

# IN.PACT™ ADMIRAL™ DRUG-COATED BALLOON NEW TECHNOLOGY ADD-ON PAYMENT (NTAP)

Medtronic

## New Technology Add-on Payment (NTAP) for DCB

### OVERVIEW

Effective October 1, 2015, hospital inpatient cases using a drug-coated balloon (DCB) are eligible for an incremental payment from Medicare (in addition to the DRG payment) to help cover the additional costs of using DCB. Medicare now provides incremental reimbursement for both hospital inpatient and hospital outpatient DCB cases. In the inpatient setting, this incremental reimbursement is called "New Technology Add-on Payment" or NTAP, and in the outpatient setting is called "Transitional Pass-Through Payment" or TPT. The DCB NTAP provides additional payment of up to \$1,035.72 for FY 2016, based on the hospital's reported cost of each actual case.

See below for more details regarding NTAP, including examples of how the additional payment is calculated and common questions. For more information about TPT for DCB, visit Medtronic's Cardiovascular Reimbursement website - [www.medtronic.com/cvreimbursement](http://www.medtronic.com/cvreimbursement)

NTAP allows Medicare to support patient access to a qualified new technology while evaluating how much it costs the healthcare system and hospital. Medicare determined that the IN.PACT Admiral DCB met all three requirements for an NTAP which are that a technology must be new, provide substantial clinical improvement over current standard of care, and meet the required cost threshold.

Medtronic has been leading the efforts with Medicare to enhance access to DCB technology for the Medicare population, based on the substantially improved clinical outcomes in patients treated with the IN.PACT Admiral DCB technology, including significantly fewer repeat interventions and improved quality of life. The NTAP approval confirms the benefits of IN.PACT Admiral in treating peripheral arterial disease (PAD) in vessels above the knee.

The actual DCB add-on payment is based on the total covered cost to hospitals for a DCB case - if the total covered costs of a discharge (derived by applying the hospital's inpatient operating cost-to-charge ratio (CCR) to the total covered charges for the case) exceed the full DRG payment (including payments for indirect medical education and disproportionate share hospitals, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of:

- 50 percent of the estimated costs of the new technology, or
- 50 percent of the difference between the full DRG payment and the hospital's estimated cost for the case.

**CMS has determined that the maximum NTAP payment for a case involving DCB will be \$1,035.72 for FY2016 (effective October 1, 2015).**

## INPATIENT CODING FOR DCB PROCEDURES

Starting October 1, 2015 when the NTAP for DCB goes into effect, all inpatient claims must be reported using ICD-10-PCS codes.

In September 2014 Medtronic applied for the creation of new ICD-10 procedure codes for DCB. In the FY2016 Inpatient Final Rule, CMS finalized a set of new ICD-10-PCS codes approved for procedures involving DCB (including the IN.PACT Admiral DCB). The complete list of procedure codes are provided in Appendix 1 and describe the use of DCB as a stand-alone angioplasty, with bare metal stenting, or with drug-eluting stenting, in the femoral and popliteal arteries (where DCB is currently indicated).

## INPATIENT CASES INVOLVING THE USE OF DCB AND ATHERECTOMY

For cases involving the use of DCB and atherectomy to treat the patient, select the appropriate DCB code from Appendix 1, and code atherectomy with the applicable ICD-10 PCS codes below (relevant codes for the femoral-popliteal territory are listed in Appendix 2)

If you have additional reimbursement questions, please contact the Medtronic Cardiovascular Reimbursement Hotline at (877) 347-9662 or [rs.cardiovascularhealthconomics@medtronic.com](mailto:rs.cardiovascularhealthconomics@medtronic.com)

## OVERVIEW OF NTAP CALCULATION

1. Determine total covered charges for the case involving DCB
2. Determine the hospital's inpatient operating cost-to-charge ratio (CCR)
3. Derive total covered costs of the case = total charges \* CCR
4. Determine hospital specific MS-DRG payment
5. Subtract the MS DRG payment from the total covered costs of the case
6. If the difference is > \$0, Medicare will make an add-on payment equal to the **lesser** of 50 percent of the difference or \$ 1,035.72

