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Trainer's Manual

odon assist™

OdonAssist™

Trainer's Manual

Inflatable device for assisted vaginal birth

Ref: TRGM-2-EN, Ver 6.0

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Legal Manufacturer: Maternal Newborn Health Innovations Singapore Pte Ltd
298 Tiong Bahru Road, #05-01, Central Plaza, Singapore 168730

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Abbreviations

AVB	Assisted vaginal birth
EU	European Union
IFU	Instructions For Use
MNHI	Maternal Newborn Health Innovations
OA	Occipito anterior
OP	Occipito posterior
OT	Occipito transverse

1 Introduction

This Trainer's Manual is intended for use by local trainers who will be running OdonAssist assisted vaginal birth (AVB) practical training sessions. Other resources available to facilitate training include:

- The Operator's Training Manual and Instructions For Use (IFU).
- The OdonAssist Operator's Videos.
- The OdonAssist Information Video for women, birthing partners and the multi-professional team.

For OdonAssist™ latest IFU version, please request a copy from the MNHI Customer Care team.

AVB involves using a medical device or instrument to assist the birth of a neonate vaginally for maternal 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 of 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 consists of three components as demonstrated in Figure 2: i) an

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).

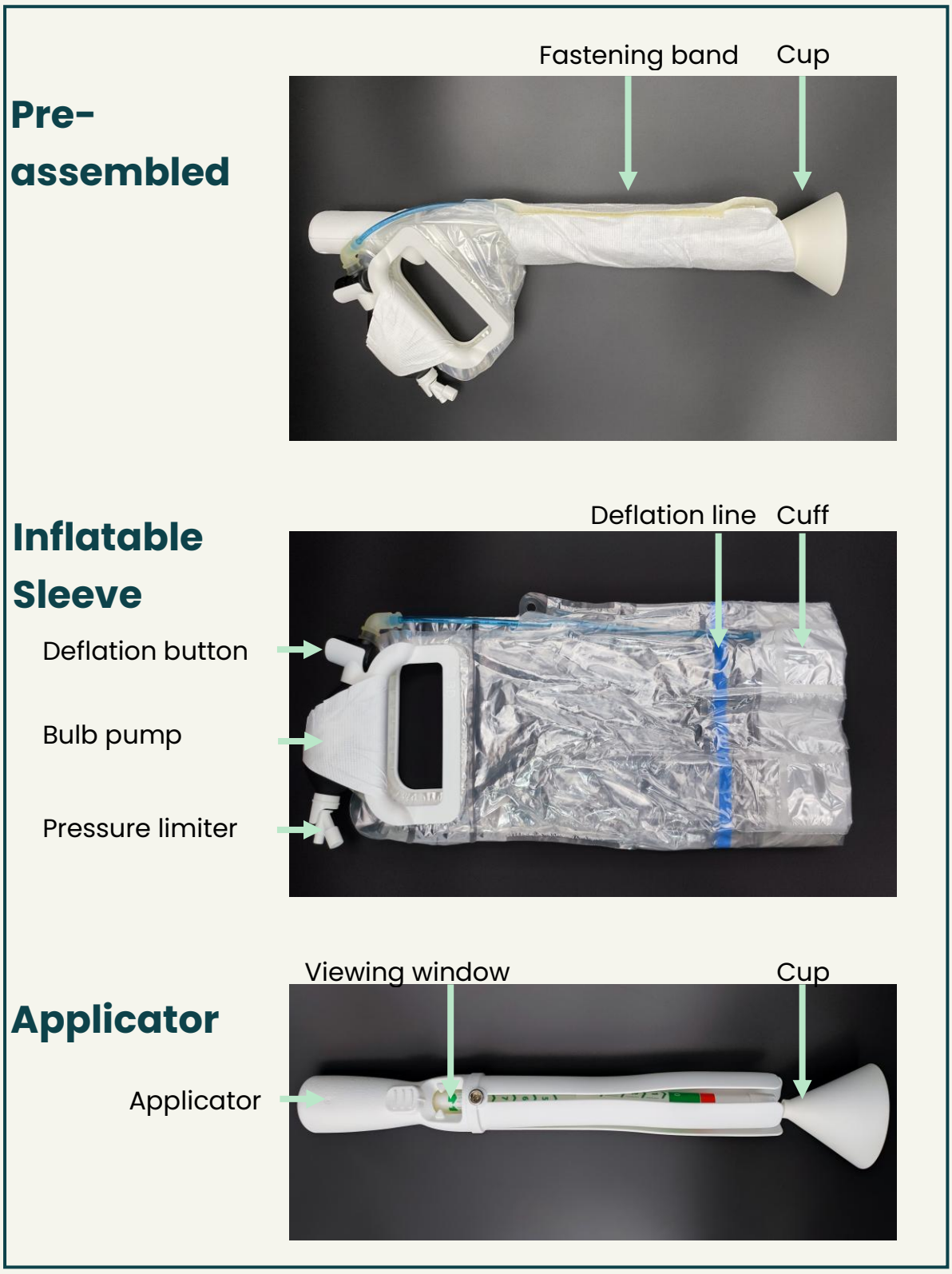

Figure 2 Components of the OdonAssist i) pre-assembled device, ii) inflatable sleeve and iii) applicator

2 Training preparation and administration

To train others in using the OdonAssist you first need to be experienced in the use of the device. Before carrying out training it may be helpful to refresh yourself on the Operator Training Manual and the IFU.

