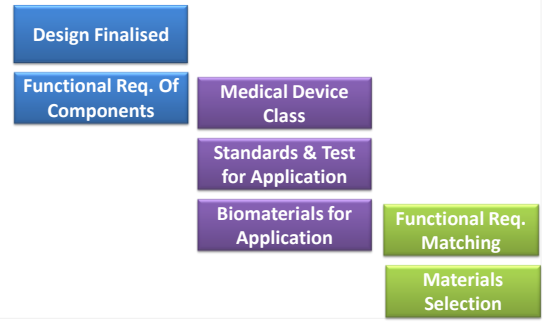
Collaborative Engineering

Bio – Materials, TKP

- Requirements of Components
- Medical Grades of TKP
- Standards of Biomaterials
- Biomaterials in TKP

OrthoCAD Lab, I.I.T. Bombay

Bio-Material Selection

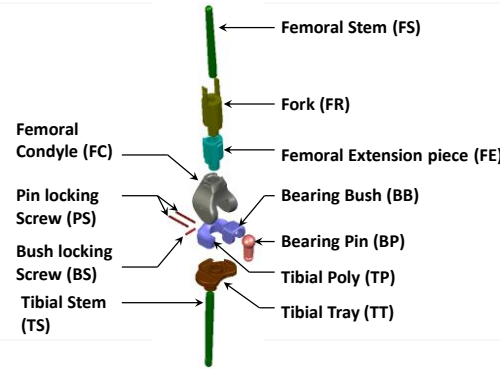


Materials Requirement for TKP

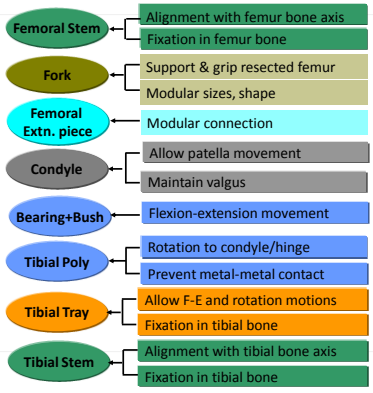
- Biologically Compatible
  - Non – Toxic
  - Non – Corrosive
  - Non – Inflammatory
- Biologically Integral
  - Tissue growth
  - Mechanical hold
- Strength during daily activities
- Life – Longevity

