

The ColpexinTM Sphere is an intra-vaginal device designed to treat pelvic organ prolapse and enhance the performance of pelvic floor muscle exercises. The device is made from a medical grade plastic and is available in six sizes. The ColpexinTM Sphere is a smooth round sphere with an attached braided nylon string for ease of removal.

Important Information About the Size of Your Sphere

Your healthcare professional will determine the correct size of your sphere during your initial examination and fitting. However, some women may need to periodically change the size of their sphere during their treatment regimen because of strengthening of their vaginal and pelvic floor muscles. This is an individual response unique to each woman, so you must see your healthcare professional for specific scheduled visits during your treatment program for selection of the proper ColpexinTM Sphere size. Following this regimen will help your healthcare professional determine the right size for you while assessing your progress. The following fitting schedule is recommended for most women:

- Return 1 week after initial fitting
- Return 4-12 weeks after initial fitting
- Return every 6-12 months thereafter.

Instructions for Care

Wash the ColpexinTM Sphere and applicator with a mild, non-perfumed soap or detergent in warm water on a daily basis. Do not use very hot or boiling water. Dry with a soft, clean towel. This is a good time to inspect your sphere for any changes. The surface of the device should be smooth and free from any cracks, and the braided string should be securely fastened to sphere and not frayed. Store your clean sphere and applicator in the storage container provided in your kit. Most women will need to replace the sphere in 6-12 months, depending on how often they use and care for the sphere. Keep storage container and travel pouch clean by washing them with soap and water.

If for any reason this product needs to be returned, it must be returned in its original packaging.

Information for Patients

Indication

The ColpexinTM Sphere is indicated for the conservative management of pelvic organ prolapse (POP) and pelvic floor muscle weakness.

Contraindications

You should not use the ColpexinTM Sphere if you have any of the following:

- Vaginal infection, lacerations, or abnormal vaginal/uterine bleeding
- Recent vaginal surgery
- Severe pelvic nerve damage with no perineal sensation
- Pelvic inflammatory disease, endometriosis, pelvic mass, prolapse limited to a large rectocele, or retroversion of the uterus
- Pregnancy
- Intrauterine device (IUD)
- During sexual intercourse
- During menstruation

Warnings

Contact your healthcare professional immediately if you experience any changes in color, amount, odor, and consistency of vaginal discharge, and/or if you have bleeding, discomfort, burning with urination, increased urinary frequency, and/or vaginal itching.

Cautions

The ColpexinTM Sphere should not be worn continuously for longer than 24 hours without removing and properly cleaning the device. (See *Instructions for Care*)

If the plastic sleeve holding the ColpexinTM Sphere is broken, wash prior to first use.

Remember to remove the device before having sexual intercourse.

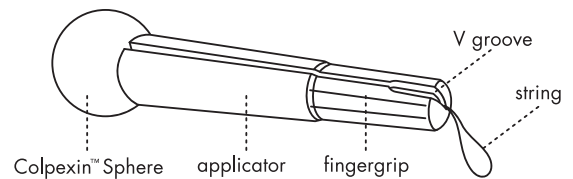
What Every Woman Needs to Know about Toxic Shock Syndrome

An association has not been established between the use of the ColpexinTM Sphere and toxic shock syndrome (TSS). However, wearing the device for prolonged periods of time may promote the growth of certain bacteria in the vaginal tract, especially during menstruation. Under certain conditions, the overgrowth of these bacteria could lead to symptoms of toxic shock syndrome.

Primary symptoms of TSS are sudden high fever (usually 102F or more), vomiting, diarrhea, fainting or near fainting when standing up, dizziness, or a rash that looks like sunburn. There may also be other signs of TSS, such as aching of muscles and joints, redness of the eyes, sore throat, and general weakness. If you have a sudden high fever and one or more of the other symptoms, remove the ColpexinTM Sphere at once and consult your healthcare professional immediately.

