

**SAFETY NOTICE**  
**Lobster Project 2.0 implantable device**

20/12/2024

Subject: Safety notice regarding the expiry date in the UDI code of the Lobster Project 2.0 implantable device

Dear customer/user,

Diametros Medical S.r.l. is sending this communication to inform of an error in the UDI code of the Lobster Project 2.0 devices.

**Problem and potential risk**

The expiry date detected by reading the DataMatrix associated with the UDI code shown on the label is incorrect, as it is entered in DDMMYY format instead of YYMMDD format. The correct expiry date is the one shown on the label flanked by the harmonized hourglass symbol (e.g.  09/2029 ).  
If the operator refers to the date detected by the optical reader, he may incur in using the device beyond the expiry date, which corresponds to guaranteeing the sterility of the medical device.

**THERE IS NO RISK OF EXPIRED DEVICES BEING IMPLANTED TO DATE, AS THE EARLIEST EXPIRY DATE OF THE DEVICES COVERED BY THIS NOTICE IS 08/2026 (AUGUST 2026).**

**Actions required for distributors and/or users**

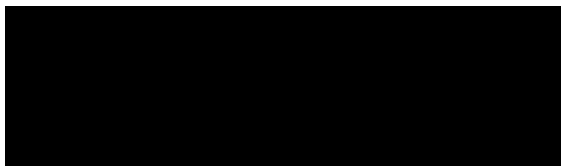
Distributors must proceed by identifying the destination of the devices covered by this notice, recalling them and returning them to Diametros Medical for relabelling.

Users who are in possession of the products covered by this notice should contact their distributor's contact person to organize the take-back procedure.

Any communication must be sent to [qualita@diametrosmed.com](mailto:qualita@diametrosmed.com)

The list of device codes and batches covered by this notice is given in Annex II.

Lorenzo Fortuna  
Managing Director  
Diametros Medical S.r.l.



**Attachments:**

- Annex I "Safety Notice Response Form".
- Annex II 'List of device codes and batches'.

## Annex I

**Safety Notice Response Form**

Reference: Safety Notice concerning the expiry date in the UDI code of the Lobster Project 2.0 implantable device

Instructions: complete and return this form to Diametros Medical s.r.l. no later than 30 days after receipt. Completion of this form confirms your understanding of the problem reported in the safety alert and the action to be taken.

Client/recipient/structure name

Full address

City/State

Actions by the client:

- See the **Required Actions for Distributors and/or Users** section of the enclosed Safety Notice.

I confirm that I have received and understood the enclosed Safety Notice and that the information in this letter has been correctly forwarded to all users of the Lobster Project 2.0 device

Name of the person filling in the form

Title

Telephone number

Email address

Compilation date

Signature

**INFORMATION ABOUT THE UNITS TO BE RETURNED:**

If you do not have any products to return, please tick the box ☐

(In case there are no products to be returned, it is assumed that all products have been used and are therefore no longer available)

| Product code | Lot number | Qty to be returned | Product code | Lot number | Qty to be returned |
|--------------|------------|--------------------|--------------|------------|--------------------|
|              |            |                    |              |            |                    |
|              |            |                    |              |            |                    |
|              |            |                    |              |            |                    |
|              |            |                    |              |            |                    |
|              |            |                    |              |            |                    |
|              |            |                    |              |            |                    |
|              |            |                    |              |            |                    |

Complete and return this form within 30 days of receipt to Diametros Medical s.r.l. by email to [qualita@diametrosmed.com](mailto:qualita@diametrosmed.com).

## Annex II

List of device codes and batches covered by the Safety Notice regarding the expiry date in the UDI code of the Lobster Project 2.0 implantable device

| Code         | Lot    | Production date | Expiry date  | Certificate | UDI product                                     |
|--------------|--------|-----------------|--------------|-------------|-------------------------------------------------|
| <b>LBS08</b> |        |                 |              |             |                                                 |
| LBS08        | 241642 | July-24         | June-29      | MDD         | (01)8052107460012(10)241642(11)240701(17)280629 |
| LBS08        | 241686 | July-24         | June-29      | MDD         | (01)8052107460012(10)241686(11)240701(17)280629 |
| <b>LBS10</b> |        |                 |              |             |                                                 |
| LBS10        | 191544 | September-21    | August-26    | MDD         | (01)8052107460029(10)191544(11)210901(17)280826 |
| LBS10        | 191546 | May-22          | April-27     | MDD         | (01)8052107460029(10)191546(11)220501(17)280427 |
| LBS10        | 191568 | September-21    | August-26    | MDD         | (01)8052107460029(10)191568(11)210901(17)280826 |
| LBS10        | 191570 | October-21      | September-26 | MDD         | (01)8052107460029(10)191570(11)211001(17)280926 |
| LBS10        | 241644 | July-24         | June-29      | MDD         | (01)8052107460029(10)241644(11)240701(17)280629 |
| LBS10        | 241687 | July-24         | June-29      | MDD         | (01)8052107460029(10)241687(11)240701(17)280629 |
| <b>LBS12</b> |        |                 |              |             |                                                 |
| LBS12        | 191573 | October-21      | September-26 | MDD         | (01)8052107460036(10)191573(11)211001(17)280926 |
| LBS12        | 191574 | July-22         | June-27      | MDD         | (01)8052107460036(10)191574(11)220701(17)280627 |
| LBS12        | 191575 | May-22          | April-27     | MDD         | (01)8052107460036(10)191575(11)220501(17)280427 |
| LBS12        | 241643 | July-24         | June-29      | MDD         | (01)8052107460036(10)241643(11)240701(17)280629 |
| <b>LBS14</b> |        |                 |              |             |                                                 |
| LBS14        | 241645 | July-24         | June-29      | MDD         | (01)8052107460043(10)241645(11)240701(17)280629 |
| LBS14        | 241688 | July-24         | June-29      | MDD         | (01)8052107460043(10)241688(11)240701(17)280629 |
| <b>LBT08</b> |        |                 |              |             |                                                 |
| LBT08        | 221418 | September-22    | August-27    | MDD         | (01)8052107460074(10)221418(11)220901(17)280827 |
| LBT08        | 221417 | September-22    | August-27    | MDD         | (01)8052107460074(10)221417(11)220901(17)280827 |
| LBT08        | 221416 | September-22    | August-27    | MDD         | (01)8052107460074(10)221416(11)220901(17)280827 |
| LBT08        | 231933 | October-23      | September-28 | MDD         | (01)8052107460074(10)231933(11)231001(17)280928 |
| LBT08        | 231925 | September-23    | August-28    | MDD         | (01)8052107460074(10)231925(11)230901(17)280828 |
| LBT08        | 231385 | May-23          | April-28     | MDD         | (01)8052107460074(10)231385(11)230501(17)280428 |
| LBT08        | 222137 | January-23      | December-27  | MDD         | (01)8052107460074(10)222137(11)230101(17)281227 |
| LBT08        | 230988 | april-23        | March-28     | MDD         | (01)8052107460074(10)230988(11)230401(17)280328 |
| LBT08        | 240284 | February-24     | January-29   | MDD         | (01)8052107460074(10)240284(11)240201(17)280129 |

Diametros Medical S.r.l.

Registered office: Via Fra' Domenico Buonvicini, Florence

Headquarters: Via di Terranuova 48/5, Montevarchi (AR)

[info@diametrosmed.com](mailto:info@diametrosmed.com)

| Code         | Lot    | Production date | Expiry date  | Certificate | UDI product                                     |
|--------------|--------|-----------------|--------------|-------------|-------------------------------------------------|
| LBT08        | 240285 | February-24     | January-29   | MDD         | (01)8052107460074(10)240285(11)240201(17)280129 |
| LBT08        | 241831 | August-24       | July-29      | MDD         | (01)8052107460074(10)241831(11)240801(17)280729 |
| <b>LBT10</b> |        |                 |              |             |                                                 |
| LBT10        | 201119 | September-21    | August-26    | MDD         | (01)8052107460081(10)201119(11)210901(17)280826 |
| LBT10        | 201688 | September-21    | August-26    | MDD         | (01)8052107460081(10)201688(11)210901(17)280826 |
| LBT10        | 210444 | September-21    | August-26    | MDD         | (01)8052107460081(10)210444(11)210901(17)280826 |
| LBT10        | 210453 | September-21    | August-26    | MDD         | (01)8052107460081(10)210453(11)210901(17)280826 |
| LBT10        | 221415 | September-22    | August-27    | MDD         | (01)8052107460081(10)221415(11)220901(17)280827 |
| LBT10        | 221419 | September-22    | August-27    | MDD         | (01)8052107460081(10)221419(11)220901(17)280827 |
| LBT10        | 221256 | August-22       | July-27      | MDD         | (01)8052107460081(10)221256(11)220801(17)280727 |
| LBT10        | 221282 | August-22       | July-27      | MDD         | (01)8052107460081(10)221282(11)220801(17)280727 |
| LBT10        | 221260 | August-22       | July-27      | MDD         | (01)8052107460081(10)221260(11)220801(17)280727 |
| LBT10        | 221281 | August-22       | July-27      | MDD         | (01)8052107460081(10)221281(11)220801(17)280727 |
| LBT10        | 231967 | October-23      | September-28 | MDD         | (01)8052107460081(10)231967(11)231001(17)280928 |
| LBT10        | 232377 | January-24      | December-28  | MDD         | (01)8052107460081(10)232377(11)240101(17)281228 |
| LBT10        | 231934 | October-23      | September-28 | MDD         | (01)8052107460081(10)231934(11)231001(17)280928 |
| LBT10        | 231427 | June-23         | May-28       | MDD         | (01)8052107460081(10)231427(11)230601(17)280528 |
| LBT10        | 231299 | May-23          | April-28     | MDD         | (01)8052107460081(10)231299(11)230501(17)280428 |
| LBT10        | 240665 | March-24        | February-29  | MDD         | (01)8052107460081(10)240665(11)240301(17)280229 |
| LBT10        | 240666 | March-24        | February-29  | MDD         | (01)8052107460081(10)240666(11)240301(17)280229 |
| LBT10        | 240736 | April-24        | March-29     | MDD         | (01)8052107460081(10)240736(11)240401(17)280329 |
| LBT10        | 241718 | July-24         | June-29      | MDD         | (01)8052107460081(10)241718(11)240701(17)280629 |
| <b>LBT12</b> |        |                 |              |             |                                                 |
| LBT12        | 221446 | September-22    | August-27    | MDD         | (01)8052107460098(10)221446(11)220901(17)280827 |
| LBT12        | 221445 | September-22    | August-27    | MDD         | (01)8052107460098(10)221445(11)220901(17)280827 |
| LBT12        | 232378 | January-24      | December-28  | MDD         | (01)8052107460098(10)232378(11)240101(17)281228 |
| LBT12        | 232379 | January-24      | December-28  | MDD         | (01)8052107460098(10)232379(11)240101(17)281228 |
| LBT12        | 231935 | October-23      | September-28 | MDD         | (01)8052107460098(10)231935(11)231001(17)280928 |

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|--------------|--------|-----------------|-------------|-------------|-------------------------------------------------|
| LBT12        | 231926 | September-23    | August-28   | MDD         | (01)8052107460098(10)231926(11)230901(17)280828 |
| LBT12        | 222363 | May-23          | April-28    | MDD         | (01)8052107460098(10)222363(11)230501(17)280428 |
| LBT12        | 221455 | January-23      | December-27 | MDD         | (01)8052107460098(10)221455(11)230101(17)281227 |
| LBT12        | 222139 | January-23      | December-27 | MDD         | (01)8052107460098(10)222139(11)230101(17)281227 |
| LBT12        | 222334 | January-23      | December-27 | MDD         | (01)8052107460098(10)222334(11)230101(17)281227 |
| LBT12        | 241744 | July-24         | June-29     | MDD         | (01)8052107460098(10)241744(11)240701(17)280629 |
| <b>LBT14</b> |        |                 |             |             |                                                 |
| LBT14        | 221422 | September-22    | August-27   | MDD         | (01)8052107460104(10)221422(11)220901(17)280827 |
| LBT14        | 222364 | June-23         | May-28      | MDD         | (01)8052107460104(10)222364(11)230601(17)280528 |