



The **C**erclage **S**uture **T**ype for an **I**nsufficient **C**ervix and its effect on **H**ealth outcomes (C-STICH)

CRF3: C-STICH Cerclage Removal

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

- A. PLEASE COMPLETE SECTIONS 1 & 4 IN ALL CASES.
- B. IF THE CERCLAGE WAS REMOVED, PLEASE ALSO COMPLETE THE REMAINDER OF THIS FORM.
- C. IF THE CERCLAGE WAS NOT REMOVED, COMPLETE Q1 OF SECTION 2, AND THEN SECTIONS 3 AND 4.

Section 1. Patient details:

Patient's trial number:

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

Section 2. Cerclage removal details:

1. Was the suture removed? :

YES ☐ If Yes, please answer the remainder of question 1.

NO ☐ If No, was the cerclage left *in situ* for further pregnancies?

YES NO

☐ ☐

If the suture was not removed, please proceed to Q11 on antibiotic use.

Monofilament Tape (Braided)

1a. Which suture material did you remove?

☐ ☐

1b. Date and time removed: - -

Time: Hrs Mins

IF REMOVED AND WHERE POSSIBLE, PLEASE RETAIN THE STITCH AND SEND IT TO THE LAB

2. Was the suture sent for microbiology assessment?:

YES NO

☐ ☐

If no, please go to Q3.

2a. If sent for microbiology assessment, date sent?:

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Section 2. Cerclage removal details continued:

3. Was the cerclage removal emergency or planned ?

Emergency

☐

Planned

☐

Please go to Q4.

3a. Please state reason/s for emergency removal:

	YES	NO
Infection	<input type="checkbox"/>	<input type="checkbox"/>
Pre-term labour commenced	<input type="checkbox"/>	<input type="checkbox"/>
Rupture of membranes	<input type="checkbox"/>	<input type="checkbox"/>
Other	<input type="checkbox"/>	<input type="checkbox"/>

If Other, please state reason:

.....

4. In the opinion of the person removing the suture, was it easy to remove?

Yes

☐

No

☐

5. Was an anaesthetic required to remove the suture?

Yes

☐

No

☐

5a. If 'YES', which type of anaesthetic was used?

General

☐

Regional

☐

Local

☐

6. Was the cervix occluded?

Yes

☐

No

☐

7. Did you see any cervical tears when the suture was removed?

Yes

☐

No

☐

7a. If 'YES', do you believe that these resulted from the placement of the suture?

Yes

☐

No

☐

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Section 2. Cerclage removal details continued:

	Hrs	Mins				
8. At what time was the speculum inserted? (24 hr clock):	<table border="1"><tr><td></td><td></td></tr></table>			<table border="1"><tr><td></td><td></td></tr></table>		
	Hrs	Mins				
8a. At what time was the speculum removed? (24 hr clock):	<table border="1"><tr><td></td><td></td></tr></table>			<table border="1"><tr><td></td><td></td></tr></table>		
	Yes	No				
9. Did someone of Consultant grade remove the cerclage?	<table border="1"><tr><td></td></tr></table>		<table border="1"><tr><td></td></tr></table>			
	Yes	No				
9a. If the cerclage was not removed by a Consultant grade, was removal supervised?	<table border="1"><tr><td></td></tr></table>		<table border="1"><tr><td></td></tr></table>			
	YES	NO				
10. Did the mother have a second cervical cerclage placed in this pregnancy? If yes please complete the remainder of Q10.	<table border="1"><tr><td></td></tr></table>		<table border="1"><tr><td></td></tr></table>			
10a. Was the suture replaced with the same suture type as the randomised suture?	<table border="1"><tr><td></td></tr></table>		<table border="1"><tr><td></td></tr></table>			
10b. Was the repeat suture placed vaginally?	<table border="1"><tr><td></td></tr></table>		<table border="1"><tr><td></td></tr></table>			
10c. What was the indication for a second cervical cerclage? (tick one box only)						
Original suture cutting through cervix	<table border="1"><tr><td></td></tr></table>					
Original suture fallen out	<table border="1"><tr><td></td></tr></table>					
Other	<table border="1"><tr><td></td></tr></table>					
If Other, please specify	<hr/>					

Section 3. Antibiotics prescribed between cerclage placement & removal:

	YES	NO	Don't Know			
11. Has the patient received any antibiotics from 72 hours after cerclage placement until removal (or delivery if the cerclage was not removed)?	<table border="1"><tr><td></td></tr></table>		<table border="1"><tr><td></td></tr></table>		<table border="1"><tr><td></td></tr></table>	
11a. If YES, please state the number of courses here:	<table border="1"><tr><td></td></tr></table>					

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Section 4. Some information about you:

Your Name:

Your Centre:

Today's date:

D	D
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M	M	M
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Y	Y	Y	Y
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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 on-
to 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 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.

If more than one stich was placed, please send just the first stich that was placed to
microbiology.