

Our Mission

Our mission is to make a **significant** global impact in helping reduce **maternal** death worldwide. We aim to support at every **delivery** across the world through access to a **safe** and clinically-effective **technology** which is **fast** acting in all conditions, **versatile** and **easy** to use.



To learn more about effectively managing PPH with CELOX™ PPH, please contact us using the details below or scan the QR code to visit celoxpph.com



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References: 1. The World health report 2005: make every mother and child count. Geneva: World Health Organisation; 2005. 2. Borovac-Piniheiro, A., Pacagnella, R.C., Cecatti, J.G., et al. Postpartum haemorrhage: new insights for definition and diagnosis. Am J Obstet Gynecol. 2018;219:162-168. 3. Celox Gauze – Post Partum Haemorrhage – Retrospective Data Analysis Report V1.1-19 May 2022 – Data on file. 4. Schmid, B.C., Reznicek, G.A., Rolf, N., et al. Uterine packing with chitosan-covered gauze for control of postpartum haemorrhage Am J Obstet Gynecol 2013;209:225.e1-5. 5. Dueckelmann, A.M., et al. Uterine packing with chitosan-covered gauze compared to balloon tamponade for managing postpartum haemorrhage. European Journal of Obstetrics & Gynecology and Reproductive Biology 240 (2019) 151-155. 6. Biele, C., et al., "Does the use of chitosan covered gauze for postpartum haemorrhage reduce the need for surgical therapy including hysterectomy? A databased historical cohort study." (in eng), J Perinat Med, May 25 2022, doi:10.1515/jpm-2021-0533. 7. Millner, RWJ., et al. Chitosan arrests bleeding in major hepatic injuries with clotting dysfunction: an *in vivo* experimental study in a model of hepatic injury in the presence of moderate systemic heparinisation. Ann R Coll Surg Engl 2010; 92: 559-561. (In-vivo) 8. Arulkumaran, S., Karoshi, M., Keith, L.G., Lalonde, A.B. and B-Lynch, C. eds., 2012. A comprehensive textbook of postpartum haemorrhage: an essential clinical reference for effective management. 2nd ed. London: Sapiens Publishing. Chapter: Burbank, F., Hemodynamic Changes in the Uterus and its Blood Vessels in Pregnancy. 9. Royal College of Obstetricians and Gynaecologists (RCOG), 2016. Heavy bleeding after birth (postpartum haemorrhage). [online] Available at: <https://www.rcog.org.uk/for-the-public/browse-our-patient-information/heavy-bleeding-after-birth-postpartum-haemorrhage/> 10. World Health Organization, 2023. WHO recommendations on the assessment of postpartum blood loss and use of a treatment bundle for the management of postpartum haemorrhage. Geneva: World Health Organization. Available at: <https://iris.who.int/bitstream/handle/10665/375199/9789240085428-eng.pdf?postpartum%20haemorrhage> 11. Say, L., et al. Global causes of maternal death: a WHO systematic analysis. Lancet Glob Health. 2014 Jun;2(6):e323-33. 12. Identifying regional variation in the prevalence of postpartum haemorrhage: a systematic review and meta-analysis. Clara Calvert I, Sara L Thomas, Carine Ronsmans, Karen S Wagner, Alma J Adler, Veronique Filippi, PLoS ONE, July 2012| volume 7 | Issue 7 | e41114. 13. Carles, G., Dabiri, C., Mchirgui, A., Saoudi, E.O., Hcini, N., Pouget, K., Seve, B. and de Matteis, B., 2017. Uses of chitosan for treating different forms of serious obstetric haemorrhages. Journal de Gynécologie Obstétrique et Biologie de la Reproduction, 46(3), pp.309-313. 14. Dueckelmann, A.M., Hermann, P., Biele, C., Leichter, C., Waldner, C., Braun, T. & Henrich, W. (2024) 'Short and long-term menstrual, reproductive, and mental health outcomes after the intrauterine use of chitosan tamponade or the Bakri balloon for severe postpartum haemorrhage: an observational study', The Journal of Maternal-Fetal & Neonatal Medicine, 37(1), pp.2354382. 15. Guo, Y., Hua, R., Bian, S., Xie, X., Ma, J., Cai, Y., Sooranna, S.R. and Cheng, W., 2018. Intrauterine Bakri Balloon and Vaginal Tamponade Combined with Abdominal Compression for the Management of Postpartum Haemorrhage. Journal of Obstetrics and Gynaecology Canada, 40(5), pp.561-565. 16. Beckmann, M. M., & Chaplin, J. (2014). Bakri balloon during cesarean delivery for placenta previa. International Journal of Gynaecology and Obstetrics, 124(2), 118-122. 17. Kong, M.C.W. and To, W.W.K., 2013. Balloon tamponade for postpartum haemorrhage: case series and literature review. Hong Kong Medical Journal, 19(6), pp.484-490. 18. Ruiz Labarta, F.J., Pintado Recarte, M.P., Joigneau Prieto, L., Bravo Arribas, C., Bujan, J., Ortega, M.A. and De León-Luis, J.A., (2021). Factors Associated with Failure of Bakri Balloon Tamponade for the Management of Postpartum Haemorrhage: Case Series Study and Systematic Review. Healthcare, 9(3), p.295. 19. Kaya, B., Tuten, A., Daglar, K., Misirligözü, M., Polat, M., Yildirim, Y., Ünal, O., Kilic, G.S. and Guralp, O., 2014. Balloon tamponade for the management of postpartum uterine haemorrhage. Journal of Perinatal Medicine, 42(6), pp.745-753. 20. Beckmann and Chaplin (2014). 19. Kong, M.C. and To, W.W., 2013. Balloon tamponade for postpartum haemorrhage: Case series and literature review. Hong Kong Medical Journal, 19(6), pp.484-490. 21. Khalil, M.I., Al-Dohami, H. and Aldahish, M.M., 2011. A method to improve the effectiveness of the Bakri balloon for management of postpartum haemorrhage at cesarean. International Journal of Gynecology & Obstetrics, 115(2), pp.204-206. <https://doi.org/10.1016/j.ijgo.2011.05.029>

