

Average 9 mm depth

Pleuri-potential cells

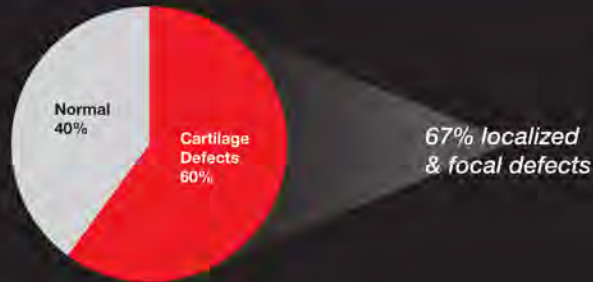
**nanofx**

**SMALLER. DEEPER. BETTER.**

# Why there is a need to treat **cartilage defects**?

Articular cartilage defects are a common pathology.

Retrospective study on 25,124 knee arthroscopies demonstrated evidence of chondral defects in 15,074 knees (60%), and up to 67% were classified as localized and focal defects.<sup>5</sup>



What happens to cartilage defects without treatment?<sup>5</sup>

Loss of cartilage leads to osteoarthritis

- Pain
- Dysfunction
- Stiffness
- Immobility

## Why **Bone Marrow Stimulation Techniques** be the treatment for articular cartilage defect?

Bone marrow stimulation introduces perforations in the subchondral bone and initiates bleeding, thereby exposing the debrided cartilage lesion to the underlying bone marrow stroma which contains a repository of pluripotent marrow derived mesenchymal cells capable of repairing soft and hard tissues.<sup>2</sup>

### **Improved surgery** technique is needed

The number of mesenchymal stem cells (MSCs) drained from bone marrow may vary depending on different bone marrow stimulation techniques (BSTs) and this could affect therapeutic efficacy of cartilage defect. As current microfracture method cannot drain the most MSCs clinically, more improved surgery technique is needed.<sup>7</sup>



### Treatment **Goal**

- Recruitment of cartilage precursor cells for cartilage repair
- Maximizing bone marrow access through trabecular channels
- Minimizing effect on subchondral bone
- Standardized treatment getting comparative results

# Nanofracture : The New Standard for Marrow Stimulation

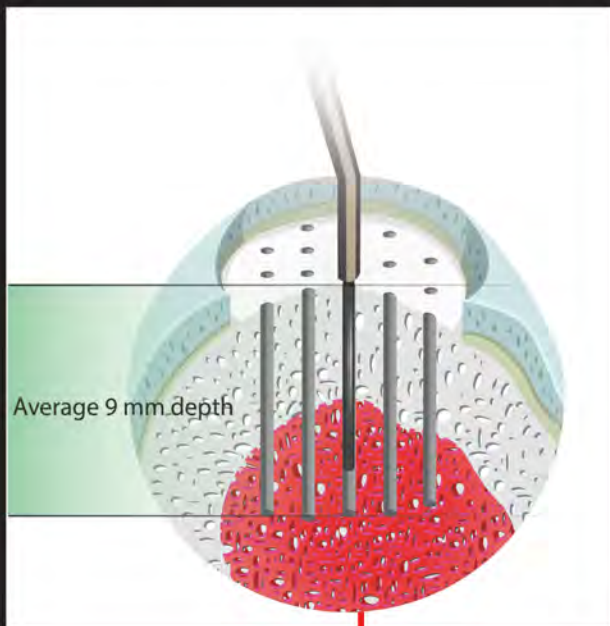
Nanofracture is a new subchondral bone needling procedure that reaches to a standardized depth of 9mm deep at width of 1mm for the treatment of small localized articular cartilage defect sites.



