LEVOPLANT TRAINEE MANUAL

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CREDITS

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Credit to EngenderHealth Source Material derived from

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Thanks to Dr. Asma Khalid and Dr. Brenda Chamalé for their contributions to these training materials.

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WomanCare academy

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INTRODUCTION TO LEVOPLANTTM

Welcome to your Levoplant[™] Training. This Manual is designed to complement your Levoplant[™] Training session and provides essential information for counselling for contraception, insertion and removal of Levoplant[™]. We would recommend that you use this Manual together with the Family Planning - A global handbook for providers (World Health Organization 2018 edition) which provides essential information on all methods of contraception.

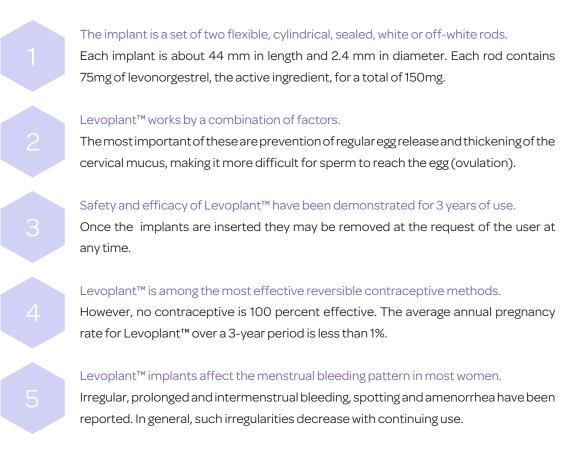
OBJECTIVES

As a provider of Levoplant[™], you must be able to provide your service users with the highest quality service. To enable this, you should:

- Be assessed by a trainer as competent for counselling, insertion and removal of Levoplant[™] so that the service you provide is safe and effective.
- Take responsibility for maintaining your own competence by accessing supportive supervision opportunities.
- Provide a rights-based environment for service delivery with attention to acceptability, accessibility and availability of services thereby fostering trust with those seeking services.

What is Levoplant[™]?

The global brand Levoplant™ is also known as Sino-implant (II).



Who can provide Levoplant[™]?

The WHO guidance for task sharing for contraceptive implant services is summarised in Table 1. All levels of health provider may be involved in provision of information about implant provision with a more restricted number of cadres who can also provide insertion and removal. It is important to be aware of what type of training is suitable for you.

In addition to having the right experience and background to provide implants, potential providers of Levoplant[™] need to be motivated to provide high quality contraceptive services as part of their day-to-day practice. Appendix 1 at the end of this manual contains a summary of information to provide to the trainers in advance of the course to ensure that you attend the training that is right for you. Even if you are familiar with the subject matter, please take this opportunity to use this Manual and the Training itself as part of you Continuing Professional Development. Table 1: Summary of WHO Guidance for task sharing for implant provision¹

ACTIVITY	CADRES
Promotion of maternal, newborn and reproductive health interventions	Lay health workers Auxiliary Nurses Auxiliary nurse midwives Nurses Midwives All doctors
Insertion and removal of contraceptive implants	Nurses Midwives Doctors
Insertion and removal of contraceptive implants (with strict monitoring and evaluation)	Auxiliary Nurses Auxiliary Midwives

¹WHO. (2017). Task sharing to improve access to family planning/contraception. (No. WHO/RHR/17.20). Geneva: World Health Organization





The training is competency-based

These competencies are outlined in Appendix 2 and provide the basis for ongoing clinical supervision; you can use this checklist for post training self-assessment and with your clinical supervisor. They also provide an objective way for the trainer to assess whether you show adequate skills to provide Levoplant[™] services. You will be formally assessed at the end of the day and receive feedback from the trainer. If you have fulfilled essential competencies, you will 'pass' the course and receive a certificate. If you do not achieve the required competencies by the end of training, you and the trainer can discuss whether you can practice under direct supervision in your home training environment before you can provide implant services independently. It may be that you and the trainer will discuss repeating the training. The possible training outcomes are summaries in Table 2. A longer version of this for you to fill in after training can be found in Appendix 3 of this manual.

