Central Drugs Standard Control Organization
Directorate General of Health Services
Ministry of Health and Family Welfare
Government of India
(Medical Devices and Diagnostics Division)
Email: ddcimd-cdsco@nic.in

Food & Drugs Administration Bhawan,
Kotla Road, New Delhi.

F.No. 29/Misc./03/2021-DC(276) **Date: 21th June 2022**

MEDICAL DEVICE ALERT

DEVICE

PALMAZ GENESIS® Peripheral Stent on OPTA® PRO .035" Delivery System (PG2990PPX-82178943, PG2990PPX-82211305, PG3990PPS-82182764, PG3990PPX-82212989, PG3990PPX-82218097)

BACKGROUND

The Cordis PALMAZ GENESIS® Peripheral Stent on OPTA® PRO .035 Delivery System is intended for use in the treatment of atherosclerotic disease of peripheral arteries below the aortic arch.

Cordis released Distributed Product Risk Assessment Form dated 18.05.2022 indicating increased complaint rate for stent dislodgement

Reason for Recall

Cordis noted an increased trend in complaints for stent dislodgement and associated failure modes related to two specific sizes of the PALMAZ GENESIS® Stent on OPTA® PRO .035 Delivery System that were produced during a particular timeframe (October 2019 to April 2021). Identified through complaint trending analysis which consists of evaluating complaints based on key demographics used to identify potential commonalities. In this case there were manufacturing months with elevated complaint rates which upon further analysis identified the noted time period and product sizes to have an elevated rate when compared to the surrounding months. The potential impacts of stent dislodgement include an intra-procedural delay as the device is exchanged for another or may result in complications such as: unplanned percutaneous or surgical intervention, GI tract trauma or perforation. The recall is being undertaken due to stent dislodgement prior to or during placement and does not affect PALMAZ GENESIS stents that have been successfully deployed. To date, there have been no deaths or serious long

term health sequelae, such as strokes, in the use of these involved complaint devices.

Potential hazards(s) and harm(s), and any immediate and /orlong range health consequences

- **User interaction with the affected device/component**: Balloon expandable stents are intended to be used as a scaffolding within a lesion or stricture to help maintain patency and improve the flow of blood and other body fluids. The Palmaz family of stents are intended for use in the peripheral vascular and the stent is delivered to the target on a balloon catheter called a stent delivery system.
- **Immediate and long Range Health Consequences**: If movement of the stent is detected before or during the procedure, the device can be exchanged resulting in an intra-procedural delay. If the stent is loose or inaccurately crimped on the balloon the stent may not be placed where intended in the target vessel. This may result in the need for additional stents to complete the procedure. In the event that none of these percutaneous methods are visible or successful the stent may be removed surgically.
  Therefore, the severity of the potential harm of a stent that dislodges from the stent delivery system is *Critical.*
- **Indirect Health Consequences**: None

Important Note: CDSCO have not received any complaints from the market on this issue.

FURTHER DETAILS & CONTACTS

M/s Cordis Cashel, Ireland has released Distributed Product Risk Assessment Form dated 18.05.2022 which is attached herewith this alert.

M/s Cardinal Health Medical Products India Pvt. Ltd.,
Bldg No. A3, Unit No. E, Babosa Ind Park, Mumbai Nashik Highway NH3,
Saravali Village, Bhiwandi,
Dist-Thane, Tal-Bhiwandi-14 (Thane Z5),
Thane, Maharashtra (India)-421302
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Distributed Product Risk Assessment Form

DPRA 100603990

Section 1: Background

Product Name(s) and Marketing Status

PALMAZ® GENESIS™ on OPTA™ Pro

Catalog Number(s)

US and Canada:

PG2990BPS
PG2990BPX
PG3990BPS
PG3990BPX

Other Countries:

PG2990PPS
PG2990PPX
PG3990PPS
PG3990PPX

Note: Each size consists of 4 catalog codes with the only difference being the delivery shaft length and the labeling for the 2 different markets.

Lot Number(s)

82178943	82178944	82180267	82182764	82184215	82184806	82185924	82191321
82191527	82191727	82193089	82193097	82195965	82206059	82208524	82208532
82208537	82211296	82211305	82212821	82212989	82218097	82218087	82208528

Business Unit/ Site

Legal Manufacturer
Cordis Cashel
Cahir Road, Cashel
Co. Tipperary
Ireland

External Manufacturer
Confluent Medical Technology, Inc
Costa Rica, S.R.L.,
Coyol Free Zone, Building B25
El Coyol, Alajuela, Costa Rica

Country or Region Where Distributed

☑ **US**	☑ **Europe EU**	☑ **Europe Non-EU**	☐ **Japan**
☑ **Asia Pacific**	☑ **Latin America**	☑ **Canada**	☐ **Australia**

Trigger Event/ Date

☐ **High Severity Event**

☑ **Complaint rate exceeds threshold (significant trend)**

☐ **Nonconformance potentially affecting distributed product**

☐ **Manufacturing or design confirmed Malfunction**

☐ **Other:** _____

Description Of The Product Issue Under Review : Increased complaint rate for stent dislodgement
Date this DPRA was initiated: 4/13/2022
Date issue was first discovered: 4/13/2022 Decision to initiate DPRA to determine risk
How issue was first discovered: Increase in complaints for SDS Stent dislodgment

Detailed Issue Description

An increase in complaints of Palmaz Genesis stent dislodgment and associated failure modes was identified for the manufacturing time period of October 2019 thru April 2021.

