### Content

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Declaration of Conformity</td>
<td>17</td>
</tr>
<tr>
<td>2. Warranty</td>
<td>17</td>
</tr>
<tr>
<td>3. Safety Information</td>
<td>17</td>
</tr>
<tr>
<td>4. Safety Instructions</td>
<td>17</td>
</tr>
<tr>
<td>4.1 Classification of the Safety Instructions</td>
<td>17</td>
</tr>
<tr>
<td>4.2 Structure of the Safety Instructions</td>
<td>18</td>
</tr>
<tr>
<td>4.3 All Instructions for a Safe Handling of the NEURO ACTIVE System Knee Joint</td>
<td>18</td>
</tr>
<tr>
<td>5. Application</td>
<td>21</td>
</tr>
<tr>
<td>6. Joint Functions</td>
<td>21</td>
</tr>
<tr>
<td>6.1 Basic Function</td>
<td>21</td>
</tr>
<tr>
<td>6.2 Alternative Function</td>
<td>21</td>
</tr>
<tr>
<td>7. Scope of Delivery</td>
<td>22</td>
</tr>
<tr>
<td>8. Load Capacity</td>
<td>22</td>
</tr>
<tr>
<td>9. Tools for Assembling the System Joint</td>
<td>23</td>
</tr>
<tr>
<td>10. Assembly/Lamination Dummies</td>
<td>23</td>
</tr>
<tr>
<td>11. Assembly Instructions</td>
<td>23</td>
</tr>
<tr>
<td>11.1 Mounting the Stops</td>
<td>23</td>
</tr>
<tr>
<td>11.2 Mounting the Cover Plate</td>
<td>23</td>
</tr>
<tr>
<td>11.3 Checking the System Joint's Free Movement</td>
<td>25</td>
</tr>
<tr>
<td>11.4 Basic Alignment</td>
<td>25</td>
</tr>
<tr>
<td>11.5 Securing the Screws</td>
<td>25</td>
</tr>
<tr>
<td>12. Advice on Production Techniques</td>
<td>26</td>
</tr>
<tr>
<td>12.1 Production Techniques Online</td>
<td>26</td>
</tr>
<tr>
<td>12.2 Parallel Alignment of System Joints</td>
<td>26</td>
</tr>
<tr>
<td>12.3 Mounting to the System Side Bar/System Anchor</td>
<td>26</td>
</tr>
<tr>
<td>13. Maintenance</td>
<td>26</td>
</tr>
<tr>
<td>13.1 Repairing the Bronze Bushing Bore</td>
<td>27</td>
</tr>
<tr>
<td>13.2 Replacing the Bronze Bushings</td>
<td>27</td>
</tr>
<tr>
<td>13.3 Cleaning</td>
<td>27</td>
</tr>
<tr>
<td>14. Spare Parts</td>
<td>28</td>
</tr>
<tr>
<td>15. Accessory Parts</td>
<td>29</td>
</tr>
<tr>
<td>16. Information for the Patient's Documentation</td>
<td>31</td>
</tr>
</tbody>
</table>
1. Declaration of Conformity

We declare that our medical devices as well as our accessories for medical devices are in conformity with the requirements of the Medical Devices Directive 93/42/EEC. Therefore, the FIOR & GENTZ products bear the CE marking.

2. Warranty

The warranty only applies if the product is used under the described conditions and for the intended purpose. The warranty expires if the product is used differently, if it is combined with other components or materials or if it is mounted according to a different production technique than the one recommended by the FIOR & GENTZ Orthosis Configurator. A combination with products from other manufacturers requires a written consent by the seller. The warranty and guarantee expire if the product is mounted several times. For further information, we refer to our General Terms and Conditions of Business Transactions, Sales, Delivery and Payment.

3. Safety Information

This manual is addressed to orthotists. That is why the content basically confines to features of the product. It does not contain any notes about dangers which are obvious to orthotists. Please note that the product is not supposed to be combined with other components or materials than with those recommended by the FIOR & GENTZ Orthosis Configurator. To achieve maximum safety, please show the patient and/or the care team how to use and maintain the product correctly. Enclosed to this manual you will find a patient information which has to be given to the patient and/or the care team. For information reasons and for the safety of your patient, please note all information provided in this manual including notes, tables and illustrations. Please note especially the safety instructions indicated by ATTENTION! CAUTION! WARNING! and DANGER! which are listed and explained in the following paragraph. Ignoring this information may lead to patient injuries and property damage.

