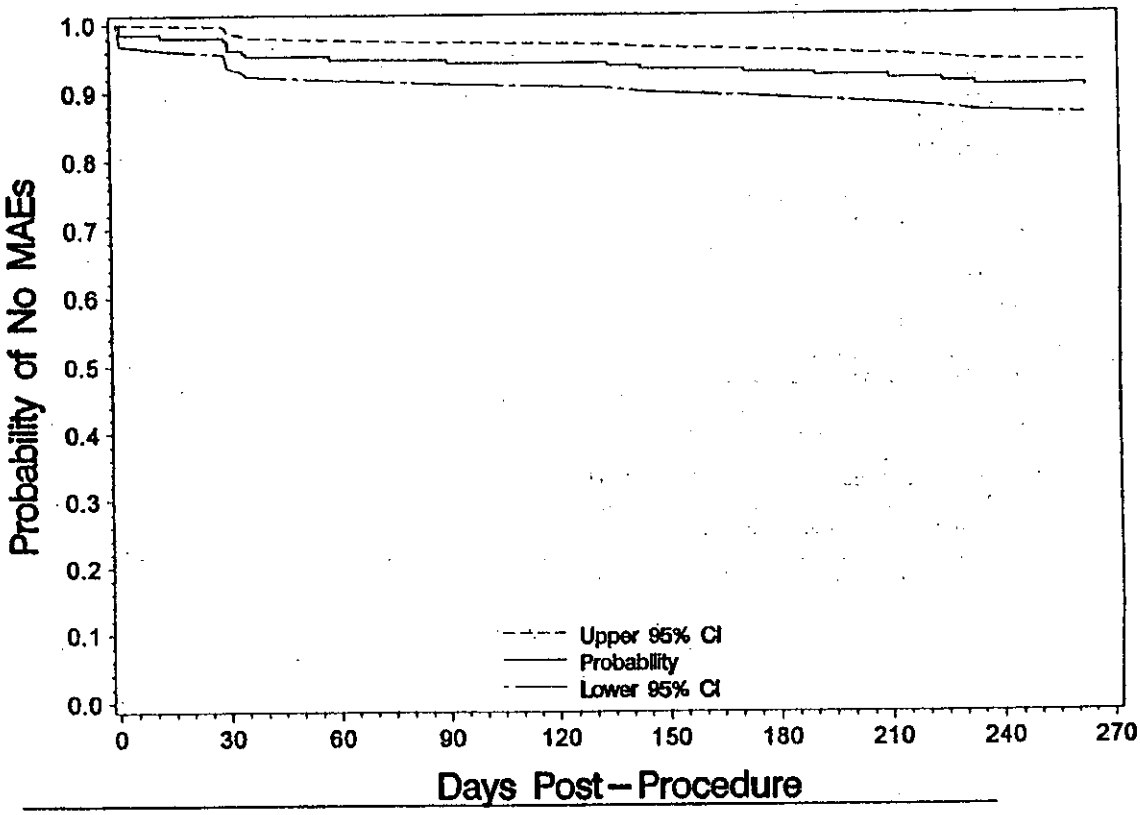
Figure 1. Freedom from Major Adverse Events (To 270 Days):
All Patients (N=208)



	Days Post-Procedure				
	0	Discharge	30	180	270
# Entered	208	208	204	195	182
# Censored	0	0	3	5	180
# At risk	208	208	204	192	177
# Events	0	4	8	6	2
# Events/Month		10	2.7	0.8	0.2
% Survived	100	98.1	94.2	91.3	90.3
SE		1	1.6	2	2.1

8.0 INDIVIDUALIZATION OF TREATMENT

The risks and benefits should be considered for each patient before use of the PALMAZ Balloon-Expandable Stent. Patients must be acceptable candidates for balloon angioplasty with stent deployment. Patients selected for treatment should include those having a failed PTRA result defined as meeting one or more of the following criteria:

- ≥ 50% residual stenosis (visual estimate)
- ≥ 20 mm Hg peak translesional pressure gradient
- ≥ 10mm Hg mean translesional pressure gradient
- Grade D dissection (a spiral shaped filling defect within the lumen of the vessel) or any dissection with significant compromise in lumen flow

Lesions to be treated may be in unilateral or bilateral renal arteries, de novo or previously treated (by PTRA, not with stents). Accessory arteries may be treated if ≥ 4 mm in diameter.

