HERMLE Coupling - Instructions for use

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Couplings covered in this IFU

Trans-Tibial (TT) coupling **305-001 0° universal**
Trans-Femoral (TF) coupling **305-105 (Left) & 305-106 (Right)**

INTENDED USE: The Hermle couplings (Fig.1) are intended for use only as the connection to modular exoskeletal prosthetic components.

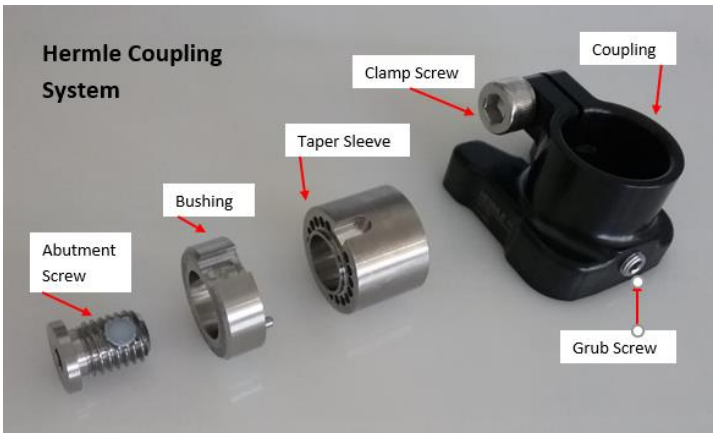

Figure 1: Hermle Coupling System

HERMLE Coupling TT	**305001**
HERMLE Coupling Left	**305105**
HERMLE Coupling Right	**305106**
Grub screw	**305150**
Clamp screw	**305151**
HERMLE Bushing 0 deg	**305124**
HERMLE Taper Sleeve	**305024**
HERMLE Abutment Screw	**305064**

1.1 GENERAL SAFETY INSTRUCTIONS
The coupling must initially be fitted by a qualified prosthetist prior to using it with an external prosthesis. Once familiar with the attachment and detachment process, always visually inspect the coupling prior to using it. Limit its utilization to its intended application and follow the instructions provided in this manual. Under no circumstances attempt to alter, repair, modify or dis-assemble the coupling. Your prosthetist can provide additional information during the fitting and additional information can be found in this instruction for use (IFU) document. The maximum allowed patient weight for the coupling is 150kg for normal activities. High-impact physical activities, such as sports, will reduce the maximum weight restriction to 110kg. The coupling is waterproof.

1.2 Product precautions
Avoid subjecting the coupling to excessive mechanical shocks or vibrations and extreme temperatures. Follow recommended appointments with your prosthetist to ensure proper continued use. Inspect the coupling prior to each use for any signs of excessive wear or damage. If the coupling appears damaged or will not connect to the adaptor, do not use it.

1.3 Indications for Use
Indicated only for Osseointegration (OI) patients for the purpose of connecting the abutment components with the prosthetic components.

1.4 CONTRAINDICATIONS FOR USE

Contraindicated for patients that exceed the weight limitation of 150kg. Contraindicated for high impact activities for patients over 110kgs inclusive of the weight of any additional equipment. Contraindicated for people who lack sufficient upper limb strength and/or dexterity to be able to ensure proper connection of the coupling.

1.5 Attachment of the coupling to the knee joint or foot- Prosthetist instruction only
Selection of the TF coupling required for attachment is made from 305-105 (Left) or 305-106 (Right) or for TT 305-001 0° universal to the attachment of the coupling to the distal standard prosthetic components occurs as per manufacturer's recommendations. The following tools are required for the fitting:

1. 8mm Hex Screwdriver for the Clamp screw tightened to 6 - 8Nm
2. 4mm hex Screwdriver for the Grub screw 305 -150 - tightened to 2 - 4Nm
3. Small torque wrench 2-10Nm.

1.5.1 Placement of the Grub screw
With the coupling and adaptor linked and under normal weight bearing, the grub screw is tightened 2Nm -4Nm. The grub screw is inserted from the inside of the coupling and screwed anti clockwise out. This is to align and to reduce play between the coupling and the abutment (Taper Sleeve and Bushing).

Do not over tighten the grub screw.

Do not try to remove the grub screw under any circumstances, it might seize and damage the coupling.

1.5.2 Placement of the Clamp screw
The Clamp screw is then tightened 6Nm-8Nm as the final closure of the coupling, after the engagement of the grub screw has been performed.

Do not over tighten the Clamp screw.

1.6 Attachment and locking the coupling to standard prosthetic components
The coupling must be locked to ensure that the system is safely fixed to the abutment. The patient must be familiar with the locking mechanism of the coupling and manually check after each attachment is locked before mobilising. Should the coupling not lock or have any play, then repeat the steps 1.5.1 and 1.5.2 after ensuring that the internal parts are clean and do not appear to be abnormal in shape or have any surface damage. Should the coupling continue not to be secure, do not use the prosthesis and contact your prosthetist.

1.7 User safety
Always exercise caution and ensure the coupling is locked prior to mobilising

1.8 Connecting and disconnecting the coupling (The patient should always be seated)
1.8.1 Connection
Place the abutment (Taper sleeve and Bushing) close to the coupling, ensure both connections freely mate and are not forced together. Check for any foreign matter or damaged parts that may interfere with the connection.

1.8.2 Locking the coupling
Follow steps 1.5.1 and 1.5.2 in that sequential order

1.8.3 Unlocking the coupling
Unlock the Clamp screw ; then Unlock of the Grub screw; in that sequential order.

1.9 USER INFORMATION
If any problems occur in achieving a solid connection between the Taper sleeve, the safety bushing and the coupling then:

1. Check the coupling and the adaptor are free of foreign material and are not damaged; and
2. If the visual inspection indicates any abnormality, do not use the coupling and contact your prosthetist.

1.10 AFTER USE
Connections
1. Clean the coupling daily with alcohol wipes. All parts should be dried with a cool hairdryer or clean towel.
2. After any contact with salt water, sand or dirt, all parts should be washed in fresh water and dried with a hair dryer or a clean towel.
3. Never dis-assemble the coupling under any circumstances.

1.11 Scheduled maintenance
You should visit a prosthetist to ensure professional inspection of all connections, the coupling, including any maintenance every 6 months.

1.12 WARRANTY
The 24 month warranty of the coupling commences from the day of the initial fitting. The warranty covers defects that are the result of flaws in the material, production or construction. The warranty shall cover repair, or replacement at no charge, but at the discretion of Hermle GmbH.

1.13 Compliance
The Hermle connector (referred to as coupling in this IFU) is manufactured to the ISO standard 13485:2016 and is a class 1 medical registered device, with CE marking.

Hermle Registration Number 8010689

FDA Regulation Number 8903420

1.14 Contact Information

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