

Patient Follow-Up FAQs

Q: Why were these products voluntarily withdrawn from the market?

A: While modular neck hip stems provide surgeons with an option to correct certain aspects of a patient's anatomy and hip biomechanics, we decided to voluntarily recall these modular-neck stem hip systems because there is a potential for fretting and corrosion at the modular-neck junction which may lead to adverse local tissue reactions.

Q: Why is Stryker updating the recall notice?

A: Stryker is suggesting that surgeons consider performing a clinical examination, such as blood work and cross sectional imaging, on all patients who received a Rejuvenate or ABG II modular-neck hip stem regardless of whether a patient is experiencing pain and/or swelling. For further information regarding patient follow-up please refer to the Product Recall Update.

Q: Why is Stryker suggesting that I contact all my patients, including asymptomatic patients?

A: In working with the medical community to better understand this matter, we have received reports of patients with mild or no symptoms that have tested positive for elevated metal ion levels or been diagnosed with adverse local tissue reaction.

Q: Are monolithic stems included in this voluntary recall?

A: No. Monolithic stems are not part of this voluntary recall.

Q: What is the appropriate patient follow-up?

A: The following information is applicable to patients with ABG II Modular and Rejuvenate Modular Hip Systems:

- Surgeons should consider performing a clinical examination, such as blood work (including infection screen and metal ion levels) and cross sectional imaging, regardless of whether a patient is experiencing pain and/or swelling.
- Repeat follow-up examination, such as blood work and cross section imaging, should be considered even in the presence of normal initial findings.
- When following up with patients, surgeons should continue to evaluate their patients for aseptic loosening and periprosthetic sepsis.
- If the surgeon's workup reveals an adverse response to metal wear debris, the surgeon should consider proceeding with a revision of the femoral component to a device without a modular neck.

Q: Is Stryker communicating to patients impacted by this recall?

A: Stryker is communicating directly with surgeons and hospitals who have appropriate patient contact information. Stryker has created a sample patient letter to assist surgeons with patient communications. This sample letter can be found on stryker.com/ModularNeckStems or provided by your sales representative. Please advise patients to contact 1-888-317-0200 (US & Canada only) or visit www.aboutstryker.com/ModularNeckStems for additional information.

Patient Follow-Up FAQs (continued):

Q: Who should surgeons contact with clinical questions regarding Rejuvenate Modular or ABG II?

A: All requests for clinical information relating to Rejuvenate Modular or ABG II should be directed to Dr. Jon Hopper, Stryker's Vice President, Global Medical Director, at 201-972-9140 or jon.hopper@stryker.com.

Q: Where should I report any claims of deficiency related to quality, reliability, safety or effectiveness of any product?

A: If you experience any adverse events related to any product, please contact your Stryker sales representative or call 1-866-OR-ASSIST to report any such events.

**Q: What should I say to my patients?
Can I refer them somewhere?**

A: To help address patient questions, Stryker has established a dedicated patient call center at 1-888-317-0200 (US & Canada only) and has posted web resources at www.AboutStryker.com/ModularNeckStems.