

Sterile Tube Packaging

INTRODUCING STERILE TUBE FROM DEPUY SYNTHES

DESIGNED TO SAVE
YOU SPACE* AND TIME





WHY NEW STERILE PACKAGING?

Medical device regulations are tightening and a shift to sterile implants is accelerating as sterility assurance standards increase and implant traceability becomes more critical. Difficulty in handling existing sterile screw packaging often adds time and disruption to trauma procedures, placing additional stress on limited resources within the OR environment.

WHAT IS THE STERILE TUBE CONCEPT?

The Sterile Tube concept consists of a solution that uses 2 tubes where one fits into the other to allow a streamlined and secure transfer of sterile implants into the sterile field. The tube shape is similar to the round screw shape, suggesting a “screw rack-like” handling to help with your transition to sterile packed screws.





Storage



Tube



Screw Holder



Identification



Traceability

PRODUCT FEATURES

The screws in Sterile Tube come sterile and are ready to use when needed.





Storage



Tube



Screw Holder



Identification



Traceability



STORAGE SPACE

Rack system and label design concept facilitates handling and reduces storage space compared to other sterile packaging.

The Sterile Tubes requires 40%¹ less space, compared to blister packaging.



Storage



Tube



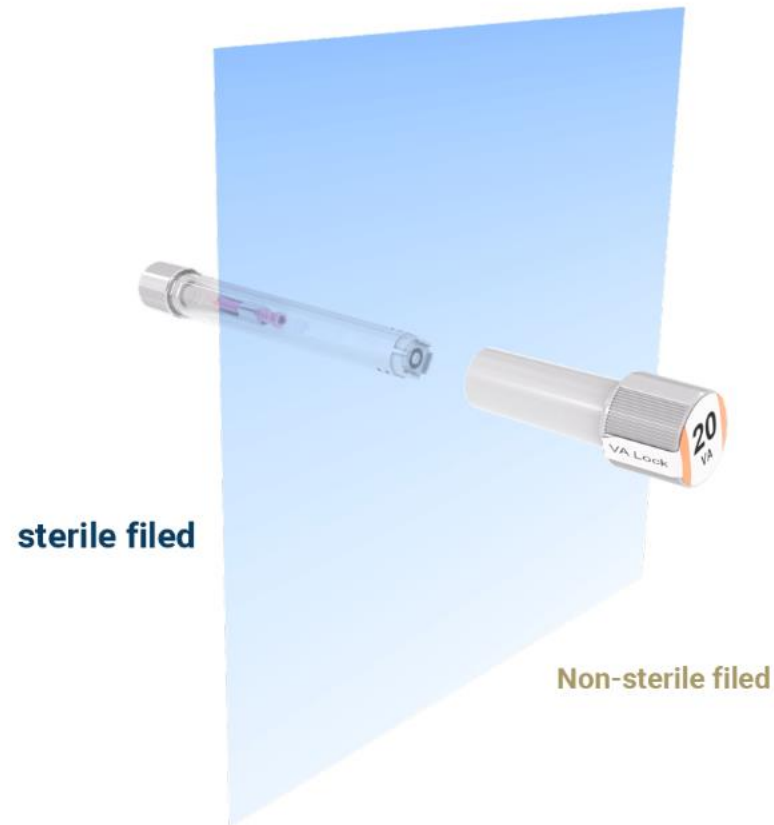
Screw Holder



Identification



Traceability



TUBE IN TUBE

“Tube in Tube” design allows a streamlined and secure transfer into the sterile field.

Sterile Tube is designed to open right before use to reduce air exposure time.



Storage



Tube



Screw Holder



Identification



Traceability



SCREW HOLDER

“Captive screw” holder design allows for a secure implant handling.

Designed to standardize aseptic technique by facilitating recommended sterile transfer technique.



