Guided surgery instruments are intended to be used for placement of Implant Direct implants. The planning tools, guides, instructions for use, and guided surgery training are used to aid the proper placement of the implant with respect to patient requirements and allow for proper tool use.

Guided Surgery instruments are packaged non-sterile. Surgical instruments should be cleaned, sterilized, and inspected for damage prior to each use.

Indications/Contraindications:
Indications for use, contraindications, cautions for dental implants are detailed in Implant Direct’s general Instructions for Use.

Warnings:
Guided surgery instruments are used as an aid for placement of Implant Direct implants. This document alone is insufficient to allow immediate use of the guided surgery instruments and procedures.

- Practitioners must have knowledge of dental implantology and instruction in the handling of Implant Direct products and instruments for safe and proper use.
- Ensure the guide system is assembled properly and all components are fixed securely to prevent parts from being aspirated or swallowed. Check proper fit of drills with guides and guides with sleeves before sterilization.
- Instruments should always be inspected before use. Tools are to be replaced after excessive wear or damage. The Drill Guide Inserts can be disassembled and replaced (see disassembly instructions below). Do not use damaged or blunt instruments.

Instrument Descriptions: The following terms are used to describe the instruments and tools used for guided surgery.

Guide Template - Rigid template customized to fit a patient to control the position, angle of the Drill Guide Insert according to prescribed drill protocol and the patient’s anatomy. The Guide Template contains one or more embedded Guide Sleeves.

Guide Sleeves - Rigid cylinders used to control the position and angle of the Drill Guide Inserts. Guide Sleeves are rigidly embedded into the Guide
Drill Guide Handle - Handle used to hold the Drill Guide Insert into the Guide Sleeves during the surgical procedure. There are two Drill Guide Inserts assembled into either end of each handle.

Drill Guide Insert - A metallic drill bushing used to control the position and angle of the cutting drill. Drill Guide Inserts are provided preassembled to handles.

Drill Guide Tool - Tool used to assemble and disassemble the Drill Guide Inserts from the handles. Drill Guide Tool is also used to disassemble the Spacer from the Drill Guide Inserts.

Spacer - A metallic ring used to position the smaller Drill Guide Insert in the larger Guide Sleeves. The Spacers snap onto the Drill Guide Insert.

Surgical Plan: Surgical plans are to be determined in accordance with Guide Template manufacturer's instructions. The guided surgical plan is to be determined using a thorough radiological evaluation by a licensed clinician who is trained in guided surgery and dental implantology. The surgical plan is to be developed with the final restoration and the surgical instrument clearances in mind for proper use.

Guide Template Fabrication: The Guide Sleeve(s) orientation is determined from the surgical plan and is ordered through the Guide Template manufacturer. Implant Direct Guide Sleeves are to be used to produce the Guide Template. Drill depth is determined from the top of the Drill Guide Handle using the prescribed drills and drill markings.

Note: Guide Templates are to be prepared and checked for proper design and construction using guided surgery techniques.

Cleaning/Disinfection/Sterilization:
Before use, wipe excess soil from tray and instruments using a disposable lint free cloth to remove gross soil. Remove instruments from tray and disassemble tray and instruments prior to Cleaning, Disinfection, and sterilization (see Instrument Disassembly Procedure below).

The Guide Template is to be cleaned, disinfected, and sterilized according to the Guide Template manufacturer's instructions. The Guide Template is to be packaged for sterilization, storage, and handling per the Guide Template manufacturer's instructions.

Preliminary Manual Cleaning and Disinfection
A preliminary manual cleaning is needed for heavily soiled instruments, instruments that have accumulated organic debris or come in contact with saline. Use a soft brush (no metal bristles) so as to completely remove residue.

1. Prepare concentrate enzymatic detergent as per manufacturer's recommendation at ¼ oz per gallon of lukewarm tap water.
2. Immerse the disassembled instruments and tray in the enzymatic solution and soak for 10 minutes.
3. Prepare neutral detergent as per manufacturer's recommendation at ¼ oz per gallon of warm tap water.
4. Immerse tray and instruments in the detergent and soak for 2 minutes.
5. Remove the tray from the detergent and rinse under running tap water.
6. Dry tray with disposable lint free cloth.
7. Prepare concentrate enzyme detergent solution per manufacturer's instructions at ¼ oz per gallon of warm tap water in a sonication unit.
8. Completely submerge instruments and tray in the detergent and sonicate for 10 minutes.
9. Remove the instruments and tray and rinse in a bath of reverse osmosis/deionized (RO/DI) water thoroughly for at least 3 minutes.
10. Repeat above two steps (8 & 9) with freshly prepared cleansing solution.
11. Dry the instruments and tray with a clean, disposable, lint free cloth.
12. Visually inspect the instruments and tray for visible soil.

