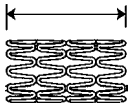
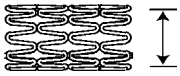
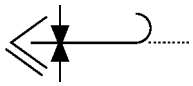
Medtronic

Endeavor

ABT-578 Eluting Coronary Stent System

INSTRUCTIONS FOR USE

Symbols used in labeling:

	Consult instructions for use		Peel here
	Contents: One (1) Endeavor ABT-578 eluting stent mounted on a rapid exchange stent delivery system	EC REP	EC authorized representative
	Use by		Stent length
	Use immediately		Stent inner diameter
	Single use only	PYROGEN	Non-pyrogenic
STERILE EO	STERILE. Sterilized using ethylene oxide		Maximum guidewire diameter
REF	Product number	MGCID	Minimum guide catheter I.D.
LOT	Lot number	NP	Nominal pressure
	Temperature Limitation	RBP	Rated burst pressure
	Manufacturer	RBP	Do not exceed rated burst pressure
	Do not use if package is damaged	MSID	Maximum stent I.D.
IP	Inflation pressure		

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1.0 DEVICE DESCRIPTION

The Endeavor ABT-578 Eluting Coronary Stent System (Endeavor Stent) consists of four subsystems:

1) Endeavor Stent - a pre-mounted cobalt alloy based stent
2) Delivery system (Rapid Exchange (RX) Coronary System)
3) Phosphorylcholine (PC) Technology[1]
4) The Drug ABT-578

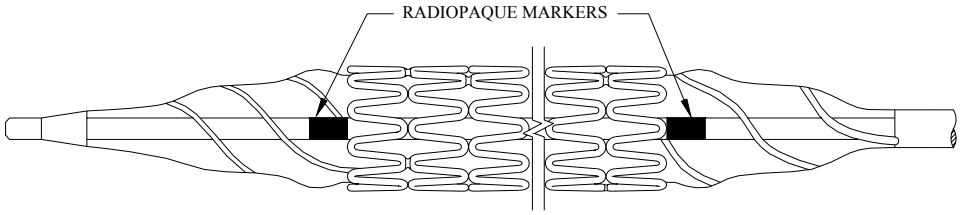
1.1 STENT

The Endeavor Stent is manufactured from a cobalt alloy. The stents are provided in a range of sizes from 2.25 mm to 4.0 mm in diameter and 8 mm to 30 mm in length.

Stent diameters 2.25, 2.5, and 2.75 mm are available in lengths of 8 , 12, 14, 18, 24, and 30 mm.
Stent diameters 3.0, 3.5, and 4.0 mm are available in lengths of 9, 12, 15, 18, 24, and 30 mm.

1.2 DELIVERY SYSTEM

The delivery system consists of a balloon-expandable intracoronary stent premounted on an RX delivery system. The delivery system has two radiopaque markers to aid in the placement of the stent during fluoroscopy. The delivery system is compatible with 0.014" (0.36 mm) guidewires and 5 Fr (1.4 mm) guide catheters.



DRAWING FOR REFERENCE ONLY; DRAWING NOT TO SCALE

1.3 POLYMER - PHOSPHORYLCHOLINE (PC) COATING

The Endeavor Stent is coated with a phosphorylcholine (PC) coating, which is a polymer that acts as a carrier for the drug ABT-578.

The PC polymer consists of 2-Methacryloyloxyethyl phosphorylcholine.

1.4 DRUG - ABT-578

The drug ABT-578 (a rapamycin analog) is a proprietary new chemical entity licensed from Abbott Laboratories. ABT-578 is a tetrazole-containing macrocyclic immunosuppressant. The suggested mechanism of action of ABT-578 is to bind to FKBP12, leading to the formation of a trimeric complex with the protein kinase mTOR (mammalian target of rapamycin), inhibiting its activity. Inhibition of mTOR results in the inhibition of protein phosphorylation events associated with translation of mRNA and cell cycle control.

The Endeavor Stent has a nominal dose of 10 μg ABT-578 per mm stent length.

[1] The PC Technology is licensed under patents or patent applications owned by Biocompatibles.

