

Date: 2024-12-11

To: Distributors, Hospitals, Physicians

Field Safety Notice

Affected Product: Figulla Flex II ASD and its Procedure Pack REF: 29ASD09F, 29ASD09P, 29ASD09FC, 29ASD09PC, 29ASD10F, 29ASD10P, 29ASD10FC, 29ASD10PC

FSN Identifier: FSN-2024-002 Notification of Device and Delivery system compatibility

Attention:

Occlutech is providing updated guidance on delivery system compatibility. Certain Figulla Flex II ASD and its Procedure Pack products have a size recommendation of Occlutech Delivery Set III (ODS III) that may lead to incompatibility.

Details on affected devices:

Product name: **Figulla Flex II ASD and its Procedure Pack** Please refer to *Attachment FSN-2024-002_List of affected products*.

Dear Customer,

This Field Safety Notice is to inform you that Occlutech has initiated a voluntary Field Safety Notice for the products listed on the *Attachment FSN-2024-002_List of affected products*. We ask that you take note of the recommendations as described below. This Field Safety Notice is limited to the serial numbers mentioned on the list attached to this Field Safety Notice.

Description of the problem:

Occlutech has identified that products affected by this corrective action have a size recommendation of ODS III (REF 98DS006) on the label of the Procedure Pack box and the sterile pouch of the implant that might lead to incompatibility.

The recommendation and labelling of the Occlutech Delivery Set with REF 51DS007 as 7F on the affected Procedure Pack box and the sterile pouch of the affected implant remains correct as per specification.

It was identified that there were some discrepancies between the labelled size for ODS III and the results from internal tests.

The size of compatible delivery system on the labels is too small. Instead of the labelled 6F ODS III size, a minimum size of 7F ODS III should be used. The usage of an undersized delivery system for the implantation of the Figulla Flex II ASD could result in damage to the Occluder device.



To date, there have been two product complaints associated with this incorrect labelling. No patient adverse events or injury have been reported.

Previously distributed marketing materials, reporting ODSIII incorrect sizes, shall be considered outdated and not valid. Updated materials will be distributed as soon as they will be available.

Actions to be taken by the distributors, physicians and/or hospitals:

- Inform clinicians and users of the updated recommendation regarding the recommendation of using 7F Occlutech Delivery Set III - ODS III (REF 98DS007) instead of 6F Occlutech Delivery Set III - ODS III (REF 98DS006) with Figulla Flex II ASD size 9 and 10.
- A written confirmation of the receipt, the reading and understanding of the Field Safety Notice should be provided to <u>info.mdso@occlutech.com</u>. Please also refer to the contact information mentioned at the end of this letter.
 If you have any questions or would like assistance with this Field Safety Notice, please contact your local Sales Representative.

Recommendation

1. Either the distributor or hospital should attach a copy of this Field Safety Notice to the outer box of any affected devices to act as a reminder.



Transmission of this Field Safety Notice (if appropriate):

This notice needs to be shared with users (physicians and/or hospitals) of the affected devices. Please assure and maintain awareness of this FSN among users of the affected Figulla Flex II ASD and its Procedure Pack products to ensure proper use of products.

Action to be taken by Occlutech:

Occlutech has taken all necessary steps to notify relevant authorities and has implement corrective and preventive actions.



FSN identifier: FSN-2024-002 FSCA identifier: FSCA-2024-002 Date: 2024-12-11

Contact reference Customer Service:

Occlutech International AB Landskronavägen 2 SE-252 32 Helsingborg, Sweden Contact Email address: <u>order@occlutech.com</u> Contact Phone Number: +46 76636 7200

Medical Device Safety Officer E-mail: info.mdso@occlutech.com

Please do not hesitate to contact Occlutech with question concerning this FSN.

We apologize for these inconveniences and are working to resolve the issue as soon as possible. We trust that this document clarifies all concerns.

