

Definity™  
Cervical Dilator

**Definity™**  
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**INSTRUCTIONS FOR USE**



**HOLOGIC®**



# Definity™ Cervical Dilator

## Instructions For Use

# HOLOGIC®

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# Definity™

## Cervical Dilator

### Caution

Federal law (USA) restricts this device to sale by or on the order of a physician.

Carefully read all instructions prior to use. Failure to observe warnings and precautions noted throughout these instructions may result in complications. Any recommendations within these instructions are designed to serve only as a general guideline and are not intended to supersede institutional protocols or professional clinical judgment concerning patient care.

### Device Description Overview

The Definity™ Cervical Dilator enables the insertion of a Dilator Balloon into the cervical canal for cervical dilation. This Dilator Balloon is introduced into the cervical canal by an inflated Membrane that pulls the Dilator Balloon across the canal.

The Definity Cervical Dilator is available in three balloon sizes: 5mm, 7mm, and 9mm.

The Definity Cervical Dilator consists of two parts:

- The **Inflation Device**, which is a screw syringe with a capacity of **10cc**. It is used to pressurize the Dilator Catheter through the rotation of its plunger. The pressure in the Dilator Catheter is indicated on the Inflation Device by the Pressure Indicator. Figure 1 illustrates the components of the Inflation Device and Table 1 lists and describes each component.
- The **Dilator Catheter**, which contains a Membrane that facilitates travel through the cervix. The Membrane is attached to and covers the Dilator Balloon used to dilate the cervix. When connected to the Inflation Device and pressurized with saline, the Membrane is advanced through the cervix thereby pulling the Dilator Balloon across the cervix. Figure 2 illustrates the components in the Dilator Catheter and Table 2 lists and describes each component.

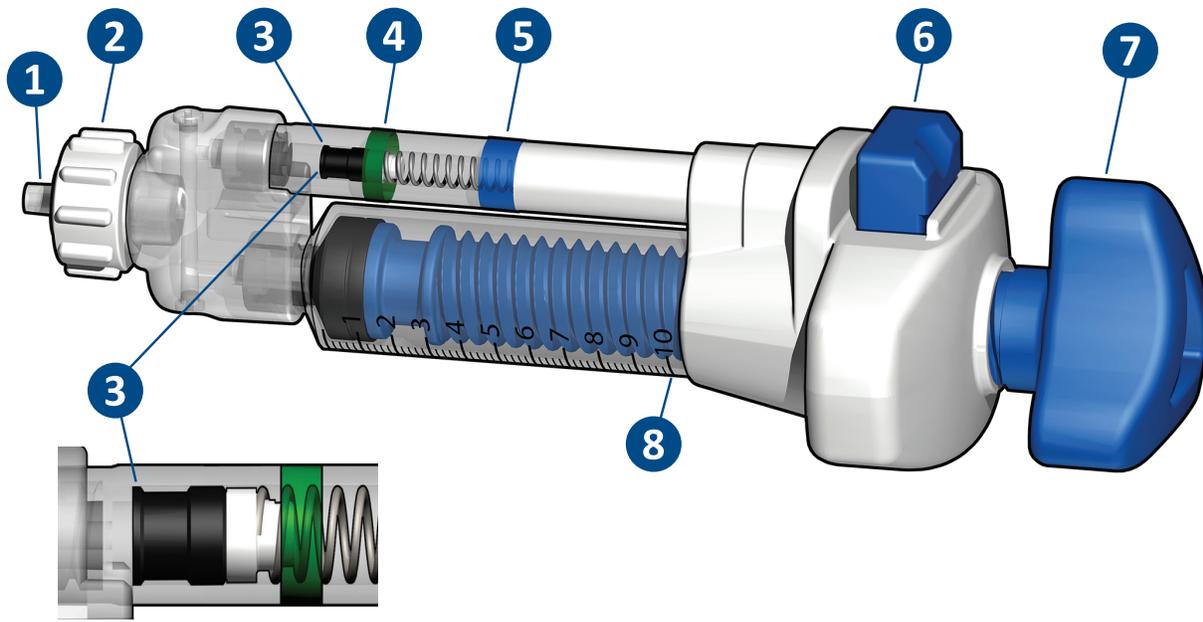


Figure 1: Inflation Device

Table 1: Inflation Device Components

Item	Name	Description/Function
1	Luer Connector	Connects Dilator Catheter to the Inflation Device.
2	Locking Nut	Secures the Dilator Catheter to the Inflation Device.
3	Pressure Indicator	Moves proximally (toward the operator) to indicate increasing pressure in the Cervical Dilator. The distal Acorn Tip of the rubber stopper is used to indicate pressure level.
4	Charge Zone	<b>GREEN</b> marker area. Used with the Pressure Indicator to indicate the Cervical Dilator is charged. When charged, the Dilator Balloon and Membrane (Table 2) can be advanced through the cervix.
5	Dilation Zone	<b>BLUE</b> marker area. Used with the Pressure Indicator to indicate the Dilator Balloon is fully dilated.
6	Release Button	When pressed, allows the Plunger to be pushed and pulled manually. Used to rapidly fill the Inflation Device or release pressure.
7	Plunger	Used to pressurize the Cervical Dilator by rotating clockwise when the Inflation Device is connected to the Dilator Catheter. Can also be pushed or pulled while the Release Button is depressed (in order to fill the Inflation Device more quickly).
8	10cc mark	The mark to which the saline is filled for performing the procedure.

