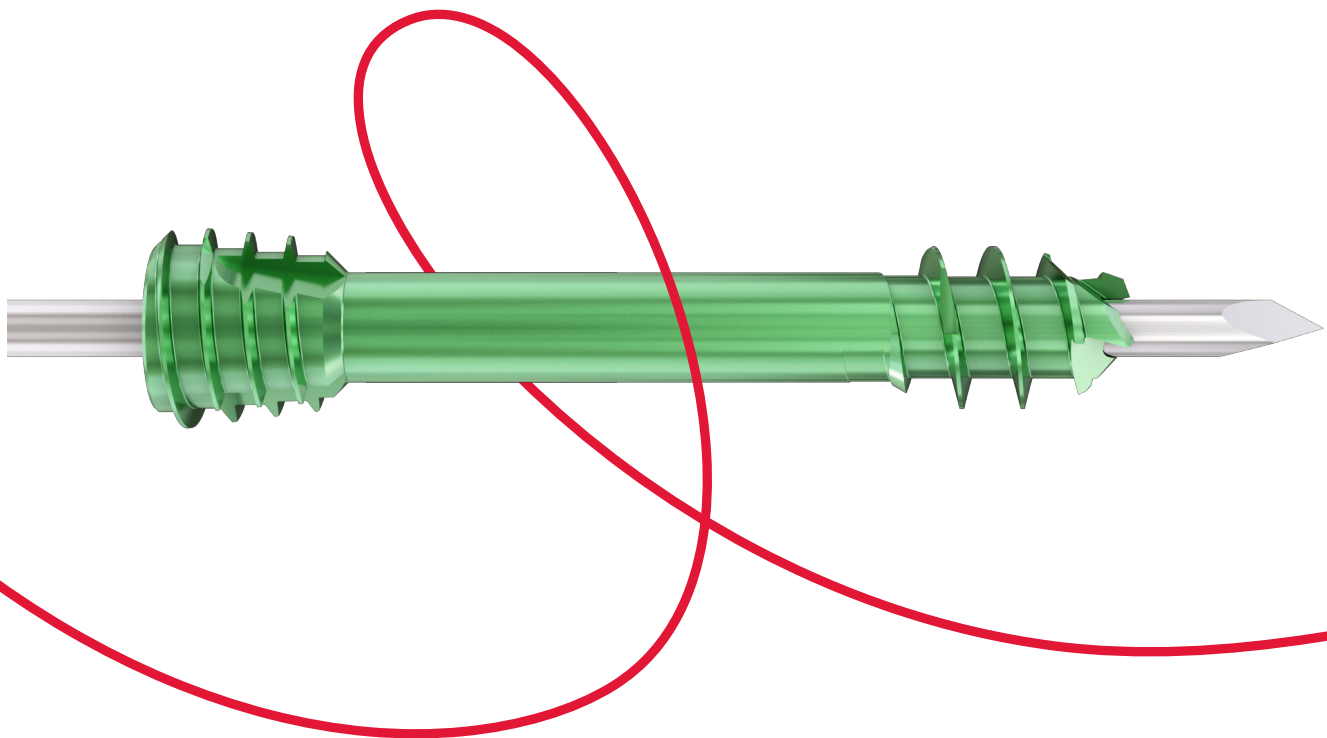


CANNULATED COMPRESSION HEADLESS SCREW SYSTEM

The Cutting Edge In Screw Technology
For Uncompromised Precision

Value Analysis Brief



CCHS Offers Surgeons

Uncompromised Precision Through:

Innovative cutting edge for improved cutting efficiency¹⁻³

Cobalt Chrome Guide Wire for less deflection⁴

Most comprehensive portfolio on the market to address a wide range of surgical needs⁵

 **DePuy Synthes**
THE ORTHOPAEDICS COMPANY OF *Johnson & Johnson*

CLINICAL RELEVANCE

A cannulated screw system offers a guided insertion of the screw over a guide wire allowing for precise placement and facilitation of percutaneous technique. Cannulated screws are a very widespread and commonly used technology with usage spanning the entire anatomy.

