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# Operator's Training Manual

odon assist™

# OdonAssist™

# Operator's Training Manual

## Inflatable device for assisted vaginal birth

**Ref: TRGM-1-EN, Ver 5.0**

*For OdonAssist™ training materials refer to:www.mnhi.com*

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# Acknowledgements

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# Abbreviations

| | |
|---|---|
| AVB | Assisted vaginal birth |
| BD | Becton Dickinson |
| EU | European Union |
| IFU | Instructions For Use |
| MNHI | Maternal Newborn Health Innovations |
| OA | Occipito anterior |
| OASI | Obstetric anal sphincter injury |
| OP | Occipito posterior |
| OT | Occipito transverse |
| WHO | World Health Organization |

# 1 Introduction

Assisted vaginal birth (AVB) involves using a medical device or instrument to assist the birth of a neonate vaginally for maternal and/or fetal indications. Commonly used devices include the forceps, vacuum cup (also known as a ventouse) and spatulas. Choice of instrument may be influenced by clinical circumstances, operator preference, experience and availability.[1] There are also international trends in rates and types of AVB, which reflect local practice patterns, lack of international consensus guidelines and variation in the number of trained clinicians.[2] The rate of second-stage caesarean birth is rising in incidence[3] and in part this may be due to a loss of skill in AVB. Many women have negative perceptions of forceps[4] and ventouse[5], leading to the exploration of a new device for AVB.

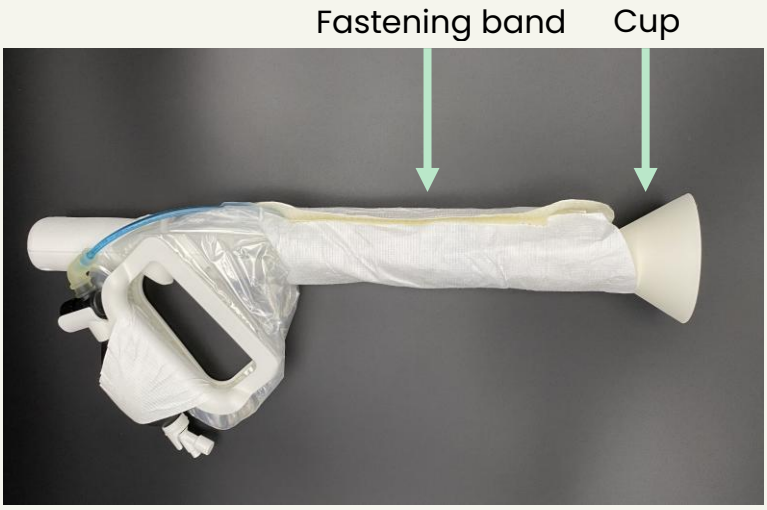
## 1.1 OdonAssist

The OdonAssist (Figure 1) is used to perform assisted vaginal birth in women with term pregnancies and cephalic vertex presentation (occiput anterior, occiput posterior and occiput transverse fetal head positions) with fetal stations at 1cm or below ischial spines. The device uses a flexible sleeve and an inflatable air cuff to help ease the fetal head out of the birth canal. The OdonAssist has been designed and developed by a multi-professional team of doctors, midwives, and medical engineers as a possible alternative to established devices for AVB. The OdonAssist consists of three components as demonstrated in Figure 2: i) a applicator, ii) a flexible sleeve with an inflatable air cuff, and iii) a fastening band.

Figure 1 Images of the OdonAssist

The OdonAssist is a Class I sterile device under the European Union (EU) Framework for Classification of Medical Devices (Regulation [EU] 2017/745). The device was originally designed in Argentina by Jorge Odón. After designing the new device, Odón took it to a local obstetrician, who immediately recognised its potential. It has since gained the attention of the World Health Orgainzation (WHO), which identified the need to support the development of research to evaluate this novel device. From 2014 to 2021 Becton Dickinson (BD) worked with scientific and clinical teams to further develop the device. In 2022, the public benefit corporation Maternal Newborn Health Innovations (MNHI) acquired the right of the device and Maternal Newborn Health Innovations Singapore, Pte. Ltd. was founded to become the legal manufacturer of OdonAssist.

## Pre-assembled

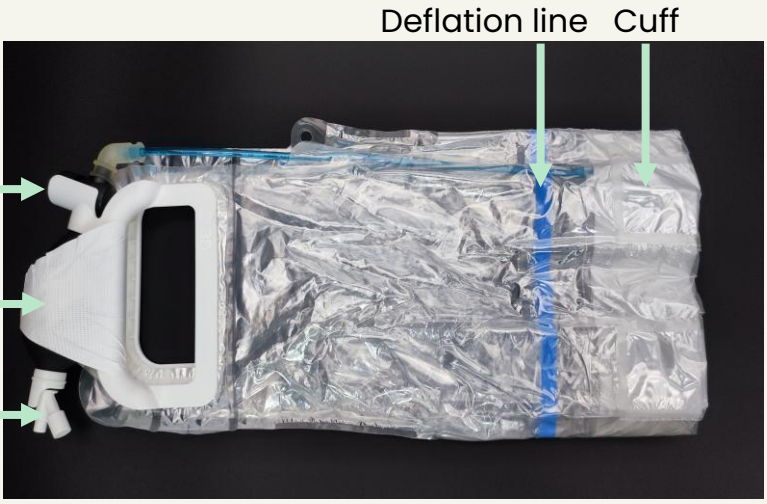



## Inflatable Sleeve

Deflation button

Bulb pump

Pressure limiter




## Applicator

Applicator


Figure 2 Components of the OdonAssist i) pre-assembled device, ii) inflatable sleeve and iii) applicator

Since its origins in Argentina, multi-professional teams of clinicians and non-clinicians have continued to develop the OdonAssist (historically called the Odon Device) with the aim of improving its safety and efficacy. Between 2011 and 2017 a first-in-human study was conducted by the WHO to evaluate early prototypes of the OdonAssist in 49 women.[7] The device was used in women who were about to achieve a spontaneous vaginal birth and therefore did not require assistance at the end of their labour. Between 2017 and 2019, pre-clinical testing of an improved version of OdonAssist was undertaken. This comprised simulation research[8–10] (three studies of 1,845 simulated births) and animal testing.[11] Initial simulations established that the OdonAssist behaved in a safe and predictable manner.[8] It was demonstrated that device reliably positioned over a safe area of the fetal head,[9] that the pressure generated by the air cuff was less than the pressure generated by the forceps,[10] and that when correctly used, it did not produce greater perineal distension than the ventouse.[9]

Following on from these studies, an international human factors study was performed, which included 390 simulated births performed by over 100 clinicians from 14 different countries. It demonstrated that clinicians were able to use the device correctly, reliably and successfully in simulation.[8]

Collectively, these studies[7–11] ascertained that the OdonAssist appeared to be safe for women who were about to achieve a spontaneous vaginal birth and their babies and following this in simulated cases of indicated AVB. The next logical step was to research the device in the intended clinical population; women requiring assistance with birth for a standard clinical indication.

The ASSIST study (undertaken in Bristol, UK) was a feasibility study of the OdonAssist, aiming to explore the efficacy and safety of the device for AVB and the possibility of conducting a definitive trial assessing its clinical effectiveness.[12,13] The study recruited 40 women who required assistance at the end of their labour for a clinical indication. The ASSIST study demonstrated that it is feasible to recruit women to a study investigating an innovative device for AVB with a high recruitment rate of 78%. Although able to assist birth, the success rate of the OdonAssist was lower than expected (48%) and lower than

the published success rates of both vacuum and forceps (which is often >65%).[14–16] However, this feasibility study was the first time the device was used to expedite birth in clinically indicated circumstances, and the device design, technique of device use and clinical parameters for device use had not yet been fully determined. There were no significant maternal or neonatal safety concerns associated with the use of the device, although the number of births was small.

