

“亞培” 恩希快克冠狀動脈氣球擴張導管

回收警訊

許可證字號：衛署醫器輸字第 023212 號

產品英文名稱：“Abbott” NC TREK RX Coronary Dilatation Catheter

受影響規格/型號/批號：

型號	產品型號敘述	批號	進口數量
1012448-08	NC TREK RX 2.75 X 8MM BDC	60419G1	4
1012448-08	NC TREK RX 2.75 X 8MM BDC	60420G1	6
1012448-08	NC TREK RX 2.75 X 8MM BDC	60603G1	11
1012448-08	NC TREK RX 2.75 X 8MM BDC	60906G1	5
1012448-08	NC TREK RX 2.75 X 8MM BDC	61121G1	9
1012448-12	NC TREK RX 2.75 X 12MM BDC	60607G1	9
1012448-12	NC TREK RX 2.75 X 12MM BDC	60705G1	6
1012448-12	NC TREK RX 2.75 X 12MM BDC	60804G1	3
1012448-12	NC TREK RX 2.75 X 12MM BDC	60818G1	5
1012448-12	NC TREK RX 2.75 X 12MM BDC	60921G1	20
1012448-12	NC TREK RX 2.75 X 12MM BDC	60921G2	17
1012448-12	NC TREK RX 2.75 X 12MM BDC	61108G1	30
1012448-12	NC TREK RX 2.75 X 12MM BDC	61111G1	11
1012448-12	NC TREK RX 2.75 X 12MM BDC	61128G1	4
1012448-12	NC TREK RX 2.75 X 12MM BDC	61128G2	10
1012448-12	NC TREK RX 2.75 X 12MM BDC	61218G1	31
1012448-15	NC TREK RX 2.75 X 15MM BDC	60616G1	2
1012448-15	NC TREK RX 2.75 X 15MM BDC	60721G1	11
1012448-15	NC TREK RX 2.75 X 15MM BDC	60809G1	2
1012448-15	NC TREK RX 2.75 X 15MM BDC	60912G1	11
1012448-15	NC TREK RX 2.75 X 15MM BDC	61028G1	68
1012448-15	NC TREK RX 2.75 X 15MM BDC	61206G1	41
1012448-20	NC TREK RX 2.75 X 20MM BDC	60310G1	1
1012448-20	NC TREK RX 2.75 X 20MM BDC	60421G1	4
1012448-20	NC TREK RX 2.75 X 20MM BDC	60527G1	7
1012448-20	NC TREK RX 2.75 X 20MM BDC	60716G1	23

