

SUPERHAWK™ Brace System

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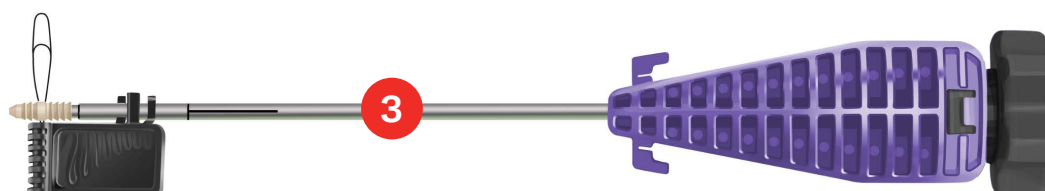
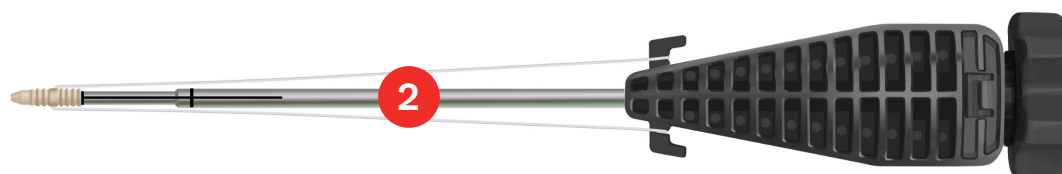
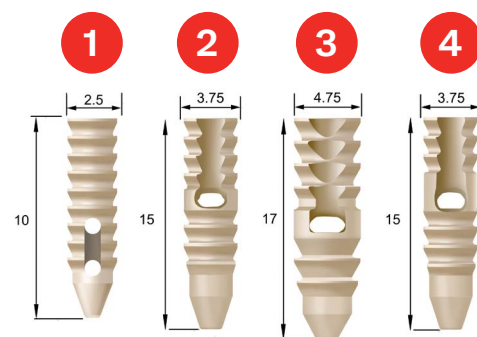
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1. Implant sizing

AGILE™ & SUPERHAWK™ Anchor Assemblies

PEEK anchors assembled on a disposable inserter with either 2.3mm Suture tape, a suture thread pull tab, or standard #2 Suture.



Part number	Part name	Anchor diameter (mm)	Image
285945	AGILE 2.5mm Assembly	2.5	1
285925	SUPERHAWK Assembly 3.75mm Start w/2.3mm Suture Tape	3.75	2
	SUPERHAWK Assembly 4.75mm	4.75	3
285926	SUPERHAWK Assembly 3.75mm End	3.75	4

2. Surgical procedure

A) Standard access and prep

Use standard approach through either an open procedure or making standard anteromedial and anterolateral portals and debride the joint.

B) AGILE Anchors for soft tissue repair (optional)

i) Bone Drilling

Place the AGILE 2.5mm Drill Guide on the fibula at desired location, typically 1 cm proximal to the tip of the distal fibula (Fig. 1). Insert the drill into the drill guide until the drill is near the bone surface. Drill to create the pilot hole. The collar on the drill will bottom out on the drill guide at proper hole depth (Fig. 2). Keeping the drill guide in place, remove the drill.

ii) Anchor insertion

Insert the AGILE Anchor Inserter Assembly into the drill guide and advance the inserter until the anchor is near the bone surface (Fig. 3). Mallet on the inserter handle until the circumferential laser mark on the inserter shaft near the anchor is fully beneath the bone surface and the circumferential lasermark on the inserter shaft near the handle is flush with the top of the drill guide (Fig. 4). Remove the suture from the cleats on the inserter handle and remove the inserter by pulling back (Fig. 5).



