# The Cutting Balloon™
# Instructions For Use

**Caution**

*US Law restricts this device to sale by or on the order of a physician.*

**Device Description:**

The Cutting Balloon consists of a non-compliant balloon with 3 or 4 atherotomes™ (microsurgical blades) mounted longitudinally on its outer surface. When the Cutting Balloon is inflated, the atherotomes score the plaque, creating initiation sites for crack propagation. This process referred to as atherotomy®, allows dilatation of the target lesion with less pressure.

The Cutting Balloon catheter shaft consists of two lumens. The outer lumen is used to inflate and deflate the balloon. The inner lumen permits the passage of a PTCA guidewire to aid placement of the Cutting Balloon. At the proximal end of the catheter is a Y-connector with standard luer fittings.

**Intended Use / Indications:**

The Cutting Balloon is indicated for dilatation of stenoses in coronary arteries for the purpose of improving myocardial perfusion in those circumstances where a high pressure balloon resistant lesion is encountered. In addition, the target lesion should possess the following characteristics: discrete (≤15 mm in length) or tubular (10 to 20 mm in length); with a reference vessel diameter ranging from 2.0 mm to 4.0 mm; readily accessible to the device; light to moderate tortuosity of proximal vessel segment, non-angulated lesion segment (<45°), smooth angiographic contour; and absence of angiographically-visible thrombus and/or calcification.

**Contraindications:**

- Coronary artery spasm in the absence of a significant stenosis.

**Warnings:**

- This device is intended for one time use only. Do *not* resterilize and/or reuse it, as this can potentially result in compromised device performance and increased risk of inappropriate sterilization and cross contamination.

- Atherotomy, because of its mechanism of action, may pose a greater risk of perforation than that observed with conventional PTCA. Oversizing increases the risk of perforation. To reduce the potential for vessel damage the inflated diameter of the Cutting Balloon should approximate a 1.1:1 ratio of the diameter of the vessel just proximal and distal to the stenosis.

- Atherotomy in patients who are not acceptable candidates for coronary artery bypass surgery requires careful consideration, including possible hemodynamic support during atherotomy, as treatment of this patient population carries special risk.

- When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding.

- Balloon pressure should not exceed the rated burst pressure. The rated burst pressure is based on the results of *in vitro* testing. At least 99.9% of the balloons, (with a 95% confidence) will not burst at or below their rated burst pressure. Use of a pressure monitoring device is recommended to prevent over pressurization.

- Atherotomy should only be performed at hospitals where emergency coronary artery bypass graft surgery can be quickly performed in the event of a potentially injurious or life-threatening complication.

- Use only the recommended balloon inflation medium (e.g.- contrast medium). Never use air or any gaseous medium to inflate the balloon.

- Use the catheter prior to the "Use Before" date specified on the package.

**Precautions:**

- Prior to atherotomy, the catheter should be examined to verify functionality and ensure that its size and shape are suitable for the specific procedure for which it is to be used.

- The Cutting Balloon should be used only by physicians who have received the appropriate training by Interventional Technologies Inc.

- During the Cutting Balloon procedure, appropriate anticoagulant and coronary vasodilator therapy should be provided to the patient. Anticoagulant therapy should be continued for a period of time after the procedure to be determined by the physician.

- Do not over-tighten the hemostatic connector around the shaft of the Cutting Balloon. Otherwise, constriction of the inflation/deflation lumen may occur, resulting in increased inflation/deflation time.

- The Cutting Balloon is not designed for, and therefore, cannot be used to monitor *in vivo* arterial pressures.

**Adverse Events**

*Observed Adverse Events*

The Adverse Events reported in this section were those observed in two clinical investigations: the Resistant Lesion Registry (RLR), which demonstrated the ability of the Cutting Balloon to dilate lesions in a series of patients whose lesions could not be dilated with conventional balloon angioplasty; and the Global

Randomized Trial (GRT), a multi-centered, randomized trial designed to compare the Cutting Balloon with conventional angioplasty. Twenty-nine patients were entered into the RLR and a total of 1245 patients were randomized in the GRT; 622 to the Cutting Balloon arm and 623 to the PTCA arm. Seven patients (5 in the Cutting Balloon arm and 2 in the PTCA arm) were deregistered after randomization but before receiving the assigned treatment. Therefore, there were 1238 evaluable patients in the GRT.

