

Zimmer Biomet Statement on Warsaw North Campus FDA Inspection

May 16, 2018

As previously disclosed, the U.S. Food and Drug Administration (“FDA”) recently performed an inspection of Zimmer Biomet Holdings, Inc.’s North Campus manufacturing facility in Warsaw, Indiana (“Warsaw North Campus”). At the conclusion of the inspection on April 24, 2018, the FDA issued a Form 483 with 11 inspectional observations. None of the observations identified a specific issue regarding the performance of any particular product and all products continue to be manufactured by the facility. Zimmer Biomet stands behind the safety of the products manufactured at the Warsaw North Campus. [View the FDA Form 483.](#)

The Company notes that this re-inspection occurred as it continues to execute against its approximately two-year quality remediation plan at the Warsaw North Campus. Zimmer Biomet believes that considerable progress has been made over the past year, but more work remains to be completed. The Company takes the FDA’s observations very seriously and, as part of the ongoing two-year remediation effort, continues to work diligently with independent consultants to address both existing and new Form 483 observations.

Quality excellence is an integral aspect of Zimmer Biomet’s commitment to the patients and surgeons who rely on its products every day. The Company’s primary focus has always been, and continues to be, patient safety. Zimmer Biomet remains committed to operating a first-rate quality management system across its global manufacturing network and maintaining the quality, safety and efficacy of the products manufactured at the Warsaw North Campus facility.