In March 2021, the issue was escalated by the Product Safety Clinician to the Cordis EM team and Confluent. An investigation by Confluent (COMP-00026) concluded that there was no evidence to show that the customer complaints were related to manufacturing deficiencies.

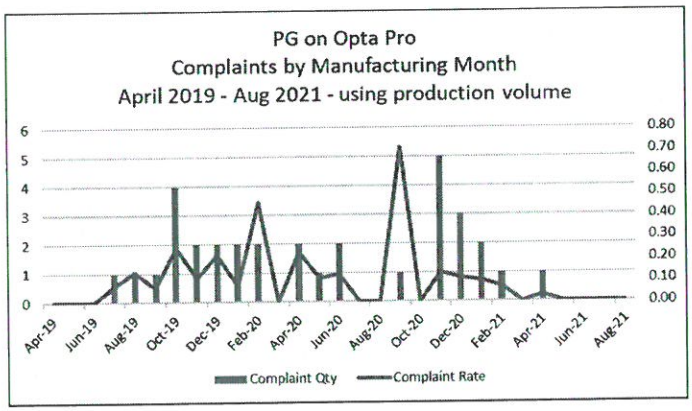
In February 2022, the Product Safety Clinician escalated concerns of stent dislodgment to an action item via Monthly Complaint Review Meeting.

In March 2022, Product Safety Clinician presented data that identified an increase in complaints for 2021. Additional review requested to be conducted by EM Manufacturing team.

In April 2022, the decision was made to initiate a risk assessment to further capture the investigation, assess the risk to the patient and escalate accordingly. As part of that investigation, an assessment of the complaint data was pefromed to determine if any trends could be identified. A total of 105 complaints were identified for the time period Jan 2017 to Feb 2022 and further analyzed. 42 events implied a strong correlation between the failure and procedural/handling factors (force applied, off label use, etc.). Of the remaining 63 events Palmaz Genesis on Opta Pro (table below) was identified to have a rate above the expected occurrence per the SDS family risk management documents and was the driver of the identified increase in complaints.

Product	Complaint Rate%
PG_OPTA	0.07
BLUE_AVIATOR	0.01
BLUE_SLALOM	0.01
PG_AMIIA	0.00
PG_SLALOM	0.00
Total	**0.04**

The complaint data for PG on Opta Pro was further analyzed and revealed the start of the increase in complaint rates was for lots linked to a manufacturing timeperiod starting in October 2019 and continuing through to April 2021.



The data was further refined to focus on products manufactured between Oct 2019 and Aprl 2021. The data

revealed that the 2990 and 3990 product sizes were the main contributer to the increase in complaints.

Stent/Balloon Size	Complaint Count	Rate of total Distributed
2990	10	0.021
3990	8	0.017
2980	3	0.006
2590	1	0.002
2910	1	0.002
3910	3	0.006
2510	1	0.002
5980	1	0.002
2480	1	0.002
2960	1	0.002
2970	1	0.002
5990	1	0.002

Design or Manufacturing Factors Related to Issue

Manufacturing Factors That May Contribute To Product Risk: The following manufacturing processes and failure modes have been identified in the pFMEA (owned by Confluent) as potential causes for stent dislodgement. As part of the investigation, these processes are being assessed to determine root cause. To date, all processes are operating as intended and product is conforming. The investigation is ongoing.

Process name / Function	Potential Failure Mode	Potential Cause(s)	Process Defect
Pre-Crimping	Incorrect mandrel	Procedure not followed	Incorrect mandrel
	Incorrect protective tube	Operator Error Handling/ procedure not followed	Incorrect protective tube
	incorrect time	Operator Error Handling/ procedure not followed	incorrect time
	Incorrect closing pressure	Operator Error Handling/ procedure not followed	Incorrect closing pressure
Crimping	Incorrect mandrel	Operator Error Handling/ procedure not followed	Incorrect mandrel
	Incorrect protective tube	Operator Error Handling/ procedure not followed	Incorrect protective tube
	Incorrect Time	Operator Error Handling/ procedure not followed	Incorrect Time
	Incorrect closing pressure	Operator Error Handling/ procedure not followed	Incorrect closing pressure
Nesting	Incorrect protective tube	Operator Error Handling/ procedure not followed	Incorrect protective tube
	Incorrect Die	Incorrect set up/ setup procedure not followed	Incorrect Die
Plasma treatment	Incorrect Pressure	Incorrect set up/ setup procedure not followed	Incorrect Pressure
	Incorrect time	Incorrect set up/ setup procedure not followed	Incorrect time
	Incorrect potency	Incorrect set up/ setup procedure not followed	Incorrect potency

Design Factors That Might Contribute To The Product Risk: No design factors have been identified to contribute to the product risk.

