GTK Disposable Needle Guides
- Instructions for Use -

Descriptive Information:

Purpose of the device (indications for use):

GTK Disposable Needle Guides when used in conjunction with ultasound system transducer where configuration is suitable (e.g. Aloka, Alpinion, BK, Esaote, GE, Hitachi, Medison, Mindray, Philips, Toshiba, Siemens, and Shimadzu ultrasound systems) and attached to the ultrasound system's transducers, is to facilitate proper needle placement to access anatomical structures.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

Description of the device:

The GTK Disposable Needle Guides are disposable, single use, EO sterilized devices with a 5-year shelf life. They are individually packaged in soft pouches, with or without probe covers and should be stored at 5-30ºC and %30-70 relative humidity not in direct heat or direct sun light. The package label comprises all product information with regards to description and relative use, code, production lot, expiry date, and type of sterilization. The GTK Disposable Needle Guides are polymeric needle guides made from molded ABS/PC plastic and some models have a stainless-steel cannula. The GTK Disposable Needle Guides holds both the ultrasound probe and the needle guide in place relative to each other while the ultrasound-guided biopsy is being performed. The GTK Disposable Needle Guides is an assembly of 1 or 2 components, either just a carriage or a carriage with a rail (cannula).

Each GTK Disposable Needle Guide identified in this IFU may be provided in a kit configuration which includes a Polyurethane Sheathes3D™ Viral Barrier Ultrasound Probe Cover. This way the needle guide can be used with the appropriate probe either with the probe cover supplied, or without it. Safety and performance testing has been conducted using both methods for each probe/guide combination. Please see the Probe Compatibility Table in this IFU for Guide-Probe-Cover compatibility.

When the device should not be used (contraindications):

- **Device is not intended for fetal use.**
- Device should not be used if patient has demonstrated hypersensitivity to ABS or Polycarbonate or where patient may have a Latex allergy,
- Device has not been evaluated for safety and compatibility in an MR environment, or
- Do not continue use in the face of an unacceptably hazardous adverse event.

General warnings and precautions:

- This device should be used by a physician trained in Ultrasonography and familiar with the possible side effects, typical findings, limitations, indications and contraindications of USG guided biopsy procedures
- Although the material used to make the device has been tested to be biocompatible, in rare cases where a patient may have an allergy to ABS or Polycarbonate a slight irritation could develop in the contact area. If so it should clear up on its own.
- Although the devices have been tested for pyrogen and endotoxin, the device has not been tested for Latex and no claims are being made for Latex Free and no claims are being made for Non-Pyrogenic.
- Some possible side effects due to allergic reaction or another source could include mild pain, fever, bleeding, or hematuria and infection. These are not typically associated with the devices use in most patients, but are general risks associated with any surgical procedure.
- These devices are ethylene oxide sterilized. Check the package. if package damaged or opened do not use the products. Check the expiry date and the gauge. Store in dry place, between 5 – 30 ºC temperature, protect from sun light.
- Users should be trained on using the device and be familiar with the device and procedures. Device is intended for single patient use only and should not be cleaned or resterilized.
- Device should not be used in an MRI environment since it has not been tested for safety or compatibility in an MR environment.
- After use, this product should be disposed of according to hospital procedures as it may be a potential biohazard. Dispose of in accordance with applicable laws and regulations.
- Please double check for device function and possible damage for correct implantation and do not use if package is opened or damaged.
- These instructions are NOT meant to define or suggest any medical or surgical technique. The individual practitioner is responsible for the proper procedure and techniques to be used with this device.
- Confirm that the guide is installed correctly.
- Use a straight, new needle and needle guide for each procedure.
- Do not rely on the visibility of the needle tip on the screen. Use other tactile or visual indicators to determine whether you are at or in the correct location.
- If unable to visualize the needle at the target, ensure that the correct needle guide hasbeen selected needle and needle guide are correctly attached.
- Use only the applicable needle guide (as identified in this manual), supplies, components, and accessories. Other brands may not properly fit on the intended transducers.
- If the needle guide or needle breaks during the procedure, verify that all pieces of the equipment are recovered.
- Follow Universal Precautions when inserting and maintaining a medical device for interventional and intraoperative procedures.
- Appropriate training in interventional and intraoperative procedures as dictated by current relevant medical practices as well as in proper operation of the ultrasound system and transducer is required. During access, the potential exists for serious complications including without limitation the following: pneumothorax, arterial puncture, guidewire misplacement, and risks normally associated with local or general anesthesia, surgery, and post-operative recovery.

