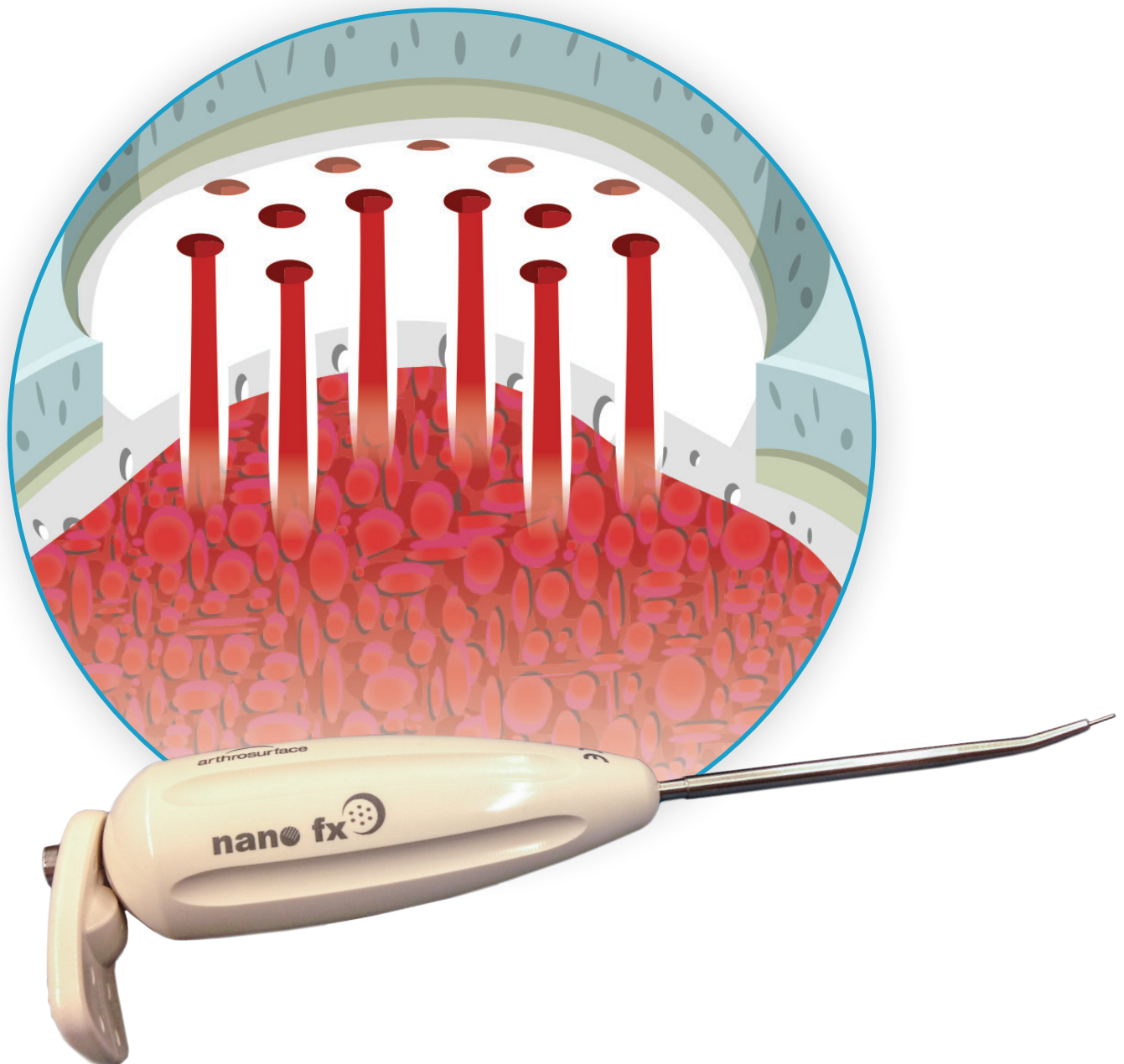


NanoFx[®]

Microfracture System

Surgical Technique Guide



NanoFx[®] Microfracture System

Description

The NanoFx instruments consist of a reusable **Hand Instrument**, an optional reusable **Thumble Thumb Tab**, a single-use disposable **PleuriStik[™] Guide Wire**, and/or 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 NanoFx is the same as those who would benefit from any microfracture procedure.

Factors	Better Results With
Age	<40 years
Duration of symptoms	<12 months
Lesion size	Up to 2cm x 2cm
Lesion depth	<5mm
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

NanoFx **Hand Instruments** and reusable **Thumble Thumb Tab** 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 NanoFx **Hand Instruments** and reusable **Thumble Thumb Tab** Instructions for Use for additional details on device cleaning and sterilization.

