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Allergan wins FDA nod for Natrelle Inspira SoftTouch breast implant

JANUARY 3, 2017 BY FINK DENSFORD — LEAVE A COMMENT











Allergan (NYSE:AGN) said today it won FDA approval for its Natrelle Inspira SoftTouch breast implants designed for breast reconstruction, augmentation or revision surgeries.

The newly cleared Inspira SoftTouch implant is designed from a new medium firmness gel, the company said, bringing the total number of firmness options or its Natrelle line up to 3.

"I am excited to have yet another option available within the Natrelle portfolio. This is one of the most exciting times in the history of breast surgery and what a great time for women, who are looking to have augmentation or have to have reconstruction/ My patients now have so many options available to them thanks to companies like Allergan who are supporting ongoing research and innovation in this area," PeaceHealth Plastic Surgery's Dr. Allen Gabriel said in prepared remarks.

"Adding Natrelle Inspira SoftTouch breast implants to our already robust line of offerings gives Allergan the most extensive variety of implants in the industry and provides doctors with a wide range of options. Now, the Inspira line of breast implants helps physicians to better meet diverse, patient-specific needs based on available breast tissue and desired outcomes. We're delighted to have this offering available in the U.S. since they are so popular with doctors and patients internationally," chief R&D officer David Nicholson said in a press release.

In September, Allergan said it won FDA pre-market approval a high-gel fill ratio of its Natrelle Inspira cohesive breast implants.

In Nov. 2014, Allergan said the FDA approved 2 new styles of its Natrelle 410 silicone-filled breast implants, the Natrelle X and L. The implants were approved for use in women undergoing breast augmentation, reconstruction or revision surgery.

The Natrelle 410 1st won FDA approval in February 2013, but the federal watchdog agency stipulated that Allergan run a post-approval study to keep an eye on its long-term safety and effectiveness.

FILED UNDER: COSMETIC/AESTHETIC, FOOD & DRUG ADMINISTRATION (FDA), REGULATORY/COMPLIANCE, WOMEN'S HEALTH

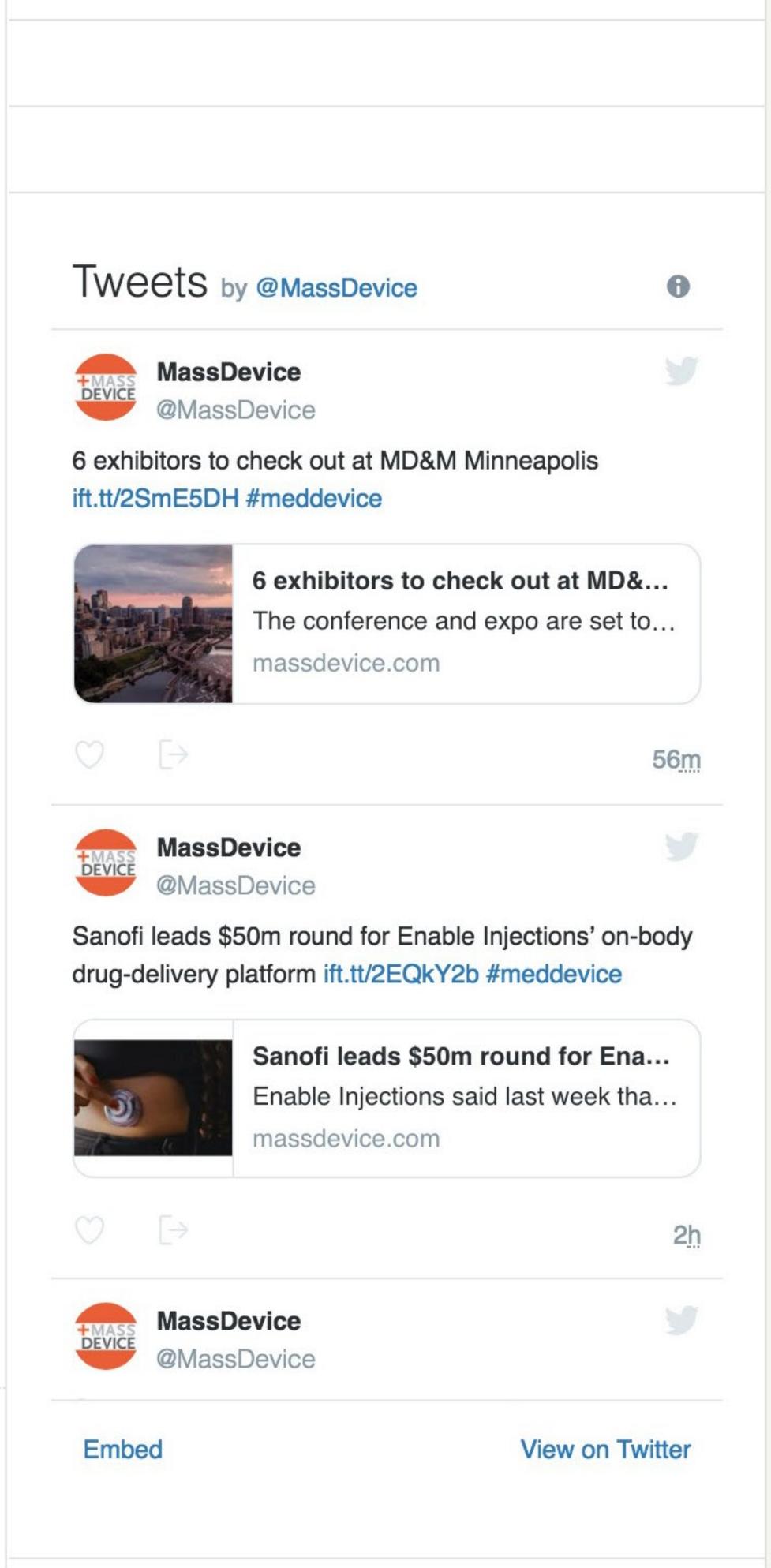
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