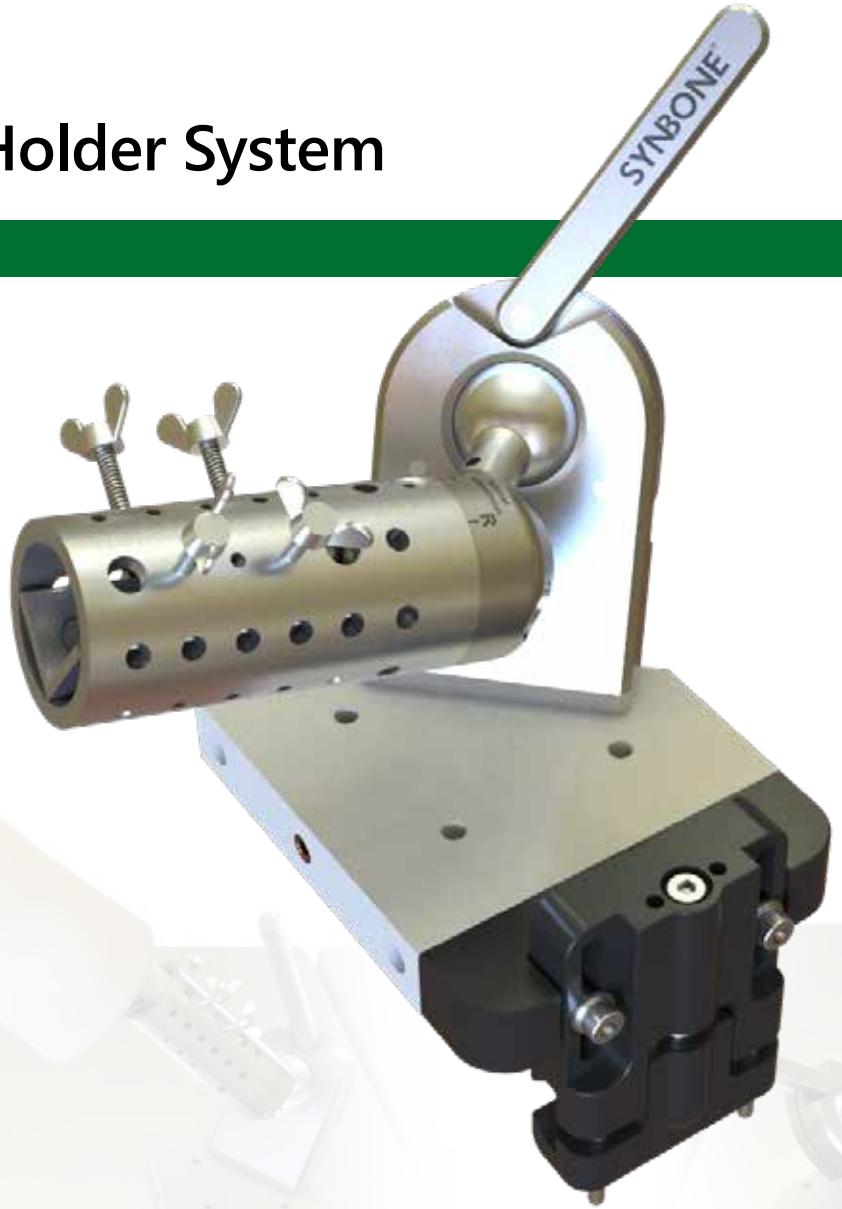
Instructions for use

0037.C05 CAD Leg Holder System

SYNBONE®

better education outcome



PN 0037.C05.81 / V 1.0 / January 2025

Instructions for use
0037.C05 CAD Leg Holder System

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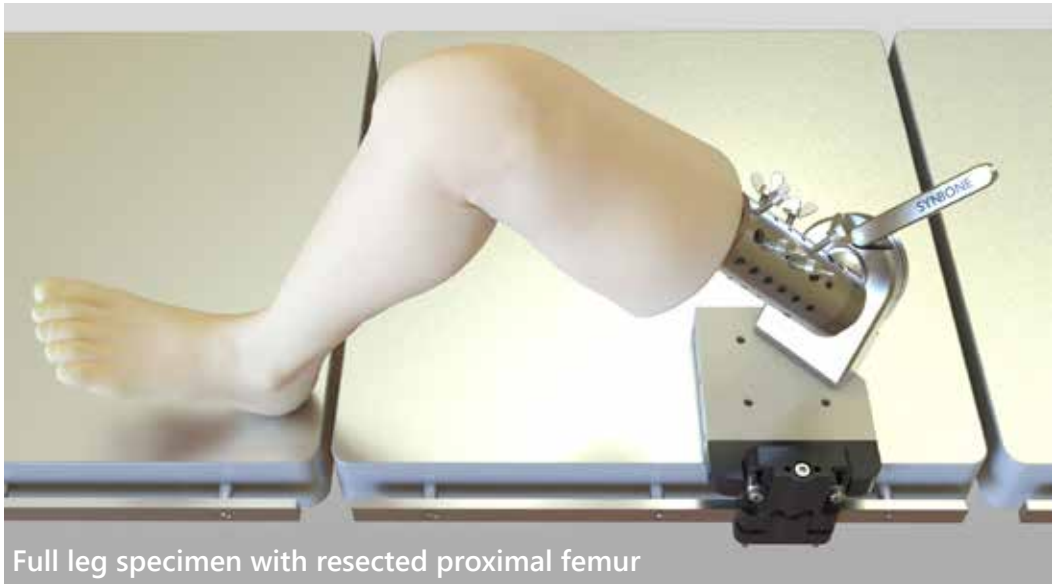
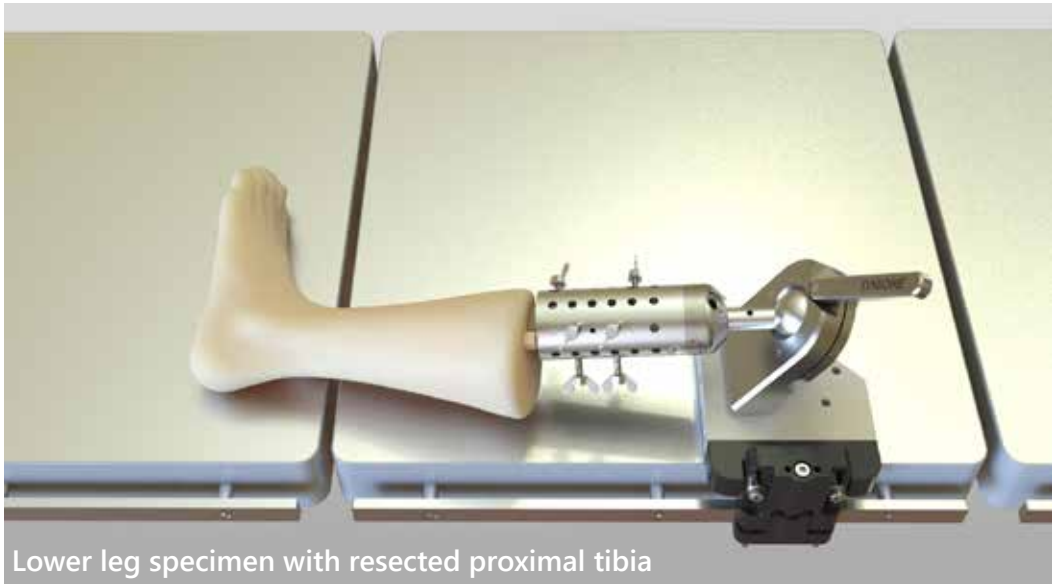
Introduction

One System for various applications/procedures – for left and right cadaver specimens - for use on an Operating Table



Full leg specimen with resected proximal femur


Lower leg specimen with resected proximal tibia

Intended use

- TKA standard (including robotics & navigated procedures)
- TKA revision
- Knee arthroscopy
- Tibia nailing and all other lower leg applications