Fig. 1

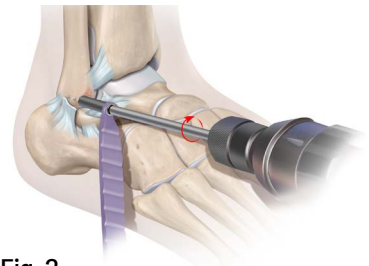


Fig. 2

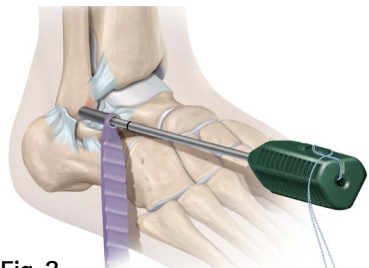


Fig. 3

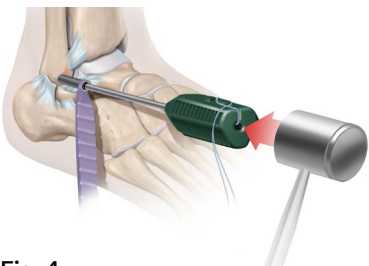


Fig. 4

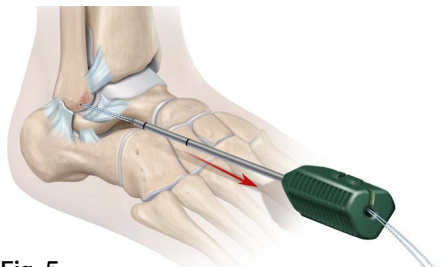


Fig. 5

2. Surgical procedure

iii) Tissue repair

After placing the desired amount of AGILE Anchors, place the tail of one suture through the nitinol looped end of the provided AGILE Free Needle (Fig. 6). Use the free needle to shuttle the suture through the tissue. Repeat this step for all suture tails. Once all suture tails have been shuttled through the tissue, tie down the sutures and trim the suture ends, so that they lie flush on the retinaculum (Fig. 7).

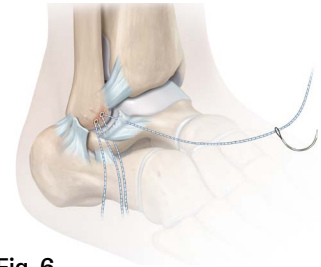


Fig. 6

SUPERHAWK Anchors for augmented Brostrom repair

C) First anchor hole prep (3.75mm Start)

Position the SUPERHAWK Round Drill Guide on the talus or at desired insertion location. Drill with the SUPERHAWK 3.75mm Drill (black band) until it bottoms out on the round drill guide (Fig. 8). Keeping the round drill guide in place, remove the drill. Optional: The SUPERHAWK Guide Wire and SUPERHAWK Drill Guide Insert may be used along with the SUPERHAWK 3.75mm Cannulated Drill to aid in drilling position.



Fig. 7

D) First anchor insertion (3.75mm Start)

Insert the SUPERHAWK 3.75mm Start Anchor Assembly (black handle) through the round drill guide and advance the inserter. Mallet on the inserter handle until the circumferential laser mark on the inserter shaft is flush with the round drill guide top surface (Fig. 9). The anchor will be fully beneath the bone surface.

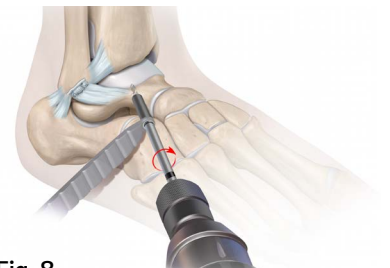


Fig. 8

Remove the suture from the cleats on the inserter handle and remove the inserter by pulling up. Note: The 3.75mm Start Anchor comes preloaded with 2.3 mm suture tape pre-locked to the anchor. If desired, unlock the suture tape by simply rotating the inserter handle counterclockwise. Always remember to lock the suture prior to inserter removal.



Fig. 9

2. Surgical procedure

E) Second anchor hole prep (4.75mm)

i) Drilling

Position the SUPERHAWK Round Drill Guide at the fibula or at desired insertion location. Drill with the SUPERHAWK 4.75mm Drill (purple band) until it bottoms out on the drill guide (Fig. 10). Remove the instruments and set aside. Optional: The SUPERHAWK Guide Wire and SUPERHAWK Drill Guide Insert may be used along with the SUPERHAWK 4.75mm Cannulated Drill to aid in drilling position.

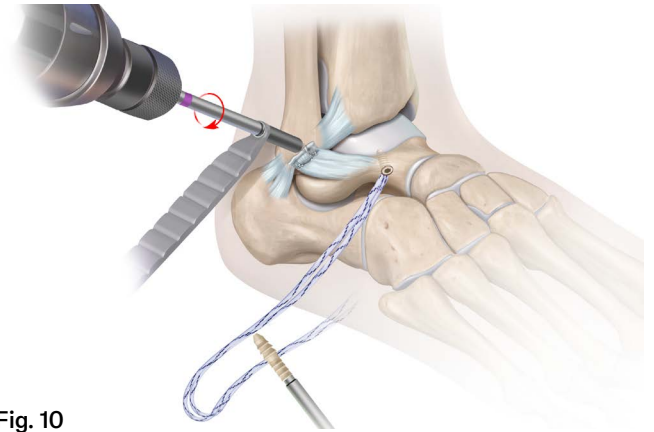


Fig. 10

ii) Broaching

Select the 4.75mm Broach Assembly (purple handle). Align the direction of the 4.75mm broach wings with the targeted suture direction. Insert the broach in the correct orientation with the mallet until the top flat of the wings is just below the cortical layer (Fig. 11). Remove the broach.

