IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) DEVICES

Ellipse™ VR

Single-chamber Implantable
Cardioverter Defibrillator (ICD)

MR

Merlin@home™ Transmitter Compatible

Product Highlights

- MRI Ready device has been tested for safe performance of an MRI scan using a 1,5 Tesla field-strength MRI scanner when used in combination with an MR Conditional lead[1,2]
- Improved shape with reduced volume and thickness
- Parylene coating for improved abrasion resistance
- DynamicTx™ Over-current Detection Algorithm automatically changes shock configurations to ensure delivery of high voltage therapy when high current is detected
- Cold can programmability provides an additional RV-SVC shock configuration to decouple the can from the shocking vector parameters in cases of lead problems
- ShockGuard™ technology with DecisionTx™ programming designed to reduce inappropriate therapy and minimise the need for programming adjustments at implant
  - SecureSense™ RV lead noise discrimination algorithm detects sustained and short bursts of lead noise that would otherwise go unnoticed or potentially lead to one or more inappropriate shocks
  - Far Field MD™ morphology discrimination improves SVT and VT discrimination for reduced inappropriate therapies
- Low frequency attenuation filter designed to enhance sensing performance and may reduce the possibility of oversensing T waves
- Sense*Ability*™ sensing algorithm feature provides flexibility to fine-tune programming around T wave oversensing without decreasing sensitivity
- DF4 connector designed to streamline defibrillation connections into a single terminal pin and reduce the number of set screws
- CorVue™ congestion monitoring feature monitors the intrathoracic impedance in multiple vectors for improved accuracy, and it provides the option for both patient and physician alerts
- Antitachycardia pacing (ATP) while charging and prior to charging in the VF zone further extends the programming options for terminating tachyarrhythmias without a high voltage shock
- ST monitoring capability provides unprecedented, continuous insight into significant ST shift events and associated ventricular arrhythmias through enhanced monitoring of iEGM and ST-segment as a diagnostic tool to help guide appropriate clinical action
- 36 J delivered energy safety shock option can provide a greater DFT safety margin
- DeFT Response™ technology offers the most noninvasive options for managing high DFTs
- QHR‡ chemistry battery provides greater capacity for enhanced longevity and improved charge time performance compared to previous SVO batteries

Ordering Information

Contents: Single-chamber Implantable Cardioverter Defibrillator (ICD)

MODEL NUMBER	DIMENSIONS (H × W × T, MM)	WEIGHT (G)	VOLUME (CC)	CONNECTOR DEFIBRILLATION	CONNECTOR SENSE/PACE
CD1377-36C	68 × 51 × 12	66	31	DF1	IS-1
CD1377-36QC*	66 × 51 × 12	67	30	DF4	DF4

*Indicates models that are MR Conditional[1,2]

Indications: The devices are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

Contraindications: Contraindications for use of the implantable cardioverter defibrillator include ventricular tachyarrhythmias resulting from transient or correctable factors such as drug toxicity, electrolyte imbalance, or acute myocardial infarction.

Adverse Events: Implantation of the implantable cardioverter defibrillator, like that of any other device, involves risks, some possibly life-threatening. These include but are not limited to the following: acute hemorrhage/bleeding, air emboli, arrhythmia acceleration, cardiac or venous perforation, cardiogenic shock, cyst formation, erosion, exacerbation of heart failure, extrusion, fibrotic tissue growth, fluid accumulation, hematoma formation, histotoxic reactions, infection, keloid formation, myocardial irritability, nerve damage, pneumothorax, thromboemboli, venous occlusion. Other possible adverse effects include mortality due to: component failure, device-programmer communication failure, lead abrasion, lead dislodgment or poor lead placement, lead fracture, inability to defibrillate, inhibited therapy for a ventricular tachycardia, interruption of function due to electrical or magnetic interference, shunting of energy from defibrillation paddles, system failure due to ionising radiation. Other possible adverse effects include mortality due to inappropriate delivery of therapy caused by: multiple counting of cardiac events including T waves, P waves, or supplemental pacemaker stimuli. Among the psychological effects of device implantation are imagined pulsing, dependency, fear of inappropriate pulsing, and fear of losing pulse capability.

