



September 2024

# **Safe Harbor**

This presentation contains "forward-looking statements," which are statements related to events, results, activities or developments that Tenon Medical expects, believes or anticipates will or may occur in the future. Forward-looking often contain words such as "intends," "estimates," "anticipates," "hopes," "projects," "plans," "expects," "seek," "believes," "see," "should," "will," "would," "target," and similar expressions and the negative versions thereof. Such statements are based on Tenon Medical's experience and perception of current conditions, trends, expected future developments and other factors it believes are appropriate under the circumstances, and speak only as of the date made. Forward-looking statements are inherently uncertain and actual results may differ materially from assumptions, estimates or expectations reflected or contained in the forward-looking statements as a result of various factors. For details on the uncertainties that may cause our actual results to be materially different than those expressed in our forward-looking statements, please review our 10-K on file with the Securities and Exchange Commission at www.sec.gov, particularly the information contained in the section entitled "Risk Factors." We undertake no obligation to publicly update or revise any forward-looking statements to reflect new information or future events or otherwise unless required by law.



# **Highlights**

## FDA Cleared & Commercially Launched



Catamaran™ Fixation Device

Distinct and Innovative Approach to the Anatomy (inferior-posterior) combined with a unique implant designed to fuse the SI Joint

A Large and Dynamic Market Projected to Deliver 18% + CAGR and reaching SAM of **\$661M by 2028**<sup>1</sup>

A Favorable Reimbursement Environment for the Physician and Facilities

A powerful and expanding Intellectual Property Portfolio protecting critical aspects of systems and methods

Emerging Revision and Adjunct to Multi Level Fusion Applications

#### Critical Clinical Milestone Achieved



PRESS RELEASE

Catamaran SI Joint Fusion System MAINSAIL™ Study:

Six-month clinical outcomes and twelve-month radiographic findings: A prospective, single-arm, multi-center, post-market investigation.

Davies, Matthew et al. / Journal: Expert Review of Medical Devices / August 2024 DOI: 10.1080/17434440.2024.2394168 80% of patients met primary end point at 6 months – statistically significant improvement in VAS scores

Zero device related SAE's

Statistically significant improvement in ODI

93% + patient satisfaction at 6 months

Clear and definitive radiographic proof of remodeled / bridging bone across the joint



MLD061 Rev 0

### Critical Commercial Milestone Achieved



Taking a Unique Approach to SI Joint Procedures!

IMPLANTATIONS TO DATE!

- Utilizing proven AO
   Principles of Arthrodesis
- Single titanium implant that Transfixes the SI Joint
- Stabilization in the long axis of the joint
- Compelling safety profile
- Category 1 CPT coding: 27279 or 27280

MLD053 Rev. 1

To learn more about the Catamaran SI Joint Sytem, visit: www.tenonmed.com/catamaran

Vastly improved safety profile while authentically addressing the SI Joint for fusion

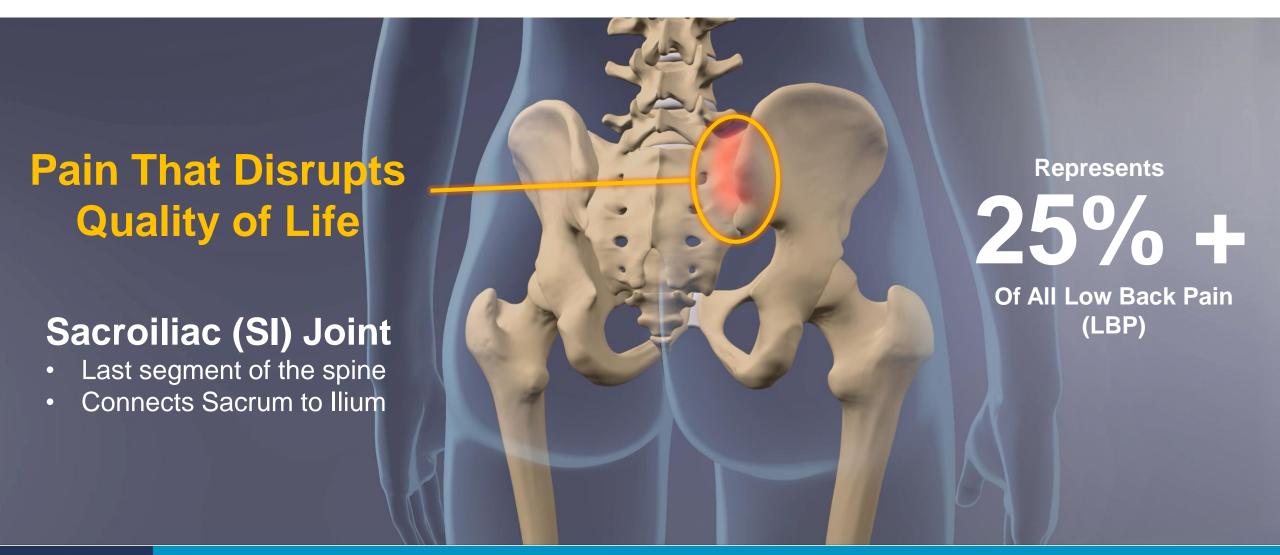
Efficient learning curve – multi-specialty

