

HUMERUS TRAINING KIT

Patient Information



NOTE:
Not available for sale in USA. Not FDA-Approved.

Integrum

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INTENDED USE

The Humerus Training Kit is intended to be used with the OPRA™ Implant System for individuals with transhumeral (above the elbow) amputations.

The Humerus Training Kit should be used on humeral level only and can be used for both the left and the right arm, respectively.

The system is designed to be used for training and controlled loading after the stage 2 (S2) surgery. The aim is to gradually increase the loading of the OPRA™ Implant over time. This is achieved by adding weights to the Rod included in the Humerus Training Kit and by performing the training described in these instructions. The training should be performed according to the training program or as specified by your responsible clinician. The Humerus Training Kit is primarily aimed at being used during early training, before you are fitted with your final prosthesis.

WARNINGS & PRECAUTIONS

- Not following instructions can lead to component failures.
- The Humerus Training Kit shall not be used for any other activity than the rehabilitation training.
- The Humerus Training Kit is intended to be used together with the OPRA™ Implant System only and for transhumeral amputations only.
- The Humerus Training Kit must be installed and serviced by a certified clinician.
- Do not use the Humerus Training kit in crowded places or playing with small children.
- The Humerus Training Kit does not protect the OPRA™ Implant System. High forces on the components could cause damage to the OPRA™ Implant system.
- The components should not be used in sand, sauna or in dirty environment.
- Be careful with hand cream and grease when in contact with the Humerus Training Kit.

- The Humerus Training Kit should not be used when sleeping or when doing activities where there is risk for high or uncontrolled loads.
- Do not adjust the alignment or attachment function of the Humerus Training Kit on your own. If you have problems or questions, please contact your responsible clinician.
- If you have pain when using the Humerus Training Kit, immediately stop using the Training Kit and contact your responsible clinician.
- Not cleaning the Attachment device provided in the Humerus Training Kit properly can cause:
 - Bacterial infection
 - Device to fall off
 - Device not functioning according to specifications
 - Cross contamination between patient and personnel
- The components may alert in security control, ask your responsible clinician to provide a certificate.
- If you have any questions, contact your responsible clinician.

PRODUCT DESCRIPTION

THE HUMERUS TRAINING KIT CONSISTS OF 10 PARTS:

- Attachment Device
- Alignment Device
- Rod
- Safety Stop
- Hex Key
- 5 weights: 1 pcs 50g, 1 pcs 100g, 1 pcs 200g, 2 pcs 400g



Figure 1 - Humerus Training Kit

HOW TO ATTACH THE HUMERUS TRAINING KIT

1. Place the puck on the abutment.
2. Attach the Humerus Training Kit placing the Attachment Device over the puck, close the lever arm.
3. Make sure the Attachment Device is properly attached to the puck.
4. If you can't obtain a stable connection, please contact your clinician.

HOW TO ATTACH AND CHANGE THE WEIGHTS ON THE HUMERUS TRAINING KIT

Put the weights on the Rod and lock with the locking screw using the Hex Key. Attach the Safety Stop to the end of the Rod.

WARNING! Never change the weights when wearing the prosthesis. Do not tighten the locking screw to hard. Start off with the weight placed on the training prosthesis closest to the stump. Move the weight downward, one step at the time during the week, towards the end of the rod. Secure with the Hex Key.

WARNING! Not attaching the Safety Stop increases the risk of dropping the weights and hurting other people by the sharp edges.

DO-ON/DO-OFF OF THE HUMERUS TRAINING KIT

The Humerus Training Kit is attached / detached by using the lever arm on the Attachment Device.

STANDARD TRAINING SCHEME USING THE HUMERUS TRAINING KIT

Start with 100 grams attached to the Rod. Put the weight close to the stump and move the weight downwards along the Rod during the week.

Pain level less than 5 on the VAS pain score is normal during training. If pain is 5 or higher, rest for at least one day. If the pain subsides, start again with closest lower weight. If the pain level remains above 4, contact your responsible clinician.

Start to wear the Humerus Training Kit 2 hours in the morning and 2 hours in the afternoon and then increase the wearing time during the week. Do not wear it in any risk situations or at night.

Increase the weight by 100g per week or as prescribed by your clinician.

0-10 VAS NUMERIC PAIN DISTRESS SCALE



The Visual analogue scale for pain
(0= no pain, 10= max. pain)

HOW TO ASSEMBLY THE CORRECT WEIGHT FOR THE HUMERUS TRAINING KIT

Training-weight	50g	100g	200g	400g
50	1	0	0	0
100	0	1	0	0
150	1	1	0	0
200	0	0	1	0
250	1	0	1	0
300	0	1	1	0
350	1	1	1	0
400	0	0	0	1
450	1	0	0	1
500	0	1	0	1
550	1	1	0	1
600	0	0	1	1
650	1	0	1	1
700	0	1	1	1
750	1	1	1	1
800	0	0	0	2

LOADING WITH THE HUMERUS TRAINING KIT ON A SCALE

Place the bathroom scale on top of a table. Press the end of the Rod against the scale.

- Start off with 5 kg the first week twice daily with 10 repetitions
- Press for 10 sec.
- Rest 5 sec. in between and repeat 9 times
- The second week increase the time for the loading exercises to 20 sec.
- Increase the weight by 1 kg/week
- Max. 10 kg

If you experience pain, above 5 on the VAS, stop the loading exercises for at least 1 day. If pain, go back to the closest lighter weight. The training should be performed according to the training program or as specified by your responsible clinician. The Humerus Training Kit is primarily aimed at being used during early training, before you are fitted with your final prosthesis.



CLEANING AND HYGIENE INSTRUCTIONS

The Humerus Training Kit should be cleaned daily. Use a tissue or cotton pins with soap, water or alcohol.

MAINTENANCE

- The Humerus Training Kit should be visually inspected regularly for signs of damage, wear and fatigue. Please contact your responsible prosthetist if you find any signs of damage or wear.
- For any other questions, please contact your responsible clinician.

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