Difference between Total Covered Costs of Case and MS-DRG Payment										
Hospital Inpatient Scenarios w/ DCB	1 Hospital Total Case Charges	X	2 Hospital IP Operating CCR	=	3 Hospital Total Cost	-	4 MS-DRG Payment	=	5 Difference Between Cost & Payment	6
MS-DRG 252 – Other vascular procedures w/ MCC	\$101,779	X	0.250	=	\$ 25,444.75	-	\$ 19,410.00	=	\$ 6,034.75	
MS-DRG 253 – Other vascular procedures w/ CC	\$81,199	X	0.250	=	\$ 20,299.75	-	\$ 15,369.00	=	\$ 4,930.75	
MS-DRG 254 – Other vascular procedures w/o MCC or CC	\$56,667	X	0.250	=	\$ 14,166.75	-	\$ 10,175.00	=	\$ 3,991.75	

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## EXAMPLES OF NTAP CALCULATION

The following examples are designed to illustrate how the NTAP formula is utilized to determine any add-on payment with an inpatient claim.

All scenarios below use national average hospital total costs of inpatient discharges for peripheral interventions (in DRGS 252-254) assessed using FY2013 Medicare claims data, inflated to 2015.

The scenarios only differ with respect to the cost-to-charge ratio (CCR) used to adjust hospital charges to costs. CCRs may be obtained from the FY2016 IPPS Final Rule Impact File (see FAQ #10 for a link to the FY2016 CCR file).

### Scenario 1: NTAP calculation for a peripheral intervention admission using DCB Median hospital inpatient operating CCR of 0.324

To qualify for an NTAP, total covered case costs (based on total calculated costs) must be greater than the MS-DRG payment for that case					For qualifying cases, NTAP Amount = 50% of Excess Case Costs OR Maximum Add-On Payment – whichever is <b>lower</b>				Total Hospital Inpatient Payment												
	Difference Between Total Calculated Costs of Case and MS-DRG Payment				50% of the Excess Cost over MS-DRG Payment			Maximum Add-On Payment													
	National Average Hospital Total Case Charges	X	Hospital CCR (Natl Median)	=	Hospital Total Covered Cost	-	MS-DRG Payment		=	Covered Cost Minus DRG Payment (Reduced 50%)	=	50% of Cost in Excess of MS-DRG	or	New Tech Add-On Payment (NTAP)	+	MS-DRG Payment	=	Total Hospital Payment			
MS-DRG 253: Other Vascular Procedures w MCC	\$101,779	X	0.324	=	\$32,976.40	-	\$19,410	=	\$13,566.40	X	50%	=	\$6,783.20	or	\$1,035.72	=	\$1,035.72	+	\$19,410	=	\$20,446
MS-DRG 253: Other Vascular Procedures w CC	\$81,199	X	0.324	=	\$26,308.48	-	\$15,369	=	\$10,939.48	X	50%	=	\$5,469.74	or	\$1,035.72	=	\$1,035.72	+	\$15,369	=	\$16,405
MS-DRG 254: Other Vascular Procedures w/o CC/MCC	\$56,667	X	0.324	=	\$18,360.11	-	\$10,175	=	\$8,185.11	X	50%	=	\$4,092.55	or	\$1,035.72	=	\$1,035.72	+	\$10,175	=	\$11,211

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**Scenario 2: NTAP calculation for a peripheral intervention admission using DCB**  
**Average hospital inpatient operating CCR of 0.293**

To qualify for an NTAP, total covered case costs (based on total calculated costs) must be greater than the MS-DRG payment for that case					For qualifying cases, NTAP Amount = 50% of Excess Case Costs OR Maximum Add-On Payment – whichever is lower				Total Hospital Inpatient Payment												
	Difference Between Total Calculated Costs of Case and MS-DRG Payment				50% of the Excess Cost over MS-DRG Payment			Maximum Add-On Payment	New Tech Add-On Payment (NTAP)	MS-DRG Payment	Total Hospital Payment										
	National Average Hospital Total Case Charges	x	Hospital CCR (Natl Median)	=	Hospital Total Covered Cost	-	MS-DRG Payment					=	Covered Cost Minus DRG Payment (Reduced 50%)	=	50% of Cost in Excess of MS-DRG	or					
MS-DRG 253: Other Vascular Procedures w MCC	\$101,779	x	0.293	=	\$29,821.25	-	\$19,410	=	\$10,411.25	x	50%	=	\$5,205.62	or	\$1,035.72	=	\$1,035.72	+	\$19,410	=	\$20,446
MS-DRG 253: Other Vascular Procedures w CC	\$81,199	x	0.293	=	\$23,791.31	-	\$15,369	=	\$8,422.31	x	50%	=	\$4,211.15	or	\$1,035.72	=	\$1,035.72	+	\$15,369	=	\$16,405
MS-DRG 254: Other Vascular Procedures w/o CC/MCC	\$56,667	x	0.293	=	\$16,603.43	-	\$10,175	=	\$6,428.43	x	50%	=	\$3,214.22	or	\$1,035.72	=	\$1,035.72	+	\$10,175	=	\$11,211