Backed by peer reviewed data

Does not require adjunct technology

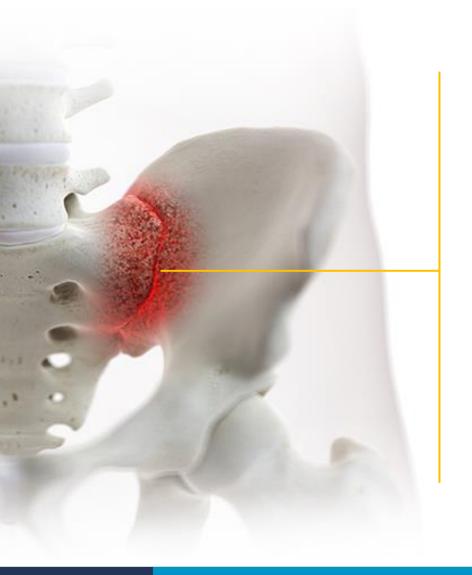


# What Are We Treating?





# Total Addressable Market (TAM) of \$2B +



Global SI Joint Fusion market is estimated to grow to SAM of \$661M by 2028<sup>1</sup>

- 18% + CAGR Driven By:
  - Improved Surgical Approaches
  - Specialized Implant Design
  - Procedure Safety and Efficiency
  - Enhanced Physician Reimbursement
- Physician Recognition Growing:
  - Adoption Rates Remain Relatively Low
  - Physicians Seeking Better Options

# **Competitive Offerings to SI Fusions**

## **Not Without Risks and Complications**

- Up to 16% complication rate at 3 and 6 months (Humana Data)<sup>2</sup>
- "Lateral SI joint fusion is a relatively safe procedure but is not without certain risks and complications."

 "The majority of complications...are user error due to improper placement of implants."

#### Three areas of concern:

- 1. Tissue Disruption
- 2. Superior Gluteal Artery Injury
- 3. Nerve Impingement



# **Limitations to Lateral Approach**

Relatively safe procedure but is not without certain risks and complications.<sup>3</sup>

#### Schoell, et al. 2016<sup>4</sup>

- Source: Humana Claims Data
- 16.4% Overall Complication Rate at 6 Months

#### Rahl, et al. 2022:5

Manufacturer and User Facility Device Experience (MAUDE) database (2011-2020)

- 1,107 Total Complications (130 per year)
  - 99.5% Used Lateral approach
- Estimated 35% Under-reporting







The Spine Journal 16 (2016) 1324-1332

Clinical Study

Postoperative complications in patients undergoing minimally invasive sacroiliac fusion

Kyle Schoell, BA<sup>a</sup>, Zorica Buser, PhD<sup>b,\*</sup>, Andre Jakoi, MD<sup>b</sup>, Martin Pham, MD<sup>c</sup>, Neil N. Patel, MD<sup>b</sup>, Patrick C. Hsieh, MD<sup>c</sup>, John C. Liu, MD<sup>c</sup>, Jeffrey C. Wang, MD<sup>b</sup>

\*Department of Orthopaedic Surgery, Keck School of Medicine, Elaine Survey Hoffman Medical Research Center, University of Southern California, HMR
710, 2017 Zonal Ave, Los Aegles, CA 90033, VI.

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#### PRIMARY RESEARCH

#### Analysis of Complications in Sacroiliac Joint Fusions Using FDA 510(k) Cleared Devices

Michael D. Rahl, MD, Joseph Weistroffer, MD, and Bruce E. Dall, MD

Study Design: This was a level III-retrospective cohort study.

Objective: The objective of this study was to present an unbiased report of the current rate of severe complications for Federal Drug Administration (FDA) 510(k) cleared sacrofilac joint (SIJ) fusions and investigate the underlying cause of these complications.

