



FREQUENTLY ASKED QUESTIONS

What is the mode of action of CELOX™ PPH?

Step 1 – Absorbs fluid from the blood to create a robust gel, which seals the site of bleeding, independently of the body's natural clotting cascade.

Step 2 – Develops mucoadhesive properties to the tissue surrounding the site of bleeding, maintaining the gel plug in place and minimising re-bleed during movement of the patient.

Step 3 – Attracts anionic red blood cells to the site of bleeding creating conducive environment for the body's natural clotting cascade.

Step 4 – Maintains gel plug in place whilst natural clot forms and then naturally breaks down through enzyme degradation (lysozyme) into glucosamine, which is excreted from the body.

When can CELOX™ PPH be used?

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.

How is CELOX™ PPH packaging opened?

Tear open the package at the tear notches. Sterile technique should be observed in delivering the sterile CELOX™ PPH to the field of application.

What instrument(s) can be used to apply CELOX™ PPH?

Use a speculum and an atraumatic instrument to grasp the cervix and manually insert the unfolding CELOX™ PPH into the uterine cavity up to the uterine fundus. Use ultrasound guidance, if available, to guide application to ensure the device reaches the site of bleeding and to minimise the risk of damaging the uterine wall. If ultrasound is not available, use external manual palpation.

How many CELOX™ PPH can be used?

Use a maximum of two CELOX™ PPH per patient over the course of treatment.

Can CELOX™ PPH be cut or torn?

Do not cut or tear CELOX™ PPH prior to application as this could increase the risk of material fragments being left in the uterus to avoid injury to the uterine wall.

How do I know that CELOX™ PPH has been applied correctly?

Use ultrasound, if available, to confirm CELOX™ PPH has reached the site of bleeding. If ultrasound is not available, use external manual palpation.

Do I need to add vaginal packing following placement of CELOX™ PPH?

If needed, the vagina may be packed with secondary sterile dressings/gauze (non CELOX™ PPH) for compression of ascending vessels.



UTERINE HAEMOSTATIC TAMPONADE

How long can I leave CELOX™ PPH indwelling?

No more than 24 hours.

Can CELOX™ PPH be used after a caesarean section?

CELOX™ PPH can be used after a c-section. Ensure the uterotomy is closed prior to applying CELOX™ PPH transvaginally.

Can CELOX™ PPH be used for vaginal haemorrhage?

CELOX™ PPH is not approved for intravaginal use, and this type of use is off label.

Can CELOX™ PPH be used in combination with uterotonics?

CELOX™ PPH can be used alongside uterotonic agents.

Can CELOX™ PPH be used in combination with compression suturing?

CELOX™ PPH can be used alongside compression suturing e.g. B-Lynch sutures. Ensure the sutures are applied prior to applying CELOX™ PPH to avoid excessive compression by the procedure resulting in difficulty to remove CELOX™ PPH following treatment completion.

Can CELOX™ PPH be used in cases of placenta previa and placenta accreta?

CELOX™ PPH can be used in cases of placenta previa and placenta accreta providing that all contraindications have been ruled out.

Is CELOX™ PPH safe for use on patients with a shellfish allergy?

Our research has shown no risk that the use of CELOX™ PPH will result in allergic response when used as a topical haemostatic agent. The rigorous manufacturing stages to produce shellfish derived chitosan used in CELOX™ PPH denatures and removes protein (tropomyosin) which is the likely cause of shellfish allergic reactions.

What steps should be taken to ensure proper insertion, positioning and coverage of CELOX™ PPH within the uterine cavity?

Ensuring proper placement of CELOX™ PPH is crucial for the effective control of uterine bleeding. The following steps are recommended to ensure accurate placement:

1. Use a-traumatic forceps to gently pack the gauze into the uterine cavity and up to the fundus until resistance is encountered.
2. Use abdominal palpation to assess the uterus and confirm that the CELOX™ PPH gauze is reaching the fundus by feeling for resistance or the presence of the gauze in the upper part of the uterine cavity.
3. If available, use ultrasound imaging to visualise the position of the CELOX™ PPH gauze within the uterine cavity. This not only aids in confirming its position but also facilitates any necessary adjustments, ensuring optimal placement up to the fundus.
4. In the event of persistent difficulty, consider packing a second CELOX™ PPH gauze into the uterine cavity, until resistance is encountered. Leave sufficient length of the end of each CELOX™ PPH protruding through the cervix and vagina to allow subsequent removal.