Additionally, data from the ASSIST study allowed the research teams to modify and adapt the OdonAssist. Rapid insights from qualitative research were used to gain information about the device use in clinical practice and how the device design, technique for device use and clinical parameters for device use should be adapted.[17] Furthermore, qualitative data found that women wanted an alternative device for AVB and were keen for a 'kinder' birth.[18]

To allow further investigation into use of the OdonAssist, two larger scale clinical trials were performed, the ASSIST II study[19, 41] (Bristol, UK) and Besançon Assist[20, 42] (Besançon, France). In Besançon, between December 2019 and March 2021, 1597 eligible women consented to participate. The OdonAssist was successful in 92/104 (88.5%) AVBs with no reports of any serious maternal or neonatal adverse events causally related to the use of the device during birth or serious adverse device effects[42]. In Bristol, preliminary data demonstrates that 69/104 (66%) of births assisted the OdonAssist were successful[41]. Again, there were no reports of any serious maternal or neonatal adverse events causally related to the use of the device during birth or serious adverse device effects.

# 2 Indications and assessment

As with any AVB, the decision whether to use the OdonAssist is multi-faceted and complex. There are many considerations that must go into the assessment for the need of assistance in the second stage of labour including: consent, preparation, performing the birth and postnatal considerations. The indications for an assisted birth are presented below. There may be cases where there are both maternal and fetal indications for AVB.

Indications for use are as follows:

• Prolonged second stage of labour.

• Suspected fetal compromise in the second stage of labour.

• Other medical indications to shorten the second stage of labour.

The contraindications to device use include:

- Cervix not fully dilated.
- Any clinical sign of cephalopelvic disproportion.
- Fetal head not fully engaged.
- Undefined presentation.
- Any non-vertex presentation.
- Membranes are not ruptured.
- Umbilical cord prolapse.
- Contraindications for vaginal births according to national or local guidelines.

Note: the OdonAssist should be used only in term pregnancies for AVB, as it has not yet been tested in pre-term birth or caesarean birth.

**Information for training**

The bulb pump of the device contains latex and therefore operators with a latex allergy should use the OdonAssist with caution to protect any reaction on their hands.

Safe use of the OdonAssist requires a careful, thorough assessment of the clinical situation, clear communication with the woman and the wider team

and expertise in use of the device. OdonAssist births should be performed by operators with the knowledge, skills, and experience necessary to complete a full assessment, complete the procedure and manage any possible complications that may arise. Shared decision making, alongside good communication, has the potential to reduce psychological morbidity following an AVB. Table 1 presents a summary of the safety criteria for an AVB with an OdonAssist.

## 2.1 Consent

Consent must be obtained from the woman after a detailed discussion of the proposed procedure and the risks. Information regarding AVB and the use of devices can be shared with women at any point in the antenatal period. Healthcare professionals should signpost women to the OdonAssist information video found at www.mnhi.com ideally before labour. International guidelines for AVB support the consideration of verbal consent if an AVB is performed in the birthing room, especially in the context of fetal distress, and written consent if transferring to theatre.[2]

## 2.2 Place of birth

As with all AVBs, if there is a low probability of failure with the OdonAssist these assisted births can often be performed safely in the birthing room. If there is a higher risk of failure after assessment by the operator this should be considered as a trial and should be performed in theatre where there is the option for immediate recourse to caesarean birth if required.

| | |
|---|---|
| **Assessment** | • Head ≤1/5 palpable per abdomen.<br>• Cervix fully dilated.<br>• Membranes ruptured.<br>• Fetal head at +1cm spines or below.<br>• Cephalic presentation (OA, OP, OT positions).<br>• Position of the fetal head determined.<br>• Less than moderate caput and moulding.<br>• Pelvis is deemed adequate and no findings of cephalopelvic disproportion – absence of significant caput or irreducible molding.<br>• Consent from the birthing person. |
| **Preparation of mother** | • Clear explanation of plan.<br>• Informed consent.<br>• Appropriate analgesia.<br>• Bladder emptied or indwelling catheter removed.<br>• Position woman lying flat in lithotomy position.<br>• Aseptic technique. |
| **Preparation of staff** | • Operator trained in use of the OdonAssist.<br>• Adequate facilities.<br>• Theatres available in case caesarean birth is required.<br>• Anticipation of complications, for example postpartum haemorrhage, shoulder dystocia.<br>• Neonatal personnel present. |

Table 1 Summary of safety criteria for assisted vaginal birth[23]

## 2.3 Analgesia

Provide adequate analgesia according to facility procedures. Options typically available are demonstrated in Table .

It is beyond the scope of this manual to discuss the clinical decision making for which analgesia option to use (if any) but as with all AVBs this needs to be a joint decision with the woman, obstetrician and if applicable, an anaesthetist.

| | |
|---|---|
| Local anaesthetic and/or nitrous oxide | Usually in the context of a low cavity or outlet AVB where assisted birth is expected to be straightforward. |
| Pudendal block | Application of local anaesthetic to the sacral nerves S2-4 for AVBs planned in the birthing room. |
| Regional anaesthetic | An epidural or spinal allows often more effective analgesia but with greater risks. |
| General anaesthetic | This is unusual unless progressing to a caesarean birth in the context of an emergency. |

Table 2 Analgesia options for AVB[24]

## 2.4 When to discontinue

As with other devices for AVB, OdonAssist could fail to deliver the neonate. The criteria to define failure and to abandon the procedure are if there:

- Is no evidence of progressive descent with moderate traction during each pull of a correctly applied instrument by an experienced operator.
- Have been three pulls and the fetal head is not on the perineum.
- Have been two slippages of the device.

**Information for training**

It is important to follow local guidelines for when to discontinue an AVB. This may include the amount of time that any device should be attempted, for example 20 minutes, before discontinuing this method of AVB.

OdonAssist births should be completed in the majority of cases with a maximum of three pulls.[23] This can be further explained as three pulls to bring the fetal head on to the perineum and three additional gentle pulls to complete the birth (other criteria may be applied in accordance with local assisted regional birth guidelines). This is in the context of sufficient fetal wellbeing and to minimise perineal trauma based on the theory presented by Vacca for ventouse delivery.[26] If there is minimum descent after two pulls the operator should trouble shoot issues with the device (detailed below), consider that

application may have been suboptimal, the fetal position incorrectly assessed or presence of cephalopelvic disproportion.

## 2.5 What to do if vaginal birth is not achieved

The use of sequential instruments is associated with increased risk of trauma to the neonate and mother.[23] It is therefore not recommended as routine. If the OdonAssist does not achieve the birth of the neonate, the operator will need to make a careful assessment of whether:

- Birth is likely to be successful with a second OdonAssist.
- Another device is required for AVB.
- Descent has been limited and a caesarean birth is felt to be safer with preparations for a possible impacted fetal head and complex operation.

## 2.6 Risks of AVB

Presently human,[12,41,42] animal,[11] and simulated[8–10] studies have not identified potential complications specific to the OdonAssist therefore this section may be updated after analyses of the safety outcomes of future research.

As with other devices for assisted vaginal birth, use of OdonAssist may be associated with maternal and neonatal complications.
Complications with the use of forceps and ventouse include maternal trauma, neonatal scalp injury, facial injury, intracranial injury, intracranial haemorrhage, cephalo-haematoma, subgaleal haemorrhage, fracture, retinal haemorrhage and bruising. Presently human, animal and simulated studies have not identified potential additional complications specific to OdonAssist.

## 2.7 Single use

**WARNING**: OdonAssist is a single use only disposable device. Do not reuse the device. Discard after one procedure. Do not reassemble the device for additional patient use. Reusing this product after exposure to blood and tissue may result in transmission of infectious disease from one patient to another. Do not attempt to re-sterilise or autoclave this device. Doing so will cause a degradation of materials that can result in device malfunction. After it has been used, the OdonAssist should be disposed of following local clinical waste procedures. MNHI will not be responsible for any damages or harm, whether direct, indirect or consequential, that may result from reuse of the device.

# 3 Introduction to technique

As with all AVBs, regardless of device used, there is no consensus for the precise technique that should be used. This includes the individual steps, force and duration of traction as there are no international practice protocols.[2] However, all AVBs should not be about force, but about flexion and realignment.[27] The technique described has been developed from three clinical trials (ASSIST,[12] ASSIST II[19,41] and ASSIST Besançon[20,42]), observed simulation and discussions between operators who were early users of the device.

The Instructions For Use (IFU) have mandatory and optional aspects to aid a safe, competent and good birth. However, as with all births, the device used to assist birth should be based on clinical circumstances and the experience of the operator.[2]

There are 22 steps to the use of the OdonAssist detailed in the IFU for the device. These steps are split into seven stages:

1. **Preparation**
2. **Application**
3. **Inflation**
4. **Traction**
5. **Deflation**
6. **Birth**
7. **Disposal**

**Information for training**

When using the OdonAssist with a manikin, lubricant should be used according to the manikin manufacturers guidelines. When using the OdonAssist in clinical practice birth lubricant should be used according to local guidelines and practice.