Dr. Morwan Choli Managing Director, Occlutech GmbH Executive Vice President RA&Q

Attachment FSN-2024-002_List of affected products



Procedure pack description	Procedure pack REF	Serial Number Implant	Expire Date
Figulla Flex II ASD 9;	29ASD09F	2331290909 01	2028-10-03
Flex-Pusher II	29ASD09F	2331290909 03	2028-10-03
	29ASD09F	2331290909 05	2028-10-03
	29ASD09F	2331290909 10	2028-10-03
	29ASD09F	2331290909_12	2028-10-03
	29ASD09F	2331290909 14	2028-10-03
	29ASD09F	2331290909 21	2028-10-03
	29ASD09F	2331290909 25	2028-10-03
	29ASD09F 29ASD09F	2331290909_23	2028-10-03
			0.02798-240593909 P C A G P (64893-04P
	29ASD09F	2331290909_28	2028-10-03
	29ASD09F	2331290909_29	2028-10-03
	29ASD09F	2343290916_02	2028-10-22
	29ASD09F	2343290916_03	2028-10-22
	29ASD09F	2343290916_06	2028-10-22
	29ASD09F	2343290916_15	2028-10-22
	29ASD09F	2343290916_16	2028-10-22
	29ASD09F	2343290916_17	2028-10-22
	29ASD09F	2343290916_18	2028-10-22
	29ASD09F	2343290916_20	2028-10-22
	29ASD09F	2343290916_23	2028-10-22
	29ASD09F	2343290916_25	2028-10-22
	29ASD09F	2343290916 27	2028-10-22
	29ASD09F	2343290916 29	2028-10-22
	29ASD09F	2344290901 02	2028-10-03
	29ASD09F	2344290901 03	2028-10-03
	29ASD09F	2344290901 04	2028-10-03
	29ASD09F	2344290901 05	2028-10-03
	29ASD09F	2344290901 06	2028-10-03
	29ASD09F	2344290901 07	2028-10-03
	29ASD09F	2344290901 09	2028-10-03
	29ASD09F	2344290901_09	2028-10-03
	29ASD09F 29ASD09F	2344290901_10	2028-10-03
			C. M. BORGA, COLDERA, AND DECK, MARKED MAKE
	29ASD09F	2344290901_12	2028-10-03
	29ASD09F	2344290901_13	2028-10-03
	29ASD09F	2344290901_14	2028-10-03
	29ASD09F	2344290901_15	2028-10-03
	29ASD09F	2344290901_17	2028-10-03
	29ASD09F	2344290901_19	2028-10-03
	29ASD09F	2344290901_21	2028-10-03
	29ASD09F	2344290901_22	2028-10-03
	29ASD09F	2344290901_24	2028-10-03
	29ASD09F	2344290901_25	2028-10-03
	29ASD09F	2344290901_26	2028-10-03
	29ASD09F	2344290901_29	2028-10-03
	29ASD09F	2344290901_30	2028-10-03
	29ASD09F	2346290914_30	2029-01-23
	29ASD09F	2403290901 01	2029-02-12
	29ASD09F	2403290901 02	2029-02-12
	29ASD09F	2403290901 03	2029-02-12
	29ASD09F	2403290901 05	2029-02-12
	29ASD09F	2403290901 06	2029-02-12
	29ASD09F 29ASD09F	2403290901_00	2029-02-12
	29ASD09F	2403290901_08	2029-02-12
	29ASD09F	2403290901_10	2029-02-12

Attachment FSN-2024-002_List of affected products



Procedure pack	Procedure pack REF	Serial Number Implant	Expire Date
description	29ASD09F	2403290901 11	2029-02-12
	29ASD09F	2403290901 12	2029-02-12
	29ASD09F		2027-03-14
	29ASD09F	2403290901_15	2027-03-14
	29ASD09F	2403290901_16	2029-02-14
	29ASD09F	2403290901_19	2029-02-14
	29ASD09F	2403290901_20	2029-02-14
	29ASD09F	2403290901_21	2029-02-14
	29ASD09F	2403290901_22	2029-02-14
	29ASD09F	2403290901_23	2029-02-14
	29ASD09F	2403290901_24	2029-02-14
	29ASD09F	2403290901_25	2027-09-27
	29ASD09F	2403290901_27	2027-09-27
	29ASD09F	2403290901_28	2027-09-27
	29ASD09F	2412290916_02	2029-04-09
	29ASD09F	2412290916_04	2029-04-09
	29ASD09F	2412290916_05	2029-04-09
	29ASD09F	2412290916 07	2029-04-09
	29ASD09F	2412290916 09	2029-04-09
	29ASD09F	2412290916 14	2029-04-09
	29ASD09F	2412290916 16	2029-04-09
	29ASD09F	2412290916 17	2029-04-09
	29ASD09F	2412290916_18	2029-04-09
	29ASD09F	2412290916 20	2029-04-09
	29ASD09F	2412290916 22	2029-04-09
	29ASD09F	2412290916_23	2029-04-09
	29ASD09F	2412290916_24	2029-04-09
	29ASD09F	2412290916_25	2029-04-09
	29ASD09F	2412290916_27	2029-04-09
	29ASD09F	2412290916_28	2029-04-09
	29ASD09F	2412290916_29	2029-04-09
	29ASD09F	2412290916_30	2029-04-09
	29ASD09F	2419290908_08	2029-04-17
	29ASD09F	2419290908_11	2029-04-17
	29ASD09F	2419290908_14	2029-04-17
	29ASD09F	2419290908_15	2029-04-17
	29ASD09F	2419290908 16	2029-04-17
	29ASD09F	2419290908_30	2029-04-17
	29ASD09F	2425290904 03	2027-06-21
	29ASD09F	2425290904 04	2027-06-21
	29ASD09F	2425290904 05	2027-06-21
	29ASD09F	2425290904 06	2027-01-09
	29ASD09F	2432290904 01	2029-05-07
	29ASD09F	2432290904 02	2029-05-07
		2346290914 01	2029-01-23
gulla Flex II ASD 9;		—	
cclutech Pistol Push		2346290914_02	2029-01-23
	29ASD09P	2346290914_03	2029-01-23
	29ASD09P	2346290914_04	2029-01-23
	29ASD09P	2346290914_05	2029-01-23
	29ASD09P	2346290914_06	2029-01-23
	29ASD09P	2346290914_07	2029-01-23
	29ASD09P	2346290914_10	2029-01-23
	29ASD09P	2346290914_11	2029-01-23
	29ASD09P	2346290914 12	2029-01-23



Procedure pack	Procedure pack REF	Serial Number Implant	Expire Date
description			
	29ASD09P	2346290914_13	2029-01-23
	29ASD09P	2346290914_14	2029-01-23
	29ASD09P	2346290914_15	2029-01-23
	29ASD09P	2346290914_16	2029-01-23
	29ASD09P	2346290914_17	2029-01-23
	29ASD09P	2346290914_18	2029-01-23
	29ASD09P	2346290914_20	2029-01-23
	29ASD09P	2346290914_21	2029-01-23
	29ASD09P	2346290914_22	2029-01-23
	29ASD09P	2346290914_23	2029-01-23
	29ASD09P	2346290914_24	2029-01-23
	29ASD09P	2346290914_26	2029-01-23
	29ASD09P	2346290914_27	2029-01-23
	29ASD09P	2346290914 28	2029-01-23
	29ASD09P	2346290914 29	2029-01-23
	29ASD09P	2414290913 01	2029-03-17
	29ASD09P	2414290913 02	2029-03-17
	29ASD09P	2414290913 03	2029-03-17
	29ASD09P	2414290913 04	2029-03-17
	29ASD09P	2414290913 07	2029-03-17
	29ASD09P	2414290913 08	2029-03-17
	29ASD09P	2414290913_09	2029-03-17
	29ASD09P	2414290913_12	2029-03-17
	29ASD09P	2414290913_17	2029-03-17
	29ASD09P	2414290913_19	2029-03-17
	29ASD09P	2414290913_30	2029-03-17
	29ASD09P	2423290905_01	2029-04-29
	29ASD09P	2423290905_02	2029-04-29
	29ASD09P	2423290905_08	2029-04-29
	29ASD09P	2423290905_09	2029-04-29
	29ASD09P	2423290905_11	2029-04-29
	29ASD09P	2423290905_12	2029-04-29
	29ASD09P	2423290905_13	2029-04-29
	29ASD09P	2423290905_14	2029-04-29
	29ASD09P	2423290905_16	2029-04-29
	29ASD09P	2423290905_17	2029-04-29
	29ASD09P	2423290905_18	2029-04-29
	29ASD09P	2423290905_19	2029-04-29
	29ASD09P	2423290905 20	2029-04-29
	29ASD09P	2423290905 23	2029-04-29
	29ASD09P	2423290906 04	2029-04-29
	29ASD09P	2423290906_05	2029-04-29
	29ASD09P	2423290906 06	2029-04-29
	29ASD09P	2423290906 07	2029-04-29
	29ASD09P	2423290906 08	2029-04-29
Figulla Flex II ASD 10		2331291011 04	2029-04-29
 A. A. M. M. D. A. A. M. M.			
Flex-Pusher II	29ASD10F	2331291011_05	2028-05-02
	29ASD10F	2331291011_11	2028-05-02
	29ASD10F	2331291011_13	2028-05-02
	29ASD10F	2331291011_15	2028-05-02
	29ASD10F	2331291011_21	2028-05-02
	29ASD10F	2331291011_29	2028-05-02
	29ASD10F	2334291014_11	2028-11-01
	29ASD10F	2334291014_16	2028-11-01



Procedure pack	Procedure pack REF	Serial Number Implant	Expire Date
lescription			
	29ASD10F	2334291014_17	2028-11-01
	29ASD10F	2334291014_19	2028-11-01
	29ASD10F	2334291014_20	2028-11-01
	29ASD10F	2334291014_21	2028-11-01
	29ASD10F	2334291014_24	2028-11-01
	29ASD10F	2334291014_25	2028-11-01
	29ASD10F	2334291014 27	2028-11-01
	29ASD10F	2334291014 28	2028-11-01
	29ASD10F	2334291014 29	2028-11-01
	29ASD10F	2334291015 03	2028-05-02
	29ASD10F	2334291015 06	2028-05-02
	29ASD10F	2334291015 09	2028-05-02
	29ASD10F	2334291015 10	2028-05-02
	29ASD10F	2334291015 11	2028-05-02
	29ASD10F	2334291015 16	2028-05-02
	29ASD10F 29ASD10F	2334291015_16	2028-05-02
			THE REPORT OF A DESCRIPTION OF A DESCRIP
	29ASD10F	2334291015_24	2028-05-02
	29ASD10F	2334291015_25	2028-05-02
	29ASD10F	2334291015_26	2028-05-02
	29ASD10F	2336291004_02	2028-10-03
	29ASD10F	2336291004_04	2028-10-03
	29ASD10F	2336291004_05	2028-10-03
	29ASD10F	2336291004_06	2028-10-03
	29ASD10F	2336291004_07	2028-10-03
	29ASD10F	2336291004_09	2028-10-03
	29ASD10F	2336291004_10	2028-10-03
	29ASD10F	2336291004_12	2028-10-03
	29ASD10F	2336291004 13	2028-10-03
	29ASD10F	2336291004 19	2028-10-03
	29ASD10F	2336291004 20	2028-10-03
	29ASD10F	2336291004 21	2028-10-03
	29ASD10F	2336291004 24	2028-10-03
	29ASD10F	2336291004 26	2028-10-03
	29ASD10F	2336291004_27	2028-10-03
	29ASD10F	2336291004 28	2028-10-03
	29ASD10F	2336291005 02	2028-09-19
		La construit franchister de la construit de la	TERMINATION STRUCTURE AND ADDRESS
	29ASD10F	2336291005_04	2028-09-19
	29ASD10F	2336291005_05	2028-09-19
	29ASD10F	2336291005_08	2028-09-19
	29ASD10F	2336291005_09	2028-09-19
	29ASD10F	2336291005_10	2028-09-19
	29ASD10F	2336291005_11	2028-09-19
	29ASD10F	2336291005_12	2028-09-19
	29ASD10F	2336291005_14	2028-09-19
	29ASD10F	2336291005_15	2028-09-19
	29ASD10F	2336291005_16	2028-09-19
	29ASD10F	2336291005_18	2028-09-19
	29ASD10F	2336291005_21	2028-09-19
	29ASD10F	2336291005 22	2028-09-19
	29ASD10F	2336291005 23	2028-09-19
	29ASD10F	2336291005 26	2028-09-19
	29ASD10F	2336291005 27	2028-09-19
	29ASD10F	2336291005 28	2028-09-19
	29ASD10F 29ASD10F	2336291005_28	2028-09-19



Procedure pack	Procedure pack REF	Serial Number Implant	Expire Date
description			
	29ASD10F	2336291005_30	2028-09-19
	29ASD10F	2336291006_02	2028-05-02
	29ASD10F	2336291006_04	2028-05-02
	29ASD10F	2336291006 05	2028-05-02
	29ASD10F	2336291006_07	2028-05-02
	29ASD10F	2336291006 08	2028-05-02
	29ASD10F	2336291006 10	2028-05-02
	29ASD10F	2336291006 11	2028-05-02
	29ASD10F	2336291006 12	2028-05-02
	29ASD10F	2336291006 13	2028-05-02
	29ASD10F	2336291006 14	2028-05-02
	29ASD10F	2336291006 15	2028-05-02
	29ASD10F 29ASD10F		2028-05-02
		2336291006_18	
	29ASD10F	2336291006_19	2028-05-02
	29ASD10F	2336291006_20	2028-05-02
	29ASD10F	2336291006_26	2028-05-02
	29ASD10F	2336291006_28	2028-05-02
	29ASD10F	2336291007_03	2028-09-19
	29ASD10F	2336291007_04	2028-09-19
	29ASD10F	2336291007_05	2028-09-19
	29ASD10F	2336291007_06	2028-09-19
	29ASD10F	2336291007_07	2028-09-19
	29ASD10F	2336291007_08	2028-09-19
	29ASD10F	2336291007 09	2028-09-19
	29ASD10F	2336291007 11	2028-09-19
	29ASD10F	2336291007 12	2028-09-19
	29ASD10F	2336291007 13	2028-09-19
	29ASD10F	2336291007 15	2028-09-19
	29ASD10F	2336291007 16	2028-09-19
	29ASD10F	2336291007 21	2028-09-19
	29ASD10F	2336291007 22	2028-09-19
	29ASD10F	2336291007_22	2028-09-19
	29ASD10F 29ASD10F	2336291007_23	2028-09-19
			The Constraint All States and The States and the
	29ASD10F	2336291007_27	2028-09-19
	29ASD10F	2336291007_28	2028-09-19
	29ASD10F	2336291007_30	2028-09-19
	29ASD10F	2344291002_01	2028-10-03
	29ASD10F	2344291002_02	2028-10-03
	29ASD10F	2344291002_05	2028-10-03
	29ASD10F	2344291002_07	2028-10-03
	29ASD10F	2344291002_08	2028-10-03
	29ASD10F	2344291002_12	2028-10-03
	29ASD10F	2344291002_17	2028-10-03
	29ASD10F	2344291002_18	2028-10-03
	29ASD10F	2344291002 20	2028-10-03
	29ASD10F	2344291002 21	2028-10-03
	29ASD10F	2344291002 22	2028-10-03
	29ASD10F	2344291002 24	2027-03-21
	29ASD10F	2344291002 26	2027-03-21
	A	2344291002_20	
	29ASD10F		2027-03-21
	29ASD10F	2344291002_28	2027-03-21
	29ASD10F	2344291002_29	2027-03-21
	29ASD10F	2344291002_30	2027-03-21
	29ASD10F	2344291003_01	2028-10-03



