Trust Standard Operating Procedure

University Hospitals Plymouth NHS Trust

Insertion of Cervical Ripening Balloons for induction of labour by midwifery staff

Issue Date	Review Date	Version
July 2020	July 2025	1.0

Purpose

The purpose of this Standard Operating Procedure (SOP) is to ensure robust, equitable and consistent management for women having a cervical ripening balloon (CRB) for induction of labour. It will ensure midwifery staff are appropriately trained to use the CRB whilst promoting quality, safety, patient choice and patient satisfaction.

Who should read this document?

All midwives
All medical staff working within Maternity Services.

Key Messages

Maintenance of effective and safe patient care.

Core accountabilities	
Owner	Rachel Marshall-Roberts *Consultant Obstetrician and Gynaecologist*
Review	Maternity Assurance Group, Women's & Children's Services
Ratification	Maternity Assurance Group
Dissemination (Raising Awareness)	All staff working within Maternity services
Compliance	

Links to other policies and procedures
Induction of labour guideline

Version History		
V1	Dec 2019	Document created

The Trust is committed to creating a fully inclusive and accessible service. Making equality and diversity an integral part of the business will enable us to enhance the services we deliver and better meet the needs of patients and staff. We will treat people with dignity and respect, promote equality and diversity and eliminate all forms of discrimination, regardless of (but not limited to) age, disability, gender reassignment, race, religion or belief, sex, sexual orientation, marriage/civil partnership and pregnancy/maternity.

An electronic version of this document is available on Trust Documents. Larger text, Braille and Audio versions can be made available upon request.

Standard Operating Procedures are designed to promote consistency in delivery, to the required quality standards, across the Trust. They should be regarded as a key element of the training provision for staff to help them to deliver their roles and responsibilities.

Standard Operating Procedure (SOP)

1 Introduction

The purpose of this SOP is to ensure effective midwifery training and ongoing assessment of practice to allow safe insertion of the cervical ripening balloon.

The Cook Cervical Ripening (double) balloon (CRB) is a double catheter device that is able to be inserted through a small and potentially closed cervical os. The uterine balloon is inflated with 50-80mls of sterile saline and pulled back. A second vaginal balloon is then inflated with the same quantity of fluid. The device aims to ripen the cervix over a 12-18 hour time period (please note the diagram below states up to 12 hours however the catheter is safe to remain in situ for 18 hours). After this time, or when the catheter falls out, it is usually possible to perform amniotomy and initiate induction with oxytocin infusion as per standard protocol.

2 Definitions

IOL Induction of labour

CRB Cervical Ripening Balloon

CTG Cardiotocograph

ARM Artificial Rupture of Membranes

3 Regulatory Background

Guidelines:

Induction of labour

4 Key Duties

Many women will choose to have CRB as a non-pharmaceutical method for IOL or choose to have this method as an outpatient IOL. If CRB is chosen and an ARM is possible then the patient may choose to proceed with an immediate ARM if the unit is able to accommodate them or to have the prostaglandin pessary (unless contraindicated).

A team of midwives will be trained in the insertion of the CRB and the counselling for its use during induction of labour. Midwives will include all band 7 midwives on central delivery suite, all ORE midwives on central delivery suite and Argyll ward.

The patients who are considered to be high risk will have already been seen by an obstetrician but this does not exclude midwifery insertion.

5 Procedure and training to Follow

The pathway of care for all inductions is to be followed from the guideline titled “Induction of Labour” available on the Trust’s G Drive within Clinical Guidelines.