1012448-20	NC TREK RX 2.75 X 20MM BDC	60819G1	30
1012448-20	NC TREK RX 2.75 X 20MM BDC	61024G2	34
1012449-08	NC TREK RX 3.00 X 8MM BDC	60502G1	2
1012449-08	NC TREK RX 3.00 X 8MM BDC	60502G2	17
1012449-08	NC TREK RX 3.00 X 8MM BDC	60525G1	16
1012449-08	NC TREK RX 3.00 X 8MM BDC	60705G1	11
1012449-08	NC TREK RX 3.00 X 8MM BDC	60801G1	10
1012449-08	NC TREK RX 3.00 X 8MM BDC	60916G1	10
1012449-08	NC TREK RX 3.00 X 8MM BDC	61018G1	20
1012449-08	NC TREK RX 3.00 X 8MM BDC	61121G1	1
1012449-08	NC TREK RX 3.00 X 8MM BDC	61121G2	3
1012449-12	NC TREK RX 3.00 X 12MM BDC	60623G1	4
1012449-12	NC TREK RX 3.00 X 12MM BDC	60805G1	14
1012449-12	NC TREK RX 3.00 X 12MM BDC	60809G1	4
1012449-12	NC TREK RX 3.00 X 12MM BDC	60812G1	3
1012449-12	NC TREK RX 3.00 X 12MM BDC	60824G1	3
1012449-12	NC TREK RX 3.00 X 12MM BDC	60926G1	26
1012449-12	NC TREK RX 3.00 X 12MM BDC	61019G1	10
1012449-12	NC TREK RX 3.00 X 12MM BDC	61020G1	54
1012449-12	NC TREK RX 3.00 X 12MM BDC	61121G1	10
1012449-12	NC TREK RX 3.00 X 12MM BDC	61122G1	13
1012449-12	NC TREK RX 3.00 X 12MM BDC	61123G1	16
1012449-12	NC TREK RX 3.00 X 12MM BDC	61201G1	28
1012449-12	NC TREK RX 3.00 X 12MM BDC	61214G2	5
1012449-12	NC TREK RX 3.00 X 12MM BDC	61216G2	32
1012449-15	NC TREK RX 3.00 X 15MM BDC	60609G1	13
1012449-15	NC TREK RX 3.00 X 15MM BDC	60621G1	6
1012449-15	NC TREK RX 3.00 X 15MM BDC	60718G1	7
1012449-15	NC TREK RX 3.00 X 15MM BDC	60809G1	17
1012449-15	NC TREK RX 3.00 X 15MM BDC	60816G1	5
1012449-15	NC TREK RX 3.00 X 15MM BDC	60906G1	67
1012449-15	NC TREK RX 3.00 X 15MM BDC	60926G1	18
1012449-15	NC TREK RX 3.00 X 15MM BDC	61104G1	41
1012449-15	NC TREK RX 3.00 X 15MM BDC	61107G1	34
1012449-15	NC TREK RX 3.00 X 15MM BDC	61122G1	14
1012449-15	NC TREK RX 3.00 X 15MM BDC	61123G1	17
1012449-15	NC TREK RX 3.00 X 15MM BDC	61128G1	8

1012449-15	NC TREK RX 3.00 X 15MM BDC	61130G1	10
1012449-15	NC TREK RX 3.00 X 15MM BDC	61202G1	9
1012449-20	NC TREK RX 3.00 X 20MM BDC	60226G1	6
1012449-20	NC TREK RX 3.00 X 20MM BDC	60516G1	36
1012449-20	NC TREK RX 3.00 X 20MM BDC	60519G1	27
1012449-20	NC TREK RX 3.00 X 20MM BDC	60721G1	11
1012449-20	NC TREK RX 3.00 X 20MM BDC	60805G1	24
1012449-20	NC TREK RX 3.00 X 20MM BDC	60824G1	26
1012449-20	NC TREK RX 3.00 X 20MM BDC	60907G1	31
1012449-20	NC TREK RX 3.00 X 20MM BDC	61004G1	29
1012449-20	NC TREK RX 3.00 X 20MM BDC	61116G1	56
1012449-20	NC TREK RX 3.00 X 20MM BDC	61128G1	12
1012450-08	NC TREK RX 3.25 X 8MM BDC	60530G1	15
1012450-08	NC TREK RX 3.25 X 8MM BDC	60803G1	12
1012450-08	NC TREK RX 3.25 X 8MM BDC	61014G1	4
1012450-08	NC TREK RX 3.25 X 8MM BDC	61206G1	2
1012450-12	NC TREK RX 3.25 X 12MM BDC	60212G1	12
1012450-12	NC TREK RX 3.25 X 12MM BDC	60412G1	5
1012450-12	NC TREK RX 3.25 X 12MM BDC	60414G1	6
1012450-12	NC TREK RX 3.25 X 12MM BDC	60528G1	12
1012450-12	NC TREK RX 3.25 X 12MM BDC	60623G1	6
1012450-12	NC TREK RX 3.25 X 12MM BDC	60831G1	2
1012450-12	NC TREK RX 3.25 X 12MM BDC	60921G1	23
1012450-12	NC TREK RX 3.25 X 12MM BDC	61104G1	2
1012450-12	NC TREK RX 3.25 X 12MM BDC	61207G1	3
1012450-12	NC TREK RX 3.25 X 12MM BDC	61209G1	5
1012450-15	NC TREK RX 3.25 X 15MM BDC	60414G2	3
1012450-15	NC TREK RX 3.25 X 15MM BDC	60613G1	8
1012450-15	NC TREK RX 3.25 X 15MM BDC	60718G1	9
1012450-15	NC TREK RX 3.25 X 15MM BDC	60810G1	10
1012450-15	NC TREK RX 3.25 X 15MM BDC	60901G1	12
1012450-15	NC TREK RX 3.25 X 15MM BDC	60922G1	19
1012450-15	NC TREK RX 3.25 X 15MM BDC	61128G1	5
1012450-15	NC TREK RX 3.25 X 15MM BDC	61130G1	14
1012450-20	NC TREK RX 3.25 X 20MM BDC	60429G1	4
1012450-20	NC TREK RX 3.25 X 20MM BDC	60613G1	8
1012450-20	NC TREK RX 3.25 X 20MM BDC	60804G1	5

