



WATKINS-CONTI
PRODUCTS INCORPORATED



Instructions For Use

This Instructions for Use contains information on how to use Yōni.Fit®. Physicians should review the document with their patients. Patients should read this document carefully before using the device for the first time and save it for future reference.

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Caution: Federal law restricts this device to sale by or on the order of a physician.

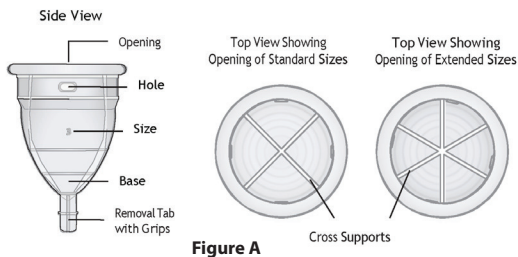
Purpose of the Device (Indications for Use)

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

Device Description

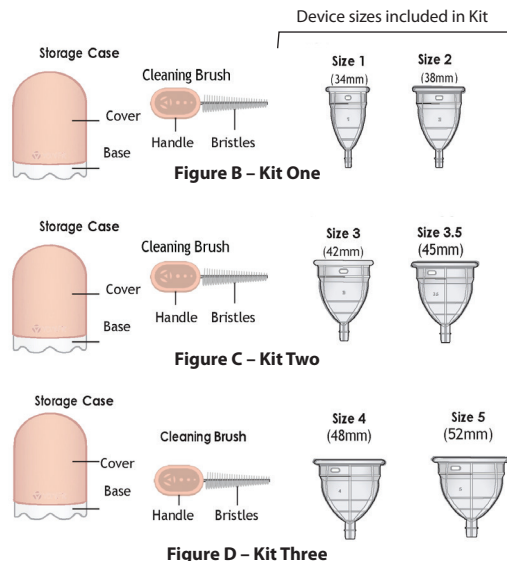
The Yöni.Fit® Bladder Support is a prescription-use vaginal pessary that is available in each of the following sizes: Standard Sizes: 34mm (Size 1), 38mm (Size 2), 42mm (Size 3), 45mm (Size 3.5) and Extended Sizes: 48mm (Size 4), and 52mm (Size 5). Three package configurations are available, each with two sizes, to allow for selection of the appropriate size. The Yöni.Fit® is provided non-sterile and must be cleaned before use (See the section entitled, "Cleaning Yöni.Fit®").

Figure A identifies various features on the Yöni.Fit® Bladder Support.



Contents of the Yöni.Fit® Sizing Kit

Each Yöni.Fit® Sizing Kit contains a storage case (cover and base), cleaning brush, and two device sizes. Each kit includes two sizes with different diameters. Kit One – Size 1 (34mm) and Size 2 (38mm); Kit Two – Size 3 (42mm) and Size 3.5 (45mm); and Kit Three – Size 4 (48mm) and Size 5 (52mm) (Figures B, C, and D). Contact your doctor if you need a size not included in your Sizing Kit.



When the Device Should not be Used (Contraindications)

- **Do not** use Yöni.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 Yöni.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 Yöni.Fit® if any part looks damaged, cloudy or has changed color.
- **Do not** share your Yöni.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 Yöni.Fit® for more than 12 hours at a time within a 24-hour period.
- **Do not** use Yöni.Fit® for more than 30 days. Long-term safety of Yöni.Fit® has not been evaluated beyond 30 days. Doctors should not renew the prescription beyond 30 days for a patient.

- **Do not** use Yöni.Fit® during your monthly menstruation cycle.
- **Do not** use intravaginal devices, Yöni.Fit®, if you have been previously diagnosed with Toxic Shock Syndrome.
- **Do not** use Yöni.Fit® if you feel any type of pelvic pain.
- **Stop using** Yöni.Fit® if you see a change in color or consistency of vaginal discharge.
- **Stop using** Yöni.Fit® if you see an increase in the amount of vaginal discharge.
- **Stop using** Yöni.Fit® if you start to have vaginal irritation, soreness, or itching (this could be a sign of vaginal infection).
- **Stop using** Yöni.Fit® if you feel unusual or unexpected vaginal bleeding or blood spots.
- **Stop using** Yöni.Fit® if you start to have a new urinary incontinence that you did not experience before using Yöni.Fit®.
- **Remove** Yöni.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** Yöni.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 Yöni.Fit® and try the next smallest size. If you cannot remove Yöni.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.

Potential Adverse Events (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.

