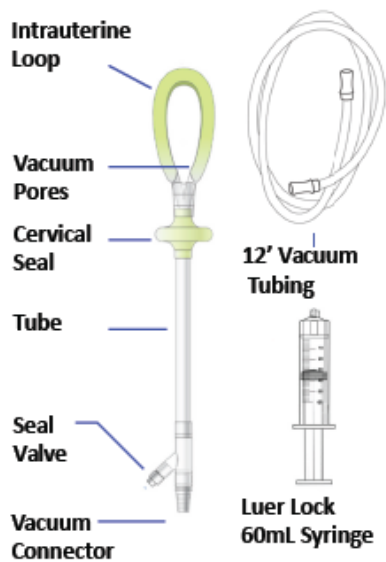


JADA® SYSTEM QUICK REFERENCE GUIDE

IMPORTANT INFORMATION: PLEASE READ BEFORE USE

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

HOW SUPPLIED



MATERIALS REQUIRED BUT NOT SUPPLIED

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

IMPORTANT: Please review full **INSTRUCTIONS FOR USE**. Please turn over for further direction regarding indications, contraindications, warnings, precautions, and other important information.

1. EVALUATE PATIENT

A. Evaluate patient for:

- Retained products
- Other sources of bleeding
- Lacerations
 - Vaginal and external lacerations can be repaired with JADA in place.

B. Remove organized clots.

C. Ensure that the bladder is empty to facilitate palpation and contraction of the uterus.

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.

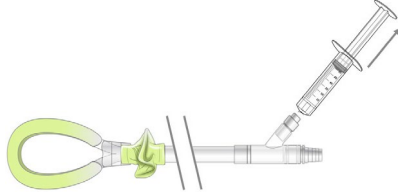
2. PREPARE JADA SYSTEM

- A. Connect tubing to vacuum canister.
- B. Set vacuum to 80 mmHg.

$$80 \text{ mmHg} = 1.5 \text{ psi} = 10.7 \text{ kPa} = 3.2 \text{ inHg} = 106.7 \text{ mbar}$$

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

- C. Remove air from Cervical Seal.

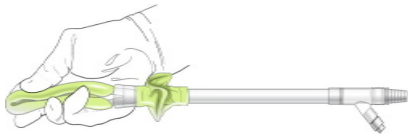


- D. Fill syringe with 60 mL sterile fluid.

3. PLACE JADA

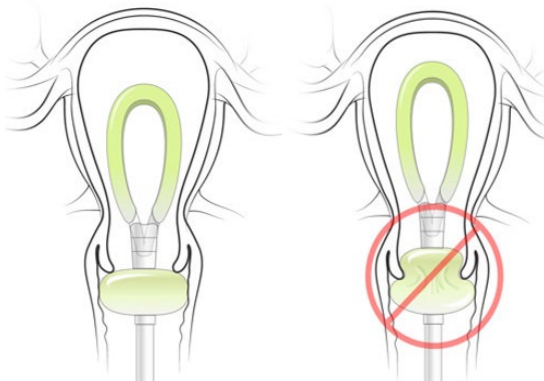
- A. Confirm cervix is dilated at least 3 cm.
- B. Insert JADA transvaginally.

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



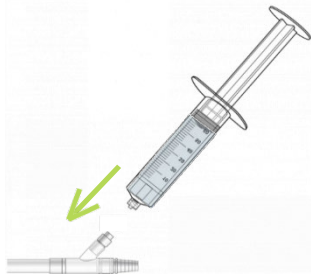
IMPORTANT: Do not grasp JADA with an instrument to facilitate intrauterine insertion.

- C. Place Cervical Seal at external cervical os.



