clinical bulletin

FTRD® System

for endoscopic full-thickness resection

Closing the gap between
endoscopy and surgery

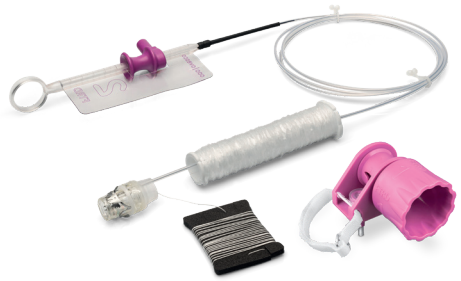
The FTRD® System

The FTRD® System (Full-Thickness Resection Device) allows for endoscopic full-thickness resection (EFTR) of lesions in the colon and rectum (colonic FTRD®) or in the stomach and duodenum (gastroduodenal FTRD®), as well as diagnostic tissue acquisition for histological examination in the case of functional diseases of the colon wall (diagnostic FTRD®).

Features:

- Complete treatment unit for endoscopic full-thickness resection
- FTRD® application cap with clip and integrated HF snare enables tissue closure and separation in a single step
- Double-sided threading of the application ring ensures even FTRD® clip application
- Transection of the organ wall only occurs after secure closure of the target site
- No opening of the organ lumen

More information on the FTRD® System



Areas of application:

- Non-lifting (recurrent) adenomas
- Adenomas on/in diverticula
- Small subepithelial tumors
- Early carcinoma
- Adenomas at the appendiceal orifice
- Hypoganglionosis and aganglionosis (e.g. Hirschsprung's disease)
- Visceral neuropathy and myopathy (e.g. in the case of chronic constipation)
- Gastrointestinal amyloidosis

Versions and delivery components:

Each FTRD® variant is supplied as a set with all the components required for the respective application.

Version	colonic FTRD®	diagnostic FTRD®	gastroduodenal FTRD®
Art. no.	**200.70**	**200.76**	**200.72**
Dimensions			
Endoscope diameter [mm]	11.5 – 13.2	10.5 – 12.0	10.5 – 12.0
Cap diameter (outside) [mm]	21	19.5	19.5
Cap diameter (inside) [mm]	13	12.1	12.1
Cap length [mm]	37		
Cap depth [mm]	23		
Required working channel diameter [mm]	3.2	3.2	3.7
Distance from snare to distal end of cap [mm]	3		
Thread length [mm]	2200		
Components included			
FTRD® Marking Probe	x	x	x
FTRD® Grasper	x	x	x
Insertion balloon			x
Guide wire			x

FTRD® application aids:

FTRD® Marking Probe
(included in 200.70, 200.72, 200.76)

FTRD® Grasper
(also available separately, 200.73)

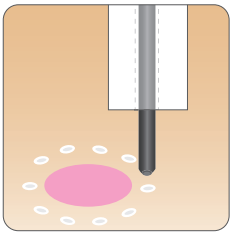
FTRD® prOVECap
(available separately, 200.71, 200.77)

OTSC® Anchor
(available separately, 200.10, 200.11)

Application Techniques

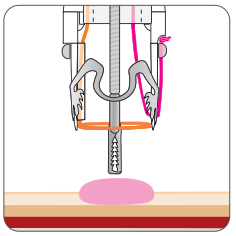
Practical use of the FTRD®

Before using the FTRD® System, the target lesion is marked with the FTRD® Marking Probe (HF coagulation probe). The marking points facilitate locating the lesion and checking that it has been completely retracted into the cap. They also make it easier to check the completeness of the resection when examining the specimen.

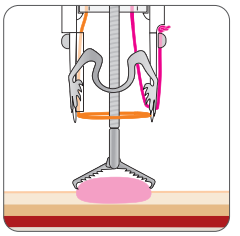


Grasper technique

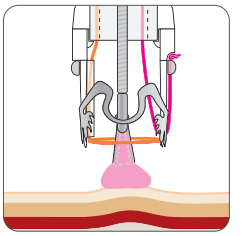
With most lesions, tissue can be mobilized using the FTRD® Grasper (grasping forceps/grasper) and securely pulled inside the application cap.

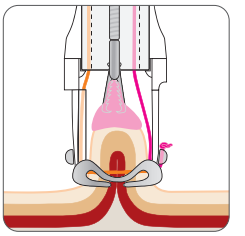


Guide the endoscope to the resection site and locate the lesion.

