Important Information – Please Read Before Use

CAUTION

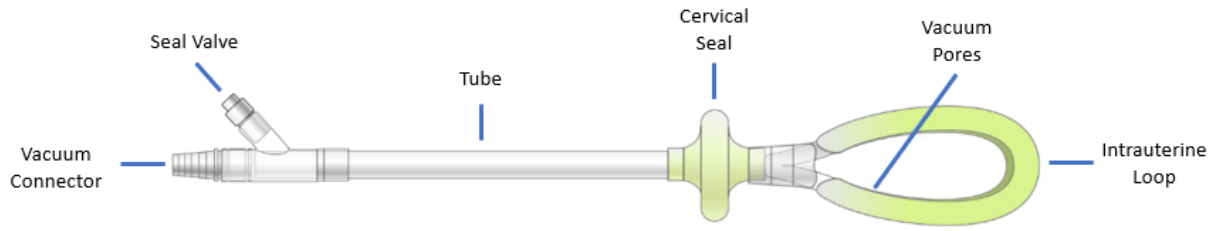
Federal law (USA) restricts this device to sale by or on the order of a physician. This medical device is intended for use by healthcare providers trained and experienced in obstetrics and gynecological techniques.

INDICATIONS FOR USE

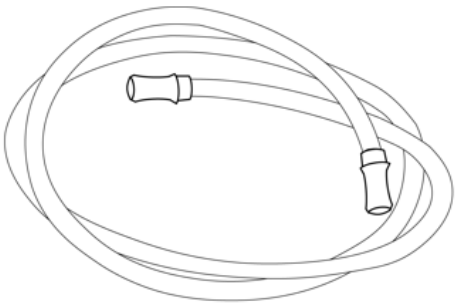
The Jada® System is intended to provide control and treatment of abnormal postpartum uterine bleeding or hemorrhage when conservative management is warranted.

DESCRIPTION

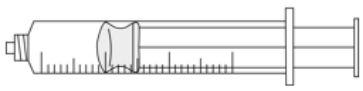
The Jada System is a 41 cm long intrauterine device made of silicone. Jada consists of an Intrauterine Loop on the distal end of a Tube. The proximal end of the Tube has a Vacuum Connector for connection to sterile vacuum tubing. The Cervical Seal proximal to the Intrauterine Loop is filled and emptied with a sterile luer tapered syringe filled with sterile fluid via the Seal Valve. The Intrauterine Loop consists of a loop tube with 20 Vacuum Pores oriented toward the inside diameter of the Intrauterine Loop. The outer surface of the Intrauterine Loop is covered by a Shield which overhangs the Vacuum Pores to protect tissue from vacuum and the Vacuum Pores from plugging with tissue and blood clots. A sterile luer tapered 60 mL syringe and a sterile 12’ vacuum tubing are supplied with the Jada System.



Jada System



12’ Vacuum Tubing



Luer Tapered 60 mL Syringe

CONTRAINDICATIONS

The following are contraindications to Jada use:

- Ongoing intrauterine pregnancy
- Untreated uterine rupture
- Unresolved uterine inversion
- Current cervical cancer
- Known uterine anomaly
- Current purulent infection of vagina, cervix, or uterus
- For C-sections: Cervix < 3 cm dilated before use of Jada

WARNINGS

- Avoid excessive force when inserting the Jada into the uterus or trauma to uterine wall may occur, including perforation.
- The safety and effectiveness of the Jada System in delivery at a gestational age < 34 weeks or, if multiples, uterus judged < 34 weeks size, have not been established. With smaller uterine size, there is potential for increased risk of perforation and expulsion.
- Signs of patient deterioration or failure to improve indicate the need for reassessment and possibly more aggressive treatment and management of postpartum hemorrhage (PPH)/abnormal postpartum uterine bleeding.
- Jada is not a substitute for surgical management and fluid resuscitation of life-threatening PPH/abnormal postpartum uterine bleeding.
- Remove air from Cervical Seal prior to device use to minimize risk of air embolism if Cervical Seal bursts.
- Always fill the Cervical Seal with sterile fluid. Never inflate with air, carbon dioxide, or any other gas to minimize risk of air embolism if Cervical Seal bursts.

