

CERT × ALIGN

ULTRASOUND NEEDLE GUIDE AND STABILIZER SINGLE USE

Instructions for Use



FOR A COMPLETE LIST OF
ULTRASOUND TRANSDUCERS
TESTED WITH THE
CERTALIGN DEVICE, SCAN
THE QR CODE BELOW



WWW.FASTNALIGN.COM/
CERTALIGN-TRANSDUCER-LIST

COMPATIBLE WITH
NEEDLES FROM
16 GAUGE - 27 GAUGE

FOR FEEDBACK OR ENQUIRIES,
PLEASE CONTACT US AT
INFO@FASTNALIGN.COM

DEVICE DESCRIPTION

- CERTALIGN is a sterile, single-use device intended to assist ultrasound-guided needle procedures performed using the in-plane technique, by stabilizing the transducer position and aligning needle insertion within the ultrasound imaging plane.

The device comprises the following components:

- Transducer Clasp: Polycarbonate
- Needle Guide and Anti-slide Bumpers: Polycarbonate;
- Colorant: GPCX-1900 Light Blue
- Elastic Securing Band: Synthetic polyisoprene

INTENDED USE

The needle guide and stabilizer provide healthcare professionals with a tool for performing needle-guided procedures with the use of ultrasound transducers.

This device is intended for use only in ultrasound-guided biopsy procedures and fine needle aspirations.

INDICATIONS FOR USE

- Abdominal – Biopsy, Fine-Needle Aspiration
- Small Parts – Biopsy, Fine-Needle Aspiration

PATIENT POPULATION

CERTALIGN is intended for use with an appropriately sized ultrasound transducer in adult and pediatric populations of all body habitus, including individuals with small or slight frames.

INTENDED USERS

- CERTALIGN should be used by healthcare professionals medically trained in the use of ultrasound for interventions. There are no other unique skills or user abilities required for use. This may include, but is not limited to: anesthesiologists, interventional radiologists, emergency and critical care physicians, nephrologists, surgeons, sonographers, physician assistants and nurses.

PERFORMANCE CHARACTERISTICS

CERTALIGN provides accurate needle guidance and ultrasound transducers stabilization.

NOTE: For a summary of clinical benefits with this product, visit <https://fastnalign.com/certalign>.

CAUTION

Federal (United States) law restricts this device to be sold on the order of a physician.

WARNING

- Before use, you should be trained in ultrasonography. For instructions on the use of your transducer, see your system's user guide.
- The device has been sterilized using ethylene oxide and is supplied sterile.
- The sterile product is intended for single-use only.
- Do not use if integrity of packaging is violated.
- Do not use if the device is damaged.
- Do not use if expiration date has passed.

- Do not reuse, reprocess or resterilize single-use device, as this may create a risk of contamination of the device, cause patient infection or cross-infection.
- Use only water-soluble ultrasound gels or agents. Petroleum or mineral oil-based materials may harm the cover.
- Ensure no air bubbles are present prior to use. Air left between cover and transducer lens may cause poor image quality.
- If the product malfunctions during use or is no longer able to achieve its intended use, stop using the product and call FASTNALIGN.
- Report serious incidents related to the product to FASTNALIGN and the competent authority or appropriate regulatory authorities.

CONTRAINDICATIONS

- Do not use for applications other than ultrasound-guided biopsy or fine-needle aspiration procedures.

PRECAUTIONS

- This device should be used only by healthcare professionals trained in ultrasound-guided procedures.
- Maintain sterile technique throughout the procedure in accordance with the applicable standard of care.
- Verified for use only with the ultrasound transducers listed at www.fastnalign.com/certalign-transducer-list; use with other transducers may result in improper fit or reduced performance.
- Intended for use with needles from 16 gauge – 27 gauge; use outside this range may affect performance

- or guidance accuracy.
- If the needle has been inserted into the patient, withdraw it fully before re-adjusting the angle.

