Point Digit

Instructions for Use

point designs

This document provides information for the prosthetists who will be installing the Point Digit.

Refer to **www.pointdesignsllc.com/resources** to ensure you have the latest copy of this document.

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CE

EC REP

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Rx ONLY

Caution: Federal law restricts this device to sale by or on the order of a prosthetist.

This symbol is used throughout the guide to indicate important cautionary information. Text following this symbol should be read carefully.

Point Digit

INSTRUCTIONS FOR USE
V2.1
MAY 10, 2021

Thank you for choosing the Point Digit and providing your client with an effective and robust prosthetic finger solution.

Whether you are retrofitting the Point Digit into an existing prosthetic socket or you are building a new prosthesis from the ground up, this guide will familiarize you with the Point Digit's functionality and installation.

The installation of any Point Digit should be performed exclusively by a licensed prosthetist or technician. Point Digits are intended to be operated by a prosthesis user following installation and setup. Any unauthorized handling or installation of a Point Digit could void their warranty.

Any questions? We are always happy to help.
Call us or send us an e-mail.

(720) 600-4753
support@pointdesignsllc.com

Point Digit

Intended Use

The Point Digit system is to be used exclusively for external prosthetic fittings of the upper limbs. It is intended to provide flexion and extension at the metacarpal phalangeal (MCP), proximal interphalangeal (PIP), and distal interphalangeal (DIP) joints in order to generate stable hand grasps.

Indications

Users of the Point Digit system will achieve the best clinical outcome if they have amputation of digits 2-5 at or near the MCP joint (slightly distal or proximal of the MCP joint is acceptable).

Intended Patient Population

The Point Digit is intended to be fit on people with amputations of digits 2-5 at or near the metacarpal phalangeal (MCP) joint.

Intended Users

The Point Digit is to be installed into a prosthetic socket by a trained prosthetist, and used by partial hand amputees. The Point Digit is compatible with most prosthetics sockets, and is installed into the prosthetic socket by a trained prosthetist or technician.

Contraindications

None known.

Table of Contents

Introduction to the Point Digit

*Images not to scale, lateral grip pads are not preinstalled

The **Point Digit** is a passive (i.e. not powered) mechanical finger for people with partial hand amputation. It features a ratcheting mechanism that enables one-handed use and up to 11 distinct locking positions. The Point Digit features integrated compliant touchscreen compatible* fingertip pads for enhanced grip. The **Point Digit** is made from titanium for ample strength.

The **Point Digit** can be flexed and locked by applying a force to the dorsal side of the fingertip. This force can be applied by the contralateral limb or by an opposing surface (e.g., leg, table, desk, wall, chair, etc.).

The **Point Digit** can be extended in one of two ways:

1) depressing the push button, or
2) fully flexing the finger to engage the auto spring-back feature.

Up to 4 **Point Digits** can be integrated into a prosthetic socket using the mounting kit, which includes a mounting bracket, lamination spacers, and mounting hardware.

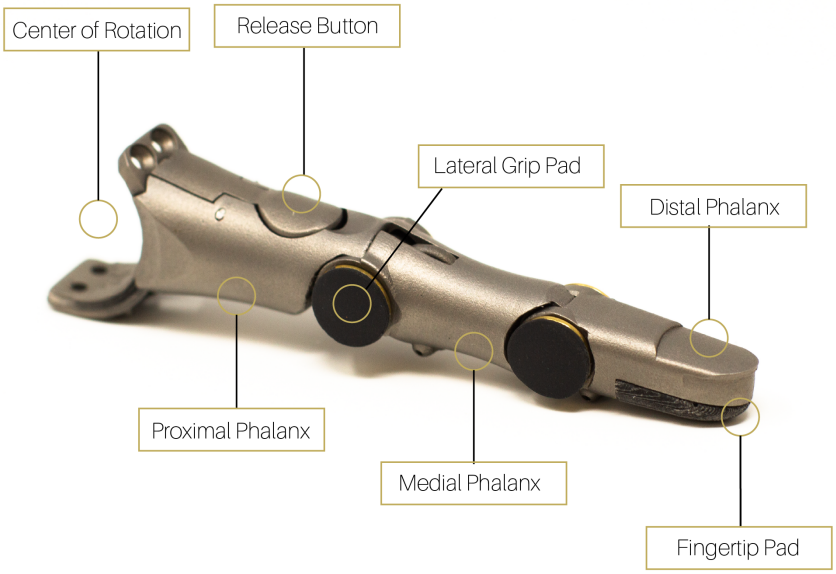
**Touchscreen compatibility is not guaranteed, but has been tested on common iOS, Android, and Windows devices using standard socket material (silicone inner liner with carbon fiber outer shell)*

