Immediately after delivery: complete details of delivery in the Immediately After Delivery section

Surgical Techniques Used: the surgeon must complete this section immediately after surgery

Give the woman the CORONIS Medical Card and a six week follow-up appointment

Before discharge from hospital: complete the Postpartum Hospital Stay section
Complete questions 1-10 BEFORE making the randomisation telephone call to the Regional Trial Office - this should be done as close to the time of surgery as possible.

1. Hospital code: 
2. Doctor code: 
3. Has the woman given consent to enter the CORONIS Trial?  [ ] Yes  [ ] No
4. Number of previous Caesarean sections: 
5. Woman's hospital record number: 

You will only be asked to give the woman's first initials over the phone but please complete her full name below.

6. Woman's family name(s): 
   (use BLOCK CAPITALS please)
7. Woman's first name(s): 
   (use BLOCK CAPITALS please)
8. Woman's date of birth: [DD] / [MM] / [YYYY] 
or age in years: 
9. Has the fetal heart beat been heard?  [ ] Yes  [ ] No
10. Is the Caesarean section being performed before the onset of labour?  [ ] Yes  [ ] No

You will NOT be asked to give the date and time on the telephone call.

The date NOW: [DD] / [MM] / [YYYY]  
The time NOW: [HH]:[MM]

Write the allocation number given over the telephone here ➔  
This is the woman’s Study Number.

Now open the envelope corresponding to the allocation number given over the telephone and tick relevant boxes below to show the allocation:

Sharp  [ ]  Ext*  [ ]  Single  [ ]  Closure  [ ]  Catgut  [ ]
Blunt  [ ]  Intra-Abdo*  [ ]  Double  [ ]  Non-Closure  [ ]  Polyglactin-910  [ ]
*Exteriorisation of the uterus for repair versus intra-abdominal repair.

Now fax the top copy of this page to the Regional Trial Office.

Please complete the next section immediately after delivery.
**IMMEDIATELY AFTER DELIVERY**

Please complete this section for all women in the study, regardless of their actual mode of delivery.

**Woman’s details - obstetric history**

1. What is this woman’s parity*? e.g. 03
2. Has the woman had a previous Caesarean section?  
   - Yes □  
   - No □  
   If Yes, was this through:  
     - abdominal incision  
     - uterine incision  
     - unknown
3. Is this woman known to be HIV antibody positive?  
   - Known positive □  
   - Known negative □  
   - Unknown

**Current pregnancy**

4. Has this woman had an intrapartum fever of 38°C or greater on any occasion during labour?  
   - Yes □  
   - No □  
   - Unknown
5. Did the membranes rupture before the delivery?  
   - Yes □  
   - No □  
   If Yes, please give number of hours before delivery: Hours □  
   - Unknown
6. Was the woman undergoing a planned ‘trial of scar’*?  
   - Yes □  
   - No □  
   - Not Applicable
7. Actual mode of delivery (if multiple birth tick all that apply)  
   - Spontaneous vaginal □  
   - Instrumental vaginal □  
   - Caesarean section □
7a. If Caesarean section, what was the main indication for this Caesarean section (please give the single main reason):  
   □
7b. Was a diagnosis of labour made prior to the Caesarean section?  
   - Yes □  
   - No □  
   If Yes, please give number of hours of labour prior to CS: Hours □  
   - Unknown
8. Is this a multiple pregnancy?  
   - Yes □  
   - No □
9. Best estimate of gestational age at time of delivery*:  
   - Weeks □  
   - Unknown
   What is this estimate based on?  
   - Last menstrual period date □  
   - Ultrasound □  
   - Clinical estimation of uterus size □

**Delivery Outcome**

10. Was this baby(ies) stillborn?  
    - Baby 1: Yes □  
    - Baby 2: Yes □  
    - Baby 3: Yes □  
    - No □  
11. Neonatal Apgar at 5 minutes (if applicable):  
    - Baby 1: □  
    - Baby 2: □  
    - Baby 3: □  
    - Not known □

