

Fabrication Guide

for Core2 and IBT Electrodes V2

www.i-biomed.com

sales@i-biomed.com

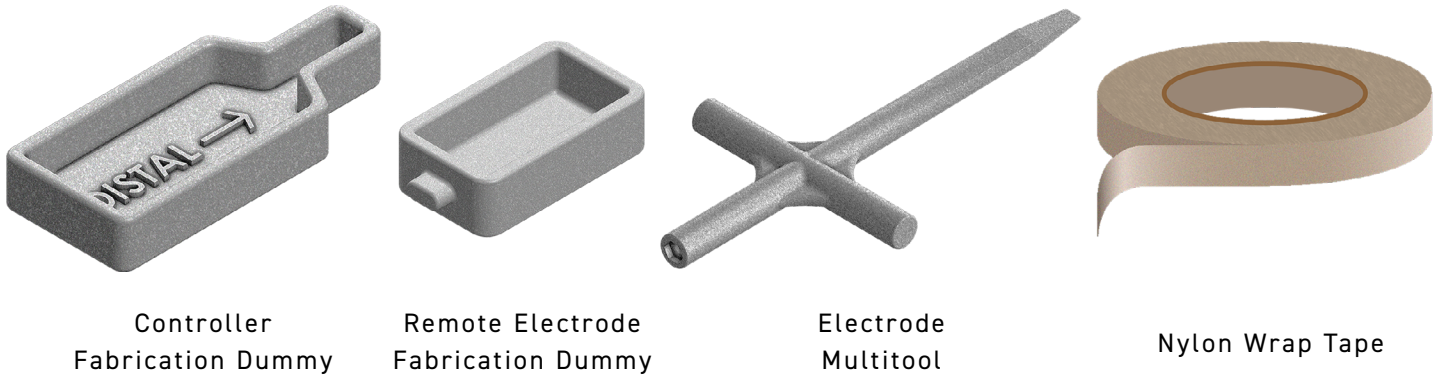
+1 (443) 451-7175

CONTENTS

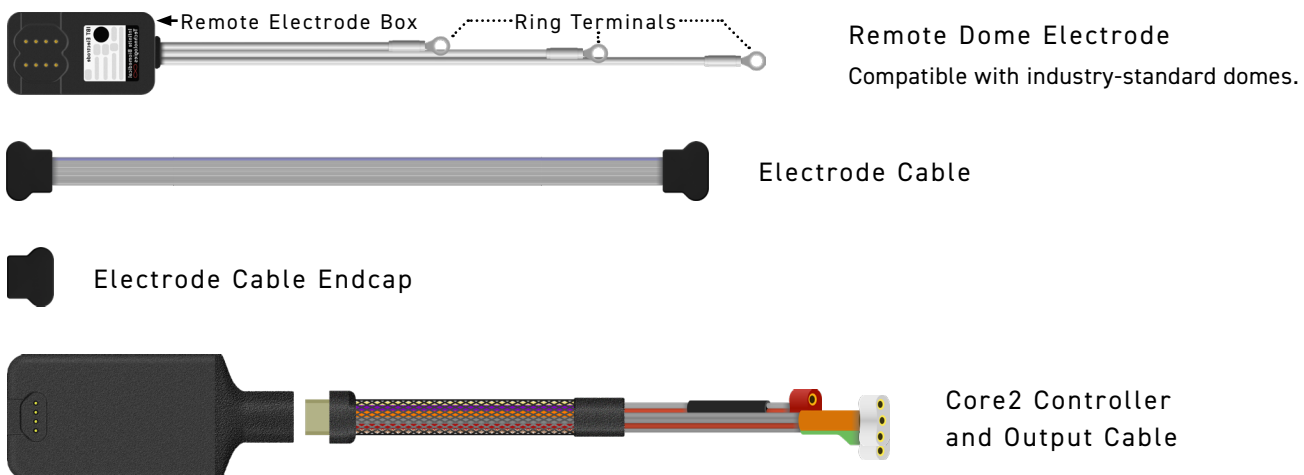
The IBT Core2 System is available with up to eight electrodes. Please see the appropriate sections for fabrication of the prosthesis relevant to you.

