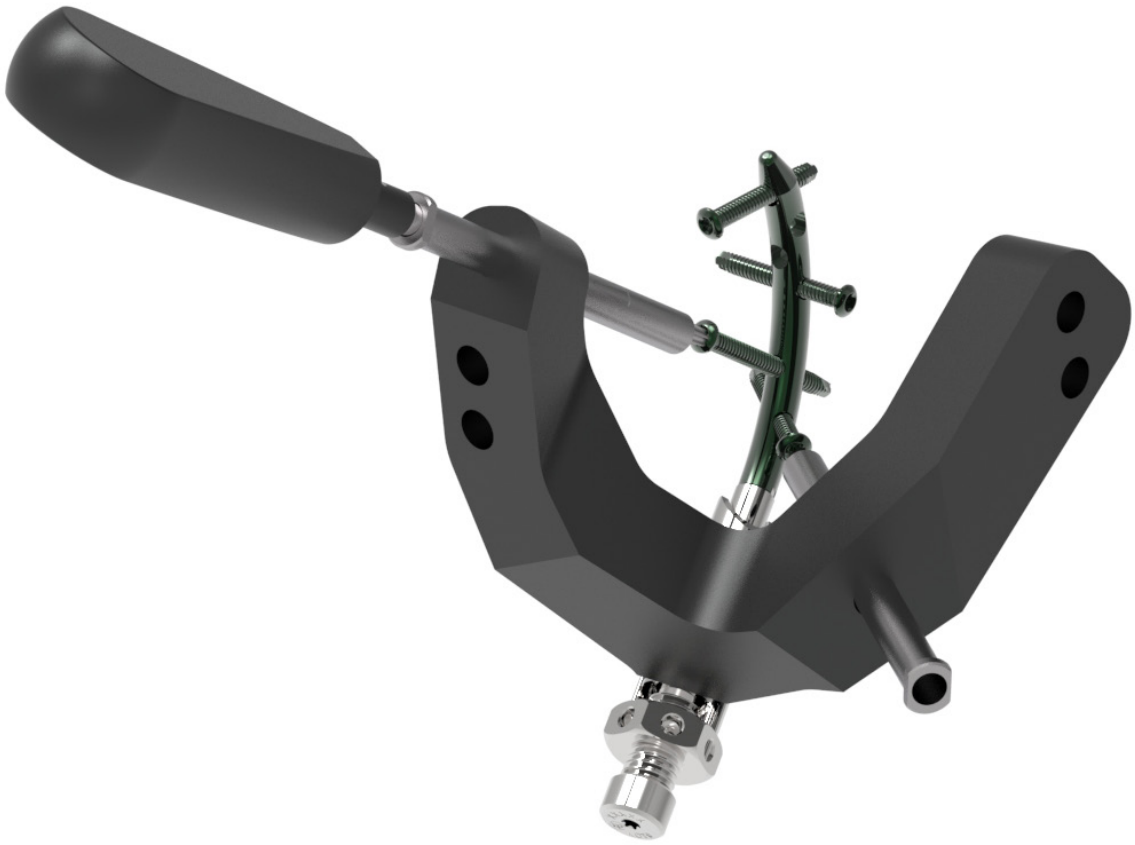
Shotel

Value Analysis Resource Guide

Shotel Ankle Arthrodesis Nail System



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About Us

Shotel Medical

Shotel Medical is the developer of the Shotel™ Ankle Arthrodesis Nail System, an entirely novel device that has the potential to transform patient care and significantly impact the healthcare landscape. Developed in conjunction with a team of biomechanical engineers, orthopedic surgeons and industry thought leaders, the device addresses the needs of patients with end-stage ankle arthritis. Its unique design provides patients with faster healing, earlier return to function, and improved quality of life compared to current treatment options. The company, founded in 2017, has offices in New Orleans and Atlanta.

BioPro, Inc

Founded as a research and development company for world-renowned surgeon, Charles Townley, MD, BioPro has been designing, developing, and manufacturing medical devices dating back to 1987. BioPro's mission is to improve the quality of life for patients needing orthopedic surgery through the design, development, manufacturing and distribution of quality orthopedic products and services. As an FDA registered and ISO certified manufacturer, BioPro designs, develops, manufactures, and distributes products for companies across the globe.