1.5 PRODUCT INFORMATION

Table 1 – Medtronic Endeavor Stent Product Information

Nominal Stent ID*	Nominal Stent Length	Nominal Stent Deployment Pressure	Rated Burst Pressure (RBP)
2.25 mm 2.5 mm 2.75 mm	8 mm 12 mm 14 mm 18 mm 24 mm 30 mm	9 atm (912 kPa)	16 atm (1621 kPa)
3.0 mm 3.5 mm	9 mm 12 mm 15 mm 18 mm 24 mm 30 mm	9 atm (912 kPa)	16 atm (1621 kPa)
4.0 mm	9 mm 12 mm 15 mm 18 mm 24 mm 30 mm	9 atm (912 kPa)	15 atm (1520 kPa))

*After deployment and recoil.
Minimum Guide catheter ID $\geq$ 5 French (0.056”/1.4 mm).

2.0 HOW SUPPLIED

STERILE. FOR SINGLE USE ONLY. The Endeavor Stent is sterilized with ethylene oxide (EtO) and is non-pyrogenic. DO NOT RESTERILIZE. Do not use if the package has been opened or damaged.

Contents: Package contains one (1) Endeavor Stent.

Storage: STORE IN THE ORIGINAL CONTAINER. Store between 15°C and 30°C. Use by the “Use By” date noted on the package.

The outer pouch contains 2 small packets (one used to remove oxygen from the pouch and one used to remove moisture). Please discard these packets after opening the pouch.

3.0 INTENDED USE

The Endeavor Stent is intended for use in patients eligible for Percutaneous Transluminal Coronary Angioplasty (PTCA) with a reference vessel diameter of 2.25 mm to 4.0 mm and a lesion length of $\leq$ 27 mm. The Endeavor Stent is intended to improve coronary luminal diameters as an adjunct to coronary interventions and reduce restenosis. The stents are intended as permanently implanted devices.

4.0 INDICATIONS FOR USE

The Endeavor Stent is indicated for improving coronary luminal diameter and reducing restenosis in patients with symptomatic ischemic heart disease in *de novo* coronary artery lesions in native coronary arteries with a reference vessel diameter of 2.25 mm to 4.0 mm and a lesion length of $\leq$ 27 mm.

5.0 CONTRAINDICATIONS FOR USE

The Endeavor Stent is contraindicated for use in:

- Patients with hypersensitivity or allergies to aspirin, heparin, clopidogrel, ticlopidine, drugs such as ABT-578, rapamycin, tacrolimus, sirolimus or similar drugs or any other analogue or derivative, cobalt, chromium, nickel, molybdenum, or contrast media.

- Patients in whom antiplatelet and/or anticoagulation therapy is contraindicated.

- Patients who are judged to have a lesion that prevents complete inflation of an angioplasty balloon.

6.0 WARNINGS AND PRECAUTIONS

- The long-term effects of ABT-578 are currently unknown.

- The patient's exposure to the drug is directly related to the total amount of stent length implanted.

- Safety and effectiveness for direct stenting has not been established.

- Safety and effectiveness for stenting of saphenous vein grafts has not been established.

- Judicious selection of patients is necessary since the use of this device carries the associated risk of complications listed in Section 7.0 Potential Adverse Events. The long-term effects of stents and the risks associated with these implants are unknown. This lack of knowledge should be considered in making a risk/benefit assessment for the patient prior to implantation.

- Administration of appropriate anticoagulant, antiplatelet and coronary vasodilator therapy is critical to successful stent implantation.

  Note: In clinical trials of the ENDEAVOR stent, clopidogrel or ticlopidine was administered pre-procedure and for a period of at least 12 weeks post-procedure. Aspirin was administered concomitantly with clopidogrel or ticlopidine and then continued indefinitely to reduce the risk of thrombosis. **See Section 5.0 CONTRAINDICATIONS FOR USE.**

- Only physicians who have received appropriate training should perform implantation of the stent.

- Stent placement should only be performed at hospitals where emergency coronary artery bypass graft surgery can be readily performed.

- Subsequent restenosis may require repeat dilatation of the arterial segment containing the stent.

- While no specific clinical data are available, drugs, like tacrolimus, that act through the same binding protein (FKBP) may interfere with the efficacy of ABT-578. Drug interaction studies have not been completed. ABT-578 is metabolized by CYP3A4. Strong inhibitors of CYP3A4 (e.g. ketoconazol) might cause increased ABT-578 exposure to levels associated with systemic effects, especially if multiple stents are deployed. Systemic exposure of ABT-578 should also be taken into consideration if the patient is treated concomitantly with systemic immunosuppressive therapy.