Summary of Background Data: The number of yearly SIJ fusions is on an upward trend. Currently, the most utilized implants to fruse the SIJ have been FDA 510(k) cleared devices. Studies reporting on complications following SIJ fusions are mostly industry-sponsored.

Materials and Methods: The Manufacturer and User Facility Device Experience (MAUDE) database was searched for all reported FDA 510(k) cleared SJJ fusion device complications. Several data points were obtained from each report and recorded. The Hospital Impatient National Statistics and the Center for Medicare and Medicaid Services (CMS) was also searched for the number of SJJ fusions performed each year.

Results: A search of the MAUDE database returned 1115 reports, with the first report on June 30, 2011, and the last report on June 32, 2020. Patient injury was the most common type of event reported at 97.5% (1080/1107). Death was reported in 3 patients (0.3%), Malphosition was the most common device problem at 49.5% (548/1107). The root cause of these events was primarily user error at 8.52% (644/107). Revision surgery or reoperation occurred in 92.8% (1028/1107) of reports. Data for SU fusions through CMS showed an overall trend of increasing yearly \$21 fusions.

Conclusions: The majority of complications reported to

The prevalence of low back pain originating from the sacrolliac joint (SIJ) is thought to range anywhere from 2½ to 30%. <sup>1-4</sup> The SIJs are mobile in all 3 anatomic planes<sup>3-8</sup> and have been shown to have intra-articular pain generators along with closely associated extra-articular pain generators. <sup>3,10</sup> When conservative treatment for SIJ pain fails, arthrodesis becomes a viable option to reduce or eliminate pain from this joint.

The number of SIJ fusions continues to be on an annually accelerating upward trend. 11.12 There are many techniques and hardware options for fusing the SIJ, with minimally invasive, Federal Drug Administration (FDA) 510(k) cleared implants being the most utilized. The complication rate for minimally invasive SIJ arthrodesis has been reported to be between 0% and 18% 11-14 with revision rates ranging from 0% to 6.3% 1.13-17 The majority of these studies are industry-sponsored and risk varying degrees of bias.

The purpose of this study was to present an unbiased report of the current rate of severe complications for FDA \$10(k) cleared SIJ fusion implants and to investigate the reported underlying cause of these complications. Our typothesis was that most of the reported complications are technical errors, which if true, could potentially be decreased with improved training, education, and oversight in coordination with the major spine research and teaching societies and government institutions.

MATERIALS AND METHODS

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# Lateral Approach – MAUDE Database<sup>5</sup>

#### **Complications:**

- 97.5% Resulted in Patient Injury
  - 34% Impingement & Breeching Neuroforamen

#### **Device Problem:**

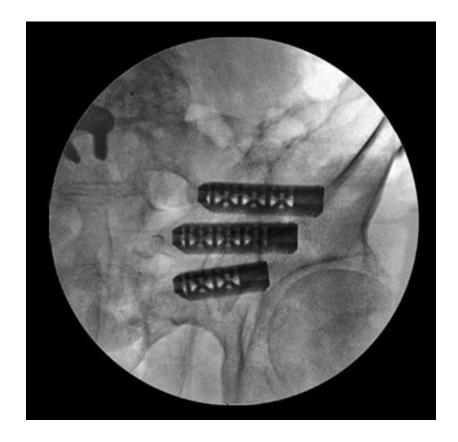
49.5% Malposition

#### **Root Cause of Device & Patient Injury:**

58.2% Technical Error

#### **Overall:**

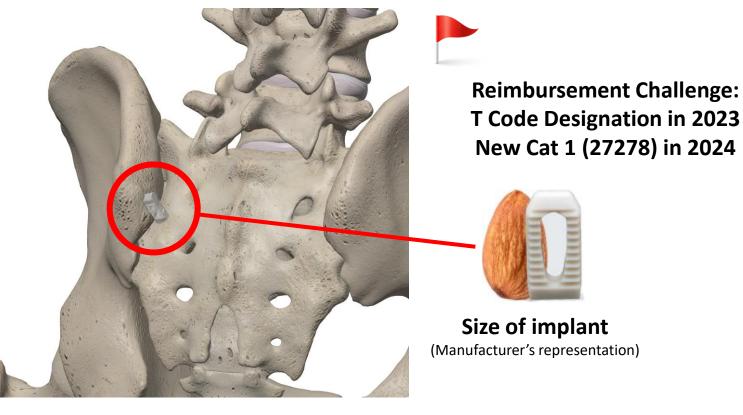
92.8% Required Revision Surgery



Each placed implant is an opportunity for misplacement and complication.



