SF Mission Bay
Birth Center Department Policy

TITLE: OUTPATIENT CERVICAL RIPENING PRIOR TO LABOR INDUCTION

PURPOSE: To provide guidance on the use of Dilapan-S or Foley catheter balloon for outpatient cervical ripening prior to induction of labor.

STATEMENT OF POLICY: Cervical ripening increases the chance for successful induction of labor among those with an unripe cervix. By offering mechanical ripening as an outpatient procedure, our goal is to decrease time admitted to the hospital prior to delivery, and increase patient satisfaction with the induction process.

Cervical ripening is recommended when the Bishop's score is ≤ 6.

Dilapan-S or Foley catheter balloon is to be placed by a qualified provider (MD/CNM/NP).

Relevant Data

The unfavorable cervix is an impediment to the successful induction of labor. Cervical ripening, either with synthetic prostaglandins or mechanical methods, increases the chance of successful induction and vaginal delivery.

Dilapan-S and intracervical Foley catheter balloon are mechanical approaches that promote cervical ripening. Dilation is caused by pressure on the internal os (Ferguson reflex) in addition to the effect of prostaglandins released in reaction to the device in the cervix. The use of Dilapan-S and intracervical Foley catheter balloon have been shown to lower cesarean delivery (CD) rates for women undergoing labor induction, and have favorable perinatal outcomes.[1-4]

Mechanical methods of cervical ripening also have a very favorable safety profile compared to other modalities; in particular, their use is not associated with tachysystole, need for emergent delivery, or increased rates of meconium passage. For these reasons, outpatient ripening with foley catheter balloon alone has been identified as a promising strategy by ACOG both in terms of effectiveness and safety, permitting that the mother and fetus otherwise have no acute medical problems requiring inpatient management. Patients with medical or obstetric conditions that are unstable or could rapidly deteriorate warrant admission in accordance with usual medical guidelines and decision-making. Likewise, patients with poor social support, unstable housing, unreliable transportation, or inability to comprehend and follow the instructions may be better served with inpatient cervical ripening.

Indications

1. Patient planning induction of labor
2. Term pregnancy (37+0 – 41+6) at time of outpatient ripening
3. Bishop's score of ≤ 6
4. Medically stable mother and fetus without indication for inpatient management or continuous fetal monitoring prior to labor
5. Patient desiring to undergo cervical ripening at home and demonstrating understanding of the instructions provided

Contraindications to Outpatient Cervical Ripening

1. Contraindications to placement of Foley balloon in general
    a. Contraindication to vaginal delivery (e.g., placenta previa, prior classical cesarean delivery, placenta accreta, active genital herpes virus infection, previous complicated myomectomy or cesarean delivery)
    b. Fetal malpresentation
    c. Rupture of membranes*
    d. Low lying placenta (current)*

    * *Note: these patients might be candidate for trial of mechanical ripening in-house, per provider discretion.*
2. Conditions that require acute evaluation and/or continuous fetal monitoring, including
    a. Unstable medical or obstetric diagnoses, such as preeclampsia with severe features, chorioamnionitis, placental abruption or active vaginal bleeding
    b. New maternal concerns such as decreased fetal movement, vaginal bleeding, leakage of fluid, severe intractable headache or other new worrisome symptoms
    c. Fetal growth restriction (FGR) with abnormal umbilical Dopplers
    d. Non-reactive fetal heart rate tracing
    e. BPP ≤ 6
3. Conditions where the unlikely possibility of precipitous labor could pose special risks
    a. Fetal anomalies requiring immediate aggressive resuscitation
    b. Unstable lie
    c. Prematurity
4. Patient unable to verbalize understanding of care plan or instructions for self-care, or lacking necessary means to fulfill outpatient plan (ex: lack of housing, phone service, transportation, or support person).