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Product Overview & Benefits

The Problem: Existing fixation options for ankle arthrodesis fall short of ideal, resulting in higher complication rates, large incisions and prolonged periods of immobilization.

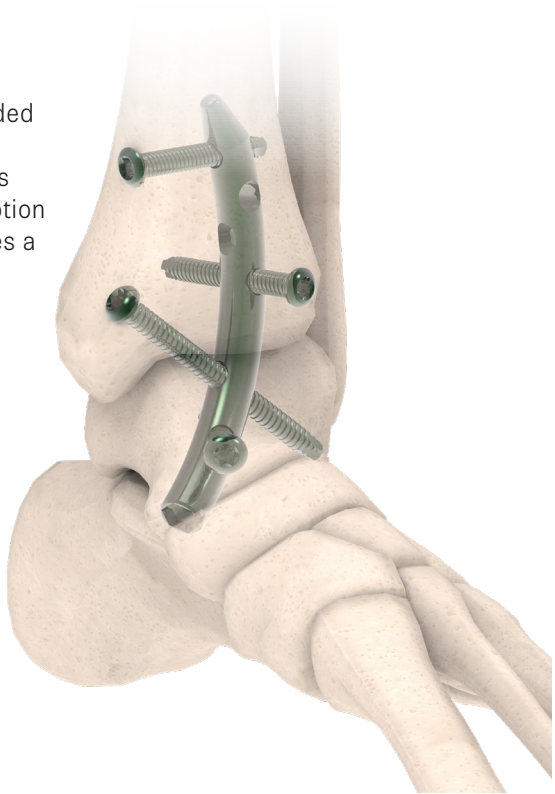
Ankle arthrodesis is still treated as the gold standard for treatment of end stage arthritis although nonunion occurs in approximately 12% (range: 3–23%) of ankle arthrodesis procedures and may occur more frequently in patients presenting with risk factors.[1] The current fixation options include tibiotalocalcaneal (TTC) intramedullary nails, plate +screw constructs and cannulated cross screws.

- Tibiotalocalcaneal (TTC) Intramedullary Nails fuse both the tibiotalar (ankle) joint and talocalcaneal (subtalar) joint through insertion of a nail in the plantar aspect of the heel. The average time of union for this procedure is 4.5 months with complications seen in 55% of cases.[2] Due to the insertion point, in some cases it requires fusion of a healthy subtalar joint which would not be required with other fixation constructs. Additionally, plantar incisions can be a cause of concern, especially with diabetic patients.
- New plate and screw fixation constructs are designed specifically to fuse the tibiotalar joint, however, have seen a much higher complication and infection rate[3] compared to intramedullary nailing and screws due to large incisions required for implantation. Additionally, these constructs don't allow early weight bearing.
- Cross cannulated screw constructs allow for minimally invasive implantation, however, lack the stability of intramedullary nailing.[4] This lack of stability may alter alignment and lead to much longer non-weight bearing periods for the patient.

The current solutions on the market may drive up healthcare costs and lead to unsatisfied patients.

The Solution: The Shotel Ankle Arthrodesis Nail

The Shotel™ Ankle Arthrodesis Nail System is an intramedullary (IM) nail intended to provide compression and rigid fixation for primary ankle fusions. The unique curved design allows an approach through the medial aspect of the talus and is designed to achieve fusion at the tibiotalar joint while allowing unrestricted motion to remain at all other joints. The Shotel™ Ankle Arthrodesis Nail System provides a minimally invasive surgical option that may allow early weight bearing.



- The only intramedullary nail specifically designed for ankle fusions
- Minimally invasive surgical approach
- Maintains motion at the talocalcaneal (subtalar) joint
- Intramedullary nail construct improves stability over plates and screws

Indications & Contraindications

The Shotel™ Ankle Arthrodesis Nail System is intended for use for the following indications:

- Charcot Foot
- Avascular necrosis of the talus
- Failed total ankle arthroplasty
- Trauma (malunited tibial pilon fracture)
- Severe deformity or instability as a result of talipes equinoivarus, cerebral vascular accident, paralysis or other neuromuscular disease
- Revision ankle arthrodesis
- Neuroarthropathy
- Rheumatoid arthritis
- Osteoarthritis
- Pseudoarthrosis
- Post-Traumatic arthrosis
- Previously infected arthrosis
- Severe end stage degenerative arthritis
- Severe defects after tumor resection
- Pantalar arthrodesis