Refer to the User's Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

Ellipse™ VR

Single-chamber Implantable Cardioverter Defibrillator (ICD)

Product Specifications

PHYSICAL SPECIFICATIONS

Models	CD1377-36C	CD1377-36QC
Telemetry	RF	RF
Delivered/Stored Energy (J)	36/39	36/39
Volume (cc)	31	30
Weight (g)	66	67
Size (mm)	68 × 51 × 12	66 × 51 × 12
Defibrillation Lead Connections	DF1	DF4
Sense/Pace Lead Connections	IS-1	DF4
High Voltage Can	Electrically active titanium can	Electrically active titanium can
Coating	Parylene	Parylene
MR Conditional	No	Yes-MRI Ready

PARAMETER	SETTINGS
Sensing/Detection	
Sense*Ability*™ Sensing Algorithm Technology	Automatic sensitivity control adjustment for ventricular events
Low Frequency Attenuation	On; Off
Threshold Start	(Post-Sensed; Ventricular) 50; 62,5; 75; 100%; (Post-Paced; Ventricular) Auto; 0,2–3,0 mV
Decay Delay	(Post-Sense/Post-Pace; Ventricular) 0–220
Ventricular Sense Refractory (ms)	125; 157
Detection Zones	3 zone programming — 1 zone, 2 zones or 3 zones (VT-1, VT-2, VF)
SVT Discriminators	Sudden Onset; Interval Stability; Sinus Interval History; Morphology Discrimination (Far Field MD™ Morphology Discrimination or Original MD) with Manual (Original MD) or Automatic Template Update
Discrimination Modes	On; Passive; Off
SVT Threshold	150–240 min^{-1}
SVT Timeout	0,25–5 min
Monitor Mode	Detection, discrimination and diagnostics, no therapy delivery (VT or VT-1 zone)
Reconfirmation	Continuous sensing during charging
Lead Noise Discrimination	SecureSense™ RV lead noise discrimination algorithm (On; On with Timeout; Passive; Off)
Antitachycardia Pacing Therapy	
ATP Configurations	Ramp; Burst; Scan; 1 or 2 schemes per VT zone
ATP in VF Zone	ATP While Charging; ATP Prior to Charging; Off
ATP Upper Rate Cutoff	150–300 min^{-1}
Burst Cycle Length	Adaptive; Readaptive or Fixed
Min. Burst Cycle Length (ms)	150–400 in increments of 5
Number of Bursts	1–15
Number of Stimuli	2–20
Add Stimuli per Burst	On; Off
ATP Pulse Amplitude (V)	7,5 Independent from Bradycardia and Post-Therapy Pacing
ATP Pulse Width (ms)	1,0 or 1,5 Independently Programmable from Bradycardia and Post-Therapy Pacing
High Voltage Therapy	
DynamicTx™ Over-current Detection Algorithm	On; Off
DeFT Response™ Technology	Programmable pulse width for P1/P2 and tilt
High Voltage Output Mode	Fixed Pulse Width; Fixed Tilt
Waveform	Biphasic; Monophasic
RV Polarity	Cathode (-); Anode (+)
Electrode Configuration	RV to Can; RV to SVC/Can; RV to SVC
Bradycardia Pacing	
Permanent Modes	Off; VVI(R)
Temporary Modes	Off; VVI; VOO
Rate-Adaptive Sensor	On; Off; Passive
Programmable Rate Parameters	Off; Base Rate (min^{-1}); Rest Rate (min^{-1}); Maximum Sensor Rate (min^{-1}); Pulse Amplitude (RV) (V); Pulse Width (RV) (ms); Hysteresis Rate (min^{-1}); Rate Hysteresis with Search
Ventricular AutoCapture™ Pacing System	On; Off
Post-Therapy Pacing (Independently Programmable from Bradycardia and ATP)	
Post-Shock Pacing Mode	Off; VVI
Post-Shock Base Rate (min^{-1})	30–100 in increments of 5
Post-Shock Pacing Duration (min)	Off; 0,5; 1; 2,5; 5; 7,5; or 10
Device Testing/Induction Methods	
DC Fibber™ Pulse Duration (sec)	0,5–5,0
Burst Fibber Cycle Length (ms)	20–100
Noninvasive Programmed Stimulation (NIPS)	2–25 stimuli with up to 3 extra stimuli

