FIOR & GENTZ

Instructions for Use for Qualified Specialists in Orthopaedic Technology
Articulated Side Bars for Knee Orthoses

EN

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1. Information

These instructions for use are addressed to qualified specialists in orthopaedic technology and do not contain any notes about dangers which are obvious to them. To achieve maximum safety, please instruct the patient and/or care team in the use and maintenance of the product.

2. Safety Instructions

2.1 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.

2.2 All Instructions for a Safe Handling of the **Articulated Side Bars for Knee Orthoses**

⚠ DANGER

Potential Traffic Accident Due to Limited Driving Ability
Advise the patient to gather information about all safety and security issues before driving a motor vehicle with orthosis. The patient should be able to drive a motor vehicle safely.

⚠ WARNING

Risk of Falling Due to Improper Handling
Inform the patient about the correct use of the articulated side bar and potential dangers especially with regards to:
- moisture and water as well as
- excessive mechanical stress (e.g. due to sports, increased activity or weight gain).

Also inform the patient that the articulated side bar may only be demounted and maintained by a qualified specialist in orthopaedic technology. Any handling of the articulated side bar and the orthosis by the patient that goes beyond the tasks described in the instructions for use for patients is not permitted.

⚠ WARNING

Risk of Falling Due to Improper Processing
Process the articulated side bar according to the information in these instructions for use. Deviating processing and modifications of the articulated side bar require the written consent of the manufacturer.

⚠ WARNING

Risk of Falling Due to Loosened Screws
Mount the cover plate to the articulated side bar according to the assembly instructions in these instructions for use. Secure the screws with the specified torque and the corresponding adhesive and make sure that no sliding washers are damaged in the process.

⚠ WARNING

Risk of Falling Due to Incorrectly Selected System Components
Make sure that the articulated side bar is not overloaded and is functionally adapted to the requirements and needs of the patient in order to avoid joint dysfunction.

⚠ WARNING

Risk of Falling Due to Permanent Higher Load
If patient data has changed (e.g. due to weight gain, growth or increased activity), recalculate the expected load on the articulated side bar, plan the treatment again and, if necessary, produce a new orthosis.

⚠ WARNING

Risk of Falling Due to False Indication
Use the articulated side bars exclusively for the production of knee orthoses. For the production of orthoses for patients with paralyses or orthoses with foot pieces use the FIOR & GENTZ system joints.

⚠ WARNING

Risk of Falling Due to Improper Processing
Errors in processing can lead to a breakage of the articulated side bars. Bend the side bar wings as described in these instructions for use. Avoid:
- notches;
- falling below the recommended bending radii;
- heating side bar wings made of metal and
- overheating side bar wings made of carbon fibre.

⚠ WARNING

Damage to the Anatomical Joint Due to Incorrect Position of the Joint's Mechanical Pivot Point
Determine the joint's mechanical pivot points correctly in order to avoid a permanent incorrect load on the anatomical joint. Please refer to the online tutorials on the FIOR & GENTZ website or contact Technical Support.

⚠ 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. Use suitable bronze bushings according to the information in these instructions for use.

NOTICE

Limitation of the Joint Function Due to Improper Processing
Errors in processing can impair the joint function. Pay particular attention to:
- greasing the joint components only **slightly** and
- adhering to the maintenance intervals.

NOTICE

Limitation of the Joint Function Due to Improper Dirt Removal
Inform the patient on how to properly remove dirt from the orthosis and the articulated side bar.

NOTICE

Limitation of the Joint Function Due to Lack of Maintenance
Respect the specified maintenance intervals in order to avoid joint dysfunction. Also inform the patient about the maintenance appointments to be respected. Enter the next maintenance appointment in the orthosis service passport of the patient.

3. Use

3.1 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. The articulated side bar may only be used for one fitting and must not be reused.

ⓘ Please note that the **articulated side bars for knee orthoses** must not be used for the production of orthoses for patients with paralyses.

3.2 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. An evaluation regarding the safe handling of the orthosis by the patient must be carried out.