Root Cause: Cordis has initiated a supplier corrective action, CA-MIA-02719 to investigate and determine corrective actions. This investigation consisted of a review of DHR's, training records, scrap rates and nonconformances with a focus on the processes that secure the stent to the balloon of the catheter. Process walk-throughs have been conducted along with a review of the stent retention testing used as an input for

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lot release as well as any significant events that occurred around the start of the increase in complaint lots linked to a manufacturing month starting in October 2019 and returning to expected levels before April of 2021. It was noted that in April 2021, the following was done: 1) an awareness training was conducted to heighten operator awareness of the procedures related to stent crimping and nesting and 2) maintenance was performed on equipment related to stent crimping and nesting to evaluate equipment performance. This correlates with the end of the noted increase in the complaint lots per manufacturing month and aligns with the timeperiod in question of October 2019 to April of 2021.

Investigations focused on the stent securing process has not identified a root cause thus far and the investigation is continuing via CA-MIA-02719.

Risk Document Review

The process FMEA pFMEA-10069 Rev A was reviewed. All known potential causes have been captured. Reference Section 3 for review of harms and severities.

ID #	Process name / Function	Potential Failure Mode	Potential Effect	Severity rank	Potential Cause(s)	Occurrence rank	Detect rank	RPN	Detection Method and Controls	Comments/ Actions	Defect Class	Process Defect
1.2.1.1 P	Pre-Crimping	Incorrect mandrel	Stent Dislodgement	8	Procedure not followed	2	1	16	PPEVI	WI-09004	I	Incorrect mandrel
1.2.2.1 P		Incorrect protective tube	Stent Dislodgement	8	Operator Error Handling/ procedure not followed	2	1	16	PPEVI	WI-09004	I	Incorrect protective tube
1.2.3.1 P		incorrect time	Stent Dislodgement	8	Operator Error Handling/ procedure not followed	2	1	16	PPEVI	WI-09004	I	incorrect time
1.2.4.1 P		Incorrect closing pressure	Stent Dislodgement	8	Operator Error Handling/ procedure not followed	2	1	16	PPEVI	WI-09004	I	Incorrect closing pressure
1.3.1.1 P	Crimping - Slalom and Aviator only	Incorrect mandrel	Stent Dislodgement	8	Operator Error Handling/ procedure not followed	2	1	16	PPEVI	WI-09005	I	Incorrect mandrel
1.3.2.1 P		Incorrect protective tube	Stent Dislodgement	8	Operator Error Handling/ procedure not followed	2	1	16	PPEVI	WI-09005	I	Incorrect protective tube
1.3.3.1 P		Incorrect Time	Stent Dislodgement	8	Incorrect Set-up/ setup procedure not followed	2	1	16	PPEVI	WI-09005	I	Incorrect Time
1.3.4.1 P		Incorrect closing pressure	Stent Dislodgement	8	Incorrect Set-up/ setup procedure not followed	2	1	16	PPEVI	WI-09005	I	Incorrect closing pressure
1.3.5.1 P		Incorrect temperature	Stent Dislodgement	8	Incorrect Set-up/ setup procedure not followed	2	1	16	PPEVI	WI-09005	I	Incorrect temperature
1.4.1.1 P	Crimping	Incorrect mandrel	Stent Dislodgement	8	Operator Error Handling/ procedure not followed	2	1	16	PPEVI	WI-09005	I	Incorrect mandrel
1.4.2.1 P		Incorrect protective tube	Stent Dislodgement	8	Operator Error Handling/ procedure not followed	2	1	16	PPEVI	WI-09005	I	Incorrect protective tube
1.4.3.1 P		Incorrect Time	Stent Dislodgement	8	Operator Error Handling/ procedure not followed	2	1	16	PPEVI	WI-09005	I	Incorrect Time
1.4.4.1 P		Incorrect closing pressure	Stent Dislodgement	8	Operator Error Handling/ procedure not followed	2	1	16	PPEVI	WI-09005	I	Incorrect closing pressure
1.5.1.1 P	Nesting	Incorrect protective tube	Stent Dislodgement	8	Operator Error Handling/ procedure not followed	2	1	16	PPEVI	WI-09007	I	Incorrect protective tube
1.5.2.1 P		Incorrect Die	Stent Dislodgement	8	Incorrect set up/ setup procedure not followed	2	1	16	PPEVI	WI-09007	I	Incorrect Die
1.6.1.1 P	Plasma treatment	Incorrect Pressure	Stent Dislodgement	8	Incorrect set up/ setup procedure not followed	2	6	96	PPEVI / Pull test (Ansi)	WI-09010	I	Incorrect Pressure
1.6.2.1 P		Incorrect time	Stent Dislodgement	8	Incorrect set up/ setup procedure not followed	2	6	96	PPEVI / Pull test (Ansi)	WI-09010	I	Incorrect time
1.6.3.1 P		Incorrect potency	Stent Dislodgement	8	Incorrect set up/ setup procedure not followed	2	6	96	PPEVI / Pull test (Ansi)	WI-09010	I	Incorrect potency

