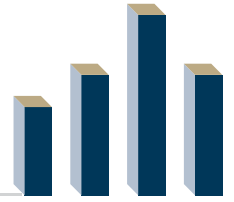
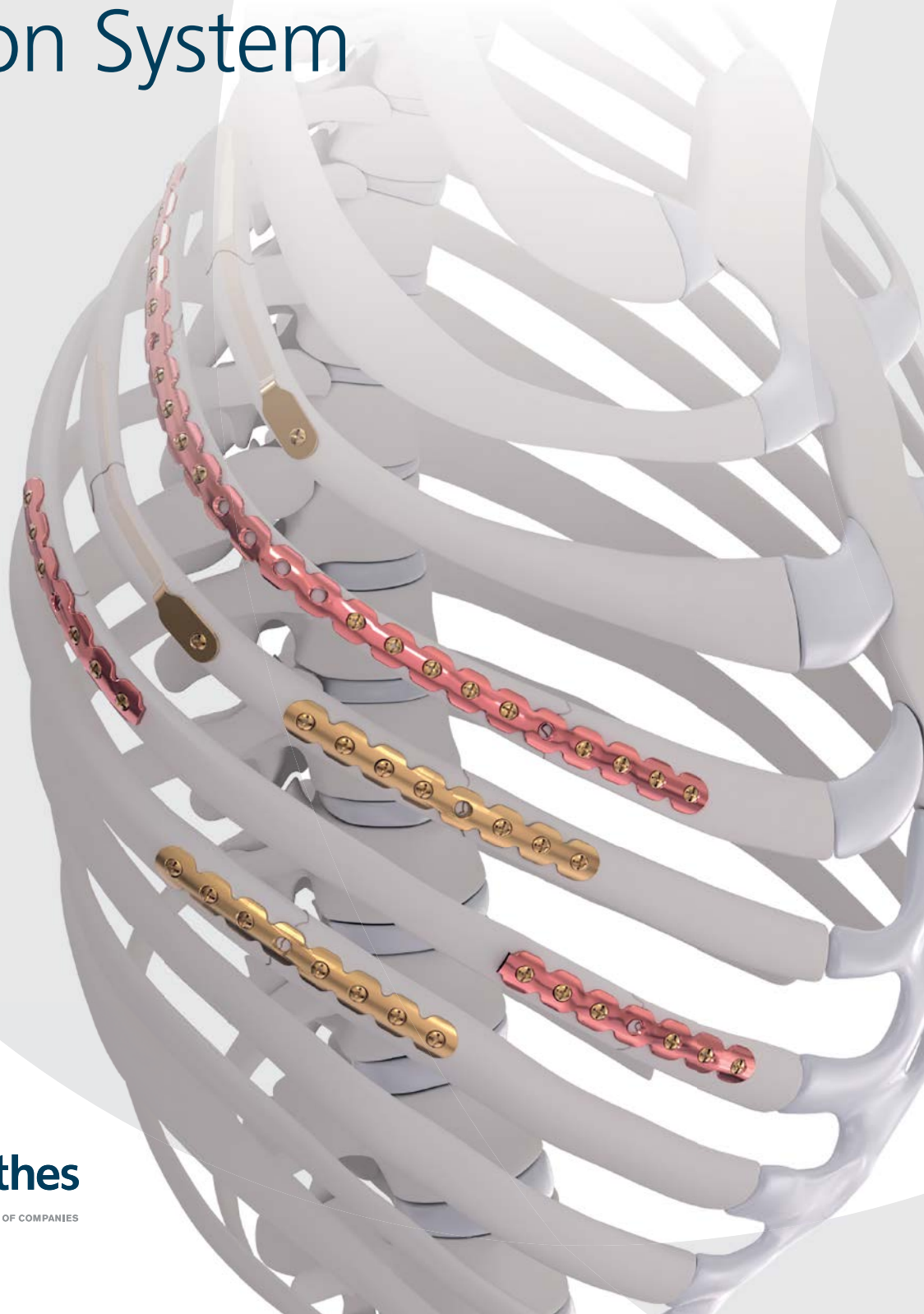


