Johnson&Johnson MedTech

DePuy Synthes

URGENT: MEDICAL DEVICE RECALL (REMOVAL)

CEREBASE DA Guide Sheath®

Part Number	Product Description	GTIN / UDI
GS9070SD	CEREBASE DA Guide Sheath	10886704082309
GS9080SD	CEREBASE DA Guide Sheath	10886704082316
GS9090SD	CEREBASE DA Guide Sheath	10886704082293
GS9095SD	CEREBASE DA Guide Sheath	10886704082323
See Attachment 1 for Impacted Product Lots, not all lots are affected		

PLEASE DISTRIBUTE THIS INFORMATION TO APPROPRIATE PERSONNEL AT YOUR FACILITY WHO MAY USE CEREBASE DA GUIDE SHEATH DEVICES SUBJECT TO THIS NOTICE

5th February 2024

Dear Valued Customer,

Medos International Sàrl (Medos) has initiated a voluntary Medical Device Recall (removal) regarding specific lots of CEREBASE DA Guide Sheath. The CEREBASE DA Guide Sheath is indicated for the introduction of interventional devices into the neurovasculature.

Reason for Customer Notification:

Medos has received an increase in complaints for CEREBASE DA Guide Sheath with reports of fractures at the distal end, which may result in surgical procedural delay, vascular injury and in extreme rare occasions it may result in embolism.

Why you are being contacted:

Our records show that your facility received one or more of the product(s) listed in Attachment 1. Please carefully review this notice for the steps that you should take to respond to this medical device recall (removal).

Please take the following actions:

1. Examine your inventory immediately to determine if you have product subject to this recall on hand and quarantine such product(s). Refer to Attachment 2 for lot identification.

2. Remove the product subject to this recall and communicate the issue to relevant operating room or materials management personnel, or anyone else in your facility who needs to be informed.

3. If any product subject to this recall has been forwarded to another facility, contact that facility to arrange return. Please include a copy of this recall letter when communicating.

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4. Complete the Business Reply Form (BRF) (Attachment 3) confirming receipt of this notice and scan and email signed form to MDFieldActionsUKirl@its.jnj.com.
    - Attention Line: Cerebase FA2350411
5. Please return the BRF even if you do not have product subject to this recall.
6. Follow instructions in the letter and immediately email MDFieldActionsUKirl@its.jnj.com to return any inventory of CEREBASE DA Guide Sheath devices subject to this recall. To receive credit reimbursement, customers must return product subject to this recall.
    - Attention Line: Cerebase FA2350411
7. Keep this notice visibly posted for awareness until all product subject to this recall has been returned. While processing your returns, please maintain a copy of this notice with the product subject to this recall and keep a copy for your records.

As with any medical device, adverse reactions or quality problems experienced with the use of this product should be reported to your local sales representative.

Contact Information:

We recognize the recall (removal) of the CEREBASE DA Guide Sheath devices may be disruptive to your facility. If you have additional questions regarding this medical device recall (removal), please contact your local sales representative or MDFieldactionsUKirl@its.jnj.com

Thank you for your attention and cooperation.

Sincerely,

Nicolas Hainard
Director, MedTech QA
Chemin Blanc 38, Le Locle, CH-2400 Switzerland

Attachments:
Attachment 1: List of Impacted Product Codes
Attachment 2: Product Lot Identification
Attachment 3: Business Reply Form

Medical Device Recall of **CEREBASE DA Guide Sheath**
Event # 2350411

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ATTACHMENT 1: List of Impacted Product Codes

LOT #	Expiration Date	LOT#	Expiration Date
31212661	01/31/2026	31121040	09/30/2025
31212653	01/31/2026	31150969	10/31/2025
31194733	12/31/2025	31150968	10/31/2025
31208988	01/31/2026	31146720	10/31/2025
31194710	12/31/2025	31133638	09/30/2025
31189206	12/31/2025	31140952	10/31/2025
31178955	12/31/2025	31140740	10/31/2025
31174927	12/31/2025	31133637	09/30/2025
31160736	11/30/2025	31121043	09/30/2025
31154809	11/30/2025	31121044	09/30/2025
31140751	10/31/2025	31121039	09/30/2025
31146719	10/31/2025	31116485	09/30/2025
31133636	09/30/2025	31116484	09/30/2025
31140739	10/31/2025	31108260	08/31/2025
31121042	09/30/2025	31103843	08/31/2025
31212663	01/31/2026	31094249	08/31/2025
31212655	01/31/2026	31208992	01/31/2026
31225738	01/31/2026	31212656	01/31/2026
31212654	01/31/2026	31178959	12/31/2025
31208989	01/31/2026	31189209	12/31/2025

