In a First, the FDA Approves a Condom for Anal Sex

The FDA says three types of ONE brand condoms, which were launched in 2004, can now be marketed as “safe and effective” for anal sex.

February 23, 2022 By Trent Straube

Talk about extended foreplay. After four decades of the HIV epidemic and a push for safer sex, the Food and Drug Administration (FDA) has for the first time approved a condom for use during anal sex. This does not mean that a new condom has been created specifically for this use, but rather than an already existing condom can be marketed as reducing an individual’s risk for sexually transmitted infections (STIs) during anal sex.

The FDA today approved three types of ONE brand male condoms—standard, thin and myONE custom-fit condoms, which are available in 54 different sizes, according to a press release from ONE Condoms, part of Global Protection Corp. Launched in 2004, ONE Condoms can also be used during vaginal sex and as contraception.

> We’re so excited to be the first ever condom brand approved for anal! Clinically tested, booty approved. ????https://t.co/JI5AT6PAnO
>
> — ONE® Condoms (@ONECondoms) February 23, 2022

“Before today’s authorization, the FDA had not cleared or approved condoms specifically indicated for anal intercourse,” noted the FDA in its own press release. “Unprotected anal intercourse carries the greatest sexual exposure risk of HIV transmission. Consistent and correct condom use has the potential to significantly help decrease the risk of STIs.… It’s important to continue to use condoms consistently and correctly to reduce the risk of STI transmission, including HIV, and to prevent pregnancy.”

Previously, condoms could only be labeled as “safe and effective” when used for vaginal sex.

That's because, according to ONE Condoms, no data specific to anal sex had been provided to the FDA.

But a study led by Aaron Siegler, PhD, MHS, at the Rollins School of Public Health at Emory University, finally provided that data. Siegler's study found that ONE Condoms failed only 0.7% of the time during anal sex.

According to The New York Times, in order to receive approval from the FDA, condom makers had to show the prophylaxis had less than a 5% failure rate during anal sex, a threshold no brand had previously reached.

In August 2021, Global Protection Corp cited that data in a request to the FDA to expand its approved marketing to include anal sex.

"A critical finding of the study was that failure was low when condom-compatible lubricant was used, and the use of lubricant is part of the new FDA label indication," noted Siegler, adding that "programs providing condoms should also be providing lubricant."

> Did you know up until TODAY condoms weren't FDA approved for anal?? This is truly wild to me. https://t.co/YD90ZRAAJt
>
> — Matt Lesky (Taylor's Version) (@MattLesky) February 23, 2022

"I think most people would be surprised to know that condoms are not approved for anal sex," said Davin Wedel, president and founder of Global Protection Corp. "With this new designation from the FDA, people will have more confidence using condoms for anal sex."

"The risk of STI transmission during anal intercourse is significantly higher than during vaginal intercourse," said Courtney Lias, PhD, an FDA director, in the FDA press release. "The FDA's authorization of a condom that is specifically indicated, evaluated and labeled for anal intercourse may improve the likelihood of condom use during anal intercourse."

Lias, the director of the FDA's Office of GastroRenal, ObGyn, General Hospital, and Urology Devices in the Center for Devices and Radiological Health, added: "This authorization helps us accomplish our priority to advance health equity through the development of safe and effective products that meet the needs of diverse populations."

In related news, ONE Condoms also promotes the annual Measure a Penis Day.

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