VALUE ANALYSIS BRIEF:
CLINICAL AND ECONOMIC EVIDENCE FOR THE VALUE OF MATRIXRIB™ FIXATION SYSTEM FOR THE SURGICAL STABILIZATION OF RIB FRACTURES
Executive Summary

Unmet Need

- Rib fractures occur in ~10% of patients admitted to a trauma center and are a marker for severe injury.\(^41\)
- Patients with multiple rib fractures or a flail chest frequently require mechanical ventilation; mortality rates of up to 33% have been reported in flail chest.\(^13,14,35,41\)
- Prevalence of chronic pain of 22% and disability of 53% among patients with rib fractures at 6 months.\(^20\)
- More than 30% of patients require additional care in post-acute settings.\(^23\)
- Despite the clinical and economic impact of rib fractures, current treatment primarily consists of little more than supportive treatment including pain control, rest and mechanical ventilation\(^5,30,35\) and the mortality and short term morbidity have not appreciably improved during the last four decades.\(^1,35\)
- Availability of rib fixation technology presents a potential option toward an effective approach to managing rib fracture.

Clinical Evidence Supporting Surgical Fixation:

- Results from two recent meta-analyses (each including >500 flail chest patients) have shown that compared to medical management (non-operative), surgical fixation patients had:\(^25,36\)
  - 57-69% less likely risk of mortality
  - 55-82% less likely to have pneumonia
  - 4.5-7.5 fewer days of mechanical ventilation
  - 3.4-4.8 fewer ICU days
  - 3.8-4.0 fewer hospital days
- Results from studies with MatrixRIB™ Fixation System demonstrated:
  - MatrixRIB Fixation System patients had a significant reduction in total ventilator days compared to the nonsurgical group (4.5 vs. 16.0; \(p = 0.04\)).\(^16\)
  - 84% of patients had no pain at 16 ± 1 month and patients who no longer had pain said their rib pain was completely gone at 5.4 ± 1.1 weeks post discharge.\(^27\)
  - The need for analgesia was significantly reduced after MatrixRIB Fixation System in patients with multiple rib fractures.\(^15\)
  - Within 3 months MatrixRIB Fixation System patients regained 84% Forced Vital Capacity(%FVC) and 77% Forced Expiratory Volume (FEV1)\(^9\)
  - At six months, 7 of 15 patients that completed followup had returned to work.\(^9\)
  - In a 16-month survey, of patients who were employed, 33 of 36 (92%) patients returned to work at the same job that they did preinjury.\(^27\)

Potential Implications

- Based on the results from two meta-analyses for every 25 flail chest patients treated with rib fixation,\(^25,36\)
  - Hospital costs may be reduced by approximately $453,375-$792,786
  - These savings would be attributed to reductions in ICU days, mechanical ventilation days and incidence of pneumonia.
Introduction
This value analysis brief presents clinical and economic evidence for the value of operative management of rib fractures and the MatrixRIB Fixation System specifically. Although some rib fractures are treated with pain management generally, as well as bracing, endotracheal intubation and mechanical ventilation if necessary, some patients could benefit from surgical stabilization (osteosynthesis). Potential benefits of surgical stabilization of rib fractures include reduced duration of mechanical ventilation support, shortened ICU stays and hospitalization, reduction in chest infection, and improved quality of life.6,7,9,16,25,27,36

Methods
A search of peer-reviewed literature published after 1990 through April 2014 using the EMBASE and Medline databases was conducted. Studies evaluating clinical and economic outcomes associated with operative fixation of rib fracture or flail chest were evaluated. Reference lists of selected studies were also reviewed for possible additional articles.

Background
Rib fractures are observed in approximately 10% of patients admitted to a trauma center and are a marker for severe injury.51 Rib fractures can lead to defects in the chest wall and significant pain which may hinder breathing. These patients have an increased risk of developing chest infection, impaired pulmonary function, sepsis, atelectasis, respiratory failure and other pulmonary pathologies as well as prolonged hospitalizations.21,33 As the number of fractured ribs increases, a patient’s risk for undesired outcomes is increased not only because of other serious injuries, but also because of the respiratory complications that are a direct consequence of the pain and impaired capacity to ventilate.10,18,28 It has also been shown that elderly patients who sustain blunt chest trauma with rib fractures have twice the mortality and thoracic morbidity of younger patients with similar injuries.17 In addition, the contribution of rib fractures to prolonged disability and chronic pain is greater than traditionally expected.17 The prevalence of chronic pain and disability among patients with rib fractures at six months have been reported as 22% and 53%, respectively.20
Patients with multiple rib fractures or a flail chest (unilateral fractures of at least 3 consecutive ribs, each with 2 or more fractures) frequently require mechanical ventilation and are at risk for death. Flail chest occurs in 5-13% of patients with chest wall trauma and has a mortality rate of up to 33%. In the US, patients with flail chest are in the hospital an average of 11 days, predominantly in the intensive care setting. More than 30% of patients require additional care in post-acute settings. Indirect societal costs result from inability to work or reduced workplace productivity.

