

# Customized Patient Instrumentation for Total Knee Arthroplasty

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# Disclosure

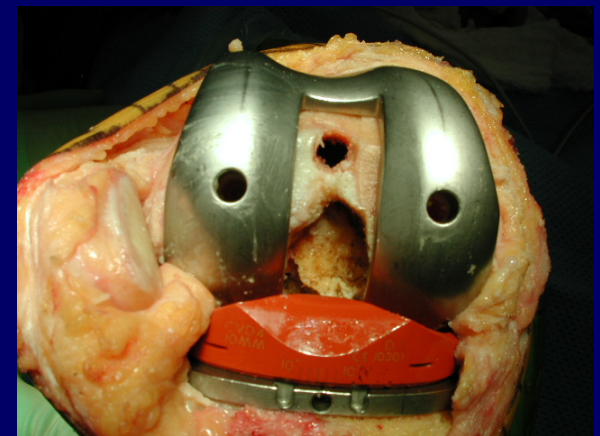
- Dr Bugbee is a paid consultant for Depuy
- Member of the CPI-Trumatch surgeon design team
  - William Bugbee (San Diego, California)
  - Andy Engh (Alexandria, Virginia)
  - Joe Moskal (Roanoke, Virginia)
  - Mark Pagnano (Rochester, Minnesota)
  - Mike Swank (Cincinnati, Ohio)

# Evolution of TKA Technique

- Semi freehand cuts to fit limited implant inventory
- EM or IM based universal cutting jigs based on average anatomy
- Use of computer assisted navigation to mount universal cutting jigs on bone
- Computer assisted image analysis to create custom fitted cutting guides

# Fundamental Arthroplasty Principles

- Bone cuts should restore mechanical axis through center of knee
- Proper component rotational alignment is essential
- Soft tissues should be well balanced



# Preoperative Planning For Total Knee Arthroplasty

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Associate Professor  
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# Why is preoperative planning important?

- Create a “blueprint” for the surgical procedure and anticipate variations in anatomy
- Improve efficiency and decrease error rate in the operating room



# Computer Assisted Surgery in Total Knee Arthroplasty

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Attending Surgeon

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Associate Professor

Department of Orthopedics

University Of California, San Diego

# Principal Steps in Navigation

## – Data Acquisition

- Pre-op imaging and kinematic data.

## – Registration

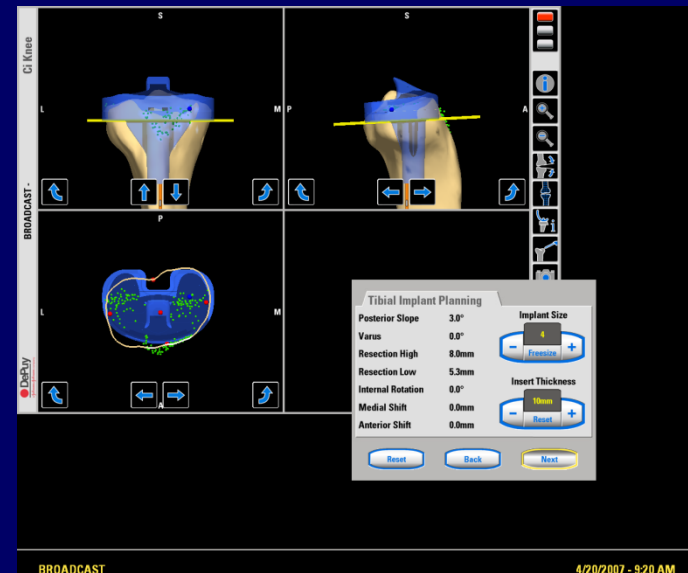
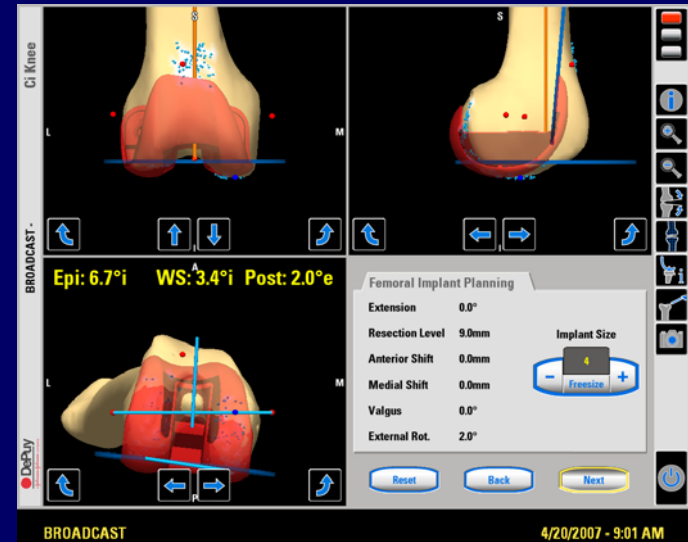
- Surgeon controlled definition of anatomic landmarks.

## – Tracking

- How the computer monitors each aspect of the surgery.

## – Verification

- Surgeon feedback to the system verifying accuracy of the model.



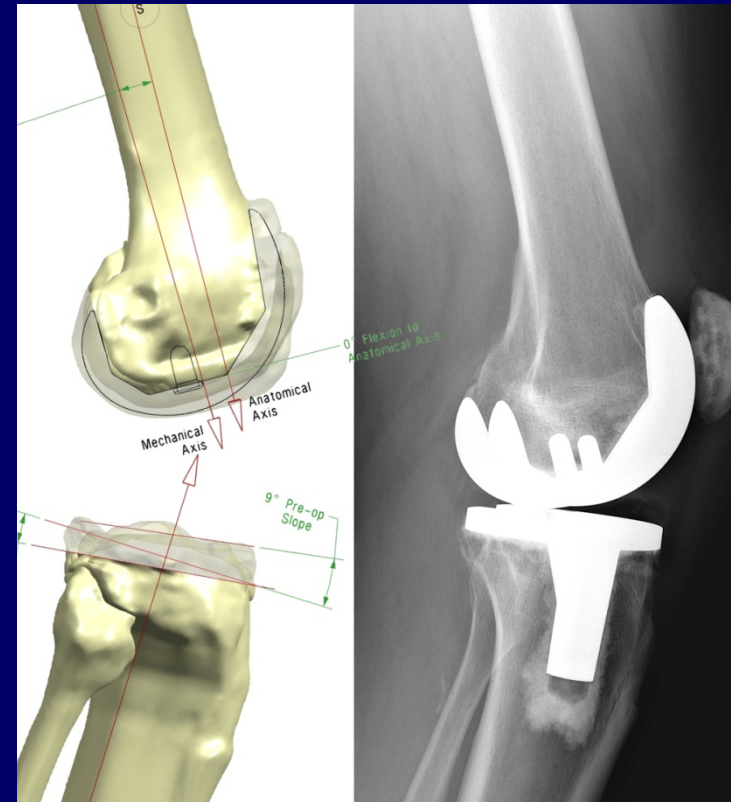


# Instruments for Navigation



# What is CPI?

- Bone resection guides manufactured by using an individual patient's anatomic information
- Information obtained from preoperative imaging studies
- Guides created as part of an overall surgical plan that is approved by surgeon prior to manufacture
- “Navigation in a box”

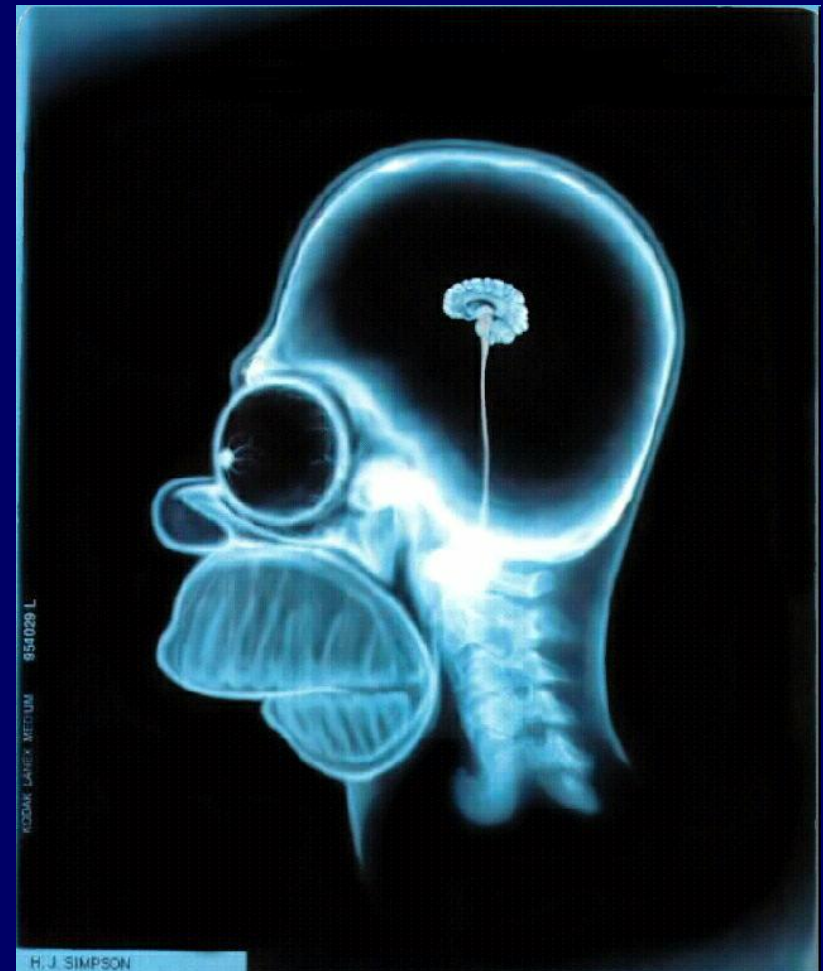


or. . . .

# Navigation for Dummies

“Every time I learn something new, it pushes some old stuff out of my brain”

- Homer Simpson



# Resection Guides



# Surgical Instrumentation



# CPI Philosophy

- Every patient is different- customization makes sense (to surgeon and patient)
- Define patient anatomy and generate surgical plan that can be reviewed (and amended) prior to surgery
- Simplifies surgical procedure
- Provides real time feedback of surgical precision and accuracy (like CAS)

# The TruMatch Process

- Patient indicated for TKA, consents to CT scan for generation of images suitable for CPI process
- CT scan data sent to Depuy
- Engineers evaluate and process scan and generate surgical plan based on predefined surgeon preferences
- Surgeon approves (or modifies) plan and Depuy manufactures custom resection guides
- Guides delivered sterile to operating room

# Choice of Imaging Studies for CPI

- Plain radiographs
  - Requires special techniques, complex algorithm for analysis (2D to 3D)
- MRI
  - Relatively inaccurate bone mapping
  - No limb alignment data
- CT
  - Faster, less expensive than MRI
  - Optimum bone mapping and limb alignment
  - Ionizing radiation, no cartilage mapping



# CPI: Pros

- Patient appreciates the concept of customization
- Surgeon gets a precise surgical plan
  - Intraoperative accuracy measurement
- Operating room requires fewer instruments
  - Inventory, sterilization
- Decreased surgical time
  - Less set-up, fewer surgical steps, no IM violation
- Cost savings for hospital
- Revenue generation from outpatient imaging studies

# CPI: Cons

- Increased preoperative logistical effort
  - CT scan (radiation)
  - Plan generation
  - Plan approval
  - Manufacture and delivery of resection guides
  - One month lead time
- Cost of CT scan
- Cost of resection guides
  - evolving
-

