

COGNITION™ featuring DiamondBack™ Technology

STAPLE SYSTEM



This surgical technique guide is intended as a reference for trained orthopedic surgeons. It does not replace the full Instructions for Use (IFU), which contains critical information pertaining to Contraindications & Warnings, MRI Safety Labelling, Sterility/Reprocessing, and other regulatory information. Surgeons should consult the IFU before use. The IFU for COGNiTiON™ is available at <https://www.orthosol.com/eifu>

The COGNiTiON™ Staple should not be used in patients with contraindications outlined in the IFU, including active infection, poor bone quality, or conditions that inhibit normal healing.

The MRI safety of this device has not been evaluated. Refer to the IFU for additional information.

This device is FDA-cleared under 510(k) number K240212



2-LEG STAPLE	INSERTER	DRILL GUIDE	DRILL BIT	TEMP. PIN
2 x 10 x 10	2 LEG x 10mm	2 LEG x 10mm	Ø2.0	Ø1.9
2 x 15 x 15	2 LEG x 15mm	2 LEG x 15mm	Ø2.7	Ø2.5
2 x 20 x 15	2 LEG x 20mm	2 LEG x 20mm	Ø2.7	Ø2.5
2 x 20 x 20	2 LEG x 20mm	2 LEG x 20mm	Ø2.7	Ø2.5
2 x 25 x 20	2 LEG x 25mm	2 LEG x 25mm	Ø2.7	Ø2.5

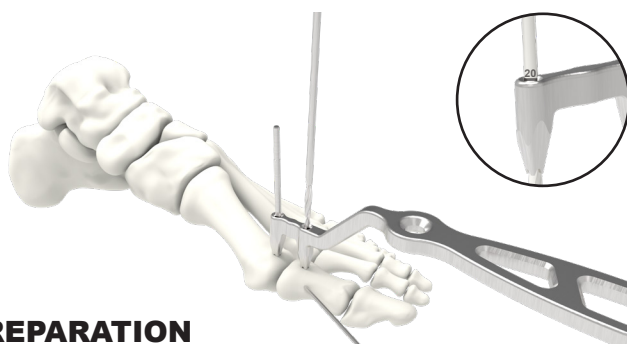


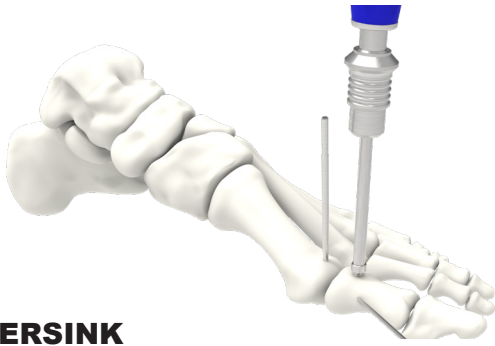
4-LEG STAPLE	INSERTER	DRILL GUIDE	DRILL BIT	TEMP. PIN
4 x 20 x 15	4 LEG x 20mm	4 LEG x 20mm	Ø2.7	Ø2.5
4 x 20 x 20	4 LEG x 20mm	4 LEG x 20mm	Ø2.7	Ø2.5
4 x 25 x 20	4 LEG x 25mm	4 LEG x 25mm	Ø2.7	Ø2.5