Intended use

- Distal Tibia applications
- Foot & Ankle procedure training
- Adaptable for left or right and any leg size

Features & benefits

- Cost reduction due to shortened specimen (without hip joint)
- Stable and safe fixation of specimen
- ROM (range of motion) as in specimen with included hip joint
- Adjustment with single locking lever for easy positioning
- No need for additional leg fixation

Features & benefits

- Costs reduction due to use of shortened specimen
- Stable and safe fixation of specimen
- Flexible positioning of specimen (360° rotation along tibial axis)
- Adjustment with single locking lever for easy positioning

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Instructions for use
0037.C05 CAD Leg Holder System

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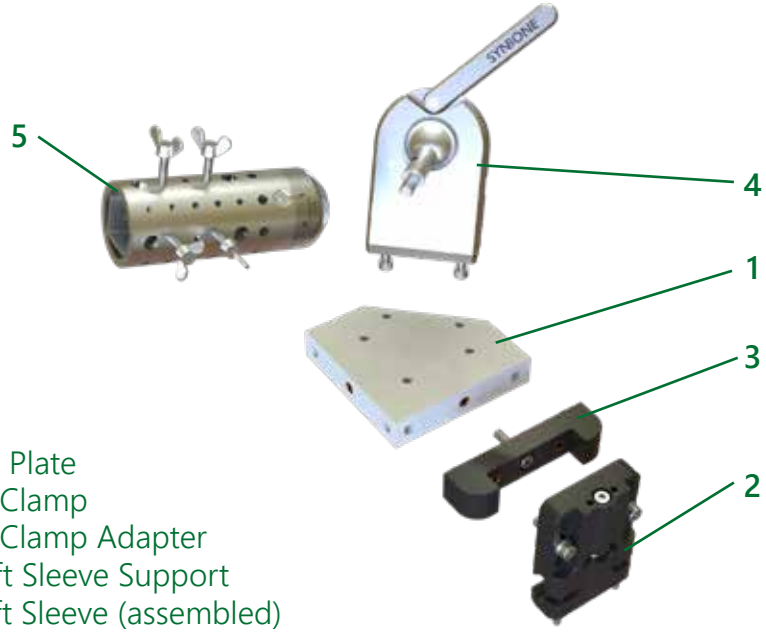
Overview main components

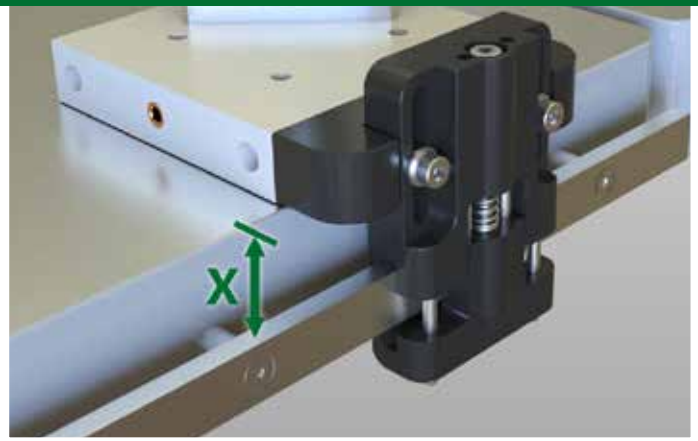


1. Base Plate
2. Rail Clamp
3. Rail Clamp Adapter
4. Shaft Sleeve Support
5. Shaft Sleeve (assembled)

Materials

- Stainless steel
- Anodized aluminium
- POM-C (DELRIN)
- Reinforced Nylon (heat & chemicals resistant)

Technical Data



- Shaft sleeve inner diameter (**D**) = Ø50mm
- Min. length of exposed specimen shaft = 55mm
- Max. length of exposed specimen shaft = 110mm
- min. distance (**X**) table surface to rail = 10mm
- max. distance (**X**) table surface to rail = 58mm

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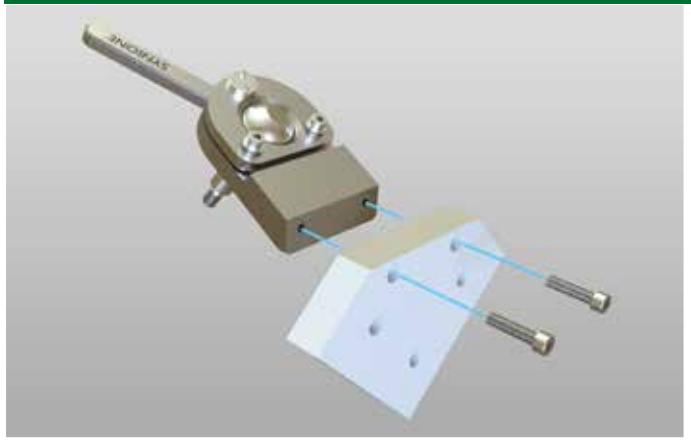
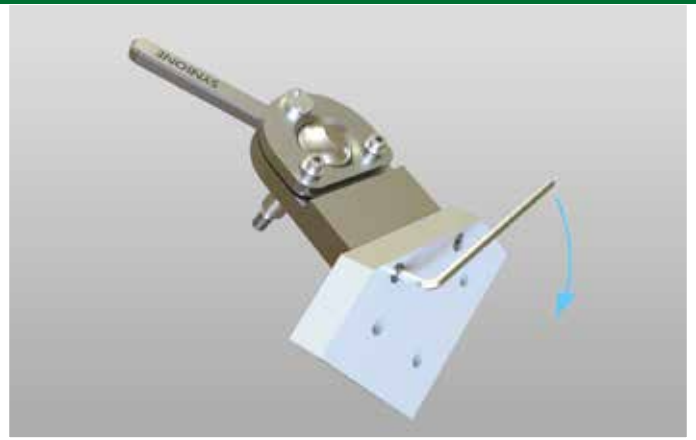
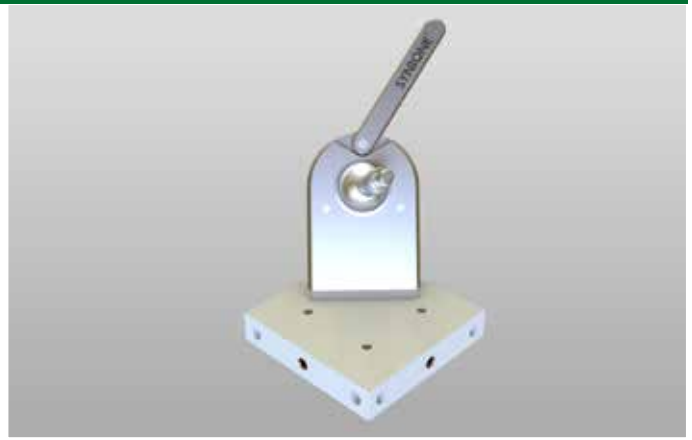
FULL LEG - Assembling Shaft Sleeve Support



Attach the Shaft Sleeve Support to the Base Plate and insert both M8 hex socket head screws into corresponding holes

