



# amniotomy hook

## Description:

The Amniotomy Hook is a plastic polymer amniotic perforator, slightly curved to follow the normal pelvic cubature, 26 cm in length.

The outer part of the tip is rounded and the hook profiled in order to prevent any damage to the surrounding tissues during insertion.

The device is designed to ensure maximum safety when used for artificial rupture of the membranes of the amniotic sac during induction of labour. The device is curved to ease the entry and movement in the vagina and access the amniotic sac.

## Intended Population:

Women of Child bearing age.

## Intended user

The device is intended to be used only by / under the supervision / training of a gynecologist / Physician.

## Contraindications

Contraindications to this procedure are few and obvious.

Artificial rupture of membranes should not be undertaken in the case of malpresentation, vasa previa, suspected velamentous insertion of the umbilical cord, or in case of the unengaged fetal head or unstable lie. If the fetal presentation is unknown or not fully engaged, the risk for cord prolapse is increased.

Additional contraindications include if the pregnant woman is not in active labor or if the patient refuses the intervention.

## Intended use :

Amniotomy Hook a surgical instrument used to rupture the amniotic membrane to assist in childbirth.

## Indications :

An instrument used to rupture the amniotic membrane to assist in childbirth. The device is designed to ensure maximum safety when used for artificial rupture of the amniotic sac membranes during labor induction. The device is curved to ease the entry and movement in the vagina and access the amniotic sac.

## Steps :

- Place the woman on her back with knees bent and thighs apart.
- Wear sterile gloves.
- Swab the perineum and the vagina with antiseptic Solution.
- Open the Pouch and take out the device With one hand, prepare access to the sac (hand well into the cervix). With the other hand, slide the amniotomy hook between the fingers of the first hand which spreads the vagina and the cervix and guides the tip and make a small cut in the sac as it bulges during a contraction. Care should be taken to protect the maternal tissues. Let the fluid drain slowly then use a finger to enlarge the opening.
- Note the colour of the amniotic fluid (clear, greenish, or blood-stained). Isolated meconium staining, in the absence of an abnormal foetal heart rate, is not diagnostic of foetal distress, but requires closer monitoring.
- The hook is then pulled through the membranes with the external hand holding the handle creating a hole in the sac.
- Make sure the cord has not prolapsed.
- Check the foetal heart rate before and after amniotomy.



## Intended clinical benefits :

Artificial rupture of amniotomy sac with reduced risk of infection and neonatal scalp lacerations.

## Side Effects

The amniotomy procedure may cause intrauterine infection, umbilical cord prolapse, foetal scalp injury, foetal shock and disruption of an occult placenta previa or vasa previa with subsequent maternal hemorrhage.

## Storage condition :

Store at 15°C to 30°C in a dry place away from direct sunlight, sources of heat, water and mechanical damage.

## Warning :

- The device must not be reused. Reuse of the device may pose risks of infection to both the mother and the foetus.
- The device must be disposed after its use, as per the local regulations.

## Sterilization :

- Device is Sterile
- Sterilization by Gamma Radiation

## Reporting of Adverse Events :

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

## Performance Characteristics :

- The device must be smooth from all sides and free from sharp edges.
- Length :  $25.5 \pm 0.5$  cm.

## Precautions :

- Do not use the device if the sterile packaging is damaged or unintentionally opened before use.
- If the device breaks while usage, discard the device and use a new one.

## "For Single Use only"

## Shelf Life : 5 Years

1	2	3	4	5	6	7
Sterile and Method of sterilization "G" gamma Sterilization by Radiation Method	Keep dry or protect from moisture	Do not use if carton is damaged	Protect from Sun light	Do not re sterilize	Do not Reuse	Consult Instructions for Use
8	9	10	11	12	13	14
Medical Device	Manufactured by	Lot No./ Batch No.	Insert Before Date	Manufacturing Date	CE Mark	Single Sterile Barrier System

[www.smbcorp.com/iud/amniotic-hook](http://www.smbcorp.com/iud/amniotic-hook)  
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