PRECAUTIONS

- The safety and effectiveness of the use of Jada in patients with placenta accreta have not been evaluated.
- Use care when suturing any lacerations to avoid puncturing or damaging the material of the Cervical Seal.
- The maximum vacuum pressure is 90 mm Hg. Do not increase the vacuum pressure higher than 90 mm Hg. (90 mm Hg = 1.7 psi = 12.0 kPa = 3.5 in Hg = 120.0 mbar) or tissue trauma may occur.
- After initiation of vacuum, blood flow into Jada or the vacuum tubing and/or improvement in uterine tone should be noted. If this does not occur, the Cervical Seal and/or the vacuum may not be effective. If so, refer to Troubleshooting section.
- During treatment, the presence of intermittent or continuous air flow through Jada and vacuum tubing may indicate an issue with the Cervical Seal location or Cervical Seal coverage. If so, refer to the Troubleshooting section.

- Jada should not be left within the uterus for longer than 24 hours due to the possibility of an adverse tissue reaction or infection.
- The safety and effectiveness of the use of Jada in patients with Disseminated Intravascular Coagulation (DIC) have not been evaluated.

SUMMARY OF CLINICAL DATA

The safety and effectiveness of the Jada System was evaluated in the PEARLE study (**P**rospectiv**e**, Single Arm, Pivotal Clinic**a**l T**r**ia**l** D**e**signed to Assess the Safety and Effectiveness of the Jada System In Treating Primary Postpartum Hemorrhage "PPH") under an approved IDE from the U.S. Food and Drug Administration (FDA).

Study Design

PEARLE was a prospective, single-arm, literature-controlled, multi-center treatment study where each enrolled subject was treated with the Jada System. The primary endpoints of the study were:

- Primary Effectiveness Endpoint: control of postpartum hemorrhage, defined as the avoidance of non-surgical, second line or surgical intervention to control uterine hemorrhage after the use of the Jada System per the Instructions for Use.
- Primary Safety Endpoint: incidence, severity and seriousness of adverse events related to Jada.

The following Secondary Endpoints were evaluated in the PEARLE study:

- Time to hemorrhage control.
- Rate of non-surgical intervention required to control PPH after Jada use.
- Rate of surgical intervention required to control PPH after Jada use.
- Assessment of device usability.
- Rate of blood product transfusion required after Jada use, and number of transfusion units when administered.

Use of the Jada System occurred after failure of first line uterotonics and uterine massage.

The comparator to the Jada System was a literature meta-analysis of the Bakri® Postpartum Balloon. Based on a random effects model used in the meta-analysis, the estimated pooled proportion of subjects who reached control of uterine hemorrhage following Bakri Postpartum Balloon treatments was 82.0% (95% CI: 73.4% to 89.2%). By this definition, the study was considered a success if the lower bound of the two-sided Exact Clopper-Pearson mid-p 95% Confidence Interval for the Study Treatment Success was greater than or equal to 73.4%.

A total of 107 subjects were enrolled in PEARLE at 12 investigational centers in the United States.

Cohort	Subjects (N)
Total Subjects Enrolled*	107
Safety/Intent to Treat (ITT)**	106
Modified Intent to Treat (mITT)***	104
Per Protocol (PP)****	97

*All subjects in whom Jada insertion was attempted.
** All subjects in whom treatment was attempted with Jada (device inserted and vacuum turned on).
***All subjects in whom treatment was attempted with Jada (device inserted and vacuum turned on) and whose treatment was not aborted early for non-Jada reasons.
**** All subjects who completed Jada treatment per Jada's Instructions for Use, and who completed their 6-week visit without any major protocol deviations.