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**Scenario 3: NTAP calculation for a peripheral intervention admission using DCB**  
**CCR less than the national median/average CCR; NTAP amount is less than the maximum allowed**

To qualify for an NTAP, total covered case costs (based on total calculated costs) must be greater than the MS-DRG payment for that case					For qualifying cases, NTAP Amount = 50% of Excess Case Costs OR Maximum Add-On Payment – whichever is lower				Total Hospital Inpatient Payment												
	Difference Between Total Calculated Costs of Case and MS-DRG Payment				50% of the Excess Cost over MS-DRG Payment			Maximum Add-On Payment	New Tech Add-On Payment (NTAP)	MS-DRG Payment	Total Hospital Payment										
	National Average Hospital Total Case Charges	X	Hospital CCR (Natl Median)	=	Hospital Total Covered Cost	-	MS-DRG Payment					=	Covered Cost Minus DRG Payment (Reduced 50%)	X	50% of Cost in Excess of MS-DRG	=	or				
MS-DRG 253: Other Vascular Procedures w MCC	\$101,779	X	0.200	=	\$20,355.80	-	\$19,410	=	\$945.80	X	50%	=	\$472.90	or	\$1,035.72	=	\$472.90	+	\$19,410	=	\$19,883
MS-DRG 253: Other Vascular Procedures w CC	\$81,199	X	0.200	=	\$16,293.80	-	\$15,369	=	\$870.80	X	50%	=	\$435.40	or	\$1,035.72	=	\$435.40	+	\$15,369	=	\$15,804
MS-DRG 254: Other Vascular Procedures w/o CC/MCC	\$56,667	X	0.200	=	\$11,333.40	-	\$10,175	=	\$1,158.40	X	50%	=	\$579.20	or	\$1,035.72	=	\$579.20	+	\$10,175	=	\$10,754

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**Scenario 4: NTAP calculation for a peripheral intervention admission using DCB**  
**Case does not qualify for NTAP; Case total costs are less than MS-DRG payment due to low CCR**

To qualify for an NTAP, total covered case costs (based on total calculated costs) must be greater than the MS-DRG payment for that case					For qualifying cases, NTAP Amount = 50% of Excess Case Costs OR Maximum Add-On Payment – whichever is lower				Total Hospital Inpatient Payment												
	Difference Between Total Calculated Costs of Case and MS-DRG Payment				50% of the Excess Cost over MS-DRG Payment			Maximum Add-On Payment	New Tech Add-On Payment (NTAP)	MS-DRG Payment	Total Hospital Payment										
	National Average Hospital Total Case Charges	X	Hospital CCR (Natl Median)	=	Hospital Total Covered Cost	-	MS-DRG Payment					=	Covered Cost Minus DRG Payment (Reduced 50%)	=	50% of Cost in Excess of MS-DRG	or					
MS-DRG 253: Other Vascular Procedures w MCC	\$101,779	X	0.150	=	\$15,266.85	-	\$19,410	=	(\$4,143.15)	X	50%	=	N/A	or	N/A	=	\$0.00	+	\$19,410	=	\$19,410
MS-DRG 253: Other Vascular Procedures w CC	\$81,199	X	0.150	=	\$12,179.85	-	\$15,369	=	(\$3,189.15)	X	50%	=	N/A	or	N/A	=	\$0.00	+	\$15,369	=	\$15,369
MS-DRG 254: Other Vascular Procedures w/o CC/MCC	\$56,667	X	0.150	=	\$8,500.05	-	\$10,175	=	(\$1,674.95)	X	50%	=	N/A	or	N/A	=	\$0.00	+	\$10,175	=	\$10,175

Case does not qualify because total covered costs do not exceed MS-DRG payment for case

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## FREQUENTLY ASKED QUESTIONS (FAQs)

### New Technology Add-On Payment (NTAP)

1. **Why did IN.PACT<sup>®</sup> Admiral<sup>®</sup> qualify for NTAP payment?**

NTAP payment allows Medicare to support patient access to a new technology while evaluating how much the new technology costs the healthcare system and hospital.