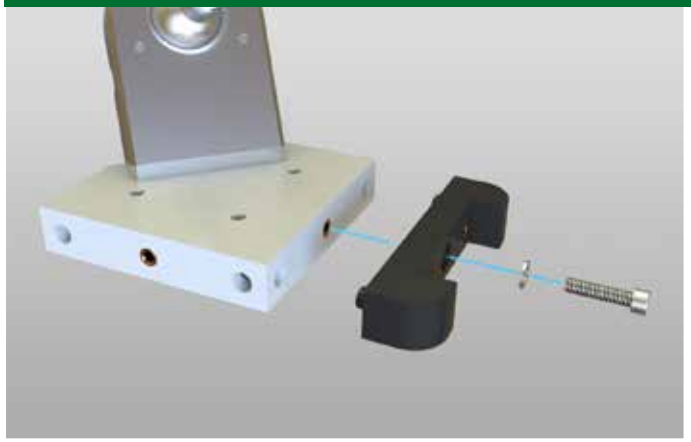


Firmly tighten the screws using the 6mm Allen Key

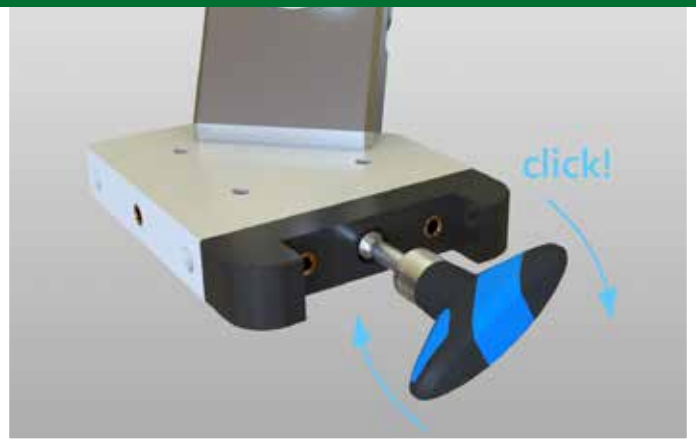


Correct alignment to use with left and right full leg specimen

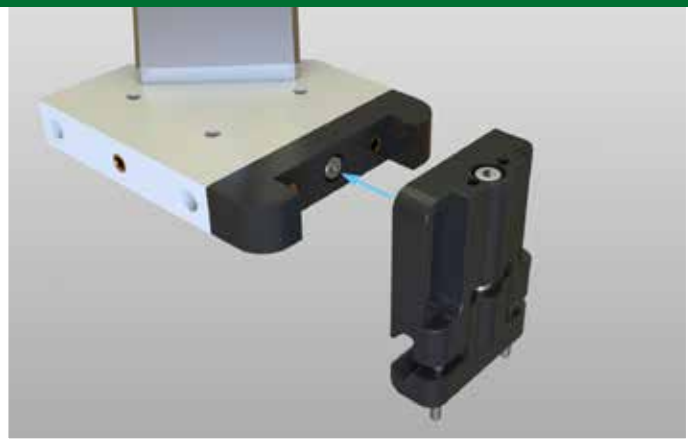
FULL LEG - Attaching Rail Clamp (left leg)



Attach the Clamp Adapter to the Base Plate and insert the M8 hex socket head screw with washer into the corresponding hole

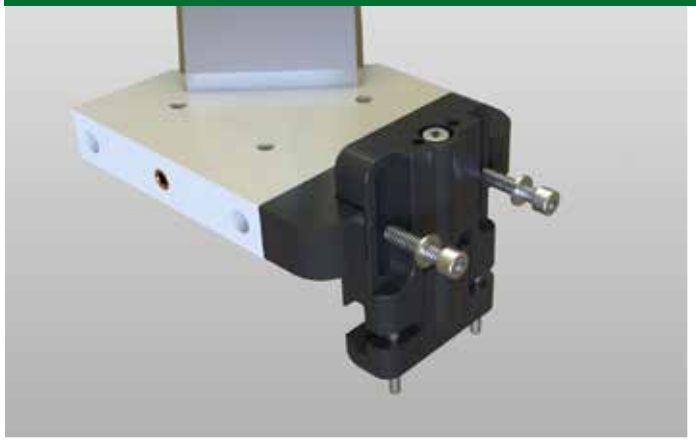


Tighten the screw. To prevent overtightening it is highly recommended to use the **4Nm** torque wrench

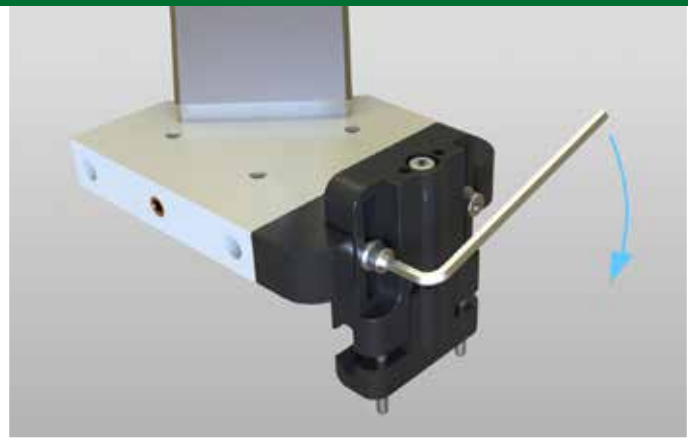


Attach the Rail Clamp to the Clamp Adapter

FULL LEG - Attaching Rail Clamp

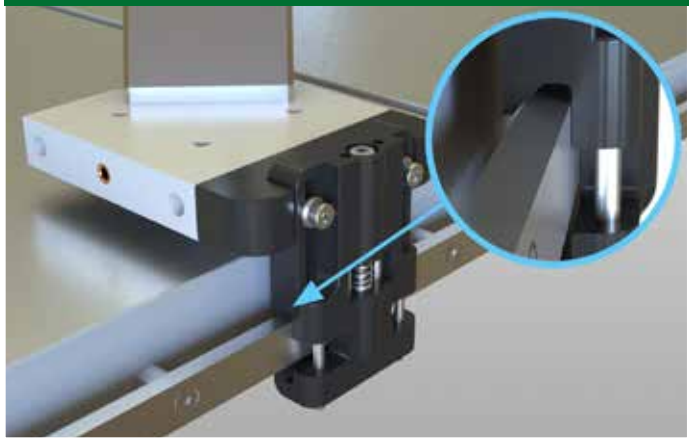


Insert both M8 hex socket head screws with washers through the Clamp's slot and into the corresponding holes of the Clamp Adapter



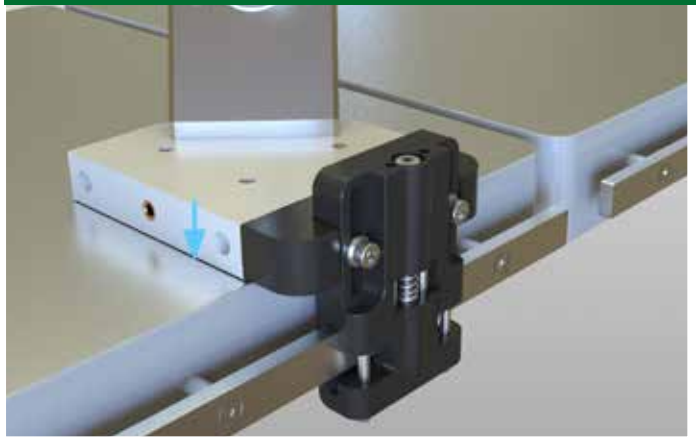
Tighten the screws using a 6mm Allen Key, ensuring they are **not fully tightened**. The Clamp **should remain adjustable and able to move up and down**

FULL LEG - Attaching Holder to the Rail

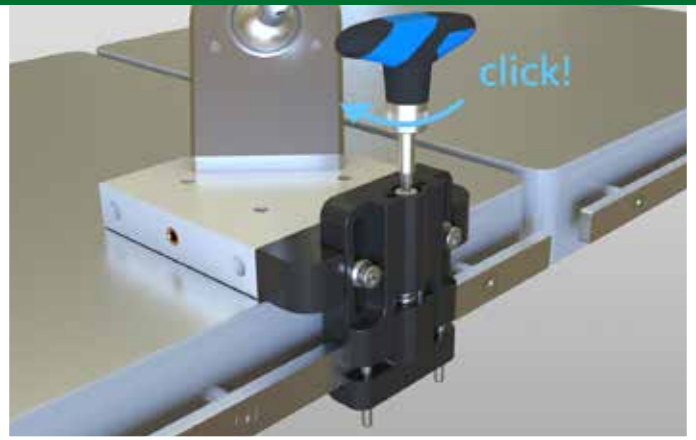


Place the upper jaw of the Clamp over the Rail...