Packaging for Sterilization
13. Prepare the instruments and tray for sterilization by double wrapping them in FDA approved wraps and an FDA cleared sterilizer for one of the following cycles.

Sterilization
14. Steam sterilize tray, handles, inserts, tools, and spacers using a gravity cycle for 15 minutes at a temperature of 132°C (270°F) with a dry cycle of 30 minutes. Steam sterilize using a pre-vacuum cycle for 4 minutes at a temperature of 132°C (270°F) with a dry cycle of 20 minutes, 4 pulses. To avoid deformation, surgical tray should not touch the walls of the steam sterilizer. When sterilizing multiple
instruments in one steam sterilization cycle, ensure that the sterilizer manufacturer’s maximum load requirements are followed.

⚠️ The Guide Template is to be sterilized according to the Guide Template manufacturer’s instructions.

Storage

15. To maintain the integrity of sterility, keep instruments and tray in the wrapped sterilization pouches and in a dry and clean environment. Maintain pouch integrity. Check before usage. The Guide Template is to be carefully handled and stored according to Guide Template manufacturer’s instructions.

Surgical Procedure

Sterilization: Ensure all surgical instruments, guide tools, Spacers, and insertion tools are cleaned and sterilized, as required, prior to assembly and use.

Instrument Assemble Procedure: After cleaning and sterilization, assemble the Drill Guide Inserts to the Drill Guide Handle in a sterile area by tightening them with the Drill Guide Tool. See Figure 1 below.

![Figure 1 - Assembly (tightening) of Drill Guide Insert to Drill Guide Handle](image)

Drilling Sequence: The sterile surgical template is placed in the patient’s mouth. Each drill size has a corresponding larger Drill Guide Insert for gradually increasing the osteotomy and for accurate guiding of the drill.

The Spacer must be used when the Guide Template contains the large Guide Sleeve (6.1mm inside diameter) in order to position the Drill Guide Insert accurately when the small drill guide handles are used. Per drill protocols, the drills are progressively increased in size (reference drilling sequence for each system).

Assemble the Spacer: When needed, the Spacer simply snaps onto the Drill Guide Insert as shown in Figures 2 and 3.

![Figure 2](image)  ![Figure 3](image)

Disassemble the Spacer: To remove the Spacers, insert the narrow end of the spacer into the hole on the side of the Spacer to pop it off (see Figure 8 and
The Optional Bone Contour drills (same as Cortical Bone Drills) cannot be inserted through the Drill Guide Insert or the Guide Sleeves. The Guide Template must be removed to use the Optional Bone Contour drills.

Drilling: Use drills in ascending order in an intermittent drill technique with sufficient cooling. Insert the drill into Drill Guide Insert before turning on motor (See Figures 4 and 5).

Drill Depth: The drill depth is determined by the location of the Guide Sleeve in the Guide Template and the location of the implant position. The surgical plan should always be followed where the drill depth is determined with the planning software.

Drill depth marks do not match implant lengths (i.e. 16mm length implant does not use the 16mm length mark on the drill) when using guided surgery.

The depth of the cutting drill is determined by the drill markings and the top of the drill guide handle. Reference the drill depths and marks to be used which are determined by the planning software. Reference the figures below for the depth markings on the surgical drills (Figures 6 and 7). When the drill protocol specifies depths of 22mm or longer, either the applicable Extra Long drill or DGDE Drill Extender (to be used with 3.4mm and larger drills) should be used. Note: The face of the handpiece should not be used as a drill depth stop.

Implant Placement: Implants are inserted according to Implant Direct’s general Instructions for Use (section Surgical Techniques For Implant Placement).

Directly after use, clean, disinfect, sterilize, and store the instruments and tray as described above. If instruments are not used directly after sterilization, ensure sterility of instruments and tray is maintained.
Instrument Disassembly Procedure:
Directly after use, wipe excess soil from tray and instruments using a disposable lint free cloth to remove gross soil. Minimize the time before manual cleaning and reprocess the tray as soon as practical following use. Thorough manual cleaning process is required. Remove instruments from tray and disassemble tray and instruments prior to cleaning. To remove Spacers, insert the narrow end of the Drill Guide Tool into the hole on the side of the Spacer and pop it off the Drill Guide Insert (Figure 8 and 9). Disassembly of Drill Guide Insert from the Drill Guide Handle assembly using the Drill Guide Tool is shown in Figure 10.

See Implant Direct catalogs and website (www.implantdirect.com) for more information.

IFU-008 Rev. 01