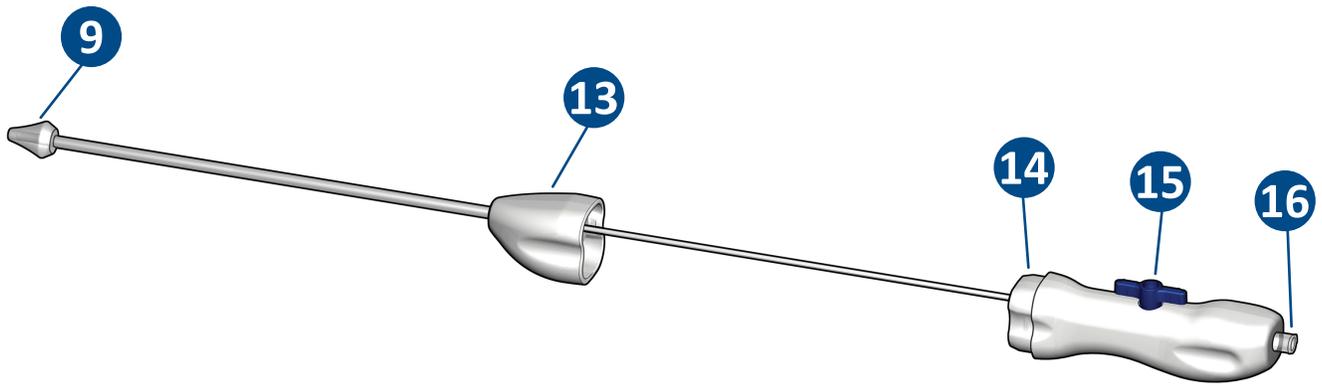


Figure 2: Dilator Catheter

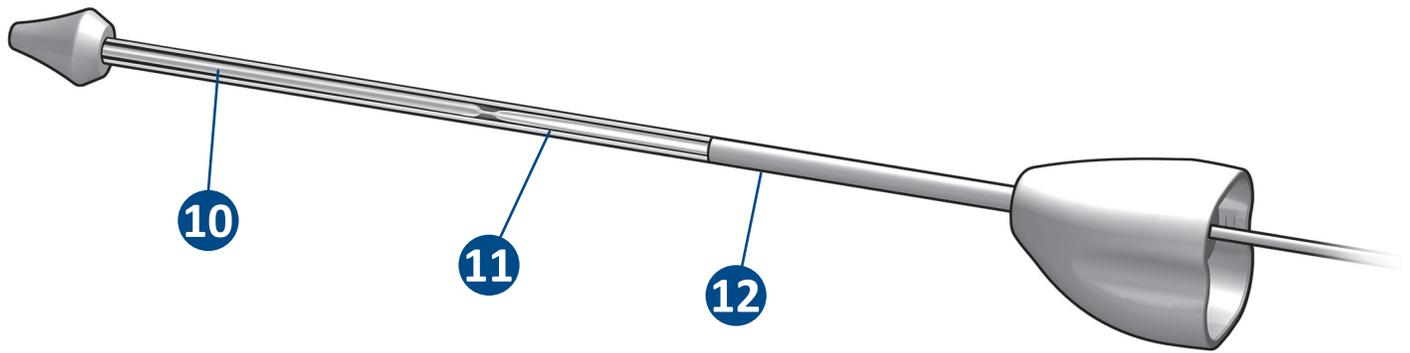


Figure 3: Dilator Catheter Cross-Section showing Membrane and Dilator Balloon

Table 2: Dilator Catheter Components

Item	Name	Description/Function
9	Acorn Tip	Used to position the Cervical Dilator when seated up against the external cervical os.
10	Membrane	Hidden within the Dilator Sheath, the Membrane is pressurized with saline in order to be advanced through the cervical canal and then split to position the Dilator Balloon.
11	Dilator Balloon	After it is positioned, the Dilator Balloon is distended with saline until the appropriate pressure for dilation is achieved.
12	Sheath	Outer tube that houses the Membrane and Dilator Balloon.
13	Distal Handle	Used to position the Acorn Tip of the Dilator Catheter against the external cervical os (this handle is closest to patient)
14	Proximal Handle	Pushed toward the Distal Handle to advance the Membrane (this handle is closest to operator).
15	Stopcock	In the open position (as shown), allows the Membrane to be pressurized. In the closed position (perpendicular to the Proximal Handle), allows flow to the Dilator Balloon.
16	Luer Connector	Connects the Dilator Catheter to the Inflation Device.

## How it Works

The following section outlines the operation of the Definity Cervical Dilator.

### Pressurization of the Definity Cervical Dilator

- The manually-operated threaded Plunger on the Inflation Device is used to pressurize the Dilator Catheter with sterile saline. Refer to Item 7 in Figure 1.
- The Inflation Device is filled with sterile saline and attached to the Dilator Catheter. Using the threaded Plunger, the Cervical Dilator can be pressurized. The pressure in the Cervical Dilator is indicated by the location of the Pressure Indicator in relation to the **GREEN** Charge Zone or **BLUE** Dilation Zone, refer to Items 3, 4, and 5 in Figure 1 respectively.

### Positioning of the Dilator Balloon

- The Dilator Catheter contains the Membrane, which is inverted within the distal end of the device prior to use, and the Dilator Balloon. The pressurized Membrane acts as a vehicle to transport the Dilator Balloon through the cervix (Figure 4).



Figure 4: Dilator Catheter Cross-Section showing Membrane and Dilator Balloon.

- The Membrane and Dilator Balloon can only advance when the Pressure Indicator is within the **GREEN** Charge Zone. The Membrane and Dilator Balloon advance by rolling into the cervix until they are in a fully deployed position.
- Once the Membrane and Dilator Balloon are in place within the cervix, the Membrane is split away by increasing the pressure in the Inflation Device. After the Membrane has been split, the Dilator Balloon can be pressurized with the Inflation Device causing the Dilator Balloon to expand. When the Pressure Indicator on the Inflation Device is within the **BLUE** Dilation Zone, the cervix is dilated.

### Fluid Flow through the Cervical Dilator

- The Dilator Catheter is comprised of two flow paths: a Membrane Flow Path and a Balloon Flow Path. Initially, both paths are open allowing the Membrane and Dilator Balloon to be pressurized. When the Stopcock is closed, flow is cut off to the Membrane so only the Dilator Balloon may be pressurized. This keeps the sterile saline from leaking into the uterine cavity following the splitting of the Membrane.

## Indications for Use

The Definity Cervical Dilator is intended to be used whenever cervical softening and dilation is desired. Some examples are:

- Treatment of cervical stenosis
- IUD placement and removal
- Placement of instruments for intrauterine radiotherapy
- Endometrial biopsy
- Global endometrial ablation
- Uterine tissue removal
- Uterine curettage
- Diagnostic hysteroscopy
- Operative hysteroscopy

This device is not intended for use in the induction of labor.