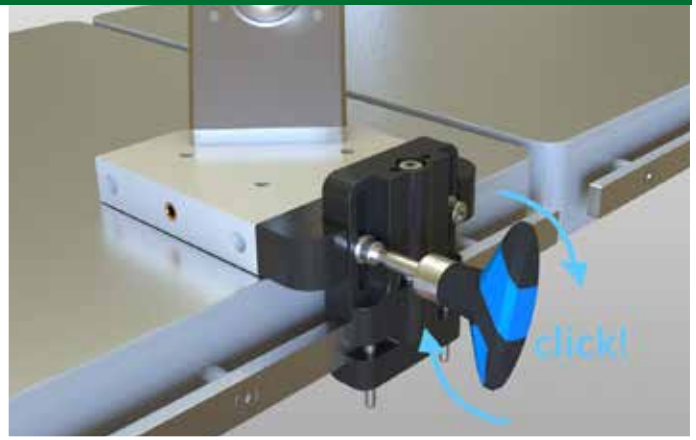
FULL LEG - Attaching Holder to the Rail



...and position the Base Plate on the surface of the OR Table



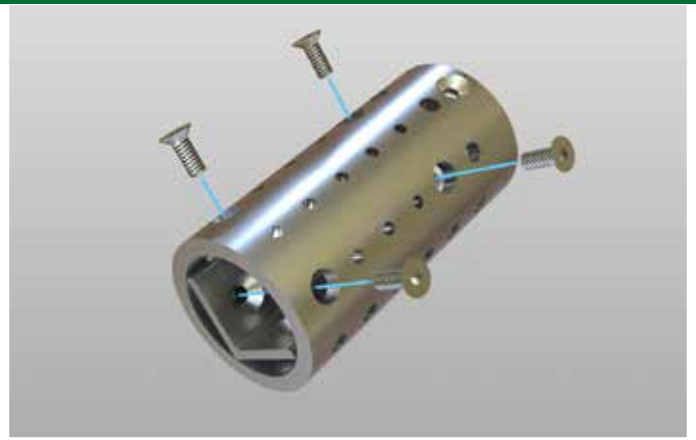
Close the Clamp by tightening the top M8 hex socket head screw. To avoid overtightening it is highly recommended to use a **4Nm** torque wrench



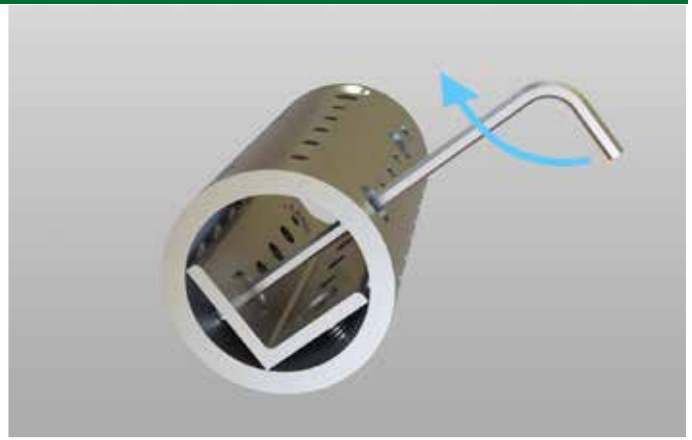
Tighten the two remaining screws using a **4Nm** torque wrench

FULL LEG - Assembling Shaft Sleeve (left leg)

Insert the L-Profile into the Shaft Sleeve

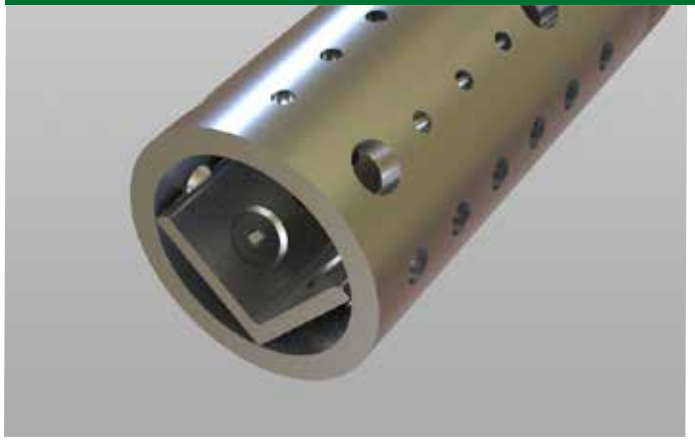


Insert four M6 countersunk head screws through the Shaft Sleeve into the corresponding countersunk holes of the L-Profile

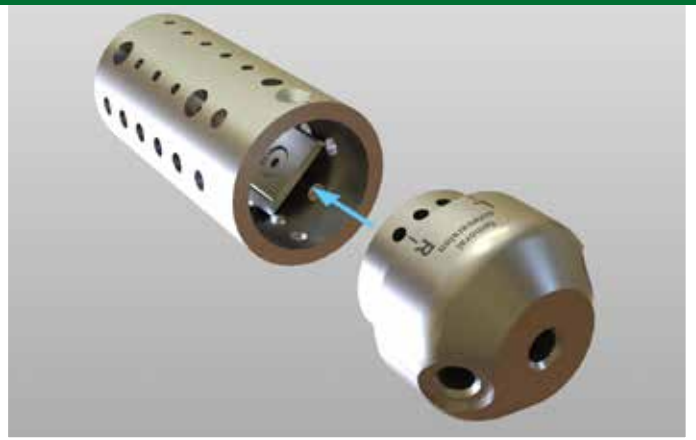


Firmly tighten the screws using a 4mm Allen Key

FULL LEG - Assembling Shaft Sleeve (left leg)



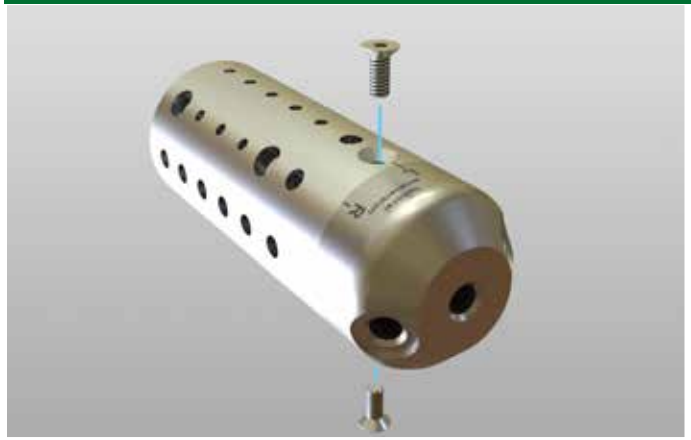
Ensure the L-Profile is in place and the screws are tightened



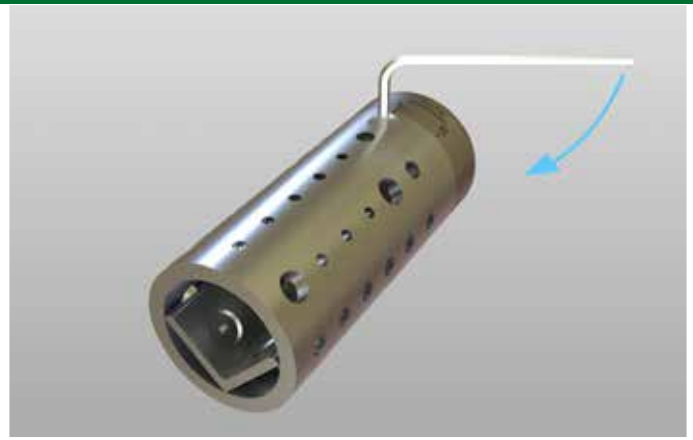
Insert the Shaft Sleeve Adapter into the Shaft Sleeve

To adjust the anteversion of the femoral neck for the left leg, slightly rotate the Adapter until the "**L**" marking aligns with the corresponding marking on the Sleeve.

