1 Purpose and use of RemovAid (1)

1.1 Intended purpose/use

- Removal of easily palpable and pinchable single rod contraceptive implants. The device is for single use.

1.2 Intended user

- Health care providers with sufficient training, skill and authorization to remove easily palpable implants, and the skills required to understand the functions and operating parameters to successfully use the RemovAid ™ device.

1.3 Indications for use

- Competent client requesting removal of single-rod contraceptive implant (e.g. Implanon NXT/Nexplanon)

1.4 Contraindications

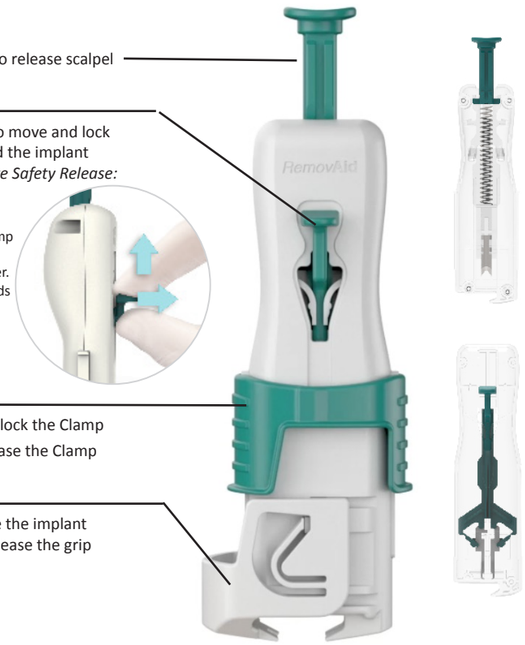
- Current signs, at operating site, of infection, rash and/or visible dirt after cleaning
- Possible or confirmed nerve pain at or near implant site.
- Implant is (partially) impalpable and/or non-pinchable, and/or appears broken in situ.
- Known allergies to the antiseptic and/or anesthetic agent

2 RemovAid™ overview

Knob
- Press completely down to release scalpel

Pincher knob
- Push completely down to move and lock tweezers/pincher around the implant
- *Pull out and up to actuate Safety Release:*

Make sure the Slider and Clamp are open so the only part gripping the skin is the Pincher. Pull the Pincher knob outwards (→) and upwards (↑) to release the Pincher.



Slider
- Push the Slider down to lock the Clamp
- Pull the Slider up to release the Clamp

Clamp
- Close the clamp to fixate the implant
- Remove the clamp to release the grip

5 Other information

1014-INS001
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5.1 Environmental and handling conditions

Operation temperature range	Room temperature
Storage temperature range	-25 to +55° Celsius
Maximum relative humidity for storage	85% RH
Drop/Free fall (in package)	max 80 cm

5.2 Specifications

Sterilized by irradiation (E-beam).
Shelf life: 3 years

5.3 Classification

Class IIa sterile (MDR 2017/745).

5.4 Contact information and support

Manufacturer
RemovAid AS
Strandveien 17
NO-1366 Lysaker
Norway

5.5 Symbols used on labels

Symbol	Meaning	Symbol	Meaning	Symbol	Meaning
	Name and address of manufacturer	REF	Catalogue number	MD	Product is a medical device
	Do not reuse	LOT	Lot number	UDI	Unique device identifier
	Last use date		Do not use if package is damaged and consult instructions for use		Contains hazardous materials
STERILE R	Sterile component		Electronic instructions for use is available online in addition to printed paper form		Single sterile barrier system
	Recommended temperature for storage		Recommended relative humidity for storage		Single sterile barrier system with protective packaging outside
	Warning: Sharp element		Date of manufacture		

www.removaid.com
support@removaid.com

REMOVAID

INSTRUCTIONS FOR USE

IMPORTANT

Please read all instructions thoroughly before use, and retain for future reference.
Perform procedure using **sterile gloves**, under **local anesthesia** and **using aseptic technique**.
For single use only, not for re-use. Handle with care, contains sharps.