# When is Trumatch Indicated?

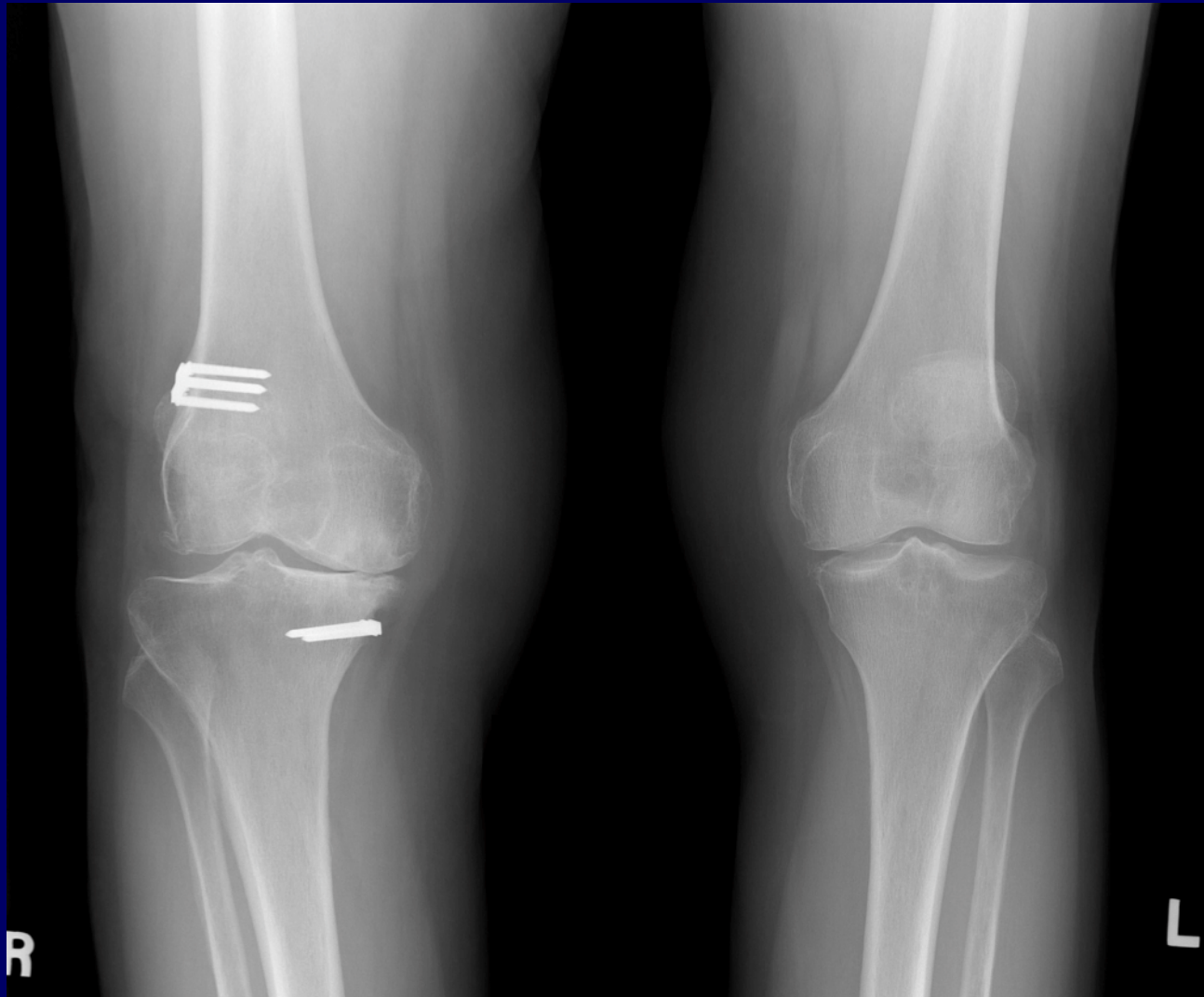
- No absolute contraindications
- Patient must be amenable to CT scan
- Particularly useful for:
  - Distorted anatomy
  - Severe OA
  - Retained hardware
  - When IM instrumentation is problematic



# My Experience with CPI Project

- Chose path of best technology vs. first to market
- Applied large and highly skilled product development team
- Evaluated and rejected existing technology
- Design team defined clear goals
  - Precision and accuracy equivalent to CAS (better than IM/EM guides)
- Multiple cadaver labs and surgical trials
- Two year process to date

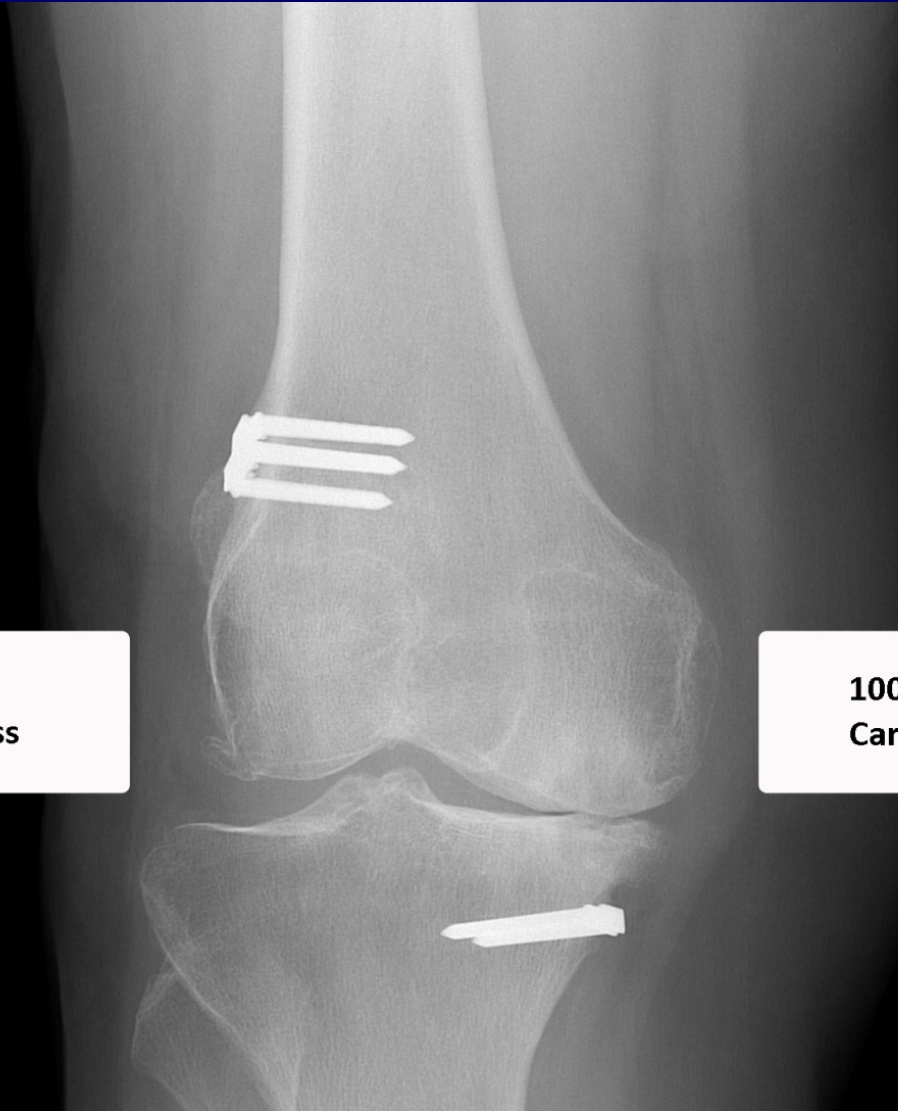
# Let's Do a Case



**RIGHT KNEE**  
**74 y.o. female**  
**CPIK001HP**

**0% Lateral  
Cartilage Loss**

**100% Medial  
Cartilage Loss**



# CT Protocol

TruMatch  
DePuy Orthopaedics, Inc.  
700 Orthopaedic Drive  
Warsaw, Indiana 46581-0988  
(800) 689-0746

**TruMatch™**  
PERSONALIZED SOLUTIONS

**Computed Tomography CT**

WI-4545 Appendix C, Rev G

## TruMatch Knee Scanning Protocol

This protocol is to ensure that an accurate 3-D model can be created by DePuy and used to design a patient specific knee instrument. Scan settings should be optimized to capture bony geometry and cartilage of the knee. The hip and ankle data is needed to align the entire leg for a total knee replacement. Review the following information before proceeding with the scanning process.

### Scanning Procedure

- All data must be collected in same-center/size study(s), with the same FOV, without gaps and minimal overlap.
- Patient movement during the scan will disqualify the study and require rescanning.
- **Minimize FOV** with a **maximum of 20 cm** so the image captures bone for the knee of interest, and corresponding hip and ankle. Leg alignment on the table will assist with this goal.
- Cropping off soft tissue to achieve a FOV of 20cm is acceptable. Only images of bone are required.
- If there are metal devices in the contralateral knee, please see page 2 for instructions.

### Scan Parameters

Contrast	Area	FOV	Center	Spacing/ Thickness	Pitch	kV	Recon Filter
None	Specified Leg	20cm Max	Constant	Equal - see diagram for values	1:1	120	Soft Tissue

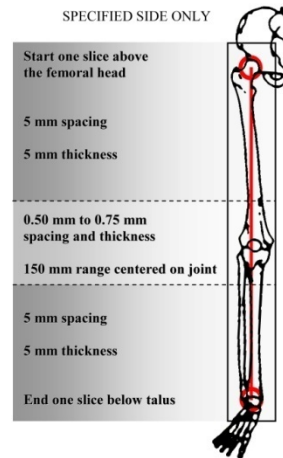
Note: If your scanner will not support the whole leg in a single study, as shown, you may perform three separate studies. To do this, set the FOV on the full leg scout and only adjust the start and stop position such that the end position of the previous study is the start of the next study.

**Center points of each study must be identical**  
**FOV of each study must be identical**

Patient movement between and during the scans will disqualify the study and require rescanning.

**TruMatch**  
**DePuy Orthopaedics, Inc.**  
**700 Orthopaedic Drive**  
**Warsaw, IN 46581-0988**  
**(800) 689-0746**

SPECIFIED SIDE ONLY



Call to arrange secure DICOM transfer to our PACS server, **70.151.27.76**, or send the electronic image data as individual DICOM images on a CD, DVD, or optical disk. Label the disk with "TruMatch Knee", patient name, doctor name, imaging facility name, and imaging facility telephone number.

06/01/2009

Ref. Case # CPIK001HP

OrderType TKA

Confidential Information

**TruMatch**  
PERSONALIZED SOLUTIONS

Dr. Bugbee

Please review the following surgical plan. On your DePuy TruMatch website use the "Make Decision" button to select the appropriate status for this case. Once your approval and feedback has been submitted, manufacturing of the custom guides will begin.

Please contact DePuy TruMatch Support if you have any questions or need further information.