- To avoid damage to the transducer, use only gels recommended by the transducer manufacturer, other ones not recommended may damage the transducer. If you have questions about gel compatibility, contact the transducer manufacturer or your local representative.

MR SAFETY: "THE GTK DISPOSABLE NEEDLE GUIDES HAS NOT BEEN EVALUATED FOR SAFETY AND COMPATIBILITY IN THE MR ENVIRONMENT. IT HAS NOT BEEN TESTED FOR HEATING, MIGRATION, OR IMAGE ARTIFACT IN THE MR ENVIRONMENT. THE SAFETY OF GTK DISPOSABLE NEEDLE GUIDES IN THE MR ENVIRONMENT IS UNKNOWN. SCANNING A PATIENT WHO HAS THIS DEVICE MAY RESULT IN PATIENT INJURY.

Operating Information:
Setup instructions:

Preparing for use
Attach the needle guide on the transducer.

Preparing for Exam
Observe the following precautionary measures before performing an exam:
- Confirm that the guide is installed correctly.
- Use a straight, new needle and needle guide for each procedure.
- Do not rely on the visibility of the needle tip on the screen. Use other tactile or visual indicators to determine whether you are at or in the correct location.

WARNING: To avoid injury or reduce the risk of infection to the patient, observe thefollowing:
- If unable to visualize the needle at the target, ensure that the correct needle guide has been selected needle and needle guide are correctly attached.
- Use only the applicable needle guide (as identified in this manual), supplies, components, and accessories. Other brands may not properly fit on the intended transducers.
- If the needle guide or needle breaks during the procedure, verify that all pieces of the equipment are recovered.
- Follow Universal Precautions when inserting and maintaining a medical device for interventional and intraoperative procedures.
- Appropriate training in interventional and intraoperative procedures as dictated by current relevant medical practices as well as in proper operation of the ultrasound system and transducer is required. During access, the potential exists for serious complications including without limitation the following: pneumothorax, arterial puncture, guidewire misplacement, and risks normally associated with local or general anesthesia, surgery, and post-operative recovery

Apply Acoustic Coupling Gel
Acoustic coupling gel must be used during all exams. Although most gels provide suitable acoustic coupling, some gels are incompatible with some transducer materials. Use gel for proper acoustic coupling. Apply a liberal amount of gel between the transducer and the body. Use sterile gel when performing an invasive procedure.

Caution: To avoid damage to the transducer, use only gels recommended by the transducer manufacturer, other ones not recommended may damage the transducer. If you have questions about gel compatibility, contact the transducer manufacturer or your local representative.

Operating instructions:

1. Adequate amount of gel should be placed on transducer surface. If Gel not included in kit, use any legally marketed ultrasound gel to improve signal.
2. Using the sterile technique, insert transducer into cover and tighten.
3. Check the needle passage before attaching the device to the transducer
4. Attach the needle guide to the transducer as shown below figures.

Be sure choosing appropriate needle length and O.D. and introduce the needle through needle guide.

