

### The First Step Towards More Effective Joint Care



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### KNEETAP™ NEEDLE GUIDE

The **KneeTap Needle Guide** enables ANY physician type to more accurately target the synovial fluid when performing a joint aspiration or injection.

#### INDICATIONS FOR USE

- **Joint Aspirations**
  - Diagnostic
  - Synovial Fluid Research
- **Joint Injections**
  - Corticosteroid
  - Hyaluronic Acid
  - PRP, BMAC, A2M, Adipose, Amniotic, Stem Cells



U.S. Patent #7,468,048

*The KneeTap Improves the Accuracy and Delivery of Joint Aspirations and Injections*

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How does the **KneeTap Needle Guide** benefit Physicians?



**Revenue:** Bill for performing improved Pneumatic-Assisted Joint Aspiration/Injection procedures with or without image-guidance (e.g. ultrasound, fluoroscopic).



**Time:** Reduces the amount of time needed to accurately target the joint space. (e.g. obese patient, dry joint, etc.).



**Risk:** Minimizes risk of a dry tap, surrounding soft tissue injury, and needle stick.



**Patient Care:** Improves patient comfort and satisfaction that therapeutics are being delivered accurately.



**Differentiation:** Provides improved patient care compared to other clinics that do not use the KneeTap.

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How does the **KneeTap Needle Guide** benefit Patients?



**Comfort:** Improves the comfort of joint aspirations & injections by increasing the accuracy and reducing procedure time<sup>1</sup>.



**Effectiveness:** Increases the effectiveness of therapeutics by removing more synovial fluid <sup>2,3</sup> and improving accuracy over current procedures.



**Satisfaction:** Increases patient satisfaction and confidence in therapeutics and care provided.

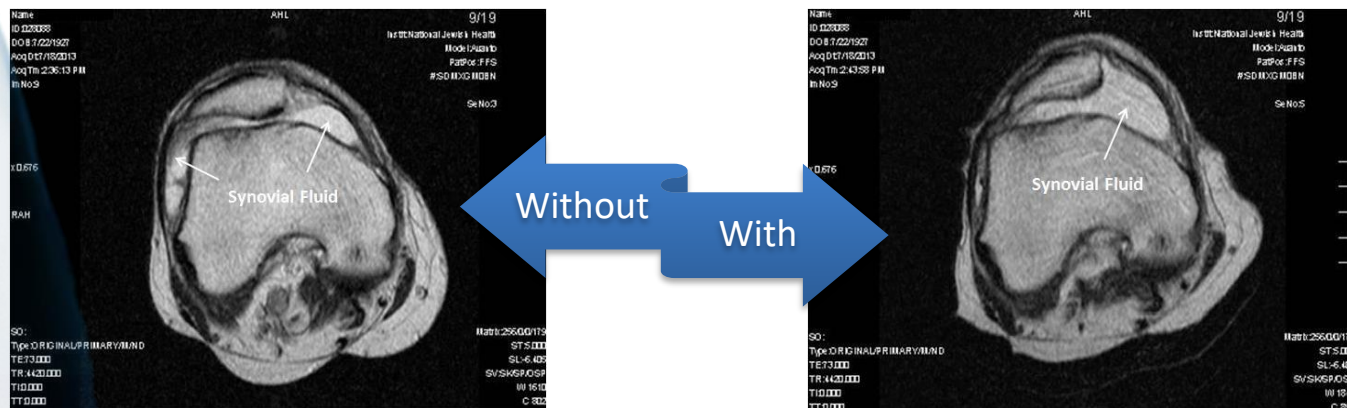
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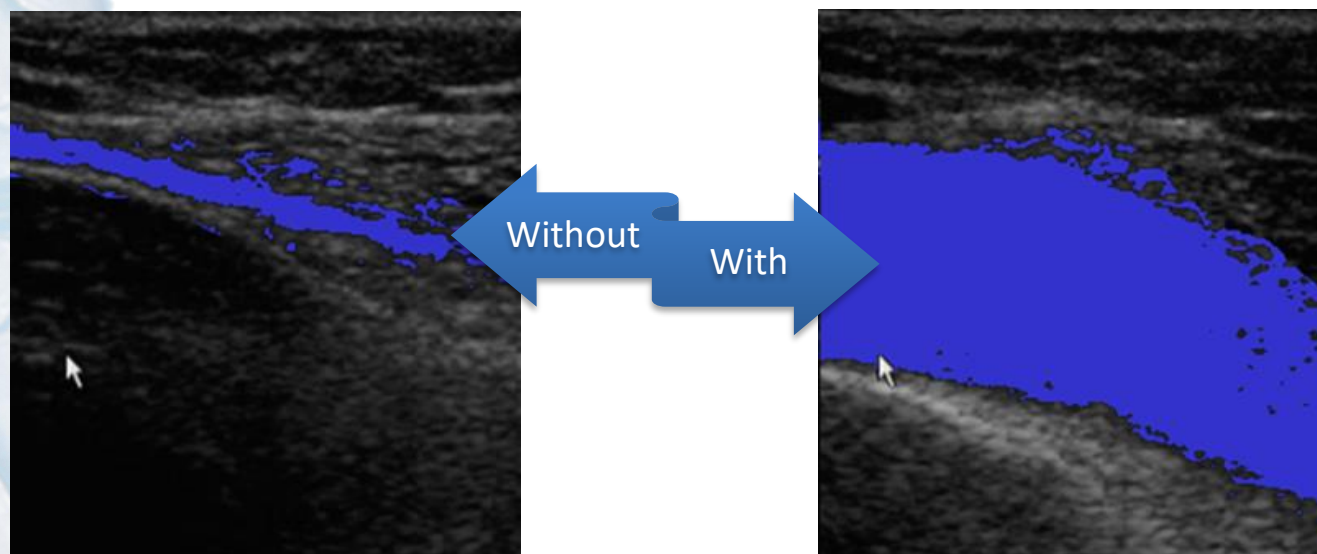
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### Consolidates Synovial Fluid From the Joint Cavities to the Target Area