Fabrication Kit	Page 1
Socket Fabrication	Page 2
Rigid Thermoplastic	
Flexible Thermoplastic	
HTV Rolled Silicone	
Laminated Frames	Page 3
Electrodes	
Controller	
Assembly	Page 4

FABRICATION KIT



COMPONENT IDENTIFICATION



SOCKET FABRICATION

Electrode Dome Orientation

Using the selected electrode site as a guide:

- Place the two signal domes 2 - 3cm apart (center-to-center) along the muscle belly. These connect to the two outer ring terminals.
- Place the reference electrode dome in a neutral location. This connects to the center ring terminal marked with white heat shrink. Keep record of where each electrode color is placed on the arm. The color of the electrode is indicated by the color of the circle on the electrode body's label, and corresponds to the color of the signal channels when viewed on the IBT Control App.

Note: The reference dome can be shared across different electrodes.

Note: Ensure domes are not contacting each other.

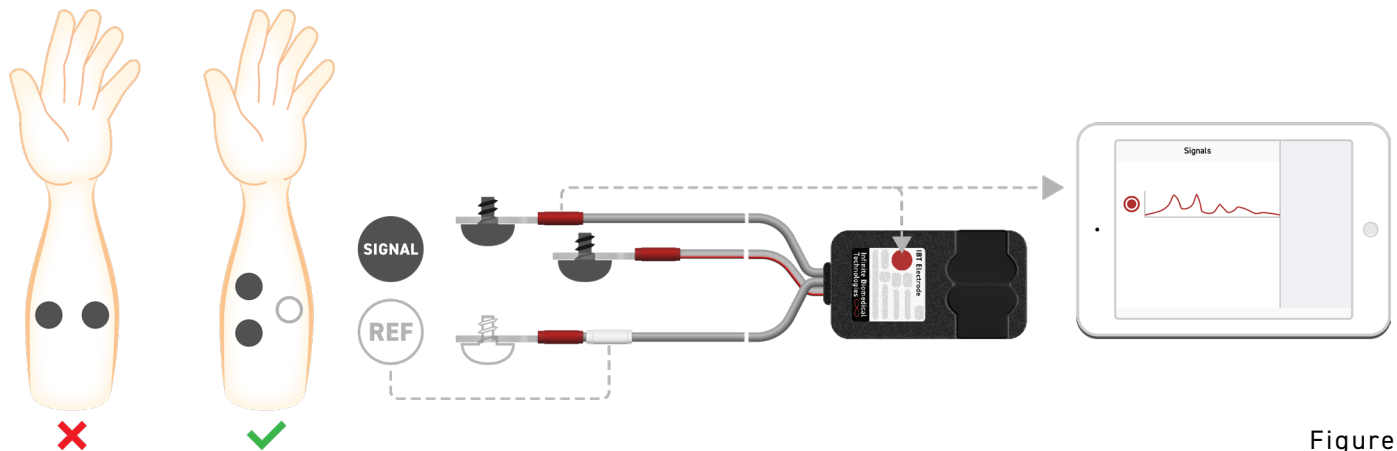


Figure 1

Rigid Thermoplastic

1. Mark electrode dome sites on the mold.
2. Vacuum form plastic using standard methods.
3. Transfer electrode dome sites to plastic and drill holes in correct orientation (Figure 1).

Flexible Thermoplastic

1. Mark electrode dome sites on the mold.
2. Vacuum form plastic using standard methods.
3. Transfer electrode dome sites to plastic and drill holes in correct orientation (Figure 1).
4. Recommended:
 - a. To ensure proper fit and electrode contact during the diagnostic phase, create a rigid frame around the flexible socket, cutting out areas around dome posts to allow spacing for the electrode domes' exit.

