

IMPROVING COPPER T 380A BY CONTROLLING COPPER ION RELEASE

Abi Santhosh Aprem

HLL Lifecare Ltd, India

Copper intra uterine devices represent an important contraceptive option for nearly 160 million women worldwide. The main attraction of copper Intra Uterine Device (IUD) is that it is comparatively less expensive and highly effective (99%) over other long term methods of contraception. Major side effect related to a copper bearing IUD is increased menstrual bleeding, cramping and abdominal pain following the insertion. Rates of removal of copper IUD range 1 to 17 per 100 women because of bleeding and pain. Research results showed that this is due to the high corrosive rate of copper during the first few months of insertion. The present study reports the modification of an existing Intra Uterine Device (IUD) with a FDA approved polymer, poly lactic acid and poly (lactic/glycolic) acid (PLGA) to control the release of active ingredient. The side effects associated with the uncontrolled release of the active ingredient is controlled effectively by providing a safe coating of PLGA over the device which in turn increase the acceptance of the device. A phase II, randomized, single blinded clinical trial is in progress in 200 women subjects across 10 different sites in India. Initial results are very encouraging and promising. The percentage change in Pictorial Blood Assessment Chart from baseline was found to be significantly decreased with the new device when compares with the reference device.

abi@lifecarehll.com