Product Range Impact

Total Number of devices in distribution: At the time of this assessment:

Catalog Code	Sum of Qty Distributed	Sum of Qty in Cordis Control
PG2990BPS	282	3
PG2990BPX	207	0
PG2990PPS	191	0
PG2990PPX	368	42
PG3990BPS	406	0
PG3990BPX	203	28
PG3990PPS	514	0
PG3990PPX	323	23
Grand Total	**2494**	**96**

Number of devices subject to review: All quantities listed above are subject to this review

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Other Product Impact: No other product ranges in other marketed countries or product lines are impacted.

Interim Product Containment Actions

The impacted lots were identified by analyzing the complaint data. The catalog codes 2990 and 3990 for lots manufactured between Oct 2019 and April 2021 have an increased complaint rate. Two stop shipments were implemented ref EVENT-2022-04717 and EVENT-2022-04738. Production of these two product codes was also stopped until corrective/interim actions are implemented via sCAPA-MIA-02719.

Internal Nonconformance Rate

N/A This DPRA was triggered by complaints.

Rate

- ☐ Frequent (20% or >)
- ☐ Probable (10% to < 20%)
- ☐ Occasional (5% to < 10%)
- ☐ Remote (3% to < 5%)
- ☐ Improbable (< 3%)
- ☑ Not Applicable

Cordis Document References:

sCAPA-MIA-02719
EVENT-2022-04717
EVENT-2022-04738
aFMEA 100170787 Rev 4
100170784 aHL Rev. 4

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Section 2: Compliance Evaluation

(Completed by QA Director or designee)

Compliance / Regulatory Evaluation	
Compliance considerations may include any of the following:	
RMB Required	☐ Product distributed without required regulatory approval (e.g., PMA, IDE, IND) or contrary to legal process (e.g., injunction, seizure, consent decree) ☐ Confirmed or suspected counterfeit product, product tampering or sabotage ☐ Entire lot does not meet label claims (e.g., identity, sterility, potency, stability) ☐ Violation of investigational product or clinical trial regulations; advertising and promotional regulations; or product labeling regulations ☐ Confirmed or potential damage to environment, facility or equipment ☐ Entire lot meets label claims, but does not meet product or process specifications ☐ Entire lot meets label claims and product/process specifications, but product design may be deficient, or processes used to manufacture the lot may not meet GMP requirements ☐ Other:
RMB Decision by QA Director or Designee	☐ Product does not meet label claims (e.g., identity, sterility, potency, stability) - Isolated event or issue is not part of a systemic issue ☐ Product meets label claims, but does not meet product or process specifications - Isolated event or issue is not part of a systemic issue ☑ Product meets label claims and product/process specifications, but product design may be deficient, or processes used to manufacture the product may not meet GMP requirements ☐ Product or lot meets label claims and product/process specifications, but the complaint or malfunction rate exceeds expectations ☐ Product or lot meets label claims and product/process specifications, and the complaint and malfunction rates are within expectations ☐ Other:

RMB Decision
☑ RMB review needed
☐ RMB review not needed because:

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Section 3: Health Hazard Evaluation

