

# PESSARY ASSISTANT™

## INSTRUCTIONS FOR USE (IFU)

PLEASE READ THIS DOCUMENT CAREFULLY AND KEEP IT FOR FUTURE REFERENCE. IT IS ALWAYS IMPORTANT TO FOLLOW YOUR HEALTHCARE PROFESSIONAL'S INSTRUCTIONS, AS WELL AS THOSE CONTAINED IN BOTH THIS LEAFLET AND THE LEAFLET FOR YOUR PESSARY.

### DESCRIPTION

PessaryAssistant™ consists of a handle with two functional ends as shown in Figure 1 below:



**FIGURE 1. PessaryAssistant™ device components:**

1. C-shaped end for removal of a ring or Gellhorn-type pessary
2. Handle
3. U-shaped end for holding a folded ring pessary
4. Retention notches to prevent folded ring pessary from slipping out of the "U"

**THIS DEVICE HELPS YOU INSERT AND REMOVE YOUR PESSARY**

**STEP-BY-STEP INSTRUCTIONS FOR INSERTION AND REMOVAL ARE ON PAGE 2**

### DEVICE IDENTIFICATION

- Device Name: PessaryAssistant™
- Model: PA0008
- Device Type: Non-sterile, reusable accessory to a vaginal pessary
- Material: Polypropylene (PP) plastic

### INTENDED USE

PessaryAssistant™ is a medical device accessory designed to facilitate both insertion and removal of a pessary by adult women, especially in cases of hand muscle weakness or arthritis. PessaryAssistant™ is designed for repeated use, at home or in a healthcare facility, by a single patient.

The device itself does not provide therapeutic benefit and is intended solely as a mechanical aid for handling a pessary.

### COMPATIBILITY

PessaryAssistant™ is compatible with most ring-shaped vaginal pessaries:

- Ring Pessaries, with or without support (diaphragm)
- Dish or Bowl type flexible incontinence pessaries
- Other similar pessaries
- Also designed to assist in retrieval of the stem of a Gellhorn-type pessary

*If you have questions before using this device, or experience difficulty using your pessary, consult your healthcare professional.*

### CLEANING, MAINTENANCE, AND STORAGE

- Before and after each use, clean with warm water and mild soap, then rinse thoroughly.
  - Allow to air dry before storing in a clean, dry place.
  - Do not use harsh chemicals or high temperatures.
  - Do not boil, autoclave, or use high-level disinfectants.
- Validated cleaning and reprocessing methods are currently under evaluation.*

### COMPOSITION AND BIOCOMPATIBILITY

PessaryAssistant™ is made from biocompatible polypropylene (PP) and does not contain latex or known harmful substances.

### DEVICE LIFETIME

This device should be replaced if signs of wear or damage, cracking, deformation, or deterioration are observed.

### WARNINGS AND PRECAUTIONS

- Use only as directed by your healthcare professional.
- Do not use if the device is damaged, cracked, or deformed.
- Discontinue use and consult a healthcare professional if you experience pain, bleeding, irritation, or discomfort.
- FOR SINGLE-PATIENT USE ONLY. Do not share this device.
- Clean the device before and after each use.

### WHEN TO CONSULT A HEALTHCARE PROFESSIONAL

If you have persistent difficulty using your pessary, experience pain, or notice other side effects, consult your healthcare professional. Refer to the package leaflet for your pessary for information on proper use and potential adverse effects.

### REPORT AN INCIDENT

- If you have a problem with this device, please contact the Manufacturer, its Authorized Representative, or your healthcare professional immediately.
  - Serious incidents must be reported to the competent authorities in accordance with Regulation (EU) 2017/745.
- In France: ANSM (<https://signalement.social-sante.gouv.fr/>)

# PESSARY ASSISTANT™

## INSTRUCTIONS FOR USE (IFU)

### INSERTING A RING-TYPE PESSARY

1. Fold your pessary in half, in the shape of a downward-turning banana or crescent (**See Figure 1**).
  - a. The end “notches” or center holes will guide the folding. It should fold easier in one direction than the other.
  - b. These “notches” or holes should be at the ends of the banana or crescent (not the middle).
2. Wedge the now-folded ring-type pessary into the “U” end of PessaryAssistant™. The 2 notches will help hold it in place.
3. Hold PessaryAssistant™ (with folded pessary inside “U”) so that “C” end is up and “U” end is down. Position your thumb toward your body, and your fingers should be on the far side of the flat handle (**See Figure 1**).
4. Place a dab of water-based intimate lubricant on the insertion end of the now-folded pessary (the side that you intend to insert first).
5. Place the insertion end of the now-folded pessary at the vaginal opening.
6. Use your other hand (or smaller 1-3 fingers of your same hand holding PessaryAssistant™) to insert your folded pessary into the vagina. The folded pessary will essentially “pass through” the “U”, so that it stays folded for as long as possible before “springing” open. The PessaryAssistant™ “U” end stays outside the vagina. It and the adjacent flat handle simply rest vertically against your vulva.
7. Use one finger to push the now unfolded (sprung-open) pessary deep into the vagina.
8. If you are using a “supportive” pessary (i.e., membrane inside the ring rather than empty space), try to orient one of the larger holes so that it is closest to the vaginal opening (**See Figure 2**). This will make it easier to remove your pessary in the future

### REMOVING A RING OR GELLHORN-TYPE PESSARY

1. Place one finger inside the vagina to locate the rim, edge, or stem of your pessary, as well as one of the larger holes if it is a “supported” ring pessary (**See Figure 2**).
2. Use your inserted finger to guide the “C” end of your PessaryAssistant™ inside the vagina. The “C”-shaped hook can point up or down, depending on what feels most appropriate for your resting pessary position. An anterior rim might be easier to hook from below. A posterior rim might be easier to hook from above.
3. Manipulate the handle of PessaryAssistant™ until you have gently hooked your pessary rim or stem (**See Figure 3**).
  - a. If you use a “supported” ring pessary, the “C” will pass through one of the larger holes in the membrane.
  - b. Use PessaryAssistant™ to gently pull down and remove your pessary, while using your free hand to “fold” your pessary on the way out. This decreases the diameter of the pessary, which makes passage through the vaginal opening less tender.



Figure 1

Figure 2

Figure 3

### SYMBOLS IN ACCORDANCE WITH ISO 15223-1

Symbol	Definition
	Catalog number
	Lot number
	Medical Device
	CE marking (European Conformity) according to Regulation (EU) 2017/745
	Unique Device Identifier
	Manufacturer
	Importer
	Distributor
	European Union Representative (authorized representative in the European Union)
	One patient, Multiple use
	NON-STERILE
	Patient Information Website
	View IFU Instructions For Use
	No Expiration Date
	Medical Grade Polypropylene