Building upon the foundation of polyaxial and closure mechanism innovations, the EXPEDIUM® Spine System represents the next engineering triumphs to enhance the MOSS MIAMI® System’s reputation for leadership in philosophy based, technological advancement.

The EXPEDIATE Spine System incorporates technique-simplifying designs, including a state-of-the-art internal closure mechanism and a comprehensive set of implants designed in harmony with the instruments, which maximize performance and meet the challenge of even the most difficult pathologies.

Developed for multi-pathology application, the EXPEDIATE Spine System offers advanced instruments that work in harmony with the implants to amplify procedural precision and ease. The new benchmark for speed, security, and simplicity is the EXPEDIATE Spine System.

The EXPEDIATE Spine System

The fundamental design goal of the EXPEDIATE Spine System was to ensure speed, security, and simplicity. In order to maximize the performance of the EXPEDIATE Spine System, considerable attention and development resources were dedicated to the following areas:

1. Closure Mechanism – Square Thread vs. Buttress Thread
2. Implant Access – TOP NOTCH® Implant/Instrument Interface
3. Screw Design – Double Lead vs. Single Lead; Tapered Tip
4. Approximation Implants – Extended Tab Screws and Translation Hooks

The discussion that follows describes the clinical issues to be addressed, the inherent design challenges and the subsequent design solutions. These solutions, applied to an extremely versatile selection of implants, make the EXPEDIATE Spine System uniquely capable of managing a complete range of challenging spine pathologies.
Clinical Challenge

Many implant systems incorporate top-loading, rod-ready designs to connect the spine anchor to the longitudinal member. As screw thread designs have been optimised over several generations, the design and use of the closure mechanism has become the primary challenge.

Historically, closure mechanisms have been the source of both intra-operative challenges and post-operative complications. An effective closure mechanism must reliably lock the rod to the anchor while maintaining a balance between secure closure and implant profile. Rod/implant loosening may be attributed to spreading forces created via the axial tightening force on an open anchor, necessarily split to accept the longitudinal member. The closure mechanism must be robust enough to secure the rod in place, while withstanding the axial shear forces acting on the threads. Furthermore, the screw flanges must have adequate stiffness to minimise head splay and ensure adequate closure mechanism thread engagement. These points notwithstanding, unnecessarily large profiles can limit the anchor site selection and available room for bone graft, both of which can potentially hinder fusion success and, as such, should be minimised.

Design Challenge

The clinical considerations specifically addressed by the EXPEDIUM Spine System design process were:

A. Minimisation of intra-operative challenges
B. Minimisation of spreading forces directed to the open implant head during final tightening
C. Exceptional axial and polyaxial slip strength
D. Reduction of implant profile

Design Solutions

A. Minimisation of intra-operative challenges

Construct assembly, especially in long constructs, can present a significant challenge. The ability to easily capture and secure the longitudinal member is critical. The loose thread engagement of the standard buttress thread permits the screw to advance despite being misaligned. This misalignment propagates as the set screw is allowed to advance, potentially leading to a false indication that the rod is securely locked. The EXPEDIUM Spine System has been specifically designed with an internal set screw that incorporates a unique square thread design (Figure 1). The square thread design provides smooth insertion that lessens the likelihood of a false start. The thread engagement does not permit a misaligned screw to advance.

EXPEDIATE SQUARE THREAD VERSUS STANDARD BUTTRESS THREAD

The tightly controlled features of the square thread design prevent misalignment and therefore reduce cross-threading.

FIGURE 1: The smaller the difference (D) between the thread crest (a) and the thread opening (b) the less likely the set screw is to skip a thread and advance off axis. The design of the EXPEDIUM Spine System substantially minimises that clearance as compared to the standard buttress thread.

B. Minimisation of spreading forces

A closure mechanism internal to the head of an implant provides for a smaller overall profile. This maximises working room and available area for bone graft placement. However, when tightened, internal mechanisms often apply a spreading force to the head of the implant increasing the potential for undesired results. The EXPEDIATE Spine System was designed to have an internal closure mechanism that would greatly minimise these spreading forces (Figure 2). A combination of two design features achieved the desired result.

HEAD SPREADING OF OPEN IMPLANTS AT FINAL TIGHTENING TORQUE

The head spreading of EXPEDIUM implants compared favorably to other systems.

FIGURE 2: The EXPEDIUM open implants exhibited the least spreading when compared to other open (rod-ready) implant systems when tightened to the respective recommended tightening torques (Data on file).
CLOSURE MECHANISM (CONT.)

EXPEDIUM SQUARE THREAD MECHANICS

1. Square Thread Technology: The unique square thread design (Figure 3) balances the securing forces vertically, thus virtually eliminating the outward forces of buttress threads. In this manner, the tightening forces are more efficiently applied directly to the rod and, therefore, maximise the hold on the rod.

