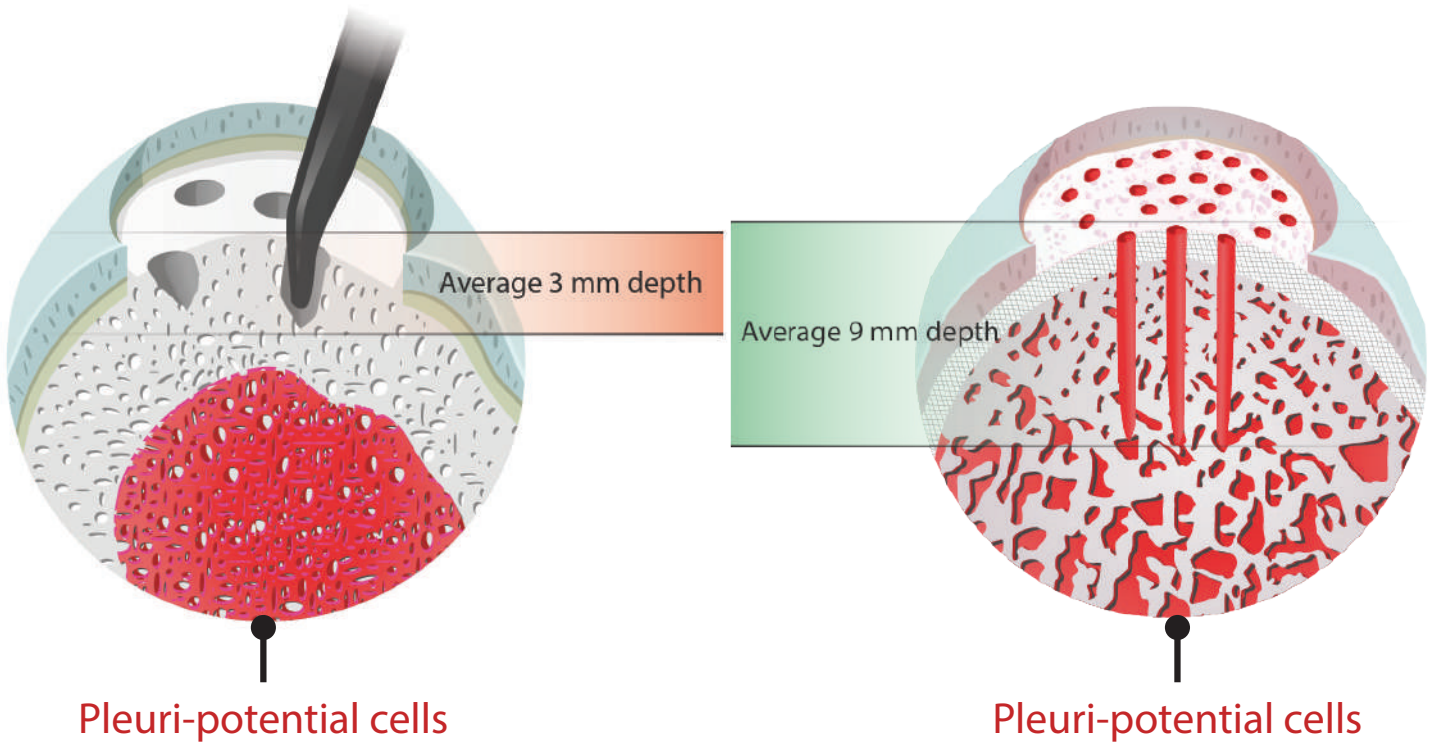


Microfracture



SMALLER. DEEPER. BETTER.

Description

The Arthrosurface NanoFx instruments consist of a reusable **Hand Instrument**, a single use disposable **PleuriStik Guide Wire**, and a single use **Thumble Thumb Tab Accessory**. These instruments are used to perform a microfracture technique for the treatment of small localized articular cartilage defect sites.

Patient Population

The patient population most likely to benefit from the Arthrosurface NanoFx is the same as that targeted for any microfracture procedure.