Toll Free number: 1-800-689-0746

E-mail: cpisupport@dpus.jnj.com

Cordially,



DePuy Orthopaedics - TruMatch Design Team

Patient Name:			
Gender: F	DOB:	Height: 5 ft, 3 in	Weight: 150 lb
Patient Special Considerations:		Affected Side: R	
Profile: Varus	Cartilage Loss: M100%	L0%	Surgery Date:

Surgeon Name:	Dr. William Bugbee	Facility:	Scripps Green Hospital
Contact Email:	bugbee.william@scrippshdth.org		
DePuy Sales Rep:	Jared Colbert		

Device Information:

Implant System:	PFC Sigma	Instrument System:	Specialist II
Fem. Component:	Sz 3 CR	Poly Component:	Sz 2.5 x 8.0 Tib Component: Fixed Bearing

Alignment Information:

Fem. Sizing Ref:	Anterior Down	External Rotation Ref:	Posterior Condyles	External Rot:	3°
Distal Fem. Resect:	9.0 + 2.0 = 11.0	Valgus Rotation Ref:	Mechanical Axis	Valgus Rot:	0°
Prox. Tib. Resect:	8.0 + 2.0 = 10.0	Posterior Tib. Slope:	Match with limit of 7°		

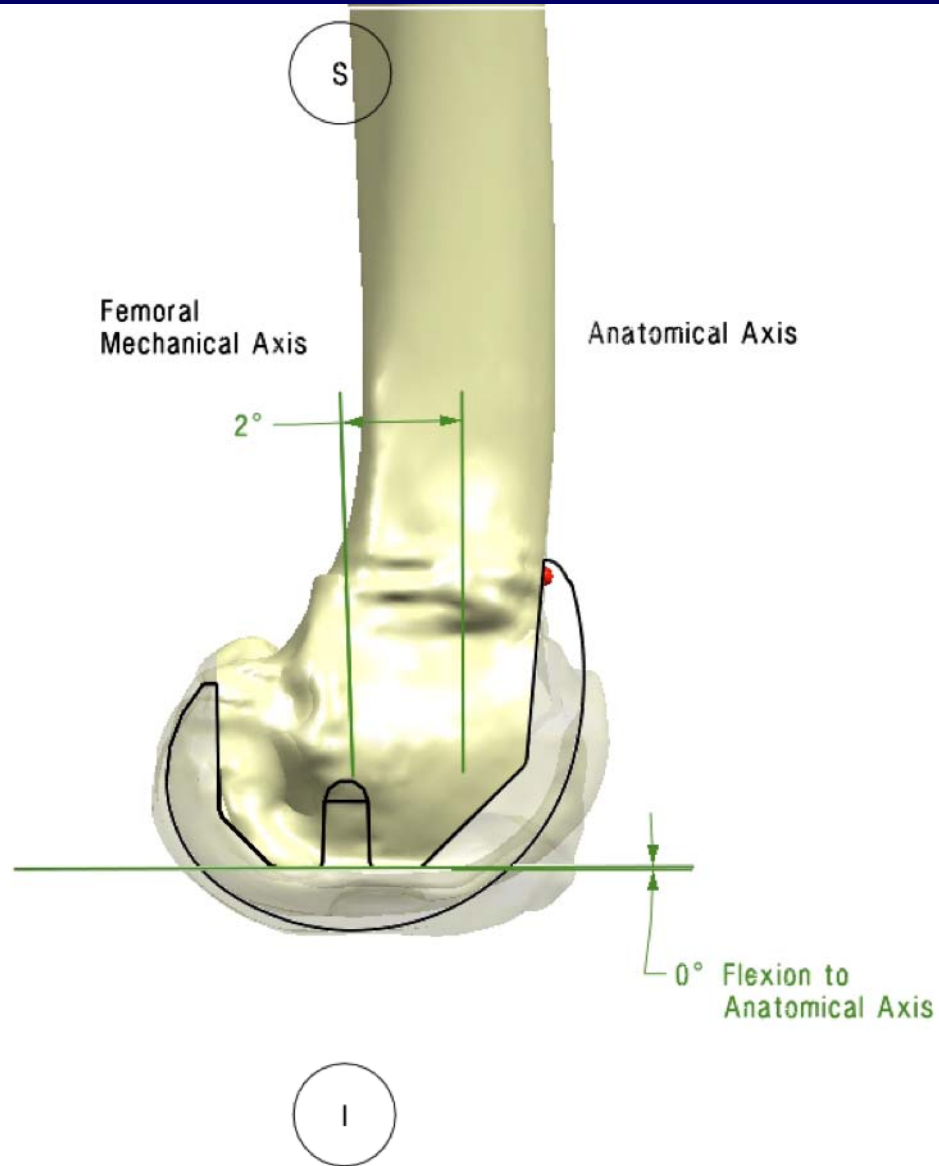
Notes / Comments:

1. The Patient has Trauma devices implanted. There is a image included in this proposal.
2. Osteophyte shown in red will need removed in order for tibial block to have proper contact area.

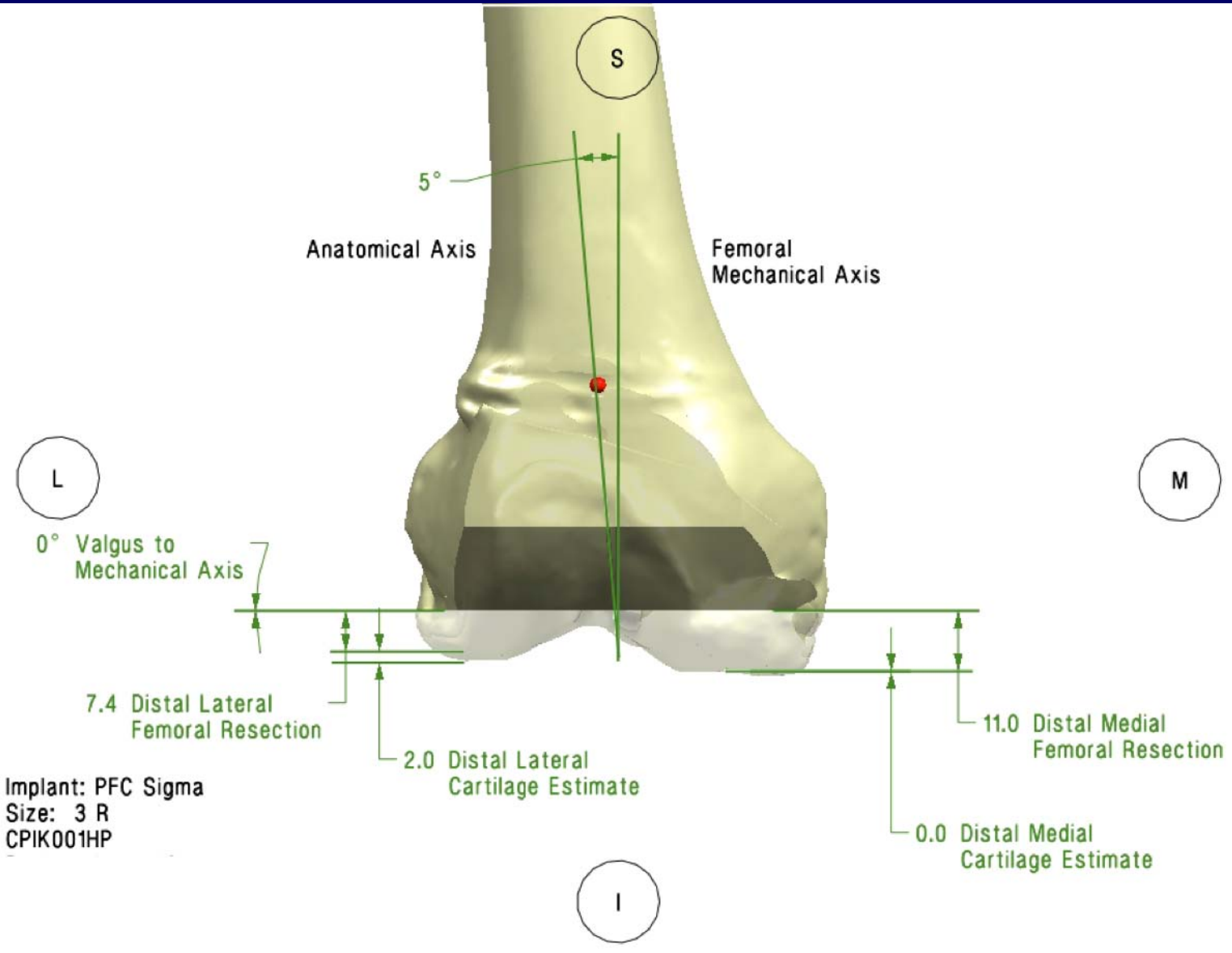
Proposal Revision: 2

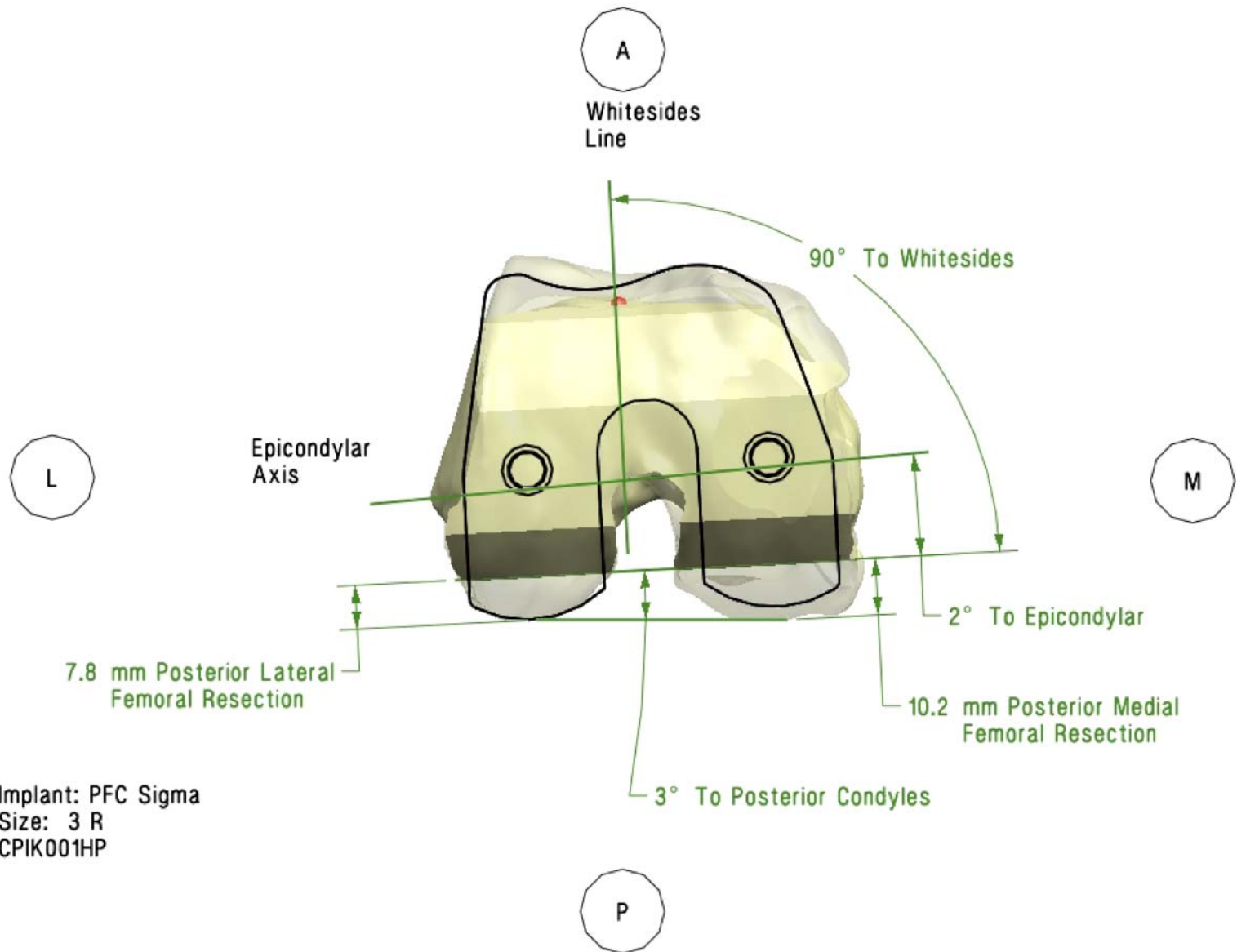
Upon your approval, DePuy will manufacture the custom instruments based upon the listed information supplied by you. DePuy has not verified the information supplied by you and makes no warranty as to the correctness or applicability of such information to the custom instruments to be manufactured or supplied pursuant to your request and therefore makes no warranty and disclaims any warranty that such custom instruments are fit and sufficient for the purpose intended. Notwithstanding the foregoing, DePuy warrants that the custom instruments to be supplied under this request are merchantable, of good quality and free from defects, whether patent or latent, in materials or workmanship; and that the custom instruments sold hereunder conform to or exceed the higher grading standards recognized by DePuy's industry. DePuy further warrants that it has good title to the custom instruments and that the custom instruments are free and clear from all liens and encumbrances.





Implant: PFC Sigma  
Size: 3 R  
CPIK001HP





Implant: PFC Sigma  
 Size: 3 R  
 CPIK001HP

S

Mechanical Axis

8° Natural Slope

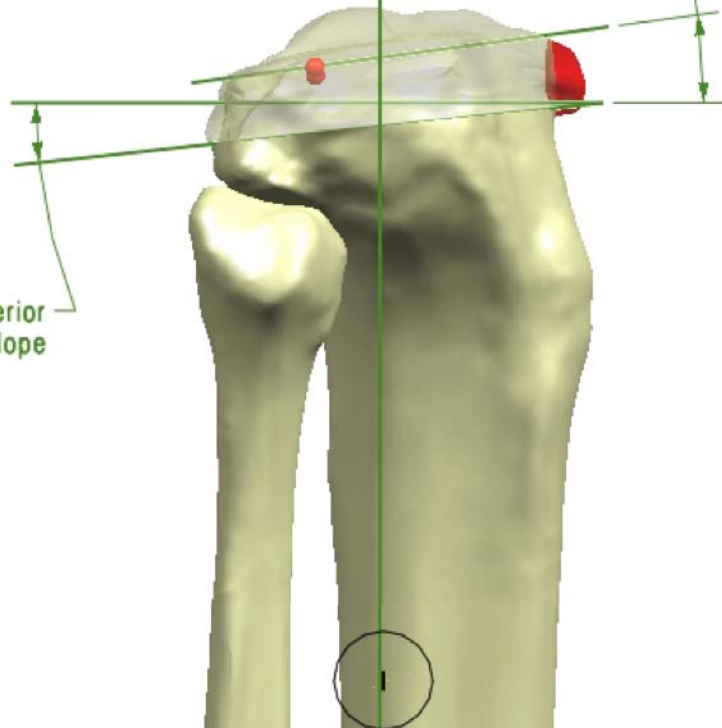
P

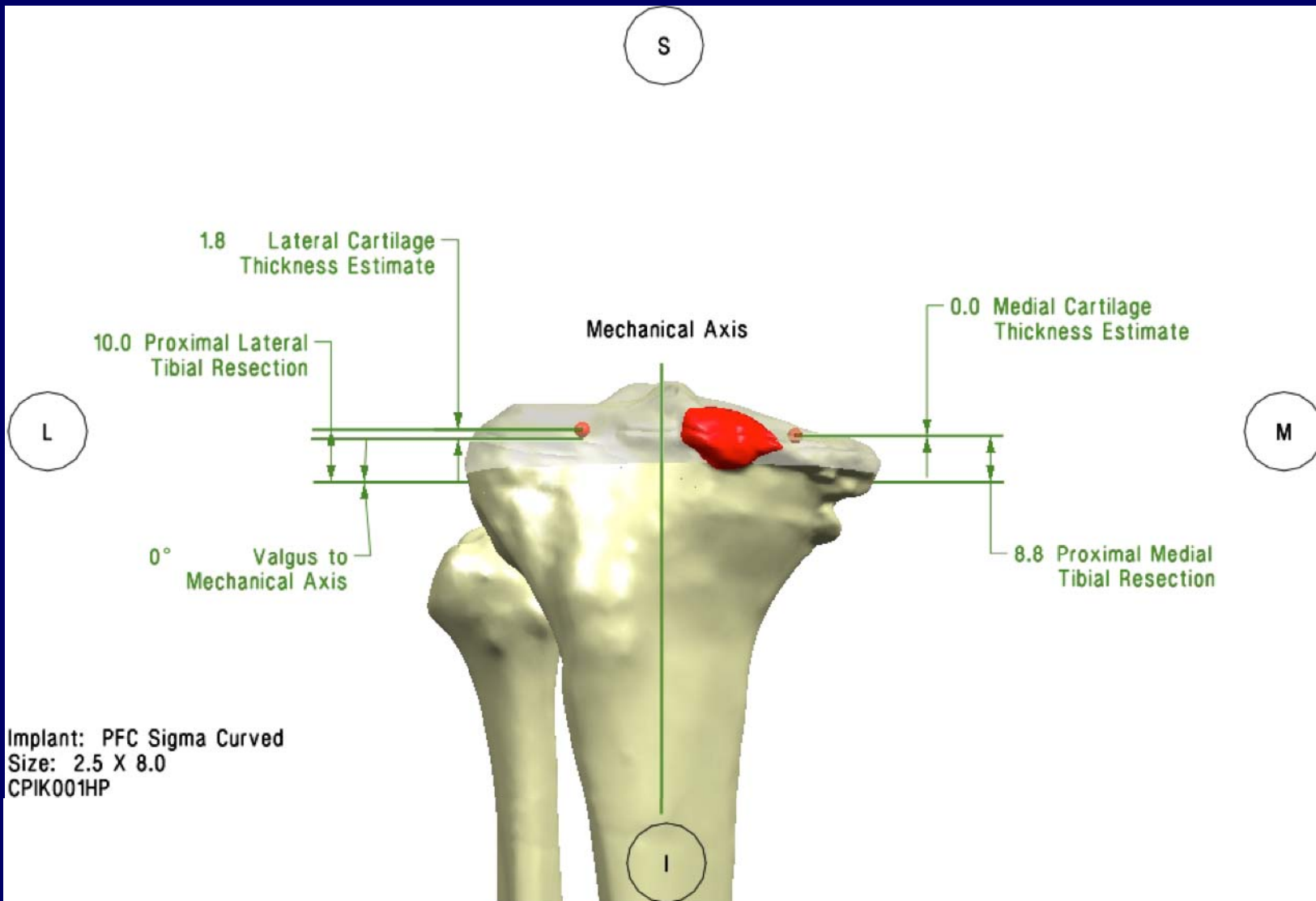
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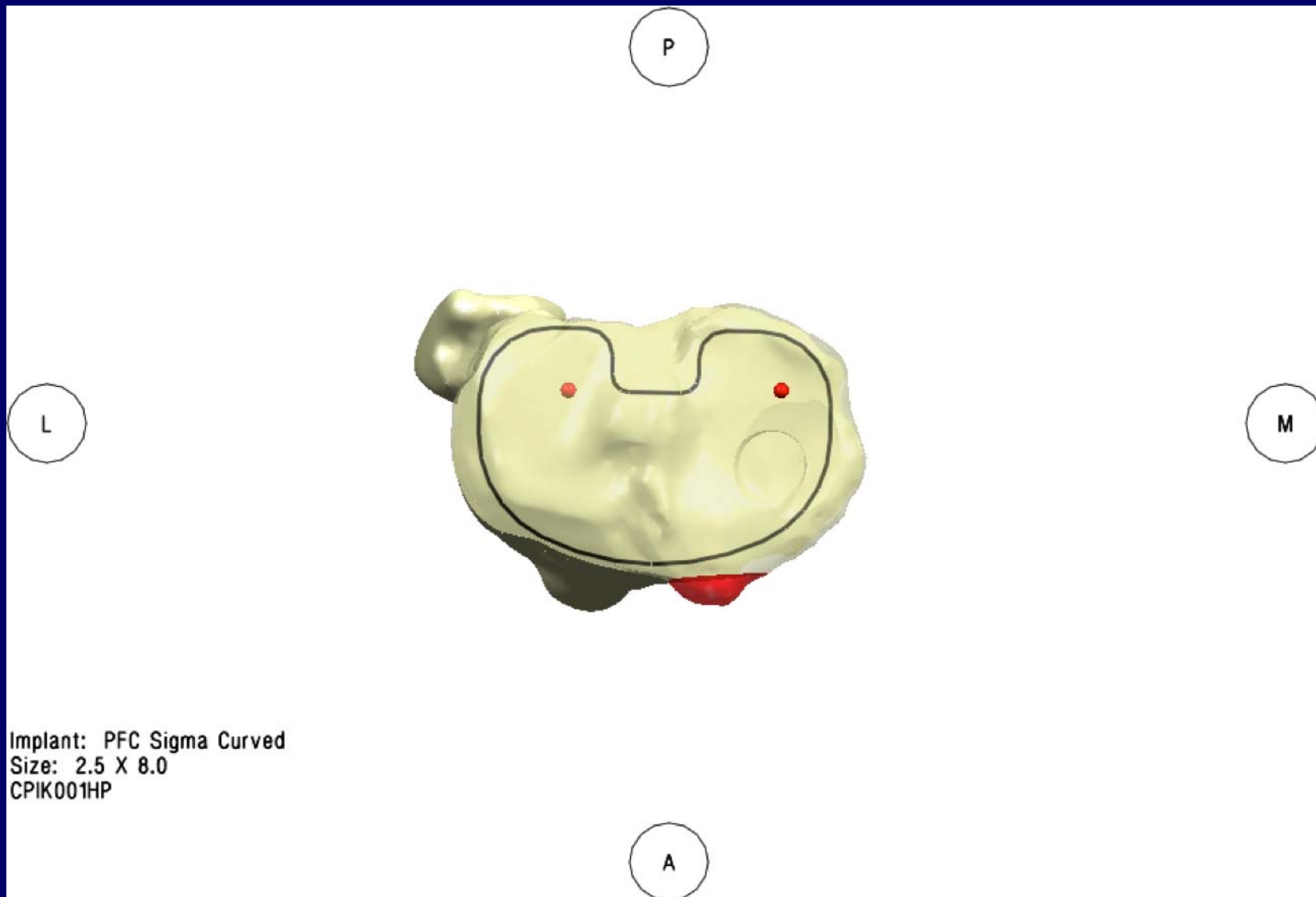
6° Posterior Slope