2. Thread Clocking: A new proprietary manufacturing process was incorporated which 'clocks' the threads in the screw head. This 'clocking' cuts the start of the threads at an optimal position for every screw and ensures that there are an equal number of complete threads on each side of the screw head. Equally important is the cross-section of the thread immediately above the rod. This thread experiences the highest load during tightening and the 'clocking' process ensures that this thread has the greatest cross-sectional area possible. Standard processing techniques potentially result in a partial thread in this critical area. By having a complete thread on each side of the screw head, the applied forces are less apt to cause a failure through deformation when compared to the same forces applied to the partial thread.

The result of these two design features allows for a high torque to be applied without a failure due to shear and/or head splay.

C. Exceptional axial and polyaxial slip strength.

Axial slip testing was conducted according to the methods described by G. R. Fogel, M.D. et al.* Although rare clinically, axial slip along the rod is a measure of pedicle screw performance. Similar testing was conducted to evaluate polyaxial slip strength. The results of these tests (Figure 4) indicate that the EXPEDIUM Polyaxial Screw meets the high standards of security and performance established by and validated through the long clinical history of the MOSS MIAMI Spine System.

AXIAL AND POLYAXIAL SLIP STRENGTH

Parallel surfaces and uninterrupted threads ensure balanced forces. These features combine to maximise axial and polyaxial slip strength.

CLOSURE MECHANISM (CONT.)

EXPEDIUM IMPLANT PROFILE

The EXPEDIUM Implants achieve an ideal balance between anatomy-friendly profile and clinical performance.

D. Reduction of implant profile.

The internal design of the EXPEDIUM Closure Mechanism provides a significant advantage over outer closure mechanism devices. A direct relationship exists between implant profile and anchor site selection. This is particularly evident in the thoracic spine where bony anatomy often dictates implant choice. Also, bone graft placement is negatively impacted by implants that are prohibitively large. The EXPEDIUM implants were designed with tissue sparing features that minimise M/L profile, run-on-rod, as well as height above and below the rod. Significant attention was given to the EXPEDIUM Instruments further minimising working profile along the rod and around the implants. A concerted effort was made to ensure that the profile of the implant/instrument construct did not impinge on any of the surrounding tissue while maintaining the integrity of implant performance.

Summary

The EXPEDIUM Single Inner Set Screw is designed to address ease of assembly, security and intra-operative profile. The unique square thread design and manufacturing process significantly improves the assembly process and limits head spread to less than other internal threaded closure mechanisms currently available. With this comprehensive design approach to all aspects of the closure mechanism performance, the EXPEDIUM Spine System can be utilised for even the most complex of spine pathologies.

IMPLANT ACCESS

Clinical Challenge

As spine surgery continues to advance and techniques become more refined, the challenges specific to the different areas of the spine become more evident. The struggle against bony tissue, especially in the thoracic spine, increases the complexity of the corrective procedures. To this point, the instrument interface features on most spine anchors have been located such that implant access is often severely impaired.

TOP NOTCH FEATURE

The TOP NOTCH feature makes implant manipulation significantly easier when compared to systems with more distally placed access features.

Design Challenge

Minimise intra-operative challenges associated with implant access.

Design Solutions

The EXPEDIUM Implants have been designed in harmony with the instruments. Each incorporates the TOP NOTCH design feature, a design advancement that allows for easier access in the spine. By placing the instrument interface at the most proximal point on the implant, manipulation (i.e. placement, rod reduction, etc.) becomes significantly easier. Surgeons are no longer required to search for the interface features deep in a lumbar wound where soft tissue and body fluid hinder visibility. The same advantage applies in the thoracic spine where the bony elements impair traditional implant attachment.

Summary

The TOP NOTCH feature gives surgeons easier access to the implants in both the lumbar and thoracic spine. Each spinal region has its own unique anatomical challenges, but the TOP NOTCH feature reduces the impact of these challenges with respect to implant attachment.
Clinical Challenge
Pedicle screws have been well accepted as a safe and strong anchor to the lumbar spine for many years. Surgeons are increasingly realising that pedicle screw instrumentation for spinal deformity, trauma and tumour applications provides greater correction capabilities. As such, pedicle screw usage in the thoracic spine is becoming more common. With the increased use of pedicle screws as anchors to the spine, there is an increase in the awareness of the intraoperative challenges associated with such usage.

With the exception of the self-tapping flute, very few design innovations have accompanied pedicle screw development over the years. And while the self-tapping features do reduce OR time by removing an operative step, some surgeons feel an aggressive flute design is not optimal because of the potential for the screws to diverge from the ideal path and breach the pedicle wall. The design of the EXPEDİUM Polyaxial Screw is the first to achieve the delicate balance between function and safety. The innovative shank and thread design provide true self-tapping capability while providing for safe, bi-cortical fixation.