MT-25-020

CELOX™ PPH
UTERINE HAEMOSTATIC TAMPONADE

Every new life needs a safe pair of hands.

For *Rapid* and *Effective* control of
Uterine Postpartum Haemorrhage (PPH).

CELOX™ PPH. *Safe hands save lives.*

CELOX™ PPH. Ground-breaking innovation to help save lives.

Every five minutes, a woman dies from postpartum haemorrhage (PPH), which is the leading cause of maternal mortality worldwide. The World Health Organization (WHO) estimates that approximately 14 million women experience PPH each year, resulting in about 80,000 maternal deaths globally.¹

This condition often necessitates urgent surgical interventions to control the bleeding, and even when women survive, they may face lifelong reproductive disabilities. Addressing PPH effectively is crucial to reducing maternal mortality and improving women's health outcomes globally.^{1,2}

Introducing an innovative solution to revolutionise PPH management: the CELOX™ PPH Uterine Haemostatic Tamponade. Developed by pioneering experts in haemostatic technology with a proven legacy of success in military and emergency care, CELOX™ PPH effectively controls severe uterine bleeding ensuring rapid and effective intervention when it matters most.

With its innovative design and proven clinical efficacy, CELOX™ PPH is set to transform the standard of care in managing PPH.

14
million women
experience PPH
each year¹

80,000
maternal deaths
globally¹

Every
5
minutes a woman
dies from PPH¹

The benefits of CELOX™ PPH



FAST ACTING

- + Addresses a wide range of uterine PPH indications^{3,4,5,6}
- + Rapid haemostasis achieved independently of the patient's clotting ability^{3,4,5,6}
- + Highly effective bleeding control for patients on anti-coagulants or with trauma-induced coagulopathy⁷



SAFE AND CLINICALLY EFFECTIVE

- + 100% haemostasis for grade 1 and 2 bleeding (up to 2500mls) in all deliveries³
- + 95.65% haemostasis for grade 1 to 3 bleeding (up to 8000mls) for vaginal deliveries³
- + 78% reduction in hysterectomies vs current standard of care^{3,6}
- + Supported by a range of peer-reviewed published clinical papers^{3,4,5,6}



VERSATILE AND EASY TO USE

- + Lightweight and easy to apply and remove quickly^{3,4,5,6}
- + Limited training needed; aligned with standard uterine packing technique^{3,4,5,6}
- + Robust design with a 5-year shelf life, requiring no special storage, preparation, or additional materials


