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Update – Critical Product Correction and Product Alert

ACCOLADE™ single chamber (SR), dual chamber (DR) standard life (SL) and DR extended life (EL) pacemakers; and VISIONIST™ cardiac resynchronization therapy pacemakers (CRT-Ps)

ARTG Numbers: 400400, 400396, 400399, 400403, 400404 and 400405

TGA Ref: RC-2024-RN-001116-1

September 2025

Subject: Update to December 2024 Product Correction and Product Alert (RC-2024-RN-001116-1)

PRODUCT CORECTION

- Model 3869 v2.04 software to enhance Safety Architecture is available and designed to detect high battery impedance and prevent initiation of Safety Mode in ACCOLADE™ devices[1].

PRODUCT ALERT

- Unintended Behaviours observed with the Model 3869 v2.04 software released in Australia, New Zealand and United States
  (Boston Scientific Field Action Reference: 97125289F-FA).

Dear Physician or Healthcare Professional (HCP),

This letter provides an update to the information regarding the enhanced software Model 3869 v2.04 of unintended behaviours observed since the release of this software. The updated recommendations for device management in consideration of software availability are included within. It is essential that this letter be read in its entirety to ensure a comprehensive understanding of the related subject matter.

*Note: Appendices at the end of this letter provide further information regarding high battery impedance-related behaviours described in the original December 2024 Product Correction (**TGA Ref: RC-2024-RN-001116-1** (Appendix A) and precise details about the bounding of affected devices (Appendix B).*

1. Model 3869 v2.04 Software Availability

This notice provides an update to December 2024 Product Correction (TGA Ref: RC-2024-RN-001116-1) regarding the potential for the ACCOLADE family of pacemakers to initiate Safety Mode due to a high battery impedance state.

- A software upgrade (Model 3869 v2.04) is available for the LATITUDE™ Programming System, Model 3300 (programmer), which upon interrogation of a pacemaker from the ACCOLADE family, is intended to enable detection of an elevated battery impedance via an alert and disable wandless ZIP™ telemetry (i.e., radio frequency) in a device with sufficiently high impedance to prevent initiation of Safety Mode.
- Patients will not receive this software until their pacemaker is interrogated by an upgraded programmer at their next in-person visit.

[1]ACCOLADE family of devices include ACCOLADE, PROPONENT™, ESSENTIO™, and ALTRUA™ 2 dual chamber (DR) standard life (SL) and DR extended life (EL) pacemakers; and VISIONIST™ and VALITUDE™ cardiac resynchronization therapy pacemakers (CRT-Ps).

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- Disablement of ZIP telemetry is intended to prevent initiation of Safety Mode in an ambulatory setting for any device upgraded with this software that is experiencing a high battery impedance state.
- Sensing, therapy, and other programmed functions are unaffected if ZIP telemetry is disabled.
- When a pacemaker receives this enhanced software, prophylactic replacement is no longer recommended for patients at risk of harm due to the non-programmable parameters in Safety Mode, see updated recommendations below in Table 1.
- All ACCOLADE pacemakers will benefit from this software upgrade. Boston Scientific is expanding our recommendations to all device types in the Accolade family. For precise details about the bounding of affected devices, see Appendix B.

Physician / Health Care Professional Customer Recommendations

These recommendations are intended to promote a risk-stratified, timely upgrade of pacemaker software to mitigate the occurrence of Safety Mode in an ambulatory setting due to a high battery impedance state.

- Connect your LATITUDE programmer to the internet (e.g., via WiFi, ethernet, or cell adapter), select Utilities>Software Update>Easy Install, and wait for the programmer to install Model 3869 v2.04 software. Maintain internet connection and power until the installation is complete.
- If your programmer cannot be connected to the internet, contact your local Boston Scientific sales representative or call Technical Services (+61 2 80638299) to arrange for your programmer's software to be upgraded.

Table 1 Recommendations for ACCOLADE pacemakers with availability of Model 3869 v2.04 software.

