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## **Instead, Inc. Secures Approval to Launch Disposable Diaphragm in Russia**

***Russian Academy of Medical Sciences will prioritize clinical tests of Modified  
Instead® Softcup® and Amphora® for pregnancy and STD prevention***

**San Diego (August 25, 2003)** – Instead, Inc., today announced it has received approval from the Russian Academy of Medical Sciences to market a version of its Instead® Softcup® as an over-the-counter disposable contraceptive diaphragm in the Russian Federation beginning immediately.

Further, the Academy and Instead announced they will start clinical trials in September to test the efficacy of the modified Softcup and its patented microbicidal and spermicidal gel Amphora® in protecting women against pregnancy and sexually transmitted diseases and infections, including AIDS and HIV.

In June, Instead announced plans to market Amphora as a vaginal lubricant in the United States beginning in January 2004. The original Instead Softcup, a feminine hygiene product that collects, rather than absorbs, menstrual flow, is currently sold in more than 19,000 stores throughout the US, Canada and in seven European countries. Unlike tampons, the Softcup can be worn for up to 12 hours.

“The Russian Academy has evaluated the potential of new reproductive health technologies that can provide women with the ability to control pregnancy and prevent disease,” noted Vladimir I. Kulakov, the executive chief of the Academician Committee and Research Centre of Obstetrics, Gynecology and Perinatology at the Russian Academy of Medical Sciences.

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“After extensive review, the Academy has approved the Instead Softcup as a contraceptive diaphragm when used in connection with a spermicide. Further, based upon clinical tests that have been conducted on Amphora, the Academy has agreed to conduct additional clinical tests of Softcup containing Amphora for the prevention of sexually transmitted diseases, including AIDS, and unplanned pregnancies.”

He continued: “We have emphasized the importance and priority of these studies and directed our staff at the research centers to cooperate with and to render all necessary and appropriate assistance to our colleagues at Instead in order to support fully this important and worthwhile project.”

Professor Vera Prilepskaya, M.D., Chief of the Department of Pharmacology Committee at the Russian Ministry of Public Health will oversee the studies. Plans call for the trials to begin the first week of September, with results on the contraceptive properties of the product expected within six months after launch.

The Ministry of Public Health will conduct the studies in its medical clinics at multiple locations, so that data on a large number of subjects can be collected and managed efficiently.

Since 1995, Amphora has undergone a series of laboratory (*in vitro*) studies, animal studies and two Phase I clinical trials at multiple locations in the United States, Brazil and India with support from several foundations and government organizations.

The tests showed high spermicidal effectiveness in women even eight hours after application of the gel, which would allow the insertion of a Softcup/Amphora device hours before anticipated intercourse. Studies also confirmed the safety of Amphora in women when used consecutively for six days; and in animals for the prevention of the transmission of Gonococci, Herpes and Chlamydia.

“This is an exciting new step for our company,” said Instead CEO Joseph Pike. “We finally see the possibility of commercializing and bringing into the market a product that can give a woman total control over her reproductive health in a way that is actually beneficial to her health. Clinical studies have showed that Amphora maintains a woman’s natural pH balance while providing both spermicidal and microbicidal properties.”

Pike noted that surveys conducted by the European Commission’s AIDS project, the Guttmacher Institute and the University of Campinas in Brazil have estimated the

total market worldwide for a microbicidal product like the Instead Softcup with Amphora, exceeds \$10 billion, with the US market alone approaching \$900 million.

“This data would suggest that the Softcup as a delivery device with Amphora would be a favorable alternative to the condom.”

Additional testing on Amphora is expected to begin in Brazil, India and Africa during the next 12 months.

**About Acidform**

Acidform was developed by the Program for the Topical Prevention of Conception and Disease (TOPCAD) from Rush-Presbyterian-St. Luke’s Medical Center and the University of Illinois at Chicago. Development and testing of the product involved an international effort by individuals from the Contraceptive Research and Development (CONRAD) Program in Washington, DC; Eastern Virginia Medical School in Norfolk, VA; University of Campinas, Campinas, Brazil; the National Institute of Pharmaceutical Education and Research, Nagar, Punjab, India; Mount Sinai Medical Center in New York; Southern Illinois University in Springfield; Harvard Medical School; Santa Monica UCLA Medical Center; University of Texas at Galveston; the University of Texas Health Science Center in Houston; the Centers for Disease Control and Prevention (CDC) in Atlanta; the Uniformed Services University of the Health Sciences in Bethesda; The Milton Hershey Medical Center in Hershey, Pa.; and the Institute for Reproductive Health in Monterey, Calif. Financial support for the development of Amphora has been provided primarily by CONRAD and the Andrew W. Mellon Foundation.

**About Instead**

Instead, Inc. is dedicated to developing and marketing over-the-counter products that focus on women’s sexual health and quality of life. Instead is best known for the Instead® Softcup®, a feminine hygiene product that collects, rather than absorbs, menstrual flow. The Instead Softcup is sold at retail outlets nationwide, including Target and Walgreens, as well as select regional drug stores and groceries. In May 2003, Instead signed a national distribution agreement with Wal-Mart. The Instead Softcup is also sold online at [www.softcup.com](http://www.softcup.com). In addition to a new superior personal lubricant product called Amphora® containing the microbicide Acidform®, the company currently has under development a vaginal itch cream and several other products.

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