Postpartum Haemorrhage (PPH)


At term, uterine blood flow increases from about 100 ml/min to 800 ml/min, roughly 8-9 times prepregnancy levels. This supports the fetus but raises the risk of postpartum bleeding. While the body adapts for blood loss, imbalances can cause PPH.⁸


Primary PPH, more common than secondary PPH, occurs within 24 hours of delivery and involves blood loss of 500 ml or more. Secondary PPH occurs between 24 hours and 6 weeks postpartum.⁹ Initial management includes uterine massage and medications like oxytocin, misoprostol, and tranexamic acid. If needed, second-line options such as uterine balloon tamponade or uterine artery embolisation are used. Severe cases may require uterine compression sutures or a hysterectomy. Adjunctive therapies, including blood replacement and anti-shock garments, play a vital role in stabilising patients¹⁰ and managing PPH effectively.


20%
Failure rates
of existing devices³


14m
Women impacted
globally by PPH¹


20%
Maternal deaths due
to PPH worldwide¹¹


80k
Annual Deaths caused by PPH²
PPH is the leading cause
of maternal mortality, causing 80,000+
deaths annually worldwide.

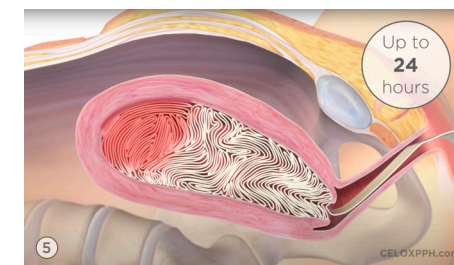
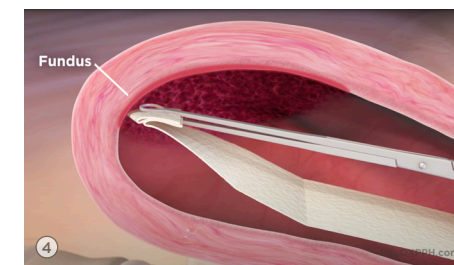
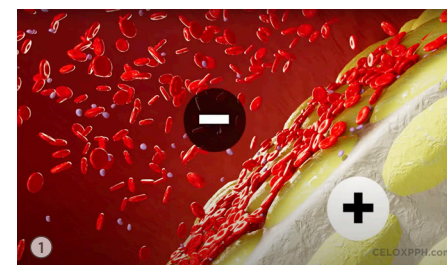

7.2% to 25.7%
Rate of PPH (Blood loss >500ml)
across all global markets¹²
PPH affects 7.2% to 25.7% of vaginal births
globally, impacting over 14 million women.

CELOX™ PPH OFFERS A VERSATILE SOLUTION THAT ADDRESSES PPH WITH CONFIDENCE AND EFFICIENCY, BACKED BY A WEALTH OF EXTENSIVE RESEARCH AND CLINICAL EXPERTISE ACCUMULATED OVER MANY YEARS.

How CELOX™ PPH works Using CELOX™ PPH

The CELOX™ PPH gauze is embedded with haemostatic granules which, when applied directly to the bleed site (see picture 1 below), absorb blood and fluid to swell and form a robust gel-like plug (see picture 2 below). The gauze adheres to the surrounding tissue through mucoadhesion (see picture 3 below), creating an environment which allows clot formation under the plug.

Sterile, pre-packaged and ready-to-use, CELOX™ PPH is simply applied through a standard uterine packing technique after the cervix and up to the fundus of the uterus, having made sure no remnants of placenta or clots remain. Once inserted, haemostasis is rapid and CELOX™ PPH can be left in place for up to 24 hours before being removed.



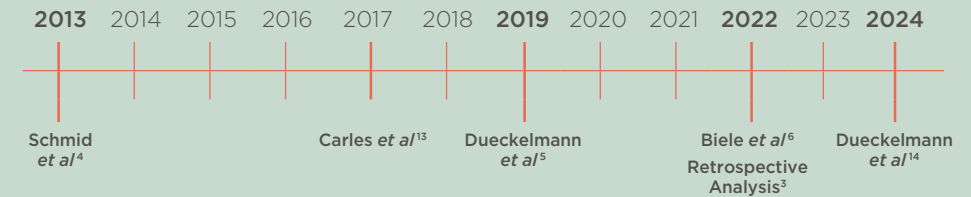
1. Application of CELOX™ PPH at the fundus of the bleeding uterus. 2. CELOX™ PPH is removed within 24 hours after initial application, and after haemostasis has occurred.

