JADA® SYSTEM

IMPORTANT INFORMATION: PLEASE READ BEFORE USE

CAUTION: This medical device is intended for use by healthcare providers trained and experienced in obstetrics.

INDICATION FOR USE

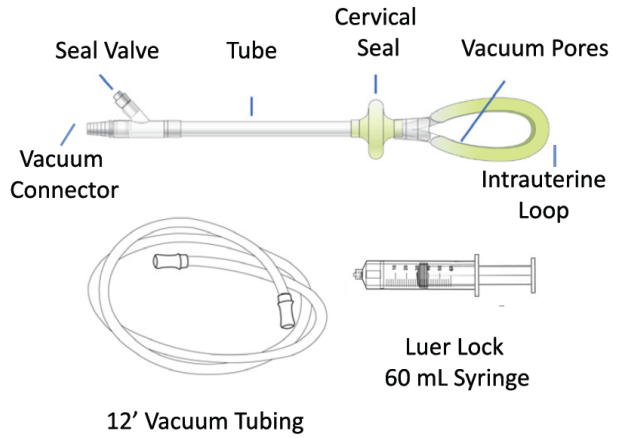
The JADA® System is intended to provide control and treatment of abnormal postpartum uterine bleeding or hemorrhage when conservative management is warranted.

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 lock syringe filled with sterile fluid via the Seal Valve. The Intrauterine Loop consists of a loop tube with 21 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 lock 60 mL syringe and a sterile 12’ vacuum tubing are supplied with the JADA System.

HOW SUPPLIED

JADA System



WARNING: Do not use JADA or other components if damage is apparent or there is doubt as to whether the device or components are sterile. Use of non-sterile device or components may lead to increased risk of infection.

- JADA, luer lock 60 mL syringe and 12’ vacuum tubing are supplied sterile.
- JADA sterilization is performed using gamma radiation.
- JADA and other components are sterile if package is unopened or undamaged.

MATERIALS REQUIRED BUT NOT SUPPLIED

- Sterile fluids
- Vacuum canister

- Regulated vacuum source
- Tape

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 is less than 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 use of JADA is not a substitute for appropriate medical management of Disseminated Intravascular Coagulation (DIC). The safety and effectiveness of the use of JADA in patients with DIC have not been evaluated.
- The safety and effectiveness of the JADA System in delivery at a gestational age under 34 weeks or, if multiples, uterus judged under 34 weeks size, have not been established. With smaller uterine size, there is potential for increased risk of perforation and expulsion.
- The safety and effectiveness of the JADA System after the first 24 hours following delivery have not been evaluated.
- Signs of patient deterioration or failure to improve indicate the need for reassessment and possibly more aggressive treatment and management of postpartum hemorrhage (PPH) or abnormal postpartum uterine bleeding.
- JADA is not a substitute for surgical and medical management and fluid resuscitation of life-threatening PPH/abnormal postpartum uterine bleeding.
- Remove air from the Cervical Seal prior to device use to minimize risk of air embolism if the 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 the Cervical Seal bursts.
- JADA and other components are for single patient use only. Do not reuse, reprocess, or re-sterilize. Reuse of JADA and other components may lead to cross contamination, infection, or patient death.
- Do not use JADA or other components if damage is apparent or there is doubt as to whether the device or components are sterile. Use of non-sterile device or components may lead to increased risk of infection.

PRECAUTIONS

- The safety and effectiveness of the use of JADA in patients with known or suspected Placenta Accreta Spectrum (PAS) disorders (e.g. placenta accreta, percreta or increta) have not been evaluated.
- Use care when suturing any lacerations to avoid puncturing or damaging the material of the Cervical Seal or when placing a surgical compression suture to avoid inadvertently suturing the intrauterine loop of the JADA in place.
- The maximum vacuum pressure to use with JADA is 90 mmHg. Do not increase the vacuum pressure higher than 90 mmHg or tissue trauma may occur.

  - **Note:** (90 mmHg = 1.7 psi = 12.0 kPa = 3.5 inHg = 120.0 mbar)
- After connection 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.
- If the clinical situation warrants use of JADA for longer than 24 hours, the risk increases for the possibility of an adverse tissue reaction or infection.
- If prolonged use is necessary due to persistent or continued bleeding, consider prophylactic antibiotics.
- To avoid uterine inversion, do not remove JADA while vacuum is applied. Always disconnect JADA from vacuum tubing before removal.
- Remove all fluid from the Cervical Seal prior to removing JADA to avoid tissue disruption.
- Uterine damage or disruption of hysterotomy sutures could occur if the Cervical Seal is inflated past the external cervical os.

INSTRUCTIONS FOR USE

IMPORTANT: Always complete the patient evaluation before using the JADA System.

1. EVALUATE PATIENT

A. Evaluate for lacerations, retained products of conception, or other causes of bleeding.
B. Remove any organized clots prior to using JADA.
C. Prior to insertion of JADA, and for duration of use, ensure the patient's bladder is empty (periodic straight catheter or place Foley) to facilitate palpation and contraction of the uterus.

