CELOX™ PPH

UTERINE HAEMOSTATIC TAMPONADE

HOW TO USE CELOX PPH

CELOX™ PPH should be used when postpartum haemorrhage does not respond to initial management such as uterine massage, volume replacement, and standard medical treatment with uterotonic and antifibrinolytic agents.

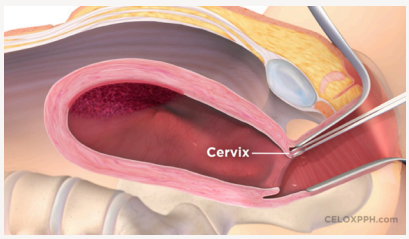
Refer to the Instructions for Use for complete information on CELOX™ PPH usage and a complete list of contraindications, warnings and precautions.

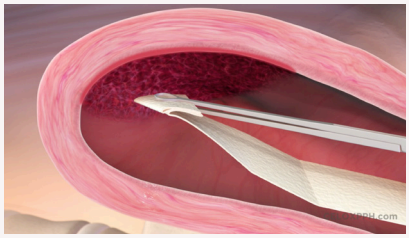
Prior to application

- Ensure the patient does not present with any contraindications for use of CELOX™ PPH.
- After caesarean deliveries ensure the uterotomy is closed prior to applying CELOX™ PPH trans-vaginally.
- Ensure any retained placenta tissue, blood clots or membranes are removed from the uterus prior to uterine packing with CELOX™ PPH.
- Remove any equipment applying external pressure to the uterus (e.g., pressure pads) prior to applying CELOX™ PPH.

Application

- Tear open the package at the tear notches. Sterile technique should be observed in delivering the sterile CELOX™ PPH to the field of application.
- Place the patient in a lithotomy position, and with the aid of a speculum grasp the cervix with an atraumatic instrument, if necessary, and manually insert the unfolding CELOX™ PPH into the uterine cavity with atraumatic forceps up to the fundus. Avoid excessive force.
- Use ultrasound guidance if available to guide application to ensure the CELOX™ PPH reaches the site(s) of bleeding and to minimise the risk of damaging the uterine wall.
- If ultrasound is not available, use external manual palpation to avoid injury to the uterine wall by the insertion of CELOX™ PPH.
- Allow the CELOX™ PPH to unfold externally to the patient whilst applying the device.
- Leave sufficient length of the end of each CELOX™ PPH protruding through the cervix and vagina to allow subsequent removal.
- Following haemostasis, excess CELOX™ PPH can be cut from the ends protruding from the vagina (leaving sufficient length of each CELOX™ PPH to be noticeable and to allow removal).
- Leave CELOX™ PPH in place for up to 24 hours if clinically feasible, but no longer





More information overleaf...

MT-23-180

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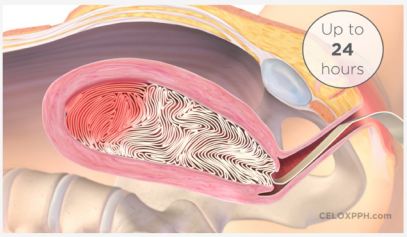
- Use at least one CELOX™ PPH for each patient and do not cut or tear CELOX™ PPH prior to application as this could increase the risk of material fragments being left in the uterus.
- Use a maximum of 2 CELOX™ PPH per patient over the course of treatment.
- CELOX™ PPH must contact the site(s) of bleeding.

- If needed, the vagina may be packed with secondary sterile dressings/gauze (non CELOX™) for compression of ascending vessels.
- While CELOX™ PPH is in place, compression is to be applied for a sufficient duration according to clinical judgement to enable haemostasis.
- Monitor the patient carefully for signs of rebleeding (e.g. clinical signs, monitoring of blood values and using ultrasound scans if available).
- Treatment with oxytocic/ uterotonic drugs may continue during this time.
- If postpartum haemorrhage continues, remove CELOX™ PPH and revert to the next stage of the standard of care/protocol for post-partum haemorrhage.

Removal

- CELOX™ PPH should be removable by pulling the end left outside the vagina.
- Upon removal, inspect the end of the fabric for an intact edge to determine integrity and completeness. Adequate revision action steps should be initiated when incomplete removal is observed or suspected. No fabric fragments should be left behind.
- Dispose of the used CELOX™ PPH according to standard hospital procedures for clinical waste.



- It is expected loose residual granules or gelled material from CELOX™ PPH will be expelled in the lochia of the patient and potentially upon menstruation restarting. This could potentially be several weeks after use. This information should be conveyed to the patient.

Scan here to visit website

Wyłączny dystrybutor w Polsce
PARAMEDYK
www.paramedyk.pl

For more information visit: www.celoxpph.com