TheraFuze™ Instruments
INSTRUCTIONS FOR USE

GENERAL INFORMATION

This document is intended to provide detailed instructions for processing reusable surgical instruments manufactured by TheraCell. TheraCell instruments are manufactured from various materials commonly used in reusable medical and surgical instruments, including stainless steel, aluminum and polymers. TheraCell has validated the processes provided in these instructions. Alternative methods of processing outside the scope of this document may be suitable for reprocessing. However, these processes must be validated by the user.

The TheraCell TheraFuze Instruments are general surgical instruments for use in orthopaedic surgery. The instruments comprise four awls for preparation of insertion sites for pedicle or other orthopedic screws and a Graft Funnel system for the introduction of bone graft into operative sites in a patient. The instruments are provided in a tray that is suitable for their storage and sterilization, as detailed below.

Catalog Number	Description
TC-IA-5560	Awl for 5.5 / 6.0mm Screws
TC-IA-6570	Awl for 6.5 / 7.0mm Screws
TC-IA-7580	Awl for 7.5 / 8.0mm Screws
TC-IA-8590	Awl for 8.5 / 9.0mm Screws
TC-IB-6MM	Graft Funnel System - 6mm
TC-IA-0000	Handle 1/4" Drive
TC-IT-0001	Instrumentation Tray

WARNINGS

- Instruments are provided non-sterile and must be cleaned and sterilized before use. The validated cleaning process is provided in the MANUAL CLEANING INSTRUCTIONS section of this document; and validated sterilization parameters are described in the STERILIZATION INSTRUCTIONS section of this document.
- Some instruments may have sharp edges. Care should be taken in handling such instruments to avoid injury to the user or patient.
- Staff should wear suitable protective clothing and equipment at all times. Special note should be taken of the instructions provided by the manufacturers of the cleaning agents used in the cleaning process.
- The surgeon should have a complete understanding of the surgical technique and of the function and limitations of each instrument.
- Surgeon should be cautious of the possibility of damaging soft or hard tissue during introduction, malleting or removal of instruments from the surgical site. Use should be guided by open or fluoroscopic visualization.

THERAFUZE AWLS

The awls have a ¼" drive and are designed to be used with the handle. The awls are shaped to match the root dimensions of the screw and have a cutting feature that aids in the insertion of the awl. Each Awl is labeled with the corresponding screw size and will fit down any introducer / cannula with greater than 8.5mm inner diameter. The awl will also tend to push bone laterally and as such will provide compaction of the bone to further aid fixation. The awl should be inserted so that the 3cm long tip of the awl is within the pedicle, with the end of the tip region at the pedicle surface. The TheraFuze awls are cannulated and may be used over a 1.4mm guide wire if desired. The shaft of the awl is laser marked at 1cm intervals and these marks may be used to reference the position, or changes to the position of the awl. Use should be guided by open or fluoroscopic visualization.

The awls are also sized correctly to allow placement of the TheraFuze DBF® Fiber Anchor.

THERAFUZE GRAFT FUNNEL SYSTEM

The TheraFuze Graft Funnel system comprises a 6mm inside diameter, 7mm outside diameter stainless steel tube. The handle is formed to have a funnel feature to facilitate introduction of graft material. The pusher is designed to push graft through and out of the tube. The graft funnel should be introduced into the patient with the pusher inserted to prevent any tissue being pushed up into the tube. The shaft of the funnel is laser marked at 1cm intervals and these marks may be used to reference the position, or changes to the position of the funnel. Use should be guided by open or fluoroscopic visualization. Graft material should be less than 6mm in diameter in order to be capable of being introduced by the system.

The TheraFuze Graft Funnel system can be used to introduce TheraFuze DBF® 6mm caliber Fiber Bullets. These are ideally introduced into the patient in their lyophilized state so that they may hydrate in situ.

CLEANING AND MAINTENANCE

All instruments must be free of packaging material and biocontaminants prior to sterilization. Cleaning, maintenance and mechanical inspection must be performed by hospital personnel trained in the general procedures involving contaminant removal. Only neutral pH cleaners or detergents labeled for use in cleaning medical devices should be used for cleaning components. Only lubricants that are intended for use on surgical instruments should be used to lubricate instruments. Follow directions from the manufacturer of lubricating and cleaning agents regarding handling, concentration and use of those agents.

Cleaning instructions are provided in accordance with recognized standards and regulations, and are intended to supplement a hospital's existing device cleaning and disinfecting protocols. Contaminated devices should be wiped clean of visible soil at the point of use prior to being transferred to a central processing unit for cleaning and sterilization. Contaminated devices must be cleaning promptly after use per these provided instructions in order to ensure effective cleaning.

Instruments should be visually inspected for any damage between surgeries. Functionality of mating fits and of moving parts should also be checked between surgeries. The latch mechanisms on the Tray should be visually assessed between surgeries for functionality.

MANUAL CLEANING INSTRUCTIONS

Follow the instructions listed below prior to sterilization.

1. Rinse instrument thoroughly with running warm (35-40°C) tap water for 1 minute. While rinsing, use a soft bristle brush to loosen and remove as much visible soil as possible from components. A syringe, pipette, water jet, wire guide and/or pipe cleaner should be used to aid in cleaning lumens/cannulations or other challenging areas.
2. Soak instrument in Enzol® enzymatic cleaner solution (or equivalent pH neutral enzymatic cleaner) for a minimum of 10 minutes. Prepare the solution using the manufacturer's instructions. Fully immerse the instrument in the cleaner solution. After the soak, scrub the instrument in the soak solution with a soft bristle brush paying particular attention to hard to reach areas such as mated surfaces and lumens. A syringe, pipette, water jet, wire guide and/or pipe cleaner should be used to aid in cleaning lumens/cannulations or other challenging areas.

3. Thoroughly rinse the instrument with running warm (35-40°C) tap water for 1 minute. While rinsing, a soft bristle brush, syringe, pipette, water jet, wire guide and/or pipe cleaner should be used to aid in cleaning lumens/cannulations or other challenging areas.
4. Prepare an ultrasonic bath and sonicate the devices while immersed in the hospital approved cleaning solution (Enzol®) for 10 minutes. Follow the cleaner manufacturer's instructions for cleaner preparation.
5. Rinse instrument thoroughly with deionized or purified water for 1 minute. A soft bristle brush, syringe, pipette, water jet, wire guide and/or pipe cleaner should be used to aid in cleaning lumens/cannulations or other challenging areas. Actuate all movable parts to fully irrigate all areas.
6. Visually inspect components for soil. Repeat the cleaning procedure if necessary, until no visible soil remains on the instrument.
7. Perform a final rinse on the instrument using deionized water or purified water.
8. Dry the instrument using clean compressed air or a soft, lint-free, clean cloth.

STERILIZATION INSTRUCTIONS

Non-sterile instruments should be autoclave sterilized using the following validated cycle parameters.

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	Pre-vacuum	270°F (132°C)	4 minutes	40 minutes

Note: Sterilization parameters were validated using standard blue sterile wraps.

Cleaning and sterilization parameters were validated per FDA Guidance for Industry (March 17, 2015), Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, ANSI/AAMI/ISO 17665-1: 2006/(R)2013 , ANSI/AAMI ST79:2017, *AAMI TIR12:2010 and AAMI TIR30:2011*. These parameters were validated to a sterility assurance level (SAL) of 10^{-6}. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications (time and temperature).

INFORMATION

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

MANUFACTURER OF RECORD:

TheraCell Inc.
671 Great Road, Unit 3, Littleton, MA 01460
(630) 953-9594
www.theracellinc.com