Clinical Benefits of the Point Digit

The Point Digit provides patients with several key clinical benefits. First and most importantly, the Point Digit allows for one-handed operation, not requiring the contralateral limb to position the finger. In effect, the one-handed operation feature of the Point Digit makes it the only clinically sound passive prosthetic finger for people with bilateral partial hand amputations. Second, the strength of the Point Digit is the highest reported prosthetic partial finger strength in the field which allows patients to perform high-load activities such as those in industrial or recreational environments. Third, there are 11 standard lengths of the Point Digit, accomodating the 1st to 99th percentile male patients and 1st to 100th percentile female patients. Fourth, the Point Digit is the only prosthetic partial finger with 3 moveable joints providing for improved anatomical accuracy. Fifth, the Point Digit has a virtual center of rotation about the MCP joint which provides for proper anatomical alignment of the finger joints. Sixth, and finally, the Point Digit provides up to 11 locking positions to ensure stable grasps of (nearly) any sized object.

Component description

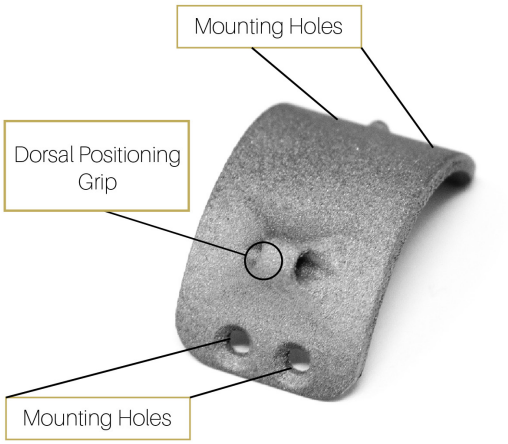
THE POINT DIGIT



The **Point Digit** comes assembled as one unit. The **Point Digit** is comprised of a curved knuckle track, proximal phalanx, medial phalanx, distal phalanx, a release button, fingertip pads, lateral grip pads and several other internal parts. The curved knuckle track has 4 mounting holes.

LAMINATION SPACERS

The lamination spacers are curved components with mounting holes and a dorsal positioning grip to help maintain mounting hole alignment and structural rigidity during the lamination process, and prevent resin from seeping into the mounting area or mounting holes.



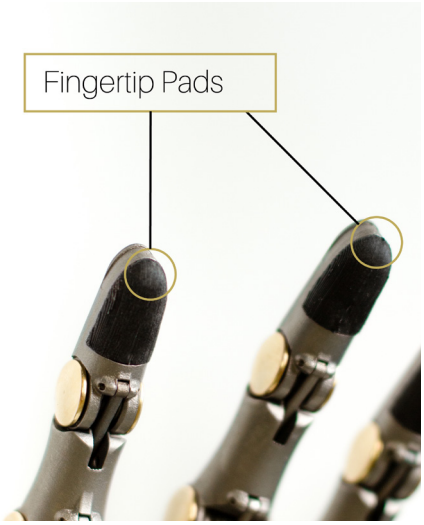
MOUNTING SCREWS

Torx® mounting screws (M2 x 5 mm) are provided for attaching the lamination spacers to the bracket during the lamination process and for mounting the fingers to the bracket. 8 screws per finger are supplied with each *Point Digit*.