Figure 1

1 BONE PREPARATION

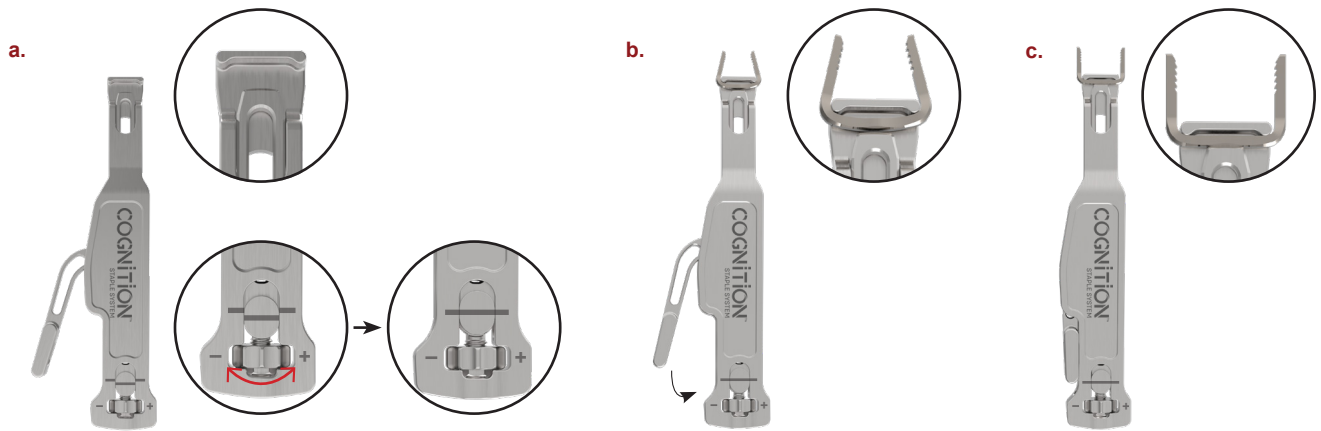
Once your osteotomy or fusion site is prepped and desired reduction is achieved, select the desired implant size via the sizing template and select the corresponding inserter and drill guide (see figure 1). Align the drill guide along the center of the osteotomy or fusion site using the laser-line located on the drill guide. The provided drill bit (see figure 1) can be used to drill for the first hole. Use the laser-line on the drill bit to find the appropriate staple leg length, then the temporary holding pin should be placed in the first hole. The drill bit can then be used to drill for the second hole. Repeat steps for 4-Leg COGNiTiON™ implant.





2 COUNTERSINK

COGNiTiON implants have been optimized for high-stress with reinforced shoulders. In instances of dense bone, a countersink is provided to increase the pilot hole opening.



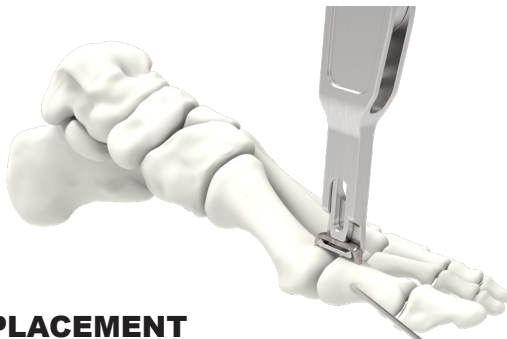
3 IMPLANT PREPARATION

Remove the COGNiTiON™ implant from the sterile box and select the corresponding inserter from the tray. Align the laser-lines on the inserter using the dial (a) and place the COGNiTiON™ implant in the cradle (b). Proceed to close the lever so that the legs of the implant are parallel and line up with the pre-drilled holes (c).

Note: It is important to ensure that the staple bridge is NOT over compressed to a point where the staple legs are beyond parallel. Under any circumstances, do not force the lever arm closed if experiencing extreme difficulty - simply rotate the dial counterclockwise to decrease the amount of compression on the staple bridge.

If the legs do not reach parallel, open the lever arm and rotate the dial clockwise to make adjustments.

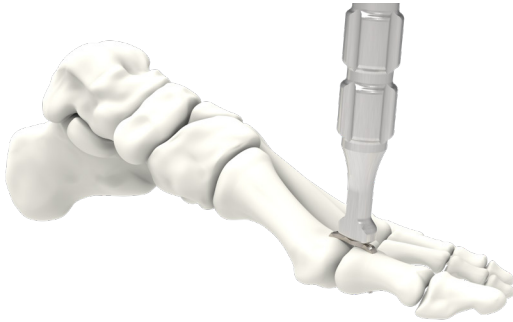
Note: If incremental adjustments are needed once the lever arm is in a closed position, an inserter socket wrench is provided. If adjustments are intended to be made freehanded when the staple is not loaded, it is recommended that two points of contact (i.e. two fingers) are placed on the adjuster to ensure efficient use of the mechanism.



4 IMPLANT PLACEMENT

Remove the drill guide and holding pins from the osteotomy or fusion site. Advance the inserter until the bottom of the cradle is flush to the bone. A mallet can be used to provide additional insertion force if needed.

Fluoroscopy can be used to confirm implant placement prior to removing the inserter. Once satisfied, open the lever on the inserter and simply slide the cradle from underneath the staple bridge.



5 TAMPING

The provided tamp may be used to fully seat the implant. Ensure the COGNiTiON™ implant is fully seated and confirm placement via fluoroscopy.

Note: If explant is necessary, use the provided 1/4in. osteotome to lift the staple bridge. The inserter may then be reapplied to explant the staple.



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Consult instructions for use.



Surgeon must be fully trained in the surgical technique.

Rx only

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician

