stryker

# 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.

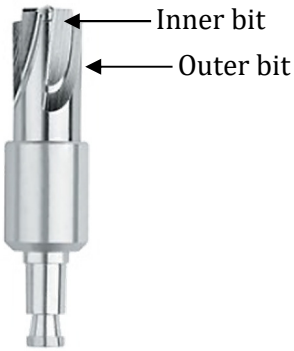
| Catalog number | Description | GTIN | Affected Lots |
|---|---|---|---|
| 5100-060-001 | Stryker Zyphr Disposable Cranial Perforator, Large 14/11 mm | 04546540716224 | Multiple, refer to list on page 2 |

### 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 disengagment 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.



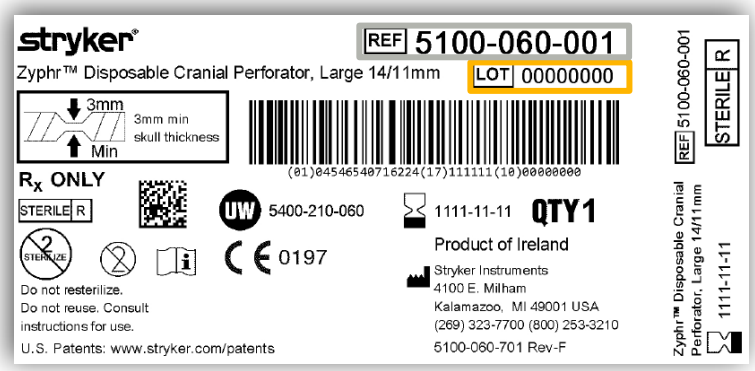

### Risk to health

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 | 20161017 |
| 20101027 | 20107027 | 20111027 | 20120027 | 20131027 | 20141027 | 20150027 | 20162017 |
| 20101037 | 20107037 | 20111037 | 20120037 | 20131037 | 20141037 | 20150037 | 20162027 |
| 20101047 | 20107047 | 20112017 | 20121017 | 20134017 | 20141047 | 20150047 | 20164017 |
| 20101057 | 20107057 | 20112027 | 20121027 | 20134027 | 20142017 | 20154017 | 20167017 |
| 20101067 | 20108017 | 20112037 | 20122017 | 20136017 | 20142027 | 20154027 | 20167027 |
| 20101077 | 20108027 | 20112047 | 20122027 | 20136027 | 20142037 | 20155017 | 20168017 |
| 20106027 | 20108037 | 20113017 | 20122037 | 20136037 | 20142047 | 20155027 | 20168027 |
| 20106047 | 20108047 | 20113027 | 20122047 | 20136047 | 20143017 | 20155037 | 20168037 |
| 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 _____