Name of trainee: Date of training: Provide independently **Requires direct** Not able provide service without need for supervision? supervision before independently? Yes/No Yes/No Yes/No Yes/No Yes/No Yes/No Yes/No Yes/No Yes/No Follow up actions agreed with timeframe: Who will support trainee in their setting? Further numbers of insertions Is the trainee competent to train others? No Yes required first: Is the trainee suitable to return for a No Unable to comment Yes training of trainers? Other reflections about Levoplant[™] and training:

Table 2: Competency Assessment for Trainees

WomanCare academy

MODULE 1

COURSE OBJECTIVES

TRAINEES TO BE ABLE TO:

- Describe the method of action, advantages, disadvantages of Levoplant[™] within the context of contraceptive choice.
- Describe and demonstrate competency in counselling for Levoplant™
- Assess client eligibility using Medical Eligibility Criteria.
- Demonstrate competency in insertion and removal of 2 rod implant and the provision of accurate discharge and follow up information.

What do providers need to know about LevoplantTM?

WHO CAN USE LEVOPLANT[™]?

Any woman of any age.

Any woman who has recently been pregnant or is breastfeeding.

Levels of levonorgestrel obtained with implants do not affect the quality or quantity of breast milk. Fully breast-feeding mothers can have implants inserted any time between giving birth and 6 months postpartum without the need for a back-up method.

Any woman who smokes.

Women who are HIV positive.

Levoplant[™] is appropriate for women who wish to space or limit births.

Changes in bleeding pattern may occur with Levoplant™; appropriate counselling may make these changes more acceptable.



SIDE EFFECTS:

The main side effect is a change in bleeding pattern including lighter, irregular and infrequent bleeding for the duration of Levoplant[™] use. Any prolonged bleeding will likely settle after 12 months. If it is becoming problematic for the user try 800 mg ibuprofen 3 times daily after meals for 5 days, or give the woman combined oral contraceptives when the bleeding starts, either one pill containing levonorgestrel daily for 21 days or 50 µg ethinyl estradiol daily for 21 days.

Abdominal pain may also be reported. In these cases, for mild abdominal pain, you can suggest aspirin (325–650 mg), ibuprofen (200–400 mg), paracetamol (325– 1000 mg).

For severe abdominal pain refer at once for immediate diagnosis and care to exclude ectopic pregnancy and non-related conditions such as appendicitis.

Other side effects include headache, nausea, weight change.

Please refer to the Prescribing Information for a complete list of side effects.



How to assess a client for suitability for Levoplant[™]?²

Examinations and tests are not necessary if the WHO Medical Eligibility Criteria (MEC) is used as a screening tool. Ask the following questions:

Do you have cirrhosis of the liver, a liver infection, or liver tumor? If so, do not provide implants and discuss non hormonal methods.

Do you have a serious blood problem now with a blood clot in your leg or lungs? If so, do not provide implants and discuss non hormonal methods.

Do you have vaginal bleeding that is unusual for you? If so, this should be investigated to exclude pregnancy or another medical issue. Hormonal methods and the copper IUD should not be used until there has been a diagnosis.

Do you have or have you ever had breast cancer? Breast cancer means that the woman is not eligible for implants or other hormonal methods.

Do you have systemic lupus erythematous with positive or unknown antiphospholipid antibodies? If so, do not use implants.

Use of Levoplant[™] is also contraindicated in patients with hypersensitivity to levonorgestrel or any other component of Levoplant[™] or other diagnosed or suspected sex hormonedependent neoplasia.

The prescribing information of concomitant medications should be used to identify potential drug interactions. Those that decrease effectiveness of implants include anti epilepsy drugs (but not valproate) and the antibiotics rifampicin and griseofulvin.

What happens If the implant fails?

If the woman falls pregnant, the implants must be removed. Animal studies have shown that very high doses of progestogenic substances may cause masculinization of female foetuses. However, there is no evidence that exposure to combinations of estrogens and progestogens will have a teratogenic or fetotoxic effect.

