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Rev 1: September 2018

FSN Ref: 3005031160-12/31/2018-001-R FSCA Ref: 3005031160-1 2/31/2018-001-R

Date: 04/15/2019

Urgent Field Safety Notice
Calix Spinal Implant System,
Icalix P and Calix T - Plasma Coated Implants

For Attention of*: Highland Medical, NIK Medical, Youspine LDA

Contact details of local representative (name, e-mail, telephone, address etc.)*
…… …… …… …… ……

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Urgent Field Safety Notice (FSN)
Calix Spinal Implant System,
Calix Pand Calix T - Plasma Coated Implants
Risk addressed by FSN

	1. **Information on Affected Devices***
1	1. Device Type(s)*
	Calix P and T Lumbar Plasma Coated Implants
1	2. Commercial name(s)
	Calix P and T Lumbar Plasma Coated Implants
1	3. Unique Device Identifier(s) (UDI-DI)
	M697X0340172PC1 M697X0340173PX1 M697X0340240PC1 M697X0340241PC1 M697X0340242PC1 M697X0340243PC1 M697X0340280PC1 M697X0340281PC1 M697X0340282PC1 M697X0340283PC1 M697X0340284PC1 M697X0340285PC1 M697X0340286PC1 M697X0340287PC1 M697X0340288PC1 M697X0340289PC1 M697X0340290PC1 M697X0340387PC1 M697X0340388PC1 M697X0340389PC1 M697X0340390PC1 M697X0340391 PC1 M697X0340392PC1 M697X0340393PC1 M697X0340394PC1 M697X0340395PC1 M697X0340396PC1
1	4. Primary clinical purpose of device(s)*
	The Calix® Lumbar Spina! Implant System is intended for spina! fusion procedures at one or two contiguous levels (L2 - S1 inclusive) in skeletally mature patients with degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the lumbosacral spine. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spina! surgery at the involved level(s). These implants are to be packed with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft, and implanted via an anterior, posterior, and/or transforaminal approach. Patients should receive at least six (6) months of non-operative treatment prior to treatment with a lumbosacral intervertebral fusion device. This device is intended to be used with supplemental spina! fixation

	systems that have been cleared for use in the lumbosacral spine (i.e., posterior pedicle screw and rod svstems, anterior plate svstems, and anterior screw and rod svstems).
1	5. Device Model/Cataloque/part number(s)*
	X034-0172PC, X034-0173PC, X034-0140PC, X034-0241PC, X034-0242PC, X034-0243PC, X034-0280PC, X034-0281PC, X034-0282PC, X034-0283PC, X034-0284PC, X034-0285PC, X034-0286PC, X034-0287PC, X034-0288PC, X034-0289PC, X034-0290PC, X034-0387PC, X034-0388PC, X034-0389PC, X034-0390PC, X034-0391PC, X034-0392PC, X034-0393PC, X034-0394PC, X034-0395PC, X034-0396PC
1	6. Software version
	NA
1	7. Affected serial or lot number range
	See Appendix 1
1	8. Associated devices
	NA

2	**Reason for Field Safety Corrective Action (FSCA)***
2	1 . Description of the product problem*
	The company distributed Calix P and T Lumbar Plasma Coated implants initially cleared by FDA in 2009 under K083637 and K112036 subsequent Letters to file. The company updated the 510k and received clearance for K170119 on 09/29/2017. While the prior Letters to File for K112036 did not require sterile packaging for the device, K170119 clearance required the Calix P and T Plasma Coated implants to be provided clean, individually packaged, and sterile. Shipment of products compliant with this requirement should have begun in September 2017 but did not. The company continued to ship product in a manner consistent with the Letter to File, which meant products that were clean, not individually packaged or sterile. The product was distributed to the EU in accordance with the Technica! File that was approved by the Notified Body and CE Mark was approved.
2	2. Hazard qiving rise to the FSCA*
	The potential product problem that emerges is an increased probability that product not shipped individually packaged and sterile could lead to increased infection rates for patients receiving the product. At this point in time, the company's complaint / MOR rate does not indicate that an actual problem has emerged in the marketplace. There are no immediate health consequences that may result form use or exposure to a device exhibiting contamination failure. The long-range health consequences that may result from use or exposure toa device exhibiting contamination failure include localized reaction or infection, systemic reaction, or infection or disease transmission. Proper care and storage of the devices including adhering to the validated cleaning and sterilization procedures described for the device system in the instructions for use mav mitioate the risk.
2	3. Probabilitv of problem arisinq
	There have not been any adverse events associated with this device exhibiting contamination failure. The HHE indicated that it is unlikely that use of the Calix Lumbar PC devices distributed clean and non-sterile will result inanv adverse events.
2	4 . Predicted risk to patient/users
	There have not been any adverse events associated with this device exhibiting contamination failure. The HHE indicated that it is unlikely that use of the Calix Lumbar PC devices distributed clean and non-sterile will result in any adverse events.
2	5 . Further information to help characterise the problem
	NA
	6. Backqround on Issue

2	The problem occurred when the company failed to translate the requirements of the 51Ok K170119 related to packaging and sterilization into the final product specification and subsequent quality system documentation allowing release of the product. Given that the product had been in commercial distribution prior to K170119 being cleared by the Agency in a non-sterile configuration, the company did not update its internal procedures requiring the new configuration as specified in K170119.
2	7. Other information relevant to FSCA
	NA

	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User*** D Identify Device D Quarantine Device Return Device D Destroy Device D On-site device modification/inspection D Follow patient management recommendations D Take note of amendment/reinforcement of Instructions For Use (IFU) D Other D None Provide further details of the action(s) identified.	
3.	2. By when should the action be completed?	Immediately upon notice
3.	3. Particular considerations for: Implantable device Is follow-up of patients or review of patients' previous results recommended? No At this time, there is no indication that it is necessary to notify patients of this Voluntary Recall.	
3.	4. Is customer Reply Required? * (If yes , form attached specifying deadline for return)	Yes, Xtant Medical's Distributors are required to replv.
3.	**5. Action Being Taken by the Manufacturer** D Product Removal D On-site devic e rnodification/inspection D Software upgrade D IFU or labelling change Other D None Upon return, the product will be re-worked, packaged clean and sterile.	
3	6. By when should the action be completed?	The action is on-going as returned product is received. Re-worked, clean, sterile packed devices are already becoming available.
3.	7. Is the FSN required to be communicated to the patient /lay user?	No

3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet? Choose an item. Choose an item.	
	4. Genera! Information*	
4.	1. FSN Type*	Update
4.	2. For updated FSN, reference number and date of previous FSN	3005031160-12/31/2018-001-R, 02/11/2019
4.	**3.** For Updated FSN, key new information as follows:	
	The FSCA is considered complete in the EU.	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	NA	
4	6. Anticipated timescale for follow-up FSN	NA
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSNJ	
	a. Company Name	X-spine Systems, Ine.
	b. Address	664 Cruiser Lane, Belgrade, MT 59714
	C. Website address	www.xtantmedical .com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	Appendix 1
4.	10. Name/Signature	..... ……

	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.

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MEDICAL

Rev 1: September 2018

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	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.

Appendix 1

UPC Code	UDI Number	Lot Numbers
X034-0172PC	M697X0340172PC1	19211-2, 21017-1
X034-0173PC	M697X0340173PC1	041790, 17075-5, 17196-3
X034-0240PC	M697X0340240PC1	042050, 18890-1, 20745-1, 17196-12, 18216-1
X034-0241PC	M697X0340241PC1	039171, 042071,054614, 056529,057161, 058525,17196-13,20745-2
X034-0242PC	M697X0340242PC1	20962,054621,055442,058526,20745-3
X034-0243PC	M697X0340243PC1	042073, 054624, 058527, 16730-15, 17075-16, 17196-15,18216-4, 19212-4, 20745-4
X034-0280PC	M697X0340280PC1	043764,062836, 063476,065284,040738PC,19626-1, 19903-1,20164-1,20774-1
X034-0281PC	M697X0340281 PC1	040746PC, 043852,054531,055202, 055436,055742,056756, 059809, 061983,062837, 17304-2, 19903-2, 19212-7, 19626-2, 19891-1, 20164-2, 20774-2, 21269-2
X034-0282PC	M697X0340282PC1	040757PC,043765, 054532, 054539, 055203,055437,055745, 056757, 059810, 062080, 062838, 063529, 19212-8, 19626-3, 19742-319903-1, 19903-3,20164-3, 20774-3,
X034-0283PC	M697X0340283PC1	040759PC,043853,054370, 054540,055204,055438,055746, 056758, 059811, 062081, 062839, 064312, 19212-9, 19626-4, 19742-4, 19903-4, 20462-3, 20774-4, 20164-4, 21269-3
X034-0284PC	M697X0340284PC1	040758PC,043854,054399,054541,055205,055439,055747,056759,059812,062082, 19147-8A, 19903-5, 19212-10, 19626-5, 19742-5, 20164-5, 20462-4A
X034-0285PC	M697X0340285PC1	040761PC, 043855, 054401, 055206, 054542, 055206,055440, 055748,056760,059821, 19147-10, 19626-6, 20164-6
X034-0286PC	M697X0340286PC1	055441, 055749, 059822, 040809PC, 17304-7, 19212-12, 19626-7, 19742-7, 19903-7, 20164-7, 20462-5
X034-0287PC	M697X0340287PC1	040937PC, 19147-4, 19217-1, 19742-8, 20164-8, 20462-6
X034-0288PC	M697X0340288PC1	043856, 040810PC, 19147-5, 19147-5A, 19217-2, 19742-9, 19903-9
X034-0289PC	M697X0340289PC1	040938, 040938PC, 19147-6, 19217-3, 19147-6A, 19742-10, 20164-10
X034-0290PC	M697X0340290PC1	040745, 043859, 17304-11, 17304-11PC, 18574-7, 19147-11, 19147-11A, 19217-4, 19903-11, 20164-11
X034-0387PC	M697X0340387PC1	039775, 041928, 17075-4, 19217-5, 20745-5
X034-0388PC	M697X0340388PC1	055534, 061988,18607-2, 19058, 20590-9,20745-6
X034-0389PC	M697X0340389PC1	041929, 055443, 056752,059802, 17075-18, 18861-8, 19217-6, 20745-7, 21273-2
X034-0390PC	M697X0340390PC1	054837,055207,055444,055543,055544,056753,059805,063120, 19217-7, 18007-4, 18567-3, 20745-8
X034-0391PC	M697X0340391PC1	054403,054626, 055208, 055446, 055544,059806,063121,20745-9
X034-0392PC	M697X0340392PC1	054413,054627, 055209,055447,055545, 056754,063122,17591-5, 18007-5, 18889-5, 18890-520590-10, 20745-10
X034-0393PC	M697X0340393PC1	038451,038567,054407,054928,055210, 055448,055547,056755, 20745-11, 21273-3
X034-0394PC	M697X0340394PC1	055211,055449, 055548,061987,064315,17756, 18007-6, 18890-6,20590-5,20745-12
X034-0395PC	M697X0340395PC1	16730-21, 19374-7, 17075-21, 20745-13, 21017-4
X034-0396PC	M697X0340396PC1	059807, 17591-6, 18890-7, 20745-14