



Cochlear™ Baha® System

Surgical Tools

Reprocessing Guidelines

Contents

1. Introduction	4
2. General safety precautions	4
3. Warnings	5
4. Device description	6
5. Intended use	7
6. Before first use	7
7. Instrument care	8
a. Limitations on reprocessing	8
b. Cleaning and sterilization instructions	8
c. From point of use	8
d. Preparation before automated cleaning	8
e. Cleaning – automated	8
f. Cleaning – manual	9
g. Inspection and functional testing	9
8. Sterilization	10
9. Warranty	11

Symbols



Caution (no harm)

Special care to be taken to ensure safety and effectiveness. Could cause damage to equipment.



Note

Additional helpful tips and instructions.

01 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® Systems and Vistafix® Products.

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.

02 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

03 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.

04 Device description

The surgical tools are supplied as non-sterile, reusable instruments 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



95180
Bone bed
Indicator



95070
Soft Tissue
Gauge 6 mm



91095
Indicator for
Baha Implant



90944
Raspatorium



91116
Drill Indicator
for WS-75
and Osscora



90943
Dissector



90474
Abutment
Insert



90381
Machine
Screwdriver
Unigrip 25mm



92142
Implant
Insert



90469
Screwdriver
Unigrip 95mm

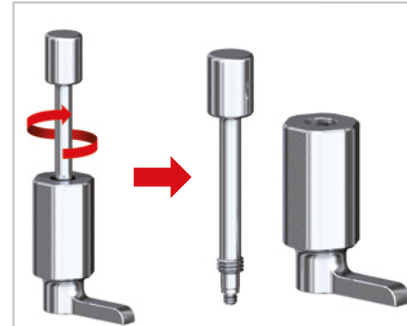


92143
Multi Wrench
with ISO
Adapter

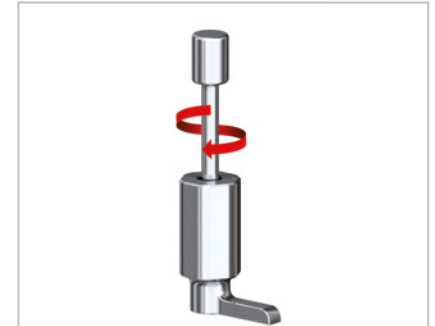


HIA 009-0
Counter
Torque
Wrench

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



Disassembly of Bone bed indicator



Reassembly of Bone bed indicator

05 Intended use

The surgical tools are to be used in the surgical implantation of the Baha Connect and Baha Attract Systems.



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

06 Before first use

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

07 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.

Phase	Recirculation Time	Water Temperature	Detergent Type and Concentration
Pre-Wash	2 minutes	Cold tap water	N/A
Wash 1	4 minutes	Hot (60°C)	Renu-Klenz™ or equivalent. Minimum of 1/4 oz per gallon.
Rinse 1	15 seconds	Hot (43.3°C)	N/A
Dry	6 minutes	82.2°C	N/A

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.



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.

08 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

09 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.

Hear now. And always

As the global leader in implantable hearing solutions, Cochlear is dedicated to helping people with moderate to profound hearing loss experience a life full of hearing. We have provided more than 600,000 implantable devices, helping people of all ages to hear and connect with life's opportunities.

We aim to give people the best lifelong hearing experience and access to innovative future technologies. We collaborate with leading clinical, research and support networks.

That's why more people choose Cochlear than any other hearing implant company.

This content is meant for professional use. If you are a consumer, please seek advice from your medical practitioner or health professional about treatments for hearing loss. They will be able to advise you on a suitable solution for your hearing loss condition. All products should be used only as directed by your medical practitioner or health professional. Not all products are available in all countries. Please contact your local Cochlear representative.

©Cochlear Limited 2021. All rights reserved. Hear now. And always and other trademarks and registered trademarks are the property of Cochlear Limited or Cochlear Bone Anchored Solutions AB. The names of actual companies and products mentioned herein may be the trademarks of their respective owners.

Manufacturer: Cochlear Bone Anchored Solutions AB Konstruktionsvägen 14, SE - 435 33 Mölnlycke, Sweden Tel: +46 31 792 44 00 Fax: +46 31 792 46 95

www.cochlear.com/us

Cochlear Americas
10350 Park Meadows Drive
Lone Tree, CO 80124 USA
Telephone: 303 790 9010
Support: 800 483 3123

Cochlear Canada Inc.
2500-120 Adelaide Street West
Toronto, ON M5H 1T1 Canada
Support: 800 483 3123



BUN257 ISS5 JUL21

Follow us on