Medicare provides NTAP for qualified technologies that meet pre-established criteria including:

- The technology must represent a “substantial clinical improvement” over the current standard of care
- The technology must be new
- The technology must meet certain cost thresholds

2. **Will the NTAP apply to all FDA-approved DCBs?**

Yes. The NTAP applies to all FDA-approved DCBs.

3. **When is the NTAP effective?**

The NTAP payments for DCB go into effect on October 1, 2015. This is because the Medicare Inpatient Hospital Fiscal Year begins on October 1 of each year and ends on September 30 the next.

4. **How should a DCB case be billed in the hospital inpatient setting?**

There are no special billing requirements placed on the hospital for processing the NTAP payment, other than using the appropriate **ICD-10-PCS codes** that describe the use of DCB as part of the peripheral intervention procedure. The procedure codes listed above indicate a procedure involving the use of DCB. The use of any one of these codes will trigger a calculation of the NTAP payment by your Fiscal Intermediary/Medicare Administrator’s claims processing system.

5. **Is there a fixed payment amount for each inpatient DCB case?**

The NTAP amount is not a fixed amount and can vary for each case. It is calculated on a case-by-case basis. As explained in the previous scenarios, CMS has determined that the maximum amount that a hospital can receive (in addition to the full DRG payment) is **\$1,035.72 per case**. The exact payment amount per case is not fixed and depends on the total costs of the case.

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6. **Is the DCB NTAP amount paid per device (unit) used, or once per case?**

The NTAP amount is paid once per case and not per unit of new technology used; however, the total costs of the new technology (including multiple units) are part of the total case costs that go into the calculation of both the eligibility for NTAP and the NTAP amount.

7. **What is the total payment amount for the DCB case if it qualifies for an NTAP?**

The total payment amount for a DCB case that qualifies for an NTAP will consist of the full DRG payment and 50% of the difference between the actual cost of the case and the MS-DRG payment, up to a maximum of \$1,035.72 per case.

8. **What are the DRGs to which cases involving DCB track?**

Most cases involving the use of DCB will fall into one of the three following MS DRGs: 252, 253, or 254. The descriptions and payment amounts for FY2016 are shown below.

MS-DRG	Description	FY2016 National Unadjusted Payment
252	Other Vascular Procedures w/ MCC	\$ 19,410
253	Other Vascular Procedures w/ CC	\$ 15,369
254	Other Vascular Procedures w/o CC/ MCC	\$ 10,162

9. **How is the actual cost of the case determined?**

CMS derives the total covered cost of the case based on the total covered hospital charges for each case, and the hospital's inpatient operating cost to charge ratio determined from its cost report.

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10. **Where can a hospital find the hospital inpatient operating cost-to-charge-ratio (CCR) used in the NTAP payment calculation?**

The CY 2016 CCRs by provider number are available at:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2016-IPPS-Final-Rule-Home-Page-Items/FY2016-IPPS-Final-Rule-Data-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending>.

Download the FY2016 Impact File, and search the excel file by Medicare provider number. The CCR is listed in Column AE (last column in the file). If you do not know your Medicare provider number, please contact us via email at <mailto:rs.cardiovascularhealthconomics@medtronic.com?subject=IPCCR> with the name and location of your hospital and we can look it up for you.

11. **What should you do if your hospital encounters issues with claims using the ICD-10-PCS codes involving the use of DCB (including denial)?**

The best source of information regarding claims processing issues is the payer – either the patient's private insurance company or, the Medicare Administrative Contractor (for traditional Medicare A/B patients). Providers should contact the appropriate payer to report the problem and seek clarification about the issue.

