Inside Out Technique for Central Venous Occlusions

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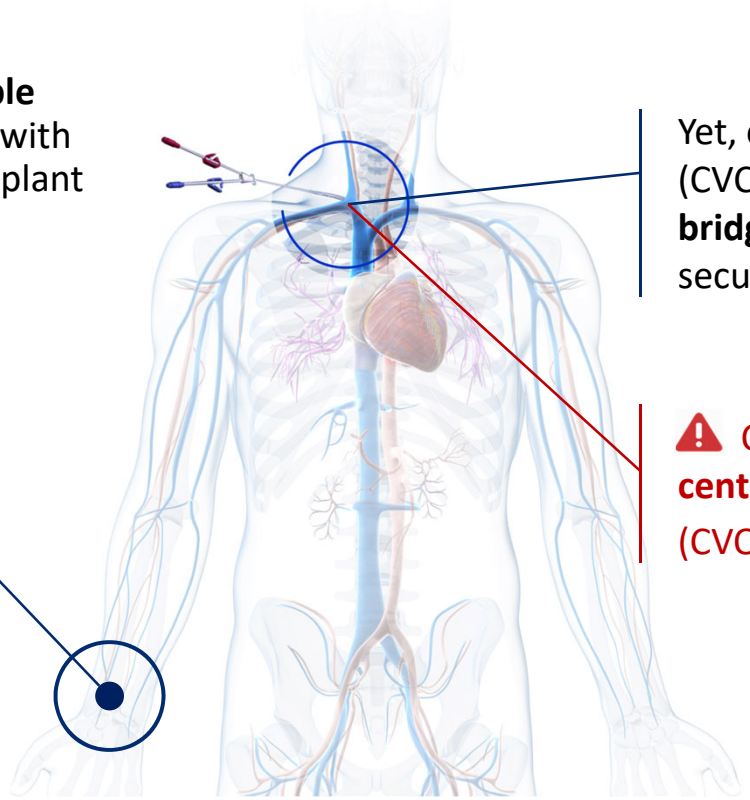
COI

- Principle investigator for Surfacer U.S. IDE clinical study

CVO is a Significant Problem in Vascular Access

An estimated **2M people** ww require treatment with dialysis or kidney transplant to stay alive[1]