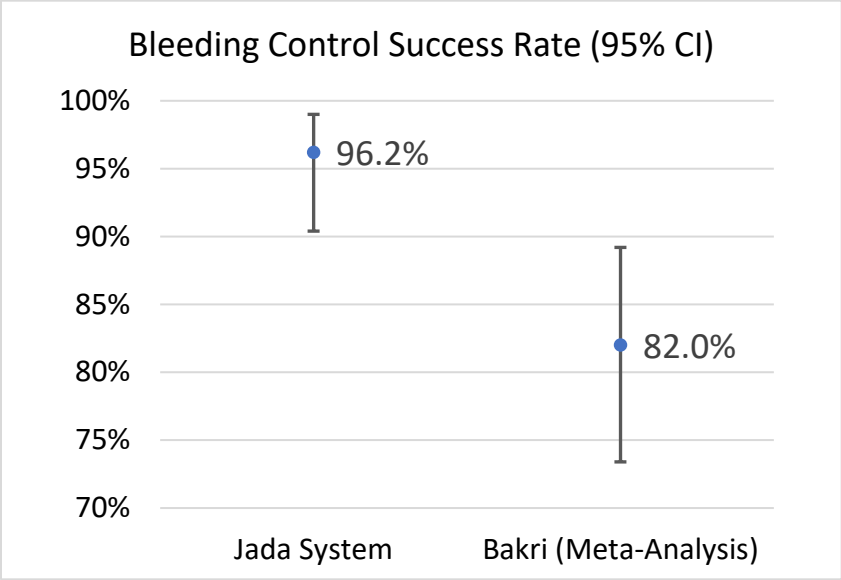
Primary Endpoints

Effectiveness

The analysis of effectiveness was based on the 106 subjects in the ITT Cohort. Results from the 104 subjects in the mITT and 97 subjects in the PP Cohort are also presented. The treatment success rate in the ITT Cohort was 94.3% (100/106, p<0.001), with a lower bound 95% confidence limit of 88.1%. One subject counted as a success in the study was treated with uterine balloon tamponade (UBT) prior to meeting the minimum EBL threshold. The UBT treatment was unsuccessful and continued blood loss occurred. After meeting the EBL threshold, the subject was treated with Jada which controlled hemorrhage without requiring further treatment. The treatment success rate of the comparator, the Bakri Postpartum Balloon, was 82.0% (95% CI: 73.4% to 89.2%). The treatment success rate in the mITT Cohort was 96.2 (95% CI: 90.4%, 98.9%). The confidence intervals for the mITT cohort and the meta-analysis of the comparator do not overlap.

Primary Effectiveness			
Cohort (N)	**Treatment Success**	**95% Confidence Limit (2-sided)**	***P* value**
ITT (N=106)	94.3% (100/106)	88.1%, 97.9%	<0.001
mITT (N=104)	96.2% (100/104)	90.4%, 98.9%	<0.001
PP (N=97)	99.0% (96/97)	94.4%, 100%	<0.001

Jada Success Rate Compared to Bakri Postpartum Balloon (mITT Cohort).



Safety

The analysis of safety was based on the 106 subjects in the Safety / ITT Cohort. There were no adverse events judged definitely related to the device or the procedure and there was a low rate of possibly related adverse events, all of which were anticipated in this patient population and with introduction of an intrauterine device. Five possibly device-related adverse events were rated as “mild” and three were rated as “moderate” without any event in this group rated “severe”. The three moderate events were cases of endometritis, which is a known risk of long labor, vaginal exam, and PPH.

Secondary Endpoints

Control of hemorrhage was defined in the protocol as the time from connecting the vacuum source to Jada to the time the first of any of the following occurs: there is no blood being collected in the tubing or canister, or the blood loss is observed as leveled off in the canister, or blood loss is at a rate of < 500 mL in 24 hours. The median time to control of PPH in the ITT, mITT and PP population was 3 minutes.

Timing of the procedure and duration of treatment was tracked from diagnosis through treatment and patient discharge for subjects enrolled in PEARLE. Jada was used most often within one hour after delivery. Bleeding was controlled quickly from the time of connection of vacuum, with a median control in three minutes. The duration of treatment with active vacuum connected was a median of 2 hours and 24 minutes with total in-dwelling time median of 3 hours and 11 minutes.

Duration of Treatment (ITT Cohort (N=106*))				
Procedural Steps	**Time (minutes)**			
	Mean	**SD**	**Median**	**Min, Max**
Time to control of hemorrhage	4.2	5.3	3.0	0, 35.0

Duration of Vacuum Treatment (Protocol: ≥ 60 minutes)	248.8	261.1	144.0	57, 1276
Total in-dwelling time (Treatment + Verification)	306.0	274.9	191.0	70, 1400

*Timing of steps was available in 100 subjects in whom bleeding was successfully controlled with Jada alone.