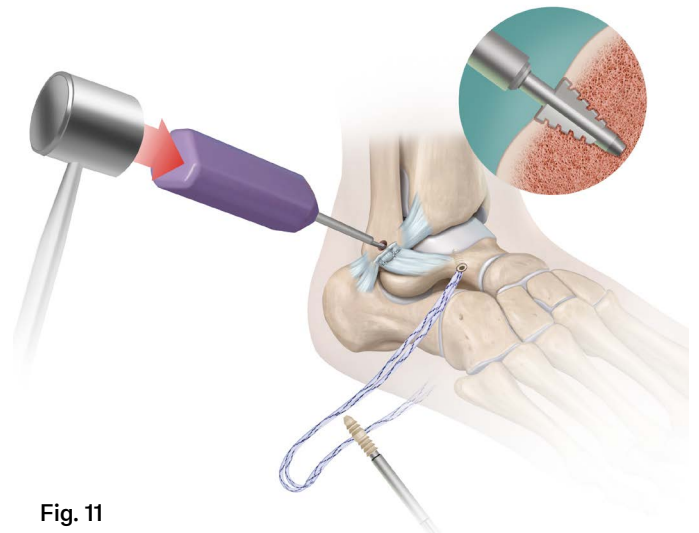


Fig. 11

F) Second anchor insertion (4.75mm)

i) Suture tape loading

Insert the round ends of the repair suture tape tails through the nitinol loops of the Pull Tab on the SUPERHAWK 4.75mm Anchor Inserter Assembly (purple handle). Pull the tab laterally away from the anchor, detaching it from the inserter shaft and pulling the suture tape tails through the anchor eyelet. Pull the tab until the suture tape tails are fully passed through the anchor and the wire loop is free (Fig. 12). Discard the pull tab.

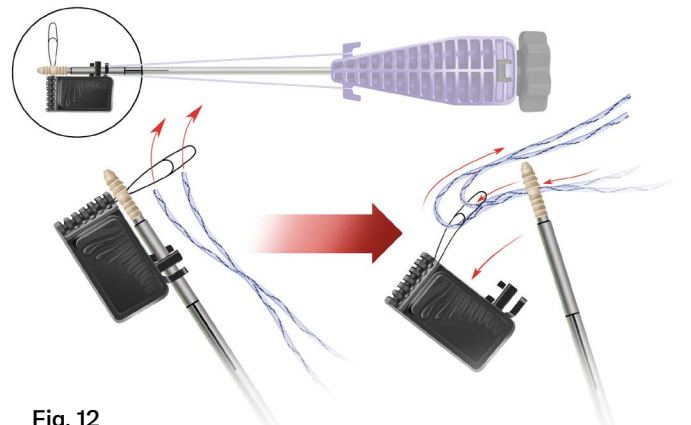


Fig. 12

2. Surgical procedure

ii) Suture anchor insertion

Insert the 4.75mm anchor until the circumferential laser mark on the inserter shaft near the anchor is fully beneath the bone surface. Take care to maintain alignment of the suture and anchor relative to the broach direction (Fig. 13). The anchor should be fully beneath the bone surface.

Remove the #0 holding suture and discard.

iii) Suture tape tensioning

Pull upwards on the suture tape tails evenly with increasing tension while keeping constant downwards pressure on the inserter (Fig. 14 - 1) until the desired tension is reached. Perform range of motion on patient and tighten or loosen the suture tape tension until desired tension is reached with range of motion confirmation (Fig. 14 - 2). Optional: When tensioning the suture tape place the tails around one of the cleats on the inserter and pull downwards. This will both tension the suture and apply downwards pressure to the inserter.

iv) Suture tape locking

Once desired tension has been reached, maintain the tension by holding the suture tape or optionally wrap the suture tape tails around the inserter cleats. Confirm the #0 holding suture has been removed and discarded.

