BME 361 Term Project - Group 2

03/24/25

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OVERVIEW: SACROILIAC (SI) JOINT

- connects the **sacrum** bone of the spine to the **ilium** bones of the pelvis
- **absorbs shock** during force transmission from the upper body to the hips and legs

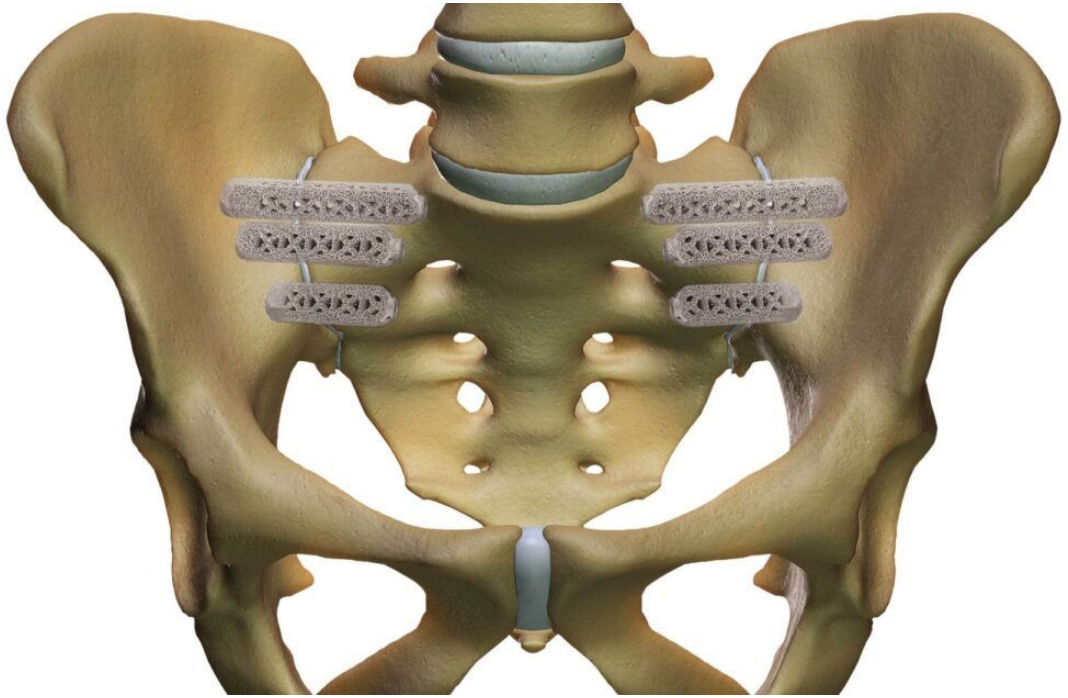
- damage causes pain in the lower back and extremities
- can be a result of injury, arthritis, pregnancy, etc.
- treatment options
  - spine injection
  - radiofrequency ablation on nerves
  - SI joint fusion

[1]

OVERVIEW: SI JOINT FUSION

- surgical procedure for patients suffering from SI joint pain that have been unable to find relief from other treatment options

- permanent screw implants secure and compress the sacrum and ilium together
- promotes **bone fusion** over time to **reduce motion** in the SI joint
  - motion causes pain and inflammation



[2]

OVERVIEW: SI FUSION SCREWS

- orthopaedic implant

- maximize fixation
- promote osseointegration
- enhance mechanical stability
- minimize surgical risks

[3]

