

K962706

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**Section 510(k)  
Premarket Notification**

**Summary of Safety and Effectiveness Information**

**Regulatory Authority:** Safe Medical Devices Act of 1990, 21 CFR 807.92

**Device Trade Name:** EZ-Fix™ Cannulated Screw System

**Common Name:** Large Cannulated Screws

**Registration Number:** 888.3040

**Classification Name:** Screw, Fixation, Bone

**Establishment Name & Registration Number:**

**Name:** Biodynamic Technologies, Inc.  
East Newport Center Drive  
Deerfield Beach, Florida 33442  
(305) 421-3166 (305) 570-6368 FAX

**Number:** 1035157

**Classification:**

**Device Class:** Class II

**Classification Panel:** Orthopedic

**Contact Person:**

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East Newport Center Drive  
Deerfield Beach, Florida 33442  
(305) 421-3166 (305) 570-6368 FAX

**Special Controls:**

Not applicable to this device.

**Device Description:**

The EZ-Fix™ Cannulated Screws are indicated for single use to stabilize intracapsular, certain cervical and subcapital fractures of the femur; fractures of the distal femur and

proximal tibia; pelvis and acetabular fractures and certain fractures of the shoulder and elbow. They are contraindicated for attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, lumbar spine.

The EZ-Fix™ Cannulated Screws are fabricated from titanium alloy (Ti-6Al-4V ELI). They are tested per ASTM standards and have a thread diameter and length of 7.3 mm and 20 mm respectively and a shaft diameter of 5.3 mm. They accept a 3.2 mm guide pin through the 3.45 mm cannulation. They are self reaming and tapping and have reverse cutting flutes.

The EZ-Fix™ Cannulated Screws are available in 35 mm to 125 mm lengths are supplied non-sterile.

### Substantially Equivalent Devices:

1. **Alphatec Large Cannulated Screw System**  
See Appendix III for promotional materials for the comparison device.
2. **Richards Universal and 8.0 mm Cannulated Screw**  
See Appendix III for promotional materials for the comparison device.
3. **Ace Screw**  
See Appendix III for promotional materials for the comparison device.
4. **Howmedica Asnis 2 Guided Screw System**  
See Appendix III for promotional materials for the comparison device.

### Comparison to Predicate Device:

The EZ-Fix™ Cannulated Screws are substantially equivalent to the Alphatec, Ace, Richards and Howmedica large cannulated screws in that they are bone fixation screw devices indicated for single use to stabilize intracapsular, certain cervical and subcapital fractures of the femur; fractures of the distal femur and proximal tibia; pelvis and acetabular fractures and certain fractures of the shoulder and elbow. They are contraindicated for attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine. They are fabricated and tested per ASTM standards, they accept a 3.2 mm guide pin, they are self tapping, and they are supplied non-sterile. Like Alphatec, Richards and Howmedica, they have reverse cutting flutes.

The EZ-Fix™ Cannulated Screws are substantially equivalent to the Alphatec and Ace screws in that they are made from titanium alloy (Ti-6Al-4V ELI).

The EZ-Fix™ Cannulated Screws are substantially equivalent to the Alphatec, Ace and Howmedica screws in that they are self reaming and have thread lengths of 20 mm.

The EZ-Fix™ Cannulated Screws are substantially equivalent to the Alphatec screws in they are made available in lengths from 35 mm to 125 mm.

The EZ-Fix™ Cannulated Screws are substantially equivalent to the Howmedica and Richards screws in that they have a thread diameter of 7.3 mm (Howmedica and Richards screws have thread diameters of 7.0 mm and 8.0 mm respectively).

**FAXED**  
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**Packaging:**

The EZ-Fix™ Cannulated Screws and all instruments are supplied non-sterile.

**Sterilization / Re-sterilization:**

The EZ-Fix™ Cannulated Screws and all instruments are supplied non-sterile.

Steam autoclavable sterilization trays will be designed to contain the EZ-Fix™ Cannulated Screw System and maintain adequate separation of the implants and instruments.

Sterilization cycles should be followed appropriately to achieve a 10<sup>-6</sup> sterility assurance level (SAL).

See Appendix I for Sterilization Procedure

The EZ-Fix™ is non-pyrogenic. Pyrogenicity testing of the EZ-Fix™ to determine level of endotoxin performed using LAL (Limulus Amebocyte Lysate) method.

**Testing:**

Awaiting from Orthopaedics Biomechanics Laboratory.

**Equivalence :**

These test values are identical to those obtained on the referenced equivalent.

**Conclusion:**

Based on the materials, intended uses, design, testing, and manufacturing, the EZ Fix™ Cannulated Screw System is equivalent to the referenced legally marketed comparison devices. The feature comparison chart below graphically demonstrates equivalence.

**Comparison Table:**

<b>EZ-Fix™ Cann. Screw</b>	<b>Alphatec Lg. Cann. Screw</b>	<b>Ace® Screw</b>	<b>Richards Universal and 8 MM</b>	<b>Howmedica Asnis 2™</b>	<b>SE</b>
<b><u>Materials</u></b>					
Titanium Alloy	Titanium Alloy	Titanium Alloy	Stainless Steel Stainless Steel	Stainless Steel	Yes/No
<b><u>MRI Compatible</u></b>					
Yes	Yes	Yes	No No	No	Yes/No
<b><u>Cannulated</u></b>					
Yes	Yes	Yes	Yes Yes	Yes	Yes

<b><u>Thread Diameter</u></b>					
7.3 MM	6.5 MM	6.5 MM	6.5 MM 8.0 MM	7.0 MM	Yes/No
<b><u>Guide Pin Diameter</u></b>					
3.2 MM	3.2 MM	3.2 MM	2.4 MM 3.2 MM	3.2 MM	Yes/No
<b><u>Screw Lengths</u></b>					
35 - 125 MM	35 - 125 MM	25-120 MM	25 - 120 MM 50 - 125 MM	35 -130 MM	Yes/No
<b><u>Thread Lengths</u></b>					
20 MM	20 MM	20 MM	16 MM 16 MM	20 MM	Yes/No
<b><u>Intended Use</u></b>					
Single Use	Single Use	Single Use	Single Use Single Use	Single Use	Yes
<b><u>Indications</u></b>					
Intracapsular, certain cervical and subcapital fractures of the femur. Distal femur and proximal tibia fractures. Pelvis and acetabular fractures. Certain fractures of the shoulder and elbow.	Same	Same	Same Same	Same	Yes
<b><u>Contraindications</u></b>					
Attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine	Same	Same	Same Same	Same	Yes
<b><u>Performance Standards</u></b>					
ASTM F117	Same	Same	Same Same	Same	Yes
<b><u>Self Reaming</u></b>					
Yes	Yes	Yes	No No	Yes	Yes/No
<b><u>Self Tapping</u></b>					
Yes	Yes	Yes	Yes Yes	Yes	Yes
<b><u>Reverse Cutting</u></b>					
Yes	Yes	No	Yes Yes	Yes	Yes
<b><u>Sterile</u></b>					
Non-Sterile	Non-Sterile	Non-Sterile	Non-Sterile Non-Sterile	Non-Sterile	Yes