Completed by Medical Director or designee

Product description and intended use:
A PALMAZ stent placement is a procedure used to treat peripheral vascular conditions. There are a multitude of medical devices that are used or can be used to treat these conditions. For the current situation mentioned above, most of such products used in a catheterization procedure are affected. Such product families affected are PALMAZ Mounted Stents. Product descriptions and the indications for use can be found in each product lines respective instructions for use.
Description of potential hazard(s) and harm(s), and any immediate and/or long range health consequences
User interaction with the affected device/component: Balloon expandable stents are intended to be used as a scaffolding within a lesion or stricture to help maintain patency and improve the flow of blood and other body fluids. The PALMAZ family of stents are intended for use in the peripheral vasculature and within ducts of the hepato-biliary system. The stent is delivered to the target on a balloon catheter called a stent delivery system. **Immediate and Long Range Health Consequences:** If movement of the stent is detected before or during the procedure, the device can be exchanged resulting in an intra-procedural delay. If the stent is loose or inaccurately crimped on the balloon the stent may not be placed where intended in the target vessel. This may result in the need for additional stents to complete the procedure. It may also cause the stent to become dislodged from the stent delivery system in the body, away from the target lesion. If the stent remains on the guidewire it may be recaptured with a smaller balloon placed within the stent to withdraw it or deploy it where it is, or a buddy guidewire may be used to entangle with the stent wire and thus recapture it. However, if the stent is no longer on the guidewire it may be snared by using a snare device to lasso it. If that is not possible then the stent may be jailed against the wall of the vessel using another stent to prevent embolization of the stent to a smaller vessel or organ where it could obstruct flow. It is possible that embolization could result in peripheral ischemia. This may result in permanent impairment or damage to a body structure In the event that none of these percutaneous methods are viable or successful the stent may be removed surgically. Therefore, the severity of the potential harm of a stent that dislodges from the stent delivery system is *Critical.* **Indirect Health Consequences:** None
User or procedural factors related to issue
Factors That May Mitigate the Risk including product's labeling assessment: Highly trained teams that are experienced in identifying and treating hazards that may arise during interventional procedures perform these procedures. The IFU (PALMAZ GENESIS® Peripheral Stent on OPTA® PRO .035" Delivery System 1539296 rev11) warns "Prior to stenting, the PALMAZ GENESIS® Peripheral Stent on OPTA® PRO .035" Delivery System should be examined to verify functionality and integrity. Do not attempt to remove or readjust the stent on the delivery system. Inspect the crimped stent for adherence to the balloon and centered placement in relation to the balloon marker bands. Do not reposition the stent or hand crimp." **If Device Failure Occurs Can It Be Recognized By The User:** Offset, loosely crimped and/or dislodged stents can be recognized by the user.
Segment of the Population Most at Risk
None
Health Consequence/ Public Health Impact Beyond Users
If device is removed from the field, the impact to the patient/end user will be limited. Additional Cordis

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and competitor products are available on the market with the same indications for use.

Analysis of any other factors contributing to the situation:

None

Complaint Information/ Rate

☐ **N/A**

Number Of Complaints: The Cordis complaint database was queried for all complaints related to 29x90 and 39x90 Palmaz Genesis on Opta Pro for stent-dislodged, premature deployment, inaccurate placement and stent-offset/out of position manufactured between October 2019 and April 2019.

Complaint #	Complaint Create Date	Event Country	Catalog	Lot	MFG Month	Category Code	Patient Outcome
CASE-2020-00119575-1	Jul-20	UNITED STATES	PG2990BPX	82185924	Feb-20	STENT-DISLODGED	No patient injury (occurred during prep)
CASE-2020-00119680-1	Jul-20	NETHERLANDS	PG3990PPS	82178944	Oct-19	STENT-DISLODGED	No patient injury (occurred during prep)
CASE-2021-00138854-1	Jan-21	UNITED STATES	PG2990BPX	82185924	Feb-20	STENT-DISLODGED	No patient injury (unknown where/when stent dislodged)
CASE-2021-00139009-1	Jan-21	CHINA	PG2990PPX	82178943	Oct-19	STENT-OFFSET/OUT OF POSITION	No patient injury (occurred during prep)
CASE-2021-00145791-1	Mar-21	UNITED STATES	PG3990BPX	82208524	Dec-20	STENT-DISLODGED	**Expanded at unintended location**
CASE-2021-00148677-1	Mar-21	UNITED STATES	PG3990BPX	82208524	Dec-20	STENT-DISLODGED	No patient injury (occurred during prep)
CASE-2021-00149907-1	Apr-21	CHINA	PG2990PPX	82191727	Apr-20	STENT-LOOSE CRIMP	No patient injury (occurred during prep)
CASE-2021-00152266-1	Apr-21	UNITED STATES	PG3990BPS	82193089	Jun-20	STENT-DISLODGED	**Expanded at unintended location**
CASE-2021-00152871-1	May-21	UNITED STATES	PG2990BPS	82184806	Jan-20	STENT-OFFSET/OUT OF POSITION	No patient injury (removed with stent delivery system)
CASE-2021-00153684-1	May-21	UNITED STATES	PG2990BPX	82185924	Feb-20	STENT-DISLODGED; STENT-STRUT UPLIFT	No patient injury (removed with stent delivery system)
CASE-2021-00154015-1	May-21	CHINA	PG2990PPX	82191727	Apr-20	STENT-DISLODGED	aa in sheath removed with sheath
CASE-2021-00156107-1	Jun-21	UNITED STATES	PG2990BPS	82208532	Nov-20	STENT-DISLODGED	No patient injury (occurred during prep)
CASE-2021-00161752-1	Aug-21	CHINA	PG2990PPX	82191727	Apr-20	STENT-DISLODGED	aa in sheath removed with sheath
CASE-2021-00165957-1	Sep-21	UNITED STATES	PG2990BPS	82184806	Jan-20	STENT-DISLODGED	No patient injury (occurred during prep)
CASE-2021-00167025-2	Oct-21	FRANCE	PG3990PPS	82208537	Nov-20	STENT-DISLODGED	No patient injury (occurred during prep)
CASE-2021-00167416-2	Oct-21	UNITED STATES	PG2990BPS	82208532	Nov-20	STENT-DISLODGED	No patient injury (removed with