Storage



Tube



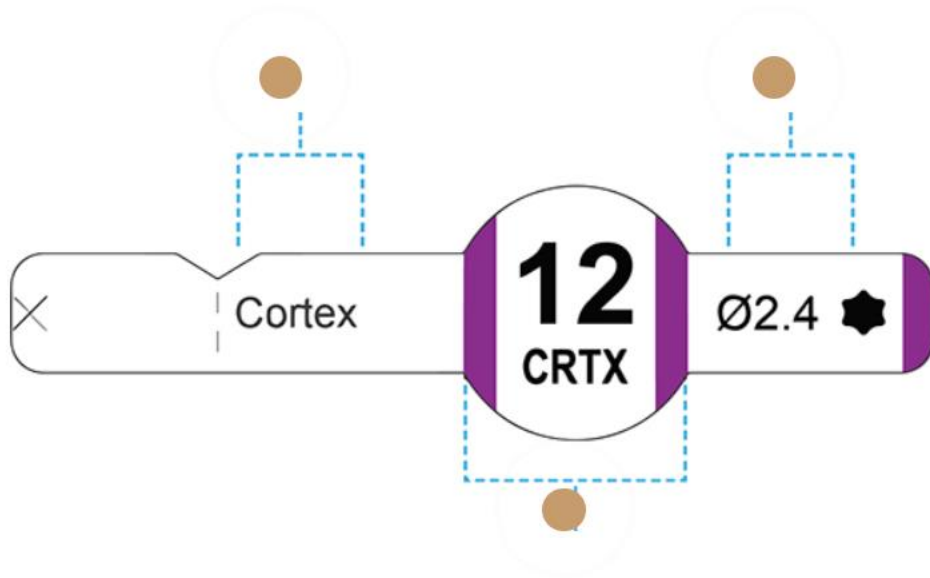
Screw Holder



Identification



Traceability



IDENTIFICATION

The screw diameter is color coded for quick identification in the screw tube rack, and each tube is additionally marked for screw length, type and recess.

Designed for faster, more accurate screw identification compared to blister packaging.





Storage



Tube



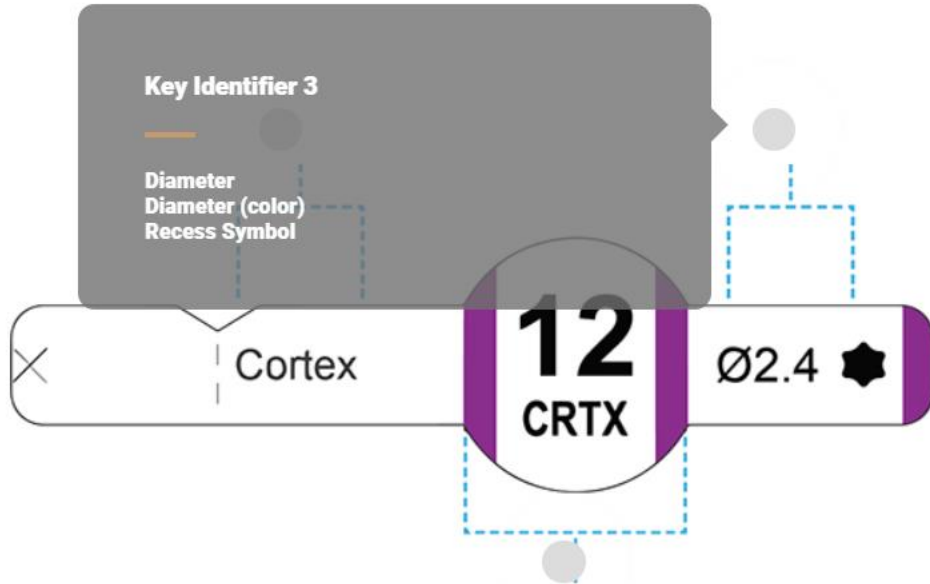
Screw Holder



Identification



Traceability



IDENTIFICATION

The screw diameter is color coded for quick identification in the screw tube rack, and each tube is additionally marked for screw length, type and recess.

Designed for faster, more accurate screw identification compared to blister packaging.