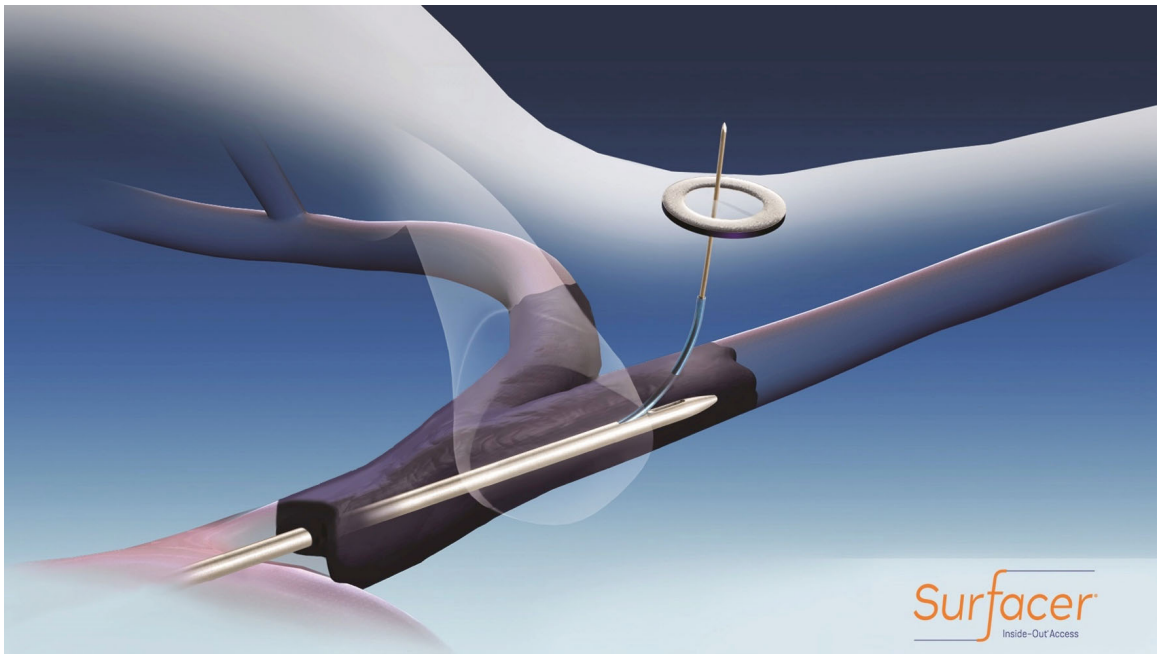


Yet, **central venous catheters** (CVCs) serve as an **important bridge** while waiting to secure access

Chronic CVC use leads to **central venous obstruction** (CVO) in **40% of cases**[2]

Permanent arteriovenous fistulas (AVFs) remain the preferred form of vascular access

[1] https://www.kidney.org/kidneydisease/global-facts-about-kidney-disease
[2] *Data on file at Bluegrass Vascular Technologies, Inc.*



BVT has pioneered an innovative inside-out approach to achieve reliable and repeatable RIJ access for hemodialysis patients.

Surfacer System is CE Marked – Not available for sale in the United States. Limited by Federal (or United States) law to investigational use.

Technique video available at http://bluegrassvascular.com/surfacer/

No Current Standard of Care

- No standard care algorithm when confronting occluded central veins
  - Re-establish access in the current vein or “try another vein”
  - Over time, all central veins become destroyed
- Lack of solution drives limited appreciation of problem and downstream consequences of progressively occluding veins

The Surfacer® Story

A UNIQUE APPROACH TO RESTORE VASCULAR ACCESS

Developed by **interventional cardiologist John Gurley, M.D.** at a leading U.S. academic institution

Over **600 Inside-Out® procedures** performed to-date

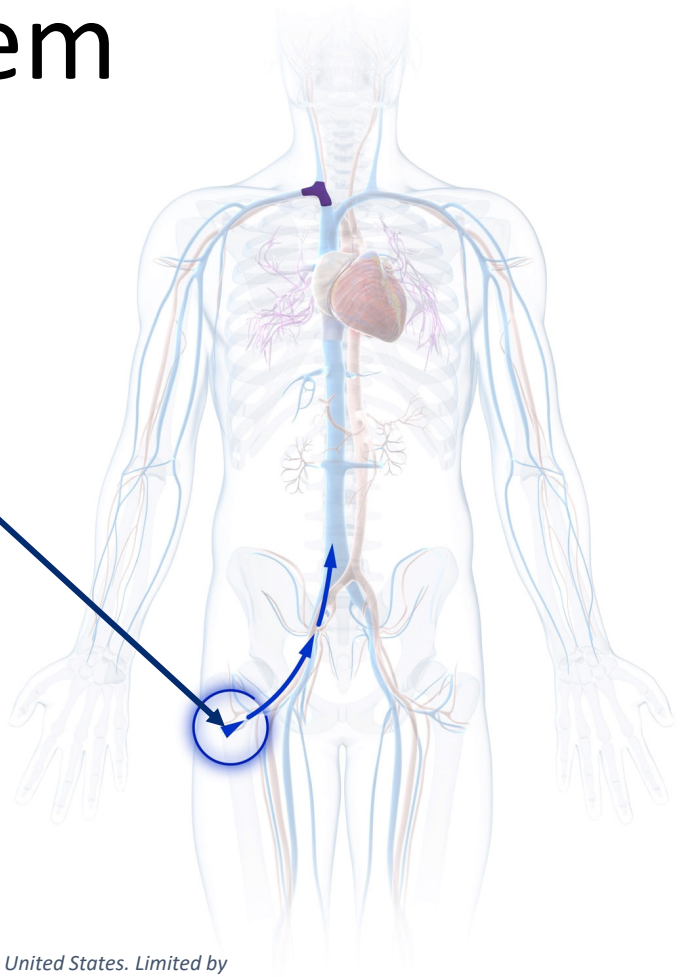
CE Mark Approved
July 2016

Dr. John Gurley, M.D., Interventional Cardiologist
Founder Of Bluegrass Vascular Technologies

