CurvaFix Receives FDA 510(k) Clearance for CurvaFix Rodscrew

Company's Innovative Curved Device to aid Orthopedic Trauma Surgery

Bellevue, Wash., March 5, 2019 – CurvaFix, Inc., a developer of medical devices to repair bone fractures in orthopedic trauma patients, today announced that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the CurvaFix® Intramedullary Rodscrew. CurvaFix's patented solution has the potential to improve outcomes and enable a less invasive approach in pelvic trauma surgery.

"With the FDA's clearance for the CurvaFix Rodscrew, we are excited about our opportunity to advance care for pelvic fracture patients," said Steve Dimmer, CEO for CurvaFix. "Over the past four years, we have engaged with numerous orthopedic trauma surgeons as we developed the rodscrew.

"We believe surgeons will welcome an implantable device that adapts to the patient's own bone curvature and we anticipate that the CurvaFix Rodscrew will improve fixation, shorten surgeries and reduce care costs," continued Dimmer.

The rodscrew is a flexible device that is implanted through a small skin incision into the intramedullary space (center of the bone) and then converted into a rigid state to stabilize and repair a bone fracture. The CurvaFix Rodscrew is the only intramedullary implant capable of following the natural bone shape of curved bones such as the pelvis.

Pelvic fractures, often caused by car accidents or falls, are among the most serious and technically complex injuries treated by orthopedic surgeons. Stabilizing and repairing the bone to enable appropriate healing is a process called fixation. Utilizing existing pelvic fracture fixation methods can require lengthy, complex surgery and can sometimes result in suboptimal bone stabilization. This can slow recovery, cause ongoing pain, and may contribute to long-term disability.

About CurvaFix, Inc.
CurvaFix, Inc. is a privately held medical device company headquartered in Bellevue, Wash. The idea for the company germinated when the former division head of orthopedic trauma at the University of British Columbia, Professor Robert Meek, M.D., believed there was a better way to repair pelvic fractures. Today, CurvaFix is developing implantable products to improve bone repair following serious fracture and injury. The company's first product, the CurvaFix Rodscrew, received FDA 510(k) clearance in 2019 for use in the treatment of pelvic fractures.

###

Media Contact:
Lorraine Marshall Wright
206.605.4553
Lmwright@curvafix.com

1000 124th Ave NE
Suite 100
Bellevue, WA 98005
curvafix.com
+1.425.276.8800