- There are no adequate or well-controlled studies in pregnant women, lactating women, or men intending to father children for this product.

- Subsequent restenosis may require repeat dilatation of the arterial segment containing the stent. The long-term outcome following repeat dilatation of endothelialized cornonary stents is unknown at present.

- When multiple stents are required, stent materials should be of similar composition. Placing multiple stents of different materials in contact with each other may increase potential for corrosion. Data obtained from *in vitro* corrosion tests using F562 CoCr alloy stent (Medtronic Driver Coronary Stent) in combination with a 316L stainless steel alloy stent (Medtronic S7 Coronary Stent) do not suggest an increased risk of *in vivo* corrosion.

6.1 STENT HANDLING – PRECAUTIONS

- Do not use if package has been opened or damaged.

- **For single use only**. Do not re-sterilize or reuse. Note product "Use By" date.

- **Do not remove stent from the stent delivery system** as removal may damage the stent and/or lead to stent embolization**.** The Endeavor Drug Eluting Rapid Exchange Coronary Stent System is intended to perform as a system. The stent is not designed to be crimped onto another delivery device.

- The Endeavor Coronary Stent Delivery System should not be used in conjunction with any other stents or for post-dilatation.

- Excessive manipulation, e.g., rolling the mounted stent, may cause dislodgement of the stent from the delivery balloon.

- Special care must be taken not to handle or in any way disrupt the stent position on the delivery device. This is most important during catheter removal from packaging, placement over guidewire, and advancement through rotating hemostatic valve adapter and guiding catheter hub.

- **The Endeavor Stent must not be exposed to any direct handling (e.g. rolling of the stent) or contact with liquids prior to preparation and delivery as the coating may be susceptible to damage or premature drug elution.**

- Do not expose or wipe the device with organic solvents such as alcohol.

- Use only the appropriate balloon inflation media. Do not use air or any gaseous medium to inflate the balloon as it may cause uneven expansion and difficulty in deployment of the stent.

6.2 STENT PLACEMENT – PRECAUTIONS

- **Do not prepare or pre-inflate the stent delivery system prior to stent deployment,** other than as directed. Use balloon-purging technique described in Section 9.3 Preparation of Delivery System.

- Safety and effectiveness of total stented lengths longer than 48 mm has not been established. If additional stenting is required, stent materials of similar composition should be used.

- Implanting a stent may lead to dissection of the vessel distal and/or proximal to the stented portion, and may cause acute closure of the vessel requiring additional intervention (e.g., CABG, further dilatation, or placement of additional stents).

- Do not expand the stent if it is not properly positioned in the vessel (See Section 9.7 Stent / Delivery System Removal Precautions).

- The long-term outcome following repeat dilatation of endothelialized coronary stents is unknown at present.

- Placement of the stent has the potential to compromise side branch patency.

- **Do not exceed Rated Burst Pressure as indicated on product label.** Balloon pressures should be monitored during inflation. Use of pressures higher than those specified on product label may result in a ruptured balloon and potential intimal damage and dissection (See Table 1).

- Stent retrieval methods (use of additional wires, snares and/or forceps) may result in additional trauma to the coronary vasculature and/or the vascular access site. Complications can include bleeding, hematoma or pseudoaneurysm.

6.3 POST-IMPLANT– PRECAUTIONS

Care must be exercised when **crossing a newly deployed stent** with an intravascular ultrasound (IVUS) catheter, a coronary guidewire, or a balloon catheter to avoid disrupting the coating and/or the stent geometry of the Endeavor Stent.

Non-clinical magnetically induced deflection and torque testing at 3 Tesla, maximum spatial gradient of 525 gauss/cm (5.25 Tesla/meter) indicates that the Endeavor Stent should not move or migrate immediately post-implantation.

The Endeavor Stent produces a temperature rise of less than 0.5 degrees C in association with MR imaging performed at a whole body averaged specific absorption rate (SAR) of 2.0 W/kg, spatial peak SAR of 4.0 W/kg for 20 minutes. The effect of performing MRI procedures using higher levels of RF energy on a patient with the Endeavor Stent has not been determined. The results may not apply to overlapping stents. The effect of heating in association with MRI on the drug or polymer coating is unknown.

MR image quality may be compromised if the area of interest lies close to or is in the same position as the stent.

