

**N.M.B. Medical Applications Ltd. Obtains FDA Clearance for Marketing its ENDOLIGN®-Made QUANTUM™ Composite Nailing System for Treatment of Humeral Fractures**

***Stronger and More Elastic than Titanium, Carbon Fiber Reinforced PEEK-OPTIMA® Compound Provides Clear, Scatter-Free, MRI-Compatible Imaging***

**THORNTON-CLEVELEYS, UK** (MARCH 3, 2010) – CE-approved in 2009 and now cleared by the FDA within nine months of 510(k) submission, the QUANTUM™ Humeral Composite Nailing System from N.M.B. Medical Applications Ltd. is an innovative intramedullary interlocking nail made of ENDOLIGN® (from Invibio® Biomaterial Solutions). ENDOLIGN is an inherently pure and inert composite of continuous carbon fibers in a PEEK-OPTIMA® polymer matrix, to enable patient/surgeon benefits and advance the treatment of long bone fractures. Regulatory clearance was supported by biocompatibility data, Master File and other biomaterial and technical expertise provided by Invibio. The QUANTUM Composite Nail design combines with ENDOLIGN's unique material characteristics and performance capabilities to challenge the limitations of Titanium and Stainless Steel.



**Fig. 1. The QUANTUM Composite Nail, made with ENDOLIGN polymer, challenges the limitations of Titanium and Stainless Steel**

According to Elad Einav, N.M.B. Project Manager, Invibio's advanced biomaterial gives the QUANTUM Composite Nail more highly tailored elasticity, higher fatigue strength, and MRI-compatibility, which is helpful in the MRI fracture follow-up. In addition, the nail's radiolucent properties enable fluoroscopic and CT visualization of the bone fracture site during implantation as well as during follow-up. PEEK-OPTIMA's proven, 10-year+ clinical history of safety as a raw material for implantable devices is another major advantage.



**Fig 2: Radiopaque longitudinal marking and markers over the distal interlocking holes enable easy insertion, positioning and follow -up.**

The radiolucent QUANTUM Composite Nail incorporates longitudinal marking for easy insertion, positioning and follow-up. Radiopaque markers over the distal interlocking holes enable easier drill trajectory adjustment. A propriety disposable radiolucent drill drive is also available.

“The QUANTUM Nail is the first nail designed to treat long bone fractures that allows the surgeons to clearly see the fracture site and surrounding structures,” Mr. Einav added. “This is especially important in cancer cases where it is critical that the bone structures and soft tissue are visible in follow-up.”

ENDOLIGN composite is an excellent material for structural uses and the replacement of metals in high sustained or cyclic load applications requiring blood, bone or tissue contact of more than 30 days. ENDOLIGN

offers a unique combination of features and benefits, including:

- Excellent tensile strength, stiffness and fatigue behavior allows metal replacement in structural implants.
- MRI, CT and X-ray compatibility allows artifact-free postoperative images and clear visualization of the healing site.
- Biocompatibility ensures safe, long-term implantation.
- Mechanical properties can be tailored to meet a wide range of needs.

### **About Invibio**

Invibio® is a global leader providing high performance biomaterials, advanced technical research and consultative solutions to medical device manufacturers across a wide range of markets. The company provides medical device manufacturers with PEEK-OPTIMA® polymer and compounds, MOTIS™ polymer,

ENDOLIGN® composite and PEEK-CLASSIX™ polymer for the development of long- and short-term implantable medical devices.

For more information, please contact Invibio at: 866 468 4246 or +484 342 6004 (U.S.), +44 (0) 1253 898000 (U.K.), +852 2366 4448 (Asia Pacific) or online at [www.invibio.com](http://www.invibio.com).

**About N.M.B.**

N.M.B. Medical Applications Ltd. (formerly Disc-O-Tech Medical Technologies Ltd.), is engaged in developing, manufacturing and marketing of innovative solutions for the fixation of long bones fractures. The company uses its cumulative knowledge and expertise in the field of orthopedics to develop products which enhance the quality of life of patients and are more user-friendly for surgeons. The company has a full line of trauma products, including the Fixion® Intramedullary Nailing family that comprises expandable metal nails. The Fixion products are marketed world-wide, with over 60,000 implantations performed thus far.

For more information, please contact N.M.B. Medical Applications Ltd. at: +972-9-9511-511, or online at [www.nmb-med.com](http://www.nmb-med.com).