# 4 Stage one: Preparation

Key points

Ensure all of the conditions for safe application of OdonAssist are met (Table 3), if not consider another method to assist birth.

Make sure that the woman is appropriately prepared including consent, full explanation of the process of an OdonAssist birth, maternal positioning on the bed and analgesia.

Carefully prepare the OdonAssist for use including sufficient lubrication.

1. Ensure conditions for safe application of OdonAssist are met. Table provides a summary:

| Fetal considerations | Maternal considerations |
|---|---|
| • Term pregnancy.<br>• Full dilation of cervix.<br>• Fetal head at 1 cm or below ischial spines.<br>• Cephalic vertex presentation (OA, OP, OT positions).<br>• Rupture of membranes.<br>• Re-confirm fetal position. | • Provide adequate analgesia according to facility procedures.<br>• Position woman lying flat in lithotomy position.<br>• Empty bladder (deflate balloon if indwelling catheter). |

Table 3 Fetal and maternal conditions for safe use of the OdonAssist

N.B. If using a manikin for training purposes you will also need to use the recommended lubricant to lubricate the maternal manikin birth canal and fetal manikin prior to setting up your trolley and preparing the OdonAssist for use.

**Top tip**

To aid insertion the woman needs to be lying flat in lithotomy position, as demonstrated below in Figure 3.

Figure 3 Woman lying in the correct position for an AVB with the OdonAssist

2. Open the device onto a general AVB trolley ensuring aseptic technique (Figure 4). Ensure that the packaging is not damaged prior to use. Discard product if the packaging is found to be damaged.

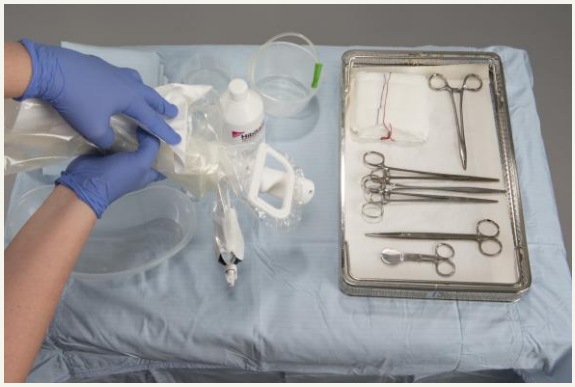


Figure 4 Open the OdonAssist onto your AVB trolley

Your general AVB trolley is likely to include (Figure 5): cord clamps, scissors for episiotomy and cutting the cord, swabs, needles and syringes for cord gases, local anaesthetic (if required) and surgical instruments for suturing. You will also need birth lubricant and a pot for this, a syringe with or without a quill, a urinary catheter, dish for urine, sterile drapes and sterile gloves.

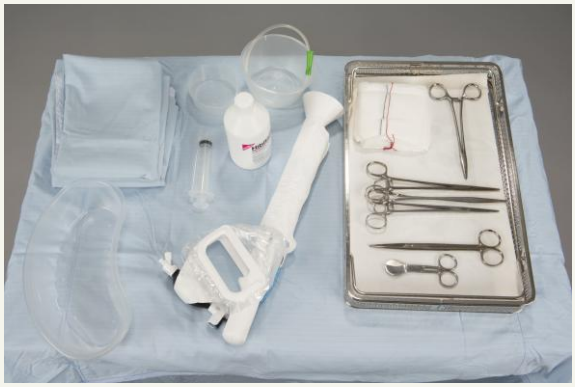


Figure 5 A possible layout for an AVB trolley using the OdonAssist

3. Start lubricating the four inner channels of the sleeves from the handle side. This stage is important to facilitate withdrawal of the applicator. To do this you can either use a syringe or a syringe and quill.

**Syringe only**

i. Open a 20 mL sterile syringe (Figure 6).
ii. Ensure you have at least 20 mL of birth lubricant in a sterile container.
iii. Draw up 20 mL of birth lubricant (Figure 7A).
iv. Insert approximately 5 mL of birth lubricant into each of the four spatula pockets. To do this, hold the device with the cup facing down, allowing the sleeve handles to flop downwards (Figure 8).
v. Insert the tip of the syringe as far as you can into the spatula pocket, following the path of the white spatula (Figure 9A). Then inject approximately 5 mL of birth lubricant into the pocket.
vi. Repeat this (step v.) for all four spatula pockets.
vii. Starting from the handles and working down towards the cup, squeeze firmly along the sleeve to spread the birth lubricant inside the channels to the tips of the spatulas (Figure 10).

Figure 6 Ask your assistant to open a sterile syringe with/or without quill

**Syringe and quill**

i. Open a 20 mL sterile syringe and quill.
ii. Attach the quill to the end of the syringe.
iii. Ensure you have at least 20 mL of birth lubricant in a sterile container.
iv. Draw up 20 mL of birth lubricant (Figure 7B).
v. Insert approximately 5 mL of birth lubricant into each of the four spatula pockets. To do this, hold the device with the cup facing down, allowing the sleeve handles to flop downwards (Figure 8).
vi. Insert the tip of the quill as far as you can into the spatula pocket, following the path of the white spatula (Figure 9B). Then inject approximately 5 mL of birth lubricant into the pocket.
vii. Repeat this (step vi.) for all four spatula pockets.
viii. Starting from the handles and working down towards the cup, squeeze firmly along the sleeve to spread the birth lubricant inside the channels to the tips of the spatulas (Figure 10).

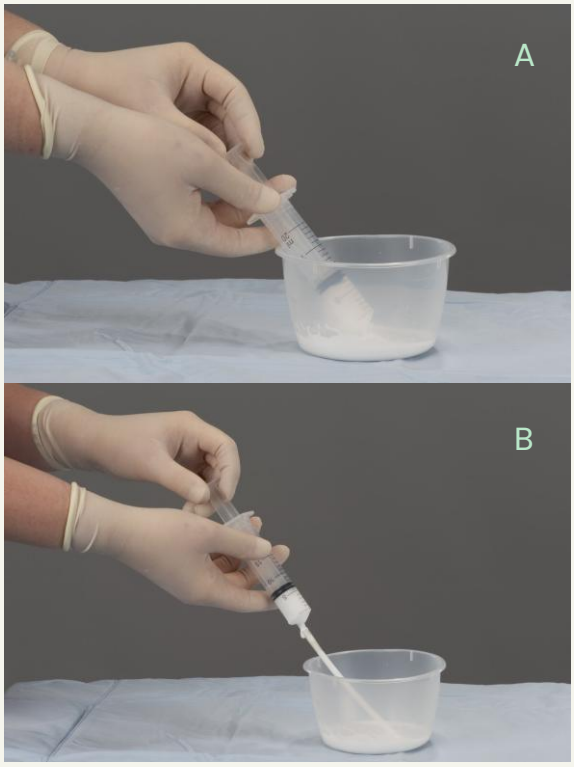



Figure 7 Draw up 20 mL of birth lubricant into your syringe without (A) or with (B) a quill

Figure 8 Hold the device with the cup facing downwards

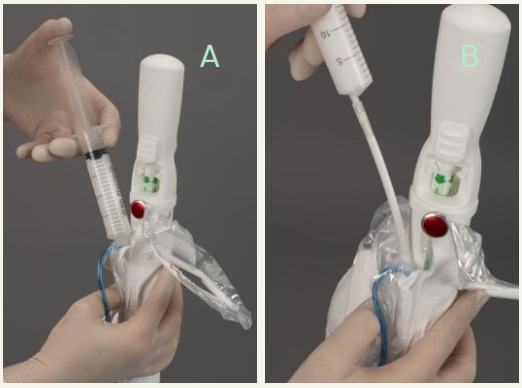



Figure 9 Insert the tip of the syringe (A) or quill (B) into the spatula pocket, following the path of the spatula

Figure 10 Squeeze firmly along the sleeve to spread the birth lubricant

**Top tips**

Concentrate on lubricating the inside of the sleeve as this is the part of the OdonAssist that articulates with the fetal head.

