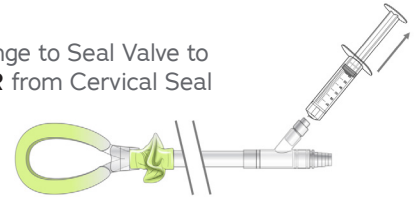


1. EVALUATE PATIENT & PREPARE JADA

Evaluate patient for lacerations, retained products of conception, or other causes of bleeding before using Jada.

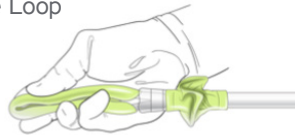
Connect a vacuum canister and standard vacuum tubing to a regulated vacuum source.

Connect syringe to Seal Valve to **REMOVE AIR** from Cervical Seal before use.



2. INSERT JADA

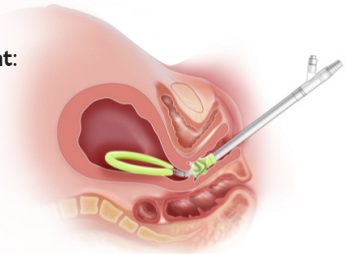
Manually compress Intrauterine Loop and **insert transvaginally**. Avoid excessive force. Do not grasp Jada with an instrument to facilitate intrauterine insertion.



Use gentle traction on the anterior cervical lip to stabilize the cervical opening, if needed.

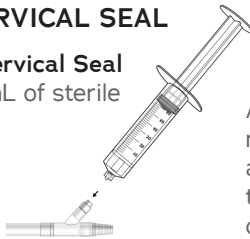
Ensure correct placement:

Intrauterine Loop within the uterus and Cervical Seal within the vagina at the external cervical os.



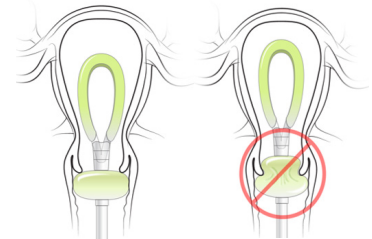
3. FILL CERVICAL SEAL

Fill the Cervical Seal with 60 mL of sterile fluid.

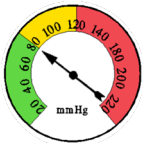


Add up to another 60 mL of fluid, if needed, to achieve full coverage of the external cervical os; do not exceed 120 mL.

Do NOT advance Cervical Seal into the uterus while filling. Confirm Cervical Seal is outside cervical os.



4. TURN ON & SET VACUUM, THEN CONNECT TUBING



Turn on vacuum source and set to 80 mm Hg (+/- 10 mm Hg) while occluding the end of the tubing. Maximum vacuum pressure is 90 mm Hg.

80 mm Hg = 1.5 psi = 10.7 kPa = 3.2 in Hg = 106.7 mbar

Connect Jada to vacuum tubing.

5. TREATMENT

- **Leave Jada in place** with vacuum applied, using tape to secure the Tube to the patient's inner thigh.
- Blood flow into the vacuum tubing and/or improvement in uterine tone should be noted after initiation of vacuum.
- 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.
- **Verify bleeding is controlled.**
- **Leave vacuum on for at least one hour** after bleeding is controlled, and verify the uterus is firm and patient is stable before disconnecting vacuum.
- Consider prophylactic antibiotics for prolonged use.
- **Do not leave the Jada in place for >24 hours.**

6. VERIFY

- Ensure Tube remains secured with tape to patient's inner thigh.
- **Disconnect vacuum tubing** from Jada while vacuum is on.
- **Remove all sterile fluid** from Cervical Seal.
- **Wait at least 30 minutes** to verify bleeding is controlled.
- If bleeding recurs, repeat steps 3 – 6, if appropriate.

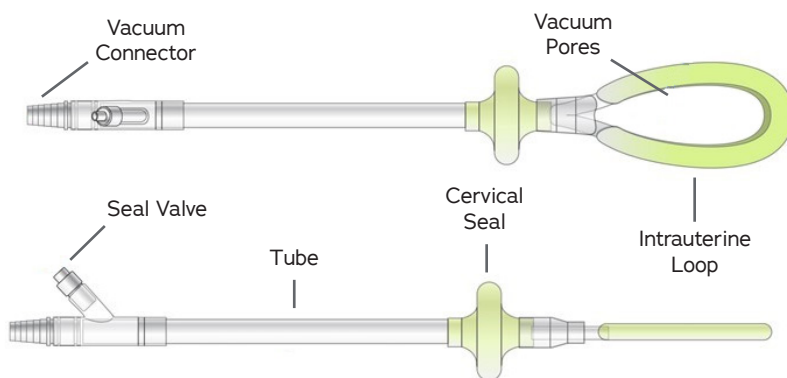
7. REMOVE JADA

- If bleeding remains controlled and the uterus remains firm, **remove the Jada slowly** while supporting the uterine fundus.

TROUBLESHOOTING

SITUATION	RECOMMENDED ACTION
Vacuum is not detected at the end of the vacuum tubing.	<p>a) Check connection on all system components:</p> <ul style="list-style-type: none"> • 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. <p>b) Confirm desired vacuum level is regulated in the appropriate units (i.e. mm Hg vs. cm Hg).</p>
Vacuum system is connected and working but uterus does not collapse and/or bleeding does not stop.	<p>a) Increase vacuum pressure to maximum (90 mm Hg).</p> <p>b) Disconnect the vacuum tubing from Jada and occlude the end of the tubing to check vacuum.</p> <p>c) Confirm appropriate Jada placement, with ultrasound if needed:</p> <ul style="list-style-type: none"> • 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. <p>d) Re-evaluate patient for other sources of bleeding.</p>

JADA COMPONENTS



MATERIALS REQUIRED BUT NOT SUPPLIED

- Regulated Vacuum Source
- Vacuum Canister
- Tape
- Sterile Vacuum Tubing: 10'-12'
- 60 mL Sterile Fluid (Max 120 mL)
- Sterile Luer Tapered Syringe: 60 mL recommended

CAUTION: Please refer to the Jada System Instructions for Use (IFU) for complete information. The Jada System IFU can be found at www.alydiahealth.com/IFU

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

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