# PRIVATE TAXPAYER RULING LR98-003

March 3, 1998

The following private taxpayer ruling is in response to your letter dated December 10, 1997. You have requested a ruling regarding the application of transaction privilege tax to your sales of coronary stent catheters and related products. As was stated in the interim letter, this private taxpayer ruling is limited to a determination of whether coronary stent catheters and the related products listed in your letter are prosthetic appliances for purposes of an exclusion from transaction privilege tax under the retail classification.

The following is a restatement of the facts in your letter.

**Statement of Facts:**

... is a distributor of coronary stent catheters and related products. ... purchases coronary stent catheters and related products from .... ... manufactures medical products used in the treatment of coronary artery disease through a procedure called coronary stenting. The ... products are as follows:

(1) Coronary stent catheter (coronary stent and coronary angioplasty balloon catheter)

(2) Coronary guide wires

(3) Coronary guiding catheters

(4) Accessories

- Inflation device
- Angioject (syringe)
- Hemostatic valve
- Guide wire introducer
- Torque device
- Accessory kit (includes one inflation device, one hemostatic valve, one guide wire introducer and one torque device)

- Guide wire accessory kit (includes one hemostatic valve, one guide wire introducer and one torque device)

Balloon angioplasty is a medical procedure used to widen narrowings in the coronary artery without surgery. Narrowings are caused by a gradual build-up of fat (cholesterol) or calcium deposits within the artery walls.

The major challenge to angioplasty is clinical restenosis, or the re-narrowing of the blood vessel following the angioplasty procedure. Clinical restenosis can manifest as either the collapse of the artery as a result of the weakening of the artery walls following angioplasty or as the reoccurrence of the cholesterol or calcium deposits within the artery wall. Clinical restenosis may occur immediately following the angioplasty procedure, or anytime over the next several months or years. Treatment of clinical restenosis generally requires a subsequent angioplasty procedure or, in more severe instances, surgery. Clinical restenosis occurs in approximately twenty to thirty percent of patients undergoing angioplasty procedures.

Coronary stenting is a technique which mechanically props open the artery through implementation of a small, latticed stainless steel tube at the site of the narrowing. The stainless steel tube - the stent - is pre-mounted on a coronary angioplasty balloon catheter. As the balloon catheter is inflated during angioplasty, the stent expands and is compressed against the artery walls. When the balloon is deflated, the expanded stent remains implanted in the artery. This technique of mechanically propping open the artery with the stent greatly reduces the rate of clinical restenosis.

The patient is awake during coronary stenting. A local anesthetic is injected where the catheter is inserted, the skin is punctured with a hollow gauge needle to gain access to the artery. Once the artery is located, an introducer sheath is inserted. This sheath provides a direct and smooth pathway for the catheter to enter the artery.

A *coronary guiding catheter is* inserted into the introducer sheath. The coronary guiding catheter is advanced to the part of the aorta where the coronary arteries branch off to the heart. A *hemostatic valve,* which controls the flow of blood through the artery, is attached to the end of the coronary guiding catheter to allow for the insertion of coronary catheters. Note that a coronary guiding catheter is a conduit for the coronary guide wire and the coronary catheters to access the coronary artery. Coronary catheters rely on the support provided by the coronary guiding catheter.

A manifold device is also fastened to the guiding catheter. The manifold has three valves. One is used to monitor the patient's blood pressure, another is used to inject contrast medium (x-ray dye) and the other is used for a flushing solution. An *angioject syringe* is used at the end of the manifold to inject contrast medium so the physician can visualize the coronary arteries.

A *coronary guide wire is* loaded into the coronary guiding catheter through the use of a *guide wire introducer,* and advanced to the cardiac vessel just past the narrowing. Coronary guide wires are used to

support the coronary catheters as they are advanced across the artery narrowing. A *torque device is* placed on the end of the coronary guide wire and is used to steer the coronary guide wire to the artery until its tip is beyond the narrowing.

A *coronary stent catheter is* inserted at the distal end of the coronary guide wire and is advanced across the narrowing over the coronary guide wire through the guiding catheter. The balloon catheter that holds the stent has gold markers at the proximal and distal ends of the balloon. These markers are visible on an x-ray monitor and allow the physician to properly position the catheter across the narrowing. Once in position, the balloon is inflated with contrast medium (x-ray dye) using an *inflation device.* The inflation device is specifically designed for the purpose of inflating the balloon. The inflation device hooks up to a side port valve, outside the body on the coronary stent catheter. It also measures and monitors the amount of pressure required to inflate the balloon. Inflation of the balloon compresses the plaque against the wall of the artery and causes the stent to expand and press against the vessel wall. When the balloon is deflated, the expanded stent remains as a reinforcement for the artery wall.

Depending upon the condition and position of the narrowing and the preference of the physician, the stenting procedure may be preceded and/or followed with separate angioplasty procedures. These procedures either pre-dilate the lesion allowing better access for the coronary stent catheter or post dilate the lesion allowing the physician to ensure proper deployment of the stent.

After the plaque has been compressed and the artery has been opened sufficiently, the deflated coronary stent catheter, coronary guide wire and coronary guiding catheter are removed and disposed. The stent remains permanently in the body, holding the artery open and thus improving blood flow.

**Issues:**

1. Are the following ... products prosthetic appliances for purposes of an exclusion from transaction privilege tax under the retail classification?

