

ニフリート
NiFreeT
Titanium-Tantalum Alloy

New **NICKEL-FREE**
Biomaterial



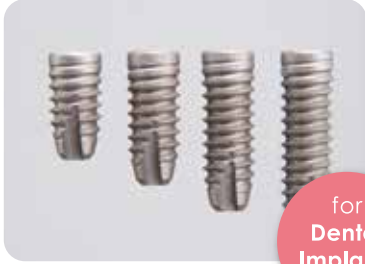
for
Surgical
Tools

NiFreeT

ニフリート

Titanium-Tantalum Alloy

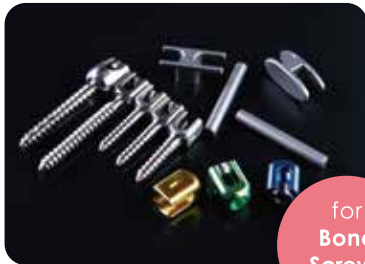
Since NiFreeT is a Nickel-free alloy, it is highly biocompatible and MRI compatible. It also has good machinability, very high corrosion resistance and heat resistance.



for
Dental
Implants



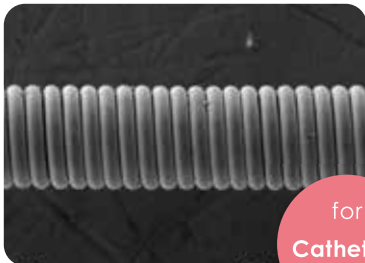
MRI
Compatible



for
Bone
Screws



Radiopaque



for
Catheters



for
Accessories



for
Stents



for
Eyeglasses



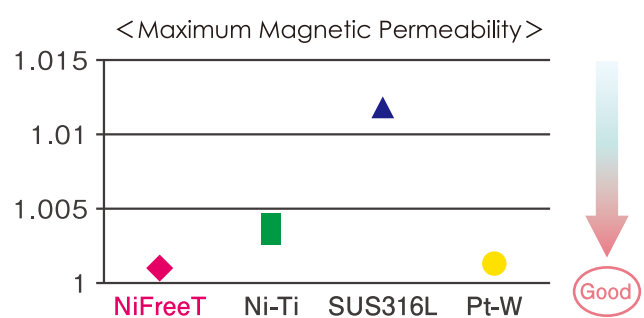
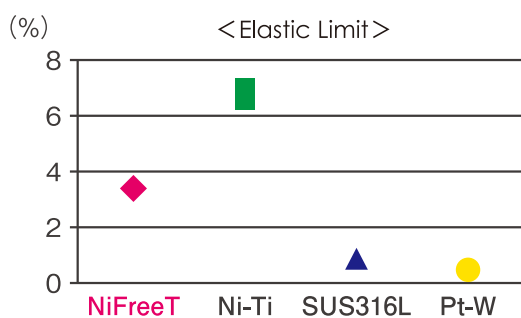
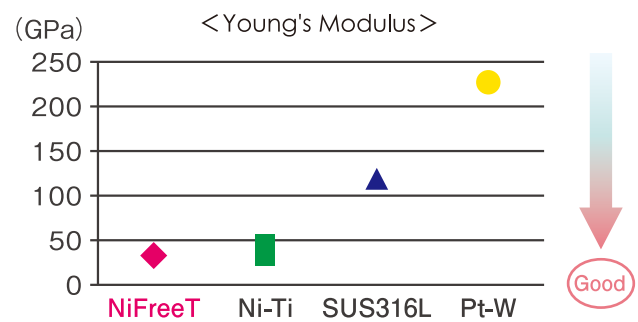
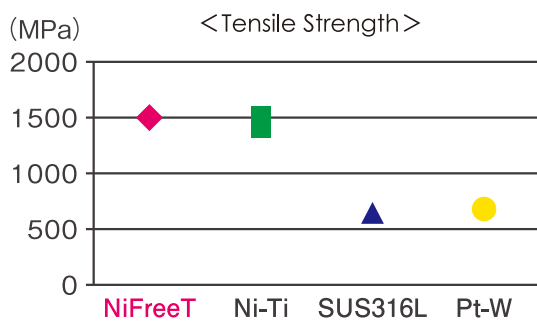
for
Pacemakers



Brand	NiFreeT <small>ニフリート</small>		
Components (Wt %)	Titanium (Ti)	Tantalum (Ta)	Tin (Sn)
	approx. 44 %	approx. 52 %	approx. 4 %
Density	approx. 7.44		
Patent	PENDING		
Features	High biocompatibility, MRI compatibility, radiopacity, corrosion resistance, superior physical properties and machinability.		

Physical Properties

POINT 1 NiFreeT is a Nickel-Free and non-magnetic alloy with high tensile strength, low young's modulus, near that of human bone, and very high elastic limit.



Heat In Temperature by MRI

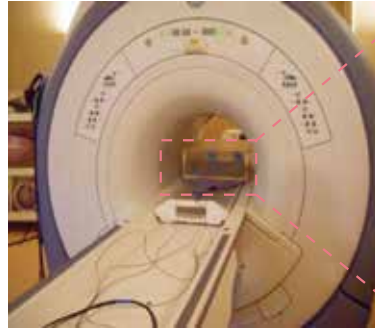
POINT 2 Both NiFreeT and Platinum test pieces were heated up 0.1°C by MRI.

Assessed by Bio View, Inc.

Test Piece: OD 1.3mm, Length 2.0mm

Test Method: Set NiFreeT and Platinum test pieces in humanoid phantom filled with polyacrylic gel. Then monitor rise in temperature near the test pieces according to ASTM RF irradiance condition.

Test Result: Both NiFreeT and Platinum rise 0.1 degree celsius. They don't effect rise in temperature in MRI.



Model No.: GE3.0T Signa HDxt Optima Edition
Magnetostatic Strength: 3.0T
Frequency: 128MHz



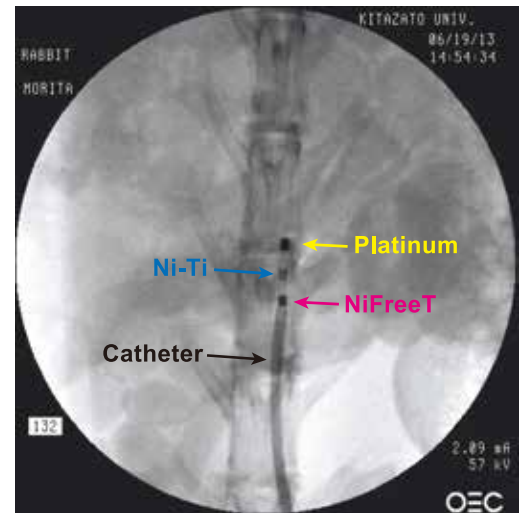
Visibility on X-ray Imaging

POINT 3 NiFreeT has superior visibility than Ni-Ti and similar visibility with Platinum.

< Imaging Condition >

Appartus: Transmission X-ray system
OEC9600 (Dicom View)

Test Piece: OD 1.27mm, ID 1.07mm, Length 2.0mm



Corrosion Resistance

POINT 4 NiFreeT has resistance to sodium hypochlorite.

Test Piece: Diameter 0.5mm, Length 30mm

Test Method: Soak NiFreeT and Ni-Ti test pieces in sodium hypochlorite for 144 hours (6 days) in a row.

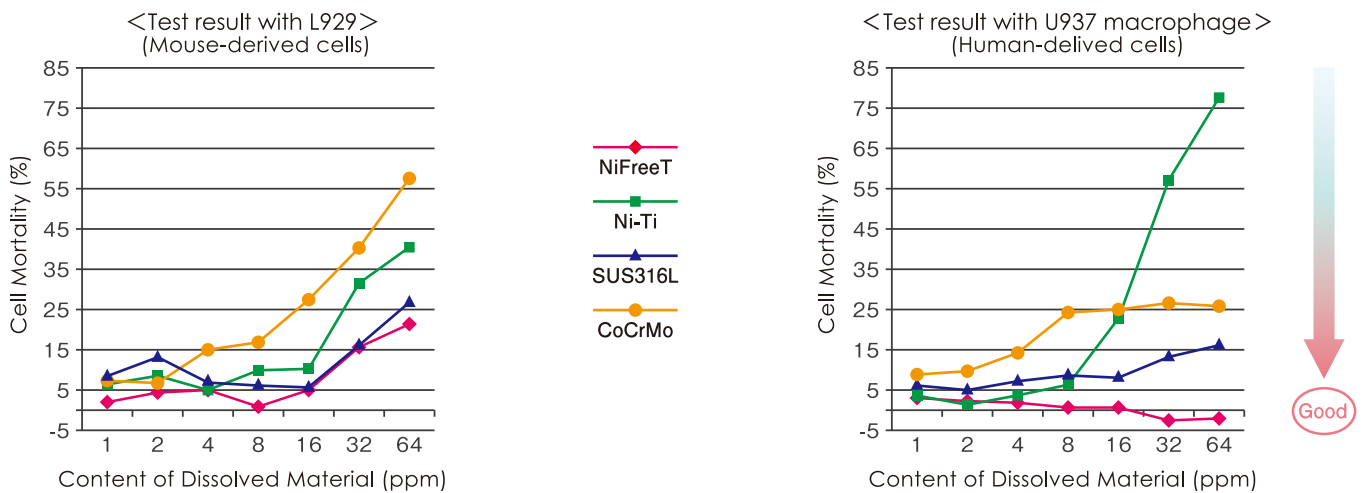
Test Result: NiFreeT shows no differences between before and after the test.
On the other hand, Ni-Ti fragments into pieces.

	Before	After 6 consecutive days in sodium hypochlorite	
NiFreeT			No Changes
Ni-Ti			Fragment into pieces

Superiority as Biomaterial

POINT 5 NiFreeT shows the lowest cytotoxicity compared with existing biomaterials.

(1) Cytotoxicity Test (Assessed by Saitama University)



POINT 6 NiFreeT is Implantable.

(2) Biocompatibility Tests according to ISO10993 (assessed by Food and drug safety center, Japan)

	Test	Result
①	Gene Mutation Inducibility	Passed
②	Intractaneous Reactivity	Passed
③	Colonization	Passed
④	Guinea Pig Maximization Test	Passed

(2) Biocompatibility Tests according to ISO10993 (assessed by American Preclinical Services LLC)

	Test	Result
⑤	Materials Mediated Pyrogenicity	Passed
⑥	Acute Systemic Toxicity	Passed
⑦	Intramuscular Implantation (4 weeks)	Passed
⑧	Hemolysis	Passed
⑨	PTT	Passed

Machinability

POINT 7 NiFreeT is brazable and weldable as pure Titanium.

(1) Manufacturability: Crack-Free Processing Limit Test

	Swaging Process		Cumulative Wire Drawing Rate	
NiFreeT	Room Temperature up to 900°C	Good	up to 90%	Good
Ni-Ti	Room Temperature up to 600°C	No Good	up to 40%	Good
	700°C	Good	45% and more	No Good

(2) Assessment of Processing Properties

	Press-Formability	Machinability	Brazing and Welding
NiFreeT	Good	Good	Possible
Ni-Ti	Proficiency is required	Proficiency is required	almost Impossible

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