

GTK Disposable Needle Guides - Instructions for Use -

indications for use:

used in conjunction with ultrasound system transducer where configuration is suitable and attached to the ultrasound system's transducers to facilitate proper needle placement to access anatomical structures.

contraindications:

- 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.

Possible Side Effects: Pain, fever, bleeding, hematuria and infection.

General warnings and precautions:

Please double check for device function and possible damage for correct implantation and do not use if package is opened or damaged.

- 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 °C 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 has been selected and 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: “GEOTEK 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 the following:

- If unable to visualize the needle at the target, ensure that the correct needle guide has been selected and 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 Matrix

Model	Compatible Probe	
GTK01	HITACHI	EUP-V33, EUP-CC31, EUP-V33W, EUP-CC531 EUP-V53W, EUP-V12
GTK02	BK	8808
GTK03	TOSHIBA	PVF-620ST, PVL-625RT
GTK04	TOSHIBA	PVT-661VT, PVM-651VT, PVQ-641V
	SIEMENS	EC9-4
GTK05	SHIMADZU	UB10R-065U
GTK06	ALOKA	UST-670P, UST-675P, UST-676P
GTK07	TOSHIBA	PVM-740-RT, PVT-770-RT
GTK08	SIEMENS	BE9-4, EC9-4
	ESAOTE	EC123, EC1123, SE3123
	GE	IC5-9RS
	ALPINION	E3-10
	TOSHIBA	SSA-790A
GTK08-R	PHILIPS	BP10-5EC, C9-4EC
GTK09	GE	E72, E8C, E8CS, IC5-9-D, IC5-9H
GTK09-S	GE	E721
GTK10	GE	BE9C
		BE9CS
GTK11	SIEMENS	EC7, EC10C5, 6.5EC10, EC9-4
	ESAOTE	E8-5R10
	MEDISON	EC4-9IS, EC4-9ES, ER4-9ES
	MINDRAY	V10-4B, V10-4, CB10-4, 6CV1s, V11-3Ws
GTK11-R	GE	E7C-RC
GTK12	SIEMENS	EC9-4W (ACUSON 3000), MC9-4 (S1000 / S2000)
GTK13	BK	8808e, 8818
GTK100	ALOKA	UST-984-5, UST-9112-5, UST-981-5
GTK101	ALOKA	UST-9118, UST-9124
GTK110	PHILIPS	C8-4V, C9-3V, C9-4V
GTK120	SIEMENS	Endo-V II
GTK122	SIEMENS	EC9-4, EV9-4
GTK130	TOSHIBA	PVT-781VT, PVU-781VT
GTK140	GE	RIC5-9W-RS, RIC6-12-D, RIC5-9-D, RIC5-9H
GTK141	GE	IC9, IC9-RS (VOLUSON S10)

Fig. a)

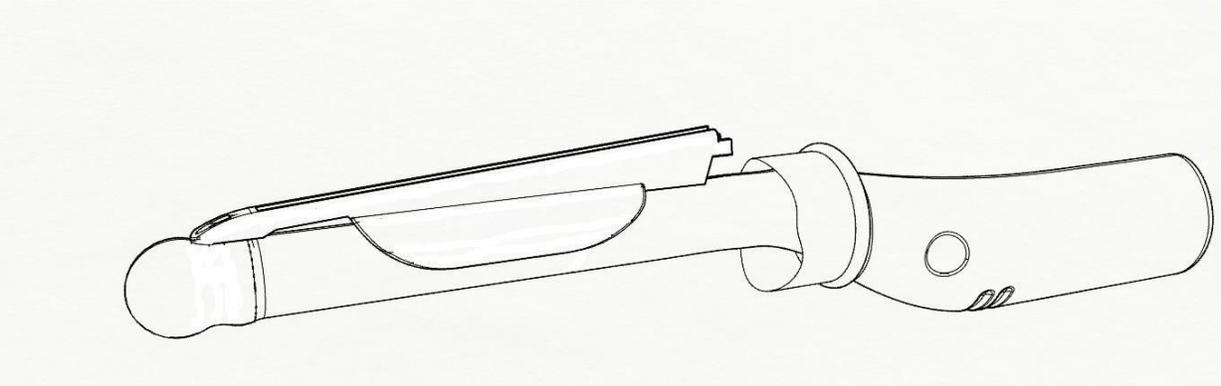
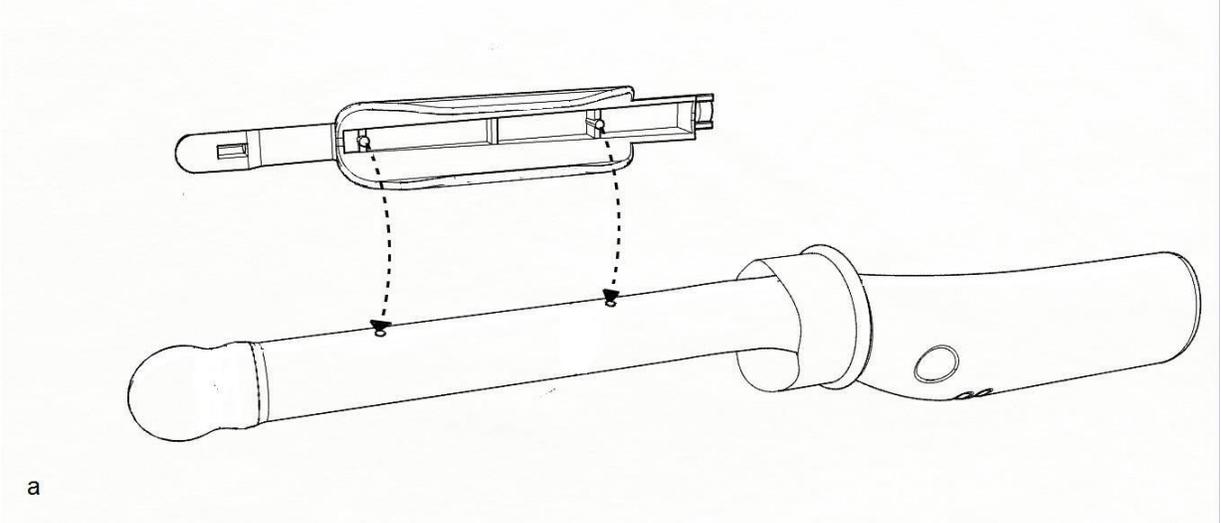