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

D. Post-Caesarean Patients:
- Confirm cervix is dilated at least 3 cm.
- Confirm closure of hysterotomy prior to insertion.

NOTE: JADA will be placed transvaginally.

2. PREPARE JADA SYSTEM

WARNING: Do not use JADA or other components if damage is apparent or there is doubt as to whether the device or components are sterile. Use of non-sterile device or components may lead to increased risk of infection.

A. Inspect the packaging and JADA for possible signs of damage before use.

NOTE: JADA and other components are sterile if package is unopened or undamaged.

B. Connect a vacuum canister and the vacuum tubing to a regulated vacuum source.
C. While occluding the end of the tubing set the vacuum source to 80 mmHg.

NOTE: (80 mmHg = 1.5 psi = 10.7 kPa = 3.2 inHg = 106.7 mbar)

IMPORTANT: Do not attach vacuum to JADA until Step 5.

D. Attach the syringe to the Seal Valve.
E. Remove any air in the Cervical Seal using the syringe.
F. Remove syringe from Seal Valve.
G. Fill the syringe with 60 mL of sterile fluid.

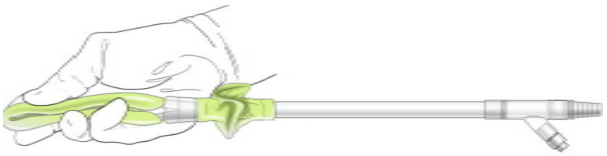
H. Set aside syringe for later use.

3. PLACE JADA

IMPORTANT: JADA can be placed post Vaginal Delivery or Post Caesarean Section After Closure of Hysterotomy.

WARNING: Avoid excessive force when inserting the JADA into the uterus or trauma to uterine wall may occur, including perforation.

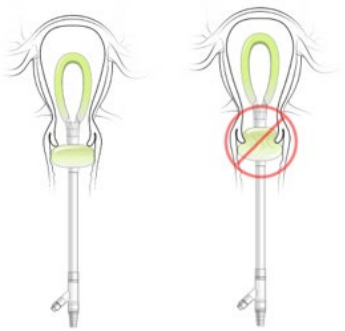
A. Confirm cervix is dilated at least 3 cm.
B. Using one hand, compress the Intrauterine Loop near the distal tip.
C. Insert JADA transvaginally, leading with the Intrauterine Loop. Avoid excessive force.



NOTE: If needed, use gentle traction on the anterior cervical lip to stabilize the cervical opening.

IMPORTANT: If needed, an instrument can be placed on the anterior cervical lip, but **do not** grasp JADA with an instrument to facilitate intrauterine insertion.

D. Place JADA such that:
- The Intrauterine Loop is located in the uterus,
- The Seal Valve is easily accessible (recommended around 3 or 9 o'clock position), AND
- The Cervical Seal is located within the vagina at the external cervical os.

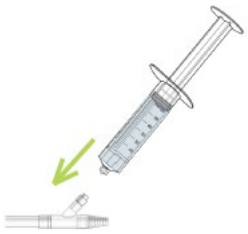


NOTES:
- Ultrasound may be used to confirm proper intrauterine placement.

- If clinically indicated, a surgical compression suture may be used in conjunction with JADA.

4. FILL CERVICAL SEAL

A. Avoid movement of the Cervical Seal.
B. Securely hold the Seal Valve.
C. Attach the filled syringe to the Seal Valve.

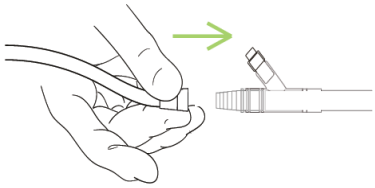


D. Fill the Cervical Seal with **60 mL** of sterile fluid.
E. Ensure Cervical Seal covers the external cervical os. This will create a seal for the vacuum.

NOTE: If needed, add up to another **60 mL** of sterile fluid to cover the external cervical os.

5. START TREATMENT

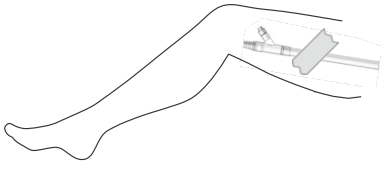
A. Connect vacuum tubing to JADA. Maximum vacuum pressure to use with JADA is 90 mmHg.



B. After connecting vacuum **CHECK**:
- Blood flows into the vacuum tubing and/or
- Improvement in uterine tone is observed.
- The Cervical Seal is positioned at the external cervical os.
- The Cervical Seal is filled, and the vacuum is connected.
- Reposition JADA, if required, to create a seal.

IMPORTANT:
- After connection 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.**

C. To avoid unintentional dislodgement, secure JADA with tape to the patient's inner thigh without tension.



6. ACTIVE TREATMENT

A. Leave JADA in place with the vacuum applied until:
   - PPH/abnormal postpartum uterine bleeding is **CONTROLLED FOR AT LEAST 1 HOUR**,
   - AND the uterus is firm,
   - AND the patient is clinically and hemodynamically stable.

