
Urgent Field Safety Notice

Product name: Bipolar Head, Bionit2
FSCA ID no.: FSCA 16/01
Type of action: Replacement of products bearing the wrong expiry date

Bettlach, 26 January 2016

Issued by: Mathys Ltd Bettlach
Addressee: OR management
CC: Purchasing department

Affected products:

Item number	Item description	Batch numbers
1413.61.3	Bipolar head Bionit2 43/28	see Annex
1414.61.3	Bipolar head Bionit2 45/28	see Annex
1415.31.3	Bipolar head Bionit2 47/28	see Annex
1416.61.3	Bipolar head Bionit2 49/28	see Annex
1417.61.3	Bipolar head Bionit2 51/28	see Annex
1418.61.3	Bipolar head Bionit2 53/28	see Annex
1419.61.3	Bipolar head Bionit2 55/28	see Annex
1420.61.3	Bipolar head Bionit2 57/28	see Annex

Ladies and Gentlemen

Mathys Ltd Bettlach hereby notifies you of a voluntary Field Safety Corrective Action (FSCA) affecting the item and batch numbers of Bipolar head Bionit2 listed in the Annex. Our records indicate that you have received one or several of the affected batches and are therefore subject to this safety-relevant action.

Description of the problem

Mathys Ltd Bettlach has detected an inconsistency in the shelf-life of Bipolar heads made out of Bionit2 (ceramic) with a UHMWPE retaining ring. In 2011 the shelf-life was erroneously defined as ten years.

As a corrective measure, the shelf-life of the Bipolar heads was reduced to the correct shelf-life of five years.

Potential hazards

If a Bipolar head is used after the guaranteed shelf life of 5 years, a slightly higher wear rate of the UHMWPE retaining ring might be observed. Testing showed that UHMWPE oxidises slowly during storage due to gamma-sterilisation and under presence of oxygen remaining in the packaging.

Sterility will, however, not be affected, because the packaging system ensures sterility for up to 10 years of storage.

There is no risk to patients already implanted with a Bipolar head because all implanted Bipolar heads were within the guaranteed shelf life of 5 years.

The first batches which are labelled with the incorrect shelf-life of ten years, will exceed the new, corrected shelf-life of five years in July 2016.

Immediate measures to be taken by the customer:

- Read this Field Safety Notice carefully and make sure that all relevant departments and positions are informed of its content.
- **Immediately separate out all the products carrying the item and batch numbers indicated above.**
- A Mathys representative will contact you in order to support you with this procedure and organise the replacement.
- Third parties to whom affected products have been forwarded must be informed and instructed accordingly.
- Please complete the enclosed confirmation form and return it to the address indicated or hand it over to your Mathys representative. *(This will stop Mathys from sending you further reminders concerning this FSCA.)*
- The present Field Safety Notice must be observed until the action has been completed within your organisation. Please keep a copy of this Field Safety Notice.
- For questions regarding the replacement, please contact the Mathys representative responsible for your organisation or your local Mathys office.
- For questions regarding this Field Safety Notice, please contact us at the following address: vigilance@mathysmedical.com

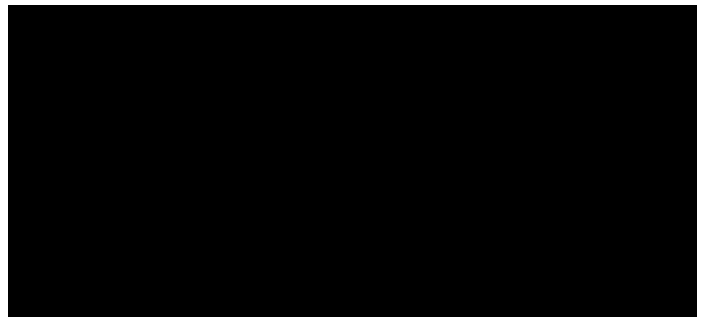
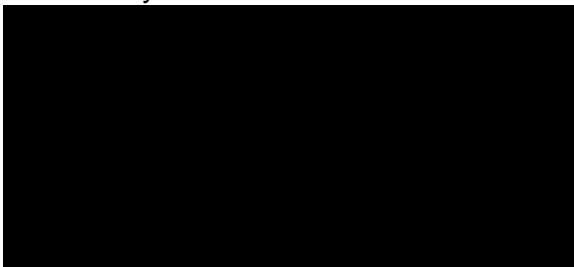
Information on materiovigilance:

The competent national authorities have been notified of this action.

Please notify Mathys Ltd Bettlach of any adverse event in connection with the affected product or any other Mathys product. You can report adverse events to Mathys at vigilance@mathysmedical.com or via your local Mathys office.

We very much regret the inconvenience caused to you. If you have any further queries, please do not hesitate to contact us.

Mathys Ltd Bettlach



Confirmation form FSCA 16/01

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Product name: **Bipolar Head, Bionit2**

FSCA ID no.: **FSCA 16/01**

Type of action: **Replacement of products bearing the wrong expiry date**

Confirmation of receipt

Please complete:

Customer no. _____
Hospital _____
Post code, town _____
Contact
(Name/position) _____

By completing and returning the present form I confirm that I have received and read this Field Safety Notice:

- Our stocks do not contain any affected products
- Our stocks contain the following affected products:

Item number	Batch	Number of units

Place/date: _____ Signature: _____

Please return this form by e-mail or fax to the following address: