INSTRUCTIONS FOR USE

DEVICE DESCRIPTION

The Protégé™ GPS self-expanding peripheral stent system is a self-expanding Nitinol stent system intended for permanent implantation. The Protégé GPS stent is made of a nickel titanium alloy (Nitinol) and comes pre-mounted on a 6 F 0.013” over-the-wire (OTW) delivery system. The stent is cut from a Nitinol tube in an open lattice design and has tantalum radiopaque markers at the proximal and distal ends of the stent. Upon deployment, the stent achieves its predetermined diameter and exerts a constant, gentle outward force to establish patency.

The Protégé™ GPS delivery system, as shown in Figure 1 and 1a, is comprised of an inner subassembly (1) and outer (2) subassembly, which are locked together with a safety lock (3). The inner subassembly terminates distally in a flexible catheter tip (4) and orients proximally at the hub (5).

The distal portion of the delivery system, as shown in Figure 1a, is comprised of two radiopaque markers, one marker distal (6) and one marker/retainer proximal (7) to the constrained stent, are on the inner subassembly. The outer sheath connects proximally to the manifold subassembly (8). The self-expanding stent is constrained within the space between the inner and outer subassemblies. This space is flushed prior to the procedure through the stopcock (9). The outer subassembly has a radiopaque marker at its distal end (10).

The stent is positioned at the target lesion using the two radiopaque markers on the inner subassembly and the radiopaque markers on the stent. For stent deployment, turn the safety lock counterclockwise to unlock the outer subassembly. The outer subassembly retracts by pulling the distal grip (11) toward the proximal grip (12). Stent deployment is complete when the radiopaque marker on the outer subassembly passes the proximal radiopaque marker on the inner subassembly.

Figure 1a: Distal Portion of 20 – 80 mm Delivery

Figure 1: Stent on Delivery System

1. Inner Subassembly
2. Outer Subassembly
3. Safety Lock
4. Distal Catheter Tip
5. Proximal Hub
6. Inner Subassembly Distal Marked Band
7. Inner Subassembly Proximal Marker Band/Retainer
8. Manifold Subassembly
9. Stopcock
10. Outer Subassembly Distal Marker Band
11. Distal Grip
12. Proximal Grip

INDICATIONS FOR USE

The Protégé™ GPS self-expanding peripheral stent system is indicated for improving luminal diameter in patients with atherosclerotic disease of the common and/or external iliac arteries up to and including 100 mm in length, with a reference vessel diameter of 7.5 – 11 mm.

CONTRAINDICATIONS

• Patients in whom anticoagulant and/or antiplatelet therapy is contraindicated
• Patients with known hypersensitivity to nickel titanium
• Patients who are judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the stent or stent delivery system.

WARNINGS

• The device is provided STERILE for single use only. Do not reprocess or resterilize. Reprocessing and resterilizing could increase the risk of patient infection and risk of compromised device performance.
• If resistance is encountered at any time during the insertion procedure, do not force passage. Resistance may cause damage to stent or vessel. Carefully withdraw the stent system without deploying the stent.
• If resistance is felt when initially pulling back on the distal grip, do not force deployment. Carefully withdraw the stent system without deploying the stent.
• If resistance is met during delivery system withdrawal, advance the outer sheath until the outer sheath marker contacts the catheter tip and withdraw the system as one unit.

PRECAUTIONS

• Carefully inspect the sterile package and device prior to use to verify that no damage occurred during shipment.
• Do not exceed 300 psi / 20 ATM while flushing the delivery system.
• Do not use if the stent is partially deployed upon removal from the package, or before starting the deployment procedure.
• Support from a sheath is necessary to minimize lengthening or shortening during stent deployment.

• Always use a sheath during the implant procedure to protect both the vessel and puncture site.
• Failure to pre-dilate the lesion may impair the ability to remove the stent system after stent deployment.
• The stent system is not designed for recapturing or repositioning after establishing vessel apposition.
• Failure to hold the proximal grip in a fixed position may result in partial deployment, foreshortening, lengthening or increased deployment force.
• The stent is not designed to be lengthened or shortened past its nominal length. Excessive stent lengthening or shortening may increase the risk of stent fracture.
• Use caution when crossing a deployed stent with any adjunct device.
• Stent should not be expanded past its nominal diameter.