Procedure pack	Procedure pack REF	Serial Number Implant	Expire Date
description	•		
	29ASD10F	2344291003_03	2028-10-03
	29ASD10F	2344291003 04	2028-10-03
	29ASD10F	2344291003 05	2028-10-03
	29ASD10F	2344291003 06	2028-10-03
	29ASD10F	2344291003 10	2028-10-03
	29ASD10F	2344291003 12	2028-10-03
	29ASD10F	2344291003 18	2028-10-03
	29ASD10F	2344291003 20	2028-10-03
	29ASD10F	2344291003 21	2028-10-03
	29ASD10F	2344291003 22	2028-10-03
	29ASD10F	2344291003 24	2028-10-03
	29ASD10F	2344291003 26	2028-10-03
	29ASD10F	2344291003 28	2028-10-03
	29ASD10F 29ASD10F	2346291015 03	2028-10-03
	29ASD10F 29ASD10F	2346291015_03	2028-10-22
	29ASD10F	2346291015_05	2028-10-22
	29ASD10F	2346291015_06	2028-10-22
	29ASD10F	2346291015_07	2028-10-22
	29ASD10F	2346291015_08	2028-10-22
	29ASD10F	2346291015_09	2028-10-22
	29ASD10F	2346291015_11	2028-10-22
	29ASD10F	2346291015_13	2028-10-22
	29ASD10F	2346291015_14	2028-10-22
	29ASD10F	2346291015_15	2028-10-22
	29ASD10F	2346291015_16	2028-10-22
	29ASD10F	2346291015_17	2028-10-22
	29ASD10F	2346291015_19	2028-10-22
	29ASD10F	2346291015_23	2028-10-22
	29ASD10F	2346291015_24	2028-10-22
	29ASD10F	2346291015_25	2028-10-22
	29ASD10F	2346291015_26	2028-10-22
	29ASD10F	2346291015_27	2028-10-22
	29ASD10F	2346291015 28	2028-10-22
	29ASD10F	2346291015_29	2028-10-22
	29ASD10F	2346291015 30	2028-10-22
	29ASD10F	2405291004 02	2029-02-12
	29ASD10F	2405291004 03	2029-02-12
	29ASD10F	2405291004 04	2029-02-12
	29ASD10F	2405291004 06	2029-02-12
	29ASD10F	2405291004 09	2029-02-12
	29ASD10F	2405291004 11	2029-02-12
	29ASD10F	2405291004 12	2029-02-12
	29ASD10F	2405291004 14	2029-02-12
	29ASD10F	2405291004_14	2029-02-12
	29ASD10F 29ASD10F	2405291004_18	2029-02-12
	29ASD10F 29ASD10F	2405291004_21	2029-02-12
	29ASD10F 29ASD10F	2405291004_22	2029-02-12
	29ASD10F 29ASD10F	2405291004_25	2029-02-12
	Contraction of the state of the		10000000000000000000000000000000000000
	29ASD10F	2405291004_26	2029-02-12
	29ASD10F	2405291004_27	2029-02-12
	29ASD10F	2405291004_29	2029-02-12
	29ASD10F	2405291004_30	2029-02-12
	29ASD10F	2408291012_01	2029-04-17
	29ASD10F	2408291012_02	2029-04-17



Procedure pack	Procedure pack REF	Serial Number Implant	Expire Date
lescription			
	29ASD10F	2408291012_05	2029-04-17
	29ASD10F	2408291012_06	2029-04-17
	29ASD10F	2408291013_02	2029-02-12
	29ASD10F	2408291013_04	2029-02-12
	29ASD10F	2408291013_05	2029-02-12
	29ASD10F	2408291013_06	2029-02-12
	29ASD10F	2408291013_07	2029-02-12
	29ASD10F	2408291013_08	2029-02-12
	29ASD10F	2408291013 09	2029-02-12
	29ASD10F	2408291013 10	2029-02-12
	29ASD10F	2408291013 11	2029-02-12
	29ASD10F	2408291013 13	2029-02-12
	29ASD10F	2408291013 22	2029-01-15
	29ASD10F	2408291013 23	2029-01-15
	29ASD10F	2408291013 24	2029-01-15
	29ASD10F	2411291016 02	2026-06-12
	29ASD10F	2411291016_02	2026-06-12
	29ASD10F 29ASD10F	2411291016_00	2026-06-12
		2411291016_07	2026-06-12
	29ASD10F		といわれたないはないか したれないか 一分二一の
	29ASD10F	2411291016_11	2026-06-12
	29ASD10F	2411291016_12	2026-05-14
	29ASD10F	2411291016_13	2026-05-14
	29ASD10F	2411291016_15	2026-05-14
	29ASD10F	2411291016_16	2026-05-14
	29ASD10F	2411291016_17	2026-05-14
	29ASD10F	2415291002_04	2029-04-09
	29ASD10F	2415291002_05	2029-04-09
	29ASD10F	2415291002_08	2029-04-09
	29ASD10F	2415291002_10	2029-04-09
	29ASD10F	2415291002_11	2029-04-09
	29ASD10F	2415291002 12	2029-04-09
	29ASD10F	2415291002 15	2029-04-09
	29ASD10F	2415291002 16	2029-04-09
	29ASD10F	2415291002_17	2029-04-09
	29ASD10F	2415291002 18	2029-04-09
	29ASD10F	2415291002 19	2029-04-09
	29ASD10F	2415291002_19	2029-04-09
	29ASD10F 29ASD10F	2415291002_22	2029-04-09
	29ASD10F 29ASD10F	2415291002_23	2029-04-09
		2415291002_24	2029-04-09
	29ASD10F		Independent of the service of
	29ASD10F	2415291002_27	2029-04-09
	29ASD10F	2415291002_30	2029-04-09
	29ASD10F	2418291014_01	2029-04-17
	29ASD10F	2418291014_02	2029-04-17
	29ASD10F	2418291014_03	2029-04-17
	29ASD10F	2418291014_05	2029-04-17
	29ASD10F	2418291014_06	2029-04-17
	29ASD10F	2418291014_07	2029-04-17
	29ASD10F	2418291014_09	2029-04-17
	29ASD10F	2418291014_11	2029-04-17
	29ASD10F	2418291014 12	2029-04-17
	29ASD10F	2418291014 14	2029-04-17
	29ASD10F	2418291014 15	2029-04-17
	29ASD10F	2418291014 16	2029-04-17