Fig. b)

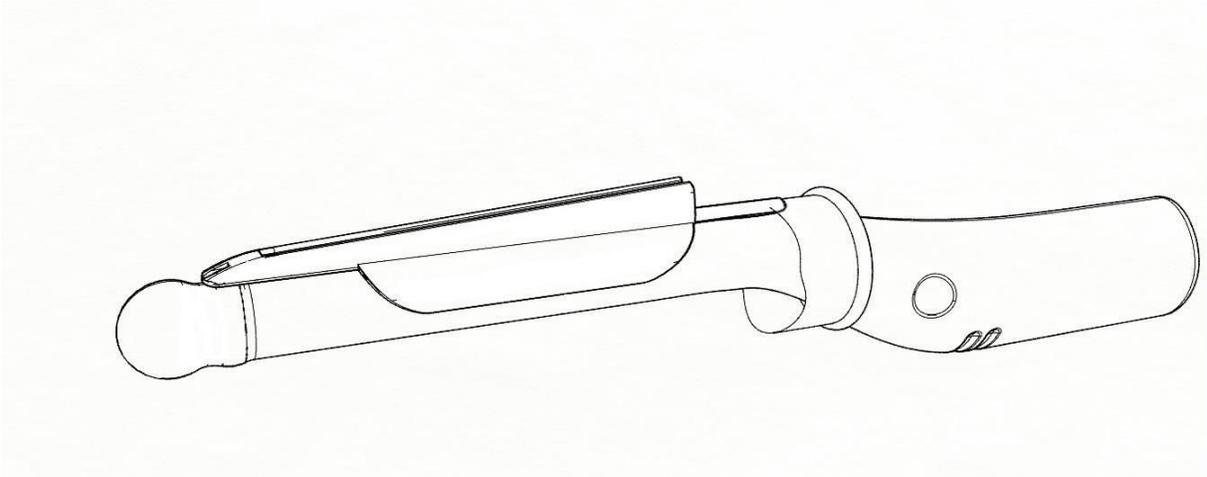
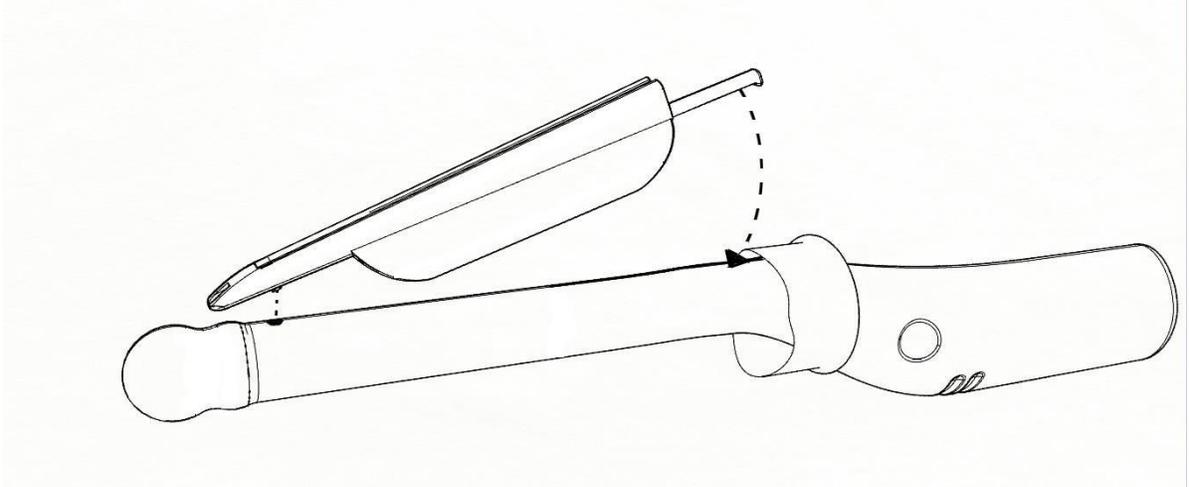