Unmet Need
Despite the measurable clinical and economic impact of rib fractures, current treatment of the majority of patients consists of little more than supportive treatment including pain control, rest and mechanical ventilation and the mortality and short term morbidity of this entity have not appreciably improved during the last four decades.

The relatively recent availability of fixation technology specifically tailored to rib fixation presents a potential option toward a more effective approach to managing rib fracture.

MatrixRIB Fixation System
The MatrixRIB Fixation System is comprised of:
- Pre-contoured titanium alloy locking low profile 1.5 mm thick plates with 2.9 mm diameter locking screws
- The plates are pre-contoured to fit the average rib shape, minimizing Intra-operative bending
- Plate stiffness of the MatrixRIB Fixation System is similar to cadaveric osteoporotic rib, allowing for flexibility of the rib cage
- The pre-contoured plates are long enough to fixate multiple and comminuted/oblique fractures
- Anterior plating technique designed to avoid surgical disruption of intercostal soft tissues, and intramedullary splints allow minimally invasive procedures
- Instruments that enable rib stabilization of sub-scapular fractures
Clinical Effectiveness of Surgical Fixation vs. Medical (Non-operative) Management

Numerous studies comparing surgical fixation vs. medical (non-operative) management have been reported in the literature. The studies examined a variety of clinical endpoints, trial designs, and patient populations. There is no definitive clinical trial that delineates the role of surgery in the management of patients with multiple rib fractures, recent guidelines published by the National Institute for Health and Clinical Excellence (NICE) recommend surgical stabilization of a flail chest based on consistent evidence of its efficacy and lack of major safety concerns. Also, according to guidelines from the Eastern Association for the Surgery of Trauma (EAST): “Surgical fixation may be considered in cases of severe flail chest failing to wean from the ventilator or when thoracotomy is required for other reasons.” In addition, there are two recently published meta-analyses that summarize the clinical effectiveness of surgical fixation versus medical management.

Slobogean et al (2013) conducted a systematic review of previously published comparative studies using operative and nonoperative management of flail chest. A total of 11 manuscripts with 753 patients were included. Leinecke et al (2013), through an NIH-supported study, also conducted a systematic review of previously published comparative studies using operative and nonoperative management of flail chest, however, 3% of patients in the operative arm and 7% in the nonoperative arm were non-flail chest. A total of 9 studies with 538 patients met the inclusion criteria.

The meta-analyses showed significant benefit of surgical fixation in terms of mortality, pneumonia, ventilator days, ICU days, tracheostomy, and septicemia.

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Operative Management is Associated with a Statistically Significant Reduction in Mortality, Pneumonia, Tracheostomy, and Septicemia Compared to Non-Operative management

Leinecke et al., 2013
Surgical Fixation Had:
- Lower Risk of Mortality: 57%
- Lower Risk of Pneumonia: 55%
- Lower Risk of Tracheostomy: 75%

Slobogean et al., 2013
Surgical Fixation Had:
- Lower Odds of Mortality: 69%
- Lower Odds of Pneumonia: 82%
- Lower Odds of Tracheostomy: 88%
- Lower Odds of Septicemia: 64%

Mortality
- Pooled RR: 0.43; 95% CI: 0.28-0.69
- OR 0.31; 95% CI: 0.20-0.48

Pneumonia
- Pooled RR: 0.45; 95% CI: 0.29-0.67
- OR 0.18; 95% CI: 0.11-0.32

Tracheostomy
- Pooled RR: 0.25; 95% CI: 0.13-0.47
- OR 0.12; 95% CI: 0.04-0.32

Septicemia
- Pooled RR: 0.36; 95% CI: 0.19-0.71
- OR 0.36; 95% CI: 0.19-0.71
Since publication of the meta-analyses, additional studies, (Marasco et al. and Doben et al.), comparing surgical fixation to medical management for the stabilization of rib fractures have been published.\textsuperscript{16,28} Results were consistent with what was found in the meta-analyses. Marasco et al. is described below and Doben et al. is described in studies evaluating the MatrixRIB Fixation System.

- Marasco et al.\textsuperscript{28} A prospective randomized controlled trial of flail chest patients receiving mechanical ventilation compared operative rib fixation (n=23) to non-operative management (n=23) Rib fixation patients had significantly:
  - shorter ICU stay (3.08 days saved; \( p = 0.03 \))
  - less noninvasive ventilation after extubation (3 hours vs. 50 hours; \( p = 0.01 \))

### Studies Evaluating the MatrixRIB Fixation System

**Hospital Resource Utilization**

- Doben et al.\textsuperscript{16} A retrospective review of MatrixRIB Fixation System patients (n=10) matched to historical non-operative controls (n=11) found:
  - MatrixRIB Fixation System patients had a reduction in total ICU stay (18 days vs. 9 days, \( p = 0.37 \))
  - The MatrixRIB Fixation System patients had a significant reduction in total ventilator days compared to the nonsurgical group (4.5 vs. 16.0; \( p = 0.04 \))
  - Patients with surgery were permanently liberated from the ventilator within a median of 1.5 days (0-8 days)
Long-term Pulmonary Function