This Trainer's Manual will recap the steps required to carry out a successful OdonAssist AVB.

If you require any support with providing training, please access www.mnhi.com

2.1 Training manikin

Internationally many birth simulator manikins are used to train in AVB. During the development of these training materials MNHI have used the *Birthing Simulator PROMPT Flex – Standard* from Limbs & Things Ltd (Figure 3). This manikin has articulated thighs for simulating positioning of the woman. The anatomy of the perineum and birth canal allows training regarding station and traction. The model of the baby has suture lines and fontanelles for assessing position. The abdominal skin can be removed to allow visualisation of the position of the OdonAssist inflated cuff on the baby manikin's head. An additional module called the *Assisted Vaginal Birth Module (AVB) – PROMPT Flex* (Figure 4) has been developed in collaboration with MNHI and the OdonAssist to allow more realistic application of the OdonAssist with a more true-to-life maternal birth canal and uterus to simulate the resistance of applying the device. MNHI recommend the use of Limbs & Things Ltd PROMPT Flex when completing this training package for operators of the OdonAssist.

Figure 3 PROMPT Flex standard manikin.

Figure 4 Assisted vaginal birth (AVB) module.

How to set up your PROMPT Flex and AVB module:

1. Remove the abdominal skin from the PROMPT Flex by removing it from the poppers (Figure 5).

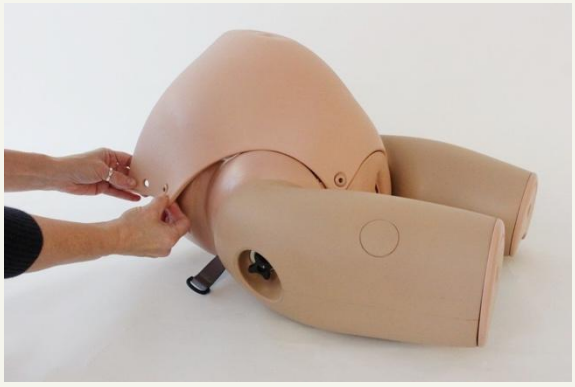

Figure 5 Remove the abdominal skin

2. Remove the pelvic ring by turning the toggle at the rear and then lifting out (Figure 6).

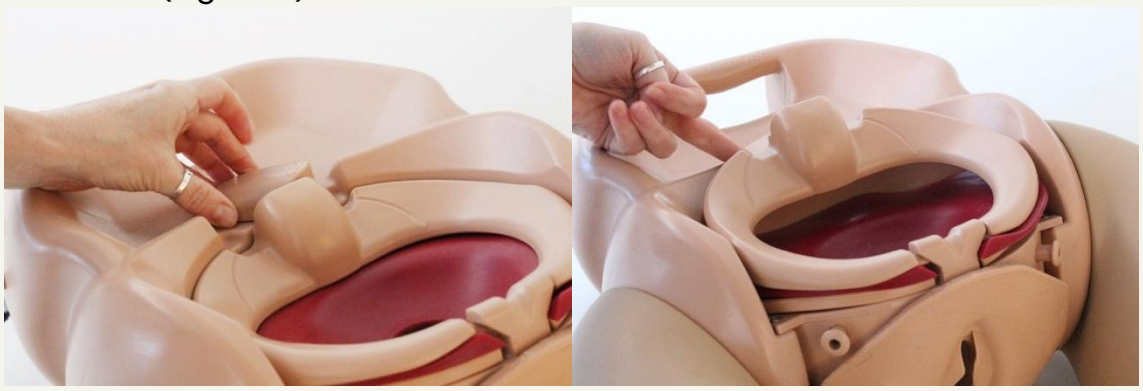

Figure 6 Remove the pelvic ring.

3. Remove the cervix by lifting off (Figure 7).

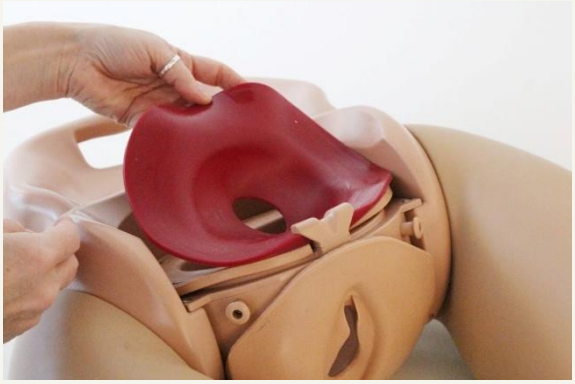

Figure 7 Remove the cervix.

4. Remove the perineum and birth canal part from the PROMPT Flex using the poppers at the front and back. Then pull the top half out through the birth canal (Figure 8).