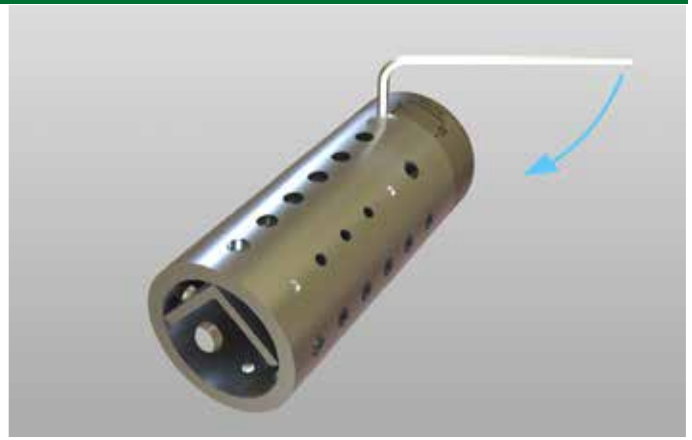
FULL LEG - Assembling Shaft Sleeve (left leg)



Insert two M6 countersunk head screws into the corresponding holes

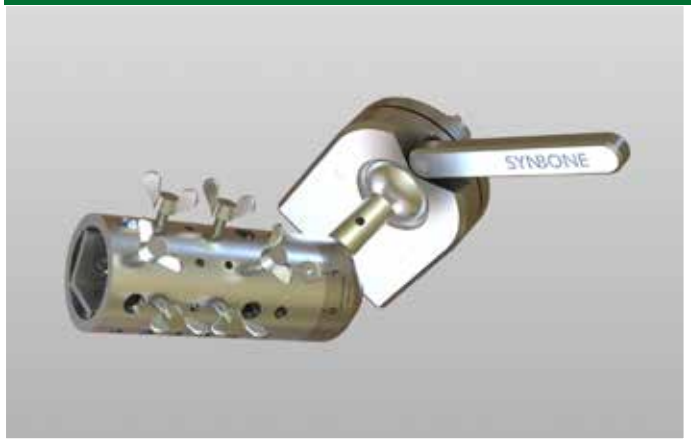


Firmly tighten the first screw using a 4mm Allen Key...



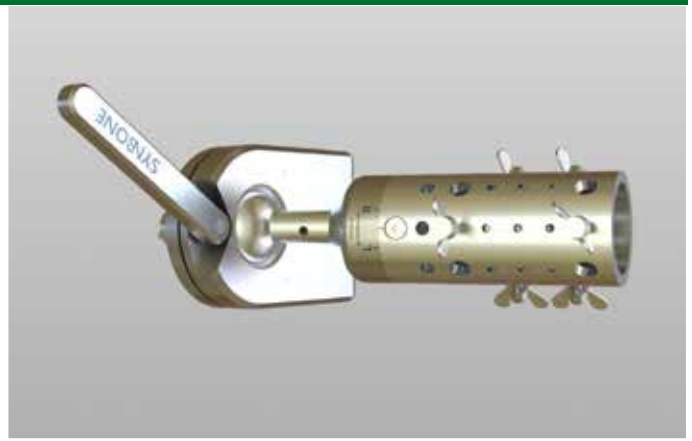
... then proceed to tighten the second screw on the opposite side

Shaft Sleeve mounting options for three different type of specimens



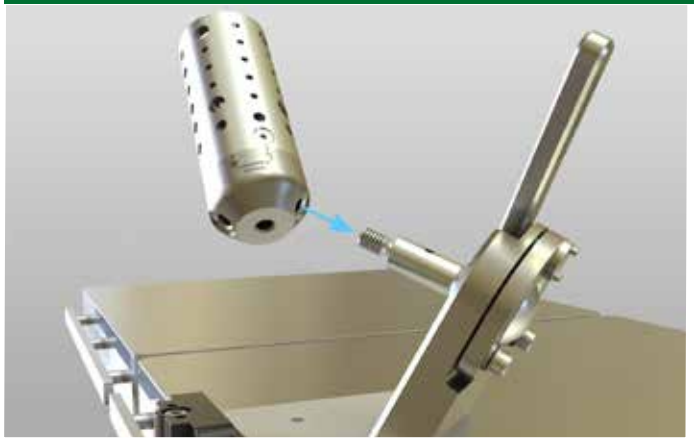
Full-Leg, **left** Specimen

Full Leg, **right** Specimen

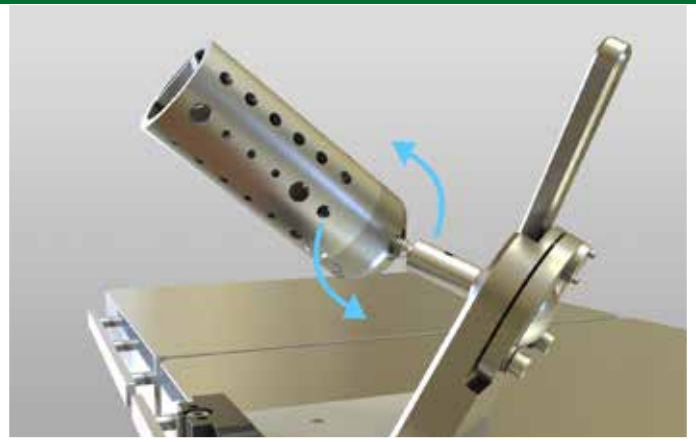


Lower Leg, **left & right** Specimen

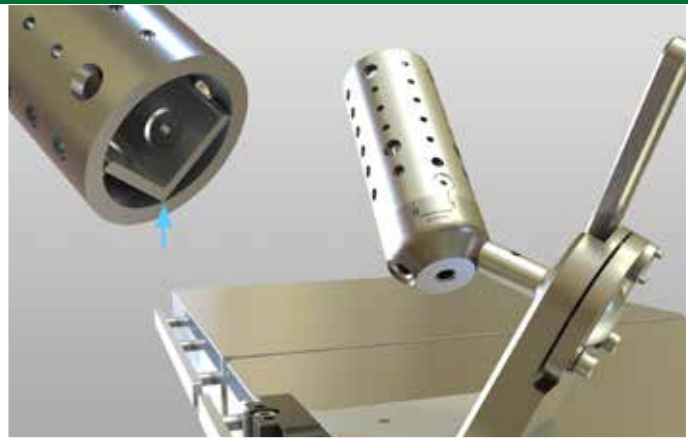
FULL LEG - Attaching Shaft Sleeve (left leg)



Use the appropriate threaded hole on the Sleeve Adapter to securely attach it to the Shaft Sleeve Support Pin

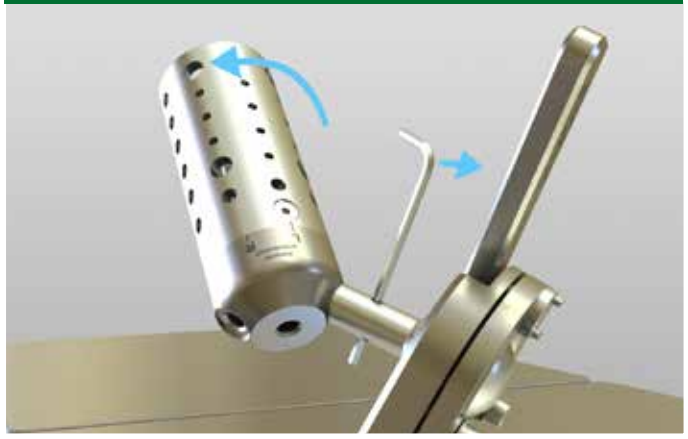


Gently rotate the Sleeve clockwise until the Pin is fully inserted



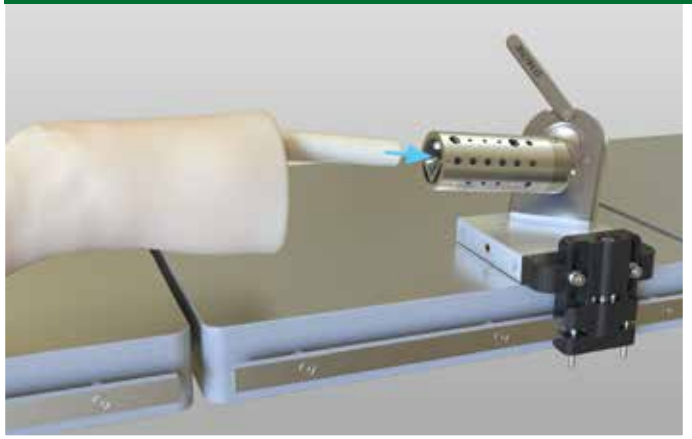
Ensure the L-profile is oriented towards the bottom of the Sleeve. If it is not, detach the Sleeve from the Pin and reattach it using the opposite hole of the Sleeve Adapter

