	Reference Number:DIOLSOP **Version Number: 1** **Next Review date: Jan 2022**

Standard Operating Procedure for the use of Dilapan

Introduction
The purpose of this standard operating procedure is to provide clear guidance on the use of dilapan.

Objectives
There are a number of objectives, including:

- Safety of women in respect of Dilapan usage
- Provide governance for the use of Dilapan

Operational Date **March 2021**	**Expiry Date** **Formal** – three years **Informal** – one year

Scope
This procedure applies to all staff on all locations across the UHB.

Equality Impact Assessment	An Equality Impact Assessment has been completed
Distribution	All staff via internet and team briefings.
To be read by	All staff involved in the administration of medicines in secondary care

Documents to be read in conjunction with this SOP:

- **CTM UHB Induction of Labour Guidelines**

Approved by	Antenatal Forum
Accountable Executive / Lead Director (responsible for formal review every three years)	CTM UHB Maternity Clinical Director
Author / Management Lead (carries out informal review annually)	CTM UHB Maternity Antenatal Forum
Freedom of Information Status	Open (most will be open, seek advice from the Head of Corporate Services if unsure)

If the review date of this policy has passed, please ensure that the version you are using is the most up to date either by contacting the document author or the Corporate Services Department.

To avoid use of out of date policies please do not print and then store hard copy of this document.

Out of date policies cannot be relied upon.

Amendment Record

If a change has been made to the document, the changes must be noted and circulated to the appropriate colleagues.

Detail of change	Why change made?	Page number	Date of change	Version	Name of Policy Author
New to CTM UHB Maternity Services				1	Ihab Abbasi

Definition of a Standard Operating Procedure

A procedure is a set of detailed step-by-step instructions that describe the appropriate method for carrying out tasks or activities to achieve a stated outcome to the highest standards possible and to ensure efficiency, consistency and safety. A Standard Operating Procedure is defined as;

'*Detailed, written instructions to achieve uniformity of the performance of a specific function'*

1.3 The aim of SOPs is to ensure that any procedure performed as part of a trial is done to a consistently high standard, thus enhancing the quality of the data produced. SOPs are of particular importance when a trial is being run over several sites. SOPs set out the way practice and procedures must (i.e. mandatory) or should (i.e. advisory) be performed. SOPs should be: clear; concise; of common style; format and content; available where and when needed; and be subject to a system of document control.

Minor Amendments

If a minor change is required to the document, which does not require a full review please identify the change below and update the version number.

Type of change	Why change made	Page number	Date of change	Version 1 to 1.1	Name of responsible person

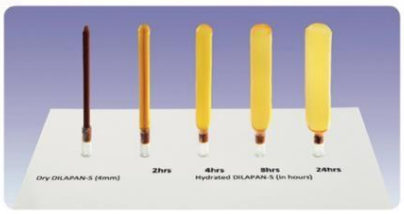
Contents

1. Standard Operating Procedure - Induction of Labour with Dilapan-S Guideline – to be used in conjunction with the CTM UHB Induction of Labour Guideline.

1.1 Introduction

DILAPAN–S® is a fast-acting synthetic osmotic cervical dilator made of patented AQUACRYL® hydrogel specifically developed and approved for cervical ripening.

Dilapan–S® doesn't contain any pharmacologically active substance, which could be released during its use



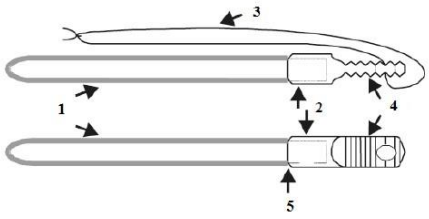
This is how DILAPAN-S® rod looks like over time period of 24 hours.

