

FusionFrame Walkie Pucks Utilization Instructions

IMPORTANT: Do NOT sterilize this component

Walkie Pucks

REF No.	Description	Height without spacer	Height with spacer
F-WP-SP	Short Puck Kit	15mm	35mm
F-WP-TP	Tall Puck Kit	25mm	35mm

What this kit contains:

This Walkie Puck Kit includes six (6) units of the Short Puck (F-WP-SP) or six (6) units of the Tall Puck (F-WP-TP) in the following configuration:

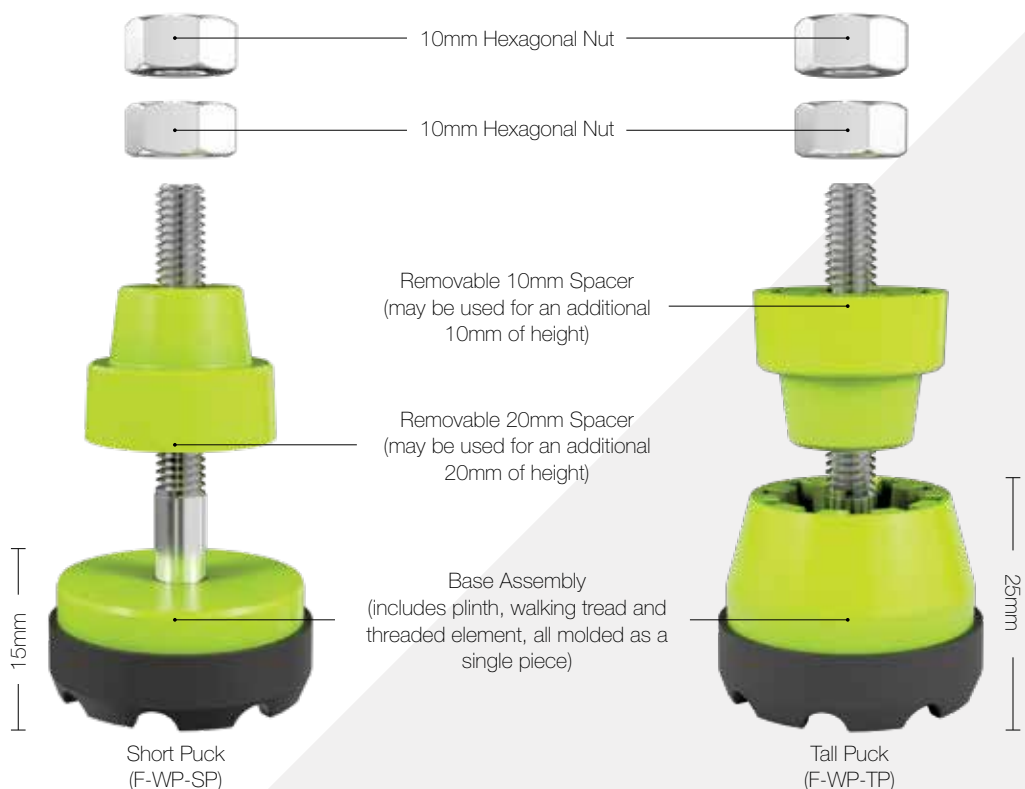


Fig. 1

⚠ WARNING

Walkie Pucks are an optional component that may be added to the FusionFrame construct postoperatively, outside of the sterile field, to facilitate off-loading of the patient's foot during ambulation.

Under no circumstances should the Walkie Pucks ever be sterilized, nor should they be used or assembled within the sterile field.

CAUTION:

Patients must be instructed to avoid walking on wet, oily, greasy, dusty or otherwise unstable surfaces to prevent slipping and possible injury. Patients must be instructed to exercise caution and common sense whenever standing or walking.

NOTIFICATION:

U.S. Federal Law prohibits the use or sale of this or any other FusionFrame device without physician prescription.

NOTIFICATION:

Prior to using the Walkie Pucks, the surgeon must be proficient in the use of the FusionFrame and be familiar with the Operative Technique and all Instructions for Use (IFU).

Additionally Required Instrumentation:

To properly assemble and mount the Walkie Pucks onto the FusionFrame construct, one 10mm Open or Angled Wrench (OW-10 or AW-10, respectively; or a 10mm wrench equivalent) will be needed. The FusionFrame wrenches are not contained in this kit and are supplied separately.

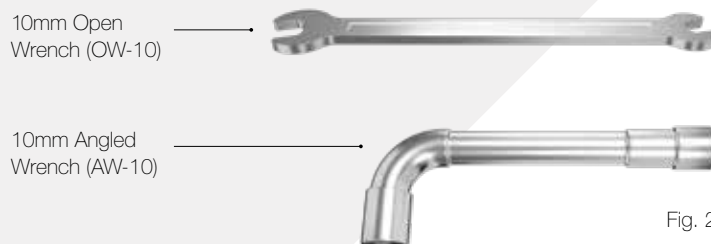


Fig. 2

Mounting and Assembly Instructions:

The Walkie Pucks are placed on the FusionFrame construct after the patient has been removed from the sterile field. This may be done at any time postoperatively. The Walkie Pucks Kit must be removed from the Fusion Frame System Tray and **under no circumstances should the Walkie Pucks be sterilized.**

1. Make certain that the Walkie Puck Kit contains six (6) units of the configuration as illustrated in Fig. 1 above and that all constituent elements are present for each unit.
2. Ensure that you have access to one 10mm wrench, as shown in Fig. 2. A wrench will be needed for proper final tightening of the connections.
3. Preplan the installation arrangement of 4 – 6 Walkie Pucks so that they are positioned as symmetrically and evenly spaced as possible, using the available (empty) holes on the Foot Plate.
4. Decide if the 10mm spacer will be used. If not, remove the spacers from all Walkie Pucks. If yes, leave them in place, as shown in Figs. 1 and 3. All Walkie Pucks on any single FusionFrame construct must be of the same height; all Pucks should either include the spacer or all Pucks should have the spacers removed. Never mix Pucks with spacers with those that do not have spacers, and vice-versa, on any given construct.
5. Remove both hexagonal Nuts and place the threaded element of the Walkie Puck base assembly through the inferior side of an available hole in the Foot Plate as shown in Fig. 3. Use outer holes whenever possible.



Fig. 3

6. Place one of the provided 10mm Nuts onto the threaded element that protrudes on the superior side of the Foot Plate and finger tighten (Fig. 4).



Fig. 4

7. Securely tighten the connection using a 10mm Wrench (Fig. 5).



Fig. 5

8. Place a second 10mm Nut over the first and securely tighten with Wrench (Figs. 6a and 6b). The second Nut is necessary and used to definitively lock the connection. Its presence will minimize loosening caused by the cyclical loading and vibrations due to ambulation and other movements of the patient.



Fig. 6a



Fig. 6b

9. Repeat above steps for the remaining 3 – 5 Walkie Pucks, making certain to position them on the Foot Plate as symmetrically and evenly spaced as possible.
10. Ask the patient to stand and ambulate in your presence to ensure that there is no discomfort, improper gait or suboptimal balance associated with the usage of the Walkie Pucks.

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