Post Dilatation: All efforts should be made to assure that the stent is not underdilated. If the deployed stent is not fully apposed to the vessel wall, the stent may be expanded further with a larger diameter balloon that is slightly shorter (about 2 mm) than the stent. The post-dilatation can be done using a low-profile, high pressure, and non-compliant balloon catheter and the balloon should not extend outside of the stented region.

7.0 POTENTIAL ADVERSE EFFECTS

The following complications may be associated with the use of coronary stenting devices, IVUS, or PTCA (listed in order of severity):

- Death
- Aneurysm, pseudoaneurysm, or arteriovenous fistula
- Damage to the stent or injury to the artery requiring emergency coronary artery bypass graft (CABG)
- Stroke / transient ischemic attack
- Cardiac tamponade
- Dissection, perforation, or rupture of the coronary artery
- Embolism (air, tissue, device, or thrombus)
- Stent thrombosis / occlusion
- Total occlusion of the artery
- Acute myocardial infarction
- Restenosis of the stented artery
- Arrhythmias
- Hemorrhage requiring transfusion
- Shock/pulmonary edema
- Abrupt vessel closure or spasm
- Hypotension / hypertension
- Allergic reaction (to contrast, antiplatelet therapy, stent material or drug coating)
- Peripheral ischemia / peripheral nerve injury
- Infection or fever
- Unstable angina
- Pain/reaction at catheter insertion site
- Balloon rupture
- Stent migration
- Failure to deliver the stent
- Stent misplacement
- Hematoma

The occurrence of the above listed complications may lead to the need for a repeat catheterization and/or percutaneous coronary intervention, myocardial infarction, emergency bypass surgery, or death. The following additional side effects/complications may be associated with, but not limited to the use of ABT-578, including i.v. administration of ABT-578 (listed in alphabetical order):

- Anemia
- Circumoral paresthesia
- Diarrhea
- Dry skin
- Headache
- Hematuria
- Infection
- Injection site reaction
- Pain (abdominal, arthralgia, injection site)
- Rash

8.0 PATIENT SELECTION AND TREATMENT

The risks and benefits described above should be carefully considered for each patient before use of the Endeavor ABT-578 Eluting Coronary Stent System.

The safety and effectiveness of using mechanical atherectomy devices (directional atherectomy catheters, rotational atherectomy catheters), or laser angioplasty catheters, to treat in-stent stenosis have not been established.

9.0 CLINICIAN USE INFORMATION

9.1 INSPECTION PRIOR TO USE

Carefully inspect the sterile package before opening. Do not use if the package has been damaged or opened. Do not use the product after the "Use By" date.

If the sterile package appears intact, carefully remove the system from the package and inspect for bends, kinks and other damage. Verify that the stent is located between the radiopaque markers. Do not use if any defects are noted.

9.2 MATERIALS REQUIRED

- 5 F Guiding catheter with minimum inner diameter of 0.056" (1.4 mm)
- 20 cc syringe
- Heparinized normal saline
- 0.014 inch (0.36 mm) guidewire
- Rotating hemostatic valve
- Contrast medium diluted 1:1 with heparinized normal saline
- Inflation device
- Torque device
- Three-way stopcock

9.3 PREPARATION OF DELIVERY SYSTEM

1. Prepare the guide catheter and guide wire according to the manufacturer's instructions. The Endeavor Stent is compatible with 0.014" (0.36mm) guide wires. Refer to product labeling or Section 9.2 for specific guiding catheter compatibility.

2. Careful stent sizing is important to successful stenting. Select stent length appropriate for the target lesion (≥ 3 mm longer than the lesion length). Ensure the selected stent is long enough to cover the lesion completely.

   Note: The inflated balloon diameter measures slightly larger than the labeled stent inner diameter to allow for stent recoil following expansion.

3. Remove the stent delivery system from the package.

4. Remove protective sheath covering from the stent/balloon. Special care must be taken not to handle the stent in any way that may disrupt its placement on the balloon

5. Inspect the stent to ensure it has not been damaged or displaced from its original position on the balloon. Verify that the stent is positioned between the proximal and distal balloon markers.

   Note: Should there be movement of or damage to the stent, do not use.