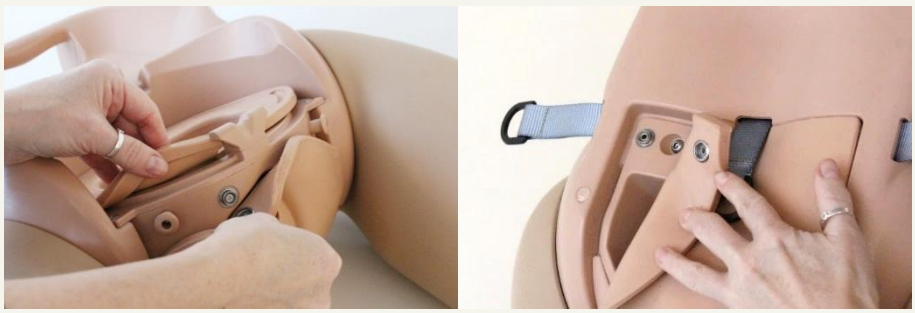

Figure 8 Remove the perineum and birth canal.

Assemble the foam inserts into the AVB perineum and birth canal (Figure 9) Ensure that the arrow on the foam part point forward toward the vaginal opening. The arrow should also be on the top half of the foam (Figure 10).

Figure 9 PROMPT Flex perineum and birth canal (left) and the AVB version (right).

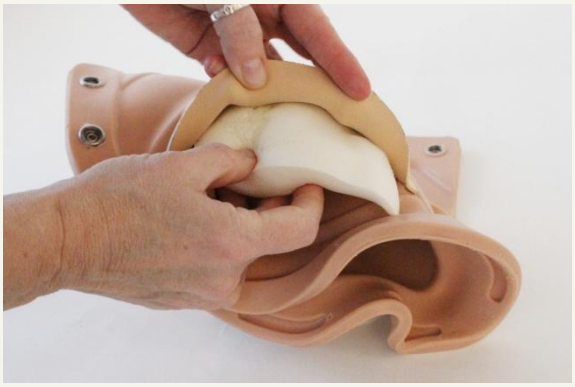

Figure 10 Assemble the foam inserts.

5. Assemble the AVB perineum and birth canal into the PROMPT Flex (Figure 11). Attach the poppers at the rear of the product. Fold the upper part and insert it through the pelvic opening. Attach the front poppers.

Figure 11 Assemble the AVB perineum.

6. Attach the AVB uterus to the PROMPT Flex.
    a. Insert the front of the pelvic ring into the front of the PROMPT Flex (Figure 12).
    b. Drop the rear of the pelvic ring down. Turn the rear toggle to clamp the pelvic ring into place (Figure 13).

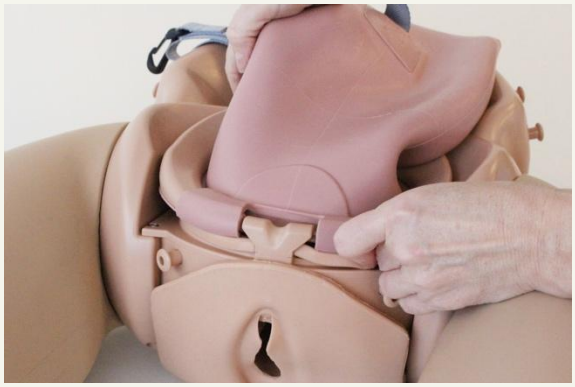

Figure 12 Insert the front of the pelvic ring.

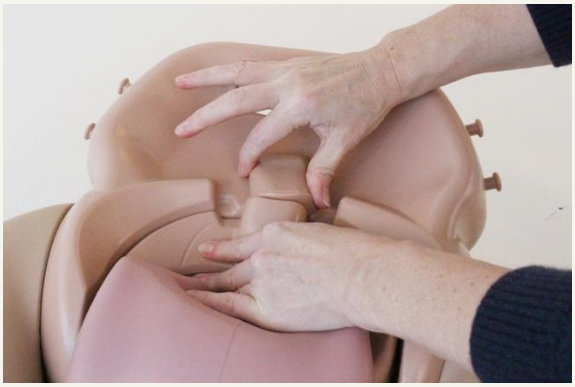

Figure 13 Turn the rear toggle.

7. Place the uterus foam insert behind the uterus (Figure 14).

Figure 14 Placing the foam insert behind the uterus.

8. Attach the abdominal skin onto the PROMPT flex using the poppers (Figure 15).

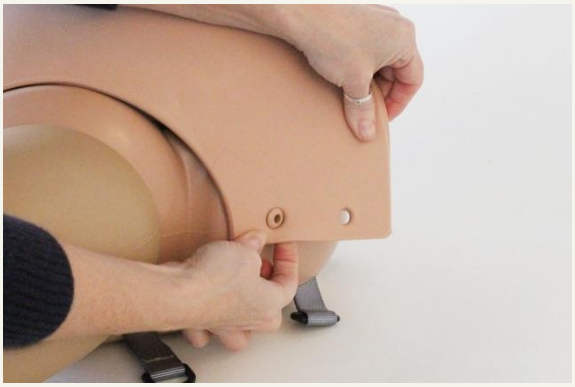

Figure 15 Attach the abdominal skin.

