



Part of the Karex worldwide family of brands
WORLD'S LARGEST CONDOM MAKER

ONE® and MyONE® Custom Fit™ Are the First Condom Brands FDA Approved for Anal Sex

Global Protection Corp. is excited to announce that our brands ONE® and MyONE® Custom Fit™ have been approved by the U.S. FDA to label our condoms safe and effective for anal sex.

Summary:

- For the first time ever, the U.S. FDA has authorized a condom to be used for anal sex, not just vaginal sex.
- Condoms have only previously been approved by the FDA for vaginal use. This is because no company had brought data from a clinical trial to the FDA showing condoms are safe and effective for anal sex.
- The FDA authorization was granted based on a clinical trial conducted by the Rollins School of Public Health at Emory University in partnership with Global Protection Corp. **The study found ONE® and MyONE® Custom Fit™ condoms used during anal sex failed less than 1% of the time.** This was the largest clinical trial of effectiveness of condoms for anal sex ever conducted, with participants split evenly between men who have sex with men (MSM) and men who have sex with women (MSW). The study was published in Lancet's EClinicalMedicine in 2019¹.
- The FDA had previously said that condoms needed to have less than a 5% failure rate for vaginal sex. The only previously existing studies of condoms for anal sex (using other brands) had shown failure rates higher than that (6-7% failure rates). Those studies had their limitations, such as not requiring condom compatible lubricant to be used.
- Global Protection Corp. used the data from the Emory University study to submit a De Novo Request to the FDA to expand the intended use

¹ Siegler AJ, Rosenthal EM, Sullivan PS, et al. Levels of clinical condom failure for anal sex: A randomized cross-over trial. EClinicalMedicine. 2019;17:100199. Published 2019 Oct 31. doi:10.1016/j.eclinm.2019.10.012

ONE®



TRUSTEX®

ATLAS

NuVo™
CONDOMS

Night Light

SATIN
CONDOMS

fantasy
brand latex condoms

claim of ONE® and MyONE® Custom Fit™ Condoms to include anal sex. On February 23rd, 2022, FDA accepted this request.

- The condoms that were tested in the clinical trial were our thin, classic and custom fit styles. That means the styles that will have the new anal use indication are our Vanish®, Super Sensitive™, Classic Select™ (distributed through our public health channel), and MyONE® Custom Fit™ condoms. As of February 2022, the FDA approved these condoms as the first brands ever to be labeled safe and effective for anal sex.
- This process has taken approximately **10 years**.
- This recognition from the FDA highlights the substantial protection our condoms provide for anal sex, which we hope enhances trust, leads to increased condom and lubricant use, and reduces the new cases of sexually transmitted infections.

Important for Public Health:

- The FDA anal use indication allows educators to have conversations about safer sex practices in a new way, and provides people confidence on the effectiveness of condoms for anal sex. In the clinical trial, condoms used during anal sex failed less than 1% of the time (0.7%).
- A previous study led by faculty at Emory University found **69% of MSM reported they would be more likely to use condoms more frequently if the condoms were FDA label-indicated for anal sex²**.
- In the Emory University clinical trial¹, **condom failure was lower for anal sex than for vaginal sex**. The researchers hypothesized this difference was driven by the much higher use of lubricant for acts of anal sex (98.3%) compared with vaginal sex acts (41.6%) due to study design. **When the researchers controlled for the use of lubricant, they found no difference in condom failure for anal sex versus vaginal sex**. This highlights the importance of using lubricant with condoms to prevent condom failure.

² Siegler AJ, Ahlschlager L, Rosenthal EM, Cecil MP, Kelley CF, Rosenberg ES, et al. Utility of a US Food and Drug Administration (FDA) label indication for condoms for anal sex. Sex Health 2019



Frequently Asked Questions:

Is this a new product?

- We did not create a new product that is specifically designed for anal use. All ONE® and MyONE® Custom Fit™ products tested in the clinical trial and that now have the new FDA anal use indication are existing products.

Which products are FDA approved for anal use?

- The condoms that were tested in the clinical trial were our thin, classic and custom fit styles. These are our Vanish®, Super Sensitive™, Classic Select™ (distributed through our public health channel), and MyONE® Custom Fit™ condoms. MyONE® is a hyperthin condom, includes more than 50 sizes, and we offer sample kits to test out on the myonecondoms.com website.

Will other ONE® Condom styles get the anal use indication?

- All ONE® Condoms follow the same quality requirements as mandated by standards organizations and the FDA. We'll be researching how we can expand the new anal use indication to additional condom styles in the future.

Are these condoms only for anal use?

- Our condoms are for both vaginal and anal use. Condoms were historically approved only for vaginal use.

How will the packaging change?

- The language on the consumer packaging will change to:
When used correctly every time you have sex, these lubricated latex condoms are intended for anal or vaginal sex to prevent HIV/AIDS and other sexually transmitted infections and to prevent pregnancy. An adequate amount of condom compatible lubricant should be used during anal sex to help reduce the risk of condom failure.

Is there a latex free version of the ONE® FDA approved condoms?

- Unfortunately, we do not make a latex-free version of ONE® Condoms at this time.



Why did the FDA call your brand “One Male Condom”?

- The FDA press release wrote “One Male Condom,” when in reality our brand name is ONE® Condoms. This caused some confusion since most press reports listed our name incorrectly. As a company, we always use the term “external condom” rather than “male condom” to be inclusive.

Why is ONE® approved for anal use and other brands are not?

- Our ONE® and MyONE® Custom Fit™ condoms went through a clinical trial that showed our condoms are safe and effective for anal sex. They are also safe and effective for vaginal use.
- Other brands will need to do a clinical trial and submit that safety and effectiveness data to the FDA in order to also list their products are safe and effective for anal sex.
- There are differences in formulations and manufacturing methods for different condom brands. However, all condoms are classified as a medical device under the FDA, and must meet strict regulatory and testing standards.

For more information:

Contact:

Milla Impola, Director of Marketing and Communications,
Global Protection Corp. |
mimpola@globalprotection.com | 617-946-2800

Visit: globalprotection.com | onecondoms.com | myonecondoms.com