The median hospital length of stay from delivery time was 2.2 days.

The need for non-surgical intervention after use of Jada was rare, with only 2 subjects receiving non-surgical intervention in the ITT Cohort.

Surgical intervention after Jada treatment was reported in three subjects: one subject received a B-Lynch compression suture in conjunction with Jada, one subject received B-Lynch compression suture followed by hysterectomy, and one subject underwent hysterectomy.

Rate of Non-surgical and Surgical Intervention After Jada Use			
Cohort	**Non-Surgical Intervention**	**Surgical Intervention**	**No Intervention Needed**
ITT	2/106 (1.9%) (95% CI: 0.2%, 6.7%)	3/106 (2.8%) (95% CI: 0.6%, 8.1%)	101*/106 (95.3%)
mITT	1/104 (0.9%) (95% CI: 0%, 5.2%)	3/104 (2.9%) (95% CI: 0.6%, 8.2%)	100/104 (96.2%)
PP	0/97 (0%)	1/97 (1.0%)	96/97 (99%)

*One subject who did not meet the success criteria in the ITT Cohort did not have any further intervention for uterine bleeding post Jada use.

The device usability was notably positive by investigators on all measurements.

Investigators Experience with Jada Use (N=107)	
Category Evaluated	**Response (Agreed or Strongly Agreed)**
IFU and device training clearly explained use	100%
Jada was easy to insert and position	96.3%
Jada was easy to remove	98.1%
Jada use did not inhibit other care	98.1%
Jada was easy to use	98.1%
Would recommend Jada to treat PPH	97.2%

In the study, 40 subjects (37.7%) in the ITT Cohort, 38 subjects (36.5%) in the mITT Cohort and 33 subjects (34.0%) in the PP Cohort received any blood product replacement. Transfusion of four or more units of packed red blood cells (PRBC) occurred in five subjects (4.7%) in the ITT Cohort, five subjects (4.8%) in the mITT Cohort and four subjects (4.1%) in the PP Cohort. No subject developed disseminated intravascular coagulation (DIC) on the study.

Additional Treatment

A subset of subjects received tranexamic acid (TXA) along with uterotonics and uterine massage for treatment of PPH. TXA was used in 41/106 (39%) subjects in the ITT cohort.

Summary of TXA Usage in Study Subjects (ITT Cohort (N=106))	
Timing of TXA Usage	**Number of Subjects (%)**
Any use of TXA in Study Subject	41/106 (39%)
Before Jada Use	22/106 (21%)
During Jada Use	10/106 (9%)
After Jada Use	3/106 (3%)
Before and During Jada Use	4/106 (4%)
Before and After Jada Use	2/106 (2%)

The safety data evaluation showed there were no device deficiencies or adverse events reported related to use of TXA in study subjects.

Summary of Effectiveness Results for Subjects With and Without TXA (ITT Cohort (N=106))	
TXA Usage Timing	**Success Rate per Primary Effectiveness Endpoint % (n/N)**
No TXA Use	100% (65/65)
Any TXA Use	85% (35/41)
Before Jada Use	96% (21/22)
During Jada Use	80% (8/10)
After Jada Use	33% (1/3)
Before and During Jada Use	100% (4/4)
Before and After Jada Use	50% (1/2)

Additional Analyses by Delivery Mode

Sub-group analysis of effectiveness rate was evaluated by mode of delivery, vaginal or c-section. For the ITT population of 106 subjects, there were 91 vaginal deliveries with three failures, and 15 c-sections with three failures. One subject counted as a success in the study was treated after vaginal delivery with uterine balloon

tamponade (UBT) prior to meeting the minimum EBL threshold. The UBT treatment was unsuccessful and continued blood loss occurred. After meeting the EBL threshold, the subject was treated with Jada which controlled hemorrhage without requiring further treatment. The success rates in the ITT Cohort were 96.7% and 80.0% after vaginal and c-section birth, respectively. In the mITT Cohort, success rates were 98.9% and 80.0%, respectively. In the PP Cohort, the success rates were 100.0% and 91.7%, respectively.