Surfacer® Inside-Out® Access Catheter System

Inside-Out® Approach

- Unique, minimally invasive approach
- Delivered by inserting a guidewire, under fluoroscopy, through the femoral vein



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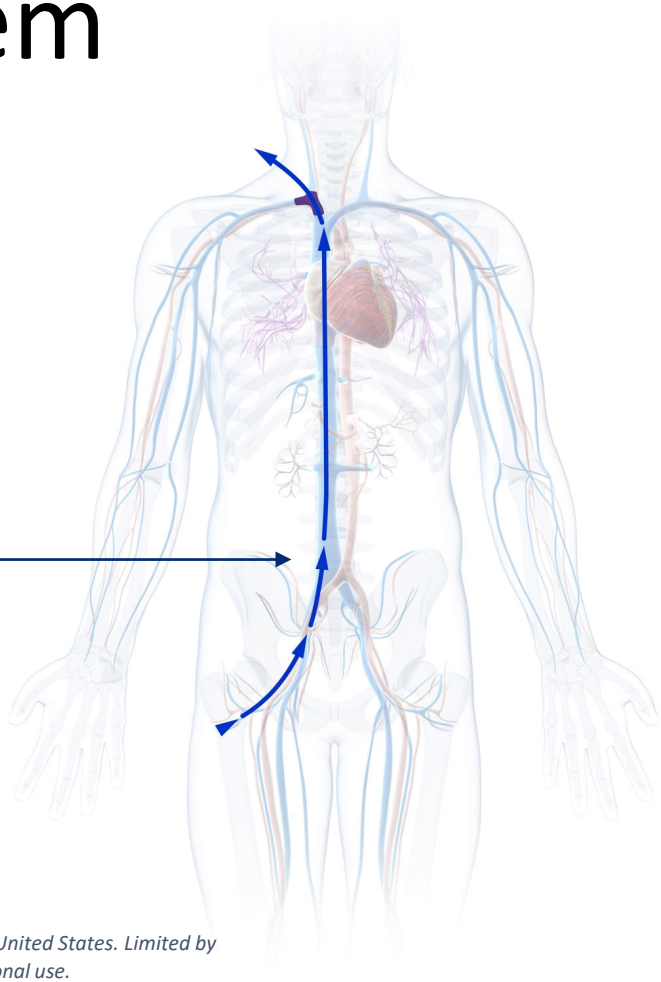
Surfacer® Inside-Out® Access Catheter System

Targeted Navigation

- The Surfacer® is navigated up through the vasculature of the torso
- The device then exits out a desired exit point in the RIJ