Contraindications

- Dysvascular limb
- Active infection
- Severe longitudinal deformity
- Insufficient plantar heel pad
- Where an isolated ankle or subtalar fusion can be performed
- Patient conditions including blood supply limitations and insufficient quantity and quality of bone
- Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions
- Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation of the device

Possible Adverse Effects

- Loosening, bending, cracking, or fracture of the nail or screws or loss of fixation in bone attributable to nonunion
- Loss of anatomic position with nonunion or malunion with rotation or angulation
- Infection, both deep and superficial
- Allergies and other reaction to the device material

Contact surgeon if a change in performance or pain level is noticed.

MR Safety Information
Warning: The Shotel Ankle Arthrodesis Nail has not been evaluated for safety and compatibility in the MR environment and has not been tested for heating or migration in the MR environment. The safety of the device in the MR environment is unknown. Scanning patients who have these devices may result in patient injury.

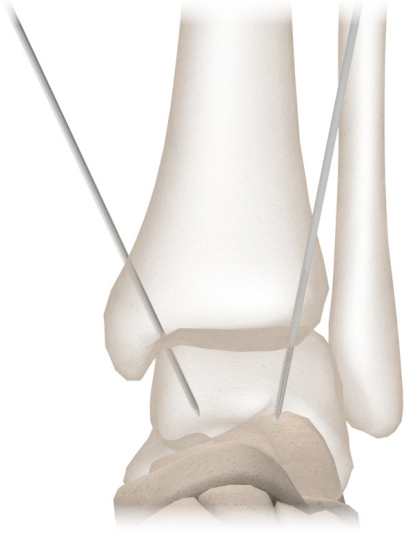
Implant Options

Nails
9mm diameter nails manufactured from medical grade titanium alloy (Ti-6Al-4V ELI).

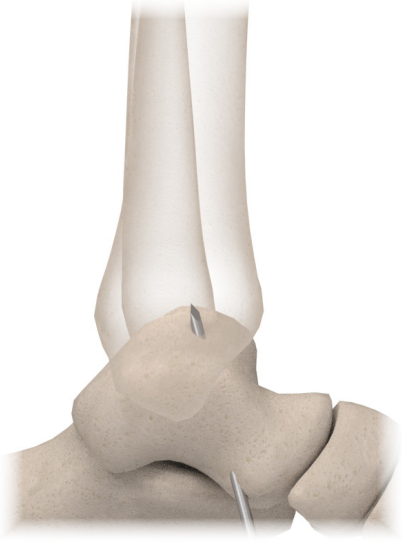
Screws
5mm diameter screws are available in lengths ranging from 20 to 80mm and manufactured from medical grade titanium alloy (Ti-6Al-4V ELI).

Surgical Technique

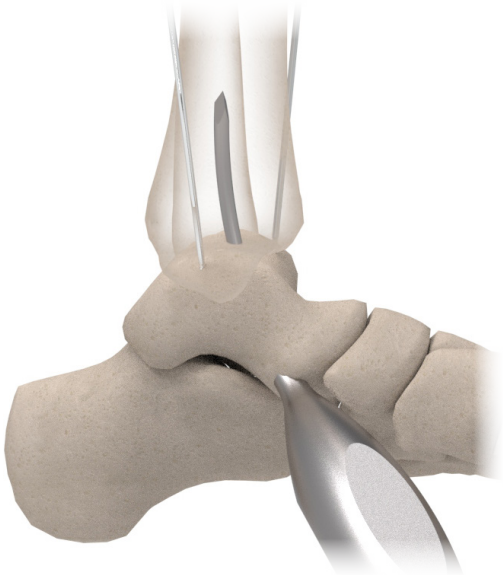
The following is an abbreviated technique. Please refer to the surgical technique for complete details.



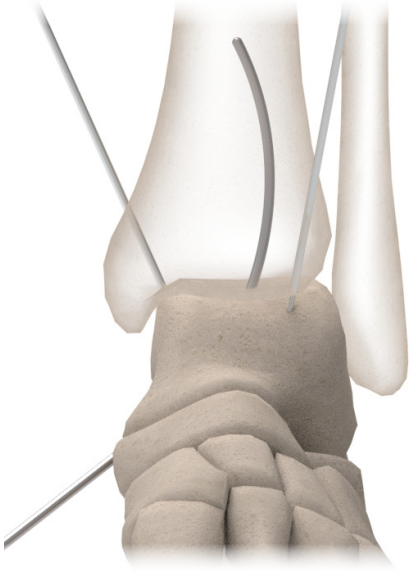
Step One
Secure temporary fixation with 2.4mm pins with the joint in optimal position for fusion.