Instructions for Insertion and Removal

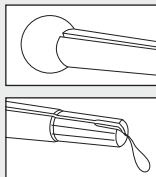
You can insert the ColpexinTM Sphere either by using the enclosed applicator or by inserting the sphere by hand. This is a personal choice, so you should decide what method you prefer to use. No matter which method is chosen, always begin by taking a deep breath and relaxing your pelvic floor muscles.



How to Insert the ColpexinTM Sphere While Using the Applicator

1. Preparing the Sphere.

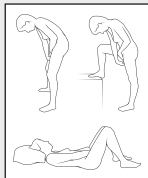
Wash your hands and remove the ColpexinTM Sphere and applicator from the plastic wrap (do not flush the plastic wrap). Place the sphere on the top of the applicator while putting the string through the slot on the side of the applicator. The string should fit into the V groove at the bottom of the applicator.



The sphere should be held snugly by placing your fingers on the finger grip and grasping the string where it exits the bottom of the applicator. If you have vaginal dryness, you may want to use a small amount of water-based lubricant or water to moisten the sphere prior to insertion.

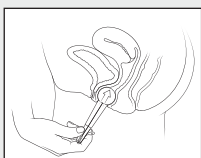
2. Choose a Comfortable Position.

You can lie on your back with your knees bent or stand with your feet apart and knees bent. Some women prefer sitting on a toilet with knees apart or standing with one foot on the toilet seat. Remember, choose a position that is right for you and relax your muscles.



3. Inserting the Sphere.

While still holding the finger grip and string snugly, gently spread your labia with your free hand and insert the sphere and applicator into the opening of your vagina pointing the applicator towards your lower back until the sphere is as far back in the vagina as possible

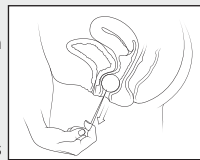


without feeling discomfort.

Once the sphere is in place, move the string out of the V groove and gently slide the applicator out of your vagina. The string should be outside your body, similar to a tampon removal string. You can perform 2-3 quick pelvic muscle contractions to make sure the sphere is comfortably in place and follow the *Instructions for Care* to clean and store the applicator.

4. Removing the Sphere.

When you are ready to remove your ColpexinTM Sphere, choose the position that you found comfortable for insertion. Relax your pelvic floor muscles and gently pull down on the string toward your buttocks until the sphere slides out.

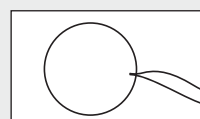


Once the sphere is removed, follow the instructions for proper cleaning and storage. (See *Instructions for Care*)

How to Insert the ColpexinTM Sphere Using Your Hand

1. Preparing the Sphere.

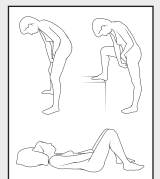
Wash your hands and remove the ColpexinTM Sphere and applicator from the plastic wrap (do not flush the plastic wrap). Place the unused applicator back in the storage container. The sphere should be held between the thumb and the index finger, while the string is fully extended.



The sphere should be held snugly by placing your fingers on the finger grip and grasping the string where it exits the bottom of the applicator. If you have vaginal dryness, you may want to use a small amount of water-based lubricant or water to moisten the sphere prior to insertion.

2. Choose a Comfortable Position.

You can lie on your back with your knees bent or stand with your feet apart and knees bent. Some women prefer sitting on a toilet with knees apart or standing with one foot on the toilet seat. Remember, choose a position that is right for you and relax your muscles.



3. Inserting the Sphere.

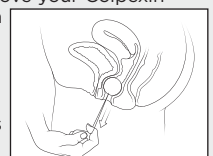
Firmly hold the sphere between your thumb and index finger, gently spread your labia with your free hand, and insert the sphere into the opening of your vagina pointing toward your lower back. Push the sphere with one or two fingers as far back into the vagina as possible without feeling discomfort.



