

Fallopian Tube Manipulator Device (Mor)

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Background:

About 15% of couples trying to conceive are facing difficulties.

Female tubal factors are by far the largest group causing 25-35% of all infertility cases, thus 2/3 of all non conceiving couples will undergo an investigation that includes tubal imaging, 10% of whom will be candidates for tubal recanalization.

As for contraceptive methods; tubal ligation is one of the leading methods, being chosen by 15% of women in reproductive age in the US.

Summary of invention:

The Fallopian Tube Manipulator Device (FTM) is a steerable catheter that is introduced through the vagina, for easy access into the fallopian tubes. It can be used to image the fallopian tube and treat a blocked tube immediately and without reapplication of a different device.

It can also be used to deliver different methods of blocking the fallopian tube for means of sterilization, for example: biological glue, heating (for ablation).

Hence the FTM includes 3 functions in 1 device:

Imaging

Recanalization

Sterilization thru tube blockage.

Possible market size:

66% of all couples having troubles to conceive will need to undergo tubal imaging, 10% will need tubal recanalization.

As for means of contraceptives, some 10,000,000 women (15% of women in reproductive age) are choosing the method of tubal ligation.

Current solutions:

Currently there are different catheters for accessing the tubes all of which have non steerable with fixed angle. Therefore currently numerous tools are being used.

For tubal ligation a hysteroscopy is done, which does not give immediate information regarding whether a blockage was effectively done or not. Thus, 3 month after the procedure x-ray is done in order to reassure blockage.

Patent & regulatory status:


US Provisional patent application to be filled on December 2008 on behalf of

Dr. Daniel Tugendreich, Gynecology department - Belinson medical center, specialized in fallopian tube imaging and treatment

(assisted by Dr. Oz Gavish, Gynecology department - Belinson medical center).

Device expected to receive 510K clarification.

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