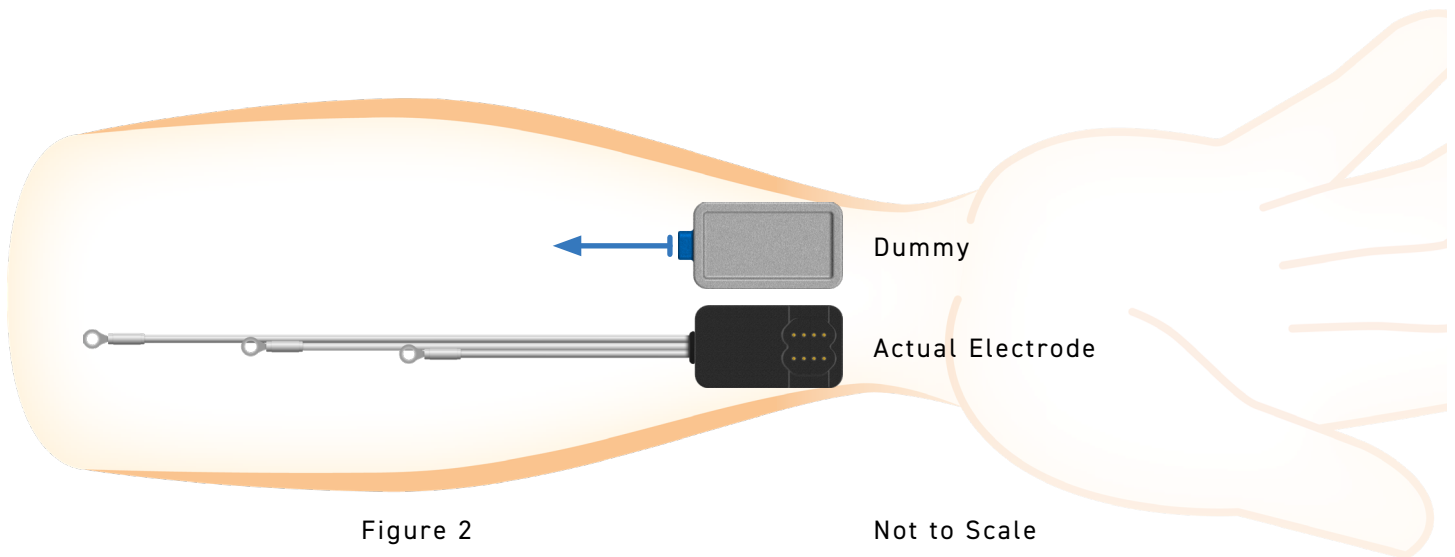
HTV Rolled Silicone

1. Mark electrode dome sites on the mold.
2. Fabricate silicone socket using standard methods.
3. Transfer electrode sites to silicone and push the domes through the silicone in correct orientation (Figure 1).
4. Recommended:
 - a. To ensure proper fit and electrode contact during the diagnostic phase, create a rigid frame around the flexible socket, cutting out areas around dome posts to allow spacing for the electrode domes' exit.
 - b. For thin definitive silicone sockets, fabricate a thin lamination directly over the rolled silicone. Anchor the silicone to the lamination to maintain the silicone's shape while donning and doffing.