Effectiveness of Jada by Delivery Type/Cohort						
	Vaginal Delivery			**C-Section**		
Primary Effectiveness	**ITT (N=91)**	**mITT (N=89)**	**PP (N=85)**	**ITT (N=15)**	**mITT (N=15)**	**PP (N=12)**
	88/91 (96.7%)	88/89 (98.9%)	85/85 (100.0%)	12/15 (80.0%)	12/15 (80.0%)	11/12 (91.7%)
Time to Hemorrhage Control with Jada Success (minutes)	**ITT (N=88)**	**mITT (N=88)**	**PP (N=85)**	**ITT (N=12)**	**mITT (N=12)**	**PP (N=11)**
Mean	3.8	3.8	3.8	7.1	7.1	7.2
SD	4.6	4.6	4.6	8.7	8.7	9.1
Median	3.0	3.0	3.0	4.0	4.0	3.0
Min, Max	0, 35	0, 35	0, 35	0, 29	0, 29	0, 29

Summary

The results of the PEARLE study demonstrated that the Jada System is safe with an effectiveness rate of 94.3% for its intended use. The effectiveness rates in the mITT and PP Cohorts were 96.2% and 99.0%, respectively. There were no adverse events judged definitely related to the device or the procedure, and there was a low rate of possibly related adverse events, all of which were anticipated in this patient population and with introduction of an intrauterine device.

The secondary endpoints were also overwhelmingly positive. Bleeding was controlled in 3 minutes in the ITT, mITT and PP populations. The rate of further surgical or non-surgical intervention after Jada was very low. The rate of blood transfusion was expected in this patient population, treated at U.S. hospitals with ready access to these resources. The median reported total time for Jada treatment with vacuum in this study was 2 hours and 24 minutes, and total in-dwelling time was 3 hours and 11 minutes.

Additional clinical data collected outside the United States

First-in-Woman Study Results

A First-in-Woman (FIW) feasibility study with Ethics Committee oversight was conducted at two clinical sites in Indonesia. The purpose of the study was to demonstrate the placement, function, and operation of the Jada System to meet its intended use.

Ten subjects were enrolled in the feasibility study. None of the subjects presented with a retained placenta, uterine lacerations, uterine scarring, or for any conditions other than atonic postpartum hemorrhage. Bleeding

was controlled within two minutes for all ten subjects. Evaluation of the primary clinical data safety endpoints determined that: 1) no safety issues were observed relative to the placement, insertion, or removal of the Jada, 2) there were no complications related to delayed arrest of blood loss, 3) there was no damage to the uterus, cervix, or vagina, and 4) no uterine inversion or folding events were observed during the Jada procedure.

Case Series Outside the United States

Thirteen subjects were enrolled at the clinical trial site at St. Francis Hospital Nsambya, in Kampala, Uganda under an earlier iteration of the PEARLE study protocol with similar inclusion/exclusion criteria.

Jada was effective at treating PPH in all 13 subjects, including three subjects who were enrolled despite estimated blood loss (EBL) at study entry significantly higher than allowed per study inclusion criterion. Hemorrhage was controlled in each subject but two subjects subsequently died due to lack of blood product supply for transfusion to treat their severe blood loss. There were no adverse events designated definitely related to the device or the procedure.

INSTRUCTIONS FOR USE

Pre-Jada Patient Evaluation

Precaution: The safety and effectiveness of the use of Jada in patients with placenta accreta have not been evaluated.

1. Evaluate for lacerations, retained products of conception, or other causes of bleeding, and remove any organized clots prior to using Jada.

Note: Prioritization of laceration repair and placement of Jada for atony-related bleeding is up to the judgment of the provider. Repair of vaginal and external genital lacerations can be performed with the Jada in place.

Precaution: Use care when suturing any lacerations to avoid puncturing or damaging the material of the Cervical Seal.