Procedure pack	Procedure pack REF	Serial Number Implant	Expire Date
description		2418291014 17	2029-04-17
	29ASD10F	2418291014 18	2029-04-17
	29ASD10F	2418291014 20	2029-04-17
	29ASD10F	2418291014 22	2029-04-17
	29ASD10F	2418291014 26	2029-04-17
	29ASD10F	2418291014_20	2029-04-17
	29ASD10F	2418291014_27	2029-04-17
	29ASD10F	2418291015_01	2029-05-07
	29ASD10F	2418291015_02	2029-05-07
	29ASD10F	2418291015_03	2029-05-07
	29ASD10F	2418291015_07	2029-05-07
	29ASD10F	2418291015_14	2029-05-07
	29ASD10F	2423291014_01	2029-05-13
	29ASD10F	2423291014_02	2029-05-13
	29ASD10F	2423291014_03	2029-05-13
	29ASD10F	2434291007_03	2029-04-29
	29ASD10F	2434291007_04	2029-04-29
	29ASD10F	2434291007_05	2029-04-29
	29ASD10F	2434291007_06	2029-04-29
	29ASD10F	2434291007_08	2029-04-29
	29ASD10F	2434291007 09	2029-04-29
	29ASD10F	2434291007 10	2029-04-29
	29ASD10F	2434291007 11	2029-04-29
	29ASD10F	2434291007 13	2029-04-29
	29ASD10F	2434291007 14	2029-04-29
	29ASD10F	2434291007 15	2029-04-29
	29ASD10F	2434291007 16	2029-04-29
	29ASD10F	2434291007 18	2029-04-29
	29ASD10F	2434291007 19	2029-04-29
	29ASD10F	2434291007_19	2029-04-29
	29ASD10F	2434291007_21	2029-04-29
			ELEPTRICE CERTS - LLAS - DA - LECCERTS
	29ASD10F	2434291007_23	2029-04-29
	29ASD10F	2434291007_24	2029-04-29
	29ASD10F	2434291007_26	2029-04-29
	29ASD10F	2434291007_27	2029-04-29
	29ASD10F	2434291007_30	2029-04-29
gulla Flex II ASD 10		2408291013_26	2029-02-26
cclutech Pistol Push	ner 29ASD10P	2408291013_18	2029-02-26
	29ASD10P	2403291002_28	2029-02-19
	29ASD10P	2403291002_29	2029-02-19
	29ASD10P	2403291002_27	2029-02-19
	29ASD10P	2411291015_18	2029-03-05
	29ASD10P	2411291015 17	2029-03-05
	29ASD10P	2411291015 16	2029-03-05
	29ASD10P	2427291022 29	2029-03-16
	29ASD10P	2408291013 29	2029-02-26
	29ASD10P	2411291015 05	2029-03-05
	29ASD10P	2415291003 13	2029-03-17
	29ASD10P	2411291015 24	2029-03-05
	29ASD10P	2411291015 29	2029-03-05
	29ASD10P 29ASD10P	2415291003 15	2029-03-05
			and a second second second second
	29ASD10P	2411291015_28	2029-03-05
	29ASD10P	2415291003_08	2029-03-17
	29ASD10P	2415291003_07	2029-03-17



