



PRESS RELEASE

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ASCENSION[®] MCP TOTAL JOINT REPLACEMENT RECEIVES FDA APPROVAL

AUSTIN, TX — November 27, 2001: Ascension Orthopedics, Inc. has received FDA approval to market the Ascension[®] MCP, a two-component total joint replacement for the metacarpophalangeal (MCP) joint of the hand. This is the first two-component MCP total joint replacement to receive FDA Premarket Approval (PMA). The Ascension[®] MCP will be available in the U.S. beginning January 2002.

The Ascension[®] MCP was developed in collaboration with Robert Beckenbaugh, M.D., hand surgeon at the Mayo Clinic. Clinical study results of patients treated at the Mayo Clinic supported the approval.

Following PMA approval Dr. Beckenbaugh stated, "After initiating this effort in 1977, it is very rewarding to bring this new concept in replacement of arthritic hand joints to the public. Use of strong, low-friction, biologically fixed, and biologically inert PyroCarbon material represents a significant breakthrough in hand surgery. Patients now have the opportunity to replace diseased joints with an implant design close to their own joints made from a material friendly to their bodies which does not require fixation with cement or other materials."

Clinical study results demonstrated the Ascension[®] MCP is effective in relieving pain, improving or preserving motion, and reducing dislocated or subluxated MCP joints in patients suffering from osteoarthritis, rheumatoid arthritis, and arthritis due to trauma.

Prior to FDA PMA approval of the Ascension[®] MCP, the only implants approved for unrestricted use in the MCP joint were single-piece silicone rubber spacers. The Ascension[®] MCP is a two-component PyroCarbon prostheses with an anatomic shape. The device achieves fixation – without the use of bone cement – by means of direct implant/bone apposition. "The unique properties of PyroCarbon have enabled Ascension to develop this revolutionary MCP joint replacement," states Jerome Klawitter, Ascension's founder and CEO. It is the company's goal to develop an extended product line of PyroCarbon implants.

Ascension Orthopedics is dedicated to the design, manufacturing and distribution of small joints to relieve the symptoms of debilitating arthritis of the small joints of the hand, foot, and upper extremity. The Ascension[®] MCP received CE Mark registration in 1999 and was introduced in Europe in January 2000. Regulatory approval for the device has also been granted in Canada and Australia.

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