<table>
<tr><th>Actions</th><th colspan="2">Recommendations</th></tr>
<tr><td>Prophylactic Replacement</td><td colspan="2">Not recommended for patients who have been interrogated with a Model 3300 LATITUDE programmer with Model 3869 v2.04 installed.</td></tr>
<tr><td rowspan="2">Upgrade pacemaker or CRT-P firmware</td><td>For patients at risk of harm due to Safety Mode: If longevity remaining is four (4) years or less OR will reach four (4) years or less before the next scheduled follow-up, promptly schedule an in-person follow-up.</td><td>For all other patients: Schedule the next follow-up in-person.</td></tr>
<tr><td colspan="2">During the in-person follow-up, interrogate the device using a Model 3300 LATITUDE programmer installed with Model 3869 v2.04 software.</td></tr>
</table>

<table>
<tr><td>Follow-up</td><td colspan="2">Consider enrolling/following patients via remote monitoring (RM) who are deemed at risk of harm due to Safety Mode and who are not currently followed remotely.

After device firmware has been upgraded by Model 3869 v2.04 software on a Model 3300 LATITUDE programmer, perform system follow-up as described below:
For patients followed via RM, continue monitoring. If the battery voltage is too low for projected remaining capacity (Code-1003 is detected), or wandless telemetry is disabled, a Red Alert will be displayed in LATITUDE.
For patients who cannot be monitored remotely:
For patients at risk of harm due to Safety Mode, perform system follow-up one week after pacemaker firmware has been upgraded to assess whether an elevated or high battery impedance has been detected. This provides the new software algorithm time to detect and declare a sufficiently high impedance state via a Code-1003 alert or disablement of wandless telemetry (in the event the device is very near entering Safety Mode at the time of the software upgrade). After that, perform device follow-ups at three (3) month intervals.
For all other patients, perform system follow-up at an interval in accordance with the Instructions for Use (IFU).</td></tr>
<tr><td>Contact Technical Services if a high battery impedance state is detected after receiving the software upgrade</td><td colspan="2">If either an alert for voltage too low for remaining longevity (Code-1003) and/or disablement of wandless ZIP telemetry is observed after device software has been upgraded by Model 3869 v2.04 software, contact Technical Services.
Technical Services can provide a customized recommended replacement interval for high battery impedance conditions
Technical Services can assist in determining if disabled wandless telemetry is due to a false positive detection due to the presence of a magnet.</td></tr>
<tr><td>Replace the device if it enters Safety Mode before receiving the software upgrade</td><td>For patients at risk of harm due to Safety Mode non-programmable parameters: Emergent/urgent replacement</td><td>All other patients: Non-emergent replacement</td></tr>
</table>

Replacement procedure considerations for a device in Safety Mode	• When choosing a replacement interval, do not rely on previously reported battery time remaining estimates; these do not account for Safety Mode's increased outputs nor the battery's high impedance state. • During replacement of a device in Safety Mode, pacing inhibition should be anticipated during electrocautery and when the device is removed from the pocket due to unipolar pacing and high sensitivity.
Append Patient's Medical Records	• For each patient with an affected device, append/update the patient's medical record with this letter to maintain physician awareness of this topic for the remaining service life of the device. • A patient letter is available upon request, which can be distributed to the patient.

2. Model 3869 v2.04 Software New Unintended Behaviours following implementation of the patch

The recently launched Model 3869 v2.04 software, released in the United States, Australia, and New Zealand, was designed to prevent potential initiation of Safety Mode due to a high battery impedance condition in ACCOLADE pacemakers (originally described in the December 2024 Product Correction **TGA Ref: RC-2024-RN-001116-1).** This software update introduces two separate mechanisms to mitigate risks associated with this battery condition. First, the software enables detection of an elevated battery impedance condition via a telemetry activated battery test, triggering a red alert (voltage is too low for projected remaining capacity, also known as Code-1003). Second, the software disables ZIP™ telemetry (i.e., wandless, two-way radiofrequency communication) when the battery reaches a high impedance state to prevent initiation of Safety Mode in an ambulatory setting.