4. Safety Instructions

4.1 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.

- **ATTENTION!**  
  ⇒ Important information about a possible situation which, if not avoided, leads to damage of the product.
4.2 Structure of the Safety Instructions

The following example demonstrates the structure of the safety instructions:

<table>
<thead>
<tr>
<th>Attention Symbol</th>
<th>Signal Word</th>
<th>ATTENTION!</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Type of Danger</td>
<td>Mechanical load is too high!</td>
</tr>
<tr>
<td></td>
<td>Possible Consequences for Components</td>
<td>➡ Wear of the joint parts.</td>
</tr>
<tr>
<td></td>
<td>Possible Consequences for the Patient</td>
<td>➡ Maintenance intervals shorten.</td>
</tr>
<tr>
<td></td>
<td>Measures</td>
<td>Explain to the patient the correct use of the system joint and possible dangers.</td>
</tr>
</tbody>
</table>

4.3 All Instructions for a Safe Handling of the NEURO ACTIVE System Knee Joint

There is detailed information on some of the safety instructions in the course of this manual. Respect the following safety instructions to avoid patient injuries and property damage.

**DANGER!**
The patient is not able to drive a motor vehicle safely!
- Reduced driving ability and danger of traffic collision.
Make sure that the patient gathers information about all safety and security issues before driving a motor vehicle with orthosis.

**WARNING!**
Mechanical load is too high!
- Breakage of the joint parts.
- Fall.
Explain to the patient the correct use of the system joint and possible dangers.

**WARNING!**
Mechanical load is too high due to changing patient data!
- Breakage of the joint parts.
- Fall.
Recalculate the load capacity. For this purpose, use the Orthosis Configurator or contact the technical support.

**WARNING!**
Cover plate is not fixed correctly!
- Breakage of the joint parts.
- Fall.
Secure the screws for the cover plate with the given torque and the corresponding adhesive and make sure that the sliding washers are not damaged.

**WARNING!**
System side bar/system anchor is not connected to the system case of the system joint according to our recommended production technique!
- Breakage of system components.
- Fall.
Always connect the system side bar/system anchor with the system case of the system joint according to our recommended production technique.
WARNING!
*Maintenance intervals are not respected!*
- Increased wear of the joint parts.
- Fall.
Respect the maintenance intervals.

WARNING!
*Maintenance intervals are not respected!*
- Increased wear of the joint parts.
- Fall.
Respect the maintenance intervals.

WARNING!
*Moisture and water!*
- Failure of the joint function.
- Fall.
Explain to the patient the correct use of the system joint and possible dangers.

WARNING!
*Soiling caused by sand and other particles!*
- Failure of the joint function.
- Fall.
Explain to the patient the correct use of the system joint and possible dangers.

WARNING!
*False pivot point regarding statics!*
- Failure of the joint function.
- Fall.
Determine the system joint’s pivot point correctly.

WARNING!
*The patient is wearing a shoe to which the orthosis is not adjusted!*
- Failure of the joint function.
- Fall.
Point out to the patient to only wear a shoe to which the orthosis is adjusted.

CAUTION!
*False pivot point regarding anatomy!*
- Damage of the anatomical joint.
Determine the system joint’s pivot point correctly.

CAUTION!
*System joint is over-greased!*
- Quick soiling and probable failure of the joint function.
- Fall.
Grease the system joint only slightly.

CAUTION!
*System joint does not move freely!*
- Restrictions of the joint function.
- Treatment goal might not be achieved.
Check if the system joint moves freely and use the right bronze bushings.

ATTENTION!
*Mechanical load is too high!*
- Wear of the joint parts.
- Maintenance intervals shorten.
Explain to the patient the correct use of the system joint and possible dangers.
ATTENTION!
Mechanical load is too high due to changing patient data!
- Wear of the joint parts.
- Maintenance intervals shorten.
Recalculate the load capacity. For this purpose, use the Orthosis Configurator or contact the technical support.

ATTENTION!
Cover plate is not fixed correctly!
- Wear of the joint parts.
- Maintenance intervals shorten.
Secure the screws for the cover plate with the given torque and the corresponding adhesive and make sure that the sliding washers are not damaged.
5. Application

The NEURO ACTIVE system knee joint is exclusively for use for orthotic fittings of the lower extremity. It must be handled by a professionally trained user. At this point, the production of ortho-prostheses is expressly excluded. You will find more information about this product under paragraph 6 Joint Function.

DANGER!

The patient is not able to drive a motor vehicle safely!

Reduced driving ability and danger of traffic collision.

Make sure that the patient gathers information about all safety and security issues before driving a motor vehicle with orthosis.

Every mechanical joint influences the orthosis' function and thus also the function of the leg. All FIOR & GENTZ system joints were developed for everyday life activities such as standing, walking and running but not for extreme loads due to sports such as climbing and parachuting.

Depending on the type of orthotic fittings and the patient’s individual physical abilities, driving a motor vehicle safely should be guaranteed. This is subject to national laws and checked by authorised medical bodies. It is recommended to modify the motor vehicle to the patient’s special needs (e.g. automatic transmission) so that the driving ability is given even without a functioning orthosis.

6. Joint Functions

The NEURO ACTIVE system knee joint has a basic function and an alternative function. The system knee joint is preassembled in a physiological joint angle of 5°.

6.1 Basic Function

The NEURO ACTIVE system knee joint is a free moving, polycentric joint to control and support the motion. The range of motion is limited in 5° extension by the premounted 5° extension stop.

While standing, the system joint is secured through the integrated posterior offset. The posterior offset of the joint axis always corresponds to the system width (fig. 1).

<table>
<thead>
<tr>
<th>System Width</th>
<th>16mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Posterior Offset of the Joint Axis</td>
<td>16mm</td>
</tr>
</tbody>
</table>

Furthermore, it is possible to bring the system joint into a knee flexion position of 0° by exchanging components. To do so, exchange the 5° extension stop for a 0° extension stop. You will find the article numbers of the 0° extension stops in our latest product catalogue System Joints and Articulated System Side Bars.

6.2 Alternative Function

Alternatively, the range of motion in extension and flexion of the NEURO ACTIVE system knee joint can be adjusted in a variety of ways through exchangeable stops. Extension and flexion stops are available in different degrees. They can be mounted to the system joint depending on the desired extension and flexion (see paragraph 11.1).

You will find the article numbers of the desired stops in our latest product catalogue System Joints and Articulated System Side Bars.
7. Scope of Delivery

The scope of delivery includes the following articles:

<table>
<thead>
<tr>
<th>Description</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>NEURO ACTIVE system knee joint (fig. 6)</td>
<td>1</td>
</tr>
<tr>
<td>AGOMET F330, 5g (fig. 2)</td>
<td>1</td>
</tr>
<tr>
<td>orthosis joint grease, 3g (fig. 3)</td>
<td>1</td>
</tr>
<tr>
<td>orthosis joint grease for joints with gear segments, 3g (fig. 4)</td>
<td>1</td>
</tr>
<tr>
<td>assembly/lamination dummy (fig. 5)</td>
<td>1</td>
</tr>
</tbody>
</table>

8. Load Capacity

**WARNING!**
**Mechanical load is too high!**
- Breakage of the joint parts.
- Fall.

Explain to the patient the correct use of the system joint and possible dangers.

**WARNING!**
**Mechanical load is too high due to changing patient data!**
- Breakage of the joint parts.
- Fall.

Recalculate the load capacity. For this purpose, use the Orthosis Configurator or contact the technical support.

**ATTENTION!**
**Mechanical load is too high!**
- Wear of the joint parts.
- Maintenance intervals shorten.

Explain to the patient the correct use of the system joint and possible dangers.

**ATTENTION!**
**Mechanical load is too high due to changing patient data!**
- Wear of the joint parts.
- Maintenance intervals shorten.

Recalculate the load capacity. For this purpose, use the Orthosis Configurator or contact the technical support.

You can find all relevant patient data for your selected system joint in the configuration you performed with the Orthosis Configurator and/or on your completed orthotic treatment sheet.
9. Tools for Assembling the System Joint

<table>
<thead>
<tr>
<th>Tools</th>
<th>System Width</th>
</tr>
</thead>
<tbody>
<tr>
<td>4mm Allen key</td>
<td>16mm</td>
</tr>
<tr>
<td>as well as 4mm hexagon bit</td>
<td></td>
</tr>
<tr>
<td>torque screwdriver 1-6Nm</td>
<td>x</td>
</tr>
<tr>
<td>screwdriver for slotted screws with the blade size 3.5 x 0.6mm</td>
<td>x</td>
</tr>
</tbody>
</table>

10. Assembly/Lamination Dummies

Assembly/lamination dummies are included in the scope of delivery of the system joint. You can find the article numbers as well as the corresponding tools for the parallel alignment in our product catalogue System Joints and Articulated System Side Bars.

11. Assembly Instructions

The system joint is delivered fully assembled (fig. 8). All functions are checked beforehand. You have to disassemble the system joint for mounting it in the orthosis and for maintenance. When disassembling the system joint, make sure not to interchange the different parts with each other or with parts of other system joints. To ensure optimum functionality, please follow the assembly instructions below:

11.1 Mounting the Stops

Start the assembly of the NEURO ACTIVE system knee joint by mounting the extension stop (1) and flexion stop (2) correctly:

- correct position of the stops (fig. 9);
- incorrect position of the stops (fig. 10).

Turn in the slotted pan head screws.

11.2 Mounting the Cover Plate

Now, you connect the joint’s upper part with the lower part and mount the cover plate. Proceed as follows:

1. Grease the axle bore of the joint’s upper part and lower part as well as the friction surfaces of the bronze bushings with the delivered orthosis joint grease (orange marking; fig. 3).
2. Grease the two first sliding washers *slightly* on both sides and place it (fig. 11).

3. Put the bronze bushings on the sliding washers. Make sure both parts align with the threaded holes (fig. 12).

4. Grease the spaces in between gear segments of the joint’s upper part and lower part with the delivered orthosis joint grease for joints with gear segments (green marking; fig. 4).

5. Mount the joint’s upper part. The bore of the joint’s lower part must align with the threaded hole. The upper part’s face that strikes against the extension stop must touch the extension stop (fig. 13).

6. Mount the joint’s lower part. The bore of the joint’s lower part must align with the threaded hole. The lower part’s face that strikes against the extension stop must touch the extension stop (fig. 14).

**Note:**
When assembling the system joint, make sure that the gear segments of the joint’s upper and lower part mesh correctly into each other.

Incorrect assembly (fig. 15–16):
The gear segments of the joint’s upper and lower part are mounted offset to one another. Only the face of the joint’s upper or lower part touches the extension stop.

7. Apply spray adhesive on one side of the two second sliding washers and adhere them to the cover plate (fig. 17). Grease the other side of the sliding washer *slightly* with the delivered orthosis joint grease (orange marking; fig. 3).

**Note:**
Place the sliding washers so that they are not damaged when mounting the cover plate. Jammed sliding washer particles cause lateral play in the system joint and a damaged sliding washer could lead to a fall. If you have nevertheless placed a sliding washer incorrectly (fig. 18–19), remove the particles and place a new sliding washer.

8. Mount the cover plate. Turn in both countersunk flat head screws (S1 and S2; fig. 20) according to the torque given in the table (see paragraph 11.5). Clamp the bronze bushings between base and cover plate so that they cannot move. The joint’s upper and lower part should move around the bronze bushings.
11.3 Checking the System Joint’s Free Movement

**CAUTION!**
System joint does not move freely!
- Restrictions of the joint function.
- Treatment goal might not be achieved.
Check if the system joint moves freely and use the right bronze bushings.

Check if the system joint moves freely. If the system joint runs with lateral play, mount the next smaller bronze bushing and if it does not move freely (it is jammed), mount the next bigger bronze bushing. For more information about the bronze bushings see paragraph 13.2.

11.4 Basic Alignment

When mounting the extension stop, mind the correct alignment of the entire orthosis. In order for an exchanged extension stop not to affect the orthosis alignment negatively, also correct the system ankle joint, if necessary.

11.5 Securing the Screws

**WARNING!**
Cover plate is not fixed correctly!
- Breakage of the joint parts.
- Fall.
Secure the screws for the cover plate with the given torque and the corresponding adhesive and make sure that the sliding washers are not damaged.

