

**Development of a miniature, low-dose, frameless intrauterine levonorgestrel-releasing intrauterine system for contraception and treatment: a review of initial clinical experience**

Dirk Wildemeersch<sup>1,5</sup>, Etienne Schacht<sup>2</sup>, Piet Wildemeersch<sup>1</sup>, Dirk Janssens<sup>3</sup>, M. Thiery<sup>4</sup>

<sup>1</sup>Control Research, Technology Park Zwijnaarde, Ghent, Belgium

<sup>2</sup>Polymer Research Group, University of Ghent, Department of Chemistry, Ghent, Belgium

<sup>3</sup>Gynaecologische Dienst, Turnhout, Belgium

<sup>4</sup>Department of Obstetrics and Gynaecology, University Hospital, Ghent, Belgium

<sup>5</sup>Piers de Raveschootlaan 125, 8300 Knokke, Belgium. Tel. +32-50-600900; Fax +32-50-622429; e-mail: dirk.wildemeersch@control.be

**Abstract**

A low-dose levonorgestrel (LNG)-releasing intrauterine system (IUS) (FibroPlant) has been clinically developed since 1997 for endometrial suppression during hormone replacement therapy in peri- and postmenopausal women, for the treatment of menorrhagia in women with normal uteri or with uterine fibroids, for contraception, for the treatment of endometrial hyperplasia, and for alleviating primary and secondary dysmenorrhoea. Results of preliminary studies confirm the promising nature of this all-round drug delivery system. The low dose of LNG released accounts for the low hormonal side effect rate and virtual absence of amenorrhoea in premenopausal women. The system has not yet been evaluated in tamoxifen users (to protect the endometrium), or in women with rectovaginal endometriosis. However, early indications suggest that the system will also be suitable for these indications. The frameless drug delivery support of this LNG-releasing IUS has been optimized to reduce the size of the foreign body and to maximize tolerance and continuation of use while simultaneously providing for the maximum duration of action.