Yōni.Fit® Clinical Study

Watkins-Conti Products, Inc., conducted a clinical study of the Yōni.Fit® bladder support device.¹

Clinical study participants were randomly assigned to use either the Yōni.Fit®, or a device similar to a ring pessary (control device). After a brief training, participants determined the appropriate size of the device and wore it 12 hours per day. Participants wore incontinence pads to measure any potential leakage, recorded urination in diaries, and provided responses to questionnaires. At the beginning of the study (baseline, 1 week post-randomization with no device), after fitting (1 week after baseline), and after 1 week of use (efficacy evaluation), 12-hour pad weights were measured and urination diaries and participant questionnaires were collected. The primary effectiveness endpoint was a responder rate. Responders were defined as participants who experienced a reduction in their average 12-hour pad weights of more than half (> 50% reduction in average 12-hour pad weights) during the efficacy evaluation period compared to the baseline period. The

¹ Randomized, Comparator-controlled, Single Blinded, Multi-center Study Evaluating the Efficacy and Safety of the Yōni.Fit® in Women with Stress Urinary Incontinence (SUI).

primary safety endpoint was to report the percentage of participants experiencing an adverse event (or complication) and description of the adverse events.

A total of 58 participants (31 Yöni.Fit® and 27 control) were enrolled and randomly assigned to the Yöni.Fit® device group or the control device group between January of 2020 and August of 2022. There were four (2 Yöni.Fit®, 2 control) participants who had completely missing data for the efficacy evaluation phase. Participants with completely missing data for the efficacy evaluation phase were considered non-responders in the analyses and assumed to have less than a 50% reduction in their average 12-hour pad weights during the efficacy evaluation phase.

Effectiveness Results

A significantly higher percentage of participants experiencing more than a 50% reduction in their average 12-hour pad weights was observed with the Yöni.Fit® device compared to the control device. Of the participants randomly assigned to use the Yöni.Fit®, 51.6% had a more than 50% reduction in 12-hour pad weight compared to 25.9% in the control group. The two-sided 95% confidence interval for the difference in the percentage of participants experiencing more than a 50% reduction in 12-hour pad weights between the control groups was 0.0235 to 0.504.

Safety Results

Adverse events collected during the clinical study for both Yöni.Fit® and Control groups are summarized in Table 1, below. All events were considered mild or moderate in severity. Postmenopausal women (women who have been without a menstrual period for 12 months or more) were more likely to experience adverse events such as vaginal bleeding.

Table 1:

Adverse events reported by all participants during fitting and efficacy evaluation period

Event	Number (%) of Participants with Event	
	Yöni.Fit® (n=31)	Control (n=27)
Any treatment-emergent adverse event	17 (54.8%)	8 (29.6%)
Vaginal bleeding	8 (25.8%)	1 (3.7%)
Vaginal bruising	1 (3.2%)	0 (0%)
Vaginal discharge	1 (3.2%)	0 (0%)
Vaginal discomfort	9 (29.0%)	5 (18.5%)
Vaginal itching	2 (6.5%)	1 (3.7%)
Vaginal pain	6 (19.4%)	2 (7.4%)
Vaginal yeast infection	2 (6.5%)	0 (0%)
Vulvovaginal dryness	1 (3.2%)	0 (0%)
Other	6 (19.4%)	3 (11.1%)

The clinical study results confirm that the Yöni.Fit® Bladder Support device is safe and effective for its intended use.

Finding the Right Size for You

Yōni.Fit® comes in multiple sizes. Choosing the right size is key to making sure Yōni.Fit® works well for you.

1. Select the smallest size Yōni.Fit® from the box. Follow the cleaning instructions in the section entitled, “Cleaning Yōni.Fit®.”
2. Follow the insertion instructions (“Step 2: Preparing to Insert Yōni.Fit®”). Wear it for a few hours during normal daily routines.
3. Is the size right for you?

The size is right for you if:

- It is comfortable to wear.
- You can partake in normal routines without leaking urine.
- The device stays in place.

Try the next larger size if:

- You still leak.
- The device falls out or moves down to the vaginal opening.
- The tab of the device feels uncomfortable.

Try the next smaller size if:

- You have problems passing urine or having a bowel movement.
- The device is difficult to insert or remove.
- You have vaginal pain or bleeding.
- The device extends outside of the vaginal opening.

Contact your doctor if you need a larger size than those in the Sizing Kit.

Once you find the size that works best for you, use that size, and throw away the others.

Storing Yōni.Fit®

Store Yōni.Fit® in a clean dry place or use the optional Storage Case (Figure E).