**ATTENTION!**
Cover plate is not fixed correctly!
- Wear of the joint parts.
- Maintenance intervals shorten.
Secure the screws for the cover plate with the given torque and the corresponding adhesive and make sure that the sliding washers are not damaged.

After the orthosis has been produced and tried on and before it will be given to the patient, secure the screws for the cover plate with a torque which corresponds to the system width (see table) and LOCTITE 243 medium strength (article no.: KL2000). Let the adhesive harden (final strength after approx. 24 hours).

<table>
<thead>
<tr>
<th>Position of the Screw (fig. 20)</th>
<th>System Width</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>16mm</td>
</tr>
<tr>
<td>S1</td>
<td>4Nm</td>
</tr>
<tr>
<td>S2</td>
<td>4Nm</td>
</tr>
</tbody>
</table>

Note:
The screws of the cover plate are not secured with the necessary torque at delivery.
12. Advice on Production Techniques

Use the system components determined by the Orthosis Configurator when producing an orthosis and mind the recommended production technique.

12.1 Production Techniques Online

You will find detailed information about our production techniques in the section “Orthosis Production” under “Online Tutorials” and “Producing the Orthosis” on our website www.fior-gentz.com.

12.2 Parallel Alignment of System Joints

You will find the necessary tools for the parallel alignment of the system joints on the positive cast in our latest product catalogue System Joints and Articulated System Side Bars.

12.3 Mounting to the System Side Bar/System Anchor

WARNING!

System side bar/system anchor is not connected to the system case of the system joint according to our recommended production technique!

- Breakage of system components.
- Fall.

Always connect the system side bar/system anchor with the system case of the system joint according to our recommended production technique.

Depending on the production technique, the system side bar/system anchor must be adhered and screwed or sewed together with the system joint (fig. 21-23). You will find further information concerning the different production techniques on the internet or in the manual System Side Bars and System Anchors (article no.: PB1000-SA).

13. Maintenance

WARNING!

Maintenance intervals are not respected!

- Increased wear of the joint parts.
- Fall.

Respect the maintenance intervals.

We recommend to check the system joint’s functionality and wear every 6 months. Check the following parts in particular:

<table>
<thead>
<tr>
<th>Joint Part</th>
<th>Problem</th>
<th>Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>gear segments of the joint's upper and lower part</td>
<td>wear of the teeth</td>
<td>replacing the joint’s upper or lower part</td>
</tr>
<tr>
<td>bore of the bronze bushing</td>
<td>oversize</td>
<td>inserting repair bushing, see paragraph 13.1</td>
</tr>
<tr>
<td>bronze bushing</td>
<td>wear</td>
<td>replacing, see paragraph 13.2</td>
</tr>
<tr>
<td>stop faces</td>
<td>wear</td>
<td>replacing extension and, if necessary, flexion stop</td>
</tr>
<tr>
<td>sliding washers</td>
<td>wear</td>
<td>replacing</td>
</tr>
</tbody>
</table>
13.1 Repairing the Bronze Bushing Bore

If the bore for the bronze bushing in the joint’s upper or lower part is worn out, bore (fig. 24) and ream (fig. 25) it with a reamer (see product catalogue System Joints and Articulated System Side Bars) in order to insert a repair bushing (boring and reaming measurements see table). For a centred boring and reaming, clamp the joint’s upper or lower part firmly. After inserting the repair bushing made of a special plastic (fig. 26), the bore has the specified size again (fig. 27). The system joint is free of play again (fig. 28).

![Fig. 24](image1.png) ![Fig. 25](image2.png) ![Fig. 26](image3.png) ![Fig. 27](image4.png) ![Fig. 28](image5.png)

**Boring and Reaming Measurements [mm]**

<table>
<thead>
<tr>
<th>System Width</th>
<th>Bronze Bushing Outer Ø</th>
<th>Repair Bushing Inner Ø</th>
<th>Repair Bushing Outer Ø</th>
<th>Ø Measurement for Boring</th>
<th>Ø Measurement for Reaming</th>
<th>Art. No. Repair Bushing</th>
</tr>
</thead>
<tbody>
<tr>
<td>16mm</td>
<td>9.6</td>
<td>9.6</td>
<td>10.5</td>
<td>10.2</td>
<td>10.5 H7</td>
<td>BP1110-L039</td>
</tr>
</tbody>
</table>

13.2 Replacing the Bronze Bushings

If the premounted bronze bushings wear out, they have to be replaced for new ones with the same height. The article number of the premounted bronze bushings are on the back page of this manual. The last three digits of the article number stand for the height (h) of the bronze bushing, e.g. BB9662-09 (fig. 29). The height of this bronze bushing is 2.09mm. It is engraved on the outside of the bronze bushing (fig. 30). Note and respect that when reordering. If the digits are illegible, measure the height.

