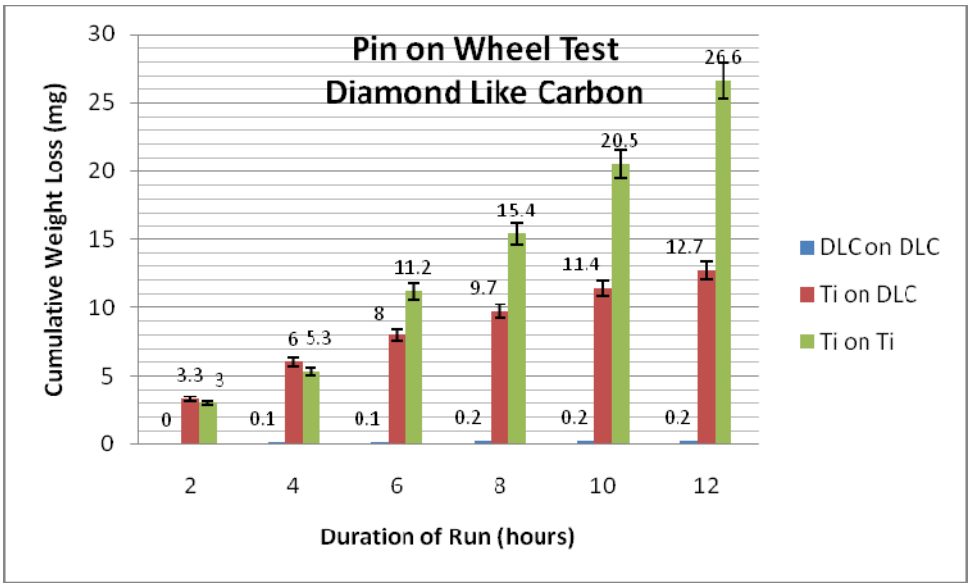
Tecvac Limited

Diamolith Coatings Biocompatibility Certificate

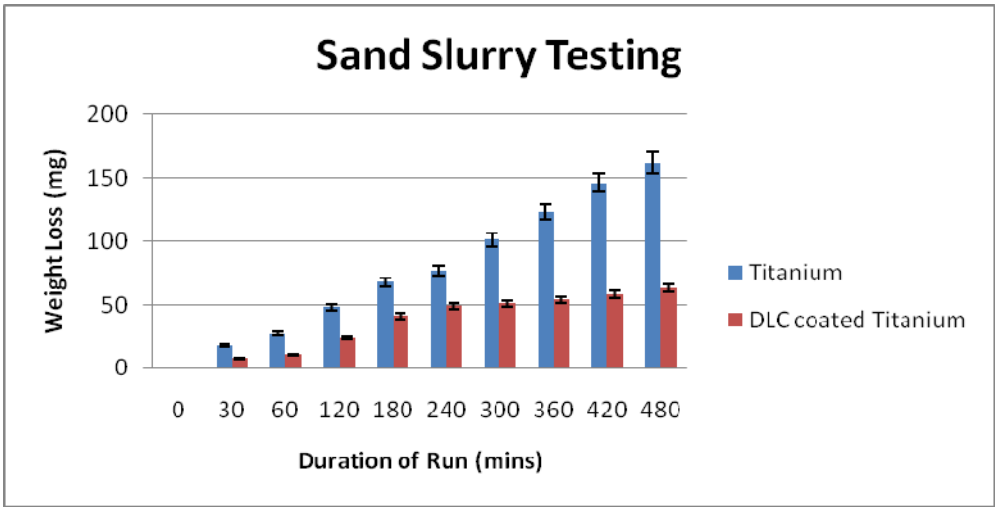
Contents

1. Mechanical Tests

1.1. Durability / Pin on Wheel Test



1.2. Sand Slurry Testing



2.0 Medical Applications for DLC Coatings

2.1 Implantation Devices

- Dental Implants
- Hip Replacement Components
- Knee Replacement Components
- Spinal Components
- Nails, Pins and Screws
- Heart Valve Components

2.2. Orthopedic Tools

- Drills
- Reamers
- Broaches
- Cutters
- Scalpels
- Pharmaceutical Powder Punches

2.3. Mechanical Components

- Blood Pump Components
- Syringe Needles
- Ultrasound Scanner Components
- Arthroscope Components
- Microscopy Components

3.0 Biological Evaluation

3.1 Cytotoxicity an Cytocompatibility

Test	Aim	Protocol	Result
General Cytotoxicity	Cellular response to L929 Fibroblast Cells	ISO 10993-5	PASSED Adhesion pattern of thickly populated endothelial cells on DLC makes l suitable for vascular applications

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3.2 Toxicology

Test	Aim	Protocol	Result
Haemolysis	To assess the in vitro haemolytic activity of the material	O'Leary and Guess	PASSED Haemolysis of the DLC coated Titanium (0.098%) and Titanium metal 0.066% were below the normal range
Sensitisation	To determine the potential for a material to elicit contact dermal allergenicity	ISO 10993-10	NON SENSITIZING DLC coated Ti produced n greater reaction than that of the control material (Titanium) – A Biocompatible metal
Intra-cutaneous Irritation	To evaluate the local responses to the extracts of a material under test following intra-cutaneous injection into rabbits	ASTM F749-7	PASSED Saline and cottonseed oil extract on both DLC coated Ti and Ti metal produced the same average irritation of "00"
Systemic Toxicity	To evaluate the systemic response to extract of materials under test following injection	ISO 10993-11	PASSED Saline and cottonseed oil extracts on DLC coated Ti and Titanium Metal did not produce any toxic symptoms during the experimental period (intravenous and intraperitoneal injections

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4.0

3.3. **Mutagenicity**

Test	Aim	Protocol	Result
Gentotoxicity	Ti + Diamolith	ISO 10993-3	No Clastogen Activity with human Lympocytes
Carcinogentoxicity	Ti + Diamolith	ISO 10993-3	No Clastogen Activity with human Lympocytes
Reproductive Toxicity	Ti + Diamolith	ISO 10993-3	No Clastogen Activity with human Lympocytes

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Agreement: ACCREDITATION ACCORDING EN 45001 by COFRAQ Registered No 1-0616

3.4 **Intramuscular Implantation in Rabbits up to 1 year**

PASSED

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Parameters	Time Period in Months							
	One		Three		Six		Twelve	
	DLC/Ti	Ti	DLC/Ti	Ti	DLC/Ti	Ti	DLC/Ti	Ti
Necrosis	+/-	+/- to 1+	0	0	0	0	0	0
Neutrophilis	1+	0	0	0	0	0	0	0
Macrophages	1 to 3	+/- to 3+	+/-	+/-	+/-	+/-	+/-	0
Lymphocytes	+/-to 2	+/- to 2	+/-	+/-	+/-	+/-	+/-	0
Plasma Cells	0	0	0	0	0	0	0	0
Giant Cell	Muscule 1+	Muscule 1+	0	0	0	0	0	0
Eosinophils	0	0	0	0	0	0	0	0
Foreign Body	0	0	0	0	0	0	0	0
Fibroblast	1 to 3	1 to 3	+/- to 3	1 to 2+	+/-	2+	+/-	+/-
Fibrocytes	1+	+/- to 2+	+/- to 1+	1+	+/- to 2+	1+	+/-	+/-
Fatty Infiltration	+/-	0	+/-	+/-	2+	+/-	1+	1+
Calcification	0	0	0	0	0	0	0	0
Haemorrage	0	0	0	0	0	0	0	0
Oedema	0	0	0	0	0	0	0	0

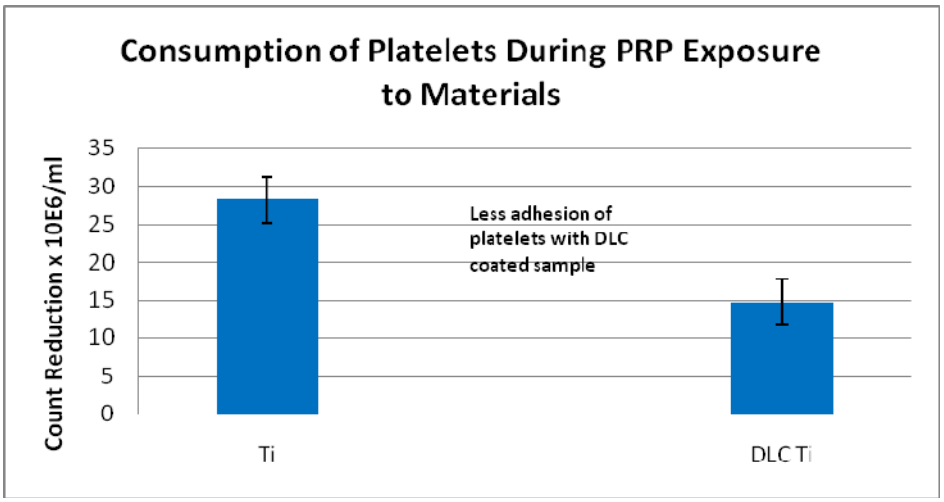
Any Other	0	0	0	0	0	0	0	0

Table above is a summary of light microscopy observations around the coated and uncoated implant sites: 0 = Item not present : +/- item occasionally present; 1+ item present to a small degree; 2+ item present to a moderate degree; 3 + item present to a large degree

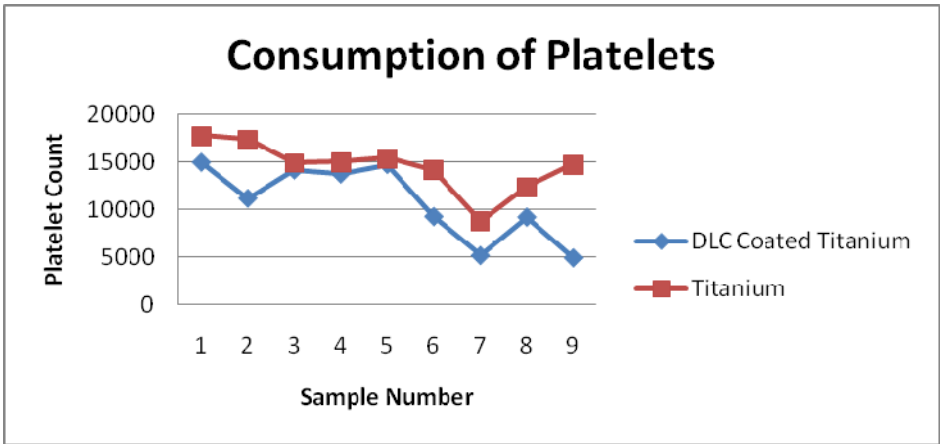
3.5 Blood Compatability

a) Invitro PASSED

- **Platelet Adhesion**



- **Consumption of Platelets**



b) **Invivo**

Decrease of thrombosis with Diamolith