Bayer

September 2021

URGENT MEDICAL DEVICE FIELD CORRECTIVE ACTION

Attention Cardiovascular and/ or Interventional Radiology Department

RE: MEDRAD® Twist & Go (TAG 150 SYR) Syringe
Field Corrective Action (Lot 8415317)
FCA ID: SA-21-RAD-02 – Product Return Request

Dear Valued Customer,

[Local Country Address]
[Contact Details]

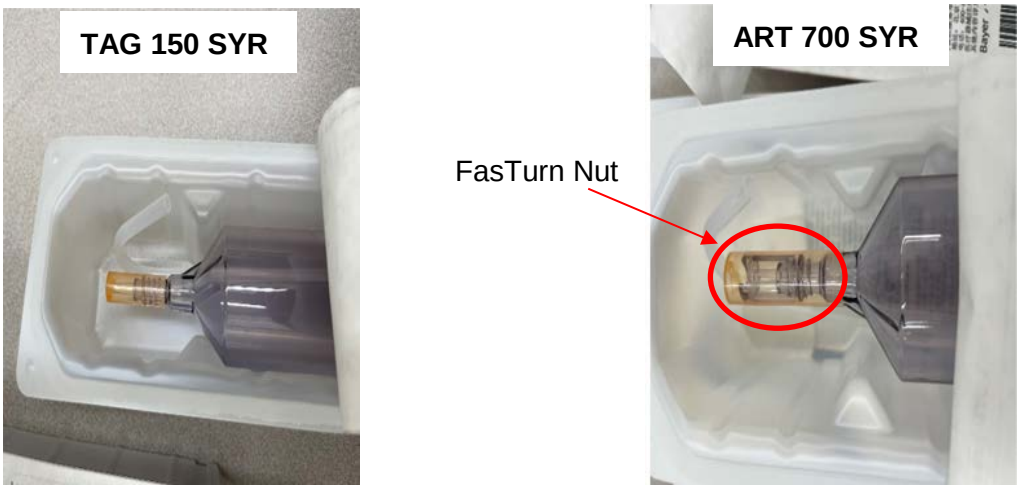
www.radiology.bayer.com

Bayer is issuing a field corrective action for one lot of MEDRAD® Twist & Go Syringes (TAG 150 SYR) used in conjunction with the MEDRAD® Mark 7 Arterion Injection System. It has been identified that there may be a labeling error which resulted in several MEDRAD® Mark 7 Arterion Injection System Syringes (ART 700 SYR) being labeled as Twist & Go Syringes in certain instances.

NOTE: There is no safety or efficacy issue as a result of the mislabeled product (ART 700 SYR in place of TAG 150 SYR). Internal testing has shown that the FasTurn nut on the ART 700 SYR can be removed and TAG 150 SYR tubing can be seamlessly connected. There are ***NO*** adverse health consequences.

NOTE: This error only impacts one lot of TAG 150 SYR (Lot 8415317). The affected lot was distributed between February 22, 2021 and July 7, 2021. Our records indicate that your facility received at least one box which may contain affected product subject to this field corrective action.

Exhibit 1



The ART 700 SYR includes a FasTurn nut and a longer dust cap as compared to the TAG 150 SYR.

Please immediately take the following steps:

1. Review your current inventory for affected Lot 8415317 and quarantine, as appropriate.
2. Complete the included response form and submit to *[Enter local customer support phone and/ or email address here]*. ***Please complete the Customer Response Form regardless of whether you have affected product or not. This action will assist us in tracking all affected product.***
3. You will receive a Return Goods Authorization (RGA) number to return any affected syringes remaining in your inventory for a credit. We can send new syringes with a separate purchase order, as necessary.
4. Place the affected product in a box and label the outside of the container with the RGA number in large, bold writing. Use the shipping label provided via email when you receive your RGA number. Please return affected product ***no later than November 30, 2021.***
5. Upon Bayer receipt of returned product, you will receive a credit on your account.

Please distribute this letter to other appropriate departments and personnel within your facility who may need to maintain awareness of this field corrective action. **Note:** The national competent authority has been notified.

We aspire for quality in all we do and regret that we failed to meet this standard. We apologize for any inconvenience caused and promise to learn and improve our performance in the future.

Sincerely,

[Insert Country Head or other country rep name/signature here]

Enclosure: Response Form and Instruction Sheet to locate Lot Information