## Contraindications

Use of the Definity Cervical Dilator is contraindicated in patients with:

- An active genital tract infection such as genital herpes
- Pelvic structure abnormality that prevents passage of the device
- Invasive cervical cancer

This device is also contraindicated for the induction of labor.

## Warnings

- Do not advance the Dilator Catheter into the uterus when the Dilator Balloon is pressurized. Retract the pressurized Dilator Balloon after the dilatation pressure has been achieved and stabilized.
- If resistance is encountered at any time during the insertion procedure, do not force passage. Stop the procedure and remove the Dilator Catheter.
- Always inflate the Definity Cervical Dilator with sterile saline. Never inflate with air, carbon dioxide, or any other gas or liquids.
- Do not overinflate. Using excessive pressure to inflate the Membrane and Dilator Balloon may lead to incorrect function and patient harm.
- The safety and effectiveness of the device for use in induction of labor has not been established.

## Precautions

- The Definity Cervical Dilator is a single-use device (Sterile). None of the catheter’s components should be re-used or re-sterilized.
- Do not use after the “Use By” date.
- Do not use if packaging integrity of any part of the Cervical Dilator has been compromised.
- Careful placement of the device is essential to avoid traumatic injury to the cervix or uterus.
- The device should not be left in place more than 5 minutes.
- The Definity Cervical Dilator is designed to slowly dilate the cervix with pressurized saline. *Slowly* pressurize the Dilator Balloon until the indicated pressurization level on the Inflation Device has been achieved (when the Pressure Indicator on the Inflation Device is within the **BLUE** Dilation Zone) and is stabilized without requiring additional saline.

## Potential Risks

Possible risks include, but are not limited to, the following:

- Bleeding from the cervix or uterus (light, mild or severe bleeding)
- Cervical or uterine laceration and/or perforation could occur if advancing into the uterus after the Dilator Balloon has been pressurized
- Device expulsion from the cervix
- Device entrapment and/or fragmentation
- Patient discomfort during and after dilation

## Required Items for Procedure

- Definity Cervical Dilator
- 0.9% Sterile Saline

## Instructions for Using the Definity Cervical Dilator

This section provides step-by-step instructions for:

- Unpacking the Definity Cervical Dilator
- Preparing the Definity Cervical Dilator for use
- Checking the Membrane prior to insertion
- Performing the cervical dilation procedure using the Definity Cervical Dilator
- Removing the Definity Cervical Dilator

## Unpacking the Definity Cervical Dilator

**IMPORTANT:** USE STERILE TECHNIQUE TO REMOVE THE COMPONENTS FROM THE PACKAGING.

1. Perform the following steps to unpack the Definity Cervical Dilator:
  - a. Peel back the sterile pouch and remove the tray.
  - b. Place the tray on a sterile surface.
  - c. Remove the tray lid by lifting from the section labeled **Lift** (Figure 5).

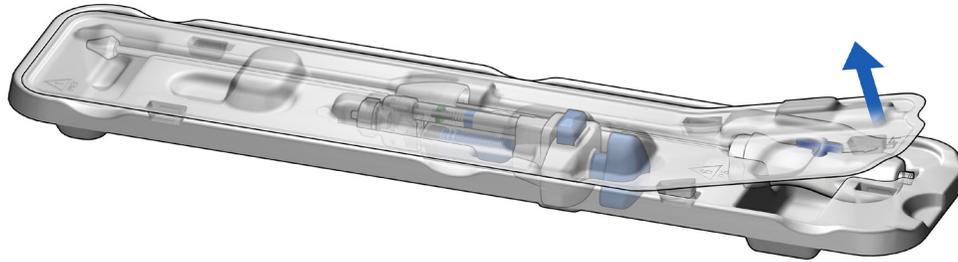


Figure 5: Lifting the packaging tray lid

- d. Remove the Dilator Catheter from the package (Figure 6).

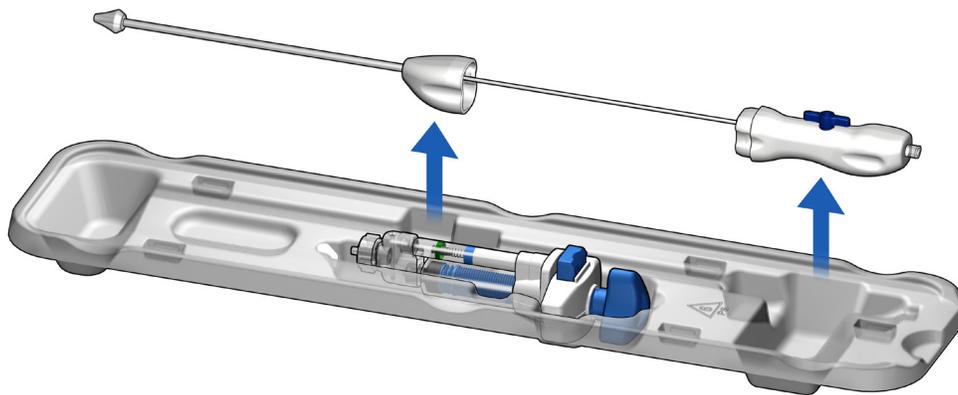


Figure 6: Removing the Dilator Catheter from packaging

- e. Remove the Inflation Device from the packaging (Figure 7).

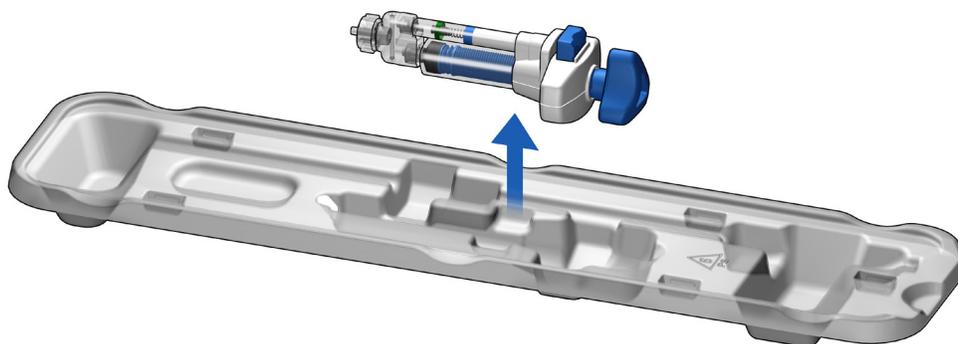


Figure 7: Removing the Inflation Device from packaging

## Preparing the Definity Cervical Dilator for Use

1. Fill the Inflation Device with sterile saline (Figure 8):
  - a. Place tip of the Inflation Device in a container of saline.
  - b. Press and hold the Release Button and pull back on the Plunger until the saline has reached the **10cc** mark.
2. If necessary, remove any air bubbles from the Inflation Device (Figure 9):
  - a. Hold down the Release Button and push forward on the Plunger until there are no air bubbles in the Inflation Device.
  - b. Ensure saline is at the **10cc** mark.