Name of person completing this section □

Date section completed □/□/□

* See definitions at the back of this Data Collection Booklet
<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Actual date and time of start of Caesarean section (knife to skin):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type of anaesthesia (tick all that apply):</td>
<td>Local</td>
<td>Spinal</td>
</tr>
<tr>
<td>Method of emptying bladder prior to surgery:</td>
<td>‘in out’ catheterisation</td>
<td>in-dwelling catheter for the duration of the operation only</td>
</tr>
<tr>
<td>Abdominal entry:</td>
<td>Sharp</td>
<td>Blunt</td>
</tr>
<tr>
<td>How difficult was abdominal entry?</td>
<td>Easy</td>
<td>Difficult</td>
</tr>
<tr>
<td>Were abdominal packs used?:</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Was the bladder reflected off the lower uterine segment?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Uterine entry: After entering the uterus was the uterine incision extended</td>
<td>by tearing (blunt dissection)?</td>
<td>by cutting (sharp dissection)?</td>
</tr>
<tr>
<td>What was the presentation of the fetus (first fetus if more than one)</td>
<td>Cephalic</td>
<td>Breech</td>
</tr>
<tr>
<td>Were forceps used to effect delivery?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Removal of placenta:</td>
<td>Controlled cord traction</td>
<td>Manual removal</td>
</tr>
<tr>
<td>Was the uterine cavity swabbed after delivery of the placenta?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Exteriorisation of uterus for uterine repair:</td>
<td>Exteriorised</td>
<td>Not exteriorised</td>
</tr>
<tr>
<td>Repair of uterus:</td>
<td>Single layer</td>
<td>Double layer</td>
</tr>
<tr>
<td>Suture material used for uterine repair:</td>
<td>Polyglactin-910</td>
<td>Chromic catgut</td>
</tr>
<tr>
<td>Suturing technique for first layer uterine repair:</td>
<td>Continuous non-locking</td>
<td>Continuous locking</td>
</tr>
<tr>
<td>Question</td>
<td>Options</td>
<td>Other Options</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>13c Suturing technique for second layer uterine repair (where applicable):</td>
<td>Continuous non-locking, Continuous locking, Interrupted, Other</td>
<td>If Other, please specify:</td>
</tr>
<tr>
<td>13d Were any additional sutures required to achieve haemostasis?</td>
<td>Yes, No</td>
<td></td>
</tr>
<tr>
<td>13e How many sutures were used?</td>
<td>Number</td>
<td></td>
</tr>
<tr>
<td>14 Pelvic peritoneum:</td>
<td>Closed, Not closed</td>
<td>If different from allocation, please give reason:</td>
</tr>
<tr>
<td>14a If closed, suture material used:</td>
<td>Polyglactin-910, Chromic catgut, Other</td>
<td>If Other, please specify:</td>
</tr>
<tr>
<td>14b If closed, suturing technique used:</td>
<td>Continuous non-locking, Continuous locking, Interrupted, Other</td>
<td>If Other, please specify:</td>
</tr>
<tr>
<td>15 Parietal peritoneum:</td>
<td>Closed, Not closed</td>
<td></td>
</tr>
<tr>
<td>15a If closed, suture material used:</td>
<td>Polyglactin-910, Chromic catgut, Other</td>
<td>If Other, please specify:</td>
</tr>
<tr>
<td>16 Closure of the rectus sheath:</td>
<td>Closed, Not closed</td>
<td></td>
</tr>
<tr>
<td>16a If closed, suture material used:</td>
<td>Polyglactin-910, Chromic catgut, Other</td>
<td>If Other, please specify:</td>
</tr>
<tr>
<td>16b If closed, suturing techniques used:</td>
<td>Continuous non-locking, Continuous locking, Interrupted, Other</td>
<td>If Other, please specify:</td>
</tr>
<tr>
<td>17 Was a sub-rectus sheath wound drain used?</td>
<td>Yes, No</td>
<td></td>
</tr>
<tr>
<td>17a If drain was used, was it:</td>
<td>a closed system e.g. Redivac, an open system e.g. corrugated drain</td>
<td></td>
</tr>
<tr>
<td>18 Superficial fat/fascia layer:</td>
<td>Closed, Not closed</td>
<td></td>
</tr>
<tr>
<td>18a If closed, suture material used:</td>
<td>Polyglactin-910, Chromic catgut, Other</td>
<td>If Other, please specify:</td>
</tr>
<tr>
<td>18b If closed, suturing technique used:</td>
<td>Continuous non-locking, Continuous locking, Interrupted, Other</td>
<td>If Other, please specify:</td>
</tr>
</tbody>
</table>
SURGICAL TECHNIQUES USED Continued

18c Was a superficial fat/fascia layer drain used?