FULL LEG - Attaching Shaft Sleeve

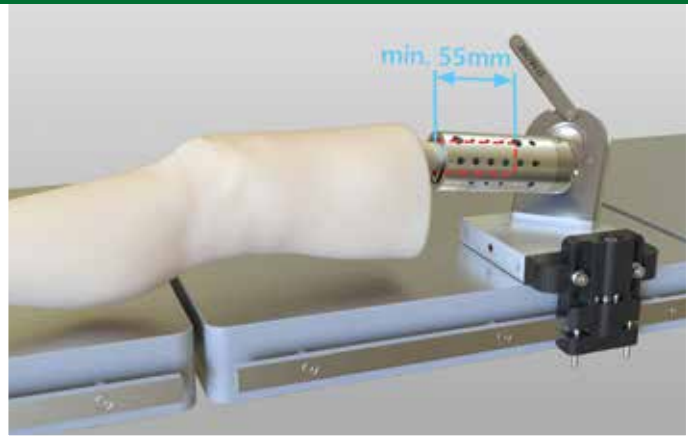


A 4mm Allen key can be used to tighten the Sleeve-Pin connection securely

FULL LEG - Attaching Specimen

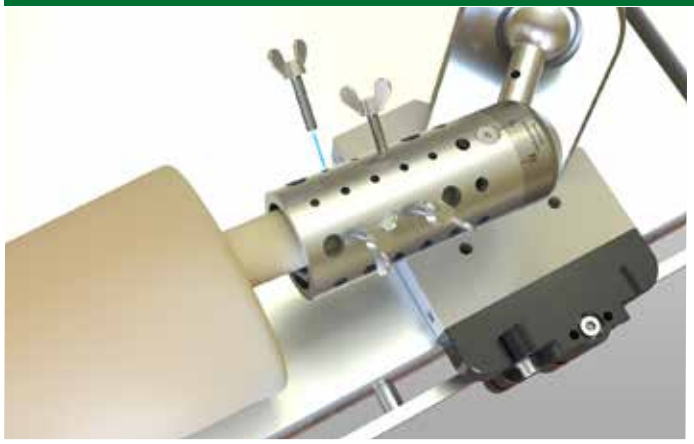


Insert the exposed femoral shaft of the specimen into the Shaft Sleeve

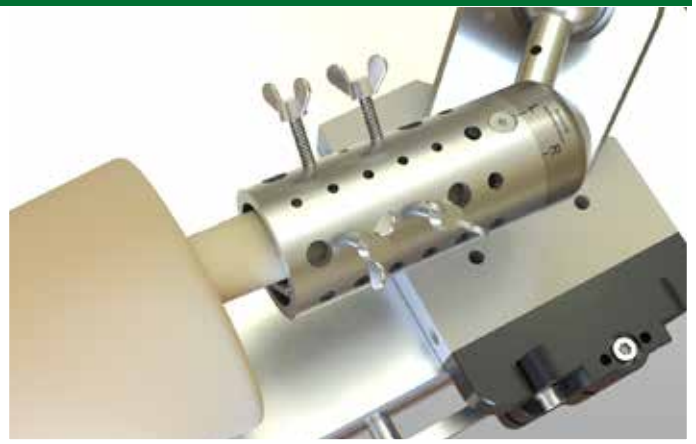


To ensure secure fixation, the femoral shaft must be inserted **at least 55mm** into the Shaft Sleeve

FULL LEG - Attaching Specimen



To securely fix the femoral shaft, insert the wing screws into the appropriate holes of the Shaft Sleeve

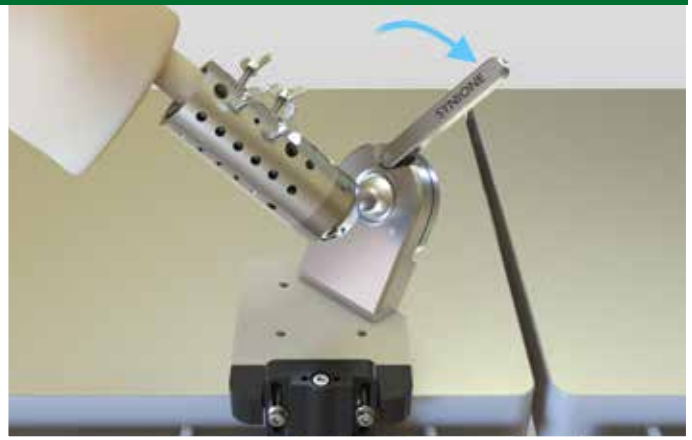


It is recommended to use at least 3 to 4 wing screws to ensure secure fixation of the femoral shaft when the Shaft Sleeve is used in combination with the inserted L-profile

FULL LEG - Using the CAD Leg Holder

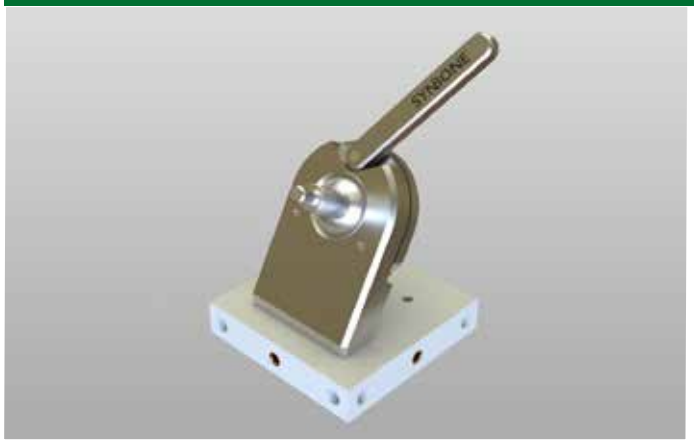
To enable the specimen's hip rotation, unlock the Lever of the Shaft Sleeve Support by swiveling it to the left

Position the leg into the desired orientation, such as flexion



To keep the specimen in the desired position, swivel the locking Lever to the right until the desired holding force is achieved

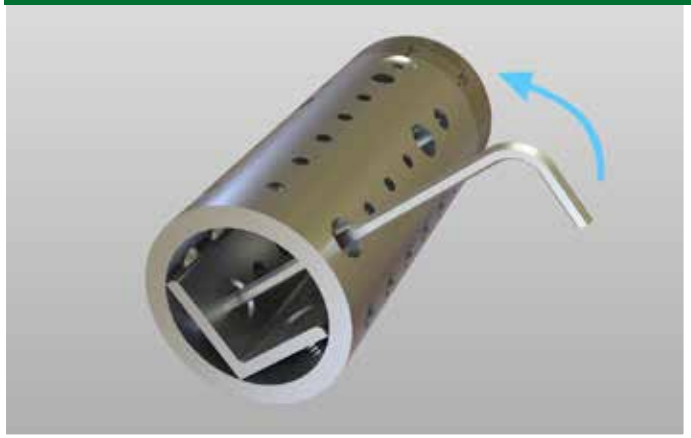
LOWER LEG - Settings (left side)



