El INVIMA informa a los usuarios en general que el Grupo de Tecnovigilancia ha emitido una comunicación relacionada con un Retiro de Producto del Mercado asociado a:

NOMBRE DEL DISPOSITIVO MÉDICO	Suturas y Ligaduras Quirúrgicas CARDIOXYL / CARDIOFLON
NO. IDENTIFICACIÓN RISARH	R1410-399
REFERENCIAS DEL DISPOSITIVO MEDICO	Para CARDIOFLON: 19P20Q, 19P30AC, 19P30AE, 19P30AK, 19P30AN, 19P30AQ, 19P30N, 19P30R, 19P30S, 19P30T, 19P30U, 19P30V, 19P30X, 19S15A, 19S15G, 19S20J, 19S20R, 19S30AB, 19S30AE, 19S30AK, 19S30AQ, 19S30AW, 19S30AX, 19S30AY, 19S30B, 19S30C, 19S30Z, 19S35A. Para CARDIOXYL: 73P20B, 73P30AA, 73P30AG, 73P30AI, 73P30AM, 73P30AN, 73P30BQ, 73P30CN, 73P30CR, 73P30D, 73P30E, 73P30F, 73P30O, 73P30P, 73P30Q, 73P30R, 73P30T, 73P30U, 73P30V, 73P30U, 73P30Y, 73P35E, 73S10H, 73S30AE, 73S30AT", lotes específicos.
REGISTRO SANITARIO	2010DM-0006207
INDICACIONES Y USO ESTABLECIDOS	Usado en cirugía cardiovascular, implante de anillo y válvula cardiaca, implante de parche, seguridad de drenaje toraxico, EEC para asegurar las cánulas, apertura costal y esternal.
NOMBRE DEL FABRICANTE	Peters Surgical
DESCRIPCION DEL PROBLEMA	El fabricante determinó que el tratamiento de superficie de los extremos del hilo puede desprenderse ocasionando microfragmentos que pueden ocluir vasos pequeños, conllevando a que se presenten potencialmente eventos adversos sobre el paciente.
FUENTE	ANEXO 1
FECHA DE NOTIFICACION	03 de Octubre de 2014

RECOMENDACIÓN:

En caso de identificar la existencia del producto mencionado anteriormente comuníquese con su proveedor quien determinara las acciones que se llevaran a cabo.

Es importante mantener un estado de alerta, realizando un seguimiento permanente a los productos que se fabrican y/o comercializan en el país, divulgando la información de seguridad respectiva entre los profesionales de la salud que realizan uso de estos recursos tecnológicos.

Para mayor información comuníquese al teléfono 2948700 extensión 3880 en Bogotá, ó al correo electrónico tecnovigilancia@invima.gov.co

ANEXO 1

A22628 01 - Normal Priority Medical Device Alert

Medical Device Ongoing Action
Updated: October 1, 2014
UMDNS Terms:
- Sutures, Synthetic, Nonabsorbable, Polyester, Monofilament [22902]
- Sutures, Synthetic, Nonabsorbable, Polyester, Multifilament [22903]

Suggested Distribution:
- Dermatology
- Emergency/Outpatient Services
- Materials Management
- Nursing
- OR/Surgery

Geographic Regions:
- (Impact in specific regions has not been identified or ruled out at the time of this posting)
- Worldwide

*Péters Surgical—Various Sutures: Surface Treatment of Thread Ends May Split [Update]

Product Identifier:

Synthetic Non-Absorbable Surgical Sutures:	Item Reference Nos.:	GTIN on Box Labels:	Batch Nos.:
CARDIOFLON Evolution	19P20Q	3661522034989	1135 EXP OCT 2018
CARDIOFLON Evolution	19P30AC	3661522034446	942720 EXP MAR 2018
CARDIOFLON Evolution	19P30AE	3661522034477	7627 EXP APR 2019, 942910 EXP FEB 2018, 971670 EXP MAY 2018
CARDIOFLON Evolution	19P30AK	3661522034552	942530 EXP MAR 2018, 978580 EXP JUN 2018
CARDIOFLON Evolution	19P30AN	3661522034576	942500 EXP FEB 2018
CARDIOFLON Evolution	19P30AQ	3661522034606	2480 EXP OCT 2018, 5508 EXP FEB 2018, 994990 EXP JUL 2018, 1008710 EXP AUG 2018
CARDIOFLON Evolution	19P30N	3661522034262	942420 EXP FEB 2018
CARDIOFLON Evolution	19P30R	3661522034279	4370 EXP JAN 2019, 5021 EXP JAN 2019, 5557 EXP FEB 2019, 948700 EXP MAR 2018, 978410 EXP JUN 2018
CARDIOFLON Evolution	19P30S	3661522034323	994580 EXP JUL 2018
CARDIOFLON Evolution	19P30T	3661522034347	4371 EXP JAN 2019, 4974 EXP JAN 2019, 948740 EXP MAR 2018
CARDIOFLON Evolution	19P30U	3661522034354	948770 EXP MAR 2018
CARDIOFLON Evolution	19P30V	3661522034286	4372 EXP JAN 2019, 948790 EXP MAR 2018, 992210 EXP JUL 2018

CARDIOFLON Evolution	19P30X	3661522034392	967150 EXP MAY 2018, 999390 EXP SEP 2018
CARDIOFLON Evolution	19S15A	3661522035009	2192 EXP OCT 2018
CARDIOFLON Evolution	19S15G	3661522035061	2195 EXP OCT 2018, 2440 EXP OCT 2018, 942960 EXP FEB 2018, 970060 EXP MAY 2018, 982470 EXP JUN 2018, 994930 EXP JUL 2018
CARDIOFLON Evolution	19S20J	3661522034910	942940 EXP MAY 2018, 966100 EXP AUG 2018
CARDIOFLON Evolution	19S20R	3661522037539	1872 EXP SEP 2018
CARDIOFLON Evolution	19S30AB	3661522034439	7057 EXP APR 2019, 991250 EXP JUL 2018, 999910 EXP AUG 2018
CARDIOFLON Evolution	19S30AE	3661522034460	942400 EXP MAR 2018, 984600 EXP JUN 2018
CARDIOFLON Evolution	19S30AK	3661522034538	942510 EXP FEB 2018, 992600 EXP JUL 2018, 1011370 EXP SEP 2018
CARDIOFLON Evolution	19S30AQ	3661522034590	942580 EXP MAR 2018
CARDIOFLON Evolution	19S30AW	3661522037492	1485 EXP SEP 2018
CARDIOFLON Evolution	19S30AX	3661522037508	1486 EXP SEP 2018
CARDIOFLON Evolution	19S30AY	3661522037515	1487 EXP SEP 2018
CARDIOFLON Evolution	19S30B	3661522034118	3403 EXP JAN 2019, 5136 EXP FEB 2019, 6222 EXP FEB 2019, 942350 EXP MAR 2018, 1009510 EXP AUG 2018