In the RLR, dissection was the only in-lab complication recorded. Dissections occurred 14 times: six times prior to Cutting Balloon treatment; two times after Cutting Balloon treatment; and six times as part of the post-Cutting Balloon adjunctive treatment.

One patient death from a cardiac arrest and acute pulmonary edema occurred in the RLR 24-48 hrs post-procedure. This patient was treated for a mid-RCA lesion with a series of four inflations with a PTCA balloon catheter, followed by a single inflation with the Cutting Balloon. A dissection was noted following use of the Cutting Balloon. Adjunctive treatment included two inflations with a second PTCA balloon catheter followed by placement of a stent.

The major adverse events occurring in the GRT are listed in Table 1.

There were eight deaths among the patients randomized to the Cutting Balloon arm. Two deaths occurring during the procedure involved perforations. In the first case, the perforation was associated with contrast extravasation and a Grade F dissection which was treated with balloon angioplasty and one stent. QCA reported TIMI 3 flow with a 35% residual stenosis and persistent contrast extravasation at the end of the procedure. Tamponade developed and the patient died during surgery. An intramyocardial hematoma was identified. In the second case, the coronary artery ruptured at the Cutting Balloon site and the patient developed ventricular fibrillation. The patient was resuscitated and treated emergently for tamponade, but expired following CABG. In both of these cases, the Cutting Balloon was oversized. The balloon:artery ratio, as determined by QCA, was 1.25:1 and 1.8:1, respectively.

A perforation also occurred in the death of another patient who was randomized to the Cutting Balloon arm, but treated with a PTCA balloon because of a failure to cross the lesion with the Cutting Balloon. This patient died 105 days post-procedure due to complications of a CABG performed at that time.

One patient died within an hour of the procedure from a presumed re-occlusion.

A fifth patient died at 130 days post-procedure from a reported heart attack. Two deaths occurred following exacerbation of a pre-existing chronic obstructive pulmonary disease and respiratory failure (20 days), and emergency surgery for an abdominal aortic aneurysm (50 days). The

remaining death was reported as the result of respiratory failure caused by chronic obstructive pulmonary disease.

Perforation was observed in five cases, all in the Cutting Balloon arm. As described above, in two of these cases the patient died acutely. Perforations were treated with PTCA, a stent or both.

**Table 1 - GRT Major Adverse Events Occurring Within 270 Days (1238 Patients)**

| *Adverse Event* | *Cutting Balloon** | *Conventional Balloon** | *Difference [95% CI]†* |
|---|---|---|---|
| **MACE‡** | 13.6% (84/617) | 15.1% (94/621) | -1.5% [-5.4%, 2.4%] |
| **Death** | 1.3% (8/617) | 0.3% (2/621) | 1.0% [0.0%, 2.0%] |
| **MI** | 4.7% (29/617) | 2.4% (18/621) | 1.8% [-0.3%, 3.9%] |
| **Q Wave MI** | 1.5% (9/617) | 1.1% (7/621) | 0.3% [-0.9%, 1.6%] |
| **Non-Q Wave MI** | 3.2% (20/617) | 1.3% (11/621) | 1.5% [-0.3%, 3.2%] |
| **Emergent CABG** | 1.0% (6/617) | 1.0% (6/621) | 0% [-2.3%, 1.7%] |
| **TLR§** | 11.7% (72/617) | 14.8% (92/621) | -3.1% [-6.9%, 0.6%] |
| **CABG (per pt.)** | 1.5% (9/617) | 2.1% (13/621) | -0.6% [-2.1%, 0.8%] |
| **PTCA (per pt.)** | 10.5% (65/617) | 12.7% (79/621) | -2.2% [-5.8%, 1.4%] |
| **Subacute Closure** | 1.3% (8/617) | 1.6% (10/621) | -0.3% [-1.5%, 3.0%] |
| **Bleeding Complications** | 0.3% (2/617) | 0.0% (0/621) | 0.3% [-1.9%, 0.7%] |
| **Vascular Complications¶** | 0.3% (2/617) | 0.2% (1/621) | 0.1% [-1.9%, 1.0%] |
| **Clinical Perforations** | 0.8% (5/617) | 0.0% (0/621) | 0.8% [-0.4%, 2.3%] |

