



*Juna*TM

Instructions for Use & Safety

Surgical Removal Assistant

BEFORE OPERATING JUNA, THE USER MUST READ AND UNDERSTAND THIS INSTRUCTIONS FOR USE DOCUMENT. A FULL UNDERSTANDING OF THE DEVICE'S INTENDED USE, PROCEDURE, AND SAFETY INFORMATION IS REQUIRED TO LIMIT PATIENT HARM. FAILURE TO READ AND UNDERSTAND THIS DOCUMENT MAY ENDANGER THE PATIENT AND/OR OPERATOR.



Instructions for Use & Safety

These instructions explain how to use Juna™ in removing subdermal contraceptive implants. For training videos and questions, visit:

WWW.JUNAMEDICAL.COM or email us INFO@JUNAMEDICAL.COM.

Safety Regulations

- Dispose of the used device in accordance with accepted medical practice and applicable local and national regulations. The used device may represent a potential biohazard.
- Juna has a shelf life of 1 year.
- Any serious incident that has occurred 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

Juna 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

Juna is for **single-use**.

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

Packaging and Instruction for Use Symbols



Manufacture



Date of manufacture



Do not reuse



Use by date



Catalogue or model number



Batch code



Do not use if package is damaged and consult instructions for use



Consult instructions for use or consult electronic instructions for use



Storage temperature range



Medical Device



Unique device identifier

Intended Use

Intended Users

The intended user for Juna is a health care provider with sufficient training, skills, and authorization to remove a palpable, subdermal implant.

Intended Use

The device is intended to aid in the removal of a palpable, subdermal implant. The device is single use.

Indications for Use

- Patient is at least 18 years.
- Patient consents removal of implant using the Juna device.
- Implant is palpable.

Contraindications

- Skin overlaying 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.

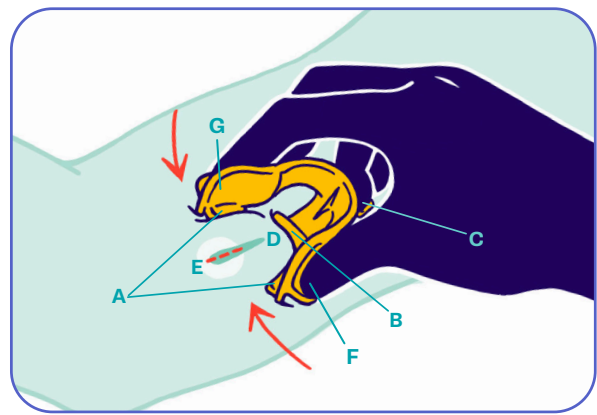
Environmental and Handling Conditions

- Operation temperature range:
Room Temperature
- Storage temperature range: -25°C to 55°C
- Maximum relative humidity for storage: 90% RH
- Drop/Free fall (in package): max 100 cm

Classification

Juna is classified as a Class I device, General & Plastic Surgery (21 CFR 878.4800)

Juna accepts responsibility for the device's safety and performance **only** if used in accordance with its intended use and accompanying documentation.



Device Description

Side Tabs (A)

The side tabs hug the patient's skin and apply a pressure to the tissue around the implant causing it to migrate towards the surface of the patient's skin.

Rear tab (B)

The rear tab is an extension of the device designed to deliver uniform, controlled pressure on the skin when held above the implant to gently shift its position during removal.

Back Rest (C)

The back rest allows the user to apply a third point of contact to the patient's skin at the proximal end of the implant. This pressure point encourages the implant's distal end to point towards the surface of the patient's skin.

Proximal End of Implant (D)

The proximal end is the portion of the implant closest to the patient's core. Pressure gets applied on the skin near the implant's proximal end to facilitate easier removal.

Distal End of Implant (E)

The distal end is the portion of the implant closest to the incision site. The pressure from the device raises this end of the implant to the surface, to facilitate gentler removal.

Contact Points (C, F, G)

The three contact points are designed for optimal pressure placement. This single-hand design allows the user to apply the appropriate pressures to the skin while leaving their other hand free to create an incision and remove the implant with forceps.

How to Use

Pre-Procedure

1. Prepare the patient according to the standard of care.
2. Apply anesthetic near the distal end of the implant prior to removal.
3. Position the patient resting comfortably on their back, palm facing up either behind their head or rested on a flat surface.
4. Confirm the implant is palpable.
5. Prepare the patient's skin with an antiseptic and allow the area to completely dry.

Procedure

6. To hold device, grip drip device wings with thumb and index finger and rest another finger on backrest (C).
7. Place device on patient arm, with open side facing distally and wings symmetrical to the implant.
8. Using fingers on contact points (C, F, G), press down rear tab (B) at proximal end of implant (D).
9. Press and squeeze together side tabs (A) onto skin to further raise distal end of implant (E) in mound of skin. Once the distal end of implant is well pronounced in mound, implant is ready for removal.
10. While device is hugging the implant, remove implant according to the standard of care. With the operator's free hand, make an incision near the distal end of the implant.
11. Replace the scalpel with forceps to remove the implant. Using the pressure from the rear tab on the proximal end of the implant, gently guide the implant out of the incision, using forceps to complete removal.

Before Use Device Operator Must:



- Visually inspect the Juna device and packaging. Do **not** use the device if it appears to be damaged.
- Ensure the Juna device is within its expiration date.

Post-Procedure

12. Measure the implant to ensure it was entirely removed.
13. Close and dress the wound according to the standard of care.
14. Dispose of the device in accordance with local regulations for the handling of biohazardous waste.



Do **not** attempt to reuse the device. The Juna is for **single use only**.

Adverse Events

- 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.



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