²Further information can be found in the Medical Eligibility Criteria for Contraceptive Use, 5th Edition, 2015 https://apps.who.int/iris/bitstream/handle/10665/181468/9789241549158_eng.pdf?sequence=9

When to insert LevoplantTM?

The guidance for when to start Levoplant[™] is the same for other two rod implants and is summarised in Table 3 below:

Table 3: Guidance for initiating Levoplant[™]

WOMAN'S SITUATION	WHEN TO START
Having menstrual cycles or switching from a nonhormonal method	If she is starting within seven days after the start of her monthly bleeding there is no need for a backup method.
	If it is more than seven days after the start of her monthly bleeding she can have Levoplant [™] inserted if she is reasonably certain she is not pregnant. She will need a backup method for the first seven days after insertion.
	If switching from an IUD she can have Levoplant [™] inserted immediately.
Switching from a hormonal method	She can have the implant immediately if she has been using the hormonal method consistently and correctly or if it is otherwise reasonably certain she is not pregnant. There is no need to wait for her next monthly bleeding. There is no need for a backup method.
Fully or nearly fully breastfeeding: less than six months after childbirth	If she gave birth less than six weeks ago delay insertion until at least six weeks after giving birth.
	If monthly bleeding has not returned Levoplant [™] can be inserted any time. There is no need for a backup method.
	If monthly bleeding has returned she can have Levoplant [™] inserted as advice for women having menstrual cycles.
Fully or nearly fully breastfeeding more than six months after childbirth	If her monthly bleeding has not returned she can have Levoplant [™] if it is reasonably certain she is not pregnant. She will need a backup method for the first seven days after insertion.
	If I monthly bleeding has returned she can have Levoplant [™] inserted as advised for women having menstrual cycles

How to exclude pregnancy in a potential user of Levoplant[™]?

NO	1 Did your last menstrual period start within the past 7 days? YES
NO	2 Have you abstained from sexual intercourse since your last menstrual period or delivery? YES
NO	3 Have you been using a reliable contraceptive method consistently and correctly since your last menstrual period or delivery or miscarriage?
NO	4 Have you had a baby in the last 4 weeks? YES
NO	5 Did you have a baby less than 6 months ago, are you fully or nearly-fully breastfeeding, and have you had no menstrual period since then? YES
NO	6 Have you had a miscarriage or abortion in the past 7 days? YES

If the client answer NO to all of the questions, pregnancy cannot be ruled out using the checklist. Rule out pregnancy by other means the client answered YES to at least one of the questions and she is free of signs or symptoms of pregnancy, you can be reasonably sure she is not pregnant.

RIGHTS'-BASED APPROACH TO HIGH QUALITY CONTRACEPTIVE SERVICE DELIVERY

The principles of a rights-based approach to service delivery are that clients or end-users must not only have access to safe, effective, acceptable care – there should effort to increase access, equity and availability in a healthcare environment that is acceptable. Examples of how to promote a rights-based service for Levoplant[™] include:



Ensuring availability through avoiding stock outs and having a full range of contraceptive methods to maximise choice.



Promote acceptability of services by providing an environment where there is visual and auditory privacy, confidentiality, dignity and respect. 3

Increase access by changing appointment times or have walk-in clinics to suit local populations.

Ensure safety and effectiveness by ensuring that all provider skills and knowledge are up-to-date and there is a steady supply of high quality equipment and Levoplant[™].

Verified Levoplant[™] distributors can be found at www.dktwomancare.org,

and you can always email orders@dktwomancare.org for more information on how to procure Levoplant[™].