# **Dorsal Approaches – In Dorsal Recess**



"Implants placed through the ligamentous portion of the joint span a larger intraarticular distance, decreasing the chance for bony bridging across the joint and decreasing implant purchase."

- Cognetti 2021



Failed dorsal fusion. Revised with Catamaran



Inferior-Posterior Approach

Catamaran™ SI Joint Fusion System

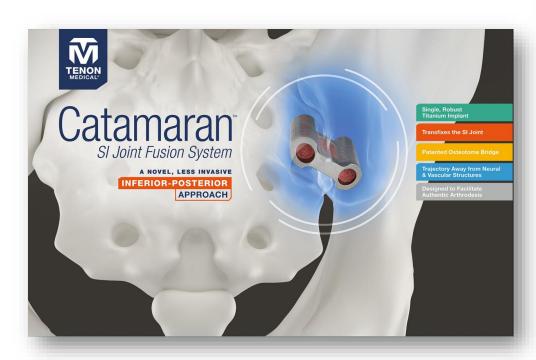


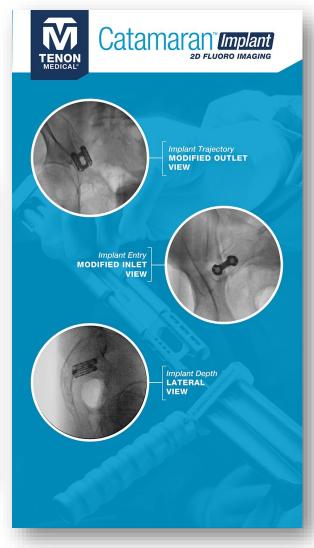


# A Better Option for SI Joint Fusion

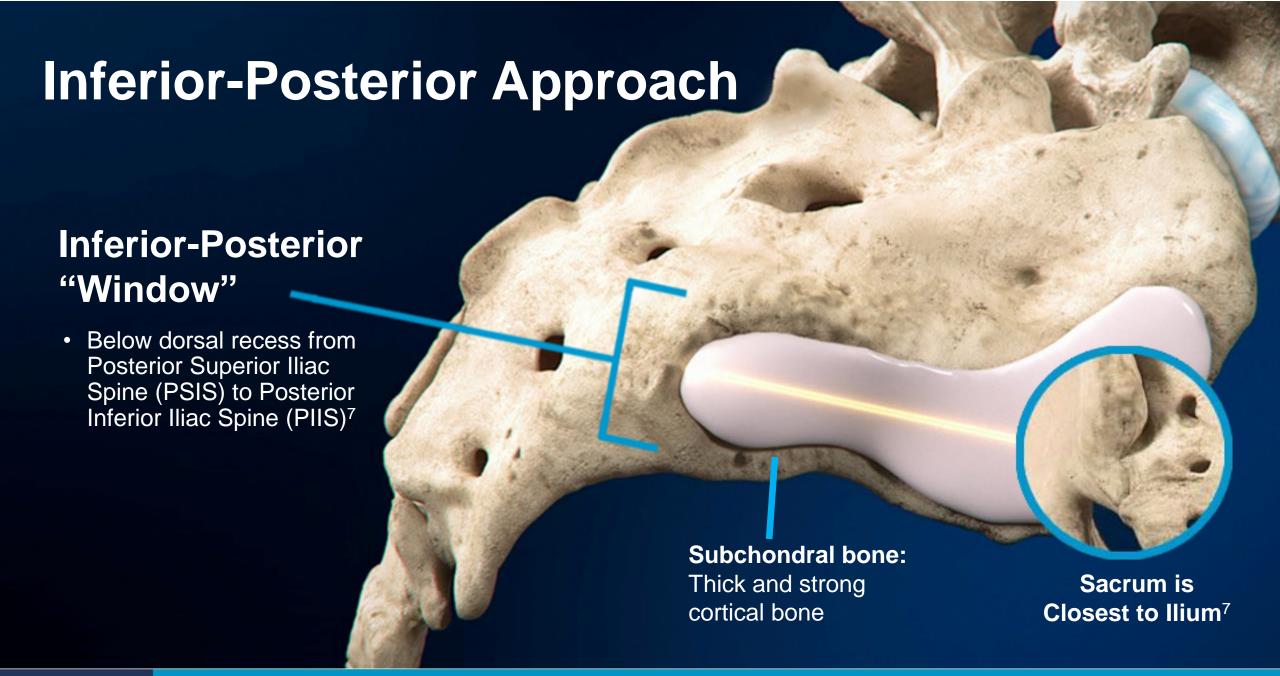
# The Catamaran® SI Joint Fusion System

- Optimized surgical approach for SI Joint Fusion
- A specifically designed titanium implant & delivery tools for surgery via a less invasive inferior-posterior approach
- Single implant surgery
- Transfixes the sacrum & the ilium to stabilize the joint
- Implant filled with autologous bone