1012450-20	NC TREK RX 3.25 X 20MM BDC	60929G1	17
1012451-08	NC TREK RX 3.50 X 8MM BDC	60526G1	9
1012451-08	NC TREK RX 3.50 X 8MM BDC	60531G1	10
1012451-08	NC TREK RX 3.50 X 8MM BDC	60623G1	9
1012451-08	NC TREK RX 3.50 X 8MM BDC	60713G1	4
1012451-08	NC TREK RX 3.50 X 8MM BDC	60805G1	1
1012451-08	NC TREK RX 3.50 X 8MM BDC	60819G1	9
1012451-08	NC TREK RX 3.50 X 8MM BDC	60929G1	15
1012451-08	NC TREK RX 3.50 X 8MM BDC	61104G1	11
1012451-08	NC TREK RX 3.50 X 8MM BDC	61204G1	3
1012451-08	NC TREK RX 3.50 X 8MM BDC	61206G1	9
1012451-08	NC TREK RX 3.50 X 8MM BDC	61207G1	6
1012451-12	NC TREK RX 3.50 X 12MM BDC	60527G2	10
1012451-12	NC TREK RX 3.50 X 12MM BDC	60601G1	17
1012451-12	NC TREK RX 3.50 X 12MM BDC	60629G1	21
1012451-12	NC TREK RX 3.50 X 12MM BDC	60805G1	22
1012451-12	NC TREK RX 3.50 X 12MM BDC	60818G1	8
1012451-12	NC TREK RX 3.50 X 12MM BDC	60829G1	8
1012451-12	NC TREK RX 3.50 X 12MM BDC	60907G1	7
1012451-12	NC TREK RX 3.50 X 12MM BDC	60922G1	32
1012451-12	NC TREK RX 3.50 X 12MM BDC	61003G1	6
1012451-12	NC TREK RX 3.50 X 12MM BDC	61108G1	45
1012451-12	NC TREK RX 3.50 X 12MM BDC	61114G1	4
1012451-12	NC TREK RX 3.50 X 12MM BDC	61122G1	1
1012451-12	NC TREK RX 3.50 X 12MM BDC	61123G1	13
1012451-12	NC TREK RX 3.50 X 12MM BDC	61130G1	20
1012451-12	NC TREK RX 3.50 X 12MM BDC	61213G1	10
1012451-15	NC TREK RX 3.50 X 15MM BDC	60408G1	1
1012451-15	NC TREK RX 3.50 X 15MM BDC	60607G1	9
1012451-15	NC TREK RX 3.50 X 15MM BDC	60628G1	10
1012451-15	NC TREK RX 3.50 X 15MM BDC	60727G1	12
1012451-15	NC TREK RX 3.50 X 15MM BDC	60801G1	2
1012451-15	NC TREK RX 3.50 X 15MM BDC	60826G2	51
1012451-15	NC TREK RX 3.50 X 15MM BDC	60909G1	37
1012451-15	NC TREK RX 3.50 X 15MM BDC	60909G2	10
1012451-15	NC TREK RX 3.50 X 15MM BDC	60913G1	16
1012451-15	NC TREK RX 3.50 X 15MM BDC	61024G1	23