3.3 Contraindication

The articulated side bar is not suitable for treatments that were not described in paragraph 3.2, such as a treatment of the upper extremity or a treatment with a prosthesis or ortho-prosthesis, for example after amputations of leg segments.

3.4 Qualification

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

3.5 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.

4. Joint Functions

4.1 Basic Function

The articulated side bars have free moving, polycentric joints. The range of motion is limited in 0° extension by the premounted 0° extension stop.

4.2 Alternative Function

Alternatively, the range of motion in direction of extension and flexion of the articulated side bars 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 joint depending on the desired extension and flexion.

5. Scope of Delivery

Description	Quantity	
	Piece	Pair
articulated side bar for knee orthoses (fig. 4)	1	2
orthosis joint grease, 3g (fig. 1)	1	1
orthosis joint grease for joints with gear segments, 3g (fig. 2)	1	1
assembly/lamination dummy (fig. 3)	1	2

fig. 1

fig. 2

fig. 3

fig. 4

6. Load

The actual load on the articulated side bars is based on the relevant patient data. The load and the appropriate system components can be determined by using the Orthosis Configurator. We recommend that you use the system components determined by the Orthosis Configurator when producing an orthosis and mind the recommended production technique. You will find information on the production techniques in the section "Online Tutorials" on the FIOR & GENTZ website.

7. Tools for Assembling the Articulated Side Bars for Knee Orthoses

Tools	Centre Distance	
	16mm	20mm
3mm hexagon screwdriver/bit	x	-
4mm hexagon screwdriver/bit	-	x
torque screwdriver, 1–6Nm	x	x
slotted screwdriver, 3.5 x 0.6mm	x	x
slotted screwdriver, 5.5 x 1.0mm	x	x

8. Assembly Instructions

The **articulated side bars for knee orthoses** are delivered fully assembled. All functions are checked beforehand. You have to disassemble the articulated side bars for mounting them in the orthosis and for maintenance. To ensure an optimal functioning, follow the assembly instructions below. Secure all screws with the torque specified in paragraph 8.5.

You can find more information on the assembly in the online tutorial **Joint Assembly Articulated Side Bars for Knee Orthoses** (see QR code, fig. 5) on the FIOR & GENTZ website.

fig. 5

Only use the FIOR & GENTZ orthosis joint grease and orthosis joint grease for joints with gear segments to grease the system components.

8.1 Mounting the Stops

When mounting the extension stop, mind the correct alignment of the entire orthosis.

1 Mount the extension (1) and flexion stop (2) in the correct position (fig. 6).

2 Tighten the slotted pan head screws.

fig. 6

8.2 Mounting the Cover Plate

Make sure not to damage the sliding washers during the assembly. Jammed sliding washer particles can cause lateral play in the joint.

1 Before the assembly, clean the threads of the cover plate with LOCTITE® 7063 Super Clean. Allow the threads to air-dry for 10 minutes.

2 Grease the axle bore of the femoral and tibial side bar wings as well as the sliding surfaces of the bronze bushings with orthosis joint grease (orange marking on the tube; fig. 1).

3 Screw in both countersunk flat head screws on the back of the base plate.

4 Place the bronze bushings onto the countersunk flat head screws (fig. 7).

5 Apply spray adhesive on one side of the two first sliding washers and adhere them over the bronze bushings to the base plate. The bronze bushings serve as guidance (fig. 8).

6 Remove the bronze bushings and the countersunk flat head screws.

7 Grease the other side of the sliding washers **slightly** with orthosis joint grease (orange marking on the tube; fig. 1).

8 Screw in both countersunk flat head screws on the back of the cover plate.

9 Place the bronze bushings onto the countersunk flat head screws.

10 Apply spray adhesive on one side of the two second sliding washers and adhere them over the bronze bushings to the cover plate.

11 Remove the bronze bushings and the countersunk flat head screws (fig. 9).

12 Grease the other side of the sliding washers **slightly** with orthosis joint grease (orange marking on the tube; fig. 1).

13 Mount the femoral side bar wing. Make sure that it is positioned on the threaded hole. The face of the femoral side bar wing that strikes against the extension stop must touch the extension stop (fig. 10).