	Expected Dilation (in mm)	
Time in situ (hours)	One DILAPAN-S (3 mm)	One DILAPAN-S (4 mm)
2	7.2 - 8.3	7.8 - 10.0
4	8.4 - 9.5	10.0 - 11.2
6	9.0 - 10.0	10.1 - 12.5
24	9.6 - 11.3	12.7 - 14.6

Device description

The Dilapan-S is available in boxes 25 dilators (individually packaged and sterilised) and in the following dimensions: 4 mm x 65 mm, 4 mm x 55 mm, 3 mm x 55 mm. 4mm x 55mm rods are used for IOL. 1. Dilating part made of hydrogel

2. Knob/collar
3. Marker string
4. Handle
5. Point of maximal insertion



1.2 Multiple modes of action mimic physiological processes of the labour:

1. Mechanical: It absorbs fluids from surrounding tissue expanding in size. Controlled pressure on the cervical wall dilates the cervix
2. Biophysical: Partial reversible osmotic dehydration softens the tissue
3. Physiological: Promotion of endogenous prostaglandins release causing collagen degradation and tissue restructuring

1.3 Unique combination of efficacy, safety and patient satisfaction Efficacy

- Significant Bishop score increase with cervical ripening achieved in 90%. [1, 2, 5, 6.]
- Vaginal delivery rate over 70% [1,2,3, 7]
- Suitable and licenced for all patients requiring IOL. [4] **Safety**
- No hyperstimulation or fetal pathology during cervical ripening [1-3, 6, 7, 9, 10]
- No infectious complications [1-3, 6, 7, 9, 10]
- No limitation related to mother's gestational age and/or comorbidities [4]
- One contraindication: clinically apparent genital tract infection [4] **Patient satisfaction**
- Low rate of uterine contractions during cervical ripening [1, 3, 4, 7, 9, 10]
- Up to 90% of women can relax or sleep during cervical ripening [1,3, 5]

- Minimised vaginal examinations during cervical ripening. [4] **Cost-effectiveness**
- One-time application and no need of continuous CTG monitoring [4]
- Out-patient regimen (home cervical ripening) for low-risk groups of patients [4]
- Potential prevention of CS in VBAC [8]

2. PROCEDURE FOR DILAPAN-S USE

2.1 Exclusion criteria: Following women should not be offered Dilapan-S.

1. Clinically apparent genital tract infection [4]

2.3 Pre-insertion requisites of Dilapan-S

2.3.1. Communication and Information

Give the patient information leaflet for Dilapan-S – kept in induction bay in maternity unit

Discuss the risks and benefits of Induction of labour (IOL). Take into account individual needs and preferences, to enable the woman to make an informed decision

Ensure that the following has been completed:

A. **Cervical Assessment** – Consider doing Bishop Score and where possible perform stretch and sweep (document the reasons of not doing Bishop Score prior to booking IOL e.g. Diabetes etc.)
B. **Discussion** - Risks, benefits, pain relief, alternative options, delays and postponement of IOL has been discussed with a woman. C. **Indication**- Reason of IOL mentioned in the notes.
D. **Booking process** - IOL has been booked appropriately as per the IOL booking proforma; recording the date, time and location of IOL along with the indication, BMI, gestational age and the name of a consultant involved in decision making.
E. **Documentation** - Verbal consent has been obtained i.e. that the woman has agreed to the IOL and has understood the IOL. This should be clearly documented in the notes in accordance with the IOL guidelines.

2.4 Good Practice Points

- All inductions other than low risk inductions may only be booked after agreement from a consultant obstetrician.
- A consultant should be aware and agree the decision regarding induction of labour for low risk women on admission and **must have confirmed the intention to induce and the management plan for high-risk pregnancies.**
- IOL should be a continuous process once initiated.
- IOL should go ahead irrespective of the time of the day.
- If there is a delay in transferring the woman to labour ward due to increased activity, the midwife co-ordinator should discuss with the consultant and make a plan of care while woman is waiting in the ward.