1012451-15	NC TREK RX 3.50 X 15MM BDC	61101G1	1
1012451-15	NC TREK RX 3.50 X 15MM BDC	61115G1	43
1012451-15	NC TREK RX 3.50 X 15MM BDC	61123G1	9
1012451-15	NC TREK RX 3.50 X 15MM BDC	61123G2	10
1012451-15	NC TREK RX 3.50 X 15MM BDC	61202G1	25
1012451-15	NC TREK RX 3.50 X 15MM BDC	61204G1	4
1012451-15	NC TREK RX 3.50 X 15MM BDC	61214G1	33
1012451-20	NC TREK RX 3.50 X 20MM BDC	60419G1	2
1012451-20	NC TREK RX 3.50 X 20MM BDC	60419G2	15
1012451-20	NC TREK RX 3.50 X 20MM BDC	60519G1	32
1012451-20	NC TREK RX 3.50 X 20MM BDC	60603G1	20
1012451-20	NC TREK RX 3.50 X 20MM BDC	60824G1	11
1012451-20	NC TREK RX 3.50 X 20MM BDC	60901G1	36
1012451-20	NC TREK RX 3.50 X 20MM BDC	60927G1	14
1012451-20	NC TREK RX 3.50 X 20MM BDC	61115G1	16
1012451-20	NC TREK RX 3.50 X 20MM BDC	61201G1	31
1012452-08	NC TREK RX 3.75 X 8MM BDC	50319G1	2
1012452-08	NC TREK RX 3.75 X 8MM BDC	50513G1	7
1012452-08	NC TREK RX 3.75 X 8MM BDC	51022G1	4
1012452-08	NC TREK RX 3.75 X 8MM BDC	60112G1	5
1012452-08	NC TREK RX 3.75 X 8MM BDC	60603G1	2
1012452-08	NC TREK RX 3.75 X 8MM BDC	60810G1	2
1012452-08	NC TREK RX 3.75 X 8MM BDC	60921G1	1
1012452-08	NC TREK RX 3.75 X 8MM BDC	61216G1	4
1012452-12	NC TREK RX 3.75 X 12MM BDC	50109G1	3
1012452-12	NC TREK RX 3.75 X 12MM BDC	50306G1	2
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1012452-12	NC TREK RX 3.75 X 12MM BDC	50817G1	17
1012452-12	NC TREK RX 3.75 X 12MM BDC	50928G1	9
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1012452-12	NC TREK RX 3.75 X 12MM BDC	60311G1	3
1012452-12	NC TREK RX 3.75 X 12MM BDC	60712G1	6
1012452-12	NC TREK RX 3.75 X 12MM BDC	61102G1	10
1012452-12	NC TREK RX 3.75 X 12MM BDC	61122G1	6
1012452-15	NC TREK RX 3.75 X 15MM BDC	50105G1	7
1012452-15	NC TREK RX 3.75 X 15MM BDC	50316G1	2
1012452-15	NC TREK RX 3.75 X 15MM BDC	50319G1	17