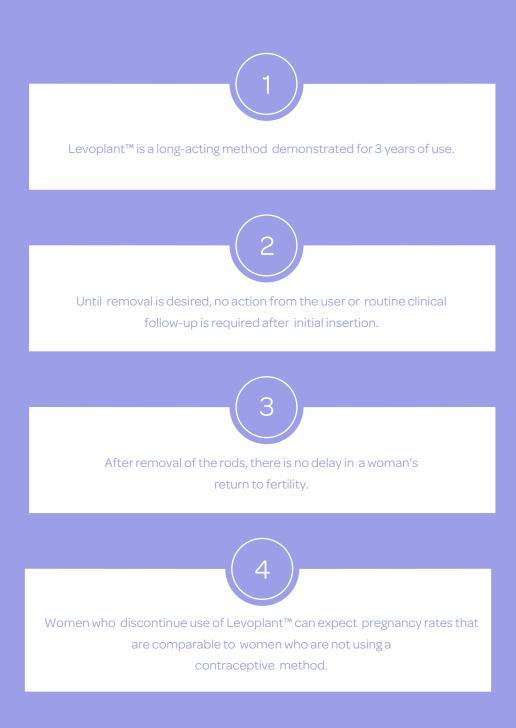
Rights based framework for counselling and informed consent

A well-known rights-based framework for good contraceptive counselling uses the 'REDI' approach. This is summarised in Table 4 below. Information specific to Levoplant[™] and other contraceptive methods can be communicated using this approach.

Table 4: Good counselling techniques - the REDI approach (courtesy of EngenderHealth)



WHAT DO WOMEN SPECIFICALLY NEED TO KNOW ABOUT LEVOPLANT TO MAKE AN INFORMED DECISION?





MODULE 2

HOW TO INSERT LEVOPLANTTM

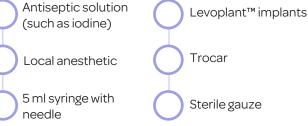


Antiseptic soap and



Gallipot

- Kelly or Crile forceps (5.5″ or 14 cm)
- Sterile surgical drapes
 - One pair of sterile talc-free gloves

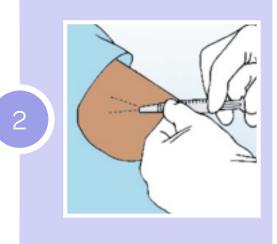


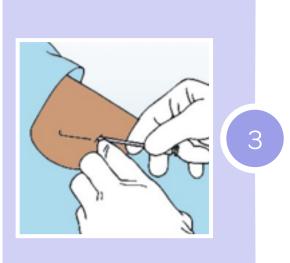


- Explain the procedure to the client and encourage questions.
- Determine that required sterile or high-level disinfected instruments and implants are present.
- Wash hands and thoroughly dry them.
- Check to be sure that the client has thoroughly washed and rinsed her entire arm.
- Position the woman's arm and place a clean, dry cloth under her arm.
- Mark position on arm for insertion of rods 6 cm to 8 cm above the elbow folder (this should form a "V" pattern).
- Put on a sterile pair of hand gloves.



- Set up sterile field and place implant rods and trocar on it.
- Prep insertion site with antiseptic solution.
- Place sterile or high-level disinfected drape over arm.
- Inject 2 ml of local anesthetic applied just under the skin, raising a wheal at the insertion point and advancing up to 5 cm along the first insertion track, injecting 1 ml of local anesthetic along the track as you withdraw. Without completely removing the needle, reorient to the second insertion track, advance up to 5cm, and again inject 1 ml of local anesthetic along track as needle is withdrawn. Let the arm rest for approximately 5 minutes and check for anesthetic effect before making skin incision.

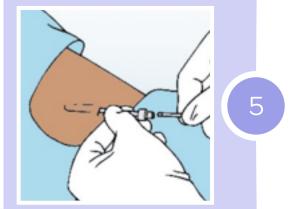




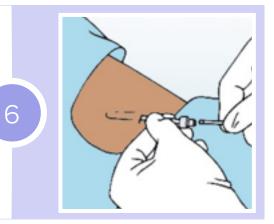
- Make a small incision with a scalpel in the skin on the inside of the upper arm. Alternatively, use the trocar to puncture the skin. Insert the tip of the trocar beneath the skin at a shallow angle.
- Gently advance the trocar superficially under the skin with the bevel facing up while tenting the skin. Tenting of the skin enables the implant to be placed under the skin and not deeper into the arm. The rod should be placed parallel to the skin. Take great care not to insert trocar into the arm muscle.

