FIOR & GENTZ

Instructions for Use for Patients
Articulated Side Bars for Knee Orthoses

EN

Content **Page**

1. Safety Instructions 3
   - 1.1 Classification of the Safety Instructions 3
   - 1.2 All Instructions for Your Safety 3
2. Use 5
   - 2.1 Intended Use 5
   - 2.2 Indication 5
   - 2.3 Contraindication 5
   - 2.4 Qualification 5
   - 2.5 Application 5
3. Maintenance 5
   - 3.1 Dirt Removal 5
4. Storage 6
5. Disposal 6
6. Signs and Symbols 6
7. CE Conformity 7
8. Legal Information 7
9. Handing Over the Orthosis 8

Instructions for Use for Patients
Articulated Side Bars for Knee Orthoses

Dear Patient,

You have received an individually produced orthosis with high quality FIOR & GENTZ **articulated side bars for knee orthoses** from a qualified specialist in orthopaedic technology.

1. Safety Instructions

1.1 Classification of the Safety Instructions

⚠ **DANGER**	Important information about a possible dangerous situation which, if not avoided, leads to death or irreversible injuries.
⚠ **WARNING**	Important information about a possible dangerous situation which, if not avoided, leads to reversible injuries that need medical treatment.
⚠ **CAUTION**	Important information about a possible dangerous situation which, if not avoided, leads to light injuries that do not need medical treatment.
NOTICE	Important information about a possible situation which, if not avoided, leads to damage of the product.

All serious incidents according to Regulation (EU) 2017/745 which are related to the product have to be reported to the manufacturer and to the competent authority of the Member State in which the qualified specialist in orthopaedic technology and/or the patient is established.

1.2 All Instructions for Your Safety

⚠ DANGER

Potential Traffic Accident Due to Limited Driving Ability
Gather information about all issues concerning safety and security and potential dangers before driving a motor vehicle with orthosis.

⚠ WARNING

Risk of Falling Due to Improper Handling
Have a qualified specialist in orthopaedic technology inform you about the correct use of the articulated side bar and potential dangers. Do not use the orthosis if you notice any damage on the articulated side bar. Avoid contact with moisture and water.

⚠ WARNING

Risk of Falling Due to Improper Handling
Articulated side bar components and orthosis components may only be demounted and maintained by a qualified specialist in orthopaedic technology. Any handling of the articulated side bar and the orthosis from your side that goes beyond the activities described in these instructions for use is not permitted.

⚠ WARNING

Risk of Falling Due to Permanent Higher Load
Do not engage in sport activities with the orthosis that expose it to excessive load. If your patient data has changed (e.g. due to weight gain, growth or increased activity), consult a qualified specialist in orthopaedic technology and have them check the suitability of your orthosis with regard to the changed load. You will find the next maintenance appointment in your orthosis service passport.

⚠ WARNING

Risk of Falling Due to Changes in the Orthosis
If you notice any changes in the orthosis (e.g. loosely attached joint components, loosened screws, play in the articulated side bar or change in performance), immediately contact a qualified specialist in orthopaedic technology. Do not secure screws for the articulated side bar on your own. All settings must be checked by a qualified specialist in orthopaedic technology before handing over the orthosis and during the maintenance appointments. You will find the next maintenance appointment in your orthosis service passport.

⚠ WARNING

Jeopardising the Therapy Goal by Not Providing the Necessary Free Movement
Check if the articulated side bar moves freely in order to avoid restrictions of the joint function.

NOTICE

Limitation of the Joint Function Due to Improper Dirt Removal
Remove dirt from the orthosis and the articulated side bar as described in these instructions for use. Do not grease the articulated side bar on your own. If necessary, consult a qualified specialist in orthopaedic technology.

NOTICE

Limitation of the Joint Function Due to Lack of Maintenance
Have a qualified specialist in orthopaedic technology inform you about the maintenance intervals to be observed in order to avoid joint dysfunctions. You will find the next maintenance appointment in your orthosis service passport.

2. Use

2.1 Intended Use

The FIOR & GENTZ **articulated side bars for knee orthoses** must be used exclusively for the orthotic treatment of the knee joint. The articulated side bar is only allowed to be used for producing a KO. Every articulated side bar influences the orthosis' function and thus also the function of the leg.

2.2 Indication

The indications for the treatment with an orthosis for the lower extremity are insecurities when standing and walking that lead to a pathological gait. This can be caused, for example, by structurally conditioned deformities/malfunctions or as a result of physical trauma and/or surgery.

The physical conditions of the patient, such as muscle strength or activity level, are crucial for the orthotic treatment. A safe handling of the orthosis must be ensured. A qualified specialist in orthopaedic technology selects the appropriate articulated side bars for the orthosis.

2.3 Contraindication

The articulated side bar is not suitable for treatments that were not described in paragraph 2.2, such as a treatment of the upper extremity or a treatment with a prosthesis or ortho-prosthesis, for example after amputations of leg segments.

2.4 Qualification

The articulated side bars must only be handled by a qualified specialist in orthopaedic technology.