3. Pre IOL checks and assessment

- Review maternal history, gestation, indication of IOL - check the medical records
- Perform baseline maternal observations (e.g. temperature, pulse, SaO2 respiratory rate and blood pressure)
- Perform abdominal palpation to confirm uterine size, fetal lie, position, engagement and presentation
- Assess fetal wellbeing by CTG for 30 minutes.
- Assess for contraindications to IOL. Assess membrane status (ruptured or intact)
- The workflows on the IOL pathway should be completed as indicated

4. Cervical assessment

A Modified Bishop Score (MBS) should be performed before induction of labour. Each feature of the cervix is scored and then the scores are summed. The state of the cervix is one of the important predictors of successful IOL. The cervix is unfavourable if the MBS is 6 or less.

5. Documentation

- If CTG is reassuring for 30 minutes and Bishop Score is 6 or less, insert DilapanS as per instructions below.
- Document findings of abdominal palpation and vaginal examination.
- Dilapan-S should not fall out if inserted correctly, past the internal cervical os.
- If Dilapan-S does fall, reinsert new rods if still required.
- Document the time of insertion, removal and number of Dilapan-S rods.
- Commence the audit check list of Dilapan-S.

6. Insertion/removal/extraction of Dilapan-S

6.1 The required equipment is:

- Two sponge forceps
- Speculum
- Gel
- Gloves
- Good source of light
- Dilapan-S 4mm x 55mm size rods.

The woman can remain on her bed with her legs folded upwards. Special stirrups or the lithotomy position is not usually necessary.

If there is need for any local anaesthesia instillagel may be used.

6.2 The cervix is visualized with a sterile vaginal speculum and suitable lighting. In some cases with an unfavourable or posterior cervix, **sponge forceps** can be used to stabilize the anterior lip of the cervix and to straighten the cervical canal for easier insertion of the rods.

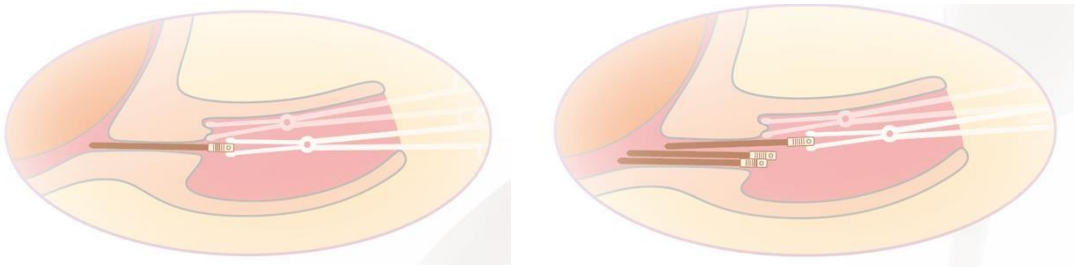
Dilapan-S rods can be moistened with sterile water, saline or gel to lubricate the surface prior to insertion. This must be performed by a skilled clinician.

6.3 Using sponge forceps, the rod is inserted through the external cervical os gradually and without undue force. It is **essential** that the **tip of the rod goes through the internal os. Do not insert the Dilapan-S rod past the handle**. A **minimum** of **3 Dilapan-S rods** (and up to 5 rods) are inserted into the cervical canal. The number of pieces inserted varies, since different patients have different pelvic or cervical exam/dilation.

Each rod can act as a guide for subsequent rods to be inserted (see image below) If a small amount of the brown part of the rod is left outside the external os on the first rod, it can sometimes make it easier to insert the subsequent rods. It should be checked that all rods are fully inserted (plastic handle visible outside the external os) before removing the speculum. Be careful not to dislodge the rods when removing the speculum.

Woman should be informed that some minor bleeding can occur during insertion; this is common and should not be a concern.

Insert a gauze pad to help to keep the Dilapan-S in place, only if needed.



6.4 20 minutes CTG can be performed post insertion. The next CTG monitoring can be performed after 12 hours unless other indications for earlier monitoring arise.

7. <u>When to remove Dilapan-S</u>

The rods should be left in place for **12-15 hours**, which is usually sufficient time for increasing the Bishop score adequately. Do not leave the rods in place for longer than 24 hours. 80 percent of expansion occurs in first 6-8 hours. Dilapan-S can be removed from 12 hours onwards for assessment. Dilapan-S can remain in the vagina for up to 24 hours **maximum.** There is no further growth of the rods after 12 hours.