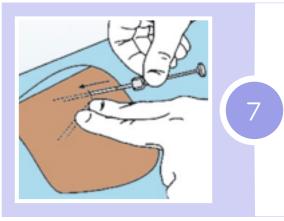
Note: The trocar has two marks on it. The mark closest to the hub indicates how far the trocar should be introduced under the skin to place the implants. The mark closest to the tip indicates how much of the trocar should remain under the skin following placement of the first implant.

• When the trocar has been inserted to the mark closest to the hub, remove the obturator and load the first implant into the trocar, using thumb and forefinger.



• Using the obturator to push, gently advance the implant towards the tip of the trocar until you feel resistance. *Never force the obturator.* Holding the obturator stationary, withdraw the trocar to the mark closest to the trocar tip. The implant should be released under the skin at this point. It is important to keep the obturator stationary and to avoid pushing the implant into the tissue.
 Do not completely remove the trocar until both implants have been placed.





- To place the second implant, align the trocar so that the second implant will be positioned at about a 30° angle relative to the first implant. Repeat steps 3-4. The rods are placed in the shape of a V opening toward the shoulder. Leave a distance of about 5 mm between the incision and the tips of the implants.
 Remove the trocar and immediately dispose of it in a sharps container.
- Remove drape and wipe the client's skin with alcohol.
- Bring edges of incision together and close it using surgical tape, then cover it with tape on a sterile gauze (2x2) or an adhesive bandage.
- Apply pressure dressing snuggly.
- Instruct client regarding wound care:
 - * Keep the area around the insertion site dry and clean for at least 48 hours.
 - * Leave the gauze pressure bandage in place for 48 hours and the surgical tape or adhesive bandage in place until the incision heals (normally 3-5 days).
- Discuss with the client what to do if she experiences any problems following insertion or side effects from the implant.
- Advise client that she can have the rods removed at any time if she desires.
- Make return visit appointment, if necessary.
- Observe the client for at least 15-20 minutes before discharging.

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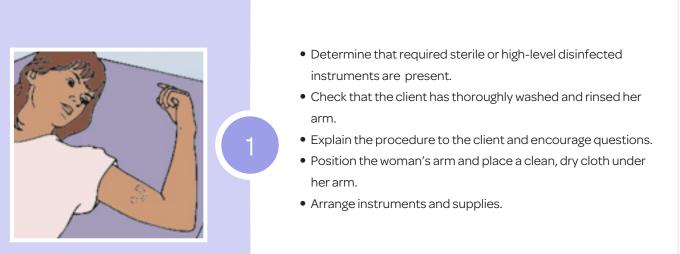


See Appendix 2 for Competencies for Levoplant™ insertion and removal

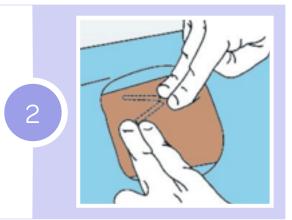
MODULE 3

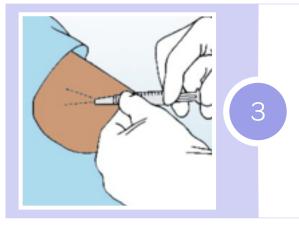
HOW TO REMOVE LEVOPLANTTM





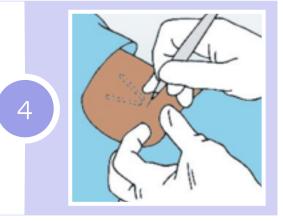
- Before starting the removal, the implants must be located by palpation with ungloved fingers and the position of each rod marked.
- After marking implant position, put on a sterile pair of hand gloves.
- Prep removal site with antiseptic solution twice.
- Place sterile or high-level disinfected drape over arm. Check for anesthetic effect before making skin incision.

