The Cerclage Suture Type for an Insufficient Cervix and its effect on Health outcomes (C-STICH)

CRF2: C-STICH Cerclage Placement

PLEASE COMPLETE THIS FORM TO LET US KNOW THE DETAILS OF THE CERCLAGE PROCEDURE.

A. PLEASE COMPLETE SECTIONS 1 & 6 IN ALL CASES.

B. IF THE CERCLAGE WAS PLACED, PLEASE ALSO COMPLETE THE REMAINDER OF THIS FORM.

C. IF THE CERCLAGE WAS NOT PLACED, COMPLETE Q1&2 OF SECTION 2 AND SECTION 6 ONLY.

Section 1. Patient Details:

Patient's trial number: ☐☐☐☐

Patient's Date of Birth (MMM-YYYY): ☐☐☐ - ☐☐☐☐

Participant BMI (at booking): ☐☐.☐

Section 2. Treatment Details:

1. Was a cerclage placed?:

YES ☐ **On what date was it placed?** ☐☐ - ☐☐☐ - ☐☐☐☐

Please go to question 2

NO ☐ **Please tick 'Yes' or 'No' to the following to indicate why the cerclage was not placed*:**

	YES	NO
Patient refused or did not attend?	☐	☐
Cervix too short?	☐	☐
Cervix too dilated?	☐	☐
Membranes ruptured?	☐	☐

	YES	NO
Cervical bleeding?	☐	☐
Infection?	☐	☐
Other?	☐	☐

If 'Other', please specify:

_____

**Please now go to Section 6, 'Some Information about You', and sign and date this form*

Section 2. Treatment Details (continued):

2. Can the site perform microbiology assessment on swabs and sutures?:

YES ☐ **NO** ☐

If you tick 'No' to any of questions 2, 2a, 2c, please go to question 3.

Important: If taking a swab, this should be taken before cleaning and preparation and before the patient commences any antibiotics.

2a. If 'Yes', was a swab taken? **YES** ☐ **NO** ☐

2b. If 'Yes' at what time was it taken? **Hrs** ☐☐ **Mins** ☐☐

2c. If taken, was the swab sent for microbiology assessment? **YES** ☐ **NO** ☐

2d. If 'YES', date sent: D D - M M M - Y Y Y Y

If the swab was sent for microbiology assessment, please ensure to complete CRF 4 Microbiology Assessment when the results are in.

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3. Was vaginal prepping done? **YES** ☐ **NO** ☐

3a. If vaginal prepping was done, please specify the type of preparing below:

Chlorhexidine based	*Iodine based*	*Aqueous based*	**Other, please specify*
X	X	X	

	YES	**NO**
4. Did placing the cerclage involve bladder dissection?	☐	☐

Your responses to Qs 5 and 6 will help us to determine the length of time of cerclage placement.

	Hrs	**Mins**
5. At what time was the speculum inserted? (24 hr clock):	☐☐	☐☐
6. At what time was the speculum removed? (24 hr clock):	☐☐	☐☐

	YES	**NO**
7. Did someone of Consultant grade place the cerclage?	☐	☐
7a. If 'No', was the cerclage placed under supervision?	☐	☐

Section 2. Treatment Details (continued):

8. Were membranes visible? YES ☐ NO ☐

9. Which anaesthetic was used to place the cerclage? General ☐ Regional ☐ Local ☐

10. Were myometrial depressants used to place the cerclage? YES ☐ NO ☐

10a. If myometrial depressants were given, please indicate what these were:

Indomethacin ☐ **Other** ☐ **please specify**_____

Nifedipine ☐

11. Which suture material did you use to place the cerclage? Monofilament ☐ Tape (Braided) ☐

11a. Please circle the 'X' under the material used to indicate the brand that was used:

	Braided	Monofilament
Mersiline (Ethicon)	X	
Ethibond Excel (Ethicon)	X	
Ethilon (Ethicon)		X
Prolene (Ethicon)		X
Norolon (Ethicon)		X
Surgipro (Covidien)		X
Monosof (Covidien)		X
Dermalon (Covidien)		X
Other	X	X

11b. If 'Other', please state what this was: ……

11c. If the suture material used differs from that allocated at randomisation please state why this was changed?:

……

……

Section 2. Treatment Details (continued):

12. How many bites were placed in the cervix?: ☐

	Posteriorly	Anteriorly
13. Where was the knot placed?	☐	☐

	Yes	No
14. Has the suture closed the cervix to your satisfaction?	☐	☐
15. Has an additional occluding stitch been placed to close the external os?	☐	☐
15a. If 'Yes', was the occluding stitch placed with the same suture type as the randomised cervical suture?	☐	☐

Section 3. Treatment Complications:

*Please report complications with an asterisk as an SAE.