4. Grasp the fastening band (Figure 11) and keeping the hook and loop strip sealed, pull back firmly on the fastening band to expose the sleeve (Figure 12), and using your hand generously lubricate the inside and the outside of the sleeve and the cup with birth lubricant (Figure 13).

N.B. If using a manikin for training purposes you will also need to use the recommended lubricant to lubricate the OdonAssist.

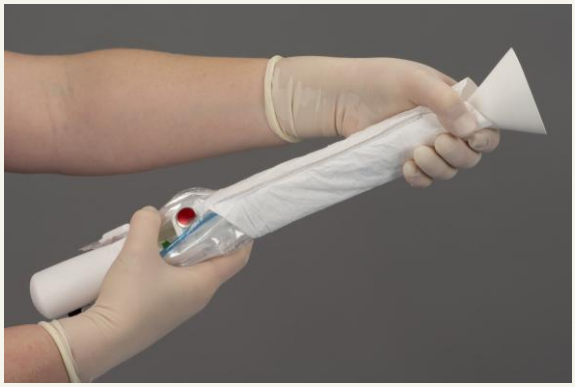


Figure 11 Grasp the fastening band firmly

Figure 12 Pull back firmly on the fastening band to expose the sleeve

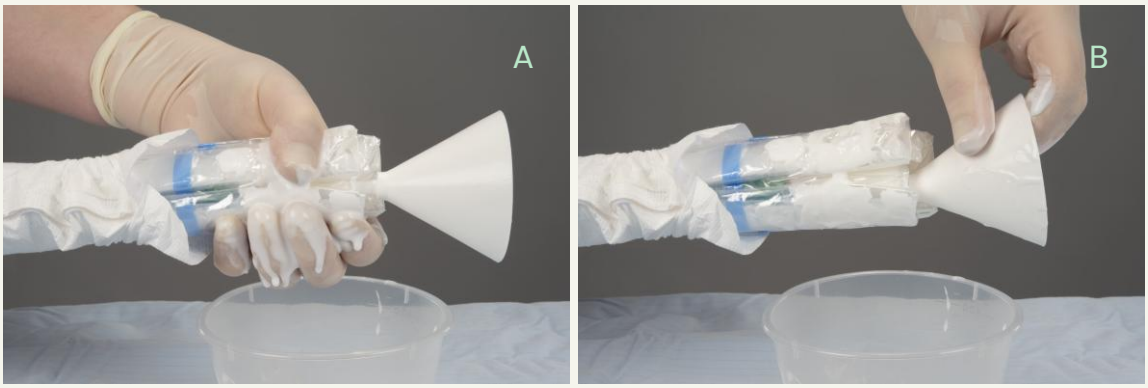


Figure 13 Lubrication of the applicator sleeve (A) and lubrication of applicator cup (B)

5. Replace the fastening band by gently sliding it back over the top of the sleeve while holding the applicator handle (Figure 14).


Figure 14 After device lubrication ensure the fastening band is replaced correctly

# 5 Stage two: Application

Key points

Application should only be during a contraction (with or without maternal effort).

Ensure that the device is orientated the correct way by keeping the viewing window facing upwards.

The cup is applied to the baby's head to enable device application, it does not have to be over the flexion point.

6. Grip the applicator handle and ensure the viewing window is facing upwards (Figure 15).

Figure 15 Correct orientation of the applicator

7. Fold the cup (Figure 16) and gently insert it through the vulva towards the baby's head and check the cup has regained its circular shape (Figure 17). Unlike a ventouse, application does not need to be on the flexion point, and can be placed on the nearest part of the fetal head. The cup can be applied with or without a contraction, it is just preparing the device for application.

Figure 16 Fold the cup

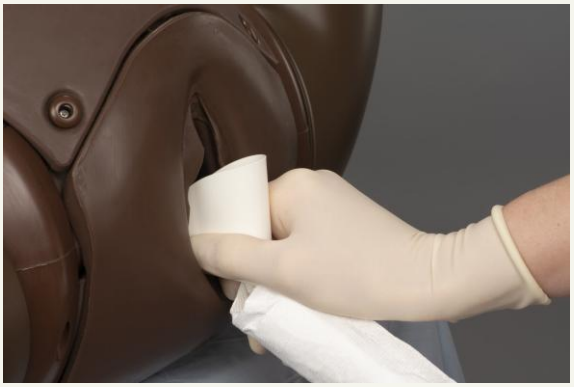


Figure 17 To apply the cup, it must first be folded to be inserted through the vulva

**Top tips**

Applying the cup during a contraction or asking the mother to push while the cup is applied can aid application.

The cup can be slippery following device lubrication so wiping your hands on gauze may help folding the cup.

8. With a single finger, circumferentially check that there is no maternal tissue trapped between the cup and the fetal head (Figure 18). The tips of all four spatulas should be within the introitus, check this with a single finger sweeping circumferentially around the labia (Figure 19).

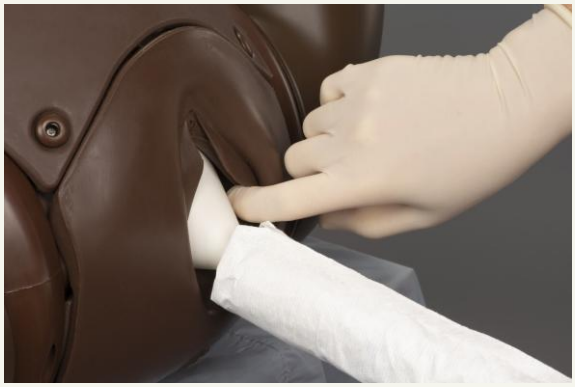


Figure 18 Before fully applying the device, check for any trapped maternal tissue

**Trouble-shooting: what to do if there is maternal tissue trapped between the cup and the baby's head?**

- Sweep any maternal tissue out of the way by using a single finger.
- If the tissue remains trapped, you may need to remove the cup and apply it to the baby's head again.

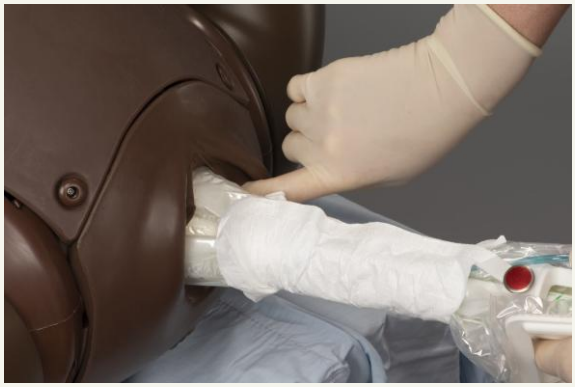


Figure 19 Before fully applying the device, check the tips of all four spatulas are within the introitus

9. Holding only the white plastic applicator handle, push the device carefully and slowly to advance the sleeve up towards the fetal head.

- Sleeve application is only with a contraction and/or maternal effort.
- Sleeve application is slow and steady – this may occur over one or more contractions.
- Do not hold the sleeve with your other hand as this will interfere with application (Figure 20).

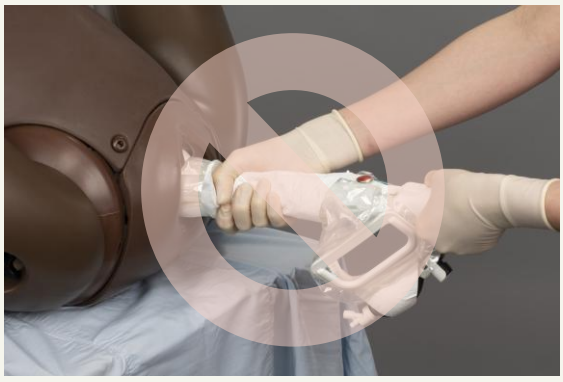


Figure 20 Do not hold the sleeve when applying the OdonAssist, it will interfere with application

10. As the fastening band nears the introitus (Figure 21), unfasten the red button (Figure 22).

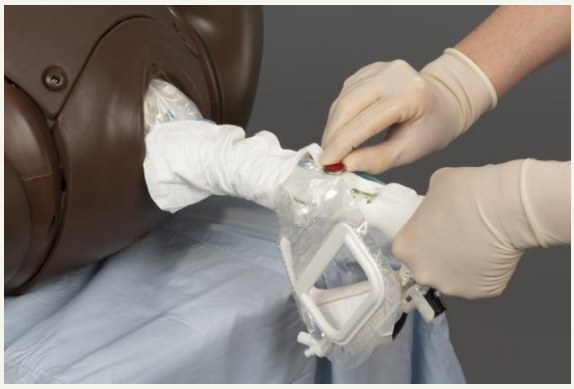


Figure 21 Prepare to unfasten the red button when the fastening band nears the introitus

