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

Description

Flow-Drill™ is a sterile packaged, single-use instrument manufactured with surgical grade stainless steel that are in routine surgical use.

Indications for Use

Flow-Drill™ is intended for manual use with surgical driver handles using HMT (Zimmer-Hall) connectors. It may be used for single-use delivery of flowable biologic materials and bone void fillers after appropriate placement over a guide-wire and guide-wire removal. The Flow-Drill may also serve as a manual Biopsy needle when advanced past the guide-wire tip.

Duration of Use

Flow-Drill™ is not an implant and should be removed in less than 24 hours.

Product Storage

Flow-Drill™ 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.

Sterilization

Flow-Drill™ is provided sterile via gamma irradiation (Cobalt Co-60) after packaging. Contents are sterile unless package has been opened or damaged.

Contraindications

Do not use Flow-Drill™ with materials that are not known to flow through the instrument in a satisfactory manner.

Warnings and Precautions

Flow-Drill™ is a single patient, single-use instrument intended for disposal after use.

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

Do not use Flow-Drill™ without prior placement of a guide-wire in desired location.

Do not force the Flow-Drill™ over kinked or burred guide-wires.

Do not use Flow-Drill™ in multiple sites if potential wound contamination is present.

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

When used to drill more than one hole or deliver biologics to more than one site, appropriate care should be taken to ensure that all biologic material has been satisfactorily removed from the Flow-

Drill™ cannulation prior to drilling another hole. Any remaining material that may cause the guide-wire to bind in the drill indicates the need to use a new Flow-Drill™.
When used to drill more than one hole, ensure that the drill has not been bent prior to drilling additional holes. A bent drill will cause the guide-wire to bind and advance past the desired location**.**

Flow-Drill™ works well with materials that can be delivered through a 16-gauge needle. If materials of increased viscosity are used, flow through Flow-Drill™, as well as use of the guide-wire as a plunger, will become more difficult. For best results, prior validation of material flow characteristics by Flow-FX or the operating surgeon is recommended.

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 strongly recommended for most effective use.

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

Possible Complications

Using the Flow-Drill™ for its indicated and marketed purpose requires insertion with a steady, forward rotating action. Any wavering may cause kinking of the guide-wire and unwanted binding of the drill.

Any binding of the guide-wire inside the Flow-Drill™ can cause the guide-wire to advance past the desired location and cause injury to the patient.

Failure of the Flow-Drill™ instrument due to inappropriate usage, guide-wire kinking, bending of drill indicates the need for immediate removal from patient.

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.

Directions for Use

PREPARATION

1. If fracture is present, reduce the fracture as required.
2. Using Fluoroscopic guidance, place a guide-wire directly into the desired area. Such areas may include avascular necrosis, subchondral inflammation, severely osteoporotic among others.

Flow-Drill™ is designed to work with most guide-wires for the appropriately sized implant when an implant is to be used. Flow-Drill™ is named to reflect the outer drill diameter. Sizing and guide-wire fit should be confirmed prior to usage. Select the correct Flow-Drill™ guide-wire from the table below:

Name	Flow-Drill Cat #	Outer Diameter	Maximum Guide-Wire
Flow-Drill™ 2.4mm	110-24K	2.4mm	1.6mm
Flow-Drill™ 3.0mm	110-30K	3.0mm	1.6mm
Flow-Drill™ 3.6mm	110-36K	3.6mm	2.0mm
Flow-Drill™ 4.8mm	110-48K	4.8mm	2.8mm

3. Using a manual, cannulated handle with a HMT (Zimmer-Hall) connector, place the Flow-Drill™ over the guide-wire with a steady, forward, rotational motion. Take care not to advance the guide-wire during this action by using direct guide-wire observation and fluoroscopy. After drilling into the desired area, retract the drill (if desired) to create more space for material delivery.
4. Remove the guide-wire and attach the biologic or bone void filler syringe to the Luer fitting at proximal end as per instructions below.
5. Multiple guide-wires/drill channels may be placed to facilitate decompression or revascularization. When used to drill more than one hole or deliver biologics to more than one pathway, appropriate care should be taken to ensure that all biologic material and bone has been satisfactorily removed from the Flow-Drill™ cannulation prior to drilling another hole. Any remaining material that may cause the guide-wire to bind in the drill indicates the need to use a new Flow-Drill™.
6. If using Flow-Drill as a biopsy trephine, advance the Flow-Drill past the guide-wire tip into the desired biopsy site. Remove the Flow-Drill and guide-wire simultaneously or by removing the guide-wire first. Use the guide-wire to plunge the Flow-Drill and expel the biopsy material.

DELIVERY OF BIOLOGIC/BONE VOID FILLER (BVF)

7. Prepare the biologic or BVF.
    - Prepare the biologic or BVF per the manufacturer's instructions.
    - Remove guide-wire from drill. If material is being delivered to a peri-articular area, injection of a radio-opaque contrast material through the Flow-Drill™ may be useful to confirm that the joint surface has not been breached prior to material delivery.
    - Attach biologic/bone void filler syringe to Luer fitting at proximal end of drill.

8. Dispensing the biologic or BVF.
    - Dispense the material with a smooth gradual action requiring low-pressure tactile force. If significant pressure is required with a Flow-FX validated material, either the material has begun to cure prior to injection or the drill should be backed out partially to create more area.

9. Plunge the Flow-Drill™ with the guide-wire to ensure full delivery of the material.

10. Remove the Flow-Drill™. If implant placement is planned, the guide-wire should be removed after Flow-Drill removal and device should be placed freehand. Tapping of hole should be performed prior to BVF delivery. If repeated usage is planned in the individual patient, thorough rinsing and repeated plunging should be performed immediately after removal to ensure that the drill may be used in drilling another hole without the guide-wire binding and advancing. Guide-wire works effectively as a plunger**.**

PROCEED WITH IMPLANT IF INDICATED

11. Implant placement as per implant Instructions for Use excepting use of no guide-wire after BVF injection.

Manufacturer:
Flow-FX, LLC
9301 W. 191st St.
Mokena, IL 60448
815-531-4424
www.Flow-FX.net