Aim to do ARM as soon as possible following removal of rods. If this is not possible due to acuity it is preferable to leave Dilapan-S in situ within the 24h limit until ARM is possible.

Reasons for examining or removing the dilators prematurely include:

- Spontaneous onset of labour (defined as regular, strong uterine contractions with an effaced cervix >80% and a cervical dilation >3 cm)
- Concerns on fetal heart rate tracing

- PV bleeding **(not just blood-stained show)**
- At least 30 minutes prior to starting an intravenous infusion of Oxytocin
- Spontaneous rupture of membranes or need for amniotomy
- Spontaneous expulsion of dilators
- Maternal request

8. Removal instructions

- Carefully remove the Dilapan-S by gently pulling the string (speculum not required) and they usually come out as a clump. Occasionally, it may be necessary to use forceps to grasp the handle of the Dilapan-S and exert steady traction for several minutes.
- Do not twist the Dilapan-S during removal.
- Do not grasp the knob/collar with forceps.
- In extremely rare cases a “tight cervix” has been known to cause ballooning of the inserted Dilapan-S above and/or below the internal cervical os, making it difficult to remove. In this case a senior obstetrician should be informed. This is corrected by sliding a sequence of graduated sizes of metal dilators alongside the Dilapan-S and through the internal os until sufficient dilation takes place to allow easy withdrawal.
- If the Dilapan-S has somehow migrated or been placed outside cervical canal, it may be located using ultrasound. Dilapan-S is not radiopaque.
- Please ensure and **document** all inserted rods are removed. The Bishop score can be determined at the end of removal procedure.

9. Unsuccessful dilatation after 12-24 hours of Dilapan-S

- If the cervix remains unfavourable after the first series of dilators, a **second series can be inserted** to continue the cervical ripening for up to additional 24 hours (but this is usually not necessary, the cervical ripening success rate is over 90%).
- Consider alternative methods like prostaglandin pessary or gel.
- Caesarean may be offered only after careful consultant led counselling.

10. Precautions

- Clinical trials have not demonstrated any allergic reactions to the device. Dilapan-S is latex-free and vegan (synthetic material). However, an allergic reaction could result from hypersensitivity to any of its components.
- Clinical trials have not demonstrated any infections related to Dilapan-S.
- However, in the presence of known pathogens, contamination of the device during insertion is possible.
- This is a single-use device and should not be re-sterilized or re-used.
- Careful placement of the device is essential to avoid traumatic injury to the cervix
- or uterus and to avoid migration of the device either upward into the uterus or
- downward into the vagina.

- Sterile, unless package is opened or damaged. Do not use if package is broken.
- The device should not be left in the cervix for more than 24 hours.
- Any cervical manipulation may cause a vaso-vagal reaction. Patients should be
- monitored for evidence of any unusual pallor, nausea, vertigo or weakness. By
- remaining recumbent for 3 to 10 minutes these symptoms usually disappear.

11. Potential risks to be discussed with the woman for consent

Risks associated with use of the Dilapan-S may include, but are not limited to: •
Device entrapment and/or fragmentation or detachment of the handle

- Device expulsion
- Device retraction into the uterus
- Patient discomfort or bleeding during and/or after insertion
- Spontaneous rupture of membranes
- Spontaneous onset of labour
- Cervical laceration

12. Training requirements

Dilapan-S is for use by trained healthcare professionals.
Short training session for Dilapan-S insertion.
Awareness to manage the complications if any.

13. References

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5. Clinical Audit data from another NHS trust.

