

FDA approves first condom designed for anal sex

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The first condom specifically designed to prevent the transmission of

HIV and other sexually transmitted infections during anal sex has been approved for sale in the United States, the U.S. Food and Drug Administration says.

The One Male Condom can also be used to help reduce the risk of pregnancy and sexually transmitted infections (STIs) during vaginal intercourse.

When having anal sex, the FDA said the condom should be used with a condom-compatible lubricant.

"The risk of STI transmission during [anal intercourse](#) is significantly higher than during vaginal intercourse. 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," said Courtney Lias, of the FDA's Center for Devices and Radiological Health.

The condom is marketed by Global Protection Corp. It was assessed in a clinical trial that included 252 men who have sex with men and 252 men who have sex with women. All were between the ages of 18 to 54.

The rate of [condom failure](#) (slippage, breakage or both slippage and breakage) was 0.68% during anal intercourse and 1.89% during [vaginal intercourse](#).

The overall rate of adverse events was 1.92%. This included symptomatic STIs or recent STI diagnosis, condom or lubricant-related discomfort, partner discomfort with lubricant and partner [urinary tract infection](#), all occurring in less than 1% of participants.

The symptomatic STIs or recent STI diagnoses were self-reported by study participants, who weren't checked for STIs at the start of the study.

That means [sexually transmitted infections](#) may have occurred due to having intercourse without a condom or before participants started using the One Male Condom, according to the FDA.

The [condom](#) was approved through the De Novo premarket review pathway for low- to moderate-risk devices of a new type.

"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," Lias said in an agency news release.

More information: For more on sexually transmitted infections among gay men, see the [U.S. Centers for Disease Control and Prevention](#).

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