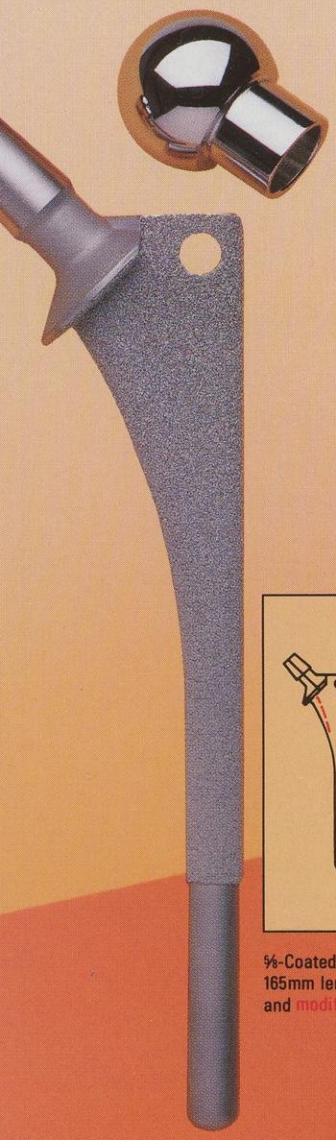
# AML Total Hip System advertisement.

[s.l.]: [s.n.], 1988

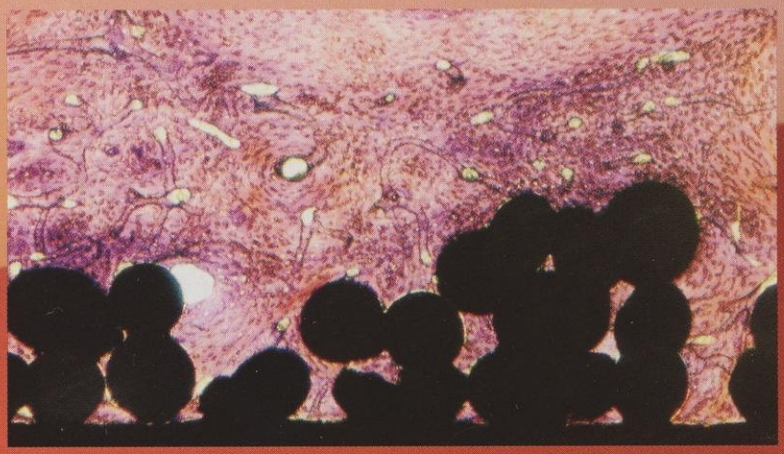




⅝-Coated Collared Stem – 165mm length – standard and modified medial aspect

# Consider over 50,000 successful arthroplasties over 10 years.

No other porous-coated hip can make this claim. **Not one!**



## the AML® Total Hip System with Porocoat®

**Advanced DePuy® micro-fusion sintering technology** – creates a dramatically higher shear strength – as high as 10,000 psi – as compared to in-grown tissue or bone cement, which guards the mechanical integrity of the bead sub-strate bond.

**Available for biological fixation** – the only commercially available ⅝-coated stem... with optimum pore size for rapid initial fixation.

**Optimum patient fit/results** – the only system with a choice of proximal triangle sizes plus multiple cup/head/neck/stem combinations.

For more information, contact DePuy,® P.O. Box 988, Warsaw, IN 46580 or call (219) 267-8143.
*TWX 810 298 0915*

*WARNING: Only these asterisked devices have not been approved for biological application and should not be confused with the AML® stem device available for non-cemented use.

Porocoat® is protected by U.S. Patent No. 3,855,638 and foreign patents. AML® and Porocoat® are both registered trademarks of DePuy® Division of Boehringer Mannheim Corporation.

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# THE AML® TOTAL HIP SYSTEM WITH POROCOAT®

**FOR CEMENTLESS USE.**

## DESCRIPTION

The Porocoat® AML® total hip prosthesis is a straight stemmed, collared hip prosthesis designed for cementless use. Fixation is achieved through bone ingrowth into the porous coating of the femoral stem. The coating is designed to provide a pore size of 50 to 400 $\mu$m which has been found to be optimal for biological fixation. The stem and porous coating are fabricated of Co-Cr-Mo alloy which meets ASTM F-75 specifications and has been shown through extensive clinical use to be biocompatible and biomechanically suitable for this use.

