

Health Canada

Santé Canada

Mandatory Medical Device Problem Reporting Form for Industry CANADA VIGILANCE - MEDICAL DEVICE PROBLEM REPORTING PROGRAM If more space is required, please attach additional sheets Fields required to be completed for updates/final reports are indicated by an *

manufacturer? O Yes ONO 2. Reporter Contact Information * O5b362d241cc5745ddfd4d0a228bb46 If "update/final", date the previous report was st Health Canada: O5b362d241cc5745ddfd4d0a228bb46 O Date Submitted * 2020-11-23 Manufacturer Theoreter 7. Name and Address: DEPUY ORTHOPAEDICS, INC. 700 Orthopaedic Drive, P.O. Box 988 Warsaw, IN, US, 46582 Whitehall Dr., Markham, ON 8. Health Canada assigned company identification number (if known): 9. Establishment Licence Number (if applicable): 321	A. REPORTER INFORMATION				
In the case where the reporter is the importer: ii. Did the importer report the incident to the manufacturer? ② Yes ② No iii. Is the importer also submitting the report on behalf of the manufacturer? ② Yes ② No ② Yes ② No ② Reporter Contact Information * If "preliminary" only, anticipated date for the alth Canada: If "update/final", date the previous report was st Health Canada: If "update/final", date the previous report was st Health Canada: If "update/final", date the previous report was st Health Canada: Importer 7. Name and Address: DEPUY ORTHOPAEDICS, INC. 700 Orthopaedic Drive, P.O. Box 988 Warsaw, IN, US, 46582 N/A DEPUY ORTHOPAEDICS, INC. 700 Orthopaedic Whitehall Dr., Markham, OX 8. Health Canada assigned company identification number (if known): 9. Establishment Licence Number (if applicable): 8. INCIDENT INFORMATION 1. Classification of Incident *	1. i. Reporter Type	3. Reporter File No. *			
ii. Did the importer report the incident to the manufacturer? ② Yes ② No iii. Is the importer also submitting the report on behalf of the manufacturer? ③ Yes ② No 2. Reporter Contact Information * iii. Submitted * 2020-11-23 Manufacturer			PC-000471938		
S. Type of Report * Oreliminary Oupdate Final Opreliminary Oupdate Final Opreliminary Open Manufacturer? Oreliminary Oupdate Final Opreliminary Open Manufacturer If & "preliminary" only, anticipated date for the Health Canada: Obb362d241cc5745ddfd4d0a228bb46 Obs362d241cc5745ddfd4d0a228bb46 Obs362d241cc5745ddfd4daa28bb46 Obs362d241cc5745ddfd4daa28bb46 Obs	In the case where the reporter is the importer:		4. Health Canada File No. (if applicable) *		
iii. Is the importer also submitting the report on behalf of the manufacturer? ② Yes			N/A		
manufacturer? ② Yes ② No 2. Reporter Contact Information * 1. Reporter Contact Information * 1. Supporter Contact Information * 1. Su	⊙ Yes ⊙ No		5. Type of Report *		
© Yes			OPreliminary OUpdate OFinal OPreliminary & Final		
2. Reporter Contact Information * If "update/final", date the previous report was st Health Canada: Contact Information Health Canada:			If & "preliminary" only, anticipated date for the final report:		
Health Canada: Common					(YYYY-MM-DD)
Manufacturer Importer	2. Reporter Contact Information *		If "update/final", date the previous report was submitted to Health Canada:		
Manufacturer Importer	905b362d241cc5745ddfd4d0a228bb46				(YYYY-MM-DD)
Manufacturer Importer 7. Name and Address: DEPUY ORTHOPAEDICS, INC. 700 Orthopaedic Drive, P.O. Box 988 Warsaw, IN, US, 46582 Whitehall Dr., Markham, ON Whitehall Dr., Markham, ON Whitehall Dr., Markham, ON Markham, ON Whitehall Dr., Markham, ON			6. Date Submitted *		
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Drive, P.O. Box 988 Warsaw, IN, US, 46582 Whitehall Dr., Markham, ON 8. Health Canada assigned company identification number (if known): 9. Establishment Licence Number (if applicable): 8. INCIDENT INFORMATION 1. Classification of Incident * i.		Manufac	eturer	Importer	
S. Hattil Canada as signed company identification number (if known):				Johnson & Johnson Medical Products, 200 Whitehall Dr., Markham, ON, L3R 0T5	
Classification of Incident *	company identification number	103025		N/A	
1. Classification of Incident * i.				321	
i. 010-day 030-day ii. 0Canadian Foreign iii. Investigational testing Special Access Program Radiation emitting device (if applicable) 2. Date of Incident 2019-05-28 (YYYY-MM-DD) 3. Reporter's Awareness Date 2019-05-28 (YYYY-MM-DD)	B. INCIDENT INFORMATION				
ii. Canadian Foreign iii. Investigational testing Special Access Program Radiation emitting device (if applicable) 2. Date of Incident 2019-05-28 (YYYY-MM-DD) 3. Reporter's Awareness Date 2019-05-28 (YYYY-MM-DD)	1. Classification of Incident *		5. Details of Incident		
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2019-05-28 (YYYY-MM-DD)		(1111-WW-DD)			
40-1-7-0-54060-105-44017007-7		(VVVV MM DD)			
4. I attent Consequences		13eb7e0a519fbe2d9	ecfe410ed7907a7		
4ec9183dcaf1907b757988647d0f8cf9					

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	E. INVESTIGATION INFORMATION
C. MEDICAL DEVICE INFORMATION	1. Investigative Actions and Timeline
1. Trade/Brand Name *	
TRI-LOCK POR. COATED HIP PRO. STEMS	
2. Control/Lot/Serial No.	
(N/A)/HR3366/(N/A)	
3. Expiration Date	
(YYYY-MM-DD)	
4. i. Device Classification	
OI OII OIV	
	7d2ff55733c12730762860cdc3b81698
ii. Device License No. 11031	
iii. Device Identification No	
iv. Manufacturer's Medical Device Identifier (catalogue/model no.)	
1012-04-040	
5. Software Version	
6. Age of Device	This section only applies for preliminary & final, and final reports
	2. Root Cause of Problem
7. How long was the device in use?	
8. Was the device labelled as sterile?	
Yes No	
9. Availability of device for evaluation	
Destroyed • Returned to Manufacturer/Importer	
Neither (with explanation)	ec8853697883091af77b60a53368bbe1
D. COMPLAINANT INFORMATION	
1. Complainant is a:	
Consumer Health Professional Other	
2. Name of Complainant	
2. Name of Companiant 02e94f2a9f68281955b1dfac01f94dc3	
3. Name of Health Care Facility (if applicable)	
dccc6eb2baa1b0d1db6ede0591d3878c	
4. Address	
4. Address	
a57947ef34781f462138d7c370661615	6ec21b8fc6fce281f06a66496c708e29
bb82670f59f93334aff0cd306e76afdb	
Medical Device Problem Reporting Program, information related to the identity of the complainant and/or reporter will be protected as personal	
information under the <i>Privacy Act</i> , and under the <i>Access to Information Act</i> in the case of an access to information request. For details with regard to personal	
information collected under this program, visit the Personal Information Bank;	
Health Canada; Health Products and Food Branch; Branch Incident Reporting System; HC PPU 088 at: http://infosource.gc.ca/inst/1476/1476-fedemp00-	
eng.asp	