
OPENSAIL® Coronary Dilatation Catheter
Information for Prescribers

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Note: These instructions pertain to all available balloon catheter lengths and diameters.

CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE. OBSERVE ALL WARNINGS AND PRECAUTIONS NOTED THROUGHOUT THESE INSTRUCTIONS. FAILURE TO DO SO MAY RESULT IN COMPLICATIONS.

1.0 DEVICE DESCRIPTION

The OPENSAIL Coronary Dilatation Catheter is a two-lumen catheter with a balloon near the distal tip. One lumen is used for inflation of the balloon with contrast medium. The second lumen permits the use of a guide wire to facilitate advancement of the dilatation catheter to and through the stenosis to be dilated, and the injection of contrast and / or medication through the distal tip. The dilatation catheter is coated with Hydrocoat hydrophilic coating which is activated when wet.

This device has several markers. The balloon has radiopaque marker(s) to aid in positioning the balloon in the stenosis, and is designed to provide an expandable segment of known diameter and length at a specific pressure. The proximal shaft has proximal markers which aid in gauging dilatation catheter position relative to the guiding catheter tip (marker located closest to the dilatation catheter adapter is for femoral guiding catheters and the other marker is for brachial guiding catheters).

The two-arm adapter on the proximal end of the dilatation catheter provides access to the inflation and the guide wire lumen. The side arm communicates with the inflation lumen and has a Luer-lock fitting for connecting the dilatation catheter to an inflation device. The central arm communicates with the guide wire lumen, which allows for free movement of the inserted guide wire.

2.0 HOW SUPPLIED

Sterile. Sterilized with ethylene oxide gas. Non-pyrogenic. Do not use if the package is open or damaged.

Contents. One (1) OPENSAIL Coronary Dilatation Catheter, one (1) protective / regrooming sheath

Storage. Store in a dry, dark, cool place.

3.0 INDICATIONS

The OPENSAIL Coronary Dilatation Catheter is indicated for:

- a) Balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.
- b) Balloon dilatation of a coronary artery occlusion for the purpose of restoring coronary flow in patients with ST-segment elevation myocardial infarction.

4.0 CONTRAINDICATIONS

The OPENSAIL Coronary Dilatation Catheter is not intended to be used:

- In an unprotected left main coronary artery.
- To treat coronary artery spasm in the absence of a significant stenosis.

5.0 WARNINGS AND PRECAUTIONS

5.1 Warnings

This device is intended for one time use only. DO NOT resterilize and / or reuse it, as this can compromise device performance and increase the risk of cross contamination due to inappropriate reprocessing.

PTCA 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.

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

Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.

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

To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.

Use the catheter prior to the "Use By" date specified on the package.

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 and no resistance is felt. If there is resistance, determine the cause before proceeding. Continuing to advance or retract the catheter while under resistance may result in damage to the vessels and / or damage / separation of the catheter.

Never apply extreme bending or twisting force to any section of the catheter in order to prevent kinking or damage / separation of the shaft.

Treatment of moderately or heavily calcified lesions is considered to be moderate risk, with an expected success rate of 60% – 85% and increases the risk of acute closure, vessel trauma, balloon burst, balloon entrapment and associated complications. If resistance is felt, determine the cause before proceeding. Continuing to advance or retract the catheter while under resistance may result in damage to the vessels and / or damage / separation of the catheter.

In the event of catheter damage / separation, recovery of any portion should be performed based on physician determination of individual patient condition and appropriate retrieval protocol.

This catheter is not intended for use with stents.

5.2 Precautions

If the surface of the OPENSAIL Coronary Dilatation Catheter becomes dry, wetting with heparinized normal saline will reactivate the coating.

Do not reinsert the OPENSAIL Coronary Dilatation Catheter into the coil dispenser after procedural use.

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

The catheter system should be used only by physicians trained in the performance of percutaneous transluminal coronary angioplasty (PTCA).

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

With 4.5 mm and 5.0 mm balloon dilatation catheters, some increased resistance may be noted upon insertion or withdrawal into or out of the guiding catheter. Choosing a larger guiding catheter size may minimize this.

6.0 ADVERSE EVENTS

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

7.0 CLINICAL AND LABORATORY RESULTS

To evaluate the safety and effectiveness of direct PTCA as a treatment for patients with ST-segment elevation acute myocardial infarction, Guidant Corporation's subsidiary ACS conducted a multi-center, prospective, randomized clinical trial using primarily Guidant Coronary Dilatation Catheters. The GUSTO II Direct PTCA Substudy (GUSTO IIb) evaluated treatment of patients presenting within 12 hours of ST-segment elevation myocardial infarction with direct PTCA or accelerated recombinant tissue plasminogen activator (t-PA). The primary hypothesis was that for patients with suspected acute myocardial infarction, with ST-segment elevation, direct PTCA would result in a lower rate of 30-day mortality, non-fatal reinfarction, and non-fatal disabling stroke when compared with thrombolytic therapy.

A total of 1138 patients were enrolled in this trial at 60 centers in 9 countries from North America, Europe, and Australia over a period of 17 months. Investigator selection criteria included those physicians who had significant experience performing primary angioplasty for patients with acute myocardial infarctions, who fulfilled the 1993 ACC volume criteria of at least 50 to 75 cases of angioplasty per year. Investigational institutions were required to have performed at least 200 angioplasties per year and have a 24 hour on call team with an established system for operating room back-up. Five hundred sixty-five patients were assigned to primary angioplasty and 573 to accelerated recombinant tissue plasminogen activator (t-PA). At initial enrollment, the first 1012 patients were also randomized in a factorial design, to intravenous heparin or intravenous hirudin, as part of the GUSTO II trial. Thereafter, all patients received intravenous heparin. At enrollment, patients were given chewable aspirin (160 mg was recommended) followed by a daily dose of 80 mg to 325 mg. Patients received standard medical care post assigned treatment. Other testing and adjunctive therapies were left up to the discretion of the physician.

Of the patients randomized to t-PA, 94.6% (542/573) received t-PA, 1.6% (9/573) received streptokinase, and 1.7% (10/573) had direct angioplasty. Eighty-two patients (14.4%) required emergency angiography and sixty (10.5%) required emergency PTCA. Two hundred seventy (47.3%) had elective angiography and 61 (10.7%) had elective PTCA. The in-hospital procedural characteristics for patients randomized to PTCA, were 73.3% (374/510) of the infarct arteries occluded (TIMI grade 0 or 1 flow) at initial catheterization (core lab) and 79.2% (446/563) patients received PTCA. Patency after angioplasty (TIMI grade 2 or 3 flow) was achieved in 93.1% (473/508) of patients (core lab). Twenty-two (4%) required emergency angiography and 19 (3.5%) required emergency PTCA. Nineteen (3.5%) had elective angiography, and 5 (0.9%) had elective PTCA. The mean time from arrival at the hospital to treatment for patients randomized to accelerated t-PA was 1.2 ±0.9 hours and for the PTCA treatment group was 2.2 ±0.9 hours.

When comparing the treatment of patients with ST-segment elevation myocardial infarction with direct PTCA to treatment with accelerated t-PA, PTCA resulted in a statistically significant lower 30-day composite endpoint rate of death, reinfarction, and non-fatal disabling stroke of 9.6% versus 13.7%, respectively, (odds ratio = 0.67, p = 0.033). Additionally, the direct PTCA group had a statistically significant lower rate of recurrent ischemia at 30 days when compared to the t-PA group 5.5% (29/526) versus 9.0% (48/532) respectively, (odds ratio = 0.59, p = 0.03). The overall stroke rate for this study was 1.6% (18/1133). The stroke rate for patients treated with direct PTCA was 1.3% (7/562) versus 1.9% (11/571) for patients treated with t-PA (odds ratio = 0.64, p value = 0.36). The accelerated t-PA treatment group had a statistically significant higher rate of intracranial hemorrhagic strokes when compared to PTCA, 1.5% (8/571) versus 0%, respectively (odds ratio = 0.06, p = 0.005). There was a statistically significant higher overall rate of bleeding in the PTCA group versus the t-PA group 40.3% (227/563) versus

34.2% (195/571) (odds ratio = 1.30, p = 0.03). The rate of severe or life threatening bleeding was equivalent in both treatment groups. Seventy percent (161/227) of bleeding complications in the PTCA treatment group were related to vascular access, and 62.9% (142/227) were mild in nature.

