

DF2[®] BRACE SYSTEM

USER MANUAL



1 - Intended Use

The **DF2 Brace** is intended for femur fractures and post-operative stabilization in pediatric population patients from approximately 6 months to 5 years of age instead of spica cast by providing immobilization of the femur, knee, and hip.

2 - Device Summary

The **DF2 Brace** is available in **6 sizes, XS, S, M, L, XL, and XXL**. Each brace comes pre-configured in Left and Right options.

Each brace includes the following components:

Fracture Sock: standard sock to protect skin from brace and prevent skin irritation/ degradation. Each brace comes with two socks.

Pelvic Girdle: comprised of foam, hard plastic and adjustable hook and loop strap to anchor brace in correct position throughout treatment.

Hip Hinge: maintains fracture fixation and allows for practitioner adjustment of flexion/ extension as well as adduction/abduction as needed. Brace can be locked at these angles, and can be unlocked at the practitioner's discretion. Flexion/extension portion of hip hinge can angle from **-100°** to **+100°**. Abduction/adduction portion can angle from **-180°** to **+180°**. A 1/8 hex driver is used to adjust abduction/adduction and a 3/32 driver for flexion/extension. The height of the hip hinge relative to the brace can also be adjusted.

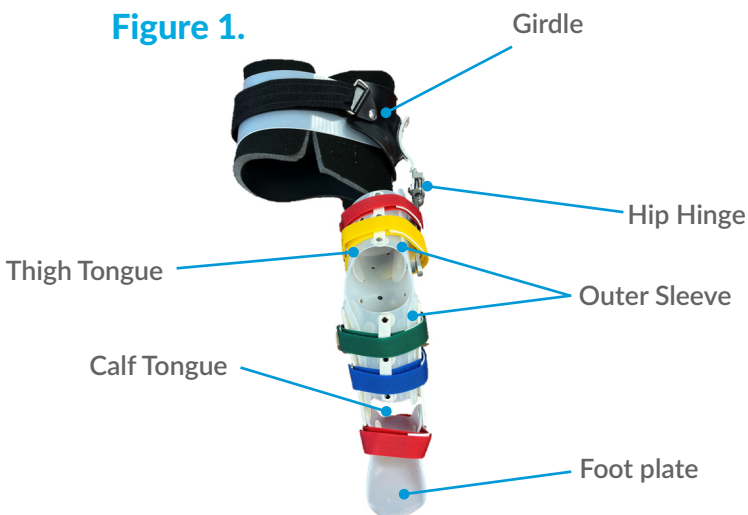
Outer Sleeve: polyethylene component that covers the thigh and the tibia while immobilizing the knee at a flexion angle of **pre-set flexion angle of 55°**.

Thigh Tongue: covers the anterior portion of the thigh and sits within the outer sleeve.

Calf Tongue: covers the anterior portion of the calf and sits within the outer sleeve. Tongues should be cut to size to encourage brace breathability.

Foot Plate: removable component that helps protect foot and prevent rotation of the patient's leg.

Note: if any screws are loosened, consider adding a threadlocker prior to re-tightening.



3 - Determining Proper Brace Size

Proper brace sizing is important for fracture healing and patient comfort. It is recommended to measure the unaffected limb to reduce patient pain and discomfort. This can prevent the impact of swelling and shortening which could lead to incorrect brace size selection.

Consider increasing measured circumferences approximately 5% to accommodate swelling due to injury. To determine the appropriate size brace for a patient, the primary measurements to be taken are the following:

- Knee Center (KC) to Proximal Medial Thigh
- Knee Center (KC) to Proximal Lateral Thigh
- Proximal Thigh Circumference
- Knee Center (KC) to End of Brace
- Largest Calf Circumference

See [Figure 2](#). for a diagram of required patient measurements.

Once the primary patient measurements are taken, refer to [Table 1](#). to determine the best brace size for the patient. The fracture should be fully encapsulated in the brace once fitted correctly. The brace and straps can be shortend using standard bandage scissors.

