

WORK INSTRUCTIONS		
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WI-28-F006	3D FDM Splint Strapping, Packaging, and Labeling Work Instructions	0

1 PURPOSE

- 1.1 The purpose of the following work instructions is to establish standardized procedures for packaging 3D FDM printed Dimension Ortho splints.

2 SCOPE

- 2.1 These work instructions apply to all personnel responsible for manufacturing and packaging 3D FDM printed Dimension Ortho splints.

3 RESPONSIBILITIES

Operators	Execute WI steps, ensure safety compliance, log usage
Supervisors	Verify training and adherence to WI
All Personnel	Read, understand, and implement all policies and procedures related to correction and removal.
RA/QA	- Ensure compliance with policies and procedures governing the correction and removal. - Maintain documentation, validate corrective actions, audit WI compliance

4 RECORDS

- 4.1 Records will maintain information regarding description of the product recalled, description of the problem, corrective action, meeting minutes and correspondence with any regulatory agencies.

5 RELATED ITEMS

WI-28-F007	Upper Extremity Fitting Guide 2026
WI-28-F008	Upper Extremity Strapping Guide

6 REQUIRED MATERIALS

- 6.1 Printed and post-process 3D-printed cast
- 6.2 2-inch straps
- 6.3 1-inch straps
- 6.4 Velcro dots
- 6.5 Double-sided Velcro
- 6.6 Scissors

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- 6.7 Strapping Guide
- 6.8 Cast IFU Form
- 6.9 Patient Order Form (if required)
- 6.10 Date stamp (if Patient Order Form required)
- 6.11 Pen

7 SAFETY PRECAUTIONS

- 7.1 Assure that the post-processed cast does not exhibit sharp edges that present the risk of cuts and scratches

8 PROCEDURE

- 8.1 Assure that splint has been thoroughly post-processed of rough edges and defects and residual dust has been brushed off
- 8.2 Assure that the splint corresponds to the order form
- 8.3 If required, stamp the order form with the date packaged and technician initials denoting approval. Write any notable remarks on the order form, such as irregular offsets, adjusted delivery schedules, or if an order is a reprint
- 8.4 Strap splint according to SKU

8.4.1 Volar Wrist

- 8.4.1.1 Cut one Velcro dot in half. For each half, cut off and round sharp corners. They should look like rounded half-circles



- 8.4.1.2 Cut one Velcro dot into quarters. For each quarter, cut off and round sharp corners. They should look similar to guitar picks

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- 8.4.1.3 For the top forearm strap, cut a 1-inch strap so that its length matches the “Volar Forearm” in the Upper Extremity Strapping Guide (WI-28-F007). The width of the strap does not need to be altered
- 8.4.1.4 For the bottom forearm strap, cut a 2-inch strap so that its length matches the “Volar Forearm” in the Strapping Guide. The width of the strap does not need to be altered
- 8.4.1.5 For the top hand strap, cut a 1-inch strap so that its length matches the “Volar Hand” in the Strapping Guide. The width of the strap does not need to be altered
- 8.4.1.6 Attach the quarter Velcro pieces to the ends of each 1-inch strap, and attach the halve Velcro pieces to the ends of the 2-inch strap
- 8.4.1.7 Cut off the corners of the ends of the straps, so that they are rounded and border the Velcro dots



- 8.4.1.8 For each strap, loop one end from inside the splint through the radial strap holes and around the splint edge to adhere onto itself. The smooth side of the strap should be facing towards the splint while the Velcro adhesive side faces away from it. This end of the strap is not meant to be adjusted
- 8.4.1.9 For each strap, loop the other end from the inside of the splint through the ulnar strap holes and around the splint edge to adhere onto itself. Again, the smooth side of the strap should be facing towards the splint while the Velcro adhesive side faces away from it. This end of the strap is meant to be adjusted to fit the patient’s unique arm size

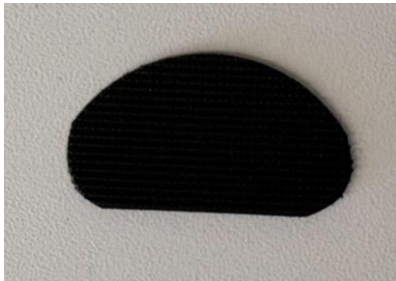
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8.4.2 Thumb Spica (Hand-Based)