Equipment

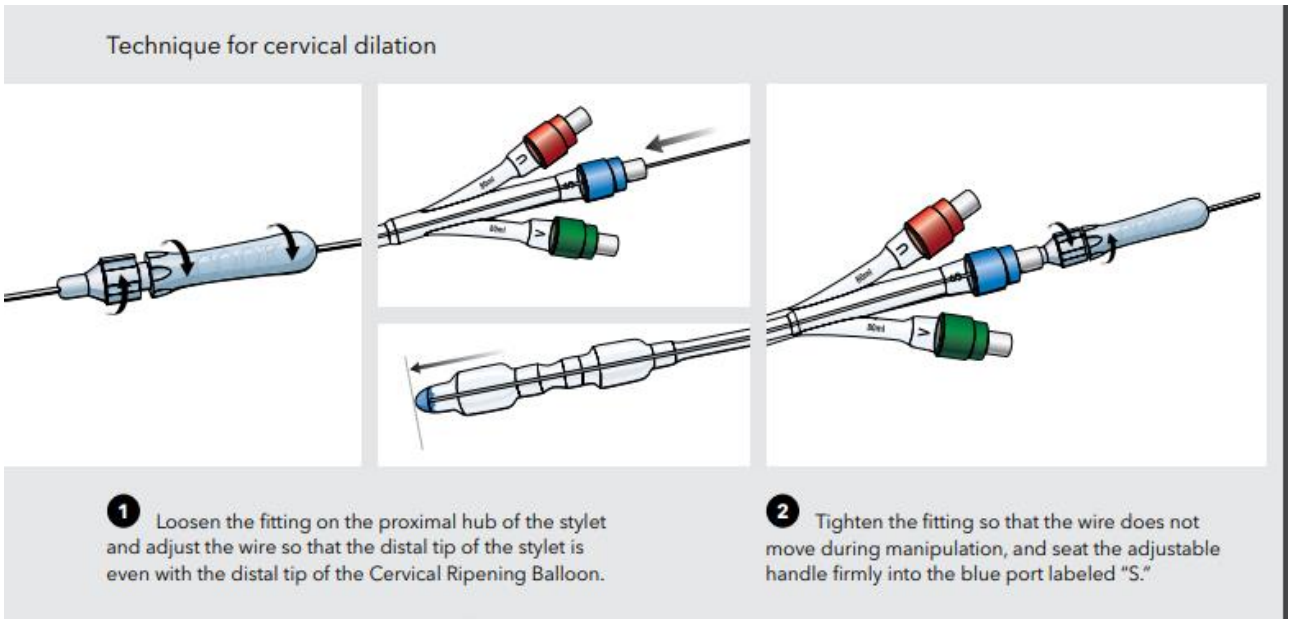
If inserting digitally (preferred option)	**If using speculum (patient request or is clinically indicated e.g. difficult digital examination)**
Sterile gloves CRB Lubricant Entonox available 50ml syringe 20ml syringe Normal saline 60mls Entonox available CTG	Sterile speculum pack Sterile disposable cusco speculum CRB Lubricant Light Sterile gloves Sponge holder forceps 50ml syringe 20ml syringe Normal saline 60 mls Entonox available CTG