8.1 Use in Special Populations

The safety and effectiveness of the PALMAZ Balloon-Expandable Stent has not yet been established in the following patient populations:

- Patients with more than one lesion in a renal artery.
- Patients with renal arteries < 4 mm or > 8 mm in normal diameter by visual estimate.
- Patients with a total occlusion of the renal artery.
- Patients with lesions requiring more than two stents.
- Patients with lesions due to any causes of renal artery stenosis, other than atherosclerosis.
- Patients with advanced renal disease as evidenced by serum creatinine greater than or equal to 3.0mg/dl or kidney length < 8 cm.
- Patients with a recent Q-way myocardial infarction.
- Patients with an abdominal aortic aneurysm > 4.0 cm in diameter.
- Patients with confirmed pregnancy.
- Patients with a total occlusion of the renal artery.
- Patients with a stenosis of the common femoral artery.

9.0 HOW SUPPLIED

The PALMAZ Balloon-Expandable Stent and plastic crimping tube are supplied sterile. The stent is supplied in three nominal lengths: 10 mm, 15 mm, and 20 mm and is designed to be expanded from 4 to 8 mm in diameter. The PALMAZ Balloon-Expandable Stent is provided unmounted and is recommended for use with commercially available Cordis POWERFLEX Plus balloon catheter (see Table 1).

IMPORTANT: When using the POWERFLEX PLUS balloon catheter, use the crimping tube that is packaged with the balloon, NOT the Stent. The crimping tube supplied with the Stent is NOT compatible with the POWERFLEX PLUS balloon catheter.

The stent is mounted on the balloon catheters utilizing Cordis (CRT20) crimping tool (provided separately). The Cordis (INTR4) introducer tube (provided separately) may be used for passage of the balloon/stent assembly through the catheter sheath introducer gasket. The crimping tool and introducer are provided non-sterile and must be sterilized by autoclaving in accordance with hospital procedures.

10.0. OPERATOR'S MANUAL

10.1 Pre-Procedure

a. The patient may be started on enteric coated or non-enteric coated aspirin 81-500 mg per day beginning one or two days prior to the procedure if deemed appropriate to the physician.

b. The percutaneous placement of the stent in the renal artery should be done in an angiography procedure room. Angiography should be performed to map out the extent of the lesion. If thrombus is present or suspected, thrombolysis should precede stent deployment using standard acceptable practice. Access vessels must be sufficiently patent, or sufficiently recanalized, to proceed with further intervention. Patient preparation and sterile precautions should be the same as for any angioplasty procedure.

10.2 Select Stent Size

a. Measure the length of the target lesion to determine the length of stent required. Size the stent length to extend slightly proximal and distal to the lesion, taking foreshortening in to account (refer to Table 1 for stent length when fully expanded).

b. The appropriate stent length should be selected based on covering the entire obstructed segment with a single stent. Should more than one stent be required, place the stent most distal from the puncture site first, followed by placement of the proximal stent in tandem.

c. Measure the diameter of the lesion to determine the appropriate size delivery system for stent expansion.

10.3 Stent Preparation

a. Open the carton to reveal the pouch containing the stent and crimping tube. Do not use if the inner tray is open or damaged.

b. Inspect the stent package for damage to the sterile barrier. Remove the stent and crimping tube from the package and rinse in sterile heparanized saline.

c. **IMPORTANT: When using the POWERFLEX PLUS balloon catheter, use the crimping tube that is packaged with the balloon, NOT the Stent. The crimping tube supplied with the Stent is NOT compatible with the POWERFLEX PLUS balloon catheter.**

10.4 Preparation of Stent Delivery Catheter

a. Select a stent delivery balloon, which is of a size that approximates the true diameter of the renal artery.

b. See Instructions for Use provided with the recommended balloon catheter. **Note: Preinflation of the balloon catheter is NOT recommended prior to mounting the stent on the balloon.**

10.5 Preparation of Stent Delivery System

a. Remove the balloon protector and visually inspect the balloon to ensure that it is properly folded to its lowest profile.

b. Attach a stopcock to the catheter's inflation port.

c. Open the stopcock and induce negative pressure.

d. Hold the proximal end of the catheter above the distal end. Hold the balloon vertically with the balloon tip pointing down.

e. Close the stopcock.

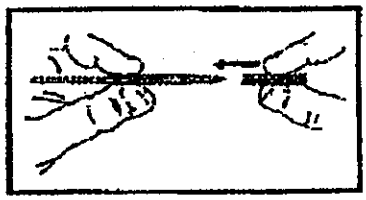
f. Ensure that the air contained in the balloon and inflation lumen is removed. Repeat steps c through e.

g. Place the balloon catheter through a guide catheter that is long enough to reach the lesion, with the balloon extending completely outside the guide catheter.

h. Visually inspect the balloon to assure that it is properly folded to its lowest profile in preparation for the stent application to the balloon.