Fig. c)

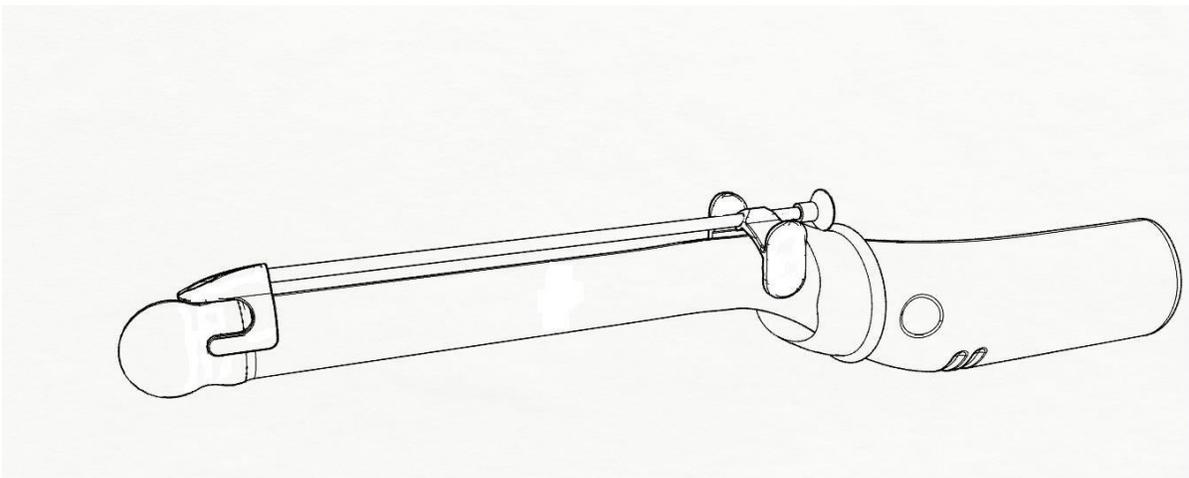
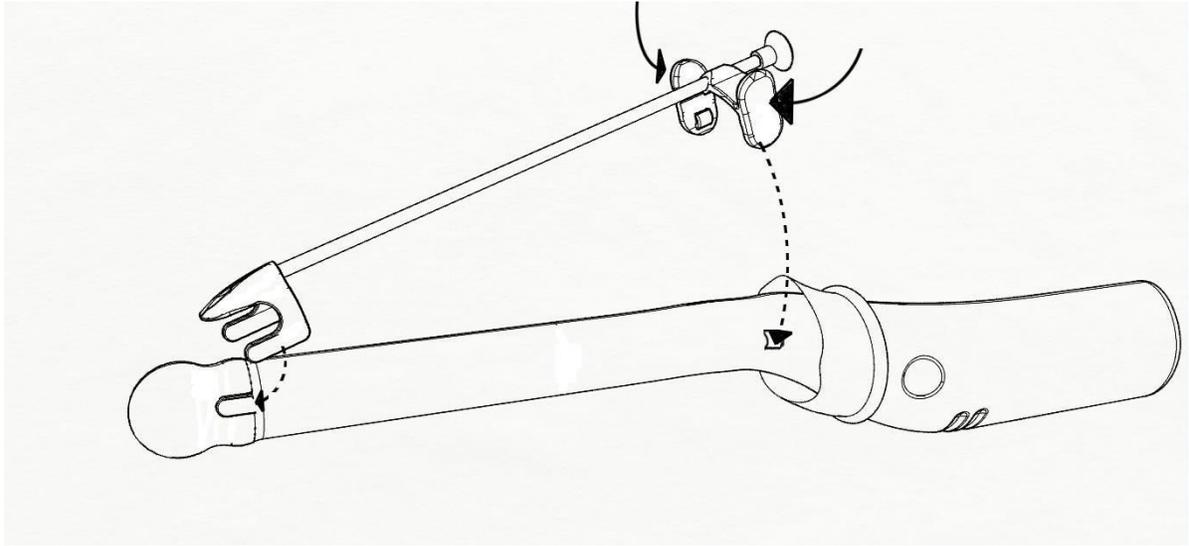
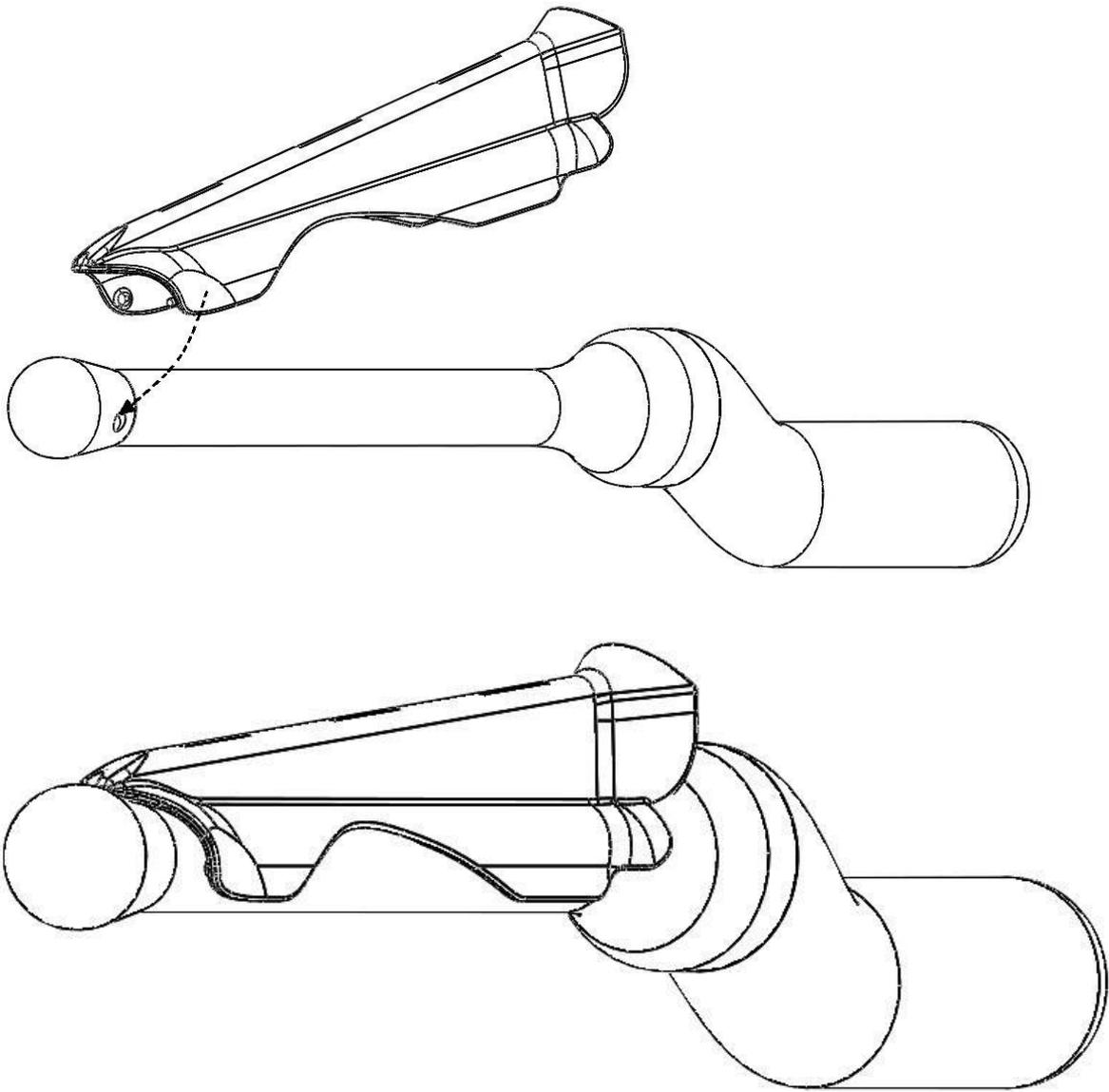


Fig. d)



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:

GEOTEK MEDİKAL VE SAĞLIK HİZ.LTD.STİ
İVEDİK OSB. AĞAÇ-METAL SİTESİ 1436 SK. NO:12 YENİMAHALLE - ANKARA
TEL:+90312 3959852
FAX:+90312 3959853

Date of Printing:

May 1, 2017



Single Use



Storage limits



Expiry Date

STERILE EO

: Ethylen oxide sterilized