*Numbers are % (counts/sample size)

†Difference = $S_{CB}$-$S_{PTCA}$ $SE_{Dif}$=sqrt[$SE_{CB}^2$+$SE_{PTCA}^2$] CI=Diff±1.96*$SE_{Dif}$

‡Major Adverse Cardiac Events (MACE): Death, Q Wave MI, emergent CABG, target lesion CABG or TL-PTCA

§Target lesion revascularization (TLR) at 9 months: any "clinically driven" PTCA (TL-PTCA) or bypass surgery (TL-CABG) performed on the target lesion after documentation of recurrent angina and/or evidence of myocardial ischemia by stress testing.

¶Vascular complications: Any vascular complication requiring surgical repair.

**Potential Adverse Events**

*Potential adverse events include, but are not limited to, the following:*

- Death
- Acute myocardial infarction
- Total occlusion of the coronary artery or bypass graft
- Coronary vessel dissection, perforation, rupture, or injury
- Aneurysm

- Restenosis of the dilated vessel
- Unstable angina
- Embolism
- Arrhythmias, including ventricular fibrillation
- Hypo/hypertension
- Coronary artery spasm
- Hemorrhage or hematoma
- Arteriovenous fistula
- Drug reactions, allergic reactions to contrast medium
- Infection.

**Observed Device Malfunctions**
There were no cutting Balloon malfunctions in the RLR.

A total of 15 Cutting Balloon malfunctions were recorded in the GRT. Two devices failed to inflate. Thirteen cases of balloon leak or rupture were reported: 9 with the first inflation and 4 with the second inflation.

**CLINICAL STUDIES:**
**Resistant Lesion Registry (RLR)**
The Resistant Lesion Registry (RLR) contains registry data on 30 lesions in 29 patients. All patients were enrolled at a single site between November 1996 and November 1999.

*Study Endpoints*
The primary endpoint was acute lesion success defined as a reduction in lumen narrowing of at least 20%. The secondary endpoint was procedural success. Procedural success was defined as lesion success, a final residual stenosis of ≤50% after all devices are used and no major adverse events (MACE, defined as death, CABG, or non-fatal MI).

*Study Population*
The RLR patients were selected for treatment on the basis of failed conventional angioplasty, defined as failure to reduce the lumen diameter narrowing by >20% and the final residual stenosis ≥50% with PTCA balloon inflation pressures > 10 atmospheres. The demographics, risk factors and prior history of these patients are shown in Table 2.

**Table 2 - Demographics, Risk Factors and Prior Procedures.**

| | |
|---|---|
| **Demographics:** | |
| %Male | 69% (20/29) |
| Age | 65 ± 8.4 |
| Angina Class (CCS) | 2.8 ± 0.8 |
| **Risk Factors:** | |
| Diabetes | 14% (4/28) |
| Smoking | 39% (11/28) |
| HB Pressure | 29% (8/28) |
| Hyperlipidemia | 48% (13/27) |
| **Prior Procedures:** | |
| MI | 33% (9/27) |
| CABG | 22% (6/27) |
| PTCA | 22% (6/27) |

*Methods*
Patient data were obtained prospectively on 6 patients under a formal clinical protocol and retrospectively on 23 patients. For both prospective and retrospective patient

groups, conventional balloon angioplasty was used as the initial treatment in all but two cases. In these two cases the Cutting Balloon was used as the first treatment for dilatation of an unprotected left main, a vessel known to be resistant to PTCA dilatation. Physician discretion was used to further decrease the residual stenosis with additional adjunctive devices following treatment with the Cutting Balloon.

*Results*

Of the 29 patients entered into the RLR, balloon resistant lesions were treated in 26 native vessels and 4 saphenous vein grafts (SVGs). Patients were treated with a sequence of devices including the Cutting Balloon. The Cutting Balloon was usually used as the second (14 cases) or third (10 cases) device in each treatment sequence. In three cases, the Cutting Balloon failed to cross the lesion on the initial attempt. Successful crossing was achieved with the second attempt (2 cases) following an additional crossing with a PTCA balloon. In the third case there were no further attempts to cross the lesion.