ADVERSE EVENTS

The EverFlex™ self-expanding peripheral stent system and the Protégé™ GPS self-expanding stent system (the “Device”) were evaluated in the DURABILITY Iliac study. A total of 75 subjects were enrolled; 45 of these subjects were implanted with the Protégé GPS stent(s). The primary objective was to confirm the safety and effectiveness of primary stenting using the stents for the treatment of stenotic, restenotic or occluded lesions in the common and external iliac arteries.

Table 1 provides a summary of the Clinical Events Committee (CEC) adjudicated Serious Adverse Events (SAEs) for all subjects implanted with the Protégé GPS stent in the DURABILITY Iliac study. They are summarized by MedDRA System/Organ Class and include all reported serious adverse events, regardless of study device, study procedure or study requirement relatedness. The data are presented as a percentage of subjects experiencing SAEs followed by the total number of events in brackets.

Table 1: Summary of Serious Adverse Events

<table>
<thead>
<tr>
<th>MedDRA System Organ Class</th>
<th>≤ 30 Days % (n/N) [Events]</th>
<th>≤ 9 Months % (n/N) [Events]</th>
<th>≤ 3 Years % (n/N) [Events]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular Disorders</td>
<td>15.6% (17/45) [24]</td>
<td>35.8% (16/45) [24]</td>
<td>40% (18/45) [49]</td>
</tr>
<tr>
<td>Gastrointestinal Disorders</td>
<td>2.2% (1/45) [1]</td>
<td>6.7% (3/45) [4]</td>
<td>13.6% (6/45) [12]</td>
</tr>
<tr>
<td>Con genital, familial and genetic disorders</td>
<td>0.0% (0/45) [0]</td>
<td>2.2% (1/45) [1]</td>
<td>2.2% (1/45) [1]</td>
</tr>
<tr>
<td>Gastrointestinal Disorders</td>
<td>2.2% (1/45) [1]</td>
<td>4.4% (2/45) [2]</td>
<td>6.7% (3/45) [3]</td>
</tr>
<tr>
<td>General disorders and administration site conditions</td>
<td>0.0% (0/45) [0]</td>
<td>2.2% (1/45) [1]</td>
<td>8.9% (4/45) [5]</td>
</tr>
<tr>
<td>Infections and infestations</td>
<td>0.0% (0/45) [0]</td>
<td>4.4% (2/45) [2]</td>
<td>4.4% (2/45) [3]</td>
</tr>
<tr>
<td>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</td>
<td>0.0% (0/45) [0]</td>
<td>2.2% (1/45) [1]</td>
<td>4.4% (2/45) [2]</td>
</tr>
<tr>
<td>Nervous system disorders</td>
<td>2.2% (1/45) [1]</td>
<td>2.2% (1/45) [1]</td>
<td>2.2% (1/45) [1]</td>
</tr>
<tr>
<td>Respiratory, thoracic and mediastinal disorders</td>
<td>0.0% (0/45) [0]</td>
<td>0.0% (0/45) [0]</td>
<td>2.2% (1/45) [1]</td>
</tr>
</tbody>
</table>

* A total of 45/75 subjects were implanted with the Protégé GPS stent in the DURABILITY Iliac study.

POTENTIAL ADVERSE EVENTS

The potential adverse events (e.g., complications) that may occur and/or require intervention with the use of this device include, but are not limited to:

- Abrupt or sub-acute closure
- Allergic reaction to device materials or procedure medications
- Allergies reaction to Nitinol
- Amputation
- Anaemia
- Anaphylaxis
- Arterio-venous fistula
- Artery injury (e.g., dissection, perforation, or rupture)
- Bleeding requiring transfusion
- Bruising
- Contracted medium reaction/renal failure
- Death
- Device breakage
- Embolism
- Failure to deploy stent
- Fever
- Gastrointestinal bleeding due to anticoagulation
- Hematoma
- Hyperesthesia/Hypotension
- Infection
- Inflammation
- Intraluminal thrombus
- Myocardial infarction
- Pain
- Partial stent deployment
- Pulmonary oedema
- Renal failure
- Renal insufficiency
- Restenosis
- Septic
- Shock
- Stroke
- Stent collapse or fracture
- Stent migration
- Stent misplacement
- Thrombosis/occlusion of the stent
- Transient ischemic attack
- Venous thromboembolism
- Vessel spasm
- Worsening claudication or rest pain

CLINICAL STUDIES

The DURABILITY Iliac study was a prospective, multi-center, non-randomized, single arm study to evaluate the EverFlex™ self-expanding stent system and the Protégé™ GPS self-expanding stent system (the stents) for the treatment of stenotic, restenotic (from PTA or adjunct therapy, not including stents or stent grafts) or occluded lesions of the common and/or external iliac arteries. The objective of the study was to confirm the safety and effectiveness of primary stenting.

A total of 75 subjects were enrolled at 13 US and two European investigational sites; 45 of the 75 subjects had Protégé GPS stent(s) implanted. Subject follow-up occurred at pre-discharge, 30 days, 90 days, 1, 2 and 3 years post procedure. The primary outcome for the study was Major Adverse Event (MAE) at 9 months. Secondary outcomes were MAE Rate at 30 days, primary patency rate at 9 months, change of ankle-brachial index at 30 days and 9 months, device success, change in walking impairment questionnaire core at 30 days and 9 months, and clinically driven target vessel revascularization at 30 days and 9 months.
Table 3: Demographics and Baseline Clinical Characteristics

<table>
<thead>
<tr>
<th>Subject Characteristics</th>
<th>N=45*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yrs.), Mean± SD (N), [Median (Min, Max)]</td>
<td>62.4 ± 9.2 (45) [62.0 (41.0, 78.0)]</td>
</tr>
<tr>
<td>Male</td>
<td>73.3% (33/45)</td>
</tr>
<tr>
<td>Race</td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>91.1% (41/45)</td>
</tr>
<tr>
<td>African American</td>
<td>6.7% (3/45)</td>
</tr>
<tr>
<td>Asian</td>
<td>0.0% (0/45)</td>
</tr>
<tr>
<td>American Indian or Alaska Native</td>
<td>0.0% (0/45)</td>
</tr>
<tr>
<td>Native Hawaiian or other Pacific Islander</td>
<td>2.2% (1/45)</td>
</tr>
<tr>
<td>Other</td>
<td>0.0% (0/45)</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>2.2% (1/45)</td>
</tr>
<tr>
<td>Not Hispanic</td>
<td>97.8% (44/45)</td>
</tr>
<tr>
<td>Risk Factors and Medical History</td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td>17.8% (8/45)</td>
</tr>
<tr>
<td>Type I</td>
<td>12.5% (1/8)</td>
</tr>
<tr>
<td>Type II</td>
<td>87.5% (7/8)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>68.9% (31/45)</td>
</tr>
<tr>
<td>Renal insufficiency</td>
<td>0.0% (0/45)</td>
</tr>
<tr>
<td>Current smoker</td>
<td>64.4% (29/45)</td>
</tr>
<tr>
<td>Angina</td>
<td>13.3% (6/45)</td>
</tr>
<tr>
<td>Arrhythmia</td>
<td>6.7% (3/45)</td>
</tr>
<tr>
<td>Congestive Heart Failure (CHF)</td>
<td>6.7% (3/45)</td>
</tr>
<tr>
<td>Stroke</td>
<td>4.4% (2/45)</td>
</tr>
<tr>
<td>Transient Ischemic Attack (TIA)</td>
<td>4.4% (2/45)</td>
</tr>
<tr>
<td>Myocardial Infarction (MI)</td>
<td>24.4% (11/45)</td>
</tr>
<tr>
<td>Non-healing ischemic ulcers in the lower extremities</td>
<td>0.0% (0/45)</td>
</tr>
<tr>
<td>Amputation of the lower extremities</td>
<td>0.0% (0/45)</td>
</tr>
<tr>
<td>Peripheral Intervention**</td>
<td>17.8% (8/45)</td>
</tr>
</tbody>
</table>