6. Flush Stent Delivery System guidewire lumen with heparinized normal saline until fluid exits the distal tip.

7. Fill a 20 cc syringe with 5 cc of contrast/heparinized normal saline mixture (1:1).

8. Attach to delivery system and apply negative pressure for 20-30 seconds.

9. Slowly release pressure to allow negative pressure to draw mixture into balloon lumen.

10. Detach syringe and leave a meniscus of mixture on the hub of the balloon lumen.

11. Prepare inflation device in standard manner and purge to remove all air from syringe and tubing.

12. Attach inflation device to catheter directly ensuring no bubbles remain at connection.

13. Leave on ambient pressure (neutral position).

Note: Do not apply negative pressure on inflation device after balloon preparation and prior to delivering the stent.

9.4 DELIVERY PROCEDURE

1. Prepare vascular access site according to standard PTCA practice.

2. Pre-dilate the lesion with a balloon diameter 0.5 mm smaller than the stent and balloon length equal to or shorter than the target lesion length. The length of the pre-dilatation balloon must be shorter than the stent to be implanted.

3. Maintain neutral pressure on inflation device. Open rotating hemostatic valve to allow for easy passage of the stent.

   Note: If resistance is encountered, DO NOT FORCE PASSAGE. Resistance may indicate a problem and may result in damage to the stent if it is forced. Remove the system and examine.

4. Ensure guiding catheter stability before advancing the Stent Delivery System into the coronary artery. Carefully advance the Stent Delivery System into the hub of the guiding catheter

5. **Note:** If the physician encounters resistance to the Stent Delivery System prior to exiting the guiding catheter, **do not force passage**. Resistance may indicate a problem and may result in damage to the stent if it is forced. Maintain guidewire placement across the lesion and remove the Stent Delivery System as a single unit (See Section 9.7 Stent Delivery System Removal – Precautions)

6. Advance delivery system over the guidewire to the target lesion under direct fluoroscopic visualization. Utilize the proximal and distal radiopaque markers on the balloon as a reference point. If the position of the stent is not optimal, it should be carefully repositioned or removed (See Section 9.7 Stent/ Delivery System Removal Precautions) Expansion of the stent should not be undertaken if the stent is not properly positioned in the target lesion segment of the vessel.

7. Sufficiently tighten the rotating hemostatic valve. Stent is now ready to be deployed.

9.5 STENT DEPLOYMENT PROCEDURE

1. Prior to stent expansion, utilize high-resolution fluoroscopy to verify the stent has not been damaged or shifted during positioning.

2. Maintain inflation pressure for 15-30 seconds for full expansion of the stent.

3. **Do not exceed Rated Burst Pressure. The Endeavor Stents should not be expanded to a diameter beyond 0.5 mm of its nominal expansion.**

Note: In smaller or diffusely diseased vessels, the use of high balloon inflation pressures may over-expand the vessel distal to the stent and could result in vessel dissection.

Note: Under-expansion of the stent may result in stent movement. Care must be taken to properly size the stent to ensure the stent is in full contact with the arterial wall upon deflation of the balloon.

9.6 REMOVAL PROCEDURE

1. Deflate the balloon by pulling negative pressure on the inflation device. Allow adequate time, at least 15 seconds, for full balloon deflation. Longer stents may require more time for deflation. **Deflation of the balloon should be confirmed by absence of contrast within the balloon.**

2. Open the hemostatic valve to allow removal of the delivery system.

3. Maintain position of guiding catheter and guidewire to prevent it from being drawn into the vessel. Very slowly, withdraw the balloon from the stent maintaining negative pressure, allowing movement of the myocardium to gently dislodge the balloon from the stent.

4. After removal of the delivery system, tighten the hemostatic valve.

5. Repeat angiography and visually assess the vessel and the stent for proper expansion.

   Note: Should the need arise for placement of a second stent to adequately cover the lesion length, placement of the stent most distal in the artery should be done prior to placement of the proximal stent, if possible. Safety and effectiveness of total stent lengths larger than 48 mm has not been established.

6. **Note:** Observation of the patient and angiographic evaluation of the stent site should be performed periodically within the first 30 minutes after stent placement. If stent placement is associated with the onset of thrombus or suspected thrombus in the region of the stented segment, an intracoronary infusion of a thrombolytic agent is recommended.

9.7 STENT / DELIVERY SYSTEM REMOVAL PRECAUTIONS

If removal of a stent system is required prior to deployment, ensure that the guide catheter is coaxially positioned relative to the stent delivery system and cautiously withdraw the stent delivery system into the guide catheter. **Should unusual resistance be felt at any time when withdrawing the stent towards the guide catheter, the Stent Delivery System and the guiding catheter should be removed as a single unit. This must be done under direct visualization with fluoroscopy.**

When removing the Stent Delivery System and Guiding Catheter as a single unit:

- **Do not retract the Stent Delivery System into the guiding catheter.** Maintain guidewire placement across the lesion and carefully pull back the Stent Delivery System until the proximal balloon marker of the Stent Delivery System is aligned with the distal tip of the guiding catheter.