B. After initial evacuation of any pooled blood, appearance 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.
C. If blood flow does not stop or slow sufficiently, consider increasing the vacuum pressure in accordance with your clinical judgment. Do not exceed a maximum pressure of 90 mmHg.

PRECAUTION: The maximum vacuum pressure to use with JADA is 90 mmHg. Do not increase the vacuum pressure higher than 90 mmHg or tissue trauma may occur.

NOTE: (90 mmHg = 1.7 psi = 12.0 kPa = 3.5 inHg = 120.0 mbar)

PRECAUTION: If the clinical situation warrants use of JADA for longer than 24 hours, the risk increases for the possibility of an adverse tissue reaction or infection.

PRECAUTION: If prolonged use is necessary due to persistent or continued bleeding, consider prophylactic antibiotics.

7. VERIFY AND END TREATMENT

PRECAUTION: To avoid uterine inversion, do not remove JADA while vacuum is applied. Always disconnect JADA from vacuum tubing before removal.

A. **Before disconnecting vacuum,** assess the patient to confirm that treatment is no longer needed.
B. Turn off the vacuum.
C. Disconnect the vacuum tubing from JADA.
D. Set aside vacuum tubing in case re-application of vacuum is needed.
E. Attach the syringe to the Seal Valve.
F. Use the syringe to remove the fluid from the Cervical Seal.
G. **Before removing JADA,** observe the patient for a minimum of **30 minutes** to ensure:
   - PPH/abnormal postpartum bleeding is controlled.
   - The uterus is firm.
   - The patient is clinically and hemodynamically stable.

IMPORTANT: If bleeding recurs, re-evaluate patient and consider repeating Steps 4-7, if appropriate.

8. JADA REMOVAL

PRECAUTION: Remove all fluid from the Cervical Seal prior to removing JADA to avoid tissue disruption.

A. Place one hand on the abdomen to secure the uterine fundus.
B. Slowly withdraw the device with your other hand.

NOTES:

- If there is difficulty removing JADA in a patient in whom a surgical compression suture was placed, consider the possibility that the JADA device has been inadvertently sutured by the surgical compression suture.
- If suspected, the surgical compression suture may need to be removed before JADA can be removed, to avoid harm to the uterine wall or the device.

C. Always inspect JADA after removal to ensure it is intact.

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 vacuum pressure setting is appropriate for units of measure on the regulator.
Uterus does not collapse and/or bleeding does not stop.	A. 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. B. Increase vacuum pressure to **MAXIMUM 90 mmHg.** If bleeding continues and/or uterus does not collapse, **DO NOT INCREASE VACUUM PRESSURE ABOVE 90 mmHg OR TISSUE TRAUMA MAY OCCUR**. C. Consider whether clots may be present within the uterus, occluding the Vacuum Pores. • If clots are suspected, JADA may need to be removed to remove clots. D. Disconnect the vacuum tubing from JADA and occlude the end of the tubing to check vacuum. E. Re-evaluate patient for other sources of bleeding.

RE-STERILIZATION/RE-USE

WARNING: JADA and other components are for single patient use only. Do not reuse, reprocess, or re-sterilize. Reuse of JADA and other components may lead to cross contamination, infection, or patient death.

STORAGE

Handle with care. Do not store in direct sunlight. Store in original packaging in a dry location.

DISPOSAL

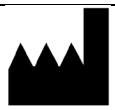
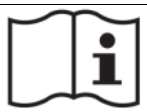
Always follow current local regulations governing biohazard waste to safely handle and dispose of biohazard waste.

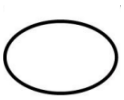
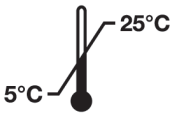
Questions / Concerns:
1-844-820-5468
dpoc.canada@organon.com

Manufacturer: Organon LLC, 30 Hudson Street, Jersey City, NJ 07302 USA

Distributor: Organon Canada Inc., 16766 Trans-Canada Highway, Suite 300, Kirkland (Québec), Canada, H9H 4M7

SYMBOL GLOSSARY

SYMBOL	DESCRIPTION	SYMBOL	DESCRIPTION
	Manufacturer		Sterilized using irradiation
	Do not use if package is damaged and consult instructions for use		Sterilized using ethylene oxide
	Do not re-use		Do not re-sterilize
	Consult instructions for use or electronic instructions for use		Batch Code
	Use-by date		Catalog Number
	Does not contain natural rubber latex		Keep away from sunlight
	Medical Device		Keep dry
	Date of manufacture		Exercise caution when using the device. Refer to the Instructions for Use for important safety information.

	Important		Caution/Precaution
	Troubleshooting		Warning
	Single sterile barrier system		Single sterile barrier system with protective packaging outside
	Storage temperature range		