2.5 Application

All FIOR & GENTZ articulated side bars were developed for everyday life activities such as standing and walking. Extreme impact stress, which occurs for example during long jump, climbing, parachuting and football, is excluded.

3. Maintenance

Ask a qualified specialist in orthopaedic technology to maintain the joint of your orthosis **regularly**. When the orthosis is handed over to you, you receive an orthosis service passport. Bring this orthosis service passport to each follow-up and let a qualified specialist in orthopaedic technology enter the next maintenance appointment. For your own safety, respect the maintenance appointments. Never carry out maintenance work or other adjustments and repairs yourself. In the case of children and people with cognitive impairments, we would like to point out to you as parents or care team that you must regularly check the orthosis and the joint for signs of wear. If you notice any changes, immediately contact a qualified specialist in orthopaedic technology.

3.1 Dirt Removal

Remove dirt from the joints on a regular basis. Use a dry cloth and clean the joint only superficially. Then, remove visible dust and lint from the mechanics by using tweezers. Check the orthosis in straight and flexed position.

4. Storage

We recommend not storing the articulated side bar in a damp environment.

5. Disposal

If you no longer need the orthosis, please return it to a qualified specialist in orthopaedic technology. The product must not be disposed of with the residual waste (fig. 1).

fig. 1

6. Signs and Symbols

CE labelling according to Regulation (EU) 2017/745 for medical devices

MD — medical device

REF — article number

manufacturer

LOT — batch code

SN — serial number

follow the instructions for use

single patient – multiple uses

UDI — Unique Device Identifier – product identification number

7. CE Conformity

We declare that our medical devices as well as our accessories for medical devices are in conformity with the requirements of Regulation (EU) 2017/745. Therefore, the FIOR & GENTZ products bear the CE marking.

8. Legal Information

With the purchase of this product, our General Terms and Conditions of Business Transactions, Sales, Delivery and Payment will apply. The warranty expires, for example, if the product is mounted several times. Please note that the product is not supposed to be combined with other components or materials than with those recommended in the configuration result of the FIOR & GENTZ Orthosis Configurator. The combination of the product with products from other manufacturers is not permitted.

The information in these instructions for use is valid at the date of printing. The contained product information serves as guidelines. Subject to technical modifications.

All copy rights, particularly the distribution, copy and translation of these instructions for use or any part of them, must be authorised by FIOR & GENTZ Gesellschaft für Entwicklung und Vertrieb von orthopädietechnischen Systemen mbH. Reprints, copies and any other electronic reproductions, even partial, are not permitted to be distributed without being authorised in writing by FIOR & GENTZ Gesellschaft für Entwicklung und Vertrieb von orthopädietechnischen Systemen mbH.

9. Handing Over the Orthosis

When handing over the orthosis to the patient, parents or care team by the qualified specialist in orthopaedic technology, they also received the instructions for use for patients as well as the orthosis service passport. The functions and handling of the orthosis were explained in detail by means of these instructions for use. Enter the next maintenance appointment in the orthosis service passport.

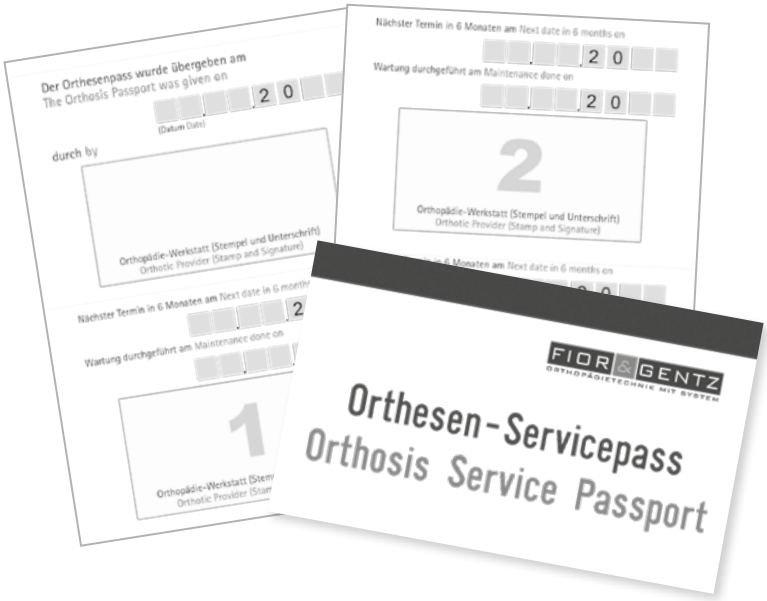
Place, Date

Signature Qualified Specialist in Orthopaedic Technology

FIOR & GENTZ

ORTHOSIS SERVICE PASSPORT

Have you not yet received an orthosis service passport?
Ask the qualified specialist in orthopaedic technology!



PB1000-KS-1D-2025-12

CE

FIOR & GENTZ
Gesellschaft für Entwicklung und Vertrieb von orthopädietechnischen Systemen mbH
Dorette-von-Stern-Straße 5 21337 Lüneburg (Germany)
+49 4131 24445-0 +49 921 95659554
info@fior-gentz.de www.fior-gentz.com