9. Insert the baby into the uterus from the top, after having applied lubricant to the baby and the inside of the birth canal (Figure 16).

Figure 16 Insert the baby into the uterus.

10. Roll the opening of the uterus up. Attach the webbing strap of the uterus to the clip on the PROMPT Flex (Figure 17).

Figure 17 Roll the top of the uterus up and use the webbing strap.

3 Practical advice for facilitating training

3.1 Attitude

As an OdonAssist trainer it is important to have an enthusiastic and supportive approach to training and AVB. Many individuals may feel nervous when learning to use the device, and there are aspects of its use that are different compared to forceps, ventouse or spatulas. Gentle prompting may be needed in this situation.

3.2 Equipment

It is important to be prepared before any training session. This includes making sure that you have all of the equipment commonly used during AVB as per your local standards and guidelines.

3.3 Group size

Training can be one-to-one to allow the most focused feedback and assistance to a participant, or in small groups. We recommend no more than six people in a group to ensure adequate hands-on training time. The time dedicated to the session also needs to reflect the group's size to allow all participants to work through all aspects of training. Groups can be multi-professional, with midwives and other relevant members of the maternity team observing the practical sessions, so they gain more knowledge on how the OdonAssist is used, which is important when communicating to women and their birth partners.

4 Equipment checklist example

Trainers may adapt the list below based on local AVB standards and guidelines.

Equipment	Tick when acquired
Maternal and fetal manikin	
Training version of OdonAssist (if possible, more than one training device) • Applicator, sleeve, fastening band	
Lubricant for manikin (according to the manufacturer's recommendations for the manikin)	
Luer tip syringe	
Non-sterile gloves (small, medium, large)	
Theatre drapes	
Assisted vaginal birth set (what is routine in your unit) For example: • In/out catheter • Dish for urine • Episiotomy scissors • Spencer Wells x 2 • Small clips x 4 • Needle holder • Cord scissors • Receiver dish for placenta • Sterile pot for lubricant	
Swabs	
Operator's training manual	
Whiteboard pens	
Staff role sticky labels	
AVB operating note and clinical records (ideally use local documentation)	
Printed IFU	
Consent form (ideally use local documentation)	

Figure 18 An example of equipment checklist for an AVB training using the OdonAssist

5 General training prompts

Training a clinician to use the OdonAssist can be split broadly into:

- Teaching each of the components needed for a successful AVB – this can be thought of as hands-on practical skills, breaking down the assisted birth into core steps as outlined in the IFU.
- Simulating an entire AVB scenario using the OdonAssist– this is when a clinician can perform each of the steps safely, performing this as a simulated birth; from assessment to birth, including discussion of the postnatal considerations.

5.1 Hands-on practical skills – simulating each component of an OdonAssist birth

5.1.1 Setting up the OdonAssist – including re-assembling the device for repeated use during training

Warning Box

Do not reassemble or reuse the device in a clinical setting. Reuse may cause undetectable damage that can lead to device malfunction. MNHI shall not be liable for any direct, indirect, or consequential damage or harm resulting from reuse.

For a 'human' birth, a new device will be used each time, so the OdonAssist device will already be assembled. However, for training sessions, you will likely be using the same device several times to practice key components of the birth, so you will need to be fully familiar with how to re-assemble it. Re-assembly of the device requires careful re-introduce the four spatulas into the four channels in the plastic sleeve (Figure 19 - Figure 22). Because the anterior spatulas are shorter than the posterior spatulas, it is important that these are reinserted in the correct orientation.

Figure 19 Introducing one posterior spatula

Figure 20 Introducing the second posterior spatula

Figure 21 Introducing the first anterior spatula

Figure 22 Introducing the second anterior spatula

In a smooth motion push the spatulas to the base of the sleeve (Figure 23). If any of the spatulas come out of the channel the device will not re-assemble correctly (Figure 24) and the device will fail to work. Following this, attach the red button (Figure 25) and wrap the fastening band around the device, sealing along the hook and loop strip (Figure 26).

Training tip

Insert the longer posterior spatulas first as they are less likely to 'ping' out, followed by the anterior spatulas. The trainer should practice this a few times before their first training session. Reloading the device can also take some time, so if possible, have an additional person present to reload the OdonAssist between training simulated births. Make sure that you have at least two OdonAssist devices available for use when training.

Figure 23 Ensure the spatulas are at the base of the pockets

Figure 24 If incorrectly assembled the device will not work

Figure 25 Attach the fastening band through clipping the red button

Figure 26 Wrap the fastening band around the device

Training tip

Before wrapping the fastening band around the device, make sure all the air has been released from the air cuff, because if any is left it will be difficult to seal the hook and loop strip.

Make sure that the mother and baby manikins are adequately lubricated, using the recommended lubricant. Also lubricate the outside of the OdonAssist with the lubricant. In human use, birth lubricant will be used on the device, and the birth canal does not need to be lubricated.