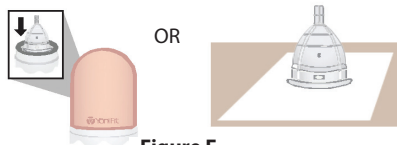


Figure E

Step 1: Cleaning Yōni.Fit®

Important:

The Yōni.Fit® and Storage Case are non-sterile. Thoroughly clean your Yōni.Fit® and Storage Case before you use them for the first time, and after every use.

Cleaning your Yōni.Fit® and Storage Case removes contaminants, which is important for them to be used safely. Failure to clean the Yōni.Fit® and Storage Case, using improper cleaning solutions, or not following the described cleaning methods may result in injury to the vagina, including a risk of infection.

1.1

Gather your supplies:

- Yōni.Fit® device
- Mild, scent free, oil-free soap. Refer to soap labeling for warnings and precautions.
- Yōni.Fit® cleaning brush
- Yōni.Fit® storage case

1.2

Wash your hands using warm water and a mild, scent free, oil-free soap (Figure F).

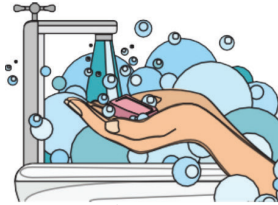


Figure F

1.3

Rinse the inside and outside of your Yōni.Fit® and Storage Case with warm water (Figure G).

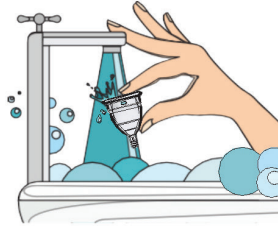


Figure G

1.4

Rinse the Cleaning Brush with warm water, and apply a small amount of mild, scent free, oil-free liquid soap (Figure H).

Do not use any of these products to clean your Yōni.Fit®:

- Scented/fragranced soap
- Oil-based soap
- Antibacterial soap
- Dishwashing soap
- Rubbing alcohol
- Vinegar
- Baking soda
- Hydrogen peroxide
- Bleach
- Household cleaning products
- Boiling water

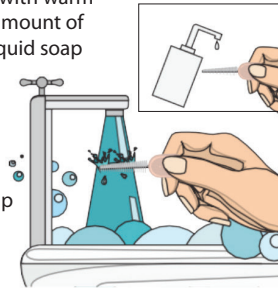


Figure H

1.5

Thoroughly clean the device by gently scrubbing the inside and outside of the Yōni.Fit® with the soapy Cleaning Brush, giving attention to these areas:

- The inside of all openings between the cross supports and the bottom inside of the cup (Figure I),
- The outside surface and the removal tab (Figure J), and
- All holes on the sides (Figure K).

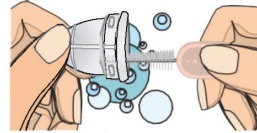


Figure I
Clean Inside

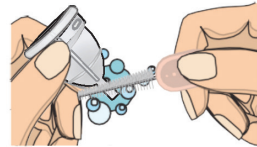


Figure J
Clean Removal Tab
and Outside



Figure K
Clean All Holes

Thoroughly clean the Storage Case by gently scrubbing the inside and outside of the Storage Case with the soapy Cleaning Brush.

1.6

Rinse the Cleaning Brush with warm water to remove all soap and any foreign substance (Figure L).

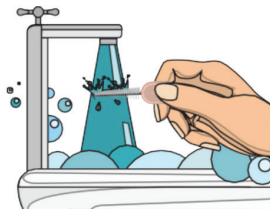


Figure L

1.7

Rinse the inside and outside of the Yōni.Fit® and Storage Case with warm water to make sure all soap and material are removed (Figure M).

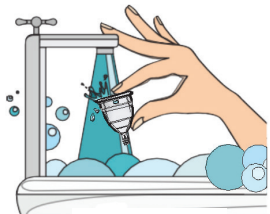


Figure M

1.8

Check your Yōni.Fit® and Storage Case. They should look clean and free of soap or other residue (Figure N).

Do not use or store Yōni.Fit® or Storage Case if they do not appear clean and free of soap or other residue. If needed, repeat the cleaning Steps 1.1 – 1.8.

Check that your Yōni.Fit® and Storage Case is clean and free of soap

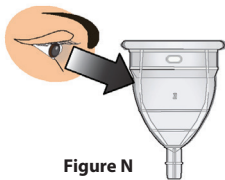


Figure N

1.9

Allow your Yōni.Fit® to dry in a clean, dry place or use the optional Storage Case (Figure E).

Let the Cleaning Brush air-dry before storing in a clean, dry place (Figure O).

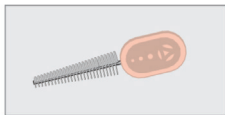


Figure O

What's Next?

