INSTRUCTIONS FOR USE

REMOVAID

IMPORTANT

Please read all instructions before use. The removal procedure shall be performed using sterile gloves, under local anesthesia and using aseptic technique.

Manufacturer
RemovAid AS
Gaustadalleen 21
NO-0349 Oslo
Norway

Instructions for the medical device: the RemovAid™

Intended use

Intended users

The intended user is the RemovAid™ operator; a health care provider with sufficient training, skills and authorization to remove single-rod contraceptive implants, that has been specifically trained on this device and is familiar with the content of RemovAid's Experienced Provider Training Video™ and possesses the skills required to understand the functions and operating parameters to successfully use the RemovAid™ device.

Intended use

The device is intended to remove completely and easily palpable and pinchable single-rod contraceptive implants only (i.e. Implanon/Nexplanon). The device is for single use.

Indications for use

- Client at least 18 years old
- Client desires removal of one-rod contraceptive implant
- Implant is "pinchable" – i.e. it can be gripped by the operator, and the grip can be maintained while gently rolling the implant between the thumb and forefinger.
- Implant is completely and easily palpable

Contraindications

- Skin overlying the implant shows signs of current infection, rash or remains visibly dirty after cleaning the area.
- Possible or confirmed nerve pain near implant site.
- Implant is impalpable, partially impalpable or non-pinchable.
- Implant appears to be broken in situ.
- Client has a known allergy to the antiseptic and/or anesthetic to be used.

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

Specifications

The RemovAid™ is sterilized by irradiation (E-beam).

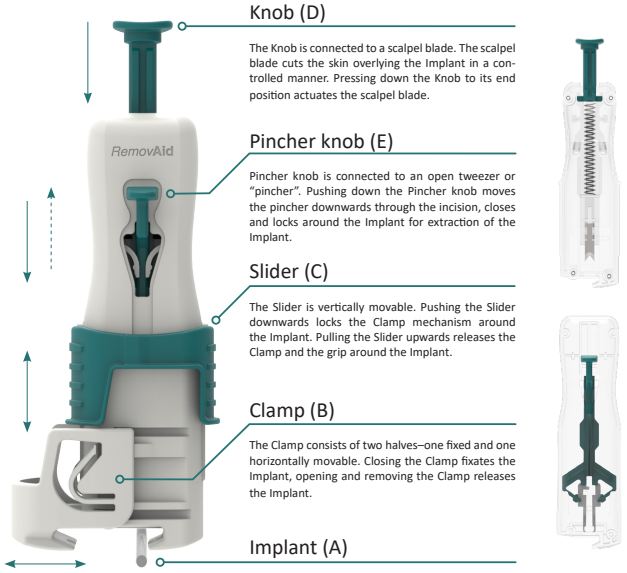
Classification

The RemovAid™ is classified as Class IIa according to the Medical Devices Regulation (MDR 2017/745).

RemovAid only accepts responsibility for the equipment's safety, usability and performance if:

- the equipment is used in accordance with its intended use, and
- the equipment is used in accordance with the product documentation.

Description of RemovAid™



Knob (D)

The Knob is connected to a scalpel blade. The scalpel blade cuts the skin overlying the Implant in a controlled manner. Pressing down the Knob to its end position actuates the scalpel blade.

Pincher knob (E)

Pincher knob is connected to an open tweezer or "pincher". Pushing down the Pincher knob moves the pincher downwards through the incision, closes and locks around the Implant for extraction of the Implant.

Slider (C)

The Slider is vertically movable. Pushing the Slider downwards locks the Clamp mechanism around the Implant. Pulling the Slider upwards releases the Clamp and the grip around the Implant.

Clamp (B)

The Clamp consists of two halves–one fixed and one horizontally movable. Closing the Clamp fixates the Implant, opening and removing the Clamp releases the Implant.

Implant (A)

Implanon or Nexplanon contraceptive implant only.

⚠ Package and device inspection

Visual inspection

The operator is required to:

- Ensure the packaging is intact. Do not use if it appears to be damaged.
- Ensure that the RemovAid™ is within its expiration date.
- Visually inspect the RemovAid™ for any signs of damages and/or exposed metal components at the base of the device after removal from sterile packaging. Do not use the RemovAid™ if it appears to be damaged.
- Avoid placing pressure on the Knob or Pincher knob while handling the RemovAid™ prior to the intended operation.

The instructions for use

This instructions for use describes use of the RemovAid™
Users must read this instructions for use carefully prior to using the RemovAid™ for the first time so that all features are thoroughly understood. Please keep this instructions for use for future reference.