Storage



Tube



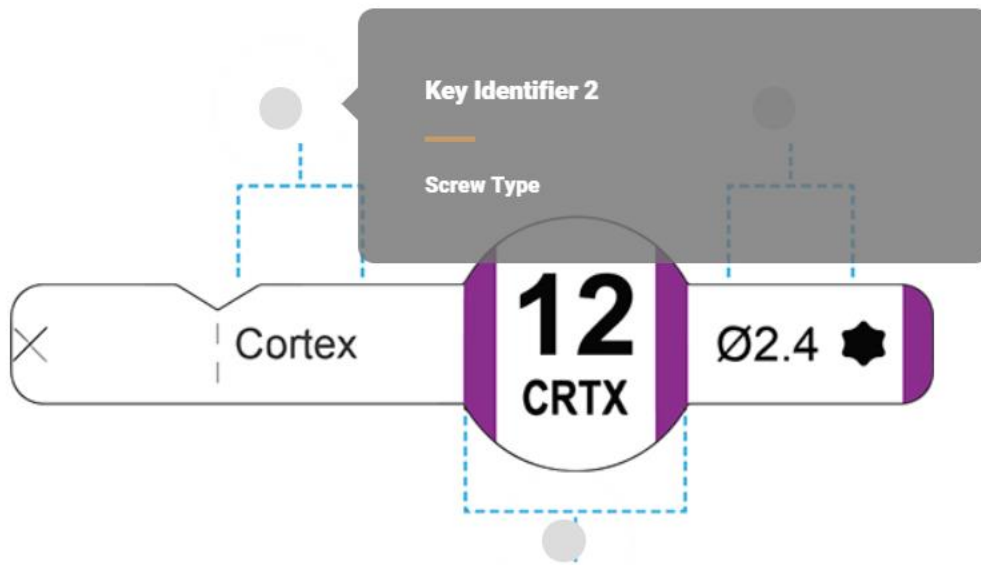
Screw Holder



Identification



Traceability



IDENTIFICATION

The screw diameter is color coded for quick identification in the screw tube rack, and each tube is additionally marked for screw length, type and recess.

Designed for faster, more accurate screw identification compared to blister packaging.



Storage



Tube



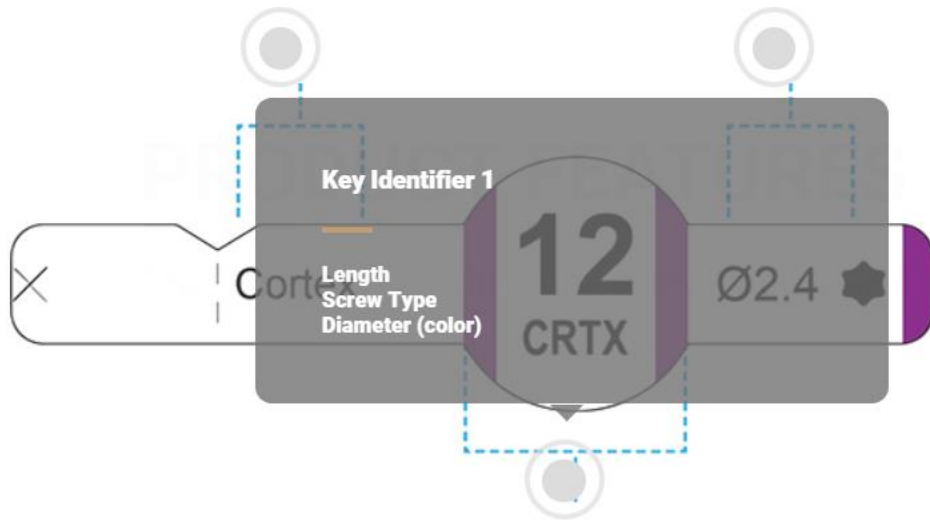
Screw Holder



Identification



Traceability



IDENTIFICATION

The screw diameter is color coded for quick identification in the screw tube rack, and each tube is additionally marked for screw length, type and recess.

Designed for faster, more accurate screw identification compared to blister packaging.



