

## SUPERIOR STRENGTH AND COMPATIBILITY OFFER DESIGN FREEDOM FOR ADVANCED STRUCTURAL IMPLANTS

ENDOLIGN™ composite material from Invibio® brings the strength of metal and the benefits of a polymer to the design of advanced structural implants, providing design and processing freedom not possible with other materials.

The result of close collaboration with our manufacturing and processing partners, ENDOLIGN composite is composed of continuous carbon fibers in a PEEK-OPTIMA® polymer matrix. It 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 significantly enhanced mechanical properties and provides engineers and designers an advanced *implantable-grade composite material with a unique combination of features and benefits*:

- **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
- **Drug and Device Master files lodged with the US FDA** can reduce approval time
- **Both FDA and CE approvals** have been received for ENDOLIGN composite-based implantable devices

## EXCEPTIONAL MECHANICALS AND TAILORABILITY

In high load applications, the proven strength of ENDOLIGN composite allows it to be a true replacement of traditionally used metallic biomaterials, such as cobalt chromium alloys, titanium alloys and stainless steel.

The strength of ENDOLIGN parts can in fact be tailored such that it meets, or exceeds, that of metals by modifying the orientation of the continuous carbon fibers. Pre-preg layers may be arranged into unidirectional (U.D.) or multidirectional (M.D.) lay-ups, or complex 3-D configurations, offering a range of tensile strengths which compare favorably to metals.

Elastic (Young's) modulus tailoring may be accomplished similarly, as in Chart 1.

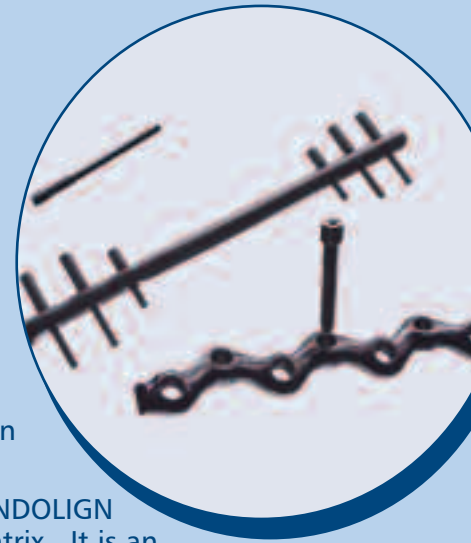
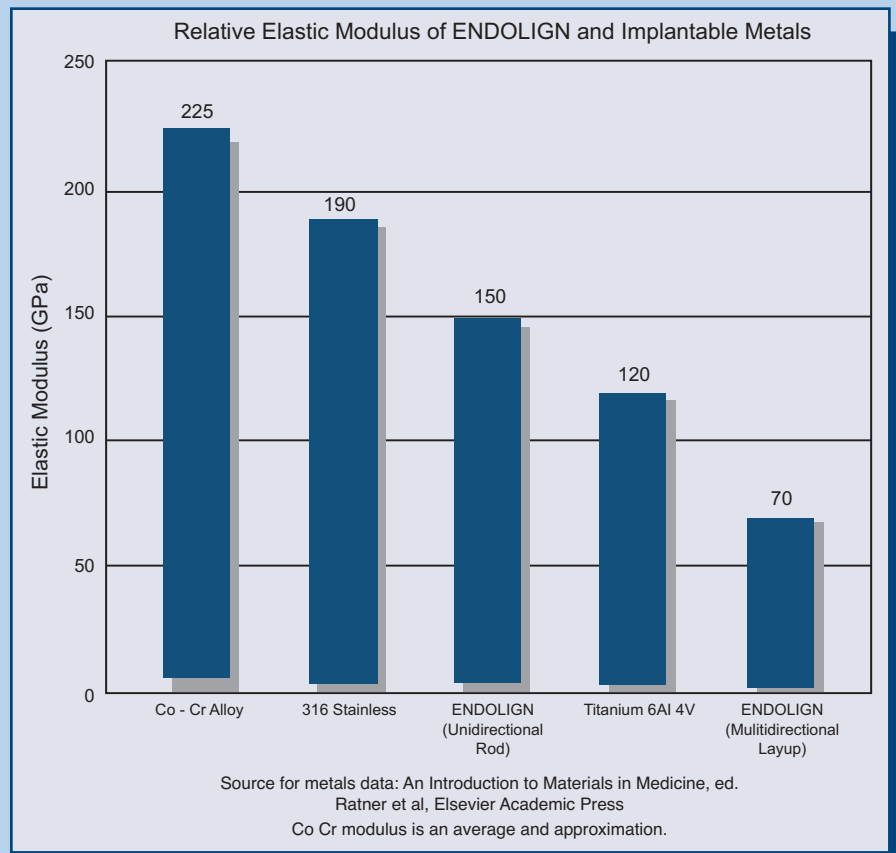


Chart 1



### Typical Mechanical Properties ENDOLIGN Composite Material

- Flexural Strength (U.D. Rod) > 1100 MPa
- Tensile Strength (U.D. Rod) 2000 MPa
- Tensile Strength (Multi-directional Rod) 900 MPa

## BIOCOMPATIBILITY

Biocompatibility testing confirms that ENDOLIGN composite exceeds the requirements of ISO 10993 standards for long-term implantable medical devices. Extensive results have been lodged with the FDA and can help reduce the time and expense related to FDA approval. Testing demonstrated:

- *No evidence of cytotoxicity, systemic toxicity, irritation or macroscopic reaction response*
- *No evidence that harmful leachable ingredients and/or residues are contained in the material nor released in vivo*

## IMAGE COMPATIBILITY

ENDOLIGN composite offers superior imaging compatibility. Its radiolucent properties enable clear visualization of the healing site through imaging techniques such as X-ray and Computer Tomography (CT), and it is compatible with MRI.

Unique to ENDOLIGN, **implant visibility** can be *achieved and controlled without artifacts or scatter* by adding tantalum wires in optimal concentrations.

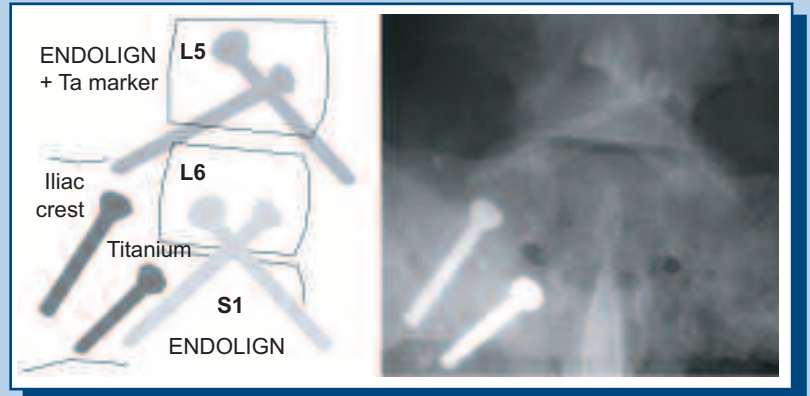
## FORMS & PROCESSING

ENDOLIGN composite is available as:

**Pre-impregnated tape** (pre-preg) *that can be compression molded, filament wound or pultruded into plaques or profiles.*

**Rods** *that can be heat formed or transformed through Composite Flow Molding\*\* into the final part.*

\*\* Composite Flow Molding is a proprietary molding process offered by icotec AG of Switzerland ([www.icotec.ch](http://www.icotec.ch))



Excellent healing site visibility and control of ENDOLIGN imaging properties.  
Courtesy of icotec AG, Switzerland.



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