### Increases Physicians Target Area by an Average of 3x



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# KneeTap™



## Product Validation



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### **Ultrasound Measurement of Knee Synovial Fluid During External Pneumatic Compression**

Meehan, R. , Wilson, C. , Hoffman, E. , Altimier, L. , Kaessner, M. and Regan, E. A. (2019), Ultrasound measurement of knee synovial fluid during external pneumatic compression. J. Orthop. Res., 37: 601-608.  
doi:[10.1002/jor.24216](https://doi.org/10.1002/jor.24216)

### **Ultrasound Quantification of Fluid Shifts in the Knees of Arthritis Patients before and after Inflation of a Pneumatic Compressive Device**

C. Wilson<sup>2,1</sup>, E. Hoffman<sup>1</sup>, L. Altimier<sup>1</sup>, E. Regan<sup>1</sup>, M. Kaessner<sup>1</sup>, R. Meehan<sup>1</sup>

<sup>1</sup>National Jewish Health - Denver, CO; <sup>2</sup>University of Colorado Anschutz Medical Campus – Aurora, CO

### **Synovial Fluid Cytokines as a Biomarker of Cartilage Degradation due to Arthritis, and Unloading Associated with Spinal Cord Injury and Microgravity**

R.T. Meehan<sup>1</sup>, V. Knight<sup>1</sup>, R. Scheuring<sup>2</sup>, E. Hoffman<sup>1</sup>, J. Berliner<sup>3</sup>, E. Regan<sup>1</sup>, J. Crooks<sup>1</sup>, L. Morse<sup>3</sup>, J. Hill<sup>4</sup>, K. Pacheco<sup>1</sup>

<sup>1</sup>National Jewish Health, Denver, CO, <sup>2</sup>NASA-Johnson Space Center, Houston, TX, <sup>3</sup>Craig Hospital, Denver, CO, <sup>4</sup>Sports Medicine, University of Colorado, Denver, CO

### **Enhancement of Hyalgan™ Efficacy and tolerability using a Joint/knee Aspirate Facilitator Device during knee injections**

Personnel: R Meehan (PI)<sup>1,2</sup>, Elizabeth Regan MD PhD (Co-I)<sup>1</sup>, Eric Hoffman (Co-I)<sup>1,2</sup>

<sup>1</sup>National Jewish Health, <sup>2</sup>Arthroventions

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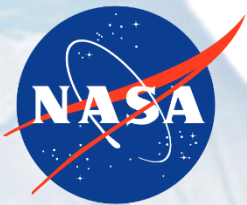
**“The chance of getting a successful aspiration in a normal knee without [the KneeTap] is... much harder and chances are it’ll probably hurt the patient more.”**

