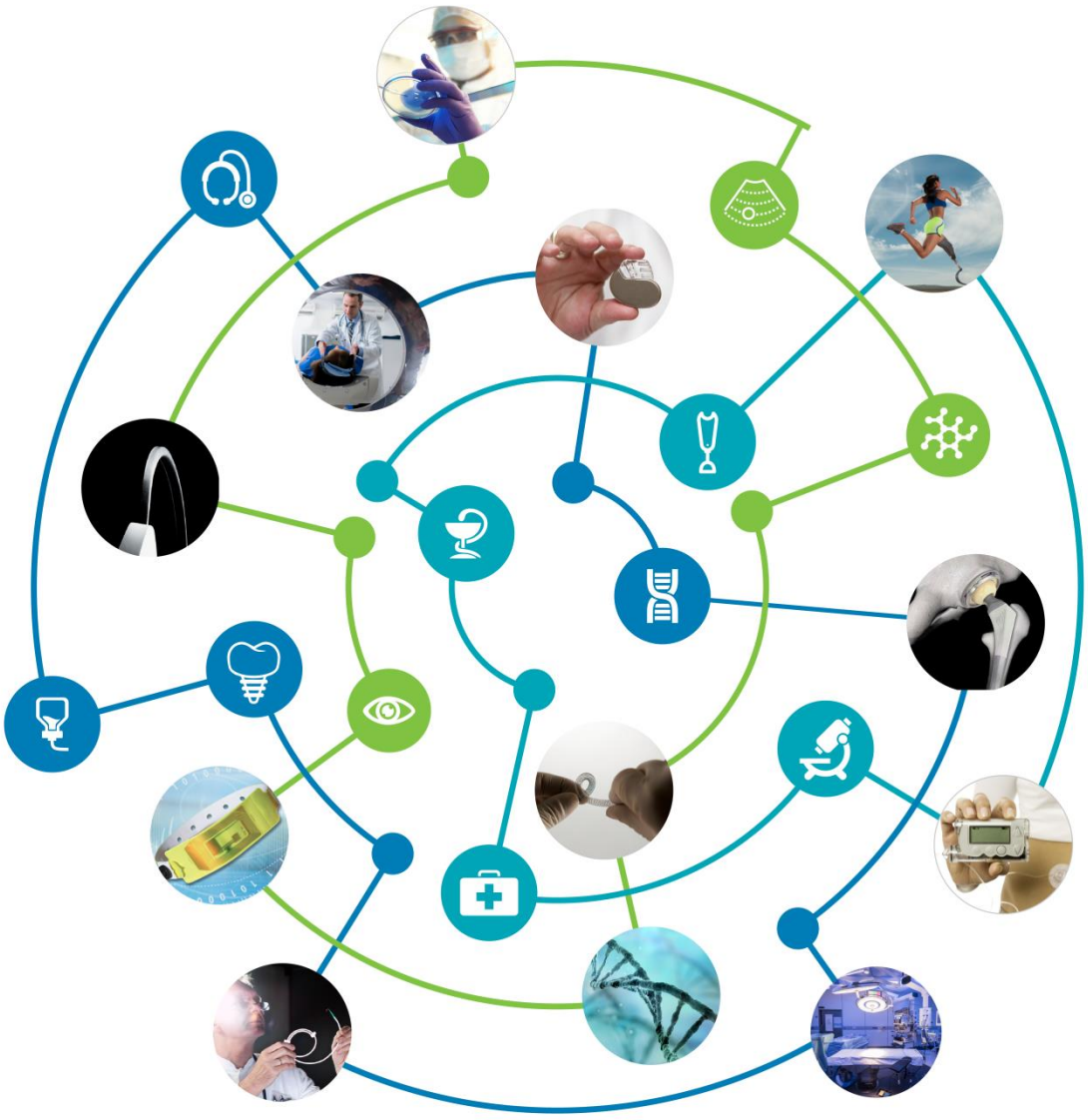
AdvaMed Medtech Value Assessment Framework *in Practice*



Application of the Medtech Value Assessment Framework to Rotation Medical's Bioinductive Implant

rotation MEDICAL

AdvaMed
Advanced Medical Technology Association

Value Framework Overview

In response to the growing need to demonstrate how medical technologies fit into the emerging value-based paradigm for providers, payers, and patients, AdvaMed launched a Strategic Value Initiative to develop an approach to value assessment for medical technologies that can be used by Medical technology companies as well as by health systems, payers, and other stakeholders.[1]

AdvaMed's Value Assessment approach goes beyond traditional Health Economic Outcomes Research (HEOR) and clinical efficacy metrics to assess the value that medical technologies may contribute to improving patient care and experience, economic outcomes, and the overall health of populations. This approach uses four broad categories, or "value drivers," to describe the value of medical technologies: clinical impact, non-clinical patient impact, care delivery revenue and cost impact, and
public/population impact relevant to an array of stakeholders who may evaluate and measure value differently.

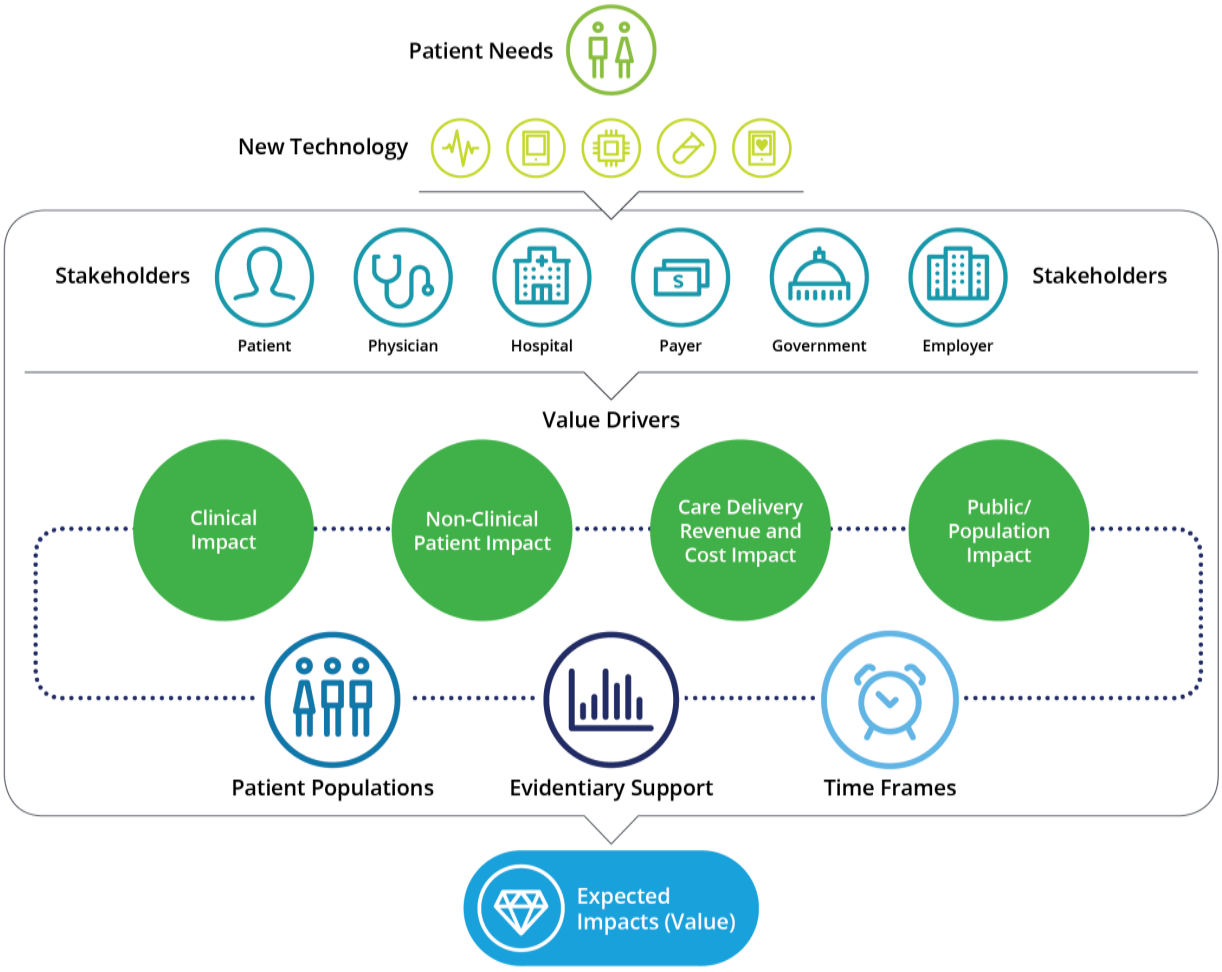
The AdvaMed Value Assessment approach can be used to guide the development of a value proposition that successfully communicates the full breadth of expected impacts offered by medical technologies while taking into account the demands of the changing health care ecosystem. The collection of information associated with the value drivers reflects quantitative and qualitative metrics of value, gives appropriate weight to patient experience and societal impacts, and also accounts for the consideration of evidence collected through a variety of methods. An illustration highlighting the value drivers and components of AdvaMed's approach is on the following page.