Value Analysis Brief



Evidence for MatrixRIB[®] Fixation System



Clinical and Economic Burden and the Treatment of Severe Rib Fractures

Management of Severe Rib Fractures

- ★ Severe rib fractures can be devastating, life-altering events with high morbidity and mortality rates.¹
- As the number of fractured ribs increases, risk for undesired outcomes increases 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.¹⁻⁵
 - Patients with flail chest (unilateral fractures of at least 3 consecutive ribs, each with 2 or more fractures^{6,7}) frequently require mechanical ventilation and are at risk for death.⁸
 - **Flail chest occurs in 5% to 13%** of patients with chest wall trauma⁹ and has a **mortality rate of 10% to 20%**.^{5,7,8,10}
 - Studies have reported a prevalence of **chronic pain of 22%** and **disability of 53%** among patients with rib fractures.¹¹
 - Up to **one-third of patients require prolonged rehabilitation**.⁸



Image courtesy of Mario G. Gasparri, MD at Medical College of Wisconsin, USA

The Benefits of Operative Fixation for Severe Rib Fractures

- ★ The strongest evidence for the effectiveness of rib fracture fixation is in patients with flail chest.¹ Members of the Chest Wall Injury Society also recommend surgical fixation for most patients with non-flail, displaced rib fractures. However, this recommendation is contingent upon patient age, degree of traumatic brain injury, and pulmonary clinical status.¹²
- Swart and colleagues (2017) conducted a systematic literature review and meta-analysis on outcomes after operative fixation of flail chest injuries and found a **significant reduction related to operative treatment in terms of intensive care unit (ICU) stay, hospital length of stay (LOS), mortality, pneumonia, and need for tracheotomy compared to nonoperative rib fixation ($P < 0.05$)**.¹

56%

lower risk of **mortality**
(Risk ratio [SD] 0.44 [±0.09])

3.25

less **ICU days**
(SD ±1.29)

41%

lower risk of **pneumonia**
(Risk ratio [SD] 0.59 [±0.10])

4.84

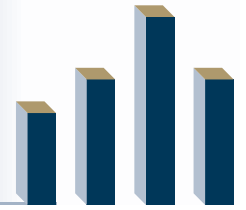
less **hospital days**
(SD ±1.98)

48%

lower risk of **tracheotomy**
(Risk ratio [SD] 0.52 [±0.07])

4.57

less **ventilator days**
(SD ±0.59)



Clinical Implications of Surgical Fixation

For every 100 flail chest patients treated with surgical fixation, there are expected to be:

7 deaths
prevented^{1,5,10}



19 cases of pneumonia
prevented¹



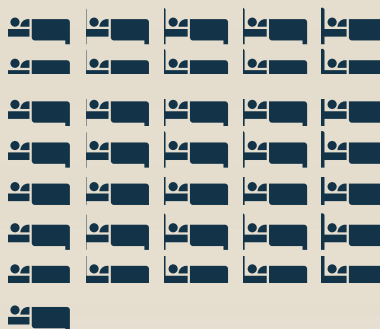
22 tracheotomies
prevented¹



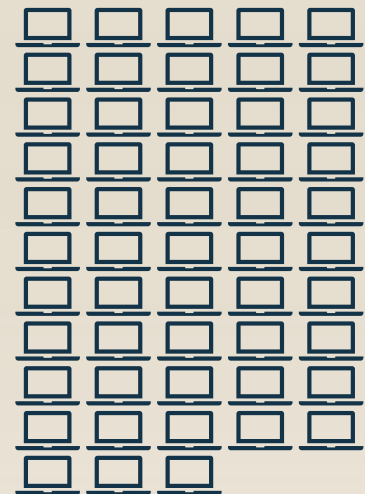
32 to 68
ICU days saved¹



30 to 48
hospital days saved¹



46 to 60
mechanical ventilation days saved¹



The MatrixRIB® Fixation System

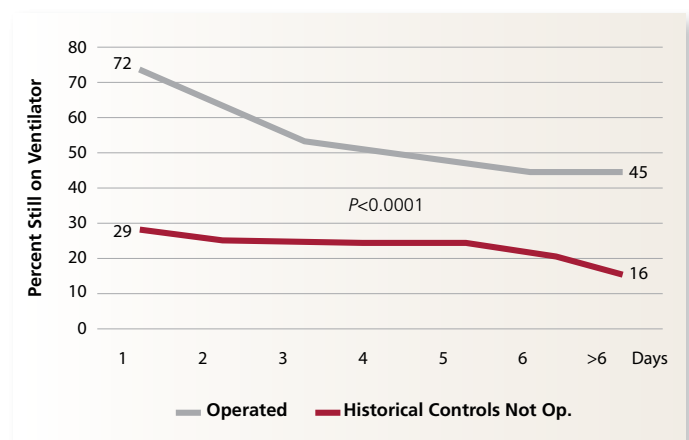
- The MatrixRIB® Fixation System is designed to provide stable fixation of normal and osteoporotic ribs.
- To date, the MatrixRIB® System has been evaluated in **52 published studies** involving 1,028 patients.
 - These studies included 1 randomized controlled trial (29 patients), 4 comparative cohort studies (261 patients), 18 case series studies (694 patients), 3 conference proceedings (29 patients), and 25 case reports (35 patients).
 - Study findings from the MatrixRIB® System studies confirmed the meta-analysis findings regarding the benefits of surgical fixation vs nonoperative treatment in flail chest.

MatrixRIB® System Reduces Mechanical Ventilation Days

- A study of 21 patients with flail chest found that the surgical fixation group treated with the MatrixRIB® System demonstrated a significant reduction in total ventilator days as compared with the nonsurgical group (4.5 [0-30] vs 16.0 [4-40]; $P=.040$).¹³
- Patients treated with the MatrixRIB® System were permanently liberated from the ventilator within

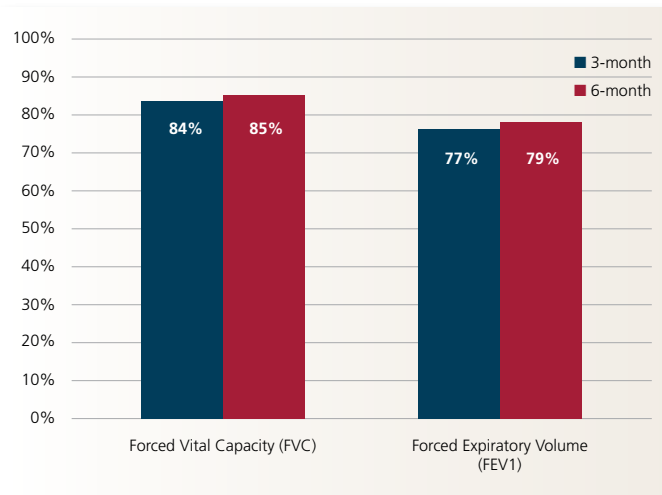
a median of 1.5 days (0-8 days).¹³

- Another study of patients with flail chest or multiple rib fractures resulting in unstable thoracic cage showed that the mean time in ventilator was 9.0 days for nonoperative patients (n=153) compared to 2.7 for those patients treated with the MatrixRIB® System (n=60) ($P<0.0001$).¹⁴



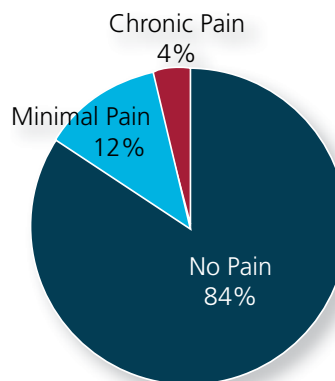
MatrixRIB® System Improves Pulmonary Function

