TRAUMA PEDIATRIC SOLUTIONS

••••••

Brochure



Upper Extremity, Lower Extremity, Deformity Correction and Biomaterials



Table of Contents

Pediatric Product Solutions

Overview	4
_ower Extremity Fractures	5

Trauma Product Solutions - Upper Extremity

Overview	7
Upper Extremity Fractures	11

Trauma Product Solutions - Lower Extremity

Overview	8
Lower Extremity Fractures	12

Deformity Correction

Overview	9
Deformity Correction-Upper Extremity	15
Deformity Correction-Lower Extremity	16

Biomaterials

Overview	10
Bone Void Repairs	18

DePuy Synthes Companies of Johnson & Johnson

The formation of the DePuy Synthes Companies of Johnson & Johnson created an organization inspired to provide a vast portfolio of pediatric patient care solutions worldwide. Our product offerings provide an extensive portfolio addressing patient needs in trauma and deformity correction. This symbiosis enables us to better serve clinicians and hospitals. We are inspired to help return pediatric patients to active and fulfilling futures.





Pediatric Product Solutions

Titanium Elastic Nails Stainless Steel Elastic Nails Adolescent Lateral Entry Femoral Nail-EX (ALFN) Cannulated Pediatric Osteotomy System (CAPOS) Pediatric LCP[™] Condylar Plates Pediatric LCP[™] Hip Plate System Medium External Fixator - Pediatric Femoral Shaft Frame 7.3 mm Slipped Capital Femoral Epiphysis (SCFE) Screws



Products displayed from left to right: CAPOS, ALFN, and Elastic Nails.

Pediatric Product Solutions

Lower Extremity Fractures

Titanium Elastic Nail (TEN™) and Stainless Steel (STEN) Systems

- Facilitates biological, minimally invasive fracture treatment
- Biomechanical principal based on symmetrical bracing action of two elastic nails inserted into the metaphysis, each of which bears against the inner bone at three points to create four properties essential for recommended results
- Six diameters are available, in titanium and stainless steel
- End caps may limit nail migration. End caps are recommended to cover the cut part of the nail as it may have burr or sharp edges.

Adolescent Lateral Entry Femoral Nail-EX (ALFN)

- Three proximal locking options: two 5.0 mm recon screws, one 4.0 mm 120° antegrade, or one transverse 4.0 mm static or dynamic
- Small distal diameter 8.2 mm, 9.0 mm, or 10.0 mm

Cannulated Pediatric Osteotomy System (CAPOS)

- · Osteotomy plates are offered in a variety of sizes
- Cannulated chisels and guide wires
 simplify surgical technique







Pediatric Product Solutions

Lower Extremity Fractures

Pediatric LCP[™] Fracture Plates

- Anatomic plate shape designed for fraxture fixation
- Initial plate positioning with k-wires allows for intraoperative flexibility
- Variety of plate sizes (3.5 mm and 5.0 mm) and screw lengths all patient specific fit



- Initial plate positioning with K-wires allows for intraoperative flexibility and correction
- Variety of plate sizes (2.7 mm, 3.5 mm and 5.0 mm), angles (90° – 150°) and screw lengths allow optimal patient fit. 130° plate length up to 175 mm for fracture fixation
- Calcar screw for added fixation

7.3 mm Slipped Capital Femoral Epiphysis (SCFE) Screws

- 10 mm or 20 mm threads offer option to cross physis or gain compression
- Cannulated shaft screw design (with shaft same diameter as threads) facilitates screw insertion and removal
- 9.8 mm diameter head with STARDRIVE[™] Recess reduces the possibility of screw head stripping during insertion or removal



