HEGENBERGER RETRACTOR

Instructions for Use

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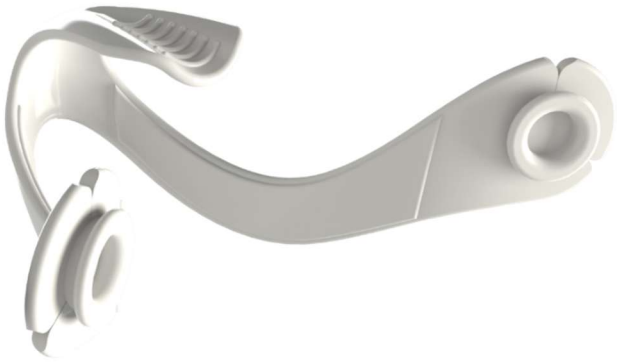


Hegenberger Medical
165 Broadway, 23rd Floor
New York, New York 10006 USA

CAUTION

This medical device is intended for use by trained clinical professionals experienced in obstetrics and gynecological techniques.

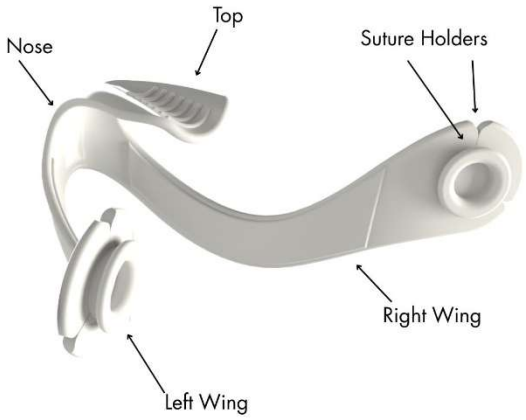
CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE. OBSERVE ALL CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS NOTED THROUGHOUT THESE INSTRUCTIONS. FAILURE TO DO SO MAY RESULT IN HARM.

INDICATIONS FOR USE

The Hegenberger Retractor is intended for use after vaginal delivery to support the diagnosis and suturing of perineal and vaginal tears and episiotomies.

PRODUCT DESCRIPTION

The Hegenberger Retractor is a vaginal retractor made of a biocompatible, flexible, high-impact, 100% latex-free material. The vaginal retractor is a self-retaining medical device used to maintain vaginal exposure by separating the edges of the vagina and holding back the tissue.



CONTRAINDICATIONS

- Not to be used with pediatric patients.
- Not intended for use during pregnancy.
- Not for placement in patients who have not delivered vaginally.
- Not to be used during active postpartum hemorrhage. May be placed following clinical control of any postpartum hemorrhage.

- Not to be used for anterior wall procedures.

WARNINGS

- Do not use excessive force when inserting a Hegenberger Retractor into the vagina. Excessive force may cause soft tissue damage.
- Do not rotate the Hegenberger Retractor while inside the patient's body.
- Intended for one-time use. Do not reuse, reprocess, or re-sterilize. Reuse may compromise sterility, mechanical integrity, and safety, resulting in device malfunction, patient injury, or adverse clinical outcomes.
- Do not use a Hegenberger Retractor if the product or packaging is damaged. Compromise of sterility and/or functional integrity may result in increased patient harm or device malfunction.
- Do not use a Hegenberger Retractor if it is past the Use-by Date. Expired product may compromise sterility, material integrity, or performance, increasing the risk of malfunction and patient harm.

PRECAUTIONS

- If the patient has continuous discomfort following placement and positioning, assess the patient for bladder fullness. If needed, the Retractor can be removed to allow the bladder to be emptied. The Retractor may then be re-inserted.
- Do not apply gel or lubrication to prevent the device from slipping out.
- Attempting to insert the Retractor with the patient in Semi-Fowler's position risks expulsion.
- The Hegenberger Retractor is supplied sterile and is intended to be used for postpartum repairs using sterile technique.

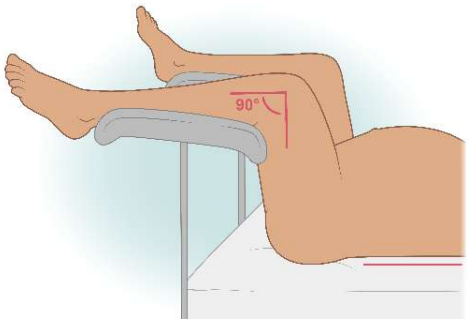


*Figure 1: **Patient Positioning:** patient positioning prior to device insertion in the supine position with the legs in lithotomy position*

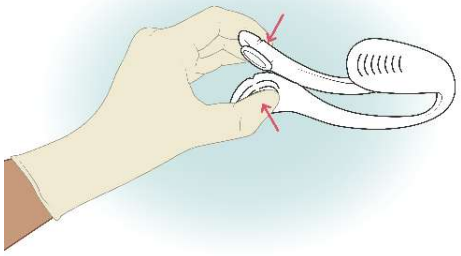


*Figure 2: **Preparation:** compress the Wings prior to insertion*

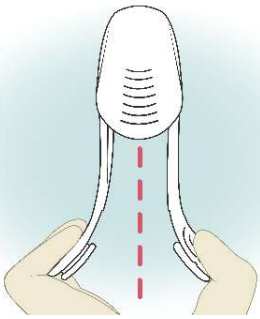


*Figure 3: **Orientation**: Orient the device so the Wings are centered around the tear*