Patient Notifiers	
Programmable Notifiers (On; Off)	Device at ERI; Charge Time Limit Reached; Possible HV Circuit Damage; Ventricular Lead Impedance Out of Range; High Voltage Lead Impedance Out of Range; %V pacing; CorVue™ Congestion Monitoring Trigger; SecureSense lead noise detected, non-sustained lead noise detected, ST Episodes (Type I only)
Device Parameter Reset	On
Entry into Backup VVI Mode	On
Vibration Duration (sec)	2; 4; 6; 8; 10; 12; 14; 16
Number of Vibrations per Notification	2
Number of Notifications	1–16
Time Between Notifications (hours)	10; 22
Electrograms and Diagnostics	
Stored Electrograms	Up to 25 minutes including up to one minute programmable pre-trigger data per VT/VF diagnosis/detection electrograms; triggers include: diagnosis; detection; therapy; PC shock delivery; noise reversion; magnet reversion; morphology template verification; lead noise detected; non-sustained lead noise detected; NSVT/NSVF
Therapy Summary	Diagram of therapies delivered
Episodes Summary	Directory listing of up to 60 episodes with access to more details including stored electrograms
Lifetime Diagnostics	History of bradycardia events and device-initiated charging
Ventricular HV Lead Impedance Trend	Multi-Vector Trend Data
Histograms	Event Histogram; Ventricular Heart Rate Histogram; Exercise and Activity Trending; DirectTrend™ reports up to 1 year
Real-Time Measurements (RTM)	Pacing lead impedances; high voltage lead impedances; and signal amplitudes
ST Monitoring	ST Histogram Data; Long-term ST Deviation Trend; ST Episode Log; ST Episode Details; 24-Hour ST and HR Trend; ST EGM Baseline and Snapshots prior to ST Episode; VT/VF; Interrogation (Snapshots and 24-hour trend at time of interrogation)
CorVue™ Congestion Monitoring	On; Off
CorVue Congestion Trigger	8–18 days

MRI Scan Parameters

If the implanted system is comprised of a combination of leads that have differing RF Power (SAR), scan region and/or additional considerations, use the most restrictive of each to determine the overall set of scan conditions applicable for the total system.

LEAD MODEL	LEAD LENGTHS	RF POWER (SAR)	SCAN REGION
Durata™ Defibrillation Lead 7120Q, 7122Q	58, 65 cm	Normal Operating Mode**	Full Body
Optisure™ Lead LDA210Q, LDA220Q	58, 65 cm		

**As defined in IEC 60601-2-33, Normal Operating Mode corresponds to RF Power SAR: ≤ 2 W/kg, Head SAR ≤ 3.2 W/kg.

1. MR Conditional Field Strength: 1,5 Tesla.

2. See MRI-Ready Systems Manual for approved MR Conditional systems device/lead combinations and scan parameters.

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St. Jude Medical is now Abbott.

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Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

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Ellipse™ DR

Dual-chamber Implantable Cardioverter Defibrillator (ICD)

