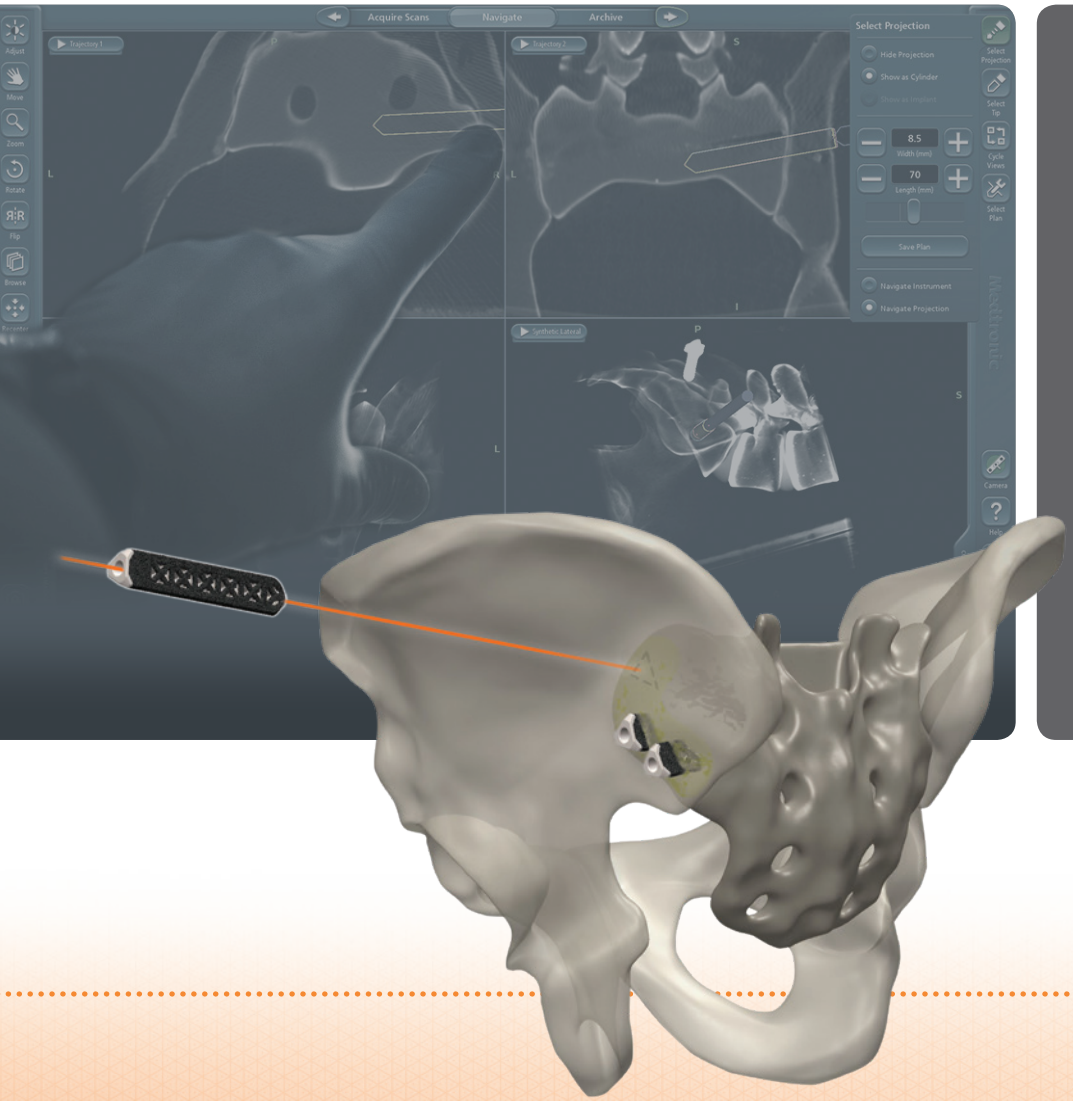
iFuse-Navigation™ Instrument Set

iFuse-Navigation™ Instruments are designed to allow surgeons using Medtronic O-arm® Imaging System and StealthStation™ Navigation System to perform SI-BONE's iFuse sacroiliac joint fusion procedure.



Instrumentation for iFuse procedure:

- SI-BONE™ iFuse-Navigation™ Instrument Set
- SI-BONE™ Radiolucent Instrument Set
- SI-BONE™ 3.1 mm Threaded Tip and Blunt Tip Pins

Additional Instrumentation:

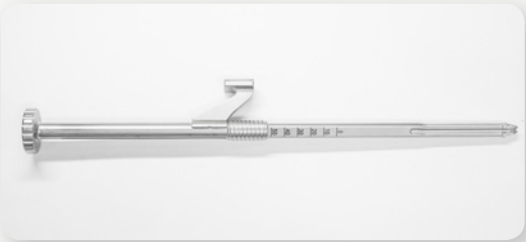
- Medtronic O-arm® Imaging System/StealthStation™
- Medtronic StealthStation™ Universal Drill Guide Set
- Medtronic StealthStation™ Spine Referencing Set
- Medtronic Disposable Perc Pin (100mm or 150mm)
- Medtronic TeraTrackers (3 different colored TeraTrackers from the StealthStation™ Tactile Probe Set are needed)

The iFuse-Navigation™ System* has been designed by SI-BONE, Inc. and cleared by FDA for use with the Medtronic StealthStation Navigation System and the TeraTrackers. The iFuse-Navigation Instruments are independently developed, manufactured and distributed by SI-BONE, Inc.

* 510(k) K172268

iFuse-Navigation™ Instrument Set Components

Broach 7.0 mm



Impactor

Impactor/Removal Adapter

Slap Hammer

Adjustable Parallel Pin Guide

Funnel

Plunger

Implant Orientation Guide

Not included in tray are the *3.1 mm Threaded Tip* and *Blunt Tip Pins*. Order separately for use.

iFuse-Navigation™ instruments are intended to be used with the iFuse Implant System® to assist the surgeon in precisely locating anatomical structures in iFuse procedures, in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the pelvis or vertebra can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy. iFuse-Navigation instruments are intended to be used with the Medtronic StealthStation™ System.

The iFuse Implant System is intended for sacroiliac fusion for conditions including sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months. There are potential risks associated with the iFuse Implant System. For information about risks, visit *www.si-bone.com/risks*

SI-BONE® | **iFuse** Implant System®
Minimally Invasive Sacroiliac Joint Surgery

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