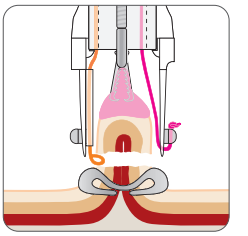


Grasp and mobilize the lesion with the FTRD® Grasper.





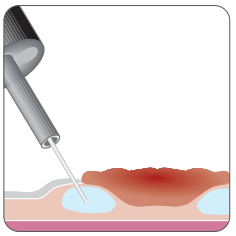
Once the lesion is completely in the cap, fix the FTRD® Grasper and apply the clip.



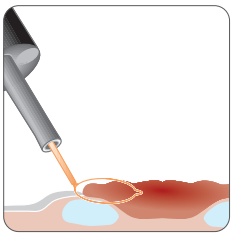
Resect the tissue and retrieve the specimen.

Hybrid-FTRD® technique

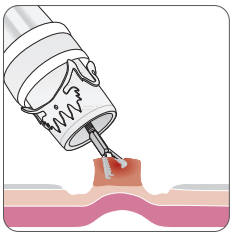
Hybrid-FTRD® combines EMR and FTRD® in the same session and is often used for lesions with significant scarring or non-lifting lesions that are too large for complete resection using FTRD®.



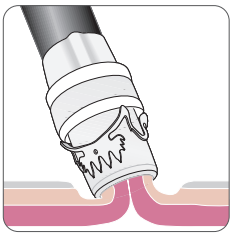
Injection



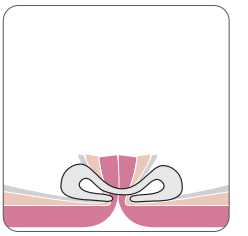
Remove lifted areas of the lesion in a piecemeal EMR technique.



Grasp the remaining non-lifting part of the lesion with the FTRD® Grasper.



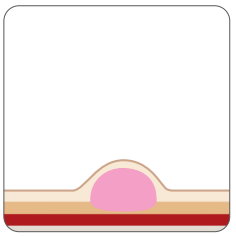
Once the lesion is completely in the cap, fix the FTRD® Grasper and apply the clip.



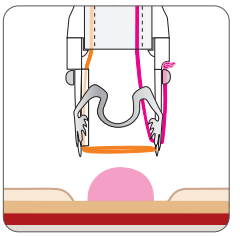
Resect the tissue and retrieve the specimen.

Mucosa uncapping

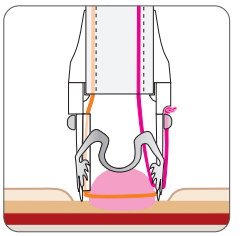
In the case of submucosal findings such as GIST lesions (especially in the stomach), the mucosa can be removed using a snare, for example, to simplify the retraction of the lesion into the cap.



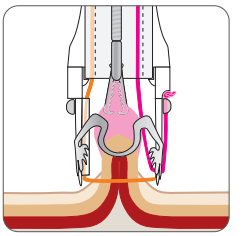
Removal of the mucosa and exposure of the findings in the muscularis.



Guide the FTRD® cap to the finding that has been uncapped.



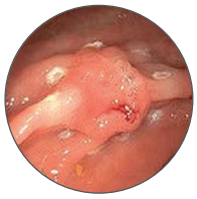
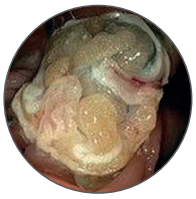
Place the cap over the exposed finding.



Grasp the lesion with the FTRD® Grasper, apply the clip, resect the tissue and retrieve the specimen.

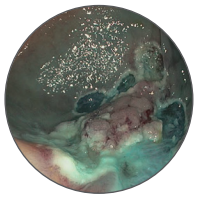
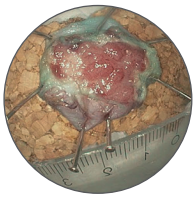
Case Studies

Lesion | Resected tissue/ resection site

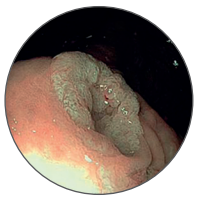
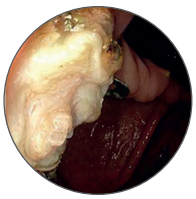
T1 colorectal cancer

FTRD® resection of T1 colorectal cancer.
Source: Zwager et al. (2021), Endoscopy.

