



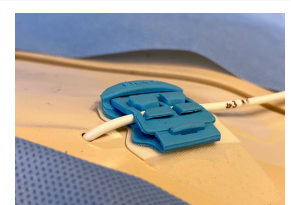
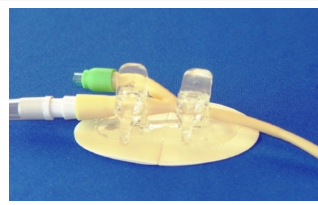
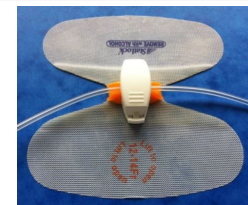
PERFORMANCE

Performance review of June 2022
Version: 1.0

Bedal performance review of the FlexGRIP Universal stabilization devices compared to available alternatives

Selected fixation products

For the performance review, the selected stabilization products are (from left to right): a fixation device with snap part, a specific engineered fixation device with straps and the Bedal Flex S.



Scope of this overview

This overview aims to give a summarized analysis of the comparison of the FlexGRIP Universal device with a selection of available alternatives. Tests have been performed in an in-house lab setting, aimed at the direct and objective comparison of performance of the devices.

Performance parameters

The main parameters for the comparison of the devices are:

1. Strength of the fixation of the catheter
2. Impact on the flow of the catheter

How do the Bedal devices work?

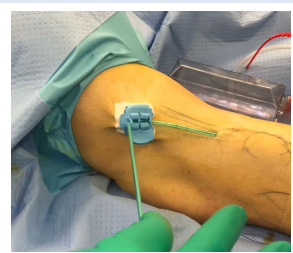
The technology that is used to create a fixation of the catheter is the usage of minimal 2 air filled chambers that are positioned on both sides of the catheter. Upon closing of the leash, the catheter is pressed between the air filled chambers, that will deform around the catheter, creating a friction and a fixation force. This results in a strong fixation, with a low impact on the flow.



Performance: strain relief

The strength of the fixation is considered to be the main performance parameter, and is measured in a standardized test setup, where the catheter is stabilized in the fixation device, and the tensile strength required to displace the catheter is recorded.

Catheters in different French sizes are used, ranging from 6.6Fr to 10.6Fr. The devices are positioned on the skin of the test subject, and the max pulling force for displacement is recorded.

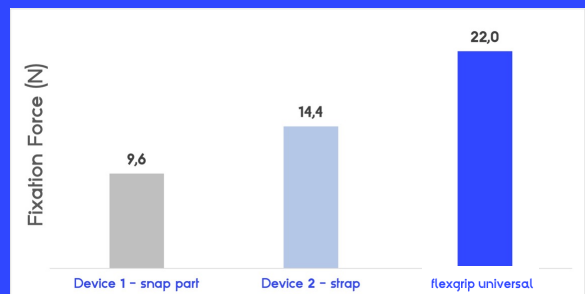


Results

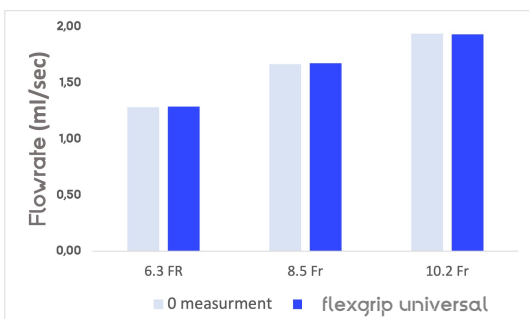
FlexGRIP Universal has a **performance** that is **consistently higher** than all other fixation methods.

Strength of fixation

Comparing the strength of fixation versus alternative fixation devices. Fixation force for stabilizing a drainage catheter between 6Fr and 10.3Fr are measured.



Bedal delivers the strongest fixation of all fixation methods



Impact on the flow

In order to compare the impact of the fixation device on the flow in the catheter, a test setup is used where the flow in the catheter is measured in a setup without any fixation device, and then compared to the flow with the FlexGRIP Universal on the shaft of the catheter.

Test results show that no flow impact for the both situations is detected for the whole range of diameters (6.6Fr to 10.6Fr), not even for silicone catheters. It can be concluded that the **FlexGRIP Universal has no measurable impact on the flow in the catheter.**

The FlexGRIP Universal has no measurable impact on the flow.