- ★ A study of 16 patients treated with the MatrixRIB® System found that, within 3 months, patients regained 84% forced vital capacity (FVC) and 77% forced expiratory volume (FEV1).⁷
- Another study evaluating lung function over time in 54 patients treated with the MatrixRIB® System found that peak expiratory flow (PEF) significantly increased by 28.5% (SD 20.4; $P < .001$) from 3 months to 1 year. After 1 year, the mean FVC was 106%, PEF was 110%, and FEV1 was 80% compared to predicted values.¹⁵

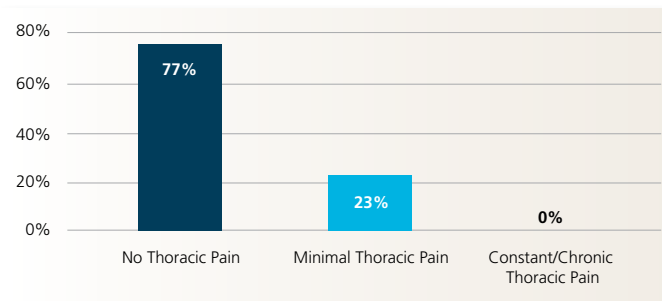


MatrixRIB® System Reduces Pain

- ★ Pain was gone at 5.4 ± 1.1 weeks post-discharge and 84% of patients had no pain at 16 ± 1 months ($n=50$).¹⁶



- Another study showed that, at 27.6 (12–68) months follow-up ($n=18$), 77% of patients had no pain and 13% of patients had minimal pain.¹⁷



- Patient pain and analgesia use was found to decrease over time during the year after surgery.¹⁵

Symptoms	6 weeks (n=34)	3 months (n=34)	6 months (n=37)	1 year (n=45)
Pain at Rest	12 (35.3%)	4 ^{*a} (11.8%)	6 (16.2%)	6 ^{*c} (13.3%)
Pain on Breathing	8 (23.5%)	5 (14.7%)	3 (8.1%)	4 ^{*c} (8.9%)
Local Discomfort	14 (41.2%)	17 (50.0%)	19 (51.4%)	21 (46.7%)
Breathlessness	14 (41.2%)	12 (35.3%)	10 (27.0%)	7 ^{*c} (15.6%)
Analgesia Use	18 (52.9%)	13 (38.2%)	5 ^{+b} (13.5%)	4 ^{+c} (8.9%)

$P < .05$; ⁺ $P < .01$; [†] $P < .001$.

^aDifference from 6 weeks to 3 months ($n=27$); ^bDifference from 6 weeks to 6 months ($n = 27$); ^cDifference from 6 weeks to 1 year ($n=33$).