Design Finalised

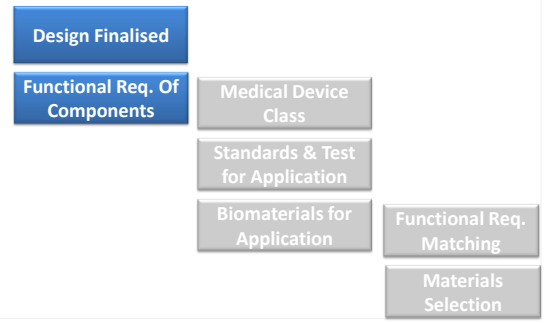
TKP Components



Functional Requirement Mapping

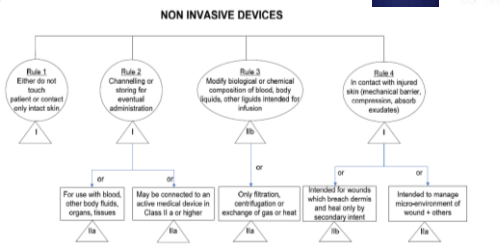


Bio-Material Selection

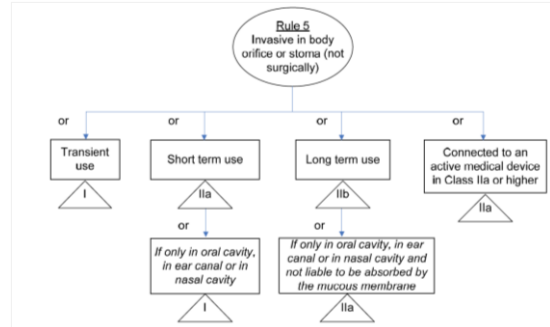


Standards Medical Devices

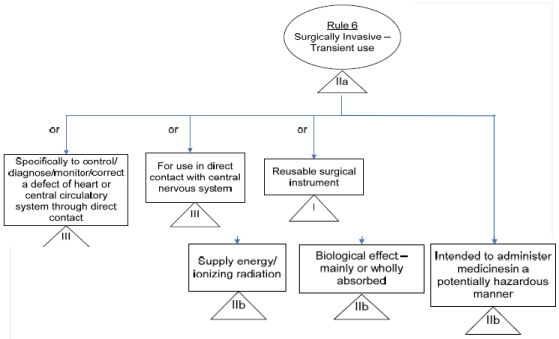
- FDA, CE – Classification of Medical Devices, Implants, instruments
- Classification: Class I, IIa,b, III



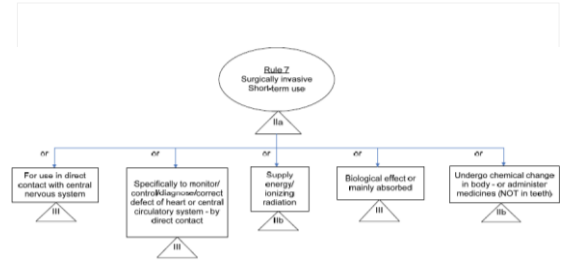
Classification: Non Surgical – I, IIa,b



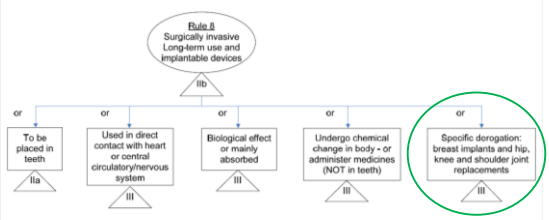
Classification: Surgical – Transient



Classification: Surgical – Short Term Use



Classification: Surgical – Long Term Use



Class III Device

Bio-compatibility Tests

- Orthopaedic Application Bio-Materials
- Key Standards: Bio-compatibility Tests

- ISO 10,993 – A standard for biological evaluation of medical devices
- ASTM F981 – Assessment of Compatibility of Biomaterials for Surgical Implants w.r.t. Effect of Materials on Muscle and Bone

- ASTM F748 – 06 – standard for: *Which Biocompatibility tests to do!*

Manufacturing Process

- **(ISO) 10,993 – A standard for biological evaluation of medical devices**

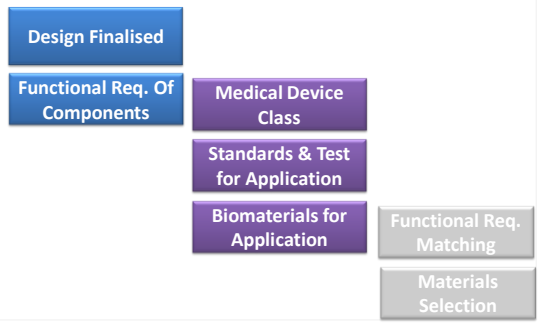
10993-1: "Guidance on Selection of Tests"
10993-2: "Animal Welfare Requirements"
10993-3: "Tests for Genotoxicity, Carcinogenicity, and Reproductive Toxicity"
10993-4: "Selection of Tests for Interactions with Blood"
10993-5: "Tests for Cytotoxicity-In Vitro Methods"
10993-6: "Tests for Local Effects After Implantation"
10993-7: "Ethylene Oxide Sterilization Residuals"
10993-8: "Selection and Qualification of Reference Materials for Biological Tests"
10993-9: "Framework for Identification and Quantification of Potential Degradation Products"
10993-10: "Tests for Irritation and Delayed-Type Hypersensitivity"
10993-11: "Tests for Systemic Toxicity"

