Accu-Tatt Instructions for Use

Caution: Federal Law restricts this device to sale by or on the order of a licensed Physician or Radiation Therapist.

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.

Accu-Tatt is available in the following sizes.

REF	Description	Color of Needle Guard
UTRT-3100	Accu-Tatt Ink Ampoule with 18 Gauge Safety Needle	Pink
UTRT-3105	Accu-Tatt Ink Ampoule with 22 Gauge Safety Needle	Gray

INDICATIONS

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.

WARNINGS

- 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

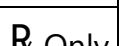
Note: It is the user's responsibility to dispose of all parts according to hospital protocol / local regulations. Recommended disposal procedures include:

1. Disposing the needle into a sharps container.
2. Disposing the ink ampoule and needle cap into a trash 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 "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 apply the needle guard
8. Remove excess ink from skin
9. Dispose of needle into sharps container; Accu-Tatt ampoule can be disposed of in the trash

Label Symbol Glossary (Note: not all symbols may be applicable to this product)

Symbol	Title of Symbol	Description of Symbol	Symbol Designation Number	Title of Symbol Standard Development Org. Standard
	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	5.1.1	ISO 15223-2012
	Authorized representative in the European Community	Indicates the authorized representative in the European Community.	5.1.2	ISO 15223-2012
	Date of manufacture	Indicates the date when the medical device was manufactured.	5.1.3	ISO 15223-2012
	Use-By Date	Indicates the date after which the medical device is not to be used.	5.1.4	ISO 15223-2012
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	5.1.5	ISO 15223-2012
	Catalog Number	Indicates the manufacturer's catalog number so that the medical device can be identified.	5.1.6	ISO 15223-2012
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified	5.1.7	ISO 15223-2012
	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.	5.2.3	ISO 15223-2012
	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.	5.2.4	ISO 15223-2012
	Do Not Resterilize	Indicates a medical device that is not to be resterilized.	5.2.6	ISO 15223-2012
	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.	5.2.7	ISO 15223-2012
	Do Not Use if Package is Damaged	Indicates a medical device that should not be used if the package has been damaged or opened.	5.2.8	ISO 15223-2012
	Biological Risks	Indicates that there are potential biological risks associated with the medical device.	5.4.1	ISO 15223-2012
	Do Not Reuse	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	5.4.2	ISO 15223-2012
	Consult Instructions For Use	Indicates the need for the user to consult the instructions for use.	5.4.3	ISO 15223-2012
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	5.4.4	ISO 15223-2012
	European Conformity	EC Declaration of Conformity by Notified Body	Annex XII	MDD 93/42/EEC:2007
	European Conformity	EC Declaration of Conformity by Manufacturer	Annex XII	MDD 93/42/EEC:2007
	By Prescription Only	Federal (USA) law restricts this device to sale, distribution, and use by or on the order of a physician.	N/A	FDA 81 Federal Register pg. 38911-38931
	MR Safe	Indicates an item that poses no known hazards in all MR environments.	7.4.3.1 or 7.4.4.1	F2503-13

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