CU Sports Medicine  
Sports Medicine Physician



**“One of the easiest injections I've done!!! And the patient found it impressive as well.”**

Kaiser Permanente  
Family Medicine Physician



**“So easy even a NASA flight surgeon can use it.”**

NASA Flight Surgeon  
Sports Medicine Physician

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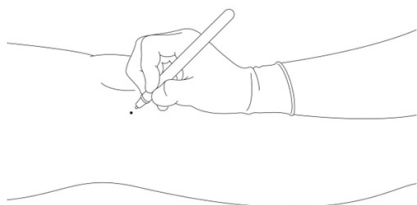
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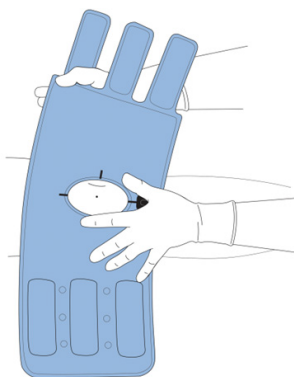


### KneeTap™ Needle Guide

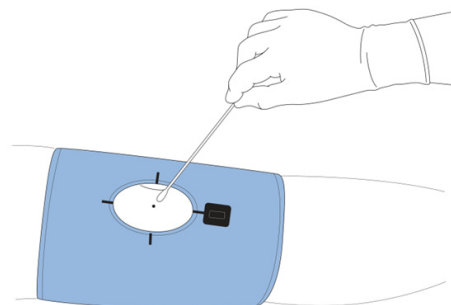
1. Determine medial or lateral approach and site for needle insertion.



2. Place access hole directly over the injection site. Wrap the device around the knee and secure firmly with the straps.



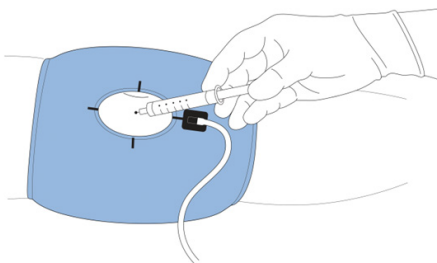
3. Using sterile technique, clean the injection site with a topical antiseptic.



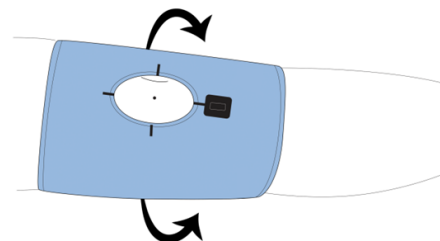
4. Connect the handheld manometer and inflate the device to a pressure between 90 and 100 mmHg. Do not inflate the device above 110 mmHg.



5. Perform the arthrocentesis procedure as trained. Deflate the device before removing the needle.



6. Disconnect the manometer from the device. Remove and dispose of the KneeTap.



KneeTap – Instructions for Use – v1.2

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### Indication for Use

The **KneeTap** may be used in arthrocentesis or intra-articular injection procedures targeting the joint space of the knee.

### Contraindications for Use

Contraindications for arthrocentesis or intra-articular injection procedures apply such as bleeding tendency, infection or a surrounding soft tissue injury.

### Reimbursement

CPT Code	Description
20610	Arthrocentesis, aspiration and/or injection, major joint or bursa (eg, knee); without ultrasound guidance.
20611	Arthrocentesis, aspiration and/or injection, major joint or bursa (eg, knee); with ultrasound guidance, with permanent recording and reporting.
Cash / Charge Code / ABN / CPT 20999	Pneumatic-assisted guidance for arthrocentesis, aspiration and/or injection; all joints.

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## Diagnostics Codes – Rheumatoid Arthritis