Figure 8: Filling Inflation Device with Saline



Figure 9: Removing Air from Inflation Device

3. Connect the Inflation Device to the Dilator Catheter:
  - a. Insert the Inflation Device's Luer Connector into the Proximal Handle's Luer Connector (Figure 10).

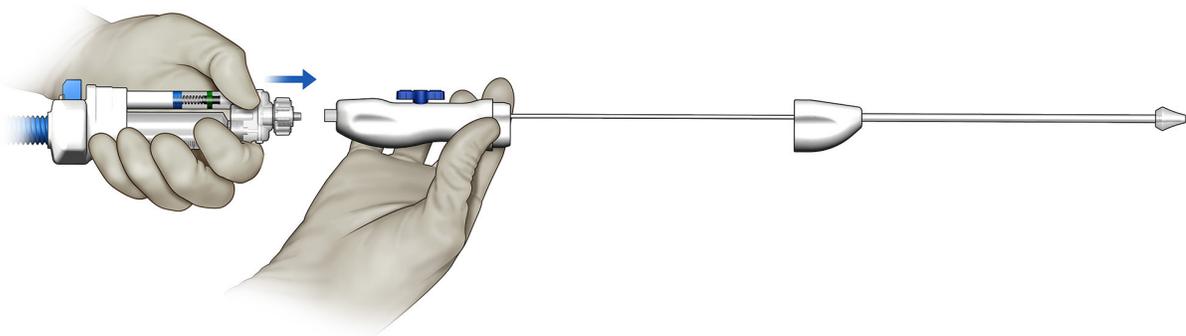


Figure 10: Connecting Inflation Device to Proximal Handle

## Preparing the Definity Cervical Dilator for Use

- b. Tighten the Locking Nut (Figure 11) on the Inflation Device to ensure both components are securely connected.

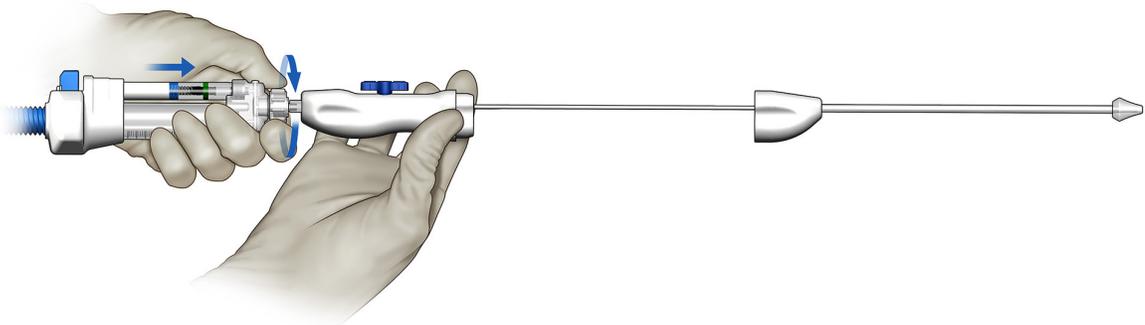


Figure 11: Tightening Lock Nut

### 4. Charging the Dilator Catheter:

- a. Rotate the Plunger **CLOCKWISE** until the Pressure Indicator (tip of rubber stopper) is within the **GREEN** Charge Zone (Figure 12 and Figure 13).
- b. **STOP** rotating the Plunger when the Pressure Indicator is within the **GREEN** Charge Zone on the syringe.

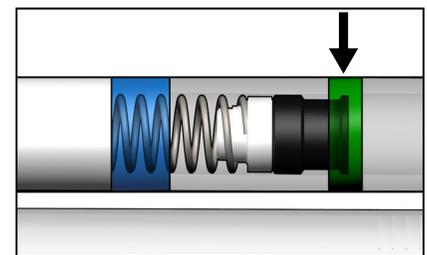


Figure 12: Pressure Indicator in GREEN Charge Zone

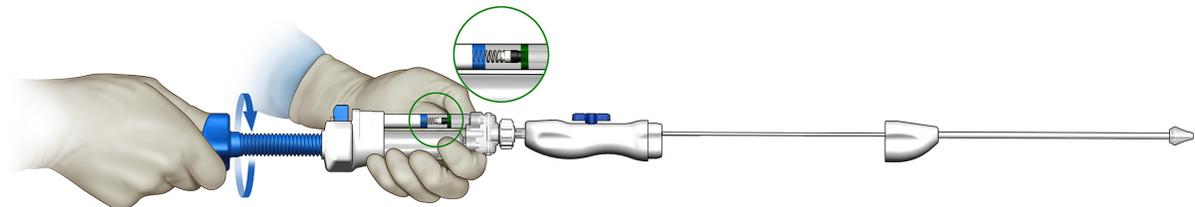


Figure 13: Injecting Saline

## Checking the Membrane Prior to Use

This step ensures that the Dilator Catheter is charged and ready for use.

1. Advance and visualize the Membrane (Figure 14):
  - a. Hold the Distal Handle on the Dilator Catheter with one hand while supporting the Inflation Device and Proximal Handle in the other hand.
  - b. Push the Inflation Device/Proximal Handle forward so that the Membrane extends approximately 1 to 2 cm beyond the Acorn Tip.
  - c. Pull the Inflation Device/Proximal Handles back to retract the Membrane back into the Acorn Tip (Figure 15).

