

DF2[®] BRACE SYSTEM

USER MANUAL



1 - Intended Use

The **DF2® Brace** is intended for femur fracture fixation in pediatric 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 **3 sizes S, M, L**. 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

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 surgeon adjustment of flexion/ extension as well as adduction/abduction as needed. Brace can be locked at these angles, and can be unlocked at the surgeon'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**.

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

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 thread locker prior to re-tightening.

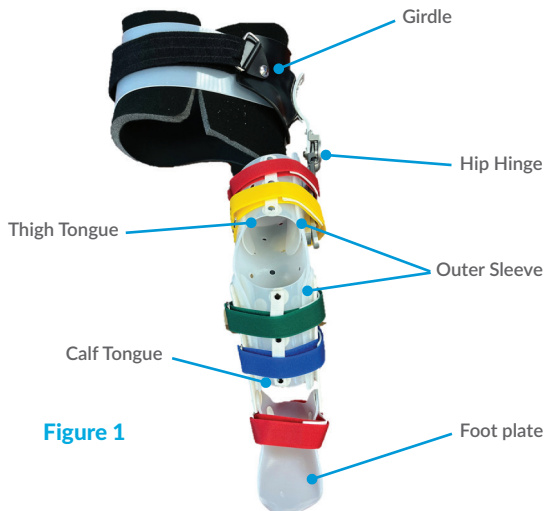


Figure 1

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 to Proximal Medial Thigh
- Knee Center to Proximal Lateral Thigh
- Proximal Thigh Circumference
- Knee Center to end of brace
- Largest Calf Circumference

See Figure 2 for 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 modified using standard bandage scissors.

If measurements are in between sizes, select the larger brace and trim as needed.

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

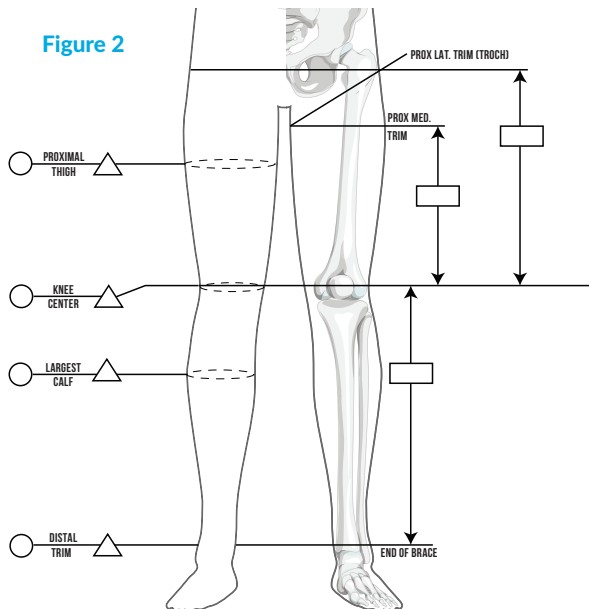


Table 1. Sizes below are actual brace measurements

SIZE	Prox. Thigh Circumference Range (mm)	Nominal KC to Medial Height (mm)	KC to Lateral Height (mm)	Largest Calf Circumference (mm)	KC to End of Brace (mm)
S	235 to 320	115	150	125	185 to 230
M	255 to 345	135	175	140	195 to 240
L	280 to 370	155	200	155	205 to 250

4 - Applying the Brace

Follow proper protocols to ensure patient comfort before applying brace to the patient. Place fracture sock on patient's leg prior to applying brace.

After brace is properly sized, place brace on patient over stockinette and tighten straps so they are snug. It is recommended to tighten thigh straps first, then tibia and foot before fastening pelvic girdle.

Apply gentle traction on bent knee while loading laterally if the fracture is shortened and/or displaced in a varus position.

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.

Surgeon may choose to flex hip 30°- 60° and abduct to 20°- 40° to maintain fracture reduction and accommodate patient 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. Beware, visualization on the lateral x-ray is often obstructed by the brace.

5 - Suggested Treatment Protocol*

Patients are typically seen at **weeks 1, 2, 4, & 6** until brace is remove and patient is healed.

Initial Patient Presentation: if fracture reduction is not taking place in operating room under general anesthetic, consider alternate analgesia prior to usual manipulation in clinic or emergency department.

Note: Only the treating surgeon and/or orthotist should adjust brace, family should never adjust brace

At each visit -

- X-rays are taken at each visit or as routinely ordered by treating surgeon
- Check alignment and adjust for abduction and/or flexion as needed for mild alignment changes
- Ensure straps and screws are tight
- Check skin and change fracture sock as needed

Specifically check: posterior heel, medial/lateral malleoli, patella, medial/lateral femoral condyles, distal calf and posterior/proximal thigh where the leg portion of the brace ends.
- Check in with family to answer questions and ensure next steps are understood

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



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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