MatrixRIB® System Accelerates Return to Work

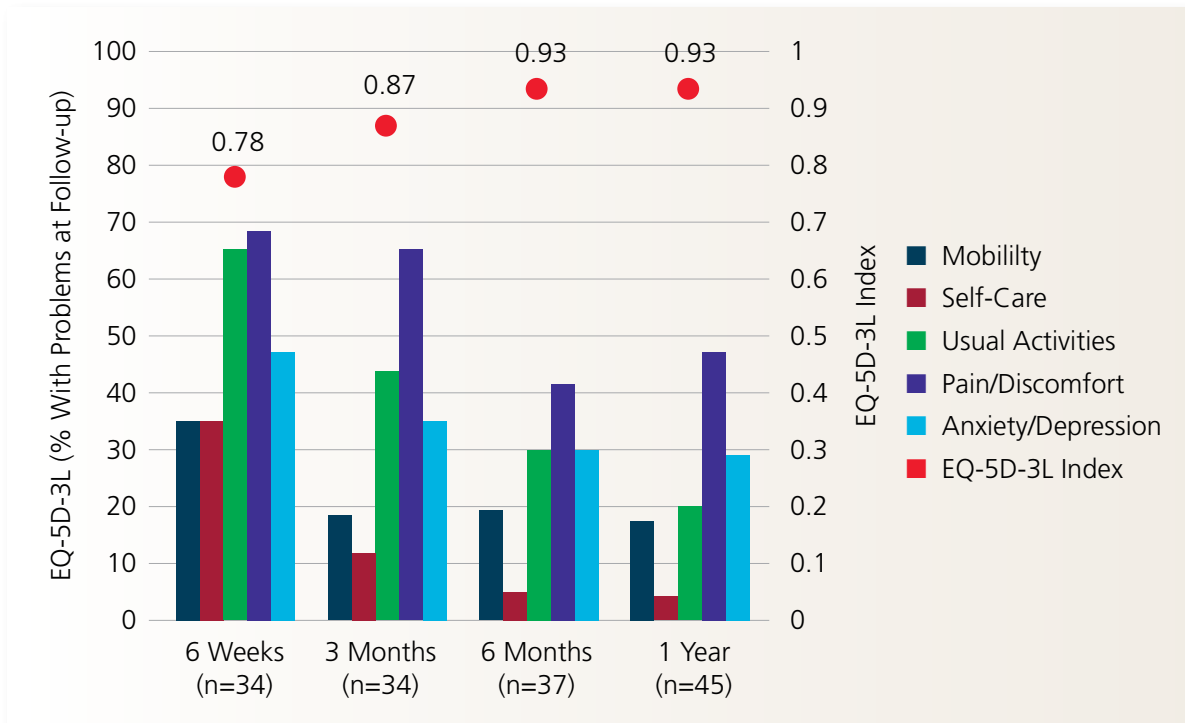
Return to work was evaluated in two studies with the MatrixRIB® System.^{7,16} One study showed that at three months, 31% of patients returned to work, and that at six months, 7 of 15 (47%) patients that completed follow-up had returned to work.⁷ In a 16-month survey, 90% of employed patients (n=36) returned to the same work at 8.5±1.2 weeks.¹⁶

MatrixRIB® System Ensures Patient Satisfaction

- ★ 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 the MatrixRIB® System and the results of the procedure as 9.2±0.2.¹⁶
- Ninety-four percent of patients who received surgical fixation with the MatrixRIB® System stated that they would recommend the surgery to injured friends/family.¹⁶