Percutaneous technique is especially valuable when formal open reduction and internal fixation is contraindicated because of associated soft-tissue compromise and swelling⁶. Approximately 20% of all trauma procedures are done with cannulated screws⁷. Headless cannulated screws are especially useful in situations where soft-tissue coverage is low such as foot, ankle and hand.

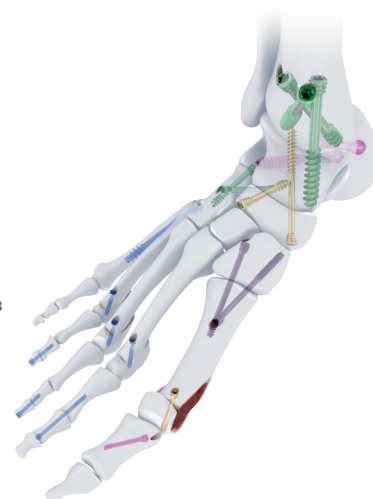
CLINICAL VALUE OF CCHS SYSTEM

The DePuy Synthes Cannulated Compression Headless Screws (CCHS) offer an unique cutting tip that is designed for improved cutting efficiency¹. Tests have shown superior cutting tip efficiency vs Stryker® Fixos/Fixos 2® and Acumed® Acutrak 2® screws².

Additionally, the CCHS system consists of a wide range of screw diameters: 2.0, 2.5, 3.0, 3.5, 4.0, 4.5, 5.5, 6.5, 7.5mm and lengths from 10 to 140mm. Screws are made of Titanium Alloy (TAV) providing biocompatibility.

- CCHS system has the potential to cover **72% of your trauma and elective procedures**⁸

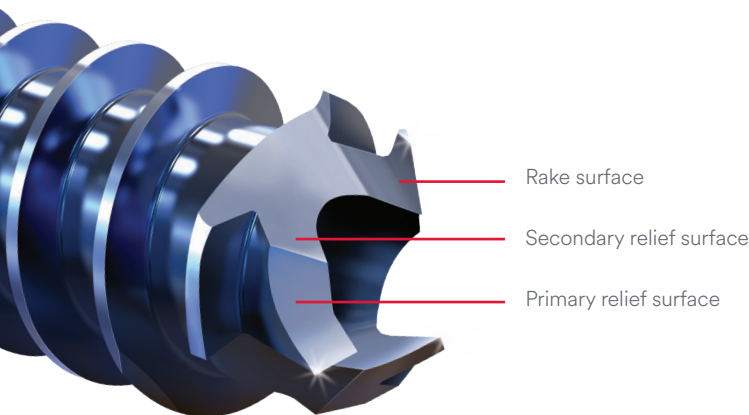
It offers surgeons the **broadest range of diameters** of cannulated headless screws for trauma as well as elective surgeries⁸; such as bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of bone⁹.



	The CCHS System offers:
Screw Cutting Performance	Unique cutting tip design with improved cutting efficiency ²
Guide Wire	29% higher bending stiffness of Cobalt Chrome Guide Wire compared to Stainless Steel Guide Wire ⁴
Solution	The most comprehensive portfolio of cannulated compression headless screw offerings on the market ⁵

THE CUTTING EDGE IN SCREW TECHNOLOGY

CCHS Offers Surgeons Uncompromised Precision Through



- Innovative cutting edge for improved cutting efficiency¹⁻³
- Cobalt Chrome Guide Wire for less deflection⁴
- Most comprehensive portfolio on the market to address a wide range of surgical needs⁵

Innovative Cutting Edge Of CCHS

Three uniquely angled surfaces form an innovative compound cutting edge designed to reduce insertion force and minimize the need for pre-drilling¹⁻³.