Storage



Tube



Screw Holder



Identification



Traceability



TRACEABILITY

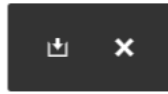
The Sterile Tubes contain 4 patient labels to ensure recording, tracking, and reordering of the product.

Sterile packaging supports convenient and more accurate implant traceability compared to non-sterile.

WATCH A DEMO



IMPLANTS OVERVIEW FOR TRAUMA



2.0 mm Screws

Cortex Screw Stardrive® Ø 2.0 mm
Locking Screw Stardrive® Ø 2.0 mm
VA Locking Screw Stardrive® Ø 2.0 mm



2.4 mm Screws

Cortex Screw Stardrive® Ø 2.4 mm
Locking Screw Stardrive® Ø 2.4 mm
VA Locking Screw Stardrive® Ø 2.4 mm



2.7 mm Screws

Cortex Screw Stardrive® Ø 2.7 mm
Low Profile Metaphyseal Screw Stardrive® Ø 2.7 mm
Locking Screw Stardrive® Ø 2.7 mm
VA Locking Screw Stardrive® Ø 2.7 mm



3.5 mm Screws

Cortex Screw Stardrive® Ø 3.5 mm
Locking Screw Stardrive® Ø 3.5 mm
Locking Screw Stardrive® perforated Ø 3.5 mm
VA Locking Screw Stardrive® Ø 3.5 mm



4.0 mm Screws

Cancellous Bone Screw Ø 4.0 mm





OBJECTION HANDLING

✓ **What is the benefit of having a holder for the screw inside the tube?**

The holder keeps the screw in place during transportation, storage and use of the Sterile Tube. The holder keeps the screw always stable in the same position.

Without the holder the screw is loose in the tube and needs to be dumped on the OR table to remove it from the inner tube. Then, the screw needs to be picked up in order to be connected with the screw driver which results in more steps compared to having a holder.

> **What do the colors on the label mean?**

> **What are the advantages of using sterile over non-sterile screws?**

> **What to do if a wrong sterile screw has been opened but not been used?**

> **Part Numbers - How can I identify Sterile tubes from blister packs?**

> **Will the screws in sterile tubes be higher priced compared to existing sterile screws?**

> **Can Sterile Tubes be recycled?**

> **Why is there a shrink sleeve?**



OBJECTION HANDLING

> **What is the benefit of having a holder for the screw inside the tube?**

✓ **What do the colors on the label mean?**

The color marking on the tube cap is related to the screw diameter

> **What are the advantages of using sterile over non-sterile screws?**

> **What to do if a wrong sterile screw has been opened but not been used?**

> **Part Numbers - How can I identify Sterile tubes from blister packs?**

> **Will the screws in sterile tubes be higher priced compared to existing sterile screws?**

> **Can Sterile Tubes be recycled?**

> **Why is there a shrink sleeve?**



OBJECTION HANDLING

> **What is the benefit of having a holder for the screw inside the tube?**

> **What do the colors on the label mean?**

✓ **What are the advantages of using sterile over non-sterile screws?**

Sterile packed screws provide recording and traceability of implants. Furthermore, sterile screws are always ready to be used and have never been re-sterilized before in comparison to non-sterile screws.

Additionally, Sterile Tubes have the potential to reduce inventory and sterilization cost. This is due to ability to streamlined implant portfolio by not needing a full range of implants available in every set configuration. Furthermore, there is no cost in regard to re-sterilization of implants.

Trends show an increasing number of sterile implants being used. This trend might accelerate further with the expected implementation of MDR regulations. As a vendor DePuy Synthes strives to offer the best possible product offering to its customers for both sterile as well as non-sterile.

> **What to do if a wrong sterile screw has been opened but not been used?**

> **Part Numbers - How can I identify Sterile tubes from blister packs?**

> **Will the screws in sterile tubes be higher priced compared to existing sterile screws?**

> **Can Sterile Tubes be recycled?**

> **Why is there a shrink sleeve?**

110314-190326 03/19 DePuy Synthes 2019. All rights reserved

This publication is not intended for distribution in the USA

All surgical techniques and IFUs are available as PDF files at www.depuysynthes.com/ifu

Reference:

¹ DePuy Synthes Test Data on File. Windchill 0000280686.