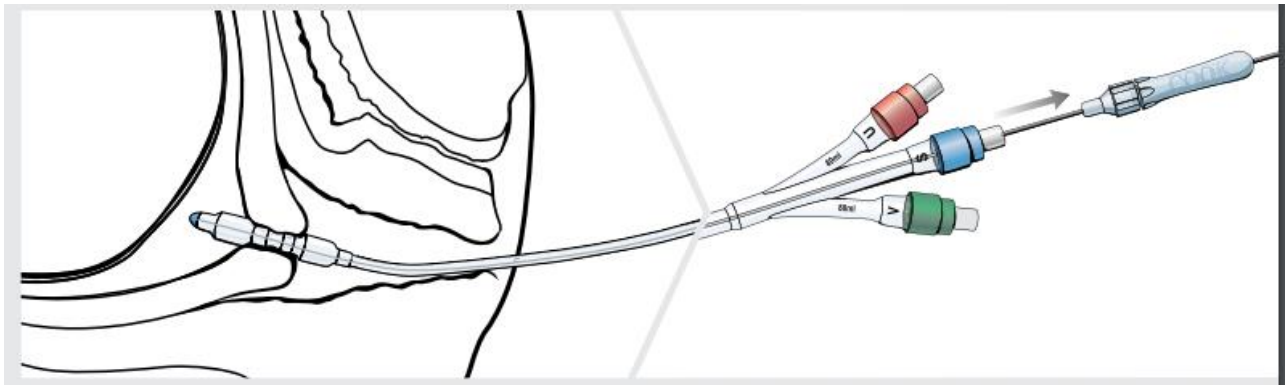
Procedure for digital insertion

- Ensure patient suitability and appropriate counselling as per guidelines
- Palpate the uterus to assess fetal growth, presentation and engagement
- Perform a full set of observations and a CTG
- CRB not to be inserted if the head is 5/5 palpable
- Perform a vaginal examination, the CRB is indicated only if the cervix is unfavourable (this is based on clinical judgement)
- Follow the guidance from the images below for insertion
- Insert the catheter and inflate the balloons as per diagrams
- Once the balloons are filled adequately the speculum is removed
- The external end of the device may be loosely taped to the woman’s thigh
- Repeat the CTG

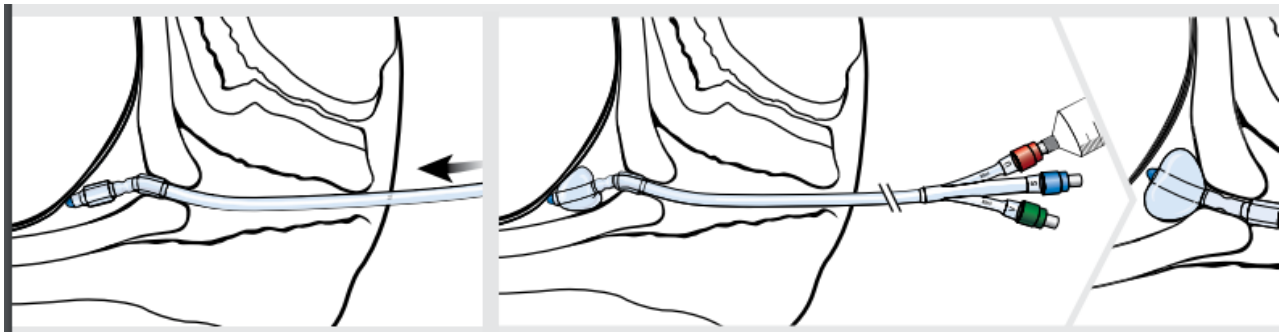
Procedure for speculum insertion

- Ensure patient suitability and appropriate counselling as per guidelines
- Palpate the uterus to assess fetal growth, presentation and engagement
- Perform a full set of observations and a CTG
- CRB not to be inserted if the head is 5/5 palpable
- Perform a vaginal examination, the CRB is indicated only if the cervix is unfavourable (this is based on clinical judgement)
- Follow the guidance from the images below for insertion
- The use of lithotomy is not always needed.
- Pass a sterile speculum into the vagina to gain access to the cervix
- Insert the catheter and inflate the balloons as per diagrams
- Once the balloons are filled adequately the speculum is removed
- The external end of the device may be loosely taped to the woman's thigh
- Repeat the CTG