**NOTE:** IF THE MEMBRANE DOES NOT ADVANCE PAST THE ACORN TIP, ENSURE THE PRESSURE INDICATOR IS WITHIN THE **GREEN** CHARGE ZONE. SEE FIGURE 12.

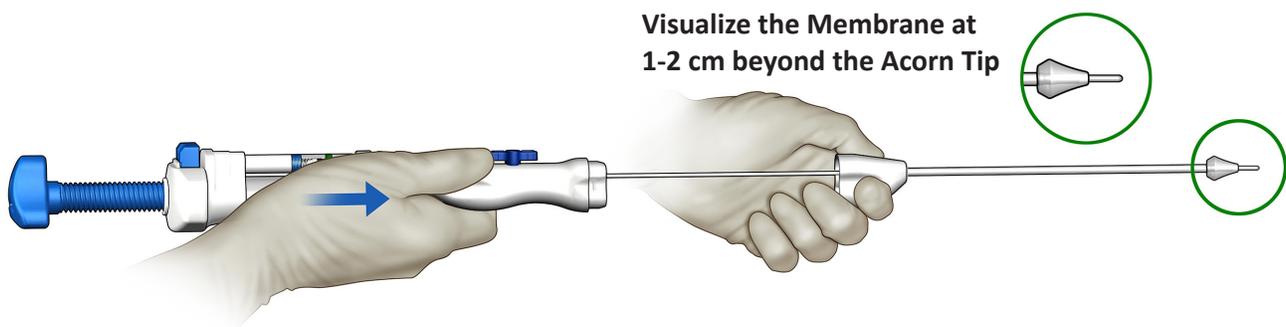


Figure 14: Advancing and Visualizing the Membrane Prior to Use

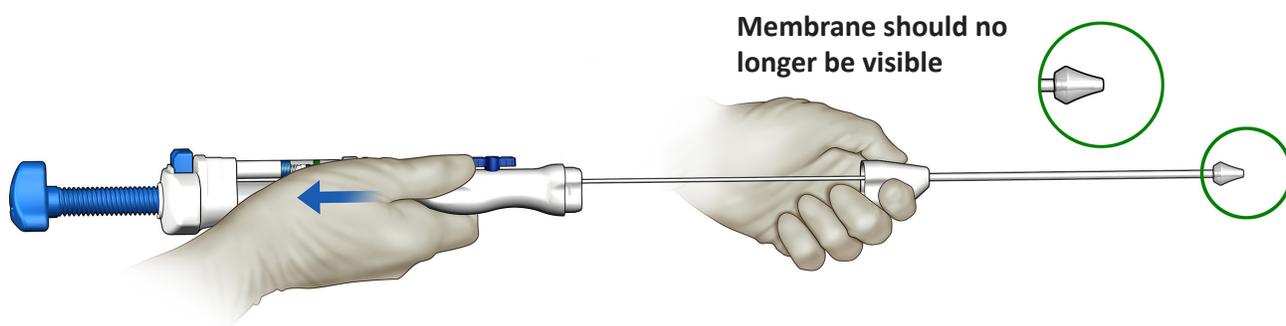


Figure 15: Retracting the Membrane back into the Acorn Tip

## Performing the Procedure

1. Insert the Acorn Tip of the Dilator Catheter through the vaginal canal.
2. Place the Acorn Tip against the external cervical os (Figure 16).

**NOTE:** ENSURE THE ACORN TIP OF THE DEVICE REMAINS AGAINST THE CERVIX.

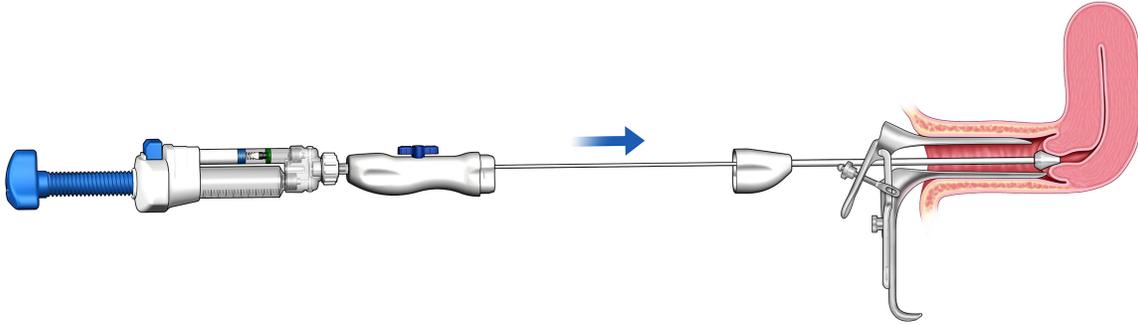


Figure 16: Inserting Dilator Catheter's Acorn Tip Against External Cervical Os

3. Advance the Membrane through the cervical canal:
  - a. Push the Inflation Device toward the Distal Handle until the Proximal and Distal Handles connect (Figure 17 and Figure 18).

This fully advances the Membrane into the cervical canal.

**IMPORTANT:** VERIFY THAT THE MEMBRANE IS NOT VISIBLE AT THE CERVIX OR IN THE VAGINA (HAS NOT ENTERED THE CERVIX). IF THE MEMBRANE IS VISIBLE, RETRACT THE MEMBRANE AND RESTART THE PROCEDURE AT STEP 1 IN THIS SECTION (PAGE 11).

