USF Health Outpatient Cervical Ripening Protocol

Purpose To outline the management of patients needing induction for medical reasons or for postdates who have a Bishop score of less than 6.

- **Procedure** This policy is to be used as a guideline for care. However individualized medical care is directed by the patient's healthcare provider.
- **Justification** This policy is intended for cervical ripening for more effective induction of labor and to reduce the possibility of cesarean delivery due to induction with an unfavorable cervix.
- **Responsibility** Procedure is to be performed by MD or CNM in clinic after review of chart, review of the exclusion criteria, obtaining informed consent from the patient for the procedure and a reactive NST. The week prior to insertion, the provider must also schedule the patient for induction with TGH Labor and Delivery for the day following insertion. The provider must also verify that the scheduled day of Cervical Foley Balloon insertion there will be a provider in clinic that is willing to perform the insertion.
- **The provider** will send a notification of Induction a week prior to the date of induction to the Surgery Scheduling Pool in Epic with

Patients identifying information, Date desired for induction EDC Gestational age Indication for induction Bishop Score Also, indicate that **cervical balloon** is being used for cervical ripening The scheduling provider will also cc the patient's chart and above information to the provider who will be doing the

insertion if the scheduling provider is not available in clinic that day.

Eligibility with Non-Medical Indications for Cervical Ripening or Induction of Labor as an Outpatient

Multiparous Patient with at least one previous vaginal delivery, no cesareans

39 weeks gestational age or greater at time of cervical ripening procedure

Bishop score less than 6

This type of induction cannot be scheduled more than 7 days in advance

Eligibility with Medical indications for Cervical Ripening or Induction of Labor as an Outpatient

Fetal demise Gestational Hypertension Chronic Hypertension Postdates pregnancy Diabetes Mellitus

There may be other medical indications not listed here. If there is a question of appropriateness, the indication will need to be reviewed by MFM or the OB Department Chief or designee.

Contraindications to Cervical Ripening or Induction of Labor as an Outpatient

Known Vasa Previa **Complete Placenta Previa** Abnormal Fetal Lie or non-Cephalic lie **Umbilical Cord Prolapse** Active Genital Herpes **Category III Fetal Heart Tracing** Chorioamnionitis Abruptio Placenta Polyhydramnios **Invasive Cervical Cancer** Inadequate Pelvis or Pelvic Abnormality **Ruptured Membranes Multiple Gestation** Severe Maternal Hypertension **Previous Uterine Incision** Any Contraindication to Induction of Labor

There may be an instance where the provider determines that the use of the Balloon Cervical Dilator is indicated in the presence of a condition listed as a contraindication by the manufacturer. In that case, the provider would document the indication and the plan of care in the medical record.

Method Obtain Consent Form for patient and provider to review and sign (Appendix A)

Confirm that patient is on schedule at TGH for induction the day after this procedure

Obtain Supplies

Foley catheter 16-26 gauge with a 30cc balloon Sterile saline 100cc Speculum Ring forceps 30-60 cc syringe Foley plug

Assist provider with insertion of catheter and inflate with 40-60 cc NS when in place

Assess vital signs, fetal heart rate and uterine activity before and after the procedure with NST

for 30 minutes or until reactive.

Notify provider of suspected rupture of membranes, fever, abnormal bleeding, non-reassuring FHT or tachysystole.

Provide patient with and review post procedure instructions (Appendix B)

Appendix A

Informed consent for cervical ripening with Foley Balloon

Patient Label Here

Dr_____ has recommended that you have cervical ripening with the Foley balloon prior to your induction. This procedure is expected to improve your chances of a vaginal delivery by improving the dilation, effacement and consistency of your cervix.

Your baby is Head Down	Yes	No	(provider to circle one)
Your membranes are intact	Yes	No	
Your cervical exam today			
Your Bishop Score Today			

The use of the foley balloon for cervical ripening is a common practice among OB/Gyn physicians but is not the intended purpose of the foley balloon. Therefore, this is considered an "off label" use for this device.

With insertion of the foley balloon into your cervix you may experience cramping and bleeding. Cervical foley balloon use success is equal to hospital induction with cervidil. The advantage is the ability to do this process as an outpatient. Alternatives to this procedure include inpatient induction or waiting for natural labor to occur depending on your health conditions during this pregnancy.

There is the chance that your membranes may rupture spontaneously. You may have a chance of infection but this is no greater than normal. Overall if your Bishop score is less than 7 your chances of an improved Bishop score and of vaginal delivery is greater after the cervical foley balloon procedure than if you didn't have one placed. Should the balloon burst or fall out on its own, please come to TGH Labor and Delivery at your appointed induction time.

Please come earlier to TGH Labor and Delivery if your water breaks, you have heavy bleeding, your contractions are painful and regular for 1 hour every 3-5 minutes or if you don't feel your baby moving as usual.

By signing below, you acknowledge that you understand the purpose of and agree to this procedure, that the risks, benefits, complications and alternatives have been reviewed with you to your satisfaction, and that your questions have been answered in full.

Patient's Signature	Date
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I have reviewed the above with the patient. The benefits, risks, complications and alternatives (including but not limited to those listed above) have been discussed and her questions answered.

Physician's Signature	 _ Date

Appendix B

Post Procedure Instructions for

Foley Balloon Placement for Cervical Ripening

After your procedure, you may experience

- Bleeding, spotting to light bleeding
- Cramping, like period cramps
- Flushing, or hot flashes

These are normal and expected reactions and this is what will help you become dilated and effaced. These symptoms may continue through the night and hopefully by the time you come to Labor and Delivery the Foley Balloon should have dilated you to more than 3 cm.

Feel free to walk, do chores, be active.

Gravity will help your baby and the balloon do all the work.

DO NOT take any tub baths, take showers only

DO NOT have any intercourse

DO NOT insert anything into the vagina

Please come to Labor and delivery before your appointed induction time

If You BLEED heavily needing more than one pad per hour

If You BREAK your water or think you may have, especially if you are GBS positive

If Your Baby DOESN'T MOVE ten times in two hours

If you have CONTRACTIONS that are strong enough you can't talk through them for 1 hour

Call 813-259-8500 with any questions or concerns

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