Factors	Better Results With
Age	< 40 years
Duration of symptoms	< 12 months
Lesion size	Up to 2 x 2 cm
Lesion depth	< 5 mm
Body mass index	<30 kg/m ²
Preoperative activity level Tegner score	> 4 (better with higher preop activity levels)
Previous surgery	Primary microfracture
Repair cartilage volume	Good defect fill (>66%)
Mechanical alignment	Normal
Joint anatomy	Normal
Joint stability	Ligamentously stable with adequate muscle strength
Meniscus	Normal without loss of meniscal tissue

Sterilization

Arthrosurface NanoFx **Hand Instruments** are provided NON-STERILE. They must be properly cleaned and sterilized before each use and should be regularly inspected for signs of wear or damage. Please refer to the Arthrosurface NanoFx **Hand Instruments** Instructions for Use for additional details on device cleaning and sterilization.

The Arthrosurface NanoFx **PleuriStik Guide Wires** and **Thumble Thumb Tab Accessories** are provided STERILE, SINGLE USE via exposure to gamma radiation. Do not resterilize or reuse NanoFx **PleuriStik Guide Wires** or **Thumbles**.

Instructions for Use

Treatment using the ArthroSurface NanoFx instruments will typically be accomplished as part of an arthroscopic or minimal access surgical procedure. No specific or unique surgical incisions are required.

1. The ArthroSurface NanoFx **PleuriStik Guide Wire** (with **Thumble Thumb Tab Accessory** attached) is placed tip first into the proximal lumen of the **Hand Instrument**.

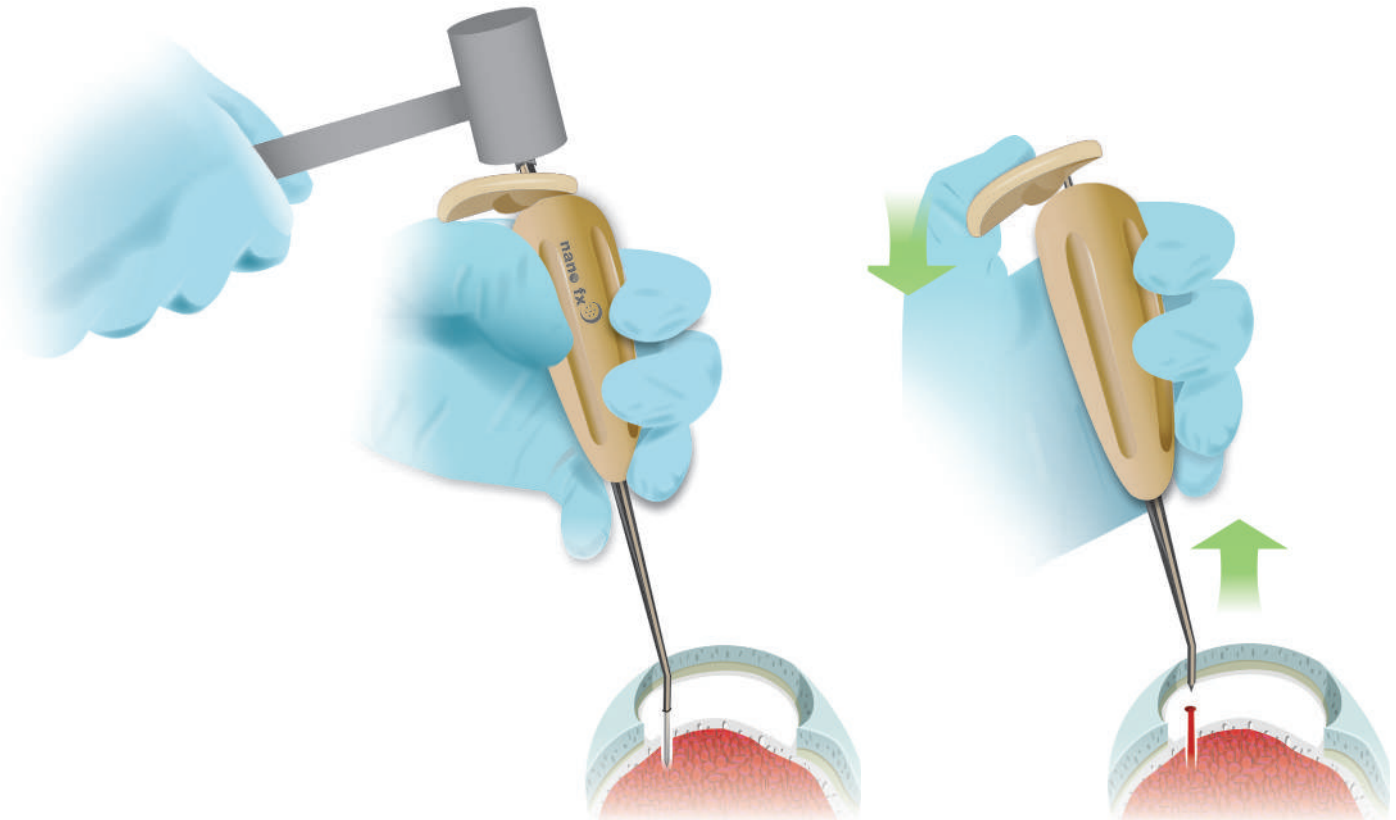
*Note: The **Thumble Thumb Tab Accessory** will be used later to expedite removal and repositioning of the **PleuriStik Guide Wire**.*