Yes ☐ No ☐

19 Skin closure:

Staples ☐ Polyglactin-910 ☐
Nylon ☐ Silk ☐
Other ☐

If Other, please specify:

19a Suturing technique used (if applicable):

Subcuticular ☐ Continuous ☐
Interrupted ☐
Other ☐

If Other, please specify:

20 Prophylactic antibiotics used:

Yes ☐ No ☐

21 Prophylactic heparin used:

Yes ☐ No ☐

22 Prophylactic uterotonic:

Not given ☐ Oxytocin bolus ☐
Oxytocin infusion ☐ Ergometrine bolus ☐
Other ☐

If Other, please specify:

23 Duration of Caesarean section procedure*:

mins

24 Was the baby(ies) cut during uterine entry?

Baby 1: Yes ☐ No ☐
Baby 2: Yes ☐ No ☐
Baby 3: Yes ☐ No ☐

Please ensure you have completed questions 21 to 24

Name of operator

Status of operator

Name of assistant

Status of assistant

Signature of operator

Date section completed

Thank you

* See definitions at the back of this Data Collection Booklet

OXTREC 013-06 - ISRCTN31089967

V1 Dec 2006
POSTPARTUM HOSPITAL STAY

To be completed by a health professional during the woman’s postpartum stay until the time of discharge from hospital.

1. Was this woman in hospital on day TWO?  
   - [ ] Yes  
   - [ ] No  
   
   If [Yes], was additional analgesia given, other than routine, to this woman for pain between 24 and 48 hours after delivery?  
   - [ ] Yes  
   - [ ] No  
   
   If [Yes], give details below:

<table>
<thead>
<tr>
<th>Generic name of drug</th>
<th>Mode of administration(eg oral)</th>
<th>Total dose</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. Was the woman admitted to Intensive care?  
   - [ ] Yes  
   - [ ] No  
   
   If [Yes], date admitted:  
   
   Date discharged:  
   
   Reason for Admission:

3. Did this woman receive any blood (packed cells, whole blood, plasma or clotting factors) while in this hospital?  
   - [ ] Yes  
   - [ ] No  
   
   If [Yes], give details below:

<table>
<thead>
<tr>
<th>Type of blood product given</th>
<th>Indication for blood product(s)</th>
<th>Date transfusion started</th>
<th>Time transfusion started</th>
<th>Total number of units given during this hospital stay</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4. During this woman’s postpartum stay were any of the following conditions diagnosed?  
   
   (a) postpartum fever of 38°C or greater on two or more occasions?  
   - [ ] Yes  
   - [ ] No  
   
   (b) wound infection?  
   - [ ] Yes  
   - [ ] No  
   
   If [Yes], was this treated with antibiotics  
   - [ ] Yes  
   - [ ] No  
   
   Were any of following features present (tick all that apply)?  
   
   fever  
   pus draining from wound  
   induration of wound  
   wound dehiscence  
   erythema of wound edges  
   leukocytosis
Were any microbiological investigations done?  Yes [ ]  No [ ]

Were any organisms found?  Yes [ ]  No [ ]

If Yes, please complete table below:

<table>
<thead>
<tr>
<th>Name of isolated organism(s)</th>
<th>Site</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(c) endometritis?

If Yes, was this treated with antibiotics? Yes [ ]  No [ ]

Were any of following features present *(tick all that apply)*

- offensive lochia
- abdominal tenderness
- fever
- cervical excitation
- leukocytosis

Were any microbiological investigations done?  Yes [ ]  No [ ]

Were any organisms found?  Yes [ ]  No [ ]

If Yes, please complete table below:

<table>
<thead>
<tr>
<th>Name of isolated organism(s)</th>
<th>Site</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5  Was this woman was prescribed any antibiotics during her postpartum stay in hospital (other than prophylactic antibiotics)?  Yes [ ]  No [ ]

If Yes, please give details below (do not include antimalarials):