What practical guidance and tips are available for the optimal insertion of CELOX™ PPH?

For optimal insertion of CELOX™ PPH, the following steps are recommended:

1. Use a-traumatic forceps and wrap the CELOX™ PPH gauze around the tip of the forceps, ensuring the edges are neatly folded inward.
2. Apply a small amount of blood from the vaginal area to the surface of the CELOX™ PPH gauze edges to soften for entry.

For more information visit: www.celoxpph.com

Can CELOX™ PPH be removed before the recommended 24 hour duration, if bleeding control is achieved earlier?

The timing of removal OF CELOX™ PPH can be influenced by the successful control of bleeding and the patient's overall condition, as determined through comprehensive assessments. This includes:

- Haemostasis achievement,
- Vital signs for overall stability,
- Regular blood tests tracking, such as haematocrit and haemoglobin levels,
- Uterine tone assessment,
- Close observation for ongoing symptoms, and,
- Utilisation of ultrasound imaging (if available) to visualise the uterine cavity.

What steps should be taken following the removal of CELOX™ PPH?

It is advised to conduct routine follow-up procedures post-removal.

Is there a need for anaesthesia when removing CELOX™ PPH?

Our clinical experts suggest that CELOX™ PPH is generally well tolerated by patients with less pain while in situ within the uterine cavity, and its removal can typically be accomplished without the need for anaesthesia.

Are there established local protocols for the application of CELOX™ PPH or contacts for experienced users?

CELOX™ PPH has demonstrated its effectiveness through widespread adoption by clinicians in German hospitals for the treatment of uterine postpartum haemorrhage for over 12 years. Professor Wolfgang Henrich of Charite Hospital, Berlin has developed a PPH treatment algorithm, providing invaluable guidance for incorporating CELOX™ PPH into local protocols. This resource (as referenced on figure 6, page 15 of the CELOX PPH Clinical and Scientific Monograph) proves particularly beneficial for clinicians new to the product. For more information on users in specific locations, please feel free to contact us directly.

What is the success rate of CELOX™ PPH?

CELOX™ PPH users experience success rates ranging from 95.6% to 100%. Numerous papers have been published in leading OBGYN journals supporting the use and efficacy of CELOX™ PPH, as follows:

Schmid BC, Rezniczek GA, Rolf N, Saade G, Gebauer G, Maul H (2013) 'Uterine packing with chitosan-covered gauze for control of postpartum hemorrhage', *American Journal of Obstetrics and Gynecology*, Vol. 209 (e1-5), pp. 225.

Carles G, Dabiri C, Mchirgui A, Saoudi EO, Hcini N, Pouget K, Seve B, de Matteis B (2017) 'Uses of chitosan for treating different forms of serious obstetrics hemorrhages'. *Journal of Gynecology Obstetrics and Human Reproduction*, Vol 46 (9), pp. 693-695.

Dueckelmann AM, Hinkson L, Nonnenmacher A, Siedentopf JP, Schoenborn I, Weizsaecker K, Kaufner L, Henrich W, Braun T (2019) 'Uterine packing with chitosan-covered gauze compared to balloon tamponade for managing postpartum hemorrhage', *European Journal of Obstetrics & Gynecology and Reproductive Biology*, Vol. 240, pp. 151-155.

Biele C, Radtke L, Kaufner L, Hinkson L, Braun T, Henrich W, Dückelmann AM (2022) 'Does the use of chitosan covered gauze for postpartum hemorrhage reduce the need for surgical therapy including hysterectomy? A databased historical cohort study', *Journal of Perinatal Medicine*, Vol. 50, (8), pp. 1078-1086.

Dueckelmann AM (2022) 'CELOX™ GAUZE Post-Partum Hemorrhage Retrospective Data Analysis Report - October 2016 to June 2018' (2022) Unpublished.