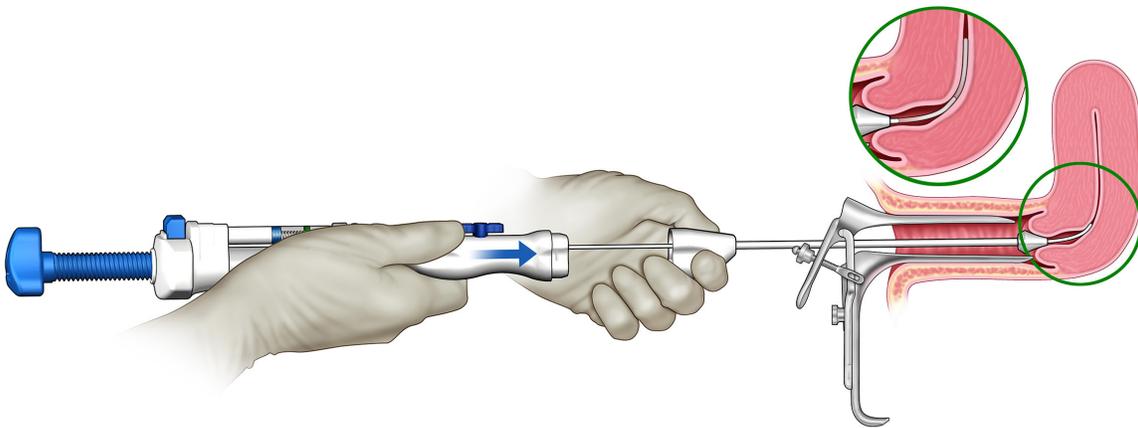


Figure 17: Advancing the Membrane

## Performing the Procedure

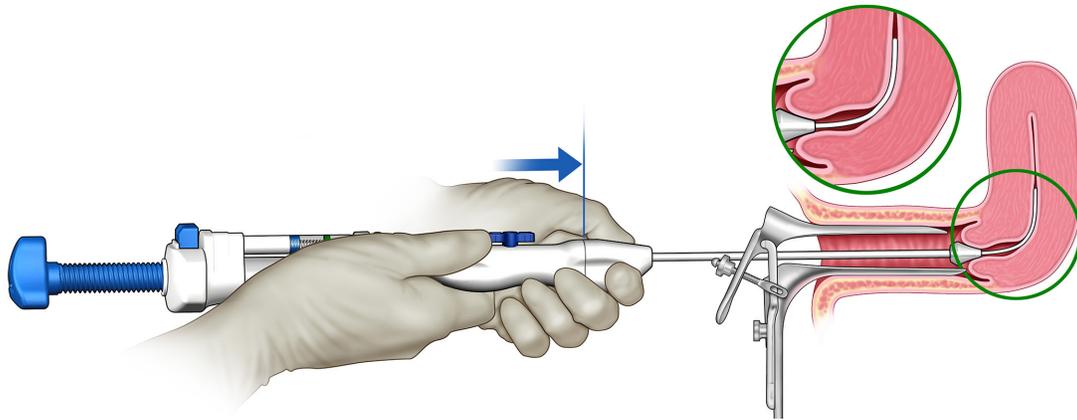


Figure 18: Handles are Connected to Indicate the Membrane is Fully Advanced

4. Ensure the Stopcock is in the initial position (refer Figure 2, item 15).
5. Pressurize the Dilator Balloon with saline to split the Membrane (Figure 19):
  - a. While holding the Inflation Device, rotate the Plunger **CLOCKWISE** until there is a drop in pressure. This drop in pressure may also be characterized by an audible sound or tactile response.
  - b. **STOP** rotating the Plunger once the pressure drops.

**NOTE:** ROTATING THE PLUNGER AFTER THE MEMBRANE HAS SPLIT COULD REQUIRE ADDITIONAL SALINE TO BE ADDED. AVOID ROTATING THE PLUNGER AFTER THE PRESSURE INDICATOR IS BELOW THE **GREEN** CHARGE ZONE.

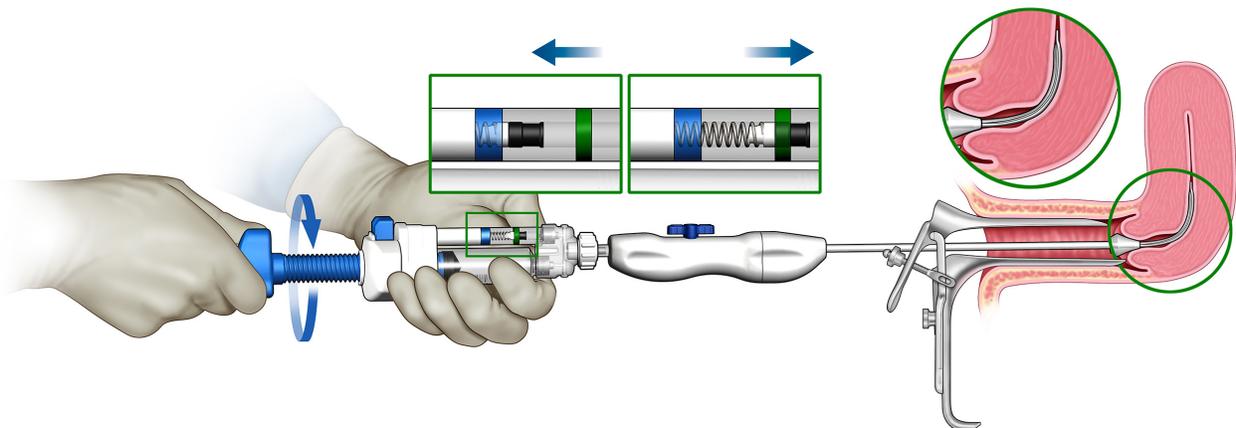


Figure 19: Splitting the Membrane

## Performing the Procedure

### 6. Rotate Stopcock (Figure 20):

- a. Turn the Stopcock so that it is perpendicular to the Proximal Handle as shown. This closes off the Membrane Flow Path leaving only the Balloon Flow Path open.

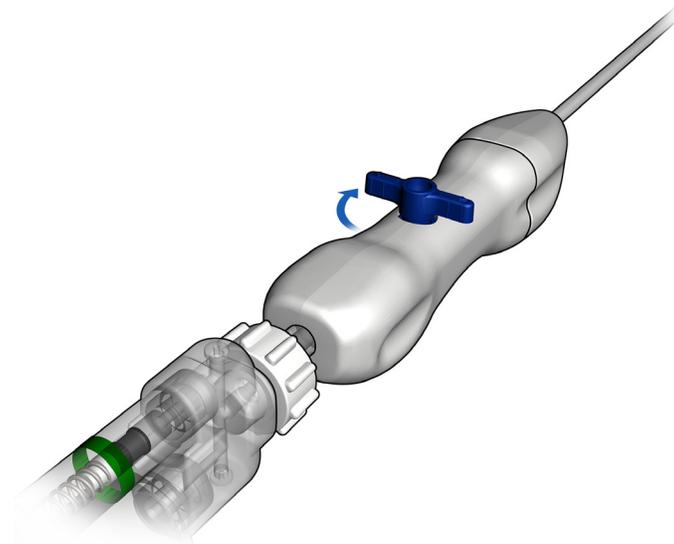


Figure 20: Position the Stopcock to Prepare the Dilator Balloon.