ICD-10 Dx Code	Dx* Descriptor
M05.66 (NOT BILLABLE CODE)	Rheumatoid arthritis of knee with involvement of other organs and systems
M05.661	Rheumatoid arthritis of right knee with involvement of other organs and systems
M05.662	Rheumatoid arthritis of left knee with involvement of other organs and systems
M05.669	Rheumatoid arthritis of unspecified knee with involvement of other organs and systems
M05.69	Rheumatoid arthritis of multiple sites with involvement of other organs and systems
M05.76 (NOT BILLABLE CODE)	Rheumatoid arthritis with rheumatoid factor of knee without organ or systems involvement
M05.761	Rheumatoid arthritis with rheumatoid factor of right knee without organ or systems involvement
M05.762	Rheumatoid arthritis with rheumatoid factor of left knee without organ or systems involvement
M05.769	Rheumatoid arthritis with rheumatoid factor of unspecified knee without organ or systems involvement
M05.79	Rheumatoid arthritis with rheumatoid factor of multiple sites without organ or systems involvement
M05.86 (NOT BILLABLE CODE)	Other rheumatoid arthritis with rheumatoid factor
M05.861	Other rheumatoid arthritis with rheumatoid factor of right knee
M05.862	Other rheumatoid arthritis with rheumatoid factor of left knee
M05.869	Other rheumatoid arthritis with rheumatoid factor of unspecified knee
M05.89	Other rheumatoid arthritis with rheumatoid factor of multiple sites
M06.06 (NOT BILLABLE CODE)	Rheumatoid arthritis without rheumatoid factor, knee
M06.061	Rheumatoid arthritis without rheumatoid factor, right knee
M06.062	Rheumatoid arthritis without rheumatoid factor, left knee
M06.069	Rheumatoid arthritis without rheumatoid factor, unspecified knee
M06.09	Rheumatoid arthritis without rheumatoid factor, multiple sites
M06.86 (NOT BILLABLE CODE)	Other specified rheumatoid arthritis, knee
M06.861	Other specified rheumatoid arthritis, right knee
M06.862	Other specified rheumatoid arthritis, left knee
M06.869	Other specified rheumatoid arthritis, unspecified knee
M06.89	Other specified rheumatoid arthritis, multiple sites

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## Diagnostic Codes - Osteoarthritis

ICD-10 Dx Code	Dx* Descriptor	Disease Description
M17 (NOT BILLABLE CODE)	Osteoarthritis of knee	Generic classification of disease
M17.0	Bilateral primary osteoarthritis of knee	Osteoarthritis of both knees in elderly patients with no known previous injury, obesity, rheumatic disease, etc
M17.1 (NOT BILLABLE CODE)	Unilateral primary osteoarthritis of knee	Generic osteoarthritis of one knee (not specified), in elderly patients with no known previous injury, obesity, rheumatic disease, etc
M17.10	Unilateral primary osteoarthritis of knee, not specified	Generic osteoarthritis of one knee (not specified), in elderly patients with no known previous injury, obesity, rheumatic disease, etc
M17.11	Unilateral primary osteoarthritis of knee, right knee	Osteoarthritis of one knee (right), in elderly patients with no known previous injury, obesity, rheumatic disease, etc
M17.12	Unilateral primary osteoarthritis of knee, left knee	Osteoarthritis of one knee (left), in elderly patients with no known previous injury, obesity, rheumatic disease, etc
M17.2	Bilateral posttraumatic osteoarthritis of knee	Osteoarthritis of both knees resulting from known injury
M17.3 (NOT BILLABLE CODE)	Unilateral posttraumatic osteoarthritis of knee	Osteoarthritis of one knee (not specified), resulting from known injury
M17.31	Unilateral posttraumatic osteoarthritis of knee, right knee	Osteoarthritis of one knee (right), resulting from known injury
M17.32	Unilateral posttraumatic osteoarthritis of knee, left knee	Osteoarthritis of one knee (left), resulting from known injury
M17.4	Other bilateral secondary osteoarthritis of knee	Osteoarthritis of knee, not associated with age or injury (eg, obesity, genetics, etc)
M17.5	Other unilateral secondary osteoarthritis of knee	Osteoarthritis of knee (not specified), not associated with age or injury (eg, obesity, genetics, etc)
M17.9	Osteoarthritis of knee, unspecified	Generic osteoarthritis of knee, not specified

\*Dx = Diagnostic.

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<b>Proprietary Name:</b>	JointTap; KneeTap
<b>Classification Name:</b>	GUIDE, NEEDLE, SURGICAL
<b>Product Code:</b>	<a href="#">GDF</a>
<b>Device Class:</b>	1
<b>Regulation Number:</b>	<a href="#">878.4800</a>
<b>Medical Specialty:</b>	General & Plastic Surgery
<b>Registered Establishment Name:</b>	<a href="#">ARTHROVENTIONS, LLC</a>
<b>Registered Establishment Number:</b>	3013554422
<b>Owner/Operator:</b>	<a href="#">Arthroventions, LLC</a>
<b>Owner/Operator Number:</b>	10054560
<b>Establishment Operations:</b>	Specification Developer; Complaint File Establishment

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### Reimbursement Options

Clinics have several different options for receiving reimbursement for a Pneumatic-Assisted joint injection or aspiration.

#### A. Cash / Regenerative Therapies

Provide the option for patients to pay out of pocket for a Pneumatic-Assisted procedure.

