Attention: BBraun Surgical, S.A. (distributor) and final user

Urgent Field Safety Notice

Name of medical device: Cellistypt, Cellistypt D-K and Cellistypt F

FSCA – identifier: BB30102015

Quarantine and cease use of all batches stored in BBraun warehouse since May 2014 to October 2015 when the storage temperature 25°C (upper limit) was exceeded.

<u>Quarantine and cease use of all batches of the below listed devices:</u>

2014		
REF	**NAME**	**LOT**
2080501 and 2080508 and 2080541	CELLISTYPT® (ORIGINAL)	**045/14**
2080536 and 2080541	CELLISTYPT® (ORIGINAL)	**046/14**
2080511	CELLISTYPT® (ORIGINAL)	**047/14**
2080501 and 2080508 and2080511 and 2080515 and 2080536 and 2080541	CELLISTYPT® (ORIGINAL)	**070/14**
2080541	CELLISTYPT® (ORIGINAL)	**071/14**
2080501 and 2080508 and 2080515	CELLISTYPT® (ORIGINAL)	**075/14**
2080511	CELLISTYPT® (ORIGINAL)	**091/14**
2080541	CELLISTYPT® (ORIGINAL)	**092/14**
2080536	CELLISTYPT® (ORIGINAL)	**093/14**
2080511	CELLISTYPT® (ORIGINAL)	**099/14**
2080501 and 2080508 and 2080536 and 2080541	CELLISTYPT® (ORIGINAL)	**100/14**
2080541	CELLISTYPT® (ORIGINAL)	**114/14**
2080511 and 2080541	CELLISTYPT® (ORIGINAL)	**115/14**
2080508 and 2080536	CELLISTYPT® (ORIGINAL)	**116/14**
2080508 and 2080536	CELLISTYPT® (ORIGINAL)	**126/14**
2080511 and 2080541	CELLISTYPT® (ORIGINAL)	**129/14**
2080536 and 2080541	CELLISTYPT® (ORIGINAL)	**130/14**
2081209 and 2081203	CELLISTYPT® D-K (DENSE KNITTED)	**003.2/14**
2081210 and 2081240 and 2081275	CELLISTYPT® D-K (DENSE KNITTED)	**004.1/14**

Synthesia, a.s., Pardubice, Semtín 103, 530 02 Pardubice, Czech Republic
Identification number: 60108916 • VAT: CZ60108916
phone: +420 466 821 111 • fax: +420 466 822 900 • e-mail: synthesia@synthesia.eu
www.synthesia.eu

2081209 and 2081210 and 2081240 and 2081275 and 2081203	CELLISTYPT® D-K (DENSE KNITTED)	**005/14**
2081203	CELLISTYPT® D-K (DENSE KNITTED)	**005.2/14**
2081209 and 2081210 and 2081240 and 2081275 and 2081203	CELLISTYPT® D-K (DENSE KNITTED)	**006/14**
2081210 and 2081240	CELLISTYPT® D-K (DENSE KNITTED)	**007/14**
2081209 and 2081210 and 2081240 and 2081275 and 2081203	CELLISTYPT® D-K (DENSE KNITTED)	**008.2/14**
2081240	CELLISTYPT® D-K (DENSE KNITTED)	**009/14**
2081203 and 2081209 and 2081210 and 2081240	CELLISTYPT® D-K (DENSE KNITTED)	**010/14**
2081275	CELLISTYPT® D-K (DENSE KNITTED)	**009.2/14**
2082005 and 2082010 and 2082025 and 2082056	CELLISTYPT® F (FIBRILLAR)	**011/14**
2082020	CELLISTYPT® F (FIBRILLAR)	**012/14**
2082005 and 2082025	CELLISTYPT® F (FIBRILLAR)	**014/14**
2082005 and 2082010	CELLISTYPT® F (FIBRILLAR)	**015/14**
2082005 and 2082025	CELLISTYPT® F (FIBRILLAR)	**018.1/14**
2082010 and 2082020	CELLISTYPT® F (FIBRILLAR)	**019/14**
2082005 and 2082056	CELLISTYPT® F (FIBRILLAR)	**020/14**
2082005 and 2082010 and 2082025 and 2082056	CELLISTYPT® F (FIBRILLAR)	**021/14**
2082005 and 2082010 and 2082025 and 2082056	CELLISTYPT® F (FIBRILLAR)	**023/14**
2082005 and 2082010 and 2082056	CELLISTYPT® F (FIBRILLAR)	**028/14**
2082005	CELLISTYPT® F (FIBRILLAR)	**030.2/14**
2082005 and 2082010	CELLISTYPT® F (FIBRILLAR)	**031/14**
2082005 and 2082025	CELLISTYPT® F (FIBRILLAR)	**031.1/14**