Clinical Characteristics

Rutherford Clinical Category

2= Moderate claudication 22.2% (10/45)
3= Severe claudication 77.8% (35/45)
4= Ischemic rest pain 0.0% (0/45)

Ankle-Brachial Index (ABI) 0.67 ± 0.19 (45) [0.67 (0.12, 1.05)]

Table 4 presents baseline characteristics assessed by the angiographic core laboratory for the subjects treated with the Protégé GPS stent(s).

Table 4: Baseline Target Lesion Characteristics

<table>
<thead>
<tr>
<th>Lesion Characteristics</th>
<th>N=47 (# of lesions)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right Iliac Artery</td>
<td>51.1% (24/47)</td>
</tr>
<tr>
<td>Common</td>
<td>75.0% (18/24)</td>
</tr>
<tr>
<td>External</td>
<td>25.0% (6/24)</td>
</tr>
<tr>
<td>Left Iliac Artery</td>
<td>48.9% (23/47)</td>
</tr>
<tr>
<td>Common</td>
<td>73.9% (17/23)</td>
</tr>
<tr>
<td>External</td>
<td>26.1% (6/23)</td>
</tr>
</tbody>
</table>

Lesion Morphology

Distance from Ostium (mm)

- Right Iliac Artery 25.4 ± 36.8 (47) [0.0, 0.168.0]
- Left Iliac Artery 47.1 ± 28.3 (47) [22.2 (15.0, 122.2)]

Eccentric Lesion

Right Iliac Artery 59.6% (28/47)
Left Iliac Artery 13.4 ± 14.1 (47) [10.0 (0.0, 80.0)]

Thrombus

Right Iliac Artery 0.0% (0/47)
Left Iliac Artery 0.0% (0/47)

Any Calcification

Right Iliac Artery 74.5% (35/47)
Left Iliac Artery 48.9% (23/47)

None/Mild

Right Iliac Artery 25.3% (12/47)
Left Iliac Artery 48.9% (23/47)

Moderate

Right Iliac Artery 4.0% (2/47)
Left Iliac Artery 4.0% (2/47)

Severe

Right Iliac Artery 25.5% (12/47)
Left Iliac Artery 2.2% (1/47)

Ulcation present

Right Iliac Artery 27.7% (13/47)
Left Iliac Artery 4.0% (2/47)

Anomalous present

Right Iliac Artery 8.5% (4/47)
Left Iliac Artery 8.5% (4/47)

TASC II

Type A 55.3% (26/47)
Type B 34.0% (16/47)
Type C 6.4% (3/47)
Type D 4.3% (2/47)

Quantitative Angiographic Results

Pre-procedure Reference Diameter (mm) 8.4 ± 1.4 (47) [8.0 (5.9, 11.7)]
Pre-procedure Minimal Lumen Diameter (mm) 4.0 ± 0.9 (47) [3.3 (0.0, 5.5)]
Pre-procedure % Diameter Stenosis 76.2 ± 15.5 (47) [72.8 (51.6, 100.0)]
Percent Total Occlusions (100% stenosis) 23.4% (11/47)

Pre-procedure Reference Diameter (mm) 8.4 ± 1.4 (47) [8.0 (5.9, 11.7)]
Pre-procedure Minimal Lumen Diameter (mm) 4.0 ± 0.9 (47) [3.3 (0.0, 5.5)]
Pre-procedure % Diameter Stenosis 76.2 ± 15.5 (47) [72.8 (51.6, 100.0)]
Percent Total Occlusions (100% stenosis) 23.4% (11/47)

* A total of 45/75 subjects were implanted with the Protégé GPS stent(s). One subject had two target lesions, one treated with the Protégé GPS stent and one treated with the Everflex stent.