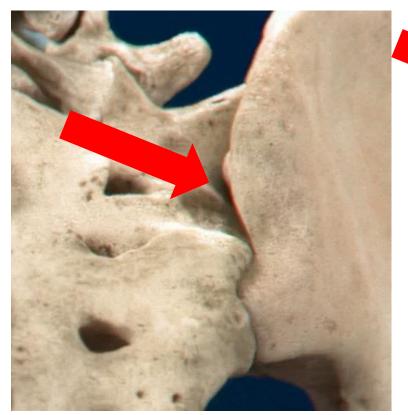








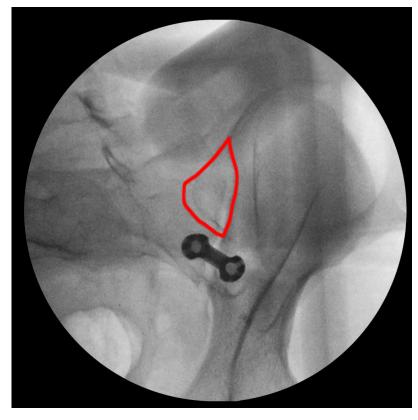
# Inferior-Posterior: Avoid Dorsal Recess



Variable Region Superior to Articular Surface of SI Joint



Dorsal Recess as Seen Under Navigation

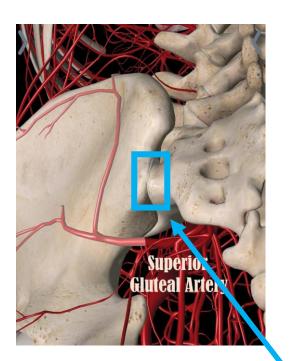


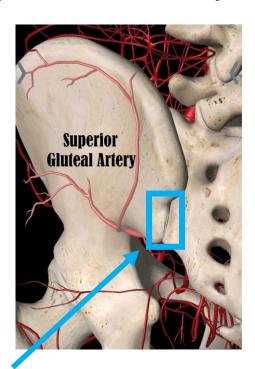
Placement of Catamaran Below Dorsal Recess



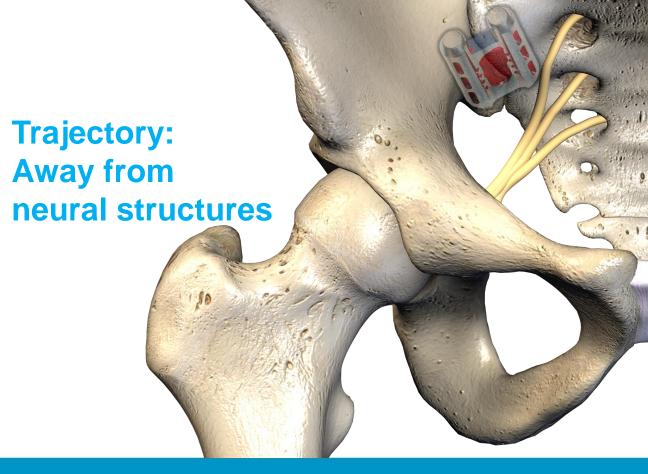
Trajectory: Away from Key Vascular & Neural Structures