MatrixRIB® System Continuously Improves Quality of Life

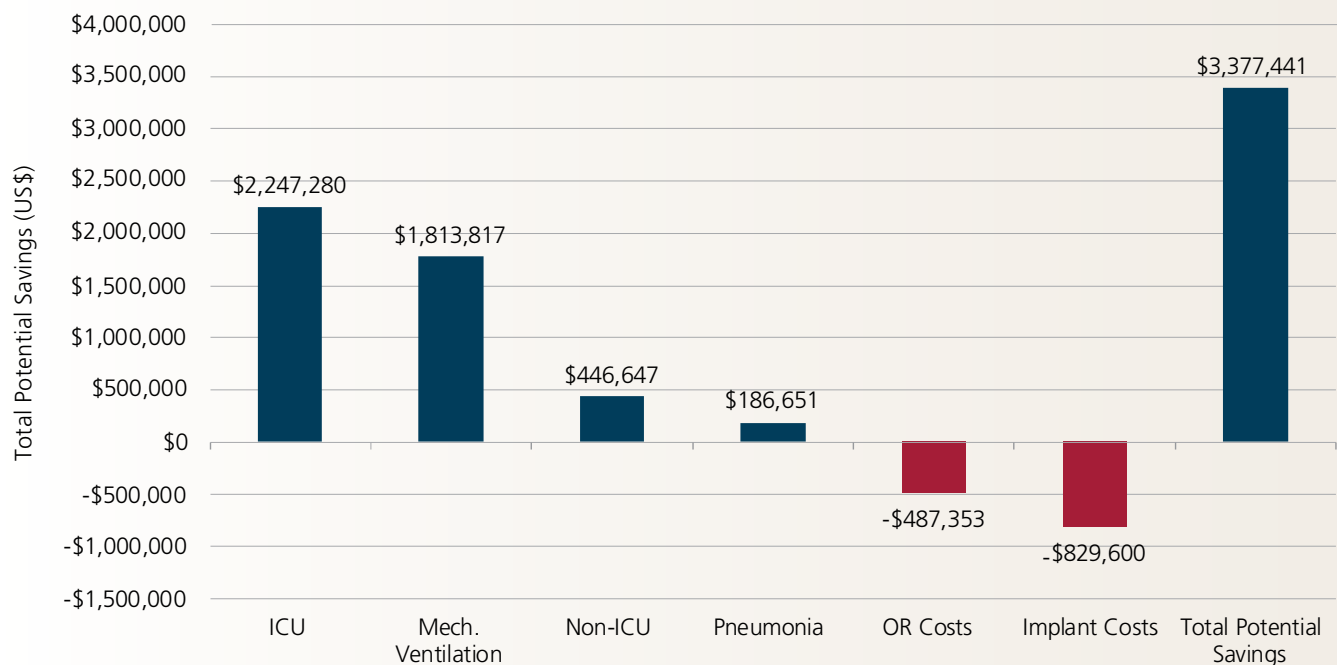
Change in QoL over time was evaluated using the EQ-5D-3L, showing the percentage of patients with some or extreme difficulties and median QoL.¹⁵ Patients show a gradual improvement of symptoms, therefore the final outcome of surgery cannot be assessed before 1 year postoperatively.



Economic Impact

Economic Impact of the MatrixRIB® System

- The increased cost of surgery is offset by decreased length of stay in both the ICU and non-ICU, by decreased duration of mechanical ventilation, and by decreased cost due to pneumonia.^{1,7,17-20*}
- **The total potential savings with use of the MatrixRIB® System are estimated to be ^\$3.4M for 100 patients with flail chest.**^{1,7,17-20*}



*Values based on US costs from US Hospital Inpatient National Statistics.

^Cost saving calculator may not be in local currencies. The economic analysis was performed according to hospital data set in countries outside of Australia and New Zealand.