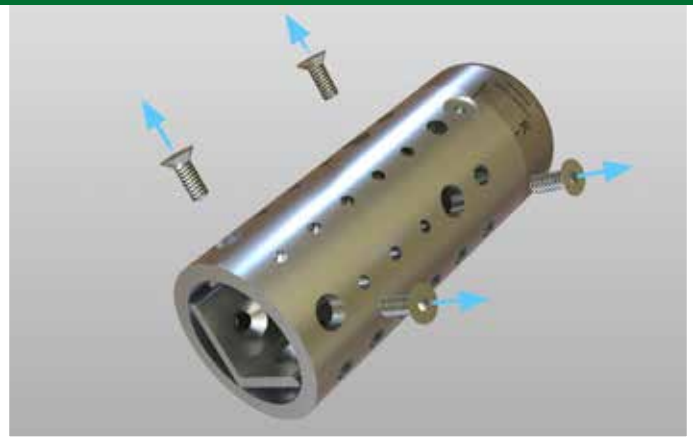
Ensure the Shaft Sleeve Support is mounted as shown

Attach the Holder to the OR Table by following steps outlined on **Page 5**

LOWER LEG - Preparing Shaft Sleeve



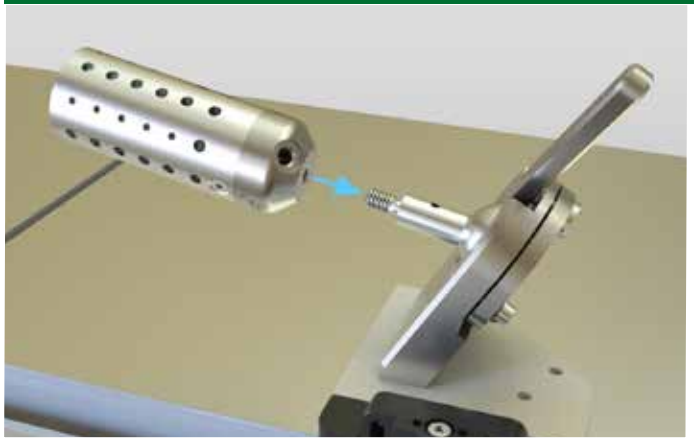
Loosen the four M6 countersunk screws using a 4mm Allen Key



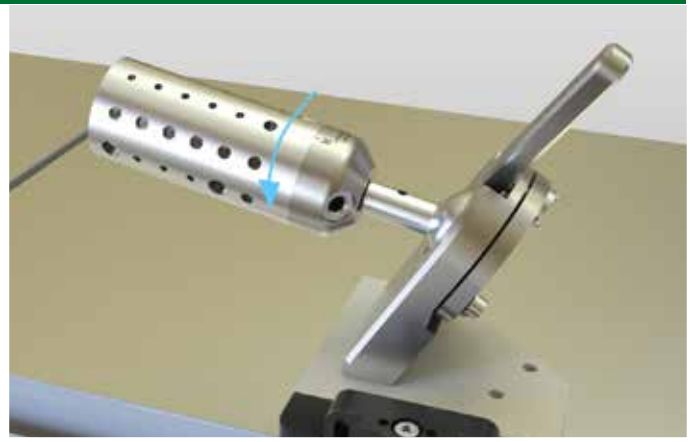
Remove the screws...

...and the L-Profile

LOWER LEG - Attaching Shaft Sleeve

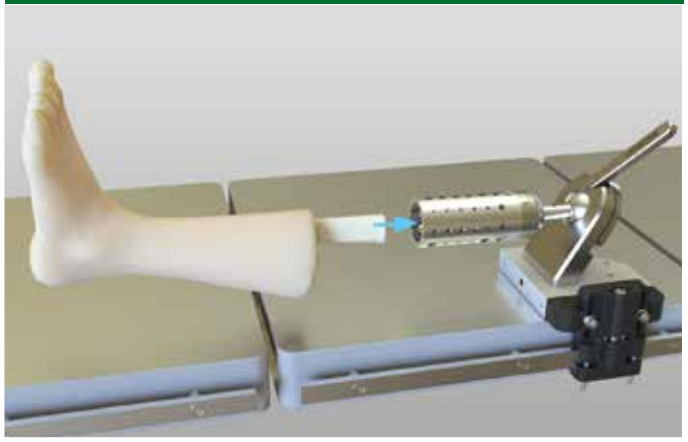


Use the appropriate threaded hole on the Sleeve Adapter to securely attach it to the Shaft Sleeve Support Pin



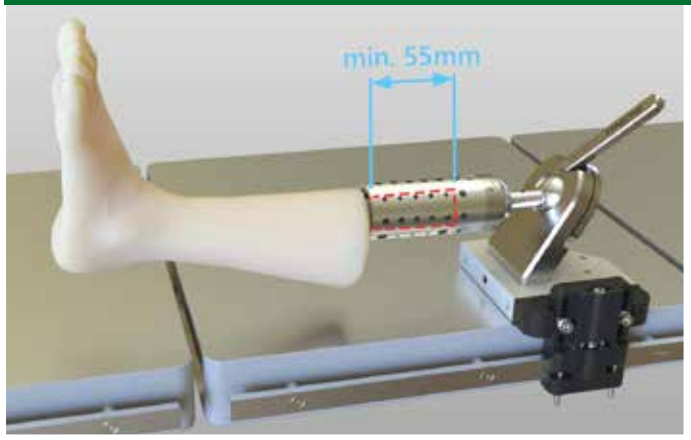
Gently rotate the Sleeve clockwise until the Pin is fully inserted

LOWER LEG - Attaching Specimen

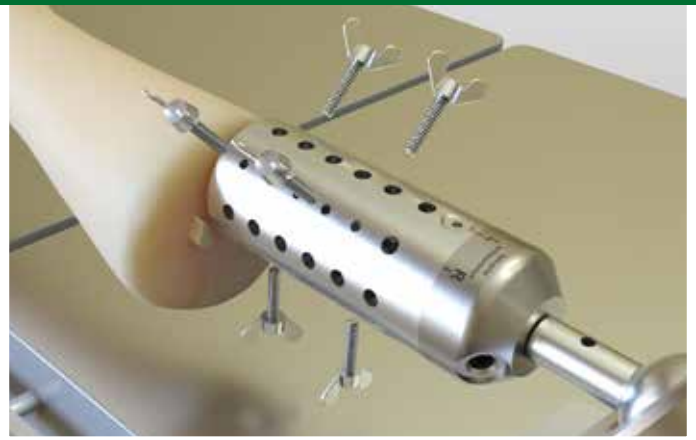


Insert the exposed tibial shaft of the specimen into the Shaft Sleeve

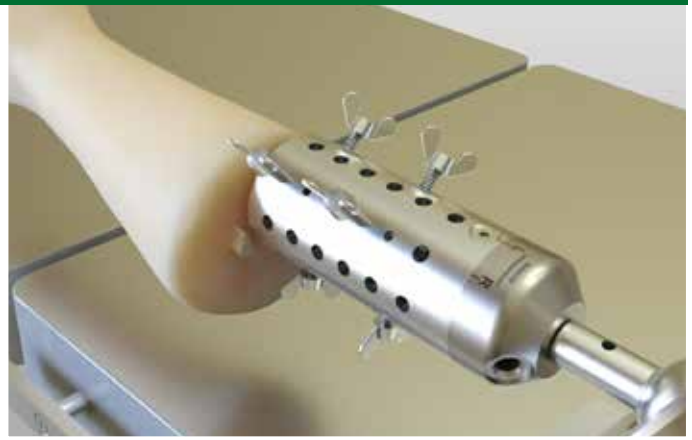
LOWER LEG - Attaching Specimen



To ensure secure fixation, the tibial shaft must be inserted **at least 55mm** into the Shaft Sleeve