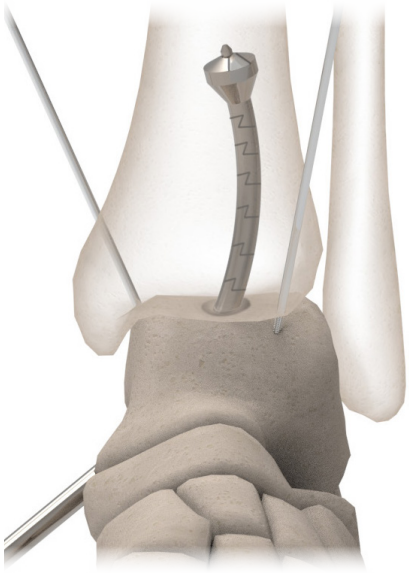
Step Two
Initiate the entry portal at the insertion site using the straight entry awl.



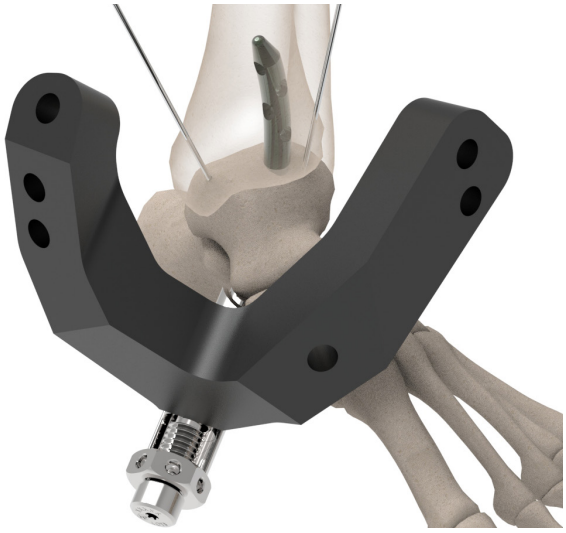
Step Three
Mallet the curved trocar across the joint line into the tibia creating a curved pathway.



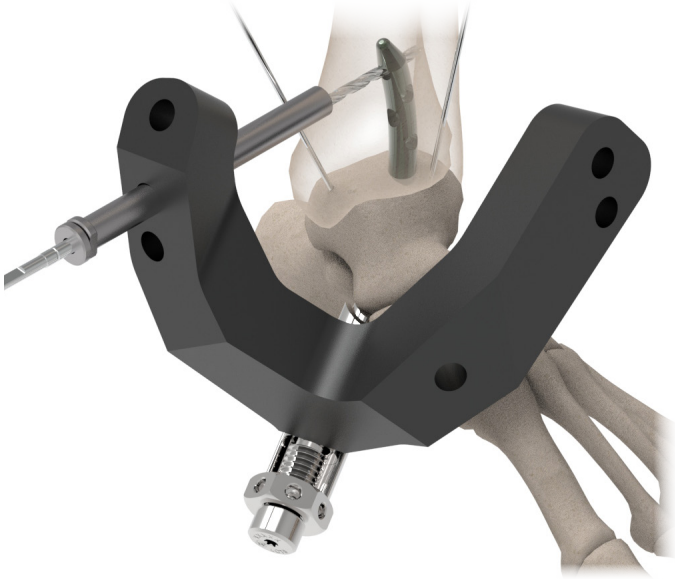
Step Four
Insert the rigid stainless steel guide wire into the prepared curved pathway.