Gently slide your fingers from your body. The string should be outside your body, similar to a tampon removal string. Wash your hands.

4. Removing the Sphere.

When you are ready to remove your ColpexinTM Sphere, choose the position that you found comfortable for insertion. Relax your pelvic floor muscles and gently pull down on the string toward your buttocks until the sphere slides out.



Once the sphere is removed, follow the instructions for proper cleaning and storage. (See *Instructions for Care*)

Frequently Asked Questions

Will inserting and removing the Colpexin™ Sphere hurt?

No. The sphere has been designed with a round shape and smooth surface to make insertion and removal simple and easy. Just follow the four simple steps outlined in the instructions.

What if I have difficulty inserting the sphere?

Make sure that you are in a comfortable position and relax your pelvic floor muscles. Mild pressure on the perineum towards your lower back can help when you are guiding the sphere into your vagina. If you feel your prolapse extending outside of the vaginal opening, you may need to gently push it in before inserting your sphere. You may need to lie on your back to do this properly.

If you have vaginal dryness, you may want to use a little water-based lubricant such as KY® Jelly or water to help moisten the sphere prior to insertion.

What do I do if my sphere falls out?

Your sphere may fall out if it is too large or too small. Remember, your body is changing as you use the sphere and perform pelvic floor muscle exercises, so you may need periodic size adjustments. If the sphere does fall out, follow the instructions for proper cleaning and try reinserting it. If the problem continues, contact your healthcare professional to schedule an appointment for resizing and pelvic floor muscle assessment.

Can the Colpexin™ Sphere become uncomfortable while I am wearing it?

A properly fitted sphere should not cause pain or discomfort. If you do develop discomfort while using the sphere, contact your healthcare professional. You may need a size adjustment if your pelvic floor muscles have become stronger.

What if I can't find the string to remove the sphere?

Don't panic. Gently insert your index finger into your vagina and feel the sides of the sphere. Once your finger touches the string, ease the string out of your body and follow the instructions for removing the sphere. If you still can't find the string and remove the sphere, call your healthcare professional and schedule an appointment.

Can I wear the sphere when I go to the bathroom?

Yes. The sphere should not interfere with elimination, but some women find supporting the sphere with their index finger while urinating or having a bowel movement to be more comfortable. Other women feel more at ease removing the sphere before moving their bowels. Just make sure that you keep the string away from this area of the body and choose the method most comfortable for you.

Will I always need to use the Colpexin™ Sphere?

Not necessarily. Your vaginal and pelvic floor muscles may strengthen enough that you no longer need to wear the sphere on a daily basis. You may want to wear your sphere only when you are participating in sports or strenuous exercise, but discuss this with your healthcare professional before making changes to your treatment regimen. Remember to use the sphere at least two times per week along with pelvic floor muscle exercises in order to maintain the positive effects of your treatment.

How often should I remove the Colpexin™ Sphere?

You should remove your sphere daily and follow the instructions for proper cleaning.

Do I wear my sphere during the day and at night?

Your healthcare professional will determine the best treatment schedule for your individual needs. Recommendations can vary from starting therapy with only nighttime use to wearing the sphere only in the daytime or to wearing the sphere both day and night. Remember, you should remove your sphere at least once in 24 hours for proper cleaning. Your personalized treatment plan will outline your schedule and pelvic floor muscle exercise regimen designed to get the best results for you.

Can I wear the Colpexin™ Sphere during sex?

No. Remember to remove the sphere before having sexual intercourse.

Can I wear the Colpexin™ Sphere during my period?

No. Remove your sphere when you have your period. Always remember to place your clean sphere and applicator in the storage case when not in use.

What do I do if I have a discharge?

Contact your healthcare professional if you experience any changes in your vaginal secretions or if you develop any discomfort while urinating.

When do I need to replace my Colpexin™ Sphere?