Merlin@home™ Transmitter Compatible

Product Highlights

- MRI Ready device has been tested for safe performance of an MRI scan using a 1,5 Tesla field-strength MRI scanner when used in combination with MR Conditional leads[1,2]
- Improved shape with reduced volume and thickness
- Parylene coating for improved abrasion resistance
- DynamicTx™ Over-current Detection Algorithm automatically changes shock configurations to ensure delivery of high voltage therapy when high current is detected
- Cold can programmability provides an additional RV-SVC shock configuration to decouple the can from the shocking vector parameters in cases of lead problems
- ShockGuard™ technology with DecisionTx™ programming designed to reduce inappropriate therapy and minimise the need for programming adjustments at implant
  - SecureSense™ RV lead noise discrimination algorithm detects sustained and short bursts of lead noise that would otherwise go unnoticed or potentially lead to one or more inappropriate shocks
  - Far Field MD™ morphology discrimination and chamber onset discrimination improve SVT and VT discrimination for reduced inappropriate therapies
- Low frequency attenuation filter designed to enhance sensing performance and may reduce the possibility of oversensing T waves
- Sense*Ability*™ sensing algorithm feature provides flexibility to fine-tune programming around T wave oversensing without decreasing sensitivity
- DF4 connector designed to streamline defibrillation connections into a single terminal pin and reduce the number of set screws
- CorVue™ congestion monitoring feature monitors the intrathoracic impedance in multiple vectors for improved accuracy, and it provides the option for both patient and physician alerts
- Antitachycardia pacing (ATP) while charging and prior to charging in the VF zone further extends the programming options for terminating tachyarrhythmias without a high voltage shock
- ST monitoring capability provides unprecedented, continuous insight into significant ST shift events and associated ventricular arrhythmias through enhanced monitoring of iEGM and ST segment as a diagnostic tool to help guide appropriate clinical action
- 36 J delivered energy safety shock option can provide a greater DFT safety margin
- DeFT Response™ technology offers the most noninvasive options for managing high DFTs
- QHR‡ chemistry battery provides greater capacity for enhanced longevity and improved charge time performance compared to previous SVO batteries

Ordering Information

Contents: Dual-chamber Implantable Cardioverter Defibrillator (ICD)

MODEL NUMBER	DIMENSIONS (H × W × T, MM)	WEIGHT (G)	VOLUME (CC)	CONNECTOR DEFIBRILLATION	CONNECTOR SENSE/PACE
CD2377-36C	69 × 51 × 12	66	31	DF1	IS-1
CD2377-36QC*	70 × 51 × 12	68	31	DF4	IS-1; DF4

*Indicates models that are MR Conditional[1,2]

Indications: The devices are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

Contraindications: Contraindications for use of the implantable cardioverter defibrillator include ventricular tachyarrhythmias resulting from transient or correctable factors such as drug toxicity, electrolyte imbalance, or acute myocardial infarction.

Adverse Events: Implantation of the implantable cardioverter defibrillator, like that of any other device, involves risks, some possibly life-threatening. These include but are not limited to the following: acute hemorrhage/bleeding, air emboli, arrhythmia acceleration, cardiac or venous perforation, cardiogenic shock, cyst formation, erosion, exacerbation of heart failure, extrusion, fibrotic tissue growth, fluid accumulation, hematoma formation, histotoxic reactions, infection, keloid formation, myocardial irritability, nerve damage, pneumothorax, thromboemboli, venous occlusion. Other possible adverse effects include mortality due to: component failure, device-programmer communication failure, lead abrasion, lead dislodgment or poor lead placement, lead fracture, inability to defibrillate, inhibited therapy for a ventricular tachycardia, interruption of function due to electrical or magnetic interference, shunting of energy from defibrillation paddles, system failure due to ionising radiation. Other possible adverse effects include mortality due to inappropriate delivery of therapy caused by: multiple counting of cardiac events including T waves, P waves, or supplemental pacemaker stimuli. Among the psychological effects of device implantation are imagined pulsing, dependency, fear of inappropriate pulsing, and fear of losing pulse capability.

Refer to the User's Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

Ellipse™ DR

Dual-chamber Implantable Cardioverter Defibrillator (ICD)

Product Specifications

PHYSICAL SPECIFICATIONS

Models	CD2377-36C	CD2377-36QC
Telemetry	RF	RF
Delivered/Stored Energy (J)	36/39	36/39
Volume (cc)	31	31
Weight (g)	66	68
Size (mm)	69 × 51 × 12	70 × 51 × 12
Defibrillation Lead Connections	DF1	DF4
Sense/Pace Lead Connections	IS-1	IS-1; DF4
High Voltage Can Coating	Electrically active titanium can Parylene	Electrically active titanium can Parylene
MR Conditional	No	Yes-MRI Ready