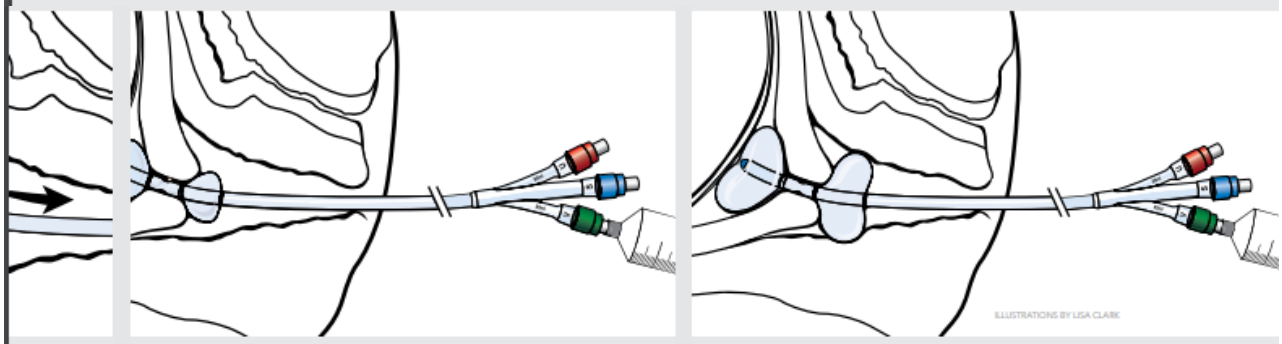


3 Use the stylet with the Cervical Ripening Balloon to traverse the cervix. **Note**: Once the cervix has been traversed and the uterine balloon is above the level of the internal uterine opening (internal os), remove the stylet before further advancing the catheter.



4 Advance the Cervical Ripening Balloon through the cervix until both balloons have entered the cervical canal.

5 Inflate the uterine balloon with 40 mL of saline. Once the uterine balloon is inflated, pull the device back until the balloon abuts the internal cervical os.



6 The vaginal balloon is now visible outside the external cervical os and should be inflated with 20 mL of saline.

7 Once the balloons are situated on each side of the cervix and the device has been fixed in place, add more fluid to each balloon in turn, until each balloon contains a maximum of 80 mL of fluid. Time the balloon placement so that the balloon is in place no longer than 12 hours before active labor is induced.

Training

Midwives will be trained to insert CRB and will have an assessment of competence regularly performed.

The initial training will be provided by an obstetrician and other midwifery staff who are competent. A video on CRB insertion will be shown (available through the cook medical website https://www.cookmedical.com/products/wh_crbs_webds/) whilst having the device available for inspection. There will be a discussion on counselling and patient safety.
The first two insertions of the CRB will be supported by a competent obstetrician (ST3-7 and above) or a midwife. Once this training is complete they will be deemed competent and able to support colleagues who are achieving competence.

Ongoing assessment of competence will include providing evidence of the number and complications associated with CRB for each individual practitioner. A minimum of 3 insertions per year are expected to maintain competence. If the desired number of insertions falls then retraining can be instigated depending on level of support that is required.

6 Document Ratification Process

The design and process of review and revision of this procedural document will comply with The Development and Management of Formal Documents.

The review period for this document is set as default of five years from the date it was last ratified, or earlier if developments within or external to the Trust indicate the need for a significant revision to the procedures described.

This document will be reviewed by the guideline group and ratified by the Maternity Assurance Group and Director of Midwifery.

Non-significant amendments to this document may be made, under delegated authority from the Director of Midwifery and guideline group, by the nominated author. These must be ratified by the Maternity Assurance Group.

Significant reviews and revisions to this document will include a consultation with named groups, or grades across the Trust. For non-significant amendments, informal consultation will be restricted to named groups, or grades who are directly affected by the proposed changes.

7 Dissemination and Implementation

Following approval and ratification, this procedural document will be published in the Trust's formal documents library and all staff will be notified via the Maternity newsletter.

Document control arrangements will be in accordance with The Development and Management of Formal Documents.

The document author(s) will be responsible for agreeing the training requirements associated with the newly ratified document with the Director of Midwifery and Maternity Assurance Group, and for working with the Trust's training function, if required, to arrange for the required training to be delivered.

8 Monitoring and Assurance

Discuss any concerns identified in the new pathway with Dr Marshall-Roberts, Dr Hein, Lauren Graham, Natalie Adams or members of the risk team.

The out-patient audit is already continuously performed and audits regarding other aspects of the induction process are intermittently performed. An audit regarding CRB will be commenced.

Each midwife will be asked to audit their own results. This audit will include the number of CRBs inserted, whether they fell out without the patient being favourable for IOL or if there was a complication specifically attributed to the CRB.

9 Reference Material

https://www.nice.org.uk/guidance/cg70/resources/inducing-labour-pdf-975621704389

https://www.nice.org.uk/guidance/ipg528/resources/insertion-of-a-double-balloon-catheter-for-induction-of-labour-in-pregnant-women-without-previous-caesarean-section-pdf-1899871812579013

https://www.nice.org.uk/guidance/cg70/resources/inducing-labour-pdf-975621704389