![Fig. 29](image6.png) ![Fig. 30](image7.png)

13.3 Cleaning

**WARNING!**
Moisture and water!
- Failure of the joint function.
- Fall.
Explain to the patient the correct use of the system joint and possible dangers.

**WARNING!**
Soiling caused by sand and other particles!
- Failure of the joint function.
- Fall.
Explain to the patient the correct use of the system joint and possible dangers.

While using the orthosis, the system joint has to be cleaned if needed and during regularly carried out maintenance. For this purpose, disassemble the system joint and clean the soiled parts with a dry cloth.
14. Spare Parts (see table and fig. 31)
<table>
<thead>
<tr>
<th>Item</th>
<th>Article Number for System Width 16mm</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>SK0250-ST</td>
<td>base plate</td>
</tr>
<tr>
<td>2</td>
<td>GS2210-050</td>
<td>sliding washer</td>
</tr>
<tr>
<td>3</td>
<td>BB966*</td>
<td>bronze bushing*</td>
</tr>
<tr>
<td>4</td>
<td>SK0203-L/ST</td>
<td>upper part, left lateral or right medial, straight, steel</td>
</tr>
<tr>
<td>4</td>
<td>SK0203-R/ST</td>
<td>upper part, left medial or right lateral, straight, steel</td>
</tr>
<tr>
<td>4</td>
<td>SK0223-L/ST</td>
<td>upper part, left lateral or right medial, bent inwards, steel</td>
</tr>
<tr>
<td>4</td>
<td>SK0223-R/ST</td>
<td>upper part, left medial or right lateral, bent inwards, steel</td>
</tr>
<tr>
<td>5</td>
<td>SK0213-L/ST</td>
<td>lower part, left lateral or right medial, straight, steel</td>
</tr>
<tr>
<td>5</td>
<td>SK0213-R/ST</td>
<td>lower part, left medial or right lateral, straight, steel</td>
</tr>
<tr>
<td>5</td>
<td>SK0233-L/ST</td>
<td>lower part, left lateral or right medial, bent inwards, steel</td>
</tr>
<tr>
<td>5</td>
<td>SK0233-R/ST</td>
<td>lower part, left medial or right lateral, bent inwards, steel</td>
</tr>
<tr>
<td>6</td>
<td>BK9051-E005</td>
<td>5° extension stop</td>
</tr>
<tr>
<td>7</td>
<td>SC2103-L08</td>
<td>slotted pan head screw</td>
</tr>
<tr>
<td>8</td>
<td>SK0251-ST</td>
<td>cover plate</td>
</tr>
<tr>
<td>9</td>
<td>SC1016-L12</td>
<td>countersunk flat head screw with hexagon socket and shank</td>
</tr>
</tbody>
</table>

* Bronze Bushings

<table>
<thead>
<tr>
<th>Article Number and Height for System Width 16mm</th>
<th>Ø = 9.6mm</th>
<th>Height (h)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BB9664-86</td>
<td>4.86mm</td>
<td></td>
</tr>
<tr>
<td>BB9664-89</td>
<td>4.89mm</td>
<td></td>
</tr>
<tr>
<td>BB9664-92</td>
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<td>BB9665-01</td>
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<tr>
<td>BB9665-04</td>
<td>5.04mm</td>
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</table>

Note: When reordering, note and respect the engraved height on the outside of the bronze bushing (explanation see paragraph 13.2).

15. Accessory Parts

You will find a big variety of accessory parts in our latest product catalogue System Joints and Articulated System Side Bars.
Der Qualitätsstandard der Firma FIOR & GENTZ ist durch eine unabhängige Zertifizierungsgesellschaft nach den internationalen Normen ISO 9001 und ISO 13485 geprüft und bescheinigt worden. The quality standard of the FIOR & GENTZ company has been controlled and certified by an independent certification organisation according to the international standards ISO 9001 and ISO 13485.