Superior Cutting Performance

DePuy Synthes Cannulated Compression Headless Screws offer an unique cutting tip designed to reduce the axial force required for the screw to self-tap compared to Stryker® Fixos/Fixos 2® (Figs. 1 and 2) and Acumed® Acutrak 2® Micro (Fig. 1) Headless Screws¹⁻³.

Screw Insertion Force Comparison Of Headless Screws²

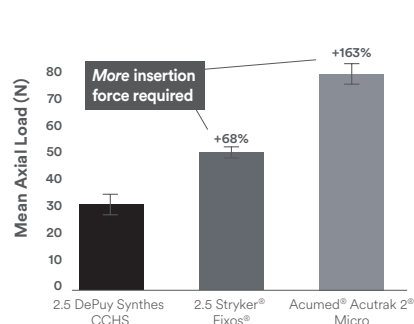


Figure 1: Small Headless Compression Screws (40 pcf)

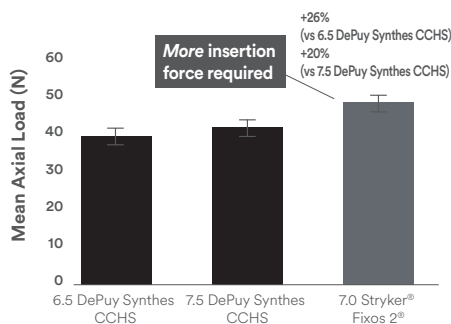
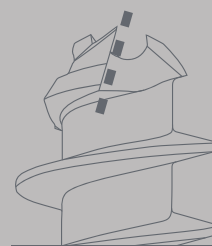


Figure 2: Large Headless Compression Screws (20 pcf)

Design Rationale

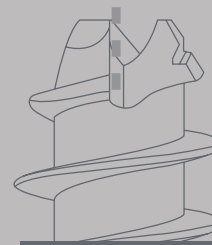
CCHS Positive Rake Angle



CCHS Cutting Tip

- Positive rake angle cutting tip design offers a **sharp cutting edge**
- May require **less force** to insert^{1,3}

Generic Neutral Rake Angle



Competitive Cutting Tip

- By definition a neutral rake angle cutting tip design has **less sharpness** at the cutting edge
- May require **more force** to insert^{1,3}

The lower the value for screw insertion force is, the less force is required to insert the screw. Required higher force to insert the screw can lead to displacement of the bone fragments. If displaced fragments are not reduced then there is a risk of malunion, leading to potential reoperation.

The CCHS innovative compound cutting edge is designed to minimize displacement of the far fragment and maintain intended alignment. This is especially important when utilizing a percutaneous technique where the incision is small. The advantages to utilizing a percutaneous technique include lower complication rates and faster recovery times¹⁰.