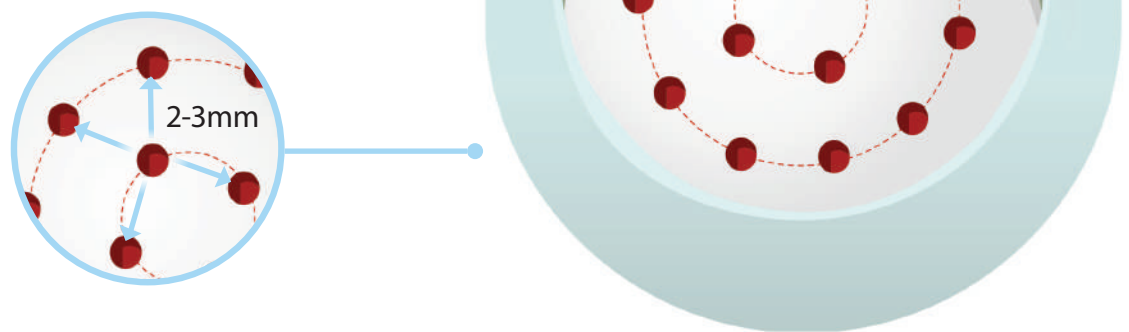
2. Place the distal tip of the NanoFx **Hand Instrument** at the target site, approximately 2mm from the healthy cartilage wall.



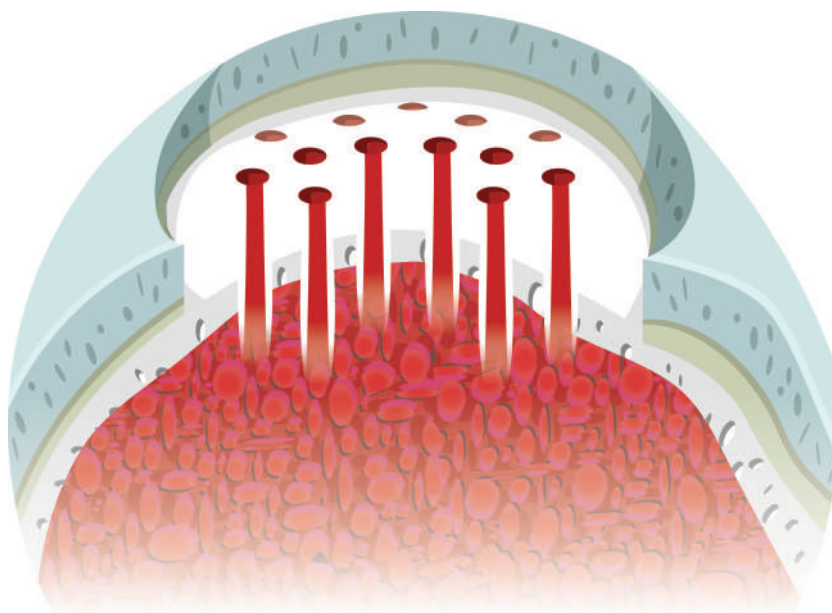
3. A light mallet strike on the exposed proximal tailstock of the **PleuriStik Guide Wire** is sufficient to drive the **PleuriStik Guide Wire** to its full depth of 9mm. After this is achieved, use the **Thumble** for one-handed extraction of the **PleuriStik Guide Wire**.



