InterSpace® Hip Tapered Wedge Stem Trial

Hip • Knee • Knee ATS Component • Shoulder

OPERATIVE INSTRUCTIONS FOR INTERSPACE® HIP TAPERED WEDGE STEM TRIAL

Content:

1 InterSpace® Hip Tapered Wedge Stem Trial size 46
1 InterSpace® Hip Tapered Wedge Stem Trial size 54
1 InterSpace® Hip Tapered Wedge Stem Trial size 60

Warnings:

- Thoroughly inspect trials prior to use. Trials showing cracks, deformation, abrasion, or other obvious defects should not be used and should be replaced. Laboratory testing through 50 sterilization cycles has not shown any sign of deterioration.
- The InterSpace® Hip Tapered Wedge Stem Trial must be used only to determine the right size of the InterSpace® Hip Tapered Wedge Stem to be implanted.
- The InterSpace® Hip Tapered Wedge Stem Trial must not be implanted.

Cleaning and Sterilization:

- After use, the device must be cleaned with detergent diluted in water with a pH between 6 and 8 at room temperature. Thoroughly rinse in water to eliminate any trace of detergent. For the final rinse, use sterile water and dry immediately.
- Caution: Detergent or disinfectant substances containing chlorine, iodine, acids, alkalis or mercury have to be verified before use.
- Before being used, the device must be perfectly cleaned and sterilized in the vapour autoclave, according to a validated procedure that provides for a previous empty cycle.
- The following cycles are recommended:

– Pressure + 1 bar, temperature 121°C, minimum holding time 15 minutes.
– Pressure + 2 bar, temperature 134°C, minimum holding time 4 minutes.

INTERSPACE® HIP TAPERED WEDGE STEM TRIAL XL

HIP • KNEE • KNEE ATS COMPONENT • SHOULDER

OPERATIVE INSTRUCTIONS FOR INTERSPACE® HIP TAPERED WEDGE STEM TRIAL XL

Content:

1 InterSpace® Hip Tapered Wedge Stem Trial size 46XL
1 InterSpace® Hip Tapered Wedge Stem Trial size 54XL
1 InterSpace® Hip Tapered Wedge Stem Trial size 60XL

Warnings:

- Thoroughly inspect trials prior to use. Trials showing cracks, deformation, abrasion, or other obvious defects should not be used and should be replaced. Laboratory testing through 50 sterilization cycles has not shown any sign of deterioration.
- The InterSpace® Hip Tapered Wedge Stem Trial must be used only to determine the right size of the InterSpace Hip Tapered Wedge Stem to be implanted.
- The InterSpace® Hip Tapered Wedge Stem Trial must not be implanted.

Cleaning and Sterilization:

- After use, the device must be cleaned with detergent diluted in water with a pH between 6 and 8 at room temperature. Thoroughly rinse in water to eliminate any trace of detergent. For the final rinse, use sterile water and dry immediately.
- Caution: Detergent or disinfectant substances containing chlorine, iodine, acids, alkalis or mercury have to be verified before use.
- Before being used, the device must be perfectly cleaned and sterilized in the vapour autoclave, according to a validated procedure that provides for a previous empty cycle.
- The following cycles are recommended:

– Pressure + 1 bar, temperature 121°C, minimum holding time 15 minutes.
– Pressure + 2 bar, temperature 134°C, minimum holding time 4 minutes.

InterSpace® Knee Trials

Hip • Knee • Knee ATS Component • Shoulder

OPERATIVE INSTRUCTIONS FOR INTERSPACE® KNEE TRIAL

Content:

1 InterSpace® Knee Trial size 6054
1 InterSpace® Knee Trial size 7064
1 InterSpace® Knee Trial size 8074

Warnings:

- Thoroughly inspect trials prior to use. Trials showing cracks, deformation, abrasion, or other obvious defects should not be used and should be replaced. Laboratory testing through 50 sterilization cycles has not shown any sign of deterioration.
- The InterSpace® Knee Trial must be used only to determine the right size of the InterSpace® to be implanted.
- The InterSpace® Knee Trial must not be implanted.

Cleaning and Sterilization:

- After use, the device must be cleaned with detergent diluted in water with a pH between 6 and 8 at room temperature. Thoroughly rinse in water to eliminate any trace of detergent. For the final rinse, use sterile water and dry immediately.
- Caution: Detergent or disinfectant substances containing chlorine, iodine, acids, alkalis or mercury have to be verified before use.
- Before being used, the device must be perfectly cleaned and sterilized in the vapour autoclave, according to a validated procedure that provides for a previous empty cycle.
- The following cycles are recommended:

– Pressure + 1 bar, temperature 121°C, minimum holding time 15 minutes.
– Pressure + 2 bar, temperature 134°C, minimum holding time 4 minutes.

INTERSPACE® KNEE TRIALS XL

HIP • KNEE • KNEE ATS COMPONENT • SHOULDER

OPERATIVE INSTRUCTIONS FOR INTERSPACE® KNEE TRIAL XL

Content:

1 InterSpace® XL Knee Trial size 9084

Warnings:

- Thoroughly inspect trials prior to use. Trials showing cracks, deformation, abrasion, or other obvious defects should not be used and should be replaced. Laboratory testing through 50 sterilization cycles has not shown any sign of deterioration.
- The InterSpace® Knee Trial XL must be used only for the short time to determine if InterSpace® Knee XL size 9084 is the right size of InterSpace® Knee to be implanted.
- The InterSpace® Knee Trial XL must not be implanted.