Probe Compatibility Table

Model	Compatible Probe		Kit Component – US Probe Cover
GTK01	HITACHI	EUP-V33, EUP-CC31, EUP-V33W, EUP-CC531 EUP-V53W, EUP-V12	Sheathes3D™ Viral Barrier US Probe Cover
GTK02	BK	8808	Sheathes3D™ Viral Barrier US Probe Cover
GTK03	TOSHIBA	PVF-620ST, PVL-625RT	Sheathes3D™ Viral Barrier US Probe Cover
GTK04	TOSHIBA	PVT-661VT, PVM-651VT, PVQ-641V	Sheathes3D™ Viral Barrier US Probe Cover
	SIEMENS	EC9-4	Sheathes3D™ Viral Barrier US Probe Cover
GTK05	SHIMADZU	UB10R-065U	Sheathes3D™ Viral Barrier US Probe Cover
GTK06	ALOKA	UST-670P, UST-675P, UST-676P	Sheathes3D™ Viral Barrier US Probe Cover
GTK07	TOSHIBA	PVM-740-RT, PVT-770-RT	Sheathes3D™ Viral Barrier US Probe Cover
GTK08	SIEMENS	BE9-4, EC9-4	Sheathes3D™ Viral Barrier US Probe Cover
	ESAOTE	EC123, EC1123, SE3123	Sheathes3D™ Viral Barrier US Probe Cover
	GE	IC5-9RS	Sheathes3D™ Viral Barrier US Probe Cover
	ALPINION	E3-10	Sheathes3D™ Viral Barrier US Probe Cover
	TOSHIBA	SSA-790A	Sheathes3D™ Viral Barrier US Probe Cover
GTK08-R	PHILIPS	BP10-5EC, C9-4EC	Sheathes3D™ Viral Barrier US Probe Cover
GTK09	GE	E72, E8C, E8CS, IC5-9-D, IC5-9H	Sheathes3D™ Viral Barrier US Probe Cover
GTK09-S	GE	E721	Sheathes3D™ Viral Barrier US Probe Cover
GTK10	GE	BE9C, BE9CS	Sheathes3D™ Viral Barrier US Probe Cover
GTK11	SIEMENS	EC7, EC10C5, 6.5EC10, EC9-4	Sheathes3D™ Viral Barrier US Probe Cover
	ESAOTE	E8-5R10	Sheathes3D™ Viral Barrier US Probe Cover
	MEDISON	EC4-9IS, EC4-9ES, ER4-9ES	Sheathes3D™ Viral Barrier US Probe Cover
	MINDRAY	V10-4B, V10-4, CB10-4, 6CV1s	Sheathes3D™ Viral Barrier US Probe Cover
GTK11-R	GE	E7C-RC	Sheathes3D™ Viral Barrier US Probe Cover
GTK13	BK	8818, 8808e	Sheathes3D™ Viral Barrier US Probe Cover
GTK14	TOSHIBA	PVU770-ST	Sheathes3D™ Viral Barrier US Probe Cover
GTK15	Samsung MEDISON	EV4-9/10ED, EVN4-9, ER4-9/10ED	Sheathes3D™ Viral Barrier US Probe Cover
GTK16	PHILIPS	C10-4ec	Sheathes3D™ Viral Barrier US Probe Cover
GTK18	HITACHI	C41V1, EUPV73W	Sheathes3D™ Viral Barrier US Probe Cover
GTK100	ALOKA	UST-984-5, UST-9112-5, UST-981-5	Sheathes3D™ Viral Barrier US Probe Cover
GTK101	ALOKA	UST-9118, UST-9124	Sheathes3D™ Viral Barrier US Probe Cover
GTK110	PHILIPS	C8-4V, C9-3V	Sheathes3D™ Viral Barrier US Probe Cover
GTK120	SIEMENS	Endo-V II	Sheathes3D™ Viral Barrier US Probe Cover

GTK122	SIEMENS	EC9-4, EV9-4	Sheathes3D™ Viral Barrier US Probe Cover
GTK130	TOSHIBA	PVT-781VT, PVU-781VT	Sheathes3D™ Viral Barrier US Probe Cover
GTK140	GE	RIC5-9W-RS, RIC6-12-D, RIC5-9-D	Sheathes3D™ Viral Barrier US Probe Cover
GTK141	GE	IC9-RS	Sheathes3D™ Viral Barrier US Probe Cover
GTK150	BK	8848, 9048	Sheathes3D™ Viral Barrier US Probe Cover
GTK133	HITACHI	C41L47RP-Hitachi U533	Sheathes3D™ Viral Barrier US Probe Cover
GTK134	GE	ERB7	Sheathes3D™ Viral Barrier US Probe Cover
	SONOSCAPE	BCL10-5	Sheathes3D™ Viral Barrier US Probe Cover
	TERASON	8BP4	Sheathes3D™ Viral Barrier US Probe Cover
	ESAOTE	TRT33	Sheathes3D™ Viral Barrier US Probe Cover
GTK151	BK	E14C4t(9018) - 8818	Sheathes3D™ Viral Barrier US Probe Cover
GTK152	BK	E14C4t(9018) - 8818	Sheathes3D™ Viral Barrier US Probe Cover
GTK153	HITACHI	C41L47RP-Hitachi U533	Sheathes3D™ Viral Barrier US Probe Cover
GTK154	GE	ERB7	Sheathes3D™ Viral Barrier US Probe Cover
	SONOSCAPE	BCL10-5	Sheathes3D™ Viral Barrier US Probe Cover
	TERASON	8BP4	Sheathes3D™ Viral Barrier US Probe Cover
	ESAOTE	TRT33	Sheathes3D™ Viral Barrier US Probe Cover
GTK155	BK	8848, 9048	Sheathes3D™ Viral Barrier US Probe Cover