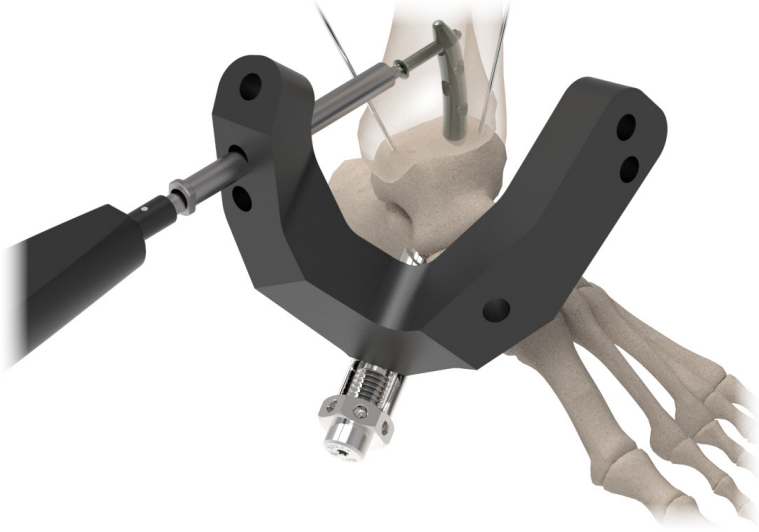
Step Five
Enlarge the pathway diameter using the appropriate sized flexible reamer.



Step Six
Insert the appropriate size Shotel Nail.



Step Seven
Insert the three piece drill sleeve assembly (trocar/drill sleeve/screw sleeve) through the desired hole in the drill guide. Drill the screw hole to the appropriate depth and then measure with the provided depth gauge.



Step Eight
Insert the appropriate length screw into the drill hole. Complete the construct. Remove the Drill Guide and insert a Nail Cap.

A New Technique For Tibiotalar Arthrodesis: Shotel Ankle Arthrodesis Nail System

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SurgiColl. 2023;1(4). doi:10.58616/001c.90445

Objectives
This study aimed to present the short-term outcomes of tibiotalar joint arthrodesis using the Shotel ankle arthrodesis nail system.

Methods
10 patients underwent ankle arthrodesis using the new nail system between 2021 and 2022 due to advanced arthritis. Patients were followed up for a mean of nine months. Outcomes were assessed using metrics such as radiographic union, pain, and patient-reported outcomes questionnaires. We explained a stepwise description of a novel technique for isolated tibiotalar ankle arthrodesis using a curved nail. We also presented our postoperative protocol, including weight-bearing and rehabilitation protocol.

Results
The union rate was 100% after a mean time of nine months of follow-up. There were no complications related to the hardware requiring revision or removal. Pain was measured with a visual analog scale and improved from a mean of 6.7 to 4.2.

Conclusion
Patients undergoing tibiotalar arthrodesis using the Shotel nail have acceptable outcomes. Considering this technique as a minimally invasive intervention, we believe that soft tissue complications are less than conventional open techniques

Ordering

Fusion Nails

ITEM#	DESCRIPTION	QTY
21406	9MM FUSION NAIL, LEFT	2
21409	9MM FUSION NAIL, RIGHT	2

Nail Caps

ITEM#	DESCRIPTION	QTY
21433	9MM NAIL CAP	2

Sterile Accessories

ITEM #	DESCRIPTION
21674	STEINMANN PIN SINGLE TROCAR 12" 2.4 MM
22687	CURVED GUIDE WIRE SS
22390	FLEXIBLE REAMER WITH MULTIPLE FLUTE TIP, 10.5 MM
21659	4.2 MM DRILL BIT