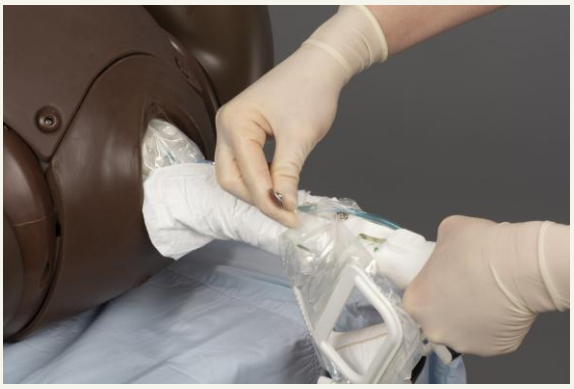


Figure 22 Unclip the red button to remove the fastening band

11. Open and completely remove the fastening band once the cup has been placed inside the vulva (Figure 23). Ensure sleeve and applicator remain in place in the introitus.

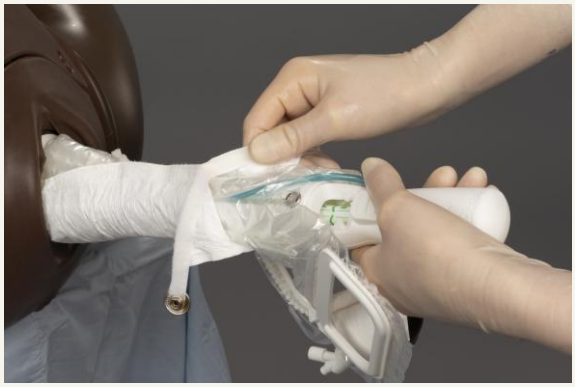


Figure 23 Open fastening band to remove

12. During contractions and/or maternal effort, gently push the applicator over the baby's head. Dependent on the operator preference this may be with two hands or one hand (Figure 24):
    - Keeping both hands away from the sleeve when doing this.
    - Monitor the progress of application by looking at the viewing window.

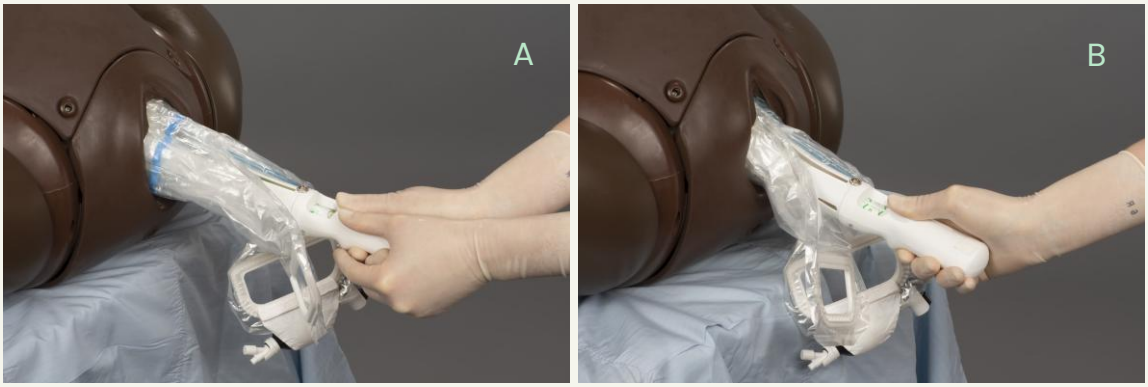


Figure 24 Apply the OdonAssist over the baby's head using either (A) a two-handed technique or (B) a one-handed technique

13. Continue to insert Odon Assist™ and stop when '0' appears in the viewing window. This means the device is fully inserted (Figure 25).


Figure 25 Apply the device fully (to when '0' appears in the viewing window)

**Top tip**

If it is difficult to reach '0' it may be that you are inserting the device along the incorrect angle.

Take a moment to consider the angle of insertion and what the path of least resistance is, and make adjustments to your angle of insertion.

# 6 Stage three: Inflation

Key points

There is a pressure limiter in the bulb pump which prevents over inflation of the cuff.

Eight pumps of the bulb pump are required for inflation. Even if you feel like you are reaching maximum cuff pressure before the eighth pump, the recommendation is to continue and perform all eight pumps, this ensures you reach the right pressure level and will not cause harm to the baby.

Withdrawing the applicator should be initially difficult due to resistance from maternal tissues - this implies that the device is in the correct place.

14. Squeeze the bulb pump fully at least eight times to inflate the cuff (Figure 26). There is a pressure limiter in the bulb which prevents over inflation of the cuff. Do not push the blue deflation button while inflating the air cuff as this will prevent proper inflation.

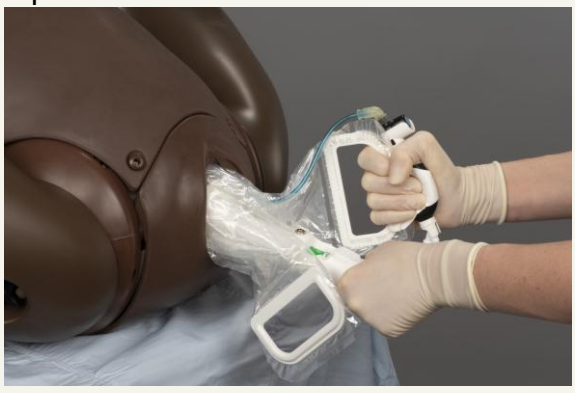


Figure 26 Fully inflate the air cuff by squeezing the bulb pump

**Top tip**

The bulb should be completely compressed during each "squeeze" to ensure adequate inflation of the cuff.

15. With one hand, protect the perineum as per your local practice and guidelines (Figure 27) and with the other hand hold the applicator handle and completely withdraw the applicator and cup (Figure 28), leaving only the sleeve in place (Figure 29). You may encounter some resistance during applicator removal which is indicative of a correctly sited sleeve. If it is very easy to remove it implies that the device may not be correctly placed. When the applicator and cup have been removed, open both handles of the sleeve to check the station of the baby's head (Figure 30).

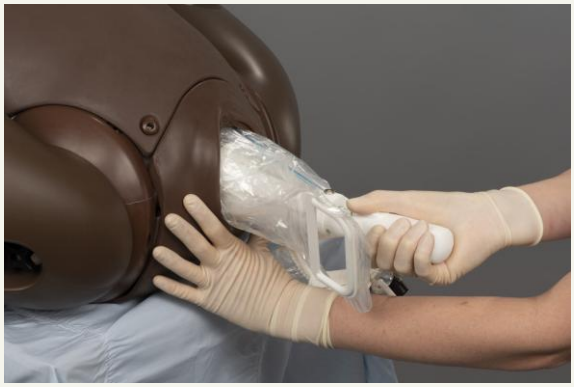


Figure 27 Protect the perineum during applicator removal

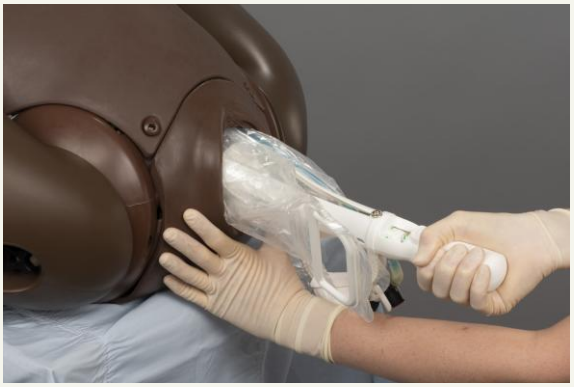


Figure 28 Slowly and progressively remove the applicator

Figure 29 Following applicator removal, the inflated air cuff and sleeve are left on the baby's head

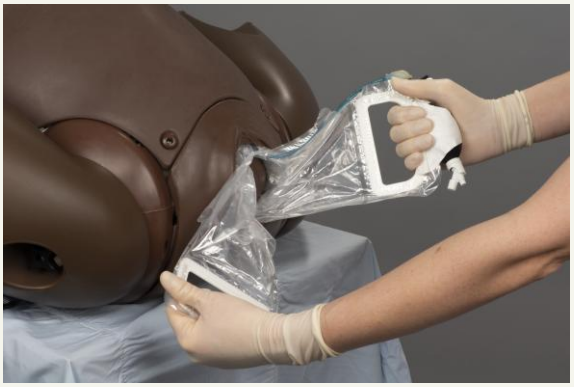


Figure 30 Opening the sleeve handles can help check the station of the baby's head

**Top tip**

As with application, when removing the applicator and cup some operators prefer to use one or two hands to perform this action.