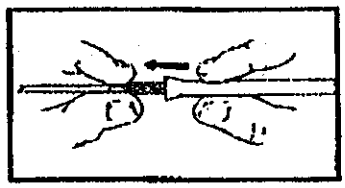
i. Mount the stent on the balloon utilizing the appropriate hand-operated reusable mechanical crimping tool, provided separately (see steps below). The mechanical crimping tool is provided NON-STERILE and must be sterilized prior to use. Plastic crimping tubes and metal introducer tubes are not interchangeable. **(See III below regarding crimping tubes.)**

I. Slide the stent over the distal end of the balloon, maintaining the balloon fold, until the radiopaque markers are equidistant from the ends of the stent.

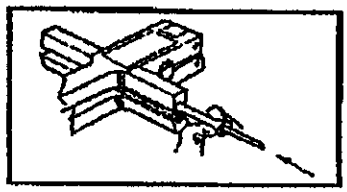


II. Gently pre-crimp the stent on the balloon manually (with fingers). This will enable the crimping tube to more easily slide over the stent once loaded on the catheter.

III. **IMPORTANT: When using the POWERFLEX PLUS balloon catheter, use the crimping tube that is packaged with the balloon, NOT the Stent. The crimping tube supplied with the Stent is NOT compatible with the POWERFLEX PLUS balloon catheter.** Place the plastic crimping tube over the stent. Insert the stent/tube assembly into the crimping tool until the edges of the stent are aligned within the jaws of the crimping tool. The stent is now in a position to be crimped onto the balloon.



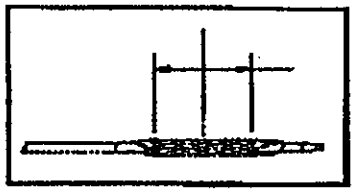
IV. Close the crimping tool until it comes to a fixed stop. The fixed stop prevents excessive crimping and subsequent damage to the stent or balloon. The tool delivers a radial compressive force to the stent.



V. Rotate stent and balloon approximately 90° and repeat step IV.

VI. After crimping, withdraw the balloon, stent and tube assembly from the crimping tool. Remove the tube from the stent and discard it.

VII. Visually inspect the balloon/stent assembly to assure proper placement of the stent between the radiopaque markers of the balloon. Do not reposition stent or manually re-crimp. Carefully pull the stent/balloon assembly back into the guide catheter so that the stent is completely within, and the tip of the balloon extends slightly past, the edge of the guide catheter.



h. Open the stopcock allowing the inflation lumen and the balloon lumen to fill with diluted contrast medium. **NOTE**: Never use air or any gaseous medium to inflate the balloon. The delivery system is not designed for use with power injection systems.

10.6 Insertion of Cordis Sheath Introducer (CSI) and Guidewire

a. Access should be obtained in the standard fashion through the femoral approach. The brachial route may be used in cases where the anatomy dictates this would be a more favorable approach. Gain access at the appropriate site utilizing the recommended CSI (see Table 1). A CSI of the appropriate size and length should be used.

CAUTION: Always use a CSI for the implant procedure to protect the puncture site and avoid dislodging the stent from the balloon.

b. Place the stent/balloon catheter assembly and guiding catheter through the CSI to the aortic bifurcation, using the guidewire as a leader to avoid penetration of the vessel and stent dislodgment.

c. Insert a .035" (.89mm) guidewire of the appropriate length across the lesion to be stented through the CSI. NOTE: If the physician determines that predilation is necessary, standard PTA techniques may be used. Maintain lesion access with the .035" (.89mm) guidewire.

d. Insert a sterile stainless steel introducer tube (supplied NON-STERILE) through the hemostatic valve of the introducer assembly (CSI). This tube facilitates insertion of the stent/balloon assembly through the introducer and prevents the hemostatic valve from potentially stripping the stent from the balloon during insertion.

10.7 **Stent Deployment Procedure** – NOTE: When ready to proceed with stent deployment, 3000 to 5000 units of heparin (depending on patient size) may be given intravenously or intra-arterially.

a. The stent/balloon assembly within the guiding catheter is advanced over the guidewire and through the CSI. Carefully cross the lesion site with the stent.

b. Verify correct stent positioning using multiple oblique views as necessary. After correctly positioning the stent within the renal artery, retract the guiding catheter to completely expose the stent/balloon and expand the stent by inflating the POWERFLEX PLUS balloon catheter to the nominal inflation pressure. Appropriate expansion of the balloon/stent should be determined fluoroscopically. Do not exceed the labeled rated burst pressure (RBP). See Table 5 for the nominal pressure and the labeled RBP.