<table>
<thead>
<tr>
<th>Generic name of antibiotic</th>
<th>Indication (eg endometritis, wound infection)</th>
<th>Mode of admin. (eg oral)</th>
<th>Dosing regimen (eg 250mg 4hrly)</th>
<th>Date of start of course (dd/mm/yy)</th>
<th>Duration of course (days)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
6 Has this woman undergone any further operative procedures on her Caesarean wound*?  
   Yes ☐  No ☐  
   If Yes, please describe:  
   (a) Indication(s):  
   
   (b) Procedure(s):  
   
7 Has this woman undergone or received any of the following (tick all that apply)?  
   Yes ☐  No ☐  
   Exploration of uterus under anaesthetic ☐  
   *Curettage of uterus ☐  
   *Laparotomy ☐  
   *Internal iliac artery or any other major artery ligation ☐  
   *Brace suture (eg. B-lynch suture) ☐  
   *Balloon tamponade or uterine packing ☐  
   *Hysterectomy ☐  
   Additional uterotonic*ics (other than those given for prophylaxis) ☐  
   If additional uterotonic*ics were given, please detail below:  
   
<table>
<thead>
<tr>
<th>Name of uterotonics</th>
<th>Mode of administration (eg IV)</th>
<th>Dose given</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*If any of the questions marked + have been ticked, complete a Serious Adverse Event Form immediately and fax it to the Regional Trial Office.

8 Did this woman have any severe or unexpected adverse events*?  
   Yes ☐  No ☐  
   If Yes, please complete a Serious Adverse Event Report Form immediately and fax it to the Regional Trial Office.

9 Outcome  
   (a) Death ☐  
      Date of death ☐/☐/☐ DAY/MONTH/YEAR  
      Cause of death:  
      
   (b) Discharged home ☐  
      Date of discharge home ☐/☐/☐ DAY/MONTH/YEAR  

* See definitions at the back of this Data Collection Booklet.
(c) Transferred to another hospital

If transferred to another hospital, please give details of receiving hospital:

Name: 
Address: 
Tel. No: 

Date of discharge or transfer: 

(d) Date of 6 week follow-up appointment

Place of 6 week follow-up appointment

Hospital 
Local clinic 
Home 
Phone 

Woman's details:

Name: 
Address: 
Tel: 
Mobile number: 

Husband/Partner's details:

Name: 
Address: 
Tel: 
Mobile number: 

Woman's mother or other reliable contact details e.g grandparents or name and address of employer etc.:

Name: 
Address: 
Tel: 
Mobile number: 

Referring doctor's details (if appropriate):

Name: 
Address: 
Tel: 

Name of person completing this section (please print) 

Date section completed: 

Is there any reason why this woman cannot be seen at 6-weeks post-discharge?

Please fax or send top copies of pages 2 – 9 to your Regional Trial Office immediately.

Thank you
SIX WEEKS AFTER DISCHARGE
To be completed by a health professional six weeks after the woman is discharged from hospital.

If the woman has died since discharge from hospital please give date and cause of death.
Date of death: [ ] / [ ] / [ ]
Cause of death:

TODAY

1. Ask the woman how she is feeling physically, today?
   - Very well [ ]  
   - Quite well [ ]  
   - Not very well [ ]  
   - Very unwell [ ]

2. Is her baby(ies) alive?
   - Baby 1: Yes [ ]  No [ ]
   - Baby 2: Yes [ ]  No [ ]
   - Baby 3: Yes [ ]  No [ ]

SINCE DISCHARGE FROM HOSPITAL

3. Since discharge from hospital have any of the following conditions been diagnosed?
   (a) wound infection? [ ]
      - If Yes, was this treated with antibiotics? [ ]
      - Were any of the following features present (tick all that apply)?
        - fever [ ]
        - pus draining from wound [ ]
        - induration of wound [ ]
        - wound dehiscence [ ]
        - erythema of wound edges [ ]
   (b) endometritis [ ]
      - If Yes, was this treated with antibiotics? [ ]
      - Were any of the following features present (tick all that apply)?
        - offensive lochia [ ]
        - abdominal tenderness [ ]
        - fever [ ]
        - cervical excitation [ ]

4. If either wound infection or endometritis was treated with antibiotics, please detail them below (do NOT include antimalarials):
   (Check against Medical Card)