Remove the applicator at an approximately 45 degree angle.

Make sure you squeeze the cup when it is being removed to make it more comfortable for the woman.

16. To compensate for possible reduction in cuff pressure, squeeze the bulb pump fully, twice more prior to traction.

**Trouble-shooting: what if I accidentally press the deflation button?**

- If ever accidentally pressed, immediately re-inflate with eight pumps.
- Remember that you can never over inflate the OdonAssist.

# 7 Stage four: Traction

Key points

Initially grasp both sleeve handles (one in each hand) to apply traction during contractions.

Pull the sleeve handles progressively and gently.

For the direction of traction, follow the path of the maternal birth canal.

Open sleeve handles to aid visualisation of the baby's head and confirm descent.

17. Grasp the sleeve handles, and during contractions and/or maternal effort pull progressively and gently, following the path of the birth canal (Figure 31).

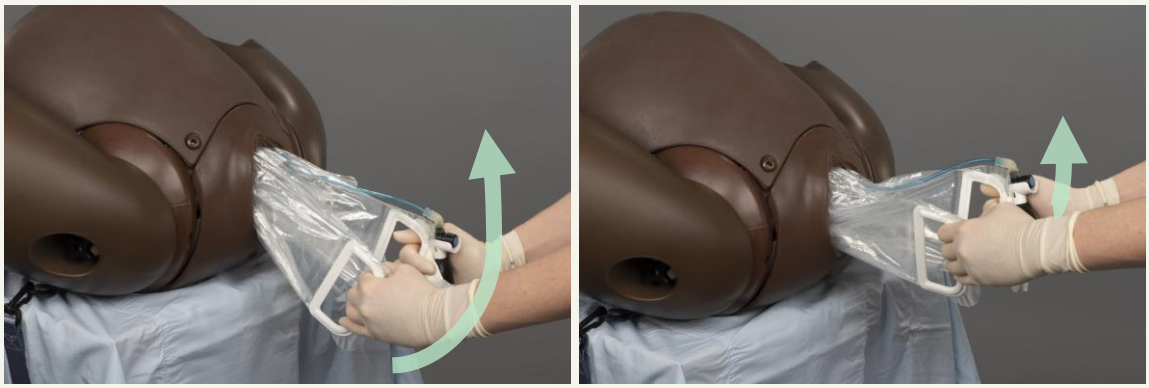


Figure 31 Traction should be following the angle of the birth canal

18. If the head has not delivered in the first contraction, open the sleeve handles to check the station of the baby and pump twice more on the bulb pump. Then continue to provide traction with the next contraction.

**Trouble shooting: what if the head is not delivered during the first contraction?**

- It is likely to take more than one contraction (or pull) to deliver the baby's head.
- Between contractions, pump the air cuff two more times to check it is fully inflated – you can do this between several contractions. Note, if the cuff is already fully inflated, you may not be able to compress the bulb pump completely.
- Open the handles of the sleeve to aid visualisation of the baby's head and to confirm descent.
- The cuff slipping off or failure of the fetal head to descend with appropriate traction may be an important clinical sign, for example obstructed labour or macrosomia. This may suggest the need for careful consideration before reapplying the OdonAssist or proceeding to a different device for AVB or considering a caesarean birth.

19. When the head starts pressing on the perineum (Figure 32), begin to pull up allowing the head to extend gently, whilst supporting the perineum. Keep one hand holding both sleeve handles whilst the other guards maternal tissues (Figure 33). Now change your angle of traction to pull upwards, following the path of the birth canal (Figure 34).

Figure 32 Change the traction angle as soon as the head is on the perineum

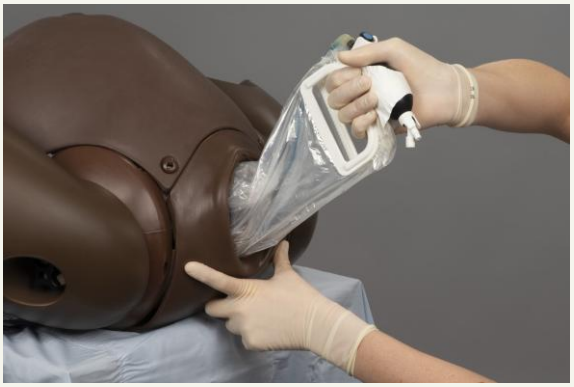


Figure 33 Perineal support is important

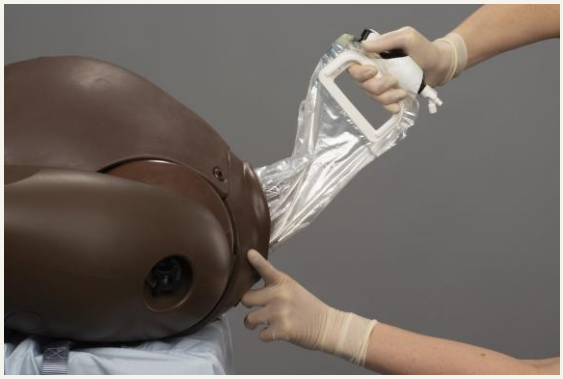


Figure 34 Pulling upwards allowing the head to extend gently, whilst supporting the perineum.

# 8 Stage five: Deflation

Key points

As soon as the baby's head is on the perineum the blue deflation button should be pressed and held.

The blue deflation line on the sleeve of the device is intended as a reminder for the operator to deflate the cuff, if this has not already been done.

Ensure the perineum is suppported during delivery of the baby's head.

Once the head is delivered, the birth should follow normal procedure as for any assisted vaginal birth.

20. As soon as the head begins to crown, press and hold the blue deflation button (Figure 35) whilst continuing to pull gently on the sleeve until the sleeve is removed from the baby's head (Figure 36). Ensure the perineum is supported during this stage.

Figure 35 Press and hold the deflation button

Figure 36 Until the sleeve is removed

**Top tip**

You can feel the inflated cuff through the perineum, this is a trigger for you to deflate the air cuff.

The intended purpose of the blue deflation line is to remind the operator to deflate the cuff if it has not been done already.

# 9 Stage six: Birth

21. Proceed to assist the birth of the baby as per normal procedure (Figure 37).

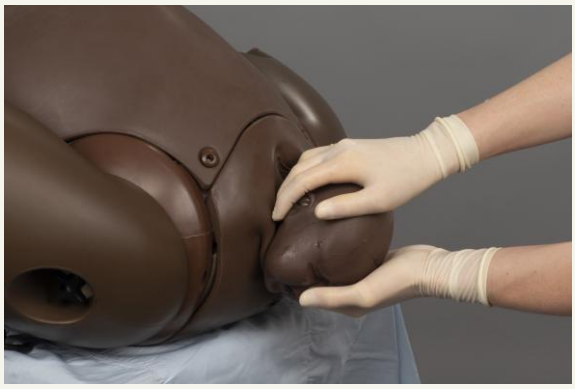


Figure 37 After the head has been delivered, continue to assist birth as per usual procedure

# 10 Stage seven: Disposal

22. Discard disposable applicator, sleeve and fastening band according to local appropriate clinical waste procedure (Figure 38). Do not reuse.

Disposal of the device should be into an appropriate clinical waste refuse unit. All parts of device as single use and should therefore be disposed of. No parts of the device are sharp, but have been in human contact and therefore should be disposed of appropriately.

