

INTERSPACE® HIP TRIAL

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The InterSpace® Hip Trial is a polypropylene (PP) device designed to fit the anatomy of the patient. The InterSpace® Hip Trial is available in 3 sizes (small, medium, large) and two lengths (short and long).

Step 1: Choose the InterSpace® Hip Trial based on the dimension of the removed prosthesis.

Step 2: Test the trial in the patient to determine if the prosthesis is anatomically correct and stable.

Step 3: Once the trial has been tested and verified, remove it from the patient, and use it as a reference to prepare the InterSpace® Hip Spacer or the InterSpace® GV Hip Spacer which will be implanted.

Step 4: After use, the device must be cleaned.

CLEANING & STERILIZATION

InterSpace® Hip Trial components are provided nonsterile. Before each use, the device must be cleaned and sterilized.

CLEANING RECOMMENDATIONS:

1. Prepare neutral pH enzyme and cleaning agents at the use-dilution and temperature recommended by the manufacturer.
2. Completely submerge the instrument in enzyme solution and allow it to soak for at least 1 minute, or the minimum soak time recommended by the cleaning agent manufacturer. Use a soft-bristled brush to gently clean the device (paying close attention to all threads, crevices and other hard-to-clean areas) until all visible soil has been removed. Any instruments with lumens or cannulas should be cleaned with a long, narrow, soft-bristled brush (i.e. pipe cleaner brush). The enzyme solution should be changed when it becomes grossly contaminated.

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3. Remove the trials from the enzyme solution and rinse in purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled) for a minimum of 3 minutes. Thoroughly flush lumens, holes and other difficult to reach areas.
4. Prepare the neutral pH cleaning (detergent) solution and place in a sonication unit.
5. Completely submerge trials in cleaning solution and sonicate for 10 minutes, preferably at 40-45 kHz.
6. Rinse instrument in purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled) thoroughly for at least 3 minutes or until there is no sign of blood or soil in the rinse stream.
7. Repeat steps 5 and 6 with freshly prepared cleaning solution until the instruments are thoroughly clean.
8. Dry instrument with a clean, disposable, absorbent, non-shedding wipe.

In case of use of automatic cleaning cycle, check the compatibility with the instructions.

RECOMMENDED STERILIZATION CYCLE*:

Method:	Moist Heat (steam)
Cycle:	Dynamic Air Removal (Prevacuum) Steam
Temperature:	132°C (270°F)
Exposure Time:	4 Minutes
Dry Time:	Wrapped Devices** – 30 Minutes

** An FDA-cleared sterilizer should be used.*

*** Prior to sterilization, the trials should be placed in an FDA-cleared wrap.*

The above sterilization cycle achieves a sterility assurance level (SAL) of 10⁻⁶.

WARNING: Strict surgical aseptic technique must be observed. The InterSpace® Hip Trial must be used only to determine the anatomically correct size of the InterSpace® Hip Spacer or the InterSpace® GV Hip Spacer to be implanted. The trial device must not be implanted. Instruments must always be examined by the user pre/post cleaning and prior to surgery. Examination should be thorough and must include a visual and functional inspection of the working surfaces, pivots, racks, spring or torsional operation, cleanliness of holes or cannulations, and the presence of any cracks, bending, deformation, or distortion, and that all components are complete. Do not use the trial if it appears damaged (deformation, loss of the information marked on the trial, etc.). The trial needs to be replaced if it appears damaged after a visual inspection.

DISPOSAL: When the device has to be disposed follow national or local guidelines for disposal of surgical waste materials.

CAUTION

Federal law (USA) restricts this device to sale by or on the order of a physician. Store in cool and dry environments.

DESCRIPTION	REF CODE
InterSpace® Hip Trial, 46mm Short	IHT46S
InterSpace® Hip Trial, 54mm Short	IHT54S
InterSpace® Hip Trial, 60mm Short	IHT60S
InterSpace® Hip Trial, 46mm Long	IHT46L
InterSpace® Hip Trial, 54mm Long	IHT54L
InterSpace® Hip Trial, 60mm Long	IHT60L
Interspace® Hip Kit w Trials	ISKITH

Symbols

NONSTERILE

Nonsterile

REF

Catalog Number

LOT

Batch Number



Caution



Consult Instructions For Use



Date of Manufacture

UDI

Unique Device Identifier



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