14 Place the first bronze bushing (fig. 11).

15 Mount the tibial side bar wing. Make sure that it is positioned on the threaded hole. The face of the tibial side bar wing that strikes against the extension stop must touch the extension stop. The gear segments of the side bar wings must mesh (fig. 12).

16 Place the second bronze bushing (fig. 13).

17 Place the cover plate onto the joint.

18 Screw in the countersunk flat head screws (S1 and S2; fig. 14). Clamp the bronze bushings between base and cover plate so that they cannot move. The femoral and tibial side bar wing should move around the bushings.

fig. 7

fig. 8

fig. 9

fig. 10

fig. 11

fig. 12

fig. 13

fig. 14

8.3 Checking the Free Movement

Tighten the screws for the cover plate with the appropriate torque (see paragraph 8.5). Check if the articulated side bars move freely. If the articulated side bar runs with lateral play, mount the next smaller bronze bushing. If it does not move freely (it is jammed), mount the next larger bronze bushing.

8.4 Greasing the Femoral and Tibial Side Bar Wing

1 Demount the cover plate.
2 Grease the gear segments of the femoral and tibial side bar wings with orthosis joint grease for joints with gear segments (green marking on the tube; fig. 2).
3 Place the cover plate onto the joint again and screw in the countersunk flat head screws (S1 and S2).

8.5 Securing the Screws

The screws are secured after the orthosis has been produced and tried on and before it is handed over to the patient.

1 Loosen the screws for the cover plate (fig. 14) after checking the free movement and remove them from the cover plate.
2 Apply a small drop of LOCTITE® 243 medium strength to the thread of the screws.
3 Secure the screws for the cover plate (fig. 14) with the torque corresponding to the system width.
4 Let the adhesive harden (final strength after approx. 24 hours).

Screws for Cover Plate	Centre Distance	
	16mm	22mm
S1 (screw 1)	4Nm	4Nm
S2 (screw 2)	4Nm	4Nm

The screws for the cover plate are not secured with the necessary torque at delivery. You can also find information on the torque in the openings of the cover plate.

9. Processing the Side Bar Wings

To ensure an optimal functioning of the **articulated side bars for knee orthoses**, please note the following processing steps and explanations when forming and bending the side bar wings.

9.1 Forming the Side Bar Wings Made of Carbon Fibre

fig. 15

1 Screw the side bar wings on the corresponding joint retainers.
2 Always wear heat-resistant gloves when working at heating sources.
3 Heat the surface with a hot-air gun (fig. 15) to 175°C in circling movements. When heating, keep a distance of about 20cm between material and source of heat. To ensure the proper processing temperature, use the FIOR & GENTZ temperature marker.
4 Form the heated material extensively on the positive cast.
5 Wait for the side bar wings to be completely cooled down before proceeding with the next work step.

9.2 Forming the Side Bar Wings Made of Metal

- Screw the side bar wings on the corresponding joint retainers.
- Do not use a hammer to bend the side bar wings.
- In order to avoid notches, use a bending iron with round edges for bending the side bar wings (fig. 16). Both bending irons with straight and with curved edges can easily cause breakage of the side bar wings.
- Bending is a cold working technique. Do not heat the material since the material's characteristics can change permanently.
- To avoid fractures when bending the side bar wings, make sure not to fall below the radii given in the table (fig. 17). The bending radius depends on the thickness of the material (see table).

fig. 16

Material	Calculating the Minimum Bending Radius [R]*
steel	R = 3 x material thickness
titanium	R = 10 x material thickness

* Calculation example: A side bar wing made of titanium is 2mm thick. Multiplied by 10, the bending radius is 20mm. This value is the minimum radius.

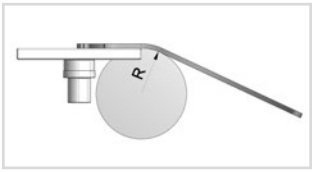

fig. 17

When bending the side bar wings, wear working clothes with long sleeves as well as work gloves and goggles to avoid injuries in case the side bar wings break.