ECONOMIC VALUE

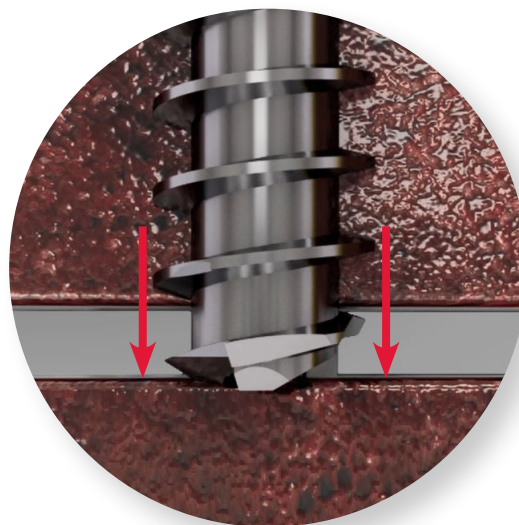
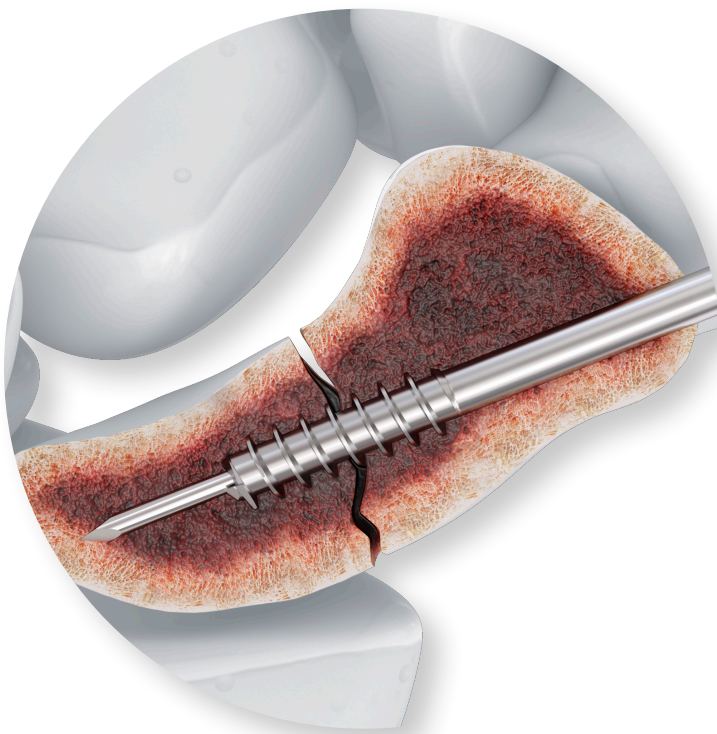
Key cost drivers for surgery are often implants and consumable instruments.

The DePuy Synthes CCHS system is designed to improve cost efficiency in hospitals by reducing consumable cost during surgery while maintaining quality of care. Since CCHS are used for a wide range of surgical needs, this benefit multiplies.

18% Potential cost saving* of consumable instruments during surgery¹¹

Improved cutting tip designed to reduce the need of pre-drilling²

The DePuy Synthes CCHS cutting tip offers a cost-effective solution by reducing the likelihood of using drill bits for pre-drilling. The saving is on average \$467 (€413) per screw size and per surgery in the US¹¹.



Conventional screws:

Cutting tip with a neutral rake angle may require more force to insert which can lead to a displacement of the distal fragment.

* If drill bit and countersink are not used.

SURGICAL EFFICIENCY

With Three Steps To Bone Fixation

Due to its unique cutting tip³, the self-drilling/self-tapping CCHS allow for fewer surgical steps when no pre-drilling is required¹². The three surgical steps are: guide wire insertion, depth measurement and screw insertion.

Up To 40% Fewer Steps¹²

DePuy Synthes CCHS system offers at least 40% fewer steps when compared with Zimmer Herbert Partially Threaded system and 25% fewer steps when compared to Acumed Acutrak 2, Zimmer MAX VPC, Arthrex, Arthrex Partially Threaded and Paragon28 Monster screw Fully Threaded and DePuy Synthes Headless Compression Screws system.

1. Guide Wire Insertion

- ✓ The CCHS system offers stiffer Guide Wires for less deflection⁴
- ✓ 29% higher bending stiffness of Cobalt Chrome Guide Wires compared to Stainless Steel Guide Wires⁴

