

Information Regarding Johnson & Johnson COVID-19 Pause

In accordance with guidance from the United States Food and Drug Administration (FDA) and Virginia Department of Health (VDH), Inova has paused administration of the Johnson & Johnson (J&J) COVID-19 vaccine at our Inova Primary Care locations as we await further guidance from the FDA and VDH.

According to the FDA, adverse side effects from this vaccine are very rare. If you received the J&J vaccine, there is nothing you need to do at this time. People who have received the J&J vaccine who develop severe headache, abdominal pain, leg pain, or shortness of breath within three weeks after vaccination should contact their health care provider.

The Inova Stonebridge Vaccination Center, the Inova Vaccine Center at the Inova Center for Personalized Health, and team member vaccine sites have always administered the Pfizer-BioNTech vaccine and will continue to do so. If you are scheduled to receive the J&J vaccine from an Inova Primary Care clinic, we will contact you to cancel that appointment and reschedule you to receive the Moderna vaccine.

This is a fluid situation and we expect more information to come from the FDA in the coming days. Inova's Research Committee will continue to monitor and review any new guidance from the FDA and VDH and update our position accordingly.

CDC Information about J&J Vaccine Pause

What should I do if I experience symptoms?

According to the CDC:

- If you got this vaccine more than three weeks ago, your risk of developing a blood clot is very low.
- If you got this vaccine within the last three weeks, your risk of developing a blood clot is also very low. However, you should contact your healthcare provider if you experience symptoms of a blood clot such as:
 - Severe headache
 - o Blurred vision
 - Fainting
 - Seizures
 - Pain in your abdomen (chest or stomach)
 - Leg pain or swelling
 - o Shortness of breath

Will this decision impact my appointment at the Inova Stonebridge COVID-19 Vaccination Center or the Inova COVID-19 Vaccine Center at the Inova Center for Personalized Health (ICPH)? No, your appointment at these locations will not be impacted. Inova is only administering the Pfizer-BiNTech COVID-19 vaccine at these two locations.

Should I cancel my appointment for the J&J vaccine

If you are scheduled to get the J&J/Janssen COVID-19 Vaccine at an Inova Primary Care Clinic, you will be contacted to reschedule an appointment to receive the Moderna vaccine.

What does a "pause" mean?*

On April 13, 2021, the <u>CDC and the US Food and Drug Administration (FDA) recommended a pause</u> in the use of Johnson & Johnson's Janssen (J&J/Janssen) COVID-19 Vaccine. Although the J&J vaccine is still authorized for use, the CDC and FDA recommend this vaccine not be given to anyone until we know more. This gives scientists a chance to review the data and decide if recommendations on who should get the vaccine need to change. The CDC and FDA will share more information as soon as possible with healthcare providers, people who got the vaccine, and the public.

What do I need to know about the possible safety issue?

The CDC explains that "scientists and doctors always look carefully at all reported side effects." Of the more nearly seven million people who received the J&J vaccine, a very small number experienced a rare and severe type of blood clot. The reported cases were all found in women between the ages of 18 and 48, and developed up to two weeks after vaccination.

Has this issue been seen in any other COVID-19 vaccines?*

No. According to the FDA, no cases of the blood clot issue have been reported among the 180 million people who received the Pfizer-BioNTech or Moderna COVID-19 vaccines.

Are COVID-19 vaccines safe?

Yes. COVID-19 vaccine safety is a top priority for Inova, the CDC and the FDA and all vaccines available in the U.S. were appropriately tested and investigated before receiving Emergency Use Authorization. The CDC states that "COVID-19 vaccines have undergone and will continue to undergo the most intensive safety monitoring in U.S. history." Learn more about how vaccine safety systems work.