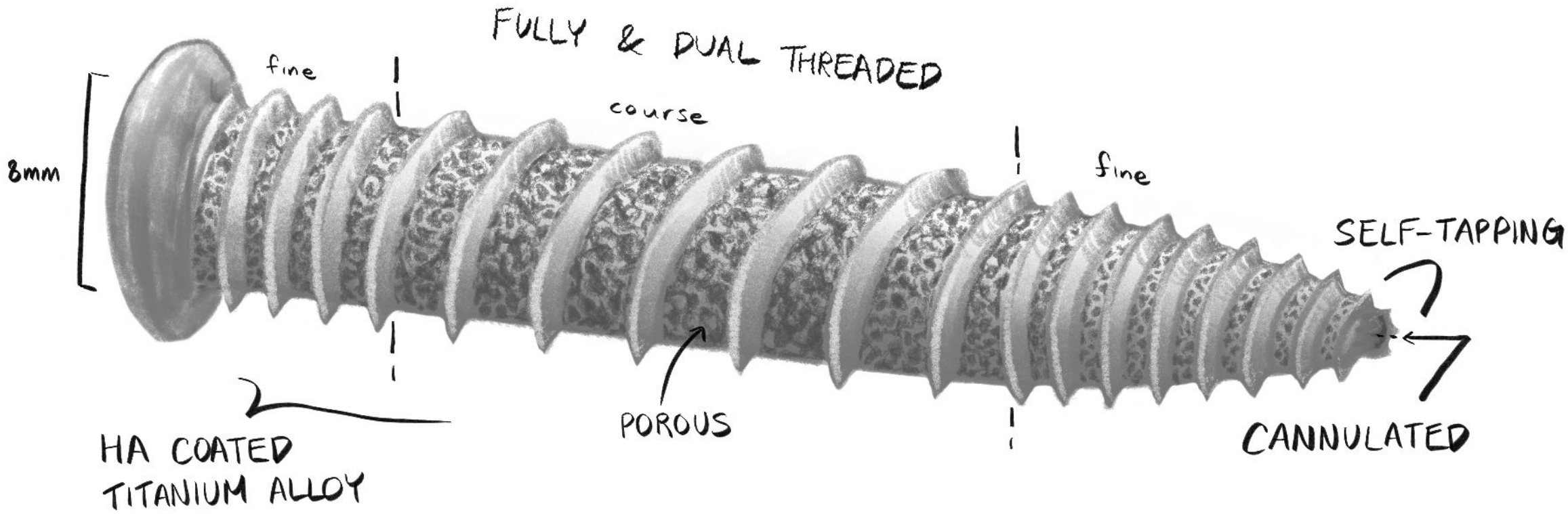
OVERVIEW: SI FUSION SCREWS

- **titanium alloys**: mechanical compatibility with bone and long-term biostability
- **fully threaded**: resistance to deformation and high shear strength
- **dual thread**: bone engagement
  - anchors to both dense cortical bone (fine threading) and spongy cancellous bone (coarse threading)
- **self-tapping tips and cannulation**: enhance surgical accuracy and reduce operative time
- **porous structure**: facilitate bone integration
- **hydroxyapatite (HAp) coating**: promote bone growth and lower infection risk
  - chemically similar to bone

partially vs fully threaded [4]

dual thread [5]

OUR PRODUCT



Available with an 8 mm screw diameter and multiple length options.

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Summary of Regulatory Pathway

Product Code: OUR

FDA Classification: Class II

- not high risk
- not life-sustaining
- cannot qualify for HUD, HDE, or De Novo clearances

Selected method: 510(k)

- prove substantial equivalence to existing FDA-cleared devices

- Class II devices are subject to General Controls for Medical Devices
  - QMS guidelines include ISO 13845:2016 and 21 CFR 820
  - no special controls apply to SI fusion screws

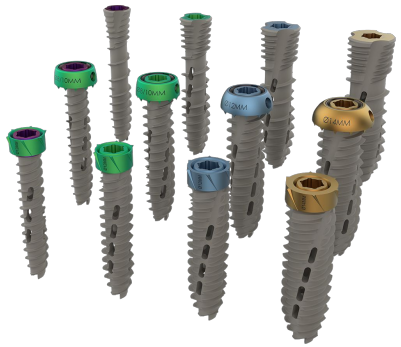
Intended Use Statement

"The proposed device is indicated for sacroiliac joint fusion for sacroiliac joint dysfunction including sacroiliac joint disruption and degenerative sacroiliitis, to augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients."

Predicate Devices

Predicate Devices

- REUNION Sacroiliac Joint Fusion Screw System (K232211)
  - **titanium alloy**, **fully threaded**, **dual threaded**, **cannulated**, **self-tapping**, fenestrated, micro-textured, modular screw head



[6]

- iFuse TORQ Implant System (K241574)
  - **titanium alloy**, **fully threaded**, **dual threaded**, **cannulated**, **porous**, fenestrated, optional washers

[5]

- SI-LOK Sacroiliac Joint Fusion System (K183119)
  - **titanium alloy**, **fully threaded**, **HAp coating**, **cannulated**, fenestrated, washers

[7]

RISK ASSESSMENT

	Potential Hazard	Effects of Hazard	RPN (before/after)	
RISK-01	Allergic reaction to HAp/other materials	Adverse reactions requiring removal	8	2
RISK-02	Implant fails to integrate properly	Implant loosens and loses efficacy	9	9
RISK-03	Complications during implant removal	Threading and excess force damages bone	12	6
RISK-04	Physical and chemical contaminants	Adverse reactions requiring removal	12	8

USER NEEDS & DESIGN INPUTS: SOURCES

	User Need	Design Input
PR-01-01	ASTM F543	Stevenson University
PR-01-02	ASTM F543, ASTM F3574-22	BMC Musculoskeletal Disorders
PR-01-03	ASTM F543, ASTM F3574-22	Journal of Orthopaedic Surgery Research
PR-01-04	ASTM F543	Medical Engineering & Physics
PR-01-05	ASTM F3574-22	ASTM F3574-22
PR-02-01	ASTM F543	AO Foundation
PR-02-02	Applied Sciences	Applied Sciences
PR-02-03	World Biomaterials Congress	World Biomaterials Congress
PR-03-01	ASTM F543	
PR-03-02	Bioactive Materials	Bioactive Materials
PR-03-03	Int J Advanced Manufacturing Tech	Int J Advanced Manufacturing Tech
PR-04-01		Int J of Biomed Eng Technol
PR-04-02	Archives of Orthopaedic and Trauma Surgery	Archives of Orthopaedic and Trauma Surgery
PR-04-03	Journal of Orthopaedic Surgery Research	Journal of Orthopaedic Surgery Research