In most cases, the Cutting Balloon was inflated once (78%, 25/32); while the number of inflations with the PTCA catheter, prior to the Cutting Balloon, varied from 1 (31%, 14/45), 2 (36%, 16/45), 3 (18%, 8/45) to ≥4 (16%, 7/45) inflations. Inflation pressures ranged from 8-16 atmospheres for the Cutting Balloon and 4-25 atmospheres for the PTCA catheters. The average inflation pressure for the Cutting Balloon was significantly less than the average pressure used for the PTCA catheters [9.3±1.8 atm (n=32) versus 15.4±3.6 atm (n = 45), $p < 0.0001$].

The principal safety and efficacy results of the RLR are shown in Table 3. The primary and secondary endpoints, used for the prospectively enrolled patients, were also applied to the patients enrolled retrospectively.

Table 3 - Principal Effectiveness and Safety Results Resistant Lesion Registry
(n= 29 patients, 30 lesions)

| **Effective Measures:** | **Cutting Balloon %, (n/N), [95% CI]** |
|---|---|
| Acute Lesion Success | 78% (18/23) [56%, 93%] |
| Procedural Success | 74% (17/23) [52%, 90%] |
| %DS - Initial | 73% (30) [70%, 77%] |
| Post PTCA | 51% (17) [44%, 59%] |
| Post CB | 36% (22) [28%, 45%] |
| Final | 16% (30) [8%, 23%] |
| **Safety Measures:** | |
| MACE | 3% (1/30) [1%, 10%] |
| Dissection, Prior to Cutting Balloon | 20% (6/30) [8%, 39%] |
| Dissection, Cutting Balloon + Adjunctive Use | 12% (8/30) [12%, 47%] |

**Global Randomized Trial (GRT)**

The Global Randomized Trial (GRT) was a multi-centered, randomized trial designed to compare the Cutting Balloon with conventional angioplasty. Patient enrollment in the GRT occurred between June 1994, and November 1996, at 31 centers in the US, Canada, France, Belgium and the Netherlands. Of the 1245 patients enrolled, 622 were assigned to the Cutting Balloon arm and 623 to the PTCA arm. Seven patients (5 in the Cutting Balloon and 2 in the PTCA arm) were deregistered after randomization but before receiving the assigned treatment. Deregistration occurred for the following reasons: resolution of the stenosis between the prior angiogram and the index procedure (3 cases), the presence of calcification requiring atherectomy (1 case), and failing to meet the inclusion criteria (3 cases).

*Study Endpoints*

The primary endpoint was angiographic restenosis at 6 months. Secondary endpoints included TLR and MACE at 9 months. A clinical events committee blinded to treatment assignment adjudicated all major clinical events.

*Study Population*

Patients, between the ages of 25 and 75 years, with atherosclerotic coronary artery disease were eligible for enrollment in the GRT if they were suitable candidates for coronary artery bypass graft surgery and the target lesions were *de novo* Type A or B lesions in native arteries without total obstructions or visible thrombus, and were accessible to the Cutting Balloon.

*Methods*

Patients were prospectively randomized to treatment with either the Cutting Balloon or PTCA. Access to the target lesion was gained through the femoral artery approach. The reference vessel diameter (located just proximal to the target lesion) was measured by quantitative angiography.

Selection of the Cutting Balloon with the appropriately sized balloon diameter was based on the reference vessel diameter. If necessary, tandem dilatations were allowed for lesion lengths ≤ 20 mm. Oversizing of the balloon was not recommended in the PTCA arm.

The protocol allowed for a single inflation of the CB up to 8 atmospheres for a maximum of 90 seconds. Subsequent dilatation(s) with a PTCA balloon were allowed only if the residual stenosis was > 40%. In the PTCA arm, the inflation times and pressures were left to the discretion of the investigator. Serial inflations with a single balloon, or subsequent inflations with increased diameter PTCA balloons were allowed to achieve a ≥20% reduction in stenosis and a ≤50% residual stenosis. Multiple violations of the procedural protocol were reported in the CB arm [33% (212/617) of the Cutting Balloon subjects were not treated per protocol].

Clinical follow-up was performed at 6 weeks, 6 months and 9 months. Baseline quantitative coronary angiography (QCA) was performed pre-procedure, following device use, and after the final treatment in all patients. Follow-up quantitative coronary

angiography at 6 months was required in all patients. Anti-coagulation included aspirin 325 mg/day throughout the study.

*Results*

The acute and 6 month angiographic and clinical results demonstrated that the Cutting Balloon was similar to PTCA with respect to Procedure Success (defined as achievement of <50% residual diameter stenosis and freedom from in-hospital major adverse cardiac events [MACE, defined as death, Q wave MI, emergent coronary artery bypass surgery, or repeat target lesion revascularization]), 30-Day incidence of MACE, and Angiographic Restenosis (defined as >50% minimum lumen diameter stenosis at follow-up angiography). The principal safety and efficacy results are shown in Table 4.

## Table 4 - Principal Effectiveness and Safety Results (Intent-to-Treat) All Randomized Lesions Treated (1238 Patients, 1385 Lesions)

| Efficacy Measures (per lesion) | Cutting Balloon (N=689) | PTCA (N=696) | Relative Risk [95% C.I.] | Difference [95% C.I.] |
|---|---|---|---|---|
| Lesion Success | 95.5% (642/672) | 96.5% (668/692) | 0.99 [0.97,1.01] | -1.0% [-3.1%,1.1%] |
| Device Success | 77.7% (473/609) | 77.8% (460/617) | 1.00 [0.94,1.06] | -0.1% [-4.8%,4.5%] |
| Procedure Success | 92.9% (566/609) | 94.7% (584/617) | 0.98 [0.95,1.01] | 1.0% [-1.1%,3.1%] |
| MLD after Device (mm) Range (min,max) | 2.05±0.52 (672) (0.00, 4.14) | 2.13±0.53 (692) (0.00, 4.07) | N/A | -0.08 [-0.14,-0.03] |
| %DS after Device Range (min, max) | 29%±14% (672) (-13%, 100%) | 27%±13% (692) (-12%, 100%) | N/A | 1.6% [0.1%,3.0%] |
| MLD after 6 months (mm) Range (min,max) | 1.63±0.62 (551) (0.00, 3.44) | 1.65±0.61 (559) (0.00, 3.40) | N/A | -0.02 [-0.10,0.05] |
| %DS after 6 months Range (min, max) | 42%±19 (551) (-11%, 100%) | 42%±19% (559) (-4%, 100%) | N/A | 0.1% [-2%,2%] |
| Restenosis Rate at 6 months | 31.4% (173/551) | 30.4% (170/559) | 1.03 [0.87,1.23] | 1.0% [-4.5%,6.4%] |
| TLR-free at 9 months* | 89.3% | 86.1% | 1.04 [1.00,1.08] | 3.2% [-0.3%,6.7%] |
| TVR-free at 9 months† | 88.5% | 84.6% | 1.05 [1.00,1.09] | 3.9% [0.3%,7.5%] |
| TVF-free at 9 months‡ | 86.9% | 84.8% | 1.03 [0.98,1.07] | 2.2% [-1.7%,6.1%] |
| **Safety Measures and Other Clinical Events (per patient)** | **(N=617)** | **(N=621)** | **Relative Risk [95% C.I.]** | **Difference [95% C.I.]** |
| MACE ≤ 30 days | 3.7% (23/617) | 2.7% (17/621) | 1.36 [0.74,2.52] | 1.0% [-1.0%,3.0%] |
| MACE> 30 days | 10.0% (62/617) | 12.9% (80/621) | 0.78 [0.57,1.06] | -2.8% [-6.4%,0.7%] |
| Perforations | 0.8% (5/617) | 0% (0/621) | N/A | 0.8% [-0.4%, 2.3%] |
| Vascular Complications | 0.3% (2/617) | 0.2% (1/621) | 2.01 [0.19,21.11] | 0.2% [-0.4%,0.7%] |

Numbers are % (counts/sample size) or Mean ± 1 SD. CI = Confidence interval.
Survival estimates by Kaplan-Meier method; Standard Error estimates by Greenwood formula.
Relative Risk = $S_{CB}/S_{PTCA}$ $SE_{RR}$= sqrt[$(SE_{CB}/S_{CB})^2$ +$(SE_{PTCA}/S_{PTCA})^2$] CI=RR*exp(1.96*$SE_{RR}$)
Difference = $S_{CB}$ - $S_{PTCA}$ $SE_{Diff}$= sqrt[$SE_{CB}^2$ + $SE_{PTCA}^2$] CI=Diff±1.96*$SE_{Diff}$
Lesion success: Lesion success was defined as the achievement of a final residual diameter stenosis of <50% (by QCA core laboratory) using any percutaneous method.
Device success: Achievement of a final residual diameter stenosis of <50% (by QCA core laboratory) in the absence of unplanned coronary stenting, randomized treatment failure or crossover.
Procedure success: Achievement of a final residual diameter stenosis of <50% (by QCA core laboratory) in the absence of : In-Hospital MACE or target lesion revascularization within 7 days after the index procedure.
* - TLR-free: Survival free from target lesion revascularization at 9 months estimated using Kaplan-Meier methods.
† - TVR-free: Survival free from target vessel revascularization at 9 months estimated using Kaplan-Meier methods.
‡ - TVF-free: Survival free from target vessel failure (death, Q wave myocardial infaction, or target vessel revascularization) at 9 months estimated using Kaplan-Meier methods.
Major Adverse Cardiac Events (MACE): Death, Q wave MI, emergent CABG, target lesion CABG or TL-PTCA.
Primary endpoint: Death, Q wave MI, emergent CABG, target lesion revascularization, or subacute closure within 30 days of the index procedure.
Vascular complications: Any vascular complication requiring surgical repair

**Individualization of Treatment**
Avoid use in patients whose lesions possess the following characteristics: reference coronary artery diameter of less than 2.0 mm; diffuse (>20 mm in length); total obstruction (occlusion); heavy calcification; excessive tortuosity of proximal vessel segment; moderate to extreme angulation of target lesion segment (≥45°); inaccessible to the device; thrombus present.

Appropriate sizing of the Cutting Balloon is extremely important. Do not exceed a balloon:artery ratio of 1.1 to 1.

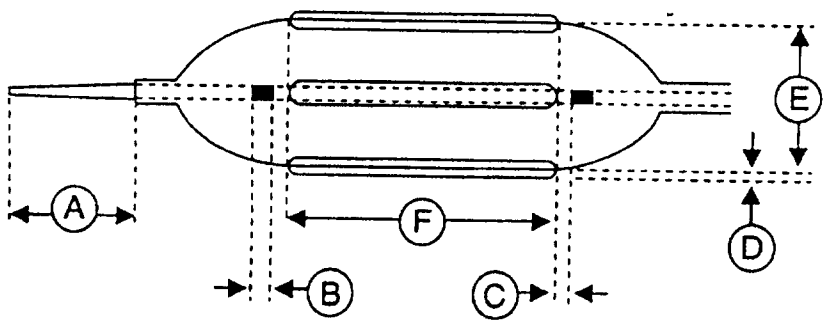
Delivery failures are likely to be more frequent with the Cutting Balloon than with conventional PTCA. This occurs for two reasons. First, the Cutting Balloon has a larger profile than a conventional PTCA catheter of the same nominal inflated diameter. Second, the materials of construction prevent the Cutting Balloon from being as flexible as a conventional balloon.

If you intend to use a 15 mm device, but suspect that you may have difficulty in reaching the lesion because of tortuosity, consider using a 10 mm device with tandem inflations.

Specifications

| Maximum Recommended Guidewire Diameter | Distal Balloon Tip Length (A — Fig 1) | Radiopaque Marker Width (B — Fig 1) | Distance Between Radiographic Markers & Atherotomes (C — Fig 1) | Working Atherotome Height (D — Fig 1) | Nominal Inflation Pressure | Rated Burst Pressure (RBP) |
|---|---|---|---|---|---|---|
| 0.014" | .25 cm | .050" (1.3 mm) | .023" (.6 mm) | .005" - .007" | 6 atm | 10 atm |