OBJECTION HANDLING

- > **What is the benefit of having a holder for the screw inside the tube?**
- > **What do the colors on the label mean?**
- > **What are the advantages of using sterile over non-sterile screws?**
- ✓ **What to do if a wrong sterile screw has been opened but not been used?**

Same as for existing products supplied in a non-sterile condition, opened but unused screws must be cleaned and steam sterilized prior to surgical use according to the Synthes “Important Information” (SE_023827) (www.depuysynthes.com/ifu). As a result lot tracking will be lost in that process.

The screws are labelled as single-use devices and must not be re-used as stated on the label and in the “Instruction for Use – Plate and Screw Implants” (SE_532121) (www.depuysynthes.com/ifu). Contaminated implants must not be reprocessed. Any DePuy Synthes implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol.

- > **Part Numbers - How can I identify Sterile tubes from blister packs?**
- > **Will the screws in sterile tubes be higher priced compared to existing sterile screws?**
- > **Can Sterile Tubes be recycled?**
- > **Why is there a shrink sleeve?**



OBJECTION HANDLING

- > **What is the benefit of having a holder for the screw inside the tube?**
- > **What do the colors on the label mean?**
- > **What are the advantages of using sterile over non-sterile screws?**
- > **What to do if a wrong sterile screw has been opened but not been used?**
- ✓ **Part Numbers - How can I identify Sterile tubes from blister packs?**

The Sterile Tubes have new part numbers (“TS” suffix to existing non-sterile part number) in order to be able to clearly differentiate between the tube packaging and other sterile packaging. This way the customer always knows exactly what they will get.

- > **Will the screws in sterile tubes be higher priced compared to existing sterile screws?**
- > **Can Sterile Tubes be recycled?**
- > **Why is there a shrink sleeve?**



OBJECTION HANDLING

- > **What is the benefit of having a holder for the screw inside the tube?**
- > **What do the colors on the label mean?**
- > **What are the advantages of using sterile over non-sterile screws?**
- > **What to do if a wrong sterile screw has been opened but not been used?**
- > **Part Numbers - How can I identify Sterile tubes from blister packs?**
- ✓ **Will the screws in sterile tubes be higher priced compared to existing sterile screws?**

For detailed information on pricing for your country please refer to regional or local guidance from strategic pricing department or related functions.

- > **Can Sterile Tubes be recycled?**
- > **Why is there a shrink sleeve?**



OBJECTION HANDLING

- > **What is the benefit of having a holder for the screw inside the tube?**
- > **What do the colors on the label mean?**
- > **What are the advantages of using sterile over non-sterile screws?**
- > **What to do if a wrong sterile screw has been opened but not been used?**
- > **Part Numbers - How can I identify Sterile tubes from blister packs?**
- > **Will the screws in sterile tubes be higher priced compared to existing sterile screws?**
- ✓ **Can Sterile Tubes be recycled?**

Sterile Tube packaging components are PET-G, HDPE and TPE plastics. Any recycling of plastics should be undertaken in compliance with local and national requirements for the handling of waste from a medical environment. DePuy Synthes is exploring opportunities to help our customers increase the recycling of plastic waste. These studies are in early feasibility stage and more details will be shared at a later date.

- > **Why is there a shrink sleeve?**



OBJECTION HANDLING

- > **What is the benefit of having a holder for the screw inside the tube?**
- > **What do the colors on the label mean?**
- > **What are the advantages of using sterile over non-sterile screws?**
- > **What to do if a wrong sterile screw has been opened but not been used?**
- > **Part Numbers - How can I identify Sterile tubes from blister packs?**
- > **Will the screws in sterile tubes be higher priced compared to existing sterile screws?**
- > **Can Sterile Tubes be recycled?**
- ✓ **Why is there a shrink sleeve?**

The shrink sleeve indicates that the product has never been opened and the sterile barrier is still intact.