I

Implant: PFC Sigma Curved  
Size: 2.5 X 8.0  
CPIK001HP





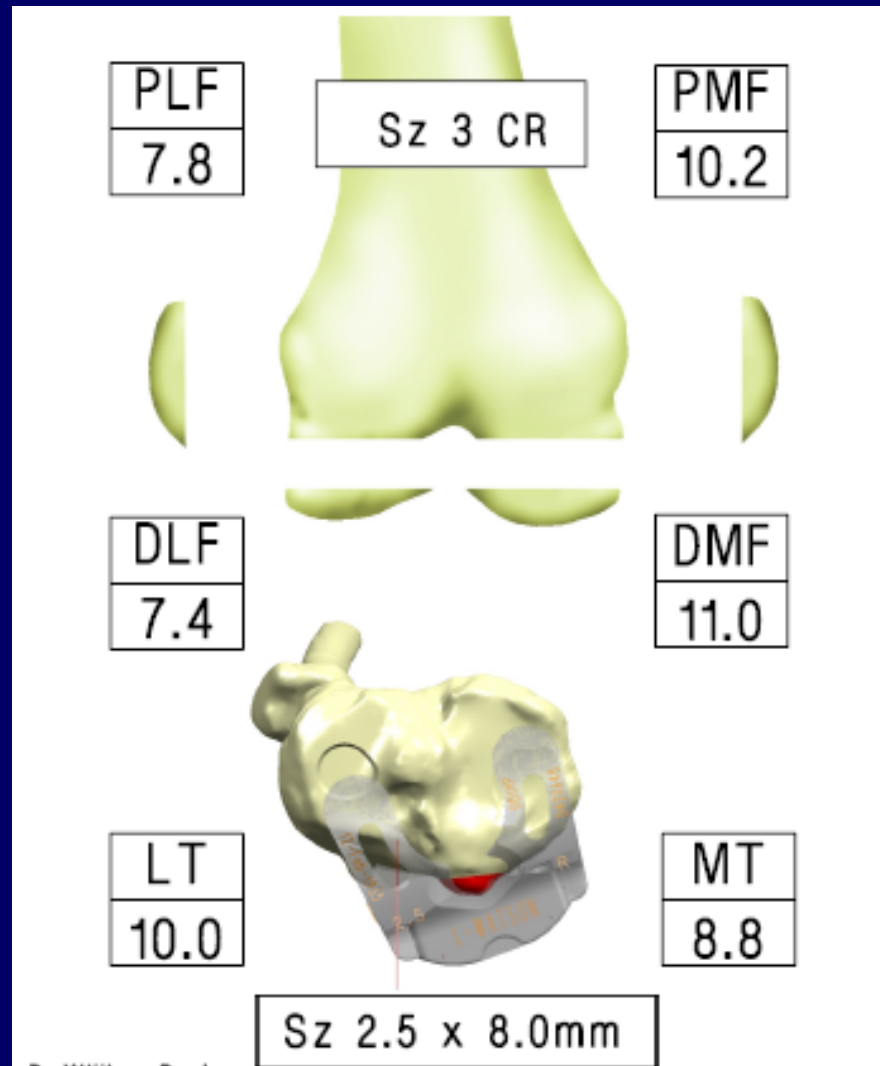


Implant: PFC Sigma Curved  
Size: 2.5 X 8.0  
CPIK001HP

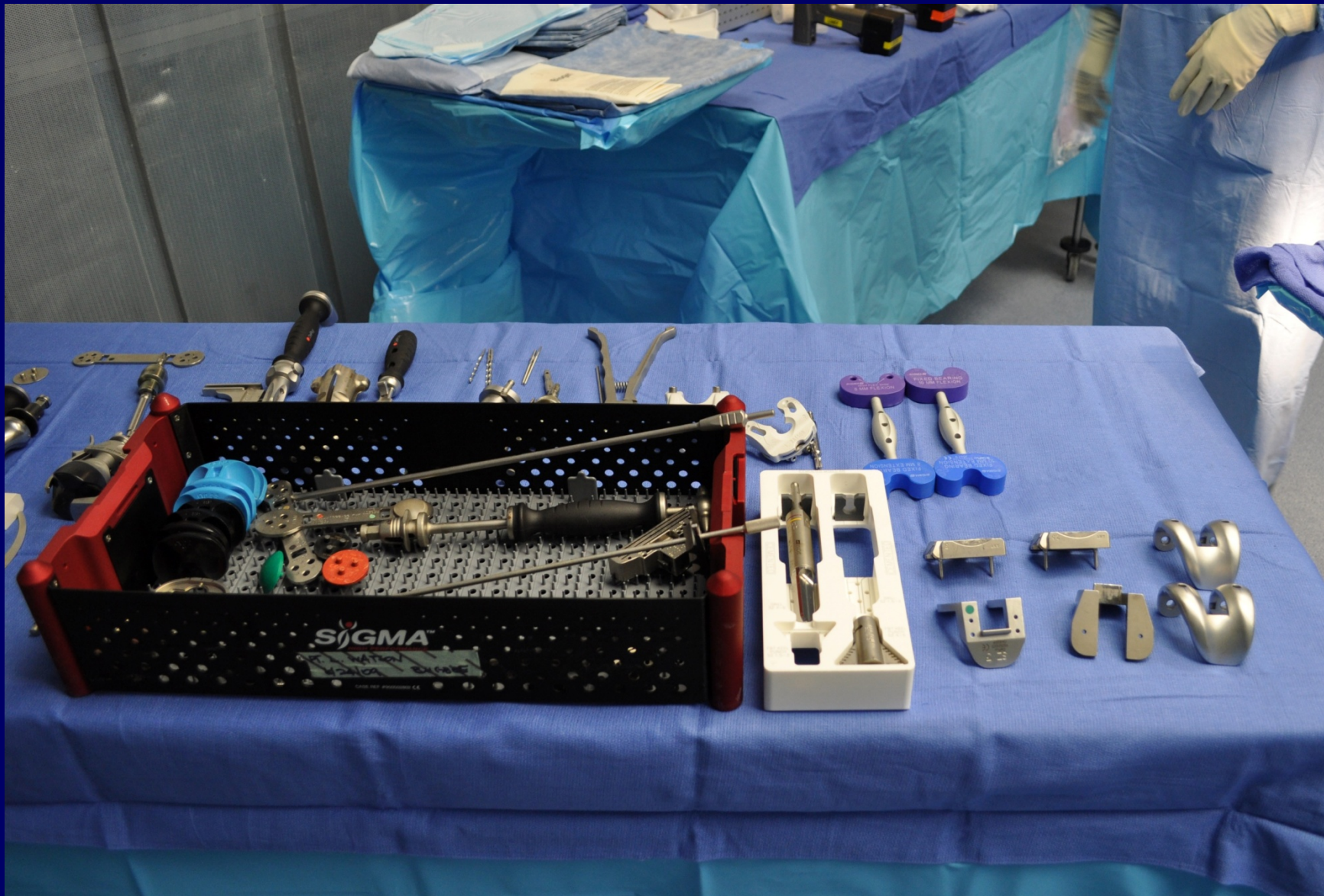


Dr. William Bugbee  
CPIK001HP  
24-Jun-2009

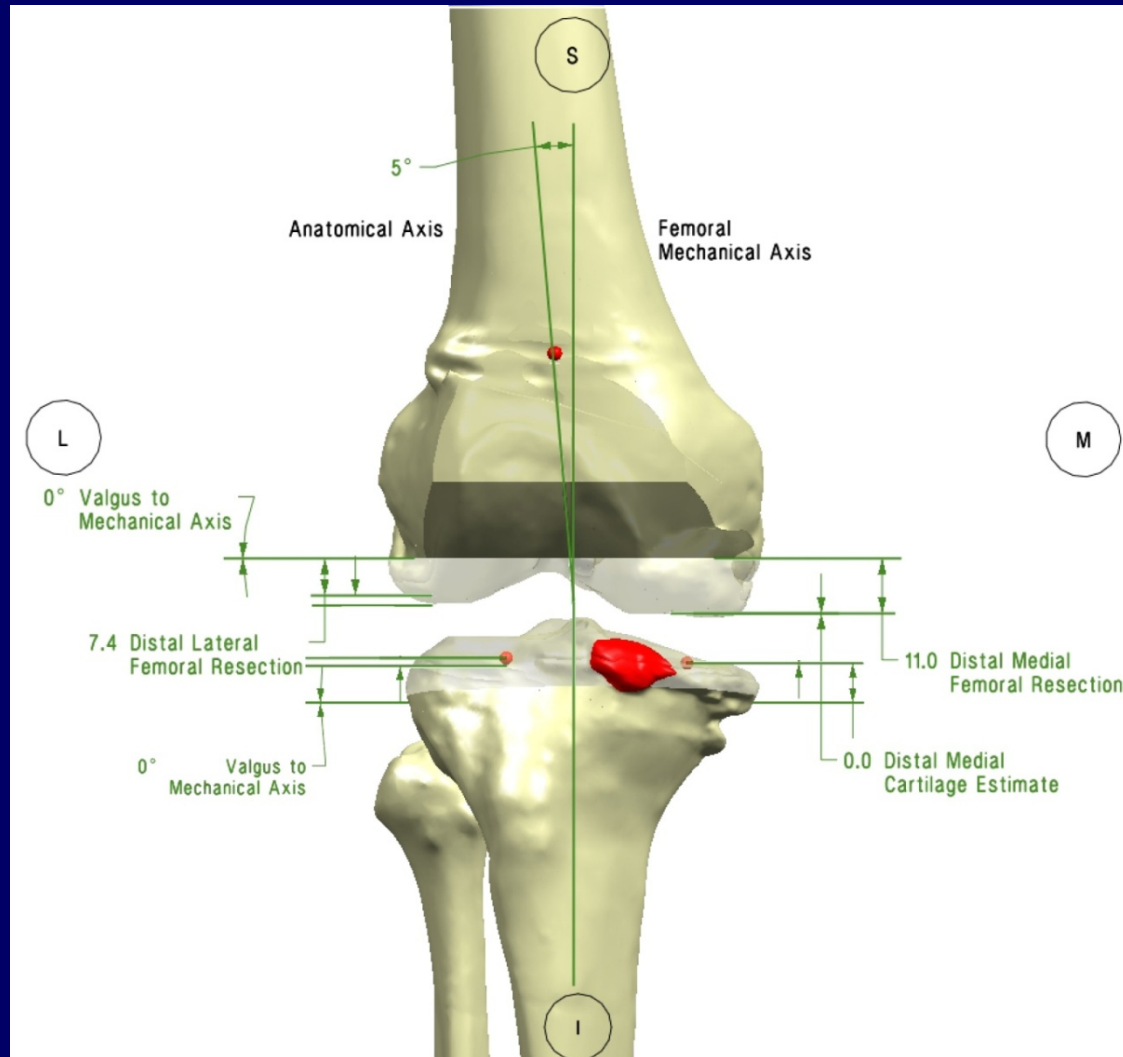
# “The Money Page”