Jada Preparation

2. Inspect the packaging and Jada before use.
3. Ensure that the bladder is empty (straight cath or place Foley) in order to facilitate palpation and contraction of the uterus.
4. Connect a vacuum canister and sterile standard vacuum tubing to a regulated vacuum source.
5. Attach a sterile luer tapered syringe to remove any air that is in the Cervical Seal.
6. Fill sterile luer tapered syringe with 60 mL of sterile fluid.

Jada Placement: Post Vaginal Delivery or Post Cesarean Section After Closure of Hysterotomy

7. Secure visualization of the cervix to confirm it is dilated ≥ 3 cm to allow for placement of Jada.
8. Using a hand, compress the Intrauterine Loop near the distal tip for support and insert Jada transvaginally, leading with the Intrauterine Loop (**See Figure 1**). Avoid excessive force. Use gentle traction on the

anterior cervical lip to stabilize the cervical opening, if needed. An instrument can be placed on the anterior cervical lip, but do not grasp Jada with an instrument to facilitate intrauterine insertion.

9. Place Jada such that the Intrauterine Loop is located in the uterus and is oriented in the frontal plane of the body by assuring the Seal Valve is oriented at either 3 or 9 o'clock. Ultrasound may be used to confirm proper placement of the Intrauterine Loop within the uterus.

10. After insertion, the Intrauterine Loop should be within the uterus while the Cervical Seal should be located within the vagina at the external cervical os (**See Figure 2**).

Note: If clinically relevant, a B-Lynch compression suture may be used in conjunction with Jada.

Filling of Cervical Seal and Connection of Vacuum

11. While securely holding the Seal Valve and avoiding unintentional proximal or distal movement of the Cervical Seal away from the external cervical os, attach a sterile luer tapered syringe to fill the Cervical Seal with 60 mL of sterile fluid. If needed, add up to another 60 mL of sterile fluid to achieve coverage of the external cervical os and create a seal for vacuum (**See Figure 3**).

12. Set the vacuum source to 80 mm Hg +/- 10 mm Hg while occluding the end of the tubing (80 mm Hg = 1.5 psi = 10.7 kPa = 3.2 in Hg = 106.7 mbar) (**See Figure 4**).

Precaution: The maximum vacuum pressure is 90 mm Hg. Do not increase the vacuum pressure higher than 90 mm Hg. (90 mm Hg = 1.7 psi = 12.0 kPa = 3.5 in Hg = 120.0 mbar) or tissue trauma may occur.

13. After the vacuum pressure has been set and confirmed, connect Jada to the sterile vacuum tubing (**See Figure 5**). Blood flow into the vacuum tubing and/or improvement in uterine tone should be noted after initiation of vacuum.

Note: Confirm that the Cervical Seal is positioned at the external cervical os after the system is in place (Cervical Seal is filled and the vacuum is connected). Reposition Jada if required to facilitate a seal.

14. After initial evacuation of any pooled blood, presentation may vary during treatment: there may be no further blood evacuation, or additional blood moving into the tubing, or accumulation of blood in the canister. If blood flow does not stop or slow sufficiently, consider increasing the vacuum pressure in accordance with your clinical judgment, not to exceed a maximum pressure of 90 mm Hg.

15. Tape Jada to the patient's inner thigh without tension.

Precaution: Ensure Jada is secured with tape to avoid unintentional dislodgement.

16. Leave Jada in place with the vacuum applied until:

    - PPH/abnormal postpartum uterine bleeding is controlled for at least 1 hour,
    - The uterus is firm,
    - Patient is stable.

17. Consider prophylactic antibiotics for prolonged use.

Verify and End Treatment

18. Before disconnecting vacuum, assess the patient to confirm that treatment is no longer needed.

19. Disconnect vacuum tubing from Jada while vacuum is on to collect any blood from the tubing into the canister. Secure tubing in case re-application of vacuum is needed.

20. Attach a luer tapered syringe to remove the fluid from the Cervical Seal and keep the Jada System in place for at least 30 minutes while monitoring for any recurrent uterine bleeding.

Jada Removal

Precaution: to avoid uterine inversion, do not remove the Jada while vacuum is applied. Always disconnect Jada from vacuum tubing before removal.

Precaution: remove all fluid from the Cervical Seal prior to removing Jada to avoid disruption of the vaginal mucosa or any sutured lacerations.