Since the launch of Model 3869 v2.04 software in August 2025 and subsequent device firmware upgrades via the Model 3300 LATITUDE™ programmer, Boston Scientific has identified two unintended behaviours associated with the software. Device sensing, therapy delivery, and all programmed functions remain unaffected, except for the noted changes to wandless telemetry operation (described below). **Despite the possible occurrence of these unintended behaviors, the benefits of implementing the Model 3869 v2.04 software outweigh the risks associated with prophylactic replacement.** As such, Boston Scientific strongly recommends the continued installation of this software for **all devices** within the ACCOLADE family; all ACCOLADE pacemakers are intended to receive this software/firmware upgrade.

NEW BEHAVIOURS:

Although Model 3869 v2.04 software has significantly mitigated the initiation of Safety Mode associated with a high battery impedance condition, it does not fully eliminate this potential risk. Boston Scientific has identified two possible unintended behaviours associated with the Model 3869 v2.04 software design:

1. *Incomplete disablement of wandless automatic telemetry after detecting a high battery impedance condition.* If an ACCOLADE family device with an elevated battery impedance induced Code-1003 remains in service, the software's new telemetry activated battery test is designed to continue assessing battery impedance and disable all wandless telemetry operation before high impedance is achieved and device resets can initiate Safety Mode.

- For devices exhibiting a high battery impedance condition, Safety Mode typically occurs during active LATITUDE programmer or communicator interrogation sessions, which draw the highest power. *The software's new telemetry activated battery test is operating as intended and is effective in disabling wandless telemetry operation before successive device resets can initiate Safety Mode associated with these active-telemetry scenarios.*
- *However, automatic low power telemetry wakeups are not disabled as intended in association with a high battery impedance condition.* The software allows for continuation of automatic, low power telemetry wakeups used to initiate a Remote Monitoring session after a high battery impedance condition is detected in the device. As the battery impedance continues to increase, the telemetry wakeup power draws may trigger Safety Mode. The risk of automatic telemetry wakeups causing a device to enter Safety Mode increases as the battery nears its normal replacement time, albeit at a much lower observed occurrence than active telemetry-associated Safety Mode initiations.

2. *Potential for the software's new daily battery test to misinterpret measurements in the presence of a magnet*, *initiating a false positive response that results in disablement of wandless telemetry sessions*. For patients monitored via LATITUDE, this will trigger an alert message indicating an erroneous explant indicator (e.g., explant indicator was reached January 1, 2000) if the device had not previously reached replacement indication, stating that LATITUDE is no longer available, and prompting to contact Technical Services. Note that this false positive behaviour is not possible if the device's magnet response is turned off. Disabled wandless telemetry prevents subsequent Remote Monitoring and wandless telemetry sessions using a LATITUDE Programmer; wanded telemetry continues to operate as intended and will be required during programming sessions.

Solution for the two unintended new behaviours:

Boston Scientific is actively developing a software update to address these unintended behaviours associated with the Model 3869 v2.04 software design. Specifically, forthcoming updated software will eliminate false positive detection of high battery impedance due to interaction with a magnet, fully disable the remaining wandless automatic telemetry wakeups after detecting a high battery impedance state, and re-enable wandless telemetry in the case of a previous false positive response and telemetry inactivation due to interaction with a magnet. Until this updated software is available, please refer to the recommendations as per Table 1.

Additional Information

This action is being conducted following consultation with the Therapeutic Goods Administration (TGA). Please report any adverse events through the TGA website https://www.tga.gov.au/resources/resource/guidance/reporting-adverse-events and scroll down to "Reporting medical device adverse events", then follow the prompts for health professionals.

Patient safety remains Boston Scientific's highest priority, and we are committed to communicating up-to-date information with physicians and healthcare professionals to ensure you have timely, relevant information for managing your patients. Product performance information, including this topic, a device lookup tool is available, within our Product Performance Resource Center at www.bostonscientific.com/ppr.

If you have additional questions regarding this information or would like to report an adverse event, please contact your Boston Scientific representative Technical Services (+61 2 8063 8299) or email ANZ_Incident_report@bsci.com.

Yours sincerely,

Seamus Gallagher
Senior Quality Assurance Manager | Boston Scientific Pty Ltd Australia and New Zealand

Appendix A – Battery High Impedance Condition/Potential for Safety Mode and Software Update

Clinical Impact

Safety Mode provides back-up pacing under critical circumstances; it is not intended to be a substitute for chronic pacing therapy. The non-programmable Safety Mode pacing parameters (Table 3) may not provide optimal support of a patient's cardiac condition; patients at risk of harm for Safety Mode include those with an inadequate underlying escape rhythm, a need for AV/VV pacing for cardiac synchrony, and/or a potential for pacing inhibition due to myopotential oversensing. Pacing inhibition due to myopotential oversensing for unipolar sensing configurations is well documented; however, provocative maneuvers, including isometric exercises, are not a reliable predictor of myopotential oversensing susceptibility for patients who may transition to Safety Mode.

The most common clinical outcome of this behaviour is early device replacement. In certain patients, Safety Mode may result in unintended clinical impact such as pacing inhibition/pauses, muscle stimulation (e.g., skeletal muscle or phrenic nerve stimulation), or heart failure decompensation prior to device replacement. Among patients at risk of harm whose pacemaker initiates Safety Mode, Caughron et al. reported a 52% rate of major complications due to presyncope, syncope, fall with trauma, pauses/asystole, and death.[2] Remote monitoring, a standard of care[3], is a critical device management capability, and is an important means to detect onset of high battery impedance with this software upgrade.

The worst case reported patient harm has been loss of pacing with serious injury or life-threatening outcome. There have been two (2) deaths in pacemaker dependent patients after initiating Safety Mode in an ambulatory setting and no additional deaths have been reported. Details about the ACCOLADE subpopulations and lifetime occurrence rate for each device type are reported in Table 2. Occurrence rates for various device types are reported in Figures 1 and 2.

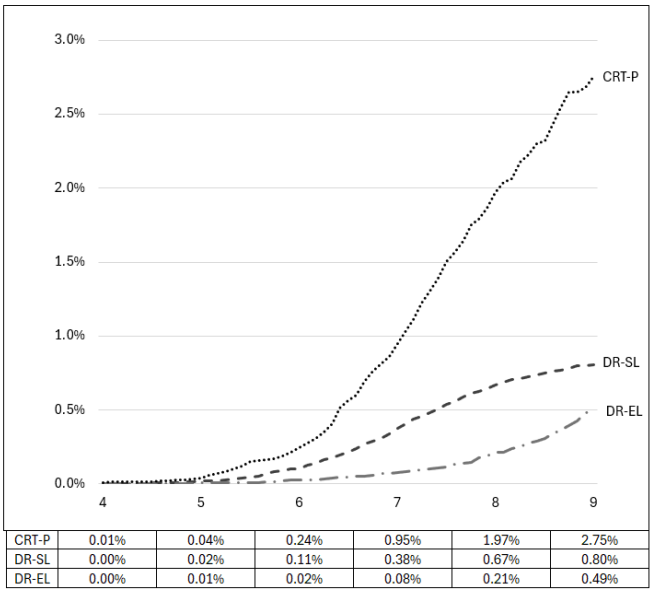
Table 2 ACCOLADE populations and occurrence rates for Safety Mode (SM) due to high battery impedance

Population	Device Type	Estimated WW Active Population	Estimated WW Distributed Population	SM Events	Lifetime SM Occurrence Rate
Dec 2024 Advisory Population	CRT-P	8,500	21,300	281	3.27% at 117 months
	DR EL	34,300	58,600	183	3.27% at 158 months*
	DR SL	56,500	123,400	605	0.75% at 102 months
All other devices	CRT-P	92,500	124,100	83	1.16% at 117 months
	DR EL	444,300	534,200	23	1.16% at 158 months*
	DR SL	539,700	683,000	125	0.14% at 102 months
	SR SL	189,500	294,900	60	0.19% at 117 months
Total		1,365,300	1,839,400	1,360	