In order to demonstrate the application of this framework across different types of technologies, AdvaMed has partnered with member companies to develop use cases. These use cases address the clinical need for the technology, alternative and existing technologies on the market, the expected impacts of the technology, and the evidence to support such a value assessment. The use cases have been developed as a way to directly demonstrate the application of the AdvaMed Value Framework to the featured technology and should not be construed as an endorsement or promotion thereof.

Rotation Medical

This use case demonstrates the value of the RM BioInductive Implant technology across all of the identified value drivers and for a range of stakeholders.

Illustration of AdvaMed's Value Assessment Approach



Source: "A Framework for Comprehensive Assessment of Medical Technologies: Defining Value in the New Health Care Ecosystem", co-developed with Deloitte Consulting LLP

RM BioInductive Implant

Medtech companies with a new product concept in development should start early, not only to address the FDA requirements, but also the value proposition that the technology conveys to patients, providers, and the health care system.

The RM BioInductive implant serves as an example of the appropriate application of the AdvaMed value assessment approach in establishing value for a range of stakeholders.

Clinically, RM's technology impacts the method used by the surgeon performing rotator cuff repair and the time needed to complete the surgery. Use of the technology eliminates the need for the surgeon to cut 'good tissue' and avoids the need to repair the tendon with sutures and anchors. RM's implant also produces a range of beneficial non-clinical impacts for stakeholders such as patients, hospitals, and insurers: the implant generates significantly shorter rehab times, faster return to daily activities, and reduced operating room times. Additionally, the RM implant creates an opportunity to treat patients that would otherwise avoid surgery due to long and painful rehab and less than optimal results.

> The RM implant impacts cost and care delivery by reducing the surgical time, reducing the risk of re-tear and the need for repeat surgical intervention, and reducing rehab "episode" costs.

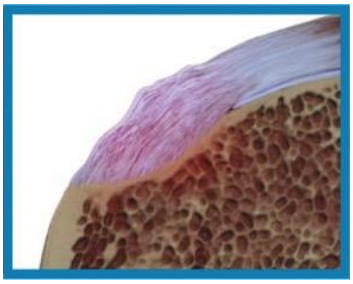
Lastly, the RM technology benefits society through reducing recovery time, thereby allowing affected patients to return to work faster, and through potential reductions in medication and addiction costs by providing a treatment that alleviates long-standing pain in patients who may have avoided surgery or lacked a surgical alternative.

Unmet Need

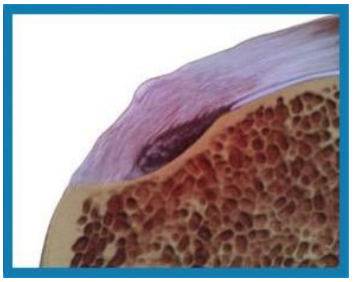
AdvaMed's assessment process begins with understanding and addressing the unmet need and value imparted through the new technology.

Unmet patient need can be framed in terms of clinical efficacy, safety, patient preferences, costs, quality of care, ease of use, etc.