Procedure pack	Procedure pack REF	Serial Number Implant	Expire Date
lescription			
	29ASD10P	2415291003_17	2029-03-17
	29ASD10P	2415291003_06	2029-03-17
	29ASD10P	2403291002_20	2029-02-19
	29ASD10P	2403291002_05	2029-02-19
	29ASD10P	2403291002 03	2029-02-19
	29ASD10P	2411291015 07	2029-03-05
	29ASD10P	2411291015 06	2029-03-05
	29ASD10P	2427291022 21	2029-03-16
	29ASD10P	2427291022 20	2029-03-16
	29ASD10P	2411291015 21	2029-03-05
	29ASD10P	2415291003 12	2029-03-17
	29ASD10P	2415291003 11	2029-03-17
	29ASD10P	2411291015 12	2029-03-05
	29ASD10P	2411291015 01	2029-03-05
	29ASD10P	2427291022 09	2029-03-16
	29ASD10P	2415291022_09	2029-03-10
	29ASD10P 29ASD10P	2408291013 19	2029-02-26
	29ASD10P	2411291015_10	2029-03-05 2029-03-05
	29ASD10P	2411291015_08	
	29ASD10P	2403291002_21	2029-02-19
	29ASD10P	2408291013_28	2029-02-26
	29ASD10P	2408291013_27	2029-02-26
	29ASD10P	2408291013_16	2029-02-26
	29ASD10P	2403291002_17	2029-02-19
	29ASD10P	2403291002_13	2029-02-19
	29ASD10P	2403291002_08	2029-02-19
	29ASD10P	2427291022_19	2029-03-16
	29ASD10P	2427291022_18	2029-03-16
	29ASD10P	2427291022_17	2029-03-16
	29ASD10P	2427291022 14	2029-03-16
	29ASD10P	2427291022 13	2029-03-16
	29ASD10P	2427291022 27	2029-03-16
	29ASD10P	2403291002 24	2029-02-19
	29ASD10P	2411291015_19	2029-03-05
	29ASD10P	2427291022 12	2029-03-16
	29ASD10P	2411291016 27	2029-04-23
	29ASD10P	2415291003 20	2029-04-23
	29ASD10P	2411291015 25	2029-03-05
	29ASD10P 29ASD10P	2411291015_25	2029-03-05
		A DEST DE SECONDE DA SECONDERSE DE SECONDE SECONDE DE SECONDE DE SECONDE DE SECONDE DE SECONDE SECONDE DE SECONDE SECONDE DE SECONDE DE SECONDE DE SECONDE SECONDE DE SECONDE S	2029-02-19
	29ASD10P	2403291002_26	INTERNICIPAL DEPLEMENTS
	29ASD10P	2403291002_25	2029-02-19
	29ASD10P	2411291015_13	2029-03-05
	29ASD10P	2403291002_18	2029-02-19
	29ASD10P	2411291015_22	2029-03-05
	29ASD10P	2408291013_15	2029-02-26
	29ASD10P	2408291013_14	2029-02-26
	29ASD10P	2408291013_21	2029-02-26
	29ASD10P	2408291013_20	2029-02-26
	29ASD10P	2411291016_26	2029-04-23
	29ASD10P	2411291016_19	2029-04-23
	29ASD10P	2415291003_18	2029-03-17
	29ASD10P	2411291015_15	2029-03-05
	29ASD10P	2411291015_14	2029-03-05
	29ASD10P	2403291002 01	2029-02-19

Attachment FSN-2024-002_List of affected products



Procedure pack description	Procedure pack REF	Serial Number Implant	Expire Date
	29ASD10P	2427291022_11	2029-03-16
	29ASD10P	2427291022_10	2029-03-16
	29ASD10P	2408291013_30	2029-02-26
	29ASD10P	2427291022_24	2029-03-16
	29ASD10P	2427291022_22	2029-03-16
	29ASD10P	2403291002_23	2029-02-19
	29ASD10P	2411291016_25	2029-04-23