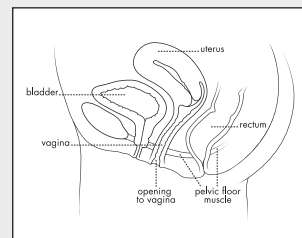
With proper care, you should be able to use the same sphere for about 6-12 months. Some women will need to have a different size sphere because of changes to their muscles during treatment. If you need a new size, discard your old sphere and start using the newly sized sphere.

What if my sphere becomes damaged?

The surface of your sphere should be smooth and free from any cracks, and the braided string should be securely fastened to the sphere and not frayed. Remember to inspect your sphere for any changes during daily cleaning. Do not use a damaged sphere, and call your healthcare professional for a replacement if your sphere does become damaged. For more information, please contact our customer service department at 1-866-871-9654 or visit us at www.colpexin.com.

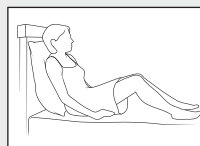
Pelvic Floor Muscle Exercises

The **pelvic floor muscles (PFM)** are a very important muscle group for women - they help support the pelvic organs (the bladder, uterus, and colon), assist in stopping and starting the flow of urine or the passage of gas or stool, and aide in sexual satisfaction. Attached to the pelvic bones, PFM are located at the bottom of your pelvis and form a funnel that spans the width and breadth of the pelvis. When contracted, a deep feeling of tension and firmness is sensed. the muscles move upward. and the openings of the vagina and anus close.



PFM Exercise Program

To begin, empty your bladder and lie on your back on a flat surface with your Colpexin™ Sphere in place. Keep your knees bent and apart and your head elevated and supported with several pillows. Remember, doing your exercises with the Colpexin™ Sphere in place will allow you to be sure you are using the right muscle group.



1. Contract or tighten the muscles around the vaginal opening and feel for a lifting of the Colpexin™ Sphere and closure of the vaginal opening. Locate the string on your Colpexin™ Sphere and gently pull on it so you can feel that the sphere is in the correct position, above the PFM. Now relax your muscles.
2. Perform the PFM contraction (feel for lifting of the Colpexin™ Sphere and closure of the vaginal opening).
3. Initially, you may only be able to hold each contraction for 1-2 seconds, gradually increasing the time to 3-5 seconds, relaxing for 3-5 seconds for up to 5 repetitions. As you get stronger, you can extend the time, holding the contraction for 5-8 seconds for 8 repetitions. Your goal is to reach 10 second contractions for 10 repetitions. Remember to always relax the PFM for an equal amount of time between contractions.
4. Do these exercises two times a day.

A Few Helpful Hints...

If you are unable to feel your PFM contract around the vaginal opening, try placing a folded hand towel between your knees squeezing them together for 1-2 seconds until you gradually build up your strength.

The quality of the exercises is more important than the number you perform or the seconds you are able to hold each contraction. As with all exercise, you will build strength over time as you follow your treatment regimen.

Avoid straining, holding your breath, or using your buttock muscles while you exercise the PFM. Counting out loud can help prevent this from happening. If you still notice that you use your buttock muscles or hold your breath, you are probably contracting your muscles incorrectly. Review your exercise instructions and try again. If the problem continues, notify your healthcare provider for more instructions.

As your strength continues to improve, you may want to challenge your muscles further by gently tugging on the string while tightening your PFM. Be sure not to pull so hard as to cause the Colpexin™ Sphere to actually come out while exercising. If the sphere does come out when you add resistance, just reinsert it according to the directions and return to doing the exercises without adding resistance (pulling on the string).

Pelvic floor muscle exercises are a very important part of your treatment, so try to incorporate these exercises into your daily routine. For example, if you wear your sphere only during the day, try doing your exercises once in the morning after inserting the Colpexin™ Sphere and once in the evening before you remove your sphere. Make it a habit like brushing your teeth and you will be less likely to forget.