Many more…

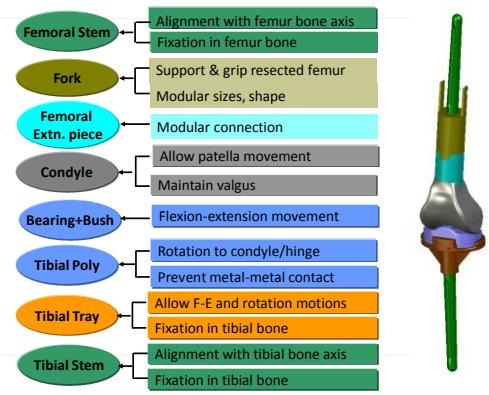
List of Bio-Materials with Properties

MATERIAL	CONDITION	UTS (MPa)	Yield Stress (MPa)	Young's modulus ($x10^3$ MPa)	Elongation at fracture (%)	Vickers hardness	Fatigue strength (MPa, 10^8 cyc)
316L	Annealed	465	170	200	40	183	245-300
316L	Cold worked	505-605	195-295	200	35	320	300
High-N	Annealed	740	430	200	30	269	460
High-N	Cold worked	1150	810	200	15	365	640
Co-Cr-Mo	Casted (giuten)	665	450	200	8	300	235-340
Co-Cr-Ni-Mo	Medium hard	1000	650	230	20	350	400-450
Titanium pure	Annealed)	240	170	127	24	240	250-280
Ti-6Al-4V	Annealed)	860	780	111	10	350	400-440
Al_2O_3		270	-	380	0	2000	-
Polyethylene	UHMW	35	21	0.5	350	-	-
PMMA	Bone cement	25	-	2	5	-	<14

Bio-Material Selection



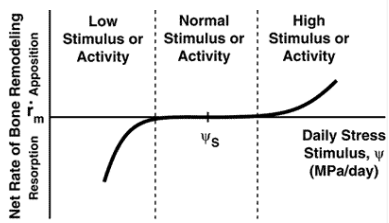
Functional Requirement Mapping



Bone Remodelling

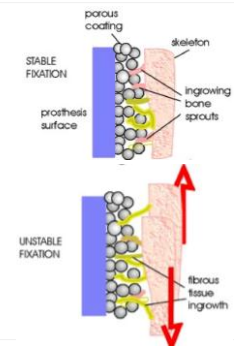
- **Depends on Loading/ Activity – Stress Shielding**

Wolff's Law



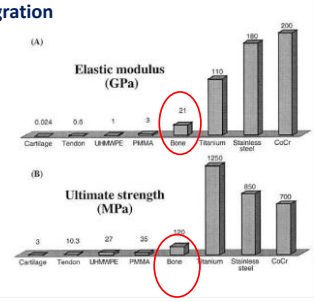
Bone Remodelling

- **Depends on Loading/ Activity**
- **Movement affects integration**



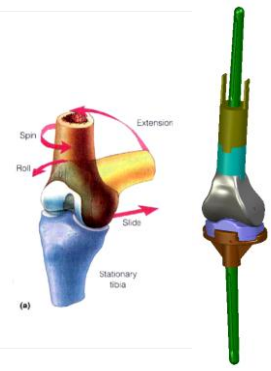
Bone Remodelling

- Depends on Loading/ Activity
- Movement affects integration
- Stiffness Mismatch



Knee Joint

- Wear Resistance
- Natural Lubrication
- Reduced Friction
- Load Bearing



Friction - Biomaterials

Material combinations	Lubricant	μ_s (start)	μ_k (gliding)
Rubber/concrete	None	1.0	0.7
Rubber/concrete	Water	0.7	0.5
Leather/wooden	None	0.5	0.4
Steel/steel	None	-	0.5
Steel/polyethylene	None	-	0.1
Steel/ice	Water	0.03	0.01
Cartilage/cartilage (joint)	Synovial fluid	-	0.002
	Ringer's buffer	-	0.01-0.005
	None	-	0.55
CoCr/CoCr (joint prostheses) [a]	Veronal buffer	-	0.22
	Serum	-	0.13
	Synovial fluid	-	0.12
	Albumin	-	0.11
CoCr/UHMWPE [a]	Serum	-	0.08
Al_2O_3/Al_2O_3 [b]	Ringer's buffer	-	0.1-0.05

