Minerva Surgical Requests Immediate Retraction of Misleading Int'l Journal of Women's Health Publication that Compares NovaSure to Minerva®, Sponsored by Hologic

FDA's Center for Devices and Radiological Health, Office of Compliance formally notified of materially misleading statements in publication

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REDWOOD CITY, Calif., April 26, 2018 /PRNewswire/ -- Minerva Surgical has filed a formal written complaint, and a request for immediate retraction, with Dove Medical Press, regarding a recent publication in their *International Journal of Women's Health, or the IJWH,* titled: *Efficacy and patient satisfaction after NovaSure and Minerva endometrial ablation for treating abnormal uterine bleeding: a retrospective comparative* study. Hologic, the study sponsor, and the Food and Drug Administration's (FDA) Center for Devices and Radiological Health, Office of Compliance, were also notified with a copy of the complaint.

The allegedly material misleading statements that violate the Committee of Publication Ethics (COPE) guidelines, which the *IJWH* states it follows during the peer review process, appear in the Study Criteria section of the publication as follows:

> " *We assumed that there would be fewer Minerva vs. NovaSure subjects in general across study sites because of its relatively new introduction. Therefore,* ***at each study site we enrolled all Minerva subjects*** *and an equivalent number of NovaSure subjects.*"

Minerva believes the statement that " *all Minerva subjects*" were enrolled is inaccurate, as only 92 Minerva patients were surveyed as part of the study, while Minerva has evidence that 256 patients were treated with the Minerva device at the four clinical sites during the study period, including 169 patients at the lead author's clinical site alone. Also troubling is Minerva's understanding, as the patient selection process. The same Hologic personnel had access to the patient charts (electronic medical records) at the clinics, and selected which Minerva patients and which NovaSure patients were enrolled in the study. This obviously biased patient selection process is not fully disclosed in the paper.

A second materially misleading statement is:

"No subject's post-procedure bleeding status was reviewed, queried, nor known at enrollment, in either study arm ."

This statement is suspect, as Minerva has obtained and provided to Dove Medical Press,Hologic and FDA. a copy of an earlier study manuscript draft that included the post-procedure bleeding status analysis. This manuscript draft was submitted to, and rejected by, the well-respected Journal of Minimally Invasive Gynecology and the Journal of Gynecologic Surgery. This analysis indicates that at the time of the early post-operative visit, that an average occurred 59 days after treatment, patients selected by Hologic for study participation exhibited the following early outcomes:

- NovaSure patients had a 31% higher Amenorrhea rate (zero bleeding) vs. Minerva.
- NovaSure patients had a 27% higher Success rate vs. Minerva.
- NovaSure patients had a 0% failure rate due to heavy bleeding vs. 7% for Minerva.

Because early post-procedure bleeding status is a strong indicator of longer term efficacy, this analysis was reported a reason for rejection of the manuscripts. Equally troubling is the fact that this analysis was subsequently deleted from the manuscript submitted to the *IJWH* and replaced with the above statement.

Hologic's access to the patient's early post-procedure bleeding status, when combined with the study sponsor's full control over the patient selection process, data collection, and analysis, resulted in a study population that was clearly biased in favor of the NovaSure arm of the study.

Minerva believes that failure to disclose the actual methodology of a study constitutes a clear violation of the COPE guidelines, hides potentially significant selection bias, and distorts any study conclusions.

According to David Clapper, President and CEO of Minerva:

" *We trust that Hologic will live up to its Code of Ethics published on their website that commits them to ethical conduct, to honesty, and to being truthful and upfront with customers and shareholders. We also trust that the International Journal of Women's Health will live up to its commitment to abide by the COPE guidelines. Minerva looks forward to the timely announcement that the Int'l Journal of Women's Health has retracted this publication.*"

Minerva and NovaSure Pivotal Study Information: The pivotal studies supporting FDA approvals of the Minerva System (7/28/15) an NovaSure system (9/28/01) were separate, randomized, prospective, multi-center clinical studies, in which the Minerva and NovaSure systems were compared to a control arm of the wire loop resection plus rollerball endometrial ablation (hysteroscopic endometrial ablation). The Minerva study arm reported 1-year success rate of 93% and 1-year amenorrhea rates of 72%, while the NovaSure study arm reported 1-year success rates of 77.7% and 1-year amenorrhea rates of 36%.

For more information on the Minerva procedure and full product labeling, visit www.MinervaSurgical.com

About Minerva Surgical: Minerva Surgical in an innovative medical technology company focused on improving women's health by developing treatments for excessive menstrual bleeding. Minerva and Minerva ES, and associated logos are trademarks and/or registered trademarks of Minerva Surgical in the United States and/or other countries. All other trademarks, registered trademarks, and product names are the property of their respective owners.

Important Safety Information: Minerva endometrial ablation is for premenopausal women with heavy periods due to benign causes who are finished childbearing. Pregnancy following the Minerva procedure can be dangerous. The Minerva procedure is not for those who have or suspect uterine cancer; have an active genital, urinary or pelvic infection; of an IUD. Minerva endometrial ablation is not a sterilization procedure. Rare but serious risks include, but are not limited to, thermal injury, perforation and infection. Temporary side effects may include cramping, nausea, vomiting, discharge and spotting. For detailed benefit and risk information please consult the IFU.