(1) Manufacturer only accepts responsibility for safety, usability and performance if the equipment is used in accordance with its intended purpose and use

3 Procedure

3.1 Preparations and equipment

- Palpate to locate the implant
- Clean and anesthesize the removal area ⚠1
- Position client on an examination table, arm flexed at 90°
- Confirm the implant remains completely and easily palpable and pinchable after anesthetic administration.
- Clean skin ovelying implant with antiseptic and allow to completely dry
- Prepare equipment, put on sterile gloves

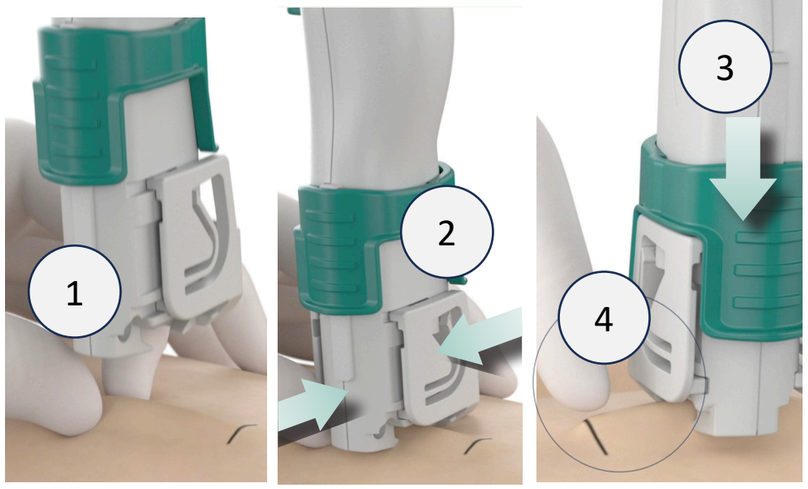
Equipment ⚠2

- RemovAid™ device in sterile packaging ⚠3
- Sterile gloves
- Anesthetic agent ⚠4
- Antiseptic agent
- Sterile swabs
- Wound closure strips
- Sterile wound dressing
- Pressure bandage
- Examination table for client to lie on

Complete instructions and animations available
password: removaid21

In case of discrepancies between video and written IFU, the written IFU is considered valid

3.2 Fixation



1. Use your non-dominant hand to securely pinch up a skinfold containing the implant. Maintain the grip.
2. Use your dominant hand to place the wide open clamp around the bulge, and push the Clamp firmly together around the middle of the implant*.
3. Pull the Slider **completely down** to lock the Clamp.
4. Lift and rotate the RemovAid™ to ensure the implant is securely engaged**.

⚠5,6

* If a new implant is planned for insertion, placement near the distal end of the implant is recommended. Then the incision may be used for reinsertion of the new implant.

** The implant contours should be visible and moving on both sides of the Clamp. If the implant is not securely engaged, release the Clamp and repeat fixation. Fixation is usually well tolerated. If the clamp fails to fixate the implant after three attempts, it is recommended to discontinue the RemovAid procedure.Do not proceed if the implant cannot be fixated.

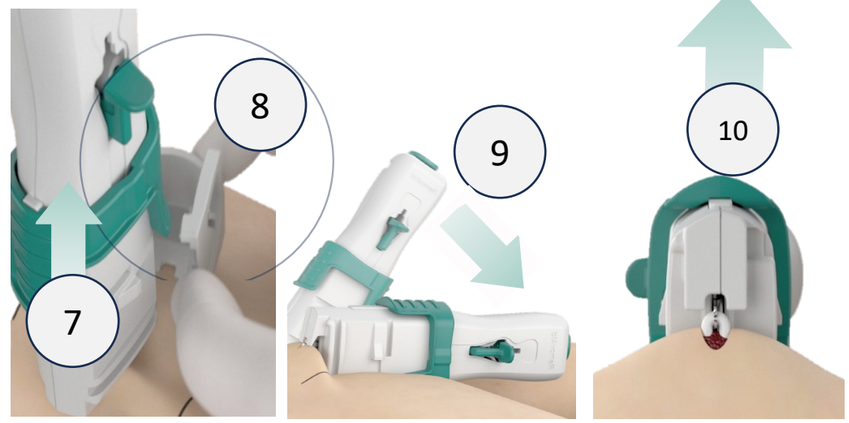
3.3 Make incision and grip the implant

5. Hold the RemovAid with a slight downward pressure and push the Knob **completely down** until a clear "CLICK" is heard and felt.