Ideal positioning of the stent is within the renal artery ostium entirely covering the lesion with no more than 1-2mm of stent extending into the aorta.

10.8 Delivery System Withdrawal

a. After deploying the stent, deflate the balloon by pulling a vacuum, allowing adequate time for the balloon to fully deflate prior to removal.

b. Carefully rotate the balloon counterclockwise to ensure separation of the balloon from the stent.

c. While maintaining negative pressure on the balloon, slowly withdraw the balloon from the stent. Observe removal of the balloon under fluoroscopy to ensure that the balloon disengages from the stent.

d. Remove the deflated balloon, keeping the guidewire in place in the renal artery. A post-stent angiogram should be obtained. After a satisfactory post stent angiogram is obtained, remove the guiding catheter and then the guidewire.

e. Remove the CSI.

f. Discard the delivery system and guidewire.

g. The diameter of the stent may be increased post-placement by repeat balloon dilatation with the same and/or larger diameter balloons. The labeled maximum diameter of the stent should not be exceeded.

h. If the stent does not entirely cover the lesion, a second stent may be placed, with 1-3mm of the overlap between the two stents. Efforts should be made to achieve an optimal result with a minimal residual stenosis and to eliminate the peak-to-peak pressure gradient.

10.9 Post Stent Placement

Compress the puncture site to achieve hemostasis.
NOTE: Physician experience and discretion will determine the appropriate post-procedure drug regimen for each patient.

10.10 In Vitro Information

The data below are based on *in vitro* testing of the PALMAZ Stent on the POWERFLEX PLUS delivery systems. Actual diameters *in vitro* are within 10% of the specified diameter at both nominal and rated burst pressure (RBP). The balloon and stent compliance data should be used to determine what pressure will be needed to achieve the intended stent diameter.

FIGURE 2 - Compliance Chart
Stent Diameter as a Function of Pressure

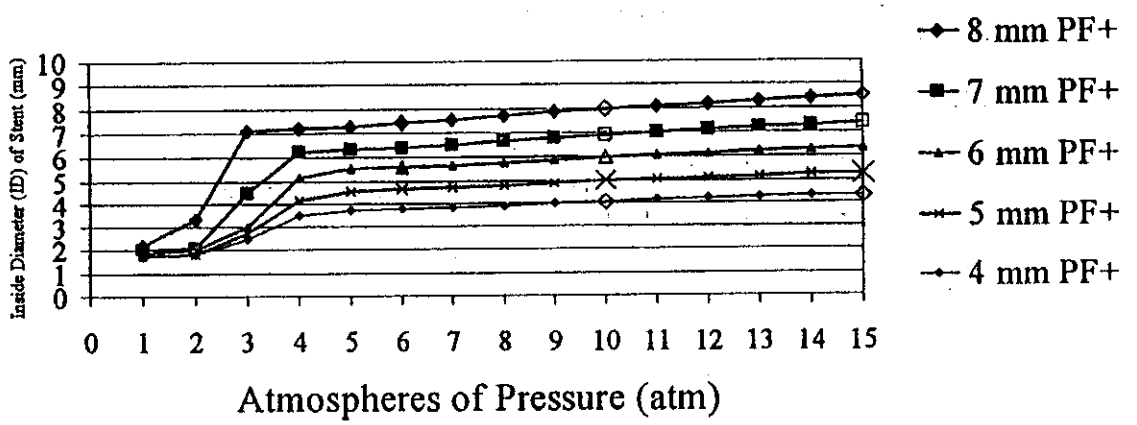


FIGURE 2 NOTES:

- The open markers represent the Nominal and the Rated Burst Pressure (RBP) specifications for the POWERFLEX PLUS (PF+) balloon. Do not exceed the RBP of 15 atmospheres of pressure.
- Each line represents the average stent diameter combining the data from the P104R, P154R and P204R stents.

Table 5 – Compliance Table for the PALMAZ Stent on the POWERFLEX PLUS Balloon Catheter (PF+)

	Expanded Inside Diameter (mm) of the Stent				
Inflation Pressure	4 mm PF+	5 mm PF+	6 mm PF+	7 mm PF+	8 mm PF+
1 atm	1.71	1.76	1.84	2.00	2.20
2 atm	1.82	1.80	2.03	2.06	3.32
3 atm	2.45	2.72	3.01	4.50	7.08
4 atm	3.51	4.14	5.13	6.25	7.19
5 atm	3.70	4.56	5.49	6.33	7.27
6 atm	3.75	4.62	5.59	6.41	7.41
7 atm	3.82	4.68	5.65	6.52	7.54
8 atm	3.90	4.77	5.75	6.65	7.69
9 atm	3.98	4.86	5.86	6.78	7.84
10 atm (Nominal)	**4.06**	**4.95**	**5.96**	**6.90**	**7.99**

11 atm	4.13	5.02	6.05	7.01	8.10
12 atm	4.19	5.09	6.13	7.11	8.21
13 atm	4.25	5.15	6.20	7.20	8.31
14 atm	4.30	5.22	6.28	7.28	8.42
15 atm (RBP)	**4.34**	**5.27**	**6.34**	**7.36**	**8.51**

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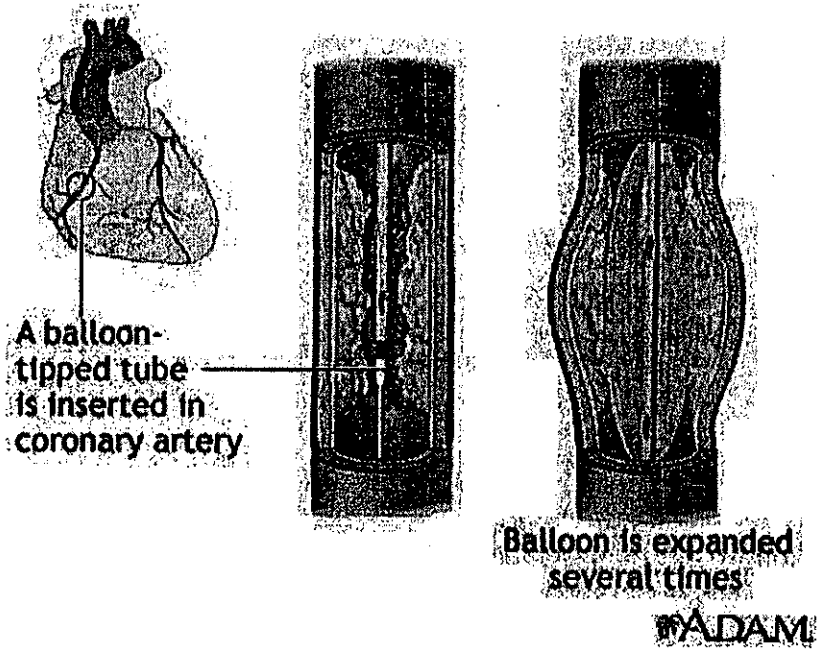
Medical Encyclopedia

Coronary artery balloon angioplasty - series: Procedure, part 3



Coronary artery balloon angioplasty - series Illustrations:

- Normal anatomy
- Indication
- Procedure, part 1
- Procedure, part 2
- Procedure, part 3
- Procedure, part 4
- Procedure, part 5
- Aftercare, part 1
- Aftercare, part 2

The first catheter is exchanged out over the guidewire for a guiding catheter and the guidewire is removed. A smaller guidewire is advanced across the blocked section of the coronary artery and a balloon -tipped tube is positioned so the balloon part of the tube is beside the blockage. The balloon is then inflated for a few seconds to compress the blockage against the artery wall. Then the balloon is deflated. The doctor may repeat this a few times, each time pumping up the balloon a little more to widen the passage for the blood to flow through. This treatment may be repeated at each blocked site in the coronary arteries.

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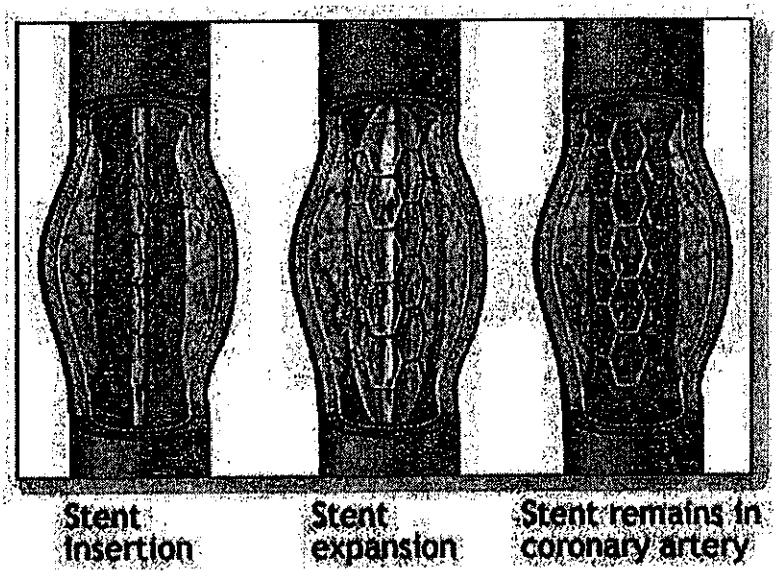
Medical Encyclopedia

