

(English) OSTEOPLASTY DELIVERY SYSTEMS

CONTROLLED DELIVERY FOR OSTEOPLASTY (CDO™) SYSTEM

LOW PRESSURE + LOW PROFILE (LP2™) SYSTEM

DUAL CHAMBER DELIVERY (DCD™) SYSTEM

LP2 CORTICAL BONE ACCESSORIES

INDICATIONS FOR USE

The Osteoplasty Delivery Systems consist of manual surgical instruments intended to be used in various general surgical procedures.

The Osteoplasty Delivery Systems are designed for the delivery of biological and other biocompatible substances into bone. These systems can be clinically used in either percutaneous, or open, surgical procedures.

DESCRIPTION OF DEVICE

The Osteoplasty Delivery Systems consist of a series of guidewires, a series of cannulae and extensions for insertion over the guidewires to dilate the incision and provide access to the bone, a series of plungers for advancing the substance through the cannula into the operative site, and syringes for delivery of the substance to the cannula.

The Osteoplasty Delivery System components are manufactured from stainless steels as described by ASTM F899, aluminum as described by ASTM B221, and plastics as described by ASTM D4181, with the cannulae incorporating radiopaque gold-coated tips to provide for visualization of the distal end during insertion.

PRODUCT CONFIGURATIONS

The Controlled Delivery for Osteoplasty (**CDO**) System, Low Pressure + Low Profile (**LP2**) System, Dual Chamber Delivery (**DCD**) System, and **LP2** Cortical Bone Accessories, are provided sterile and are for single use only.

CDO Instrumentation and the **LP2** T-Handle are provided nonsterile.

INSTRUCTIONS FOR USE

CDO System:

1. Place and advance the guidewire into the bone site using standard surgical procedure.
2. Manually introduce the aligning cannula over the guidewire and advance until it aligns with the distal tip of the guidewire.
3. Attach the tamp to the outer cannula. Insert the tamp/outer cannula assembly over the aligning cannula until it is aligned with the guidewire tip.
4. Remove the tamp.
5. Remove the guidewire and aligning cannula.
6. Fill the syringe with an appropriate substance, depending on surgical preference.
7. Connect the syringe to the outer cannula via the luerlock attachment on its proximal end or by attaching it to the connecting hose. Attach the connecting hose to the outer cannula in the same manner. Inject the substance into the cannula.
8. Remove the syringe. Using the plunger, manually push the substance into the bony cavities. Remove the plunger and outer cannula after the injected substance is in place and/or set up.

Low Pressure + Low Profile (LP2) System:

1. Place and advance the guidewire into the bone site using standard surgical procedure.
2. Attach the tamp to the delivery cannula. Insert the tamp/outer cannula assembly over the delivery cannula until it is aligned with the guidewire tip.

3. Remove the tamp.
4. Remove the guidewire.
5. Fill the syringe with an appropriate substance, depending on surgical preference.
6. Connect the syringe to the delivery cannula via the luerlock attachment on its proximal end or by attaching it to the connecting hose. Attach the connecting hose to the delivery cannula in the same manner. Inject the substance into the cannula.
7. Remove the syringe. Using the plunger, manually push the substance into the bony cavities. Remove the plunger and outer cannula after the injected substance is in place and/or set up.

LP2 Cortical Bone Accessories:

1. Place one of the two trocar tips through the stainless steel cannula, turning it in a clockwise direction, securing the trocar to the cannula.
2. Snap the trocar/cannula assembly into the quick connect T-Handle. The T-Handle has a locking mechanism that allows the assembly to click and lock into place.
3. Place and advance the assembly into the bone site using standard surgical procedure.
4. Following placement of the assembly into the bone, the quick connect T-Handle and trocar should be removed, while the cannula is left in place.
5. The Guidewire from the **LP2 System** should then be placed into the stainless steel cannula to maintain positioning.
6. The Cannula should then be removed and replaced by the **LP2 Delivery Cannula**.

Dual Chamber Delivery (DCD) System:

1. Attach the gold extension chamber to the delivery cannula of either the **CDO** or **LP2 System**.
2. Attach the syringe to the opposite end of the extension chamber, using the white adaptor. Inject the substance into the cannula.
3. Using the plunger, manually push the substance through the extension chamber, and the delivery cannula, into the bony cavity.
4. Remove all components after the injected substance is in place and/or setup.

WARNINGS

1. Do not use this device if the sterile package has been opened or damaged.
2. Read the instructions prior to use.

PRECAUTIONS

CDO System, LP2 System, DCD System, LP2 Cortical Bone Accessories, and Modular Tamp:

Instruments that are labeled, or designated as single use devices should not be resterilized, or re-used, and should be disposed of properly after use. This device is labeled as single use to ensure quality patient care.

Osteoplasty Delivery Systems Instrumentation:

Proper handling, decontamination, including pre-rinsing, washing, rinsing and sterilization, storage and utilization are important for the long and useful life of all instruments (e.g. drills, reamers, rasps, gouges, guides and chisels), and driving instruments (e.g. drivers, mallets, tamps, pins, extractors and impactors). These items are often subjected to high loads and/or impact forces. Under such conditions, breakage can occur, particularly when the item is corroded, damaged, nicked or scratched.

Before each use, carefully inspect all instruments. Do not use a driving instrument that is severely marred and worn, or a cutting instrument with dull edges.

Note that at some point in time, instruments wear out and should be replaced.

STERILIZATION

CDO System, LP2 System, DCD System, LP2 Cortical Bone Accessories, and Modular Tamp:

CDO System, LP2 System, DCD System, LP2 Cortical Bone Accessories, and Modular Tamp are sterilized by ethylene oxide or gamma irradiation and are not intended for resterilization. All packaging

should be sealed and intact upon receipt. If the package or product is damaged, the package should not be used and returned immediately.

Osteoplasty Delivery Systems Instrumentation:

Osteoplasty Delivery Systems Instrumentation is provided nonsterile and must be sterilized prior to use. The instrumentation must be sterilized in a properly functioning, calibration steam sterilizer. High temperature steam sterilization should be used. All packaging materials must be removed prior to sterilization. The following sterilization cycle has been validated.

Method:	Steam
Cycle:	Pre-vacuum
Temperature:	132°C (270°F)
Exposure Time:	4 minutes

CAUTION

Federal (USA) law restricts these devices to sale by or on the order of a licensed physician.

INFORMATION

For further information, please contact the Customer Service Department at:

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