**Entry point avoids Superior Gluteal Artery** 



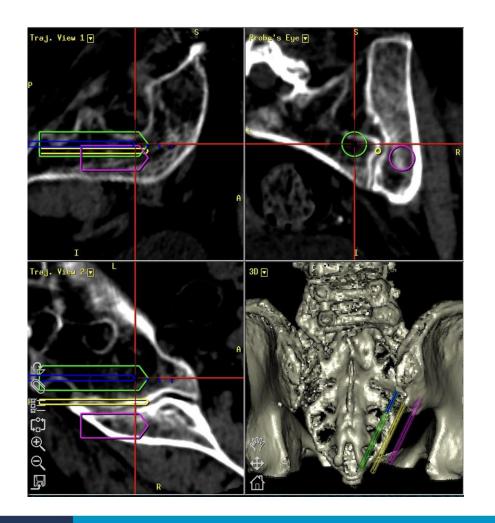


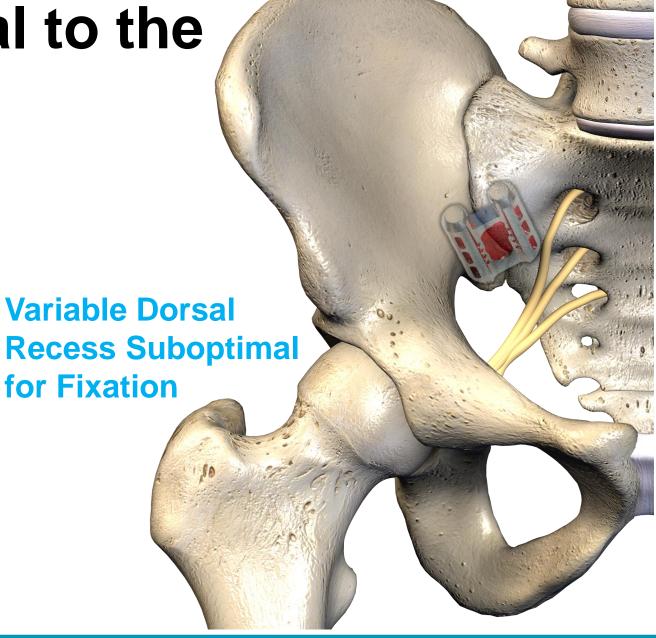
**Catamaran Entry Point** 





Placement Ventral to the Dorsal Recess

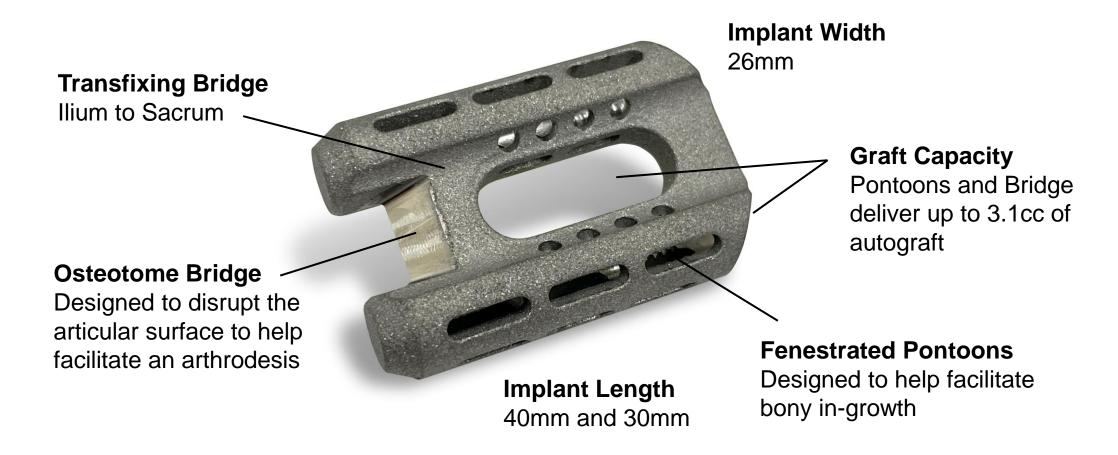






# Catamaran® SI Joint Fusion System

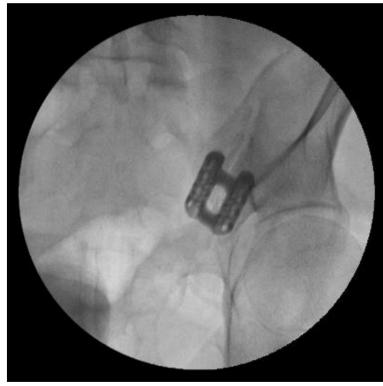
Robust, Single, Titanium Implant





# **Catamaran Final Placement**







**Modified Inlet View** 

**Modified Outlet View** 

Lateral View



#### **SI Revision**

Significant data emerging that (as expected) intra articular bone procedures lack adherence to principles of arthrodesis and do not heal / fuse. Patients are returning for further care in the 8-to-24-month time frame:

- 1. Inferior Posterior Approach Ideal?
- 2. No Extraction of Bone Implant Required?
- 3. No Imaging Issues / Challenges?

"The fastest and safest way I've found to revise failed intra articular procedures" Mark Stouffer, MD

#### Case Stud

# Failed intraarticular implant revised with Catamaran SI Joint Fusion System

Mark Stouffer, MD-St. George Orthopedic Spine, St. George, UT

#### **Patient History**

The patient is a 67-year-old female with long-standing low back pain on her right side. She was seen and evaluated at another clinic and diagnosed with sacroillits of the right sacroilliac (S1) joint. She was identified as a candidate for right S1 joint surgery and underwent a fixation procedure using a dowel made of human cortical bone (SiLO, Aurora Spine). She reported approximately one month of relief before her pain returned with increasing intensity. Her pain was then exacerbated by a fall. She was treated nonoperatively, including physical therapy and injection of the right S1 joint, but without reliefs. She was then referred to me.