STORAGE CONDITIONS

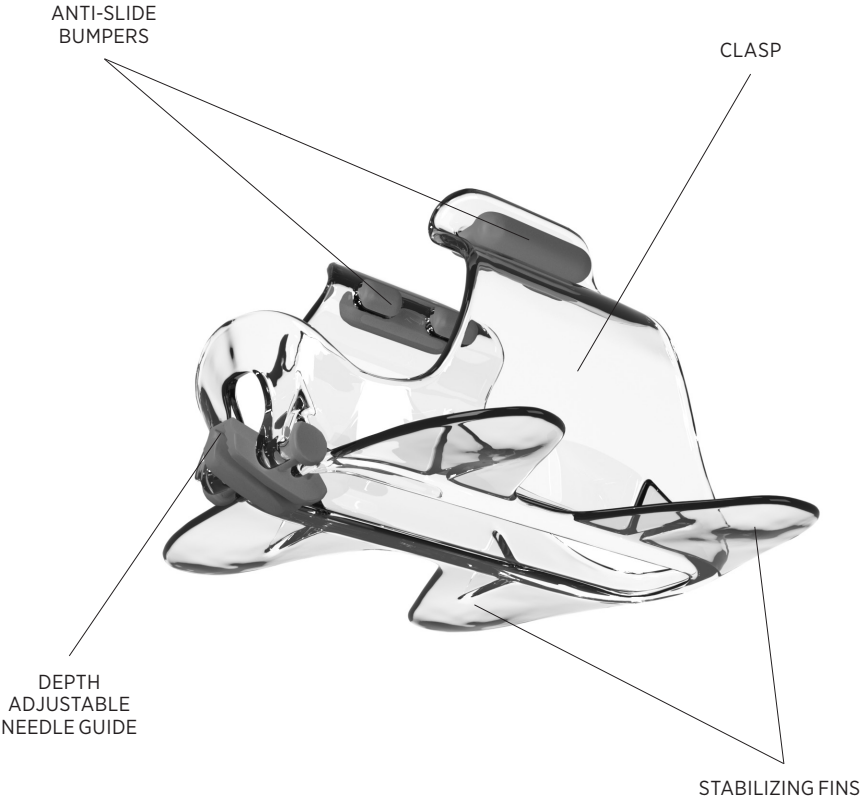
- Store in a clean, dry environment at room temperature. Protect from excessive heat, moisture, and direct sunlight.
- Handle with care to maintain package integrity and sterility.

MANUFACTURED FOR
FASTNALIGN HOLDINGS INC
206 SPRING STREET FLOOR 3
NEW YORK NY 10012

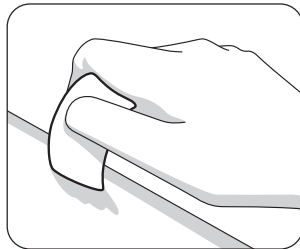
FOR FURTHER INFORMATION OR TO
ORDER ADDITIONAL PRODUCTS,
OR TO MAKE A COMPLAINT PLEASE
CONTACT:
EMAIL: INFO@FASTNALIGN.COM
PHONE: +1 347 405 3842
OR VISIT WWW.FASTNALIGN.COM

PN 42278 REV. 03

SYMBOL	SYMBOL TITLE
	MANUFACTURER
	UNIQUE DEVICE IDENTIFIER
	CATALOG NUMBER
	BATCH CODE (LOT)
	PRESCRIPTION ONLY
	EXPIRATION DATE
	STERILIZED USING ETHYLENE OXIDE
	SINGLE USE ONLY
	CAUTION
	TEMPERATURE LIMIT
	KEEP DRY
	DO NOT USE IF PACKAGING IS DAMAGED
	CONSULT INSTRUCTIONS FOR USE

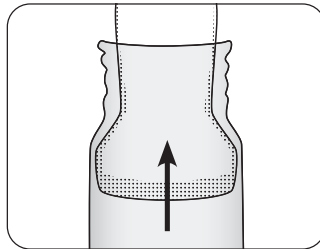


Preparation



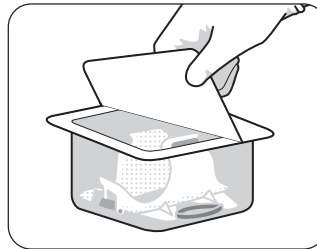
1. Prepare the Procedure Site

- Select and prepare the target site according to standard clinical practice.
- Clean and disinfect the procedure site in accordance with the standard of care.



2. Prepare the Ultrasound Transducer

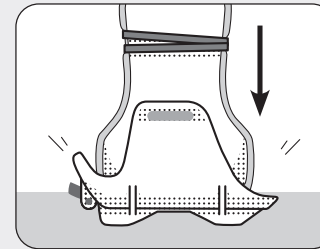
- Prepare the sterile field or procedure table.
- Apply sterile ultrasound gel to the transducer.
- Apply a sterile transducer probe cover over the probe and secure it with an elastic band, if required.



3. Open the CERTALIGN Package

- Inspect the CERTALIGN sterile packaging for any signs of damage. Discard the device if the packaging is found damaged.
- Peel back the lid of the sterile tray to expose the CERTALIGN device.