21. If PPH/abnormal postpartum uterine bleeding remains controlled and the uterus remains firm for a minimum of 30 minutes after vacuum is disconnected, remove Jada.
22. Place one hand on the abdomen to secure the uterine fundus while the other hand slowly withdraws the device.

TROUBLESHOOTING

SITUATION	**RECOMMENDED ACTION**
Vacuum is not detected at the end of the vacuum tubing.	a) Check connection on all system components: • Confirm vacuum source is functional, including regulator. • Confirm lid of vacuum canister is fully seated and that canister is not cracked. • Confirm vacuum tubing is securely connected at both ends and any connection in between. b) Confirm desired vacuum level is regulated in the appropriate units (i.e. mm Hg vs. cm Hg).
Vacuum system is connected and working but uterus does not collapse and/or bleeding does not stop.	a) Increase vacuum pressure to maximum (90 mm Hg). b) Disconnect the vacuum tubing from Jada and occlude the end of the tubing to check vacuum. c) Confirm appropriate Jada placement, with ultrasound if needed: • Confirm proper placement of Intrauterine Loop in uterus (vs. misplacement in posterior vaginal fornix). • Confirm proper placement of Cervical Seal outside of the cervical os (vs. misplacement into uterus). • Ensure Cervical Seal is sufficiently filled with sterile fluid to create adequate seal at the cervix. d) Re-evaluate patient for other sources of bleeding.

HOW SUPPLIED

Jada, luer tapered 60 mL syringe and vacuum tubing are supplied sterile. Jada and other components are sterile if package is unopened or undamaged. Do not use Jada or other components if there is doubt as to whether the devices are sterile.

MATERIALS REQUIRED BUT NOT SUPPLIED

- Sterile fluids
- Vacuum canister
- Regulated vacuum source
- Tape

STORAGE

Handle with care. Store in original packaging in a clean, cool, and dry location. Avoid exposure to temperature and humidity extremes.

RE-STERILIZATION/RE-USE

Jada, luer tapered 60 mL syringe and vacuum tubing are for single-patient use only. Do not reuse, reprocess, or re-sterilize. Reuse of Jada, luer tapered 60 mL syringe or vacuum tubing may lead to cross contamination, infection, or patient death.

SYMBOL GLOSSARY

Sources: **21 CFR 801** Labeling and **ISO 15223-1:2016** *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.*

Symbol	Title	Meaning/Definition	Standard/ Ref. Number
	Catalog Number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	ISO 15223-1 5.1.6
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1 5.1.5
	Date of manufacture	Indicates the date when the medical device was manufactured.	ISO 15223-1 5.1.3
	Use-by date	Indicates the date after which the medical device is not to be used.	ISO 15223-1 5.1.4
	Prescription Only	"CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN."	21 CFR 801.109
	Consult instructions for use or consult	Indicates the need for the user to consult the instructions for use.	ISO 15223-1 5.4.3

Symbol	Title	Meaning/Definition	Standard/ Ref. Number
	electronic instructions for use		
	Caution	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.	ISO 15223-1 5.4.4
	Keep away from sunlight	Indicates a medical device that needs protection from light sources.	ISO 15223-1 5.3.2
	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.	ISO 15223-1 5.2.4
	Sterilized using ethylene oxide treatment	Indicates a medical device that has been sterilized using ethylene oxide.	ISO 15223-1 5.2.3
	Does not contain natural rubber latex	Indicates the absence of dry natural rubber or natural rubber latex as a material of construction within the medical device or the packaging of a medical device.	ISO 15223-1 5.4.5
	Keep Dry	Indicates a medical device that needs to be protected from moisture.	ISO 15223-1 5.3.4
	Do not re-use	Indicates a medical device that is intended for one single use only.	ISO 15223-1 5.4.2
	Do not use if package is damaged and consult instructions for use	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.	ISO 15223-1 5.2.8
	Do not resterilize	Indicates a medical device that is not to be resterilized.	ISO 15223-1 5.2.6
	Manufacturer	Indicates the medical device manufacturer	ISO 15223-1 5.1.1

