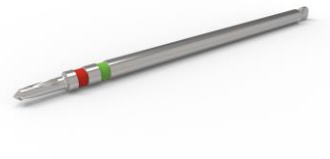
Field Safety Notice: RA2021-2876278

5mm Twist Drill

Attn:

November 25, 2021



Product affected

Catalog number	UDI	Product description	Serial/Lot number(s)	Distribution Dates
60-15105	(01)07613154183999 (10)6000091378	Drill for 5mm, Stryker-Shaft	6000091378	21Jun2021 –22.Jul2021

Product description

Stryker and Luhr Twist drills are available in a variety of lengths and diameters to meet clinical requirements. The drills are manufactured from stainless steel and in some instances include color-coding for ease of identification.

Primary clinical purpose of device(s)

The Stryker Twist Drills are intended to be used for drilling holes in large and small bone during orthopedic, spinal, neurosurgical, medical sternotomy, and oral and maxillofacial procedures.

Product issue

We have received customer complaints that are related to wrong twist drills inside the package. We have confirmed these complaints and have determined that they are limited to the lot identified above.

Potential hazard and risks

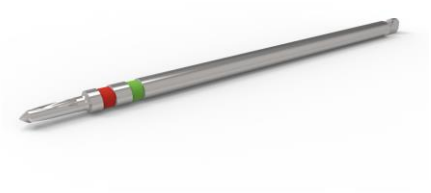
There is no potential health risk since the color-coded twist drill is obvious to the user and the twist drill is laser marked correctly.

Actions needed

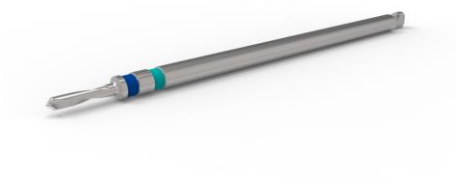
Our records indicate that you have received at least one of the subject devices and you are therefore affected by this action.

We request that you read this notice carefully and complete the following actions:

1. Immediately visually check your internal inventory if the products are affected. The colors are visible through the transparent packaging.
   Correct colors (correct drill in the package)
   - Article: **60-15105**
   - color: red / green



Correct



Incorrect

2. Quarantine all subject devices that are the **wrong colors** (ultramarine blue / turquoise blue) and return them to Stryker.

3. Circulate this Field Safety Notice internally to all interested/affected parties.

4. Maintain awareness of this notice internally until all required actions have been completed within your facility.

5. Inform Stryker if any of the subject devices have been distributed to other organizations.
   a. Please provide contact details so that Stryker can inform the recipients appropriately.
   b. If you are a Distributor, note that you are responsible for notifying your affected customers.

6. Please inform Stryker of any adverse events concerning the use of the subject devices.
   a. Please comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.

7. Complete the attached customer response form. It may be that you no longer have any physical inventory on site. Completing this form will allow us to update our records and will also negate the need for us to send any further unnecessary communications on this matter. Therefore, please complete even if you no longer have any of the subject devices in your physical inventory.

8. Return the completed form to your nominated Stryker Representative (indicated below) for this PFA

a. On receipt of the form, a Stryker Representative will contact you to organize any applicable ongoing actions.

We request your support in finalizing the required steps within 14 calendar days from the date of receipt.

Your designated contact person for this action is given below. Should you have any queries concerning this matter please do not hesitate to contact them directly.

Name: Position: email:

In line with the recommendations of the Meddev Vigilance Guidance document Ref 2.12-1, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

On behalf of Stryker we thank you sincerely for your help and support in completing this action within the target date and regret any inconvenience that may be caused. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards, remain on the market.

Sincerely,

Katharina Feige-Götz
Product Field Action Coordinator
Stryker Craniomaxillofacial (CMF)

stryker

Business Reply Form- response required

5mm Twist Drill

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Please complete and sign this form. Email the completed form xxxx@Stryker.com by <MMM DD YYYY>

Note: Your signature indicates that you have received and understand the enclosed notification and that you have performed all actions requested.

Catalog number	Product	Serial/Lot number(s)	Colors	Quantity on hand*
60-15105	Drill for 5mm, Stryker-Shaft	6000091378	**ultramarine blue / turquoise blue (Wrong)**	

*If no affected devices are available for return please enter 0 (zero).

Form completed by:

Printed name		**Title**	
Signature		**Phone**	
Date		**Email**	

If you have further distributed any affected product, please indicate to whom:

Product(s) distributed		**Quantity distributed**	
Facility name		**Contact person**	
Full address			