Component description

FINGERTIP PADS

The **Point Digit** features integrated compliant touchscreen compatible* fingertip pads for enhanced grip. Each Point Digit comes with one preinstalled fingertip pad, 5 replacement pads, and an installation tool. Additional replacement pads can be acquired by contacting **support@pointdesignsllc.com**

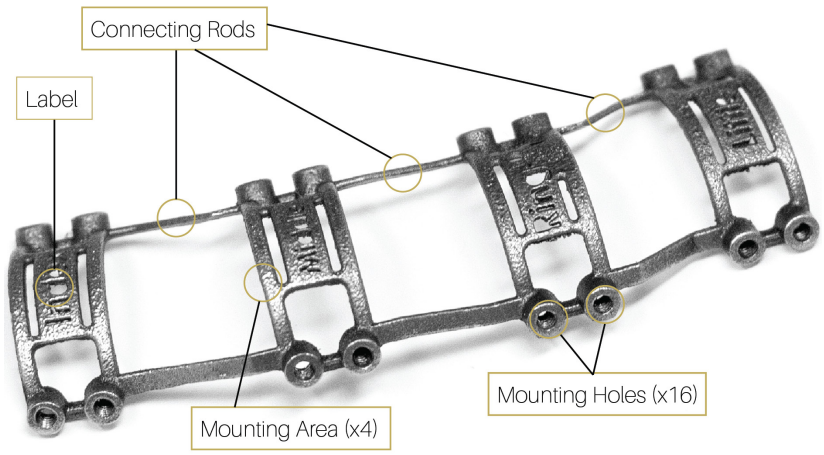


LATERAL GRIP PADS

The Point Digit comes with lateral grip pads to be installed after socket fabrication and final digit mounting. The lateral grip pads are intended for the index finger joints to improve lateral grip, but can be applied to any digit. Ten lateral grip pads and several surface preparatory wipes are included with each order.

**Touchscreen compatibility is not guaranteed, but has been tested on common iOS, Android, and Windows devices using standard socket material (silicone inner liner with carbon fiber outer shell)*

MOUNTING BRACKET



The mounting bracket is a single part comprised of 4 mounting areas with **labels**, 16 mounting holes (4 per mounting area), and **connecting rods** that tie the mounting areas together.

The **labels** denote Point Digit locations and are index, middle, ring, and little.

The **connecting rods** are cut prior to installation to retain only the mounting areas needed.

for example for an index and middle finger installation, the connecting rods between the middle and ring mounting areas are cut and filed down to retain only the index and middle mounting areas.

The mounting bracket comes in either a left-handed or a right-handed version denoted by the Ring finger label, i.e., Ring-R (for right) or Ring-L (for left).

Specifications

Material	*Titanium*
Expected service life	*3 years*
Rated pinch grip strength	*667 N (150 lbf)*
Rated hook grip strength	*667 N (150 lbf)*
Rated tear out strength	*1334 N (300 lbf)*

Installation

BEFORE YOU BEGIN

Included in the package:

- Up to four (4) **Point Digit**(s)
- One (1) mounting bracket
- Up to four (4) lamination spacer(s) [one (1) per **Point Digit**]
- Up to thirty-two (32) mounting screws [four (4) per **Point Digit** and four (4) spare per digit]
- Up to twenty-four (24) fingertip pads, [one (1) per **Point Digit** and five (5) spare per digit]
- Fingertip Installation Tool
- Ten (10) lateral grip pads, uninstalled
- Surface preparatory alcohol wipe
- Torx® tool size T6

What you will need:

- Prefabricated patient socket (e.g., carbon fiber & silicone)
- Lamination supplies (e.g., prepreg carbon fiber, adhesive, silicone, etc.)
- Lamination tools (dremel®, files, PVA bag, etc.)
- Blue thread locker (Loctite® Blue 242® or similar)

The following installation instructions assume that the plaster model of the amputated partial hand has been prepared with a custom silicone socket and a thin carbon fiber prepreg shell, and that a prepreg carbon fiber lamination process will be used to install the **Point Digit** system.
The **Point Digit** installation principles presented in this document can be applied to differing socket lamination and fabrication techniques.