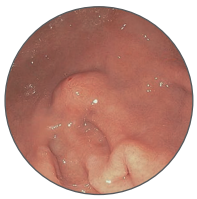
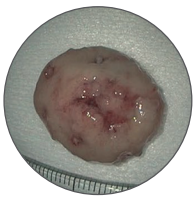
Large advanced adenoma in the cecum

Successful resection using Hybrid-FTRD® of a larger non-lifting lesion in the cecum with a positive lateral lifting sign. Firstly, piecemeal EMR, followed directly by EFTR with FTRD ®.
Source: Meier et al. (2017), Surgical Endoscopy.

Polyp at the appendix

Treatment of a polyp on the appendix with the FTRD® System.
Source: Bronzwaer et al. (2018), Endoscopy International Open.

Gastrointestinal stromal tumor (GIST) in the stomach

Resection of a subepithelial tumor (SET) in the antrum using the gastroduodenal FTRD®.
Source: Dr. B. Meier et al. (2020), Surgical Endoscopy.

Follow-up and MRI Information

After successful application, the FTRD® clip usually stays in situ for several weeks to several months. The exact duration depends on the amount of tissue secured and its properties. The FTRD® clip will leave the gastrointestinal tract naturally in the majority of cases. In cases in which a clip removal is necessary, e.g. in the event of local complications, misplacement, a necessary follow-up resection with the FTRD® or to better access the biopsy site, the FTRD® clip can be easily removed using the Ovesco remOVE System.

The FTRD® clip is **MR conditional** (as well as all other endoscopic clips from Ovesco). Therefore, patients can be examined safely in an MRI system after clip placement under the following conditions: a) static magnetic field of 3 Tesla or less, b) maximum spatial gradient of the magnetic field of 4,000 gauss/cm (40T/m). For further details, please refer to the MRI safety information in the instructions for use.

Clinical Evidence

The FTRD® System: an established procedure in clinical routine

FTRD® removes non-lifting and other complex GI lesions that previously required surgery.
The multicenter, prospective Wall Resect study shows that **a variety of lesions that are difficult to resect, such as adenomas with non-lifting signs or subepithelial tumors, can be effectively removed with FTRD®**. The technical success rate here was 89.5 %, the R0 resection rate was 76.9 %. In 2.2 % of cases, patients required surgery due to complications.[1]
This data was also verified by the **extensive data of the German FTRD® registry**. With an R0 resection rate of 80.0 % in 1,178 cases from 65 centers, the German colonic FTRD® registry shows the **effectiveness of FTRD® in clinical practice** and in hospitals at different care levels. The technical success rate was 88.2 % and the rate of complications requiring surgery was 2.0 %. It is the largest study of colorectal EFTR with FTRD® to date and confirms its efficacy and safety in the treatment of lesions that are difficult to resect in a real-world setting.[2]

Table: Data comparison Wall Resect and German FTRD® registry.

	Wall Resect study	colonic FTRD® registry
Number of patients	**181**	**1,178**
Number of participating centers, type	**9,** high volume centers	**65,** high volume centers, medium, small
Max. diameter of the lesion, mm (range)	**15** (2–20)	**15x15** (3x3–56x45*)
Median procedure time, min (range)	**50** (3–190)	**35** (2–203)
Technical success (macroscopically complete)	**89.5 %** (162/181)	**88.2 %** (998/1,131**)
Full-thickness resection (histologically verified)	**80.6 %** (146/181)	**89.9 %** (970/1,079***)
R0 resection (histologically verified)	**76.9 %** (139/181)	**80.0 %** (823/1,029****)
Difficult adenomas	77.7 %	77.2 %
Adenocarcinomas	72.4 %	82.8 %
Subepithelial tumors	87.0 %	97.1 %
R0 resection of lesions ≤ 20 mm	81.2 %	77.6 %
R0 resection of lesions > 20 mm	58.1 %	81.0 %
Complications	**9.9 %** (18/181)	**12.1 %** (142/1,178)
Surgery due to complications	**2.2 %**	**2.0 %**

*Hybrid cases included **EFTR terminated (n=47) due to technical problems or complications ***Histology available (n=1,086). Excluding: status of full-thickness resection not available (n=7).
****Histology available (n=1,086). Excluding: diagnostic EFTR (n=14), R status not determinable due to combined EFTR/EMR (n=36), R status not available (n=7).