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							sheath)
CASE-2021-00169983-1	Nov-21	UNITED STATES	PG2990BPX	82208528	Nov-20	STENT-CRIMPING DIFFICULTY, STENT-DISLODGED; STENT-PREMATURE DEPLOYMENT, STENT-STRUT UPLIFT	No patient injury (occurred during prep) and off-label use (had crimped).
CASE-2022-00178498-1	Feb-22	UNITED STATES	PG3990BPX	82208524	Dec-20	STENT-DISLODGED	No patient injury (occurred during prep)
CASE-2022-00178768-1	Feb-22	BRAZIL	PG2990PPX	82211305	Jan-21	STENT-DISLODGED	No patient injury (occurred during prep)

The overall rate for this subset is 19/2494 units distributed x 100 = 0.76%, Occasional.

Injuries and Deaths Reported: See complaints CASE-2021-00145791-1 and CASE-2021-00152871-1 above.

Hazard Occurrence Rate

☐ **N/A - Refer to Hazard Occurrence Rate for Cordis Santa Clara below**

Expected per FMEA Mounted SDS aFMEA 100170787 Rev 4	**Complaint Rate**
☐ Frequent (10% or >) ☐ Probable (1% to < 10%) ☐ Occasional (0.02% to < 1%) ☑ Remote (0.002% to < 0.02%) ☐ Improbable (< 0.002%) ☐ Not Applicable	☐ Frequent (10% or >) ☐ Probable (1% to < 10%) ☑ Occasional (0.02% to < 1%) ☐ Remote (0.002% to < 0.02%) ☐ Improbable (< 0.002%)

Hazard Occurrence Rate for Cordis Santa Clara (only)

☑ **N/A - Refer to Hazard Occurrence Rate above**

Expected per FMEA	**Complaint Rate**
☐ Very High (> 1%) ☐ High (0.5% to < 1%) ☐ Moderate (0.1% to < 0.5%) ☐ Low (< 0.1%) ☐ Not Applicable	☐ Very High (> 1%) ☐ High (0.5% to < 1%) ☐ Moderate (0.1% to < 0.5%) ☐ Low (< 0.1%)

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Health Risk Assessment
Using the following definitions list any reasonable and foreseeable Harm and determine the levels of severity and likelihood:

Severity of Potential Harm	
SL5	Life-threatening (death has or could occur) (Cordis Severity level: Critical [4] or Cordis Santa Clara Severity level: Critical [4])
SL4	Results in permanent impairment of body function or permanent damage to a body structure. (Cordis Severity level: Severe [3] or Santa Clara Severity level: Critical [4])
SL3	Necessitates medical or surgical treatment to preclude permanent injury. (Cordis Severity Level: Severe [3] or Santa Clara Severity level: Serious [3])
SL2	Temporary or reversible (a medical condition which would likely resolve itself and where medical treatment is optional).(Cordis Severity level: Moderate[2] or Cordis Santa Clara Severity level: Moderate [2])
SL1	Limited (transient, minor impairment, no medical treatment required). (Cordis Severity level: Limited [1] or Cordis Santa Clara Severity level: Minor [1])
SL0	No adverse health consequences (Cordis Severity level: Negligible [0] or Cordis Santa Clara, Severity level: Minor [1])
Likelihood of Harm	
L4	The product problem, when it exists, will always or almost always result in the identified harm.
L3	The product problem has resulted, or can be reasonably expected to result, in the identified harm under normal circumstances at least some of the time.
L2	The product problem has been known to result in the identified harm (documented or reported in clinical practice), but only occasionally and/or under unusual circumstances.
L1	The product problem has never been known to result in the identified harm, and it is not reasonable to expect that it ever would.

	Harm	Severity	Likelihood (General Population)	Likelihood (Population at Greatest Risk)
Peripheral Indication	Intraprocedural Delay	SL1	L4	L4
	Damage to Healthy Intima	SL2	L3	L3
	Additional Intervention (percutaneous)	SL2	L3	L3
	Vasospasm (peripheral)	SL2	L3	L3
	Ischemia (peripheral)	SL2	L2	L2
	Perforation (peripheral)	SL3	L2	L2
	Additional Intervention (surgical)	SL3	L3	L3
	Dissection (peripheral)	SL3	L2	L2
	Thrombosis (peripheral)	SL3	L2	L2
Additional harms r/t Biliary Indication	GI Tract Trauma	SL1	L3	L3
	GI Tract Perforation	SL5	L2	L2
Applicable FMEA document and revision number: The Confluent process FMEA pFMEA-10069 Rev A was reviewed. However, the harms associated with the Biliary indication are not included. An update is required to add these to the pFMEA. A Change Task will be created in MyCordisPLM to track the required update to closure.				