POSITIONING

Take care not to lose any of the mounting hardware.

1. Begin by cutting and filing down the mounting bracket to retain only the mounting locations needed for the installation.
2. Align the bracket with fingers attached for best position on the carbon shell.
3. Mount the fingers to the mounting bracket using the supplied mounting hardware and Torx® tool.

Ensure that the unlock feature in full flexion can be achieved. In other words, the fingers must not be pre-flexed to a point where the finger tips will contact the palm before the unlock is achieved.

4. Use your preferred adhesive to tack the mounting bracket into position, then remove the fingers using the Torx® tool.

5. Apply additional adhesive to create a secure bond of the mounting bracket.

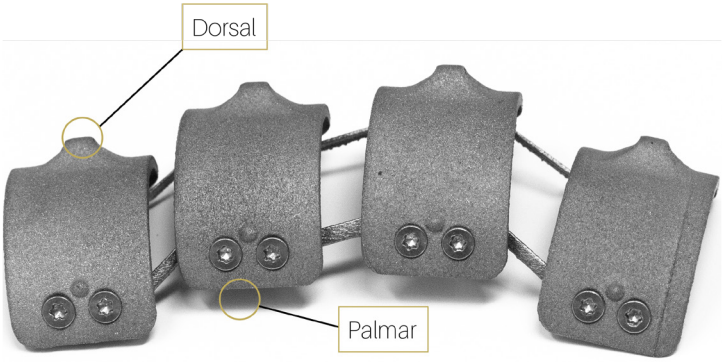
Use only enough adhesive to ensure a secure fixation of the bracket. Voids will be filled with prepreg carbon fiber in a later step.

POSITIONING

6. Remount the fingers using the supplied mounting hardware and the Torx® tool. Inspect the clearance around the finger mount, considering that there will be some layers of prepreg carbon fiber added later. Remove fingers.

LAMINATION

1. Mount lamination spacers using the supplied mounting hardware and the Torx® tool.



2. Check clearance between the lamination spacers and the adhesive.

3. Shape adhesive with dremel® (or similar) as needed.

4. Remove lamination spacers.

5. Pack carbon prepreg ***under*** the mounting bracket to fill any voids.

6. Add carbon prepreg to fill the area over the bracket up to the height of the threaded mounts.

7. Add carbon prepreg over entire model excluding the threaded mount faces.

Be careful not to obstruct the mounting holes with carbon or resin.

8. Apply a very thin layer of non-curing silicone to the underside of the lamination spacer so it will form to the prepreg and apply pressure.

9. Fill threaded mounting holes with silicone grease to ease later removal of screws by preventing prepreg epoxy from flowing into threads.

10. Reapply lamination spacers using supplied mounting hardware and the Torx® tool.

Lamination spacer appearance may vary. They may be metal as on page 11 or plastic as shown here.

11. Remove excess silicone that is pressed out during reapplication of lamination spacers.

12. Apply more silicone putty to blend lamination spacers to the model.

13. Fill over mounting screws with silicone.

14. Apply a PVA bag under the prepreg shell.

15. Apply a second PVA bag over the entire model.

16. Apply vacuum.

17. After curing is complete and the model has cool, clean up the prepreg and remove the lamination spacers.

18. Mount the Point Digit(s) using the mounting hardware provided and the Torx® tool. Inspect the Point Digit(s) for proper function. When satisfied with function, apply blue thread locker to each mounting screw.

PRE-FITTING FUNCTION CHECKLIST

The prosthetist should ensure that all the following functions are checked prior to fitting the user with the prosthesis.
If any of the functions are not working properly, please either review the installation instructions and/or contact **support@pointdesignsllc.com**

- ☐ Each **Point Digit** flexes and locks into the following number of distinct levels of flexion (including full extension) for the corresponding Point Digit size: 7 levels - 55mm, 8 levels - 60mm, 9 levels - 65mm, 10 levels - 70mm - 75mm, and 11 levels - 80mm to 105mm
- ☐ The button on each **Point Digit** can be pressed easily
- ☐ The button rebounds to a flush position when released
- ☐ Pressing the button while each P**oint Digit** is in a flexed position causes position release and easy extension
- ☐ Full flexion of each **Point Digit** can be achieved
- ☐ Release of each **Point Digit** after full flexion results in spring back to full extension and ratchet mechanism reset.

