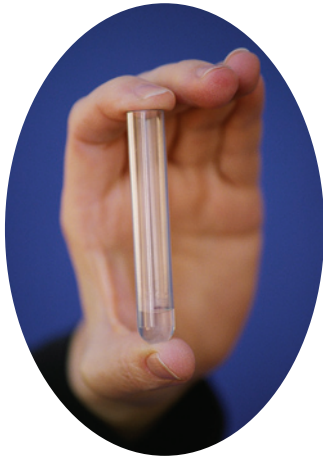
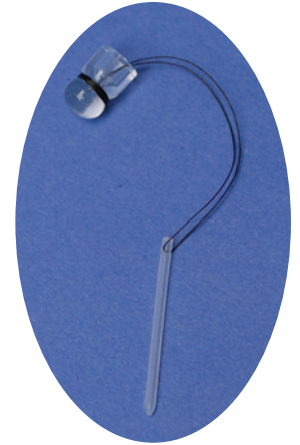


# New contraceptives for men in clinical trials

## Intra Vas Device (IVD)

- Implants in vas deferens block sperm, designed for easy removal
- Two designs in clinical trials are substantially different:
  - » Chinese design has completed Phase II trials; nylon mesh plug core lets vasal fluid pass through
  - » US design beginning Phase I trial; dual flexible silicone plugs
- FDA device regulations are less onerous than those for drugs, could be faster approval process



## RISUG

- Gel injected into the vas deferens, effective within days
- In Phase III clinical trials in multiple centers in India
- Developed by Indian university research group and ICMR
- Available within India in 5 years if manufacturing problems resolved; could be available to other countries if Phase III trials adhere to ICH GCP protocols

## Male Hormonal Contraceptive

- Various formulations under investigation:
  - » Schering & Organon have completed European Phase II trials of testosterone undecanoate depot injection + etonogestrel implant
  - » WHO & CONRAD in 10-country Phase II trials of testosterone undecanoate + norethisterone enanthate combined depot injection
- Surveys of trial participants show most find the method acceptable



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