### 7. Inject saline to distend the Dilator Balloon within the cervical canal:

- a. Rotate the Plunger **CLOCKWISE** until the Pressure Indicator moves within the **BLUE** Dilation Zone (Figure 21 and Figure 22).
- b. If the Pressure Indicator falls below or outside of the **BLUE** Dilation Zone, inject more saline until the Pressure Indicator remains stable in the BLUE Dilation Zone (when the Pressure Indicator does not continue to move).
- c. **STOP** rotating the Plunger when the Pressure Indicator reaches and remains in the **BLUE** Dilation Zone.

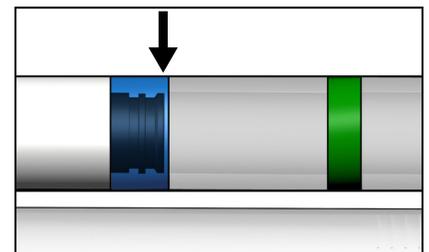


Figure 21: Pressure Indicator in BLUE Dilation Zone

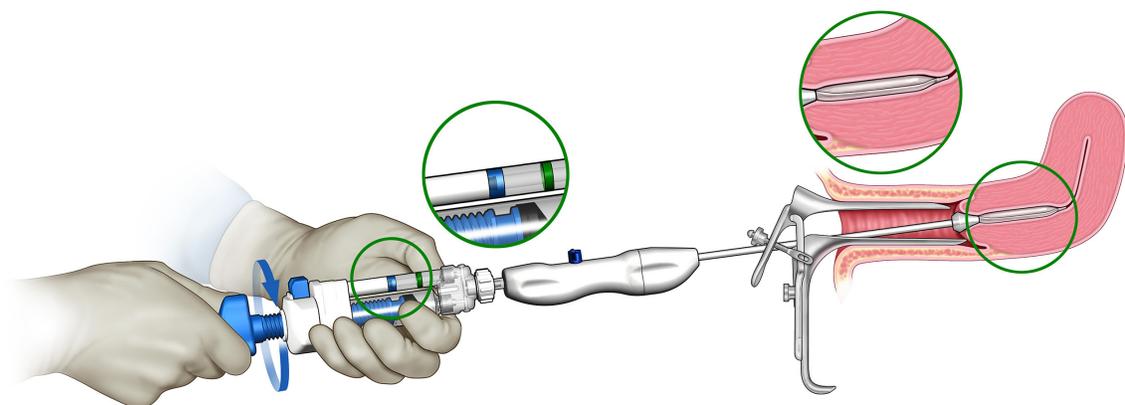


Figure 22: Dilating the Cervix

## Removing the Dilator Catheter

1. Remove the Dilator Catheter (Figure 23):
  - a. Slowly pull the entire Definity Cervical Dilator backward to remove the Dilator Catheter from the patient.

**NOTE:** THE DILATOR BALLOON DOES NOT REQUIRE DEPRESSURIZATION / DEFLATION TO BE REMOVED.

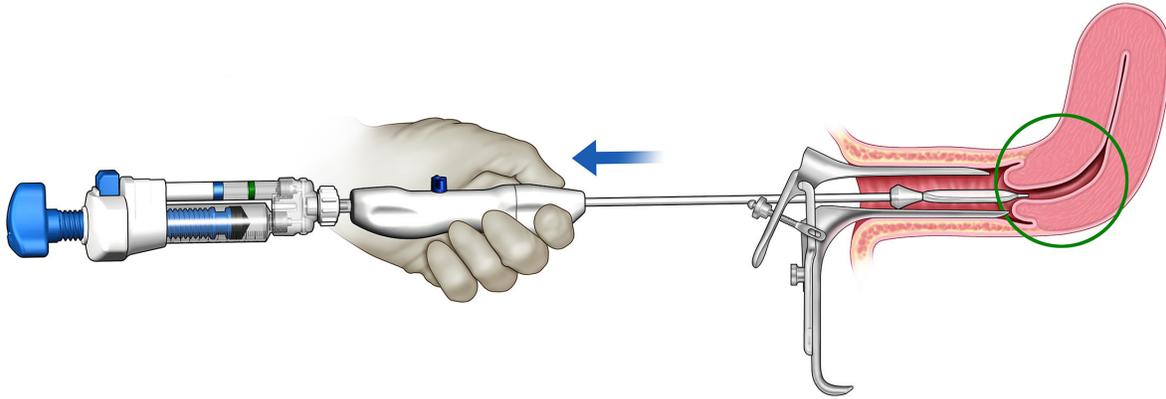


Figure 23: Removing the Dilator

## Troubleshooting

Table 3 lists the troubleshooting issues and resolutions.

