

# Indication and Important Safety Information

**Indications for Use:** The Yōni.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 Yōni.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 Yōni.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 Yōni.Fit® if any part looks damaged, cloudy or has changed color. **Do not** share your Yōni.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 Yōni.Fit® for more than 12 hours at a time within a 24-hour period. **Do not** use Yōni.Fit® for more than 30 days. Long-term safety of Yōni.Fit® has not been evaluated beyond 30 days. Doctors should not renew the prescription beyond 30 days for a patient. **Do not** use Yōni.Fit® during your monthly menstruation cycle. **Do not** use intravaginal devices, Yōni.Fit®, if you have been previously diagnosed with Toxic Shock Syndrome. **Do not** use Yōni.Fit® if you feel any type of pelvic pain. **Stop using** Yōni.Fit® if you see a change in color or consistency of vaginal discharge. **Stop using** Yōni.Fit® if you see an increase in the amount of vaginal discharge. **Stop using** Yōni.Fit® if you start to have vaginal irritation, soreness, or itching (this could be a sign of vaginal infection). **Stop using** Yōni.Fit® if you feel unusual or unexpected vaginal bleeding or blood spots. **Stop using** Yōni.Fit® if you start to have a new urinary incontinence that you did not experience before using Yōni.Fit®. **Remove** Yōni.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** Yōni.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** Yōni.Fit® and try the next smallest size. If you cannot remove Yōni.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 Yōni.Fit® Bladder Support. **Precautions:** Prior to using Yōni.Fit®, carefully read and understand all instructions in the Instructions for Use (this document). Ask your doctor before using Yōni.Fit® if: You have had vaginal or pelvic floor surgeries, You have pain with sex. Yōni.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 Yōni.Fit®. Do not use Yōni.Fit® when you: Use a tampon, Have sex, or Are pregnant or think you might be pregnant. Yōni.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 Yōni.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 Yōni.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 Yōni.Fit® Bladder Supports and TSS has not been established. In the clinical study of Yōni.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