LAMINATED FRAMES

Electrodes

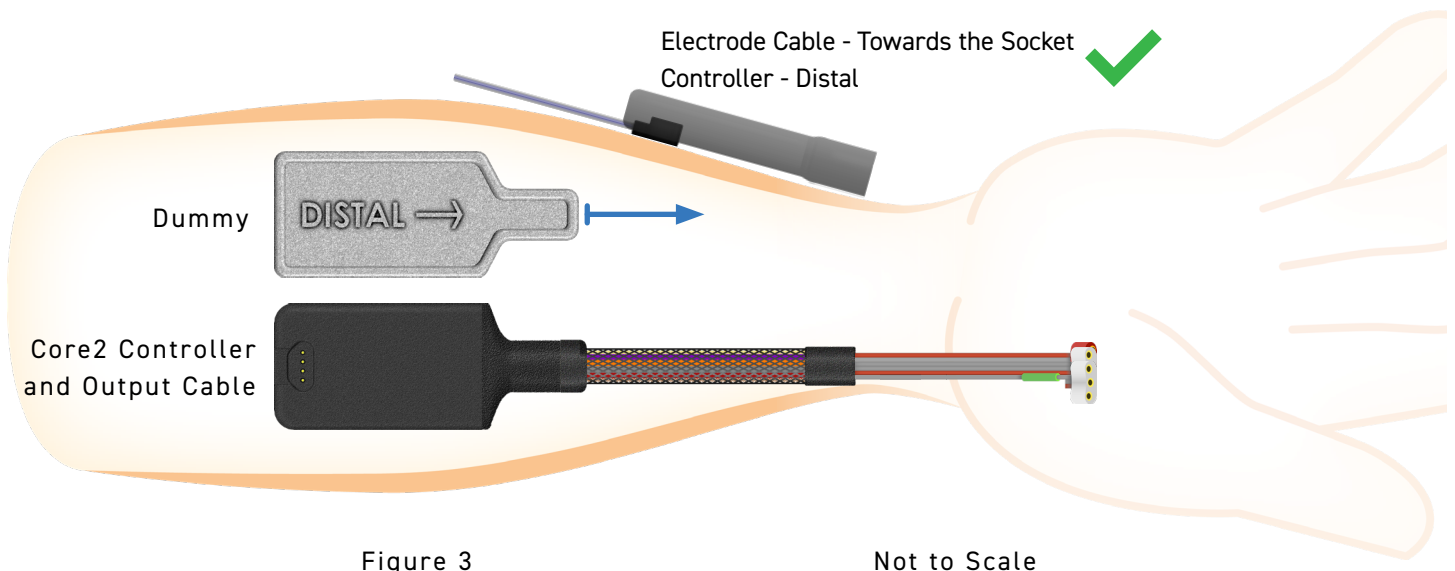
1. Build up sufficient space for all electrode dome assemblies. The minimum space required for the dome assemblies is 7mm (Figure 1).
2. Place the Remote Electrode Fabrication Dummies to ensure there is sufficient space for all remote electrode boxes. The small extension on the Remote Electrode Fabrication Dummy should point towards the electrode dome sites (Figure 2).



Controller

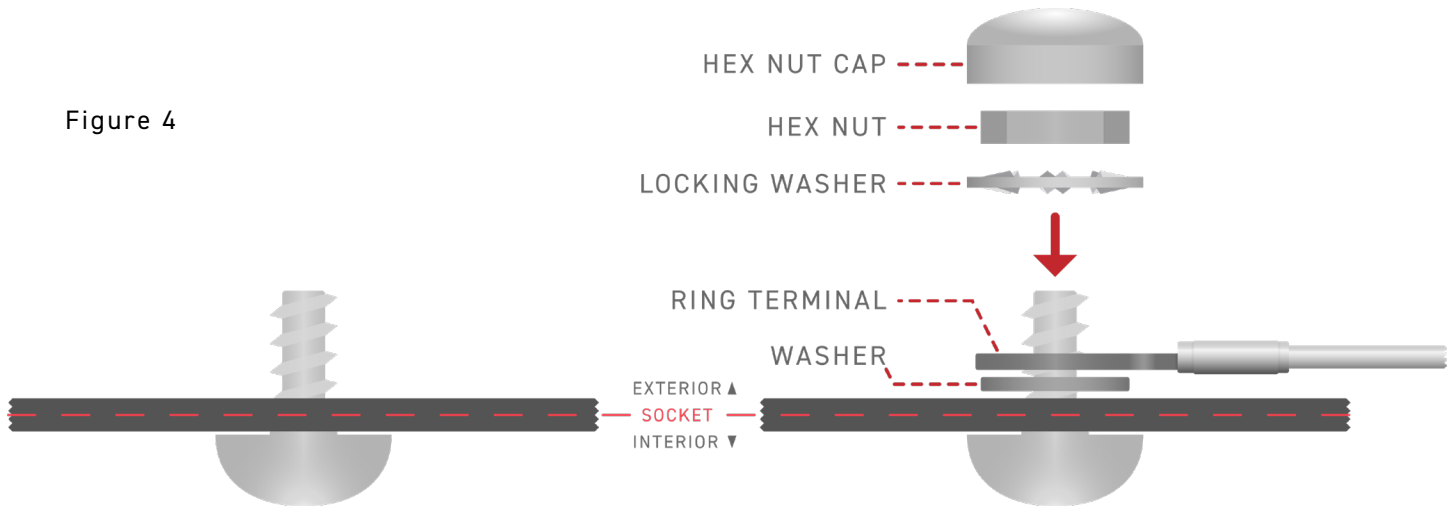
1. Place the Controller Fabrication Dummy in the desired location for fabricating the prosthesis frame. For optimal cable connection security and Bluetooth performance, place the Core2 Controller distally and with the Electrode Cable connection towards the socket.
2. Ensure the dummy is oriented with the cable exit towards the distal end, marked "Distal" on the dummy.