[a] Weightman et al (1972) [b] Dörre et al (1975)

Bio-Metals

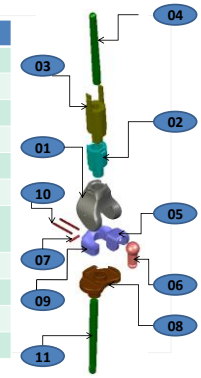
Advantages	Disadvantages
High mechanical strength Fatigue resistant	Modulus (mechanical) mismatch
Easy to produce and work Shape-memory properties possible	Can be prone to corrosion
Release normally few wear particles	Metal ions leah out – hypersensitivity and toxicity (Co, Cr, Ni)
Can show good corrosion resistance	Metal – metal contact produces sound
Ease of sterilisation	Welded implants can fail

TKP Bio-Material – Characteristics

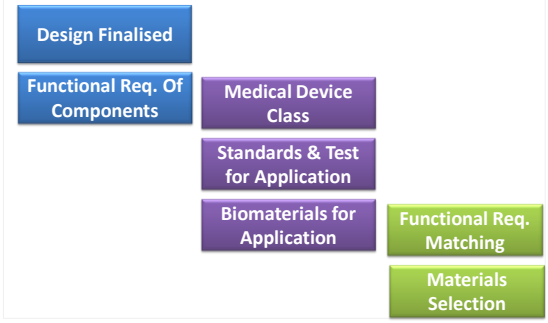
Characteristics	Stainless Steel - 316L	Ti-6Al-4V	Cobalt - Chromium	UHMW-PE
Stiffness	High	Low	Medium	Low
Strength	Medium	High	Medium	Medium
Corrosion Resistance	Low	Medium	High	High
Manufacturing Efficiency	High	Low	Medium	High
Bio-compatibility	Low	High	Medium	Medium
Fatigue Strength	Medium	High	High	Medium

Materials of Components

S.No	Part ID	Description	Qty	Material
01	FC	Femoral condyle	01	CoCrMo
02	FE	Femoral extension	01	Ti-6Al-4V
03	FR	Fork	01	Ti-6Al-4V
04	FS	Femoral stem	01	Ti-6Al-4V
05	BB	Bearing bush	01	UHMWPE
06	BP	Bearing pin	01	CoCrMo
07	BS	Bush locking screw	01	CoCrMo
08	TT	Tibial tray	01	Ti-6Al-4V
09	TP	Tibial poly	01	UHMWPE
10	PS	Pin locking screw	02	CoCrMo
11	TS	Tibial stem	01	Ti-6Al-4V



Bio-Material Selection



Manufacturing Process – Co-Cr

- TKP – Functional Material
  - Co-Cr Condyle
  - Near net rapid casting route

- Co-28Cr-6Mo – ASTM F75 (UNS R30075)
- Alloy Developed in-house
- Achieved by > 1750°C & nominal Vacuum levels
- Uniform Dissolution & Distribution - Mo & Cr in Co
- Porosity Free Casting
- No Machining Required on Condyle surface

Manufacturing Process – UHMWPE

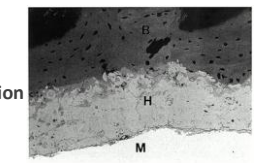
- TKP – Functional Material
  - UHMWPE Finishing
  - Hot forming / Machining

- Imported as Extruded Rods/ Compression Molded Sheets
- Roughness optimized 0.35 – 0.4 microns
- Process Parameters Optimized (10 Trials)
- Forming Thickness (~ 2mm)
- Job-Material Time Temperature Relationship
- Die @ 600°C & UHMWPE @ RT

Osteo – Integration

- "Hydroxyapatite" – porous calcium phosphate ceramic
- Pore size
- Pore type
- Surface roughness
- Growth factors/ inhibitors
- Drug deliver

- BONE GROWTH – Bio-integration
- Mfg - Plasma Spray



M-Metal Substrate, H- Hydroxyapatite, B-Bone

SUMMARY

- Application Oriented Selection
- Medical Class of device
- Functional Role of Components
- Mechanical Properties Required