6. Push the Pincher knob **completely down** to lock the Pincher around the implant.

⚠7

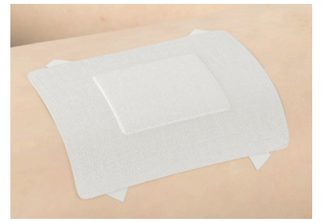
3.4 Extraction



7. Pull the Slider upwards,
8. Remove the Clamp completely.
9. Angle the device 90° or more, away from you and towards the removed clamp side
10. Pull the device firmly upwards (maintain the angle). You may require a sterile swab to carefully release the implant from the surrounding tissue. ⚠8

3.5 Post-procedural care

- Visually inspect the implant. ⚠9,10
- Compress the wound with a sterile swab until bleeding is reduced
- Close and cover the wound with wound closure strips. ⚠11
- Cover with a sterile adhesive wound dressing (4-5 days)
- Apply a pressure bandage, can be removed after 24 hours
- Dispose of the device. ⚠12, 13



4 Safety

Symbol	Meaning
⚠	Failure to follow instructions may endanger the patient and/or the operator.

1: Injected anesthetic may cause swelling and make fixation more difficult. A topical anesthetic is recommended, and should be applied over the center and entire length of the implant, 2 hours prior to removal.

2: The following equipment may be required and is recommended available at the clinic: Syringe, needle, injectable anesthetic, sterile scalpel, sterile forceps (1-2 pairs).

3: Visually inspect the packaging and the RemovAid for signs of damage. Do not use if the device and/or packaging appears damaged, and/or if metal components are exposed at the base of the device, or device has expired.
Avoid placing pressure on the "knob" prior to intended use, as this may trigger the scalpel.

4: Confirm that the client has no allergies to the anesthetic and/or antiseptic to be used

5: Any RemovAid™ used for unsuccessful fixation shall be disposed.

6: In the unlikely event the client is experiencing any shooting or radiating pain, this may indicate a trapped nerve. Detach the clamp and refer for ultrasound-guided removal

7: Avoid accidentally pushing the Pincher knob back up as this will retract the Pincher's hold on the implant

8: In the event where ordinary manual forces are insufficient to extract the implant, the client experiences shooting or radiating pain, or upon operator discretion, the Pincher may be released by following the Safety Release Procedure.

9: Measure the implant to confirm the entire implant is extracted. If the RemovAid device fails to extract the (entire) implant, the operator may attempt using sterile fingers and/or forceps to gently extract the implant (parts). If the (entire) implant cannot easily be extracted, additional equipment may be required.

10: If the (entire) implant was not removed within 20 minutes, close wound and refer to a provider experienced in complex implant removals. Ensure that the client receives adequate contraceptive coverage until the entire implant can be completely removed.

11: Post-removal bleeding should be controlled in order to attach Steristrips properly. Further, it is important to apply a pressure bandage to avoid bleeding after the consultation. Note that topical anestetic agents do not contain adrenaline. Adrenaline acts as a vasoconstrictor and reduces bleeding.

12: Dispose of the used product as a sharp in accordance with accepted medical practice and applicable local and national regulations. Do not attempt to re-attach the clamp following use. Used product may represent a potential biohazard.

13: The RemovAid™ is for single-use. Attempting to use the same device for multiple patients can potentially injure patients.

Adverse events and complications

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

- In the unlikely event of a suspected nerve injury following the removal procedure, the client should be urgently referred for microsurgical repair to avoid permanent nerve damage.
- In the unlikely event of a sharps injury to the operator during handling or disposal of the RemovAid™, follow local sharps injury recommendations at your centre.
- Instruct the patient to contact the provider if they experience signs of wound infection subsequent to implant removal.
- Other potential adverse events may include bleeding, bruising/hematoma or superficial incisions.
- If part of the Implant remains in situ following the procedure, there may be residual contraceptive function.