Rev 1: September 2018

FSN Ref: VI-2020-11 FSCA Ref: Vi-2020-11

Date: 11.09.2020

Urgent Field Safety Notice
E-ventus BX Peripheral Stent Graft System

For Attention of*:Healthcare Providers

Contact details of local representative (name, e-mail, telephone, address etc.)*
This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages

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Urgent Field Safety Notice (FSN)

E-ventus BX Peripheral Stent Graft System

Risk of Rupture/Endoleak Type IIId in Case of Off-label Use

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Implantable stent graft system
1.	2. Commercial name(s)
	E-ventus BX Peripheral Stent Graft System
1.	3. Unique Device Identifier(s) (UDI-DI)
	N/A
1.	4. Primary clinical purpose of device(s)*
	The E-ventus BX Peripheral Stent Graft System is indicated for intraluminal chronic placement in iliac and renal arteries for restoring and improving the patency and treating aneurysms, acute perforations, acute ruptures and fistulas.
1.	5. Device Model/Catalogue/part number(s)*
	E-ventus BX Peripheral Stent Graft System all catalogue numbers
1.	6. Affected serial or lot number range
	E-ventus BX Peripheral Stent Graft System all lot numbers

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	None; reinforcement of the Instruction for Use.
2.	2. Hazard giving rise to the FSCA*
	In the device risk management JOTEC has identified that one of the potential hazards of off-label use may be a failure of the stent graft when used in combination with other products outside the defined indication. There are several potential hazardous situations to off-label use: • Stent rupture (individual stent graft or rupture into multiple pieces) • Damage to the sheathing / Endoleak type IIId
2.	3. Probability of problem arising
	Post-market data suggests that there is a very low chance of stent fracture or endoleak type IIId provided that healthcare professionals follow the intended purpose of the device.
2.	4. Predicted risk to patient/users
	In very rare cases (probability of occurrence <1%) these hazardous situations can cause the following potential harms: reintervention, aneurysm growth, aneurysm rupture or death.

3. Type of Action to mitigate the risk*

3. 1. Action To Be Taken by the User*

☐ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device

☐ On-site device modification/inspection

☐ Follow patient management recommendations

☒ Take note of amendment/reinforcement of Instructions For Use (IFU)

☐ Other ☐ None

JOTEC has become aware by means of reported incidents of the fact that in a very small number of cases stent fractures and endoleaks type IIId may occur due to off-label use of the medical device.

In the device risk management JOTEC has identified that one of the potential hazards of off-label use may be a failure of the stent graft when used in combination with other products outside the defined indication.

There are several potential hazardous situations:

- Stent fracture (individual stent structs or fracture into multiple pieces)
- Damage to the sheathing / Endoleak type IIId

These hazardous situations can cause the following potential harms:

- Reintervention
- Aneurysm growth
- Aneurysm rupture
- Death

The current frequencies of stent fracture or endoleak type IIId due to off-label use for the initial and modified stent graft design of the E-ventus BX Peripheral Stent Graft System are summarized below, with each affected stent graft evaluated (26.100 sold units in total as of July 31, 2020).

	Stent Fracture [%]	**Leakage [%]**
Initial Design	0.22	0.28
Modified Design (from October 2015)	0.12	0.06
Total	0.14	0.10

The numbers suggest a positive development related to stent fractures as well as endoleaks type IIId as a result of the implemented design change in October 2015. The implemented design change has proven to be effective.

Furthermore, JOTEC is currently conducting three observational, prospective, non-randomized, multicenter studies in which peripheral covered stents are used off-label as bridging stents. The E-ventus BX Peripheral Stent Graft System is among multiple peripheral stents from JOTEC, Gore, Bard, Getinge and Bentley which are used to bridge the side branches of the stent grafts under evaluation with the intended

	anatomic structures. In all three studies the treatment of the patient is at the discretion of the physician and the patient. Participating physicians are asked to provide their observations collected during routine care by transferring the clinical data from the patient file into the eCRF. A preliminary analysis of the gathered clinical data from these ongoing studies suggests that the rate of stent fractures and endoleaks type IIId that are related to the E-ventus BX Peripheral Stent Graft System used as bridging stents is comparable with peripheral stent grafts from other manufacturers. In total 192 E-ventus BX Peripheral Stent Graft System were used throughout the three studies. Among these only 1 case of endoleak type IIId related to the E-ventus BX Peripheral Stent Graft System has been observed. Please find attached more details on the preliminary study information in the appendix. Nevertheless, JOTEC strongly advises healthcare professionals to adhere to the intended purpose of the E-ventus BX Peripheral Stent Graft System as stated in the instructions for use and to refrain from off-label use. JOTEC cannot guarantee the safety and performance of the medical device in case of off-label use.	
3.	2. Particular considerations for: Implantable device Is follow-up of patients or review of patients' previous results recommended? Yes Frequent follow-ups of patients with "grafted" aneurysms are mandatory, as this is standard procedure. Please ensure a rigid and frequent follow-up procedure with your patients particularly in case you have used the E-ventus BX Peripheral Stent Graft System beyond its indications.	
3.	3. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	No
3.	**4. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☒ None A design change as well as an update of the Instructions for Use emphasizing the risks of off-label use have already been implemented and proven to be effective. No further actions are required as of now.	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. Further advice or information already expected in follow-up FSN? *	No
4.	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	JOTEC GmbH
	b. Address	Lotzenäcker 23, 72379 Hechingen/Germany
	c. Website address	https://www.jotec.com
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	5. List of attachments/appendices:	APPENDIX 7_2020.09.09 Preliminary Study Information for Field Safety Note; Attachment_FSCA Report E-ventus BX Peripheral Stent Graft System _09.09.2020
4.	6. Name/Signature	Monika Schulze, Director Quality & Safety Officer

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.