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

Safety regulations

General safety regulations

⚠ Dispose of the used product in accordance with accepted medical practice and applicable local and national regulations. Used product may represent a potential biohazard.

⚠ The RemovAid™ has a shelf life of 3 years.

⚠ Handle with care, contains sharp parts.

⚠ 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.

Operational safety

⚠ The RemovAid™ should only be operated by medical personnel with training in removal of subdermal contraceptive implants. Such personnel is referred to as the *operator* throughout this manual.

Patient safety

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

⚠ Usage of the RemovAid™ in a way that contradicts the intended use could result in injury to the patient and/or the operator.

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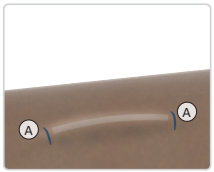
Procedure

Preparations

#1 Local anesthesia

Locate the implant and confirm it is completely and easily palpable and "pinchable". Confirm the client does not have a known allergy to the antiseptic and/or anesthetic to be used.



Anesthetize the removal area. This procedure should be performed using a topical anesthetic to ensure the device's best efficacy and ease of implant removal. The topical anesthetic must be applied over the implant midpoint 2 hours prior to removal to provide adequate anesthetic effect.

Apply the chosen anesthetic per the manufacturer's instructions for use. For specific application instructions of the topical patch, please refer to the RemovAid™ training video.

#2 Prepare and locate

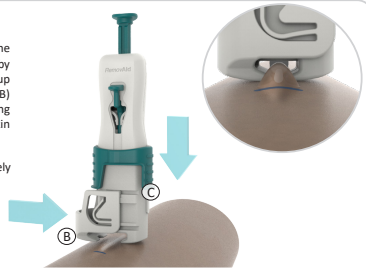
Position the client on an examination table with the arm flexed 90 degrees at the elbow. Remove the anesthetic, wipe away any residual and confirm adequate anesthetic effect. Confirm the implant is completely and easily palpable and "pinchable". If the implant is not completely and easily palpable and/or "pinchable", do not proceed with a RemovAid™ removal and revert to the standard removal method.

Mark both Implant ends with a suitable marker (A). Ensure the procedure is performed using aseptic technique. Clean the overlying skin with an antiseptic and allow to completely dry. Wash and dry your hands thoroughly. Prepare required equipment and put on sterile gloves.

Removal procedure

#3 Fixate the implant

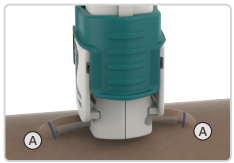
Place the Clamp (B) of the RemovAid™ between the 2 marks and attempt to capture the implant (A) by pinching a skinfold containing the implant (A) up with your fingers and then pressing the Clamp (B) together manually (→). Lock the Clamp (B) by pulling down (↓) the Slider (C). This should create a skin bulge containing the Implant (A).



⚠ Confirm that the Slider is pulled completely down without gaps before proceeding.

#4 Ensure correct fixation of the implant

Once the Clamp is locked, lift and rotate the RemovAid™ to ensure the implant is securely engaged. Visualize the implant tips move under the surface of the skin on both sides of the Clamp. The implant contours should be visible/palpable on both sides.



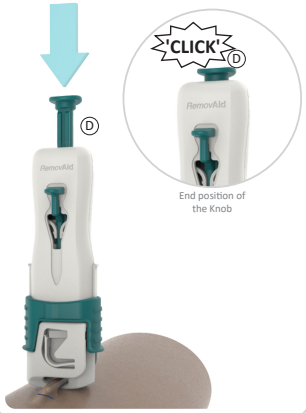
If the implant appears not to be securely engaged, release the Clamp and repeat step 3 above until the implant is successfully fixated. It is the responsibility of the operator to continually assess whether the client tolerates additional fixation attempts. If the implant fails to be successfully fixated after three attempts, it is the manufacturer's recommendation that the operator use a standard technique for implant removal.

⚠ Do not proceed unless the Implant is successfully fixated. Any RemovAid™ used for unsuccessful fixation shall be disposed.

⚠ Ensure the client is not experiencing any shooting or radiating pain distal to the Clamp, as this may indicate a trapped nerve. If the client is experiencing radiating pain, detach the Clamp and refer the client for ultrasound-guided removal.