*DR-EL rate is projected based on the experience of CRT-P, which uses the same EL battery

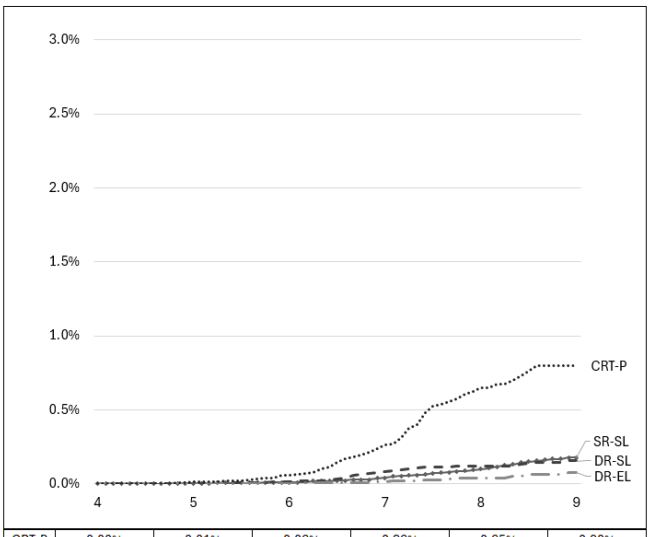
[2]Caughron H, Dhruva SS, Raitt MH. Complications Associated With Safety Mode Initiation in Recalled Boston Scientific Pacemakers. J Am Coll Cardiol. 2025 Apr 5:S0735-1097(25)05926-1. doi: 10.1016/j.jacc.2025.03.501. Epub ahead of print. PMID: 40202463.

[3]In patients with CIEDs, RM is recommended as part of the standard of care (COR-1/LOE-A) pg e99. Ferrick AM Raj SR, Deneke T, et al. 2023 HRS/EHRA/APHRS/LAHRS expert consensus statement on practical management of the remote device clinic. Heart Rhythm, ISSN: 1547-5271, Vol: 20, Issue: 9, Page: e92-e144. https://doi.org/10.1016/j.hrthm.2023.03.1525.



CRT-P	0.01%	0.04%	0.24%	0.95%	1.97%	2.75%
DR-SL	0.00%	0.02%	0.11%	0.38%	0.67%	0.80%
DR-EL	0.00%	0.01%	0.02%	0.08%	0.21%	0.49%

Figure 1 Occurrence rates for high battery impedance induced Safety Mode in the December 2024 advisory population



CRT-P	0.00%	0.01%	0.06%	0.26%	0.65%	0.80%
SR-SL	0.00%	0.01%	0.01%	0.04%	0.10%	0.18%
DR-SL	0.00%	0.00%	0.02%	0.08%	0.12%	0.16%
DR-EL	0.00%	0.00%	0.00%	0.02%	0.04%	0.08%

Figure 2 Occurrence rates for high battery impedance induced Safety Mode in remaining devices

Description of Software Enhancement

Wandless ZIP telemetry operations (such as active telemetry sessions and automatic ZIP wakeups) are the highest power operations performed in the ACCOLADE family of pacemakers and account for all confirmed instances of Safety Mode events associated with high battery impedance conditions. This software (Model 3869 v2.04) enhances Safety Architecture by adding a new daily wandless ZIP telemetry activated battery test[4] that assesses the battery's response to short bursts (e.g., milliseconds) of telemetry, detects/alerts onset of a high battery impedance state, and intervenes three (3) or more months later to prevent Safety Mode initiation. Note that this time period may be shortened for devices that triggered a voltage alert within a week of the software upgrade.

This is accomplished in two separate stages.

