



The Population Council's biomedical research extends from reproductive biology and immunology to product development.

The Population Council has developed and licensed some of the most widely used, long-acting reversible contraceptives in the world today, including:

- **ParaGard®**, the Copper T 380A intrauterine device
- **Mirena®**, a levonorgestrel-releasing intrauterine system
- **Norplant®**, a six-rod levonorgestrel hormonal implant system
- **Jadelle®**, a two-rod levonorgestrel hormonal implant system



## ABOUT THE POPULATION COUNCIL

The Population Council, an international, nonprofit, nongovernmental organization established in 1952, seeks to improve the well-being and reproductive health of current and future generations around the world and to help achieve a humane, equitable, and sustainable balance between people and resources. The Council works in three programmatic areas: Reproductive Health; HIV & AIDS; and Poverty, Gender, & Youth.

## POPULATION COUNCIL LOCATIONS

### United States

New York, NY  
Headquarters  
Center for Biomedical  
Research  
Washington, DC

### Latin America and the Caribbean

La Paz, Bolivia  
Campinas, Brazil  
Guatemala City, Guatemala  
Mexico City, Mexico

### South and East Asia

Dhaka, Bangladesh  
New Delhi, India  
Bangkok, Thailand  
Hanoi, Vietnam

### Sub-Saharan Africa

Ouagadougou, Burkina Faso  
Accra, Ghana  
Nairobi, Kenya  
Bamako, Mali  
Dakar, Senegal  
Johannesburg, South Africa  
Lusaka, Zambia

### West Asia and North Africa

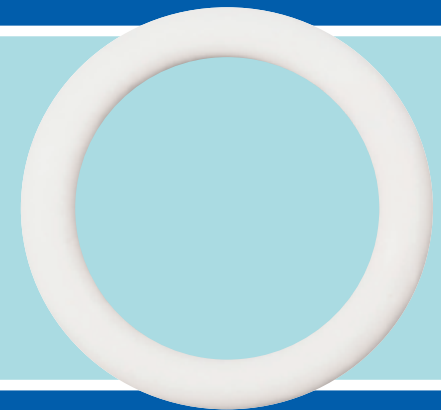
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# THE ONE-YEAR CONTRACEPTIVE RING

A TECHNOLOGY IN DEVELOPMENT



 Population Council

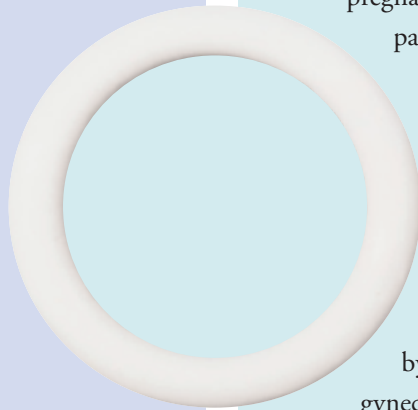
The Population Council has developed an innovative contraceptive vaginal ring made of silicone rubber and containing Nestorone<sup>®</sup>, a potent 19-nor progesterone derivative, and a low dose of ethinyl estradiol.

This new system provides one year (13 cycles) of easy-to-use, female-controlled contraception.

Data from Phase 1 and 2 trials demonstrate promising results for the ring's safety, efficacy, and ability to provide good bleeding control.

Nestorone is inactive when given orally, but highly active with other modes of delivery.

Nestorone's high potency in certain routes, such as vaginal delivery systems, implants, and transdermal preparations, makes it an excellent compound for use in long-term contraceptive delivery systems.



## PHASE 3 CLINICAL TRIAL

Given the promising results from Phases 1 and 2, the Population Council has launched a Phase 3 clinical trial of the Nestorone/ethinyl estradiol contraceptive vaginal ring.

**Efficacy** will be measured by the cumulative pregnancy rate among the 2200 study participants and the Pearl index after 1 year of use. The study will evaluate cycle control by tracking the number of bleeding/spotting days per cycle.

**Safety** of participants will be monitored carefully throughout the trial by regular health assessments, including gynecologic health and laboratory testing to measure renal and liver function and hematologic status. Data from these assessments will be compared to baseline information and used to identify the incidence of clinically significant results. Tracking and documentation of the frequency of adverse and serious adverse events will occur throughout the study. A Data Safety Monitoring Board will regularly review safety and efficacy data from the trial.



**Acceptability** of the new contraceptive vaginal ring, including the perceptions of the women's sexual partners, will be measured through interviews with participants in the Phase 3 study.

This Phase 3 trial is funded by the United States Agency for International Development, the National Institutes of Health (NIH), and the World Health Organization. There will be two studies, one of which will include the 12 US sites from the Contraceptive Clinical Trials Network of the National Institute of Child Health & Human Development of the NIH. The other study will comprise 10 sites—3 in Latin America, 3 in Europe, 1 in Australia, and 3 in the United States.

For information about licensing opportunities for the ring and other Council products, go to [www.popcouncil.org/licensing](http://www.popcouncil.org/licensing) or e-mail [licensing@popcouncil.org](mailto:licensing@popcouncil.org).

For more information about the Population Council, go to [www.popcouncil.org](http://www.popcouncil.org).