

Urgent Field Safety Notice

**Eckert & Ziegler
BEBIG GmbH**

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Subject: Wet IsoStrands
Commercial Name of Affected Product: IsoStrand® I25.S061-10S
Reference: 2014 I25.S061-10S
Date of Notification: 16.September.2014
Type of Action: Awareness for visual check of the product

Description of Problem:

- Inefficient drying of the IsoStrand® packaging was found for IsoStrands with production date as of 22.August.2014. Due to a human failure the inside of the stainless steel tube was not completely dried from water from the automatic cleaner.
- IsoStrands delivered between 22. August and 15. September could be wet, which makes them sticky and difficult to cut and load into the implantation needle.
- Careful visual check of the strands' integrity should be performed by the customer prior to cutting it and loading it into the needle.
- All packagings on stock have been double checked and deliveries of IsoStrands since 15.September 2014 can be used without any further precautions.

This notice needs to be passed on to all those who need to be aware of it within your organisation or to any organisation to which the IsoStrands have been forwarded.

Please reply to this email confirming you received and understood this information and that you forwarded it to the people that are in touch with the IsoStrand®.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

We sincerely apologise for any inconvenience caused by the required actions and thank you in advance for your cooperation. For further information please feel free to contact us.

Kind regards,

Heiko G. Jacobs
Head of Quality Management

CONFIRMATION

**Urgent Field Safety Notice from Eckert & Ziegler BEBIG GmbH,
Reference**

This is to confirm that we have received and understood the Field Safety Notice. It was forwarded inside our clinic to the respective personnel.

Name of clinic:

Signature, date: