

CELDA TOOLS service notice

CELDA[®] TOOLS manufactured by Likvor AB
Reference: 2012-03 B11

Date: 2012-03-14

Attention:

Likvor communicates information regarding a problem with CELDA[®] TOOLS units that has been damaged in transport.

Intended audience:

Users of the LIKVOR CELDA[®] SYSTEM and CELDA[®] TOOLS.

This notice should be passed on to all those who need to be aware within your organization.

Affected devices:

| | |
|--------------|---|
| Name | CELDA [®] TOOLS |
| Order number | CT001-SV-02, CT001-EN-02, CT001-DA-02, CT001-FI-02, |
| Batch number | 104911, 111414 |

Description:

Likvor has experienced an increased number of damages to the outer package of our sterile accessory CELDA[®] TOOLS. We have already a Warning in the package stating:

1. Verify that the tube set is unused and sterile by checking that the packaging has not been damaged and the expiration date has not passed.

But we urge you to be extra careful in examining the packages, especially for the batches mentioned above.

Workaround:

We ask our customers to check their inventory of CELDA[®] TOOLS with batch numbers [104911, 111414] and to please remove any units with packaging defects.

File a reclamation case for all units where a breach of the packaging cannot be ruled out using the regular procedure found on our website. Please store the removed units and await further information regarding transportation of the units back to Likvor AB.

If you don't have any products from those batch numbers no further actions are needed.

Solution:

The defects are associated with clearly visible packaging damage and there is no indication of any added risk to continue to use CELDA[®] TOOLS units that has undamaged packaging.

Likvor has informed the corresponding competent authority and is currently investigating the root cause of the packaging damage and suitable corrections to the distribution and packaging of CELDA[®] TOOLS.

Contact Information:

We appreciate your cooperation in dealing with this matter and apologize for any inconvenience. If you have any questions please contact Jan Sandström on +46 90 190507 or jan.sandstrom@likvor.com.

| CEO Likvor AB: | Signature: | Date: |
|-----------------------|------------------------------|------------|
| Maria Wallin Wållberg | <i>Maria Wallin Wållberg</i> | 2012-03-14 |