The Cochlear™ Baha® System
Surgical Tools Reprocessing Guidelines
1. Introduction.................................................................................................. 1
2. General Safety Precautions ................................................................. 1
3. Warnings ................................................................................................. 1
4. Device Description ................................................................................ 2
5. Intended Use ........................................................................................ 2
6. Before First Use..................................................................................... 2
7. Instrument Care....................................................................................... 3
   A. Limitations On Reprocessing .......................................................... 3
   B. Cleaning And Sterilization Instructions ......................................... 3
   C. From Point Of Use ........................................................................ 3
   D. Preparation Before Automated Cleaning ..................................... 3
   E. Cleaning – Automated ................................................................. 3
   F. Cleaning – Manual ........................................................................ 4
   G. Inspection And Functional Testing .............................................. 4
8. Sterilization .......................................................................................... 5
9. Warranty .............................................................................................. 5

SYMBOLS

Caution (no harm)
Special care to be taken to ensure safety and effectiveness.
Could cause damage to equipment.
1. Introduction

This instruction for use (IFU) provides important information that will enable you to use the Surgical Tools in a safe and effective manner. The instructions will also help you to avoid potential application hazards to the patient and are intended for use by qualified professionals trained in the surgical implantation of Baha and Vistafix Systems.

These guidelines are based on validated procedures, if your institutions procedures conflict with these recommendations, please contact Cochlear to rectify the discrepancy to ensure the integrity or functioning of the tools will not be compromised.

2. General Safety Precautions

The manufacturer will not accept any claims for liability or offer a guarantee for damage, which is attributed to the improper repair or modifications made to the surgical tools by unauthorized persons.

The user of this product is solely responsible for any damage resulting from:

- Improper handling
- Incorrect maintenance
- Non observance of the contents of this IFU

3. Warnings

- Follow instructions and warnings as issued by manufacturers of any decontaminants and cleaning agents used. Whenever possible avoid use of mineral acids and harsh, abrasive agents.
- Care must be taken when handling the surgical tools
- Do not permit sharp instruments or edges to contact the surgical tools
- Cochlear accepts no responsibility for any adverse outcomes if the instruments are used with products not recommended by Cochlear.
- The Conical Guide Drill and Widening Drills are provided sterile and must be discarded after use. They cannot be reprocessed.

Note: when reprocessing Cochlear Instruments, always handle with care, wearing protective clothing, gloves and eyewear in accordance with local health and safety procedures.
4. Device Description

The surgical tools are supplied as non-sterile, reusable instrument comprised of stainless steel. They must be cleaned and sterilized before use in accordance with established hospital procedures.

- 93571 Indicator for Baha Attract
- 94071 Implant Magnet template
- 93572 Bone bed indicator
- 95070 Soft tissue gauge 6 mm

The Bone bed indicator should be disassembled prior to cleaning, and then reassembled before sterilization:

Please consult the Baha Attract Surgery Guide for complete instructions on the use of these instruments in the surgical procedure.

5. Intended Use

The Surgical Tools are to be used in the surgical implantation of the Baha Attract System.

6. Before First Use

Instruments are provided non-sterile, and must be cleaned and sterilized in accordance with these instructions before they are used.
7. Instrument Care

a. Limitations on Reprocessing

Repeated processing has not been shown to have an effect on these instruments.

b. Cleaning and Sterilization Instructions

The Surgical Tools are provided non-sterile and must be cleaned and sterilized before use.

c. From Point Of Use

Wherever possible, do not allow blood, debris or bodily fluids to dry on the instruments. For best results, and to prolong the life of the instruments, reprocess immediately after use. If they cannot be reprocessed immediately, use a damp cloth over the instrument to help prevent the soil from drying.

d. Preparation before AUTOMATED CLEANING

- Rinse with cold running tap water until all visible soil is removed.
- Pre-clean the instruments by fully immersing the instrument and using a soft bristled brush with the enzymatic detergent to scrub the instrument. Make sure to brush all crevices, grooves and slots taking care to ensure that the instrument is not damaged.
- Rinse the instruments until no visible detergent is present.

e. Cleaning – AUTOMATED

- Use only FDA cleared washer-disinfector machines and low foaming, non-ionizing cleaning agents and detergents following the manufacturer’s instructions for use, warnings and recommended cycles.
- Place instruments in washer-disinfector such that the instrument will drain completely.
- Program the washer with the following parameters, then activate the wash: Motor speed set to high.
### f. Cleaning – MANUAL

- Rinse with cold running tap water until all visible soil is removed.
- Prepare the enzymatic detergent; Enzol® or equivalent, using manufacturer’s recommendations.
- Fully immerse the instrument into the prepared detergent and soak for a minimum of 20 minutes. Scrub the instrument, using a soft-bristled brush, making sure to brush all crevices, grooves and slots taking care to ensure the instrument is not damaged.
- Rinse with distilled or demineralized water, agitating for 1 minute to remove any residual detergent; repeat rinse for a total of two times.
- Dry the instrument using a soft, lint-free cloth.
- Visually verify that the instrument is clean. If visible soil remains, repeat cleaning procedure again.

### g. Inspection and Functional Testing

> Examine the instrument corrosion or other damage and replace them if necessary.
8. Sterilization

- Use FDA-Cleared pre-vacuum steam sterilization systems.
- When sterilizing multiple instruments in one cycle, load the sterilizer in accordance with the manufacturer’s recommendations, and do not exceed the maximum load.
- Ensure instruments are dry before sterilization.
- Use an FDA-cleared sterilization container and wrapping that is compatible with the sterilizer.
- Follow these validated sterilization parameters:
  - Sterilizer Type: .................................. Pre-vacuum
  - Minimum Temperature: .................. 135°C (275°F)
  - Minimum Exposure Time: ............. 3 minutes
  - Minimum Dry Time: ....................... 16 minutes

It is the responsibility of the user to establish whether or not the sterilizer has been validated to meet the recommended parameters listed above. Only use indicators and accessories cleared by the FDA and labeled for use with your recommended sterilization parameters.

9. Warranty

**Warranty:**
We, Cochlear, warrant to you, the consumer of the Product, that:

- **a.** Each Product is of merchantable quality;
- **b.** Each Product is reasonably fit for the purpose or purposes for which it is supplied by us; and
- **c.** Each Product will be free from defects in design, workmanship and materials for the Warranty Period.

This warranty excludes liability for the defects or damage arising from, associated with, or related to the use of this Product with any non-Cochlear processing unit and/or any non-Cochlear implant. **Warranty period:** 1 year from 2 weeks after shipping.
As your patient's partner in hearing for life, Cochlear believes it is important to convey not only the benefits, but also the potential risks associated with a Baha procedure.

Not everyone with hearing loss is a candidate for a Baha. Baha is contraindicated in patients with inadequate bone quality or quantity to provide stability and support for the implant, or in patients who will be unable to maintain and clean the skin around the abutment. In the U.S., use of the implanted fixture is also contraindicated in children under age 5 years.

All surgical procedures include an element of risk, and it is impossible to guarantee success. The device may fail to osseointegrate for a number of reasons, including physiological and surgical issues as well as traumatic impact to the implant site. On rare occasions the skin around the abutment may become inflamed from a mild infection or the skin may grow back towards its original thickness. For complete information regarding the risks and benefits of a Baha procedure, please refer to the Instructions for use for the Baha implant available at www.Cochlear.com/US/BahaIndications.