Please also contact us at the Medtronic Cardiovascular Reimbursement Hotline (877-347-9662) or send us an email at <mailto:rs.cardiovascularhealthconomics@medtronic.com> with the details of the issue for additional support and guidance.

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## Physician Reimbursement

### 12. How are physician payments impacted by using DCB?

Physician professional payments are not impacted when using DCB. The physician will continue to use the same CPT code to describe the work of performing a peripheral angioplasty with a DCB or other balloon angioplasty catheter.

CPT Code and Description	CY2015 Medicare Facility Unadjusted Fee Schedule Payment
<b>37224 – Fem-Pop Angioplasty only</b>	\$ 481.97
<b>37226 – Fem-Pop Angioplasty + Stent</b>	\$ 566.00
<b>37225 – Fem-Pop Angioplasty + Atherectomy</b>	\$ 651.09
<b>37227 – Fem-Pop Angioplasty + Stent + Atherectomy</b>	\$ 783.03

### Reimbursement for DCB Cases in the Hospital Outpatient Setting, ASC, and Physician Office Setting

#### 13. Does the NTAP payment apply to DCB cases performed in the outpatient setting, and ambulatory surgery center (ASC), or in physician office-based labs?

##### *Hospital Outpatient Setting*

NTAP payment does not apply to the outpatient setting. However, DCB has been approved for a hospital outpatient specific add-on payment called the “Transitional Pass Through” payment, which has been in effect since April 1, 2015. For additional details regarding the TPT payment for DCB, please refer to the FAQ document addressing this topic.

##### *Ambulatory Surgery Centers*

Providers in the ASC setting of care are also approved for a TPT payment for DCB cases.

##### *Physician Office-Based Labs*

TPT and NTAP payments do not apply to physician office-based labs. There is no separate coding or payment mechanism to capture the additional DCB technology cost for physician office-based labs.

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## APPENDIX 1:

### ICD-10-PCS CODES FOR DCB<sup>i</sup>

Femoral Artery		
ICD-10 PCS Code	Description	Procedure Type
047K041	Dilation of right femoral artery with drug-eluting intraluminal device using drug-coated balloon, open approach	DCB with DES, open
047K0D1	Dilation of right femoral artery with intraluminal device using drug-coated balloon, open approach	DCB with BMS, open
047K0Z1	Dilation of right femoral artery using drug-coated balloon, open approach	DCB only, open
047K341	Dilation of right femoral artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous approach	DCB with DES, percutaneous
047K3D1	Dilation of right femoral artery with intraluminal device using drug-coated balloon, percutaneous approach	DCB with BMS, percutaneous
047K3Z1	Dilation of right femoral artery using drug-coated balloon, percutaneous approach	DCB only, percutaneous
047K441	Dilation of right femoral artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous endoscopic approach	DCB with DES, percutaneous endoscopic
047K4D1	Dilation of right femoral artery with intraluminal device using drug-coated balloon, percutaneous endoscopic approach	DCB with BMS, percutaneous endoscopic
047K4Z1	Dilation of right femoral artery using drug-coated balloon, percutaneous endoscopic approach	DCB only, percutaneous endoscopic
047L041	Dilation of left femoral artery with drug-eluting intraluminal device using drug-coated balloon, open approach	DCB with DES, open
047L0D1	Dilation of left femoral artery with intraluminal device using drug-coated balloon, open approach	DCB with BMS, open
047L0Z1	Dilation of left femoral artery using drug-coated balloon, open approach	DCB only, open
047L341	Dilation of left femoral artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous approach	DCB with DES, percutaneous
047L3D1	Dilation of left femoral artery with intraluminal device using drug-coated balloon, percutaneous approach	DCB with BMS, percutaneous
047L3Z1	Dilation of left femoral artery using drug-coated balloon, percutaneous approach	DCB only, percutaneous
047L441	Dilation of left femoral artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous endoscopic approach	DCB with DES, percutaneous endoscopic
047L4D1	Dilation of left femoral artery with intraluminal device using drug-coated balloon, percutaneous endoscopic approach	DCB with BMS, percutaneous endoscopic
047L4Z1	Dilation of left femoral artery using drug-coated balloon, percutaneous endoscopic approach	DCB only, percutaneous endoscopic

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**(APPENDIX 1, CONTINUED – ICD-10-PCS CODES FOR DCB)**

