

Allergan to acquire a MedTech firm, earFold

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Allergan has announced that it has entered into an agreement under which Allergan will acquire Northwood Medical Innovation, developer of innovative implant technology, earFold, an innovative medical device for the correction of prominent ears, with or without asymmetry, in patients aged 7 years and older.

earFold received a CE mark in April 2015, and has been made available by Northwood Medical Innovation Ltd to trained and accredited plastic surgeons, otolaryngologists (Ear, Nose and Throat) and maxillo-facial surgeons, primarily in the UK. Upon closure of the deal with Northwood Medical Innovation Ltd, Allergan intends to commercialise the product widely across Europe, in line with its CE mark, and will continue to explore the regulatory pathways and necessary clinical data requirements to commercialise this medical device in other countries, including the United States of America.

"Allergan is constantly searching to partner with or acquire companies with disruptive technologies that offer substantive value to our customers, often opening up new categories or setting new trends within our specialist segments. An example of this is the strategic acquisition of KYTHERA, with KYBELLA (marketed as BELKYRA in Canada) (deoxycholic acid) injection, the only FDA approved non-surgical pharmaceutical treatment for reduction of submental fat, or double chins," said Mr Paul Navarre, president and EVP of International Brands at Allergan.

He added, "earFold technology adds another innovative product to our medical aesthetics product portfolio, especially for the plastic surgeons we serve today, and has the potential to expand the number of patients interested in corrective surgery as it provides an alternative treatment that may appeal to those who have been reluctant to undergo traditional surgical

procedures. Many of Allergan's plastic surgery customers currently perform otoplasty procedures, emphasizing our commitment to serving the unmet needs and practice of plastic surgery."

earFold is a small implantable medical device made from a short strip of nitinol metal alloy, which is specifically designed to retain a preset shape. Following injection of a local anaesthetic, it is carefully inserted under the skin using an introducer, and works by gripping the cartilage of the ear, enhancing or creating the shape of the anti-helical fold - thereby reducing the prominence of the ear. Including the initial consultation, the procedure takes about 15-20 minutes to complete and can be performed within an outpatient setting, reducing the risk associated with a general anaesthetic.

Given the preset nature of the nitinol strip, treatment with earFold can deliver a consistently effective outcome. By contrast, otoplasty or pinnaplasty is a complex surgical procedure that requires a visit to a fully-fitted operating suite, requires a general anaesthetic and is associated with significant down-time post treatment. The results from otoplasty surgery can be more difficult to predict in advance of surgery as the adjustments to the ear's shape can only happen during the procedure itself and are therefore left to the surgeon to control.

"Following a complex outcome after a standard otoplasty procedure, early in my career, I was motivated to develop an alternative approach to correcting prominent ears," said Mr Norbert Kang, consultant plastic surgeon and creator of the earFold. "In my clinical practice, there are a significant number of patients who are reluctant to undergo surgery and so put up with accepting the social hindrance of prominent ears. The beauty of the earFold™ treatment system is that it offers an evidenced-based alternative to standard otoplasty surgery that may meet the needs of a wider range of patients, by delivering immediate and predictable results, without the risks associated with general anaesthetic."

On completion of this deal, Allergan will establish a standardised training programme for surgeons on the earFold treatment system, in order to bring this valuable treatment option to more patients and ensure effective and safe outcomes