9 September 2020

Clinical experience with the use of E-ventus BX Peripheral Stent Graft System as bridging stent:

JOTEC is conducting three observational, prospective, non-randomised, multicenter studies in which peripheral covered stents are used as bridging stents. In all three studies the treatment of the patient is at the discretion of the physician and the patient. Participating physicians are asked to provide their observations collected during routine care by transferring the clinical data from the patient file into the eCRF.

Information about the studies:

PLIANT:

ClinicalTrials.gov Identifier: NCT02209194

Title: PLIANT - A post-market registry in **P**atients with i**LI**ac **A**neurysm undergoing endovascular stenting with a **N**ew generation of low profile E-liac S**T**ent Graft System

Objective: To evaluate clinical and technical success as well as safety and feasibility of the E-liac Stent Graft System used in endovascular treatment of uni- or bilateral aorto-iliac or iliac aneurysm. Main study target is the exclusion of aneurysm with primary patency of the arteria iliaca interna and the arteria iliaca externa on iliac implantation side.

Patient Population: A total number of 40 male and female patients with unilateral or bilateral common iliac aneurysm, treated with the E-liac Stent Graft System.

Study status:

- Study start: July 2014
- End of study: July 2019
- Participating centers: 11
- Patients enrolled: 45
- Follow-up: 3 years

Peripheral covered stents used to bridge the side branch of the E-liac Stent Graft with the internal iliac artery:

- **Total number: 62**
    - E-ventus BX (JOTEC) 46
    - Advanta V12 (Getinge) 13
    - Lifestream (Bard) 2
    - B-Graft (Bently) 1

Observed incidents related to the peripheral covered stents:

- None

PLIANTII:

ClinicalTrials.gov Identifier:

Title: PLIANTII - Prospective multicenter registry to examine the real-world performance of the E-liac Stent Graft System for treatment of uni- or bilateral aorto-iliac or iliac aneurysms

Objective: The PLIANT II registry is undertaken to examine the real-world outcome after treatment of consecutive patients with uni- or bilateral aorto-iliac or iliac aneurysms using the E-liac Stent Graft System.

Patient Population: A total number of 400 - 500 male and female patients with uni- or bilateral aorto-iliac or iliac aneurysm, treated with the E-liac Stent Graft System. Recruitment period is estimated to last 5 years and is conducted in up to 60 clinical European centers.

Study status:

- Start of enrollment: July 2018
- Patients enrolled: 90 (recruitment is ongoing)
- Participating centers: 26

Peripheral covered stents used to bridge the side branch of the E-liac Stent Graft with the internal iliac artery:

- **Total number: 136**
    - o E-ventus BX (JOTEC) 57
    - o Advanta V12 (Getinge) 31
    - o Viabahn VBX (Gore) 30
    - o B-Graft (Bently) 10
    - o Viabahn Endoprosthesis (Gore) 3
    - o Fluency (Bard) 2
    - o Covera (Bard) 2
    - o Unknown 1

Observed incidents related to the peripheral covered stents:

- One patient with endoleak type IIId due to PTFE detachment (E-ventus BX)

CONNECT:

ClinicalTrials.gov Identifier: NCT03295682

Title: CONNECT - Registry in Patients with Thora**CO**abdomi**N**al A**N**eurysms Tr**E**ated with Multi-bran**C**h Stent Grafts **T**ailored to Their Individual Anatomies

Objective: The CONNECT registry is undertaken to evaluate clinical and technical success as well as safety and feasibility of the in-house manufactured multi-branch stent graft systems used in endovascular treatment of thoracoabdominal aortic aneurysms that cannot be treated with commercially available devices. Primary endpoint of this study is the rate of patients with stable or decreasing aneurysm size at 12 months follow-up.

Patient Population: A total number of 40 male and female patients with asymptomatic thoracoabdominal aortic aneurysm, treated with a contract manufactured multi-branch stent graft system.

Study status:

- Start of enrollment: September 2017
- Patients enrolled: 37 (recruitment is ongoing)
- Participating centers: 7

Peripheral covered stents used to bridge the side branches of the multi-branch stent graft with the visceral arteries (celiac trunk, superior mesenteric artery) and renal arteries:

- **Total number: 161**
    - E-ventus BX (JOTEC) 89
    - Viabahn VBX / Endoprosthesis(Gore) 44
    - Lifestream (Bard) 13
    - Advanta V12 (Getinge) 9
    - B-Graft (Bently) 2
    - Unknown 4

Observed incidents related to the peripheral covered stents:

- None