- **If you are ready to insert your Yōni.Fit®**, continue to Step 2, Preparing to Insert Yōni.Fit®.
- **If you are not ready to insert your Yōni.Fit®** refer to the Storing Yōni.Fit® section for information on how to store it.

Step 2: Preparing to Insert Yōni.Fit®

2.1

Wash your hands using warm water and a mild, scent free, oil-free soap (Figure F).

Check your clean Yōni.Fit® for damage or change in color (Figure P). It should look smooth and clear, with no signs of damage such as

- Tears
- Roughness
- Change color
- Odor
- Sticky or powdery film

Do not use Yōni.Fit® if it is damaged or changed in color. Throw away in household trash.

Check for Damage and Discoloration

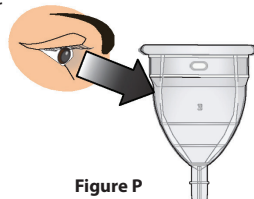


Figure P

Step 3: Inserting Yōni.Fit®

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,
- Are pregnant or think you might be pregnant, or
- Have vaginal or pelvic floor surgery. Ask your doctor when you can start using Yōni.Fit® again after surgery.

3.1

Get into a comfortable position and relax your vaginal muscles. You can:

- Stand,
- Sit on the toilet,
- Squat, or
- Lie down.

Note: Squatting may be easiest until you find the position that works best for you. If you are unable to squat, lying down may be the easiest position.

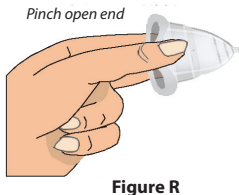
3.2

Hold the open end of Yōni.Fit® with your thumb and fingers (Figure Q).



3.3

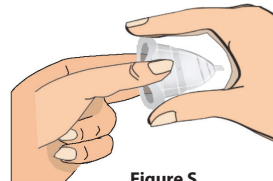
Pinch the center of the open end of Yōni.Fit® closed (Figure R).



3.4

Grasp the long sides of Yōni.Fit® with your other hand (Figure S).

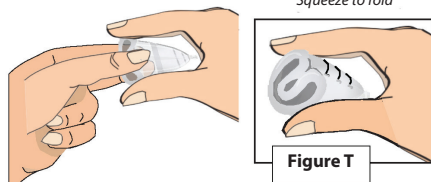
Grasp long sides with other hand



3.5

Holding the open end closed, fold Yōni.Fit® lengthwise (Figure T).

Squeeze to fold



3.6

Hold the folded Yōni.Fit® in your dominant hand (Figure U).

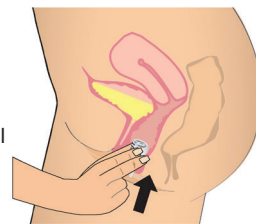
Apply water-based lubricant to folded open end, if needed.

Tip: If vaginal dryness makes it difficult or painful to insert Yōni.Fit®, apply a small amount of water-based lubricant to the folded open end.



3.7

Insert Yōni.Fit® into your vagina by pushing the folded end into the vaginal opening at an angle that is easy for you (Figure V).



3.8

Continue pushing Yōni.Fit® into the vagina with your fingers until the removal tab is just inside the vaginal opening (Figure W).

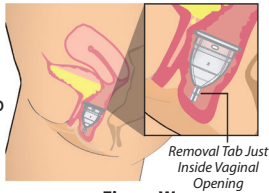


Figure W

Yōni.Fit® will unfold as you continue pushing it into the vagina.

Do not push the removal tab too far inside the vaginal opening. Inserting Yōni.Fit® too far may make it difficult to remove.

3.9

Once Yōni.Fit® is inserted, use the removal tab to rotate or adjust Yōni.Fit® until it is comfortable (Figure X).

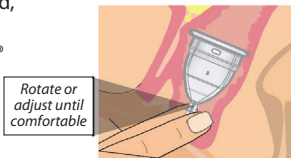


Figure X

Note: It is normal to experience some mild discomfort or light spotting of blood in the first week, while you determine the right size for you.

Warning:

Remove Yōni.Fit® right away if:

- You cannot pass urine,
- You have not passed urine for 6 hours, or
- You cannot have a bowel movement for 8 hours.

This means the Yōni.Fit® size may be too large. Remove Yōni.Fit® and try the next smallest size. If you cannot remove Yōni.Fit®, call your doctor right away.

Step 4: Removing Yōni.Fit® After 12 Hours

Remove Yōni.Fit® after 12 hours of use.

4.1

Wash your hands using warm water and a mild, scent free, oil-free soap (Figure Y).

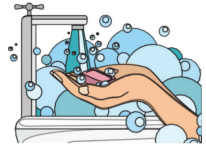


Figure Y

4.2

Get into a comfortable position and relax your vaginal muscles.

You can:

- Stand,
- Sit on the toilet,
- Squat, or
- Lie down.

Note: Squatting may be easiest until you find the position that works best for you. If you are unable to squat, lying down may be the easiest position.

4.3

Grip and gently pull the removal tab until you get a hold of the base (area just above the removal tab) (Figure Z).

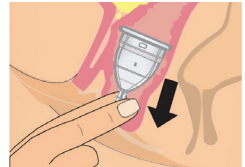


Figure Z

If needed, contract your abdominal muscles (like you would for a bowel movement) to help push the Yōni.Fit® towards your fingers.

4.4

Adjust fingers to squeeze the base and continue pulling until Yōni.Fit® is fully removed (Figure AA).

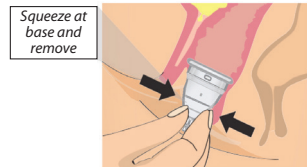


Figure AA

Troubleshooting

If Yöni.Fit® is difficult to remove, try the following:

- Extend one finger into the vagina and press on the side of the device to partially collapse it. This breaks any suction and makes the device smaller and easier to remove.
- Try to remove the device in a different position such as standing, sitting, squatting, or lying down.
- Take a break and try again after a few minutes. It can take a few times until you find a way that works for you.

Contact your doctor right away for help with removal if:

- The device has been inside for more than 12 hours and you cannot remove it after trying the Remove Yöni.Fit® steps (Step 4.1-4.4) a few times.
- You cannot remove the device and:
 - You cannot pass urine,
 - You have not passed urine for 6 hours, or
 - You need to pass stool but cannot do so.

4.5

After removing Yöni.Fit®, clean the device right away before using it again or storing it. See Cleaning Yöni.Fit® (Step 1.1-1.8) for cleaning instructions. See Storing Yöni.Fit® section on page 13 for information on how to store it.








Disposing of Yöni.Fit® After 30 Days

- Throw away Yöni.Fit® into household trash after 30 days of use (Figure AB).
- Do not flush Yöni.Fit® in the toilet.
- Do not use Yöni.Fit® if it is damaged or discolored.
- Do not use Yöni.Fit® for more than 30 days.
- If your Yöni.Fit® gets damaged before you have used it for 30 days, contact your doctor for a replacement device.



Figure AB

Glossary of Symbols

Symbol	Standard Reference	Standard title	Symbol title	Explanatory text
LOT	EN 980, Clause 5.4	Symbols for use in the labelling of medical devices.	Batch code	Indicates the manufacturer's batch or code so that the batch or lot can be identified.
	ISO 15223-1, Clause 5.1.5	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.		
REF	EN 980, Clause 5.10	See above, EN 980.	Catalog or model number	Indicates the manufacturer's catalog number so that the medical device can be identified.
	ISO 15223-1, Clause 5.1.6	See above, ISO 15223-1.		
UDI	ISO 15223-1, Clause 5.7.10	See above, ISO 15223-1.	Unique device identifier	Indicates a carrier that contains unique device identifier information.
	ISO 15223-1 Clause 5.3.7	See above, ISO 15223-1.	Temperature limits	Indicates the temperature limits to which the device can be safely exposed
	ISO 15223-1 Clause 5.2.7	See above, ISO 15223-1.	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.
	EN 980, Clause 5.6	See above, EN 980.	Date of manufacture	Indicates the date when a medical device was manufactured.
	ISO 15223-1, Clause 5.1.3	See above, ISO 15223-1.		
	EN 980, Clause 5.3	See above, EN 980.	Use by	Indicates the date after which the medical device is not to be used.
	ISO 15223-1 Clause 5.1.4	See above, ISO 15223-1.		
	EN 980, Clause 5.18	See above, EN 980.	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	ISO 15223-1 Clause 5.4.3	See above, ISO 15223-1.		
	EN 980, Clause 5.12	See above, EN 980.	Manufacturer	Indicates the medical device manufacturer.
	ISO 15223-1 Clause 5.1.1	See above, ISO 15223-1.		
	21 CFR 801.15 (c) (1)(i)(f)	Labeling - Medical devices; prominence of required label statements.	Prescription only	Indicates that the product requires prescription in the United States.
	21 CFR 801.109	Labeling- Prescription devices.		



WATKINS-CONTI
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Watkins-Conti Products, Inc.
3841 East Danforth Drive, Suite 109
Edmond, OK 73034



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