MISHA®
KNEE SYSTEM

MISHA® KNEE SYSTEM REHABILITATION GUIDELINES

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Note: These guidelines were developed by three physical therapists from the Ohio State University for the Calyspo Study. Individual patient physical therapy is prescribed at the discretion of the surgeon. There are no device-specific limitations on return to weight bearing or activities, but initiation of post-surgery physical therapy is recommended within 3 - 5 days post-op. All patients should check with their surgeon before beginning or resuming physical activities.

WHAT IS THE MISHA KNEE SYSTEM?

The MISHA Knee System is an implantable shock absorber (ISA) that unloads the medial knee to provide pain relief for patients with knee osteoarthritis (OA). The MISHA Knee System (Figure 1) is implanted subcutaneously, but outside of the joint capsule. It consists of a cylindrical absorber located between bases fixed with locking screws to the medial cortices of the distal femur and proximal tibia.

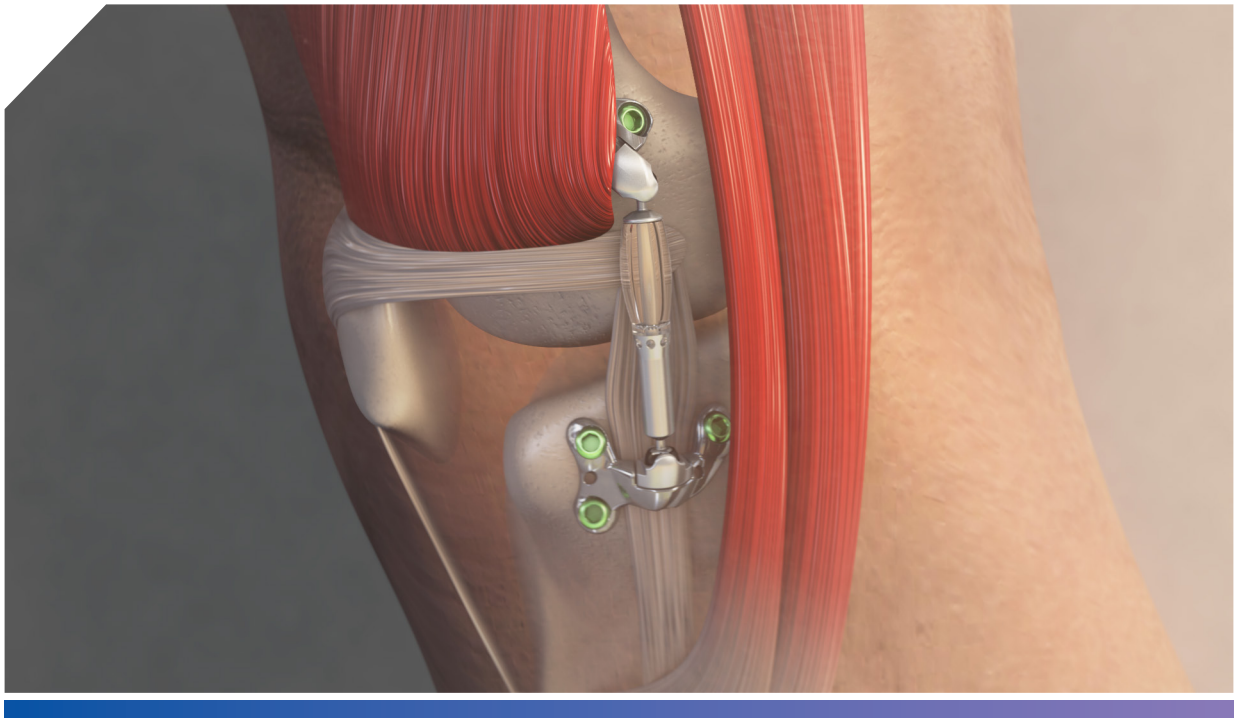

Figure 1: MISHA Knee System

The ISA provides compressive load absorption, and articulating ball-and-socket joints accommodate the natural motions of the knee. By providing a supplemental load path to the affected medial portion of the joint, the MISHA Knee System reduces the amount of load carried by the degenerated or damaged surfaces of the medial knee joint.

The ISA is implanted through a single incision in the subcutaneous tissue of the medial extra-capsular space. The shock absorber spans the joint, superficial to the medial collateral ligament and isolated from the articular surfaces of the knee. Surgical implantation is completed using standard orthopedic tools and techniques in conjunction with single use, sterile instruments unique to the MISHA Knee System.

INTRODUCTION TO MISHA REHABILITATION GUIDELINES

The MISHA Knee System rehabilitation guideline resembles that recommended for a unicompartmental knee replacement (UKA) with the following exceptions:

- Timelines and treatment progressions below may be quicker due to the anatomic location of the MISHA Knee System (extracapsular) and reduced invasiveness of the MISHA Knee System procedure.
- During the early recovery phase (weeks 0 - 6), the emphasis is on wound healing, range of motion, and linear/uniplanar exercises to safely regain patient strength and flexibility.
- It is recommended that all early phase tasks be monitored with respect to wound healing. See Appendix A for further guidance of these skilled activities.