Coronary artery balloon angioplasty - series: Procedure, part 4



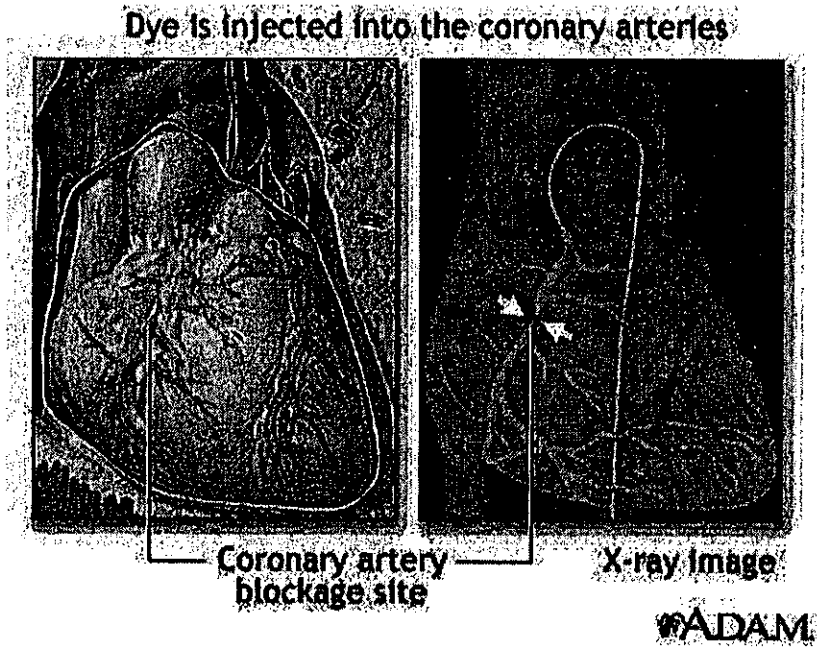
Coronary artery balloon angioplasty - series illustrations:

- Normal anatomy
- Indication
- Procedure, part 1
- Procedure, part 2
- Procedure, part 3
- Procedure, part 4
- Procedure, part 5
- Aftercare, part 1
- Aftercare, part 2

A device called a stent may be placed. A stent is a latticed, metal scaffold that is placed within the coronary artery to keep the vessel open.

Medical Encyclopedia

Coronary artery balloon angioplasty - series: Procedure, part 2



Coronary artery balloon angioplasty - series illustrations:

- Normal anatomy
- Indication
- Procedure, part 1
- Procedure, part 2
- Procedure, part 3
- Procedure, part 4
- Procedure, part 5
- Aftercare, part 1
- Aftercare, part 2

Next, a diagnostic catheter, which is a long narrow tube, is advanced through the introducer over a .035"guidewire, into the blood vessel. This catheter is then guided to the aorta and the guidewire is removed. Once the catheter is placed in the opening or ostium of one of the coronary arteries, the doctor injects dye and takes a series of X-rays (film of the images).

Medical Encyclopedia

Coronary artery balloon angioplasty - series: Procedure, part 5

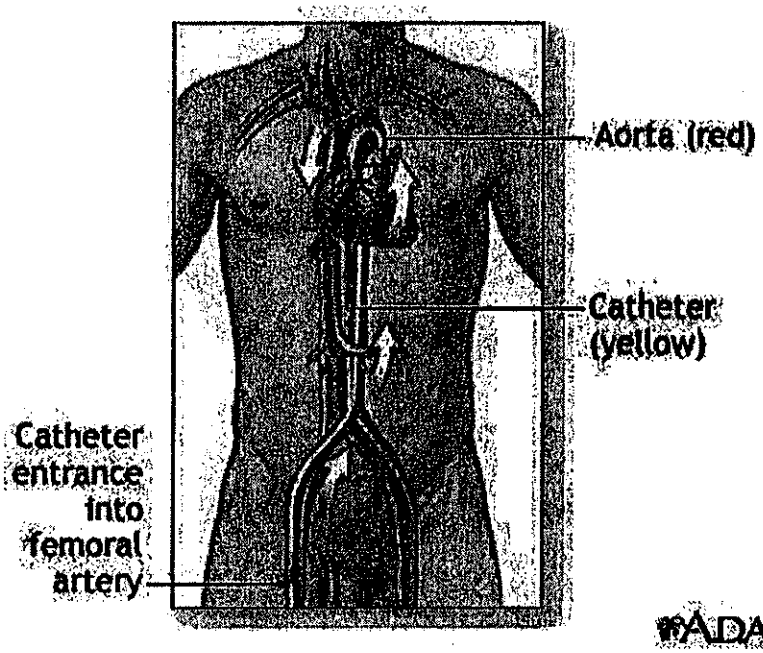
Coronary artery balloon angioplasty - series Illustrations:

- Normal anatomy
- Indication
- Procedure, part 1
- Procedure, part 2
- Procedure, part 3
- Procedure, part 4
- Procedure, part 5
- Aftercare, part 1
- Aftercare, part 2

Once the catheter has been positioned at the coronary artery origin, contrast media is injected and a series of X-rays (film) are taken to check for any change in the arteries. Following this, the catheter is removed and the procedure is completed.

Medical Encyclopedia

Coronary artery balloon angioplasty - series: Procedure, part 1



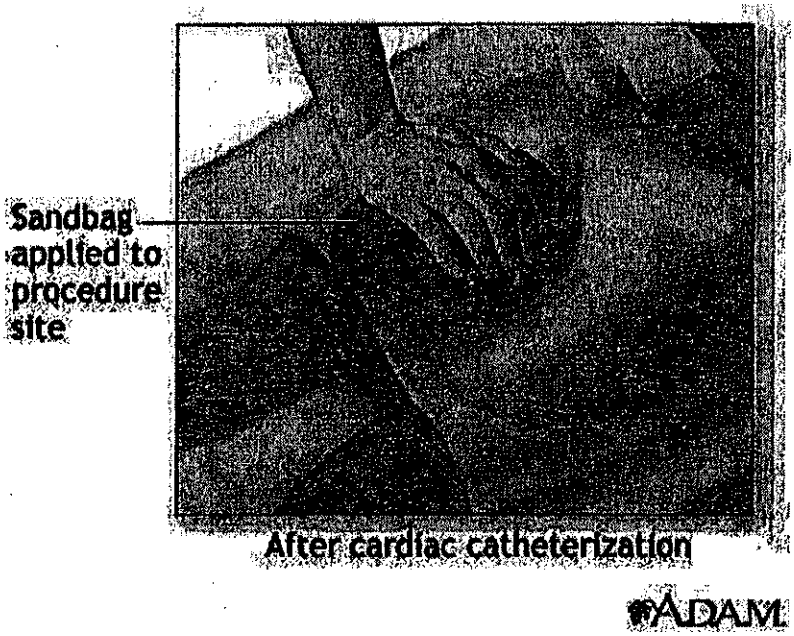
Coronary artery balloon angioplasty - series Illustrations:

- Normal anatomy
- Indication
- Procedure, part 1
- Procedure, part 2
- Procedure, part 3
- Procedure, part 4
- Procedure, part 5
- Aftercare, part 1
- Aftercare, part 2

While the patient is awake and pain-free (local anesthesia), a catheter is inserted into an artery at the top of the leg (the femoral artery). The procedure begins with the doctor injecting some local anesthesia into the groin area and putting a needle into the femoral artery (the blood vessel that runs from the heart down the leg). Once the needle is inserted, a guide wire is placed through the needle, into the blood vessel. Following this step, the guide wire is left in the blood vessel and the needle is removed. A large needle called an introducer is then placed over the guide wire and the guide wire is removed.

Medical Encyclopedia

Coronary artery balloon angioplasty - series: Aftercare, part 2



Coronary artery balloon angioplasty - series illustrations:

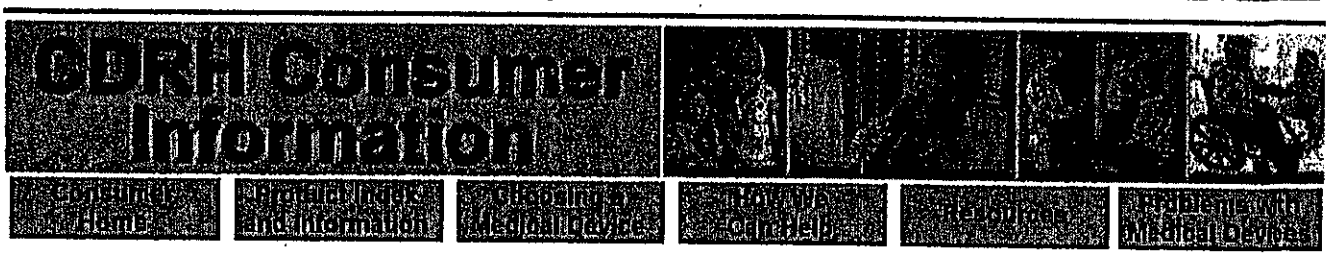
- Normal anatomy
- Indication
- Procedure, part 1
- Procedure, part 2
- Procedure, part 3
- Procedure, part 4
- Procedure, part 5
- Aftercare, part 1
- Aftercare, part 2

Immediately after the procedure, a ten-pound sandbag may be placed over the femoral artery puncture site in the leg and remain there for 6 hours. This is done to help the artery heal.

2．検索の事例

（3）UBIS 5000 Ultrasound Bone Sonometer – P000055［原文］

・概要	資料(3)-2-(3)-1
・詳細	
・パート１　認証時文書	資料(3)-2-(3)-2
・パート２　安全性と予想される利点	資料(3)-2-(3)-3
・パート３　使用情報	資料(3)-2-(3)-4
・他の情報	資料(3)-2-(3)-5



New Device Approval

UBIS 5000 Ultrasound Bone Sonometer – P000055

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: UBIS 5000 Ultrasound Bone Sonometer
Manufacturer: Diagnostic Medical Systems
Address: Parc de la Méditéranné, Chemin de la Foire, District de Montpellier
34470 Perols, France
Approval Date: July 17, 2001
Approval Letter:http://www.fda.gov/cdrh/pdf/p000055a.pdf

What is it? The UBIS 5000 Ultrasound Bone Sonometer is a portable medical device that uses ultrasound to measure the strength of the heel bone (calcaneus). Since the heel bone is similar to the bones in the hip and spine, this measurement can indicate the strength of those bones as well.

How does it work? The UBIS 5000 Ultrasound Bone Sonometer sends a beam of ultrasound across the heel to a detector that measures the strength of the beam after it has passed through the bone. This is then compared to the average of measurements that have been obtained from young, healthy Caucasian (white) women. If the two measurements are similar, the patient's bone strength is considered normal. If the patient's measurement shows a lower strength than the normal value, this may indicate that the patient has osteoporosis, a thinning and weakening of the bone that can increase the risk of fracture. Although osteoporosis most often occurs in women past menopause, thinning and weakening of the bone can also occur in younger people with certain diseases. For these people, the measurement from the UBIS 5000 Ultrasound Bone Sonometer can be compared to normal values that take into account age, gender and ethnic background.

When is it used? To measure the bone loss of women past menopause, as well as other patients who may have diseases that cause bone loss.

What will it accomplish? The physician can use the results of the UBIS 5000 Ultrasound Bone Sonometer heel bone test, along with other clinical risk factors, to diagnose osteoporosis, to estimate the risk of fracture, and to detect other medical conditions that can result in bone loss.

When should it not be used?

- On patients under 20 or over 80 years old, as the meaning of measurements on such patients has not been determined
- On feet with open skin or sores

What are the limitations of this and ALL machines that measure bone density?

- A single reading may suggest an increased fracture risk, but cannot predict whether or not a fracture will occur.
- Measurements should only be compared to other measurements from machines of the same make and model.

Additional information: The SSED and Labeling will be available at: http://www.fda.gov/cdrh/pdf/p000055.html
Other:
National Osteoporosis Foundation: http://www.nof.org
FDA Office of Women's Health (OWH): http://www.fda.gov/womens

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2001

Diagnostic Medical Systems
% Mr. Frank Ferguson
Ferguson Medical
P.O. Box 12038
La Jolla, CA 92039-2038

Re: PMA P000055
UBIS 5000
Filed: December 18, 2000
Amended: July 16, 2001

Dear Mr. Ferguson:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the UBIS 5000. The UBIS 5000 is a quantitative ultrasound (QUS) bone sonometer and is indicated for the measurement of broadband ultrasound attenuation (BUA) of the calcaneus, as an aid to diagnose osteoporosis and to estimate the risk of subsequent atraumatic fracture. The output is expressed in terms of both BUA and T-score.

We are pleased to inform you that the PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device upon receipt of this letter.

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that, to ensure the safe and effective use of the device, the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

CDRH will notify the public of its decision to approve your PMA by making available a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at:
http://www.fda.gov/cdrh/pmapage.html.