5.1.2 Preparing the assisted birth trolley

Prompt the operators to set up their trolley and surgical instruments as they would for an assisted birth with any instrument, to aid simulation of the birth in its entirety (Figure 27).

Figure 27 A possible layout for an AVB trolley using the OdonAssist

5.1.3 Simulating each component of an OdonAssist birth

It can be useful to demonstrate each separate step of device use. It may be useful to have a copy of the IFU available whilst doing this, to help consolidate learning. The five steps are:

1. **Preparation**
2. **Application**
3. **Inflation**
4. **Traction**
5. **Deflation**

5.2 Simulation

A full simulated scenario can be useful for consolidating the five steps of an OdonAssist birth.

5.2.1 Observation of an OdonAssist birth

During the observation of another operator, you will need to consider whether to prompt the operator if they are making any significant errors or struggling with the AVB, or to allow the simulation to progress and provide feedback at the end.

If you are training with a group of people, it may be useful to ask them to focus on use of the OdonAssist algorithm, and also specific elements of the AVB, for example:

- Communication – simulating what you would say to the person in labour can be very useful to allow you to work out wording that you find helpful.
- Device preparation – ensuring you understand why device preparation is important.
- Applying the device – simulating contractions to enable you to learn applying the device over more than one contraction.
- Air cuff inflation – clarifying the number of inflations as you perform them.
- Traction – simulating multiple fetal head positions and stations within the inclusion criteria enabling comfort when using the device in different clinical settings.
- Deflation – simulating deflation and delivery of the head is an important step to cover during training.

6 AVB using the OdonAssist explained in detail

6.1 Stage one: Preparation

Training points

Remember to outline all conditions required for safe application for the OdonAssist.

Demonstrate different methods for adequate lubrication of the device. If using a training manikin you will also need to lubricate the manikin birth canal and the baby with simulation lubricant.

Ensure the you can set up the rest of the equipment for an AVB and open the device in a sterile manner.

1. Ensure conditions for safe application of OdonAssist are met. Fetal considerations: term pregnancy, full dilation of cervix, fetal head at 1 cm or below ischial spines, cephalic vertex presentation (OA, OP, OT positions) and rupture of membranes. Maternal considerations: adequate analgesia, position the woman lying flat in lithotomy position (Figure 28) and empty the bladder.

Top tip

To aid insertion the woman needs to be lying flat in lithotomy position, as demonstrated below in Figure 28.

Figure 28 Woman lying in the correct position for an AVB with the OdonAssist

Training tip

If using a manikin for training purposes, you will need to lubricate the birth canal and fetal manikin at this stage, with simulation lubricant.

2. Open the device on to a general assisted vaginal birth trolley ensuring aseptic technique (Figure 29). Ensure that the packaging is not damaged prior to use. Discard product if the packaging is found to be damaged.

Training tip

You will only have a limited number of devices for training purposes so make sure that you keep the packaging to ensure you can demonstrate how the OdonAssist is packaged to the operators during the training sessions.

Figure 29 Open the OdonAssist onto your AVB trolley

3. Start lubricating the four inner channels of the sleeves from the handle side using birth lubricant. This stage is important to facilitate withdrawal of the applicator. To do this you:

i. Open a sterile luer tip syringe.
ii. Place birth lubricant in a sterile container.
iii. Draw up birth lubricant into the luer tip syringe (Figure 30).
iv. Insert 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 31).
v. Insert the tip of the luer tip syringe as far as you can into the spatula pocket, following the path of the white spatula (Figure 32). Then inject 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 lubricant (Figure 33).

Figure 30 Draw up lubricant into the luer tip syringe

Figure 31 Hold the device with the cup facing downwards

Figure 32 Insert the tip of the luer tip syringe into the spatula pockets, injecting birth lubricant

Figure 33 Squeeze firmly along the sleeve to spread the lubricant

Clinically, lubricating other parts of the device sleeve is optional. Operators may determine the type, amount and locations of lubrication that achieve best results. In simulation however, lubrication of the inside of the sleeve is important.

Training tip

It will be hard to achieve a birth in simulation without lubricating the inside of the sleeve. This is because, in simulation, there is no amniotic fluid to act as a natural lubricant.

4. Optional clinical lubrication includes: grasping the fastening band firmly (Figure 34) and, keeping the hook and loop strip sealed, pull back firmly on the fastening band to expose the sleeve (Figure 35). Use your hand to lubricate the inside and/or outside of the sleeve and/or the cup with birth lubricant (Figure 36).

5. Replace the fastening band by gently sliding it back over the top of the sleeve while holding the applicator handle (Figure 37).