Optimal Candidates for Outpatient Cervical Ripening :

1. Medical indications:
    a. Gestational diabetes (well controlled)
    b. Chronic hypertension (well controlled & stable)
    c. Gestational hypertension (well controlled & stable)
2. Obstetric Indications:
    a. 41 weeks or greater gestational age
    b. Advanced maternal age
3. Elective inductions

Potential Candidates that Require Individualized Decision -Making may include:

1. Concerns about patient reliability or safety, for example, patient who has demonstrated difficulty attending appointments or following through with medical advice
2. Twin pregnancy
3. Intrahepatic cholestasis of pregnancy*
4. Preeclampsia without severe features*
5. IUGR without abnormal dopplers or other worrisome features*
6. Oligohydramnios (isolated)*
7. Polyhydramnios (isolated)*

**if the patient has been managed as an outpatient thus far, has been clinically stable, and has a scheduled induction for these indications, then undergoing outpatient cervical ripening the evening prior to planned induction may be reasonable.*

Description of Procedure:

EQUIPMENT

- Silicone Foley catheter with 30ml or 60ml balloon, or Dilapan-S 3-5 rods
- 35-60 ml sterile normal saline drawn up in syringe(s)
- Speculum and ring forceps x 2 available. Betadine & fox swabs if speculum used.
- large fox swab if needed for digital placement
- Sterile gloves
- OR marker pen
- Ultrasound
- Doppler

PATIENT EDUCATION

1. Prior to procedure
    - Provide pre-procedure patient education materials (patient handout Attachment C)
    - Assess patient's and family's understanding of the procedure and expectations.
    - Offer additional instructions as needed.

2. Prior to release home
    - Provide and review follow-up instructions (Attachment D)
    - Verify that induction of labor is scheduled for the patient the following day
    - Review plan of care with the patient and family.
    - Confirm accurate teach-back from patient regarding the instructions given.

3. After discharge instruct patient to call Labor and Delivery for (See Attachment D):
    - ROM, VB, strong UC
    - Shaking chills, fever 100.4 or higher
    - Severe pain
    - Decreased FM
    - Any other new concerning symptoms

PATIENT PREPARATION

To be performed by MA:

- Verify medical record number and patient name
- Verify counseling has been performed & documented in APEX and patient has reviewed pre-procedure education materials (video vs handout)
- Verify patient has induction of labor scheduled in 12-24 hours
- Ask patient to complete pre-procedure questionnaire (see Appendix B)
- Obtain maternal vital signs including temperature, BP, HR, O2 Saturation
- Instruct patient to use the bathroom then return to room & undress from waist down for exam and procedure
- MA to assist provider with procedure and offer emotional support to patient as needed.

To be performed by medical provider (MD/NP/CNM):

- If medically indicated, confirm NST completed within planned timeframe (ex: patients undergoing weekly NST should have had NST within 7 days; patients undergoing twice weekly NST should have had NST within 4 days).

- Auscultate and document fetal heart rate in the normal range (120-160 bpm).
- Confirm & document cephalic presentation by ultrasound and normal deepest vertical pocket (DVP) if not done within past week. If cephalic presentation documented by ultrasound within the week, cephalic presentation can be assessed using Leopold maneuvers, with ultrasound used as an adjunct in cases of uncertainty.

PROCEDURE

- Provider performs digital cervical exam. If Bishop score > 6 cervix is already ripe and patient can be sent home from clinic with plan to return to L&D for induction at scheduled time. If Bishop's score of ≤ 6 proceed with plan for outpatient cervical ripening if no contraindications present.
- Ensure proper equipment has been assembled and MA or other assistant is present
- Foley Balloon Dilation:
  - If placement of Foley deemed very easy by provider, i.e., cervix is dilated and cervical canal relatively straight, OK to place Foley balloon digitally
  - If digital foley placement not deemed to be easily performed, prepare for speculum placement. See Appendix F for illustrations. Position patient in dorsal lithotomy on exam table.
  - Make a mark on the catheter at a distance below the balloon equal to the length of the cervix. This will help guide you in placing the balloon just proximal to or above the internal os.
  - Place speculum and cleanse cervix with betadine or chlorhexadine.
  - Use the ring forceps to thread the Foley balloon through the cervix with attention to passing through both the external and internal os. A "hand over hand" technique with two ring forceps often works well. If unable to easily pass the internal os, stabilizing the cervix may help: grasp one side of the cervix with a ring forceps to straighten (usually the side further from view of the provider) and then proceed as above. Slowly inflate to 35-60ml (depending on balloon size used). If any question about proper placement above the internal os, an ultrasound may be used to confirm position.
  - Remove speculum and allow patient to clean and re-dress; provide a peri-pad.
- Dilapan S:
  - Place speculum and cleanse cervix as described above
  - Use the ring forceps to insert Dilapan-S (~3-5 rods)

