

MATERIAL SAFETY DATA SHEET – BICON IMPLANTS

1. PRODUCT AND COMPANY IDENTIFICATION

Trade Name (As Labeled): Integra-Ti, Integra-CP
Product Use: Dental Use
Supplier/Manufacturer: Bicon, LLC
Address: 501 Arborway
Boston, MA 02130
Emergency Telephone: 1-800-882-4266
Email Address: support@bicon.com

2. HAZARDS IDENTIFICATION

Physical State: Solid
Color: Gray to off-white
Hazard Status: Non-hazardous
Emergency Overview: Chemically stable, incombustible. May cause eye or respiratory tract irritation.
Route of Entry: Dermal contact. Eye contact. Inhalation. Ingestion.
Potential Acute Health Effects
Skin: May have a drying effect on the skin.
Eyes: Inert foreign body hazard only.
Inhalation: Temporary irritation to mucous membranes from excessive exposure.
Ingestion: Irritating if swallowed. Seek medical attention.
Potential Chronic Health Effects
Carcinogenic Effects: None
Mutagenic Effects: None
Teratogenic Effects: None
Medical Conditions Aggravated
By Over-Exposure: None known

3. COMPOSITION/INFORMATION ON INGREDIENTS

IMPLANT

| Name | % |
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| Titanium | Balance |
| Aluminum | 5.5-6.5 |
| Vanadium | 3.5-4.5 |
| Iron | 0-0.25 |
| Oxygen | 0-0.13 |
| Carbon | 0-0.08 |
| Nitrogen | 0-0.03 |
| Hydrogen | 0-0.0125 |

COATING

| Name | % |
|-------------------------|---------|
| Hydroxyapatite | 95-100% |
| a-TCP, b-TCP, TTCP, CaO | 0-5% |

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4. FIRST AID MEASURES

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| <u>Skin Contact:</u> | Clean thoroughly with soap and water. |
| <u>Eye Contact:</u> | Check for and remove contact lenses; keep eyelid open, rinse under running water for at least 20 minutes. If irritation occurs, seek medical advice. |
| <u>Inhalation:</u> | If inhaled, remove to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical advice if adverse effects continues after removal to fresh air. |
| <u>Ingestion:</u> | Do not induce vomiting – seek medical advice. If unconscious, do not administer anything orally. Place in stable side position and seek medical advice. |

5. FIRE FIGHTING MEASURES

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| <u>Flammability:</u> | Non-flammable |
| <u>Fire Extinguishing Materials:</u> | None required. |
| <u>Fire Extinguishing Materials Not To Be Used:</u> | None known |
| <u>Protection of Firefighters:</u> | No special measures required. |

6. ACCIDENTAL RELEASE MEASURES

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| <u>Personal Precautions:</u> | Use suitable protective equipment. |
| <u>Environmental Precautions:</u> | Avoid dispersal of spilled material. |
| <u>Methods for Cleanup:</u> | Use any feasible mechanical means to remove spilled material, such as a broom, brush, scoop, or vacuum. |

7. HANDLING AND STORAGE

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| <u>Handling:</u> | Use only with adequate ventilation. Wash hands thoroughly after handling. |
| <u>Storage:</u> | No special storage procedures required. |

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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| <u>Exposure Guidelines:</u> | None established |
| <u>Personal Protection:</u> | Use protective gloves. If eye protection is necessary, use safety glasses or goggles. |

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9. PHYSICAL AND CHEMICAL PROPERTIES

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| <u>Physical State:</u> | Solid |
| <u>Odor:</u> | Odorless |
| <u>Specific Gravity:</u> | Not available |
| <u>Color:</u> | Gray to off-white |
| <u>Solubility:</u> | Insoluble in water |
| <u>pH:</u> | Not applicable |
| <u>Boiling Point:</u> | Not established |
| <u>Melting/Freezing Point:</u> | 1600-1760°C |

10. STABILITY AND REACTIVITY

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| <u>Stability and Reactivity:</u> | The product is stable under normal temperature and pressure. |
| <u>Incompatibility Information:</u> | None known |
| <u>Hazardous Decomposition:</u> | None known |
| <u>Hazardous Reactions:</u> | None known |

11. TOXICOLOGICAL INFORMATION

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| <u>LD50:</u> | Not established |
| <u>Cytotoxicity:</u> | Does not induce cytotoxicity in L929 cells. |
| <u>Acute Systemic Injection:</u> | No signs of toxicity (mice) |
| <u>Potential Acute Health Effects</u> | |
| <u>Skin:</u> | May have a drying effect on the skin. |
| <u>Eyes:</u> | Inert foreign body hazard only. |
| <u>Inhalation:</u> | Temporary irritation to mucous membrane from excessive exposure. |
| <u>Ingestion:</u> | Irritating if swallowed. Seek medical attention. |
| <u>Potential Chronic Health Effects</u> | |
| <u>Carcinogenic Effects:</u> | None |
| <u>Mutagenic Effects:</u> | None |
| <u>Teratogenic Effects:</u> | None |

12. ECOLOGICAL INFORMATION

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| <u>Ecological Information:</u> | Ecological harm not known or expected under normal use. |
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13. DISPOSAL CONSIDERATIONS

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| <u>Waste Disposal:</u> | The generation of waste should be avoided or minimized wherever possible. Waste disposal must comply with the requirements of environmental protection and waste disposal legislation and any regional and local authority requirements. |
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14. TRANSPORT INFORMATION

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| <u>Regulations:</u> | This product is not classified as dangerous goods. |
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15. REGULATORY INFORMATION

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| <u>TSCA Status:</u> | The components are listed on the TSCA Inventory or are exempted from listing. |
| <u>SARA Reporting:</u> | No reportable components |
| <u>WHMIS (Canada):</u> | Not controlled. All components listed on DSL. |

This product has been classified in accordance with the hazard criteria of the Canadian CPR and the United States OSHA. This MSDS contains all of the information required by those regulations.

16. OTHER INFORMATION

The information contained herein is based on data considered accurate. However, no warranty is expressed or implied regarding the accuracy of these data or the results to be obtained from the use thereof. Bicon, LLC assumes no responsibility for injury to the vendee or third persons proximately caused by the material if reasonable safety procedures are not adhered to as stipulated in the data sheet. Additionally, Bicon, LLC assumes no responsibility for injury to vendee or third persons proximately caused by abnormal use of the material even if reasonable safety procedures are followed. Furthermore, vendee assumes the risk in use of the material.