Overall, the data from various clinical publications show comparable values in terms of the R0 rate and the low rate of complications requiring surgery, as demonstrated by two meta-analyses.
The meta-analysis from Wannhoff et al. included 26 studies with a total of **1,538 FTRD® procedures**. The results show a high rate of technical success and R0 resection (pooled rate for reaching the target lesion: 96.1 %; pooled rate for technically successful resection: 90.0 %; **pooled rate for histologically complete resection: 77.8 %**). The risk of adverse events was a pooled rate of 8.0 %. In most cases, **adverse events could be treated successfully using conservative or endoscopic methods**. The rate of necessity of surgical treatment after FTRD® was only 1.0 % (95 % CI: 0.4 – 1.8, PI: 0.4 – 1.9).[3]

A new meta-analysis from Nabi et al. in 2024 verifies these results. A total of 29 studies were included in the analysis, 27 of which included the resection procedure using the FTRD® System. The pooled rate of technical success was 87.1 %, for en bloc resection 88.1 % and **R0 resection was 81.8 %** (95 % CI 79–84.3 %, I^2 56 %).

A **subanalysis** showed pooled R0 rates for subepithelial lesions of 94.3 % (95 % CI 89.7 – 96.9 %, I^2 0 %). The pooled rate for polyps ≤ 20 mm was 80.4 % (95 % CI 77.4 – 83.2 % I^2 0 %), for polyps > 20 mm it was 59 % (95 % CI 40.1 – 75.6 %, I^2 76 %) and for adenocarcinomas (T1) it was 76.2 % (95 % CI 68.6 – 82.4 %, I^2 72 %).[4]
Adverse events occurred in 11.9 % of cases, of which 2.5 % required surgery (95 % CI 2.0 – 3.1 %, I^2 0 %).[4]

The data from FTRD® show consistent results overall with regard to the relevant parameters and illustrate **the effective treatment of even difficult lesions** with FTRD®.

Table: Comparison of pooled values of the FTRD® meta-analyses

	Wannhoff et al.	Nabi et al.
Number of patients	1,538	3,467
Technical success (macroscopically complete)	90.0%	87.1%
R0 resection (histologically verified)	**77.8%**	**81.8%**
Complications	8.0%	11.9%
Surgery due to complications	**1.0%**	**2.5%**

Clinical Evidence

FTRD® for early-stage colorectal cancer

Studies show that **FTRD® is becoming increasingly important in the treatment of early-stage colorectal cancer.** In the retrospective study by Kuellmer et al., a total of 156 patients with histological evidence of adenocarcinoma were analyzed. 64 cases included EFTR after incomplete resection of a malignant polyp and 92 non-lifting lesions. **The overall technical success rate was 92.3 % and the R0 resection rate was 71.8 %.** The curative resection rate was 87.5 % for follow-up resections of malignant polyps and 60.9 % for non-lifting lesions. The rate of severe adverse events was 3.8 %. For 34 % of patients (n=53), a follow-up oncological resection was performed due to high risk, while 62 % (n=98) could be further treated endoscopically.[5]

The retrospective analysis of EFTR for T1 CRC (colorectal cancer) of the Dutch colorectal EFTR register (Zwager et al.) confirms the high success rate of FTRD® for this indication. The study included 330 interventions (132 primary resections and 198 secondary scar resections after incomplete T1 CRC resection). The overall technical success rate was 87.0 %, the R0 resection rate was 85.6 %. **The curative resection rate was 23.7 % (95 % CI 15.9 –33.6 %) for primary resection of T1 CRC and 60.8 % after exclusion of deep submucosal infiltration as a risk factor.** The rate of severe adverse events was 2.2 %. An additional oncological operation was performed in 15.3 % (49/320) of cases.[6]

The first long-term analyses are also promising. Albers et al. of the Dutch EFTR group demonstrated a low recurrence rate after 3 years: **3-year DFS (disease-free survival) and 3-years OS (overall survival) were 95.6 % and 83.4 %, respectively,** for the high-risk pT1 monitoring group (n=66), 97.2 % and 92.6 % for the low-risk pT1 monitoring group (n=72) and 98.2 % and 100 % for the pT1 completion surgery (CS) group (n=36).[7]