Note: Ensure there is sufficient space between the inner socket and frame for all cabling.

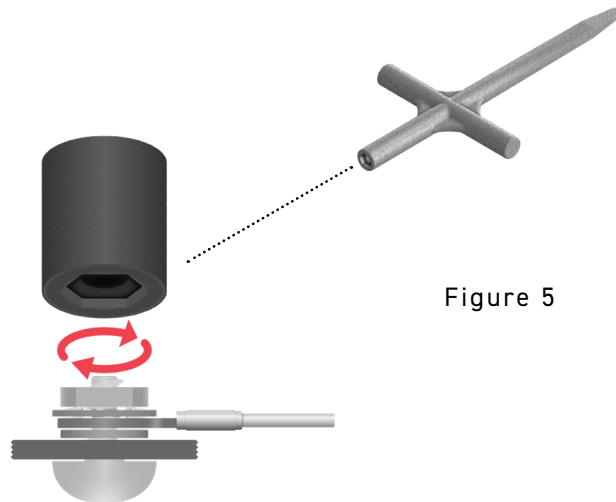


ASSEMBLY

1. Place the electrode dome through each hole from the inside of the socket (Figure 4, left).
2. Electrode dome assembly will depend on the electrode dome kit purchased. By default, follow the instructions in Figure 4, right, to assemble the dome components. If using the Steeper domes, apply the locking washers and hex nut caps from the provided kit to complete the assembly. If using the Coapt ControlSeal™ domes, follow the instructions provided with the packaging.



3. For Steeper domes, tighten the hex nut with the provided Electrode Multitool until snug (Figure 5). For Coapt ControlSeal™ domes, use the appropriate screwdriver according to their instructions.



4. See provided diagrams for input and output connections to assemble all cables.
5. To reduce cable damage:
 - a. Tape or wrap all cabling and control units before inserting the inner socket into the frame. Nylon wrap tape is included (Figure 6).
 - b. Remove Electrode Cables from the Remote Electrode boxes using the provided Electrode Multitool.

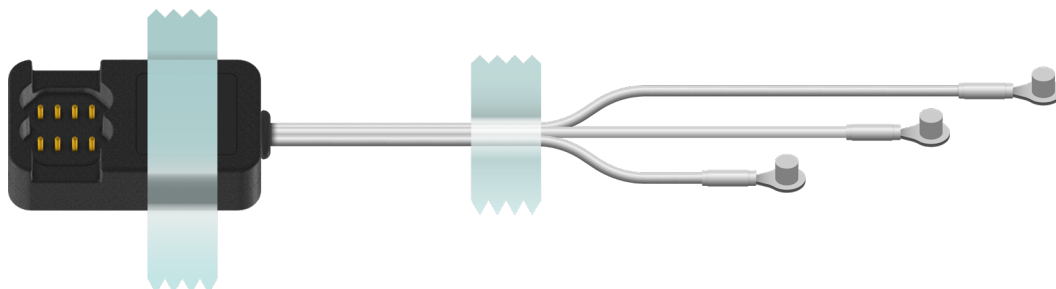


Figure 6

6. Place the Electrode Cable Endcap in the last empty space on the electrode chain. This will secure cable connections and protect the electrode pins.
7. See Figure 7 for final assembly.