2015

REF	NAME	LOT
2080501	CELLISTYPT® (ORIGINAL)	**008/15**
2080511 and 2080541	CELLISTYPT® (ORIGINAL)	**009/15**
2080501 and 2080508 and 2080536	CELLISTYPT® (ORIGINAL)	**012/15**
2080511 and 2080515 and 2080541	CELLISTYPT® (ORIGINAL)	**014/15**
2080508 and 2080536 and 2080541	CELLISTYPT® (ORIGINAL)	**032/15**
2080501 and 2080508 and 2080511 and 2080536	CELLISTYPT® (ORIGINAL)	**033/15**
2080515 and 2080541	CELLISTYPT® (ORIGINAL)	**041/15**
2080501 and 2080508 and 2080511 and 2080536	CELLISTYPT® (ORIGINAL)	**042/15**
2080541	CELLISTYPT® (ORIGINAL)	**050/15**
2080541	CELLISTYPT® (ORIGINAL)	**051/15**
2080536 and 2080541	CELLISTYPT® (ORIGINAL)	**052/15**
2080508 and 2080536	CELLISTYPT® (ORIGINAL)	**053/15**
2080501 and 2080508 and 2080511 and 2080515 and 2080536	CELLISTYPT® (ORIGINAL)	**054/15**
2080541	CELLISTYPT® (ORIGINAL)	**075/15**
2080501 and 2080508 and 2080511 and 2080515 and 2080536 and 2080546	CELLISTYPT® (ORIGINAL)	**076/15**

2080536	CELLISTYPT® (ORIGINAL)	**082/15**
2081203 and 2081209 and 2081210 and 2081240 and 2081275	CELLISTYPT® D-K (DENSE KNITTED)	**001/15**
2081210	CELLISTYPT® D-K (DENSE KNITTED)	**001.2/15**
2081209 and 2081210	CELLISTYPT® D-K (DENSE KNITTED)	**002.2/15**
2081209 and 2081210	CELLISTYPT® D-K (DENSE KNITTED)	**004.2/15**
2081203 and 2081209 and 2081240 and 2081275	CELLISTYPT® D-K (DENSE KNITTED)	**008.1/15**
2082005	CELLISTYPT® F (FIBRILLAR)	**001/15**
2082025 and 2082056	CELLISTYPT® F (FIBRILLAR)	**003/15**
2082005 and 2082010 and 2082025	CELLISTYPT® F (FIBRILLAR)	**003.2/15**
2082005 and 2082010	CELLISTYPT® F (FIBRILLAR)	**005/15**
2082025	CELLISTYPT® F (FIBRILLAR)	**005.1/15**
2082025	CELLISTYPT® F (FIBRILLAR)	**006/15**
2082005	CELLISTYPT® F (FIBRILLAR)	**007.2/15**
2082005 and 2082010 and 2082020	CELLISTYPT® F (FIBRILLAR)	**008/15**
2082005 and 2082020 and 2082025	CELLISTYPT® F (FIBRILLAR)	**009/15**
2082005 and 2082010 and 2082025	CELLISTYPT® F (FIBRILLAR)	**017/15**
2082020	CELLISTYPT® F (FIBRILLAR)	**018/15**

Description of the problem:

Medical Devices Cellistypt, Cellistypt D-K and Cellistypt F were stored at the warehouse of BBraun Surgical, S.A. (distributor) with the higher storage temperature than 25 °C (upper limit). Incorrect storage conditions caused that medical device is browning and has tendency to crumble and disintegrate. Affected medical device lost mechanical properties and correct way of usage.

Action to be taken by BBraun Surgical, S.A.

- Stop distribution of the affected batches and recall all these affected batches
- Quarantine the affected products and then dispose of medical devices
- Distribute the FSN to all subjects and end-users to whom the devices were sold
- Fill out and return the attached “confirmation of receipt of FSN”

Action to be taken by the user

- Cease implantation of the affected medical devices
- Quarantine the affected medical devices until passing it on to BBraun representative
- Fill out and return the attached “confirmation of receipt of FSN”

Synthesia, a.s. is conducting this recall in the continuing interest of ensuring the delivery of quality medical devices and safety.

Product information

The product line includes regular density Cellistypt products, is used to control capillary, minor venous and minor arteriolar bleeding.
High density Cellistypt D-K products providing greater thickness and improved endurance, is used to control higher volume capillary, venous or arteriolar bleeding.
Fibrillar version of the Cellistypt F product with reduced weight and extremely high flexibility, is used to control hemostasis over a large area and for surface application, irregularly shaped bleeding sites or on areas that are difficult to access, as the desired amount can be grasped with forceps and easily placed onto the bleeding site.

Transmission of this Field Safety Notice

Please forward this message to relevant person in your organization.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

In addition, if you have further distributed these products, please notify the consignees at once of this notification.

A copy of this letter should be attached to notification for your customers.

This notification should be carried out to the user level. Your assistance is appreciated and necessary.

The undersigned confirms that this notice has been notified to the appropriate Competent Authorities.

If you have any questions, please contact us at:

Address: Semtín 103, 530 02 Pardubice- Semtín
Phone: +420 466 824 577
Gsm: +420 724 401 144
Mail: hana.demele@synthesia.eu

Yours sincerely,

[redacted]

Hana Demele
Quality Manager of BU Oxycellulose, Synthesia, a.s.