



Bladder Support

Indications for Use: The YoniFit® Bladder Support is intended for the temporary management of urine leakage caused by stress urinary incontinence (SUI) in women, 18 years and older.

Provider Instructions

Determining the right size:

- 1. YoniFit comes with** diameters ranging from 34mm to 52mm. See details below:

Size 1: 34 mm diameter **Size 2:** 38 mm diameter

Size 3: 42 mm diameter **Size 3.5:** 45 mm diameter

Size 4: 48 mm diameter **Size 5:** 52 mm diameter

- 2. The diameter should be based from your measurement of the mid-vagina.** The goal is to measure the widest point where the top of the YoniFit will sit and put gentle pressure on the urethra. There are two ways to perform the measurement, either:

A. Horizontal width measurement:

Place two fingers in the vagina and estimate the width of the vagina halfway between the urethra and cervix.

B. Vertical measurement vertical length measurement:

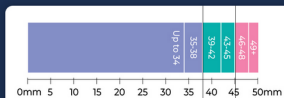
Place two fingers in the vagina at the level of the posterior fornix and estimate the length between the pubic notch and the posterior fornix.

- 3. Place two fingers on the measurement chart to determine the correct size and discard it after use. →**

- 4. At the follow-up visit,** if the patient reports discomfort, the sizing may not be appropriate and another fit kit with different sizes may be needed.



All measurements are in millimeters



Place two fingers with the estimated width of the mid-vagina on the chart above to determine the correct YoniFit size.



Scan Here
For the complete
Instructions For Use

yonifit.com

See reverse side of this page for Important Safety Information →

SUI affects about 2 in 3 women worldwide.



Dignity comes in many sizes
(6 of them, to be exact).



**Leaking urine negatively
impacts emotional well-being,
and symptoms may get worse
over time if left untreated.**

Indication and Important Safety Information

Indications for Use: The Yoni.Fit® Bladder Support is intended for the temporary management of urine leakage caused by stress urinary incontinence (SUI) in women, 18 years and older.

Contraindications: Do not use Yoni.Fit® if you leak urine due to a sudden urge to pass urine or not being able to make it to the toilet on time (also known as Urge Urinary Incontinence). **Do not use Yoni.Fit® if:** You are younger than 18 years old, You have an allergy to silicone health products, You are pregnant or think you might be pregnant, You gave birth in the recent past and have not been cleared by your doctor for sexual activity, use of tampons or placing any medical devices in the vagina, You have signs or symptoms of a urinary tract infection (UTI), such as pain or burning when you pass urine. You have signs or symptoms of a vaginal infection or sexually transmitted disease (STD), such as: Discharge that is not normal or smells bad, Pelvic pain, Vaginal soreness, Irritation, itching or discomfort, Bleeding not caused by your period, Pain when you pass urine. **Warnings:** Keep out of reach of children and pets. **Do not use Yoni.Fit®** if any part looks damaged, cloudy or has changed color. **Do not share your Yoni.Fit®** with others, even if the device is new or has been cleaned. You may give other people a severe infection or get a severe infection from them. **Do not use Yoni.Fit®** for more than 12 hours at a time within a 24-hour period. **Do not use Yoni.Fit®** for more than 30 days. Long-term safety of Yoni.Fit® has not been evaluated beyond 30 days. Doctors should not renew the prescription beyond 30 days for a patient. **Do not use Yoni.Fit®** during your monthly menstruation cycle. **Do not use intravaginal devices, Yoni.Fit®,** if you have been previously diagnosed with Toxic Shock Syndrome. **Do not use Yoni.Fit®** if you feel any type of pelvic pain. **Stop using Yoni.Fit®** if you see a change in color or consistency of vaginal discharge. **Stop using Yoni.Fit®** if you see an increase in the amount of vaginal discharge. **Stop using Yoni.Fit®** if you start to have vaginal irritation, soreness, or itching (this could be a sign of vaginal infection). **Stop using Yoni.Fit®** if you feel unusual or unexpected vaginal bleeding or blood spots. **Stop using Yoni.Fit®** if you start to have a new urinary incontinence that you did not experience before using Yoni.Fit®. **Remove Yoni.Fit® immediately** if you think you have Toxic Shock Syndrome (TSS) and contact your doctor or go to the emergency room at the closest hospital right away. Symptoms of TSS are a fever of 102°F (39°C) and one or more of these symptoms: Diarrhea, Vomiting, Sore throat, Red eyes, Weak, dizzy, or fainting, Muscle or joint aches, Rash. **Remove Yoni.Fit® immediately** if: You cannot pass urine, You have not passed urine for 6 hours, or You need to pass stool but cannot do so. This means the device size is too large. **Remove Yoni.Fit®** and try the next smallest size. If you cannot remove Yoni.Fit®, see your doctor right away. **Postmenopausal patients** (women who have been without a menstrual period for 12 months or more) in the clinical study were noted to have more adverse events, such as vaginal bleeding, than premenopausal patients. Postmenopausal patients should have appropriate follow up with their healthcare provider two weeks after fitting and initiation of use of the Yoni.Fit® Bladder Support. **Precautions:** Prior to using Yoni.Fit®, carefully read and understand all instructions in the Instructions for Use [this document]. Ask your doctor before using Yoni.Fit® if: You have had vaginal or pelvic floor surgeries, You have pain with sex, Yoni.Fit® is not a method of birth control and does not prevent sexually transmitted diseases (STDs). During routine use, there are times when you should remove or not insert Yoni.Fit®. Do not use Yoni.Fit® when you: Use a tampon, Have sex, or Are pregnant or think you might be pregnant. Yoni.Fit® and its storage case must be cleaned before and after use according to the cleaning instructions in this document. Refer to the section entitled, "Cleaning Yoni.Fit®" for cleaning instructions. **Complications:** The manufacturer has conducted a thorough assessment of potential risks and provided mitigations, where possible. However, you may experience one or more complications associated with the use of this device. Based on the risk assessment, literature, and the clinical study of the Yoni.Fit® device, the following potential complications exist: Increased vaginal discharge and odor, Unexpected vaginal bleeding, Pelvic or vaginal pain or discomfort, Vaginal bruising, Vaginal itching, Vulvovaginal dryness, New onset of difficulty in urinating, Spontaneous expulsion of the device from the vagina, Vaginal infection, Vaginal erosion, **Toxic Shock Syndrome (TSS).** Symptoms of TSS include a fever (102°F or 39°C) and one or more of the following: diarrhea, vomiting, sore throat, red eyes, weakness, dizziness, fainting, muscle aches, joint aches, or a rash. However, an association with use of Yoni.Fit® Bladder Supports and TSS has not been established in the clinical study of Yoni.Fit®, described in the next section, adverse events observed were mild or moderate. Post-menopausal women were more likely to experience adverse events, such as vaginal bleeding.