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CEREBASE DA Guide Sheath®

LOT #	Expiration Date	LOT#	Expiration Date
31208990	01/31/2026	31194736	12/31/2025
31194735	01/31/2026	31194713	12/31/2025
31208991	01/31/2026	31174931	12/31/2025
31204436	01/31/2026	31168612	11/30/2025
31194734	12/31/2025	31163814	11/30/2025
31189208	12/31/2025	31168613	11/30/2025
31194711	12/31/2025	31160739	11/30/2025
31194712	01/31/2026	31161162	11/30/2025
31189207	12/31/2025	31121041	09/30/2025
31178958	12/31/2025	31154812	11/30/2025
31178957	12/31/2025	31150970	10/31/2025
31178956	12/31/2025	31140755	10/31/2025
31174928	11/30/2025	31146721	10/31/2025
31174930	11/30/2025	31140754	10/31/2025
31168611	11/30/2025	31133639	09/30/2025
31168610	11/30/2025	31133640	10/31/2025
31160737	11/30/2025	31121045	09/30/2025
31160738	11/30/2025	31116486	09/30/2025
31154810	10/31/2025	31108262	08/31/2025
31154811	10/31/2025	31103844	08/31/2025
31091318	07/31/2025	31108261	08/31/2025

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ATTACHMENT 2: Product Lot Identification

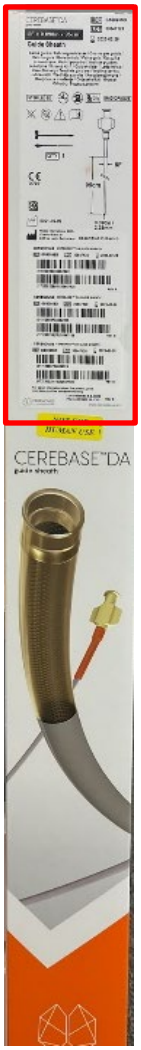

Figure 1 – Sample Outer Package

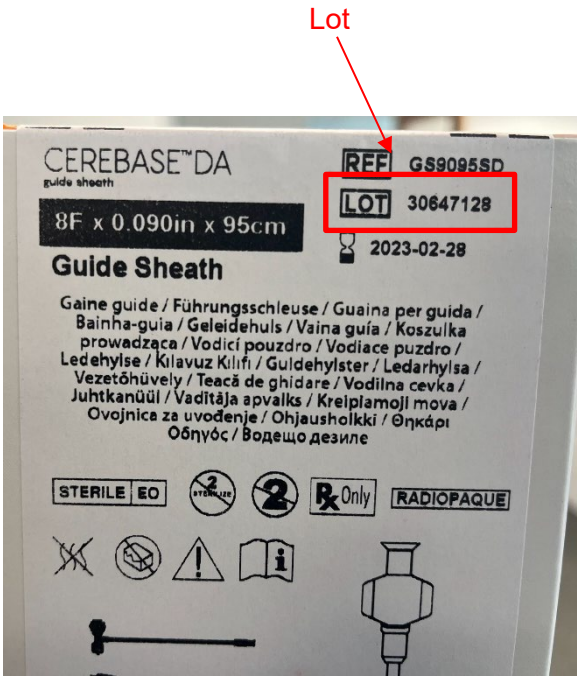

Figure 2 – Sample Outer Package Label

Step 1: Refer package box label (see Figure 1) to identify the LOT number associated with your product.

Step 2: Identify LOT number (see Figure 2) and compare with the impacted lots listed in Attachment 1.

Step 3: If you have product subject to this recall on hand quarantine such product(s) and email completed form to MDFieldActionsUKirl@its.jnj.com

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ATTACHMENT 3: Business Reply Form (BRF)

Your timely response to this customer notification is requested. Please complete this form and scan and email signed form to MDFieldActionsUKirl@its.jnj.com **within 3 business days, even if you do not have product subject to this recall to return.**

If you have unused product subject to this recall (removal) to return, please make a photocopy of your completed Business Reply Form and enclose with your return. Thank you for your cooperation.

Print Name and Title of Person Completing Business Reply Form:	Telephone Number:
Hospital Name and Collection address:	Date:
Signed*: **Your signature provides confirmation that you have received and understood this notification*	
Your comments are welcome.	

Product Inventory – *please check one*

☐ **We have NO CEREBASE DA Guide Sheath devices subject to this recall (removal).**

☐ **We have CEREBASE DA Guide Sheath devices subject to this recall (removal) and are returning the following products:**

CEREBASE DA was further distributed. We notified our customers: Yes, No, N/A

PRODUCT NAME	PRODUCT CODE	PRODUCT LOT	GTIN / UDI Number	Quantity Returning (Units)

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