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ID #	Process name / Function	Potential Failure Mode	Potential Effect	Severity rank	Potential Cause(s)	Occurrence rank	Detect rank	RPN	Detection Method and Controls	Comments/ Actions	Defect Class	Process Defect
1.2.1.1 P	Pre-Crimping	Incorrect mandrel	Stent Dislodgement	8	Procedure not followed	2	1	16	PPEWI	WI-09004	I	Incorrect mandrel
1.2.2.1 P		Incorrect protective tube	Stent Dislodgement	8	Operator Error Handling/ procedure not followed	2	1	16	PPEWI	WI-09004	I	Incorrect protective tube
1.2.3.1 P		incorrect time	Stent Dislodgement	8	Operator Error Handling/ procedure not followed	2	1	16	PPEWI	WI-09004	I	incorrect time
1.2.4.1 P		Incorrect closing pressure	Stent Dislodgement	8	Operator Error Handling/ procedure not followed	2	1	16	PPEWI	WI-09004	I	Incorrect closing pressure
1.3.1.1 P	Crimping - Slalom and Aviator only	Incorrect mandrel	Stent Dislodgement	8	Operator Error Handling/ procedure not followed	2	1	16	PPEWI	WI-09005	I	Incorrect mandrel
1.3.2.1 P		Incorrect protective tube	Stent Dislodgement	8	Operator Error Handling/ procedure not followed	2	1	16	PPEWI	WI-09005	I	Incorrect protective tube
1.3.3.1 P		Incorrect Time	Stent Dislodgement	8	Incorrect Set-up/ setup procedure not followed	2	1	16	PPEWI	WI-09005	I	Incorrect Time
1.3.4.1 P		Incorrect closing pressure	Stent Dislodgement	8	Incorrect Set-up/ setup procedure not followed	2	1	16	PPEWI	WI-09005	I	Incorrect closing pressure
1.3.5.1 P		Incorrect temperature	Stent Dislodgement	8	Incorrect Set-up/ setup procedure not followed	2	1	16	PPEWI	WI-09005	I	Incorrect temperature
1.4.1.1 P	Crimping	Incorrect mandrel	Stent Dislodgement	8	Operator Error Handling/ procedure not followed	2	1	16	PPEWI	WI-09005	I	Incorrect mandrel
1.4.2.1 P		Incorrect protective tube	Stent Dislodgement	8	Operator Error Handling/ procedure not followed	2	1	16	PPEWI	WI-09005	I	Incorrect protective tube
1.4.3.1 P		Incorrect Time	Stent Dislodgement	8	Operator Error Handling/ procedure not followed	2	1	16	PPEWI	WI-09005	I	Incorrect Time
1.4.4.1 P		Incorrect closing pressure	Stent Dislodgement	8	Operator Error Handling/ procedure not followed	2	1	16	PPEWI	WI-09005	I	Incorrect closing pressure
1.5.1.1 P	Nesting	Incorrect protective tube	Stent Dislodgement	8	Operator Error Handling/ procedure not followed	2	1	16	PPEWI	WI-09007	I	Incorrect protective tube
1.5.2.1 P		Incorrect Die	Stent Dislodgement	8	Incorrect set up/ setup procedure not followed	2	1	16	PPEWI	WI-09007	I	Incorrect Die
1.6.1.1 P	Plasma treatment	Incorrect Pressure	Stent Dislodgement	8	Incorrect set up/ setup procedure not followed	2	6	96	PPEWI / Pull test (Ansi)	WI-09010	I	Incorrect Pressure
1.6.2.1 P		Incorrect time	Stent Dislodgement	8	Incorrect set up/ setup procedure not followed	2	6	96	PPEWI / Pull test (Ansi)	WI-09010	I	Incorrect time
1.6.3.1 P		Incorrect potency	Stent Dislodgement	8	Incorrect set up/ setup procedure not followed	2	6	96	PPEWI / Pull test (Ansi)	WI-09010	I	Incorrect potency

The Cordis Mounted SDS aFMEA 100170787 Rev 4 and Mounted SDS 100170784 aHL Rev. 4 were reviewed. Per CMO, necrosis would not occur. Additional assessment required (literature search) followed by review IFUs and Risk Management documents to remove necrosis. Change Tasks will be created in MyCordisPLM to track these items to closure.