USER NEEDS & DESIGN INPUTS: REGULATORY

PR-01-01	PR-01-02	PR-01-03	PR-01-04	PR-01-05
Implant must have sufficient strength to resist breakage under stress.	Implant must not be easily loosened.	Implant must allow easy insertion.	Implant's self-tapping must demonstrate significant benefit.	Implant must resist mechanical failure over time.
Must have a breaking angle of at least 1 rad, or 57.3°*.	Must be able to withstand an axial pullout force of at least 1700 N.	Must have an insertion torque under 5 Nm*. *higher threshold allowed due to dual thread	Must have a self-tapping force of at least 0.15 N/mm* at any insertion depth.	Must undergo and withstand cantilever bending fatigue testing of up to 2,500,000 cycles.

***internal value, reconfirm**

USER NEEDS & DESIGN INPUTS: CUSTOMER

PR-02-01	PR-02-02	PR-02-03
Must improve efficiency and accuracy of implantation for surgeons.	Implant must have long-term implant stability for patients.	Implant must effectively integrate into bone.
Self-tapping feature to eliminate pre-drilling. Cannulated design for guidewire.	Fully threaded dual-pitch design to improve bone purchase, control compression, and axial load resistance.	Porous surface & hydroxyapatite coating to promote osseointegration.

USER NEEDS & DESIGN INPUTS: TECHNICAL

PR-03-01	PR-03-02	PR-03-03
Implant must fit within most patients' anatomy.	Implant must promote bone integration.	Implant must promote osseointegration.
All dimensions in mm: Shaft Ø: 4.5±0.2 Head Ø: 8.0±0.5 Head height: 1.9±0.1 Head top Ø: 6.3±0.3	Porosity of 30-40% with a pore size range of 250-300 µm	Must have S_a (roughness parameter) value between 0.200 and 0.500 µm.

USER NEEDS & DESIGN INPUTS: PERFORMANCE

PR-04-01	PR-04-02	PR-04-03
Implant must not loosen over time.	Implant must allow bone ingrowth and prevent fibrous tissue formation.	Implant must ensure sustained joint stability and prevent early loosening.
Must have a minimum axial fatigue life of n=75,000 cycles for an implant depth of 30 mm.	Maximum micro-movement must not exceed 150 μm.	Must retain ≥50% of initial compressive load for an extended period and show controlled load relaxation profile.

TRACEABILITY MATRIX/DESIGN V&V: REGULATORY

	Verification	Validation
PR-01-01	Breaking angle testing as per ASTM F543	Cadaveric/artificial bone testing
PR-01-02	Axial pullout testing as per ASTM F543-17	Cadaveric/artificial bone testing
PR-01-03	Driving torque testing as per ASTM F543-17	Cadaveric/artificial bone testing
PR-01-04	Self-tapping testing as per ASTM F543-17	Cadaveric/artificial bone testing
PR-01-05	Cantilever testing as per ASTM F3574-22	In-vivo animal testing (rat femoral model)
PR-02-01	Self-tapping testing as per ASTM F543-17	Cadaveric/artificial bone testing
PR-02-02	Axial fatigue testing as per paper	Cadaveric/artificial bone testing
PR-02-03	Osseointegration testing as per ASTM F2721-09	In-vivo animal testing (rat femoral model)
PR-03-01	Dimensional inspection	Feedback from surgeons
PR-03-02	Dimensional inspection (porosimetry)	In-vivo animal testing (rat femoral model)
PR-03-03	Dimensional inspection (profilometry)	In-vivo animal testing (rat femoral model)
PR-04-01	Axial fatigue testing as per aper	Cadaveric/artificial bone testing
PR-04-02	Micro-motion testing as per paper	Cadaveric/artificial bone testing
PR-04-03	Compressive load retention testing as per paper	Cadaveric/artificial bone testing

Product Summary

Overview

- SI Joint Fusion Screw treats joint pain
- Self-tapping, fully-threaded, dual-threaded, porous titanium alloy design featuring an HAp coating and a cannulated design

Regulatory Pathway

- OUR, Class II: 510(k) with 3 predicate devices

Product Requirements and Testing

- Risk analysis conducted
- UNDI from standards and publications
- Verification through preclinical mechanical testing
- Validation through cadaver and animal testing

References

[1]https://www.physicianpartnersofamerica.com/medical-services/treatments/sacroiliac-si-joint-fusion/

[2]https://si-bone.com/si-joint-faqs/bilateral-si-joint-fusion

[3]https://utswmed.org/medblog/sacroiliac-joint-fusion-surgery/

[4]https://www.indiamart.com/proddetail/hex-bolt-full-thread-and-half-thread-2046430988.html

[5]https://si-bone.com/si-joint-pain-treatment/ifuse-implant-systems/ifuse-torq

[6]https://asturamedical.com/press-item/astura-medical-receives-fda-510k-clearance-for-the-reunion-sacroiliac-si-joint-fusion-system/

[7]https://www.globusmedical.com/products/si-lok/