- 8.4.2.1 For the hand strap, cut a 2-inch strap so that its length and width match the “Volar Hand” in the Strapping Guide
- 8.4.2.2 Cut one Velcro dot in half. For each half, cut the width according to that of the hand strap, then cut off and round sharp corners. They should look like rounded half-circles



- 8.4.2.3 Attach the halved Velcro pieces to the ends of the hand strap
- 8.4.2.4 Cut off the end corners of the straps, so that they are rounded and border the Velcro dots

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- 8.4.2.5 Loop one end of the hand strap from inside the splint through the radial strap holes and around the splint edge to adhere onto itself. The smooth side of the strap should face towards the splint inside while the Velcro adhesive side faces away from it. This end of the strap is not meant to be adjusted
- 8.4.2.6 Loop the other end from the inside of the splint through the ulnar strap holes and around the splint edge to adhere onto itself. Again, the smooth side of the strap should face towards the splint while the Velcro adhesive side faces away from it. This end of the strap is meant to be adjusted to fit the patient's unique hand size
- 8.4.2.7 Roughly wrap double-sided Velcro around the thumb area to estimate and cut the length of the thumb strap
- 8.4.2.8 Cut the thumb strap so that the width is about 10-12 mm
- 8.4.2.9 Round and cut off the edges of the thumb strap
- 8.4.2.10 Loop each end of the thumb strap from inside the thumb insert outwards through each strap hole and back around the splint edge to then adhere onto itself. The loop (soft) side of the strap should be facing towards the splint while the hook (rough) side faces away from it. Either end can be adjusted to better fit patient thumb size



8.4.3 Thumb Spica (Forearm Based)

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- 8.4.3.1 Refer to the strapping instructions for the volar wrist splint (8.6.1) for cutting Velcro as well as for hand and forearm strapping
- 8.4.3.2 Roughly wrap double-sided Velcro around the thumb area to estimate and cut the length of the thumb strap
- 8.4.3.3 Cut the thumb strap so that the width is about 10-12 mm
- 8.4.3.4 Round and cut off the edges of the thumb strap
- 8.4.3.5 Loop each end of the thumb strap from inside the thumb insert outwards through each strap hole and back around the splint edge to then adhere onto itself. The loop (soft) side of the strap should be facing towards the splint while the hook (rough) side faces away from it. Either ends can be adjusted to better fit patient thumb size



8.4.4 Ulnar Gutter (Hand-Based)

- 8.4.4.1 For the bottom hand strap that will wrap below the thumb, cut a 1-inch strap so that its length and width match the “Ulnar Gutter Below Thumb Strap” in the Strapping Guide
- 8.4.4.2 For the top hand strap that will wrap around the MCP joint, cut a 1-inch strap so that its length and width match the “Ulnar/Radial Gutter MCP Joint Strap” in the Strapping Guide
- 8.4.4.3 Cut one Velcro dot into quarters. For each quarter, cut the width according to that of the hand straps, then cut off and round sharp corners. They should look like rounded half-circles

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8.4.4.4 Attach the quarter Velcro pieces to the ends of each hand strap

8.4.4.5 Cut off the corners of the ends of the straps, so that they are rounded and border the Velcro dots



8.4.4.6 For each hand strap, loop one end of the hand strap from inside the splint through the dorsal strap holes and around the splint edge to adhere onto itself. The smooth side of the strap should be on the inside while the Velcro adhesive side faces outwards. This end of the strap is not meant to be adjusted

8.4.4.7 For each hand strap, loop the other end from the inside of the splint through the palmar strap holes and around the splint edge to adhere onto itself. Again, the smooth side of the strap should be on the inside while the Velcro adhesive side faces outwards. This end of the strap is meant to be adjusted to fit the patient's unique hand size

8.4.4.8 For the finger strap, cut a 1-inch strap so that its length and width match the "Ulnar Gutter Distal Strap" in the Strapping Guide

8.4.4.9 Cut one Velcro dot into quarters. For two quarters, cut the width according to that of the finger strap, then cut off the edges until it is a small oval. Only two of the ovals will be used

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- 8.4.4.10 Cut off the end corners of the finger strap, so that they are rounded and border the Velcro dots



- 8.4.4.11 Feed one end of the strap from the back of the splint into the dorsal strap hole behind the pinky finger and out through the dorsal strap hole behind the ring finger.



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- 8.4.4.12 Continue threading the strap from the inside of the splint out through the strap hole in front of the ring finger.