References

1. Swart E, Laratta J, Slobogean G, Mehta S. Operative treatment of rib fractures in flail chest injuries: a meta-analysis and cost-effectiveness analysis. *J Orthop Trauma*. 2017;31(2):64-70.
2. Testerman GM. Adverse outcomes in younger rib fracture patients. *South Med J*. 2006;99(4):335-339.
3. Brasel KJ, Guse CE, Layde P, Weigelt JA. Rib fractures: relationship with pneumonia and mortality. *Crit Care Med*. 2006;34(6):1642-1646.
4. Fligel BT, Luchette FA, Reed RL, et al. Half-a-dozen ribs: the breakpoint for mortality. *Surgery*. 2005;138(4):717-723; discussion 723-715.
5. Simon B, Ebert J, Bokhari F, et al. Management of pulmonary contusion and flail chest: an Eastern Association for the Surgery of Trauma practice management guideline. *J Trauma Acute Care Surg*. 2012;73(5)(suppl 4):351S-361S.
6. Helzel I, Long W, Fitzpatrick D, Madey S, Bottlang M. Evaluation of intramedullary rib splints for less-invasive stabilisation of rib fractures. *Injury*. 2009;40(10):1104-1110.
7. Bottlang M, Long WB, Phelan D, Fielder D, Madey SM. Surgical stabilization of flail chest injuries with MatrixRIB implants: a prospective observational study. *Injury*. 2013;44(2):232-238.
8. Kasotakis G, Hasenboehler EA, Streib EW, et al. Operative fixation of rib fractures after blunt trauma: A practice management guideline from the Eastern Association for the Surgery of Trauma. *J Trauma Acute Care Surg*. 2017;82(3):618-626.
9. LoCicero J, Mattox KL. Epidemiology of chest trauma. *Surg Clin North Am*. 1989;69(1):15-19.
10. Dehghan N, de Mestral C, McKee MD, Schemitsch EH, Nathens A. Flail chest injuries: a review of outcomes and treatment practices from the National Trauma Data Bank. *J Trauma Acute Care Surg*. 2014;76(2):462-468.
11. Gordy S, Fabricant L, Ham B, Mullins R, Mayberry J. The contribution of rib fractures to chronic pain and disability. *Am J Surg*. 2014;207(5):659-662; discussion 662-653.
12. Pieracci FM, Agarwal S, Doben A, et al. Indications for surgical stabilization of rib fractures in patients without flail chest: surveyed opinions of members of the Chest Wall Injury Society. *Int Orthop*. 2018;42(2):401-408.
13. Doben AR, Eriksson EA, Denlinger CE, et al. Surgical rib fixation for flail chest deformity improves liberation from mechanical ventilation. *J Crit Care*. 2014;29(1):139-143.
14. Granhed HP, Pazooki D. A feasibility study of 60 consecutive patients operated for unstable thoracic cage. *J Trauma Manag Outcomes*. 2014;8(1):20.
15. Caragounis E-C, Fagevik Olsén M, Pazooki D, Granhed H. Surgical treatment of multiple rib fractures and flail chest in trauma: a one-year follow-up study. *World J Emerg Surg*. 2016;11:27-27.
16. Majercik S, Cannon Q, Granger SR, VanBoerum DH, White TW. Long-term patient outcomes after surgical stabilization of rib fractures. *Am J Surg*. 2014;208(1):88-92.
17. Michelitsch C, Acklin YP, Hassig G, Sommer C, Furrer M. Operative Stabilization of Chest Wall Trauma: Single-Center Report of Initial Management and Long-Term Outcome. *World J Surg*. 2018;42(12):3918-3926.
18. Agency for Healthcare Research and Quality (AHRQ) Healthcare Cost and Utilization Project (HCUP). 2016 Costs for Flail Chest and Pneumonia. <https://hcupnet.ahrq.gov/#setup>. Accessed May 21, 2019.
19. Zilberberg MD, Shorr AF. Prolonged acute mechanical ventilation and hospital bed utilization in 2020 in the United States: implications for budgets, plant and personnel planning. *BMC Health Serv Res*. 2008;25;8:242.
20. Childers CP, Maggard-Gibbons M. Understanding costs of care in the operating room. *JAMA Surg*. 2018;153(4):e176233.

The third party trademarks used herein are the trademarks of their respective owners.

Please also refer to the package insert(s) or other labeling associated with the devices identified in this value analysis brief for additional information.

CAUTION: Federal Law restricts these devices to sale by or on the order of a physician.

Some devices listed in this value analysis brief may not have been licensed in accordance with Canadian law and may not be for sale in Canada.

Please contact your sales consultant for items approved for sale in Canada.

Not all products may currently be available in all markets.



Manufactured or distributed by:

Synthes USA Products, LLC
1302 Wrights Lane East
West Chester, PA 19380

Synthes USA, LLC
1101 Synthes Avenue
Monument, CO 80132

Johnson & Johnson Medical Pty Ltd
t/a Depuy Synthes
1-5 Khartoum Road
North Ryde NSW 2113 Australia
168270-210225 02/2021

Note: For recognized manufacturer, refer to the product label.

^www.depuyssynthes.com

^This website is not owned by Johnson & Johnson Medical Pty Ltd t/a Depuy Synthes, and we do not review or control the content on this website. Products discussed on this website may not be approved for use or may be approved for different indications in your country. Before using any medical device, review all relevant Instructions for Use, Packaging Inserts or Summary of Product Characteristics. We do not endorse the use or promotion of unapproved products or indications. Any demonstrations of approved medical devices should be considered as information only and are not a surgical training guide.