#### **Patient Examination and Diagnosis**

On physical examination, the patient demonstrated positive Fortine Finger sign with tenderness to palpation at the site, positive FABER's exam of the right SI joint, positive right thigh thrust exam, and positive compression of the right SI joint. These results, combined with the patient's history of right-side low back pain that worsened with change in position from sitting to standing, and difficulty sleeping indicated that the right SI joint was the source of her pain. Repeat diagnostic injection of the right SI joint gave 100% relief for the first 90 minutes, confirming the right SI joint as the pain generator.

CT SCANS (Figure 1A and 1B)
DEMONSTRATE RADIOLUCENCY AROUND THE BONE DOWE





# Catamaran Revision of Lateral Screws Catamaran® SI Joint Fusion System









Inlet

Outlet Lateral

# Adjunct to Multi – Level Lumbar Fusion

(High Acuity)

Expanding and active discussion / debate in the complex spine surgery community:

Stabilizing and Fusing the SI Joint as an Adjunct to Long Construct

**Biomechanical Considerations** 

**Grafting Considerations** 

**Stand-Alone Option** 

Protection of Al Hardware (short term)

True Fusion of the SI Joint (long term)

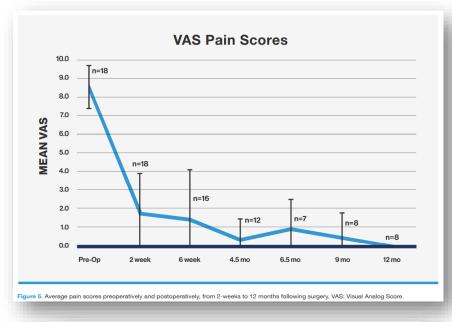


# Patient Outcomes – The Catamaran Fusion System

Early clinical experience has shown Catamaran via an Inferior-Posterior approach has the potential to deliver significant & sustained reduction in SI Joint Pain, as well as:

- Minimal Blood Loss & Fluoroscopy Time
- Reduced Post-Op Pain
- Rapid Reduction in Pain Medications
- Insertion Pathway away from Neural and Vascular Structures
- Known Approach for Physicians
- Ideally Suited for ASC / Outpatient

# Significant Reduction in SI Joint Pain (VAS)<sup>1</sup>







# Post Market Clinical Research Plan

# **Strategic 50 Patient Trial**

- Prospective, multi-center, single arm
- IRB Controlled
- Patients followed 24 months

# Nearing Enrollment Completion

- Preliminary data shows primary end points trending in a positive direction
- Preliminary secondary endpoint (12 months CT) showing fusion

#### PRESS RELEASE

#### Tenon Medical Receives Institutional Review Board Approval for Two Post Market Studies with the Company's Catamaran™ SI Joint Fusion System

~ WCG IRB approves Catamaran studies that will assess patient pain scores, fusion and other patient reported outcomes out to 12 and 24 months ~

LOS GATOS, Calif. – October 25, 2022 - Tenon Medical, Inc. ("Tenon" or the "Company") (NASDQ: TNON), a company transforming care for patients suffering with certain sacroiliac joint disorders, today announced Institutional Review Board (IRB) approval from WCG IRB for two separate Tenon-sponsored post market clinical studies of the Company's Catamaran SI Joint Fusion System. The approval by WCG now allows designated Catamaran study centers to begin recruiting and enrolling patients into the respective studies.

The first approval from WCG IRB will support a prospective, multi-center, single arm post market study that will evaluate the clinical outcomes of patients with sacroiliac joint disruptions or degenerative sacroilitis treated with the Catamaran SI Joint Fusion System. Patients will be followed out to 24 months assessing various patient reported outcomes, radiographic assessments, and adverse events.

The second prospective, multi-center, Catamaran study will evaluate 6-to-12-month radiographic outcomes to assess fusion of patients that have already undergone treatment with the Catamaran SI Joint Fusion System. In addition, retrospective and prospective clinical outcomes will be evaluated.