CLINICAL RESULTS

Primary Outcome

The primary outcome of the study is MAE rate at 9 months (270 days) post-procedure. An MAE was defined as a composite of periprocedural death, in hospital MI, clinically-driven target lesion revascularization, and amputation of treated limb, as adjudicated by the Clinical Event Committee (CEC). The 9-month MAE rate for subjects implanted with the Protégé GPS stent(s) was 2.2% (1/45) (Table 5).

Table 5: Summary of Primary Outcome

<table>
<thead>
<tr>
<th>9-Month MAE % (n/N) [Events]</th>
</tr>
</thead>
<tbody>
<tr>
<td>9-Month MAE</td>
</tr>
<tr>
<td>Periprocedural Death</td>
</tr>
<tr>
<td>In hospital MI</td>
</tr>
<tr>
<td>Clinically-driven TLR</td>
</tr>
</tbody>
</table>

Amputation of the Treated limb | 0.0% (0/45) [0] |

* A total of 45/75 subjects were implanted with the Protégé GPS stent(s). One subject had two target lesions, one treated with the Protégé GPS stent and one treated with the Everflex stent.

**Types of historical peripheral interventions included: PTA, Stenting, Atherectomy or other types of interventions. There was no history of Cryoplasty, Laser interventions, or Bypass.

Figure 2 displays the freedom from Major Adverse Event at 9 months.
WARNING: The device is provided STERILE for single use only. Do not reprocess or resterilize.

The results of the study provide reasonable assurance that the Protégé GPS stent is safe and effective for the treatment of stenotic, restenotic or occluded lesions in the common and external iliac arteries.

### PROCEDURE

#### PREPARATION PROCEDURES

**WARNING:** The device is provided STERILE for single use only. Do not reprocess or resterilize.

Reprocessing and resterilizing could increase the risk of patient infection and risk of compromised device performance.

1. **Required Items for Implantation Procedure:**
   - 5-10 cc syringe filled with heparinized saline
   - 0.035" exchange guidewire
   - Hemostatic sheath
   - PTA balloon

2. **Select Stent Size**
   *Refer to Table 7 for stent diameter sizing. Measure the diameter of the reference vessel (proximal and distal to lesion). Measure the length of the target lesion. Choose a stent length that will extend proximal and distal to the target lesion.*

### Table 7: Stent Diameter and Length Sizing

<table>
<thead>
<tr>
<th>Device Diameter (mm)</th>
<th>Recommended Vessel Diameter (mm)</th>
<th>Introducer Sheath (F)</th>
<th>Introduced Size %a</th>
<th>Catheter Lengths (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>9</td>
<td>7.5 – 8.5</td>
<td>6</td>
<td>0.035</td>
<td>20, 30, 40, 60, 80</td>
</tr>
<tr>
<td>10</td>
<td>8.5 – 9.3</td>
<td>6</td>
<td>0.035</td>
<td>20, 30, 40, 60, 80</td>
</tr>
<tr>
<td>12</td>
<td>9.5 – 11.0</td>
<td>6</td>
<td>0.035</td>
<td>20, 30, 40, 60, 80</td>
</tr>
</tbody>
</table>

### Table 8: Stent Foreshortening

<table>
<thead>
<tr>
<th>Diameter (mm)</th>
<th>Recommended Vessel Diameter (mm)</th>
<th>Foreshortening (%a)</th>
<th>Foreshortening Average%a</th>
</tr>
</thead>
<tbody>
<tr>
<td>9x20</td>
<td>7.5 – 8.5</td>
<td>Min 3.4 Max 1.0 St. Dev. 1.3</td>
<td>-1.1</td>
</tr>
<tr>
<td>9x80</td>
<td>7.5 – 8.5</td>
<td>Min 2.9 Max 0.5 St. Dev. 0.6</td>
<td>-1.8</td>
</tr>
<tr>
<td>10x20</td>
<td>8.5 – 9.5</td>
<td>Min 6.8 Max 2.0 St. Dev. 2.0</td>
<td>-1.1</td>
</tr>
<tr>
<td>10x80</td>
<td>8.5 – 9.5</td>
<td>Min 5.9 Max 2.0 St. Dev. 2.0</td>
<td>-0.9</td>
</tr>
<tr>
<td>12x20</td>
<td>9.5 – 11.0</td>
<td>Min 3.7 Max 4.5 St. Dev. 4.3</td>
<td>1.5</td>
</tr>
<tr>
<td>12x80</td>
<td>9.5 – 11.0</td>
<td>Min 1.3 Max 0.7 St. Dev. 0.6</td>
<td>-0.2</td>
</tr>
</tbody>
</table>