10. Maintenance

Check the **articulated side bars for knee orthoses** regularly for wear and functionality. In particular, check the joint components listed in the following table for the possible problems described and, if necessary, take the appropriate measures. Also check the functionality after every maintenance carried out. It must be possible to move the joint without problems or unusual noises. Make sure that there is no lateral play.

Joint Component	Potential Problem	Measure	Recommended Inspection, Potential Replacement*	Latest Replacement
sliding washer	wear	replacing sliding washer	every 6 months	every 18 months
cover plate	wear	replacing cover plate	every 6 months	every 36 months
base plate	wear	replacing base plate	every 6 months	every 36 months
countersunk flat head screw with hexalobular socket	wear	replacing countersunk flat head screw	every 6 months	every 36 months
bronze bushing	wear	replacing bronze bushing, see paragraph 10.2	every 6 months	every 36 months
femoral and/or tibial side bar wing	wear	replacing femoral and/or tibial side bar wing	every 6 months	every 36 months
extension stop	wear	replacing extension stop	every 6 months	if required
flexion stop	wear	replacing flexion stop	every 6 months	not necessary

* depending on the assessment of the distributor of the custom-made product regarding the patient's usage behaviour

Clean the threads of the base plate with LOCTITE® 7063 Super Clean at every maintenance. Allow the threads to air-dry for 10 minutes.

Secure the screws for the cover plate with the appropriate torque and LOCTITE® 243 medium strength during every maintenance (see paragraph 8.5). Remove all adhesive residues first.

10.1 Documentation of Maintenance in the Orthosis Service Passport

The patient receives an orthosis service passport (fig. 18) from a qualified specialist in orthopaedic technology when the orthosis is handed over. The orthosis must be checked regularly according to the specifications in the maintenance plan in order to maintain its function and to ensure the safety of the patient. The maintenance appointments are noted and confirmed in the orthosis service passport.

fig. 18

10.2 Replacing the Bronze Bushings

Bronze bushings are available in different heights (e.g. BB855**2–91** is 2.91mm high). The height (h) is engraved on the outside of the bronze bushing (fig. 19). If it is illegible, measure the height of the bronze bushing (fig. 20). You will find the article numbers of the premounted bronze bushings on the back page of these instructions for use.

fig. 19

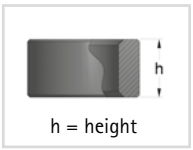

fig. 20

10.3 Dirt Removal

Dirt must be removed from the **articulated side bars for knee orthoses** when necessary and during regular maintenance. For this purpose, disassemble the articulated side bar and clean the soiled parts with a dry cloth.

11. Period of Use

To guarantee a safe use and complete functionality as well as an unlimited period of use of the articulated side bars, you must adhere to the following conditions:

- Adhere to the specified maintenance intervals without interruption and document each maintenance (see paragraph 10).
- Adhere to the determined maintenance conditions (see paragraph 10).
- Check the wear parts, as required, and exchange them at the defined intervals (see paragraph 10).
- Check the adjustment of the articulated side bar during maintenance and correct it, if necessary (see paragraph 10).
- Check the functionality of the articulated side bar during maintenance (see paragraph 10).
- The maximum load determined during the planning of the custom-made product shall not be exceeded by changes in the patient data (e.g. due to weight gain, growth or increased activity). If the determined maximum load on the articulated side bars is exceeded, the articulated side bar must no longer be used. When planning the custom-made product, expected changes in patient data need to be taken into account.
- The period of use of the articulated side bars ends with the period of use of the custom-made product (orthosis).
- The multiple use of the articulated side bar in another custom-made product is not allowed (see paragraph 17).

12. Storage

It is recommended to store the articulated side bar in its original packaging until the custom-made product is produced.