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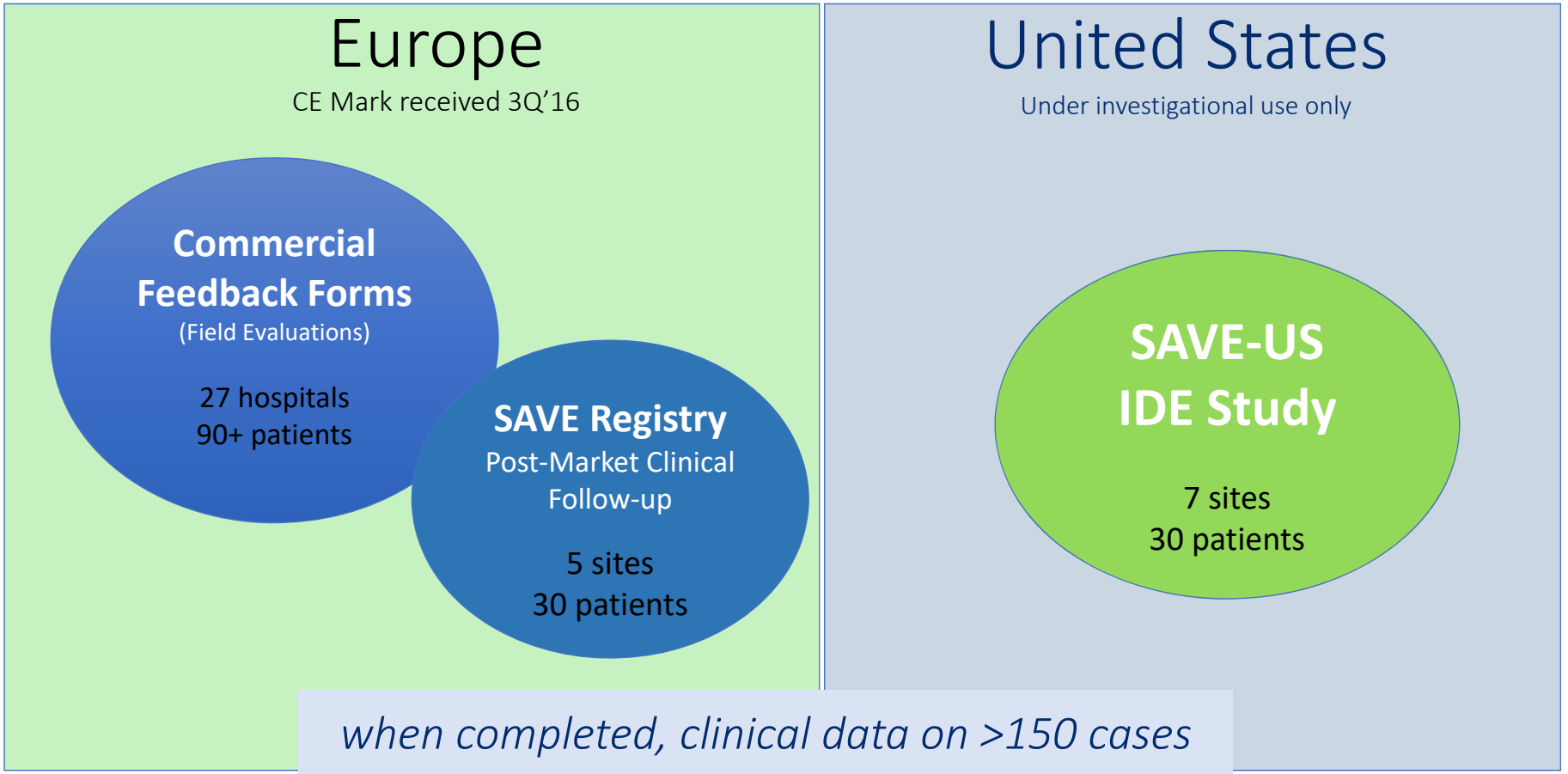