## INDICATIONS

The Porocoat® AML® total hip is indicated for use as primary intervention in cases of osteoarthrosis or rheumatoid arthritis with a nonacute fracture of the neck of the involved hip, osteoarthrosis in which both femoral and acetabular surfaces are involved, and idiopathic avascular (osteo-) necrosis where radiographic evidence of sufficient sound bone to seat the prosthesis is present.

## CONTRAINDICATIONS

The following conditions are contraindications for porous-coated total hip arthroplasty.

**1.** Local infection, recent or old. **2.** Destruction of the proximal femur to preclude rigid fixation of the femoral component. **3.** Prior presence of a cemented femoral component. **4.** Loss of musculature, neuromuscular compromise or vascular deficiency in the affected limb rendering the procedure unjustifiable. **5.** Charcot's arthropathy/disease. **6.** Paget's disease. **7.** Poor bone quality, such as osteoporosis, where there could be considerable migration of the femoral component and/or risk of fracturing the diaphysis.

## WARNINGS AND PRECAUTIONS

The long-term safety and effectiveness of this device remains under investigation. The following conditions, singularly or concurrently, tend to impose severe loading on the affected extremity, thereby placing the patient at higher risk of failure.

**1.** Obesity. **2.** Heavy labor. **3.** Active sports participation. **4.** Likelihood of falls. **5.** Alcohol or drug abuse. **6.** Other disabilities.

The safety and effectiveness of this device in patients of age less than 40 are unknown.

## ADVERSE EFFECTS

Long-term effects of the use of the Porocoat® femoral prosthesis have not yet been fully determined. Short-term complication rates have been similar to those occurring with any total hip arthroplasty.

**1.** Change in the position of the prosthesis. **2.** Early or late infection. **3.** Early or late loosening of one or more prosthetic components. **4.** Fracture of the femoral stem.

### Intraoperative

**1.** Acetabular perforation. **2.** Femoral perforation. **3.** Femoral fissure at the calcar when the stem is driven and impinges on the anterior cortical wall. **4.** Femoral fracture which may necessitate internal fixation. **5.** Trochanteric fracture. **6.** Damage to blood vessels (iliac, obturator and femoral artery). **7.** Death (secondary to cardiac arrest). **8.** Temporary or permanent nerve damage (femoral, obturator or isolated peroneal nerve) resulting in weakness, pain or numbness of the affected extremity. **9.** Subluxation or dislocation of the implant due to selection, positioning of components and/or muscle and fibrous tissue laxity. **10.** Undesirable shortening of the affected extremity. **11.** Traumatic arthrosis of the knee from intraoperative positioning of the extremity. **12.** Inadequate abutment in the direction of the resultant joint force.

### Early Postoperative

**1.** Cardiovascular disorders including venous thrombosis, pulmonary embolism, cerebrovascular accident, myocardial infarction, and death. **2.** Hematoma and delayed wound healing. **3.** Infection of wound. **4.** Pneumonia and atelectasis.

### Late Postoperative

**1.** Trochanteric avulsion from excessive muscular tension or early weight bearing and inadvertent intraoperative weakening. **2.** Aggravated problems in the knee and ankle joints of the affected or contralateral extremities caused by leg length discrepancy, femoral medialization or muscular deficiencies. **3.** Femoral or acetabular fracture by trauma or excessive loading, particularly in the presence of poor bone stock caused by severe osteoporosis, bone defects from previous surgery or reaming and bone resorption. **4.** Excessive wear of the acetabular socket may be aggravated by inadvertent intraoperative damage to the prosthetic head and by loose cement fragments broken from the acetabular rim after poor cementing technique or from inadequate cleaning prior to reduction and wound closure. **5.** Tissue reactions, allergic reactions, and loosening caused by metallic corrosion products, or the accumulation of wear debris from the acetabular socket or loose cement particles.

## INFORMATION

A surgical technique brochure is available which includes additional information regarding this product and its use. Complete product information is also available on the package insert accompanying each packaged device.

## CAUTION

Federal Law (USA) restricts this device to sale, distribution and use by or on the order of a physician.

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