



Womed Leaf[®]

Intrauterine Adhesion Barrier Film



About intrauterine adhesions

Intrauterine adhesions (IUA) or synechiae are fibrous strings at opposing walls of the uterus leading to partial or complete obliteration of the cavity. They may occur as a consequence of surgery in the uterine cavity and are generally the major long term complications of operative hysteroscopy.

Origin and Incidence

Hysteroscopic
removal of
fibroids

Postpartum
manual uterine
examination

Dilatation and
curettage for
miscarriage or
abortion

Curettage for
retained
products of
conception

Fibroids
embolization

Myomectomy
with cavity
opening

The reported incidence may be as high as :

- 20% following dilatation and curettage (D&C) for miscarriages and retained products of conception ^{1,2},
- 31% in case of second D&C³,
- 45% following hysteroscopy myomectomy^{4,5}

The recurrence rate after intrauterine adhesiolysis can reach 76% in case of severe adhesions⁶.

Clinical consequences

- Major cause of infertility
- Menstrual disorders
- Miscarriages

1 Salazar et al. A comprehensive review of Asherman's syndrome: causes, symptoms and treatment options Curr Opin Obstet Gynecol 2017; 29:249–256

2 Hooker et al. Systematic review and meta-analysis of intrauterine adhesions after miscarriage: prevalence, risk factors and long-term reproductive outcome Human Reproduction Update, 2014;20(2):262–278

3 Hooker, Angelo B et al. Prevalence of intrauterine adhesions after the application of hyaluronic acid gel after dilatation and curettage in women with at least one previous curettage: short-term outcomes of a multicenter, prospective randomized controlled trial. Fertility and sterility vol. 107,5 (2017): 1223-1231.e3.

4 Taskin et al. Role of endometrial suppression on the frequency of intrauterine adhesions after resectoscopic surgery. The Journal of the American Association of Gynecologic Laparoscopists 2000;7(3):351–4

5 Guida et al. Effectiveness of auto-crosslinked hyaluronic acid gel in the prevention of intrauterine adhesions after hysteroscopic surgery: a prospective, randomized, controlled study. Human Reproduction 2004;19(6):1461–64

6 Fernandez, Hervé et al. Effectiveness of degradable polymer film in the management of severe or moderate intrauterine adhesions (PREG-2): a randomized, double-blind, multicenter, stratified, superiority trial. Fertility and sterility vol. 122,6 (2024): 1124-1133.

Womed Leaf®

Womed Leaf is the **first and only MECHANICAL BARRIER** to prevent adhesions. This device is indicated for use in **all transcervical procedures**.

After insertion into the uterine cavity, the Womed Leaf film soaks uterine fluids and expands to provide **complete protection of the cavity**, for approximately **7 days**.

Womed Leaf has been designed from well known **highly biocompatible** compounds:

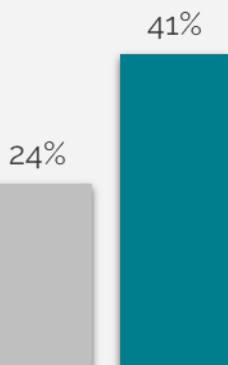
- Polylactic acid (PLA),
- Polyethylene oxide (PEO).



Clinical evidence

Absence of IUA at SLH*

■ Control ■ Womed Leaf



Odds Ratio = 2,4 [1,2-5,1]
p = 0,019

2,4 X
times more
chances to
be free
from IUA⁷

International Randomized Controlled Trial PREG2⁷

160 hysteroscopic adhesiolysis of symptomatic severe or moderate adhesions

Safe : No Adverse Events related to Womed Leaf^{**}, confirming the safety results obtained in PREG1⁸

Effective : Statistically significant reduction in the number and severity of intrauterine adhesions (IUA) at follow-up

Womed Leaf is the **first intrauterine barrier** to demonstrate a **clinically significant and meaningful improvement** in the challenging **severe IUA** indication.

*Second Look Hysteroscopy

**No proven or probable causal link

7 Fernandez, Hervé et al. Effectiveness of degradable polymer film in the management of severe or moderate intrauterine adhesions (PREG-2): a randomized, double-blind, multicenter, stratified, superiority trial. Fertility and sterility vol. 122,6 (2024): 1124-1133.

8 Weyers, Steven et al. Safety and Efficacy of a Novel Barrier Film to Prevent Intrauterine Adhesion Formation after Hysteroscopic Myomectomy: The PREG1 Clinical Trial. Journal of minimally invasive gynecology vol. 29,1 (2022): 151-157.



Simple, Safe and effective



Mechanical barrier

Womed Leaf adhesion barrier film self deploys and **keeps the uterine walls apart** after an intrauterine procedure.



Long lasting effect

Womed Leaf acts as a mechanical barrier **during a week**, i.e. the critical part of the healing phase.



Full cavity protection

Thanks to its swelling ability when in contact with water, Womed Leaf grows to fill the entire uterine cavity.



Rapid insertion

At the end of the surgical procedure, Womed Leaf is inserted through the cervix with a flexible inserter, just like an IUD. The uterine film is not sticky and the insertion takes less than 1 minute.



No follow-up required

After a week, the uterine film **breaks-up, dissolves and is naturally discharged** through the cervix without any intervention of a healthcare professional.



Ordering information:

Product Code	Description	Unit of Measure
EL-ADHME-S	Intrauterine Adhesion Barrier Film — SMALL size (uterine depth < 5 cm)	Box of 1
EL-ADHME	Intrauterine Adhesion Barrier Film — MEDIUM size (uterine depth 5-7 cm)	Box of 1
EL-ADHME-L	Intrauterine Adhesion Barrier Film — LARGE size (uterine depth 7-10 cm)	Box of 1

GYNURO-EN-BRWOMEDLEAF-03-25

KEBOMED

Device class : IIa

Name and number of the notified body : mdc
medical device certification GmbH, # 0483

Document created for the Healthcare Professionals.
Before use, refer to the instructions attached to
medical device.

Distributor:
Kebomed AB
Kanalvägen 6
194 61 Upplands Väsby
Sweden

Tel. : +46 040 305105
Fax : +46 040 305106
E-Mail : info@kebomed.se

Manufacturer :
Womed SAS
1919 route de Mende
CIT, Bâtiment Balard
34090 Montpellier


womed