Bone Screws

ITEM	# DESCRIPTION	QTY
21611	5 MM BONE SCREW X 20 MM	4
21612	5 MM BONE SCREW X 22 MM	4
21613	5 MM BONE SCREW X 24 MM	4
21614	5 MM BONE SCREW X 26 MM	4
21615	5 MM BONE SCREW X 28 MM	4
21352	5 MM BONE SCREW X 30 MM	4
21353	5 MM BONE SCREW X 32 MM	4
21354	5 MM BONE SCREW X 34 MM	4
21355	5 MM BONE SCREW X 36 MM	4
21356	5 MM BONE SCREW X 38 MM	4
21357	5 MM BONE SCREW X 40 MM	4
21358	5 MM BONE SCREW X 42 MM	4
21359	5 MM BONE SCREW X 44 MM	4
21360	5 MM BONE SCREW X 46 MM	4
21361	5 MM BONE SCREW X 48 MM	4
21362	5 MM BONE SCREW X 50 MM	4
21363	5 MM BONE SCREW X 52 MM	4
21364	5 MM BONE SCREW X 54 MM	4
21365	5 MM BONE SCREW X 56 MM	4
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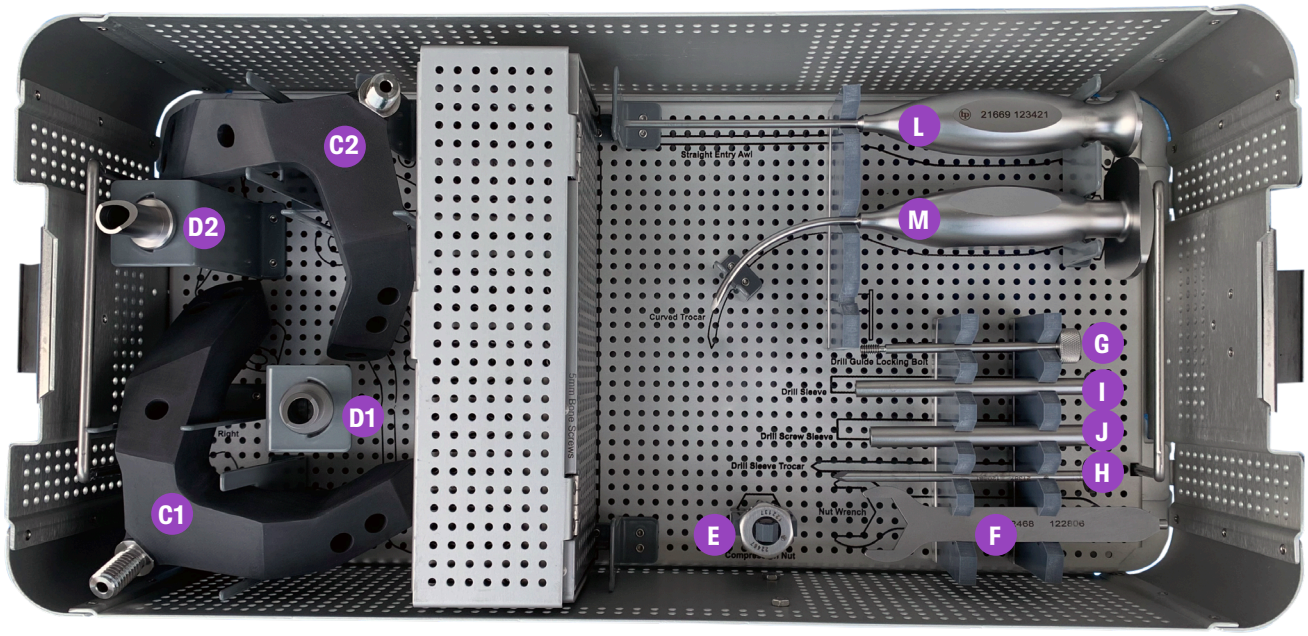
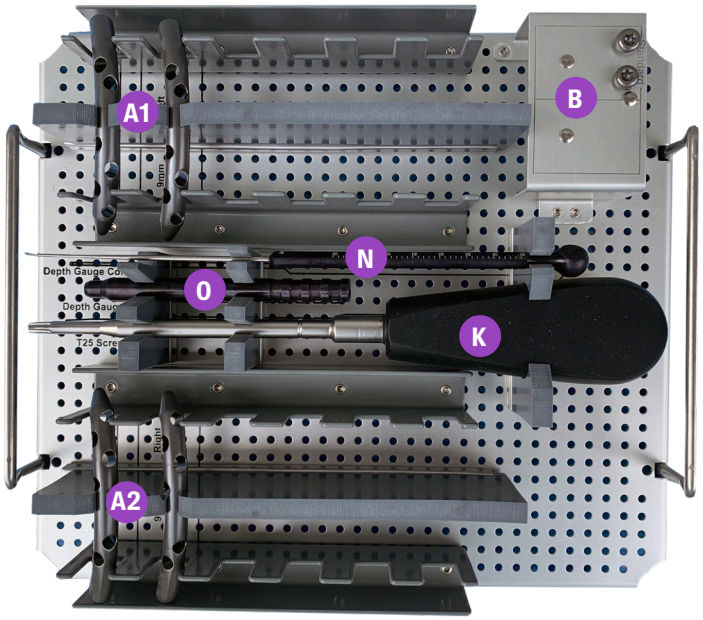
21370	5 MM BONE SCREW X 66 MM	4
21371	5 MM BONE SCREW X 68 MM	4
21372	5 MM BONE SCREW X 70 MM	4
21616	5 MM BONE SCREW X 72 MM	4
21617	5 MM BONE SCREW X 74 MM	4
21618	5 MM BONE SCREW X 76 MM	4
21619	5 MM BONE SCREW X 78 MM	4
21620	5 MM BONE SCREW X 80 MM	4