As a diagnostic procedure, FTRD® is also very efficient: it **allows precise histological risk stratification for patients with suspected T1 carcinoma** and makes it possible to avoid surgery for low-risk lesions. Both the study by Kuellmer et al. and that by Zwager et al. showed that **risk stratification was possible in 99.3 % of all cases.**[5, 6]

In conclusion, FTRD® is a viable, minimally invasive treatment alternative for resection of T1 CRC, both as primary and secondary treatment, and can help to reduce surgical overtreatment.

FTRD® at the appendix

The studies by Bronzwaer et al. (n=7 patients) and Schmidbaur et al. (n=50 patients) show technical success rates of 100 % and 96 %, respectively. **Depending on the patient cohort, an R0 resection could be achieved in 85.7 % and 64 % of cases.** Since in some cases it is not possible to assess macroscopically how far a lesion grows into the appendix, the R0 rate at this localization may be lower under certain circumstances. The rate of appendicitis after EFTR was similar in both studies. One in seven patients in the study by Bronzwaer et al. developed secondary appendicitis (14.3 %) and underwent laparoscopic appendectomy. Schmidbaur et al. reported 7 patients who developed acute appendicitis (14 %), of whom 4 could be treated conservatively and 3 required surgical appendectomy.

The data from Schmidbaur et al. suggests that **early onset and detection of secondary appendicitis was associated with milder progression and conservative treatment options.**[8,9]

EFTR of polyps at the appendiceal orifice is an alternative to surgery with a manageable level of risk of secondary appendicitis and the potential need for appendectomy. Therefore, comprehensive patient information is particularly important in these cases.

Hybrid-FTRD®

Hybrid-FTRD® is an effective treatment method for advanced adenomas that cannot be removed by EMR or EFTR alone.

The **hybrid approach, combining EMR and FTRD®, can be used for lesions that are too large for en-bloc resection** and for which a resection in toto with FTRD® alone is not possible. At the same time, this approach allows the resection of significantly larger lesions than with FTRD® alone. The study by Mahadev et al., which compares standalone FTRD® (n=38) with Hybrid-FTRD® (n=31), shows that the **resectable lesion size is significantly larger (up to 70 mm) with this combined technique, while maintaining safety and efficacy.** There was no difference between Hybrid-FTRD® and standalone FTRD® with regard to technical success (83 %) and R0 rate (81 %).[10]

A more recent study by Meier et al. with 75 patients also shows the successful use of the Hybrid-FTRD® technique. With a technical success rate of 100 % and a **macroscopically complete resection rate of 97.3 %,** Hybrid-FTRD® has proven to be clinically relevant. In the study, Hybrid-FTRD® was used mainly for sessile polyps and LST in the right-sided colon that showed lifting signs in the periphery suitable for piecemeal EMR and had a remaining central non-lifting part (≤20 mm) suitable for EFTR. Lesions up to 60 mm could be removed. The rate of adverse events was low (6.7 %) and the recurrence rate (11.4 %) was comparable to that of piecemeal EMR.[11]

The **hybrid approach reduces the risk of incomplete resection and broadens the endoscopic options for resecting larger lesions.** The method broadens the indications for EFTR with a faster and steeper learning curve compared to ESD.

Clinical Evidence

FTRD® for use in the stomach and duodenum

Initial studies are also available for the use of FTRD® in the stomach, which in particular demonstrate the **high diagnostic benefit of the technique.** In a prospective study by Meier et al., the lesions of 29 patients with suspected subepithelial tumors in the stomach were resected using FTRD®. The technical success rate was 89.7 %, the R0 rate was 76 % and the full-thickness resection rate was 65.5 %. The complication rate was 31 %, all of which involved minor bleeding that occurred periprocedurally. In all cases, a **precise histological diagnosis could be provided for the findings, including some that had previously been unknown.**[12]

