

PMA P050016 Cormet 2000 Hip Resurfacing System

Post PMA-Approval Study
Proposed Protocol

Gaithersburg, Maryland
February 22, 2007



Purpose of the Investigation

- Monitor clinical performance of the Cormet implant system for a period of up to 10 years post-operative
- Confirm that there are no unexpected reductions in device performance following PMA approval – e.g., HHS and revisions
- Condition of FDA PMA market approval

Study Design

Prospective, single arm, multi-center study

- Device: Cormet Hip Resurfacing implant system (PMA #P050016)

377 procedures at 5 largest investigational sites

- 291 unilateral procedures
- 86 bilateral procedures

Pivotal Study Group

Location	Unilateral	Bilateral	# Procedures
Springfield IL	31	10	41
Mobile AL	6	4	10
Englewood NJ	6	2	8
Columbia SC	134	46	180
Rockledge FL	21	7	28
Galesburg IL	38	8	46
Cleveland OH	2	4	6
Sarasota FL	46	6	52
Durham NC	3	0	3
New York NY	6	0	6
Baltimore MD	42	16	58
Los Angeles, CA	4	0	4
Total			442

Endpoints

Primary endpoint

- Maintain good clinical status to 10 years post-operative
 - HHS \geq 80
 - No revision, removal, replacement

Secondary endpoints

- HHS components (total score, pain, function, ROM)
- Device related adverse events
- Device survival

Eligibility Criteria

- Subject in the Cormet IDE pivotal study
- All surviving and actively enrolled subjects at time of PMA approval at 5 sites
- Agrees to participate in the Post-PMA Approval Surveillance study

Control Group

- Concurrent control group has not been a requirement for pre-approval studies for either hip resurfacing
- THA is not an appropriate long term (e.g., 5-10yrs) control
- No long term data for hard on hard bearing surfaces available

Sample Size

- PMA Pivotal Unilateral Subjects
 - 291 subjects among the 5 sites
- Target is 250 subjects at 5 yrs
 - With this sample size the percentage achieving post approval success criteria will be estimated with a margin of error of no larger than 6.2% (conservative est.)

Follow-Up

- Commitment to make every effort to maximize follow-up compliance at 5 and 10 yrs
- Will attempt to consent subjects for 10 yr follow-up
- Achieving high compliance at 10 yrs will be challenging

Patient Evaluations

	1y	2y	3y	4y	5y	6y	7y	8y	9y	10y
HHS MFA AP/Lat x-rays (same as IDE)	X	X	X	X	X					
HHS only								X		X
Study Follow-up Questionnaire						X	X		X	
Complications/ Adverse Events	X	X	X	X	X	X	X	X	X	X

Analysis Plan

Annual estimates* of the proportion of successes based upon study success criteria & the bounds of the 95% CI

- Detects clinically meaningful reductions in the proportions of patients maintaining at least good clinical results

Hypothesis testing unwarranted

- Would be compromised by likely lower follow-up at 10 yrs
- No long term data available on hard on hard bearings

* Annual analysis in years 1-5, 8 & 10.

Analysis Plan

Secondary (analysis at 5 & 10 yr follow-up)

- HHS components
 - Frequency distributions of total score, functional score and pain score
- Survivorship
 - K-M Survival curve
- Complications/adverse events
 - Summary of operative hip related, device related, events that affect HHS

Summary

Purpose of the Cormet Post PMA-Approval Surveillance Study

- Monitor clinical performance of the Cormet implant system for a period of up to 10 years post-operative
- Clinical success criteria:
 - Device survival
 - Patient function
- Long term safety of the device

Thank You