**SMALLER** holes for more cell channels

**DEEPER** holes for increased cell quantity

**BETTER** cell recruitment for a better repair

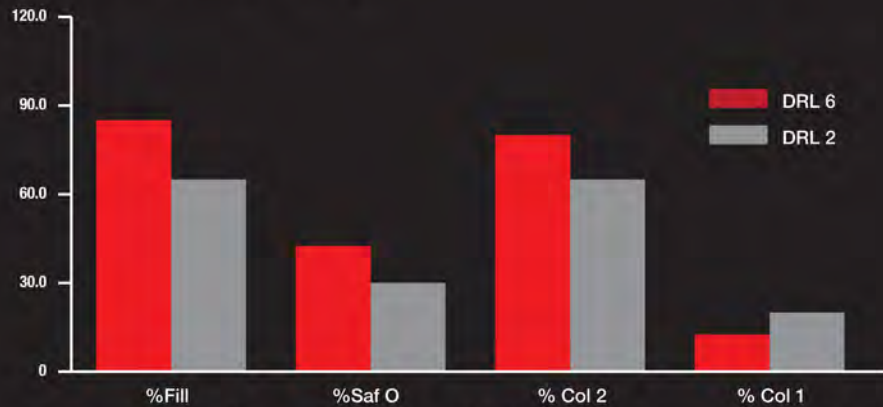


Pleuri-potential cells

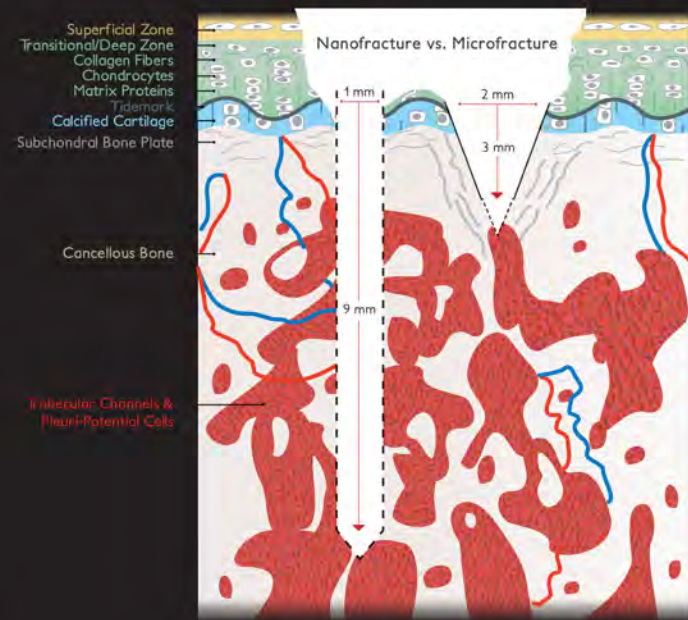


# Deeper channel elicited a greater fill of the cartilage defect<sup>2,3</sup>

- More hyaline character in the repair matrix
- Increased in cartilage defect fill
- Increased in glycosaminoglycan
- Increased in Type II collagen
- Decreased in Type I collagen



Histomorphometric analyses of soft tissue repair. \*Significant effect ( $p=0.015$ ,  $N=8$ ) for DRL6 vs DRL2. Improvement in tissue repair due to deep compared to shallow drilling was significant ( $p=0.021$ ) when the four parameters (%Fill, %Saf O, % Col2, and %Col 1) were analyzed together as repeated-measure variables for an aggregate indicator of overall repair quantity and quality.



# Subchondral Response to Marrow Stimulation<sup>4,5</sup>



**Low Response to Microfracture:**  
Low Flow, Low Fill



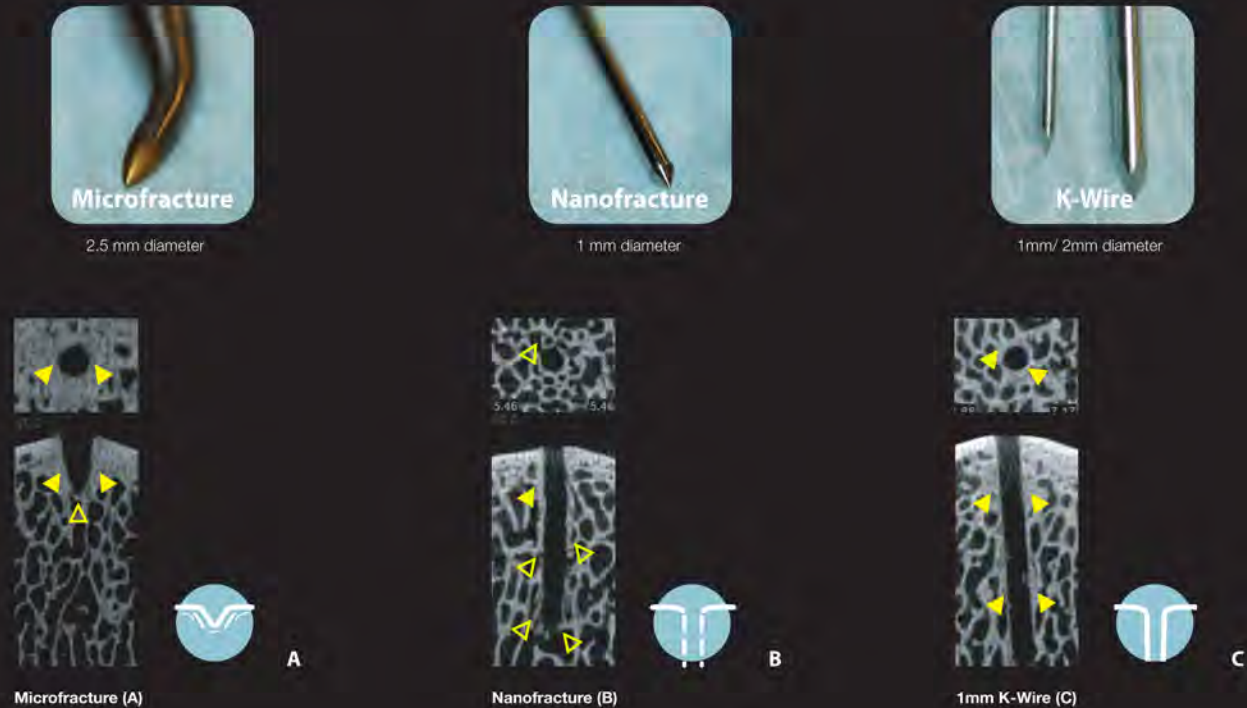
**High Response to Nanostructure:**  
High Flow, High Fill