FINGERTIP PAD INSTALLATION

The Fingertip Pad will have either 2 holes (for 95 mm-105 mm digits) or 1 hole (for 55 mm-90 mm digits), and the distal phalange of the **Point Digit** will have a corresponding number of posts.

Point Digit

Installation Tool

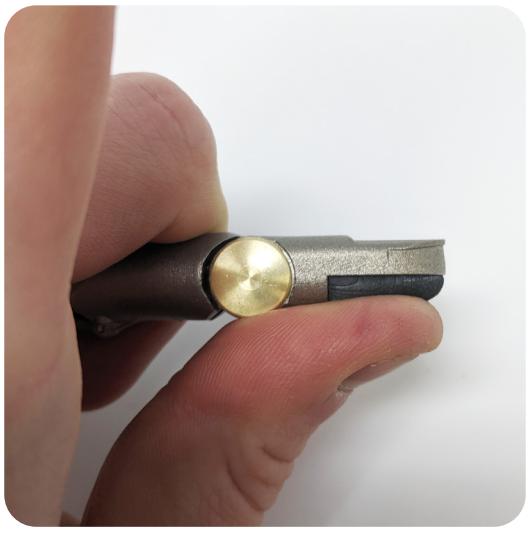
Fingertip Pad

> The 2 hole pads are larger than the 1 hole pads, so make sure you have the correct pad for the distal phalange you are working with.

1. Press the pad down onto the post(s) so that they seat into the holes in the pad. Start by pressing on the proximal end of the pad and work your way distal. Maintain pressure on top of the pad as you move to Step 2.

2. With the pad mostly seated onto the post(s), use the Installation Tool to press the edges of the pad under the lip of the distal phalange. Start this process at the proximal end and then work your way distal. Make sure to maintain pressure on the top of the pad during this process.

3. With the edges pressed in, apply pressure to the top of the pad and rock back and forth gently to help make sure the pad is fully seated. If the pad looks to be bulging out still, then repeat Step 2.

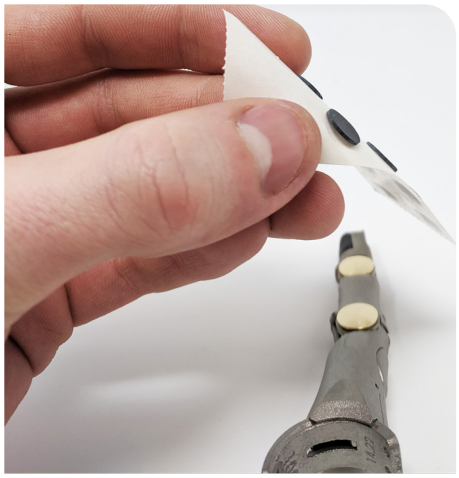


LATERAL GRIP PAD INSTALLATION

The Lateral Grip Pads come in a pack of 10 adhered to a polymer liner. Only 2 pads are needed as they are only installed on the lateral side of an index finger.

1. Clean both brass Chicago Bolts with the alcohol wipe (included).

2. Remove the Lateral Grip Pad from the backing

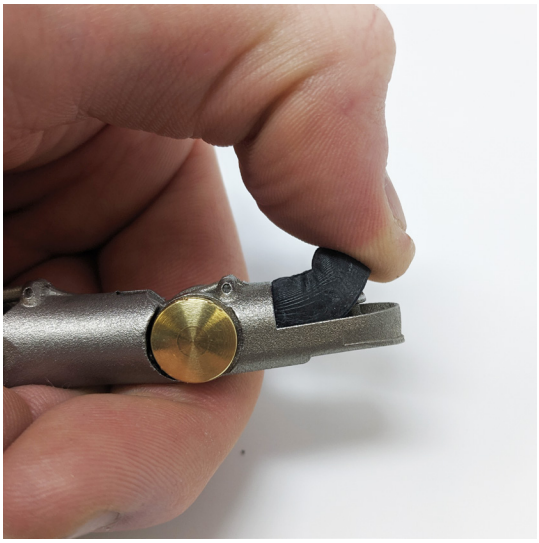


3. Center over the joint, then press on to the Chicago Bolt and hold pressure for at least 10-20 seconds. Clamping the pad down for 72hrs will yield optimal results, but is not necessary.