Following early stages of recovery, progression to multi-planar motions can be initiated as long as quality movement patterns are first achieved in sagittal plane tasks and emphasized/maintained in progression of activities. It is recommended that progression of weight bearing tasks focus on normalizing movement patterns of the lower extremity and pelvis, as well as progressive transition from double limb ➔ single limb tasks, sagittal ➔ frontal ➔ transverse planes of motion.

After implantation, there are no device-specific weight-bearing or return to activity restrictions. The goal is for patients to establish realistic expectations for post-treatment activity levels. Each surgeon may recommend different levels of appropriate recreational activities on an individualized basis, depending upon level of disease and pre-operative function; a realistic goal may be achievement of pre-operative activity levels with reduced pain. Therefore, it is highly recommended to discuss anticipated post-operative function and the highest level of activity expected with each patient's surgeon, to ensure appropriate progression through guidelines and adequate preparation for return to activity.

Suggested therapeutic interventions are provided for each stage in Appendix A. While performance of these tasks or similar activities are encouraged, if tasks are unfamiliar to the provider, do not attempt to perform. A glossary of acronyms and terms used throughout these guidelines can be found in Appendix B.

It is strongly recommended that patients schedule their first post-op physical therapy evaluation as soon as their surgical date is known, as initiating physical therapy within 3 - 5 days post-op is recommended.

APPENDIX A: SUGGESTED THERAPEUTIC INTERVENTIONS BY STAGE

Therapeutic Interventions / Considerations

Weeks	Milestones	Criteria to Progress	Key Considerations	Strength/NM Control/ Functional Training	Stretching / Mobility
Pre-surgery	Review post-op rehab expectations: 1) Immediate WBAT with assistive device 2) Immediate full extension; Progress knee flexion as tolerated with a minimum goal of 90 degrees by 2 weeks	N/A	Self-directed pre-habilitation, or single pre-op visit with physical therapist Review of patient post-operative recreational and fitness goals Quad strengthening, restoration of normal gait mechanics, learn walking with assist devices/crutches	Quad sets Crutch proficiency WBAT Gait mechanics	Educate on flexion and extension exercises
0-2	Provide home exercise program, starting night of surgery; set expectations during pre-surgery visit. Start 1st PT appointment by 3-5 days post-op. (WBAT) for evaluation of progress. Reset goals/ frequency as necessary Progress knee ROM as tolerated with a minimum goal of 90 deg by 2 weeks	First 0 to 96 hours critical to monitor for infection, DVT, edema/ pain control, quad activation prior to safe initiation of WB with crutches	Pain and swelling management (ice, elevation above the heart, compression) Early WBAT Quad activation	Ankle pumps Quad sets with short arc leg raises Glute squeezes	Recommend gentle hamstring stretching (tibial base sits near pes insertion), Gastroc stretching Patella mobilizations Encouraging full knee extension immediately post-op (heel props, towel stretch) *(Noyes, 1992, Noyes 1997)*

Note: the goal is to allow the medial incision to heal and decrease swelling

Weeks	Milestones	Criteria to Progress	Key Considerations	Strength/NM Control/ Functional Training	Stretching / Mobility
2-4	Knee ROM 0-full (target 120 deg flex no later than 4 weeks) *(Bowditch et al., 2012; Ekhtiari et al.,2017; Husain 2017; Maloney et al., 2002)* Goal: discharge assistive device by end of week 2 (Target to achieve by post-op day 30) when ambulating without a limp. *Return to driving:* Requires MD clearance *Return to work:* No earlier than 18 days p/o for good outcomes (3 wks - light duties; 4-6 wks - moderate; 8+ wks heavy/manual labor) *(Clifford et al., 2013)*	Criteria to d/c assist device: good quad control SLR x 10, no limp, pain and minimal swelling *Return to driving:* Requires MD clearance *Return to work:* Requires MD clearance	**Contact MD if patient has not achieved 90 degrees knee flexion by week 4** *(Ekhtiari et al., 2017; Husain 2017; Maloney et al., 2002)* Contact MD if patient still requires an assistive device by week four (pain, lack of ROM, etc.) Goal: achieve SL stance 30 sec good proximal stability Scar mobility permitted once incision is closed *(Hardy 1989, Kannus 2003)*	Bridges Partial WB squats Mini squats or wall squats Sit-stand Initate step-up Mini lunge Standing 4-way hip Prone knee flexion Multi Angle isometric quad/knee extension Emphasis on quad strengthening *(Mizner 2005, Yoshida 2008, Mizner 2005, Machner 2002, Valtonen 2009)*	Bike half to full revolutions (ROM only) Lateral hip and IT band mobility Patella mobilizations Extension mobilizations Wall slides with patient overpressure or heel slide with belt (week 4)
4-6	Knee ROM: 0-full *(Smith 2011; Hayes 2015; Ekhtiari et al., 2017)* Ascend/descend stairs with reciprocal gait pattern (Luepongask 2002) Sit <-> stand with symmetric weight bearing between extremities Progressing with community distance ambulation Wk 4: may begin aquatic activities (pool walking or lap swim) as long as incision site is fully healed (freestyle only, no flip turns for lap swim, no butterfly kick)		Independence with functional tasks/ADLs (sit<->stand, bed mobility, ascending stairs) *(Valtonen 2009)* At 6 weeks, encourage and initiate kneeling activities on foam pad *(Jenkins 2008)* Initiate return to light strength activities (gym, etc). Ensure maintained or improved strength in non-operative limb *(Zeni 2010)*	Elliptical (6 week) Full squat to 90 degrees only Side steps with band Resisted walking Heel taps ASD, lat step down Cone taps Resisted quad/ hamstring Advanced bridges (SL, SBall) SLS progressions (unstable surface, ball toss, eyes closed, etc.)	Continue mobility interventions listed above and address soft tissue restrictions as appropriate (ie. lateral hip, quad, IT band, adductors, etc.)