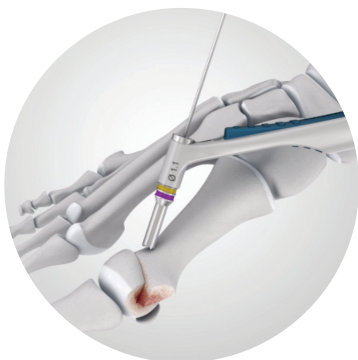
2. Measure Depth

- ✓ Color-coded instrumentation for surgical efficiency and easy identification

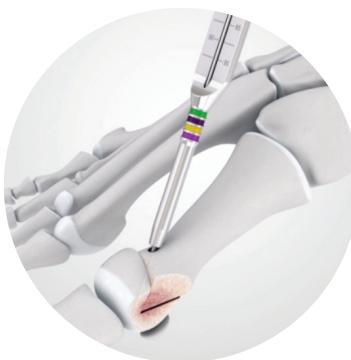
3. Screw Insertion

- ✓ Unique cutting tip³ with improved cutting tip designed to²:
 - reduce the need of pre-drilling
 - minimize displacement of far fragment
- ✓ Precise placement and improved cutting performance to maintain intended alignment
- ✓ Screws are offered in color-coded titanium alloy, which indicates the diameter and corresponding instrumentation

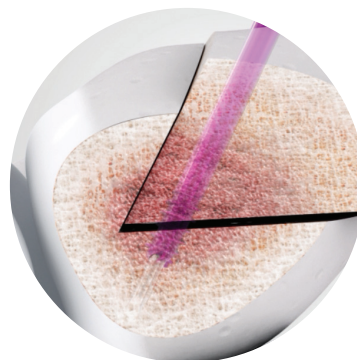
1. Guide Wire Insertion



2. Measure depth



3. Screw Insertion



Precise placement and improved cutting performance to maintain intended alignment.

The CCHS also has reverse cutting flutes across all diameters to facilitate screw removal. Many other current systems on the market do not provide reverse cutting flute capability¹³.

Note: Drilling is optional due to the self-drilling, self-tapping features of the screws. Drilling makes it easier to insert the screw into dense bone.

HIGH USAGE & FLEXIBILITY

Broad Usage

Most comprehensive portfolio on the market to address a wide range of surgical needs⁵.
System is easy to understand.

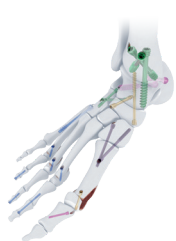
Maximize Set Turn Within Hospital/Center

Instruments trays and screws racks can be used as stand-alone and used in different OR's.

Flexibility Through Modularity

Instrument sets are designed to be modular for optimal flexibility.

Modules can be used as stand-alone in order to increase the turn rate of the system



CCHS can be used for different procedures⁹. The below procedures are examples of potential use*.

Chevron osteotomy^{14,15}:
2.5/3.0 CCHS
L 12 – 22 mm

Metacarpal neck fracture¹⁸:
2.0 CCHS
L 12 – 22 mm

Scarf osteotomy¹⁶:
ø 3.5 CCHS
L 16 – 22 mm

Scaphoid fracture¹⁹:
ø 2.5 CCHS
L 22 - 26 mm

Lapidus fixation¹⁷:
ø 3.5/4.0 CCHS
L 28 – 50 mm

Radial head fracture²⁰:
ø 3.5 CCHS
L 22 – 30 mm



CCHS Small Set including 2.0, 2.5, 3.0, 3.5 and 4.0 mm screws and three instrument trays: 2.0, 2.5/3.0 and 3.5/4.0.

Hospital staff only needs to learn one system that can cover a wide range of indications.

Color-coded, streamlined instrumentation helps with easy identification and surgery efficiency.

* It is up to the surgeon to decide which implants should be used.

PRODUCT OFFERING

CCHS Implants – Short / Long Threads

- The CCHS system offers the widest range of screw diameters (diameter symbol 2.0-7.5mm) and lengths (10-140mm)⁵
- Short or Long Thread options
- Non-sterile or sterile packaged