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ID1	General Step	ID2	Procedure Step	List of AFMEA Hazards													
				ID3	Hazard Description	Hazardous Situation(s)	Potential Harm	SEV	Potential Cause of Failure	Occ.	Risk Level before RCM	Risk Control Measures	Verification Risk Control Measures		Occ. after RCM	Risk Level after RCM
													Implementation	Effectiveness		
				1.4.2.3.A	Stent Dislodgement	Increased intraoperative time. Deterioration or loss of device function. Stent may become detached from device resulting in a potential embolization or tissue damage.	Intra- Procedural Delay AFMEA Hazard - Harm: 10.1	1	vessel/lesion characteristics	N/A	N/A	IFU Caution: Should unusual resistance be felt at any time during either stricture access or removal of the delivery system prior to stent implantation, the system should be removed.	All IFUs. See Parking Lot.	The IFU is not intended as a risk control measure, but it makes the user aware of risks. No further mitigations can be taken.	1	ALAP
							GI Tract Trauma AFMEA Hazard - Harm: 10.2	1								
							Damage to healthy intima AFMEA Hazard - Harm: 10.3	2								
							Additional intervention (percutaneous) AFMEA Hazard - Harm: 10.4	2								
							Vasospasm (Peripheral) AFMEA Hazard - Harm: 10.5	2								
							Ischemia (Peripheral) AFMEA Hazard - Harm: 10.6	2								
							Additional intervention (surgical) AFMEA Hazard - Harm: 10.7	3								
							Dissection (peripheral) AFMEA Hazard - Harm: 10.8	3								
							Thrombosis (Peripheral) AFMEA Hazard - Harm: 10.9	3								
							Necrosis (Peripheral) AFMEA Hazard - Harm: 10.10	3								
							Perforation (Peripheral) AFMEA Hazard - Harm: 10.11	3								
							GI tract perforation AFMEA Hazard - Harm: 10.12	4								

Applicable Hazard List:

10A	Stent Dislodgement	1	Intra- Procedural Delay AFMEA - Potential Harm: 4.2.3.1	1	1	ALAP	1.4.2.3
			GI Tract Trauma AFMEA - Potential Harm: 4.2.3.2	1	1		1.5.1.3
			Damage to healthy intima AFMEA - Potential Harm: 4.2.3.3	2	1		1.5.3.1
			Additional intervention (percutaneous) AFMEA - Potential Harm: 4.2.3.4	2	1		1.6.2.3
			Vasospasm (Peripheral) AFMEA - Potential Harm: 4.2.3.5	2	1		1.6.3.3
			Ischemia (Peripheral) AFMEA - Potential Harm: 4.2.3.6	2	1		1.7.1.2
			Additional intervention (surgical) AFMEA - Potential Harm: 4.2.3.7	3	1		1.7.2.3
			Dissection (peripheral) AFMEA - Potential Harm: 4.2.3.8	3	1		1.7.3.2
			Thrombosis (Peripheral) AFMEA - Potential Harm: 4.2.3.9	3	1		1.7.4.3
			Necrosis (Peripheral) AFMEA - Potential Harm: 4.2.3.10	3	1		
			Perforation (Peripheral) AFMEA - Potential Harm: 4.2.3.11	3	1		
			GI tract perforation AFMEA - Potential Harm: 4.2.3.12	4	1		

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Escalation Recommendation				
Likelihood\ Severity	**L1**	**L2**	**L3**	**L4**
SL5	☐ RMB required	☑ RMB required	☐ RMB required	☐ RMB required
SL4	☐ RMB decision by Medical Director or Designee (requires review by QA Director)	☐ RMB required	☐ RMB required	☐ RMB required
SL3	☐ RMB decision by Medical Director or Designee (requires review by QA Director)	☑ RMB required	☑ RMB required	☐ RMB required
SL2	☐ RMB not required	☑ RMB decision by Medical Director or designee	☑ RMB decision by Medical Director or Designee (requires review by QA Director)	☐ RMB required
SL1	☐ RMB not required	☐ RMB not required	☑ RMB decision by Medical Director or designee	☑ RMB decision by Medical Director or designee
SL0	☐ RMB not required	☐ RMB not required	☐ RMB not required	☐ RMB not required

RMB Recommendation By Medical Director or designee

☐ RMB not required (As per Escalation Recomendation table above)

☑ RMB review needed

☐ RMB review not needed because:

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Section 4: Decision Outcomes

RMB Decision

- [x] RMB required by Compliance evaluation in section 2
- [x] RMB required by Health Risk Assessment Escalation in section 3
- [ ] RMB required if product does not meet label claims (section 2) and severity of the potential harm is SL2, SL3, SL4 or SL5 (Cordis Severity level 2-4).
- [ ] RMB required if product does not meet product or process specifications (section 2) and severity of the potential harm is SL2, SL3, SL4 or SL5 (Cordis Severity Level 2-4).
- [ ] RMB not required, review by QA Director (section 3)
- [ ] RMB not required (none of the conditions above met)

CAPA Decision by Quality Assurance Director

- [x] N/A Issue escalated to RMB. The CAPA decision will be made by RMB and documented in the meeting minutes.

Note: sCAPA-MIA-02719 has been issued to Confluent Medical Technologies.

- [ ] CAPA needed - record CAPA number, if available:
- [ ] CAPA not needed because:
- [ ] CAPA decision deferred pending the following data:

Risk Management or Labeling Updates

- [x] N/A issue escalated to RMB. If updates to risk documents or labeling updates are required, the decision will be made by RMB and documented in the meeting minutes.
- [ ] No Risk Document or Labeling updates needed because:
- [ ] Risk Documents or Labeling updates needed. List documents to be updated:

Other Decisions or Comments

N/A