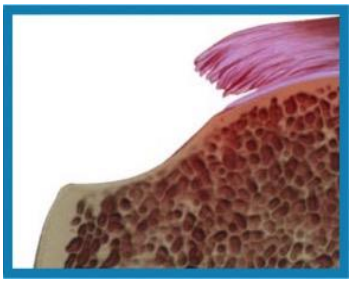
DISEASE PROGRESSION



Severe Tendinosis



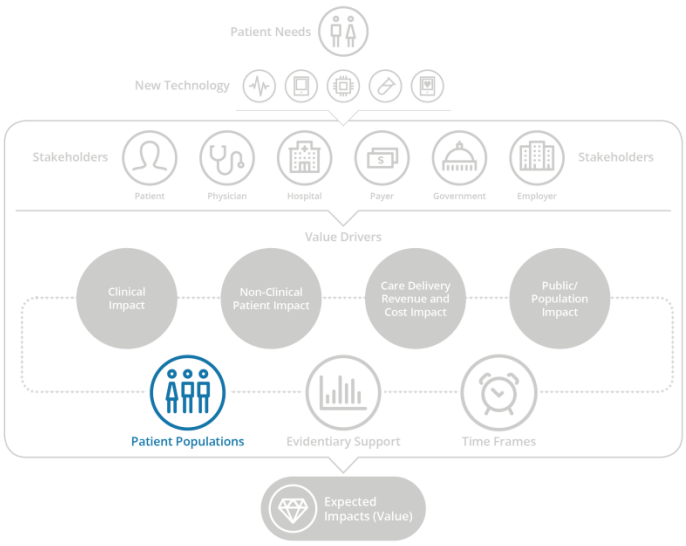
Partial-Thickness Tear



Full-Thickness Tear

There are three phases in the progression of Rotator Cuff Disease: severe tendinosis, partial-thickness tear, and full-thickness tear. Severe tendinosis often starts with a milder form of tendinosis—thinning of the tendon that causes it to become more susceptible to tearing. Tendinosis interferes with a patient's daily activities and quality of life. Symptoms are only treated with physical therapy (PT), with limited effectiveness, as there is no good surgical intervention. Chronic rotator cuff tendinopathy has been identified as a primary cause of rotator cuff tears. Both partial-thickness and full-thickness tears require surgical intervention and long, painful rehab. Because of this extensive rehab process, many patients with partial tears elect to opt out of surgery and live with pain. The more severe the tear, the worse the prognosis—patients with extensive tears have the highest rates of revision surgeries.

The RM BioInductive Implant addresses this needed innovation by healing and inducing growth of new tendinous tissue.[2] This tissue has been clinically shown to thicken the tendon and fill in tendon defects. The proprietary implant design allows for rapid infiltration of fibroblasts and new blood vessels. The RM BioInductive Implant is absorbed within six months of implantation, leaving a layer of new tendon-like tissue to biologically augment the existing tendon.



Patient Populations

Assessments should consider the extent to which a technology may be more or less effective for various patient populations and align with the population focus of the stakeholder evaluating the technology.

This section demonstrates the value of the technology to patients by addressing the need for the technology in the context of the affected patient sub-population and the available alternatives to treat their condition.

Rotator Cuff Disease is the most common shoulder disorder in America. Approximately one-quarter of adults over 40 years of age in the United States, and more than half of adults over the age of 60, have a rotator cuff tear. There are an estimated 4 million people with Rotator Cuff Disease who are at risk for disability. Since this is a degenerative disease, the older the patient population, the more prevalent the disorder becomes.

RM's solution and evidence focuses on a surgical option for patients with all stages of Rotator Cuff Disease including those with severe tendinosis, high-grade partial thickness tears as well as full-thickness tears. The current surgical treatment for partial-thickness tears involves the mechanical reattachment of tendon to bone with suture and anchors. There is significant disagreement among surgeons regarding the best approach to treat these types of tears. It is a lengthy procedure that can require cutting healthy tissue. Patient rehab is long and painful. Suture and anchors are effective for reattaching the tissue back to bone but do not treat the root cause of this degenerative disease, the biology of the tissue. The most cited need by orthopedic surgeons is "…innovation in technologies that speed up the recovery process, such as biologics, grafts, PRP and other materials that can foster growth and faster healing."[3]

Time Frames

The assessment should identify time frames that are important in understanding the value of the technology.