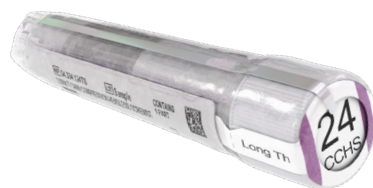


Diameter	Color	Short Thread	Long Thread
2.0 mm	Blue	10–30 mm (2 mm increments)	20–30 mm (2 mm increments)
2.5 mm	Purple	10–40 mm (2 mm increments)	20–40 mm (2 mm increments)
3.0 mm	Yellow	10–40 mm (2 mm increments)	20–40 mm (2 mm increments)
3.5 mm	Purple	14–50 mm (2 mm increments)	24–50 mm (2 mm increments)
4.0 mm	Green	14–60 mm (2 mm increments)	24–60 mm (2 mm increments)
4.5 mm	Yellow	20–50 mm (2 mm increments) 55–110 mm (5 mm increments)	30–50 mm (2 mm increments) 55–110 mm (5 mm increments)
5.5 mm	Blue	20–50 mm (2 mm increments) 55–110 mm (5 mm increments)	30–50 mm (2 mm increments) 55–110 mm (5 mm increments)
6.5 mm	Purple	30–130 mm (5 mm increments)	45–130 mm (5 mm increments)
7.5 mm	Green	30–140 mm (5 mm increments)	45–140 mm (5 mm increments)

For sterile implants, add suffix “TS” to Part Number for screw sizes 2.0 - 4.0 mm and suffix “S” to Part Numbers for screw sizes 4.5 - 7.5 mm. Sterile part availability might be different depending on the country or region.

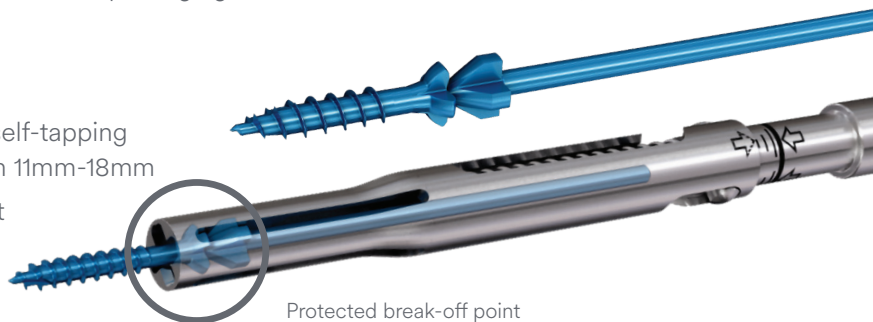
Sterile Packaged CCHS And QIS Implants In Sterile Tubes

- Designed to save you space and time²¹
- The Sterile Tube provides 40% more space saving than blister packaging²¹



Quick Insertion Screws

- 2.0 mm Quick Insertion Screws are self-drilling and self-tapping Twist-off-Style Screws offered in length ranging from 11mm-18mm
- Unique Easy Loader Screwdriver designed to prevent premature post breakage of the screws



PRODUCT OFFERING

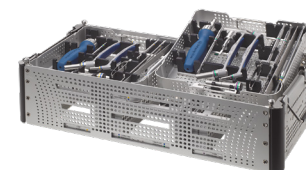
CCHS Small Set

The set includes an outer case that hosts three Instrument Trays with instruments (2.0, 2.5/3.0, 3.5/4.0, and QIS), the corresponding Screw Racks (2.0, 2.5/3.0, 3.5/4.0) with implants and an empty Auxiliary Instrument Tray.



CCHS Large Set

This set includes an outer case that hosts two Instrument Trays with instruments (4.5/5.5 and 6.5/7.5) and the corresponding Screw Racks (4.5, 5.5/7.5 and 6.5) with implants.



Sterile-Packaged Solution

Sterile-packaged screws sizes 2.0 - 4.0 mm are packaged in sterile tubes and stored in plastic screw racks. Sterile-packaged screws sizes 4.5 - 7.5 mm are provided in sterile double peel pouch boxes.



Consumable instruments such as Guide Wires, Drill Bits and Countersinks are available nonsterile and sterile packaged.