POST-PROCEDURE ASSESSMENT

- Auscultate and document fetal heart rate
- Observe patient for 10 minutes post-procedure, ensuring she is comfortable enough for safe discharge home.
- Complete post-procedure safety checklist (see Appendix E)
- If significant discomfort, heavy bleeding, suspected rupture of membranes, or symptoms of active labor, consider further monitoring on L&D.

DOCUMENTATION

- Use APEX smartset and note template, and document initiation of cervical ripening as outpatient. **For Dilapan-S, document number of rods placed.**

Appendices:

- Appendix A: Bishop's score
- Appendix B: Pre-procedure questionnaire
- Appendix C: Pre-procedure patient handout
- Appendix D: Post-procedure patient handout
- Appendix E: Post-procedure checklist
- Appendix F: Outpatient Foley Balloon Placement Technique
- Appendix G: Dilapan-S Instruction Guide: Induction of Labor

References:

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Appendix A: Bishop's Score

BISHOP SCORING SYSTEM TO EVALUATE THE CERVIX				
FACTOR	0	1	2	3
DILITATION	0 cm	1-2 cm	3-4 cm	5-6 cm
EFFACEMENT Or CERVICAL LENGTH	0-30% >4cm	40-50% 2-4cm	60-70% 1-2cm	80%+ <1cm
STATION	-3	-2	1 or 0	+1 or +2
CERVICAL CONSISTENCY	Firm	Medium	Soft	
CERVICAL POSITION	Posterior	Middle	Anterior	

Appendix B: Pre-procedure questionnaire

Has your baby been moving well today?	Yes	No	Not sure
Are you feeling strong OR regular contractions today?	Yes	No	Not sure
Have you had vaginal bleeding or spotting this week?	Yes	No	Not sure
Have you had leaking of water from the vagina this week?	Yes	No	Not sure
Has your labor induction been scheduled?	Yes	No	Not sure
Have you received instructions about how to take care of yourself at home after your visit today?	Yes	No	Not sure
Do you have any concerns you want to discuss today regarding the procedure today?	Yes	No	

If yes or not sure for any answer, please explain:

Appendix C: Patient's Instructions for Outpatient Management: Pre-procedure

You and your provider have planned for an induction of labor. Induction of labor means stimulating labor to start before it begins on its own. About 1 in 4 American women have their labors induced. Common reasons for recommending an induction include medical conditions such as diabetes or high blood pressure, or going past your due date. Your provider has recommended that you undergo induction of labor at *** weeks due to ***..

Induction of labor can be a slow process, lasting 1-3 days. The first part of an induction is to ensure that the cervix is ripe, or ready for labor. A ripe cervix is soft, thin (effaced) and may be a few centimeters open (dilated). Having a ripe cervix increases the chance of a successful induction. If your cervix is not ripe yet, then the first step of your induction will likely be to ripen the cervix (more on this below!). Once the cervix is ripe, labor contractions can be stimulated. This can be done with an oxytocin drip through an IV (Pitocin), breaking the bag of water, or both.

This handout focuses on cervical ripening for women who may be able to begin the cervical ripening portion of their induction at home.

