



Indications for Use

AVALIGN Obstetrical Forceps are intended to grasp and apply traction to the fetal head to facilitate delivery in cases of prolonged second stage, suspicion of immediate or potential fetal compromise, or shortening of the second stage for maternal benefit, provided that the cervix is fully dilated and the fetal head is positioned appropriately in the vagina.

Caution: Federal U.S. laws restrict this device to sale, distribution, and use, by, or on the order of a physician.

Caution: Obstetrical forceps should not be used by individuals who are not fully trained in proper use of forceps and the potential complications associated with their use. Consult relevant medical literature for the appropriate obstetric indications, prerequisites, techniques, and risks of operative vaginal delivery prior to the performance of any forceps delivery.

Read the Instructions for Use prior to using this device.

Caution: Obstetrical forceps should only be used in settings in which personnel are readily available to perform cesarean delivery in the event that operative delivery is unsuccessful.

Warnings:

1. AVALIGN Obstetrical Forceps are not approved for use for > 45 degree rotation of the fetal head.
2. Use of forceps may result in maternal complications to include lacerations of the vagina and cervix, pelvic hematoma, episiotomy extension, hemorrhage resulting from these events, and possibly injury to the pelvic floor.
3. Use of forceps may result in fetal complications to include: minor lacerations, forceps marks, rare facial and brachial plexus palsies, cephalhematoma, skull fracture, and intracranial hemorrhage.
4. Use caution in attempting multiple efforts at vaginal delivery with different instruments, i.e., forceps and vacuum.
5. Use caution in performance of operative vaginal delivery in cases of presumed macrosomia.
6. Adhering to established obstetric guidelines for the use of forceps and careful placement of forceps helps minimize the risks of forcep assisted delivery.
7. If this device is/was used in a patient with, or suspected of having Creutzfeldt-Jakob Disease (CJD), the device cannot be reused and must be destroyed due to the inability to reprocess or sterilize to eliminate the risk of cross-contamination!



Contraindications

Obstetrical forceps should not be used in the following situations:

1. **If a live fetus is known to have a bone demineralization condition or bleeding disorder**
2. **The fetal head is unengaged**
3. **The position of the fetal head is unknown**

Instructions for Use

Warning:

Remove all protective caps and sheaths carefully. Prior to surgical use, the instrument must be cleaned, lubricated, decontaminated, sterilized and inspected. Instruments are reusable and supplied as non-sterile.

Attention:

Risk of damage - The forceps is a precision device. Careful handling is important for accurate functioning of the product. Improper external handling (e.g. bending, banging, dropping, etc.) can cause product malfunction.

Control function before use:

Before using, the general functioning and preparation of the instrument and accessories must be controlled. Please confirm prior to use.

Instructions for Placing the Forceps

1. Ensure that all prerequisites for operative vaginal delivery are met prior to performing forceps assisted delivery.
2. Insert the forceps one blade at a time. The blades should lie evenly against the sides of the head, reaching to and beyond the malar eminences, symmetrically covering the space between the orbits and the ears.
3. Lock the forceps and check their position to ensure even and symmetric placement.
4. Apply traction in a downward and outward direction to accomplish delivery of the fetal head.
5. An axis-traction device may be used to assist with the initial downward force.
6. Episiotomy may be performed at the discretion of the physician.
7. The forceps blades may be disarticulated during crowning or after delivery of the fetal head.
8. After delivery, closely inspect the cervix, vagina, and perineum for lacerations.
9. Inform neonatal care providers of the use of forceps during the delivery.

References

American College of Obstetricians and Gynecologists, Operative vaginal delivery.
ACOG practice bulletin no 17. Washington, DC:
American College of Obstetricians and Gynecologists, 2000



Decontamination / Cleaning / Sterilization

Decontamination: Take the device with the adapter(s) and accessories to the decontamination area. Clean, decontaminate, and sterilize the device, adapter(s), and accessories following the instructions in the IFUs.

Warning - Risk of infection!: Before use, the entire device, including its accessories must be decontaminated. Inadequate, incorrect, or superficial decontamination can create a serious risk of infection in patients and/or users.

Cleaning: Clean the instrument externally with a soft sponge and a soft brush.

Sterilization: Autoclave sterilization: Use steam autoclave sterilization only. Standard autoclave cycle. Steam sterilize at 270°F for fifteen (15) minutes. Other time and steam temperature cycles may also be used. However, user must validate any deviation from the recommended time and temperature. (Note: Contact the manufacturer of your steam autoclave to confirm appropriate temperatures and sterilization times.) Caution: Autoclave temperatures should not exceed 280°F.

Make certain that the instrument container is sealed in appropriate packaging for sterilization. Sterilize in compliance with the local guidelines for hospital hygiene.

AVALIGN instruments are reusable and meet AAMI standards for sterilization.

Maintenance:

Attention: Apply lubricant only on the connecting elements (locking mechanism) and moving parts.

Repair: To ensure that all repairs are completed according to the manufacturer's specifications, the precision device should be repaired by AVALIGN or by an authorized service agency only.

Warranty: All AVALIGN products are guaranteed to be free from defects in material and workmanship at the time of shipping. All of our products are designed and manufactured to meet the highest quality standards. We cannot accept liability for failure of products which have been modified in any way from their original design.

AVALIGN German Specialty Instruments

626 Cooper Court
Schaumburg, IL 60173; USA
Tel: +1 877 289 1096
product.questions@avalign.com

NOTE: IT IS THE RESPONSIBILITY OF THE REPROCESSOR TO ENSURE THAT THE REPROCESSING IS ACTUALLY PERFORMED USING EQUIPMENT, MATERIALS AND PERSONNEL IN THE REPROCESSING FACILITY TO ACHIEVE THE DESIRED RESULT. THIS REQUIRES VALIDATION AND ROUTINE MONITORING OF THE PROCESS. LIKEWISE, ANY DEVIATION BY THE REPROCESSOR FROM THE INSTRUCTIONS PROVIDED MUST BE PROPERLY EVALUATED FOR EFFECTIVENESS AND POTENTIAL ADVERSE CONSEQUENCES.