It is important to maximize the height of the brace relative to the patient. If the measurements are in-between sizes, please size up to a larger brace and trim as needed.

In order to allow for as much breathability as possible, it is recommended to trim the thigh and calf tongues such that only ~1.5 - 2cm of overlap remains on each side.

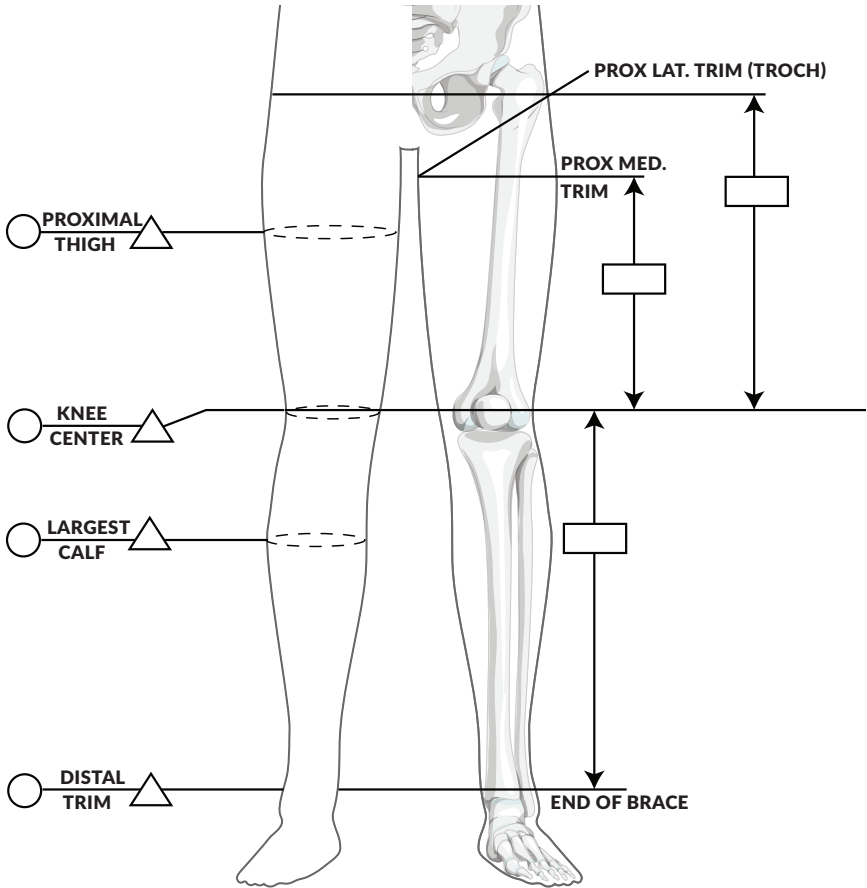
In the event that brace modifications are needed for proper fit:

- Do not leave any sharp edges; sand brace after cuts are made, if necessary.
- Ensure brace fully covers fracture site in order to maintain reduction.

Table 1. Sizes below are actual brace measurements

SIZE	Prox. Thigh Circumference Range (mm)	KC to Medial Height (mm)	KC to Lateral Height (mm)	KC to End of Brace (mm)	Largest Calf Circumference Range (mm)
XS	185 - 305	98	126	112	154 - 217
S	235 - 320	115	150	125	185 - 230
M	255 - 345	135	175	140	195 - 240
L	280 - 370	155	200	155	205 - 250
XL	295 - 400	180	232	172	220 - 260
XXL	315 - 420	198	252	189	225 - 270

Figure 2.



4 - Applying the Brace

Follow proper protocols to ensure patient comfort. Prior to applying brace, undo all velcro straps and remove foot plate. Set hip joint to desired flexion angle and lock into place. Unlock the abduction portion of the hinge.