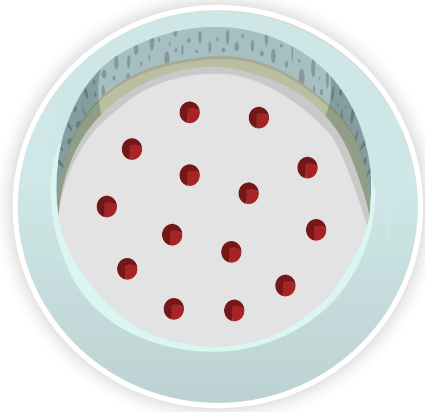
The NanoFx **PleuriStik Guide Wires** and sterile **Thumble Thumb Tab Accessories** are provided single-use and sterile via exposure to gamma radiation. Do not resterilize or reuse NanoFx **PleuriStik Guide Wires** or sterile **Thumbles**.

Surgical Technique

NanoFx Microfracture System

Instruction for Use

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



Step 1

The 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**.



NanoFx Surgical Technique *Continued*

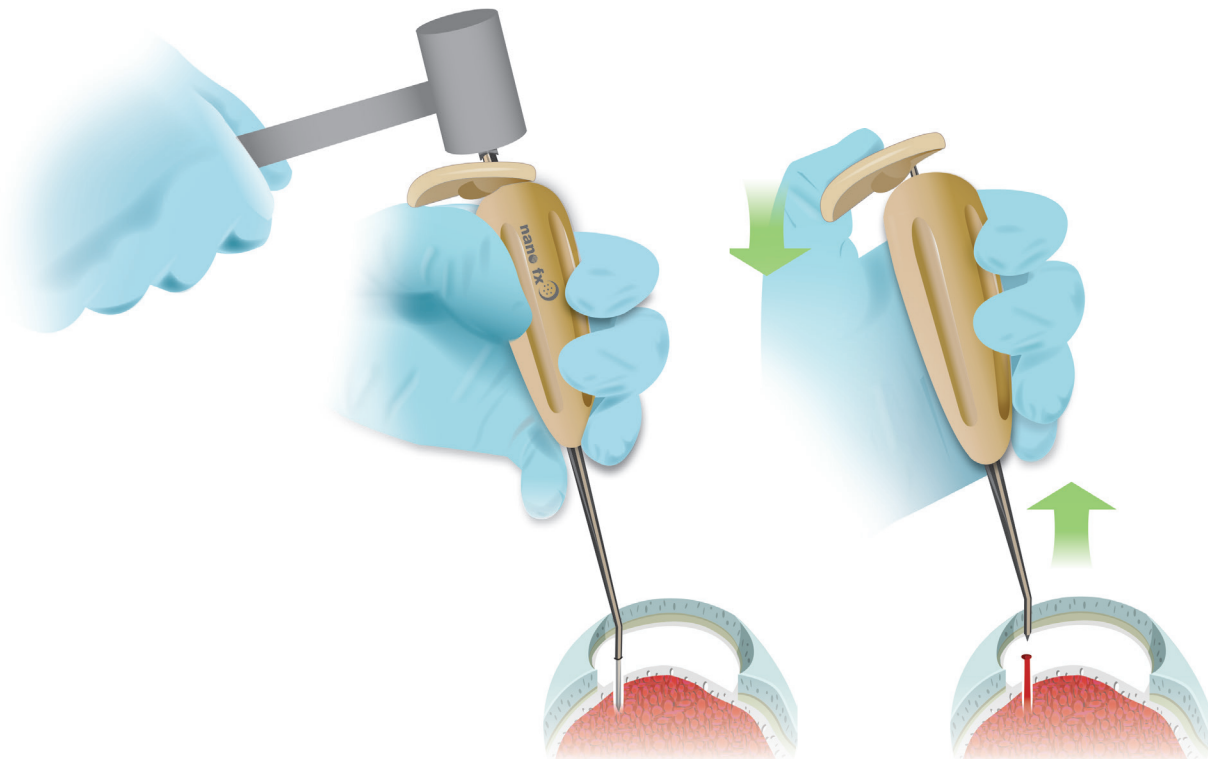
Step 2

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



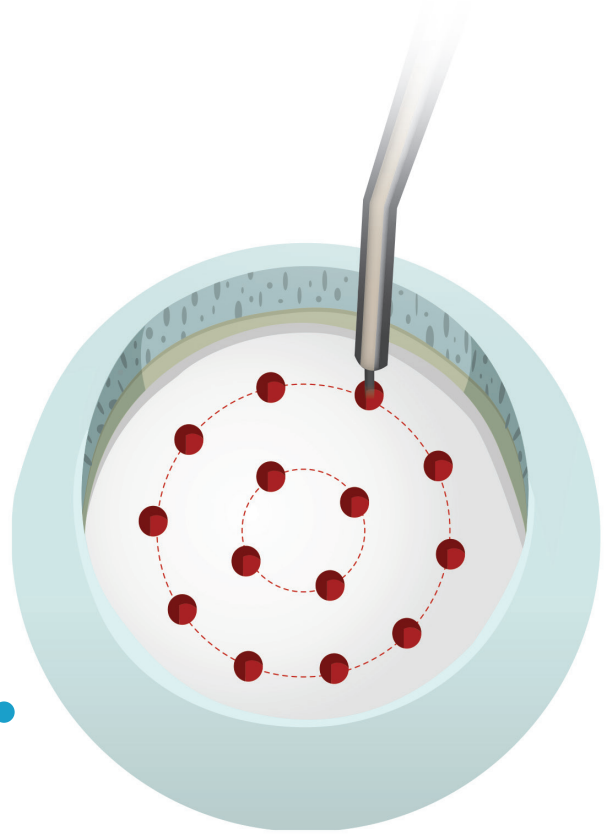
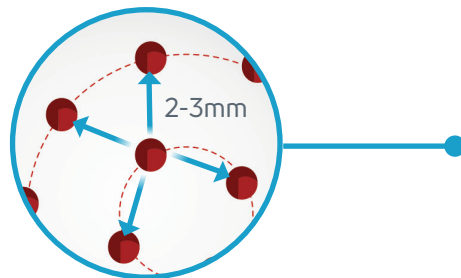
Step 3

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**.



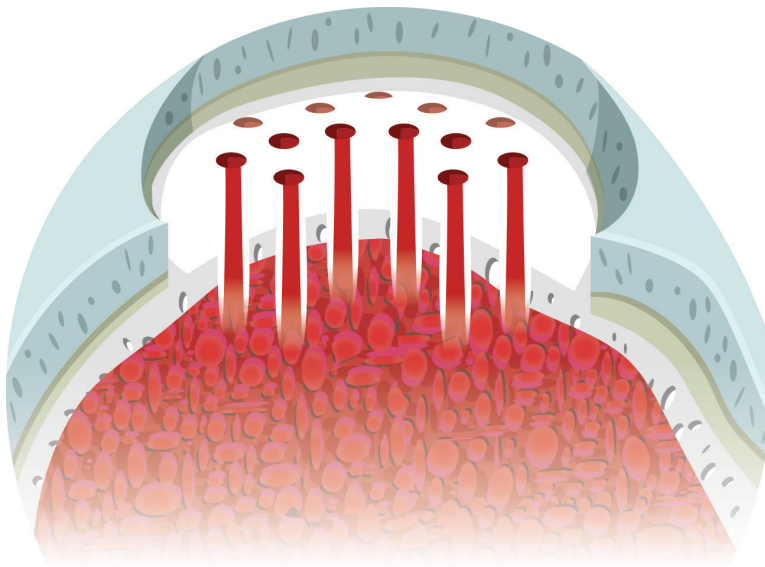
Step 4

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.



Step 5

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



Instrumentation & Ordering Info

15°



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



Hand Instrument (**5500-1020**)



Angled Tip



Thumble Thumb Tab Accessory (**Non-Sterile: FURS-010R / Sterile 5-Pack: FURS-0100**)

A-CURVE



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



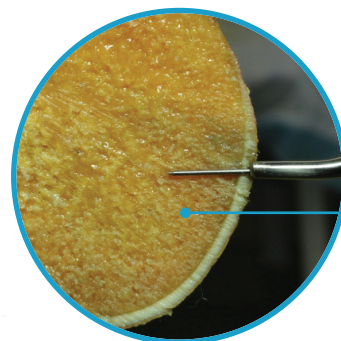
Thumble Thumb Tab Accessory
(**Non-Sterile: FURS-010R / Sterile 5-Pack: FURS-0100**)



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



Complete NanoFx System



9mm 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 NanoFx Hand Instruments, PleuriStik™ Guide Wires and Thumbles are designed to be used exclusively with NanoFx branded devices. Use of the NanoFx instrumentation with devices from different manufacturers may create patient safety issues.

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.

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System designed and manufactured in the USA | Printed in the USA

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AML-900-724 REV 01