Weeks	Milestones	Criteria to Progress	Key Considerations	Strength/NM Control/ Functional Training	Stretching / Mobility
6-8	Knee ROM: full by week 8 *(Smith 2011; Hayes 2015; Ekhtiari et al., 2017)*	Return to heavy labor work duties no earlier than 8 weeks as appropriate per MD *(Clifford et al., 2013; Hoorntje et al., 2017)*	Ok to progress strengthening exercises and functional tasks as appropriate pending no reactive pain or effusion Increase aerobic conditioning / endurance (low impact activities) monitoring reactive edema May progress swimming strokes at this time (only linear strokes (back/fly/free)	Progressive resistance exercises for all LE musculature Pending appropriate mechanics, loading with squats, DL squats, deadlifts, lunges Incorporate multi-planer SL activities and progress unstable surfaces	Continue mobility interventions listed above and address soft tissue restrictions as appropriate (ie. lateral hip, quad, IT band, adductors, etc.)
8-12			Encourage continued progression of low impact activities for cardiovascular fitness and community endurance	Continue progressive strengthening and proprioceptive activities as appropriate	
>12		Return to appropriate recreational activities pending adequate LE strength, ROM, and neuromuscular control: Pass PT/ATC functional progression program (per appropriate professional in state laws) Criteria to initiate jogging: • Full, pain free ROM • Minimal effusion (less than 1+) • 20 forward step downs from 8in step with good mechanics via Forward Step-Down Test *(Park, 2013)* Pivoting sports: not until endurance/fitness level >> pre-op level, gait normal, and atrophy reversed.	General guidelines for returning to sport (note that patients should not expect to exceed pre-treatment abilities) • 4 to 6 weeks before swimming, cycling, or golfing, • 2 to 3 months before jogging, • 3 to 6 months before playing racquet sports • at least 6 months before skiing *(Bowditch et al., 2012)* *(Clifford et al., 2013)* *(Hoorntje et al., 2017)* Low impact activities encouraged; potential for high-impact tasks per MD discretion *(Hopper 2008, Waldstein 2017, Walker 2015, Witjes 2016, Boyd 2014; Hoorntje et al., 2017).*		

APPENDIX B: GLOSSARY OF ACRONYMS AND TERMS

ACRONYMS

- **ASD** - anterior step down
- **BKFO** - bent knee fall out
- **Heel taps ASD** – heel taps anterior step down
- **LAQ** - long arc quad
- **LE** - lower extremity
- **S Ball** - Swiss ball
- **SL stance** - single leg stance
- **SLR** - straight leg raises
- **SLS** - single leg stance
- **SLS progressions** - single leg squat progressions
- **Standing TKE** - terminal knee extension

TERMS

- **Deep Vein Thrombosis (DVT)** - occurs when a blood clot (thrombus) forms in one or more of the veins in your body. Deep vein thrombosis can cause leg pain or swelling but can also occur with no symptoms.
- **Desensitization** - treatment technique utilized to modify how sensitive an area is to particular stimuli. Desensitization is used to decrease, or normalize, the body's response to particular sensations. The goal is to inhibit or interrupt the body's interpretation of routine stimuli as painful.
- **Effusion** - increased fluid within a joint cavity.
- **Neuromuscular Electrical Stimulation** - elicitation of muscle contraction using electric impulses. The impulses mimic the action potential that comes from the central nervous system, causing the muscle to contract.
- **Reactive Edema** - response of increased swelling caused by overuse or increased activity causing an excess amount of fluid within your body's tissues or joint spaces. Reactive edema can be treated with rest, ice, compression, and elevation to decrease risk of adverse reactions including pain and injury to the soft tissue and joint space.
- **Scar Mobilization** - treatment technique utilized to help remodel scar tissue that has developed in injured or post-surgical tissue. Cross friction massage and myofascial release techniques can be used to improve scar tissue pliability. Scar tissue manipulation (forceful approach performed to break up scar tissue adhesions) is not a form of treatment to be performed following surgical insertion of the MISHA Knee System.
- **Unicompartmental Knee Arthroplasty (UKA)** - surgical procedure used to relieve arthritis in one of the knee compartments in which the damaged parts of the knee are replaced.
- **Weight Bearing As Tolerated (WBAT)** - there is no limitation on the amount of weight you can place through the operated leg. You may place as much weight through the leg as tolerated, to your comfort level.

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