1. DePuy Synthes. Screw and System Design Feature Memo. 7th Aug 2019. Windchill #0000286734. 2. DePuy Synthes. Screw Cutting Performance Memo. 29th Jan 2020. Windchill #0000288513. Bench testing may not be indicative of clinical performance. (Windchill #0000288513). Axial load of 5 samples of each screw type were measured. Test groups were DePuy Synthes CCHS 2.5, 3.0, 4.0, 4.5, 6.5 and 7.5 mm, DePuy Synthes HCS 2.4, 4.5 and 6.5mm and Stryker Fixos 2.5 and 4.0mm, Stryker Fixos2 7.0 mm screws, Acumed Acutrak2 Micro. 3. DePuy Synthes Patent Application: Angled Flutes in Cannulated Bone Screws. 2018/0303529 A1. 4. DePuy Synthes. Guide Wire Stiffness Memo. 28th Apr 2020. Windchill #0000287828. Bench testing may not be indicative of clinical performance. CoCr Guide Wire compared to SS Guide Wire of same diameter. 5. DePuy Synthes. Competitor Analysis. 16th Dec 2020. Windchill #0000286547. Research was performed (June 2019) comparing cannulated headless screw offerings among all main competitors who offer this product line. Main competitors were defined based on market report Medtech 360 Trauma Devices Market Analysis US (2018). Most comprehensive is defined as the widest range of portfolio of available cannulated headless screw diameters currently marketed. 6. Moehring HD & Johnson PG. The use of cannulated screws in musculoskeletal trauma. A review of surgical techniques. Orthop Rev. 1994 Aug; Suppl:10-21. 7. DePuy Synthes internal data. 4th Dec 2020. Windchill #0000308131. 8. DePuy Synthes. Analysis of trauma and elective procedures of adults requiring bone fixation with an implant. 14th Dec 2020. Windchill #0000308135. 9. eIFU at cchs.info. Contraindicated for Spine and CMF. 10. Botezatu I et al. Minimally invasive-percutaneous surgery – recent developments of the foot surgery techniques. J Med

Life. 2015; 8(Spec Issue): 87–93. 11. DePuy Synthes. Cost analysis using US DRG data from rolling 12 months was performed June 2020. 14th Dec 2020. Windchill #0000308142. Consumable instruments of Cannulated Headless Screw systems of key competitor were included. Key competitor were defined as described (0000286547). 12. DePuy Synthes. Competitor surgical steps analysis 2020. 14th Dec 2020. Windchill #0000308143. 13. DePuy Synthes. CCHS Competitor Feature Analysis. Competitor features were analyzed based on material available on internet, April 2020. 14th Dec 2020. Windchill #0000308144. 14. Vanore J. The Austin Bunionectomy: The Author's 20+ Year Experience. Podiatry Institute. Online. 2002:149-152. 15. Andrews BJ, Fallat LM, Kish JP. Screw Versus Plate Fixation for Chevron Osteotomy: A Retrospective Study. J Foot Ankle Surg. 2016;55(1):81-84. 16. Farrar NG, Duncan N, Ahmed N, Rajan RA. Scarf osteotomy in the management of symptomatic adolescent hallux valgus. J Child Orthop. 2012;6(2):153-157. 17. Groves M. Functional Position Joint Sectioning: Pre-Load Method for Lapidus Arthrodesis. Podiatry Institute. Online. 2015:23-29. 18. Verhiel S. et al. Carpometacarpal 4/5 Fracture Dislocations: Fracture Morphology and Surgical Treatment. J Hand Microsurg. 2019. 1-7. 19. Jupiter JB, Ring DC. Hand and Wrist. Stuttgart: Thieme; 2004. 20. Wu PH, Dixit A, Kiat Tan DM, Shen L, Chee YH. Prospective study of surgical fixation of radial head fractures using cannulated headless compression screws for simple and complex radial head fractures. J Orthop Surg (Hong Kong). 2017;25(2):2309499017716278. 21. DePuy Synthes. Tubes Space Saving Claims Evidence. Space saving results have been shown in comparison to blister packaging using M size tube. 25th Aug 2020. Windchill #0000280686.

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