PARAMETER	SETTINGS
AF Management	
AF Suppression™ Pacing	On; Off
No. of Overdrive Pacing Cycles	15–40 in steps of 5
Maximum AF Suppression Rate	15–40 in steps of 5
Sensing/Detection	
Sense*Ability*™ Sensing Algorithm Technology	Automatic sensitivity control adjustment for atrial and ventricular events
Low Frequency Attenuation	On; Off
Threshold Start	(Post-Sensed; Atrial) 50; 62,5; 75; 100%; (Post-Paced; Atrial) 0,2–3,0 mV; (Post-Sensed; Ventricular) 50; 62,5; 75; 100%; (Post-Paced; Ventricular) Auto; 0,2–3,0 mV
Decay Delay	(Post-Sense/Post-Pace; Atrial/Ventricular) 0–220
Ventricular Sense Refractory (ms)	125; 157
Detection Zones	3 zone programming — 1 zone, 2 zones or 3 zones (VT-1, VT-2, VF)
SVT Discriminators	AV Rate Branch; Arrhythmia Onset (Chamber Onset or Sudden Onset); Interval Stability; AV Association; Morphology Discrimination (Far Field MD™ Morphology Discrimination or Original MD) with Manual (original MD only) or Automatic Template Update
Monitor Mode	Detection, discrimination and diagnostics, no therapy delivery (VT or VT-1 zone)
Discrimination Modes	On; Passive; Off
SVT Threshold	150–240 min^{-1}
SVT Timeout	0,25–5 min
Reconfirmation	Continuous sensing during charging
Lead Noise Discrimination	SecureSense™ RV lead noise discrimination algorithm (On; On with Timeout; Passive; Off)
Antitachycardia Pacing Therapy	
ATP Configurations	Ramp; Burst; Scan; 1 or 2 schemes per VT zone
ATP in VF Zone	ATP While Charging; ATP Prior to Charging; Off
ATP Upper Rate Cutoff	150–300 min^{-1}
Burst Cycle Length	Adaptive; Readaptive or Fixed
Min. Burst Cycle Length (ms)	150–400 in increments of 5
Number of Bursts	1–15
Number of Stimuli	2–20
Add Stimuli per Burst	On; Off
ATP Pulse Amplitude (V)	7,5 Independent from Bradycardia and Post-Therapy Pacing
ATP Pulse Width (ms)	1,0 or 1,5 Independently Programmable from Bradycardia and Post-Therapy Pacing
High Voltage Therapy	
DynamicTx™ Over-current Detection Algorithm	On; Off
DeFT Response™ Technology	Programmable pulse width for P1/P2 and tilt
High Voltage Output Mode	Fixed Pulse Width; Fixed Tilt
Waveform	Biphasic; Monophasic
RV Polarity	Cathode (-); Anode (+)
Electrode Configuration	RV to Can; RV to SVC/Can; RV to SVC
Bradycardia Pacing	
Permanent Modes	Off; DDD(R); DDI(R); VVI(R); AAI(R)
Temporary Modes	Off; DDD; DDI; VVI; AAI; AAT; DOO; VOO; AOO
Rate-Adaptive Sensor	On; Off; Passive
Programmable Rate and Delay Parameters	Base Rate (min^{-1}); Rest Rate (min^{-1}); Maximum Tracking Rate (min^{-1}); Off; Maximum Sensor Rate (min^{-1}); Paced AV Delay (ms); Sensed AV Delay (ms); Rate Responsive AV Delay (Atrial and RV) (ms); Hysteresis Rate (min^{-1}); Rate Hysteresis with Search
Ventricular AutoCapture™ Pacing System	On; Off
ACap™ Confirm Feature	On; Monitor; Off
QuickOpt™ Timing Cycle Optimisation	Sensed/Paced AV delay
Auto Mode Switch (AMS)	Off; DDI(R); VVI(R)
Atrial Tachycardia Detection Rate (min^{-1})	110–300
AMS Base Rate (min^{-1})	40; 45;...135
Auto PMT Detection/Termination	Atrial Pace on PMT; Off; Passive
Rate Responsive PVARP/VREF	Off; Low; Medium; High
Ventricular Intrinsic Preference (VIP™)	Off; On (50–200)
Post-Therapy Pacing (Independently Programmable from Bradycardia and ATP)	
Post-Shock Pacing Mode	Off; AAI; VVI; DDI; DDD
Post-Shock Base Rate (min^{-1})	30–100 in increments of 5
Post-Shock Pacing Duration (min)	Off; 0,5; 1; 2,5; 5; 7,5; or 10
Device Testing/Induction Methods	