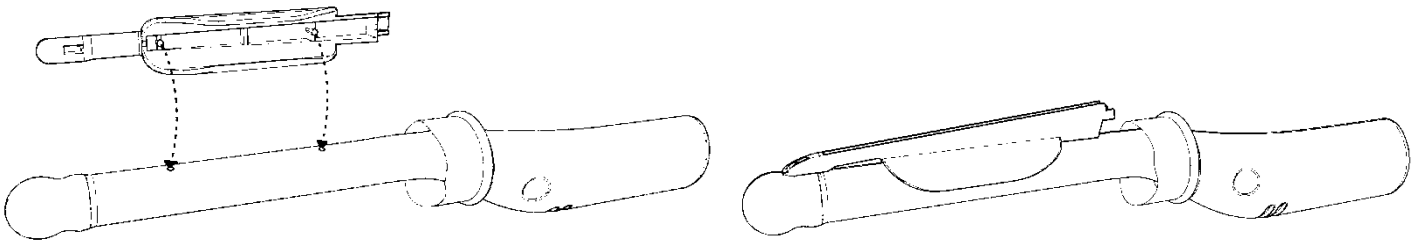
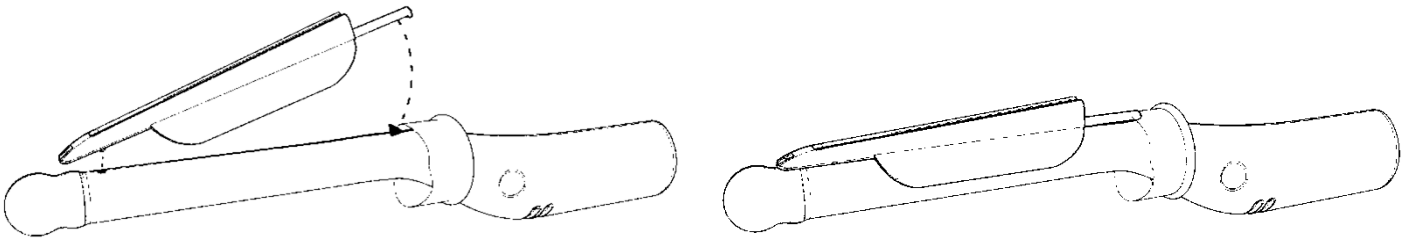


Figure a.



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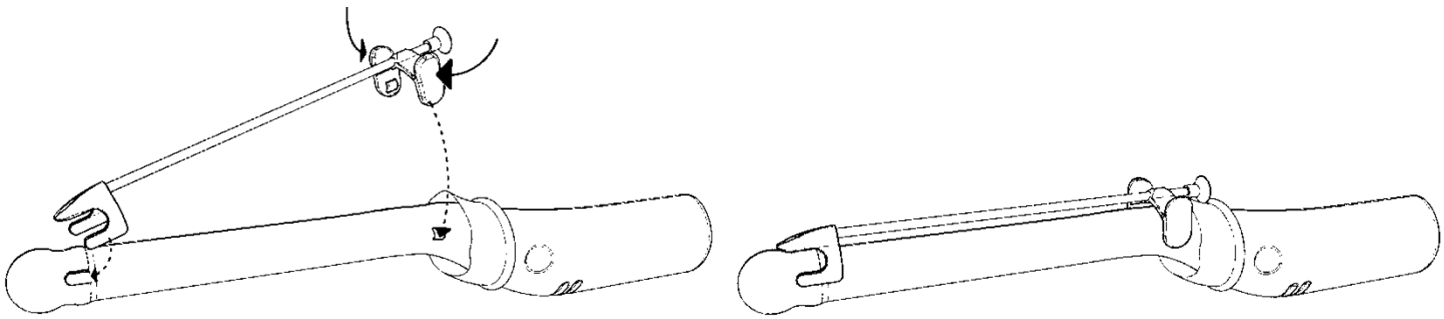

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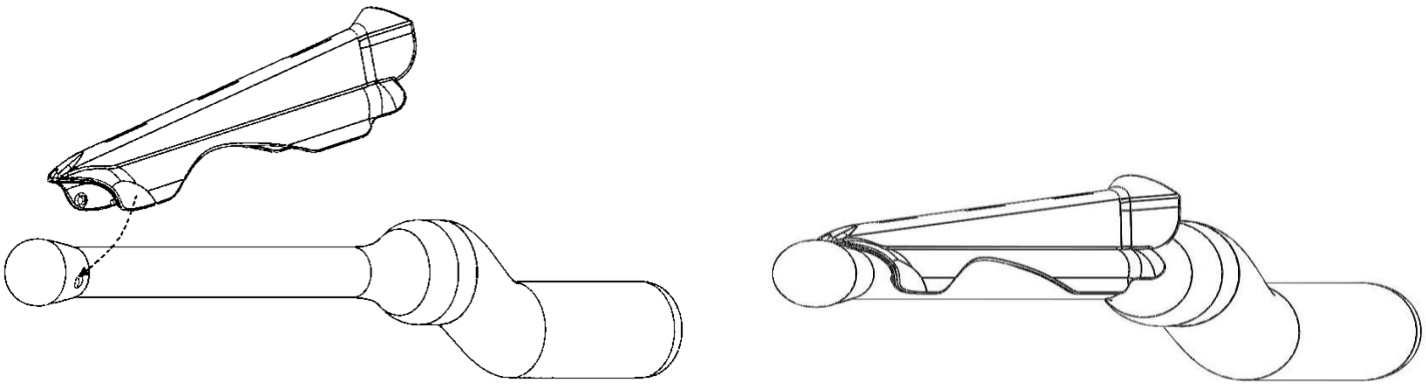