Table 3: Troubleshooting

Issue	Resolution
Pressure Indicator is not moving when attempting to reach the <b>GREEN</b> Charge Zone during Device Preparation	<ul style="list-style-type: none"> <li>• Ensure the Release Button is not being held down.</li> <li>• Ensure the Plunger is being rotated clockwise.</li> <li>• Ensure the Inflation Device and Dilator Catheter are connected.</li> </ul>
Cannot visualize Membrane when pushing the handles together during the Membrane check step.	<ul style="list-style-type: none"> <li>• Ensure the Pressure Indicator is within the <b>GREEN</b> Charge Zone.</li> <li>• Ensure the Inflation Device has not become disconnected.</li> <li>• If handles do not easily advance toward each other, use fingers to push on the catheter shaft close to the distal handle in order to overcome resistance and get the catheter to slide through the distal handle.</li> </ul>
Membrane does not fully retract into the catheter Acorn Tip after the Membrane check step.	<ul style="list-style-type: none"> <li>• The Membrane does not need to be fully retracted into the catheter to achieve successful insertion into the cervical canal; therefore proceed to performing the procedure as described on page 11, step 1.</li> </ul>
When advancing the Membrane through the cervical canal, the Membrane is visible (has not entered the cervix)	<ul style="list-style-type: none"> <li>• Restart procedure but ensure that the Acorn Tip is held against the cervical os and not allowed to pull away.</li> </ul>
Pressure Indicator is not moving when attempting to split the Membrane.	<ul style="list-style-type: none"> <li>• Ensure the Inflation Device has not become disconnected.</li> <li>• Ensure the Plunger is being rotated clockwise.</li> <li>• If the Pressure Indicator is still not increasing, then the Membrane may have already split. Ensure the Inflation Device is connected to the Dilator Catheter, close the Stopcock, and continue to pressurize the Dilator Balloon.</li> </ul>
Pressure Indicator is not moving when attempting to distend the Dilator Balloon.	<ul style="list-style-type: none"> <li>• Ensure the Inflation Device has not become disconnected.</li> <li>• Ensure the Plunger is being rotated clockwise.</li> <li>• Ensure the stopcock is closed prior to increasing pressure in the Dilator Balloon.</li> <li>• Ensure there is enough fluid in the Inflation Device. If not, refill.</li> </ul>
There is not enough saline to complete the procedure.	<ul style="list-style-type: none"> <li>• Disconnect the Inflation Device from the Dilator Catheter and refill the syringe as per Step 2 on page 8.</li> </ul>
Dilator Balloon is difficult to remove when procedure is complete.	<ul style="list-style-type: none"> <li>• Ensure the Acorn Tip is located at the external cervical os and is not pushed into the cervix.</li> <li>• If the Acorn Tip is not within the cervix, reduce pressure by rotating the Plunger counterclockwise and remove the device.</li> </ul>

## Disposal

Dispose of the entire Definity Cervical Dilator components according to your facility's policies and procedures concerning biohazardous materials.

## General specifications

The Definity Cervical Dilator components have been sterilized with Ethylene oxide. It is not made with natural rubber latex.

Item	Specification
Catheter Working length	23 cm (230 mm) total working length
Dilator Balloon length	5 cm (50 mm)
Dilator Balloon diameter	5 mm, 7mm, or 9mm See product labeling for balloon diameter
Storage conditions	Relative humidity: <80% Temperature: -29°C to 60°C with good ventilation

## Warranty

Except as otherwise expressly stated in the Agreement: i) Equipment manufactured by Hologic is warranted to the original Customer to perform substantially in accordance with published product specifications for one (1) year starting from the date of shipment, or if Installation is required, from the date of Installation ("Warranty Period"); ii) digital imaging mammography x-ray tubes are warranted for twenty-four (24) months, during which the x-ray tubes are fully warranted for the first twelve (12) months and are warranted on a straight-line prorated basis during months 13-24; iii) replacement parts and remanufactured items are warranted for the remainder of the Warranty Period or ninety (90) days from shipment, whichever is longer; iv) consumable Supplies are warranted to conform to published specifications for a period ending on the expiration date shown on their respective packages; v) licensed Software is warranted to operate in accordance with published specifications; vi) Services are warranted to be supplied in a workman-like manner; vii) non-Hologic Manufactured Equipment is warranted through its manufacturer and such manufacturer's warranties shall extend to Hologic's customers, to the extent permitted by the manufacturer of such non-Hologic Manufactured Equipment. Hologic does not warrant that use of Products will be uninterrupted or error-free, or that Products will operate with non-Hologic authorized third-party products.

These warranties do not apply to any item that is: (a) repaired, moved, or altered other than by Hologic authorized service personnel; (b) subjected to physical (including thermal or electrical) abuse, stress, or misuse; (c) stored, maintained, or operated in any manner inconsistent with applicable Hologic specifications or instructions, including Customer's refusal to allow Hologic recommended Software upgrades; or (d) designated as supplied subject to a non-Hologic warranty or on a pre-release or "as-is" basis.

## For More Information

For Technical Support or reorder information in the United States, please contact:



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www.hologic.com

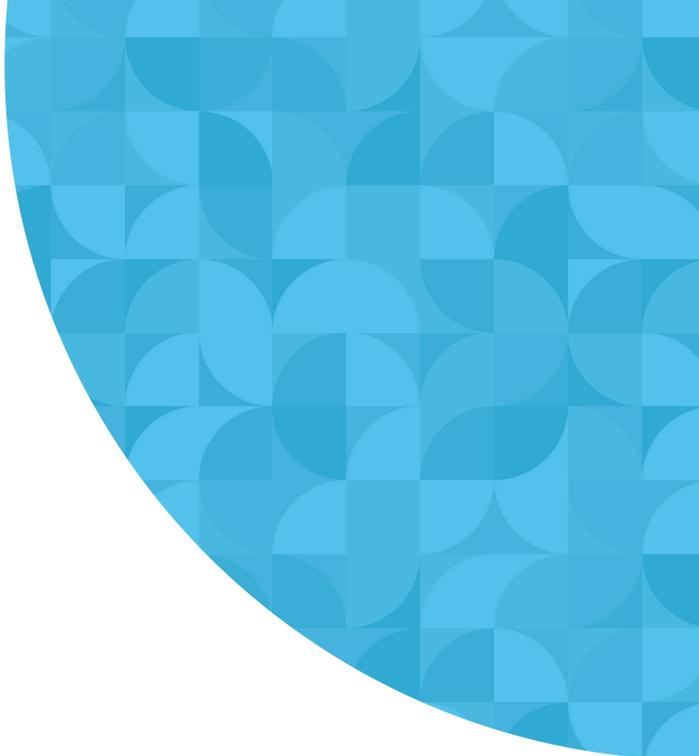
## Symbol Key

	Lot Number		Follow Instructions for Use
	Catalog Number		Manufacturer
	Quantity		Temperature Range is -29°C to 60°C
	Do not use if package is damaged		Humidity Range is 0 to 80%
	Do Not Reuse		Use By Date
	Do Not Re-sterilize		Consult Instructions for Use
	Sterilized by ETO		Prescription Use Only

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# Definity™

Cervical Dilator



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MAN-06489-001 Rev. 002