*Figure 1*

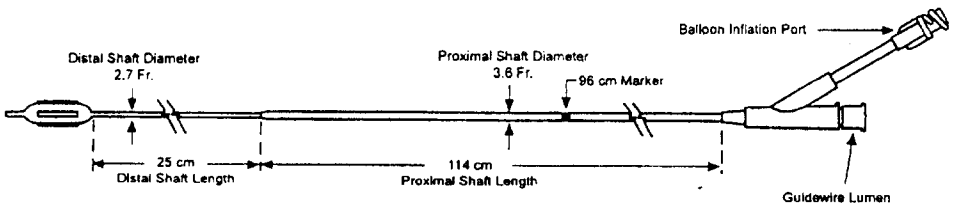


## Specifications:

| Model Number | Inflated Profile (mm) (E — Fig 1) | Deflated Profile | Number of Atherotomes | Atherotomes Length (mm) † (F — Fig 1) |
|---|---|---|---|---|
| B120010 | 2.00 | .041" | 3 | 10 |
| B122510 | 2.25 | .041" | 3 | 10 |
| B125010 | 2.50 | .041" | 3 | 10 |
| B127510 | 2.75 | .041" | 3 | 10 |
| B130010 | 3.00 | .041" | 3 | 10 |
| B132510 | 3.25 | .041" | 3 | 10 |
| B135010 | 3.50 | .044" | 4 | 10 |
| B137510 | 3.75 | .044" | 4 | 10 |
| B140010 | 4.00 | .046" | 4 | 10 |
| B120015 | 2.00 | .041" | 3 | 15 |
| B122515 | 2.25 | .041" | 3 | 15 |
| B125015 | 2.50 | .041" | 3 | 15 |
| B127515 | 2.75 | .041" | 3 | 15 |
| B130015 | 3.00 | .041" | 3 | 15 |
| B132515 | 3.25 | .041" | 3 | 15 |
| B135015 | 3.50 | .044" | 4 | 15 |
| B137515 | 3.75 | .044" | 4 | 15 |
| B140015 | 4.00 | .046" | 4 | 15 |

†Balloon working length = atherotome length.

*Figure 2*



**List of Additional Supplies:**
In addition to the Cutting Balloon, the following supplies should be prepared for use:

- .014" coronary guidewire (with Teflon® as a component of its coating);
- Large-lumen 8 Fr. or 9 Fr. guide catheter;
- Heparinized saline solution;
- Radiopaque contrast medium;
- Infusion manifold/apparatus;
- Pressure-indicating inflation/deflation device;
- Appropriately-sized vessel introducer;
- Other supplies and medications per local protocols.

**Directions for Use:**
All equipment to be used for the procedure, including the Cutting Balloon, should be examined carefully to verify functionality. Inspection prior to use should verify that the catheter has not been damaged in shipment and that it is ready to be used. The Cutting Balloon should be prepared and tested following the directions provided below prior to insertion into the body.

**1. Cutting Balloon Preparation**
Sizing the Cutting Balloon to the reference artery is extremely important for a successful dilation. Oversizing the balloon increases the risk of perforation. To reduce the potential for vessel damage, the inflated diameter of the Cutting Balloon should approximate a ratio of 1.1:1 in relation to the average diameter of the reference coronary artery.

**Caution:**
*This is a wet negative prep procedure. Customary balloon preparation methods do not apply. These steps must be followed exactly.*

a. Using sterile technique, remove the Cutting Balloon from its package and place onto sterile field. Remove the Cutting Balloon from its protective ring. Do not remove the blue protective sheath from the catheter tip.

b. Flush the guidewire lumen of the Cutting Balloon with heparinized saline.

c. Connect a three-way stopcock to the balloon port (Luer hub). Attach a 20cc syringe with full-strength contrast to the opposite port of the stopcock.

d. Shut stopcock port off to the balloon and purge air out of 20 cc syringe and stopcock.

e. Holding the syringe vertically above the Cutting Balloon, open stopcock to the balloon and draw a full vacuum stroke on the syringe. Pause long enough for air bubbles to flow into the syringe. Then allow the syringe to go forward slowly and contrast to enter the "Y" connector.

f. Draw back another full vacuum stroke on the syringe. Observe for a large volume of air coming from the balloon. If this does not occur, repeat prior steps. Always maintain negative pressure on

the balloon. Do not inflate balloon.