Cleaning and Sterilization:

- In order to eliminate any residue, after use the device must be cleaned with detergent diluted in water having pH between 6 and 8 at room temperature. Rinse repeatedly in water to eliminate any trace of detergent. For the final rinse use sterile water and dry immediately.
- Caution: Detergent or disinfectant substances containing chlorine, iodine, acids, alkalis or mercury have to be verified before use.
- Before being used, the device must be perfectly cleaned and sterilized in the vapour autoclave, according to a validated procedure that provides for a previous empty cycle.
- The following cycles are recommended:

– Pressure + 1 bar, temperature 121°C, minimum holding time 15 minutes.
– Pressure + 2 bar, temperature 134°C, minimum holding time 4 minutes.

INTERSPACE® KNEE ATS COMPONENT TRIAL

HIP • KNEE • KNEE ATS COMPONENT • SHOULDER

OPERATIVE INSTRUCTIONS FOR INTERSPACE® KNEE ATS TRIAL KIT

Content:

1X InterSpace® Knee ATS Trial 60/07
1X InterSpace® Knee ATS Trial 60/12
1X InterSpace® Knee ATS Trial 80/07
1X InterSpace® Knee ATS Trial 80/12

Warnings:

- Thoroughly inspect trials prior to use. Trials showing cracks, deformation, abrasion, or other obvious defects should not be used and should be replaced. Laboratory testing through 50 sterilization cycles has not shown any sign of deterioration.
- The InterSpace® Knee ATS Trial Kit must be used only to determine the right size and thickness of the InterSpace® Knee ATS to be implanted.
- InterSpace® Knee ATS Trial Kit must be used in combination with the InterSpace® Knee Trial and InterSpace® Knee Trial XL. The allowed combinations between InterSpace® Knee ATS Trial and the InterSpace® Knee Trial/InterSpace® Knee Trial XL are reported in the table below:

InterSpace® Knee ATS Trial Kit (Ref Code: SPK90Z2)	**Combination with InterSpace® Knee Trial** (Ref Code: SPK90Z1) **And InterSpace® Knee Trial XL** (Ref Code: SPK03Z1)
InterSpace® Knee ATS Trial 60/07	InterSpace® Knee Trial (6054) or InterSpace® Knee Trial (7064)
InterSpace® Knee ATS Trial 60/12	
InterSpace® Knee ATS Trial 80/07	InterSpace® Knee Trial (8074) or InterSpace® Knee Trial XL (9084)
InterSpace® Knee ATS Trial 80/12	

InterSpace® Knee ATS Component Trial

Hip • Knee • Knee ATS Component • Shoulder

OPERATIVE INSTRUCTIONS FOR INTERSPACE® KNEE ATS TRIAL KIT (cont.)

• The InterSpace® Knee ATS Trial devices must not be implanted.

Cleaning and Sterilization:

• In order to eliminate any residue, after use the device must be cleaned with detergent diluted in water having pH between 6 and 8 at room temperature. Rinse repeatedly in water to eliminate any trace of detergent. For the final rinse use sterile water and dry immediately.

• Caution: Detergent or disinfectant substances containing chlorine, iodine, acids, alkalis and mercury have to be verified before use.

• Prior to use, the clean device must sterilized by steam autoclaving following a validated sterilization procedure.

• The following cycles are recommended:

– Pressure + 1 bar, temperature 121°C, minimum holding time 15 minutes.
– Pressure + 2 bar, temperature 134°C, minimum holding time 4 minutes.

InterSpace® Shoulder Trials

Hip • Knee • Knee ATS Component • Shoulder

OPERATIVE INSTRUCTIONS FOR INTERSPACE® SHOULDER TRIAL

Content:

1 InterSpace® Shoulder Trial size 41

1 InterSpace® Shoulder Trial size 46

Warnings:

- Thoroughly inspect trials prior to use. Trials showing cracks, deformation, abrasion, or other obvious defects should not be used and should be replaced. Laboratory testing through 50 sterilization cycles has not shown any sign of deterioration.
- The InterSpace® Shoulder Trial must be used only to determine the right size of InterSpace® Shoulder to be implanted.
- The InterSpace® Shoulder Trial must not be implanted.

Cleaning and Sterilization:

- In order to eliminate any residue, after use the device must be cleaned with detergent diluted in water having pH between 6 and 8 at room temperature. Rinse repeatedly in water to eliminate any trace of detergent. For the final rinse use sterile water and dry immediately.
- Caution: Detergent or disinfectant substances containing chlorine, iodine, acids, alkalis and mercury have to be verified before use.
- Before being used, the device must be perfectly cleaned and sterilized in the vapour autoclave, according to a validated procedure that provides for a previous empty cycle.
- The following cycles are recommended:

– Pressure + 1 bar, temperature 121°C, minimum holding time 15 minutes.
– Pressure + 2 bar, temperature 134°C, minimum holding time 4 minutes.

Symbols:

NON STERILE

Non Sterile

REF

Catalogue Number

LOT

Batch Number

Caution

Consult Instructions For Use

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