

**RA2020-2509167**

**URGENT FIELD SAFETY NOTICE**

**Stryker Zyphr Disposable Cranial Perforator, Large 14/11 mm**

Attn: Risk Manager, Materials Manager, OR Director  
October 20, 2020

The purpose of this notification is to advise you that Stryker Instruments is voluntarily recalling 241 specific lots of Large Cranial Perforator bits.

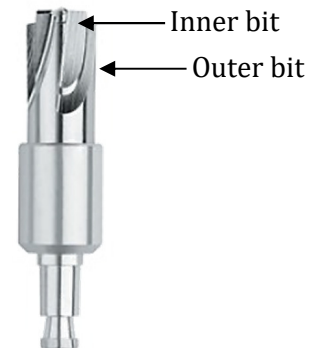
Catalog number	Description	GTIN	Affected Lots
5100-060-001	Stryker Zyphr Disposable Cranial Perforator, Large 14/11 mm	04546540716224	Multiple, refer to list on page 2

**Product description**

The Stryker Zyphr Disposable Cranial Perforator, Large 14/11 mm (perforator) is a sterile, single use cutting accessory intended for cutting an 11 mm diameter access hole through the cranium of adult patients. The drill assembly consists of an inner cutting bit that protrudes out slightly past the outer cutting bit.

**Product issue**

There is a potential for the inner bit to contain a crack, that may or may not be visible, which may lead to metal fragments entering the surgical site and/or delayed disengagement during use. This issue was identified internal to Stryker; to date, Stryker has not been made aware of any adverse events related to this issue.



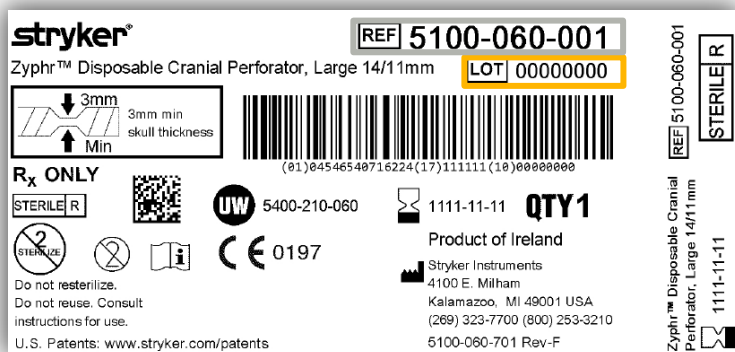
**Risk to health**

A crack can lead to metal fragments chipping off the bit and being retained in the surgical site, which can lead to patient injury; however, standard surgical procedure of a saline flush for debris may remove any fragments.

A crack can lead to failure of the device to disengage or delayed disengagement, which can potentially cause patient injury due to unintentional cutting of cranial structures.

**Product identification**

Location of Product Number (Grey) and Lot Number (Gold) on Stryker labels:



### Affected lots

A total of 240 lots are affected within the scope of this recall and are listed below.

2002XXXX	2003XXXX	2004XXXX	2005XXXX	2006XXXX	2007XXXX	2008XXXX	2009XXXX
20029027	20030077	20040027	20051017	20062017	20071017	20080017	20094017
	20030087	20041017	20052017	20062027	20071027	20083017	20094027
	20031017	20042017	20052047	20062037	20072017	20083027	20094037
	20031027	20044017	20055017	20062047	20079017	20084017	20094047
	20034017	20044027	20055027	20063017	20079027	20084027	20099017
	20035017	20047017	20055037	20063027		20084037	20099027
	20035027	20048017	20055047	20064017		20084047	20099037
	20035037	20048027	20056017	20066017		20084057	
	20036017	20048037	20057017	20066027			
	20036027		20057037	20066037			
	20038017		20058017	20066047			
	20038027		20058027	20069017			
			20059017	20069027			
			20059027				
			20059037				
			20059047				

2010XXXX	2011XXXX	2012XXXX	2013XXXX	2014XXXX	2015XXXX	2016XXXX
20101017	20107017	20111017	20120017	20131017	20141017	20150017
20101027	20107027	20111027	20120027	20131027	20141027	20150027
20101037	20107037	20111037	20120037	20131037	20141037	20150037
20101047	20107047	20112017	20121017	20134017	20141047	20150047
20101057	20107057	20112027	20121027	20134027	20142017	20154017
20101067	20108017	20112037	20122017	20136017	20142027	20154027
20101077	20108027	20112047	20122027	20136027	20142037	20155017
20106027	20108037	20113017	20122037	20136037	20142047	20155027
20106047	20108047	20113027	20122047	20136047	20143017	20155037
20106087	20108057	20113037	20125017	20136057	20143027	20156017
20106107	20108067	20118017	20127027	20136067	20146017	20157017
20106117		20118037	20127037	20136077	20146027	20157027
20106127			20127047	20139017	20147017	20157037
20106137			20128017	20139027	20147027	
			20128027	20139037	20147037	
			20128037		20147047	
			20128047		20148017	
			20128057		20148027	
			20129017		20148037	

2017XXXX	2018XXXX	2019XXXX	2020XXXX	2021XXXX	2022XXXX
20171017	20189017	20190017	20202017	20211017	20220017
20171027	20189027	20190027	20202027	20211027	20220027
20171037	20189037	20192017	20203017	20211037	20220037
20171047	20189047	20195037	20203027	20211047	20220047
20171057	20189057	20197017	20203037	20217017	20220057
20171067	20189067	20199027	20204017	20217027	
20171077		20199037	20204027	20217037	
20171107		20199047	20204037		
20177017		20199057	20204047		
20177027		20199067	20206017		
20177037			20206027		
20178017			20206037		
20178027			20206047		
20178037			20206057		
			20206067		

## Actions to be taken:

1. Immediately check your internal inventory to locate the affected products. Quarantine and **discontinue use of any Large Perforator Bits.**
2. Circulate this Field Notice internally to all interested/affected parties.
3. Maintain awareness of this notice internally until all required actions have been completed within your facility.
4. Inform Stryker if any of the subject devices have been distributed to other organisations. Even if you have distributed all product to another location, please complete the attached business reply form and indicate each location that received product.
  - 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.
5. 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.
6. 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.
7. Return the completed form to your nominated Stryker Representative (indicated below) for this FSCA.
  - a. On receipt of the form, a Stryker Representative will contact you to organise any applicable ongoing actions.

We request that you respond to this notice within 7 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:**

**E-mail:**

**Phone:**

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 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 and your expectations, remain on the market.

**Sincerely,**

# Business Reply Form



Account number: <#####>  
 Account name: <NAME>  
 Account Address: <ADDRESS>  
 <ADDRESS>

## Stryker Zyphr Disposable Cranial Perforator, Large 14/11 mm

**Recall Number: RA2020-2509167**

**October 20, 2020**

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

Catalog number	Product	Lot number	Quantity on hand*
5100-060-001	Stryker Zyphr Disposable Cranial Perforator, Large 14/11 mm		
5100-060-001	Stryker Zyphr Disposable Cranial Perforator, Large 14/11 mm		
5100-060-001	Stryker Zyphr Disposable Cranial Perforator, Large 14/11 mm		
5100-060-001	Stryker Zyphr Disposable Cranial Perforator, Large 14/11 mm		

\*If all devices have been used and 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			

Please complete and sign this form.

Email the completed form to [Redacted]