

## The Risk of Uterine Perforation when Using Levonorgestrel Intrauterine System and Copper IUD

The latest safety information related to uterine perforation when using LNG – IUS (Levonorgestrel Intrauterine System) and Copper IUD has been published based on the result study of European Active Surveillance Study for Intrauterine Device (EURAS – IUD).

The study of EURAS – IUD is a prospective cohort study that is comparative and non-interventional when using intrauterine contraceptive (IUC) included LNG – IUA and Copper IUD. The main outcome is a uterine perforation. The result study of EURAS – IUD shows that:

- Uterine perforation incidents observed when using IUC are approximately 1 incident in every 1000 insertions.
- The most significant risk factor is the breastfeeding status when the insertion is performed, and when the insertion is carried out (36 weeks after delivery) regardless the type of IUD used.

	<i>Breastfeeding at time of insertion</i>	<i>Not breastfeeding at time of insertion</i>
<i>Insertion ≤ 36 weeks after delivery</i>	<i>5.6 per 1000 (95% CI: 3.9–7.9, n=6,047 insertions)</i>	<i>1.7 per 1000 (95% CI: 0.8-3.1, n=5,927 insertions)</i>
<i>Insertion &gt; 36 weeks after delivery</i>	<i>1.6 per 1000 (95% CI: 0.0-9.1, n=608 insertions)</i>	<i>0.7 per 1000 (95% CI: 0.5–1.1, n= 41,910 insertions)</i>

**Table: uterine perforation incident per 1000 insertions for all cohort studies, Differentiated based on breastfeeding status and time of insertion after delivery**

- IUC has a high effective contraception: the study reaffirms that the benefit of IUC is more than its risks for most women, including women who breastfeed their babies or who has just given a birth.

The risk of uterine perforation will raise during insertion on mothers who still breastfeed their babies, when IUS/IUD is inserted on the first 36th weeks after delivery. Women with fixed retroverted uterus will face the same risk. The symptoms of uterine perforation include:

- Chronic pain at pelvis after the insertion (worse than menstrual cramp)
- Does not feel the thread
- Pain or increased bleeding after insertion continuing up to several weeks
- Sudden change in menstrual cycles
- Pain when having sexual intercourse

Information concerning the increasing risk of uterine perforation has been put on product information of permitted LNG – IUS distributed in Indonesia. Until now, NADFC-RI, as the National Centre of Pharmacovigilance/MESO has accepted 5 reports of unexpected incidents, namely genital hemorrhage (vaginal hemorrhage) when using LNG – IUS.

NADFC – RI has given the information to health professionals in order to raise the awareness and to take into consideration in the use of LNG – IUS contraception. Health professionals are urged to report the ESO using MESO Yellow Form or to make an online report at <http://e-meso.pom.go.id> sub-site to NADFC – RI as the National Pharmacovigilance Centre/MESO.