



# DF2<sup>®</sup> 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 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 of 55 degrees**.

**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 threadlocker 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 (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

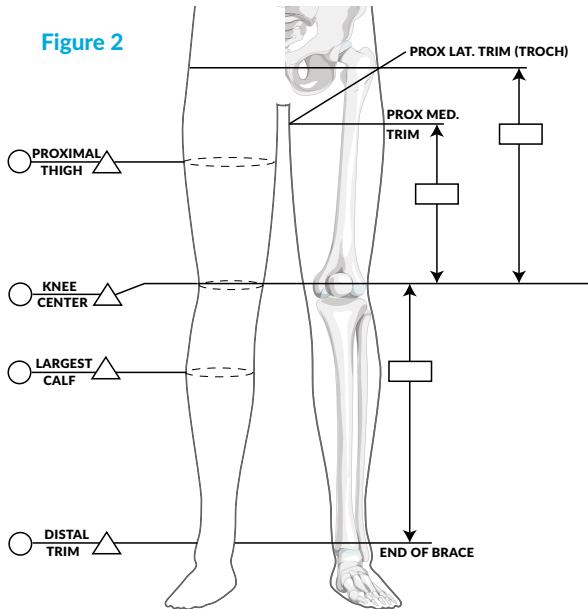
See **Figure 1** for a diagram of required patient measurements.

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 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)	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

## 4 - Applying the Brace

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Follow proper protocols to ensure patient comfort. Prior to applying brace, undo all vercro 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 tighten straps so they are snug. It is recommended to tighten thigh straps first, then tibia and foot before fastening the pelvic girdle.

***Apply gentle traction on the 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 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. Beware, visualization on the lateral x-ray is often obstructed by the brace.

## 5 - Suggested Follow-Up Treatment Protocol\*

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### At each visit

- X-rays are taken at each visit or as routinely ordered by treating surgeon.
- The patient should be checked for skin integrity, paying special attention to: posterior heel, medial / lateral malleoli, patella, medial / lateral femoral condyles, distal calf, posterior / proximal thigh, and wherever segments of the brace end.
- 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.

Ensure proper tightness of the brace straps and screws. Screws should only be adjusted by treating surgeons / orthotists.

### Femur Fracture

Patients should follow surgeon's routine femur fracture protocol and are then seen at routine intervals until the fracture is healed; first visit will typically 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 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 surgeon or APP 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 when the surgeon or APP considers this to be beneficial.

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.

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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