- 8.4.4.13 Allow both ends to adhere onto the hooked side of the strap. Again, the smooth side of the strap should be facing the splint while the Velcro adhesive side faces away from it. Either end can be adjusted to better fit patient



8.4.5 Ulnar Gutter (Forearm Based)

- 8.4.5.1 Cut one Velcro dot in half. For each half, cut off and round sharp corners. They should look like rounded half-circles

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- 8.4.5.2 For the forearm strap, cut a 2-inch strap so that its length matches the “Volar Forearm” in the Strapping Guide. The width of the strap does not need to be altered
- 8.4.5.3 Attach the halve Velcro pieces to the ends of the 2-inch strap
- 8.4.5.4 Cut off the corners of the ends of the straps, so that they are rounded and border the Velcro dots



- 8.4.5.5 Loop one end from inside the splint through the radial strap holes and around the splint edge to adhere onto itself. The smooth side of the strap should be facing towards the splint while the Velcro adhesive side faces away from it. This end of the strap is not meant to be adjusted
- 8.4.5.6 Loop the other end from the inside of the splint through the ulnar strap holes and around the splint edge to adhere onto itself. Again, the smooth side of the strap should be facing towards the splint while the Velcro adhesive side faces away from it. This end of the strap is meant to be adjusted to fit the patient’s unique arm size
- 8.4.5.7 Refer to the strapping instructions for the Ulnar Gutter (hand-based) (8.6.4.8) for cutting finger strapping

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8.4.6 Radial Gutter (Hand-Based)

- 8.4.6.1 For the hand strap, align a 1-inch strap against a hand cutout to measure the desired width of the strap
- 8.4.6.2 Cut the hand strap so that its length matches the “Ulnar/Radial Gutter MCP Joint Strap” in the Strapping Guide
- 8.4.6.3 Cut one Velcro dot into quarters. For two quarters, cut the width according to that of the hand straps, then cut off and round sharp corners. They should look similar to guitar picks
- 8.4.6.4 Attach the quarter Velcro pieces to the ends of each hand strap
- 8.4.6.5 Cut off the corners of the ends of the straps, so that they are rounded and border the Velcro dots
- 8.4.6.6 Loop one end of the hand strap from inside the splint through the dorsal strap holes and around the splint edge to adhere onto itself. The smooth side of the strap should be facing towards the splint while the Velcro adhesive side faces away from it. This end of the strap is not meant to be adjusted
- 8.4.6.7 Loop the other end from the inside of the splint through the palmar strap holes and around the splint edge to adhere onto itself. Again, the smooth side of the strap should be facing towards the splint while the Velcro adhesive side faces away from it. This end of the strap is meant to be adjusted to fit the patient’s unique hand size
- 8.4.6.8 Refer to the strapping instructions for the Ulnar Gutter (hand-based) (8.6.4.8) for cutting finger strapping

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8.4.6.9 See the Fitting Guide for visual reference

8.4.7 Radial Gutter (Forearm-Based)

8.4.7.1 Cut one Velcro dot in half. For each half, cut off and round sharp corners. They should look like rounded half-circles

8.4.7.2 For the forearm strap, cut a 2-inch strap so that its length matches the “Volar Forearm” in the Strapping Guide. The width of the strap does not need to be altered

8.4.7.3 Attach the halve Velcro pieces to the ends of the 2-inch strap

8.4.7.4 Cut off the corners of the ends of the straps, so that they are rounded and border the Velcro dots

8.4.7.5 Loop one end from inside the splint through the radial strap holes and around the splint edge to adhere onto itself. The smooth side of the strap should be facing towards the splint while the Velcro adhesive side faces away from it. This end of the strap is not meant to be adjusted

8.4.7.6 Loop the other end from the inside of the splint through the ulnar strap holes and around the splint edge to adhere onto itself. Again, the smooth side of the strap should be facing towards the splint while the Velcro adhesive side faces away from it. This end of the strap is meant to be adjusted to fit the patient’s unique arm size

8.4.7.7 Refer to the strapping instructions for the Ulnar Gutter (hand-based) (8.6.4.8) for cutting finger strapping

8.4.7.8 See the Fitting Guide for visual reference

9 DOCUMENTATION

9.1 Write any notable remarks in the work management platform or on the order form, such as irregular offsets, adjusted delivery schedules, or if an order is a reprint

9.2 Update order status as “Ready for Delivery” on work management application

10 REVISION HISTORY

Version	CO Number	Description of Change	Initiator
0	CO-00002	Initial Release	A. Arquitola