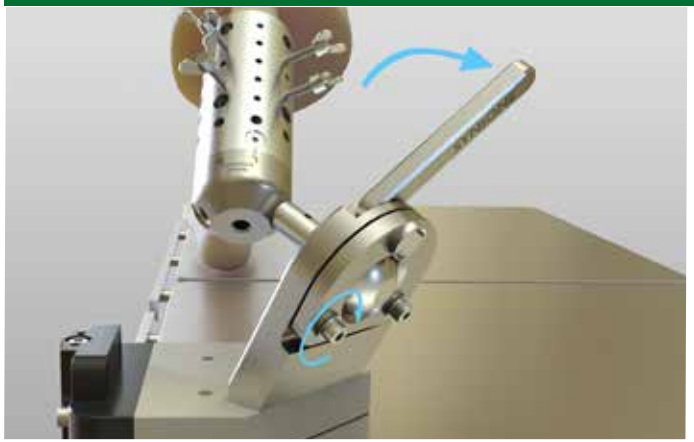


To securely fix the tibial shaft, insert the wing screws into the appropriate holes of the Shaft Sleeve



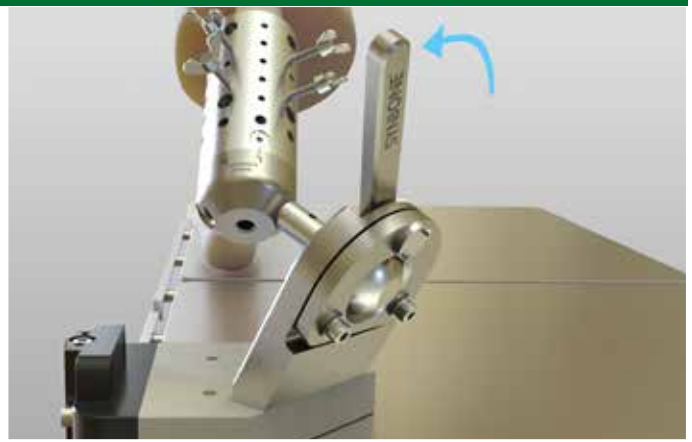
It is recommended to use at least six wing screws arranged in a circular pattern to ensure secure fixation of the tibial shaft

Adjusting clamping force



Unlock the Lever and gently turn the screw head clockwise by hand...

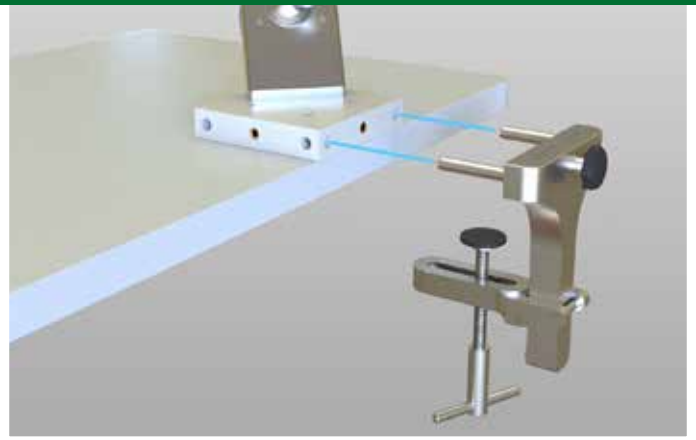
...or use a 6mm Allen key until slight resistance is noticeable



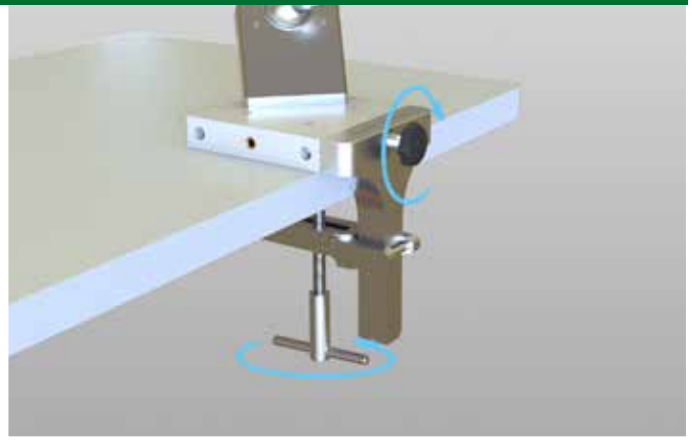
Lock the Lever again. If the Lever connection is too tight, reopen the Lever and slightly loosen the screw

Optional Accessory:

The **SYNBONE Universal Table Clamp** (Art. No. **0033**) allows the CAD Leg Holder to be securely attached to a standard table



Insert the two pins of the Table Clamp into desired holes on the Base Plate



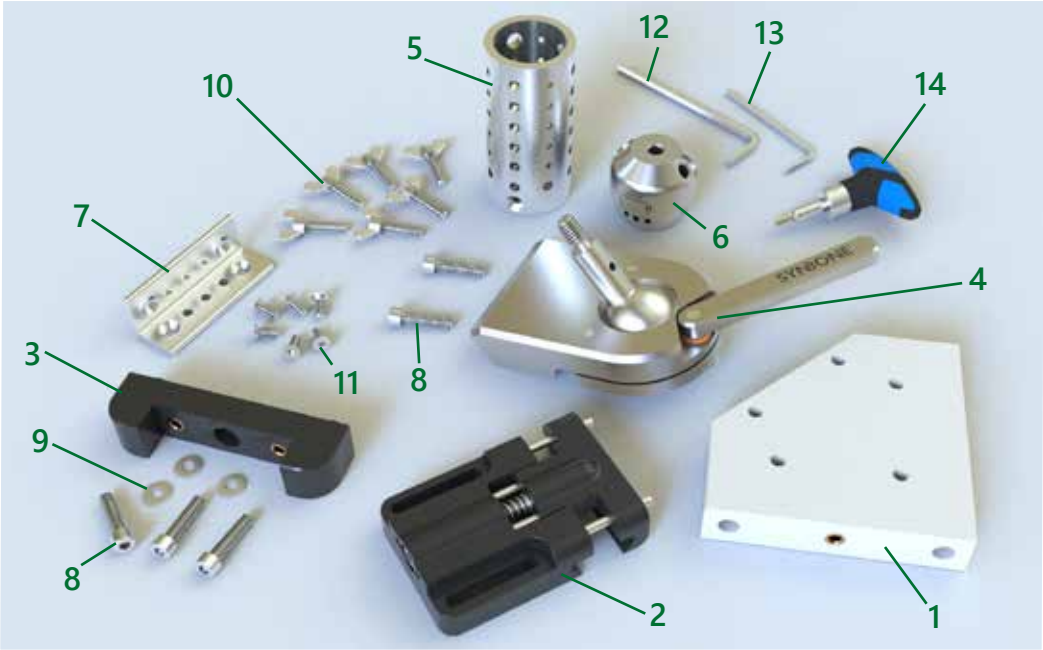
Tighten the Star Knob and secure the Clamp to the table by turning the Spindle clockwise

Cleaning Recommendations

To ensure thorough cleaning, particularly of the parts that come into direct contact with the specimen, the CAD Leg Holder must be disassembled into its individual components as illustrated.

It is recommended to follow a standard sterilization procedure (autoclave) up to 140°C or perform a hand wash after 24-hour disinfection with Gigazyme.

BOM / Components List



No.	Item:	Qty:
1.	Base Plate	1
2.	Rail Clamp	1
3.	Rail Clamp Adapter	1
4.	Shaft Sleeve Support	1
5.	Shaft Sleeve	1
6.	Shaft Sleeve Adapter	1
7.	L-Profile	1
8.	Hex socket head cap screw M8 x 35	5
9.	Washer (M8)	3
10.	Wing screw M6 x 30	6
11.	Countersunk head screw M6 x 16	6
12.	6mm Allen Key	1
13.	4mm Allen Key	1
14.	4Nm Torque Wrench (6mm Bit)	1

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