CARDIOFLON Evolution	19S30C	3661522034125	3995 EXP JAN 2019, 4920 EXP JAN 2019, 5158 EXP FEB 2019, 6554 EXP MAR 2019, 977760 EXP JUN 2018, 988910 EXP JUL 2018
CARDIOFLON Evolution	19S30Z	3661522034415	942670 EXP MAR 2018
CARDIOFLON Evolution	19S35A	3661522034675	942760 EXP APR 2018
CARDIOXYL	73P20B	3661522016527	1902 EXP SEP 2018, 987180 EXP JUL 2018, 997390 EXP AUG 2018
CARDIOXYL	73P30AA	3661522016701	932870 EXP FEB 2018
CARDIOXYL	73P30AG	3661522029510	931880 EXP DEC 2017, 932880 EXP JAN 2018, 952490 EXP MAR 2018, 954720 EXP APR 2018, 961280 EXP JUN 2018, 967610 EXP JUL 2018, 967620 EXP OCT 2018, E04258 EXP DEC 2018
CARDIOXYL	73P30AI	3661522016923	2415 EXP OCT 2018, 911280 EXP NOV 2017, 953070 EXP MAR 2018, 997980 EXP SEP 2018
CARDIOXYL	73P30AM	3661522024348	5006 EXP JAN 2019, 913570 EXP DEC 2017
CARDIOXYL	73P30AN	3661522024256	4282 EXP DEC 2018, 904700 EXP DEC 2017, 961770 EXP APR 2018, 989950 EXP AUG 2018
CARDIOXYL	73P30BQ	3661522030004	6068 EXP FEB 2019
CARDIOXYL	73P30CN	3661522033265	5884 EXP FEB 2019, 933320 EXP JAN 2018, 950890 EXP MAR 2018, 967120 EXP MAY 2018, 967660 EXP MAY 2018, 967670 EXP JUL 2018, 967680 EXP OCT 2018

CARDIOXYL	73P30CR	3661522033456	953110 EXP MAR 2018, 967190 EXP MAY 2018, 967490 EXP MAY 2018, 967540 EXP JUL 2018, 967550 EXP OCT 2018
CARDIOXYL	73P30D	3661522011829	2965 EXP NOV 2018, 962430 EXP MAR 2018, 985250 EXP JUL 2018, 1002680 EXP AUG 2018
CARDIOXYL	73P30E	3661522011836	352 EXP NOV 2018, 4145 EXP FEB 2019, 945250 EXP MAR 2018, 953660 APR 2018, 989250 EXP JUL 2018
CARDIOXYL	73P30F	3661522011843	3845 EXP DEC 2018, 994880 EXP JUL 2018
CARDIOXYL	73P30O	3661522011904	866 EXP OCT 2018, 4174 EXP JAN 2019, 911760 EXP DEC 2017, 923610 EXP DEC 2017, 994970 EXP JUL 2018
CARDIOXYL	73P30P	3661522011911	1136 EXP OCT 2018, 4937 EXP JAN 2019
CARDIOXYL	73P30Q	3661522011928	3426 EXP NOV 2018, 933160 EXP JAN 2018, 987680 EXP JUL 2018, 990070 EXP JUL 2018, 999820 EXP OCT 2018
CARDIOXYL	73P30R	3661522011935	4114 EXP JAN 2019
CARDIOXYL	73P30T	3661522011959	950930 EXP MAR 2018, 967130 EXP MAY 2018
CARDIOXYL	73P30U	3661522014103	1543 EXP SEP 2018, 4168 EXP FEB 2019, 916660 EXP DEC 2017, 930430 EXP DEC 2017, 970800 EXP MAY 2018, 985280 EXP JUL 2018

CARDIOXYL	73P30V	3661522014110	2446 EXP OCT 2018, 3656 EXP NOV 2018, 4126 EXP JAN 2019, 4127 EXP MAR 2019, 972030 EXP MAY 2018, 1007320 EXP AUG 2018
CARDIOXYL	73P30U	3661522014103	970800 EXP MAY 2018, 985280 EXP JUL 2018
CARDIOXYL	73P30Y	3661522016268	899000 EXP NOV 2017, 915630 EXP DEC 2017, 992250 EXP JUL 2018
CARDIOXYL	73P35E	3661522024409	956930 EXP APR 2018, 964930 EXP MAY 2018
CARDIOXYL	73S10H	3661522029961	944410 EXP FEB 2018, 999710 EXP AUG 2018
CARDIOXYL	73S30AE	3661522016466	938640 EXP FEB 2018
CARDIOXYL	73S30AT	3661522021637	940360 EXP FEB 2018
SURGIKIT	Not listed	Not listed	Not listed

[Consumable]

Distributor:
- MED Alliance Group Inc3825 Commerce Dr, St. Charles, IL 60174, United States