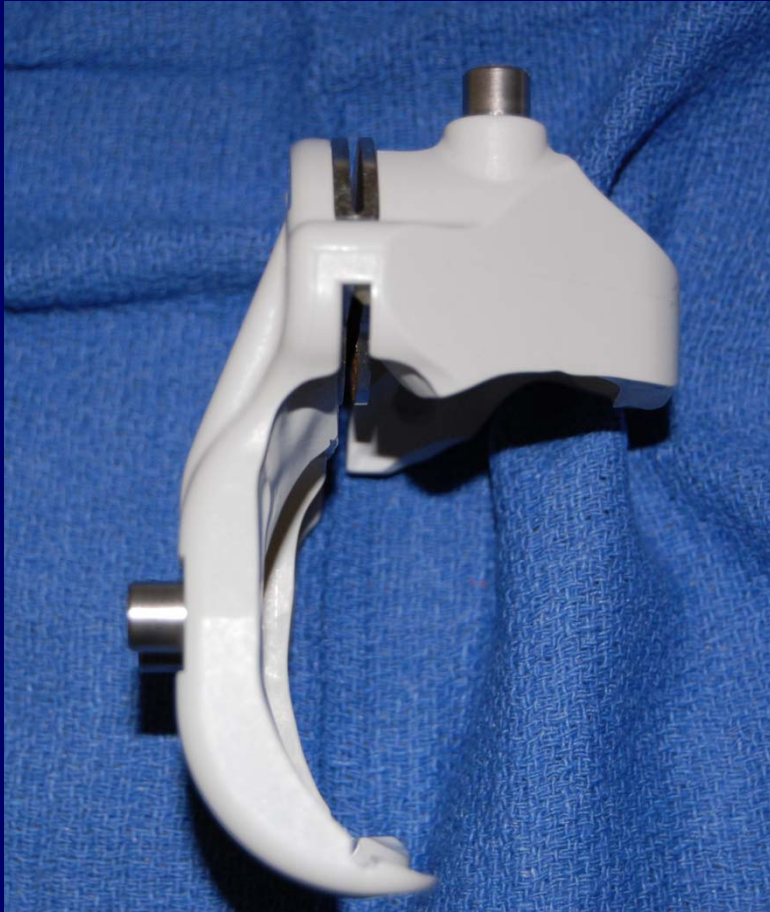




# Surgical Plan

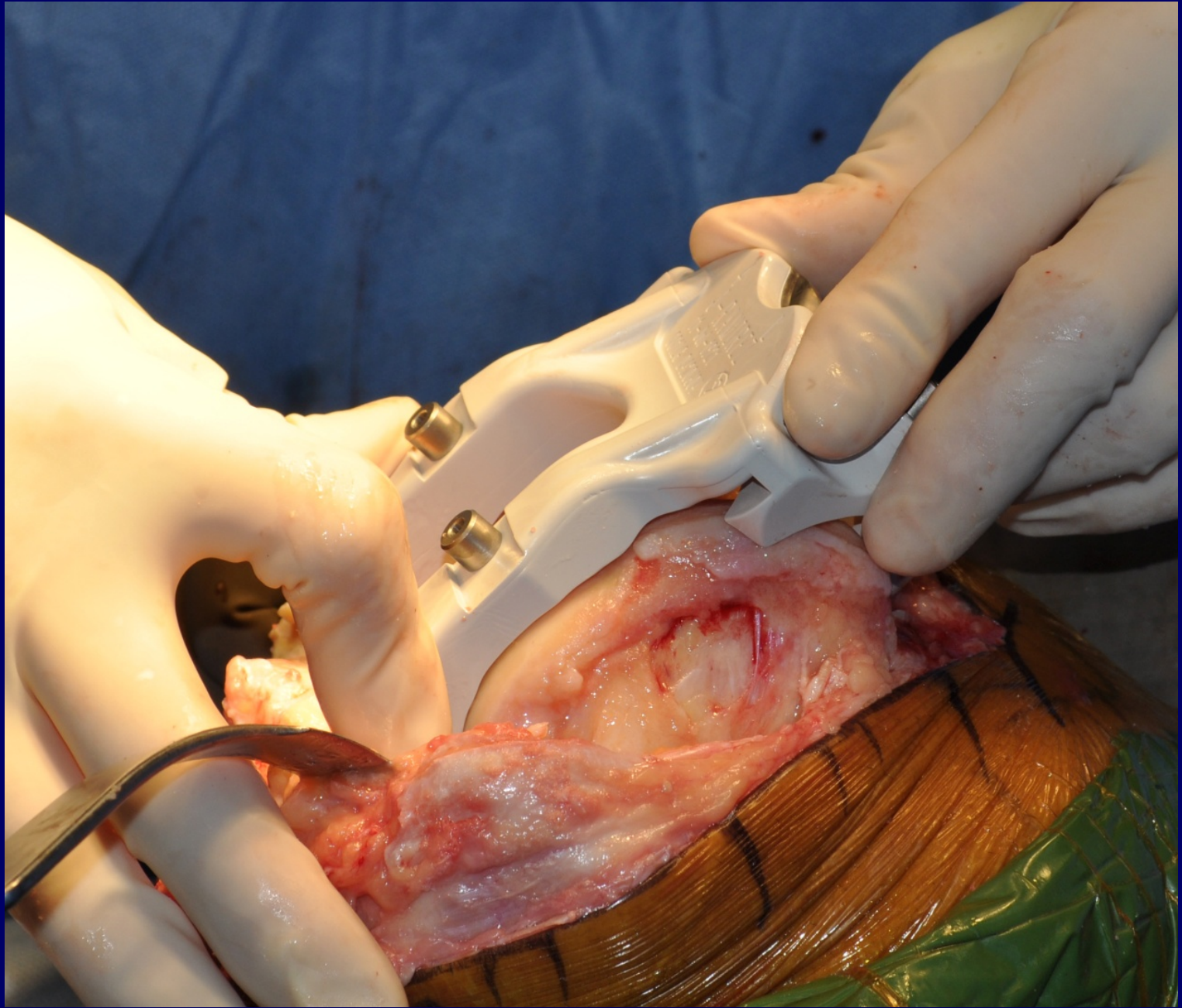


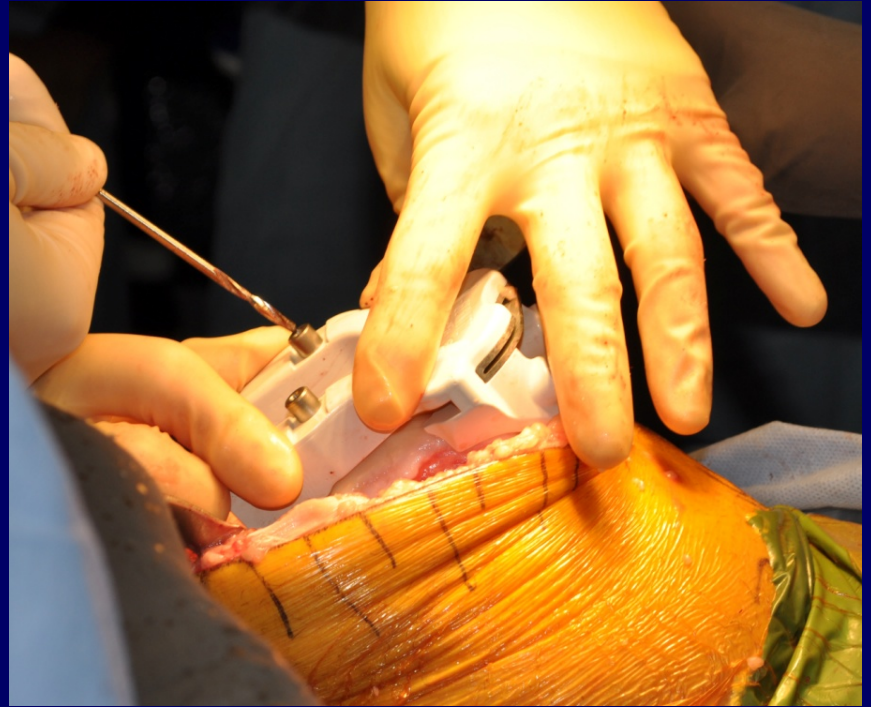
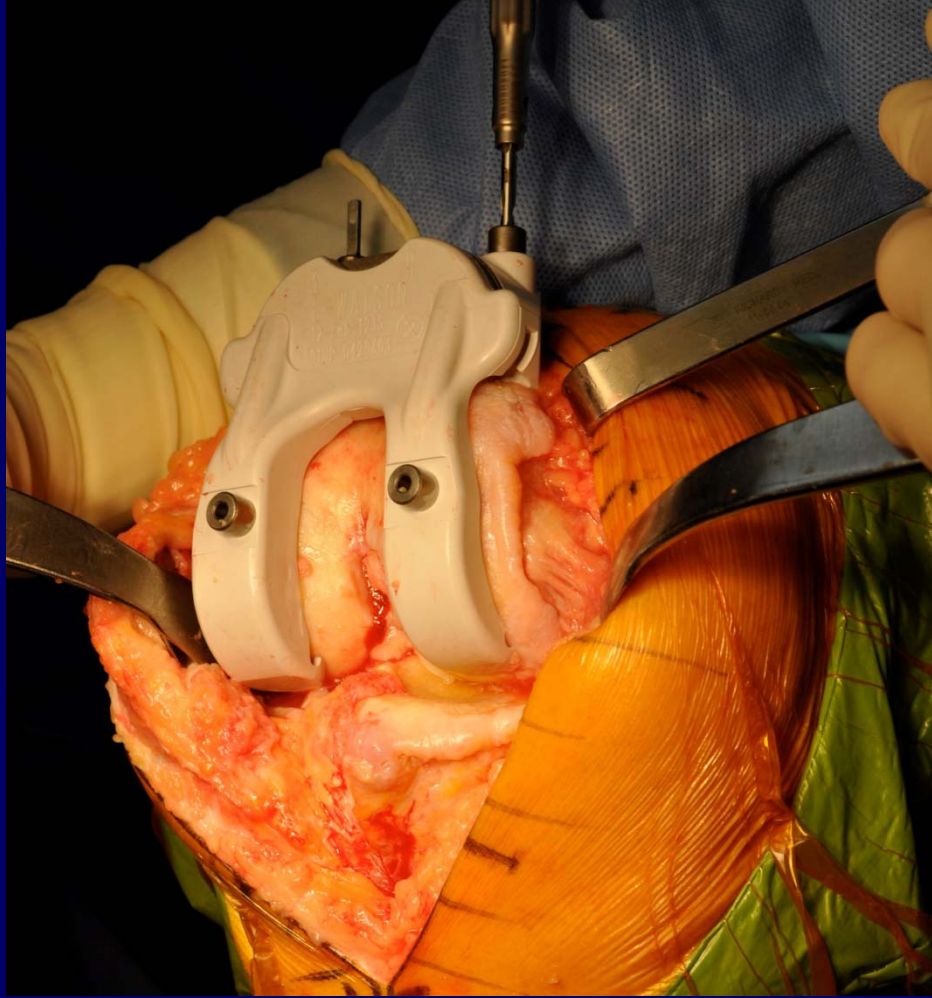
# Femoral Resection Guide

