

Dear Patient Caregiver,

Distraction is a treatment that requires the distractor to be activated with a special instrument called a Patient Activation Instrument (PAI) etched with "CMF Distraction System". Your doctor will instruct you on how many turns and how many times to activate (turn) the distractor(s) per day.

Please read and follow the information within this guide and the instructions provided by your doctor. Your doctor will talk with you about hazards, harms and proper use of the distractor.

Seek Emergency Care immediately if the patient experiences any difficulty in breathing.

Contact your Doctor if any of the following occur:

- The patient has changes/increased difficulty eating
- The patient experiences excessive pain during activation
- You are unable to activate the distractor with the PAI
- The distractor seems like it has become loose
- You see any redness or drainage from the skin
- Your PAI has a label and it has fallen off or become unreadable
- Your PAI has loose or broken parts
- You lose your PAI or it needs a replacement
- You have missed a turn or if you turned the distractor more than instructed
- You have any concerns or questions

General Warnings:

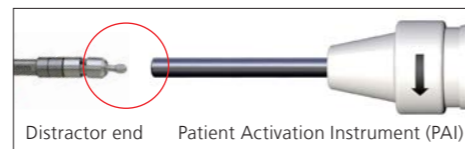
- Take care to prevent distractor damage or breakage during physical activity and/or sleep. Protect the distractor end from catching on objects that could pull the device(s) and cause the patient pain or injury.
- Do not tamper with the distractor(s) or the PAI.
- Use only the PAI to activate the distractor; do not try to turn the distractor with your fingers.

Cleaning and Care Instructions:

- Clean the PAI before each activation by doing the following:
 - Wipe the PAI handle and shaft with 70% isopropyl alcohol
 - Place ONLY the tip of the PAI shaft in 70% isopropyl alcohol for 5 minutes; allow to dry
- Do not soak the PAI handle, do not place under running water, and do not place in the dishwasher
- Store the PAI in a clean, dry environment between activations
- Follow your doctor's instructions to keep the wound clean
- Follow your doctor's instructions to maintain good oral hygiene, if distractor is placed on the jaw

Daily Instructions

It is very important to follow these instructions for the correct activation of the distractor.



1. Place the PAI on the end of the distractor. Be certain the PAI fully covers and is aligned straight with the distractor end.
2. Holding the PAI by the handle (not the metal shaft), and without covering the arrow, turn the device as instructed by your doctor.
 - When using the PAI to turn the distractor, do not pinch the distractor end with your fingers, as the PAI must be able to turn the distractor.

- Activation of the distractor should be done with the instrument held in a straight line with the distractor. The distractor arm should not be curved or at an angle (bent). See Figure to the right. This alignment prevents pressure from being placed on the device and patient's bone which may cause loosening of the distractor from the bone.



- To make a full turn, rotate the PAI in the direction of the arrow until the arrow has reached its original or starting position.
If the arrow is moving in the backwards direction or a click is heard coming from the PAI, the instrument is being turned in the wrong direction. Immediately stop turning the device.



- If your surgeon suggests a half turn, rotate the PAI in the direction of the arrow until the dot (•) on the opposite side of the instrument is facing you.



PLEASE NOTE: It is important to only turn the PAI in the direction of the arrow marked on the handle. Although the PAI is intended to prevent activation in the wrong direction, it is possible that turning in the wrong direction (opposite of arrow) can cause the device to reverse and may, in severe cases, lead to choking (if used on the mandible) or brain injury (if used on the cranium).

Notes:

- **Distractor position may vary according to each patient's treatment needs.**
- **The PAI should be disposed of in the trash at the end of treatment.**

CMF Distractor

Patient Care Guide



DePuySynthes

PART OF THE **Johnson & Johnson** FAMILY OF COMPANIES

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Note: For recognized manufacturer, refer to the product label.
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