Trauma Product Solutions Upper Extremity Fractures

- 2.4 mm VA LCP[™] Distal Radius Plate System*
- 2.7 mm VA LCP[™] Clavicle Plate System^{*}
- 2.7 mm/3.5 mm VA LCP[™] Anterior Clavicle Plate*
- 2.7 mm/3.5 mm VA LCP[™] Elbow System^{*}
- 3.5 mm LCP[™] Superior Anterior Clavicle Plate^{*}
- 3.5 mm LCP[™] Superior Clavicle Plate^{*}
- 3.5 mm and 4.5 mm Curved LCP[™] Plates
- 3.5 mm and 4.5 mm LCP[™] Plates
- **Stainless Steel Elastic Nails**
- Titanium Elastic Nail (TEN™) System
- Variable Angle Locking Hand*

0000

0 (C) (C) (C) (C) (O)

Products displayed from left to right: Clavicle Plate System and Elbow System

*Also indicated for adolescents (12-21) and transitional adolescents (18-21) in which the growth plates have fused or will not be crossed. Please refer to product insert for full list of indications, warnings, and precautions.

0°00 0.00

Trauma Product Solutions

Lower Extremity Fractures

2.2 mm/2.7 mm VA LCP[™] Forefoot/Midfoot System*

2.7 mm/2.5 mm VA LCP[™] Ankle Trauma System^{*}

3.5 mm and 4.5 mm LCP[™] Plates

3.5 mm and 4.5 mm Curved LCP[™] Plates

6.5 mm Cannulated Screws

7.3 mm Slipped Capital Femoral Epiphysis (SCFE) Screws

Adolescent Lateral Entry Femoral Nail-EX (ALFN)

Cannulated Pediatric Osteotomy System (CAPOS)

Femoral Neck System***

Femoral Recon Nail***

Hip Preservation Surgery Set**

Medium External Fixation System

Pediatric LCP[™] Condylar Plates

Pediatric LCP[™] Hip Plate System

RIA 2

Stainless Steel Elastic Nails

Titanium Elastic Nail (TEN[™]) System

TFN-ADVANCED[™] Proximal Femoral Nailing System^{***}

TN-ADVANCED[™] System

VA LCP[™] Proximal Tibia Plates^{*}



Products displayed from left to right: Proximal Tibia Plates and Forefoot/Midfoot System

* Also indicated for adolescents (12-21) and transitional adolescents (18-21) in which the growth plates have fused or will not be crossed. Please refer to product insert for full list of indications, warnings, and precautions.

** Contains class 1 instruments intended for the general population.

***Indicated in adults and adolescents (12-21) in which the growth plates have fused or will not be crossed. Please refer to product insert for full list of indications, warnings, and precautions.

Deformity Correction

2.2 mm/2.7 mm VA LCP[™] Forefoot/Midfoot System*

2.7 mm LCP[™] Ulna Osteotomy System*

2.7 mm/2.5 mm VA LCP[™] Ankle Trauma System*

6.5 mm Cannulated Screws

7.3 mm Slipped Capital Femoral Epiphysis (SCFE) Screws

Cannulated Pediatric Osteotomy System (CAPOS)

Hip Preservation Surgery Set**

MAXFRAME[™] Multi-Axial Correction System^{*}

Medium External Fixation System

Medium External Fixator - Pediatric Femoral Shaft Frame

Medium External Fixator Modular Frame Upper Extremity

Pediatric LCP[™] Hip Plate System

Pediatric LCP[™] Condylar Plates

VA LCP[™] Proximal Tibia Plates^{*}



Products displayed from left to right: SCFE Screw and Ulna Osteotomy System

* Also indicated for adolescents (12-21) and transitional adolescents (18-21) in which the growth plates have fused or will not be crossed. Please refer to product insert for full list of indications, warnings, and precautions.

** Contains class 1 instruments intended for the general population.

***Indicated in adults and adolescents (12-21) in which the growth plates have fused or will not be crossed. Please refer to product insert for full list of indications, warnings, and precautions.

