

# Re-use of Orthotic Joints

Orthotic joints from Ortho-Systems, like those of other joint manufacturers, are necessary for the manufacture of an orthosis and maintaining the mobility of the patient. This view is shared by the patient, paying agency, and the technical orthopaedic profession. Orthotic joints are not intended to be re-used. They are, therefore, suitable for use in one orthosis only. This point is stated in our Instructions for Use (included with the product) under point 1.4 regarding re-use.

#### Mobility

Suppose for a moment, that the orthotic joints from a soon-to-be ill-fitting orthosis were taken out and built into a new orthosis. This would necessitate the patient be without an orthosis during the entire fabrication period, restricting his/her standing and walking throughout that time. Furthermore, it would be impossible for the patient to sustain his independence and performance at school or work. "The orthosis itself neither produces nor replaces a function, but makes it possible for the patient to do so." (Adriano Ferrari [-3-])

#### **Orthosis Fabrication**

The role of an orthosis used in the case of paralysis, is to replace affected musculature. This means supporting the skeleton and mechanically permitting or guiding still-present movements. In contrast to prosthetic components, orthotic joints are modified to the shape of the leg through bending, and then affixed to the orthosis either by way of lamination or with screws and rivets. This attachment allows the body-supporting orthosis to absorb and overcome all occurring forces. In order to break this solid connection, the joint and its uprights must be re-processed.

#### **Fitting**

In contrast to double-sided joints, the unilateral joint system permits vertical and horizontal adjustments for growth. Take, for example, the technique of overlapping the unilateral joint uprights in a laminated orthosis. This method allows, through sliding of the upright bars, a vertical lengthening of the orthosis. Using this technique, AFOs and KAFOs can be adjusted in the calf section, and HKAFOs and RGOs in both the calf and thigh sections. Furthermore, many of our customers fabricate their orthoses using metal reinforced cuffs, permitting volume changes (i.e., widening of the cuffs) without affecting static alignment of the orthosis.

As opposed to the health insurers, the responsibility for our product lies with us, the manufacturer. We construct our joints according to function, and use a weight classification for the corresponding strength requirements. The reality of building orthoses in the orthotic clinic does not permit a thorough, in-depth check of the loads present for every single aid. As the range of loads for patients with varying lesion heights, body heights, and weights is considerable, the orthotic joints sooner or later reach the limits of their capacity. We continually improve our products according to CIP and offer a comprehensive guarantee on all incidents concerning our joints.

#### Decision

An important matter for a patient with a new orthosis is the fitting and break-in phase. New changes are not only of static origins; the leg itself must also adapt to new pressure changes within the orthotic cuffs. It is not uncommon for an orthosis wearer to require more than a few weeks to get used to his new orthosis. The fitting of the orthosis itself is generally concluded quickly and smoothly, without any major restrictions. It is important, however, that the patient and his family consider what is involved before proceeding with the time and energy consuming process of having a new orthosis made.

#### Warranty

If orthotic joints were to be re-used in a new orthosis and retain their guarantee under the Medical Products Law (Medizin Produkte Gesetz in Germany), it would be necessary to return the joints to the manufacturer for inspection. Only then, after undergoing a thorough examination for wear and tear, hair-line cracks, and material fatigue could the producer possibly issue a new warranty. The advantage of this time consuming and costly inspection process (including X-rays) is, in our point of view, questionable.

#### **Demands**

The use of one's legs to walk, run and stand is a *basic need*, essential at all times and places. Unilateral orthotic joints use today's best available technology to afford, in as much as possible, this basic need. The improvements offered by these unique joints, as compared with conventional joints, are not only limited to special activities or merely to provide convenience or comfort, but to offer orthotic improvements affecting *everyday life*.

### Basic Constitutional Law of the Federal Republic of Germany

- I. Basic Rights, Article 3 [Equality before the law; Equal rights for men and women; Discrimination prohibited]
- (1) All persons shall be equal before the law. (2) Men and women shall have equal rights. The state shall promote the actual implementation of equal rights for women and men and take steps to eliminate disadvantages that now exist. (3) No person shall be favoured or disfavoured because of sex, parentage, race, language, homeland and origin, faith, or religious or political opinions. **No person shall be disfavored because of disability.** (15 November 1994)



# Re-Use of Foot-Walker and Stehbrett Standing Platform

The podium product group uses a connecting plate to attach a custom-made body shell. In the case of the podium, the only modifications performed are by way of the integrated adjustment mechanism. For this reason, we strongly recommend re-use of the podium product group. As its guarantee is limited solely for use by one patient, before re-using the podium for another it must be forwarded to us for inspection and overhaul. Through continual improvements, we are able to increase the quality and durability of our products. In order to keep re-used products up to date, components may be replaced.

## **Podium Replacement**

The custom-made body shell can be detached from the Foot-Walker and Standing Platform via the connecting plate. The Foot-Walker and Standing Platform are interchangeable with one another, as well as with the next size up, meaning only the podium can be exchanged at anytime (e.g., to accommodate growth) without changes to the body shell.

June 2007