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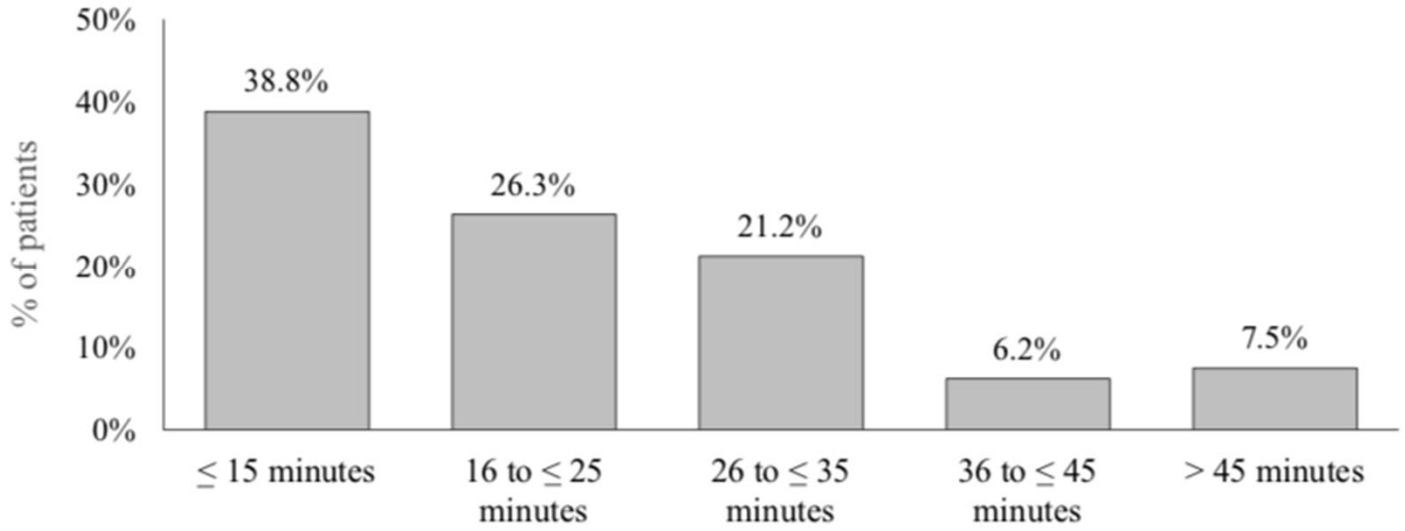
Surfacer Procedure Time



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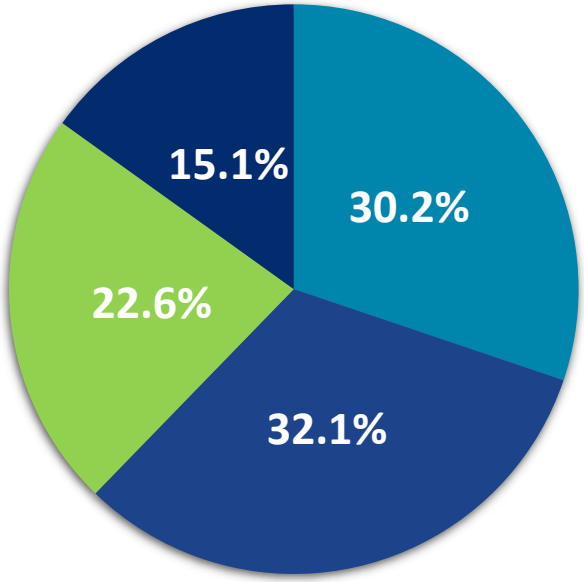
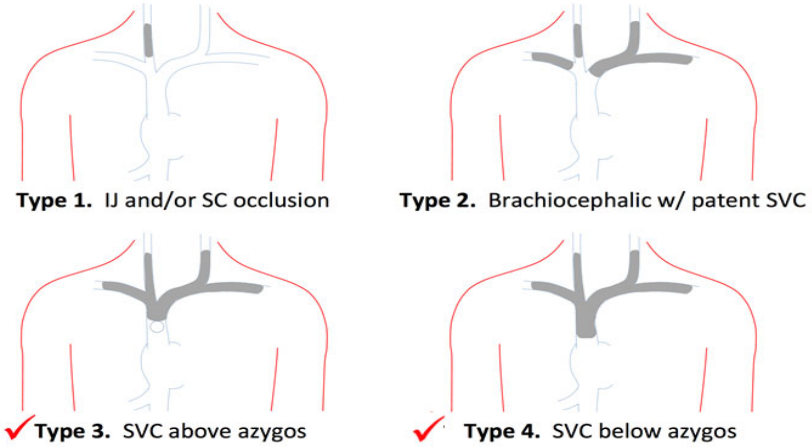
SAVE Registry Occlusion Types*