1012452-15	NC TREK RX 3.75 X 15MM BDC	50420G1	7
1012452-15	NC TREK RX 3.75 X 15MM BDC	50609G1	4
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1012452-15	NC TREK RX 3.75 X 15MM BDC	60505G1	4
1012452-15	NC TREK RX 3.75 X 15MM BDC	60826G1	8
1012452-15	NC TREK RX 3.75 X 15MM BDC	61115G1	4
1012452-15	NC TREK RX 3.75 X 15MM BDC	61128G1	8
1012452-15	NC TREK RX 3.75 X 15MM BDC	61208G1	6
1012452-20	NC TREK RX 3.75 X 20MM BDC	50106G1	7
1012452-20	NC TREK RX 3.75 X 20MM BDC	50603G1	4
1012452-20	NC TREK RX 3.75 X 20MM BDC	51110G1	12
1012452-20	NC TREK RX 3.75 X 20MM BDC	60412G1	6
1012452-20	NC TREK RX 3.75 X 20MM BDC	60607G1	4
1012452-20	NC TREK RX 3.75 X 20MM BDC	61018G1	4
1012453-08	NC TREK RX 4.00 X 8MM BDC	60405G1	1
1012453-08	NC TREK RX 4.00 X 8MM BDC	60413G1	9
1012453-08	NC TREK RX 4.00 X 8MM BDC	60413G2	2
1012453-08	NC TREK RX 4.00 X 8MM BDC	60425G1	9
1012453-08	NC TREK RX 4.00 X 8MM BDC	60425G2	6
1012453-08	NC TREK RX 4.00 X 8MM BDC	60621G1	16
1012453-08	NC TREK RX 4.00 X 8MM BDC	60720G1	2
1012453-08	NC TREK RX 4.00 X 8MM BDC	60729G1	1
1012453-08	NC TREK RX 4.00 X 8MM BDC	60819G1	7
1012453-08	NC TREK RX 4.00 X 8MM BDC	61026G1	17
1012453-08	NC TREK RX 4.00 X 8MM BDC	61130G1	10
1012453-08	NC TREK RX 4.00 X 8MM BDC	61204G1	16
1012453-12	NC TREK RX 4.00 X 12MM BDC	60503G1	4
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1012453-12	NC TREK RX 4.00 X 12MM BDC	60621G1	3
1012453-12	NC TREK RX 4.00 X 12MM BDC	60705G1	19
1012453-12	NC TREK RX 4.00 X 12MM BDC	60722G1	13
1012453-12	NC TREK RX 4.00 X 12MM BDC	60810G1	10
1012453-12	NC TREK RX 4.00 X 12MM BDC	60907G1	16
1012453-12	NC TREK RX 4.00 X 12MM BDC	61004G1	24
1012453-12	NC TREK RX 4.00 X 12MM BDC	61012G1	20
1012453-12	NC TREK RX 4.00 X 12MM BDC	61218G1	5
1012453-15	NC TREK RX 4.00 X 15MM BDC	60428G1	7

1012453-15	NC TREK RX 4.00 X 15MM BDC	60613G1	3
1012453-15	NC TREK RX 4.00 X 15MM BDC	60617G1	6
1012453-15	NC TREK RX 4.00 X 15MM BDC	60721G1	6
1012453-15	NC TREK RX 4.00 X 15MM BDC	60819G1	13
1012453-15	NC TREK RX 4.00 X 15MM BDC	61026G1	15
1012453-20	NC TREK RX 4.00 X 20MM BDC	60505G1	1
1012453-20	NC TREK RX 4.00 X 20MM BDC	60623G1	11
1012453-20	NC TREK RX 4.00 X 20MM BDC	60810G1	10
1012453-20	NC TREK RX 4.00 X 20MM BDC	60926G1	16
1012453-20	NC TREK RX 4.00 X 20MM BDC	61122G1	14
總計進口數量			2,776

發布對象：醫療從業人員/醫療器材專業人員

警訊說明：(回收/矯正原因描述)

“亞培”恩希快克冠狀動脈氣球擴張導管的特定批號產品，有可能因不易移除氣球保護鞘而導致氣球無法充氣或洩氣。此種狀況可能產生下列風險：氣泡栓塞、額外處置、血栓及心肌梗塞。根據全球案例，目前其中一例國外通報案例中，原手術所使用的氣球擴張導管因無法洩壓，而導致病人因術後多項併發症死亡。

國內矯正措施：

經查，國內進口之受影響產品數量共 2,776 支，美商亞培股份有限公司台灣分公司已於 106 年 3 月 22 日起通知使用單位並提供建議事項。前述回收行動預計於 106 年 5 月 31 日完成。

廠商聯絡資訊

公司名稱：美商亞培股份有限公司台灣分公司

聯絡電話：02-21836813

聯絡人電子郵件：christie.ho@abbott.com

相關警訊來源(網址)：廠商提供紙本資料