Holding the handle steady, rotate the knob clockwise until it clicks (Fig. 15). This will lock the suture tape to the anchor. Unwrap the suture tape tails from the inserter cleats and remove the inserter by pulling up. Note: The knob will continue to click if over rotated, but the locking mechanism will not be further tightened.

If no third anchor is desired, proceed to suture trimming (step "I", page 11)

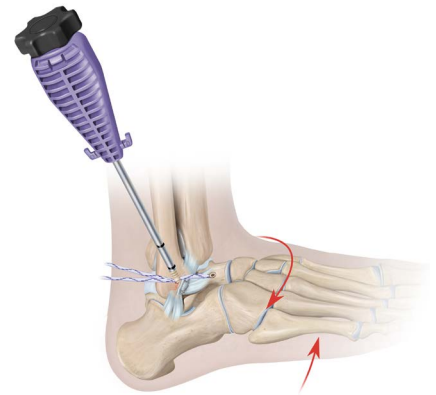


Fig. 13

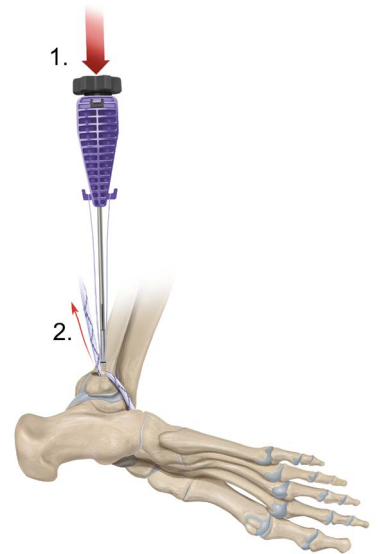


Fig. 14



Fig. 15

2. Surgical procedure

G) Third anchor hole prep (3.75mm End) (optional)

i) Drilling

The third anchor acts as an additional point of contact for an increased strength of repair and as such should be placed at surgeon's discretion and locational choice. The steps for the third anchor preparation and insertion are similar to the ones used for the second anchor, with the exception that the SUPERHAWK 3.75mm End Assembly (black handle) is used in this case.

Position the SUPERHAWK Round Drill Guide at the desired location. Drill with the SUPERHAWK 3.75mm Drill (black band) until it bottoms out on the drill guide. Remove and set aside.

Optional: The SUPERHAWK Guide Wire and SUPERHAWK Drill Guide Insert may be used along with the SUPERHAWK 3.75mm Cannulated Drill to aid in drilling position.

ii) Broaching

Select the 3.75mm Broach Assembly (black handle). Align the direction of the 3.75mm broach wings with the targeted suture direction. Using the mallet, insert the broach in the correct orientation until the top flat of the wings is just below the cortical layer. Remove the broach.

2. Surgical procedure

H) Third anchor insertion (3.75mm End)

i) Suture tape loading

Insert the round ends of the repair suture tape tails through the nitinol loops of the Pull Tab on the SUPERHAWK 3.75mm End Anchor Inserter Assembly (black handle). Pull the tab laterally away from the anchor, detaching it from the inserter shaft and pulling the suture tape tails through the anchor eyelet (Fig. 16). Pull the tab until the suture tape tails are fully passed through the anchor and the wire loop is free. Discard the pull tab.

ii) Suture anchor insertion

Insert the SUPERHAWK 3.75mm End anchor until the circumferential laser mark on the inserter shaft near the anchor is fully beneath the bone surface. Take care to maintain alignment of the suture and anchor relative to the broach direction.

Remove the #0 holding suture and discard

iii) Suture tape tensioning

Pull upwards on the suture tape tails evenly with increasing tension while keeping constant downwards pressure on the inserter until the desired tension is reached. Perform range of motion on patient and tighten or loosen the suture tape tension until desired tension is reached with range of motion confirmation. Optional: When tensioning the suture tape place the tails around one of the cleats on the inserter and pull downwards. This will both tension the suture and apply downwards pressure to the inserter.