								 •										•																					
• •		•	•	•	•		•	•	 •	•	•	• •		• •	•	•	• •	•		• •	• •	•	•	• •	•	• •	• •	• •	• •										
• •			 •		•	• •	•	•	 •		. 🔴 (• •	. •	• •				•	1.	• •						• •		• •											
		•		•			•	•	 •		. • •	• •		• •				•		• •			•			• •													

Biomaterials

ViviGen[®] & ViviGen Formable[®] Cellular Bone Matrix PliaFX[®] Prime Moldable Demineralized Fibers



Products displayed from left to right: PliaFX Prime and ViviGen Formable

Upper Extremity Fractures

2.7 mm VA LCP™ Clavicle Plate System

- Mapping clavicle variation, advancing anatomical fit¹⁻⁴
- Reduced construct prominence, comparable strength⁺²⁻⁵
- Simplified plate selection based on correlation between patient height and clavicle size**6



2.7 mm/3.5 mm VA LCP[™] Elbow System

- Comprehensive system consisting of five (5) distal humerus plates and three (3) types of olecranon plates
- Options for parallel and perpendicular plating of the distal humerus: Medial, extended Medial, lateral, posterolateral, and posterolateral distal Humerus plates with lateral support
- Options for olecranon plating: proximal olecranon plate, olecranon plate, and extra articular proximal ulna plate
- Low-profile design with rounded plate edges, and recesses for screw heads designed to help reduce soft tissue irritation

Distal Radius Plates

- Comprehensive portfolio with 132 plate choices in Stainless Steel and Titanium
- Features three head sizes to accommodate patient anatomy
- Low profile construct
- Streamlined instrument sets promote procedural efficiency

+ Compared to Stryker VariAx 2 Clavicle System and Acumed Clavicle System.

DePuy Synthes

⁺⁺ Compared to clavicle systems that use screw holes to define plate size.

Lower Extremity Fractures

3.5 mm and 4.5 mm Curved LCP[™] Plates/Straight Plates

- Anatomically contoured for long bones
- COMBI holes provide the choice of axial compression or locking capability throughout the length of the plate
- Limited-contact profile

VA LCP[™] Proximal Tibia Plates

- Available in two bends (small and large bend) to accommodate varying anatomies
- Plate head includes six 3.5 mm VA LCP variable angle locking holes and five K-wire holes with notches
- Plate neck includes two 3.5 mm VA LCP variable angle locking holes for kickstand screws and one elongated hole that accommodates 3.5 mm cortex screws for compression, preliminary fixation, and plate adjustment

2.7 mm/3.5 mm VA LCP[™] Ankle Trauma System

- Comprehensive system consisting of five (5) distal tibia plates and one (1) fibula plate
- Multiple options for plating of the distal tibia: medial, anteromedial, anterolateral, and t- and l- distal tibia plates
- Low-profile design¹, rounded plate edges², and recesses for screw heads designed to help reduce soft tissue irritation³
- Compression and distraction system for fracture reduction⁴
- 2.7 mm Metaphyseal screws for low-profile fixation
- Two new reduction instruments



Lower Extremity Fractures

2.4 mm/2.7 mm VA LCP[™] Forefoot/ Midfoot System

- System consists of anatomic- and procedure-specific plates, variable angle locking and cortex screws, and compression feature, to aid in reconstructive foot surgery
- Plates feature variable angle locking holes, with or without the dynamic compression portion
- Compression system has tactile compression and is designed within the plate to minimize additional soft tissue dissection

Medium External Fixation System

- Modular system with inter-system compatibility
- · Clip-on clamps with pin-to-pin or pin-to-bar flexibility
- · Clamp functionalities allow customized frames

Femoral Neck System

- A published biomechanical study shows that FNS offers 100% more resistance to varus collapse when compared to multiple cannulated screws⁵
- The FNS has up to a 150% increase in rotational stability when compared to multiple cannulated screws⁷
- With a compact design, FNS is intended to minimize invasiveness on the patient including up to 20 mm of guided collapse, without lateral protrusion of the bolt for the first 15 mm⁸
- All steps of the procedure can be completed after placement of one central guide wire into the femoral head, enabling a repeatable approach