At 180 days, there was no statistical difference in the composite rate of death, reinfarction, and non-fatal disabling stroke for accelerated t-PA versus direct PTCA, 16.8% (87/517) versus 14.7% (75/509) respectively, (odds ratio = 0.88, p = 0.36). The overall rate of re-admission to the hospital for chest pain, myocardial infarction, stroke and repeat cardiac procedures were similar between the two groups. At one year there is no statistical difference in the rate of death for accelerated t-PA versus PTCA 10.3% (52/507) versus 9.2% (46/500) respectively (odds ratio = 0.89, p = 0.57).

Direct PTCA with ACS Coronary Dilatation Catheters is safe and effective in eligible patients presenting within 12 hours of ST-segment elevation myocardial infarction, providing a reduced composite event rate at 30 days with an equivalent clinical outcome at 180 days and one year compared with accelerated t-PA.

Direct angioplasty, when it can be accomplished on a prompt basis by experienced physicians at centers with catheterization laboratory availability, should be considered a primary treatment option for patients with acute myocardial infarction.

8.0 CLINICIAN USE INFORMATION

8.1 Materials Required

Item Description (Single-use items only. Do not resterilize or reuse.)

- Femoral or brachial guiding catheter in the appropriate size and configuration to select the coronary artery
- Hemostatic valve(s)
- 60% contrast medium diluted 1:1 with normal saline
- Sterile heparinized normal saline
- 20 cc Luer-lock syringe (optional)
- Inflation device
- Appropriately sized guide wire (diameter not to exceed the maximum guide wire for the dilatation catheter; see product label)
- Guide wire introducer
- Guide wire torque device

8.2 Preparation for Use

Prior to use examine all equipment carefully for defects. Examine the dilatation catheter for bends, kinks or other damage. Do not use any defective equipment.

Prepare equipment to be used following manufacturer's instructions or standard procedure.

Complete the following steps to prepare the OPENSAIL Coronary Dilatation Catheter for use:

1. Remove the protective mandrel from the distal tip of the dilatation catheter

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2. Slide the protective sheath off the balloon.

Note: Submerge the balloon in sterile heparinized normal saline during balloon preparation to activate the coating.

3. Prepare an inflation device with the recommended contrast medium according to the manufacturer's instructions.
4. Evacuate air from the balloon segment using the following procedure:
 - a. Fill a 20 cc syringe or the inflation device with approximately 4 cc of the recommended contrast medium.
 - b. After attaching the syringe or inflation device to the balloon inflation lumen, orient the catheter with the distal tip and the balloon pointing in a downward vertical position.
 - c. Apply negative pressure and aspirate for 15 seconds. Slowly release the pressure to neutral, allowing contrast to fill the shaft of the dilatation catheter.
 - d. Disconnect the syringe or inflation device from the inflation port of the dilatation catheter.
 - e. Remove all air from the syringe or inflation device barrel. Reconnect the syringe or inflation device to the inflation port of the dilatation catheter. Maintain negative pressure on the balloon until air no longer returns to the device.
 - f. Slowly release the device pressure to neutral.
 - g. Disconnect the 20 cc syringe (if used) and connect the inflation device to the inflation port of the dilatation catheter without introducing air into the system.

CAUTION: All air must be removed from the balloon and displaced with contrast prior to inserting into the body (repeat steps 4a through 4g, if necessary); otherwise, complications may occur.

8.3 Instructions for Use

1. Flush and fill the guide wire lumen of the dilatation catheter with heparinized normal saline.
2. Insert a guide wire carefully into and through the lumen of the dilatation catheter via the guide wire port of the two-arm adapter using a guide wire introducer, if desired. When complete, withdraw the guide wire introducer, if used.
3. Open the hemostatic valve. Insert the dilatation catheter and guide wire assembly through the hemostatic valve into the guiding catheter. To facilitate insertion, the balloon must be fully deflated to negative pressure.

Note: Shaft diameter differences should be taken into consideration when opening and tightening the hemostatic valve and upon withdrawal of the catheter.

4. Tighten the hemostatic valve to create a seal around the dilatation catheter without inhibiting movement of the dilatation catheter. This will allow continuous recording of the proximal coronary artery pressure.

Note: It is important that the hemostatic valve be closed tightly enough to prevent blood leakage around the catheter shaft, yet not so tight that it restricts the flow of contrast into and out of the balloon or restricts guide wire movement.

5. Advance the dilatation catheter and guide wire until the appropriate proximal marker aligns with the hemostatic valve hub. This indicates that the dilatation catheter tip has reached the guiding catheter tip.
6. Attach a torque device for the guide wire, if desired. Under fluoroscopy, advance the guide wire to the desired vessel, then across the stenosis.

Note: The OPENSAIL Coronary Dilatation Catheter is designed to allow the exchange of guide wires while maintaining position of the dilatation catheter in the coronary artery.

7. Advance the dilatation catheter over the guide wire and into the stenosis. Inflate the balloon to a very low pressure (1 atm or 1 bar or 15 psi) to confirm that the balloon is correctly positioned.

Note: When using the dual wire technique, a DUOSTAT[®] (or equivalent) dual hemostatic valve should be used and care taken when introducing, torquing and removing one or both wires to avoid entanglement. Guide wires should not be rotated more than 180 degrees in either direction during the dual wire procedure. It is recommended that one wire be completely withdrawn from the patient before removing additional equipment.

8. Inflate the balloon to perform PTCA per standard procedure. Maintain negative pressure on the balloon between inflations.
9. Withdraw the deflated dilatation catheter and guide wire from the guiding catheter through the hemostatic valve. Tighten the hemostatic valve.

Note: After the deflated balloon dilatation catheter is withdrawn, it should be wiped clean with gauze soaked with sterile heparinized normal saline and stored, submerged in a basin of sterile heparinized normal saline. Prior to reinsertion, the balloon should be submerged in sterile heparinized normal saline to reactivate the coating.

9.0 REFERENCES

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

10.0 PATENTS

This product and / or its use are covered by one or more of the following United States Patents:








4,748,982; 4,771,776; 4,771,777; 4,771,778; 4,775,371; 4,782,834; 4,790,315; 4,793,350;
4,821,722; 4,877,031; 4,892,519; 4,938,220; 4,940,062; 4,964,409; 4,976,720; 4,981,478;
4,998,917; 4,998,923; 5,002,532; 5,003,989; 5,040,548; 5,042,985; 5,046,503; 5,061,273;
5,090,959; 5,135,535; 5,137,513; 5,154,725; 5,158,548; 5,159,937; 5,176,661; 5,195,971;
5,234,002; 5,242,394; 5,242,396; 5,242,399; 5,256,143; 5,279,562; 5,290,230; 5,300,025;
5,300,085; 5,316,706; 5,318,527; 5,324,259; 5,334,154; 5,344,426; 5,346,505; 5,348,537;
5,350,395; 5,360,401; 5,397,305; 5,411,476; 5,423,755; 5,451,209; 5,451,233; 5,458,613;
5,480,383; 5,496,275; 5,496,346; 5,498,240; 5,507,301; 5,507,768; 5,507,795; 5,516,336;
5,525,388; 5,533,968; 5,542,925; 5,549,551; 5,549,554; 5,554,120; 5,554,121; 5,558,643;
5,565,523; 5,573,508; 5,573,509; 5,632,754; 5,636,641; 5,637,089; 5,693,015; 5,695,506;
5,709,658; 5,743,875; 5,747,591; 5,749,888; 5,769,868; 5,782,855; 5,807,355; 5,816,923;
5,830,181; 5,849,846; 5,868,706; 5,868,767; 5,891,090; 5,902,290; 5,931,819; 5,989,218;
5,993,460; 6,013,054; 6,013,069; 6,013,728; 6,019,777; 6,027,475; 6,036,707; 6,036,715;
6,059,748; 6,059,770; 6,061,588; 6,117,106; 6,126,634; 6,126,635; 6,129,707; 6,136,011;
6,139,525; 6,156,047; 6,165,152; 6,165,292; 6,179,810; 6,193,686; 6,206,852; 6,217,547;
6,221,425; 6,224,803; 6,238,376; 6,248,092; 6,251,094; 6,368,301; 6,488,688; 6,561,788;
6,572,813; 6,733,486; 6,835,059; RE 34,564. Other U.S. patents pending. Foreign patents
issued and pending.

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**GRAPHICAL SYMBOLS FOR
MEDICAL DEVICE LABELING**

 Manufacturer	 Outer Diameter
REF Catalogue Number	 Date of Manufacture
F French Size	 Use By
 Consult Instructions for Use	LOT Batch Code
 Contents (Numeral represents quantity of units inside.)	
 Do Not Reuse	
STERILE EO Sterilized using Ethylene Oxide	

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