<b>Popliteal Artery</b>		
<b>ICD-10 PCS Code</b>	<b>Description</b>	<b>Procedure Type</b>
047M041	Dilation of right popliteal artery with drug-eluting intraluminal device using drug-coated balloon, open approach	DCB with DES, open
047M0D1	Dilation of right popliteal artery with intraluminal device using drug-coated balloon, open approach	DCB with BMS, open
047M0Z1	Dilation of right popliteal artery using drug-coated balloon, open approach	DCB only, open
047M341	Dilation of right popliteal artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous approach	DCB with DES, percutaneous
047M3D1	Dilation of right popliteal artery with intraluminal device using drug-coated balloon, percutaneous approach	DCB with BMS, percutaneous
047M3Z1	Dilation of right popliteal artery using drug-coated balloon, percutaneous approach	DCB only, percutaneous
047M441	Dilation of right popliteal artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous endoscopic approach	DCB with DES, percutaneous endoscopic
047M4D1	Dilation of right popliteal artery with intraluminal device using drug-coated balloon, percutaneous endoscopic approach	DCB with BMS, percutaneous endoscopic
047M4Z1	Dilation of right popliteal artery using drug-coated balloon, percutaneous endoscopic approach	DCB only, percutaneous endoscopic
047N041	Dilation of left popliteal artery with drug-eluting intraluminal device using drug-coated balloon, open approach	DCB with DES, open
047N0D1	Dilation of left popliteal artery with intraluminal device using drug-coated balloon, open approach	DCB with BMS, open
047N0Z1	Dilation of left popliteal artery using drug-coated balloon, open approach	DCB only, open
047N341	Dilation of left popliteal artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous approach	DCB with DES, percutaneous
047N3D1	Dilation of left popliteal artery with intraluminal device using drug-coated balloon, percutaneous approach	DCB with BMS, percutaneous
047N3Z1	Dilation of left popliteal artery using drug-coated balloon, percutaneous approach	DCB only, percutaneous
047N441	Dilation of left popliteal artery with drug-eluting intraluminal device using drug-coated balloon, percutaneous endoscopic approach	DCB with DES, percutaneous endoscopic
047N4D1	Dilation of left popliteal artery with intraluminal device using drug-coated balloon, percutaneous endoscopic approach	DCB with BMS, percutaneous endoscopic
047N4Z1	Dilation of left popliteal artery using drug-coated balloon, percutaneous endoscopic approach	DCB only, percutaneous endoscopic

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## APPENDIX 2:

### ICD-10-PCS CODES FOR ATHERECTOMY

ICD-10 PCS Code	Description	Procedure Type
04CK0ZZ	Extirpation of right femoral artery, open approach	Atherectomy, open
04CK3ZZ	Extirpation of right femoral artery, percutaneous approach	Atherectomy, percutaneous
04CK4ZZ	Extirpation of right femoral artery, percutaneous endoscopic approach	Atherectomy, percutaneous endoscopic
04CL0ZZ	Extirpation of left femoral artery, open approach	Atherectomy, open
04CL3ZZ	Extirpation of left femoral artery, percutaneous approach	Atherectomy, percutaneous
04CL4Z	Extirpation of left femoral artery, percutaneous endoscopic approach	Atherectomy, percutaneous endoscopic
04CM0ZZ	Extirpation of right popliteal artery, open approach	Atherectomy, open
04CM3ZZ	Extirpation of right popliteal artery, percutaneous approach	Atherectomy, percutaneous
04CM4ZZ	Extirpation of right popliteal artery, percutaneous endoscopic approach	Atherectomy, percutaneous endoscopic
04CN0ZZ	Extirpation of left popliteal artery, open approach	Atherectomy, open
04CN3ZZ	Extirpation of left popliteal artery, percutaneous approach	Atherectomy, percutaneous
04CN4ZZ	Extirpation of left popliteal artery, percutaneous endoscopic approach	Atherectomy, percutaneous endoscopic

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## Indications for Use:

The IN.PACT Admiral Paclitaxel-Coated PTA Balloon catheter is indicated for percutaneous transluminal angioplasty, after pre-dilatation, of de novo or restenotic lesions up to 180 mm in length in native superficial femoral or popliteal arteries with reference vessel diameters of 4-7 mm.