### 3. Preparation of Stent Delivery System

- Open the shelf box to reveal the pouch containing the stent and delivery catheter.
- After careful inspection of the pouch, looking for damage to the sterile barrier, carefully peel open the outer pouch and extract the tray with contents.
- Set the tray on a flat surface. Carefully pull the lid off the tray and remove the stent delivery system.

**CAUTION:** Carefully inspect the sterile package and device prior to use to verify that no damage occurred during shipment.

- Verify the device is locked by tightening the safety knob clockwise.
- Set the tray on a flat surface. Carefully pull the lid off the tray and remove the stent delivery system.

**CAUTION:** Do not exceed 300 psi / 20 ATM while flushing the delivery system.

- Attach a 5-10 cc syringe filled with heparinized saline to the stopcock on the manifold. Open the stopcock and vigorously inject saline into the annular space between the shafts until it comes out the outer sheath.
- Attach a 5-10 cc syringe filled with heparinized saline to the proximal luer lock injection hub. Inject the saline solution through the guidewire lumen until it comes out the catheter tip.

### Reference:


### MR CONDITIONAL

- Non-clinical testing demonstrated that the Protégé GPS stent in single and overlapped conditions is MR Conditional for stents <= 15 mm. A patient may be scanned safely, immediately after stent placement under the following conditions:
  - Static magnetic field of 1.5-Tesla or 3.0-Tesla.
  - Maximum gradient magnetic field of 4.000 Gauss/cm (extrapolated) or less (40 T/m).

### MRI-RELATED HEATING

- Under the scan conditions defined above, the Protégé GPS stent is expected to produce a maximum temperature rise less than or equal to 4.2º C after 15 minutes of continuous scanning (per pulse sequence).

### ARTIFACT INFORMATION

- The maximum artifact size as seen on the gradient echo pulse sequence at 3-Tesla extends approximately 5 mm relative to the size and shape of the Protégé GPS stent. The lumen of the stent cannot be visualized using the T1-weighted, spin echo and gradient echo pulse sequences at 3-Tesla.
WARRANTY DISCLAIMER

Although this product has been manufactured under carefully controlled conditions, Covidien Inc. has no control over the conditions under which this product is used. Covidien Inc. therefore disclaims all warranties, both express and implied, with respect to the product including, but not limited to, any implied warranty of merchantability or fitness for a particular purpose. Covidien Inc. 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 Covidien Inc. to any representation or warranty with respect to the product.

The exclusions and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of this Disclaimer of Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of this Disclaimer of Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Disclaimer of Warranty did not contain the particular part or term held to be invalid.

SYMbOL LEGEND

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>MR</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>i</td>
<td>Consult instructions for use</td>
</tr>
<tr>
<td>STERile EO</td>
<td>Sterilized using ethylene oxide</td>
</tr>
<tr>
<td>REF</td>
<td>Catalogue number</td>
</tr>
<tr>
<td>LOT</td>
<td>Batch code</td>
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<tr>
<td>☉</td>
<td>Keep dry</td>
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<tr>
<td>☀</td>
<td>Keep away from sunlight</td>
</tr>
<tr>
<td>❌</td>
<td>Use by date</td>
</tr>
<tr>
<td>❌</td>
<td>Do not reuse</td>
</tr>
<tr>
<td>❌</td>
<td>Do not use if package is damaged</td>
</tr>
<tr>
<td>☏</td>
<td>Telephone</td>
</tr>
<tr>
<td>FAX</td>
<td>Facsimile</td>
</tr>
<tr>
<td>Rx ONLY</td>
<td>For prescription use only</td>
</tr>
</tbody>
</table>

CONTACT INFORMATION

If you have any questions or comments regarding the use of this product contact:

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