Bottlang et al. conducted a 6-month prospective cohort study, funding support from Synthes CMF, of MatrixRIB Fixation System patients and measured long-term pulmonary function at 3- (n=16) and 6-months (n=15) post-surgery.9

- At 3 months, patients regained an average % Forced Vital Capacity (FVC) of 84% and a Forced Expiratory Volume (FEV1) of 77%
- At 6 months, the average % FVC and % FEV1 was 85% and 79%, respectively

Patient-Centered Outcomes

Pain

Majercik et al. performed a long term (16-month) post-discharge telephone survey and chart review of patients treated with MatrixRIB Fixation System (n=50). Results showed that 84% of patients had no pain at 16 ± 1 month and patients who no longer had pain said their rib pain was completely gone at 5.4 ± 1.1 weeks post discharge. Of the 16% (8 patients) with pain, six patients reported that the pain is minimal or intermittent, and did not interfere with daily activities.27 In a study conducted by DeMoya et al the authors found that the need for analgesia was significantly reduced after MatrixRIB Fixation in patients with multiple rib fractures.15

Patient Satisfaction

Majercik et al. measured satisfaction with MatrixRIB Fixation System on a scale of 1 to 10, with 1 being not satisfied at all, and 10 being very satisfied, patients (n=50) rated their experience with MatrixRIB Fixation System and the results of the procedure as 9.2 ± 0.2.27 Ninety-four percent stated that they would recommend the surgery to injured friends/family.27
Return to Work
Return to work was evaluated in two studies with MatrixRIB Fixation System. Bottlang et al. showed that at six months, 7 of 15 patients that completed follow-up had returned to work. In a 16-month survey, Majercik et al found that of the patients who were employed, 33 of 36 (92%) patients returned to work at the same job that they did preinjury. Mean time to get back to full-time work was $7.9 \pm 1.0$ weeks.

Quality of life
In patients who underwent surgery using the MatrixRIB Fixation System, Billè et al. found the median Quality of Life and general health score (n=6) according to the QLQ-C30 were 7 (range 6-7).

Clinical and Economic Implications of the MatrixRIB Fixation System
Based on the results of the Leinecke et al. and Slobogeant et al. meta-analyses, the Bottlang et al. MatrixRIB Fixation System prospective cohort study, published ICU and national costing data for pneumonia, and Bureau of Labor Statistics Consumer Price Index medical care inflation, it is projected that the use of MatrixRIB Fixation System in 25 flail chest patients could potentially result in a cost-savings between $453,375-$792,786. These savings would be attributed to reductions in ICU days, mechanical ventilator days and incidence of pneumonia.

Cost-savings per 25 Flail Chest Patients Undergoing Rib Fixation Surgery

<table>
<thead>
<tr>
<th></th>
<th>Leinecke et al.</th>
<th>Slobogeant et al.</th>
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<tbody>
<tr>
<td>ICU Cost</td>
<td>$(292,500)</td>
<td>$(413,011)</td>
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<tr>
<td>non-ICU Cost</td>
<td>$(13,982)</td>
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<tr>
<td>MV Cost</td>
<td>$(394,055)</td>
<td>$(656,758)</td>
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<td>Pneumonia Cost</td>
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<td>Cost of Surgery</td>
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<tr>
<td>Cost of Device</td>
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Discussion

Although some rib fractures are treated with pain management and bracing, as well as endotracheal intubation and mechanical ventilation if necessary, some patients could benefit from surgical stabilization. Two meta-analyses demonstrated the efficacy of surgical fixation in the treatment of rib fractures and its superiority to medical management (non-operative).

In a literature search conducted by Girwicz et al, the nine studies reviewed support the use of surgical stabilization in the management of isolated multiple non-flail and painful rib fractures. Benefit was shown not only in terms of pain and respiratory function but also in improved quality of life and reduced socio-professional disability.\(^1^9\)

Based on these results, use of the MatrixRIB Fixation System has the potential to lead to fewer ICU days, mechanical ventilation days, cases of pneumonia, tracheostomies, mortality, cases of septicemia, and lower cost compared to medical (non-operative) management of multiple rib fractures. Studies evaluating the MatrixRIB Fixation System showed that patients had a significant reduction in total ventilator days compared to a nonsurgical group and that most patients regained long-term pulmonary function 3 and 6 months post-surgery.\(^1^6\) Patient-centered outcomes, including pain, satisfaction, quality of life, and return to work, were favorable with the MatrixRIB Fixation System in these case series.\(^7,9,15,27\)
References

*Please refer to the MatrixRIB Fixation System technique guide and package insert for complete indications, contraindications, instructions for use, warnings and/or precautions.

**Caution:** USA Law restricts these devices to sale by or on the order of a physician.
Not all products are currently available in all markets.