- The system should be pulled back into the descending aorta toward the arterial sheath. As the distal end of the guiding catheter enters into the arterial sheath, the catheter will straighten, allowing safe withdrawal of the Stent Delivery System into the guiding catheter and the subsequent removal of the Stent Delivery System and the guiding catheter from the arterial sheath.

Failure to follow these steps and/or applying excessive force to the Stent Delivery System can potentially result in loss or damage to the stent and/or Stent Delivery System components such as the balloon.

Table 2 - Endeavor Drug Eluting Rapid Exchange Coronary Stent System
Inner Diameter (mm) vs. Inflation Pressure (atm/kPa)

Average Deployed Stent Inner Diameter (mm) at Pressure per Diameter													
Size (mm)	6 atm (608 kPa)	7 atm (709 kPa)	8 atm (811 kPa)	9 atm (912* kPa)	10 atm (1013 kPa)	11 atm (1115 kPa)	12 atm (1216 kPa)	13 atm (1317 kPa)	14 atm (1418 kPa)	15 atm (1520 kPa)	16 atm (1621** kPa)	17 atm (1722 kPa)	18 atm (1824 kPa)
2.25	2.08	2.14	2.19	2.25	2.27	2.30	2.33	2.36	2.39	2.43	2.46	2.50	2.54
2.5	2.34	2.39	2.45	2.50	2.54	2.57	2.60	2.63	2.66	2.68	2.71	2.74	2.77
2.75	2.58	2.65	2.71	2.75	2.79	2.83	2.86	2.89	2.92	2.95	2.99	3.03	3.07
3.0	2.84	2.89	2.95	3.00	3.02	3.05	3.08	3.12	3.15	3.19	3.22	3.25	3.29
3.5	3.30	3.38	3.44	3.50	3.52	3.56	3.59	3.63	3.67	3.71	3.75	3.78	3.82
4.0	3.77	3.86	3.93	4.00	4.06	4.10	4.15	4.19	4.23	4.29	4.34	4.39	4.44

* Nominal Deployment Pressure (9 atm /912 kPa)

Rated Burst Pressure. 16 atm (1621 kPa) for stent diameters up to 3.5 mm, 15 atm (1520 kPa) for 4.0 mm stents. **DO NOT EXCEED.

Note: The nominal *in vitro* device specification does not take into account lesion resistance. Stent sizing should be confirmed angiographically.

Note: Do not dilate the Endeavor Stent beyond the compliance chart provided on the package. Do not dilate the Endeavor Stent beyond 0.5mm greater than its nominal pressure.

Note: Balloon pressures should be monitored during inflation. Do not exceed Rated Burst Pressure as specified on product label as this may result in a ruptured balloon with possible intimal damage and dissection.

DISCLAIMER OF WARRANTY

NOTE: ALTHOUGH THE MEDTRONIC ENDEAVOR STENT, HEREAFTER REFERRED TO AS "PRODUCT," HAS BEEN MANUFACTURED UNDER CAREFULLY CONTROLLED CONDITIONS, MEDTRONIC, INC. AND THEIR AFFILIATES (COLLECTIVELY, "MEDTRONIC") HAVE NO CONTROL OVER CONDITIONS UNDER WHICH THIS PRODUCT IS USED. MEDTRONIC, THEREFORE, DISCLAIMS ALL WARRANTIES, BOTH EXPRESSED AND IMPLIED, WITH RESPECT TO THE PRODUCT, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. MEDTRONIC SHALL NOT BE LIABLE TO ANY PERSON OR ENTITY FOR ANY MEDICAL EXPENSES OR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES CAUSED BY ANY USE, DEFECT, FAILURE OR MALFUNCTION OF THE PRODUCT, WHETHER A CLAIM FOR SUCH DAMAGES IS BASED UPON WARRANTY, CONTRACT, TORT OR OTHERWISE. NO PERSON HAS ANY AUTHORITY TO BIND MEDTRONIC TO ANY REPRESENTATION OR WARRANTY WITH RESPECT TO THE PRODUCT.

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