

Ballerine® is safe and highly effective (99%) with a side-effect profile comparable to acceptable scientific rates of traditional IUDs.

Known and expected side-effects are stated in the IFU of all IUDs and are collected by OCON on a regular basis.

In 2019 and 2020 around 8'000 Ballerine® were inserted in The Netherlands and OCON collected the following events:

	Total	Expulsion	Pregnancy	Perforation	Embedment	Other
Ballerine Events	266	164	22	14	3	17
Ballerine Rate	3.3%	2.0%	0.27%	0.17%	0.04%	0.21%
Traditional T-IUDs Acceptable Scientific Rate		5-9%^{1,2}	1%³	0.2%⁴	up to 18%⁵	

¹ Madden et al. Association of age and parity with intrauterine device expulsion. *Obstet Gynecol.* 2014 Oct;124(4):718-726. doi: 10.1097/AOG.0000000000000475

² https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/018680s069s070lbl.pdf

³ Aoun et al. Effects of age, parity, and device type on complications and discontinuation of intrauterine devices. *Obstet Gynecol.* 2014 Mar;123(3):585-592. doi: 10.1097/AOG.000000000000144.

⁴ Bosco-Lévy et al. Safety of levonorgestrel 52 mg intrauterine system compared to copper intrauterine device: a population-based cohort study. *Contraception.* 2019 Jun;99(6):345-349. doi: 10.1016/j.contraception.2019.02.011. Epub 2019 Mar 12.

⁵ Migration of Intrauterine Devices: Radiologic Findings and Implications for Patient Care, Hillary E. Boortz et al. Department of Radiology, University of California at Los Angeles, Ronald Reagan UCLA Medical Center, Published online 10.1148/rg.322115068