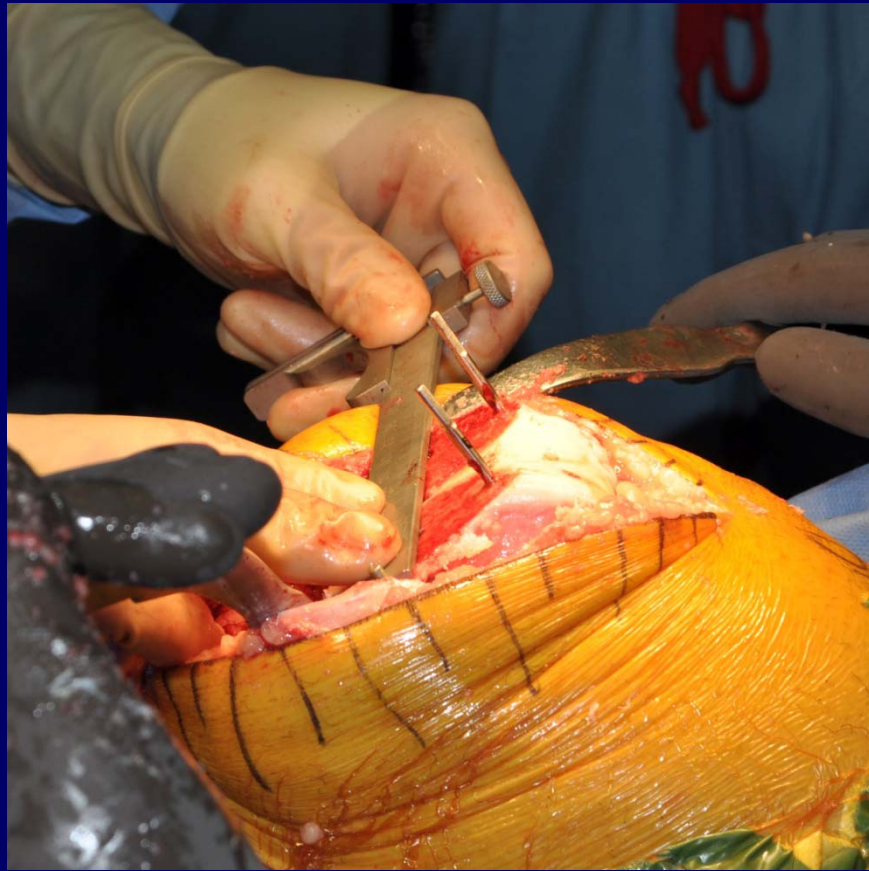


# Tibial Resection Guide













L

Epicondylar Axis

M

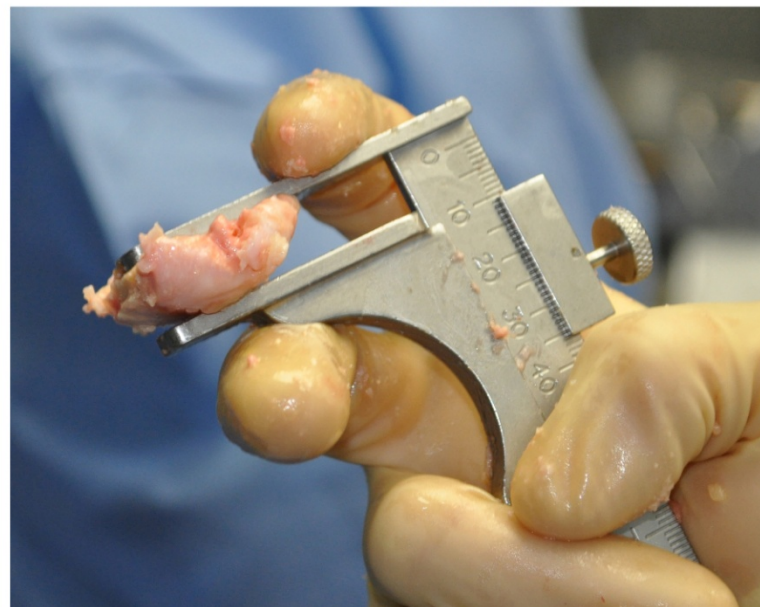
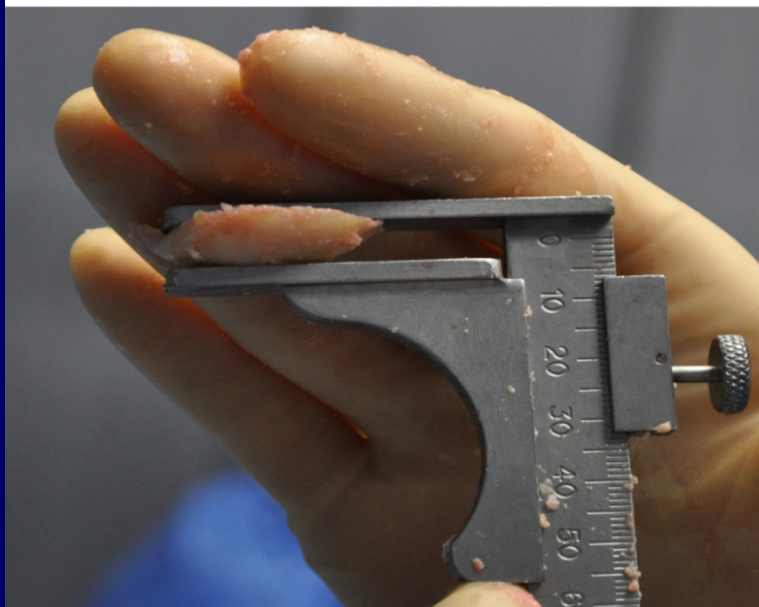
90° To Whitesides

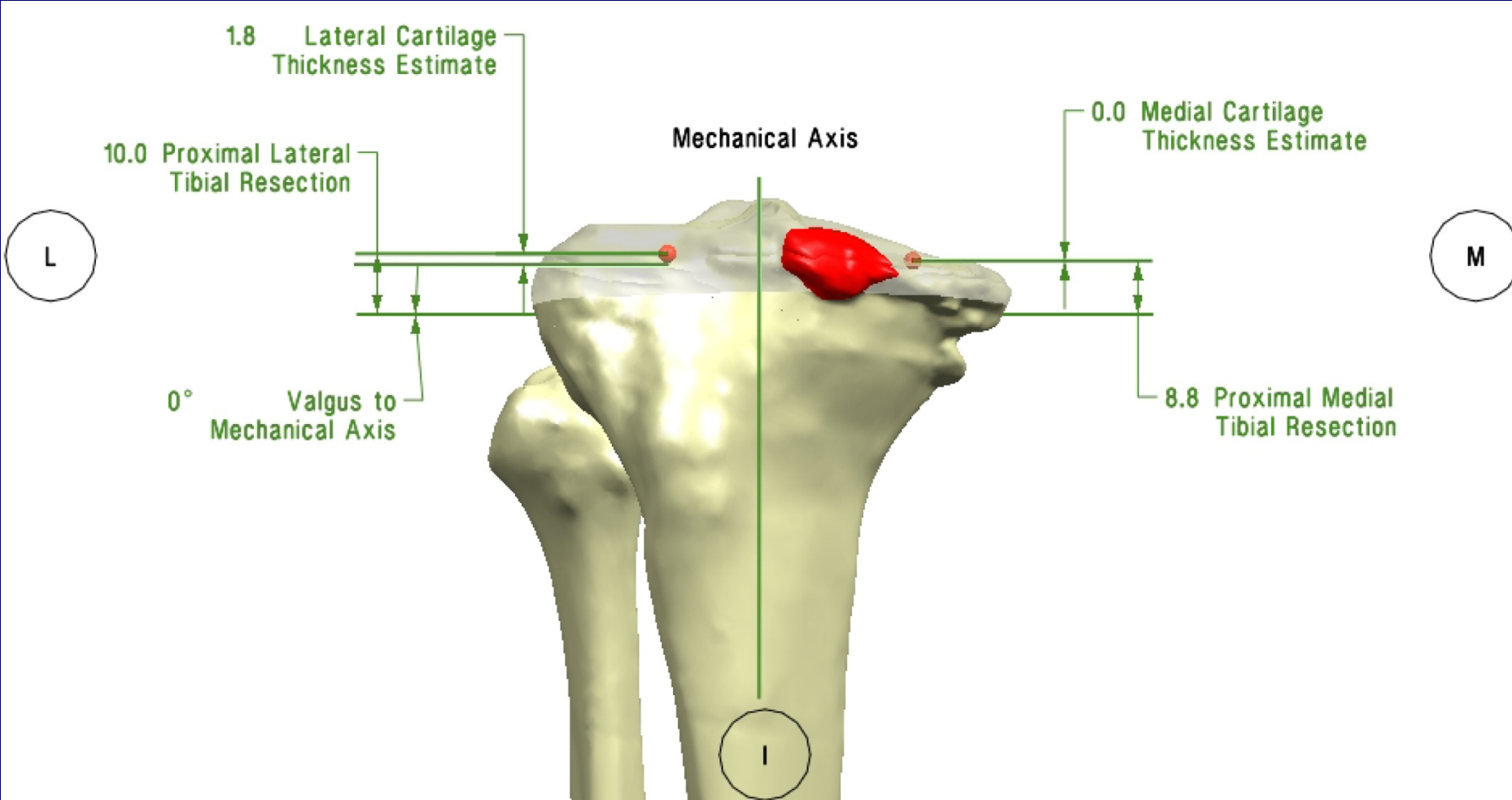
2° To Epicondylar

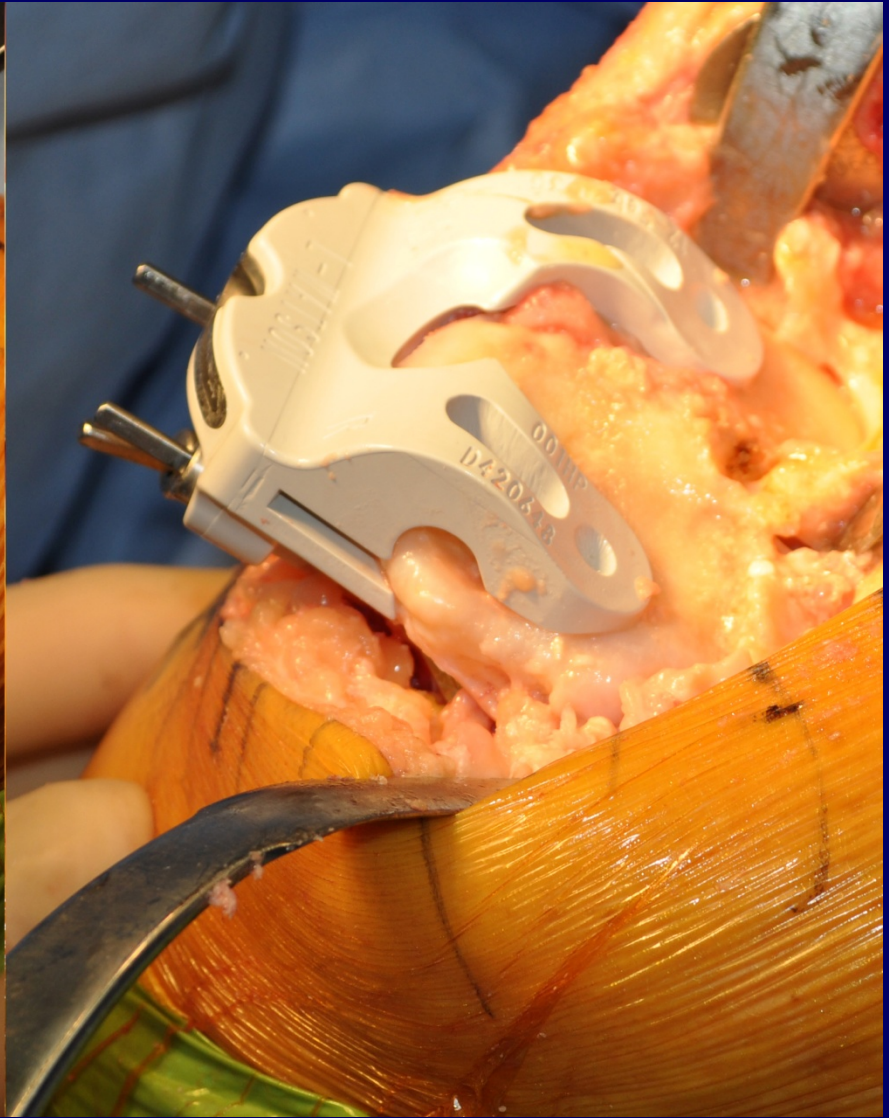
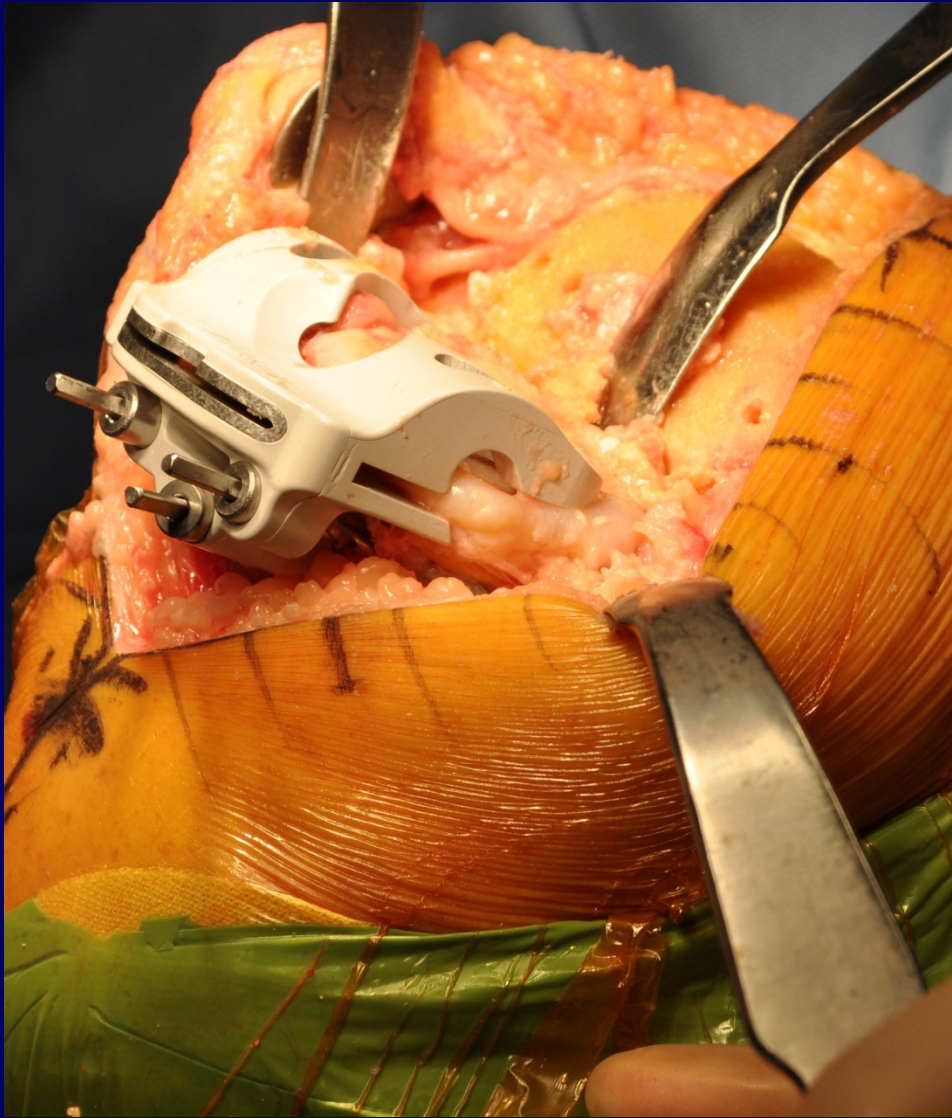
7.8 mm Posterior Lateral Femoral Resection