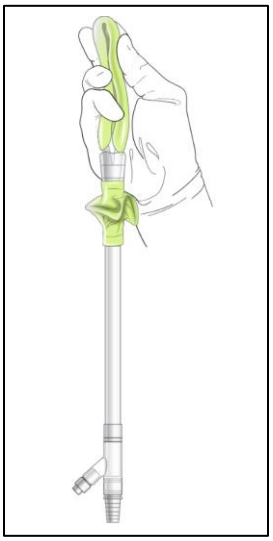


Figure 1

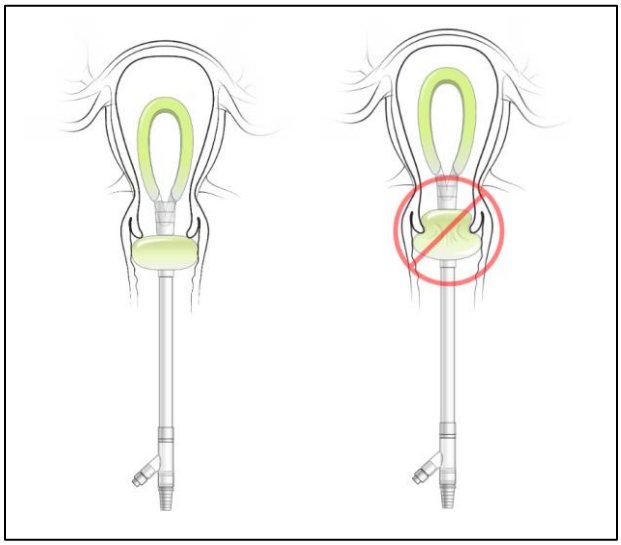


Figure 2

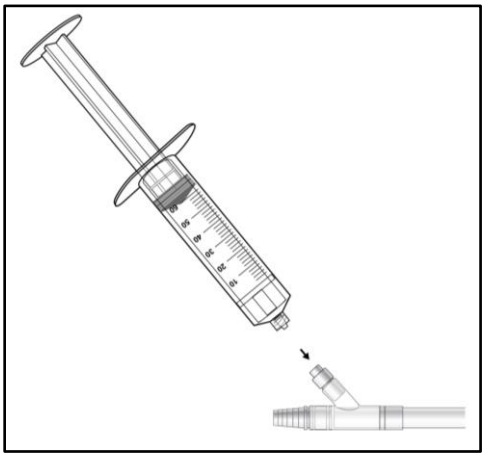


Figure 3

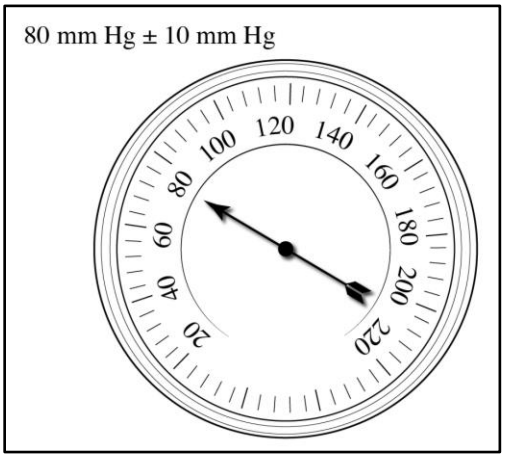


Figure 4

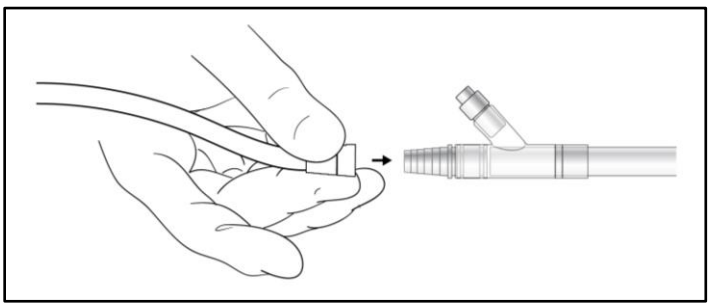


Figure 5

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For patent information: www.organon.com/our-solutions/patent/

LBL-24 v3.0 | Effective 10/31/2022

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