1. If this telemetry activated battery test detects an elevated battery impedance state, the following alert: "Voltage too low for projected remaining longevity" (Code-1003) will be displayed via the LATITUDE programmer or LATITUDE RM. This first stage is designed to detect and alert users about an elevated battery impedance condition at least three (3) months before pacemakers without this software would have initiated Safety Mode.
2. If a pacemaker from the ACCOLADE family with an elevated battery impedance induced Code-1003 remains in service, this telemetry activated battery test continues assessing the battery impedance and disables wandless ZIP telemetry operation before a high impedance condition results in successive device resets leading to initiation of Safety Mode.

   Note: In certain cases, in which a device has a sufficiently high battery impedance at the time of receiving the software, the algorithm will disable ZIP wandless telemetry without first issuing a Code-1003.

By design, this daily wandless ZIP telemetry activated battery test enhances the ACCOLADE family's Safety Architecture by mitigating the potential for Safety Mode initiation in an ambulatory setting due to a high battery impedance state. Please note the following:

[4]The daily wandless ZIP telemetry activated battery test is estimated to reduce device longevity by one (1) day for every 10 years of testing.

- Code-1003 is a general alert condition that can be initiated for a high battery impedance state or detection of other anomalous system conditions. By contacting Technical Services when a Code-1003 is observed, an engineering analysis can determine a customized replacement interval.
- By design, the earliest Code-1003 alert will be initiated is four (4) days after the in-office programmer interrogation when the pacemaker's software is upgraded.

Description of High Battery Impedance Behaviour Without Software Upgrade
As described in the original December 2024 Product Correction (**TGA Ref: RC-2024-RN-001116-1**, ACCOLADE devices have a potential to exhibit a high impedance condition because of an unanticipated concentration of lithium salts resulting from variability of battery assembly techniques. This may result in a lack of available electrolyte between the battery anode and cathode.

High battery impedance may cause a device to exhibit transient voltage decreases during wandless ZIP telemetry operations. If the battery voltage drops below a minimum threshold during a high-power state (e.g., active ZIP telemetry), a system reset is automatically performed, and the conditions of the high-power state are interrupted. Subsequent high-power states may result in additional system resets due to the high battery impedance.

If three (3) system resets occur within a 48-hour period, the device is designed to enter Safety Mode to maintain backup pacing with pre-defined, non-programmable settings (Table 3). When a device is in Safety Mode, healthcare professionals (HCPs) are directed to contact Boston Scientific via a LATITUDE programmer warning screen and a LATITUDE remote patient management system red alert. Once a device enters Safety Mode, life-sustaining therapy continues to be available while battery capacity is available. The susceptibility of experiencing a high battery impedance and entering Safety Mode has been observed when the device reaches approximately four (4) years or less of remaining battery longevity.

Table 3 Safety Mode Non-Programmable Settings

Parameter	Setting
Mode	VVI, biventricular pacing for CRT-Ps
Rate	72.5 ppm
Sensitivity	Automatic Gain Control (AGC) 0.25 mV
Output	5.0 V at 1.0 ms RV (and LV for CRT-Ps)
Lead Configuration	RV/LV Unipolar sensing/pacing
RVRP	250 ms
Noise response	VOO
LV Offset (CRT-Ps only)	0 ms
Magnet Response	Disabled

Per the IFU, Safety Mode is intended to provide life-sustaining therapy if repeated system resets occur with the following pre-defined, non-programmable parameters. A device that enters Safety Mode should be replaced.

When replacing a device in Safety Mode, the following conditions may interrupt pacing during the procedure:

- During applications of electrocautery, pacing may be inhibited due to Safety Mode's high sensitivity setting and unipolar sensing configuration.
- When removing the device from the pocket, loss of capture will occur due to Safety Mode's unipolar pacing configuration.

During normal operations when a device is indicated for replacement, the system is designed to reserve sufficient battery capacity to support device operations for three (3) months to allow for a replacement procedure to be scheduled. However, if a device without upgraded software enters Safety Mode due to high battery impedance, the reserve battery capacity may not be sufficient to support device operations for three months and should be

scheduled for replacement soon thereafter and emergently for patients at risk of harm from Safety Mode parameters.