DC Fibber™ Pulse Duration (sec)	0,5–5,0
Burst Fibber Cycle Length (ms)	20–100
Noninvasive Programmed Stimulation (NIPS)	2–25 stimuli with up to three extra stimuli
Patient Notifiers	
Programmable Notifiers (On; Off)	Device at ERI; Charge Time Limit Reached; Possible HV Circuit Damage; Atrial Lead Impedance Out of Range; Ventricular Lead Impedance Out of Range; High Voltage Lead Impedance Out of Range; AT/AF Burden; V Rate During AT/AF; % V pacing; CorVue Congestion Trigger; SecureSense – lead noise detected; non-sustained lead noise detected; ST Episodes (Type I only)
Device Parameter Reset	On
Entry into Backup VVI Mode	On
Vibration Duration (sec)	2; 4; 6; 8; 10; 12; 14; 16
Number of Vibrations per Notification	2
Number of Notifications	1–16
Time Between Notifications (hours)	10; 22
Electrograms and Diagnostics	
Stored Electrograms	Up to 25 minutes including up to one minute programmable pre-trigger data per VT/VF diagnosis/detection electrograms; triggers include diagnosis; detection; therapy; atrial episode; PMT termination; PC shock delivery; noise reversion; magnet reversion; morphology template verification; lead noise detected; non-sustained lead noise detected; NSVT/NSVF
Therapy Summary	Diagram of therapies delivered
Episodes Summary	Directory listing of up to 60 episodes with access to more details including stored electrograms
Lifetime Diagnostics	History of bradycardia events and device-initiated charging
AT/AF Burden Trend	Trend data and counts
Ventricular HV Lead Impedance Trend	Multi-Vector Trend Data
Histograms	Event Histogram; AV Interval Histogram; Mode Switch Duration Histogram; Peak Filtered Rate Histogram; Atrial Heart Rate Histogram; Ventricular Heart Rate Histogram; AT/AF Burden; Exercise and Activity Trending; V Rates during AMS; DirectTrend™ reports up to 1 year
PMT Data	Information regarding PMT detections
Real-Time Measurements (RTM)	Pacing lead impedances; high voltage lead impedances; and signal amplitudes
ST Monitoring	ST Histogram Data; Long-term ST Deviation Trend; ST Episode Log; ST Episode Details; 24-Hour ST and HR Trend; ST EGM Baseline and Snapshots prior to ST Episode; VT/VF; Interrogation (Snapshots and 24-hour trend at time of interrogation)
CorVue™ Congestion Monitoring	On; Off
CorVue Congestion Trigger	8–18 days

MRI Scan Parameters

If the implanted system is comprised of a combination of leads that have differing RF Power (SAR), scan region and/or additional considerations, use the most restrictive of each to determine the overall set of scan conditions applicable for the total system.

LEAD MODEL	LEAD LENGTHS	RF POWER (SAR)	SCAN REGION
Tendril MRI™ Lead LPA1200M	46, 52, 58 cm	Normal Operating Mode**	Full Body
Tendril™ STS Pacing Lead 2088TC	46, 52 cm		
IsoFlex™ Optim™ Pacing Leads 1944	46, 52 cm		
Durata™ Defibrillation Lead 7120Q, 7122Q	58, 65 cm		
Optisure™ Lead LDA210Q, LDA220Q	58, 65 cm		

**As defined in IEC 60601-2-33, Normal Operating Mode corresponds to RF Power SAR: ≤ 2 W/kg, Head SAR ≤ 3.2 W/kg.

1. MRI Conditional Field Strength: 1,5 Tesla.

2. See MRI-Ready Systems Manual for approved MR Conditional systems device/lead combinations and scan parameters.

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SJM.com
St. Jude Medical is now Abbott.

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Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

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