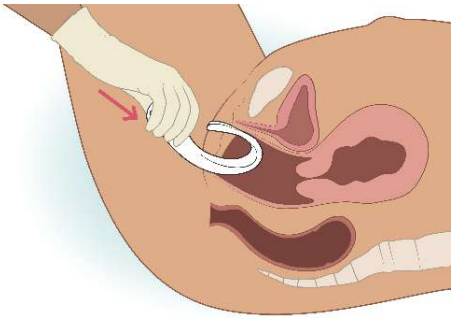
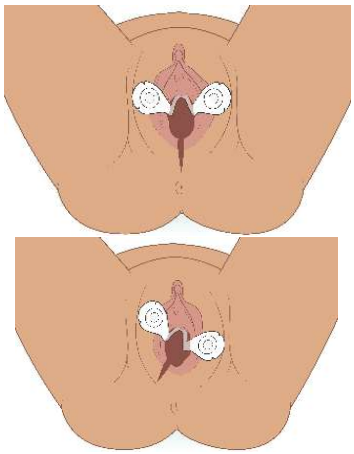


*Figure 4: **Placement:** Device insertion into the vaginal canal*



*Figures 5&6: **Confirmation:** Device orientation for standard (top) and episiotomy/lateral tears (bottom)*

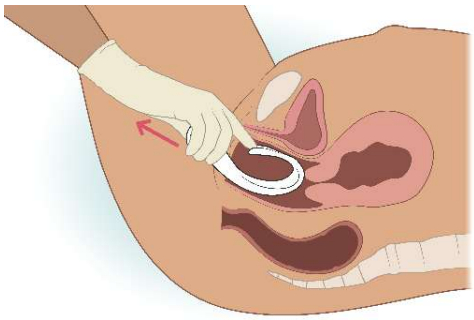


*Figure 7: **Removal:** Positioning of hand on device and device removal*

INSTRUCTIONS FOR USE

Assessment

1. Examine the patient for location and degree of tear.

Patient Positioning

2. Place the patient in a supine position, with both legs elevated using leg rests in a lithotomy position. **Do not attempt to place the device with the patient in the Semi-Fowler's position**. Consider local anesthesia for patient comfort, as needed. *See Figure 1.*

Preparation

3. Open the sterile pouch and remove the Hegenberger Retractor. **Do not apply gel or lubrication.**
4. Compress the Wings. *See Figure 2.*

Orientation

5. Before insertion, orient the device so that the tear is centered between the Wings. Orientation may be midline or lateral depending on the location of the tear. *See Figure 3.*

Placement

6. While maintaining compression, insert the device into the vaginal canal. *See Figure 4.*
7. Ask the patient to relax her bottom before gently releasing the Wings and removing your hand.

Confirmation

8. Confirm placement by:
   - ✓ Ensuring that the ends of the Wings rest on the inside of the labia
   - ✓ The tear is centered between the Wings
   - ✓ The device is stable in place

   See Figures 5 and 6.

9. If more than one tear needs repair, remove the device, then rotate and reorient the device so that the second tear is centered between the Wings before reinserting it. **Do not rotate the device when it is inside the patient.**

Removal

10. Gently place the tip of the index finger on the ridges of the Top, compress the Wings, then press down to guide the retractor out of the vagina. Note: When positioned midline, depressing the Top is essential for releasing it from under the pubic bone. *See Figure 7.*

TROUBLESHOOTING

Situation	Recommended Action
The device slides out of the vagina	• Check that the patient is in the correct position: lower back flat in the bed with legs in lithotomy position. She should not be in a semi-reclined position. • Check that the device is inserted completely, with the Wings located on the inside of the labia. • Ensure that gel or lubrication was not used during device placement. • If the device is in the midline position, the Top must be placed behind the pubic bone.
There is more than one tear requiring repair	Choose the tear you want to suture first and orient the Wings so they are centered over the primary tear. After the first tear is repaired, gently remove the device, then rotate and reorient the device so that the second tear is centered between the Wings before reinserting it into the vagina. Do not rotate the device when it is inside the patient.
Difficulty closing the last part of the repair	Gently compress the Wings together and pull down the tissue on each side to expose more tissue to work with. Release the Wings before continuing with the repair. Alternatively, you may remove the device to complete the final portion of the repair.
Patient is hemorrhaging	Assess the cause of the hemorrhage; if it is unrelated to the tear, remove the device and treat the hemorrhage before proceeding with the repair.

HOW SUPPLIED

The Hegenberger Retractor is supplied sterile. Always use sterile technique when handling the Hegenberger Retractor.

STORAGE

Handle with care. Store in original packaging in a clean, cool, and dry location at an ambient temperature between 0 and 30 degrees Celsius. Avoid exposure to extreme temperatures and humidity.

RESTERILIZATION/RE-USE

The Hegenberger Retractor is for single patient use only. Do not reuse, reprocess, or re-sterilize. Reuse of a Hegenberger Retractor on different patients or during separate clinical procedures may lead to cross-contamination, infection, or patient death.

SYMBOL GLOSSARY

Explanation of labeling on labels and Instructions for Use.

	See Instructions for Use		Manufacturing day		Don’t reuse
	Article number		Expiration date		Don’t sterilize for reuse
	Lot number		Don’t use if package is damaged		Temp range 0 to 30° C
	Medical Device		Humidity 0-70%		Sterilized with ethylene oxide
	Keep dry		Protect from sunlight		Latex free
					Manufacturer



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