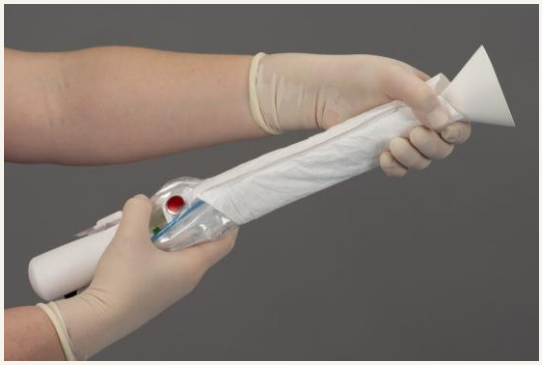

Figure 34 Grasp the fastening band firmly

Figure 35 Pull back firmly on the fastening band to expose the sleeve

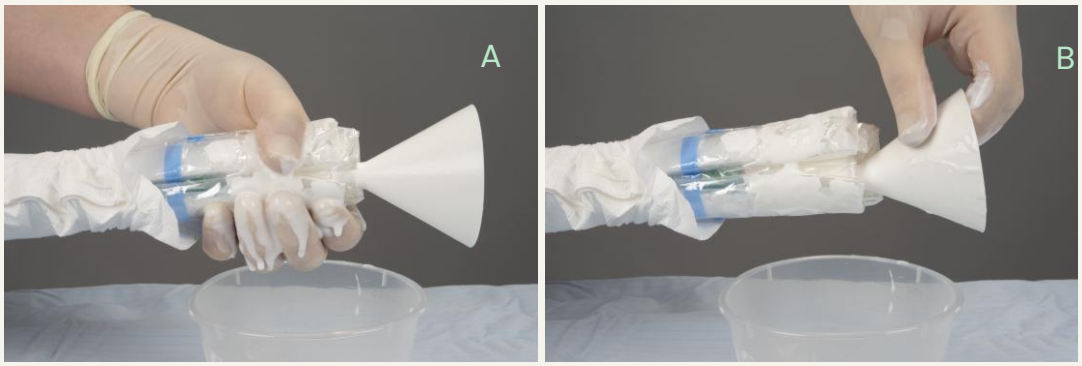

Figure 36 Lubrication of the applicator sleeve (A) and lubrication of applicator cup (B)

Figure 37 After device lubrication ensure the fastening band is replaced correctly

6.2 Stage two: Application

Training points

Talk through each aspect of applying the device.

Talk through when there is a contraction to emphasise the need to advance the sleeve during this time.

It is useful to simulate application taking more than one contraction, to replicate clinical practice.

If using a manikin with removable abdominal skin, noting the correct placement of the sleeve on the baby manikin head can be useful to visulise application.

6. Grip the applicator handle and ensure the viewing window is facing upwards (Figure 38).

Figure 38 Correct orientation of the applicator

7. Fold the cup (Figure 39) and gently insert it through the vulva towards the baby's head and check the cup has regained its circular shape (Figure 40).

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 39 Fold the cup

Figure 40 To apply the cup, it must first be folded to be inserted through the vulva

Top tips

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.

Training tip

You may try and place the cup on the flexion point or be concerned about cup placement. Remember that this is a different method to assist birth and there is no stipulation of the location of cup placement, only that it is placed on the baby's head.

8. With a single finger, circumferentially check that there is no maternal tissue trapped between the cup and the fetal head (Figure 41). Check this with a single finger sweeping circumferentially around the labia (Figure 41). The tips of all four spatulas should be within the introitus (Figure 42).

Figure 41 Before fully applying the device, check for any trapped maternal tissue

Figure 42 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 with a contraction and/or maternal effort.
- Sleeve application is slow and steady – this may occur over one or more contractions.

10. Do not hold the sleeve with your other hand as this will interfere with application (Figure 43).

Warning box

Holding and pushing the sleeve simultaneously does not work as the applicator and sleeve are attached together by the red button. This movement hinders device application.

Figure 43 Do not hold the sleeve during insertion, it will interfere with application

11. As the fastening band nears the introitus (Figure 44), unfasten the red button (Figure 45).

Figure 44 Prepare to unfasten the red button when the fastening band nears the introitus

Figure 45 Unclip the red button to remove the fastening band

Training tip

This button keeps the applicator and sleeve attached together. If it is not removed, you will be unable to use the OdonAssist.

12. Open and completely remove the fastening band once the cup has been placed inside the vulva (Figure 46). Ensure sleeve and applicator remain in place in the introitus (Figure 47).

Figure 46 Open fastening band to remove

Figure 47 Sleeve and applicator in place

13. During contractions and/or maternal effort, gently push the applicator over the baby's head.

- Keeping both hands away from the sleeve when doing this (Figure 48).
- Monitor the progress of application by looking at the viewing window.