#5. Release incision mechanism

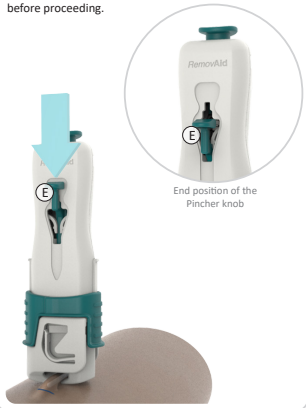
While maintaining a firm downward pressure on the RemovAid™, push the Knob (D) on the top of the RemovAid™ down (↓) to its end position until a clear **'CLICK'** is heard and felt. This will release the incision mechanism of the RemovAid™.



#6. Push the Pincher knob downwards

While holding the RemovAid™ steady, push the Pincher knob (E) on the front of the RemovAid™ downwards (↓) to its end position. This will actuate the Pincher of the RemovAid™.

Visualize that the Pincher knob is in its end position before proceeding.



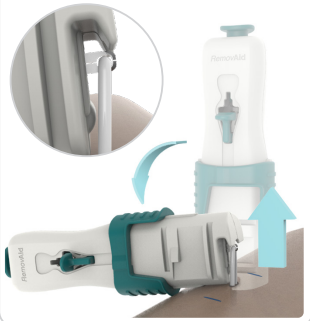
#7. Release and remove the clamp

Pull the Slider (C) upwards (↑) to release the Clamp (B). Remove the Clamp (B) to increase visibility.

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

#8. Extract the implant

Angle the device 90+ degrees with the removed Clamp side down. Apply normal manual force and steadily pull the RemovAid™ straight upwards (↑) to release the Implant from surrounding tissue and extract it through the incision. Make sure not to press the (skin above the) Implant downward during extraction, as this may disengage the implant from the Pincher.



⚠ In the event where ordinary manual forces are insufficient to extract the Implant or the client experiences shooting or radiating pain, the Pincher may be released by following the Safety Release Procedure. After completing the safety release procedure, extract the Implant by using a standard removal technique, then continue to step 11 (Close and cover the wound).

Additional removal recommendations

#9. Inspect the results of the extraction

Visually inspect the implant.

⚠ If the RemovAid™ device fails to extract the (entire) implant, try using sterile fingers or forceps to gently extract the implant parts. If the (entire) implant cannot be easily extracted using fingers or forceps, please follow the techniques and recommendations as provided in the standard removal method, using the equipment as described by the implant manufacturer and as listed under Additional accessories required.

Confirm the entire implant is removed

#10 Measure the implant

Measure the implant to confirm the entire implant is extracted. If the implant is successfully removed or a maximum of 20 minutes has passed without successfully removing the (entire) implant, proceed to step 11 (Close and cover the wound).

Post procedural care

#11. Close and cover the wound

Close the wound by pushing the two wound edges slightly together and plaster with wound closure strips. Cover with a sterile adhesive wound dressing.

⚠ If the (entire) implant was not removed, 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.

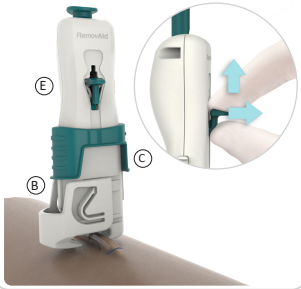
#12. Dispose of the device

Dispose of the RemovAid™ as a sharp, in accordance with local regulations for the handling of biohazardous waste. Do not attempt to reattach the Clamp or to remove the implant from the Pincher before disposal. The RemovAid™ is for single use only, not for re-use.

Safety release procedure

If, for any reason, the operator needs to release the Pincher's grip during or after the operation, follow the safety release procedure as outlined below:

i. Make sure the Slider (C) and Clamp (B) are loosened so the only part gripping the skin is the Pincher.
ii. Change your grip on the Pincher knob (E) to hold with your thumb and forefinger as shown in the picture below.
iii. Holding the RemovAid steady, pull the Pincher knob outwards (→) and upwards (↑) to release the Pinchers grip.
iv. Procedure completed, Pincher grip is released.



Safety and Adverse events

⚠ 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.

Additional accessories required

- Examination table for client to lie on
- Suitable marker
- Sterile gloves
- Topical anesthetic agent
- Skin disinfectant, sterile swabs for application
- Wound closure strips, sterile wound dressing

If at any time in the procedure you must revert to the standard removal technique, you may also require standard removal equipment, including:

- Syringe/needle for injecting local anesthetic
- Scalpel
- Forceps (1-2 pairs)

Symbols used on labels

The RemovAid™ has been labeled with the following symbols:

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	SN	Serial number
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		

Contact information

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The Experienced Provider Training Video™ is available upon request. If you have questions or concerns related to this manual or the RemovAid™ device, contact us at support@removaid.com.