Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

21 JUN 2017

FDA ADVISORY
No. 2017-184

TO: **THE GENERAL PUBLIC AND ALL HEALTHCARE CONCERNED PROFESSIONALS**

SUBJECT: **VOLUNTARY RECALL NC TREX RX CORONARY DILATATION CATHETER, WITH MDR-00260**

All are hereby advised by the Food and Drug Administration (FDA) about the voluntary recall of the following NC Trex Rx coronary dilatation catheter with MDR-00260 product code 1012448-06,1012448-08,1012448-12,1012448-20, 1012449-08, 1012449-12, 1012449-20, 1012449-25, 1012450-06, 1012450-08, 101250-15, 101251-12, 101251-15, 1012452-08, 1012452-12, 1012453-12, 1012453-15, 1012453-20 distributed by Getz Bros. Philippines, Inc. 5th Floor Ortigas Bldg., Ortigas Avenue, Pasig City:

PRODUCT CODE:	**MDR-00260**		
DESCRIPTION:	**NC Trex Rx Coronary Dilatation Catheter (2. 75 Mm, 3.00 Mm, 3.25 Mm, 3.50 Mm, 3.75 Mm & 4.00 Mm)**		
Product Code	**Lot Numbers**	**Product Code**	**Lot Numbers**
1012448-06	60414G1 60721G1	**1012448-20**	60310G1 60421G1 60421G2 60527G1 60716G1 60819G1 60024G2
1012448-08 **1012551-25**	60208G1 60419G1 60420G1 60603G1 60906G1 61121G1 61121G2 60809G1	**1012449-08**	60317G1 60318G1 60412G1 60419G1 60502G1 60502G2 60525G1 60705G1 60801G1 60809G1 60826G1 60916G1 61121G1 61121G2
1012448-12	60225G1 60229G1 60318G1 60318G2 60429G1 60429G2 60607G1 60705G1	**1012449-12**	60218G1 60303G1 60330G1 60330G2 60406G1 60406G2 60406G3 60406G4 60408G1

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	60705G1		60406G4
	60804G1		60408G1
	60818G1		60413G1
	60921G1		60413G2
	60921G2		60425G1
1012448-12	61108G1		60429G1
	61111G1		60511G1
	61128G1		60512G1
	61128G2		60531G1
	61218G1		60607G1
			60623G1
	60126G1		60713G1
	60223G1		60721G1
	60225G1		60804G1
	60226G1		60805G1
	60323G1		60809G1
	60331G2		60816G1
	60516G1	**1012449-12**	60824G1
1012449-20	60519G1		60926G1
	60721G1		60929G1
	60805G1		61012G1
	60824G1		61019G1
	60907G1		61019G2
	61004G1		61020G1
	61116G1		61115G1
	61130G1		61121G1
			61122G1
	60209G1		61123G1
	60226G1		61123G2
1012453-20	60505G1		61201G1
	60623G1		61208G1
	61122G1		61214G1
			61214G2
			61216G1
			61216G2
	60205G1		60405G1
1012451-12	60214G1	**1012449-25**	60412G1
	60502G1		60805G1
	61108G1		
	61213G1		
		1012450-06	60610G1
	60810G1		61101G1
1012452-08	60921G1		
	61007G1		60530G1
	61216G1		60803G1
		1012450-08	61014G1
	60315G1		61206G1
	61130G1		
	60718G1		50109G1
1012450-15	60901G1		50316G1
	60922G1	**1012452-12**	50210G1
	61128G1		
	60414G2		60705G1
	60505G1		60810G1
	60331G1	**1012453-12**	60502G1

1012451-15	60224G1 60210G1 60224G1 60331G1 60505G1 60408G2 60913G1 60909G2 60828G2 60826G1 60727G1 60701G1 60607G1 60603G1	**1012453-15**	60621G1 60301G1 61111G1 61026G1 61121G1 60822G1 60428G1 60819G1 60331G1 60721G1 60909G1 60613G1 60303G1 60617G1

The cited product are being voluntarily recalled by Getz Bros. Philippines, Inc. because Abbot Vascular has initiated a voluntary field action regarding specific lots of the NC Trex Rx Coronary Dilatation Catheter, NC Traveller Rx Coronary Dilatation Catheter, and NC Tenku Rx PTCA Ballon Catheter.

Production from the identified lots may exhibit difficult in removing the protective ballon sheath which can result in issues with inflating or deflating the ballon. The worldwide frequency of tight sheath removal, inflation and deflation and reported event is 0.12%. Potential risks associated with ballon inflation and deflation difficulties include air embolism, additional intervention, thrombosis, and myocardiac infarction. In one reported case, failure to deflate the ballon necessitated surgery, leading to multiple post-operative complication and death.
Distributors, retailers, hospitals that have any of the stated medical device product are instructed to discontinue further distribution, sale and use. All consumers are likewise advised not to purchase or use the affected product lots.

Any suspected adverse reaction experienced or any incident of the same cases from the use of the device but not limited to the lots stated above, should be reported immediately to FDA at telephone no. (02) 857-1900 loc. 8301 or email us at cdrrhr_prsdd@fda.gov.ph.

Dissemination of the information to all concerned is requested.

NELA CHARADE G. PUNO, R.Ph
Director General

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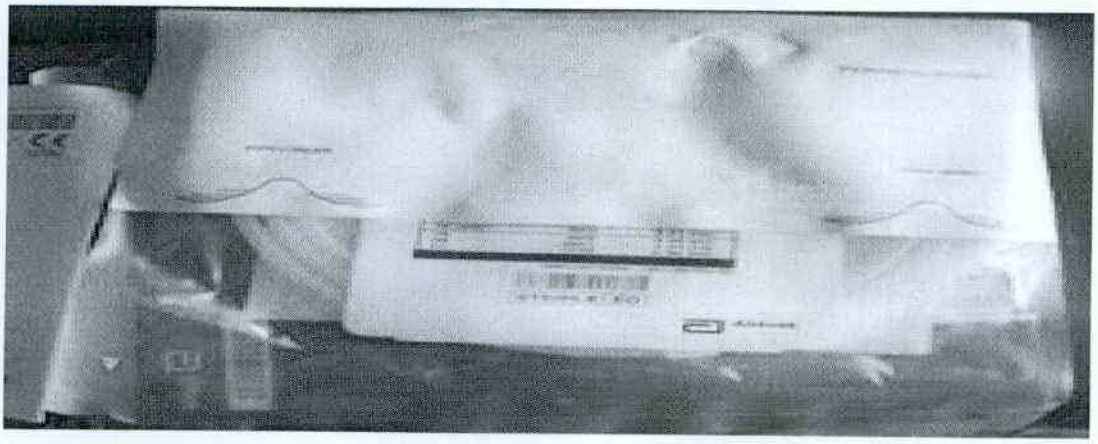

26 April 2017
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