<table>
<thead>
<tr>
<th>Generic name of antibiotic</th>
<th>Indication</th>
<th>Mode of admin. (eg oral)</th>
<th>Dosing regimen (eg 250mg 4hrly)</th>
<th>Date of start of course (dd/mm/yy)</th>
<th>Duration of course (days)</th>
</tr>
</thead>
</table>
5 Has this woman undergone any further operative procedures on her Caesarean wound?  
Yes  No  
If Yes, please describe:
  a) Indication(s) 
  b) Procedure(s) 

6 Have antibiotics been prescribed for any other condition?  
Yes  No  
If No, please go to Q7

If Yes, who prescribed the antibiotics and what was the main reason for giving them? 
(Check against Medical Card) 
First course 
Hospital doctor  Family doctor  Other health professional  
What was the main reason for the first course of antibiotics? 

Second course 
Hospital doctor  Family doctor  Other health professional  
What was the main reason for the second course of antibiotics? 

7 Has the woman experienced much pain from the wound, if any?  
No pain  Occasional pain  Continual pain  

8 Have painkillers been prescribed since discharge from hospital because of pain in the wound?  
Yes  No  
If No, please go to Q9

If Yes, list pain killers prescribed since discharge from hospital 
(Check against Medical Card) 

* See definitions at the back of this Data Collection Booklet
9 Has the woman been back to hospital since going home after her caesarean section?

If Yes, please give reasons for hospital visit and dates below:

(Check Medical Card)

<table>
<thead>
<tr>
<th>Reason</th>
<th>Date of visit</th>
<th>Admitted? Yes/No</th>
<th>Date of discharge (if different from date of visit)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Which hospital(s) did she attend? *(please give us as full an address as you can)*

Please provide hospital name(s) and address(es):

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

10 Has the woman suffered any of the following? *(please tick all that apply)*

- severe secondary post-partum haemorrhage *(blood loss > 1000mls)*
- deep venous thrombosis
- pulmonary embolism
- septicaemia or septic shock

If Yes, to any of these, please describe where appropriate, the method of diagnosis (including organisms if known) and treatment(s) given

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Method of Diagnosis</th>
<th>Organism</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

11 If the woman has any other medical problems not covered above, please describe below.

Please provide full details here

Name of person completing this section *(please print)*

Date section completed [DAY] / [MONTH] / [YEAR]

Now remove the top copies of pages 10-12 and fax or send them to your Regional Trial Office immediately. Keep the completed Data Collection Booklet in your Document Box.

Thank you
Definitions for the section IMMEDIATELY AFTER DELIVERY

Parity:
Include all births (livebirth or stillbirth) of viable fetus (estimated gestational age ≥24 weeks)

Best estimate of gestational age:
Please use the estimate of gestational age which is being used for clinical decision making. This may be based on the known last menstrual period date, an ultrasound scan or in the absence of this information, clinical examination of the uterus size.

Planned trial of scar:
This is women who have had a previous Caesarean section who are in labour as anticipated. If a woman with a previous Caesarean section presents in labour while waiting for her planned Caesarean section, tick the ‘No’ box.

Duration of Caesarean section procedure:
Length of operation in minutes from first skin incision until operative procedure is complete.

Definitions for the sections POSTPARTUM STAY IN HOSPITAL and SIX WEEKS AFTER DISCHARGE

Operative procedures on wound:
This includes any procedures undertaken on the wound once the woman has left the operating theatre following her Caesarean section. It also includes further procedures under anaesthesia and removal of sutures without anaesthesia because of wound haematoma or infection. Operative procedures do NOT include use of pressure dressings. If uncertain, please tick ‘Yes’ and describe the procedure in the box provided.

Severe or unexpected maternal events:
Any severe or unexpected morbidity should be reported. This is most likely to include:

peritonitis, severe haemorrhage (requiring transfusion of six units or more of blood), repeat laparotomy, hysterectomy, deep venous thrombosis, curettage of uterus, internal iliac artery or other major artery ligation, brace suture (e.g. B-lynch suture), balloon tamponade or uterine packing, pulmonary embolism and septicaemia. If uncertain, please tick ‘Yes’ and report the adverse event on the Serious Adverse Event Report Form.

NOTES
Continue here if required, (please clearly specify which question the notes refer to e.g. Q12 Surgical Techniques Used section, Page 3):

If you have any queries about completing this booklet please consult the Handbook or telephone your Regional Trial Office.

OXTREC 013-06 - ISRCTN31089967