



Occlutech International AB • Landskronavägen 2 • SE-252 32 Helsingborg • Sweden

FSN identifier: FSN-2024-002
FSCA identifier: FSCA-2024-002

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.



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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Previously distributed marketing materials, reporting ODSIII incorrect sizes, shall be considered outdated and not valid.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:

1. 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.
2. A written confirmation of the receipt, the reading and understanding of the Field Safety Notice should be provided to info.mds@occlutech.com. 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.



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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.



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Contact reference Customer Service:

Occlutech International AB
Landskronavägen 2
SE-252 32 Helsingborg,
Sweden

Contact Email address: order@occlutech.com
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.

Signiert von:

Name des Unterzeichners: Morwan Choli
Signiergrund: Ich genehmige dieses Dokument
Signierzeit: 2024-12-11 | 7:28:46 PM MEZ
00975642173D49F8AB3EC4927D9BDE9F

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

Procedure pack description	Procedure pack REF	Serial Number Implant	Expire Date
Figulla Flex II ASD 9; Flex-Pusher II	29ASD09F	2331290909_01	2028-10-03
	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	2331290909_27	2028-10-03
	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_10	2028-10-03
	29ASD09F	2344290901_11	2028-10-03
	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	2403290901_07	2029-02-12
	29ASD09F	2403290901_08	2029-02-12
	29ASD09F	2403290901_10	2029-02-12

Procedure pack description	Procedure pack REF	Serial Number Implant	Expire Date
	29ASD09F	2403290901 11	2029-02-12
	29ASD09F	2403290901 12	2029-02-12
	29ASD09F	2403290901 13	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
Figulla Flex II ASD 9; Occlutech Pistol Pusher	29ASD09P	2346290914 01	2029-01-23
	29ASD09P	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 description	Procedure pack REF	Serial Number Implant	Expire Date
	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 10,5; Flex-Pusher II	29ASD10F	2331291011 04	2028-05-02
	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 description	Procedure pack REF	Serial Number Implant	Expire Date
	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	2334291015 17	2028-05-02
	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
	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	2336291005 29	2028-09-19

Procedure pack description	Procedure pack REF	Serial Number Implant	Expire Date
	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	2336291006 18	2028-05-02
	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
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	29ASD10F	2336291007 09	2028-09-19
	29ASD10F	2336291007 11	2028-09-19
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	29ASD10F	2336291007 16	2028-09-19
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	29ASD10F	2336291007 24	2028-09-19
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	29ASD10F	2336291007 28	2028-09-19
	29ASD10F	2336291007 30	2028-09-19
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	29ASD10F	2344291002 02	2028-10-03
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	29ASD10F	2344291002 07	2028-10-03
	29ASD10F	2344291002 08	2028-10-03
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	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
	29ASD10F	2344291002 27	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 description	Procedure pack REF	Serial Number Implant	Expire Date
	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	2346291015 03	2028-10-22
	29ASD10F	2346291015 04	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
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	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 description	Procedure pack REF	Serial Number Implant	Expire Date
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	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 06	2026-06-12
	29ASD10F	2411291016 07	2026-06-12
	29ASD10F	2411291016 10	2026-06-12
	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
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	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
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Procedure pack description	Procedure pack REF	Serial Number Implant	Expire Date
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	29ASD10F	2418291014 28	2029-04-17
	29ASD10F	2418291015 01	2029-05-07
	29ASD10F	2418291015 02	2029-05-07
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	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
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Figulla Flex II ASD 10,5; Occlutech Pistol Pusher	29ASD10P	2408291013 26	2029-02-26
	29ASD10P	2408291013 18	2029-02-26
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	29ASD10P	2427291022 29	2029-03-16
	29ASD10P	2408291013 29	2029-02-26
	29ASD10P	2411291015 05	2029-03-05
	29ASD10P	2415291003 13	2029-03-17
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Procedure pack description	Procedure pack REF	Serial Number Implant	Expire Date
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	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	2415291003 28	2029-03-17
	29ASD10P	2408291013 19	2029-02-26
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	29ASD10P	2403291002 21	2029-02-19
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	29ASD10P	2408291013 16	2029-02-26
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	29ASD10P	2403291002 08	2029-02-19
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	29ASD10P	2427291022 18	2029-03-16
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Procedure pack description	Procedure pack REF	Serial Number Implant	Expire Date
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	29ASD10P	2427291022_24	2029-03-16
	29ASD10P	2427291022_22	2029-03-16
	29ASD10P	2403291002_23	2029-02-19
	29ASD10P	2411291016_25	2029-04-23