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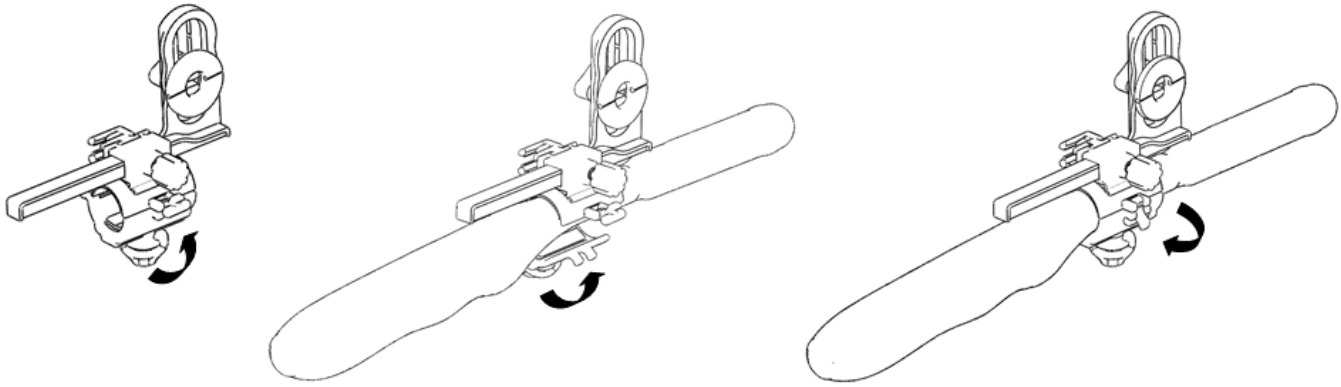

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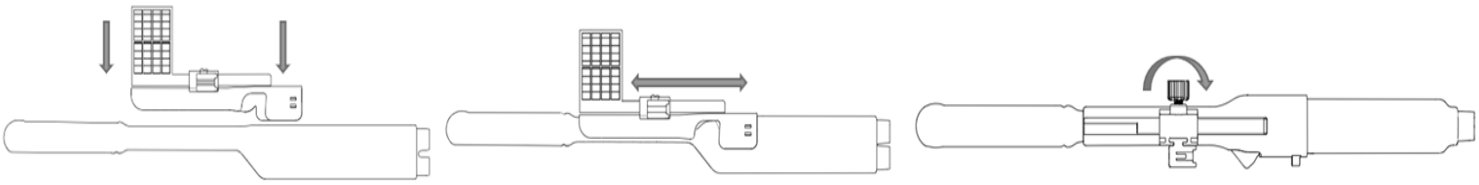

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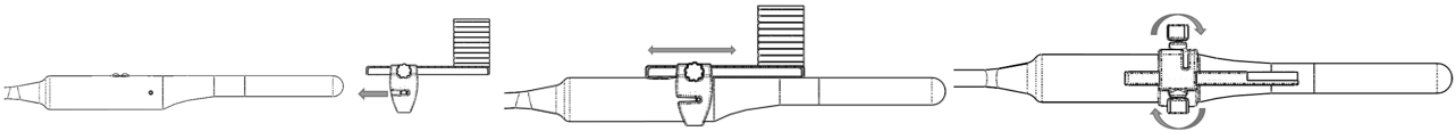

Figure g.

Storage instructions:

Temperature and humidity limits
The temperature and humidity limits for the needle guides are as follows:

- Shipping: -40 55°C (-40 131°F); 85% R.H.
- Storage: 11 29°C (52 84°F); 85% R.H.

Instructions on how to safely dispose of the device:

Discard the used contaminated device according to local and hospital procedures.

Manufactured by:

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Revision History:

03: TERASON Probe code was corrected for GTK134 and GTK154 models.

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