## Contraindications

The IN.PACT Admiral DCB is contraindicated for use in:

- Coronary arteries, renal arteries, and supra-aortic/cerebrovascular arteries
- Patients who cannot receive recommended antiplatelet and/or anticoagulant therapy
- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system
- Patients with known allergies or sensitivities to paclitaxel
- Women who are breastfeeding, pregnant or are intending to become pregnant or men intending to father children. It is unknown whether paclitaxel will be excreted in human milk and whether there is a potential for adverse reaction in nursing infants from paclitaxel exposure.

## Warnings

- Use the product prior to the Use-by Date specified on the package.
- Contents are supplied sterile. Do not use the product if the inner packaging is damaged or opened.
- Do not use air or any gaseous medium to inflate the balloon. Use only the recommended inflation medium (equal parts contrast medium and saline solution).
- Do not move the guidewire during inflation of the IN.PACT Admiral DCB.
- Do not exceed the rated burst pressure (RBP). The RBP (14 atm [1419 kPa]) is based on the results of in vitro testing. Use of pressures higher than RBP may result in a ruptured balloon with possible intimal damage and dissection.
- The safety and effectiveness of implanting multiple IN.PACT Admiral DCBs with a total drug dosage exceeding 20,691 µg of paclitaxel in a patient has not been clinically evaluated in the IN.PACT SFA Trial.

## Precautions

- This product should only be used by physicians trained in percutaneous transluminal angioplasty (PTA).
- This product is designed for single patient use only. Do not reuse, reprocess, or resterilize this product. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.
- Assess risks and benefits before treating patients with a history of severe reaction to contrast agents.
- The safety and effectiveness of the IN.PACT Admiral DCB used in conjunction with other drug-eluting stents or drug-coated balloons in the same procedure or following treatment failure has not been evaluated.
- The extent of the patient's exposure to the drug coating is directly related to the number of balloons used. Refer to the *Instructions for Use* (IFU) for details regarding the use of multiple balloons and paclitaxel content.
- The use of this product carries the risks associated with percutaneous transluminal angioplasty, including thrombosis, vascular complications, and/or bleeding events

## Potential Adverse Events

Adverse events that may occur or require intervention include, but are not limited to the following: abrupt vessel closure; access site pain; allergic reaction to contrast medium, antiplatelet therapy, or catheter system components (materials, drugs, and excipients); amputation/loss of limb; arrhythmias; arterial aneurysm; arterial thrombosis; arteriovenous (AV) fistula; death; dissection; embolization; fever; hematoma; hemorrhage; hypotension/hypertension; inflammation; ischemia or infarction of tissue/organ; local infection at access site; local or distal embolic events; perforation or rupture of the artery; pseudoaneurysm; renal insufficiency or failure; restenosis of the dilated artery; sepsis or systemic infection; shock; stroke; systemic embolization; vessel spasms or recoil; vessel trauma which requires surgical repair.

Potential complications of peripheral balloon catheterization include, but are not limited to the following: balloon rupture; detachment of a component of the balloon and/or catheter system; failure of the balloon to perform as intended; failure to cross the lesion.

Although systemic effects are not anticipated, potential adverse events that may be unique to the paclitaxel drug coating include, but are not limited to: allergic/immunologic reaction; alopecia; anemia; gastrointestinal symptoms; hematologic dyscrasia (including leucopenia, neutropenia, thrombocytopenia); hepatic enzyme changes; histologic changes in vessel wall, including inflammation, cellular damage, or necrosis; myalgia/arthralgia; myelosuppression; peripheral neuropathy.

Refer to the Physician's Desk Reference for more information on the potential adverse events observed with paclitaxel. There may be other potential adverse events that are unforeseen at this time.

Please reference appropriate product *Instructions for Use* for a detailed list of indications, warnings, precautions and potential adverse events. This content is available electronically at [www.manuals.medtronic.com](http://www.manuals.medtronic.com).

**CAUTION:** Federal (USA) law restricts the use of this device to sale by or on the order of a physician.

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<sup>i</sup> The safety and effectiveness of the IN.PACT Admiral DCB used in conjunction with other drug-eluting stents or drug-coated balloons in the same procedure or following treatment failure has not been evaluated.

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