6. Roztocil A et al.: A comparison of three preinduction cervical priming methods: Prostaglandines E2 gel, Dilapan–S® rods and Estradiol gel. CZ Gynecol. 63, 1998, č. 1, str. 3–9 https://www.ncbi.nlm.nih.gov/pubmed/9650373

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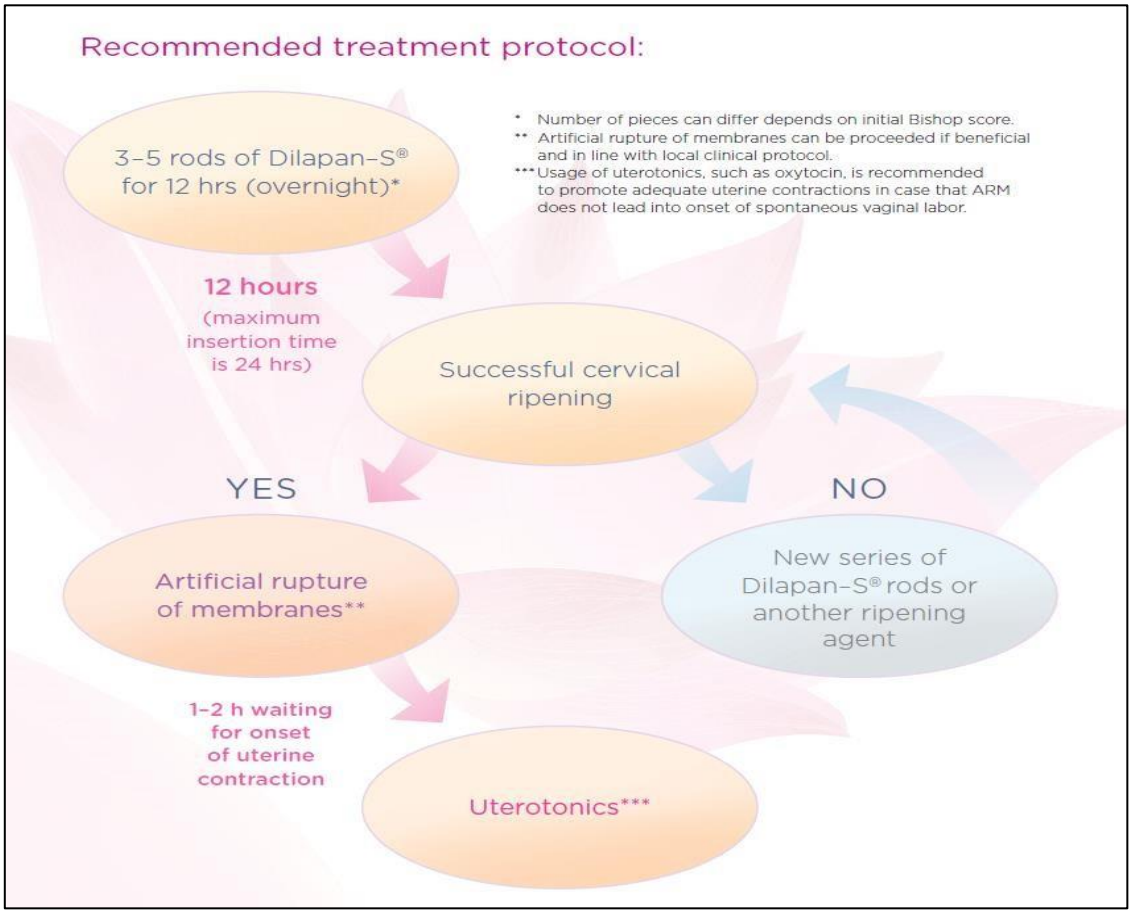
Appendix 1

Treatment protocol



Document Control

The Health Board must be able to demonstrate that the documents are researched and based on best practice and that all guidelines are audited and reviewed therefore:

Approved – 01/02/2021

Target Staff Group

Obstetricians, Midwives, Matrons, Paediatricians, Neonatal Staff

Auditable Standards and Frequency

The process and outcome of Dilapan-S method will be regularly audited as per the standards

Implementation strategy

- Inform staff at Clinical Governance Meetings
- Disseminate through ward meetings, with a read and signature list Email to all staff

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