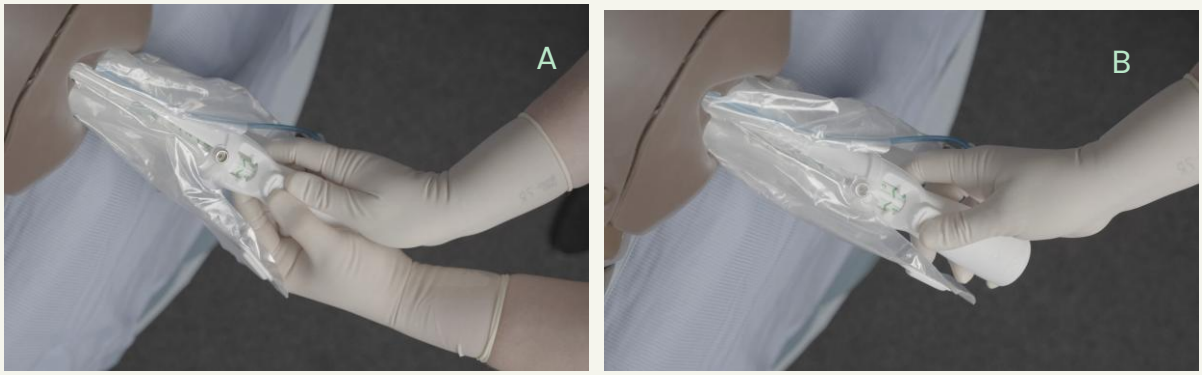

Figure 48 Apply the OdonAssist over the baby's head using either (A) a two-handed technique or (B) a one-handed technique

14. Continue to insert OdonAssist and stop when '0' appears in the viewing window. This means the device is fully inserted (Figure 49).

Figure 49 Apply the device fully
(to when '0' appears in the viewing window and it is all green)

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.

Troubleshooting: what if the applicator enters the red zone?

- The red zone is an alert to the operator that the device is inserted too far (Figure 52).
- It is important to pull back slightly to ensure that the device is inserted to a safe level.
- Be aware that if the woman pushes or there is a contraction, before the air cuff is inflated, there is a risk of the applicator entering the red zone. Do not panic, just withdraw the applicator slightly.

Figure 50 The red zone seen in the viewing window

Some application tips from experienced operators include:

1. Utilise maternal effort during application.
2. Initially aim over the occiput at the beginning of application to aid application.
3. Use micro-adjustments to follow the curve of the birth canal during application.
4. If the fetal head is rising or amniotic fluid leakage is noted, pause briefly and look for a more favourable angle for insertion.
5. At '0' tilt the applicator handle towards the baby's face to gain a more optimal cuff placement.
6. Continue to keep light pressure on the applicator handle to ensure it remains at the '0'position.

6.3 Stage three: Inflation

Training points

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

Use your whole hand to inflate the air cuff.

Removal of the applicator should be initially difficult and that this is an indicator that the sleeve has been applied in the correct position.

15. Squeeze the bulb pump fully at least eight times to inflate the cuff (Figure 51). 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 51 Fully inflate the air cuff by squeezing the bulb pump

Training tip

Operators often take their left hand off the device when squeezing the bulb pump –keep your hand on the device handle as it is important to stabilise and hold the device with your left hand whilst the air cuff is being inflated, to ensure for correct positioning.

16. With one hand, protect the perineum as per your local practice and guidelines (Figure 52) and with the other hand hold the applicator handle and completely withdraw the applicator and cup (Figure 53 and Figure 54), leaving only the sleeve in place (Figure 55). 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.

Training tip

Demonstrate to operators that they should squeeze the cup as they remove it from the introitus (Figure 54), to reduce the risk of damage to maternal vulval tissue and to make it more comfortable for the woman.

Figure 52 Protect the perineum during applicator removal

Figure 53 Slowly and progressively remove the applicator

Figure 54 Squeeze the cup during removal

Figure 55 Following applicator removal, the inflated air cuff and sleeve are left on the baby's head

17. When the applicator and cup have been removed, open both handles of the sleeve to check the station of the baby's head (Figure 56).

Figure 56 Opening the sleeve handles can help check the station of the baby's head

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

Top tip

As with application, when removing the applicator and cup some operators prefer to use one or two hands to perform this action. Tilting the applicator at an angle may help facilitate removal.

6.4 Stage four: Traction

Training points

Try both methods of grasping the handles (either separately or together) and see the difference in visulisation of the baby's head during descent.

Remember to follow the direction of the birth canal for the angle of traction.

Discuss possibilities for clinical management if the OdonAssist birth is not successful - you can use a second device.

19. Grasp the sleeve handles, and during contractions and/or maternal effort pull progressively and gently, following the path of the birth canal (Figure 57).

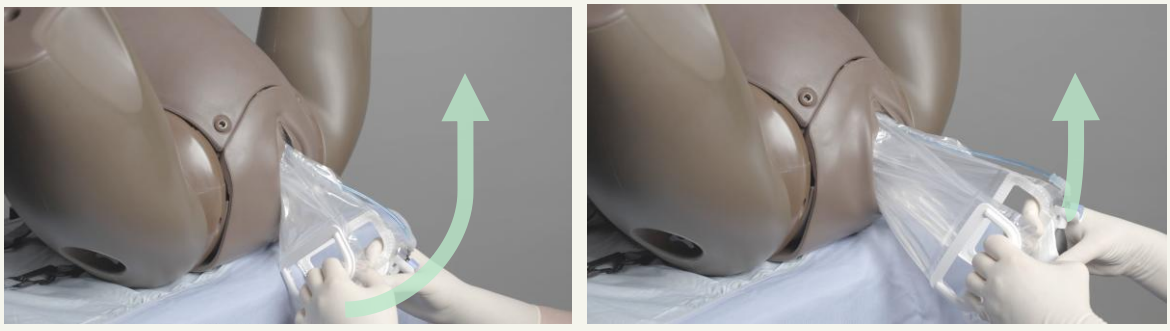

Figure 57 Traction should follow the angle of the birth canal

Warning box

Never apply traction through one handle only (Figure 58).