Scan the code to see how CELOX™ PPH works and how to use it.



The clinical evidence

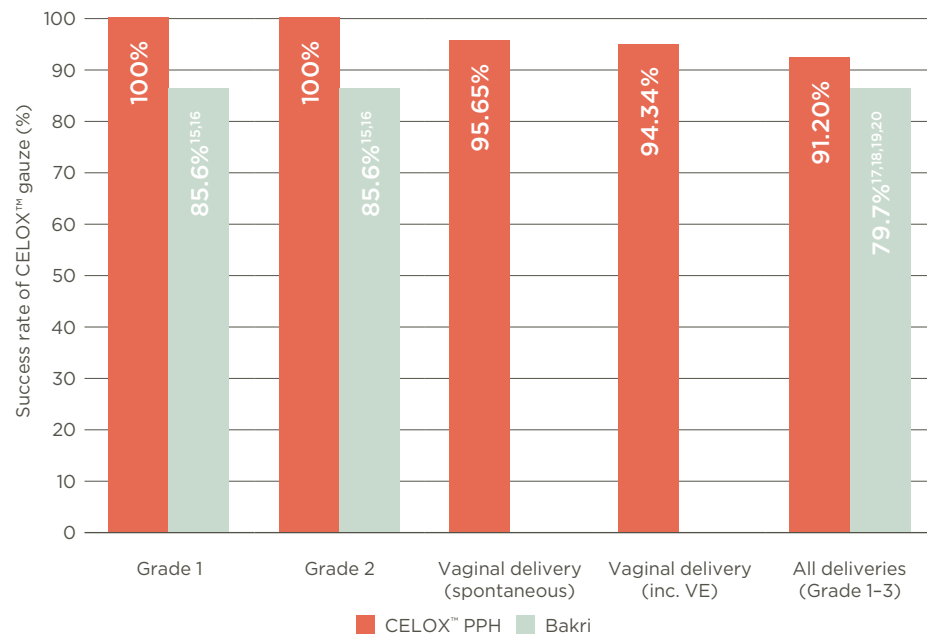
12+ years of clinical studies have demonstrated the effectiveness of CELOX™ PPH in the treatment of PPH.



In a retrospective analysis study from 2022, CELOX™ PPH was shown to be more effective than standard of care in stopping bleeding and reducing the need for additional interventions. It was also found to be safe and well-tolerated by patients:

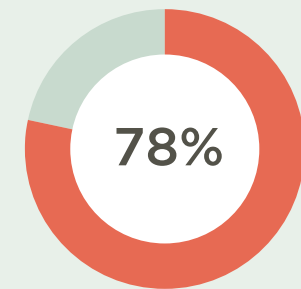
Retrospective Data Analysis from the Department of Obstetrics at Charité University Hospital, Berlin³

Efficacy Comparison: CELOX™ PPH Retrospective Analysis vs. Bakri Balloon Meta-analysis



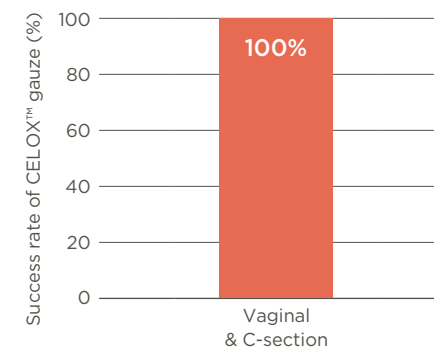
Findings

- **100% haemostasis** for Grade 1 and 2 bleeds
- Success was **consistently achieved within 2 to 5 minutes**
- **95.65% haemostasis** in Grade 1-3 bleeds (up to 8000ml)
- **78% reduction** in Hysterectomy Rates vs Standard of Care (Bakri Balloon)
- **No device-related adverse events**



Significant reduction in the incidence of hysterectomies following the use of CELOX™ PPH gauze.

Patients with PPH Grade 1 & 2 bleeds (from 800ml to 2500ml)



Conclusions

The findings strongly support the safety and efficacy of CELOX™ PPH, which has emerged as a highly promising alternative to standard care for controlling bleeding in critical cases of PPH.