Design Challenge
The design goals of the screws in the EXPEDİUM Spine System were to:

A. Minimise OR time by reducing screw insertion time
B. Minimise risk of damage to surrounding tissue
C. The EXPEDİUM Polyaxial Screw demonstrates enhanced performance under specific and demanding criteria. The double-lead thread provides the benefits of faster insertion into the pedicle. The balance between the need for safe bicortical purchase compatible with a self-tapping feature has been achieved by means of a unique taper of the distal tip. The EXPEDİUM Polyaxial Screw represents the culmination of a design process integrating a complex set of design goals and challenging mechanical performance criteria.

Design Solutions
A. Minimise OR time by reducing screw insertion time
The design of the EXPEDİUM Polyaxial Screw represents a natural evolution of the MOSS MIAMI Spine System’s long, successful and well-established clinical history with polyaxial screws. Like its predecessors, the EXPEDİUM Polyaxial Screw includes a consistent thread crest and a constant pitch over the entire length of the screw shank. However, the double-lead thread pattern is a significant change from previous designs. A screw with a double-lead thread pattern will enter the bone at twice the rate of a traditional, single-lead screw (Figure 8). For example, fully seating a 30mm EXPEDİUM Polyaxial Screw takes a mere 5 revolutions versus 10 revolutions for a single-lead screw.

B. Minimise risk of damage to surrounding tissue
The design of the EXPEDİUM Polyaxial Screw also includes a tapered minor and major diameter within the distal 10mm of the screw shank. This taper eliminates the need for self-tapping flutes and allows for a blunt, tissue-friendly tip, thereby making the screw safe for procedures requiring bi-cortical fixation. Other benefits of the taper include:

1. Faster start within the pedicle – As compared to standard screw designs, the distal minor and major taper makes it possible to have uninterrupted screw threads along the entire length of the screw shank. Extending the threads to the very tip of the screw means the screw will gain purchase in the bone immediately upon engagement with less effort.

2. Find the optimal trajectory – Much like a pedicle probe, as the tip approaches the more compact cortical shell of the pedicle, it will re-direct the trajectory and allow the screw to find the appropriate angle of insertion. This is especially critical in the thoracic spine, where spinal deformity can cause gross irregularities in pedicle geometry.

Summary
C. The EXPEDİUM Polyaxial Screw demonstrates enhanced performance under specific and demanding criteria. The double-lead thread provides the benefits of faster insertion into the pedicle. The balance between the need for safe bicortical purchase compatible with a self-tapping feature has been achieved by means of a unique taper of the distal tip. The EXPEDİUM Polyaxial Screw represents the culmination of a design process integrating a complex set of design goals and challenging mechanical performance criteria.
The EXPEDIUM Spine System improves the surgical experience through intra-operative versatility, ease of use and implant selection. Most notably, the implants were designed in harmony with the instruments to ensure an almost effortless interaction between the components. Every effort was taken to maximise the performance of the EXPEDIUM Spine System. Specifically, these key features were painstakingly designed and verified for optimal clinical success.

- **Closure Mechanism** – Simplified insertion eliminates implant head spread during final tightening. Minimised implant profile, specifically run-on-rod
- **Implant Access** – Simplified implant access reduces intra-operative challenges
- **Screw Design** – Faster pedicle engagement and reduced insertion time with a safe, fully threaded, blunt-tip screw shank
- **Approximation Implants** – Reduction capabilities decrease the need for extra instruments

Extensive laboratory testing, theoretical analyses (FEA) and clinical experience have verified that these designs will meet the needs of spine surgeons in performing procedures of varying complexity covering a multitude of pathologies.

**APPENDIX IMPLANTS**

**Clinical Challenge**
As spine surgery continues to advance, implants are expected to do more to facilitate simpler, more efficient procedures, involving challenging pathologies. Implants have a unique role in their ability to make a difficult procedure simpler and easier to accomplish the desired outcome.

**Design Challenge**
Minimise the need for traditional reduction tools.

**Design Solutions**
EXPEDIUM Translation Hooks and Polyaxial Screws incorporate removable, threaded Extended Tabs. These tabs facilitate approximation of the rod into the Polyaxial Screw head and have several uses that add versatility to the Polyaxial Screw including:

- **Closure Mechanism**
- **Implant Access**
- **Screw Design**
- **Approximation Implants**

Once the rod is secured with the Single Inner Set Screw, the Extended Tabs are easily removed.

**Summary**
As advances in surgery are made and new technologies are discovered, surgeons look to implants to help reach their surgical goals while minimising the need for difficult maneuvers and complex rod contouring. The EXPEDIUM Approximation Implants help achieve both of these goals in an intuitive and safe manner.
INDICATIONS:
The EXPENDIUM® Spine System is intended to provide immobilisation and stabilisation of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine. The EXPENDIUM® Spine System metallic components are intended for noncervical pedicle fixation and nonpedicle fixation for fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumour, pseudoarthrosis; and failed previous fusion in skeletally mature patients. The EXPENDIUM® PEEK rods are only indicated for fusion procedures for spinal stenosis with instability (no greater than Grade I spondylolisthesis) from L1-S1 in skeletally mature patients.

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