"We are excited to have received IRB approvals from WCG IRB for our Catamaran clinical study protocols. This approval allows selected centers to move efficiently to enrollment initiation." states Steven M. Foster, President, and CEO of Tenon. "Our investment in these two important studies shows continued commitment in validating and differentiating patient outcomes and radiographic assessment when utilizing a single, titanium Catamaran fixation device from an Inferior-Posterior approach to treat SI joint disruption and degenerative sacroilitis."

#### About Tenon Medical, Inc.

Tenon Medical, Inc., a medical device company formed in 2012, has developed The Catamaran™ SI Joint Fusion



# Definitive Radiographic Confirmation of Fusion

12 Months Post-Op



Preliminary Fusion Results Based on Independent Radiologist Review

MLD047 Rev. 0



# Definitive Radiographic Confirmation of Fusion

## 20 Months Post-Op



Modified Inlet Slice 1



Modified Inlet Slice 2



# Reimbursement: Disruptive in our Favor

#### 2024 Physician and Facility Billing Guide Sacroiliac Joint Fusion

PHYSICIAN CURRENT PROCEDURAL TERMINOLOGY CPT®										
CPT/ HCPCS	Description	Total Facility RVUs	Total Non-Facility RVUs	Medicare Physidan Fee						
				Facility	Non-Facility					
27278	Arthrodesis, sacrolliac joint, percutaneous, with image guidance, including placement of intraarticular implants(s) (eg. bone allograft(s), synthetic device(s)), without placement of transfixation device	14.03	364.53	\$459	\$11,936					
27279	Arthrodesis, sacrolliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device		N/A	\$791	N/A					
27290	Arthrodesis, open, sacrolliac joint, including obtaining bone graft, including instrumentation, when performed	41.14	N/A	\$1,347	N/A					

#### HOSPITAL OUTPATIENT AMBULATORY PAYMENT CLASSIFICATION (APC) & AMBULATORY SURGERY CENTER (ASC)

		HOSPITAL OUTPATIENT			ASC			
CPT* Code	Description	APC	Group Title	SI	CY 2024 National Medicare Average Payment	PI	Payment	
27278	Arthrodesis, sacrollac joint, percutaneous, with image guidance, including placement of intraarticular implants(s) (eg. bone allograft(s), synthetic device(s)), without placement of transfixation device	5116	Level 6 Musculoskeletal Procedures	JI	\$17,756	J8	\$11,684	
27279	Arthrodesis, sacrolliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed and placement of transfixing device implantable/insertable device, not otherwise classified	5116	Level 6 Musculoskeletal Procedures	JI	\$17,756	Je	\$14,703	
27290	Arthrodesis, open sacroilliac joint including obtaining bone graft, including instumentation when performed	INPATIENT-ONLY						

In the hospital outpatient prospective payment system (OPPS) CMS assigns all CPT and HCPCS codes a status indicator (Si) to indicate if and how a service is reimbursed. In Ambulatory Surgical Center (ASC), CMS assigns CPT and HCPCS codes a Payment indicators (Pi) to indicate how payment is determined. Below is a list of Sis, Pis, and abbreviations used in this guide and their definitions:



J1 - Paid under OPPS; all covered Part B services on the claim are packaged with the primary "J1" service for the claim, except services with OPPS SI-F, G, H, L and U. Note: in the ASC, comprehensive APCs do not apply; procedures are paid separately if applicable.

<sup>.8 -</sup> Device-Intensive procedure added to ASC list in CY 2008 or later, paid at adjusted rate.

# Compelling Benefits to all Stakeholders



#### **Patients**

- Safe and efficient outpatient procedure
- Reduced post-op pain
- Reduced revision requirements
- Robust titanium implant



#### **Physicians**

- More efficient single-implant procedure
- High procedural success
- Emotionally rewarding
- Radiographic confirmation of fusion
- Reimbursement flexibility



#### **Payors**

- Proven diagnostic protocol to ensure patient will likely benefit from the procedure
- Fewer complications quicker recovery
- May reduce overall and longterm patient cost to payors
- True same day / outpatient (optimized for ASC setting)



#### Hospitals

- An established procedure with an increased revenue stream through facility payments
- Access a large pool of new patients who do not qualify for minimally invasive SIJ reimbursement
- Competitive differentiation



# Strong And Expanding IP Position



Eight (4 US, 4 OUS) issued

Eighteen (18 US, 2 OUS) pending

Broad range of claims including an inferior - posterior approach to

Sacroiliac Joint Fusion



Claims directed to systems and methods



Additional patents pending OUS



Developing new cases to expand claims



# **Experienced Management Team**

Track Record of Building Successful MedTech Companies









**Richard Ferrari,**Founder, Executive Chairman



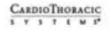
















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