

## **Abstract**

The CuFix (GyneFix), conceived in 1985, was developed to minimize three major problems frequently associated with discontinuation of IUD use: expulsion, bleeding and pain. Since the initial clinical investigations, over 10,000 woman years of experience and up to 8 years of follow-up in international multicenter, non-comparative and comparative clinical trials, including a large proportion of nulligravid/nulliparous women, have been collected. Based on new clinical information about the GyneFix from a long-term multicenter clinical trial, conducted in young nulligravid/nulliparous and parous women, the importance of this new contraceptive is discussed. The following conclusions were reached: The unique design characteristics of the GyneFix (frameless, flexible and fixed to the fundus of the uterus) have resulted in optimal tolerance and almost complete absence of expulsion. The result is enhanced effectiveness (comparable to OCs and male/female sterilization) and a high rate of continued use. The GyneFix reduces the IUD failure rate to a minimum and is, therefore, a welcome reversible alternative to OCs and female surgical contraception. Framelessness and flexibility explain the absence of side-effects and adverse events caused by dimensional incompatibility between the frame of conventional IUDs and the uterine cavity and may also explain the absence of PID and ectopic pregnancies in any of the clinical studies. The GyneFix is a promising new, highly effective and safe, contraceptive option for parous women and an equally effective and well-accepted method for nulliparous women.