The cervix can be ripened using medications called "prostaglandins" (ex: misoprostol), and it can be ripened mechanically with a Foley catheter balloon or Dilapan-S. Often a combination of both medications and mechanical methods are used. Ripening the cervix with medication requires staying in the hospital for close monitoring, since the medicine can also produce contractions and everyone's body responds a bit differently. However, mechanical ripening does not start labor contractions, so it can safely be done at home for many women who don't yet need to be in the hospital. Both methods are similarly effective for ripening the cervix, and both take about the same amount of time, on average.

Mechanical ripening is most commonly done with a Foley balloon catheter. This is a soft rubber or plastic tube with an inflatable balloon at its tip. When inflated with sterile water, the balloon applies gentle pressure to the inner part of the cervix. This works to ripen the cervix by gradually dilating (opening) the cervix a few centimeters, as well as by stimulating the cervix to release natural prostaglandins, the local hormones that ripen the cervix. Mechanical ripening can also be done with a product called Dilapan-S, an FDA approved small rod, similar in size to a matchstick, a few of which are inserted into the cervix. Once in place, they absorb moisture and gradually swell in size, gently opening the cervix.

What should I expect?
You and your provider will decide together if you can start your labor induction at home with the Foley balloon or Dilapan-S. If so, you will schedule an appointment to have one of them placed in clinic the day before you are admitted to Labor & Delivery to have your baby.

At the clinic visit, you will have either the Foley catheter balloon or Dilapan-S placed. If you have the Foley catheter balloon, the provider will gently guide the catheter through the natural hole in the cervix, and inflate the balloon just inside the cervix (but outside the bag of water). This can be done with a speculum exam (the provider places a speculum to open the vagina and see the cervix as the catheter is inserted), or with a digital exam (the provider wears sterile gloves and uses their fingers to guide the catheter into place). If you have Dilapan-S, the provider will always perform a speculum exam, and then guide the Dilapan-S inserts into place within the cervix.

You may have some cramping and discomfort when the foley catheter or Dilapan-S is placed, but most women find it resolves shortly after the procedure is over. Once it is in place, you may not feel it at all, or it may feel

similar to a tampon. You can walk and use the bathroom as usual with it in place. In the unlikely event that you experience heavy vaginal bleeding or had breakage of your bag of water at the time of the placement you would be admitted to Labor & Delivery from your appointment to begin your induction.

You will then go home and return to the hospital the following day for your induction. As you are waiting at home, the cervix will soften and open gradually. You will likely notice some bloody show (blood-tinged mucous). You may also continue to have some mild-moderate cramping from the prostaglandins that are being stimulated as your body gets ready for labor. Once the cervix is open enough, the Foley catheter balloon or Dilapan-S may fall out. Often women feel cramping when the balloon passes through the cervix into the vagina, after which the sensation tends to fade. If you can feel the balloon or inserts in your vagina, you may remove and discard them and still come in at the planned time for your induction.

Complications are extremely rare, especially with low risk patients. Your provider will screen you to ensure that you are a good candidate for the outpatient cervical ripening.

If you have any questions, please talk to your provider!

Appendix D: Post-procedure patient handout

Outpatient Cervical Ripening: Going home with your balloon or dilators

Congratulations! You're one step closer to having your baby. You now have a

Circle one: Foley Catheter balloon *or* Dilapan-S in your cervix, and the plan is to go home while your cervix is ripening (getting ready for labor). You should return to the hospital for your labor induction, or sooner if any problems arise. Your induction is currently scheduled:

Day: _____

Time: ____:____

What to expect at home:

It is common to have mild cramping (as you might before a period) while the balloon is in place. Most women will also have some bloody show (light spotting, or blood-tinged mucous). Neither of these is a cause for alarm. The balloon may remain in place the entire time you're at home, or it may fall out at some point. If the balloon does fall out, do not be worried--it has done its job, and you are likely a few centimeters dilated! You may discard it if it falls out. Often, while the balloon is in the process of falling out through the cervix, women will have in increase in cramping. This should quickly resolve after the balloon has passed through the cervix and is sitting in the vagina or has fallen all the way out.

