Kits, Packs and Trays FAQ

What is Kitting?
- Kitting is the act of taking individual medical products purchased from medical device and drug manufacturers and packaging them together for hospitals, surgery centers, physician offices, and home healthcare agencies. The products are often placed side-by-side for efficient use by the healthcare provider.
- Healthcare providers order custom kits for the purpose of performing a specific medical or surgical procedure (e.g., inserting an intravenous line, closing a wound, knee replacement or open heart surgery).

Why do healthcare providers value Kits, Packs and Trays?
- **Improves efficiency:** Using a Kit, Pack or Tray for a surgical or medical procedure is efficient for healthcare providers as less staff time is focused on collecting the necessary medical products for a procedure.
- **Improves productivity:** Kitting enables valuable clinical resources to focus on the critical task of patient care.
- **Improves safety:** Using Kits, Packs and Trays assists providers in improving patient safety because all of the necessary components are in one place.

How should Kits, Packs and Trays be treated in the implementation of the medical device excise tax?
Kits, Packs and Trays should be exempt from the medical device excise tax. Kitting is a value-added service and is not considered manufacturing. Instead of providing products in a series of boxes, the healthcare provider receives the necessary products for a medical procedure in a single, ready-to-use Kit, Pack or Tray. All of the products included in the Kit, Pack or Tray are medical products that are individually taxable items.

Does Kitting meet the definition of manufacturing?
No, Kitting does not meet the definition of “further manufacture” as detailed in Chapter 32 of the Internal Revenue Code regarding manufacturer excise taxes. The definition regarding substantial transformation clearly demonstrates this point. Specifically, the premise of substantial transformation is that if raw materials were transformed into something else, effectively in a non-reversible form, then that constitutes manufacturing and, generally, the person causing the transformation is the manufacturer. Kitting does not meet this definition because the medical devices included in Kits, Packs and Trays:

1) are purchased from the manufacturer;
2) are not altered or changed;
3) are all used as they were originally intended by the manufacturer; and
4) all function independently from one another.

Is there precedent that supports an exemption for Kits, Packs and Trays?
Yes. In previous rulings, the Treasury Department has concluded that the assembly of two or more articles constitutes manufacturing. Therefore the party responsible for paying the excise tax was the organization that combined or assembled two or more articles to produce a taxable product that were not taxable items themselves individually. The medical products used in Kits, Packs and Trays are already taxable medical devices. The process of Kitting medical devices does not constitute the combination or assembly of two or more articles to produce a taxable product. The medical devices themselves are already an individually taxable product and remain commercially, distinct items.

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1 Sub Part F of Chapter N, Chapter 1 of Internal Revenue Code
2 Treas. Reg. § 48, includes the assembly of two or more articles in definition of manufacturing. This definition was upheld in Technical Advice Memorandum 200022011, February 23, 2000, regarding the Manufacturers Excise Tax imposed by section 4161 of Chapter 32.