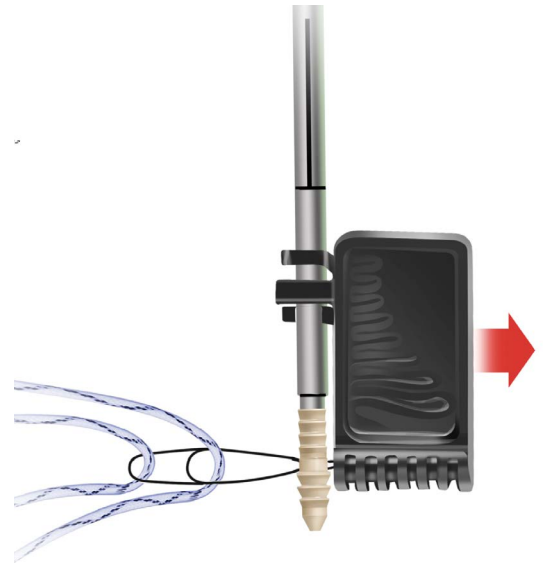


Fig. 16

2. Surgical procedure

iv) Suture tape locking

Once desired tension has been reached, wrap the suture tape tails around the inserter cleats to maintain tension. Confirm the #0 holding suture has been removed and discarded. Holding the handle steady, rotate the knob clockwise until it clicks. This will lock the suture tape to the anchor. Unwrap the suture tape tails from the inserter cleats and remove the inserter by pulling up. Note: The knob will continue to click if over rotated, but the locking mechanism will not be further tightened.

I) Suture trimming

After final anchor placement is completed, cut the remnant suture tape (Fig. 17).

■ Note

At the discretion of the surgeon, an alternative technique may be employed for reinforcement following the completion of soft tissue repair. This involves the insertion of the SUPERHAWK 3.75mm Start Anchor into the fibula, followed by the placement of a second anchor, the SUPERHAWK 4.75mm Anchor, into the talus.

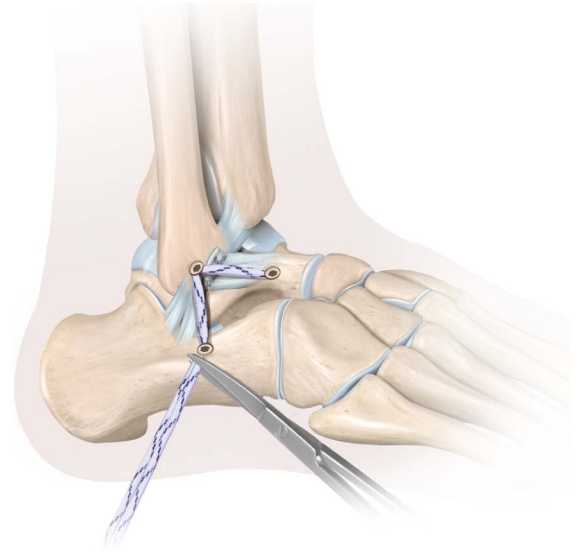
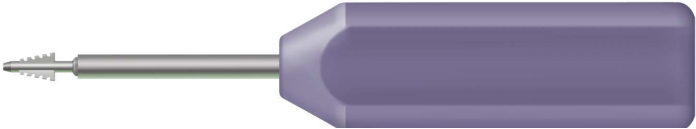


Fig. 17

3. Instrument sets

SUPERHAWK instruments

SUPERHAWK Drills (sizes 3.75 and 4.75)	3.75mm (Black Band)	
	4.75mm (Purple Band)	
SUPERHAWK Cannulated Drills (sizes 3.75 and 4.75)	3.75mm (Black Band)	
	4.75mm (Purple Band)	
SUPERHAWK Guide Wire		
SUPERHAWK Drill Guide Insert		
SUPERHAWK Round Drill Guide		
SUPERHAWK Broach Assemblies (sizes 3.75 and 4.75)	3.75mm (Black Handle)	
	4.75mm (Purple Handle)	

4. Reorder list

Reorder Code

Name

285925	SUPERHAWK 3.75mm Start & 4.75mm Assembly
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285926	SUPERHAWK 3.75mm End Assembly
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285945	AGILE Suture Anchor, Short
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Instruments

285932	SUPERHAWK Drill 3.75mm
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285930	SUPERHAWK Drill 4.75mm
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285931	SUPERHAWK Cannulated Drill 3.75mm
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285933	SUPERHAWK Cannulated Drill 4.75mm
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285934	SUPERHAWK Guide Wire
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285936	SUPERHAWK Drill Guide Insert
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285939	SUPERHAWK Drill Guide Round
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285937	SUPERHAWK Broach 3.75mm
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285938	SUPERHAWK Broach 4.75mm
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285946	AGILE Instruments (drill, drill guide, 2 free needles)
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5. Instructions for use

Refer to the 000137-0000 Instructions for Use document

Important information: Prior to use, refer to the instructions for use supplied with the device(s) for indications, contraindications, side effects, warnings and precautions.
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