4. FILL CERVICAL SEAL

A. Fill Cervical Seal.

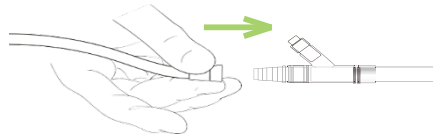


60-120 mL

B. Ensure Cervical Seal covers external cervical os.

5. START TREATMENT

A. Connect JADA to vacuum tube.

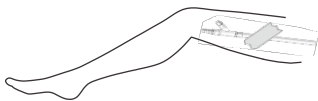


B. After connecting vacuum CHECK:

- Blood flows into the vacuum tubing and/or
- Improvement in uterine tone is observed.
- The Cervical Seal is positioned at the external cervical os.

See **TROUBLESHOOTING** section if this does not occur.

C. Secure JADA to patient's inner thigh with tape.



6. ACTIVE TREATMENT

A. Leave vacuum applied until:

- Bleeding is **CONTROLLED FOR AT LEAST 1 HOUR,**
- AND uterus is firm,
- AND patient is stable.



B. If blood flow does not stop, consider increasing pressure to maximum 90 mmHg.

$$90 \text{ mmHg} = 1.7 \text{ psi} = 12.0 \text{ kPa} = 3.5 \text{ inHg} = 120.0 \text{ mbar}$$

See **TROUBLESHOOTING** if bleeding continues.

PRECAUTION: Do not increase the vacuum pressure higher than 90 mmHg or tissue trauma may occur.

7. VERIFY AND END TREATMENT

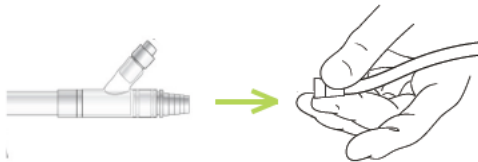
PRECAUTION: To avoid uterine inversion, do not remove JADA while vacuum is applied. Always disconnect JADA from vacuum tubing before removal.

A. Confirm treatment no longer needed.



B. Turn off vacuum.

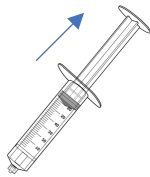
C. Disconnect vacuum tubing.



D. Set aside vacuum tubing in case of re-application of vacuum.

E. Attach syringe to seal valve.

F. Remove fluid from Cervical Seal.



G. Observe patient for **AT LEAST 30 MINUTES** to ensure:

- Bleeding is controlled,
- Uterus is firm,
- Patient is stable.

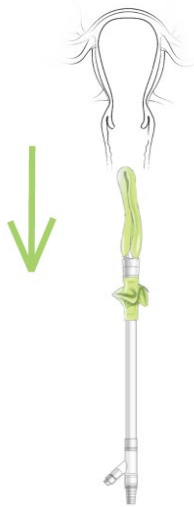


IMPORTANT: If bleeding recurs, re-evaluate patient and consider repeating steps 4-7, if appropriate.

8. JADA REMOVAL

PRECAUTION: Remove all fluid from the cervical seal prior to removing JADA to avoid tissue disruption.

- A. Place hand on abdomen.
- B. Slowly remove JADA.



- C. Inspect JADA after removal to ensure it is intact.

9. DISPOSAL

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

TROUBLESHOOTING

VACUUM IS NOT DETECTED

Confirm:

- Vacuum is functional.
- Vacuum canister lid is fully seated.
- Vacuum canister lid is not cracked.
- Vacuum tubing is connected securely at both ends.
- Vacuum pressure setting is appropriate for units of measure on the regulator.
 - 80 mmHg = 1.5 psi = 10.7 kPa = 3.2 inHg = 106.7 mbar
 - 90 mmHg = 1.7 psi = 12.0 kPa = 3.5 inHg = 120.0 mbar

UTERUS DOES NOT COLLAPSE AND/OR BLEEDING DOES NOT STOP

- Confirm correct placement of JADA (with ultrasound if needed).
- Increase vacuum pressure to 90 mmHg maximum.
- If clots are suspected, remove JADA to remove clots.
- Disconnect vacuum tubing.
- Check vacuum is functional.
- Re-evaluate patient.