After brace is properly sized, place brace on patient over stockinette and secure straps so they are snug. **These straps do not need to be tight.** It is recommended to secure thigh straps first, then tibia and foot before fastening the pelvic girdle.

Do not over-tighten the brace, as this could lead to skin irritation. Apply gentle traction across the fracture site either from the knee or below.

Use of a fracture sock or cotton stockinette is required to minimize risk of skin irritation while using the brace. This will prevent skin breakdown and improve overall hygiene during patient's time in the brace.

Ensure sock is not too small for the patient. If sock requires significant stretching to fit, size up to a larger sock.

Ensure the hip hinge is located at the patient's hip. Practitioner may choose to flex hip 30° - 60° and abduct to 20° - 40° to maintain fracture reduction and accommodate the patient's lifestyle (e.g sitting in car seat, high chair, etc.).

Tighten all screws and trim ends of straps as needed.

Fracture alignment can be confirmed via AP and lateral x-rays. Note: Visualization on the lateral x-ray is often obstructed by the brace.

If screws on the proximal or distal hip hinge bars are adjusted, please add Loctite to the screw tips to prevent screws from loosening during correction.

5 - Suggested Follow-Up Treatment Protocol*

Follow up visits at 1 week, 2 weeks, 4 weeks, and 6 weeks are strongly recommended.

At Each Visit.

- X-rays are taken at each visit or as routinely ordered by treating practitioner.
- The patient should be checked for skin integrity, paying special attention to: the thigh, skin, snugness of fit, posterior heel, medial / lateral malleoli, patella, medial / lateral femoral condyles, distal calf, posterior / proximal thigh, and at all trim lines of the brace.
- Change the patient's sock at each visit, if tolerated by the patient. Patient should not have the same sock on for more than one week. If the sock is visibly soiled, the sock must be changed.
- Check alignment and adjust for abduction and/or flexion as needed for mild alignment changes. Should the fracture drift into varus, the abduction hinge can be adjusted. The flexion hinge can also be adjusted if necessary.
- The treating practitioner will advise at what time point it is appropriate for the family to change the sock at home as well as bathing.

Ensure all straps are secured and check tightness of the screws. Screws should only be adjusted by treating medical professionals.

Femur Fracture

Patients should follow practitioner's routine femur fracture protocol and are to be seen at routine intervals until the fracture is healed; first visit should be at week one for clinical follow up and x-ray check.

In the early phase, it is recommended that the practitioner see the patient more frequently (1 week, 2 weeks, 4 weeks, 6 weeks) to become comfortable with the brace.

The foot portion of the brace can be removed at any point should the practitioner feel that ankle and foot motion is satisfactory and/or weight bearing is desired.

Post-Operatively

Should the brace be used following open reduction or osteotomy, the practitioner should pay attention to the integrity of the incision. The brace can be modified as needed to best avoid at-risk areas (pelvic foam and plastic can be trimmed / sanded down, etc. as required).

Brace fitting is followed by multiple follow-up visits until the brace is removed.

X-rays are taken at the routine intervals and the brace is discontinued when healing is sufficient.

The hip hinge can be adjusted to reposition the lower extremity. The Healthcare provider has the option to lock the hinge at a single angle, lock within a range of motion, or unlock for free motion.

If suggested by the practitioner, the brace can be removed during the day for range of motion or physical therapy, and then replaced at night as a splint. Parents should not remove brace without explicit instructions from the healthcare provider.

Consider diapering the patient at night to reduce likelihood of soiling the brace.

It is not recommended that the brace be used during weight bearing activities during early fracture or post operative healing. Foot plate must be removed prior to any weight bearing activity.

** Please note that these are only suggestions. The healthcare provider should develop a treatment plan that works best for the patient's needs.*



The DF2 brace is MR unsafe and should remain outside the MRI scanner room



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2850 Frontier Drive | Warsaw, IN 46582
ph: 574.268.6379 or 877.268.6339 | fax: 574.268.6302
www.OrthoPediatrics.com

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