Instrument Kit

SHOTEL IMPLANT & INSTRUMENT KIT - 22909



LOCATION	QTY	ITEM #	DESCRIPTION
A1	2	21406	9MM FUSION NAIL LEFT
A2	2	21409	9MM FUSION NAIL RIGHT
B	2	21433	9MM FUSION NAIL CAP
C1	1	22837	DRILL GUIDE, RIGHT-CF
C2	1	22834	DRILL GUIDE, LEFT-CF
D1	1	22840	COMPRESSION SLEEVE, RIGHT-CF
D2	1	22839	COMPRESSION SLEEVE, LEFT-CF
E	1	22467	COMPRESSION NUT
F	1	22468	NUT WRENCH
G	1	22841	DRILL GUIDE LOCKING BOLT-CF
H	1	21387	DRILL SLEEVE TROCAR
I	1	21388	DRILL SCREW SLEEVE
J	1	21658	DRILL SLEEVE
K	1	21390	T25 SCREW DRIVER
L	1	21669	STRAIGHT ENTRY AWL
M	1	22684	CURVED TROCAR
N	1	22411	DEPTH GAUGE ASSEMBLY
O	1	22410	DEPTH GAUGE BODY



Reimbursement

Outpatient Reimbursement		National Medicare Average	
CPT Code	Description	Hospital Outpatient	Ambulatory Surgical Center
27870	Arthrodesis, ankle, open	$12,539	$9,293

Physician Reimbursement		National Medicare Average
CPT Code	Description	Payment (Facility)
27870	Arthrodesis, ankle, open	$996

†Payment may vary by location. Prices shown are national averages, based on Medicare's 2024 payments and copayments. Treatments may include one or more procedures.

The CPT codes provided in this reimbursement guide are for informational purposes only. The information provided is based upon AMA guidelines and CPT coding guidelines. CPT coding and billing is the sole responsibility of the billing party to ensure that all coding requirements, medical necessity standards and documentation requirements are met. BioPro assumes no responsibility for billing errors or billing decisions due to reliance on the CPT codes provided in this reimbursement guide, and, further, BioPro makes no claims, promises, or guarantees as to the availability of reimbursement for any of the CPT codes referenced herein. This reimbursement guide is not intended to constitute reimbursement or legal advice, nor is it intended to increase or maximize reimbursement by any payors. BioPro vigorously recommends consultation with payor organizations for insight as to their reimbursement policies prior to executing any billing decisions. Please contact your Medicare Contractor, other payors, and/or reimbursement specialists for interpretation of coding, coverage and payment policies.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 13, 2017

Biopro, Inc.
% Al Memmolo
President
Convergent Clinical, Inc.
6648 Surf Crest St.
Carlsbad, California 92011

Re: K163627
Trade/Device Name: Shotel Ankle Arthrodesis Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB
Dated: August 10, 2017
Received: August 11, 2017

Dear Al Memmolo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Vincent J. Devlin -S

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

References

1. Thevendran G, Shah K, Pinney SJ, Younger AS. Perceived risk factors for nonunion following foot and ankle arthrodesis. Journal of Orthopaedic Surgery. 2017;25(1). doi:10.1177/2309499017692703

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3. Van Den Heuvel, S. B., Penning, D., & Schepers, T. (2022). Open ankle arthrodesis: A retrospective analysis comparing different fixation methods. The Journal of Foot and Ankle Surgery, 61(2), 233–238. https://doi.org/10.1053/j.jfas.2021.07.012

4. Berend ME, Glisson RR, Nunley JA. A biomechanical comparison of intramedullary nail and crossed lag screw fixation for tibiotalocalcaneal arthrodesis. Foot Ankle Int. 1997 Oct;18(10):639-43. doi: 10.1177/107110079701801007. PMID: 9347301.

Shotel

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PATENT 9,782,205 B2

ISO 13485:2016 CERTIFICATION intertek ™

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