13. Spare Parts

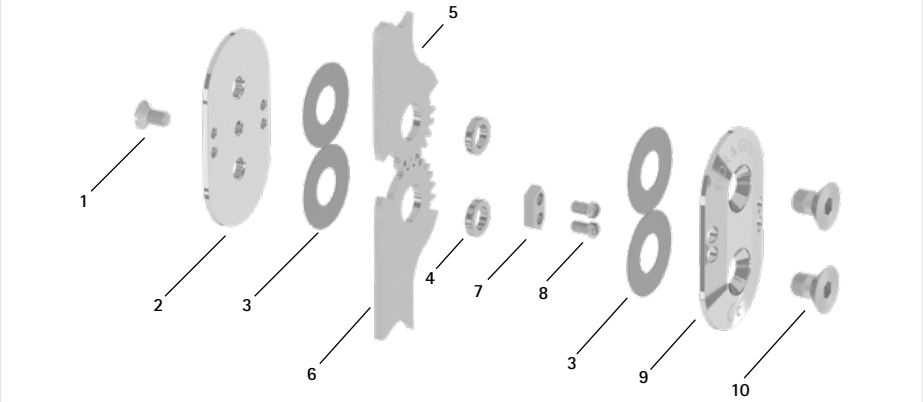

fig. 21

Item	Article Number for Centre Distance Side Bar Type A 16mm	Side Bar Type B, E, F 22mm, 2mm Side Bar Wing Thickness	Side Bar Type C 22mm, 3mm Side Bar Wing Thickness	Side Bar Type D 22mm, 3.3mm Side Bar Wing Thickness	Description
1	SC1104-L05	SC1104-L05	SC1104-L05	SC1104-L05	slotted countersunk flat head screw
2	KS0150-AL	KS0100-ST	KS0100-ST	KS0210-AL	base plate
3	GS1609-050	GS2210-050	GS2210-050	-	sliding washer
4	BB855x-xx**	BB966x-xx**	BB966x-xx**	-	bronze bushing**
7	KS9402-E000	KS9401-E000	KS9301-E000	-	0° extension stop
7	-	KS9401-E006	-	-	6° extension stop
8	SC2103-L05	SC2103-L05	SC2103-L06	SC2103-L08	slotted pan head screw
9	KS0151-AL/FG	KS0101-ST/FG	KS0101-ST/FG	KS0211-AL/FG	cover plate
10	SC1015-L09	SC1016-L09	SC1016-L11	SC1016-L13	countersunk flat head screw with hexagon socket

Item	Article Number for Centre Distance Side Bar Type A 16mm	Side Bar Type B, E, F 22mm, 2mm Side Bar Wing Thickness	Side Bar Type C 22mm, 3mm Side Bar Wing Thickness	Side Bar Type D 22mm, 3.3mm Side Bar Wing Thickness	Description
Side Bar Wings for Joint Lamination/Prepreg Technique: ACL, PCL, Gonarthrosis, Varus Deformity, Valgus Deformity					
5	KS0052-ST	KS0012-ST	KS0026-ST	-	femoral side bar wing, straight, steel
5	KS0052-TI	KS0012-TI	KS0026-TI	-	femoral side bar wing, straight, titanium
5	-	-	-	KS0012-C	femoral side bar wing, straight, carbon fibre
5	KS0050-ST	KS0010-ST	KS0024-ST	-	femoral side bar wing, bent, steel
5	KS0050-TI	KS0010-TI	KS0024-TI	-	femoral side bar wing, bent, titanium
5	-	-	-	KS0010-C	femoral side bar wing, bent, carbon fibre
6	KS0051-ST	KS0011-ST	KS0025-ST	-	tibial side bar wing, bent, steel
6	KS0051-TI	KS0011-TI	KS0025-TI	-	tibial side bar wing, bent, titanium
6	-	-	-	KS0011-C	tibial side bar wing, bent, carbon fibre
6	KS0053-ST	KS0013-ST	KS0027-ST	-	tibial side bar wing, calf curved, steel
6	KS0053-TI	KS0013-TI	KS0027-TI	-	tibial side bar wing, calf curved, titanium
6	-	-	-	KS0013-C	tibial side bar wing, calf curved, carbon fibre
Side Bar Wings for Side Bar Shell Technique: ACL					
5	-	KS0014-ST	-	-	femoral side bar wing, bent, steel
5	-	KS0014-TI	-	-	femoral side bar wing, bent, titanium
6	-	KS0015-ST	-	-	tibial side bar wing, bent, steel
6	-	KS0015-TI	-	-	tibial side bar wing, bent, titanium
Side Bar Wings for Side Bar Shell Technique: Gonarthrosis					
5	-	KS0016-L/ST	-	-	femoral side bar wing, left lateral or right medial, straight, steel
5	-	KS0016-R/ST	-	-	femoral side bar wing, left medial or right lateral, straight, steel