The time frames over which the technology provides impact should be considered and documented. Defining the relevant time frames for purposes of valuing the impact of a medical technology should include both short and long term impacts. Overall costs to the health care system may vary depending upon the stage of Rotator Cuff Disease and the mode of treatment selected by the patient. For instance, many patients with severe tendinosis who choose to forego treatment and who opt to live with pain may potentially become disabled, leaving the workforce and creating long-term system costs. Patients with partial-thickness and full-thickness tears who undergo traditional anchor and suture repairs which result in costly surgery, lengthy rehabilitation, and potential re-tear risk, generate more immediate system costs. Conversely, treating each of these patients with the RM BioInductive Implant may generate both short and long-term system savings.

Stakeholders

The intended audience for a value assessment affects the framing of the assessment and the drivers and metrics that could be highlighted.

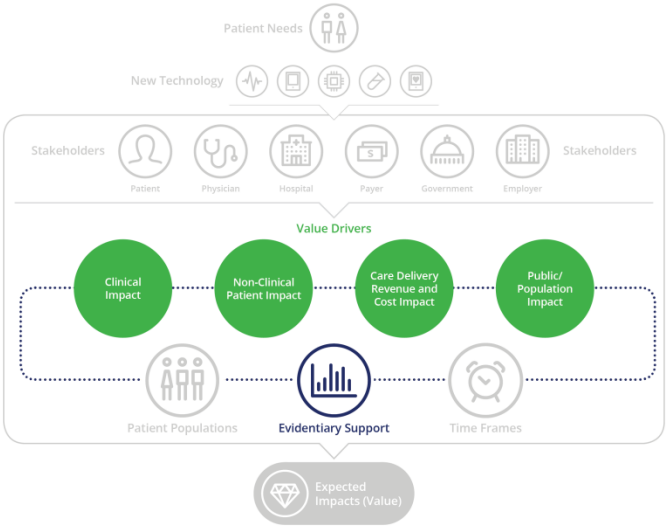
Both the intended audience/stakeholders and the purpose of the assessment should dictate which types of value are considered and emphasized via the assessment process, as well as the types and quality of evidence needed to support evidence development needs and appropriate strategies for collecting annual performance information.

It is important for stakeholders to consider the full range of value drivers and impacts.

The following chart highlights potential value for various stakeholders based on use of the RM technology in high-grade partial-thickness tear surgery. A similar chart could be developed for patients with severe tendinosis or full-thickness tear.

Bioinductive Implant Value Drivers Impact by Stakeholder

	Clinical Impact	Non-Clinical Impact	Care Delivery Revenue and Cost Impact	Public/Population Impact
Patient	• Shortens rehab times from 4-6 months to 1-2 months • Reduces potential for re-tears and additional surgery • Thickened and healed tendon • Thickened and healed tendon	• Quicker return to work • Ability to resume activities quicker • Lower out of pocket costs • Shortens recovery times from 4-6 weeks to 1-2 days • Higher patient satisfaction with procedure outcomes	• Performed routinely in the outpatient setting • Lower rehab costs • Lower out of pocket costs	• Quicker return to work • Less pain and less need for narcotics • Reduced caregiver burden with faster recovery
Surgeon	• Thickened and healed tendon tissue • Avoids need to use sutures and anchors • Less trauma to healthy tissue • Higher patient satisfaction quality scores • Provides ability to intervene earlier and potentially reverse the natural progression of the disease		• Performed routinely in the outpatient setting • Shortens procedure time by 30-45 minutes	• Provides ability to prescribe less narcotics
Hospital	• Reduces potential for re-tears and additional surgery • Greater throughput • Higher patient satisfaction quality scores • Thickened and healed tendon tissue • Provides ability to intervene earlier and potentially reverse the natural progression of the disease	• Enhances reputation as a leader in providing innovative treatments	• Fewer revision surgeries • Creates opportunity to treat more patients • Shortens procedure time by 30-45 minutes • Lower rehab costs crucial to accountable care model • Reduced costs associated with pain medication prescriptions • Disposable instrumentation reduces potential for instrument related infections and large infrastructure to support instrument sterilization	• Faster recovery time • Lower costs associated with opioid addiction
Insurer	• Reduces potential for re-tears and additional surgery • Higher patient satisfaction quality scores		• Performed routinely in the outpatient setting • Lower rehab costs crucial to accountable care model • Fewer revision surgeries • Reduced costs associated with opioid addiction • Reduced costs associated with pain medication prescriptions and costs associated with opioid addiction	• Lowers overall healthcare costs • Reduced opioid addiction and associated costs • Lower rehab costs crucial to accountable care model • Quicker return to work