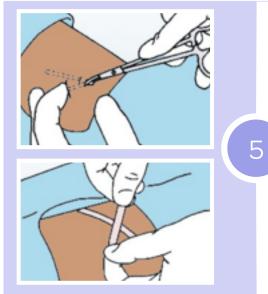




- Inject 1ml of local anesthetic applied at the incision site and under the end of the rods.
- To help view the proximal tip near the insertion incision (bottom of the V), push down on the distal end of the implant.
 Anesthetic injected over the implants may obscure their position and make removal more difficult.

- Check for anesthetic effect before making skin incision.
- A small skin incision of 2-4 mm is made close to the ends of the implants (below the bottom of the V).
 Do not make a large incision.





- Push each implant gently with your fingers towards the incision.
- When the tip is visible in the incision, grasp it with the straight Crile/Kelly forceps and gently pull out the rod without twisting or pulling on the rod, as this may lead to rod breakage.
- After the procedure is completed, close the incision and bandage it as after insertion.

The arm should be kept dry for 24-28 hours.



Considerations for Implant Removal

Levoplant[™] should be removed after 3 years of use or at the request of the client at any time. Removal implants can be done at any time in the menstrual cycle.

When removing, if the tip of the implant does not become visible in the incision, gently insert the curved Crile/Kelly forceps into the incision, trying to grasp the implant. Flip the forceps over with your other hand and with the scalpel, carefully dissect the tissue around the implant to expose it and then grasp the implant with the straight Crile/Kelly forceps. The implant can then be removed, being careful to avoid a twisting or pulling motion.

If the implant is encapsulated, grasp and stabilize the exposed rod with the curved Crile/Kelly forceps. Use the scalpel to very gently make a small incision into the tissue sheath to expose the tip of the rod. Use the tip of the scalpel to gently separate the encapsulated tissue from the rod, moving distally, keeping light but steady traction on the rod until the rod is completely freed from the tissue.

Mosquito forceps can be used if Crile/Kelly forceps are not available; however, use of Crile/Kelly forceps has been shown to minimize damage to the implants during removal.

The implants should be removed very gently. This will take more time than the insertion. The implants may be nicked, cut or broken during removal. If removal proves difficult or both implants cannot be removed, the patient should be asked to return for a second visit after the removal area has healed. A non-hormonal method of contraception should be used until both implants have been completely removed.

If the patient wishes to continue using the method, a new set of Levoplant[™] may be inserted through the same incision, either in the same or in the opposite direction. Loss of contraceptive effect occurs practically immediately after removal, and another contraceptive method should be applied unless pregnancy is desired. Following removal, pregnancy may occur at any time.

What to do after the insertion or removal

After insertion and removal of Levoplant[™] make it clear that the woman can come back any time if she has any questions or worries. Give her a phone number or the location of the clinic that she can contact if required.



APPENDICES





APPENDIX1

Pre-training questionnaire to submit prior to training

Name of trainee:	Date of training:
What is your role?	
Are you eligible to provide counselling for implants?	
Are you eligible to insert and remove implants?	
Do you have experience of inserting or removing 2 rod implants? If yes, how many cases do you see per month?	
How many potential implant users do you see in your practice per month?	
Is there anyone who will assist you with ongoing educational support?	
What is your motivation to provide high quality contraceptive services?	



APPENDIX 2

Competencies for Levoplant[™] insertion and removal 1/2

LEVOPLANT [™] AND COUNSELLING (observed during role play)			
Competency	Achieved	Not Achieved	Plans for improvement
Understand principles of rights- based care			
Able to discuss full range of contraceptive options			
Knowledge of Levoplant [™] – risk benefits, knowledge of eligibility criteria			
Observed ability to counsel and provide client centred information. Build rapport. Good body language or talk through what is required for good counselling			
Able to take consent			
List all equipment and supplies required for insertion and removal of Levoplant™			
INSERTION OF LEVOPLANT™			

Competency	Achieved	Not Achieved	Plans for improvement
Wash hands			
Clean skin and ensure infection control throughout			
Position arm correctly			
Mark correct position on arm for insertion			
Correct technique in local anaesthetic injection			
Check for anaesthetic effect			
Make skin incision with blade/scalpel			
Correct insertion and advancement of trocar			
Correct loading of obturator			
Correct placement techniques of both implant rods			
Bring together incision close with sterile gauze or tape. Apply pressure			



APPENDIX 2 cont.

