

# FC2 Female Condom Update

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# The Basics: What are Female Condoms?

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**Female Health  
Company FC1 and FC2**



**PATH Woman's Condom**



**VA-Feminine  
Condom aka Reddy  
Female Condom**



# Why Female Condoms?

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- ❑ Available for use *now*
- ❑ Designed for women to initiate
- ❑ Expands prevention options for both men and women
- ❑ Dual protection against HIV and unwanted pregnancy
- ❑ Many potential benefits for HIV+ women
- ❑ Widespread acceptability
- ❑ Used for anal intercourse
- ❑ Prepares consumers, policy makers and distributors for future interventions such as microbicides

**Despite the benefits that female condoms offer, they are still not readily accessible in most countries**

# Challenges

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- ❑ Misunderstanding and misconceptions about product
- ❑ Cost
- ❑ Lack of comprehensive and effective programming
- ❑ Cultural and societal attitudes and behavior
- ❑ Political will

# FC2 Female Condom

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- ❑ Same design, appearance and use as FC1
- ❑ New material: nitrile (synthetic rubber)
- ❑ Can still be used with water and oil-based lubricants
- ❑ Less costly production process; lower cost to consumer



# International Status of FC2

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- ❑ WHO conducted safety and effectiveness review of FC2 and found it comparable to FC1
- ❑ Cleared for purchase by U.N. agencies; UNFPA already procuring FC2
- ❑ USAID only distributes FDA approved products; indicated will switch to FC2 pending approval

# FC2 Review at the FDA

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- ❑ Advisory committee hearing Dec 11, 2008
  - Panel of experts; rigorous review of evidence
  - Public comment – important role of advocates
- ❑ Committee voted unanimously to recommend FDA approve FC2 (15-0)
  - FDA usually follows committee's lead
- ❑ Timeline: FC2 approval likely, next 1-3 months

# FDA FC2 Approval: Implications for U.S.

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- ❑ Product re-launch likely
- ❑ FC2 “on the shelves” 1-2 months after approval
- ❑ Lower price for consumers
- ❑ Critical role of advocates
  - Awareness-raising & education
  - Advocacy
  - Pooled purchasing



# FDA FC2 Approval: International Implications

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- ❑ USAID indicated it will phase out procurement of FC1
- ❑ Lower costs means more FCs can be procured, distributed and programmed overseas

# What Advocates Can Do

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- ❑ Continued education and awareness-raising
- ❑ Media outreach; build favorable public climate
- ❑ Bring the FC2 to your community: contact us!
- ❑ Stay informed and take action

# Thank you!

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Visit [www.preventionnow.net](http://www.preventionnow.net) for  
female condom advocacy resources  
and to join the Prevention Now!  
Campaign