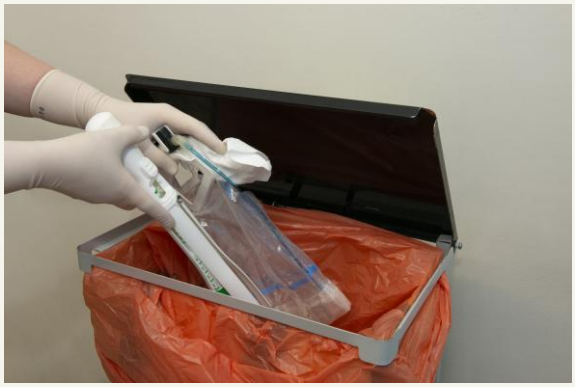


Figure 38 Dispose in a clinical waste bin

# 11 Additional considerations

## 11.1 Perineal protection

Perineal protection should be performed as with all AVBs according to local guidelines. Like with any AVB, if you feel an episiotomy is required then perform it. Episiotomy should have been discussed with the woman as part of consent for an AVB. When performing a mediolateral episiotomy the cut should be at 60 degrees when the fetal head is distending the perineum to reduce the risk of OASI.[28] As with all AVBs there is no evidence to support routine use of episiotomy,[23] therefore the operator will need to make a careful assessment at the time of birth.

## 11.2 Neonatal care

As with all AVBs care for the baby after birth is paramount. A member of the neonatal team should be present at birth according to local guidelines for any AVB. To reduce the risk of neonatal anaemia, aim for delayed/timely cord clamping. Where clinically appropriate facilitate early skin to skin with the mother. As with all AVBs paired cord samples should be processed and recorded where recommended according to local guidelines.

## 11.3 Documentation

Documentation for OdonAssist is crucial, as with all AVBs. It informs short- and long-term care including the plans and counselling in future pregnancies. Documentation should include information on:

- Assessment.
- Decision making.
- Procedure
- Plan for postnatal care.

You should use local documentation tools to capture the details of birth.

## 11.4 Maternal aftercare

As with all AVBs the following aftercare will need to be considered and completed according to local guidelines:

- Prophylactic antibiotics – a single dose of prophylactic antibiotics (for example amoxicillin and clavulanic acid) should be recommended after an OdonAssist birth to reduce the risk of maternal infection.[30,31]
- Analgesia should be offered – for most women this will include regular paracetamol and the consideration of non-steroidal anti-inflammatory drugs with escalation as required.[32]
- Bladder care – there is a risk of urinary retention with any AVB,[33] the timing and volume of the first void of urine should be monitored and documented and if regional anaesthetic was use for delivery the short-term use of an indwelling catheter in the bladder should be considered.
- Discussion about pelvic floor exercises – to prevent the risk of urinary or faecal incontinence pelvic floor exercises and/or physiotherapy should be discussed.[2]
- Debriefing – women and their birth partners should be debriefed immediately after an AVB, and at a later time in the postnatal period when the woman can have a chance to ask questions.

# 12 Non-technical skills

Non-technical skills are cognitive, social and personal resource skills that complement the clinical and technical skills required for an OdonAssist birth.[34] It is beyond the scope of this manual to include teaching on this vital skill set, but it is important to remember that good non-technical skills, including effective communication within the clinical team and with the woman, are central to the provision of safe healthcare, and a positive birth experience for a woman and her family.

The main categories of non-technical skills for health care staff can be divided into include situational awareness, decision making, communication with the team and the woman and teamwork and leadership (Table 4).

| Category | Element | Examples relevant to an OdonAssist birth |
|---|---|---|
| Situational awareness | • Gather information.<br>• Analyse information.<br>• Anticipate difficulties.<br>• Plan contingencies. | • Ensure comprehensive review of birthing person.<br>• Determine with all the information that an OdonAssist is the correct decision for this birth.<br>• Consider aspects of the AVB that might be challenging.<br>• Make a plan if the OdonAssist does not achieve vaginal birth (another device or caesarean birth). |
| Decision making | • Consider all options. | • Constant evaluation and reassessment of the decision for OdonAssist. |
| Communication and teamwork | • Exchanging information.<br>• Have respect for all members of the team.<br>• Co-ordinating team activities. | • Clear and concise handover of clinical information.<br>• Listens to the concerns of team members and the patient, asks for opinions of senior colleagues if necessary.<br>• Allocates tasks appropriately during an OdonAssist birth. |
| Leadership | • Supporting others.<br>• Maintain professional behaviour. | • Modifies behaviour according to the situation.<br>• Calm, confident and assertive and appears comfortable if challenged. |

Table 4 Non-technical skills relevant for an OdonAssist birth. Content modified from Jackson et al, 2013[34]

# 13 Communication

Communication during an AVB is of paramount importance. Both between the operator and the birthing person and their birth partner, but also between team members in the delivery room or theatre.[35] Participation in research for the OdonAssist was often found to be motivated by women wanting a kinder birth, with some aversion to the existing methods of AVB.[36] Therefore, communication during this highly emotive and stressful time in a woman's life needs to be carefully considered.[37] Introducing yourself and the other members of the team present in the room, explaining your roles and the proposed procedure of an OdonAssist in clear and understandable terms are important. Then discussing potential complications, addressing potential concerns and obtaining informed consent all need to have taken place before the OdonAssist is used. Involving the birth partner in the decision making process is also necessary when appropriate. As with all AVBs this may be a time sensitive emergency which may alter the decision making at the time.[38] During the birth an attempt should be made to maintain the dignity of the patient and using tailored communication for that particular woman's needs. Updating the woman and her partner at each stage of the devices use in a calm and considered manner.[39]

The aim of the operator is to provide accurate and truthful information to give further support and encouragement ensuring that women have the autonomy to make informed choices.[27] After the birth, a de-brief or an explanation of events can help understanding and can aid satisfaction and psychological recovery from the event.[40] De-briefing the patient some weeks after birth may also help reduce the risk of grief reaction, fear of subsequent childbirth or post-traumatic stress disorder[2], especially if there have been any complications or in a case of poor outcome.

# 14 Summary

- The OdonAssist is a novel method for assisting vaginal birth.
- Research has already been performed in both the UK and France in a clinical setting, with ASSIST II and Besançon Assist.
- The IFU for the OdonAssist includes 22 steps for safe use of the device.
- These steps can be split into seven stages: preparation, application, inflation, traction, deflation, birth and disposal.
- Consent, non-technical skills and communication are key to a successful birth with the OdonAssist.
- Care for the mother and baby should follow the guidelines for any AVB, but should include de-briefing, analgesia, bladder care, thromboprophylaxis assessment and any neonatal input that the baby requires.

Other resources to provide guidance for operators are available at www.mnhi.com these include:

1. Information video for women, birthing partners and the multi-professional team.
2. Instructions For Use.
3. Operator training video.
4. A brief overview video.

*This training, and any other training materials, should always be used in conjunction with the IFU. Always follow all the instructions, including any warnings and precautions, to ensure the best outcomes.*

# 15 References

1. Verma GL, Spalding JJ, Wilkinson MD, Hofmeyr GJ, Vannevel V, O'Mahony F. Instruments for assisted vaginal birth. Cochrane Syst Rev. 2021;2021:CD005455.

2. Tsakiridis I, Giouleka S, Mamopoulos A, Athanasiadis A, Daniilidis A, Dagklis T. Operative vaginal delivery: a review of four national guidelines. J Perinat Med. 2020;48:189–98.

3. Vousden N, Cargill Z, Briley A, Tydeman G, Shennan AH. Caesarean section at full dilatation: incidence, impact and current management. Obstet Gynaecol. 2014;16:199–205.

4. Hitt JM, Martin AS, Dietrich JE, Ahmed N, Lee GT. How do pregnant women's perceptions of obstetric forceps change according to their demographic background: a cross sectional study. BMC Pregnancy and Childbirth. 2021;21(1):371.

5. Hotton EJ, Blencowe NS, Lenguerrand E, Draycott TJ, Crofts JF, Wade J. Women's experiences of the Odon Device to assist vaginal birth and participation in intrapartum research: a qualitative study in a maternity unit in the Southwest of England. BMJ Open. 2021;11(12):e057023.

6. Crossland N, Kingdon C, Balaam MC, Betrán AP, Downe S. Women's, partners' and healthcare providers' views and experiences of assisted vaginal birth: a systematic mixed methods review. Reprod Health. 2020;17:83–112.

7. Schvartzman JA, Krupitzki H, Merialdi M, Betrán AP, Requejo J, Nguyen MH, et al. Odon device for instrumental vaginal deliveries: results of a medical device pilot clinical study. Reprod Health. 2018;15:45–54.