Competencies for Levoplant[™] insertion and removal 2/2

CORRECT INSERTION AFTERCARE ADVICE			
Competency	Achieved	Not Achieved	Plans for improvement
Keep site clean and dry for 48 hours			
Leave dressing in place for 3-5 days			
Follow up instructions if concerns or worries			
REMOVAL OF LEVOPLANT [™]			
Competency	Achieved	Not Achieved	Plans for improvement
Use of HLD or sterile equipment			
Clean skin and ensure infection control throughout			
Palpate rods to determine point of removal			
Correct technique in local anaesthetic injection under ends of implant			
Check for anaesthetic effect			
Correct placement of small incision with blade/scalpel			
Guide implant by pushing rods toward incision			
Grasp with straight Crile/Kelly forceps, gentle removal of rod without twisting			
Bring together incision close with sterile gauze or tape. Apply pressure			
CORRECT REMOVAL AFTERCARE ADVICE:			
Competency	Achieved	Not Achieved	Plans for improvement
Keep site clean and dry for 48 hours			
Leave dressing in place for 3-5 days			
Follow up instructions if concerns or worries			
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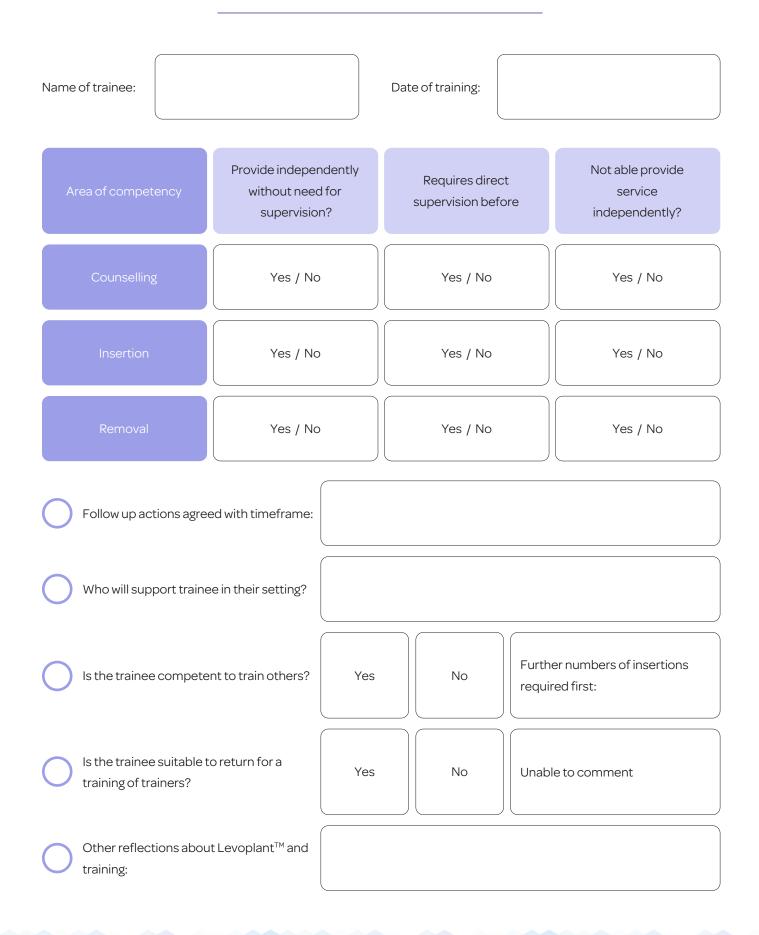
Name of trainee:

Date of training:



APPENDIX 3

Competency assessment for trainees





Contact

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