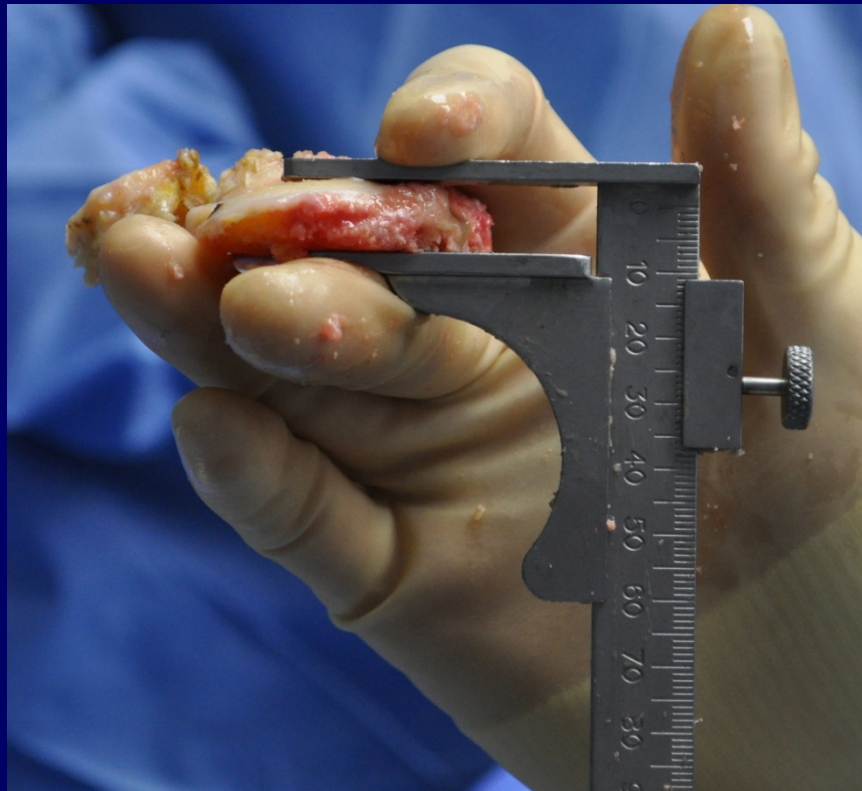
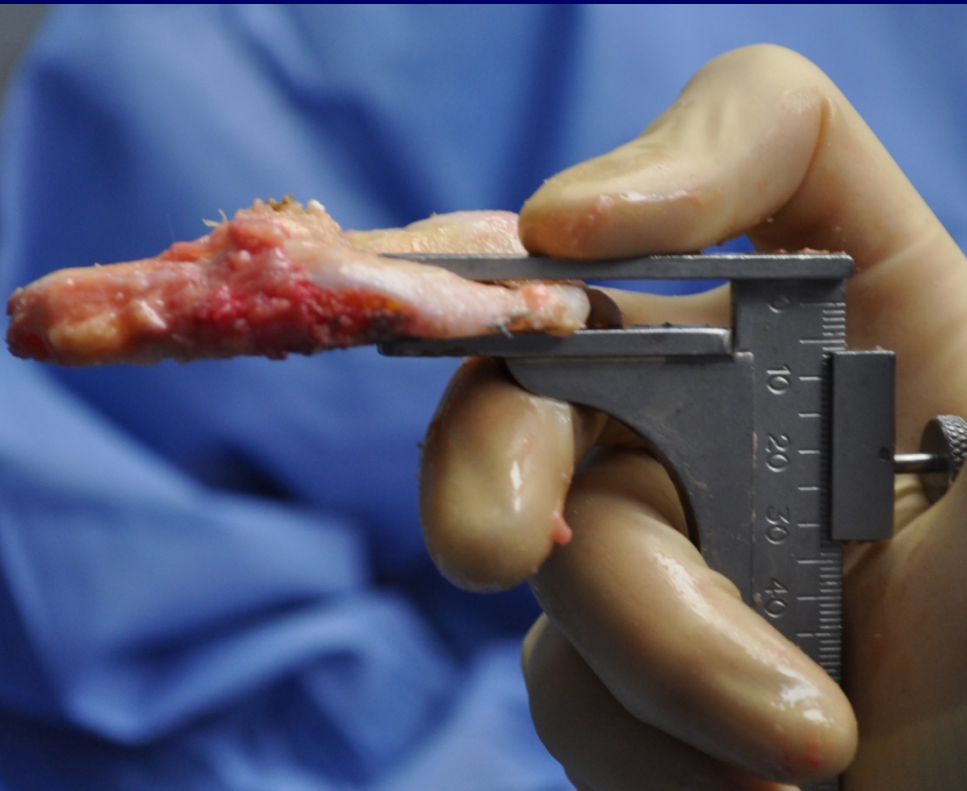
3° To Posterior Condyles

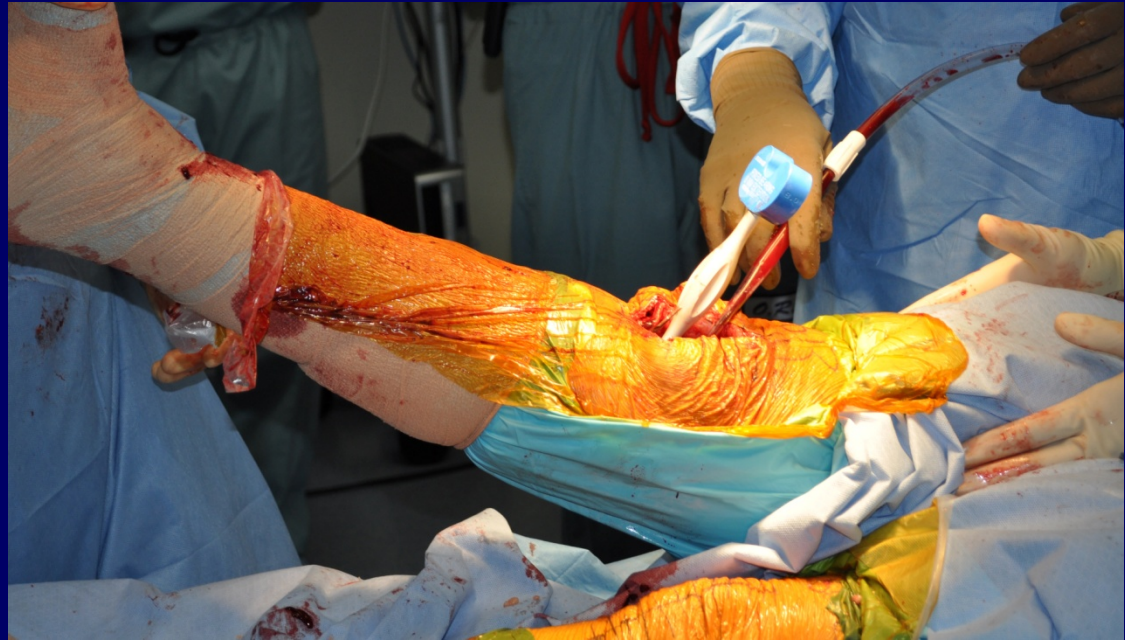
10.2 mm Posterior Medial Femoral Resection













# Customized Patient Instrumentation

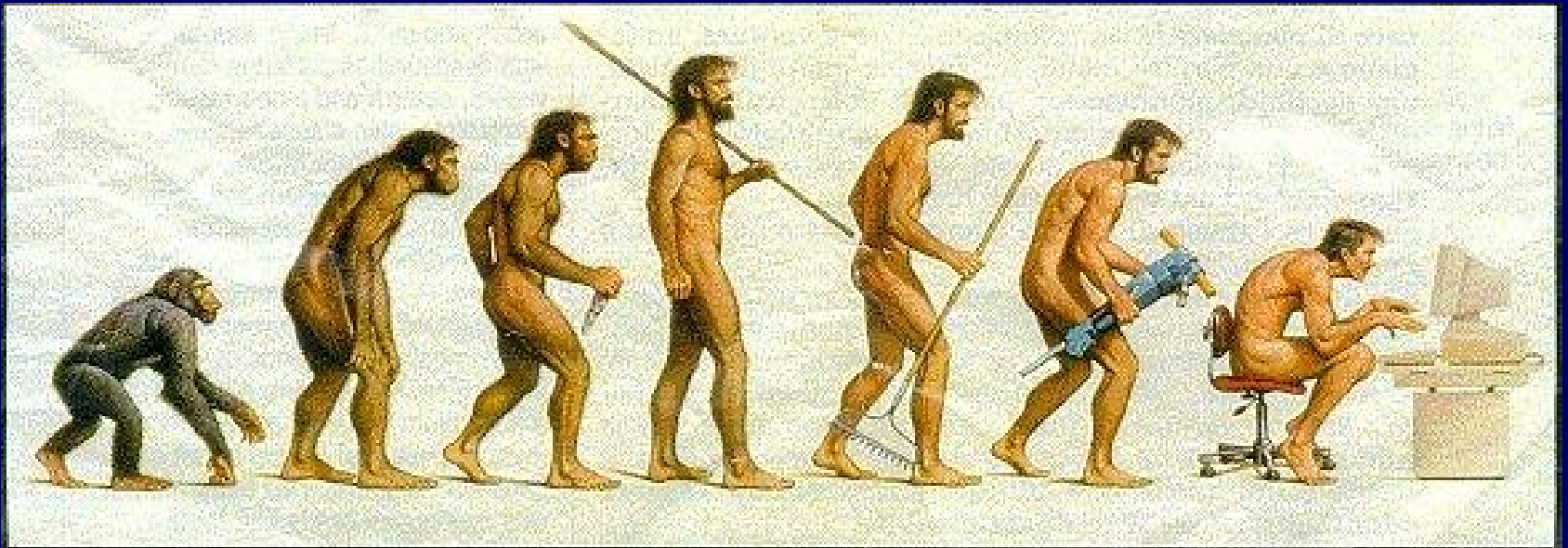
- The next great thing in TKA
- Potential benefits to all stakeholders
- Every implant company has versions in development or in marketplace
- Depuy TruMatch has specific advantages
  - Surgical plan
  - Validated accuracy and precision
  - High quality resection guides

# “Old School”





# Thank You



**Somewhere, something went terribly wrong**