Evidence Across the Value Drivers

Medical Technology innovators must determine the best way to show value with evidence.

It is critical to identify and evaluate the quantity and quality of available types of evidence for the technology early in product development and on an ongoing basis to determine how each can be used across the relevant drivers to offer robust evidentiary support.

RM has been engaged in the development of a variety of evidence types to support the effectiveness of its technology and to demonstrate the value that it brings to the health care system. Specifically, RM has published a biopsy study and has completed and published the results of an Australian clinical study. To date the RM technology has been used in ~3000 commercial cases with favorable results.

RM has conducted a U.S. clinical study, which has been submitted for publication, that tracks partial-thickness progression tears and re-tears of full thickness tears. Additionally, a U.S. registry study has been initiated by RM to look at multiple patient-reported metrics, such as pain, opioid use, and patient satisfaction, as well as rehab time and time back to activity. The results of this registry will be compared to an Arthroscopy Association of North America (AANA) database which includes thousands of patients that have received rotator cuff surgeries with traditional treatments. The information gleaned from the study and registry data will be useful in identifying impacts of the RM technology over varying timeframes.

The chart on the following page highlights evidence that applies to high-grade partial thickness tear patient populations:

Bioinductive Implant Value Drivers by Evidence Source

Evidence	Type of Evidence	Clinical Impact	Non-Clinical Patient Impact	Care Delivery Revenue and Cost Impact	Public/Population Impact
Australian Clinical Study (Published)	RCT	• Safe • Durable tendon healing • Higher patient reported outcomes (less pain, greater mobility, faster) • Improvements in Constant and ASES pain and overall scores over the 24-month period were statistically significant		• Eliminates device related infections • Higher OR throughput	• Less pain should lead to lower opioid use • Greater mobility should lead to quicker return to work
US Post-Market Clinical Study (Publication in Process)	Clinical Trial				
3,000 commercial cases (in Process)	Retrospective Study	• Patient testimonials have indicated less pain and faster recovery times		• Eliminates device related infections	• Patient testimonials have indicated less pain and faster recovery times
Biopsy study (Published)	Histologic Study	• Clinically demonstrates growth of new connective tissue			
US Registry (in Process)	Registry Data	• Higher patient reported outcomes (less pain, greater mobility, faster)	• Quicker return to daily activities	• Higher patient satisfaction scores • Significantly lower rehab costs • A comparison is being done between RM results and the Surgical Outcomes System (SOS) data to evaluate the clinical and economic metrics and to validate observational results	• Quicker return to worker productivity • Reduced opioid use and potential for addiction
Economic Analysis and Value Assessment	Health Economic Outcomes/Analysis			• Savings on initial procedure, rehab after procedure, revision surgery, non-surgical treatment (complications, rehab, steroid injections)	

Expected Impacts (Value)

The value assessment should clearly demonstrate the impact of the technology across select value drivers including clinical impact, non-clinical patient impact, care delivery revenue and cost impact, and societal impact.

These impacts would be offset by the cost of acquiring the technology to derive the total expected value impacts.