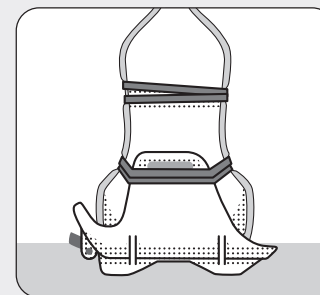
Application + Use



4. Attach the Device to the Transducer

Option A – Attach While Device is in the Tray

- While the device remains in the sterile tray, press the ultrasound transducer straight down into the CERTALIGN device, with the transducer orientation marker towards the needle guide.
- Push until the distal end of the transducer is flush with the base of the CERTALIGN device.



- Slide the transducer fully toward the needle guide until it stops.
- Lift the ultrasound transducer with the attached CERTALIGN device from the sterile tray.
- Anchor the elastic band just below the anti-slide bumpers. Use a double loop to ensure a tight fit.

Option B - To attach the device to the transducer on a sterile field, first remove the CERTALIGN device from the sterile tray onto the field, and then follow the same steps as above.

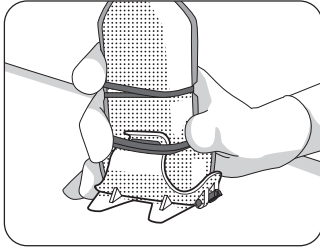
SCAN THE QR CODE BELOW TO
WATCH THE SUPPLEMENTARY
CERTALIGN INSTRUCTIONAL VIDEO



WWW.FASTNALIGN.COM
/CERTALIGN-INSTRUCTIONAL-VIDEO

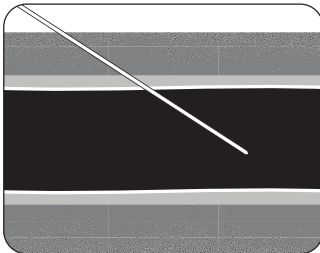
CERT × ALIGN

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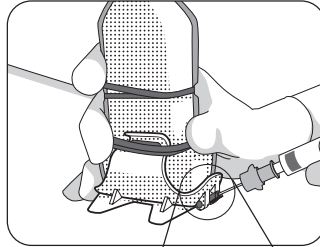
5. Locate the Target Site

- Apply sterile ultrasound gel to the procedure site as required.
- Place the transducer with the attached CERTALIGN device on the target site.



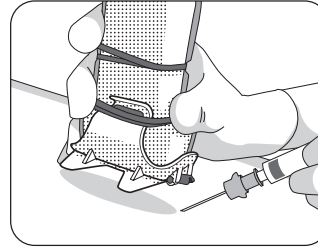
LONG-AXIS, IN-PLANE ULTRASOUND VIEW OF BLOOD VESSEL

- Adjust transducer position until the target anatomy is clearly visualized on the ultrasound monitor in the long-axis/in-plane view.



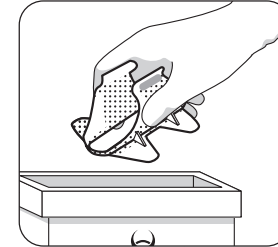
6. Insert the Needle into the Blue Needle Guide

- Insert the needle into the blue needle guide, located at the front of the device.
- As you advance the needle, ensure that it remains in contact with the top of the needle guide.
- The depth adjustable needle guide allows the needle angle to be changed during the procedure.



7. Complete the Procedure

- When the procedure is complete and ultrasound guidance is no longer required, carefully lift the ultrasound transducer together with the attached CERTALIGN device away from the procedure site.
- Use care to avoid disturbing any needles, catheters, guidewires, lines, or other devices that may have been placed during the procedure.
- Detach the CERTALIGN device from the ultrasound transducer.



8. Disposal

- CERTALIGN is a **single-use device**: Dispose of the device in accordance with local regulations for biohazardous medical waste.

Disposal

Best Practice Guidance

The needle guide is designed for the long-axis/in-plane view. For healthcare professionals who prefer the short-axis/out-of-plane view, the CERTALIGN device may be used for stabilization only.

Secure the transducer with the elastic band. Add the band onto the transducer, prior to attaching the CERTALIGN device.

Push the transducer all the way towards the end of the clasp, towards the needle guide.

Ensure the transducer is central in the guide.

Ensure the needle is inserted into the blue needle guide.

As you advance the needle, ensure that it remains in contact with the top of the needle guide.

Ensure there is no undue downward pressure while performing the procedure.