How to take care of yourself at home:

Try to get as much rest as you can tonight. It's fine to take a warm bath before bed to help you sleep, or use a heating pad or Tylenol if you're having mild cramping or mild low back ache. Drink plenty of fluids, and eat light, nutritious meals to keep up your strength. Stretching and gentle exercise help many women to feel well (ex: walking, yoga).

It's safe to shower or bathe normally, and use the restroom as you normally would. However, do not place anything inside the vagina (no sex, no douching).

When to call Labor & Delivery:

Please call right away if you experience any of the following:

- Heavy vaginal bleeding
- Watery fluid leaking from your vagina (this could indicate your bag of water is broken)
- Strong uterine contractions every 4-5 minutes for more than an hour
- Severe pain of any type
- Fever of 100.4 degrees or over, or chills/severe body aches
- You don't feel the baby moving normally
- Any other new symptom that concerns you

You can call UCSF Birth Center triage unit 24/7 at (415) 353-1787. Let the nurse know you are doing outpatient cervical ripening.

Self-Care in Early Labor

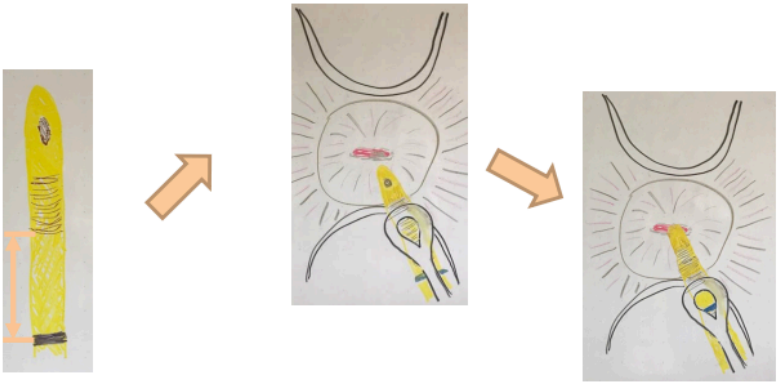
In the early stages of labor, you may experience backaches, pelvic cramping, and even moderate intensity contractions. The following strategies may help to soothe you and to pass the time while also promoting rest to help save your energy for labor:

- Distract your mind & body with gentle activity like going for a walk, doing yoga, cleaning the house or playing with your other children
- Have close friends or family over to visit
- Watch a movie or show, perhaps while sitting on a birth ball or doing gentle stretches
- Warm the tender spots with a heating pad or hot water bottle. A sock filled with uncooked rice can be microwaved to serve this purpose.
- Take a warm bath or shower; warm water helps your body relax and eases the pain of contractions. If you have a bathtub, try lying on your side on towels or a non-stick mat and pour warm water over yourself or have someone else pour water over you.
- Slow, steady rhythmic breathing exercises can be relaxing and distracting. Deep breathing exercises can also reduce nausea and dizziness.
- Massage and pressure on aching spots can help to block pain. You can massage yourself by rubbing your belly or laying on your back with a tennis ball/ foam roller/ water jug between your back and the floor. You can also have someone else massage you. Often just firm counter-pressure or pushing hard against a sore muscle/back/hips provides relief. Warm the area with a hot towel and use lotion or oil to help your hands move easily across your skin.
- Try changing positions. Often this simple strategy feels better than you anticipate. Try laying on both sides, sitting, sitting forward with hands on knees, squatting, hands & knees, elbows (on a pillow) & knees, and rocking back & forth in any position. Use pillows or a birthing ball.
- Sometimes energetic music and conversation can help distract you; other times mellow music or even a quiet room can allow you to focus on your breathing, relaxing the areas of tension and trying to get some rest.
- Active relaxation techniques can help you release tension and pain. This can involve either progressive relaxation where you focus on a wave of relaxation moving through your body one muscle group at a time, or it can be paired with massage/touch from a partner or support person.
- Meditation may help manage pain by focusing your mind on a certain object, picture or sound instead of on the discomfort. There are many guided meditations available online or on free medication & mindfulness apps. A simple version is to focus on a chosen picture or object or image or sound, or to repeat a word or phrase over & over to yourself. When you become distracted, just bring your attention back to the focal point.
- Guided imagery also can help to focus your mind away from discomfort. You may find some helpful recordings online or on free mindfulness & meditations apps. You can also simply close your eyes and choose a favorite place or memory to imagine: focus on all the tiny details of color, smell, sounds, textures, the air. You can play soft music or sounds to help you feel like you're really there.

