

Device manufacturer's response to letters regarding 'Safety issue with TT380 Slimline intrauterine device'

Our devices have been distributed by Durbin plc in the UK since 2005. As of 30 June 2017, 276 265 TT 380 Slimline Standard and 36 668 TT 380 Slimline Short intrauterine devices (IUDs) have been distributed. Over this period, we have recorded 29 incidents of this nature, a rate of 0.0093%.

The new pusher rod that will be offered to Durbin plc is now distributed not only in Canada and New Zealand but also in France, Australia and the Gulf States. It is not yet available in the UK because the current UK versions of the TT 380 Slimline IUDs have 12 cm long inserter tubes which are longer than the tubes used in other countries, and the new pusher rod design is not yet suitable for longer tubes.

The new pusher rod is the result of a collaboration between our company and several French gynaecologists. As Dr Trewinnard rightly points out,¹ its design has made it possible to eliminate the problems of folds of the inserter tube at the base of the IUD which sometimes still occur in the UK. Contrary to Dr Trewinnard's view, however, the risk of uterine perforation is not aggravated by the new design. Indeed the notch of the pusher contains only the foot of the device over a length of 1.6 cm, thus allowing the arms of the device to fold freely along the upper body. The length of the free part of the stem is 1.8 cm for the Standard version and 1.3 cm for the Short version, thus avoiding any possible contact of the pusher rod with the uterine wall. We have not recorded any incidents of this nature either in France since June 2016 or in Canada since May 2016 and, to date, in any of the countries where these new devices are now distributed. Over this period we also did not record any incidents of tubes bending.

Our French and Canadian distributors are very satisfied with this new design. It seems to us that this modification of the pusher rod is an improvement of this device, contrary to the views expressed in Dr Trewinnard's letter. We suggest that we send her a supply of devices of the new design in the expectation that she will change her impression.

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REFERENCE

- 1 Trewinnard K. Follow-up response by author of letter on 'Safety issue with TT380 Slimline intrauterine device'. *BMJ Sex Reprod Health* 2018;**44**:69.