The ACCOLADE family of pacemakers includes a standard life (SL) battery for single chamber (SR) and dual chamber (DR) pacemakers and a larger, extended life (EL) battery for DR pacemakers and cardiac resynchronization therapy pacemakers (CRT-Ps). Because of disparate batteries (e.g., SL vs. EL) and therapies provided (e.g., SR/DR pacemakers vs. CRT-Ps), the occurrence rates vary (Figures 1 and 2). However, the susceptibility for a device to enter Safety Mode due to high battery impedance occurs when the device reaches approximately four (4) years or less of remaining battery longevity. A retrospective study of 121 US Department of Veterans Affairs (VA) Centers found that, of ACCOLADE and INGENIO devices initiating Safety Mode due to high battery impedance, 100% did so with 4 years or less time remaining and 92% with 2 years or less time remaining.[5]

[5]Caughron H,. 2025 Apr 5:S0735-1097(25)05926-1. doi: https://doi.org/10.1016/j.jacc.2025.03.501.

Appendix B – Advisory Population

Although high battery impedance induced Safety Mode occurs later in the life of the pacemaker, the population has been expanded to include recently implanted devices from the ACCOLADE family with a use-by-date (UBD) on or before 30 June 2025. All patients will benefit from this software update. This bounding is intended to prioritize pacemakers presently susceptible to Safety Mode due to a high battery impedance state with consideration for the additional in-clinic follow-up burden. The expanded advisory population includes the following model numbers; however, these device attributes are not sufficient to precisely identify individual devices in the advisory population. Contact your local Boston Scientific sales professional for an affected serialized device list or enter a model/serial into the device lookup tool at www.BostonScientific.com/lookup.

GTIN	Model	Product Name
00802526559204	L310	ACCOLADE SR SL MRI
00802526559211	L310	ACCOLADE SR SL MRI
00802526572364	L310	ACCOLADE SR SL MRI
00802526572371	L310	ACCOLADE SR SL MRI
00802526572388	L310	ACCOLADE SR SL MRI
00802526576454	L310	ACCOLADE SR SL MRI
00802526576959	L310	ACCOLADE SR SL MRI
00802526578069	L310	ACCOLADE SR SL MRI
00802526609015	L310	ACCOLADE SR SL MRI
00802526611803	L310	ACCOLADE SR SL MRI
00802526559228	L311	ACCOLADE DR SL MRI
00802526559235	L311	ACCOLADE DR SL MRI
00802526572395	L311	ACCOLADE DR SL MRI
00802526576461	L311	ACCOLADE DR SL MRI
00802526578076	L311	ACCOLADE DR SL MRI
00802526559266	L331	ACCOLADE DR EL MRI
00802526559273	L331	ACCOLADE DR EL MRI
00802526572456	L331	ACCOLADE DR EL MRI
00802526576485	L331	ACCOLADE DR EL MRI
00802526578083	L331	ACCOLADE DR EL MRI
00802526592201	L331	ACCOLADE DR EL MRI
00802526559433	U225	VISIONIST CRT-P EL
00802526572630	U225	VISIONIST CRT-P EL
00802526577048	U225	VISIONIST CRT-P EL
00802526577116	U225	VISIONIST CRT-P EL
00802526578809	U225	VISIONIST CRT-P EL
00802526559457	U226	VISIONIST CRT-P EL
00802526559464	U226	VISIONIST CRT-P EL
00802526577062	U226	VISIONIST CRT-P EL
00802526577123	U226	VISIONIST CRT-P EL
00802526559488	U228	VISIONIST CRT-P EL MRI
00802526572692	U228	VISIONIST CRT-P EL MRI
00802526577130	U228	VISIONIST CRT-P EL MRI
00802526578830	U228	VISIONIST CRT-P EL MRI

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