FINGERTIP PAD REMOVAL

1. Use the Installation Tool (or any similar tool such as a flat head screwdriver) to slide between the pad and wall of the distal phalange and pry the pad up.

2. With the pad partially pried up, use your fingers to grab the pad and pull it the rest of the way out.



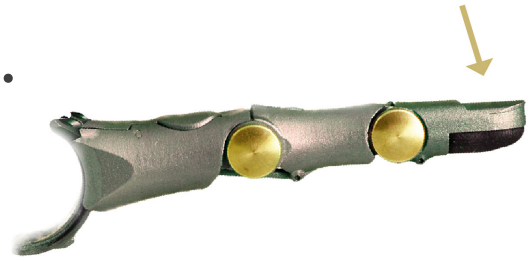
LATERAL GRIP PAD REMOVAL

1. Peel the pad off of the Chicago Bolt using your fingernail or any appropriate tool.

Using The Point Digit

POSITIONING / FLEXION

1.



Push on finger to desired degree of flexion.

2.

RELEASE / EXTENSION

There are two methods for extending the finger from a locked flexion position,
1) the manual release button, and
2) the auto spring-back function.

1. MANUAL RELEASE

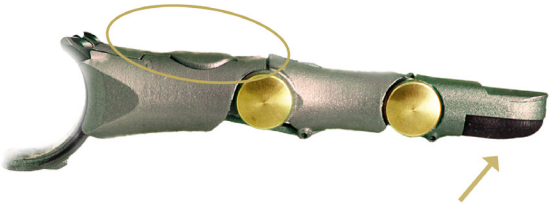
3.

4.

2. SPRING BACK

1. Fully flex finger

2. Release



If button doesn't reset, apply force in extension

Troubleshooting

In case of a problem, this section is intended to help you troubleshoot the operation of the Point Digit.

We have included a few possible issues with solutions below. If your issue is not addressed, email us for support at ***support@pointdesignsllc.com.***

The Point Digit moves freely and does not lock into position

OR

Cannot press Point Digit button or button is stuck in depressed position

Most likely, the ratcheting mechanism has not been reset after the auto spring-back feature was activated. To resolve this issue, apply a force to the fingertip in extension until the finger "clicks", resetting the ratchet mechanism.

Point Digit does not flex all of the way

Clean curved knuckle track of debris using a clean cloth, mild detergent, or compressed air. If problem persists, contact us for support.

Point Digit resets prior to reaching full extension

The button lever did not reset properly in extension. Ensure that the digit reaches full flexion and the button is propped up in full flexion.

Point Digit is loose or came off mounting bracket

Make sure thread locker has been applied to Torx screws, and then tighten them. If Torx screws are unable to be tightened, contact us for additional support.

Point Digit is corroded.

Contact us for support.

Users and/or patients should report any serious incident that has occured in relation to the device to:

- Point Designs at support@pointdesignsllc.com
- FDA via MAUDE (for cases in US)
- The competent authority of the Member States in which they are established in EU/EEA (for cases in the EU/EEA)

Maintaining Point Digits

PREVENTATIVE INSPECTION

All Point Digit systems undergo extensive quality assurance inspections prior to shipping. Regularly inspect **Point Digits** for dirt/grime in the joints, ratchet teeth, and sliding track. Clean **Point Digits** (see MAINTENANCE section below) if decreased performance occurs.

MAINTENANCE

The **Point Digit** can be cleaned with a cleaning solution such as soap + water or mild detergent + water. Dry the digit with a clean towel or compressed air. Be sure to dry a **Point Digit** completely after getting wet, especially when the liquid is likely to accelerate corrosion (e.g., salt water, sweat, etc.).