The international, multicenter retrospective study by Hajifathalian et al. included 56 patients from 13 centers who had an endoscopic resection of an upper GI lesion using FTRD®. The most common lesions were mesenchymal neoplasias (41 %), adenomas (13 %) and hamartomas (11 %). 84 % of the lesions were located in the stomach and 14 % in the duodenum, with an average size of 14 mm. **The technical success rate was 93 %, the R0 rate was 68 %.** In 21 % of cases, mild or moderate complications occurred that could be treated endoscopically or conservatively.[13]

FTRD® has proven to be an efficient resection method, particularly for duodenal NETs. A recent retrospective, multicenter study by Wannhoff et al. included 170 cases in 35 centers. The technical success rate for resection with FTRD® was high at 95.9 % (163/170). **The R0 resection rate in the duodenum was high at 83.7 %.** However, lesions near the pylorus remain technically challenging and have a lower R0 rate of 62.0 %. The complication rate was 19.4 % (intraprocedural n=10, postinterventional n=24 and late n=1).[14]

The data demonstrate the high potential of FTRD® as an effective treatment for dNETs and lesions in the stomach.

Cost effectiveness

Based on the clinical data from the prospective, single-arm WALL RESECT study, Küllmer et al. analyzed the cost effectiveness of the FTRD® System compared to surgical and existing endoscopic treatment alternatives. The treatment costs and reimbursement were calculated in euros according to the 2017 and 2019 coding rules (EFTR). The R0 resection rate was used to measure the effectiveness. For analysis, the cost effectiveness parameters ACER (Average Cost Effectiveness Ratio; costs incurred in order to reach a clinically successful treatment result) and ICER (Incremental Cost Effectiveness Ratio; difference in costs of two different interventions divided by the difference in clinical outcome) were calculated from the perspective of the health care provider.

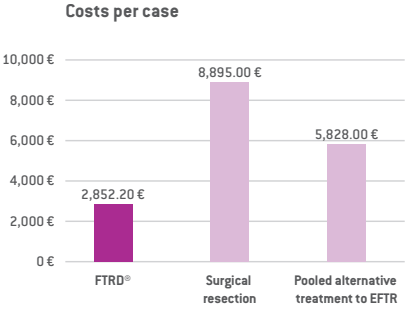
The cost per case was € 2,852.20 for FTRD®, € 8,895 for surgical resection and € 5,828 for the pooled alternative treatment to EFTR.

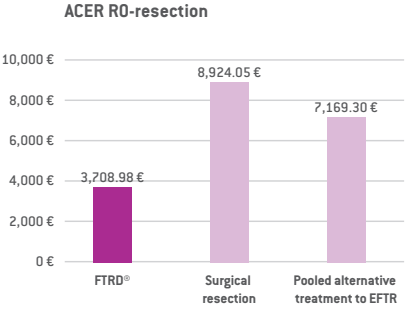
The ACER (mean cost per R0 resection) was € 3,708.98 for EFTR, € 3,115.10 for SER (submucosal endoscopic resection), € 8,924.05 for surgical treatment, and € 7,169.30 for all pooled and alternative treatments to EFTR. The ICER (incremental cost per R0 resection compared to EFTR) was € 5,196.47 for SER, € 26,533.13 for surgical resection and € 67,768.62 for the pooled alternative treatments. **Thus, the use of FTRD® results in a cost reduction of almost 60 % per R0 resection or –€ 27,000 compared to surgery.**[15]

The analysis shows that FTRD® should be considered as the initial treatment for difficult-to-treat lesions in the colon or rectum before surgical intervention.

Table: FTRD® vs. surgical and alternative endoscopic therapies, a cost effectiveness analysis (Küllmer et al., 2020)

	Costs per case	ACER R0 resection	ICER FTRD®
FTRD®	€2,852.20	€3,708.98	-€27,000
Surgical resection	€8,895.00	€8,924.05	
Pooled alternative treatments to EFTR	€5,828.00	€7,169.30	





Summary

Significant scientific evidence shows the clinical benefit of EFTR using FTRD® in endoluminal surgery. FTRD® effectively and safely closes the gap between endoscopy and surgery.

Treatment with the FTRD® System offers a number of advantages compared to surgical and alternative endoscopic therapies:

- FTRD® extends the range of endoscopic treatments with a transluminal and minimally invasive method
- FTRD® enables accurate risk stratification and presents a viable option for local endoscopic treatment
- Full-thickness resection with FTRD® is an established method with a very good clinical data basis and high R0 rates

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