#### B. Private Insurance

Create a new charge code for a Pneumatic-Assisted procedure under CPT Codes 20610 or 20611.

#### C. Medicare / Medicaid

Bill the patient using an Advanced Beneficiary Notice (ABN) for a Pneumatic-Assisted procedure and report the joint injection or aspiration to Medicare/Medicaid using CPT Codes 20610 or 20611.

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### **About Arthroventions:**

Arthroventions™ is a Colorado LLC that is improving the quality of life for patients with joint disease by developing technologies that enable more effective joint care.



### **Eric Hoffman:** **Chief Executive Officer**

Eric Hoffman is an entrepreneur and biomedical engineer. He has worked for several large pharmaceutical companies and consulted to the FDA, before co-founding Arthroventions.



### **Dr. Richard Meehan:** **Chief Medical Officer**

Dr. Richard Meehan is a Rheumatologist and a Professor of Medicine at National Jewish Health, where he specializes in autoimmune diseases and rheumatic conditions. Dr. Meehan is a serial inventor and a former Navy Reserve physician.

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1. **Joint compression increases the amount of synovial fluid that can be aspirated improving the success, cost-effectiveness, and efficacy of diagnostic & therapeutic arthrocentesis.**

Bhavsar TB, Sibbitt WL, Band PA, et al. Improvement in diagnostic and therapeutic arthrocentesis via constant compression. Clin Rheumatol. 2017;

2. **Performing a complete arthrocentesis before injecting hyaluronic acid (HA) significantly improved VAS pain and WOMAC function scores vs no arthrocentesis before injection.**

Zhang Q, Zhang T. Effect on Pain and Symptoms of Aspiration Before Hyaluronan Injection for Knee Osteoarthritis: A Prospective, Randomized, Single-blind Study. Am J Phys Med Rehabil. 2016;95(5):366-71.

3. **Performing a complete arthrocentesis before injecting corticosteroids improves therapeutic efficacy and reduces the risk of arthritic relapse.**

Weitoft T, Uddenfeldt P. Importance of synovial fluid aspiration when injecting intra-articular corticosteroids. Ann Rheum Dis. 2000;59(3):233-5.

4. **Anti-inflammatory properties of PRP may contribute to an improvement in osteoarthritic symptoms.**

Cole BJ, Karas V, Hussey K, Pilz K, Fortier LA. Hyaluronic Acid Versus Platelet-Rich Plasma: A Prospective, Double-Blind Randomized Controlled Trial Comparing Clinical Outcomes and Effects on Intra-articular Biology for the Treatment of Knee Osteoarthritis. Am J Sports Med. 2017;45(2):339-346.

5. **Intra-articular Platelet-Rich Plasma injections decrease synovial fluid protein concentrations and volumes while reducing knee pain severity after 3 and 6 months.**

Chen CPC, Cheng CH, Hsu CC, Lin HC, Tsai YR, Chen JL. The influence of platelet rich plasma on synovial fluid volumes, protein concentrations, and severity of pain in patients with knee osteoarthritis. Exp Gerontol. 2017;93:68-72.

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- 6. The KneeTap increases in the target area by squeezing the joint fluid from the joint cavity compartments.**

Wilson, C., E. Hoffman, L. Altimier, E. Regan, M. Kaessner, and R. Meehan. Ultrasound Quantification of Fluid Shifts in the Knees of Arthritis Patients before and after Inflation of a Pneumatic Compressive Device. National Jewish Health, n.d.

- 7. One in five blinded injections were inaccurate and ultrasound-guided injections improved short-term outcomes.**

Maricar N, Parkes MJ, Callaghan MJ, Felson DT, O'Neill TW. Where and how to inject the knee--a systematic review. Semin Arthritis Rheum. 2013;43(2):195-203.

- 8. One in three blinded injections were inaccurate, ultrasound-guided improved accuracy, and accurate injections improved joint function.**

Cunnington J, Marshall N, Hide G, et al. A randomized, double-blind, controlled study of ultrasound-guided corticosteroid injection into the joint of patients with inflammatory arthritis. Arthritis Rheum. 2010;62(7):1862-9.

- 9. Ultrasound-guided injections decreased procedure pain by 48% and reduced pain on follow-up by 42%**

Cunnington J, Marshall N, Hide G, et al. A randomized, double-blind, controlled study of ultrasound-guided corticosteroid injection into the joint of patients with inflammatory arthritis. Arthritis Rheum. 2010;62(7):1862-9.

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