4. Once the **PleuriStik Guide Wire** is removed, reposition to create additional penetration sites approximately 2mm apart. Use a systematic spiral pattern of microfracture penetrations of the subchondral bone plate throughout the cartilage lesion, allowing for a homogeneous distribution of the microfractures while maintaining sufficient subchondral bone bridges between individual penetrations.



7. The NanoFx channels are created until there are a sufficient amount within the target site.



Instrumentation & Ordering Information

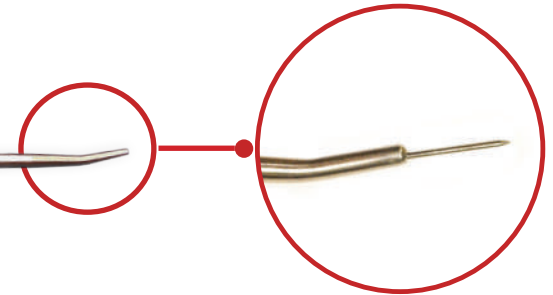
15°



PleuriStik Guide Wire (**FURS-2101**)



Hand Instrument (**5500-1020**)



Angled Tip



Thumble Thumb Tab Accessory (**FURS-0100**)

A-CURVE



A-Curve Hand Instrument (**5500-4010**)



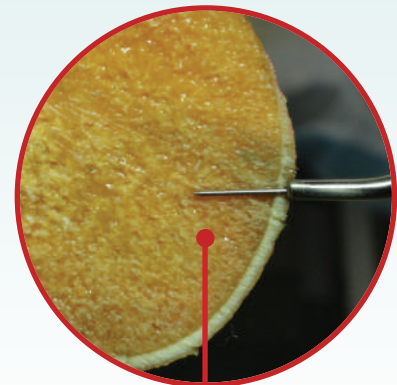
Thumble Thumb Tab Accessory (**FURS-0100**)



PleuriStik Guide Wire (**FURS-4101**)



Complete NanoFx System



nano fx
9 mm deep

“Deeper versus shallower elicited greater fill of the cartilage defect with a more hyaline character in the repair matrix.”

Chen H, Hoemann CD, Sun J, Chevrier A, McKee MD, Shive MS, Hurtig M, Buschmann MD. Depth of subchondral perforation influences the outcome of bone marrow stimulation cartilage repair. J Orthop Res. 2011 Aug;29(8):1178-84.

Warnings and Precautions

The Arthrosurface NanoFx **Hand Instruments, PleuriStik Guide Wires** and **Thumbles** are designed to be used exclusively with Arthrosurface NanoFx branded devices. Use of the Arthrosurface NanoFx instrumentation with devices from different manufacturers may create patient safety issues.

Arthrosurface NanoFx **PleuriStik Guide Wires** are made from implant grade NITINOL per ASTM F 2063-05. The surgeon shall be thoroughly familiar with the instruments and microfracture surgical technique prior to performing the procedure.

PleuriStik Guide Wires are to be driven with mallet strike only. **Do not drive with drill or powered handpiece.** Maintain tip of NanoFx **Hand Instrument** firmly in place when striking NanoFx **PleuriStik Guide Wire** to avoid bending of the **PleuriStik Guide Wire** tip. If the **PleuriStik Guide Wire** is bent it should be replaced before proceeding. Dispose of the **PleuriStik Guide Wire** in an appropriate sharps container.

Possible Adverse Effects

Complications reported with microfracture surgery include general surgical complications (infection, blood clot, incisional irritation). Complications specific to the microfracture technique are poor tissue differentiation or repair, and osteophyte formation.

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

SMALLER

Smaller holes for more cell channels

DEEPER

Deeper holes for increased cell quantity

BETTER

Better cell recruitment for a better repair

PATENTS PENDING

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