

## Press Release

# nice!Innovation's „snakeFX“ achieves convincing test results

## External fixator shows superior usability characteristics

**Erlangen, Germany, October 10, 2017 – nice!Innovations GmbH today announced the top line results of the first usability studies with their innovative external fixator „snakeFX“. The response is encouraging: surgeons like stability, user comfort and the chance for a fast fixation in emergencies with snakeFX.**

As the first prototypes of snakeFX have been finalized, the later users of snakeFX now had the chance to put the product through their paces in the framework of structured usability tests according to ISO 62366, the international standard for usability of medical devices. The usability investigations have been conducted by independent Activoris Medizintechnik GmbH, which supports the regulatory development strategy of snakeFX.

Five orthopedists and surgeons from Switzerland and Germany, each with a different professional background and experience, participated in the investigations. To examine the snakeFX, a simulated bone fracture had been used to perform mounting and dismounting of the external fixator. Different aspects of the device handling were analyzed by video and the time needed to complete certain steps of application was measured. After the test session, each test person completed a structured interview.

The results undermine the innovative concept of snakeFX. On the internationally standardized System Usability Scale (SUS), snakeFX reached 87 of 100 points, meaning the usability is “good”, at to border to “excellent”. Mounting, alignment and final fixation with snakeFX took eight minutes in average, which was considerably below the pre-determined time threshold. Further, the test persons see the most valuable advantages of the product: good stability, user comfort during mounting and the chance to apply a fast fixation in emergency cases.

Dr. Heiko Durst, CMO at nice!Innovations GmbH, commented: „we are extremely happy about these positive results from the future users of snakeFX as it confirms that we are on the right track. We would therefore like to expressly thank all physicians for the participation and the useful recommendations. The snakeFX design has already been further optimized and we are pushing the development for a small-scale production in view of a clinical trial.

“The results of this usability trial exhibit clearly that the snakeFX system is perfectly suited for the intended purpose. All test persons experienced the snakeFX as convenient and responded very positively to this innovative concept of bone fixation,” added Axel Fischer, CEO of Activoris Medizintechnik. “The results further indicate that the snakeFX device can be applied safely even by non-experienced surgeons. We are looking forward to supporting the highly motivated team at nice!Innovations GmbH during the further development and clinical steps”.

## About snakeFX

The patent-protected external fixator “snakeFX”, by its “one-step repaired fixation” technology, allows the fixation at the pins, alignment of positioning and stabilization in one step. Thus, the mounting time during a surgery can be reduced dramatically. Patients are stabilized rapidly, can be transported or handed-over to intensive care.

## Background: Stabilization of bone fractures with external fixators

For stabilization of fractures in severely injured polytrauma patients, open fractures and dislocated joints and for transportation of patients in crisis areas and battle zones an external fixation system is commonly used.

The assembly of an external fixator has to be accomplished as quickly as possible to enable intensive care support. An open fracture has to be cleaned as quickly as possible, it cannot be stabilized as usual because of a high risk of a wound infection when implants (intramedullary nail, plate etc.) are applied. Dislocated joints have to be repositioned as quickly as possible to prevent damage on nerves and blood vessels. This joint bridging fixation can only be achieved with an external fixator.

For assembly of an external fixator 4 - 6 bone pins are inserted through the skin into bone. Then the actual external fixator is fixated onto these bone pins. Common external fixators hardly differ from each other: rods are screwed onto these bone pins with numerous bolts and nuts and the rods are connected with each other by additional bolts and nuts. This very laborious principle of fixation is extremely time-consuming and error-prone. Only very experienced trauma surgeons can perform this operation reliably. In many cases this kind of operation is accompanied by an critical delay in an high-risk emergency situation.

## About nice!Innovations GmbH

Nice!innovations GmbH is a medtech startup located at Medical Valley Europäische Metropolregion Nürnberg. Nice!Innovations develops the revolutionary external fixator „snakeFX“ for the temporary external fixation of bone fractures with severely injured patients, open bone fractures, joint luxations and for the transport of injured in crisis areas.

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## About Activoris

Activoris is the German medical device specialist, building up on decades of management experience in the medtech and pharma industry. Activoris supports its clients with contract manufacturing, device developments, regulatory and business consulting as well as administration support.

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