Lower Extremity Fractures

RIA 2 System

- Reaming with irrigation and aspiration for reduced heterotopic ossification, fat embolism, and thermal necrosis⁹⁻¹³
- Efficient method for removal of infected bone tissue¹⁴
- Allows harvesting of autogenous bone graft with higher volume¹⁵, decreased complications⁹ and higher quality graft vs. iliac crest bone graft¹⁶
- Now with simplified assembly and handling for improved set up efficiency
- Advanced design allows reaming of smaller anatomies



Deformity Correction-Upper Extremity

2.7 mm LCP Ulna Osteotomy Plate

- Smooth, low-profile plate with rounded edges and tapered ends with a thick center to bury lag screw
- COMBI holes accept 2.7 mm locking and 2.7 mm cortex screws allowing for flexible screw placement (lag screw, neutral, locking)
- Parallel saw blades, specific to oblique or transverse cut and amount of shortening, allow surgeon to create osteotomy in one cut (compatible with DePuy Synthes Power Tools only)
- Drill templates allow for pre-drilling of plate fixation holes before cut is made, ensuring correct rotational alignment; 2.0 mm, 2.5 mm, 3.0 mm, 4.0 mm, and 5.0 mm shortening lengths
- Saw guide attaches to drill template and offers assisted guidance during oblique cuts



Deformity Correction-Lower Extremity

6.5 mm Cannulated Screws

- High thread-to-core ratio for pullout resistance
- Reverse-cutting threads for removal
- Stainless steel and titanium



Hip Preservation Surgery Set

- Instruments for periacetabular osteotomy and hip impingement procedures
- Osteotomes include etch lines for measuring depth and are used in combination with a hammer
- Retractors are made by aluminum and have radiolucent properties. Femoral head templates are transparent to aid with reshaping of the femoral head

MAXFRAME[™] Multi-Axial Correction System

- Facilitates angular corrections, lengthening and compression
- Modular for multiple frame options
- MAXFRAME 3D Software is designed to reduce treatment plan error





Deformity Correction-Lower Extremity

MAXFRAME AUTOSTRUT[™] Multi-Axial Correction System

- First-of-its-kind hexapod ring fixation system offering fully automated strut adjustments up to 20 times per day
- Compatible with the MAXFRAME[™] Multi-Axial Correction System
- Cutting-edge technology



Biomaterials Bone Void Repairs

ViviGen[®] and ViviGen Formable[®] Cellular Bone Matrix

- ViviGen is a cellular allograft intended for repair or reconstruction of musculoskeletal defects¹⁷
- ViviGen is the first and only cryopreserved cellular allograft focused on protecting and maintaining lineage-committed bone cells
- ViviGen cells are in a state ready to produce calcium deposits to form bone as early as day 7^{18, 19}
- ViviGen[®] and ViviGen Formable[®] provide the same advantages with alternative formulations to meet surgeons' clinical needs

PliaFX[®] Prime Moldable Demineralized Fibers

- PliaFX Prime is 100% bone fibers, demineralized to encourage bone formation and healing
- The fibers interlock, allowing the graft to become moldable upon rehydration without the use of a carrier.²⁰
- 100% bone grows more bone than DBMs containing a carrier, as demonstrated in literature.²¹
- PliaFX Prime easily mixes with autograft, allograft, and/or fluid of surgeon's choice