Figure 58 Never apply traction through one handle only

20. You can repeatedly inflate during traction, and this may be beneficial in maintaining cuff pressure if the space surrounding the air cuff changes during descent due to maternal anatomy.

Top tip

The angle of traction should follow descent and, if applicable, the natural rotation of the fetal head in the birth canal. Traction should be progressive and gentle.

Training tip

Take the opportunity to solidify the importance of a safe assisted birth and re-iterate the guidance for safe traction:

- Should be progressive descent with moderate traction during each contraction.
- If slippage occurs, you can use a second OdonAssist device.
- Abandon if birth is not imminent after three pulls with correctly applied air-cuff.
- If one device fails then you can use a second OdonAssist or another device for AVB, if it is still your assessment that AVB is safe.
- Consider pros and cons of second instrument.
- Consider conversion to caesarean birth.

Training tip

There are two methods for providing traction. The method used most predominantly is the "two-handed technique". Demonstrate both to operators and allow them to try the methods on manikins.

The two-handed traction technique (Figure 59)

This requires the operator to hold one handle in each hand. It enables visualisation of the baby's head and perhaps more control during descent.

Figure 59 The two-handed traction technique

The one-handed traction technique (Figure 60)

This requires the operator to hold both handles in their dominant hand.

Figure 60 The one-handed traction technique

21. If the head has not delivered in the first contraction, open the sleeve handles to check the station of the baby (Figure 61) and pump twice more on the bulb pump. Then continue to provide traction with the next contraction. Like with all AVBs, the delivery of the head is often over more than one contraction. The OdonAssist devices allows the operator to palpate anatomy and landmarks on the baby without disturbing placement.

Figure 59 Opening the sleeve handles enables you to visualise the station

Training tip

- Inflation throughout traction is useful to maintain the cuff pressure.
- Moving the hand(s) up and down during traction may aid the operator to find the best angle for progression. It is useful to demonstrate this on a manikin. The angles will be different depending on the position and station of the baby.
- Traction is often required over several contractions. Between contractions visualising the baby's head and checking the air cuff is fully inflated (by pumping two more times) are useful to perform to confirm correct cuff placement.

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

- It is likely to take more than one contraction.
- 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.

22. When the head starts pressing on the perineum (Figure 62), keep one hand holding both sleeve handles (Figure 63) whilst the other guards maternal tissues (Figure 64). Now change your angle of traction to pull upwards, following the path of the birth canal (Figure 65).

Figure 60 Recognise that the head is on the perineum

Figure 61 Put both handles in one hand

Figure 62 Perineal support is important

Figure 63 Change the angle of traction as soon at the head is on the perineum

6.5 Stage five: Deflation

Training points

The blue line should serve as a prompt only. By the time that this is seen, the cuff should already have been deflated.

Pressing and holding the blue button ensures all air is removed from the cuff. A quick press will not release all the air.

Simulate the deflation button being accidently pressed and the device deflating during the simulated assisted birth, then trouble shoot how to manage this.

23. As soon as the head is on the perineum, press and hold the blue deflation button (Figure 66) whilst continuing to pull gently on the sleeve until the sleeve is removed from the baby's head. Ensure the perineum is supported during this.

Figure 64 Press and hold the deflation button

24. If this button is accidentally pressed during an assisted birth, re-inflate with eight pumps.

25. Episiotomy is possible with the OdonAssist and could be considered, if appropriate, as per your local guidelines and practice.

Training tip

See what happens if you only "quickly" press the deflation button – the cuff does not fully deflate, leaving a potential increased risk of maternal perineal trauma.

Remember to press and hold the deflation button until the sleeve is removed from the baby's head.

Top tip

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

6.6 Birth

26. Proceed to assist the birth of the baby as per normal procedure (Figure 67).

Figure 65 After the head has been delivered, continue to assist birth as per usual procedure

6.7 Disposal

27. Discard disposable applicator, sleeve and fastening band according to local appropriate clinical waste procedure (Figure 68). Do not reuse.

Disposal of the device should be into an appropriate clinical waste refuse unit. All parts of device are 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 66 Dispose of the device in a clinical waste bin

7 Consent

Consent for an assisted birth using the OdonAssist should be based on your local procedures and guidelines.

8 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 typically includes information on:

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

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

9 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, ASSIST II and Besançon ASSIST studies.
- The IFU for the OdonAssist includes 22 steps for safe use of the device.
- These can be split into preparation, application, inflation, traction and deflation.
- 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 AVB in your local practice.

Other resources to provide guidance for trainers are available at www.mnhi.com. These include:

1. Information Video for women, birthing partners and the multi-professional team.
2. Operator Training Video.
3. A Brief Overview Video.
4. Operator's Manual

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.

For further information please visit www.mnhi.com

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