

InkWell Health

INDICATIONS FOR USE

The InkWell Health system captures images of a temporary tattoo applied to a patient's skin (or bandage) to enable a physician to remotely monitor qualitative changes in swelling, range of motion and temperature over time, or after a knee surgery or knee injury.

DESCRIPTION

Users must be of legal age, or age of majority, to consent to the use of the application. The tattoo may be purchased with the authority of a qualified health care provider or a patient, but a prescription is not needed. Temporary tattoos, if required, are to be replaced with a new temporary tattoo after the old one's remnants are removed.

There are six different part numbers as follows:

Part Number	Description	# of Tattoos
LGLKNEE-MTT	Large Left Knee Medial Temporary Tattoo	<u>1</u>
LGRKNEE-MTT	Large Right Knee Medial Temporary Tattoo	<u>1</u>
LGLKNEE-MTT-1KT	Large Left Knee Medial Temporary Tattoo 1 Month Kit	<u>3</u>
LGRKNEE-MTT-1KT	Large Right Knee Medial Temporary Tattoo 1 Month Kit	<u>3</u>
LGLKNEE-MTT-3KT	Large Left Knee Medial Temporary Tattoo 3 Month Kit	<u>12</u>
LGRKNEE-MTT-3KT	Large Right Knee Medial Temporary Tattoo 3 Month Kit	<u>12</u>

WARNINGS

Do not apply to sensitive skin, in the eye and lip area or if allergic to adhesive.

CONTRAINDICATIONS

The tattoo can be placed over a post-operative bandage, but should not be applied over broken skin or unhealed incisions.

PRECAUTIONS

Patients with discolorations or with some skin conditions, as outlined below, should be aware that the system may not be able to properly detect the tattoo and as a result, swelling and range motion calculations may be inaccurate or not work:

- 1) Patients with skin marks, growths and/or color changes;
- 2) Patients with existing tattoo(s);
- 3) Patients with excessive hives, urticaria, moles or eschars;
- 4) Patients with severe sunburns where the skin is reddened and/or peeling;
- 5) Patients with Ehlers-Danlos Syndrome where the skin may become fragile and oily.

TO REMOVE: ONLY USE WIPES PROVIDED BY THE COMPANY, OTHERWISE USE RUBBING ALCOHOL (PREFERRABLY 70% ALCOHOL) OR BABY OIL, WAIT 10 SECONDS, THEN GENTLY RUB THE TATTOO REMANTS AWAY WITH COTTON BALL MOISTENED WITH RUBBING ALCOHOL OR BABY OIL. DO NOT SCRUB WITH SOAP AND WATER.

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GUIDELINES / INSTRUCTIONS FOR USE / DIRECTIONS

These directions are intended as general guidelines. Wherever possible, qualified healthcare practitioners should place the initial tattoo on the patient using these instructions. Replacement tattoos are typically applied by the patient; however, patients can also apply the initial tattoo if required.

- Always keep the components and/or their packaging at room temperature or in a cool, dry place. Extreme humidity or extreme temperatures can damage the product.
- Inspect the packaging and check for damage prior to use. Do not use if damaged.
- Carefully remove hair prior to positioning the temporary tattoo on the inside of the knee.
- Wipe the area clean and dry the area.
- Cut around the tattoo, removing excess white paper to make it easier to place the tattoo.
- Remove the plastic cover and place that side on the skin in the appropriate position.
- The tattoo can be placed over a post-operative bandage, but not over broken skin.
- Cover the tattoo with a damp towelette or cloth that is placed over the back-side (paper side) of the tattoo and hold in place for at least 30 seconds, taking care not to move the tattoo.
- Carefully remove the paper backing by peeling it away from the skin.
- Ensure patient has downloaded the Inkwell Health (**INKWELLP52023**) Mobile Patient Application from either the Apple App Store or Google Play Store, depending on smartphone type.
 - iPhones must have iOS 13 or greater for the application to work optimally.
 - Android Phones must have OS 5 or greater for the application to work optimally.
- After the initial (or new tattoo) has been applied, the patient should submit their first picture entry with the InkWell Health mobile application.
- Patient should enter any new Clinician measurements when possible with a new entry.
- To take pictures, follow the instructions in the application.

Note: A qualified health care practitioner should review the picture taking instructions with the patient so that the patient is able to take pictures on their own in a safe and effective manner. The mobile application provides instructions on how to take pictures, as well as what position the patient should be in when taking the pictures; however, the health care practitioner should instruct the patient as required, depending on that patient's surgery, injury and ability.

- The App is designed so the patient can take the picture themselves.
- If someone is taking the picture for the patient, stand beside them holding the camera as the patient would.
- Camera must be upright (portrait mode) for all pictures. Do not turn the phone sideways.
- For the temperature and swelling picture, place a temperature sticker on your tattoo and once the 4 green shapes are aligned with the shapes on your tattoo, the application will automatically take the picture.
- Straighten your leg as much as possible for the straight leg picture and once all 3 crosses are located the application will automatically take the picture for you.
- The application will use the front camera of your smartphone for the bent leg entry. Bend your knee as much as possible and once all 3 crosses are located the application will automatically take the picture.

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In addition, to ensure accurate entries, the patient should be instructed to take pictures in the same position, or as close as possible, for all picture entries.

- After successfully submitting pictures, the patient can enter their pain score, activities, as well as enter any notes they wish to relay to their clinician.
- The Inkwell Health Mobile Patient application also collects data on steps, and requires the users approval.

CARING FOR YOUR TATTOO

To ensure your tattoo lasts as long as possible, avoid excessive friction, and keep the skin well-moisturized.

- Avoid rubbing or scratching the area and pat the area dry after getting wet.
- Keep the skin moisturized by applying lotion as needed.
- Wear loose-fitting clothing, especially at night, to avoid rubbing the tattoo.

If one or more crosses are not visible, the rest of the tattoo will need to be remove and a new tattoo applied. Use one of the wipes provided to gently remove the remnants of your tattoo. Gently rub the tattoo off and do not scrub. If you do not have any more wipes you can use rubbing alcohol on cotton rounds. Once removed, clean and dry the area and apply a new tattoo by following the directions above.

REPORTING OF DEVICE MALFUNCTIONS AND SERIOUS INCIDENTS

Any malfunction, failure, or unexpected performance of this device should be reported to the manufacturer. To report a complaint, contact Inkwell Health at support@inkwellhealth.com. Please include part number, and a description of the issue. In the event of a serious incident involving this device, users must notify the manufacturer and the competent authority in their country. A serious incident is defined as any event that led to death, serious deterioration in health, or required medical intervention to prevent such outcomes.













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SYMBOL LEGEND

	Manufacturer		Caution or Warning
	Catalog or Reference number		Keep Dry
	Batch or Lot code		Medical Device
	Use by date		UKCA Marking of Conformity
	Do not reuse		Do not use if packaging is damaged
	Consult instructions for use		Quantity: 1 