



November 30, 2018

Below is a statement from NuVasive, Inc. regarding its MAGEC rod technology:

MAGnetic Expansion Control (MAGEC®) rods are used to treat a relatively small subset of pediatric patients who suffer from rare, severe, progressive spinal deformities that can lead to life-threatening conditions caused by early-onset scoliosis. As such, treatment is not generally considered “elective.” Unlike traditional fixed growing rods, magnetic, adjustable MAGEC rods allow healthcare providers to lengthen the rods non-invasively during an office visit, thereby helping to avoid the need for planned lengthening surgeries. Due to the challenging nature of early-onset scoliosis, complications can occur regardless of the chosen treatment. We encourage parents and patients to discuss the benefits and risks of treatment options with their doctors and healthcare teams.

We stand behind the safety and efficacy of MAGEC, as demonstrated by pre-clinical testing, clinical use and our robust post-market surveillance.

For nearly a decade since MAGEC rods became available, families and doctors have chosen MAGEC because it has been shown to be effective in treating early-onset scoliosis, while also helping to avoid increased pain, elevated complication rates, and psychological distress regularly encountered in planned rod lengthening surgeries relative to traditional fixed growing rod treatments. MAGEC treatment also helps to avoid repeated exposure to anesthesia in children, which can lead to developmental delays and lower levels of cognitive function later in life.

Input received from surgeons, patients and their families helps to guide our efforts to continuously improve upon our spinal solutions, including MAGEC rod technology. All iterations of MAGEC rods have been shown to be clinically effective for their indicated use, with reported complication rates generally consistent with published reports of alternative treatments. Moreover, MAGEC has met and exceeded the international standards, regulations and processes relevant to medical device design and testing, and obtained necessary clearances and approvals from regional and global agencies prior to commercialization in the countries where treatment is offered.

At NuVasive, our top priority has always been the well-being of our patients. We are privileged to serve patients of all ages, and surgeons around the world, with leading technologies to improve the human condition against some of the most debilitating spine pathologies. We take that privilege seriously and are committed to the highest standards of quality and safety.

We see every day the challenges brought on by early-onset scoliosis and, while no technology in these patients is without risk, we have also seen MAGEC rebuild patient and family lives.

A joint statement from the British Orthopaedic Association (BOA) and the British Scoliosis Society (BSS) also speaks to the safety and efficacy of MAGEC, and can be found [here](#).

To hear from families and pediatric surgeons who specialize in the treatment of early-onset scoliosis (EOS) regarding their experience with EOS and MAGEC, click [here](#).

The MAGEC rod should be used in accordance with its indications for use within each region that it is used. Applicable clearances and approvals have been obtained and labels applied, according to local regulations.

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