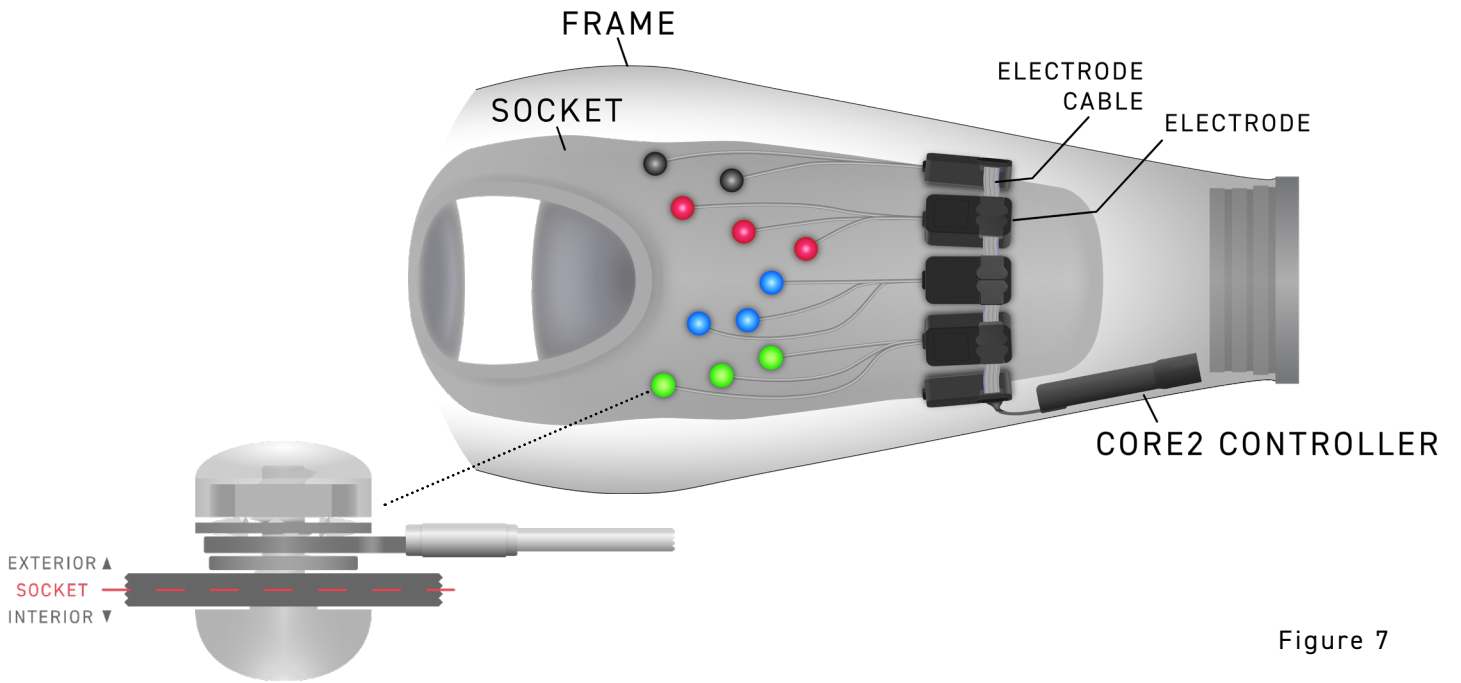


Figure 7