Clinical Impact Value – RM's implant provides benefits to the clinician using the device. RM's technology impacts the method used by the surgeon performing the repair and the time needed to complete the surgery. Use of the technology eliminates the need for the surgeon to cut 'good tissue' and avoids the need to repair the tendon with sutures and anchors. Surgeons using the RM implant can complete tear repair surgery in an average of 15 minutes or less vs. an average of 45-60 minutes for a traditional repair.

Non-Clinical Impact Value – RM's implant also produces beneficial non-clinical impacts for a range of stakeholders including patients, hospitals, and insurers. These impacts take the form of significantly shorter rehab times, faster return to daily activities, and reduced operating room/suite times. Patients treated with the RM implant undergo minimal rehab post-procedure compared to 4-6 weeks of rehab with the traditional repair technique. The RM implant patients are also able to resume daily activities sooner—spending 1-2 days in a sling compared to 4-6 weeks with the traditional repair. The RM implant also creates an opportunity to treat more patients that would otherwise avoid surgery due to long and painful rehab and less than optimal results—leading to higher patient satisfaction.

Care Delivery Revenue and Cost Impact Value – The RM implant impacts cost and care delivery by reducing the potential for new/revision surgery; reducing the surgical time; and reducing rehab "episode" costs. The potential for cost savings attributable to use of the RM technology is also substantial. The value that this device brings to the treatment of high-grade partial thickness rotator cuff tears merits that it be recognized, covered, and paid for in this patient population.

Public/Population Impact Value – The RM technology creates beneficial societal impacts through reducing recovery time thereby allowing affected patients to return to work faster and potentially lowering pain medication costs and costs associated with opioid addiction through providing a treatment that alleviates long-standing pain in patients who may otherwise have avoided surgery or lacked a surgical alternative.

[1] "A Framework for Comprehensive Assessment of Medical Technologies: Defining Value in the New Health Care Ecosystem", available at www.advamed.org and co-developed with Deloitte Consulting LLP
[2] Bokor et al. "Evidence of healing of partial-thickness rotator cuff tears following arthroscopic augmentation with a collagen implant: a 2-year MRI follow-up." *Muscles, Ligaments and Tendons Journal* 6.1 (2016): 16-25.
[3] Swann et al., "The Future of Growth & Innovation in U.S. Extremities Ortho Reconstruction" (2013).

Medtech Value Assessment Framework *in Practice*

Rotation Medical: Bioinductive Implant

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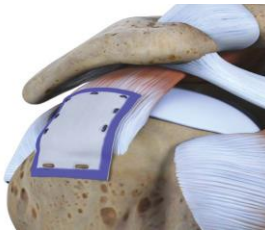

Patient Needs

New Technology

Stakeholders: Patient, Physician, Hospital, Payer, Government, Employer — **Stakeholders**

Value Drivers

Clinical Impact

- Thickened and healed tendon tissue
- Less trauma to healthy tissue
- Reduced re-tear risk

Non-Clinical Patient Impact

- Faster recovery time
- Faster rehab time
- Faster return to work and activities

Care Delivery Revenue and Cost Impact

- Reduced surgery time
- Reduced rehab costs
- Reduced need for revision surgery

Public/ Population Impact

- Faster return to work
- Decreased opioid use

Patient Populations

- Patients at all stages of Rotator Cuff Disease:
  - Severe Tendinosis
  - Partial-thickness Tear
  - Full-thickness Tear

Evidentiary Support

- Published Australian RCT
- US Post Market Study
- 3000 Commercial Cases
- Biopsy Study
- US Registry
- Economic Analysis and Value Assessment

Time Frames

- Surgical Time
- Recovery Time
- Rehab Time

Expected Impacts (Value)

- Thickened and healed tissue
- Less trauma to healthy tissue
- Faster recovery time: 1-2 days in sling v. 4-6 weeks
- Minimal rehab time: 1-2 v. 4-6 months
- Faster return to activities like driving: 11.15 days v. 35 days
- Surgical time reduced from 40-60 minutes to ~15 minutes
- Lower rehab episode costs
- Reduced hospital time
- Return to work 9.84 days faster; ~$2,053/patient productivity loss savings
- Opioid use reduced to 10 days v. 35 days

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