	YES	NO
16. Were there any complications to do with the cerclage?	☐	☐
16a. If 'YES', please tell us the type of complications here below:	☐	☐
Cervical Laceration*	☐	☐
Bleeding from cervix	☐	☐
Ruptured membranes*	☐	☐
Bladder Injury*	☐	☐
Raised temperature (>38°C)	☐	☐
Other	☐	☐

16b. If other complications, please tell us what these were:

……

……

……

Section 4. Antibiotics (Given during cerclage procedure):

	YES	NO
17. Did the mother receive prophylactic antibiotics at cerclage insertion?	☐	☐

17a. If yes please specify what these were:	YES	NO
Intravenous benzyl penicillin	☐	☐
Intravenous cephalosporin	☐	☐
Intravenous Co-amoxiclav	☐	☐
Intravenous Clindamycin	☐	☐
Other	☐	☐

17b. If Other, please state what these were:

……

	YES	NO
18. Was the mother taking antibiotics when the cerclage was placed? (excluding prophylactic antibiotics given at cerclage insertion)	☐	☐

18a. If 'Yes', which of the following antibiotic/s were taken?

β-lactam antibiotics:	YES	NO
Phenoxymethyl penicilllin or benzyl penicillin	☐	☐
Amoxicillin or ampicillin	☐	☐
Co-amoxiclav	☐	☐
Cephalosporin	☐	☐

Other antibiotics:	YES	NO
Erythromycin	☐	☐
Clindamycin	☐	☐
Trimethoprim	☐	☐
Nitrofurantoin	☐	☐
Metronidazole	☐	☐
Other	☐	☐

18b. If other, please specify what these were:……

Section 4. Antibiotics (During Procedure) Continued:

18c. What was the indication for antibiotics (please tick all that apply)?

Urinary Tract Infection ☐

Bacterial Vaginosis ☐

Other (pregnancy related) ☐ **Please specify** .....

Other (non pregnancy related) ☐ **Please specify** .....

Section 4. Antibiotics (Following Procedure):

	YES	NO
19. Did the mother receive prophylactic antibiotics following the cerclage procedure (up to 72 hours)?	☐	☐

19a. If 'Yes', which of the following antibiotic/s were taken?

β-lactam antibiotics:	YES	NO
Oral benzyl penicillin	☐	☐
Oral cephalosporin	☐	☐
Oral co-amoxiclav	☐	☐
	☐	☐

Other antibiotics	YES	NO
Oral clindamycin	☐	☐
Per vaginal clindamycin	☐	☐
Oral metronidazole	☐	☐
Other	☐	☐

19b. If other, please state what these are .....

Section 5. Antifungals:

	YES	NO
20. Did the mother receive any antifungals at the time the cerclage was placed or within the 72 hours before or after?	☐	☐

20a. If 'Yes', which antifungals did the mother receive?	YES	NO
PO Fluconazole	☐	☐
PV Clotrimazole	☐	☐

20b. What was the indication for the antifungals?

	YES	NO
Candidiasis (HVS confirmed)	☐	☐
Candidiasis (Clinical diagnosis)	☐	☐
Prophylaxis	☐	☐

Section 6. Some information about you:

Your Name: .....

Your Centre: .....

Today's date: D D - M M M - Y Y Y Y

THANK YOU FOR COMPLETING THIS FORM

Please enter the information from this CRF into the C-STICH online database by logging in at trials.bham.ac.uk/CSTICH

OR return a copy of the completed form to the trials office to be entered onto the database.
Please return to:

C-STICH Trial, FREEPOST RTGS-UKLK-JKHS, Birmingham Clinical Trials Unit, Institute of Applied Health Research, University of Birmingham, B15 2TT

Or by fax to **0121 415 9136** Or via email to cstich@trials.bham.ac.uk

Instructions on transferring the swab and suture to microbiology

Please place the source material into a dry, sterile transit tube and send it to your local Microbiology Department. Your Microbiology Department should be able to advise on this.