**Please see Instructions for Use for details.

References

- 1. DePuy Synthes. Validation Report Plate Profile Memo. 9/25/12. Windchill Document # 0000076314
- 2. DePuy Synthes. Comparison Sheet for Ankle Trauma Plate Edges Memo. 8/23/12. Windchill Document # 0000073566
- 3. DePuy Synthes. Functional and Design Requirements Matrix VA Ankle Trauma. 12/11/12. Windchill Document # 0000050386
- 4. DePuy Synthes. Design Verification and Validation Method for Compression and Distraction forceps Report. 9/20/12. Windchill Document # 0000075656
- Stoffel K, Zderic I, Gras F, Sommer C, Eberli U, Mueller D, Oswald M, Gueorguieve B. Biomechanical evaluation of the femoral neck system in unstable Pauwels III femoral neck fractures: a comparison with the dynamic hip scre and cannulated screws. J Orthop Trauma. 2017;31(3):131-137
- 6. DePuy Synthes Engineering Memo Morphology, 7/31/18 Windchill #0000273619
- 7. DePuy Synthes Report: Static Cut Through Rotation Text in Bone Foam. 2018. Windchill 0000277853.7
- 8. DePuy Synthes, Memo FNS Design and Procedure Comparison. 5/3/2018. Windchill #0000274963 v. A.6
- 9. Dimitriou R, Mataliotakis GI, Angoules AG, Kanakaris NK, Giannoudis PV. Complications following autologous bone graft harvesting from the iliac crest and using the RIA: a systematic review. Injury. 2011;42-Suppl 2:S3-S15
- 10. Higgins TF, Casey V, Bachus K. Cortical heat generation using an irrigating/aspirating single-pass reaming vs. conventional stepwise reaming. J Orthop Trauma. 2007; 21(3):192-197
- 11. Furlong AJ, Giannoudis PV, Smith RM. Heterotopic ossification: a comparison between reamed and unreamed femoral nailing. Injury. 1997; 28(1):9-14
- 12. Hall JA, McKee MD, Vicente MR, et al. A prospective randomized trial investigating the effect of the reamer-irrigator-aspirator (RIA) on the volume of embolic load and respiratory functions during intramedullary nailing of femoral shaft fractures. Orthopedic Trauma Association 2013 Annual Meeting; October 9-12, 2013; Phoenix, AZ, USA
- 13. Volgas DA, Burch T, Stannard JP, Ellis T, Bilotta J, Alonso JE. Fat embolus in femur fractures: a comparison of two reaming systems. Injury 2010;41 Suppl 2:S90-3
- 14. Zalavras CG, Singh A, Patzakis MJ. Novel technique for medullary canal debridement in tibia and femur osteomyelitis. Clin Orthop Relat Res 2007;461:31-4
- 15. Dawson J, Kiner D, Gardner W, 2nd, Swafford R, Nowotarski PJ. The reamer-irrigator-aspirator as a device for harvesting bone graft compared with iliac crest bone graft: union rates and complications. J Orthop Trauma. 2014; 28(10):584--590. (4)
- 16. Sagi HC, Young ML, Gerstenfield L, Einhorn TA, Tornetta P. Qualitative and quantitative differences between bone graft obtained from the medullary canal (with a reamer/irrigator/aspirator) and the iliac crest of the same patient. J Bone Joint Surg Am. 2012; 94(23):2128-2135. (3)
- 17. 63-0146 IFU, ViviGen
- 18. Data on file LifeNet Health 65-0347
- 19. In vitro results may not be predictive of performance in humans
- 20. Data on file LifeNet Health ES-17-090
- 21. Boyan BD, Ranly DM, McMillan J, et al. Osteoinductive Ability of Human Allograft Formulations. J Periodontol. September 2006

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

PliaFX is a registered trademark of LifeNet Health.

ViviGen Formable is a registered trademark of LifeNet Health.

ViviGen is a registered trademark of LifeNet Health.

Please refer to the instructions for use for a complete list of indications, contraindications, warnings and precautions.



Manufactured or distributed by:

Synthes USA, LLC 1101 Synthes Avenue Monument, CA 80132 Synthes GmbH Luzernstrassee 21 4528 Zuchwil, Switzerland

To order (USA): 800-523-0322 To order (Canada): (844)-243-4321

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

depuysynthes.com

© DePuy Synthes 2022. All rights reserved. 206066-220311 DSUS