- Bilateral IJ and SC occlusions (Type 1)
- Brachiocephalic (Type 2)
- SVC occlusion above azygos (Type 3)
- Total occlusion of the SVC (Type 4)

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SAVE Registry Results

- All endpoints met (primary and secondary)
  - Primary Performance (successfully place access): 97%
  - Primary Safety: (acute safety, absence of device related AEs): 100%
  - Secondary Performance (ability to place access): 97%
  - Secondary Safety (technique conversion): 97%
- No adverse events or post-op complications reported
- Fluoroscopy times averaged 6.8 min
- Contrast use on average: 29.7 cc
- Average procedure times
  - Workstation Sheath Insertion to Removal = 23 min (6-70 min range)
  - Surfacer Insertion to Needle Wire Exit = 5 min (0-60 min)

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Surfacer System US IDE Clinical Study

- IDE study Inclusion: up to 30 patients that require central venous access
- Primary endpoints:
  - Performance:
    - Rate of successful transient CVCs created across venous occlusions where success definition is placement of patent operational CVCs.
  - Safety:
    - Acute device safety, defined as the absence of procedural complications at discharge and 7 days post-procedure
    - Overall device and procedure related anticipated adverse events compared to historical safety data from CV placement procedures.
- Secondary endpoints:
  - Performance:
    - Device able to advance from femoral vein to subclavian exit to facilitate catheter placement, etc.
  - Safety:
    - Technique conversion rate/causes and catheter malposition

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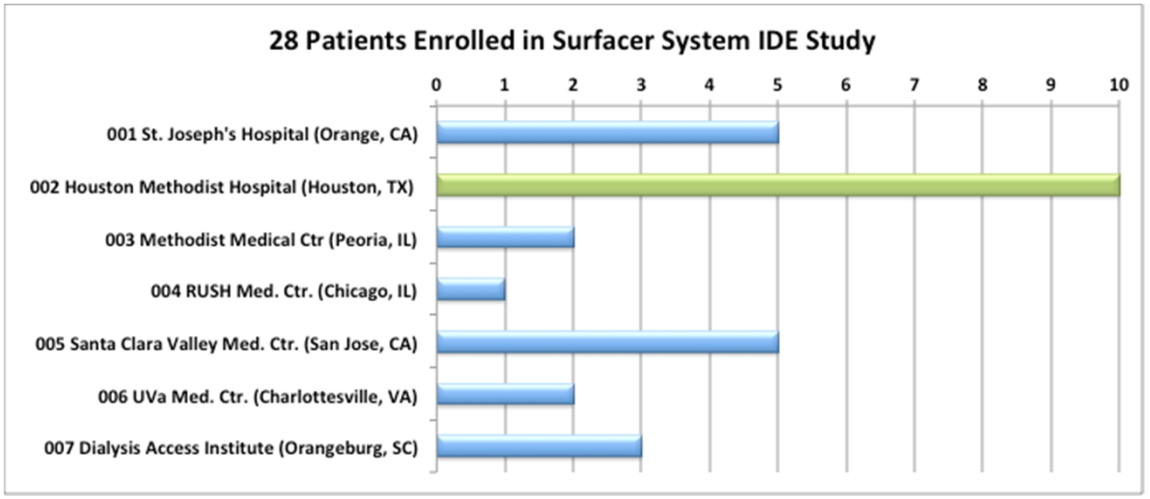
IDE Surfacer System Interim Results

- **28** patients enrolled, **25** treated successfully with 2 conversions due to tortuous anatomy and 1 technique aborted due to abnormal anatomy
- 100% access gained/device performed in treated patients, with no serious device related adverse events
- All primary and secondary endpoints met



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