
























Accu-Tatt®

INSTRUCTIONS FOR USE (IFU)



SYMBOL GLOSSARY

(Note: All symbols may not be applicable to this product)

	Medical Device		Do Not Use if Package is Damaged
	Manufacturer		Do Not Reuse Single- Use Device
	Date of Manufacture		Single patient- multiple use
	Use-By Date		Consult Instructions For Use (IFU)
	Lot Code		Caution
	Reorder Number		Warning
	Serial Number		Authorized representative in the European Community
	Sterilized using irradiation		European Conformity
	Do not resterilize		Prescription Only or "For Use by or on the order of a licensed medical professional"
	Non- sterile		Temperature limitation
	Biological Risks		MR Safe
	European Conformity		

CAUTION

Federal (United States) law restricts this device to sale by or on the order of a physician.

DEVICE DESCRIPTION

Accu-Tatt consists of a plastic ampoule which houses tattoo ink and a standard hypodermic safety needle. The plastic ampoule contains a breakable membrane which allows ink to flow at the time of tattoo application. The needle is attached to the plastic ampoule and is used to dispense the tattoo ink onto the patient's skin. Additionally, the needle tip is used to temporarily breach the surface of the patient's skin to apply the tattoo. Accu-Tatt is gamma sterilized and is provided sterile to the end-user.

PRODUCT OFFERING

REF **UTRT-3100: Accu-Tatt (18 gauge needle; Pink Needle Guard)**

25 pouches per box (Includes 1st safety needle and a black ink ampoule in every pouch)

REF **UTRT-3105: Accu-Tatt (22 gauge needle; Gray Needle Guard)**

25 pouches per box (Includes 1st safety needle and a black ink ampoule in every pouch)

INDICATIONS FOR USE

Accu-Tatt is indicated for use, by a healthcare professional, on patients undergoing Radiation Therapy procedures who need a permanent mark for repeatability and reproducibility.

INTENDED USE

The Accu-Tatt is an all-inclusive, sterile, single-use tattoo device intended to apply a permanent reference mark to a patient's skin.

CONTRAINDICATIONS

Do not use if the patient:

- Has received a tattoo in the past and experienced the formulation of granulomas at the tattoo site or experienced other adverse events/reactions.

ADVERSE REACTIONS

The following potential side-effects are considered unlikely to occur in the majority of patients.

- Formation of granulomas (small knots or bumps) at the tattoo site.
- Systemic or tattoo-site specific allergic reactions.

WARNING

- *Accu-Tatt must be used prior to the Use By date shown on the product label.*
- **DO NOT** use Accu-Tatt if the package is damaged or open.
- *Accu-Tatt is for **SINGLE USE ONLY**; DO NOT reuse. Attempts to reuse may result in infection and / or patient injury.*
- **DO NOT** re-sterilize any components of Accu-Tatt. Attempts to re-sterilize may damage the device and result in infection and/or patient injury.
- *When administering the tattoo, do not squeeze the ink ampoule while the needle is inserted into the patient's skin.*
- *Over-insertion of the needle may lead to patient injury*

STORAGE

Store in a cool, dry environment.



DISPOSAL PROCEDURE

NOTE: It is the user's responsibility to dispose of all parts according to hospital protocol / local regulations. Recommended disposal procedures include:

1. Dispose of all Accu-Tatt components in a sharps container.

INSTRUCTIONS FOR USE

1. Shake device well.
2. Attach the provided hypodermic safety needle to the luer end of the Accu-Tatt.
3. Carefully break the internal membrane by gently using two fingers to apply force to the Accu-Tatt ampoule along the words "SQUEEZE HERE TO USE."
4. Remove needle cap.

5. Before inserting the needle into the skin, apply a drop of ink to the patient's skin in the desired location for the mark.
6. Insert the needle into the drop of ink and allow the needle to breach/puncture the patient's skin.
 - a.  **DO NOT** squeeze ampoule while needle is inserted into patient's skin.
 - b. Be careful not to over insert needle.
7. Remove needle from patient's skin and grasp the device at the luer lock (Figure A).
 **DO NOT hold the device at the ampoule when attempting to apply the needle guard, as the ampoule can bend and point the needle back towards you (Figure B).**
8. Apply the needle guard (Figure C).
9. Remove excess ink from skin.
10. Dispose of all Accu-Tatt components in a sharps container.

Hold the device at the luer lock when preparing to apply the needle guard.

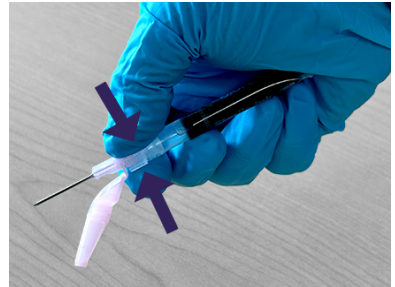



Figure A

 **DO NOT** hold the device at the ampoule when attempting to apply the needle guard.

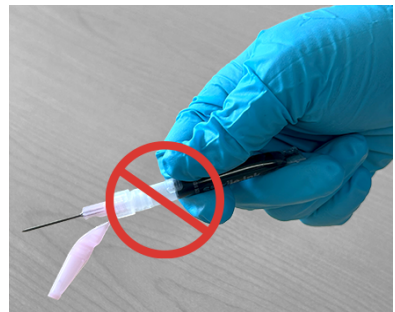


Figure B

Apply the needle guard.



Figure C



Rx ONLY

**MADE IN
THE USA**



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