Instructions for Use

Caution: *United States law restricts these devices to sale, distribution, and use by or on the order of a physician.*

Description

2-CAN is a sterile packaged, single-use instrument manufactured with surgical grade plastics, polyetheretherketones, stainless steel and adhesives that are in routine surgical use.

Indications for Use

2-CAN is intended for single-use delivery of flowable biologic materials, bone void fillers, and sterile irrigation fluids after appropriate placement over a guide-wire and pre-drilling or reaming.

Duration of Use

2-CAN is not an implant and should be removed in less than 24 hours.

Product Storage

2-CAN shelf life is indicated on the label when stored in normal hospital environmental conditions. Store the product in the original protective packaging. Do not remove the product from the packaging until it is ready to be used. Do not use expired product. DO NOT store the 2-CAN in conditions that are outside ambient temperatures of a hospital setting, such as the trunk or interior of a vehicle. Failure to store in ambient conditions, such as in high heat or humidity, could result in loss of sterility or product failure.

Sterilization

2-CAN is provided sterile via gamma irradiation (Cobalt Co-60) after packaging. Contents are sterile unless package has been opened or damaged. If packaging appears open or damaged do not use.

Contraindications

Do not use 2-CAN with materials that are not known to flow through the instrument in a satisfactory manner.

Warnings and Precautions

2-CAN should only be used by a surgeon familiar with the indications and appropriate surgical technique (see Directions for Use section).

Do not use 2-CAN without pre-drilling or reaming over a guide-wire.

Do not force the 2-CAN over kinked or burred guide-wires, or through fractures that have not been reduced.

Do not use 2-CAN for internal splinting or temporary skeletal stabilization.

Do not use 2-CAN in multiple sites if potential wound contamination is present.

Use of contrast media in patients with a known contraindication to contrast.

2-CAN is a single patient, single-use instrument intended for disposal after use. Attempted reuse risks include but are not limited to device failure, infection, and loss of bone void filler.

2-CAN should be used in low pressure conditions where flow is enabled by normal tactile pressure. Significant force may cause the 2-CAN tip to separate from the cannula requiring an additional surgical procedure to retrieve the tip. Rotation of 2-CAN should not be forced if resistance is felt.

2-CAN works well with materials that can be delivered through a 16-gauge needle. If materials of increased viscosity are used, flow through 2-CAN, as well as use of the plunger, will become more difficult.

Syringe should stay attached to 2-CAN after injection to prevent back flow.

The plunger works well multiple times with tested biologics and bone void fillers – other materials may make plunging a one-time event or cause it to fail if used too forcefully. The smaller 2-CANs have minimal material left in the cannula without plunging.

Delivering flowable biologics or bone void fillers in a pressurized manner may lead to alterations in homeostasis and/or embolism.

Aseptic technique is necessary even if potential wound contamination is present.

Fluoroscopic guidance is advisable for most effective use.

If delivery of a bone void filler is required in an area adjacent to a joint, injection of 4cc of radiopaque contrast through the 2-CAN is recommended to confirm the integrity of the articular surface. If the articular surface is not intact, delivery of bone void filler in that area is not recommended.

Any sign of instrument defect or breakage should lead to immediate discard and replacement.

Possible Complications

Delivering flowable biologics or bone void fillers in a pressurized manner may lead to alterations in homeostasis and/ or embolism. Using slow, smooth delivery at normal tactile pressures is preferred method. Any alteration in blood pressure, heart rate or oxygen saturation should raise concern of embolus.

Delivering large amounts of flowable biologics or bone void fillers into a closed myofascial space or compartment may lead to compartment syndrome and require surgical decompression. Frequent neurovascular checks after surgery will minimize likelihood of significant tissue damage from compartment syndrome.

Delivering flowable biologics or bone void fillers without fluoroscopic localization may result in inaccurate, unacceptable placement. Fluoroscopy should be used in all cases where precise delivery of material is desired.

Failure of the 2-CAN instrument due to inappropriate usage, guide-wire kinking, bone fragments, etc. may require additional procedure(s) to remove any retained fragments. Any catching, hesitation in movement or difficulty with advancement should cause immediate removal of 2-CAN. Any deformity of 2-CAN seen under fluoroscopy should also cause immediate removal of the 2-CAN cannula.

Directions for Use

PREPARATION

1. If fracture is present, reduce the fracture as required.
2. If implant is to be used, prepare the bone for the implant per the implant surgical technique. Upon completion, the bone will have a pilot hole for the nail / screw and have the guide-wire still in place.

DELIVERY OF BIOLOGIC/BONE VOID FILLER (BVF)

3. 2-CAN is designed to work with most guide-wires for the appropriately sized implant when implant is to be used. Sizing and guide-wire fit should be confirmed prior to usage. Select the correct 2-CAN from the table below:

Name	2-CAN Cat #	Guide-Wire	Pilot Hole
2-CAN 5.5	103-1-02	2.0mm	3.6mm
2-CAN 6.5/7.3	103-1-03	2.8mm	4.8mm
2-CAN 8.0 Long	103-1-04	3.2mm	8.0mm
2-CAN 8.0 Short	103-1-05	3.2mm	8.0mm

4. Prepare the biologic or BVF.

- Prepare the biologic or BVF per the manufacturer's instructions.
- Retract the over-guide-wire 2-CAN plunger.
- Attach the loaded syringe to the over-guide-wire 2-CAN Luer fitting.

5. If delivery of a bone void filler is required in an area adjacent to a joint, injection of 2-4cc of radiopaque contrast through the 2-CAN is recommended to confirm integrity of articular surface. If the articular surface is not intact, delivery of bone void filler is not recommended. Do not use contrast media in patients with known allergy.

6. Dispensing the biologic or BVF.
   - Insert the center hole of the 2-CAN over the guide-wire and push the cannula into the pilot hole in the bone.
   - Slide the 2-CAN in until the tip is just past the void to be filled. The depth of the 2-CAN can be judged under imaging as the tip is radiopaque. The material will flow out of the 2-CAN in the vicinity of the tip only opposite the side with the syringe attachment. Therefore, rotate the cannula about the guide-wire, as desired, to properly target the void.
   - Plunge the material with syringe attached to prevent potential back flow.
7. Plunge the cannula (for 2-CAN size 5.5 mm and larger).
   - When the syringe is empty, deliver the material that remains in the cannula by pressing the plunger forward until it comes to the end of the cannula.
   - Remove the over-guide-wire 2-CAN with the syringe and plunger attached leaving the guide-wire in place.

Manufacturer:
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