Lubrication (e.g., WD-40, graphite, etc.) may be applied to the joints and track after cleaning if increased resistance occurs.

No regular care is needed for the fingertip pads, but they can be cleaned with isopropyl alcohol if needed.

For any abnormal issues, discontinue use and contact Point Designs for support.

DISPOSAL

A **Point Digit** should not be thrown away with common household waste. Dispose of the **Point Digit**(s) by either returning the unit(s) to Point Designs or taking the unit(s) to your nearest metal recycling center.

REPAIRS, RETURNS + WARRANTY

Please contact Point Designs at **support@pointdesignsllc.com** regarding repairs and returns. **The Point Digit** comes with a 1-year manufacturer's defect warranty.

Details of the warranty are in seperate documentation available at **www.pointdesignsllc.com/resources.**

Safety and Warnings

WARNING: The **Point Digit** is not designed to operate continuously in wet environments. A **Point Digit** may get wet occasionally, but the user should be advised to thoroughly dry the **Point Digit** after exposure to any liquid. Prolonged exposure to liquid may cause corrosion.

WARNING: The **Point Digit** is electrically conductive and thus presents a potential electric shock hazard if it contacts a voltage difference and the user's (or someone else's) skin simultaneously. The **Point Digit** should not be used around high voltage/current.

WARNING: The **Point Digit** is thermally conductive and thus presents a potential burn hazard if it contacts a heat source and then the user's (or someone else's) skin subsequently. The **Point Digit** should be kept away from hot objects. If a **Point Digit** becomes hot, it should be allowed to cool before skin contact.

WARNING: The **Point Digit** contains ferrous material, and can therefore interact with magnetic fields. Care should be taken when using a **Point Digit** around magnets to avoid accidental attraction. For example, *keep away from MRI machines.*

WARNING: The **Point Digit** contains moving parts (e.g., linkages, springs, ratcheting mechanisms, etc.), and thus presents a minor pinching hazard. The user should take care to keep loose skin, clothing, etc. from the moving parts of the **Point Digit.**

WARNING: The Point Digit contains internal springs under tension. The spring-back mechanism causes the finger to extend rapidly presenting a minor hazard. The user should take care to keep the Point Digit away from self and others during spring-back.

WARNING: Any unauthorized modification to a Point Digit System can pose a safety risk to the user and will void the warranty. Changes or modifications not expressly approved by point designs could void the user's authority to operate the equipment.

WARNING: Adding material (e.g., coverings, etc.) to a Point Digit that can trap moisture is not advised due to the likelihood of accelerated corrosion.

WARNING: Care should be taken when grasping objects to ensure a secure grip.

*Warnings covered in this section are residual risks associated with use of the Point Digit.

Annex I

DESCRIPTION OF SYMBOLS FROM PRODUCT LABEL

Symbol	Description
REF	CATALOG/PART NUMBER
	CAUTION
	DATE OF MANUFACTURE
EC REP	EUROPEAN AUTHORIZED REPRESENTATIVE
	REFER TO INSTRUCTIONS FOR USE
LOT	LOT NUMBER/BATCH CODE
	MANUFACTURER
MD	MEDICAL DEVICE
SN	SERIAL NUMBER

NOTES

NOTES

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L0030 - Point Digit - Instructions for use (DOC-70) Ver. 2

Approved By:

(CO-14) Point Digit Technical File Revisions (Part 2)

Description

Further revisions of the Point Digit technical file based on feedback from AR.

Justification

Need to revise technical file to bring it into compliance with MDR

Assigned To:	Initiated By:	Priority:	Impact:
Benjamin Pulver	Benjamin Pulver	Urgent	Major

Version History:

Author	Effective Date	CO#	Ver.	Status
Susan Waruinge	May 26, 2021 10:37 AM MDT	CO-14	2	Published
Susan Waruinge	May 7, 2021 8:59 AM MDT	CO-6	1	Superseded
Levin Sliker	March 17, 2021 10:21 AM MDT	CO-3	0	Superseded