g. After negative prep is accomplished, withdraw full negative on the syringe and shut stopcock off to the balloon and remove syringe.

h. Prepare an inflation device with 5 cc of undiluted contrast media. Attach inflation device to stopcock. Purge stopcock by flushing 2cc of contrast media through the middle port.

i. Turn stopcock lever toward middle port and immediately withdraw inflation device plunger to full vacuum and lock.

j. Remove the blue protective sheath from the catheter tip with a gentle, straight motion. Do not use a twisting motion. Do not manipulate the balloon.

k. Insert a .014 inch coronary guidewire through the Cutting Balloon guidewire lumen. Retract distal end of guidewire into the distal tip of Cutting Balloon.

l. Insert Cutting Balloon into the guiding catheter through fully-opened hemostasis valve. Once balloon has passed through the hemostasis valve's "O-ring", tighten hemostasis valve to minimize back-bleeding.

**2. Cutting Balloon Positioning:**

a. Position the Cutting Balloon, under fluoroscopy, proximal to the first curve of the guiding catheter (a 96 cm marker is provided for easy reference for use with conventional PTCA guiding catheters). Advance guidewire across target lesion and position tip in distal vessel.

b. Advance Cutting Balloon over the guidewire and position balloon within lesion so that the lesion is centered between the radiopaque markers of the Cutting Balloon.

**3. Cutting Balloon Inflation:**

a. Under fluoroscopy, slowly inflate the Cutting Balloon (1 atm/ 5sec) until balloon indentation is no longer visible or to a minimum of 6 atm. Do not inflate the Cutting Balloon above 10 atm.

b. When using the Cutting Balloon on long lesion segments (≤20mm), the distal portion(s) of the target lesion should be treated first. Then, overlapping dilatation of the proximal lesion segment may be performed. However, ***do not perform repeat dilatation of the same lesion segment.***

**4. Cutting Balloon Removal:**

a. Deflate the Cutting Balloon by applying vacuum with inflation/deflation device. Maintain vacuum on the Cutting Balloon and verify deflation with fluoroscopy. Withdraw Cutting Balloon into the guiding catheter.

b. Repeat coronary arteriography to confirm successful result.

c. Dispose of entire Cutting Balloon. *For single use only.*

**Storage:**
The Cutting Balloon should be handled with care and stored in an area with good ventilation under conditions which protect it from extremes of temperature and humidity. Cartons containing this item should be protected from liquids and should be stacked in a manner to avoid crushing. Proper stock rotation should be accomplished.

**Shelf Life:**
The Cutting Balloon is supplied sterile and will remain so as long as the package is unopened and undamaged. The recommended shelf life for this product is printed on the product label. Interventional Technologies does not make provisions for reprocessing or replacing outdated products.

**References:**
The physician should consult recent literature on current medical practice on balloon dilatation, such as that published by ACC/AHA.

Bertrand OF., et al. Management of Resistant Coronary Lesions by the Cutting Balloon: Initial Experience. Cathet Cardiovasc Diagn 1997;41:179-184.

Interventional Technologies Inc. (Interventional) warrants that each component of this system has been manufactured, packaged and tested with reasonable care and will be free from defects in workmanship and materials. Interventional will not be liable for any incidental, special or consequential loss, damage or expense direct or indirect, from the use of this product. Interventional's sole obligation shall be to repair or replace, at its option, any device that we feel was defective at the time of shipment if notice thereof is received before the device's expiration date indicated on the package. Buyer assumes all liability, whether arising on warranty, contract, negligence or otherwise, from the handling, possession, use or misuse of the product. Because Interventional has no control over the operation, inspection, maintenance or use of its products after sale and has no control over the selection of patients, *This warranty is expressly in lieu of any other express or implied warranty of merchantability or fitness for any particular purpose, and of any other obligation on the part of the seller.* The remedies set forth in this Warranty and Limitations shall be the exclusive remedy available to any person. No Agent, employee or representative of Interventional has any authority to change any of the foregoing or assume or bind Interventional to any additional liability or responsibility in connection with this device.

**Questions:**
Call Interventional Technologies Customer Service Department at (800) 545-1901.



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