8. O'Brien SM, Mouser A, Odon JE, Winter C, Draycott TJ, Sumitro T, et al. Design and development of the BD Odon Device™: a human factors evaluation process. BJOG. 2017;124:35–43.

9. O'Brien SM, Winter C, Burden CA, Boulvain M, Draycott TJ, Crofts JF. Fetal head position and perineal distension associated with the use of the BD Odon Device™ in operative vaginal birth: a simulation study. BJOG. 2017;124:10–8.

10. O'Brien SM, Winter C, Burden CA, Boulvain M, Draycott TJ, Crofts JF. Pressure and traction on a model fetal head and neck associated with the use of forceps, Kiwi™ ventouse and the BD Odon Device™ in operative vaginal birth: a simulation study. BJOG. 2017;124:19–25.

11. Lange C de, Saugstad OD, Solberg R. Assessment of cerebral perfusion with contrast-enhanced ultrasound during constriction of the neck mimicking malposition of the BD Odon Device™: a study in newborn piglets. BJOG. 2017;124:26–34.

12. Hotton EJ, Lenguerrand E, Alvarez M, O'Brien S, Draycott TJ, Crofts JF, et al. Outcomes of the novel Odon Device in indicated operative vaginal birth. Am J Obstet Gynecol. 2021;224:607:e1-17.

13. O'Brien S, Hotton EJ, Lenguerrand E, Winter C, Draycott TJ, Crofts JF, et al. The ASSIST Study - The BD Odon Device for assisted vaginal birth: a safety and feasibility study. Trials. 2019;20:159–67.

14. O'Mahony F, Hofmeyr GJ, Menon V. Choice of instruments for assisted vaginal delivery. O'Mahony F, editor. Cochrane Database Syst Rev. 2010;10:201–307.

15. Murphy D, Strachan B, Bahl R, RCOG. Assisted Vaginal Birth: green-top guideline no.26. BJOG. 2020;127:e70–112.

16. Attilakos G, Sibanda T, Winter C, Johnson N, Draycott T. A randomised controlled trial of a new handheld vacuum extraction device. BJOG. 2005;112:1510–5.

17. Hotton EJ, Blencowe NS, Bale N, Lenguerrand E, Draycott TJ, Crofts JF, et al. Novel device for assisted vaginal birth: using integrated qualitative case study methodology to optimise Odon Device use within a feasibility study in a maternity unit in the Southwest of England. BMJ Open. 2022;12(8):e059115.

18. Hotton EJ, Blencowe NS, Lenguerrand E, Draycott TJ, Crofts JF, Wade J. Women's experiences of the Odon Device to assist vaginal birth and participation in intrapartum research: a qualitative study in a maternity unit in the Southwest of England. BMJ Open. 2021;11(12):e057023.

19. Hotton EJ, Alvarez M, Lenguerrand E, Wade J, Blencowe NS, Draycott TJ, et al. The Odon Device™ for assisted vaginal birth: a feasibility study to investigate safety and efficacy-The ASSIST II study. Pilot Feasibility Stud. 2021;7:72–81.

20. Mottet N, Bourtembourg A, Eckman-Lacroix A, Forner O, Mougey C, Metz JP, et al. [Focus on the Odon Device™: Technical improvements, mechanical principles and progress of the clinical research program]. Gynecol Obstet Fertil Senol. 2020;48:814–9.

21. Mottet N, Bourtembourg A, Eckman A, Hotton E, Crofts J, Riethmuller D. 390 The odon device for assisted vaginal birth – update from the besancon assist study. Eur J Obstet Gynecol Reprod Biol. 2022;270:e134.

23. Murphy D, Strachan B, Bahl R, RCOG. Assisted Vaginal Birth. Green-Top Guideline No. 26. 2020. Available from URL https://www.rcog.org.uk/guidance/browse-all-guidance/green-top-guidelines/assisted-vaginal-birth-green-top-guideline-no-26/. 2020.

24. Cambic CR, Wong CA. Labour analgesia and obstetric outcomes. Br J Anaesth. 2010;105:i50–60.

25. Bahl R, Murphy DJ, Strachan B. Qualitative analysis by interviews and video recordings to establish the components of a skilled rotational forceps delivery. Eur J Obstet Gynecol Reprod Biol. 2013;170(2):341–7.

26. Vacca A. The trouble with vacuum extraction. Curr Opin Obstet Gynecol. 1999;9:41–5.

27. Wright A, Nassar AH, Visser G, Ramasauskaite D, Theron G, Committee for the FSM and NH. FIGO good clinical practice paper: management of the second stage of labor. Int J Gynecol Obstet. 2021;152(2):172–81.

28. Leeuw JD, Wit CD, Kuijken J, Bruinse H. Mediolateral episiotomy reduces the risk for anal sphincter injury during operative vaginal delivery. BJOG. 2008;115:104–8.

29. RCOG. Operative Vaginal Delivery (Consent Advice No. 11). Available from URL https://www.rcog.org.uk/guidance/browse-all-guidance/consent-advice/operative-vaginal-delivery-consent-advice-no-11/.

30. Knight M, Chiocchia V, Partlett C, Rivero-Arias O, Hua X, Hinshaw K, et al. Prophylactic antibiotics in the prevention of infection after operative vaginal delivery (ANODE): a multicentre randomised controlled trial. Lancet. 2019;393:2395–403.

31. Humphreys ABC, Linsell L, Knight M. Factors associated with infection following operative vaginal birth – a secondary analysis of the ANODE randomized controlled trial. Am J Obstet Gynecol. 2022;

32. Nikpoor P, Bain E. Analgesia for forceps delivery. Cochrane Syst Rev. 2013;9:CD008878.

33. Carley ME, Carley JM, Vasdev G, Lesnick TG, Webb MJ, Ramin KD, et al. Factors that are associated with clinically overt postpartum urinary retention after vaginal delivery. Am J Obstet Gynecol. 2002;187:430–3.

34. Jackson KS, Hayes K, Hinshaw K. The relevance of non-technical skills in obstetrics and gynaecology. Obstetrician Gynaecol. 2013;15:269–74.

35. Rönnerhag M, Severinsson E, Haruna M, Berggren I. A qualitative evaluation of healthcare professionals' perceptions of adverse events focusing on communication and teamwork in maternity care. J Adv Nurs. 2019;75:585–93.

36. Hotton EJ, Alvarez M, Lenguerrand E, Wade J, Blencowe NS, Draycott TJ, et al. The Odon Device™ for assisted vaginal birth: a feasibility study to investigate safety and efficacy—The ASSIST II study. Pilot Feasibility Stud. 2021;7:72.

37. Kennedy S, Lanceley A, Whitten M, Kelly C, Nicholls J. Consent on the labour ward: A qualitative study of the views and experiences of healthcare professionals. Eur J Obstet Gyn R B. 2021;264:150–4.

38. Bohren MA, Tunçalp Ö, Miller S. Transforming intrapartum care: Respectful maternity care. Best Pract Res Cl Ob. 2020;67:113–26.

39. Moridi M, Pazandeh F, Hajian S, Potrata B. Midwives' perspectives of respectful maternity care during childbirth: A qualitative study. Plos One. 2020;15:e0229941.

40. Abdollahpour S, Khosravi A, Motaghi Z, Keramat A, Mousavi SA. Effect of Brief Cognitive Behavioral Counseling and Debriefing on the Prevention of Post-

traumatic Stress Disorder in Traumatic Birth: A Randomized Clinical Trial. Community Ment Hlt J. 2019;55:1173–8.

41. Hotton E, Bale N, Rose C, White P, Wade J, Mottet N, Loose A, Elhodaiby M, Languerrand E, Draycott T, Crofts J. The Odon AssistTM inflatable device for assisted vaginal birth - the Assist II study (UK) Am J Obstet Gynecol. 2024 Mar; 230(S): S932-S946. Doi: 10.1016/j.ajog.2023.05.018.

42. Mottet N, Hotton E, Eckmann-Lacroix A, Bourtembourg A, Metz JP, Cot S, Poitrey E, Delhomme L. Languerrand E, Nallet C, Lallemant M, Draycott T, Rietmuller D. Safety and efficacy of the OdonAssist inflatable device for assisted vaginal birth: the BESANCON ASSIST study. Am J Obstet Gynecol. 2024 Mar;230(3S): S947-S958. doi: 10.1016/j.ajog.2023.05.016.

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