Manufacturer:
- Péters Surgical42 rue Benoit Frachon, ZI Les Vignes, 93013 Bobigny Cedex, France

Summary:
This Alert provides additional information based on FDA Center for Devices and Radiological Health (CDRH) source material regarding Alert Accession No. A22628. FDA's CDRH states that the manufacturer notified MED Alliance, the sole U.S. distributor, of the recall by e-mail on July 16, 2014. FDA's CDRH also states that MED Alliance initiated a subrecall by Voluntary Product Recall Withdrawal letter dated June 25, 2014. Additional information is provided in the following fields:
- Product Identifier (see bolded information)
- Geographic Regions field (see bolded region)
- Action Needed

Problem:
[July 21, 2014]
In June 17, 2014 Important and Urgent Batch Recall Procedure letter posted by the U.K. Medicines and Healthcare Products Regulatory Agency (MHRA) and the German Federal Institute for Drugs and Medical Devices (BfArM), Péters Surgical states that the surface treatment of the thread ends on the above sutures may split, potentially leading to occlusions of small vessels by the detached microfragments of the treatment substance. Péters Surgical also states that this problem can be identified by a simple visual inspection of the sutures, that it does not affect all sutures, and that it does not compromise the integrity and quality of the sutures, which are compliant with the pharmacopeias in force. The manufacturer has not confirmed the information provided in the source material.

Action Needed:
Identify, isolate, and discontinue use of any affected product in your inventory. If you have affected product purchased from MED Alliance, verify that you have received the June 25, 2014, Voluntary Product Recall Withdrawal letter and Returned Good Authorization (RGA) Form from MED Alliance. To arrange for product return, contact MED Alliance by telephone or e-mail using the information below. Complete the RGA Form, and return it to MED Alliance using the instructions on the form. Return affected product to MED Alliance.

If you have purchased affected product from Péters Surgical, verify that you have received the June 17, 2014, Important Urgent Batch Recall Procedure letter and reply form from Péters Surgical. Complete the reply form, and return it to Péters Surgical using the instructions on the form.

For Further Information:
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Website: Click here

References:
United States:
- Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall Peters Surgical CARDIOFLON Evolution [online]. 2014 Sep 22 [cited 2014 Sep 24]. Available from Internet: Click here.
- Food and Drug Administration. Center for Devices and Radiological Health. Class 2 device recall Peters Surgical CARDIOXYL [online]. 2014 Sep 22 [cited 2014 Sep 24]. Available from Internet: Click here.

Great Britain. Medicines and Healthcare Products Regulatory Agency. Peters Surgical. Suture, non-absorbable. CARDIOXYL ®, CARDIOFLON® Evolution, SURGIKIT®[online]. London: Department of Health; 2014 Jun 30 [cited 2014 Jul 18]. (Field safety notice; reference no. 2014/006/026/081/036) Available from Internet: Click here.
Germany. Federal Institute for Drugs and Medical Devices. Recall for the products Cardioxyl®, Cardioflon® Evolution und Surgikit®, Péters Surgical [online]. 2014 Jul 1 [cited 2014 Jul 18]. Available from Internet: Click here.

Comment:
- This alert is a living document and may be updated when ECRI Institute receives additional information. In circumstances in which we determine that it is appropriate for customers to repeat their review of an issue (e.g., when additional affected product has been identified), we will post a separate update alert. In other cases, we may add information, such as additional commentary, recommendations, and/or source documents, to the original alert. For additional information regarding the format of this alert, refer to our HDA Format Guide.

Source(s):
- 2014 Sep 24. FDA CDRH Database. Class II. Z-2675/2676-2014
- 2014 Sep 24. MHRA FSN. 2014/006/026/081/036
- 2014 Sep 24. MHRA FSN. O. Ref: MRS/14-080 (includes reply form)
- 2014 Sep 24. BfArM (Germany). 3529/14
- 2014 Sep 24. BfArM (Germany). O. Ref.: MRS/14-080 (includes reply form)