Invibio's PEEK-OPTIMA Polymer Used in Aesculap's FDA 510k Cleared EnduRo Rotational Knee System

Thornton Cleveleys, UK -- Invibio® Biomaterial Solutions, the market leader in providing PEEK-based biomaterial solutions to medical device manufacturers around the world, announced today that its PEEK-OPTIMA® Carbon Fibre Reinforced (CFR) polymer is utilized in Aesculaps FDA 510k cleared and CE-Marked EnduRo knee revision system. Developed to combat the predominant causes of knee implant failure, luxation, wear and malpositioning associated with metal components, Aesculaps EnduRo knee revision system relies on PEEK-OPTIMA CFR polymer to increase the implant service life and reduce the necessity of subsequent revision surgery. Through use of PEEK-OPTIMA CFR polymer, the service life of the EnduRo knee implant system rotational hinge mechanisms matches that of established primary condylar implants.

The EnduRo knee is used in the treatment of severe bone defects and insufficiency of the ligamented apparatus. It has been commercially available in Europe since January 2010 and received FDA 510k clearance in December 2010 - only 6 months after submission.

A contributing factor to its fast FDA clearance time is Invibios accomplished history of use in FDA-cleared long term implantable devices and the wealth of data Invibio provides to support companies through their submission process. According to Aesculap, the EnduRo knee has received strong European market reception, gaining a 14% market share in Germany during the first year of availability and with more than 2000 prostheses implanted to date. Whilst in the US, Aesculap received a strong launch into the market with the first implantation of the EnduRo knee in November 2011.

In 2010, Millennium Research Group estimated that there were more than 90,000 knee revision surgeries performed in the US and Europe, indicating that some eight percent of all knee implant procedures result from failure of the initial knee implant. A contributing factor to these failures is dislocation, whereby the rotational axis slips out of its guide, requiring total replacement of the implant. EnduRo knee`s innovative hinge mechanism, joined cone design and the use of PEEK-OPTIMA CFR polymer are intended to prevent dislocation compared to traditional hinge mechanism types that use UHMWPE. PEEK-OPTIMA CFR provides greater wear and cold flow resistance as well as dimensional stability during the lifetime of the device (>15 years), which aids resistance to dislocation.

According to Dipl.-Ing. (FH) Ulf Grimm, Aesculap Product Manager for Knee Endoprostheses, PEEK-OPTIMA CFR provides valuable surgeon and patient benefits, including:

- Proven biocompatibility and biostability that provides safety and implant longevity;
- Flexural strength similar to the cortical bone thus reducing stress shielding and improving patient comfort;
- Excellent wear performance and creep resistance to prevent dislocation;
- Processing and design flexibility that assists surgery planning and enhances patient mobility; and,
- History of use in FDA approved long term implantable devices for both patient and surgeon reassurance.

In addition to providing significant patient benefits over primary condylar implants, the EnduRo knee design extends surgical options and minimizes complexity. For example, using the EnduRo system cone connector to link the rotational axis and hinge ring of the femoral component, surgeons can eliminate the need for condylar drilling. This, in turn, minimizes the risk of ligament and soft tissue trauma.

"Aesculap and Invibio have benefited from a long, mutually beneficial relationship based on sharing expertise and knowledge. It was through technical expertise, an understanding of our requirements and a long history of proven biocompatibility and implantation success that Invibio was able to provide us with an exceptional solution," stated Herr Grimm.

"Throughout this process Invibio has provided valuable processing support and a manufacturing network with the flexibility and scope to meet our device and time targets. Working with Invibio provided us with both a material and processing solution package that enabled our accelerated time to market requirement," he added.

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.

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About Aesculap Division
Aesculap, a division of one of the worlds leading healthcare suppliers B. Braun Melsungen, stands for quality and innovation. With an international service network, Aesculap focuses on products and services for all of the core processes in surgery. Whilst their product catalogue ranges from surgical instruments for open to minimally invasive approaches through to implants for orthopaedic, neurosurgery and spinal surgery. Aesculap places strict demands on product safety and quality,

providing reliable products and services to the global market.

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