Appendix E: Post-procedure checklist

- ❑ Problem list updated to include "Foreign Body" with foley type & number of mL instilled, or number of Dilapan-S placed
- ❑ Patient observed for 10 minutes post-procedure. Send to triage for monitoring if:
  - ➢ heavy vaginal bleeding
  - ➢ concern for ROM
  - ➢ significant discomfort that does not quickly improve
  - ➢ Syncope or presyncope
  - ➢ Any other acute concerns about patient or fetal wellbeing
- ❑ FHT documented post-procedure: Rate _____
- ❑ Post-procedure patient handout given & reviewed
- ❑ Labor induction scheduling for the next day confirmed, and charge nurse notified that patient has begin outpatient cervical ripening.

Appendix F: Outpatient Foley Balloon Placement Technique



1. Use sterile marking pen to mark estimated cervical length from lower edge of balloon
2. Place a speculum (ideally warmed & generously coated in lubricant), taking care to properly center the cervix. If needed, having the patient briefly in McRobert's position can help bring the cervix into view
3. Using ring forceps, guide the foley through the cervical os
4. Continuing advancing until the mark is at the external os (this should ensure balloon is beyond the internal os, as desired)
5. Inflate balloon to 35ml with sterile saline
6. Remove the speculum. Leave foley to gravity or tape to thigh for patient comfort (no tension)

Adapted from:
https://www.cmqcc.org/news/webinar-recording-induction-labor-risks-benefits-and-techniques-increasing-success

Appendix G: Dilapan-S Instruction Guide: Induction of Labor

Source: https://www.dilapan.com/hcp/

B/ The cervix is visualized with a sterile vaginal speculum. Appropriate cleaning solution (e._g. iodine) is recommended, but not necessary to clean the cervix. Sponge forceps rather than a tenaculum should be used to stabilize the anterior lip of the cervix and to straighten the cervical canal for easier insertion of the rods. It can be benefi cial especially in case of highly unmatured cervix. DILAPAN–S_rod can be moistened with sterile water or saline to lubricate the surface prior to insertion.

C/ Using a second 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_past the handle. As many as possible pieces (usualy 3_—_5) of DILAPAN–S_are inserted into the cervical canal. The number of pieces inserted varies, since di_ erent patients have different pelvic or cervical exam/dilation. Each rod can act as a guide for subsequent rods to be inserted.
Mother 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, if needed.

D/ Another 20 minutes CTG is recommended to be performed after completion and the patient could be o_ ered to leave the hospital and spend the ripening period at home.
The patient is instructed to report any excessive bleeding, pain or other concerns.
Under no circumstances should the woman try to remove the rods herself.
The patient is allowed to shower and perform regular activities, but should avoid bathing, douching and sexual intercourse while the rods are in place.

E/ The rods should be left in place up to 12 hours, which is usually sufficient time for increasing the Bishop score adequately. Do not leave the rods in place for longer than 24 hours.
Reasons for examining or removing the dilators prematuraly include:
_• Spontaneous onset of labor (defined as regular, firm uterine contractions with an effaced cervix >_80_% and a cervical dilation >_3 cm)
_• Category III fetal heart rate tracing
_• Spontaneous rupture of membranes or need for amniotomy
_• Spontaneous expulsion of dilators

F/ While removing the rods, use sponge forceps to grasp a handle of the rod. They usually come out as a clump. Please ensure all inserted rods are removed.
The Bishop score can be determined at the end of removal procedure during the same vaginal examination.
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 94_%).

G/ After the removal of DILAPAN–S_, use ARM and oxytocin administration to promote uterine contractions and reach vaginal delivery.