Item	Article Number for Centre Distance Side Bar Type A 16mm	Side Bar Type B, E, F 22mm, 2mm Side Bar Wing Thickness	Side Bar Type C 22mm, 3mm Side Bar Wing Thickness	Side Bar Type D 22mm, 3.3mm Side Bar Wing Thickness	Description
5	-	KS0016-TI	-	-	femoral side bar wing, straight, titanium
6	-	KS0017-L/ST	-	-	tibial side bar wing, left lateral or right medial, calf curved, steel
6	-	KS0017-R/ST	-	-	tibial side bar wing, left medial or right lateral, calf curved, steel
6	-	KS0017-TI	-	-	tibial side bar wing, calf curved, titanium
Side Bar Wings for Joint Lamination/Prepreg Technique: Hyperextension, Varus Deformity, Valgus Deformity					
5	-	-	KS0018-ST	-	femoral side bar wing, straight, steel
5	-	-	KS0018-TI	-	femoral side bar wing, straight, titanium
6	-	-	KS0019-ST	-	tibial side bar wing, calf curved, steel
6	-	-	KS0019-TI	-	tibial side bar wing, calf curved, titanium

** Bronze Bushings [mm]				
Centre Distance	Side Bar Thickness	Article Number	Outer Ø	Height (h)
Steel and Titanium Articulated Side Bars with Gear Segments				
16mm	2mm	BB8552-85	8.50	2.85
		BB8552-88	8.50	2.88
		BB8552-91	8.50	2.91
		BB8552-94	8.50	2.94
		BB8552-97	8.50	2.97
		BB8553-00	8.50	3.00
		BB8553-03	8.50	3.03
		BB8553-06	8.50	3.06
		BB8553-09	8.50	3.09

** Bronze Bushings [mm]				
Centre Distance	Side Bar Thickness	Article Number	Outer Ø	Height (h)
Steel and Titanium Articulated Side Bars with Gear Segments				
22mm	2mm	BB9662-83	9.60	2.83
		BB9662-86	9.60	2.86
		BB9662-89	9.60	2.89
		BB9662-92	9.60	2.92
		BB9662-95	9.60	2.95
		BB9662-98	9.60	2.98
		BB9663-01	9.60	3.01
		BB9663-04	9.60	3.04
		BB9663-07	9.60	3.07
		BB9663-10	9.60	3.10
		BB9663-13	9.60	3.13
22mm	3mm	BB9663-92	9.60	3.92
		BB9663-95	9.60	3.95
		BB9663-98	9.60	3.98
		BB9664-01	9.60	4.01
		BB9664-04	9.60	4.04
		BB9664-07	9.60	4.07
		BB9664-10	9.60	4.10
		BB9664-13	9.60	4.13
		BB9664-16	9.60	4.16
		BB9664-19	9.60	4.19
		BB9664-22	9.60	4.22
Carbon Fibre Articulated Side Bars with Gear Segments				
22mm	3.3mm	BB1065-70	10.00	5.70
		BB1065-80	10.00	5.80
		BB1065-90	10.00	5.90
		BB1066-00	10.00	6.00
		BB1066-10	10.00	6.10
		BB1066-20	10.00	6.20
		BB1066-30	10.00	6.30

14. Disposal

Dispose of the articulated side bars and their individual parts properly. The product must not be disposed of with the residual waste (fig. 22). Please comply with the applicable national laws and local regulations for the proper recycling of recyclable materials.

fig. 22

For proper disposal, it is necessary to remove the articulated side bars from the orthosis.

15. 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

16. 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.

17. 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.

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FIOR & GENTZ

Mounted Bronze Bushings

BB _____ - _____

PB1000-KS-DE/GB-2025-11

CE

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