*In Vivo Response Adult Ovine Model*

*In Vivo Response Adult Ovine Model*

# Nanofracture vs Microfracture vs Drilling<sup>4</sup>

Nanofracture resulted in thin, fragmented cancellous bone channels without rotational heat generation. Compared to microfracture and K-Wire stimulation, nanofracture showed superior bone marrow access with multiple trabecular access channels extending 9mm into subchondral bone.<sup>4</sup>



**Figure A,B,C:**

▲ open trabecular channels;  
▲ closed trabecular channels,  
microCT comparison:  
Axial (top), Sagittal (bottom).

- Shallow Depth.
- Non-standardized depth and diameter.
- Trabecular wall thickness and density increased by apparent bone compression.
- Limited trabecular channel access.
- Channel borders with non-anatomic regularity.
- Microfracture channel margins: Dense, compressed bone deposit (right)

- Deep cancellous bone perforation.
- Standardized depth and diameter.
- Trabecular wall thickness and density appears normal.
- Large number of open trabecular channels.
- Anatomic irregularity of trabecular channel borders intact.
- Nanofracture channel margins: Course and fragmented trabecular bone deposits (right)

- Created well defined channel wall
- Non-standardized depth
- Standardized diameter
- Limited to perpendicular joint surface access
- Trabecular wall thickness and density close to normal.
- Limited trabecular channel access.
- Channel borders with non-anatomic regularity.
- K-wire channel margins: Pulverized and dense osseous deposits (right)

Drilling by using K-wire creates smooth surface without flutes and may then compress bone debris without removal, leading to increase bone density and increased heat due to friction. This causes thermal damage of subchondral bone resulting in bone necrosis.<sup>2</sup>



**1. PleuriStik Guide Wire** (single use disposable)

PleuriStik Guide Wire is provided STERILE, SINGLE USE via exposure to gamma radiation. Do not resterilize or reuse.



**2. Hand instrument** (Reusable)

Hand instrument is provided NON-STERILE. It must be properly cleaned and sterilized before each use and should be regularly inspected for signs of wear or damage.



**3. Thumble Thumb Tab Accessory**

Surgical Technique<sup>5</sup>

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

1. 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 Tab Accessory** will be used later to expedite removal and repositioning of the **PleuriStik Guide Wire**.



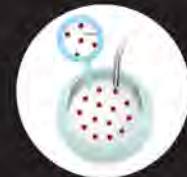
2. Place the distal tip of the NanoFx **Hand Instrument** at the target site, approximately 2mm from the healthy cartilage wall.



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.



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



# Rehabilitation

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- Non weight bearing for 6 weeks post op:
  - Allow cartilage repair to progress
  - Protection of subchondral bone after nanofracture
  - Premature weight bearing can lead to displacement of the repair clot, inferior tissue integration and can impact subchondral bone remodelling
- CPM started immediately 6-8 hours a day with ROM from 30-70 degrees. Gradual increase by 10-20 deg until full passive ROM is achieved
- Patella mobility exercises, quadriceps sets, SLRs, hamstring stretching and ankle pumps are initiated on Day 1.
- Stationary cycling without resistance and deep water exercises are initiated at 1-2 weeks post-op
- After 8 weeks patients are progressed to weight bearing as tolerated
- Low impact exercises to restore normal muscular function emphasised during weeks 9-16.
- Return to sports at least after 4-9 months post-op.

# SMALLER.

Smaller holes for more cell channels

# DEEPER.

Deeper holes for increased cell quantity

# BETTER.

Better cell recruitment for a better repair



References:

1. Hongmei Chen, Jun Sun, et al.2009. Drilling and microfracture lead to different bone structure and necrosis during bone marrow stimulation for cartilage repair. J Orthop Res 27:1432-1438.
2. Hongmei Chen, Caroline D. Hoemann, et al. 2011. Depth of subchondral perforation influences the outcome of bone marrow stimulation cartilage repair. J Orthop Res 29:1179-1184.
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4. W.R. Walsh,Ph.D, N Bertollo, Ph.D, et al. 2013. Nanofracture: Bone marrow stimulation in cartilage repair comparing microfracture, Nanofracture, and K-Wire perforations. Surgical &Orthopaedic Research Laboratories.Prince of Wales Clinical School.The University of New South Wales. Sydney, Australia.
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6. Widuchowski W, Widuchowski J, Trzaska T. 2007. Articular cartilage defects: study of 25,124 knee arthroscopies. Knee 14:177-182
7. Byong-Hyun Min et al. 2013. Effect of different bone marrow stimulation techniques on MSCs mobilization. J Orthop Res 31:1814-1819.

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