- (1) Coronary stent catheter (coronary stent and coronary angioplasty balloon catheter)

(2) Coronary guide wires

(3) Coronary guiding catheters

(4) Accessories

- Inflation device
  - Angioject (syringe)

- Hemostatic valve
- Guide wire introducer
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2. How would the state tax the stents if they are purchased separately from the coronary angioplasty balloon catheter, i.e. the doctors would manually mount the stents on the catheter?

**Your Position:**

Under Arizona Revised Statutes (A.R.S.) § 23-501, prosthetic appliances are exempt from the retail classification when prescribed or recommended by a licensed health professional. Arizona Administrative Code (A.A.C.) R15-5-156(A)(1) defines 'prosthetic appliance" as an artificial device that fully or partially replaces a part or function of the human body or increases the acuity of a sense organ.

It is ...'s opinion that the coronary stent catheters are exempt as prosthetic appliances. These catheters replace a function of the human body by supporting the flow of blood which delivers oxygen and other nutrients to the heart muscle by widening the arteries. In addition, the stent, which becomes permanently implanted in the artery, reinforces and holds the artery open, thus improving the flow of blood.

The coronary guide wires, guiding catheters and accessories are necessary to the proper functioning of the coronary stent catheters. As such, they are exempt under A.A.C. R15-5-156(C) which exempts the sale of component and repair parts for any property included in this rule.

**Applicable Law:**

A.R.S. § 42-1310.01(A) states that "[T]he retail classification is comprised of the business of selling tangible personal property at retail. The tax base for the retail classification is the gross proceeds of sales or gross income derived from the business."

A.R.S. § 42-1310.01(A)(9) provides that the tax imposed on the retail classification does not apply to the gross proceeds of sales or gross income from "[p]rosthetic appliances as defined in §23-501 prescribed or recommended by a health professional licensed pursuant to title 32, chapter 7, 8, 11, 13, 14, 15, 16, 17 or 29." These chapters refer to podiatrists, doctors of chiropractic, dentists, physicians and surgeons,

naturopathic physicians, nurses, osteopathic physicians and surgeons, and homeopathic physicians.

A.R.S. § 23-501 defines "prosthetic appliance" as "an artificial device necessary to support or take the place of a part of the body, or to increase the acuity of a sense organ."

A.R.S. § 42-1329 states that it is "presumed that all gross proceeds of sales and gross income derived by a person from business activity classified under a taxable business classification comprise the tax base for the business until the contrary can be established."

A.A.C. R15-5-156 defines "prosthetic appliance" as "an artificial device which fully or partially replaces a part or function of the human body or increases the acuity of a sense organ." Subsection C of this rule provides that the sale of component or replacement parts for an exempt prosthetic appliance is also exempt.

**Discussion:**

An exclusion from the transaction privilege tax on retail sales is provided for the sale of prosthetic appliances that are prescribed or recommended by a physician or surgeon.

In order to qualify for the exclusion the item sold must be a "prosthetic appliance" as defined by statute. "Prosthetic appliance" is defined as an artificial device necessary to support or take the place of a part of the body or to increase the acuity of a sense organ. A.A.C. R15-5-156 which states that prosthetic appliance "means an artificial device which fully or partially replaces a part or function of the human body or increases the acuity of a sense organ" provides additional clarification.

The coronary stent is implanted in the body and is used to support or take the place of a section of artery. Therefore, the coronary stent qualifies as an exempt prosthetic appliance.

However, the coronary angioplasty balloon catheters, coronary guide wires, coronary guiding catheters, and accessories do not support or take the place of a part of the body, they are tools used to insert the coronary stent. Therefore, the coronary angioplasty balloon catheters, coronary guide wires, coronary guiding catheters, and accessories do not qualify as exempt prosthetic appliances.

In addition, although the coronary angioplasty balloon catheters, coronary guide wires, coronary guiding catheters, and accessories are necessary to properly implant the coronary stent, these items are not part of the stent. Therefore, the coronary angioplasty balloon catheters, coronary guide wires, coronary guiding catheters, and accessories do not qualify as component or repair parts of the exempt coronary stent.

All of ...'s sales are considered taxable until the contrary is established. Therefore, if the sale price of the exempt coronary stent is not separately stated in your books and records from the sale price of the taxable items, the entire sale price is subject to transaction privilege tax under the retail classification.

**Conclusion and Ruling:**

The following ruling is given based on the facts presented in your request.

The department rules that: coronary stents qualify as prosthetic appliances for purposes of an exclusion from transaction privilege tax under the retail classification.

The department also rules that: coronary angioplasty balloon catheters, coronary guide wires, coronary guiding catheters, and accessories do not qualify as prosthetic appliances or component parts of prosthetic appliances. Therefore, the gross proceeds of sales or gross income from the sale of coronary angioplasty balloon catheters, coronary guide wires, coronary guiding catheters, and accessories are subject to tax under the retail classification unless another exemption applies.

In addition, the department rules that: if the sale of the exempt coronary stent is not separately stated in your books and records from the sale price of the taxable items, the entire sale price is subject to transaction privilege tax under the retail classification.

The conclusions in this private taxpayer ruling do not extend beyond the facts presented in your letter dated December 10, 1997.

This response is a private taxpayer ruling and the determination herein is based solely on the facts provided in your request. The determination in this taxpayer ruling is the present position of the department and is valid for a period of four years from the date of issuance except as set out herein. This determination is subject to change should the facts prove to be different on audit. If it is determined that undisclosed facts were substantial or material to the department's making of an accurate determination, this taxpayer ruling shall be null and void. Further, the determination is subject to future change depending on changes in statutes, administrative rules, case law or notification of a different department position.