

### Company Profile

Orthoforge, Inc. is a pre-clinical development stage medical device company that is combining ultrasound-based signals with advanced data analysis, telemedicine and artificial intelligence to measure bone and soft tissue healing following an injury. We are developing a 21<sup>st</sup> century solution for bone and soft tissue healing analysis via telemedicine.

Orthoforge was recently accepted as a resident of JPOD-Philadelphia, which is an incubation center for Johnson & Johnson Innovations. J&J Innovations established JPOD centers to empower and enable start-up companies with promising technologies to improve patient care.

### Market Need

A market survey was conducted among orthopaedic surgeons, physical therapists and athletic trainers to determine the need for this technology. 98% responded that there is a need for this kind of technology for monitoring bone healing. 98% responded that there is a need for a device that quantified when a bone was completely healed. 96% responded that there is a benefit to this device not exposing patients or health care providers to radiation.

### The Orthoforge Solution

The Orthoforge solution combines non-harmful ultrasound energy with proprietary algorithms and artificial intelligence to provide objective data on bone healing after a fracture. This objective data is transmitted to a physician via telemedicine. This solution provides several benefits, including:

- Quantified data from a fracture site as the fracture heals.
- Reduced office visits by using telemedicine for patient-physician interconnectivity.
- Reduced exposure to radiation.

### Clinical Utility

The Orthoforge technology provides adjunctive and objective data that will help clinicians make more informed decisions regarding bone fracture healing. Orthoforge will produce objective data without exposure to radiation that provides the clinician with actionable intelligence such as:

- How well a bone is healing
- When a bone is completely healed
- If a bone is healing asymmetrically
- Cross-sectional analysis of bone healing
- When a patient is ready to return to activity
- When a fracture fixation device is ready to be removed
- Identifying challenged fracture healing

## Intellectual Property

US application number 15351324 and PCT/US16/61921 has been assigned over to Orthoforge Inc. As company owned intellectual property, no licensing fees or royalties are owed to any outside entity.



## Bone Healing

When a bone fractures, it begins to heal in four overlapping phases: inflammation, bone production (soft and then hard callus formation) and then bone remodeling. During these stages, bone density and other complex, heterogenous physiological processes change as the fracture site progresses from a soft inflammation to a hardened fully remodeled bone. The Orthoforge system sends ultrasound waves that measure the density of bone healing. These ultrasound waves are analyzed with a proprietary algorithm and then the specific phase of bone healing is identified.

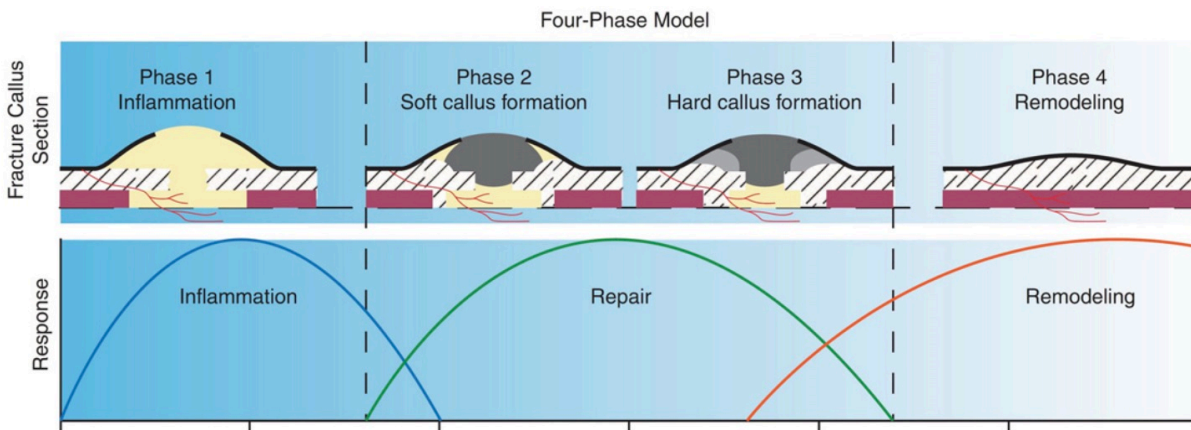


Figure 1: Model of Phases of Bone Healing (Science Direct, 2017)

## Market for Bone Fracture Healing Analysis

Each year, in the United States, 17.1 million fractures<sup>1</sup> are diagnosed and treated by health care professionals. 7.2 million of these fractures are classified as long bone fractures (National Ambulatory Medical Care Survey). Orthoforge will initially concentrate on monitoring long bone fractures. The overall orthopaedic trauma market, including soft tissue injuries is expected to reach \$14.0 billion by 2028.

# of Fractures in the US		
Fracture Type	2020	2024
Lower Arm	3,822,565	4,082,500
Lower Leg	2,988,055	3,191,246
Foot	2,027,611	2,165,488
Hand	1,814,178	1,937,543
Upper Arm	1,600,745	1,709,596
Ankle	1,327,447	1,417,714
Upper Leg	1,173,880	1,253,704
Wrist	1,102,176	1,177,124
<b>TOTAL:</b>	<b>15,856,661</b>	<b>16,934,914</b>

Figure 2: CMS Data for Bone Fractures in the United States

<sup>1</sup> National Center for Health Services (NCHS) Database